

Carescape™ ONE

User Manual

Carescape™ Software version 4 (4.0)



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General User Documentation

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Legal manufacturer information

Manufacturer information

Carescape ONE, TruSignal ECG MM, TruSignal PRES MM, TruSignal SpO₂ MM 1.8M, TruSignal SpO₂ MM 3.0M, TruSignal TEMP MM, FloTrac CCO ADPTR, Carescape Dock F0, Carescape Software



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NOTE
CARESCAPE SpO₂ — Masimo, CARESCAPE SpO₂ — Nellcor, CARESCAPE CO₂ — LoFlo, CARESCAPE CO₂ — Microstream, INVOS rSO₂ MM, and FloTrac Pressure Cable – GE HealthCare are CE marked by their respective manufacturers.

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Introduction to this manual

Intended use of this manual

This manual is an integral part of the device and describes its intended use. It should always be kept in a place accessible to users, and information indicating that place should be available close to the equipment. Observance of the manual is mandatory for proper performance and correct operation and ensures patient and user safety. Information which refers only to certain versions of the product(s) is accompanied by the model number(s) of the product(s) concerned. The model number is given on the device plate of the product. The information in this manual applies to the software version listed on the first page of the manual.

The list below indicates the products (brands, models and descriptions as applicable) with which this manual is to be used. Other products are covered by the manuals that were delivered with those products. Carescape™ products may also be called by their previous name CARESCAPE™.

- Carescape™ ONE
- Carescape™ Software version 4 (4.0)
- TruSignal™ ECG MM
- TruSignal™ PRES MM
- TruSignal™ TEMP MM
- TruSignal™ SpO₂ MM 1.8M
- TruSignal™ SpO₂ MM 3.0M
- CARESCAPE™ SpO₂ — Masimo
- CARESCAPE™ SpO₂ — Nellcor
- CARESCAPE™ CO₂ — LoFlo
- CARESCAPE™ CO₂ — Microstream
- FloTrac CCO MM 3.6M including FloTrac CCO ADPTR
- Carescape™ Dock F0
- Carescape™ ONE Mini-Dock
- Micro-module Dock 1
- Micro-module Dock 3
- Micro-module Dock 4
- Micro-module Dock 5

Intended audience of this manual

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology required to provide patient

care. Using the system should never replace nor impede the human intervention and required patient care provided by clinical professionals.

Training requirements

Users of this product are either under the direct supervision of a licensed healthcare practitioner within a professional healthcare facility or personnel trained by the facility in the care of patients using this type of medical equipment. No product-specific training is required by the manufacturer for the use of this product.

Manual conventions

This manual uses the following styles to emphasize text or indicate an action.

Item	Description
Courier	Indicates hardware keys and connectors.
bold	Indicates software terms.
<i>italic</i>	Indicates terms for emphasis.
>	Indicates menu options to select consecutively.
select	The word select means choosing and confirming.
NOTE	Note statements provide application tips or other useful information.

Monitor naming conventions

In this manual, the following monitor naming conventions are used:

Product name	Name used in this manual
Carescape ONE	Carescape ONE, CS ONE, device, or monitor When used as an independent device: also Monitor (in software references) When connected to the host monitor and micro-modules: acquisition platform When wirelessly linked to the host monitor: transport device
Carescape Canvas 1000 Carescape Canvas Smart Display	Host monitor

Micro-module naming conventions

In this manual, micro-modules is used as a generic term when referring to all of the products that are listed in the following table. If there are several graphics that can appear on the device, all are listed.

Graphic on the micro-module	Explanation
TruSignal MM  or CARESCAPE 	Micro-module for measuring ECG. Note that in the manual, the following names are used instead of the graphic: TruSignal ECG micro-module or TruSignal ECG. This micro-module may also be called by its previous name CARESCAPE ECG.
TruSignal MM  or CARESCAPE 	Micro-module for measuring invasive pressures. Note that in the manual, the following names are used instead of the graphic: TruSignal Pressure micro-module or TruSignal Pressure. This micro-module may also be called by its previous name CARESCAPE Pressure.
TruSignal MM  or CARESCAPE 	Micro-module for measuring temperature. Note that in the manual, the following names are used instead of the graphic: TruSignal Temperature micro-module or TruSignal Temperature. This micro-module may also be called by its previous name CARESCAPE Temperature.
TruSignal MM 1.8M  or TruSignal MM 3.0M  or CARESCAPE 	Micro-module for measuring SpO₂ with TruSignal technology. Note that in the manual, the following names are used instead of the graphic: TruSignal SpO₂ micro-module or TruSignal SpO₂. This micro-module may also be called by its previous name CARESCAPE SpO₂.
INVOS  MM	Micro-module for measuring regional oxygen saturation of blood (rSO₂) in cerebral and somatic tissues with INVOS technology. Note that in the manual, the following names are used instead of the graphic: INVOS rSO₂ micro-module or INVOS rSO₂.
CARESCAPE  -LoFlo	Micro-module for measuring CO₂ with Respironics LoFlo technology. Note that in the manual, the following names are used instead of the graphic: LoFlo CO₂ micro-module or LoFlo CO₂.
CARESCAPE  - Microstream	Micro-module for measuring end-tidal carbon dioxide (EtCO₂), FiCO₂, and respiration rate with Microstream technology. Note that in the manual, the following names are used instead of the graphic: Microstream CO₂ micro-module or Microstream CO₂.
CARESCAPE  - Masimo	Micro-module for measuring SpO₂ with Masimo rainbow SET technology. Note that in the manual, the following names are used instead of the graphic: Masimo SpO₂ micro-module or Masimo SpO₂.
CARESCAPE  - Nellcor	Micro-module for measuring SpO₂ with Nellcor™ sensors with OxiMax™ technology. Note that in the manual, the following names are used instead of the graphic: Nellcor SpO₂ micro-module or Nellcor SpO₂.

Graphic on the micro-module	Explanation
	Adapter used with FloTrac Pressure Cable – GE HealthCare for measuring continuous cardiac output and invasive pressures with Edwards technology. Note that in the manual, the following name is used instead of the graphic: FloTrac CCO adapter.

In this manual, FloTrac CCO micro-module is used when referring to the micro-module that consists of the FloTrac CCO adapter and FloTrac Pressure Cable – GE HealthCare.

In this manual, CO₂ micro-modules is used as a generic term when referring to all of the following micro-modules: LoFlo CO₂ and Microstream CO₂.

In this manual, SpO₂ micro-modules is used as a generic term when referring to all of the following micro-modules: TruSignal SpO₂, Nellcor SpO₂, and Masimo SpO₂.

Other naming conventions

For technical documentation purposes, the following conventions are used:

- GE HealthCare is used for the legal entity names, GE Medical Systems Information Technologies, Inc., and GE Healthcare Finland Oy.
- The phrase supplemental information is used for information that appears in the appendices of the manual or in the supplements provided.

In addition, the following product naming conventions are used in this manual:

Product name	Name used in this manual
Carescape Dock F0 and F2-01	When connected to the Carescape One: powered docking solution.
FloTrac CCO ADPTR	FloTrac CCO adapter
FloTrac Pressure Cable – GE HealthCare	Edwards FloTrac CCO pressure cable

Illustrations and names

This manual uses illustrations as examples only. Illustrations in this manual may not necessarily reflect all system settings, features, configurations, or displayed data.

Names of persons, institutions, and places and related information are fictitious; any similarity to actual persons, entities, or places is purely coincidental.

Related documents

- Carescape Canvas 1000 and Carescape Canvas Smart Display User Manual
- Carescape Canvas 1000 and Carescape Canvas Smart Display Supplemental Information Manual
- Carescape Monitors Cleaning and Disinfection Supplement
- Carescape ONE Service Manual
- Carescape ONE compatibility supplement
- Carescape ONE supplies and accessories supplement
- Carescape ONE user guide for electronically delivered manuals

- Carescape Network Infrastructure Configuration Guide
- Carescape Monitors Privacy and Security Manual. Security related documents can be downloaded from <https://securityupdate.gehealthcare.com>.

For information on products made by manufacturers other than GE HealthCare, see the applicable instructions for use provided by the manufacturer.

For a list of third-party or open-source software included in the device, contact your GE HealthCare service representative.

Ordering manuals

A paper copy of this manual will be provided upon request. Contact your local GE HealthCare representative and request the part number on the first page of the manual.

Revision history

Revision	Description
1 st edition	Initial release.

Accessing manuals online

To obtain the latest version of the manual:

1. Go to <https://www.gehealthcare.com/support/manuals>.
2. Enter the product name or document number into the search field. Check that the selected language is correct. When searching with a document number, wrong language selection causes the search to fail.
3. Click the search icon at the end of the search field to launch the search.
4. Select the tab according to the type of manual you are looking for:
 - **All**: opens the list of all manuals related to the selected product
 - **Service**: opens the list of service manuals related to the selected product
 - **User/Operation**: opens the list of user manuals related to the selected product
 - **Installation**: opens the list of installation manuals related to the selected product
 - **Others**: opens the list of other types of manuals related to the selected product
5. Identify the manual and select **Download**.

NOTE

It is recommended to download the .zip files for User Documentation Sets or Service Manuals Sets if available because they include all user or service publications for that product. Otherwise, download the individual PDF files.

6. Select **Accept** in the copyright popup window to initiate the download.
Manuals are downloaded to the Downloads folder of your device.
7. If you downloaded a .zip file, unzip the files.

The manuals are in PDF format. Make sure that your viewing device (for instance, computer) has software to open the PDF files (for instance, Adobe® Acrobat® Reader).

Security related documents can be downloaded from <https://securityupdate.gehealthcare.com>.

Product availability

NOTE

Due to continual product innovation, design and specifications for these products are subject to change without notice.

Some of the products mentioned in this manual may not be available in all countries. Please consult your local representative for the availability.

Trademarks

Carescape and Carescape Canvas are trademarks of GE HealthCare.

12RL, DINAMAP, IntelliRate, Ohmeda, and TruSignal are trademarks of GE HealthCare.

Third party trademarks

Masimo, Masimo SET, rainbow, rainbow SET, Adaptive Probe Off Detection, and APOD are trademarks of Masimo Corporation.

Covidien, INVOS, LoSat, Medtronic, Microstream, Nellcor, OxiMax, and SatSeconds are trademarks of a Medtronic company.

Edwards, Edwards Lifesciences, and FloTrac are trademarks of Edwards Lifesciences Corporation.

Respironics and LoFlo are trademarks of Koninklijke Philips Electronics N.V.

Manufacturer responsibility

GE HealthCare is responsible for the effects on safety, reliability, and performance of the equipment only if:

- Assembly operations, extensions, readjustments, modifications, servicing, or repairs are carried out by authorized service personnel.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

WARNING

SAFETY HAZARD. To avoid risks to personnel and patient, or damage to the equipment, only perform maintenance procedures described in this manual. Unauthorized modifications can lead to safety hazards.

System installation and commissioning, and planned and corrective maintenance and upgrade activities must be performed by qualified service personnel according to the service manual.

System security and privacy

Applicability of local laws and regulations

Australia

If applicable, your facility's security strategy should align with the Privacy Act and all applicable amendments, along with the Australian Privacy Principles (APPs), which govern the handling of personal information, including health data. These regulations set standards for data collection, storage, security, and patient access to their health information.

Canada

If applicable, your facility's security strategy should align with Canada's Personal Information Protection and Electronic Documents Act (PIPEDA), which sets out rules for the collection, use, and disclosure of personal information during commercial activities. Additionally, provincial laws, such as Ontario's Personal Health Information Protection Act (PHIPA), may apply for handling health information.

European Union

If applicable, your facility's security strategy should align with the latest EU standards on the protection of individuals regarding the processing of personal data and the free movement of such data. This includes compliance with the General Data Protection Regulation (GDPR) which sets stringent requirements for data protection, security measures, and individual privacy rights. Additional national regulations within European Union member states may impose further standards.

United States of America

If applicable, your facility's security strategy should align with the latest standards set forth in the Health Insurance Portability and Accountability Act (HIPAA), as updated by the United States Department of Health and Human Services. You should consider both the security and privacy rules, including recent amendments, when designing policies and procedures.

Safeguarding sensitive information

Protecting Personally Identifiable Information (PII) and Protected Health Information (PHI) is essential. Each facility using the monitors must ensure security mechanisms are implemented in line with applicable laws and facility policies. Effective protection requires a multi-layered security approach, including:

- Physical access controls: Limit physical and system access to authorized personnel only, ensuring that only approved users can access sensitive data on monitors.

- Operational controls: Ensure that device is being operated in its intended environment and as per security recommendations set forth in user, service, and security manuals. For example, maintain strict access controls by not sharing passwords with unauthorized personnel.
- Process controls: Assign monitor access based on specific staff roles, defining clear access rights and responsibilities to reduce potential exposure to PHI. For example, service users typically do not need access to clinical data to perform their tasks.

Further details on privacy and security

Additional security and privacy information can be found in the following documents, available upon request from GE HealthCare sales representatives or via the GE HealthCare Product Security Portal at <https://securityupdate.gehealthcare.com>.

- Manufacturer Disclosure Statement for Medical Device Security – MDS2: The Manufacturer Disclosure Statement for Medical Device Security (MDS2) is a standardized document that outlines the security features of medical devices. It helps healthcare providers evaluate cybersecurity risks related to data handling, including transmission, storage, and protection of patient health information.
- Privacy and Security Manual: The Privacy and Security Manual describes the device's privacy and security capabilities and their appropriate use.

Safety and intended use

Safety message signal words

Safety message signal words designate the severity of a potential hazard.

DANGER

Indicates a hazardous situation that, if not avoided, will result in death or serious injury.

WARNING

Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION

Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

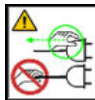


NOTICE

Indicates a hazardous situation not related to personal injury that, if not avoided, could result in property damage.

Safety symbols

Symbol	Explanation
	General warning sign. ISO 7010. This symbol is identified by a yellow background, black triangular band, and a black symbol. In this manual this symbol is used only in connection with those warning statements that the labels on the equipment refer to.
	Caution. ISO 7000. This symbol is identified by a white background, black triangular band, and a black symbol.
	Follow instructions for use. ISO 7010. This symbol indicates mandatory action and it is identified by a blue background and a white symbol.
	MR Unsafe. Indicates that the device is not intended for use in an MR environment. This symbol is identified by a white background, red or black circular band, and a black symbol.
	Electrostatic sensitive device.
	Non-ionizing electromagnetic radiation. Interference may occur in the vicinity of this device.
	Type BF applied part. Type BF (IEC 60601-1) protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, excluding direct cardiac application.

Symbol	Explanation
	Defibrillation-proof type BF applied part. Type BF (IEC 60601-1) defibrillation-proof protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, excluding direct cardiac application.
	Type CF applied part. Type CF (IEC 60601-1) protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, including direct cardiac application.
	Defibrillation-proof type CF applied part. Type CF (IEC 60601-1) defibrillation-proof protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, including direct cardiac application.
 U.S. only: 	Safety ground. Remove power cord from the mains source by grasping the plug. Do not pull on the cable.
	Class II equipment with Functional Earth.
 ≤12 kg	No heavy load. Do not place any heavy objects beyond the limit shown.

System safety

System safety messages apply to the entire system. Safety messages specific to parts of the system are found in the relevant section.

Reporting of serious incidents

Any serious incident related to the use of this device should be reported to both the manufacturer and the health authority/competent authority where the device is installed.

To report to GE HealthCare, contact your local service representative or report to In-box.complaints@gehealthcare.com.

Please provide the following information:

- The catalogue number or the model designation of the device as stated on its identification plate affixed on the device
- The System ID/serial number/lot number of the device
- Date of incident
- Description of incident, including any patient or user impact/injury
- Your contact information (facility, address, contact name, title, and telephone number)

System warning safety messages

The following warning safety messages apply to this monitoring system.

Accessories warnings

WARNING

PATIENT SAFETY. Single-use products are not designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, and cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization and/or reuse.

WARNING

PATIENT SAFETY. Use only approved accessories, including mounts, and defibrillator-proof cables and invasive pressure transducers. For a list of approved accessories, see the supplemental information provided. Other cables, transducers and accessories may cause a safety hazard, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

WARNING

ELECTRIC SHOCK. Only use protected leadwires and patient cables with this device. The use of unprotected leadwires and patient cables creates the potential for making an electrical connection to ground or to a high voltage power source which can cause serious injury or death to the patient.

WARNING

PATIENT SAFETY. When using any supply or accessory, make sure that you are familiar with their use to avoid any risk to the patient or user. For detailed instructions and information regarding supplies and accessories, always refer to their own instructions for use.

Battery warnings

WARNING

EXPLOSION OR FIRE. Using non-recommended batteries could result in injury/burns to the patients or users. Only use batteries recommended or manufactured by GE HealthCare. The warranty can be voided if non-recommended batteries are used.

WARNING

PHYSICAL INJURY. Do not install the device above a patient. Make sure the battery is completely inserted and the battery door is completely closed. Falling batteries could seriously or fatally injure neonatal or other vulnerable patients.

WARNING

PHYSICAL INJURY. Do not install the device above a patient. Leaks from the battery cells can occur under extreme conditions. The liquid is caustic to the eyes and skin. If the liquid comes in contact with eyes or skin, flush with clean water and seek medical attention.

WARNING

EXPLOSION HAZARD. Do not incinerate a battery or store at high temperatures. Serious injury or death could result.

Cables warnings

WARNING

CABLES. Route all cables away from patient's throat to avoid possible strangulation.

WARNING

CABLES. Route all cables in such a way that they are not under the patient to avoid the risk of possible pressure sores.

WARNING

PERSONAL INJURY. To avoid personal injury to users or any other persons moving in the vicinity of the cables or tubing, route all cables and tubing in such a way that they do not present a tripping hazard.

WARNING

PERSONAL INJURY. To avoid burns in an *elevated temperature environment* (for example, a neonatal incubator), do not place parameter cable electronics and housings in a location where contact with the patient may occur. This excludes leadwires, sampling lines, sensors, and sensor cables.

WARNING

SAFETY GROUND. Remove power cord from the mains source by grasping the plug. Do not pull on the cable.

Care warnings

WARNING

EQUIPMENT FAILURE. Regular preventive maintenance should be carried out as indicated in the device service manual. Failure to implement the maintenance schedule may cause equipment failure and possible health hazards.

WARNING

SAFETY HAZARD. To avoid risks to personnel and patient, or damage to the equipment, only perform maintenance procedures described in this manual. Unauthorized modifications can lead to safety hazards.

WARNING

ELECTRIC SHOCK. Non-medical equipment does not provide the same level of protection against electrical shock. Do not touch the patient and any part of non-medical equipment at the same time. Some examples of non-medical equipment are laser printers and non-medical computers.

WARNING

EQUIPMENT DAMAGE. If liquid has accidentally entered the system or its parts, disconnect the power cord from the power supply, remove the battery, and have the equipment serviced by qualified service personnel.

WARNING

ENVIRONMENTAL HAZARD. Cleanup and disposal of broken displays must be in compliance with the safety and waste control guidelines regulating this product.

Cleaning warnings

WARNING

EQUIPMENT DAMAGE. Avoid using chemicals other than the ones described in this manual as they may damage device surfaces, labels, or cause equipment failures.

WARNING

EQUIPMENT DAMAGE. If liquid has accidentally entered the system or its parts, disconnect the power cord from the power supply, remove the battery, and have the equipment serviced by qualified service personnel.

WARNING

ENVIRONMENTAL HAZARD. Cleanup and disposal of broken displays must be in compliance with the safety and waste control guidelines regulating this product.

WARNING

EQUIPMENT DAMAGE. Never immerse any part of the device, cables, or leadwires in liquids or allow liquid to enter the interior of the device.

WARNING

EQUIPMENT DAMAGE. Do not autoclave any part of the system with steam (including cables or leadwires) or sterilize with ethylene oxide.

WARNING

EQUIPMENT DAMAGE. Do not pour or spray any liquid so that it may seep into connections or openings.

WARNING

EQUIPMENT DAMAGE. Never use conductive solutions, wax, or wax compounds to clean the device, cables, or leadwires.

WARNING

CORROSION. Never use oxidizing agents on connector contact surfaces to prevent corrosion, which could possibly result in connection reliability issues.

WARNING

CROSS CONTAMINATION. When using reusable accessories that can come into contact with the patient, always follow the manufacturer's instructions for reuse. Accessories may need to be cleaned, disinfected, and/or sterilized between patients. Failure to follow the manufacturer's instructions may lead to cross contamination and infection or transmission of disease.

Defibrillation warnings

WARNING

ELECTRIC SHOCK. To avoid the risk of electric shock, do not touch the patient, table, bed, instruments, modules or the monitor during defibrillation.

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

Dock warnings

WARNING

PHYSICAL INJURY. Take care when mounting devices to an IV pole. If a device is mounted too high the IV pole may become unbalanced and tip over.

WARNING

PHYSICAL INJURY. Never install equipment above the patient.

WARNING

PHYSICAL INJURY. Use only manufacturer specified mounts.

WARNING

ERRONEOUS READINGS. The device/system should not be used adjacent to, or stacked with, other equipment. Consult qualified personnel regarding device/system configuration.

Electrical warnings

WARNING

POWER SUPPLY. Always connect the device power cable to a properly installed power outlet with protective earth contacts before connecting any other interface cables. If the integrity of the protective earth conductor is in doubt, disconnect the monitor from the power line and use it with the battery option. If the installation does not provide for a protective earth conductor, disconnect the device power cable from the power line after having disconnected all other interface cables. All devices of a system must be connected to the same power supply circuit. Devices which are not connected to the same circuit must be electrically isolated when operated.

WARNING

EXCESSIVE LEAKAGE CURRENT. Do not use a multiple socket outlet or extension cord. A failure in a multiple socket outlet or extension cord may cause increased leakage current when many devices are sharing the same multiple socket outlet or extension cord.

WARNING

EXCESSIVE LEAKAGE CURRENT. To avoid summation of leakage currents when interfacing the device with other equipment, the devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of the connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC 60601-1 clause 16 must be complied with.

WARNING

EXCESSIVE TOUCH CURRENT. To avoid excessive patient leakage current, do not simultaneously touch the patient and the electrical connectors located at the rear panel of the monitor or the F0 power output connector.

WARNING

EXCESSIVE LEAKAGE CURRENT. Connect only certified IEC 62368-1/IEC 60950-1 or IEC 60601-1 compliant equipment to the Carescape Dock F0 RJ-45 connection.

WARNING

INTERFACING OTHER EQUIPMENT. Connect only items that are specified as part of the system and as compatible. For more information, see the supplemental information provided.

WARNING

INTERFACING OTHER EQUIPMENT. Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of the connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC 60601-1 clause 16 must be complied with.

WARNING

ELECTRIC SHOCK. To avoid the risk of electric shock, do not under any circumstances remove the grounding conductor from the power plug. Always check that power cord and plug are intact and undamaged.

WARNING

ELECTRIC SHOCK. Do not touch the electrical connector located in the Carescape Dock F0 to avoid the risk of electric shock.

WARNING

PATIENT SAFETY. During intracardiac application of a device, a defibrillator and pacemaker whose proper functioning has been verified must be kept at hand to ensure timely intervention if necessary.

WARNING

EQUIPMENT DAMAGE. If liquid has accidentally entered the system or its parts, disconnect the power cord from the power supply and have the equipment serviced by qualified service personnel. Otherwise, there is a risk of damage to the equipment.

WARNING

DISCONNECTION FROM MAINS. When disconnecting the device from the power line, remove the plug from the wall outlet first. Then you may disconnect the power cord from the device. If you do not observe this sequence, there is a risk of coming into contact with line voltage by inserting metal objects, such as the pins of leadwires, into the sockets of the power cord by mistake.

WARNING

INTRACARDIAC APPLICATION. When applying devices intracardially, electrically conductive contact with parts connected to the heart (pressure transducers, metal tube connections and stopcocks, guide wires, etc.) must be avoided in all cases. To prevent electrical contact, we recommend the following:

- always wear isolating rubber gloves,
- keep parts that are conductively connected to the heart isolated from ground,
- if possible, do not use tube fittings or stopcocks made of metal.

Monitoring warnings

WARNING

PATIENT SAFETY. Carescape ONE only supports one measurement device at a time for each of the following parameters: ECG, impedance respiration, SpO₂, CO₂, and temperature. If multiple measurement devices have been connected for any of these parameters, remove the measurement devices that have been most recently connected. You can also remove all measurement devices, then reconnect a single measurement device for the intended parameter.

WARNING

PATIENT SAFETY. Carescape ONE supports a maximum of two TruSignal Pressure micro-modules at a time for invasive blood pressure. Each TruSignal Pressure micro-module supports two channels of invasive blood pressure measurement. If more than two TruSignal Pressure micro-modules have been connected, remove the micro-modules that have been most recently connected.

WARNING

PATIENT SAFETY. Carescape ONE supports a maximum of two INVOS rSO₂ micro-modules at a time for regional oxygen saturation. Each INVOS rSO₂ micro-module supports two channels of regional oxygen saturation measurement. If more than two INVOS rSO₂ micro-modules have been connected, remove the micro-modules that have been most recently connected.

WARNING

MISINTERPRETATION. Always make sure that the waveform size is sufficient for the care environment to ensure that the waveforms can be interpreted correctly and no details are missed.

WARNING

LOSS OF MONITORING and MISSED ALARMS. When starting to monitor a patient, always make sure that you are in the normal monitoring mode and not in the **DEMO mode**. Ensure that there is no **DEMO MODE** text in the waveform fields, no low priority **DEMO MODE Not for clinical use!** alarm in the alarm area, no **DEMO** MRN identification, and no **DEMO PATIENT** name in the patient information area. You can exit the **DEMO mode** by restarting the device or by selecting  from the main menu and then **Defaults & Service > Exit DEMO**. If the **DEMO mode** is active when you start monitoring, there is a risk of loss of monitoring and missed alarms.

WARNING

MISINTERPRETATION OF DATA. To identify the **DEMO mode** data, special attention should always be paid to the **DEMO mode** indications (like **DEMO Patient** name, **DEMO** MRN identification). Otherwise there is a risk of misinterpreting the **DEMO mode** data as actual clinical data.

WARNING

MISSED ALARMS. Patient profiles contain default alarm settings based on patient demographics or care unit. Selecting a profile that is unsuitable for the monitored patient may result in missed alarms and/or nuisance alarms.

Operation warnings

WARNING

PATIENT SAFETY. After transferring or reinstalling the device, always check that it is properly connected and all parts are securely attached. Otherwise, there may be a risk of something falling on the patient and causing injury.

WARNING

ACCURACY. If the accuracy of any value displayed on the monitor or central station is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

WARNING

ERRONEOUS READINGS. The device/system should not be used adjacent to, or stacked with, other equipment. Consult qualified personnel regarding device/system configuration.

WARNING

ACCURACY. Operation of Carescape ONE outside the specified performance range may cause inaccurate results.

Service warnings

WARNING

PATIENT SAFETY. Do not perform any service activities on the monitor in the patient vicinity while a patient is connected to the monitor.

Site requirement warnings

WARNING

BEFORE INSTALLATION. Compatibility is critical to safe and effective use of this device. Verify the compatibility of all system components and device interfaces, including hardware and software versions, prior to installation and use.

System warnings

WARNING

EXPLOSION. Do not use this system in the presence of flammable anesthetics, vapors or liquids.

WARNING

PATIENT SAFETY. If an error message appears during operation, it is the licensed medical practitioner's responsibility to decide whether the device is still suitable for patient monitoring. As a general rule, monitoring should only continue in extremely urgent cases and under the direct supervision of a licensed healthcare practitioner. The device must be repaired before being used again on a patient. If an error message appears after power-up, the device must be repaired before being used on a patient.

WARNING

PATIENT SAFETY. To avoid risks to patient safety, never modify or alter the connectors on product or accessories in any way. Alterations or modifications may affect patient safety, performance, and accuracy.

WARNING

EQUIPMENT DAMAGE. If the Carescape ONE, power supply, docks, or micro-modules are dropped from a height greater than 1 m, have them checked by qualified service personnel before taking them back into use.

WARNING

PATIENT SAFETY. Do not use micro-modules or the TruSignal Pressure micro-module dual adapter cable if you see any visual signs of damage.

WARNING

PATIENT SAFETY. Do not place the Carescape ONE in a patient bed.

WARNING

INACCURATE RESULTS. Do not use or store the equipment outside the specified temperature, humidity, or altitude ranges, or outside the specified performance range. Using or storing the equipment outside the specified operating environment or outside the specified performance range may cause inaccurate results.

WARNING

LOSS OF MONITORING. The Carescape ONE must always be used with a battery inserted. This will ensure the functioning of the monitor during possible supply mains interruptions.

WARNING

ELECTRIC SHOCK. Do not touch the electrical connector located in the Carescape Dock F0 to avoid the risk of electric shock.

System caution safety messages

The following caution safety messages apply to this monitoring system.

Battery cautions

CAUTION

LOSS OF MONITORING. To prevent loss of monitoring, only change the Carescape ONE battery when Carescape ONE is connected to a powered docking solution.

Cleaning cautions

CAUTION

EQUIPMENT DAMAGE. Do not apply pressurized air or gas to any outlet or tubing connected to the monitor. Pressure may destroy sensitive elements.

Disinfection cautions

CAUTION

IMMERSION. Never immerse Carescape ONE components in cleaning fluids or disinfecting agents.

Disposal cautions

CAUTION

DISPOSAL. At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of each product. If you have any questions concerning disposal of a product, please contact GE HealthCare or its representatives.

CAUTION

PACKAGING DISPOSAL. Dispose of the packaging material, observing the applicable waste control regulations.

Electrical caution

CAUTION

POWER REQUIREMENTS. Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the device's label. If this is not the case, do not connect the system to the power line until you adjust the device to match the power source. In U.S.A., if the installation of this equipment will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit. This equipment is suitable for connection to public mains as defined in CISPR 11.

Loss of data

CAUTION

LOSS OF DATA. Should the monitor at any time temporarily lose patient data, the potential exists that active monitoring is not being done. Close patient observation or alternate monitoring devices should be used until monitor function is restored. If the monitor does not automatically resume operation within 60 seconds, power cycle the monitor by turning it off and then on again. Once monitoring is restored, you should verify correct monitoring state and alarm function.

Monitoring cautions

CAUTION

PATIENT SAFETY. The waveform autoscaling feature automatically updates the display from the best possible signal amplitude. Always make sure that the waveform display scale is correctly understood and does not lead to delayed patient treatment.

CAUTION

DISCHARGE TO CLEAR PATIENT DATA. When admitting a new patient/starting a new case, you must clear all previous patient data from the system. To accomplish this, disconnect the patient cables, then discharge the previous patient/end the case.

CAUTION

MISINTERPRETATION OF HISTORICAL DATA. To avoid possible misinterpretation of historical data when viewing it, special attention should always be paid to the time and date information.

Site requirement caution

CAUTION

LOSS OF MONITORING. Leave space for circulation of air to prevent the device from overheating. The manufacturer is not responsible for damage to device caused by improperly vented cabinets, improper or faulty power, or insufficient wall strength to support device mounted on such walls.

Touchscreen caution

CAUTION

LOSS OF FUNCTIONALITY. To prevent loss of touchscreen functionality, the device screen should be kept clean.

Notice safety messages

The following notice safety message applies to this monitoring system:



NOTICE

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

Network safety messages

The following safety messages apply when using Carescape ONE in the wireless transport mode.

Network warnings

WARNING

PATIENT SAFETY. Alarms do not sound, alarm histories are not stored, and alarms are not sent to the network when the alarms are turned off. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS. Alarms do not sound and alarms are not sent to the Carescape Network during Audio Pause. As this may lead to missed alarms, observe the patient frequently.

WARNING

PATIENT SAFETY. Only the most recent, highest priority alarm is sent to remote devices on the Carescape Network. Therefore, less recent alarms of equal or lower priority may not be displayed or may not be indicated with their associated priority remotely. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS. Equipment malfunctions, network disconnection, and alarm volume settings may result in missed alarms. Always keep the patient under close surveillance.

WARNING

MISSED ALARM. Do not rely on receipt of certain alarm conditions at a central station, remote bedside, or alarm notification device when connected to the Carescape Network. Notification of any of these alarms will only be given when it is the most recent, highest priority active alarm coming from the bedside monitor. This applies to those limit alarms and technical alarms that are defined as broadcast only alarms in this manual.

WARNING

MISSED ALARMS. The audible alarm signal may be paused temporarily from a central station or remote monitor. Always pay attention to the alarm signal status and observe the patient frequently.

Network cautions

CAUTION

MISINTERPRETATION. System time changes will result in time differences between stored and realtime data. Always check the times carefully to avoid the risk of misinterpretation.

CAUTION

MISINTERPRETATION OF HISTORICAL DATA. Changing the date and time on one network device on the Carescape Network will also update the date and time for all other devices on the same network. To avoid possible misinterpretation of historical data when viewing it, special attention should always be paid to the time and date information.

Safety messages for parts of the system

Safety messages specific to parts of the system are found here as well as in the relevant sections of this document.

Alarm warnings

WARNING

PATIENT SAFETY. When the alarms are off or while alarm audio is paused either temporarily or indefinitely, observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS. Always make sure that the audio alarm volume level is adequate in your care environment to avoid missing alarms or not recognizing them due to too low a volume. Audio levels that are less than ambient levels may lead to unrecognized or missed alarms.

WARNING

MISSED ALARMS. Always make sure that the alarm light brightness is adequate in your care environment to avoid missing any alarms.

WARNING

PATIENT SAFETY. Always make sure that necessary alarm limits are active and set according to the patient's clinical condition when you start monitoring a patient, to avoid any risks to patient safety caused by erroneous or no alarms.

WARNING

PATIENT SAFETY. Verify that alarm processing is active and check the patient to ensure no arrhythmias occurred during a power interruption. Otherwise, there is a risk of compromised patient safety.

WARNING

MISSED ALARMS. Always check the alarm status after a prolonged power interruption to avoid missing any alarms.

WARNING

PATIENT SAFETY. Alarms do not sound and alarm histories are not stored when the alarms are turned off. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

PATIENT SAFETY. There are no alarm indications until parameter-specific alarm prerequisites have been met. Keep the patient under close surveillance when starting monitoring.

WARNING

PATIENT SAFETY. Alarm messages may not be visible on the alarm display area when three higher priority alarms are active. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

PATIENT SAFETY. Latched alarms are not retained through a monitor reset if the alarm condition has been removed. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS. Equipment malfunctions, network disconnection, and alarm volume settings may result in missed alarms. Always keep the patient under close surveillance.

WARNING

MIXED ENVIRONMENT. A hazard can exist when the same type of monitors in the same care area are using different monitoring profiles and default configuration settings.

WARNING

MISSING CRITICAL EVENTS. Reducing the physiological alarms' priority levels lower than the default level can lead to missed detection of critical or serious events and therefore to adverse patient outcome. Keep the patient under close surveillance if you adjust the priority levels lower than the default value for the following physiological alarms:

- V Tach
- Ventricular and atrial arrhythmias
- Tachy/PR high
- Brady/PR low
- Frequent PVCs and SVCs
- ST low/high
- SpO₂ low/high
- RR (Impedance) low/high, RR (CO₂) low/high
- Apnea (Impedance), Apnea (CO₂)
- NIBP low/high
- IP, CPP low/high
- CO₂ low/high
- Temperature low/high

WARNING

MISSING CRITICAL EVENTS. NICU software package only: Selecting the Off alarm priority for V Tach results in the system no longer monitoring ventricular tachycardia from ECG. If you select this option, keep the patient under close surveillance to avoid missing any critical events.

WARNING

MISSED ALARMS. Reducing the technical alarms' priority levels lower than the default level can lead to missed detection of critical events and therefore to adverse patient outcome. If you adjust the priority levels for ECG lead off, ECG Leads off, Noisy ECG, Arrhythmia paused, Resp (Imped.) measurement paused, or SpO₂ probe off alarms lower than the default value, keep the patient under close surveillance.

WARNING

MISSED ALARMS. The Carescape ONE provides two different types of audible alarm tones, IEC and legacy. To avoid user confusion with alarm tones, configure all Carescape monitors to the same type of audible alarm tones used in your clinical environment.

ECG warnings

WARNING

ELECTRIC SHOCK. To avoid the risk of shock caused by leadwire set clips or snaps, which may conduct electricity, make sure that they do not touch any electrically conductive material including earth.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

MISINTERPRETATION. This device is intended to record electrocardiograms from surface ECG electrodes. It is not meant for positioning (floating) temporary pacemaker leadwires, performing pericardiocentesis, or other internal applications. Using the device in ways other than its intended use may lead to misinterpretation of measurement data.

WARNING

MISINTERPRETATION. The **Maximum** filter may alter the displayed ECG morphology. Do not make measurements from the displayed or printed ECG when this filter is selected. Displayed ST values are calculated before applying the **Maximum** filtering and may differ from values measured from the displayed or printed ECG.

WARNING

MISSED ALARMS. Disconnected electrodes or loose electrode connections can lead to missed critical severity ECG alarms. If the device reports **Leads off** after you have selected **Update lead set**, always check the electrode connections to the patient.

WARNING

CONDUCTIVE CONNECTIONS. Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input.

WARNING

DELAYED ASYSTOLE ALARM. The pulsatile heart rate may have a slower response time than the electrical heart rate where there is a low perfusion patient condition. When using the IntelliRate feature in this situation, the device may delay calling an ASYSTOLE patient alarm. The user may elect to turn the IntelliRate feature off for patients at risk of these events, otherwise patient treatment may be delayed. Such patients should always be kept under close observation.

WARNING

NOISY ECG ALARM. The **Noisy ECG** alarm indicates that the system is no longer monitoring ECG and there may be no **Tachy** or **Brady** alarms. If you adjust the alarm priority level lower than the default value, keep the patient under close surveillance.

WARNING

ARRHYTHMIA PAUSED ALARM. The **Arrhythmia paused** alarm indicates that the system is no longer monitoring ECG and there may be no **Tachy** or **Brady** alarms. If you adjust the alarm priority level lower than the default value, keep the patient under close surveillance.

WARNING

INACCURATE HEART RATE INDICATION. The electrical and pulsatile heart rate values provided by the various monitored parameters (ECG, SpO₂, blood pressures) may differ markedly. These differences may be due to underlying physiologic conditions (e.g., electromechanical dissociation, pulseless electrical activity, non-perfusing rhythms) or to inaccuracies in the heart rate values caused by artifact, poor signal quality, or arrhythmias. The user may elect to turn the IntelliRate feature off for patients at risk of these events, otherwise patient treatment may be delayed. Such patients should always be kept under close observation.

WARNING

ELECTRODES. Whenever patient defibrillation is a possibility, use non-polarizing (silver/silver chloride construction) electrodes for ECG monitoring. Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge will block acquisition of the ECG signal.

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires.

WARNING

HEART RATE ALARM INTERFERENCE. Poor cable positioning or improper electrode preparation may cause line isolation monitor transients to resemble actual cardiac waveforms and thus inhibit heart rate alarms. To minimize this problem, follow proper electrode placement and cable positioning guidelines provided with this device.

ECG cautions

CAUTION

SKIN IRRITATION. The patient's skin may become irritated after prolonged contact with electrode gel or adhesive. To avoid skin irritation, periodically check the patient, and if possible, avoid extended measurement periods.

Pacemaker detection warnings

WARNING

RATE METERS. Keep pacemaker patients under close observation. Rate meters may continue to count the pacemaker rate during cardiac arrest and some arrhythmias. Therefore, do not rely entirely on rate meter alarms. See the supplemental information provided for disclosure of the pacemaker pulse rejection capability of this device.

WARNING

FALSE CALLS. False low heart rate indicators or false Asystole calls may result with certain pacemakers because of pacemaker artifact such as electrical overshoot of the pacemaker overlapping the true QRS complexes.

WARNING

MONITORING PACEMAKER PATIENTS. The monitoring of pacemaker patients can only occur with the pace program activated.

WARNING

PACEMAKER INDICATION. Pacemaker activity is indicated on the electrocardiogram through the display of a different colored pacemaker marker pulse. All pacemaker marker pulses appear upright and uniform and should not be used for diagnostic interpretation.

WARNING

PATIENT HAZARD. A pacemaker pulse can be counted as a QRS during Asystole when pacemaker detection is on. Keep pacemaker patients under close observation.

WARNING

PATIENT HAZARD. Asystole may not be detected if the patient has a pacemaker that produces high-amplitude pacer spikes and pacemaker detection is on. Keep pacemaker patients under close observation.

Arrhythmia monitoring warnings

WARNING

MISSED ALARMS. V Fib/V Tach should not be considered a substitute for the V Tach arrhythmia alarm. Efforts to lower the V Tach alarm level can result in missed ventricular tachycardia alarms.

WARNING

LOSS OR DETERIORATION OF ARRHYTHMIA DETECTION. Automated arrhythmia analysis programs may incorrectly identify the presence or absence of an arrhythmia. A physician must therefore interpret the arrhythmia information in conjunction with other clinical findings. Please take special note of the following ECG waveform conditions:

- Noisy waveforms. Noisy portions of ECG waveforms are typically excluded from analysis. The exclusions are necessary to reduce the occurrence of inaccurate beat interpretations and/or rhythm alarms. If the excluded noisy portions of the ECG waveform contain true arrhythmia events, those events may remain undetected by the system.
- Beat amplitude and duration. Accurate detection and interpretation of beats becomes increasingly difficult as the amplitude and/or duration of those beats approach the design limits of the analysis program. Thus, as beats become extremely wide or narrow, or especially as beats become small, arrhythmia interpretation performance may degrade.
- Other morphology considerations. Automated arrhythmia detection algorithms are designed fundamentally to detect significant changes in QRS morphology. If an arrhythmia event is present and does not exhibit a significant change from the patient's predominant morphology, it is possible for those events to remain undetected by the system.

WARNING

PAUSED ANALYSIS. Certain conditions pause arrhythmia analysis. When paused, arrhythmia conditions are not detected and alarms associated with arrhythmias do not occur. Conditions causing paused arrhythmia analysis include arrhythmia off, arrhythmia paused, leads fail, alarm pause, all alarms off, and discharged patient. Always keep the patient under close surveillance.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. Always monitor ECG for arrhythmia detection purposes. HR calculated from pulsatile SpO₂ waveform may differ significantly from ECG HR measured values. Users should be aware that the **SpO2 probe off** and **Check SpO2 probe** technical alarms escalate no higher than a **Medium** priority.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. The SpO₂ parameter pulsatile heart rate measurement is based on the optical detection of a peripheral flow pulse and therefore cannot detect arrhythmias. The pulse oximetry parameter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

WARNING

ARRHYTHMIA PAUSED alarm. The **Arrhythmia paused** alarm indicates that the system is no longer monitoring arrhythmia or heart rate from ECG. If you adjust the alarm priority level lower than the default value, keep the patient under close surveillance.

Respiration warnings

WARNING

ELECTRIC SHOCK. To avoid the risk of shock caused by leadwire set clips or snaps, which may conduct electricity, make sure that they do not touch any electrically conductive material including earth.

WARNING

ERRONEOUS READINGS. The impedance respiration measurement is inherently very sensitive as it measures very small physiological signals (changes of impedance of the patient's chest area). Electromagnetic interference may cause erroneous measurements at various frequencies, for example interference with the signal/ waveform, leading to respiration rate readings inconsistent with the patient's true respiration rate. If you notice this, use another form of respiration monitoring, for instance end-tidal CO₂.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

APNEA EVENTS. The device may not detect all episodes of inadequate breathing, nor does it distinguish between central, obstructive, and mixed apnea events.

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires.

WARNING

ELECTRODE CONFIGURATION. Impedance respiration monitoring is not reliable when ECG electrodes are placed anywhere but on the chest.

WARNING

ELECTRODES. Whenever patient defibrillation is a possibility, use non-polarizing (silver/ silver chloride construction) electrodes for ECG monitoring. Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge will block acquisition of the ECG signal.

Respiration cautions

CAUTION

PATIENT SAFETY. The impedance respiration measurement may cause rate changes in Minute Ventilation Rate Responsive Pacemakers. Set the pacemaker rate responsive mode off or turn off the impedance respiration measurement on the monitor to avoid risks to the patient.

SpO₂ warnings

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

WARNING

PATIENT SAFETY. The operator is responsible for checking the compatibility of the pulse oximetry device, sensor, and patient cable prior to use. Incompatible components can result in degraded performance, device malfunction, and/or compromised patient safety.

WARNING

PATIENT SAFETY. If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs, then check for conditions that may cause inaccurate SpO₂ readings. If the problem is still not resolved, check the Carescape ONE, SpO₂ micro-module, and sensor for proper functioning.

WARNING

PATIENT SAFETY. A pulse oximeter should not be used as an apnea monitor. A pulse oximeter should be considered an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.

WARNING

PATIENT SAFETY. Check that the pulse oximetry waveform is physiological in shape to ensure waveform quality and minimize noise spikes caused by motion conditions. Otherwise, there is a risk of compromised patient safety. (Not applicable when monitoring SpO₂ with Masimo SET technology.)

WARNING

PATIENT SAFETY. To prevent erroneous readings, do not use a physically damaged SpO₂ micro-module or sensors. Discard damaged sensors immediately. Never repair a damaged sensor or SpO₂ micro-module; never use a sensor or SpO₂ micro-module repaired by others.

WARNING

PATIENT SAFETY. Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore does not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis. Otherwise, there is a risk of compromised patient safety.

WARNING

PATIENT SAFETY. Cable/sensor after care:

- Do not reuse sensors intended for single patient use.
- Do not sterilize sensors or patient cables by irradiation, steam, or ethylene oxide.
- Clean the surface of the reusable probe before and after each patient use.
- Allow sensor and cable to dry completely after cleaning. Moisture and dirt on the connector can affect the measurement accuracy.
- If a probe is damaged in any way, discontinue use immediately.
- Inaccurate SpO₂ data can result if a sensor is past its useful life. Therefore, re-evaluate the measurement periodically by performing additional assessment of the patient and equipment, including consideration of use of alternate monitoring methods such as direct measurement of arterial oxyhemoglobin saturation (SaO₂).
- A damaged sensor may cause burns during electrosurgery.

WARNING

PATIENT SAFETY. Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high. Always keep the patient under close observation.

WARNING

NEONATAL INACCURATE RESULTS. The display of inaccurate pulse oximetry (SpO₂) values has been linked to the presence of poor signal strength or artifact due to patient motion during signal analysis. This condition is most likely to be encountered when the monitor is used on neonates or infants. These same conditions in adults do not impact the SpO₂ values to the same extent.

We recommend the application of the following criteria when using the pulse oximetry function on neonates and infants:

- The peripheral pulse rate (PPR) as determined by the SpO₂ function must be within 10% of the heart rate, and
- The SpO₂ signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of the **Low signal quality** message.

Procedures or devices previously applied in your facility for SpO₂ monitoring should be used in the event the SpO₂ value from the monitor cannot be validated by the above criteria.

WARNING

ERRONEOUS READINGS. Many factors may cause inaccurate readings and alarms, decreased perfusion, and or low signal strength:

- Interfering substances:
 - Carboxyhemoglobin may erroneously increase SpO₂ reading.
 - Methemoglobin (MetHb) usually represents less than 1% of the total Hb, but in the case of methemoglobinemia that can be congenital or induced by some IV dyes, antibiotics (such as sulphas), inhaled gases, etc., this level increases sharply and thus can cause inaccuracies in the SpO₂ reading.
 - Intravascular dyes (such as indocyanine green, methylene blue, etc.)
- Physiological characteristics:
 - Cardiac arrest
 - Hypotension
 - Shock
 - Severe vasoconstriction
 - Severe anemia
 - Hypothermia
 - Venous pulsations
 - Darkly pigmented skin
 - Ventricular septal defects (VSDs)
 - Nail polish or artificial nails at the measurement site
- Environmental conditions:
 - Electromagnetic interference
 - Excessive ambient light
 - Electrical interference
 - Electrosurgery
 - Defibrillation - May cause inaccurate reading for a short amount of time.
 - Excessive patient/sensor motion. Artifact can simulate an SpO₂ reading, so that the device fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.
- Sensor placement:
 - Incorrect sensor placement - prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. It is recommended that you check the probe site every four hours (more frequently for poor perfusion or for neonates). Refer to the instructions supplied with the sensor.
 - Sensor placement on the same extremity as a blood pressure cuff, arterial catheter or intravascular line; or arterial occlusion proximal to the sensor.
 - Poor sensor fit or sensor applied too tightly.

- Do not allow tape to block the sensor light emitter and detector.
- Improper connection to the monitor or interconnect cable.
- Contamination of lenses inside the sensor.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. Always monitor ECG for arrhythmia detection purposes. HR calculated from pulsatile SpO₂ waveform may differ significantly from ECG HR measured values. Users should be aware that the **SpO₂ probe off** and **Check SpO₂ probe** technical alarms escalate no higher than a **Medium** priority.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. The SpO₂ parameter pulsatile heart rate measurement is based on the optical detection of a peripheral flow pulse and therefore cannot detect arrhythmias. The pulse oximetry parameter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

WARNING

PATIENT SAFETY. Using the **Maximum** sensitivity setting delays the **SpO₂ probe off** detection alarm. It is recommended to use the **Maximum** sensitivity setting in care areas where the application site is inspected frequently. (Available when monitoring SpO₂ with Masimo SET technology.)

WARNING

PATIENT SAFETY. With deactivated **SpO₂ probe off** alarm, keep the patient under close surveillance.

WARNING

MISSED ALARM. Check the SpO₂ measurement when switching the SpO₂ measurement sources to avoid missed SpO₂ alarms.

WARNING

SKIN IRRITATION. Prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. It is recommended that you check the probe site every four hours (more frequently in case of poor perfusion or neonatal patients). Refer to the instructions supplied with the sensor.

The following warnings apply to Nellcor SpO₂ micro-module only.

WARNING

CHOKING HAZARD. The Nellcor SpO₂ micro-module contains small detachable parts.

WARNING

ELECTRIC SHOCK. Do not insert any foreign objects into the connector of the Nellcor SpO₂ micro-module.

SpO₂ cautions

CAUTION

BURNS. A damaged sensor or a sensor soaked in liquid may cause burns during electrosurgery. To avoid this risk, always ensure that the sensor is undamaged and dry.

NIBP warnings

WARNING

PATIENT SAFETY. The NIBP parameter will not measure blood pressure effectively on patients who are experiencing seizures or tremors.

WARNING

PATIENT SAFETY. Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure and may extend the time beyond the capabilities of the parameter.

WARNING

ERRONEOUS READINGS. Do not apply external pressure against the cuff while monitoring. Doing so may cause inaccurate blood pressure values. Use care when placing the cuff on an extremity used to monitor other patient parameters.

WARNING

ERRONEOUS READINGS. NIBP cuff inflation/deflation may lead to inaccurate values from other monitored patient parameters that are measured distally from the NIBP measurement site at the same extremity.

WARNING

PATIENT SAFETY. Ensure that the connection tubing is not kinked. Kinked tubing may cause continuous cuff pressure, which can interfere with the blood flow and cause injury to the patient.

WARNING

PATIENT SAFETY. Do not place the cuff on the arm on the side of a mastectomy or lymph node clearance as this may lead to injury or swelling of the arm due to cuff pressurization. To avoid this risk, use another limb if possible.

WARNING

PATIENT SAFETY. Do not place the cuff over a wound as this may cause further injury.

WARNING

PATIENT SAFETY. To prevent injury to the patient, do not place the cuff on a limb being used for A-V fistulas, intravenous infusion or on any area where circulation is compromised or has the potential to be compromised. To avoid this risk, use another limb if possible.

WARNING

ERRONEOUS READINGS. GE HealthCare NIBP devices are designed for use with dual-hose cuffs and tubing. The use of single-hose cuffs with dual hose tubing can result in unreliable and inaccurate NIBP data.

WARNING

ERRONEOUS READINGS. Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper size cuff.

WARNING

NIBP READINGS MAY TIME OUT WHEN USING IABP. An IABP creates non-physiological arterial waveforms. These waveforms create an oscillometric signal that may not be interpreted by the NIBP algorithm, causing NIBP to time out. The patient's invasive blood pressure can be monitored from the balloon pump device.

WARNING

PATIENT SAFETY. The NIBP patient type must be correctly selected in the NIBP **Settings** window to obtain reliable NIBP data and to prevent excessive cuff pressure during infant or child use.

WARNING

PATIENT SAFETY. Always ensure that you are using NIBP infant settings when monitoring neonatal patients. Using other settings may lead to risks to the patient due to wrong alarm limits or cuff pressure, for example.

WARNING

ERRONEOUS READINGS. If a patient's beat-to-beat pulse amplitude varies significantly (e.g., because of pulsus alternans, atrial fibrillation, or the use of a rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic, and an alternate measuring method should be used for confirmation.

WARNING

ERRONEOUS READINGS. For SuperSTAT NIBP (Adult/Child) only. It takes one to three minutes for the NIBP parameter to identify an irregular rhythm after ECG is connected. For patients with irregular rhythms, wait three minutes after ECG has been connected and ECG heart rate is present on the screen before performing an NIBP determination.

WARNING

PREGNANT PATIENTS. Effectiveness of the NIBP measurement has not been established in pregnant (including pre-eclamptic) patients.

WARNING

PATIENT SAFETY. The NIBP device sets the inflation pressure automatically according to the previous measurement. Reset the case or discharge the patient to reset the inflation limits before measuring NIBP on a new patient.

WARNING

PATIENT SAFETY. Devices that exert pressure on tissue have been associated with purpura, skin avulsion, compartmental syndrome, ischemia, and/or neuropathy. To minimize these potential problems, especially when monitoring at frequent intervals or over extended periods of time, make sure the cuff is applied appropriately and examine the cuff site and the limb distal to the cuff regularly for signs of impeded blood flow. Periodically check patient limb circulation distal to the cuff. Check frequently when using auto NIBP in 1 and 2 minute intervals. The 1 and 2 minute intervals are not recommended for extended periods of time.

Invasive pressure warnings



WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

WARNING

PATIENT SAFETY. All invasive procedures involve risks to the patient. Use aseptic technique. Incorrect use of the catheter can lead to vessel perforation. Follow catheter manufacturer's instructions.

WARNING

ELECTRIC SHOCK. To avoid the risk of electric shock, make sure that no part of the patient connections touches any electrically conductive material including earth.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

ERRONEOUS READINGS. Mechanical shock to an invasive blood pressure transducer may cause severe shifts in the zero balance and cause erroneous readings.

WARNING

ERRONEOUS READINGS. Repositioning the patient after a completed zeroing procedure may cause incorrect measurement values.

WARNING

INCORRECT PULSE RATE. Be sure to turn off the IABP setting when the cardiac assist device is no longer used. Failure to do so could result in incorrect pulse rate readings.

WARNING

EQUIPMENT DAMAGE. Do not immerse the cable connectors in liquids or allow liquid to enter the cable connectors.

WARNING

ERRONEOUS READINGS. Setting the invasive pressure noise reduction filter below 12Hz may impact systolic and diastolic measurement accuracy and pressure waveform. Before applying the filter, ensure that the physical measurement system (catheter/tubing/transducer) does not contribute to noise or artifacts in the measurement.

Invasive pressure cautions

CAUTION

PATIENT HAZARD. If you choose to trigger the balloon pump from the monitor, contact the balloon pump manufacturer directly for interface requirements, as they vary among manufacturers. Some trigger modes on certain balloon pump devices may not be compatible with the GE HealthCare analog output signal, and use may contribute to patient injury or sub-optimal pumping results.

Temperature warnings

**WARNING**

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

PATIENT SAFETY. There are hazards associated with the reuse of single-use temperature probes.

WARNING

PATIENT SAFETY. Use of devices containing phthalates should be limited to the amount of time treatment is medically necessary, especially for neonates and pregnant or nursing mothers.

Temperature cautions

CAUTION

INACCURATE READINGS. To obtain accurate temperature measurements, use only 400 series temperature probes. Using other types of probes can lead to inaccurate readings.

CO₂ warnings

WARNING

PATIENT SAFETY. Always inspect the airway adapter for a tight connection and proper operation before attaching it to the breathing circuit.

WARNING

ERRONEOUS READINGS. Leaks in the gas sampling circuit (sampling line) may cause inaccurate readings.

WARNING

WATER TRAP BLOCKAGE. Remove the airway sampling line from the patient's airway while nebulized medications are being delivered.

WARNING

STRANGULATION. Route all tubing away from the patient's throat to avoid strangulation.

WARNING

INFECTION HAZARD. To avoid the spread of infectious disease, do not allow the exhaust to discharge in the direction of the patient or user.

WARNING

APNEA EVENTS. The device may not detect all episodes of inadequate breathing, nor does it distinguish between central, obstructive, and mixed apnea events.

WARNING

ERRONEOUS READINGS. O₂, N₂O and anesthetic agent gases may interfere with EtCO₂ readings.

WARNING

CROSS-INFECTION. To avoid the risk of patient cross-infection, do not return the sampled gas to the breathing system.

WARNING

ERRONEOUS READINGS. Strong scavenging suction may change the operating pressure of the module and cause inaccurate readings or excessive sample gas flow.

WARNING

INACCURATE READINGS. Do not allow the exhaust line to become kinked or blocked. Back pressure may cause inaccurate gas readings.

WARNING

PATIENT SAFETY. An alarm for low flow rate is generated when the flow drops to approximately 20% of the nominal flow rate of 50 ml/min. This rate is below the lowest specified flow rate of 40 ml/min.

WARNING

PATIENT SAFETY. Do not use this device on patients that cannot tolerate the removal of 50 ml/min $\pm$ 10 ml/min from their total minute ventilation.

WARNING

PATIENT SAFETY. Use of devices containing phthalates should be limited to the amount of time treatment is medically necessary, especially for neonates and pregnant or nursing mothers.

WARNING

PATIENT SAFETY. Always ensure the correct size and fit of accessories according to patient type and application, especially when monitoring pediatric and neonatal patients. The size and fit of accessories may impact the measured gas concentration values at low tidal volumes. It is recommended to have the gas sampling port close to the proximal end of the endotracheal tube. Excessive dead space in the circuit, including the accessories, may cause re-breathing of gases. Very low accessory dead space between the breathing circuit Y-piece and the gas sampling site may impact the measured gas concentration due to dilution of the sampled exhaled gas with fresh gas from the ventilator. To confirm accurate correlation with measured gases and blood, check arterial blood gas values to confirm a suitable setup is used.

WARNING

PATIENT SAFETY. With deactivated **Apnea** alarm, keep the patient under close surveillance.

WARNING

INACCURATE READINGS. To avoid the risk of inaccurate CO₂ readings, you must select the appropriate patient age range before starting a CO₂ measurement with Microstream CO₂ micro-module.

CO₂ cautions

CAUTION

EQUIPMENT DAMAGE. Do not apply pressurized air or gas to any outlet or tubing connected to a CO₂ micro-module or Carescape ONE. Pressure may destroy sensitive elements.

CAUTION

EQUIPMENT DAMAGE. Do not insert any appendage, tool, sharp object, or liquid into the sample receptacle.

CAUTION

SYSTEM PERFORMANCE. The nasal and oral/nasal cannula kits are intended for single use. Do not reuse or sterilize the cannula kit as system performance will be compromised.

Indications for use

Carescape ONE indications for use

Carescape ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility.

Carescape ONE is indicated for the monitoring of hemodynamic and respiratory physiological parameters.

When the Carescape ONE is operated as a standalone multi-parameter physiological patient monitor, it provides the following physiological parameters:

- ECG (heart rate, ST segment, and arrhythmia detection)
- Pulse oximetry (pulse rate, functional oxygen saturation [SpO₂])
- Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)
- Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)
- Temperature
- Respiratory carbon dioxide (EtCO₂, FiCO₂, and respiration rate)
- Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible host monitor, it provides the following physiological parameters to the host monitor:

- ECG (heart rate, ST segment, and arrhythmia detection)
- Pulse oximetry (pulse rate, functional oxygen saturation [SpO₂], and total hemoglobin concentration [SpHb])
- Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)
- Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)
- Cardiac output (pulse contour)
- Regional oxygen saturation (rSO₂)
- Temperature
- Respiratory carbon dioxide (EtCO₂, FiCO₂, and respiration rate)
- Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible host monitor, visual and audible alarms, user controls, and user interface are provided on the compatible host monitor and not on Carescape ONE.

When Carescape ONE is operated as a transportable monitor, it can interface with a compatible host monitor to provide data for remote viewing and data management software devices via a network.

Carescape ONE is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

Carescape ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the proper use of the equipment in a professional healthcare facility.

Contraindications for using Carescape ONE

The Carescape ONE is not intended for use within a controlled MR environment.

Clinical benefits of using the monitor

The clinical benefit of a monitoring device is to provide real-time data of monitored parameters, alarms, trends, snapshots, and events to support decision-making of licensed healthcare practitioners for clinical assessment and context of patient status.

Micro-module indications for use

TruSignal ECG micro-module indications for use

The TruSignal ECG micro-module (TruSignal ECG MM) is intended for monitoring of electrocardiogram. TruSignal ECG micro-module is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

TruSignal Pressure micro-module indications for use

The TruSignal Pressure micro-module (TruSignal PRES MM) is intended for monitoring of invasive pressure and pulse rate. TruSignal Pressure micro-module is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

TruSignal Temperature micro-module indications for use

The TruSignal Temperature micro-module (TruSignal TEMP MM) is intended for monitoring of temperature. TruSignal Temperature micro-module is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

TruSignal SpO₂ micro-module indications for use

The TruSignal SpO₂ micro-module (TruSignal SpO₂ MM 1.8M/3.0M) is intended for monitoring arterial oxygen saturation and pulse rate. TruSignal SpO₂ micro-module is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

FloTrac CCO adapter indications for use

The FloTrac CCO adapter (FloTrac CCO ADPTR) is intended for use as an interface module connecting compatible FloTrac Pressure Cable—GE HealthCare to a host device within a professional healthcare facility. The FloTrac CCO adapter cannot be used for measurement as a standalone device. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using micro-modules

The following is applicable for all micro-modules listed in the Indications for use sections of this manual: The device is not intended for use within a controlled MR environment.

Clinical benefits of using micro-modules

Clinical benefits of the TruSignal ECG micro-module

The TruSignal ECG micro-module (TruSignal ECG MM) enables monitoring of electrocardiogram during patient care. Electrocardiogram (ECG) measurement data can help the clinical professional to evaluate the patient's hemodynamic condition and respiratory status and aid in timely patient care decisions when needed.

Clinical benefits of the TruSignal Pressure micro-module

The TruSignal Pressure micro-module (TruSignal PRES MM) enables monitoring of invasive pressure and pulse rate during patient care. Invasive pressure and pulse rate measurement data can help the clinical professional to evaluate the patient's hemodynamic condition and intracranial pressure, and aid in timely patient care decisions when needed.

Clinical benefits of the TruSignal Temperature micro-module

The TruSignal Temperature micro-module (TruSignal TEMP MM) enables monitoring of temperature during patient care.

Temperature measurement data can help the clinical professional to evaluate the patient's temperature and aid in timely patient care decisions when needed.

Clinical benefits of the TruSignal SpO₂ micro-module

The TruSignal SpO₂ micro-module (TruSignal SpO₂ MM 1.8M/3.0M) enables continuous non-invasive monitoring of arterial oxygen saturation and pulse rate during patient care. Arterial oxygen saturation and pulse rate measurement data can help the clinical professional to evaluate the patient's oxygenation and circulatory condition, and aid in timely patient care decisions when needed.

Clinical benefits of the FloTrac CCO adapter

The FloTrac CCO adapter (FloTrac CCO ADPTR) connects FloTrac Pressure Cable—GE HealthCare to the host monitor, thereby enabling clinical monitoring with the compatible FloTrac Pressure Cable.

Carescape Dock F0 indications for use

Carescape Dock F0 is intended for providing a DC power source to a docked Carescape ONE, which also charges the Carescape ONE battery. Carescape Dock F0 is intended to provide a docked Carescape ONE with communication to the host monitor.

The Carescape Dock F0 is indicated for use in multiple areas within a professional healthcare facility.

The Carescape Dock F0 is indicated for use under the direct supervision of a licensed healthcare practitioner, or by person trained in proper use of the equipment in a professional healthcare facility.

The Carescape Dock F0 is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time.

Contraindications for using the Carescape Dock F0

The Carescape Dock F0 is not intended for use within a controlled MR environment.

Clinical benefits of Carescape Dock F0

The Carescape Dock F0 enables interfacing Carescape ONE to a host device as well as providing a DC power source to a docked Carescape ONE.

Indications for use safety precautions

Indications for use warnings

WARNING

PATIENT SAFETY. Read all the safety information before using the device for the first time. This manual contains instructions necessary to operate this device safely and in accordance with its functions and intended use. This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology, as required for the monitoring of all patients.

WARNING

SINGLE PATIENT USE. This equipment is designed for use on one patient at a time. Using this equipment to monitor different parameters on different patients at the same time compromises the accuracy of data acquired.

WARNING

INSTRUCTIONS FOR USE. For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

WARNING

INTRAHOSPITAL TRANSPORT. Vibrations during intrahospital transport may disturb SpO₂, ECG, impedance respiration, NIBP, and IP measurements.

Indications for use cautions

CAUTION

PATIENT SAFETY. U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION

SUPERVISED USE. This equipment is intended for use under the direct supervision of a licensed healthcare practitioner.

Electromagnetic compatibility

EMC warnings

WARNING

PATIENT SAFETY. Use only approved accessories, including mounts, and defibrillator-proof cables and invasive pressure transducers. For a list of approved accessories, see the supplemental information provided. Other cables, transducers and accessories may cause a safety hazard, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

WARNING

EQUIPMENT DAMAGE AND PATIENT SAFETY. Do not use the device in high electromagnetic fields (for example, during magnetic resonance imaging).

WARNING

EMC. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Changes or modifications to this device/system not expressly approved by GE HealthCare may cause EMC issues with this or other equipment. This device/system is designed and tested to comply with applicable standards and regulations regarding EMC and needs to be installed and put into service according to the EMC information stated as follows: This device/system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Mains power should be that of a typical commercial or hospital environment. Device is compliant to Class A.

WARNING

ERRONEOUS READINGS. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Consult qualified personnel regarding device/system configuration.

WARNING

DEGRADED PERFORMANCE. Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of this device/system, including cables specified by the manufacturer. Otherwise, the performance of this device/system may degrade.

WARNING

PATIENT SAFETY. Other equipment may interfere with the system, even if that other equipment complies with CISPR emission requirements. This may lead to compromised patient safety.

WARNING

PARTIAL LOSS OF PARAMETERS. To prevent partial loss of parameters, do not route patient cables along with the AC mains power cord or ePort cable. Doing so may affect acquisition of parameter data.

Electromagnetic compatibility cautions

CAUTION

DEGRADED PERFORMANCE. Use of known RF sources, such as cell/portable phones, RFID, electronic article surveillance (EAS) systems, diathermy, or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation of this device/system. Consult qualified personnel regarding device/system configuration.

ESD safety precautions

WARNING

EQUIPMENT DAMAGE. Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless electrostatic discharge (ESD) precautions are used.

To avoid electrostatic charges building up, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or greater.

To prevent applying a possible electrostatic charge to the ESD sensitive parts of the equipment, touch the metallic frame of the component or a large metal object located close to the equipment. When working with the equipment and specifically when the ESD sensitive parts of the equipment may be touched, a grounded wrist strap intended for use with ESD sensitive equipment should be worn. See the documentation provided with the wrist straps for details of proper use. Floors should be covered by ESD dissipative carpets or similar. Special ESD-protective clothing, or optionally cotton-based clothing with natural fibres, should be used when working with the component.

System description

System safety precautions

System warnings

WARNING

EXPLOSION. Do not use this system in the presence of flammable anesthetics, vapors or liquids.

WARNING

PATIENT SAFETY. If an error message appears during operation, it is the licensed medical practitioner's responsibility to decide whether the device is still suitable for patient monitoring. As a general rule, monitoring should only continue in extremely urgent cases and under the direct supervision of a licensed healthcare practitioner. The device must be repaired before being used again on a patient. If an error message appears after power-up, the device must be repaired before being used on a patient.

WARNING

PATIENT SAFETY. To avoid risks to patient safety, never modify or alter the connectors on product or accessories in any way. Alterations or modifications may affect patient safety, performance, and accuracy.

WARNING

EQUIPMENT DAMAGE. If the Carescape ONE, power supply, docks, or micro-modules are dropped from a height greater than 1 m, have them checked by qualified service personnel before taking them back into use.

WARNING

PATIENT SAFETY. Do not use micro-modules or the TruSignal Pressure micro-module dual adapter cable if you see any visual signs of damage.

WARNING

PATIENT SAFETY. Do not place the Carescape ONE in a patient bed.

WARNING

INACCURATE RESULTS. Do not use or store the equipment outside the specified temperature, humidity, or altitude ranges, or outside the specified performance range. Using or storing the equipment outside the specified operating environment or outside the specified performance range may cause inaccurate results.

WARNING

LOSS OF MONITORING. The Carescape ONE must always be used with a battery inserted. This will ensure the functioning of the monitor during possible supply mains interruptions.

WARNING

ELECTRIC SHOCK. Do not touch the electrical connector located in the Carescape Dock F0 to avoid the risk of electric shock.

Operation warnings

WARNING

PATIENT SAFETY. After transferring or reinstalling the device, always check that it is properly connected and all parts are securely attached. Otherwise, there may be a risk of something falling on the patient and causing injury.

WARNING

ACCURACY. If the accuracy of any value displayed on the monitor or central station is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

WARNING

ERRONEOUS READINGS. The device/system should not be used adjacent to, or stacked with, other equipment. Consult qualified personnel regarding device/system configuration.

WARNING

ACCURACY. Operation of Carescape ONE outside the specified performance range may cause inaccurate results.

Carescape ONE installation points to note

- To avoid electrostatic charges building up, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or greater. Floors should be covered by ESD dissipative carpets or similar ESD dissipative products. Non-synthetic clothing should be used when working with the component.
- Choose a location that affords an unobstructed view of the display and easy access to the operating controls. Position the equipment so that access to disconnection via appliance coupler or mains plug is easy and unobstructed.
- Set up the monitor in a location that affords sufficient ventilation.
- The environmental operating conditions specified in the technical specifications must be ensured at all times.
- The monitor is designed to comply with the requirements of IEC 60601-1.
- Normal operating position of the Carescape ONE is mounted in a Carescape Dock F0 or Mini Dock.
- For a list of available mounting solutions, refer to the supplies and accessories supplement.
- For instructions regarding unpacking and how to proceed if the packaging has been damaged, unintentionally opened, or exposed to environmental conditions outside of those specified, see the service manual.

CAUTION

PACKAGING DISPOSAL. Dispose of the packaging material, observing the applicable waste control regulations.

Short description of the equipment



Carescape ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility.

Carescape ONE is indicated for the monitoring of hemodynamic and respiratory physiological parameters.

When the Carescape ONE is operated as a standalone multi-parameter physiological patient monitor, it provides the following physiological parameters:

- ECG (heart rate, ST segment, and arrhythmia detection)
- Pulse oximetry (pulse rate, functional oxygen saturation [SpO₂])
- Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)
- Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)
- Temperature
- Respiratory carbon dioxide (EtCO₂, FiCO₂, and respiration rate)
- Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible host monitor, it provides the following physiological parameters to the host monitor:

- ECG (heart rate, ST segment, and arrhythmia detection)
- Pulse oximetry (pulse rate, functional oxygen saturation [SpO₂], and total hemoglobin concentration [SpHb])
- Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)
- Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)
- Cardiac output (pulse contour)
- Regional oxygen saturation (rSO₂)
- Temperature
- Respiratory carbon dioxide (EtCO₂, FiCO₂, and respiration rate)
- Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible host monitor, visual and audible alarms, user controls, and user interface are provided on the compatible host monitor and not on Carescape ONE.

When Carescape ONE is operated as a transportable monitor, it can interface with a compatible host monitor to provide data for remote viewing and data management software devices via a network.

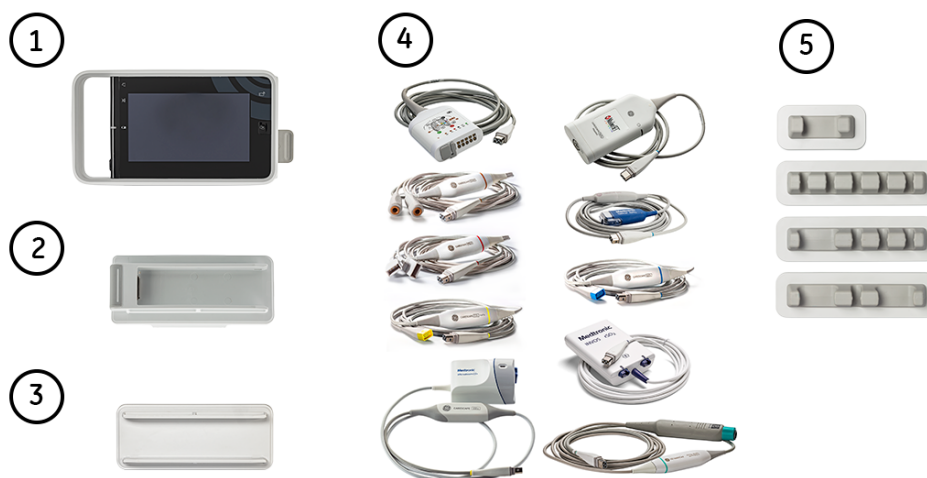
Carescape ONE is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

Carescape ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the proper use of the equipment in a professional healthcare facility.

Carescape ONE system components

All components listed below can be used within the patient environment.

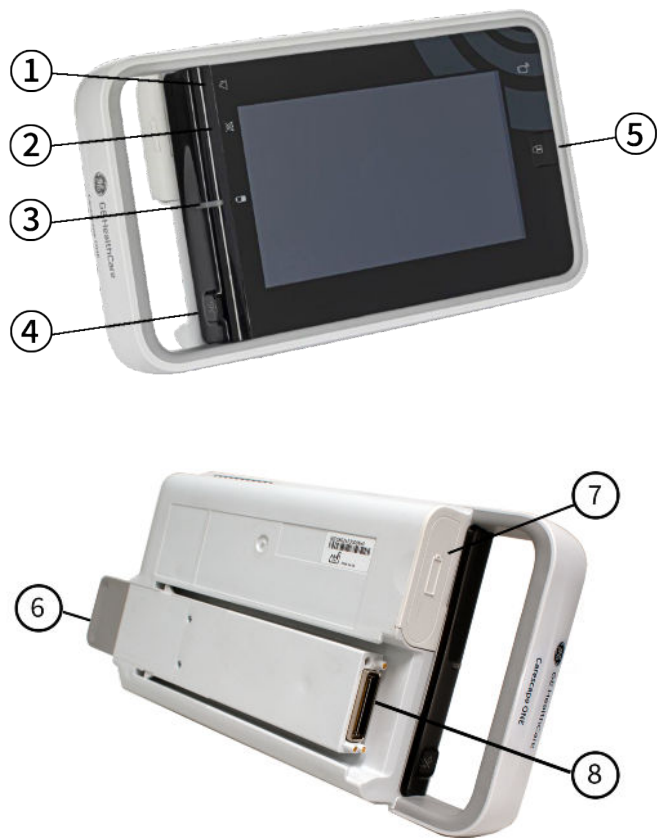
Your system may not include all these components. Consult your local representative for the available components.



1. Carescape ONE
2. Carescape Dock F0: Provides powered docking and battery charging for Carescape ONE.
3. Mini Dock: Provides unpowered docking for Carescape ONE.
4. Micro-modules used with Carescape ONE:
 - TruSignal ECG
 - TruSignal Temperature
 - TruSignal Pressure
 - LoFlo CO₂ (LoFlo CO₂ micro-module is an end-of-life product. For more information, see the Compliance appendix.)
 - Microstream CO₂
 - Masimo SpO₂
 - Nellcor SpO₂

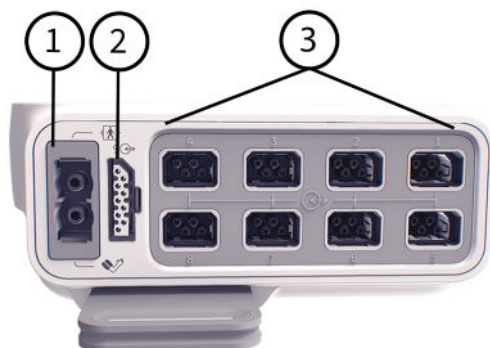
- TruSignal SpO₂
 - INVOS rSO₂
 - FloTrac CCO
5. Micro-module Dock 1, Micro-module Dock 3, Micro-module Dock 4, and Micro-module Dock 5:
Allows micro-modules to be mounted.

Carescape ONE front and back views



1	Alarm light area (blue, yellow, or red)
2	Audio alarm paused/off indicator (blue)
3	Battery status indicator (yellow or green)
4	Power on/standby button
5	Screen lock/unlock button
6	Pull tab
7	Battery door
8	Docking interface connector to the Carescape Dock F0

Carescape ONE side view



1	NIBP hose connector
2	Analog out / Defibrillator synchronization connector Connect IEC 60601-1 compliant medical devices to this port only.
3	Micro-module connectors, numbered from 1 to 8.

Micro-modules

NOTE

Some micro-modules are considered identical and should not be used simultaneously in the same monitoring system.

Parameter	Micro-module	Simultaneous use
ECG	TruSignal ECG 3, 5, or 6 leads, or 12 leads viewed with a 10-leadwire set	Only one per system.
Impedance respiration	TruSignal ECG	Only one per system.
Invasive pressures	TruSignal Pressure, FloTrac CCO Up to 5 measurement sites	One or two TruSignal Pressure micro-modules and one Flo-Trac CCO micro-module per system.
NIBP	No micro-module required, measurement is available with NIBP hose connected directly to Carescape ONE	N/A
Temperature	TruSignal Temperature Up to 2 measurement sites	Only one per system.
SpO ₂ TruSignal	TruSignal SpO ₂	Only one SpO ₂ micro-module per system (TruSignal SpO ₂ , Masimo SpO ₂ , or Nellcor SpO ₂).
SpO ₂ Masimo	Masimo SpO ₂	
SpO ₂ Nellcor	Nellcor SpO ₂	
CO ₂	LoFlo CO ₂ or Microstream CO ₂	Only one CO ₂ micro-module per system (LoFlo CO ₂ or Microstream CO ₂).

Parameter	Micro-module	Simultaneous use
rSO ₂	INVOS rSO ₂ Up to 4 measurement sites NOTE The rSO ₂ parameter can only be measured when the Carescape ONE is used as an acquisition platform with a host monitor. Refer to the host monitor manuals and the Instructions for use for INVOS rSO ₂ micro-module for more information.	Only two per system.
Continuous cardiac output	FloTrac CCO NOTE The continuous cardiac output parameter can only be measured when the Carescape ONE is used as an acquisition platform with a host monitor. Refer to the host monitor manuals for more information.	Only one per system.

FloTrac CCO micro-module and continuous cardiac output monitoring

The continuous cardiac output parameter can only be measured when the Carescape ONE is used as an acquisition platform connected to a host monitor. When the Carescape ONE is operating in standalone mode, continuous cardiac output monitoring, including trend collection, is paused, and the message **CCO measurement discontinued** is displayed on the Carescape ONE.

For information about monitoring the continuous cardiac output parameter, refer to the host monitor manuals.

INVOS rSO₂ micro-module and rSO₂ monitoring

The rSO₂ parameter can only be measured when the Carescape ONE is used as an acquisition platform connected to a host monitor. When the Carescape ONE is operating in standalone mode, rSO₂ monitoring, including trend collection, is paused, and the message **rSO₂ measurement disconnected** is displayed on the Carescape ONE.

For information on how to connect the INVOS rSO₂ micro-module to the patient and to the Carescape ONE, refer to the documentation provided with the INVOS rSO₂ micro-module.

For information about monitoring the rSO₂ parameter, refer to the host monitor manuals.

SpO₂ micro-module and monitoring SpO₂ with Masimo rainbow SET technology

Additional Masimo parameters (total hemoglobin, pleth variability index, and perfusion index) can only be measured with the Masimo rainbow SET technology when the Carescape ONE is used as an acquisition platform connected to a host monitor. When the Carescape ONE is operating in standalone mode, the monitoring of these parameters, including trend collection, is paused. For information about monitoring these parameters, refer to the host monitor manuals.

Power status indicator

The power on/standby indicator shows the power status.

LED	Description
Power on/standby (yellow) 	Indicates one of the following: - The device is connected to an external power source and is in battery charging only (standby) mode. - The device is booting up.
Power on/standby (green) 	Indicates that the device is ready for operation.
Power on/standby (unlit) 	Indicates that there is no power applied to the device.

Battery



WARNING

LOSS OF MONITORING. The Carescape ONE must always be used with a battery inserted. This will ensure the functioning of the monitor during possible supply mains interruptions.

The Carescape ONE is designed to operate on battery power when used for intra-hospital transport or whenever AC power is interrupted. A complete battery management system allows you to obtain maximum battery performance. On-screen capacity gauges indicate battery charge condition and capacity.

The Lithium-Ion battery is a rechargeable battery containing Lithium-Ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit. The processor within the equipment communicates with both the battery and the charger.

Battery status indicator

LED	Description
Yellow	Solid yellow indicates the battery is being charged.
Yellow, blinking once every 1 to 5 seconds	Slow blinking yellow indicates one of the following: - The device battery is not present. - A battery is present, but device communication with the battery cannot be established.
Yellow, blinking multiple times per second	Fast blinking yellow indicates the battery charge capacity is less than 60% of the design capacity.
Green and yellow, blinking once every 1 to 5 seconds	Slow blinking green and yellow indicates the battery time to empty is 20 minutes or less.

LED	Description
Green	Solid green indicates the device battery is in use.
Green and yellow, blinking multiple times per second	Fast blinking green and yellow indicates the battery time to empty is 5 minutes or less.

Installing batteries

WARNING

EXPLOSION OR FIRE. Using non-recommended batteries could result in injury/burns to the patients or users. Only use batteries recommended or manufactured by GE HealthCare. The warranty can be voided if non-recommended batteries are used.

WARNING

PHYSICAL INJURY. Do not install the device above a patient. Make sure the battery is completely inserted and the battery door is completely closed. Falling batteries could seriously or fatally injure neonatal or other vulnerable patients.

WARNING

EXPLOSION HAZARD. Do not incinerate a battery or store at high temperatures. Serious injury or death could result.

Batteries must be installed and fully charged prior to taking into use.

Testing the battery charge

Before installing a battery, verify the battery's state of charge. Each battery must be fully charged before use.

1. Press the **TEST** button on the battery and check the green charging level indicators to see how much charge is left:
 - Four LEDs illuminated: 75% to 100% of full-charge capacity.
 - Three LEDs illuminated: 50% to 74.9% of full-charge capacity.
 - Two LEDs illuminated: 25% to 49.9% of full-charge capacity.
 - One LED illuminated: 11% to 24.9% of full-charge capacity.
 - One LED flashing: < 11% of full-charge capacity.

Inserting and removing the Carescape ONE battery

WARNING

EXPLOSION OR FIRE. Using non-recommended batteries could result in injury/burns to the patients or users. Only use batteries recommended or manufactured by GE HealthCare. The warranty can be voided if non-recommended batteries are used.

WARNING

PHYSICAL INJURY. Do not install the device above a patient. Make sure the battery is completely inserted and the battery door is completely closed. Falling batteries could seriously or fatally injure neonatal or other vulnerable patients.

WARNING

PHYSICAL INJURY. Do not install the device above a patient. Leaks from the battery cells can occur under extreme conditions. The liquid is caustic to the eyes and skin. If the liquid comes in contact with eyes or skin, flush with clean water and seek medical attention.

CAUTION

LOSS OF MONITORING. To prevent loss of monitoring, only change the Carescape ONE battery when Carescape ONE is connected to a powered docking solution.

1. To insert a battery:
 - a. Open the battery door by gently peeling down the corner of the battery door pull tab.



- b. Position the battery with the connector end facing towards the battery slot and insert the battery all the way into the battery slot.



- c. Close the battery door. Ensure that the battery door tightly seals the battery into the battery slot.

2. To remove a battery:
 - a. Open the battery door by gently pulling on the battery door pull tab.
 - b. Pull on the battery cord to remove the battery from the battery slot.



Checking the battery status

1. To view the battery information, select the battery status area in the upper right corner of the screen.

You can also select  from the main menu and then **Battery** (or **Battery & network** if the WLAN license is in use and WLAN has been enabled during the configuration).

Docks

Connecting the Carescape ONE to a dock

WARNING

PHYSICAL INJURY. Take care when mounting devices to an IV pole. If a device is mounted too high the IV pole may become unbalanced and tip over.

WARNING

PHYSICAL INJURY. Never install equipment above the patient.

WARNING

PHYSICAL INJURY. Use only manufacturer specified mounts.

WARNING

ERRONEOUS READINGS. The device/system should not be used adjacent to, or stacked with, other equipment. Consult qualified personnel regarding device/system configuration.

The Carescape ONE has an integrated slide mount for mounting onto the Carescape Dock F0 or the Mini Dock. The docks facilitate all mounting options for the Carescape ONE. Refer to the supplemental information provided to identify compatible mounting hardware options. For information on using the F2 frame, refer to the host monitor manuals.

1. Align the Carescape ONE with the dock rails.
2. Push the Carescape ONE into the dock until it stops. You will hear a click when it is fully docked.



Disconnecting the Carescape ONE from a dock

1. Pull the pull tab out and slide the Carescape ONE out of the dock rails.
2. Hold onto the Carescape ONE to make sure it does not drop when it comes out.

Carescape Dock F0

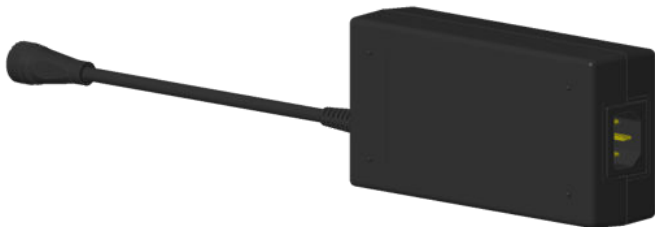


WARNING

ELECTRIC SHOCK. Do not touch the electrical connector located in the Carescape Dock F0 to avoid the risk of electric shock.

The Carescape Dock F0 provides a DC power source to a docked Carescape ONE, which also charges the Carescape ONE battery. The Carescape Dock F0 connects with a host monitor to provide a docked Carescape ONE with communication to the host monitor. For information on using the F2 frame, refer to the host monitor manuals.

AC mains to DC power supply for Carescape Dock F0

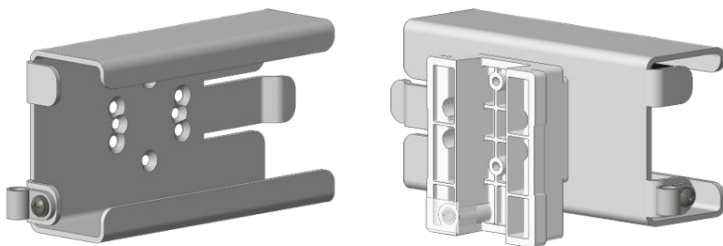


The AC mains to DC power supply connects to the Carescape Dock F0 power receptacle and provides power to a docked Carescape ONE. When connected to the host monitor as an acquisition platform, the host monitor provides power to the Carescape ONE, unless a 30 m host cable is used for the connection. In this case, the host monitor does not provide power and the Carescape ONE must be connected to the AC mains to DC power supply for power.

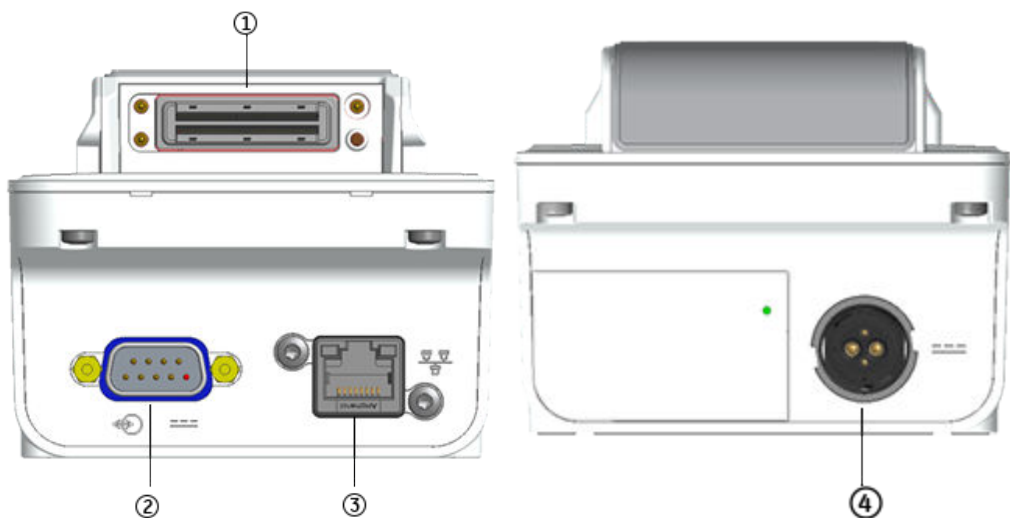
Power supply mounting bracket

The power supply mounting bracket captures the power supply and allows the power supply to be mounted to a roll stand.

Front and back views.



Carescape Dock F0 side views



1	Docking interface connector to the Carescape ONE.
2	ePort connector to the host monitor.

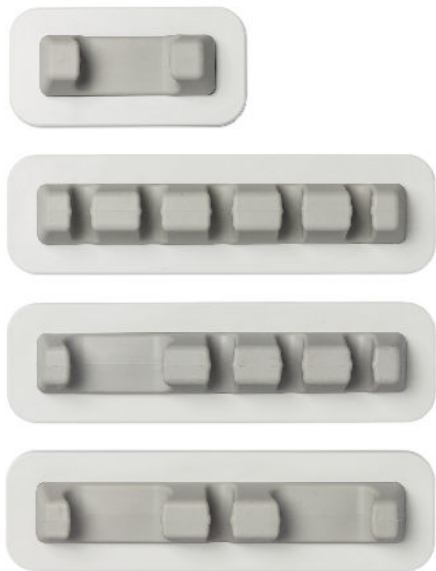
3	RJ-45 connector. The service port is configured for direct connection to a service PC only. Do not connect the service port to a network.
4	Power receptacle for the AC mains to DC power supply.

Mini Dock



The Mini Dock is an unpowered mount that allows the docked Carescape ONE to be mounted to a bed rail for use during transport. This mount cannot be used to charge Carescape ONE.

Micro-module docks



The Micro-module Dock 1, Micro-module Dock 3, Micro-module Dock 4, and Micro-module Dock 5 provide multiple mounting options for the micro-modules.

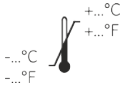
Equipment markings

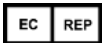
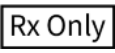
The following symbols may appear on one or more of the devices.	
	Bell cancel. Audio off.

The following symbols may appear on one or more of the devices.	
	General alarm.
	Battery.
	Battery (monitor). Test button on the battery to check the battery charge level.
	Power on/standby button.
	Non-invasive blood pressure.
	USB connectors.
	Ethernet connectors.
	Input/output.
	Gas inlet.
	Gas outlet.
IP1	Invasive Pressure 1
IP2	Invasive Pressure 2
IPXX	Degree of protection provided by enclosures. Degree of protection provided by the enclosure against the ingress of solid foreign objects and against ingress of water with harmful effects per IEC 60529.
	Do not reuse.
	Use by.
	Latex-free.
	Electrical equipment designed primarily for indoor use.

The following symbols may appear on one or more of the devices.	
	Consult operating instructions. / Operating instructions.
	Alternating current. Green symbol on the front panel: the device is being used on mains power.
	Direct current.
	Stacking limit by number (number varies).
	Date of manufacture. This symbol indicates the date of manufacture of this device. The first four digits identify the year, the following two digits identify the month, and the last two digits identify the day. Country of origin may appear within the symbol (country codes per ISO 3166-1).
	Manufacturer address and date of manufacture. The first four digits identify the year, the following two digits identify the month, and the last two digits identify the day.
	Manufacturer name and address.
Assembled in	Country of manufacturing, followed by the name of the country in English
Made in	Country of manufacturing (which may also be the country of origin), followed by the name of the country in English
	Batch or lot number.
lbl p/n	Abbreviation for label part number.
P/N	Abbreviation for product number.
	Identifies device model number.
	Catalogue or orderable part number.
	Device serial number.
	Device hardware version.
	Every device has a unique marking for identification. The UDI marking appears on the device label.
	Indicates that the product is a medical device per MDR 2017/745 Regulation (EU) of the European Parliament and of the Council on Medical Devices.

The following symbols may appear on one or more of the devices.	
TruSignal_{MM}  or CARESCAPE 	Micro-module for measuring ECG and impedance respiration.
TruSignal_{MM}  or CARESCAPE 	Micro-module for measuring invasive blood pressures
TruSignal_{MM}  or CARESCAPE 	Micro-module for measuring temperature
CARESCAPE  -LoFlo	Micro-module for measuring CO ₂ with Respironics LoFlo technology
CARESCAPE  - Microstream	Micro-module for measuring end-tidal carbon dioxide (EtCO ₂), FiCO ₂ , and respiration rate with Microstream technology
TruSignal_{MM 1.8M}  or TruSignal_{MM 3.0M}  or CARESCAPE 	Micro-module for measuring SpO ₂ with TruSignal SpO ₂ technology
CARESCAPE  - Masimo	Micro-module for measuring SpO ₂ with Masimo rainbow SET technology.
	NOTE Some Masimo rainbow SET features, such as pleth variability index, perfusion index, and total hemoglobin measurement, are only available when the Carescape ONE is used as an acquisition platform with a host monitor. Refer to the host monitor manuals for more information.
CARESCAPE  - Nellcor	Micro-module for measuring SpO ₂ with Nellcor Oximax technology

The following symbols may appear on one or more of the devices.	
	Micro-module for measuring regional oxygen saturation of blood (rSO₂) in cerebral and somatic tissues with INVOS technology. NOTE The rSO₂ parameter can only be measured when the Carescape ONE is used as an acquisition platform with a host monitor. Refer to the host monitor manuals and the Instructions for use for INVOS rSO₂ micro-module for more information.
	Adapter used with Edwards FloTrac CCO pressure cable for measuring continuous cardiac output and invasive pressures with Edwards technology. NOTE The continuous cardiac output parameter can only be measured when the Carescape ONE is used as an acquisition platform with a host monitor. Refer to the host monitor manuals for more information.
	Mass of typical portable RGM (respiratory gas monitor) configuration. The indicated mass (12 kg in this example) varies per RGM configuration.
	Locked. Touchscreen lock key.
	RF reader indicator.
	Atmospheric pressure limitations.
	Temperature limitations.
	Humidity limitations.
	Keep dry. Protect from rain.
	Fragile. Handle with care.
	This way up.

The following symbols may appear on one or more of the devices.	
	Quantity by number (number varies).
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Recycled materials or may be recycled.
	Recyclable Lithium-Ion.
	European authorized representative.
	Swiss authorized representative.
	European Union Conformity Mark.
	Indicates that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards. Either of these two symbols may appear on the device.
	UK Conformity Assessed marking.
	Indicates that the product is compliant to North American safety standards. Applies to Masimo components only.
	FCC. USA only. Complies with applicable US government (Federal Communications Commission) radio-frequency interference regulations.
Rx ONLY U.S. 	CAUTION PATIENT SAFETY. U.S. Federal law restricts this device to sale by or on the order of a physician. Either of these two symbols can appear on the device.
	Eurasian Economic Union countries only. Eurasian Conformity mark. Conformity to applicable technical regulations of Customs Union.
	Brazil only. INMETRO certificate.

The following symbols may appear on one or more of the devices.	
    	The following symbols (required by China law only) are representative of what you may see on your equipment. The number in the symbol indicates the EFUP period in years, as explained below. Check the symbol on your equipment for its EFUP period. This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572. Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year". In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly. Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures. This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning. This symbol indicates that this electronic information product does not contain any hazardous substance or elements above the maximum concentration value established by the Chinese standard GB/T 26572, and can be recycled after being discarded, and should not be casually discarded.
	Underwriters Laboratories product certification mark.
IC	Canada only. Industry Canada certification number indicates that this product meets the applicable Industry Canada technical specifications.
	China only. Chinese Compulsory Certification as required by AQSIQ. Safety & EMC compliance.
	India only. Indian Conformity Assessment Certification granted by the Bureau of Indian Standards.
CMIIT ID	China only. China Ministry of Industry and Information Technology identification number for Radio Transmission Equipment Type Approval.
	Australia and New Zealand only. RCM compliance. Indicates compliance with electrical safety, EMC, electromagnetic energy, and telecommunications requirements applicable to each product.
	Australia only. The product complies with the applicable Australian standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance.

The following symbols may appear on one or more of the devices.	
	Japan only. The PSE mark (Product Safety Electric Appliance and Materials) is a mandatory mark required on Electrical Appliances in Japan as authorized by the Electrical Appliance and Material Safety Law (DENAN). This mark signifies that a product complies with the law according to a set of standards for electric devices.
	Japan only. Approved under Japan TELEC requirements.
	Brazil only. Approved under ANATEL (Agência Nacional de Telecomunicações) requirements.
	South Africa only. Approved under ICASA (Independent Communications Authority of South Africa) requirements.
	Korea only. Approved under KCC (Korea Communications Commission) requirements.
	Ukraine only. Mark of conformity with the Technical Regulations. This product meets the requirements of the Technical Regulations on medical devices, approved by Resolution No. 753 of the Cabinet of Ministers of Ukraine on October 2nd 2013
	Vietnam only. MIC Vietnam/MOST Vietnam conformity mark.
	Malaysia only. Malaysian Communication and Multimedia Commission (MCMC) certification mark.
	Taiwan only. Taiwan Regulator National Communications Commission (NCC) approval mark.
TRA Registered No	United Arab Emirates only. United Arab Emirates Telecommunications Regulatory Authority (TRA) conformity mark indicating the product registration number.
Dealer No	United Arab Emirates only. United Arab Emirates dealer number.
CNC ID	Argentina only. Argentinian Comisión Nacional de Comunicaciones (CNC) identification number.
ictQATAR	Qatar only. Supreme Council of Information and Communication Technology.
Type Approval Reg. No.	Qatar only. Supreme Council of Information and Communication Technology type approval registration number.
Importer No.	Qatar only. Importer identification number.
R-NZ	New Zealand only. Radio label for radio products not harmonized with Australia.
IFETEL	Mexico only. Instituto Federal de Telecomunicaciones or the Mexican Federal Telecommunications Institute.
IMDA	Singapore only. Info-communications Media Development Authority

Unique Device Identifier (UDI)

UDI  (01) 1234567891234(21) SJN14241237HA(11) 150628	Unique Device Identifier. (UDI) Every medical device has a unique marking for identification. The UDI marking appears on the device labeling and in Monitor Settings > Product tab > page 2. Note that this is only an example of a UDI marking. The device may have a linear barcode as in this example, or a DataMatrix code, or only alphanumeric identifiers with no barcode. Also the identifiers vary per product.
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The characters used in the UDI marking represent specific identifiers. In the example above:

Device identifier:

- (01) = GS1 global trade item number (GTIN) of the device.
- 1234567891234 = Global trade item number.

Production identifiers:

- (21) = GS1 application identifier for the serial number of the device.
- SJN14241237HA = Serial number.
- (11) = GS1 application identifier for the manufacturing date of the device.
- 150628= Manufacturing date: year-month-day (YYMMDD).

Note that for some product types the production identifier can have other elements instead of the ones listed above:

- (10) = GS1 application identifier for the batch or lot number, followed by the batch or lot number.
- (17) = GS1 application identifier for the expiration date of the device, followed by the expiration date.

Monitoring basics

Screen layout

Carescape ONE displays alarms, information, trends, waveforms, parameter windows, and the main menu on the screen. The screen is divided into three areas:

- alarm and information area
- page area (also called: a page)
- main menu area

The contents of the page can be edited, and there are two possible layouts: **Classic** or **Box**. The alarm and information area and the main menu area are fixed and cannot be changed by the user.

Depending on what has been configured in **Monitor Settings > Defaults & Service > Default settings > Page management** (password protected), you can create, duplicate, or delete pages and edit the pages that have not been locked from editing. In addition, you can always edit the **Home** page. You can select which parameter windows and waveforms are displayed on the page and the location and size of each parameter window according to your monitoring needs.

Parameter windows

The parameter windows show numeric and/or graphic presentations of the measurement data. The displayed parameter windows and waveforms are scaled according to the connected parameters and available space on the page.

On any new page that you have created, the **Home** page, or any other page that has not been locked from editing, you can select which parameter windows are displayed and the location and size of each parameter window. If you create a new page, the ECG parameter window is displayed by default, but it can also be edited or removed from the page.

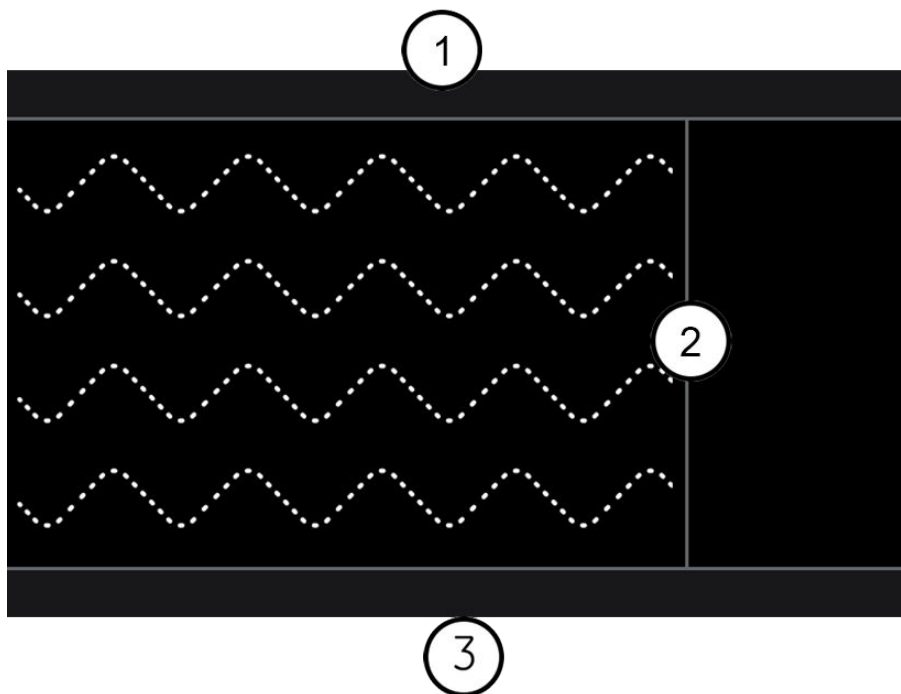
You can configure the information displayed in each parameter window in the parameter menus.

To access the parameter menus, select  from the main menu and the parameter you want to configure on the **Parameters** tab.

Classic view

The **Classic** view shows parameters on a maximum of four rows and up to four columns on each row. If there are more than two parameters on a row, all waveforms on that row are hidden.

The following figure shows the different areas of the **Classic** view:

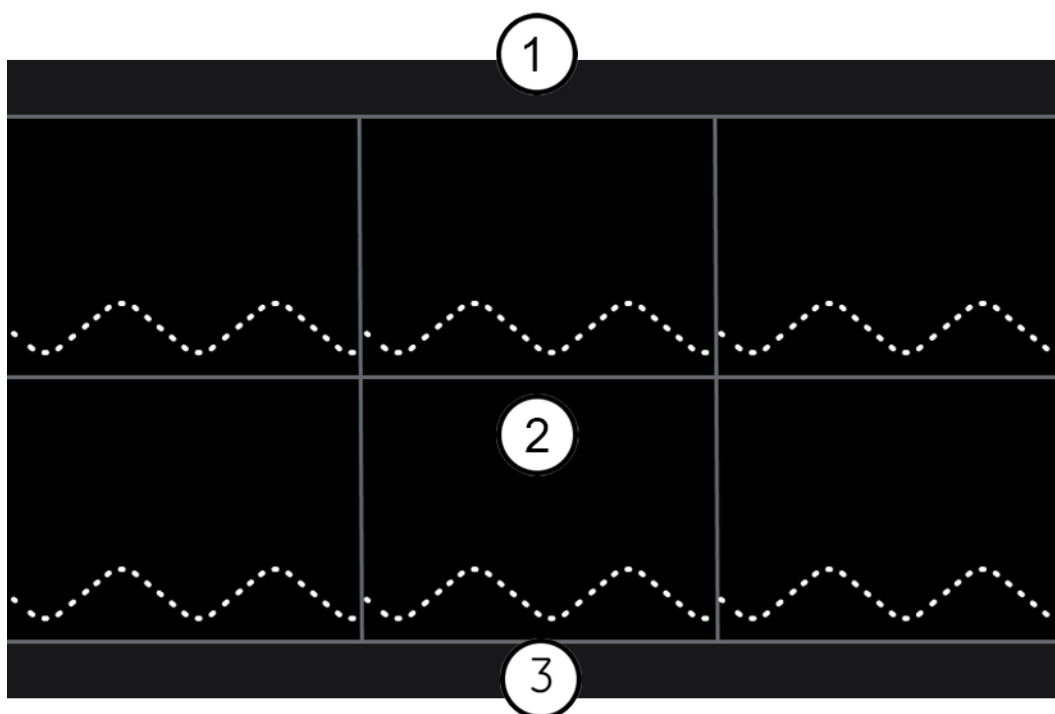


1. Alarm and information areas
2. Page area that shows parameter windows and waveforms
3. Main menu area

Box view

The **Box** view shows parameters on a maximum of two rows and up to three columns on each row. The numeric data and embedded waveforms are shown in boxes positioned across the page area.

The following figure shows the different areas of the **Box** view:

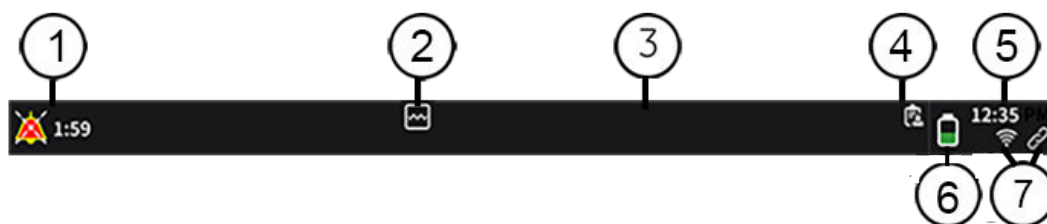


1. Alarm and information areas
2. Page area that shows parameter information and waveforms
3. Main menu area

Alarm and information areas

Information related to alarms, the current patient, and other monitoring issues is always displayed in the upper part of the screen, regardless of the selected page layout.

The following figure shows the different elements on the screen:



1. Alarm area which displays visual alarm indications, alarm status information, and alarm messages.
2. Page icon appears next to the name of the selected page.
3. Patient name (if entered) and profile name that is being used for patient monitoring.
4. Patient icon for accessing **Admit/Discharge** or **Case Settings** menu.
5. Current time of day.
6. Battery icon for accessing the **Battery** menu (**Battery & Network** if the WLAN license is in use).
7. Network connection and wireless link indicators (if the WLAN license is in use).

NOTE

Some elements may be covered by an alarm message if there are two or more active alarms.

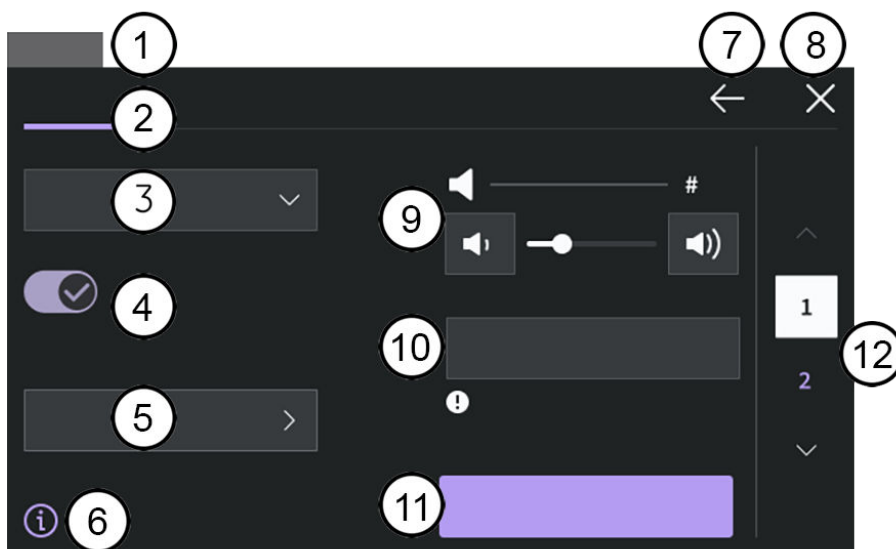
Main menu keys

Various functions of the monitor can be accessed through the main menu keys.

Key	Function
	Home. Closes all menus/applications displayed on the monitor.
	Access to Alarm Settings menu: alarm limits, alarm priorities, and audible and visual alarm indicators.
	Monitor Settings. Access to: • General: screen setup, sweep speeds, parameter colors, sound volumes, brightness settings, battery and network information, admit/discharge (ICU, ED, NICU software packages) or case setup (OR, PACU software packages), and standby settings. • Parameters: parameter settings. • Defaults & Service: default settings, service calibrations, and service features. • Product: monitor hardware and software information.
	Access to Trends menu.
	Access to Screen Settings & Pages: you can select the page displayed on the screen, create new pages and edit, duplicate, or delete pages for the monitor.
	Starts a single NIBP measurement. After selection, the icon changes to stop single NIBP measurement key. Measurement does not start unless the patient type is defined.
	Stops a single NIBP measurement. After selection, the icon changes to start single NIBP measurement key.
	Starts automatic NIBP measurement at timed intervals. After selection, the icon changes to stop automatic NIBP measurement key. Measurement does not start unless the patient type is defined.
	Stops automatic NIBP measurement at timed intervals. After selection, the icon changes to start automatic NIBP measurement key.
	Zero all invasive pressure channels. This does not apply to ICP.
	Pauses the audio alarms. Pause active audio alarms or pre-pause audio for incoming active alarms.

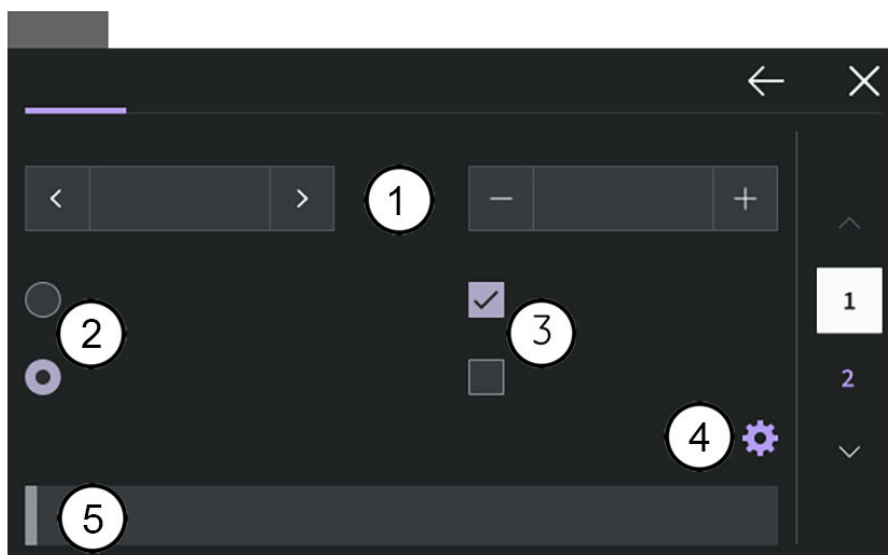
Menu examples

The following figure shows examples of the menu components and how they are referred to in this manual:



1. Menu title (for example, **ECG**)
2. Tab (for example, **Settings** or **Alarms**)
3. Dropdown list: when selecting the arrow, a list of options appears
4. Toggle switch for enabling or disabling a feature
5. Direction button that navigates to another menu
6. Information indicator: when selected, additional information is shown
7. Icon for returning to the previous view.
8. Icon for closing the menu.
9. Volume slider and volume controls
10. Field for entering text
11. Action button for user operations
12. Additional menu pages (highlighted number shows the current page). You can also swipe up or down with one finger to change the menu page.

The following figure shows additional menu components:



1. Boxes for changing a value with arrows or plus/minus keys
2. Radio buttons for selecting or deselecting a feature from the available options
3. Check boxes for selecting or deselecting a feature
4. Icon for accessing additional user-configurable settings
5. Informational notification

NOTE

Not all menus have these same components.

Menu options

In this manual, the term select means using the touchscreen display to select an item on the screen.

Selecting menu options with the touchscreen

CAUTION

LOSS OF FUNCTIONALITY. To prevent loss of touchscreen functionality, the device screen should be kept clean.

NOTE

Do not use pencils, pens, or other sharp objects to activate the touchscreen. The touchscreen may not function properly if tape or paper is stuck to the display surface.

1. Touch the menu option with your finger.
2. Lift your finger off the screen, and the selected function is performed (e.g., a list opens).

Data field entries

You can use the on-screen keyboard to type data into a data field. Data fields are selectable with the touchscreen.

Entering data

When data entry is required, the monitor automatically displays an on-screen keyboard for you to use.

1. Select the desired data field.

The selected field turns white, indicating that you can begin entering the text.

2. Enter data by selecting the characters using the touchscreen.

About the user default settings

User default settings mean those password-protected settings (like profiles) that the user has saved into the monitor to replace the factory default settings. The monitor uses these settings when it is turned on, after a power off situation that lasts more than 2 hours, or after a patient is discharged/case is reset. If there are no user default settings, factory default settings are used. For information on user default settings when using Carescape ONE as an acquisition platform for the host monitor, refer to the host monitor manuals.

About profiles

When you start monitoring a patient, you can use the startup profile (set during configuration) or select another profile. According to the configuration, your software may have up to eight profiles to choose from. Profiles control many settings, including parameter defaults, alarm detection limits, and alarm functionality.

Profiles are set and changes to them are saved through **Monitor Settings > Defaults & Service > Default settings > Save profiles**, and they are password protected.

For more information, see the supplemental information provided in the appendices.

Selecting a profile

Monitoring starts with the startup profile, but you can select another profile according to your needs. You can also change the profile while monitoring a patient without losing any patient data.

1. Select the patient information area (indicated by  on the screen.

You can also select  from the main menu and then **Admit/Discharge** or **Start / Reset Case**.

2. Select the **Profile** tab and select a profile from the **Current profile** list.

To return to the previous profile, select **Return to profile** (followed by the name of the selected profile). The selection is disabled if no other profile has been selected.

If you make changes to a profile while using it and need to return to its previous settings, first select another profile and then re-select the one you were using. If only one profile has been enabled during configuration, the only way to return to saved profile settings is through patient discharge/case end or device reset.

Supply mains interruption

If the supply mains to the equipment is interrupted, Carescape ONE shuts down unless equipped with an internal battery. The Carescape ONE runs on the internal battery until the battery power is depleted.

If the Carescape ONE is shut down for less than 2 hours, the monitor keeps the trend data and the latest user-made settings. After 2 hours, all patient information and trend data is lost and the monitor returns to the saved user default settings. For more information, see the service manual.

WARNING

LOSS OF MONITORING. The Carescape ONE must always be used with a battery inserted. This will ensure the functioning of the monitor during possible supply mains interruptions.

User interface indicators

The following indicators appear in the software user interface.	
	Home indicator. Close all menus/applications displayed on the monitor.
	Alarm Settings menu.
	In the main menu: Monitor Settings . Also indicates entry to any user-configurable settings.
	Trends menu.
	Screen Settings & Pages menu.
	Lock key.
	Start single NIBP measurement.
	Stop single NIBP measurement.
	Start automatic NIBP measurement.
	Stop automatic NIBP measurement.
	Zero all invasive pressure channels. This does not apply to ICP.
	Alarms audio pause indicator. Displays in the upper left corner of the alarm message and indicates that alarm audio pause has been activated.

The following indicators appear in the software user interface.	
	Alarm audio muted.
	Alarm off indicator.
	Alarm volume indicator. Adjust the alarm tone volume.
	Alarm volume adjustment for high and medium priority. Can also be used to adjust low priority alarm volume when high, medium, and low priority alarms are configured in Care unit settings to Common for all .
	Alarm volume adjustment for low priority.
	Audio alarms off indicator. The indicator will include a text indication of the silenced alarms: ECG (ECG) , APN (Apnea) , or APN ECG (Apnea & ECG) , or ALL (All alarms) .
	Audio alarms paused indicator with countdown timer - Indicates all audio alarms are paused and the amount of time remaining for the alarm pause period displays as a countdown timer.
	General warning sign. Displays when the priority setting deviates from the recommendation of international alarm safety standards.
	Low priority audio off alarm indicator. Indicates that audio indicators have been turned off for low priority alarms (visual indicators are still active).
	Saves the current selections and closes the menu, window, or message displayed on the screen. Acknowledge alarms indicator. Displays in the upper right corner of the alarm message and indicates that this alarm can be acknowledged by touching the alarm message or with the pause audio key. In case there are latched alarms, they will all be acknowledged.
	Page indicator.
	Alarm limit indicator.
	Editable content. Select to edit the information displayed on the screen.
	Delete item.
	Go back.
	Page layout: Classic .
	Page layout: Box .

The following indicators appear in the software user interface.	
	Parameter window setup: Increase width.
	Parameter window setup: Increase height.
	Parameter window setup: Decrease width.
	Parameter window setup: Decrease height.
	Indicates an item that can be moved on the screen.
	Show preview.
	Hide preview.
	Information point sign. Select to access additional information.
	Information related to menu selections or other user actions.
	Red indicator is displayed for error situations.
	Timer indicator.
	Touch indicator.
	Patient indicator.
	Network connection and signal strength indicator. Indicates the Carescape ONE is connected to the wireless local area network (WLAN). Gray icon indicates a connection to an access point. White icon and strength bars indicate connection to the Carescape Network. The number of segments corresponds to the signal strength: the more segments, the stronger the signal.
	Wireless transport mode indicator. White icon indicates that there is a wireless link between the Carescape ONE and the host monitor. When the icon is gray, it indicates that there is currently no wireless link between the Carescape ONE and the host monitor but the wireless transport mode is available for use.
	Wireless transport mode indicator with warning triangle. Indicates that the wireless link between the Carescape ONE and the host monitor is temporarily disconnected.

The following indicators appear in the software user interface.	
	Wireless transport mode indicators for the network connection and wireless link status: - Green icon indicates Connected status. - Red icon indicates Connecting... status. - Gray icon indicates Disconnected status.
	Access point indicator.
	Battery and network information indicator.
	Battery is full indicator.
	Battery indicator (green). Indicates that the charge level of the battery is 75%.
	Battery indicator (green). Indicates that the charge level of the battery is 50%.
	Battery indicator (orange). Indicates that the charge level of the battery is 20%.
	Battery indicator (red). Indicates that the charge level of the battery is 5%.
	Battery is charging indicator (flashing from left to right).
	Battery failure indicator. Indicates a missing battery or a battery failure.
	Red indicator (blinking): beat source indicator in a parameter window. White indicator: beat volume and beat source indicator in a parameter menu.
	Respiration indicator. Indicates a breath is detected by the impedance respiration algorithm.

The following indicators appear in the software user interface.	
	Impedance respiration lead I selection indicator.
	Impedance respiration lead I selection indicator for neonates.
	Impedance respiration lead II selection indicator.
	Impedance respiration lead II selection indicator for neonates.
	Impedance respiration lead RL-LL selection indicator.
	Impedance respiration lead RL-LL selection indicator for neonates.
	Electrode error indicator (red halo around the circle). Indicates that the lead is off (ECG).
  	Sound volume control indicator. Adjust the volume with the keys: Increase the sound volume. Decrease the sound volume.
	Nellcor™ OxiMax™ SatSeconds™ alarm management indicator. Indicates the amount of time the SpO ₂ saturation is outside the limits before alarms are generated.
	SpO ₂ signal strength indicator. Indicates the signal strength, with three asterisks indicating the normal signal.
	Progress bar indicator. Indicates the amount of time remaining until the next automatic measurement.
	Required input indicator.

The following indicators appear in the software user interface.	
	Color settings.
	Sweep speeds settings.
  	Brightness control indicator. Adjust the brightness with the keys. Increase brightness on the scale. Decrease brightness on the scale.
	European Union Conformity Mark indicator appears in Monitor Settings > Product tab.
	Indicates that the product is a medical device per MDR 2017/745 Regulation (EU) of the European Parliament and of the Council on Medical Devices. The medical device indicator appears in Monitor Settings > Product tab.
	Every device has a unique marking for identification. The UDI indicator appears in Monitor Settings > Product tab.
	The Manufacturer indicator appears in Monitor Settings > Product tab.

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Setting up the monitor before use

Page setup

Depending on what has been configured in **Monitor Settings > Defaults & Service > Default settings > Page management** (password protected), you can edit, create, duplicate, or delete pages, and switch between pages that have been assigned to the selected profile. There may be pages designed, for instance, for physicians, surgeons, or nurses. The **Home** page is always available and can be edited by the user.

Any changes to the page setup are only valid until the case is reset/the patient is discharged. The page setup changes are not permanent unless they are saved through **Default settings > Page management > General Settings > Save** (password protected). The page setup changes are also kept in the device memory for 2 hours after the power is turned off.

For more information on page management, see the supplemental information provided in the appendices.

Selecting the page

In addition to the **Home** page, you can select any page assigned to the profile in **Default settings > Page management** (password protected) or any new page you have created for the current patient. To switch to another page on the screen, either swipe the page left or right with two fingers or:

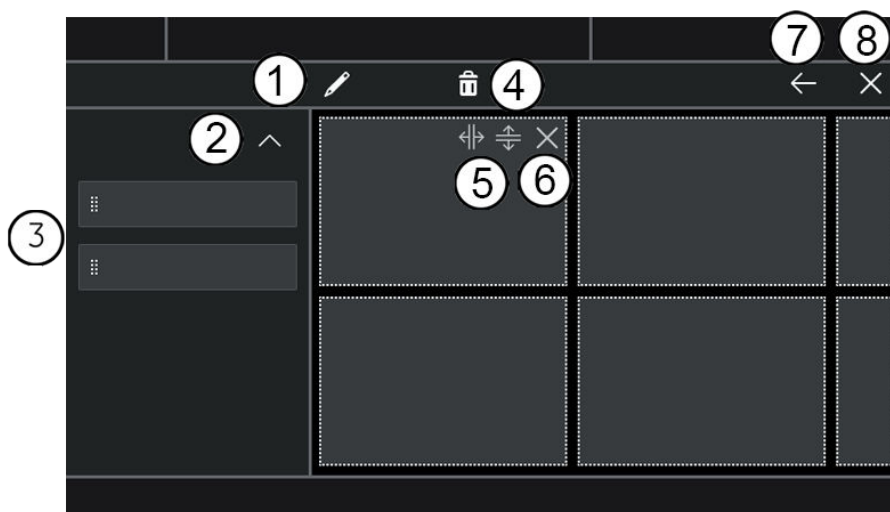
1. Select  from the main menu.
2. Select the page you want to display on the screen. You can scroll through the available options with the arrow icons or swipe the screen left or right.
3. Select  to close the menu.

Displaying the page setup view

You can edit the **Home** page or any other page that has not been locked in **Default settings > Page management > Assign Pages** (password protected). To display the page setup view:

1. Select  from the main menu.
2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen left or right.
If editing a page is not allowed, there is a lock symbol next to it.
3. Select **Edit page**.

The page setup view is shown on the screen. The following is an example of the view:



1. Icon for changing the page name
2. Drop-down list for selecting parameters
3. Parameters that can be added to the page
4. Icon for deleting the page
5. Icons for changing the parameter window size
6. Icon for removing a parameter from the page
7. Icon for returning to the previous view
8. Icon for closing the page

Creating a new page

You can create or duplicate pages according to your monitoring needs if it has been allowed in **Default settings > Page management > Allow to create new, duplicate and delete pages** (password protected). There can be a maximum of 16 pages displayed in the **Screen Settings & Pages** menu.

1. Select  from the main menu.
2. To create a new page from scratch, select **Create new** and **Classic** or **Box** as the page layout.
3. To create a duplicate of an existing page, select a page and then **Duplicate**.
4. Enter a new name for the page with the displayed on-screen keyboard.
There can be up to nine characters in the page name.
5. Configure the page according to your monitoring needs.

When you create a new page, the ECG parameter window is displayed by default.

Adding a parameter to a page

You can add parameters to the **Home** page or any other page that has not been locked in **Default settings > Page management > Assign Pages** (password protected).

1. Select  from the main menu.

2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen.
If editing a page is not allowed, there is a lock symbol next to the page name.
3. Select **Edit page**.
4. Select one of the dropdown lists displayed on the left side of the screen. The choices are:
 - **ECG**
 - **SpO2 & NIBP**
 - **Invasive pressures**
 - **Imped. resp & CO2**
 - **Other**

When the list opens, the selectable parameters are shown.

5. Drag and drop the appropriate parameter to the desired location on the page.
You can also add a parameter to the page by selecting the parameter and then selecting the desired location.

Changing the location or size of a parameter window

You can change the location or size of parameter windows on the **Home** page or any other page that has not been locked in **Default settings > Page management > Assign Pages** (password protected).

1. Select  from the main menu.
2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen.
If editing a page is not allowed, there is a lock symbol next to the page name.
3. Select **Edit page**.
4. To change the location of a parameter window on the page, select the window and drag and drop it to the desired location on the screen.

You can also move a window on the page by selecting the window and then selecting the desired location.

5. To change the size of a parameter window, use the keys on the upper-right corner of the window. The keys are disabled and shown in gray if the selection is not available (for example, due to space limitations). If needed, remove parameters from the page to increase the size of a window.

The available options for the parameter window size are the following:

- Height: Single height or double height (for ECG parameter window: single height, double height, or triple height)
- Width: Single width or double width

Key	Functionality
	Changes the size to double width.
	Changes the size to single width.

Key	Functionality
	Classic pages only: Increases the size (from single to double height or from double to triple height). Adjusts the size of all parameter windows that are located on the same row on the screen.
	Classic pages only: Reduces the size (from double to single height or from triple to double height). Adjusts the size of all parameter windows that are located on the same row on the screen. With the ECG parameter window, also removes one waveform if more than one is shown.

Showing ECG waveforms on a page

Depending on the selected page layout, you can either show 1-3 waveforms (on a **Classic** page) or one waveform (on a **Box** page) on the page.

1. Select  from the main menu.
2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen. If editing a page is not allowed, there is a lock symbol next to the page name.
3. Select **Edit page**.
4. Select the **ECG** dropdown list displayed on the left side of the screen.
5. Drag and drop the parameter to the desired location on the page.
6. On a **Classic** page: Select the appropriate radio button in the **ECG** dropdown menu: **1 waveform** (default), **2 waveforms**, or **3 waveforms**.

If there is not enough space on the page, **2 waveforms** and/or **3 waveforms** radio button is disabled. To enable the selections, you must first remove other parameters from the page.

Removing a parameter from a page

You can remove parameters from the **Home** page or any other page that has not been locked in **Default settings > Page management > Assign Pages** (password protected).

1. Select  from the main menu.
2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen. If editing a page is not allowed, there is a lock symbol next to the page name.
3. Select **Edit page**.
4. To remove a parameter from the page, select  on the top-right corner of the parameter window.

Changing the page name

You can change the name of a page that has not been locked in **Default settings > Page management > Assign Pages** (password protected). You cannot change the name of the **Home** page.

1. Select  from the main menu.

2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen.
If editing a page is not allowed, there is a lock symbol next to the page name.
3. Select **Edit page**.
4. Select the  icon next to the current page name shown above the page area.
5. Enter a new name for the page with the displayed on-screen keyboard.
There can be up to nine characters in the page name.
6. To save the page name, select **Confirm**. To cancel the changes, select **Cancel**.

Deleting a page

You can delete pages from the list of available pages if it has been allowed in **Default settings > Page management** (password protected). It is not possible to delete the **Home** page, which is always available.

1. Select  from the main menu.
2. Select the page you want to delete.
You can scroll the list with the arrow icons or swipe the screen.
3. Select **Edit page**.
The page is displayed on the screen.
4. Select **Delete page** (next to the  icon).
The page is deleted from the list of pages available for the current patient. To make this change permanent, the change must be saved through **Default settings > Page management > General Settings > Save** (password protected).

Parameter configurations

Before monitoring a patient, always check the parameter settings. To configure parameter settings:

1. Select  from the main menu.
2. Select the **Parameters** tab and the parameter you want to configure.
You can also access the parameter configurations by selecting the parameter window of a parameter that has already been configured to the page.

Waveform field safety precautions

WARNING

Always make sure that the waveform size is sufficient for the care environment.

CAUTION

The waveform autoscaling feature automatically updates the display from the best possible signal amplitude. Always make sure that the waveform display scale is correctly understood and does not lead to delayed patient treatment.

Locked alarm and parameter settings

Some profile settings can be locked. Clinicians cannot adjust the locked settings for the admitted patient. These settings are indicated with a lock symbol: .

The alarm and parameter settings that can be locked are set in **Locking settings** and they are password protected.

For more information, see the supplemental information provided in the appendices.

Selecting waveform sweep speeds

1. Select  from the main menu.
2. Select **General > Sweep speeds**.
3. Adjust the sweep speeds for the following waveforms as needed:
 - **Hemodynamic**
 - **CO2**
 - **Resp**

The smaller the value, the slower the sweep speed.

Color selections

You can select display colors for all parameters according to your needs.

For more information, see the supplemental information provided in the appendices.

Selecting colors for IP channels

1. Select  from the main menu.
2. Select **General > Colors**.
3. Select the **Invasive Pressures** tab.
4. Select colors from the dropdown lists for each label.

Selecting colors for other parameters

1. Select  from the main menu.
2. Select **General > Colors**.
3. Select the **Basic** tab and then the colors from the dropdown lists: **ECG**, **SpO2**, **NIBP**, **Resp**, **Temp**, and **CO2**.

Adjusting sound volumes

You can adjust various sound volumes according to your care environment needs. While you are adjusting the volume, you will hear a corresponding sound that will guide you in determining a suitable level. All volumes other than **Alarm volume** can be set to 0 if required.

1. Select  from the main menu.
2. Select **General > Sound volumes**.
3. Adjust the different sound volumes:
 - **Alarm volume**
 - **Beat volume**
 - **Completed NIBP volume**
 - **Touch volume**

Adjusting the display brightness

You can set the display brightness level according to your needs.

1. Select  from the main menu.
2. Select **General > Brightness**.
3. Adjust the brightness on the **Display brightness (%)** scale in the range of 10% to 100%.

Checking the battery status

1. To view the battery information, select the battery status area in the upper right corner of the screen.

You can also select  from the main menu and then **Battery** (or **Battery & network** if the WLAN license is in use and WLAN has been enabled during the configuration).

Setting the touchscreen off

1. Press the hard key  on the Carescape ONE once to lock the touchscreen and prevent user interaction.
2. To unlock the touchscreen, press the hard key  on the Carescape ONE again.

Other setup changes

All other setup changes, like care unit settings, page management settings, profile settings, time and date settings, and software package related changes require a password. Also entering the **DEMO mode** requires a password.

For more information, see the supplemental information provided in the appendices.

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Starting and ending monitoring

Software packages and terminology

The terminology used in different software packages varies: in OR and PACU, you start or reset a case, and in other software packages you admit or discharge a patient. Read all instructions carefully.

Turning on the Carescape ONE

Carescape ONE can operate via battery power using its own battery, or via DC power when connected to a powered docking station. Refer to the device labeling for voltage and current requirements.

1. Ensure all cables are properly connected.
2. Press the power on/standby button on the handle side of the Carescape ONE. The welcome screen will appear.

Turning off the Carescape ONE

1. Ensure that the patient has been discharged/the case has been ended.
2. Press the power on/standby button again within 10 seconds to shut down the Carescape ONE.

If you do not press the power on/standby button again within 10 seconds, the Carescape ONE remains on and the **Confirm shutdown** window is removed from the display.

Starting monitoring

A case automatically starts/a patient is admitted when the monitor detects any of the following vital signs: ECG, impedance respiration, Art, Fem, UAC, NIBP, SpO₂, or CO₂. Each vital sign has activation criteria that must be met before the vital sign is considered active. Refer to the individual parameter chapters for more information.

A case manually starts/a patient is admitted when any patient data is entered.

Always observe the monitor and the patient carefully during startup periods and when connecting micro-modules.

WARNING

LOSS OF MONITORING and MISSED ALARMS. When starting to monitor a patient, always make sure that you are in the normal monitoring mode and not in the **DEMO mode**.

Ensure that there is no **DEMO MODE** text in the waveform fields, no low priority **DEMO MODE Not for clinical use!** alarm in the alarm area, no **DEMO MRN** identification, and no **DEMO PATIENT** name in the patient information area. You can exit the **DEMO mode** by

restarting the device or by selecting  from the main menu and then **Defaults & Service > Exit DEMO**. If the **DEMO mode** is active when you start monitoring, there is a risk of loss of monitoring and missed alarms.

WARNING

MISINTERPRETATION OF DATA. To identify the **DEMO mode** data, special attention should always be paid to the **DEMO mode** indications (like **DEMO Patient** name, **DEMO** MRN identification). Otherwise there is a risk of misinterpreting the **DEMO mode** data as actual clinical data.

WARNING

MISSED ALARMS. Patient profiles contain default alarm settings based on patient demographics or care unit. Selecting a profile that is unsuitable for the monitored patient may result in missed alarms and/or nuisance alarms.

CAUTION

DISCHARGE TO CLEAR PATIENT DATA. When admitting a new patient/starting a new case, you must clear all previous patient data from the system. To accomplish this, disconnect the patient cables, then discharge the previous patient/end the case.

The following are generic instructions listing the basic steps for starting monitoring. Parameter-specific instructions are more detailed and should always be followed as well.

1. Connect the patient to the Carescape ONE according to the measurement setup requirements in the parameter-specific chapters of this document. The alarms and parameter settings become active.
2. If the startup profile is not suitable, select another profile.
3. Enter patient demographics.
4. Start the measurement.
5. Zero invasive pressure lines. Refer to the invasive pressures chapter in this document.
6. If required, change the parameters displayed on screen.
7. Check alarm limits and adjust if necessary.

Pre-monitoring checklist

Before you start monitoring a patient check the following:

- Micro-modules are properly connected.
- Accessories are intact and properly connected.
- The Carescape ONE is displaying the monitoring screen.
- No messages display indicating the Carescape ONE or micro-modules are not functioning.
- Desired parameters are selected to view on the screen.
- Alarm signals are working and can be seen and heard in your care environment.
- Required parameter calibrations are completed.

Performance check

After turning on the Carescape ONE, and during operation, the monitor runs automatic self-tests. If a malfunction is detected, the Carescape ONE displays a message or an alarm, depending on the severity of the malfunction.

Entering patient data

1. Select the patient information area (indicated by  on the screen.

You can also select  from the main menu and then **Admit/Discharge** or **Start / Reset Case**.
2. On the **Patient** tab, select each field that you wish to edit and enter the data or select the desired value from the list.

Adding or removing parameters during an active patient case

During an active patient case, parameters can be added or removed by connecting or disconnecting micro-modules. When a micro-module is connected, it will be shown if it has been added to the selected page. When a micro-module is disconnected, the Carescape ONE display will automatically adjust and remove the parameter from all pages where it had been added (except ECG). There is also an alarm for the removed measurement that you need to acknowledge.

NOTE

The ECG and impedance respiration parameters behave differently than the other parameters on Carescape ONE. Once monitoring of these parameters has started during an active patient case, the parameter window will be displayed for the duration of the patient case. If the TruSignal ECG micro-module is disconnected, a **Leads off** alarm will be generated and the ECG and impedance respiration parameter windows will remain on the display. To remove these parameters, select  from the main menu > **Edit page** and then select  on the top-right corner of the parameter window.

Resetting a case/discharging a patient

Resetting a case/discharging a patient deletes all patient information and returns the monitor to the defined startup profile. This also happens when the Carescape ONE is in **DEMO mode**.

All settings, including alarm limits and page setup changes, return to their default values. All patient data is removed from the monitor and any pages that have been created but not saved are deleted.

The Carescape ONE may be configured in care unit settings with an automatic case reset/patient discharge timer. Care unit settings are password protected. For more information, see the supplemental information provided in the appendices. If an automatic case reset/patient discharge is configured and there are no active parameters and no use of the touchscreen, monitoring will end automatically after the configured time has elapsed.

1. Disconnect patient cables.
2. Select the patient information area (indicated by  on the screen.

You can also select  from the main menu and then **Admit/Discharge** or **Start / Reset Case**.

3. Select the **Discharge / Reset Case** tab > **Confirm**.

About standby

When you remove the patient temporarily from the monitor, you can use the standby option to put the monitor on standby until the patient is reconnected to the monitor. You can also use the standby option before a patient is admitted to the monitor/patient case is started. Configure the current patient settings for the incoming patient, then put the monitor in standby to prevent nuisance alarms or automatic discharge due to monitor inactivity.

Starting standby

1. Select  from the main menu.
2. Select **General > Standby**.
3. If no patient is connected (no micro-modules are connected to the Carescape ONE), select **Enter standby**, and the monitor will immediately enter standby.

If a patient is connected, select **Prepare for standby** to pause audible alarms for 2 minutes. This allows time to disconnect patient cables.

4. Disconnect the patient cables and check that **Automatic NIBP** is toggled off.

If patient cables are still connected and the monitor receives vital signs, a message indicating that audio alarms have been paused appears. All audible alarms are turned off except for breakthrough alarms.

If you do not disconnect the cables and vital signs are still present after the audio pause time expires, the standby is canceled. You can also cancel the standby before the timer expires by selecting **Cancel standby**.

The monitor will automatically enter standby when all cables are disconnected and **Automatic NIBP** is toggled off. The screen goes blank and the company logo with the message **Standby** appears.

End of standby

The monitor ends the standby automatically when any of the following conditions occur:

- The touchscreen is pressed.
- At least one micro-module is connected and active parameter data is detected.

Alarms

Alarm safety precautions

Alarm warnings

WARNING

PATIENT SAFETY. When the alarms are off or while alarm audio is paused either temporarily or indefinitely, observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS. Always make sure that the audio alarm volume level is adequate in your care environment to avoid missing alarms or not recognizing them due to too low a volume. Audio levels that are less than ambient levels may lead to unrecognized or missed alarms.

WARNING

MISSED ALARMS. Always make sure that the alarm light brightness is adequate in your care environment to avoid missing any alarms.

WARNING

PATIENT SAFETY. Always make sure that necessary alarm limits are active and set according to the patient's clinical condition when you start monitoring a patient, to avoid any risks to patient safety caused by erroneous or no alarms.

WARNING

PATIENT SAFETY. Verify that alarm processing is active and check the patient to ensure no arrhythmias occurred during a power interruption. Otherwise, there is a risk of compromised patient safety.

WARNING

MISSED ALARMS. Always check the alarm status after a prolonged power interruption to avoid missing any alarms.

WARNING

PATIENT SAFETY. Alarms do not sound and alarm histories are not stored when the alarms are turned off. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

PATIENT SAFETY. There are no alarm indications until parameter-specific alarm prerequisites have been met. Keep the patient under close surveillance when starting monitoring.

WARNING

PATIENT SAFETY. Alarm messages may not be visible on the alarm display area when three higher priority alarms are active. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

PATIENT SAFETY. Latched alarms are not retained through a monitor reset if the alarm condition has been removed. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS. Equipment malfunctions, network disconnection, and alarm volume settings may result in missed alarms. Always keep the patient under close surveillance.

WARNING

MIXED ENVIRONMENT. A hazard can exist when the same type of monitors in the same care area are using different monitoring profiles and default configuration settings.

WARNING

MISSING CRITICAL EVENTS. Reducing the physiological alarms' priority levels lower than the default level can lead to missed detection of critical or serious events and therefore to adverse patient outcome. Keep the patient under close surveillance if you adjust the priority levels lower than the default value for the following physiological alarms:

- V Tach
- Ventricular and atrial arrhythmias
- Tachy/PR high
- Brady/PR low
- Frequent PVCs and SVCs
- ST low/high
- SpO₂ low/high
- RR (Impedance) low/high, RR (CO₂) low/high
- Apnea (Impedance), Apnea (CO₂)
- NIBP low/high
- IP, CPP low/high
- CO₂ low/high
- Temperature low/high

WARNING

MISSING CRITICAL EVENTS. NICU software package only: Selecting the Off alarm priority for V Tach results in the system no longer monitoring ventricular tachycardia from ECG. If you select this option, keep the patient under close surveillance to avoid missing any critical events.

WARNING

MISSED ALARMS. Reducing the technical alarms' priority levels lower than the default level can lead to missed detection of critical events and therefore to adverse patient outcome. If you adjust the priority levels for ECG lead off, ECG Leads off, Noisy ECG, Arrhythmia paused, Resp (Imped.) measurement paused, or SpO₂ probe off alarms lower than the default value, keep the patient under close surveillance.

WARNING

MISSED ALARMS. The Carescape ONE provides two different types of audible alarm tones, IEC and legacy. To avoid user confusion with alarm tones, configure all Carescape monitors to the same type of audible alarm tones used in your clinical environment.

Alarm overview

Alarm types

There are two types of alarm settings, system and patient-specific. System alarm settings are set globally across an entire care environment. They are configured at the time of installation and are password protected. Examples of configurable system alarm settings are:

- Minimum alarm volume allowed
- Audio and alarm light off allowed

Patient-specific alarm settings are individualized, based on a patient's current condition. Examples of patient-specific alarm settings are:

- Parameter alarm limits
- Arrhythmia alarm priority settings

Alarm conditions

- Physiological alarm conditions are triggered by a patient measurement being outside the parameter limits, by apnea, or by an arrhythmia condition.
- Technical alarm conditions are triggered by an electrical, mechanical, or other failure of the equipment, or by failure of a sensor or component. Technical alarm conditions may also be caused when an algorithm cannot classify or interpret the available data. The visual manifestation of a technical alarm is active as long as the reason for that alarm exists.
 - Certain technical alarms can be deactivated with the pause audio key. Some alarms can be configured in the **Care unit settings** and they are password protected.
For more information, see the supplemental information provided in the appendices.

Alarms in dual monitoring

NOTE

During preparation for and return from transport, the Carescape ONE is connected to a host monitor in dual monitoring. In dual monitoring, alarm messages are not shown in the alarm area and parameter window numerics do not flash on the Carescape ONE display during an alarm condition because the Carescape ONE is acting as an acquisition platform for the host monitor.

At all other times when the Carescape ONE is connected to a host monitor, the Carescape ONE display remains off and all information is presented on the host monitor only.

Alarm transfer from Carescape ONE to a host monitor

When the Carescape ONE with an active patient case/admitted patient and active or latched alarms is connected to a host monitor, these alarms will become latched on the host monitor. Transferred alarms are considered newer than the existing alarms on the host monitor, which affects the priority order of the displayed alarms. Also note that after connection, Carescape ONE alarms are reevaluated against the host monitor alarm limits and may be reactivated. If the **Continue** menu is opened, the alarm transfer only happens after a selection is made, meaning that alarm evaluation is happening independently on the Carescape ONE and the host monitor until a selection is made.

Checking alarm function

1. Set a parameter alarm limit outside of the current measured patient values. For example, connect the SpO₂ sensor and adjust the SpO₂ high limit under the measured SpO₂ values.
2. Confirm that the following alarm notification events occur:
 - The audible alarm sounds the correct tone.
 - The alarm light illuminates.
 - The background color of the SpO₂ numeric value is shown correctly in the parameter window according to the alarm priority level.
3. Audio pause the alarms and confirm that the alarms are paused and that the alarm silence indicator light is a solid blue color.
4. Return the parameter alarm limit to the original value.

Visual alarm indications

Alarm icons on the screen

Icon	Explanation
	Alarm off indicator

Icon	Explanation
	Alarm volume indicator. Adjust the minimum alarm tone volume.
	Alarm volume high or medium indicator. Adjust the tone volume.
	Alarm volume low indicator. Adjust the tone volume.
	Audio alarms off indicator. The indicator will include a text indication of the silenced alarms: ECG (ECG audio off), APN (apnea audio off), APN ECG (apnea & ECG audio off), or ALL (all alarm audio off).
	Audio alarms paused indicator with countdown timer. Indicates that all audio alarms are paused and the amount of time remaining for the alarm pause period as a countdown timer.
	Alarms audio pause indicator. Displays in the upper left corner of the alarm message and indicates that the alarm audio pause has been activated.
	Alarm audio muted.
	Acknowledge alarms indicator. Displays in the upper right corner of the alarm message and indicates that the alarm can be acknowledged by touching the alarm message or with the pause audio key. When there are latched alarm, they will all be acknowledged.
	Low priority audio off alarm indicator. Indicates that audio indicators have been turned off for low priority alarms (visual indicators are still active).
	Alarm Settings
	Alarm limit indicator.
	Alarm light brightness controls.
	General warning sign. Displays when the priority setting deviates from the recommendation of international alarm safety standards.
	Information point sign. Select to access additional information.

Description of alarm and information messages

Alarm and information messages can be displayed in three areas:

- The parameter window
- The waveform field
- Alarm area (upper part of the screen)

In the alarm area, up to three alarm or information messages may be displayed from left to right, from the newest highest priority alarm to the oldest lowest priority alarm.

Alarm and information messages are stored in the clinical logs. Access to the clinical logs is a service-level function and it is password protected. The alarm and information messages stored in the clinical logs include:

- Time of occurrence
- Alarm or information message text
- Current value and the associated alarm limit if a limit alarm
- Alarm priority

About alarm message functionality

Alarm messages have alarm icons with touchable functionality. The audio pause functionality will affect all active alarms, but the alarm acknowledged only applies to the alarm you touch except when you have latched physiological alarms. They all disappear when you touch any alarm. Alarms can also be acknowledged with the pause audio key.

Touchable alarms have the following icons:

Icon	Explanation
	Alarms audio pause indicator. Displays in the upper left corner of the alarm message and indicates that the alarm audio pause has been activated.
	Acknowledge alarms indicator. Displays in the upper right corner of the alarm message and indicates that this alarm can be acknowledged by touching the alarm message or with the pause audio key. In case there are latched alarms, they will all be acknowledged.

Visual alarm signals and priority levels

Alarm signals indicate that an alarm condition is present. The alarm priority levels are also indicated. The alarm signals assume that the patient monitor and the operator are within the patient environment (1 meter / 3.3 feet).

The following table lists visual alarm signals for different alarm priority levels:

Visual signals	Priority level			
	High	Medium	Low	Informational
Parameter window physiological data values	Background color flashes to red.	Background color flashes to yellow.	Black text inside a cyan (blue) box.	Not applicable.
Alarm area	White text inside a red box.	Black text inside a yellow box.	Black text inside a cyan (blue) box.	Black text inside a gray box.
Waveform field messages	Text	Text	Text	Text
Alarm light indicator ¹	Flashes red	Flashes yellow	Solid blue	No effect

¹ When the audible alarms are turned off or are paused, the silence alarm indicator light is a solid blue color.

Setting the alarm light brightness

1. Select  from the main menu.
2. Select the **Audible & Visual** tab.
3. Select **Volume & light**.

4. Adjust the brightness on the **Alarm light brightness (%)** scale with the  and  keys in the range of 40% to 100%.

If turning the alarm light off has been allowed in **Care unit settings** (password protected), the allowed range is of 0% to 100%.

Audible alarm indications

Audible alarm signals

When more than one alarm occurs at the same time, the monitor will sound an alarm tone for the highest priority alarm. Any lower priority audible alarm tones are suppressed by the higher priority alarm tone.

Alarm tones

WARNING

MISSED ALARMS. The Carescape ONE provides two different types of audible alarm tones, IEC and legacy. To avoid user confusion with alarm tones, configure all Carescape monitors to the same type of audible alarm tones used in your clinical environment.

The alarm tones may be configured to sound in one of two different tone patterns: **Legacy** or **IEC**. **IEC** tones are 60601-1-8 compliant. **Legacy** alarm tones match the tones used on some previous GE HealthCare monitoring devices.

For more information, see the supplemental information provided in the appendices.

Adjusting the alarm volume

The selections in the **Alarm Settings** menu vary according to what has been configured in the **Care unit settings > Alarms** (password protected).

1. Select  from the main menu.
2. Select the **Audible & Visual** tab.
3. Select **Volume & light** and do either of the following:
 - Adjust the **Alarm volume** value. This is the volume for all alarms.
 - Adjust the **Alarm volume for:** separately for **High & medium priority** and **Low priority**.

The lower the number, the quieter the alarm volume. Note that the minimum allowed alarm volume levels are set in the **Care unit settings**, and they are password protected.

Audible alarm signals and priority levels

Alarm signals indicate that an alarm condition is present. The alarm priority levels are also indicated. The alarm signals assume that the patient monitor and the operator are within the patient environment (1 meter / 3.3 feet).

The following table lists alarm signals for different alarm priority levels:

Audible signals	Priority level			
	High	Medium	Low	Informational
Audible tone pattern ¹ (IEC 60601-1-8)	Repeats a pattern of 5-beep tones played two times	Repeats pattern of 3-beep tones	1-beep tone once or repeatedly at 25 ±0.5 second interval (user-selectable)	None
Audible tone pattern (legacy)	Repeats pattern of 3-beep tones (crisis)	Repeats pattern of 2-beep tones (warning)	1-beep tone (advisory) once or repeatedly at 5.5 ±0.5 second interval (user-selectable)	None
¹ The IEC audible tone pattern is the factory default setting.				

Auditory information signals

The monitor performs a self-diagnostic procedure at startup and generates an auditory test signal. There are also other auditory information signals indicating the status of some parameter measurements.

For more information, see the supplemental information provided in the appendices.

Parameter alarms

Alarm locks

Alarm locks prevent parameter alarm limits from being turned off. When an alarm is locked, the on/off check box for the alarm is hidden and replaced by the lock icon. Parameter alarm locks are set in the **Locking Settings** and they are password protected.

For more information, see the supplemental information provided in the appendices.

About critical alarms

You can configure two different levels of alarms for HR and SpO₂ alarms: basic and critical. This enables an alarm to start with the basic alarm level and priority indication, and then change to the high alarm indication once the selected critical alarm level is reached. The critical alarm is always indicated as high, but you can select the priority for the basic alarm. You can set critical alarms only if the corresponding basic alarm is on. Always check that you are configuring the right alarm.

Basic and critical alarm settings are available as follows:

- Primary ECG: basic alarm **HR Brady/Tachy (/min)**, critical alarm **Critical Brady/Tachy (/min)**
- SpO₂: basic alarm **SpO2 (%)**, critical alarm **SpO2 critical (%)**

You must always set the critical alarm level limits so that they are outside the basic alarm limits. If you try to set them inside the basic alarm limits, the basic alarm limits will also change at the same time. Also note that once you have set the critical alarm limits, the basic alarm settings can only be set inside those limits.

Setting alarms and alarm limits

Parameter alarm limits may be set through the **Limits** menu or in the parameter menus. For instructions on setting alarms and alarm limits in the parameter menu, see the parameter-specific chapter.

Alarm limits should not be set beyond reasonable physiological boundaries in order to maintain patient safety. If an alarm is set outside reasonable boundaries, the alarm becomes ineffective.

1. Select  from the main menu > **Limits**.
2. Select the parameter for which you want to set alarms and alarm limits. A table with the alarm limits appears on the screen.
3. To turn an alarm on, select the check box for the alarm. To turn an alarm off, deselect the check box.

When an alarm is turned off, the alarm limits are shown in gray color in the alarm table.

4. To set the alarm limits:
 - a. Select the value that you wish to change.
A numerical keyboard appears on the screen.
 - b. Enter the required value with the keyboard.
 - c. To save the changed alarm limit, select **OK**. To cancel the changes, select **Cancel**.

Setting alarm limits automatically

When selected, the **Set auto limits** feature automatically sets new high limit and low limit values, based upon the current physiological value. The **Set auto limits** should only be used for patients whose currently measured values are considered safe.

1. Select  from the main menu.
2. Select **Limits > Default & auto limits**.
3. Select **Set auto limits**.
4. Select **Confirm** or **Cancel** in the pop-up window.

Default auto alarm limits

Parameter	High limit	Low limit
NIBP	Adult and child cuff: Sys/Dia/Mean: NIBP*1.25+10 Infant cuff: Sys/Dia/Mean: NIBP*1.25+2	Adult and child cuff: Sys/Dia/Mean: NIBP*0.75-10 Infant cuff: Sys/Dia/Mean: NIBP*0.75-2
All HR/PR parameters (ECG, SpO ₂ , UAC, Art, Fem)	All HR*1.25 of the current HR value	All HR*0.75 of the current HR value
Critical HR	All HR*1.4375 of the current HR value	All HR*0.5625 of the current HR value
PVC	PVC+10	Not applicable
SVC	SVC+10	Not applicable
EtCO ₂	EtCO ₂ +1%	EtCO ₂ -1%

Parameter	High limit	Low limit
SpO ₂	SpO ₂ +5%	SpO ₂ -5%
Critical SpO ₂	SpO ₂ +15%	SpO ₂ -15%
Art, Fem	Sys/Dia/Mean: Value*1.25+10 mmHg Value*1.25+1.3 kPa	Sys/Dia/Mean: Value*0.75-10 mmHg Value*0.75-1.3 kPa
FemV, CVP, PA, RAP, RVP, LAP, ICP, CPP, P1, P2, P3, P4	Mean: Value*1.25+5 mmHg Value*1.25+0.67 kPa	Mean: Value*0.75-5 mmHg Value*0.75-0.67 kPa
UAC	Sys/Dia/Mean: Value*1.25+5 mmHg Value*1.25+0.67 kPa	Sys/Dia/Mean: Value*0.75-5 mmHg Value*0.75-0.67 kPa
UVC	Mean: Value*1.25+5 mmHg Value*1.25+0.67 kPa	Mean: Value*0.75-5 mmHg Value*0.75-0.67 kPa
Temperature	Tx+1°C Tx+1.8°F	Tx-1°C Tx-1.8°F
Tx-Ty (e.g., T2-T1)	Tx-Ty+1°C Tx-Ty+1.8°F	Tx-Ty-1°C Tx-Ty-1.8°F
RR	RR*1.25+2	RR*0.75-2

Returning the default alarm limits

1. Select  from the main menu.
2. Select **Limits > Default & auto limits**.
3. Select **Set default limits**.
4. Select **Confirm** or **Cancel** in the pop-up window.

Checking user-configured alarm delays

You can check the user-configured delays for alarms.

1. Select  from the main menu.
2. Select **Limits > Default & auto limits**.
3. Select **Alarm delays**.

The user-configured delays are shown in a pop-up window.

Alarm priorities and escalation

Alarm priority levels

Physiological and technical alarms are categorized by priority level:

- High priority alarms require an immediate response.
- Medium priority alarms require a prompt response.
- Low priority alarms require you to be aware of this condition.
- Informational priority messages provide information you should know.

Alarm priority escalation

An escalating alarm starts at a designated priority level (low or medium) and will escalate to the next higher priority level of alarm (after a set number of seconds) if the alarm condition has not been resolved. It is important to note that these escalate up to the next level but will not reset until the condition has been resolved.

NOTE

Alarm priority escalation affects the currently ongoing alarm condition, not any future alarms of the same type. Any new alarms will alarm at their designated priority level, not at the escalated level.

For more information, see the supplemental information provided in the appendices.

Selecting parameter alarm priority levels

Escalating an alarm priority increases the priority of the alarm condition or increases the sense of urgency of an alarm signal. The alarm priority is based on clinical considerations.

The allowed priorities for different alarms are defined in the **Care unit settings**, and they are password protected.

For more information, see the supplemental information provided in the appendices.

1. Select  from the main menu.
2. Select the **Priorities** tab.
3. Select **ECG**, **Arrhythmia**, **SpO2**, **Pressures**, **CO2**, or **Other**.

If you select **Arrhythmia**, the **Arrhythmia** menu is displayed. For more information on setting arrhythmia priorities, see the ECG chapter.

For other alarms, select the alarm and its priority from the list. Selectable alarms are:

- **ECG: Brady/PR low, Tachy/PR high, ST segment low/high, Frequent PVCs, Frequent SVCs, ECG lead off, ECG leads off, Noisy ECG, and Arrhythmia paused**
- **SpO2: SpO2 low, SpO2 high, and SpO2 probe off**
- **Pressures: NIBP low/high, Art low/high, Fem low/high, UAC low/high, CVP low/high, UVC low/high, FemV low/high, PA low/high, RAP low/high, RVP low/high, LAP low/high, ICP low/high, CPP low/high, P1 low/high, P2 low/high, P3 low/high, and P4 low/high**

- **CO2: RR (CO2) low/high, Apnea (CO2), and CO2 low/high**
- **Other Priorities: RR (Imped.) low/high, Apnea (Imped.), Resp (Imped.) measurement paused, and Temp low/high**

Pausing and silencing alarms

Audible alarms off behavior

Depending on the **Allow audio alarm off** default settings configured during installation (password protected), you can turn on or turn off audible alarms. For more information, see the supplemental information provided in the appendices.

When audible alarms are turned off:

- All audible alarms are turned off except for breakthrough alarms.
- The audio off bell icon displays in the upper left corner of the display screen.
- The silence alarm indicator light is solid blue when audible alarms are paused or when audio off is selected for an alarm group.

Turning audible alarms on/off

You can turn on/off the audible physiological alarm tones for an alarm group or for all alarms.

NOTE

This feature must be enabled in **Care unit settings**.

1. Select  from the main menu.
2. Select the **Audible & Visual** tab.
3. Select **Audio on/off**.
4. Select an alarm group for **Set audible alarms permanently off:**. Choices are:
 - **None:** No audible alarms are turned off.
 - **Apnea:** Turns off audible alarms for apnea, EtCO₂, FiCO₂, and respiration rate limit alarms.
 - **ECG:** Turns off audible alarms for all HR and PR source limit and arrhythmia alarms.
 - **Apnea & ECG:** Turns off audible alarms for all HR and PR source limit, arrhythmia, apnea, EtCO₂, FiCO₂, and respiration rate limit alarms.
 - **All alarms:** Turns off all audible alarms.
5. To turn on all audible alarms again, select **Audible & Visual > Activate all audible alarms**, or select **None** as instructed above.

NOTE

If alarms are turned off for any of the defined alarm groups and an alarm occurs within the alarm group, a beep tone will sound every 2 minutes as a reminder that alarms are turned off.

Pause audio behaviors

Selecting the pause audio results in different alarm behaviors depending on whether the alarms are active and/or latched or not. Acknowledging or pausing audio alarms does not affect other alarm indicators. They will still continue indicating alarms.

Active and/or latched alarms	
Selection	Result
Select  once	• Pauses all active audio alarms for 2 minutes. • Removes all latched alarms. • Deactivates some technical alarms.
Second selection of  during the 2 minute pause	• Starts a 2 or 5 minute audio pause period for all alarms except the break-through alarms. The following alarms will break through when escalated to or activated at high priority alarm condition: Asystole, V Fib/V Tach, V Tach, SpO2 Critical, Critical Brady/Tachy in all software packages; in addition, Brady in the NICU software package. The 2 or 5 minute duration is a care unit setting and password protected. • Removes all new latched alarms. • Some technical alarms may also be deactivated with this selection.
Select  once during audio pause	• Ends the audio pause period. • Restores all audio paused alarms if the alarm condition still exists.
No active or latched alarms	
Selection	Result
Select  once	• Starts a 2 or 5 minute audio pause period for all alarms except the break-through alarms. The following alarms will break through when escalated to or activated at high priority alarm condition: Asystole, V Fib/V Tach, V Tach, SpO2 Critical, Critical Brady/Tachy in all software packages; in addition, Brady in the NICU software package.
Select  once during audio pause	• Ends the audio pause period. • Restores all audio paused alarms if the alarm condition still exists.

Pausing alarms for 5 minutes

You can pause audible alarms with the pause audio key for 2 or 5 minutes according to the care unit settings. You can also pause all alarms for 5 minutes through the **Alarm Settings** menu.

1. Select  from the main menu.
2. Select the **Audible & Visual** tab.
3. Select **Pause all audio for 5 min**. This will pause all alarms, including the breakthrough alarms. It also removes latched alarms.

Activating all audible alarms

If necessary, you can activate all paused audible alarms before the 2 or 5 minute pause expires. Use the pause audio key, or:

1. Select  from the main menu.
2. Select the **Audible & Visual** tab.
3. Select **Activate all audible alarms**.

Technical alarm deactivation with the pause audio key

Certain technical alarms can be deactivated with the pause audio key. The **Alarm deactivation** setting is configured in the **Care unit settings** and it is password protected.

For more information, see the supplemental information provided in the appendices.

Technical alarms for which the deactivation with the pause audio key can be allowed are:

- **ECG leads off**
- **Arterial disconnect**
- **SpO2 probe off**

Apnea alarm deactivation with the pause audio key

Apnea alarms can be deactivated with the pause audio key if **Allow alarm deactivation with the Audio Pause key for: Apnea (CO2/Imped.)** check box has been selected in the **Care unit settings**. This setting is password protected.

For more information, see the supplemental information provided in the appendices.

Breakthrough alarms

If one of the following alarms is triggered during a 2 to 5 minute audio pause period, the alarm will break through when escalated to or activated at high priority alarm condition: **Asystole, V Fib / V Tach, V Tach, Critical Brady/Tachy (/min), Brady** (in the NICU software package only), and **SpO2 critical (%)**.

NOTE

If **Alarm Settings > Audible & Visual > Pause all audio for 5 min** is selected before an alarm is triggered, no alarms break through the alarm pause. The pause audio behavior is configured in **Care unit settings** and the setting is password protected.

Latched alarms

When alarms are latched, the audible alarm and visual message remain after the alarm condition no longer exists. The audible alarm can be paused with the pause audio key, and this also clears the alarm message from the screen. Alarms can be configured to latch for high priority alarms only, all alarm priorities, or none. Only physiological alarms can be latched. The **Latching alarms** setting is configured in the **Care unit settings** and it is password protected.

For more information, see the supplemental information provided in the appendices.

Alarm settings after a power loss

If the Carescape ONE loses power, the amount of time without power affects whether or not you need to reset the alarm settings.

Power loss duration	Alarm setting status after a power loss
Up to 2 hours	The alarm settings that are in effect before the power loss are restored automatically.
Greater than 2 hours	The alarm settings revert back to the user default settings (startup profile). You must reconfigure any patient-specific alarm settings.

Alarm data stored in Clinical logs

Access to the Clinical logs is a service-level function and it is password protected.

Carescape ONE stores a record of patient-related alarms and information messages as well as any adjustments to the alarm limits in the Clinical logs.

The log storing capacity for Clinical logs is 50 MiB for the period of seven days.

The system periodically rotates logs, which is an act of compressing and removing old logs. The rules for rotation are:

- Log file size exceeds 50 MiB, or one week has passed since the last rotation.
- A maximum of five older log files are kept, older log files are deleted.
- The kept old log files are compressed.

Compressed files have a numeric suffix, and the lowest value is the most recent log file.

Stored alarm data during a power cycle or power loss

If the Carescape ONE goes through a power cycle or a loss of power, the stored alarm data in the Clinical log is not affected. The alarm data remains stored in the Clinical log until the monitor automatically clears the oldest stored data to allow new data to be stored. All information is stored in English only.

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Intra-hospital transport use

Transport monitoring

You can use the Carescape ONE for uninterrupted monitoring when transferring a patient from one location to another within the hospital. When the Carescape ONE is used as an acquisition platform with a host monitor, you can disconnect it from the host monitor, retain the patient data in the Carescape ONE, and continue to monitor as you move the patient.

After transport, you can return the Carescape ONE to the host monitor, reconnect it as an acquisition platform, and resume monitoring the patient on the host monitor.

Dual monitoring and transport

During normal monitoring when the Carescape ONE is connected to the host monitor as an acquisition platform, the Carescape ONE display is not active. A screen saver is displayed, and all parameter data and alarm signals are presented on the host monitor because the Carescape ONE is acting as an acquisition platform. You can activate the Carescape ONE display screen by touching it. When the Carescape ONE display is activated, the message **Acquisition mode - view only** is displayed on it, indicating that only viewing is allowed. Parameter data will be shown on the Carescape ONE for two minutes before it returns to the screen saver.

NOTE

Although parameter data is displayed on the Carescape ONE when you touch the screen, alarm messages are not shown in the alarm area and parameter window numerics do not flash on the Carescape ONE display during an alarm condition because the Carescape ONE is acting as an acquisition platform for the host monitor. When the Carescape ONE is connected to the host monitor as an acquisition platform, alarms can only be viewed on the host monitor.

Upon return from transport when the Carescape ONE is reconnected to the host monitor and the host monitor has relearned ECG, the Carescape ONE display remains illuminated for two minutes so you can ensure the host monitor is displaying waveforms and parameter data. During these two minute dual monitoring periods, any alarms are generated on the host monitor only.

Wireless transport mode

NOTE

To use this feature, the wireless transport mode must be configured and the WLAN license must be in use on the Carescape ONE.

Wireless transport mode allows you to establish a wireless link between the host monitor and the Carescape ONE that is used for transport monitoring. In the wireless transport mode, the Carescape ONE sends the patient data and alarms to the central station via the host monitor. The host monitor is in standby and forwards the patient data and alarms to the central station.

When using the wireless transport mode, patient information can be entered locally using the Carescape ONE or entered remotely using a central station. Carescape ONE cannot load trend data from the Carescape Network in wireless transport mode.

See the host monitor user manual for instructions on setting the host monitor to standby and starting wireless transport mode.

Alarms in wireless transport mode

In the wireless transport mode, the Carescape ONE sends alarms to the central station via the host monitor. The host monitor is in standby and forwards the alarms to the central station. There are no visual or audible alarms on the host monitor.

The most recent of the alarms that has the highest priority level at this moment is the alarm that is broadcast on the network. For example, if there is one medium-priority alarm and a low-priority alarm appears, the medium-priority alarm is broadcast, not the most recent (low-priority) alarm. If there is one medium-priority alarm and another medium-priority alarm appears, the latest alarm that appeared is broadcast. Physiological alarms always take precedence over technical alarms.

Alarms can also be paused and acknowledged at the central station if so configured. By default this is not allowed.

NOTE

Informational messages are not sent to the network, and they are never latched.

Broadcast only alarms

Alarms are sent to the Carescape Network and displayed on the central station or remote monitor according to the following mapping.

Feature	Message on the bedside monitor in wireless transport mode	Message sent to the Carescape Network and displayed on the central station/remote monitor
ECG	ECG measurements removed	ECG REMOVED
ECG	Noise	NOISY ECG
ECG	Arrhythmia paused	ARRH PAUSED
ECG	Leads off	LEADS FAIL
ECG	ECG malfunction ECG device failure: Call service Identical ECG device Insufficient power for ECG device Move ECG device to a cooler location ECG device overheated. Shutting down	CHECK ECG
ECG	ECG Analog output malfunction	ECG ANALOG
Impedance respiration	Imped. malfunction	CHECK IMPED
Impedance respiration	Resp (Imped.) measurement paused	IMPED PAUSED
NIBP	Check NIBP NIBP over range NIBP under range	CHECK NIBP
NIBP	NIBP auto stopped NIBP STAT stopped	NIBP STOPPED
NIBP	Cuff occlusion	OCCCLUSION

Feature	Message on the bedside monitor in wireless transport mode	Message sent to the Carescape Network and displayed on the central station/remote monitor
SpO ₂	Identical SpO ₂ device	SPO2 IDENT
SpO ₂	SpO ₂ measurement removed	SPO2 REMOVED
SpO ₂	No adhesive SpO ₂ probe No SpO ₂ cable	NO SPO2 PROBE
SpO ₂	Check SpO ₂ probe SpO ₂ malfunction SpO ₂ device overheated Shutting down Insufficient power for SpO ₂ device	CHECK SPO2
SpO ₂	SpO ₂ faulty probe Faulty adhesive SpO ₂ probe SpO ₂ faulty cable	SPO2 FAULTY
SpO ₂	Incompatible SpO ₂ probe Incompatible adhesive SpO ₂ probe	SPO2 INCOMPAT
SpO ₂	Incompatible SpO ₂ probe	INCOMP SPO2-2
IP, CCO	Check XXX waveform Identical IP/CCO devices Insufficient power for IP/CCO device Move IP/CCO device to a cooler location IP/CCO measurement removed	CHECK IP/CCO
IP	Pressure measurement removed	IP REMOVED
IP	Channel X sensor failed, where Channel = IP channel label and X = channel number	SENSOR FAIL
IP	P1 pressure malfunction P2 pressure malfunction P3 pressure malfunction P4 pressure malfunction P8 pressure malfunction	CHECK P1 CHECK P2 CHECK P3 CHECK P4 CHECK P8
IP	Pressure device failure: Call service Identical pressure devices Move pressure device 1/2 to a cooler location Move pressure device 3/4 to a cooler location Pressure device overheated. Shutting it down	CHECK IP
IP	IP Analog output malfunction	IP ANALOG
Temperature	Temp measurement removed	TEMP REMOVED

Feature	Message on the bedside monitor in wireless transport mode	Message sent to the Carescape Network and displayed on the central station/remote monitor
Temperature	Temperature malfunction Move Temp device to a cooler location Identical Temp device Temp device failure: Call service Temp device overheated. Shutting down	CHECK TEMP
CO ₂	Check CO2 adapter	ADAPTER
CO ₂	Sample line blocked	BLOCKED LINE
CO ₂	Check gas flow CO2 device overheated Shutting down CO2 device failure: Call service CO2 device malfunction CO2 sensor removed Identical CO2 device Insufficient power for CO2 device Move CO2 sensor to a cooler location Select age for CO2	CHECK CO2
CO ₂	CO2 measurement removed	CO2 REMOVED
CO ₂	CO2 zero required	ZERO CO2
CO ₂	Check sample line Sample line disconnected	SAMPLE LINE
CO ₂	Service CO2 sensor	SERVICE CO2

Arrhythmia alarm mapping

Certain arrhythmias are only annunciated locally. Since the Carescape Network and Carescape Central Station are unfamiliar with some of these new arrhythmias, they are mapped to corresponding known arrhythmias in the Event directory of the Carescape Central Station when using the wireless transport mode. Consult the following table for more details:

Measurement on the monitor	Alarm message on the monitor	Alarm message on the central station alarm display unit (ADU)	Event directory on the central station	Alarm level control on the central station
HR high/low	Tachy/PR high Brady/PR low	Tachy/Brady	TACHY/BRADY	Parameter: HR high/low ¹⁾
PVC count	Frequent PVCs	Frequent PVCs	PVC	Parameter: PVC
Multifocal PVCs	Multifocal PVCs	Multifocal PVCs	PVC	Arrhythmia: PVC
Missing beat	Missing Beat	Missing Beat	PAUSE	N/A
Pause	Pause	Pause	PAUSE	Arrhythmia: PAUSE
SVC count	Frequent SVCs	Frequent SVCs	IRREGULAR	N/A
SV tachy	SV Tachy	SV Tachy	TACHY	Arrhythmia: TACHY

Measurement on the monitor	Alarm message on the monitor	Alarm message on the central station alarm display unit (ADU)	Event directory on the central station	Alarm level control on the central station
¹⁾ Note the following regarding Carescape Central Station v2.0 or earlier and alarm priorities for Tachy/PR high and Brady/PR low: - If you have selected different priorities on the monitor for high and low alarms, the alarm level control at the Carescape Central Station will be inactivated. This situation is also indicated as an empty cell in the central station's table of parameter limits and alarm levels. - If the HR high/low alarm level control is active at the central station and it is selected, the selection applies to Tachy/PR high and Brady/PR low, provided that you have selected the same priority for high and low alarms on the monitor. Otherwise the monitor will discard the central station selection, resulting in an empty cell in the central station's table of parameter limits and alarm levels.				

Time change during a patient case

CAUTION

MISINTERPRETATION. System time changes will result in time differences between stored and realtime data. Always check the times carefully to avoid the risk of misinterpretation.

CAUTION

MISINTERPRETATION OF HISTORICAL DATA. Changing the date and time on one network device on the Carescape Network will also update the date and time for all other devices on the same network. To avoid possible misinterpretation of historical data when viewing it, special attention should always be paid to the time and date information.

Time adjustment is allowed during a patient case if the monitor is configured to the Carescape Network, independent on its connection status to the network. When the time is adjusted, the monitor shifts the timestamps of continuous trend data. Measurement times for NIBP are not shifted with the respective trend data. If you adjust the time backwards, make sure that the patient's date of birth is not set in the future after the change. The monitor will invalidate any birth date set in the future and this can result in loss of patient data.

Time and date settings are changed by selecting  from the main menu and then **Defaults & Service > Default settings > Time & date**, and they are password protected.

For more information, see the supplemental information provided.

Checking the network connections

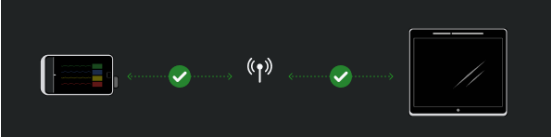
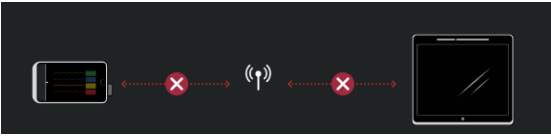
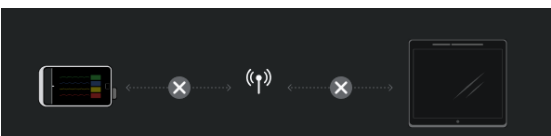
The following network connections are required for the use of wireless transport mode:

- To establish a link to the host monitor, Carescape ONE must be connected to the wireless network.
- To forward the patient data and alarms to the central station, the host monitor must be connected to the Carescape Network.

Follow these steps to check the status of the network connections:

- Select the battery status area in the upper right corner of the screen, or select  from the main menu and then **Battery & network**.
- Select the **Network** tab.
- Check the displayed information.

The following status notifications and visual indicators show the network connection and wireless link status:

Notification	Indicator	Description
Network status: Connected		- Carescape ONE: Connected to the wireless network. - Host monitor: Connected to Carescape Network.
Network status: Connecting...		- Carescape ONE: Connected to the wireless network. - Host monitor: Connecting to Carescape Network.
Network status: Connecting...		- Carescape ONE: Connecting to the wireless network. - Host monitor: Connecting to Carescape Network.
Network status: Disconnected		- Carescape ONE: Disconnected from the wireless network. - Host monitor: Disconnected from Carescape Network.

End of wireless transport mode

NOTE

Monitoring continues in standalone mode until the patient is discharged from the Carescape ONE.

To end the wireless transport mode, reconnect Carescape ONE to a host monitor.

Alternatively, you can end the wireless transport mode during transport as follows:

1. Select the battery status area in the upper right corner of the screen, or select  from the main menu and then **Battery & network**.
2. Select the **Link** tab > **Disconnect**.
3. Select **Disconnect** in the pop-up window. The host monitor changes to the basic standby mode.

In addition, the wireless transport mode ends automatically when any of the following conditions occur:

- Wireless link is disconnected from the host monitor.
- Carescape ONE is connected to a new host monitor.
- Carescape ONE is shut down for at least 2 hours.
- Patient is discharged / case is reset.
- A new acquisition device is connected to the host monitor.

Preparing to transport a patient

1. Place the host monitor into standby mode.

If the wireless transport mode is in use on the host monitor and Carescape ONE, you can set the host monitor to standby and establish a wireless link between Carescape ONE and the host monitor for the duration of the transport. If you wish to use the wireless transport mode, check that the following indicators are displayed on the Carescape ONE:  (gray) and  (white) before disconnecting the Carescape ONE from the Carescape Dock F0.
2. Connect micro-modules needed for transport to the Carescape ONE, or remove those not needed for transport.
3. Ensure that the parameters you need to monitor during transport are selected to display on the Carescape ONE screen. Refer to the chapter “Setting up the monitor before use” for more information on selecting parameters to the screen.
4. Ensure that there is a charged battery installed in the Carescape ONE.
5. If you wish to use the wireless transport mode, set the host monitor to standby. When the wireless connection has been established,  icon turns white. See the host monitor user manual for instructions on setting the host monitor to standby in wireless transport mode.
6. Disconnect the Carescape ONE from the Carescape Dock F0.
7. Place the Carescape ONE in the transport location. Use a Mini Dock and/or a Micro-module Dock 1, Micro-module Dock 3, Micro-module Dock 4, or Micro-module Dock 5 to secure the Carescape ONE and micro-modules during transport.

WARNING

PATIENT SAFETY. Do not place the Carescape ONE in a patient bed.

NOTE

Make sure the cables do not drag on the floor or interfere with the movement or operation of the transport bed. The cables must be placed so that they do not entangle infusion pump lines or become a hazard to the patient.

NOTE

To maintain visibility of the Carescape ONE display, the bedrail mount should be mounted on a rail or headboard that provides support to the back of the mount. The bedrail mount should be used on stationary bedrails or headboards only.

NOTE

The pole mount is intended for use on a vertical pole only, and should not be used on a horizontal bedrail.

8. Transport the patient.

Returning a patient from transport

Follow these steps to return the patient to the same host monitor after transport, retaining the patient data.

1. Return the patient to the room.

2. Remove the Carescape ONE from the Mini Dock.
3. Connect the Carescape ONE to the Carescape Dock F0 at the host monitor.

Patient monitoring will automatically resume on the host monitor if the patient case matches. Patient data acquired on the Carescape ONE during transport will be available on the host monitor.

If the patient case does not match between the host monitor and the Carescape ONE, then the **Select patient and data** window will open on the host monitor. There are four possible options:

- You can select the patient in the Carescape ONE to continue the Carescape ONE patient case. This option is shown with the CS ONE indicator, along with the patient name and MRN number.
- You can select the patient in the host monitor to continue the host monitor patient case. This option will only appear if a patient is admitted to the host monitor. It is shown as the host monitor bed name plus the patient name and MRN number.
- You can merge the Carescape ONE patient case with the host monitor patient case. This option is shown as the host monitor bed name + CS ONE indicator.
- You can select **New patient** to discharge the patient from the Carescape ONE, deleting all patient data and history, and start monitoring a new patient/case at the host monitor.

For more information on the selections on the host monitor, refer to the host monitor user manual.

4. If needed, reconnect any parameters that were disconnected during transport.

There are limits on the amount of data that the Carescape ONE provides to a different host monitor upon connection after transport from another host monitor. The transferred history is limited to 36 ECG and arrhythmia related events, 10 ST events, and 24 hours of trended data excluding high resolution trends.

For more information, see the Transport patient settings and Transport care unit settings sections in this chapter, and the About continuing monitoring section in the Starting and ending monitoring chapter.

Transport patient settings

The following patient settings are transferred from the Carescape ONE to the host monitor at connection when a patient case from a Carescape ONE is loaded to the host monitor.

Current patient settings transferred from the Carescape ONE to the host monitor	
ECG	• ECG 1 lead • ECG 2 lead • ECG 3 lead • Lead analysis • ST analysis • Va lead position • Vb lead position
Impedance respiration	• Respiration lead selection • Respiration measurement on/off • Size (%) • Patient type

Current patient settings transferred from the Carescape ONE to the host monitor	
SpO ₂	None
Non-invasive blood pressure	• Automatic NIBP • Cycle time
Invasive blood pressure	• Channel label (if the Carescape ONE channel is zeroed) • Filter (Hz) (if the Carescape ONE channel is zeroed) • IABP on (if the Carescape ONE channel is zeroed)
Temperature	• T1 on on/off • T2 on on/off
CO ₂	None

If a patient is not admitted on the Carescape ONE at connection, the following patient settings from the host monitor are transferred to the Carescape ONE. If you make changes to any of these settings on the host monitor, the changes are continuously synchronized with the Carescape ONE while the Carescape ONE remains connected to the host monitor. When you take the Carescape ONE on transport, these synchronized settings are used.

The settings listed in the table above are included in the settings that are continuously synchronized between the devices while the Carescape ONE remains connected to the host monitor. These settings are also listed in the table below showing the synchronized settings.

Current patient settings synchronized with the host monitor and the Carescape ONE

ECG

NOTE

When a Carescape ONE is connected to a host monitor, the host monitor displays the heart rate reading sent by the Carescape ONE until the host monitor's ECG algorithm has successfully learned the ECG rhythm.

NOTE

Carescape ONE does not have group ST alarm settings in standalone mode. When a host monitor is using the group settings for ST alarm limits, individual ST alarm limits and on/off statuses are transferred to the Carescape ONE when it is disconnected from the host monitor for transport. Upon reconnection after transport, the host monitor group settings are used again.

You should always check the ST alarm settings on the Carescape ONE after disconnecting for transport to make sure they are appropriate for the patient being transported.

- **A Fib > Priority**
- **A Fib > Create snapshot**
- **Accelerated Ventricular > Priority**
- **Accelerated Ventricular > Create snapshot**
- **Arrhythmia**
- **Arrhythmia paused** alarm priority
- **Asystole > Create snapshot**
- **Bigeminy > Priority**
- **Bigeminy > Create snapshot**
- **Couplet > Priority**
- **Couplet > Create snapshot**
- **ECG 1 lead**
- **ECG 2 lead**
- **ECG 3 lead**
- **ECG lead off** alarm priority
- **ECG leads off** alarm priority
- **Frequent PVCs** high alarm priority
- **Frequent SVCs** high alarm priority
- **HR** alarm limits
- **HR** alarm on/off
- **Minimum HR (/min)**
- **HR for SVT (/min)**
- **Tachy/PR high** alarm priority
- **Brady/PR low** alarm priority
- **Irregular > Priority**
- **Irregular > Create snapshot**
- **ISO point**
- **J point**
- **Lead analysis**
- **Missing Beat > Priority**
- **Missing Beat > Create snapshot**
- **Multifocal PVCs > Priority**
- **Multifocal PVCs > Create snapshot**

Current patient settings synchronized with the host monitor and the Carescape ONE	
	• Noisy ECG alarm priority • Pacemaker detection • Pause > Priority • Pause > Create snapshot • Pause interval (s) • PR (SpO2/IP) low/high (s) alarm delay • Primary HR source • Frequent PVCs alarm limits • Frequent PVCs alarm on/off • QRS width • R on T > Priority • R on T > Create snapshot • Size • ST XXX alarm limits; where XXX = ECG site label • ST XXX alarm on/off; where XXX = ECG site label • ST analysis • ST point (ms) • ST segment low/high alarm priority • SV Tachy > Priority • SV Tachy > Create snapshot • Frequent SVCs alarm limits • Frequent SVCs alarm on/off • SVT length (beats) • Trigeminy > Priority • Trigeminy > Create snapshot • Va lead position • Vb lead position • V Brady > Priority • V Brady > Create snapshot • V Fib / V Tach > Create snapshot • V Tach > Priority • V Tach > Create snapshot • VT > 2 > Priority • VT > 2 > Create snapshot
Impedance respiration	• Apnea (Imped.) limit seconds • Apnea (Imped.) alarm priority • Resp (Imped.) measurement paused alarm priority • Respiration lead selection • Respiration measurement on/off • RR (Imped.) (X) alarm limits • RR (Imped.) (X) alarm on/off • RR (Imped.) low/high alarm priority • RR (Imped.) high (s) alarm delay • RR (Imped.) low (s) alarm delay

Current patient settings synchronized with the host monitor and the Carescape ONE	
SpO ₂	• SpO2 averaging (s) • PR (SpO2) (/min) alarm limits • PR SpO2 alarm on/off • Response • Sensitivity • Show SatSeconds • SatSeconds • SpO2 (%) alarm limits • SpO2 alarm on/off • SpO2 high (s) alarm delay • SpO2 high alarm priority • SpO2 low (s) alarm delay • SpO2 low alarm priority • SpO2 probe off alarm priority
Non-invasive blood pressure	• Patient type • Cycle time • Diastolic alarm limits • Diastolic alarm on/off • Mean alarm limits • Mean alarm on/off • Automatic NIBP • NIBP low/high alarm priority • Systolic alarm limits • Systolic alarm on/off

Current patient settings synchronized with the host monitor and the Carescape ONE	
Invasive blood pressure	• Channels 1, 2, 3, 4, and 8 systolic alarm limits • Channels 1, 2, 3, 4, and 8 systolic alarm on/off • Channels 1, 2, 3, 4, and 8 diastolic alarm limits • Channels 1, 2, 3, 4, and 8 diastolic alarm on/off • Channels 1, 2, 3, 4, and 8 mean alarm limits • Channels 1, 2, 3, 4, and 8 mean alarm on/off • Channel label • Filter (Hz) • IABP on • Art low/high alarm priority • CPP low/high alarm priority • CVP low/high alarm priority • Fem low/high alarm priority • FemV low/high alarm priority • ICP low/high alarm priority • IP low/high alarm priority levels allowed • P1 low/high alarm priority • P2 low/high alarm priority • P3 low/high alarm priority • P4 low/high alarm priority • PA low/high alarm priority • LAP low/high alarm priority • RAP low/high alarm priority • RVP low/high alarm priority • UAC low/high alarm priority • UVC low/high alarm priority
Temperature	• T1 alarm limits • T1 alarm on/off • T1 label • T1 on on/off • T2 label • T2 on on/off • T1-T2 or T2-T1 alarm limits • T2 alarm limits • T2 alarm on/off • Temp low/high alarm priority

Current patient settings synchronized with the host monitor and the Carescape ONE	
CO ₂	• Apnea (CO₂) (X) • Apnea (CO₂) alarm priority • CO₂ average (s) • CO₂ low/high alarm priority • EtCO₂ (X) alarm limits • FiCO₂ (X) alarm limits • FiCO₂ (X) alarm on/off • FiO₂ level (%) • N₂O level (%) • RR (CO₂) low/high alarm limits • RR (CO₂) low/high alarm priority

Transport care unit settings

If a Carescape ONE is taken to another unit and connected to a different host monitor as an acquisition platform, the Carescape ONE uses the receiving host monitor's care unit settings. For example, if the Carescape ONE is disconnected from a host monitor in the ICU, the care unit settings used during transport are those from the ICU host monitor that are listed in the table below. Care unit settings not listed in the below table remain as set on the Carescape ONE defaults. If that same Carescape ONE is then taken to the OR and connected to a different host monitor there, upon connection the Carescape ONE will use the OR host monitor's care unit settings. Any changes made during transport when the Carescape ONE is not docked to a host monitor are not saved when the Carescape ONE is connected to another host monitor.

Care unit settings transferred from the host monitor to the Carescape ONE	
ECG	• Allowed arrhythmia levels • Allow informational level for arrhythmia alarms • ECG lead off alarm priority levels allowed • ECG leads off alarm priority levels allowed • HR Alarms (Single or Multiple) • Allow low priority for Brady/Tachy and PR low/high • Noisy ECG, Arrhythmia paused alarm priority levels allowed • Size • Allow informational level for ST alarms • ST point (ms) • V Tach alarm priority levels allowed
Impedance respiration	• Apnea (Imped.) alarm priority levels allowed • Resp (Imped.) measurement paused alarm priority levels allowed • RR (Imped.) low/high alarm priority levels allowed
SpO ₂	• Allow low priority for SpO₂ low • SpO₂ probe off alarm priority levels allowed
Non-invasive blood pressure	• NIBP low/high alarm priority allowed levels
Invasive blood pressure	None

Care unit settings transferred from the host monitor to the Carescape ONE	
Temperature	- Configurable label Allow informational level for temperature alarms
Wireless transport mode	Send alarms from transport device to network (Audible and visual or Visual only) Allow audio pause: From remote location Allow remote pausing of (Low priority alarm, Low & medium priority alarms, or All alarms)

Transport troubleshooting

Problem	Solution
A parameter is not visible on the Carescape ONE during transport	- Check that the micro-module is connected to the Carescape ONE. - Check that the parameter has been added to one of the pages that can be viewed on the Carescape ONE. Keep in mind that you may need to switch the page that is currently shown on the screen. - The parameter may only be available when Carescape ONE is operating as an acquisition platform for a host monitor.
The host monitor does not recognize the patient case when returning from transport	- Check that the Carescape ONE is securely connected to the powered docking solution. - Is the host monitor the same one used for this patient previously? If yes, the host monitor may have been discharged remotely while the patient was on transport. Use the host monitor Select patient and data window to select the Carescape ONE patient.

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ECG

ECG compatibility limitations

For detailed information regarding Carescape ONE, micro-modules, and accessory compatibility, see the supplemental information provided.

ECG safety precautions

ECG warnings

WARNING

ELECTRIC SHOCK. To avoid the risk of shock caused by leadwire set clips or snaps, which may conduct electricity, make sure that they do not touch any electrically conductive material including earth.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

MISINTERPRETATION. This device is intended to record electrocardiograms from surface ECG electrodes. It is not meant for positioning (floating) temporary pacemaker leadwires, performing pericardiocentesis, or other internal applications. Using the device in ways other than its intended use may lead to misinterpretation of measurement data.

WARNING

MISINTERPRETATION. The **Maximum** filter may alter the displayed ECG morphology. Do not make measurements from the displayed or printed ECG when this filter is selected. Displayed ST values are calculated before applying the **Maximum** filtering and may differ from values measured from the displayed or printed ECG.

WARNING

MISSED ALARMS. Disconnected electrodes or loose electrode connections can lead to missed critical severity ECG alarms. If the device reports **Leads off** after you have selected **Update lead set**, always check the electrode connections to the patient.

WARNING

CONDUCTIVE CONNECTIONS. Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input.

WARNING

DELAYED ASYSTOLE ALARM. The pulsatile heart rate may have a slower response time than the electrical heart rate where there is a low perfusion patient condition. When using the IntelliRate feature in this situation, the device may delay calling an ASYSTOLE patient alarm. The user may elect to turn the IntelliRate feature off for patients at risk of these events, otherwise patient treatment may be delayed. Such patients should always be kept under close observation.

WARNING

NOISY ECG ALARM. The **Noisy ECG** alarm indicates that the system is no longer monitoring ECG and there may be no **Tachy** or **Brady** alarms. If you adjust the alarm priority level lower than the default value, keep the patient under close surveillance.

WARNING

ARRHYTHMIA PAUSED ALARM. The **Arrhythmia paused** alarm indicates that the system is no longer monitoring ECG and there may be no **Tachy** or **Brady** alarms. If you adjust the alarm priority level lower than the default value, keep the patient under close surveillance.

WARNING

INACCURATE HEART RATE INDICATION. The electrical and pulsatile heart rate values provided by the various monitored parameters (ECG, SpO₂, blood pressures) may differ markedly. These differences may be due to underlying physiologic conditions (e.g., electromechanical dissociation, pulseless electrical activity, non-perfusing rhythms) or to inaccuracies in the heart rate values caused by artifact, poor signal quality, or arrhythmias. The user may elect to turn the IntelliRate feature off for patients at risk of these events, otherwise patient treatment may be delayed. Such patients should always be kept under close observation.

WARNING

ELECTRODES. Whenever patient defibrillation is a possibility, use non-polarizing (silver/silver chloride construction) electrodes for ECG monitoring. Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge will block acquisition of the ECG signal.

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires.

WARNING

HEART RATE ALARM INTERFERENCE. Poor cable positioning or improper electrode preparation may cause line isolation monitor transients to resemble actual cardiac waveforms and thus inhibit heart rate alarms. To minimize this problem, follow proper electrode placement and cable positioning guidelines provided with this device.

ECG cautions

CAUTION

SKIN IRRITATION. The patient's skin may become irritated after prolonged contact with electrode gel or adhesive. To avoid skin irritation, periodically check the patient, and if possible, avoid extended measurement periods.

ECG measurement considerations

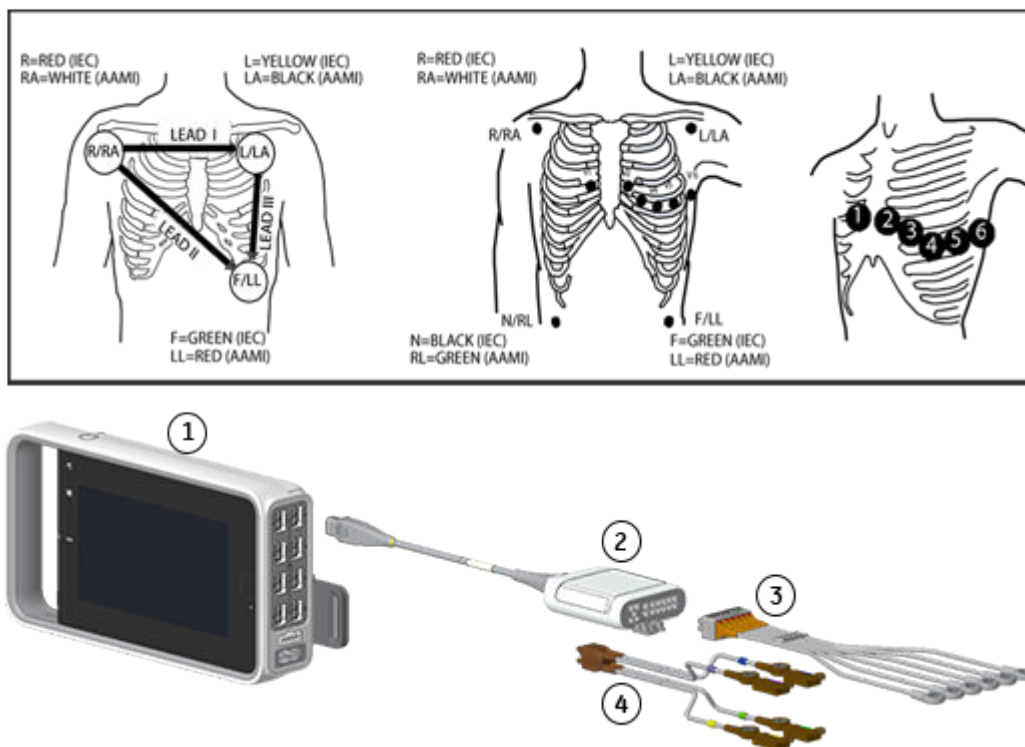
- The monitor will display a **Leads off** message in an input overload condition, or upon disconnection of electrode leadwires.

ECG points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 60601-2-27 clause 202.6.2.101 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Defibrillator discharge may affect the ECG measurement. Defibrillation recovery time after discharge is < 5 seconds.
- Pre-gelled ECG electrodes are recommended. Check the expiration date.
- Make sure the electrode gel is moist.
- Make sure the electrodes have good skin contact.
- Replace all electrodes at least every 24 to 48 hours.
- Select the **Deactivate ECG leads off** option to remove a **Leads off** message from the display when a cable is off.

ECG measurement setup

ECG equipment to patient connection with Carescape ONE



1. Carescape ONE
2. TruSignal ECG micro-module
3. AAMI/AHA or IEC 3-leadwire, 5-leadwire, or 6-leadwire set
4. AAMI/AHA or IEC precordial leads leadwire set

Preparing the patient's electrode sites

Excessive body hair or skin oil reduces electrode contact with the skin and decreases the quality of electrode signal. When preparing the electrode sites, avoid bones close to skin, obvious layers of fat and major muscles.

1. Shave any hair from the electrode site.
2. Gently rub the surface of the skin to increase capillary blood flow.
3. Clean the skin with alcohol or a mild soap and water solution to remove skin oil and dead or abraded skin cells.
4. Dry the skin completely before applying the electrodes.

Applying the electrodes to the patient

1. Place the electrodes on the prepared sites.

2. Stabilize the electrode and leadwire with a leadwire stress loop near the electrode.
3. Tape the stress loop to the patient (excluding neonates).



A secured stress loop prevents leadwire rotation about the electrode snap, leadwire tugging at the electrode, and ECG artifact.

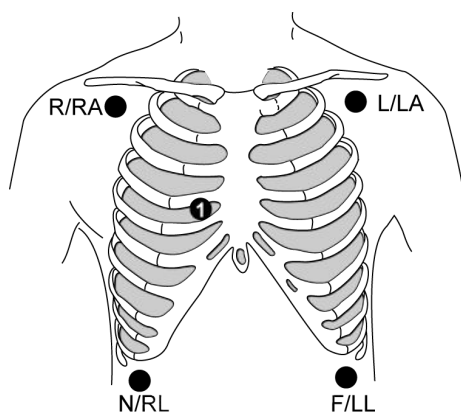
Checking the ECG measurement

1. Check that the waveforms and parameter values are displayed without any error messages when the cable is connected to the patient.

You can also check the electrode status by selecting the ECG parameter window > **Leads** and selecting page 2. The indicators show the electrode status.

3- lead or 5-lead ECG electrode placement

For a 3-leadwire electrode placement, the R/RA, L/LA, and F/LL electrodes should be used.

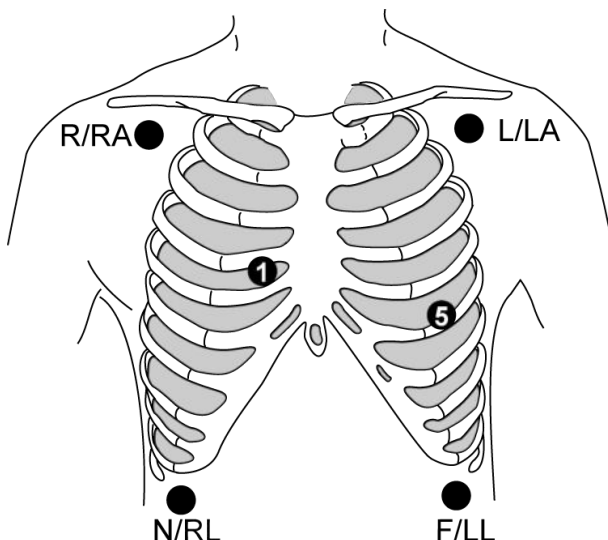


IEC	AAMI/AHA	Electrode placement
R (red)	RA (white)	Just below the right clavicle.
L (yellow)	LA (black)	Just below the left clavicle.
User defined C1-C6 (Indicated as 1 in the electrode placement graphic.)	User defined V1-V6 (Indicated as 1 in the electrode placement graphic.)	For the 5-lead placement, place the precordial electrode according to the physician's preference.
N (black)	RL (green)	Lower right edge of the rib cage.
F (green)	LL (red)	Lower left edge of the rib cage.

6-lead ECG electrode placement

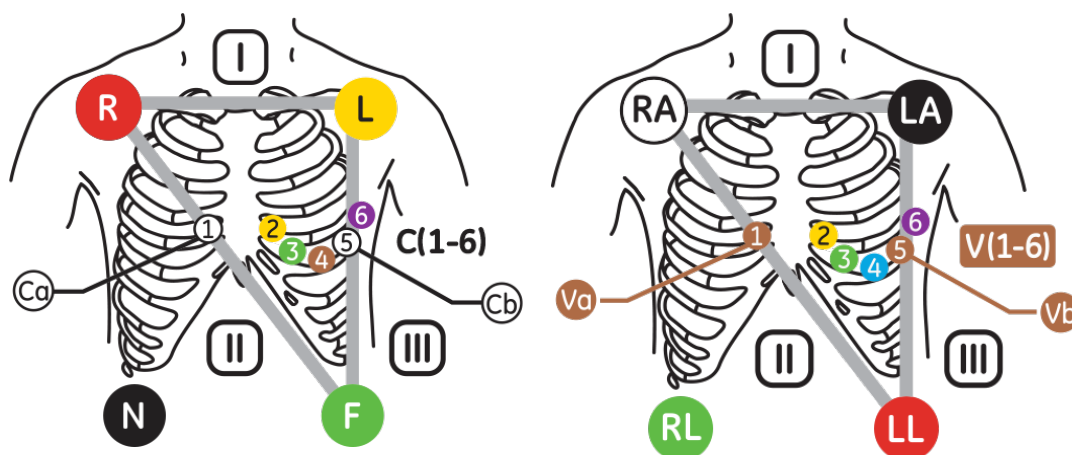
NOTE

A 6-leadwire cable should be used for 12RL™ monitoring. Position the Ca/Va electrode in the C1/V1 position and place the Cb/Vb electrode in the C5/V5 position. The leadwire labels for the Ca/Va and Cb/Vb leads are white (IEC) or brown (AAMI/AHA). The 12RL should be used for adult patients only.



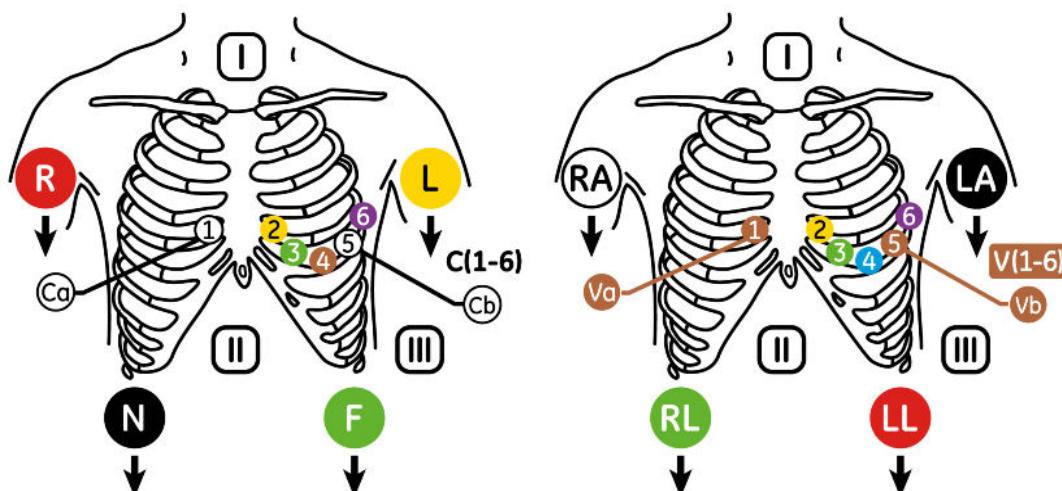
IEC	AAMI/AHA	Electrode placement
R (red)	RA (white)	Just below the right clavicle.
L (yellow)	LA (black)	Just below the left clavicle.
Ca/C1 (white)	Va/V1 (brown)	4 th intercostal space, right sternal border.
Cb/C5 (white)	Vb/V5 (brown)	Left anterior axillary line at C4/V4 level.
N (black)	RL (green)	Lower right edge of the rib cage.
F (green)	LL (red)	Lower left edge of the rib cage.

10-lead ECG electrode placement for cardiac monitoring



IEC	AAMI/AHA	Electrode placement
R (red)	RA (white)	Just below the right clavicle.
L (yellow)	LA (black)	Just below the left clavicle.
N (black)	RL (green)	Lower right edge of the rib cage.
F (green)	LL (red)	Lower left edge of the rib cage.
Ca/C1 (white)	Va/V1 (brown)	4 th intercostal space, right sternal border.
C2 (white/yellow)	V2 (brown/yellow)	4 th intercostal space, left sternal border.
C3 (white/green)	V3 (brown/green)	Midway between C2/V2 and C4/V4.
C4 (white/brown)	V4 (brown/blue)	5 th intercostal space, mid-clavicular line.
Cb/C5 (white/black)	Vb/V5 (brown/orange)	Left anterior axillary line at C4/V4 level.
C6 (white/purple)	V6 (brown/purple)	Mid-axillary line at C4/V4 and Cb/C5/Vb/V5 levels.

Standard resting 10-lead ECG electrode placement



IEC	AAMI/AHA	Electrode placement
R (red)	RA (white)	Right deltoid or wrist.
L (yellow)	LA (black)	Left deltoid or wrist.
N (black)	RL (green)	Right thigh or ankle.
F (green)	LL (red)	Left thigh or ankle.
Ca/C1 (white)	Va/V1 (brown)	4 th intercostal space, right border of the sternum.
C2 (white/yellow)	V2 (brown/yellow)	4 th intercostal space, left border of the sternum.
C3 (white/green)	V3 (brown/green)	Midway between C2/V2 and C4/V4.
C4 (white/brown)	V4 (brown/blue)	5 th intercostal space, mid-clavicular line.
Cb/C5 (white/black)	Vb/V5 (brown/orange)	Left anterior axillary line at C4/V4 level.
C6 (white/purple)	V6 (brown/purple)	Mid-axillary line at C4/V4 and Cb/C5/Vb/V5 levels.

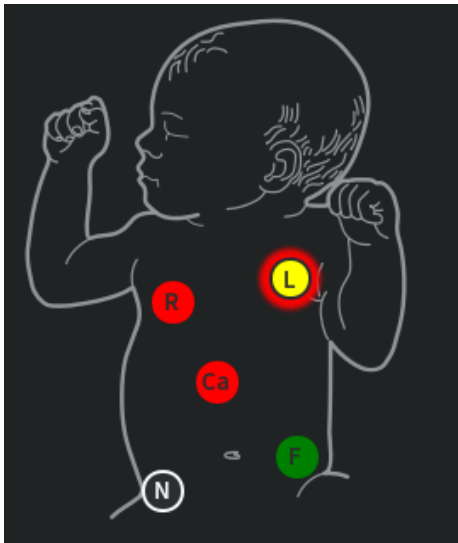
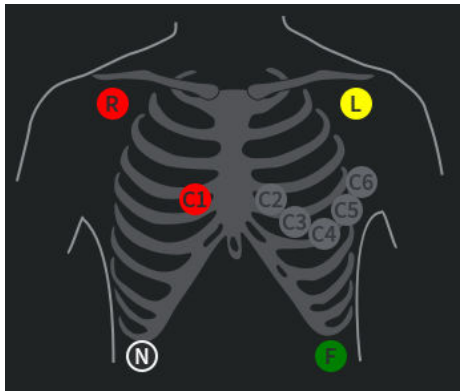
Electrode status indicators in the ECG menu

To display the ECG status electrode indicators, select the ECG parameter window > the **Leads** tab > page 2.

The following table describes how the electrode status is displayed for adult and neonatal patients with different indicators:

Indicator description	Examples of displayed indicators	Meaning
Indicator with standard color (per the IEC or AAMI/AH standard)		Connected electrode detected.
Grayed out indicator		Electrode not included in the active lead set.
Indicator with halo effect		Disconnected electrode detected.

The following example figures show how the different electrode status indicators appear for adult and neonatal patients on the **Leads** tab:



NOTE

There may be a delay in detecting the status of a connected or disconnected electrode.

Showing ECG waveforms on a page

Depending on the selected page layout, you can either show 1-3 waveforms (on a **Classic** page) or one waveform (on a **Box** page) on the page.

1. Select  from the main menu.

2. Select the page you want to edit. You can scroll the list with the arrow icons or swipe the screen. If editing a page is not allowed, there is a lock symbol next to the page name.
3. Select **Edit page**.
4. Select the **ECG** dropdown list displayed on the left side of the screen.
5. Drag and drop the parameter to the desired location on the page.
6. On a **Classic** page: Select the appropriate radio button in the **ECG** dropdown menu: **1 waveform** (default), **2 waveforms**, or **3 waveforms**.

If there is not enough space on the page, **2 waveforms** and/or **3 waveforms** radio button is disabled. To enable the selections, you must first remove other parameters from the page.

About the ECG analog output signal

Maximum delay of the ECG analog output signal is 35 ms. Pacemaker pulse indication is included when appropriate and it is summed in to the ECG waveform.

ECG synchronization pulse delay from the R-wave peak is <35 ms, with the exception of wide QRS (120 ms/0.5 mV).

For more information and detailed specifications, refer to the supplemental information provided in the appendices.

The analog output signal is ECG 1 lead (top waveform position).

Using the ECG measurement

The first three displayed ECG leads

You can choose the order of the ECG waveforms displayed in the ECG waveform area.

Lead selection depends on the type of ECG cable used.

The **ECG 1 lead** setting affects arrhythmia detection.

When **ECG 1 lead**, **ECG 2 lead**, or **ECG 3 lead** are changed manually and the lead becomes inactive due to a disconnection, the monitor looks to the ECG lead saved in the patient profile. If the saved **ECG 1 lead** is not available, the monitor looks for lead II, then lead I, and lastly lead III. Later, if the manually selected lead becomes available again, the monitor will change back to this lead.

Selecting the first displayed ECG lead

The **ECG 1 lead** is the first ECG lead displayed in the ECG waveform area. For single-lead analysis when aVR, aVL, or aVF is set as the **ECG 1 lead**, the following mapping is used: aVR = II, aVL = I, aVF = III.

1. Select the ECG parameter window > **Leads**.
2. Select a lead from the **ECG 1 lead** list.

Selecting the second displayed ECG lead

The **ECG 2 lead** is the second ECG lead displayed in the waveform area.

1. Select the ECG parameter window > **Leads**.

2. Select a lead from the **ECG 2 lead** list.

If your selection is **Cascade**, the displayed **ECG 1 lead** waveform continues into the **ECG 2 lead** waveform area.

Selecting the third displayed ECG lead

The **ECG 3 lead** is the third ECG lead displayed in the waveform area.

1. Select the ECG parameter window > **Leads**.
2. Select a lead from the **ECG 3 lead** list.

If your selection is **Cascade**, the displayed **ECG 2 lead** waveform continues into the **ECG 3 lead** waveform area.

Selecting the Va ECG lead

NOTE

12RL™ monitoring - The Va lead is the first V-lead label used with a 6-leadwire ECG cable for 12RL monitoring. An accurate 12RL is possible only if the Va is set to V1. Be sure to place the leads correctly to obtain an accurate 12RL.

The factory default for the Va lead is V1, however you may choose a different lead.

The Va lead is the only V-lead used with a 5-leadwire ECG cable.

1. Select the ECG parameter window > **Leads**.
2. Select a lead from the **Va lead position** list.

Selecting the Vb ECG lead

NOTE

12RL™ monitoring - The Vb lead is the second V-lead label used with a 6-leadwire ECG cable for 12RL monitoring and must be set to **V5** for an accurate 12RL. Be sure to place the leads correctly to obtain an accurate 12RL.

When using a 6-leadwire ECG cable, the factory default for the Vb lead is V5, however you may choose a different lead.

1. Select the ECG parameter window > **Leads**.
2. Select a lead from the **Vb lead position** list.

Changing to an ECG cable with fewer leadwires

This selection will update the measurement mode among 3-, 5-, 6-, 12RL™ and 10-lead mode when changing to fewer leadwires. Transition from the 12RL mode to the 6-lead mode is detected automatically.

1. Select the ECG parameter window > **Leads**.
2. Select **Update lead set**.

Deactivating the ECG leads off alarm

The selection is available when there are not enough leads connected for arrhythmia or heart rate detection. This selection will acknowledge the **ECG leads off** alarm, but it will not change the measurement mode to fewer leads.

There are two options to deactivate the **ECG leads off** alarm, from the ECG menu or using the audio pause key. To deactivate the alarm from the parameter menu:

1. Select the ECG parameter window > **Leads**.
2. Select **Deactivate ECG leads off**.

If deactivation with the audio pause key has been enabled, **ECG leads off** deactivation can be acknowledged by selecting  twice.

Setting the beat volume

1. Select the ECG parameter window > **More Settings** tab.
2. Select page 2 and adjust the volume on the **Beat volume** slider with the volume control keys. The range is 0 (volume off) to 10.

Selecting the beat source

1. Select the ECG parameter window > **More Settings** tab.
2. Select page 2 and . The following choices are shown in the pop-up window:
 - **Primary HR** (The beat source is the same as the primary HR source selection.)
 - **ECG** (The beat source is ECG regardless of the primary HR source selection.)
 - Invasive pressure channel(s) labeled **Art X**, **Fem X**, or **UAC X**, where X = channel number. If the FloTrac CCO micro-module is connected, **Art 8** and **Fem 8** are not shown in the list.
 - **Pleth(SpO2)**

The beat source indicator  will appear beside the chosen beat source on the screen, and the beat sound will reflect the beat of that source.

Setting the beep tone during bradycardia alarms

NOTE

NICU software package only.

This selection is available if the **Beat volume** for QRS is set to 0 (off).

If the alarm for bradycardia has been set to off or silenced, or the ECG alarms are silenced permanently, then the QRS tone does not sound, either.

1. Select the ECG parameter window > **More Settings**.

2. Select page 2 and toggle on **Beat tone on brady only** to enable the beep tone.

When the beep tone is on, the QRS tones will sound only with **Brady** alarm conditions.

- If the alarm volume has been set to below 8, the QRS tones will sound at the selected alarm volume level +2 more levels.
- If the alarm volume has been set to 8 or more, the QRS tones will sound at alarm volume level 10.

Selecting the ECG waveform size

This selection adjusts the size of the displayed ECG waveform.

1. Select the ECG parameter window > **Settings**.
2. Select a value for **Size**.

The selections are **0.5x**, **1x**, **2x**, **4x**. The smaller the value, the smaller the waveform.

NOTE

The **Size** setting affects arrhythmia detection and heart rate calculation sensitivity. Normal waveform size/QRS detection sensitivity is **1x**. Size **2x** and greater increases the QRS detection sensitivity. This may be helpful for low amplitude QRS waveforms. Use with caution since baseline artifact may be detected as a QRS complex.

Selecting the ECG waveform filter

You can select how the waveform appears on the display.

1. Select the ECG parameter window.
2. Select **More Settings**.
3. Select a filter from the **Waveform filter** list. Choices are:
 - **Diagnostic**: 0.05 Hz to 150 Hz
 - **Monitoring**: 0.05 Hz to 32 Hz (with 50 Hz powerline frequency), 0.05 Hz to 40 Hz (with 60 Hz powerline frequency)
 - **Moderate**: 0.05 Hz to 23 Hz
 - **Maximum**: 4.5 Hz to 27 Hz

When the **Maximum** filter is selected, the prompt text **Warning: Maximum filter alters the displayed ECG morphology.** is displayed at the bottom of the setting window.

Setting the QRS width

NOTE

This setting affects the arrhythmia detection sensitivity.

If the **QRS width** is locked in the **Locking Settings**, the option is not selectable.

1. Select the ECG parameter window.
2. Select **More Settings**.

3. Select a setting from the **QRS width** list. Choices are:
 - **Narrow:** Intended for use with all neonates and the pediatric patient with a QRS complex width of 100 ms or less. This is the default setting for the NICU software package and for the **Infant** and **Pediatric** profiles.
 - **Normal:** Intended for ECG rhythms that have wider QRS complex widths, for example, almost all adult patients and any patient with electronic ventricular pacing.

Selecting the leads for ECG analysis

You can choose whether the monitor performs an ECG analysis using single lead ECG data or data from multiple ECG leads. Multiple ECG leads will typically reduce false alarms and improve the detection sensitivity. However, if most leads are noisy or low amplitude, the **Single** mode using the best available ECG lead will help.

With a 3-leadwire cable the setting is **Single** and cannot be changed. If the measurement mode is changed from the 3-leadwire mode to 5-, 6-, 10-lead or 12RL™ mode, the setting changes to **Multiple**.

1. Select the ECG parameter window > **Leads** > page 2.
2. Select the appropriate radio button for **Lead analysis**. The choices are:
 - **Single:** The EK-Pro algorithm uses one of the leads I, II, III, or V1 for the analysis. If aVR, aVL, or aVF is set as the **ECG 1 lead**, then EK-Pro algorithm uses the following mapping: aVR = II, aVL = I, aVF = III. Also note that the ST values are only calculated for the single lead.
 - **Multiple:** The EK-Pro algorithm uses the following leads:
 - 5-lead and 6-lead mode: I, II, III, and any lead assigned to Va.
 - 10-lead mode: I, II, III, and Va.
 - 12RL mode: I, II, III, and V1.

Relearning the patient's QRS pattern

During ECG monitoring, you may need to use the **Relearn QRS** feature when a dramatic change in the patient's ECG pattern has occurred. Allowing the monitor to learn the new ECG pattern corrects false arrhythmia alarms and heart rate values, and restores the ST measurements. Relearning takes typically 30 seconds or less. The message **Learning** displays in the ECG1 waveform area while the monitor relearns the QRS pattern. During this time, arrhythmia detection is not available. If the monitor is not able to relearn due to a low amplitude QRS, for example, the **Arrhythmia paused** alarm is triggered. Be aware that if arrhythmia is turned off, the **Noisy ECG** alarm is triggered instead.

1. Select the ECG parameter window > **Leads** > page 2.
2. Select **Relearn QRS**.

Automatic relearning takes place when:

- The measurement mode changes between the 3-lead mode and any other lead mode.
- The **ECG 1 lead** selection is changed in the 3-lead mode or in single-lead analysis.
- The Va lead selection is changed in the 5-lead, 6-lead, 12RL™ and 10-lead modes.
- The **Lead analysis** setting is changed from **Multiple** to **Single**.
- The patient is discharged/case is ended.

Setting the primary HR source

The primary heart rate can be calculated from the ECG leads, SpO₂ measurement, or invasive pressure waveform.

NOTE

This setting adjusts the primary heart rate source for all of the hemodynamic parameters.

1. Select the ECG parameter window.
2. Select the **More Settings** tab.
3. Select a parameter from the **Primary HR source** list. The selection list will only show active measurements and **AUTO**, **IntelliRate**, or **ECG**. Choices are:
 - Single HR: **AUTO**, **IntelliRate**, **ECG**, invasive pressure channel(s) labeled **Art X**, **Fem X**, or **UAC X** where X = channel number, **Pleth(SpO2)**. If the FloTrac CCO micro-module is connected, **Art 8** and **Fem 8** are not shown in the list.
 - Multiple HR: **AUTO**, **IntelliRate**, **ECG**.

For more information about **AUTO** and **IntelliRate**, see the ECG measurement practicalities section in this chapter.

Selecting the HR alarm range

With the **Single HR alarms** setting only.

HR alarm range can be set to **20 - 300** if the primary HR source is ECG or invasive pressure measurement. With any other primary HR source, **HR alarm range** is **30-240**.

1. Select the ECG parameter window.
2. Select the **More Settings** tab.
3. Select the heart rate alarm range from the **HR alarm range** list:
 - **30-240**
 - **20 - 300**

Showing another value in the HR parameter window

In addition to the primary HR, you can display another value in the HR parameter window.

1. Select the ECG parameter window.
2. Select the **Settings** tab > page 2.
3. In **Show in ECG parameter window:**, select the check boxes for the measurements you want to show on the screen.
 - **2nd HR source**
 - If the primary HR source is **ECG**, **AUTO** (ECG), or **IntelliRate** (ECG), the secondary HR source displayed in the order: primary arterial source (**Art X**, **Fem X**, or **UAC X**, where X = channel number), **SpO2**.
 - If the primary HR source is anything other than mentioned above, the secondary HR source is always **ECG**.

- **ST highest deviation lead**
- **PVC**

Displaying the ECG grid

You can have a reference grid in the **ECG 1 lead**, **ECG 2 lead**, and **ECG 3 lead** waveform areas. The grid lines will be at 200 ms horizontally and 0.5 mV vertically.

1. Select the ECG parameter window.
2. Select **More Settings**.
3. Select page 2 and toggle on **Show ECG waveform grid** to display the grid.

ECG alarm limits

To set **HR Alarms** to **Single** or **Multiple**, select  from the main menu and then **Defaults & Service** > **Default settings** > **Care unit settings** > **Parameters**. This setting is password protected.

The **Single** heart rate alarm setting allows you to set one common HR limit for multiple sources (e.g., ECG, SpO₂, Art) and the PVC and SVC alarm limits for ECG from the **Alarms** tab. With this setting activated, turning off the SpO₂ or invasive pressure (Art, Fem, UAC) HR alarm limits also turns off the primary HR alarm, and adjusting the SpO₂ or invasive pressure (Art, Fem, UAC) HR limit values also adjusts the primary HR limit value.

The **Multiple** heart rate alarm setting allows you to set a primary heart rate/pulse rate source and up to three individual heart rate/pulse rate alarms and limits from the **Alarms** tab. It also allows you to set PVC and SVC alarm limits for ECG. With the **Multiple** heart rate setting activated, turning off the SpO₂ HR alarm limits does not turn off the primary HR alarm. The invasive pressure channels that appear on the **Alarms** tab depend on the channels that are configured for arterial pressures. A maximum of 5 channels will appear if all invasive pressure channels are configured to arterial pressures, (e.g., **Fem 1**, **Art 2**, etc.).

With invasive pressures or SpO₂ as the pulse rate source, the PR alarm delay is configurable from 0 to 20 seconds in increments of 5 seconds. For more information, see the supplemental information provided in the appendices.

Setting HR/PR alarm limits

1. Select the ECG parameter window.
2. Select the **Alarms** tab.
The **Alarms** table is displayed.
3. Check that the required alarm is turned on.

If a feature is not active, alarm limits are greyed out. Select **Alarm on** check box to set the alarm limits.

4. Set the alarm limits.

If the current alarm priority settings deviate from the recommendation of international alarm safety standards, there is a notification with the general warning sign . If needed, you can change the alarm priorities in **Alarm Settings** > **Priorities**.

You also have the option to select **Critical Brady/Tachy (/min)** alarm. This enables different alarm limit configurations for basic alarms and critical alarms.

Always check that you are configuring the right alarm. Note that the **Critical Brady/Tachy (/min)** alarm limits must always be set outside the basic alarm limits.

Setting PVC alarm limits

Available only when full arrhythmia detection is enabled.

1. Select the ECG parameter window.
2. Select the **Alarms** tab > page 2.
3. Check that the **PVC** alarm is turned on.

If a feature is not active, alarm limits are greyed out. Select **Alarm on** checkbox to set the alarm limits.

4. Set the alarm limit.

Always check that you are configuring the right alarm.

Setting SVC alarm limits

Available only when full arrhythmia is enabled.

1. Select the ECG parameter window.
2. Select the **Alarms** tab > page 2.
3. Check that the **SVC** alarm is turned on.

If a feature is not active, alarm limits are greyed out. Select **Alarm on** checkbox to set the alarm limits.

4. Set the alarm limits.

Configurable PR alarm delays

The alarm delay for **PR (SpO2/IP) low/high (s)** is configurable from 0 to 20 seconds in increments of 5 seconds. This delay is set through **Monitor Settings > Defaults & Service > Default settings > Alarm delays** and it is password protected.

You can check the delays by selecting the parameter window > **Alarms > Alarm delays**. The user-configured delays are shown in a pop-up window.

For more information, see the supplemental information provided in the appendices.

ECG alarm priorities

You can set the alarm priorities for certain ECG alarms through **Alarm Settings > Priorities > ECG**. The allowed priorities are defined in the **Care unit settings**, and they are password protected.

ECG measurement practicalities

Alternate pulse rate source

The alternate pulse rate source allows clinicians to acquire a pulse rate from a source other than ECG (Art, Fem, UAC, or SpO₂). The following circumstances may warrant the use of an alternate pulse rate source:

- Excessive artifact due to an electrical interference from equipment (e.g., electrosurgical device).
- Excessive patient movement causing significant artifact (e.g., seizure activity).
- Inability to use standard lead placement (e.g., burns).

IntelliRate algorithm

The **IntelliRate** algorithm extracts information from multiple physiological signals (ECG, SpO₂, and Art, Fem or UAC when selected as the primary arterial channel) and applies rule-based logic to determine which heart rate source has the highest likelihood of being accurate. The **IntelliRate** algorithm can also suppress alarms for **Asystole**, **V Fib / V Tach**, and **V Tach** if the algorithm determines that there is a high likelihood of a false arrhythmia call. By reporting the most accurate rate, the trended pulse rate is more accurate, and occurrences of false pulse rate limit violation alarms are greatly reduced. The alternate pulse rate source value replaces the standard heart rate value in the HR parameter window.

Auto algorithm

The **AUTO** algorithm selects the first available heart rate source based on a predefined parameter priority:

1. ECG
2. Primary arterial site
3. SpO₂

ECG troubleshooting

Problem	Solution
ECG signal is noisy or no QRS is detected	• Ensure that the patient is not shivering. • Check the electrode quality and positioning. Do not place electrodes on body hair, bones close to skin, layers of fat and major muscles. Pre-gelled electrodes are recommended. • Change the lead in ECG1 to the best available signal and consider using the Single mode. • Consider using Size 2x or 4x. • Try an alternative location for the Va lead to improve signal quality. In some cases, like if the patient has a significant heart failure, changing for example from V5 to V1 can result in a considerable difference in the signal amplitude. • Select the appropriate filter to apply to the displayed waveforms by selecting the ECG parameter window > More Settings > Waveform filter. This does not affect QRS detection or arrhythmia analysis. • Check all cable connectors. • Check the lead connections by selecting the ECG parameter window > Leads > page 2.
Why are the QRS complexes marked with an X?	Defibrillator synchronization markers are identified with an X on the QRS complexes.
Numeric values are replaced by dashes.	• Reconnect the TruSignal ECG micro-module. • Replace the TruSignal ECG micro-module. • If the problem persists, contact qualified service personnel.

About the 12RL™ feature

NOTE

12RL is not available with the NICU software package.

NOTE

Although reconstructed (interpolated) leads can be viewed on the Carescape ONE in standalone mode, the Carescape ONE must be connected to a host monitor as an acquisition platform to obtain a 12RL report.

NOTE

Reconstructed (interpolated) leads cannot be selected for pacemaker detection or impedance respiration monitoring.

12RL uses a standard 6-leadwire electrode placement to acquire leads I, II, III, AVR, AVF, AVL, V1 and V5. The four precordial leads (V2, V3, V4, V6) are not acquired from the patient. This reconstruction assumes accurate electrode placement and typical anatomy.

For 12RL monitoring, a 6-leadwire cable must be used.

On the monitor, reconstructed (interpolated) leads can be identified by the letter d (for derived) before the lead name: **dV2**, **dV3**, **dV4**, and **dV6**.

Pacemaker detection

Pacemaker detection warnings

WARNING

RATE METERS. Keep pacemaker patients under close observation. Rate meters may continue to count the pacemaker rate during cardiac arrest and some arrhythmias. Therefore, do not rely entirely on rate meter alarms. See the supplemental information provided for disclosure of the pacemaker pulse rejection capability of this device.

WARNING

FALSE CALLS. False low heart rate indicators or false Asystole calls may result with certain pacemakers because of pacemaker artifact such as electrical overshoot of the pacemaker overlapping the true QRS complexes.

WARNING

MONITORING PACEMAKER PATIENTS. The monitoring of pacemaker patients can only occur with the pace program activated.

WARNING

PACEMAKER INDICATION. Pacemaker activity is indicated on the electrocardiogram through the display of a different colored pacemaker marker pulse. All pacemaker marker pulses appear upright and uniform and should not be used for diagnostic interpretation.

WARNING

PATIENT HAZARD. A pacemaker pulse can be counted as a QRS during Asystole when pacemaker detection is on. Keep pacemaker patients under close observation.

WARNING

PATIENT HAZARD. Asystole may not be detected if the patient has a pacemaker that produces high-amplitude pacer spikes and pacemaker detection is on. Keep pacemaker patients under close observation.

Pacemaker detection points to note

- Pacemaker detection is on by default. If you turn pacemaker detection off, you should turn it back on for patients with pacemakers. Pacemaker detection must be used whenever the monitored patient has a pacemaker.
- The following leads are used for pacemaker detection:
 - 5-lead mode: Leads R/RA, L/LA, F/LL, and C/V
 - 10-lead mode: Leads R/RA, F/LL, C1/V1, and C5/V5
- Pacemaker detection is done on leads I, II, and V simultaneously.
- The V lead plays a critical role in pacemaker detection.

Selecting pacemaker detection

Pacemaker detection must be turned on. However, you may disable pacemaker event processing by turning off pacemaker detection. When pacemaker detection is turned off, the monitoring device ignores pacemaker pulse detections, which may adversely affect the heart rate accuracy of the monitoring device.

1. Select the ECG parameter window.
2. Select the **Settings** tab.
3. Select a value from the **Pacemaker detection** list.
 - **Sensitive (Pace 2)**: Includes pacemaker marker pulses in the waveform with a more sensitive lower threshold on the pace pulse amplitude.
 - **Normal (Pace 1)**: Detects and draws pacemaker marker pulses in the waveform. The detection is less sensitive to electromagnetic interference. This option is recommended when the interference level is high, for example due to an LVAD device or infusion pumps.
 - **Off**: Pacemaker pulse are not detected or marked with pacemaker marker bars. Pacemaker pulses are shown as they appear in the waveform signal.

When the pacemaker detection is turned off, the message **Pacer off** is displayed in the **ECG 1 lead** waveform field.

Pacemaker detection troubleshooting

Problem	Solution
How does activating pacemaker detection impact monitoring?	• Beats that would otherwise be classified as ventricular are instead classified as V-paced if a ventricular pacemaker event is detected. • Residual pacemaker energy that might otherwise appear in the ECG is removed, and a pacemaker enhanced spike is placed in the ECG. • On the ECG waveform, pacemaker detection is indicated by uniform, upright pacemaker enhancement spikes in the ECG data.
How can pacemaker detection be improved?	• Possible problems include: ◦ Heart rate double counting. ◦ Inaccurate alarms for low heart rate or asystole. ◦ Pacemaker spikes not recognized by the software. ◦ False PVC detections and arrhythmia alarms. • Possible solutions include: ◦ Relearn ECG. ◦ Re-prepare the patient skin, replace the electrodes, and adjust the electrode placement. ◦ Try an alternate electrode placement. ◦ Try single-lead analysis, if available. ◦ Switch to another pacemaker detection mode.

Problem	Solution
Why is the monitor double-counting the heart rate, alarming for a low heart rate, or not detecting pacemaker spikes?	The monitor is not detecting pacemaker activity. Causes may include: • The pacemaker detection program is turned off. Turn it on, reprep the skin and reposition the electrodes if necessary. Relearn ECG. • The pacemaker signal is too weak for the monitor to detect. • The ECG signal is too weak for the monitor to detect. • The monitor is detecting atrial pacemaker artifact or non-QRS features as beats. If the monitor is alarming for low heart rate or asystole, assess the QRS amplitude: • View each ECG lead to assess the amplitude of the QRS complexes. To ensure correct HR readings, a 0.5 mV QRS amplitude is recommended for a normal ECG signal. If the QRS amplitude drops below 0.5 mV or an abnormal QRS width occurs (more than 120 ms), QRS detection may be reduced, leading to false asystole alarms. • If necessary, reprep the skin and reposition the electrodes. • Relearn ECG.

Arrhythmia monitoring

Arrhythmia monitoring warnings

WARNING

MISSED ALARMS. V Fib/V Tach should not be considered a substitute for the V Tach arrhythmia alarm. Efforts to lower the V Tach alarm level can result in missed ventricular tachycardia alarms.

WARNING

LOSS OR DETERIORATION OF ARRHYTHMIA DETECTION. Automated arrhythmia analysis programs may incorrectly identify the presence or absence of an arrhythmia. A physician must therefore interpret the arrhythmia information in conjunction with other clinical findings. Please take special note of the following ECG waveform conditions:

- Noisy waveforms. Noisy portions of ECG waveforms are typically excluded from analysis. The exclusions are necessary to reduce the occurrence of inaccurate beat interpretations and/or rhythm alarms. If the excluded noisy portions of the ECG waveform contain true arrhythmia events, those events may remain undetected by the system.
- Beat amplitude and duration. Accurate detection and interpretation of beats becomes increasingly difficult as the amplitude and/or duration of those beats approach the design limits of the analysis program. Thus, as beats become extremely wide or narrow, or especially as beats become small, arrhythmia interpretation performance may degrade.
- Other morphology considerations. Automated arrhythmia detection algorithms are designed fundamentally to detect significant changes in QRS morphology. If an arrhythmia event is present and does not exhibit a significant change from the patient's predominant morphology, it is possible for those events to remain undetected by the system.

WARNING

PAUSED ANALYSIS. Certain conditions pause arrhythmia analysis. When paused, arrhythmia conditions are not detected and alarms associated with arrhythmias do not occur. Conditions causing paused arrhythmia analysis include arrhythmia off, arrhythmia paused, leads fail, alarm pause, all alarms off, and discharged patient. Always keep the patient under close surveillance.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. Always monitor ECG for arrhythmia detection purposes. HR calculated from pulsatile SpO₂ waveform may differ significantly from ECG HR measured values. Users should be aware that the **SpO2 probe off** and **Check SpO2 probe** technical alarms escalate no higher than a **Medium** priority.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. The SpO₂ parameter pulsatile heart rate measurement is based on the optical detection of a peripheral flow pulse and therefore cannot detect arrhythmias. The pulse oximetry parameter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

WARNING

ARRHYTHMIA PAUSED alarm. The **Arrhythmia paused** alarm indicates that the system is no longer monitoring arrhythmia or heart rate from ECG. If you adjust the alarm priority level lower than the default value, keep the patient under close surveillance.

Arrhythmia measurement considerations

- Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.
- The **Size** and **QRS width** settings affect arrhythmia detection and heart rate calculation sensitivity.
- If QRS amplitude is low, the monitor might not be able to calculate HR and false **Asystole**, **Arrhythmia paused**, or **Brady** alarms may occur.
- If the learning phase takes place while arrhythmia is already occurring, it may affect the subsequent arrhythmia detection.
- During the learning phase of the algorithm, arrhythmia detection is not available. As a result, the patient condition should be closely monitored during the learning phase and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.

Setting the arrhythmia category to alarm

Depending on what has been allowed in **Care unit settings > Parameters > Allowed arrhythmia levels**, you can select different arrhythmia categories to alarm.

1. Select the ECG parameter window.
2. Select **Settings**.
3. Select **Arrhythmia**.
4. Select the radio button for the arrhythmia category that you want to alarm:
 - **Full**: All arrhythmias alarm.

- **Lethal:** Only lethal arrhythmias alarm.
- **Off:** No arrhythmia alarms are generated.

Setting arrhythmia alarms

While monitoring ECG, you can adjust the settings for arrhythmia alarm conditions.

1. Select the ECG parameter window.
2. Select **Settings**.
3. Select **Arrhythmia**.
4. Select **Lethal alarms**, **Ventricular alarms**, or **Atrial alarms**.
5. Select the appropriate value for each arrhythmia alarm in the **Priority** column.
6. Select the check box for **Create snapshot** if you wish to activate an arrhythmia snapshot creation.

Snapshots are not displayed on the Carescape ONE, but they can be viewed on a host monitor when the Carescape ONE is connected as an acquisition platform.

Selecting V Tach criteria

This setting determines how the time and HR criteria are applied to determine the **V Tach** alarm. The selection is shown only if the **Allow V Tach event duration criteria** has been allowed during configuration through **Monitor Settings > Defaults & Service > Default settings > Alarm delays**. This setting is password protected. For more information, see the supplemental information provided in the appendices.

1. Select the ECG parameter window > **Settings** tab.
2. Select **Arrhythmia > Lethal alarms**.
3. Select page 2 > **V Tach criteria**.
4. Select **Minimum HR (/min) AND Event duration (s)** or **Minimum HR (/min) OR Event duration (s)**.

Setting minimum HR for V Tach

This setting determines the minimum value for the HR to trigger the **V Tach** alarm. The minimum value can only be changed if the setting has been unlocked in the default settings. For more information, see the supplemental information provided in the appendices.

1. Select the ECG parameter window.
2. Select **Arrhythmia > Lethal alarms**.
3. Select page 2 > **V Tach criteria**.
4. Select a value from **Minimum HR (/min)**. The options are 90 to 300 beats per minute, in increments of 10.

Setting V Tach event duration

This setting determines how long a time the algorithm needs to trigger the **V Tach** alarm. The selection is shown only if the **Allow V Tach event duration criteria** has been allowed during configuration through **Monitor Settings > Defaults & Service > Default settings > Alarm delays**. This setting is password protected. For more information, see the supplemental information provided.

1. Select the ECG parameter window > **Settings** tab.
2. Select **Arrhythmia** > **Lethal alarms**.
3. Select page 2 > **V Tach criteria**.
4. Select a value in seconds for **Event duration (s)**.

Setting the pause interval

You can set the time interval between the two adjacent beats before the pause alarm condition is annunciated.

1. Select the ECG parameter window.
2. Select **Settings** tab > **Arrhythmia** > **Atrial alarms**.
3. Select page 2 and set the appropriate value for **Pause interval (s)**.

Setting the SVT length

This setting determines how many consecutive SVCs are needed to trigger the **SV Tachy** alarm.

1. Select the ECG parameter window.
2. Select **Settings** tab > **Arrhythmia** > **Atrial alarms**.
3. Select page 2 and set the appropriate value for **SVT length (beats)**.

Setting HR for SVT

This setting determines the minimum value for the HR to trigger the **SV Tachy** alarm.

1. Select the ECG parameter window.
2. Select **Settings** tab > **Arrhythmia** > **Atrial alarms**.
3. Select page 2 and set the appropriate value in **HR for SVT (/min)**.

Arrhythmia alarm messages

NOTE

A clinician must analyze the arrhythmia information in conjunction with the other clinical findings.

Alarm message	Arrhythmia analysis	Alarm priority default	Arrhythmia detection criteria
A Fib	Full All software packages except NICU	According to priority setting	Absence of P-waves and irregular RR-interval.
Accel. Ventric.	Full	According to priority setting	Accelerated ventricular rhythm - Run of PVCs with a run length of at least six beats and the requirements for user defined V Tach Criteria or V Brady are not met.
Asystole	Full, lethal	High	HR decreased to zero, or beat detection has not occurred in the last 5 seconds.

Alarm message	Arrhythmia analysis	Alarm priority default	Arrhythmia detection criteria
Bigeminy	Full	According to priority setting	Every other beat is PVC (N-V-N-V-N-V).
Couplet	Full	According to priority setting	Two consecutive PVCs are detected between normal beats, N-V-V-N. The coupling interval between the PVCs must be less than 600 ms.
Irregular	Full NICU software package only	According to priority setting	Six consecutive normal RR intervals vary by 100 ms or more.
Missing Beat	Full All software packages except NICU	According to priority setting	Actual RR interval more than 1.8 times the average RR interval.
Multifocal PVCs	Full	According to priority setting	Within 16 previous beats two or more PVCs with different morphologies are detected.
Pause	Full	According to priority setting	Coupling interval between two beats exceeds 1 to 5 seconds (configurable).
R on T	Full	According to priority setting	Isolated PVC is detected within 100 ms of the peak of the T-wave of the patient's predominant normal beat.
SV Tachy	Full	According to priority setting	A run of SVCs is detected with a run length of at least the set SVT length (beats) and the heart rate is at least the set HR for SVT (/min) .
Trigeminy	Full	According to priority setting	Every third beat is PVC (N, N, V, N, N, V, N, N, V).
V Brady	Full	According to priority setting	Run of PVCs are detected with a run length of at least three beats. In addition, at least two consecutive RR intervals in the run must have an effective heart rate less than 50 bpm.
V Fib / V Tach	Full, lethal	High	ECG waveform indicates a chaotic ventricular rhythm.
V Tach	Full, lethal	According to priority setting. Always High if V Tach duration >30 seconds, and HR ≥180 bpm in NICU or ≥150 bpm in other software packages, and HR is over the user adjusted HR high limit.	A run of PVCs is detected with a run length of six beats or more and the effective HR and V Tach duration meet the user defined criteria.
VT > 2	Full	According to priority setting	A run of PVCs is detected with a run length of more than two beats but less than six beats. In addition at least two consecutive RR intervals in the run must have an effective HR that is equal to or exceeds the V Tach Minimum HR (/min) . For example, if V Tach Minimum HR (/min) is set to 90, then HR needs to be equal to or exceed 90 bpm.

About the arrhythmia detection

When an ECG signal is detected at the start of monitoring, the arrhythmia detection algorithm begins acquiring and analyzing QRS complexes in the leads used for arrhythmia detection. This phase is known as learning. Once learning is complete, the dominant QRS complex is stored as a reference template. The reference template is used as a normal morphology of that patient and it is compared with incoming beats to identify possible arrhythmias.

The EK-Pro arrhythmia detection algorithm is used. EK-Pro simultaneously analyzes leads I, II, III, and V or Va. Once learning is complete, the dominant QRS complex becomes the template.

The algorithm uses continuous correlation, incremental template updating and contextual analysis. Continuous correlation attempts to find the best match between each incoming complex and the set of stored (learned) templates. If no match is found with the existing template, a new template is stored for the identified new QRS shape. Incremental template updating allows information from each beat, that correlates over time, to be reflected in the associated template. Contextual analysis uses information from neighboring QRS complexes along with existing template measurements to make the best possible decision regarding the beat's origin (e.g., early, wide).

Arrhythmia troubleshooting

Problem	Solution
Why is the monitor alarming for asystole, bradycardia, pause, or inaccurate heart rate when a visible QRS waveform is present?	The monitor may not be detecting sufficient QRS amplitude in all analyzed leads. Multiple leads are used for arrhythmia processing. 1. Assess the patient. 2. Check the ECG signal acquired from the patient. 3. View all ECG leads to assess the amplitude of the QRS complexes. To ensure correct HR readings, a 0.5 mV QRS amplitude is recommended for a normal ECG signal. If the QRS amplitude drops below 0.5 mV or an abnormal QRS width occurs (more than 120 ms), QRS detection may be reduced, leading to false Asystole alarms. 4. Relearn the ECG rhythm. It is important to relearn the patient's ECG pattern any time the electrode configuration is adjusted. 5. The ECG size settings affect the arrhythmia detection and heart rate calculation. Increase the ECG size by selecting a value for Size. If the problem continues, switch to the ECG lead with the greatest amplitude, display that lead, then switch to single lead analysis so all arrhythmia interpretations are based on this single ECG lead.
How does the IntelliRate algorithm impact an Asystole alarm with a QRS waveform?	IntelliRate will report Asystole when the following conditions are met: • The ECG HR has been valid and stable during the previous 30 seconds. • The invasive pressure pulse rate was valid earlier, but does not indicate beat detections in the previous 30 seconds. • The mean arterial blood pressure of the invasive pressure pulse rate source is below the user-selected limit. • The SpO₂ parameter if available does not indicate beat detections in the previous 30 seconds. NOTE IntelliRate performs this analysis only when pacemaker detection is configured on.

Problem	Solution
Why is the monitor calling V Tach when the patient is not in V Tach?	The monitoring system may be detecting a wider QRS complex or artifact in some of the analyzed ECG waveforms. In addition, the V leads may be exhibiting polarity changes, which may occasionally cause an inaccurate call. 1. Assess the patient. 2. Check the ECG signal acquired from the patient. • View each ECG lead to assess the width of the QRS complexes in the analyzed leads. • If artifact exists in any of the analyzed leads, reprep the patient's skin, replace electrodes, and adjust the electrode placement. • It may be beneficial to move V lead electrodes (chest lead) to alternate precordial electrode placements to improve detection. 3. Relearn the ECG rhythm. It is important to relearn the patient's ECG pattern any time the electrode configuration is adjusted. If the problem continues, determine the lead with the narrowest QRS complex, display that lead, then switch to single lead analysis so all arrhythmia interpretations are based on this single ECG lead.

ST detection

About ST analysis

If enabled, ST analysis starts automatically after the ECG leads have been connected and QRS detection has started. Once the program has completed the learning phase, ST values are updated every 10 seconds.

ST detection

During the learning period, the algorithm uses the isoelectric reference and the J+ reference points to calculate the ST values. The algorithm automatically searches for the J and ISO points.

ST detection measurement considerations

- ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.
- Changes in heart rate may affect ST.
- The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes needs to be determined by a physician.

ST detection points to note

ST segment deviations are not displayed for patients with ventricular pacemakers or if the rhythm is considered as from ventricular origin.

Starting ST detection

1. Select the ECG parameter window.
2. Toggle on **ST analysis**.

ST alarm limits

You may set the ST alarm limits for individual leads.

Setting alarm limits for individual leads

1. Select the ECG parameter window.
2. Select the **Alarms** tab > **ST limits**.
3. To set an alarm on, select the checkbox for the alarm. To set an alarm off, deselect the checkbox.
If the alarm is locked, there is a lock symbol beside the check box and the selection is not available.
4. Set the alarm limits.

Impedance respiration

Impedance respiration compatibility limitations

For detailed information regarding Carescape ONE, micro-modules, and accessory compatibility, see the supplemental information provided.

Respiration safety precautions

Respiration warnings

WARNING

ELECTRIC SHOCK. To avoid the risk of shock caused by leadwire set clips or snaps, which may conduct electricity, make sure that they do not touch any electrically conductive material including earth.

WARNING

ERRONEOUS READINGS. The impedance respiration measurement is inherently very sensitive as it measures very small physiological signals (changes of impedance of the patient's chest area). Electromagnetic interference may cause erroneous measurements at various frequencies, for example interference with the signal/ waveform, leading to respiration rate readings inconsistent with the patient's true respiration rate. If you notice this, use another form of respiration monitoring, for instance end-tidal CO₂.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

APNEA EVENTS. The device may not detect all episodes of inadequate breathing, nor does it distinguish between central, obstructive, and mixed apnea events.

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires.

WARNING

ELECTRODE CONFIGURATION. Impedance respiration monitoring is not reliable when ECG electrodes are placed anywhere but on the chest.

WARNING

ELECTRODES. Whenever patient defibrillation is a possibility, use non-polarizing (silver/silver chloride construction) electrodes for ECG monitoring. Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge will block acquisition of the ECG signal.

Respiration cautions

CAUTION

PATIENT SAFETY. The impedance respiration measurement may cause rate changes in Minute Ventilation Rate Responsive Pacemakers. Set the pacemaker rate responsive mode off or turn off the impedance respiration measurement on the monitor to avoid risks to the patient.

Respiration measurement considerations

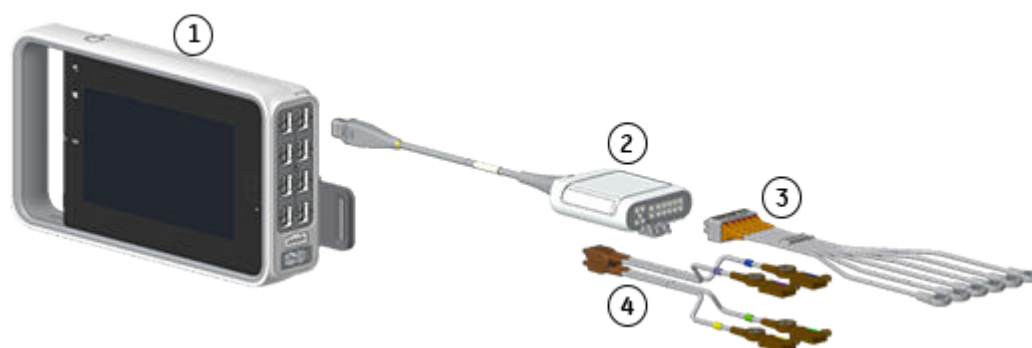
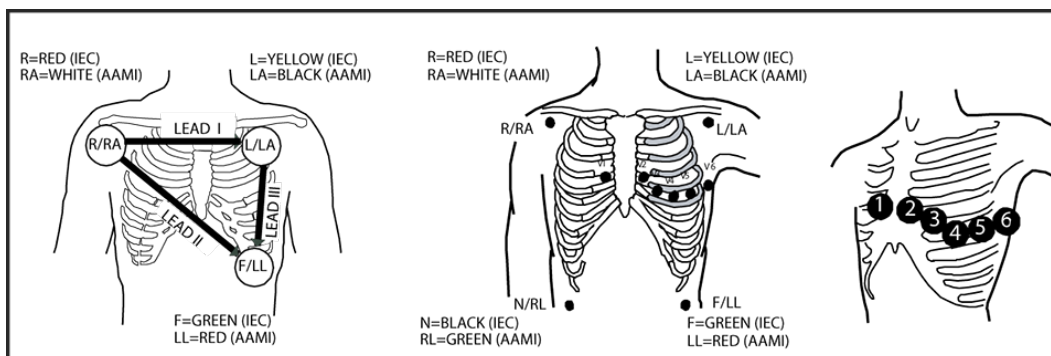
- Electrical devices, such as electrosurgery units and infrared heaters, that emit electromagnetic disturbance, may cause artifacts or disable the respiration measurement completely.
- Movement artifacts, shivering, arrhythmia, pacemaker, and interference from the heart may interfere with the respiration measurement.
- In some rare cases the patient's respiration rate and pulse rate values can be very close to each other, potentially leading to too low respiration rate values and false alarms.
- The system uses heart rate information for impedance respiration signal processing. If QRS complexes cannot be detected or the heart rate is lower than 25 beats per minute, the respiration rate value is invalidated.

Respiration points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Connect only one TruSignal ECG micro-module to Carescape ONE.
- Do not place electrodes on obvious layers of fat, or major muscles.
- Make sure the electrode gel is moist.
- Make sure electrodes have good skin contact.
- Since respiration monitoring is so closely linked with ECG monitoring, patient preparation and electrode placement are important.
- Intermittent mechanical ventilation: During spontaneous breathing the ventilator may at times support the patient's ventilation with an extra inspiration. If these ventilator inspirations are substantially larger than the spontaneous breaths, the respiration calculation may mistakenly count only the inspirations and expirations produced by the ventilator.

Respiration measurement setup

Respiration equipment to patient connection with Carescape ONE



1. Carescape ONE
2. TruSignal ECG micro-module
3. AAMI/AHA or IEC 3-leadwire, 5-leadwire, or 6-leadwire set
4. AAMI/AHA or IEC precordial leads leadwire set

Preparing the patient's respiration electrode sites

Excessive body hair or skin oil reduces electrode contact with the skin and decreases the quality of electrode signal.

When preparing the electrode sites, avoid obvious layers of fat and major muscles.

1. Shave any hair from the electrode site.
2. Gently rub the surface of the skin to increase capillary blood flow.
3. Clean the skin with alcohol or a mild soap and water solution to remove skin oil and dead or abraded skin cells.
4. Dry the skin completely before applying the electrodes.

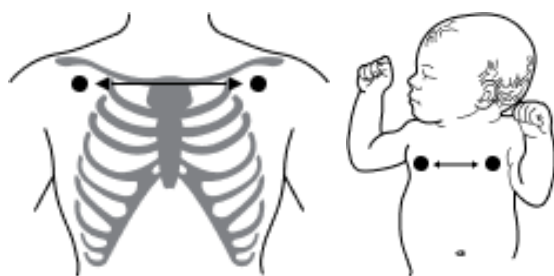
Respiration lead and breath detection

Respiration leads identify the ECG leads used for respiration measurement. Each respiration lead is suited for specific breath detection conditions:

Lead	Description
Lead I	Best for detecting thoracic breathing, but is more susceptible to cardiogenic artifact.
Lead II	Equally good at detecting thoracic or abdominal breathing, but is more susceptible to cardiogenic and motion (head, neck, or arm) artifact.
Lead RL-LL	Best at detecting abdominal breathing and is not as susceptible to cardiogenic or motion artifact. Not available for 3-lead measurement.

Even though the same electrodes are used for ECG and respiration monitoring, it is possible to get a lead fail message for respiration without one for ECG. The impedance may be too high for respiration detection, but the electrode is still good for ECG detection.

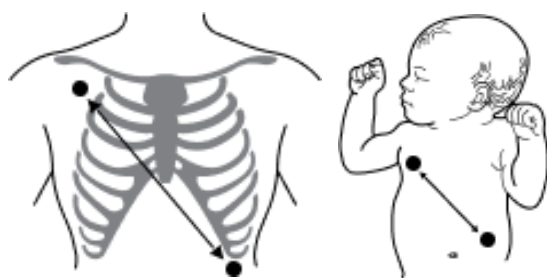
Respiration lead I electrode placement



ECG lead I for upper chest breather

IEC	AAMI/AHA	Electrode placement
R (red)	RA (white)	Just below the right clavicle.
L (yellow)	LA (black)	Just below the left clavicle.

Respiration lead II electrode placement

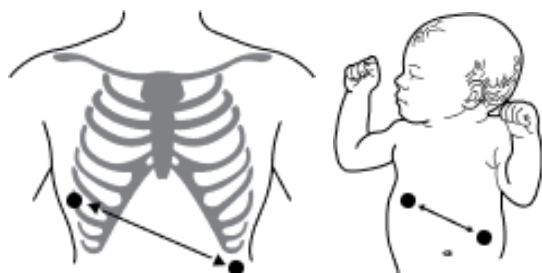


ECG lead II for chest or upper abdominal breather

IEC	AAMI/AHA	Electrode placement
R (red)	RA (white)	Just below the right clavicle.
F (green)	LL (red)	Lower left edge of the rib cage.

Respiration lead RL-LL electrode placement

When monitoring respiration through the RL-LL vector, use a standard 5- or 6-leadwire electrode placement, except place the RL electrode on the fifth intercostal space on the right side of the chest. Impedance respiration lead between RL and LL provides maximum respiration signal strength, minimum noise/artifact content, and minimum cardiogenic artifact.



RL-LL vector for abdominal breather

IEC	AAMI/AHA	Electrode placement
N (black)	RL (green)	Fifth intercostal space on the right.
F (green)	LL (red)	Lower left edge of the rib cage.

Respiration measurement checks

NOTE

The factory default setting for respiration monitoring is off. You need to turn respiration on when the cable is connected to the patient.

1. Check that the waveform and parameter value are displayed when the cable is connected to the patient.

NOTE

There may also be a respiration rate value displayed in the CO₂ parameter window. Only the value in the respiration parameter window is measured from the impedance respiration source.

Respiration measurement on the monitor screen

- The respiration indicator  indicates the detected inspiration and expiration phases in the parameter window. The blinking indicator appears at every inspiration and disappears at every expiration.

Using the respiration measurement

Turning on the respiration measurement

Follow these steps if the respiration measurement is not displaying and you want to turn it on.

1. Select the impedance respiration parameter window.
2. Select the **Settings** tab.
3. Toggle on **Respiration measurement**.

When the respiration measurement is on, the message **Imped on** is displayed in the **ECG 1 lead** waveform field.

Selecting the respiration lead

1. Select the impedance respiration parameter window.
2. Select the **Settings** tab.
3. Select the appropriate radio button for the respiration lead: **I**, **II**, or **RL-LL**.

Lead selections are presented as graphical icons.

Selecting the patient type

The selected patient type (**Adult/pediatric** or **Neonate**) affects how the impedance respiration signal is processed and breaths are detected for the respiration rate calculation. If **Neonate** is selected, the different physiology of a neonate patient is taken into account in the processing. For example, the heart rate of a neonate patient can be close to the respiration rate, whereas the heart rate of pediatric or adult patients is typically significantly higher than the respiration rate. Neonate patients also typically have a higher respiration rate.

1. Select the impedance respiration parameter window.
2. On the **Settings** tab, select page 2.
3. Select the appropriate radio button for **Patient type: Adult/pediatric** or **Neonate**.

Selecting the respiration waveform size automatically

You can automatically size the current waveform to fit the available space.

1. Select the impedance respiration parameter window.
2. On the **Settings** tab, select page 2.
3. Select **Autosize waveform**.

Selecting the respiration waveform size manually

1. Select the impedance respiration parameter window.
2. On the **Settings** tab, select page 2.
3. Select a value for **Size (%)**.

The greater the value, the larger the waveform size.

Relearning the respiration pattern

If the patient's breathing pattern changes after the initial learning process has taken place, it may be necessary to relearn. There is no respiration rate displayed during the relearning process. When relearning is complete, the **Relearning** message will clear and the respiration rate will be displayed.

1. Select the impedance respiration parameter window.
2. On the **Settings** tab, select page 2.
3. Select **Relearn respiration**.

The waveform size update after the new respiration pattern is learned.

Turning on or off the respiration rate alarm

1. Select the impedance respiration parameter window.
2. Select the **Alarms** tab.
3. Select the **Alarm on** check box to turn the alarm on for **RR (Imped.)**. Deselect it to turn the alarm off.

If you deselect **Alarm on**, you cannot adjust the alarm limits.

Setting the respiration alarm limits

1. Select the impedance respiration parameter window.
2. Select the **Alarms** tab.
3. Set the **RR (Imped.)** limits.

Configurable RR alarm delays

Alarm delays for **RR (Imped.) high (s)** and **RR (Imped.) low (s)** are configurable from 0 to 30 seconds in increments of 5 seconds. The delays are set through **Monitor Settings > Defaults & Service > Default settings > Alarm delays** and they are password protected.

You can check the delays by selecting the impedance respiration parameter window > **Alarms > Alarm delays info**. The user-configured delays are shown in a pop-up window.

For more information, see the supplemental information provided in the appendices.

Apnea alarm deactivation with the pause audio key

Apnea alarms can be deactivated with the pause audio key if **Allow alarm deactivation with the Audio Pause key for: Apnea (CO2/Imped.)** check box has been selected in the **Care unit settings**. This setting is password protected.

For more information, see the supplemental information provided in the appendices.

Setting the apnea alarm delay

You can select the apnea alarm delay by defining seconds in the **Apnea (Imped.)** setting. If anything other than the default (20 seconds) is selected, the selected seconds are displayed in the parameter window.

1. Select the impedance respiration parameter window.
2. Select the **Alarms** tab.
3. Set the appropriate value for **Apnea (Imped.)**.

Respiration alarm priorities

You can select priorities for the **Apnea (Imped.)**, **Resp (Imped.) measurement paused**, and **RR (Imped.) low/high** alarms through **Alarm Settings > Priorities > Other**. The available choices depend on what has been allowed in the **Care unit settings** (password protected setting). If all priorities have been allowed, you can select one of the following:

- **Escalating**
- **High**
- **Medium**
- **Low**
- **Informational**
- **Alarm off**, for **Resp (Imped.) measurement paused** only

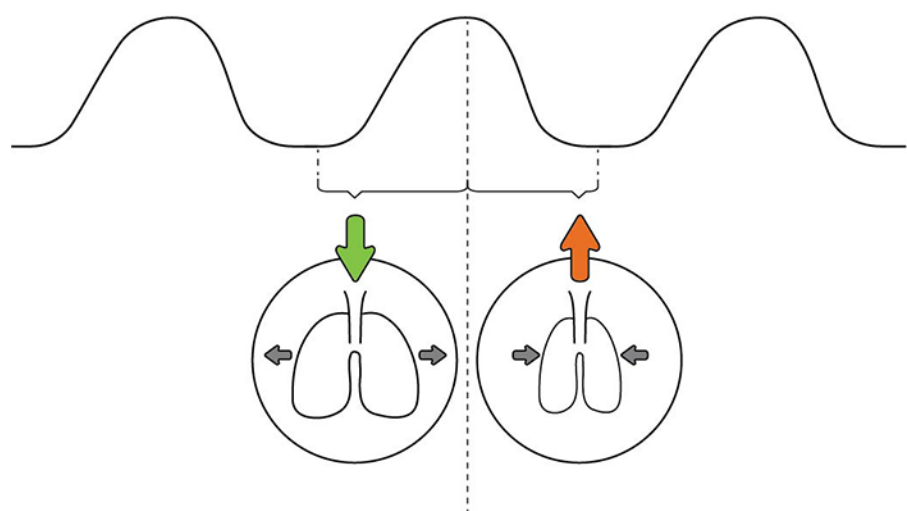
Turning off the respiration measurement

1. Select the impedance respiration parameter window.
2. Select the **Settings** tab.
3. Toggle off **Respiration measurement**.

Respiration measurement description

Respiration measurement is based on the variation of the bio-impedance of the patient's thorax and abdomen. To measure impedance, the respiration sensor sends a small electric current to the patient through the electrodes placed on the torso. Air flowing in and out, as well as changes in geometry, change the electrical properties of the body. The impedance respiration waveform reflects those changes.

The following graphic illustrates how inhalation and exhalation are reflected in the respiration waveform:



When starting respiration monitoring, the system “learns” the patient’s respiration pattern. The respiration rate is calculated from impedance changes and a respiration waveform is displayed. The learning completes and the system shows the first respiration rate value after it has detected four breaths.

Respiration troubleshooting

Problem	Solution
What can I do if the respiration measurement fails?	• Relearn respiration. • Select a different lead for respiration rate monitoring. • Check electrode quality and positioning. • Check that the correct Patient type is selected. • If ventilator and impedance respiration rate show different values during ventilator-supported breathing, refer to the ventilator for the most accurate respiration rate.

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SpO₂

SpO₂ compatibility limitations

For detailed information regarding Carescape ONE, micro-modules, and accessory compatibility, see the supplemental information provided.

SpO₂ safety precautions

SpO₂ warnings

WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

WARNING

PATIENT SAFETY. The operator is responsible for checking the compatibility of the pulse oximetry device, sensor, and patient cable prior to use. Incompatible components can result in degraded performance, device malfunction, and/or compromised patient safety.

WARNING

PATIENT SAFETY. If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs, then check for conditions that may cause inaccurate SpO₂ readings. If the problem is still not resolved, check the Carescape ONE, SpO₂ micro-module, and sensor for proper functioning.

WARNING

PATIENT SAFETY. A pulse oximeter should not be used as an apnea monitor. A pulse oximeter should be considered an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.

WARNING

PATIENT SAFETY. Check that the pulse oximetry waveform is physiological in shape to ensure waveform quality and minimize noise spikes caused by motion conditions. Otherwise, there is a risk of compromised patient safety. (Not applicable when monitoring SpO₂ with Masimo SET technology.)

WARNING

PATIENT SAFETY. To prevent erroneous readings, do not use a physically damaged SpO₂ micro-module or sensors. Discard damaged sensors immediately. Never repair a damaged sensor or SpO₂ micro-module; never use a sensor or SpO₂ micro-module repaired by others.

WARNING

PATIENT SAFETY. Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore does not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis. Otherwise, there is a risk of compromised patient safety.

WARNING

PATIENT SAFETY. Cable/sensor after care:

- Do not reuse sensors intended for single patient use.
- Do not sterilize sensors or patient cables by irradiation, steam, or ethylene oxide.
- Clean the surface of the reusable probe before and after each patient use.
- Allow sensor and cable to dry completely after cleaning. Moisture and dirt on the connector can affect the measurement accuracy.
- If a probe is damaged in any way, discontinue use immediately.
- Inaccurate SpO₂ data can result if a sensor is past its useful life. Therefore, re-evaluate the measurement periodically by performing additional assessment of the patient and equipment, including consideration of use of alternate monitoring methods such as direct measurement of arterial oxyhemoglobin saturation (SaO₂).
- A damaged sensor may cause burns during electrosurgery.

WARNING

PATIENT SAFETY. Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high. Always keep the patient under close observation.

WARNING

NEONATAL INACCURATE RESULTS. The display of inaccurate pulse oximetry (SpO₂) values has been linked to the presence of poor signal strength or artifact due to patient motion during signal analysis. This condition is most likely to be encountered when the monitor is used on neonates or infants. These same conditions in adults do not impact the SpO₂ values to the same extent.

We recommend the application of the following criteria when using the pulse oximetry function on neonates and infants:

- The peripheral pulse rate (PPR) as determined by the SpO₂ function must be within 10% of the heart rate, and
- The SpO₂ signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of the **Low signal quality** message.

Procedures or devices previously applied in your facility for SpO₂ monitoring should be used in the event the SpO₂ value from the monitor cannot be validated by the above criteria.

WARNING

ERRONEOUS READINGS. Many factors may cause inaccurate readings and alarms, decreased perfusion, and or low signal strength:

- Interfering substances:
 - Carboxyhemoglobin may erroneously increase SpO₂ reading.
 - Methemoglobin (MetHb) usually represents less than 1% of the total Hb, but in the case of methemoglobinemia that can be congenital or induced by some IV dyes, antibiotics (such as sulphas), inhaled gases, etc., this level increases sharply and thus can cause inaccuracies in the SpO₂ reading.
 - Intravascular dyes (such as indocyanine green, methylene blue, etc.)
- Physiological characteristics:
 - Cardiac arrest
 - Hypotension
 - Shock
 - Severe vasoconstriction
 - Severe anemia
 - Hypothermia
 - Venous pulsations
 - Darkly pigmented skin
 - Ventricular septal defects (VSDs)
 - Nail polish or artificial nails at the measurement site
- Environmental conditions:
 - Electromagnetic interference
 - Excessive ambient light
 - Electrical interference
 - Electrosurgery
 - Defibrillation - May cause inaccurate reading for a short amount of time.
 - Excessive patient/sensor motion. Artifact can simulate an SpO₂ reading, so that the device fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.
- Sensor placement:
 - Incorrect sensor placement - prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. It is recommended that you check the probe site every four hours (more frequently for poor perfusion or for neonates). Refer to the instructions supplied with the sensor.
 - Sensor placement on the same extremity as a blood pressure cuff, arterial catheter or intravascular line; or arterial occlusion proximal to the sensor.
 - Poor sensor fit or sensor applied too tightly.

- Do not allow tape to block the sensor light emitter and detector.
- Improper connection to the monitor or interconnect cable.
- Contamination of lenses inside the sensor.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. Always monitor ECG for arrhythmia detection purposes. HR calculated from pulsatile SpO₂ waveform may differ significantly from ECG HR measured values. Users should be aware that the **SpO2 probe off** and **Check SpO2 probe** technical alarms escalate no higher than a **Medium** priority.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA. The SpO₂ parameter pulsatile heart rate measurement is based on the optical detection of a peripheral flow pulse and therefore cannot detect arrhythmias. The pulse oximetry parameter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

WARNING

PATIENT SAFETY. Using the **Maximum** sensitivity setting delays the **SpO2 probe off** detection alarm. It is recommended to use the **Maximum** sensitivity setting in care areas where the application site is inspected frequently. (Available when monitoring SpO₂ with Masimo SET technology.)

WARNING

PATIENT SAFETY. With deactivated **SpO2 probe off** alarm, keep the patient under close surveillance.

WARNING

MISSED ALARM. Check the SpO₂ measurement when switching the SpO₂ measurement sources to avoid missed SpO₂ alarms.

WARNING

SKIN IRRITATION. Prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. It is recommended that you check the probe site every four hours (more frequently in case of poor perfusion or neonatal patients). Refer to the instructions supplied with the sensor.

The following warnings apply to Nellcor SpO₂ micro-module only.

WARNING

CHOKING HAZARD. The Nellcor SpO₂ micro-module contains small detachable parts.

WARNING

ELECTRIC SHOCK. Do not insert any foreign objects into the connector of the Nellcor SpO₂ micro-module.

SpO₂ cautions

CAUTION

BURNS. A damaged sensor or a sensor soaked in liquid may cause burns during electrosurgery. To avoid this risk, always ensure that the sensor is undamaged and dry.

SpO₂ measurement considerations

- The pulse oximeter cannot distinguish between oxyhemoglobin and dyshemoglobins.
- Poor perfusion may affect the accuracy of measurement, especially when using an ear sensor.
- To avoid erroneous measurements, do not use a blood pressure cuff on the same limb as the SpO₂ sensor.
- There are several factors that may cause inaccurate readings and alarms. Familiarize yourself with the SpO₂ safety precautions so that you are aware of these factors and can take them into consideration.

SpO₂ points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Defibrillator discharge may affect the SpO₂ measurement. Defibrillation recovery time after discharge is ≤ 15 seconds.
- TruSignal sensors are not made with natural rubber latex.
- For more detailed information regarding sensor accuracies, refer to the supplemental analysis graphs provided.
- Use dry and clean sensors only.
- Do not use damaged sensors.
- Check that you are not re-using a disposable sensor or other disposable accessories.
- Refer to the sensor instructions for use for the recommended maximum application times for different sensor types.
- Always check the patient and the sensor site if the accuracy of the SpO₂ values is questionable.
- Depending on the SpO₂ technology used, not all SpO₂ measurements and settings are available to view or change.
- With Nellcor™ sensors with OxiMax™ technology and Masimo SET technology, the pulse oximetry waveform is a normalized waveform. It is not normalized with TruSignal technology. TruSignal technology provides the actual IrMod% values.
- There are three supported pulse oximetry technologies:
 - TruSignal
 - Masimo SET
 - Nellcor sensors with OxiMax technology (Covidien)

Masimo safety precautions

Masimo warnings

WARNING

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING

Do not place the pulse oximetry device or accessories in any position that might cause it to fall on the patient.

WARNING

Do not start or operate the pulse oximetry device unless the setup was verified to be correct.

WARNING

Do not use the pulse oximetry device during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING

Do not use the pulse oximetry device if it appears or is suspected to be damaged.

WARNING

Explosion hazard: Do not use the pulse oximetry device in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING

To ensure safety, avoid stacking multiple devices or placing anything on the instrument during operation.

WARNING

To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean the device while monitoring a patient.

WARNING

To protect from electric shock, always remove the sensor and completely disconnect the pulse oximetry device before bathing the patient.

WARNING

If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximetry device for proper functioning.

WARNING

Inaccurate SpO₂ readings may be caused by:

- Improper sensor application.
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO₂. When elevated levels of COHb or MetHb are suspected, laboratory analysis (co-Oximetry) of a blood sample should be performed.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

WARNING

Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

WARNING

The pulse oximetry device should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING

The pulse oximetry device is not an apnea monitor.

WARNING

The pulse oximetry device may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING

The pulse oximetry device may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING

The pulse oximetry device should not be used for arrhythmia analysis.

WARNING

SpO₂ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING

Do not adjust, repair, open, disassemble, or modify the pulse oximetry device or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximetry device for servicing if necessary.

Masimo cautions

CAUTION

Do not place the pulse oximetry device where the controls can be changed by the patient.

CAUTION

Electrical shock and flammability hazard: Before cleaning, always turn off the instrument and disconnect from any power source.

CAUTION

When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION

Do not place the pulse oximetry device on electrical equipment that may affect the instrument, preventing it from working properly.

CAUTION

If the SpO₂ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

CAUTION

If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

CAUTION

If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.

CAUTION

The instrument must be configured to match your local power line frequency to allow for the cancellation of noise introduced by fluorescent lights and other sources.

CAUTION

To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximetry device is used.

CAUTION

Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

CAUTION

Do not submerge the pulse oximetry device in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximetry device.

CAUTION

Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

CAUTION

Disposal of product - Comply with local laws in the disposal of the instrument and/or its accessories.

CAUTION

To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximetry device.

Masimo points to note

- A functional tester cannot be used to assess the accuracy of the pulse oximetry device.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximetry device to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of the Sensor Off detection may be compromised. If the instrument is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental “noise” such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Some Masimo rainbow SET features, such as pleth variability index, perfusion index, and total hemoglobin measurement, are only available when the Carescape ONE is used as an acquisition platform with a host monitor. Refer to the host monitor manuals for more information.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor’s directions for use (DFU).
- Cables and sensors are provided with X-Cal technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the cable or sensor directions for use for the specified duration of the patient monitoring time.

SpO₂ measurement guidelines

TruSignal technology and sensor measurement guidelines

The following measurement guidelines apply to the TruSignal SpO₂ technology:

- The time period for acquiring a measurement average is adjustable.
- The SpO₂ waveform corresponds to (but is not proportional to) the arterial pressure waveform.

- Only TruSignal sensors are supported.
- Use the following guidelines when using TruSignal sensors and cables:
 - Read the sensor instructions for use of the SpO₂ sensor before using it.
 - Periodically inspect extension cables and sensors for damage.
 - Do not use damaged sensors.
 - Refer to the cleaning instructions in the instructions for use of reusable TruSignal sensors.
 - Do not use NIBP or constricting instruments on the same appendage as the SpO₂ sensor.

Masimo SET technology and sensor measurement guidelines

With motion, the plethysmographic waveform (or SpO₂ waveform) is often distorted and may be obscured by the artifact. With Masimo SET technology, the plethysmographic waveform is not an indication of signal quality or validity. Even with a waveform obscured by artifact, Masimo SET technology is able to read through the noise and locate the arterial pulsation.

Although Masimo SET technology processes SpO₂ measurements differently than other SpO₂ technologies, the function and appearance is essentially the same as other technologies. The following measurement guidelines apply to Masimo SET technology only:

- The time period for acquiring a measurement average is adjustable.
- Only Masimo RD SET and LNCS sensors are supported. Masimo RD SET or LNCS sensors non-invasively measure pulse rate and the amount of oxygenated hemoglobin. Use the following guidelines when using Masimo RD SET or LNCS sensors:
 - Read the sensor directions before use.
 - Only use sensors with Masimo SET technology.
 - Do not use damaged sensors.
 - Do not use a sensor with exposed optical components.
 - Refer to the cleaning instructions in the directions for use for reusable Masimo RD SET or LNCS sensors.

Additional information for Masimo SET technology

NO IMPLIED LICENSE: Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device. Sensors that are designated for single use are licensed for use on a single patient only, and are not sold. There is no license, implied or otherwise, that would allow use of single use Masimo Sensors beyond their intended single use. After use of single use Masimo Sensors, the license is exhausted, there is no further license granted by MASIMO, and they must be discarded.

This device is covered under one or more patents as set forth at <http://www.masimo.com/patents.htm>.

Masimo SET SpO₂ technology is designed to be used with Masimo Sensors only. Use of sensors other than Masimo Sensors may yield unreliable results. We recommend the use of Masimo SET sensors for use with Masimo technology.

Nellcor™ sensors with OxiMax™ technology and sensor measurement guidelines

The following measurement guidelines apply to Nellcor sensors with OxiMax technology:

- The SpO₂ waveform corresponds to (but is not proportional to) the arterial pressure waveform.
- Only Nellcor sensors with OxiMax technology are supported. Use the following guidelines when using OxiMax technology accessories and sensors:
 - Periodically inspect interconnect cables and sensors for damage and discontinue use if damage is found.
 - Do not immerse sensors.
 - Do not use NIBP or constricting instruments on the same appendage as the SpO₂ sensor.

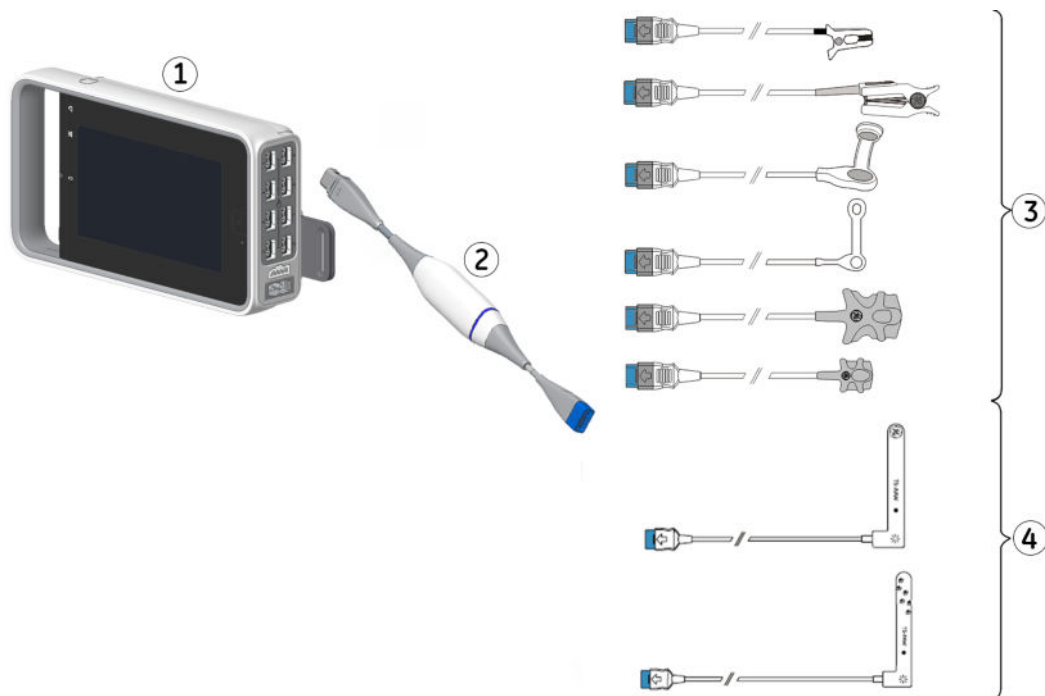
Additional information for Medtronic technology

NOTICE: Purchase of this instrument confers no express or implied license under any Medtronic patent to use this instrument with any oximetry, level of consciousness, regional oxygen saturation, respiration rate, or other Sensor that is not manufactured or licensed by Medtronic.

For patients with SpO₂ levels in the 60% to 80% range, the LoSat™ accuracy feature is available. For more information, see the supplemental information provided in the appendices.

SpO₂ measurement setup

SpO₂ equipment to patient connection with Carescape ONE



1. Carescape ONE
2. SpO₂ micro-module
3. Reusable sensors
4. Single-patient use sensors

Preparing the SpO₂ connection

1. Connect the SpO₂ micro-module to Carescape ONE.
2. Connect the sensor cable to the SpO₂ micro-module.
3. Clean the surface of reusable sensors.
4. Prepare the application site. Remove nail polish and earrings.
5. Follow the sensor manufacturer's instructions to position the sensor.
6. Attach the sensor to the patient.
7. Stabilize the sensor cable to minimize sensor movement.

Checking the SpO₂ measurement

1. Check that the red light is lit in the sensor.
2. Check that the waveforms and parameter values are displayed when the sensor is connected to the patient.

SpO₂ functional testers

You can verify the functionality of pulse oximeter sensor and monitor with a functional SpO₂ tester but you cannot evaluate their accuracy with such a device. For more information, refer to the standard ISO 80601-2-61 Annex FF (Simulators, calibrators and functional testers for pulse oximeter equipment).

Using the SpO₂ measurement

Changing the SpO₂ waveform scale

NOTE

TruSignal technology only.

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.
3. Select the scale from the **Scale** list:
 - **AUTO**: The scale is automatically selected according to the IrMod % (infrared modulation percentage) received from the measurement source.
 - Other scale options are **2, 5, 10, 20**, or **50 %**.

Changing the SpO₂ waveform size

NOTE

Masimo SET technology and Nellcor™ sensors with OxiMax™ technology only.

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.
3. Select the size from the **Size** list.

Selecting SpO₂ as the primary heart rate source

The primary heart rate can be calculated from the ECG leads, SpO₂ measurement, or invasive pressure waveform.

NOTE

This setting adjusts the primary heart rate source for all of the hemodynamic parameters.

NOTE

HR alarms must be configured as **Single** to enable the SpO₂ as the primary heart rate source. This setting is in **Care unit settings** and is password protected.

SpO₂ can be the **Primary HR source**.

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.

3. Select the heart rate source from the **Primary HR source** list.

Showing the SpO₂ pulse rate

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.
3. To show the SpO₂ pulse rate on the screen, select **Show in parameter window > PR** check box.
To hide the measurement, deselect the check box.

Adjusting the SpO₂ pulse beep volume

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.
3. Adjust the volume on the **Beat volume** slider with the volume control keys.

Selecting beat source settings

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.
3. Select . The **Beat source settings** pop-up window opens.
4. Select the beat source from the **Beat source** list.

The beat source indicator  will appear beside the chosen beat source on the screen, and the beat sound will reflect the beat of that source.

5. From the **Variable beat tone source** list, select **SpO2** or **Off**.

You can set the SpO₂ variable beat tone to affect the pitch of the heart rate beep tone. When turned on, the heart rate beep pitch changes according to increasing and decreasing SpO₂ values. Higher SpO₂ saturation values have a higher pitch beep tone, and lower values have a lower pitch.

6. Select **Close**.

For more information, see the supplemental information provided in the appendices.

Masimo SET data averaging and updating

For Masimo SET technology, when using the default averaging time of 8 seconds, there is a maximum data-averaging signal processing time of 10 seconds from real time plus an additional delay of 2 seconds to update the displayed waveform.

Selecting the SpO₂ averaging time

NOTE

Masimo SET technology and Masimo sensors or TruSignal technology and TruSignal sensors only.

You can have an average of the SpO₂ measurement on screen, and you can select how many seconds are used for this averaging. With Masimo SET technology, the options are: **2, 4, 8, 10, 12, 14, or 16**. With TruSignal technology, the options are **5 and 12**.

1. Select the SpO₂ parameter window.
2. Select the **More Settings** tab.
3. Select how many seconds are used for **SpO2 averaging (s)**.

Selecting the Masimo SpO₂ sensor sensitivity level

NOTE

Masimo SpO₂ technology and Masimo sensors only.

1. Select the SpO₂ parameter window.
2. Select the **More Settings** tab.
3. Select the appropriate setting in the **Sensitivity** list:
 - Use the **Normal** sensitivity setting for normal patient monitoring purposes.
 - Only available with Masimo rainbow SET: Use the **APOD** (Adaptive Probe Off Detection) setting for protection against erroneous pulse rate the SpO₂ readings. It is recommended to use this setting in care areas where patients are not visually monitored continuously or where there is a high probability of the sensor becoming detached.
 - Use the **Maximum** sensitivity setting for improved poor perfusion performance. Using the **Maximum** sensitivity setting can reduce the **SpO2 probe off** detection alarm. It is recommended to use this setting in care areas where the application site is inspected frequently.

Nellcor™ sensors with OxiMax™ technology data averaging and updating

The Nellcor sensor with OxiMax technology algorithm automatically extends the amount of data required for measuring SpO₂ and pulse rate depending on the measurement conditions. During normal measurement conditions in the normal response mode, the averaging time is 6 to 7 seconds.

During difficult measurement conditions, which can be caused by low perfusion, motion, ambient light, electrocautery, other interference, or a combination of these factors, the OxiMax algorithm automatically extends the dynamic averaging time required beyond 7 seconds.

If the resulting dynamic averaging time exceeds 20 seconds, a low signal quality status is reported, while SpO₂ and pulse rate values continue to be updated every second.

As the measurement conditions become even more difficult, the amount of data required continues to expand. If dynamic averaging time reaches 40 seconds, a **Check SpO2 probe** status is reported and the device will report dashes during pulse timeout and pulse search condition.

Selecting the SpO₂ response time

NOTE

Nellcor™ sensors with OxiMax™ technology only.

You can select the response (averaging) time. **Normal** (default) is the recommended setting.

1. Select the SpO₂ parameter window.
2. Select the **More Settings** tab.
3. Select the radio button for the response time: **Normal** or **Fast**.

Nellcor™ OxiMax™ SatSeconds™ alarm management

NOTE

Nellcor sensors with OxiMax technology only.

Nellcor OxiMax technology uses SatSeconds alarm management to decrease the likelihood of false SpO₂ saturation alarms caused by motion artifact. It does not apply to pulse rate.

With both traditional and SatSeconds pulse oximetry alarm management, upper and lower saturation alarm limits are set. With traditional alarm management, as soon as a limit is reached or violated, an alarm is generated. With SatSeconds alarm management, a cumulative limit violation index is calculated, and when this index reaches the SatSeconds alarm management limit, an alarm is generated. The cumulative limit violation index is simply the sum of violation magnitudes calculated each second the limit is being violated.

For example, suppose that the SpO₂ low alarm limit is 90%, meaning that 91% is the lowest value not producing an alarm in the traditional case. Now suppose the following consecutive values are recorded each second: 92%, 89%, 85%, 85%, 80%. The corresponding violation magnitudes are 0, 1, 5, 5, 10, and the cumulative limit violation index is correspondingly 0, 1, 6, 11, 21. If the SatSeconds limit setting was 20, an alarm would be annunciated at this point, or after four seconds. When the SpO₂ saturation value is no longer in violation, the alarm notification clears and the cumulative limit violation index decrements in the same manner in which it increments.

With some patients, saturation levels may frequently drop below the limit, but not staying below the limit long enough for the SatSeconds alarm management time setting to be reached. In such situations, that is, when three or more limit violations occur within 60 seconds, an alarm sounds even if the cumulative limit violation index has not reached the SatSeconds alarm management time setting value.

SatSeconds™ alarm management response example

Saturation levels may fluctuate above and below an alarm limit, re-entering the acceptable range (non-alarm range) several times. During such fluctuation, the SpO₂ device integrates the number of SpO₂ saturation points, both positive and negative, until either the SatSeconds alarm management limit is reached or the saturation level returns to within the normal range and remains there.

When an SpO₂ saturation value exceeds an alarm limit, a pie chart (circular graph) in the SpO₂ parameter menu begins to fill in a clockwise direction. As seconds pass and the value is compared against the alarm limits and the SatSeconds alarm management setting, the chart fills proportionately. When the pie chart is completely filled, indicating that the SatSeconds alarm management limit has been reached, an alarm sounds. When the SpO₂ value is within the set limits, the SatSeconds alarm management pie chart empties in a counterclockwise direction.

Showing SatSeconds™ alarm management in the SpO₂ parameter window

NOTE

Nellcor™ sensors with OxiMax™ technology only.

1. Select the SpO₂ parameter window.
2. Select the **More Settings** tab.
3. Toggle on **Show SatSeconds**.

Setting the SatSeconds™ alarm management threshold

NOTE

Nellcor™ sensors with OxiMax™ technology only.

1. Select the SpO₂ parameter window.
2. Select the **More Settings** tab.
3. Set the threshold for **SatSeconds** with the arrow keys.

Setting the SpO₂ alarms and alarm limits

The tabs for configuring alarms and alarm limits depend on what has been configured in the **Care unit settings** (password protected). For more information, see the supplement information provided in the appendices.

1. Select the SpO₂ parameter window.
2. Select the tab for the desired alarms setting:
 - With **Care unit settings** > **Parameters** > **HR alarms** > **Single** selection:
 - On the **Alarms** tab, set the alarm limits for **SpO2 (%)** and **SpO2 critical (%)** alarms.
 - On the **HR Alarms** tab, set the alarm limits for **HR Brady/Tachy (/min)** or **Critical Brady/Tachy (/min)** alarms.
 - With **Care unit settings** > **Parameters** > **HR alarms** > **Multiple** selection:
 - On the **Alarms** tab, set the alarm limits for **SpO2 (%)**, **SpO2 critical (%)**, and **PR (SpO2) (/min)** alarms.

If the current alarm priority settings deviate from the recommendation of international alarm safety standards, there is a notification with the general warning sign . If needed, you can change the alarm priorities in **Alarm Settings** > **Priorities**.

Deactivating the SpO₂ probe off alarm

This feature is meant to be used when ending SpO₂ monitoring. It should not be used during active SpO₂ monitoring. This setting can be enabled in **Default settings** and the setting is password protected. There are two options to deactivate the SpO₂ probe off alarm, from the SpO₂ menu or using

the audio pause key. If it has been enabled, there will be a button on the **SpO2** tab that allows you to deactivate the alarm:

1. Select the SpO₂ parameter window.
2. Select the **Settings** tab.
3. Select **Deactivate SpO2 probe off**.

If deactivation with the audio pause key has been enabled, **SpO2 probe off** deactivation can be acknowledged by selecting  twice.

When the alarm is deactivated, there will be no audible or visual **SpO2 probe off** alarm indications. The alarm is automatically reactivated if SpO₂ vital signs are detected and alarm condition is met again.

WARNING

With deactivated **SpO2 probe off** alarm, keep the patient under close surveillance.

Configurable SpO₂ alarm delays

Alarm delays for **SpO2 high (s)** and **SpO2 low (s)** are configurable from 0 to 15 seconds in increments of 5 seconds. This delay is set through **Monitor Settings > Defaults & Service > Default settings > Alarm delays** and it is password protected.

You can check the delays by selecting the SpO₂ parameter window > **Alarms > Alarm delays**. The user-configured delays are shown in a pop-up window.

When using SatSeconds™ alarm management, the SpO₂ saturation alarm delays are configured by the alarm management feature.

For more information, see the supplemental information provided in the appendices.

Configurable PR alarm delays

The alarm delay for **PR (SpO2/IP) low/high (s)** is configurable from 0 to 20 seconds in increments of 5 seconds. This delay is set through **Monitor Settings > Defaults & Service > Default settings > Alarm delays** and it is password protected.

You can check the delays by selecting the parameter window > **Alarms > Alarm delays**. The user-configured delays are shown in a pop-up window.

For more information, see the supplemental information provided in the appendices.

SpO₂ alarm priorities

You can select priorities for the **SpO2 high**, **SpO2 low**, and **SpO2 probe off** alarms through **Alarm Settings > Priorities > SpO2**. The choices are **Low**, **Medium**, **High**, and **Escalating**. For **SpO2 low**, **Low** priority is only available if it has been enabled during configuration in the **Care unit settings**. For **SpO2 probe off**, **Low** and **Medium** priorities are only available if they have been enabled during configuration in the **Care unit settings**. Care unit settings are password protected. For more information, see the supplemental information provided in the appendices.

Stopping the SpO₂ measurement

1. Remove the SpO₂ sensor from the patient.
2. Disconnect the sensor from the SpO₂ micro-module.
3. Disconnect the SpO₂ micro-module from Carescape ONE.
4. Select  to acknowledge the **SpO2 measurement removed** alarm.
5. Discard single-use sensors.
 - For Masimo SET technology, always disconnect the RD SET or LNCS sensor from the SpO₂ micro-module before repositioning the sensor. Reconnect the sensor after it has been repositioned.
 - Use only sensors and cables listed in the supplemental information provided.

How to interpret the SpO₂ values

SpO₂ signal strength

For TruSignal technology and Nellcor™ sensors with OxiMax™ technology, signal strength is indicated with asterisks in the parameter window. The signal strength indicator refers to the amplitude of the plethysmographic waveform, not the quality of the waveform. Three asterisks indicate strong pulsation.

For Masimo SET technology, the signal strength indicator refers to Masimo’s proprietary measurement, Signal Identification and Quality (Signal IQ) indicator. The Signal IQ provides an indicator of the assessment of the confidence in the displayed SpO₂ value.

SpO₂ waveform quality

NOTE

Not for Masimo SET technology.

Under normal conditions, the SpO₂ waveform corresponds to (but is not proportional to) the arterial pressure waveform. The SpO₂ waveform can provide guidance to the user in the identification of good peripheral perfusion.

The information in the following table is adapted from Jubran A (1998) Pulse oximetry. In: Tobin MJ (ed) Principles and practice of intensive care monitoring. McGraw-Hill, New York, pp 261–287.

Examples of pulse oximetry waveforms	
	Normal waveform

Examples of pulse oximetry waveforms

Motion artifact

If noise (artifact) is seen on the waveform because of poor SpO₂ sensor placement, the photodetector may not be flush with the tissue. Check that the sensor is secured and the tissue sample is not too thick. Also motion at the sensor site is indicated by noise spikes in the normal waveform. Pulse rate is determined from the SpO₂ waveform, which can be disrupted by hemodynamic pressure disturbances.

SpO₂ waveform stability

The stability of the displayed SpO₂ values can also be used as an indication of signal validity. To aid you in successful SpO₂ monitoring, messages are provided in the SpO₂ parameter window.

SpO₂ wavelengths and optical output power

TruSignal, Nellcor™ sensors with OxiMax™ technology, and Masimo SET pulse oximetry technologies are calibrated to display functional saturation.

This information may be useful to clinicians such as those performing photodynamic therapy:

- Nellcor sensors with OxiMax technology contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm. The total optical output power of the sensor LEDs is less than 15 mW.
- Masimo SET pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm for RD SET and LNCS, and approximately 653 nm and 880 nm for RD SET and LNCS tip clips. The total optical output power of the LEDs is less than or equal to 15 mW.
- TruSignal pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 663 nm and infrared light at a wavelength of approximately 890 or 940 nm. The maximum optical output power for each LED is less than 15mW.

SpO₂ measurement and interference

These types of interference can influence the function of SpO₂:

- Incorrect sensor application, e.g., sensor placement on an extremity with a blood pressure cuff, arterial catheter, or intravascular line, sensor applied too tightly.
- Intravascular dyes, such as indocyanine or methylene blue.
- Externally applied coloring agents with opaque materials in high ambient light conditions, e.g., conditions created from one or more of the following sources:
 - Surgical lights, especially xenon light sources
 - Bilirubin lamps
 - Fluorescent lights

- Infrared heating lamps
- Direct sunlight
- Excessive patient activity
- Venous pulsation
- Dysfunctional hemoglobin
- Poor (low) peripheral perfusion
- Arterial occlusion proximal to the sensor
- Loss of pulse (cardiac arrest)
- Electromagnetic interference (EMI)
- Ventilator-induced pressure change

SpO₂ troubleshooting

Problem	Solution
SpO ₂ signal is poor	• Check the sensor and sensor position. • Make sure the patient is not shivering, moving, or does not have tremors. • The patient's pulse may be too weak to measure.
Deactivated SpO ₂ probe off alarm keeps alarming when the sensor is disconnected from the patient.	Ensure that the sensor is protected from ambient light.
Why does the pulse oximeter sometimes read differently than a blood gas analyzer?	Blood gas analyzers calculate the O ₂ saturation based on normal values for pH, PaCO ₂ , Hb, temperature, etc. (i.e., a normal oxyhemoglobin dissociation curve). Depending on the patient's physiologic and metabolic status, this curve and all values may be shifted away from normal. Thus the oximeter, which measures O ₂ saturation, may not agree with the blood gas.
What effect can ambient light have on pulse oximetry monitoring?	Light sources such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, and sunlight can cause poor waveform quality and inaccurate readings. Error messages are possible. Shielding the sensor with the posey wrap or other dark or opaque material can increase oximetry accuracy, verified by good waveform and signal strength.
What does electrosurgical interference look like and how can it be minimized?	Electrosurgical interference is most obvious on the displayed waveform. It is a very spiky, erratic looking waveform caused by the electrosurgical unit's overwhelming interference. It can result in grossly inaccurate pulse oximeter results. Electrosurgical interference can be minimized by: • Making sure the pulse oximeter sensor is as far away from the return pad and operating site as possible. • Making sure the sensor is not between the return pad and operating site. • Keeping the power cord and sensor cable away from the power cord of the electrosurgical unit. • Plugging the electrosurgery unit into a separate set of outlets from the monitoring device.

Problem	Solution
What does motion artifact look like, what problems can it cause, and how can it be corrected?	Motion artifact occurs with excessive motion of the sensor, the cable leading to the sensor, or the cable/sensor junction. In other words, anything that causes any of these things to move, like the patient moving his hands, or the cable lying across the ventilator tubing and being moved with every cycle, can cause motion artifact. A non-arterial, often erratic looking waveform and a pulse rate that does not coincide with the heart rate on the ECG will result. Motion artifact can be reduced, if not eliminated, by selecting a “quieter” site on the patient. An ear sensor if the hands do not remain still, an adhesive sensor on the toe, or an adhesive sensor on the little finger for an adult or on the sole of the foot in a newborn can help greatly. Cable movement can be reduced by applying the sensor with the cable leading toward the patient, then taping the cable to the side of the hand or foot. The cable and sensor can also be stabilized with a stress loop near the sensor. Tape the stress loop to the patient (excluding children). In the case of the butterfly sensor, the tape was designed to secure the cable to the finger. It has been noted that letting the patient view the SpO₂ waveform enables the patient to assist in reducing motion artifact.
Why is the parameter window not displayed on screen after connecting the SpO₂ interface cable and sensor?	No SpO₂ data is displayed due to a hardware failure or an unrecognized or defective sensor or cable. • Make sure the accessories are compatible. • Make sure the sensor is attached to the SpO₂ micro-module and the SpO₂ micro-module is connected to Carescape ONE. • Disconnect and reconnect the sensor. • Disconnect and reconnect the cable. • Change the sensor. • Change the cable. If the problem persists, contact qualified service personnel.

Non-invasive blood pressure

NIBP compatibility limitations

For detailed information regarding Carescape ONE, micro-modules, and accessory compatibility, see the supplemental information provided.

NIBP safety precautions

NIBP warnings

WARNING

PATIENT SAFETY. The NIBP parameter will not measure blood pressure effectively on patients who are experiencing seizures or tremors.

WARNING

PATIENT SAFETY. Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure and may extend the time beyond the capabilities of the parameter.

WARNING

ERRONEOUS READINGS. Do not apply external pressure against the cuff while monitoring. Doing so may cause inaccurate blood pressure values. Use care when placing the cuff on an extremity used to monitor other patient parameters.

WARNING

ERRONEOUS READINGS. NIBP cuff inflation/deflation may lead to inaccurate values from other monitored patient parameters that are measured distally from the NIBP measurement site at the same extremity.

WARNING

PATIENT SAFETY. Ensure that the connection tubing is not kinked. Kinked tubing may cause continuous cuff pressure, which can interfere with the blood flow and cause injury to the patient.

WARNING

PATIENT SAFETY. Do not place the cuff on the arm on the side of a mastectomy or lymph node clearance as this may lead to injury or swelling of the arm due to cuff pressurization. To avoid this risk, use another limb if possible.

WARNING

PATIENT SAFETY. Do not place the cuff over a wound as this may cause further injury.

WARNING

PATIENT SAFETY. To prevent injury to the patient, do not place the cuff on a limb being used for A-V fistulas, intravenous infusion or on any area where circulation is compromised or has the potential to be compromised. To avoid this risk, use another limb if possible.

WARNING

ERRONEOUS READINGS. GE HealthCare NIBP devices are designed for use with dual-hose cuffs and tubing. The use of single-hose cuffs with dual hose tubing can result in unreliable and inaccurate NIBP data.

WARNING

ERRONEOUS READINGS. Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper size cuff.

WARNING

NIBP READINGS MAY TIME OUT WHEN USING IABP. An IABP creates non-physiological arterial waveforms. These waveforms create an oscillometric signal that may not be interpreted by the NIBP algorithm, causing NIBP to time out. The patient's invasive blood pressure can be monitored from the balloon pump device.

WARNING

PATIENT SAFETY. The NIBP patient type must be correctly selected in the NIBP **Settings** window to obtain reliable NIBP data and to prevent excessive cuff pressure during infant or child use.

WARNING

PATIENT SAFETY. Always ensure that you are using NIBP infant settings when monitoring neonatal patients. Using other settings may lead to risks to the patient due to wrong alarm limits or cuff pressure, for example.

WARNING

ERRONEOUS READINGS. If a patient's beat-to-beat pulse amplitude varies significantly (e.g., because of pulsus alternans, atrial fibrillation, or the use of a rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic, and an alternate measuring method should be used for confirmation.

WARNING

ERRONEOUS READINGS. For SuperSTAT NIBP (Adult/Child) only. It takes one to three minutes for the NIBP parameter to identify an irregular rhythm after ECG is connected. For patients with irregular rhythms, wait three minutes after ECG has been connected and ECG heart rate is present on the screen before performing an NIBP determination.

WARNING

PREGNANT PATIENTS. Effectiveness of the NIBP measurement has not been established in pregnant (including pre-eclamptic) patients.

WARNING

PATIENT SAFETY. The NIBP device sets the inflation pressure automatically according to the previous measurement. Reset the case or discharge the patient to reset the inflation limits before measuring NIBP on a new patient.

WARNING

PATIENT SAFETY. Devices that exert pressure on tissue have been associated with purpura, skin avulsion, compartmental syndrome, ischemia, and/or neuropathy. To minimize these potential problems, especially when monitoring at frequent intervals or over extended periods of time, make sure the cuff is applied appropriately and examine the cuff site and the limb distal to the cuff regularly for signs of impeded blood flow. Periodically check patient limb circulation distal to the cuff. Check frequently when using auto NIBP in 1 and 2 minute intervals. The 1 and 2 minute intervals are not recommended for extended periods of time.

NIBP measurement considerations

- A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease heart rate.
- Although automated NIBP is generally safe and accurate, it has some limitations. It may be difficult to obtain reliable readings under the following circumstances:
 - Shock accompanied by low blood pressure and pulse.
 - Variations in blood pressure and pulse rate.
 - In patients with anatomic abnormalities, such as calcified (hardened) arteries or subclavian compression.
 - Compression of the cuff caused by shivering, seizures, arm movement, or bumping against the cuff.
- Proper sizing and position of the cuff are essential to obtaining reliable readings:
 - Too large a cuff is better than too small a cuff, which may yield falsely high readings.
 - The cuff should also fit properly over the brachial artery (or whatever artery is being used) so that the cuff is sufficiently sensitive to vibrations in the artery.

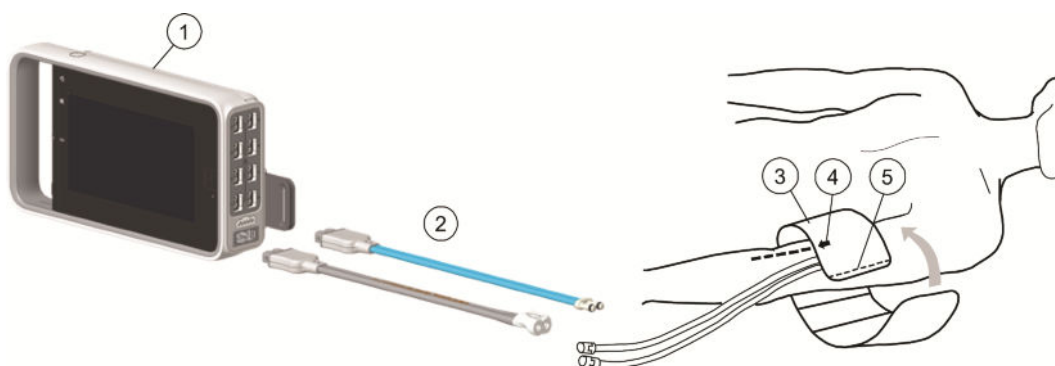
NIBP points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-30 clause 202.8.101 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Use the appropriate size NIBP cuff for the patient (adult, child, or infant).
- The NIBP **Infant** software settings apply to the following patient populations:
 - Neonates from birth to 29 days of age.
 - Infants from 1 month to 3 years of age.
- Operator position: Make sure you do not lean on the cuff or hoses, and do not disturb the patient in any way during the measurement. Position yourself accordingly.
- The measurement site, patient's position (standing, sitting, lying down), exercise, or physiologic condition can affect the NIBP readings.
- With mobile patients and when taking routine resting blood pressure, ensure that:
 - The patient is comfortably seated, with their legs uncrossed and feet flat on the floor.

- The patient's arms and back are supported.
- The middle of the cuff is at the level of the right atrium of the patient's heart.
- Also consider the following recommendations:
 - Allow 5 minutes to pass before taking the first measurement.
 - Ensure that the patient is relaxed and does not talk during the measurement.

NIBP measurement setup

NIBP equipment to patient connection with Carescape ONE



1. Carescape ONE
2. Cuff hose (blue for neonatal, gray for adult)
3. Cuff of correct size
4. Brachial artery arrow (printed on cuff)
5. Cuff index line (printed on cuff)

Preparing the NIBP patient connection

1. Select an appropriate NIBP cuff size for the patient.
2. Connect the NIBP cuff hose to the NIBP connector on the acquisition platform.
3. Position the NIBP cuff on the patient:
 - Place the cuff arrow over the brachial artery (or whatever artery is being used).
 - Make sure that the cuff index line falls within the range markings on the cuff.
 - Wrap the cuff around the limb.
4. Make sure that the NIBP cuff tubes are not kinked, compressed, or stretched.
5. Select the NIBP parameter window > **Settings** tab. Check the **Patient type** and change it, if necessary.
6. Select the **More Settings** tab. Check the selection in **Initial pressure (mmHg)** or **Initial pressure (kPa)** and change it, if necessary.

To manually change the NIBP inflation pressure, you must first toggle off **Auto initial inflate**.

Checking the NIBP measurement

1. Check that the pressure values are displayed.
2. Always select the NIBP patient type before starting a measurement. If you are trying to start the measurement without selecting the patient type first, the NIBP **Settings** menu opens automatically with the **Patient type** list open.

NIBP measurement on screen

You can have a time progress bar in the NIBP parameter window with **Automatic NIBP** and

Continuous NIBP for 5 min modes:  2 min

With **Automatic NIBP** mode this may be replaced by a count down indicator. The selection of either the **Graphical** progress bar or the **Numerical** indicator is a care unit setting and it is password protected.

- **Automatic NIBP**: Auto mode uses clock synchronization. The number of lit segments indicates the difference between the cycling time since the last measurement and the time remaining until the next measurement.
- **Continuous NIBP for 5 min**: The bar indicates the time that the mode will continue. **Continuous NIBP for 5 min** holds multiple measurements for 5 minutes.

Single NIBP measurements

Starting or stopping a single NIBP measurement from the main menu

1. Start the measurement by selecting  from the main menu.
2. Stop the measurement by selecting  from the main menu.

Starting or stopping a single NIBP measurement from the NIBP settings

1. Select the NIBP parameter window > **Settings** tab.
2. Start the measurement by selecting **Start single**.
3. Stop the measurement by selecting **Cancel single**.

Automatic NIBP measurements

Automatic NIBP mode

The **Automatic NIBP** mode initiates repeated measurements for the selected **Cycle time**. There will be at least a 30 second delay between two consecutive NIBP measurements during auto cycling.

Starting or stopping the automatic NIBP measurement from the main menu

1. Start the measurement by selecting  from the main menu.
2. Stop the measurement by selecting  from the main menu.

Starting or stopping the automatic NIBP measurement from the NIBP settings

1. Select the NIBP parameter window > **Settings** tab.
2. Select **Start cycling**.
3. Stop the measurement by selecting **Stop cycling**.

Setting the cycle time between NIBP measurements

Select the cycle time if the default value is not suitable for your needs. The default value is 5 minutes for the ED, OR, and PACU software packages, 10 minutes for the NICU software package, and 15 minutes for the ICU software package.

1. Select the NIBP parameter window > **Settings** tab.
2. Select the appropriate value for **Cycle time**.

Automatic NIBP measurements and monitor clock synchronization

The timing of the automatic NIBP measurements varies according to what has been configured in the **Care unit settings > Parameters > NIBP clock synchronization** (password protected). If **NIBP clock synchronization** is disabled, the measurements are taken regularly at selected intervals. If **NIBP clock synchronization** has been enabled, automatic NIBP measurement time intervals are automatically synchronized with the monitor clock.

For example, if automatic measurements are initiated for five minute intervals at 4:02 and **NIBP clock synchronization** is enabled, the first measurement is taken immediately at 4:02. The next measurement will be taken at 4:05 (interval and clock are now synchronized). All measurements will continue at five minute intervals (i.e., 4:10, 4:15, etc.). There will always be at least a 30 second delay between two consecutive NIBP measurements during auto cycling. If an automatic measurement completes with less than 30 seconds to the next scheduled measurement, the monitor will delay the scheduled measurement until 30 seconds have passed. The cycling synchronization is not done during these 30 seconds but it will be done after the delayed automatic measurement starts.

Examples with a 5 minute cycling time when **NIBP clock synchronization** has been enabled:

Completion with less than 30 seconds to the next scheduled measurement	Completion after the next scheduled measurement should have started
• First automatic measurement starts: 4:59:00 • First automatic measurement completes: 4:59:40 • Second automatic measurement starts: 5:00:20 (not clock synchronized) • Third automatic measurement starts: 5:05:00 (clock synchronized)	• First automatic measurement starts: 4:59:00 • First automatic measurement completes: 5:00:10 • Second automatic measurement starts: 5:05:00

Continuous five-minute NIBP measurements (STAT mode)

NOTE

Not available in the NICU software package.

The **Continuous NIBP for 5 min** measurement (also called **STAT** mode) initiates a continuous cycle of measurements for five minutes. The message **STAT** displays in the NIBP parameter window when **Continuous NIBP for 5 min** is started. A new NIBP measurement starts after the previous measurement completes. The amount of time between measurements varies. It is at least four seconds for adult and child cuff sizes and at least eight seconds for infant cuff size. The early systolic value is measured and displayed until the final result is available, but is never produced for the first measurement in a series of **Continuous NIBP for 5 min** measurements. After five minutes, the monitor automatically returns to the previously selected cycling interval or the single measurement mode.

Starting or stopping continuous five-minute NIBP measurements

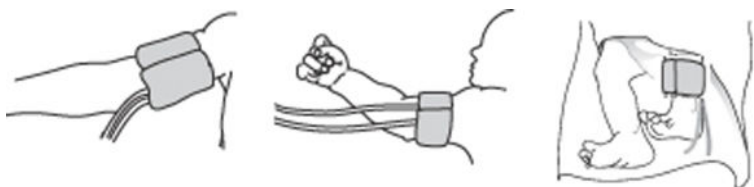
You can set the NIBP measurement to continue for five consecutive minutes.

1. Select the NIBP parameter window > **Settings** tab.
2. Select **Start STAT**.
3. Stop the measurement by selecting **Stop STAT**.

NIBP cuffs

NIBP cuff selection and placement

Always choose the appropriate blood pressure measurement site. In adult and child patients, the upper arm is preferred for convenience and because normative values are generally based on this site. When factors prohibit use of the upper arm, the clinician must plan patient care accordingly, taking into account the patient’s cardiovascular status and the effect of an alternative site on blood pressure values, proper cuff size, and comfort.



Adult and child

Infant

Always measure patient's limb and select appropriately sized cuff according to size marked on cuff or cuff packaging. When cuff sizes overlap for a specified circumference, choose the larger size cuff.

If patient is standing, sitting, or lying, ensure that cuffed limb is supported to maintain the cuff at level of patient's heart. If the cuff is not at heart level, the difference in the measured pressure values due to hydrostatic effect must be considered.

Selecting the patient type

You must first select the patient type before starting an NIBP measurement. The patient type must be selected for each individual patient.

NOTE

In the NICU software package, infant ranges are equal to neonatal ranges.

1. Select the NIBP parameter window > **Settings** tab.
2. Select **Patient type: Adult, Child, or Infant**.

Initial NIBP cuff inflation pressure

Patient type	Initial inflation pressure
Adult	135 mmHg (18 kPa)
Child	125 mmHg (16.7 kPa)
Infant	100 mmHg (13.3 kPa)

NOTE

When the **Auto initial inflate** setting has been toggled on, the initial cuff inflation pressures are dependent on the selected patient type. The initial target pressure preset can be adjusted if you desire a lower or higher initial target pressure.

Selecting the initial NIBP cuff inflation pressure

You can determine the cuff inflation pressure automatically based on the patient type.

1. Select the NIBP parameter window > **More Settings** tab.
2. Toggle on **Auto initial inflate**.

Setting the target NIBP inflation pressure

You can manually change the target inflation pressure for the first NIBP measurement.

1. Select the NIBP parameter window > **More Settings** tab.
2. Check that **Auto initial inflate** is toggled off.
3. Select the **Initial pressure (mmHg)** (or **Initial pressure (kPa)**) value with the plus and minus keys.

NIBP volume and display settings

Adjusting the NIBP measurement completion tone volume

1. Select the NIBP parameter window > **More Settings** tab.
2. Set the **Completed NIBP volume**.

The lower the value, the softer the tone.

Setting the NIBP display format

1. Select the NIBP parameter window > **More Settings** tab.
2. Select the appropriate radio button for **Display format**:
 - **SYS/DIA (M)**: All values are shown, but the sys/dia values are shown in a bigger font.
 - **(M) SYS/DIA**: All values are shown, but the mean value is shown in a bigger font.

NIBP alarms

Setting NIBP alarms

NOTE

The most recent saved alarm on/off settings apply to all patient types.

1. Select the NIBP parameter window.
2. Select the **Alarms** tab.

The **Alarms** table is displayed.

3. Select **Systolic**, **Mean**, or **Diastolic** pressure.

If the feature is not active, the alarm limits are greyed out. Select **Alarm on** to set the alarms.

4. Set the alarm limits.

If the current alarm priority settings deviate from the recommendation of international alarm safety standards, there is a notification with the general warning sign . If needed, you can change the alarm priorities in **Alarm Settings > Priorities**.

NIBP alarms' deactivation with pause audio key

Unlike the continuously monitored parameters, NIBP is measured periodically, and its physiological alarms can be deactivated with the pause audio key. Deactivating a physiological NIBP alarm will clear that active alarm until the next NIBP measurement is taken. If the new measurement is outside the alarm limits, the alarm is activated again.

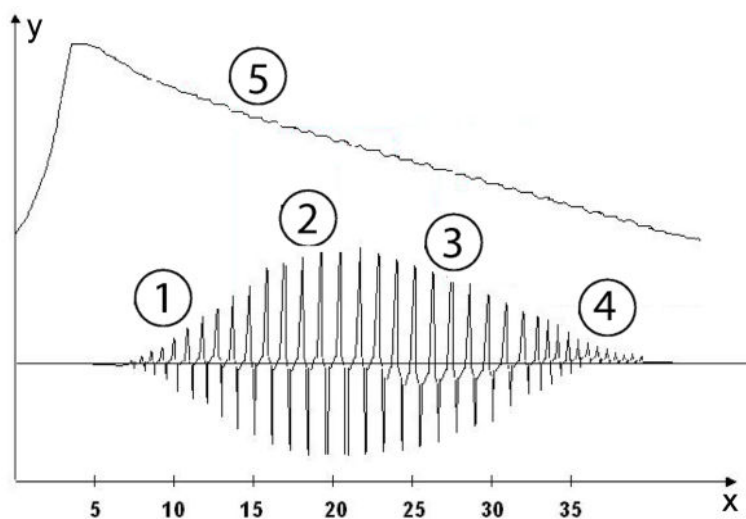
NIBP recheck after alarm violation (control measurement)

If the NIBP value exceeds the alarm limits and the NIBP alarm priority selection is **Escalating**, a new measurement takes place automatically. If the NIBP measurement is taken manually, the recheck measurement is taken 4 seconds (**Adult** or **Child** patient type) or 8 seconds (**Infant** patient type) after the first measurement. When the NIBP measurement is taken automatically, the recheck measurement is delayed by 30 seconds before the second measurement is taken.

NIBP measurement description

NIBP is acquired using oscillometric technology. Oscillometry is the most commonly used means of indirect blood pressure measurement in automated devices. It is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall.

Oscillometric devices use a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure. By measuring and analyzing at various cuff pressures, the amplitude (which changes based on the pressure within the cuff) and the frequency of these pulsations (which is dependent on the patient's heart rate), oscillometric devices can non-invasively determine blood pressure.



- x = Time(s)
- y = Pressures

1. Systolic
2. Mean
3. Diastolic
4. Extracted pulse wave
5. Cuff pressure

NIBP measurement technologies

DINAMAP SuperSTAT NIBP technology

The DINAMAP SuperSTAT technology estimates the systolic, mean arterial, and diastolic values by evaluating all cuff pressure data gathered during an NIBP determination.

For adults and children, when ECG is being monitored it provides and confirms more detailed timing information for the SuperSTAT algorithm. At the beginning of a SuperSTAT NIBP determination, the coefficient of variation from the previous 120 ECG RR intervals is used to determine if an irregular rhythm is present.

The first determination initially pumps up to a default target cuff pressure of about 135 mmHg for adults, 125 mmHg for child, or 100 mmHg for infant. The initial target pressure preset can be adjusted if you desire a lower (or higher) initial target pressure. To allow for rapid settling of cuff pressure, the monitor will momentarily inflate to a higher pressure, then immediately deflate to the target pressure.

As a determination is taken, the pattern of the patient's oscillation size is stored as a function of pressure. In any subsequent determination, as few as four pressure steps may be necessary to complete the process. When employing fewer pressure steps, the system uses the stored information from the previous blood pressure determination to decide the best pressure steps to take. The consistency of pulse sizes are measured to tell if the oscillations taken at a step are good and if more steps are needed.

If the current blood pressure reading is similar to the previous reading, some information from the previous blood pressure may be used in the current determination. The data is constantly evaluated during a measurement to try to perform a blood pressure determination in the shortest possible time, providing greater comfort to the patient.

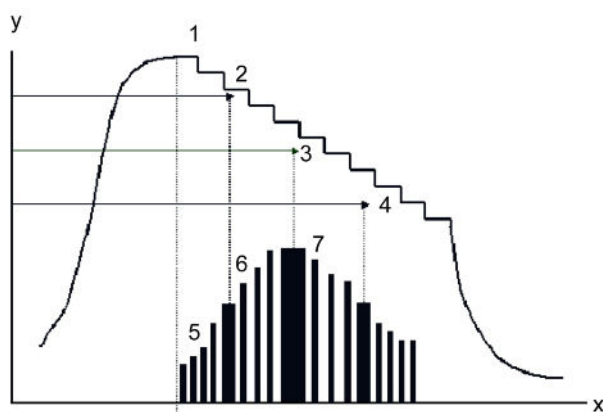
If it has been 16 minutes or less since the last determination and the current blood pressure is similar to the previous reading, the monitor will try to make an accelerated determination of blood pressure.

During irregular rhythms, only pulses from the current determination are used in calculating the blood pressure values. In order to ensure adequate artifact rejection capability and optimal SuperSTAT NIBP performance, several criteria used to match and qualify the oscillometric pulses at each pressure step are relaxed while supplementing the criteria with additional information from ECG.

DINAMAP Step Deflation technology

The DINAMAP SuperSTAT technology includes the DINAMAP Step Deflation technology. During the deflation process, the Carescape ONE measures two consecutive pulsations in cuff pressure. If their amplitude differs by an acceptably small amount and the time interval between the pulsations matches the previous time intervals, the pulsations are averaged and stored along with the corresponding cuff pressure. The cuff is then deflated to the next step (in steps of 5-10 mmHg). As the deflation occurs, oscillation waves are assessed for strength and amplitude until the maximum oscillation amplitude or MAP is obtained.

If either of the above criteria is not met, the cuff pressure is maintained until two consecutive pulsations are detected that meet the criteria. Eventually, if the cuff is maintained at one pressure step for longer than one minute or the determination time exceeds 85 seconds (infant cuffs) or two minutes (adult and child cuffs), the Carescape ONE will time out and display an error.



- x = Cuff pulsation waveform
 - y = Cuff pressure
1. Cuff deflation
 2. Systolic pressure (ratio of maximum amplitude)
 3. Mean arterial pressure (maximum pulsation amplitude)
 4. Diastolic pressure (ratio of maximum amplitude)
 5. Cuff pulsations (each pulsation represents one heart beat)
 6. Amplitude (changes based on cuff pressure)
 7. Resulting waveform

Systolic and diastolic determinations are based on a mathematical calculation within the algorithm. The deflation mode is heart rate dependent, it is typically longer with heart rates that are slow and/or irregular.

This patented process of finding two matched pulsations of relatively equal amplitude and frequency at each step rejects artifact due to patient movement or other deviations from ideal conditions (e.g., cuff disturbances) and greatly enhances the overall accuracy of the measurement.

NOTE

NIBP values are based on the oscillometric method of non-invasive blood pressure measurement taken with a cuff on the arm of adult and child patients, and a cuff on the calf of infants. The values correspond to comparisons with intra-arterial values within IEC particular standards for accuracy (a mean difference of ± 5 mmHg, and a standard deviation of < 8 mmHg).

NIBP calibration

The NIBP calibration procedure is explained in the service manuals. The calibration procedure is password protected.

NIBP troubleshooting

Problem	Solution
NIBP measurement does not work or the values seem unstable.	• Check that the cuff tubing is not bent, stretched, compressed, or loose. • Check the cuff position and cuff tube connection. • Prevent motion artifact. • Use NIBP cuffs of correct size.
NIBP measurement does not start.	• Ensure that the patient type has been selected.
Why is the cuff re-inflating automatically?	The cuff target pressure must be higher than the patient's systolic pressure to obtain an accurate systolic and diastolic measurement. If a systolic blood pressure cannot be found, a systolic reading is searched by re-inflating the cuff to a higher pressure. During a systolic search, the maximum cuff inflation pressure will not exceed the normal pressure range of the cuff. For more information, refer to the technical specifications. A control measurement may be taking place. If the measured NIBP value exceeds the alarm limits, a single low priority alarm sounds and a new measurement is automatically taken. If the new value (the control measurement) also exceeds the alarm limits the alarm priority escalates to medium. In Single NIBP mode and Continuous NIBP for 5 min mode there are at least four seconds between the first measurement and the control measurement for Adult and Child patient types, eight seconds for Infant patient type. In Automatic NIBP mode there are at least 30 seconds between the first measurement and the control measurement.
Unexpected NIBP readings	• Ensure that the correct patient type has been selected. • Check that the cuff is positioned correctly. • Reduce sources of motion artifact. • Calibrate the device.

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Invasive pressures

Invasive pressures compatibility limitations

For detailed information regarding Carescape ONE, micro-modules, and accessory compatibility, see the supplemental information provided.

Invasive pressure safety precautions

Invasive pressure warnings

**WARNING**

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

WARNING

PATIENT SAFETY. All invasive procedures involve risks to the patient. Use aseptic technique. Incorrect use of the catheter can lead to vessel perforation. Follow catheter manufacturer's instructions.

WARNING

ELECTRIC SHOCK. To avoid the risk of electric shock, make sure that no part of the patient connections touches any electrically conductive material including earth.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

ERRONEOUS READINGS. Mechanical shock to an invasive blood pressure transducer may cause severe shifts in the zero balance and cause erroneous readings.

WARNING

ERRONEOUS READINGS. Repositioning the patient after a completed zeroing procedure may cause incorrect measurement values.

WARNING

INCORRECT PULSE RATE. Be sure to turn off the IABP setting when the cardiac assist device is no longer used. Failure to do so could result in incorrect pulse rate readings.

WARNING

EQUIPMENT DAMAGE. Do not immerse the cable connectors in liquids or allow liquid to enter the cable connectors.

WARNING

ERRONEOUS READINGS. Setting the invasive pressure noise reduction filter below 12Hz may impact systolic and diastolic measurement accuracy and pressure waveform. Before applying the filter, ensure that the physical measurement system (catheter/tubing/transducer) does not contribute to noise or artifacts in the measurement.

Invasive pressure measurement considerations

- FloTrac CCO micro-module measurement is not available in the NICU software package. For other FloTrac CCO micro-module measurement considerations, refer to the instructions for use in the micro-module package.

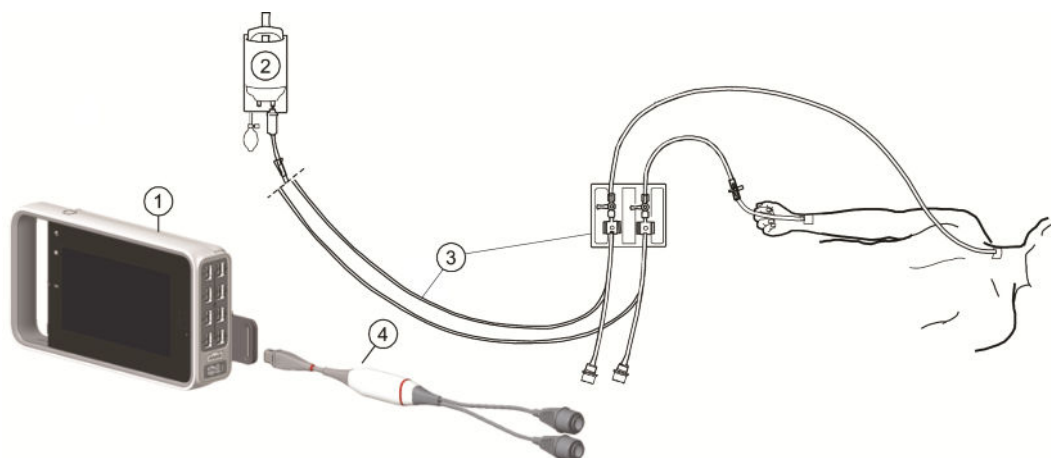
Invasive pressure points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 60601-2-34 clause 202.6.2.101 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Defibrillator discharge may affect the invasive pressure measurement. Defibrillation recovery time after discharge is < 10 seconds.
- Do not turn on the IABP algorithm unless a balloon pump is in use.
- There are two supported invasive pressure measurement technologies:
 - TruSignal
 - FloTrac

You can monitor up to five pressures when using the TruSignal Pressure micro-module and the FloTrac CCO micro-module. The TruSignal Pressure micro-module provides up to four measurement channels and the FloTrac CCO micro-module provides one measurement channel.

Invasive pressure measurement setup with TruSignal Pressure

Invasive pressure equipment to patient connection with TruSignal Pressure micro-module

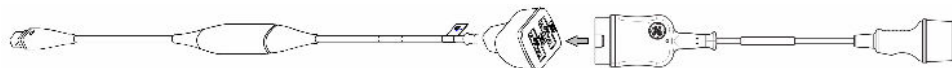


1. Carescape ONE
2. Fluid bag with pressure infusor
3. Transducer setup
4. TruSignal Pressure micro-module

Connecting the invasive pressure transducer and cable

Each TruSignal Pressure micro-module can be used to measure 2 invasive pressures. Up to 2 TruSignal Pressure micro-modules can be connected to Carescape ONE simultaneously, allowing up to 4 invasive pressures to be measured.

1. Prepare the transducer kit according to the manufacturer's instructions.
2. The TruSignal Pressure micro-module can be ordered with a connector that connects directly to the invasive pressure transducer, or it may require an invasive blood pressure (IBP) interface transducer connector cable. If the TruSignal Pressure micro-modules used at your facility require an IBP interface transducer connector cable, connect the IBP interface transducer connector cable to the TruSignal Pressure micro-module as shown.



3. Connect the transducer setup to the TruSignal Pressure micro-module or to the IBP interface transducer connector cable, as required.
4. Remove entrapped air from within the transducer setup by tapping the setup and by turning it into different positions.

5. Connect the TruSignal Pressure micro-module to Carescape ONE.

The first TruSignal Pressure micro-module that is connected to Carescape ONE is assigned to channels 1 and 2. The second one connected is assigned to channels 3 and 4.

6. Connect the transducer to the patient line.

7. Zero the invasive pressure transducer(s).

Before zeroing, you can change the channel assignments by removing both TruSignal Pressure micro-modules, then reconnecting them in a different order. Once the invasive pressure transducers are zeroed, the channel assignments are locked until the patient is discharged from the Carescape ONE.

Checking the invasive pressure measurement

1. Make sure that all the transducers are zeroed correctly.
2. Check that the monitor recognizes cable connections (activates the display) for all the pressure channels used and the pressure values and appropriate waveforms are displayed.

Invasive pressure measurement on the monitor screen with TruSignal Pressure

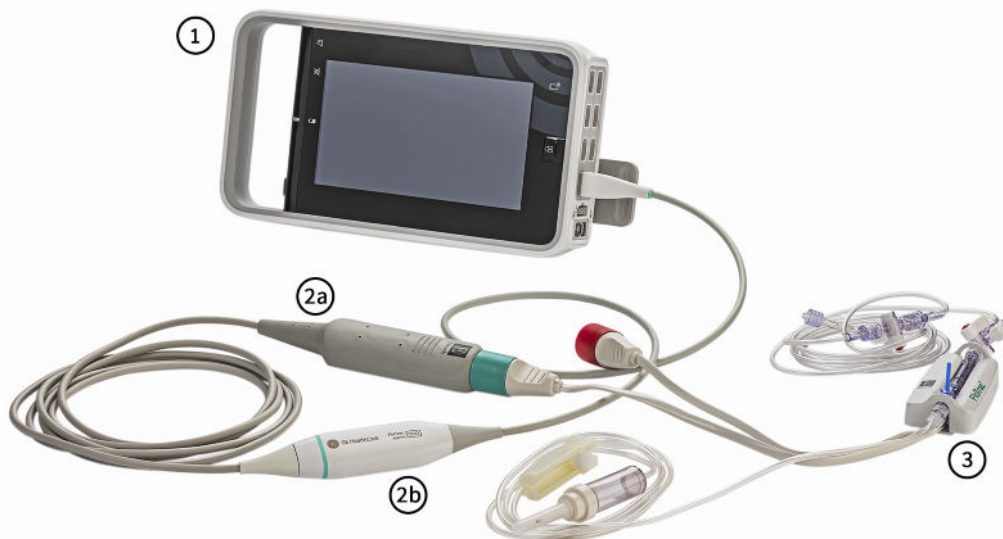
When using the TruSignal Pressure micro-module, the invasive pressure channel labels are as follows. “X” indicates the channel number, for example, **Art 2**. Throughout this document, when an invasive pressure label is followed by an “X”, the “X” represents the channel number.

With the exception of PA, more than one channel can have the same channel label, for example, **Art 1** and **Art 2**. Only one channel can be labeled **PA**.

Label	Description
Art X	Arterial pressure
Fem X	Femoral arterial pressure
FemV X	Femoral venous pressure
PA X	Pulmonary arterial pressure
CVP X	Central venous pressure
LAP X	Left atrial pressure
RAP X	Right atrial pressure
ICP X	Intracranial pressure
RVP X	Right ventricular pressure
UAC X	Umbilical arterial pressure
UVC X	Umbilical venous pressure
P1 to P4	Non-specific pressure channel labels

Invasive pressure measurement setup with FloTrac CCO

Equipment connection with FloTrac CCO micro-module



1. Carescape ONE
2. FloTrac CCO micro-module, which consists of:
 - a. Edwards FloTrac CCO pressure cable
 - b. FloTrac CCO adapter
3. FloTrac sensor with green connector

NOTE

Do not connect and use the red connector of the FloTrac sensor.

Preparing the setup for FloTrac CCO micro-module

1. Follow the instructions for use provided in the micro-module package.
2. Connect FloTrac CCO micro-module to the Carescape ONE.

Checking the invasive pressure measurement

1. Make sure that all the transducers are zeroed correctly.
2. Check that the monitor recognizes cable connections (activates the display) for all the pressure channels used and the pressure values and appropriate waveforms are displayed.

Invasive pressure measurement on the monitor screen with FloTrac CCO

When using the FloTrac CCO micro-module, the available invasive pressure channel labels are:

- **Art 8:** Arterial pressure
- **Fem 8:** Femoral arterial pressure

Using the invasive pressure measurement

Invasive pressure analog output

NOTE

TruSignal Pressure micro-module only.

Carescape ONE sets the first available arterial channel (**Art X**, **Fem X**, **UAC X**) for invasive pressure analog output.

- If there are no arterial channels available, the first zeroed channel will be used.
- If there are no zeroed channels available, a flat line will be the output of the IP Analog output channel.

About zeroing the invasive pressure transducers

Prior to monitoring, zero transducers at the patient's phlebostatic axis. Zeroing the pressure transducers is very important for accurate pressure measurements. To avoid inaccurate measurements, you must zero the pressure transducers:

- Before measuring invasive pressures.
- Before initiating treatment changes reliant upon pressures data.
- When using a new transducer or tubing.
- After reconnecting the transducer cable to a micro-module.
- Whenever the patient's position is changed.
- Whenever the pressure reading is questionable.
- Whenever the altitude or temperature of the operating environment has changed.

Pressures can be zeroed individually by selecting **Zero** in the pressure menu. You can zero all pressures except ICP by selecting **→0←** in the main menu.

About zeroing reconnected micro-modules

You do not need to zero the transducers again if one or more micro-modules are disconnected and reconnected to the Carescape ONE within 2 minutes. When micro-modules(s) are reconnected, the measurement values are displayed and the mapping of the pressure channels is restored.

Zeroing the invasive pressure transducers

1. Level the transducer following your care unit's policy (usually level of the phlebostatic axis).
2. Close the transducer stopcock to the patient and open the venting stopcock to air.
3. If the pressure line you are trying to zero does not have the transducer open to air, the message **Pressure sensed** displays.
4. You can zero all connected pressure transducers simultaneously by selecting **→0←** from the main menu, or you can zero a single active pressure transducer by selecting the invasive pressure parameter window > **Settings** > **Zero**.

NOTE

Selecting **→0←** does not zero a connected ICP channel. The ICP channel must be zeroed separately. When the **Zero ICP separately** message displays, you can zero the ICP channel by selecting the invasive pressure parameter window > **Settings** > **Zero**.

5. Check that a zero reference has been established. Watch the pressure parameter window for messages.
6. Close the venting stopcock to air and open the transducer stopcock to the patient.
7. Check that pressure numerics and/or waveforms display on screen.

Selecting an invasive pressure channel label

1. Select the invasive pressure parameter window.
2. Select the **Settings** tab.
3. Select a channel label from the **Label** list.

The channel label **PA** can only be used for one channel label. All other labels names can be used for more than one channel label, if desired.

Selecting the scale of the invasive pressure waveform

1. Select the invasive pressure parameter window.
2. Select the **Settings** tab.
3. Set the waveform scale with the **Scale (X)** arrows. **X** represents the unit of measure.

The waveform is adjusted to match the scale value.

Optimizing the invasive pressure waveform scale

You can select an automatic calculation for an optimized waveform size. This size will then be used for the local waveform, minitrend, and waveform printouts. Other instances (e.g., information sent to the network in wireless transport mode) will use the scale selection that is as close as possible to the upper limit of the optimized scale.

The algorithm uses the last four seconds of the waveform data to calculate the scale. If you notice a considerable change in the waveform during that time, wait for the waveform to stabilize and perform the operation again.

1. Select the invasive pressure parameter window.
2. Select the **Settings** tab.
3. Select **Optimize scale**.

The **Scale (X)** selection will now show the automatic limit range. "X" represents the unit of measure.

NOTE

The **Optimize scale** selection changes the scale once to match the waveform. The scale does not change until you manually adjust it again or the patient is discharged/case is reset.

Selecting the displayed invasive pressure format

You can choose to display systolic, diastolic or mean pressure values in different formats.

1. Select the invasive pressure parameter window.
2. Select the **More Settings** tab.
3. Select the **Display format**.

The choices are:

- **(M)**: Only the mean value is shown.
- **SYS/DIA (M)**: All values are shown, but the sys/dia values are shown in a bigger font.
- **(M) SYS/DIA**: All values are shown, but the mean value is shown in a bigger font.
- **SYS/DIA (M)**: All values are shown in the same size font.

Display format setting may be on page 2 of the **More Settings** tab, depending on the selected label.

Selecting invasive pressure as the primary heart rate source

The primary heart rate can be calculated from the ECG leads, SpO₂ measurement, or invasive pressure waveform.

NOTE

This setting adjusts the primary heart rate source for all of the hemodynamic parameters.

NOTE

This setting is available for **Art X**, **Fem X**, or **UAC X** invasive pressure channels only.

NOTE

HR alarms must be configured as **Single** to enable invasive pressure as the primary heart rate source.

1. Select the invasive pressure parameter window.
2. Select the **More Settings** tab.

3. Select the heart rate source from the **Primary HR source** list.

NOTE

Only channels that have been configured with arterial pressure labels will appear in the list. If the FloTrac CCO micro-module is connected, **Art 8** and **Fem 8** are not shown in the list.

Selecting the primary arterial source

The arterial pressure channel selected as the primary arterial source is used as the source for the primary HR, the secondary HR, CPP, and MAP.

1. Select the invasive pressure parameter window.
2. Select the **More Settings** tab.
3. Select an option from the **Primary arterial source** list.

The selection applies to all invasive pressure channels with an arterial pressure label (**Art**, **Fem**, **UAC**).

The **AUTO** option defaults to the first zeroed arterial site that has had a valid pulse rate for at least 10 seconds. For example, if both the **Art 1** channel and the **Fem 2** channel are zeroed and have valid pulse rates for at least 10 seconds, the **AUTO** option will be **AUTO Art 1** because that is the lowest valid channel number.

If the selected primary arterial source's site label is changed to another arterial site label, for example, **Art** to **Fem**, the primary arterial source label will be updated to the new label. If the primary arterial source's site label is changed to a non-arterial site label, such as **CVP**, the primary arterial source selection will change to **AUTO**.

Showing the pulse rate in the invasive pressure parameter window

NOTE

This setting is available for **Art X**, **Fem X**, or **UAC X** invasive pressure channels only.

1. Select the invasive pressure parameter window.
2. Select the **Settings** tab.
3. Select **Show in parameter window > PR** check box.

Showing the CPP value in the ICP parameter window

A valid mean arterial pressure is required to compute the cerebral perfusion pressure (CPP) value.

1. Select the invasive pressure parameter window.
2. Select the **Settings** tab.
3. Select **Show in parameter window > CPP** check box.

Using the IP channel standby

If you wish to prepare and zero a channel beforehand, you can use the channel standby.

1. Select the invasive pressure parameter window.

2. Select the **Settings** tab.
3. Select **Standby** [channel label channel number]. The channel label and channel number text depends on the channel label and channel number of the invasive pressure parameter window that was selected, for example, **Standby Art 2**.

Channel alarms and measurement are disabled until **Activate** [channel label channel number] is selected or pressure is detected. The channel label and channel number text depends on the channel label and channel number of the invasive pressure parameter window that was selected, for example, **Activate Art 2**.

Selecting the invasive pressure noise reduction filter

WARNING

ERRONEOUS READINGS. Setting the invasive pressure noise reduction filter below 12Hz may impact systolic and diastolic measurement accuracy and pressure waveform. Before applying the filter, ensure that the physical measurement system (catheter/tubing/transducer) does not contribute to noise or artifacts in the measurement.

NOTE

TruSignal Pressure micro-module only.

NOTE

If arterial pressure is used to trigger the intra-aortic balloon pump, ensure that the 40 Hz pressure filter is in use.

1. Select the invasive pressure parameter window.
2. Select the **More Settings** tab.
3. Select a numeric value from the **Filter (Hz)** list.

The smaller the filter value, the greater the degree of filtering that occurs. If the filter value is below the recommendation in the international standards (below 12 Hz), there is a notification with the general warning triangle.

Selecting Smart BP

NOTE

TruSignal Pressure micro-module and **Art** and **Fem** invasive pressure channels only. Not available in the NICU software package.

Smart BP is an algorithm that temporarily deactivates the arterial and femoral alarms when it detects the zeroing of a transducer, fast flushing of the system, or blood draws. The message **Artifact** displays during the alarm deactivation. When pulsatile pressure returns and 15-20 beats are detected, numerics are displayed and alarms are reactivated.

1. Select the invasive pressure parameter window.
2. On the **More Settings** tab, select page 2.
3. Toggle on **Smart BP**.

Enabling or disabling an arterial pressure disconnection alarm

NOTE

TruSignal Pressure micro-module only.

The catheter disconnection alarm activates if the mean **Art**, **Fem**, or **UAC** pressure falls below 10 mmHg (1.33 kPa). The catheter disconnection alarm for each arterial pressure (Art, Fem, UAC) is enabled by default. If **Allow alarm off for Art disconnect**, **Allow alarm off for Fem disconnect**, or **Allow alarm off for UAC disconnect** option is enabled in **Care unit settings**, you can enable or disable the alarm for the corresponding arterial pressure. Care unit settings are password protected. Refer to the supplemental information provided in the appendices for more information.

1. Select the invasive pressure parameter window.
2. On the **More Settings** tab, select page 2.
3. To enable the alarm, toggle on **Catheter disconnect alarm**. To disable the alarm, toggle off **Catheter disconnect alarm**.

Setting invasive pressure alarm limits

The tabs for configuring alarms and alarm limits depend on what has been configured in the **Care unit settings** (password protected). For more information, see the supplement information provided in the appendices.

1. Select the invasive pressure parameter window.
2. Select the tab for the desired alarms setting:
 - With **Care unit settings** > **Parameters** > **HR alarms** > **Multiple** selection:
 - Select **Alarms** tab and set the alarm limits.
 - With **Care unit settings** > **Parameters** > **HR alarms** > **Single** selection:
 - Select **Alarms** tab or **HR Alarms** and set the alarm limits.

If the current alarm priority settings deviate from the recommendation of international alarm safety standards, there is a notification with the general warning sign . If needed, you can change the alarm priorities in **Alarm Settings** > **Priorities**.

NOTE

If a feature is not active, the alarm limits are greyed out. You can set them on by selecting **Alarm on**.

Configurable PR alarm delays

The alarm delay for **PR (SpO2/IP) low/high (s)** is configurable from 0 to 20 seconds in increments of 5 seconds. This delay is set through **Monitor Settings** > **Defaults & Service** > **Default settings** > **Alarm delays** and it is password protected.

You can check the delays by selecting the parameter window > **Alarms** > **Alarm delays**. The user-configured delays are shown in a pop-up window.

For more information, see the supplemental information provided in the appendices.

Invasive pressures alarm priorities

You can select priorities for the **Art low/high**, **Fem low/high**, **FemV low/high**, **CVP low/high**, **PA low/high**, **RAP low/high**, **RVP low/high**, **LAP low/high**, **ICP low/high**, **CPP low/high**, **UAC low/high**, **UVC low/high**, and **P1 low/high** to **P4 low/high** alarms through **Alarm Settings > Priorities > Pressures**. The choices are **Escalating**, **High**, **Medium**, and **Low**.

Low priority is only available if it has been allowed in **Care unit settings**. Care unit settings are password protected. When an invasive pressure alarm priority has been set to **Low**, a warning text appears on the invasive pressure alarms tab, indicating that the alarm priority has been set to **Low**.

Intra-aortic balloon pump

NOTE

Not available with the FloTrac CCO micro-module or in the NICU software package.

When using Carescape ONE, there are two options available to trigger an intra-aortic balloon pump (IABP).

The first option uses the intra-aortic balloon pump itself. This option does not require use of the Defib Sync port on the Carescape ONE, but does require ECG electrodes, ECG leadwires, and arterial pressure connections to the IABP separate from those to the Carescape ONE.

The second option uses the existing ECG electrodes and leadwires or the existing arterial pressure connection to the Carescape ONE, along with a Defib Sync connection between the Carescape ONE and the IABP. **ECG 1 lead** and the first zeroed arterial pressure (**Art X** or **Fem X**) are available on the Defib Sync port and may be selected by the intra-aortic balloon pump for triggering.

Compensating for intra-aortic balloon pump (IABP) waveform irregularities

WARNING

INCORRECT PULSE RATE. Be sure to turn off the IABP setting when the cardiac assist device is no longer used. Failure to do so could result in incorrect pulse rate readings.

CAUTION

PATIENT HAZARD. If you choose to trigger the balloon pump from the monitor, contact the balloon pump manufacturer directly for interface requirements, as they vary among manufacturers. Some trigger modes on certain balloon pump devices may not be compatible with the GE Healthcare analog output signal, and use may contribute to patient injury or sub-optimal pumping results.

NOTE

TruSignal Pressure micro-module and **Art** and **Fem** invasive pressure channels only. Not available in the NICU software package.

1. Select the invasive pressure parameter window.
2. On the **More Settings** tab, select page 2.
3. Toggle on **IABP on**.

IABP now displays in the invasive pressure channel parameter window.

Triggering intra-aortic balloon pumps

NOTE

If you choose to use the monitor for triggering, use the following instructions. Failure to follow these instructions may result in an incompatible analog output signal, which may contribute to patient injury.

1. Contact the balloon pump manufacturer for interface requirements. See the technical specifications for the ECG analog output delay.
2. Connect a compatible analog output cable to the Defib Sync connector.
3. Adjust the invasive pressure filter. If arterial pressure is used to trigger the balloon pump, use the 40 Hz pressure filter.
4. Primary displayed ECG lead: If the balloon pump triggers off the R wave of the ECG, review the patient's ECG leads and place the one with the greatest amplitude in the top (primary) position on the monitor display.
5. Pacemaker detection: If the patient has a pacemaker, be sure the pacemaker detection is turned on. Failure to turn pacemaker detection on may cause poor beat detection, which may result in inadequate triggering of the balloon pump.

Effects of IABP on displayed values

Displayed pressure values are affected by the intra-aortic balloon pump. The IABP program displays three values, for example 150/45 (98). The first value is the systolic value, the second is the diastolic value, and the third is the mean value. The displayed numeric values are indicating a rapidly varying waveform generated during IABP treatment and do not always reflect a true arterial blood pressure.

For accuracy and reliability, combine these recommended methods for reading arterial and/or femoral blood pressure:

- The IABP waveform displayed on the screen (use scales for evaluation)
- The display on the balloon pump device, if available

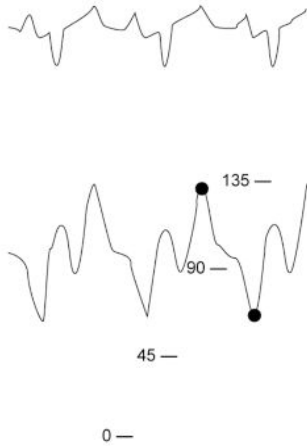
Since there are a number of points along the IABP waveform that could be the displayed value, it is important to know which points the program uses. The values displayed will differ depending on the timing of the pump.

1:1 or 1:2 timing

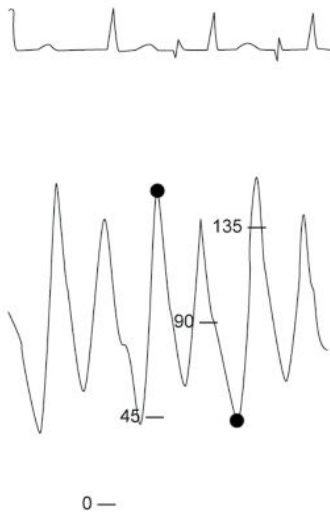
Diastolic numerics: The displayed diastole always equals the balloon end diastole.

Systolic numerics:

- When the augmented diastole is greater than the patient systole, the displayed systole equals the augmented diastole.

Art 134/63

- When the patient systole is greater than the augmented diastole, the displayed systole equals the patient systole.

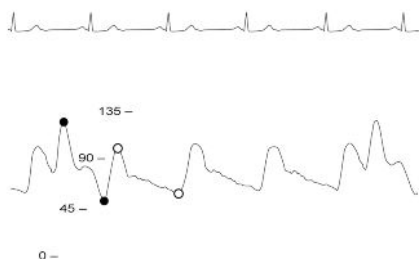
Art 160/45

1:3 or more timing

Diastolic numerics: The displayed diastole switches between the balloon end diastole and the patient end diastole.

Systolic numerics: The displayed systolic numerics switch between the augmented diastole and patient systole.

- Displayed values will switch between: Art 123/51 (●) and Art 100/60 (○)



Invasive pressure practicalities

Invasive pressure parameters

The measured invasive pressure parameters are systolic, diastolic, and mean. Pulse rate can be monitored with any arterial site. CPP is a calculated value that requires a valid ICP value and a valid mean arterial pressure.

You can monitor up to five pressures.

The following table lists the available site names and displayed values. The “X” after the site name represents the channel number, for example, **Art 2**:

Site	Site name	Carescape ONE displayed values
General site name for the specific invasive pressure channels 1 to 4	P1 to P4	Mean
Arterial	Art X	Pulse rate, systolic, diastolic, mean
Central venous	CVP X	Mean
Femoral arterial	Fem X	Pulse rate, systolic, diastolic, mean
Femoral venous	FemV X	Mean
Intracranial	ICP X	Mean
Left atrial	LAP X	Mean
Pulmonary artery	PA X	Systolic, diastolic, mean
Right atrial	RAP X	Mean
Right ventricular	RVP X	Mean
Umbilical artery catheter	UAC X	Pulse rate, systolic, diastolic, mean
Umbilical venous catheter	UVC X	Mean

Invasive pressure troubleshooting

Problem	Solution
Artifact detected and the Smart BP option is toggled on.	• Check the patient. • Reposition the catheter. • Zero the transducer. • If the problem persists, toggle off the Smart BP option. • If the Smart BP option is toggled off, use the audio pause feature before drawing blood and before zeroing to reduce nuisance alarms.
Invasive pressure readings seem unstable.	• Make sure there are no air bubbles in the transducer systems. • Flush and zero. • Place the transducer on the patient's phlebostatic axis.
---/--- (80) Systolic and diastolic pressure values do not display.	This may be due to the Smart BP option detecting artifact. When artifacts are detected, only Mean values are displayed. • Check the patient. • Toggle off Smart BP if required.
Invasive pressure waveform is displayed but no numeric values are displayed.	• Zero the channel. Invasive pressure numeric values are displayed only for successfully zeroed channels.
Zeroing of invasive pressure channel(s) fails.	• Ensure that the channels are open to air.
The channel standby is not selectable, or it is terminated without the user giving the activation request.	• If the pressures remain between 10 mmHg and 250 mmHg for 10 seconds or more, the selection is disabled or the standby is terminated.
Why are displayed pressure values different than expected?	• Check the patient. Values could be valid, the patient could be lying on the tubing, or the tubing could be kinked. • Check tubing for bubbles. • Remove excess tubing. • Check phlebostatic axis placement of transducer. • Rezero pressure. • If patient is on IABP, verify that the monitor's IABP program is turned on. If necessary, turn it on.
Why are the arterial, non-invasive (oscillometric), and auscultated blood pressure readings indicating different values?	The three measurement methods use different technologies. Auscultation and oscillometric are both indirect methods of measuring blood pressure. In auscultation, changes in arterial sounds during cuff deflation are related to systolic and diastolic pressure. With oscillometric measurement, changes in measured pressure oscillations during cuff deflation are related to systolic, mean and diastolic pressures. Changes in the vascular tone of the arterial system can cause these two indirect methods to differ from one another and from direct arterial pressure measurements. Invasive arterial blood pressure is a direct method of measuring blood pressure. Differences between direct and indirect blood pressure measurements are expected. These differences occur because direct methods measure pressure and indirect methods measure flow. In addition, differences occur because the measurement location is not the same (e.g., brachial artery for NIBP vs. radial artery for invasive arterial pressure monitoring).

Problem	Solution
Why is the monitor alarming arterial disconnect?	- Check the patient immediately in the event the catheter has been dislodged. - If the arterial disconnect alarm is turned on and the mean pressure falls below 10 mmHg, the monitor alarms. When zeroing a pressure line, start the zeroing process within 8 seconds. After that time the disconnect alarm is activated. - If zeroing, close the stopcock. Once the monitor detects the return of waveform and numeric data, the alarm will reset.
Why is there a flashing heart icon displayed next to the PR value in the corresponding parameter window?	Art X, Fem X, or UAC X (where X represents the channel number) has been selected as the Beat source in the ECG or SpO2 menu. No action is required.
It is not clear if the selected invasive pressure labels are set up correctly.	NOTE You need to disconnect one of the TruSignal Pressure micro-modules, which will cause invasive pressure waveforms and numerics to be lost for several seconds. Keep the patient under close surveillance while performing this procedure. FloTrac CCO micro-module is always mapped to Art 8 or Fem 8. - Ensure that one or more of the invasive pressure parameters is displaying on the Carescape ONE. You may need to swipe to another page of the normal screen on the Carescape ONE to display it. - Determine which label (e.g., Art 1) corresponds to which invasive pressure channel (P1 to P4) on the monitor. To check this, select  from the main menu and then Parameters > Invasive pressures. NOTE Invasive pressure channels are listed in numerical order on the screen. - After noting which label corresponds to which invasive pressure channel on the Carescape ONE display, close the Invasive pressures menu. - Trace each cable from the patient connection to determine which TruSignal Pressure micro-module each invasive pressure source is connected to. Each TruSignal Pressure micro-module has 2 channels labeled P1 and P2, so the second TruSignal Pressure micro-module will display as P3 and P4 on the monitor. - Disconnect one of the TruSignal Pressure micro-modules at the Carescape ONE side. - If the Carescape ONE is configured to display invasive pressure waveforms, the waveforms for the TruSignal Pressure micro-module that was unplugged will stop immediately. - The parameter window will close. - Plug the TruSignal Pressure micro-module back into Carescape ONE as soon as possible. As long as the same TruSignal Pressure micro-module is reconnected to Carescape ONE, and the disconnection time was less than 2 minutes, the invasive pressure line will not need to be re-zeroed. Monitoring will resume normally.
With the FloTrac CCO micro-module: Why are the invasive pressure readings unstable when patient demographics are adjusted?	When the FloTrac CCO micro-module is in use and the patient demographics are adjusted, the invasive pressure measurement calculation restarts. The readings stabilize in a few seconds. No action is required.

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Temperature

Temperature compatibility limitations

For detailed information regarding Carescape ONE, micro-modules, and accessory compatibility, see the supplemental information provided.

Temperature safety precautions

Temperature warnings



WARNING

DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection and enable successful defibrillation, use only the recommended cables and leadwires. Using other cables or leadwires may result in damage to the equipment and compromise patient and user safety.

WARNING

BURNS. When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

- Proper contact of the ESU return electrode to the patient.
- ESU return electrode near the operating area.
- Measurement electrodes, leadwires and probes far from the surgical site and the ESU return electrode.

WARNING

PATIENT SAFETY. There are hazards associated with the reuse of single-use temperature probes.

WARNING

PATIENT SAFETY. Use of devices containing phthalates should be limited to the amount of time treatment is medically necessary, especially for neonates and pregnant or nursing mothers.

Temperature cautions

CAUTION

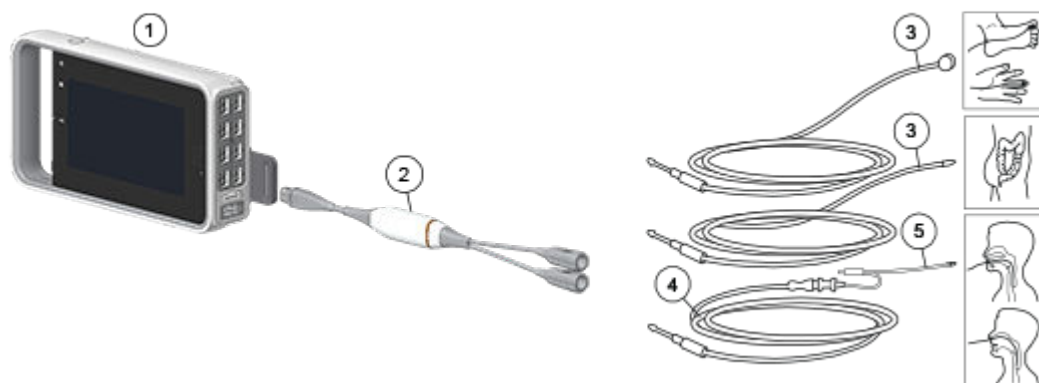
INACCURATE READINGS. To obtain accurate temperature measurements, use only 400 series temperature probes. Using other types of probes can lead to inaccurate readings.

Temperature points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Use only GE HealthCare approved temperature accessories.
- For more detailed information regarding the temperature probes, refer to their own instructions for use.
- The temperature measurement uses direct mode. Displayed temperature values represent the probe temperature of the measurement site on the patient.
- A temperature channel is activated when Carescape ONE detects the TruSignal Temperature micro-module.
- A temperature channel is deactivated when the TruSignal Temperature micro-module is detached from Carescape ONE.

Temperature measurement setup

Temperature equipment to patient connection with Carescape ONE



1. Carescape ONE
2. TruSignal Temperature micro-module (dual)
3. Reusable temperature probe (example)
4. Temperature interconnect cable for disposable temperature probes
5. Disposable temperature probe (example)

Preparing the patient for temperature measurement

1. Follow the manufacturer's instructions for probe application.

2. Connect the TruSignal Temperature micro-module to the Carescape ONE.

Checking the temperature measurement

1. Check that the temperature value is displayed when the probe is connected to the TruSignal Temperature micro-module.

Temperature measurement on screen

Up to two temperature measuring sites can be simultaneously measured and monitored.

Temperature monitoring provides numerics only. No waveform is generated or displayed. The default temperature measuring site labels are as follows:

T1, T2 = general label	
Eso = esophageal	Skin = skin
Naso = nasal	AirW = airway
Tymp = tympanic	Room = room
Rect = rectal	Myo = myocardial
Blad = bladder	Core = core
Axil = axillary	Surf = surface

Using the temperature measurement

Temperature mappings

Temperature measurements are mapped to channels **T1** or **T2**.

Starting the temperature measurement

NOTE

Before starting the monitoring, make sure that the selected temperature measurement unit is correct for your needs. If needed, the unit can be changed in the **Care unit settings** > **Units** (password protected).

Connect the temperature probe to start the measurement. If the parameter window displays **Off** in the value field:

1. Select the temperature parameter window.
2. Confirm that the measurement (**T1 on** and/or **T2 on**) is toggled on.

Changing the temperature site label

1. Select the temperature parameter window.
2. Choose a site label from the dropdown list for the measurement (e.g. **T1 label**).

Showing temperature values in the parameter window

1. Select the temperature parameter window.
2. From the **Show in parameter window** list, select the check boxes for the measurements you want to show on the screen.

The selection for delta value (**T1-T2** or **T2-T1**) varies according to what has been selected in **Care unit settings > Parameters** (password protected).

Setting temperature alarms

1. Select the temperature parameter window.
2. Select the **Alarms** tab.

The **Alarms** table is displayed. If the feature is not active, the alarm limits are greyed out. Select **Alarm on** check box to set the alarms. If the informational priority level has been selected for the alarm, a notification is displayed.

3. Set the alarm limits for the alarm you wish to configure.

If the setting of an alarm limit has been disabled during configuration, the setting is marked with a lock symbol: .

Stopping the temperature measurement

1. Select the temperature parameter window.
2. Toggle off the measurement (e.g., **T1 on**).

Temperature practicalities

- Each temperature label can be changed to reflect the temperature measurement site.
- Individual temperature sites can be turned off.
- The TruSignal Temperature micro-module allows a two-channel measurement.
- The signal input is a high-insulation port to ensure patient safety and to protect the device during defibrillation and electrosurgery.
- The temperature measurements are automatically calibrated at startup and then at least once a minute.

Temperature troubleshooting

Problem	Solution
Temperature measurement fails	• Check that the TruSignal Temperature micro-module is properly connected to Carescape ONE. • Check that there is only one TruSignal Temperature micro-module connected to Carescape ONE • Check that the probe is properly connected to the TruSignal Temperature micro-module or interconnect cable. • Check that you are using the correct probe for the anatomical location being monitored. • Use a probe that is compatible with your system. • Try using a known good probe in case the probe is damaged. • Check the patient connection. • If the problem persists, contact qualified service personnel.
Measurement with Carescape ONE triggers error messages.	• Check the TruSignal Temperature micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Wait until the message disappears. • Try connecting the TruSignal Temperature micro-module to another micro-module connector. • If the problem persists, contact qualified service personnel.
Numeric values are replaced by dashes. In addition, the message Temperature malfunction appears on screen.	• Reconnect the TruSignal Temperature micro-module. • Replace the TruSignal Temperature micro-module. • If the problem persists, contact qualified service personnel.

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CO₂

CO₂ compatibility limitations

For detailed information regarding Carescape ONE, micro-modules and accessory compatibility, see the supplemental information provided.

CO₂ safety precautions

CO₂ warnings

WARNING

PATIENT SAFETY. Always inspect the airway adapter for a tight connection and proper operation before attaching it to the breathing circuit.

WARNING

ERRONEOUS READINGS. Leaks in the gas sampling circuit (sampling line) may cause inaccurate readings.

WARNING

WATER TRAP BLOCKAGE. Remove the airway sampling line from the patient's airway while nebulized medications are being delivered.

WARNING

STRANGULATION. Route all tubing away from the patient's throat to avoid strangulation.

WARNING

INFECTION HAZARD. To avoid the spread of infectious disease, do not allow the exhaust to discharge in the direction of the patient or user.

WARNING

APNEA EVENTS. The device may not detect all episodes of inadequate breathing, nor does it distinguish between central, obstructive, and mixed apnea events.

WARNING

ERRONEOUS READINGS. O₂, N₂O and anesthetic agent gases may interfere with EtCO₂ readings.

WARNING

CROSS-INFECTION. To avoid the risk of patient cross-infection, do not return the sampled gas to the breathing system.

WARNING

ERRONEOUS READINGS. Strong scavenging suction may change the operating pressure of the module and cause inaccurate readings or excessive sample gas flow.

WARNING

INACCURATE READINGS. Do not allow the exhaust line to become kinked or blocked. Back pressure may cause inaccurate gas readings.

WARNING

PATIENT SAFETY. An alarm for low flow rate is generated when the flow drops to approximately 20% of the nominal flow rate of 50 ml/min. This rate is below the lowest specified flow rate of 40 ml/min.

WARNING

PATIENT SAFETY. Do not use this device on patients that cannot tolerate the removal of 50 ml/min $\pm$ 10 ml/min from their total minute ventilation.

WARNING

PATIENT SAFETY. Use of devices containing phthalates should be limited to the amount of time treatment is medically necessary, especially for neonates and pregnant or nursing mothers.

WARNING

PATIENT SAFETY. Always ensure the correct size and fit of accessories according to patient type and application, especially when monitoring pediatric and neonatal patients. The size and fit of accessories may impact the measured gas concentration values at low tidal volumes. It is recommended to have the gas sampling port close to the proximal end of the endotracheal tube. Excessive dead space in the circuit, including the accessories, may cause re-breathing of gases. Very low accessory dead space between the breathing circuit Y-piece and the gas sampling site may impact the measured gas concentration due to dilution of the sampled exhaled gas with fresh gas from the ventilator. To confirm accurate correlation with measured gases and blood, check arterial blood gas values to confirm a suitable setup is used.

WARNING

PATIENT SAFETY. With deactivated **Apnea** alarm, keep the patient under close surveillance.

WARNING

INACCURATE READINGS. To avoid the risk of inaccurate CO₂ readings, you must select the appropriate patient age range before starting a CO₂ measurement with Microstream CO₂ micro-module.

CO₂ cautions

CAUTION

EQUIPMENT DAMAGE. Do not apply pressurized air or gas to any outlet or tubing connected to a CO₂ micro-module or Carescape ONE. Pressure may destroy sensitive elements.

CAUTION

EQUIPMENT DAMAGE. Do not insert any appendage, tool, sharp object, or liquid into the sample receptacle.

CAUTION

SYSTEM PERFORMANCE. The nasal and oral/nasal cannula kits are intended for single use. Do not reuse or sterilize the cannula kit as system performance will be compromised.

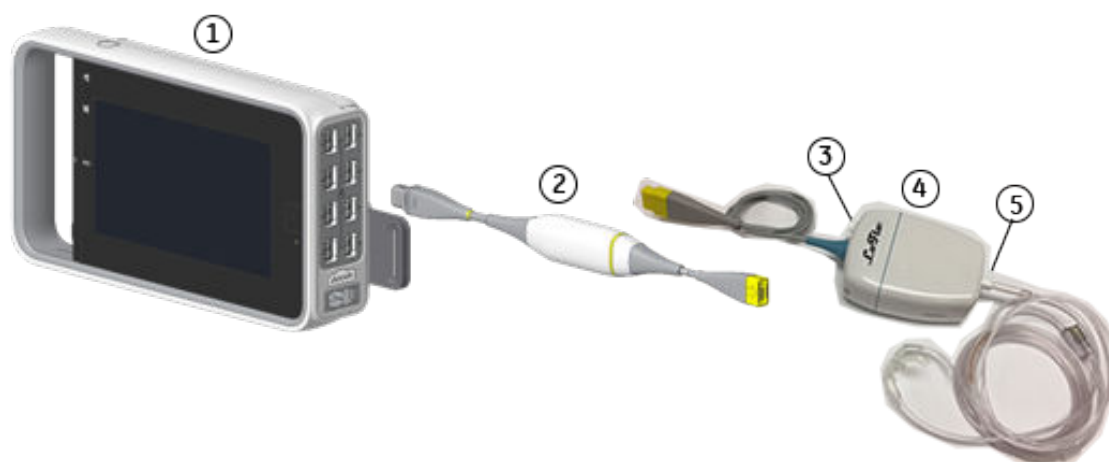
CO₂ points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Disturbances from HF surgical equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- For more information about using the Microstream CO₂ micro-module, refer to the instructions for use for the Microstream CO₂ micro-module.
- The water trap is contained within the sample lines.
- Place the airway adapter with all sampling ports upwards.
- Always check the tightness of all connections.
- Materials used in accessories are not toxic. Accessories do not contain natural rubber latex. Also see the instructions for use in the accessory package.
- The system automatically performs barometric pressure compensation to meet the stated accuracy of the LoFlo Sidestream Module.
- Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO₂ measurement with Respironics LoFlo.
- If nitrous oxide is used, always use N₂O compensation.

CO₂ measurement setup

Equipment connection with LoFlo CO₂ micro-module

For intubated and non-intubated patients.



1. Carescape ONE
2. LoFlo CO₂ micro-module
3. Exhaust port
4. LoFlo Sidestream Module
5. Accessory port (for sample lines, nasal cannulas, etc.)

Preparing the setup for LoFlo CO₂ micro-module

1. Connect the LoFlo Sidestream Module to the LoFlo CO₂ micro-module.
2. Connect the LoFlo CO₂ micro-module to Carescape ONE.
3. Connect the sample line to the LoFlo Sidestream Module.
4. Zero the LoFlo Sidestream Module.
5. Connect the sample line to the patient's breathing circuit if an airway adapter accessory is used, or place on the patient if a nasal cannula is used.

Equipment connection with Microstream CO₂ micro-module

For intubated and non-intubated patients.



1. Carescape ONE
2. Gas exhaust port and breather holes
3. Microstream CO₂ micro-module
4. Functional status LED
5. CO₂ port (for sample lines, nasal cannulas, etc.)
6. Sample line

Preparing the setup for Microstream CO₂ micro-module

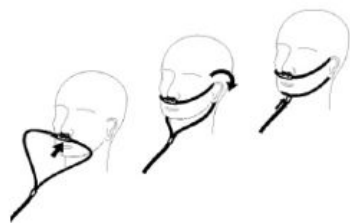
1. Follow the setup instructions in the Microstream CO₂ micro-module instructions for use.
2. Connect Microstream CO₂ micro-module to the Carescape ONE.

About sidestream kits

CAUTION

SYSTEM PERFORMANCE. The nasal and oral/nasal cannula kits are intended for single use. Do not reuse or sterilize the cannula kit as system performance will be compromised.

- Select the kit that has the best fit and most comfort for the patient. For example, the kit labeled as Pediatric may have the best fit and be more comfortable on a small-statured adult than the adult cannula kit. The cannula kits are equally functional regardless of which is used.
- Verify that the cannula kit is clean, dry and undamaged. Replace the cannula kit if necessary.
- Insert the sample cell into the sample cell receptacle. With the LoFlo CO₂ micro-module, you will hear a click when the sample cell is properly inserted. With the Microstream CO₂ micro-module, use a twist and lock motion to secure the sample cell.
- If you are using the LoFlo CO₂ micro-module, zero the LoFlo Sidestream Module.
- Place the nasal cannula kit onto the patient:



See the accessory-specific instructions for use for more detailed information.

Using the CO₂ measurement

Pump on or off with LoFlo CO₂ micro-module

The pump is automatically turned on when a sample line is inserted into the LoFlo Sidestream Module. When connected properly, you will hear a click. When the sample line is removed, the pump turns off immediately. When a blocked line occurs, the pump turns off after 2 minutes of unsuccessfully trying to remove the blockage.

CO₂ measurement unit

NOTE

Before starting the monitoring, make sure that the selected CO₂ measurement unit is correct for your needs. If needed, the unit can be changed in the **Care unit settings > Units** (password protected).

Selecting the age range

NOTE

Microstream CO₂ micro-module only.

WARNING

INACCURATE READINGS. To avoid the risk of inaccurate CO₂ readings, you must select the appropriate patient age range before starting a CO₂ measurement with Microstream CO₂ micro-module.

1. Select the CO₂ parameter window.
2. Select **Settings**.
3. Select an option from the **Age** list based on the age of the patient. The options are **0-12 months** and **Over 12 months**.

Selecting the CO₂ scale

If EtCO₂ is above 6% (45 mmHg), change the scale for the capnogram.

1. Select the CO₂ parameter window.
2. Select **Settings**.

3. Select an option for **CO₂ scale (X)**.

NOTE

"X" represents the selected unit of measure.

Setting CO₂ limit alarms

1. Select the CO₂ parameter window.
2. Select **Alarms**.
3. Select the parameter (**EtCO₂ (X)**, **FiCO₂ (X)**, or **RR (CO₂) (X)**) and then set the limits.

NOTE

X represents the unit of measure.

Deactivating the apnea alarm

NOTE

This feature is meant to be used when ending CO₂ monitoring. It should not be used during active CO₂ monitoring.

This setting can be enabled in **Care unit settings**. Care unit settings are password protected. If it has been enabled, there will be a selection in the CO₂ **Settings** menu that allows you to deactivate the alarm:

1. Select the CO₂ parameter window.
2. Select **Settings**.
3. Select **Deactivate apnea alarm**.

WARNING

PATIENT SAFETY. With deactivated **Apnea** alarm, keep the patient under close surveillance.

NOTE

When the alarm is deactivated, there will be no audible or visual **Apnea** alarm indications. The alarm is automatically reactivated if CO₂ vitals signs are detected and alarm condition is met again.

NOTE

EtCO₂, FiCO₂, and respiration rate are not trended while apnea is deactivated.

Apnea alarm deactivation with the pause audio key

Apnea alarms can be deactivated with the pause audio key if **Allow alarm deactivation with the Audio Pause key for: Apnea (CO₂/Imped.)** check box has been selected in the **Care unit settings**. This setting is password protected.

For more information, see the supplemental information provided in the appendices.

Selecting CO₂ average

NOTE

LoFlo CO₂ micro-module only.

You can select a time window that is used to select the displayed CO₂ value. The highest peak EtCO₂ value within the time window is selected as the CO₂ value displayed.

1. Select the CO₂ parameter window.
2. Select **Settings**.
3. Select the appropriate radio button for **CO2 average (s)**.

Selecting the FiO₂ level

NOTE

LoFlo CO₂ micro-module only.

The presence of a large concentration of oxygen causes the CO₂ level to appear lower than the actual value. Use this option to compensate for the presence of O₂.

1. Select the CO₂ parameter window.
2. Select **Settings**.
3. Select the appropriate radio button for **FiO2 level (%)**: **21-40** or **40-100**.

Selecting the N₂O level

NOTE

LoFlo CO₂ micro-module only.

The presence of N₂O causes the CO₂ value to appear higher than the actual value. Use this option to compensate for the presence of N₂O.

1. Select the CO₂ parameter window.
2. Select the **Settings** tab.
3. Select the appropriate radio button for **N2O level (%)**: **0-40** or **40-80**.

Selecting the apnea alarm limit

The apnea alarm can be enabled to select a time delay before an apnea alarm is generated. The delay is defined with the **Apnea (CO₂) (X)** setting. **X** represents the unit of measure. If anything other than the default (20 seconds) is selected, the number of seconds selected for the delay displays in the parameter window.

1. Select the CO₂ parameter window.
2. Select **Alarms**.
3. Set the appropriate value for **Apnea (CO₂) (X)**.

Zeroing the LoFlo Sidestream Module

When the message **CO2 zero required** appears in the alarm messages area, or the message **Zero required** appears in the CO₂ parameter window, the LoFlo Sidestream Module needs to be zeroed.

NOTE

For best results, allow five minutes for module warm-up before starting the zero.

You should also zero the LoFlo Sidestream Module after connecting or reconnecting a sample line.

1. Disconnect the patient from CO₂ monitoring.
2. Connect the LoFlo Sidestream Module and, if necessary, wait until the sensor warm-up message disappears.
3. Connect a LoFlo sampling accessory to the LoFlo Sidestream Module. Ensure that the accessory is exposed to room air and away from all sources of CO₂, including the ventilator, the patient's breath, and your own breath.
4. Select the CO₂ parameter window.
5. Select the **Zeroing** tab.
6. Select **Zero to room air**.

A status message **Zero OK** appears in the **Zeroing** window when the zero is complete. This message disappears automatically.

7. Reconnect the patient to resume CO₂ monitoring.

Preventing care area pollution

When N₂O and volatile anesthetics are used, prevent care area pollution by connecting the sample gas outlet to the scavenging system.

Connecting to scavenging systems

The gas exhaust may be scavenged using the scavenging adapter package.

1. Remove the exhaust tube from the package.
2. Attach the connector end of the exhaust tube to the exhaust port.
3. Install the exhaust adapter into an open scavenging system, following the manufacturer's recommended procedure.

NOTE

Do not use a strong vacuum scavenging system.

4. Drape the exhaust tube so that it does not interfere with the work area.

Stopping the CO₂ measurement

1. Remove the added adapters from the patient's breathing circuit and gas scavenging, or remove the cannula from a non-intubated patient.
2. Check the patient's breathing circuit to ensure it is reassembled properly.

3. Remove the sample cell and discard the sampling kit.
4. Remove all components of LoFlo CO₂ micro-module or Microstream CO₂ micro-module from the Carescape ONE when it is not in use.

Basics of CO₂ measurement

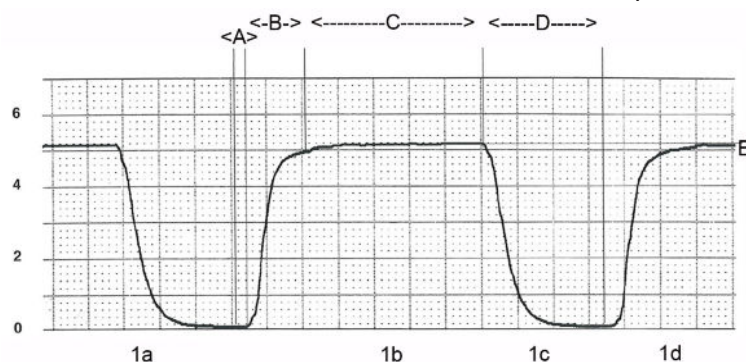
Normal CO₂ waveform

The CO₂ waveform is referred to as capnogram and it reflects the different stages in breathing. The capnogram of a healthy patient under controlled ventilation has a normal shape. Changes in the CO₂ waveform may indicate compromised patient respiratory and/or circulatory function or improper mechanical ventilator functionality.

The origin of the CO₂ waveform

The following illustration shows a normal capnogram. In this illustration, the letters indicate the following:

- A: The gas first exhaled is from the anatomical and apparatus dead-space. It contains no CO₂ because it has not been in the alveoli and no gas exchange has taken place.
- B: Briefly, the exhaled gas is a mixture of gas from the anatomical dead-space and gas from the alveoli.
- C: A plateau is reached when the gas exhaled is entirely from the alveoli. The end-tidal CO₂ (EtCO₂) concentration is measured at the end of this plateau.
- D: When the next inspiration starts the capnogram rapidly falls towards the baseline. The minimum level of CO₂ measured during the inspiratory phase is called the inspired CO₂ concentration.
- E: With a scale, the height of the capnogram tells you the end-tidal CO₂ concentration. EtCO₂ is automatically calculated and displayed in numbers. EtCO₂ approximates the alveolar CO₂ concentration because it is measured when the patient exhales virtually pure alveolar gas.



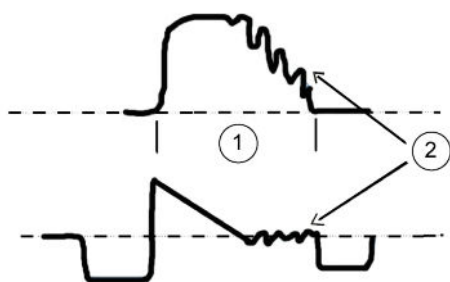
- 1a and 1c = inhalation
- 1b and 1d = exhalation

Dips in capnogram

The dips seen in the capnogram during expiration are related to the sidestream gas sampling, the continuous gas flow to the Y-piece, and patient's cardiac contractions, which cause intra-thoracic pressure changes and therefore flow variations.

The alterations in expired CO₂ waveform are cardiogenic movements of exhaled and circuit gas at the sidestream gas sampling site. When the respiratory gas flow drops below the gas sampling rate, a variable mixture of CO₂-free fresh gas and exhaled CO₂-rich gas is sampled. This causes variations in sampled CO₂ concentrations.

In the illustration below, the CO₂ waveform is the one on top, and flow is the lower waveform.



1. Expiration
2. Cardiogenic oscillations

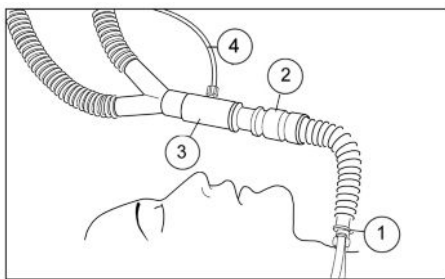
Cardiogenic oscillations appear when:

- A continuous fresh gas flow is fed into the patient Y-piece.
- Sidestream gas sampling is done at the Y-piece.
- The patient is ventilated with a long expiration time or low respiration times, and when there is a long zero flow at end-expiration for some other reason.

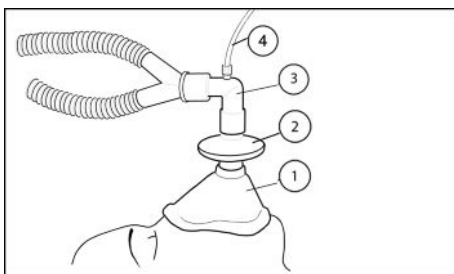
CO₂ measurement practicalities

Prevention of breathing system contamination

You can use a microbial filter between the endotracheal tube and the airway adapter. Change the filter for every patient. Change the patient circuit at intervals given in the circuit manufacturer's documentation, and according to your hospital protocols. The following illustrations show examples of placement.



1. Tracheostomy tube with 15 mm connector
2. Heat and Moisture Exchanger (HME)
3. Airway adapter
4. Sample line



1. Mask
2. Bacterial filter
3. Airway adapter
4. Sample line

How to prevent effects of humidity

Mechanical ventilation with active humidification system used in intensive care increases the humidity in the breathing system. More humidity and heat enter the circuit from the CO₂ absorber and from the air exhaled by the patient. During low flow anesthesia, more rebreathed gas circulates through the CO₂ absorber. Water traps placed in the inspiratory and expiratory limbs of the breathing system are useful for collecting condensed water from the breathing system during mechanical ventilation with active humidification system or long-lasting anesthesia.

CO₂ troubleshooting

Problem	Solution
CO ₂ waveform seems abnormal.	• Check the patient: ◦ Check for any change in patient condition. ◦ If the patient has a cannula, check for proper placement of the nasal prongs. ◦ If the patient is breathing through the mouth, ensure that an oral/nasal accessory is used. ◦ Abnormal waveforms can be seen if the patient is talking. • Check the sample lines and airway adapters. Replace if necessary.

Problem	Solution
Elevated baseline.	- Check the patient status. - Check the LoFlo Sidestream Module or the Microstream CO₂ micro-module. - Make sure the patient is not breathing CO₂. Check that the amount of fresh gas is sufficient for the patient, and check that the CO₂ absorber is in good condition. - Make sure the sample cell is properly connected (a click is heard upon connection) before zeroing. - If the elevated baseline is seen when the accessory is sampling room air, perform a zero.
Excessive secretions in sample lines.	- Check the orientation of the airway adapter port. - Use accessories with dehumidification tubing. - If the message Sample line blocked appears, replace the sample lines and airway adapters.
Measurement is not working.	- With LoFlo CO₂: check the LoFlo Sidestream Module and adapter positioning. - With Microstream CO₂: check the micro-module and positioning.
LoFlo CO ₂ or Microstream CO ₂ micro-module is not working.	Contact qualified service personnel.
Readings seem inaccurate.	- Check the patient status. - Check that the gas exhaust line is not kinked or blocked. - Check the breathing circuit for possible leaks.
Why can we see dips in the capnogram during expiration?	- Dips in the capnogram can be due to patient conditions. “Clefts” in the capnogram are seen as action of muscle relaxant is impacted by spontaneous ventilation. - The dips seen in the capnogram during expiration may be related to the sidestream gas sampling, the continuous gas flow to the Y-piece, and patient’s cardiac contractions, which cause intra-thoracic pressure changes and therefore flow variations. A pressure transducer in the LoFlo Sidestream Module minimizes flow variations by measuring and adjusting for changes in airway pressures.
EtCO ₂ value is higher than expected	- Possible reasons are some surgical procedures such as laparoscopy. During laparoscopic surgery CO₂ may be used to inflate the abdomen to elevate the abdominal wall, which may lead to an increase in EtCO₂ due to enhanced CO₂ absorption from the peritoneal cavity into circulation.¹ - Ensure that ventilator settings are appropriate for the patient’s condition to prevent hypoventilation and CO₂ build-up. - Perform the gas calibration check. See the instructions in the service manuals.
FiCO ₂ value is higher than expected	- Possible technical reasons are faulty unidirectional valves, exhausted soda lime, and inadequate O₂ flow in non-rebreathing systems.² - Check and replace the CO₂ absorber, if necessary. - Inspect the breathing circuit, including valves and connections, regularly for leaks or assembly errors. - Evaluate and adjust the fresh gas flow rates to ensure adequate CO₂ elimination. - Ensure that ventilator settings are appropriate for the patient’s condition to prevent hypoventilation and CO₂ build-up. - Check dead space in the circuit.

Problem	Solution
Why is the EtCO ₂ value considerably lower than the CO ₂ partial pressure determined by blood gas analysis?	• EtCO₂ values are always lower than paCO₂ values measured by blood gas analysis. • The typical clinical reasons are dead-space ventilation, ventilation/perfusion mismatch, a drop in cardiac output, alveolar shunts, and incomplete emptying of the alveoli. • The EtCO₂ - paCO₂ gradient can be an indicator of a clinical condition such as an increase in alveolar dead space. • Also check the integrity of the breathing circuit; blood-gas analysis corrected to a lower temperature in case of hypothermia.
For LoFlo CO ₂ micro-module, the sample cell is inserted, but the pump does not turn on and the Check Adapter message is displayed.	• Check that the sample cell is fully inserted. • The LoFlo Sidestream Module may need to warm up to be detected. • Check that the LoFlo Sidestream Module is connected to the LoFlo CO₂ micro-module. • Check the sample cell of the accessory for damage or occlusion.
¹ Gutt, C.N., Oniu T., Mehrabi A., Schemmer P., Kashfi A., Kraus T., and Büchler M.W. "Circulatory and Respiratory Complications of Carbon Dioxide Insufflation" Digestive Surgery 2004;21:95–105. ² Solhpour, A., Tajbakhsh, A., Safari, S. et al. "Inadvertent severe hypercapnia during general anesthesia: drop-in oxygen saturation or electrocardiography changes; which one warns us earlier?" Ain-Shams Journal of Anesthesiology 2022; 14, 9.	

Trends

Viewing numeric trends

Numeric trends contain 3 tabs with 24 hours of trend data. The lowest row shows the time indication and the top of the view shows the highest priority realtime waveform. You cannot configure the layout of the **Numeric Trends** view.

1. Select  from the main menu.
2. Select a parameter group tab to view the trends:
 - **Vital**
 - **IP**
 - **Temp & Gases**

To see more numeric trend data, scroll the data in horizontal direction.

Changing the time interval of numeric trends

Numeric trends display values according to the selected time interval. Numeric trends are updated with averaged measurement data once a minute independent of the selected time interval.

1. Select  from the main menu.
2. Select the **Settings** tab.
3. Select a value for **Time interval (min)**.

For example, a 5 minute interval will show data for every 5 minutes, and a 30 minute interval will show data for every 30 minutes. The data is displayed in columns on the screen.

About snapshots and graphic trends

The Carescape ONE records snapshots when it is operating as a standalone monitor. In the wireless transport mode, the host monitor forwards snapshots to the central station. Snapshots are only viewable locally on the host monitor when the Carescape ONE is connected to a host monitor as an acquisition platform.

Graphic trends are only viewable on the host monitor when the Carescape ONE is connected to a host monitor as an acquisition platform. Only numeric trends are available on the Carescape ONE when it is operating as a standalone monitor. In the wireless transport mode, the host monitor forwards graphic and numeric trends to the central station.

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Cleaning, disinfection, and care

About cleaning, disinfection, and care instructions

The following care information applies to devices, device components, supplies, and accessories manufactured by GE HealthCare. You can check the compatibility from the supplemental information provided.

For cleaning and disinfection information that applies to devices, device components, and supplies manufactured by GE HealthCare, see the cleaning and disinfection supplement. For details about cleaning and disinfecting accessories manufactured by GE HealthCare, see the instructions for use in the accessory package.

For cleaning, disinfection, and care information for devices, device components, supplies, and accessories made by manufacturers other than GE HealthCare, contact the manufacturer or see the applicable instructions for use provided by the manufacturer.

In addition, always follow your care unit's policy and procedures for cleaning, disinfection, and care.

If liquid is spilled on any equipment, follow your care unit's policy and procedures and the cleaning, disinfection, and care information listed in this section.

Care

Care safety precautions

Care warnings

WARNING

EQUIPMENT FAILURE. Regular preventive maintenance should be carried out as indicated in the device service manual. Failure to implement the maintenance schedule may cause equipment failure and possible health hazards.

WARNING

SAFETY HAZARD. To avoid risks to personnel and patient, or damage to the equipment, only perform maintenance procedures described in this manual. Unauthorized modifications can lead to safety hazards.

WARNING

ELECTRIC SHOCK. Non-medical equipment does not provide the same level of protection against electrical shock. Do not touch the patient and any part of non-medical equipment at the same time. Some examples of non-medical equipment are laser printers and non-medical computers.

WARNING

EQUIPMENT DAMAGE. If liquid has accidentally entered the system or its parts, disconnect the power cord from the power supply, remove the battery, and have the equipment serviced by qualified service personnel.

WARNING

ENVIRONMENTAL HAZARD. Cleanup and disposal of broken displays must be in compliance with the safety and waste control guidelines regulating this product.

Disposal warnings

WARNING

EXPLOSION HAZARD. Do not incinerate a battery or store at high temperatures. Serious injury or death could result.

Disposal cautions

CAUTION

DISPOSAL. At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of each product. If you have any questions concerning disposal of a product, please contact GE HealthCare or its representatives.

CAUTION

PACKAGING DISPOSAL. Dispose of the packaging material, observing the applicable waste control regulations.

Care schedules

See the service manual for more comprehensive checks.

Daily checks

- Check that the accessories, cables, cable connectors, micro-modules, Carescape ONE, and display parts are clean and intact. Check the following:
 - No loose connectors, cracks, or other visible sign of damage.
 - No signs of fluid contamination or stains.
 - Product labeling, markings, and symbols are intact and readable.
 - Monitor and the connected devices are properly attached to the mounts.
- Check that there are no messages indicating that the Carescape ONE or micro-modules are not functioning.
- Check the charge of the battery.

NOTE

If you notice any issues or technical alarms related to the micro-modules, replace the micro-module and contact qualified service personnel.

Check every 24 months

- Check the calibration of NIBP.

For calibration instructions, see the service manual.

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Messages

Messages related to ECG measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• A Fib	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• Accel. Ventric.	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• Arrh off	• param.	The arrhythmia detection level is set to Off .	• If arrhythmia detection is needed, set the detection level to Full or Lethal .
• Arrhythmia paused • Arrh paused	• al. area • wavef.	ECG channels have not been available for analysis for the last 20 seconds due to excessive artifact, or the internal HR calculation has not been updated for the last 30 seconds, or in single lead analysis when arrhythmia detection is set to Full or Lethal , the ECG 1 lead has not been active for the last 5 seconds.	• Check the patient status. • Check electrode placement. • Prepare the patient's skin at electrode sites. • Change or move electrodes.
• Artifact	• wavef.	Muscle artifact, high or low frequency noise, or pacemaker artifact.	• Check electrode contact. • Check lead placement. • Perform skin preparation. • Reposition/replace electrodes. • Request the patient to remain still. • Check if any electrical devices are too close to the patient.
• Asystole	• al. area, param., wavef.	Physiological alarm.	• Check the patient status.
• Bigeminy	• al. area, wavef.	Physiological alarm.	• Check the patient status.

Message	Location	Possible causes	Suggested actions
• Brady • HR low • HR(ECG) low	• al. area	Physiological alarm. Measurement values are equal to or outside the basic or critical alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Check device • ECG malfunction	• wavef. • al. area	Hardware or software fault in the TruSignal ECG micro-module: • Cable fault • No updated data • Data sample drift • Configuration failure	• Reconnect the TruSignal ECG micro-module. • Replace the TruSignal ECG micro-module. • If the problem persists, contact qualified service personnel.
• Couplet	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• Device overheating • Move ECG device to a cooler location	• wavef. • al. area	The surface temperature of the TruSignal ECG micro-module is too high.	• Check the TruSignal ECG micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the TruSignal ECG micro-module.
• ECG device failure: Call service	• al. area	TruSignal ECG micro-module start-up or initialization failure.	• Reconnect the TruSignal ECG micro-module. • Replace the TruSignal ECG micro-module. • If the problem persists, contact qualified service personnel.
• ECG device overheated. Shutting down	• al. area	Carescape ONE turns off the TruSignal ECG micro-module because its surface temperature is too high.	• Check the TruSignal ECG micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the TruSignal ECG micro-module.
• ECG measurements removed	• al. area	TruSignal ECG micro-module has been removed.	• Check all connections and reconnect as required.
• Frequent PVCs	• al. area	Physiological alarm.	• Check the patient status.
• Frequent SVCs	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• Identical ECG device	• al. area	There are two TruSignal ECG micro-modules.	• Remove one TruSignal ECG micro-module.
• Insufficient power for ECG device	• al. area	There is not enough power for the TruSignal ECG micro-module.	• Remove other connected devices if possible.
• Irregular	• al. area, wavef.	Physiological alarm.	• Check the patient status.

Message	Location	Possible causes	Suggested actions
• Lead off • LA/L lead off • LL/F lead off • RA/R lead off • RL/N lead off • V2/C2 lead off • V3/C3 lead off • V4/C4 lead off • V5/C5 lead off • V6/C6 lead off • V/C lead off • Va/Ca lead off • Vb/Cb lead off	• al. area, wavef.	One or more leadwires or electrodes disconnected. Other ECG leads are available for arrhythmia detection.	• Check the leadwire and electrode connections.
• Lead changed	• wavef.	The monitor automatically switches the ECG1 waveform selection to a measurable ECG Lead (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 or V6) if the current ECG1 waveform is not measurable. This message also appears when the user changes the ECG1 lead selection.	• Note that the ECG waveform will be from the lead selected for the ECG1 lead. Check the lead.
• Leads off	• al. area, wavef.	One or more of the connected leadwires is disconnected and arrhythmia detection is not possible.	• Check the connections.
• Learning	• wavef.	ECG algorithm is in learning phase, message shown e.g. when ECG measurement is started.	• No action required.
• Missing Beat	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• Multifocal PVCs	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• No beat sound	• al. area	Beat source is determined to be Art or Fem 8 while FloTrac CCO is in use. FloTrac CCO does not support beat detection.	• Consider using another beat source.
• Noisy ECG • Noise	• al. area • wavef.	Arrhythmia alarm category has been set to Off in the Arrhythmia settings of the ECG menu, and the ECG channels have not been available for analysis for the last 20 seconds due to excessive noise; the internal HR calculation has not been updated for the last 30 seconds, which compromises the accuracy of detecting events; or in single lead analysis when arrhythmia detection is set to Off , the ECG 1 lead has not been active for the last 5 seconds.	• Check and remove the source of excessive noise if possible.

Message	Location	Possible causes	Suggested actions
• Pause	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• R on T	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• ST XXX high / ST XXX low where XXX = ECG lead label	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• SV Tachy	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• Tachy • HR high • HR(ECG) high	• al. area	Physiological alarm. Measurement values are equal to or outside the basic or critical alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Trigeminy	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• V Brady	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• V Fib / V Tach	• al. area, param., wavef.	Physiological alarm.	• Check the patient status.
• V Tach	• al. area, param., wavef.	Physiological alarm.	• Check the patient status.
• VT > 2	• al. area, wavef.	Physiological alarm.	• Check the patient status.
• VT off	• param.	NICU software package: V Tach arrhythmia detection is set to off.	• If V Tach arrhythmia detection is needed, select a priority other than Off.

Messages related to impedance respiration measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• Apnea (Imped.) • APN • Apnea	• al. area • param. • wavef.	No breathing detected.	• Check the patient status. • Check the ventilator and breathing status.
• Apnea deactivated	• param.	The case has just been started/patient admitted on the monitor, or the measurement has just been started.	• Wait. The message disappears after the respiration rate is ≥ 3 /min.

Message	Location	Possible causes	Suggested actions
• Check device • Imped. malfunction	• param., wavef. • al. area	Hardware or software fault in the TruSignal ECG micro-module: • Cable fault • Configuration failure • No updated data • Data sample drift	• Reconnect the TruSignal ECG micro-module. • Replace the TruSignal ECG micro-module. • If the problem persists, contact qualified service personnel.
• Lead I failed	• param., wavef.	Lead I has been selected for measurement, but the RA or LA electrode is off or is not adhered to the patient well enough to get a sufficient signal for respiration monitoring.	• Check the electrodes and their connections. • You may need to prep the skin and replace the electrode.
• Lead II failed	• param., wavef.	Lead II has been selected for measurement, but the RA or LL electrode is off or is not adhered to the patient well enough to get a sufficient signal for respiration monitoring.	• Check the electrodes and their connections. • You may need to prep the skin and replace the electrode.
• Lead RL-LL failed	• param., wavef.	Lead RL-LL has been selected for measurement, but the RL or LL electrode is off or is not adhered to the patient well enough to get a sufficient signal for respiration monitoring.	• Check the electrodes and their connections. • You may need to prep the skin and replace the electrode.
• Measurement off • OFF	• param., wavef. • param.	ECG leads not connected to the patient. Measurement has been turned off from the setup menu.	• Connect the ECG leads to the patient to start the impedance respiration measurement. • Turn on the measurement from the setup menu.
• Relearning	• param., wavef.	The patient's breathing pattern is being relearned because the measurement has just been turned on, the user has activated relearning, a lead has been changed, or a lead has been reconnected after a lead fail situation.	• Wait until the message disappears.
• Resp (Imped.) measurement paused • Measurement paused	• al. area • wavef.	This alarm is triggered when apnea alarm is enabled and respiration rate has been invalid for the last 18 seconds in the NICU software package or for the last 50 seconds in other software packages due to: • A lead fail. • Ongoing automatic relearning. • Impedance respiration malfunction.	• Check the patient status. • Check the electrodes and their connections. • Acknowledge the alarm.
• RR (Imped.) high (s) / RR (Imped.) low (s)	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.

Messages related to SpO₂ measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• Artifact	• param.	Artifact detected.	• Check sensor contact. • Reposition or replace sensor. • Request the patient to remain still.
• Check device • SpO₂ malfunction	• param. • al. area	SpO ₂ micro-module malfunction. No SpO ₂ data detected.	• Check the SpO₂ micro-module. • Replace if needed.
• Check probe • Check SpO₂ probe	• param. • al. area	There is no detectable SpO ₂ signal, the sensor is faulty or is detached from the patient. With Nellcor SpO ₂ micro-module this message also appears when the saturation updates exceed 30 seconds, the pulse rate is lost, or the pulse timeout condition occurs.	• Check the sensor and connections. • Check the patient status.
• Demo mode • SpO₂ Demo mode	• param. • al. area	Masimo SpO ₂ micro-module is in demo mode.	• Exit Demo mode. See the supplemental information provided in the appendices.
• Expiring cable	• param.	Masimo SpO ₂ micro-module has detected that the interconnect cable is near its expiration date.	• Replace the interconnect cable.
• Expiring probe	• param.	Masimo SpO ₂ micro-module has detected that the sensor or adhesive sensor is near its expiration date.	• Replace the sensor or adhesive sensor.
• Faulty cable • SpO₂ faulty cable	• param. • al. area	Masimo SpO ₂ micro-module has detected a defective interconnect cable.	• Replace the interconnect cable.
• Faulty probe • SpO₂ faulty probe • Faulty adhesive SpO₂ probe	• param. • al. area	The sensor has failed. The adhesive sensor has failed.	• Replace the sensor. • Replace the adhesive sensor.
• Identical SpO₂ device	• al. area	You can only have one SpO ₂ micro-module in the system (TruSignal SpO ₂ , Masimo SpO ₂ , or Nellcor SpO ₂).	• Remove all but one SpO₂ micro-module.

Message	Location	Possible causes	Suggested actions
• Incompatible cable • Incompatible SpO2 cable	• param. • al. area	Masimo SpO ₂ micro-module has detected that an incompatible or unrecognized interconnect cable has been connected.	• Connect a Masimo compatible interconnect cable.
• Incompatible probe • Incompatible SpO2 probe • Incompatible adhesive SpO2 probe	• param. • al. area	The sensor is not compatible or it is not recognized. Adhesive sensor is not compatible or it is not recognized.	• Replace the sensor with a compatible one. See the supplemental information provided. • If the problem persists, contact qualified service personnel.
• Incompatible SpO2 device	• al.area	SpO₂ micro-module startup or initialization failure. SpO₂ micro-module hardware fault.	• Reconnect the SpO₂ micro-module. • Replace the SpO₂ micro-module. • If the problem persists, contact qualified service personnel.
• Insufficient power for SpO2 device	• al. area	There is not enough power for the SpO ₂ micro-module.	• Connect the acquisition platform to a host or use mains power. • Charge the Carescape ONE battery.
• Low perfusion	• param.	Low perfusion at the measurement point.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• Low signal	• param.	The quality of the signal is questionable.	• Check the sensor placement and the patient status.
• Low signal quality	• param.	The quality of the signal is questionable.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• Motion detected	• param.	Patient movement detected.	• Reposition sensor.
• Move SpO2 device to a cooler location	• al. area	Surface temperature of the SpO ₂ micro-module is too high.	• Check the SpO₂ micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the SpO₂ micro-module.
• No cable • No SpO2 cable	• param. • al. area	Interconnect cable is not connected to the Masimo SpO ₂ micro-module.	• Check the connection between the interconnect cable and SpO₂ micro-module.
• No probe • No SpO2 probe • No adhesive SpO2 probe	• param. • al. area	Sensor is not connected to the SpO₂ micro-module. Adhesive sensor is not connected to the SpO₂ micro-module.	• Check the connection between the sensor and the SpO₂ micro-module.

Message	Location	Possible causes	Suggested actions
PR(SpO2) high / PR(SpO2) low	al. area	Measurement values are equal to or outside the alarm limits.	- Check the patient status. - Adjust alarm limits if necessary.
Probe initializing	param.	Masimo SpO2 micro-module has detected that the sensor is initializing.	SpO2 monitoring will begin after initialization is complete.
- Probe off - SpO2 probe off	- param. - al. area	The sensor may be defective or it is not connected to the patient.	- Check the patient status. - Reposition the SpO2 sensor. - Replace the SpO2 sensor.
Pulse search	param.	The measurement is starting normally. Defective or damaged sensor or cable. Sensor is off of the patient. Detection of a repeatable pulse has stopped. Pulse is not recognized by the algorithm due to a low amplitude signal.	- Wait for waveforms and parameter values to display. - Check the sensor and cable. - Reposition or replace sensor.
- Replace cable - Replace SpO2 cable	- param. - al. area	Masimo SpO2 micro-module has detected that the interconnect cable has expired.	Replace the interconnect cable.
- Replace probe - Replace SpO2 probe - Replace adhesive SpO2 probe	- param. - al. area	Masimo SpO2 micro-module has detected that the sensor has expired. Masimo SpO2 micro-module has detected that the adhesive sensor has expired.	Replace the sensor.
SpO2 device failure: Call service	al. area	SpO2 micro-module startup or initialization failure.	- Reconnect the SpO2 micro-module. - Replace the SpO2 micro-module. - If the problem persists, contact qualified service personnel.
SpO2 device overheated Shutting down	al. area	The surface temperature of the SpO2 micro-module is too high and Carescape ONE turns the SpO2 micro-module off.	- Check the SpO2 micro-module placement and ensure that it is not covered by anything that might lead to overheating. - Replace the SpO2 micro-module.
SpO2 high / SpO2 low	al. area	Measurement values are equal to or outside the alarm limits.	- Check the patient status. - Adjust alarm limits if necessary.
SpO2 measurement removed	al. area	SpO2 micro-module is disconnected.	Connect an SpO2 micro-module.

Messages related to rSO₂ measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area

Message	Location	Possible causes	Suggested actions
• rSO₂ measurement disconnected	• al. area	INVOS rSO ₂ micro-module is connected to a Carescape ONE that is not connected to a host monitor.	• Acknowledge the alarm. • Disconnect the INVOS rSO₂ micro-module from Carescape ONE. To restart the measurement, connect Carescape ONE to the host monitor and then reconnect the micro-module to Carescape ONE.

Messages related to NIBP measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- report = report view
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• Calibrated	• param.	Channel calibrated successfully.	• Wait until the message disappears before starting a measurement.
• Calibrating	• param.	Calibration of a channel is in progress.	• No action required.
• Calibration error	• param.	Calibration has failed.	• Recalibrate. • If the problem persists, contact qualified service personnel.
• Call service	• param.	NIBP hardware fault in Carescape ONE.	• Contact qualified service personnel.
• Check NIBP	• al. area	Systolic and/or diastolic results missing.	• Check the patient status. • Check NIBP cuff and hoses. • Repeat the measurement.
• Control measurement	• param.	Pressure alarm limit exceeded.	• Allow measurement to complete. • Check the patient status.

Message	Location	Possible causes	Suggested actions
• Cuff occlusion	• param.	Occlusion during measurement or overpressured cuff.	• Check the cuff.
• Cuff loose	• param.	Loose cuff or cuff hose.	• Check the cuff and cuff hose. • If the problem persists, contact qualified service personnel.
• Cuff overpressure	• param.	NIBP cuff is squeezed during measurement and exceeded the pressure safety limits.	• Check NIBP cuff and hoses. • Repeat the measurement.
• Long meas. time	• param.	The measurement time is long. The triggering values vary according to the cuff type in use: • >2 min for adult/ child, 85 s for infant	• Check the patient status. • Check the cuff and hose connections. • If the problem persists, contact qualified service personnel.
• NIBP alarm limits changed	• al. area	The alarm limits have changed due to cuff size or profile change.	• Check that the cuff size is correct. • Check that the new alarm limits are correct. • Silence the alarm.
• NIBP cuff occlusion	• al. area	Occlusion during measurement or overpressured cuff.	• Check the cuff.
• NIBP cuff loose	• al. area	Loose cuff or cuff hose.	• Check the cuff and cuff hose. • If the problem persists, contact qualified service personnel.
• NIBP Dia high / NIBP Dia low • NIBP Mean high / NIBP Mean low • NIBP Sys high / NIBP Sys low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• NIBP auto stopped	• al. area	Automatic NIBP mode is stopped because of a loose cuff or cuff hose.	• Check the cuff and cuff hose. • Restart the Automatic NIBP mode.
• NIBP malfunction	• al. area	NIBP hardware fault in Carescape ONE.	• Contact qualified service personnel.
• NIBP over range • NIBP under range	• al. area	At least one measurement value (systolic, diastolic, or mean) is outside the NIBP display range.	• Start a new measurement. • Check the patient status.
• NIBP STAT stopped	• al. area	Continuous NIBP for 5 min mode is stopped because of a loose cuff or cuff hose.	• Check the cuff and cuff hose. • Restart the Continuous NIBP for 5 min mode.
• Select cuff size	• param.	Patient type has not been selected.	• Select the patient type from the NIBP settings.
• Zeroing	• param.	Zeroing is in progress.	• Wait until the zeroing is completed.
• Zero OK	• param.	Zeroing was successful.	• No action required.

Messages related to invasive pressures measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

NOTE

When an invasive pressure label is followed by an **X**, the **X** represents invasive pressure channel number.

Message	Location	Possible causes	Suggested actions
• > 220 /min • P8 PR over range	• al. area • param.	Pulse rate measurement is over range.	• Check the patient status. • Check the patient's pulse rate by alternative means. • Check the cable and connections. • Rezero the transducer.
• > 312 mmHg or > 42 kPa • Px over range	• param. • al. area	Measurement is over range, or the sensor or cable is faulty.	• Check the patient status. • Check the patient's pressure by alternative means. • Check the cable and connections. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Replace the micro-module. • If the problem persists, contact qualified service personnel.
• < -34 mmHg or < -5 kPa • Px under range	• param. • al. area	Measurement is under range, or the sensor or cable is faulty.	• Check the patient status. • Check the patient's pressure by alternative means. • Check the cable and connections. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Replace the micro-module. • If the problem persists, contact qualified service personnel.

Message	Location	Possible causes	Suggested actions
• Art X sys high / Art X sys low • Art X mean high / Art X mean low • Art X dia high / Art X dia low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Artifact	• param.	If Smart BP is enabled, this is normal behavior when zeroing, flushing, or sampling is performed. If Smart BP is not enabled, this message indicates that the measurement is disturbed by artifact. Systolic and diastolic numerics are also invalidated if an artifact event is detected while Smart BP is enabled.	• Check the patient status. • Check cable contact. • Minimize tubing length. • Rezero the transducer.
• Check device • P1 pressure malfunction • P2 pressure malfunction • P3 pressure malfunction • P4 pressure malfunction • P8 pressure malfunction	• param. • al. area	The micro-module has malfunctioned.	• Check the patient status. • Check connections. • If the problem persists, contact qualified service personnel.
• Check XXX waveform where XXX = invasive pressure channel label (Art 8 or Fem 8) • Check pressure • Waveform not stable	• al. area • param. • wavef.	FloTrac CCO micro-module cannot measure invasive pressure values.	• Check the patient status. • Check the arterial waveform. • Check connections. • Rezero the transducer.
• CPP (X) (where X = 1) high / CPP (X) (where X = 1) low to CPP (X) (where X = 4) high / CPP (X) (where X = 4) low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• CVP 1 mean high / CVP 1 mean low to CVP 4 mean high / CVP 4 low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Device overheating • Move IP/CCO device to a cooler location	• param. • al. area	The FloTrac CCO micro-module temperature is too high.	• Check the FloTrac CCO micro-module placement and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the FloTrac CCO micro-module.

Message	Location	Possible causes	Suggested actions
• Device overheating • Move pressure device 1/2 to a cooler location • Move pressure device 3/4 to a cooler location	• param. • al. area	The surface temperature of the TruSignal Pressure micro-module is too high.	• Check the TruSignal Pressure micro-module placement and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the TruSignal Pressure micro-module.
• Disconnected • Art X disconnect	• param. • al. area	No arterial invasive pressure is detected.	• Check the patient status. • Check connections. • If pressure drops because of zeroing, perform the zeroing process.
• Disconnected • Fem X disconnect	• param. • al. area	No arterial invasive pressure is detected.	• Check the patient status. • Check connections. • If pressure drops because of zeroing, perform the zeroing process.
• Disconnected • UAC X disconnect (where X = 1 to 4)	• param. • al. area	No arterial invasive pressure is detected.	• Check the patient status. • Check connections. • If pressure drops because of zeroing, perform the zeroing process.
• Fem X sys high / Fem X sys low • Fem X mean high / Fem X mean low • Fem X dia high / Fem X dia low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• FemV 1 mean high / FemV 1 mean low to FemV 4 mean high / FemV 4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• ICP 1 mean high / ICP 1 mean low to ICP 4 mean high / ICP 4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Identical IP/CCO devices	• al. area	There are two or more FloTrac CCO micro-modules connected.	• Remove all but one FloTrac CCO micro-module.
• Identical pressure devices	• al. area	There are three or more TruSignal Pressure micro-modules connected.	• Remove all but two TruSignal Pressure micro-modules.
• Insufficient power for IP/CCO device	• al. area	There is not enough power for the FloTrac CCO micro-module.	• Remove other connected devices.

Message	Location	Possible causes	Suggested actions
• IP/CCO device overheated. Shutting it down.	• al. area	Carescape ONE turns off the FloTrac CCO micro-module because the surface temperature is too high.	• Check the FloTrac CCO micro-module placement and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the FloTrac CCO micro-module.
• IP/CCO measurement removed	• al. area	FloTrac CCO micro-module has been removed or active pressure channel becomes inactive.	• Check all connections and re-connect as required.
• Sensor • [Invasive pressure channel label] X sensor disconnected, where [Invasive pressure channel label] = Art, CVP, Fem, FemV, ICP, LAP, P, PA, RAP, RVP, UAC, or UVC	• param. • al. area	The transducer detected a disconnection.	• Check the patient status. • Check connections. • Acknowledge the alarm if you are intentionally disconnecting the invasive pressure line.
• Sensor • [Invasive pressure channel label] X sensor failed, where [Invasive pressure channel label] = Art, CVP, Fem, FemV, ICP, LAP, P, PA, RAP, RVP, UAC, or UVC	• param. • al. area	Faulty sensor or transducer.	• Check cable and transducer connections. • Replace the transducer.
• PX not zeroed	• param.	There is at least one invasive pressure channel that has not been zeroed.	• Perform zeroing for all channels.
• LAP 1 mean high / LAP 1 mean low to LAP 4 mean high / LAP 4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• PX standby	• param.	The IP channel has been set to standby.	• Reactivate the channel by selecting Activate P1 to Activate P4. • Channels are reactivated if pressures have remained between 10 and 250 mmHg for 10 seconds or longer.
• P1 mean high / P1 mean low to P4 mean high / P4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.

Message	Location	Possible causes	Suggested actions
• PA 1 sys high / PA 1 sys low to PA 4 sys high / PA4 sys low • PA 1 mean high / PA 1 mean low to PA 4 mean high / PA 4 mean low • PA 1 dia high / PA 1 dia low to PA 4 dia high / PA 4 dia low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• PR [Invasive pressure channel label] high X / PR [Invasive pressure channel label] low X, where [Invasive pressure channel label] = Art, Fem, or UAC	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Pressure device failure: Call service	• al. area	Faulty micro-module.	• Contact qualified service personnel.
• Pressure device initializing	• al. area	New software is being downloaded to the TruSignal Pressure micro-module.	• Wait. The message will clear when the download is complete.
• Pressure device overheated. Shutting it down	• al. area	Carescape ONE turns off the micro-module because its surface temperature is too high.	• Check the micro-module placement and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the micro-module.
• Pressure measurement removed	• al. area	The micro-module has been removed or active pressure channel becomes inactive.	• Check all connections and reconnect as required.
• Pressure sensed	• param.	Pressure has been sensed during zeroing.	• Open the venting stopcock to air. • Re-zero.
• PX zeroing failed	• param.	The channel has not been zeroed successfully.	• Repeat the zeroing.
• RAP 1 mean high / RAP 1 mean low to RAP 4 mean high / RAP 4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• RVP 1 mean high / RVP 1 mean low to RVP 4 mean high / RVP 4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.

Message	Location	Possible causes	Suggested actions
• UAC 1 sys high / UAC 1 sys low to UAC 4 sys high / UAC 4 sys low • UAC 1 mean high / UAC 1 mean low to UAC 4 mean high / UAC 4 mean low • UAC 1 dia high / UAC 1 dia low to UAC 4 dia high / UAC 4 dia low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• UVC 1 mean high to UVC 4 mean high / UVC 1 mean low to UVC 4 mean low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Zeroed	• param.	Zeroing was successful.	• No action required. Message is automatically removed after 10 seconds.
• Zeroing	• param.	IP channel is currently being zeroed.	• No action required. Message is automatically removed and replaced with the zeroing results after completion.
• Zero ICP separately	• al. area	The ICP channel must be zeroed separately from all other invasive pressures.	• Zero the channel using the Zero option found under the ICP channel setup menu.

Messages related to temperature measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• Calibration fail • T1 calibration fail / T2 calibration fail	• param. • al. area	Calibration of a channel failed.	• Check connections. • If the problem persists, contact qualified service personnel.
• Check device • Temperature malfunction	• param. • al. area	Hardware or software fault in the TruSignal Temperature micro-module: • Cable fault • Data out of expected range	• Reconnect the TruSignal Temperature micro-module. • Replace the TruSignal Temperature micro-module. • If the problem persists, contact qualified service personnel.

Message	Location	Possible causes	Suggested actions
• Device overheating • Move Temp device to a cooler location	• param. • al. area	The surface temperature of the TruSignal Temperature micro-module is too high.	• Check the TruSignal Temperature micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the TruSignal Temperature micro-module.
• Identical Temp device	• al. area	There are two TruSignal Temperature micro-modules.	• Remove one TruSignal Temperature micro-module.
• No sensor detected	• param.	No probe detected, or the probe is not compatible. Also when the temperature probe check fails.	• Check the probe and connections. • Ensure that you are using a compatible probe.
• Select parameters	• param.	No parameters have been selected to be shown in the parameter window.	• Select the displayed parameters from the temperature settings.
• T1 high / T1 low • T2 high / T2 low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• X-Y high where X-Y = T1-T2 or T2-T1	• al. area	Measured delta value is equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Temp measurement removed	• al. area	TruSignal Temperature micro-module has been removed or active temperature channel becomes inactive.	• Check all connections and reconnect as required.
• Temp device failure: Call service	• al. area	TruSignal Temperature micro-module startup or initialization failure.	• Reconnect the TruSignal Temperature micro-module. • Replace the TruSignal Temperature micro-module. • If the problem persists, contact qualified service personnel.
• Temp device overheated. Shutting down	• al. area	Carescape ONE turns off the TruSignal Temperature micro-module because its surface temperature is too high.	• Check the TruSignal Temperature micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the TruSignal Temperature micro-module.

Messages related to CCO measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area

Message	Location	Possible causes	Suggested actions
• CCO measurement discontinued	• al. area	The acquisition platform is disconnected from the host monitor while FloTrac CCO micro-module is used as the active CCO source.	• Acknowledge the alarm. • Disconnect the FloTrac CCO micro-module from Carescape ONE. To restart the CCO measurement, connect Carescape ONE to the host monitor and then reconnect the micro-module to Carescape ONE.

Messages related to CO₂ measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided in the appendices.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• Apnea (CO₂) • APN • Apnea	• al. area • param. • wavef.	No breathing detected. The alarm can only be triggered if the CO₂ micro-module has first detected three breaths within one minute.	• Check the patient status. • Wait. The message disappears after a breath is detected.
• Apnea deactivated	• param.	A new case has just been started/a new patient admitted, or the measurement has just been started and the apnea alarm is not active yet, or the user has deactivated the apnea alarm.	• Wait. The message disappears after 3 breaths are detected within one minute.
• Calibrating	• param.	Microstream CO ₂ micro-module calibration is in progress.	• No action required.
• Calibration error	• param.	Microstream CO ₂ micro-module calibration failed.	• Contact qualified service personnel.
• Calibration required	• param.	Microstream CO ₂ micro-module needs calibration.	• Contact qualified service personnel.
• Check CO₂ adapter • Check Adapter	• al. area • param.	There is an obstruction in the LoFlo receptacle sample cell, or the LoFlo receptacle sample cell is not within the optimal operating range for CO ₂ measurement.	• Ensure that the sampling line connector is correctly and fully inserted. • Check that the sample cell windows and receptacle windows do not have any foreign material on them. • Perform zeroing procedure to optimize the operation. • If the problem persists, replace the adapter.

Message	Location	Possible causes	Suggested actions
• Check sample line	• al. area • param.	Sample flow rate is lower or higher than the nominal flow due to an obstruction in the sample line or exhaust port, or a cut or split in the sample line. The filter in the sample line is completely saturated. If the situation persists for more than 2 minutes, the pump will turn off.	• Check the sample line and exhaust port for obstructions. • Check the sample line for cuts or splits and replace if necessary. • Remove the sample line and dispose of it following hospital protocol. • If the pump has shut off, disconnect then reconnect the accessory to restart the pump
• CO₂ device failure: Call service	• al. area	CO ₂ micro-module startup or initialization failure.	• Reconnect the CO₂ micro-module. • Replace the CO₂ micro-module. • Contact qualified service personnel.
• CO₂ device malfunction • Check device	• al. area • param.	CO ₂ micro-module startup or run-time failure.	• Reconnect the CO₂ micro-module. • Replace the CO₂ micro-module. • Contact qualified service personnel.
• CO₂ device overheated Shutting down	• al. area	The surface temperature of the LoFlo CO ₂ micro-module is too high and the Carescape ONE turns the measurement off.	• Check the LoFlo CO₂ micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the LoFlo CO₂ micro-module. • Contact qualified service personnel.
• CO₂ measurement purging • Purging	• al. area • param.	There is a blockage in the Microstream CO ₂ micro-module sample line.	• Remove the blockage. • Replace the sample line.
• CO₂ measurement removed	• al. area	The CO ₂ micro-module has been disconnected from the Carescape ONE.	• Connect the CO₂ micro-module if you want to restart the measurement.
• CO₂ sensor overheated Shutting down	• al. area	The sensor temperature of the Microstream CO ₂ micro-module is too high and the measurement device is turned off.	• Check the Microstream CO₂ micro-module placement and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the Microstream CO₂ micro-module. • Contact qualified service personnel.

Message	Location	Possible causes	Suggested actions
• CO₂ sensor removed • Sensor removed	• al. area • param.	The LoFlo Sidestream Module has been disconnected from the LoFlo CO ₂ micro-module.	• Connect the LoFlo Sidestream Module to the LoFlo CO₂ micro-module if you want to restart the measurement.
• CO₂ zero required • Zero required	• al. area • param.	The LoFlo CO ₂ micro-module needs zeroing.	• Disconnect the patient and perform zeroing from the CO₂ menu: Zeroing > Zero to room air. • If the problem persists, replace the sampling line and zero again.
• Continuous blockage. Check sample line.	• wavef.	The sampling line of the Microstream CO ₂ micro-module is blocked.	• Remove the blockage. • Replace the sampling line. • If the pump has shut down, disconnect and then reconnect the accessory to restart the pump.
• EtCO₂ high • EtCO₂ low	• al. area	Measurement values are equal to or outside the alarm limits. The alarm can only be triggered if the CO ₂ micro-module has first detected three breaths within one minute.	• Check the patient status. • Check the ventilator and fresh gas flow settings. • Check arterial blood gas values. • Adjust alarm limits if necessary.
• FiCO₂ high • FiCO₂ low	• al. area	Measurement values are equal to or outside the alarm limits. The alarm can only be triggered if the CO ₂ micro-module has first detected three breaths within one minute.	• Check the patient status. • Check the ventilator or absorber, breathing circuit, and fresh gas flow settings. • Adjust alarm limits if necessary.
• Identical CO₂ device	• al. area	There is more than one CO ₂ micro-module in the system.	• Remove all but one CO₂ micro-module.
• Insufficient power for CO₂ device	• al. area	There is not enough power for the CO ₂ micro-module.	• Remove other connected devices if possible.
• Move CO₂ device to a cooler location • Device overheating	• al. area • param.	The surface temperature of the LoFlo CO ₂ micro-module is too high.	• Check the LoFlo CO₂ micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the LoFlo CO₂ micro-module. • Contact qualified service personnel.

Message	Location	Possible causes	Suggested actions
• Move CO₂ sensor to a cooler location • Sensor overheating	• al. area • param.	The internal temperature of the LoFlo Sidestream Module or Microstream CO ₂ micro-module is too high.	• Check the LoFlo Sidestream Module or Microstream CO₂ micro-module placement and ensure that it is not covered by anything that might lead to overheating. • Replace the LoFlo Sidestream Module or Microstream CO₂ micro-module. • Contact qualified service personnel.
• Over range	• param.	The CO ₂ value is outside the measurable range and cannot be measured	• With LoFlo CO₂, zero CO₂. • Replace the CO₂ micro-module. • Contact qualified service personnel.
• Over scale	• wavef.	The CO ₂ signal exceeds the waveform area.	• Check the patient status. • Select a larger scale for the waveform.
• RR (CO₂) high • RR (CO₂) low	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient status. • Adjust alarm limits if necessary.
• Sample line blocked	• al. area • param.	The Microstream CO ₂ micro-module sample line is blocked.	• Remove the blockage. • Replace the sampling line. • If the pump has shut down, disconnect and then reconnect the accessory to restart the pump.
• Sample line disconnected • Line disconnected	• al. area • param.	The sample line is disconnected.	• With Microstream CO₂: check the sample line connection and reconnect as needed. • With LoFlo CO₂: check the sample line connection and reconnect as needed, then perform zeroing.
• Select age for CO₂ • Select age	• al. area • param.	The age of the patient must be selected before starting the measurement with Microstream CO ₂ micro-module.	• Select the age of the patient and start the measurement.
• Service CO₂ sensor • Check sensor	• al. area • param.	There is a problem with the LoFlo Sidestream Module or the Microstream CO ₂ micro-module.	• Replace the LoFlo Sidestream Module or the Microstream CO₂ micro-module. • Contact qualified service personnel.
• Warming up	• param.	The LoFlo Sidestream Module or the Microstream CO ₂ micro-module is warming up.	• Wait until the warm-up is completed and the message disappears.
• Zeroing	• wavef. • param.	Zeroing is in progress.	• Wait until the zeroing is completed and the message disappears.

Messages related to various technical issues

The following table lists messages that are not directly related to any parameter or measurement. They are mostly technical messages related to hardware, configuration, network, security, and similar issues.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• Alarm setup changed remotely	• al. area	The alarm setup is retrieved from the central station.	• Check the alarm settings and adjust if necessary.
• Alarm volume changed	• al. area	The network connection is lost, and the local alarm volume is increased.	• Readjust volume if desired.
• Alarms acknowledged remotely	• al. area	The alarms have been acknowledged from the central station.	• No action required but you may wish to confirm in alarm history which alarm has been acknowledged.
• Analog output malfunction	• al. area	Carescape ONE analog output voltage failure.	• Contact qualified service personnel.
• Battery empty!	• al. area	The Carescape ONE is being used on battery power, and there is less than 5 minutes of charge left.	• Charge the battery by connecting the Carescape ONE to a powered docking solution.
• Battery failure	• al. area	The battery is faulty.	• Replace the battery.
• Battery low	• al. area	The Carescape ONE is being used on battery power, and there is less than 20 minutes of charge left.	• Charge the battery by connecting the Carescape ONE to a powered docking solution.
• Battery temp high	• al. area	Battery temperature is too high.	• Replace the battery. • If the problem persists, contact qualified service personnel.
• Call Service: Text(s) missing	• al. area	The software text is missing in this language; the text file may be corrupted.	• Contact qualified service personnel.
• Call service: Check WLAN certificate.	• al. area	The WLAN certificate will soon expire.	• Contact qualified service personnel.
• Call service: WLAN certificate expired.	• al. area	The WLAN certificate has expired.	• Contact qualified service personnel.
• Case ended	• al. area	OR and PACU software packages: There is no active patient case.	• No action required.
• Case started	• al. area	OR and PACU software packages: A new case has just been started.	• No action required.

Message	Location	Possible causes	Suggested actions
• Check gas flow • Check flow	• al. area • param.	The sample flow rate is lower or higher than the nominal flow due to an obstruction in the gas exhaust or a leak.	• Check the measurement setup and gas exhaust. • If the pump has shut down, disconnect and then reconnect the accessory to restart the pump.
• Condition battery	• al. area	The battery needs to be conditioned.	• Replace the battery, and condition the battery that was removed.
• Configuration change(s)	• al. area	The monitor was restarted while the Configuration changes. Restart required. was displayed.	• Acknowledge the alarm.
• Configuration changes. Restart required.	• al. area	The language, licenses, DEMO mode Simulation data set, DEMO mode Software Package, DEMO mode license, or DEMO mode language was changed.	• Restart the monitor.
• Configuration error(s)	• al. area	One or more errors have been detected in the configuration.	• Contact qualified service personnel.
• CS ONE Faulty Device Connected	• al. area	One of the micro-modules has a communication failure.	• Disconnect the micro-module from Carescape ONE and reconnect it. • Replace the micro-module. • If the problem persists, contact qualified service personnel.
• CS ONE faulty device in port #X where X is the micro-module port number	• al. area	Carescape ONE is detecting a failure in the micro-module connected to port #x.	• Disconnect the micro-module from Carescape ONE and reconnect it. • Replace the micro-module. • If the problem persists, contact qualified service personnel.
• CS ONE unknown device in port #X where X is the micro-module port number	• al. area	Carescape ONE could not identify the micro-module. An unauthorized device is connected to a Carescape ONE micro-module port.	• Disconnect the micro-module from Carescape ONE and reconnect it to a different micro-module port if available. • If the problem persists, contact qualified service personnel.
• CS ONE Speaker Failure	• al. area	The speaker is inoperative.	• Contact qualified service personnel.
• DEMO MODE	• wavef.	The monitor is in Demo mode.	• To start monitoring a patient, restart the monitor, or select  from the main menu > Defaults & Service > Exit DEMO > Confirm.
• DEMO MODE Not for clinical use!	• al. area	DEMO mode has been enabled.	• To start monitoring a patient, restart the monitor, or select  from the main menu > Defaults & Service > Exit DEMO > Confirm..

Message	Location	Possible causes	Suggested actions
• ECG Analog output malfunction • Analog output malfunction	• al. area • wavef.	Hardware or software fault in the analog output of the TruSignal ECG micro-module: • Cable fault • Configuration failure • No updated data • Data sample drift	• Contact qualified service personnel.
• Entering standby	• al.area	Activate standby has been selected.	• Continue disconnecting the patient to enter standby mode.
• Identical IP address noticed	• al.area	Two or more network devices have the same IP address.	• Contact qualified service personnel.
• IP Analog output malfunction • Analog output malfunction	• al. area • wavef.	Hardware or software fault in the analog output of the TruSignal Pressure micro-module: • Cable fault • Configuration failure • No updated data • Data sample drift	• Contact qualified service personnel.
• Measurement error	• al.area	Technical fault in the monitor.	• Contact qualified service personnel.
• Monitor restarted. Check patient.	• al.area	Monitor warm start has occurred.	• Check the patient. • Reset the alarm by pressing the  key twice or by discharging the patient/ending the case.
• Network down	• al.area	Carescape Network connection has failed.	• Try to re-establish the connection. • If the problem persists, contact qualified service personnel.
• No battery backup	• al. area	There is no battery in the Carescape ONE.	• Install a battery in the Carescape ONE battery compartment.
• Patient admitted	• al. area	ICU, NICU, and ED software packages: The current patient has just been admitted.	• No action required.
• Patient discharged	• al. area	ICU, NICU, and ED software packages: There is no admitted patient.	• No action required.
• Powering down!	• al. area	The Carescape ONE is being used on battery power and there is less than 1 minute of charge left.	• Charge the battery by connecting the Carescape ONE to a powered docking solution.
• Replace battery	• al. area	The battery is not working properly.	• Replace the battery.
• Service CS ONE and specific error indication	• al. area	Technical fault in the monitor.	• Contact qualified service personnel.
• Service CS ONE Activation Failed	• al. area	Software activation failed on the Carescape ONE.	• Contact qualified service personnel.

Message	Location	Possible causes	Suggested actions
• Service CS ONE Calibrate NIBP	• al. area	The Carescape ONE NIBP requires calibration.	• Contact qualified service personnel.
• Service CS ONE ECG Analog Out	• al. area	ECG analog output was never calibrated and default calibration values are being used.	• Contact qualified service personnel.
• Service CS ONE faulty port #X where X is the micro-module port number	• al. area	Carescape ONE is detecting a fault on a micro-module port.	• Contact qualified service personnel.
• Service CS ONE IP Analog Out	• al. area	IP analog output was never calibrated and default calibration values are being used.	• Contact qualified service personnel.
• Service CS ONE power failure	• al. area	The Carescape ONE has lost communication with the power management controller.	• Contact qualified service personnel.
• SW update in progress on CS ONE port #X where X is the micro-module port number	• al. area	A software update is in progress. One of the connected micro-modules is updating software from Carescape ONE.	• Wait until the software update to the micro-module is successfully completed and the message disappears from the screen. This may take up to 1 minute. • Do not disconnect the micro-module from Carescape ONE before the software update is completed.
• Unable to read licenses	• al. area	The license file could not be read.	• Contact qualified service personnel.
• Wireless link disconnected	• al. area	The wireless link between the Carescape ONE and the host monitor has been disconnected.	• No action required if the wireless link has been disconnected intentionally. • Otherwise, re-establish the wireless link between Carescape ONE and the host monitor. For instructions, refer to the host monitor user manual.

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Abbreviations

List of abbreviations

The abbreviations that appear in the monitor software are indicated with bold typeface. Other abbreviations listed in this table appear in this manual. Some abbreviations listed have multiple meanings but are differentiated by the context in which they appear.

/min	beats per minute, breaths per minute
°C	Celsius degree
°F	Fahrenheit degree
μ	micro
12RL	twelve reduced leads
a	arterial
A Fib	atrial fibrillation
AAMI	Association for the Advancement of Medical Instrumentation
AC	alternating current
Accel. Ventric.	accelerated ventricular rhythm
AHA	American Heart Association
Amp	amplitude
ANATEL	Agência Nacional de Telecomunicações
APN	apnea
APOD	Adaptive Probe Off Detection
APPs	Australian Privacy Principles
Arrh	arrhythmia
Art	arterial pressure
Auto	continuous NIBP measurement mode
AUTO	primary HR source
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
Axil	axillary temperature
Blad	bladder temperature
bpm	beats per minute
Brady	bradycardia
BSA	body surface area
C (C1 - C6)	chest
C1 to C6	ECG lead C1 to ECG lead C6

CCO	Continuous cardiac output
CISPR	International Special Committee on Radio Interference
CO2	carbon dioxide
Core	core temperature
CPP	cerebral perfusion pressure
CVP	central venous pressure
d	day
dB	decibel
DC	direct current
DEMO	demonstration (mode)
Dia; DIA	diastolic pressure
ECG	electrocardiogram
ED	emergency department
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ESD	electrostatic discharge electrostatic sensitive devices
Eso	esophageal temperature
ESU	electrosurgical unit
ET; Et	end-tidal concentration
Exp	expiratory
exp	expiration
F	foot (describing location)
Fem	femoral
FemV	femoral venous
Fib	fibrillation
FiCO2	fraction of inspired carbon dioxide
FiO2	fraction of inspired oxygen
Fr	French (unit of measure for a Catheter diameter scale)
ft	feet foot
g	gram
GDPR	General Data Protection Regulation
h	hour
Hb	hemoglobin
Hemo	hemodynamic
HF	high frequency
HIPAA	Health Insurance Portability and Accountability Act
hPa	hectopascal

HR	heart rate
Hz	hertz
I	lead I
IABP	intra-aortic balloon pump
ICASA	Independent Communications Authority of South Africa
ICP	intracranial pressure
ICU	intensive care unit
ID	identification
IEC	International Electrotechnical Commission
II	lead II
III	lead III
Imped.	impedance
Imped.	impedance respiration
in	inch
Insp	inspiratory
insp	inspiration
IP	invasive blood pressure
Iso	isoelectric
ISO	International Standards Organization
IV	intravenous
J	joule
KCC	Korea Communications Commission
kg	kilogram
kPa	kilopascal
l	liter
LA	left arm (describing location)
LAP	left atrial pressure
lb, lbs	pound, pounds
LCD	liquid crystal display
LED	light emitting diode
LL	left leg (describing location)
MAP	mean arterial pressure
Max.	maximum
MDS2	Manufacturer Disclosure Statement for Medical Device Security
ME	medical equipment
Mean; M	mean blood pressure
MetHb	methemoglobin
mg	milligram

min	minute
ml	milliliter
mm	millimeter
mmHg	millimeters of mercury
MR	magnetic resonance
MRI	magnetic resonance imaging
MRN	medical record number
ms	millisecond
Myo	myocardial temperature
N	neutral
N/A	not applicable
N ₂	nitrogen
N2O	nitrous oxide
Naso	nasopharyngeal temperature
Neo	neonate
Neuro	neurological
NIBP	non-invasive blood pressure
NICU	neonatal intensive care unit
O2	oxygen
OR	operating room
P	pressure
PA	pulmonary arterial pressure
PACU	post anesthesia care unit
PHI	Protected Health Information
PHIPA	Personal Health Information Protection Act
PII	Personally Identifiable Information
PIPEDA	Personal Information Protection and Electronic Documents Act
Pleth	plethysmographic pulse waveform
PR	pulse rate
PVC	premature ventricular contraction
QRS	QRS complex
R	right (describing location)
R on T	early PVC, close to the T wave of the preceding normal beat
RA	right arm (describing location)
RAP	right atrial pressure
Rect	rectal temperature
Resp	respiration rate
Resp	respiration

RF	radio frequency
RFID	radio frequency identification
RL	reduced leadset right leg
Room	room temperature
RR	respiration rate
rSO ₂	regional oxygen saturation
s	second
SaO2	arterial oxygen saturation
Skin	skin temperature
SN	serial number
SpO2	oxygen saturation
ST	ST segment
STAT	five minute continuous NIBP measurement mode
Surf	surface temperature
SV	supraventricular
SW; sw	software
SVC	supra ventricular contraction
SV Tachy	supra ventricular tachycardia
Sys; SYS	systolic pressure
T	temperature
Tab	tabular
Tachy	tachycardia
Temp	temperature
Tx-Ty	temperature difference
Tymp	tympanic temperature
UAC	umbilical arterial catheter
UI	user interface
UVC	umbilical venous catheter
V	ventricular
V (V1-V6)	chest
V Brady	ventricular bradycardia
V Fib	ventricular fibrillation
V Tach	ventricular tachycardia
v	venous
V1 to V6 (V1-V6)	ECG lead V1 to ECG lead V6 (V1-V6)
Vol; V	volume
VT > 2	ventricular tachycardia with more than two consecutive ventricular beats
WLAN	wireless local area network

y	years
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Skills checklist

System security and privacy

To familiarize yourself with these functions and features, study the topics listed as recommended reading. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
APPLICABILITY OF LOCAL LAWS AND REGULATIONS Australia on page 31 Canada on page 31 European Union on page 31 United States of America on page 31		
SAFEGUARDING SENSITIVE INFORMATION Safeguarding sensitive information on page 31		
FURTHER DETAILS ON PRIVACY AND SECURITY Further details on privacy and security on page 32		

System description

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
SYSTEM SAFETY PRECAUTIONS System warnings on page 35 System cautions on page 42		
CARESCAPE ONE SYSTEM COMPONENTS Carescape ONE system components on page 72		
MONITOR BATTERY Monitor battery on page 76		
DOCKS Docks on page 79		
EQUIPMENT MARKINGS Equipment markings on page 82		
USER INTERFACE INDICATORS User interface indicators on page 98		

Starting and ending

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
CASE START / PATIENT ADMISSION Starting monitoring on page 113		
USING STANDBY Starting standby on page 116 Ending standby on page 116		
CASE RESET / PATIENT DISCHARGE Resetting a case/discharging a patient on page 115		

Monitoring basics

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
MAIN KEYS Main keys on page 94		
SCREEN LAYOUT Screen layout on page 91		
OPERATION SAFETY PRECAUTIONS Operation warnings on page 41		
MONITOR INSTALLATION POINTS TO NOTE Installation points to note on page 70		
TURNING ON THE MONITOR Turning on the monitor on page 113		
PAGE SETUP Page setup on page 105		
PRE-MONITORING CHECKLIST Pre-monitoring checklist on page 114		

Alarms

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
SAFETY PRECAUTIONS Alarm warnings on page 46		
OVERVIEW Alarm types on page 119 Alarm conditions on page 119 Alarm priority levels on page 127 Selecting parameter alarm priority levels on page 127		

Recommended reading	Completed	Not applicable
Alarm priority escalation on page 127		
Critical alarms on page 124		
CHECKING THE FUNCTION Checking alarm function on page 120		
ALARM INDICATIONS Alarm icons on the screen on page 120		
Setting the alarm light brightness on page 122		
Adjusting the alarm volume on page 123		
Audible alarm signals on page 123		
ALARM DEACTIVATION Technical alarm deactivation with the pause audio key on page 130		
Apnea alarm deactivation with the pause audio key on page 130		
Turning audible alarms on/off on page 128		
Pausing alarms for 5 minutes on page 129		
BREAKTHROUGH AND LATCHED ALARMS Breakthrough alarms on page 130		
Latched alarms on page 130		

Transport

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
WIRELESS TRANSPORT MODE - Wireless transport mode on page 133 - Checking the network connections on page 137 - End of wireless transport mode on page 138		
TRANSPORT MONITORING - Preparing to transport a patient on page 139 - Returning a patient from transport on page 139		
TRANSPORT SETTINGS Transport patient settings on page 140		

ECG

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW ECG warnings on page 48		

Recommended reading	Completed	Not applicable
ECG cautions on page 50		
ECG measurement considerations on page 151		
ECG points to note on page 151		
ECG equipment to patient connection with Carescape ONE on page 152		
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Applying the electrodes to the patient on page 152		
3-lead or 5-lead ECG electrode placement on page 153		
6-lead ECG electrode placement on page 154		
10-lead ECG electrode placement for cardiac monitoring on page 154		
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ECG alarm limits on page 163		
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Pacemaker detection warnings on page 50		
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Arrhythmia monitoring warnings on page 50		
Arrhythmia measurement considerations on page 170		

Recommended reading	Completed	Not applicable
Setting the arrhythmia category to alarm on page 170		
Setting arrhythmia alarms on page 171		
Arrhythmia alarm messages on page 172		
ST DETECTION		
ST detection measurement considerations on page 175		
Starting ST detection on page 175		

Impedance respiration

To familiarize yourself with this parameter and its use, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW		
Respiration warnings on page 52		
Respiration cautions on page 53		
Respiration measurement considerations on page 178		
Respiration points to note on page 178		
Respiration measurement checks on page 181		
Respiration equipment to patient connection with Carescape ONE on page 179		
RESPIRATION LEADS		
Respiration lead and breath detection on page 180		
Respiration lead I electrode placement on page 180		
Respiration lead II electrode placement on page 180		
Respiration lead RL-LL electrode placement on page 181		
USING THE MEASUREMENT		
Selecting the patient type on page 182		
Setting the respiration alarm limits on page 183		
Turning on or off the respiration rate alarm on page 183		
Setting the apnea alarm delay on page 184		
Respiration alarm priorities on page 184		

Pulse oximetry (SpO₂)

To familiarize yourself with this parameter and its use, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW		
SpO₂ warnings on page 53		
SpO₂ cautions on page 56		

Recommended reading	Completed	Not applicable
• SpO₂ measurement considerations on page 191		
• SpO₂ points to note on page 191		
• Checking the SpO₂ measurement on page 198		
• SpO₂ equipment to patient connection with Carescape ONE on page 198		
• Preparing the SpO₂ connection on page 198		
MEASUREMENT GUIDELINES		
• Masimo SET technology and sensor measurement guidelines on page 196		
• Nellcor OxiMax technology and sensor measurement guidelines on page 197		
• TruSignal technology and sensor measurement guidelines on page 195		
USING THE MEASUREMENT		
• Selecting SpO₂ as the primary heart rate source on page 199		
• Adjusting the SpO₂ pulse beep volume on page 200		
• Masimo SET data averaging and updating on page 200		
• Nellcor OxiMax data averaging and updating on page 201		
• Setting the SpO₂ alarms and alarm limits on page 203		
• Deactivating the SpO₂ probe off alarm on page 203		

Non-invasive blood pressure

To familiarize yourself with this parameter and its use, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW		
• NIBP warnings on page 57		
• NIBP measurement considerations on page 211		
• NIBP points to note on page 211		
• Checking the NIBP measurement on page 213		
• NIBP equipment to patient connection with Carescape ONE on page 212		
CUFF APPLICATION		
• Preparing the NIBP patient connection on page 212		
• NIBP cuff selection and placement on page 215		
SINGLE NIBP MEASUREMENT		
• Starting or stopping a single NIBP measurement from the main menu on page 213		
• Starting or stopping a single NIBP measurement from the NIBP settings on page 213		

Recommended reading	Completed	Not applicable
AUTOMATIC NIBP MEASUREMENTS Starting or stopping the automatic NIBP measurement from the main menu on page 214		
Starting or stopping the automatic NIBP measurement from the NIBP settings on page 214		
CONTINUOUS NIBP MEASUREMENT FOR 5 MINUTES Starting or stopping continuous five-minute NIBP measurements on page 215		

Invasive pressures

To familiarize yourself with this parameter and its use, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW Invasive pressure warnings on page 59		
Invasive pressure points to note on page 224		
Checking the invasive pressure measurement on page 226		
- Invasive pressure equipment to patient connection with TruSignal Pressure micro-module on page 225 - Equipment connection with FloTrac CCO micro-module on page 227		
ZEROING Zeroing the invasive pressure transducers on page 229		
USING THE MEASUREMENT Selecting an invasive pressure channel label on page 229		
Selecting the scale of the invasive pressure waveform on page 229		
Optimizing the invasive pressure waveform scale on page 229		

Temperature

To familiarize yourself with this parameter and its use, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW Temperature warnings on page 60		
Temperature cautions on page 61		
Temperature points to note on page 242		
Checking the temperature measurement on page 243		
Temperature equipment to patient connection with Carescape ONE on page 242		

Recommended reading	Completed	Not applicable
TEMPERATURE MEASUREMENT START Starting the temperature measurement on page 243		
TEMPERATURE SITE NAME CHANGES Changing the temperature site label on page 243		

CO₂

To familiarize yourself with this parameter and its use, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
GENERAL MEASUREMENT OVERVIEW - CO₂ warnings on page 61 - CO₂ cautions on page 62 - CO₂ points to note on page 249 - Equipment connection with LoFlo CO₂ micro-module on page 249 - Equipment connection with Microstream CO₂ micro-module on page 250 - Preparing the setup for LoFlo CO₂ micro-module on page 250 - Preparing the setup for Microstream CO₂ micro-module on page 251		
USING THE MEASUREMENT - Selecting the CO₂ scale on page 252 - Setting CO₂ limit alarms on page 253		
ZEROING Zeroing the LoFlo Sidestream Module on page 255		
SCAVENGING Connecting to scavenging systems on page 255		

Trends

To familiarize yourself with these functions and features, study the topics listed as recommended reading.

Recommended reading	Completed	Not applicable
NUMERIC TRENDS Viewing numeric trends on page 261		

Compliance

Standards compliance

The system complies with the following standards.

- IEC 60601-1:2020-08
- IEC 60601-1-2:2020-09
- IEC 60601-1-6:2020-07
- IEC 62366-1:2020-06

Compliance to parameter and function specific standards is disclosed in the applicable sections.

Compliance applies only to those products that are currently being manufactured and shipped. It does not apply to older devices or devices that have had their software upgraded.

IEC 60601-1

- Type of protection against electrical shock: Class II.
- Degree of protection against electrical shock: applied parts are marked with a symbol indicating degree of protection.
- Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide: Not suitable.

WARNING

EXPLOSION. Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

- Degree of enclosure protection against solid objects and water ingress ratings are specified in the Design, environmental, and physical specifications appendix.
- Mode of operation: Continuous.

Compliant devices

The devices listed in the following table have been verified to be compliant with the standard 60601-1:2020, 3.2 edition:

Monitor	Carescape ONE with software version 4.0
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Micro-modules	TruSignal ECG micro-module TruSignal Pressure micro-module TruSignal Temperature micro-module TruSignal SpO ₂ micro-module Masimo SpO ₂ micro-module Nellcor SpO ₂ micro-module Microstream CO ₂ micro-module FloTrac CCO micro-module
Docks and frames	F2-01 F0 docking station Mini Dock Micro-module Dock 1 Micro-module Dock 3 Micro-module Dock 4 Micro-module Dock 5

NOTE

LoFlo CO₂ micro-module is an end-of-life product, and it is thus not listed above.
Compliance tests for IEC 60601-1:2012 are applicable for the LoFlo CO₂ micro-module.

Design, environmental, and physical specifications

Carescape ONE specifications

WARNING

Operation of Carescape ONE outside the specified performance range may cause inaccurate results.

For additional specifications or required environmental conditions, refer to the documentation provided with your equipment.

Carescape ONE	
Size (H x W x D), width excludes pull tab	15.5 cm x 27.0 cm x 6.5 cm (6.1 in x 10.6 in x 2.6 in)
Weight	less than 1.95 kg (4.30 lbs) with battery
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	10% to 95% RH (non-condensing)
Non-operating humidity range	10% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP44. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of splashing water per IP44 rating in IEC 60529.
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
Shock	Withstand shock in accordance with IEC 60068-2-27: 2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstand broad-band random vibration in accordance with IEC 60068-2-64: 2008 using conditions set in IEC 60721-4-7:2001, class 7M3
Power source	Battery or DC input from Carescape F0 Dock
Cooling	Natural convection
Display size	7 inch diagonal
Display type	Active matrix color TFT LCD
Display resolution	800 x 480
Number of waveform fields	Up to 4 full-length waveforms
Number of parameter windows	Classic view: Up to 16 simultaneously Box view: Up to 6 simultaneously
Display layout and colors	User-configurable
Touchscreen technology	Projected Capacitive Touch screen with direct function keys, selections and adjustments in menus Compatible with latex gloves, nitrile gloves and stylus as small as 8 mm

Carescape ONE	
Display rotation	Display image rotates when Carescape ONE is rotated 180 degrees
Micro-module connectors	Eight USB 2.0 full speed parameter connections
Analog out / Defibrillator synchronization connector	Invasive pressure and ECG analog outputs Defibrillator synchronization input and output signals

Battery	
Battery type	One removable Lithium-Ion battery
Battery voltage	10.8 Volt (nominal)
Size (L x W x D)	15.2 cm x 5.9 cm x 2.2 cm (6.0 in x 2.3 in x 0.9 in)
Weight	0.35 kg (0.77 lbs)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Storage temperature range	-20°C to 60°C (-4°F to 140°F)
Operating humidity range	10% to 95% RH (non-condensing)
Storage humidity range	10% to 90% RH (non-condensing)
Operating altitude range	-500 m (1075 hPa) to 4000 m (616 hPa)
Non-operating altitude range	-500 m (1075 hPa) to 5573 m (500 hPa)
Battery capacity	3.8 Amp hour minimum (new)
Battery charge time	<3h to 90% capacity at 25°C ¹
Battery run time	5 hours minimum (new, fully charged) ¹
Battery charging temperature range	10°C to 35°C (50°F to 95°F)
Battery life	300 deep discharge cycles to 60% of design capacity
Battery fuel status	LED indicators on the battery
¹ System includes dual invasive pressure, dual temperature, 12 lead ECG, TruSignal SpO ₂ or Nellcor SpO ₂ micro-module, 70% display brightness, 15 minute NIBP Cycles, and high priority alarms with maximum volume and alarm light brightness at 100%.	

External AC-DC power supply	
Size (H x W x D)	7.5 cm x 15.0 cm x 4.0 cm (2.9 in x 5.9 in x 1.5 in)
Weight	less than 0.46 kg (1.0 lb)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP42. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of dripping water (15° tilted) per IP42 rating in IEC 60529.
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1.

External AC-DC power supply	
Output voltage	15 VDC nominal
Rated output power	60 W maximum
Input voltage and frequency	100 - 240 VAC, 50 - 60 Hz
Rated Input current	1.5 A - 0.75 A
AC input In-rush current	less than < 50 A peak with a 2 ms width at 264 VAC

Wireless connection specifications

WLAN network (Wi-Fi) specifications	
Bands	2.4 GHz: Note the available channels for 802.11 b/g operation in the US are Channels 1 to 11. The range of channels is limited by firmware. 5.0 GHz: The use in the UNII (Unlicensed National Information Infrastructure) band 1 5150-5250 MHz band is restricted to indoor use only to reduce potential for harmful interference to co-channel mobile satellite systems. Any other use will make the operation of this device illegal.
Protocols	Radio support IEEE 802.11 a/b/g/n
Radio regulations	- USA: FCC Part 15.247, 15.407 - European Union: Radio Equipment Directive (RED) 2014/53/EU - EN300328, EN301893 - Canada: RSS-247
Maximum transmission power	2400.0 MHz to 2483.5 MHz EIRP: +17.1 dBm (ETSI) 2400.0 MHz to 2483.0MHz EIRP: +18.3 dBm (FCC/ISED) 5170 MHz to 5835 MHz EIRP: +15.4 dBm (ETSI) 5170 MHz to 5835 MHz EIRP: +18.6 dBm (FCC/ISED) NOTE: May be further restricted on some channels according to regulatory domain.

Wireless network (MBAN) specifications	
Note that MBAN is not in use with the current Carescape Software version.	
Bands	2.39-2.4 GHz US MBAN 2.4-2.4835 GHz ISM
Radio regulations	- USA: FCC Part 15 Subpart C, Part 95 Subpart I - Canada: RSS-247 - European Union: Radio Equipment Directive (RED) 2014/53/EU - EN300328
Maximum transmission power	2390 MHz to 2400 MHz EIRP +11.06 dBm (FCC) 2400 MHz to 2483.5 MHz EIRP +15.20 dBm (FCC and ISED) 2400 MHz to 2483.5 MHz EIRP +11.70 dBm (ETSI)

Wireless network (NFC) specifications	
Note that NFC is not in use with the current Carescape Software version.	
Bands	13.56 MHz ISM

Wireless network (NFC) specifications	
Radio regulations	• USA: FCC Part 15 Subpart C • European Union: Radio Equipment Directive (RED) 2014/53/EU ◦ EN 300 330 • Canada: RSS-210
Maximum transmission power	N/A (near field inductive antenna, EIRP cannot be defined)
Wireless network (RFID) specifications	
Bands	865 MHz - 868 MHz ISM (ETSI) 902 MHz - 928 MHz ISM (FCC and ISSED)
Radio regulations	• European Union: Radio Equipment Directive (RED) 2014/53/EU ◦ EN 302 308
Maximum transmission power	N/A (passive tag, transmission power depends on RFID reader)

FCC information

To view the FCC information for the Carescape ONE, select  from the main menu and then the **Product** tab > page 2.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device may not interfere with stations authorized to operate on a primary basis in the 2360-2400 MHz band, and must accept any interference received, including interference that may cause undesired operation.

NOTE

"Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Radio Equipment Directive (RED) information

This device complies with Radio Equipment Directive (2014/53/EU). Only indoors usage is permitted with 5150 to 5350 MHz WLAN.

ISED information

To view the ISED information for the Carescape ONE, select  from the main menu and then the **Product** tab > page 2.

This device complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. l'appareil ne doit pas produire de brouillage;
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

5150-5250 MHz band is restricted to indoor operation only.

La bande 5150-5250 MHz est restreinte à une utilisation à l'intérieur seulement.

High-power radars are allocated as primary users (i.e. priority users) for the bands 5250-5350 MHz and 5650-5860 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Les radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5250-5350 MHz et 5650-5860 MHz, et ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LAN-EL.

RF exposure information

NOTE

Carescape ONE should not be placed within 20 cm from the patient's body or head area for an extended period of time.

Carescape ONE has been tested and meets the applicable limits (RED EN 50566:2017+AMD1 2023, FCC 47CFR §2.1093 and ISSED RSS-102, Issue 6) for radio frequency exposure (Specific Absorption Rate, SAR). The SAR refers to the rate at which the body absorbs RF energy. The highest reported SAR values for Carescape ONE are as follows:

- Limb SAR 1.61W/kg (limit 4.0W/kg over 10 g of tissue)

Carescape Dock F0 specifications

Size (H x W x D)	9.0 cm x 21.0 cm x 7.5 cm (3.5 in x 8.3 in x 3.0 in)
Weight	Less than 0.5 kg (1.0 lb)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP42. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of dripping water (15° tilted) per IP42 rating in IEC 60529.
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1.
Shock	Withstands shock in accordance with IEC 60068-27:2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstands broad-band random vibration in accordance with IEC 60068-2-64:2008 using conditions set in IEC 60721-4-7:2001, class 7M3

System power consumption	- Worst case configuration includes external supply efficiency - Carescape F0 Dock powered by External AC-DC supply or ePort host connection. No Charging: 17.6 W maximum Battery Charging: 32.4 W maximum
ePort interface connector	Interface with a host monitor (DB-9 connector) - Power from host (8.5V to 17.3V) - Ethernet communication
Ethernet port connector	Interface with a service PC for ethernet communication (RJ45 connector)
Power receptacle	Interface with the AC mains to DC power supply (15 VDC)

Mini Dock and Micro-module Docks specifications

Mini Dock size (H x W x D)	8.5 cm x 19.0 cm x 3.0 cm (3.5 in x 8.3 in x 3.0 in)
Micro-module Dock 1 size (H x W x D)	8.3 cm x 16.1 cm x 5.0 cm (3.3 in x 6.3 in x 2.0 in)
Micro-module Dock 3 size (H x W x D)	8.3 cm x 28.8 cm x 5.5 cm (3.3 in x 11.3 in x 2.2 in)
Micro-module Dock 4 size (H x W x D)	8.3 cm x 28.8 cm x 5.5 cm (3.3 in x 11.3 in x 2.2 in)
Micro-module Dock 5 size (H x W x D)	8.3 cm x 28.8 cm x 5.5 cm (3.3 in x 11.3 in x 2.2 in)
Mini Dock weight	Less than 0.15 kg (0.33 lb)
Micro-module Dock 1 weight	Less than 0.20 kg (0.44 lb)
Micro-module Dock 3 weight	Less than 0.35 kg (0.77 lb)
Micro-module Dock 4 weight	Less than 0.35 kg (0.77 lb)
Micro-module Dock 5 weight	Less than 0.35 kg (0.77 lb)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m (1075 hPa) to 4000 m (616 hPa)
Non-operating altitude range	-500 m (1075 hPa) to 5573 m (500 hPa)
Carescape Mini-Dock Kit	Secures Carescape ONE from either end of the dock.
Micro-module Dock 1	Secures 1 large micro-module ¹ .
Micro-module Dock 3	Secures up to 2 large micro-modules ¹ .
Micro-module Dock 4	Secures 1 large micro-module ¹ and up to 3 small micro-modules ² .
Micro-module Dock 5	Secures up to 5 small micro-modules ² .
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
¹ For example, TruSignal ECG or Masimo SpO ₂ micro-modules. ² For example, TruSignal SpO ₂ , TruSignal Pressure, TruSignal Temperature, LoFlo CO ₂ , Nellcor SpO ₂ , or FloTrac CCO micro-modules.	

TruSignal ECG micro-module specifications

Length	3.6 m or 1.8 m (12.1 ft or 6.2 ft)
Weight	Less than 0.57 kg (1.26 lb), includes long 10 leadwire set
Operating temperature range	0°C to 35°C (32°F to 95°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
Power consumption	625 mW maximum
Power requirement - input voltage	5 VDC $\pm$ 0.25 VDC
Power requirement - input current	125 mA maximum
1 m drop	Drop from 1m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
Shock	Withstands shock in accordance with IEC 60068-27:2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstands broad-band random vibration in accordance with IEC 60068-2-64:2008 using conditions set in IEC 60721-4-7:2001, class 7M3

SpO₂ micro-module specifications

TruSignal SpO ₂	
Length	3.0 m or 1.8 m (9.8 ft or 5.9 ft)
Weight	less than 0.17 kg (0.38 lb)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
Power consumption	375 mW maximum
Power requirement - input voltage	5 VDC $\pm$ 0.25 VDC
Power requirement - input current	75 mA maximum

TruSignal SpO₂	
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1.
Shock	Withstands shock in accordance with IEC 60068-27:2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstands broad-band random vibration in accordance with IEC 60068-2-64:2008 using conditions set in IEC 60721-4-7:2001, class 7M3

Masimo SpO₂	
Length	1.9 m or 1.0 m (6.2 or 3.3 ft)
Weight	less than 0.33 kg (0.82 lb)
Operating temperature range	0°C to 35°C (32°F to 95°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
Power consumption	2.15 W maximum
Power requirement - input voltage	5 VDC ± 0.25 VDC
Power requirement - input current	430 mA maximum
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
Shock	Withstand shock in accordance with IEC 60068-2-27: 2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstand broad-band random vibration in accordance with IEC 60068-2-64: 2008 using conditions set in IEC 60721-4-7:2001, class 7M3

Nellcor SpO₂	
Length	3.0 m or 1.8 m (9.8 ft or 5.9 ft)
Weight	Less than 0.22 kg (0.47 lb)
Operating temperature range	0°C to 35°C (32°F to 95°F)
Non-operating temperature range	-40°C to 70°C (-40°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5572 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
Power consumption	350 mW maximum

Nellcor SpO₂	
Power requirement - input voltage	5 VDC $\pm$ 0.25 VDC
Power requirement - input current	70 mA maximum
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
Shock	Withstand shock in accordance with IEC 60068-2-27: 2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstand broad-band random vibration in accordance with IEC 60068-2-64: 2008 using conditions set in IEC 60721-4-7:2001, class 7M3

Pressure micro-module specifications

TruSignal Pressure	
Length	3.6 m or 1.8 m (11.8 ft or 5.9 ft)
Weight	less than 0.26 kg (0.57 lb)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
Power consumption	425 mW maximum
Power requirement - input voltage	5 VDC $\pm$ 0.25 VDC
Power requirement - input current	85 mA maximum
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
Shock	Withstands shock in accordance with IEC 60068-27:2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstands broad-band random vibration in accordance with IEC 60068-2-64:2008 using conditions set in IEC 60721-4-7:2001, class 7M3

FloTrac CCO adapter	
Length	0.9 m (2.9 ft)
Weight	Less than 0.22 kg (0.49 lb)
Operating temperature range	0°C to 35°C (32°F to 95°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	10% to 90% RH (non-condensing)
Non-operating humidity range	10% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)

FloTrac CCO adapter	
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
Power consumption	3.05 W maximum
Power requirement - input voltage	5 VDC $\pm$ 0.25 VDC
Power requirement - input current	610 mA maximum
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1:2012 clause 15.3.4.1
Broad-band random vibration	Withstand broad-band random vibration in accordance with IEC 60068-2-64: 2008 using conditions set in IEC 60721-4-7:2001, class 7M3

For Edwards FloTrac CCO pressure cable specifications, refer to the manufacturer's Instructions for use for the Edwards FloTrac CCO pressure cable.

TruSignal Temperature micro-module specifications

Length	With reusable sensor interface cable: 1.5 m (4.9 ft) With disposable sensor interface cable: 3.0 m or 1.5 m (9.8 ft or 4.9 ft)
Weight	less than 0.22 kg (0.49 lb)
Operating temperature range	0°C to 40°C (32°F to 104°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 95% RH (non-condensing)
Non-operating humidity range	5% to 95% RH (non-condensing)
Operating altitude range	-500 m to 4000 m (1075 hPa to 616 hPa)
Non-operating altitude range	-500 m to 5573 m (1075 hPa to 500 hPa)
Power consumption	325 mW maximum
Power requirement - input voltage	5 VDC $\pm$ 0.25 VDC
Power requirement - input current	65 mA maximum
Degree of enclosure protection against solid objects and water	IP47. Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529.
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1 clause 15.3.4.1
Shock	Withstands shock in accordance with IEC 60068-27:2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstands broad-band random vibration in accordance with IEC 60068-2-64:2008 using conditions set in IEC 60721-4-7:2001, class 7M3

CO₂ micro-module specifications

For Microstream CO₂ micro-module specifications, refer to the Instructions for use for the Microstream CO₂ micro-module.

LoFlo CO₂	
Length	3.0 m (9.8 ft)
Weight	Less than 0.37 kg (0.81 lb)
Operating temperature range	0°C to 35°C (32°F to 95°F)
Non-operating temperature range	-30°C to 70°C (-22°F to 158°F)
Operating humidity range	5% to 90% RH (non-condensing)
Non-operating humidity range	10% to 90% RH (non-condensing)
Operating altitude range	-350 m to 4000 m (1056 hPa to 616 hPa)
Non-operating altitude range	-350 m to 5572 m (1056 hPa to 500 hPa)
Degree of enclosure protection against solid objects and water	IP47 (micro-module enclosure). Protected against the ingress of solid foreign objects over 1 mm diameter and the harmful effects of temporary immersion in water per IP47 rating in IEC 60529. IP24 (CO₂ LoFlo Sidestream Module Assembly enclosure). Protected against the ingress of solid foreign objects over 12.5 mm diameter and the harmful effects of splashing water per IP24 rating in IEC 60529.
Power consumption	3.75 W maximum
Power requirement - input voltage	5 VDC ± 0.25 VDC
Power requirement - input current	750 mA maximum
1 m drop	Drop from 1 m in multiple orientations onto a hard surface per the test in IEC 60601-1:2012 clause 15.3.4.1
Shock	Withstand shock in accordance with IEC 60068-2-27: 2008 using conditions set in IEC 60721-4-7:2001 class 7M3
Broad-band random vibration	Withstand broad-band random vibration in accordance with IEC 60068-2-64: 2008 using conditions set in IEC 60721-4-7:2001, class 7M3

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Alarm specifications

Alarm standards compliance

The system complies with IEC 60601-1-8:2020-07.

NOTE

Legacy alarm tones do not meet the audio requirements defined in IEC 60601-1-8 Clause 6.3.3.1.

Auditory alarm volume, IEC tones

Tested in accordance with IEC 60601-1-8 subclause 6.3.3.2 with alarm volume control set to maximum and measurement radius of 1 m.

The values are given with an accuracy of ± 0.5 dBA.

Alarm volume setting	Sound pressure level
1	High priority alarm: 24 dB(A) Medium priority alarm: 26 dB(A) Low priority alarm: 25 dB(A)
6 Level 6 corresponds to the factory default minimum allowed setting for volume level.	High priority alarm: 57 dB(A) Medium priority alarm: 55 dB(A) Low priority alarm: 54 dB(A)
10	High priority alarm: 81 dB(A) Medium priority alarm: 79 dB(A) Low priority alarm: 77 dB(A)

Auditory alarm volume, legacy tones

Tested in accordance with IEC 60601-1-8 subclause 6.3.3.2 with alarm volume control set to maximum and measurement radius of 1 m.

The values are given with an accuracy of ± 0.5 dBA.

Alarm volume setting	Sound pressure level
1	High priority alarm: 24 dB(A) Medium priority alarm: 24 dB(A) Low priority alarm: 24 dB(A)
6 Level 6 corresponds to the factory default minimum allowed setting for volume level.	High priority alarm: 55 dB(A) Medium priority alarm: 52 dB(A) Low priority alarm: 51 dB(A)

Alarm volume setting	Sound pressure level
10	High priority alarm: 76 dB(A) Medium priority alarm: 74 dB(A) Low priority alarm: 74 dB(A)

Audio alarm sound tolerances

Tolerances for sounds (total pulse duration with rise and fall times) are:

- Time < 1000 ms: $\pm 5\%$
- Time ≥ 1000 ms: ± 250 ms
- Frequencies: ± 5 Hz

IEC alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep “C” (523 Hz/100 ms) Silence (100 ms) • Beep “F” (698 Hz/100 ms) Silence (100 ms) • Beep “G” (784 Hz/100 ms) Silence (300 ms) • Beep “A” (880 Hz/100 ms) Silence (100 ms) • Beep “B” (988 Hz/100 ms) Silence (1 s) • Beep “C” (523 Hz/100 ms) Silence (100 ms) • Beep “F” (698 Hz/100 ms) Silence (100 ms) • Beep “G” (784 Hz/100 ms) Silence (300 ms) • Beep “A” (880 Hz/100 ms) Silence (100 ms) • Beep “B” (988 Hz/100 ms) Silence (5 s)
Medium	• Beep “C” (523 Hz/200 ms; Silence (200 ms) • Beep “G” (784 Hz/200 ms; Silence (200 ms) • Beep “B” (988 Hz/200 ms) Silence (19 s)
Low	Beep “C” (523 Hz/200 ms) Silence is 24.8 s if Low priority alarm tone is set to Repeat .

Legacy alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep (500 & 510 Hz/100 ms) Silence (100 ms) • Beep (500 & 510 Hz /100 ms) Silence (100 ms) • Beep (500 & 510 Hz/100 ms) Silence (500 ms)
Medium	• Beep (397 & 441 Hz/100 ms) Silence (100 ms) • Beep (397 & 441 Hz/100 ms) Silence (2.4 s)
Low	Beep (397 Hz/500 ms) Silence is 5 s if Low priority alarm tone is set to Repeat .

Auditory information signal characteristics

Measurement and start-up related information signals		
Signal	Frequency (Hz)	Duration (ms)
Start-up sound	523	1000
QRS/Pulse beep	815	10 when Beat tone sound is set to Sharp . 40 when Beat tone sound is set to Soft .
SpO ₂ oxygen saturation level indicator (pitch)	920 at 100% SpO ₂ 900 at 98% SpO ₂ --- 240 at 32% SpO ₂ 220 at 30% SpO ₂	100
NIBP ready prompt	250	500
UI touch tone	660	100
Reminder tone	523	125

Visual information signals

For information regarding visual information signals, see the Alarms chapter.

Alarm delay specifications

The disclosed alarm system delays are measured by simulator or respective methods, which represent optimal signals. Possible interferences and poor quality signals in a clinical environment may extend the disclosed alarm system delays.

The alarm generation consists of two components: the algorithm delay of each parameter and the fixed delay of the monitor software. Both of these components are included in each alarm system delay.

The determination of an alarm condition has nominal factors: signal quality, movement artifact, heart rate for ECG related alarms, and respiration rate for impedance respiration and CO₂ related alarms.

The following disclosures list the alarm system delays as an average and include the delay of the first activated priority alarm.

Alarms with alarm delays of more than 10 s are specified with the average, minimum, and maximum values obtained from five trial measurements.

NOTE

Any alarm delays that are less than 5 s are given as <5 s.

Time to alarm for tachycardia

When tested in accordance to IEC 60601-2-27 Clause 201.7.9.2.9.101 b) 6), according to Figure 201.101, the times to alarm for tachycardia are as follows:

Carescape ONE
Ventricular tachycardia (206 bpm); halved amplitude: 6.3 s (average) (5.9 to 6.8 s range)
Ventricular tachycardia (206 bpm); normal amplitude: 8.6 s (average) (6.7 to 9.5 s range)
Ventricular tachycardia (206 bpm); doubled amplitude: 5.7 s (average) (4.5 to 6.4 s range)
Ventricular tachycardia (195 bpm); halved amplitude: 7.7 s (average) (7.1 to 8.0 s range)
Ventricular tachycardia (195 bpm); normal amplitude: 6.6 s (average) (5.9 to 7.5 s range)
Ventricular tachycardia (195 bpm); doubled amplitude: 5.3 s (average) (4.9 to 5.8 s range)

Physiological alarm delay specifications

Alarm delay specifications for ECG alarms

The following table lists the alarm delays for physiological alarms related to the ECG measurement. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Limit range	Limit increment	Alarm delay
A Fib			27 s (average) (20 to 34 s range). A Fib detection delay is usually 30 - 60 seconds.
Accel. Ventric.			10 s
Asystole			7 s
Bigeminy			8 s
Brady HR low HR(ECG) low	20 to 300 bpm The Brady limit matches the low heart rate limit. If the low heart rate limit is changed, the Brady limit changes.	1 bpm	8 s
Couplet			6 s
Frequent PVCs	1 to 100 per minute	1 per minute	8 PVCs: 49 s (average) (47 to 51 s range)
Frequent SVCs	1 to 100 per minute	1 per minute	6 SVCs: 21 s (average) (18 to 23 s range)
Irregular			12 s (average) (9 to 17 s range)
Missing Beat			<5 s
Multifocal PVCs			8 s
Pause			6 s
R on T			5 s (average) (5 to 6 s range)
ST XXX high where XXX = ECG lead label	-12.0 to +12.0 mm	0.1 mm	86 s (average) (82 to 90 s range)
ST XXX low where XXX = ECG lead label	-12.0 to +12.0 mm	0.1 mm	86 s (average) (82 to 89 s range)
SV Tachy			5 s

Alarm	Limit range	Limit increment	Alarm delay
Tachy HR high HR(ECG) high	20 to 300 bpm The Tachy limit matches the high heart rate limit. If the high heart rate limit is changed, the Tachy limit changes.	1 bpm	9 s
Trigeminy			10 s
V Brady			11 s
V Fib / V Tach			14 s
V Tach			7 s
VT > 2			10 s

Alarm delay specifications for impedance respiration alarms

The following table lists the alarm delays for physiological alarms related to the impedance respiration measurement. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Limit range	Limit increment	Alarm delay
Apnea			10 to 60 s, configurable
RR (Imped.) high (s)	4 to 120 breaths per minute	1 breath per minute	When RR (Imped.) high (s) delay is configured to 0 s: • Patient type = Adult/pediatric: 10 s • Patient type = Neonate: 7 s
RR (Imped.) low (s)	4 to 120 breaths per minute	1 breath per minute	When RR (Imped.) low (s) delay is configured to 0 s: • Patient type = Adult/pediatric: 8 s • Patient type = Neonate: 7 s

Alarm delay specifications for SpO₂ alarms

The following table lists the alarm delays for physiological alarms related to the SpO₂ measurement. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Limit range	Limit increment	Alarm delay
PR(SpO2) high	30 to 240 bpm	1 bpm	• TruSignal: 14 s (average) (12 to 16 s range) • Masimo: 9 s • Nellcor: 9 s
PR(SpO2) low	30 to 240 bpm	1 bpm	• TruSignal: 17 s (average) (10 to 20 s range) • Masimo: 15 s (average) (14 to 17 s range) • Nellcor: 14 s (average) (9 to 17 s range)
SpO2 high	30 to 100%	1%	• TruSignal: 10 s • Masimo: 15 s (average) (9 to 17 s range) • Nellcor: 12 s (average) (11 to 13 s range)

Alarm	Limit range	Limit increment	Alarm delay
SpO2 low	30 to 100%	1%	• TruSignal: 10 s • Masimo: 17 s (average) (9 to 20 s range) • Nellcor: 13 s (average) (12 to 15 s range)

Pulse oximetry saturation and pulse rate averaging time	
TruSignal	The TruSignal algorithm provides averaging time options of 5 and 12 seconds. The overall alarm generation delay of SpO ₂ is typically less than 28 seconds from the actual SpO ₂ value in the patient. This delay is due to the SpO ₂ averaging, signal processing, and data transmission delays. The delay consists of the alarm condition and alarm generation delay, being typically < 10 seconds and < 18 seconds respectively. For pulse rate the alarm generation delay is typically less than 11 seconds, in which the alarm signal delay is less than a second. The SpO ₂ and pulse rate data is updated every second.
Masimo	The Masimo algorithm provides averaging time options of 2, 4, 8, 10, 12, 14, and 16 seconds. When using the default averaging time, the overall alarm generation delay of SpO ₂ is typically less than 28 seconds from the actual SpO ₂ value in the patient. This delay is due to the SpO ₂ averaging, signal processing, and data transmission delays. The delay consists of the alarm condition and alarm generation delay, being typically < 10 seconds and < 18 seconds respectively. For pulse rate, the alarm generation delay is typically less than 11 seconds, in which the alarm signal delay is less than a second. The SpO ₂ and pulse rate data is updated every second.
Nellcor	The Nellcor OxiMax algorithm automatically extends the amount of data required for measuring SpO ₂ and pulse rate depending on the measurement conditions. There are various matrices within the saturation pulse rate detection algorithm. Some of these are used to assess the severity of conditions presented to the measuring of SpO ₂ and pulse rate on a patient. These individual matrices or combinations of these matrices are used to determine the quality of the received SpO ₂ signal. The advanced signal processing in the algorithms automatically extends the amount of data required for measuring SpO ₂ and pulse rate depending on the measuring conditions. During normal measurement conditions, the averaging time is approximately 3 seconds. The overall alarm generation delay of SpO ₂ is typically less than 28 seconds from the actual SpO ₂ value in the patient. This delay is due to the SpO ₂ averaging, signal processing, and data transmission delays. The delay consists of the alarm condition and alarm generation delay, being typically < 10 seconds and < 18 seconds respectively. For pulse rate, the alarm generation delay is typically less than 11 seconds, in which the alarm signal delay is less than a second. The SpO ₂ and pulse rate data is updated every second.

Alarm delay specifications for NIBP alarms

The following table lists the alarm delays for physiological alarms related to the non-invasive blood pressure measurement. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Limit range	Limit increment	Alarm delay
• NIBP Sys high / NIBP Sys low • NIBP Mean high / NIBP Mean low • NIBP Dia high / NIBP Dia low	• Adult: 25 to 260 mmHg • Child: 25 to 190 mmHg • Infant: 15 to 140 mmHg	Adult: 5 mmHg Child: 5 mmHg Infant: 1 mmHg	<5 s

Alarm delay specifications for invasive pressures alarms

The following table lists the alarm delays for physiological alarms related to the invasive pressures measurement. Any alarm delays that are less than 5 s are given as <5 s.

NOTE

When an invasive pressure label is followed by an **X**, the **X** represents invasive pressure channel number.

Alarm	Limit range	Limit increment	Alarm delay
Art X sys high / Art X dia high / Art X mean high CVP X mean high Fem X sys high / Fem X dia high / Fem X mean high FemV X mean high ICP X mean high LAP X mean high P1 mean high to P4 mean high PA X sys high / PA X dia high / PA X mean high RAP X mean high RVP X mean high UAC X sys high / UAC X dia high UAC X mean high UVC X mean high	-25 to 320 mmHg (-3.3 to 42.7 kPa)	1 mmHg (0.1 kPa)	- Systolic: 13 s (average) (12 to 14 s range) - Diastolic: 13 s (average) (12 to 15 s range) - Mean: 14 s (average) (13 to 15 s range)

Alarm	Limit range	Limit increment	Alarm delay
Art X sys low / Art X dia low / Art X mean low CVP X mean low Fem X sys low / Fem X dia low / Fem X mean low FemV X mean low ICP X mean low LAP X mean low P1 mean low to P4 mean low PA X sys low / PA X dia low / PA X mean low RAP X mean low RVP X mean low UAC X sys low / UAC X dia low / UAC X mean low UVC X mean low	-25 to 320 mmHg (-3.3 to 42.7 kPa)	1 mmHg (0.1 kPa)	- Systolic: 14 s (average) (14 to 16 s range) - Diastolic: 15 s (average) (14 to 15 s range) - Mean: 15 s (average) (14 to 15 s range)
CPP (X) high	-25 to 320 mmHg (-3.3 to 42.7 kPa)	1 mmHg (0.1 kPa)	16 s (average) (14 to 17 s range)
CPP (X) X low	-25 to 320 mmHg (-3.3 to 42.7 kPa)	1 mmHg (0.1 kPa)	18 s (average) (16 to 20 s range)
PR (Art) X high Fem X high PR(UAC) X high	20 to 300 bpm	1 bpm	7 s
PR (Art) X low PR (Fem) X low PR(UAC) X low	20 to 300 bpm	1 bpm	7 s

Alarm delay specifications for temperature alarms

The following table lists the alarm delays for physiological alarms related to the temperature measurement. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Limit range	Limit increment	Alarm delay
T1 high T2 high T1 low T2 low	10 to 45°C (50 to 113°F)	0.1°C (0.18°F)	61 s (average) (60 to 61 s range)
X-Y high where X-Y = T1-T2 or T2-T1	0 to 20°C (0 to 36°F)	0.1°C (0.18°F)	61 s (average) (60 to 61 s range)

Alarm delay specifications for CO₂ alarms

The following table lists the alarm delays for physiological alarms related to the CO₂ measurement. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Limit range	Limit increment	Alarm delay
Apnea (CO₂)			19 s (average) (18 to 19 s range)
EtCO₂ high / EtCO₂ low	0 to 13%	0.1%	21 s (average) (20 to 21 s range)
FiCO₂ high	0.0% to 3%	0.1%	21 s (average) (20 to 21 s range)
FiCO₂ low	0.0% to 3%	0.1%	22 s (average) (21 to 22 s range)
RR (CO₂) high / RR (CO₂) low	4 to 60 breaths per minute NICU sw package: 4 to 100 breaths per minute	1 breath per minute	22 s (average) (21 to 22 s range)

Technical alarm delay specifications

The following table lists the alarm delays for technical alarms. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Parameter	Alarm delay
[Invasive pressure channel label] X sensor disconnected , where [Invasive pressure channel label] = Art, CVP, Fem, FemV, ICP, LAP, P, PA, RAP, RVP, UAC, or UVC , and X = invasive pressure channel number Sensor	Invasive pressures	6 s (TruSignal Pressure micro-module) <5 s (FloTrac CCO micro-module)
[Invasive pressure channel label] X sensor failed , where [Invasive pressure channel label] = Art, CVP, Fem, FemV, ICP, LAP, P, PA, RAP, RVP, UAC, or UVC , and X = invasive pressure channel number. Sensor	Invasive pressures	8 s
Arrhythmia paused	ECG	21 s (average) (20 to 22 s range)
Art X disconnect Fem X disconnect UAC X disconnect , where X = invasive pressure channel number Disconnected	Invasive pressures	8 s
Battery empty!		<5 s
Battery failure		<5 s
Battery low		<5 s

Alarm	Parameter	Alarm delay
Battery temp high		<5 s
Calibration fail T1 calibration fail T2 calibration fail	Temperature	<5 s
Check XXX waveform where XXX = invasive pressure channel label (Art or Fem, followed by the channel number) Check pressure Waveform not stable	Invasive pressures	<5 s
Check CO2 adapter	CO ₂	42 s (average) (41 to 42 s range)
Check device CO2 device malfunction	CO ₂	<5 s
Check device ECG malfunction	ECG	<5 s
Check device Imped. malfunction	Impedance respiration	<5 s
Check device P1 pressure malfunction P2 pressure malfunction P3 pressure malfunction P8 pressure malfunction	Invasive pressures	<5 s
Check device SpO2 malfunction	SpO ₂	<5 s
Check device Temperature malfunction	Temperature	<5 s
CCO measurement discontinued	Continuous cardiac output	<5 s
Check gas flow	CO ₂	42 s (41 to 42 s range)
Check NIBP	NIBP	<5 s
Check sample line	CO ₂	54 s (average) (48 to 57 s range)
Check sensor Service CO2 sensor	CO ₂	<5 s
Check SpO2 probe Check probe	SpO ₂	< 30 s
CO2 device failure: Call service	CO ₂	8 s
CO2 device overheated Shutting down	CO ₂	10 s
CO2 measurement purging	CO ₂	27 s (26 to 27 s range)
CO2 measurement removed	CO ₂	<5 s
CO2 sensor overheated Shutting down	CO ₂	10 s

Alarm	Parameter	Alarm delay
CO2 sensor removed CO2 sensor removed	CO ₂	<5 s
CO2 zero required Zero required	CO ₂	42 s (average) (41 to 42 s range)
Condition battery		<5 s
CS ONE Faulty Device Connected		<5 s
CS ONE faulty device in port #X where X is the micro-module port number		<5 s
CS ONE Speaker Failure		<65 s
CS ONE unknown device in port #X where X is the micro-module port number		<5 s
DEMO MODE Not for clinical use!		<5 s
Device overheating Move IP/CCO device to a cooler location	Invasive pressures	6 s
Device overheating Move CO2 device to a cooler location	CO ₂	6 s
Device overheating Move ECG device to a cooler location	ECG	6 s
Device overheating Move pressure device 1/2 to a cooler location Move pressure device 3/4 to a cooler location	Invasive pressures	6 s
Device overheating Move Temp device to a cooler location	Temperature	7 s
ECG Analog output malfunction	ECG	<7 s
ECG device failure: Call service	ECG	7 s
ECG malfunction	ECG	<5 s
ECG device overheated. Shutting down	ECG	10 s
ECG measurements removed	ECG	<5 s
Identical CO2 device	CO ₂	<5 s
Identical ECG device	ECG	<5 s
Identical IP address noticed		40 s (average)
Identical IP/CCO devices	Invasive pressures	<5 s

Alarm	Parameter	Alarm delay
Identical pressure devices	Invasive pressures	<5 s
Identical SpO2 device	SpO ₂	<5 s
Identical Temp device	Temperature	<5 s
Incompatible adhesive SpO2 probe	SpO ₂	6 s
Incompatible probe Incompatible SpO2 probe	SpO ₂	7 s
Incompatible SpO2 device	SpO ₂	8 s
Insufficient power for CO2 device	CO ₂	<5 s
Insufficient power for ECG device	ECG	<5 s
Insufficient power for SpO2 device	SpO ₂	<5 s
Insufficient power for IP/CCO device	Invasive pressures	<5 s
IP/CCO device overheated. Shutting it down.	Invasive pressures	9 s
IP/CCO measurement removed	Invasive pressures	<5 s
IP's not zeroed	Invasive pressures	301 s (average) (300 to 301 s range)
IP Analog output malfunction	Invasive pressures	<7 s
LA/L lead off LL/F lead off RA/R lead off RL/N lead off	ECG	LA/L lead off, LL/F lead off: 10 s RA/R lead off: 11 s (average) (10 to 11 s range) RL/N lead off: 16 s (average) (15 to 17 s range)
Leads off	ECG	7 s
Measurement error		7 s
Monitor restarted. Check patient.		16 s
Move CO2 sensor to a cooler location Sensor overheating	CO ₂	6 s
Move SpO2 device to a cooler location	SpO ₂	6 s
Network down		33 s
NIBP auto stopped NIBP STAT stopped	NIBP	<5 s
NIBP cuff loose Cuff loose	NIBP	22 s
NIBP cuff occlusion Cuff occlusion	NIBP	35 s (average) (32 to 37 s range)
NIBP malfunction	NIBP	<5 s

Alarm	Parameter	Alarm delay
NIBP over range NIBP under range	NIBP	<5 s
No adhesive SpO2 probe	SpO ₂	7 s
No battery backup		<5 s
No beat sound	ECG	<5 s
Noise Noisy ECG	ECG	27 s (average) (25 to 27 s range)
No SpO2 cable	SpO ₂	7 s
No SpO2 probe	SpO ₂	• TruSignal: 6 s • Masimo: 7 s • Nellcor: 7 s
P8 PR over range	Invasive pressures	11 s
Px over range Where x = invasive pressure channel number	Invasive pressures	7 s
Px under range Where x = invasive pressure channel number	Invasive pressures	7 s
Powering down!		<5 s
Pressure device failure: Call service	Invasive pressures	7 s
Pressure device initializing	Invasive pressures	8 s
Pressure device overheated. Shutting it down	Invasive pressures	10 s
Pressure measurement removed	Invasive pressures	<5 s
Replace adhesive SpO2 probe	SpO ₂	<5 s
Replace battery		<5 s
Replace SpO2 cable	SpO ₂	<5 s
Replace SpO2 probe	SpO ₂	<5 s
Resp (Imped.) measurement paused Measurement paused	Impedance respiration	50 s (average) (49 to 51 s range) for all software packages except NICU. NICU software package: 18 s (average) (17 to 20 s range)
rSO2 measurement disconnected	rSO ₂	< 5 s
Sample line blocked	CO ₂	<5 s
Sample line disconnected Sample line disconnected	CO ₂	42 s (average)
Select age for CO2	CO ₂	21 s
Service CS ONE and specific error code		<15 s

Alarm	Parameter	Alarm delay
Service CS ONE faulty port #X where X is the micro-module port number		<5 s
Service CS ONE power failure		<5 s
SpO2 Demo mode	SpO ₂	<5 s
SpO2 device failure: Call service	SpO ₂	6 s
SpO2 device overheated Shutting down	SpO ₂	11 s (average) (9 to 12 s range)
SpO2 faulty cable	SpO ₂	7 s
SpO2 faulty probe Faulty adhesive SpO2 probe	SpO ₂	7 s
SpO2 measurement removed	SpO ₂	<5 s
SpO2 probe off	SpO ₂	• TruSignal: 9 s (average) (8 to 10 s range) • Masimo: 7 s (average) (7 to 8 s range) • Nellcor: 12 s (average) (10 to 12 s range)
SW download failed on CS ONE port #X where X is the micro-module port number		<5 s
SW update in progress on CS ONE port #X where X is the micro-module port number		<5 s
Temp device failure: Call service	Temperature	8 s
Temp device overheated. Shutting down	Temperature	8 s
Temperature malfunction	Temperature	< 5 s
Temp measurement removed	Temperature	<5 s
Wireless link disconnected		<5 s

Alarm priorities and escalation times

Alarm priorities and escalation times for ECG

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
A Fib		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
Accel. Ventric.		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
Arrh off		param.	0 s			
• Arrhythmia paused • Arrh paused		• alarm • wavef.	0 s if no patient case/no admitted patient	0 s, according to priority setting: high, medium, low		
• Arrhythmia paused • Arrh paused	Alarm priority = Escalating	• alarm • wavef.	0 s if no vital signs		0 s	40 s
Artifact		wavef.	0 s			
Asystole		alarm, param., wavef.				0 s
Bigeminy		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
Brady	Unit setting HR Alarms = Single ; Primary HR source AUTO, IntelliRate, or ECG.	alarm		0 s, according to priority setting: high, medium, low		
Brady	Unit setting HR Alarms = Single ; Alarm priority = Escalating ; Primary HR source AUTO, IntelliRate, or ECG.	alarm			0 s	69 s
Brady	Alarm priority = Escalating ; HR <0.75 x low limit; Primary HR source AUTO, IntelliRate, or ECG.	alarm				0 s
Brady	Unit setting HR Alarms = Single ; non-ECG source and Primary HR source AUTO, IntelliRate.	alarm		High, medium, or low according to the priority setting. The alarm delay is equivalent to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.		

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Brady	Unit setting HR Alarms = Single ; Alarm priority = Escalating ; non-ECG source and Primary HR source AUTO, IntelliRate.	alarm			According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.	Alarm delay + 64 s
Brady	Alarm priority = Escalating ; HR <0.75 x low limit; non-ECG source and Primary HR source AUTO, IntelliRate.	alarm				According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.
Brady	HR ≤ low critical alarm limit	alarm				0 s NOTE: Basic alarm delay is applied if the critical alarm limits are exceeded immediately.
Check device		wavef.	0 s			
Couplet		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
Device overheating		wavef.	0 s			
ECG device failure: Call service		alarm			0 s	
ECG device overheated. Shutting down		alarm			0 s	
ECG malfunction		alarm			0 s	
ECG measurements removed		alarm	0 s if no patient case/no admitted patient		0 s if active patient case/admitted patient	
Frequent PVCs	Alarm priority = Escalating	alarm		0 s	13 s	
Frequent PVCs		alarm	0 s, according to priority setting: high, medium, low, info			
Frequent SVCs	Alarm priority = Escalating	alarm, wavef.		0 s	13 s	
Frequent SVCs		alarm, wavef.	0 s, according to priority setting: high, medium, low, info			

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
HR high	Unit setting HR Alarms = Multiple ; non-ECG source and Primary HR source not AUTO, IntelliRate, or ECG.	alarm		PR alarm delay setting, according to priority setting: high, medium, low		
HR high	Unit setting HR Alarms = Multiple ; Alarm priority = Escalating ; non-ECG source and Primary HR source not AUTO, IntelliRate, or ECG.	alarm			According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.	Alarm delay + 64 s
HR high	Unit setting HR Alarms = Multiple ; Alarm priority = Escalating ; HR > 1.25 x high limit; non-ECG source.	alarm				According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.
HR high	HR ≥ high critical alarm limit	alarm				0 s NOTE: Basic alarm delay is applied if the critical alarm limits are exceeded immediately.
HR low	Unit setting HR Alarms = Multiple ; Primary HR source not AUTO, IntelliRate, or ECG.	alarm		Non-ECG source: PR alarm delay setting 5 s, according to priority setting: high, medium, low		
HR low	Unit setting HR Alarms = Multiple ; Alarm priority = Escalating ; non-ECG source and Primary HR source not AUTO, IntelliRate, or ECG.	alarm			According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.	Alarm delay + 64 s
HR low	Unit setting HR Alarms = Multiple ; Alarm priority = Escalating ; HR < 0.75 x low limit; non-ECG source.	alarm				According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
HR low	HR $\leq$ low critical alarm limit	alarm				0 s NOTE: Basic alarm delay is applied if the critical alarm limits are exceeded immediately.
HR(ECG) high	Unit setting HR Alarms = Multiple	alarm		0 s, according to priority setting: high, medium, low		
HR(ECG) high	Unit setting HR Alarms = Multiple; Alarm priority = Escalating	alarm			0 s	69 s
HR(ECG) high	Unit setting HR Alarms = Multiple; Alarm priority = Escalating; HR $>1.25 \times$ high limit	alarm				0 s
HR(ECG) high	Unit setting HR Alarms = Multiple; HR $\geq$ high critical limit	alarm				0 s NOTE: Basic alarm delay is applied if the critical alarm limits are exceeded immediately.
HR(ECG) low	Unit setting HR Alarms = Multiple	alarm		0 s, according to priority setting: high, medium, low		
HR(ECG) low	Unit setting HR Alarms = Multiple; Alarm priority = Escalating	alarm			0 s	69 s
HR(ECG) low	Unit setting HR Alarms = Multiple; Alarm priority = Escalating; HR $< 0.75 \times$ low limit	alarm				0 s
HR(ECG) low	Unit setting HR Alarms = Multiple; HR $\leq$ low critical alarm limit	alarm				0 s NOTE: Basic alarm delay is applied if the critical alarm limits are exceeded immediately.
Identical ECG device		alarm			0 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Insufficient power for ECG device		alarm			0 s	
Irregular	NICU software package only.	alarm, wavef.	0s, according to priority setting: high, medium, low, off, info			
• LA/L lead off • LL/F lead off • RA/R lead off • RL/N lead off • V/C lead off • Va/Ca lead off • Vb/Cb lead off • V2/C2 lead off • V3/C3 lead off • V4/C4 lead off • V5/C5 lead off • V6/C6 lead off		wavef.	0 s	0 s		
Lead changed		wavef.				
Lead off		alarm	7 s	7 s		
Leads off	Alarm priority = Escalating	alarm, wavef.		3 s	12 s (30 s in OR software package)	60 s
Leads off		alarm, wavef.		3 s, according to priority setting: high, medium, low		
Learning		wavef.	0 s			
Missing Beat		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
Move ECG device to a cooler location		alarm		0 s		
Multifocal PVCs		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
No beat sound		alarm		0 s		
• Noisy ECG • Noise		• alarm • wavef.		5 s, according to priority setting: high, medium, low		
• Noisy ECG • Noise	Alarm priority = Escalating	• alarm • wavef.		5 s	12 s	
Pause		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
R on T		alarm, wavef.	0 s, according to priority setting: high, medium, low, off, info			
ST XXX high / ST XXX low where XXX = ECG lead label		alarm	60 s, according to priority setting: high, medium, low, info			

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
SV Tachy		alarm, wavef.	0 s, according to priority setting: high, medium, low, info			
Tachy	Unit setting HR Alarms = Single . Primary HR source AUTO, IntelliRate or ECG).	alarm		0 s, according to priority setting: high, medium, low		
Tachy	Unit setting HR Alarms = Multiple ; Alarm priority = Escalating ; Primary HR source AUTO, IntelliRate or ECG.	alarm			0 s	69 s
Tachy	Alarm priority = Escalating ; Primary HR source AUTO, IntelliRate or ECG. HR > 1.25 x high limit	alarm				0 s
Tachy	Unit setting HR Alarms = Single ; non-ECG source and Primary HR source AUTO, IntelliRate.	alarm		High, medium, or low according to the priority setting. The alarm delay is equivalent to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.		
Tachy	Unit setting HR Alarms = Multiple ; Alarm priority = Escalating ; non-ECG source and Primary HR source not AUTO, IntelliRate.	alarm			According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.	Alarm delay + 64 s
Tachy	Alarm priority = Escalating ; HR > 1.25 x high limit; non-ECG source and Primary HR source AUTO, IntelliRate.	alarm				According to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.
Tachy	HR ≥ high critical alarm limit	alarm				0 s NOTE: Basic alarm delay is applied if the critical alarm limits are exceeded immediately.
Trigeminy		alarm, wavef.	0s, according to priority setting: high, medium, low, off, info			

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
V Brady		alarm, wavef.	0s, according to priority setting: high, medium, low, off, info			
V Fib/V Tach		alarm, param., wavef.				0 s
V Tach		alarm, param., wavef.	0s, according to priority setting: high, medium, low, info The alarm priority is always high if the duration is over 30 s, the set HR high limit is exceeded, and the HR is over 180 in NICU sw package or over 150 in all other sw packages.			
VT>2		alarm, wavef.	0s, according to priority setting: high, medium, low, off, info			

Alarm priorities and escalation times for impedance respiration

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Apnea (Imped.)	OR sw package, adjustable limit seconds	alarm, wavef.		X seconds (X = adjustable limit)	X + 40 s	X + 102 s
Apnea (Imped.)	PACU, ED, ICU, NICU sw packages, adjustable limit seconds	alarm, wavef.		X seconds (X = adjustable limit)	X + 20 s	X + 40 s
Apnea (Imped.)	Alarm priority set to info, low, medium or high	alarm	X s, according to priority setting: high, medium, low, info (X = adjustable limit)			
Apnea deactivated		param.	0 s			
Check device		param., wavef.			0 s	
Imped. malfunction		alarm			0 s	
• Lead I failed • Lead II failed • Lead RL-LL failed		param., wavef.	0 s			
Measurement off OFF		• param. • wavef.	0 s			

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Measurement paused Resp (Imped.) measurement paused	Alarm priority set to Escalating	- wavef. - alarm		18 s for NICU software package 50 s for ICU, ED, OR, PACU software packages	38 s for NICU software package 70 s for ICU, ED, OR, PACU software packages	78 s for NICU software package 110 s for ICU, ED, OR, PACU software packages
Measurement paused Resp (Imped.) measurement paused	Alarm priority set to info, low, medium or high	- wavef. - alarm	18 s, according to priority setting: high, medium, low, or info for NICU software package 50 s, according to priority setting: high, medium, low, or info for ICU, ED, OR, PACU software packages			
Relearning		param., wavef.	0 s			
RR (Imped.) high / RR (Imped.) low	Alarm priority set to Escalating	alarm		X seconds (X = adjustable limit)	X + 40 s	
RR (Imped.) high / RR (Imped.) low	Alarm priority set to info, low, medium or high	alarm	High, medium, low, or info according to priority setting. The alarm delay is equivalent to the set respiration rate alarm delay, which is configurable from 0 to 30 s in increments of 5 s.			

Alarm priorities and escalation times for SpO₂

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Artifact	TruSignal, Masimo	param.	0 s			
Check device		param.	0 s			
Check probe		param.	0 s			
Check SpO₂ probe		alarm		5 s	30 s	
Demo mode SpO₂ Demo mode	Masimo	param., alarm			0 s	
Expiring cable	Masimo	param.	0 s			
Expiring probe	Masimo	param.	0 s			
Faulty adhesive SpO₂ probe	Masimo	alarm		5 s	30 s	
Faulty cable	Masimo	param.	0 s			
Faulty probe		param.	0 s			
Identical SpO₂ device		alarm			0 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Incompatible cable Incompatible SpO2 cable	Masimo	param., alarm	0 s			
Incompatible SpO2 device		alarm			0 s	
Incompatible adhesive SpO2 probe	Masimo	alarm		5 s	30 s	
Incompatible probe		param.	0 s			
Incompatible SpO2 probe		alarm		5 s	30 s	
Insufficient power for SpO2 device		alarm			0 s	
Low perfusion	TruSignal, Masimo	param.	0 s			
Low signal	Masimo	param.	0 s			
Low signal quality	Nellcor, Masimo	param.	0 s			
Motion detected	Nellcor	param.	0 s			
Move SpO2 device to a cooler location		alarm		0 s		
No cable		param.	0 s			
No adhesive SpO2 probe	Masimo	alarm		5 s	30 s	
No probe		param.	0 s			
No SpO2 cable	All profiles except Perfusion	alarm		5 s	30 s	
No SpO2 probe	All profiles except Perfusion	alarm		5 s	30 s	
PR(SpO2) high	Unit setting HR alarms = Multiple	alarm		PR alarm delay setting, according to priority setting: high, medium, low		
PR(SpO2) high	Unit setting HR alarms = Multiple; Priority = Escalating	alarm			PR alarm delay setting	PR alarm delay setting + 64 s
PR(SpO2) high	Unit setting HR alarms = Multiple; Priority = Escalating; HR > 1.25 x high limit	alarm				PR alarm delay setting
PR(SpO2) low	Unit setting HR alarms = Multiple	alarm		PR alarm delay setting, according to priority setting: high, medium, low		

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
PR(SpO2) low	Unit setting HR alarms = Multiple; Priority = Escalating	alarm			PR alarm delay setting	PR alarm delay setting + 64 s
PR(SpO2) low	Unit setting HR alarms = Multiple; Priority = Escalating ; HR < 0.75 x low limit	alarm				PR alarm delay setting
Probe initializing	Masimo	param.	0 s			
Probe off		param.	0 s			
Pulse search		param.	0 s			
Replace cable Replace SpO2 cable	Masimo	param., alarm	0 s	0 s		
Replace probe Replace adhesive SpO2 probe	Masimo	param., alarm	0 s	0 s		
Replace probe Replace SpO2 probe	Masimo	param., alarm	0 s	0 s		
SpO2 device failure: Call service		alarm			0 s	
SpO2 device overheated Shutting down		alarm			0 s	
SpO2 faulty cable	Masimo	alarm		5 s	30 s	
SpO2 faulty probe Faulty probe		alarm		5 s	30 s	
SpO2 high / SpO2 low	OR software package, escalating alarm priority	alarm			SpO2 high or low alarm delay setting	SpO2 high or low alarm delay setting + 60 s
SpO2 high / SpO2 low	ICU, NICU, PACU, ED software package, escalating alarm priority	alarm			SpO2 high or low alarm delay setting	SpO2 high or low alarm delay setting + 30 s
SpO2 high / SpO2 low	OR software package and saturation seconds on, escalating alarm priority	alarm			0 s	60 s

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
SpO2 high / SpO2 low	ICU, NICU, PACU, ED software package and saturation seconds on, escalating alarm priority	alarm			0 s	30 s
SpO2 high / SpO2 low	Alarm priority set to low, medium or high	alarm		SpO ₂ high or low alarm delay setting		
SpO2 high / SpO2 low	Alarm priority set to low and saturation seconds on	alarm		0 s		
SpO2 high / SpO2 low	Alarm priority set to medium and saturation seconds on	alarm			0 s	
SpO2 high / SpO2 low	Alarm priority set to high and saturation seconds on	alarm				0 s
SpO2 malfunction		alarm			0 s	
SpO2 measurement removed		alarm	0 s if no patient case/no admitted patient		0 s if active patient case/admitted patient	
SpO2 probe off	Escalating alarm priority, all profiles except Perfusion	alarm		5 s	30 s	
SpO2 probe off	Alarm priority set to high, medium, or low; all profiles except Perfusion	alarm		5 s, according to priority setting: high, medium, low		

Alarm priorities and escalation times for rSO₂

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
rSO2 measurement disconnected		alarm			0 s	

Alarm priorities and escalation times for NIBP

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Calibrated	Displays for 10 s	param.	0 s			
Calibrating		param.	0 s			
Calibration error		param.	0 s			
Call service		param.	0 s			
Check NIBP		alarm			0 s	
Control measurement	Displays for 10 s	param.	0 s			
Cuff loose		param.			0 s	
Cuff occlusion		param.	0 s			
Cuff overpressure	Displays for 10 s	param.	0 s			
Long meas. time	Displays for 10 s	param.	0 s			
NIBP alarm limits changed		alarm	0 s			
NIBP cuff loose		alarm			0 s	
NIBP cuff occlusion		alarm		0 s	40 s	
NIBP auto stopped NIBP STAT stopped		alarm			0 s	
NIBP malfunction		alarm			0 s	
NIBP over range		alarm			0 s	
NIBP under range		alarm			0 s	
• NIBP Sys high / NIBP Sys low • NIBP Mean high / NIBP Mean low • NIBP Dia high / NIBP Dia low		alarm		0 s	0 s, after control measurement	0 s if Primary HR high/ low alarm also active
• NIBP Sys high / NIBP Sys low • NIBP Mean high / NIBP Mean low • NIBP Dia high / NIBP Dia low	Alarm priority set to low, medium or high	alarm		0 s, according to priority setting: high, medium, low		
Select cuff size		param.	0 s			
Zero OK	Displays for 10 s	param.	0 s			
Zeroing		param.	0 s			

Alarm priorities and escalation times for invasive pressures

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

NOTE

When an invasive pressure label is followed by an **X**, the **X** represents invasive pressure channel number.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
> 220 /min		param.	0 s			
> 312 mmHg or > 42 kPa		param	0 s			
< -34 mmHg or < -5 kPa		param.	0 s			
Art X disconnect Fem X disconnect UAC X disconnect		alarm				5 s
Art X sensor disconnected CVP X sensor disconnected Fem X sensor disconnected FemV X sensor disconnected ICP X sensor disconnected LAP X sensor disconnected P X sensor disconnected PA X sensor disconnected RAP X sensor disconnected RVP X sensor disconnected UAC X sensor disconnected UVC X sensor disconnected		alarm			0 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Art X sensor failed CVP X sensor failed Fem X sensor failed FemV X sensor failed ICP X sensor failed LAP X sensor failed P X sensor failed PA X sensor failed RAP X sensor failed RVP X sensor failed UAC X sensor failed UVC X sensor failed		alarm			0 s	
Art X sys high / Art X sys low Art X mean high / Art X mean low Art X dia high / Art X dia low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/low alarm also present
Art X sys high / Art X sys low Art X mean high / Art X mean low Art X dia high / Art X dia low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Artifact		param.	0 s			
Check device		param.	0 s			
Check pressure		param.	0 s			
Check XXX waveform where XXX = invasive pressure channel label (Art or Fem , followed by the channel number)		alarm			0 s	
CPP (X) high / CPP (X) low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/low alarm also present

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
CPP (X) high / CPP (X) low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
CVP X mean high / CVP X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/low alarm also present
CVP X mean high / CVP X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Disconnected		param.	0 s			
Device overheating		param.	0 s			
Fem X sys high / Fem X sys low Fem X mean high / Fem X mean low Fem X dia high / Fem X dia low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
Fem X sys high / Fem X sys low Fem X mean high / Fem X mean low Fem X dia high / Fem X dia low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
FemV X mean high / FemV X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
FemV X mean high / FemV X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
ICP X mean high / ICP X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
ICP X mean high / ICP X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Identical IP/CCO devices		alarm			0 s	
Identical pressure devices		alarm			0 s	
Insufficient power for IP/CCO device		alarm			0 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
IP/CCO measurement removed		alarm	0 s if no patient case/no admitted patient		0 s if active patient case/admitted patient	
IP/CCO device overheated. Shutting it down.		alarm			0 s	
IP's not zeroed		alarm	0 s	300 s		
LAP X mean high / LAP X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
LAP X mean high / LAP X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Move IP/CCO device to a cooler location		alarm		0 s		
Move pressure device 1/2 to a cooler location Move pressure device 3/4 to a cooler location		alarm		0 s		
P1 mean high / P1 mean low to P4 mean high / P4 mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
P1 mean high / P1 mean low to P4 mean high / P4 mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Px over range		al. area			5 s	
P1 pressure malfunction to P4 pressure malfunction		alarm			0 s	
P8 pressure malfunction		alarm			0 s	
P8 PR over range		alarm			5 s	
Px not zeroed		param.	0 s			
PX standby		param.	0 s			
Px under range		al. area			5 s	
PX zeroing failed		param.	0 s			

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
PA X sys high / PA X sys low PA X mean high / PA X mean low PA X dia high / PA X dia low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
PA X sys high / PA X sys low PA X mean high / PA X mean low PA X dia high / PA X dia low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
PR [Invasive pressure channel label] high X / PR [Invasive pressure channel label] low X , where [Invasive pressure channel label] = Art, Fem, or UAC	Unit setting HR Alarms = Multiple	alarm		High, medium or low according to priority setting. The alarm delay is equivalent to the set PR alarm delay, which is configurable from 0 to 20 s in increments of 5 s.		
PR [Invasive pressure channel label] high X / PR [Invasive pressure channel label] low X , where [Invasive pressure channel label] = Art, Fem, or UAC	Unit setting HR Alarms = Multiple; Priority = Escalating	alarm			According to the set alarm delay, which is configurable from 0 to 20 s in increments of 5 s.	Alarm delay + 64 s
PR [Invasive pressure channel label] high X / PR [Invasive pressure channel label] low X , where [Invasive pressure channel label] = Art, Fem, or UAC	Unit setting HR Alarms = Multiple; Priority = Escalating ; HR > 1.25 x high limit or < 0.75 x low limit	alarm				According to the set alarm delay, which is configurable from 0 to 20 s in increments of 5 s.
Pressure device failure: Call service		alarm			0 s	
Pressure device overheated. Shutting it down		alarm			0 s	
Pressure measurement removed		alarm	0 s if no patient case/ no admitted patient		0 s if active patient case/ admitted patient	
Pressure sensed		param.	0 s			

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
RAP X mean high / RAP X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
RAP X mean high / RAP X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
RVP X mean high / RVP X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
RVP X mean high / RVP X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Sensor		param.	0 s		0 s	
UAC X sys high / UAC X sys low UAC X mean high / UAC X mean low UAC X dia high / UAC X dia low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
UAC X sys high / UAC X sys low UAC X mean high / UAC X mean low UAC X dia high / UAC X dia low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
UVC X mean high / UVC X mean low	Alarm priority set to Escalating	alarm		10 s	30 s	10 s if Brady/Tachy or HR high/ low alarm also present
UVC X mean high / UVC X mean low	Alarm priority set to low, medium, or high	alarm		10 s, according to priority setting: high, medium, low		
Waveform not stable		wavef.	0 s			
Zero ICP separately		alarm	0 s			
Zeroed		param.	0 s			
Zeroing		param.	0 s			

Alarm priorities and escalation times for temperature

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Calibration fail		param.	0 s			
Check device		param.	0 s			
Device overheating		param.	0 s			
Identical Temp device		alarm			0 s	
Move Temp device to a cooler location		alarm		0 s		
No sensor detected		param.	0 s			
T1 calibration fail / T2 calibration fail		alarm			0 s	
T1 high / T1 low T2 high / T2 low		alarm	60 s	60 s according to priority setting: medium, low		
T1 high / T1 low T2 high / T2 low	Alarm priority set to Escalating.	alarm		60 s	120 s	
X-Y high where X-Y = T1-T2 or T2-T1		alarm	60 s	60 s according to priority setting: medium, low		
X-Y high where X-Y = T1-T2 or T2-T1	Alarm priority set to Escalating.	alarm		60 s	120 s	
Temp device failure: Call service		alarm			0 s	
Temp measurement removed		alarm	0 s if no patient case/ no admitted patient		0 s if active patient case/ admitted patient	
Temperature malfunction		alarm			0 s	
Temp device overheated. Shutting down		alarm			0 s	

Alarm priorities and escalation times for CCO

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
CCO measurement discontinued		alarm			0 s	

Alarm priorities and escalation times for CO₂

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Apnea (CO ₂)	OR sw package, adjustable limit seconds	alarm, wavef., param.	0 s	X seconds (X = adjustable limit)	X + 40 s	X + 102 s
Apnea (CO ₂)	PACU, ED, ICU, NICU sw packages, adjustable limit seconds	alarm, wavef., param.	0 s	X seconds (X = adjustable limit)	X + 20 s	X + 40 s
Apnea (CO ₂)	With alarm priority set to medium or high	alarm			X seconds (X = adjustable limit), according to priority setting: high, medium	
Apnea deactivated		param.	0 s			
Check Adapter		param.	0 s			
Check CO ₂ adapter		alarm		40 s	60 s	
Check device		param.	0 s			
Check gas flow		alarm			40 s	
Check sample line		alarm, param.	0 s	40 s	60 s	
Check sensor		param.	0 s			
CO ₂ device failure: Call service		alarm			0 s	
CO ₂ device initializing		alarm			0 s	
CO ₂ device malfunction		alarm			0 s	
CO ₂ device overheated Shutting down		alarm			0 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
CO2 measurement purging		alarm		25 s		
CO2 measurement removed		alarm	0 s if no patient case/ no admitted patient		0 s if active patient case/ admitted patient	
CO2 sensor overheated Shutting down		alarm			0 s	
CO2 sensor removed		alarm	0 s if no patient case/ no admitted patient		0 s if active patient case/ admitted patient	
CO2 zero required		alarm			40 s	
Device overheating		param.	0 s			
EtCO2 high / EtCO2 low	Alarm priority set to Escalating	alarm		20 s	60 s	
EtCO2 high / EtCO2 low	Alarm priority set to medium or high	alarm			20 s, according to priority setting: high, medium	
FiCO2 high / FiCO2 low	Alarm priority set to Escalating	alarm		20 s	60 s	
FiCO2 high / FiCO2 low	Alarm priority set to medium or high	alarm			20 s, according to priority setting: high, medium	
Identical CO2 device		alarm			0 s	
Insufficient power for CO2 device		alarm			0 s	
Line disconnected		param.	0 s			
Move CO2 device to a cooler location		alarm		0 s		
Move CO2 sensor to a cooler location		alarm		0 s	120 s	
Over range		param.	0 s			
Over scale		wavef.	0 s			
RR (CO2) high / RR (CO2) low	Alarm priority set to Escalating	alarm		20 s	60 s	
RR (CO2) high / RR (CO2) low	Alarm priority set to medium or high	alarm			20 s, according to priority setting: high, medium	
Sample line blocked		param.	0 s			
Sample line disconnected		alarm			40 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Select age for CO2		alarm			20 s	
Sensor overheating		param.	0 s			
Sensor removed		param.	0 s			
Service CO2 sensor		alarm			0 s	
Warming up		param.	0 s			
Zero required		param.	0 s			
Zeroing		param., wavef.	0 s			

Alarm priorities and escalation times for various situations

The following table shows the messages with their priorities and escalation times. In the table, the message location is indicated by the following: alarm = alarm area; param. = parameter window; and wavef. = waveform area. In the following table, 0 s = no intended delay. For more information on alarm messages, refer to the user information provided.

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Alarm setup changed remotely		alarm	0 s			
Alarm volume changed		alarm	0 s			
Alarms acknowledged remotely		alarm	0 s			
Analog output malfunction		alarm			0 s	
Battery empty!		alarm			0 s	
Battery failure		alarm		0 s		
Battery low		alarm		0 s		
Battery temp high		alarm		0 s		
Call service: Check WLAN certificate.		alarm	0 s			
Call Service: Text(s) missing		alarm	0 s			
Call service: WLAN certificate expired.		alarm	0 s			
Case ended		alarm	0 s			
Case started		alarm	0 s			
Condition battery		alarm		0 s		

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Configuration change(s)		alarm	0 s			
Configuration changes. Restart required.		alarm	0 s			
Configuration error(s)		alarm	0 s			
CS ONE Faulty Device Connected		alarm			0 s	
CS ONE faulty device in port #X where X is the micro-module port number		alarm			0 s	
CS ONE removed		alarm	0 s if no patient case/ no admitted patient		0 s if active patient case/ admitted patient	
CS ONE Speaker Failure		alarm			0 s	
CS ONE unknown device in port #X where X is the micro-module port number		alarm			0 s	
DEMO MODE	Not for patient monitoring use!	alarm	0 s			
DEMO MODE Not for clinical use!	Not for patient monitoring use!	alarm		0 s		
ECG Analog output malfunction		alarm			0 s	
Entering standby		alarm	0 s			
Identical IP address noticed		alarm			0 s	
IP Analog output malfunction		alarm			0 s	
License(s) expired		alarm	0 s			
Monitor restarted. Check patient.		alarm			0 s	
Network down		alarm		40 s		
No battery backup		alarm		0 s		
Patient admitted		alarm	0 s			
Patient discharged		alarm	0 s			
Powering down!		alarm			0 s	

MESSAGE	NOTES	LOCATION	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Replace battery		alarm		0 s		
rSO2 measurement disconnected		alarm			0 s	
Service CS ONE Activation Failed		alarm	0 s			
Service CS ONE Calibrate NIBP		alarm	0 s			
Service CS ONE ECG Analog Out		alarm	0 s			
Service CS ONE faulty port #X where X is the micro-module port number		alarm			0 s	
Service CS ONE IP Analog Out		alarm	0 s			
Service CS ONE power failure		alarm			0 s	
Service CS ONE and specific error code		alarm			0 s	
SW download failed on CS ONE port #X where X is the micro-module port number		alarm		0 s		
SW update in progress on CS ONE port #X where X is the micro-module port number		alarm	0 s			
Unable to read licenses		alarm	0 s			
Wireless link disconnected		alarm	0 s (when wireless link is disconnected from CS ONE)	0 s (when wireless link is disconnected from host monitor)		

Parameter specifications

Parameter specifications

WARNING

INACCURATE RESULTS. Do not use or store the equipment outside the specified temperature, humidity, or altitude ranges, or outside the specified performance range. Using or storing the equipment outside the specified operating environment or outside the specified performance range may cause inaccurate results.

ECG standards compliance

The system with the TruSignal ECG micro-module complies with IEC 60601-2-27:2011-03.

NOTE

Moderate and maximum reduced bandwidths do not comply with all requirements of the IEC 60601-2-27 standard.

The TruSignal ECG micro-module enclosure and interface cable are treated as TYPE CF DEFIBRILLATION-PROOF APPLIED PARTs per IEC 60601-2-27 Clause 201.8.3 and Clause 201.8.5.5. Compatible leadwires are TYPE CF DEFIBRILLATION-PROOF APPLIED PARTs.

ECG performance specifications

ECG heart rate range	20 to 300 bpm NOTE Values in the range of 301 to 360 bpm are displayed as 300 bpm.
ECG heart rate accuracy	±1% or ±1 bpm, whichever is greater
ECG heart rate resolution	1 bpm
ECG heart rate sensitivity	≥ 0.5 mV peak
ECG heart rate response time	Indicates a new heart rate for a step increase of 80 to 120 bpm and a step decrease of 80 to 40 bpm in < 10 s
Heart rate accuracy and response to irregular rhythm	Heart rate calculation operates with irregular rhythms of IEC 60601-2-27 Clause 201.7.9.2.9.101 b) 4), according to Figure 201.101, as follows: Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 59 bpm Rapid alternating ventricular bigeminy: 126 bpm Bidirectional systoles: 110 bpm
ECG heart rate averaging	12-second median HR values 12-second HR median calculation extended to a maximum of 32 seconds based on signal noise when software package is ICU, ED, OR, or PACU

ECG heart rate display update interval	< 2 seconds
ECG QRS detection range	± 0.5 to ± 5 mV
ECG QRS detection width	40 to 120 ms (Q to S)
PVC rate range	0 to 300 PVCs per minute
PVC rate resolution	1 PVC per minute
ST numeric range	-20.0 to 20.0 mm
ST numeric resolution	0.1 mm
ST numeric accuracy	Per EC57 (ESC database): - ST Mean Absolute Difference < 100 μV - ST Mean Difference (Mean error) < 50 μV - Correlation coefficient > 0.90 - ST tolerance ± 0.4 mm or 20%, whichever is greater
QRS numeric accuracy	Per EC57 (AHA and MIT-BIH databases): - QRS sensitivity >97.5% - QRS positive predictivity: >97.5%
VEB numeric accuracy	Per EC57 (AHA and MIT-BIH databases): - VEB sensitivity >90% - VEB positive predictivity: >90%
VF numeric accuracy	Per EC57 (AHA and MIT-BIH databases): - VF episode sensitivity >95% - VF episode positive predictivity: >95%
ECG gain selections	0.5x = 5 mm/mV 1x = 10 mm/mV 2x = 20 mm/mV 4x = 40 mm/mV
ECG signal gain accuracy	$\pm 5\%$
Sampling rate	500 samples/second
ECG display bandwidth (based on ECG waveform filter setting) Diagnostic and Monitoring (at 60 Hz powerline frequency) bandwidths as per IEC 60601-2-27 Clause 201.12.1.101.8. With Monitoring (at 60 Hz powerline frequency) bandwidth recorder tested for clause a) Frequency response method A but not tested for Method B. Moderate, Maximum and Monitoring (at 50 Hz powerline frequency) bandwidths not tested as per IEC 60601-2-27 Clause 201.12.1.101.8	- Diagnostic: 0.05 to 150 Hz - Monitoring: 50 Hz powerline frequency: 0.05 to 32 Hz 60 Hz powerline frequency: 0.05 to 40 Hz - Moderate: 0.05 to 23 Hz - Maximum: 4.5 to 27 Hz
ECG differential offset voltage (allowable offset)	± 0.4 V
ECG input impedance	Differential: > 2.5 M Ω from 0.67 Hz to 40 Hz
ECG system noise	< 30 μ V (referred to input)

Common mode rejection	90 dB minimum at 50/60 Hz
Maximum tall T-wave rejection capability (with a 1 mV QRS test signal)	< 4.5 mV
ECG sweep speed options	6.25, 12.5, 25, and 50 mm/s
ECG leads available	I, II, III, V1 to V6, aVR, aVL, aVF
ECG lead sets supported	3-, 5-, 6-, and 10-leadwire
Pacemaker pulse display capability	- Sensitive pacemaker detection: voltage range of ± 1.2 mV to ± 700 mV with pulse widths of 0.1 ms to 2 ms - Normal pacemaker detection: voltage range of ± 2.4 mV to ± 700 mV with pulse widths of 0.1 ms to 2 ms Pacemaker pulse indication visible on the display with an amplitude no less than 0.2 mV referred to the input Normal not tested to down to ± 2 mV per IEC 60601-2-27 clause 201.12.1.101.12
Pacemaker pulse rejection capability	Voltage range: ± 2 to ± 700 mV Pulse width: 0.1 to 2 ms Overshoot measured using Method A IEC 60601-2-27 Clause 201.12.1.101.13 with amplitude maximum 2 mV Time constant: 4 ms to 8 ms NOTE According to IEC 60601-2-27 Clause 201.12.1.101.13 an atrial pace pulse with identical amplitude and duration precedes ventricular pace pulse by 150 ms to 250 ms.
ECG lead fail sensing direct current for leads-off detection	- Active patient electrode: 12.8 nA typical (each) - Reference electrode: < 150 nA maximum
ECG lead fail	Identifies failed electrodes and switches to those intact.
Defibrillation protection	5000 V, 360 J
Replaceable interface cable	Tool removable USB interface cable
ECG analog output signal gain	1 V/1 mV $\pm 10\%$
ECG analog output bandwidth (based on ECG waveform filter setting)	- Diagnostic: 0.05 to 125 Hz - Monitoring: 0.05 to 40 Hz - Moderate: 0.05 to 25 Hz - Maximum: 0.05 to 25 Hz
ECG analog output delay	< 35 ms
Pacemaker marker	5 V, 2 ms pulse summed with the ECG analog output
Defibrillator sync output signal	Square pulse, low level 0 V to 0.8 V, high level 9 V to 10.5 V, duration 10 ms ($\pm 10\%$); output load impedance < 10k Ω
Defibrillator sync input signal	Signal amplitude of -2.0 V to -25.0 V or +2.0 V to +25.0 V for a duration of 2.5 ms and greater is detected as a synchronization pulse
Defibrillator sync output delay	< 35 ms

Impedance respiration standards compliance

The TruSignal ECG micro-module enclosure and interface cable are treated as TYPE CF DEFIBRILLATION-PROOF APPLIED PARTS per IEC 60601-2-27 Clause 201.8.3 and Clause 201.8.5.5. Compatible lead wires are TYPE CF DEFIBRILLATION-PROOF APPLIED PARTS.

Impedance respiration performance specifications

Impedance respiration rate measurement range	- Adult/Pedi: 0 to 120 breaths per minute - Neonate: 0 to 200 breaths per minute
Impedance respiration measurement accuracy	4 to 120 breaths per minute: ± 1 breath per minute 121 to 200 breaths per minute: ± 3 breaths per minute
Impedance respiration rate resolution	1 breath per minute
Impedance respiration input impedance range	Static: 100 to 1500 Ω @ 52.3 kHz
Impedance respiration normalized respiration sensing current	$< 100 \mu A_{RMS}$
Impedance respiration carrier frequency	52.3 kHz
Impedance respiration leads available	I, II, RL-LL
Impedance respiration waveform sweep speed options	0.625 mm/s, 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s

SpO₂ standards compliance

The system with compatible SpO₂ micro-module complies with ISO 80601-2-61:2017-12 + Corrected version: 2018-02.

The TruSignal SpO₂ micro-module sensor interface cable, excluding the module strain relief, and compatible sensors are type BF DEFIBRILLATION-PROOF APPLIED PARTS per IEC 60601-1 Clause 8.3 and ISO 80601-2-61 Clause 201.8.3.101.

The Masimo SpO₂ micro-module enclosure and interface cable, excluding the connector and strain relief on the host end of the cable, is treated as a type BF DEFIBRILLATION-PROOF APPLIED PART. Compatible sensor interface cables and SpO₂ sensors are type BF DEFIBRILLATION-PROOF APPLIED PARTS per ISO 80601-2-61 Clause 201.8.3.101.

The Nellcor SpO₂ micro-module OxiCOR Module enclosure and cable from the OxiCOR module to the strain relief on the Isolation Module are treated as type BF DEFIBRILLATION-PROOF APPLIED PARTS. Compatible SpO₂ sensors are type BF DEFIBRILLATION-PROOF APPLIED PARTS per ISO 80601-2-61 Clause 201.8.3.101.

SpO₂ displayed saturation values

TruSignal, Masimo SET and Nellcor OxiMax pulse oximetry are calibrated to display functional saturation.

NOTE

You can verify the functionality of pulse oximeter sensor and monitor with a functional SpO₂ tester but you cannot evaluate their accuracy with such a device. For more information, refer to the standard ISO 80601-2-61:2018-02 Annex FF (Simulators, calibrators and functional testers for pulse oximeter equipment).

SpO₂ summary of clinical studies used to establish accuracy claims

Accuracy of Nellcor™ sensors with Oximax™ technology

Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ± 1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range.

Adult specifications are shown for OxiMax MAXA and MAXN sensors with the pulse oximeter.

Neonate specifications are shown for OxiMax MAXN sensors with the pulse oximeter.

Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO₂ accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 61 observations made spanning a range of 77% to 98% SaO₂.

Accuracy of Masimo SET technology with Masimo SET sensors

The Masimo SET Technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals ± 1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

For detailed information, refer to the supplemental analysis graphs in sensor-specific instructions for use provided by the sensor manufacturer.

Accuracy of TruSignal technology with TruSignal sensors

The TruSignal technology with TruSignal sensors has been validated for no motion accuracy in controlled hypoxia studies with healthy non-smoking adult volunteers over the specified saturation SpO₂ range(s). Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by a laboratory co-oximeter. Subjects comprised both healthy adult men and women and spanned a range of ages and skin pigmentations.

For more detailed information, refer to the supplemental analysis graphs in the appendix (Bland and Altman. Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582).

Neonatal clinical performance of TruSignal technology with TruSignal sensors

As suggested in “Pulse Oximeters – Premarket Notification Submissions [510(k)s], Guidance for Industry and Food and Drug Administration Staff, March 4, 2013” convenience samples were collected in neonatal patients to demonstrate clinical performance.

For TruSignal technology with TruSignal Sensitive Skin (TS-SE-3) sensors, a clinical study was conducted using 40 patients, including 19 females and 21 males. Test subjects ranged in age from 1 day to 19 days, and ranged in weight from 0.7 kg to 4.4 kg. The skin tone of the test subjects included in the study ranged from light to dark. An observed A_{rms} of 2.57% was obtained from 52 observations spanning a range of 86.8% to 100.2% SaO₂.

SpO₂ test methods used to establish accuracy claims during motion

Nellcor™ sensors accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ± 1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range.

Nellcor™ sensors motion performance was validated during a controlled hypoxia blood study over an SaO₂ span of 70% to 98.9% and a convenience-sample heart range of 41-105 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OxiMax MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

The Masimo SET Technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in the range of 70% to 100% SpO₂ against a laboratory CO-oximeter and ECG monitor. This variation equals ± 1 standard deviation, which encompasses 68% of the population.

NOTE

Accuracy during motion has not been specified for Masimo SET sensors TC-I.

Measurement modules using TruSignal Technology with compatible sensors have been validated for motion accuracy in controlled hypoxia studies with healthy non-smoking adult volunteers over the specified saturation SpO₂ range(s). The following motion types were used: mechanically induced 3 Hz tapping motion at an amplitude of 1-2 cm, patient induced non-repetitive rubbing motion, and patient induced non-repetitive hand motion in supine position. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by CO-oximetry. Subjects comprised both adult men and women and spanned a range of skin pigmentations.

SpO₂ test methods used to establish accuracy claims during low perfusion

Low perfusion accuracy of Nellcor Oximax technology with Oximax sensors

Specification applies to monitoring cable performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Low perfusion accuracy of Masimo SET technology

The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ± 1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Low perfusion accuracy of TruSignal technology with TruSignal sensors

TruSignal technology with TruSignal sensors have been validated for low perfusion accuracy in a simulator test for saturation ranging from 70% to 100%. The test was conducted using a Fluke ProSim 8 simulator using 0.03% pulse amplitude and Thin Finger transmission setting.

SpO₂ test methods used to establish pulse rate accuracy

Pulse rate accuracy of Nellcor Oximax technology with Oximax sensors

Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ± 1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range.

Adult specifications are shown for OxiMax MAXA and MAXN sensors with the pulse oximeter.

Neonate specifications are shown for OxiMax MAXN sensors with the pulse oximeter.

Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO₂ accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 61 observations made spanning a range of 77% to 98% SaO₂.

Specification applies to monitoring cable performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Nellcor™ sensors motion performance was validated during a controlled hypoxia blood study over an SaO₂ span of 70% to 98.9% and a convenience-sample heart range of 41-105 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OxiMax MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

Pulse rate accuracy of Masimo SET technology with Masimo sensors

Masimo SET Technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. The variation equals plus or minus one standard deviation, which encompasses 68% of the population.

Pulse rate accuracy of TruSignal technology with TruSignal sensors

TruSignal technology with TruSignal sensors has been validated for pulse rate accuracy over the specified range in bench top testing against a patient simulator.

SpO₂ performance specifications

NOTE

Technical specifications given for the Masimo SpO₂ micro-module are based on Masimo Corporation owned Masimo SET technology and sensors. For more detailed information, refer to the micro-module and sensor instructions for use.

NOTE

Technical specifications given for the Nellcor SpO₂ micro-module are based on Covidien AG owned technology and sensors. For more detailed information, refer to the micro-module and sensor instructions for use.

The following specifications apply to all SpO₂ micro-modules unless otherwise indicated.

Pulse oximetry saturation display resolution	1 digit (% of SpO ₂)
Pulse oximetry peripheral pulse rate display resolution	1 bpm
Pulse oximetry display data update period	< 30 s
Pulse oximetry sweep speed options	6.25, 12.5, 25, and 50 mm/s
Pulse oximetry waveform scale options	TruSignal technology: AUTO, 50, 20, 10, 5, 2

	Masimo and Nellcor technologies: 1x, 2x, 4x, and 8x
Wavelength information for SpO ₂ probe LEDs	This information can be especially useful to clinicians such as those performing photodynamic therapy. TruSignal pulse oximetry sensor LED peak wavelengths are within 600 to 1000 nm and the maximum optical output power for each LED is less than 15 mW. Nellcor OxiMax pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm. The total optical output power of the sensor LEDs is less than 15 mW. Masimo SET pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm for LNOP and LNCS, approximately 653 nm and 880 nm for LNOP and LNCS tip clips, and approximately 660 nm and 880 nm for LNOP and LNCS transreflectance forehead sensors. The total optical output power of the LEDs is less than 15 mW.
Pulse oximetry parameters monitored	Arterial oxygen saturation (SpO ₂) and pulse rate
Pulse oximetry saturation measurement value and display range	TruSignal: 0 to 100% Masimo: 0 to 100% Nellcor: 1 to 100%
Pulse oximetry declared pulse rate range	TruSignal: 30 to 300 bpm Masimo: 25 to 240 bpm Nellcor: 20 to 250 bpm
Pulse oximetry displayed pulse rate range	TruSignal: 30 to 300 bpm Masimo: 26 to 239 bpm Nellcor: 20 to 250 bpm
Pulse oximetry saturation measurement value accuracy	The specified accuracy for each technology is the root-mean-square (RMS) difference between the measured values and the reference values. Because pulse oximetry equipment measurements are statistically distributed, only about two-thirds of the pulse oximetry equipment measurements can be expected to fall within the $\pm 1 A_{rms}$ of the value measured by a CO-oximeter. Actual accuracy depends on sensor. Please refer to the sensor instructions for use for more detailed information. TruSignal accuracy: - Without motion: - SpO₂ (70 to 100%): ± 2 Adult, ± 2 Pediatric, ± 3 Neonatal - SpO₂ (<70%): Unspecified - With motion: - SpO₂ (70 to 100%): ± 3 Adult, ± 3 Pediatric, ± 3 Neonatal - SpO₂ (<70%): Unspecified - Low perfusion: - SpO₂ (70 to 100%): ± 2 Adult, ± 2 Pediatric, ± 3 Neonatal - SpO₂ (<70%): Unspecified Masimo accuracy:

	The following accuracy specifications represent only the device's portion of the integrated Masimo rainbow SET technology performance. The actual measurement performance and accuracy depends on the accessory used and can be limited by the accessory as specified in the micro-module and sensor instructions for use. - Without motion: - SpO₂ (70 to 100%): $\pm 2\%$ Adult, Pediatrics, Infants, $\pm 3\%$ Neonate - SpO₂ (<70%): Unspecified - With motion: - SpO₂ (70 to 100%): $\pm 3\%$ All Patient Populations - SpO₂ (<70%): Unspecified - Low perfusion: - SpO₂ (70 to 100%): $\pm 2\%$ All Patient Populations - SpO₂ (<70%): Unspecified Nellcor accuracy: Saturation accuracy varies by sensor type. Adult specifications are shown for OxiMax MAXA and MAXN sensors with the pulse oximeter. Neonate specifications are shown for OxiMax MAXN sensors with the pulse oximeter. For accuracy information for other sensors, refer to the section Additional accuracy information for Nellcor™ sensors of this manual or to the manufacturer's micro-module and sensor instructions for use. Contact Medtronic for more detailed information. - Without motion: - SpO₂ (70 to 100%): ± 2 Adult, ± 2 Neonatal - SpO₂ (60 to 80%): ± 3 Adult, ± 3 Neonatal - SpO₂ (< 60%): Unspecified - With motion: - SpO₂ (70 to 100%): ± 3 Adult, ± 3 Neonatal - SpO₂ (< 70%): Unspecified - Low perfusion: - SpO₂ (70 to 100%): ± 2 Adult, ± 2 Neonatal - SpO₂ (< 70%): Unspecified
Pulse oximetry peripheral pulse rate accuracy	The specified accuracy for each technology is the root-mean-square (RMS) difference between the measured values and the reference values. Actual accuracy depends on sensor. Please refer to the sensor instructions for use for more detailed information. TruSignal accuracy: - Without motion (30 to 250 bpm): ± 2 Adult, ± 2 Pediatric, ± 2 Neonatal - With motion (30 to 250 bpm): ± 5 Adult, ± 5 Pediatric, ± 5 Neonatal - Low perfusion (30 to 250 bpm): ± 3 Adult, ± 3 Pediatric, ± 3 Neonatal (251 to 300 bpm): Unspecified Masimo accuracy: - Without motion (25 to 240 bpm): ± 3 bpm All Patient Populations - With motion (25 to 240 bpm): ± 5 bpm All Patient Populations - Low perfusion (25 to 240 bpm): ± 3 bpm All Patient Populations Nellcor accuracy:

	Saturation accuracy varies by sensor type. Contact Medtronic for sensor accuracy information. Adult specifications are shown for OxiMax MAXA and MAXN sensors with the pulse oximeter. Neonate specifications are shown for OxiMax MAXN sensors with the pulse oximeter. • Without motion (20 to 250 bpm): ±3 bpm Adult, ±3 bpm Neonatal • Low perfusion (20 to 250 bpm): ±3 bpm Adult, ±3 bpm Neonatal • With motion (20 to 250 bpm): ±5 bpm Adult, ±5 bpm Neonatal
Pulse oximetry low perfusion range	TruSignal: 0.03 to 20% Masimo: 0.02 to 20% Nellcor: 0.03 to 20%
Signal strength indication	Signal strength is indicated through the display of asterisks (No asterisk, *, **, or ***). Three asterisks indicate good signal quality and no asterisks indicate poor signal quality. All waveforms are normalized to fit the allocated display area. The TruSignal pleth waveform is not normalized. The Masimo pleth waveform is not normalized. The Nellcor pleth waveform is not normalized.

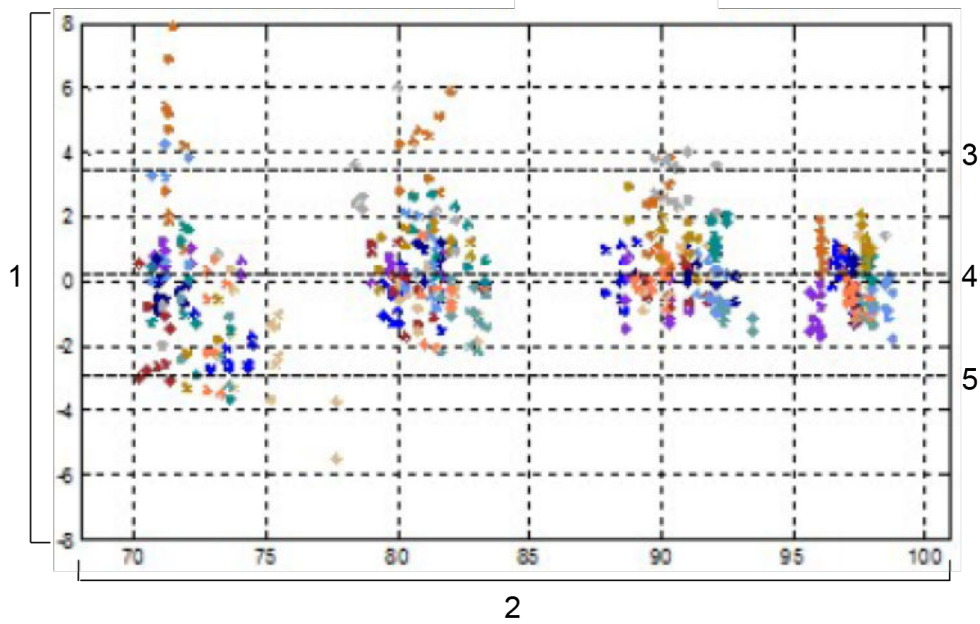
SpO₂ supplemental analysis graphs

Additional accuracy information for Nellcor™ sensors

The table information provides supplemental data analysis for Nellcor sensors' measurement accuracy. The tables are provided by Covidien.

The following modified Bland-Altman plots show SpO₂ data by sensor type. Each individual subject is represented by a unique marker on the plots. Subject identification numbers are indicated in the legend with each plot.

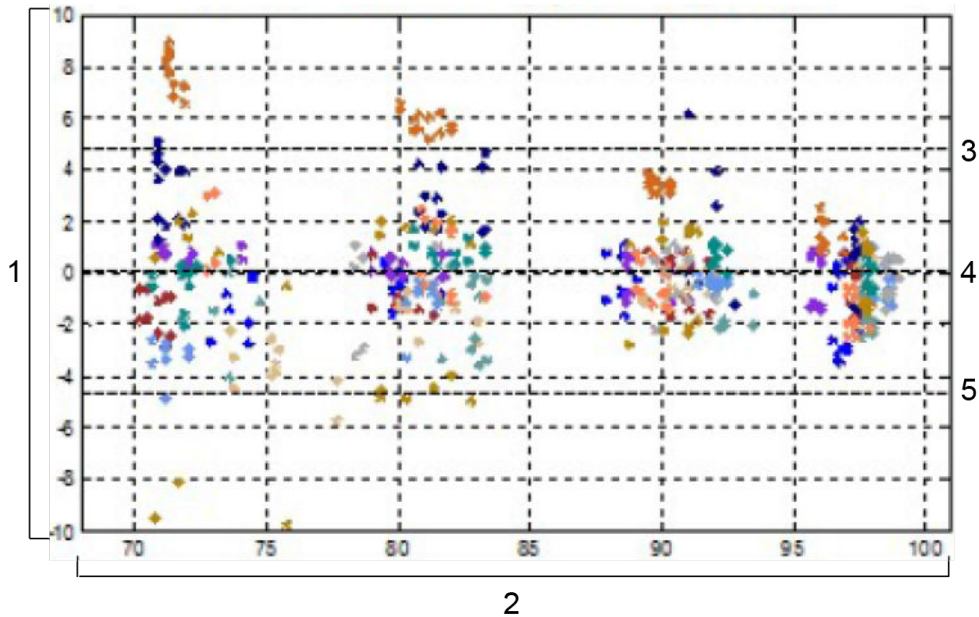
For other Nellcor sensors, refer to sensor-specific and micro-module instructions for use provided by the sensor manufacturer.

Modified Bland-Altman for SpO₂ - DS-100A Sensor: SaO₂ vs. (SpO₂ - SaO₂)

1. SpO₂ - SaO₂ (%)
2. SaO₂ (%)
3. Bias + (1.96 x σ (errs))
4. Bias
5. Bias - (1.96 x σ (errs))

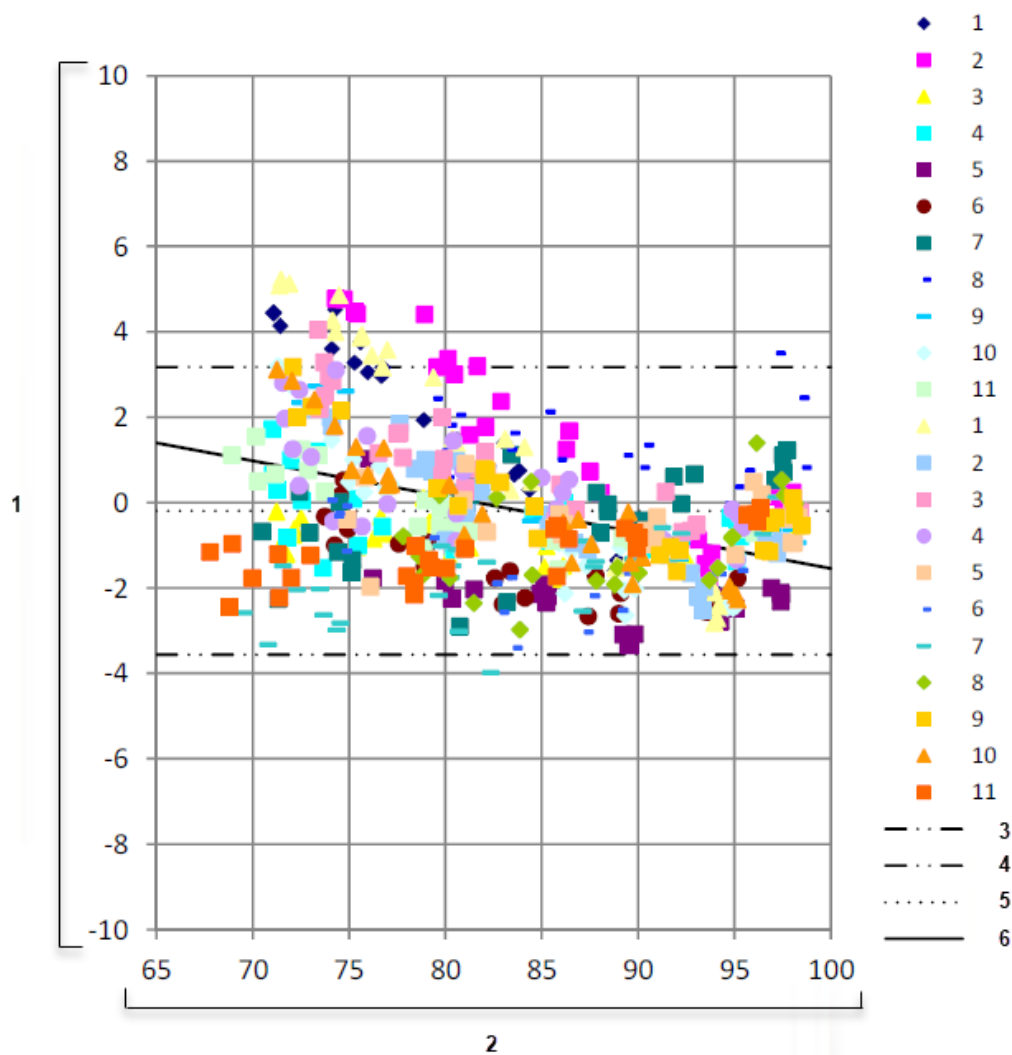
Measured A _{RMS} values	
Range	A _{RMS}
90-100%	1.16%
80-90%	1.67%
70-80%	2.25%

Modified Bland-Altman for SpO₂ - D-YS, D-YSE, D-YSPD, OXI-A/N, OXI-P/I Sensors: SaO₂ vs. (SpO₂ - SaO₂)



- 1. SpO₂ - SaO₂ (%)
- 2. SaO₂ (%)
- 3. Bias + (1.96 x σ (errs))
- 4. Bias
- 5. Bias - (1.96 x σ (errs))

Measured A _{RMS} values	
Range	A _{RMS}
90-100%	1.38%
80-90%	2.5%
70-80%	3.6%

FLEXMAX reusable sensor

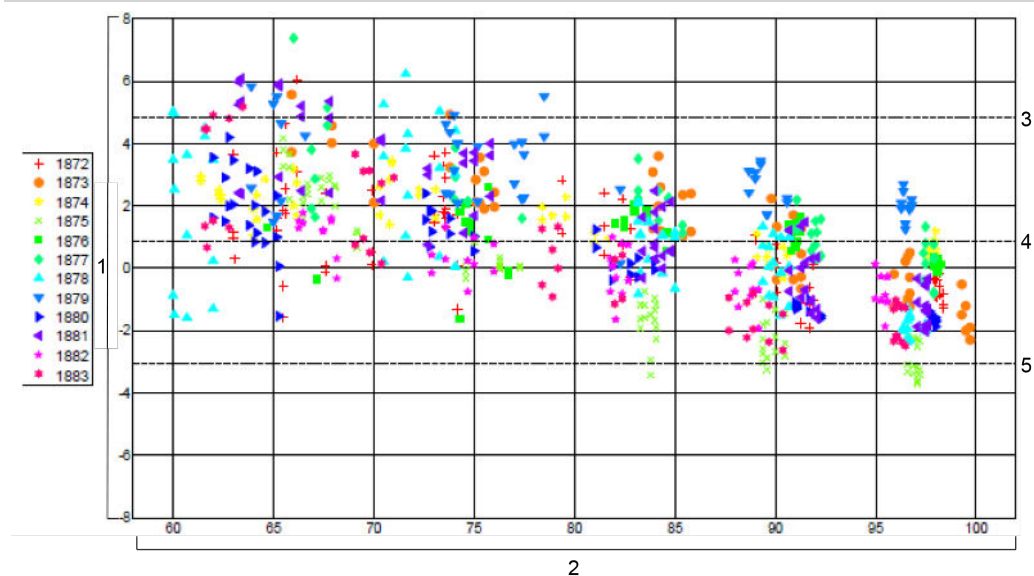
1. $SpO_2 - SaO_2$ (%)
2. $(SaO_2 + SpO_2)/2$
3. Upper 95% Limits of Agreement
4. Lower 95% Limits of Agreement
5. Mean
6. Regression line

Measured A_{RMS} values	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
70-100 ^a	1.7
90-100	1.5
80≤90	1.3
70≤80 ^b	2.1

^a The range of 70% to 100% includes reference data down to 67%.

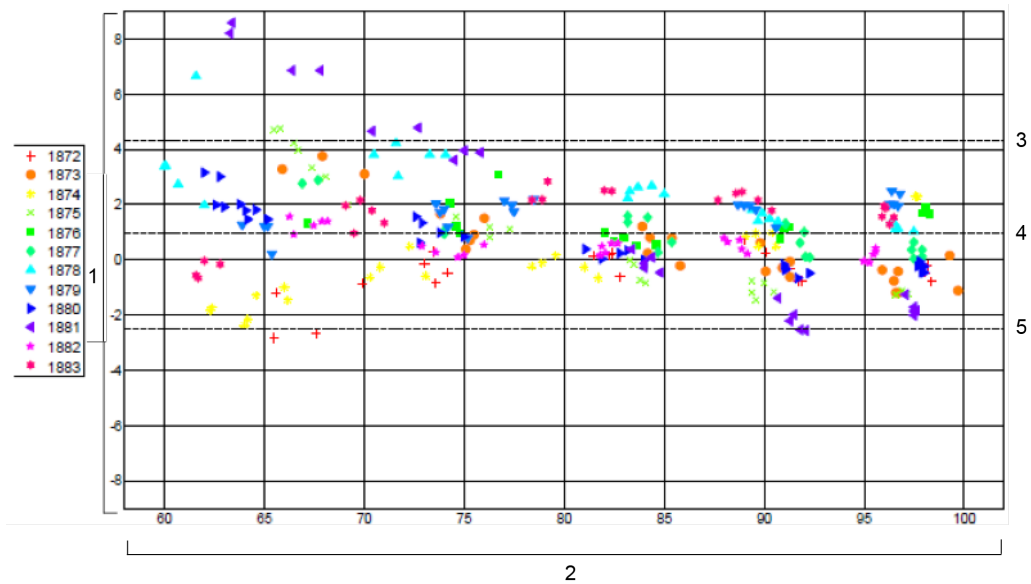
^b The range of 70% to 80% includes reference data down to 67%.

Modified Bland-Altman for SpO₂ - MAX-A, MAX-AL, MAX-N, MAX-I, MAX-P, MAX-R Sensors: SaO₂ vs. (SpO₂ - SaO₂)



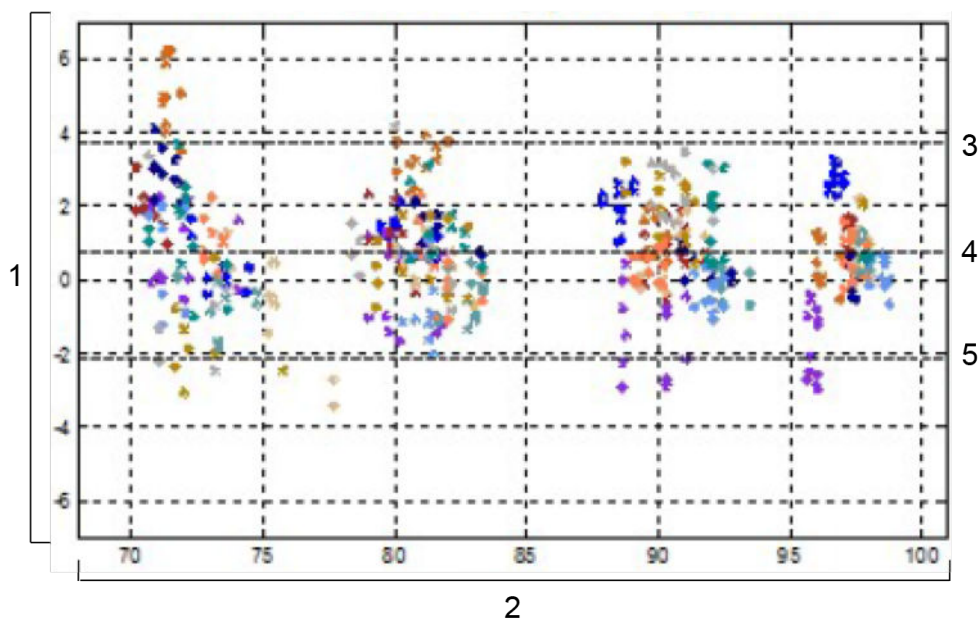
1. SpO₂ - SaO₂ (%)
2. SaO₂ (%)
3. Upper 95%
4. Mean Bias
5. Lower 95%

Measured A _{RMS} values	
Range	A _{RMS}
90-100%	1.49%
80-90%	1.57%
70-80%	2.5%

Modified Bland-Altman for SpO₂ - MAXFAST Sensor: SaO₂ vs. (SpO₂ - SaO₂)

1. SpO₂ - SaO₂ (%)
2. SaO₂ (%)
3. Upper 95%
4. Mean Bias
5. Lower 95%

Measured A _{RMS} values	
Range	A _{RMS}
90-100%	1.24%
80-90%	1.26%
70-80%	2.05%

Modified Bland-Altman for SpO₂ - SC-A, SC-NEO, SC-PR Sensors: SaO₂ vs. (SpO₂ - SaO₂)


1. SpO₂ - SaO₂ (%)
2. SaO₂ (%)
3. Bias + (1.96 x σ (errs))
4. Bias
5. Bias - (1.96 x σ (errs))

Additional accuracy information for Masimo sensors

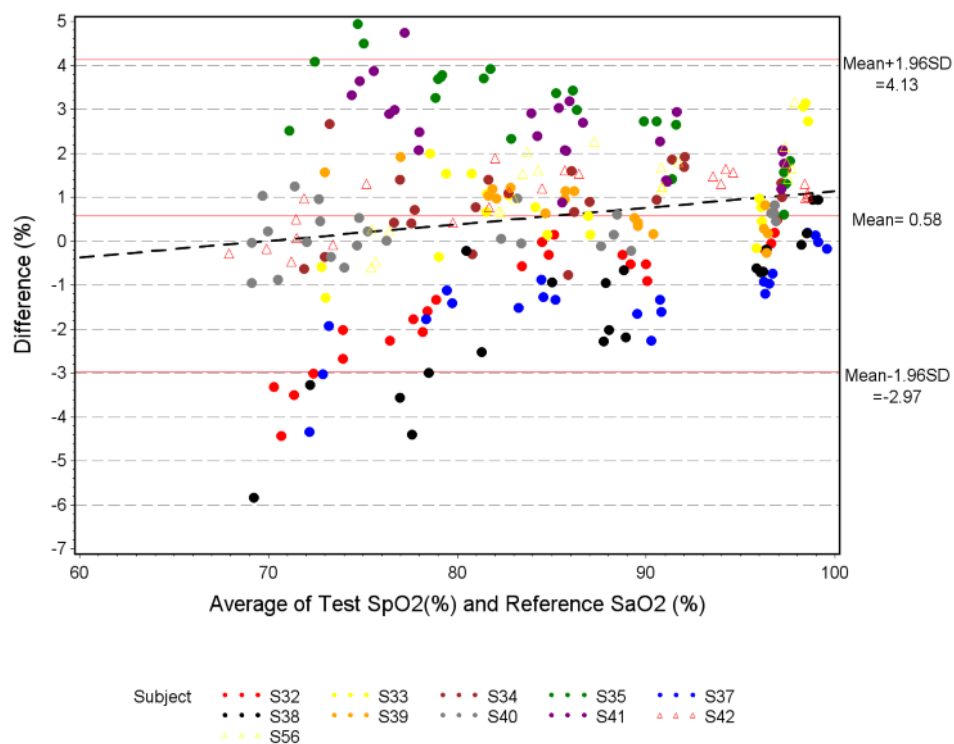
Refer to the instructions for use of Masimo sensors for measurement accuracy information.

Additional accuracy information for TruSignal sensors

The table information provides supplemental data analysis for TruSignal sensors' measurement accuracy.

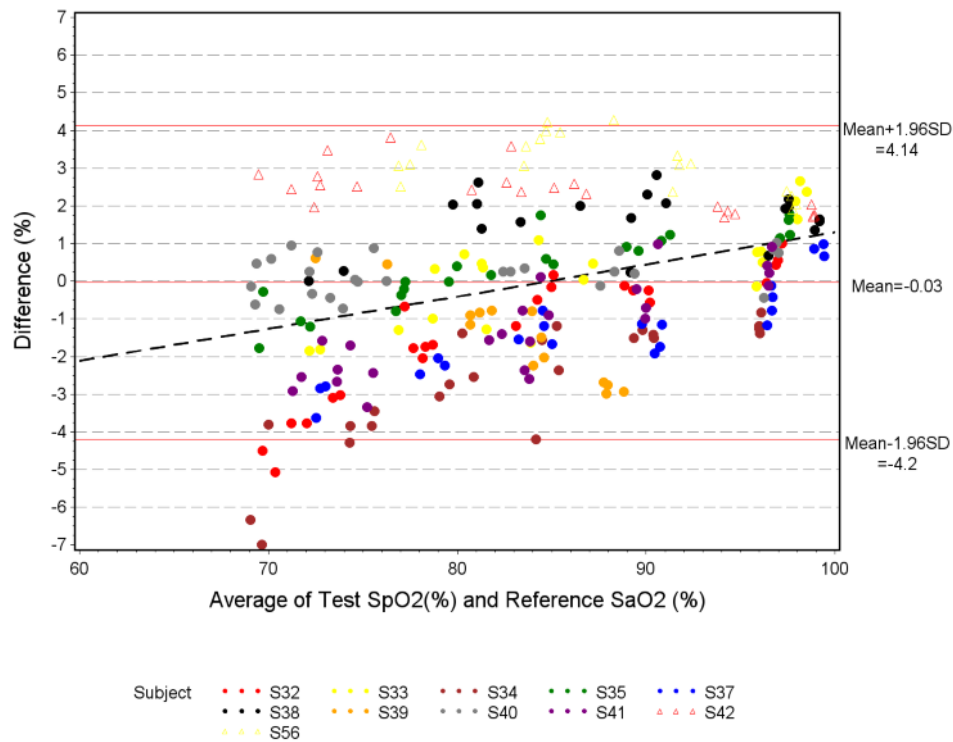
The following modified Bland-Altman plots show SpO₂ data by sensor type.

Bland-Altman plot for SpO₂ - TS-W-D sensor

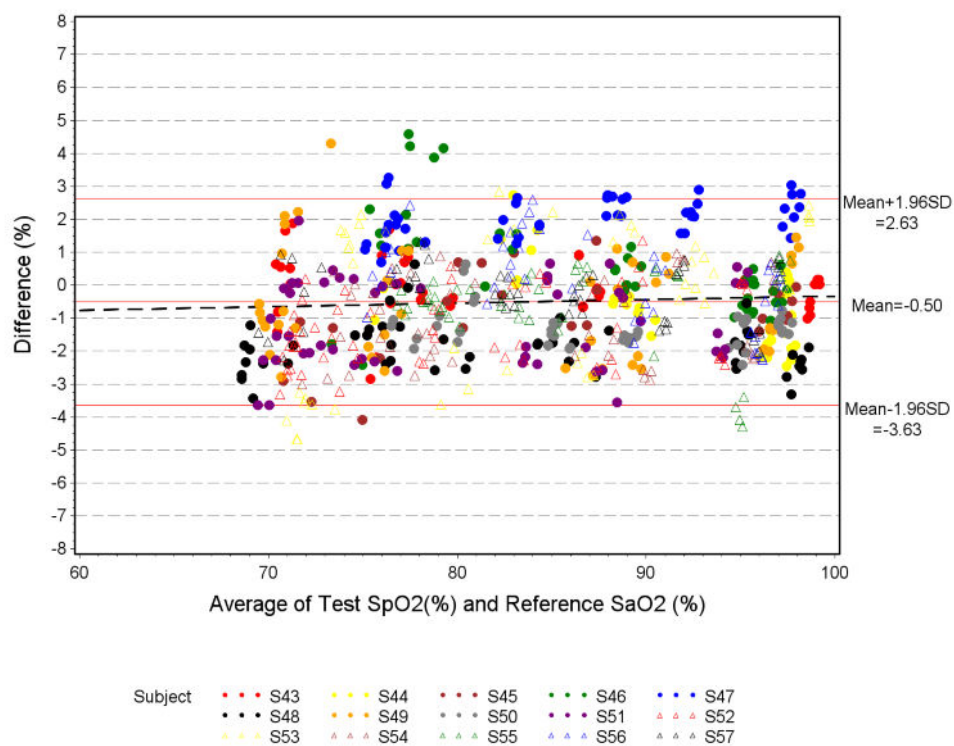


TS-W-D sensor accuracy		
Accuracy 70-80% (ARMS)	Accuracy 80-90% (ARMS)	Accuracy 90-100% (ARMS)
2.503	1.555	1.411

Bland-Altman plot for SpO₂ - TS-SE-3 sensor

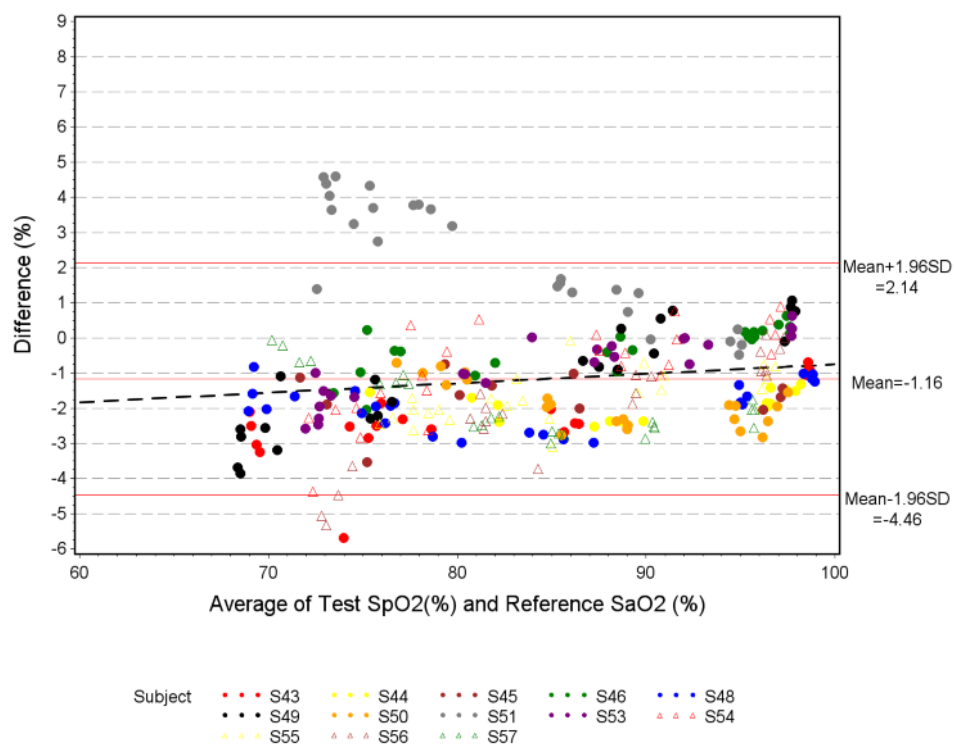


TS-SE-3 sensor accuracy		
Accuracy 70-80% (ARMS)	Accuracy 80-90% (ARMS)	Accuracy 90-100% (ARMS)
2.586	1.997	1.52

Bland-Altman plot for SpO₂ - TS-E-D sensor

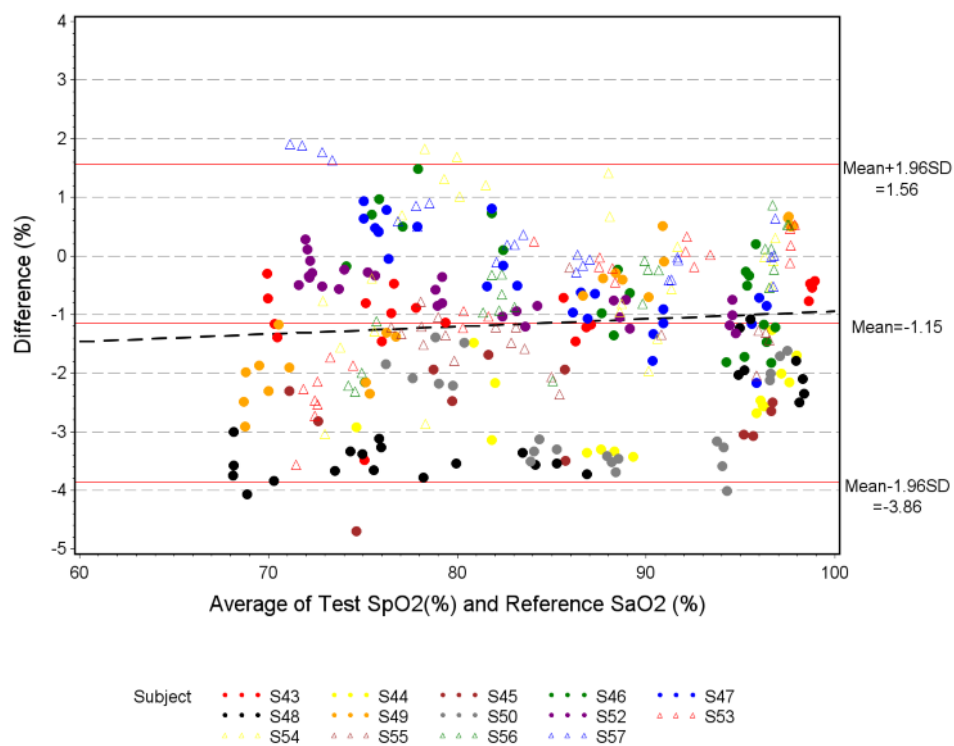
TS-E-D sensor accuracy		
Accuracy 70-80% (ARMS)	Accuracy 80-90% (ARMS)	Accuracy 90-100% (ARMS)
1.831	1.502	1.567

Bland-Altman plot for SpO₂ - TS-F-D sensor



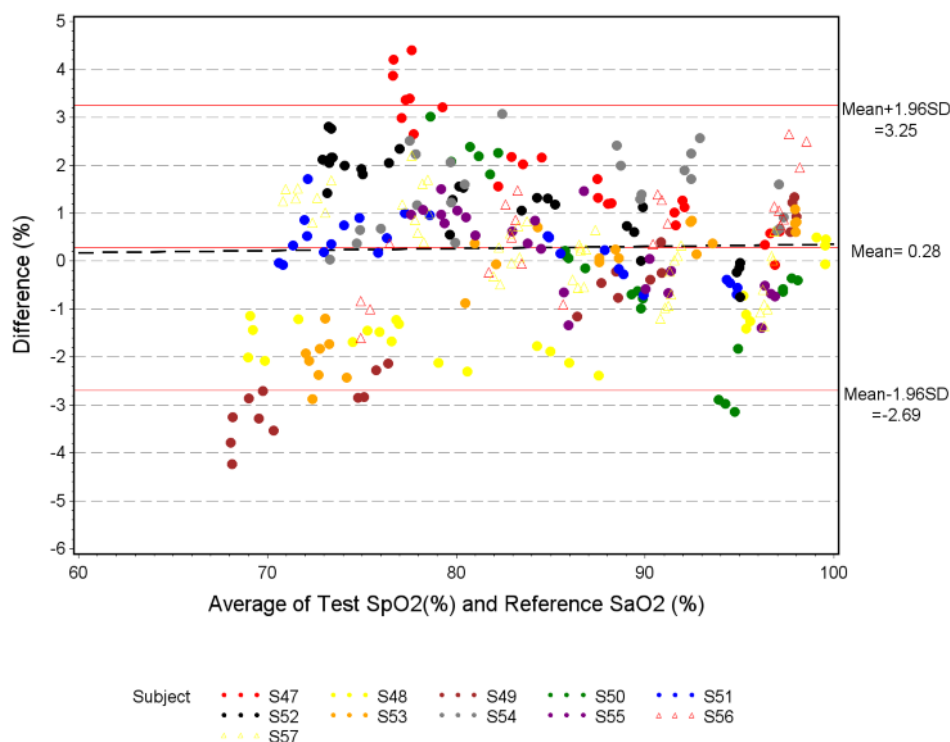
TS-F-D sensor accuracy		
Accuracy 70-80% (ARMS)	Accuracy 80-90% (ARMS)	Accuracy 90-100% (ARMS)
2.587	1.895	1.376

Bland-Altman plot for SpO₂ - TS-SA-D and TS-SP-D sensors



TS-SA-D and TS-SP-D sensor accuracy		
Accuracy 70-80% (ARMS)	Accuracy 80-90% (ARMS)	Accuracy 90-100% (ARMS)
1.874	1.78	1.597

Bland-Altman plot for SpO₂ - TS-AAW-10, TS-AAW-25, TS-PAW-10, and TS-PAW-25 sensors



TS-AAW-10, TS-AAW-25, TS-PAW-10, and TS-PAW-25 sensor accuracy		
Accuracy 70-80% (ARMS)	Accuracy 80-90% (ARMS)	Accuracy 90-100% (ARMS)
1.945	1.156	1.117

rSO₂ performance specifications

Refer to the documentation provided with the INVOS rSO₂ micro-module for performance specifications related to rSO₂ monitoring.

Continuous cardiac output performance specifications

Refer to the Instructions for use for Edwards FloTrac CCO pressure cable for performance specifications related to continuous cardiac output monitoring.

NIBP standards compliance

The system complies with IEC 80601-2-30:2018-03.

The system was clinically investigated according to ISO 81060-2:2013. The measurement has been validated with patient populations requiring clinical investigations according to ISO 81060-2:2013 apart from pregnant and pre-eclamptic women.

WARNING

PREGNANT PATIENTS. Effectiveness of the NIBP measurement has not been established in pregnant (including pre-eclamptic) patients.

The non-invasive blood pressure hose and cuff accessory applied parts as classified as DEFIBRILLATION PROOF APPLIED PARTs per IEC 80601-2-30:2018 Clause 201.8.5.5 and TYPE BF APPLIED PARTs per IEC 60601-1:2020-08 Clause 8.3.

NIBP performance specifications

NIBP measurement technique	Oscillometric
NIBP displayed parameters	Systolic, diastolic, and mean pressures, time of last measurement, cuff pressure
NIBP measurement supported modes	Manual, Auto, and STAT
NIBP measurement range	- Adult: 15 to 300 mmHg (2.0 to 40.0 kPa) - Child: 15 to 260 mmHg (2.0 to 34.7 kPa) - Infant: 15 to 145 mmHg (2.0 to 19.3 kPa)
NIBP measurement range accuracy	±5 mmHg (0.7 kPa) average error, 8 mmHg (1.1 kPa) standard deviation
NIBP measurement display resolution	1 mmHg (0.1 kPa)
NIBP measurement default initial inflation pressure	- Adult: 135 mmHg (18.0 kPa) - Child: 125 mmHg (16.7 kPa) - Infant: 100 mmHg (13.3 kPa) NOTE In the NICU software package, infant ranges are equal to neonatal ranges.
Supported cuff sizes	- Disposable: Large adult, adult, small adult, pediatric, child, and neonatal - Reusable: Adult thigh, large adult, adult, small adult, small adult/child, child, and infant
Cuff pressure range	0 to 315 mmHg (0.0 to 42.0 kPa)
NIBP cuff pressure display resolution	1 mmHg (0.1 kPa)
Cuff maximum inflation pressure	- Adult: 300 mmHg (40.0 kPa) - Child: 260 mmHg (34.7 kPa) - Infant: 150 mmHg (20.0 kPa)
NIBP measurement available automatic cycle times	1 min, 2 min, 2.5 min, 3 min, 4 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 2 h, and 4 h
Auto zero	Auto zero pressure reference
NIBP total cycle time	20 to 40 seconds typical (depending on heart rate, pressure, and motion artifact)
Automatic cuff deflation conditions	- Power off - Adult and child cuff cycle time exceeding 125 seconds - Infant cuff cycle time exceeding 90 seconds - Adult and child cuff pressure exceeding 300 mmHg (40.0 kPa) - Infant cuff pressure exceeding 150 mmHg (20.0 kPa)

Invasive pressure standards compliance

The system with TruSignal Pressure micro-module complies with IEC 60601-2-34:2011-05.

The TruSignal Pressure micro-module, including the enclosure and USB interface cable, are not applied parts or treated as applied parts. The TruSignal Pressure micro-module sensor interface cable and compatible sensors, excluding the TruSignal Pressure micro-module connector, excluding the strain relief, and if present, excluding the TruSignal Pressure micro-module dual adapter cable, are type CF DEFIBRILLATION-PROOF APPLIED PARTs per IEC 60601-2-34 Clause 201.8.3 and Clause 201.8.5.5.1.

Invasive pressure performance specifications

For more information regarding FloTrac CCO micro-module performance specifications, refer to the Instructions for use provided with the micro-module.

The following specifications apply to all compatible micro-modules:

Number of invasive pressure channels	5
Invasive pressure display resolution	1 mmHg
Invasive pressure units of measure	mmHg or kPa
Invasive pressure pulse rate display resolution	1 bpm
Invasive pressure physiological range ¹	-25 to 320 mmHg (-3.3 to 42.7 kPa)
Invasive pressure sweep speed options	6.25, 12.5, 25, and 50 mm/s
Invasive pressure waveform display scale	User and automatic
Invasive pressure waveform display scale selections	0-10 to 0-300 mmHg, with a step size of 10 mmHg (0.0-2.0 to 0.0-40.0 kPa, with a step size of 2.0 kPa); or automatic scale based on valid waveform values from last 4 seconds with a lower limit of -100 mmHg (-14 kPa) and an upper limit of 350 mmHg (48 kPa) and a step size of 10 mmHg (2.0 kPa)
Invasive pressure waveform display range	-30 to 300 mmHg (-4.0 to 40.0 kPa)
¹ Invasive pressure physiological alarm limits can be adjusted to this range.	

The following specifications apply to TruSignal Pressure micro-module only:

Invasive pressure measurement range	-30 to 320 mmHg (-4 to 42.7 kPa)
Invasive pressure measurement accuracy	-30 to 349 mmHg (-4.0 to 46.5kPa) • $\pm 0.5\% \pm 1.50$ mmHg (excluding transducer) • $\pm 4\%$ or ± 4 mmHg, which ever is greater (including transducer) -98 to -31 mmHg (-13.1 to -4.1kPa) • Unspecified
Invasive pressure pulse rate range	0 to 360 bpm
Invasive pressure pulse rate accuracy	$\pm 2\%$ or ± 2 bpm, whichever is greater

Invasive pressure transducer sites, site name, and displayed values	• Arterial (Art): Systolic, diastolic, mean, rate • Femoral (Fem): Systolic, diastolic, mean, rate • Femoral vein (FemV): Mean • Pulmonary artery (PA): Systolic, diastolic, mean • Central venous pressure (CVP): Mean • Intra-cranial pressure (ICP): Mean • Left atrial (LAP): Mean • Pressure channel (P1 to P4): Mean • Right atrial (RAP): Mean • Right vein (RVP): Mean • Umbilical artery (UAC): Systolic, diastolic, mean, rate • Umbilical vein (UVC): Mean
Invasive pressure frequency response (waveform filter) The filter settings of 12 Hz and above tested as per IEC 60601-2-34 Clause 201.12.1.101.3. Filter settings below 12 Hz not tested as per IEC 60601-2-34 Clause 201.12.1.101.3.	Upper limit user-selectable as DC to 4 Hz, 5 Hz, 6 Hz, 7 Hz, 8 Hz, 9 Hz, 11 Hz, 14 Hz, 17 Hz, 22 Hz or 40 Hz (-3dB)
Invasive pressure transducer interfaces supported	Argon Medical, ICU Medical, Edwards Lifesciences, Utah Medical
Invasive pressure transducer excitation voltage	+2.5 VDC $\pm$ 1.0 %
Invasive pressure transducer sensitivity	5 μ V/V/mmHg
Replaceable sensor interface cable	Tool removable sensor interface cable
Invasive pressure analog output signal accuracy (gain and offset)	1V/100 mmHg $\pm$ 0.5% $\pm$ 2 mmHg, pressure < 100 mmHg (excludes transducer) 1V/100 mmHg $\pm$ 1.5% $\pm$ 1 mmHg, pressure 100 mmHg or greater (excludes transducer)
Invasive pressure analog output bandwidth	0 to 40Hz
Invasive pressure analog output delay	< 35 ms
Invasive pressure zero balance range	$\pm$ 150 mmHg ($\pm$ 20.0 kPa)
Invasive pressure zero balance accuracy	$\pm$ 1 mmHg ($\pm$ 0.1 kPa)

The following specifications apply to FloTrac CCO micro-module only:

Invasive pressure transducer sites, site name, and displayed values	• Arterial (Art): Systolic, diastolic, mean, rate • Femoral (Fem): Systolic, diastolic, mean, rate
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Temperature standards compliance

The system with TruSignal Temperature micro-module complies with ISO 80601-2-56:2017-03 + Amendment 1:2018-11.

The TruSignal Temperature micro-module sensor interface cable and compatible probe accessories are TYPE CF DEFIBRILLATION-PROOF APPLIED PARTs per IEC 60601-1:2020-08 Clause 8.3.

Temperature performance specifications

Number of channels	2
Temperature parameters displayed	T1, T2
Temperature range	0°C to 45°C (32°F to 113°F), delta values -45°C to 45°C (-81°F to 81°F)
Temperature system measurement accuracy	Carescape ONE system with series 400 reusable temperature probes with $\pm 0.1^\circ\text{C}$ accuracy: 18 to 45°C (64 to 113°F): $\pm 0.2^\circ\text{C}$ ($\pm 0.4^\circ\text{F}$), rated output range 0 to less than 18°C (32 to 64°F): $\pm 0.3^\circ\text{C}$ ($\pm 0.5^\circ\text{F}$), extended output range Carescape ONE system with series 400 disposable temperature probes with $\pm 0.2^\circ\text{C}$ accuracy: 18 to 45°C (64 to 113°F): $\pm 0.3^\circ\text{C}$ ($\pm 0.5^\circ\text{F}$), rated output range 0 to less than 18°C (32 to 64°F): $\pm 0.4^\circ\text{C}$ ($\pm 0.7^\circ\text{F}$), extended output range
Temperature display resolution	0.1°C (0.1°F)
Temperature measurement probe response time	< 3 minutes
Temperature measurement units	°C or °F
Temperature probe types supported	Series 400
Temperature test measurement cycle	Every minute
Reusable and disposable temperature probe support	Sensor interface cables provide reusable or disposable temperature probe interfaces.
Replaceable sensor interface cable	Tool removable sensor interface cable

CO₂ standards compliance

The system with Microstream CO₂ micro-module complies with ISO 80601-2-55:2018-02 + Amendment 1:2023-12.

The LoFlo CO₂ micro-module accessories that are intended to be connected with the breathing system are TYPE BF DEFIBRILLATION-PROOF APPLIED PARTs per ISO 80601-2-55:2018 Clause 201.4.6.

CO₂ performance specifications

For more Microstream CO₂ or LoFlo CO₂ micro-module performance specifications, refer to the Instructions for use provided with the micro-module.

The following specifications apply to both micro-modules:

CO ₂ display resolution	- Numeric: 1.0 mmHg (0.1 kPa) - Wave: 0.1 mmHg (0.01 kPa)
Respiratory rate display resolution	1 bmp
CO ₂ sweep speed options	0.625, 6.25, 12.5, 25, and 50 mm/s

The following specifications apply to Microstream CO₂ micro-module only:

Respiration rate display range	1 to 150 bmp
CO ₂ display range	0 to 150 mmHg
Total system response time	• < 6 s with 2 m sampling line length • < 9 s with 4 m sampling line length

The following specifications apply to LoFlo CO₂ micro-module only:

Respiration rate display range	1 to 148 bmp
CO ₂ display range	0 to 148 mmHg
Total system response time	3 seconds for on-airway adapter kits (Additional 30 ms for sidestream sampling cannulas) (Additional 2 seconds for extension line and dehumidification tubing)

Default settings

Understanding your monitor configuration

The monitor's configuration is dependent on the equipment used, the software enabled, and the settings that define how the software application behaves.

Software packages

The monitor can have up to five software packages, but only one can be enabled at a time. Software packages pre-configure the monitor's behavior and appearance for a specific clinical environment. There are five software packages:

- **ICU:** Intensive Care Unit (also called Critical Care)
- **OR:** Operating Room (also called Anesthesia Care)
- **PACU:** Post Anesthesia Care Unit (also called Post Anesthesia Care)
- **ED:** Emergency Department (also called Emergency Care)
- **NICU:** Neonatal Intensive Care Unit (also called Neonatal Care)

ICU is the factory default software package. Software packages cannot be customized, but the profile and care unit settings for a software package can be customized.

Licensed software options

The following table lists the software options available for purchase. These options are enabled with licenses during installation/configuration. For more information, refer to the appropriate service manual.

Name	Feature code	Availability
12RL 12-lead ECG	P12R	Standard NICU: Not available
Bx50 Monitor DEMO SW	DEMO	Standard
Full Arrhythmia	PARR	Standard
Multi-lead ST Analysis	12ST	Standard
Wireless LAN	WLAN	Optional

Software profiles

Each software package supports up to eight active profiles. A profile is a group of unique settings suited to a particular care unit or patient demographic within the broader software package clinical environment (e.g., alarm limits, available pages, trends and snapshot settings). Profile settings can be customized.

Default settings: profiles

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
Profiles 1 to 8 enabled	true	true	true	true	true
Profile 1 name	Medical	Perfusion	General	Medical	Premature
Profile 2 name	Surgical	General	Invasive	Trauma	Cardiac
Profile 3 name	Cardiac	Invasive	Regional	Cardiac	Full-term
Profile 4 name	Neuro	Regional	Neuro	Neuro	Infant
Profile 5 name	Trauma	Neuro	PreRegional	Respiratory	User defined.
Profile 6 name	Adolescent	Adolescent	Adolescent	Adolescent	User defined.
Profile 7 name	Pediatric	Pediatric	Pediatric	Pediatric	User defined.
Profile 8 name	Infant	Infant	Infant	Infant	User defined.
Startup profile	Medical	General	General	Medical	Premature

ICU is the factory default software package.

Software settings

NOTE

The enabled software profile and micro-modules used determine which configurable settings display on the Carescape ONE. Some settings may not appear in all configurations.

NOTE

Some settings vary by configuration. These settings are indicated where applicable.

If the monitor resets while monitoring a patient, care should be taken to confirm the settings are appropriate for the current patient, making changes where necessary.

When the supply mains to the equipment is interrupted for more than 30 seconds while the monitor is on, the monitor shuts down. When restarted within 2 hours, it will continue monitoring with the previously selected user settings.

Care unit settings

Care unit settings are password protected. Care unit settings are established during installation/configuration of the monitor. Instructions to access the care unit settings are provided in this document. The care unit settings factory default values are also provided.

Care unit settings apply to the software package and all associated profiles. Care unit settings have two values:

- **Current values:** Values displayed on the monitor, saved during configuration/installation of the monitor to meet the needs of a particular clinical environment.
- **Factory default values:** Permanent values used in case of failure that allow the software application to recover from failure by reverting to these values for system operation.

The care unit settings reset varies by setting. There are three types of reset:

- **Case reset/discharge:** Case is reset/patient is discharged from the monitor.
- **Cold start:** Start-up of the software application after the monitor is shut down for 2 hours or more.
- **Warm start:** Start-up of the software application after the monitor is shut down for less than 2 hours.

Configuring care unit settings

To access and customize the care unit settings:

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username:** clinical.
4. Enter the password for the clinical user account.
5. Select **Care unit settings**.
6. Change the settings as needed in **Alarms, Parameter alarms, Admit/discharge, Units, and Parameters**. All changes are automatically saved and applied.
 - To revert to the factory default care unit settings, end the case/discharge the patient and select **Restore factory defaults > Confirm**.

Configuring Time & Date settings

Time & date settings can be changed during an active case/admitted patient.

CAUTION

MISINTERPRETATION OF HISTORICAL DATA. Changing the date and time on one network device on the Carescape Network will also update the date and time for all other devices on the same network. To avoid possible misinterpretation of historical data when viewing it, special attention should always be paid to the time and date information.

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username:** clinical.

4. Enter the password for the clinical user account.
5. Select **Time & date**.
6. Change the settings as needed for **Hour, Minutes, Year, Month, Day**, and **Time format (h)**.
7. Select **Save**.

Page management settings

Page management settings are password protected. You can select whether clinical users can create, duplicate, or delete pages and which pages clinical users can edit. Page management settings also determine which pages are assigned to each profile. The **Home** page is always selectable and can be edited by clinical users.

Any changes that clinical users make to the page setup are only valid until the case is reset/the patient is discharged. To make the changes permanent, they must be saved through **Default settings > Page management > General Settings > Save**. The page setup changes are also kept in the device memory for 2 hours after the power is turned off.

Saving changes to page setup

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Page management**.
6. To save the current page setup, select **General Settings > Save**.

Assigning pages to profiles

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Page management > Assign Pages** tab.
6. Select a page in the **Page name** dropdown list.

The **Home** page cannot be selected in the **Page name** drop-down list because it is displayed for every profile.

7. Select the check box for each desired profile.

There can be a maximum of 16 pages (including the **Home** page) assigned for each profile.

Configuring other page settings

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.

3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Page management**.
6. To select whether users can create, duplicate, and delete saved pages:
 - a. Select the **General Settings** tab.
 - b. Toggle **Allow to create new, duplicate and delete pages** on or off.
7. To select which pages users can edit:
 - a. Select **Assign Pages**.
 - b. Select the page in the **Page name** dropdown list.
 - c. To prevent users from editing a page, toggle on **Lock page from editing**. To allow users to edit a page, toggle off **Lock page from editing**.

The **Home** page cannot be selected in the **Page name** drop-down list because it cannot be locked.

Profile settings

Profile settings are password protected. Profile settings are established during installation/configuration of the monitor. Instructions to access the profile settings are provided in this document. The profile setting factory default values are also provided.

Profile settings only apply to a specific profile. Profile settings have the following values:

- Saved values: Values selected and saved during configuration/installation of the monitor to meet the needs of a particular clinical environment.
- Factory default values: Permanent values used in case of failure that allow the software application to recover from failure by reverting to these values for system operation.

Profile settings generally share the same reset behavior. There are three types of reset:

- Case reset/discharge: Case is reset/patient is discharged from the monitor. Generally, the saved value is retained and used after the reset.
- Cold start: Start-up of the software application after the monitor is shut down for 2 hours or more. Generally, the saved value is retained and used after the reset.
- Warm start: Start-up of the software application after the monitor is shut down for less than 2 hours. Generally, the current value is retained and used after the reset.

Saving current settings to a profile

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Change the settings as needed in **Alarm delays**, **Invasive pressures**, **Save profiles**, and **Locking settings**.

6. To save the current settings to a profile:
 - a. Select **Save profiles**.
 - b. Select the profile in the **Profile** dropdown list.

If prompted to confirm patient settings, review the selected settings and confirm if applicable to the profile.
 - c. Select **Save** and **Confirm**.

This selection only save changes to profile settings. To save page setup changes, select **Default settings > Page management > Save**.

NOTE

Some settings do not display in all software packages.

Selecting the startup profile

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Save profiles**.
6. Select the profile in the **Startup profile** dropdown list.

Enabling and disabling profiles

To choose which profiles clinicians can select for the current patient:

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Save profiles**.
6. Select the profile in the **Profile** dropdown list.
7. Toggle on **Enable profile** to enable the profile. Toggle off **Enable profile** to disable the profile.

Renaming profiles

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Save profiles**.
6. Select the profile from the **Profile** dropdown list and select **Rename**.

7. Enter the new name in the **Profile name** field with the displayed on-screen keyboard and select **Confirm**.

Restoring factory default profile settings

1. Select  from the main menu.
2. Select **Defaults & Service > Default settings**.
3. Enter the **Username**: clinical.
4. Enter the password for the clinical user account.
5. Select **Save profiles**.
6. Select the profile in the **Profile** dropdown list and then **Restore factory defaults**.
7. Select **Confirm**. The profile is reset to factory default settings.

NOTE

Some settings do not display in all software packages.

Configuring locking settings

Some profile and care unit settings can be locked. Clinicians cannot adjust locked settings for the current patient.

Select  from the main menu and then **Monitor Settings > Defaults & Service > Default settings > Locking settings**.

Current patient settings

Current patient settings are non-password protected settings that are adjusted to meet the needs of the current patient. The current patient settings are not saved to the monitor's permanent memory, but most current patient settings are configured to persist over a warm start (Carescape ONE is shut down for less than 2 hours).

DEMO mode

Entering the **DEMO mode** is password protected. The **DEMO mode** can only be activated (confirmed) if there is no active patient monitoring occurring.

When you exit the **DEMO mode**, the monitor restarts with the same settings that were used in the actual monitoring mode before entering the **DEMO mode**. In other words, any changes made to the settings in the **DEMO mode** do not affect the actual monitoring mode.

NOTE

The **DEMO mode** is *not* meant for actual patient monitoring, it is for demonstration purposes only.

Exiting the DEMO mode

To avoid the risk of missed alarms and loss of monitoring, always exit **DEMO mode** when simulated monitoring is no longer needed. Restart the monitor, or:

1. Select  from the main menu.
2. Select **Defaults & Service**.
3. Select **Exit DEMO > Confirm**.

The monitor will shut down and restart in the normal monitoring mode utilizing the defined start up profile.

Default settings: alarms

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow turning alarm light off	false	true	false	false	false
Alarm tones	IEC	IEC	IEC	IEC	IEC
Alarm volume control	Common for all	Common for all	Common for all	Common for all	Common for all
Allow alarm deactivation with the Audio Pause key for: ECG leads off	false	false	false	false	false
Allow alarm deactivation with the Audio Pause key for: Arterial disconnect	false	false	false	false	false
Allow alarm deactivation with the Audio Pause key for: ECG leads off	false	false	false	false	false
Allow alarm deactivation with the Audio Pause key for: SpO2 probe off	false	false	false	false	false
Allow audio alarm off	false	false	false	false	false
Allow all audio pause for 5 min	false	false	false	false	false
Latching alarms	High	None	None	High	High
Low priority alarm tone	Single	Single	Single	Single	Single

Setting	ICU	OR	PACU	ED	NICU
Allowed minimum alarm volume for: High & medium priority	6	6	6	6	6
Allowed minimum alarm volume for: Low priority	6	6	6	6	6
Reminder volume	5	5	5	5	5
Show alarm limits	true	true	true	true	true
Audio pause time	2	2	2	2	2
PROFILE SETTINGS					
Alarm light brightness (%)	100	100	100	100	100
Alarm volume When the Alarm volume control setting is set to Common for all .	7	6	7	7	7
Alarm volume for: Low priority When the Alarm volume control setting is set to Separate for low .	7	6	7	7	7
Set audible alarms permanently off:	None	None Perfusion: Apnea & ECG	None	None	None

Default settings: monitor and page settings

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

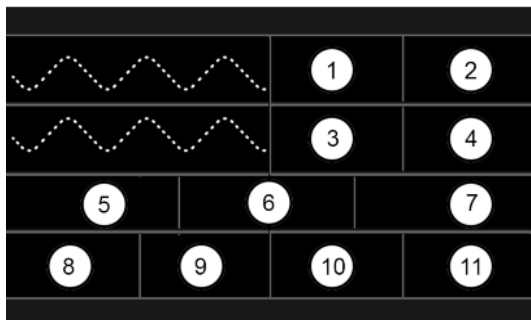
- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Display brightness (%)	50	50	50	50	50
Allow to create new, duplicate and delete pages	true	true	true	true	true
PROFILE SETTINGS					
Touch volume	2	2	2	2	2

Setting	ICU	OR	PACU	ED	NICU
Selected page For default page configurations, see below.	Home	Home	Home	Home	Home

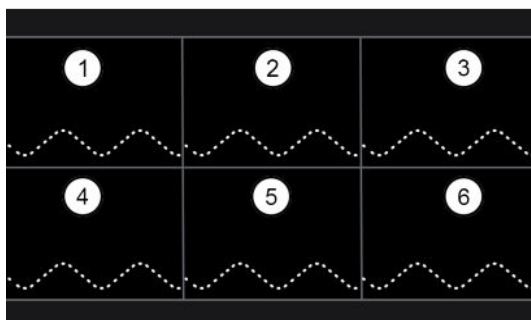
Default page configurations

Home page, **Classic** view. Page is editable, but cannot be deleted.



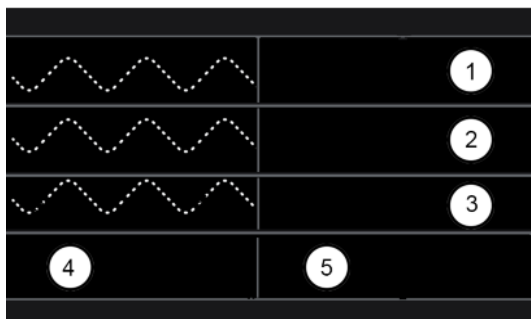
1. **ECG 1**
2. **Fem3** (**Art3** in **NICU**)
3. **SpO2**
4. **PA4** (**CVP4** in **NICU**)
5. **Art1** (**UAC1** in **NICU**)
6. **Art8** (not with **NICU**)
7. **CO2**
8. **Imped. resp**
9. **CVP2** (**UVC2** in **NICU**)
10. **Temp**
11. **NIBP**

Box page, **Box** view. Page is editable and can be deleted.



1. **ECG**
2. **SpO2**
3. **Art 1** (**UAC1** in **NICU**)
4. **NIBP**
5. **Imped. resp**
6. **CO2**

Non-inv. page, **Classic** view. Page is editable and can be deleted.



1. **ECG1**
2. **SpO2**
3. **Imped. resp**
4. **NIBP**
5. **CO2**

Invasive page, **Classic** view. Page is editable and can be deleted.



1. **ECG1**
2. **SpO2**
3. **Art 1 (UAC1 in NICU)**
4. **Art 8 (not in NICU)**
5. **CO2**

Default settings: patient data management

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow remote discharge	false	false	false	false	false
Auto discharge time	24 h	15 min	15 min	24 h	24 h
Height unit	cm	cm	cm	cm	cm
PROFILE SETTINGS					
Age unit	Years Infant: Days	Years Infant: Days	Years Infant: Days	Years Infant: Days	Days
Weight unit	kg Pediatric, Infant: g	kg Pediatric, Infant: g	kg Pediatric, Infant: g	kg Pediatric, Infant: g	g

Default settings: ECG

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allowed arrhythmia levels	Full, lethal	Full, lethal	Full, lethal	Full, lethal	Full, lethal
ECG lead off Allowed priority levels	Low	Low	Low	Low	Low
ECG leads off	Escalating, high	Escalating, high	Escalating, high	Escalating, high	Escalating, high
Noisy ECG, Arrhythmia paused	Escalating, high	Escalating, high	Escalating, high	Escalating, high	Escalating, high
Beat tone sound	Soft	Soft	Soft	Soft	Soft
Size ECG waveform size	1x	1x	1x	1x	1x
HR Alarms One or many alarm sources	Multiple	Multiple	Multiple	Multiple	Multiple
HR alarm range Setting available with HR Alarms > Single and low alarm guard limit <30 or high alarm guard limit >240	30 - 240	30 - 240	30 - 240	30 - 240	30 - 240
Allow informational level for arrhythmia alarms	true	true	true	true	true
Lead analysis	Multiple	Multiple	Multiple	Multiple	Multiple
Brady/PR low Low alarm priority allowed	false	false	false	false	false
PROFILE SETTINGS					
Arrhythmia Arrhythmia detection level	Full	Lethal Perfusion: Off	Full	Full	Full
PR(Art) alarm ON	true	true Perfusion: false	true	true	true
PR (Art) Alarm locked	false	false	false	false	false
PR(Art) high alarm limit	150 Neuro: 120 Pediatric: 170 Infant: 180	160 Neuro: 120 Adolescent: 150 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	200 Infant: 180

Setting	ICU	OR	PACU	ED	NICU
(PR)Art low alarm limit	50 Pediatric: 70 Infant: 80	40 Neuro, Adolescent: 50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	90 Infant: 80
Beat source	Primary HR	Primary HR	Primary HR	Primary HR	Primary HR
Beat tone on brady only	false	false	false	false	false
Beat volume	0	5	0	0	0
PR(SpO2) alarm ON	true	true Perfusion: false	true	true	true
ECG and primary HR alarm ON	true	true Perfusion: false	true	true	true
ECG and primary HR Alarm locked	false	false	false	false	true
ECG and primary HR critical alarm ON	false	false	false	false	false
ECG and primary HR critical alarm locked	false	false	false	false	false
ECG and primary HR critical high alarm limit	180 Neuro: 150 Pediatric: 200 Infant: 210	190 Neuro: 150 Adolescent: 180 Pediatric: 200 Infant: 210	180 Neuro: 150 Pediatric: 200 Infant: 210	180 Neuro: 150 Pediatric: 200 Infant: 210	230 Infant: 210
ECG and primary HR critical low alarm limit	40 Pediatric: 55 Infant: 65	40 Pediatric: 55 Infant: 65	40 Pediatric: 55 Infant: 65	40 Pediatric: 55 Infant: 65	75 Infant: 65
ECG and primary HR high alarm limit	150 Neuro: 120 Pediatric: 170 Infant: 180	160 Neuro: 120 Adolescent: 150 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	200 Infant: 180
ECG and primary HR critical low alarm limit	50 Pediatric: 70 Infant: 80	40 Neuro, Adolescent: 50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	90 Infant: 80
ECG 1 lead, 10 leadwires	II	II	II	II	II
ECG 1 lead, 3 leadwires	II	II	II	II	II
ECG 1 lead, 5 leadwires	II	II	II	II	II
ECG 1 lead, 6 leadwires	II	II	II	II	II
ECG 2 lead, 10 leadwires	V1	V5	V1	V1	V1
ECG 2 lead, 3 leadwires	Cascade	Cascade	Cascade	Cascade	Cascade

Setting	ICU	OR	PACU	ED	NICU
ECG 2 lead , 5 leadwires	Va lead position	Va lead position	Va lead position	Va lead position	Va lead position
ECG 2 lead , 6 leadwires	Va lead position	Vb lead position	Va lead position	Va lead position	Va lead position
ECG 3 lead , 10 leadwires	aVL	aVL	aVL	aVL	aVL
ECG 3 lead , 3 leadwires	Cascade	Cascade	Cascade	Cascade	Cascade
ECG 3 lead , 5 leadwires	aVL	aVL	aVL	aVL	aVL
ECG 3 lead , 6 leadwires	aVL	aVL	aVL	aVL	aVL
ECG Parameter color	Green	Green	Green	Green	Green
Show ECG waveform grid	false	false	false	false	false
ECG HR alarm ON	true	true Perfusion: false	true	true	true
HR single: Brady/Tachy , HR multiple: Brady/Tachy Alarm locked	false	false	false	false	true
ECG HR high alarm limit	150 Neuro: 120 Pediatric: 170 Infant: 180	160 Neuro: 120 Adolescent: 150 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	200 Infant: 180
ECG HR low alarm limit	50 Pediatric: 70 Infant: 80	40 Neuro, Adolescent : 50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	90 Infant: 80
Arrhythmia paused Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
ECG lead off Alarm priority	Low	Low	Low	Low	Low
ECG leads off Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
Noisy ECG Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
Fem PR alarm ON	true	true Perfusion: false	true	true	true
PR (Fem) Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
PR(Fem) high alarm limit	150 Neuro: 120 Pediatric: 170 Infant: 180	160 Neuro: 120 Adolescent : 150 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	200 Infant: 180
PR(Fem) low alarm limit	50 Pediatric: 70 Infant: 80	40 Neuro: 50 Adolescent: 50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	90 Infant: 80
HR high alarm priority	Escalating	Escalating	Escalating	Escalating	High
HR low alarm priority	Escalating	Escalating	Escalating	Escalating	High
Tachy/PR high Alarm priority	Escalating	Escalating	Escalating	Escalating	High
Brady/PR low Alarm priority	Escalating	Escalating	Escalating	Escalating	High
HR /min Trend scale	0-150	0-150	0-150	0-150	0-300
Sweep speeds > Hemodynamic	25	25	25	25	25
ECG leadwire standard	IEC	IEC	IEC	IEC	IEC
PR alarm delay	5 s	5 s	5 s	5 s	5 s
PVC alarm ON	true	false	true	true	false
Frequent PVCs Alarm locked	false	false	false	false	false
Frequent PVCs Alarm priority	Low	Escalating	Low	Low	Low
PVC alarm limit	10	6	10	10	10
Pacemaker detection	Sensitive (Pace 2)	Sensitive (Pace 2)	Sensitive (Pace 2)	Sensitive (Pace 2)	Sensitive (Pace 2)
Primary HR alarm ON	true	true Perfusion: false	true	true	true
Primary HR Critical alarm ON	false	false	false	false	false
HR single: Critical Brady/Tachy, HR multiple: Critical Brady/Tachy Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
Primary HR critical high alarm limit	180 Neuro: 150 Pediatric: 200 Infant: 210	190 Neuro: 150 Adolescent: 180 Pediatric: 200 Infant: 210	180 Neuro: 150 Pediatric: 200 Infant: 210	180 Neuro: 150 Pediatric: 200 Infant: 210	230 Infant: 210
Primary HR critical low alarm limit	40 Pediatric: 55 Infant: 65	40 Pediatric: 55 Infant: 65	40 Pediatric: 55 Infant: 65	40 Pediatric: 55 Infant: 65	75 Infant: 65
Primary HR high alarm limit	150 Neuro: 120 Pediatric: 170 Infant: 180	160 Neuro: 120 Adolescent: 150 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	200 Infant: 180
Primary HR low alarm limit	50 Pediatric: 70 Infant: 80	40 Neuro, Adolescent: 50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	90 Infant: 80
Primary HR source	AUTO	AUTO	AUTO	AUTO	AUTO
QRS width	Normal Pediatric, Infant: Narrow	Normal Pediatric, Infant: Narrow	Normal Pediatric, Infant: Narrow	Normal Pediatric, Infant: Narrow	Narrow
QRS width: Normal Feature locked	false Pediatric: true Infant: true	false Pediatric, Infant: true	false Pediatric, Infant: true	false Pediatric: true Infant: true	true
SVC alarm ON	false	false	false	false	false
Frequent SVCs Alarm locked	false	false	false	false	false
Frequent SVCs Alarm priority	Low	Low	Low	Low	Low
SVC alarm limit	10	10	10	10	10
PR(SpO2) alarm ON	true	true Perfusion: false	true	true	true
PR (SpO2) Alarm locked	false	false	false	false	false
PR(SpO2) high alarm limit	150 Neuro: 120 Pediatric: 170 Infant: 180	160 Neuro: 120 Adolescent: 150 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	150 Neuro: 120 Pediatric: 170 Infant: 180	200 Infant: 180

Setting	ICU	OR	PACU	ED	NICU
PR(SpO2) low alarm limit	50 Pediatric: 70 Infant: 80	40 Neuro, Adolescent: 50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	50 Pediatric: 70 Infant: 80	90 Infant: 80
Show in ECG parameter window: > 2nd HR source	false	false	false	false	true
Show in ECG parameter window: > PVC	true	false	true	true	true
PR(UAC) alarm ON	true	true Perfusion: false	true	true	true
PR (UAC) Alarm locked	false	false	false	false	false
PR(UAC) high alarm limit	200 Infant: 180	200 Infant: 180	200 Infant: 180	200 Infant: 180	200 Infant: 180
PR(UAC) low alarm limit	90 Infant: 80	90 Infant: 80	90 Infant: 80	90 Infant: 80	90 Infant: 80
V Lead A	V1	V1	V1	V1	V1
V Lead B	V5	V5	V5	V5	V5
Waveform filter	Monitoring	Monitoring	Monitoring	Monitoring	Monitoring

Default settings: lethal arrhythmias

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
V Tach Allowed alarm priorities	High	High	High	High	High
PROFILE SETTINGS					
Asystole > Create snapshot	true	true	true	true	true
V Fib / V Tach > Create snapshot	true	true	true	true	true
V Tach > Priority	High	High	High	High	High

Setting	ICU	OR	PACU	ED	NICU
V Tach > Create snapshot	true	true	true	true	true
V Tach Criteria Criteria rule	V Tach criteria rule: AND	V Tach criteria rule: AND	V Tach criteria rule: AND	V Tach criteria rule: AND	V Tach criteria rule: AND
V Tach criteria rule: AND Setting locked	false	false	false	false	false
V Tach minimum HR HR value to be used for V Tach	100	100	100	100	160
V Tach minimum HR Alarm locked	true	true	true	true	true
Allow V Tach event duration criteria	false	false	false	false	false
Event duration (s) V Tach event duration	0	0	0	0	0

Default settings: atrial arrhythmias

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
A Fib > Priority	Off	Low	Off	Off	Off
A Fib > Create snapshot	false	false	false	false	true
Asystole > Priority	Off	Low	Off	Off	Off
Asystole > Create snapshot	false	false	false	false	true
Irregular > Priority	Low	Low	Low	Low	Low
Irregular > Create snapshot	false	true	false	false	true
Missing Beat > Priority	Off	Low	Off	Off	Off
Missing Beat > Create snapshot	false	false	false	false	false
Pause > Priority	Low	Low	Low	Low	Low
Pause > Create snapshot	false	true	false	false	false

Setting	ICU	OR	PACU	ED	NICU
Pause criteria: Pause interval (s)	3	3	3	3	5
SV Tachy > Priority	Off	Off	Off	Off	Off
SV Tachy > Create snapshot	false	false	false	false	false
SVT length (beats) The number of beats before the SV Tachy alarm sounds	6	6	6	6	6
HR for SVT (/min) The number of beats per minute before the SV Tachy alarm sounds	120	120	120	120	180

Default settings: ventricular arrhythmias

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Accelerated Ventricular > Priority	Low	Low	Low	Low	Low
Accelerated Ventricular > Create snapshot	false	false	false	false	true
Bigeminy > Priority	Low	Low	Low	Low	Low
Bigeminy > Create snapshot	true	true	true	true	true
Couplet > Priority	Low	Low	Low	Low	Low
Couplet > Create snapshot	true	true	true	true	true
Multifocal PVCs > Priority	Off	Off	Off	Off	Off
Multifocal PVCs > Create snapshot	false	false	false	false	false
R on T > Priority	Medium	Medium	Medium	Medium	Medium
R on T > Create snapshot	false	false	false	false	false
Trigeminy > Priority	Low	Low	Low	Low	Low

Setting	ICU	OR	PACU	ED	NICU
Trigeminy > Create snapshot	false	true	false	false	true
V Brady > Priority	Medium	High	Medium	Medium	Medium
V Brady > Create snapshot	true	true	true	true	true
VT > 2 > Priority	Medium	Medium	Medium	Medium	Medium
VT > 2 > Create snapshot	true	true	true	true	true

Default settings: ST

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow informational level for ST alarms	false	false	false	false	false
PROFILE SETTINGS					
ST segment low/high Alarm priority	Medium	Medium	Medium	Medium	Low
ST analysis Analysis enabled	true Adolescent, Pediatric, Infant: false	true Perfusion, Adolescent, Pediatric, Infant: false	true Adolescent, Pediatric, Infant: false	true Adolescent, Pediatric, Infant: false	false
ST analysis: ON Analysis locked	false	false	false	false	false
ST(I) alarm ON	true	true	true	true	true
ST (I) Alarm locked	false	false	false	false	false
ST I high alarm limit	2	2	2	2	2
ST I low alarm limit	-2	-2	-2	-2	-2
ST II alarm ON	true	true	true	true	true
ST (II) Alarm locked	false	false	false	false	false
ST II high alarm limit	2	2	2	2	2

Setting	ICU	OR	PACU	ED	NICU
ST II low alarm limit	-2	-2	-2	-2	-2
ST III alarm ON	true	true	true	true	true
ST (III) Alarm locked	false	false	false	false	false
ST III high alarm limit	2	2	2	2	2
ST III low alarm limit	-2	-2	-2	-2	-2
ST Lead 1, 10 leadwires	II	II	II	II	II
ST Lead 1, 3 leadwires	II	II	II	II	II
ST Lead 1, 5 leadwires	II	II	II	II	II
ST Lead 1, 6 leadwires	II	II	II	II	II
ST Lead 2, 10 leadwires	V5	V5	V5	V5	V1
ST Lead 2, 3 leadwires	NONE,CASC	NONE,CASC	NONE,CASC	NONE,CASC	NONE,CASC
ST Lead 2, 5 leadwires	VLEADA	VLEADA	VLEADA	VLEADA	VLEADA
ST Lead 2, 6 leadwires	VLEADB	VLEADB	VLEADB	VLEADB	VLEADA
ST Lead 3, 10 leadwires	AVL	AVL	AVL	AVL	AVL
ST Lead 3, 3 leadwires	NONE,CASC	NONE,CASC	NONE,CASC	NONE,CASC	NONE,CASC
ST Lead 3, 5 leadwires	AVL	AVL	AVL	AVL	AVL
ST Lead 3, 6 leadwires	AVL	AVL	AVL	AVL	AVL
ST V1 alarm ON	true	true	true	true	true
ST (V1) Alarm locked	false	false	false	false	false
ST V1 high alarm limit	2	2	2	2	2
ST V1 low alarm limit	-2	-2	-2	-2	-2
ST V2/dV2 alarm ON	true	true	true	true	true
ST (V2/dV2) Alarm locked	false	false	false	false	false
ST V2/dV2 high alarm limit	2	2	2	2	2
ST V2/dV2 low alarm limit	-2	-2	-2	-2	-2
ST V3/dV3 alarm ON	true	true	true	true	true
ST (V3/dV3) Alarm locked	false	false	false	false	false
ST V3/dV3 high alarm limit	2	2	2	2	2
ST V3/dV3 low alarm limit	-2	-2	-2	-2	-2
ST V4/dV4 alarm ON	true	true	true	true	true
ST (V4/dV4) Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
ST V4/dV4 high alarm limit	2	2	2	2	2
ST V4/dV4 low alarm limit	-2	-2	-2	-2	-2
ST V5 alarm ON	true	true	true	true	true
ST (V5) Alarm locked	false	false	false	false	false
ST V5 high alarm limit	2	2	2	2	2
ST V5 low alarm limit	-2	-2	-2	-2	-2
ST V6/dV6 alarm ON	true	true	true	true	true
ST (V6/dV6) Alarm locked	false	false	false	false	false
ST V6/dV6 high alarm limit	2	2	2	2	2
ST V6/dV6 low alarm limit	-2	-2	-2	-2	-2
ST aVF alarm ON	true	true	true	true	true
ST aVF Alarm locked	false	false	false	false	false
ST aVF high alarm limit	2	2	2	2	2
ST aVF low alarm limit	-2	-2	-2	-2	-2
ST aVL alarm ON	true	true	true	true	true
ST aVL Alarm locked	false	false	false	false	false
ST aVL high alarm limit	2	2	2	2	2
ST aVL low alarm limit	-2	-2	-2	-2	-2
ST aVR alarm ON	true	true	true	true	true
ST aVR Alarm locked	false	false	false	false	false
ST aVR high alarm limit	2	2	2	2	2
ST aVR low alarm limit	-2	-2	-2	-2	-2
Show in ECG parameter window: > ST highest deviation lead	false	false	false	false	false

Default settings: Qt/QTc

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow informational level for QT/QTc alarms	false	false	false	false	false
PROFILE SETTINGS					
QT/QTc Alarm priority	Low	Low	Low	Low	Low
QT alarm ON	true	true	true	true	true
QT Alarm locked	false	false	false	false	false
QT analysis Analysis enabled	true	true Perfusion: false	true	true	true
QT high alarm limit	450	450	450	450	500
QTc alarm ON	true	true	true	true	true
QTc Alarm locked	false	false	false	false	false
QTc high alarm limit	500 Pediatric: 480 Infant: 460	500 Pediatric: 480 Infant: 460	500 Pediatric: 480 Infant: 460	500 Pediatric: 480 Infant: 460	460

Default settings: impedance respiration

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Apnea (Imped.) Allowed alarm priority	Escalating, high	Escalating, high	Escalating, high	Escalating, high	Escalating, high
RR (Imped.) low/high Allowed alarm priority	Escalating, high	Escalating, high	Escalating, high	Escalating, high	Escalating, high
Resp (Imped.) measurement paused Allowed alarm priority	Escalating, high	Escalating, high	Escalating, high	Escalating, high	Escalating, high
Respiration lead	II	II	II	II	II
Size (%)	20%	20%	20%	20%	20%
PROFILE SETTINGS					
Apnea (Imped.) Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
Apnea (Imped.) s	20	20	20	20	20
Resp Parameter color	White	White	White	White	White
Patient type	Adult/pediatric	Adult/pediatric	Adult/pediatric	Adult/pediatric	Neonate
Respiration measurement Measurement ON	false	false	false	false	false
Sweep speeds > Resp	6.25	6.25	6.25	6.25	6.25
RR (Imped.) high (s) Alarm delay	15 s Pediatric, Infant: 10 s	15 s Pediatric, Infant: 10 s	15 s Pediatric, Infant: 10 s	15 s Pediatric, Infant: 10 s	10 s
RR (Imped.) low (s) Alarm delay	15 s Pediatric, Infant: 10 s	15 s Pediatric, Infant: 10 s	15 s Pediatric, Infant: 10 s	15 s Pediatric, Infant: 10 s	10 s
Resp (Imped.) measurement paused Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
RR (Imped.) low/high Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
RR (Imped.) Alarm ON	true	true	true	true	true
RR (Imped.) Alarm locked	false	false	false	false	false
RR (Imped.) High alarm limit	40	40 Perfusion: Off	40	40	75
RR (Imped.) Low alarm limit	4	Off	4	4	20

Default settings: pulse oximetry

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow low priority for SpO2 low	false	false	false	false	false
SpO2 probe off Allowed alarm priority	Escalating, high	Escalating, high	Escalating, high	Escalating, high	Escalating, high
Size Waveform display size, Masimo SET and Nellcor OxiMax only.	1x	1x	1x	1x	1x
Scale Waveform scale, TruSignal technology only	1	1	1	1	1
Scale > AUTO AUTO selection enabled, TruSignal technology only	true	true	true	true	true
Allow alarm deactivation with the Audio Pause key for: ECG leads off	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed
PROFILE SETTINGS					
SatSeconds Nellcor only	10	10	10	10	10
Show SatSeconds Nellcor only	false	false	false	false	false
SpO2 Alarm locked	false	false	false	false	false
SpO2 averaging (s)	Masimo: 8 TruSignal technology: 12	Masimo: 8 TruSignal technology: 12 Perfusion: 5	Masimo: 8 TruSignal technology: 12	Masimo: 8 TruSignal technology: 12	Masimo: 12 TruSignal technology: 12

Setting	ICU	OR	PACU	ED	NICU
SpO2 critical Alarm locked	false	false	false	false	false
SpO ₂ critical high alarm limit	Off	Off	Off	Off	Off
SpO ₂ critical alarm ON	false	false	false	false	false
SpO ₂ critical low alarm limit	88	88	88	88	88
SpO ₂ high alarm limit	Off Trauma: 100	Off	Off	Off	100
SpO ₂ limit alarms ON	true	true Perfusion: false	true	true	true
SpO ₂ low alarm limit	90 Neuro: 94 Adolescent, Pediatric, Infant: 92	90 Neuro, Infant: 94	90 Neuro, Infant: 94	90 Neuro, Infant: 94	88 Infant: 92
SpO2 Parameter color	Yellow	Yellow	Yellow	Yellow	Yellow
SpO2 high (s) Alarm delay	5 s	5 s	5 s	5 s	5 s
SpO2 high Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
SpO2 low (s) Alarm delay	5 s	5 s	5 s	5 s	5 s
SpO2 low Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
SpO2 probe off Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
Response Averaging time, Nellcor only	Normal	Normal	Normal	Normal	Normal
Sensitivity Masimo only	Normal	Normal	Normal	Normal	Normal
Show in parameter window > PR	false	false	false	false	false
Variable beat tone source	Off	Off	Off	Off	Off

Default settings: non-invasive blood pressure

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allowed priorities: Allowed alarm priority levels	Escalating, high, medium	Escalating, high, medium	Escalating, high, medium	Escalating, high, medium	Escalating, high, medium
Automatic NIBP	false	false	false	false	false
Blood pressure Measurement unit	mmHg	mmHg	mmHg	mmHg	mmHg
NIBP clock synchronization	true	true	true	true	true
NIBP cycle time display	Graphical	Graphical	Graphical	Graphical	Graphical
PROFILE SETTINGS					
Completed NIBP volume	5	5	5	5	5
Diastolic High alarm limit, Adult patient type	100 Adolescent: 80	100 Neuro: 90 Adolescent: 80	100 Adolescent: 80	100 Adolescent: 80	100
NIBP Dia Alarm locked, Adult patient type	false	false	false	false	false
Diastolic Low alarm limit, Adult patient type	40	40	40	40	40
Diastolic High alarm limit, Child patient type	80	80	80	80	60
NIBP Dia Alarm locked, Child patient type	false	false	false	false	false
Diastolic Low alarm limit, Child patient type	40	40	40	40	40

Setting	ICU	OR	PACU	ED	NICU
Diastolic High alarm limit, Infant patient type	70	70	70	70	50 Cardiac, Full-term, Infant: 60
NIBP Dia Alarm locked, Infant patient type	false	false	false	false	false
Diastolic Low alarm limit, Infant patient type	30	30	30	30	20
Patient type	Select Adolescent profile: Adult Pediatric profile: Child Infant profile: Infant	Select Adolescent profile: Adult Pediatric profile: Child Infant profile: Infant	Select Adolescent profile: Adult Pediatric profile: Child Infant profile: Infant	Select Adolescent profile: Adult Pediatric profile: Child Infant profile: Infant	Infant
Initial pressure (mmHg) Adult cuff initial inflation pressure.	135	135	135	135	135
Initial pressure (mmHg) Child cuff initial inflation pressure.	125	125	125	125	125
Initial pressure (mmHg) Infant cuff initial inflation pressure.	100	100	100	100	100
Mean High alarm limit, Adult patient type	140 Adolescent: 110	140 Adolescent: 110	140 Adolescent: 110	140 Adolescent: 110	140
NIBP Mean Alarm locked, Adult patient type	false	false	false	false	false
Mean Low alarm limit, Adult patient type	60 Adolescent: 50	60 Adolescent: 50	60 Adolescent: 50	60 Adolescent: 50	60
Mean High alarm limit, Child patient type	100	100	100	100	90
NIBP Mean Alarm locked, Child patient type	false	false	false	false	false
Mean Low alarm limit, Child patient type	50	50	50	50	50
Mean High alarm limit, Infant patient type	80	80	80	80	60 Cardiac, Full-term, Infant: 70

Setting	ICU	OR	PACU	ED	NICU
NIBP Mean Alarm locked, Infant patient type	false	false	false	false	false
Mean Low alarm limit, Infant patient type	40	40	40	40	30 Cardiac, Full-term, Infant: 40
Priorities Alarm priorities	High	High	High	High	High
Auto initial inflate	true	true	true	true	true
NIBP Parameter color	Red	Red	Red	Red	Red
Cycle time	15 min	5 min	5 min	5 min	10 min
Diastolic Alarm ON	false	false	false	false	false
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
Mean Alarm ON	false Adolescent: true	false Infant: true	false Infant: true	false Infant: true	true
Systolic Alarm ON	true	true	true	true	true
IP/NIBP Graphic trend scales	0-300 Pediatric: 50-150 Infant: 0-100	0-300 Pediatric: 50-150 Infant: 0-100	0-300 Pediatric: 50-150 Infant: 0-100	0-300 Pediatric: 50-150 Infant: 0-100	0-100 Infant: 50-150
NIBP Display Timeout	60min/4h	5min	30min/1h	60min/4h	60min/4h
Systolic High alarm limit, Adult patient type	180 Adolescent: 150	180 Neuro: 160 Adolescent: 150	180 Adolescent: 150	180 Adolescent: 150	180
Systolic Alarm locked, Adult patient type	false	false	false	false	false
Systolic Low alarm limit, Adult patient type	80	80	80	80	80
Systolic High alarm limit, Child patient type	130	130	130	130	120
Systolic Alarm locked, Child patient type	false	false	false	false	false
Systolic Low alarm limit, Child patient type	70	70	70	70	70

Setting	ICU	OR	PACU	ED	NICU
Systolic High alarm limit, Infant patient type	120	120	120	120	90 Cardiac, Full-term, Infant: 100
Systolic Alarm locked, Infant pa- tient type	false	false	false	false	false
Systolic Low alarm limit, Infant patient type	50	50	50	50	40

Default settings: invasive pressures

Invasive pressures care unit settings

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow alarm off for Art disconnect	true	true	true	true	true
Art > IABP on	false	false	false	false	false
Channel 1 to Channel 4 > IABP on	false	false	false	false	false
Allow alarm off for Fem disconnect	true	true	true	true	true
Fem > IABP on	false	false	false	false	false
P1 low/high to P8 low/high	Escalating, high, medium	Escalating, high, medium	Escalating, high, medium	Escalating, high, medium	Escalating, high, medium
Allow alarm off for UAC disconnect	true	true	true	true	true

Invasive pressures, Primary arterial source

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Primary arterial source	AUTO	AUTO	AUTO	AUTO	AUTO

Invasive pressures channel settings

The monitor uses invasive pressure channel default settings. Once you select a label for a channel, the label's default settings are taken into use.

Default settings: invasive pressure channels P1-P4

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
P1-P4 Parameter color	White	White	White	White	White
P1-P4 Mean high alarm limit	15 Infant: 10	15 Infant: 10	15 Infant: 10	15 Infant: 10	5
P1-P4 Mean > Alarm on	true Neuro, Trauma: false	true	true	true	true
P1-P4 Mean low alarm limit	0	0 Perfusion: -5	0	0	0

Default settings: invasive pressure channel 1

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Channel 1 default site name:

- **ICU, OR, PACU**, and **ED** software packages: **Art**
- **NICU** software package: **UAC**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Diastolic high alarm limit	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	50 Cardiac, Full-term, Infant: 60
Diastolic > Alarm on	false	false	false	false	false
Diastolic low alarm limit	40 Infant: 30	40 Infant: 30	40 Infant: 30	40 Infant: 30	20
Catheter disconnect alarm	true	true	true	true	true
Channel display color In format Xy, where X = selected label and y = channel number. E.g., Art 1	Red	Red	Red	Red	Red
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
Mean high alarm limit	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	60 Cardiac, Full-term, Infant: 70
Mean > Alarm on	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	true
Mean low alarm limit	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	30 Cardiac, Full-term, Infant: 40
Show in parameter window > PR	false	false	false	false	false
Smart BP	true	true	true	true	true
Systolic high alarm limit	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Perfusion: 120 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	90 Cardiac, Full-term, Infant: 100

Setting	ICU	OR	PACU	ED	NICU
Systolic > Alarm on	true	true	true	true	false
Systolic low alarm limit	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Perfusion: 40 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	40
Filter (Hz)	12	12	12	12	12
Scale (X) Where X = kPa	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Perfusion: 16 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16	14 Infant: 16
Scale (X) Where X = mmHg	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Perfusion: 120 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120	100 Infant: 120

Default settings: invasive pressure channel 2

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Channel 2 default site name:

- **ICU, OR, PACU,** and **ED** software packages: **CVP**
- **NICU** software package: **UVC**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Diastolic high alarm limit	10	10	10	10	10
Diastolic > Alarm on	false	false	false	false	false
Diastolic low alarm limit	-5	-5	-5	-5	-5
Catheter disconnect alarm	true	true	true	true	true

Setting	ICU	OR	PACU	ED	NICU
Channel display color In format Xy, where X = selected label and y = channel number. E.g., CVP 2	Cyan	Cyan	Cyan	Cyan	White
Display format	(M)	(M)	(M)	(M)	(M)
Mean high alarm limit	15 Infant: 10	15 Infant: 10	15 Infant: 10	15 Infant: 10	5
Mean > Alarm on	true Neuro, Trauma: false	true	true	true	true
Mean low alarm limit	0	0 Perfusion: -5	0	0	0
Show in parameter window > PR	false	false	false	false	false
Smart BP	false	false	false	false	false
Systolic high alarm limit	20	20	20	20	15
Systolic > Alarm on	false	false	false	false	false
Systolic low alarm limit	5	5	5	5	5
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4 Infant: 2	4 Infant: 2	4 Infant: 2	4 Infant: 2	2
Scale (X) where X = mmHg	20 Infant: 10	20 Infant: 10	20 Infant: 10	20 Infant: 10	10

Default settings: invasive pressure channel 3

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Channel 3 default site name:

- **ICU, OR, PACU, and ED** software packages: **Fem**
- **NICU** software package: **Art**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					

Setting	ICU	OR	PACU	ED	NICU
Diastolic high alarm limit	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	50 Cardiac, Full-term, Infant: 60
Diastolic > Alarm on	false	false	false	false	false
Diastolic low alarm limit	40 Infant: 30	40 Infant: 30	40 Infant: 30	40 Infant: 30	20
Catheter disconnect alarm	true	true	true	true	true
Channel display color In format Xy, where X = select- ed label and y = channel number. For example, Fem 3	Red	Red	Red	Red	Red
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
Mean high alarm limit	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	60 Cardiac, Full-term, Infant: 70
Mean > Alarm on	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	true
Mean low alarm limit	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	30 Cardiac, Full-term, Infant: 40
Show in parameter window > PR	false	false	false	false	true
Smart BP	true	true	true	true	true
Systolic high alarm limit	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	90 Cardiac, Full-term, Infant: 100
Systolic > Alarm on	true	true	true	true	true

Setting	ICU	OR	PACU	ED	NICU
Systolic low alarm limit	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Perfusion: 40 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	40
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16	14
Scale (X) where X = mmHg	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120	100

Default settings: invasive pressure channel 4

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Channel 4 default site name:

- **ICU, OR, PACU,** and **ED** software packages: **PA**
- **NICU** software package: **CVP**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Diastolic high alarm limit	20	20	20	20	10
Diastolic > Alarm on	true	true	true	true Trauma, Neuro: false	false
Diastolic low alarm limit	5	5	5	5	-5
Catheter disconnect alarm	true	true	true	true	true

Setting	ICU	OR	PACU	ED	NICU
Channel display color In format Xy, where X = selected label and y = channel number. For example, PA 4	Yellow	Yellow	Yellow	Yellow	Cyan
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	(M)
Mean high alarm limit	30	30	30	30	5
Mean > Alarm on	true	true	true	true	true
Mean low alarm limit	5	5	5	5	0
Show in parameter window > PR	false	false	false	false	false
Smart BP	false	false	false	false	false
Systolic high alarm limit	40	40	40	40	15
Systolic > Alarm on	false	false	false	false	false
Systolic low alarm limit	10	10	10	10	5
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	8 Pediatric, Infant: 6	8 Pediatric, Infant: 6	8 Pediatric, Infant: 6	8 Pediatric, Infant: 6	2
Scale (X) where X = mmHg	60 Pediatric, Infant: 40	60 Pediatric, Infant: 40	60 Pediatric, Infant: 40	60 Pediatric, Infant: 40	10

Default settings: invasive pressure channel 8

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Channel 8 default site name is **Art**.

Setting	ICU	OR	PACU	ED
PROFILE SETTINGS				

Setting	ICU	OR	PACU	ED
Diastolic high alarm limit	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70
Diastolic > Alarm on	false	false	false	false
Diastolic low alarm limit	40 Infant: 30	40 Infant: 30	40 Infant: 30	40 Infant: 30
Channel display color In format Xy, where X = selected label and y = channel number. For example, Art 8	Red	Red	Red	Red
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
Mean high alarm limit	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80
Mean > Alarm on	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true
Mean low alarm limit	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40
Show in parameter window > PR	false	false	false	false
Systolic high alarm limit	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Perfusion: 120 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120
Systolic > Alarm on	true	true	true	true
Systolic low alarm limit	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Perfusion: 40 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50
Scale (X) Where X = kPa	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Perfusion: 16 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16	30 Adolescent: 24 Pediatric: 20 Infant: 16

Setting	ICU	OR	PACU	ED
Scale (X) Where X = mmHg	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Perfusion: 120 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120	200 Adolescent: 170 Pediatric: 140 Infant: 120

Invasive pressures label settings

The monitor uses invasive pressure channel default settings. Once you select a label for a channel, the label's default settings are taken into use.

Default settings: invasive pressures, label Art

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Art low/high Alarm priority	High	High	High	High	High
Art Dia high alarm limit	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	50 Cardiac, Full-term, Infant: 60
Art Dia > Alarm on	false	false	false	false	false
Art Dia Alarm locked	false	false	false	false	false
Art Dia low alarm limit	40 Infant: 30	40 Infant: 30	40 Infant: 30	40 Infant: 30	20
Catheter disconnect alarm	true	true	true	true	true
Art Parameter color	Red	Red	Red	Red	Red
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	(M) SYS/DIA

Setting	ICU	OR	PACU	ED	NICU
Art Mean high alarm limit	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	60 Cardiac, Full-term, Infant: 70
Art Mean > Alarm on	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	true
Art Mean Alarm locked	false	false	false	false	false
Art Mean low alarm limit	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	30 Cardiac, Full-term, Infant: 40
Show in parameter window > PR	false	false	false	false	true
Smart BP	true	true	true	true	true
Art Sys high alarm limit	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Perfusion: 120 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	90 Cardiac, Full-term, Infant: 100
Art Sys > Alarm on	true	true	true	true	true
Art Sys Alarm locked	false	false	false	false	false
Art Sys low alarm limit	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Perfusion: 40 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	40
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	30	30	30	30	14
Scale (X) where X = mmHg	200	200	200	200	100

Default settings: invasive pressures, label UAC

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Catheter disconnect alarm	true	true	true	true	true
UAC low/high Alarm priority	High	High	High	High	High
UAC Dia high alarm limit	50	50	50	50	50 Cardiac, Full-term, Infant: 60
UAC Dia > Alarm on	false	false	false	false	false
UAC Dia Alarm locked	false	false	false	false	false
UAC Dia low alarm limit	20	20	20	20	20
Allow alarm off for UAC disconnect	true	true	true	true	true
UAC Parameter color	Red	Red	Red	Red	Red
UAC > Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
UAC Mean high alarm limit	70	70	70	70	60 Cardiac, Full-term, Infant: 70
UAC Mean > Alarm on	true	true	true	true	true
UAC Mean Alarm locked	false	false	false	false	false
UAC Mean low alarm limit	30	30	30	30	30 Cardiac, Full-term, Infant: 40

Setting	ICU	OR	PACU	ED	NICU
Show in parameter window > PR	false	false	false	false	false
UAC Sys high alarm limit	90	90	90	90	90 Cardiac, Full-term, Infant: 100
UAC Sys > Alarm on	false	false	false	false	false
UAC Sys Alarm locked	false	false	false	false	false
UAC Sys low alarm limit	40	40	40	40	40
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	16	16	16	16	14
Scale (X) where X = mmHg	120	120	120	120	100

Default settings: invasive pressures, label CVP

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
CVP low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
CVP Parameter color	Cyan	Cyan	Cyan	Cyan	Cyan
Display format	(M)	(M)	(M)	(M)	(M)
CVP Mean high alarm limit	15 Infant: 10	15 Infant: 10	15 Infant: 10	15 Infant: 10	5
CVP Mean > Alarm on	true Neuro, Trauma: false	true	true	true	true
CVP Mean Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
CVP Mean low alarm limit	0	0 Perfusion: -5	0	0	0
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	2
Scale (X) where X = mmHg	20	20	20	20	10

Default settings: invasive pressures, label UVC

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
UVC low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
UVC Parameter color	White	White	White	White	White
Display format	(M)	(M)	(M)	(M)	(M)
Mean high alarm limit	15	15	15	15	5
UVC Mean > Alarm on	false	false	false	false	true
UVC Mean Alarm locked	false	false	false	false	false
UVC Mean low alarm limit	0	0	0	0	0
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	2
Scale (X) where X = mmHg	20	20	20	20	10

Default settings: invasive pressures, label Fem

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
Fem low/high Alarm priority	High	High	High	High	High
Fem Dia high alarm limit	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	100 Adolescent, Pediatric: 80 Infant: 70	50 Cardiac, Full-term, Infant: 60
Fem Dia > Alarm on	false	false	false	false	false
Fem Dia Alarm locked	false	false	false	false	false
Fem Dia low alarm limit	40 Infant: 30	40 Infant: 30	40 Infant: 30	40 Infant: 30	20
Catheter disconnect alarm	true	true	true	true	true
Fem Parameter color	Red	Red	Red	Red	Red
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
Fem Mean high alarm limit	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	140 Adolescent: 110 Pediatric: 100 Infant: 80	60 Cardiac, Full-term, Infant: 70
Fem Mean > Alarm on	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	false Adolescent, Pediatric, Infant: true	true
Fem Mean Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
Fem Mean low alarm limit	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	60 Adolescent, Pediatric: 50 Infant: 40	30 Cardiac, Full-term, Infant: 40
Show in parameter window > PR	false	false	false	false	true
Smart BP	true	true	true	true	false
Fem Sys high alarm limit	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Perfusion: 120 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	180 Neuro: 160 Adolescent: 150 Pediatric: 130 Infant: 120	90 Cardiac, Full-term, Infant: 100
Fem Sys > Alarm on	true	true	true	true	true
Fem Sys Alarm locked	false	false	false	false	false
Fem Sys low alarm limit	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	80 Neuro: 90 Pediatric: 70 Infant: 50	40
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	30	30	30	30	14
Scale (X) where X = mmHg	200	200	200	200	100

Default settings: invasive pressures, label CPP

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
CPP low/high Alarm priority	Medium	Medium	Medium	Medium	Medium

Setting	ICU	OR	PACU	ED	NICU
CPP high alarm limit	100 Infant: 90	100 Infant: 90	100 Infant: 90	100 Infant: 90	100
CPP > Alarm on	true	true	true	true	true
CPP Alarm locked	false	false	false	false	false
CPP low alarm limit	60 Infant: 50	60 Infant: 50	60 Infant: 50	60 Infant: 50	40
Show in parameter window > CPP	true	true	true	true	true

Default settings: invasive pressures, label FemV

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
FemV low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
FemV Parameter color	Cyan	Cyan	Cyan	Cyan	Cyan
Display format	(M)	(M)	(M)	(M)	(M)
FemV Mean high alarm limit	15 Infant: 10	15 Infant: 10	15 Infant: 10	15 Infant: 10	5
FemV Mean > Alarm on	true	true	true	true	true
FemV Mean Alarm locked	false	false	false	false	false
FemV Mean low alarm limit	0	0	0	0	0
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	2
Scale (X) where X = mmHg	20	20	20	20	10

Default settings: invasive pressures, label ICP

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
ICP low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
ICP Parameter color	White	White	White	White	White
Display format	(M)	(M)	(M)	(M)	(M)
ICP Mean high alarm limit	15 Infant: 9	15 Infant: 9	15 Infant: 9	15 Infant: 9	9
ICP Mean > Alarm on	true	true	true	true	true
ICP Mean Alarm locked	false	false	false	false	false
ICP Mean low alarm limit	0	0	0	0	0
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	2
Scale (X) where X = mmHg	30	30	30	30	20

Default settings: invasive pressures, label LAP

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
LAP low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
LAP Parameter color	White	White	White	White	White
Display format	(M)	(M)	(M)	(M)	(M)
LAP Mean high alarm limit	20 Pediatric, Infant: 15	20 Pediatric, Infant: 15	20 Pediatric, Infant: 15	20 Pediatric, Infant: 15	10
LAP Mean > Alarm on	true	true	true	true	true
LAP Mean Alarm locked	false	false	false	false	false
LAP Mean low alarm limit	5	5	5	5	2
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	4
Scale (X) where X = mmHg	20	20	20	20	20

Default settings: invasive pressures, label PA

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
PA low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
PA Dia high alarm limit	20	20	20	20	20
PA Dia > Alarm on	true	true	true	true Trauma, Neuro: false	true
PA Dia Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
PA Dia low alarm limit	5	5	5	5	5
PA Parameter color	Yellow	Yellow	Yellow	Yellow	Yellow
Display format	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)	SYS/DIA (M)
PA Mean high alarm limit	30	30	30	30	30
PA Mean > Alarm on	true	true	true	true	true
PA Mean Alarm locked	false	false	false	false	false
PA Mean low alarm limit	5	5	5	5	5
PA Sys high alarm limit	40	40	40	40	40
PA Sys > Alarm on	false	false	false	false	false
PA Sys Alarm locked	false	false	false	false	false
PA Sys low alarm limit	10	10	10	10	10
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	8	8	8	8	6
Scale (X) where X = mmHg	60	60	60	60	40

Default settings: invasive pressures, label RAP

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
RAP low/high Alarm priority	Medium	Medium	Medium	Medium	Medium

Setting	ICU	OR	PACU	ED	NICU
RAP Parameter color	White	White	White	White	White
Display format	(M)	(M)	(M)	(M)	(M)
RAP Mean high alarm limit	15 Pediatric, Infant: 10	15 Pediatric, Infant: 10	15 Pediatric, Infant: 10	15 Pediatric, Infant: 10	5
RAP Mean > Alarm on	true	true	true	true	true
RAP Mean Alarm locked	false	false	false	false	false
RAP Mean low alarm limit	0	0	0	0	0
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	2
Scale (X) where X = mmHg	20	20	20	20	10

Default settings: invasive pressures, label RVP

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
PROFILE SETTINGS					
RVP low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
RVP Parameter color	White	White	White	White	White
Display format	(M)	(M)	(M)	(M)	(M)
RVP Mean high alarm limit	35 Pediatric, Infant: 25	35 Pediatric, Infant: 25	35 Pediatric, Infant: 25	35 Pediatric, Infant: 25	25
RVP Mean > Alarm on	true	true	true	true	true
RVP Mean Alarm locked	false	false	false	false	false

Setting	ICU	OR	PACU	ED	NICU
RVP Mean low alarm limit	5	5	5	5	5
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	8	8	8	8	4
Scale (X) where X = mmHg	60	60	60	60	40

Default settings: invasive pressures, label P1 to P4

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
P1 low/high to P4 low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
Display format	(M)	(M)	(M)	(M)	(M)
P1 Mean to P4 Mean Alarm locked	false	false	false	false	false
Filter (Hz)	12	12	12	12	12
Scale (X) where X = kPa	4	4	4	4	2
Scale (X) where X = mmHg	20	20	20	20	10

Default settings: temperature

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow informational level for temperature alarms	false	false	false	false	false
Temperature Unit	°C	°C	°C	°C	°C
PROFILE SETTINGS					
Show temperature difference	T2-T1	T2-T1	T2-T1	T2-T1	T2-T1
Show in parameter window > T2-T1	true	true	true	true	true
Show in parameter window > T1	true	true	true	true	true
Show in parameter window > T2	true	true	true	true	true
T1 Alarm locked	false	false	false	false	false
T1 alarm ON	false	true Perfusion: false	false	false	false
T1 label	T1	T1	T1	T1	T1
T1 high alarm limit	38.5 Pediatric, Infant: 38.0	38.5 Pediatric, Infant: 38.0	38.5 Pediatric, Infant: 38.0	38.5 Pediatric, Infant: 38.0	37.5
T1 low alarm limit	34.0 Pediatric, Infant: 35.5	34.0 Pediatric, Infant: 35.5	34.0 Pediatric, Infant: 35.5	34.0 Pediatric, Infant: 35.5	36.0
T2 Alarm locked	false	false	false	false	false
T2 alarm ON	false	true Perfusion: false	false	false	false
T2 label	T2	T2	T2	T2	T2
T2 high alarm limit	38.5 Pediatric, Infant: 38.0	38.5 Pediatric and Infant: 38.0	38.5 Pediatric, Infant: 38.0	38.5 Pediatric, Infant: 38.0	37.5
T2 low alarm limit	34.0 Pediatric, Infant: 35.5	34.0 Pediatric, Infant: 35.5	34.0 Pediatric, Infant: 35.5	34.0 Pediatric, Infant: 35.5	36.0
T2-T1 alarm locked	false	false	false	false	false
T2-T1 alarm ON	false	false	false	false	false
T2-T1 high alarm limit	4.0	4.0	4.0	4.0	4.0
Temp low/high Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating

Setting	ICU	OR	PACU	ED	NICU
Temp Parameter color	White	White	White	White	White
T1 on Measurement enabled	true	true	true	true	true
T2 on Measurement enabled	true	true	true	true	true

Default settings: CO₂

For more information, refer to the relevant sections in this user manual. The following table lists the factory default settings.

In this table:

- true = setting is enabled
- false = setting is disabled
- When used, the following instances in the table refer to profiles. If no profile is mentioned, the same default applies to all profiles.
 - **Adolescent, Cardiac, Full-term, General, Infant, Invasive, Medical, Neuro, Pediatric, Perfusion, Premature, PreRegional, Regional, Respiratory, Surgical, Trauma**

Setting name	ICU	OR	PACU	ED	NICU
CARE UNIT SETTINGS					
Allow alarm deactivation from the parameter menu for: > Apnea (CO₂)	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed
Deactivate apnea alarm	false	false	false	false	false
Age	Select	Select	Select	Select	Select
CO₂ Measurement unit	%	%	%	%	%
PROFILE SETTINGS					
Apnea (CO₂) Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
CO₂ low/high Alarm priority	Medium	Medium	Medium	Medium	Medium
Apnea (CO₂) (X) Where X = s	20	20	20	20	20
CO₂ average (s)	10	10	10	10	10
CO₂ Parameter color	White	White	White	White	White
CO₂ scale (X) % Where (X) = measurement unit	0	0	0	0	0
Sweep speeds > CO₂	6.25	6.25	6.25	6.25	6.25

Setting name	ICU	OR	PACU	ED	NICU
EtCO2 high alarm limit	8 Neuro, Trauma: 6	8 Perfusion, Neuro: 6	8 Neuro: 6	8 Neuro, Trauma: 6	8
EtCO2 low alarm limit	3 Neuro, Trauma: 2.7	3 Perfusion, Neuro: 2.7	3 Neuro: 2.7	3 Neuro, Trauma: 2.7	3
FiCO2 Alarm locked	false	false	false	false	false
FiCO2 high alarm limit	3	3	3	3	3
FiCO2 alarm ON	true	true Perfusion: false	true	true	true
FiCO2 low alarm limit	Off	Off	Off	Off	Off
RR (CO2) (X) Where X = s Alarm priority	Escalating	Escalating	Escalating	Escalating	Escalating
Respiration rate high alarm limit	60	60 Perfusion: Off	60	60	75
Respiration rate low alarm limit	Off Infant: 15	Off	Off	Off	20

Maintenance

Planned maintenance

Service personnel shall perform the required planned maintenance activities according to the procedures and schedule specified in the service manual.

Recommended regular checks

Daily checks

- Check that the accessories, cables, cable connectors, micro-modules, Carescape ONE, and display parts are clean and intact. Check the following:
 - No loose connectors, cracks, or other visible sign of damage.
 - No signs of fluid contamination or stains.
 - Product labeling, markings, and symbols are intact and readable.
 - Monitor and the connected devices are properly attached to the mounts.
- Check that there are no messages indicating that the Carescape ONE or micro-modules are not functioning.
- Check the charge of the battery.

NOTE

If you notice any issues or technical alarms related to the micro-modules, replace the micro-module and contact qualified service personnel.

Check every 24 months

- Check the calibration of NIBP.

For calibration instructions, see the service manual.

Cable maintenance

Before use, check that the product is intact and clean.

NOTE

Do not treat the cables with oils (e.g., household or lubricating) or aggressive fluids or solvents (e.g., acetone).

Nellcor SpO₂ micro-module maintenance

There are no user-serviceable parts inside the Nellcor SpO₂ micro-module. Users may not modify any components. The Nellcor SpO₂ micro-module requires no calibration.

For technical information and assistance if unable to correct a problem, or to order parts contact your GE HealthCare representative or a local Medtronic representative.

www.medtronic.com

When contacting a local Medtronic representative, have the Nellcor SpO₂ micro-module serial number available.

Maintaining the battery

About the lithium-ion battery

The lithium-ion (Li-Ion) battery is a rechargeable battery containing lithium-ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.

- The battery discharges on its own, even when it is not installed in the equipment. This discharge is the result of the lithium-ion cells and the bias current required for the integrated electronics.
- The self-discharge rate of lithium-ion cells double for every 10°C (18°F) rise in temperature.
- The capacity loss of the battery degrades significantly at higher temperatures.
- As the battery ages, the full-charge capacity of the battery degrades and is permanently lost. As a result, the amount of charge that is stored and available for use is reduced.

The following terms are used to define the battery capacity:

- | | |
|-----------------------------|---|
| • Design capacity | The rated/minimum capacity of the battery cells when the battery is new. |
| • Full-charge capacity | The actual amount of charge the battery can store and deliver. |
| • Remaining charge capacity | The amount of full-charge capacity currently remaining in the battery. This is a percent of full-charge capacity. |

Improving battery performance

Follow these guidelines to improve the battery performance:

1. Position the equipment in a location that does not artificially increase the operating temperature of the battery.
2. GE HealthCare recommends using an approved GE HealthCare external battery charger to charge the battery whenever possible. The external battery charger maintains a lower battery cell temperature during the charge cycle.

This reduction in temperature can extend the life of the battery.

3. To check if the battery needs conditioning:
 - a. Select  from the main menu and then **Battery** or **Battery & network** (if the WLAN license is in use and WLAN has been enabled during the configuration).
 - b. On the **Battery** tab, check the **Battery quality** field. If the displayed value is **Condition**, battery conditioning is required.

Battery conditioning re-calibrates the electronic fuel gauge. GE HealthCare recommends using an approved GE HealthCare external battery charger to condition the battery.
4. Follow the external battery charger instructions for use to condition the battery.

Battery storage recommendations

GE HealthCare recommends storing the battery outside of the device at a temperature between 20°C to 25°C (68°F to 77°F) if the device will not be used for a long period of time.

Testing the battery charge

Before installing a battery, verify the battery's state of charge. Each battery must be fully charged before use.

1. Press the **TEST** button on the battery and check the green charging level indicators to see how much charge is left:
 - Four LEDs illuminated: 75% to 100% of full-charge capacity.
 - Three LEDs illuminated: 50% to 74.9% of full-charge capacity.
 - Two LEDs illuminated: 25% to 49.9% of full-charge capacity.
 - One LED illuminated: 11% to 24.9% of full-charge capacity.
 - One LED flashing: < 11% of full-charge capacity.

Charging a battery inside the Carescape ONE

The battery is charged whenever the Carescape ONE is connected to a Carescape Dock F0 and the dock is connected to an AC power source. The battery charges both when the Carescape ONE is turned on and when it is in standby mode.

There are some special conditions when the Carescape ONE battery charging is temporarily denied, for example, when the battery temperature is too high.

Charging a battery using an external battery charger

1. Follow the external battery charger instructions for use to charge the battery.

Replacing the Carescape ONE battery

CAUTION

LOSS OF MONITORING. To prevent loss of monitoring, only change the Carescape ONE battery when Carescape ONE is connected to a powered docking solution.

1. Open the battery door by gently peeling down the corner of the battery door pull tab.



2. Pull on the battery cord to remove the battery from the battery slot.



3. Position the battery with the connector end facing up and insert the battery all the way into the battery slot.



4. Close the battery door. Ensure that the battery door tightly seals the battery into the battery slot.

WARNING

PHYSICAL INJURY. Do not install the device above a patient. Make sure the battery is completely inserted and the battery door is completely closed. Falling batteries could seriously or fatally injure neonatal or other vulnerable patients.

5. Press the Power/Standby button on the Carescape ONE.
6. Check that the Power LED illuminates amber while the Carescape ONE powers up, then illuminates green.
7. Check that the battery status icon displays on screen without battery error messages.

Battery recycling



This product contains Lithium-Ion batteries. At the end of their service life, batteries in this product must be recycled or disposed in accordance with local or national regulations. Do not dispose of batteries as trash or unsorted municipal waste. Requirements and services for recycling of batteries vary between countries.

- **USA:** You may follow the battery manufacturers instructions on the battery to recycle it. Alternatively, you may return GE HealthCare product batteries to GE HealthCare for recycling. For information about returning batteries to GE HealthCare, contact your authorized GE HealthCare Service representative or contact GE HealthCare Equipment Services at 1-800-437-1171.
- **Canada:** Contact the approved battery stewardship program in your province for information on recycling your batteries.
- **Other countries:** Recycle batteries through your local, regional or national collective scheme in accordance with your local or national regulations.

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Electromagnetic compatibility

IEC 60601-1-2

The system complies with IEC 60601-1-2:2020-09, and complies with the EMC requirements in IEC 80601-2-49:2024 and in the other parameter specific IEC 60601-2-xx and IEC/ISO 80601-2-xx standards.

- Compliance with the standard IEC 60601-1-2:2020-09 applies only to those products that are currently being manufactured and shipped. For standards compliance information, refer to the supplemental information provided with the device.

According to parameter-specific IEC 60601-2-xx and IEC 80601-2-xx series standard requirements for ESU (electrosurgical unit) tests, the equipment is protected against malfunction caused by electrosurgery.

Electromagnetic compatibility safety precautions

Electromagnetic compatibility warnings

WARNING

PATIENT SAFETY. Use only approved accessories, including mounts, and defibrillator-proof cables and invasive pressure transducers. For a list of approved accessories, see the supplemental information provided. Other cables, transducers and accessories may cause a safety hazard, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

WARNING

PATIENT SAFETY. Other equipment may interfere with the system, even if that other equipment complies with CISPR emission requirements. This may lead to compromised patient safety.

WARNING

EMC. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Changes or modifications to this device/system not expressly approved by GE HealthCare may cause EMC issues with this or other equipment. This device/system is designed and tested to comply with applicable standards and regulations regarding EMC and needs to be installed and put into service according to the EMC information stated as follows: This device/system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Mains power should be that of a typical commercial or hospital environment. Device is compliant to Class A.

WARNING

ERRONEOUS READINGS. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Consult qualified personnel regarding device/system configuration.

WARNING

DEGRADED PERFORMANCE. Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of this device/system, including cables specified by the manufacturer. Otherwise, the performance of this device/system may degrade.

WARNING

DEGRADED PERFORMANCE. Use of known RF sources, such as cell/portable phones, RFID, electronic article surveillance (EAS) systems, diathermy, or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation of this device/system. Consult qualified personnel regarding device/system configuration.

WARNING

EMC INTERFERENCE. The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

EMC INTERFERENCE. Changes or modifications to this device/system not expressly approved by GE HealthCare may cause EMC issues with this or other equipment.

NOTE

Electromagnetic disturbance may cause, for example, temporary loss of measurement or changes in the values or the appearance of the displayed waveforms (such as excessive noise or a sine wave).

Essential performance in EMC

The table lists the essential performance tested in EMC as defined by the manufacturer and by the Compliance standards (reference Standards Compliance section).

When the accuracies listed below cannot be met, the system generates an alarm or recovers to normal operation within 10 or 30 seconds after exposure to transient electromagnetic disturbance, according to the parameter-specific IEC 60601-2-xx and IEC/ISO 80601-2-xx standards.

Parameter	Essential performance
ECG	- ECG heart rate accuracy: $\pm 1\%$ or ± 1 bpm, whichever is greater - ST numeric accuracy: ST Mean Difference (Mean error) $< 50 \mu V$
Impedance respiration	Impedance respiration rate accuracy: ± 1 breath per minute (4 to 120 breaths per minute)
Invasive blood pressure	No invasive pressure error greater than $\pm 4\%$ of reading or ± 0.5 kPa (± 4 mmHg), whichever is greater.

Parameter	Essential performance
Temperature	With reusable sensors: - Extended output range (0°C to 18°C): ± 0.3 °C - Rated output range (18°C to 45°C): ± 0.2 °C With disposable sensors: - Extended output range (0°C to 18°C): ± 0.4 °C - Rated output range (18°C to 45°C): ± 0.3 °C
CO ₂ (RGM)	LoFlo CO ₂ : - No error in CO₂ greater than ± 2 mmHg of gas level with the gas level set between 0 mmHg to 40 mmHg. - No change in respiration rate greater than ± 1 breath per minute over a range of 2 to 150 breaths per minute. - CO₂ flow rate: 50 ml /min ± 10 ml/min. Microstream CO ₂ : - No error in CO₂ greater than ± 2 mmHg of gas level with the gas level set between 0 mmHg to 38 mmHg. - No change in respiration rate greater than ± 1 breath per minute over a range of 0 to 70 breaths per minute. - CO₂ flow rate 50 ml /min ± 5 ml/min.
SpO ₂ : TruSignal, Nellcor, Masimo	- No errors in pulse rate greater than ± 2 bpm for TruSignal SpO₂ or greater than ± 3 bpm for Nellcor and Masimo SpO₂. - No error in saturation greater than $\pm 4\%$.
Non-invasive blood pressure	No error for the measurement of the cuff pressure greater than ± 2 mmHg (± 0.3 kPa).
rSO ₂	For INVOS rSO₂ micro-module essential performance, refer to the supplemental information provided with the host monitor.
SpHb	For Masimo SpHb essential performance, refer to the host monitor's patient monitor labeling.

Microstream CO₂ micro-module and electromagnetic compatibility

The Microstream CO₂ micro-module meets the IEC 60601-1-2:2020 standard requirements for immunity with the following exceptions:

- The radiated RF immunity compliance level of the Microstream CO₂ micro-module measurement is X V/m with some frequencies. Higher levels may cause disturbance to the CO₂ curve and numerical values. Based on the standard, these degradations of the CO₂ measurement are acceptable as they do not cause an unacceptable risk to the user or patient.

The user can easily notice the electromagnetic disturbance because CO₂ measurement has changes in the CO₂ values and in the appearance of the CO₂ curve (for example, excessive noise or a sine wave). If you suspect electromagnetic disturbance to the CO₂ measurement, it is recommended that you select the CO₂ curve to be shown on the screen.

Depending on the error that the system detects if exposed to a significant electromagnetic interference, different actions may be required from the user. If there is a disturbance on the CO₂

curve and/or values, increase the distance between Microstream CO₂ micro-module and portable RF communications equipment.

Electromagnetic emissions

Guidance and manufacturer's declaration — electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Carescape ONE uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Electromagnetic immunity

Guidance and manufacturer's declaration — electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	

Guidance and manufacturer's declaration — electromagnetic immunity This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Voltage dips IEC 61000-4-11	$U_t = 0\%$, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 315 degrees) $U_t = 0\%$, 1 cycle $U_t = 70\%$, 25/30 cycles (0 degrees)	$U_t = 0\%$, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 315 degrees) $U_t = 0\%$, 1 cycle $U_t = 70\%$, 25/30 cycles (0 degrees)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$U_t = 0\%$, 250/300 cycles	$U_t = 0\%$, 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Immunity to proximity magnetic fields IEC 61000-4-39	134.2 kHz 65 A/m 13.56 MHz 7.5 A/m	134.2 kHz 65 A/m 13.56 MHz 7.5 A/m	Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_t is the AC mains voltage prior to application of the test level.			

Electromagnetic immunity for RF

Guidance and manufacturer's declaration — electromagnetic immunity This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz ^a	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz ^a	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance for 1 W: $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz

Guidance and manufacturer's declaration — electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Radiated RF IEC 61000-4-3	3 V/m ^b 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz. $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^c should be less than the compliance level in each frequency range^d. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE At 80 MHz and 800 MHz, the higher frequency range applies. NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by reflection from structures, objects, and people.			
^a The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. ^b For more information, see section Proximity field immunity compliance. ^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment. ^d Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device.			
This device is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance in meters (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23

Recommended separation distances between portable and mobile RF communications equipment and the device. This device is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance in meters (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance [d] in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Proximity field immunity compliance

Guidance and manufacturer's declaration — electromagnetic immunity (IEC/EN 60601-1-2, 4.1 Edition)							
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity compliance level (V/m)	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430 to 470	GMRS 460, FRS 460	FM $\pm$ 5kHz deviation 1 kHz sine	2	0.3	28 X for Micro-stream CO ₂ micro-module	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28
1720 1845	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900;	Pulse Modulation 217 Hz	2	0.3	28	28

Guidance and manufacturer's declaration — electromagnetic immunity (IEC/EN 60601-1-2, 4.1 Edition)							
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity compliance level (V/m)	Immunity test level (V/m)
1970		DECT; LTE Band 1, 3, 4, 25; UMTS					
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
5500							
5785							
NOTE The distance values represent the recommended separation distance between interfering equipment and the monitor.							

Compliant cables and accessories

WARNING

PATIENT SAFETY. Use only approved accessories, including mounts, and defibrillator-proof cables and invasive pressure transducers. For a list of approved accessories, see the supplemental information provided. Other cables, transducers, and accessories may cause a safety hazard, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

Minimizing electromagnetic interference

Electromagnetic interference (EMI) can cause erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site of use to determine the source of this disruption, and take the listed actions to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the interfering equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and Carescape ONE and micro-modules.
- Bundle the affected measurement leads together to minimize the impact to the measurement.

Carescape ONE and micro-modules can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may themselves cause harmful interference with other susceptible devices in the vicinity. It may be necessary to reorient or relocate Carescape ONE and the micro-modules to prevent interference in nearby equipment.



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