BeneHeart C & BeneHeart S Series

Automated External Defibrillator

Operator's Manual

(BeneHeart C1/BeneHeart C1A/BeneHeart C2/BeneHeart C2A/
BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/
BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/
BeneHeart S1/BeneHeart S1A/BeneHeart S2/BeneHeart S2A/
BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/
BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic)

CE 2797

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- the product is used in accordance with the instructions for use.

WARNING

- **This equipment must be operated by persons who have been trained in its operation. The operator should be trained in basic life support, advanced cardiac life support or other emergency medical response.**

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- Others not caused by instrument or part itself.

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Notification of Adverse Events

As a health care provider, you should report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

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 intended for persons who have been trained in equipment's operation. The operator should be trained in basic life support, advanced cardiac life support or other emergency medical response.

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.

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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 by following the prompts provided by the equipment, this electrical energy may cause serious injury or death. Do not attempt to operate this equipment unless thoroughly familiar with the operations and functions of all controls, indicators, connectors, and accessories.**
- **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.**
- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.**
- **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 wet ground.**
- **For the treatment of patients with implantable pacemakers, place the electrode 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 or other live equipment if in contact with the patient; otherwise patient injury may result.**
- **Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.**
- **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 the wireless 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.**
- **During normal use, the operator shall stand in a location where the equipment can be easily viewed and operated.**
- **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
	Manufacturer		Date of manufacture
IP55	Dust-protected Protected against water jets		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.
	Maximum stacks		Temperature limitations
	Humidity limitations		Atmospheric pressure limitations
	Fragile		Keep dry
	This way up	SN	Serial number
	USB connector		Non-ionizing electromagnetic radiation
	DEFIBRILLATION-PROOF TYPE BF APPLIED PART		General symbol for recovery/ recyclable
MD	Medical Device	UDI	Unique Device Identification
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		
CE 2797	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation. Note: The product complies with the Council Directive 2011/65/EU.		
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.		

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric shape	Meaning	Safety color	Contrast color	Graphical symbol color
	Mandatory action	Blue	White	White
	Warning	Yellow	Black	Black

2 Equipment Introduction

2.1 Overview

The BeneHeart C & S series automated external defibrillator is designed for treating life-threatening heart beat irregularities.

There are two types of product models provided: semi-automatic and fully automatic. Characteristics of the product models are detailed in the following table.

Model		Defibrillation mode	With the Shock button?	Screen size
BeneHeart C series	BeneHeart C1	semi automatic	Yes	1.96 inches
	BeneHeart C1A			
	BeneHeart C2			7 inches
	BeneHeart C2A			
	BeneHeart C1 Fully Automatic	fully automatic	No	1.96 inches
	BeneHeart C1A Fully Automatic			
	BeneHeart C2 Fully Automatic			7 inches
	BeneHeart C2A Fully Automatic			
BeneHeart S series	BeneHeart S1	semi automatic	Yes	1.96 inches
	BeneHeart S1A			
	BeneHeart S2			7 inches
	BeneHeart S2A			
	BeneHeart S1 Fully Automatic	fully automatic	No	1.96 inches
	BeneHeart S1A Fully Automatic			
	BeneHeart S2 Fully Automatic			7 inches
	BeneHeart S2A Fully Automatic			

After the electrode pads are applied to the patient's chest, the equipment analyzes the patient's heart rhythm.

- If a shockable rhythm is detected, the semi-automatic model requires the operator to deliver the shock, the fully automatic model delivers the shock without any intervention.
- If non-shockable rhythm is detected, the equipment enters CPR status by default.

Both types of models provide audio and visual instructions that guide you through the entire defibrillation process. A flashing Shock button on the semi-automatic model is also presented to reinforce the voice prompts

The equipment also provides real-time CPR feedback if it is connected with a CPR sensor.

2.2 Intended Use

2.2.1 Intended Purpose Statement

The equipment is intended for semi-automated external defibrillation and automated external defibrillation. It also provides CPR feedback.

2.2.2 Indication for Use

The equipment is intended for patients with ventricular fibrillation, pulseless ventricular tachycardia and ventricular flutter.

2.2.3 Intended Users

The operator should be trained in basic life support or other emergency medical response.

2.2.4 Intended Patient Population

The equipment is intended to be used on adults and pediatric patients in a sudden cardiac arrest. The patients must be:

- Unresponsive
- Not breathing or not breathing normally

2.2.5 Intended Medical Conditions

The equipment is to be used in public places and facilities by persons who have been trained in its operation.

2.2.6 Contra-indications

The equipment is contraindicated in the treatment when the patient is showing any of the following:

- Consciousness
- Breathing
- Detectable pulse or other signs of circulation

2.2.7 Side-effects

Through clinical data from literature and clinical data from post-market surveillance activity of subject device, there is no side-effects identified.

2.2.8 Clinical Benefit

Semi-automated external defibrillation or automated external defibrillation can directly improve patient survival, relieve symptoms and improve quality of patient's life.

CPR feedback could standardize the chest compression procedure.

2.3 Applied Parts

The applied parts of the equipment are:

- Electrode pads
- CPR sensor (if configured)

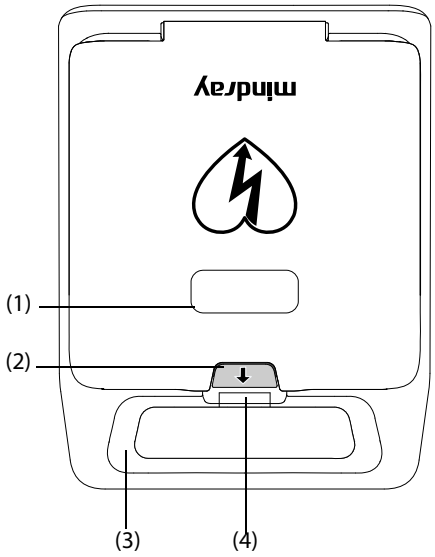
WARNING

- **When the equipment is placed at a an ambient temperate above 50°C, the surface temperature of applied parts should be limit to below 52°C.**

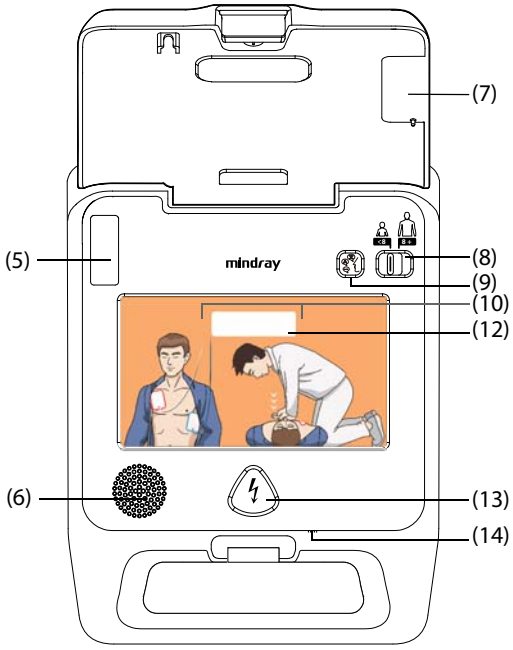
2.4 Main Unit

Based on the clinical application, the view that the equipment laid on the ground with lid opened is taken as the reference direction. The following views are defined by the reference direction.

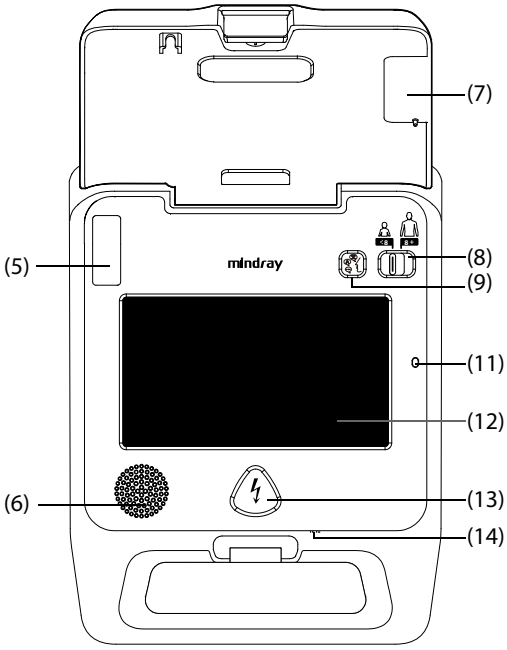
2.4.1 Top View



Equipment with lid closed



Equipment configured with 1.96-inch screen



Equipment configured with 7-inch screen

(1) Pad expiration window: checks the expiration date of pads.

(2) Latch: opens or closes the lid.

(3) Handle

(4) Status indicator
- Steady green: the equipment is turned on, and can work correctly.
- Flashing green: the equipment is in the standby status, and is ready for operation at any time.
- Flashing red: auto test failure is detected or no pads connector is connected with the equipment.
- Off: no battery is installed or the battery is malfunctioning.

(5) Pads connector: connects the electrode pads.

(6) Speaker: the equipment automatically adjusts the volume depending on surrounding noise levels by default.

(7) Pads package holder: stores the electrode pads.

(8) Adult/Child mode switch: flip right or left to switch between adult and child.

(9) Language button: press to switch between the configured languages.

(10) Maintenance buttons: simultaneously press and hold to perform the user test. For more information, see *8.3.1 User Test*.

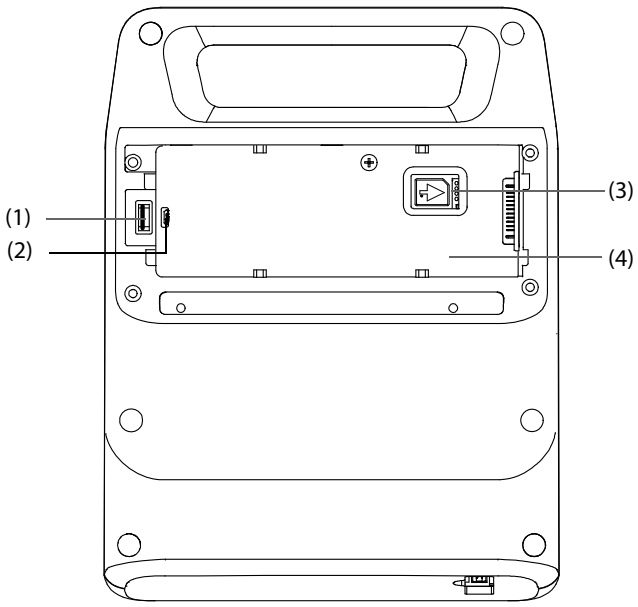
(11) Optical sensor: the equipment automatically adjusts the screen brightness depending on surrounding light by default.

(12) Display screen: provides AED display.

(13) Shock button (for semi-auto model): press to deliver a shock to the patient.

(14) Microphone: records voices. It is available only when the record function is enabled.

2.4.2 Bottom View



The battery compartment provides the following connectors.

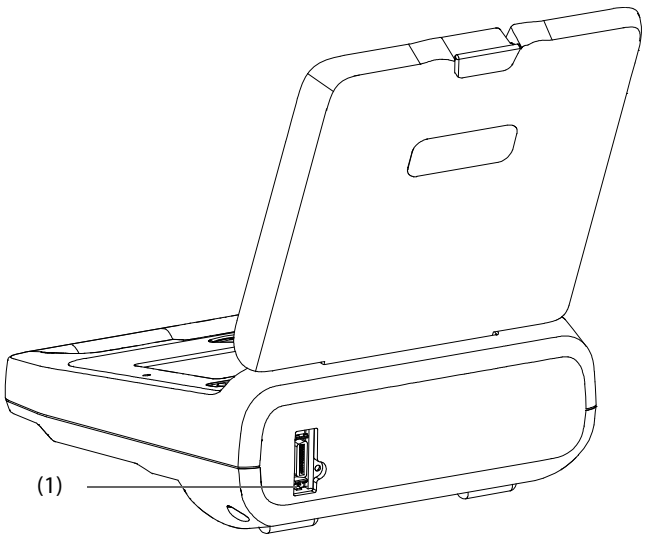
(1) USB connector: connects the USB flash memory.

(2) micro USB connector: connects the computer.

(3) Network connector (for equipment configured with the cellular module): connects the SIM card.

(4) Battery compartment: stores the battery.

2.4.3 Back View



(1) Multifunction connector (for equipment configured with the CPR sensor: connects the CPR sensor.

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3 Getting Started

3.1 Preparation Safety Information

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 altering, 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

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **The equipment 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.**

3.2 Equipment Installation

3.2.1 Unpacking and Checking

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

3.2.2 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 the sides of 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.

3.2.3 Connecting the Electrode Pads

1. Open the socket cover, and plug the pads connector into the pads socket.
2. Put the socket cover back. Ensure the socket cover is centered and closed.
3. Place the pads package into the pads package holders properly and carefully. Ensure the expiration date of pads can be viewed from the pad expiration window.

4. Route the pads cable in the pad package holders.

WARNING

- **Keep the pads cable connected to the equipment at all times.**
- **Do not open sealed pads until immediately prior to use.**
- **Do not bend the electrode pads forcefully.**
- **Make sure the pads package is intact before use. Otherwise, replace it with a new one.**

3.2.4 Installing the Battery

For more information, see *6.3 Replacing the Battery*.

3.3 Turning on the Equipment

Before turning on the equipment, perform the following inspections:

- Check for mechanical damage on the equipment or other damage on the pads package.
- Make sure the pads cable is properly connected and battery installed.
- Check the expiration date of the pads on the pads package.

Open the AED lid, then the equipment automatically powers on.

3.4 Switching Voice Language

You can press the Language button until the desired language is selected. At most three voice languages can be configured.

3.5 Turning off the Equipment

Before turning off the equipment, perform the following inspections:

1. Confirm that the patient therapy is completed.
2. Disconnect the used electrode pads from the patient.
3. Plug in the pads connector of new electrode pads. For more information, see *3.2.3 Connecting the Electrode Pads*.

To turn off the equipment, close the AED lid.

WARNING

- **If the patient is not connected to the equipment, and no operation is found performed on the equipment within 30 minutes, the equipment will automatically shut down.**

NOTE

- **You should check that the pads connector is connected before a normal shutdown. Otherwise, the equipment cannot detect the electrode pads and the status indicator will flash in red after shutdown.**

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4 Using the Equipment

4.1 AED Safety Information

DANGER

- **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.**

WARNING

- **The equipment automatically removes the stored energy internally in following conditions.**
  - **A rhythm change is detected and a shock is no longer appropriate.**
  - **Electrode pads malfunction is detected.**
  - **The Shock button is not pressed within the configured time on the semi-automatic models.**
- **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.**
- **During defibrillation, air pockets between the skin and the electrode pads can cause patient skin burns. To help prevent air pockets, make sure the electrode pads are completely adhered to the skin.**
- **During defibrillation, never press the Adult/Child mode switch to the Adult mode when using pediatric pads for children. Otherwise the electrode pads might be damaged and could result in delayed analysis.**
- **Do not use dried-out electrode pads.**

CAUTION

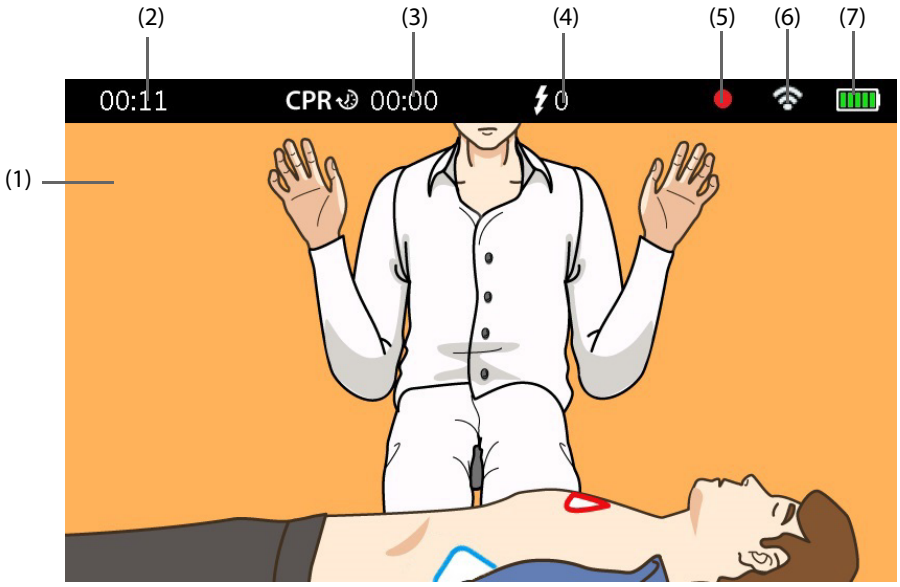
- **Prevent the electrode pads from contamination by dust or water before they are attached to the patient. Otherwise, incorrect or delayed analysis may result.**

NOTE

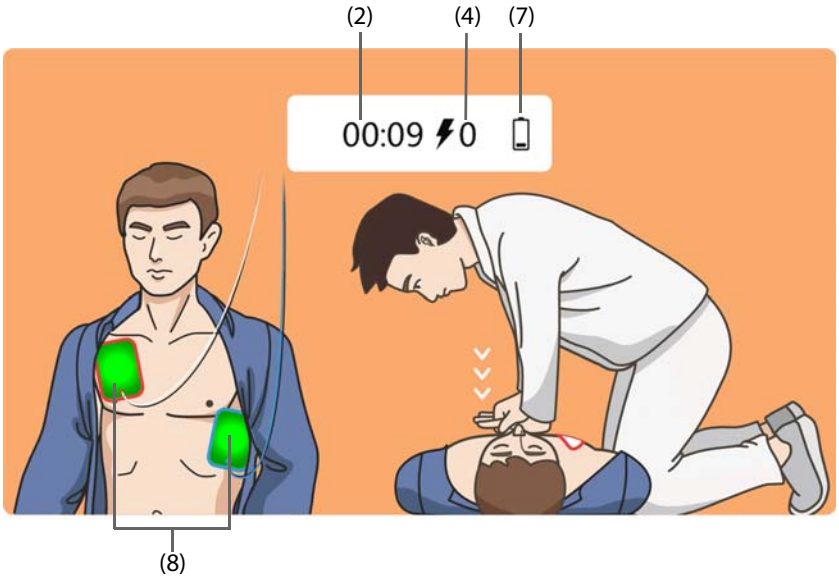
- **Use pediatric pads for children. If pediatric pads are not available, you can use adult pads, press the Adult/Child mode switch to the Child mode and apply the electrode pads.**
- **If MR62/MR63 electrode pads are used, the equipment automatically recognizes the patient type after power on. When the patient type indicating by the Adult/Child mode switch is found to be inconsistent with that recognized by the equipment, you should confirm you use the correct pads type and use the Adult/Child mode switch to change the patient type.**
- **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.**
- **If the equipment prompts you to plug in the pads connector or apply pads, the pads are not connected in place. Reconnect the electrode pads immediately to avoid any delayed analysis.**
- **In emergency, if there are no spare pads nearby, continue patient treatment with the expired electrode 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.**
- **For the semi-automatic models, the Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.**
- **Impedance is the resistance between the electrode pads 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 prompt "Shock cancelled. Press pads firmly to patient's bare skin." is provided, make sure that the patient's skin has been dried and chest hair has been clipped. If the prompt persists, change the electrode pads.**

4.2 AED Display



Equipment configured with 7-inch screen



Equipment configured with 1.96-inch screen

(1) ECG rhythm: displays one ECG waveform acquired from the electrode pads if **ECG Display** is set to **On**.

(2) Runtime area: displays the equipment's operating time since powered on.

(3) CPR time

(4) Number of delivered shocks

(5) Record icon: available when the sound recording function is enabled.

(6) Network type indicator

- : indicates the equipment is configured with the Wi-Fi module, and is connected to the AED ALERT system through the Wi-Fi network.
- **4G**: indicates the equipment is configured with the cellular module, and is connected to the AED ALERT system through the cellular network.

(7) Battery status indicator: indicates battery status. For details, see *6 Battery*.

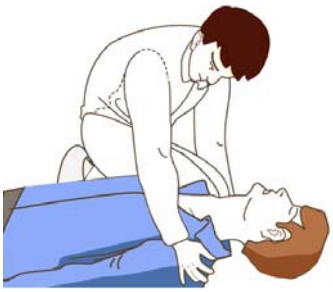
(8) Contact indicator: indicates the contact status between the patient and electrode pads.

- Steady green: the electrode pads are properly applied on the patient.
- Flashing green: the pads cable falls off or electrode pads are not firmly attached on the patient. You should immediately take correction actions according to the voice prompts. For details, see *E Voice Prompts*.

4.3 Responds to a Rescue

You should perform the general steps for a rescue.

1 **Assess the Patient**

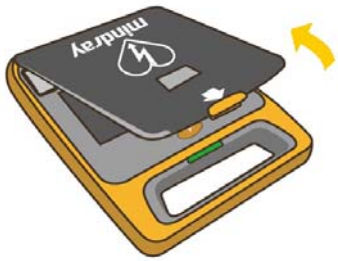


Confirm that the patient is both:

- Unresponsive,
- Not breathing or not breathing normally

CALL EMERGENCY MEDICAL SERVICE!

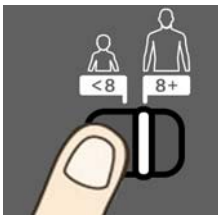
2 **Turn on the Equipment**



Open the lid.

You hear:
Powered on. Stay calm. Follow the instructions.

3 Check Patient Category



Flip the Adult/Child mode switch left or right:

- For an adult

You hear:

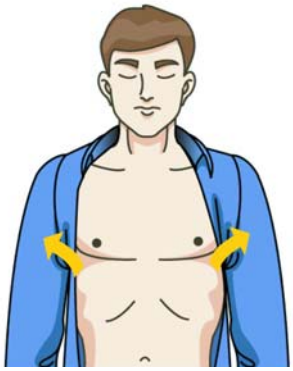
Adult mode

- For a child

You hear:

Child mode

4 Prepare the Patient



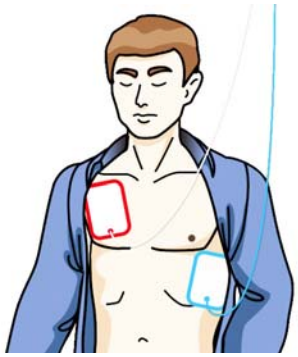
Expose the patient's bare chest:

- Ensure the patient's skin is clean and dry.
- Dry the patient's chest and shave excessive hair if necessary.

You hear:

Remove clothing from patient's chest. Apply pads as shown on Pads.

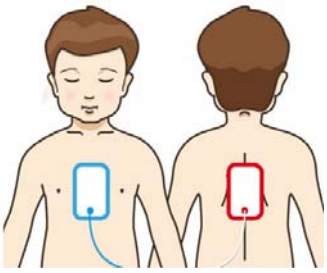
5 Apply the Electrode Pads



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

For an adult:

- Blue (apex) pad placement: place the blue pad as the blue area (below left nipple, on the left midaxillary line) illustrated in the picture
- Red (sternum) pad placement: place the red pad as the red area (below the clavicle, lateral to the sternum) illustrated in the picture



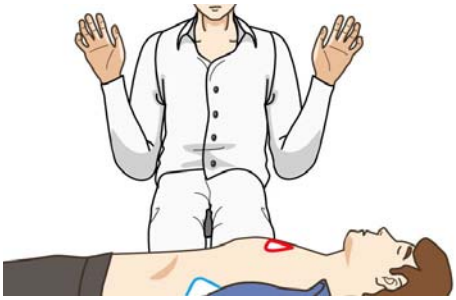
For a child:

- Blue (apex) pad placement: place the blue pad as the blue area (on the chest middle line) illustrated in the picture
- Red (sternum) pad placement: place the red pad as the red area (on the back middle line) illustrated in the picture

You hear:

Apply pads firmly to patient's bare chest as shown on Pads.

6 Analyze Heart Rhythm



Do not touch the patient, waits for heart rhythm analysis.

You hear:
Do not touch the patient. Analyzing heart rhythm.

7 Deliver a Shock

If Shock Advised

- For fully automatic models:

The equipment automatically shocks the patient.

You hear:
Shock advised. Shock will be delivered in: 3, 2, 1

- For semi-automatic models:

Press the Shock button within the configured time.

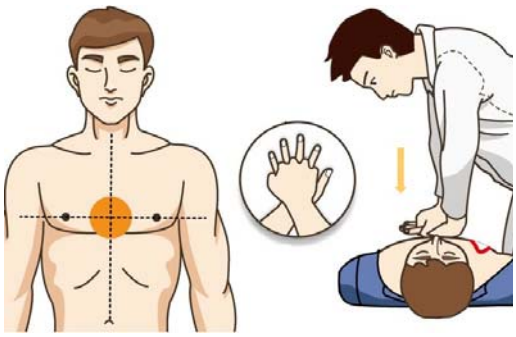
You hear:
Shock advised. Press flashing shock button.

If No Shock Advised

Go to Step 8.

You hear:
No shock advised.

8 Perform CPR



Perform CPR according to the prompts.

- If the CPR time expires, repeat Step 6.
- If the patient is conscious and breathing normally, wait for emergency medical services to arrive.

4.4 Performing CPR

The equipment enters the CPR status in the following conditions.

- Non-shockable rhythm is detected with a prompt "**No shock advised**".
- After a shock delivered and heart rhythm analysis pauses.

CPR status continues for 2 minutes.

WARNING

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

4.4.1 Using the 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.

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.**

4.4.2 Using the CPR Sensor

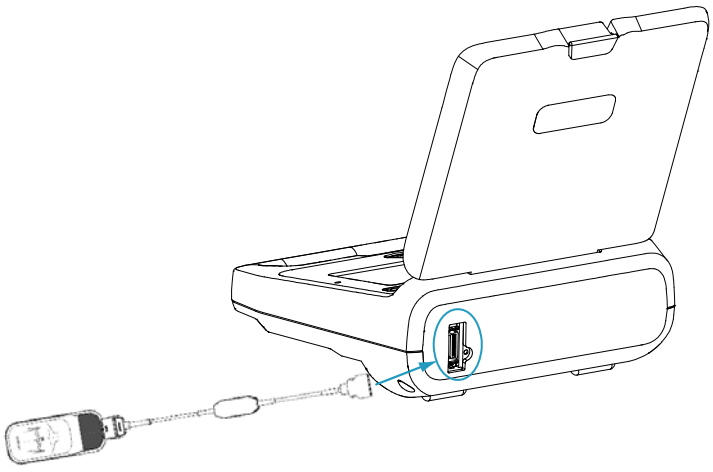
The equipment provides voice instructions about real-time compression feedbacks if it is connected with a CPR sensor. For more information about voice prompts provided by the CPR sensor, see *E Voice Prompts*.

NOTE

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

To connect the CPR sensor, follow this procedure.

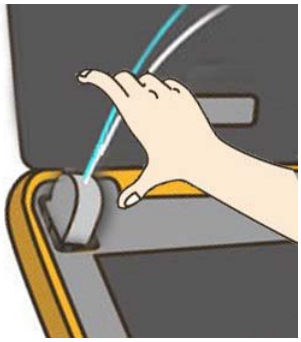
1. Hold one end of the CPR sensor cable, and plug it into the CPR sensor connector.
2. Fasten the CPR sensor cable with the cable retainer.
3. Try to pull the CPR sensor cable to make sure that the cable is securely connected.
4. Plug the other end of the sensor cable into the CPR sensor connector of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



For more information on using the CPR sensor, see *MR6401 CPR Sensor Operator's Manual*.

4.5 Preparation for Next Rescue

1. Retrieve the rescue data stored in the equipment. For more information, see *5 Data Management*.
2. Remove the pads connector.



3. Replace with the new electrode pads. For more information, see *3.2.3 Connecting the Electrode Pads*.
4. Ensure the Adult/Child mode switch is available by flipping it right or left.
5. Close the lid and check the Status indicator illuminates in green.

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5 Data Management

5.1 Data Management Overview

The following table lists data stored in the equipment and how to manage these data.

Data Type		Description	Management Method
Patient Data	Patient information	Patient ID, patient category	Patient data can be stored in real time during the use. If the data is needed, contact your local distributor.
	ECG data	Heart rhythm	
	Events	AED analysis, CPR operation, system operations and prompts	
	Recordings	Audio recorded during a rescue	
	Rescue data	Total rescue time, CPR duration, total shocks	
	CPR data	Compression rate and depth provided by using the CPR sensor.	
Configurations		Configurable setup options	AED Tool software
Equipment information		Equipment model, serial number, software version, total runtime, battery information, electrode pads information, total auto tests	
Equipment status		Powered on, powered off, out of location	AED ALERT Device Management system V2.0
Auto test data		Last selftest report, fault codes if auto test fails	

NOTE

- **The equipment is capable of 1 Gbit internal data storage.**

5.2 Generating a Patient File

Once turned on with a patient connected, the equipment automatically generates a patient ID and starts to record clinical data for this ID. If turned off, the equipment automatically discharges the patient, and the patient becomes a discharged patient.

NOTE

- **Earlier stored data will be overwritten by later ones if the equipment capacity is reached.**

5.3 Exporting Data

You can use a USB flash memory to export data. The data that can be exported includes patient data, configurations, equipment information and auto test data.

To export data, follow this procedure:

■ Equipment configured with 1.96-inch screen:

1. Connect the USB flash memory to the USB connector of the equipment.
2. Open the lid. **Export** is displayed on the screen.
3. Press the right maintenance button. **Export Or Not** is displayed on the screen.
4. Press the right maintenance button again for confirmation.

■ Equipment configured with 7-inch screen

1. Connect the USB flash memory to the USB connector of the equipment.
2. Open the lid. Data will be automatically exported from the equipment.

You can also export data through AED Tool software. For more information on specific operations, see *AED Tool Instructions for Use*.

5.4 Managing Configurations

If you purchase the AED Tool software, you can:

■ Viewing equipment Information

■ Viewing configurations

■ Changing configurations

■ Restoring to the factory default configurations

For more information on specific operations, see *AED Tool Instructions for Use*.

CAUTION

- **The configurations can only be changed by trained equipment managers.**

5.5 AED ALERT System V2.0

5.5.1 AED ALERT System Overview

The equipment can be connected to the AED ALERT Device Management system V2.0, hereinafter called the AED ALERT system, through a Wi-Fi or cellular network. With the AED ALERT system, you can view data uploaded from the equipment and manage your equipment. The AED ALERT system should be used by emergency equipment managers at your facility.

The AED ALERT system may provide the following features, depending on your subscription type and service area.

■ Managing equipment, such as register, edit, delete, import or export the equipment information.

■ Managing users, such as create a secondary account, edit or delete the user information.

■ Managing rescuers, such as associate a rescuer with the equipment, edit, delete or import the rescuer information.

■ Making statistics for registered equipment and rescuers, giving brief statistical graphs.

■ Viewing the equipment information

■ Monitoring equipment status and sending email or message notifications when the equipment is turned on or off.

■ Instructing a lost equipment by sending its approximate location (only available for a cellular connection)

■ Sending email notifications when auto test fails, no auto test detected, low battery or expired electrode pads.

■ Giving alerts for the electrode pads nearing the expiration date.

For more information on specific system operations, see the instructions for use provided on the AED ALERT system.

NOTE

- **If any equipment failure is found or no equipment information is displayed when using the AED ALERT system, the equipment manager must go to the scene to clear the failure.**
- **The AED ALERT system is not available in all countries.**

5.5.2 Accessing the AED ALERT System

If the equipment is connected to the AED ALERT system through the wireless network, you can access the system on the Internet.

To access the AED ALERT system, follow this procedure.

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

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6 Battery

6.1 Battery Introduction

The equipment is designed to operate using a disposable battery.

6.2 Battery Safety Information

WARNING

- **Never charge the disposable battery under any circumstances.**
- **Do not disassemble, puncture or incinerate batteries. Do not short the battery terminals. They may ignite, explode, or leak, causing personal injury.**
- **Keep a new spare battery available at all times.**
- **Battery operating time depends on the time and frequency of using the equipment. Improper use of the battery will reduce its operating time.**

NOTE

- **Battery operating time depends on the ambient temperature, equipment configuration and operation.**
- **Poor network quality connecting AED ALERT system will reduce the battery standby life.**

6.3 Replacing the Battery

Before replacing the battery, perform the following inspections.

- Make sure the equipment is turned off.
- Make sure the battery to be replaced is intact.

To replace the battery, follow this procedure.

1. Place the equipment on the worktable with face down.
2. Remove the screws from the battery door.
3. Remove the battery door as indicated.

4. Slide the battery to the left, and lift it to remove from the battery compartment.

5. Align the battery pins, slide the battery into the battery compartment.
6. Re-install the battery door with the screws.
7. Perform the test by referring to *8.3.1 User Test*.

NOTE

- **Install and use the battery before the expiration date displayed on the battery label.**
- **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.**

6.4 Battery Indications

On-screen battery symbols and battery related voice prompts indicate the current battery status.

6.4.1 Battery Symbols

The on-screen battery symbol indicates the battery status. The battery symbol consists of 5 portions, each portion represents a charge of approximately 20% of capacity.

■ For equipment configured with 7-inch screen

indicates that battery works correctly. The green portion represents the remaining charge.

indicates that the battery power is low or almost depleted. You need to replace the battery immediately.

■ For equipment configured with 1.96-inch screen

indicates that battery works correctly. The black portion represents the remaining charge.

indicates that the battery power is low or almost depleted. You need to replace the battery immediately.

6.4.2 Battery Prompts

When the battery has low or depleted charge, the equipment indicates it to you through voice prompts. In this case, you should take actions by referring to the following table.

Voice Prompt	Recommended Action
Low battery! Please replace battery as soon as possible	The battery charge is low. Replace the battery with a new battery immediately. If not, this voice prompt will be repeated every five minutes.
Battery depleted! Please replace battery immediately	The battery is almost depleted. Replace the battery with a new battery immediately. If not, this voice prompt will be repeated every minute and the equipment automatically shuts down in three minutes.

6.5 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.

NOTE

- **Storing batteries at temperature above 38 °C (100 °F) for an extended period of time significantly shortens the battery operating time and standby life.**
- **The battery storage temperature is between -5 °C and 35 °C. Storing batteries in a cool place can slow the aging process. Ideally the batteries should be stored at 15 °C.**

6.6 Recycling Batteries

Discard a battery in the following situations:

- The battery has visual signs of damage.
- The battery fails.

Properly dispose of batteries according to local regulations.

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7 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.

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

7.1 General Points

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

- Always dilute following 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

- **The equipment manager shall carry out all cleaning and disinfection procedure specified in this chapter.**

CAUTION

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

7.2 Cleaning

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

Recommended cleaning agents are:

- Water
- Sodium hypochlorite bleach (10%, Sodium hypochlorite)
- Hydrogen peroxide (3%)
- Ethanol (75%)
- Isopropyl alcohol (70%)
- Perform® classic concentrateOXY ($KHSO_4$ solution)

To clean your equipment, follow these rules:

1. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
2. Clean the exterior surface of the equipment using a soft, clean cloth dampened with a glass cleaner.
3. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
4. Dry your equipment in a ventilated, cool place.

7.3 Disinfecting

Disinfect the equipment as required in your facility servicing schedule. Cleaning equipment before disinfecting is recommended.

7.4 Sterilization

Sterilization is not recommended for the equipment unless otherwise indicated in the Instructions for Use that accompany the product.

8 Maintenance and Testing

8.1 Maintenance Introduction

Regular maintenance is essential to ensure that the equipment functions properly. This chapter contains information on periodic testing and maintenance. For details about the electrical safety test, see *BeneHeart C & S Series Automated External Defibrillator Service Manual*.

8.2 Maintenance Safety Information

WARNING

- **Failure for the responsible institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and delayed analysis.**
- **No modification of this equipment is allowed.**
- **This equipment contains no user serviceable parts.**
- **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.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**

CAUTION

- **Do not perform any functional check and maintenance if the equipment is connected to a patient; otherwise the patient might be shocked.**
- **If you discover a problem with any of the equipment, contact your local distributor, service personnel or Mindray.**
- **Use and store the equipment within the specified temperature, humidity, and barometric ranges.**
- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**

NOTE

- **If needed, contact the manufacture for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.**

8.3 Performing Maintenance

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

Maintenance Item	Recommended Frequency	Test Item
User test	• After installing the battery • After replacing the battery • After each use	Performs function tests of the main control module, the therapy module, the power module, electrode pads, 1J charge and discharge, 360J charge and discharge, controls, the speaker.
Auto test	Automatically, whenever the equipment is powered on, or when a battery is installed.	Performs function tests of the main control module, the therapy module, the power module
	Once a day	Performs function tests of the main control module, the therapy module, the power module, 1J charge and discharge
	Once a week	
	Once a month	Performs function tests of the main control module, the therapy module, the power module, electrode pads expiration, 1J charge and discharge, 200J charge and discharge, the speaker.
	Once a quarter	Performs function tests of the main control module, the therapy module, the power module, electrode pads expiration, 1J charge and discharge, 360J charge and discharge, the speaker.
Electrode pads check	Once a month	Checks the electrode pads are not expired.

The equipment connected to the AED ALERT system can be managed remotely, which could reduce the site maintenance All the maintenances performed on the AED ALERT system must be in compliance with the local regulations.

NOTE

- **Auto test checks the expiration of electrode pads only when the electrode pads have such function.**

8.3.1 User Test

You can use the already installed battery or a replaced battery to perform the user test on the equipment.

To perform the battery installation test, follow this procedure:

1. Choose any of the following ways to start the test.
   - ◆ Install the battery for the first time or replace the battery after it is taken out for over three minutes.
   - ◆ Not taking out the battery, hold the Language button for 5 seconds and flip the Adult/Child mode switch twice.
   - ◆ Not taking out the battery, hold the Shock button for 5 seconds and flip the Adult/Child mode switch twice.
   - ◆ For equipment configured with 1.96-inch screen, simultaneously press and hold two maintenance buttons and then press the left maintenance button for confirmation.
2. Perform operations following the voice instructions.

All items are tested hereafter automatically after you respond to the equipment. If any failure is detected, corresponding prompts are provided.

You can also perform the user test using the AED Tool software. For more information, see *AED Tool Instructions for Use*.

CAUTION

- **Frequently turning on or off the equipment during the user test will reduce the battery standby life.**

NOTE

- **If you mistakenly access the maintenance status by pressing maintenance buttons, you can close the lid to exit.**
- **Once the equipment is turned on, you are recommended to perform a user test before turning it off.**
- **After you pass the user test and turn off the equipment, the status indicator flashing in red indicates that the pads connector is not connected and electrode pads cannot be detected. You should check that the pads connector is connected before a normal shutdown.**

8.3.2 Auto Test

The equipment with a battery installed carries out auto test at the configured time even when powered off to check the equipment's operational performance and alert the operator if a problem exists. Auto test is initiated at 3:00 am every day by default.

The equipment provides no voice prompts during auto test. The test result can be checked on the status indicator and buzzer:

- Status indicator flashes in green (flashing every 5 seconds, lasting 1 second each time): the auto test passes. An auto-test report is saved automatically when the test is completed.
- Status indicator flashes in red:
  - A failure is detected, the auto test fails. If the equipment is connected to the AED ALERT system, an auto-test report is saved and uploaded automatically to the system when the test is completed.
  - The pads connector is not connected, and electrode pads cannot be detected.
- Buzzer: if the auto test fails, the buzzer gives a beep at the configured frequency.

Mindray recommends you check the status indicator every day, and record the result according to *G Inspection Record*.

CAUTION

- **With the equipment powered off, auto test can be performed only when the battery is installed.**

NOTE

- **The status indicator flashes in green to indicate the equipment is ready for use. If the status indicator does not flash, flashes at a interval of more than 5 seconds, or flashes for more than 1 second each time, the equipment fails the auto test and requires attention.**
- **When the equipment is placed at a temperature below -20°C, the auto test cannot be carried out, and incorrect status indication could result.**

8.3.3 Electrode Pads Check

The expiration date of electrode pads should be checked every month. You can check the expiration date from the pad expiration window, and record it according to *G Inspection Record*.

8.4 Disposing the Equipment

Dispose of the equipment and its accessories when its service life is reached. Follow local regulations regarding the disposal of such product.

WARNING

- **For disposal of parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.**

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9 Accessories

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

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the 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.**

CAUTION

- **The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date if their expiry date is indicated.**
- **The disposable accessories shall be disposed of according to local regulations.**

9.1 Therapy Accessories

Description	Model	Applicable patient	Remark	PN
Multifunction electrode pads	MR60	Adult, Child	Disposable (5 sets/pack)	0651-30-77007
	MR61	Child		0651-30-77008
	MR62	Adult, Child	Disposable (5 sets/pack), the adult pads are automatically detected, the pediatric pads need to be manually selected.	125-000061-00
	MR63	Child	Disposable (5 sets/pack), the pediatric pads are automatically detected.	115-035427-00
CPR sensor	MR6401	/	Reusable, without a battery	115-044803-00
CPR sensor cable	MR6801	/	Reusable	040-003096-00
CPR adhesive tape	MR6921	/	Disposable (3 sets/pack)	040-003123-00

9.2 Miscellaneous

Description	Model	PN
Disposable battery	LM34S002A	022-000425-00

A Specifications

A.1 Safety Specifications

A.1.1 Safety Classifications

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

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.
Mode of operation	Continuous
Degree of protection against harmful ingress of solid Degree of protection against harmful ingress of water	IP55
Degree of mobility	Portable

A.1.2 Environmental Specifications

WARNING

- **When the temperature changes from the lowest storage temperature to the room temperature (non−condensing), it is recommended to use the equipment at least one hour later for proper operation.**
- **The equipment may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.**

Item	Temperature	Relative humidity	Barometric
Operating conditions	-5°C to 50°C (at least 60 minutes of working time when the temperature reduces from room temperature to -20°C)	5% to 95%, non-condensing	57.0 to 106.2 kPa (-381m to 4575m)
Short-term storage conditions	-30°C to 70°C	5% to 95%, non-condensing	57.0 to 106.2 kPa (-381m to 4575m)
Long-term storage conditions	15°C to 35°C		
Shock			
Complies with requirements of 6.3.4, EN 1789:2020 /10.1.3, IEC 60601-1-12:2014+AMD1:2020: Peak acceleration: 1000m/s^2 (102g) Duration: 6ms Pulse shape: half-sine Number of shocks: 3 shocks per direction per axis (18 shocks in total)			
Vibration			

Complies with requirements of 6.3.4, EN 1789:2020/10.1.3, IEC 60601-1-12:2014+AMD1:2020: Acceleration amplitude: 10 Hz to100 Hz: 5.0 $(m/s^2)^2$/Hz- 100 Hz to 200 Hz: -7 dB/octave 200 Hz to 2000 Hz: 1.0 $(m/s^2)^2$/Hz Duration: 30 minutes per perpendicular axis (3 axises in total)
Bump
Complies with requirements of EN 60068-2-29:1993/IEC 60068-2-29:1987: Peak acceleration: 15 g Pulse duration: 6 ms Number of bumps: 1000 Direction: vertical, with the equipment in its normal operating position(s)
Free fall
Complies with requirements of EN 60068-2-32:1993/IEC 60068-2-32:1990: Height of fall: 1.5 m Number of falls: 1 on each of the six surfaces.

A.2 Physical Specifications

Main Unit	Size (Width × depth × height)	Weight
BeneHeart C1/BeneHeart C1A/ BeneHeart S1/BeneHeart S1A	21.0 cm×28.6 cm×7.8 cm (± 2cm)	2.0 ± 0.4 kg, including one battery, excluding the Wi-Fi and cellular modules.
BeneHeart C2/BeneHeart C2A/ BeneHeart S2/BeneHeart S2A		2.3 ± 0.3 kg, including one battery, excluding the Wi-Fi and cellular modules.
BeneHeart C1 Fully Automatic/ BeneHeart C1A Fully Automatic/ BeneHeart S1 Fully Automatic/ BeneHeart S1A Fully Automatic		2.0 ± 0.4 kg, including one battery, excluding the Wi-Fi and cellular modules.
BeneHeart C2 Fully Automatic/ BeneHeart C2A Fully Automatic/ BeneHeart S2 Fully Automatic/ BeneHeart S2A Fully Automatic		2.3 ± 0.3 kg, including one battery, excluding the Wi-Fi and cellular modules.

A.3 Display Specifications

Equipment configured with 1.96-inch screen	
Screen type	dot-matrix LCD
Screen size	1.96 inches
Resolution	240×64 pixels
Equipment configured with 7-inch screen	
Screen type	TFT color LCD
Screen size	7 inches
Resolution	800×480 pixels

Brightness	Auto, Outdoor Mode, Indoor mode. In the auto mode, the equipment automatically adjusts the screen brightness according to the ambient light.
Viewed waveforms	1
Wave viewing time	Max. ≥ 6s (ECG)

A.4 Audio Indicators

Speaker	Gives prompt tones (65 dB to 78 dB). Supports multi-level tone modulation.
Buzzer	Gives acoustic alarms.

A.5 Interface Specifications

USB connector	1, USB 2.0
micro USB connector	1, supports Windows 7 or above operating system
Network connector	1, connects the Wi-Fi or cellular (2G/3G/4G) network.
Multifunction connector	1, connects the CPR sensor.

A.6 Battery Specifications

<table>
<tr><td>Battery type</td><td colspan="2">Disposable battery</td></tr>
<tr><td>Battery voltage</td><td colspan="2">12V</td></tr>
<tr><td>Battery capacity</td><td colspan="2">4200mAh</td></tr>
<tr><td rowspan="8">Equipment configured with 1.96-inch screen</td><td>Operating time</td><td>Testing condition</td></tr>
<tr><td>≥ 15 hours</td><td>The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, wireless function off, not performing defibrillation charges or discharges, voice volume set to low.</td></tr>
<tr><td>300 200J discharges</td><td rowspan="2">The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low, with one minute of CPR between discharges</td></tr>
<tr><td>190 360J discharges</td></tr>
<tr><td>510 150 J discharges</td><td rowspan="3">The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low, with three discharges every minute</td></tr>
<tr><td>400 200J discharges</td></tr>
<tr><td>200 360J discharges</td></tr>
</table>

<table>
<tr><td rowspan="6">Equipment configured with 7-inch screen</td><td>Operating time</td><td>Testing condition</td></tr>
<tr><td>≥ 12 hours</td><td>The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, wireless function off, not performing defibrillation charges or discharges, voice volume set to low.</td></tr>
<tr><td>270 200J discharges</td><td rowspan="2">The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low, with one minute of CPR between discharges</td></tr>
<tr><td>170 360J discharges</td></tr>
<tr><td>450 150J discharges</td><td rowspan="3">The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low, with three discharges every minute</td></tr>
<tr><td>350 200J discharges</td></tr>
<tr><td>200 360J discharges</td></tr>
<tr><td>Battery fuel gauge</td><td colspan="2">Battery symbol on the display indicating the current battery level</td></tr>
<tr><td rowspan="2">Remaining charge after “Low Battery” is prompted</td><td colspan="2">For BeneHeart C1/BeneHeart C1A/BeneHeart C1 Fully Automatic/ BeneHeart C1A Fully Automatic/BeneHeart S1/BeneHeart S1A/BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic:
• At least 30 minutes operating time (at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low) and at least 10 200J discharges (with one minute of CPR between discharges)
• At least 30 minutes operating time (at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low) and at least 6 360J discharges (with one minute of CPR between discharges)</td></tr>
<tr><td colspan="2">For BeneHeart C2/BeneHeart C2A/BeneHeart C2 Fully Automatic/ BeneHeart C2A Fully Automatic/BeneHeart S2/BeneHeart S2A/BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic:
• At least 30 minutes operating time (at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low, screen brightness set to indoor mode) and at least 10 200J discharges (with one minute of CPR between discharges)
• At least 30 minutes operating time (at 20 °C± 5 °C of ambient temperature, wireless function off, voice volume set to low, screen brightness set to indoor mode) and at least 6 360J discharges (with one minute of CPR between discharges)</td></tr>
<tr><td rowspan="4">Battery standby life</td><td>Standby life</td><td>Testing condition</td></tr>
<tr><td>5 years</td><td>The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, performing auto test every day, equipment not in use, not sending selftest report</td></tr>
<tr><td>3 years</td><td>The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, performing auto test every day, equipment not in use, sending selftest report every week through the wireless network</td></tr>
<tr><td>2 years</td><td>The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, performing auto test every day, equipment not in use, sending selftest report every day through the wireless network</td></tr>
</table>

CAUTION

- **If the equipment is connected through the wireless network in low strength signal, the battery standby life will be shortened.**

A.7 Data Storage

Waveform storage	Up to 5 hours of ECG waveforms, with a resolution of 1 second
Events	Up to 500 events
Voice recording	Up to 1 hour
CPR data	Up to 5 hours
Selftest reports	1000 records
Patient files	Up to 5 patient files

A.8 Wireless Specifications

Wi-Fi	
Standard	IEEE 802.11 a/b/g/n
Operating frequency	IEEE 802.11 b/g/n (at 2.4G): 2.412 GHz to 2.472 GHz IEEE 802.11 a/n (at 5G): 5.18 GHz to 5.24 GHz, 5.745 GHz to 5.825 GHz
Data security	Standards: WPA-PSK, WPA2-PSK, WPA-Enterprise,WPA2-Enterprise EAP method: EAP-TLS, PEAP-GTC, PEAP- MSCHAPv2 Encryption: TKIP, AES
Modulation mode	DSSS and OFDM
Output Power	≤20 dBm
Cellular	
Operating frequency	For EU: • LTE-FDD: B1/B3/B7/B8/B20/B28A • LTE-TDD: B38/B40 For global: • LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B12/B13/B18/B19/B20/B25/B26/B28 • LTE-TDD: B38/B39/B40/B41 • UMTS: B1/B2/B4/B5/B6/B8/B19 • GSM: B2/B3/B5/B8
Standard/Modulation mode	3GPP E-UTRA Release 11: LTE-FDD/LTE-TDD
Output Power	≤25 dBm

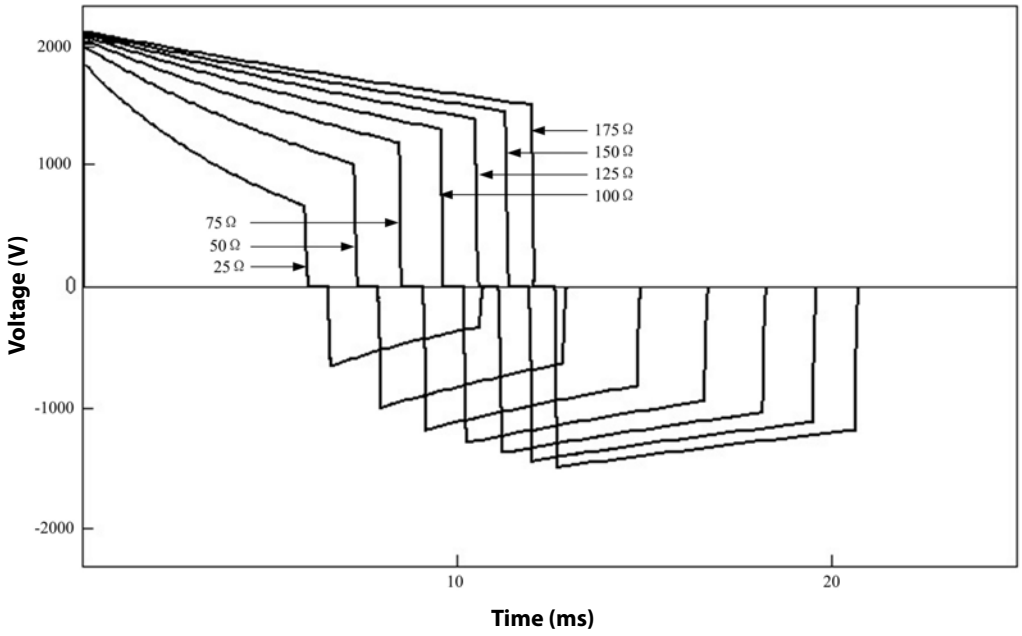
NOTE

- **Only one of Wi-Fi and 4G modules can be configured on the equipment.**

A.9 Defibrillator Specifications

Standards	Meet standards of IEC 60601-2-4
Defibrillation mode	• BeneHeart C1/BeneHeart C1A/BeneHeart C2/BeneHeart C2A/ BeneHeart S1/BeneHeart S1A/BeneHeart S2/BeneHeart S2A: semi automatic external defibrillation • BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/ BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/ BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/ BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic: fully automatic external defibrillation
Defibrillation waveform	Biphasic truncated exponential (BTE) waveform, auto-compensation according to patient impedance
Defibrillation electrodes	Multifunction electrode pads.
Range of selected energy	For adults: 100 J, 120 J, 150 J, 170 J, 200 J, 300 J, 360 J. For children: 10 J, 15 J, 20 J, 25 J, 30 J, 50 J, 70 J, 100 J, 120 J, 150 J, 170 J, 200 J.
Patient impedance range	25 to 300 Ω
Shockable rhythm analysis time	< 5s
Shock series	Energy level: 100 to 360 J, configurable for adult; 10 to 200 J, configurable for pediatric; Shocks: 1, 2, 3, configurable; Meeting 2020 AHA/2021 ERC guidelines by default.
ECG Analysis Performance	See B Mindray Shockable Rhythm Analysis Algorithm.

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



NOTE

- **For fully automatic model, when its battery power reduced from 15 times of 360J charges and the energy level is configured as 360J, the response time to ECG rhythm change (from shockable to nonshockable) is less than 25s.**

Selected energy	Impedance							Accuracy
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	
10 J	9.7 J	10 J	9.7 J	9.3 J	8.9 J	8.5 J	8.1 J	±10% or ±2J, whichever is greater
15 J	15 J	15 J	15 J	14 J	13 J	13 J	12 J	
20 J	20 J	20 J	20 J	19 J	18 J	17 J	16 J	
25 J	24 J	25 J	24 J	23 J	22 J	21 J	20 J	
30 J	29 J	30 J	29 J	28 J	27 J	25 J	24 J	
50 J	49 J	50 J	49 J	47 J	45 J	43 J	41 J	
70 J	68 J	70 J	68 J	65 J	62 J	60 J	57 J	
100 J	97 J	100 J	97 J	93 J	89 J	85 J	81 J	
120 J	116 J	120 J	116 J	111 J	106 J	101 J	97 J	
150 J	146 J	150 J	146 J	140 J	134 J	128 J	122 J	
170 J	166 J	170 J	166 J	159 J	151 J	145 J	138 J	
200 J	195 J	200 J	195 J	187 J	178 J	170 J	163 J	
300 J	292 J	300 J	292 J	280 J	267 J	255 J	244 J	
360 J	351 J	360 J	350 J	336 J	321 J	306 J	293 J	

Charge time (at 20 °C± 5 °C of ambient temperature)					
Battery status	From lid opened to charge done		From initiation of rhythm analysis to charge done		From initial power on to charge done
	200J	360J	200J	360J	200J
New battery	<8 s	<15 s	<5 s	<12 s	<7 s
New battery after 15 times of 360J discharges	<8 s	<15 s	<5 s	<12 s	<7 s

A.10 ECG Specifications (for Equipment Configured with 7-inch Screen)

ECG inputs	Multifunction electrode pads
Gain	Auto
Sweep speed	25 mm/s, error no more than ± 5%
Common mode rejection	>90 dB
Recovery time	<2.5 s (after defibrillation)

A.11 Electrode Pads Specifications

Electrode Pads	**MR60**	**MR61**	**MR63**	**MR62**
Electrode shape	Oval			
Cable length	1.2 m preconnectable			
Total area	115±5 cm^2	75±5 cm^2	75±5 cm^2	115±5 cm^2
Adhesive area	80±5 cm^2	43±5 cm^2	43±5 cm^2	80±5 cm^2
Maximum number of defibrillation shocks	Up to 50 shocks (360J monophasic and biphasic)			
Shelf life (with sealed package)	36 months			60 months
Storage condition	0°C to 50°C			15°C to 35°C The shelf life assumes a storage temperature of 25°C. Storage temperature above 25°C will reduce the shelf life.

A.12 Software Operating Evnironment

Host CPU	NXP Processor
Primary programming language	C++
Operating system	FreeRTOS kernel V9.0.0

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.

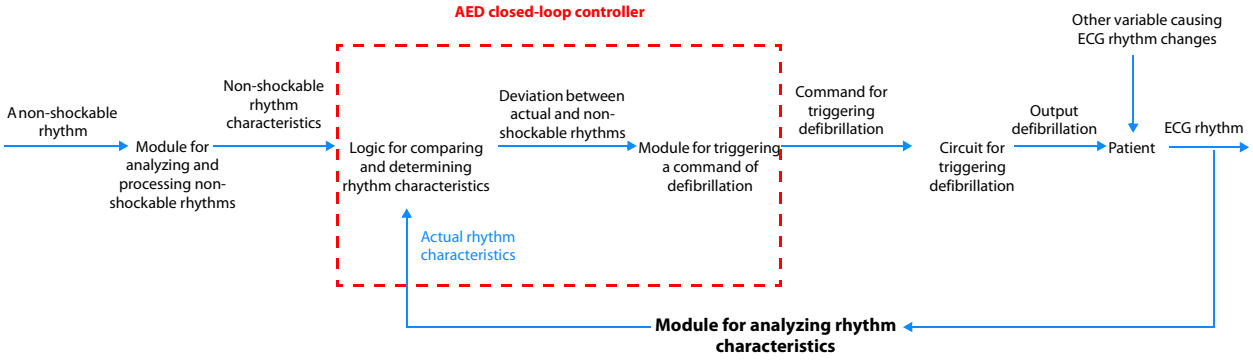
Rhythm category	Minimum sample size (cases)	Performance goal	Sample size tested (cases)	Test result
Shockable (sensitivity): Coarse VF Rapid VT	 200 50	 >90% >75%	 205 80	 Met Met
Nonshockable (specificity): Normal sinus rhythm Asystole Other nonshockable rhythms	300 100 100 30	 >99% >95% >95%	 171 180 385	 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.

B.3 Theory of Operation (for Fully Automatic Models)

For fully automatic models, ECG signals are acquired from the patient's skin through electrode pads, which are then analyzed by the equipment. If ECG signals are evaluated not have non-shockable rhythm characteristics but significant characteristics of shockable rhythm, the equipment will give a command to trigger the defibrillation circuit, and then provide audio/visual indications to prompt the rescuer or operator. After the audio countdown, the defibrillation circuit will then automatically deliver the shock to the patient. These activities above form a closed-loop controller system for the defibrillation process.



AED closed-loop controller system

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C EMC and Radio Regulatory Compliance

C.1 EMC

This product complies with the EMC standard IEC60601-1-2:2020.

Intended Environments: home healthcare environment and professional healthcare facility environment.

WARNING

- **The use of unapproved accessories may diminish product performance.**
- **This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Use of this product adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this product and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this product could result in increased electromagnetic emissions or decreased electromagnetic immunity of this product and result in improper operation.**
- **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 this product, including cables specified by the manufacturer. Otherwise, degradation of the performance of this product could result.**
- **Other devices may interfere with this product even though they meet the requirements of CISPR.**
- **When the input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**
- **Use of portable or mobile communications devices can degrade product performance.**

If this product is operated within the electromagnetic environment listed in TABLE EMC-2, TABLE EMC-3, TABLE EMC-4 and TABLE EMC-5, This product will remain safe and will provide the following basic performances: energy accuracy, CPR function, alarm, data stored.

TABLE EMC-1:

Guidance and Mindray Declaration - Electromagnetic Emissions		
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This product 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	This product is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

TABLE EMC-2:

Guidance and Mindray Declaration - Electromagnetic Immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product 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; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact; ±2 kV, ±4 kV, ±8 kV,±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

TABLE EMC-3:

Guidance and Mindray Declaration - Electromagnetic Immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product 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 0.15 MHz to 80 MHz	3 Vrms 0.15 MHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V1}\right] \times \sqrt{P}$ $d = \left[\frac{12}{V2}\right] \times \sqrt{P}$ $d = \left[\frac{12}{E1}\right] \times \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{23}{E1}\right] \times \sqrt{P}$ 800 MHz to 2.7 GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b], should be less than the compliance level in each frequency range[c]. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM and amateur radio bands[a] between 0.15 MHz and 80 MHz	6 Vrms (V2) in ISM and amateur radio bands[a] between 0.15 MHz and 80 MHz	
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m (E1) 80 MHz to 2.7 GHz	
	20V/m 80 MHz to 2.7GHz (IEC60601-2-4)	20V/m 80 MHz to 2.7GHz (IEC60601-2-4)	
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] 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.

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

TABLE EMC-4:

Guidance and Mindray Declaration - Electromagnetic Immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz CW	8 A/m 30 kHz CW	/
	65 A/m 134.2 kHz Pulse modulation 2.1 kHz	65 A/m 134.2 kHz Pulse modulation 2.1 kHz	
	7.5 A/m 13.56 MHz Pulse modulation 50 kHz	7.5 A/m 13.56 MHz Pulse modulation 50 kHz	

TABLE EMC-5:

Recommended separation distances between portable and mobile RF communications equipment and this product						
This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:						
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380 to 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						

810	800 to 960	GSM 800/ 900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

TABLE EMC-6:

Recommended separation distances between portable and mobile RF communications equipment and this product

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz out ISM and amateur radio bands $d = \left[\frac{3.5}{V1}\right] \times \sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = \left[\frac{12}{V2}\right] \times \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{12}{E1}\right] \times \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{23}{E1}\right] \times \sqrt{P}$
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.4	3.8	7.3
100	12	20	12	23

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

C.2 Radio Regulatory Compliance

CE

The device complies 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 the wireless function is in use.**

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D Default Settings

The following tables list all configurable setup options for the equipment with all functions. Your equipment may not have all of them.

D.1 General Setup

Menu Item		Description	Options/Range	Default
System Date	Year	Sets the system date. Configurable range: 2007-01-01 to 2099-05-31.	2007 to 2099	/
	Month		01 to 12	
	Day		01 to 31	
System Time	Hour	Sets the system time.	0 to 23	
	Minute		0 to 59	
	Second		0 to 59	
Language		Sets the language for voice prompts.	At most three languages	/
Voice Recording		Selects whether the recording function is enabled.	On, Off	Off
Voice Volume		Sets the volume level for voice prompts. • **Auto**: the equipment automatically adjusts the volume according to the ambient noise. • Low level if noise < 30 db • Hight level if noise > 80 db • Not specified if other ranges	Auto, High, Low	Auto
Brightness		Sets the screen brightness. **Auto**: the equipment automatically adjusts the screen brightness according to the ambient light.	Auto, Outdoor Mode, Indoor mode	Auto
Patient Type		Sets the patient category.	Adult, Pediatric	Adult

D.2 AED Setup

Menu Item	Description	Options/Range	Default
Shock Series	Sets the number of shocks. If it is set to greater than one, the equipment resumes analyzing the patient's rhythm after the shock is delivered to determine if the shock was successful. Prompts for shock counter are provided to guide you delivering additional shocks.	1, 2, 3	1
Energy 1 (Adult)	Sets the defibrillation energy level for the first shock on the adult patient.	100 J, 120 J, 150 J, 170 J, 200 J, 300 J, 360 J	200 J
Energy 2 (Adult)	Energy 1 ≤ configurable value ≤ Energy 3	Energy 1 to 360 J	300 J
Energy 3 (Adult)	Energy 2 ≤ configurable value	Energy 2 to 360 J	360 J
Energy 1 (Pediatric)	Sets the defibrillation energy level for the first shock on the children.	10 J, 15 J, 20 J, 25 J, 30 J, 50 J, 70 J, 100 J, 120 J, 150 J, 170 J, 200 J	100 J
Energy 2 (Pediatric)	Energy 1 ≤ configurable value ≤ Energy 3	Energy 1 to 200 J	100 J
Energy 3 (Pediatric)	Energy 2 ≤ configurable value	Energy 2 to 200 J	200 J
Initial CPR	Selects whether the equipment enters the CPR status directly after turned on.	On, Off	Off
ECG Display	Selects whether the ECG waveform is displayed.	On, Off	Off
Auto Release Time	Sets the time the equipment automatically removes the stored energy internally.	30 s, 60 s, 90 s, 120 s	30 s

D.3 CPR Setup

Menu Item	Description	Options/Range	Default
CPR Mode (Adult)	Sets the rate of compression and ventilation.	30:2, 15:2, Hands-Only	30:2
CPR Mode (Pediatric) (for Australia and New Zealand)			30:2
CPR Mode (Pediatric) (for other regions)			15:2
CPR Voice with Sensor	Selects whether voice prompts are provided when using a CPR sensor.	On, Off	On

D.4 Test Setup

Menu Item	Description	Options/Range	Default
Auto Test Time	Sets the start time for auto test.	00:00, 01:00, 02:00, 03:00, 04:00, 05:00	03:00
Auto Test Period	Sets the interval for auto test startup.	Daily, Weekly	Daily
Transmission Interval	Sets the interval for sending auto test report to the AED ALERT system. • If no fault is found, the equipment sends auto test report within the configured interval. • If any fault is found, the equipment sends auto test report at any time.	Daily, Weekly	Weekly
Buzzer Interval	Sets the interval for buzzer giving a beep.	Off, 30 s, 15 min, 3 h	3 h

D.5 WLAN Setup

If the equipment is configured with the Wi-Fi module, the related setup options are shown as below.

Menu Item	Description	Options/Range	Default
Device Management System Site	Input the IP address or domain name of AED ALERT system	/	3.122.182.109
Device Management System Port	Input the port of AED ALERT system	0 to 65535	16903
Network Name	Input the network name of Wi-Fi hotspot.	0 to 32 characters	/
Address Type	**Manual: Address Type**, **IP Address**, **Subnet Mask** are required. **DHCP**: the equipment automatically gets IP address.	Manual, DHCP	DHCP
IP Address		4 segments, and editable range 0 to 255 for each	/
Subnet Mask			
Gateway			
Security	/	WPA/WPA2 PSK, WPA/ WPA2 EAP	WPA/WPA2 PSK
Password	/	0 to 64 characters	/
WLAN Band	/	5G, 2.4G	2.4G

If the equipment configured with the cellular module, the related setup options are shown as below.

Menu Item	Description	Options/Range	Default
Device Management System Site	Input the IP address or domain name of AED ALERT system	/	10.6.144.28
Device Management System Port	Input the port of AED ALERT system	0 to 65535	16903
APN	Input the access point name of AED ALERT system	/	aed.mr.gdsp

D.6 AED ALERT Related Setup

If the equipment is connected to the AED ALERT system through the wireless network, the related setup options are shown as below.

Menu Item	Description	Options/Range	Default
Device Enabled Reminder	Sends messages to the designated person on the AED ALERT system when the equipment is turned on, turned off or out of the specified location.	On, Off	On
Auto Upload Rescue Data	Uploads the rescue events (not including ECG waveforms) automatically to the AED ALERT system after a rescue.	On, Off	On

E Voice Prompts

The following table lists voice prompts that may occur during a rescue.

Condition	Voice Prompt	Description
Open the lid	Powered on. Stay calm. Follow the instructions.	The lid is opened.
	Device error. Recommended to replace the Device. Stay calm. Follow the instructions.	The equipment malfunctions, use one standby equipment or start CPR immediately.
After turning on the equipment	Adult mode	The Adult/Child mode switch is pressed to Adult, or the electrode pads connected to the equipment are detected for the adult patient.
	Child mode. if the patient is an Adult, adjust the Adult/Child mode switch to Adult mode.	The Adult/Child mode switch is pressed to Child.
	Child mode	The Adult/Child mode switch is pressed to Child, or the electrode pads connected to the equipment are detected for the children.
Place the electrode pads	Remove clothing from patient's chest. Apply pads as shown on Pads.	Detecting the response time to the voice prompts, the equipment provides an intelligent voice guide here. This guide quickly helps the rescuer to remove the patient's clothing and place the electrode pads.
	Remove clothing from patient's chest. Plug in pads connector.	
	Remove pads package from lid of AED.Tear open package. Apply pads as shown on Pads.	
	Apply pads as shown on Pads.	
	Apply pads firmly to patient's bare chest as shown on Pads.	
	Abnormal Pads connection.	Pads connection failure, start CPR immediately.

Condition	Voice Prompt	Description
The equipment analyzes the patient's heart rhythm.	Do not touch the patient. Analyzing heart rhythm.	Repeats until analysis of the patient's heart rhythm is completed. This prompt will be interrupted if the equipment is ready to shock.
	No shock advised.	Notifies non-shockable rhythm has been detected.
	Motion detected. Do not touch or move the patient.	The equipment detects ECG noise artifacts, stop moving or touching the patient.
	Noise detected. Make sure pads are firmly attached.	The equipment detects ECG noise artifacts, better pads contact on the patient's skin is required.
	Pads off. Analysis interrupted.	Pads connection failure, the equipment automatically stops the heart rhythm analysis. Reconnect the electrode pads.
The equipment delivers a shock.	Shock advised.	Notifies a shockable rhythm has been detected.
	Shock will be delivered in: 3, 2, 1	Prompts the equipment is fully charged and is preparing to deliver a defibrillation shock.
	Shock delivered.	Prompts the shock is delivered.
	Press flashing shock button.	Prompts the equipment is fully charged and ready to deliver the defibrillation shock.
	Shock cancelled. Shock button was not pressed.	The Shock button is not pressed within the configured time and the equipment cancels the shock.
	Device error, charge failed.	The equipment is unable to start charging because of a fault condition. The equipment resumes the rhythm analysis after a charging failure. After three consecutive charging failures, the equipment automatically enters the CPR status.
	Device error, shock failed.	The equipment is unable to deliver a shock because of a fault condition. Or, it is not suitable to deliver a shock to the patient. The equipment disarms itself and resumes the rhythm analysis after a discharging failure. After three consecutive discharging failures, the equipment automatically enters the CPR status.
	Shock cancelled. Press pads firmly to patient's bare skin.	
	Shock cancelled. Pads must not be touching each other.	
	Rhythm change, shock cancelled	The equipment detects a rhythm change and cancels the shock

Condition	Voice Prompt	Description
Perform CPR	Start CPR immediately.	Prompts to prepare to provide compressions and breaths CPR.
	Give chest compressions immediately.	Prompts to prepare to provide compressions-only CPR.
	Continue to compress without rescue breaths.	
	Place one hand on center of chest, the other hand should be on top of first hand. Interlock the fingers. Continue to push down hard.	
	Place one hand on center of chest. Keep arms straight. Continue to push down hard.	
	Keep arms straight.Continue to push down hard.	
	Interlock the fingers. Continue to push down hard.	
	100 compressions remaining.	
	50 compressions remaining.	
	20 compressions remaining.	
Perform CPR	Push down hard.	Prompts to use more effort for compressions.
	Continue to push down hard.	
	Stop CPR.	Prompts to stop CPR.
	Continue with compressions.	Prompts to continue CPR.
	Give two rescue breaths.	Prompts to give breath to the patient.
	One	
	Two	
	Follow the metronome to give 200 compressions approximately.	Prompts the CPR metronome pacing the speed of compressions.
	Follow the metronome to give 30 compressions and 2 rescue breaths.	Prompts to prepare to provide compressions and breaths CPR.
	Follow the metronome to give 15 compressions and 2 rescue breaths.	
Use a CPR sensor for CPR	Incomplete recoil	Prompts to use more effort and release all pressure when moving hands up.
	Compress faster	Prompts to adjust the compression rate.
	Compress slower	
	Compress deeper	Prompts to adjust the compression rate.
	Compress shallower	

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F Abbreviations

Abbreviation	Full Name
ºC	centigrade
ºF	fahrenheit
Ω	ohm
AED	Automated external defibrillator
AHA	American Heart Association
bpm	beat per minute
CE	Conformité Européenne
CISPR	International Special Committee on Radio Interference
CPR	Cardiopulmonary resuscitation
dB	decibel
ECG	electrocardiograph
EMC	electromagnetic compatibility
GHz	gigahertz
h	hour
HR	heart rate
Hz	hertz
ID	identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IP	internet protocol
J	Joule
kg	kilogram
kPa	kilopascal
LCD	liquid crystal display
LED	light emitting diode
m	meter
mAh	Milliampere hour
min	minute
mm	millimeter
mmHg	millimeters of mercury
ms	millisecond
mV	millivolt

Abbreviation	Full Name
MRI	magnetic resonance imaging
s	second
V	volt

G Inspection Record

Daily Checklist			Current Date (Month/Year):_____/_____		
Inspection Date	**Status indicator flashes**	**Inspected by**	**Inspection Date**	**Status indicator flashes**	**Inspected by**
1.	in green ☐ in red ☐		17.	in green ☐ in red ☐	
2.	in green ☐ in red ☐		18.	in green ☐ in red ☐	
3.	in green ☐ in red ☐		19.	in green ☐ in red ☐	
4.	in green ☐ in red ☐		20.	in green ☐ in red ☐	
5.	in green ☐ in red ☐		21.	in green ☐ in red ☐	
6.	in green ☐ in red ☐		22.	in green ☐ in red ☐	
7.	in green ☐ in red ☐		23.	in green ☐ in red ☐	
8.	in green ☐ in red ☐		24.	in green ☐ in red ☐	
9.	in green ☐ in red ☐		25.	in green ☐ in red ☐	
10.	in green ☐ in red ☐		26.	in green ☐ in red ☐	
11.	in green ☐ in red ☐		27.	in green ☐ in red ☐	
12.	in green ☐ in red ☐		28.	in green ☐ in red ☐	
13.	in green ☐ in red ☐		29.	in green ☐ in red ☐	
14.	in green ☐ in red ☐		30.	in green ☐ in red ☐	
15.	in green ☐ in red ☐		31.	in green ☐ in red ☐	
16.	in green ☐ in red ☐		**Remarks:** • Place a "√" in the corresponding box. • For details about the status indicator in normal condition, see *8.3.2 Auto Test*.		
Monthly Checklist					
Expiration date of electrode pads:					

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H Declaration of Conformity

Declaration of Conformity V1.0

CE

Declaration of Conformity

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-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
Model:	BeneHeart C1/BeneHeart C1A/BeneHeart C2/BeneHeart C2A/BeneHeart S1/BeneHeart S1A/BeneHeart S2/BeneHeart S2A/BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic

We herewith declare 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:

☒ **IEC 60601-1:2005+A1:2012+A2:2020**	☒ **IEC 60601-1-2:2014**
☒ **EN IEC 62311:2020**	☒ **ETSI EN 301 489-1 V2.2.3**
☒ **ENSI EN 301 489-3 V2.1.1**	☒ **ENSI EN 301 489-17 V3.2.4**
☒ **ETSI EN 301 489-52 V1.2.1**	☒ **ETSI EN 301 893 V2.1.1**
☒ **ETSI EN 301 908-1 V15.1.1**	☒ **ETSI EN 301 908-13 V13.2.1**
☒ **ETSI EN 300 328 V2.2.2**	☒ **ETSI EN 300 440 V2.2.1**

Place, Date of Issue: Shenzhen, 2024.6.1X

Signature:

Name of Authorized Signatory: Wang Xinbing

Position Held in Company: Deputy director, Technical Regulation

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