BeneVision TMS60

Telemetry Monitoring System

Operator's Manual

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Company Contact

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, Hi-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680

Distributor:	Mindray DS USA, Inc.
Address:	800 MacArthur Boulevard, Mahwah, New Jersey 07430 USA
Tel:	1.800.288.2121, 1.201.995.8000
Website:	www.mindray.com

EC-Representative:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact Mindray.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your patient monitor.

Conventions

- *Italic text* is used in this manual to quote the referenced chapters or sections.
- **Bold text** is used to indicate the screen texts and names of hard keys.
- → is used to indicate operational procedures.

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1 Safety

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1.1 Safety Information

WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Warnings

WARNING

- **The TD60 is intended to be used for a single patient at a time.**
- **The Telemetry Monitoring System (TMS60) must be operated by medical personnel in hospitals or medical institutions.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.**
- **Do not use this equipment in conjunction with Electro Surgical Unit (ESU).**
- **Do not expose the equipment to a Magnetic Resonance (MR) environment.**
  - **Thermal injury and burns may occur due to the metal components of the equipment which can heat during MR scanning.**
  - **The equipment may present a risk of projectile injury due to the presence of ferromagnetic materials which can be attracted by the MR magnet core.**
  - **The leadwires and electrodes will generate artifacts in the MR image.**
  - **The equipment will not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner.**
- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
- **Do not touch the patient and live parts simultaneously.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel.**
- **Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**
- **The physiological data and alarm messages displayed on the system are for reference only and cannot be directly used for diagnostic interpretation.**

WARNING

- **Do not operate the touch screen with water on the hand.**
- **Only use parts and accessories specified in this manual.**
- **Route, wrap and secure the cables to avoid inadvertent disconnection, stumbling and entanglement.**
- **To avoid risk of electric shock, RC60 and central charger must only be connected to a supply mains with protective earth.**

1.1.2 Cautions

CAUTION

- **Do not let the display directly touch the patient when the display is on.**
- **When the central station presents the alarm "No RF Signal", the setting being performed on the TD60 may not be transferred to the central station. Check the patient condition and the settings on the central station.**
- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **After the configurations, such as the patient category, paced status, are changed at the TD60, the medical personnel shall check those configurations at the CS to make sure both of the configurations are consistent.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external equipment operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI equipment are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- **Dry the equipment immediately in case of rain or water spray.**
- **The system generates and uses the Radio Frequency (RF) energy. If it is not installed correctly or not used as per the manual, RF interference to other equipment could result.**

CAUTION

- **Signal quality can be impacted on an ambulatory patient by the construction materials used within the hospital.**
- **At the end of its service life, the equipment, and its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact Mindray.**
- **When programming the frequency for a transmitter,the frequencies allocated to all other transmitters need to be considered to ensure that no two transmitters are programmed with the same frequency.**

1.1.3 Notes

NOTE

- **Put the equipment in a location where you can easily see the screen, and access the operating controls.**
- **The software was developed in compliance with IEC60601-1-4. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your equipment may not have all of them.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**

1.2 Equipment Symbols

Symbol	Description	Symbol	Description
	Power On/Off key		Main menu key
	Nurse call key		Alternating current (AC)
	Defibrillation-proof Type CF applied part	SN	Serial number

Symbol	Description	Symbol	Description
	Date of Manufacture		Symbol for “MANUFACTURER”
	MR Unsafe – do not subject to magnetic resonance imaging (MRI)	IPX7	Protection against fluid ingress
	Interference may occur in the vicinity of equipment marked with this symbol		General warning sign
	Refer to instruction manual/booklet		
ETL CLASSIFIED C ETL US Intertek 3191955	The presence of this label indicates the machine was certified by ETL with the statement: Conforms to AAMI Std ES 60601-1, IEC 60601-1-6, IEC Std 60601-1-8, IEC Std 60601-2-27, IEC Std 60601-2-49, ISO Std 80601-2-61 Certified to CSA Std C22.2 NO. 60601-1, NO. 60601-1-6, NO. 60601-1-8, NO.60601-2-27, NO. 60601-2-49, NO.80601-2-61		

NOTE

- **Some symbols may not appear on your equipment.**

2 General Product Description

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System Components 2-3
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Telemetry Receiver (RC60) 2-5
Touch Screen Display 2-5

2.1 Intended Use

The TMS60 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO_2 physiological data. The physiological data can be reviewed locally on the display of the transmitter. The CentralStation will support ECG, Heart Rate, SpO_2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS60.

It must be operated by trained medical personnel in hospitals or medical institutions.

WARNING

- **Only skilled/trained clinical professionals should operate this equipment.**
- **The equipment is not designed for monitoring critically ill patients.**
- **If the accuracy of any value displayed at the CS or Telemetry transmitter (TD60) is questionable, determine the patient's vital signs by alternative means and verify that the TMS is working correctly.**
- **The system transmits the data through the wireless connection. There might be a risk of data loss.**

2.2 Applied Parts

The equipment has the following applied parts:

- ECG leadwires
- SpO_2 cables
- SpO_2 sensors

2.3 Key Features

- 3.5" color PTC touch screen display is easy for clinicians to use.
- Small, portable, and lightweight for patients to wear.
- Supports 3/5 lead ECG.
- Supports Masimo and Nonin SpO_2 modules.
- Communication to the CS utilizes the protected WMTS 608-614 band.
- Displays the battery status and supports the multiple levels of battery alarms.
- Displays Heart Rate (HR) and SpO_2 parameters, ECG and SpO_2 waveforms.
- Battery options of two AA, three AA, or lithium-ion battery pack are available.

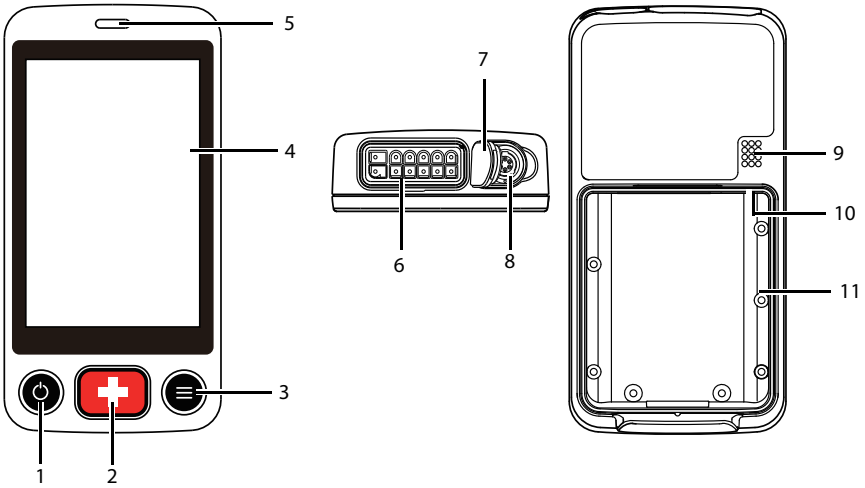
- Display supports Parameter auto-sizing.

2.4 System Components

The telemetry monitoring system (TMS60) includes the following components:

- Telemetry transmitter (TD60)
- Telemetry antenna array
- Telemetry receiver (RC60)

2.5 TD60 Physical View



1. Display Activation (Power On/Off) key

   When the TD60 is powered off

   - Pressing this key will turn the TD60 on.

   When the TD60 is powered on

   - If the screen display is on, pressing this key will turn the display off.
   - If the screen display is off, pressing this key will turn the display on.
   - Press and hold this key for two seconds to display the power off confirmation menu.

2. Nurse Call key

   Pressing this key will send a nurse call request to the CS. The alarm light/indicator will illuminate cyan, and a “Nurse Call Initiated” message will display in the message area if the display is on.

3. Main Menu key

   - Pressing this key when on the main screen will open the main menu.
   - Pressing this key when a menu is open will return to the main screen.
   - Pressing this key when the display is off will turn the display on.
   - Pressing this key when the screen lock mode is configured for View Only will display the **Screen Locked** menu.

4. Display

   Touch screen display for viewing patient information and adjusting patient settings.

5. Alarm light/indicator

   Flashes in different color and frequency corresponding to the alarm level.

6. ECG connector

   ECG lead connector.

7. SpO_2 cap

   Covers SpO_2 connector when SpO_2 is not in use.

8. SpO_2 connector

   Connects the SpO_2 module.

9. Speaker

10. USB connector

    It is only available for authorized service personnel.

11. Battery compartment

    Contains the lithium-ion battery pack or AA battery tray.

2.6 Antenna Array

The antenna array must be installed and configured by Mindray authorized personnel. For more details about the antenna array installation, calibration, and validation, refer to the ***Telemetry Monitoring System Installation Guide (P/N 046-007624-00)***.

WARNING

- **Authorized Mindray personnel are required to confirm the coverage area of the antenna array in the following situations:**
  - **When the antenna array is initially installed.**
  - **When the antenna array is modified.**
  - **When the building construction is modified.**

2.7 Telemetry Receiver (RC60)

The RC60 receives the data from the TD60 via the antenna array, and sends the data to the CS for analysis and display.

For details about the general wireless communication problems, refer to ***"General Problems" on page 12 - 2***.

For details about the frequency allocation and receiver connection, refer to the ***Telemetry Monitoring System Installation Guide (P/N 046-007624-00)***.

For details about the RC60, refer to the ***TMS60 Service Manual (P/N 046-007057-00)***.

2.8 Touch Screen Display

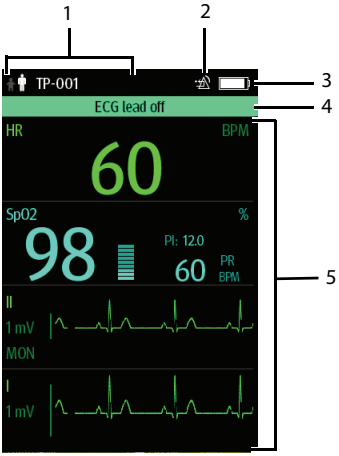
WARNING

- **Do not operate the touch screen with water on the hand.**

Move your finger on the touch screen display to operate the TD60. For details about the supported touch gestures, refer to ***"Understanding the Screen Display Orientation" on page 3 - 10***.

2.8.1 Display Screen

The main screen displays patient parameters and waveforms. A typical display screen is shown below.



1. Patient information area

   This area shows the patient information such as patient category, device name, and department. Tapping this area displays the **Patient Info** menu.

2. Alarm symbols

   - indicates that the alarm system is reset.
   - indicates that the technical alarm audio is turned off.

3. Battery symbol

   This symbol indicates the battery charge status. Refer to ***"Checking the Battery Charge Status" on page 11 - 4*** for details. Tapping the battery symbol opens the **System Info** menu to the battery section.

4. Message area

   This area shows technical alarm messages and informational messages, where there are multiple messages, the messages scroll.

5. Patient data area

   This user configurable area can display parameter/waveform data. The parameter/waveform is labeled in the upper left corner. You may also tap this area to display the Setup menu for the corresponding parameter/waveform.

For details about the touch screen operations, refer to ***"Basic Operations" on page 3 - 9***.

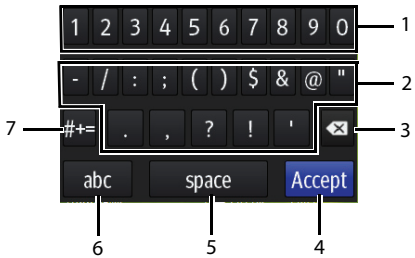
2.8.2 On-Screen Keyboard

The TD60 uses an on-screen keyboard to enter alphanumeric information, such as the device name and passwords.

2.8.2.1 Alphabetic Keyboard

1. Alphabetic buttons: tap to input the desired alphabetic text.
2. Delete button: tap to erase the text to the left of the cursor.
3. Accept button: tap to save the settings and exit the keyboard.
4. Space button: tap to input a space.
5. Numeric switch button: tap to switch to the numeric layout.
6. Case shift button: tap to switch the case of the letter.
   This switch is active for one character entry.

2.8.2.2 Numeric Keyboard



1. Numeric buttons: tap to input the desired numbers.
2. Punctuation buttons: tap to input the desired punctuation mark or symbol.
3. Delete button: tap to erase the text to the left of the cursor.
4. Accept button: tap to save the settings and exit the keyboard.
5. Space button: tap to input a space.
6. Alphabetic switch button: tap to switch to the alphabetic layout.

7. More punctuation buttons: tap to display the punctuation keyboard, as shown below.

3 Getting Started

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WARNING

- **The telemetry monitoring system (TMS60) shall be installed by Mindray authorized personnel.**
- **The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to altering, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Connect only approved devices to this system. Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Mindray.**
- **If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.**
- **Contact Mindray to relocate the TMS60.**
- **Only Mindray authorized personnel can update the TMS60.**

3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or Mindray.

If the packing case is intact, open the package and remove the device and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact Mindray in case of any problem.

WARNING

- **Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**
- **Do not let the display directly touch the patient when the display is on.**

NOTE

- **Save the packing case and packaging material as they can be used if the device must be reshipped.**

3.2 Environmental Requirements

The operating environment of the system must meet the requirements specified in this manual.

The equipment operating environment should be reasonably 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

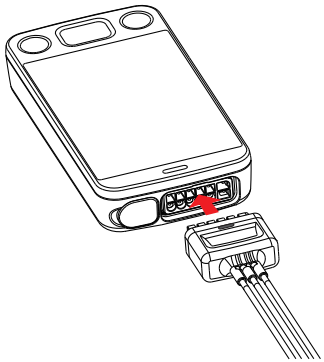
- **Make sure that the device operating environment meets the specifications. Otherwise unexpected consequences, e.g. damage to the device, could result.**

NOTE

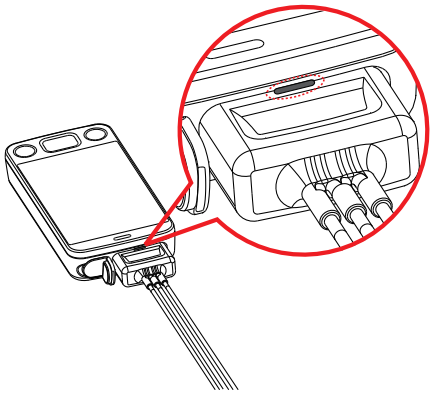
- **The system transmits data through a wireless connection. External radio frequency interference may result in occasionally data dropout. Contact Mindray for any questions regarding the electromagnetic environment.**

3.3 Connecting the ECG Leadwire

1. Align the ECG leadwire plug with the ECG connector as indicated by the arrow in the following figure.



2. Insert the ECG leadwire plug into the ECG connector as shown in the enlarged figure below.



WARNING

- **Insert the ECG lead set into the ECG connector. The following performance may be affected by a weak connection:**
  - **ECG signal quality**
  - **Wireless signal strength**
  - **Water resistance**
- **Do not use the ECG leadwire to move or lift the TD60. This may cause the device to fall, which may damage the equipment or injure the patient.**

NOTE

- **ECG leadwires are used as the antenna for the TD60. To ensure good radio performance, always connect the ECG leadwires to the ECG connector while monitoring the patient.**
- **Insert the SpO_2 cap in the SpO_2 connector when SpO_2 is not in use.**

3.4 Installing the Batteries

You can use two AA, three AA batteries or a lithium-ion rechargeable battery pack to run the TD60. The runtime is dependent on the battery solution you chose. A lithium-ion battery pack will provide the longest runtime. For details about the recommended AA batteries, refer to ***"Miscellaneous" on page 15 - 5***.

NOTE

- **Always keep the battery compartment dry.**
- **Never use brute force to install the lithium-ion battery pack or AA battery tray. Otherwise the waterproof ring surrounding the battery frame edge may be broken to affect the waterproof performance.**

3.4.1 Installing the Lithium-ion Rechargeable Battery

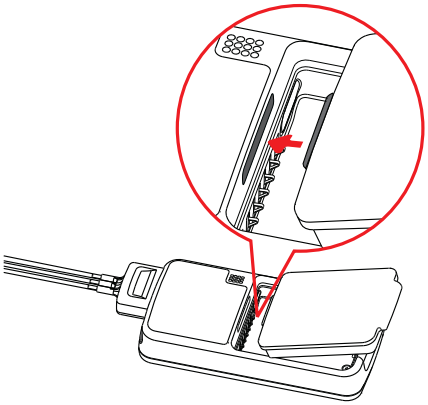
WARNING

- **Only use specified lithium-ion rechargeable batteries. Use of other lithium-ion batteries will adversely affect the batteries:**
  - **Level reporting**
  - **Low battery alarms**
  - **Life performance**

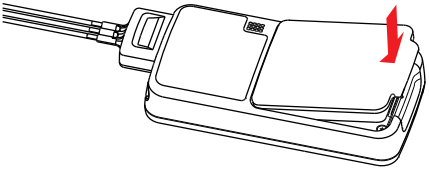
NOTE

- **The lithium-ion rechargeable battery should be fully charged prior to first use.**

1. Make sure the battery compartment is empty.
2. Align the hook on the upper part of the lithium-ion battery pack with the slot on the battery compartment, as indicated by the enlarged figure below.



3. Press down the battery pack until it is installed firmly, as indicated by the arrow in the following figure.



The TD60 is automatically powered on after the battery is installed.

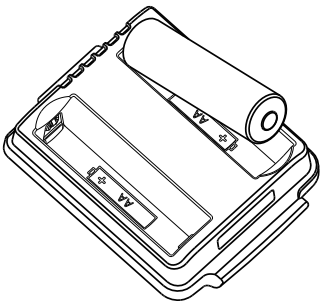
3.4.2 Installing the AA Batteries

There are two types of AA battery trays, which are used for holding AA batteries:

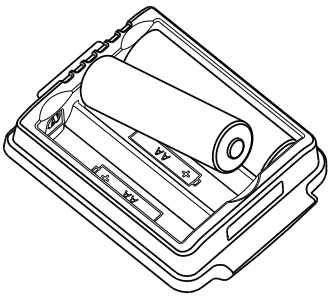
- TP-2AA battery tray can hold two AA batteries.
- TP-3AA battery tray can hold three AA batteries.

To install the AA batteries:

1. Make sure the battery compartment is empty.
2. Insert two or three 1.5V alkaline AA batteries according to the diagram in the bottom of the battery tray as shown in the images below.

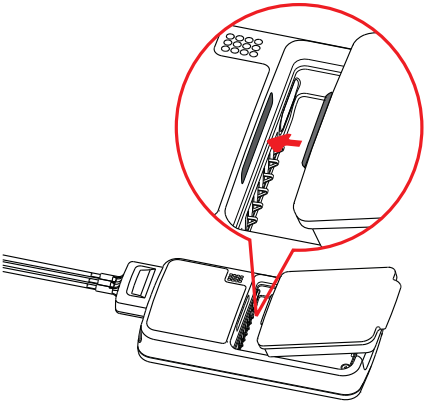


Installing two AA batteries

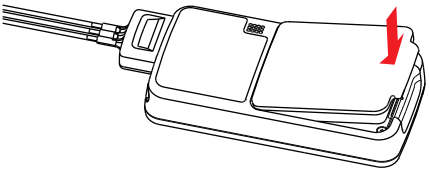


Installing three AA batteries

3. Align the hook on the upper part of the battery tray with the slot on the battery compartment, as indicated by the enlarged part in the following figure.



4. Press down the battery tray until it closes firmly, as indicated by the arrow in the following figure.



The TD60 is automatically powered on after the batteries are installed.

3.5 Powering On the Unit

Press the key to turn on the TD60. The cyan alarm light will momentarily turn on to indicate that the device is starting. The TD60 performs a self-test during startup. The device sounds a beep, and the alarm light serially turns red, yellow, cyan, and then off. This indicates that the alarm system functions correctly.

Upon powering up, there are two situations:

- If the TD60 is turned on at first time, the device will request you to configure first time startup. Refer to the ***TMS60 Service Manual (P/N 046-007057-00)*** for details.
- If the TD60 is turned on next time, the device will prompt whether it is a new patient. Select **Yes** or **No** as desired. If the device is a lock mode, a passcode is required.

WARNING

- **Check that visual and auditory alarm signals are presented correctly when the equipment is powered on. Do not use the equipment for any monitoring procedure on a patient if you suspect the equipment is not working properly or if the equipment is mechanically damaged. Contact your service personnel or Mindray.**

3.6 Understanding Touch Gestures

Before using the TD60, understand the supported touch screen gestures:

Gesture	Description
Tap	Briefly touch the surface with your fingertip to select a target.
Press and hold	Touch the surface for extended period of time.
Drag	Move your fingertip over the surface without losing contact.
Swipe	Quickly brush the surface with your fingertip.

3.7 Basic Operations

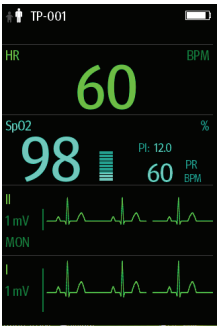
This section describes the basic operations for the TD60.

WARNING

- **Patients should be instructed not to interact with the display of the device and to not open the battery compartment while the TD60 is in use.**

3.7.1 Understanding the Screen Display Orientation

The TD60 supports both the portrait and landscape display orientations.



Example of portrait display

Example of landscape display

- Portrait: both digital and waveform tiles take up the entire width of the screen.
- Landscape: the digital tile takes up one half of the width of the screen; the waveform tile takes up the entire width of the screen.

3.7.2 Browsing the Screen Display

To scroll through the waveforms/parameters, swipe your finger up or down on the screen.

3.7.3 Switching the Screen Display Orientation

1. Swipe your finger down from the top of the main screen to display the drop-down menu.
2. Tap the desired option to switch the screen display orientation.

For example, to switch from portrait display to landscape display:

1. Swipe your finger down from the top of the main screen to display the drop-down menu.
2. Tap **Landscape** to switch to landscape display.

3.7.4 Flipping the Landscape Display

1. Swipe your finger down from the top of the main screen to display the drop-down menu.
2. Tap **Flip Display** to horizontally flip the landscape display.

3.7.5 Displaying the Quick Keys Area

Swipe your finger up from the bottom of the main screen to display the quick keys area.

The following table lists the six default quick keys:

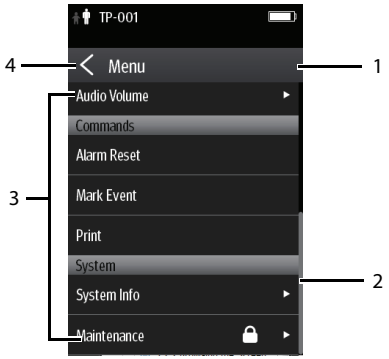
Quick keys	Description
Discharge Patient	Tap the button to enter the **Discharge Patient** menu. Refer to ***"Discharging the Patient" on page 5 - 4*** for details.
Standby	Tap the button to enter the **Standby** menu. Refer to ***"Placing a Device in Standby" on page 5 - 3*** for details.
Change Lead	Tap the button to change the current first ECG lead waveform to the next ECG lead waveform that is available in sequential order. For example, if the current first ECG lead waveform is I lead, tap the button, the I lead waveform is changed to II lead waveform.
Print	Tap the button to notify the central station (CS) to start real-time print. The "Print Initiated" message displays on the screen.
Manual Event	Tap the button to notify the CS to save the event to the event database. The "Manual Event" message displays on the screen.
Alarm Reset	Tap the button to reset the alarm system. Refer to ***"Resetting the Alarms" on page 6 - 5*** for details.

You can customize the most frequently used functions to the quick keys. For details about setting the quick keys, refer to ***"Quick Keys Menu" on page 10 - 5***.

3.7.6 Entering the Main Menu

Press the key to enter the main menu.

The main menu allows access to most of the system functions and settings.



All menus contain the following parts:

1. Heading: displays the current menu title.
2. Scroll bar: indicates the current scroll position within the menu.
3. Main body: contains menus, buttons, and other controls to configure and operate the device.

Controls	Description
	Accesses a submenu to reveal more options or information.
	Indicates that a password is required for access.
Submenus	Contains more operations or information related to the corresponding menu.
Buttons	Provides an option to operate a function.
Switch	Drag to right to enable the switch; drag to left to disable the switch.

4. exits the current menu and return to the previous menu or the main screen.

3.7.7 Turning the Display Off

You can manually turn the display off, or let the display automatically turn off based on the configured timeout.

Press the key to manually turn the display off.

If the touch screen is not touched for the configured Display Auto Off time, then the screen will turn off after the configured Display Auto Off time.

For details about configuring the time for Display Auto Off, refer to ***"Configuring the General Menu" on page 10 - 2***.

NOTE

- **While the display is off, the TD60 enters the power saving mode, and does not provide audio and visual alarms.**

3.7.8 Turning the Display On

If the screen is off, press the ⏻ or ≡ key to turn the display on.

CAUTION

- **Do not let the display directly touch the patient when the display is on.**

3.7.9 Unlocking the Screen

If you set the screen lock, you need to input the correct passcode to unlock the screen after the display turns off.

To unlock the screen in Locked mode:

1. If the screen is off, press the ⏻ or ≡ key to turn the display on and access the **Screen Locked** menu.
2. Input the passcode to unlock the screen.

   Once the passcode is entered the screen is temporarily unlocked. If the ⏻ is pressed or the device times out, the screen will lock again and a passcode must be entered.

To unlock the screen in View Only mode:

1. If the screen is off, press the ⏻ or ≡ key to turn the display on.
2. Press the ≡ key to display the **Screen Locked** menu.
3. Input the passcode to unlock the screen.

   Once the passcode is entered the screen is temporarily unlocked. If the ⏻ is pressed or the device times out, the screen will lock again and a passcode must be entered.

For details about setting the screen lock, refer to ***"Screen Lock Menu" on page 10 - 8***.

3.7.10 Acknowledging the Nurse Call

To acknowledge the triggered nurse call, tap **Attendant Present** in the main menu. The “Nurse Call Cancelled” message will display in the message area.

For details about how to trigger a nurse call, refer to **"**TD60 Physical View" on page 2 - 3.

WARNING

- **Do not only rely on the nurse call function, the medical personnel should also pay close attention to the patient's condition.**

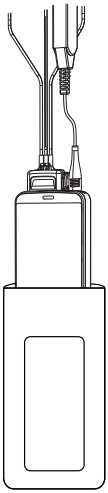
3.8 Using the Pouch

The TD60 is not intended for direct contact with the patient's skin. During normal use, the TD60 could be worn over clothing, in a pocket, or in a pouch. The waterproof pouch with clear front is an appropriate means for holding the TD60. Both disposable and reusable pouches specified in this manual can be used for the TD60. For details about the pouch, refer to ***"Miscellaneous" on page 15 - 5***.

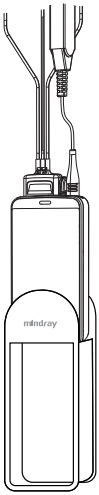
3.8.1 Securing the Pouch

To secure the pouch:

1. Place the TD60 into the pouch with the ECG leadwires and the SpO_2 sensor cable, if used, exiting from the pouch opening, as shown in the following figures.

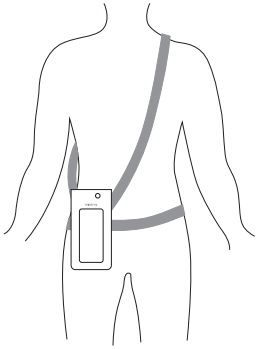


For disposable pouch

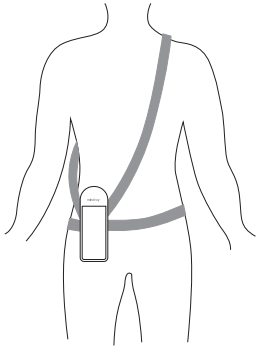


For reusable pouch

2. Pinch the snap-fastener to close the pouch.
3. Secure the pouch on the patient with ties around the patient's shoulder and under the arm, as shown in the following figure.



Wearing the disposable pouch



Wearing the reusable pouch

WARNING

- **While using a pouch with the TD60 on the patient, consider the patient's condition. Be careful about the placement of the straps, as the straps could present a strangulation hazard.**

NOTE

- **The pouch is used only for the TD60. The pouch cannot be used for carrying other personal devices, such as a mobile phone.**

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4 User Configurations

Introduction.....4-2
Configuring the Display.....4-2
Configuring the Audio Volume.....4-5

4.1 Introduction

This chapter describes the configurations available for users to do, such as configuring the Display Setup, and Audio Volume.

4.2 Configuring the Display

You can configure the display by setting the display layout, display orientation, and screen brightness.

In the main menu, tap **Display Setup** to enter the **Display Setup** menu.

4.2.1 Setting the Default Display Orientation

For details about the display orientation, refer to ***"Understanding the Screen Display Orientation" on page 3 - 10***.

1. In the **Setup** section of the **Display Setup** menu, tap **Default Orientation**.

   Two buttons display: **Portrait** and **Landscape**.

2. Tap a button to set the default orientation.

   The selected orientation displays to the right of **Default Orientation**.

3. Restart the TD60 to apply the setting.

4.2.2 Understanding Portrait Orientation Display Rules

In portrait orientation, both digital and waveform areas take up the entire width of the screen. Therefore, these parameters will be displayed in the exact order of the **Display Setup** menu, provided the sensor is attached and monitoring data.

4.2.3 Setting the Portrait Display

1. In the **Portrait** section of the **Display Setup** menu, tap **Rows**.

   Three options display: **2**, **3**, and **4**.

2. Tap an option to set the row numbers.

   The selected option displays to the right of **Rows**.

3. Tap **Portrait Order** to enter the **Portrait Order** menu.
4. Tap a parameter or waveform to select it.

   The icon displays to the right of the selected parameter or waveform.

5. Drag the selected parameter or waveform to the desired position, and then release it.
6. Repeat steps 4 and 5 until the desired order is configured.
7. Tap the icon to exit the **Portrait Order** menu.

4.2.4 Understanding Landscape Orientation Display Rules

In landscape orientation, waveform areas take up the entire width of the screen. Digital areas only take up one half of the width of the screen. The following rules define how the tiles will be laid out:

1. The areas shall be displayed in the order of the **Display Setup** menu except the digital area locations shall be optimized to reduce blank tiles.
2. A waveform area always takes up the entire width of the screen.
3. A digital area always takes up one half of the width of the screen. Therefore, a row with a digital tile in it shall be split into two half tiles.
4. A digital area shall not be the only parameter in a row unless an odd number of digital areas exist. In this case, the last digital parameter area shall have one tile on the left side and the right half will be blank.
5. Digital areas shall be paired with the next available digital area to satisfy rule 4. This means that a digital area may be moved ahead of a waveform area if a half of a row needs to be filled.

For example, if the landscape display rows is set to **3** and the parameter order is as follows:

HR
ECG I
ECG II
ECG III
ECG aVR
ECG aVF
ECG aVL
ECG V
SpO_2
PLETH

The landscape layout displays as follows:

HR*	**SpO_2**
ECG I	
ECG II	
ECG III	
ECG aVR	
ECG aVF	
ECG aVL	
ECG V	
PLETH	

* *Bold is displaying on screen; non-bold data need to be scrolled to.*

4.2.5 Setting the Landscape Display

1. In the **Landscape** section of the **Display Setup** menu, tap **Rows**.

   Three options display: **2**, **3**, and **4**.
2. Tap an option to set the row numbers.

   The selected option displays to the right of **Rows**.
3. Tap **Landscape Order** to enter the **Landscape Order** menu.
4. Tap a parameter or waveform option to select it.

   The icon displays to the right side of the selected parameter or waveform.
5. Drag the selected parameter or waveform to the desired position, and then release it.
6. Repeat steps 4 and 5 until the desired order is configured.
7. Tap the icon to exit the **Landscape Order** menu.

4.2.6 Setting the Display Brightness

1. In the **Setup** section of the **Display Setup** menu, tap **Display Brightness**.

   The **Display Brightness** menu displays.
2. Drag the slider to left or right to adjust the brightness.
3. Tap the icon to exit the **Display Brightness** menu.

4.3 Configuring the Audio Volume

You can independently set the technical alarm volume, touch screen click, and systole beep volume. The method for setting the three volumes are the same.

To change the volume settings:

1. In the main menu, tap **Audio Volume**.
2. In the **Technical Alarm**, **Touch Screen Click**, or **Systole Beep** section, drag the slider to the left or right to adjust the volume.
3. Tap the icon to exit the **Audio Volume** menu.

NOTE

- **The icon indicates that the audio volume is turned off.**
- **The minimum value for the technical alarm volume depends on the minimum technical alarm volume, refer to *"Configuring the Alarms Menu" on page 10 - 3* for details.**

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5 Patient Management

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Admitting a Patient 5-2
Changing the Patient Category 5-2
Placing a Device in Standby 5-3
Resume Monitoring 5-4
Discharging the Patient 5-4

5.1 Introduction

The chapter describes how to admit a patient, change the patient size, enter and exit the Standby mode, and discharge the patient.

5.2 Admitting a Patient

When admitting a TMD860 for the first time, the device must be admitted to the system through the CS. For details about admitting a patient through the CS, refer to the ***BeneVision Central Station Operator's Manual (P/N 046-007960-00)***.

After first admitting the device to the CS, you can directly admit the new patient at the TD60 by discharging the current patient, and then pressing the key to admit a new patient. Refer to ***"Discharging the Patient" on page 5 - 4*** for details.

5.3 Changing the Patient Category

NOTE

- **Ensure the patient category selection is appropriate for the patient before monitoring begins.**

1. In the main menu, tap **Patient Info**.
2. In the **Patient Info** menu, tap **Patient Category** to select the desired patient category.

   The screen displays the "Are you sure you want to change patient category?" message.
3. Select **Yes** to confirm that the patient category is changed.

   The selected patient category displays to the right of **Patient Category**.
4. Tap the icon to exit the **Patient Info** menu.

NOTE

- **The patient category can only be changed at the TD60.**
- **Adjusting patient category restores the TD60 to the default (preset) settings but does not clear patient information or data.**

NOTE

- **When the device is connected to the CS, the patient category at the CS is updated if the patient category is changed at the TD60. Refer to the *BeneVision Central Station Operator's Manual (P/N 046-007960-00)* for details.**

5.4 Placing a Device in Standby

NOTE

- **When connected to the CS, and a device enters or exits Standby mode, the CS is also notified to enter or exit Standby mode. Refer to the *BeneVision Central Station Operator's Manual (P/N 046-007960-00)* for details.**

To enter the Standby mode:

1. In the main menu, tap **Standby**.
2. In the **Standby** confirmation menu, select **Yes**.

Placing a device into Standby mode does the following:

- Suspends patient monitoring
- Alarms are suspended
- Displays **Standby** on the screen.
- The screen display automatically turns off after the device enters the Standby mode for 30 seconds.

NOTE

- **When connected to the CS, and a device enters or exits Standby mode, the CS is also notified to enter or exit Standby mode.**

5.5 Resume Monitoring

Press the key to exit Standby mode.

Resume monitoring:

- Restores patient's settings, resumes alarm notification on the TD60 and the CS.
- Alarm system is activated.
- The TD60 notifies the CS of returning to the Monitoring mode.

5.6 Discharging the Patient

Discharging the patient will stop monitoring, clear patient information, and restore default (preset) settings on the TD60. When a new patient is admitted, the user configuration will be applied. If the user configuration has not been saved, the factory default configuration will be applied.

A patient can be discharged by selecting the **Discharge Patient** menu, or restarting the TD60 and selecting that a new patient is on the TD60.

NOTE

- **Discharging the patient on the TD60 discharges the patient from the CS. Refer to the *BeneVision Central Station Operator's Manual (P/N 046-007960-00)* for details.**

5.6.1 Selecting the Discharge Patient menu

1. In the main menu, tap **Discharge Patient**.
2. In the **Discharge Patient** confirmation menu, select **Yes**.
   - The patient is discharged from both the TD60 and the CS.
   - The patient's configuration is cleared and the configuration is restored to the saved user configuration or factory default configuration.
   - The patient will be added to the **Discharged Pat.** list at the CS.
3. Press the key to admit a new patient.

5.6.2 Restarting the TD60

1. If the TD60 is powered off, press the key to turn on the TD60.

   The device will prompt as to whether this is a new patient or not.

2. Select **Yes** if this is a new patient. Select **Yes** when asked to confirm that the discharge should begin. Refer to ***"Selecting the Discharge Patient menu" on page 5 - 4*** for details on the discharge process.

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6 Alarms

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6.1 Introduction

Alarms, triggered by technical problems, are visually and audibly indicated to the user when the display is on.

The TD60 provides a subset of the technical alarms, this chapter describes the technical alarms presented at the TD60 only. For details regarding full list of the technical alarms as well as the physiological alarms displayed at the central station (CS), refer to ***"Physiological Alarms" on page 9 - 2***.

WARNING

- **The reception failure of alarm signals may occur in the distributed alarm system.**

6.2 Alarm Categories

The TD60 alarm system only supports technical alarms, see the ***BeneVision Central Station Operator's Manual (P/N 046-007960-00)*** for details on physiological alarms.

Technical alarms are triggered by system status, patient status, a device malfunction or a patient data distortion due to improper operation or mechanical problems. Technical alarms are available both at the TD60 and the CS.

In addition to the technical alarms, the TD60 also displays informational message to inform the user of patient/system status. The TD60 will display informational messages in the message area at the top of the display.

6.3 Alarm Levels

The alarms can be classified into three severity levels: high level, medium level and low level.

Alarm Levels	Technical alarms
High level	Indicates a severe device malfunction or an improper operation, which could make it possible that the monitor cannot detect critical patient status and thus threaten the patient's life, such as low battery.
Medium level	Indicates a device malfunction or an improper operation, which may not threaten the patient's life but may compromise the monitoring of vital physiological parameters.
Low level	Indicates a device malfunction or an improper operation, which may compromise a certain monitoring function but will not threaten the patient's life.

6.4 Alarm Indicators

When a technical alarm occurs, the TD60 notifies the user through visual or audible alarm indications.

- Alarm light
- Audible alarm tones
- Alarm message

NOTE

- **When the TD60 display is off, the user must activate the screen to view any local alarms.**

6.4.1 Alarm Light

If a technical alarm occurs, the alarm light on the TD60 flashes. The color and flashing frequency correspond to the alarm level as follows:

- High level alarms: the lamp quickly flashes red.
- Medium level alarms: the lamp slowly flashes yellow.
- Low level alarms: the lamp lights cyan without flashing.

6.4.2 Alarm Tones

The TD60 has three alarm tone configurations: ISO, Mode 1 and Mode 2. For each configuration, the alarm tones enunciate the alarm levels as follows:

- ISO pattern:
  - High level alarms: triple+double+triple+double beep
  - Medium level alarms: triple beep
  - Low level alarms: single beep
- Mode 1:
  - High level alarms: high-pitched single beep
  - Medium level alarms: double beep
  - Low level alarms: low-pitched single beep
- Mode 2:

- High level alarms: high-pitched triple beep
- Medium level alarms: double beep
- Low level alarms: low-pitched single beep

NOTE

- **When multiple technical alarms of different levels occur simultaneously, the TD60 selects the alarm of the highest level to light the alarm light and sound alarms accordingly, while all the alarm messages scroll in the message area on the top of the screen.**

6.4.3 Alarm Messages

When a technical alarm occurs on the TD60 screen, the alarm message appears in the message area. The background color of the alarm message and the asterisk symbols (*) before the alarm message are designed to indicate the alarm level.

Alarms	Background color	Asterisk symbols (*)
High level alarms	red	***
Medium level alarms	yellow	**
Low level alarms	cyan	*

6.4.4 Alarm Status Symbols

The TD60 still uses the following symbols indicating the alarm status:

: indicates the technical alarm audio is turned off.

: indicates the alarm system is reset.

6.5 Configuring the Alarms

- For details on configuring the technical alarm volume, refer to "Configuring the Audio Volume" on page 4 - 5.
- For details on configuring the TD60 technical alarm settings, refer to ***"Configuring the Alarms Menu" on page 10 - 3***.
- For the CS alarm configurations, refer to the ***BeneVision Central Station Operator's Manual (P/N 046-007960-00)***.

6.6 Resetting the Alarms

You can acknowledge the on-going alarms by resetting the alarms. After being reset the alarm system can respond to a subsequent alarm condition.

When a technical alarm occurs, follow this procedure to reset the TD60 alarm system.

- Press the key to enter the main menu, and then tap **Alarm Reset** from the **Commands** section.

OR

1. Swipe your finger up at the bottom of the main screen to display the quick keys area.
2. Tap the **Alarm Reset** quick key to reset the alarm system.

When the alarm system is reset, depending upon the technical alarm there are several ways the alarm system may respond as follows:

- The alarm sound will be silenced, the alarm light will continue to indicate the alarm, a √ will appear before the alarm message. The symbol appears on the top of the main screen.
- The technical alarm will be changed to the prompt message, it will not longer make sound or be indicated by the alarm light.
- The technical alarms are cleared, there will be no alarm indications.

For details about the indications of technical alarms when the alarm system is reset, refer to ***"Technical Alarm Messages at the TD60" on page 12 - 5***.

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7 Monitoring ECG

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7.1 Introduction

The chapter describes the ECG monitoring function of the TD60, including skin preparation and lead placement, ECG Setup, ECG Waveform, and Pacer.

The TD60 can obtain an ECG value by using a 3/5 lead ECG leadwires in conjunction with the matching skin electrodes.

For details about CS configuration of the ECG parameters, QT analysis, ST analysis, and Arrhythmia analysis, refer to ***Chapter 9 Monitoring with the TD60 at the CS***.

7.2 Safety

WARNING

- **Use manufacturer specified electrodes and lead wires.**
- **Make sure the conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, do not contact any other conductive parts including earth.**
- **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**
- **Do not touch the patient or any device connected to the patient, including the bed and gurney, during defibrillation. Otherwise serious injury or death could result.**

CAUTION

- **Interference from a non-grounded instrument near the patient and electro-surgery interference can cause problems with the waveform.**

NOTE

- **After defibrillation, the waveform recovers within 10 seconds applied in accordance with the manufacturer's instructions for use.**

7.3 Preparation for Monitoring ECG

7.3.1 Preparing the Patient's Skin

Proper skin preparation is essential in obtaining an accurate ECG reading. Electrode sites should be clean and dry and should provide a smooth flat surface. Incidental electrical activity and inaccurate readings may arise from incorrect skin preparation.

The following procedure is recommended for secure electrode application:

1. Shave the chest hair from the electrode sites in a circular area with a diameter of 2 to 4 inches.
2. Use a dry gauze pad to remove excess skin oils, skin cells and residue from the electrode sites. Never rub the skin until it is raw or bleeding.

NOTE

- **Prepare the electrode site with alcohol only if the skin is extremely greasy. If alcohol is used as a drying agent, always allow the skin to dry before placing the electrode on the skin.**

7.3.2 Positioning the Electrodes

NOTE

- **Store electrodes at room temperature and open just prior to use.**
- **Avoid more than one type of electrode on a patient because of variations in electrical resistance.**
- **Avoid placing electrodes directly over bone prominences or over any high activity movement areas such as shoulders or arms because muscle motion produces electrical activity. If an electrode is placed over a large muscle such as the pectorals, the device may detect this additional muscle activity and could lead to false arrhythmia calls.**
- **Using a Transcutaneous Electrical Nerve Stimulator (TENS): Since a TENS unit transmits electrical impulses, avoid placing ECG electrode near the TENS electrodes. ECG electrodes may need to be repositioned and the ECG lead viewed may need to be adjusted until the optimum ECG tracing is obtained.**

1. Peel the backing off of the electrode. Visually inspect the contact gel medium for moistness. If the gel medium is not moist, do not use the electrode patch. Dry electrode patches are not conductive.

NOTE

- **To prevent evaporation of the contact gel medium, peel the backing off of the electrode patch only when it is ready for use.**
- **If using the snap type lead wires, attach the electrode to the lead wire before placing the electrode on the patient.**

2. Attach the electrode patch to the skin at the prepared site. Smooth the electrode patch down in a circular motion to ensure proper skin contact. If using soft gel electrodes, never push down directly over the contact gel medium as this may displace the gel and cause monitoring artifact. If using hard gel electrodes, it is recommended that during application, the center of the electrode should be slightly pressed onto the skin to ensure direct contact. Consult the electrode manufacturer's instructions for specific use.
3. Secure the lead wires to the patient according to hospital practice.

CAUTION

- **Route leadwires neatly. Ensure leadwires are kept away from patient's neck to avoid strangulation. Keep floors and walkways free of cables to reduce risk to hospital personnel, patients and visitors.**

NOTE

- **It is recommended that the electrodes be changed at least every 24 to 36 hours to maintain proper contact with the skin, although some patients may require more frequent changing. Do not reapply disposable electrode. Try to avoid reusing the exact same electrode site during reapplication. If an electrode becomes wet with fluid, change the electrode.**

7.3.3 Setting ECG Lead Labeling

7.3.3.1 Lead Naming Standards

This manual presents lead placement according to the guidelines of the American Heart Association (AHA) and the International Electro-Technical Commission (IEC).

Lead position	AHA		IEC	
	Label	Color	Label	Color
Chest	V	Brown	C	White
Left Leg	LL	Red	F	Green
Right Leg	RL	Green	N	Black
Left Arm	LA	Black	L	Yellow
Right Arm	RA	White	R	Red

7.3.3.2 Choosing Lead Labeling

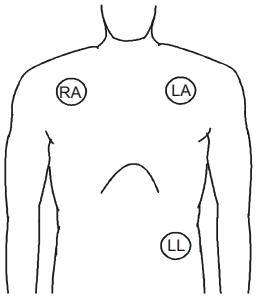
For details on choosing the lead labeling, refer to ***"Configuring the General Menu" on page 10 - 2***.

7.3.4 Placing the Electrodes

For lead placement, the ECG algorithm works best when the patient's R wave is significantly larger than the P wave or the T wave. If the R wave is not significantly larger than other lower voltage waves on the ECG tracing, the monitor may have some difficulty in identifying the appropriate waves. On some patients, electrode placement and/or the viewed ECG lead may need to be adjusted in order to obtain a significant R wave.

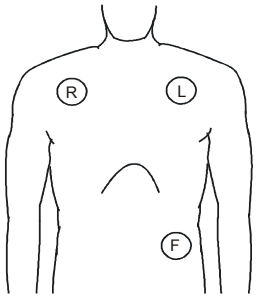
7.3.4.1 Standard 3-Leadwire Electrode Placement

A 3-wire lead set can monitor one of three ECG vectors (I, II, or III). The recommended 3-wire lead placement is as follows:



3-wire lead placement (AHA)

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.

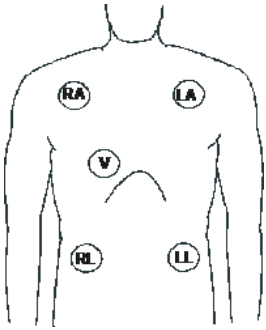


3-wire lead placement (IEC)

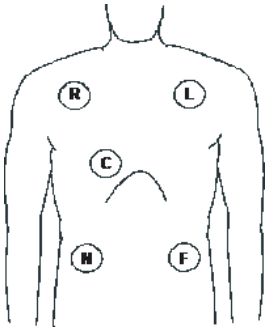
- Place the R (red) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.

7.3.4.2 Standard 5-Leadwire Electrode Placement

A 5-wire lead set can monitor seven ECG vectors (I, II, III, aVR, aVL, aVF, and V) simultaneously. The recommended 5-wire lead placement is as follows:



5-wire lead placement (AHA)



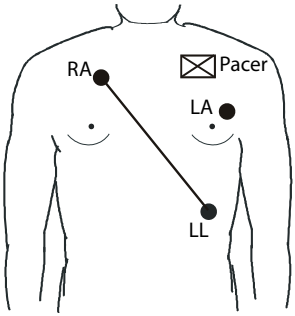
5-wire lead placement (IEC)

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.
- Place the RL (green) electrode on the patient's lower right abdomen within the rib cage frame.
- Place the V (brown) electrode in the V-lead position as shown in the figure or decided by the clinician.

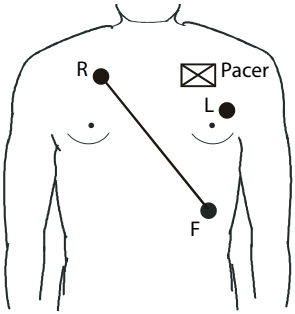
- Place the R (red) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.
- Place the N (black) electrode on the patient's lower right abdomen within the rib cage frame.
- Place the C (white) electrode in the C-lead position as shown in the figure or decided by the clinician.

7.3.4.3 Lead Placement: Pacemaker Patients

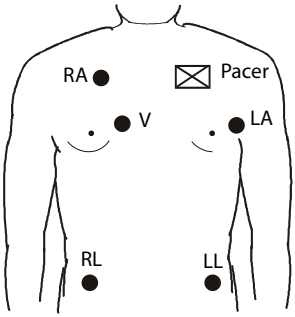
The recommended lead placement for monitoring a pacemaker patient is as follows.



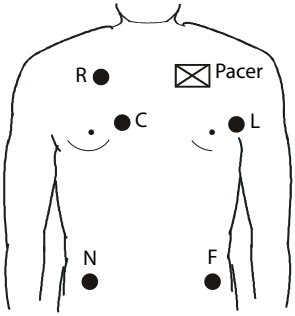
3-wire lead placement for a pacemaker patient (AHA)



3-wire Lead Placement for a Pacemaker Patient (IEC)



5-wire Lead Placement for a Pacemaker Patient (AHA)



5-wire Lead Placement for a Pacemaker Patient (IEC)

A pacemaker patient usually requires a different electrode patch placement configuration than a non-pacemaker patient.

Do not place an ECG electrode directly over the pacemaker generator. Place the electrode patches 3 to 5 inches away from the pacemaker generator area. For example, if the pacemaker generator is located in the right subclavian area, relocate the Right Arm electrode closer in towards the center of the chest.

7.3.5 Checking the Lead Placement

With the Lead Placement function, you can check the lead status, information, and lead off messages.

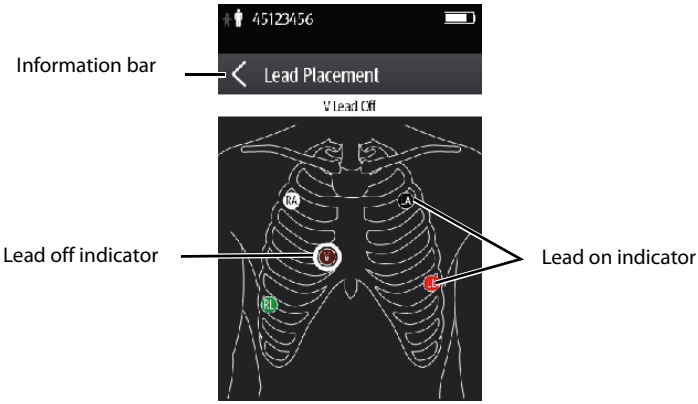
7.3.5.1 Entering the Lead Placement Menu

Enter the **Lead Placement** menu in either of the following ways:

- Tap the lead fault message in the message area of the main screen.
- In the main menu, tap **Lead Placement**.

7.3.5.2 Understanding the Lead Placement Instructions

The **Lead Placement** window indicates the lead status.



Example lead placement window

When any of the leads are off, the indications are as follows:

- The lead off message displays on the information bar.

  The background color of the information bar corresponds to the alarm level.
- A flashing circle indicates the disconnected lead.

  The color of the flashing circle is based on the alarm level.

7.3.6 Checking the Paced Status

It is important to correctly set the patient's paced status before you start monitoring ECG.

To check the paced status:

- On the main screen, tap the HR digital area or ECG waveform area to enter the **ECG** menu.

OR

1. In the main menu, tap **Patient Info**.
2. In the **Pacer** field, check the setting of the paced status.

   The current paced status setting displays to the right of **Paced**.
3. If the paced status setting is not correct, tap **Paced** and select the correct paced status.

- When **Paced** is set to **Yes** at the TD60, and the pacer pulse is detected, the symbol displays in the waveform area of the CS screen, and the pace pulse marks will display on the ECG waveform both at the TD60 and CS.

- When **Paced** is set to **No** at the TD60, and the pacer pulse is detected, the symbol displays in the waveform area of the CS screen.

WARNING

- **For paced patients, you must set Paced to Yes. If it is incorrectly set to No, the CS could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak. Do not rely entirely on rate meter alarms when monitoring patients with pacemakers. Always keep these patients under close surveillance.**
- **The pacer pulses may be counted as QRS complexes, hence leading to wrong HR readings or failure to diagnose certain arrhythmia symptoms. Be sure to keep a close eye on patient's with pacemaker devices.**
- **For non-paced patients, you must set Paced to No.**
- **False low heart rate indicators or false asystole calls may result with certain pacemakers because of pacemaker artifact such as electrical overshoot of the pacemaker overlapping the true QRS complexes.**
- **In order to minimize the possibility of interference, place electrodes, leadwires and TD60s as far away from the pacemaker as possible.**

NOTE

- **When Paced is set to Yes, the system does not detect PVC-related arrhythmia (including PVCs) resulting from pacemaker but still analyzes the normal QRS complex.**

7.4 Changing the ECG Settings

You can change the ECG settings from the ECG menu.

7.4.1 Configuring the ECG Setup

Enter the ECG menu in either of the following ways:

- On the main screen, tap the HR digital area or ECG waveform area to enter the **ECG** menu.
- In the main menu, tap **Parameter Setup** → **ECG** to enter the **ECG** menu.

1. In the **Setup** section of the ECG menu, select the options described in the following table.

Options	Description	Settings*
Lead Placement	Enters the **Lead Placement** window.	Refer to ***"Checking the Lead Placement" on page 7 - 9*** for details.
Cable Type	Selects the current ECG leadwire type.	**Auto**, 3 Lead, 5 Lead Refer to ***"ECG Leadwire Types" on page 7 - 12*** for details.
Smart Lead (Monitored Lead)	When **Cable Type** is set to **Auto**, the option displays **Smart Lead**. Drag the swtich to right or left to enable or disable the Smart Lead function. When **Cable Type** is set to **3 Lead**, the option displays **Monitored Lead**. Refer to ***"ECG Leadwire Types" on page 7 - 12*** for details.	

* *The factory default settings are in bold.*

Options	Description	Settings*
Filter	Selects the ECG filter. Monitor Use under normal measurement conditions. ST Use when ST monitoring is applied.	**Monitor**, ST
Color	Selects the ECG waveform color.	16 colors The default color is green.

* *The factory default settings are in bold.*

2. Tap to exit the **ECG** menu.

7.4.2 ECG Leadwire Types

ECG leadwire type has three options as follows:

- **Auto**: the device automatically sets the leadwire type according to the leadset connected.
- **3 Lead**: the leadwire type is set to 3-lead.

  If the leadwire type is set to 3-lead, the **Smart Lead** option becomes **Monitored Lead**. You can select the desired lead from the **Monitored Lead** option to set the first ECG waveform displayed on the main screen.
- **5 Lead**: the leadwire types is set to 5-lead.

  All waveform leads display on the main screen.

7.4.3 Configuring the ECG Waveforms

1. In the **Waveform** section of the **ECG** menu, select the options described in the following table.

Options	Description	Settings*
All Lead Size	Selects the waveform size for all the leads. To set the waveform size for a specific lead, select that lead from the **Waveform Size** section.	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, **10 mm/mV**, 20 mm/mV, 40 mm/mV, Auto
	This configuration will be applied for all ECG waveform size.	

* *The factory default settings are in bold.*

Options	Description	Settings*
Speed	Selects the waveform sweep speed.	6.25 mm/s, **12.5 mm/s**, 25 mm/s

* *The factory default settings are in bold.*

2. Tap to exit the **ECG** menu.

7.4.4 Configuring the Pacer

1. In the **Pacer** section of the **ECG** menu, tap the options described in the following table.

Options	Description	Settings*
Paced	Selects the paced status.	**Unspecified**, No, Yes **Unspecified** is only available for the first time you set the paced status. Refer to ***"Checking the Paced Status" on page 7 - 10*** for details.
Markers	Selects the pacer indicator. Line A 1 cm line shows above each ECG waveform each time the pace pulse is detected. Dot A 2 mm dot shows above each ECG waveform each time the pace pulse is detected.	**Line**, Dot, Off
Pacer Reject	Selects whether or not to reject the pace pulses.	On, **Off**

* *The factory default settings are in bold.*

2. Tap to exit the **ECG** menu.

NOTE

- **When Paced is set to Yes, the Markers and Pacer Rejection options can be available.**

7.4.5 Configuring the ECG Waveform Size

The **Waveform Size** section of the **ECG** menu lists all available leads. You can select the desired ECG lead to set the waveform size.

7.5 Understanding the ECG Display

7.5.1 HR Digital Area

The HR digital area displays:

1. Parameter name
2. Measurement unit
3. Heart rate value

7.5.2 About the HR Digital Area

- The HR area displays heart rate in the unit of bpm with a resolution of 1 bpm.
- If the HR measurement is invalid, “- - -” displays in place of the HR value.
- The HR value displays “0”, when the HR value is less than 15 bpm.

7.5.3 ECG Waveform Area

The ECG waveform area displays:

1. ECG Lead
2. ECG scale bar
3. ECG waveform
4. ECG filter setting
5. ECG scale

7.5.4 About the ECG Waveform Area

- The ECG waveform, scale indicator, lead, and filter settings display in the configured ECG color.
- The ECG waveform area provides scrolling, real-time waveform data and an erase bar to provide a time indicator of oldest and new data.
- The ECG waveform area scrolls the waveform in the configured sweep speed.
- The ECG waveform area rails the top most value when the waveform exceeds the upper scale limit for real-time waveforms.
- The ECG waveform area rails the bottom most value when the waveform exceeds the lower scale limit for real-time waveforms.
- The ECG waveform area indicates a Pacer indicator when a pace pulse is detected and Paced is enabled.

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8 Monitoring SpO_2 (Optional)

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8.1 Introduction

The chapter describes the SpO_2 monitoring function at the TD60 in detail, including connecting the SpO_2 module, configuring the SpO_2, and monitoring the SpO_2. For details about the SpO_2 parameter setup at the central station (CS), refer to ***Chapter 9 Monitoring with the TD60 at the CS***.

SpO_2 monitoring is a non-invasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photo detector in the probe. The SpO_2 module processes the electrical signal and displays a waveform and digital values for SpO_2 and pulse rate.

The TD60 can be configured with Masimo SpO_2 or Nonin SpO_2.

NOTE

- **A functional tester or SpO_2 simulator cannot be used to assess the accuracy of a SpO_2 module or a SpO_2 sensor.**
- **This device is calibrated to display functional oxygen saturation.**
- **A pulse oximeter should not be used as an apnea monitor.**
- **Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.**
- **The MS board pulse oximeter can be used during defibrillation, but the readings may be inaccurate for a short time.**

8.2 Measurement Limitations

If the SpO_2 measurement seems out of range or inaccurate, check the patient's vital signs. Then check the equipment and SpO_2 sensor. The following factors may influence the accuracy of measurement:

- Ambient light
- Physical movement
- Low perfusion
- Electromagnetic interference

- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO_2 sensor, or use of incorrect SpO_2 sensor
- Drop of arterial blood flow to immeaurable level caused by shock, anemia, low temperature or vasoconstrictor.
- Inaccurate measurements may be caused by venous pulsations.
- Placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intra-vascular line.
- Loss of pulse signal can occur when the sensor is too tight.
- Loss of pulse signal can occur when there is arterial occlusion proximal to the sensor.

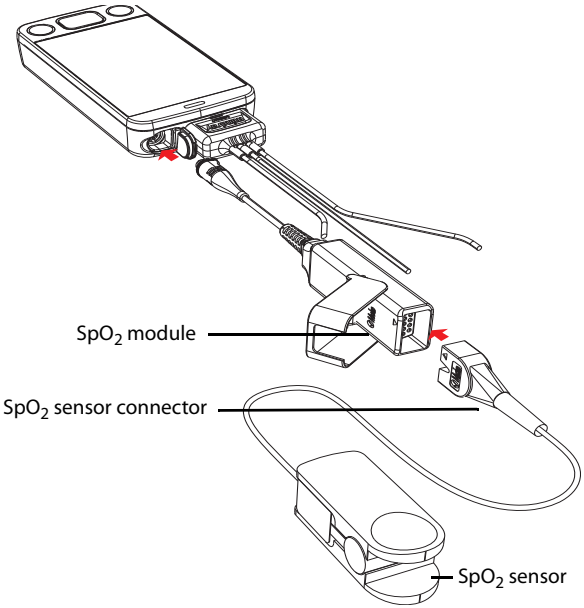
8.3 Safety

WARNING

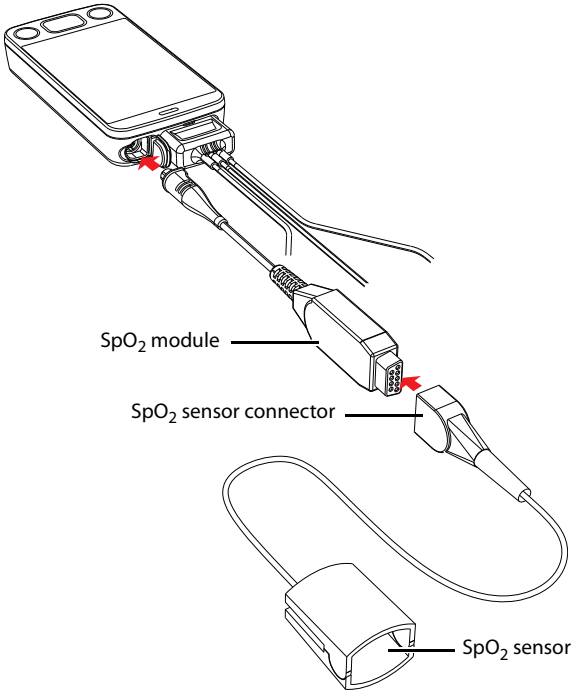
- **Only use SpO_2 sensors specified in this manual. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.**
- **The operator is responsible for checking the compatibility of the pulse oximetry monitor, sensor, and patient cable prior to use. Incompatible components can result in degraded performance and/or device malfunction.**
- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.**
- **Do not use SpO_2 sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.**
- **Prolonged and continuous monitoring may increase the temperature of the sensor and cause the patient discomfort. It is especially important to check the sensor placement, and ensure proper attachment on patients suffering from poor perfusion or skin sensitivity. Check the sensor location every two to three hours and move to another location if the skin deteriorates. More frequent examinations may be required for different patients.**

8.4 Connecting the SpO_2 Module

Connect the SpO_2 module to the TD60. The TD60 can auto detect the SpO_2 module type when the SpO_2 module is connected.



Connecting the Masimo SpO_2 module



Connecting the Nonin SpO_2 module

8.5 Changing the SpO_2 Settings

You can change the SpO_2 settings from the SpO_2 menu.

8.5.1 Configuring the SpO_2 Setup

Enter the SPO_2 menu in either of the following ways:

- On the main screen, tap the SpO_2 digital area or SpO_2 waveform area to enter the **SpO_2** menu.
- In the main menu, tap **Parameter Setup** → **SpO_2** to enter the **SpO_2** menu.

1. In the **Setup** section of the **SpO_2** menu, select the options described in the following table.

Options	Description	Settings*
Display PI (Masimo only)	Configures whether or not to show the perfusion index (PI) value in the digital area. The perfusion index allows clinicians to assess the pulse strength at the monitoring site for optimal sensor placement. PI gives the numerical value for the pulsatile to non-pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength.	**On**, Off
Sensitivity (Masimo only)	Selects the sensitivity mode depending upon signal quality and patient motion. High: This mode should be used for the sickest patients, where obtaining a reading is most difficult. High Sensitivity is designed to interpret and display data for even the weakest of signals. This mode is recommended during procedures and when clinician and patient contact is continuous. Normal: This mode provides the best combination of sensitivity and probe off detection performance. This mode is recommended for the majority of patients. APOD (Adaptive Probe Off Detection): This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. This mode is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc.)	High, Normal, and **APOD**

* *The factory default settings are in bold.*

Options	Description	Settings*
Averaging (Masimo only)	The user-selectable averaging feature allows the clinician to select the desired level of visibility to subtle variations in the measured value. Depending on the patient acuity and area of care, shorter averaging times are sometimes preferred (sleep testing) over longer averaging times (telemetry) and vice-versa. 8-second averaging is generally considered the most common averaging interval and recommended for most patients since it is short enough to provide visibility to subtle desaturations while also being long enough to minimize major changes in SpO_2 due to quick, transitory desaturations. Although averaging times greater than 10 seconds are more likely to reduce visibility to rapid, brief desaturations, this may be desirable in care areas where brief desaturations that do not require clinician intervention occur more often (such as NICU). It is also recommended that this be enabled as a "sticky" configuration so as to hold the setting after power cycles.	2-4 sec, 4-6 sec, **8 sec**, 10 sec, 12 sec, 14 sec, 16 sec
Fast SAT (Masimo only)	Selects whether or not to enable FastSat. FastSat enables rapid tracking of arterial oxygen saturation changes as may be required in urgent situations.	**On**, Off
Color	Selects the SpO_2 waveform color.	16 colors The default color is cyan.

* *The factory default settings are in bold.*

2. Tap to exit the **SpO_2** menu.

8.5.2 Configuring the SpO_2 Waveform

1. In the **Waveform** field of the **SpO_2** menu, select the options described in the following table.

Options	Description	Settings*
Speed	Selects the SpO_2 pleth waveform speed.	6.25 mm/s, **12.5 mm/s**, 25 mm/s
Display SIQ (Masimo only)	Selects whether or nor to show the Signal Indicator Quality (SIQ) in the SpO_2 waveform area. The SIQ wave indicates the confidence associated with the saturation measurement and timing of the pulse. Higher pulse indicates a better signal.	**On**, Off

* *The factory default settings are in bold.*

2. Tap to exit the **SpO_2** menu.

8.6 SpO_2 Measurement

8.6.1 Identifying SpO_2 Modules

To identify which SpO_2 module you are using, see the company logo on the SpO_2 module.

- Masimo SpO_2 module: white, with a logo of Masimo SET.
- Nonin SpO_2 module: blue, with a logo of Nonin.

8.6.2 Applying the Sensor

1. Select an appropriate sensor according to the module type, patient size, and weight.
2. Remove colored nail polish from the application site.
3. Apply the sensor to the patient.
4. Connect the sensor to the SpO_2 module and the SpO_2 module to the TD60.

   The SpO_2 measurement displays when the TD60 detects that a sensor is connected to the patient.

WARNING

- **When equipped with Masimo SpO_2 module, use only Masimo SpO_2 sensors specified in this manual. Use of other SpO_2 sensors may cause improper oximeter performance.**
- **When equipped with Nonin SpO_2 module, use only Nonin SpO_2 sensors specified in this manual. Use of other SpO_2 sensors may cause improper oximeter performance.**
- **Do not disconnect the Nonin Spo_2 sensor connector from the Nonin SpO_2 module during defibrillation.**
- **If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.**

CAUTION

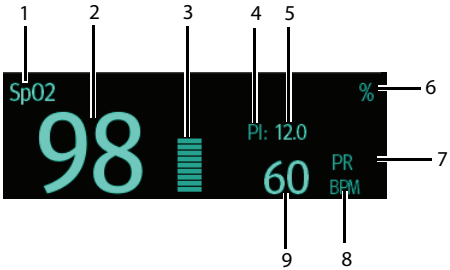
- **Many patients suffer from poor peripheral perfusion due to hypothermia, hypovolemia, severe vasoconstriction, reduced cardiac output, etc. These symptoms may cause a loss in vital sign readings.**

8.7 Understanding the SpO_2 Display

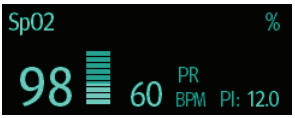
8.7.1 SpO_2 Digital Area

The SpO_2 digital area displays:

1. Parameter name
2. SpO_2 value
3. Perfusion indicator
4. Perfusion index (PI) label
5. Perfusion index value
6. SpO_2 unit of measure
7. Pulse rate (PR) label
8. PR measurement unit
9. PR value



Masimo SpO_2 digital area (for portrait display)



Masimo SpO_2 digital area (for landscape display)

Nonin SpO_2 digital area

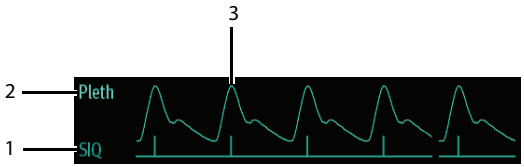
8.7.2 About the SpO_2 Digital Area

- The SpO_2 digital area displays in units of % with a resolution of 1%.
- The SpO_2 PR value displays in units of bpm with a resolution of 1 bpm.
- Displays Masimo PI resolution as 0.01 when the PI value is smaller than 10%.
- Displays Masimo PI resolution as 0.1 when the PI value is greater than or equal to 10%.
- If the SpO_2 measurement or PR is invalid, "- - -" displays in place of digits.

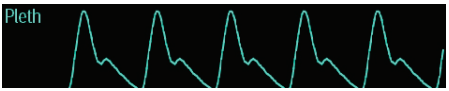
8.7.3 SpO_2 Waveform Area

The SpO_2 waveform area displays:

1. Signal Indicator Quality (SIQ)
2. Area name
3. Pleth waveform



Masimo SpO_2 waveform area (SIQ enabled)



Nonin SpO_2 waveform area

8.7.4 About the SpO_2 Waveform Area

- Displays in the configured SpO_2 color.
- Provides scrolling, real-time waveform data.
- Scrolls the waveform in the configured sweep speed.
- Automatically scales the SpO_2 waveform data area to maximize the vertical height of the Pleth waveform for the data range.
- If using Masimo SpO_2, the Signal Quality Index (SIQ) will display below the waveform if enabled.

8.8 Masimo Information

- Masimo Patents

  This device is covered under one or more the following U.S.A. patents: 5,758,644; 5,823,950; 6,011,986; 6157,850; 6,263,222; 6,501,975; 7,469,157 and other applicable patents listed at: www.masimo.com/patents.htm.

- No Implied License

  Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

9 Monitoring with the TD60 at the CS

Introduction 9-2
Physiological Alarms 9-2
ECG Monitoring 9-12
QT Monitoring 9-18
ST Monitoring 9-22
Arrhythmia Monitoring 9-27
SpO2 Monitoring 9-33

9.1 Introduction

The chapter describes the configurations and displays at the central station (CS) once the TD60 is connected to the CS.

At the CS, Mindray ECG algorithm and Mortara ECG algorithm are available. You can select either algorithm as required.

9.2 Physiological Alarms

At the CS, you can view and change the physiological alarm limits and alarm levels in the **Alarm Setup** menu. The **Alarm Setup** menu has three tabs:

- **Parameter Alarm Settings**: view and change the parameter alarm limits, alarm levels and alarm responses.
- **Arrhythmia Alarms**: view and change the arrhythmia alarms levels, and alarm responses.
- **Arrh. Threshold Setup**: view and change the arrhythmia threshold settings for some arrhythmia alarms.

For details about the **Alarm Setup** menu, refer to the ***BeneVision Central Station Operator's Manual (P/N 046-007960-00)***.

WARNING

- **Be aware that the devices in your care area may each have different alarm settings to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring.**
- **A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, such as an intensive care unit or cardiac operating room.**
- **Make sure that the alarm limits settings are appropriate for your patient before monitoring.**
- **When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.**
- **Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.**

WARNING

- **If you switch off all arrhythmia alarms, the CS cannot give any arrhythmia alarms. Always keep the patient under close surveillance.**

9.2.1 Factory Default Parameter Alarm Limits

The following table lists the factory default alarm limits for all parameters.

Parameters	Alarm limit	Step	Adult	Pediatric
HR Unit of measure: bpm Invalid data: "--"	High limit	1	(Low limit + 2) to 300 Default: 120	(Low limit + 2) to 350 Default: 160
	Low limit	1	15 to (high limit - 2) Default: 50	15 to (high limit - 2) Default: 75
ST Single Unit of measure: mV Invalid data: "--"	High limit	0.01	(Low limit + 0.20) to 2.00 Default: 0.20	(Low limit + 0.20) to 2.00 Default: 0.20
	Low limit	0.01	-2.00 to (high limit – 0.20) Default: -0.20	-2.00 to (high limit – 0.20) Default: -0.20
ST Dual Unit of measure: mV Invalid data: "--"	High limit	0.01	(Low limit + 0.20) to 2.00 Default: 0.20	(Low limit + 0.20) to 2.00 Default: 0.20
	Low limit	0.01	-2.00 to (high limit – 0.20) Default: -0.20	-2.00 to (high limit – 0.20) Default: -0.20
QTc Unit of measure: ms Invalid data: "--"	High limit	1	200 to 800 Default: 500	200 to 800 Default: 480
	Low limit	N/A	N/A	N/A
ΔQTc* Unit of measure: ms Invalid data: "--"	High limit	1	30 to 200 Default: 60	30 to 200 Default: 60
	Low limit	N/A	N/A	N/A

* *ΔQTc is only available for Mindray ECG algorithm.*

Parameters	Alarm limit	Step	Adult	Pediatric
SpO_2 Unit of measure: % Invalid data: "--"	High limit	1	(Low limit + 1) to 100 Default: 100	(Low limit + 1) to 100 Default: 100
	Low limit	1	0 to (high limit - 1) Default: 90	0 to (high limit - 1) Default: 90
SpO_2 Desat Unit of measure: % Invalid data: "--"	High limit	N/A	N/A	N/A
	Low limit	1	0 to 100 Default: 80	0 to 100 Default: 80
PR Unit of measure: bpm Invalid data: "--"	High limit	1	(Low limit + 2) to 300 Default: 120	(Low limit + 2) to 300 Default: 160
	Low limit	1	18 to (high limit - 2) Default: 50	18 to (high limit - 2) Default: 75

* *ΔQTc is only available for Mindray ECG algorithm.*

NOTE

- **The SpO_2 Desat alarm limit is restricted such that the alarm limit can not be higher than the SpO_2 low limit.**

9.2.2 Parameter Alarm Responses

At the CS, the following parameter alarm responses may occur when a parameter alarm occurs.

- Record on Alarm: directs the CS to send the alarm data to the configured recorder.
- Print on Alarm: directs the CS to send the alarm data to the configured printer.
- Paging Switch: directs the CS to send an alarm to the beeper to notify the clinician.

9.2.3 Factory Default Parameter Alarm Settings

The following table lists the factory default alarm levels and responses for all parameters.

Parameters	Alarm levels*			Activation State	Factory default alarm responses		
	High	Medium	Low		Record on Alarm	Print on Alarm	Paging Switch
HR	X	**X****	—	On	Off	Off	Off
ST Single	X	**X**	X	Off	Off	Off	Off
ST Dual	X	**X**	X	Off	Off	Off	Off
QTc	X	**X**	X	Off	Off	Off	Off
ΔQTc***	X	**X**	X	Off	Off	Off	Off
SpO_2	X	**X**	—	On	Off	Off	Off
SpO_2 Desat****	**X**	—	—	On	Off	Off	Off
PR	X	**X**	—	On	Off	Off	Off

* *X indicates available alarm level, — indicates alarm level not available*

** *The factory default settings are in bold.*

*** *ΔQTc is only available for Mindray ECG algorithm.*

**** *The alarm level option for SpO_2 Desat is not configurable.* ***High*** *is the only alarm level and cannot be changed.*

9.2.4 Factory Default Arrhythmia Alarm Settings

9.2.4.1 Mindray Algorithm

Parameters	Alarm levels*				Activation State	Factory default alarm responses		
	High	Medium	Low	Message		Record on Alarm	Print on Alarm	Paging Switch
Asystole	**X****	—	—	—	On	Off	Off	Off
VFib/VTac	**X**	—	—	—	On	Off	Off	Off
VTac	**X**	—	—	—	On	Off	Off	Off
Vent. Brady	**X**	—	—	—	On	Off	Off	Off
Extreme Tachy	**X**	—	—	—	On	Off	Off	Off
Extreme Brady	**X**	—	—	—	On	Off	Off	Off
PVCs/min	X	**X**	X	X	On	Off	Off	Off
R on T	X	**X**	X	X	On	Off	Off	Off
Run PVCs	X	X	**X**	X	Off	Off	Off	Off
Couplet	X	X	X	**X**	Off	Off	Off	Off
PVC	X	X	X	**X**	Off	Off	Off	Off
Vent. Rhythm	X	**X**	X	X	On	Off	Off	Off
Bigeminy	X	**X**	X	X	On	Off	Off	Off
Trigeminy	X	**X**	X	X	On	Off	Off	Off
Tachy	X	**X**	X	X	Off	Off	Off	Off
Brady	X	**X**	X	X	Off	Off	Off	Off
Pacer Not Pacing	X	X	X	**X**	Off	Off	Off	Off

* *X indicates available alarm level, — indicates alarm level not available*

** *The factory default settings are in bold.*

Parameters	Alarm levels*				Activation State	Factory default alarm responses		
	High	Medium	Low	Message		Record on Alarm	Print on Alarm	Paging Switch
Pacer Not Capture	X	X	X	**X**	Off	Off	Off	Off
Missed Beat	X	X	X	**X**	Off	Off	Off	Off
Multif. PVC	X	**X**	X	X	Off	Off	Off	Off
Nonsus. Vtac	X	**X**	X	X	On	Off	Off	Off
Pause	X	X	**X**	X	Off	Off	Off	Off
AFib	X	X	X	**X**	Off	Off	Off	Off
Irr.Rhythm	—	—	X	**X**	Off	Off	Off	Off
Pauses/min	X	**X**	X	X	On	Off	Off	Off

* *X indicates available alarm level, — indicates alarm level not available*

** *The factory default settings are in bold.*

NOTE

- **When Paced is set to Yes, the Missed Beat (MIS) alarm is reported as the pacer not captured (PNC) or pacer not paced (PNP) alarm.**

9.2.4.2 For Mortara Algorithm

Parameters	Alarm levels*				Activation State	Factory default alarm responses		
	High	Medium	Low	Message		Record on Alarm	Print on Alarm	Paging Switch
Asystole	**X****	—	—	—	On	Off	Off	Off
VFib	**X**	—	—	—	On	Off	Off	Off
VTac	**X**	—	—	—	On	Off	Off	Off
Extreme Tachy	**X**	—	—	—	On	Off	Off	Off
Extreme Brady	**X**	—	—	—	On	Off	Off	Off
PVCs/min	X	**X**	X	X	On	Off	Off	Off
R on T	X	**X**	X	X	On	Off	Off	Off
Run PVCs	X	X	**X**	X	Off	Off	Off	Off
Couplet	X	X	X	**X**	Off	Off	Off	Off
Vent. Rhythm	X	**X**	X	X	On	Off	Off	Off
Bigeminy	X	**X**	X	X	On	Off	Off	Off
Trigeminy	X	**X**	X	X	On	Off	Off	Off
Tachy	X	**X**	X	X	Off	Off	Off	Off
Brady	X	**X**	X	X	Off	Off	Off	Off
Pacer Not Pacing	X	X	X	**X**	Off	Off	Off	Off
Pacer Not Capture	X	X	X	**X**	Off	Off	Off	Off
Multif. PVC	X	**X**	X	X	Off	Off	Off	Off
Pause	X	X	**X**	X	Off	Off	Off	Off

* *X indicates available alarm level, — indicates alarm level not available*

** *The factory default settings are in bold.*

Parameters	Alarm levels*				Activation State	Factory default alarm responses		
	High	Medium	Low	Message		Record on Alarm	Print on Alarm	Paging Switch
Irr.Rhythm	—	—	X	**X**	Off	Off	Off	Off
Pauses/min	X	**X**	X	X	On	Off	Off	Off

* *X indicates available alarm level, — indicates alarm level not available*

** *The factory default settings are in bold.*

NOTE

- **The priority of lethal arrhythmia alarms is always high. It is unchangeable.**

In addition, the activation state of some arrhythmias can be set as a whole with the following buttons that are at the bottom of the **Arrhythmia Alarms** tab.

Button	Description
Lethals Only	Sets the lethal arrhythmia alarms to on and all non-lethal arrhythmia alarms to off.
All Alarm On	Sets all arrhythmia alarms to on.
All Alarm Off	Sets all arrhythmia alarms to off. This button is enabled when the **Lethal Arrh. OFF** option in the **Telemetry** tab from the **Admin Setup** menu is set to **Enable**.

9.2.5 Arrhythmia Threshold Settings

When an arrhythmia violates its threshold, an alarm is triggered. For the Mortara algorithm, the setting of asystole delay is related to arrhythmia relearn. When HR is less than 30 bpm, it is recommended to set asystole delay to 10 s.

9.2.5.1 Mindray ECG algorithm

Arrh. event	Range or Option	Default	Step	Unit of measure
PVCs High	1 to 100	10	1	minute
Pauses/min	1 to 15	8	1	N/A
Asys. Delay	3 to 10	4	1	second
Tachy High	60 to 300	Adult: 120 Pediatric: 160	5	bpm
Brady Low	15 to 120	Adult: 50 Pediatric: 75	5	bpm
Extreme Tachy	60 to 300	Adult: 160 Pediatric: 180	5	bpm
Extreme Brady	15 to 120	Adult: 35 Pediatric: 50	5	bpm
Multif. PVC's Window	3 to 31	15	1	/min
Vtac Rate	100 to 200	130	5	bpm
Vtac PVC	3 to 99	6	1	beat
Pause Time	1.5, 2.0, and 2.5	2.0	N/A	second
Vbrd Rate	15 to 60	40	5	bpm
Vbrd PVCs	3 to 99	5	1	beat

9.2.5.2 Mortara ECG algorithm

Arrh. event	Range or Option	Default	Step	Unit
PVCs High	1 to 100	10	1	minute
Pauses/min	1 to 15	8	1	N/A
Asys. Delay	2 to 10	4	1	seconds
Vtac Rate	100 to 200	130	5	bpm
Vtac PVC	3 to 12	6	1	beat
Extreme Tachy	Adult: 100 to 300 Pediatric: 160 to 300	Adult: 160 Pediatric: 180	5	bpm
Extreme Brady	Adult: 15 to 60 Pediatric: 15 to 80	Adult: 35 Pediatric: 50	5	bpm
Multif. PVC's Window	3 to 31	15	1	/min
Tachy High	Adult: 100 to 300 Pediatric: 160 to 300	Adult: 120 Pediatric: 160	5	bpm
Brady Low	Adult: 15 to 60 Pediatric: 15 to 80	Adult: 50 Pediatric: 75	5	bpm
Pause Threshold RR	1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, and 2.0	2.0	N/A	s

9.3 ECG Monitoring

At the CS, you can view and change the heart rate (HR), QT, ST, and arrhythmia settings in the **ECG** tab of the **Parameter Setup** menu.

For details about the **Parameter Setup** menu, refer to the ***BeneVision Central Station Operator's Manual (P/N 046-007960-00)***.

9.3.1 HR Settings

The following table lists the HR settings in the **HR** section of the **ECG** tab.

Options or Buttons	Description	Settings*
HR Activation State	Configures whether or not to enable the HR alarm.	**On**, Off
HR Alarm Priority	Configures the HR alarm levels.	High, **Med**
HR High Limit (bpm)	Configures the HR high alarm limit.	Adult: (Low limit + 2) to 300 The default is **120**. Pediatric: (Low limit + 2) to 350 The default is **160**.
HR Low Limit (bpm)	Configures the HR low alarm limit.	Adult: 15 to (high limit - 2) The default is **50**. Pediatric: 15 to (high limit - 2) The default is **75**.
Pacer Rate (bpm) (only Mortara ECG algorithm)	When some pacemaker pulses are difficult to reject, the pulses are counted as a QRS complex and could result in an incorrect HR and failure to detect some arrhythmias. Configures the pacemaker rate, the system can calculate HR and detect arrhythmias more accurately.	40 to 100 The default is **60**.
	The option is unavailable when **Paced** is set to **No** at the TD60. For details about the paced status, refer to ***"Checking the Paced Status" on page 7 - 10***.	
Sweep Speed	Configures the ECG wave speed.	6.25 mm/s, 12.5 mm/s, **25 mm/s**, 50 mm/s
HR Source	Configures the HR source.	**ECG**, SpO_2, Auto, Both

* *The factory default settings are in bold.*

Options or Buttons	Description	Settings*
HR Record on Alarm	Select whether or not to activate the option to direct the CS to send the HR alarm data to the configured recorder.	On, **Off**
Waveform Setup	Select to display the **Waveform Setup** menu.	Refer to ***"Waveform Setup" on page 9 - 13*** for details.
Other Settings	Select to display the **Other Settings** menu.	Refer to ***"Other Settings" on page 9 - 15*** for details.

* *The factory default settings are in bold.*

9.3.2 Waveform Setup

The ECG leads waveforms displayed in the waveform area are defined as the displaying lead.

The CS uses information from two leads to detect beats and to compute HR. These two leads are referred to as the primary and secondary leads. In addition, for Mortara ECG algorithm, information from an additional lead (analysis lead) is made use of to classify the beats (normal, abnormal etc). The user can select any of the available leads (depending on whether a 3 or 5 lead cable is used) as primary, secondary or other analysis leads.

For best results, the following guidelines should be used:

- The QRS complex should be tall, narrow and preferably either completely above or below the baseline. If at all possible, avoid selecting a lead where the QRS complex is biphasic.
- The P-waves and T-waves should be small compared to the QRS. They should be less than about 0.2 mV.

9.3.2.1 Changing the Setting for Analysis Leads and Displaying Leads

The default system setting for the analysis leads and displaying leads is **On**, which means that the analysis leads are consistent with the displaying leads. You can change the default setting as following steps, if necessary.

1. At the CS, click **Admin Setup** → input the password → **OK**.
2. In the **Admin Setup** menu, click the **Telemetry** tab.
3. On the left side of the **Telemetry** tab, click **Analysis Lead Setting**.

   The corresponding setting displays to the right of **Telemetry**.
4. Set **Consistent with Displayed Lead** to **On** or **Off**.
   - **On**: the analysis lead is the same as the displaying lead.
   - **Off**: the analysis lead is different from the displaying lead.

9.3.2.2 Changing ECG Wave Settings

In the **Waveform Setup** menu, you can configure the displaying leads and analysis leads as desired. The lead settings are dependent on the setting of **Analysis Lead Setting**.

- When **Analysis Lead Setting** is set to **On**, the ECG waveform configurations are applied for the displaying leads and analysis leads. Follow the steps below to configure the ECG waveform setting:

  1. In the **HR** section of the **ECG** tab, click **Waveform Setup**.

     The **Waveform Setup** menu displays.

  2. Select the options described in the following table to configure the ECG waveforms.

Options	Description	Settings*	
		Lead	Waveform size
ECG 1	Select the desired ECG lead and set the corresponding gain for ECG 1.	I, **II**, III, aVR, aVL, aVF, V	×0.125, ×0.25, ×0.5, **×1**, ×2, ×4
ECG 2	Select the desired ECG lead and set the corresponding gain for ECG 2.	**I**, II, III, aVR, aVL, aVF, V	×0.125, ×0.25, ×0.5, **×1**, ×2, ×4
ECG 3	Select the desired ECG lead and set the corresponding gain for ECG 3.	I, II, III, aVR, aVL, aVF, **V**	×0.125, ×0.25, ×0.5, **×1**, ×2, and ×4

* *The factory default settings are in bold.*

  3. Click **Exit** to save the settings and close the **Waveform Setup** menu.

- When **Analysis Lead Setting** is set to **Off**, the displaying leads and analysis leads should be configured respectively. Follow the steps below to configure the ECG waveform setting:

  1. In the **HR** section of the **ECG** tab, click **Waveform Setup**.

     The **Waveform Setup** menu displays.

  2. Select the options described in the following table to configure the ECG waveforms.

Options	Description	Settings*	
		Lead	Waveform size
ECG 1	Select the desired ECG lead and set the corresponding gain for ECG 1 to display in the waveform area.	I, **II**, III, aVR, aVL, aVF, V	×0.125, ×0.25, ×0.5, **×1**, ×2, ×4

* *The factory default settings are in bold.*

Options	Description	Settings*	
		Lead	Waveform size
ECG 2	Select the desired ECG lead and set the corresponding gain for ECG 2 to display in the waveform area.	**I**, II, III, aVR, aVL, aVF, V	×0.125, ×0.25, ×0.5, **× 1**, × 2, × 4
ECG 3	Select the desired ECG lead and set the corresponding gain for ECG 3 to display in the waveform area.	I, II, III, aVR, aVL, aVF, **V**	×0.125, ×0.25, ×0.5, **× 1**, × 2, × 4
Primary lead	Configures the primary analysis lead.	I, **II**, III, aVR, aVL, aVF, V	None
Secondary lead	Configures the secondary analysis lead.	**I**, II, III, aVR, aVL, aVF, V	None
Classification lead (only for Mortara ECG algorithm)	Configures other analysis lead.	I, II, III, aVR, aVL, aVF, **V**	None

* *The factory default settings are in bold.*

3. Click **Exit** to save the settings and close the **Waveform Setup** menu.

9.3.3 Other Settings

The following table lists all settings in the **Other Settings** menu.

Options	Description	Settings*
Paced	The option is unavailable at the CS. The paced status can be set at the TD60 only. Refer to ***"Checking the Paced Status" on page 7 - 10*** for details.	
Pacer Reject	Configures whether or not to reject the pace pulses. ■ **On**: the pace pulses are not counted as extra QRS complexes. ■ **Off**: the pace pulses are not rejected.	On, **Off**
	This **Pacer Reject** option is only available when **Paced** is set to **Yes** at the TD60.	
Filter	Configures the ECG filter in all operating modes. ■ **Monitor**: use under normal measurement conditions. ■ **ST**: use when the ST monitoring is applied.	**Monitor**, ST

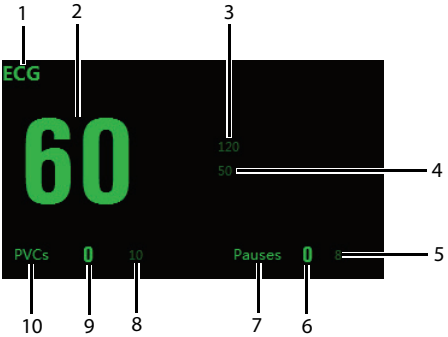
* *The factory default settings are in bold.*

9.3.4 ECG Display

9.3.4.1 ECG Digital Area

The ECG digital area displays:

1. Area name
2. HR value
3. High HR alarm limit
4. Low HR alarm limit
5. Pauses threshold
6. Pauses per minute value
7. Pauses per minute label
8. PVCs threshold
9. PVCs per minute value
10. PVCs per minute label



ECG digital area

NOTE

- **If the Activation State for HR, PVCs or Pauses alarm is set to Off, the symbol displays to the right of corresponding parameter.**

9.3.4.2 ECG Waveform Area

The ECG waveform area displays:

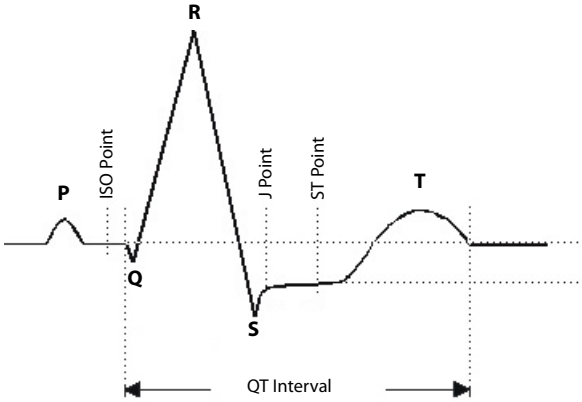
1. ECG Lead
2. ECG waveform size

3. ECG filter setting
4. Notch filter setting
5. ECG waveform
6. ECG scale

ECG waveform area

9.4 QT Monitoring

A normal ECG waveform (as shown in the following figure) typically includes a sharp and well defined QRS complexes with consistent spacing between R waves, and an ECG baseline that is free of noise and artifact.



A normal ECG waveform (for QT monitoring)

The QT interval in an ECG lead is the time interval from the onset of the earliest deflection in the QRS complex to the end of the T wave. QT monitoring can assist in the detection of prolonged QT interval syndrome.

9.4.1 Measurement Limitations

■

QT/QTc values are calculated with 3-leadwire or 5-leadwire ECG cables.

9.4.2 QT Settings

The following table lists the QT settings in the **QT Analysis** section of the **ECG** tab.

Options	Description	Settings*
QT Analysis	Enables or disables QT analysis.	On, **Off**

* *The factory default settings are in bold.*

Options	Description	Settings*
QT Computational Formula	Configures the QTc formula used.	Bazett: $QTc = QT \times \left(\frac{QTHR}{60}\right)^{1/2}$ Fridericia: $QTc = QT \times \left(\frac{QTHR}{60}\right)^{1/3}$ Framingham: $QTc = QT + 154 \times \left(1 - \frac{60}{QTHR}\right)$ Hodges: $QTc = QT + 1.75 \times (QTHR - 60)$
QT Alarm Setup	Configures the QT alarms.	■ For details about the QT alarms limits, refer to "Factory Default Parameter Alarm Limits" on page 9 - 3 for details. ■ For details about the QT alarms responses, refer to "Factory Default Parameter Alarm Settings" on page 9 - 5 for details.
	■ For Mindray algorithm, you can configure the QTc and ΔQTc alarm. ■ For Mortara algorithm, you can configure the QTc alarms.	
QT View	Select to display the **QT View** menu.	Refer to ***"QT View Menu (Only for Mindray ECG Algorithm)" on page 9 - 20*** for details.
	This button is only available for the Mindray ECG algorithm.	

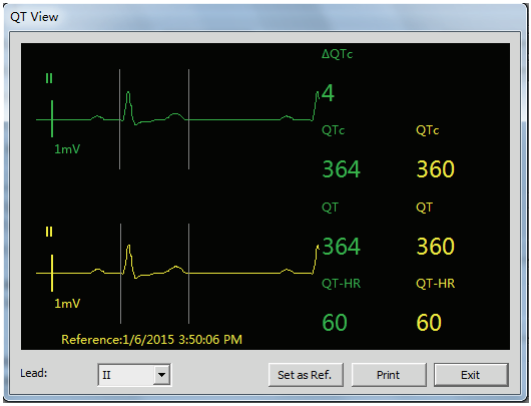
* *The factory default settings are in bold.*

9.4.3 QT View Menu (Only for Mindray ECG Algorithm)

In the **QT View** menu, you can view a snapshot of the real-time wave and to verify that the QT algorithm detects correct Q and T points.

The **QT View** menu displays, as shown in the following figure:

- The current waveform and parameter values display in green.
- The template waveform and parameter values display in yellow.
- The Q and T points are marked with a vertical line.
- The ΔQTc value is equal to the current QTc value minus the template QTc value.



QT View menu

Using the buttons described in the following table as desired.

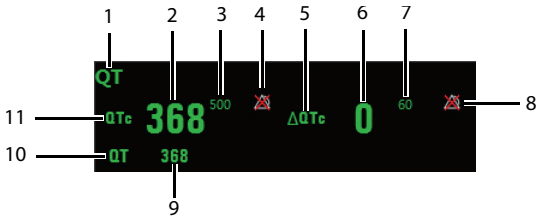
Buttons	Description	Settings*
Lead	Select the desired lead to display on the **QT View** menu screen.	**II**, I, III, aVR, aVL, aVF, V
Set as Ref.	Replaces the template waveform and QT/QTc values with the current waveform and QT/QTc values.	None
	The QT template updated time displays at the bottom of the screen.	
Print	Prints the template and current waveforms, and QT/QTc values for all leads.	None
Exit	Closes the **QT View** Menu.	None

* *The factory default settings are in bold.*

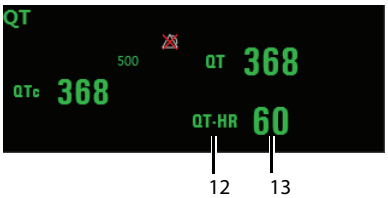
9.4.4 QT Display

When **QT Analysis** is enabled, the QT digital area displays:

1. Area name
2. QTc value
3. High QTc alarm limit
4. Activation State Off symbol for QTc alarm
5. ΔQTc label
6. ΔQTc value
7. High ΔQTc alarm limit
8. Activation State Off icon for ΔQTc alarm
9. QT value
10. QT label
11. QTc label
12. QT-HR label
13. QT-HR value

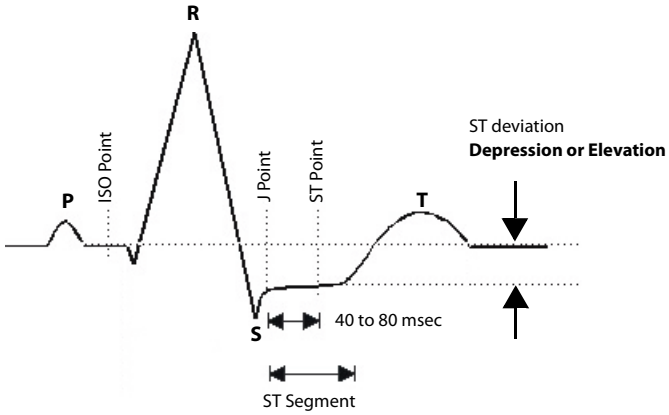


Example QT digital area (for Mindray ECG algorithm)



Example QT digital area (for Mortara algorithm)

9.5 ST Monitoring



A normal ECG waveform (for ST monitoring)

The ST segment of an ECG waveform (as shown in the above figure) represents the period from the end of ventricular de-polarization, to the beginning of ventricular re-polarization, or the end of the QRS complex (the J point) and the beginning of the T-wave. ST Segment analysis is used to monitor the oxygen supply and the viability of the heart muscle.

ST deviation is the vertical distance between the isoelectric (ISO) point level and signal level at ST point.

The ISO point is located between the end of the P-wave and the onset of the QRS complex. The ISO point provides the baseline for this measurement.

The ST point is a fixed distance from the J point at the end of the QRS complex. The ST point can be configured to 40, 60, or 80 milliseconds past the J-point, independent of the heart rate. By default, the ST point is positioned as follows:

- at 80 milliseconds for heart rates less than or equal to 120 beats per minute
- at 60 milliseconds for heart rates greater than 120 beats per minute

All available ECG leads are analyzed to measure deviations in the ST segment.

Selecting leads that contain the least amount of baseline flutter will improve measurement accuracy, but accurate ST deviation measurement is dependent on the correct location of the ISO and ST points.

- ST segment analysis calculates ST segment elevations and depressions for individual leads and then displays them as numerics in the ST digital area.
- A positive value indicates ST segment elevation; a negative value indicates ST segment depression.

WARNING

- **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.**

9.5.1 Measurement Limitations

- ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.
- Since ST is often calculated with a fixed delay from the J point, changes in heart rate may affect ST.
- The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes needs to be determined by a physician.

9.5.2 ST Settings

The following table lists the ST settings in the **ST Analysis** section of the **ECG** tab.

Options or Buttons	Description	Settings*
ST Analysis	Enables or disables ST analysis.	On, **Off**
	If **ST Analysis** is set to **On**, the **Filter** option from the **Other Settings** menu is automatically set to **ST**.	
Display ST Segments	Select whether or not to display the ST segments in the waveform area.	On, **Off**
ST Alarm Setup	Configures the ST alarm settings.	■ For details about the ST alarms limits, refer to "Factory Default Parameter Alarm Limits" on page 9 - 3 for details. ■ For details about the ST alarms responses, refer to "Factory Default Parameter Alarm Settings" on page 9 - 5 for details.
Define ST Point	Select to display the **Define ST Point** menu.	Refer to ***"Adjusting ST Measurement Points" on page 9 - 24*** for details.
	This button is only available when **ST Analysis** is set to **On**.	

* *The factory default settings are in bold.*

9.5.3 Adjusting ST Measurement Points

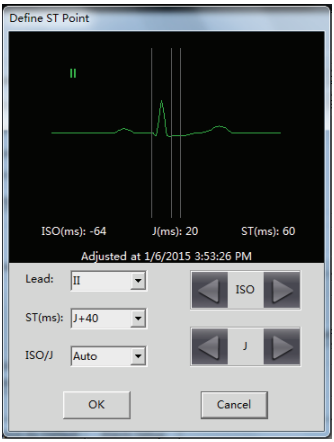
The ISO and ST points need to be adjusted when you start monitoring and if the patient's heart rate or ECG morphology changes significantly. Exceptional QRS complexes are not considered for ST-segment analysis.

WARNING

- **Always make sure that the ST measurement points are appropriate for your patient.**

1. In the **ST Analysis** section of the **ECG** tab, click **Define ST Point**.

   The **Define ST Point** menu displays, as shown in the following figure.



Define ST point menu

2. Adjust the parameter using the buttons described in the following table.

Buttons	Description	Settings*
Lead	Select the desired ECG lead.	I, **II**, III, aVR, aVL, aVF, V
ST (ms)	Based on the ms setting selected, moves the ST point further or closer to the J point in the ST template.	J+40, **J+60**, J+80, J+60/80

* *The factory default settings are in bold.*

Buttons	Description	Settings*
ISO/J	Selecting **Auto** fixes the ISO and J/ST points. Selecting **Manual** allows the clinician to manually adjust ISO and J/ST points.	**Auto**, Manual
ISO left arrow	If **ISO/J** is set to manual, the button adjusts the ISO reference line to the left.	
ISO right arrow	If **ISO/J** is set to manual, the button adjusts the ISO reference line to the right.	
J left arrow	If **ISO/J** is set to manual, the button adjusts the J reference line to the left.	
J right arrow	If **ISO/J** is set to manual, the button adjusts the J reference line to the right.	

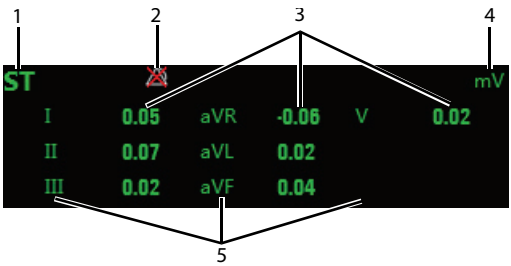
* *The factory default settings are in bold.*

3. Select the **OK** or **Cancel** button.
   - The **OK** button saves the settings and closes the menu.
   - The **Cancel** button closes the menu without saving the settings.

9.5.4 ST Display

When **ST Analysis** is enabled, the ST digital area displays:

1. Area name
2. Activation State Off icon for ST alarm
3. ST values
4. Units of measure
5. Lead identifier

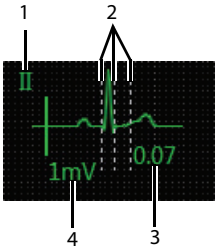


Example 5-lead ST digital area

9.5.5 ST Segment Display

When **Display ST Segments** is enabled, the ST segments display in the waveform area:

1. Lead identifier
2. ST markers (ISO, J/ST)
3. ST value
4. ECG scale



3-lead ST segment

5-lead ST segments

9.6 Arrhythmia Monitoring

WARNING

- **The arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect atrial or supraventricular arrhythmias. It may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.**
- **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.**

9.6.1 Measurement Limitations

- Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.
- The ECG size and QRS width settings affect arrhythmia detection and heart rate calculation sensitivity.
- If QRS amplitude is low, the monitor might not be able to calculate HR and false asystole may occur.
- At the algorithm learning phase, arrhythmia detection may not be available. Therefore, closely monitor the patient's condition during the learning phase and after the learning phase to allow the algorithm to reach optimal detection performance.

9.6.2 Understanding the Arrhythmia Events

9.6.2.1 Mindray ECG Algorithm

Arrhythmia message	Description	Category
Asystole	No QRS detected within the set time threshold in absence of ventricular fibrillation or chaotic signal.	Lethal arrhythmia
VFib/VTac	A fibrillatory wave for 6 consecutive seconds. A dominant rhythm of adjacent Vs and a HR > the V-Tac HR limit.	
VTac	The consecutive PVCs ≥ Vtac PVCs limit, and the HR ≥ the Vtac rate limit.	

Arrhythmia message	Description	Category
Vent. Brady	The consecutive PVCs ≥ the Vbrd threshold and the ventricular HR < the Vbrd Rate threshold.	Lethal arrhythmia
Extreme Tachy	The heart rate is equal to or greater than the extreme tachycardia limit.	
Extreme Brady	The heart rate is equal to or less than the extreme bradycardia limit.	
PVCs/min	PVCs/min exceeds high limit.	Nonlethal arrhythmia
R on T	R on T detected in normal heartbeats.	
Run PVCs	More than 2 consecutive PVCs.	
Couplet	Paired PVCs detected in normal heartbeats.	
PVC	One PVC detected in normal heartbeats.	
Vent. Rhythm	The consecutive PVCs ≥ the Vbrd PVCs limit, and the HR ≥ Vbrd Rate limit but < the Vtac Rate limit.	
Bigeminy	A dominant rhythm of N, V, N, V, N, V.	
Trigeminy	A dominant rhythm of N, N, V,N, N, V, N, N, V.	
Tachy	The average heart rate is equal to or greater than the tachycardia limit.	
Brady	The average heart rate is equal to or less than the bradycardia limit.	
Pacer Not Pacing	No pace pulse detected for 1.75 x average R-to-R intervals following a QRS complex (for paced patients only).	
Pacer Not Capture	No QRS complex detected for 300 milliseconds following a pace pulse (for paced patients only).	
Missed Beat	No beat detected for 1.75 x average R-R interval for HR <120, or No beat for 1 second with HR > 120 (for non-paced patients only), or No beat detected for more than the set pause threshold.	
Multif. PVC	Multiform PVCs detected in Multif. PVC's Window (which is adjustable).	
Nonsus. Vtac	The consecutive PVCs < the Vtac PVCs limit but > 2, and HR ≥ the Vtac Rate limit.	
Pause	No QRS detected within the set time threshold of pause.	
AFib	Continuously detect that the RR intervals of normal sinus beats irregular and no P wave of normal sinus beats.	
Irr. Rhythm	Consistently irregular rhythm.	
Pauses/min	The number of pauses detected per minute.	

9.6.2.2 Mortara ECG Algorithm

Arrhythmia message	Description	Category
Asystole	No QRS complex detected within the set time threshold (in absence of ventricular fibrillation or chaotic signals).	Lethal arrhythmia
VFib	Ventricular fibrillation occurs and persists for 6 seconds.	
VTac	Ventricular HR is greater or equal to the preset threshold and the number of consecutive PVCs is greater than the preset threshold.	
Extreme Tachy	The heart rate is equal to or greater than the extreme tachycardia limit.	
Extreme Brady	The heart rate is equal to or less than the extreme bradycardia limit.	
PVCs/min	PVCs/min exceeds high limit.	Nonlethal arrhythmia
R on T	R on T is detected.	
Run PVCs	More than 2 consecutive PVCs.	
Couplet	Paired PVCs are detected.	
Vent. Rhythm	Ventricular HR is less than the preset threshold and the number of PVCs is greater than or equal to 3.	
Bigeminy	A dominant rhythm of N, V,N, V, N, V.	
Trigeminy	A dominant rhythm of N, N, V,N, N, V, N, N, V.	
Tachy	The HR is greater than the set tachycardia high limit.	
Brady	The HR is less than the set bradycardia low limit.	
Pacer Not Pacing	No pace pulse detected for (60×1000/pace rate +90) milliseconds following a QRS complex or a pacer pulse (for paced patients only).	
Pacer Not Capture	No QRS complex detected for 300 milliseconds following a pace pulse (for paced patients only).	
Multif. PVC	More than 2 PVCs of different forms occur in the predefined search window (3-31).	
Pause	No beat detected for 1.75x average R-R interval for HR <120, or No beat for 1 second with HR >120 (for non-paced patients only), or No beat detected for more than the set pause threshold.	
Irr. Rhythm	Consistently irregular rhythm	
Pauses/min	The number of pauses detected per minute.	

9.6.3 Arrhythmia Settings

The following table lists the arrhythmia settings in the **Arrhythmia Analysis** section of the **ECG** tab.

Options or Buttons	Description	Settings*
Arrhythmia Alarms	Configures the arrhythmia alarm settings.	Refer to ***"Factory Default Arrhythmia Alarm Settings" on page 9 - 6*** for details.
Relearn	Enables an arrhythmia relearning.	Refer to ***"Relearning" on page 9 - 30*** for details.
QRS Threshold Settings	Configures the QRS threshold.	Refer to ***"Configuring the QRS Threshold" on page 9 - 31*** for details.

9.6.4 Relearning

A relearn can be done for arrhythmia, ST analysis, or for both simultaneously.

NOTE

- **ST Analysis must be turned on before it will relearn.**

The TD60 initiates the learning process for ST or Arrhythmia analysis after any of the following:

- TD60 power-up
- Return to normal monitoring from the Standby mode
- Enabling ST or Arrhythmia analysis
- The lead has been changed in ECG 1 waveform (3 lead only)
- Patient size changes
- Selecting the Relearn button in the **Arrhythmia Analysis** section

Selecting the Relearn button in the **Arrhythmia Analysis** section is recommended after one or more of the following:

- ECG electrodes have been repositioned
- Eight hours have passed since the last relearn
- Significant changes occurred to the patient QRS complex

- Significant changes occurred to the patient ECG rhythm
- A clinician has observed clinically questionable arrhythmia calls
- "Learning" occurred during a Leads Off condition

CAUTION

- **Initiate ECG relearning only during periods of normal rhythm and when the ECG signal is relatively noise-free. If ECG learning takes place during ventricular rhythm, the ectopics may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent events of V-Tach and V-Fib.**

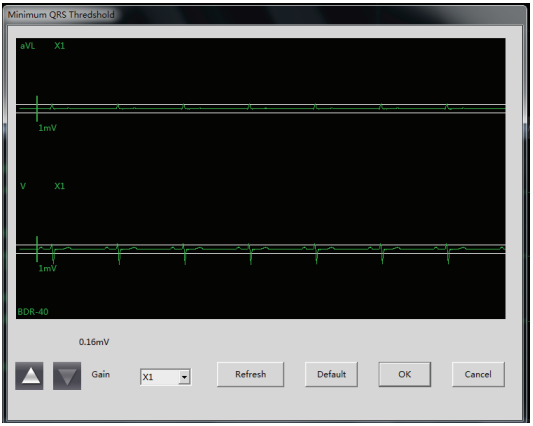
9.6.5 Configuring the QRS Threshold

The minimum detection threshold is approximately 0.16 mV. In case the P waves are very tall, one might consider moving the minimum QRS detection threshold up to be above the level of the P waves, so events like ventricular standstill are not missed.

Two horizontal lines (one below and one above the baseline) appear on the screen. These represent the current minimum detection threshold on the positive and negative sides of the baseline so manual adjustment for both positive and negative going QRS's can be made. Using the commands provided, move the minimum detection threshold up or down to ensure it is above the level of the P waves but below the peak of the R-wave. Since the P-wave height could vary a little from beat to beat, do not set the horizontal line representing the minimum detection threshold at or barely above the level of the peak of the P wave. Ensure that it is at least one or two millimeters above the peak of the P wave but below the peak of the R-wave.

1. In the **Arrhythmia Analysis** section of the **ECG** tab, click **Minimum QRS Threshold**.

   The **Minimum QRS Threshold** menu displays, as shown in the following figure.



Minimum QRS Threshold menu

The current waveform displays the data of previous eight seconds. Use the buttons described in the following table as desired.

Buttons	Description	Settings*
Gain	Select the desired ECG waveform size.	**X1**, X2, X4
Refresh	Displays the real-time waveform.	
Default	Automatically sets the default threshold: 0.16 mV.	
or	Manually adjust the minimum QRS detection threshold. Select the button to move the threshold line above the P wave, or select the button to move the threshold line down closer to the P wave.	

* *The factory default settings are in bold.*

2. Select the **OK** or **Cancel** button.
   - Once the threshold is in the desired position, select the **OK** button to save the settings and close the menu.
   - To quit adjusting the threshold, select the **Cancel** button to close the menu without saving the settings.

9.7 SpO_2 Monitoring

At the CS, you can view and change the SpO_2 settings in the **SpO_2** tab of the **Parameter Setup** menu.

For details about the **Parameter Setup** menu, refer to the ***BeneVision Central Station Operator's Manual (P/N 046-007960-00)***.

9.7.1 Measurement Limitations

Refer to "Measurement Limitations" on page 8 - 2 for details.

9.7.2 SpO_2 Settings

The following table lists the SpO_2 settings in the **SpO_2** tab.

Options	Description	Settings*
Activation State	Configures whether or not to enable the SpO_2 alarm.	**On**, Off
Alarm Priority	Configures the SpO_2 alarm levels.	High, **Med**
Record on Alarm	Selects whether or not to activate the recorder when an SpO_2 alarm is triggered.	On, **Off**
Sweep Speed	Configures the SpO_2 waveform sweep speed.	6.25 mm/s, 12.5 mm/s, **25.0 mm/s**, 50.0 mm/s
Desat Limit Activation State	Configures whether or not to enable the SpO_2 Desat alarm.	**On**, Off
Sensitivity (Masimo only)	The option is not configurable. The option setting is synchronous with the setting at the TD60. Refer to "Configuring the SpO2 Setup" on page 8 - 5.	
SpO_2 High Limit (%)	Configures the SpO_2 high alarm limit.	(Low limit + 1) to 100 The default is **100**.
SpO_2 Low Limit (%)	Configures the SpO_2 low alarm limit.	0 to (high limit - 1) The default is **90**.
PR High Limit (bpm)	Configures the PR high alarm limit.	(Low limit + 2) to 300 The default for adult is **120**. The default for pediatric is **160**.
PR Low Limit (bpm)	Configures the PR low alarm limit.	18 to (high limit - 2) The default for adult is **50**. The default for pediatric is **75**.

* *The factory default settings are in bold.*

Options	Description	Settings*
Desat Limit (%)	Configures the SpO_2 Desat low limit.	0 to 100 The default is **80**.
Averaging (Masimo only)	The option is not configurable. The option setting is synchronous with the setting at the TD60. Refer to "Configuring the SpO2 Setup" on page 8 - 5 for details.	

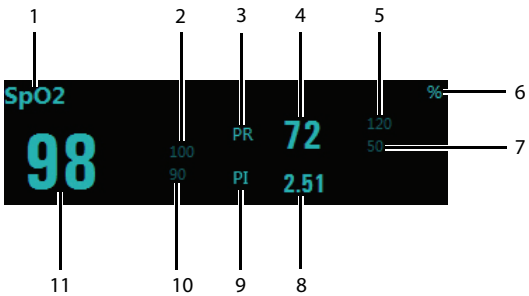
* *The factory default settings are in bold.*

9.7.3 SpO_2 Display

9.7.3.1 SpO_2 Digital Area

The SpO_2 digital area displays:

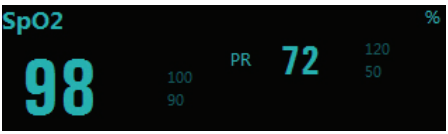
1. Area name
2. High SpO_2 alarm limit
3. PR label
4. PR value
5. High PR alarm limit
6. SpO_2 unit of measure
7. Low PR alarm limit
8. Masimo perfusion index value
9. PI label
10. Low SpO_2 alarm limit
11. SpO_2 value



Masimo SpO_2 digital area

NOTE

- **When HR Source of the ECG tab is set to Both, the PR value displays on the SpO_2 digital area.**

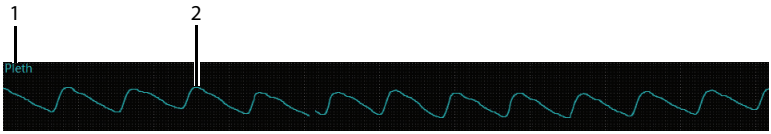


Nonin SpO_2 digital area

9.7.3.2 SpO_2 Waveform Area

The SpO_2 waveform area displays:

1. Area name
2. Pleth waveform



SpO_2 waveform area

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10 Configuring the TD60

Introduction 10-2
Maintenance Menu 10-2

10.1 Introduction

This TD60 Maintenance menu provides access to the system settings such as location, device name, alarm settings, quick keys, screen lock, and password updates. Entering this menu **requires** a password.

10.2 Maintenance Menu

The **Maintenance** menu contains the following submenus:

- General
- Alarms
- Quick Keys
- Defaults
- Screen Lock
- Edit Passcodes
- Device Name
- Demo Mode
- Service

10.2.1 Entering the Maintenance menu

1. In the main menu, tap **Maintenance**.
2. Input the maintenance password.
3. Tap **Accept** to enter the **Maintenance** menu.

10.2.2 Configuring the General Menu

Select **General** to configure the display auto off, language, location, notch filter, ECG lead labeling, SpO_2 module, SpO_2 tone, and enable or disable ECG calibration.

1. In the **Maintenance** menu, tap **General**.

   The current setting displays to the right of the option.
2. Select the options described in the following table.

Options	Description	Settings*
Display Auto Off	Configures the time for display auto off.	**1 min**, 2 min, 5 min, 15 min 30 min, Off
Language	Configures the system language.	**ENGLISH**, FRENCH

* *The factory default settings are in bold.*

Options	Description	Settings*
Location	Changes the hospital and department names.	N/A
Notch Filter	Configures the ECG Notch filter. This option is used to filter out AC line noise from the ECG waveform.	50 Hz, **60 Hz**, Off The default is **50 Hz** when the device is not configured for the US.
ECG Lead Labeling	Changes the ECG lead labeling.	**AHA**, IEC
Calibrate ECG	Enables or disables the ECG verification.	On, **Off** Refer to ***"Verifying the ECG at the TD60" on page 14 - 4*** for details.
SpO_2 Module	Changes the SpO_2 module.	**Masimo**, Nonin
SpO_2 Tone	Configures the SpO_2 tone.	**Mode 1**, Mode 2

* *The factory default settings are in bold.*

3. Tap to exit the **General** menu.

NOTE

- **Mindray recommends the same SpO_2 tone mode be used for the device within a monitoring area.**

10.2.3 Configuring the Alarms Menu

Select **Alarms** to configure the alarm tone, reminder tone, reminder interval, minimum alarm volume, and technical alarm priority.

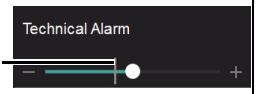
1. In the **Maintenance** menu, tap **Alarms**.

   The current setting displays to the right of the option.

2. Select the options described in the following table.

Section & Options	Description	Settings*
Sounds		

* *The factory default settings are in bold.*

Section & Options	Description	Settings*
Style	Allows an authorized user to set the alarm tone pattern.	**ISO**, Mode 1, Mode 2
Timeout		
Reminder Tone	Allows an authorized user to enable or disable the reminder tone. If the alarm tone is turned off, enabling this setting can issue a periodic reminder tone.	**On**, Off
Reminder Interval	Allows an authorized user to configure the intervals between the alarm tones.	1 min, 2 min, 3 min, **5 min**, 10 min
Minimum Alarm Volume		
Technical	Allows an authorized user to set the minimum technical alarm volume. The minimum technical alarm volume defines the minimum value you can set for the technical alarm volume. For example: If the minimum technical alarm volume is set to 5, the minimum value you can set for the technical alarm volume in the **Audio Volume** menu is 5 (as shown in the following figure). Minimum value  If the minimum technical alarm volume is set to Off, and the technical alarm volume can be set to 0, the alarm sound is turned off and the symbol appears on the screen.	Off, 1, **2**, 3, 4, 5, 6, 7, 8, 9, 10
Technical Alarm Priority		
ECG Lead Off	Allows an authorized user to configure the alarm level.	**Low**, Medium, High
SpO_2 Sensor Off	Allows an authorized user to configure the alarm level.	**Low**, Medium, High

* *The factory default settings are in bold.*

3. Tap to exit the **Alarms** menu.

WARNING

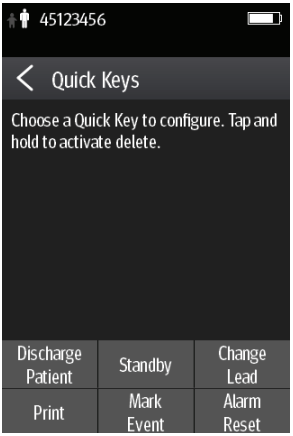
- **When the technical alarm audio volume is set to alarm sound and the alarm sound is turned off, the TD60 will not enunciate technical alarms when they occur. Be careful when turning off the alarm volume.**
- **Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**

10.2.4 Quick Keys Menu

10.2.4.1 Changing the Quick Keys

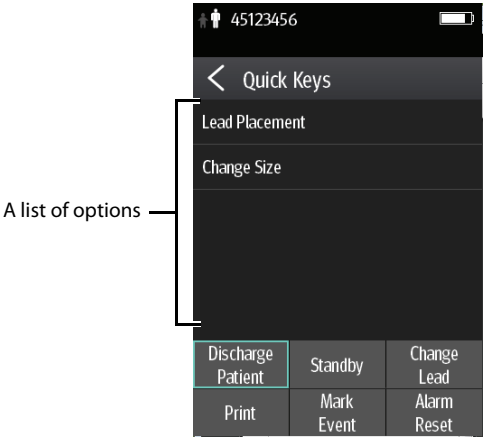
1. In the **Maintenance** menu, tap **Quick Keys**.

   The **Quick Keys** configuration menu displays.



2. From the quick keys area at the bottom of the screen, tap a quick key you want to configure.

   A list of option displays.



3. Tap the desired option from the list of options to configure the selected quick key.
4. Repeat steps 2 to 3 to configure other quick keys, if needed.
5. Tap to exit the **Quick Keys** menu.

10.2.4.2 Deleting a Quick Key

1. From the quick keys area at the bottom of the **Quick Keys** menu, press and hold the desired quick key for two seconds, and then release it.

   The quick key background turns to red and displays **Delete**.
2. Tap **Delete**.

   The quick key is removed from the quick keys area, and the area displays **Not Used**.
3. Tap to exit the **Quick Keys** menu.

10.2.5 Configuring the Defaults Menu

The **Defaults** menu allows an authorized user to manage the system configurations.

1. In the **Maintenance** menu, tap **Defaults**.
2. Select the options described in the following table.

Options	Description
Save Departmental Defaults	Allows an authorized user to save the current device settings for the selected patient category.
Export Device Settings	Copies the user configuration to the external device.

Options	Description
Import Device Settings	Copies the settings from the external device to theTD60 unit. Refer to ***"Transferring a Configuration" on page 10 - 7*** for details.
Restore Factory Defaults	Allows an authorized user to reestablish the original database power up settings to factory default values.

3. Tap to exit the **Defaults** menu.

10.2.6 Transferring a Configuration

The TD60 is capable of configuring multiple devices through one export operation via a wireless interface.

To transfer the configuration from the TD60 unit to an external device:

1. In the **Maintenance** menu of an external device, tap **Defaults** → **Import Device Settings** to enter the settings import mode.
2. In the **Maintenance** menu of the TD60 unit, tap **Defaults** → **Export Device Settings** to enter the **Export Device Settings** menu.

   The discovered external devices are listed in the **Export Device Settings** menu.
3. Select the desired external devices by tapping the check box.
4. Tap **Export** to start exporting the TD60 unit configuration.

   The selected external devices screen will shortly display the "Downloading device settings" message.

WARNING

- **Do not power off the devices during the download process.**

- On the external devices if an import is successful, the external device will display the "Download complete." message, and after 10 seconds return to the **Defaults** menu. On the TD60 unit, the status for the external device will display the "Complete" message.
- On the external device if the import fails, the external device will display the "Import attempt failed." message. On the TD60 unit, the status for the failed external device will display the "Failure" message and remain in the list.

  The user has two options when a failure occurs:

  - To stop the import from the external device, tap the icon to exit the **Import Device Settings**.

- To retry the import from the TD60 unit, tap the external device which is displaying the **Failure** message, tap the **Retry** button to restart the transfer. You may need to repeat the retry operation several times until the transfer is successful.

10.2.7 Screen Lock Menu

10.2.7.1 Understanding the Screen Lock Mode

There are two modes of being able to lock the screen to assist in preventing unauthorized use. Each mode allows the user access to certain features of the product without entering a passcode. When the correct passcode is entered, all features are available.

- Locked Mode Features:
  - Main screen and main menu are not accessible without passcode entry.
  - The message area is still viewable.
  - Hardkeys are enabled.
- View Only Features:
  - Upon powering up, the main screen will be displayed after the new patient choice is made.
  - Main Screen is accessible without passcode entry.
  - The **System Info** menu is accessible by tapping the battery symbol on the main screen.
  - The **Lead Placement** menu is accessible by tapping an “ECG Lead Off” message in the message area.
  - Ability to change display orientation.
  - Hardkeys are enabled.

10.2.7.2 Setting the Screen Lock

The initial enabling of screen lock mode requires a passcode to be entered immediately as follows:

1. In the **Maintenance** menu, tap **Screen Lock** to select a screen lock mode.
2. Enter a new passcode for the screen lock.

   After the passcode is entered, the screen exits the passcode setup menu. The selected lock mode displays to the right of **Screen Lock**.

10.2.7.3 Changing the Current Screen Lock Passcode

1. In the **Maintenance** menu, tap **Screen Lock**.
2. Tap **Screen Lock Passcode**.
3. Input the current password.
4. Input and verify the new password

10.2.8 Changing the Passwords

1. In the **Maintenance** menu, tap **Edit Passwords**.
   - Tap **Maintenance Password** and follow the on-screen instructions to change the maintenance password.
   - Tap **Service Password** and follow the on-screen instructions to change the service password.
2. Tap the icon to exit the **Edit Passwords** menu.

10.2.9 Changing the Device Name

1. In the **Maintenance** menu, tap **Device Name**.
2. Use the on-screen keyboard to input the device name.
3. Tap **Accept** to save the setting and exit the **Device Name** menu.

NOTE

- **Do not set the same device name for the TD60s.**

10.2.10 Demo Mode

Allows an authorized user to choose a demonstration mode for in-servicing staff or testing product features.

10.2.11 Service Menu

Allows an authorized user access to the passcode protected Service menu.

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11 Battery

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Safety 11-2
Installing the Battery 11-3
Checking the Battery Charge Status 11-4
Removing the Battery 11-4
Charging the Rechargeable Lithium-ion Battery 11-5
Storing the Batteries 11-6
Maintaining the Rechargeable Lithium-ion Battery 11-7
Disposing of the Batteries 11-8

11.1 Introduction

The TD60 can be powered by a lithium-ion rechargeable battery or AA batteries. This chapter provides instructions on how to use, maintain, and dispose of the batteries.

11.2 Safety

WARNING

- **Keep the batteries out of children's reach.**
- **Keep the batteries in their original package until you are ready to use them.**
- **The battery compartment should be closed during defibrillation.**
- **Only use specified AA batteries or rechargeable lithium-ion battery to power the TD60. Other power supply may cause damage to the equipment or lead to body injury.**
- **While installing AA batteries, do not apply reverse polarity.**
- **Only use specified fresh AA batteries. Using other AA batteries can give unacceptable performance.**
- **Do not mix batteries of different charge/voltage levels.**
- **Do not mix batteries of different chemistries.**
- **Only use specified rechargeable lithium-ion battery. Unspecified lithium-ion battery can give unacceptable performance.**
- **Use caution when handling the rechargeable lithium-ion battery. Misuse or abuse may cause bodily injury or device damage.**
  - ◆ **Do not short circuit. Take care that the terminals do not contact metal or other conductive materials during transport and storage.**
  - ◆ **Do not crush, drop or puncture the battery. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is externally visible or not, remove the battery from use and dispose of it properly.**
  - ◆ **Do not incinerate batteries or expose them to temperatures above 60° C (140° F).**
- **The rechargeable lithium-ion batteries should be charged in the specified central charger.**

WARNING

- **If a battery shows signs of damage or signs of leakage, replace it immediately. Use caution in removing the battery. Avoid contact with skin. Refer to qualified service personnel.**
- **Some failure conditions, such as short circuits, can cause a battery to overheat during using. High temperature can cause burns to the patient or user. If the device becomes too hot to the touch, remove it from the patient and place aside until it cools. Then remove the battery from the device, and contact your service personnel to identify the cause of overheating.**
- **Replace the battery immediately once the “Critically Low Battery” alarm message displays. Replace the battery in time once the “Low Battery” alarm message displays. If those conditions are not corrected, device shutdown and cessation of monitoring will result.**
- **To eliminate the risk of electrical shock or burn, do not carry loose batteries on your person, such as placing the battery in clothing pockets.**

CAUTION

- **Remove the battery before transporting the device or if the device is not in use or is being stored.**
- **AA batteries should be removed from the device at the end of the battery’s useful life to prevent leakage. In case of battery leakage, use caution to remove the batteries and clean the battery compartment. Install fresh AA batteries and check if the TD60 can power on properly. If the TD60 fails to power on, contact your service personnel.**

11.3 Installing the Battery

Refer to "Installing the Batteries" on page 3 - 5 for details.

11.4 Checking the Battery Charge Status

The battery symbol displaying on the top of main screen indicates the battery charge status. The white part ( ) indicates the remaining battery charge.

NOTE

- **If the "Low Battery" or "Critically Low Battery" alarm occurs, the TD60 turns off the audio, the screen display the "Local Audio Off" message, and the screen brightness turns dimmer.**

11.5 Removing the Battery

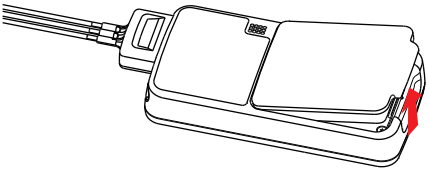
CAUTION

- **Some failure conditions, such as short circuits, can cause a battery to overheat during using. High temperature can cause burns to the patient or user. If the device becomes too hot to the touch, remove it from the patient and place aside until it cools. Then remove the battery from the device, and contact your service personnel to identify the cause of overheating.**
- **Avoid scraping the metal contact in the battery compartment while removing the lithium-ion battery pack or AA battery frame. Otherwise, the broken contact will affect the power supply performance.**
- **Remove the battery before transporting the device or if the device is not in use or is being stored.**

NOTE

- **Retain the ECG cable and SpO_2 module with the device while removing the battery.**

1. Lift up the lithium-ion battery pack or AA battery tray at the bottom of the TD60.



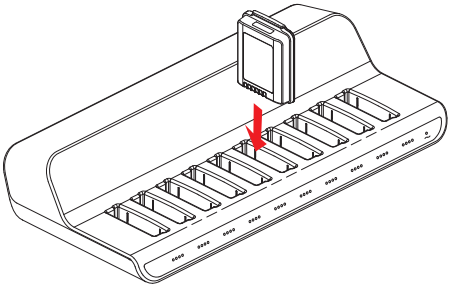
2. Remove the lithium-ion battery pack or AA battery tray from the TD60.

11.6 Charging the Rechargeable Lithium-ion Battery

WARNING

- **Only use the specified central charger to charge to the lithium-ion batteries designated by Mindray.**
- **Only use the approved power cord with the grounded mains plug to firmly connect the central charger to a grounded AC mains socket. Never refit the mains plug to fit an ungrounded AC mains socket.**
- **Do not use the Multiple Portable Socket Outlets (MPSO) or AC mains extension cords. Use an IEC 60601-1 approved isolation / separation transformer, otherwise, it may result in leakage current. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.**
- **Do not place any shield object (such as cloth or paper) to cover the central charger or batteries, and keep ventilated while charging the lithium-ion batteries.**
- **Do not connect other devices to the power supply system.**
- **Do not use the central charger to charge the lithium-ion batteries in high temperature above 40°C.**

Use the central charger to charge the lithium-ion batteries. The central charger can charge 10 lithium-ion batteries at one time. For details about the central charger, refer to the ***BeneVision Central Charger Operator's Manual (P/N 046-007059-00)***.



11.7 Storing the Batteries

11.7.1 Storing Rechargeable Lithium-ion Battery

When storing batteries, make sure that the battery terminals do not come into contact with metallic objects.

If you need to store the batteries for an extended period of time, place the batteries in a cool, dry place (ideally at 15°C or 60°F) with a partial charge of about 50% capacity (two LEDs illuminated). Storing batteries in a cool place can slow the aging process.

Stored batteries should be charged to about 50% of their capacity every six months. The battery should be fully charged prior to first use.

NOTE

- **Remove the lithium-ion battery from the device if the device is not used for a prolonged time (for example, several weeks), and keep the device in clean place to avoid the dust or liquid entering the battery compartment.**
- **Storing batteries at high temperatures for an extended period of time will significantly shorten their life expectancy.**
- **Do not store the batteries in an environment above 60°C (122°F) or lower than -20°C (4°F).**

11.7.2 Storing AA Batteries

If you remove undepleted AA batteries from the TD60 and need to store the batteries, keep the batteries together as a set for later re-use so that all batteries will have the same level of remaining power.

Do not store disposable AA batteries by leaving the batteries in the incorrect polarity position in the TD60.

NOTE

- **Replace the AA battery frame on the battery compartment after removing the AA batteries.**

11.8 Maintaining the Rechargeable Lithium-ion Battery

Take care of the rechargeable lithium-ion battery once you receive a new battery for use. The following table describes the battery maintenance activities and recommended frequency.

Activity	Recommended Frequency
Visual inspection	Before installing a battery in the TD60.
Charge the battery	Upon receipt, after use, a “Low Battery” or “Critically Low Battery” alarm occurs. To optimize performance, a fully or almost fully discharged battery must be charged immediately.
Clean the battery	At each patient discharge, or in case that the battery is exposed to contaminants. Do not clean the battery connector during the cleaning.
Charge stored battery to at least 40% of the battery capacity.	Every six months if the TD60 is not in use for an extended period of time.
Dispose of the battery	When the “Battery Maintenance Required” alarm message displays on the TD60.

The lifetime of a lithium-ion battery depends on the frequency and duration of use. With good maintenance, the useful life is approximately four years or 500 complete charge-discharge cycles. In addtion, experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. Therefore, Mindray strongly recommend that lithium-ion battery should be replaced after two years or 300 complete charge-discharge cycles. Using the outdated battery may cause the device abnormity and unacceptable performance.

The age of a lithium-ion battery begins at the date of manufacture. The date of manufacture is listed on the rear of the battery.

NOTE

- **The battery capacity degrades as using time and number of recharge cycles.Toward the end of its useful life, the battery capacity may be reduced by 20% to 25%. If the reduced battery life is unacceptable for your device, Mindray recommends the battery be replaced.**

11.9 Disposing of the Batteries

11.9.1 Disposing of the Rechargeable Lithium-ion Battery

Discard the lithium-ion battery in the following situations:

- The battery has visual signs of damage.
- The battery fails.
- The battery is aged and its runtime significantly less than the specification.
- The battery has been used for more than two years or 500 complete charge-discharge circles.

Discharge the battery and insulate the terminals with tape before disposal. Properly dispose of the batteries according to local regulations.

11.9.2 Disposing of the AA Batteries

The batteries may be subject to local regulations regarding disposal. Dispose of batteries in approved containers. Follow local regulations, if any, to recycle the batteries.

12 Troubleshooting

General Problems 12-2
Physiological Alarm Messages at the CS 12-3
Technical Alarm Messages at the TD60 12-5

12.1 General Problems

The following table lists the problems that are likely to occur. If the problem persists after corrective actions have been taken, contact your service personnel.

12.1.1 Troubleshooting Tools

- Telemetry Receiver (RC60)
- TD60
- Central Station (CS)

12.1.2 Problem List

Symptom	Possible cause	Solution
No RF Signal (The RC60 does not receive valid data for consecutive 5 seconds)	1. The TD60 battery charge is to be depleted. 2. The patient is out of the antenna array coverage area. 3. The TD60 is not connected with the ECG leadwire.	1. Check if the TD60 battery charge is depleted. 2. Check if the patient is out of the coverage area. 3. Check if the TD60 is connected with the ECG leadwire properly.
RF Interference (The TD60 receives three consecutive wrong frames.)	The TD60 signal is weak.	Check if the Patient is at the edge of the coverage area or in an elevator. Remove behind a reinforced concrete wall.
SpO_2 No Pulse	The SpO_2 sensor failed to obtain pulse signal.	Check the patient's condition and change the sensor application site. If the error persists, replace the sensor.
The CS does not display the SpO_2 data.	1. The SpO_2 module is not connected to the TD60. 2. There may be error in the SpO_2 module.	1. Connect the SpO_2 module to the TD60. 2. If there is an error in the SpO_2 module, replace the SpO_2 module with a new one.
ECG noise	ECG waveforms are overlapped with the noise interference.	Check if the ECG leadwire is intertwined with cables of other devices.
ECG Signal Saturated	The TD60 detects that ECG signal saturation or overload.	1. Check if patient has excessive movement. 2. Check if the electrodes are in good contact with the skin. 3. Check if the electrodes operating time is over the electrode service life.
Wrong Channel	The configured frequency of the transmitter does not match the channel.	Reconfigure the frequency of the transmitter to match the channel.

Symptom	Possible cause	Solution
The AC power indicator on the RC60 is off.	1. The RC60 is not connected to the power. 2. The RC60 is power off.	1. Check if the RC60 is connected to the power. 2. Check if the RC60 sounds a beep when turn the receiver on.
The TD60 or SpO_2 module restarts repeatedly.	The TD60 battery charge is to be depleted.	Replace with new batteries.

12.2 Physiological Alarm Messages at the CS

The following table lists the major telemetry-related physiological alarm messages displayed on the central station (CS) screen.

Measurement	Alarm message	Alarm level	Possible cause	Solution
Heart rate (HR)	HR High	Medium*	HR value has risen above the high alarm limit or fallen below the low alarm limit.	Check the patient's condition and make sure that the patient category and alarm limit settings are correct.
	HR Low	Medium*		

* *The asterisk (*) means the alarm level is configurable.*

Measurement	Alarm message	Alarm level	Possible cause	Solution
ECG	ECG Weak Signal	High	The ECG signal is so weak that the monitor can't perform ECG analysis.	Check the patient's condition and the ECG connections.
	Asystole	High	The patient is in arrhythmia.	Check the patient's condition and the ECG connections.
	Vfib/Vtac	High		
	VTac	High		
	Vent. Brady	High		
	Extreme Tachy	High		
	Extreme Brady	High		
	R on T	Medium*		
	VT > 2	Low*		
	Couplet	Message*		
	PVC	Message*		
	PVCs/min	Medium*		
	Bigeminy	Medium*		
	Trigeminy	Medium*		
	Tachy	Medium*		
	Brady	Medium*		
	Missed Beat	Message*		
	Vent. Rhythm	Medium*		
	Pause	Medium*		
	PNP (Pacer Not Pacing)	Message*	The pacer appears abnormal.	Check the pacer.
	PNC (Pacer Not Capture)	Message*		

* *The asterisk (*) means the alarm level is configurable.*

Measurement	Alarm message	Alarm level	Possible cause	Solution
SpO_2	SpO_2 Desat	High	The SpO_2 value has fallen below the desaturation alarm limit.	Check the patient's condition and check if the alarm limit settings are correct.
	No Pulse	High	The pulse signal was so weak that the monitor cannot perform pulse analysis.	Check the patient's condition, SpO_2 sensor and measurement site.

* *The asterisk (*) means the alarm level is configurable.*

12.3 Technical Alarm Messages at the TD60

The following table lists the major technical alarm messages displayed in the message area of the TD60.

The Alarm Indication column in the table below is capable of three different indication types: A, B, C.

- A: The alarm sound will be silenced, the alarm light will continue to indicate the alarm, a √ will appear before the alarm message. The symbol appears on the top of the main screen.
- B: The technical alarm will be changed to the prompt message, it will not longer make sound or be indicated by the alarm light.
- C: The technical alarms are cleared, there will be no alarm indications.

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
ECG	ECG Lead Off	Low*	B	The electrode has become detached from the patient or the lead wire has become disconnected from the adapter cable.	Check the connections of the electrodes and leadwires.
	ECG XX** Lead Off	Low*	B		
	ECG Module Error	High	A	An error occurred to the ECG module. There is a problem with the communications between the module and the TD60.	Restart the TD60. If the problem persists, contact your service personnel.

* *The asterisk (*) means the alarm level is configurable.*

** *XX is the ECG lead name.*

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
ECG	ECG Noise	Low	A	The ECG signal is noisy.	Check for any possible sources of signal noise around the cable and electrode, and check the patient for great motion.
	ECG Cable Type Error	Low	B	Connect wrong ECG leadwire.	Reconnect the 3 or 5 lead ECG leadwire.
	HR Overrang e	Low	A	HR exceeds the measurement limit.	Contact your medical pesonnel.
SpO_2	SpO_2 Sensor Off	Low*	B	The SpO_2 sensor has become detached from the patient or the module. There is a fault with the SpO_2 sensor. An unspecified SpO_2 sensor has been used.	Check the sensor application site and the sensor type, and make sure the sensor is not damaged. Reconnect the sensor or use a new sensor.
	SpO_2 Sensor Fault	Low	C		
	SpO_2 No Sensor	Low	B		
	SpO_2 Module Error	High	A		
	SpO_2 Too Much Light	Low	A	There is too much light on the SpO_2 sensor.	Move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
	SpO_2 No Pulse	Low	A	SpO_2 sensor failed to obtain pulse signal.	Move the sensor to a site with better perfusion.
	SpO_2 Unplugg ed	Low	C	SpO_2 module connector is disconnected from the TD60.	Reconnect the SpO_2 module to the TD60.
	PR Overrang e	Low	A	The measured PR value exceeds the measurement range.	Contact Mindray or your service personnel.

* *The asterisk (*) means the alarm level is configurable.*

** *XX is the ECG lead name.*

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
Power	Low Battery	Medium	A	The battery charge is low.	Replace with new batteries.
	Critically Low Battery	High	A	The battery charge is almost depleted.	
	Battery Mainten ance Required	Medium	A	The lithium-ion battery is aging.	
	Battery Error	Medium	A	The lithium-ion battery communication is error.	
	Battery Type Error	Medium	A	The battery contact is not making adequate connection.	
System	Device Error	High	A	The selftest of the TD60 main board is error. The selftest of the parameter module or Mindray PAN module are error. The parameter module communication is error or initialization is error.	Restart the TD60. If the problem persists, contact your service personnel.
	Real Time Clock Error	High	A	The real time clock initialization is error.	
	Restorin g Last Defaults Failed	Low	C	Restoring the last default configuration is error.	
	Loading Defaults Failed	Low	C	Loading the default configuration is error.	

* *The asterisk (*) means the alarm level is configurable.*

** *XX is the ECG lead name.*

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13 Cleaning and Disinfecting

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13.1 Introduction

Only use the substances approved by Mindray and methods listed in this chapter to clean or disinfect your device. Our warranty does not cover damage caused by unapproved substances or methods.

Mindray makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

13.2 Safety Information

WARNING

- **The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.**
- **Be sure to shut down the system before cleaning the equipment.**
- **Non-medical equipment does not provide the same level of protection against electrical shock. Do not touch the patient and any part of non-medical equipment at the same time. Some examples of non-medical equipment are laser printers and nonmedical computers.**
- **Avoid use of cleaners, materials or chemicals that may damage device surfaces, labels, or cause equipment failures.**
- **Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these guidelines:**
  - **Always dilute according to the manufacturer's instructions or use lowest possible concentration.**
  - **Do not immerse any part of the device into liquid. Do not pour liquid onto the equipment or accessories.**
  - **Do not allow liquid to enter the case and the device interior.**
  - **Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).**

CAUTION

- **If liquid has accidentally entered the system or its parts, shut down the system and have the device serviced by authorized service personnel.**
- **Remove the equipment from use if liquid is spilled on the equipment or accessories. Contact your service personnel.**
- **When cleaning, avoid the ECG leadwire connector and other connectors.**

13.3 Cleaning of the TD60

CAUTION

- **Only use the following approved cleaning solutions. The system may become inoperable or halted because of contamination or damage caused by use of unapproved cleaning solution.**

Clean your equipment on a regular basis. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agent are:

- Water
- Mild soap

Before cleaning your TD60, do the following preparations:

- Install the battery pack or battery tray to firmly close the battery compartment.
- Insert the SpO_2 cover in the SpO_2 connector when SpO_2 is not in use.
- Insert the ECG leadwire plug into the ECG connector.

WARNING

- **Never allow the cleaning solutions to spill or enter the plug, connector and battery compartment.**

To clean your TD60, follow this procedure:

1. Shut down the device.

2. Dilute the mild soap in water to make a cleaning solution.
3. Soak a clean and soft cloth in the solution and wring out excess solution.
4. Thoroughly wipe the display screen and the exterior surface of the device with the damp cloth, avoiding the connectors.
5. Wipe off all the cleaning solution with a dry cloth if necessary.
6. Dry your device in a ventilated, cool place.

13.4 Cleaning the Reusable ECG Leadwires, SpO_2 Modules and Sensors

- Check reusable sensors and cables daily for signs of damage. Replace as required.
- Clean the sensors before and after each new patient.
- Wipe sensors and cables using a soft cloth with mild soap and water solution.
- Allow the cables and sensors to completely dry before using.

Refer to the cleaning procedure described in ***"Cleaning of the TD60" on page 13 - 3***.

CAUTION

- **Never immerse cables and sensors in any fluids. Do not clean them with harsh chemicals such as acetone or non-diluted bleach.**
- **Clean the cables carefully to avoid breaking internal wires by excessive bending, strain, or flexing.**
- **Do not autoclave, radiation or steam sterilize the cables and sensors.**
- **Extended exposure to Ethylene Oxide gas may shorten life of the cables, leading to poor signal quality.**

NOTE

- **Refer to the individual instruction sheets that are packaged with the accessories for additional information.**

13.5 Cleaning the Battery and Battery Compartment

- Clean the exterior surface of the lithium-ion battery pack and AA battery tray before and after each new patient.
- Wipe the lithium-ion battery pack, AA battery tray and the battery compartment using a soft cloth with mild soap and water solution. Use caution to avoid the battery connector.
- Allow the lithium-ion battery pack, AA battery tray and the battery compartment completely dry before using.

Refer to the cleaning procedure described in ***"Cleaning of the TD60" on page 13 - 3***.

CAUTION

- **Never immerse the lithium-ion battery pack, AA battery tray and AA batteries. Do not clean them with harsh chemicals such as acetone or nondiluted bleach.**

13.6 Disinfection

Disinfect the TD60 and accessories as required in your hospital's servicing schedule. Cleaning before disinfecting is recommended.

The recommended disinfectants are:

- 70% isopropyl alcohol
- 10% sodium hypocholride (bleach) solution
- 3% hydrogen peroxide
- Virkon
- Super Sani-cloth (0.5% Quaternary ammonium chloride and 55% Isopropyl alcohol)
- 50% propyl alcohol (1-propyl alcohol)
- 70% ethanol

13.7 Sterilization

Sterilization is not recommended for this equipment, related products, accessories or supplies unless otherwise indicated in the Operating Instructions that accompany the accessories or supplies.

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14 Maintenance

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Checking the System Information 14-4
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14.1 Introduction

The chapter outlines the routine telemetry devices maintenance guidelines.

The telemetry devices are designed for stable operation over long periods of time. Under normal circumstances the devices should not require technical maintenance beyond that described in this chapter. However, routine maintenance, calibration and safety checks are recommended at least once a year or more often as required by local statutory or hospital administration practice.

14.2 Safety

WARNING

- **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.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **No modification of this equipment is allowed.**
- **To avoid the electric shock, do not open the central charger housing, otherwise .**
- **All servicing and future upgrades must be carried out by the service personnel.**
- **All replaced components and accessories as well as consumables are provided or qualified by Mindray.**
- **If you discover a problem with any of the equipment, contact your service personnel or Mindray.**
- **The service personnel must be properly qualified and thoroughly familiar with the equipment operation.**

14.3 Regular Check

Perform a visual inspection before the equipment is first used every day. Verify that the equipment meets the following requirements:

- The housing and display screen are free from cracks or other damages.
- All keys function properly.
- Connectors are not loose, cracked, or bent and cables have no cuts, nicks, or fraying.
- ECG leadwires are securely connected with the equipment.
- Battery pack is installed and has sufficient charge.
- Chest electrodes are free from cracks and limb electrodes can properly clamp.

After your equipment has been used for 6 to 12 months, or whenever your equipment is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the devices:

- Make sure that the environment and power supply meet the requirements.
- Inspect the devices and their accessories for mechanical damage.
- Inspect all plugs, connectors, leadwires for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Make sure that the alarm system functions correctly.
- Make sure that the battery meet the performance requirements.
- Make sure that the devices are in good working condition.

In case of any damage or abnormity, do not use the devices. Contact the hospital's bio-medical engineers or your service personnel immediately.

14.3.1 Power-on Test

The TD60 performs a self-test during startup. You can refer to "Powering On the Unit" on page 3 - 8 for details.

14.3.2 Battery Check

For details about the battery charge check and maintenance, refer to "Maintaining the Rechargeable Lithium-ion Battery" on page 11 - 7.

14.4 Maintenance and Testing Schedule

The following maintenance and tests, except for visual inspection, power on test, and battery check, shall be carried out by the service personnel only. Contact your service personnel if any maintenance is required. Make sure to clean and disinfect the equipment before any test and maintenance.

Check/Maintenance Item		Recommended Frequency
Visual inspection		When first installed or reinstalled.
ECG test and verification	Performance test	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3. Once every two years.
	Verification	
SpO_2 test		
Power on test		1. When first installed or reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Battery check	Functionality test	1. When first installed. 2. Whenever the battery is replaced.
	Performance test	When the battery run time reduced significantly.
Electrical safety test		At least once every two years.

14.5 Checking the System Information

To view the information about the device, radio frequency (RF), battery, MPAN, and system statistics, you can go to the main menu → **System Info**.

14.6 Verifying the ECG at the TD60

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG wave amplitude becomes greater or smaller. To verify the ECG waveform amplitude:

1. In the main menu, tap **Maintenance**.
2. Input the maintenance passcode.
3. Tap **Accept**.
4. In the **Maintenance** menu, tap **Others**.
5. Enable **Calibrate ECG**.

A square wave appears on the screen and the message **ECG Calibrating** is displayed.

6. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.
7. After completing the verification, disable **Calibrate ECG**.

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15 Accessories

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The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the device. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. For details about the accessories, refer to the instructions for use provided with the accessory.

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the monitor or not meet the claimed specifications.**
- **Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date if indicated.**
- **The disposable accessories shall be disposed of according to the hospital's regulations.**

15.1 ECG Accessories

15.1.1 ECG Electrodes

PN	Description	Applicable property	Applicable patient
0010-10-12304	Adult Electrode (Kendall, package of 10)	Disposable	Adult
9000-10-07469	Pediatric ECG electrode (3M, package of 50)	Disposable	Pediatric

15.1.2 ECG Leadsets

3-Lead

PN	Description	Applicable property	Applicable patient
009-004765-00	3-Lead, New Telemetry, AHA, Snap, 24"	Reusable	Adult, Pediatric
009-004766-00	3-Lead, New Telemetry, AHA, Snap, 36"		
009-004771-00	3-Lead, New Telemetry, AHA, Pinch, 24"		
009-004772-00	3-Lead, New Telemetry, AHA, Pinch, 36"		
009-004777-00	3-Lead, New Telemetry, Disp, AHA, Snap, 24"	Disposable	

5-Lead

PN	Description	Applicable property	Applicable patient
009-004782-00	5-Lead, New Telemetry, AHA, Snap, 24"	Reusable	Adult, Pediatric
009-004783-00	5-Lead, New Telemetry, AHA, Snap, 36"		
009-004786-00	5-Lead, New Telemetry, AHA, Pinch, 24"		
009-004787-00	5-Lead, New Telemetry, AHA, Pinch, 36"		
009-004790-00	5-Lead, New Telemetry, AHA, Snap, 24"	Disposable	

15.2 SpO_2 Accessories

The SpO_2 sensor material that contacts patients or other staff has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

15.2.1 Masimo SpO_2 Module

PN	Description	Applicable property	Applicable patient
009-004936-00	Masimo SpO_2 module (SET $uSpO_2$)	Reusable	Adult, Pediatric

15.2.2 Masimo SpO_2 Sensor

PN	Description	Applicable property	Applicable patient
0600-00-0121	LNCS Adtx-Adult Single Patient Adhesive Sensors, >30 kg (20/box)	Disposable	Adult
0600-00-0122	LNCS Pdtx-Pediatric Single Patient Adhesive Sensors,10-50 kg (20/box)		Pediatric
0600-00-0126	LNCS DCI Adult Reusable Finger Sensor, >30 kg	Reusable	Adult
0600-00-0127	LNCS DCIP Pediatric Reusable Finger Sensor, 10-50 kg		Pediatric

Wavelength emitted by the sensors is between 600 nm and 1000 nm. The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians (for example, when photodynamic therapy is performed).

15.2.3 Nonin SpO_2 Module

PN	Description	Applicable property	Applicable patient
009-004935-00	Nonin SpO_2 module (XPOD 3012LP)	Reusable	Adult

15.2.4 Nonin SpO_2 Sensor

PN	Description	Applicable property	Applicable patient
0600-00-0139-24	Nonin 7000AA SpO_2 Sensor (box of 24)	Disposable	Adult
100-000077-00	Nonin 8000AA SpO_2 Sensor	Reusable	
100-000134-00	Nonin 8000AP SpO_2 Sensor	Reusable	Pediatric
100-000135-00	Nonin 7000AP SpO_2 Sensor (box of 24)	Disposable	

15.3 Miscellaneous

PN	Description
115-026852-00	Main unit of the charger
022-000196-00	Telemetry Rechargeable battery
045-001698-00	TP-2AA battery frame
045-001699-00	TP-3AA battery frame
0000-10-10902	Alkaline 1.5 V AA battery
0146-00-0077-10	L91 AA battery
048-005247-00	Disposable pouch
048-005246-00	Reusable pouch

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A Product Specifications

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Mindray Patient Area Network (MPAN) Specification A-9
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A.1 Classifications

The Telemetry Monitoring System is classified, according to IEC60601-1:

Type of protection against electrical shock	TD60: energized from an internal electrical power source. RC60: class I. Central Charger: class I.
Degree of protection against electrical shock for the TD60	Type CF defibrillation proof for ECG, and SpO_2.
Mode of operation	Continuous
Degree of protection against harmful ingress of water	TD60: IPX7 RC60: IPX0 Central Charger: IPX0
Degree of protection against hazards of explosion	Not suitable: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air with oxygen or nitrous oxide.
Degree of protection against hazard of dropping for the TD60	No damage by dropping from a height of 1.5 m.

A.2 Environmental Specifications

WARNING

- **The devices may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.**

Item	Operating conditions	Storage conditions
Temperature	0 °C to 37 °C	-20 °C to 60 °C
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric	427.5 mmHg to 805.5 mmHg, or 57.0 kPa to 107.4 kPa	120 mmHg to 805.5 mmHg, or 16.0 kPa to 107.4 kPa

A.3 Power Supply Specifications

A.3.1 TD60

The TD60 is powered by batteries.

Battery type	AA batteries (two or three) Rechargeable lithium-ion battery (one)			
Capacity for lithium-ion battery	≥ 3500 mAh			
Safety and authentication for lithium-ion battery	UL2054, IEC62133, UN38.3			
Run time for (at the temperature 25 °C ±5 °C, the screen display is off, no sound and light as default, no alarms, at least including 15 minutes operating time when the screen display is on, AA battery with PN 0146-00-0077-10 are used)		**Two AA batteries**	**Three AA batteries**	**Lithium-ion battery**
	5-lead ECG:	≥ 48 hours	≥ 72 hours	≥ 72 hours
	5-lead ECG + Nonin SpO_2	≥ 36 hours	≥ 48 hours	≥ 48 hours
	5-lead ECG + Masimo SpO_2	≥ 36 hours	≥ 48 hours	≥ 48 hours
Power On/Off	The startup logo displaying time is less than or equal to three seconds. The time for entering the main screen to display the waveforms is less than or equal to 15 seconds.			
Shutdown delay	at least 15 minutes after the low battery alarm first occurs at least five minutes after the critically low battery alarm first occurs			

A.3.2 RC60

The telemetry receiver is powered by external AC power.

Input voltage	100 to 240 VAC (± 10%)
Frequency	50 Hz/60 Hz (± 3 Hz)
Input current	0.6 A to 0.3 A

A.3.3 Central Charger

The central charger is powered by external AC power.

Input voltage	100 VAC to 240 VAC (± 10%)
Frequency	50 Hz/60 Hz (±3 Hz)
Input current	1.5 A to 0.75 A
Charge time	At the room temperature: ≤ 5 hours The charge time definition: the time for the battery from the exhausted status to 90% battery charge (within the operating temperature range declared for the unit).
Overcharge protection function	The charger automatically stop charging when the lithium-ion battery charge is full.

A.4 Physical Specifications

A.4.1 TD60

Size	125.8 mm × 63.7 mm × 23 mm (only for the transmitter, without the ECG leadwire, SpO_2 module and any other accessories)
Weight	210 g (with two AA batteries and 3-lead ECG cable, without the SpO_2 module and any other accessories)

A.4.2 RC60

Size	120 mm × 300 mm × 350 mm
Weight	7000 g

A.4.3 Central Charger

Size	365 mm × 170.6 mm × 77.9 mm (without batteries and wall-mount bracket)
Weight	1130 g (without batteries and wall-mount bracket)

A.5 Hardware Specifications

A.5.1 TD60

Display	
Screen type	Color TFT LCD screen
Screen size	3.5"
Resolution	480 pixels × 320 pixels
Display Activation (Power On/Off) key	The switch time is less than or equal to two seconds.
LED	
Alarm lamp	1 (three colors: red, yellow, and cyan)
Audio Indicator	
Speaker	1
Sound Pressure Range	45 dBA to 85 dBA
Keys	
Nurse call	1
Power On/Off	1
Main menu	1
External Connectors	
ECG connector	1
SpO_2 connector	1

A.5.2 RC60

LED	
Communications indicator	1 (green), indicates the ready and communications status.
Power indicator	1 (green), indicates the power status.
Audio Indicator	
Buzzer	1, indicates internal abnormity.
External Connectors	
Ethernet connector	1, standard RJ45 connector
Antenna connector	2

A.5.3 Central Charger

Charger slot	10
LED	10, which indicates the battery charge status.
AC power indicator	1
Installation mode	Place on the desktop, or mount on GCX® wall channel.

A.6 WMTS Specification

A.6.1 Technical Specification

Protocol standard	Private protocol
Modulation mode	GFSK
Operating frequency	608 MHz to 614 MHz
Channel spacing	25 KHz
Wireless baud rate	8 kbps ± 3%
Output power	< 10 mW
Receiversensitivity	≤-110 dBm (Bit error rate ≤ 1%)
Data security	Private protocol

A.6.2 Implemented Functions

The transmitter sends physiological data (such as ECGand SpO_2 waveforms and parameters) and the transmitter status data (such as the status about lead, button, battery voltage, and others) to the central station (CS) via active or passive antenna array and receiver.

The receiver can measure the received signal strength indication (RSSI) fromof the transmitter, and send the information to the CS.

A.6.3 Performance Specification

WARNING

- **Do perform all network functions of data communication within an enclosed network.**

Data integrity	Bit error rate: ≤ 1%
Data latency	Total delay of data transmission from the transmitter to the CS: ≤ 3 seconds
Priority	All data types have the same priority.
Transmission distance	Distinct vision distance between the transmitter and the receiver antenna installed on the transmitter is greater than or equal to 50 meters.
Receiver capacity	16 beds
System capacity	32 beds
Dynamic networking stability	The wireless functions of the test transmitter are normal while the transmitter is moving at the rate of no more than 3.75 m/s within the coverage area of the antenna array.
Resistance to wireless interference	The wireless functions of the transmitter are normal when the following conditions exist simultaneously: ■ The distance between interfering devices and the transmitter is greater than 20 centimeters. ■ The distance between interfering devices and the receiver antenna is greater than 100 centimeters. ■ -118dBm co-channel WMTS interference exists at the receiver antenna. Note: The interfering devices include but are not limited to wireless devices operated at 2.4GHz, cellular mobile communication network devices, microwave ovens, and cordless phones.
Communication interruption alarm	When communication between the transmitter and the receiver is interrupted, the CS generates an alarm within 8 seconds.
Signal strength indicator	RSSI range: -110 dBm to -80 dBm Precision: within ±2dB

A.7 Mindray Patient Area Network (MPAN) Specification

A.7.1 Technical Specification

Modulation mode	GFSK
Operating frequency	2402MHz to 2480MHz
Channel spacing	2 MHz
Wireless baud rate	1 Mbps
Output power	≤ 2.5 mW
Data Security	128 bit AES

A.7.2 Implemented Function

The function implemented by the MPAN is transferring the configuration between the transmitters.

A.7.3 Performance Specification

Data integrity	Bit error rate: ≤ 1%
Transmission distance	Distinct vision distance between the transmitters is greater than or equal to 3 meters.
System capacity	One transmitter can transport configuration information between at least five other transmitters at the same time in 10^2 room. .
Resistance to wireless interference	The wireless functions of the transmitter are normal when the following conditions exist simultaneously: ■ The distance between interfering devices (microwave ovens and Wi-Fi devices) and the transmitter is greater than 100 centimeters. ■ The distance between interfering devices (cellular mobile communication network devices and cordless phones) and the transmitter is greater than is 20 centimeters.
Communication interruption alarm	When communication between transmitters is abnormal, a corresponding prompt message is displayed on the transmitter screen.

A.8 Measurement Specifications

A.8.1 ECG

ECG	
Standard	Meet standards of IEC60601-2-27 and IEC60601-2-25
Leadset	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V Automatic 3/5 lead recognition
ECG standard	AHA, IEC
Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s Accuracy: ± 10%
Display Sensitivity	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) Accuracy: ± 5%
Input signal range	±8 mV (peak-to-peak value)
Calibration signal	1 mV (peak-to-peak value) Accuracy: ± 5%
Differential input impedance	≥ 5 MΩ
Bandwidth (-3dB)	Monitor mode: 0.5 Hz to 40 Hz ST mode: 0.05 Hz to 40 Hz
Common mode rejection ratio (with Notch off)	Monitor mode: > 105 dB ST mode: > 105 dB
Notch	50/60 Hz, rejection capacity ≥ 20 dB
Polarizing voltage scope	± 500 mV
Noise	≤ 30 μV (p-v RTI)
Baseline recovery time	< 5 s (after defibrillation)
Direct current leakage	Input electrode: < 0. 1μA Drive electrode: <1μA
Electrode polarization recovery time	< 10 s

Defibrillation energy absorption	≤ 10% (100 Ω load)	
Pace Pulse		
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Rise time: 10 μs to 100 μs Amplitude: ≥ 0.2mV RTI	
Pace pulse rejection	When tested in accordance with the IEC60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Rise time: 10 μs to 100 μs About 50% pulse of ANSI/AAMI EC13 (5d) can trigger the pulse detector, the least changing rate is 20 V/s RTI.	
HR		
Measurement range	Adult: 0, 15 bpm to 300 bpm Pediatric: 15 bpm to 350 bpm	
Resolution	1 bpm	
Accuracy	± 1 bpm or ± 1%, whichever is greater.	
Sensitivity	**Mindray ECG algorithm**	**Mortara ECG algorithm**
	200 μV	160 μV to 480 μV

	Mindray ECG algorithm	Mortara ECG algorithm
HR averaging method	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the monitor screen is updated every second.	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC60601-2-27, the following method is used: Heart rate is computed by averaging the most recent 16 RR intervals, unless the HR by averaging the most recent 4 heart beats is less than or equal to 48 bpm. The HR value displayed on the monitor screen is updated every second.
Tall T-wave rejection capability	When the test is performed based on Clause 201.7.9.2.9.101 b) 2)of IEC60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.	
Response time to heart rate change	Meets the requirements of IEC60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 bpm to 120 bpm: less than 11 s From 80 bpm to 40 bpm: less than 11 s	
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): 80 ± 1 bpm Slow alternating ventricular bigeminy (3b): 60 ± 1 bpm Rapid alternating ventricular bigeminy (3c): 120 ± 1 bpm Bidirectional systoles (3d): 90 ± 2 bpm	
Time to alarm for tachycardia	Meets the requirements of IEC60601-2-27: Clause 201.7.9.2.9.101 b) 6). Waveform 4ah - range: < 11 s 4a - range: < 11 s 4ad - range: < 11 s 4bh - range: < 11 s 4b - range: < 11 s 4bd - range: < 11 s	
ST Segment Analysis		
Measurement range	-2.0 mV to +2.0 mV RTI	

Resolution	0.01 mV	
Accuracy	-0.8 mV to +0.8 mV: ± 0.02 mV or ± 10%, whichever is greater Beyond this range: Not specified	
Arrhythmia Analysis		
Arrhythmia analysis classifications	**Mindray ECG algorithm**	**Mortara ECG algorithm**
	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVCs/min, Pauses/min, R on T, Run PVCs, Couplet, Multif. PVC, PVC, Bigeminy, Trigeminy, Tachy, Brady, Pacer Not Pacing, Pacer Not Capture, Missed Beat, Nonsus. Vtac, Vent. Rhythm, Pause, Irr.Rhythm, Afib	Asystole, VFib, Vtac, Extreme Tachy, Extreme Brady, PVCs/min, Pauses/min, R on T, Run PVCs, Couplet, Multif. PVC, Bigeminy, Trigeminy, Tachy, Brady, Pacer Not Pacing, Pacer Not Capture, Vent. Rhythm, Pause, Irr.Rhythm
QT Analysis		
QTc formula	Bazett, Fridericia, Framingham, and Hodges	
	Mindray ECG algorithm	**Mortara ECG algorithm**
QT measurement range	200, 800 ms	300, 600 ms
QT accuracy	200, 800 ms: ± 30 ms Beyond this range: Not specified	300, 600 ms: ± 30 ms Beyond this range: Not specified
QT resolution	200, 800 ms: 4 ms Beyond this range: Not specified	300, 600 ms: 2 ms Beyond this range: Not specified
QTc measurement range	200, 800 ms	300, 600 ms
QTc resolution	200, 800 ms: 1 ms Beyond this range: Not specified	300, 600 ms: 1 ms Beyond this range: Not specified
QT-HR measurement range	Adult: 15, 150 bpm Pediatric: 15, 180 bpm	N/A

A.8.2 SpO_2

NOTE

- **A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.**

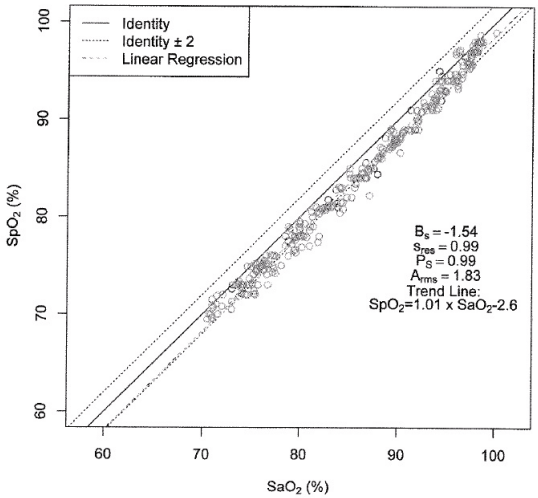
A.8.2.1 Nonin SpO_2 Module

SpO_2	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70-100%: ±3 digits 0-69%: Not specified
Data update rate	≤2s
*Studies were performed to validate the accuracy of Pulse Oximeter with Nonin SpO_2 sensors by contrast with a CO-Oximeter. In total, 12 adults (7 male & 5 female) aged from 19 to 35 years old were voluntarily involved in this study. Five are Caucasian, two are Indian, three are Asian, and two are African-American. All of them conform the clinical study requirements for age, gender, skin and health.	
The following table shows the accuracy (A_{rms}) for the SpO_2 sensors in four kinds of SaO_2 ranges. For the Fitting Curve of the SpO_2 sensors, refer to the ***"Fitting Curve for Nonin SpO2 Sensors" on page A - 15***.	
SaO_2 range	**Measured A_{rms} Value (7000A, 7000P, 8000AA, 8000AP)**
70% to 100%	1.54
70% to 80%	1.41
80% to 90%	1.97
90% to 100%	1.28
PR	
Measurement range	20 bpm to 300 pm
Resolution	1 bpm

Accuracy	±3 bpm
Response Time	
■ ≤ 25 s (PR 75 bpm, average time 4 heart beats, no disturbance, SpO_2 value rises from 70% to 100%)	
■ ≤ 35 s (SpO_2 value 98%, average time 4 heart beats, no disturbance, PR value rises from 60 bpm to 150 bpm)	

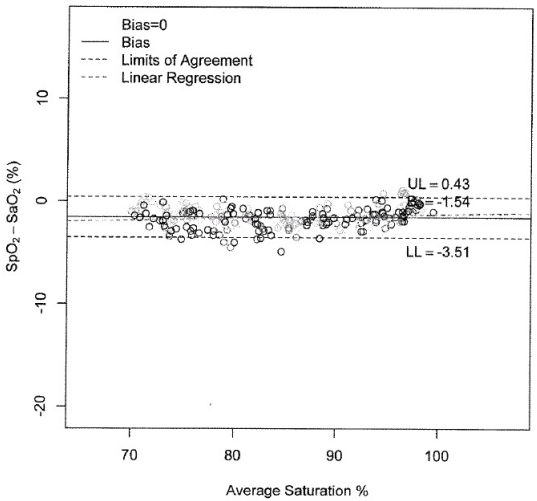
A.8.2.2 Fitting Curve for Nonin SpO_2 Sensors

7000A, 7000P, 8000AA, 8000AP



$SpO_2 = 1.01 \times SaO_2 - 2.6$

Scatter Plot of the SpO_2 versus the SaO_2



Bland-Altman Plots of the Bias versus the Mean

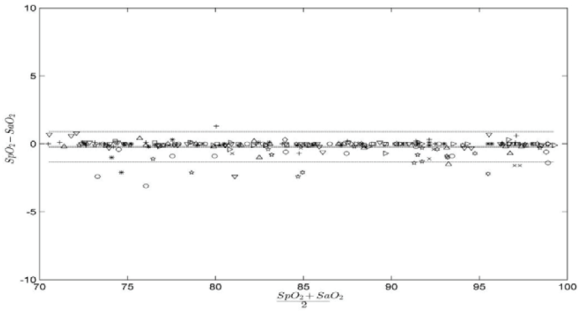
A.8.2.3 Masimo SpO_2 Module

SpO_2	
Measurement range	1% to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified.
Low Perfusion Conditions	Pulse amplitude: > 0.02% Light penetration: > 5%
Low Perfusion Accuracy	2%
*SpO_2 accuracy was determined by testing on healthy adult volunteers in the range of 60% to 100% SpO_2 against a laboratory CO-Oximeter. SpO_2 accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over range of 70-100% SaO_2 with a resultant accuracy of 2.9% SpO_2.	
The following table shows the accuracy (A_{rms}) for the SpO_2 sensors in four kinds of SaO_2 ranges. For the Fitting Curve of the SpO_2 sensors, refer to the ***"Fitting Curve for Masimo SpO2 Sensors" on page A - 18***.	

SaO_2 range	**Measured A_{rms} Values**	
	LNCS Adtx, LNCS Pdtx	**LNCS DCI, LNCS DCIP**
70% to 100%	± 2%	2%
70% to 80%	1.55%	0.60%
80% to 90%	1.07%	0.54%
90% to 100%	1.64%	0.60%
PR		
Measurement range	25 bpm to 240 bpm	
Resolution	1 bpm	
Accuracy	± 3 bpm (without motion) ± 5 bpm (with motion)	
Response Time	≤ 25 s (PR 75 bpm, average time 8 s, no disturbance, SpO_2 value rises from 50% to 100%) ≤ 20 s (SpO_2 value 98%, average time 8 s, no disturbance, PR value rises from 60 bpm to 150 bpm)	
PI		
Measurement range	0.02% to 20%	
Least resolution	0.01, use three valid digits	
Response Time		
■ ≤ 25 s (PR 75 bpm, average time 8 s, no disturbance, SpO_2 value rises from 50% to 100%) ■ ≤ 20 s (SpO_2 value 98%, average time 8 s, no disturbance, PR value rises from 60 bpm to 150 bpm)		

A.8.2.4 Fitting Curve for Masimo SpO_2 Sensors

DCI/DCIP



B EMC

The telemetry monitoring system (TMS) meets the requirements of IEC 60601-1-2.

WARNING

- **Use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the system.**
- **Devices too close or stacked may interfere with each other. Do not put devices too close or stack them together. Keep a close eye on the system in case there are other devices around it.**
- **Neighboring frequencies of transmitters too close may interfere with each other, and the CS cannot receive data or receive erroneous data. Therefore it is recommended that the interval of neighboring frequencies is not smaller than 25kHz.**
- **Devices even in compliance with CISPR transmitting requirements may interfere with the system.**
- **If the input signal is lower than the specified threshold, measurements may be inaccurate.**
- **Other equipment that have RF transmit or source may affect this device (for example, cell phones, PDAs, PCs with wireless function).**

Guidance and declaration — electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Compliance	

Guidance and declaration — electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	± 2 kV for power cord ± 1 kV for I/O cables		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV different mode ± 2 kV common mode		
Voltage dips, Short interruptions and voltage variation on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and declaration — electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conduced RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 M to 800 MHz $d = 2.3\sqrt{P}$ 800 M to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [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:
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	
Note: At 80 MHz and 800 MHz, the higher frequency range applies. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Note: The TMS that intentionally receives RF electromagnetic energy at the **exclusion band** (2395.825MHz-2487.645MHz) is exempt from the ESSENTIAL PERFORMANCE requirements, but remains safe.			
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 the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. b: Over the frequency ranges 150kHz to 80MHz, field strengths should be less than 3V/m.			

If the system is operated within the electromagnetic environment listed in ***Table Guidance and declaration — electromagnetic immunity***, the system will remain safe and provide the following essential performance:

- Operating mode
- Accuracy
- Function
- Accessories identification
- Data stored
- Alarm
- Detect for connection

Recommended separation distances between portable and mobile RF communication and the system			
The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the system as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter W (Watts)	**Separation Distance According to Frequency of Transmitter M (Meters)**		
	150kHz -80MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34
For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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C FCC Compliance

The telemetry monitoring system (TMS) complies with the requirements of FCC Part 95:

Authorized health care providers, in conjunction with the equipment manufacturers, must cooperate in the selection and use of frequencies in order to reduce the potential for interference with other wireless medical telemetry devices, or other co-primary users. Operations in the 608–614 MHz band (television channel 37) are not protected from adjacent band interference from broadcast television operating on channels 36 and 38.

As the RF range of the system is 608-614Mhz, if located near the radio astronomy observatories the two parties will interfere with each other.

Therefore, we don't suggest that the equipment can be installed or operated within 80 kilometers of:

1. National Astronomy and Ionosphere Center, Arecibo, Puerto Rico: 18°20'38.28" North Latitude, 66°45'09.42" West Longitude.
2. National Radio Astronomy Observatory, Socorro, New Mexico: 34°04'43" North Latitude, 107°37'04" West Longitude.
3. National Radio Astronomy Observatory, Green Bank, West Virginia: 38°26'08" North Latitude, 79°49'42" West Longitude.

This device and its antenna must not be located or operating in conjunction with any other antenna and transmitter.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Radio Frequency Exposure

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.
This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

Radio frequency Radiation Exposure Information

For body worn operation, this equipment has been tested and meets the FCC and CE RF exposure guidelines when used with the accessories supplied or those approved for use with this product. Use of other accessories may not ensure compliance with FCC and CERF exposure guidelines within 32 kilometers of the National Radio Astronomy Observatory centered on:

Very long baseline array stations	Latitude (north)	Longitude (west)
Pie Town, NM	34° 18′	108° 07′
Kitt Peak, AZ	31° 57′	111° 37′
Los Alamos, NM	35° 47′	106° 15′
Fort Davis, TX	30° 38′	103° 57′
North Liberty, IA	41° 46′	91° 34′
Brewster, WA	48° 08′	119° 41′
Owens Valley, CA	37° 14′	118° 17′
Saint Croix, VI	17° 46′	64° 35′
Mauna Kea, HI	19° 49′	155° 28′
Hancock, NH	42° 56′	71° 59′

If the installation distance is not enough, obtain the written concurrence of the Director of the affected radio astronomy station before the equipment can be installed or operated.

RF Parameters

RF Parameters

Item	Parameter
Operating Frequency Band (MHz)	608 to 614
Modulation	GFSK
Transmitter Output Power(e.i.r.p) (dBm)	< 10
Channel Space (KHz)	25

D Symbols and Abbreviations

Units D-2
Symbols D-3
Abbreviations D-3

D.1 Units

A	ampere
Ah	ampere hour
bpm	beats per minute
℃	centigrade
cc	cubic centimeter
cm	centimeter
dB	decibel
DS	dyne. second
°F	fahrenheit
g	gram
hr	hour
hPa	hundred pascal
Hz	hertz
in	inch
k	kilo
kg	kilogram
kPa	kilopascal
l	litre
lb	pound
m	meter
mg	milligrams
min	minute
ml	milliliter
mm	millimeters
ms	millisecond
mV	millivolt
mW	milliwatt
nm	nanometer
ppm	part per million
s	second
V	volt
VA	volt ampere
Ω	ohm
µA	microampere
µm	micron

µV	microvolt
W	watt

D.2 Symbols

-	minus
%	percent
/	per; divide; or
^	power
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

D.3 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
AHA	American Heart Association
ANSI	American National Standard Institute
ARR	arrhythmia
ART	arterial
AUX	Auxiliary output
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
CH	channel
CISPR	International Special Committee on Radio Interference
CS	central station
ECG	electrocardiograph
EMC	electromagnetic compatibility

err	error
ES	electrosurgical
ESU	electrosurgical unit
HR	heart rate
HT	height
IEC	International Electrotechnical Commission
ISO	International organization for standardization
MRI	magnetic resonance imaging
LA(L)	left arm
LAP	left atria pressure
LED	light emitting diode
LL(F)	left leg
Loop	loop read-write test fail
M, MEAN	mean pressure
O_2	oxygen
P	power
PAN	Patient Area Network
PR	pulse rate
QRS	interval of ventricular depolarization (QRS complex)
RA(R)	right arm
RL(N)	right leg
ROM	read-only memory
SpO_2	arterial oxygen saturation from pulse oximetry
VGA	Video Graphics Array

E Anomaly

E.1 Anomaly Description

This product version contains no anomalies.

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