BeneHeart D1

Automated External Defibrillator

Operator’s Manual

CE 0123

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Responsibility on the Manufacturer Party

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- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

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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- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

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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.**
- **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.**
- **Defibrillation current can cause operator or bystander severe injury or even death. Keep distance with the patient or metal devices connected to the patient during defibrillation.**

1.1.2 Warnings

WARNING

- **Check for mechanical damages before each use. If case of any damage, do not apply it to patients.**
- **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.**
- **Run the equipment only on the supplied disposable or rechargeable battery.**
- **Charge the rechargeable battery only with the supplied BatteryFeed 20 charger station.**
- **This equipment is used for single patient at a time.**

- **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 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 therapy pads away from internal pacemaker generator if possible to help prevent damage to the pacemaker.**
- **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.**
- **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.**
- **Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.**
- **Keep a distance of at least 20cm away from the equipment when Wi-Fi function is in use.**

1.1.3 Cautions

CAUTION

- **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.**
- **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.**

1.1.4 Notes

NOTE

- **Put the equipment in a location where you can easily view and operate the equipment.**
- **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.**
- **During normal use, the operator shall stand in front of the equipment.**
- **This manual describes all features and options. Your equipment may not have all of them.**
- **To ensure that the equipment is ready for any urgent use, keep it with battery installed and pads preconnected.**
- **If the equipment has been dropped or mishandled, perform a user test. If any item fails, contact the authorized service personnel.**

1.2 Equipment Symbols

	Refer to instruction manual/ booklet		General warning sign
	Shock button		Dangerous voltage
	Unlocking		Stand-by
	Manufacturer		Date of manufacture
IP55	Dust-protected Protected against splashing water		Maximum stacks
SN	Serial number		USB connector
	Open the battery door as indicated		Do not expose the battery to high heat or open flames. Do not incinerate the battery.
	Do not crush the battery.		Do not mutilate the battery or open the battery case.
	Fragile		Keep dry
	Right side up		Temperature limitations
	Humidity limitations		Atmospheric pressure limitations
	General symbol for recovery/ recyclable		Non-ionizing electromagnetic radiation
	DEFIBRILLATION-PROOF TYPE CF APPLIED PART		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		
CE 0123	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.		

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

It is important to understand that survival rates for sudden cardiac arrest are directly related to how soon victims receive treatment. For every minute of delay, the chance of survival declines by 7% to 10%. Treatment cannot assure survival. In some patients, the underlying problem causing the cardiac arrest is simply not survivable despite any available care.

2.1 Overview

The BeneHeart D1 (hereinafter called the equipment) is a lightweight and portable automated external defibrillator. There are two types of configuration: the equipment configured with AED, manual defibrillation and ECG monitoring functions, while the equipment configured with only AED function. The equipment configured with AED, manual defibrillation and ECG monitoring functions provides two operating modes: AED and Manual Defib modes. The equipment configured with only AED function provides only AED mode.

In 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.

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

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

Defibrillation is performed through multifunction electrode pads. In Manual Defib mode, you can also perform synchronized cardioversion.

In Manual Defib mode, the equipment also provides monitoring, displaying and storing of 3-lead ECG.

The equipment can be powered by a supplied disposable battery or a smart lithium ion battery which is rechargeable and maintenance-free. You can easily determine the remaining battery charge by viewing the battery power gauge displayed on the screen. For rechargeable batteries, you can also check the indicator on the battery itself.

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

2.2 Intended Use

The equipment configured with AED, manual defibrillation and ECG monitoring functions is intended for automatic defibrillation (AED) and manual defibrillation treatments. It guides operators through Cardiopulmonary resuscitation (CPR) and can also be used for ECG monitoring.

The equipment configured with only AED function is intended for AED. It also guides operators throughout CPR.The equipment is for use in 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.

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. Synchronous defibrillation is intended for termination of atrial fibrillation.

2.2.3 ECG

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

2.2.4 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.

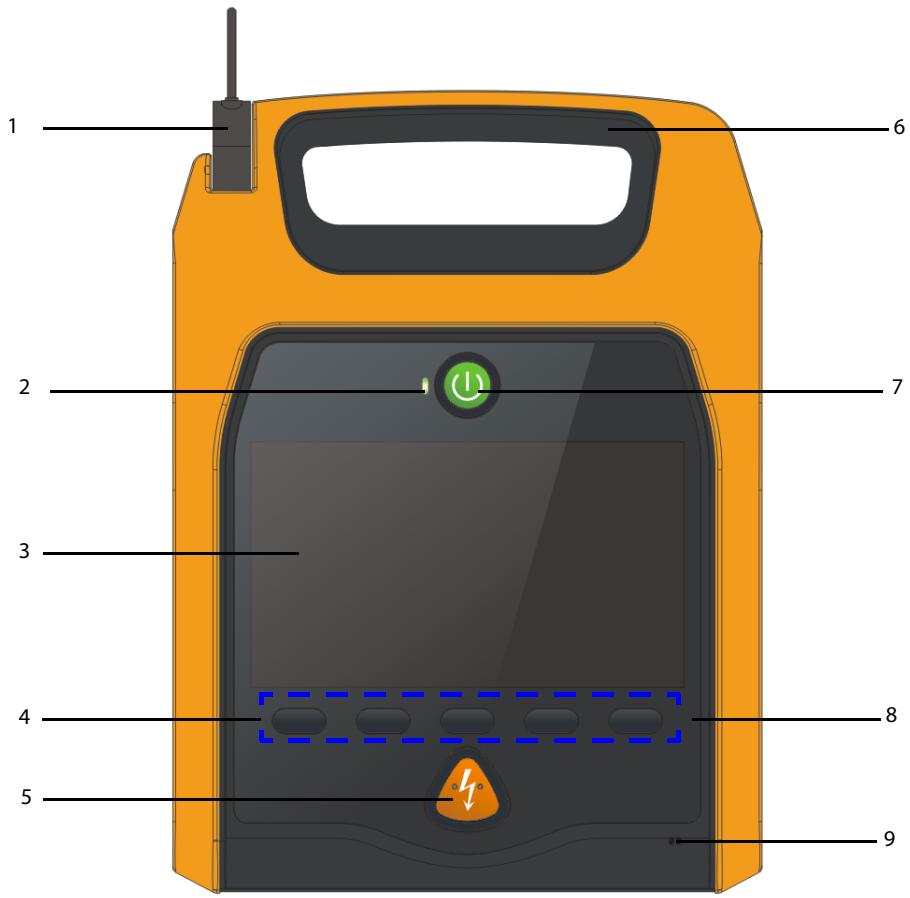
2.2.5 Applied Parts

The applied parts of the equipment are:

- ECG electrodes and leadwires
- Multifunction electrode pads
- CPR sensor

2.3 Main Unit

2.3.1 Front View



1. Pads connector

   It is used to connect the multifunction electrode pads.

2. Status indicator

   - Green: All the tests are passed, and the equipment operates properly.
   - Red Failure is detected on the equipment.

3. Display screen

4. Soft keys

   They are corresponding with the soft key labels located immediately above. The labels of the soft keys change according to the current operating mode. For the equipment configured with AED, manual defibrillation and ECG monitoring functions, there are five soft keys. For the equipment configured with only AED function, there are three soft keys.

5. Shock button

   Press this button to deliver a shock to the patient.

6. Handle

7. Power ON/OFF button

   Press this button to turn on or off this equipment.

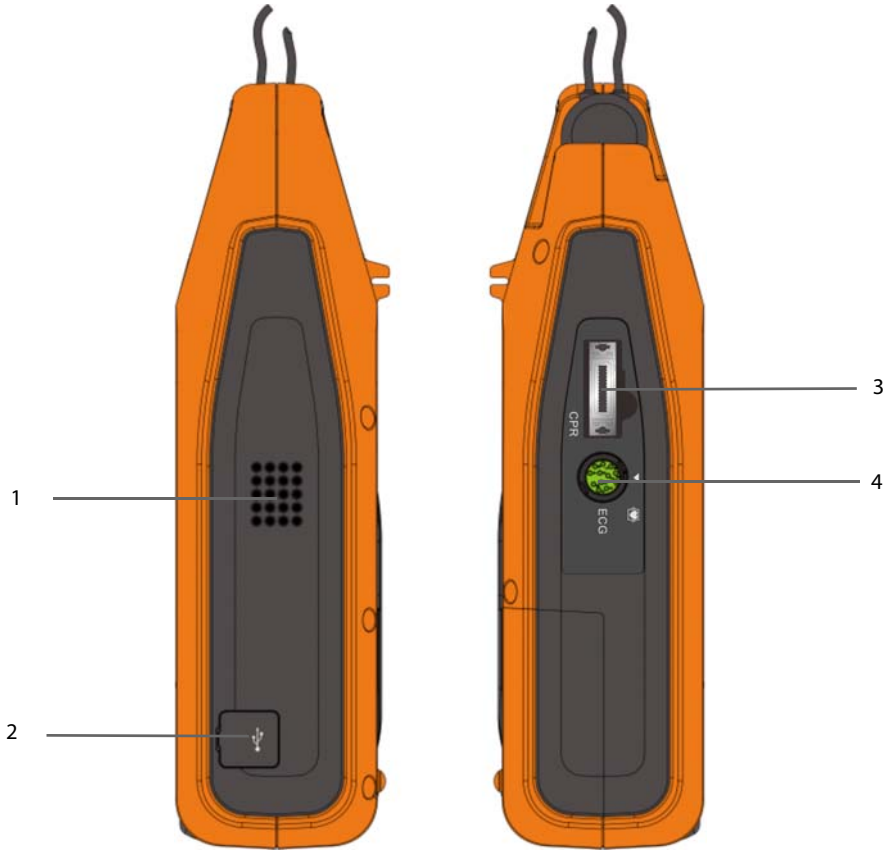
8. Optical sensor

   When [**Brightness**] is set to [**Auto**], the equipment automatically adjust the screen brightness according to the ambient light.

9. Microphone

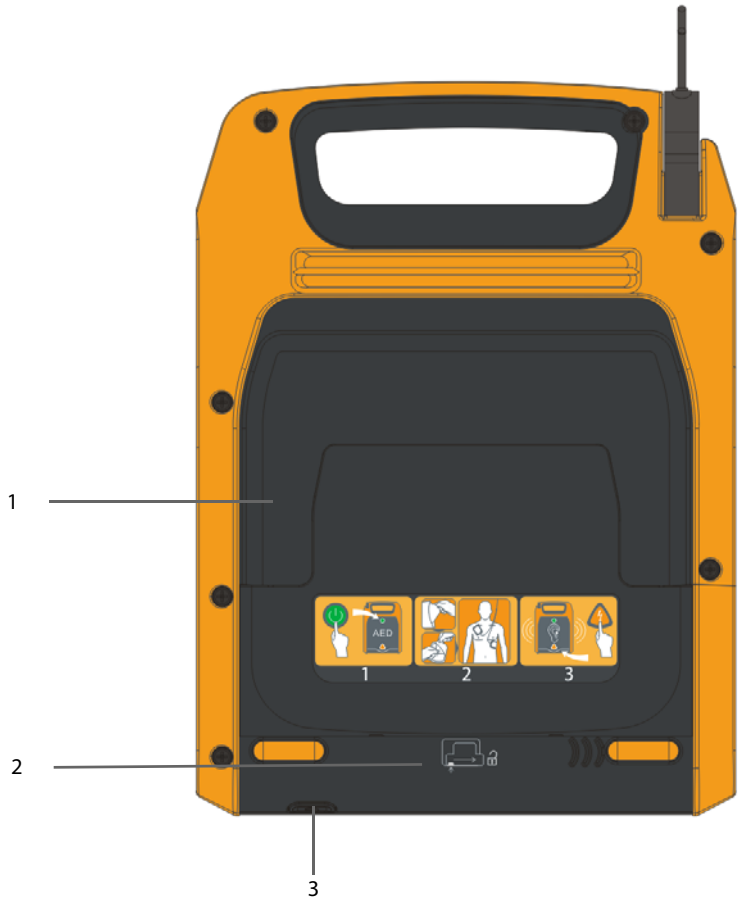
   While operating in AED mode, if [**Voice Recording**] is set to [**On**], the equipment provides voice recording. When [**Voice Volume**] is set to [**Auto**], the equipment automatically adjust the volume according to the ambient noise.

2.3.2 Side View



1. Speaker
2. USB connector
3. CPR sensor connector (for the equipment configured with the CPR sensor)
4. ECG cable connector (for the equipment configured with AED, manual defibrillation and ECG monitoring functions)

2.3.3 Rear View

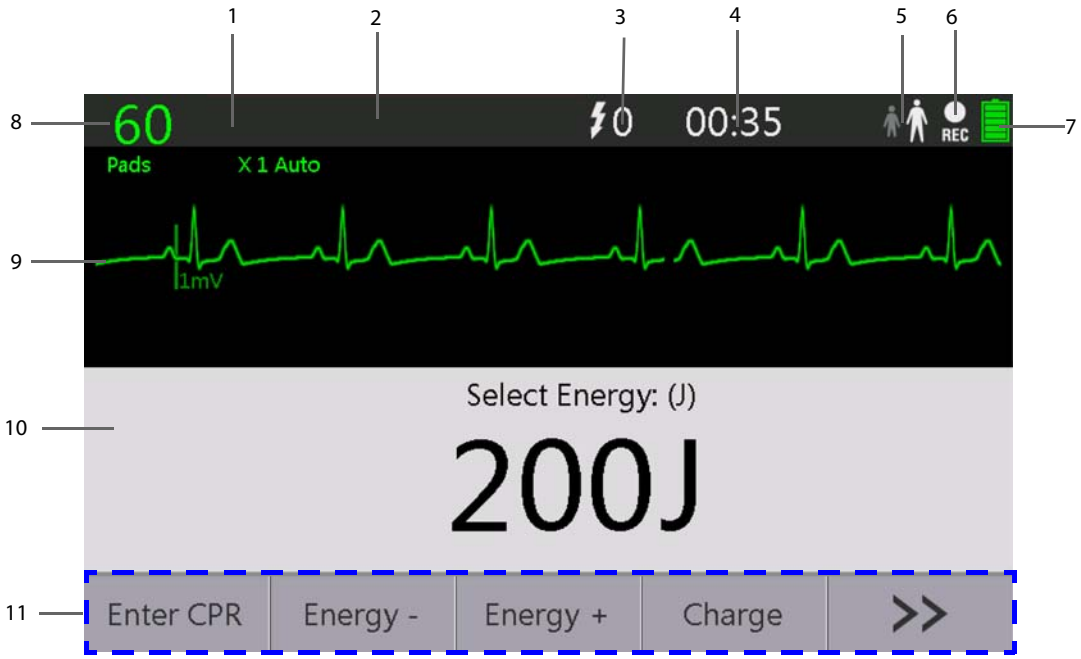


1. Pads compartment
2. Battery compartment
3. Release button

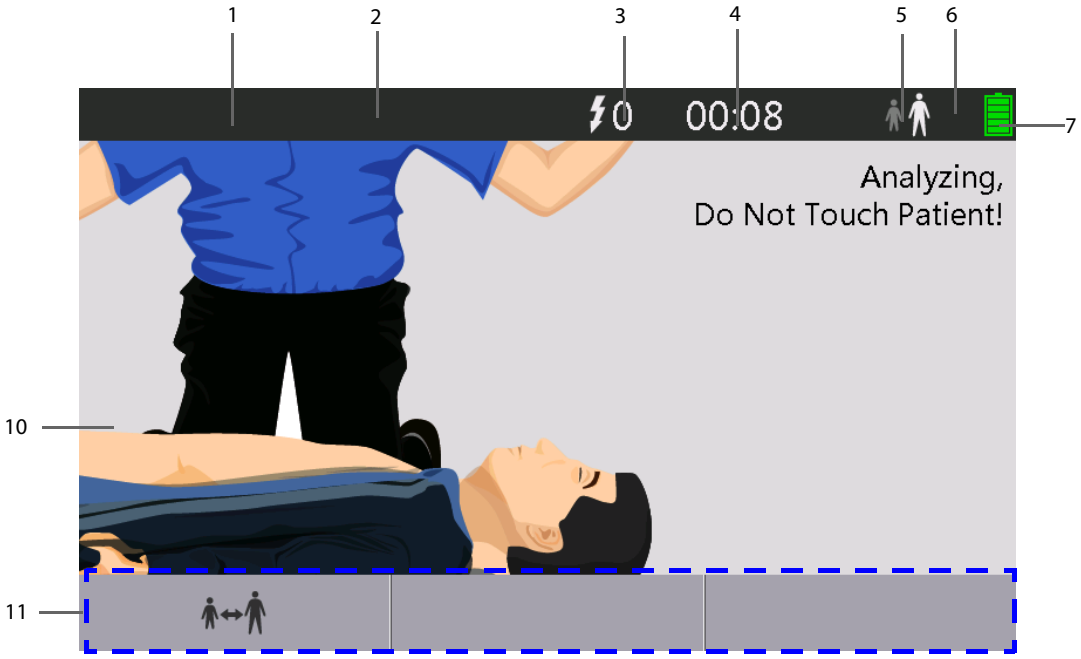
   Press down this button and slide the battery door to the right to open the battery compartment.

2.4 Display Views

For the equipment configured with AED manual defibrillation and ECG monitoring functions



For the equipment configured with only AED function



1. Alarm status symbols
   - ◆ indicates alarms are paused.
   - ◆ indicates alarm sounds are turned off.
2. Alarm area

   This area shows alarm messages. When multiple alarms occur, they will be displayed circularly.
3. Number of delivered shocks
4. Runtime area

   This area shows the equipment's operating time since it is turned on.
5. Patient type

6. Record icon

   It is displayed if the sounding recording function is enabled.

7. Battery Status indicator

   It indicates battery status. Refer to chapter *11 Battery* for details.

8. Heart rate

9. Waveform area

   This area shows the ECG waveforms.

10. Therapy information area

11. Soft Key area

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

2.5 Soft Key Symbols

Below is the description of symbols displayed in the soft key label area:

Return to the previous page

Enter/Confirm

Move to the previous item/page

Move to the next item/page

Display more options

Confirm selection

Switch to Adult or Pediatric mode

Start archive

Power off

Maintenance

Show more instructions

Change the compression/ ventilation rate

Audio Language softkey
Switch the language of audio prompts. The symbol changes if the system language is changed. The larger symbol indicates the current language while the smaller one indicates the target language.
This symbol is for the equipment configured with only AED function. It is displayed only when [**Bilingual Option**] is set to [**On**]

3 Basic Operations and Settings

3.1 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 question, 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

- **To ensure that the equipment is ready for any urgent use, keep it with battery installed and pads preconnected.**

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

- **Package material may contaminate the environment. Properly dispose of the package material according to 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.**

3.1.3 Installing the Battery

To install the battery:

1. Press down the release button and slide the battery door to the right as indicated to remove the battery door.

2. Align the battery pins with the battery connector, slide the battery into the battery compartment, and press until you hear it click into the place.
3. Cover the battery door on the compartment, and slide to the left until you hear it click into the place.

NOTE

- **Check the expiration date displayed on the disposable battery. Remove from use if the battery is expired.**
- **Make sure the battery door is reinstalled properly to protect the equipment and battery.**

3.1.4 Connecting Electrode Pads

1. Plug the pads connector into the pads socket.
2. Place the pads package into the pads compartment properly and carefully.

NOTE

- **Make sure the pads package is intact before use. Otherwise, replace it with a new one.**

3.2 Basic Operation

3.2.1 Turning Power On

1. Check for mechanical damages on the equipment or other damages on the pads package.
2. Make sure the pads cable is properly connected and battery installed.
3. Check the expiration date of the pads on the pads package.
4. Press the **Power ON/OFF** button to start the equipment.

3.2.2 Changing General Settings

You can change the general settings in the [**General Setup**] menu.

To access the [**General Setup**] menu,

- If the equipment is on, press the **Power ON/OFF** button and the "Select an option" window is displayed. Then select → [**Config.**] → [**Config. Edit**] → enter the required password → [**General Setup**].
- If the equipment is off:

- For the equipment configured with AED, manual defibrillation and ECG monitoring functions, press the **Power ON/OFF** button, the third and fourth soft keys (from left to right) simultaneously to display the maintenance screen;
- For the equipment configured with only AED function, press the **Power ON/OFF** button, the second and third soft keys (from left to right) simultaneously.

Then select [**Config.**] → [**Config. Edit**] → enter the required password → [**General Setup**].

NOTE

- **All changes made in Configuration mode are auto-saved immediately. You can turn off the equipment after the setting is finished.**

3.2.2.1 Setting the Date and Time

1. In the [**General Setup**] menu, select [**System Date**] to set the system date.
2. Select [**Time**] to set the system time.

3.2.2.2 Selecting System Language

In the [**General Setup**] menu, select [**Language**] to set the system language, which refers to the language of messages, menus, and audio prompts and so on.

If the system language is set to a non-English language, you can also set [**Bilingual Option**] in the [**General Setup**] menu. When [**Bilingual Option**] is set to [**On**], the text prompts in AED mode are displayed in English and the set system language. And for the equipment configured with only AED function, you can press the Audio Language softkey to switch the language of audio prompts. For details about the softkey, refer to *2.5 Soft Key Symbols*.

For the equipment configured with AED, manual defibrillation and ECG monitoring functions, [**Bilingual Option**] is disabled when [**ECG Display**] is set to [**On**].

3.2.2.3 Setting Default Startup Mode

For the equipment configured with AED, manual defibrillation and ECG monitoring functions, in the [**General Setup**] menu, select [**Default Startup Mode**] and set the default startup mode to:

- [**AED**]: the equipment enters AED mode by default after startup; or,
- [**Manual**]: the equipment enters Manual Defib mode by default after startup.

3.2.3 Turning off the Equipment

To turn off the equipment, follow this procedure:

1. Confirm that the patient monitoring or therapy is completed.
2. Disconnect the patient cables and sensors from the patient.
3. Press the **Power ON/OFF** button and the "Select an option" window is displayed.
4. Press the  soft key to shut down the equipment.

NOTE

- **For battery power saving, if there is no valid ECG signal and no compressions performed by the CPR sensor, the equipment will automatically shut down in 30 minutes.**

3.2.4 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 loads 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 Post Use Procedure

After the equipment has been used on a patient, the unit shall be cleaned as described in *12 Care and Cleaning*.

Then follow the procedure below to prepare the equipment for next use:

1. Connect a new pads package to the equipment as described in *3.1.4 Connecting Electrode Pads*.
2. Perform a user test as described in *13.3.5 User Test*. Check the test result and make sure all test items are passed.
3. Turn off the equipment.

4 Alarms

Alarms triggered by a vital sign that appears abnormal or by technical problems of the equipment, are indicated to the user 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.**

4.1 Alarm Categories

By nature, the equipment's alarms can be classified into two categories: physiological alarms and technical alarms. The equipment configured with only AED function provides only technical alarms.

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. In 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.

Alarm messages are displayed in the alarm area.

Apart from the physiological and technical alarms, the equipment also shows some messages indicating system status. Technically, prompt messages are not alarm messages. Messages of this kind are usually displayed 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 (For the equipment configured with AED, manual defibrillation and ECG monitoring functions)	**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.	/
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 the user through visual or audible alarm indications.

- Alarm tones
- Alarm message

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.**

4.3.1 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.

4.3.2 Alarm Message

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.

- High level alarms — shifts fast between black text on red background and red text on white background (in a frequency from 1.4 Hz to 2.8 Hz)
- Medium level alarms — shifts slowly between black text on yellow background and yellow text on white background (in a frequency from 0.4 Hz to 0.8 Hz)
- Low level alarms — black text on yellow background

4.3.3 Alarm Status Symbols

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

-  indicates the alarm sounds for current alarms are paused. If new alarms are triggered, alarm sounds restore to normal.
-  indicates alarm sounds are turned off. You can only restore the alarm sound in configuration mode.

4.4 Alarm Tone Configuration

4.4.1 Changing the Alarm Volume

1. If the equipment is on, press the Power On/Off button and then select  → [**Config.**] → [**Config. Edit**] → enter the required password → [**Alarm Setup**].
2. Set [**Alm Volume**] to any of the following:
   - [**High**]: the alarm volume is set to the highest level.
   - [**Med**]: the alarm volume is set to a medium level.
   - [**Low**]: the alarm volume is set to a lower level.
   - [**Off**]: the alarm sound is disabled.

NOTE

- **The alarm volume for special system alarms is always high and not user-adjustable**

4.4.2 Pausing Alarm Sounds

You can press the [**Silence**] softkey to temporarily disable alarm tones. In this case, the symbol will be displayed in the sound symbol area indicating all alarm sounds are silenced temporarily. In the audio paused status, all alarm indicators except audible alarm tones works properly. You can press [**Silence**] again to restore alarm sounds.

If new alarms are triggered, alarm sounds restore to normal automatically.

NOTE

- **The alarm volume for special system alarms cannot be paused.**

4.4.3 Switching Off Alarm Sounds

1. If the equipment is on, press the Power On/Off button and then select → [**Config.**] → [**Config. Edit**] → enter the required password → [**Alarm Setup**].
2. Set [**Alm Volume**] to [**Off**] to switch off the alarm sounds.

In the audio off status, appears in the sound symbol area. In this case, all alarm indicators except audible alarm tones works properly. To resume the alarm sounds, set [**Alm Volume**] to [**High**], [**Med**] or [**Low**].

When alarms or alarm sounds are turned off, the equipment can give a reminder tone of a single beep every 60 seconds. The volume for reminder tone is set to a fixed level and not user-adjustable.

4.5 Reminder Tones

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

The reminder tone is switched off by default. You can switch it on by selecting [**Alarm Setup**] →[**Reminder Tone**] in the [**Config. Edit**] menu.

4.6 Clearing Technical Alarms

For some technical alarms, their alarm message background flashing and alarm tones are cleared and the alarm messages change to prompt messages after [**Silence**] 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.

For some technical alarms, all their alarm indications are cleared after [**Silence**] 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.

For others, their alarm tones are cleared but the alarm message background flashing and alarm messages remain after [**Silence**] soft key is pressed. After the equipment restores the normal alarm status, all the alarm indications will continue if the alarm conditions still present.

4.7 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 *14 Troubleshooting*.

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5 AED

5.1 Overview

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

The equipment starts analyzing the patient's heart rhythm immediately after entering 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 pads connection occurs.

While operating in AED Mode, the capabilities of the device are limited to those essential to the performance of semi-automated external defibrillation. Only ECG signals acquired through pads are displayed.

5.2 Safety

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any equipment 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 multifunction 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.**
- **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.**

WARNING

- **During defibrillation, air pockets between the skin and multifunction electrode pads can cause patient skin burns. To help prevent air pockets, make sure defibrillation pads are completely adhered to the skin.**
- **Do not charge and deliver shocks frequently for a long time if disposable battery is used.**
- **Do not use dried-out pads.**

CAUTION

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

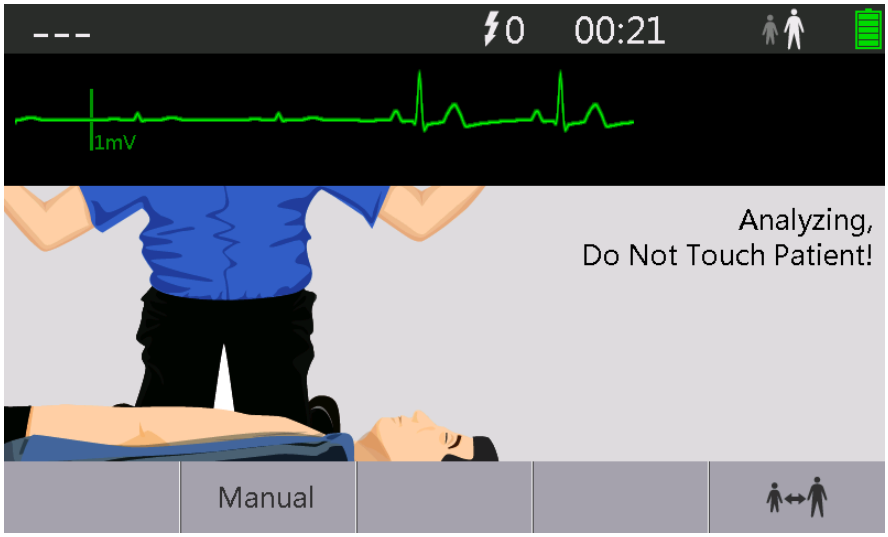
NOTE

- **If needed, perform CPR when there is delay or interruption in using of the equipment.**
- **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 defibrillator/monitor 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 device performance.**

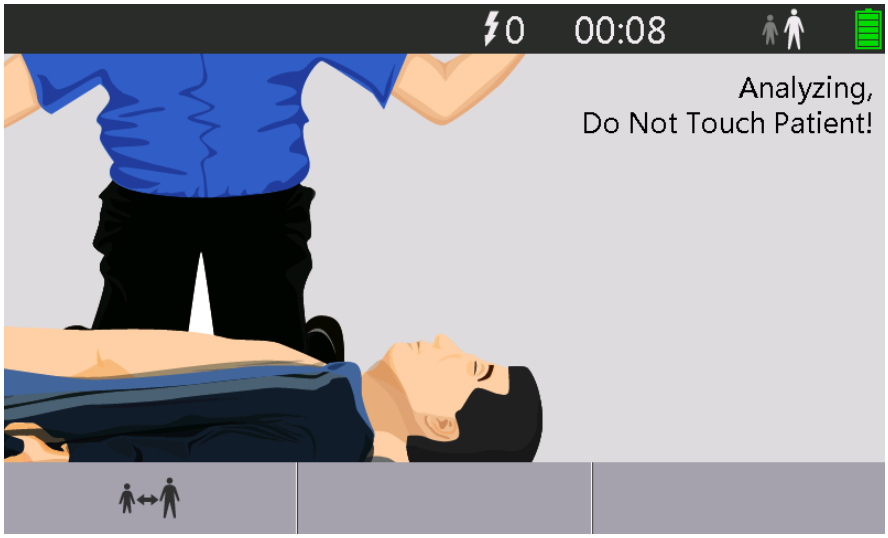
5.3 AED View

A typical screen in AED Mode is shown below.

For the equipment configured with AED, manual defibrillation and ECG monitoring functions



For the equipment configured with only AED function



In AED mode, the information area displays CPR instructions, pads connection instructions and AED prompt messages. For the equipment configured with AED, manual defibrillation and ECG monitoring functions, HR numeric and one ECG waveform acquired from the multifunction electrode pads are displayed above the information area if [**ECG Display**] is set to [**On**].

5.4 AED Procedure

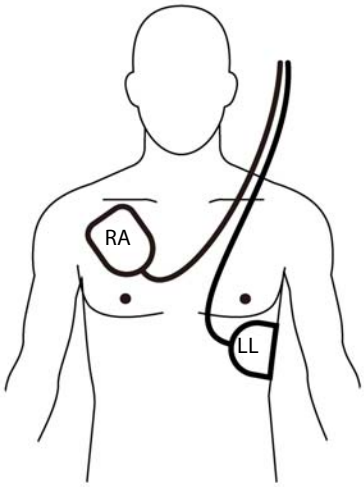
Confirm that the patient is unresponsive, not breathing or not breathing normally. Then:

1. Press the **Power On/Off** button to turn on the equipment.

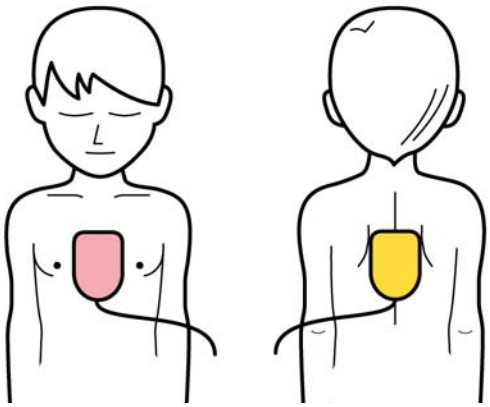
   When the equipment enters AED mode, it checks to see if the pads and pads cable are properly connected. If not, prompt messages will appear in the AED information area until corrective action has been taken.

2. Expose the patient's chest. Wipe moisture from the patient's chest and, if necessary, clip or shave excessive chest hair.

3. Apply multifunction electrode pads to the patient as directed on the pads package.



Adult (anterior-lateral)



Pediatric (anterior-posterior)

4. Follow the screen and voice prompts.
   - If a shockable rhythm is detected, the equipment charges automatically.
   - If a shockable rhythm is not detected, the system prompts "no shock advised" and then starts CPR or resume rhythm analysis according to the current [**NSA Action**] setting.

5. Press the **Shock** button, if prompted.

   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. If 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.

WARNING

- **Performing CPR or otherwise handling or moving the patient during rhythm analysis can cause incorrect or delayed analysis.**
- **For safety reasons, some low-amplitude or low-frequency heart rhythms as well as some VT rhythms may not be interpreted as shockable rhythms.**

NOTE

- **Use the defibrillator pads before the expiration date. If the pads are found expired, by checking either the expiration date on the pads package or the alarm message displayed on the screen, replace the pads immediately. In emergency, if there are no spare pads nearby, proceed patient treatment with the pads and ignore pads related alarm messages.**
- **Use pediatric pads for pediatric patients. If you are using adult pads for pediatric patients, select  and set the patient type to pediatric and follow the instructions on the screen to apply pads.**
- **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.**

- **If MR60/MR61 multifunction electrode pads are used, the equipment automatically recognizes the patient type after power on. When the current patient type is found inconsistent with the pad type, you need to manually change the patient type.**
- **The Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.**
- **Impedance is the resistance between the defibrillator's pads hat 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. Charge removed" message appears, make sure that the patient's skin has been washed and dried and that any chest hair has been clipped. If the message persists, change the pads.**
- **Most pediatric cardiac arrests are asphyxial, and the resuscitation from asphyxial arrest is best accomplished by a combination of ventilations and chest compressions. Make sure proper CPR is performed on the patient when waiting for defibrillation equipments or advance life support. Or follow your local protocol.**

5.5 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.

If the patient type is changed or pads malfunction detected during charging, the charge will be removed.

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.

5.6 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 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! Attend to patient". The message "No Shock Advised!" and "Monitoring" are shown circularly in the AED information area. You can define the frequency of these prompts by adjusting [**Voice Prompt Interval**] in [**Config. Edit**] menu.

5.7 CPR

If [**Initial CPR**] is set to [**On**], the system enters initial CPR after startup. You can set [**Initial CPR**] to [**On**] or [**Off**] in [**Config. Edit**] menu.

In CPR mode, voice instructions, pictures, and prompt messages needed for CPR are provided.

After the shock series, ECG analysis pauses and the equipment enters the CPR status. Analysis resumes at the completion of CPR.

CPR mode continues for 2 minutes.

WARNING

- **Performing CPR with pads attached on the patient might damage the pads. In this case, replace the pads.**

5.7.1 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.

You can press the  soft key repeatedly to change the compression/ventilation rate.

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.**

5.8 AED Sound Recording

The equipment include 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. Press the **Power On/Off** button and then select  → [**Config.**] → [**Config. Edit**] → enter the required password.
2. Select [**General Setup**] → [**Voice Recording**], and toggle between [**On**] and [**Off**].

The symbol 

is shown at the top right corner of the screen if the sounding recording function is enabled.

The equipment can store up to 180 minutes of recording, and one recording for one patient.

5.9 AED Setup

1. Press the **Power On/Off** button and then select  → [**Config.**] → [**Config. Edit**] → enter the required password.
2. Select [**AED Setup >>**] to enter the AED Setup menu, and then change AED settings as desired.

Refer to *10 Configuration Management* for details.

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6 Manual Defibrillation

6.1 Overview

Manual defibrillation is available only on the equipment configured with AED, manual defibrillation and ECG monitoring functions. This chapter explains how to prepare for and perform asynchronous defibrillation and synchronous cardioversion using multifunction electrode pads.

In 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.

6.2 Safety

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any equipment 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 multifunction 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.**
- **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

- **Do not charge and deliver shock frequently for an long time if disposable battery is used.**
- **Clinicians must select an appropriate energy level for defibrillation of pediatric patients.**
- **Performing CPR with pads attached on the patient might damage the pads. In this case, replace the pads.**

CAUTION

- **If the equipment runs on disposable battery, the energy level is not adjustable. To adjust the energy, access the [Manual Defib Setup] menu and change the default energy for corresponding patient type. For details about the configuration, refer to *10.6.3 Manual Defib Setup Menu*.**
- **Energy charging in Manual Defib mode might take a longer time if disposable battery is used. Replace it with a rechargeable battery if necessary.**
- **Prior to using this defibrillator, disconnect from the patient all equipment that is not defibrillator-protected.**

NOTE

- **Impedance is the resistance between the defibrillator's pads 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 Removed" message appears, make sure that the patient's skin has been washed and dried and that any chest hair has been clipped. If the message persists, change the pads.**
- **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 defibrillator/monitor 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 device performance.**

6.3 Manual Defibrillation View

A typical screen in Manual Defib Mode is shown below.

In manual defibrillation mode, an ECG waveform and related parameters are displayed. In the middle of the screen, synchronous icon, prompt message, selected energy, and a shock counter are displayed.

In manual defibrillation mode, you can perform the following operations:

- Press [**Enter CPR**] soft key to enter CPR mode.
- Press [**Energy -**] or [**Energy +**] soft keys to adjust the energy for defibrillation shock. You can accelerate the selection by pressing and holding either of the buttons. If pads are not properly connected, the two soft keys are disabled. If disposable battery is used, the two soft keys are not displayed.
- Press [**Charge**] soft key to charge.
- Press [**>>**] soft key to display more options.
- Press [**AED**] soft key to enter AED mode.
- Press [**Lead**] soft key to select leads.
- Press [**Gain**] soft key to adjust the gain of waveform.
- Press [**Enter Sync**] soft key to enter synchronous cardioversion mode.
- Press soft key to change patient type.
- Press [**Silence**] to temporarily pause the current alarm sound. This soft key is not displayed if there is no alarm sound currently.

6.4 Manual Defibrillation Procedure

1. Expose the patient's chest. Wipe moisture from the patient's chest and, if necessary, clip or shave excessive chest hair.
2. Connect pads cable to the pads interface. If pre-connected, skip this step.
3. Apply pads to the patient according to the instructions for use indicated on pads package.
4. Turn on the equipment and enter Manual Defib mode.

   You can set the [**Default Startup Mode**] to [**AED**] or [**Manual**] in the [**Config. Edit**] menu. The default setting is [**AED**].

   - If [**Default Startup Mode**] is set to [**AED**], the equipment enters AED mode after startup. You can select [**Manual**] → [**Yes**] to enter manual defibrillation mode.
   - If [**Default Startup Mode**] is set to [**Manual**], the equipment enters manual defibrillation mode directly after startup.
5. Press [**Energy -**] or [**Energy +**] soft keys to adjust the energy for defibrillation shock. If disposable battery is used, skip this step.

   You can accelerate the selection by pressing and holding either of the buttons.
6. Press [**Charge**] soft key to charge.

   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.

   For equipment powered by rechargeable battery, if you have to increase or decrease the selected energy during charging or after charging is complete, press [**Energy -**] or [**Energy +**] soft keys 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 60s, the equipment disarms automatically.
7. 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 loudly and clearly, "Stay Clear!" and then press the Shock button to deliver energy.

NOTE

- **For defibrillation of adult patients, recommended energy level is 200 Joules.**
- **Use pediatric pads for pediatric patients. If you are using adult pads for pediatric patients, select  and set the patient type to pediatric and follow the instructions on the screen to apply pads.**

6.5 Synchronized Cardioversion

Synchronized Cardioversion allows you to synchronize delivery of the defibrillator shock with the R-wave of the ECG. This function is not available if the equipment runs on disposable battery.

To use synchronized cardioversion, press the [**>>**] and then [**Enter Sync**] soft keys in the Manual Defib mode. Then "Sync" appears in the Defibrillation information area and a marker appears above each R-wave, see the figure below:

You can monitor ECG through multifunction electric pads or electrodes connected to a 3-lead ECG cable. Shock is delivered through pads.

For synchronized cardioversion, we recommend to acquire patient's ECG through ECG lead set.

6.5.1 Performing Synchronized Cardioversion

1. Connect the pads cable and apply the pads to the patient. If ECG set is used for ECG monitoring, connect the ECG cable and apply the ECG electrodes to the patient, referring to*8 Monitoring ECG*.
2. In Manual Defib mode, press the [**>>**] and then [**Enter Sync**] soft keys to activate the synchronous cardioversion function.
3. Press the **[>>**] and then [**Lead**] soft keys to 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 the equipment enters the Sync mode, as indicated by the SYNC mark shown in the defibrillation information area.
6. Press [**Energy -**] or [**Energy +**] soft keys to a desired energy level.
7. Press [**Charge**] soft key to charge.
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. The shock will be delivered when the next R-wave is detected.

NOTE

- **Once the equipment enters Synchronized Cardioversion mode, the alarms resume.**
- **During synchronized cardioversion, it is important to continue to hold the shock button until the shock is delivered. The equipment shocks with the next detected R-wave.**
- **If no R-wave is detected within 9s, a prompt message "'No R-Wave" is displayed.**

6.5.2 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 above.

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.

6.5.3 Disabling the Sync Function

To switch off the Sync function, press the [**Sync Off**] soft key to enter the Manual Defib mode.

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7 CPR Feedback

7.1 Overview

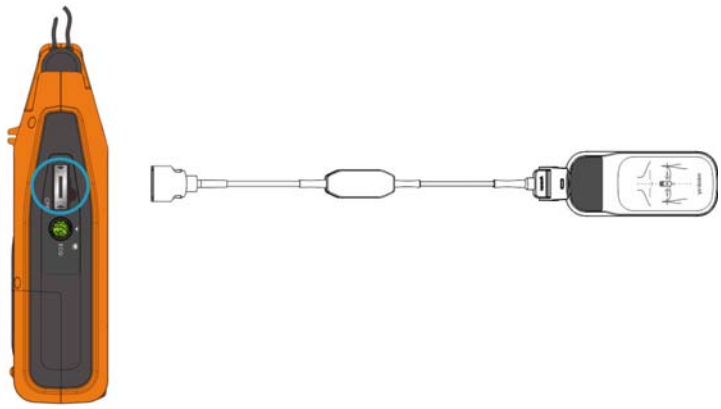
The CPR sensor can be connected to the equipment to provide real-time CPR feedback. For more information, refer to *MR6401 CPR Sensor Operator's Manual (P/N: 046-010423-00)*.

NOTE

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

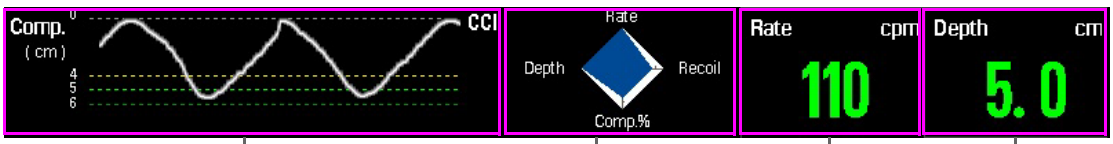
7.2 Connecting the CPR Sensor

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 CPR sensor connector at the side of the equipment.



7.3 Viewing CPR Feedback

- In manual defibrillation mode, select [**Enter CPR**] to enter the CPR mode.
- In AED mode, the system automatically enters the CPR mode.



Compression waveform area | CCI graph | Compression rate area | Compression depth area

The CPR feedback provides compression waveform, CCI graph, compression rate and compression depth.

- 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.
- 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.
- 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.
- 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 Monitoring ECG

8.1 Overview

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 and multifunction electrode pads. If both ECG sets and pads are connected, the configured ECG waveforms is displayed in the waveform area.

ECG monitoring is available only on the equipment configured with AED, manual defibrillation and ECG monitoring functions.

8.2 Safety

WARNING

- **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, do not completely rely on the heart rate reading or the heart rate alarms. Always keep paced patients under close surveillance.**

CAUTION

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

NOTE

- **If the correct electrodes are applied properly to the patient as instructed by the manufacturer, the display recovers in 10s after defibrillation.**
- **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.**
- **Use the same type of ECG electrodes when monitoring ECG through ECG lead set.**

8.3 ECG View

ECG monitoring is provided after startup in both AED and Manual Defibrillation mode. The equipment displays one ECG waveform and the heart rate reading.

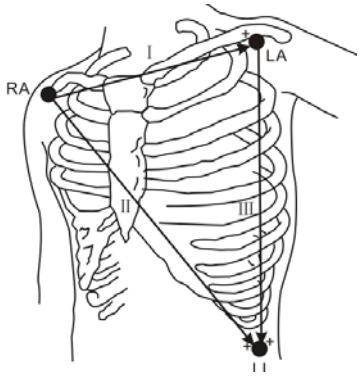
If the patient is not properly connected to the equipment, a dash line is shown in the ECG waveform area.

8.4 Preparing to Monitor ECG

8.4.1 ECG Monitoring with Electrodes

1. Prepare the patient's 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:
   - ◆ Shave hair from skin at chosen sites.
   - ◆ Gently rub skin surface at application sites to remove dead skin cells.
   - ◆ 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.
   - ◆ Dry the skin completely before applying the electrodes.
2. Attach the clips or snaps to the electrodes before placing them.
3. Place the electrodes on the patient.
4. Attach the lead wires to the ECG trunk cable.
5. Plug the trunk cable into the equipment's ECG connector.

8.4.1.1 Placing Electrode



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.

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

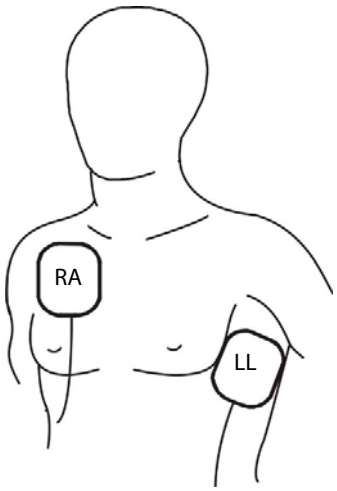
- **When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.**
- **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this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

8.4.2 ECG Monitoring with Pads

1. Prepare the patient's skin.
2. Apply pads according to the instructions for use indicated on pads package. Use anterior-lateral placement.
3. Connect the pads cable with the equipment if not pre-connected.

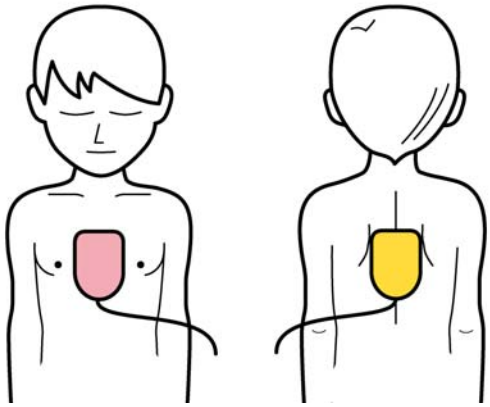
Pads placement for Adult Patient

1. Place the RA pad on the patient's upper right torso, lateral to the sternum and below the clavicle, as shown below.
2. Place the LL pad to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. See the figure below.



Pads Placement for Pediatric Patient

Place the pink pad in the center of the chest between the nipples, and the yellow one in the center of the back (anterior-posterior), as shown below:



8.5 Changing ECG Settings

8.5.1 Selecting Lead Type

In Manual Defibrillation mode, select [**>>**] and then press [**Lead**] repeatedly to set lead type as per the adopted lead type.

8.5.2 Setting Gain

If the wave is too small or clipped, you can select [**>>**] and then press [**Gain**] repeatedly in Manual Defibrillation mode to change its size.

There are altogether 7 options, namely [**Auto**], [×**0.125**], [×**0.25**], [×**0.5**], [×**1**], [×**2**] and [×**4**]. When [**Gain**] is set to [**Auto**], the system selects the most appropriate gain for the current waveform.

8.5.3 Choosing AHA or IEC Lead Placement

1. Press the **Power On/Off** button, and then select → [**Config.**] → [**Config. Edit**] → enter the required password.
2. In the [**Config. Edit**] menu, select [**ECG Setup**] → [**ECG Standard**], and then select [**AHA**] or [**IEC**] according to the standard that is applied to your hospital.

8.5.4 Setting Filter Mode

When monitoring ECG through ECG lead set, filter mode is displayed above the ECG waveform. To change the filter mode:

1. Press the **Power On/Off** button, and then select → [**Config.**] → [**Config. Edit**] → enter the required password.
2. In the [**Config. Edit**] menu, select [**ECG Setup**] → [**ECG Bandwidth**], and then select [**Therapy**] or [**Monitor**].

8.6 Arrhythmia Analysis

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

In the process of ECG monitoring, if any arrhythmia event is detected, corresponding arrhythmia alarms are reported according to the alarm level.

NOTE

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

8.6.1 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
Shockable rhythum	A fibrillatory wave for 4 consecutive seconds. A dominant rhythm of adjacent Vs and a HR > the V-Tach Heart Rate Limit.	
Vtac	The consecutive PVCs ≥ Vtac PVCs limit, and the HR ≥ the Vtac rate 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.	
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.	
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 ≥ Vbrd Rate limit but < 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.	
Irr. Rhythm	Consistently irregular rhythm.	

■ When multifunctional electrode pads are used for ECG monitoring, the equipment provides only asystole, and shockable rhythm alarms.

8.6.2 Setting Arrhythmia Analysis

To switch arrhythmia analysis on or off:

1. Press the **Power On/Off** button, and then select → [**Config.**]→ [**Config. Edit**] → enter the required password.
2. In the [**Config. Edit**] menu, select [**ECG Setup**] and set [**Arrhythmia**] to:
   - [**Lethal Arrh. Only**]: the system provides arrhythmia analysis only for lethal arrhythmia events; or,
   - [**All**]: the system provides arrhythmia analysis for all the arrhythmia events.

8.6.3 Changing Arrhythmia Threshold Settings

1. Press the **Power On/Off** button, and then select → [**Config.**] → [**Config. Edit**] → enter the required password.
2. In the [**Config. Edit**] menu, select [**ECG Setup**] and then change the arrhythmia threshold settings.

In case an arrhythmia violates its threshold, an alarm will be triggered. The setting of Asystole Delay is linked 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
Asystole. Delay	3 to 10	5	1	s
Extreme Tachy	60 to 300	Adult: 160 Pediatric: 180	5	bpm
Extreme Brady	15 to 120	Adult: 35 Pediatric: 50	5	bpm
Vbrd Rate	15 to 60	40	5	bpm
Vbrd PVCs	3 to 99	5	1	Beats
V-Tach Rate	100 to 200	130	5	bpm
V-Tach PVCs	3 to 12	6	1	Beats
Tachy	60 to 300	Adult: 120 Pediatric: 160	5	bpm
Brady	15 to 120	Adult: 50 Pediatric: 75	5	bpm
Multif. PVCs Window	3 to 31	15	1	Beats
PVCs High	1 to 10	10	1	/

8.6.4 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.

NOTE

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

8.7 ECG Troubleshooting

This section lists the problems that might occur. If you encounter problems when using the monitor 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 *14.3 Physiological Alarm Messages* and *14.4 Technical 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 more information, refer to *15.1 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 more information, refer to *8.4 Preparing to Monitor ECG*. 2. Apply fresh, moist electrodes. Avoid muscular areas.
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 *8.4 Preparing to Monitor ECG*. 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 more information, refer to *8.4 Preparing to Monitor ECG*. 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 more information, refer to *8.5 Changing ECG Settings*. 2. Perform skin preparation again and re-place the electrodes. For more information, refer to *8.4 Preparing to Monitor ECG*. 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 more information, refer to *8.5.2 Setting Gain*. 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. Refer to *8.4 Preparing to Monitor ECG*. 3. Check for ECG filter setting. Set ECG Filter mode to [**Monitor**].

9 Data Management

9.1 Introduction

Once turned on, the equipment automatically generates a patient ID and starts to record the following information for the current patient:

- Trends,
- Waveforms,
- Events; and,
- Audio recording of the rescuing process (for up to three hours).

Along with the above patient data, some device information is also exported, including intellectual property statement, device ID, software version, hardware version, work status, and battery information.

The data management function enables you to export the following patient data on the equipment to a USB flash memory:

- [**Latest**]: the latest patient document;
- [**Unexported**]: all the documents that have never been exported; and
- [**All**]: all the patient documents saved on the equipment.

NOTE

- **It is recommended to export patient data after each use. Or earlier-stored data might be overwritten by later ones.**

9.2 Recommended USB Flash Memory

Brand	Model	Size of Memory
Kingston	DataTraveler 108	8 GB
Sandisk	CZ50	4 GB
		8 GB

9.3 Exporting Data

1. Plug a USB flash memory to the USB connector on the equipment.
2. Press the **Power On/Off** button, and then select  to enter the maintenance mode.
3. Select the [**Archive**] soft key, and press or to toggle among the data to be exported, and then to confirm the selection.
4. Press  to start export. The equipment automatically searches for USB flash memory and once succeeds, starts to export data.
5. Remove the USB flash memory after the data has been exported.

CAUTION

- **To avoid shock hazard, do not connect the USB flash memory unless you are to export data. Remove it timely once finished.**

NOTE

- **If [Delete Data After Exporting] is selected before export, the exported data will be deleted from the equipment when export is completed**

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.**

10 Configuration Management

10.1 Introduction

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

- View system configuration;
- Change system configuration;
- Restore the factory default configuration; and,
- Export or import configuration files.

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

10.2 Viewing System Configuration

When the equipment is on, press the **Power On/Off** button and then select → [**Config.**] → [**View Config**] to view the current system configuration.

10.3 Password

Accessing configuration management is password protected. The required password is set to 3156 before the equipment leaves the factory.

10.4 Accessing Configuration Management

1. Press the **Power On/Off** button and then select → [**Config.**] → [**Config. Edit**], and a dialog box pops up:
   - To access the [**Config. Edit**] menu, enter the correct password.
   - To close the dialog box and return to maintenance screen, press .
2. On the [**Config. Edit**] screen, you can:
   - Press or to toggle among setting items or options; and,
   - Press to confirm the selection, and then press to return to the previous menu.

NOTE

- **Changing of setup items shall be performed under the direction of authorized personnel.**

10.5 Restoring Factory Default Configuration

1. On the [**Config. Edit**] screen, press or and then to select [**Config.**]
2. Select [**Default Config.**] and a dialog box pops up.
3. Select [**Yes**] to restore all the current settings to factory default settings.

WARNING

- **The system date, time, and language settings in [General Setup] menu and all the settings in [Network Setup] remain unchanged after restoring factory default settings.**

10.6 List of Configuration Items

The following section lists of all the configuration items in the [**Config. Edit**] menu. Those marked with "*" are for the equipment with AED, manual defibrillation and ECG monitoring functions.

10.6.1 General Setup Menu

Menu Item		Options/Range	Default	Remark
System Date	Year	2007 to 2099	/	The selectable range for system date is 2007-01-01 to 2099-05-31.
	Month	01 to 12	01	
	Day	01 to 31	01	
Time	Hour	0 to 23	01	/
	Minute	0 to 59	01	
	Second	0 to 59	01	
Language		ENGLISH, SIM. CHINESE, FRENCH, GERMAN, ITALIAN, SPANISH, PORTUGUESE, RUSSIAN, CZECH, DUTCH, CROATIA, TRA. CHINESE	/	Three languages are available on your equipment, SIM. CHINESE, ENGLISH, and your local language. For English or Chinese speaking countries, the language options are SIM. CHINESE, ENGLISH, and FRENCH/TRA. CHINESE. For more information, contact the service personnel.
Bilingual Option		On, Off	Off	Disabled when [**ECG Display**] is set to [**On**]
Default Startup Mode*		AED, Manual	AED	/
Voice Recording		On, Off	Off	/
Voice Volume		On, Off	Auto	/
Brightness		Auto, Outdoor Mode, Indoor mode	Auto	/

10.6.2 AED Setup Menu

Menu Item		Options/Range	Default	Remark
Shock Series		1, 2, 3	1	/
Energy 1	Adult	100, 150, 170, 200, 300, 360J	200 J	≤Energy 2
	Pediatric	10, 15, 20, 30, 50, 70, 100J	50 J	
Energy 2	Adult	Energy 1 to 360J	300 J	≥ Energy 1, and ≤Energy 3
	Pediatric	Energy 1 to 100 J	70 J	
Energy 3	Adult	Energy 2 to 360J	360 J	≥ Energy 2
	Pediatric	Energy 2 to 100 J	100 J	
NSA Action		Monitor, CPR	CPR	/
Voice Prompt Interval		Off, 30s, 60s, 90s, 120s, 150s, 180s	30s	/
Initial CPR*		On, Off	Off	When set to [**On**], the system enters CPR mode directly after startup.
ECG Display*		On, Off	On	When set to [**On**], the [**Bilingual Option**] setting is disabled.

10.6.3 Manual Defib Setup Menu

This setup menu is only available for the equipment with AED, manual defibrillation and ECG monitoring functions.

Menu Item	Options/Range	Default
Default Energy for Adult	100J, 150J, 170J, 200J, 300J, 360J	200J
Default Energy for Pediatric	10J, 15J, 20J, 30J, 50J, 70J, 100J	50J
Sync After Shock	Yes, No	No

10.6.4 CPR Setup Menu

Menu Item	Options/Range	Default
CPR Mode	30:2, 15:2, Hands-Only	30:2
Voice Prompts	On, Off	On

10.6.5 ECG Setup Menu

This setup menu is only available for the equipment with AED, manual defibrillation and ECG monitoring functions.

Menu Item		Options/Range	Default
ECG Bandwidth		Monitor, Therapy	Therapy
Arrhythmia		Lethal Arrh. Only, All	Lethal Arrh. Only
Asystole Delay		3 to 10	5
Extreme Tachy	Adult	60 to 300	160
	Pediatric	60 to 300	180
Extreme Brady	Adult	15 to 120	35
	Pediatric	15 to 120	50
Vbrd Rate		15 to 60	40
Vbrd PVCs		3 to 99	5
V-Tach Rate		100 to 200	130
V-tach PVCs		3 to 99	6
Tachy	Adult	60 to 300	120
	Pediatric	60 to 300	160
Brady	Adult	15 to 120	50
	Pediatric	15 to 120	75
Multif. PVCs Window		3 to 31	15
PVCs High		1 to 100	10
ECG Standard		AHA, IEC	AHA
Pacemaker Detection		On, Off	Off

10.6.6 Alarm Setup Menu

This setup menu is only available for the equipment with AED, manual defibrillation and ECG monitoring functions.

Menu Item	Options/Range	Default
Alarm Volume	High, Med, Low, Off	Low
Reminder Tone	Reminder Tone	Off

10.6.7 Test Setup Menu

Menu Item	Options/Range	Default
User Test Setup	00:00, 01:00, 02:00, 03:00, 04:00, 05:00	03:00

10.6.8 Network Setup Menu

For the equipment configured with the Wi-Fi module, the related configuration items are shown as below.

Menu Item	Options/Range	Default	Remark
Address Type	Manual, DHCP	Manual	/
IP Address	4 segments, and editable range 0 to 255 for each	/	Input Static IP address if it is set to DHCP
Subnet Mask			/
Gateway			/
DNS Address Type	Manual, DHCP	Manual	/
Preferred DNS Server	4 segments, and editable range 0 to 255 for each	/	/
Alternate DNS Server			

For the equipment configured with the 4G module, the related configuration items are shown as below.

Menu Item	Options/Range	Default	Remark
Device Management System Site	/	aed.mindray.com	Input the IP address or domain name of Device Management System
Device Management System Port	0 to 65535	1883	The device management system port is 1883 or 3600.

10.6.9 WLAN Setup Menu

For the equipment configured with the Wi-Fi module, you can make settings of WLAN, and the related configuration items are shown as below.

Menu Item	Options/Range	Default	Remark
Device Management System Site	/	aed.mindray.com	Input the IP address or domain name of Device Management System
Device Management System Port	0 to 65535	1883	The device management system port is 1883 or 3600.
Access Point	0 to 32	/	Input the network name of
Security	WEP OFF, WEP ON, WPA PSK, WPA TKIP, WPA2 PSK, WPA AES, WPA PSK AES, WPA2 AES, CCKM TKIP, CCKM AES	WEP ON	/
Password	0 to 64	/	/
WLAN Band	Auto, 5G, 2.4G	Auto	/
AUT. Server Type	ACS, SBR	ACS	/
BG Channel	All, Specified, None	All	
A Channel	All, Specified, None	All	
Network Test	Select to perform the network test and check the network connection.		

10.6.10 Certificates Maintenance Menu

For the equipment configured with the Wi-Fi module, you can manage certificates, and the related configuration items are shown as below.

Menu Item	Remark
Import certificates	Select to import the desired certificate from the USB drive.
Delete certificates	Select to view the existing certificate, or delete the desired certificate.

10.6.11 Config. Menu

Menu Item	Remark
Default Config.	Select to restore factory default setting
Config. Import	Select to import an existing configuration file
Config. Export	Select to export the current configuration as configuration file

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11 Battery

11.1 Introduction

The equipment is designed to operate on battery power. There are two types of batteries supplied, rechargeable and disposable respectively. We recommend you to check the remaining battery charge periodically to ensure enough power for defibrillation at any time.

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

On-screen battery symbol indicates the current battery status:

-  Indicates that battery works correctly. The solid green portion represents the current battery charge level. Each block represent a charge of approximately 20% capacity.
-  Indicates that the battery has low charge level and needs to be replaced.
-  Indicates that the battery is almost depleted and needs to be replaced immediately.

You can check the status of rechargeable battery 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.

If the battery charge is too low, a technical alarm will be triggered and the "Low Battery" message displayed in the alarm area. At this moment, change the battery.

WARNING

- **Keep the batteries out of children's reach.**
- **Use only specified batteries.**
- **The batteries should only be charged in Mindray BatteryFeed20 charger station.**
- **Never charge the disposable battery in any case.**

CAUTION

- **Energy charging in Manual Defib mode might take a longer time if disposable battery is used. Replace it with a rechargeable battery if necessary.**

NOTE

- **Remote upgrade might take a long time and greatly reduce the charge of the installed battery. Please check the battery status after each upgrade.**
- **After long term use, the power charge indicated by the battery symbol may be different from the actual charge. Always observe the alarm information displayed on the screen.**
- **Remove the battery before transporting or storing the equipment.**

11.2 Battery Alarms

11.2.1 Low Battery Alarm

If the battery charge is low, a technical alarm "Low Battery" will be triggered. In this case, replace the battery with a fully charged rechargeable battery or a new disposable battery on immediately.

If the battery is almost depleted, a prompt "Battery Depleted! Replace Battery Now." pops up and alarm tones are provided. In this case, replace the battery immediately. This prompt will not disappear until the battery is replaced. The equipment automatically shuts down if no action is taken in 3 minutes.

NOTE

- **The Low Battery alarm means that the battery is beginning to weaken and should be replaced at the first opportunity. At least 20 minutes of monitoring and six full energy shocks can be performed when the Low Battery alarm is activated. Replace the battery as soon as possible.**

11.2.2 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 contact our company and replace it with a new one.

11.2.3 Battery Error Alarm

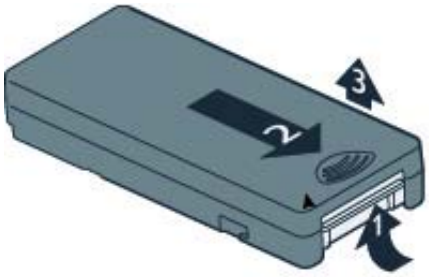
In the situation that the battery has a failure, a high level technological alarm "Battery Err" will be presented. In this case, replace the battery or contact your service personnel.

11.3 Replacing Batteries

If the battery is depleted or malfunction is detected, you need to replace the battery. Follow the procedure below:

1. Press down the release button and slide the battery door to the right as indicated to remove the battery door.

2. Pinch the latch on the battery with strength, slide the battery rightward, and lift the battery as indicated below:



3. Make sure the battery to be installed is intact. For rechargeable batteries, make sure the charge is sufficient for use.
4. Align the battery pins, slide the battery into the battery compartment, and press until you hear it click into the place.
5. Cover the battery door on the compartment, and slide to the left until you hear it click into the place.

NOTE

- **Check the expiration date displayed on the disposable battery. Remove from use if the battery is expired.**
- **Never remove the battery unless the equipment indicates to do so.**
- **Make sure the battery door is reinstalled properly to protect the equipment and battery.**

11.4 Charging Batteries

The rechargeable batteries can be charged only using Mindray BatteryFeed20 charger station. At a temperature of 25°C (77 °F), a completely discharged battery charges to 90% of its capacity in approximately 2.5 hours, and to 100% of its capacity in approximately 3 hours.

Batteries should be charged at temperatures between 0 °C (32 °F) to 45 °C (113 °F). To optimize performance, a fully (or nearly fully) discharged battery should be charged as soon as possible.

For details about the charging of rechargeable batteries, refer to the *Instructions for Use of BatteryFeed20 (P/N: 046-001947-00)*.

11.5 Storing Batteries

When storing batteries, make sure that the battery terminals do not come into contact with metallic objects. If batteries are 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 for rechargeable batteries). Storing batteries in a cool place slows the aging process. The idea storage temperature is 15 °C (60 °F). Batteries should not be stored at temperature outside the range of -20°C (-4 °F) to 60 °C (140 °F).

NOTE

- **Storing batteries at temperature above 38 °C (100 °F) for an extended period of time significantly shorten the life expectancy of a battery.**

11.6 Recycling the Batteries

A battery should be discarded if there are visual signs of damage, the battery fails, the battery aged alarm is presented, the disposable batteries has been used for more than four years, or the rechargeable batteries been used for over 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.**

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12 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 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.**

12.1 General Points

Keep you 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.
- 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 and remove the battery 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.**

12.2 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:

- sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropyl alcohol (70%)

To clean your equipment, follow these rules:

1. Shut down the equipment, disconnect cables, and remove the battery.
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. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

12.3 Disinfecting

Disinfection may cause damage to your equipment and is therefore not recommended unless otherwise indicated in your hospital's servicing schedule. Cleaning equipment before disinfecting is recommended.

The recommended disinfectants include: ethanol 70% and isopropanol 70%.

13 Maintenance and Testing

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.**

You can access the Maintenance screen in either of the following ways:

- If the equipment is on, press the **Power ON/OFF** button and the "Select an option" window is displayed.
- If the equipment is off:
  - For the equipment configured with AED, manual defibrillation and ECG monitoring functions, press the **Power ON/OFF** button, the third and fourth soft keys (from left to right) simultaneously;
  - For the equipment configured with only AED function, press the **Power ON/OFF** button, the second and third soft keys (from left to right) simultaneously.

On the Maintenance screen, the system display information about the status of equipment, the battery and the pre-connected pads. You can:

- Press [**Archives**] to export patient data;
- Press [**Config.**] to view or edit the current system configuration;
- Press [**User Test**] to perform a user test as per the instructions on the screen;
- Press [**Device Info.**] to check the product type, serial number, software and hardware versions, device status and battery information and so on; and,
- Press [**Upgrade**] to upgrade the current system software through USB device or wireless network.

NOTE

- **In Maintenance mode, only "Battery" alarm is reported.**

13.1 Overview

To ensure that the equipment is ready for operation at any time, the following tests or inspections should be performed:

- Routine check
- Automatic test
- User test
- Electrical safety tests.

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

13.2 Maintenance and Testing Schedule

To ensure that the equipment is ready for operation at any time, perform the following tests as recommended:

Inspection/Test item	After use	Daily	Monthly
Make sure that the status indicator is green	√	√	
Check the expiration date of the pads and battery			√
Perform user test	√		
Replace pads	√		

13.3 Carrying Out Maintenance and Testing

The equipment performs selftest to check the buttons, battery status, pads status, charge/shock functions, and measurement performance, including:

- Power-on test;
- Realtime test;
- Battery-insert test;
- Automatic test; and,
- User test.

You can send the test results to the Device Management System through wireless network. For more details, refer to the *Help for AED ALERT Device Management System*.

13.3.1 Power-On Test

Each time you turn the equipment on, the welcome screen is displayed, and the equipment starts power-on test immediately. If a failure is detected, related failure information is displayed.

13.3.2 Real-Time Test

Real-time test persists throughout the runtime of the equipment. If any failure is detected, corresponding alarm is reported.

13.3.3 Battery Insert Test

A battery insert test is performed automatically if a battery is installed over 5 minutes after the equipment is powered off. You can follow the screen instructions to check the following:

1. Press the corresponding soft keys and **Shock** button as indicated on the screen.
2. Select an option to respond to the equipment if you have heard the voice prompt.

Other items are tested hereafter automatically. If all items pass the test, the test result is "Test Passed". If any failure is detected, corresponding prompts and failure codes are displayed.

13.3.4 Auto Test

If battery is installed, the equipment performs auto test at the configured time even being powered off to check the equipment's operational performance and alert operators if a problem exists.

Auto test can be initiated between 0:00 am to 5:00 am. To set auto test time, on maintenance screen, select [**Config.**] → [**Config. Edit**] → enter the required password → [**Test Setup**] → [**User Test Setup**]. The default setting is 3:00 am.

The equipment displays no information on the screen during auto test. If auto test fails, the status indicator will flash in red or be off, contact your service personnel in this case.

At the completion of auto test, a report is saved automatically.

CAUTION

- **With power off, auto test is performed only when battery is installed.**

13.3.5 User Test

WARNING

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

On the maintenance screen, you can press [**User Test**] to perform user test. You need to:

1. Press the corresponding soft keys and **Shock** button as indicated on the screen.
2. Select an option to respond to the equipment if you have heard the voice prompt.

Other items are tested hereafter automatically. If all items pass the test, the test result is "Test Passed". If any failure is detected, corresponding prompts and failure codes are displayed.

13.3.6 Electrical Safety Tests

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

13.4 AED ALERT

If the equipment is configured with the Wi-Fi module, you can manage devices and users by AED ALERT Device Management System (hereinafter called AED ALERT). The equipment can be connected to LAN or WLAN through AED ALERT.

With AED ALERT, you can:

- View the device information
- Manage devices
- Manage users

13.4.1 Accessing AED ALERT

You can access AED ALERT on the Internet or local server.

To access AED ALERT on the Internet.

1. Input http://aed.mindray.com in the Browser address bar.
2. Input the user name and password.
3. Click [**Login**].

To access AED ALERT on the local server.

1. Choose [**Start**] → [**All Programs**] → [**Mindray AedManageSystem**] → [**AedManageSystem**].
2. Input the user name and password.
3. Click [**Login**].

13.4.2 Viewing the Device Information

You can view all devices listed on AED ALERT through the [**Information**] tab.

After clicking the desired device, you can view all related selftest reports listed in the list. You can click [**Detailed >>**] besides the desired selftest report to view the detailed information.

You can view the device information of the desired device by searching the following keywords.

- Device serial number
- Asset number
- Asset keeper

- Device location

NOTE

- **If selftest fails, AED ALERT will send fault messages to the device administrator's mailbox through email.**

13.4.3 Managing Devices

On the [**Device**] tab, you can:

- Register the device information
- Edit the device information
- Delete the device information

13.4.3.1 Registering the Device Information

To register the device information,

1. Click [**Add**] on the [**Device**] tab.
2. Input the device information in the pop-up dialogue box.
3. Click [**Save**].

NOTE

- **The total number of devices managed on AED ALERT is limited by License. If the number of managed devices exceeds the limit, you cannot add any devices.**

13.4.3.2 Editing/Deleting the Device Information

If you want to modify the device information, click [**Edit**] besides the desired device, and then edit the device information.

If you want to delete the device information, click [**Delete**] besides the desired device.

NOTE

- **Deleting the device information will delete all selftest reports related to this device.**

13.4.3.3 Bulk Importing the Device Information

You can register and update all device information by bulk importing an Excel file filled in with the related information.

Before the bulk import, you should click [**Template**] to download the device information template, and then fill in the information as required.

To bulk import the device information,

1. Click [**Import**] on the [Device] tab.
2. Click [**Browse**] to choose the prepared Excel file.
3. Click [**Import**].

NOTE

- **The total number of devices managed on AED ALERT is limited by License. If the number of managed devices exceeds the limit, you cannot import any devices.**

13.4.4 Managing Users

AED ALERT provides the function for the Administrator to manage users information.

On the [**Account**] tab, you can:

- Add user information
- Edit user information
- Delete user information

13.4.4.1 Adding the User Information

To add the user information,

1. Click [**Add**] on the [**Account**] tab.
2. Input the user information.
3. Click [**Save**].

13.4.4.2 Editing/Deleting the User Information

If you want to modify the user information, click [**Edit**] besides the desired user, and then edit the user information.

If you want to delete the user information, click [**Delete**] besides the desired user.

NOTE

- **Deleting the user information will not delete the device information belonged to this user.**

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14 Troubleshooting

14.1 General Problems

NOTE

- **Never try to disassemble the equipment or supplied accessories. There are no internal user-serviceable parts.**

This chapter lists the problems that are likely to 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.

Symptom	Possible Cause	Corrective Actions
The equipment does not power up.	Battery is not installed or has no charge	Check that a battery is correctly installed and has sufficient charge. If not, install a new or fully charged battery.
	Exception protection	Reinstall the battery.
	Battery or equipment malfunction	Call for service.
The equipment turns off unexpectedly.	Battery depleted	Replace the battery.
	Battery or equipment malfunction	Call for service.
No alarm sound	The audio alarm is disabled.	Select →[**Config.**] → [**Config. Edit**] → enter the required password → [**Alarm Setup**]. Then set [**Alm Volume**] to [**Low**], [**Med**] or [**High**].
	Equipment malfunction	Call for service.
The equipment charges too slowly.	Battery depleted	Replace the battery.
	Battery or equipment malfunction	Call for service.
The equipment can be properly charged, but the energy is disarmed automatically at the completion of charging.	The electrode pads are detached from the patient	Ensure good connection between the patient and electrode pad.
	The electrode pads are damaged	Replace the electrode pads.
	Equipment malfunction	Call for service.
The status indicator turns red and the equipment beeps periodically.	Failure is detected on the equipment	Perform a user test. Check the failed items. Then consult the service personnel.
USB Device does not function	The initialization of USB connector has an error	Re-plug the USB device for initialization.
	USB device malfunction	Replace the USB device.
	Equipment malfunction	Call for service.

14.2 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 the "Cause and solution" column, corresponding solutions are given instructing you to troubleshoot problems. If the problem persists, contact your service personnel.

14.3 Physiological Alarm Messages

Physiological alarm messages are for the equipment with AED, manual defibrillation and ECG monitoring functions. Alarms marked with "*" 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 normal high level physiological alarms are triggered simultaneously, only alarm message of the exclusive physiological alarm is displayed.

Measurement	Alarm Message	Alarm Level	Cause and Solution
ECG	Asystole*	High	Arrhythmia has occurred to the patient. Check the patient's condition, and the pads, electrode, cables and leadwires.
	Shockable Rhythm*	High	
	Vtac*	High	
	Extreme Tachy*	High	
	Extreme Brady*	High	
	PVCs/min	Medium	
	Nonsus. Vtac	Medium	
	Vent. Rhythm	Medium	
	Tachy	Medium	
	Brady	Medium	
	VT>2	Medium	
	Couplet	Medium	
	Multif. PVC	Medium	
	R on T	Medium	
	Bigeminy	Medium	
	Trigeminy	Medium	
	PVC	Low	
	Irr. Rhythm	Low	
	PNP	Medium	The pacer appears abnormal. Check the pacer.
	PNC*	Medium	

14.4 Technical Alarm Messages

In this chapter, the "I" column indicates how indications of technological alarms are cleared after the [**Silence**] softkey is pressed: "A" means all alarm indications are cleared; and "B" indicates only alarm tone is disabled, but other indications remain presented.

Source	Alarm Message	Alarm Level	I	Cause and Solution
ECG	ECG Noise	Low	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 Lead Off	Low	A	The ECG electrode has become detached from the patient or the connector from the equipment. Check the connection of the electrodes and leadwires.
	ECG YY Lead Off (YY represents the leadwires LL, LA, and RA, as per AHA standard, or C, F, and L as per IEC standard.)	Low	A	
	ECG Signal Invalid	Low	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.

Source	Alarm Message	Alarm Level	I	Cause and Solution
System	Unit Error!	Special	B	Equipment malfunction. Perform a user test or restart the equipment.
	Power Board Comm Err	High	B	Communication with the power management module failed. Restart the equipment.
	Power Board Selftest Err	High	B	System power failure. Restart the equipment.
	Power Board Volt Err	High	B	
	Battery Err	High	B	There is a problem with the battery. Check the battery for damage; verify that correct battery is used. Replace the battery if necessary.
	Battery Aged	Low	B	Rechargeable battery is aged. Replace the battery.
	Low Battery	High	B	Replace the battery.
	Battery Depleted!	Special	B	
	Main Control Selftest Err	High	B	An error occurred in main control power-on test. Restart the equipment.
	RT Clock Need Reset	Low	B	Reset system time.
	RT Clock Err	High	B	An error occurred to the RTC chip. Call for service.
	Memory Error	Low	B	Memory read write failure or initialization error. Restart the equipment.
	Machine Type Error	High	B	An error occurred to the system power supply. Restart the equipment.
	Disarming Failed	High	B	Failed to disarm the energy. Perform a user test. If the failure occurs, record the service code and call for service.
	Charge Failed	High	B	Failed to charge. Perform a user test. If the failure occurs, record the service code and call for service.
	Shock Failed	High	B	Failed to shock. Perform a user test. If the failure occurs, record the service code and call for service.
	Unknown Pads	Low	B	The electrode pads are not properly connected or the pads are defective. Re-plug the pads. If the problem persists, replace the pads. If the problem still remains unsolved, call for service.
	Pads Abnormal	Low	B	The type of pads is recognized, but the one-wire communication failed. Re-plug the pads. If the problem persists, call for service.
	Pads Expires	Low	B	The pads have expired. Replace the pads.
	Pads expiring soon	Low	B	The pads are expiring soon. Replace the pads timely.
	Load Config Err	Low	A	An error occurred when loading configuration file. Reconfigure the equipment. If the changes cannot be saved, call for service.
	Operation Mode Error	Low	B	When starting the main control, the obtained default startup mode is inconsistent with that from the IO. Call for service.

Source	Alarm Message	Alarm Level	I	Cause and Solution
CPR sensor	CPR Sensor Err	High	C	There is a self-test error or communication problem with the CPR sensor. Contact your service personnel.
	CPR Sensor Need Service	High	C	The compressions using the CPR sensor exceed the expected numbers. Contact your service personnel.
	CPR Sensor Cable Fault	Low	C	An error occurred to the CPR sensor cable. Replace the CPR sensor cable.

Note: The special technological alarms cannot be paused or silenced, and the alarm volume is unchangeable. These alarms stop only when the alarm condition is eliminated.

15 Accessories

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

15.1 ECG Accessories

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
	EV 6212	AHA, IEC	ESU-proof		0010-30-42724
3/5-lead	EV 6201	AHA, IEC	Defibrillation-proof	Adult, pediatric	0010-30-42719
	EV 6211	AHA, IEC	ESU-proof		0010-30-42723

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
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	/

15.2 Therapy Accessories

Description	Model	Applicable patient	Remark	PN
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
CPR sensor	MR6401	/	Reusable, without a battery	047-019406-00
CPR sensor cable	MR6801	/	Reusable	040-003096-00
CPR adhesive tape	MR6921	/	Disposable (3 sets/pack)	040-003123-00

15.3 Miscellaneous

Description	Model	PN
Rechargeable lithium ion battery	LI24I005A	115-049328-00
	LI24I001A	115-007858-00
Disposable battery	LM34S001A	115-026737-00
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

A Specifications

Items marked with "*" symbol are available for the equipment with AED, manual defibrillation and ECG monitoring functions.

A.1 General Specifications

Type of protection against electrical shock	Equipment energized from an internal electrical power source (battery).
Degree of protection against electric shock	Type BF defibrillation proof for external defibrillation.
	Type CF defibrillation proof for ECG*
Mode of operation	Continuous
Degree of protection against harmful ingress of solid	IP5X
Degree of protection against harmful ingress of water	IPX5
Degree of mobility	Portable

Size	
Width × depth × height	288 × 210 × 80 mm

Maximum Weight	
Main Unit	2.8 kg, including a battery.

Display	
Type	TFT Color LCD
Size	7 inch
Resolution	800×480 pixels
Viewed waveforms	One ECG waveform
Wave viewing time	Max. ≥ 6s (ECG)

Equipment connectors	
USB connector	Connects USB flash memory

Audio Indicator	
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.

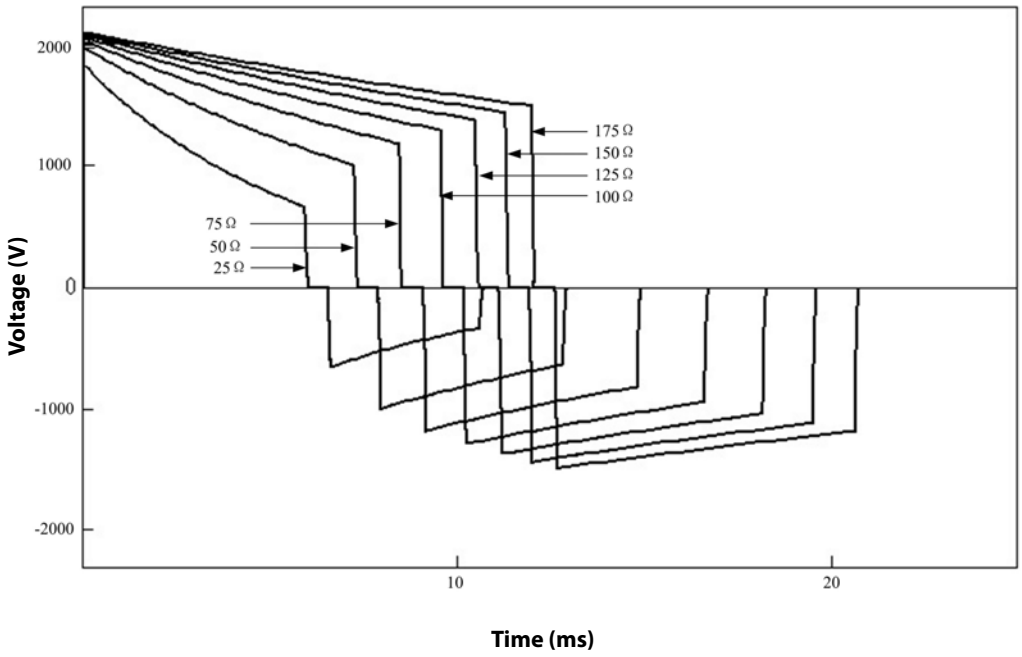
A.2 Defibrillator Specifications

Defibrillation mode	Manual defib, synchronous cardioversion, AED
Defibrillation waveform	Biphasic truncated exponential (BTE) waveform, auto-compensation according to patient impedance
Defibrillation electrodes	Multifunction electrode pads.

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

Patient impedance range	
External defibrillation	25 to 200 Ω

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



Selected energy accuracy								
Impedance / 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 °C of ambient temperature)							
		Charge time (Manual Defib)		From initiation of rhythm analysis to charge done		From initial power on to charge done	
		200J	**360J**	**200J**	**360J**	**200J**	**360J**
Rechargeable battery	New and fully charged	<5 s	<8 s	<10 s	<10 s	<20 s	<20 s
	New and fully charged after 15 times of 360J discharges	<6 s	<9 s	<10 s	<10 s	<20 s	<20 s
Disposable battery	New	<7 s	<13 s	<10 s	<17 s	<20 s	<27 s
	New after 15 times of 360J discharges	/	/	<10 s	<17 s	<20 s	<27 s

Synchronized discharge delay	
Local synchronized discharge delay	< 60ms (from the peak of R-wave)

AED	
Shock series	Energy level: 100 to 360J, configurable for adult; 10 to 100J, configurable for pediatric; Shocks: 1, 2, 3, configurable; Meeting AHA guidelines 2015 by default.

AED ECG Analysis Performance

Time from initiation of rhythm analysis to delivery of shock/no shock advised is no more than 8 s. For more information, refer to *B Mindray Shockable Rhythm Analysis Algorithm*.

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 Monitor Specifications

ECG	
Patient connection	3-lead ECG cable or multifunction electrode pads
ECG inputs	Defibrillation electrodes: pads
	3-lead ECG set: I, II, III
Gain	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4) and Auto. Error less than ± 5%
Paper speed	25 mm/s, error no more than ± 10%
Bandwidth (-3dB, ECG lead set)	Monitor mode: 0.5 to 40 Hz
	Therapy mode: 1 to 20 Hz
Bandwidth (-3dB, defibrillation electrodes)	Therapy mode: 1 to 20 Hz
Common mode rejection (ECG lead set)	Monitor mode: >90 dB Therapy mode: >90 dB
Common mode rejection (defibrillation electrodes)	Therapy mode: >90 dB
Notch filter	50/60Hz, In Monitor and Therapy mode: notch filter turns on automatically
ECG signal range	With a sensitivity of 10 mm/mv, positive and negative signals between 0.2 mV to 8 mV can be detected and HR value be displayed.
Electrode offset potential tolerance (from ECG lead set and defibrillation electrodes)	±1 V
HR measurement range	Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm
HR accuracy	±1% or ±1bpm, which ever is greater
HR resolution	1 bpm
Lead-off detection current	Measuring electrode: ≤0.1 μA Drive electrode: ≤1 μA
ESU protection	Baseline recovery time: ≤10 s
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.
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
Response to change in heart rate	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 of ANSI/AAMI EC13-2002: section 4.1.2.1 g). Waveform 4ah - range: 11 s 4a - range: 11 s 4ad - range: 11 s 4ah - range: 11 s 4bh - range: 11 s 4bd - range: 11 s

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.
Arrhythmia Analysis Classifications	Asystole, Shockable rhythm (V-Fib/V-Tach), Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVCs/min, PVC, Couplet, VT>2, Bigeminy, Trigeminy, R on T, Tachy, Brady, PNP, PNC, Vent. Rhythm, Multif. PVC, Nonsus. Vtac, Irr. Rhythm
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: 10V/s RTI

A.5 Power Supply Specifications

Rechargeable Battery (new and fully charged, at 20 °C of ambient temperature)			
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: 15.1V, 5600mAh Battery LI24I001A: 14.8V, 3000mAh		
Battery LI24I005A charge time	Less than 5 hours to 90% and less than 6 hours to 100% with BatteryFeed 20 charger station		
Battery LI24I001A charge time	Less than 2.5 hours to 90% and less than 3 hours to 100% with BatteryFeed 20 charger station		
Battery LI24I005A and LI24I001A run time	Work mode	Work time	Testing condition
	Monitoring	≥ 12 hours	LCD brightness set to low, wireless function off, not performing defibrillation charges or discharges, and audio off
	Defibrillation	≥300 discharges	200J discharges at a frequency of 3 times/min
		≥200 discharges	360J discharges at a frequency of 3 times/min
Battery fuel gauge	5 LEDs indicating the current battery charge level		
Remaining charge after "Low Battery" is reported	At least 20 minutes of ECG monitoring (under the work condition of low LCD brightness, with wireless function turned off, not performing defibrillation charges or discharges, and audio off) and at least 10 200J discharges		

Disposable Battery (new, at 20 °C of ambient temperature)			
Battery type	12V/4.2Ah, disposable battery, free of maintenance		
Shelf life(after insertion)	4 years remains in standby modewhen stored and maintained as required (under the work condition of low LCD brightness, with wireless function turned off, not performing defibrillation charges or discharges, and audio off) and at least 10 200J discharges		
	3 years remains in standby modewhen stored and maintained as required (with wireless function turned on, sending selftest report every week, equipment not in use)		
	2 years remains in standby mode when stored and maintained as required(with wireless function turned on, sending selftest report every week, equipment not in use)		
Run time	Work mode	Work time	Testing condition
	Monitoring	≥ 12 hours	LCD brightness set to low, wireless function off, not performing defibrillation charges or discharges, and audio off
	Defibrillation	≥300 discharges	200J discharge at a frequency of 3 times/ min
		≥200 discharges	360J discharge at a frequency of 3 times/ min
Battery fuel gauge	Battery symbol on the display indicating the current battery level		
Remaining charge after "Low Battery" is reported	At least 20 minutes of ECG monitoring (under the work condition of low LCD brightness, with wireless function turned off, not performing defibrillation charges or discharges, and audio off) and at least 10 200J discharges		

A.6 Alarm Specifications

Alarm Levels	High, medium, low level alarms, complying with IEC60601-1-8
Alarm Categories	Physiological alarms, technical alarms
Parameter alarm setting	ECG alarm properties can be set in the [**ECG Setup**] menu
Auto alarm limits	Parameter alarm limits can be automatically adjusted according to currently measured vital signs

A.7 Data Management Specifications

Data Storage	Inner flash memory, 512 M Bytes
Waveform storage	Up to 8 hours of consecutive ECG waveform or waveform of up to 100 patients
Event recording	Up to 1000 events
Voice recording	Max. 180 minutes in total
Data Export	Data can be export to a PC through a USB flash memory

A.8 Wi-Fi Specifications

Standard	IEEE 802.11 a/b/g/n
Modulation mode	DSSS and OFDM
Operating frequency	IEEE 802.11 b/g/n (at 2.4G): 2.4 GHz to 2.495 GHz IEEE 802.11 a/n (at 5G): 5.15 GHz to 5.82 GHz
Data security	Standards: WPA-PSK, WPA2-PSK, WPA-Enterprise,WPA2-Enterprise EAP method: EAP-FAST. EAP-TLS, EAP-TTLS, PEAP-GTC, PEAP- MSCHAPv2, PEAP-TLS, EAPLEAP Encryption: TKIP, AES

A.9 Environmental Specifications

Main unit			
Item	**Temperature (°C)**	**Relative humidity**	**Barometric**
Operating conditions	0 to 50 (At least 60 minutes of working time when the temperature reduces from room temperature to -20°C)	0% to 95%, noncondenstion	57.0 to 106.2 kPa (-381m to +4575 m)
Storage conditions	-30 to 70 °C	0% to 95%, noncondenstion	57.0 to 106.2 kPa (-381m to +4575 m)

BatteryFeed 20 charger station			
Item	**Temperature (°C)**	**Relative humidity**	**Barometric**
Operating conditions	0 to 45 °C	10% to 95%, noncondensation	57.0 to 106.2 kPa
Storage conditions	-30 to 70 °C	10% to 95%, noncondensation	57.0 to 106.2 kPa

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.

Drop
1.5 m per IEC 68-2-32

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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.**
- **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.

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, 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 ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst (EFT)IEC 61000-4-4	±1 kV for ECG patient cables (length greater than 3 m)	±1 kV for ECG patient cables (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field 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.

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)	3 V/m (E1)	
	10V/m 80 MHz to 2.7 GHz (IEC60601-2-4)	10 V/m	
	20V/m 80 MHz to 2.7 GHz (IEC60601-2-4)	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

RF parameters

Radio devices	**Wi-Fi devices**	
Operating Frequency	2.4 GHz to 2.495 GHz	5.15 GHz to 5.82 GHz
Modulation mode	DSSS and OFDM	OFDM
Output Power	≤20dBm	≤20dBm

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 Wi-Fi function is in use.**

D BeneHeart D1 Inspection Record

Equipment SN: _____ **Department:**_____ **Installation Date:** _____
Battery Expiration Date: _____ **Pad Expiration Date:** _____ **Checked by:** _____

Inspection Date	Normal equipment condition (the status indicator flashes in green)	Proper equipment installation (the display screen faces out, pads are connected)	Pads within the expiration date	Inspected by

NOTE:

- Inspect the status indicator and equipment installation once every day.
- Inspect the expiration date of pads monthly.
- Place a "√" in the corresponding box if the item passes Or, place a "×" if the item fails.
- Contact service personnel if any equipment abnormity is found.
- Contact the distributor or Mindray service personnel for replacement if the pads are expired.
- Reinstall the equipment if it is not properly installed.

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E Prompt Messages

This chapter lists the prompt audio and text messages that might appear on your equipment.

Source	Message	Audio
System	Battery Depleted! Replace Battery Now.	Battery Depleted! Replace Battery Now.
AED	/	Adult mode.
	/	Pediatric mode.
	Remove Clothing	Remove clothing from patient's chest.
	Take Out Pads Package	Take out pads package from back of AED.
	Plug in Pads Connector	Plug in Pads Connector
	Remove Pads	Tear open package and remove pads
	Peel Pads	Peel pads from plastic liner.
	Apply Pads	Apply pads to patient's bare chest as shown.
	Analyzing, Do Not Touch Patient!	Analyzing now. Do not touch the patient!
	Artifact Detected, Cannot Analyze	Artifact Detected.
	Motion Detected, Cannot Analyze	Motion Detected,
	Shock Advised! Charging to %sJ	Shock Advised! Charging
	Charge Failed!	Charge Failed!
	Do Not Touch Patient! Press Shock Button	Do Not Touch the Patient! Press the Shock Button
	Shock Delivered	Shock Delivered
	Impedance Too Low, Charge Removed	Impedance Too Low, Charge Removed
	Impedance Too High, Charge Removed	Impedance too high. Charge removed.
	Abnormal Energy Delivery	Abnormal Energy Delivery
	No Shock Advised!	No Shock Advised! It is safe to touch the patient.
	No Shock Advised! Monitoring	No Shock Advised! Attend to patient.
	Charge Removed	Charge Removed
	Shock Button Not Pressed, Charge Removed	Shock Button Not Pressed, Charge Removed
	Disarming Failed	Disarming Failed
CPR	Start CPR	Start CPR
	Interlock the Fingers Place Hands on Patient's Chest	Interlock the Fingers Place Hands on Patient's Chest
	Place One Hand on Patient's Chest	Place One Hand on Patient's Chest
	Keep Arms Straight	Keep Arms Straight
	Follow the Metronome to Compress	Follow the Metronome to Compress
	Give 2 Breaths	Give two Breaths
	Breathe	Breathe
	Continue	Continue
	Stop CPR Stop Now	Stop CPR Stop Now

Source	Message	Audio
Manual Defibrillation	/	Adult mode.
	/	Pediatric mode.
	Plug in Pads Connector	/
	Apply Pads	/
	Charging to %s J	/
	Energy Changed. Please Recharge.	/
	Charge Failed. Please Recharge.	/
	Do Not Touch Patient! Press Shock Button	/
	Shock Delivered	/
	Impedance Too Low, Charge Removed	/
	Impedance Too High, Charge Removed	/
	Abnormal Energy Delivery	/
	Are you sure to enter [Manual Defib]?	/
	Are you sure to enter [SYNC]?	/
	No R-Wave	/
	Charge Removed	/
	Shock Button Not Pressed, Charge Removed	/
	Disarming Failed	/
CPR sensor	Incomplete Recoil	Incomplete Recoil
	Compress Faster	Compress Faster
	Compress Slower	Compress Slower
	Compress Deeper	Compress Deeper
	Compress Shallower	Compress Shallower
Maintenance User test	Normal	/
	Error. Please Perform User Test to Confirm.	/
	Rechargeable. Normal.	/
	Rechargeable. Aged. Replace Battery Advised.	/
	Rechargeable. Error. Replace Battery Advised.	/
	Rechargeable. Low Battery. Replace Battery Advised.	/
	Disposable. Normal.	/
	Disposable. Error. Replace Battery Advised.	/
	Disposable. Low Battery. Replace Battery Advised.	/
	None	/
	Adult Pads. Normal. Expires X/X.	/
	Adult Pads. Abnormal. Replace Pads Now.	/
	Adult Pads,Pads Expires, Replace Pads Advised.	/
	Adult Pads,X/X Pads Expires, Replace Pads Advised.	/
	Pediatric Pads,Pads Expires, Replace Pads Advised.	/
	Pediatric Pads. Normal. Expires X/X.	/
	Pediatric Pads. Abnormal. Replace Pads Now.	/

Source	Message	Audio
Maintenance User test	Pediatric Pads, X/X Pads Expires, Replace Pads Advised.	/
	Selftest report trans. failed.	/
	Test Passed.	/
	AED is Ready for Use.	/
	Test Failed.	/
	Call for Service. Service Code:	/
	Pads Missing.	/
	Unknown Pads	/
	Pads Abnormal, Replace Pads Advised	/
	Pads Expires, Replace Pads Advised	/
	Replace Battery Advised. Service Code:	/
	Please Perform User Test to Confirm.	/
	Replace Battery Advised.	/
Configuration mode	Please enter password	/
	Password incorrect. Try again!	/
	Normal network.	/
	Connection failed. Check the network and setup.	/
	Cannot Reach the Site. Check the site and setup.	/
	Are you sure to restore to factory default?	/
	All settings restored to factory default	/
	Config. file not found.	/
	Are you sure to import the file and override the current config.?	/
	Config. updated successfully.	/
	USB memory not found!	/
	USB Memory Error. Data Export Failed!	/
	Config. file exported successfully.	/
System upgrade	Searching upgrade file.	/
	Server is busy. Please retry later.	/
	Upgrade file is not available. Upgrade cancelled.	/
Archive	USB memory not found!	/
	USB Memory Limited Space	/
	Exporting Data. Please Wait...	/
	Data Export Completed!	/
	USB Memory Error. Data Export Failed!	/

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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 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.5 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.6 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
cm	centimeter
dB	decibel
ºF	fahrenheit
h	hour
Hz	hertz
in	inch
J	Joule
kg	kilogram
kPa	kilopascal
L	litre
m	meter
min	minute
mm	millimeter
ms	millisecond
mV	millivolt
mW	milliwatt
rpm	breaths per minute
s	second
V	volt
Ω	ohm

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

AAMI	Association for Advancement of Medical Instrumentation
Adu	adult
AED	Semi-automated external defibrillation
AHA	American Heart Association
ANSI	American National Standard Institute
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
CE	Conformité Européenne
CISPR	International Special Committee on Radio Interference
CPR	Cardiopulmonary resuscitation
DC	direct current
Defib	defibrillation
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ESU	electrosurgical unit
FDA	Food and Drug Administration
HR	heart rate
ID	identification
IEC	International Electrotechnical Commission
IP	internet protocol
Iso	isoflurane
LA	left arm
LCD	liquid crystal display
LED	light emitting diode
LL	left leg
MRI	magnetic resonance imaging
Neo	neonate
O_2	oxygen
Ped	pediatric
PNC	pacer not captured
PNP	pacer not paced
PVC	premature ventricular complex
RA	right arm
Rec	record, recording
RL	right leg
Sync	synchronization
USB	universal serial bus

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 V3.0

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:	Automated External Defibrillator (Including Accessories)
Model:	BeneHeart D1

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, 2017.12.29
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

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