iT30/iT50

Telemetry Monitor

Version 0.001

User Manual

CE 0123

EDAN

About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) cannot be held liable.

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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Safety

1.1 Safety Guidance

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

WARNING

1. **Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.**
2. **The monitor can only be used on one patient at a time.**
3. **Medical technical equipment such as these monitor/monitoring systems must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.**
4. **EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.**
5. **Do not come into contact with the patient, table, or the monitor during defibrillation.**
6. **The simultaneous use of a cardiac pacemaker or other electrical stimulators may cause safety hazard.**
7. **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. In particular, there must be no contact of the neutral electrode and ground.**
8. **If leakage or foul odor is detected, ensure that there’s no fire around.**
9. **The monitor is equipped with AP to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.**
10. **Route all cables carefully to avoid possible entanglement, apnea, or electrical interference.**

WARNING

11 **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.**

12 **Do not rely exclusively on the auditory alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.**

13 **Only patient cable and other accessories supplied by EDAN can be used. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable accessory is intact. Do not use it if its casing is damaged.**

14 **Make sure networking function is used in a secure network environment.**

15 **Only recommended batteries can be used for the monitor.**

16 **If the device shuts down abnormally, the last settings are saved.**

17 **Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test, before installation and any time new medical equipment is added to the Wireless LAN coverage area.**

18 **The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.**

19 **Clinical decision making based on the output of the device is left to the discretion of the provider.**

20 **Do not service or maintain the monitor or any accessory which is in use with the patient.**

21 **Always remove non-defibrillation-proof accessories during defibrillation.**

WARNING

22 **The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.**

23 **Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.**

24 **The monitors are MR Unsafe. The monitors are not intended for use in an MRI environment.**

25 **Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.**

26 **Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in this user manual.**

27 **All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.**

28 **The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.**

29 **Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:**

a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

30 **Except the nurse call function, the patient is forbidden to operate the device.**

31 **The device should not be placed in a closed environment.**

WARNING

32 **Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.**

33 **The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.**

34 **Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously, such as USB connector or other signal input/output connectors.**

35 **SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.**

36 **SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.**

37 **When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.**

38 **To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by EDAN.**

39 **No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.**

40 **Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.**

41 **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

42 **The appliance coupler or mains plug is used as an isolation means from supply mains. Position the charger stand in a location where the operator can easily access the disconnection device.**

WARNING

43 If the accessory is accidentally disconnected, it shall be reconnected by a trained healthcare professional.

44 When the alarm system is powered down, the log is maintained. The time of powering down will not be recorded in the system log.

45 A total loss of power has no impact on the stored log.

46 As soon as the alarm event storage is full, the earliest alarm event will be replaced by the latest one.

47 If the glass of the display screen is broken, please contact customer service personnel for repair. Do not touch the display screen to avoid cutting your finger.

CAUTION

1 Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dust area, high temperature and humid environment.

2 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.

3 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

4 Do not use autoclave or gas to sterilize the monitor or any accessories.

5 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.

6 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

7 Avoid liquid splashing on the device.

8 Turn off the device and take out the battery after use.

9 To ensure patient safety, use only parts and accessories manufactured or recommended by EDAN.

10 Protect the device against mechanical damage resulting from falls, impacts, and vibration.

CAUTION

11 **Ensure that the device is supplied with continuous electric power during operation. Sudden power failure may cause failure to monitor parameters.**

12 **When a constant voltage battery is used as supply power to the device, the device cannot detect the battery voltage change. As a result, the device cannot prompt the battery low alarm.**

NOTE:

1 **The monitor is intended for and in-hospital use only, it is not suitable for airborne or road EMS environment.**

2 **This monitor is not a device for treatment purposes.**

3 **If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of EDAN.**

4 **The pictures and interfaces in this manual are for reference only.**

5 **Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.**

6 **When there's measurement beyond range, invalid measurement or no measurement value, it will display -?-.**

7 **In normal use, the operator shall stand in front of the monitor.**

8 **The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1.**

9 **The delay time from onset of ALARM CONDITION to the point where representation of ALARM CONDITION leaves the SIGNAL OUTPUT PART is less than 1 second.**

10 **Due to the delay of network transmission, data viewed at the MFM-CMS has a delay of less than 10 seconds compared with data generated at the corresponding monitoring device.**

11 **It is not recommended to use Wi-Fi and Bluetooth simultaneously; otherwise, co-channel interference may be arisen.**

12 **To avoid blocking and affecting NIBP measurement, the user should clean the battery compartment periodically by opening the door and dust the vent. Do not use wet cotton swab to clean the vent. If NIBP measurement is still affected after cleaning, contact the service personnel of the manufacturer.**

1.2 Cybersecurity Measures

1.2.1 Personal Information Safety

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. EDAN recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement security practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the monitor.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

CAUTION

1. **The access/operation of the monitor is restricted to authorized personnel only. Assign only staff with a specific role the right to use the monitor.**
2. **Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).**
3. **Ensure that the monitor is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported monitors within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.**
4. **DoS and DDoS protection of the router or switch must be turned on for defensing against attacks.**
5. **When the monitor is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the monitor.**

CAUTION

6 **Ensure that the data are deleted after the patient is discharged.**

7 **When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the monitor to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, monitor and MFM-CMS are into the same VLAN, and isolate it from other VLANs.**

8 **Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the monitor.**

9 **To avoid malicious tampering and theft of data transmitted by the network, it is recommended to switch on the TLS Encryption function. After the TLS Encryption function is turned on, the monitor will authenticate the accessed MFM-CMS devices and encrypt the transmitted data to ensure the security.**

10 **The software closes all ports by default. When connecting to the MFM-CMS, it randomly opens one port.**

NOTE:

Security-related events are recorded in log files. Log files generated by the monitor are used for system troubleshooting and do not contain protected medical data. If required, contact the manufacturer to request the log files.

1.2.2 Network Security

For more security operations, select **Menu** > **Maintenance** and enter the user maintenance password. Then select **Network Setup** > **Setting** > **Network Security**. From the network security menu, the user can enable/disable **TLS Encryption**.

To import the certificate,

1. Remove the battery, use a USB cable to connect computer and the monitor;
2. Input the **Maintenance** password on the monitor, wait for 5 seconds, till the computer displays a USB disk;
3. Create a folder named “certificates”;
4. Copy three certificate files into the folder: ca.pem, client.key.pem, client.pem;
5. Select **Network Setup** > **Setting** > **Network Security** ;
6. Click the button **Certificate Update**.

NOTE: Users need to update the relevant certificate; otherwise, the monitor will be unable to establish a connection with the MFM-CMS communication will fail.

1.2.3 Password Security

The default **Maintenance** password is 0000. For safety considerations, it is recommended to change the **Maintenance** password every 30 days, and use a 8~31 digits password combined with letters, numbers and special characters, the password should not contain spaces. To modify the maintenance password, contact the manufacturer.

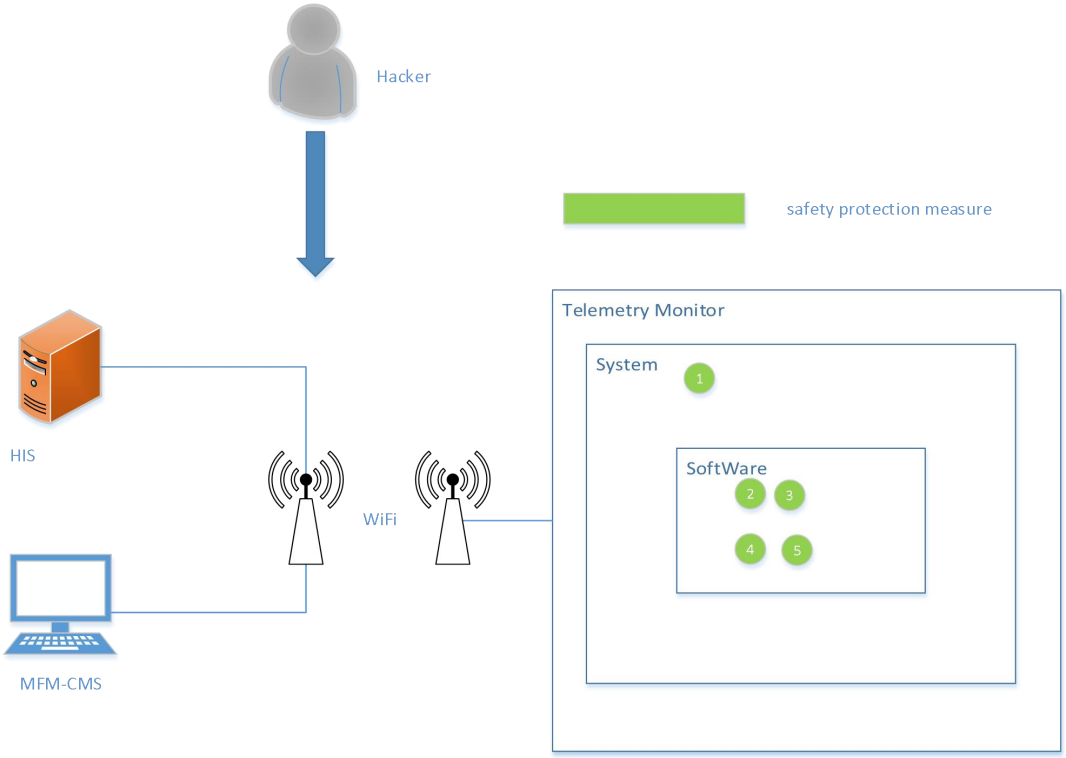
NOTE:

1 **The monitor will display "Wrong Password!" if any password is entered incorrectly.**

2 **Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the Factory Maintain settings.**

1.2.4 Multi-Patient Injury View

The multi-patient injury view is shown below.



(1) The embedded RT-Thread system is used and third-party executable files are not supported to prevent malicious programs from running and damaging the system.

(2) Close unused ports to reduce the probability of use.

(3) The device supports wireless data transmission only.

Wi-Fi security measures are as follows:

1. Wi-Fi connections require password validation.

2. Set **AP Setting** > **Security** to High Security Encryption Level (WPA2)

3. Data transmitted through Wi-Fi is encrypted using TLS (Minimum 1.2) protocol and requires bidirectional authentication with Central Monitoring System

(4) The data to be transmitted are stored in monitor. If the data transmission fails, the interrupted data transmission will be reminded by an alarm. If the network returns to a normal connection, the data transmission will be resumed for a period of 15 minutes.

(5) Telemetry Monitor and Central Monitoring System use TLS (Minimum 1.2) protocol to transmit data for confidentiality, integrity, and authenticity.

1.3 Symbols

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		Caution
3	MR	MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
4		Power supply switch
5		Nurse call
6	SN	Serial number
7		Date of manufacture
8		Manufacturer
9	P/N	Part Number
10		General symbol for recovery/recyclable

11		The products marked with this symbol apply to the European WEEE directive. This symbol Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.
12		Refer to instruction manual/ booklet (Background: Blue; Symbol: White)
13		Warning (Background: Yellow; Symbol & outline: black)
14	**IP67**	Ingress Protection: IP67 (dust-tight and protected against temporary water immersion) (iT30)
15	**IP44**	Ingress Protection: IP44 (protected against splashing water and solid foreign objects ≥ 1.0 mm diameter) (iT50)
16	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
17		This way up
18		Fragile, handle with care
19		Keep dry
20		Stacking limit by number
21		Handle with care
22		Do not step on
23	CE 0123	CE marking
24	EC REP	Authorized representative in the European Community
25		Use-by date

26	MD	Medical Device
27	UDI	Unique Device Identifier
28		Operating instructions
29		Alternating Current (Charger stand)
30		Humidity limitation
31		Atmospheric pressure limitation
32		Temperature limitation
33		Protective earth (ground) (Charger stand)
34		NIBP measurement key (iT50)

NOTE: The user manual is printed in black and white.

1.4 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation 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.

This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of 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.

WARNING

Changes or modifications not expressly approved by the party responsible compliance could void the user's authority to operate the equipment.

NOTE:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

Chapter 2 Product Overview

2.1 Intended Purpose

The product is intended for monitoring, displaying, storing, alarming, and transferring of multiple physiological parameters connecting to Central Monitoring System.

2.2 Intended Use/Indications for Use

The iT30 and iT50 Telemetry Monitor are intended for use on Adult and Pediatric patients (over three years old) to monitor ECG, SpO_2, PR, NIBP (Applicable to iT50 only), TEMP, and RESP physiological data. The physiological data can be analyzed, alarmed, stored locally on the monitor, and the Edan Central Monitoring System can configure, display and review the physiological parameters from the iT30 and iT50 Telemetry Monitor.

The iT30 and iT50 Telemetry Monitor must be used by professional trained clinical medical staff in healthcare facilities.

2.3 Contraindication

Unknown.

2.4 System Components

The telemetry monitor system consists of the following components:

◆ iT30 /iT50

iT30 and iT50 are telemetry devices that monitor patients for ECG, SpO_2, NIBP, TEMP, RESP, and PR parameters. They can not only complete the monitoring independently, but also realize the network monitoring with MFM-CMS.

◆ Central Monitoring System (hereinafter abbreviated as MFM-CMS)

The iT30 or iT50 can be networked with a central monitoring system (hereinafter referred to as MFM-CMS) to form a complete telemetry monitoring system.

Through the network, the telemetry device will send the patient information, real-time monitoring or measurement data to the MFM-CMS, and the MFM-CMS will display the data synchronously with the telemetry device. In addition, patient management, data review, report printing and other functions are implemented on the MFM-CMS. For details on the MFM-CMS, refer to the *MFM-CMS Central Monitoring System Software User Manual*.

◆ CS-10 Charger Stand

The charger stand can charge 10 lithium batteries at the same time, and indicate the charging status of each battery.

- Accessory

The selection of accessories depends on the device configuration. For details, refer to Section *Accessories*.

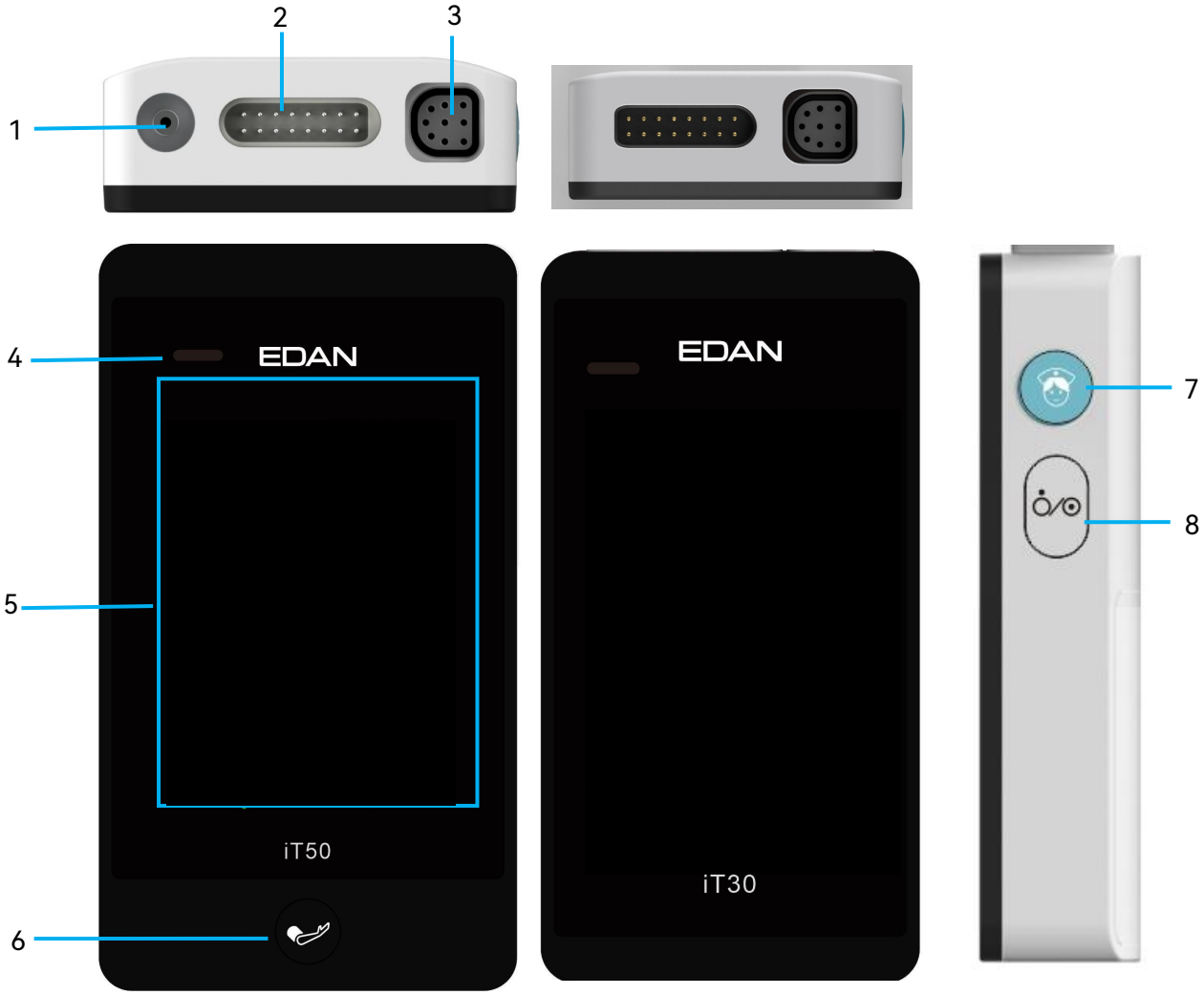
2.5 Key Features

- Support 3/5/6/10-electrode ECG.
- Support EDAN SpO_2 module.
- Communicate with the MFM-CMS.
- Display Heart Rate (HR), RESP, SpO_2, PR and NIBP value and ECG, SpO_2 and RESP waveform.
- Support three AA batteries or one lithium-ion battery pack.

2.6 Applied Parts

The applied parts of the monitor are: ECG cable and electrode, SpO_2 sensor, NIBP cuff, TEMP probe.

2.7 Physical View



1 NIBP connector (Applicable to iT50 only)

2 ECG connector

3 SpO_2 sensor /TEMP connector

4 Alarm light: When an alarm occurs, the indicator lights on or flashes with different frequencies and colors reflecting the alarm level.

5 Display

6 NIBP measurement key: Press it to start or stop NIBP measurement. (Applicable to iT50 only)

7 Nurse Call: Press this key to send a nurse call request to the MFM-CMS.

8 Startup/Shutdown/Screen-on key:

When the device is powered off, press and hold this key to turn on the device.

When the screen display is off, press this key to turn on the display. When the display is on, press this key to turn off display, press and hold it to turn off the device.

2.8 Touch Screen Display

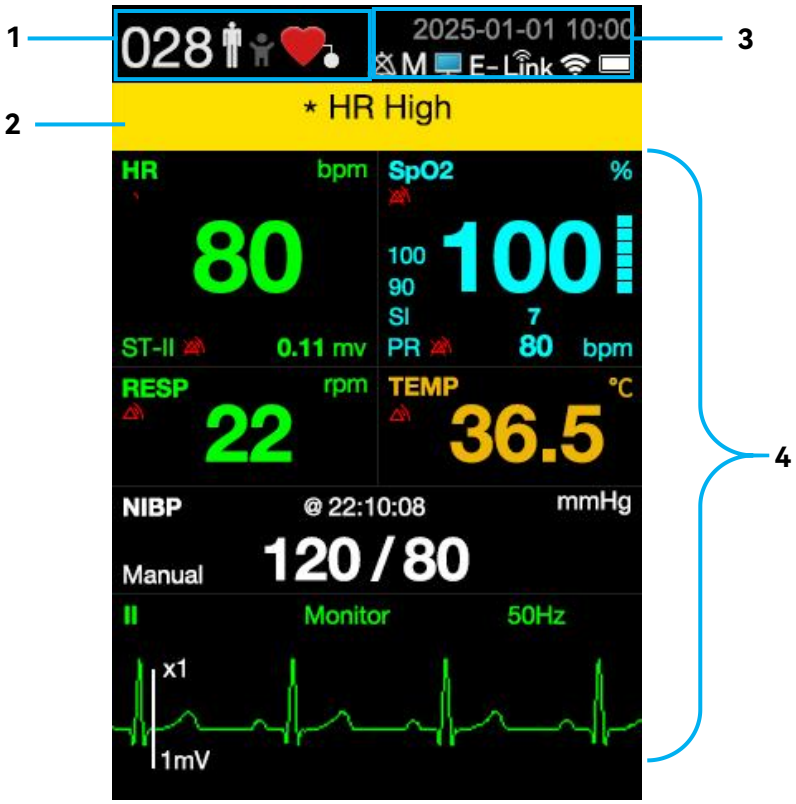
WARNING

Do not operate the touch screen with wet hands or sharp object.

2.8.1 Display Screen

Everything you need to operate the device is contained on its screen. Screen elements include values, waveforms, function keys, information area and alarm area.

iT30 Main Interface



iT50 Main Interface

1 Patient Information area: Display the Bed No., patient type, and pace status.

2 Alarm information and prompt information area: Click this area to enter the real-time alarm list.

3 System information area: The first row displays system time, and the second row displays alarm volume, alarm reset icon, work mode, network status, E-Link status, battery status, etc.

4 Patient data area: display the measurement value, measurement unit and waveform of each parameter.

Interface icon description:

Icon	Description	Icon	Description
	Patient type: adult		Patient type: pediatric
	Pace status: On		Pace status: Off
	MFM-CMS connected.		MFM-CMS is not connected.
M	Monitoring mode	T	Telemetry mode
E-Link	E-Link connected.		High level alarm
	Medium/low level alarm		Main menu
	Parameter alarm is turned off.		Alarm mute

	Alarm reset		Screen is activated.
	Wi-Fi connected Wi-Fi signal strength: Level 4		Screen is disabled.
	Wi-Fi signal strength: Level 3		Wi-Fi signal strength: Level 2
	Wi-Fi is not connected.		

2.8.2 On-Screen Keyboard

The telemetry monitor uses an on-screen keyboard to enter numeric information, such as the device name and passwords.

Chapter 3 Getting Started

NOTE:

1. **To ensure that the telemetry monitor works properly, please read the user manual and follow the steps before using the monitor.**
2. **The telemetry monitor settings must be configured by the authorized hospital personnel.**

3.1 Initial Inspection

Before unpacking, check the packaging and ensure that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove the device and accessories. Check that the contents are complete and that the correct options and accessories have been delivered. If you have any question, please contact your local supplier.

WARNING

The telemetry monitor may be subject to microbacteria contamination during storage, transport, or use. Prior to use, please verify that the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.

NOTE: Keep the packing cases and materials of the devices in good condition for re-shipment.

3.2 Environment Requirements

The operating environment of the system must meet the requirements specified in this manual. The operating environment of the device should be free from noises, vibration, dust, corrosive, flammable and explosive substances. When the device is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

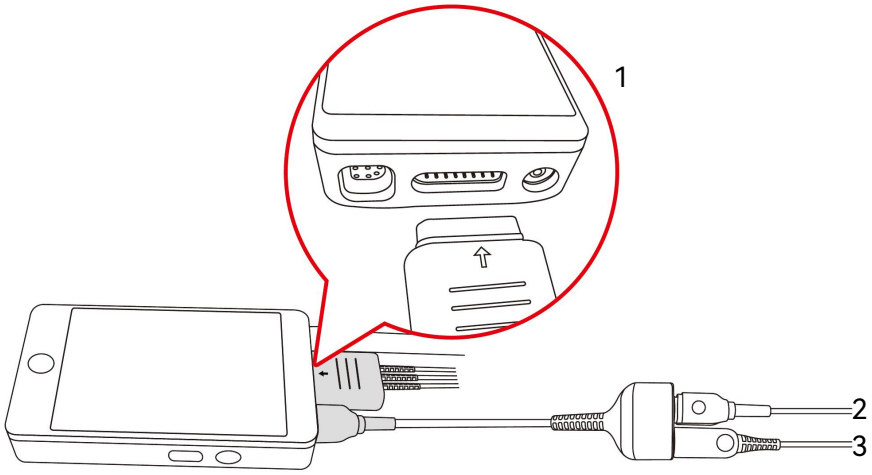
WARNING

Make sure that the device operating environment meets the specifications. Otherwise unexpected consequences, e.g. damage to the device, could result.

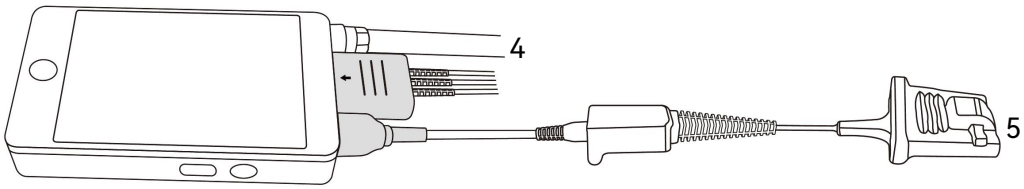
NOTE: The system transmits data through wireless connection. External radio frequency interference may result in occasionally data loss. If you have any question on Electromagnetic environment, please contact service personnel.

3.3 Connecting the Accessories

Connect the ECG electrodes connector to the ECG port as 1 in the following figure. Connect the TEMP extension cable and SpO_2 sensor separately as the 2 and 3 in the following figure.



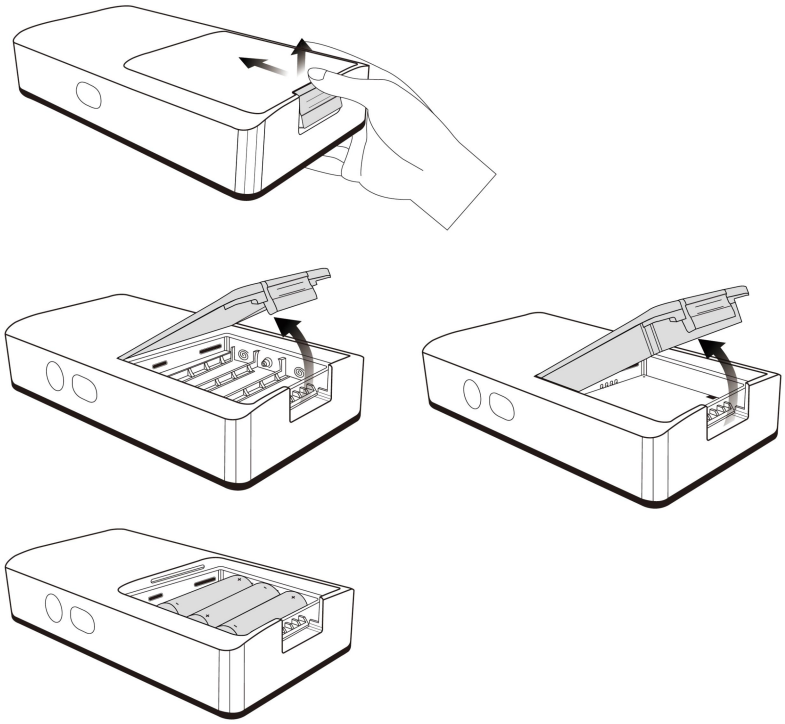
Connect the NIBP tube as 4 in the following figure. When TEMP is not required to measure, connect the SpO_2 sensor directly as 5 the following figure.



3.4 Installing the Battery

The telemetry monitor supports 3 AA alkaline batteries or lithium batteries. The running time of the device depends on the battery scheme. Generally speaking, Lithium batteries provide longer running times. For battery specifications, refer to Section *Battery* in Appendix. For details on how to remove the battery and maintain the battery, refer to Section *Using Battery and Charger Stand*.

If AA alkaline batteries are to be used, place three batteries in the battery box. The positive and negative terminals of the batteries must be the same as those marked on the battery box. If using a lithium battery, fully charge the battery before the first use. For details on how to charge lithium batteries, see the Section *Charging the Battery*.



WARNING

Using other rechargeable batteries may result in inaccurate battery power displays, low battery power alarms, or impaired battery life. Therefore, do not use rechargeable batteries not approved by the manufacturers.

NOTE:

1. **Keep the battery box dry.**
2. **Install the lithium battery correctly in the battery box. Otherwise, the waterproof ring on the edge of the battery box may be damaged and the waterproof performance may be affected.**
3. **3When installing AA alkaline batteries, install them according to the instructions of the positive and negative terminals; otherwise, the device cannot be started.**

3.5 Powering on the Device

After installing the lithium battery, press the power key, iT30 or iT50 will prompt one “Di” tone that means the audio in selftest is normal. Meantime, you must check that the alarm indicator lights are normal. This indicates that the visible and audible alarm indicators are functioning correctly, and then the monitor enters into main interface. For further testing of individual measurement alarms, perform the measurement on

yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

WARNING

If the telemetry monitor is found to be damaged or has an error message, do not use it and contact EDAN service engineer.

When the iT30 or iT50 is powered on for the first time, follow the on-screen prompts for initial Settings.

3.6 Powering off the Device

To shut down the device, click **Menu** > **Shutdown** or press and hold the power key.

3.7 Wireless Network

3.7.1 Connecting the Monitor to MFM-CMS

Telemetry monitor and MFM-CMS construct wireless network through AP. The qualified engineers specified by EDAN are responsible for installing wireless network and performance tests. After the network configuration is completed, the telemetry monitor will automatically connect to the MFM-CMS each time it is powered on. Under normal circumstances, there is no need to modify the network configuration.

NOTE:

1. **Be aware that some network-based functions may be limited for telemetry monitor on wireless networks in comparison with those on wired networks.**
2. **The obstacle may interfere with data transmission and even cause data loss.**
3. **Uses the wireless device recommended by EDAN.**
4. **The medical institution is responsible for the network management and security. Wireless performance can be affected by the network changes, and medical institution should make corresponding evaluations for the network changes to ensure clinical use.**
5. **When signal intensity is level 2 or less, signal may be unstable and quality of the signal transmission may be degraded.**
6. **When the device is connected to MFM-CMS via the wireless network, the user should set the router to a secure encryption/authentication mode (Recommended option: WPA2, with a high complexity, non-dictionary**

password).

7 **When deploying the network of the device and MFM-CMS, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security.**

8 **If select the dynamic IP address mode, query the IP address on the MFM-CMS.**

3.7.2 Network Setup

To configure the network, select **Menu** > **Maintenance** > **Network Setup** > **Setting**. Accessing **Maintenance** menu requires a password. The following items can be set:

- **AP Setting**: set **Security** to **EAP-WPA, EAP-WPA2, open, WPA, WPA2** or **WEP.** Modify the **SSID** or **password**.
- **IP Address**: enable/disable **DHCP.** When DHCP is disabled, the **Local IP**, **Gateway** or **Netmask** need to be manually entered**.**
- **Server Setup**: Enter the server **Port** and **Server IP**.
- **Wireless Advanced**:
  1. Set the **Region** to **CHINA**, **OTHERS**, **US** or **EUROPE**.
  2. Set the **Bandwidth**.
- **Network Security**: refer to section *1.2.2 Network Security***.**
- **Reset Network**: the user can reset the network after confirmation.

NOTE: Ensure that the default IP address is configured as a private IP address. Utilizing a public IP address for a local area network introduces the risk of unauthorized access given its potential accessibility to the internet.

3.8 Telemetry System Installation

Environment verification, MFM-CMS installation, wireless network installation and telemetry monitor installation should be completed by EDAN service personnel.

WARNING

1 **When the system is required to connect with other electric devices, please contact specialists in hospital or EDAN service personnel to ensure safety.**

2 **Do not plug three-pin into two-pin adaptor.**

3 **Contact EDAN to relocate the telemetry monitor.**

4 **The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.**

NOTE: Crossover Ethernet cable is connected with computer and parallel Ethernet cable is connected with HUB.

The printing function can be performed on MFM-CMS. For printing, please refer to *MFM-CMS Central Monitoring System Software (III) User manual*.

3.9 Checking the Telemetry Monitoring System

Make sure there is no damage on the accessories. Then turn on the telemetry monitor and MFM-CMS, check whether the system can work normally. Make sure the battery for telemetry monitor has enough power, MFM-CMS can prompt alarms normally and the alarm sound can be heard clearly. (please refer to chapter *Testing Alarms*).

WARNING

If any signs of damage are detected, or screen displays error messages, do not use it on patient. Contact service personnel immediately.

NOTE:

1. **Check that all monitor functions are operating correctly.**
2. **If rechargeable batteries were provided, charge them each time before using the device to ensure adequate power.**
3. **After long-time continuous running, please restart the device to ensure the steady performance and long lifespan.**

After networking, the time of the telemetry monitor is displayed synchronically with that of MFM-CMS. If the user needs to change the time, set it on the MFM-CMS. For details, please refer to *MFM-CMS Central Monitoring System Software (III) User Manual*.

NOTE: If MFM-CMS is not used for a long time, the system time may be inaccurate. If this occurs, reset the system time after MFM-CMS is turned on.

3.10 Handing Over the Telemetry Monitoring System

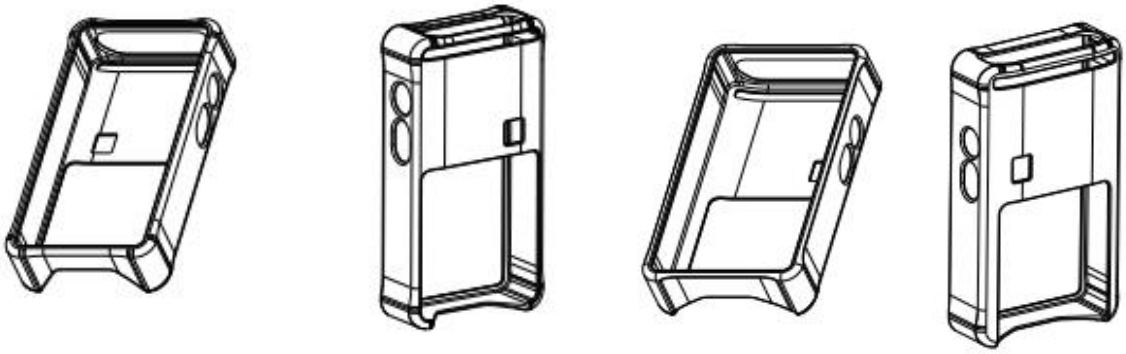
If you are handing over system to the end-users directly after installation and configuration, make sure that it is in normal working status and let user know the status.

The users must be adequately trained to use the system before monitoring a patient. To achieve this, they should have access to, and read, the following documentation delivered with system:

- User Manual (this book) – for full operating instructions.
- Quick Guide – for quick reminders during use.

3.11 Using the Protective Casing

To protect the telemetry monitor, it is recommended that the monitor be placed in a protective casing. If the monitor is dropped, the protective casing can reduce the probability of the device being damaged. Therefore, it is recommended not to remove the protective cover during use.



iT30 Host Protective Casing iT50 Host Protective Casing

Chapter 4 Basic Operation

The following features may be used frequently:

- Monitoring ECG (see the section ***Monitoring ECG***)
- Monitoring SpO_2 (see the section ***Monitoring SpO_2***)
- Monitoring PR (see the section ***Monitoring PR***)
- Monitoring NIBP (see the section ***Monitoring NIBP***)
- Alarm function (see the section ***Alarms***)

WARNING

Patients should be instructed not to interact with the display of the device and not to open the battery box while the telemetry monitor is in use.

4.1 Work Mode

The telemetry device can be set to telemetry or monitoring mode by selecting **Menu** > **Maintenance** > **Work Mode**. The default mode is Telemetry. The system information area displays T for telemetry mode or M for monitoring mode.

4.1.1 Telemetry Mode

When the telemetry monitor is networked with MFM-CMS, the telemetry monitor is in a normal monitoring state. In telemetry mode:

1. The telemetry monitor sends the measurement data to MFM-CMS;
2. The alarm volume and the alarm light are default to Off; both of them can be set.

To set the alarm volume, select **Menu** > **Maintenance** > **Work Mode** > **Telemetry.** The **Tech-Alarm Vol** or **Phys-Alarm Vol** can be set to 0~5. When the volume is 0, the audio alarm is turned off, and the general information area displays icon . When the volume is 1~5, the monitor produces alarm tone as preset volume.

To turn on the alarm light, select **Menu** > **Maintenance** > **Work Mode** > **Telemetry**, set **Alarm Light** to **On**.

3. The screen display duration of the telemetry monitor can be set. In the case of no operation, the screen display is off after reaching the duration. The screen display can be turned on by pressing the power key;
4. After the screen display is off, the monitor only provides audible alarm for Battery Low alarm, the other alarms will be displayed on MFM-CMS.

4.1.2 Monitoring Mode

In monitoring mode:

1. The telemetry monitor displays the measurement result, physiological alarm, network disconnection alarm and Battery Low alarm;
2. The default volume for physiological alarm and technical alarm is **3**, and can be set. The alarm light is default to **On**.
3. The screen display duration is Never, that is to say, the display is always **On**.

After restoring the network status, the network disconnection alarm disappears, and the data stored in the telemetry monitor is uploaded to MFM-CMS.

4.2 Screen Brightness Setup

To set the brightness of the telemetry device, select **Menu** > **Maintenance** > **Other Setup** > **Brightness**, set the brightness to 1~ 5.

4.3 Demo Mode

Select **Menu** > **Maintenance** > **Other Setup** > **Demo**, the device enters into demo mode after confirmation.

WARNING

Demo Mode is for demonstration purposes only. You must not change into Demo Mode during monitoring.

4.4 Read-only Mode

To reduce the interference of high-frequency surgical equipment, the Read-only Mode can be used. Select **Menu** > **Maintenance** > **Other Setup** > **Read-only Mode**, the device enters into read-only mode after confirmation. In Read-only Mode:

1. The telemetry device only supports the interface display function. The main interface displays "Read-only Mode".
2. The telemetry monitor communicates with MFM-CMS normally.
3. The screen of the telemetry device is on and locked, but the hard key works normally.

To exit the read-only mode, long press the power key.

4.5 Patient Management

The patient management can be implemented on the MFM-CMS:

- Set the patient's Bed No., Department, Height, Name, Patient type, Weight, Gender, Doctor, MRN, Pace, BMI, Admission Date, Birth Date, Temperature, Monitoring Equipment, etc.;
- Add remarks to describe other patient information;
- Discharge the patient;
- Transfer department;
- Search patients;
- Barcode admit patients.

After completing patient management, click **Update Monitor** to update the patient information to the telemetry device.

4.6 Data Management

In telemetry monitoring system, data management includes data storage, data export, data transmission (real-time transmission, resumable transmission) and data review.

- Data storage: the telemetry monitor stores the patient's monitoring data, parameter settings, configuration data and alarm settings.
- Data export: Data monitored by telemetry monitor can be exported in batches using USB. To export data,

1. Remove the battery, use a USB cable to connect computer and the monitor;
2. Input the **Maintenance** password on the monitor, wait for 5 seconds, till the computer displays a USB disk;
3. Enter into the USB disk, the user can export the patient data stored in the folder "datastorage" to the computer. Besides, the user can export the logs stored in folder "user" (including alarm log, alarm operation log, network log) to the computer.

- Data transmission: When the network connection is normal, the telemetry monitor transmits the patient's physiological data to MFM-CMS in real time through the wireless network. If there are some data failed to transmit, the device automatically transmits the data within 15 minutes when the network is connected again.
- Data review: MFM-CMS provides a data review interface that allows users to review the patient's full disclosure data, including parameter trend data, waveform review, alarm events, nurse call events, etc.

4.7 E-Link Function*

E-Link module can be used for data transmission.

4.8 NFC Function

The NFC function enables close-range data transmission.

4.9 System Setup

The System Setup are implemented on the MFM-CMS. The setup takes effect on the telemetry monitor immediately.

4.9.1 Parameter Switch

To turn on or off the parameters of the telemetry device, select **System Setup** icon > **ModuleSwitch** on the MFM-CMS, the device automatically adjusts the interface.

4.9.2 Volume Setting

To set the alarm volume of the telemetry monitor, select **System Setup** icon > **Sound Setup** on the MFM-CMS to set the physiological alarm volume and technical alarm volume. Alarm volume can also be set on the telemetry device, refer to Section *Setting Alarm Volume*.

4.9.3 Display Auto-Off Time Setting

To set the display auto off time of the telemetry monitor, select **Menu** > **Maintenance** > **Work Mode** of the telemetry device, and set the display auto off time to Never, 10 s, 30 s, 60 s, 90 s, 120 s, 5 m, 30 m, and 1 h. When the telemetry monitor reaches the preset time without operation, the display screen will automatically turn off. You can press the power key to light the screen and manually unlock the telemetry device to enter normal operation.

Display off can be set on the MFM-CMS side through System Setup in single bed view interface.

4.9.4 Screen Lock Code

Select **Menu** > **Maintenance** > **Work Mode**, enable the **Screen Lock Code**. The user needs to input maintenance password to unlock the screen.

4.10 Real-Time Printing

Users can remotely start real-time report printing tasks from telemetry monitor. To start printing, select **Menu** > **General Function** > **Print** on the telemetry monitor. At this time, the telemetry monitor displays the prompt message that the printing command has been sent, and the MFM-CMS executes real-time printing after receiving the command. The MFM-CMS prints the parameter value at the current time and the first 11 s waveform.

Chapter 5 Alarms

In telemetry mode, iT30/iT50 and MFM-CMS complete the alarm system setting, alarm information transmission and other functions to achieve distributed alarm.
In monitoring mode, iT30/iT50 can realize and display alarms independently.

WARNING

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

5.1 Alarm Category

The monitor provides two types of alarms: physiological alarms and technical alarms. Also, the monitor provides prompts.

5.1.1 Physiological Alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. About the detailed alarm information, please refer to the Section *Physiological Alarm Information*.

5.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms can't be disabled. About the detailed alarm information, please refer to Section *Technical Alarm Information*.

5.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions. And this character is called prompts. About the detailed alarm information, please refer to Section *Prompts*.

5.2 Alarm Levels

In terms of severity, the device's alarm levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

1. High level alarms

   A high level alarm intensively warns the operator of a high priority alarm condition which requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

2. Medium level alarms

   A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

3. Low level alarms

   A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

The high/medium/low-level alarms are indicated by the system in following different ways:

Alarm Level	Prompt
High	Mode is “DO-DO-DO------DO-DO, DO-DO-DO------DO-DO”, which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz～2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.
Medium	Mode is “DO-DO-DO”, which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz～0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is “DO-”, which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly cyan. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

The sound pressure range for audible alarm signals is from 45 dB to 85 dB, with the measurement radius of 1 meter.

The sum of the mean alarm condition delay plus the mean alarm signal generation delay is less than 10 s.

WARNING

1 **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.**

2 **Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.**

5.3 Controlling Alarm

5.3.1 Setting Parameter Alarm

Parameter alarm settings including alarm switch, alarm level and alarm limit are available on the respective alarm setup menu for each parameter. After the parameter alarm is set on MFM-CMS, the telemetry device responds immediately.

WARNING

1 **When the alarm is set to Off, the monitor will not give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.**

2 **Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.**

3 **Setting alarm limits to extreme values may cause the alarm system to become ineffective.**

4 **When monitoring patients that are not continuously attended by a clinical operator, set the alarm limits according to the patient's clinical condition.**

5.3.2 Setting Alarm Volume

To set the alarm volume, select **Menu** > **Maintenance** > **Work Mode** > **Tech-Alarm Vol** or **Phys-Alarm Vol** on the telemetry monitor. Volume can be set to 0~5. When the volume is 0, the audio alarm is turned off, and the general information area displays icon .

NOTE: If a new alarm occurs during the audio alarm off, the telemetry device will not sound an alarm tone.

5.3.3 Resetting Alarm

Alarm reset function can be activated in either of the following ways:

- Select the shortcut key on the monitor screen directly.
- The monitor receives the alarm reset command from MFM-CMS. On the MFM-CMS, to activate the alarm reset function, select in the single bed view window or select **Alarm Reset** in the setup menu of the patient sector. To enable password protection for remote control, select **Maintenance** > **Alarm Setup** > **Password Protected**.

When the alarm is reset,

- No alarms are sounding until a new alarm occurs.
- The general information area displays the reset alarm with √.
- As for the active alarms, the visual alarm indications are still displayed.
- All latching alarms are cleared. If the alarm condition is no longer present, all alarm indications stop and the alarm is reset.
- It will not influence the configuration of physiological alarm off, audio paused, and audio off status.

NOTE: If a new alarm occurs after the alarm is reset, the new alarm will be sounding.

5.3.4 Turning on/off the Alarm Light

Select **Main Menu** > **Maintenance** > **Work Mode**, set **Alarm Light** to **On** or **Off**.

5.4 Latching Alarms

To configure the alarm latching setting, select **System Setup** > **Latch Setup** to **On** on the MFM-CMS. When it is set to **Off**, alarm indications end when the alarm condition ends. When it is set to **On**, the visual alarm indication and audio alarm indication are still displayed after the alarm condition ends; meanwhile, the alarm time is also displayed for the latched alarm for your reference, the latched alarm is marked with latched icon. The indication lasts until you acknowledge the alarm.

5.5 Testing Alarms

When you switch the monitor on, the monitor will prompt one “Du” tone that means the audio in selftest is normal. Meantime, you must check that the alarm lights are normal. This indicates that the visible and audible alarm lights are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

Chapter 6 Alarm Information

6.1 Physiological Alarm Information

WARNING

Physiological alarms including ASYSTOLE, RESP No Breath Detected, SpO_2 No Pulse, and SpO_2 Desat cannot be turned off.

Message	Cause	Alarm Level
ECG		
HR High	HR measuring value is above the upper alarm limit.	User-selectable
HR Low	HR measuring value is below the lower alarm limit.	User-selectable
ST-X High	ST measuring value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
ST-X Low	ST measuring value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
PVCs High	PVCs measuring value is above the upper alarm limit.	User-selectable
ASYSTOLE	No QRS is detected for 4 consecutive seconds.	High
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.	High
VT > 2	3 ≤ the number of consecutive PVCs < 5.	User-selectable
COUPLET	2 consecutive PVCs.	User-selectable
BIGEMINY	A dominant rhythm of N, V, N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
TRIGEMINY	A dominant rhythm of N, N, V, N, N, V, N, N, V.	User-selectable
R ON T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Single PVC detected in normal heartbeats.	User-selectable

Message	Cause	Alarm Level
TACHY	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≤ 0.375 s.	User-selectable
BRADY	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≥ 1 s.	User-selectable
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.	User-selectable
IRR	Consistently irregular heart rhythm.	User-selectable
PNC	PACER NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.	User-selectable
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.	User-selectable
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.	User-selectable
QTc High	QTc measuring value is above upper alarm limit.	User-selectable
ΔQTc High	ΔQTc measuring value is above upper alarm limit.	User-selectable
RESP		
RESP No Breath Detected	RESP waveform cannot be detected within the set alarm delay time.	High
RR High	RR measuring value is above upper alarm limit.	User-selectable
RR Low	RR measuring value is below lower alarm limit.	User-selectable
SpO_2		
SpO_2 High	SpO_2 measuring value is above upper alarm limit.	User-selectable
SpO_2 Low	SpO_2 measuring value is below lower alarm limit.	User-selectable
SpO_2 No Pulse	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High
SpO_2 Desat	SpO_2 measuring value is below the SpO_2 Desat limit.	High
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm Level
TEMP		
TEMP High	Measuring value of TEMP is above upper alarm limit.	User-selectable
TEMP Low	Measuring value of TEMP is below lower alarm limit.	User-selectable
NIBP		
NIBP SYS High	SYS measuring value is above upper alarm limit.	User-selectable
NIBP SYS Low	SYS measuring value is below lower alarm limit.	User-selectable
NIBP DIA High	DIA measuring value is above upper alarm limit.	User-selectable
NIBP DIA Low	DIA measuring value is below lower alarm limit.	User-selectable
NIBP MAP High	MAP measuring value is above upper alarm limit.	User-selectable
NIBP MAP Low	MAP measuring value is below lower alarm limit.	User-selectable

6.2 Technical Alarm Information

NOTE: The ECG alarm information listed in the below table describes the electrode names in America. For the corresponding electrode names in Europe, please refer to the Section *Installing Electrodes*.

Message	Cause	Alarm Level	Action Taken
ECG			
HR Overrange	HR measuring value is out of the measure range.	High	Check lead connection and patient condition
ECG Lead Off	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LL Lead Off	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	Low	
ECG LA Lead Off	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	Low	
ECG RA Lead Off	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	Low	

Message	Cause	Alarm Level	Action Taken
ECG RL Lead Off	When electrode type is AUTO, ECG electrode RL falls off the skin or the ECG cable RL falls off the monitor, 5/6/10 electrodes switches to 3 electrodes.	Low	
ECG V Lead Off	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	Low	
ECG V1 Lead Off	ECG electrode V1 falls off the skin or the ECG cable V1 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG V2 Lead Off	ECG electrode V2 falls off the skin or the ECG cable V2 falls off.	Low	
ECG V3 Lead Off	ECG electrode V3 falls off the skin or the ECG cable V3 falls off.	Low	
ECG V4 Lead Off	ECG electrode V4 falls off the skin or the ECG cable V4 falls off.	Low	
ECG V5 Lead Off	ECG electrode V5 falls off the skin or the ECG cable V5 falls off.	Low	
ECG V6 Lead Off	ECG electrode V6 falls off the skin or the ECG cable V6 falls off.	Low	
ECG Signal Exceed	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition
ECG Noise	ECG measuring signal is greatly interrupted.	Low	

Message	Cause	Alarm Level	Action Taken
RESP			
RESP Artifact	No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact.
RESP RR Exceed	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.
RESP Noise	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.

Message	Cause	Alarm Level	Action Taken
SpO_2			
SpO_2 Comm Fail	SpO_2 module failure or communication failure.	High	Stop using measuring function of SpO_2 module, and notify biomedical engineer or manufacturer's service staff.
SpO_2 Sensor Err	Malfunction in the SpO_2 sensor or in the extension cable.	High	Replace the SpO_2 sensor or the extension cable.
SpO_2 No Sensor	No SpO_2 sensor was connected to the monitor.	Low	Make sure the monitor and sensor are well connected, reconnect the sensor.
Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO_2 value and PR value might be inaccurate then.	Low	Reconnect the SpO_2 sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO_2 Noise	There is interference with SpO_2 measurement signals due to patient movement, ambient light, electrical interference or else.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
SpO_2 Excess Light	Ambient light around the sensor is too strong.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.

Message	Cause	Alarm Level	Action Taken
SpO_2 Sensor Off	SpO_2 sensor may be disconnected from the patient measuring site.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.
NIBP			
Interval Fails	The timer is faulty, resulting in the failure of normal Auto measurement.	High	Restart the monitor and measure again. If the problem still exists, contact your service personnel.
Duration Fails	The timer is faulty, resulting in the failure of normal STAT measurement.	High	
NIBP System Fails	NIBP is not calibrated.	High	Contact your service personnel.
Aux Overpressure	Pressure has exceeded the second safety limit as specified.	High	Notify biomedical engineer or manufacturer's service staff.
NIBP Test Error	Sensor or other hardware errors.	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Overrange	All of SYS, DIA and MAP values are beyond the measurement range.	High	Use other methods to measure blood pressure.

Message	Cause	Alarm Level	Action Taken
NIBP-S Overrange	SYS (NIBP) value is beyond the measurement range.	High	
NIBP-D Overrange	DIA (NIBP) value is beyond the measurement range.	High	
NIBP-M Overrange	MAP (NIBP) value is beyond the measurement range.	High	
Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP Leak	NIBP pump, valve, cuff or tube has a leakage.	Low	Check the connections and the wrapped cuff to see whether they are all prepared well.
NIBP Overpressure	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
Init Press. High	The initial pressure is too high during measuring.	Low	
NIBP Time Out	Measuring time has exceeded the specified time.	Low	Measure again or use other measuring method.
NIBP Loose Cuff	Cuff is not properly wrapped or no cuff is connected.	Low	Properly wrap the cuff.

Message	Cause	Alarm Level	Action Taken
NIBP Airway Error	Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed.	Low	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.
NIBP Weak Signal	Cuff is too loose or patient pulse is too weak.	Low	Use other methods to measure blood pressure.
NIBP Interference	Signal noise is too large or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.
NIBP Leak Test Error	Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.	Low	Test again. If the problem still exists, contact your service personnel.
TEMP			
Excessive TEMP	TEMP measuring value is beyond measuring range.	High	Check sensor connection and patient condition.
TEMP Calibration Failed	TEMP calibration failed.	High	Please check whether the module works properly.
TEMP Sensor Off	Temperature cable of TEMP may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
Others			
Battery Low	The battery level is 0.	High	Change or charge the battery.
Board Fails	After the device is started, the main control board fails to communicate with the parameter board.	High	Contact the service staff.

Message	Cause	Alarm Level	Action Taken
Network Offline	The network is disconnected during telemetry mode.	Medium	1) Check whether the network cable is properly connected. 2) Check whether MFM-CMS is enabled. 3) Check whether the IP addresses of the telemetry device and the MFM-CMS are in the same network segment.
Audio Failed	The system detects that the speaker is improperly connected.	Low	Contact the service staff.

6.3 Prompts

Message	Cause
ARR Learning	The QRS wave template required for arrhythmia analysis is being developed.
Can't Analyze ST	The ST algorithm cannot produce valid ST value, which may be caused by the large change in the measured value of connected cardiogram ST or ventricular pacing.
Can't Analyze QT	QT algorithm cannot generate valid QT for more than 10 minutes (or 1 minute during startup).
Can't Analyze ECG	The arrhythmia algorithm cannot analyze ECG data reliably.
Electrodes Contact Poor	The electrode has bad contact with patient’s body.
RESP Electrodes Contact Poor	The electrode is used for a long time, it is not properly placed on the patient, resulting in poor electrode contact, which may affect the respiratory rate.
ECG Calibrating	ECG calibration is in process.
Switch to X-lead (X stands for 3/5/6/10)	Electrode type switch occurs.
ECG Lead off	ECG Lead falls off before monitoring ECG.

Message	Cause
QT Baseline Overrange	After modifying the calculation formula, the QTc parameter value exceeds the range.
V-Fib/V-Tach Off	V-Fib/V-Tach alarm is set to **Off**.
Poor Network	The network signal is poor.
Searching Pulse	SpO_2 module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
NIBP/SpO_2 Simul	**NIBP Simul** function is turned on.
SpO_2 Sensor Off	SpO_2 sensor falls off before monitoring SpO_2.
TEMP Sensor Off	TEMP sensor falls off before monitoring TEMP.
NIBP Starting	NIBP module is starting.
Reset	NIBP reset (manually or automatically triggered) is in process.
Battery Low, cannot start NIBP	The battery power is insufficient to initiate NIBP measurement.
Nurse Call	Manually enable the nurse call function.
Print Initiated	The printing is initiated in the telemetry device.
No SIM Detected	When the device is powered on, the SIM cannot be detected.
Patient Called	Medical staff triggers the "Call patient" function at CMS.

6.4 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows: unit (bpm)

Parameter	Patient Type	Adjustable Range
HR	ADU	15~300
	PED	15~350

ST analysis alarm limits are listed as follows: unit (mV)

Parameter	Adjustable Range
ST	-2.0~2.0

QTc and ΔQTc alarm limits are listed as follows: unit (ms)

Parameter	Adjustable Range
QTc	200~800
ΔQTc	30~200

RESP alarm limits are listed as follows: unit (rpm)

Parameter	Adjustable Range
RESP	0~200

SpO_2 alarm limits are listed as follows: unit (%)

Parameter	Adjustable Range
SpO_2	0~100

SpO_2 Desat Limits are listed as follows: unit (%)

Parameter	Adjustable Range
SpO_2 Desat Limit	0~99

NOTE: User can set the range through Parameter Maintain > SpO_2 Setup > SpO_2 Desat Limit on MFM-CMS, SpO_2 Desat Limit should be less than or equal to SpO_2 alarm low limit.

PR alarm limits are listed as follows: unit (bpm)

Parameter	Adjustable Range
PR (SpO_2)	20~300

NIBP alarm limits are listed as follows: unit (mmHg)

Patient Type	Parameter	Adjustable Range
ADU	SYS	25~290
	DIA	10~250
	MAP	15~260
PED	SYS	25~240
	DIA	10~200
	MAP	15~215

TEMP alarm limits are listed as follows:

Parameter	Adjustable Range
TEMP	0 °C (32 °F)~50 °C (122 °F)

Chapter 7 Monitoring ECG

7.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the monitor and MFM-CMS as a waveform and a numeric.

7.2 ECG Safety Information

WARNING

1. **When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.**
2. **Place the electrode carefully and ensure a good contact. Inspect the electrodes application sites every day to ensure skin integrity. If the skin quality changes, replace the electrodes or change the application site every 24 hours.**
3. **Store the electrodes in room temperature. Use the electrodes as soon as possible after opening the electrode package. Never mix electrode types or brands. This may lead to problem due to impedance difference. When applying the electrodes, avoid bones close to skin, obvious layers of fat and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of thorax, may lead to erroneous arrhythmia alarm due to excessive muscle movement.**
4. **Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message "ECG Lead OFF" and the auditory alarm is activated.**
5. **In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment.**
6. **The electrodes should be made of the same metal materials, otherwise it may affect the measurement due to electrode polarization.**
7. **ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.**

WARNING

8 **When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device: otherwise there will be a great deal of interference with the ECG signal.**

9 **Before outputting signals with defibrillator synchronization or ECG, check if the output is functioning normally.**

10 **According to AAMI specifications the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The synchronization pulse output on the patient monitors is delayed by a maximum of 35 ms from the R wave peak. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.**

11 **ECG accessories are not suitable for DIRECT CARDIAC APPLICATION.**

12 **Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. When the electrode or lead is loose or fallen, the monitor is easily affected by the transient response of certain types of insulation monitors. The transient monitor signal produced by poor insulation of the line may be very similar to the actual heart waveform, which will prevent the monitor from prompting a heart rate alarm. In order to avoid this, user should operate as *Preparing Skin* and *Installing Electrodes*.**

13 **Pacemaker Failure: During a complete cardiac block or when pacemaker is unable to pacing/capture, high P-wave (greater than 1/5 of the average height of the R-wave) may be incorrectly counted by the monitor, which leads to a missing asystole.**

14 **The monitor can only be used on one patient at a time. Monitoring more than one patient simultaneously may result in hazards to the patient.**

15 **The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.**

NOTE:

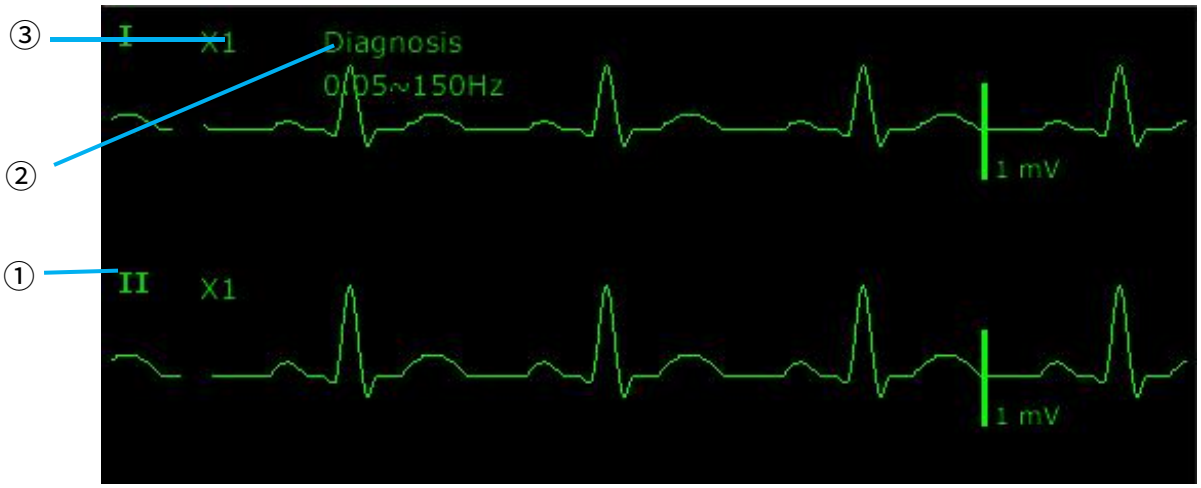
1 **Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.**

2 **IEC/EN60601-1-2 (protection against radiation is 3 V/m) specifies that the**

electrical field density exceeding 3 V/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.

7.3 ECG Display

The figure below is for reference only.



The symbol "①" indicates lead name of display waveform: there are other leads for selection, such as **I**, **II**, **III**, **aVR**, **aVF**, **aVL**, **V** (for 5 Electrodes). If you want to change the lead, please refer to Section *Selecting Calculation Lead*.

The symbol "②" indicates Filter setting, there are six options: **Monitor**, **Surgery**, **Diagnosis**, **Enhanced** and **ST**. If you want to change it, please refer to Section *Changing the ECG Filter Setting*.

The symbol "③" indicates waveform gain: there are several options, such as **X0.125**, **X0.25**, **X0.5**, **X1**, **X2**, **X4** and **AUTO**. If you want to change it, please refer to Section *Changing the Size of the ECG Wave*.

7.3.1 Changing the Size of the ECG Wave

If any of the displayed ECG waveform is too small or clipped, you can change the size of it on the screen. First select **ECG Waveform Setup** > **ECG Gain** on the MFM-CMS, then select an appropriate factor from the pop-up box to adjust the ECG waveform.

X0.125: make size of ECG signal waveform of 1mV become 1.25 mm;

X0.25: make size of ECG signal waveform of 1mV become 2.5 mm;

X0.5: make size of ECG signal waveform of 1mV become 5 mm;

X1: make size of ECG signal waveform of 1mV become 10 mm;

X2: make size of ECG signal waveform of 1mV become 20 mm;

X4: make size of ECG signal waveform of 1mV become 40 mm;

AUTO: let the monitor choose the optimal adjustment factor for all the ECG waves.

NOTE: The effect of ECG wave gain is subject to the size of the wave area. Whichever wave gain is chosen, the ECG wave has to be displayed within the wave area, the exceeded part is clipped.

7.3.2 Changing the ECG Filter Settings

The ECG filter setting defines how ECG waves are smoothed. An abbreviation indicating the filter type is shown underneath the lead label on the monitor display. Filter settings do not affect ST measurement.

To change the filter setting, select **Parameter Setup** > **ECG Setup** > **Filter** on the MFM-CMS, select the appropriate setting.

– **Monitor**: Use this mode under normal measurement conditions.

– **Surgery**: The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts and interference from electro-surgical units. Under normal measurement conditions, selecting **Surgery** may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the monitor.

– **Diagnosis**: Use when undistorted signal is required and its own characteristics can be maintained. The waveform filtered by the bandwidth of 0.05 Hz~150 Hz is displayed so that the actual changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.

– **Enhanced**: It should be used if the signal is distorted by strong interference from high frequency or low frequency. If there is still obviously interference in the signals when select **Surgery** filter mode, it is recommended to choose the enhanced mode. In this mode, QRS wave rhythm information is emphasized, its shape information cannot be considered as diagnostic criteria. Under normal measurement conditions, the selection of this mode may inhibit QRS wave group and interfere ECG analysis.

– **ST**: To meet the filtering requirements of ST analysis, it is used when ST analysis is turned on or when ST analysis results are concerned.

– **Custom**: User can set **High-pass Filter** and **Low-pass Filter** as needed. **High-pass Filter** can be selected as: **0.01 Hz**, **0.05 Hz**, **0.15 Hz**, **0.25 Hz**, **0.32 Hz**, **0.5 Hz** and **0.67 Hz**. **Low-pass Filter** can be selected as: **25 Hz**, **35 Hz**, **45 Hz**, **75 Hz**, **100 Hz**, and **150 Hz**. After **High-pass filter** and **Low-pass Filter** are set, the bandwidth range of high – pass bandwidth to low - pass bandwidth can be formed.

7.3.3 Setting Alarm Source

To change the alarm source, please select **Parameter Setup** > **ECG Setup** > **Alarm Source** on the MFM-CMS, then a pop-up box is displayed:

HR: the monitor considers the HR as HR/PR alarm source;

PR: the monitor considers the PR as HR/PR alarm source;

AUTO: If the Alarm Source is set to **AUTO**, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and valid HR value are available. The monitor will automatically switch to PR as the alarm source if:

– valid HR values can no longer be measured and

–a PR source is switched on and available.

The monitor then uses the pulse rate from the currently active measurement as system pulse. If valid HR value becomes available again, the monitor automatically uses HR as alarm source.

All: the monitor simultaneously responds to alarms generated by both HR and PR.

7.3.4 Setting QRS Source

To change the beat source, select **Parameter Setup** > **ECG Setup** > **QRS Source** on the MFM-CMS. Select from the following options:

HR: HR is HR/PR QRS source;

PR: PR is HR/PR QRS source;

AUTO: If the Beat Source is set to **AUTO**, the monitor will use HR as the beat source whenever the ECG measurement is switched on and valid HR value are available. The monitor will automatically switch to PR as the beat source if:

- valid HR values can no longer be measured and
- a PR source is switched on and available.

If valid HR value becomes available again, the monitor automatically uses HR as beat source and the monitor gives a “Di” tone. While a pulse is detected, the monitor gives

a “Da” tone.

7.3.5 Smart Lead Off

When **Electrode Type** is **5 Electrodes** or **6 Electrodes** or **10 Electrodes** and **Smart Lead Off** is set to **On**, if the current selected calculation lead cannot detect ECG signal, the monitor automatically switches the corresponding lead as calculation lead, and switches the waveform display of calculation lead at the same time. When ECG electrode is re-connected, and the original calculation lead recover its signals, the monitor automatically switch to the original calculation lead.

To change the smart lead off setting, select **Parameter Setup** > **ECG Setup** > **Smart Lead Off** on the MFM-CMS and select the desired setting.

NOTE: When Electrode Type is set to AUTO, the smart lead off function will be automatically turned on and cannot be turned off.

7.3.6 Adjusting QRS Volume

QRS volume is from HR or PR, depending on your setting of the beat source. To adjust the QRS volume, select **Parameter Setup** > **ECG Setup** > **QRS Volume** on the MFM-CMS and set an appropriate heartbeat volume. QRS frequency has positive correlation with measurement value.

7.3.7 Setting Pace Status

It is important to set the paced status correctly when you start monitoring ECG. To change the paced status, select **Parameter Setup** > **ECG Setup** > **Pace** to toggle between **On** or **Off** on the MFM-CMS. When **Pace** is set to **On**:

- Pace Pulse Rejection is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.
- Paced symbol is displayed as | on the main screen. At this time, the artifact is displayed on the screen instead of the actual pacemaker crest. All pacemaker crests are the same, so do not give a diagnostic explanation about the size and shape of the pacemaker crest.

NOTE: When monitoring a patient with a pacemaker, set Pace to On. If monitoring a patient without a pacemaker, set Pace to Off.

WARNING

1. **For patients with pacemakers, the pace must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected. When changing settings and admitting patients, please make sure the pace mode is always correct.**
2. **External pacing electrodes: When a pacemaker with external pacing electrodes is being used on a patient, arrhythmia monitoring is severely compromised due to the high energy level in the pacer pulse. This may result in the arrhythmia algorithm's failure to detect Pacer not Captured or asystole.**

Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Be sure to check the paced symbol on the display screen has correctly detected the pacing pulse. Keep pacemaker patients under close observation.

7.3.8 Setting Waveform Sweep

The default waveform speed is 6.25 mm/s, To change the waveform speed on telemetry monitor, select **Parameter Setup** > **ECG Setup** > **Sweep** on the MFM-CMS, then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

7.3.9 Selecting Calculation Lead

To set the calculation lead, select **Parameter Setup** > **ECG Setup** > **Calc. Lead** on the MFM-CMS. For 3 Electrodes, II, I, and III are selectable; For 5 Electrodes, II, I, III, aVR, aVL, aVF, and V are selectable; For 6 Electrodes, II, I, III, aVR, aVL, aVF and leads corresponding to Va and Vb are selectable. For 10 Electrodes, II, I, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6 are selectable. Normal QRS complex should be:

- The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.
- The QRS should be tall and narrow.
- The P-waves and the T-waves should be less than 0.2 mV.

NOTE: Make sure you have selected the best lead with the best waveform amplitude and highest signal-to-noise ratio. Choosing the best lead is important for heart beat test, heart beat classification and ventricular fibrillation detection.

7.4 ECG Calibration

This item is used to calibrate ECG waveform. When you select this item from ECG Setup menu again, the ECG waveform calibration ends.

NOTE: The patients can't be monitored during ECG calibration.

7.5 Monitoring Procedure

7.5.1 Preparing Skin

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Select sites with intact skin, without impairment of any kind.
- Shave hair from sites, if necessary.
- Clean the selected sites thoroughly to remove skin scurf and grease.
- Dry the skin completely before applying electrodes.

7.5.2 Connecting ECG Cables

1. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
2. Connect the electrode lead to the ECG cable.
3. Plug the ECG cable into the ECG cable connector of the telemetry monitor.

CAUTION

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by EDAN.

7.5.3 Selecting Electrode Type

To change the electrode type, please:

1. On the MFM-CMS, Select the **Parameter Setup** > **ECG Setup** menu;
2. Set **Electrode Type** to **3 Electrodes**, **5 Electrodes**, **6 Electrodes**, **10 Electrodes** or **AUTO** based on the electrodes used.

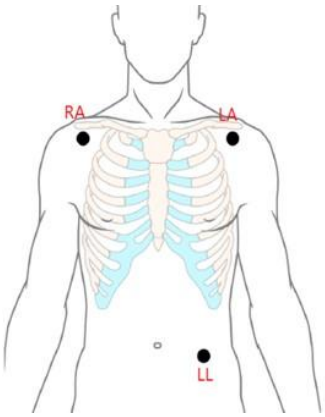
7.5.4 Installing Electrodes

AHA (American Standard)		IEC (Europe Standard)	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/ Blue	C4	White/ Brown
V5	Brown/ Orange	C5	White/ Black
V6	Brown/ Purple	C6	White/ Purple

NOTE: When connecting the electrodes, Ensure that the conductive parts of ECG electrodes and associated connectors, including the neutral electrode, do not come into contact with any other conductive parts including earth.

3 Electrodes Placement

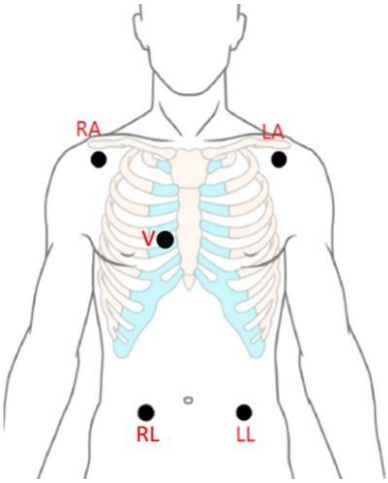
Take the American standard for example, see the following figure:



- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left hypogastrium.

5 Electrodes Placement

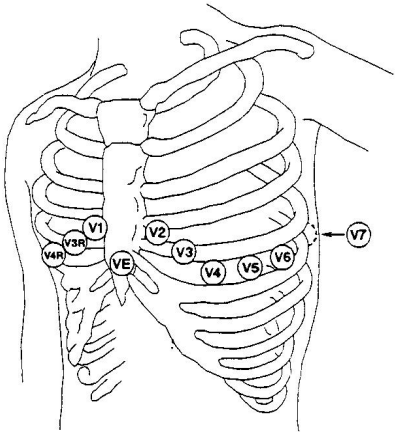
Take the American standard for example, see the following figure:



- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.

- RL placement: on the right hypogastrium.
- LL placement: on the left hypogastrium.
- V placement: on the chest, the position depends on your required lead selection.

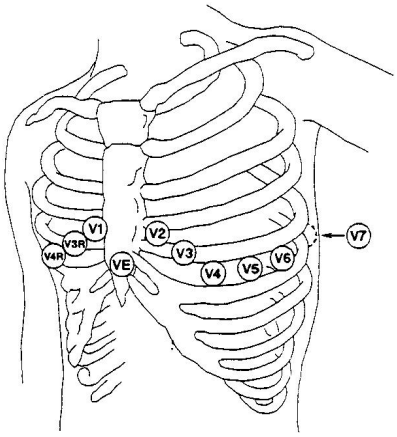
For 5 electrodes, attach the V electrode to one of the indicated positions as below:



- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R On the right side of the chest in positions corresponding to those on the left.
- VE Over the xiphoid position.
- V7 On the 5th intercostal space at the left posterior axillary line of back.
- V7R On the 5th intercostal space at the right posterior axillary line of back.

6 Electrodes Placement

For the placement of 6 electrodes, please use the position of 5 electrodes in the schematic diagram to remove the two thoracic leads. The two thoracic leads Va and Vb can be placed at any two positions from V1 to V6, as shown in the following thoracic leads. To ensure that the label is correct, the selected Va and Vb placements must be set simultaneously in **ECG Setup**.



- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.

- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.

10 Electrodes Placement

In 12-Lead ECG monitoring, the 10 electrodes are placed on the patient's four limbs and chest. The limb electrodes should be placed on the soft skin according to the physician's preference. The picture below shows the conventional 10 electrodes placement.

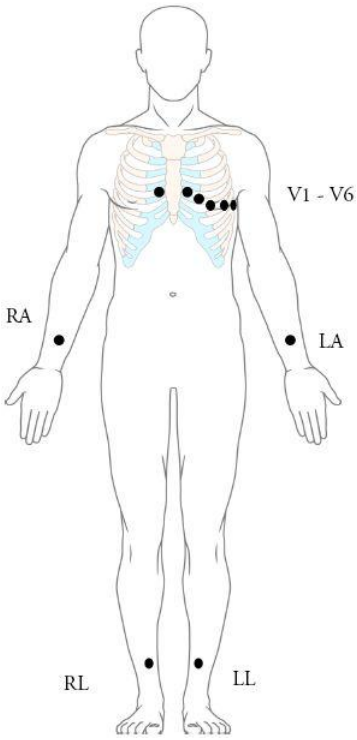
The 10 electrodes should be placed as follows:

Limb electrodes:

- RA and LA: Place arm electrodes on the inside of each arm, between the wrist and the elbow.
- RL and LL: Place leg electrodes inside of each calf, between the knee and the ankle.

Chest electrodes:

- V1: On the 4th intercostal space at the right sterna margin.
- V2: On the 4th intercostal space at the left sterna margin.
- V3: Midway between V2 and V4 electrodes.
- V4: On the 5th intercostal space at the left clavicular line.
- V5: On the left anterior axillary line, horizontal with V4 electrode.
- V6: On the left middle axillary line, horizontal with V4 electrode.



Recommended ECG Electrode Placement for Surgical Patients

WARNING

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being

performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small.

WARNING

ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

NOTE:

1. **If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the leads displayed on the screen.**
2. **Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.**

7.5.5 Electrode Diagram

The electrode diagram provides a graphical electrode indication that shows the real-time electrode connection status. Users can click **Menu** > **General Function** > **Lead Placement** to check the ECG electrode connection.

7.5.6 Improving ECG Signal Quality

When monitoring the ECG for a moving patient, the ECG lead cable may pull on the skin, creating ECG motion interference. To get a good ECG signal, it is recommended to follow these steps:

1. After installing the electrode, attach a medical tape near the electrode.

2. Apply the medical tape to the patient and secure the ECG lead cable.

7.6 Arrhythmia Monitoring

7.6.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia

events and generate alarm information. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.
The monitor can support up to 16 different arrhythmia analyses.

Arrhythmia Alarms	Occurring Condition
ASYSTOLE	No QRS is detected for 4 consecutive seconds.
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.
VT > 2	3 ≤ the number of consecutive PVCs < 5.
COUPLET	2 consecutive PVCs.
BIGEMINY	A dominant rhythm of N, V, N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
TRIGEMINY	A dominant rhythm of N, N, V, N, N, V, N, N, V.
R ON T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
PVC	Single PVC detected in normal heartbeats.
TACHY	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
BRADY	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≥ 1 s.
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.
IRR	Consistently irregular heart rhythm.
PNC	PACER NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.

Arrhythmia Alarms	Occurring Condition
NOTE: Arrhythmia monitoring is intended for use with adult patients only and is not clinically validated for use with pediatric patients. For this reason, the recommended setting for arrhythmia monitoring in pediatric modes is **Off**.	

Selecting an ECG lead for Arrhythmia:

In arrhythmia monitoring, it is important to select the appropriate lead.

For non-paced patients, the guidelines are:

- QRS should be tall and narrow (recommended amplitude > 0.5 mV)
- R wave should be above or below the baseline (but not biphasic)
- T wave should be smaller than 1/3 of the R wave height
- P wave should be smaller than 1/5 of the R wave height.

For paced patients, in addition to above guidelines, the pacemaker signal should also:

- Not wider than normal QRS
- The QRS complexes should be at least twice the height of the pacing pulse

According to Standard IEC 60601-2-27, the minimum detection level of the QRS complex is set to 0.15 mV, to prevent the detection of P-wave or baseline noise as QRS complexes. Adjusting ECG displayed waveform size (gain adjustment) won't influence ECG signals which are used for arrhythmia analysis. If the ECG signal is too small, a false asystole alarm may occur.

Aberrantly-Conducted Beats:

As not recognizing the P waves, the monitoring system is difficult to distinguish between aberrantly-conducted beats and ventricular heartbeat. If the aberrantly-conducted beat is similar to ventricular tachycardia, it may be classified as ventricular. Make sure to select such a lead, the aberrantly-conducted beats have an R wave that is as narrow as possible to minimize the incorrect calls. The ventricular should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

Intermittent bundle branch block: bundle branch block or other bundle obstruction phenomenon is a challenge for arrhythmia algorithm. If the QRS wave during the block has a considerable change in morphology compared to the normal QRS of learning, the blocked heartbeat may be misclassified as ventricular tachycardia, resulting in an incorrect chamber alarm. Make sure to select such a lead, which blocks the heartbeat of the R wave as narrow as possible to minimize the wrong classification.

Ventricular heartbeat should have a different appearance from “normal heartbeat”. Physicians should be more alert to these patients.

NOTE:

1. **Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.**
2. **Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, there may be some false arrhythmias detected; some true arrhythmia events may not be detected. This is especially true when the signal is noisy.**

7.6.2 Arrhythmia Analysis Menu

7.6.2.1 Switching Arrhythmia Analysis On and Off

To switch arrhythmia analysis on or off, on the MFM-CMS, select **Parameter Setup** > **ECG Setup** > **ARR Analysis** to toggle between **On** and **Off** from the popup interface.

7.6.2.2 Arrhythmia Alarm Setup

On the MFM-CMS, Select **Parameter Setup** > **ECG Setup** > **ARR Analysis** > **Alarm** to change the following arrhythmia alarm settings:

- Separately switch on or off each arrhythmia alarm and set the alarm level.
- Set the threshold of certain arrhythmia alarms. When an arrhythmia exceeds its threshold, an alarm will be triggered.

Click **Update Monitor** to make the settings effective on the telemetry monitor.

ASYSTOLE alarm is key arrhythmia alarms as well and they are preset to **On** and cannot be turned off.

WARNING

When the arrhythmia alarm is set to Off, the monitor will not give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient’s life, the user should use this function cautiously.

NOTE: PNC and PNP alarms are available only when Pace is set to On.

7.6.2.3 Adjustable Range of Arrhythmia Alarm Threshold

Arrhythmia Alarm	Range
PVCs High	1/min to 99/min

7.6.2.4 Arrhythmia Selflearning

Pick this item **ARR Selflearn** to start a learning procedure, and **ARR Learning** displayed on the screen.

The Arrhythmia selflearning will start automatically in the following status:

- Switching the Arrhythmia Analysis from Off to On;
- Changing patient type or electrodes type;
- Connecting or switching calculation leads;
- Changing pacemaker status;
- Switching ECG from Off to On;
- Update patients or change patient type;
- Switch the calibration mode to normal measurement mode;
- Change the filter.

NOTE:

1 **During the relearning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor the patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.**

2 **Take care to initiate arrhythmia selflearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If arrhythmia selflearning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.**

3 **If arrhythmia selflearning is performed during ventricular rhythm, ventricular heartbeats may be erroneously identified as normal QRS complexes. This may lead to missed ventricular tachycardia and ventricular fibrillation events.**

Due to this reason, you should:

1) Take care that arrhythmia selflearning may start automatically;

2) Response to electrodes off information;

3) Always check the correctness of arrhythmia alarm.

7.7 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrial paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and ST templates on the monitor.

ST segment monitoring function is shut off by default. You can switch it to **On** when necessary. When using the ST analysis function, the ST analysis results will be displayed on the right of the main screen.

NOTE:

1 **In ST analysis, the obtained ST value and ST template are all unaffected by the selected filter mode. ST algorithm itself uses a dedicated linear filter to ensure the signal is not distorted, and to better ensure the consistent and accurate measurement value and ST template can be obtained in different filter modes. If the doctor wants to observe the waveform to evaluate ST segment result, it is recommended to use the ST template for observation, as it is not affected by the filter mode. If the real-time waveform displayed on the interface is used to evaluate ST segment result, it is recommended to select Diagnosis mode.**

2 **Reliable ST monitoring may be influenced in following situations:**

- **You are unable to get a lead with low noise.**
- **If there is arrhythmia such as atrial fibrillation/flutter, the ECG baseline may be irregular.**
- **The patient is continually performing ventricular paced.**
- **The dominant template cannot be obtained for a long time.**
- **The patient has left bundle branch block.**

When any of above situations happens, ST monitoring should be switched off.

3 **The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.**

4 **If you use ST analysis, you must adjust the ST measurement point when you start the monitor. If the patient's heart rate or ECG waveform changes significantly, this will affect the size of the QT interval, so the ST point must be placed. If the equipotential or ST points are not set correctly, the ST fragments of the artifacts may be depressed or raised. Always ensure that the ST measurement point is suitable for your patient.**

5 **ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.**
6 **ST is calculated with a fixed delay from the R position. Changes in heart rate or the width of QRS may affect ST.**
7 **If the algorithm triggers self-learning (either manually or automatically), the calculation of ST segment will be reinitialized.**
8 **When the arrhythmia relearning function is enabled, the telemetry monitor cannot perform ST segment analysis.**

7.7.1 Setting ST Analysis

To change ST analysis, please select **ECG Setup** > **ST Analysis** on the MFM-CMS, then select **On** or **Off** from the pop-up list.

7.7.2 ST Alarm Setup

On the MFM-CMS, Select **Parameter Setup** > **ECG Setup** > **ST Analysis** > **ST Alarm Setup** to change the ST Alarm Mode:

Real Time: The user can set the alarm switch, alarm level and alarm limit separately for each ST or all ST.

7.8 QT Analysis

The QT interval is the time from the beginning of Q wave to the end of T wave. It measured the total duration of the depolarization (QRS duration) and repolarization (ST-T) phases of ventricular action potential. QT analysis can help detect Long QT Syndrome. The telemetry monitor uses single lead (default is II lead) to perform QT analysis, if the analysis lead is changed on MFM-CMS, the QT parameter takes effect immediately.

7.8.1 Measurement Limitations

The following clinical status of the patient may affect the QT analysis, and the inaccurate measurement may but is not limited to the following reasons:

- The T-wave is very flat
- Atrial flutter and atrial fibrillation make T wave is difficult to define
- The end of the T-wave is difficult to define because of the presence of U-waves
- A high heart rate causes the P-wave to encroach on the end of the previous T-wave

- Noise or the QRS wave variation is too big

In these cases, the user should choose a lead with good T wave amplitude and no visible oscillations, and without a dominant U wave or P wave.

In some conditions, such as left or right bundle branch block or cardiac hypertrophy causes broaden QRS complex. If long QTc is observed, verify it to ensure that it is not caused by QRS broadening.

Since normal beats followed by ventricular beats are not included in the analysis, QT measurement could not be carried out when there was bigeminy rhythm.

When the heart rate changes, it may take several minutes for the QT interval to stabilize. In order to obtain reliable QTc calculations, it is important to avoid areas where the heart rate changes.

NOTE: QT/QTc measurements should always be validated by a qualified clinician.

7.8.2 Switching QT Analysis On and Off

To switch QT Analysis on or off, on the MFM-CMS, select **Parameter Setup** > **QT** > **Setup** > **QT Analysis** to toggle between **On** and **Off** from the popup interface.

7.8.3 Selecting Calculation Formula

The monitor uses Bazett formula to correct QT values by default. There are four alternative formulas: **Bazett**, **Fridericia**, **Framingham** and **Hodges**. And the calculation formula can be selected on the MFM-CMS.

Hodges: $QTc = QT + 1.75 \times (HR - 60)$

Bazett: $QTc = QT \times \left(\frac{HR}{60}\right)^{\frac{1}{2}}$

Fridericia: $QTc = QT \times \left(\frac{HR}{60}\right)^{\frac{1}{3}}$

Framingham: $QTc = QT + 154 \times (1 - \frac{60}{HR})$

7.8.4 QTc Alarm Setup

On the MFM-CMS, select **Parameter Setup** > **QT** > **Alarm** to change the following QT alarm settings:

- Separately switch on or off QTc alarm and ΔQTc alarm and set the alarm level.
- Set the thresholds of QTc alarm and ΔQTc alarm. When QTc value or ΔQTc value exceeds the preset thresholds, an alarm will be triggered.

Chapter 8 Monitoring RESP

8.1 Overview

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

8.2 RESP Safety Information

WARNING

1. **Respiration measurements cannot detect all underexposure sudden events, nor can they distinguish between central, obstructive and mixed respiratory asphyxial events. It only prompts alarm in a predetermined time if the last breath is detected and the next breath is not detected, so it cannot be used for diagnostic purposes.**
2. **If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.**
3. **Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as $EtCO_2$ and SpO_2.**
4. **To monitor the respiration, only non-ESU-proof accessories can be used. This is because the internal impedance of the ESU-proof accessories required to be used for electrosurgical operation is too large.**
5. **RESP No Breath Detected alarm is based on inadequate thoracic impedance change.**
6. **Respiration measurement cannot be performed when ESU is used.**

WARNING

7 **Some implantable pacemakers can adjust their triggering frequency according to the "minute ventilation rate." Impedance respiration measurements may cause these pacemakers to react incorrectly. To prevent this, turn off the respiration measurement.**

8 **When ECG electrode is placed on patient's limb, the impedance respiration may be unreliable.**

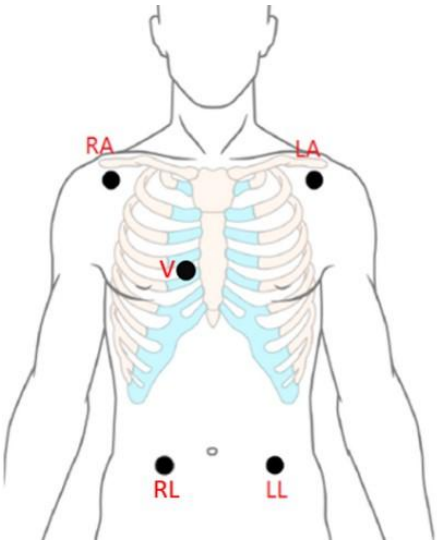
9 **RESP No Breath Detected alarm should not be used or relied upon while the patient is unattended.**

NOTE: The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

8.3 Electrode Placement for Monitoring RESP

Correct patient skin preparation techniques for electrode placement are important for RESP measurement: you will find this information in the chapter on ECG.

The RESP signal is always measured between two of the ECG electrodes. There are two standard ECG leads for selection: I lead (RA and LA) and II lead (RA and LL).

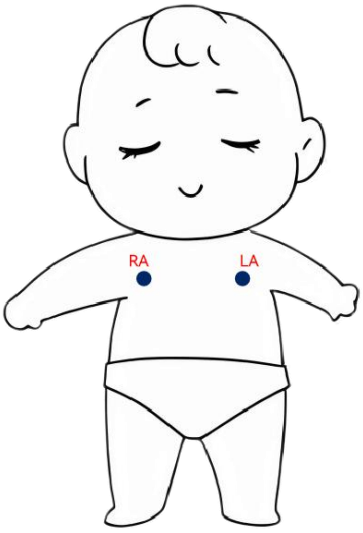


Electrodes Placement for 5 Electrodes

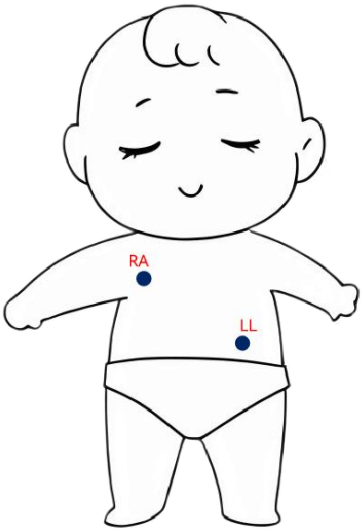
Cardiac activity that affects the RESP waveform is called cardiac overlay. It happens when the RESP electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes so

as to avoid cardiac overlay or artifacts from pulsating blood flow.

Some patients, expand their chests laterally. In these cases it is best to place the two respiratory electrodes in the right mid-axillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.



Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.



8.4 Setting RESP

RESP Setup is implemented on the MFM-CMS.

8.4.1 Changing the Size of the Respiration Wave

Select the RESP waveform area to open the **Parameter Setup** > **RESP Setup** menu:

- Select **ECG Gain**, and choose an appropriate value. The bigger the value is, the higher the waveform amplitude will be.
- Select **Speed**: select an appropriate setting from the pop-up list.

8.4.2 Changing the No Breath Detected Delay

The RESP No Breath Detected alarm is a high priority red alarm used to detect no breath. The no breath detected delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the no breath detected delay. Users should set it cautiously.

1. On the MFM-CMS, select **Parameter Setup** > **RESP Setup** > **No Breath Detected**.
2. Select the appropriate setting from the popup list.

Chapter 9 Monitoring SpO_2

9.1 Overview

SpO_2 is used to measure arterial blood oxygen saturation, which is the percentage of oxyhemoglobin in the arterial blood. SpO_2 parameter can also provide pulse rate (PR) and a plethysmogram wave (Pleth). The device is calibrated to display functional oxygen saturation.

9.2 SpO_2 Safety Information

WARNING

1. **Do not use the SpO_2 sensors if the packaging or the sensor is damaged and return them to the vendor. If the SpO_2 sensor cannot work properly, please reconnect the sensor or change a new one.**
2. **Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.**
3. **Use only EDAN permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.**
4. **When serious arrhythmia is present, the SpO_2 pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO_2) value.**
5. **Misapplied sensor or sensor that becomes partially dislodged may cause either over or under reading of actual arterial oxygen saturation.**

NOTE:

1. **Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line. When measuring SpO_2 on the limb with inflated NIBP cuff, please turn on the NIBP Simul function.**
2. **When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.**
3. **The SpO_2 pleth waveform is not normalized and is not directly proportional to the pulse volume.**
4. **A Functional tester or simulator cannot be used to assess the SpO_2 accuracy. However, it can be used to demonstrate that a particular monitor reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.**
5. **If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the measurement site to prevent burns. If the initial skin temperature is less than 35 °C, the temperature of all the listed sensors on the skin will not exceed 41 °C during working.**
6. **The cumulative use time for the SpO_2 sensor in a single patient should be less than 30 days.**

9.3 Measurement Limitations

Certain patient conditions can affect the measurements or cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- incorrect sensor application
- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight
- failure to cover the sensor with opaque material in high levels of ambient light conditions
- dysfunctional hemoglobins
- low peripheral perfusion

- excessive or violent patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- electromagnetic interference

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor
- low peripheral perfusion

NOTE:

1 **To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.**

2 **Adjacent SpO_2 sensors may interfere with each other (eg, multiple SpO_2 measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.**

3 **Move the sensor to a less active site, and keep the patient still, if possible.**

9.4 Measuring SpO_2

1. Select the correct patient category setting, as this is used to optimize the calculation of the SpO_2 and pulse numerics.
2. During measurement, ensure that the application site:
   - has a pulsatile flow, ideally with a good circulation perfusion.
   - has not changed in its thickness, causing an improper fit of the sensor.

Measurement Procedure

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient.

Before Applying the Sensor:

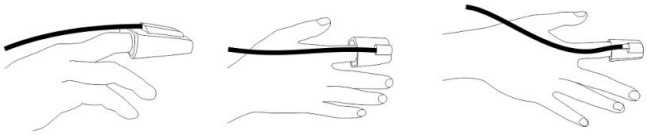
Be sure to understand all warnings listed in the previous section before applying any

sensor to a patient. Also, check the sensor as follows:

- Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.
- Any sensor showing signs of damage or alteration must not be used for further patient monitoring; instead, dispose of it using proper disposal procedures.

Applying Finger/Soft-tip Sensors:

- Nip the clamp, and choose a site that is well perfused and restricts a conscious patient's movements least. The ring finger of the non-dominate hand is preferred. Alternatively, the other fingers on the non-dominate hand may be used.
- The big toe or long toe (next to the big toe) may be used on restrained patients or patients whose hands are unavailable.
- Place the finger into the sensor according to the direction of the symbol on the sensor. Adjust the finger to ensure that the pad of the finger completely covers the sensor detection window.
- Orient the sensor so that the cable will be running towards the top of the patient's hand.
- Connect the sensor with the monitor (or with the extension cable if needed).



WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours (or more often, if indicated by circulatory status and/or skin integrity). For patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently. Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.

NOTE:

1 **Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.**

2 **Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. The sensor cable should be placed on the back of the hand.**
3 **Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.**

9.5 Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

The SpO_2 accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO_2 measurements are statistically distributed; only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies are composed of healthy men and women from age 18 to 50, with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

NOTE:

1 **The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).**
2 **During monitoring, if the monitor's reading differs significantly from the**

patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the monitor to fail to send an alarm. In order to ensure reliable monitoring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.

3 **Sensor movement, ambient light (especially strobe lights or flashing lights) or electromagnetic interference can give unexpected intermittent readings when the sensor is not attached. Especially wrap sensor designs are sensitive to minimal sensor movement that might occur when the sensor is dangling.**

9.6 SpO_2 Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

9.7 Signal Intensity*

* Only applicable to the EDAN SpO_2 module.

Signal Intensity (**SI**) is a numeric value indicating the arterial pulse signal intensity, which can be used to assess the SpO_2 signal intensity. SI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the signal quality will be. The signal quality is at its maximum when the value reaches 10. When SI is below 2, it indicates the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The SI value will be displayed in the SpO_2 parameter area.

9.8 SpO_2 Setup

The SpO_2 Setup is implemented on the MFM-CMS, and the telemetry monitor takes

effect immediately after the setting.

9.8.1 Setting Waveform Sweep

To change the waveform speed on telemetry monitor, select **Parameter Setup** > **SpO_2 Setup** > **Speed** on MFM-CMS, then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

9.8.2 Measuring SpO_2 and NIBP Simultaneously

The Simul measurement of SpO_2 and NIBP is operated on the MFM-CMS. While measuring SpO_2 and NIBP on the same limb simultaneously, the user can set **NIBP Simul** to **On** in **SpO_2 Setup** menu to lock the SpO_2 alarm status until the NIBP measurement ends. The alarm occurred before entering NIBP Simul will not disappear. If **NIBP Simul** is set to **Off**, low perfusion caused by NIBP measurement may lead to inaccurate SpO_2 readings and therefore cause false physiological alarms.

9.8.3 Setting Sensitivity

The SpO_2 reading is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient's oxygen saturation level, but the measurement accuracy is relatively low. Contrarily, the longer the averaging time is, the slower the monitor responds to the changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. When a critical patient is monitored, selecting shorter averaging time will help to understand the patient's state. The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO_2 value is the most frequent. To change the sensitivity, please follow the steps:

1. On the MFM-CMS, Select **Parameter Setup** > **SpO_2 Setup** menu;
2. Select **Sensitivity** on the interface and select **High**, **Medium** or **Low** from the popup list, which respectively correspond to 6 s, 8 s, and 12 s.

9.9 SpO_2 Relevant Data for Reference

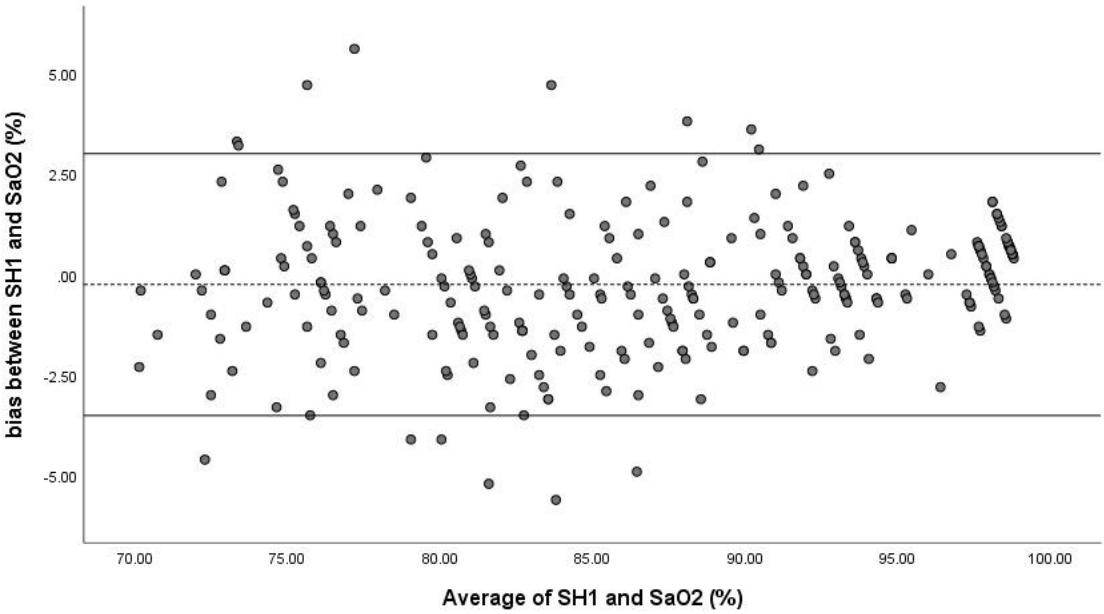
1. The table below shows Arms values measured using SH series sensors with iT30 and iT50 in a clinical study.

SaO_2 Range	Arms			
	With SH1	With SH4	With SH5	With SHD-A
90%-100%	1.01	1.29	1.10	1.15
80%-90%	2.01	2.17	2.13	2.08

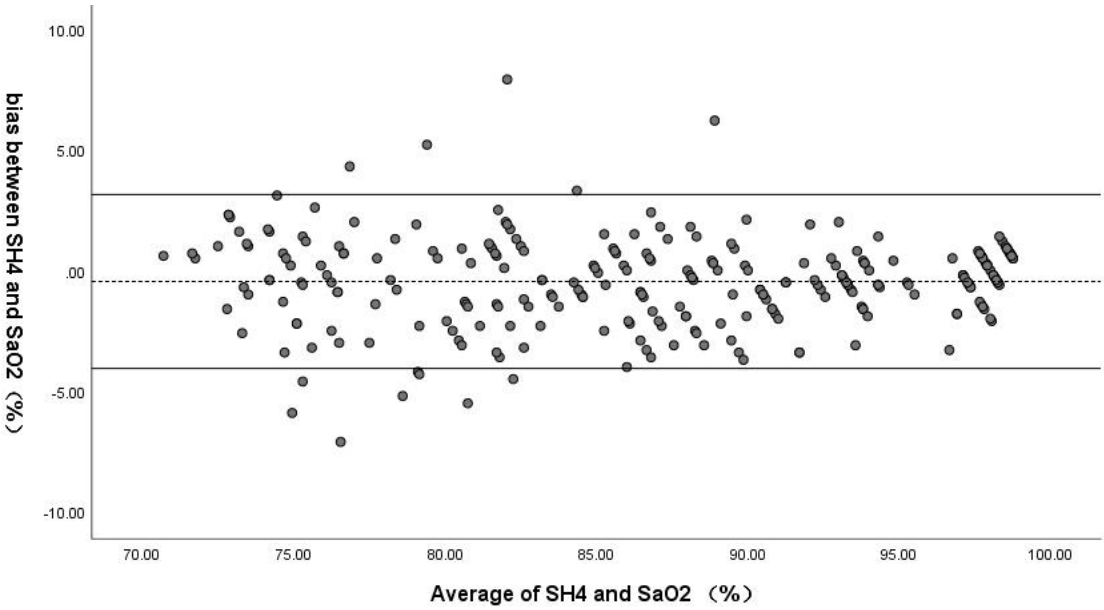
70%-80%	2.01	2.29	2.57	2.67
70%-100%	1.68	1.89	1.90	1.92

2. The figures below show the Bland-Altman Plot of SaO_2 vs SpO_2 measured using SH series sensor. In the plots, the upper and lower dotted lines represent the upper and inferior limits of the 95% consistency, and the middle dotted line represents the average of the bias.

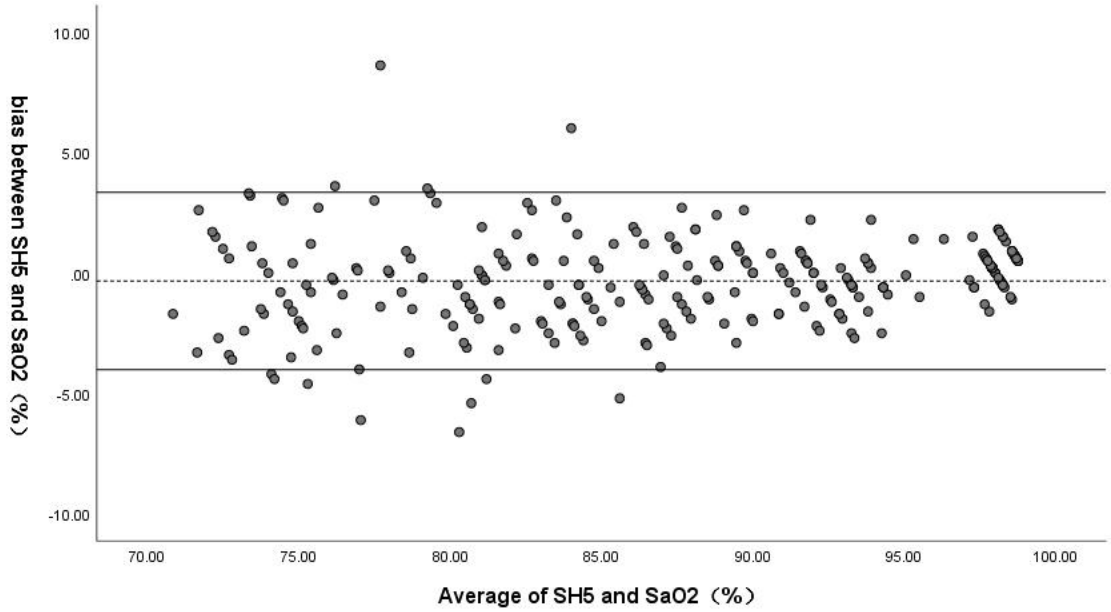
Bland-Altman plot for comparator's SaO_2 and SpO_2 of investigational device with SH1 sensor



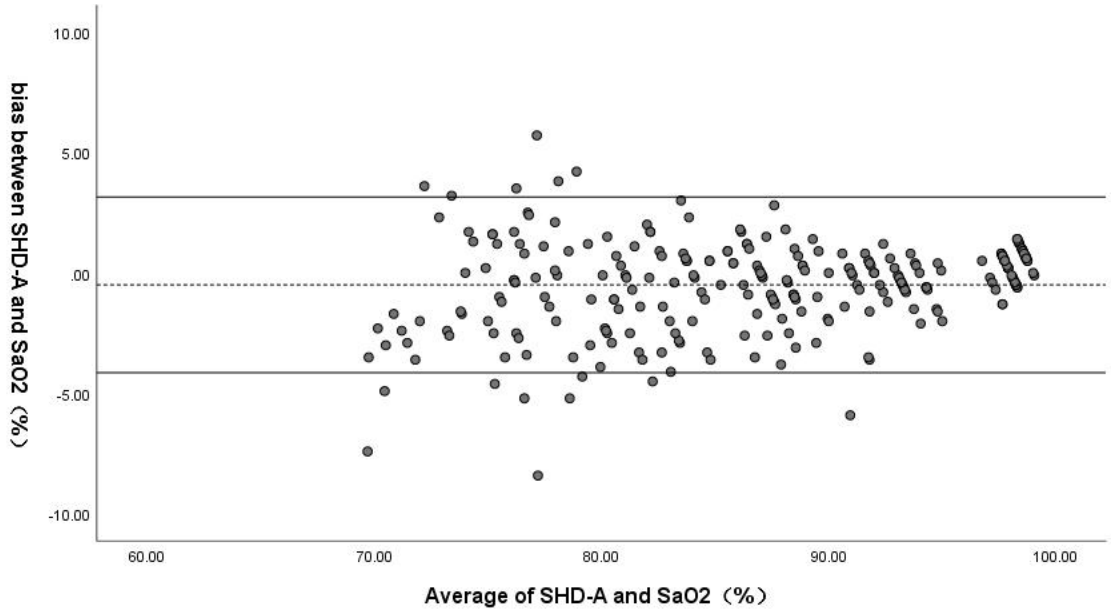
Bland-Altman plot for comparator's SaO_2 and SpO_2 of investigational device with SH4 sensor



Bland-Altman plot for comparator's SaO_2 and SpO_2 of investigational device with SH5 sensor



Bland-Altman plot for comparator's SaO_2 and SpO_2 of investigational device with SHD-A sensor



Chapter 10 Monitoring PR

10.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm).

The monitor provides PR source options. When SpO_2 is turned on, the PR source is always SpO_2. When SpO_2 is turned off, and only NIBP is turned on, the PR source is NIBP. When SpO_2 and NIBP are both turned on, the PR source is SpO_2.

10.2 Selecting the Active Alarm Source

In most cases, the HR and PR numerics are identical. In order to avoid simultaneous alarms on HR and PR, the monitor uses either HR or PR as its active alarm source. The default alarm source is **Auto**. To change the alarm source, select **Parameter Setup** > **PR Setup** or **ECG Setup** > **Alarm Source**, then a pop-up box is displayed:

- **HR**: if you want HR to be the alarm source for HR/Pulse.
- **PR**: if you select PR as the active alarm source, the monitor will prompt you to confirm your choice. Be aware that if you select PR as the alarm source, ECG HR alarms are switched off.
- **AUTO**: If the Alarm Source is set to Auto, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and valid HR value are available. The monitor will automatically switch to PR for the alarm source if:
  - valid HR values can no longer be measured and
  - a PR source is switched on and available.

The monitor uses the pulse rate from the currently active measurement as system pulse. If valid HR value becomes available again, the monitor automatically uses HR as alarm source.

- **ALL**: The telemetry monitor responds to alarms generated by both HR and PR.

Chapter 11 Monitoring NIBP

11.1 Overview

This monitor uses the oscillometric method for measuring NIBP, supporting iFAST algorithm and iCUFS algorithm. The iCUFS algorithm and iFAST algorithm can be used for adult and pediatric patients. Both measurement algorithms are also intended for use with pregnant, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.

iCUFS algorithm: Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

iFAST algorithm: During the cuff inflation, oscillometric devices detect the change of pulsation amplitude due to the cuff pressure change. The pulsations increase in amplitude and reach a maximum (which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures. Oscillometric devices terminate the NIBP measurement and deflate quickly once the systolic pressure is determined.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2) in relation to mean error and standard deviation. In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine adult diastolic pressure, and the fourth Korotkoff sound was used to determine pediatric diastolic pressure.

When selecting the patient type on the patient admitting interface, it is recommended to choose **Adult** for patients greater than 21 years of age, **Pediat** for patients greater than 3 through 21 years of age.

11.2 NIBP Safety Information

WARNING

1. **Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.**
2. **Do not measure NIBP on the arm of the same side with a mastectomy.**
3. **Use clinical judgment to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
4. **Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**
5. **Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.**
6. **Ensure that the correct patient type is selected before performing measurements.**
7. **Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.**
8. **Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.**
9. **NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.**
10. **Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.**
11. **Verifying the calibration is only applicable for adults, and it cannot be operated in automatic measuring interval. Continuous measuring cannot be operated in automatic measuring interval either.**

NOTE:

1. **It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.**
2. **If you spill liquid onto the equipment or accessories, particularly if there is a**

chance that it can get inside the tubing or the measurement device, contact your service personnel.

3. **Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient. Continuous measuring and automatic measuring in pediatric mode may result in tissue damage or ischemia to the patient.**
4. **NIBP measurement can be affected by extremes of temperature, humidity and altitude.**
5. **NIBP measurement value should be explained by qualified professionals.**
6. **The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.**
7. **The cumulative use time for the NIBP cuff in a single patient should be less than 30 days.**

11.3 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

- A regular arterial pressure pulse is hard to detect.
- Patients with cardiac arrhythmias.
- Patients with excessive and continuous movement such as shivering or convulsions.
- Patients with rapid blood pressure changes.
- Patients with severe shock or hypothermia that reduces blood flow to the peripheries.
- Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- Patients on an edematous extremity.

11.4 Measurement Procedures

To obtain accurate measurements, the following operating steps need to be

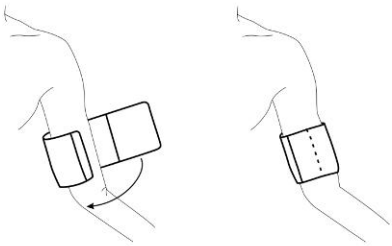
observed:

1. Ensure the patient position in normal use, including

- Comfortably seated or lie flat, legs uncrossed;
- Feet flat on the floor;
- Back and arm supported;
- Relax as much as possible, neither talking nor applying external pressure against the cuff. Rest for five minutes in a quiet environment.

2. Connect the air hose and switch on the monitor.

   Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below.



Cuff Usage

- Ensure that the cuff is completely deflated.

Apply the appropriate size cuff to the patient (About the cuff size selection, please refer to Section *NIBP accessories*), and make sure that the symbol "Φ" is over the artery. Ensure that the middle of the cuff is at the level of the right atrium of the heart and the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

3. Check whether the patient type is appropriately selected. Access the **Patient Management** on the MFM-CMS.
4. Select a measurement mode(auto, manual or STAT), algorithm(iCUFS or iFAST) and NIBP unit (mmHg, cmH_2O or kPa, 1 mmHg = 0.133 kPa, 1 mmHg=1.36 cmH_2O) in the **Parameter Setup** > **NIBP Setup** on the MFM-CMS.
5. Press the NIBP measurement key to start a measurement.
6. Wait until the first reading is taken.

NOTE:

1 The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80%-100% of the limb. The wrong size of cuff can cause

erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.

2 **If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.**

3 **Please make sure the cuff is well connected. A leak of air may cause measurement error.**

4 **Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.**

5 **Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.**

11.5 NIBP Setup

11.5.1 Setting Measurement Mode and Interval

There are three methods of measuring NIBP:

Manual - measurement on demand.

Auto - continually repeated measurements (between 1 and 480 minute adjustable interval). The interval can be user defined, and the default interval of user defined is 2.5 minutes. After the first measurement starts manually, the monitor will automatically measure NIBP as preset interval.

STAT - the measurement will run consecutively at an interval of 5 s in five minutes. After a STAT measurement series, the monitor returns to the previous mode.

WARNING

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

11.5.2 Selecting Measurement Algorithm

The EDAN NIBP module supports two measurement algorithms: iCUFS and iFAST. iCUFS measurement is the default algorithm. iFAST measurement shortens the blood

pressure measurement time and rapidly outputs values. iCUFS and iFAST are intended for use with pregnant, including pre-eclamptic patients.

To set the NIBP algorithm, select **Parameter Setup** > **NIBP Setup** on the MFM-CMS and set **NIBP Algorithm** to **iCUFS** or **iFAST**.

NOTE: The STAT measurement is disabled for the iFAST algorithm.

11.5.3 Setting Inflation Mode

To change the inflation mode:

1. On the MFM-CMS, Select **Parameter Setup** > **NIBP Setup** > **Inflation Mode**;
2. Choose **Manual** or **AUTO** from the pull-down list.
   - If **Manual** is chosen, the preset value by users will be adopted as the inflation value when measuring blood pressure.
   - If **AUTO** is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

11.5.4 Setting Inflation Value

To set the inflation value, select **Parameter Setup** > **NIBP Setup** > **Inflation Value** on the MFM-CMS.

11.5.5 Setting NIBP End Tone

The monitor can issue a reminder tone at the completion of NIBP measurement.

To set the NIBP end tone, select **Parameter Setup** > **NIBP Setup** on the MFM-CMS, **set** the appropriate volume for the **NIBP End Tone**. The volume ranges from 1 to 5 and Off. If it is set to Off, the NIBP end tone will be off.

11.6 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem, pick **Reset** in the **Menu** > **Maintenance** > **Parameter Maintain** to activate self-test procedure, and thus restore the system from abnormal performance.

11.7 Leakage Test

Leakage test is used to detect the air tightness of the NIBP pump, valve, and trachea. If not, the system will display NIBP leakage. NIBP leak detection should be performed at least once every two years or when you think the measurement is inaccurate.

WARNING

This leakage test other than being specified in the ISO 81060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of Leakage Test

1. Connect the cuff securely with the socket for NIBP air hole.
2. Wrap the cuff around the cylinder of an appropriate size, don't wrap the cuff around limbs.
3. Make sure the patient type has been set to **Adult**.
4. Access **Menu** > **Maintenance** > **Parameter Maintain**.
5. Select **Leakage Test**. Then the prompt **Testing** will appear indicating that the system has started the leakage test.

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates **Leakage Test Failed**. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

6. If the alarm information **Leakage Test Failed** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the leakage test. If the failure prompt still appears, please contact the manufacturer for repair.

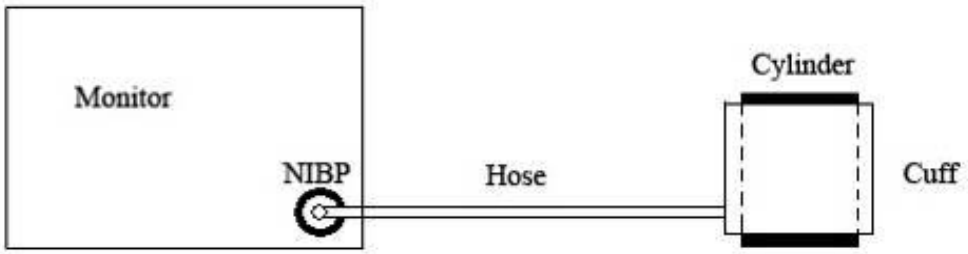


Diagram of NIBP Air Leakage Test

11.8 Manometer Mode

Manometer mode verifies accuracy of the NIBP system.

NOTE: The manometer test is for checking the measurement accuracy only and will not affect the measurement results.

Tools required: stopcock, NIBP extension tubes, cylinder (200 ml), manometer (measurement range should be within 0 to 300 mmHg; accuracy should be within ±0.3 mmHg.)

Procedure:

1. To conduct the NIBP accuracy test, access the User Maintain menu through the following sequence: **Menu** > **Maintenance** > **Parameter Maintain** > **Manometer**.
2. Connect the equipment as shown below.
3. Apply a fixed static pressure on the monitor with the help of a manometer.
4. Wait 10 seconds until the pressure stabilizes. Verify the displayed values on the monitor against the manometer setting.
5. A tolerance of ±3 mmHg is reasonable.

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Chapter 12 Monitoring TEMP

12.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin.

12.2 TEMP Safety Information

WARNING

1. **Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable from the socket, and then the screen will display the error message TEMP Sensor Off and the auditory alarm is activated.**
2. **Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.**
3. **Temperature probes do not need any probe covers; please remember to disinfect the reusable probe before and after each use on a patient.**

NOTE:

The reference body site is the same as the measuring site.

12.3 TEMP Setup

12.3.1 Selecting Measurement Site

On the MFM-CMS, select **Parameter Setup** > **T1/T2 Setup**, set the measurement site as **Skin**.

12.3.2 Setting TEMP Unit

On the MFM-CMS, select **Parameter Setup** > **T1/T2 Setup**, set the unit as ℃ or ℉.

12.3.3 Selecting TEMP Sensor Type

The user can choose the TEMP sensor type as the temperature signal source.

To configure the TEMP sensor type, on the MFM-CMS, select **Parameter Setup** > **T1/T2 Setup**, and set **Sensor Type** to **YSI-10K** or **YSI-2.252K**.

Chapter 13 Clinical Assistive Applications (CAA)

13.1 Nurse Call

Press the hard key of nurse call on the monitor, and the information of calling the nurse will be sent to the MFM-CMS. On the MFM-CMS, the waveform area of this patient will display the nurse call icon indicating that the patient is calling the nurse.

WARNING

Do not rely on the nurse call function. The medical staff must pay close attention to the condition of the patient.

Chapter 14 Using Battery and Charger Stand

If the battery is used to power the telemetry monitor, the telemetry device automatically shuts down when the battery runs out. To charge the battery, place the battery in the battery charger stand.

14.1 Battery Safety Information

WARNING

1. **Before using the rechargeable lithium-ion battery (hereinafter called lithium battery), be sure to read the user manual and safety precautions thoroughly.**
2. **The lithium battery can only be used for this device.**
3. **The lithium battery can only be charged in this battery charger stand.**
4. **Do not reverse the lithium battery polarity.**
5. **Do not connect the positive (+) and negative (-) terminals with metal objects such as lead wire, which can result in short circuits.**
6. **The cycle life of the lithium battery is 500 times. The service life of the lithium battery may shorten if it is used inappropriately. It is recommended to replace the lithium battery after 500 charge-discharge cycles, or it may cause safety risks such as heat and liquid leakage, and risks such as failure or decline of performance.**
7. **Do not heat or throw the lithium battery into a fire.**
8. **Do not immerse, throw, or wet the lithium battery in water, beverages or other liquids.**
9. **Do not use or leave lithium battery at high temperature (charging>45 ℃, discharging>60 ℃, such as in direct sunlight or in a very hot car), otherwise it may cause overheat, fire, malfunction to the lithium battery or charger stand, shorten the service life of the lithium battery or charger stand, or damage the lithium battery or charger stand.**
10. **Do not use a lithium battery of other specifications.**
11. **Keep lithium batteries out of the reach of children.**
12. **Do not hit with a hammer, step on, throw or drop to cause strong shock.**
13. **Do not weld the lithium battery directly.**
14. **Do not use a lithium battery with serious scratch or deformation.**
15. **Do not disinfect or autoclave the lithium batteries.**

WARNING

16 **Do not place the lithium battery near microwave equipment or other cooking devices. If the lithium battery is heated or subjected to strong electromagnetic radiation, liquid leakage, heat, smoke, fire, etc. may occur.**

17 **Power off the device, remove and stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage, or it may cause safety accidents such as heat, smoke, and fire.**

18 **Do not touch a leaking lithium battery. If the liquid leaked from the lithium battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.**

19 **When the device is running on lithium battery power, do not replace the lithium battery during operation of the device.**

20 **High internal temperature may also cause the lithium battery unable to be charged. Keep the device at room temperature and move it away from heat sources or out of direct sunlight. The lithium battery will resume charging when the temperature is within range again.**

21 **Lithium batteries should be charged, used and stored in places far away from static electricity.**

22 **Lithium batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or lithium batteries, please contact your local Civic Office, or the shop where you purchased the product.**

23 **Do not use lithium batteries with obvious scratches or serious deformation.**

24 **The lithium battery should be removed immediately after it has been fully charged to prevent potential overcharging and ensure optimal performance.**

14.2 Battery Charger stand Safety Information

WARNING

1 **Before using the CS-10 Charger Stand (hereinafter called battery charger stand), be sure to read the user manual and safety precautions thoroughly.**

WARNING

2 **The battery charger stand can only be used for this device.**
3 **Do not throw the charger stand into a fire.**
4 **Do not immerse, throw, or wet the charger stand in water, beverages or other liquids.**
5 **Do not use or leave the charger stand at high temperature (charging>45 ℃, discharging>60 ℃, such as in direct sunlight or in a very hot car), otherwise it may cause overheat, fire, malfunction to the lithium battery or charger stand, shorten the service life of the lithium battery or charger stand, or damage the lithium battery or charger stand.**
6 **Do not use a charger stand of other specifications.**
7 **Keep the charger stand out of the reach of children.**
8 **Do not place the charger stand near microwave equipment or other cooking devices. If the charger stand is heated or subjected to strong electromagnetic radiation, liquid leakage, heat, smoke, fire, etc. may occur.**
9 **Operate the battery charger stand on a stable and flat surface, protect the stand against mechanical damage resulting from falls, impacts, and vibration.**
10 **Do not autoclave battery charger stand.**
11 **Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.**
12 **When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.**
13 **SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.**
14 **If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.**

WARNING

15 **The appliance coupler or mains plug is used as isolation means from supply mains.**

16 **Additional multiple socket-outlets or extension cords can't be connected to the system.**

17 **SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.**

18 **Before connecting the charger stand to the AC power, make sure the voltage and the power frequency are consistent with the requirements indicated on the label or in this user manual.**

19 **The device must be connected to the ground to avoid the signal interference.**

20 **Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.**

14.3 Battery Status on the Main Screen

Battery status symbols show the status of battery and the battery power remaining.

Remaining battery power: 76%~100%.

Remaining battery power: 51%~75%

Remaining battery power: 26%~50%

Remaining battery power: 1%~25%

Battery low.

14.4 Charging the Battery

The battery charger stand can charge up to 10 lithium batteries at the same time. The procedure for charging lithium battery is as follows:

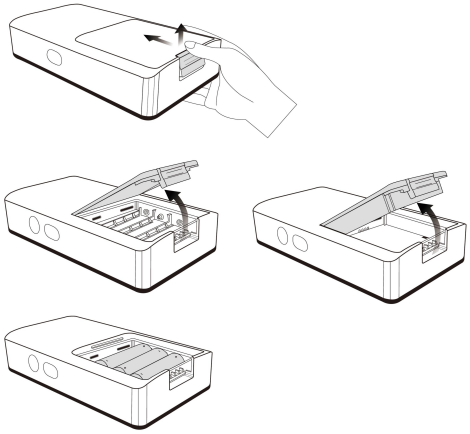
1. Load the battery into the stand and connect the charger stand to the mains power. The indicator flashes in green when battery is being charged.
2. Charge the battery until it is full, the indicator illuminates in green.

NOTE: When a charging fault occurs, the charging indicator is off. Please contact the manufacturer.

14.5 Replacing the Battery

To install or replace a battery, follow these steps:

1. Press the lower side of the battery door, push the battery door outward.
2. Take out the battery to be replaced.
3. Place one lithium battery or three new AA batteries in the battery slot.
4. Close the battery door.



14.6 Maintaining the Battery and Battery Charger Stand

The performance of rechargeable batteries may deteriorate over time. It is recommended to check and maintain the batteries regularly every 3 months.

1. Disconnect the patient from the device and stop all measurement.
2. Switch off the device, remove the batteries and load them into the charger stand, connect the charger stand to mains power, install the battery and fully charge it.
3. Disconnect the charger stand from mains power, install the batteries into the device, switch on the device and let the device run until there is no battery power left and the device shuts off.
4. Reconnect the charger stand to mains power and charge the battery until it is full for use or charge to 40%~60% for storage.

NOTE:

1 Do not use the device on a patient during the battery maintenance.

2 Do not interrupt the battery maintenance process.

Check the battery charger stand daily for signs of damage and replace it as needed. When cleaning the battery charger stand, do not touch the metal contacts of the battery charger stand or the lithium battery. Please follow the following steps to clean the charger stand:

1. Disconnect the battery charger stand from the AC power supply.

2. Wet a soft cloth with mild soapy water and wipe the battery charger stand.
3. Wipe off any cleaning solution with a dry cloth.
4. Use the battery charger stand after it is thoroughly dried.

14.7 Storing the Battery

Remove the battery and store it at a cool and dry environment if the battery or the device is not used for a long time. Charge the batteries to 40%-60% for storage. Check and maintain the batteries regularly every 3 months. For more information, please refer to Section *Maintaining the Battery and battery charger stand*.

NOTE:

1. **When storing batteries, make sure that the battery terminals do not come into contact with metallic objects.**
2. **The service life of the battery will be shortened if it is stored at high temperature for a long time. Storing batteries in a cool place can slow down the aging process. The ideal storage temperature is 15 °C.**

14.8 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. If you suspect that the battery may have failed, check the battery performance.

Refer to Step 1~Step 3 in Section *Maintaining the Battery and battery charger stand* and record the running time of the battery which reflects the battery performance directly. If the running time is obviously less than the specified time in the specification, the battery may have reached its service life or malfunctioned, please change the battery or contact the service personnel. If the running time meets the specification, then the battery can continue to be used normally.

14.9 Recycling the Battery and Battery Charger Stand

When the battery or the charger stand no longer holds a charge, it should be replaced. Remove the old battery or the charger stand and recycle it properly.

WARNING

Do not disassemble batteries or the battery charger stand, put them into fire or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

Chapter 15 Care and Cleaning

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

EDAN Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

15.1 Safety Instructions

Reusable products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

► Follow the infection prevention policies and reprocessing regulations of the health-care facility.

► Follow the national infection prevention policies and reprocessing regulations.

► Use validated procedures for reprocessing.

► Reprocess reusable products after every use.

► Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices. Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

► Check the products for signs of wear and replace them if necessary.

Disposable products

Disposable products have been designed, tested, and manufactured exclusively for single use. Reuse, reprocessing, or sterilization can result in failure of the accessory, incorrect measurements, and injury to the patient.

► Do not reuse disposable products.

► Do not reprocess disposable products.

► Do not use any disinfectants.

15.2 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer’s instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the equipment or any accessories..
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- To prevent corrosion, do not allow cleaners or disinfectants to contact with metal parts and connectors on equipment and accessories.
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

NOTE:

Automated cleaning/disinfection to the equipment and accessories are prohibited.

15.3 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. Refer to the cleaning agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

15.3.1 Cleaning the Monitor and Charger Stand

WARNING

Before cleaning the monitor, make sure that the monitor is switched off.

To surface-clean the monitor and charger stand, follow these steps:

1. Switch off the monitor, remove the batteries in the monitor and disconnect the power cable of the charger.
2. Remove all residual foreign matters from the surface of the monitor and charger stand using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Use a clean cotton swab dampened with the cleaning solution to wipe the surface apertures of the equipment and charger stand until no visible contaminants remain.
4. Use a soft clean cloth dampened with the cleaning solution to wipe the entire exterior surface of the equipment and charger stand until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
6. Dry the monitor in a ventilated and cool place.
7. If the monitor or charger stand is not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the monitor and charger stand to ensure that there is no damage.

15.3.2 Cleaning the Reusable Accessories

15.3.2.1 Cleaning the ECG Cable Assembly

1. Remove ECG cables from the monitor.
2. Remove all residual foreign matters from the surface of ECG cables using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel

dampened with tap water until no visible cleaning agent remains.

5. Wipe off residual moisture with a dry cloth.
6. Leave the cable assembly to air dry.
7. If the ECG cables are not visually clean after cleaning please repeat the cleaning steps through step 3 to step 6.
8. Inspect the ECG cables to ensure that there is no damage.

15.3.2.2 Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

1. Remove NIBP Cuff from the monitor, and take out the air bladder.
2. Remove all residual foreign matters from the surface of cuff and air bladder using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. Clean the surface of the cuff and the air bladder thoroughly until no visible contaminants remain.
4. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Air dry the cuff thoroughly after cleaning.
7. If the cuff and the air bladder are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the cuff and the air bladder to ensure that there is no damage.

Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.
2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
3. Adjust the bladder until it is in position.

15.3.2.3 Cleaning the SpO_2 Sensor

1. Remove SpO_2 sensors from the monitor.

2. Remove all residual foreign matters from the surface of SpO_2 sensors, including cables, using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
6. Wipe off residual moisture with a dry cloth.
7. Leave the sensor to air dry.
8. If the SpO_2 sensors, including cables, are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 7.
9. Inspect the SpO_2 sensors, including cables, to ensure that there is no damage.

15.3.2.4 Cleaning the TEMP Sensor

1. Remove TEMP sensors from the monitor.
2. Remove all residual foreign matters from the surface of TEMP sensors using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the sensor with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Leave the sensor to air dry.
7. If the TEMP sensors are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the TEMP sensors to ensure that there is no damage.

15.4 Disinfection

Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for disinfecting the monitor are:

- Ethanol (75%)
- Ethanol (70%)
- Isopropanol (70%)
- Hydrogen Peroxide solution 0.5-1% concentration
- PDI Sani-Cloth Bleach Germicidal Disposable Wipes. (Composition: 0.63% Sodium Hypochlorite.)
- PDI Super Sani-Cloth Germicidal Disposable Wipes. (Composition: 55% Isopropyl alchohol, 0.25% Akly dimethyl benzyl ammonium chlorides, 0.25% Akyl ethylbenzyl ammonium chloride.)
- Diversey Oxivir 1 Wipes. (Composition: 0.5% Hydrogen Peroxide)
- Diversey Oxivir Tb Wipes. (Composition: 0.5% Hydrogen Peroxide)
- Sodium Hypochlorite solution 6500 ppm (household bleach diluted ~1:10)
- Health Essence Disinfecting Effervescent Tablets. (Composition: active chlorine, trichloroisocyanuric acid 500~1000mg/L)
- Clinell Sporicidal Wipes. (Composition: peracetic acid)
- Dian Erkang II Wipes. (Composition: 1.8g/L~2.2g/L Quaternary Ammonium, 14%~17% Isopropyl Alchohol, 36%-44% Ethanol)
- Mikrozid Sensitive Wipes. (Composition: 100 g solution contains the following active substances: 0.26 g Alkyl Dimethylbenzyl Ammonium Chloride, 0.26 g Didecyldimethylammonium Chloride, 0.26 g Alkyl Ethylbenzylammonium Chloride)
- Clorox Dispatch Hospital. (Composition: Sodium Hypochlorite 0.65%)
- Dismozon plus. (Composition: Magnesium Monoperoxyphthalate Hexahydrate 958 mg/g)
- Descosept AF wipes. (Composition: 100 g solution contains the following active substances: 42 g Ethanol and 0.05 g Didecyl Dimethyl Ammonium Chloride)
- Incidin Oxywipes. (Composition: Hydrogen Peroxide 1.5%)
- Terralin Liquid. (Composition: 100 g solution contains the following active substances: 42 g Ethanol and 35 g Propyl Alcohol)
- Mikrozid universal. (Composition: 100 g solution contains the following active substances: 17.4 g Propane and 12.6 g Ethanol)
- Dian Erkang Surface Wipes. (Composition: Didecyldimethylammonium Chloride,

Dodecyl Dimethyl Benzyl Ammonium Chloride, Isopropyl Alchohol)

- Hydrogen Peroxide 3%.
- Clinell Universal Wipes. (Composition: RO pure water, surfactant, Double-Chain Quaternary Ammonium Salt Compound (w/w) 0.765%-0.935%)
- 0.5% sodium hypochlorite.
- 2% glutaraldehyde.
- 50% N-propanol.
- Clorox Bleach Gemicidal Wipes. (Composition: 0.55% Sodium Hypochlorite).
- Clorox disinfecting wipes. (Composition: 0.368% Chlorine Quaternary Ammonium Salt).
- Cleanisept wipes. (Composition: 100 g solution contains the following active substances: 0.5 g Alkyl Dimethylbenzyl Ammonium Chloride and 0.25 g Didecyldimethylammonium Chloride)
- Mikrozid AF wipes. (Composition: Ethanol, Isopropanol)
- Mikrozid PAA Wipes. (Composition: 100 g solution contains the following active substances: 0.06 g Peracetic Acid, Hydrogen Peroxide and Acetic Acid)
- Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes. (Composition: Hydrogen Peroxide 1.4%)

Final dilution shall be determined according to the chlorine concentration in the specific household bleach solution, bought from market.

The validated disinfectants for disinfecting the reusable accessories and charger stand are:

- Ethanol (75%)
- Isopropanol (70%)

Disinfecting agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. Refer to the disinfecting agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

WARNING

The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

CAUTION

1. **Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.**
2. **Although the monitor chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, unvalidated cleaners or disinfectants are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.**
3. **Do not use phenol disinfectants because vinyl absorbs them. Do not use strong aromatic, chlorinated, ketone, ether or ester solvents. Do not immerse the cables for any prolonged period in alcohol, mild organic solvents, or highly alkaline solutions. Never boil or autoclave the cable. Vinyl withstands temperatures up to 100 °C but begins to soften at around 90 °C. Handle gently when hot and wipe away from the tip toward the cable.**

15.4.1 Disinfecting the Monitor and Charger Stand

WARNING

Before disinfecting the monitor, make sure that the monitor is switched off.

To disinfect the monitor and charger stand, follow these steps:

1. Switch off the monitor. Disconnect the charger from the power cable.
2. Clean and dry the monitor and charger stand according to the methods in section *Cleaning the Monitor and Charger Stand* prior to disinfection.
3. Prepare the disinfectant solution.
4. Use a clean cotton swab dampened with the disinfectant solution to wipe the surface apertures of the equipment and charger stand. Follow the disinfectant manufacture's recommended contact time and mode.
5. Use a soft clean cloth dampened with the disinfectant solution to wipe the entire exterior surface of the equipment and charger stand. Follow the disinfectant manufacture's recommended contact time and mode.
6. After disinfection, wipe off the disinfecting agent with a new sterile cloth

dampened with sterile water.

7. Dry the monitor and charger stand for at least 30 minutes in a ventilated and cool place.
8. Inspect the monitor and charger stand to ensure that there is no damage.

15.4.2 Disinfecting the Reusable Accessories

15.4.2.1 Disinfecting the ECG Cable Assembly

1. Remove ECG cables from the monitor.
2. Clean and dry the ECG cables according to the methods in section *Cleaning the ECG Cable Assembly* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the cable assembly to air dry for at least 30 minutes.
7. Inspect the ECG cables to ensure that there is no damage.

15.4.2.2 Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

1. Remove NIBP Cuff from the monitor, and take out the air bladder.
2. Clean and dry the NIBP Cuff and air bladder according to the methods in section *Cleaning the Blood Pressure Cuff* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
5. Leave the cuff and air bladder to air dry for at least 30 minutes.
6. Inspect the cuff and the air bladder to ensure that there is no damage.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to *Cleaning the Blood Pressure Cuff* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

15.4.2.3 Disinfecting the SpO_2 Sensor

1. Remove SpO_2 sensors from the monitor.
2. Clean and dry the SpO_2 sensor according to the methods in section *Cleaning the SpO_2 Sensor* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
5. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
6. Wipe off the disinfection solution with a dry cloth after disinfection.
7. Leave the sensor to air dry for at least 30 minutes.
8. Inspect the SpO_2 sensors, including cables, to ensure that there is no damage.

15.4.2.4 Disinfecting the TEMP Sensor

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Remove TEMP sensors from the monitor.
2. Clean and dry the TEMP Sensor according to the methods in section *Cleaning the TEMP Sensor* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the sensor with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the sensor to air dry.
7. Inspect the TEMP sensors to ensure that there is no damage.

15.5 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

15.6 After Reprocessing

- After reprocessing, the equipment, cables, cuffs, sensors and other accessories should be checked to ensure there are no signs of aging, wear, cracks, deformation, discoloration or peeling, etc. Replacement should be taken or contact the service personal of the manufacturer if necessary.
- Assembling and attaching device-specific components

Prerequisite:

All components have been reprocessed and are dry.

- Preparation before next use of device

Assembling and fitting patient-specific accessories and consumables, i.e. SpO_2 sensors and NIBP Cuffs.

15.7 Storage and Transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

– Store dry and free of dust

– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

Chapter 16 Maintenance

WARNING

1. **Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
2. **If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.**
3. **The maintenance operations like software upgrade of the device can only be completed by EDAN's qualified service professionals.**
4. **Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.**

NOTE: The SBOM enables users to effectively manage their assets, understand the potential impact of identified vulnerabilities on the medical device system, and deploy countermeasures to maintain the device's safety and effectiveness. If required, contact the manufacturer to request the SBOM.

16.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, prior to use and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- Battery performance.
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

16.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for EDAN-qualified service professionals only. Contact an EDAN-qualified service provider if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

Chapter 17 Warranty and Service

17.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.
b) subsequent damage caused by improper use or maintenance.
c) damage caused by alteration or repair by anyone not authorized by EDAN.
d) damage caused by accidents.
e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

NOTE:

The products marked with this symbol apply to the European WEEE directive. This symbol Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.

17.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.

Chapter 18 Accessories

You can order accessories from EDAN supplies at www.edan.com or consult your local EDAN representative for details.

WARNING

1. **Never reuse disposable transducers, sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard.**
2. **Use only EDAN-approved accessories. Using non-EDAN-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by EDAN with patient monitors by other manufacturers.**
3. **The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.**

NOTE:

1. **Transducers and sensors have a limited shelf life. Refer to the package labeling.**
2. **Please refer to the accessory service life on the package labeling.**

The following cables may not all be available in all countries. Please check availability with your local EDAN supplier.

18.1 ECG Accessories

Part Number	Accessories
ECG Cable	
01.57.472359	iT30 3-lead Defib-proof, IEC, Snap
01.57.472360	iT30 3-lead Defib-proof, AHA, Snap
01.57.472361	iT30 3-lead Defib-proof, IEC, Clip
01.57.472362	iT30 3-lead Defib-proof, AHA, Clip
01.57.472363	iT30 5-lead Defib-proof, IEC, Snap
01.57.472364	iT30 5-lead Defib-proof, AHA, Snap
01.57.472365	iT30 5-lead Defib-proof, IEC, Clip

Part Number	Accessories
01.57.472366	iT30 5-lead Defib-proof, AHA, Clip
01.57.472367	iT30 6-lead Defib-proof, IEC, Snap
01.57.472368	iT30 6-lead Defib-proof, AHA, Snap
01.57.472369	iT30 6-lead Defib-proof, IEC, Clip
01.57.472370	iT30 6-lead Defib-proof, AHA, Clip
01.57.472371	iT30 10-lead Defib-proof, IEC, Snap
01.57.472372	iT30 10-lead Defib-proof, AHA, Snap
ECG Electrode	
01.57.471858	Disposable ECG Electrodes
01.57.471862	Disposable ECG Electrodes
01.57.471859	Disposable ECG Electrodes
01.57.471897	Disposable ECG Electrodes
01.57.471898	Disposable ECG Electrodes
01.57.472011	Disposable ECG Electrodes
01.57.472012	Disposable ECG Electrodes
01.57.472013	Disposable ECG Electrodes
01.57.472014	Disposable ECG Electrodes

18.2 SpO_2 Accessories

Part Number	Accessories
02.01.210120	SH1 Adult Reusable SpO_2 Sensor (DB9)
02.01.210122	SH4 Adult Silicone Soft-tip SpO_2 Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO_2 Sensor
01.57.471235	SHD-A SpO_2 Sensor, adult, disposable
01.57.471236	SHD-P SpO_2 Sensor, pediatric, disposable
01.57.471237	SHD-I SpO_2 Sensor, Infant, disposable
01.57.471405	SpO_2 Extension cable for telemetry monitor
02.57.225230	Silicone Soft-tip Sensor, adult, 1 m, reusable
02.57.225231	Silicone Soft-tip Sensor, pediatric, 1 m, reusable

18.3 NIBP Accessories

Part Number	Accessories
01.57.472703	NIBP Cuff, Small child E6, 3-17cm, reusable
01.57.472704	NIBP Cuff, Child E7, 16-21.5 cm, reusable
01.57.472705	NIBP Cuff, Small adult E8, Small adult, 20.5-28 cm, reusable
01.57.472706	NIBP Cuff, Adult E9, Adult, 27-35 cm, reusable
01.57.472707	NIBP Cuff, Large adult E10, Large adult, 34-43 cm, reusable
01.57.472727	NIBP Cuff, Infant E5, Infant, 10-15 cm, reusable
01.57.472010	NIBP tube

18.4 TEMP Accessories

Part Number	Accessories
02.57.472358	iT30 SpO_2 temperature connection cable
01.57.472543	Temperature Probe/Skin, adult, (2.252kΩ/0.65m) TP2AS2R
01.57.472556	Temperature Probe/Skin, adult, (10kΩ/0.65m) TP2AS10R
01.57.472557	Temperature Probe/Skin, Infant, (2.252kΩ/0.65m) TP2NS2R
01.57.472558	Temperature Probe/Skin, Infant, (10kΩ/0.65m) TP2NS10R

18.5 Other Accessories

Part Number	Accessories
01.13.036638	Power cable, length 1.8 m, VDE
01.13.037122	Power cable, length 1.8 m, American standard, medical grade
02.21.064450	Rechargeable Li-ion Battery Pack
01.56.467935	iT30&iT50 Transparent Portable Bag
01.51.414585	iT30 Host Protective Casing
01.51.414633	iT50 Host Protective Casing
01.21.064086	Alkaline Battery, LR6,1.5 V, 2600 mAh
01.56.467523	iT30&iT50 Portable Bag
83.60.262992	CS-10 Charger stand

NOTE:
The part name may vary depending on context, but the part number is constant.

A Product Specification

NOTE: The performance of the equipment with ☆ mark is determined to be essential performance.

A.1 Classification

Anti-electroshock type	iT30 & iT50: internal powered equipment
Anti-electroshock degree	DEFIBRILLATION-PROOF TYPE CF
Ingress Protection	iT30: IP67 iT50: IP44
Disinfection/sterilization method	Refer to Chapter *Care and Cleaning* for details.
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1; IEC 60601-1-2; IEC 80601-2-49.
Anti-drop degree	The monitor meets the requirements of 1.5 m drop test.

A.2 Physical Specifications

A.2.1 Size and Weight

Product	Size	Weight	
iT30	65 mm (W)*125.5 mm (H)*25 mm (D)	240 g±10%	With Li-ion battery, no accessories.
iT50	76 mm (W)*136 mm (H)*28.5 mm (D)	325 g±10%	

A.2.2 Function Configuration

Product	Standard configuration	Optional configuration
iT30	ECG	RESP, TEMP, SpO_2, PR
iT50	ECG, RESP, NIBP, PR, SpO_2	TEMP

A.2.3 Environment Specification

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature	
Working	+0 °C to +40 °C (32 ºF ~104 ºF)
Transport and Storage	-20 °C to +60 °C (-4 ºF ~140 ºF)
Humidity	
Working	15%RH ~ 95%RH (non-condensing)
Transport and Storage	15%RH ~ 95%RH (non-condensing)
Altitude	
Working	57 kPa ~ 107.4 kPa
Transport and Storage	16 kPa ~ 107.4 kPa

A.2.4 Display

Product	Display
iT30	3.5-inch color touch screen, resolution: 480*320
iT50	3.5-inch color touch screen, resolution: 480*320

A.2.5 Battery Specification

Battery	D.C. 3.8 V lithium battery (4000 mAh)
Operating Time	≥72 h (iT30 and iT50: 3/5 leads ECG continuous measurement, other parameters are off.) ≥48 h (iT30 and iT50: 5 leads ECG and SpO_2 continuous measurement, other parameters off) ≥24 h (iT50: 5 leads and SpO_2 ECG continuous measurement, NIBP automatic measurement at intervals of 30 minutes, other parameters off) Operating conditions: Fully charged new battery is used, ambient temperature is 20 ℃~30 ℃, in telemetry mode, the monitor is connected to MFM-CMS through Wi-Fi, the screen display is closed, no audio and light alarm, no pulse sound, data storage in the monitor is turned off.
Charge Time	< 5 h (charge to 90%)
Charge/Discharge Cycle	500 times

A.2.6 Charger Stand Specification

The charger stand is powered by AC power.

Anti-electroshock type	Class I equipment
Ingress Protection	IPX0
Power supply	100 V-240 V ~, 50 Hz/60 Hz, 1.54 A~0.5 A
Weight	2 kg
Size	370 mm*150 mm*70 mm

A2.7 Data Storage

Trend Data	24 Hours, Resolution 1s
Trend Waveform	24 Hours
Alarm Event	Up to 1200 sets, including physiological alarm and technical alarm
Log	Up to 1200 sets

A.3 ECG

Complies with IEC 60601-2-25, IEC 60601-2-27.

Lead Mode	3 Electrodes: I, II, III 5 Electrodes: I, II, III, aVR, aVL, aVF, V 6 Electrodes: I, II, III, aVR, aVL, aVF, and leads corresponding to Va Vb. 10 Electrodes: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Electrode Standard	AHA, IEC
☆Display Sensitivity (Gain Selection)	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4), AUTO gain
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s

Bandwidth (-3dB) (Output amplitude relative to that for a 5 Hz sinusoidal input signal)	Diagnosis: 0.05 Hz to 150 Hz ST: 0.05 Hz to 40 Hz Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Custom: High-pass Filter and Low-pass Filter (Refer to *Changing the ECG Filter Settings*)
☆CMRR (Common Mode Rejection Ratio)	≥ 123 dB
Hum Filter	In diagnosis, ST, monitor, Surgery and enhanced modes: 50 Hz/60 Hz (Hum filter can be turned on or off manually)
☆Differential Input Impedance	≥ 5 MΩ
☆Input Signal Range	±10 mV PP
☆Accuracy of Signal Reproduction	An error of ≤ ±20% of the nominal value of the output or ±100 μV, whichever is greater. The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.
☆Electrode Offset Potential Tolerance	± 500 mV
Auxiliary Current (Leads off detection)	Active electrode: < 100 nA Reference electrode: < 900 nA
☆Recovery Time After Defibrillation	< 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Leakage Current of Patient	< 10 μA
Scale Signal	1 mV PP, accuracy is ±5%
☆Input Noise	≤ 20 μVPP
☆Multichannel Crosstalk	≤ 5% of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.

☆Frequency and Impulse Response	Frequency response: Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71 % to 110 % at 0.67 Hz and 40 Hz. Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm. Impulse response: Displacement value: ≤ 0.1 mV Slope: ≤ 0.3 mV/s following the end of the pulse. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.
Sampling Frequency	111 kHz
Resolution	2.44 uV/LSB
☆ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤ 10 s
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.
Minimum Input Slew Rate (Lead II)	> 2.5 V/s
☆Baseline Reset Time	< 3 s
Pace Pulse without overshoot	
☆Pulse Indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to2.0 ms Ascending time: 10 μs to 100 μs
☆Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs
Pace Pulse Detecting Lead: one among I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6.	
Heart Rate	
HR Calculation	

☆Range	ADU: 15 bpm to 300 bpm PED: 15 bpm to 350 bpm
☆Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm (For display and alarm limit)
Sensitivity	≥ 300 μVPP
☆QRS Detection Range	The detection range has exceeded the requirement described in the standard: Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric. Amplitude: 0.5 mv~5 mv In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.
PVC	
Range	ADU: (0 to 300) PVCs/ min PED: (0 to 350) PVCs/ min
Resolution	1 PVCs/min
Pauses/min	
Range	ADU/PED: (0 to 30) pauses/min
Resolution	1 pause/min
ST value	
Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
QT measurement	
Range	200 ms ~ 800 ms
Resolution	4 ms
Accuracy	± 30 ms
QTc measurement	
Range	200 ms ~ 800 ms
Resolution	1 ms

ΔQTc measurement	
Range	-600 ms ~ 600 ms
Resolution	1 ms
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200 ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Normal	Adult: 0.5 s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric: 0.375 s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex≥ 1.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≥ 1 s.
Range of Ventricular Rhythm	
Ventricular Tachycardia	The interval of 5 consecutive ventricular beats is less than 600 ms.
Ventricular Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.
Ventricular Bradycardia	The interval of 5 consecutive ventricular beats is more than 1000 ms.
Acc. Vent Rhythm	5 consecutive ventricular beats, and 40 bpm ≤ ventricular HR < 100 bpm.
Maximum Start-up Alarm Time for Tachycardia	
Ventricular Tachycardia 1 mV 206 bpm	Gain 0.5: 10 s Gain 1.0: 10 s Gain 2.0: 10 s
Ventricular Tachycardia 2 mV 195 bpm	Gain 0.5: 10 s Gain 1.0: 10 s Gain 2.0: 10 s

Response Time of Heart Rate Meter to Change in HR	HR range: 80 bpm to 120 bpm Range : Within 11 s HR range: 80 bpm to 40 bpm Range : Within 11 s		
☆Tall T-wave Rejection	Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude		
Accuracy of Heart Rate Meter and Response to Irregular Rhythm	Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy: 80 bpm±1 bpm Slow alternating ventricular bigeminy: 60 bpm±1 bpm Rapid alternating ventricular bigeminy: 120 bpm±1 bpm Bidirectional systoles: 91 bpm±1 bpm		
Time to Alarm for Heart Rate alarm conditions	Asystole alarm: ≤ 10 s HR low alarm: ≤ 10 s HR high alarm: ≤ 10 s		
Arrhythmia analyses	ASYSTOLE	VFIB/VTAC	COUPLET
	VT > 2	BIGEMINY	TRIGEMINY
	VENT	R ON T	PVC
	TACHY	BRADY	MISSED BEATS
	IRR	VBRADY	PNC
	PNP		
12-Lead ECG Synchronization Analysis	Average parameters of heart beat		
	Heart rate (bpm)		
	Time limit of P wave (ms)		
	PR interval (ms)		
	QRS interval (ms)		
	QT/QTC (ms)		
	P-QRS-T AXIS		

A.4 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is Lead II.

Calculation Type	Automatic
Baseline Impedance Range	200 Ω to 2500 Ω (with ECG cables of 1 KΩ resistance)
Measuring Sensitivity	Within the baseline impedance range: 0.3 Ω
Waveform Bandwidth	0.2 Hz to 3.3 Hz (-3 dB)
Respiration Excitation Waveform	55.56 kHz (±10%), < 300 μA
☆Measuring Range	0 rpm ~ 200 rpm
Accuracy	±2 rpm (6 rpm~200 rpm) Undefined (0 rpm~5 rpm)
Resolution	1 rpm (For display and alarm limit)
Update time	1 s
☆Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
☆No breath Detected Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

A.5 SpO_2

Complies with ISO 80601-2-61.

Measuring Range	0% to 100%
Resolution	1% (For display and alarm limit)
☆Refreshing rate	1 s
☆Data Update Period	≤ 20 s (normal perfusion, no disturbance, SpO_2 value sudden change from 70% to 100%)
☆Accuracy	±2% (70% to 100% SpO_2)
	Undefined (0% to 69% SpO_2)
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Sensor	
Red Light	(660±3) nm
Infrared Light	(905±10) nm
Emitted Light Energy	< 15 mW
Sensor Light Intensity Display	5 levels
SI	

Measuring Range	0~10, invalid SI value is -?-
Resolution	1

NOTE: The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A.6 PR

	Measuring range	Accuracy	Resolution
PR(SpO_2)	20 bpm to 300 bpm	± 2 bpm	1 bpm(For display and alarm limit)
PR(NIBP)	40 bpm to 240 bpm	± 3 bpm or 3.5%, whichever is greater	1 bpm(For display)

A.7 NIBP*

*Applicable to iT50 only.
Complies with IEC 80601-2-30.

Technique	Oscillometry
Algorithm Selection	iCUFS, iFAST
Mode	Manual, Auto, STAT
Measuring Interval in AUTO Mode	1~480 and User Define (unit: minutes)
STAT	5 min, interval is 5 s
Measuring Parameter	SYS, DIA, MAP, PR
Pressure Unit	kPa, mmHg, cmH_2O
☆Measuring Range	
☆Adult Mode	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
☆Pediatric Mode	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
☆Alarm Type	SYS, DIA, MAP
☆Cuff Pressure Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1 mmHg (For display and alarm limit)
☆Maximum Mean Error	±5 mmHg
☆Maximum Standard Deviation	8 mmHg

Maximum Measuring Period	120 s
Typical Measuring Period	iCUFS: 30 s to 45 s (depend on HR/motion disturbance) (measured with E9 cuff, default inflation value, PR is set as 80 bpm and systolic pressure within 100~120 mmHg,) iFAST: 15s (depend on SYS, arm circumference and HR/motion disturbance) (measured with E8 cuff, PR is set as 80 bpm and systolic pressure is 100~120 mmHg)
Overpressure Protection	(297±3) mmHg (Adult)
	(245±3) mmHg (Pediatric)
Pre-inflation Pressure	
Adult Mode	Range: 80/100/120/140/150/160/180/200/220/240 mmHg
Pediatric Mode	Range: 80/100/120/140/150/160/180/200 mmHg

A.8 TEMP

Complies with ISO 80601-2-56.

Technique	Thermal resistance
Position	Skin
Channel	1
Sensor Type	YSI-10K and YSI-2.252K
Unit	°C, °F
Measuring Range	0 °C to 50 °C (32 ºF to 122 ºF)
Resolution	0.1 °C (0.1 ºF) (For display and alarm limit)
☆Accuracy	±0.2 °C at 25 °C~45 °C ±0.3°C at other range, the accuracy consists of follows: (1) Accuracy (excluding sensor error) : ±0.1 °C (2) Sensor error: 25 °C~45 °C: ±0.1°C; Other: ±0.2 °C
Refresh Time	Every 1 s to 2 s
Temperature Calibration	At an interval of 5 to 10 minutes
Measuring Mode	Direct Mode
Transient Response Time	≤ 30 s

A.9 Interfaces

Interface Name	Interface Type	Interface Quantity	Interface Specification
USB Type-C Interfaces	Input, Output	1	Support connection to PC for data exchange.
Wi-Fi	Input, Output	1	Support 2.4 GHz Wi-Fi, 5 GHz Wi-Fi.
E-link	Input, Output	1	Support connection to third party's temperature module and mobile phone for data exchange.
NFC	Input, Output	1	Support Swipe card to verify identity.

A.9.1 Wi-Fi Technical Specifications

Radio Technology	802.11 a/b/g/n
Frequency Range	2412 MHz ~ 2472 MHz, 5180 MHz-5240 MHz, 5745 MHz-5825 MHz
Modulation	CCK, BPSK, QPSK, 16-QAM, 64-QAM
Output power	≤20 dBm (CE requirement: detection mode - RMS) ≤30 dBm (FCC requirement: detection mode - peak power)
Transmit rate	IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 65 Mbps IEEE 802.11a: 6 Mbps to 54 Mbps
Bandwidth	2.4 GHz & 5 GHz 20 MHz

A.9.2 Wi-Fi Performance Specifications

System Capacity and Resistance to Wireless Interference	When the following conditions are present, ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ The AP signal strength of the monitor should be stronger than -55 dBm. ■ When the distance between the interfering devices and the monitor is more than 30 cm, and there are a co-channel interference Wi-Fi network

	(at least -80 dBm weaker than the monitor's network) and an adjacent-channel Wi-Fi network (at least -45 dBm weaker than the monitor's network) at the same time. Note: Excluding the Wi-Fi devices, the interfering devices include but are not limited to: ◆ 2.4 G or 5 G wireless devices (excluding Wi-Fi devices) ◆ Cellular mobile communication networks ◆ Microwave ovens ◆ Interphones ◆ Mobile phones ◆ ESU equipment The wireless network function of all monitors works normally and meets the following requirements: ■ Total delay time for data transmission from the monitors to MFM-CMS: ≤ 2 s. ■ Effective time for monitor-related settings configured on the MFM-CMS: ≤ 2 s.
Wi-Fi Network Stability	When the following conditions are present, ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ The AP signal strength of the monitor should be stronger than -55 dBm. The following requirements must be met: ■ Within 24 hours, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.4%. When the connected 8 monitors roam for 30 times, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.4%.
Distinct Vision Distance	The distinct vision distance between the monitor and the AP: 30 meters.

A.9.3 E-Link

Radio Technology	BLE5.1
Frequency Range	2400 MHz ~ 2483.5 MHz
Modulation	GFSK
Output power	< 20 dBm
Transmit rate	BLE: 1 Mbps
Bandwidth	BLE: 2 MHz

A.9.4 NFC

Protocol	ISO/IEC 14443, Felica, ISO15693
Frequency Range	13.56MHz
Transfer speeds	106kbit/s, 212kbit/s, 424kbit/s, 848kbit/s

B EMC Information

- Guidance and Manufacture's Declaration

B.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
iT30 & iT50 are intended for use in the electromagnetic environment specified below. The customer or the user of iT30 & iT50 should assure that they are used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iT30 & iT50 use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	iT30 & iT50 are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

NOTE: The EMISSIONS characteristics of iT30 & iT50 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) iT30 & iT50 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

B.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity
iT30 & iT50 are intended for use in the electromagnetic environment specified below. The customer or the user of iT30 & iT50 should assure that they are used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV for line to line ±2 kV for line to ground	±1 kV for line to line ±2 kV for line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of iT30 & iT50 requires continued operation during power mains interruptions, it is recommended that iT30 & iT50 be powered from an uninterruptible power supply or a battery.
IMMUNITY to proximity magnetic fields IEC 61000-4-39	Test frequency: 30 KHz; 65 A/m, Modulation: Pulse modulation, 2.1 KHz Test frequency: 134.2 KHz; 7.5 A/m, Modulation: Pulse modulation, 50 KHz Test frequency: 13.56 MHz;	Test frequency: 30 KHz; 65 A/m, Modulation: Pulse modulation, 2.1 KHz Test frequency: 134.2 KHz; 7.5 A/m, Modulation: Pulse modulation, 50 KHz Test frequency: 13.56 MHz;	--
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

B.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
iT30 & iT50 are intended for use in the electromagnetic environment specified below. The customer or the user of iT30 & iT50 should assure that they are used in such an environment.			
Immunity	**IEC/EN 60601 test**	**Compliance**	**Electromagnetic environment -**

test	level	level	guidance
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz See Table 1	3 V_{rms} 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz Comply with Table 1	Portable and mobile RF communications equipment should be used no closer to any part of iT30 & iT50, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer). 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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of

			equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur 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 iT30 & iT50 are used exceeds the applicable RF compliance level above, iT30 & iT50 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iT30 & iT50.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c 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. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a)] (MHz)	Service [a)]	Modulation [b)]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b)] 18 Hz	1.8	0.3	27

450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

B.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and iT30 & iT50

iT30 & iT50 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iT30 & iT50 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iT30 & iT50 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

C Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

Note: If your monitor has been preconfigured according to your requirements, the settings at delivery will be different from the default settings listed here.

C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

C.2 Alarm Default Settings

Alarm Settings	
Network Disconnection Alarm	On
Alarm Latch	Off

C.3 ECG Default Settings

ECG Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	120	160
Alarm Low Limit	50	75
Pace	Off	
Electrode Type	5 Electrodes	
Filter	Monitor	
Smart Lead Off	Off	
QRS Volume	3	
ST Analysis	Off	
Alarm Switch	Off	
Alarm Level	Medium	
Alarm High Limit (ST-X)	0.2	

Alarm Low Limit (ST-X)	-0.2	
QT Analysis	Off	
QTc	500	480
ΔQTc	60	
X stands for I, II, III, aVR, aVL, aVF, V, V, V1, V2, V3, V4, V5 or V6.		
Arrhythmia Analysis	On	Off
Arrhythmia Alarm Settings	Alarm Switch	Alarm Level
ASYSTOLE	On (non-adjustable)	High (non-adjustable)
VFIB/VTAC	On	High (non-adjustable)
R ON T	On	Medium
VT > 2	On	Medium
COUPLET	On	Medium
PVC	On	Medium
BIGEMINY	On	Low
TRIGEMINY	On	Medium
TACHY	On	Medium
BRADY	On	Medium
MISSED BEATS	On	Medium
IRR	On	Medium
PNC	On	Medium
PNP	On	Medium
VBRADY	On	Medium
VENT	On	Medium
ARR Analysis Threshold Value		
PVCs High	10/min	

C.4 RESP Default Settings

RESP Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	30	30
Alarm Low Limit	8	8
No Breath Detected delay	20 s	

Resp Type	II
Sweep	12.5 mm/s

C.5 SpO_2 Default Settings

SpO_2 Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	100	100
Alarm Low Limit	90	90
Sweep	12.5 mm/s	
SpO_2 Desat Limit	80%	

C.6 PR Default Settings

PR Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	120	160
Alarm Low Limit	50	75
Pulse Volume	3	
QRS Source	Auto	

C.7 NIBP Default Settings

NIBP Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit (SYS)	160	120
Alarm Low Limit (SYS)	90	70
Alarm High Limit (Map)	110	90
Alarm Low Limit (Map)	60	50
Alarm High Limit (DIA)	90	70
Alarm Low Limit (DIA)	50	40
Inflation value	160	140

Unit	mmHg
Measurement algorithm	iCUFS

C.8 TEMP Default Settings

TEMP Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	39.0	39.0
Alarm Low Limit	36.0	36.0
Unit	°C	

D Abbreviations

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
aVF	Left foot augmented electrode
aVL	Left arm augmented electrode
aVR	Right arm augmented electrode
BP	Blood pressure
Brady	Bradycardia
CCU	Cardiac care unit
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
Couplet	Ventricular couplets
DC	Direct current
Dia	Diastolic
DoS	Denial of Service
DDoS	Distributed Denial of Service
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ER	Emergency room
ESU	Electrosurgical unit
FCC	Federal Communication Commission
HR	Heart rate
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
LA	Left arm
LAP	Left atrial pressure
LCD	Liquid crystal display
LED	Light emitting diode

Abbr	English Full Name/Description
LL	Left leg
MAP	Mean arterial pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applicable
NIBP	Non-invasive blood pressure
OR	Operating room
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular contraction
R	Right
RA	Right arm
RAP	Right atrial pressure
Resp	Respiration
RL	Right leg
SpO_2	Functional oxygen saturation of arterial hemoglobin
SYS	Systolic pressure
Tachy	Tachycardia
TEMP	Temperature
USB	Universal serial bus
VFIB/VTAC	Ventricular Fibrillation/Ventricular Tachycardia
V-Tach	Ventricular Tachycardia

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FCC Warning

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 inte rference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interferenceto radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Reorient or relocate the receiving antenna.
- Reorient or relocate the receiving antenna.
- Consult the dealer or an experienced radio/TV technician for help important announcemen

Specific Absorption Rate (SAR) information:

This device meets the government's requirements for exposure to radio waves. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health. FCC RF Exposure Information and Statement the SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. The device has also been tested against this SAR limit. This device was tested for typical body-worn operations with the back of the device kept 0mm from the body. To maintain compliance with FCC RF exposure requirements, use accessories that maintain a 0mm separation distance between the user's body and the back of the device. The use of belt clips, holsters and similar accessories should not contain metallic components in its assembly. The use of accessories that do not satisfy these requirements may not comply with FCC RF exposure requirements, and should be avoided.