BeneHeart C & BeneHeart S Series

Automated External Defibrillator

Instructions for Use

(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/BeneHeartS2A/
BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/
BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic)

CE 2797

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- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

WARNING

- **This equipment must be operated by 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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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.

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.

Contents

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.**

2 Equipment Introduction

2.1 Intended Use

2.1.1 Intended Purpose Statement

The equipment is intended for semi-automated external defibrillation and automated external defibrillation.

2.1.2 Indication for Use

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

2.1.3 Intended Users

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

2.1.4 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

2.1.5 Intended Medical Conditions

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

2.1.6 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

2.1.7 Side-effects

Side-effects

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

After search the literature of similar device, the results of SOTA evaluation shown that undesirable effects may include myocardial damage.

2.2 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.**

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

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.**

3.3 Turning off the Equipment

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.**

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4 Using the Equipment

4.1 Operating 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.**
- **In emergency, if there are no spare pads nearby, continue patient treatment with the expired electrode pads and ignore pads related prompts.**
- **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 "Shock canceled. Press pads firmly to patient's bare skin" voice prompt 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 Performing CPR

WARNING

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

4.3 CPR Assistance

WARNING

- **Perform CPR on a patient on firm ground if possible. When you perform CPR on a patient lying on a mattress, a backboard must be used to limit the amount of compressed depth which is absorbed by the mattress. Depending on characteristics of the mattress, backboard and patient, the compensation depth does not guarantee that the patient chest is compressed by 50 mm.**
- **When the patient is breathing with high frequency or in the treatment of high-frequency ventilation, the CPR assistance disturbed by the thoracic movements may provide inaccurate feedback. You should count compressions by yourself and not rely on the compression rate provided by the CPR assistance in such conditions.**
- **The CPR assistance is not intended for use in a moving environment, such as an ambulance. If used during patient transport, the CPR assistance may provide inaccurate feedback. If CPR is indicated in a moving environment, do not rely on feedback provided by the CPR assistance in such conditions.**
- **The CPR metronome sounds do not indicate information regarding the patient's condition. Because patient status can change in a short time, the patient should be assessed at all times. Do not perform CPR on a patient who is responsive or is breathing normally.**

NOTE

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

5 Data Management

5.1 Data Management Overview

NOTE

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

5.2 Generating a Patient File

NOTE

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

5.3 Managing Configurations

CAUTION

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

5.4 AED ALERT System V2.0 Overview

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.**

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6 Battery

6.1 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.**

6.2 Replacing the Battery

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.**

6.3 Storing Batteries

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.**

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7 Care and Cleaning

7.1 General Points

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.**

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8 Maintenance and Testing

8.1 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.**

8.2 Performing Maintenance

CAUTION

- **Frequently turning on or off the equipment during the user test will reduce the battery standby life.**
- **With the equipment powered off, auto test can be performed only when the battery is installed.**

NOTE

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

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

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.**

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A Specifications

A.1 Safety Specifications

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.2 Environmental Specifications

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 21.102, ISO9919: Peak acceleration: 1000m/s^2 (102g) Duration: 6ms Pulse shape: half-sine Number of shocks: 3 shocks per direction per axis (18 total)
Vibration
Complies with requirements of 21.102, ISO9919.
Bump
Complies with the requirements of 6.3.4.2, EN1789. Peak acceleration: 15g Duration: 6ms Number of impacts: 1000 Impact direction: vertical impacts are applied when the equipment under test is placed at normal operating position.

Drop
1.5 m per IEC 68-2-32, 1 on each of the six surfaces.

CAUTION

- **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.**

A.3 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 ± 0.3 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 ± 0.3 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.4 Display Specifications (for Equipment Configured with the Screen)

Type	TFT Color LCD
Brightness	Auto, Outdoor Mode, Indoor mode. In the auto mode, the equipment automatically adjusts the screen brightness according to the ambient light.
Size	7 inch
Resolution	800×480 pixels
Viewed waveforms	1
Wave viewing time	Max. ≥ 6s (ECG)

A.5 Audio Indicators

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

A.6 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.7 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 without the 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>
<tr><td rowspan="7">Equipment configured with the screen</td><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 (for equipment configured with the screen)</td><td colspan="2">Battery symbol on the display indicating the current battery level</td></tr>
</table>

<table>
<tr><td>Remaining charge after “Low Battery” is prompted</td><td>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></td><td>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.8 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.9 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
Cellular	
Operating frequency	LTE-FDD B1: 1920 MHz to 1980 MHz, 2110 MHz to 2170 MHz LTE-FDD B3: 1710 MHz to 1785 MHz, 1805 MHz to 1880 MHz LTE-FDD B7: 2500 MHz to 2570 MHz, 2620 MHz to 2690 MHz LTE-FDD B8: 880 MHz to 915 MHz, 925 MHz to 960 MHz LTE-FDD B20: 832 MHz to 862 MHz, 791 MHz to 821 MHz LTE-FDD B28A:703 MHz to 733 MHz, 758 MHz to 788 MHz LTE-TDD B38: 2570 MHz to 2620 MHz LTE-TDD B40: 2300 MHz to 2400 MHz
Standard/Modulation mode	3GPP E-UTRA Release 11: LTE-FDD/LTE-TDD

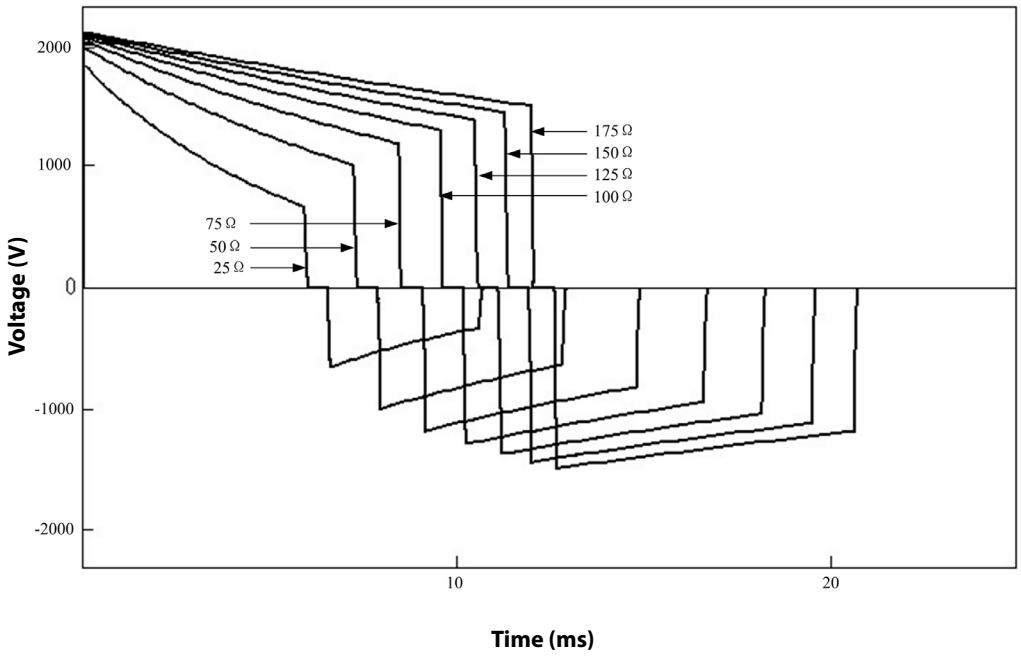
A.10 Defibrillator Specifications

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, 150 J, 170 J, 200 J, 300 J, 360 J. For children: 10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J.
Patient impedance range	25 to 300 Ω
Shock series	Energy level: 100 to 360J, configurable for adults. 10 to 100J, configurable for children. Shocks: 1, 2, 3, configurable; Meeting AHA/ECR guidelines 2015 by default.
ECG Analysis Performance	See *B Mindray Shockable Rhythm Analysis Algorithm*.

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 non-shockable) is less than 25s.**

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



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	
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	
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.11 CPR Compression Specifications

CPR Compressions from Electrodes

Compression rate	Measurement range: 60 to 200 cpm (compressions per minute) Accuracy: ±3 cpm (compression per minute)

CPR Compressions from CPR Sensor

Compression rate	Measurement range: 40 to 160 cpm (compressions per minute) Accuracy: ±2 cpm (compression per minute)

A.12 ECG Specifications (for Equipment Configured with the 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.13 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.14 Operating Environment

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

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B EMC and Radio Regulatory Compliance

B.1 EMC

The equipment meets the requirements of IEC 60601-1-2: 2014.

WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
- **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**
- **Other devices may affect this equipment even though they meet the requirements of CISPR.**
- **When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**

NOTE

- **The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Portable and mobile RF communications equipment may affect this equipment.**
- **This equipment is intended for use in professional healthcare facility environment, or in home healthcare environment such as restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres. If it is used in special environment, such as magnetic resonance imaging environment, the equipment may be disrupted by the operation of nearby equipment.**

Guidance and Declaration - Electromagnetic Emissions		
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration - Electromagnetic Immunity**, the equipment will remain safe and provide the following essential performance: energy accuracy, CPR function, data stored.

Guidance and Declaration - Electromagnetic Immunity			
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Declaration - Electromagnetic Immunity			
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conduced RF IEC 61000-4-6	3 Vrms 150k to 80 MHz	3 Vrms (V1)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ 150k to 80 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM bands and amateur radio bands[a] between 0.15 MHz and 80 MHz	6 Vrms (V2)	
Radiated RF EM fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3 V/m (E1)	
	10V/m 80 MHz to 2.7 GHz (IEC60601-2-4)	10 V/m	
	20V/m 80 MHz to 2.7 GHz (IEC60601-2-4)	20 V/m	
Proximity fields from RF wireless communication s equipment IEC61000-4-3	27 V/m 380 to 390 MHz	27 V/m	
	28 V/m 430 to 470 MHz, 800 to 960 MHz, 1700 to 1990 MHz, 2400 to 2570 MHz	28 V/m	
	9 V/m 704 to 787 MHz, 5100 to 5800 MHz	9 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
[b] Compliance level in the ISM frequency bands between 150 kHz to 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that portable/ mobile communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
[d] Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment

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

Rated Maximum Output power of Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

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

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

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

B.2 Radio Regulatory Compliance

Wi-Fi

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
Modulation mode	DSSS and OFDM
Output Power	≤20 dBm

Cellular

Operating frequency	LTE-FDD B1: 1920 MHz to 1980 MHz, 2110 MHz to 2170 MHz LTE-FDD B3: 1710 MHz to 1785 MHz, 1805 MHz to 1880 MHz LTE-FDD B7: 2500 MHz to 2570 MHz, 2620 MHz to 2690 MHz LTE-FDD B8: 880 MHz to 915 MHz, 925 MHz to 960 MHz LTE-FDD B20: 832 MHz to 862 MHz, 791 MHz to 821 MHz LTE-FDD B28A:703 MHz to 733 MHz, 758 MHz to 788 MHz LTE-TDD B38: 2570 MHz to 2620 MHz LTE-TDD B40: 2300 MHz to 2400 MHz
Standard/Modulation mode	3GPP E-UTRA Release 11: LTE-FDD/LTE-TDD
Output Power	≤25 dBm

CE

The device comply with the essential requirements and other relevant provisions of Directive 2014/53/EU.

WARNING

- **Keep a distance of at least 20 cm away from the equipment when the wireless function is in use.**

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