BeneHeart D3/BeneHeart D2

Defibrillator/Monitor

Operator’s Manual

CE 0123

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WARNING

- **This equipment must be operated by skilled/trained clinical professionals.**
- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

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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 question, please contact us.

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 equipment.

Conventions

- ***Italic*** text is used in this manual to quote the referenced chapters or sections.
- [ ] is used to enclose screen texts.
- → is used to indicate operational procedures.

Contents

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1 Safety

1.1 Safety Information

DANGER

- **Indicates an imminent hazard that, if not avoided, will result in death or serious injury.**

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 Dangers

DANGER

- **The equipment delivers up to 360 J of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this defibrillator unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.**
- **Defibrillation current can cause operator or bystander severe injury or even death. Keep distance from the patient or metal devices connected to the patient during defibrillation.**
- **Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Keep the equipment and the operating environment dry and clean.**

1.1.2 Warnings

WARNING

- **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.**
- **Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on smart lithium-ion batteries.**

- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure leads to the loss of patient data.**
- **Use and store the equipment in specified environmental condition. The equipment and accessories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.**
- **This equipment is used for single patient at a time.**
- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **Before each use, the operator must check the equipment condition to ensure that the equipment is ready for operation.**
- **Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.**
- **Do not defibrillate a patient who lies on the wet ground.**
- **Do not touch the patient and live parts simultaneously.**
- **Do not touch the patient when connecting the peripheral equipment via the I/O signal ports to prevent patient leakage current from exceeding the requirements specified by the standard.**
- **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**
- **Do not perform any functional check if the equipment is connected with a patient; otherwise the patient might be shocked.**
- **Remain attentive to the patient during applying therapy. Delay in delivering a shock may result in a rhythm that was analyzed as shockable converting spontaneously to non-shockable and could result in inappropriate delivery of a shock.**
- **For the treatment of patients with implantable pacemakers, place electrode pads or paddles away from internal pacemaker generator if possible to help prevent damage to the pacemaker.**
- **Do not place the equipment or accessories in any position that might cause it to fall on the patient.**
- **Do not start or operate the equipment unless the setup was verified to be correct.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.**
- **If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the equipment for proper functioning.**
- **Physiological data and alarm messages provided by the equipment should not be used as the sole basis for diagnosis or therapy decisions. They must be used in conjunction with clinical signs and symptoms. Misinterpretation of the measured values or other parameters can endanger the patient.**
- **Do not touch device connectors, recorder print head, battery connector or other live equipment if in contact with the patient; otherwise patient injury may result.**
- **To ensure patient safety, use only parts and accessories specified in this manual.**
- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**

1.1.3 Cautions

CAUTION

- **Use of Manual Therapy security password requires the clinician to know and remember the password. Failure to enter correct password will prevent the delivery of manual defibrillation, synchronized cardioversion and pacing therapy.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phones, X-ray equipment or MRI**

devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**
- **Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.**
- **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.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

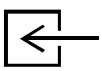
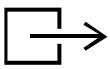
1.1.4 Notes

NOTE

- **Put the equipment in a location where you can easily view and operate the equipment.**
- **The equipment uses a mains plug as isolation means to the mains power supply. Do not locate the equipment in a place difficult to operate the mains plug.**
- **During normal use, the operator shall stand in front of the equipment.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **If the equipment operates on a DC power supply, a DC/AC adapter we supply should be used.**
- **This manual describes all features and options. Your equipment may not have all of them.**

1.2 Equipment Symbols

Symbol	Description	Symbol	Description
	Refer to instruction manual/booklet		General warning sign
	Dangerous voltage		Shock button
	Manufacturer		Date of manufacture
	Battery indicator		Alternating current
	Equipotentiality		Computer network
	DEFIBRILLATION-PROOF TYPE CF APPLIED PART		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
IP41	Protected against solid foreign objects of 1,0 mm Ø and greater Protection against vertically falling water drops	IP44	Protected against solid foreign objects of 1,0 mm Ø and greater Protected against splashing water

Symbol	Description	Symbol	Description
	Menu		Graphical record
	USB connector		Input/output
	Gas inlet		Gas outlet
	Humidity limitations		Atmospheric pressure limitations
	Temperature limitations		Non-ionizing electromagnetic radiation
	Stacking limit by number		Keep dry
	This way up		Fragile; handle with care
SN	Serial number		Unlocking
EC REP	Authorised representative in the European Community		General symbol for recovery/recyclable
	NIBP start/stop key		
CE 0123	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive. Note: The product complies with the Council Directive 2011/65/EU.		
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.		

2 The Basics

2.1 Equipment Introduction

The BeneHeart D3/BeneHeart D2 Defibrillator/Monitor (hereinafter called the equipment) is a lightweight and portable defibrillator/monitor. It provides four operating modes: Monitor, Manual Defib, AED and Pacer.

- Monitor Mode

  In the Monitor mode, the equipment is intended for monitoring, displaying, reviewing, storing and printing multiple physiological parameters and waveforms including ECG, pulse oximetry (SpO_2), respiration (Resp), pulse rate (PR), non-invasive blood pressure (NIBP) and carbon dioxide (CO_2).

- AED Mode

  In the AED mode, the equipment automatically analyzes the patient's ECG rhythm and indicates whether or not a shockable rhythm is detected. Voice prompts provide easy-to-follow instructions and patient information to guide you through the defibrillation process. Messages and flashing buttons are also presented to reinforce the voice prompts.

- Manual Defib Mode

  In the Manual Defib mode, the operator analyzes the patient's ECG, and, if appropriate, follow this procedure:

1. Select the Manual Defib mode, adjust the energy level if necessary;
2. Charge; and
3. Deliver the shock.

   Defibrillation may be performed through electrode pads, external and internal paddles. In the Manual Defib mode, you can also perform synchronized cardioversion. If desired, use of Manual Defib mode may be password protected.

- Pacer Mode

  The Pacer mode offers non-invasive transcutaneous pacing therapy. Pace pulses are delivered through electrode pads. Use of Pacer mode may also be password protected.

The equipment can be powered by smart lithium ion batteries which are rechargeable and maintenance-free. You can easily determine the remaining battery charge by viewing the battery power gauge displayed on the screen or by checking the indicator on the battery itself. An external AC mains or a DC power supply connected through a DC/AC adapter may also be used as a power source and for continuous battery charging.

The equipment can be connected to a Central Monitoring System (hereinafter called CMS) through wired and wireless networks.

The equipment automatically stores patient data in an internal storage card. You can also export the data through the USB port for viewing and editing on a PC through the data management software.

2.2 Intended Use

The equipment is intended for external defibrillation, internal defibrillation, synchronized cardioversion and semi-automated external defibrillation (AED). It can also be used for non-invasive external pacing as well as ECG, SpO_2, Resp, PR, NIBP and CO_2 monitoring.

The equipment is for use in hospital and pre-hospital settings by qualified medical personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or defibrillation.

The equipment is intended to be used by qualified medical personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or defibrillation.

2.2.1 AED

The AED mode is to be used only on cardio arrest patients. The patients must be:

- Unresponsive
- Not breathing or not breathing normally

2.2.2 Manual Defibrillation

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronized cardioversion is intended for termination of atrial fibrillation.

2.2.3 Noninvasive Pacing

Noninvasive pacing therapy is intended for patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

2.2.4 ECG

The ECG monitoring function is used to monitor and/or record the patient's ECG waveform and heart rate.

2.2.5 Resp

The respiration monitoring function is used to continuously monitor the patient's respiration rate and respiration waveform.

2.2.6 PR

The PR function is intended to measure patient's arterial pulsation in arterial blood.

2.2.7 SpO_2

The SpO_2 function is intended to measure patient's oxygen saturation in arterial blood.

2.2.8 NIBP

The NIBP function is intended for non-invasive measurement of a patient's arterial blood pressure.

2.2.9 CO_2

The CO_2 function is intended for monitoring a patient's exhaled carbon dioxide and to provide a respiration rate.

2.2.10 CPR Feedback

The CPR sensor can be connected to the equipment to provide real-time CPR feedback, including the chest compression depth, rate and interruption time.

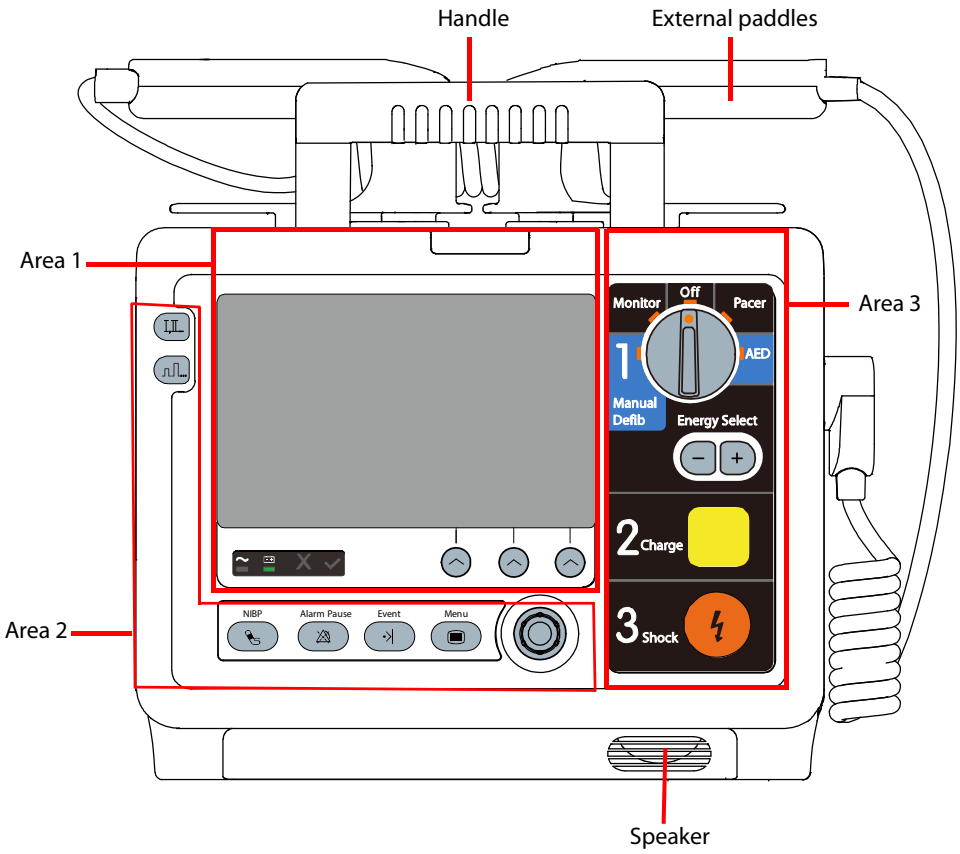
2.3 Applied Parts

The applied parts of the equipment are:

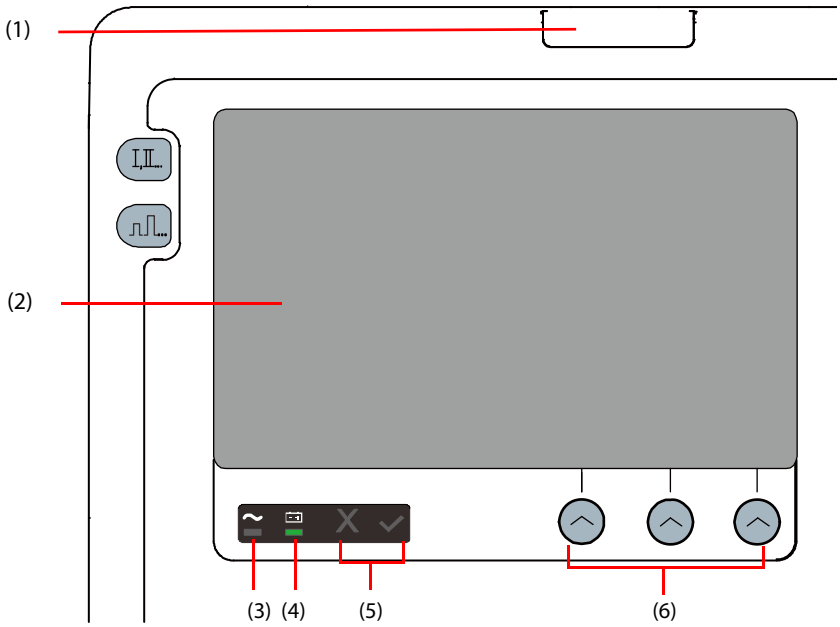
- ECG electrodes and leadwires
- SpO_2 sensor
- NIBP cuff
- CO_2 sampling line/Nasal sampling cannula, airway adapter
- External defibrillation paddles
- Internal defibrillation paddles
- Multifunction electrode pads
- CPR sensor

2.4 Main Unit

2.4.1 Front View



Area 1



(1) Alarm lamp
The Alarm lamp flashes in different color and frequency to match the alarm level.

(2) Display screen

(3) AC power indicator

- Illuminated: the AC mains is connected.
- Off: the AC mains is not connected.

(4) Battery indicator

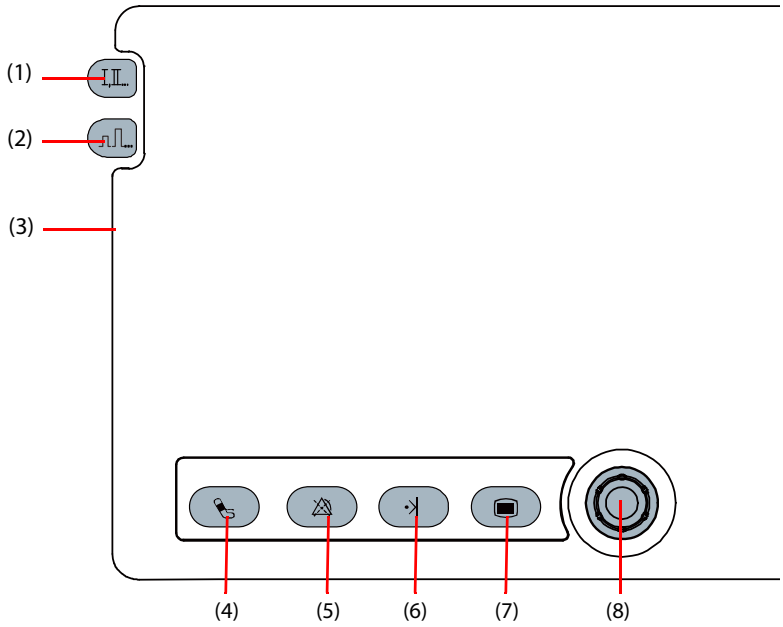
- Yellow: the battery is being charged.
- Green: the battery is fully charged or the equipment operates on battery power.
- Off: no battery is installed or battery fails.

(5) Status indicator

- Flashing (red cross): when a failure is detected, or when battery is not installed if [**No Battery**] is configured as [**Status Indicator On**].
- Illuminated (green tick): when AC mains is connected, and the equipment operates properly.
- Off: the equipment operates properly.

(6) Soft keys
They are corresponding with the soft key labels located immediately above. The labels of the soft keys changes according to the current operating mode.

Area 2



(1) Lead Select button

Press this button to select the lead for the first ECG waveform.

(2) Gain select button

Press this button to select the size of the first ECG waveform.

(3) Microphone

It is used for voice recording in AED mode.

(4) NIBP button/Record button

- NIBP button (for the equipment configured with NIBP function): press this button to start or stop NIBP measurements.
- Record button (for the equipment without NIBP function): press this button to start a recording or stop the current recording.

(5) Alarm Pause button

Press this button to pause, reactivate or switch off the alarms.

(6) Mark Event button

Press it to manually mark specified events. If a menu has been open, pressing this button will close the menu.

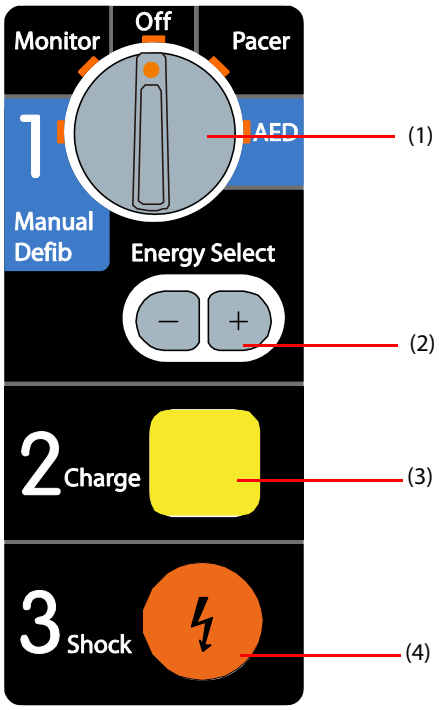
(7) Main Menu button

If no menu is displayed on the screen, pressing it will enter the main menu. If there is a menu displayed, pressing it will close that menu.

(8) Navigation knob

- Rotate it clockwise or counterclockwise to move the cursor.
- Press it to confirm the selection.

Area 3



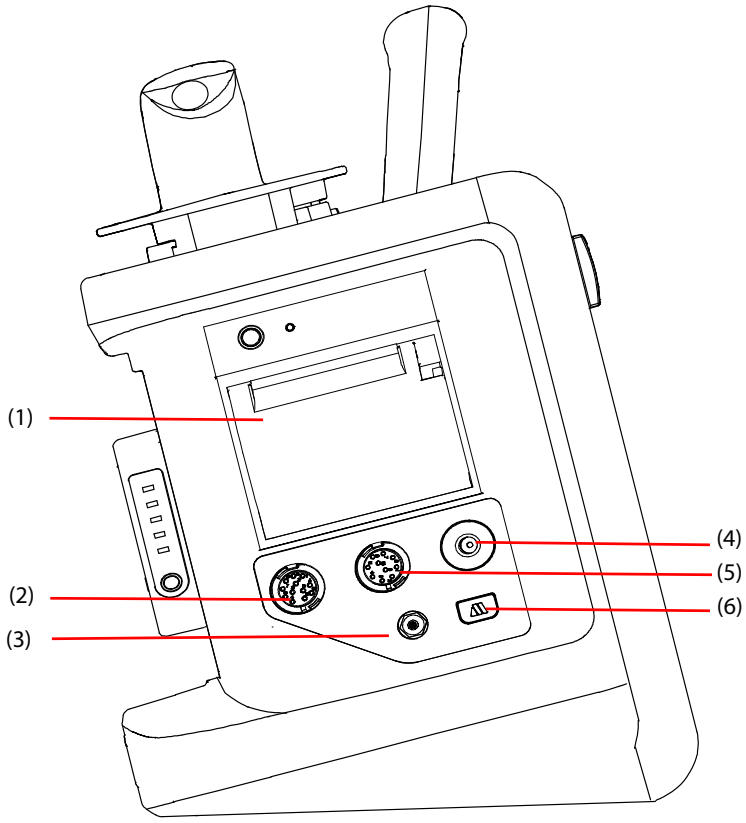
(1) Mode Select knob
Rotate this knob to select the operating mode or turn the equipment off.

(2) Energy Select button
In the Manual Defib mode, press this button to select the energy level.

(3) Charge button
Press this button to charge the defibrillator.

(4) Shock button
Press this button to deliver a shock to the patient.

2.4.2 Left View



(1) Recorder

(2) ECG cable connector

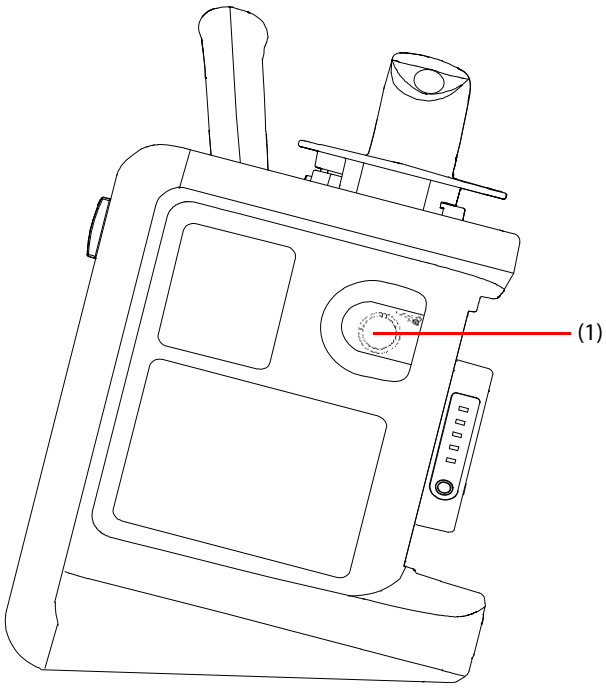
(3) Gas oulet

(4) NIBP cuff connector

(5) SpO_2 sensor connector

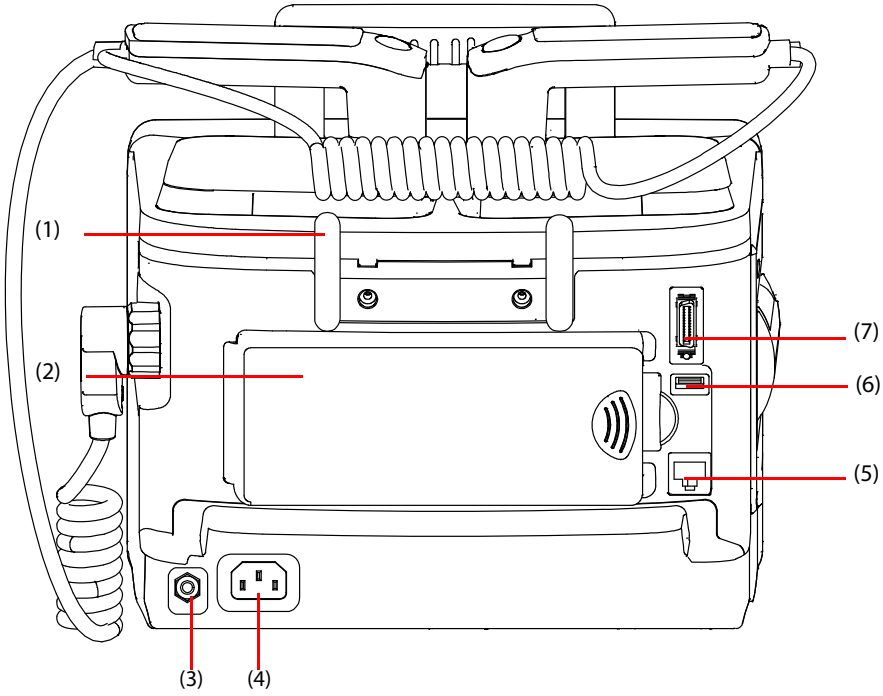
(6) CO_2 sampling line connector

2.4.3 Right View



(1) Therapy port
It is used to connect the paddles cable or pads cable.

2.4.4 Rear View



(1) Hook

(2) Battery

(3) Equipotential grounding terminal

When the defibrillator/monitor and other devices are to be used together, their equipotential grounding terminals should be connected together to eliminate the potential difference between them.

(4) External power input

It connects an AC power cord or a DC/AC adapter to run the equipment respectively on the external AC mains or DC power supply.

(5) Network connector

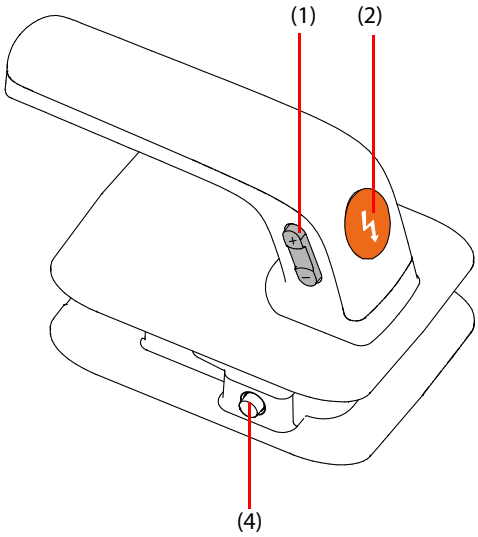
It is a standard RJ45 connector.

(6) USB connector

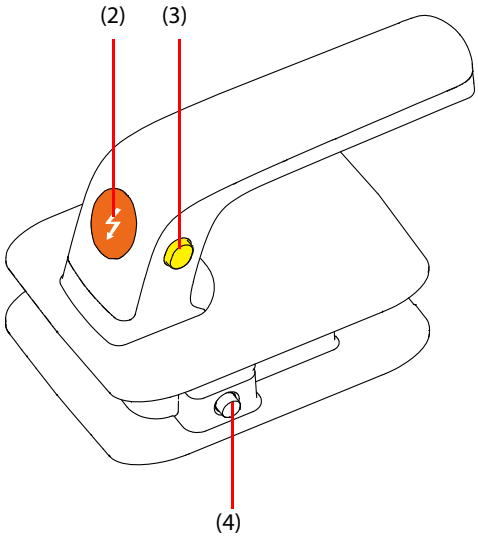
(7) Multifunctional connector

It connects a CPR sensor, provides ECG output and defib synchronization input.

2.5 External Paddles



Sternum paddle



Apex paddle

(1) Energy Select button

(2) Shock button

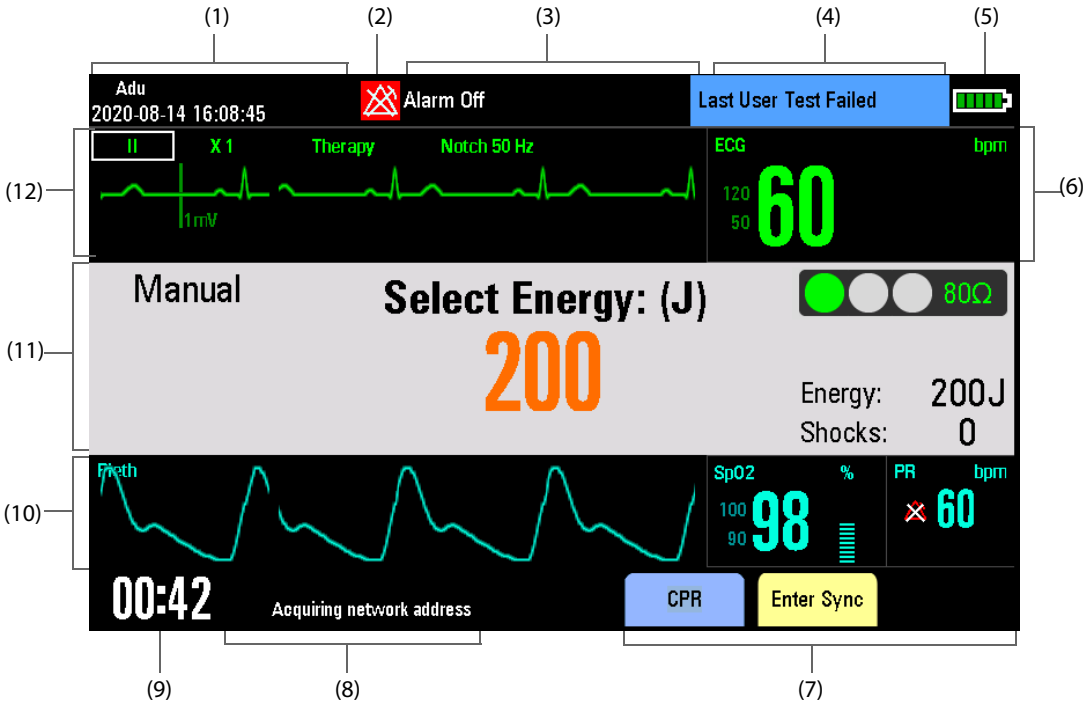
(3) Charge button

(4) Latch button

Press this button to get for pediatric paddles. For details, refer to *7.4.1 Using Pediatric Paddles*.

2.6 Display Views

A typical screen in the Manual Defib Mode is shown below.



(1) Patient Information area

This area shows patient name, patient category, paced status, and current date and time. indicates that the patient has an implanted pacemaker.

(2) Alarm status symbols

This area shows the alarm status. For details, refer to *4.3.5 Alarm Status Symbols*.

(3) Physiological Alarm area

This area shows physiological alarm messages. When multiple alarms occur, they will be displayed circularly.

(4) Technical Alarm area

This area shows technical alarm messages and prompt messages. When multiple messages occur, they will be displayed circularly.

(5) Battery Status indicator

It indicates battery status. For details, refer to *22 Battery*.

(6) Parameter area

This area shows measurement parameters. Each measurement module has a parameter block and the parameter name is displayed at the upper left corner.

(7) Soft Key area

The soft key labels correspond to the soft key buttons located immediately below. The labels of the soft keys change according to the current display view and function. Soft key labels appearing as blank indicate that the soft key is inactive.

(8) Prompt area

This area shows the prompt information.

(9) Runtime area

This area shows the operating time since the equipment is turned on.

(10) Auxiliary Parameter area

This area shows parameters that cannot be displayed in the parameter area. When this area cannot accommodate all parameters, the excess parameters will automatically occupy the area of last waveform.

(11) Manual Defib information area

This area shows the selected defibrillation energy, shock counter as well as prompts related to manual defibrillation.

(12) Waveform area

This area shows measurement waveforms. The waveform label is displayed at the upper left corner of the waveform.

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3 Basic Operations and Settings

3.1 Equipment Installation

WARNING

- **The equipment shall be installed by personnel authorized by the manufacturer.**
- **The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **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 the manufacturer.**
- **If it is not evident from the equipment specifications whether a particular combination is hazardous, for example, due to summation of leakage currents, consult the manufacturers or else an expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.**

CAUTION

- **The docking station is part of the equipment. Use only the specified docking station.**

3.1.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or the manufacturer. If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. If you have any question, please contact us.

WARNING

- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **The equipment might be contaminated during storage and transport. 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.**

NOTE

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

3.1.2 Environmental Requirements

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

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. If the equipment is installed in a cabinet, sufficient space in front and behind shall be left for convenient operation, maintenance and repair. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5 cm) away from around the cabinet.

When the equipment 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.

NOTE

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **The equipment use a mains plug as isolation means to the mains power supply. Do not locate the equipment in a place difficult to operate the mains plug.**

3.2 Basic Operation

3.2.1 Connecting the AC Mains

The equipment is powered by AC power supply. Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated besides the AC power input.

1. Connect the female end of the power cord with the AC power input.
2. Connect the male end of the power cord with a wall AC outlet.
3. Check that the power indicator is on.

The AC power indicator is off if the AC mains is not connected. When AC mains is connected, the AC power indicator is illuminated in green.

WARNING

- **Always use the accompanying power cord delivered with the equipment.**
- **Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated besides the AC power input.**
- **Use the cable retainer to secure the power cord to prevent it from falling off.**
- **Use the battery if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.**

3.2.2 Installing the Battery

The equipment is designed to operate on battery power when external power supply is not available. For more information, refer to *22 Battery*.

3.2.3 Turning On the Equipment

Before turning on the equipment, perform the following inspections:

1. Check for any mechanical damage and make sure that all external cables and accessories are properly connected.
2. Connect the power cord to the AC power source. If you run the equipment on battery power, ensure that the battery is sufficiently charged. If you run the equipment on DC power supply, a DC/AC adapter we supply should be used.

To turn on the equipment, turn the Mode Select knob to the desired mode.

After the start-up screen is displayed, the equipment gives a beep, and meanwhile, the alarm lamp is illuminated in yellow, and then turns red, and then turns off.

- If the equipment is turned on by entering the AED mode or Manual Defib mode, the alarm system is off when the alarm lamp turns off.
- If the equipment is turned on by entering the Pacer mode or Monitor m ode, the alarm system is activated when the alarm lamp turns off.

WARNING

- **Do not use the equipment for any monitoring or therapy procedure on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact your service personnel or Mindray.**

NOTE

- **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 it is not working properly, or if it is mechanically damaged. Contact your service personnel or Mindray.**

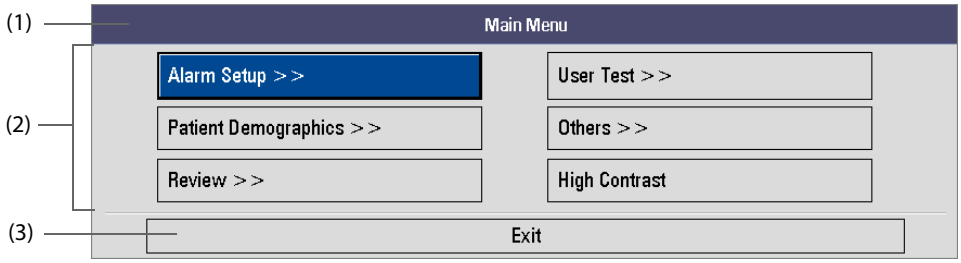
3.2.4 Starting Monitoring or Therapy

1. Decide which measurements or therapy you want to make.
2. Check that the patient cables and sensors are correct.
3. Connect the required patient cables and sensors.
4. Enter the appropriate operating mode and check that the settings are proper for your patient.

For details on performing patient monitoring and therapy, refer to the corresponding sections.

3.2.5 Using the Main Menu

To enter the main menu, press the Main Menu button on the front panel.



Other menus are similar to the main menu and contain the following parts:

(1) Heading

(2) Main body:
Displays options, buttons, prompt messages, etc. Pressing the menu button with ">>" enters a submenu with additional options or information.

(3) Exit button

3.2.6 Using the Navigation knob

■ Displaying a submenu

Rotate the Navigation knob to move the cursor on the desired item of the main menu, and then press the Navigation knob.

■ Inputting information

1. Rotate the Navigation knob to move the cursor on the desired textbox of a menu, and then press the knob.
2. Rotate the Navigation knob to move the cursor on the desired character to be inputted, and then press the Navigation knob.
   - ◆ Select [**DEL**] to delete the entire entry.
   - ◆ Select to access uppercase letters.
   - ◆ Select [**OK**] to confirm the entry and close the on-screen keyboard.
3. Repeat step 2 to complete the information input.

4. Rotate the Navigation knob to move the cursor on [**Ok**], and then press the Navigation knob to save the information inputted.

■ Changing settings

Changing the ECG lead in the Monitor mode is taken as an example below:

1. Rotate the Navigation knob to move the cursor on the ECG lead label 
2. Press the Navigation knob to highlight the selection  .
3. Rotate the Navigation knob until you find the desired item, and then press the Navigation knob to confirm the selection.

3.2.7 Editing Current Patient Information

The patient name/bed number (configurable), patient category and paced status of the current patient are displayed in the upper left corner of the main screen.

1. Press the Main Menu button on the front panel, and then select [**Patient Demographics >>**].
2. Make changes as desired.
   - ◆ Set [**Patient Cat.**] to change the patient category. You can also rotate the Navigation knob to move the cursor on the patient category of the main screen, press and rotate the Navigation knob to change the patient category.
   - ◆ Edit patient name or bed number. You can set the patient information type displayed in the upper left corner of the main screen by selecting [**General Setup**] through the Configuration Main menu.
   - ◆ Set paced status: when the [**Paced**] is set to [**Yes**], a paced symbol  is displayed in the upper left corner of the main screen.
3. Select [**Others >>**] to edit more patient information.

If the equipment is connected to the CMS, the current patient name, bed number, MRN, department, height, weight, admit date or doctor information can also be changed on the CMS.

3.2.8 Turning Off the Equipment

1. Check that the patient monitoring or therapy is completed.
2. Disconnect the patient cables and sensors from the patient.
3. Make sure to save or clear the patient data as required.
4. Turn the Mode Select Knob to Off. After 10 seconds, the equipment is shut down.

NOTE

- **To completely disconnect the power supply, unplug the power cord.**

3.2.9 Auto Restoring to Last Configuration

During operation, you may make changes to some settings. However, these changes may not be saved as user configuration. To prevent the changes from losing in case of sudden power failure, the equipment saves the settings in real time. The saved settings are the latest configuration. In case of power failure, the equipment loads the latest configuration if restarts within 60 seconds; it load the user configuration if restarts 120 seconds later after the power failure; it may load either the latest configuration or the user configuration if restarts between 60 and 120 seconds after the power failure.

3.3 Changing General Settings

3.3.1 Setting the Date and Time

Before putting the equipment into use for the first time, you should check and set the system date and time in accordance with your local time.

To set the system time, you can choose any of the following ways:

■ Using the Navigation knob

1. Use the Navigation knob to move the cursor on the system time, and press the Navigation knob.
2. Set the system time.
3. Select [**Confirm**].

■ Through the Configuration Main menu

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**General Setup**], and set the system time.
3. Select [**Return**].

■ Through the Configuration View menu

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → [**View Config**].
2. Select [**General Setup**], and set the system time. You cannot select date format and time format in this case.
3. Select [**Return**].

■ Through the CMS

If connected to the CMS, the CMS automatically synchronize the system time to the equipment, and you cannot use the Navigation knob to change the system time on the equipment. For details on connecting the CMS, refer to *20.3 Connecting the CMS*.

If the system time is changed through the Configuration Main menu or Configuration View menu, the equipment will restart. If the system time is changed using the Navigation knob, or from the CMS, the equipment will generate a event to remind you.

3.3.2 Adjusting the Screen Brightness

1. Press the Main Menu button on the front panel, and then select [**Others >>**].
2. Set [**Brightness**] to an appropriate level. 10 is the brightest, and 1 is the least bright.

You can also change the screen brightness by selecting [**Others**] from the Configuration Main menu.

3.3.3 Changing Key Volume

1. Press the Main Menu button on the front panel, and then select [**Others >>**].
2. Select [**Key Volume**] and then select an appropriate value. 0 means key volume off and 10 is the maximum volume.

You can also change key volume by selecting [**Others**] from the Configuration Main menu.

3.3.4 Selecting High Contrast Display

The equipment has the function of high contrast display so that you can view the display under high ambient illumination.

To enable or disable the high contrast display:

■ In the Monitor, Manual Defib or Pacer mode

Press the Main Menu button on the front panel, and then select [**High Contrast**] to enable the high contrast display. To disable the high contrast display, select [**Full Color**] in the main menu.

■ In the AED mode

Press the [**High Contrast**] soft key to enable the high contrast display. To disable the high contrast display, press the [**Full Color**] soft key.

Once [**High Contrast**] is selected, the high contract display remains when you change the operating mode. However, the setting will not be saved if the equipment is turned off.

3.3.5 Adjusting Waveform Position

1. Press the Main Menu button on the front panel, and then select [**Others >>**]→ [**Waves >>**].
2. Set [**Wave 2**] and [**Wave 3**]. [**Wave 1**] is always ECG1, which is unchangeable.

You can also change waveform position by selecting [**Waveform Setup**] from the Configuration Main menu.

3.4 Analog Output

The equipment is configured with a multifunction connector for ECG analog output.

4 Alarms

Alarms triggered by a vital sign that appears abnormal or by technical problems of the equipment, are indicated to you by visual and audible alarm indications.

WARNING

- **A potential hazard exists if different alarm presets are used for the same or similar device in any single area, e.g. an intensive care unit or cardiac operating room.**
- **If the equipment is connected to a CMS, remote suspension, inhibition, silence and reset of monitoring alarms via the CMS may cause a potential hazard. For details, refer to the operator's manual of the CMS.**
- **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 make sure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.**

4.1 Alarm Categories

By nature, the equipment's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

1. Physiological alarms

   Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or by an abnormal patient condition. Physiological alarm messages are displayed in the physiological alarm area. In the AED mode, no physiological alarm will be presented.

2. Technical alarms

   Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or system failure. Technical alarm messages are displayed in the technical alarm area.

3. Prompt messages

   As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarms, the equipment also shows some messages indicating system status. Messages of this kind are usually displayed in the prompt area. Therapy-related prompts are shown in corresponding information area. Some special prompts are shown in dialog boxes.

4.2 Alarm Levels

By severity, alarms can be classified into three categories: high level alarms, medium level alarms and low level alarms.

	Physiological alarms	**Technical alarms**
High level	Indicate that your patient is in a life threatening situation, such as Asystole, Vfib/Vtac and so forth, and an emergency treatment is demanded.	Indicate a severe device malfunction or an improper operation, which may result that the equipment cannot detect critical patient status or may cause therapy failed, and thus threaten the patient's life, such as low battery.
Medium level	Indicate that your patient's vital signs appear abnormal and an immediate treatment is required.	Indicate a device malfunction or an improper operation, which may not threaten the patient's life but may compromise patient monitoring or therapy.
Low level	Indicate that you patient's vital signs appear abnormal and an immediate treatment may be required.	Indicate a device malfunction or an improper operation, which may compromise a certain function but will not threaten the patient's life.

4.3 Alarm Indicators

When an alarm occurs, the equipment indicates it to you through visual or audible alarm indications.

- Alarm lamp
- Alarm tones
- Alarm message
- Flashing numeric

NOTE

- **When multiple alarms of different levels occur simultaneously, the equipment will select the alarm of the highest level and give visual and audible alarm indications accordingly. Alarm messages will be displayed circularly.**
- **Some physiological alarms, such as Asystole, are exclusive. They have identical alarm tones and alarm lights with normal high level physiological alarms, but their alarm messages are displayed exclusively. That is to say, when an exclusive physiological alarm and a normal high level physiological alarms are triggered simultaneously, only alarm message of the exclusive physiological alarm is displayed.**

4.3.1 Alarm Lamps

If an alarm occurs, the alarm lamp will flash. The color and flashing frequency match the alarm level as follows:

- High level alarms: the lamp quickly flashes red with frequency of 1.4 to 2.8 Hz, duty ratio of 20 to 60%.
- Medium level alarms: the lamp slowly flashes yellow with frequency of 0.4 to 0.8 Hz, duty ratio of 20 to 60%.
- Low level alarms: the lamp lights yellow without flashing, with duty ratio of 100%.

4.3.2 Audible Alarms

The equipment uses different alarm tone patterns to match the alarm level:

- High level alarms: triple + double + triple + double beeps.
- Medium level alarms: triple beeps.
- Low level alarms: single beep.

4.3.3 Alarm Messages

When an alarm occurs, the alarm message will appear in the technical or physiological alarm area. For physiological alarms, the asterisk symbols (*) before the alarm message match the alarm level as follows:

- High level alarms: ***
- Medium level alarms: **
- Low level alarms: *

Additionally, the alarm message has different background color which matches the alarm level.

- For physiological alarms
  - High level alarms: red
  - Medium level alarms: yellow
  - Low level alarms: yellow

- For technical alarms
  - High level alarms: red
  - Medium level alarms: yellow
  - Low level alarms: blue

4.3.4 Flashing Numerics

If an alarm triggered by an alarm limit violation occurs, the numeric of the measurement in alarm will flash every second, and corresponding alarm limit will also flash at the same frequency indicating the alarm limit is violated.

4.3.5 Alarm Status Symbols

Apart from the aforementioned alarm indicators, the equipment still uses the following symbols telling the alarm status:

 Alarm pause:	indicates alarms are paused.
 Alarm reset:	indicates alarm are reset.
 Audio off:	indicates alarm sounds are turned off.
 Alarm off:	indicates the system is in alarm off status.

4.4 Alarm Tone Configuration

4.4.1 Changing the Alarm Volume

1. Press the Main Menu button on the front panel, and then select [**Alarm Setup >>**] .
2. Set [**Alm Volume**] to an appropriate level.
   - If [**Audio Off**] is enabled, alarm volume can be set to a value between 0 and 10, in which 0 means audio off and 10 the maximum volume level.
   - If [**Audio Off**] is disabled, alarm volume can be set to a value between 1 and 10, in which 1 is the minimum volume level and 10 the maximum.

The setting of alarm volume will not be saved when the equipment is powered off.

You can also disable or enable [**Audio Off**], set the alarm volume by selecting [**Alarm Setup**] from the Configuration Main menu. In this case, the setting will be saved.

NOTE

- **You cannot adjust the alarm volume when an alarm is switched off.**

4.4.2 Setting the Reminder Tones

When alarms or alarm sounds are turned off, the equipment gives a reminder tone of a single beep every 60 seconds.

The reminder tone is switched off by default. You can switch on [**Reminder Tone**] by selecting [**Alarm Setup**] from the Configuration Main menu. You can also change the reminder volume. The default reminder volume is [**Med**].

4.4.3 Setting the Interval between Alarm Sounds

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Alarm Setup**].
3. Respectively set [**High Level Alarm (s)**], [**Med Level Alarm (s)**] and [**Low Level Alarm (s)**].

WARNING

- **Do not rely exclusively on audible alarm system. Setting alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**

4.5 Understanding the Alarm Setup Menu

Press the Main Menu button on the front panel, and then select [**Alarm Setup >>**] to enter the [**Alarm Setup**] menu.

4.5.1 Setting Alarm Properties for All Parameters

In the main menu, select [**Alarm Setup >>**] → [**Para. Alarm >>**] to enter the [**Para. Alarm**] menu, where you can review and set alarm limits, alarm switches, alarm level and alarm recordings for all parameters.

- When a parameter alarm is switched on, the equipment gives alarm indications in accordance with the preset alarm level and stores related waveforms and parameter values.
- When a parameter alarm is switched off, the alarm off symbol  is displayed in the parameter window.

  For NIBP, the alarm off symbol  is displayed only when all the NIBP alarms are switched off simultaneously.
- When the measurement's [**On/Off**] and [**Record**] are set to [**On**], automatic recording of all the measurement numerics and related waveforms is possible when a measurement alarm occurs.
- When [**Defaults**] is selected, all settings restored to the defaults.

You can also set parameter alarm properties by selecting a parameter area and select [**Para. Alarm >>**] in the pop-up menu.

WARNING

- **Make sure that the alarm limits settings are appropriate for your patient before patient monitoring.**
- **Setting the alarm limit to an extreme value may cause the alarm system to be ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration, do not set the SpO_2 high alarm limit to 100%, which is equivalent to switching the alarm off.**
- **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.**

NOTE

- **You cannot simultaneously switch on HR and PR alarms. In the case that PR alarm is on, switching on HR alarm will automatically turn off PR alarm, and vice versa.**

4.5.2 Adjusting Alarm Limits Automatically

The equipment can automatically adjust the patient's alarm limits according to the measured vital signs. When [**Auto Limits**] is selected, the equipment automatically calculates alarm limits based on the latest measured parameter values.

To enable auto alarm limits, press the Main Menu button on the front panel, and then select [**Alarm Setup >>**] → [**Para. Alarm >>**] → [**Auto Limits**].

You can also enable auto alarm limits by selecting a parameter area and then select [**Para. Alarm >>**]→ [**Auto Limits**].

When auto alarm limits have been applied, you can manually adjust the alarm limits through the [**Para. Alarm**] menu so that they are appropriate for your patient.

The equipment calculates the auto limits based on the following rules.

Module	Parameter	Low alarm limit		High alarm limit		Auto alarm limits range
		Adult/pediatric	Neonate	Adult/pediatric	Neonate	
ECG	HR	HR×0.8 or 40 bpm (whichever is greater)	(HR-30) or 90 bpm (whichever is greater)	HR×1.25 or 240 bpm whichever is lower)	(HR + 40) or 200 bpm whichever is lower)	Adult/pediatric: 35 to 240 Neonate: 55 to 225
Resp	RR	RR×0.5 or 6/min (whichever is greater)	(RR-10) or 30/ min (whichever is greater)	RR×1.5 or 30/ min (whichever is lower)	(RR+25) or 85/ min (whichever is lower)	Adult/pediatric: 6 to 55 Neonate: 10 to 90
SpO_2	SpO_2	Same as the default alarm limit	Same as the default alarm limit	Same as the default alarm limit	Same as the default alarm limit	Same as the measurement range
	PR	PR×0.8 or 40 bpm (whichever is greater)	(PR-30) or 90 bpm (whichever is greater)	PR×1.25 or 240 bpm whichever is lower)	(PR + 40) or 200 bpm whichever is lower)	Adult/pediatric: 35 to 240 Neonate: 55 to 225
NIBP	NIBP-S	SYS×0.68 + 10mmHg	(SYS-15) or 45mmHg (whichever is greater)	SYS×0.86 + 38mmHg	(SYS + 15) or 105mmHg (whichever is lower)	Adult: 45 to 270 Pediatric: 45 to 185 Neonate: 35 to 115
	NIBP-D	Dia×0.68 + 6mmHg	(Dia-15) or 20mmHg (whichever is greater)	Dia×0.86 + 32mmHg	(Dia + 15) or 80mmHg (whichever is lower)	Adult: 25 to 225 Pediatric: 25 to 150 Neonate: 20 to 90
	NIBP-M	Mean×0.68 + 8mmHg	(Mean-15) or 35mmHg (whichever is greater)	Mean×0.86 + 35mmHg	(Mean + 15) or 95mmHg (whichever is lower)	Adult: 30 to 245 Pediatric: 30 to 180 Neonate: 25 to 105
CO_2	$EtCO_2$	0-32mmHg: remains unchanged	0-32mmHg: remains unchanged	0-32mmHg: remains unchanged	0-32mmHg: remains unchanged	Same as the measurement range
		32-35mmHg: 29mmHg	32-35mmHg: 29mmHg	32-35mmHg: 41mmHg	32-35mmHg: 41mmHg	
		35-45mmHg: $EtCO_2$-6mmHg	35-45mmHg: $EtCO_2$-6mmHg	35-45mmHg: $EtCO_2$+6mmHg	35-45mmHg: $EtCO_2$+6mmHg	
		45-48mmHg: 39mmHg	45-48mmHg: 39mmHg	45-48mmHg: 51mmHg	45-48mmHg: 51mmHg	
		>48mmHg: remains unchanged	>48mmHg: remains unchanged	>48mmHg: remains unchanged	>48mmHg: remains unchanged	
	$FiCO_2$	N/A	N/A	Same as the default alarm limit	Same as the default alarm limit	Same as the measurement range
	awRR	awRR×0.5 or 6/ min (whichever is greater)	awRR-10 or 30/ min (whichever is greater)	awRR×1.5 or 30/ min (whichever is lower)	awRR+25 or 85/ min (whichever is lower)	Adult/pediatric: 6 to 55 Neonate: 10 to 90

NOTE

- **You can enable auto alarm limits only when the current parameter measurement is within the auto alarm limits range.**

4.6 Pausing Alarms

You can temporarily disable alarm indicators by pressing the Alarm Pause button on the front panel. When alarms are paused:

- For physiological alarms, no alarm indication is shown. New physiological alarm will not be presented.
- The remaining alarm pause time is displayed in the physiological alarm area.
- For technical alarms, alarm sounds are paused, but alarm lamps and alarm messages remain presented.
- The alarm pause symbol is displayed in the sound symbol area. If a new technical alarm is triggered in the alarm paused period, the alarm message will be displayed.

When the alarm pause time expires, the alarm paused status is automatically deactivated. You can also cancel the alarm paused status by pressing the Alarm Pause button .

The default alarm pause time is 2 minutes. To change alarm pause time:

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Alarm Setup**] → [**Alarm Pause Time**] and then select an appropriate value.

4.7 Switching Alarms Off

When an alarm is switched off, the alarm status is the same with that when an alarm is paused.

Alarms are switched off when:

- The Alarm Pause button is pressed if the [**Alarm Pause Time**] is set to [**Permanent**].
- The operating mode is switched to the Manual Defib mode.
- Synchronized cardioversion is exited when operating in the Manual Defib mode.

The alarm off status is exited when:

- The Alarm Pause button is pressed.
- Sync Defib is switched on in the Manual Defib mode.

4.8 Switching Off Alarm Sounds

In the event that [**Audio Off**] is enabled through the Configuration Main menu, to switch off the alarm tone, set [**Alm Volume**] to 0 while operating in the Monitor mode, Manual Defib mode or Pacer mode. In the audio off status, the audio off symbol appears in the sound symbol area. In this case, the alarm status is the same with that when alarm tones are paused.

The audio off status is exited when:

- [**Audio Off**] is set to [**Disabled**] by selecting [**Alarm Setup**] from the Configuration Management Main menu.
- The Alarm Pause button is pressed. In this case, the equipment enters the alarm paused status and the alarm volume is reset to the default level. the alarm pause symbol is displayed in the sound symbol area.
- Operating mode is switched.
- Alarm volume is changed to a value between 1 and 10.

4.9 Resetting Alarms

By pressing the [**Alarm Reset**] soft key, you can reset the alarm system and enable the alarm system to respond to a subsequent alarm condition.

For physiological alarms, when the alarm system is reset:

- The alarm sound is reset.
- A √ appears before the alarm message.
- The alarm reset symbol appears in the alarm symbol area.

- The parameter numeric and alarm limits still flash.

Technical alarms give different alarm indicators when the alarm system is reset:

- For some technical alarms, including the NIBP-related alarms, a √ appears before the alarm message and the alarm reset symbol  appears in the alarm symbol area.
- Some technical alarms are changed to the prompt messages.
- Some technical alarms are cleared. The equipment gives no alarm indications.

For details about the indications of technical alarms when the alarm system is reset, refer to *E.2 Technical Alarm Messages*.

4.10 Latching Alarms

The latching setting for physiological alarms defines how alarm indicators behave if you do not reset the alarms.

- If an alarm is latched, alarm indications remain presented even though alarm conditions end, except that:
  - The parameter reading and violated alarm limit stop flashing.
  - The time when the alarm is last triggered is displayed behind the alarm message.
- If an alarm is not latched, the alarm indications disappear as soon as the alarm conditions end.

To latch a physiological alarm:

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Alarm Setup**] and set [**Latching Alarms**] to [**Yes**].

Only physiological alarms can be latched. You can clear the latched alarms by pressing the Alarm Pause button on the front panel  .

4.11 Clearing Technical Alarms

Technical alarms give different alarm indicators after the Alarm Pause button or [**Alarm Reset**] soft key is pressed. The technical alarms are classified into three categories for easy clarification:

- Technical alarms are cleared.

  All alarm indications are cleared after the Alarm Pause button  or [**Alarm Reset**] soft key is pressed. After the equipment restores the normal alarm status, it can give alarm indications correctly in case these alarms are triggered again.

- Technical alarms are changed to the prompt messages.

  The alarm lamp flashing and alarm tones are cleared and the alarm messages change to prompt messages after the Alarm Pause button  or [**Alarm Reset**] soft key is pressed. After the equipment restores the normal alarm status, it can give alarm indications correctly in case these alarms are triggered again.

- The alarm is silenced and a √ appears before the alarm message.

  The alarm tones are cleared but the alarm lamp flashing and alarm messages remain after the Alarm Pause button  or [**Alarm Reset**] soft key is pressed. After the equipment restores the normal alarm status, all the alarm indications will continue if the alarm conditions still present.

4.12 Testing Alarms

When the equipment starts up, a selftest is performed. In this case the alarm lamp is lit in yellow and red respectively, and the equipment gives a beep. This indicates that the visible and audible alarm indicators are functioning correctly.

For further testing of individual measurement alarms, perform the measurement on yourself (for example SpO_2 or CO_2) or use a simulator. Adjust alarm limits and check that appropriate alarm behaviour is observed.

4.13 Actions When an Alarm Occurs

When an alarm occurs, observe the following steps and take proper actions:

1. Check the patient's condition.
2. Confirm the alarming parameter or alarm category.
3. Identify the alarm source.
4. Take proper action to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

For actions taken with regard to specific alarms, refer to *E Alarm Messages*.

5 Monitoring ECG

5.1 ECG Introduction

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it as waveforms and numerics. The equipment enables ECG monitoring through 3-lead ECG sets, 5-lead ECG sets, external paddles and electrode pads. If both ECG sets and external paddles/electrode pads are connected, the configured ECG waveforms are displayed in the waveform area.

ECG monitoring is intended for adult, pediatric and neonatal patients.

5.2 ECG Safety Information

WARNING

- **ECG monitoring is not suitable for direct cardiac application.**
- **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**
- **Use defibrillation-proof ECG cables during defibrillation.**
- **When monitoring a patient implanted with a pacemaker, be sure to select correct paced status. Otherwise, the pace pulses may be counted in the case of cardiac arrest or some arrhythmias. Do not completely rely on the heart rate reading or the heart rate alarms. Always keep paced patients under close surveillance.**
- **PACEMAKER PATIENTS – On ventricular paced patients, episodes of Ventricular Tachycardia may not always be detected. Do not rely entirely upon the system's automated arrhythmia detection algorithm.**

CAUTION

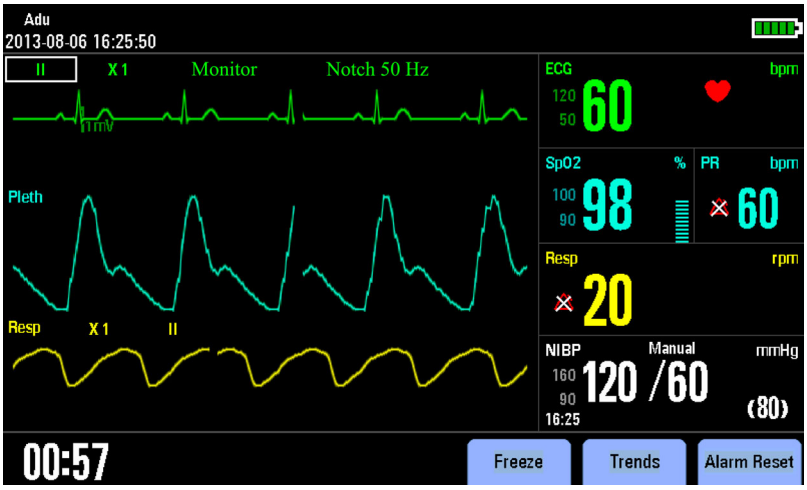
- **Interference from a non-grounded instrument near the patient and electrosurgery interference can cause problems with the waveform.**

NOTE

- **When connecting electrodes and/or patient cables, make sure that the connectors never come into contact with other conductive parts, or with earth. Particularly make sure that all of the ECG electrodes are attached to the patient.**
- **If selected lead cannot provide valid ECG signals, a dash line is shown in the ECG waveform area.**
- **Avoid using external paddles for ECG monitoring if possible.**
- **Use the same type of ECG electrodes when monitoring ECG through ECG lead set.**

5.3 Monitoring View

A typical screen in the Monitor mode is shown below.



You can enter the Monitor mode by switching the Mode Select knob to Monitor. When operating in the Monitor mode, the equipment displays up to two ECG waveforms, the heart rate reading, other available parameter values and active alarm settings.

5.4 Preparing for ECG Monitoring and Measurement

5.4.1 Preparing the Patient Skin

Proper skin preparation is necessary for good signal quality at the electrode, as the skin is a poor conductor of electricity. To properly prepare the skin, choose flat areas and then follow this procedure:

1. Shave hair from skin at chosen sites.
2. Gently rub skin surface at application sites to remove dead skin cells.
3. Thoroughly clean the sites with mild soap and water. We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.
4. Dry the skin completely before applying the electrodes.

5.4.2 ECG Monitoring with Electrodes

5.4.2.1 Applying Electrodes

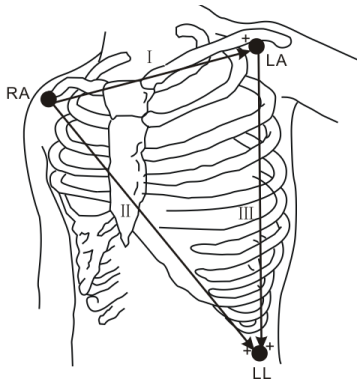
1. Attach the clips or snaps to the electrodes before placing them.
2. Place the electrodes on the patient.
3. Attach the lead wires to the ECG trunk cable and then plug the trunk cable into the ECG connector.
4. Switch the Mode Select knob to Monitor.

5.4.2.2 ECG Electrode Placements

3-Lead Placement

The following is a typical AHA electrode placement for a 3-lead ECG set:

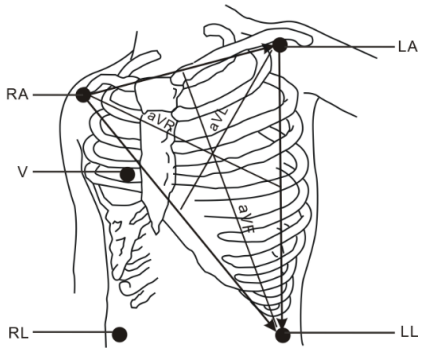
- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left lower abdomen.



5-Lead Placement

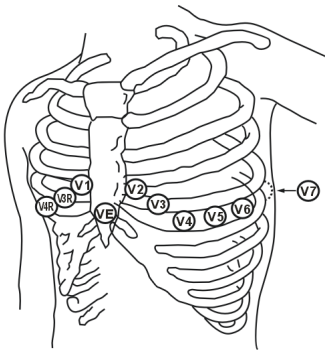
The following is a typical AHA electrode placement for a 5-lead ECG set:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right lower abdomen.
- LL placement: on the left lower abdomen.
- V placement: on the chest.



The chest (V) electrode can be placed on one of the following positions:

- V1 placement: on the fourth intercostal space at the right sternal border.
- V2 placement: on the fourth intercostal space at the left sternal border
- V3 placement: midway between the V2 and V4 electrode positions.
- V4 placement: on the fifth intercostal space at the left midclavicular line.
- V5 placement: on the left anterior axillary line, horizontal with the V4 electrode position.
- V6 placement: on the left midaxillary line, horizontal with the V4 electrode position.
- V3R-V6R placement: on the right side of the chest in positions corresponding to those on the left.
- VE placement: over the xiphoid process.
- V7 placement: on posterior chest at the left posterior axillary line in the fifth intercostal space.
- V7R placement: on posterior chest at the left posterior axillary line in the fifth intercostal space.



Electrode Placement for Surgical Patients

The surgical site should be taken into consideration when placing electrodes on a surgical patient, e.g. for open-chest surgery, the chest electrodes can be placed on the lateral chest or back. To reduce artifacts and interference from electrosurgical units, you can place the limb electrodes close to the shoulders and lower abdomen and the chest electrodes on the left side of the mid-chest. Do not place the electrodes on the upper arm. Otherwise, the ECG waveform will be very small.

WARNING

- **When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.**
- **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.**

5.4.3 ECG Measurement with Electrode Pads

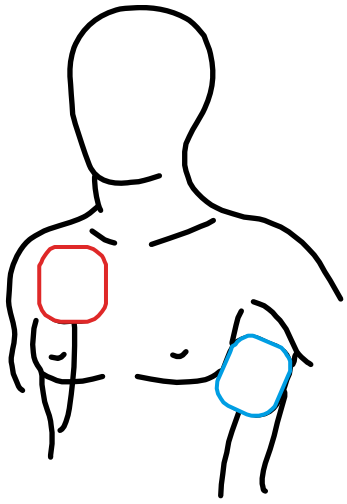
1. Apply the electrode pads to the patient as indicated on pads package.

■ For adult patients, use the anterior-lateral placement:

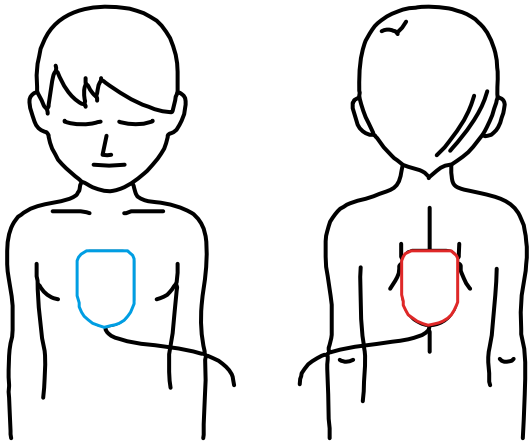
- ◆ Place the red (sternum) pad on the patient's upper right torso, lateral to the sternum and below the clavicle.
- ◆ Place the blue (apex) pad to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line.

■ For pediatric patients, use the anterior-posterior placement:

- ◆ Place the blue (apex) pad in the center of the patient's chest between the nipples.
- ◆ Place the red (sternum) pad in the center of the patient's back.



For adult Patients (anterior-lateral placement)



For pediatric patients (anterior-posterior placement)

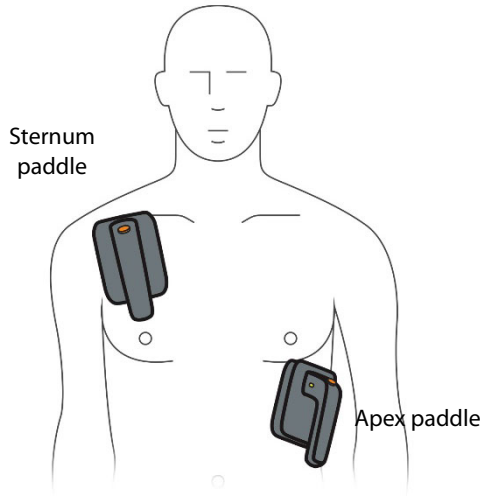
2. Connect the electrode pads to the pads cable.
3. Connect the electrode pads cable with the equipment if not connected.

NOTE

- **Anterior - lateral placement for adult patients, and anterior-posterior placement for pediatric patients are the only placement that can be used for ECG monitoring with electrode pads.**

5.4.4 ECG Measurement with External Paddles

1. Connect the paddles cable with the equipment if not connected.
2. Apply conductive gel to paddle electrodes.
3. Remove the paddle set from the paddle tray by grasping the handles and pulling them straight up.
4. Apply the external paddles to the patient by using anterior-lateral placement.
   - ◆ Place the sternum paddle on the patient's upper right torso, lateral to the sternum and below the clavicle.
   - ◆ Place the apex paddle to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line.



NOTE

- **Anterior - lateral placement is the only placement that can be used for ECG monitoring with external paddles.**

5.4.5 Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG. The paced symbol is displayed when the [**Paced**] is set to [**Yes**]. The pace pulse markers "?" are shown on the ECG wave when the patient has a paced signal.

To change the paced status, choose either of the following ways:

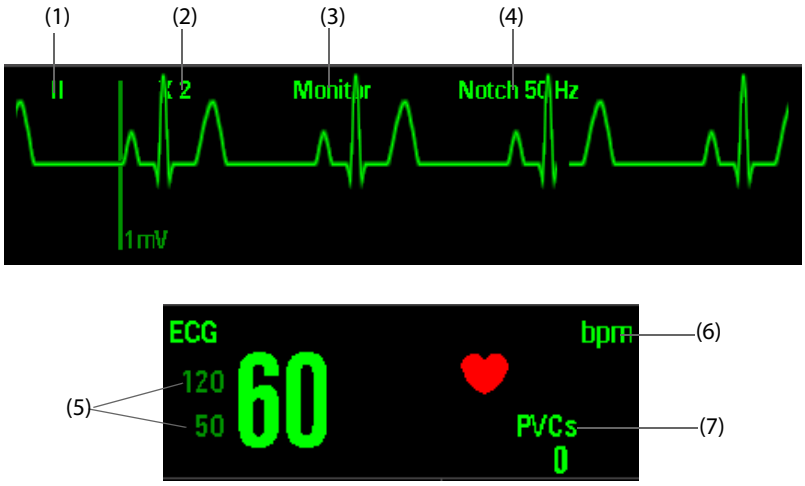
- ■ Press the Main Menu button and select [**Patient Demographics >>**], set [**Paced**].
- ■ Select the ECG parameter area and select [**Others >>**], set [**Paced**].

WARNING

- **For paced patients, you must set [Paced] to [Yes]. If it is incorrectly set to [No], the equipment 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.**
- **For non-paced patients, you must set [Paced] to [No]. If it is incorrectly set to [Yes], the equipment may be unable to detect premature ventricular beats (including PVCs).**
- **On ventricular paced patients, episodes of Ventricular Tachycardia may not always be detected.**
- **Do not rely entirely upon the system's automated arrhythmia detection algorithm. Keep pacemaker patients under close surveillance.**

5.5 ECG Display

The figure below shows the ECG monitoring view in 3-lead mode. It is for reference only. Your display may be configured to look slightly different.



(1) ECG lead label

(2) ECG waveform gain

(3) ECG filter mode

(4) Notch filter status

(5) HR alarm limits

(6) HR unit

(7) PVCs values: it is shown only when arrhythmia analysis is switched on.

When external paddles or electrode pads are used for ECG monitoring, the PVCs values is shown as "---".

5.6 Changing ECG Settings

5.6.1 Selecting the Lead Type

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Lead Set**] and toggle between [**3-Lead**] and [**5-Lead**].

You can also set lead type by selecting [**ECG Setup**] through the Configuration Main menu. The settings changed in the Configuration Main menu will be saved when the equipment is turned off.

5.6.2 Choosing the ECG Standard

1. Press the Main Menu button on the front panel, and select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**ECG Setup**] → [**ECG Standard**], and then select [**AHA**] or [**IEC**] according to the standard that is applied to your hospital.

5.6.3 Selecting the Lead of Displayed ECG Waveform

To compute heart rate and to detect and analyze arrhythmia more accurately, you can choose a lead of best quality signals as the HR calculation lead.

1. Press the Lead Select button on the front panel, or rotate the Navigation knob to move the cursor on the ECG lead label and press the Navigation knob.
2. Rotate the Navigation knob until you find the desired item, and then press the Navigation knob to confirm the selection.

The selected lead should have the following characteristics:

- The QRS should be either completely above or below the baseline and it should not be biphasic.
- The QRS should be tall and narrow.

■ The P-waves and T-waves should be less than 0.2mV.

5.6.4 Setting the ECG Waveform Layout

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Cascade**] and toggle between [**On**] and [**Off**].

5.6.5 Changing ECG Waveform Size

If the ECG waveform is too small or clipped, you change its size by using the Navigation knob.

1. Rotate the Navigation knob to move the cursor on the ECG waveform gain.
2. Press the Navigation knob to highlight it.
3. Rotate the Navigation knob until you find the desired item, and then press the knob to confirm the selection.

5.6.6 Changing ECG Waveform Speed

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Sweep**], and then choose an appropriate value. The faster the wave sweeps, the wider the wave is.

You can also set [**Sweep**] by selecting [**ECG Setup**] from the Configuration Main menu.

5.6.7 Setting the ECG Filter

■ When monitoring ECG through 3/5- lead set, filter mode is displayed above the first ECG waveform. The available filter mode settings are [**Monitor**], [**Therapy**], and [**Diagnostic**].

■ When monitoring ECG through external paddles/electrode pads, filter mode is always [**Therapy**] and can not be changed.

To set the ECG filter mode:

1. Rotate the Navigation knob to move the cursor on the ECG filter mode.
2. Press the Navigation knob to highlight it.
3. Rotate the Navigation knob until you find the desired item, and then press the knob to confirm the selection.

NOTE

- **For paced patients, you must set [Paced] to [Yes]. If it is incorrectly set to [No], the system may mistake an internal pace pulse for a QRS or fail to alarm when the pacer is broken.**

5.6.8 Switching On or Off the Notch Filter

The notch filter removes the AC line noise. Switching on the notch filter is recommended when there is interference with the waveform.

■ When the ECG filter mode is set to [**Monitor**] or [**Therapy**], [**Notch Filter**] is always [**On**].

■ When the ECG filter mode is set to [**Diagnostic**], [**Notch Filter**] can be switched on or off as required.

Set notch frequency according to the electric power frequency of your country. To switch on or off notch filter:

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Others >>**] → [**Notch Filter**], and toggle between [**On**] and [**Off**].

You can also set the power frequency of notch filter by selecting [**ECG Setup**] through the Configuration Main menu.

NOTE

- **The setting of** [**Notch Filter**] **will not be changed by restoring to factory default settings nor shutting down the system.**

5.6.9 Adjusting the QRS Volume

In the case that ECG alarm is switched on, or both ECG alarm and PR alarm are switched off, heartbeat tone is issued.

To adjust the heartbeat volume:

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Others >>**] → [**QRS Volume**]. The heartbeat volume can be set between 0 and 10, in which 0 means off, and 10 is the maximum volume.

You can also change the QRS volume by selecting [**ECG Setup**] through the Configuration Main menu.

When a valid SpO_2 value exists, the system will adjust the pitch of the heartbeat tone according to the SpO_2 value.

5.7 Arrhythmia Analysis

Arrhythmia analysis provides information about your patient's condition, including heart rate and arrhythmia alarms.

WARNING

- **Arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect 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.**
- **Atrial fibrillation (Afib) detection function is not intended for pediatric and neonatal patients.**
- **Arrhythmia analysis is not intended for neonatal patients.**

5.7.1 Understanding the Arrhythmia Events

Arrhythmia event	Description	Category
Asystole	No QRS complex for 4 consecutive seconds (in absence of ventricular fibrillation or chaotic signals).	Lethal arrhythmia
V-Fib/V-Tach	A fibrillatory wave for 4 consecutive seconds. A dominant rhythm of adjacent Vs and a HR > the V-Tach Heart Rate Limit	
V-Tach	The consecutive PVCs > Vtac PVCs limit, and the HR > the Vtac HR limit.	
Vent. Brady	The consecutive PVCs ≥ the Vbrd threshold and the ventricular HR < the Vbrd Rate threshold.	
Extreme Tachy	The heart rate is greater than the extreme tachycardia limit.	
Extreme Brady	The heart rate is less than the extreme bradycardia limit.	

Arrhythmia event	Description	Category
PVCs/min	PVCs/min exceeds high limit	Nonlethal arrhythmia
PNP**	No pace pulse detected for 1.75 x average R-to-R intervals following a QRS complex (for paced patients only).	
PNC**	No QRS complex detected for 300 milliseconds following a pace pulse (for paced patients only).	
PVC	One PVC detected in normal heartbeats	
Couplet	Paired PVCs are detected.	
VT>2	More than 2 consecutive PVCs within the last minute.	
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.	
R ON T	R on T detected in normal heartbeats.	
Missed Beat*	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.	
Brady	The average heart rate is less than 60 bpm.	
Tachy	The average heart rate is greater than 100 bpm.	
Vent Rhythm	The consecutive PVCs > the Vbrd PVCs limit, and the HR is between Vbrd Rate limit and the Vtac Rate limit.	
Multif. PVCs	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.	
Irr. Rhythm	Consistently irregular rhythm.	
A-Fib (for adult only)	P wave is absent and normal beat RR intervals are irregular.	

*: indicates that this arrhythmia alarm is not presented when [**Paced**] is set to [**Yes**].

: indicates that this arrhythmia alarm is not presented when [Paced**] is set to [**No**].

- When electrode pads are used for ECG monitoring, the equipment provides only 4 arrhythmia alarms, including asystole, ventricular fibrillation/ventricular tachycardia, PNP, and PNC.
- When external paddles are used, the equipment provides only 3 arrhythmia alarms, including ventricular fibrillation/ventricular tachycardia, PNP, and PNC.

5.7.2 Switching Arrhythmia Analysis On and Off

To switch arrhythmia analysis on or off:

1. Select the ECG parameter area to enter the [**ECG Setup**] menu,.
2. Select [**Arrhythmia >>**] → [**Arrhythmia**], and toggle between [**On**] and [**Off**].

You can also swtich on or off [**Arrhythmia**] by selecting [**ECG Setup**] from the Configuration Main menu.

5.7.3 Changing Arrhythmia Alarm Settings

To change arrhythmia alarm settings:

1. Select the ECG parameter area to enter the [**ECG Setup**] menu
2. Select [**Arrhythmia >>**] → [**Arrh. Alarm >>**], where you can set alarm switch, alarm level and alarm record switch for all the arrhythmia events.

You can also set [**ARR Alm Lev**] by selecting [**ECG Setup**] from the Configuration Main menu.

NOTE

- **The alarm level for asystole, ventricular fibrillation, ventricular tachycardia, ventricular bradycardia, extreme bradycardia, and extreme tachycardia alarms is always high and unchangeable. These alarms are always on. As long as the alarm condition occurs, corresponding alarm will be triggered whether arrhythmia analysis is switched on or off.**

5.7.4 Changing Arrhythmia Threshold Settings

To change arrhythmia threshold settings:

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Arrhythmia >>**] → [**Arrh. Threshold >>**].

In case an arrhythmia violates its threshold, an alarm will be triggered. The setting of [**Asystole Delay**] is relevant to ARR relearning. When HR is less than 30 bpm, it is recommended to set [**Asystole Delay**] to 10 seconds.

Arrh. Event	Range	Default	Step	Unit
PVCs High	1 to 10	10	1	/
Asystole Delay	3 to 10	5	1	s
Tachy	60 to 300	Adult: 120 Pediatric: 160	5	bpm
Brady	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. PVCs Window	3 to 31	15	1	Beats
V-Tach Rate	100 to 200	130	5	bpm
V-Tach PVCs	3 to 99	6	1	Beats
Pause Time	1.5, 2.0, 2.5	2.0	/	s
Vbrd Rate	15 to 60	40	5	bpm
Vbrd PVCs	3 to 99	5	1	Beats

You can also set arrhythmia threshold by selecting [**ECG Setup**] from the Configuration Main menu.

5.7.5 Initiating Arrhythmia Relearning Manually

Normally arrhythmia relearning allows the equipment to learn new ECG patterns to correct arrhythmia alarms and heart rate value. We suggest you manually initiate arrhythmia relearning when you suspect the result of arrhythmia analysis.

To initiate relearning manually:

1. Select the ECG parameter area to enter the [**ECG Setup**]menu
2. Select [**Arrhythmia >>**] → [**Relearn Arrh.**].
3. When the equipment is learning, the message **"Learning ECG"** is displayed in the technical alarm area.

NOTE

- **Arrhythmia relearning in the case of ventricular tachycardia may affect correct arrhythmia alarm.**

5.7.6 Automatic Arrhythmia Relearn

Arrhythmia relearning is initiated automatically whenever:

- The ECG lead or lead label is changed
- The ECG lead is re-connected
- Patient category is changed
- The paced status is changed
- Arrhythmia analysis is switched on
- [**Stop Calibrating**] is selected after ECG calibration is completed.

5.8 Calibrating ECG

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG wave amplitude becomes greater or smaller. In that case, you can perform ECG calibration to check if the ECG wave amplitude is in normal range.

1. Rotate the Navigation knob to move the cursor on the ECG filter mode.
2. Press the Navigation knob to highlight it.
3. Rotate the Navigation knob until you find [**Diagnostic**], and then press the Navigation knob to confirm the selection.
4. Select the ECG parameter area to enter the [**ECG Setup**] menu.
5. Select [**Others >>**] → [**Calibrate**]. In this case, a square wave appears on the screen and the message **"Calibrating ECG"** is displayed.
6. Compare the amplitude of the square wave with the 1mV wave scale. The difference should be within 5%.
7. After the calibration is completed, select [**Stop Calibrating**].

You can print out the waveform and wave scale and then measure the difference between them if necessary. If the difference exceeds 5%, contact your service personnel.

5.9 ECG Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the equipment or accessories, check the table below before requesting for services. If the problem persists after you have taken corrective actions, contact your service personnel.

NOTE

- **For the physiological and technical alarm messages, refer to *E Alarm Messages*.**

Problem	Corrective Actions
Noisy ECG traces	1. Check that electrodes are not detached or dry. Replace with fresh and moist electrodes if necessary. 2. Check that leadwires are not defective. Replace leadwires if necessary. 3. Check that patient cable or leadwires are routed too close to other electrical devices. Move the patient cable or leadwires away from electrical devices.
Excessive electrosurgical Interference	Use ESU-proof ECG cables. For details, refer to *28.1 ECG Accessories*.
Muscle Noise	Inadequate skin preparation, tremors, tense subject, and/or poor electrode placement. 1. Perform skin preparation again and re-place the electrodes. For details, refer to *5.4 Preparing for ECG Monitoring and Measurement*. 2. Apply fresh, moist electrodes. Avoid muscular areas.

Problem	Corrective Actions
Intermittent Signal	1. Check that cables are properly connected. 2. Check that electrodes are not detached or dry. Perform skin preparation again as described in *5.4 Preparing for ECG Monitoring and Measurement*. 3. Check that the patient cable or leadwires are not damaged. Change them if necessary.
Excessive alarms: heart rate, lead fault	1. Check that electrodes are not dry. Perform skin preparation again and replace the electrodes. For details, refer to *5.4 Preparing for ECG Monitoring and Measurement*. 2. Check for excessive patient movement or muscle tremor. Reposition the electrodes. Replace with fresh and moist electrodes if necessary.
Low Amplitude ECG Signal	1. Check that the ECG gain is not set too low. Adjust the gain as required. For details, refer to *5.6.5 Changing ECG Waveform Size*. 2. Perform skin preparation again and re-place the electrodes. For more information, refer to *5.4 Preparing for ECG Monitoring and Measurement*. 3. Check electrode application sites. Avoid bone or muscular area. 4. Check that electrodes are not dry or used for a prolonged time. Replace with fresh and moist electrodes if necessary.
No ECG Waveform	1. Check that the ECG gain is not set too low. Adjust the gain as required. For details, refer to *5.6.5 Changing ECG Waveform Size*. 2. Check that the leadwires and patient cables are properly connected. Change cable and lead wires. 3. Check that the patient cable or leadwires are not damaged. Change them if necessary.
Base Line Wander	1. Check for excessive patient movement or muscle tremor. Secure leadwires and cable. 2. Check that electrodes are not detached or dry and replace with fresh and moist electrodes if necessary. For details, refer to *5.4 Preparing for ECG Monitoring and Measurement*. 3. Check for ECG filter setting. Set ECG Filter mode to [**Monitor**].

6 AED

6.1 AED Introduction

This chapter describes how to operate the equipment in the AED Mode. While operating in the AED Mode, the equipment analyzes the patient's ECG waveforms and guides you through the defibrillation process.

The equipment starts analyzing the patient's heart rhythm immediately after entering the AED mode. When a shockable rhythm is detected, the equipment gives a prompt and automatically starts charging. If a shockable rhythm is not detected, a **"No Shock Advised!"** prompt is given. Smart defibrillation analysis goes through automated external defibrillation until the equipment enters CPR or abnormal electrode pads connection occurs.

While operating in the AED Mode, ECG signals acquired through electrode pads are displayed. Besides ECG, you can also select to monitor parameters from SpO_2, NIBP and CO_2. Previously set alarms and scheduled measurements are indefinitely paused and entry of patient information is disabled. Additionally, the Lead Select, Alarm Pause, NIBP Start/Stop and Main Menu buttons are inactive.

6.2 AED Safety Information

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any metal objects connected to the patient (including the bed or gurney) during defibrillation.**
- **Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.**
- **Do not allow electrode pads to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.**

WARNING

- **During defibrillation, air pockets between the skin and electrode pads can cause patient skin burns. To help prevent air pockets, make sure electrode pads are completely adhered to the skin.**
- **Do not use dried-out electrode pads.**

CAUTION

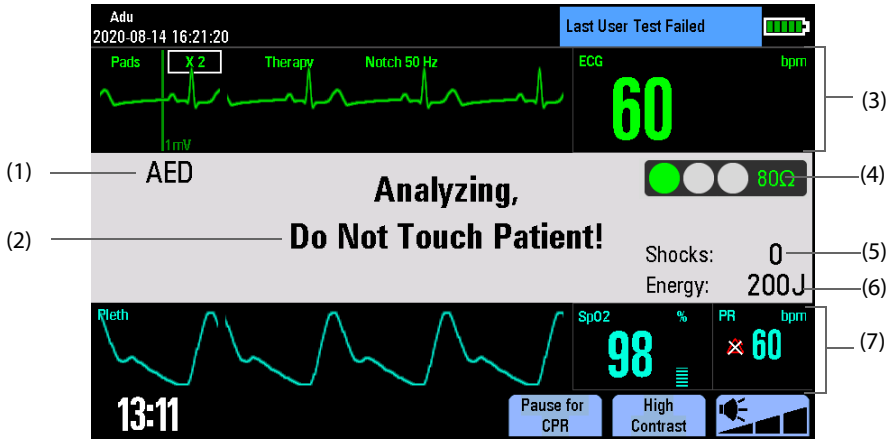
- **Aggressive handling of electrode pads in storage or prior to use can damage the electrode pads. Discard the electrode pads if they become damaged.**
- **For patients with implantable pacemaker, the sensitivity and specificity of AED algorithm may be impaired.**

NOTE

- **Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of equipment performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or equipment performance.**

6.3 AED View

A typical screen in the AED Mode is shown below.



(1) Operating mode

(2) AED prompt message

(3) ECG parameter and waveform area:
This area displays HR numeric and one ECG waveform acquired from the electrode pads.

(4) Contact impedance indicator (configurable)
It indicates the impedance between the patient and electrode pads. For details, refer to *7.7 Contact Impedance Indicator*.

(5) Shock counter

(6) Selected energy

(7) Auxiliary parameter and/or waveform area
This area displays parameters from SpO_2, NIBP or CO_2. You can define the auxiliary parameter by selecting [**Manual Defib Setup**] from the Configuration Main menu.

6.4 AED Procedure

Confirm that the patient is unresponsive, not breathing or not breathing normally. Then:

1. Prepare the patient and apply the electrode pads to the patient. For details, refer to *5.4.1 Preparing the Patient Skin* and *5.4.3 ECG Measurement with Electrode Pads*.
2. Connect the electrode pads with pads cable, and then plug the pads cable into the therapy port.

   Switch the Mode Select knob to AED. When the equipment enters the AED mode, it checks to see if the electrode pads and pads cable are properly connected. If not, the message "**Connect Pads Cable**" or "**Apply Pads**" will appear in the AED information area until corrective action has been taken.
3. Use the Navigation knob to switch the patient category between [**Adu**] and [**Ped**], if necessary. The default energy level is automatically changed.
   - For defibrillation of adult patients, recommended energy level for the first shock is 200 J.
   - For defibrillation of pediatric patients, recommended energy level for the first shock is 50 J.
4. Follow the screen and voice prompts.

   Once an ECG is detected through the electrode pads, the equipment automatically analyzes the patient's heart rhythm and warns you not to touch the patient. If a shockable rhythm is detected, the equipment charges automatically.

   You can switch on or off the voice prompt by selecting [**AED Setup**] from the Configuration Main menu or adjust the volume of the voice prompts by pressing the voice volume soft key.
5. Press the Shock button, if prompted.

   Once charging is completed, the equipment gives prompt "**Do Not Touch Patient! Press Shock Button**". Make sure no one is touching the patient, bed or any equipment connected to the patient. Call out clearly and loudly "Stay Clear". Then press the Shock button on the front panel to deliver a shock to the patient.

Delivery of the shock is confirmed by the voice and screen prompt **"Shock Delivered"** and the shock counter on the display is updated to reflect the number of shocks given. When the configured [**Shock Series**] is greater than one, the equipment resumes analyzing the patient's rhythm after the shock is delivered to see if the shock was successful. Voice and text prompts continue to guide you through additional shocks, the energy level of shock followed the first shock is automatically changed to the default level.

NOTE

- **For defibrillation of pediatric patients under 8 years, pediatric electrode pads should be used.**
- **If pediatric electrode pads are not available, the adult electrode pads may be used instead, and set the patient category to [Ped].**
- **Motion artifact may delay analysis or affect the ECG signal resulting in an inappropriate shock or no shock advised message. Keep the patient still during ECG rhythm analysis.**
- **The Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.**
- **Impedance is the resistance between the electrode pads/external paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. If the "Impedance too high. Shock not delivered" message appears, make sure that the patient's skin has been dried and that any chest hair has been clipped. If the message persists, change the electrode pads and/or the pads cable.**

6.5 Shock Advised

If a shockable rhythm is detected, the equipment automatically charges to the pre-configured energy level. A charging tone is sounded, and the Shock button flashes when the equipment is fully charged.

Heart rhythm analysis continues while the equipment charges. If a rhythm change is detected before the shock is delivered and a shock is no longer appropriate, the stored energy is removed internally.

Once you are prompted **"Do Not Touch Patient! Press Shock Button"**, if you do not do so within the configured Auto Disarm time interval, the equipment disarms itself and resumes analyzing.

When the equipment is being charged or have been fully charged, you can remove the charged energy at any time by pressing the [**Pause for CPR**] soft key.

6.6 No Shock Advised (NSA)

If a shockable rhythm is not detected, the equipment will tell you **"No Shock Advised!"**.

■ If the [**NSA Action**] is set to [**CPR**]

The equipment enters the CPR status and you will see and hear "**No Shock Advised! Paused, If Needed, Begin CPR.**" The remaining pause time is displayed as shown below.

You can set [**CPR Time**] to define the pause period by selecting [**AED Setup**] from the Configuration Main menu. Analysis resumes at the completion of the pause period or when you press the [**Resume Analyzing**] soft key in the CPR status.

■ If the [**NSA Action**] is set to [**Monitor**]

The equipment continues to monitor the ECG and automatically resumes analysis if a potentially shockable rhythm is detected. You will hear "**No Shock Advised! If needed, press "Pause for CPR**". The message **"No Shock Advised!"** and "**Monitoring**" are shown circularly in the AED information area.

You can set [**Voice Prompt Interval**] to define the frequency of prompts by selecting [**AED Setup**] from the Configuration Main menu. You may press the [**Pause for CPR**] soft key to suspend monitoring and administer CPR.

6.7 CPR

If [**Initial CPR Time**] is not configured as [**Off**], the equipment enters initial CPR if the AED mode is entered. You can set [**Initial CPR Time**] to an appropriate time or switch it off by selecting [**AED Setup**] from the Configuration Main menu.

After the shock series, ECG analysis pauses and the equipment enters the CPR status. Analysis resumes at the completion of the pause period or when you press the [**Resume Analyzing**] soft key in the CPR status.

In current shock series, the equipment enters the CPR status if you press the [**Pause for CPR**] soft key after a shock is delivered. You can set [**CPR Time**] to define the pause period by selecting [**AED Setup**] from the Configuration Main menu.

NOTE

- **You can start analyzing patient's heart rhythm again at any time by pressing the [Resume Analyzing] soft key in the CPR status.**

6.7.1 CPR Metronome

The equipment provides a CPR metronome feature that can be used to encourage rescuers to perform chest compression and ventilation at AHA/ERC recommended rate.

When activated, the metronome sounds 110 times per minute and give voice prompts to indicate you to perform ventilation at configured compression/ventilation rate.

To switch on or off CPR metronome:

1. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
2. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
3. Select [**AED Setup**] → [**CPR Metronome**], and toggle between [**On**] and [**Off**].

The CPR metronome is activated by default. You can set the compression/ventilation rate by selecting [**CPR Mode**] through the Configuration Main menu. The default rate is 30:2.

WARNING

- **The CPR metronome sounds do not indicate information regarding the patient's condition. Because patient status can change in a short time, the patient should be assessed at all times. Do not perform CPR on a patient who is responsive or is breathing normally.**

NOTE

- **The CPR metronome is deactivated when [Voice Prompts] in the [AED Setup] menu is configured off through the Configuration Main menu.**
- **The volume of CPR metronome is affected by [Voice Volume] in the [AED Setup] menu configured through the Configuration Main menu.**

6.8 AED Sound Recording

The equipment provides a sound recording function that can record the voice information during AED therapy. The sound recording function can be configured on or off.

To switch on or off the sounding recording:

1. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
2. Press the Main Menu button on the front panel, and then select → [**Others >>**] → [**Configuration >>**] → enter the required password.
3. Select [**AED Setup**] → [**Voice Recording**], and toggle between [**On**] and [**Off**].

 is shown at the top right corner of the AED information area if the sounding recording function is enabled.

The equipment can store up to 180 minutes, maximum 60 minutes for one patient, of sound recording.

6.9 AED Setup

1. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
2. Press the Main Menu button on the front panel, and then select → [**Others >>**] → [**Configuration >>**] → enter the required password.
3. Select [**AED Setup**] , and then change AED settings as desired.

For details, refer to *21.6.3 AED Setup Menu*.

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7 Manual Defibrillation

7.1 Manual Defibrillation Introduction

This chapter explains how to prepare for and perform asynchronous defibrillation and synchronized cardioversion using electrode pads, external paddles and internal paddles.

In the Manual Defib Mode, you must assess the ECG waveforms, decide if defibrillation or cardioversion is indicated, select appropriate energy setting, charge the equipment, and deliver the shock. Text messages and a contact impedance indicator on the screen provide relevant information to guide your throughout the defibrillation process.

While operating manual defibrillation, besides ECG, you can select to monitor parameters from SpO_2, NIBP and CO_2. Alarms are turned off automatically when you enter the Manual Defib mode. Pressing the Alarm Pause button  on the front panel of the equipment can turn on the alarms.

7.2 Manual Defibrillation Safety Information

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any metal objects connected to the patient (including the bed or gurney) during defibrillation.**
- **Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.**
- **Do not allow electrode pads and paddles to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.**
- **During manual defibrillation, make sure your hands are dry and free from conductive gel to avoid shock hazard.**
- **Use care when operating this equipment close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation. This can cause an explosion hazard.**

WARNING

- **During synchronized cardioversion, if monitoring patient's ECG through external paddles, artifact introduced by paddle movement may resemble an R-wave and trigger a defibrillation shock.**
- **Do not use conductive liquid. Use only conductive gel specified by the equipment manufacturer.**
- **If external paddles are used for defibrillation, apply the external paddles tightly and evenly to the patient's chest to ensure good skin contact.**
- **Never apply the paddles to human body to verify paddle connection.**
- **Clinicians must select an appropriate energy level for defibrillation of pediatric patients.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

CAUTION

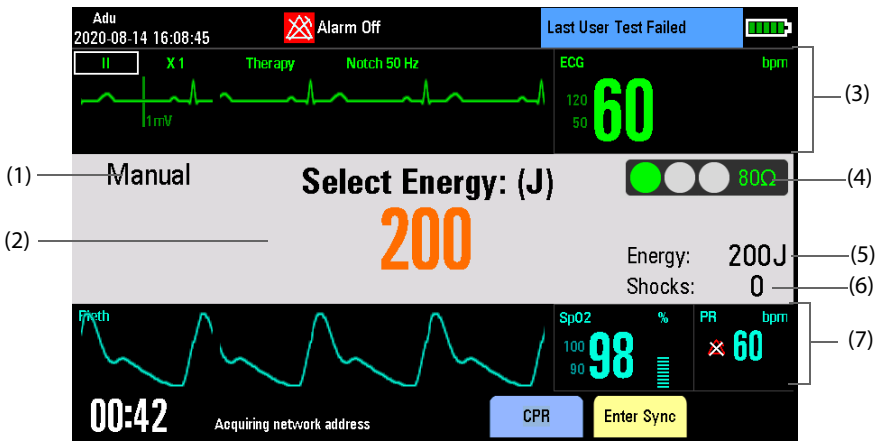
- **Use of Manual Defib mode may be password protected. Make sure the operator knows and remembers the password as defined in Configuration. Failure to enter correct password will prevent the delivery of manual defibrillation therapy.**
- **Clear the conductive gel from the external paddles at the completion of the therapy to prevent the paddles from being corroded.**
- **Prior to using the equipment, disconnect the patient from all equipment that is not defibrillator-protected.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

NOTE

- **Impedance is the resistance between the electrode pads/external paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. If the "Impedance Too High, Shock Not Delivered" message appears, make sure that the patient's skin has been dried and that any chest hair has been clipped. If the message persists, change the electrode pads and/or the pads cable.**
- **Alarms are switched off automatically and the "Alarm Off" message is displayed when the equipment enters the asynchronous defibrillation mode. Alarms remain off until toggled on by pressing the Alarm Pause button, the Sync mode, the Monitor mode or Pacer mode is entered.**
- **Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of equipment performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or equipment performance.**

7.3 Manual Defibrillation View

A typical screen in the Manual Defib Mode is shown below.



(1) Operating mode

(2) Defibrillation prompt message

(3) ECG parameter and waveform area

This area displays HR numeric and one ECG waveform acquired from the electrode pads, external paddles or internal paddles.

(4) Contact impedance indicator (configurable)

It indicates the impedance between the patient and electrode pads or external paddles. For details, refer to *7.7 Contact Impedance Indicator*.

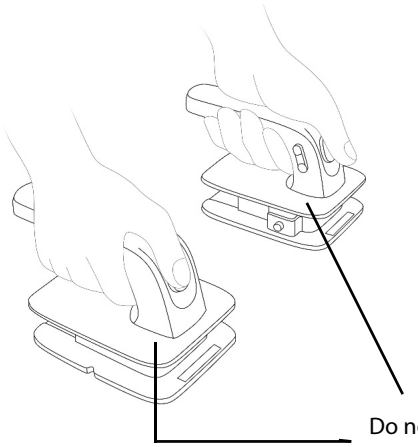
(5) Selected energy

(6) Shock counter

(7) Auxiliary parameter and/or waveform area:
This area displays parameters from SpO_2, NIBP or CO_2. You can define the auxiliary parameter by selecting [**Manual Defib Setup**] from the Configuration Main menu.

7.4 Manual Defibrillation Procedure

1. Remove clothing from the patient's chest. Wipe moisture from the patient's chest and, if necessary, clip or shave excessive chest hair.
2. Plug the therapy cable into the therapy port. Push until you hear it clicks into place.
3. Prepare the patient and apply the electrode pads/external paddles.
   - If electrode pads are used, apply electrode pads to the patient as described in *5.4.3 ECG MonitoringMeasurement with Paddles/Electrode Pads*.
   - If external paddles are used, remove the paddle set from the paddle tray by grasping the handles and pulling them straight up. Apply conductive gel to the electrode surface of each paddle. Place the external paddles as described in *5.4.4 ECG Measurement with External Paddles*.



WARNING

- **Hold only the insulating parts of the paddle handles to avoid shock hazard during charging or shock delivery.**

Switch the Mode Select knob to Manual Defib. You can define [**Manual Therapy Access**] by selecting [**Manual Defib Setup**] from the Configuration Main menu.

4. Select energy

   You can use the Navigation knob to switch the patient category between [**Adu**], [**Ped**] and [**Neo**], if necessary. The default energy level is automatically changed.
   - For defibrillation of adult patients, recommended energy level for the first shock is 200 J.
   - For defibrillation of pediatric patients, recommended energy level for the first shock is 50 J.

The current energy selection is shown in the defibrillation information area as shown below.

You can also select the desired energy level by the adjusting the Energy Select buttons on the front panel or on external paddles if external paddles are used.

5. Charge

   Press the Charge button on the front panel. If external paddles are used, the Charge button on the paddles may be used instead. As the equipment charges, a progress bar is shown in the defibrillation information area. A charging tone sounds until desired energy level is reached, when you will hear a charge done tone.

   If you have to increase or decrease the selected energy during charging or after charging is completed, adjust the Energy Select button to select the desired energy level as explained above. Then press the Charge button again to restart charging.

   To remove the energy, press the [**Disarm**] soft key. If the Shock button is not pressed within the specified time period, the equipment disarms automatically. You can set [**Time to Auto Disarm**] to define the time period by selecting [**Manual Defib Setup**] from the Configuration Main menu.

6. Shock

   Confirm that a shock is still indicated and that the equipment has charged to the selected energy level. Make sure no one is touching the patient, bed or any equipment connected to the patient. Call out clearly and loudly "Stay Clear".

   - If electrode pads are used, press the flashing Shock button on the front panel to deliver a shock to the patient.
   - If external paddles are used, simultaneously press the Shock buttons located on the paddles to deliver a shock to the patient.

NOTE

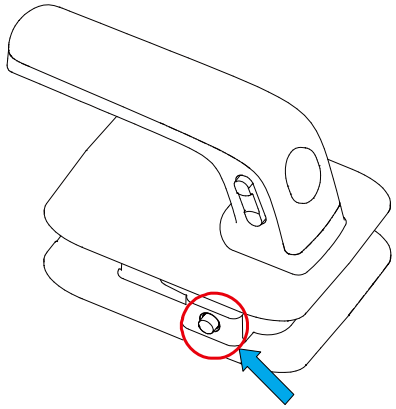
- **Defibrillation is always performed through external paddles or electrode pads. However, during defibrillation you may choose to monitor the ECG using an alternate ECG source (3- or 5-lead monitoring electrodes). If an alternate ECG source is connected, any available lead may be displayed.**
- **When external paddles are used, the Shock button on the front panel is disabled.**
- **For defibrillation of pediatric patients, you can use the default energy level, or adjust the energy level to 2-4 J/kg for the first shock and 4 J/kg for additional shocks followed the first shock.**
- **For defibrillation of pediatric patients under 8 years, pediatric electrode pads should be used.**
- **If pediatric electrode pads are not available, the adult electrode pads may be used instead, and set the patient category to [Ped].**
- **For defibrillation of neonatal patients, set the energy level according to the patient's clinical condition. The energy level for neonatal patient should be lower than the default setting.**

7.4.1 Using Pediatric Paddles

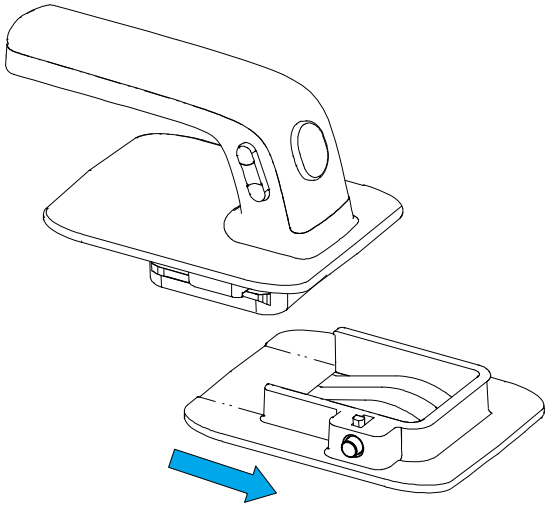
The external paddles provide both adult paddle electrodes and pediatric paddle electrodes included inside.

To use the pediatric paddles:

1. Press the latch buttons on the external paddles.



2. Pull forward the adult paddle electrodes to remove them.



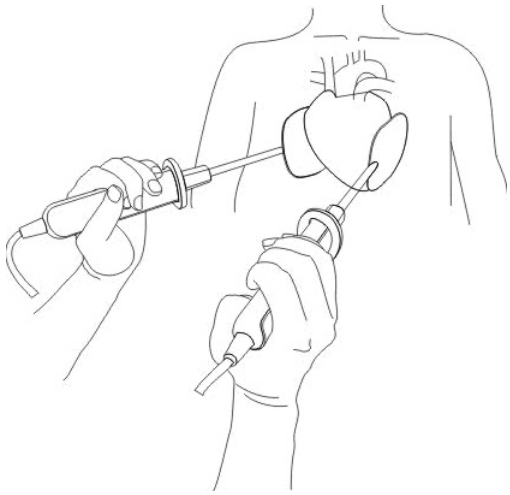
For details on the defibrillation procedures, refer to *7.4 Manual Defibrillation Procedure*.

7.4.2 Using Internal Paddles

To defibrillate using internal paddles:

1. Switch the Mode Select knob to Manual Defib.
2. Select the appropriate paddle size.
3. Connect the internal paddles to the defibrillator by aligning the white pointer on the paddles cable with the arrow on the therapy port. Push until you hear its click into place.
4. Select energy by pressing the Energy Select button on the front panel.

5. Place the conductive surface of paddle electrodes against the patient's right atrium and left ventricle, as shown in the figure below:



6. Charge the defibrillator by pressing the Charge button on the front panel.
7. Make sure no one is touching the patient or anything connected to the patient.
8. Press the Shock button on the front panel.

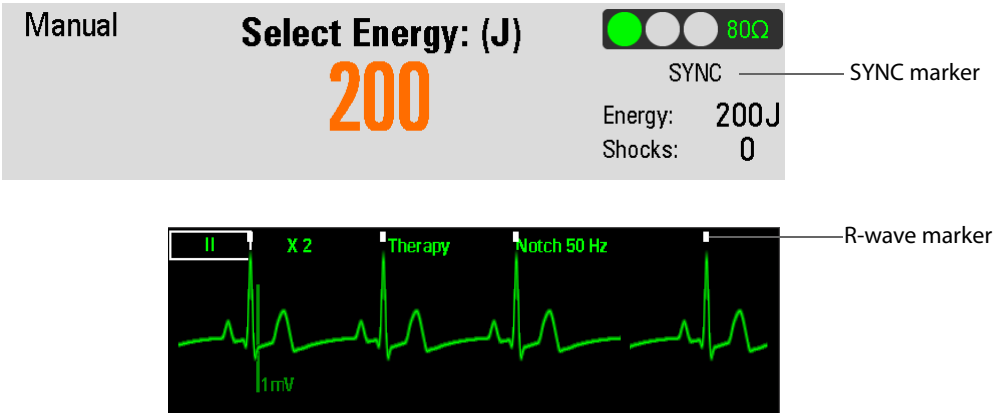
NOTE

- **When internal paddles are used for defibrillation, the energy selection is automatically limited to 50 joules because of possible cardiac damage from higher energies.**
- **Sterilize the internal paddles before each use. Otherwise, severe infection may result.**
- **Clean the internal paddles after each use.**

7.5 Synchronized Cardioversion

Synchronized cardioversion allows you to synchronize delivery of the defibrillator shock with the R-wave of the ECG. You may choose to perform synchronized cardioversion through electrode pads, external and internal paddles.

To use synchronized cardioversion, press the [**Enter Sync**] soft key in the asynchronous defibrillation mode. Then **[SYNC]** appears in the manual Defibrillation information area and a marker appears above each R-wave, see the figure below:



You can monitor ECG through electrode pads, or external paddles, or electrodes connected to a 3- or 5-lead ECG cable. Shock is delivered through either electrode pads or external paddles. For synchronized cardioversion, we recommend to acquire patient's ECG through ECG lead set.

CAUTION

- **Using internal paddles for synchronized cardioversion requires that the patient's ECG be acquired through a standard ECG cable. The patient's ECG acquired through the internal paddles may be unreliable for synchronized cardioversion due to excessive noise or artifact causing inappropriate R-wave detection.**

NOTE

- **When you access synchronized cardioversion, monitoring alarms is reactivated autonomously.**

7.5.1 Performing Synchronized Cardioversion

1. Connect the therapy cable and apply the electrode pads or external paddles to the patient. If ECG set is used for ECG monitoring, connect the ECG trunk cable and apply the ECG electrodes to the patient. For detail, refer to *5.4 Preparing for ECG Monitoring and Measurement*.
2. Switch the Mode Select knob to Manual Defib, and press the [**Enter Sync**] soft key to activate the synchronized cardioversion function.
3. Select a lead. The selected lead should have a clear signal and a large QRS complex.
4. Verify that a white R-wave marker appears above each R-wave If the R-wave markers do not appear or do not coincide with the R-waves, for example above the T-waves, select another lead.
5. Verify that you access synchronized cardioversion, as indicated by the SYNC marker shown in the defibrillation information area.
6. Press the Energy Select button to select a desired energy level.
7. Press the Charge button on the equipment, if using external paddles, the Charge button located on the handle of Apex paddle.
8. Confirm that a shock is still indicated and that the equipment has charged to the selected energy level. Make sure no one is touching the patient, bed or any equipment connected to the patient. Call out loudly and clearly "Stay Clear".
9. Press and hold the Shock button on the equipment or, if using external paddles, the Shock buttons on both paddles. The shock will be delivered when the next R-wave is detected.

NOTE

- **During synchronized cardioversion, it is important to continue to hold the shock button (or the paddle's Shock buttons) until the shock is delivered. The equipment shocks with the next detected R-wave.**

7.5.2 Delivering Additional Synchronized Shocks

If additional synchronized shocks are indicated, perform the following steps:

1. Make sure the equipment is still in Sync mode, as indicated by the presence of the Sync message in the defibrillation information area.
2. Repeat steps 4 to 9 as described in *7.5.1 Performing Synchronized Cardioversion*.

If [**Sync After Shock**] is set to [**Yes**], the equipment remains in the sync mode after a shock is delivered; if set to [**No**], the equipment exits the sync mode and enters the asynchronous defibrillation mode after a shock.

7.5.3 Disabling the Sync Function

To disable the Sync function, press the [**Exit Sync**] soft key.

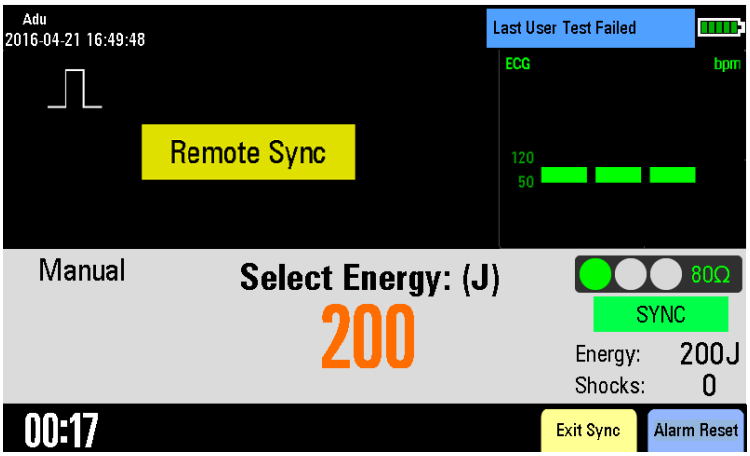
7.6 Remote Synchronized Cardioversion

The equipment can be configured to receive an ECG source from a remote patient monitor (such as a bedside patient monitor) to perform synchronized cardioversion. To do so, the remote patient monitor shall have a sync out connector and shall be connected to the multifunctional connector with a synchronous cable.

To switch on remote synchronized cardioversion, set [**Remote Sync**] to [**On**] in the [**Manual Defib Setup**] menu through the Configuration Main menu.

The remote synchronized cardioversion procedure is as follows:

1. Use a sync cable to connect the equipment with a bedside monitor through the multifunctional connector.
2. Enter the Manual Defib mode.
3. Press the [**Enter Sync**] soft key.
4. Select [**Remote**] to access remote synchronized cardioversion. Then the message "**Remote Sync**" is presented.
5. Confirm a square wave on the equipment blinks with each detected R wave on the remote monitor as shown below, indicating a sync pulse is received.



6. Connect the therapy cable to the therapy port. Push until you hear it clicks into place.
7. Apply electrode pads or external paddles to the patient.
8. Follow steps 6 to 9 as described in *7.5.1 Performing Synchronized Cardioversion* .

NOTE

- **During remote synchronized cardioversion, the local equipment does not display the ECG waveform. To view the patient's ECG, check the remote monitor.**
- **When you use a remote monitor as the ECG source, a biomedical technician must verify that the remote monitor and the equipment combination will deliver a synchronized shock within 60 ms of the peak of the R-wave.**

7.7 Contact Impedance Indicator

The contact impedance indicator is used to indicate the impedance between the patient and electrode pads/ external paddles in the Manual Defib mode and AED mode, as shown below:

The display of the contact impedance indicator is switched off by default. To switch it on, set [**Contact Impedance Indicator**] to [**On**] in the [**Manual Defib Setup**] menu through the Configuration Main menu.

The following table lists the indicator status of the measured impedance and the corresponding actions:

Contact Impedance Indicator	Description	Corrective Actions
 (illuminated in green)	indicates the patient contact is good, the impedance is suitable for the defibrillation.	/
 (illuminated in yellow)	indicates the patient contact is not good, the impedance is slightly higher for the defibrillation.	Firmly attach the electrode pads or external paddles to the patient. or adjust the placements of electrode pads or external paddles until the indicator is illuminated in green. If the indicator is still illuminated in yellow, it also can be used for the defibrillation. However, the expected effects may not be achieved in this condition.
 (illuminated in red)	indicates the patient contact is very poor, or there is a short circuit between electrode pads or external paddles.The impedance is completely not suitable for the defibrillation.	Firmly attach the electrode pads or external paddles to the patient. or adjust the placements of electrode pads or external paddles until the indicator is illuminated in green or yellow.
 (off)	indicates the ECG cable or therapy cable falls off.	Check that the ECG cable or therapy cable is properly connected to the equipment.

NOTE

- **It is recommended to perform the defibrillation on a patient when the contact impedance indicator is illuminated in green. If the contact impedance indicator is illuminated in yellow, it also can be used for the defibrillation. However, the expected effects may not be achieved in this condition.**

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8 CPR Feedback

8.1 CPR Feedback Introduction

This chapter describes how to operate the equipment when a CPR sensor is connected. For details, refer to *MR6401 CPR Sensor Operator's Manual (P/N: 046-010423-00)*.

NOTE

- **The CPR sensor is not available in the markets of UK, Germany and France.**

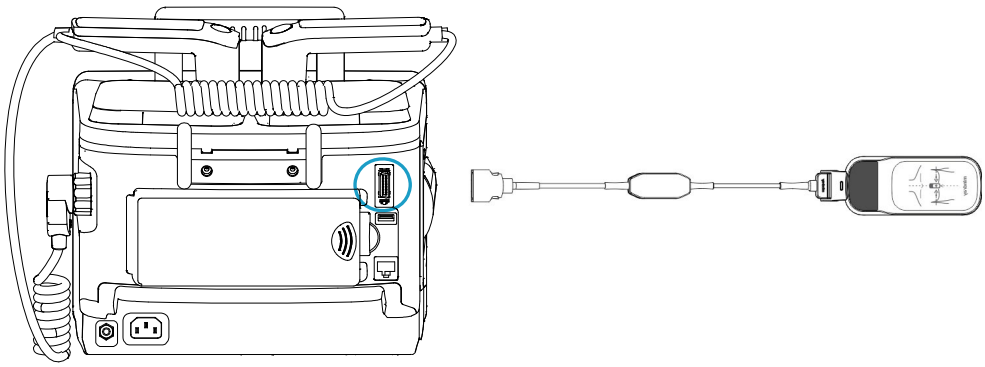
8.2 Operations with the CPR Sensor

When the equipment is connected with the CPR sensor, you can:

- View a real-time compression waveform, CCI graph, compression rate and compression depth.
- Review CPR events.
- Charge the CPR sensor configured with a battery.
- Upload the latest one-hour data from the CPR sensor. For details, refer to *8.2.5 Uploading CPR Data*.

8.2.1 Connecting the CPR Sensor

1. Hold one end of the CPR sensor cable with the Mindray logo facing up, and plug it into the CPR sensor connector.
2. Fasten the CPR sensor cable with the cable retainer.
3. Try to pull the CPR sensor cable to make sure that the cable is securely connected.
4. Plug the other end of the sensor cable into the multifunctional connector at the rear of the equipment.



8.2.2 Using CPR Filter

Performing CPR introduces CPR artifact into the ECG signal. You can enable the CPR filter to see a close approximation of the patient's underlying ECG rhythm when performing CPR.

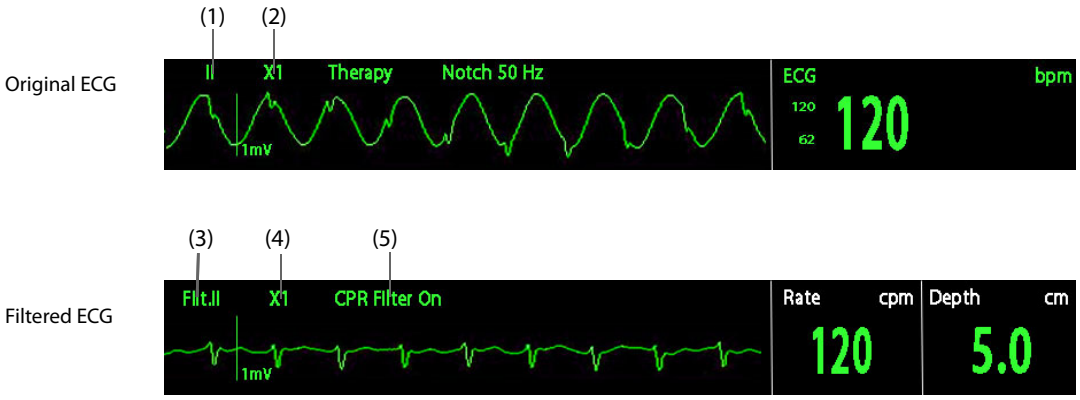
To enable CPR filter:

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**CPR Setup**] and set [**CPR Filter**] to [**On**].
3. Enter the CPR status by either of the following ways:
   - In the Manual Defib mode, shake and compress the CPR sensor, or select the [**CPR**] softkey.
   - In the AED mode, the system automatically enters the CPR status.

After you enable CPR filter, the equipment automatically starts filtering the CPR artifact when detecting the CPR compressions. The filtered ECG with the label "**Filt.**" is displayed on the second waveform of the screen.

The following figure shows the first ECG waveform and the filtered ECG waveform removing CPR artifact from the first ECG waveform. Compared with viewing the first ECG waveform, the filtered ECG is more obvious if you enable CPR filter.

When viewing the filtered ECG waveform, the CPR filter, the filter lead and filter gain cannot be set. The CPR filter can be turned on/off by setting [**CPR Filter**] through configuration management, the filter lead and filter gain can only be changed when you set lead and gain for the first ECG waveform.



(1) ECG lead label (2) ECG waveform gain (3) CPR filter lead

(4) CPR filter gain (5) CPR filter

CAUTION

- **The CPR filter works only when you perform CPR using the CPR sensor in the AED or Manual Defib mode.**
- **The CPR filter will not remove all CPR artifact. You should always follow the standard procedure of stopping CPR to verify the patient's ECG rhythm before making treatment decisions.**
- **The filtered ECG waveform must be used in conjunction with clinical signs and symptoms. It should not be used as the sole basis for diagnosis or therapy decisions.**

NOTE

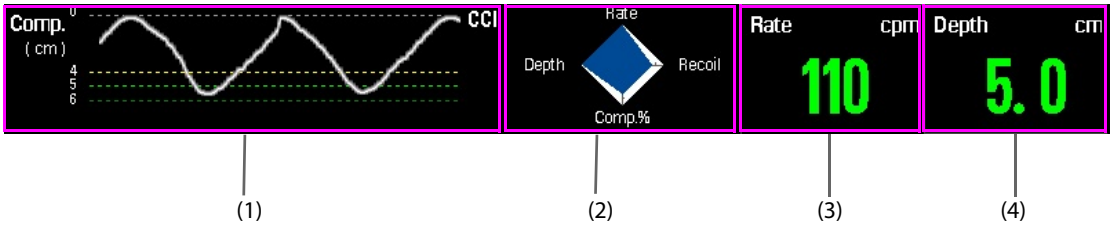
- **There is a slight delay between the original and filtered ECG waveforms.**

8.2.3 Viewing CPR Feedback

To view CPR feedback:

1. Enter the CPR status by either of the following ways:
   - In the Manual Defib mode, shake and compress the CPR sensor, or select the [**CPR**] softkey.
   - In the AED mode, the system automatically enters the CPR status.
2. From the filtered ECG displayed on the second waveform of the screen, switch the filter lead with the label "**Filt..**" to [**Comp.**] by using the Navigation knob.

The following figure shows the CPR feedback, providing compression waveform, CCI graph, compression rate and compression depth.



(1) Compression waveform area

- Compression waveform: a real-time waveform depicted when you performing CPR.
- Compression depth scale
- Interruption time: displays interruption time in seconds since the last compression. When stopping CPR, the compression waveform becomes a straight line. The system starts timing the CPR interruption.
- Prompt message: gives instructions for the current poor compression.

(2) CCI (CPR compression index) graph: indicates the current compression quality. The larger the blue area, the better the compression quality.

- Depth axis: the current compression depth.
- Rate axis: the current compression rate.
- Recoil axis: the degree of recoil. Prompt message "**Incomplete Recoil**" will appear when the compressed chest wall is not back to the natural position.
- Comp.% (Compression Fraction) axis: percentage of compression time within CPR duration.

(3) Compression rate area: indicates the current compression rate.

- Green: indicates that the compression rate is good.
- Red: indicates that the compression rate is poor. Prompt message "**Compress Faster**" or "**Compress Slower"** will appear when the compression is slow or fast.

(4) Compression depth area: indicates the current compression depth.

- Green: indicates that the compression depth is good.
- Red: indicates that the compression depth is poor. Prompt message "**Compress Deeper"** or "**Compress Shallower**" will appear when the compression is shallow or deep.

8.2.4 Reviewing CPR Events

To review CPR events on the equipment:

1. Enter the [**CPR Setup**] menu by either of the following ways:
   - Press the Main Menu button on the front panel, and then select [**Review >>**] → [**CPR Event Review >>**].
   - In the Manual Defib mode, select the compression depth area or compression rate area → [**CPR Event Review >>**].
2. In the [**CPR Event List**] window, you can:
   - Select the desired CPR event.

- Select [**Refresh**] if there is power failure or CPR is interrupted within five minutes, and then select the desired CPR event.

NOTE

- **A CPR event is automatically saved in the equipment when the interruption time exceeds five minutes.**
- **You should select [Refresh] to save a CPR event before disconnecting the CPR sensor from the equipment.**

8.2.5 Uploading CPR Data

If you use the CPR sensor independently, you can connect it to the equipment, and upload the latest one-hour data to the equipment. You can also review CPR events uploaded from the CPR sensor on the equipment.

For details about CPR event review, refer to *8.2.4 Reviewing CPR Events*.

9 Noninvasive Pacing

9.1 Pacing Introduction

In the Pacer mode, the patient's ECG is monitored through ECG lead set and pace pulses are delivered through electrode pads. The electrode pads cannot be used to monitoring ECG rhythm and deliver pacing current at the same time.

A white pace marker is shown on the ECG waveform each time a pace pulse is delivered to the patient. If pacing in demand mode, white R-wave marker also appears on the ECG waveform until capture occurs.

During pacing, parameters except Resp continue to be monitored and parameter alarms remain active.

In demand mode pacing, a 3-lead or 5-lead ECG cable and electrodes are required to acquire ECG signal. Pace pulses are delivered through electrode pads. However, the electrode pads cannot be used to monitor the ECG and deliver pace pulses simultaneously.

NOTE

- **In the Pacer mode, arrhythmia analysis is supported and available arrhythmia alarms are asystole, ventricular vibrillation and ventricular tachycardia.**

9.2 Pacing Safety Information

WARNING

- **Heart rate displays and alarms function during pacing, but they can be unreliable. Observe the patient closely while pacing. Do not rely on the indicated heart rate or heart rate alarms as a measure of the patient's perfusion status.**
- **To avoid explosion hazard when pacing a patient who is receiving oxygen delivery, properly route the oxygen delivery tube. Do not keep it close to the electrode pads.**
- **Monitoring ECG alone is sometimes not enough to verify that the patient's heart is providing cardiac output.a patient's response to pacing shall be verified by signs of improved cardiac output, such as: a palpable pulse rate the same as the rate which pace pulses are being delivered, a rise in blood pressure, and/or improved skin color.**

CAUTION

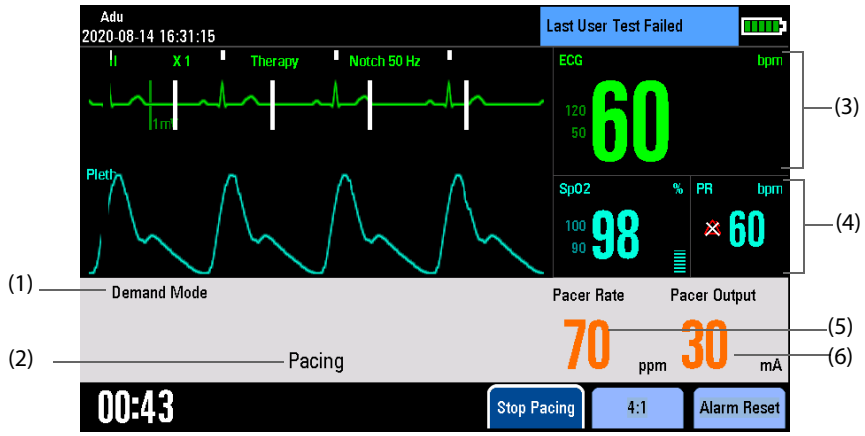
- **Use of Pacer mode may be password protected. Make sure the operator knows and remembers the password as defined in Configuration. Failure to enter correct password will prevent the delivery of pacing therapy.**
- **For treatment of patients with implanted devices such as permanent pacemakers or cardioverter-defibrillators, consult a physician and the instructions for use provided by the device's manufacturer**
- **Prolonged noninvasive pacing may cause patient skin irritation and burns. Periodically inspect the underlying skin and change ECG electrodes and electrode pads.**

NOTE

- **If pacing is interrupted for any reason, the [Start Pacing] soft key must be pressed to resume pacing.**
- **In the Pacer mode, you cannot change the patient's internal paced status from the [ECG Setup] menu.**
- **In the case that electrode pads poorly contact the patient, the alarm "Pacer Stopped Abnormally" and "Pads Off" may be presented.**
- **Electrode pads are not an available choice for the source of ECG waveform in the Pacer mode.**

9.3 Pacing View

A typical screen in the Pacer mode is shown below.



(1) Pacer mode

(2) Pacing prompt message

(3) ECG parameter and waveform area
This area displays HR numeric and one ECG waveform acquired from the ECG Lead set, and pace pulse delivered from the electrode pads.

(4) Auxiliary parameter and/or waveform area:
This area displays SpO_2 and CO_2 parameters.

(5) Pacer rate

(6) Pacer output

9.4 Pacer Mode

The equipment can deliver pace pulses in either demand or fixed mode.

- In demand mode, the pacer only delivers pace pulses when the patient's heart rate is lower than the selected pacer rate.
- In fixed mode, the pacer delivers pace pulses at the selected rate.

During pacing, you can change the pacer mode. Then the equipment continues to deliver pace pulses at selected pacer rate and pacer output.

CAUTION

- **Use demand mode pacing whenever possible. Use fixed mode pacing if noise or artifact interferes with proper sensing of R-wave or when monitoring electrodes are not available.**
- **During fixed mode pacing, R-wave markers do not appear on the paced beats.**
- **During demand mode pacing, spontaneous beats may be presented which are not associated with the delivery of pace pulse. If the patient's heart rate is above the pacer rate, pace pulses are not delivered and, therefore, pace markers do not appear.**

9.5 Preparing for Pacing

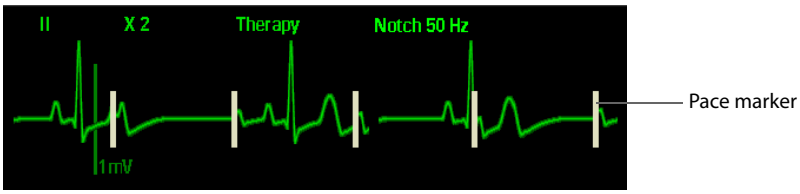
1. Connect the electrode pads with pads cable, and then plug the pads cable into the therapy port.
2. Prepare the patient and apply the electrode pads to the patient. For details, refer to *5.4.1 Preparing the Patient Skin* and *5.4.3 ECG Measurement with Electrode Pads*.
3. If pacing in demand mode, apply monitoring electrodes, and connect the ECG cable to the equipment. To get the best monitoring signal, make sure there is adequate space between ECG electrodes and therapy electrodes. For details, refer to *5.4.2 ECG Monitoring with Electrodes*.

9.5.1 Demand Mode Pacing

To pace in demand mode pacing:

1. Switch the Mode Select knob to Pacer. Thus the pacing function is enabled in demand mode automatically. ECG waveform of Lead II is displayed in the waveform area by default.

   You can define [**Manual Therapy Access**] by selecting [**Manual Defib Setup**] from the Configuration Main menu.You can also set [**Default Pacer Mode**] to define the default pacer mode by selecting [**Pacer Setup**] from the Configuration Main menu.
2. Press the Lead Select button on the front panel to select a lead with an easily detectable R-wave.
3. Verify that white R-wave markers appear above the R-waves. If the R-wave markers do not appear or do not coincide with the R-waves (for example above the T-waves), select another lead.
4. Use the Navigation knob to adjust the pacer rate, then press the Navigation knob. If necessary, select initial pacer output.
5. Press the [**Start Pacing**] soft key to start pacing. The message "**Pacing**" appears in the pacer information area.
6. Verify that white pace markers appear on the ECG waveform, as shown below:



7. Adjust pacer output. increase pacer output until cardiac capture occurs (capture is indicated by the appearance of a QRS complex after each pace marker), and then decrease the output to the lowest level that still maintains capture.
8. Verify the presence of a peripheral pulse.

You can temporarily withhold pace pulse and observe the patient's underlying rhythm by pressing and holding the [**4:1**] soft key. This causes pacing pulse to be delivered at 1/4 of the defined pacer rate. To resume pacing at set rate, release this key.

To stop pacing, press the [**Stop Pacing**] soft key. Pressing the [**Start Pacing**] soft key can resume pacing.

CAUTION

- **Routinely assess the patient's cardiac output.**

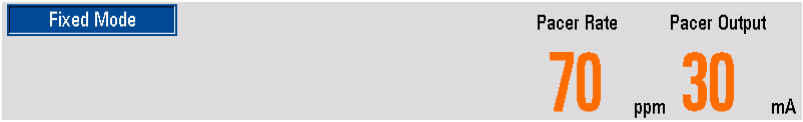
NOTE

- **Pacing will not start if there is a problem with the pads cable connection, pad patient connection, or ECG monitoring electrodes connection. If any situation occurs, a message will appear in the pacer information area to alert you that a lead is disconnected or that the electrode pads have a poor connection.**

9.5.2 Fixed Mode Pacing

To pace in fixed mode pacing:

1. Switch the Mode Select knob to Pacer.
2. Use the Navigation knob to select [**Fixed Mode**], then press the Navigation knob.



3. If ECG electrodes are applied, press the Lead Select button on the front panel to select the desired lead.
4. Use the Navigation knob to adjust the pacer rate, then press the Navigation knob in. If necessary, select initial pacer output.
5. Press the [**Start Pacing**] soft key to start pacing. The message "**Pacing**" appears in the pacer information area.
6. Verify that white pace markers appear on the ECG waveform.
7. Adjust pacer output. Increase pacer output until cardiac capture occurs (capture is indicated by the appearance of a QRS complex after each pace marker), and then decrease the output to the lowest level that still maintains capture.
8. Verify the presence of a peripheral pulse.

You can temporarily withhold pace pulse and observe the patient's underlying rhythm by pressing and holding the [**4:1**] soft key. This causes pace pulse to be delivered at 1/4 of the defined pacer rate. To resume pacing at set rate, release this key.

To stop pacing, press the [**Stop Pacing**] soft key.

WARNING

- **Use care when handling the electrode pads on the patient to avoid shock hazard during pacing.**
- **If you are using the pacing function with battery power and the Low Battery alarm is presented, connect the equipment to external power or install a fully charged battery.**

CAUTION

- **The monitoring or pacing function may be unstable in the presence of ESU or other electronic devices.**

10 Monitoring Resp

10.1 Resp Introduction

Impedance respiration is measured across the thorax. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. Respiration rate (RR) is calculated from these impedance changes, and a respiration waveform appears on the equipment screen.

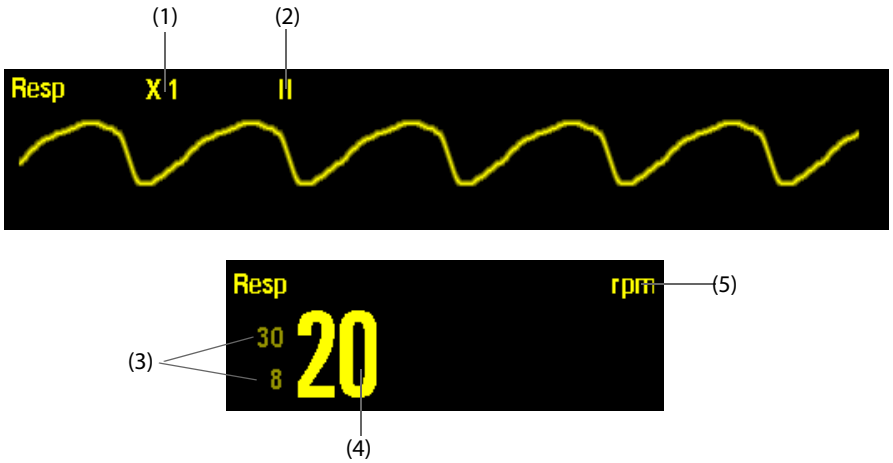
Resp monitoring is intended for adult, pediatric and neonatal patients.

10.2 Resp Safety Information

WARNING

- **When monitoring the patient's respiration, do not use ESU-proof ECG cables.**
- **The respiration measurement does not recognize obstructive and mixed apneas: it only indicates an alarm when a pre-adjusted time had elapsed since the last detected breath. The safety and effectiveness of the respiration measurement method in the detection of apnea, especially the apnea of prematurity and apnea of infancy, has not been established.**

10.3 Resp Display



(1) Resp waveform gain
(2) Resp lead label
(3) Resp alarm limits
(4) Respiration rate (RR)
(5) RR unit

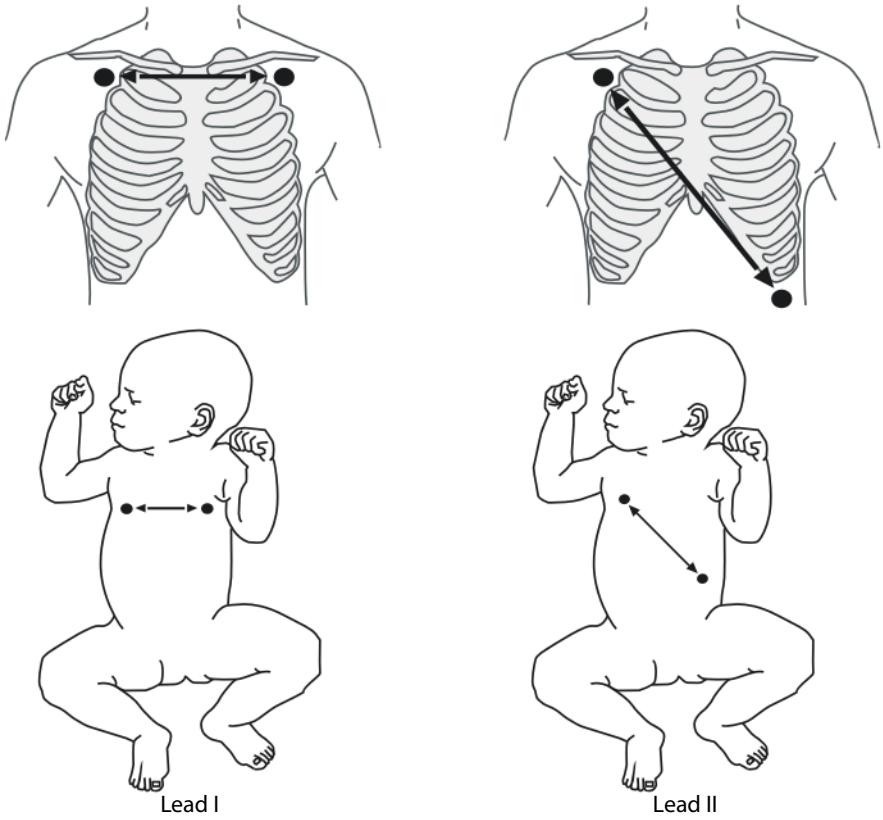
10.4 Placing Resp Electrodes

As the skin is a poor conductor of electricity, preparing the skin is necessary for a good respiration signal. For details, refer to *5.4.1 Preparing the Patient Skin*.

As the Respiration measurement adopts the standard ECG electrode placement, you can use different ECG cables (3-lead or 5-lead). Since the respiration signal is measured between two ECG electrodes, if a standard ECG electrode placement is applied, the two electrodes should be RA and LA of ECG Lead I, or RA and LL of ECG Lead II.

NOTE

- **To optimize the respiration waveform, place the RA and LA electrodes horizontally when monitoring respiration with ECG Lead I; place the RA and LL electrodes diagonally when monitoring respiration with ECG Lead II.**



10.4.1 Optimizing Lead Placement for Resp

If you want to measure Resp and you are already measuring ECG, you may need to optimize the placement of the two electrodes between which Resp will be measured. Repositioning ECG electrodes from standard positions results in changes in the ECG waveform and may influence ST and arrhythmia interpretation.

- Cardiac activity that affects the Resp waveform is called cardiac overlay. It happens when the Resp electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrodes placement can help to reduce cardiac overlay. Avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.
- Some patients with restricted movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.
- In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the respiratory waveform.

NOTE

- **Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.**

10.4.2 Changing Resp Settings

1. Select the Resp parameter area to enter the [**Resp Setup**] menu.
2. Make the following settings:
   - Select [**Gain**] and then choose an appropriate setting. The bigger the gain is, the larger the wave amplitude is.
   - Select [**Sweep**] and then choose an appropriate setting. The faster the wave sweeps, the wider the wave is.
   - Select [**Lead**] to set lead for Resp monitoring.
   - Select [**Apnea Time**] to define the time.

10.5 Resp Troubleshooting

For details, refer to *E Alarm Messages*.

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11 Monitoring PR

11.1 PR Introduction

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart. You can display a pulse from SpO_2.

(1) PR alarm limits (2) PR unit (3) PR value

NOTE

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

11.2 Adjusting Pulse Tone Volume

When PR alarm is switched on, the equipment gives out pulse tone.

To change the volume of pulse tone:

1. Select the PR parameter area to enter the [**PR Setup**] menu.
2. Set [**QRS Volume**].

When a valid SpO_2 value exists, the system will adjust the pitch of pulse tone according to the SpO_2 value.

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12 Monitoring SpO_2

12.1 SpO_2 Introduction

SpO_2 monitoring is a non-invasive technique used to measure the amount of oxygenated haemoglobin 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 photodetector in the probe. The SpO_2 module processes the electrical signal and displays a waveform and digital values for SpO_2 and pulse rate.

This equipment is calibrated to display functional oxygen saturation.

SpO_2 monitoring is intended for adult, pediatric and neonatal patients.

12.2 Identifying SpO_2 Modules

The equipment can be configured with any of the following SpO_2 modules.

- Mindray SpO_2: the connector is blue without any no logo.
- Masimo SpO_2 module: the connector is purple with a logo of Masimo SET.
- Nellcor SpO_2: the connector is grey with a logo of Nellcor.

12.3 SpO_2 Safety Information

WARNING

- **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.**
- **Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For neonates or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.**
- **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.**
- **When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.**
- **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 off the alarm.**
- **SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.**
- **The pulse oximeter is not an apnea monitor.**
- **The pulse oximeter should not be used for arrhythmia analysis.**

CAUTION

- **Change the application site or replace the sensor and/or patient cable when a persistent SpO2 Low Signal Quality message is displayed on the equipment. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.**
- **Replace the cable or sensor when a "SpO2 Sensor Off", "SpO2 No Sensor", or "SpO2 Low Signal Quality" message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.**
- **Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.**
- **Use only SpO_2 sensors specified in this manual. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.**
- **Do not place the pulse oximeter where the controls can be changed by the patient.**
- **If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.**

NOTE

- **Additional information specific to the Masimo sensors compatible with the equipment, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).**
- **Masimo cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.**
- **The SpO_2 extension cable should be compatible with the SpO_2 connectors. For example, you can only connect the Mindray SpO_2 extension cable to the Mindray SpO_2 connectors.**
- **The SpO_2 simulator can be used to verify the accuracy of the SpO_2 sensor.**

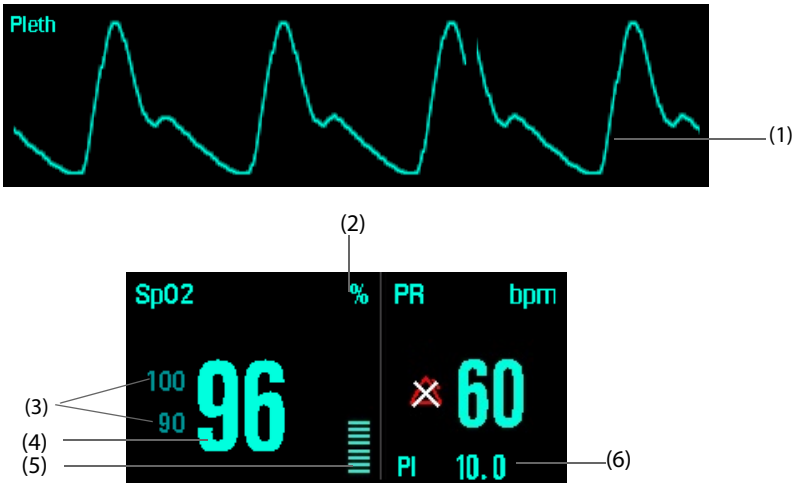
12.4 SpO_2 Measurement Limitations

The following factors may influence the accuracy of SpO_2 measurement:

- Patient physiological characteristics:
  - Cardiac arrest
  - Hypotension
  - Darkly pigmented skin
  - Shock
  - Severe vasoconstriction
  - Hypothermia
  - Severe anemia
  - Ventricular septal defects (VSDs)
  - Venous pulsations
  - Poor perfusion
  - Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
  - Elevated levels of bilirubin
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.

- Interfering substances:
  - Intravascular dyes (such as indocyanine green, methylene blue, indigo carmine, etc.)
  - Dyes in the measure site, such as nail polish.
- Environmental conditions:
  - Excessive ambient light
  - Electrosurgery equipment. The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
  - Defibrillation (may cause inaccurate reading for a short amount of time)
  - Excessive patient/sensor motion
  - Electromagnetic field
  - Arterial catheters and intra-aortic balloon
- Others
  - Inappropriate positioning of the SpO_2 sensor, or use of incorrect SpO_2 sensor
  - Cuff or arterial blood pressure measurement device on the same limb as the SpO_2 sensor.

12.5 SpO_2 Display



(1) Pleth waveform (Pleth): visual indication of patient's pulse. The waveform is not normalized.

(2) SpO_2 unit

(3) SpO_2 alarm limits

(4) Oxygen saturation of arterial blood (SpO_2): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.

(5) Perfusion indicator: the pulsatile portion of the measured signal caused by arterial pulsation.

(6) Perfusion index (PI): gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength. You can also use it to assess the SpO_2 signal strength.

- If the **"SpO2 Low Perf"** alarm persists, reposition the SpO_2 sensor or find a better site.
- If low perfusion persists, choose another method to measure oxygen saturation if possible.

NOTE

- **PI is only available for Masimo SpO_2.**

12.6 SpO_2 Monitoring Procedure

1. Select an appropriate sensor according to the module type, patient category and weight.
2. Clean the application site, e.g. removing colored nail polish from the application site.
3. Apply the sensor to the patient.
4. Select an appropriate extension cable according to the connector type and connect it with the equipment.
5. Connect the sensor cable to the extension cable.
6. Switch the Mode Select knob to Monitor.

12.7 Changing SpO_2 Settings

You can enter the [**SpO2 Setup**] menu by selecting the SpO_2 parameter area.

12.7.1 Changing the Speed of the Pleth Wave

In the [**SpO2 Setup**] menu, you select the appropriate setting from [**Sweep**]. The faster the wave sweeps, the wider the wave is.

12.7.2 Monitoring SpO_2 and NIBP on the Same Limb

When monitoring SpO_2 and NIBP on the same limb simultaneously, you can enable [**NIBP Simul**] from the [**SpO2 Setup**] menu to lock the SpO_2 alarm status until the NIBP measurement ends. If you disable [**NIBP Simul**], low perfusion caused by NIBP measurement may lead to inaccurate SpO_2 readings and therefore cause false physiological alarms.

12.7.3 Sat-Seconds Alarm Management (for Nellcor SpO_2)

With traditional alarm management, high and low alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated, an audible alarm immediately sounds. When the patient's SpO_2 value fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarm can be distracting.

The Sat-Seconds feature is available with the Nellcor SpO_2 module to decrease the likelihood of false alarms caused by motion artifacts. The Sat-Seconds limit controls the amount of time that SpO_2 saturation may be outside the set limits before an alarm sounds. The method of calculation is as follows: the number of percentage points that the SpO_2 saturation falls outside the alarm limit is multiplied by the number of seconds that it remains outside the limit. This can be stated as the equation: Sat-Seconds= Points × Seconds

Only when the Sat-Seconds limit is reached, the equipment gives a Sat-Seconds alarm. The figure below demonstrates the alarm response time with a Sat-Seconds limit set at 50 and a low SpO_2 limit set at 90%. In this example, the patient's SpO_2 drops to 88% (2 points) and remains there for 2 seconds. Then it drops to 86% (4 points) for 3 seconds, and then to 84% (6 points) for 6 seconds. The resulting Sat-Seconds are:

Points	Seconds	Sat-Seconds
2×	2 =	4
4×	3 =	12
6×	6 =	36
Total Sat-Seconds =		52

After approximately 10.9 seconds, a Sat-Second alarm would sound, because the limit of 50 Sat-Seconds would have been exceeded.

Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Normally, the patient's SpO_2 may fluctuate above and below an alarm limit, re-entering the non-alarm range several times. During such fluctuation, the system sums the number of SpO_2 points, both positive and negative, until either the Sat-Seconds limit is reached, or the patient's SpO_2 re-enters the non-alarm range and remains there.

12.7.4 Setting SpO_2 Sensitivity (for Mindray SpO_2)

The SpO_2 value displayed on the screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the equipment responds to changes in the patient's oxygen saturation level, but the measurement accuracy is relatively low. Contrarily, the longer the averaging time is, the slower the equipment responds to changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. When monitoring critically ill patients, selecting shorter averaging time will help understanding the patient's condition.

For Mindray SpO_2 module, you can set [**Sensitivity**] to [**High**], [**Med**] or [**Low**] from the [**SpO2 Setup**] menu, which respectively correspond to 7 s, 9 s and 11 s.

12.7.5 Setting SpO_2 Sensitivity (for Masimo SpO_2)

For Masimo SpO_2 module, you can set [**Sensitivity**] to [**High**], [**Normal**] or [**APOD**] from the [**SpO2 Setup**] menu.

Normal sensitivity is the recommended for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as the intensive care unit (ICU).

Adaptive Probe Off Detection (APOD) sensitivity is the recommended sensitivity mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

Maximum sensitivity is recommended for use on patients with weak signals (e.g. high ambient noise and/or patients with very low perfusion) and for use during procedures or when clinician and patient contact is continuous such as in higher acuity settings.

CAUTION

- **When using the Maximum Sensitivity setting, performance of "SpO2 Sensor Off" detection may be compromised. If the equipment and the sensor becomes detached from the patient, the potential for false readings may occur due to environmental noise such as light, and vibration.**

12.7.6 Changing Averaging Time (for Masimo SpO_2)

The SpO_2 value displayed on the screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the equipment responds to changes in the patient's oxygen saturation level, but the measurement accuracy is relatively low. Contrarily, the longer the averaging time is, the slower the equipment responds to changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. When monitoring critically ill patients, selecting shorter averaging time will help understanding the patient's condition.

For Masimo SpO_2 module, you can set [**Average Time**] to [**2-4 s**], [**4-6 s**], [**8 s**], [**10 s**], [**12 s**], [**14 s**] or [**16 s**] from the [**SpO2 Setup**] menu.

12.7.7 Enabling FastSAT (for Masimo SpO_2)

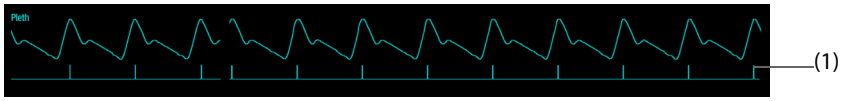
FastSAT enables rapid tracking of arterial oxygen saturation changes as may be required in urgent situations. When FastSAT is switched on, the averaging algorithm evaluates all the SpO_2 values and provides an averaged SpO_2 value that is a better representation of the patient's current oxygen saturation status.

The reliability of FastSAT is dependent on the setting for the averaging time and the input signal. To enable FastSAT, set [**Fast SAT**] to [**On**] from the [**SpO2 Setup**] menu.

12.7.8 Displaying SIQ (for Masimo SpO_2)

The signal quality indicator (SIQ) displays below the Pleth waveform. The SIQ is conveyed by vertical bars. The height of the bar provides an assessment of the confidence in the displayed SpO_2 value. The SpO_2 SIQ can also be used to identify the occurrence of a patient 's pulse.

The following picture shows the SpO2 SIQ.



(1) Signal quality indicator (SIQ)

To display SpO_2 SIQ, set [**Display SIQ**] to [**On**] from the [**SpO2 Setup**] menu.

12.7.9 Displaying PI (for Masimo SpO_2)

For Masimo SpO_2 module, you can set whether to display PI in the SpO_2 parameter area. To display PI, set [**Display PI**] to [**On**] from the [**SpO2 Setup**] menu.

12.7.10 Setting the Alarm Delay Time (for Masimo SpO_2)

For Masimo SpO_2 module, you can set [**Alarm Delay**] by selecting [**SpO2 Setup**] from the Configuration Main menu. If the alarm condition related to Masimo SpO_2 is resolved within the configured time period, the equipment does not present the alarm.

12.8 SpO_2 Desat Alarm

The equipment provides a SpO_2 Desat alarm. The SpO_2 Desat alarm provides an additional limit setting below the SpO_2 low limit setting to notify you of potentially life threatening decreases in oxygen saturation. The SpO_2 Desat alarm is a high-level exclusive alarm. You cannot change its alarm level.

To set the Desat alarm:

1. Enter the [**Para. Alarm**] menu by either of the following ways.
   - Press the Main Menu button on the front panel, and then select [**Alarm Setup >>**] → [**Para. Alarm >>**].
   - Select the SpO_2 parameter area and then select [**Para. Alarm >>**].
2. Set [**Desat**].

NOTE

- **In the case that the SpO_2 low limit alarm value is set below the Desat limit, the SpO_2 low limit is automatically adjusted to the Desat value.**

12.9 Pitch Tone

The pitch tone function enables the equipment to give variable pitches of heartbeat tone or pulse tone as the patient's SpO_2 level changes. This equipment provides two modes of pitch tones. The pitch of heartbeat tone or pulse tone rises as SpO_2 level increases and falls as SpO_2 level decreases.

There are two pitch tone modes. You can set [**Pitch Tone**] to select the pitch tone mode by selecting [**SpO2 Setup**] from the Configuration Main menu.

If the SpO_2 is disabled, the pitch tone function will be disabled also.

12.10 SpO_2 Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the equipment or accessories, check the table below before requesting for services. If the problem persists, contact your service personnel.

NOTE

- **For the physiological and technical alarm messages, refer to *E Alarm Messages*.**

Problem	Corrective Actions
Do not see SpO_2 parameter area or waveform area on the screen	Check that the cable connections of SpO_2 sensor and the extension cable are tight. Replace the SpO_2 sensor or the extension cable if needed.
Dashes "- -" display in place of numerics.	1. Check that the cable connections of SpO_2 sensor and the extension cable are tight. Replace the SpO_2 sensor or the extension cable if needed. 2. Reconnect the SpO_2 sensor if the alarm **"SpO2 Sensor Off"** appears. 3. Check the perfusion indicator. If the perfusion indicator is too low, adjust the SpO_2 sensor, or apply the sensor to the site with better perfusion. 4. Move the sensor to the place with weaker light, or cover the sensor with shade cloth if the alarm **"SpO2 Sensor Off"** appears.
Low amplitude SpO_2 signal	1. The SpO_2 sensor and NIBP cuff are placed on the same limb. Change a monitoring site if necessary. 2. Check the perfusion indicator. If the perfusion indicator is too low. Adjust the SpO_2 sensor, or apply the sensor to the site with better perfusion. 3. Check the sensor and its application site.
SpO_2 value is inaccurate	1. Check the patient's vital signs. 2. Check for conditions that may cause inaccurate SpO_2 readings. For details, refer to *12.4 SpO**2 Measurement Limitations***. 3. Check the equipment and the SpO_2 module for proper functioning.

12.11 Nellcor Information

■ Nellcor Patents

This device may be covered by one or more of the following US patents and foreign equivalents: 5,485,847, 5,676,141, 5,743,263, 6,035,223, 6,226,539, 6,411,833, 6,463,310, 6,591,123, 6,708,049, 7,016,715, 7,039,538, 7,120,479, 7,120,480, 7,142,142, 7,162,288, 7,190,985, 7,194,293, 7,209,774, 7,212,847, 7,400,919.

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13 Monitoring NIBP

13.1 NIBP Introduction

Automatic non-invasive blood pressure monitoring uses the oscillometric method of measurement. It is intended for adult, pediatric and neonatal patients. To understand how this method works, we'll compare it to the auscultative method.

With auscultation, the clinician listens to the blood pressure and determines the systolic and diastolic pressures. The mean pressure can then be calculated with reference to these pressures as long as the arterial pressure curve is normal.

Since the equipment cannot hear the blood pressure, it measures cuff pressure oscillation amplitudes. Oscillations are caused by blood pressure pulses against the cuff. The oscillation with the greatest amplitude is the mean pressure. Once the mean pressure is determined, the systolic and diastolic pressures are calculated with reference to the mean.

Simply stated, auscultation measures systolic and diastolic pressures and the mean pressure is calculated. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

As specified in ISO 80601-2-30, NIBP monitoring is allowed while an electrosurgical operation is in progress or a defibrillation shock is being delivered.

NIBP monitoring is intended for adult, pediatric and neonatal patients.

NOTE

- **Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.**

13.2 NIBP Safety Information

WARNING

- **Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise it may present a safety hazard.**
- **Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.**
- **Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.**
- **NIBP reading can be affected by the measurement site, the position of the PATIENT, exercise, or the patient's physiologic condition. If you doubt the NIBP readings, determines the patient's vital signs by alternative means and then verify that the equipment is working correctly.**
- **Do not use the NIBP cuff on the arm on the side of a mastectomy or lymph node clearance.**
- **Continuous CUFF pressure due to connection tubing kinking may cause blood flow interference and resulting harmful injury to the patient.**
- **NIBP diagnostic significance must be decided by the physician.**

13.3 NIBP Measurement Limitations

Measurements are impossible with heart rate extremes of less than 30 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine.

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

- If a regular arterial pressure pulse is hard to detect;
- With excessive and continuous patient movement such as shivering or convulsions;
- With cardiac arrhythmias;
- Rapid blood pressure changes;
- Severe shock or hypothermia that reduces blood flow to the peripheries;
- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.

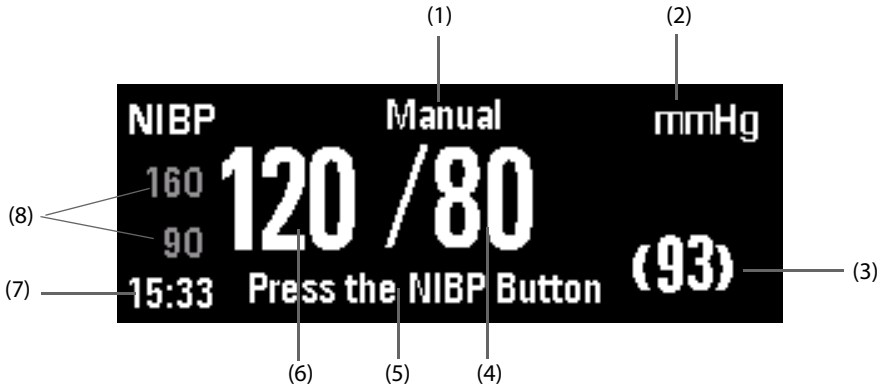
13.4 Measurement Modes

There are three modes of measuring NIBP:

- Manual: measurement on demand.
- Auto: continually repeated measurements at set intervals.
- STAT: continually rapid series of measurements over a five minute period, then return to the previous mode.

13.5 NIBP Display

The NIBP display shows numerics only as below. Your display may be configured to look slightly different.



(1) Measurement mode

(2) NIBP unit: mmHg or kPa

(3) Mean pressure at the completion of measurement, or cuff pressure during the measurement.

(4) Diastolic pressure

(5) NIBP prompt message

(6) Systolic pressure

(7) Time of last measurement

(8) NIBP alarm limits

13.6 NIBP Measurement Procedure

13.6.1 Preparing the Patient

In normal use, perform NIBP measurement on a patient who is in the following position:

- Comfortably seated
- Legs uncrossed
- Feet flat on the floor
- Back and arm supported
- Middle of the cuff at the level of the right atrium of the heart

NOTE

- **It is recommended that the patient relaxes as much as possible before performing measurement and that the patient does not talk during NIBP measurement.**
- **It is recommended that 5 min should elapse before the first reading is taken.**
- **A wrong cuff size and a folded or twisted bladder can cause inaccurate measurements.**
- **Do not touch or apply external pressure against the cuff and air tubing during NIBP measurement. This may cause inaccurate blood pressure values.**

13.6.2 Preparing for NIBP Measurement

1. Verify that the patient category is correct. Change it if necessary.
2. Plug the air tubing into the equipment's NIBP connector.
3. Select a correct sized cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
4. Apply the cuff to an upper arm or thigh of the patient and make sure the Φ marking on the cuff matches the artery location. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Make sure that the cuff edge falls within the marked range. If it does not, use a cuff that fits better.
5. Connect the cuff to the air tubing and make sure that the air tubing is not compressed or twisted. Air must pass unrestricted through the tubing.
6. Switch the Mode Select knob to Monitor.

13.6.3 Starting and Stopping NIBP Measurements

You can start and stop NIBP measurements by pressing the NIBP button  on the front panel.

13.6.4 Correcting the Measurement

The cuffed limb should be at the same level as the patient's heart. If not, correct the measurement by:

- Add 0.75 mmHg (0.10 kPa) for each centimeter higher, or
- Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower.

13.6.5 Starting Auto NIBP Measurements

1. Select the NIBP parameter area to enter the [**NIBP Setup**] menu.
2. Select [**Interval**] and then select a desired time interval except [**Manual**]. Selecting [**Manual**] switches to manual mode.
3. Press the NIBP button  on the front panel. The equipment will then automatically repeat NIBP measurements at the set time interval.

WARNING

- **Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately.**

13.6.6 Starting a STAT Measurement

1. Select the NIBP parameter area to enter the [**NIBP Setup**] menu.
2. Select [**NIBP STAT**]. The STAT mode initiates a 5-minute continuous, automatic NIBP measurement.

13.7 Setting Initial Cuff Inflation Pressure

You can set the initial cuff inflation pressure manually.

1. Select the NIBP parameter area to enter the [**NIBP Setup**] menu.
2. Select [**Initial Pressure**] and then select the appropriate setting. The cuff is inflated accordingly at the next NIBP measurement.

NOTE

- **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**
- **Setting initial cuff inflation pressure is disabled during NIBP measurement.**
- **The initial cuff inflation pressure is restored to the default setting if NIBP module has been reset or patient category has been changed.**

13.8 Setting Pressure Unit

You can set [**Press. Unit**] to change NIBP unit only by selecting [**NIBP Setup**] from the Configuration Main menu.

13.9 NIBP Troubleshooting

For details, refer to *E Alarm Messages*.

14 Monitoring CO_2

14.1 CO_2 Introduction

CO_2 monitoring is a continuous, non-invasive technique for determining the concentration of CO_2 in the patient's airway by measuring the absorption of infrared (IR) light of specific wavelengths. The CO_2 has its own absorption characteristic and the amount of light passing the gas probe depends on the concentration of the measured CO_2. When a specific band of IR light is passed through respiratory gas samples, some of IR light will be absorbed by the CO_2 molecules. The amount of IR light transmitted after it has been passed through the respiratory gas sample is measured with a photodetector. From the amount of IR light measured, the concentration of CO_2 is calculated.

CO_2 monitoring is intended for adult, pediatric and neonatal patients.

14.2 CO_2 Safety Information

WARNING

- **Remove the airway sampling line from the patient's airway while nebulized medications are being delivered.**
- **Leakage in the breathing or sampling system may cause the displayed $EtCO_2$ values to be significantly low. Always make sure that all components are securely connected.**
- **$EtCO_2$ values measured from the CO_2 module may differ from those of from the blood gas analysis.**
- **Route all tubing away from the patient's throat to avoid strangulation.**
- **Inspect the airway adapter for a tight connection and proper operation before attaching it to the patient.**
- **Squeezing or bending the sampling line during the CO_2 measurement may cause inaccurate CO_2 reading or no reading.**

14.3 CO_2 Measurement Limitations

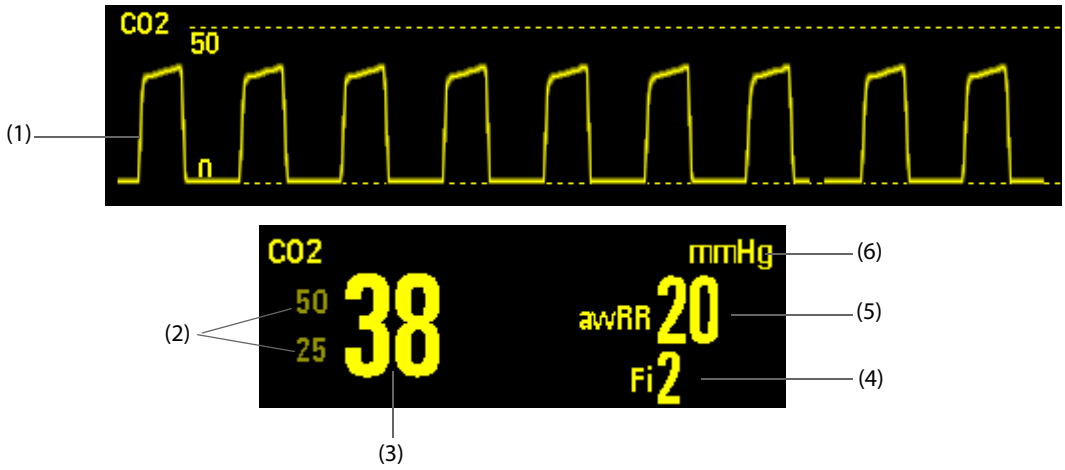
The following factors may influence the accuracy of measurement:

- Leakage or internal venting of sampled gas
- Mechanical shock
- Cyclic pressure higher than 10 kPa (100 cmH_2O) or abnormal change to airway pressure
- Other sources of interference, if any.

Measurement accuracy of the CO_2 module may be affected by the breath rate and inspiration/expiration (I/E) ratio. For details, refer to *A.5.7 CO_2 Specifications*.

14.4 CO_2 Display

The CO_2 parameter and waveform areas provide $FiCO_2$ measurement, $EtCO_2$ measurement, awRR measurement, and a CO_2 waveform.



(1) CO_2 waveform

(2) CO_2 alarm limits

(3) End tidal CO_2 value ($EtCO_2$): the highest CO_2 value measured during expiration.

(4) Fraction of inspired CO_2 ($FiCO_2$): the lowest CO_2 value measured during inspiration.

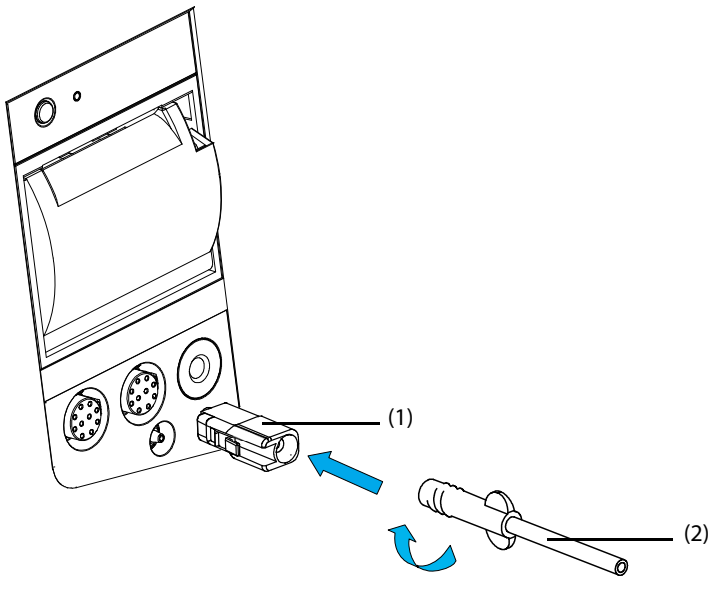
(5) Airway respiration rate (awRR)

(6) CO_2 unit

14.5 Preparing for Measuring CO_2

14.5.1 Measuring CO_2 Using the CO_2 Module

1. Select an appropriate sampling line according to the patient category.
2. Connect the sampling line to the CO_2 adapter installed on the equipment.

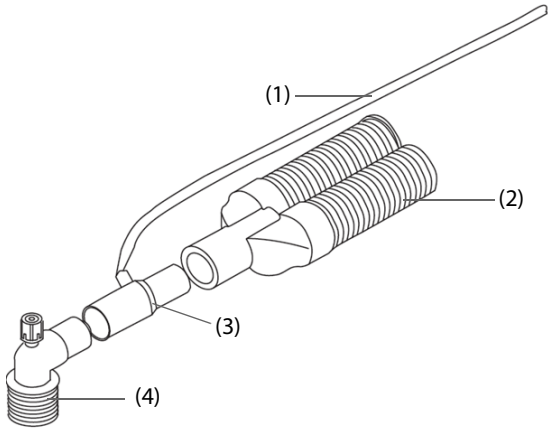


(1) CO_2 adapter

(2) Sampling line

3. Connect the other end of the sampling line to the patient.

   ◆ For intubated patients requiring an airway adapter, install the airway adapter between the patient circuit and the ventilator Y-piece.



(1) Sample line
(2) Connect to the ventilator
(3) Airway adapter
(4) Connect to the patient

   ◆ For non-intubated patients, place the nasal cannula onto the patient.

4. Connect the gas outlet to the scavenging system using an exhaust tube.

After the CO_2 module is connected, it enters measure mode by default and the equipment displays "**CO2 Startup**". CO_2 can be measured after the start-up is complete.

CAUTION

- **Connect the gas outlet to the scavenging system when measuring CO_2.**

NOTE

- **If not necessary, do not disconnect the CO_2 adapter from the equipment after the first installation. This reduces the risk of the CO_2 adapter becoming lost or damaged.**
- **When sample gas of 37 °C, sample flowrate of 50 ml/min, room temperature of 23 °C, 100% RH, the sampling line with a general type should be replaced once at most every 8 hours, and the sampling line with a humidified type should be replaced once at most every 72 hours.**

14.5.2 Zeroing the CO_2 Sensor

The zero calibration eliminates the effect of baseline drift during CO_2 measurement exerted on the readings and therefore maintains the accuracy of the CO_2 measurements.

A zero calibration is carried out automatically when necessary. You can also start a manual zero calibration if necessary.

To manually start a zero calibration:

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Maintenance >>**] → [**Installation Mode >>**] → enter the required password.
2. Select [**Maintain CO2**] → [**Zero**].

Disconnecting the patient airway is not required when performing a zero calibration.

NOTE

- **The CO_2 module temporally stops measuring during zeroing.**

14.6 Changing CO_2 Settings

14.6.1 Changing CO_2 Alarm Settings

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu.
2. Select [**Para. Alarm >>**]
3. Set the following alarm properties:
   - Switch on or switch off the alarms or alarm recording.
   - Adjust the alarm limits or alarm priority.

14.6.2 Setting Pressure Unit

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**CO2 Setup**].
3. Set [**Press. Unit**].

14.6.3 Changing CO_2 Wave Settings

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu.
2. Set the wave sweep and scale.
   - Select [**Sweep**] and then choose an appropriate setting. The faster the wave sweeps, the wider the wave is.
   - Select [**Scale**] and adjust the upper scale to change the amplitude of CO_2 waveform.
3. Select [**Others >>**] and set the wave type:
   - [**Draw**]: The CO_2 wave is displayed as a curved line.
   - [**Fill**]: The CO_2 wave is displayed as a filled area.

14.6.4 Changing CO_2 Operating Mode

To change CO_2 operating mode:

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu
2. Set [**Operating Mode**].
   - [**Measure**]: only in the Measure mode can you start the CO_2 module.
   - [**Standby**]: in the standby mode, the gas intake pump, infrared light source, etc. are automatically switched off to reduce power consumption and extend the lifetime of the CO_2 module.

14.6.5 Setting the Auto Standby Time

The equipment enters the standby mode automatically after the configured period of time if no breath is detected since the last detected breath.

To set auto standby time:

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu.
2. Select [**Others >>**].
3. Set [**Auto Standby**].

14.6.6 Setting the Apnea Alarm Delay

To set the apnea alarm delay:

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu.
2. Set [**Apnea Time**]. The equipment gives an apnea alarm if the patient has stopped breathing for longer than the preset apnea time.

14.6.7 Selecting Gas Compensations

WARNING

- **Make sure that the appropriate compensations are used. Inappropriate compensations may cause inaccurate measurement values and result in misdiagnosis.**

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu.
2. Select [**Others >>**].
3. Respectively select:
   - [**O2 Compen**]: 0 to 100%
   - [**N2O Compen**]: 0 to 100%
   - [**AA Compen**]: 0 to 24%

The sum of the three compensations should not be greater than 100%.

14.6.8 Setting Humidity Compensation

The CO_2 module is configured to compensate CO_2 reading for either Body Temperature and Pressure Saturated (BTPS) gas, to account for humidity in the patient's breath, or Ambient Temperature and Pressure Dry (ATPD) gas.

- ATPD: $P_{CO2}(mmHg)=CO_2(vol\%) \times P_{amb}/100$
- BTPS: $P_{CO2}(mmHg)=CO_2(vol\%) \times (P_{amb}- 47)/100$

Where, $P_{CO2}(mmHg)$= *partial pressure, vol%=*CO_2 *concentration,* P_{amb}*=ambient pressure, and unit is mmHg.*

You can set the humidity compensation on or off according to the actual condition.

To set the humidity compensation:

1. Select the CO_2 parameter area to enter the [**CO2 Setup**] menu.
2. Select [**Others >>**] → [**BTPS Compensation**].
3. Select either [**On**] for BTPS or [**Off**] for ATPD.

14.6.9 Barometric Pressure Compensation

The CO_2 module has the function of automatic barometric pressure compensation. That is to say, the system automatically measures the barometric pressure which the equipment is exposed to.

14.7 Removing the Exhaust Gases from the System

WARNING

- **When taking the CO_2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.**

To remove the sample gas to a scavenging system, connect an exhaust tube to the gas outlet connector of the module.

14.8 CO_2 Calibration

CO_2 calibration should be performed by Mindray-qualified service personnel only once a year or when the readings go far beyond the range. For details, refer to the relevant service manual.

CAUTION

- **Connect the gas outlet to the scavenging system when calibrating CO_2.**

14.9 CO_2 Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the equipment or accessories, check the table below before requesting for services. If the problem persists, contact your service personnel.

NOTE

- **For the physiological and technical alarm messages, refer to *E Alarm Messages*.**

Problem	Corrective Actions
$EtCO_2$ measurements too low	1. Ventilate the room if the environmental CO_2 concentration is too high. 2. Check the sample line and connectors for leakage. 3. Check the patient status.

15 Marking Events

During patient monitoring or therapy, some events may exert effects on the patient and as a result change related waveforms and parameter values. To help analyzing the waveforms or numerics at that time, you can mark these events.

Before marking an event, you can define events A to F, for example, define event D as injecting Atropine. You can only define events by selecting [**Mark Event Setup**] from the Configuration Main menu. Event A is always [**Generic**] and cannot be changed.

To mark an event,

1. In the Monitor mode, Manual Defib, mode or Pacer mode, press the Event button on the front panel to enter the [**Mark Event**] menu.
2. Select an event you want to mark from [**A**] to [**H**], or select [**Exit**] to return to the main screen.

In the AED mode, pressing the Event button on the front panel directly marks Event A "Generic".

When you mark an event, the event name and the time when the event is triggered will be displayed at the prompt information area. This information disappears automatically after a period of 5 seconds.

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16 Freezing Waveforms

During patient monitoring, the freeze feature allows you to freeze the currently displayed waveforms on the screen so that you can have a close examination of the patient's status. Besides, you can select any frozen waveform for recording. Waveforms can be frozen only in the Monitor Mode.

16.1 Freezing Waveforms

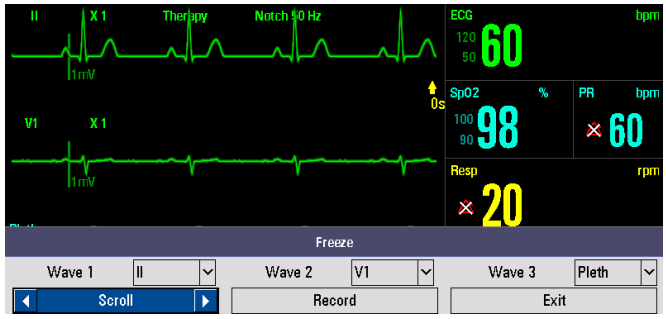
In the Monitor mode, press the [**Freeze**] soft key, then all waveforms on the screen stop refreshing or scrolling and the [**Freeze**] menu pops up. The [**Freeze**] soft key changes to [**Unfreeze**], while the parameter area remains refreshing properly.

The equipment can freeze the waveforms for 120 seconds.

16.2 Reviewing Frozen Waveforms

When waveforms are frozen, you can view the waveforms by selecting the [**Scroll**] button and then rotating the Navigation knob clockwise or counterclockwise to move the frozen waveforms right or left.

At the lower right corner of the bottommost waveform, there is an upward arrow. The frozen time is displayed below the arrow. With each step or click, the frozen time changes at intervals of 1 second. The time can be applied to all the waveforms on the screen.



16.3 Unfreezing Waveforms

To unfreeze the frozen waveforms, choose any of the following ways:

- Press the [**Unfreeze**] soft key.
- In the [**Freeze**] window, select [**Exit**].
- Perform any other action that causes the screen to be readjusted or opens a menu, such as pressing the Lead Select or Main Menu button, etc.

16.4 Recording Frozen Waveforms

1. In the Monitor mode, press the [**Freeze**] soft key.
2. Select [**Wave 1**], [**Wave 2**] or [**Wave 3**], and then respectively set the desired waveforms.
3. Select [**Record**]. The selected waveforms and all numerics at the frozen time will be printed out by the recorder.

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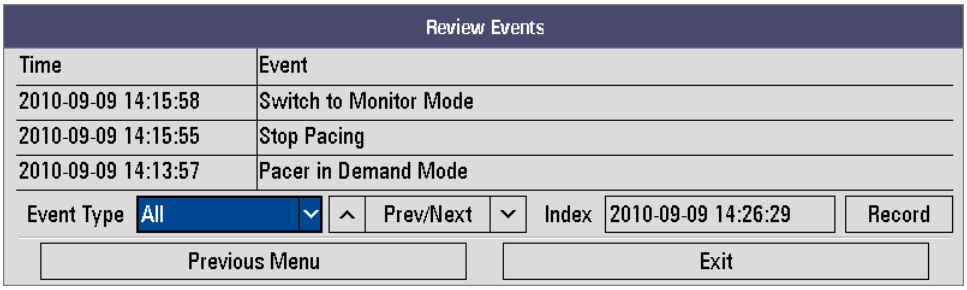
17 Review

17.1 Reviewing Events

The equipment can automatically record and save patient events.

To review events, press the Main Menu button in the Monitor mode, Manual Defib mode or Pacer mode, and then select [**Review >>**] → [**Review Events >>**].

The following figure shows the [**Review Events**] menu.



In the [**Review Events**] menu, you can:

- Select [**Event Type**], and then select [**User Initiated**], [**Phys. Alarm**], [**Arrhythmia**], [**NIBP Meas.**], [**Tech. Alarm**] or [**All**] to review events as desired.
- Select [**Prev/Next**] to page up/down to view more events.
- Select [**Index**] to enter the [**Index**] menu. In this menu, you can set the time span in which the events happened.
- Select [**Record**] to print out the current event list.
- Select [**Previous Menu**] to return to the previous menu.
- Select [**Exit**] to return to the main screen.

Patient events will be saved as archived events when the equipment is turned off. In case of power failure, the saved patient events will not be cleared or lost; they will be turned into archived events instead.

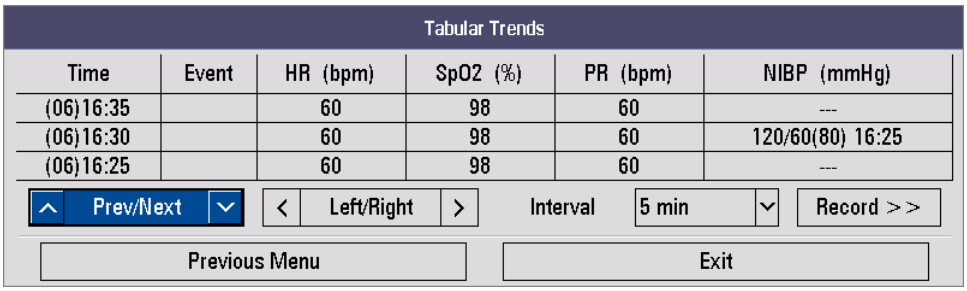
NOTE

- **Pausing or switching off alarms will not be recorded as events.**
- **A total loss of power has no impact on the saved events.**
- **Earlier-recorded events might be overwritten by later ones if it reaches capacity.**

17.2 Reviewing Tabular Trends

To review tabular trends, choose either of the following ways:

- In the Monitor, Manual Defib or Pacer mode, press the Main Menu button on the front panel, and then select [**Review >>**] → [**Trends >>**].
- In the Monitor mode, repeatedly press the [**Trends**] soft key.



17.3 Reviewing CPR Events

If CPR is delivered by using the equipment connected with the CPR sensor, you can review CPR events on the equipment.

For details, refer to *8.2.4 Reviewing CPR Events*.

18 Data Management

18.1 Data Management Overview

The data management function is available in the Monitor mode, AED mode, Manual Defib mode and Pacer mode. It enables you to:

- Edit patient information
- Review patient events
- Export patient data to USB memory

18.2 Generating Patient Data

Archive ID is created automatically when the equipment is turned on. It is unchangeable. When the equipment is turned off, the current patient is discharged and the archive ID turns to be historical archive ID.

For a new patient, if patient category is changed, the system will restore the default alarm settings of this patient category; if patient category is not changed, the alarm settings remain unchanged. If you restart the equipment after normal power-off, the default alarm settings will be loaded.

18.3 Editing Archived Patient Information

You can edit the archived patient information when the information is incomplete or changed. [**Archives ID**] and [**Patient Cat.**] are unchangeable.

1. Press the Main Menu button on the front panel, and then select [**Others >>**].
2. Select [**Archives >>**] → [**Yes**].
3. Select the desired archive ID, and select [**Patient Info**]
4. Edit the patient information as desired.

18.4 Reviewing Patient Events

1. Press the Main Menu button on the front panel, and then select [**Others >>**].
2. Select [**Archives >>**] → [**Yes**].
3. Select the desired archive ID, and select [**Patient Info**]
4. Select [**Review Events**]

18.5 Exporting Patient Data

1. Press the Main Menu button on the front panel, and then select [**Others >>**].
2. Select [**Archives >>**] → [**Yes**].
3. Select [**Export Data**] → [**USB Memory**].
4. Select the desired archive ID, and then select [**Export**].

During data export, the message "**Exporting Data. Please Wait...**" appears in the prompt information area and a progress bar is displayed. If an exception happens, data export stops automatically and the reason for interruption is presented in the prompt information area.

NOTE

- **Do not remove the USB flash memory from the equipment before data is completely exported.**

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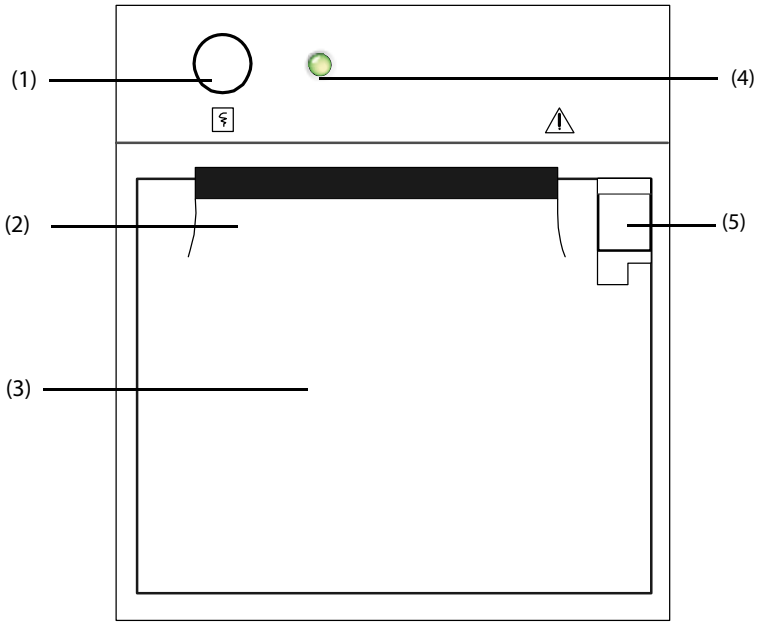
19 Recording

19.1 Using a Recorder

The thermal recorder records patient information, measurement numerics and waveforms, reviewed data, auto test report, user test report and equipment configurations.



(1) Start/Stop key
Press this key to start a recording or stop the current recording.

(2) Paper outlet

(3) Recorder door

(4) Indicator

- Illuminated: when the recorder works correctly.
- Flashes: when an error occurred to the recorder, or the recorder runs out of paper.
- Off: when the equipment is turned off.

(5) Latch

19.2 Recording Types

The equipment provides the following recordings.

- Manually-triggered realtime waveform recordings.
- Event-triggered recordings.
- Alarm recordings triggered by an alarm limit violation or an arrhythmia event.
- Manually-triggered, task-related recordings.
  - Frozen wave recording
  - Tabular trends recording
  - Event recording
  - Parameter alarm recording
  - Event review recording

- Event summary report
- Check report
- Configuration recording

For details about alarm recording, refer to *4 Alarms*.

For details about task-related recordings, refer to respective sections of this manual.

19.3 Starting Recordings

Recordings can be started manually or automatically.

NOTE

- **If you change the ECG Lead, Gain or Filter during recording, the recorded ECG waveform changes accordingly, but the label of Lead, Gain or Filter recorded remains unchanged.**

19.3.1 Manually Starting Recordings

To manually start a recording, you can either:

- Press the Record button on the front of the recorder,
- Select [**Record**] from the current display.

At the completion of recording, two columns of "*" marks will be printed to indicate the end of recording.

19.3.2 Automatic Recordings

Automatic recordings will be triggered in the following conditions:

- If both [**Alarm**] and [**Alm Rec**] for a measurement are switched on, an alarm recording will be triggered automatically when an alarm occurs.
- When related event is triggered.

19.4 Stopping Recordings

Recordings can be stopped manually or automatically.

19.4.1 Stopping Recordings Manually

To manually stop a recording, you can either:

- Press the Record button again.
- Select [**Clear All Tasks**] in the [**Record Setup**] menu.

19.4.2 Stopping Recordings Automatically

Recordings stop automatically when:

- A recording is completed.
- The recorder runs out of paper.
- The recorder has a failure.
- Operating mode is changed.

19.5 Setting the Recorder

19.5.1 Selecting Waveforms for Recording

1. Press the Main Menu button on the front panel and select [**Others >>**] → [**Record Setup >>**].
2. Select [**Wave 1**], [**Wave 2**] or [**Wave 3**], and then respectively set the desired waveforms. Selecting [**Off**] can switch off a waveform.

The selected waveforms and all numerics at the frozen time will be printed out by the recorder.

19.5.2 Setting the Realtime Recording Length

1. Press the Main Menu button on the front panel and select [**Others >>**] → [**Record Setup >>**].
2. Select [**Wave Length**] and toggle between [**8 s**], [**16 s**], [**32 s**] and [**STAT**].
   - [**8 s**]: record a waveform 4 seconds before and 4 seconds after the current moment.
   - [**16 s**]: record a waveform 8 seconds before and 8 seconds after the current moment.
   - [**32 s**]: record a waveform 16 seconds before and 16 seconds after the current moment.
   - [**STAT**]: record a waveform from the current moment until stopped manually.

19.5.3 Changing the Recording Speed

1. Press the Main Menu button on the front panel and select [**Others >>**] → [**Record Setup >>**].
2. Set [**Paper Speed**].

This setting is for all recordings containing waveforms.

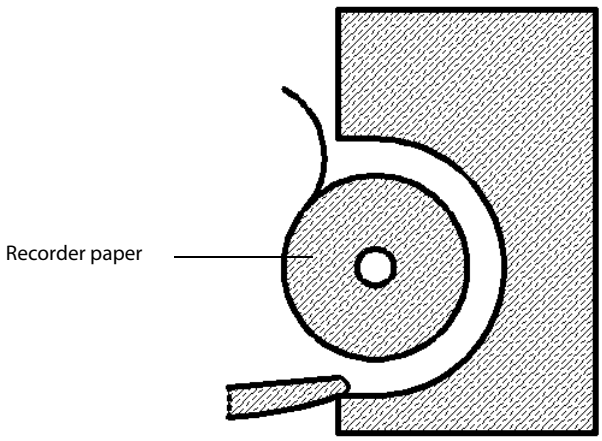
19.5.4 Switching Gridlines On or Off

1. Press the Main Menu button on the front panel and select [**Others >>**] → [**Record Setup >>**].
2. Select [**Gridlines**] and toggle between [**On**] and [**Off**].
   - [**On**]: show gridlines when recording waveforms.
   - [**Off**]: hide gridlines when recording waveforms.

This setting is for all recordings containing waveforms.

19.6 Loading Paper

1. Use the latch at the upper right of the recorder door to pull the door open.
2. Insert a new paper roll into the compartment as shown below.
3. Close the recorder door.
4. Check if paper is loaded correctly and the paper end is feeding from the top.



CAUTION

- **Use only specified thermal paper. Otherwise, it may cause damage to the recorder's print head, the recorder may be unable to print, or poor print quality may result.**
- **Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.**
- **Do not leave the recorder door open unless you have to reload paper or remove troubles.**

19.7 Removing Paper Jam

If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam first. If a paper jam is detected, follow this procedure to remove it:

1. Open the recorder door.
2. Take out the paper and tear off the draped part.
3. Reload the paper and close the recorder door.

19.8 Cleaning the Recorder Print Head

If the recorder has been used for a long time, deposits of paper debris may collect on the print head compromising the print quality and shortening the lifetime of the roller. Follow this procedure to clean the print head:

1. Take measures against the static electricity, such as disposable wrist strap, for the work.
2. Open the recorder door and take out the paper.
3. Gently wipe around the print head using cotton swabs dampened with alcohol.
4. After the alcohol has completely been dried, reload the paper and close the recorder door.

CAUTION

- **Do not use anything that may destroy the thermal element.**
- **Do not add unnecessary force to the thermal head.**

20 Network Connection

20.1 Network Introduction

The equipment supports the network function. The equipment can send real-time data to the CMS through wired and wireless networks or send HL7 messages.

20.2 General Network Settings

20.2.1 Selecting a Network Type

1. Press the Main Menu button on the front panel, and select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Network Setup**] and set [**Network Type**] to [**LAN**] or [**WLAN**].
3. Set [**Address Type**].
   - [**DHCP**]: the equipment can automatically acquire network parameters.
   - [**Manual**]: you need to manually input the IP address, subnet mask and gateway address.
4. Select [**Return**].

20.2.2 Storing Preset Sites

You can store up to 2 preset sites which can be selected in the drop-down list once successfully stored.

1. Press the Main Menu button on the front panel, and select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Network Setup**].
3. Set [**Site Setup**].
   - [**Select Site**]: select a site number in the drop-down list.
   - [**Site Name**]: manually input the name of the target CMS.
   - [**Site Address**]: manually input the IP address or domain name to specify the target CMS.
4. Select [**Return**].

20.2.3 Setting DNS

You can set DNS for connecting the CMS and server using domain name.

To set DNS:

1. Press the Main Menu button on the front panel, and select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Network Setup**].
3. Set [**DNS Address Type**].
   - [**Manual**]: the address of the DNS server must be manually entered.
   - [**DHCP**]: the equipment will automatically acquire the address of the DNS server. This is only available when [**Address Type**] is set to [**DHCP**] in the [**Network Setup**] menu.
4. If [**Manual**] was selected in Step 3, set [**Preferred DNS Server**] and [**Alternate DNS Server**].

20.3 Connecting the CMS

The following information can be transmitted to the CMS:

- Patient information
- Equipment information
- Configuration information
- Waveforms
- Monitoring parameters
- Alarms and prompt messages
- Time and date
- Working mode
- Auto test report
- User test summaries

If [**Default Network Connection**] is set to [**On**], the equipment is automatically connected to the CMS after powered on.

To connect the CMS:

1. Set the wired or wireless network. For details, refer to *20.2 General Network Settings*.
2. Press the Main Menu button on the front panel, and select [**Others >>**] → [**Configuration >>**].
3. Select a site in the drop down list after [**Select Site**] to specify the target CMS.
4. Select [**Connect Network**].
5. Exit the Network Connection menu and check the main screen. Network connection icon will be displayed in the prompt area.  indicates that the connection succeeds, while  indicates that the connection fails.

For details on transmitting user test summaries, refer to *24.3.2.3 Transmitting the User Test Summaries*.

To transmit information to the CMS, the equipment can also be connected to Pre-Hospital Emergency Information System (PHEIS) through 4G router. For details, refer to *PHEIS Installation Guide (046-005990-00)*.

20.4 Connecting the HL7 Server

The following information can be transmitted to the HL7 server:

- Waveforms
- Monitoring parameters
- Alarms and prompt messages

To connect the HL7 server:

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Make general settings of the wired and wireless networks. For details, refer to *20.2 General Network Settings*.
3. Continue to select [**Next Page**] until you turn to [**HL7 Configuration**] page.
4. Set [**Data + Waveforms**].
   - [**Destination Site**]: manually input the IP address or domain name to specify the HL7 server.
   - [**Port**]: manually input the IP port of the specified HL7 server.
   - [**Send Data**]: if set to [**On**], monitoring parameters will be automatically sent to the specified HL7 server.
   - [**Data Interval**]: the information will be sent to the HL7 server at the specified period of time.
   - [**Send Waveforms**]: if set to [**On**], waveforms will be automatically sent to the specified HL7 server.
5. Set [**Alarms**].
   - [**Destination Site**]: manually input the IP address or domain name to specify the HL7 server.
   - [**Port**]: manually input the IP port of the specified HL7 server.

- [**Send Alarms**]: if set to [**On**], alarms will be automatically sent to the specified HL7 server.

6. Select [**Return**].

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21 Configuration Management

21.1 Configuration Management Introduction

The configuration management enables you to customize you equipment to best meet your needs. With this function, you can:

- View system configurations
- Change system configurations
- Record system configurations
- Export configurations
- Import configurations
- Restore the factory default configurations

After the system configurations have been changed, the equipment restarts and new configuration settings take effect immediately.

WARNING

- **Entering the Configuration Main menu is password protected. Patient monitoring and therapy automatically ends when you access the configuration management.**
- **The configuration management tasks must be performed by clinical professionals.**
- **Never connect the equipment with the patient when accessing the configuration management.**

21.2 Modifying Configuration Management Password

The required password for entering the Configuration Main menu is set to 315666.

You can also modify the configuration password.

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Others >>**] → [**Modify Password**].
3. Respectively input the old password and new password. The maximum length of a new password can be set to 32 characters.
4. Select [**Confirm**].

21.3 Viewing Configurations

Password is not required when you view configurations.

1. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
1. Enter the Manual Defib mode, the Monitor mode, or the Pacer mode.
2. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**].
   - Selecting [**View Config**] can view the configurations.
   - Selecting [**View Config**] → [**General Setup**] can change the system time.
   - Selecting [**View Config**] → [**Record**] can record all the configurations.
   - Selecting [**Cancel**] can close the dialog box and return to the normal operating mode.

21.4 Exporting Configurations

1. Connect the USB flash memory to the equipment's USB connector.
2. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
3. Press the Main Menu button on the front panel.
4. Enter the Configuration Main menu by either of the following ways:
   - Select [**Others >>**] → [**Configuration >>**] → [**View Config**].
   - Select [**Others >>**] → [**Configuration >>**] → enter the required password
5. Select [**Config. Export**].

21.5 Importing Configurations

It is not necessary to configure each equipment separately when installing several equipments with identical configurations. A USB flash memory can by used to import configurations from one equipment to another.

1. Prepare a USB flash memory with desired configurations.
2. Connect the USB flash memory to the target equipment's USB connector.
3. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
4. Press the Main Menu button on the front panel.
5. Enter the Configuration Main menu by either of the following ways:
   - Select [**Others >>**] → [**Configuration >>**] → [**View Config**].
   - Select [**Others >>**] → [**Configuration >>**] → enter the required password
6. Select [**Config. Import**]

21.6 Changing Configurations

You can change configurations either by changing settings in each configuration setup menu, or restoring to factory defaults.

1. Switch the Mode Select knob to Monitor, Manual Defib or Pacer.
2. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
   - Selecting [**Factory Default**] can restore all the current settings to factory defaults.
   - Select the desired setup menu, and change the settings.
   - Selecting [**Record**] can record all the current settings.

21.6.1 General Setup Menu

Menu Item	Options/Range	Default	Description
Device Name	20 characters	/	Inputs the relevant information. The characters are included in the keyboard. Restoring factory default configurations does not change these settings. If the equipment is connected to the CMS, [**Bed No.**] and [**Department**]can also be changed on the CMS.
Institution	20 characters	/	
Department	20 characters	/	
Bed No.	20 characters	/	
Patient Cat.	Adu, Ped, Neo	Adu	Sets the default patient category.
Patient Info Display	Bed No., Patient Name	Bed No.	Sets the patient information type displayed in the upper left corner of the main screen.
Height Unit	cm, inch	cm	Sets the default measurement unit for the patient.
Weight Unit	kg, lb	kg	

Menu Item		Options/Range	Default	Description
Language		/--	/	Sets the language for voice and text prompts.
Date Format		yyyy-mm-dd, mm-dd-yyyy, dd-mm-yyyy	yyyy-mm-dd	Sets the system date format.
Time Format		12 h, 24 h	24 h	Sets the system time format.
System Time	Year	2007 to 2099	2007	Sets the system date. Configurable range: 2007-01-01 to 2099-05-31.
	Month	01 to 12	01	
	Day	01 to 31	01	
	Hour	24 h: 00 to 23 12 h: 12AM to 11PM	24 h: 00 12 h: 12AM	Sets the system time.
	Minute	00 to 59	00	
	Second	00 to 59	00	

21.6.2 Manual Defib Setup Menu

Menu Item	Options/Range	Default	Description
Manual Therapy Access	Direct, Confirmed, Password	Direct	Sets the way you access the Manual Defib mode and Pacer mode. • [**Direct**]: you can directly access the Manual Defib mode and Pacer mode. • [**Confirmed**]: a dialog box pops up for the confirmation when you access the Manual Defib mode and Pacer mode. • [**Password**]: a dialog box pops up requiring the password when you access the Manual Defib mode and Pacer mode.
Set Password	4 digits	0000	[**Set Password**] is active only when [**Manual Therapy Access**] is set to [**Password**].
Default Energy for Adult	100 J, 150 J, 170 J, 200 J, 300 J, 360 J	200 J	Sets the energy level for the external defibrillation.
Default Energy for Pediatric	10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J	50 J	
Internal Default	2, 5, 10, 20, 30, 50	10 J	Sets the energy level for the internal defibrillation.
Sync After Shock	Yes, No	No	Sets whether the equipment remains in synchronized cardioversion after a delivered shock.
Remote Sync	On, Off	Off	Sets whether to enable the remote synchronized cardioversion.
Time to Auto Disarm	30 s, 60 s, 90 s, 120 s	60 s	Sets the time the equipment automatically removes the stored energy internally.
Monitor Para.	SpO2, NIBP, CO2, Off	Off	Sets the parameter monitored in the auxiliary parameter area of the Manual Defib mode and AED mode.

Menu Item	Options/Range	Default	Description
Charge Tone Vol	High, Med, Low	Med	Sets the tone volume during the charge, and when the charge is completed. This setting is also effective in the AED mode.
Contact Impedance Indicator	On, Off	Off	Sets whether to display the contact impedance indicator.
Maximum Defib. Energy	360 J	360 J	Sets the maximum energy level for the delivered shock.

21.6.3 AED Setup Menu

Menu Item	Options/Range	Default	Description
Shock Series	1, 2, 3	1	Sets the number of shocks. If it is set to greater than one, the equipment resumes analyzing the patient's rhythm after the shock is delivered to determine if the shock was successful. Prompts for shock counter are provided to guide you delivering additional shocks.
Energy 1 (Adu)	100 J, 150 J, 170 J, 200 J, 300 J, 360 J	200 J	Sets the defibrillation energy level for the first shock on the adult patient.
Energy 2 (Adu)	Energy 1 to 360J	300 J	Energy 1 ≤ configurable value ≤ Energy 3
Energy 3 (Adu)	Energy 2 to 360J	360 J	Energy 2 ≤ configurable value
Energy 1 (Ped)	10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J	50 J	Sets the defibrillation energy level for the first shock on the pediatric patient.
Energy 2 (Ped)	Energy 1 to 100 J	70 J	Energy 1 ≤ configurable value ≤ Energy 3
Energy 3 (Ped)	Energy 2 to 100 J	100 J	Energy 2 ≤ configurable value
Time to Auto Disarm	30s, 60s, 90s, 120s	30s	Sets the time the equipment automatically removes the stored energy internally.
CPR Mode (Adu)	30:2, 15:2, Compression only	30:2	Sets the rate of compression and ventilation.
CPR Mode (Ped)		15:2	
CPR Time	30 s, 60 s, 90 s, 120 s, 150 s, 180 s	120 s	Sets the interval for the CPR administration.
NSA Action	Monitor, CPR	CPR	Sets what status the equipment will enter.after **"No Shock Advised!"** is given. • [**CPR**]: the equipment enters the CPR status. • [**Monitor**]: the equipment continues to monitor the ECG and automatically resumes analysis if a potentially shockable rhythm is detected.
Voice Prompts	On, Off	On	Sets whether voice prompts are provided in the AED mode.

Menu Item	Options/Range	Default	Description
Voice Volume	High, Med, Low	High	Sets the volume level for voice prompts in the AED mode.
Voice Prompt Interval	Off, 30s, 60s, 90s, 120s, 150s, 180s	30s	Sets the interval for voice prompts in the AED mode.
Voice Recording	On, Off	Off	Sets whether to enable the voice recording in the AED mode.
Initial CPR Time	Off, 30 s, 60 s, 90 s, 120 s, 150 s, 180 s	Off	Sets the initial CPR time after the AED mode is entered.

21.6.4 Pacer Setup Menu

Menu Item	Options/Range	Default	Description
Pacer Rate	30 to 210 ppm	70 ppm	Sets the delivered rate of paced pulses.
Pacer Output	0 to 200 mA	30 mA	Sets the paced pulses duration.
Pacer Output Step	1 mA, 2 mA, 5 mA	5 mA	Sets the step of paced pulses duration.
Default Pacer Mode	Demand Mode, Fixed Mode	Demand Mode	Sets the pacer mode when entering the Pacer mode.
Pacer Pulse	20 ms, 40 ms	20 ms	Sets the pacer output setting at which pace pulses are delivered.

21.6.5 CPR Setup Menu

Menu Item	Options/Range	Default	Description
CPR Metronome	On, Off	On	Sets whether the compression are performed at the setting of [**CPR Mode**]
Voice Prompts	On, Off	On	Sets whether voice prompts are provided when using a CPR sensor.
CPR Filter	On, Off	Off	Sets whether to enable the CPR filter when performing CPR.

21.6.6 ECG Setup Menu

Menu Item	Options/Range	Default	Description
ECG Standard	AHA, IEC	AHA	Sets the ECG standard according to the leadwires you are using.
Notch Filter	50 Hz, 60 Hz	50 Hz	The notch filter removes the line frequency interference.Sets notch filter frequency according to the power line frequency of your country.
ECG Bandwidth	Monitor, Therapy	Therapy	Sets the filter frequency for 3-/5-lead ECG cable.

Menu Item	Options/Range		Default	Description
Lead Set	3-Lead, 5-Lead		3-Lead	Sets the ECG lead type. This setting affects the default waveform position of the [**Waveform Setup**] menu.
QRS Volume	0 to 10		2	This setting is linked with the [**QRS Volume**] setting in the [**SpO2 Setup**] menu
ECG1	3-Lead: I, II, III		II	Available options are defined by the current setting of [**Lead Set**].
	5-Lead: I, II, III, aVL, aVR, aVF, V			
ECG2	3-Lead: I, II, III		/	• If 3-lead is used, the default setting of this item is blank and this item is inactivate. • The options of [**ECG1**] are not available for [**ECG2**].
	5-Lead: I, II, III, aVL, aVR, aVF, V		V	
Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s		25 mm/s	Sets the ECG waveform speed.
HR Alarm	On, Off		On	/
HR Alm Lev	High, Med		Med	/
HR High	Adu	(Low+2) to 300	120	Step: 1 bpm
	Ped	(Low+2) to 300	160	
	Neo		200	
HR Low	Adu	15 to (High-2)	50	
	Ped		75	
	Neo		100	
Arrhythmia	On, Off		Off	Sets whether to enable the arrhythmia analysis.
ARR Alarm	On, Off		On	/

Menu Item		Options/Range	Default	Description
ARR Alm Lev	PVCs/min	High, Med, Low	Med	/
	R ON T			
	VT>2			
	Couplet			
	PVC			
	Vent Rhythm			
	Bigeminy			
	Trigeminy			
	Tachy			
	Brady			
	PNP			
	PNC			
	Missed Beat			
	A-Fib			
	Multif. PVCs			
	Nonsus. Vtac			
	Pause			
	Irr. Rhythm			
Asystole Delay		3 to 10	5	/
V-Tach Rate		100 to 200	130	/
V-Tach PVCs		3 to 99	6	/
Vbrd Rate		15 to 60	40	/
Vbrd PVCs		3 to 99	5	/
Extreme Tachy	Adu	60 to 300	160	/
	Ped	60 to 300	180	/
Extreme Brady	Adu	15 to 120	35	/
	Ped	15 to 120	50	/
PVCs High		1 to 10	10	/
Tachy	Adu	60 to 300	120	/
	Ped	60 to 300	160	/
Brady	Adu	15 to 120	50	/
	Ped	15 to 120	75	/
Multif. PVCs Window		3 to 31	15	/
Pause Time		1.5, 2.0, 2.5	2.0	/

21.6.7 Resp Setup Menu

Menu Item	Options/Range		Default	Description
RR Alarm	On, Off		Off	/
RR Alm Lev	High, Med, Low		Med	/
Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s		6.25 mm/s	Sets the Resp waveform speed.
RR High	Adu	(Low+2) to 100	30	Step: 1 rpm
	Ped		30	
	Neo	(Low+2) to 150	100	
RR Low	Adu	6 to (High-2)	8	
	Ped		8	
	Neo		30	
Apnea Time	10 s, 15s, 20s, 25s, 30s, 35s, 40s		20 s	/

21.6.8 SpO_2 Setup Menu

Menu Item		Options/Range		Default	Description
SpO2 Alarm		On, Off		On	/
SpO2 Alm Lev		High, Med		Med	/
Sweep		12.5 mm/s, 25 mm/s		25 mm/s	Sets the SpO_2 waveform speed.
SpO2 High		Adu	(Low+1) to 100	100	Step: 1%
		Ped		100	
		Neo		95	
SpO2 Low		Adu	Desat Limit to (High-1)	90	
		Ped		90	
		Neo		90	
Desat		Adu	50 to (High-1)	80	
		Ped		80	
		Neo		80	
Pitch Tone		Mode 1, Mode 2		Mode 1	Sets the SpO_2 tone mode.
Sat-Seconds		0s, 10s, 25s, 50s, 100s		0s	For Nellcor SpO_2 module only.
Sensitivity	Mindray SpO_2	High, Med, Low		Med	Different options are available to match the SpO_2 module used.
	Masimo SpO_2	High, Normal, APOD		Normal	
Average Time		2-4s, 4-6s, 8s, 10s, 12s, 14s, 16s		8s	For Masimo SpO_2 module only.
Fast SAT		On, Off		Off	
Display SIQ		On, Off		Off	
Alarm Delay		0s to 15s		6s	

21.6.9 PR Setup Menu

Menu Item	Options/Range		Default	Description
PR Alarm	On, Off		Off	/
PR Alm Lev	High, Med, Low		Med	/
PR High	Adu	(Low+2) to 300	120	Step: 1 bpm PR ranges are different for different modules.
	Ped		160	
	Neo		200	
PR Low	Adu	15 to (High-2)	50	
	Ped		75	
	Neo		100	
QRS Volume	0 to 10		2	This setting is linked with the [**QRS Volume**] setting in the [**ECG Setup**] menu

21.6.10 NIBP Setup Menu

Menu Item		Options/Range		Default	Description
Interval		Manual, 1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 1.5 h, 2 h, 3 h, 4 h, 8 h		Manual	Sets the interval between NIBP measurements.
Press. Unit		mmHg, kPa		mmHg	Sets the NIBP measurement unit. Alarm limits are refreshed in real time when pressure unit is changed.
Alarm	NIBP-Sys	On, Off		On	/
	NIBP-Dia				
	NIBP-Mean				
Alm Lev		High, Med		Med	/
Sys High		Adu	(Low+5) to 290	160	Step: 1 mmHg
		Ped	(Low+5) to 240	120	
		Neo	(Low+5) to 140	90	
Sys Low		Adu	25 to (High-5)	90	
		Ped		70	
		Neo		40	
Mean High		Adu	(Low+5) to 260	110	
		Ped	(Low+5) to 215	90	
		Neo	(Low+5) to 125	70	
Mean Low		Adu	15 to (High-5)	60	
		Ped		50	
		Neo		25	

Menu Item	Options/Range		Default	Description
Dia High	Adu	(Low+5) to 250	90	Step: 1 mmHg
	Ped	(Low+5) to 200	70	
	Neo	(Low+5) to 115	60	
Dia Low	Adu	10 to (High-5)	50	
	Ped		40	
	Neo		20	

21.6.11 CO_2 Setup Menu

Menu Item	Options/Range		Default	Description
Alarm	On, Off		On	/
Alm Lev	High, Med		Med	/
Press. Unit	mmHg, kPa, %		mmHg	Sets the CO_2 measurement unit. Alarm limits are refreshed in real time when pressure unit is changed.
Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s		6.25 mm/s	Sets the CO_2 waveform speed.
Scale	mmHg	15, 20, 25, 40, 50, 60, 80	50	Different options are available to match the selected pressure unit.
	kPa	2, 2.5, 3.5, 5, 7, 8, 10	7	
	%	2, 2.5, 3.5, 5, 7, 8, 10	7	
$EtCO_2$ High	Adu	(Low+2) to 99	50	Step: 1 mmHg The range is different according to the selected pressure unit. The default pressure unit is mmHg.
	Ped		50	
	Neo		45	
$EtCO_2$ Low	Adu	1 to (High-2)	25	
	Ped		25	
	Neo		30	
$FiCO_2$ High	Adu	1 to 99	4	
	Ped		4	
	Neo		4	
awRR High	Adu	(Low+2) to 100	30	Step: 1 rpm
	Ped		30	
	Neo	(Low+2) to 150	100	
awRR Low	Adu	6 to (High-2)	8	
	Ped		8	
	Neo		30	
Apnea Time	10 s, 15s, 20s, 25s, 30s, 35s, 40s		20s	The equipment gives an apnea alarm if the patient has stopped breathing for longer than the preset apnea time.

21.6.12 Alarm Setup Menu

Menu Item		Options/Range	Default	Description
Alarm Pause Time		1, 2, 3, 5, 10, 15 min, Permanent	2 min	Sets the alarm pause time.
Audio Off		Enabled, Disabled	Disabled	Sets whether the audible alarm tones are turned off.
Alm Volume		• [**Audio Off**] is enabled: 0 to 10. • [**Audio Off**] is disabled: 1 to 10.	2	Sets the alarm volume level.
Reminder Tone		On, Off	Off	Sets whether the equipment gives a reminder tone when alarm or alarm sounds are turned off.
Reminder Volume		High, Med, Low	Med	Sets the reminder tone volume.
Latching Alarms		Yes, No	No	Sets how alarm indicators behave if you do not reset the physiological alarms.
Displaying Alarm Limits		Yes, No	Yes	Sets whether to display the alarm limits.
ECGLeadOff Lev.		High, Med, Low	Low	Sets the alarm level for "**ECG Lead Off**".
SpO2SensorOff Lev.		High, Med, Low	Low	Sets the alarm level for "**SpO2 Sensor Off**".
No Battery		Status Indicator On, Status Indicator Off	Status Indicator On	Sets how the status indicator behaves if no battery is installed.
Alarm Tone Interval	High Level Alarm (s)	3 to 15s	10s	Sets the interval between alarm tones.
	Med Level Alarm (s)	3 to 30s	20s	
	Low Level Alarm (s)	16 to 30s	20s	

21.6.13 Waveform Setup Menu

Menu Item		Options		Default	Description
Wave 1		/	ECG1	ECG1	Unchangeable
Wave 2		3-Lead	Pleth, CO2, Resp	Pleth	For optional parameters, options of waveforms are available only when the parameters are configured.
		5-Lead	ECG2, Pleth, CO2, Resp	ECG2	
Wave 3		3-Lead	Pleth, CO2, Resp	CO2	
		5-Lead		Pleth	
CO2 Wave Type		Draw, Fill		Draw	Set the CO_2 waveform type.
Parameter/ Wave Color	ECG	Green, Yellow, Cyan, White, Red, Blue, Purple, Orange		Green	Sets the parameter color.
	Resp			Yellow	
	SpO2			Cyan	
	NIBP			White	
	CO2			Yellow	

21.6.14 Mark Event Setup Menu

Menu Item	Options/Range	Default	Description
Event A	Generic	Generic	Unchangeable
Event B	Adrenalin, Lidocaine, Atropine, Nitroglycerin, Morphine, Intubation, IV Access, Adenosine, Amiodarone, Vasopressin, Isoprenaline, Dopamine, Aspirin, Oxygen, CPR	Adrenalin	Event names that have been selected by previous events will not be included in the options of later events.
Event C		Lidocaine	
Event D		Atropine	
Event E		Nitroglycerin	
Event F		Morphine	
Custom Event 1	Options: entering event name using the keyboard included in the [**Mark Event Setup**] menu. Range: 1 to 20 characters	/	After being defined, custom event is refreshed in real-time in the Mark Event list.
Custom Event 2			

21.6.15 Record Setup Menu

Menu Item		Options/Range	Default	Description
Wave Length		8s, 16s, 32s, STAT	8s	Sets the recording time of recorded waveform.
Paper Speed		6.25 mm/s, 12.5 mm/s, 25mm/s, 50mm/s	25mm/s	Sets the recording speed.
Energy Delivered Output		On, Off	Off	Sets whether the energy level of a delivered shock is displayed in the event recording.
Gridlines		On, Off	On	Sets whether the recording waveforms are displayed with gridlines.
Auto Record	Charge Event	On, Off	Off	Sets whether the event is automatically recorder when the related event is triggered.
	Shock Event		On	
	Marked Event		Off	
	Auto Test Report	On, Off, Only if Failed	Off	Sets whether the auto test report is automatically recorded when the auto test is completed. • [**On**]: the auto test report is automatically recorded when the auto test is completed. • [**Off**]: the auto test report is not recorded when the auto test is completed. • [**Only if Failed**]: the auto test report is automatically recorded when the auto test is completed and the auto test fails.

Menu Item		Options/Range	Default	Description
Alm Rec	HR	On, Off	Off	Sets whether the parameter is automatically recorded when the related alarm is triggered.
	ARR			
	PVCs			
	Resp			
	SpO2			
	PR			
	NIBP			
	CO2			

21.6.16 Data Management Setup Menu

Menu Item	Options/Range	Default	Description
Tabular Trends Interval	1 min, 2 min, 5 min, 10 min, 15 min, 30 min, 60 min	5 min	Sets the interval that trends are stored.
Event Wave Length	8s, 16s, 32s	16 s	Sets the length that events are stored.

21.6.17 Test Setup Menu

Menu Item	Options/Range	Default	Description
User Test Prompt	On, Off	Off	Sets whether the equipment reminds to perform the user test if the recommended test time is reached.
Auto Test Time	24 h: 00 to 23 12 h: 12AM to 11PM	3:00	Sets the initiated time for auto test performed every day.

21.6.18 Network Setup

Menu Item	Options/Range	Default	Description
Network Type	LAN, WLAN	LAN	Sets the network type.
Address Type	DHCP, Manual	DHCP	• If [**Address Type**] is set to [**DHCP**]: the equipment automatically gets the IP address. • If [**Address Type**] is set to[**Manual**]: [**Local IP Address**], [**Subnet Mask**] and [**Gateway**] are required. Restoring factory default configurations does not change this setting.
Local IP Address	0 - 255	0. 0. 0. 0	
Subnet Mask	0 - 255	0. 0. 0. 0	
Gateway	0 - 255	0. 0. 0. 0	
DNS Address Type	DHCP, Manual	DHCP	• If [**DNS Address Type**] is set to [**DHCP**]: the equipment automatically gets the DNS address. • If [**DNS Address Type**] is set to[**Manual**]: [**Preferred DNS Server**] and [**Alternate DNS Server**] are required.
Preferred DNS Server	0 - 255	0. 0. 0. 0	
Alternate DNS Server	0 - 255	0. 0. 0. 0	

Menu Item		Options/Range	Default	Description
Default Network Connection		On, Off	Off	Sets whether the CMS is automatically connected after turned on. Restoring factory default configurations does not change this setting.
Site Setup	Select Site	1, 2	1	Sets the desired CMS. Restoring factory default configurations does not change this setting.
	Site Name	0 to 20 characters	/	
	Site Address	0 to 63 characters	/	
HL7 Configuration - Data + Waveforms	Destination Site	0 to 63 characters	/	Sets the desired HL7 server.
	Port	0-65535	0	
	Send Data	On, Off	Off	Sets whether monitoring parameters are automatically sent to the HL7 server.
	Data Interval	1s, 30s, 5min, 30min, 1h	1 s	Sets the interval for sending data to the HL7 server.
	Send Waveforms	On, Off	Off	Sets whether waveforms are automatically sent to the HL7 server.
HL7 Configuration - Alarms	Destination Site	0 to 63 characters	/	Sets the desired HL7 server.
	Port	0-65535	0	
	Send Alarms	On, Off	Off	Sets whether alarms are automatically sent to the HL7 server.

21.6.19 Others Menu

Menu Item		Options/Range	Default	Description
Brightness		1 to 10	8	Sets the display brightness.
Key Volume		0 to 10	2	Sets the key volume.
Wave Line		Thick, Medium, Thin	Medium	Sets the thickness of displayed waveform.
Draw Wave		Mono, Color	Color	Sets the color mode of displayed waveform.
Modules	SpO2	On, Off	On	Sets whether to enable the parameter module.
	NIBP			
	CO2			
	Resp			
Modify Password		0 to 32 characters	/	The characters are included in the keyboard. Restoring factory default configurations does not change this setting.

22 Battery

22.1 Battery Introduction

The equipment is designed to operate on battery power when external power supply is not available. The battery is charged whenever the equipment is connected to AC mains or the DC power supply through an external DC/AC adapter, regardless of whether or not the equipment is currently turned on. In case of power failure, the equipment will automatically run power from internal batteries. So we recommend you always install a fully charged battery in the equipment.

The equipment is configured with one smart lithium ion battery which is free of maintenance.

On-screen battery symbols indicate the current battery charge status:

-  ≤100%, but >80% of capacity
-  ≤80%, but >60% of capacity
-  ≤60%, but >40% of capacity
-  ≤40%, but >20% of capacity
-  ≤ 20% of capacity
-  Low battery and charging is required immediately
-  Battery is not installed

You can also check the battery's charge status by pressing the fuel gauge button on the battery to illuminate the battery gauge. The fuel gauge consisting of 5 LEDs, each LED represents a charge of approximately 20% of capacity.

22.2 Battery Safety Information

WARNING

- **The batteries should be charged in this equipment or in a device approved by the equipment manufacturer.**
- **Keep the batteries out of children's reach.**
- **Use only specified batteries.**

NOTE

- **Always connect the equipment to AC mains whenever it is possible.**
- **Always install a fully charged battery in the equipment.**
- **After long term use, the power capacity indicated by the battery symbol may be different from the actual capacity. Always observe the alarm information displayed on the screen.**
- **Remove the battery before transporting the equipment or if the equipment will not be used for a long time.**

22.3 Installing the Battery

To install the battery:

1. Align a battery with the battery compartment.
2. Insert the battery, and press until you hear it click into the place.

To replace a battery, press the latch on the battery and push the battery to the right until you remove it. Insert a new battery into the battery compartment.

22.4 Battery Alarms

22.4.1 No Battery Alarm

You can configure the status of status indicator when no battery is installed from the Configuration Main menu.

1. Press the Main Menu button on the front panel of the equipment, and select [**Others >>**] → [**Configuration >>**] → enter the required password.
2. Select [**Alarm Setup**].
3. Set [**No Battery**].
   - [**Status Indicator On**]: the red cross status indicator flashes in the case that battery is not installed, meanwhile a message "**No Battery**" is presented.
   - [**Status Indicator Off**]: the red cross status indicator will not be illuminate in the case that battery is not installed, the message "**No Battery**" will be presented.

22.4.2 Low Battery Alarm

If the equipment is run on battery and the battery charge is low, a technical alarm "**Low Battery**" will be triggered. In this case, replace the battery with a fully charged on or connect the equipment to external power supply immediately.

If the battery is almost depleted, a prompt "**Battery depleted! System will shut down immediately. Connect to AC mains or replace battery.**" pops up. In the Monitor mode, Manual Defib mode, and Pacer mode, additional alarm lights and alarm tones are provided. In this case, take appropriate actions immediately. This prompt will not disappear until the battery is replaced or the equipment is connected to the external power supply. The equipment automatically shuts down if no action is taken within a period of about 3 minutes.

NOTE

- **The alarm "Low Battery" means that the battery is beginning to weaken and should be replaced at the first opportunity. At least 20 minutes of monitoring and six 360J shocks can be performed when "Low Battery" is triggered. Replace the battery or connect the equipment to AC mains as soon as possible.**

22.4.3 Battery Aged Alarm

If the battery runtime is significantly shorter than the specification, a low level technological alarm "**Battery Aged**" will be presented. We recommend you to replace with a new one.

22.4.4 Battery Error Alarm

In the situation that the battery has a failure, a high level technological alarm "**Battery Err**" will be presented. In this case, replace the battery or contact your service personnel.

22.5 Conditioning the Battery

The performance of batteries deteriorates over time. To extend the battery service life, you are recommended to condition the batteries every three months.

If the battery is not conditioned for a prolonged time, its charge indication may not be accurate and you may wrongly evaluate the remaining battery runtime.

To condition a battery:

1. Disconnect the equipment from the patient and stop all performances.
2. Allow the battery to be charged uninterruptedly till it is fully charged.
3. Allow the equipment to run on the battery until the battery is completely depleted and the equipment automatically shuts down.
4. Fully charge the battery again for use or charge it to 40 to 60% for storage.

NOTE

- **Do not use the equipment during battery conditioning.**
- **Do not interrupt battery conditioning.**

22.6 Checking Battery Performance

Life expectancy of a battery depends on how frequent and how long it is used. When properly used, the lithiumion battery has a useful life of approximately two years. If improperly used, its life expectancy can be shorten. We recommend replacing lithium-ion batteries every two years.

The performance of a rechargeable battery deteriorates over time. To extend the battery service life, you are recommended to check the battery performance every three months or if you doubt that the battery may fail.

See steps 1 to 3 of *22.5 Conditioning the Battery*to check battery performance. The operating time of the batteries reflects their performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, the battery may reach its service life or malfunction. If the battery performance meets the requirement, fully charge the battery again for use or charge it to 40 – 60% for storage.

NOTE

- **Battery operating time depends on the device configuration and operation. For example, measuring NIBP repeatedly will shorten the battery operating time.**

22.7 Charging the Battery

The batteries can be charged only when they are installed in the equipment or using the charger station approved by the equipment manufacturer. Batteries charge at a lower rate with the equipment turned on.

22.8 Storing Batteries

When storing batteries, make sure that the battery terminals do not come into contact with metallic objects. If batteries are not installed in the equipment, and stored for an extended period of time, they should be placed in a cool place with a partial charge of 40% to 60% capacity (3 LEDs illuminated).

Condition the stored batteries every three months. For details, refer to *22.5 Conditioning the Battery*.

NOTE

- **Remove the battery from the equipment if the equipment is not used for a prolonged time (for example, several weeks). Otherwise the battery may overdischarge.**
- **Storing batteries at high temperature for an extended period of time will significantly shorten their life expectancy.**
- **The battery storage temperature is between -20°C (-4°F) and 60°C (140°F). Storing batteries in a cool place can slow the aging process. Ideally the batteries should be stored at 15 °C.**

22.9 Recycling the Batteries

A battery should be discarded if there are visual signs of damage, the battery fails, the battery aged alarm is presented, or the batteries has been used for more than two years. Properly dispose of batteries according to local regulations.

WARNING

- **Do not disassemble, puncture or incinerate batteries. Do not short the battery terminals. They may ignite, explode, or leak, causing personal injury.**

23 Care and Cleaning

Use only the substances approved by the equipment manufacturer and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damages caused by unapproved cleaning and disinfection substances or methods.

We make 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.

In this chapter we only describe cleaning and disinfection of the main unit. For the cleaning and disinfection of external paddles, internal paddles and other reusable accessories, refer to instructions for use of corresponding accessories.

WARNING

- **The responsible hospital or institution shall carry out all cleaning and disinfection procedure specified in this chapter.**

23.1 General Points

Keep the equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Keep the paddles clean, Before user checks or after each use, thoroughly clean the paddles and paddle tray.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

WARNING

- **Be sure to shut down the system, disconnect the power cord and other cables, and remove the batteries before cleaning the equipment.**

CAUTION

- **Contact your service personnel in case of spilling liquid on the equipment or accessories.**

NOTE

- **To clean or disinfect reusable accessories, refer to the instructions for use delivered with the accessories.**

23.2 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Water
- sodium hypochlorite bleach (10%, Sodium hypochlorite)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropyl alcohol (70%)
- Perform® classic concentrate OXY ($KHSO_4$ solution)

To clean your equipment, follow these rules:

1. Shut down the equipment, disconnect the power cord and other cables, and remove the batteries.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft, clean cloth dampened with a glass cleaner.
4. Clean the paddle tray using a soft, clean cloth dampened with a glass cleaner.
5. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
6. Dry your equipment in a ventilated, cool place.

23.3 Disinfecting

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

23.4 Sterilization

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

24 Maintenance

24.1 Maintenance Introduction

The equipment must be maintained to be ready for immediate use. To ensure proper performance of the equipment, you should strictly perform the maintenance in this chapter. After the equipment has been used for 12 months, or whenever the equipment is repaired or upgraded, a thorough inspection should be performed to ensure the reliability.

Make sure to clean and disinfect the equipment before any test and maintenance.

In case of any damage or abnormality, remove the equipment from use. Contact the hospital's biomedical engineers or your service personnel immediately.

24.2 Maintenance Safety Information

WARNING

- **Failure for the responsible individual, hospital or institution employing 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 professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **If you find a problem with any of the equipment, contact your service personnel or the manufacturer.**
- **No modification of this equipment is allowed.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.**
- **Do not touch, connect or apply any electrode pads and paddles during user test and auto test. Otherwise, electric shock could result.**

24.3 Routine Maintenance

The routine maintenance should be periodically performed in conjunction with the assurance program of the hospital where the equipment is used. The following test are recommended:

Maintenance Item	Recommend Frequency	Test Item
Shift check	Every shift, or at least every day.	For details, refer to *D Defibrillator Shift Checklist*.
Auto test	Automatically, whenever the equipment is turned on.	Performs tests of the main control board, therapy module, monitor module, batteries.
	Every day, 3:00 am by default	Performs tests of the main control board, therapy module, monitor module, batteries, 1 J internal discharge, 10 J internal charge/external discharge*.
	Every week	Performs tests of the main control board, therapy module, monitor module, batteries, 1 J internal discharge, 10 J internal charge/external discharge*, 200 J and 360 J internal discharges.

Maintenance Item	Recommend Frequency	Test Item
User test	Every week	• Routine test: performs tests of the main control board, therapy module, monitor module, batteries, 1 J internal discharge, 50 J internal charge/external discharge*. • Energy delivery test: performs tests of 360 J internal charge/external discharge*, optional 200 J internal discharge connected with the battery.
	Every year	Controls test: performs tests of all knobs and buttons on the front panel, the audio, display and status indicator.
* If the pads cable is connected with 50 Ω test load or external paddles are placed in the paddle tray, an external discharge is performed. Otherwise, an internal discharge is performed.		

External paddles and pads cable are critical parts for defibrillation but damageable. It is recommended to inspect the appearance and performance of these parts every day and replace them every 3 years.

The ECG cables are critical parts for data acquisition and analysis but damageable. It is recommended to inspect the appearance and performance of the cable every day as described in *D Defibrillator Shift Checklist*.

24.3.1 Auto Test

The equipment with AC mains connected carries out auto test at the configured time even when turned off to check the equipment's operational performance and alert the operator if a problem exists.

The auto test is initiated at 3:00 am every day by default. You can change the initiated time by selecting [**Test Setup]** through the Configuration Main menu.

The equipment displays no information on the screen during the auto test.

You can check the auto test result according to the following table:

From	Pass	Fail
Status indicator and alarms	• The status indicator is off. • No alarms are displayed on the screen.	• The red cross status indicator flashes. • The equipment gives a beep periodically until the equipment is restarted. • The alar m "**Last Auto Test Failed**" is displayed.
User Test Main menu	From the User Test Main menu, select the [**History**] soft key to check the test result. For details, refer to *24.3.2.2 Viewing the User Test Summaries*.	
CMS	If the equipment is connected to the CMS, the auto test report will be automatically transmitted to the CMS at the completion of the auto test. For details on connecting to the CMS, refer to *20.3 Connecting the CMS*.	

It is recommended to perform the user test if the auto test failed. For details, refer to *24.3.2 User Test*.

When the auto test is completed, an auto-test report is saved automatically. You can select [**Record Setup**] through the Configuration Main menu to choose whether to automatically record the auto-test report or not when the auto testis completed.

NOTE

- **When the auto test is passed with the message "Test load not connected with cable", this means the equipment only passes the internal discharge test. The discharge test by connecting the test load is not performed.**
- **If turned off, the auto test is performed only when AC mains is connected.**
- **Thoroughly clean the external paddles and properly place them in the paddle tray after each use. The auto test passes only when external paddles properly contact the metal parts of the paddle tray.**
- **Install at least one battery and properly place the external paddles in the paddle tray or connect the pads cable and 50 Ω test load. Otherwise the auto test will fail.**

24.3.2 User Test

If the auto test fails, the user test must be performed to clear the faults.

When turned on, the equipment automatically checks the time to Routine Test, Energy Delivery Test and Controls Test performed last time. The equipment can be configured to give a "**User Test Due**" message to remind performing the user test. You can enable it by selecting [**Test Setup**] through the Configuration Main menu.

WARNING

- **Do not perform the user test when a patient is connected to the equipment.**

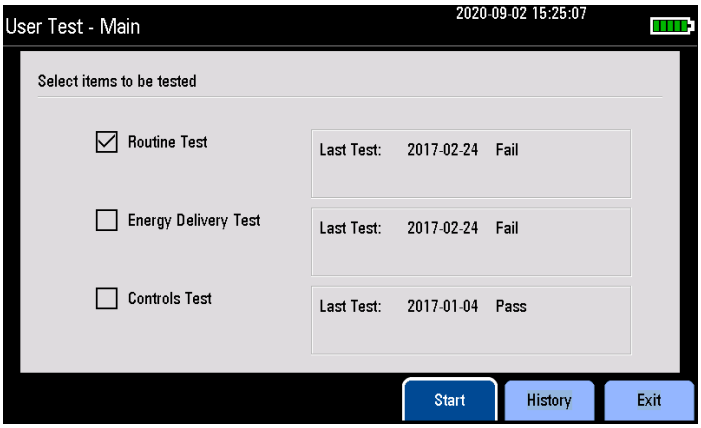
NOTE

- **Before the user test or after each use, thoroughly clean the external paddles and properly place them in the paddle tray. The user test passes only when external paddles properly contact the metal parts of the paddle tray.**
- **If the impedance value indicated by impedance indicator changes greatly, check that external paddles and metal parts of the paddle tray are clean.**
- **Install at least one battery and properly place the external paddles in the paddle tray or connect the pads cable and 50 Ω test load. Otherwise the user test will fail.**

24.3.2.1 Starting the User Test

You can start the user test mode while operating in the Monitor, Manual Defib or Pacer mode. Patient monitoring and therapy automatically end when you enter the User Test Main menu.

1. Press the Main Menu button on the front panel, and then select [**User Test >>**]→ [**Yes**].
2. Select the desired test items and select [**Start**].



3. Perform operations following the displayed instructions.

The message "**Test completed**" will be presented when selected tests have been finished. Then you can select the [**Record**] soft key to record the test result.

NOTE

- **The "Off" position of the Mode Select knob is not tested during the controls test. If you turn the knob to "Off" for more than 10 seconds, the equipment will be turned off.**
- **The tested controls are indicated in green during the controls test.**

24.3.2.2 Viewing the User Test Summaries

The results of the user test are automatically saved as summaries. The equipment can store up to 300 historical test summaries which are listed in the sequence of time, with the latest on the top.

1. Press the Main Menu button on the front panel, and then select [**User Test >>**]→ [**Yes**].
2. Select [**History**].
3. Select the desired item to check the result details.

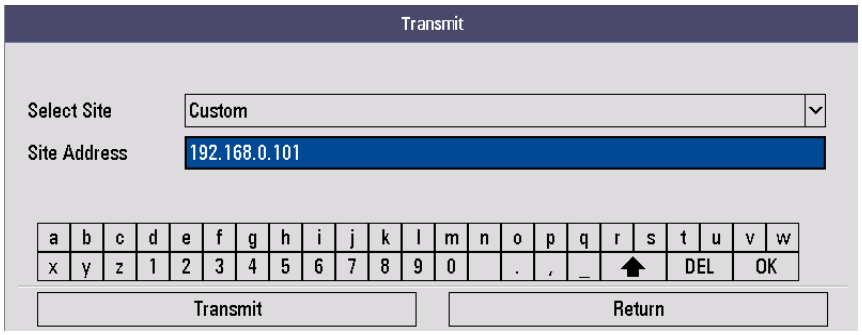
NOTE

- **If the routine test item (external discharge) of the auto test, or the energy delivery test item (external discharge) of the user test is passed, the delivered energy accuracy is displayed, but it is for your reference only.**

24.3.2.3 Transmitting the User Test Summaries

You can also send the user test summaries to the CMS.

1. Press the Main Menu button on the front panel, and then select [**User Test >>**]→ [**Yes**].
2. Enter the [**Transmit**] menu by either of the following ways.
   - Select [**Start**], and select [**Transmit**] at the completion of a user test.
   - Select [**History**], select a desired item, and select [**Transmit**].
3. Set [**Select Site**].
   - A preset site: [**Site Address**] is inputted automatically. For details on configuring a preset site, refer to *20.2.2 Storing Preset Sites*.
   - [**Custom**]: [**Site Address**] needs to be inputted manually.



4. Select [**Transmit**].

The message "**Transmission Complete!**" displays if user test summaries are successfully transmitted.

24.4 Function Checks

The function checks enhance the auto test that helps the equipment to ensure the readiness. It is recommended to perform the function checks once a year. The function checks, except the recorder check, should be performed by Mindray-qualified service personnel only.

24.4.1 Recorder Check

1. Switch the Mode Select knob to Monitor.
2. Start recording to check that the recorder works properly and the printout is legible and correct.
3. Simulate errors, such as removing the paper roll and losing the latch, check that correct information is displayed in the prompt area. The recorder works properly after the faults are cleared.

24.4.2 ECG Cable Test

Test tool: ECG simulator

1. Switch the Mode Select knob to Monitor.
2. Connect the ECG cable to the equipment, and connect the electrodes to the simulator.
3. Turn on the simulator and select a normal ECG rhythm.
4. Wait for a few seconds. Check that the waveform is displayed normally and no lead-off alarms displayed in the alarm information area.

24.4.3 Manual Defibrillation Test

Test tools: defibrillator/pacer analyzer

Charge/Discharge

1. Remove the batteries from the equipment, and connect the equipment with AC mains.
2. Switch the Mode Select knob to Manual Defib.
3. Connect the electrode pads/external paddles to the equipment, and place the electrode pads/external paddles on the defibrillator/pacer analyzer.
4. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
5. Select [**Record Setup**] and set [**Shock Event**] to [**On**].
6. Set the analyzer to Energy Measurement mode. In this case, the energy value displayed should be 0 or blank.
7. Select the energy level to 1J.
8. Charge or discharge the equipment, and check that the energies measured by the analyzer meet the following accuracy:

Selected Energy (J)	Measured Value (J)
1	0 to 3
100	85 to 115
360	306 to 414

9. Set the energy to 100J and 360J respectively, and repeat step 8.
10. Disconnect the equipment from the AC mains, and connect the equipment with fully charged battery.
11. Switch the Mode Select knob to Manual Defib.
12. Repeat steps 3 to 9, and check that the equipment records the shock events automatically and correctly.

Energy Disarming

1. Disconnect the equipment from the AC mains, and connect the equipment with fully charged battery.
2. Switch the Mode Select knob to Manual Defib.
3. Connect the electrode pads/external paddles to the equipment, and place the electrode pads/external paddles on the defibrillator/pacer analyzer.
4. Set the analyzer to Energy Measurement mode, and check that the energy value is 0 or blank.
5. Select the energy level to 360J.
6. Charge the equipment, and check that the charge tone is issued during charging.
7. Press the [**Disarm**] soft key to discharge the energy internally.
8. Check that a prompt "**Charge Removed**" appears on the screen and the charge done tone stops, the value measured by the analyzer is 0J or blank.
9. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
10. Select [**Manual Defib Setup**] and set [**Time to Auto Disarm**] to [**60s**].
11. Set the analyzer to Energy Measurement mode, and check that the energy value is 0 or blank.
12. Select the energy level to 360J.
13. Charge the equipment. After charging is completed, wait 60 seconds to check that the prompt "**Charge Removed**" appears on the equipment and the energy measured by the analyzer is 0J or blank.

Synchronized Cardioversion

1. Connect the electrode pads/external paddles to the equipment, and place the electrode pads/external paddles on the defibrillator/pacer analyzer.
2. Connect the ECG cable to the equipment, and place the ECG electrodes on the defibrillator/pacer analyzer.
3. Set the analyzer to Time Measurement Mode and output normal sinus rhythms, e.g. amplitude value 1mV and HR 60bpm.
4. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Configuration >>**] → enter the required password.
5. Select [**Manual Defib Setup**] and set [**Sync After Shock**] to [**On**].
6. Select the energy level to 10J.
7. Press the [**Enter Sync**] soft key to start synchronized cardioversion. If Remote Sync is switched on, press the [**Enter Sync**] soft key and select [**Local**] to start synchronized cardioversion.
8. Select Pads or Paddles as the ECG source, and charge the equipment.
9. Press the Shock button to deliver a shock. Check the following items:
   - The synchronized discharge succeeds and the delivered energy measured by the analyzer is 10J±2J.
   - The delay time of synchronized cardioversion measured by the analyzer is less than 60ms.
   - The synchronized discharge mark appears on the R wave.
   - The prompt messages are correct during the test.
10. Select lead II as ECG source, and charge the equipment. Repeat step 9.

24.4.4 Pacing Test

Test tools: defibrillator/pacer analyzer

1. Disconnect the equipment from the AC mains, and connect the equipment with fully charged battery.
2. Switch the Mode Select knob to Pacer.
3. Select the Fixed mode.
4. Connect the pads cable to the equipment, and place the pads on the defibrillator/pacer analyzer.
5. Set the analyzer to Pacing Measurement mode. Use test load of 50Ω.
6. Set [**Pacer Rate**] to [**70ppm**] and [**Pacer Output**] to [**30mA**].

7. Press the [**Start Pacing**] soft key. Check that the pacer rate measured by the analyzer is 70 ppm±1ppm and the pacer output measured is 30 mA±5mA.
8. Press the [**Stop Pacing**] soft key, and then set [**Pacer Rate**] to [**170ppm**] and [**Pacer Output**] to [**200mA**].
9. Press the [**Start Pacing**] soft key. Check that the pacer rate measured by the analyzer is 170 ppm±2ppm, and the measured current is 200 mA±10mA.

24.5 Preventive Maintenance

The preventive maintenance should be performed every year by Mindray-qualified service personnel only. The preventive tests includes tests performed in the installation mode, Resp test, SpO_2 test, and electrical safety tests. For details about the preventive tests, see the relevant service manual.

24.5.1 Performing Tests in the Installation Mode

You can enter the installation mode while operating in the Monitor, Manual Defib or Pacer mode. Patient monitoring and therapy automatically end when you enter the installation mode.

1. Press the Main Menu button on the front panel, and then select [**Others >>**] → [**Maintenance >>**] → [**Installation Mode >>**] → enter the required password.
2. Select the desired item and perform the test as recommended in the following table.

Test Item	Description	Recommended Frequency
Maintain NIBP	Performs the NIBP leakage test and NIBP accuracy test.	Every year, or whenever you doubt the NIBP reading
Maintain CO2	Calibrates the CO_2 module.	Every year, or when the readings go far beyond the range.
Version	Displays the equipment information.	/
CPR	Displays the battery information of the CPR sensor.	Every year.
Format Data Card	Formats the storage card.	Every year, data in the storage card is useless, or the card has a failure.
Watchdog Test	Checks if the equipment can be normally restarted.	Every year.
Modify Password	Modifies the password for entering the installation mode.	/

24.5.2 Electrical Safety Tests

For details, refer to *F Electrical Safety Inspection*.

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25 Accessories

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

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the equipment 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.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.**
- **When using the accessories, consider the accessories' operating temperature. Refer to corresponding accessory's instruction for use for details.**

25.1 ECG Accessories

25.1.1 ECG Electrodes

Model	Specification	Applicable patient	PN
31499224	10 pcs/pack	Adult	0010-10-12304
2245	50 pcs/pack	Pediatric	9000-10-07469
2258-3	3 pcs/pack	Neonate	900E-10-04880

25.1.2 12-pin Trunk Cable

Leadwire supported	Model	Compatible with	Type	Applicable patient	PN
3-lead	EV 6202	AHA, IEC	Defibrillation-proof	Pediatric, neonate	0010-30-42720
3/5-lead	EV 6201	AHA, IEC	Defibrillation-proof	Adult, pediatric	0010-30-42719

25.1.3 Lead Sets

3-Electrode Lead Sets					
Type	**Compatible with**	**Model**	**Applicable patient**	**PN**	**Remark**
Clip	IEC	EL6302A	Adult, pediatric	0010-30-42725	/
		EL6304A		0010-30-42732	Long
		EL6306A	Neonate	0010-30-42897	/
		EL6308A	Pediatric	0010-30-42899	/
	AHA	EL6301A	Adult, pediatric	0010-30-42726	/
		EL6303A		0010-30-42731	Long
		EL6305A	Neonate	0010-30-42896	/
		EL6307A	Pediatric	0010-30-42898	/
Snap	IEC	EL6302B	Adult, pediatric	0010-30-42733	/
		EL6308B	Pediatric	0010-30-42901	/
	AHA	EL6301B	Adult, pediatric	0010-30-42734	/
		EL6307B	Pediatric	0010-30-42900	/

5-Electrode Lead Sets					
Type	**Compatible with**	**Model**	**Applicable patient**	**PN**	**Remark**
Clip	IEC	EL6502A	Adult, pediatric	0010-30-42728	/
	IEC	EL6504A		0010-30-42730	Long
	AHA	EL6501A		0010-30-42727	/
	AHA	EL6503A		0010-30-42729	Long
Snap	IEC	EL6502B		0010-30-42736	/
	AHA	EL6501B		0010-30-42735	/

25.1.4 Adapting Cable

Description	Compatible with	Type	PN
12-pin to 6 pin connector	AHA, IEC	Adult, pediatric, neonate	0010-30-43054

25.2 SpO_2 Accessories

25.2.1 Extension Cables

Module type	Applicable patient	PN	Remark
Mindray SpO_2 module	Adult, pediatric, neonate	0010-20-42710	/
Masimo SpO_2 module		040-000332-00	8 pins, purple connector
		0010-30-42738	7 pins, white connector
Nellcor SpO_2 module		0010-20-42712	/

25.2.2 SpO_2 Sensors

Mindray SpO_2 module			
Type	**Model**	**Applicable patient**	**PN**
Disposable	MAX-A	Adult (>30 kg)	0010-10-12202
	MAX-P	Pediatric (10 to 50 kg)	0010-10-12203
	MAX-I	Infant (3 to 20 kg)	0010-10-12204
	MAX-N	Neonate (<3 kg), adult (>40 kg)	0010-10-12205
Single patient use	520A	Adult	520A-30-64101
	520P	Pediatric	520P-30-64201
	520I	Infant	520I-30-64301
	520N	Neonate	520N-30-64401
Reusable	DS-100A	Adult	9000-10-05161
	OXI-P/I	Pediatric, infant	9000-10-07308
	OXI-A/N	Adult, neonate	9000-10-07336
	518B	Adult, pediatric, neonate (Multi-sites)	518B-30-72107
	512E	Adult (Finger type)	512E-30-90390
	512F		512F-30-28263
	512G	Pediatric (Finger type)	512G-30-90607
	512H		512H-30-79061

Masimo SpO_2 Module				
Type	**Model**	**Applicable patient**	**PN**	**Remark**
Disposable	FPS-1901	Pediatric, neonate (wrap type)	0010-10-42626	LNCS-NeoPt-L
	FPS-1862	Neonate (wrap type)	0010-10-42627	LNCS-Neo-L
	FPS-1861	Infant (wrap type)	0010-10-42628	LNCS-Inf-L
	FPS-1860	Pediatric (wrap type)	0010-10-42629	LNCS-Pdt
	FPS-1859	Adult (wrap type)	0010-10-42630	LNCS-Adt

Masimo SpO_2 Module				
Type	**Model**	**Applicable patient**	**PN**	**Remark**
Reusable	FPS-1863	Adult (finger clip)	0010-10-42600	LNCS DC-I
	FPS-1864	Pediatric (finger clip)	0010-10-42634	LNCS-DCIP
	2258	Adult, pediatric, neonate	0010-10-43016	LNCS YI

Nellcor SpO_2 Module			
Type	**Model**	**Applicable patient**	**PN**
Disposable	MAX-A	Adult (>30 kg)	0010-10-12202
	MAX-P	Pediatric (10 to 50 kg)	0010-10-12203
	MAX-I	Infant (3 to 20 kg)	0010-10-12204
	MAX-N	Neonate (<3 kg), adult (>40 kg)	0010-10-12205
Reusable	DS-100A	Adult	9000-10-05161
	OXI-P/I	Pediatric, infant	9000-10-07308
	OXI-A/N	Adult, neonate	9000-10-07336

- 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).

25.3 NIBP Accessories

25.3.1 NIBP Hoses

Type	Applicable patient	PN
Reusable	Adult, pediatric	6200-30-09688
	Neonate	6200-30-11560

25.3.2 Cuffs

Type	Model	Applicable patient	Applied site	Limb Circumference (cm)	Bladder Width (cm)	PN
Reusable	CM1201	Infant	Upper arm	10 to 19	9.2	0010-30-12157
	CM1202	Pediatric		18 to 26	12.2	0010-30-12158
	CM1203	Adult		24 to 35	15.1	0010-30-12159
	CM1204	Large adult		33 to 47	18.3	0010-30-12160
	CM1205	Adult	Thigh	46 to 66	22.5	0010-30-12161

Type	Model	Applicable patient	Applied site	Limb Circumference (cm)	Bladder Width (cm)	PN
Single patient	CM1500A	Neonate	Upper arm	3.1 to 5.7	2.2	001B-30-70692
	CM1500B			4.3 to 8	2.9	001B-30-70693
	CM1500C			5.8 to 10.9	3.8	001B-30-70694
	CM1500D			7.1 to 13.1	4.8	001B-30-70695
	CM1501	Infant		10 to 19	7.2	001B-30-70697
	CM1502	Pediatric		18 to 26	9.8	001B-30-70698
	CM1503	Adult		25 to 35	13.1	001B-30-70699
	CM1504	Large adult		33 to 47	16.5	001B-30-70700
	CM1505	Adult	Thigh	46 to 66	20.5	001B-30-70701

25.4 CO_2 Accessories

Description	Applicable patient	Remark	PN
FilterLine Set Adult/ Pediatric	Adult, pediatric	Disposable	0010-10-42560
FilterLine H Set Adult/ Pediatric	Adult, pediatric		0010-10-42561
FilterLine H SetInfant/ Neonatal	Neonate		0010-10-42562
FilterLine Set Adult/ Pediatric Long	Adult, pediatric		0010-10-42563
FilterLine H SetAdult/ Pediatric Long	Adult, pediatric		0010-10-42564
FilterLine H SetInfant/ Neonatal Long	Neonate		0010-10-42565
S CapnoLine PlusAdult/ Intermediate	Adult		0010-10-42566
Smart CapnoLinePediatric (007266)	Pediatric		0010-10-42567
S CapnoLine Plus O2Adult/ Intermediate	Adult		0010-10-42568
Smart CapnoLine O2Pediatric (007269)	Pediatric		0010-10-42569
S CapnoLine Plus O2Adult/ Intermediate L	Adult		0010-10-42570
S CapnoLine O2 PediatricLong	Pediatric		0010-10-42571
CapnoLine HAdult(008177)	Adult		0010-10-42572
CapnoLine HPediatric(008178)	Pediatric		0010-10-42573
CapnoLine HInfant/ Neonatal(008179)	Neonate		0010-10-42574

Description	Applicable patient	Remark	PN
CapnoLine H O2Adult(008180)	Adult	Disposable	0010-10-42575
CapnoLine H O2Pediatric(008181)	Pediatric		0010-10-42576
NIV-Line Adult(008174)	Adult		0010-10-42577
NIV-LinePediatric(008175)	Pediatric		0010-10-42578

25.5 Therapy Accessories

Description	Model	Applicable patient	Remark	PN
External paddles	MR6601	Adult, pediatric	Reusable	0651-30-77001
Multifunction electrode pads	MR60	Adult	Disposable (5 sets/pack)	0651-30-77007
	MR61	Pediatric		0651-30-77008
	MR62	Adult		115-035426-00
	MR63	Pediatric		115-035427-00
Cable of electrode pads with test load (50 ohm)	MR6701	/	Reusable	040-000545-00
Conductive gel	15-25	/	Consumable	0000-10-10775
Internal paddles	MR6501	Pediatric	Reusable, 1 inch	115-018366-00
	MR6502	Adult, pediatric	Reusable, 2 inches	115-018367-00
	MR6503	Adult	Reusable, 3 inches	115-018368-00
CPR sensor	MR6401	/	Reusable, with a battery	115-044836-00
CPR sensor cable	MR6801	/	Reusable	040-003096-00
CPR adhesive tape	MR6921	/	Disposable (3 sets/pack)	040-003123-00

25.6 Miscellaneous

Description	Model	PN
Rechargeable lithium ion battery	LI24I005A	115-049328-00
	LI24I001A	115-007858-00
Test load	MR6905	040-000413-00
Bedrail hook	/	115-007587-00
Wi-Fi to 4G router kit	IR615-S-L5-WLAN	023-000726-00
Analog output cable	/	009-008524-00
Synchronous defibrillation input cable	/	009-008523-00
Grounding cable	UL1015/14AWG	1000-21-00122
DC/AC adapter	/	0010-30-12471
Patient data management software kit	/	0651-30-77145
Carrying case and shield cover	/	115-018610-00
D3 back pouch	/	115-008708-00

Description	Model	PN
Conducting gel mount kit	/	115-007857-00
Charger Station kit (International)	BatteryFeed 20	115-009187-00
Charger Station kit (US)		115-009188-00
Charger Station kit (Indian)		115-009189-00
Charger Station kit (EU)		115-009190-00
Charger Station kit (Brazilian)		115-009191-00
Charger Station kit (UK)		115-009192-00

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A Specifications

A.1 General Specifications

A.1.1 Safety Specifications

The equipment is classified, according to IEC 60601-1:

Type of protection against electrical shock	Class I, equipment energized from an external and internal electrical power source. If you suspect the integrity of the external protective earthing or the protective earthing wire, you should run the equipment on internal electrical power supply (battery).
Degree of protection against electric shock	Type BF defibrillation proof for CO_2 monitoring and external defibrillation. Type CF defibrillation proof for ECG, SpO_2, NIBP, internal defibrillation and CPR sensor.
Mode of operation	Continuous
Degree of protection against harmful ingress of solid	IP4X
Degree of protection against harmful ingress of water	IPX4 (when running on battery) IPX1 (when running on AC power supply)
Degree of mobility	Portable

A.1.2 Physical Specifications

Size (Width × depth × height)	288 mm×203 mm×275 mm
Maximum weight	6.1 kg, including a battery, external paddles and 3-leadwire.

A.1.3 Display Specifications

Type	TFT Color LCD
Size	7 inch
Resolution	800×480 pixels
Viewed waveforms	3 at maximum
Wave viewing time	16s at maximum (ECG)

A.1.4 Audio Indicators

Speaker	Gives alarm tones (45 to 85 dB), key tones, QRS tones Supports PITCH TONE and multi-level tone modulation Alarm tones comply with IEC60601-1-8.
Audio signal	Alarm tone: ISO mode with frequency of 600 Hz QRS tone: short beep with frequency of 650 Hz Charge tone: long beep with frequency of 400 Hz Charge done tone: double beeps with frequency of 870 Hz Key tone: short beep with frequency of 1000 Hz

A.1.5 Interface Specifications

USB connector	Connects USB flash memory
RJ45 connector	Connects standard network cable.
Multifunctional connector	Connects a cable for analog output or a cable for synchronized cardioversion.

A.1.6 Signal Outputs Specifications

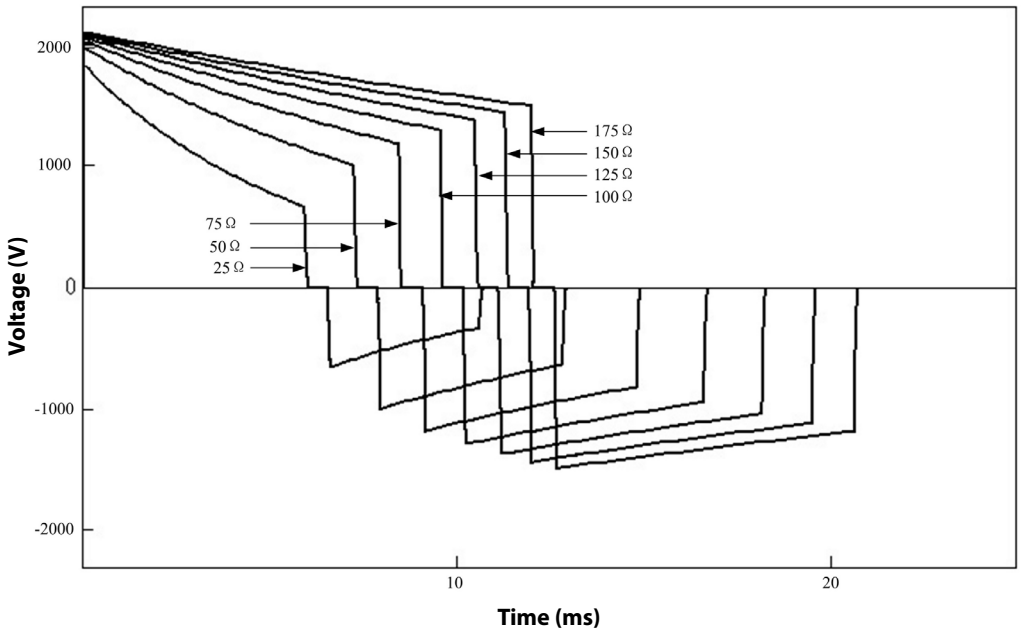
Multifunctional connector	
Standard	Meets the requirements of EN60601-1 for short-circuit protection and leakage current
ECG Analog Output (only ECG lead set)	
Bandwidth (-3 dB; reference frequency: 10 Hz)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz
Maximum QRS delay	25 ms (in diagnostic mode, and with Notch off)
Sensitivity	1 V/mV ±5%
Pace enhancement	Signal amplitude: V_{oh}≥2.5V Pulse width: 10ms±5% Signal rising and falling time: ≤100μs
Synchronous input	
Input signal range	0 to 5V (TTL level)
Input impedance	≥10 kΩ
Pulse width	>5 ms
Alarm output	
Alarm delay time from the equipment to other remote equipment	The alarm delay time from the equipment to other remote equipment is ≤4 seconds, measured at the equipment signal output connector.
Alarm signal sound pressure level range	45 db(A) to 85 db(A) within a range of one meter

A.2 Defibrillator Specifications

Standards	Meet standards of IEC 60601-2-4
Defibrillation mode	Manual defib, synchronized cardioversion, AED
Defibrillation waveform	Biphasic truncated exponential (BTE) waveform, auto-compensation according to patient impedance
Defibrillation electrodes	External paddles set coming with pediatric paddles included, multifunction electrode pads and internal paddles
Controls and indicators on external paddles	Charge button, Shock buttons, Energy Select buttons, charge done indicator
Shockable rhythm analysis time	< 8s
Range of selected energy	
External defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 150, 170, 200, 300, 360 J
Internal defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50 J
Patient impedance range	
External defibrillation	25 to 300 Ω

Internal defibrillation	15 to 300 Ω
Synchronized discharge delay	
Local synchronized discharge delay	< 60ms (from the peak of R-wave)
Remote synchronized discharge delay	< 25ms (from the rise edge of synchronous signal)
AED	
Shock series	Energy level: 100 to 360J, configurable for adult; 10 to 100J, configurable for pediatric Shocks: 1, 2, 3, configurable; Meeting AHA/ERC guidelines 2015 by default
AED ECG analysis performance	Refer to *B Mindray Shockable Rhythm Analysis Algorithm*.

360 J defibrillation waveform into impedance of 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ω



Impedance / Selected energy	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy
1 J	1	1	1	0.9	0.9	0.9	0.8	±2J
2 J	2	2	2	1.9	1.8	1.7	1.6	±2J
3 J	2.9	3	2.9	2.8	2.7	2.6	2.4	±2J
4 J	3.9	4	3.9	3.7	3.6	3.4	3.2	±2J
5 J	4.9	5	4.9	4.7	4.5	4.3	4.1	±2J
6 J	5.8	6	5.8	5.6	5.3	5.1	4.9	±2J
7 J	6.8	7	6.8	6.6	6.3	6	5.7	±2J
8 J	7.8	8	7.8	7.4	7.1	6.8	6.5	±2J
9 J	8.8	9	8.8	8.4	8	7.7	7.3	±2J
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1	±2J
15 J	15	15	15	14	13	13	12	±15%
20 J	20	20	20	19	18	17	16	±15%
30 J	29	30	29	28	27	25	24	±15%
50 J	49	50	49	47	45	43	41	±15%
70 J	68	70	68	65	62	60	57	±15%
100 J	97	100	97	93	89	85	81	±15%
150 J	146	150	146	140	134	128	122	±15%
170 J	166	170	166	159	151	145	138	±15%
200 J	195	200	195	187	178	170	163	±15%
300 J	292	300	292	280	267	255	244	±15%
360 J	351	360	350	336	321	306	293	±15%

Charge time (Note: at 20 ±5 °C of ambient temperature)												
	Manual Defib						**AED**					
	Charge time		From initial power on (from cold start) to charge done		From initial power on (from fast startup mode) to charge done		From initiation of rhythm analysis to charge done		From initial power on (from cold start) to charge done		From initial power on (from fast startup mode) to charge done	
	200J	**360J**	**200J**	**360J**	**200J**	**360J**	**200J**	**360J**	**200J**	**360J**	**200J**	**360J**
With a new, fully charged battery	<3 s	<7 s	<11 s	<14 s	<6 s	<10 s	<10 s	<12 s	<21 s	<26 s	<13 s	<15 s
With a new, fully charged battery, depleted by 15 360 J discharges	<4 s	<8 s	<12 s	<15 s	<7 s	<11 s	<11 s	<13 s	<23 s	<27 s	<14 s	<16 s
With 90% to 100% rated mains voltage	<4 s	<7 s	<11 s	<14 s	<7 s	<10 s	<11 s	<12 s	<22 s	<24 s	<14 s	<15 s

NOTE

- **The equipment startup time in the fast startup mode is less than 2s.**

A.3 CPR Compression Specifications

Compression depth	Measurement range: 0.0 to 8.0 cm Effective range: 1.5 to 8.0 cm Accuracy (for effective range): ±0.5 cm or ±10%, whichever is greater Resolution: 0.1 cm Refreshing rate: ≥0.5Hz
Compression rate	Measurement range: 40 to 160 cpm (compressions per minute) Effective range: 40 to 160 cpm (compressions per minute) Accuracy: ±2 cpm (compression per minute) Resolution: 1 cpm Refreshing rate: ≥0.5Hz
Interruption time	Measurement range: 0 to 300 s Effective range: 0 to 300 s Resolution: 1 s Refreshing rate: ≥0.5Hz

A.4 Pacer Specifications

Standards	Meet standards of IEC 60601-2-4
Pacer mode	Demand, fixed
Output waveform	Monophasic square wave pulse pulse width 20 ms or 40 ms Accuracy: ±5%
Pacing rate	30ppm to 210ppm Accuracy: ±1.5% Resolution: 5 ppm
Pacing output	0mA to 200mA, Accuracy: ±5% or ±5mA, whichever is greater Resolution: 1mA, 2mA or 5mA
Refractory period	200 to 300 ms (depending on pacing rate)
4:1 pacing	Pacing pulse frequency reduced by factor of 4 when this function is activated.
Output protection	The equipment has no sign of damage after defibrillation-proof test.

A.5 Monitor Specifications

A.5.1 ECG Specifications (from ECG Lead Set)

Standards	Meet standards of IEC 60601-2-27
Patient connection	3-lead ECG cable, 5-lead ECG cable
ECG inputs	3-lead ECG set: I, II, III 5-lead ECG set: I, II, III, aVR, aVL, aVF, V
Gain	2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto. Error less than ± 5%
Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Bandwidth (-3dB)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz

Common mode rejection	Diagnostic mode: >90 dB Monitor mode: >105 dB Therapy mode: >105 dB
Notch filter	50/60Hz, In Monitor and Therapy modes: notch filter turns on automatically In Diagnostic mode: notch filter is turned on manually
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Differential input impedance	≥5 MΩ
Electrode offset potential tolerance	±500mV
Defibrillation protection	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <2.5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27
Pace Pulse	
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs Input slew rate: 2.2 V/s ± 15% RTI
HR	
Measurement range	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm
Accuracy	±1% or ±1bpm, which ever is greater
Resolution	1 bpm
Sensitivity	200 µV (lead II)
Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, 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 screen is updated every second.
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s

Time to alarm for tachycardia	Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27. 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
Arrhythmia Analysis Classifications	Asystole, V-Fib/V-Tach, V-Tach, Vent. Brady, Extreme Tachy, Extreme Brady, PVCs/min, PVC, Couplet, VT>2,Bigeminy, Trigeminy, R ON T, Brady, Tachy, Missed Beat, PNP, PNC, Vent Rhythm, Multif. PVCs, Nonsus. Vtac, Pause, Irr. Rhythm, A-Fib
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, 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.
Lead-off detection current	Measuring electrode: ≤0.1 μA Drive electrode: ≤1 μA
Baseline recovery time	<2.5 s (after defibrillation)
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, 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

A.5.2 ECG Specifications (from Defibrillation Electrodes)

Patient connection	paddles or multifunction electrode pads
ECG inputs	pads/paddles
Gain	2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto. Error less than ± 5%
Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Bandwidth (-3dB)	Therapy mode: 1 to 20 Hz
Common mode rejection	Therapy mode: >105 dB
Notch filter	50/60Hz In Therapy mode: notch filter turns on automatically
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Differential input impedance	≥5 MΩ
Electrode offset potential tolerance	±1V
Defibrillation protection	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <2.5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27

Pace Pulse	
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
HR	
Measurement range	Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm
Accuracy	±1% or ±1bpm, which ever is greater
Resolution	1 bpm
Sensitivity	200 µV
Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, 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 screen is updated every second.
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5).
	From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s
Time to alarm for tachycardia	Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27. 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
Arrhythmia Analysis Classifications	Asystole, V-Fib/V-Tach, PNP, PNC
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, 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.
Lead-off detection current	≤0.1 µA
Baseline recovery time	<2.5 s (after defibrillation, in therapy mode)
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, 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

A.5.3 Resp Specifications

Technique	Trans-thoracic impedance
Measurement range	0 to 200 rpm
Resolution	1 rpm
Accuracy	121 to 200 rpm: ±2 rpm 0 to 120 rpm: ±1 rpm
Respiration excitation waveform	<300 μA, sinusoid, 62.8 kHz (±10%)
Minimum respiration impedance threshold	0.3Ω with× 5 gain
Bandwidth	0.2 to 2.5 Hz (-3 dB)
Reference impedance range	2200 to 4500Ω, using an ECG cable with 1 kΩ resistor
Apnea alarm time	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s

A.5.4 SpO_2 Specifications

Mindray SpO_2 Module

Standard	Meet standards of ISO 80601-2-61
Measurement range	0 to 100%
Resolution	1%
Response time	<20 s (SpO_2 value sudden changes from 70% to 100%)
Accuracy	70 to 100%: ±2% (in adult/pediatric mode) 70 to 100%: ±3% (in neonate mode) 0% to 69%: Not specified
Refreshing rate	≤2 s
*Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.	

Masimo SpO_2 Module

Standard	Meet standards of ISO 80601-2-61
Measurement range	1 to 100%
Resolution	1%
Response time	≤20 s (SpO_2 value sudden changes from 70% to 100%)
Accuracy[1]	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified
Refreshing rate	≤2 s
SpO_2 averaging time	2-4 s, 4-6 s, 8 s, 10 s, 12 s, 14 s, 16 s

[1] The Masimo pulse oximeter with sensors have been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. One percent was added to the accuracies for neonatal sensors to account for accuracy variation due to properties of fetal hemoglobin.

The Masimo pulse oximeter with sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz. At an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz. At an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Nellcor SpO_2 Module

Standard	Meet standards of ISO 80601-2-61	
Measurement range	0 to 100%	
Resolution	1%	
Accuracy	70 to 100%: 70 to 100%: 0% to 69%:	±2% (in adult/pediatric mode) ±3% (in neonate mode) Not specified
Refreshing rate	≤2 s	

A.5.5 PR Specifications

PR from Mindray SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Accuracy	±3 bpm
Response time	<20 s (PR value sudden changes from 25 to 240 bpm)

PR from Masimo SpO_2 Module

Measurement range	25 to 240 bpm
Accuracy	±3 bpm (measured without motion) ±5 bpm (measured with motion)
Response time	≤20 s (PR value sudden changes from 25 to 220 bpm)

PR from Nellcor SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Accuracy	±3 bpm (20 to 250 bpm) Not specified (251 to 300 bpm)

A.5.6 NIBP Specifications

Standards	Meet standard of IEC 80601-2-30
Technique	Oscillometry
Mode of operation	Manual, Auto and STAT

Auto mode repetition intervals	1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min				
STAT mode cycle time	5 min				
Static pressure measurement range	0mmHg to 300mmHg				
Static pressure measurement accuracy	±3mmHg				
Maximum measurement time	Adult, Pediatric: 180s Neonate: 90s				
Initial cuff inflation pressure range	Adult: 80 to 280 mmHg Pediatric: 80 to 210 mmHg Neonate: 60 to 140 mmHg				
Default Initial cuff inflation pressure	Adult: 160 mmHg Pediatric: 140 mmHg Neonate: 90 mmHg				
Measurement range			Adult	Pediatric	Neonate
	Systolic	mmHg	25 to 290	25 to 240	25 to 140
	Diastolic	mmHg	10 to 250	10 to 200	10 to 115
	Mean	mmHg	15 to 260	15 to 215	15 to 125
Software overpressure protection	Adult: 297±3 mmHg Pediatric: 297±3 mmHg Neonate: 147±3 mmHg				
Measurement accuracy*	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg				
Resolution	1 mmHg				

*Measurement accuracy verification: In adult and pediatric modes, the blood pressure measurements measured with this device are in compliance with the Standard for Non-invasive sphygmomanometers (ISO 81060-2)in terms of mean error and stardard deviation by comparing with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. For auscultatory reference, the 5th Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements measured with this device are in compliance with the American National Standard for Non-invasive sphygmomanometers (ISO 81060-2) in terms of mean error and stardard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.

A.5.7 CO_2 Specifications

Measurement range	0 to 150 mmHg
Accuracy*	Full accuracy mode: 0 to 40 mmHg: ±2 mmHg 41 to 76 mmHg: ±5% of reading 77 to 99 mmHg: ±10% of reading 100 to 150 mmHg: ±(3 mmHg+8% of reading) ISO accuracy mode: Add ±2mmHg to the full accuracy mode
Sart-up time	20 s (typical), 90 s (maximum)
Accuracy drift	Meets the requirement for measurement accuracy within 6 hours.
Resolution	1mmHg
Sample flowrate	Connecting the Oridion sampling line: 50 ml/min

Sample flowrate tolerance	±15% or ±15 ml/min, whichever is greater.	
Rise time	Measured with a Oridion sampling line: ≤250 ms @ 50 ml/min (standard sampling line) or ≤280 ms @ 50 ml/min (extended sampling line)	
Response time	Measured with a Oridion sampling line: ≤5 s @ 50 ml/min (standard sampling line) or ≤6.5 s @ 50 ml/min (extended sampling line)	
awRR measurement range	0 to 150 rpm	
awRR accuracy	<60 rpm: ±1 rpm 60 to 150 rpm: ±2 rpm	
awRR resolution	1 rpm	
Effect of interference gases on CO_2 measurements		
Gas	**Concentration (%)**	**Quantitive effect***
N_2O	≤60	±1 mmHg
Hal	≤4	
Sev	≤5	
Iso	≤5	
Enf	≤5	
Des	≤15	±2 mmHg
*: means an extra error should be added in case of gas interference when CO_2 measurements are performed between 0-40mmHg. Inaccuracy specifications are affected by the breath rate and I: E change. The $EtCO_2$ accuracy is within specification for breath rate ≤ 60rpm and I/E ratio ≤1:1, or breath rate ≤30rpm and I/E ratio ≤ 2:1.		

A.6 Power Supply Specifications

A.6.1 External Power Supply Specifications

AC power	
Line voltage	100 to 240 VAC (±10%)
Current	1.8 to 0.8A
Frequency	50/60Hz (±3Hz)
DC Power (with an external DC/AC adapter)	
Input voltage	12VDC
Power consumption	150W

A.6.2 Battery Specifications

Battery type	Smart lithium ion battery, rechargeable and free of maintenance, one battery can be installed, two types of batteries can be configured Battery LI24I005A: 14.4V, 5600mAh Battery LI24I001A: 14.8V, 3000mAh	
Battery LI24I005A charge time	Charged by the equipment connected to the AC power	Less than 3 hours to 90% and less than 4 hours to 100% with equipment power off;
		Less than 5 hours to 90% and less than 6 hours to 100% with equipment power on.
	Charged by the charger station	Less than 5 hours to 90% and less than 6 hours to 100%.

Battery LI24I001A charge time	Charged by the equipment connected to the AC power		Less than 2 hours to 90% and less than 3 hours to 100% with equipment power off;
			Less than 3.5 hours to 90% and less than 4.5 hours to 100% with equipment power on.
	Charged by the charger station		Less than 2.5 hours to 90% and less than 3 hours to 100%.
Battery LI24I005A run time	Operating mode	One new fully charged battery	Testing condition
	Monitoring	≥6 h	The equipment is configured with a 5-lead ECG, Resp, SpO_2 and CO_2, NIBP measurements set at an interval of 15 minutes. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Defibrillation	≥200 discharges	360J discharge, the equipment is configured with a 5-lead ECG, Resp, SpO_2, NIBP and CO_2. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Defibrillation	≥300 discharges	200J discharge, the equipment is configured with a 5-lead ECG, Resp, SpO_2, NIBP and CO_2. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Pacing	≥4.5 h	50 Ω load impedance, pacing rate 80ppm, pacing output 60mA. The equipment is configured with a 5-lead ECG, Resp, SpO_2, NIBP and CO_2. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
Battery LI24I001A run time	Operating mode	One new fully charged battery	Testing condition
	Monitoring	≥3 h	The equipment is configured with a 5-lead ECG, Resp, SpO_2 and CO_2, NIBP measurements set at an interval of 15 minutes. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Defibrillation	≥100 discharges	360J discharge at intervals of one minute, without recording
	Pacing	≥2 h	50 Ω load impedance, pacing rate 80ppm, pacing output 60mA, without recording
Battery fuel gauge	5 LEDs indicating the current battery charge level		
Shutdown delay	At least 20 minutes of monitoring and six 360J discharges (after the low battery alarm occurs)		

Note: The specifications above are based on a new battery, and at 20°C±5 °C of ambient temperature.

A.7 Recorder Specifications

Method	High-resolution thermal dot array
Number of waveforms	3 at maximum
Paper speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Paper width	50 mm
Grid lines	The operator can choose to print grid lines or not
Auto record	Charge events, shock events, marked events, auto test report, parameter alarms, ARR alarms, if configured on

A.8 Alarm Specifications

Alarm Levels	High, medium, low level alarms, complying with IEC60601-1-8
Alarm Categories	Physiological alarms, technical alarms; Latched alarms and unlatched alarms.
Alarm lamp	Independent alarm LED
Parameter alarm setting	Alarm properties of all available parameters can be set simultaneously in the Para. Alarm menu
Auto alarm limits	Parameter alarm limits can be automatically adjusted according to currently measured vital signs

A.9 Data Storage

Internal storage	1G Bytes
Marking events	16 types of events, user customized
Events	At least 1000 events for each patient.
Waveforms	At least 24 hours of consecutive ECG waveform
Voice recording (available in the AED mode)	At least 180 minutes in total, more than 60 minutes for each patient
Data export	Data can be export to a PC through a USB flash memory
Tabular trends	Up to 72 hours for all measured parameters with the resolution no less than 1 minute.
Patient archives	Up to 100

A.10 Wi-Fi Specifications

Protocol	IEEE 802.11a/b/g/n
Modulation mode	DSSS and OFDM
Operating frequency	IEEE 802.11b/g/n (at 2.4G): 2.4 GHz to 2.495 GHz IEEE 802.11a/n (at 5G): 5.15 GHz to 5.825 GHz
Channel spacing	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n (at 5G): 20 MHz
Wireless baud rate	IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 72.2 Mbps IEEE 802.11a: 6 Mbps to 54 Mbps
Output power	<20dBm (CE requirement: detection mode- RMS) <30dBm (FCC requirement: detection mode- peak power)
Operating mode	Infrastructure
Data security	Standards: WPA-PSK, WPA2-PSK Encryption: TKIP, AES
System capacity and resistance to wireless interference	When the following conditions exist simultaneously, ■ Number of the equipments supported by a single AP: ≤ 4 ■ Each equipment can communicate with the CMS. ■ The weakest AP signal strength detected at the equipment's position cannot be less than -65 dBm. ■ When the distance between interfering devices and the equipment is greater than 20 cm, and a co-channel interference Wi-Fi network (at least -85 dBm weaker than the monitor's network) and an adjacent-channel Wi-Fi network (at least -50 dBb weaker than the monitor's network) also synchronously exist. Note: The interfering devices do not include Wi-Fi devices. They include but are not limited to: ◆ 2.4 G wireless devices (excluding Wi-Fi devices) ◆ Cellular mobile communication networks ◆ Microwave ovens ◆ Interphones ◆ Cordless phones ◆ ESU equipment The total delay of data transmission from the monitors to the Central Station: ≤ 4 seconds.
Wi-Fi network stability	When the following conditions exist simultaneously, ■ Number of the equipments supported by a single AP: ≤ 4 ■ Each equipment can communicate with the CMS. ■ The weakest AP signal strength detected at the equipment's position cannot be less than -65 dBm. The time percentage of any equipment failing to transmit data to the CMS does not exceed 0.1% over a 24-hour period.
Distinct vision distance	The distinct vision distance between the equipment and the AP is greater than or equal to 50 meters.

A.11 Environmental Specifications

WARNING

- **The equipment may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.**

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

NOTE

- **The environmental specification of unspecified modules are the same as those of the main unit.**

Main Unit			
Item	**Temperature**	**Relative humidity**	**Barometric**
Operating condition	0°C to 45°C (at least 60 minutes of working time when the temperature reduces from room temperature to -20°C)	10% to 95%, non-condensing	-381m to 4575m (57kPa to 106.2kPa)
Storage condition	-30°C to 70°C		
CO_2 module			
Item	**Temperature**	**Relative humidity**	**Barometric**
Operating condition	5°C to 40°C	10% to 95%, non-condensing	430mmHg to 790 mmHg (57.3kPa to 105.3kPa)
Storage condition	-20°C to 60°C		

Shock
Complies with requirements of 21.102, ISO9919: Peak acceleration: 1000m/s^2 (102g) Duration: 6ms Pulse shape: half-sine Number of shocks: 3 shocks per direction per axis (18 total)
Vibration
Complies with requirements of 21.102, ISO9919.
Bump
Complies with the requirements of 6.3.4.2, EN1789. Peak acceleration: 15g Duration: 6ms Number of impacts: 1000 Impact direction: vertical impacts are applied when the equipment under test is placed at normal operating position.
Free fall
Complies with the requirements of 6.3.4.3, EN1789. Drop height: 0.75 m Number of drops: once for each of the six surfaces

B Mindray Shockable Rhythm Analysis Algorithm

The equipment configured with Mindray shockable rhythm analysis algorithm acquires and analyzes the patient's ECG signals to determine whether or not to give a defibrillation shock. If a shockable rhythm is detected, the algorithm recommends a defibrillation shock. If a nonshockable rhythm is detected, the algorithm recommends no shocks, avoiding unnecessary defibrillation shock to the patient.

Mindray shockable rhythm analysis algorithm has been validated by using the database for evaluation of Mindray algorithm performance.

B.1 Rhythm Recognition and Annotation Methodology

This section describes the recording method, rhythm source, rhythm selection criteria, annotation methods and criteria the database for evaluation of Mindray shockable rhythm analysis algorithm.

B.1.1 Database for Evaluation of Mindray Algorithm Performance

The database for evaluation of Mindray algorithm performance includes international standard database and Mindray clinical database for evaluating the ECG data. The ECG data for evaluation is selected according to AHA recommendations[a] with a 10-second wave length.

Database for evaluation of Mindray shockable rhythm analysis algorithm includes:

- MIT-BIH: The Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database (from Holter)
- AHA: The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (from Holter)
- VFDB: MIT-BIH Malignant Ventricular Arrhythmia Database (from Holter)
- CU: The Creighton University Sustained Ventricular Arrhythmia Database [the third edition] (from hospital monitor)
- NST: The Noise Stress Test Database (12 ECG records of 30 minutes each plus 3 records of noise only - supplied with the MIT–BIH database)
- Mindray clinical data (from Mindray monitors, defibrillator monitors and automated external defibrillators)

B.1.2 Rhythm Categories

Each rhythm category for evaluating the ECG data has been confirmed by the clinical experts.

- Shockable rhythms
  - Coarse ventricular fibrillation (VF): amplitude ≥0.2mV
  - Rapid ventricular tachycardia (VT): HR≥150bpm, QRS duration ≥120ms
- Nonshockable rhythms
  - Normal sinus rhythm
  - Asystole: amplitude <0.1mV
  - Atrial fibrillation/flutter, supraventricular tachycardias, sinus bradycardia, idioventricular rhythms, heart block, premature ventricular contractions, etc
- Intermediate rhythms
  - Fine ventricular fibrillation: 0.1mV < amplitude <0.2mV
  - Other VT: ventricular tachycardia that does not meet criteria for VT in the shockable rhythms category

B.2 Mindray Shockable Rhythm Analysis Algorithm Performance

Test results on the performance of the equipment configured with Mindray shockable rhythm analysis algorithm meet IEC 60601-2-4 requirements[b] and AHA recommendations[a].

Test results on IEC 60601-2-4 requirements are shown below.

Rhythm category	Requirement	Test result
Shockable (sensitivity): Coarse VF Rapid VT	 >90% >75%	 Met Met
Nonshockable (specificity)	>95%	Met
Positive predictive value	Report only	>98%
False positive rate	Report only	<2%

Test results on AHA recommendations are shown below.

Rhythm category	Minimum sample size (cases)	Performance goal	Sample size tested (cases)	Test result
Shockable (sensitivity): Coarse VF Rapid VT	 200 50	 >90% >75%	 205 80	 Met Met
Nonshockable (specificity): Normal sinus rhythm Asystole Other nonshockable rhythms	300 100 100 30	 >99% >95% >95%	 171 180 385	 Met Met Met
Intermediate: Fine VF Other VT	 25 25	 Report only Report only	 27 42	 66.67% shockable 76.19% nonshockable

[a]. Kerber RE, et al, "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety: A Statement for Health Professionals from the American Heart Association Task Force on Automatic External Defibrillation", Subcommittee on AED Safety and Efficacy. Circulation, 1997: Vol. 95: 1677-1682.

[b]. Clause 201.7.9.3.103 "Essential Performance data of the Rhythm Recognition Detector" and clause 201.107 "Requirements for Rhythm Recognition Detector," International Electrotechnical Association, IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators: 2010.

C EMC and Radio Regulatory Compliance

C.1 EMC

The equipment meets the requirements of IEC 60601-1-2: 2014.

WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
- **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
- **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**
- **Other devices may affect this equipment even though they meet the requirements of CISPR.**
- **When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**

NOTE

- **The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Portable and mobile RF communications equipment may affect this equipment.**
- **This equipment is intended for use in professional healthcare facility environment, or in home healthcare environment such as restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres. If it is used in special environment, such as magnetic resonance imaging environment, the equipment may be disrupted by the operation of nearby equipment.**

Guidance and Declaration - Electromagnetic Emissions		
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment 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 B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60601-1-2 EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 60601-1-2 EN 61000-3-3	Complies	

If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration — Electromagnetic Immunity**, the equipment will remain safe and provide the following essential performance: HR accuracy, Resp accuracy, SpO_2 accuracy, PR accuracy, NIBP accuracy, CO_2 accuracy, Pacing rate accuracy, Pacing output accuracy, energy accuracy, CPR function, alarm, data stored, user's interface function.

Guidance and Declaration - Electromagnetic Immunity			
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment 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	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips and Voltage interruptions IEC 61000-4-11	0% U_T for 0,5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/300 cycle	0% U_T for 0,5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/300 cycle	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 uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity

The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment 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 150k to 80 MHz	3 Vrms (V1)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ 150k to 80 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range [d] Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM bands and amateur radio bands[a] between 0.15 MHz and 80 MHz	6 Vrms (V2)	
Radiated RF EM fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz (IEC60601-2-27, IEC60601-2-25, IEC60601-2-49)	3 V/m (E1)	
	10V/m 80 MHz to 2.7 GHz (IEC60601-2-4)	10 V/m	
	20V/m 80 MHz to 2.7GHz (IEC60601-2-4, IEC80601-2-30, ISO 80601-2-55,, ISO 80601-2-61)	20 V/m	
Proximity fields from RF wireless communications equipment IEC61000-4-3	27 V/m 380 to 390 MHz	27 V/m	
	28 V/m 430 to 470 MHz, 800 to 960 MHz, 1700 to 1990 MHz, 2400 to 2570 MHz	28 V/m	
	9 V/m 704 to 787 MHz, 5100 to 5800 MHz	9 V/m	

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

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

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] Compliance level in the ISM frequency bands between 150 kHz to 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that portable/ mobile communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment			
The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00
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 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

C.2 Radio Regulatory Compliance

CE

The device comply with the essential requirements and other relevant provisions of Directive 2014/53/EU.

WARNING

- **Keep a distance of at least 20 cm away from the equipment when wireless function is in use.**

D Defibrillator Shift Checklist

Equipment Name: _____ **Serial Number:** _____ **Department:** _____

Item	Pass/ Fail	Corrective Actions/Remarks
1. Equipment Appearance ◆ Clean, no foreign substance, no crack		
2. Cables/Connectors ◆ Cables not frayed, connectors and pins not broken or loose ◆ Connectors engage securely		
3. Batteries ◆ Battery installed with at least 60% of battery capacity ◆ Fully charged spare battery available		
4. Necessary Accessories (Electrode pads, electrodes, paddles or recorder paper) ◆ Present and sufficient ◆ Inspected to be used normally		
5. Auto Test ◆ Status indicator off		
6. Shock Test ■ **If the external paddles are used:** a. Connect the equipment with AC power supply, and the AC power indicator is illuminated. b. Connect the paddles cable to the equipment, and place the external paddles in the paddle tray. c. Press the Charge button on the external paddles, and charge the equipment to **50J**. d. Press the Shock button on the external paddles. e. The system prompts that the shock is delivered normally.		
6. Shock Test ■ **If the electrode pads are used:** a. Connect the equipment with AC power supply, and the AC power indicator is illuminated. b. Connect the pads cable to the equipment. c. Perform the Energy Delivery test item of the user test with the test load connected. d. The system prompts that the Energy Delivery test is passed.		
7. Monthly Check on Expiration Date ◆ The electrode pads are not expired.		
Checked by: _____ **Date:** _____		

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E Alarm Messages

This chapter lists only the most important physiological and technical alarm messages. Some messages appearing on your equipment may not be included.

In this chapter:

- The "I" column indicates how indications of technological alarms are cleared after the Alarm Pause button or [**Alarm Reset**] soft key is pressed: "A" means all alarm indications are cleared; "B" indicates alarm light and alarm tones are cleared and the alarm messages change to prompt messages; and "C" indicates only alarm tone is disabled, but alarm light and alarm message remain presented.
- The "L" column indicates the alarm level: "H" refers to high, "M" refers to medium, and "L" refers to low. "*" means the alarm level is user-adjustable.
- XX represents a measurement or parameter label, such as ECG, NIBP, HR, PVCs, RR, SpO_2, PR, etc.

In the "Cause and solution" column, corresponding solutions are given instructing you to troubleshoot problems. If the problem persists, contact your service personnel.

E.1 Physiological Alarm Messages

Measurement	Alarm Message	L	Cause and solution
XX	XX Too High	M*	XX value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
	XX Too Low	M*	
ECG	Asystole	H	Arrhythmia has occurred to the patient. Check the patient's condition and the ECG connections.
	V-Fib/V-Tach	H	
	Vent. Brady	H	
	Extreme Tachy	H	
	Extreme Brady	H	
	Brady	M*	
	Tachy	M*	
	R ON T	M*	
	PVC	M*	
	VT>2	M*	
	Couplet	M*	
	Bigeminy	M*	
	Trigeminy	M*	
	Missed Beat	M*	
	Vent Rhythm	M*	
	Multif. PVCs	M*	
	Nonsus. Vtac	M*	
	Pause	M*	

Measurement	Alarm Message	L	Cause and solution
ECG	Irr. Rhythm	M*	Arrhythmia has occurred to the patient. Check the patient's condition and the ECG connections.
	A-Fib	M*	
	PNP	M*	The pacer appears abnormal. Check the pacer.
	PNC	M*	
Resp	Resp Apnea	H	The respiration signal was so weak that the equipment cannot perform respiration analysis. Check the patient's condition and the Resp connections.
	Resp Artifact	H	The respiration circuit is disturbed. Check for any possible sources of signal noise.
SpO2	SpO2 Desat	H	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	L	The pulse signal was so weak that the equipment cannot perform pulse analysis. Check the patient's condition, SpO_2 sensor and measurement site.
CO2	CO2 Apnea	H	The patient stops breathing, or the respiration signal was so weak that the equipment cannot perform respiration analysis. Check the patient's condition, CO_2 accessories and airway connections.

E.2 Technical Alarm Messages

Measurement	Alarm Message	L	I	Cause and solution
XX	XX SelfTest Err	H	C	An error occurred to the XX module, or there is a problem with the communications between the module and the main unit. Restart the equipment.
	XX Init Err	H	C	
	XX Comm Err	L	C	
	XX Comm Stop	H	C	
	XX Overrange	L	C	The measured XX value is not within the specified range for XX measurement. Contact your service personnel.
ECG	ECG Lead Off	L*	B	The ECG electrode has become detached from the patient or the lead wire has become disconnected from the trunk cable. Check the connection of the electrodes and leadwires.
	ECG YY Lead Off (YY represents the leadwires V, LL, LA, and RA, as per AHA standard, or C, F, L and R as per IEC standard.)	L*	B	
	Pads/Paddles Off	L*	B	The pads/paddles have been detached from the patient or the therapy cable is loose. Check that the electrode pads/paddles and therapy cable are properly connected.
	ECG Noise	L	A	The ECG signal is noisy. Check for any possible sources of signal noise form the area around the cable and electrode, and check the patient for excessive motion.
	ECG Signal Invalid	L	A	ECG amplitude is so low that ECG signal is undetectable. Check for any possible source of interference from the area around the cable and electrode; check the patient's condition.

Measurement	Alarm Message	L	I	Cause and solution
SpO2	SpO2 Sensor Off	L*	B	The SpO_2 sensor has become detached from the patient or the module, or there is a fault with the SpO_2 sensor, or 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.
	SpO2 Sensor Fault	L	C	
	SpO2 No Sensor	L	B	
	SpO2 Unknow Sensor	L	C	
	SpO2 Sensor Incompatible	L	C	
	SpO2 Too Much Light	L	C	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.
	SpO2 Low Signal	L	C	The SpO_2 signal is too low or too weak. Check the patient's condition and change the sensor application site. If the error persists, replace the sensor.
	SpO2 Weak Signal	L	C	
	SpO2 Weak Pulse	L	C	
	SpO2 Non-Pulsatile	L	C	
	SpO2 Low Perf	L	B	
	SpO2 Interference	L	C	The SpO_2 signal has been interfered. Check for any possible sources of signal noise form the area around the sensor, and check the patient for excessive motion.
	SpO2 Board Fault	L	C	There is a problem with the SpO_2 measurement board. Do not use the module and contact your service personnel.
NIBP	NIBP Loose Cuff	L	A	The NIBP cuff is not properly connected, or there is a leak in the airway.
	NIBP Air Leak	L	A	
	NIBP Pneumatic Leak	L	A	Check the NIBP cuff and pump for leakages.
	NIBP Cuff Type Wrong	L	A	The cuff type applied mismatches the patient category. Verify the patient category and replace the cuff.
	NIBP Air Press. Err	L	A	An error occurred to the air pressure. Verify that the equipment application site meets the environmental requirements and check if there is any source that affects the air pressure.
	NIBP Weak Signal	L	A	The patient's pulse is weak or the cuff is loose. Check the patient's condition and change the cuff application site. If the problem persists, change the cuff.
	NIBP Sig. Saturated	L	A	The NIBP signal is saturated due to excess motion or other sources.
	NIBP Overrange	L	A	The patient's NIBP value may be beyond the specified measurement range.
	NIBP Excessive Motion	L	A	Check the patient's condition and reduce the patient motion.
	NIBP Equip Err	H	A	An error occurred during NIBP measurement and therefore the equipment cannot perform analysis correctly. Check the patient's condition and NIBP connections, or replace the cuff.
	NIBP Time Out	L	A	
	NIBP Measure Failed	L	A	
	NIBP Reset For Err	L	A	An illegal reset occurred during NIBP measurement. Check if the airway is occluded.

Measurement	Alarm Message	L	I	Cause and solution
CO2	CO2 Sensor High Temp	L	C	Check, stop using or replace the sensor.
	CO2 No Watertrap	L	B	Check the watertrap connections.
	CO2 Zero Failed	L	A	Check the CO_2 connections. After the sensor's temperature becomes stabilized, perform a zero calibration again.
	CO2 Module Error	L	C	There is a problem with the CO_2 module, or a problem with the communications between the main unit and the CO_2 module. Restart the equipment.
	CO2 Occlusion	L	C	The airway was occluded. Check the airway and remove the occlusion.
CPR sensor	CPR Sensor Err	H	C	There is a self-test error or communication problem with the CPR sensor. Contact your service personnel.
	CPR Sensor Low Battery	M	C	The battery power of the CPR sensor is low. Charge the battery by connect the CPR sensor to the equipment.
	CPR Sensor Need Service	H	C	The compressions using the CPR sensor exceed the expected numbers. Contact your service personnel.
	CPR Sensor Cable Fault	L	C	An error occurred to the CPR sensor cable. Replace the CPR sensor cable.
	Change CPR Sensor Battery	L	C	The CPR sensor battery is aging. Contact your service personnel.
	CPR Sensor Bat. Charge Err	L	C	The CPR sensor cannot be charged. Contact your service personnel.
Main control system	No Speaker	L	C	Make sure that the speaker is connected.
	Power Board Comm Err	H	C	An error occurred to the power board, or there is a problem with the communications between the power board and the main unit. Restart the equipment.
	Keyboard Comm Err	L	C	An error occurred to the keypad board, or there is a problem with the communications between the keypad board and the main unit. Restart the equipment.
	Therapy Module Comm Err	S	C	An error occurred to the therapy module, or there is a problem with the communications between the therapy module and the main unit. Restart the equipment. If the problem persists, contact your service personnel.
	Main Control Selftest Err	H	C	The main control voltage is abnormal. Replace the main control board.
	Wifi Module Fault	L	C	Contact your service personnel.
	Machine Type Error	H	C	
	RT Clock Need Reset	L	C	Reset system time.
	RT Clock Err	H	C	An error occurred to the RTC chip, or the button cell is depleted. Replace corresponding part.
	Memory Error	L	C	There is a problem with the data card. Format the CF card. If the problem persists, contact your service personnel.
	Last User Test Failed	L	C	Run a successful user test.
	Last Auto Test Failed	L	C	Run a successful user test again.
	NO CMS.	L	C	The equipment is disconnected from the CMS. Check the network connection.
	IP Address Conflict	L	C	Network IP conflicts. Check the network settings.

Measurement	Alarm Message	L	I	Cause and solution
Power board	Power Board Selftest Err	H	C	An error occurred to the system power supply. Restart the equipment.
	Power Board Volt Err	L	C	
	Low Battery	S	C	Change battery or connect the equipment to the AC power source to charge the batteries.
	No Battery	L	C	Battery is not installed. Install the battery.
	Battery Depleted! System will shut down immediately. Connect to AC mains or replace battery.	S	C	Connect the equipment to AC mains.
	Battery Err	H	C	There is a problem with the batteries. Check the batteries for damage; verify that correct batteries are used. Replace the batteries if necessary.
	Battery Aged	L	C	Replace the battery.
	Battery failed charging	M	C	Battery failure or power board hardware failure. Replace the battery. If the problem persists, contact your service personnel.
Therapy module	Therapy Equip Selftest Err	S	C	An error occurred during therapy module self test. Restart the equipment or replace the therapy module low voltage board.
	Defib Malfunction	S	C	The defibrillation function fails or both the defibrillation and pacing functions fail. Restart the equipment and test defibrillation function. If the problem persists, contact your service personnel.
	Pacer Malfunction	S	C	The pacing function fails. Restart the equipment and test pacer function. If the problem persists, contact your service personnel.
	Disarming Failed	H	C	There is a problem with the therapy module disarming circuit. Replace the therapy module low voltage board and high voltage board.
Monitoring module	Monitor Module Selftest Err	H	C	An error occurred during MPM module power-on self test. Replace the MPM module.
	Monitor Module Reset Err	H	C	MPM module reset abnormally. In this case, the MPM module restores to default configuration. You can ignore this problem.
	Monitor Module Voltage Err	L	C	The voltage of MPM module is abnormal. Replace the MPM module.
Recorder	Recorder Init Err	L	A	Restart the equipment.
	Recordhead Overheated	L	A	The recorder has been working for a prolonged time. Clear the recording tasks and resume the recording till the recorder's print head cools down.
	Recorder Overcurrent	L	A	Re-load the recorder paper.
Pacer	Pads Cable Off	H	C	Check that pads cable is properly connected.
	Pads Off	H	C	Check that electrode pads are properly connected.
	ECG Lead Off	H	C	Check that ECG leadwires are properly connected.
	Pacer Stopped Abnormally	H	C	Check that electrode pads well contact with patient's skin. Make sure electrode pads are properly applied, and then start pacing again.
Others	Load Config Err	L	A	Check if the configuration is correct, or restore the factory configuration.

NOTE

- **In the "L" column "S" refers to special technological alarm. The special technological alarms cannot be paused or silenced, and the alarm volume is unchangeable. These alarms stops only when the alarm condition is eliminated.**

F Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed by using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe, such as Fluke, Metron or Gerb, may require modifications to the procedure. Please follow the instructions of the analyzer manufacturer.

The electrical safety inspection should be periodically performed per year. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

F.1 Power Cord Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

F.2 Device Enclosure and Accessories

F.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

F.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

F.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facilities are present and legible.

- Main unit label
- Integrated warning labels

F.4 Protective Earth Resistance

1. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
2. Test the earth resistance with a current of 25 A.
3. Verify the resistance is less than limits.

LIMITS

For all countries, R = 0.2 Ω Maximum

F.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test:

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)

LIMITS

For UL60601-1,

- 300 µA in Normal Condition
- 1000 µA in Single Fault Condition

For IEC60601-1,

- 500 µA in Normal Condition
- 1000 µA in Single Fault Condition

F.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)
- normal polarity with open earth (Single Fault Condition)
- reverse polarity with open earth (Single Fault Condition)

LIMITS

For CF  applied parts

- 10µA in Normal Condition
- 50µA in Single Fault Condition

For BF applied parts

- 100μA in Normal Condition
- 500μA in Single Fault Condition

F.7 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity
- Reversed Polarity

LIMITS

- For CF applied parts: 50 μA
- For BF applied parts: 5000 μA

F.8 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connector s. All measurements may have a true RMS only response.

The following outlet conditions apply when performing the Patient Auxiliary Current test.

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)
- normal polarity with open earth (Single Fault Condition)
- reverse polarity with open earth (Single Fault Condition)

LIMITS

For CF applied parts,

- 10μA in Normal Condition
- 50μA in Single Fault Condition

For BF applied parts,

- 100μA in Normal Condition
- 500μA in Single Fault Condition

NOTE

- **Make sure the safety analyzer is authorized comply with requirement of IEC61010-1.**
- **Follow the instructions of the analyzer manufacturer.**

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G Symbols and Abbreviations

G.1 Units

µA	microampere
µV	microvolt
A	ampere
Ah	ampere hour
bpm	beat per minute
bps	bit per second
ºC	centigrade
cc	cubic centimeter
cm	centimeter
dB	decibel
DS	dyne second
ºF	fahrenheit
g	gram
GHz	gigahertz
GTT	gutta
h	hour
Hz	hertz
in	inch
J	Joule
k	kilo
kg	kilogram
kPa	kilopascal
L	litre
lb	pound
m	meter
mAh	Milliampere hour
Mb	mega byte
mcg	microgram
mEq	milli-equivalents
mg	milligram
min	minute
ml	milliliter

mm	millimeter
mmHg	millimeters of mercury
ms	millisecond
mV	millivolt
mW	milliwatt
MΩ	megaohm
nm	nanometer
rpm	breaths per minute
s	second
V	volt
VA	volt ampere
Ω	ohm
W	watt

G.2 Symbols

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

G.3 Abbreviations and Acronyms

$AaDO_2$	alveolar-arterial oxygen gradient
AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
ACI	acceleration index
Adu	adult
AG	anaesthesia gas
AED	Semi-automated external defibrillation
AHA	American Heart Association

ANSI	American National Standard Institute
Ao	aortic pressure
Art	arterial
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
awRR	airway respiratory rate
BAP	brachial aterial pressure
BIS	bispectral index
BP	blood pressure
BPSK	binary phase shift keying
BSA	body surface area
BT	blood temperature
BTPS	body temperature and pressure, saturated
C.I.	cardiac index
C.O.	cardiac output
CaO_2	arterial oxygen content
CCO	continuous cardiac output
CCU	cardiac (coronary) care unit
CE	Conformité Européenne
CIS	clinical information system
CISPR	International Special Committee on Radio Interference
CMOS	complementary metal oxide semiconductor
CMS	central monitoring system
CO_2	carbon dioxide
COHb	carboxyhemoglobin
CP	cardiopulmonary
CPR	Cardiopulmonary resuscitation
CVP	central venous pressure
DC	direct current
Defib	defibrillation
Des	desflurane
Dia	diastolic
DPI	dot per inch
DVI	digital video interface
ECG	electrocardiograph
EDV	end-diastolic volume
EEC	European Economic Community

EEG	electroencephalogram
EMC	electromagnetic compatibility
EMG	electromyograph
EMI	electromagnetic interference
Enf	enflurane
ESU	electrosurgical unit
Et	end-tidal
$EtCO_2$	end-tidal carbon dioxide
EtN_2O	end-tidal nitrous oxide
EtO	ethylene oxide
EtO_2	end-tidal oxygen
FAP	femoral arterial pressure
FCC	Federal Communication Commission
FDA	Food and Drug Administration
Fi	fraction of inspired
$FiCO_2$	fraction of inspired carbon oxygen
FiN_2O	fraction of inspired nitrous oxide
FiO_2	fraction of inspired oxygen
FPGA	field programmable gate array
FV	flow-volume
Hal	halothane
Hb	hemoglobin
Hb-CO	carbon mono-xide hemoglobin
HbO_2	oxyhemoglobin
HIS	hospital information system
HR	heart rate
I:E	inspiratory-expiratory ratio
IBP	invasive brood pressure
ICG	impedance cardiography
ICP	intracranial pressure
ICT/B	intracranial catheter tip pressure transducer
ICU	intensive care unit
ID	identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IP	internet protocol
Iso	isoflurane
IT	injectate temperature

LA	left arm
LAP	left atrial pressure
Lat	lateral
LCD	liquid crystal display
LCW	left cardiac work
LCWI	left cardiac work index
LED	light emitting diode
LL	left leg
LVDS	low voltage differential signal
LVET	left ventricular ejection time
LVSW	left ventricular stroke work
LVSWI	left ventricular stroke work index
MAC	minimal alveolar concentration
MAP	mean arterial pressure
MDD	Medical Device Directive
MetHb	methemoglobin
MRI	magnetic resonance imaging
MVe	expiratory minute volume
MVi	inspiratory minute volume
N/A	not applied
Neo	neonate
NIBP	noninvasive blood pressure
NIP	negative inspiratory pressure
O_2	oxygen
O_2CI	oxygen consumption index
O_2R	oxygen extraction ratio
OR	operating room
oxyCRG	oxygen cardio-respirogram
PA	pulmonary artery
Paw	airway pressure
PAWP	pulmonary artery wedge pressure
PD	photodetector
Ped	pediatric
PEEP	positive end expiratory pressure
PEF	peak expiratory flow
PEP	pre-ejection period
PIF	peak inspiratory flow
PIP	peak inspiratory pressure

Pleth	plethysmogram
Pmean	mean pressure
PNC	pacer not captured
PNP	pacer not paced
Pplat	plateau pressure
PR	pulse rate
PVC	premature ventricular complex
PVR	pulmonary vascular resistance
PVRI	pulmonary vascular resistance index
R	right
RA	right arm
RAM	random access memory
RAP	right atrial pressure
Raw	airway resistance
Rec	record, recording
Resp	respiration
RHb	reduced hemoglobin
RL	right leg
RM	respiratory mechanics
RR	respiration rate
RSBI	rapid shallow breathing index
SaO_2	arterial oxygen saturation
SEF	spectral edge frequency
Sev	sevoflurane
SFM	self-maintenance
SI	stroke index
SMR	satellite module rack
SpO_2	arterial oxygen saturation from pulse oximetry
SQI	signal quality index
SR	suppression ratio
STR	systolic time ratio
SV	stroke volume
SVR	systemic vascular resistance
SVRI	systemic vascular resistance index
Sync	synchronization
Sys	systolic pressure
Taxil	axillary temperature
TD	temperature difference

Temp	temperature
TFC	thoracic fluid content
TFI	thoracic fluid index
TFT	thin-film technology
Toral	oral temperature
Trect	rectal temperature
TVe	expiratory tidal volume
TVi	inspiratory tidal volume
UAP	umbilical arterial pressure
UPS	uninterruptible power supply
USB	universal serial bus
UVP	umbilical venous pressure
VAC	volts alternating current
VEPT	volume of electrically participating tissue
VI	velocity index
WOB	work of breathing

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H Device Tracking

In order to provide high quality product and perform better service, we are going to track our product. Please contact us with the device tracking information when you have received your defibrillator/monitor:

Please fill the information in the next page, cut the table and fax it to +86 755 26582934. You can also email your information to service@mindray.com.

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Device Tracking Information			
User Information			
Customer Name			
Department name			
Address			
City	State	Zip/Post Code	Country
Contact Person			
Tel No.		Fax No.	
Email Address			
Device Information			
Product name	Serial number	Model	Installation Date

Declaration of Conformity

Declaration of Conformity V2.0

CE

Declaration of Conformity

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Defibrillator/Monitor (Including accessories and Vehicle Mount kit)

Model: BeneHeart D2/BeneHeart D3

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

☒ EN 60601-1:2006/A1:2013	☒ EN 60601-1-2: 2015
☒ EN 62311:2008	☒ EN 50385:2002
☒ ETSI EN 301 489-17 V3.1.1	☒ EN 300 328 V2.1.1
☒ ETSI EN 301 489-1 V2.2.0	☒ ETSI EN 301 893 V2.1.1

Start of CE-Marking: 2017-6-13

Place, Date of Issue: Shenzhen, 2018.12.29

Signature: .....

Name of Authorized Signatory: Wang Xinbing

Position Held in Company: Manager, Technical Regulation

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