BeneHeart R12/BeneHeart R12A

Electrocardiograph

Operator's Manual

CE 0123

For this Operator's Manual, the issue date is 2020-03.

⚠ WARNING

- **Federal Law (USA) restricts this device to sale by or on the order of a physician.**

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WARNING

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

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- Others not caused by instrument or part itself.

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Preface

Manual Purpose

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

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

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

Intended Audience

This manual is geared for clinical professionals who are expected to have corresponding working knowledge of medical procedures, practices and terminology as required for the treatment of patients.

Illustrations

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

Conventions

- ***Italic text*** is used 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

⚠ WARNING

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

⚠ CAUTION

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

NOTE

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

1.1.1 Warnings

⚠ WARNINGS

- **This equipment is used for a single patient at a time.**
- **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.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on battery power, if possible.**
- **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.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
- **Do not touch the patient when connecting peripheral equipment via the I/O signal ports to prevent patient leakage current exceeds the requirements of applicable standards.**
- **This equipment is not intended for use with high frequency surgical units.**
- **Do not contact the patient during defibrillation. Otherwise serious injury or death could result.**
- **For paced patients, the equipment may mistake a pace pulse for a QRS complex if several adverse conditions exist simultaneously. Always keep these patients under close surveillance.**
- **The physiological data and waveforms displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.**
- **To avoid electric shock or equipment malfunction liquids is not allowed to enter the equipment. If liquids have entered the equipment, remove the equipment from use and have it checked by service personnel before it is used again.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce the risk of entanglement or strangulation by patients or clinical personnel.**
- **Properly dispose of the package material according to applicable waste control regulations and keeping it out of children's reach.**

1.1.2 Cautions

⚠ CAUTIONS

- **Use only parts and accessories specified in this manual.**
- **This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.**
- **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. If you have any questions concerning disposal of the equipment, please contact us.**
- **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 phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**

1.1.3 Notes

NOTES

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

1.2 Equipment Symbols

	Equipotentiality		Analog out
	Network connector		USB connector
	Telephone line connector		ON/OFF for part of equipment
	Battery indicator		Alternating current (AC)
	General warning sign		Refer to instruction manual/ booklet
	DEFIBRILLATION-PROOF TYPE CF APPLIED PART		Serial number
	Manufacturer		DATE OF MANUAFACTURE
	Non-ionizing electromagnetic radiation		Authorized representative in the European Community
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. Note: The product complies with the Council Directive 2011/65/EU.		
	Dispose of in accordance to your country's requirements		

NOTE

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

2 Equipment Overview

2.1 Intended Use

BeneHeart R12/BeneHeart R12A electrocardiographs (hereafter referred to as "the equipment" or "the system") are intended to acquire, analyze, display, store, and record electrocardiographic information for adult and children of any age from birth upwards for clinical diagnosis and study.

The equipment is intended to be used by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.

2.2 Applied Parts

The applied parts of the equipment are:

- ECG electrodes
- Patient cable

2.3 Major Functions

The equipment can be used to:

- Acquire, analyze, display, and record 12-lead ECG information.
- Provide ECG algorithm to automatically analyze the acquired ECG waveforms; output measurements and diagnosis.
- Support auto measurement, manual measurement, and rhythm measurement.
- Print ECG reports through either an internal thermal recorder or an external printer.
- Store, preview, and review ECG reports.
- Connect LAN or Wi-Fi to send ECG data.
- Support entering patient information through the keyboard or a barcode reader.
- Present messages in case of lead off, interference, low battery, or other abnormity.

2.4 Main Unit

2.4.1 Front and Side View

1. Thermal recorder: prints reports.
2. Hard keys: see ***Hard Keys and Indicators*** below.
3. Indicators: see ***Hard Keys and Indicators*** below.
4. Display screen: presents waveforms and text.
5. Soft keys: for the equipment configured with a touchscreen. Press the soft keys to select the options.

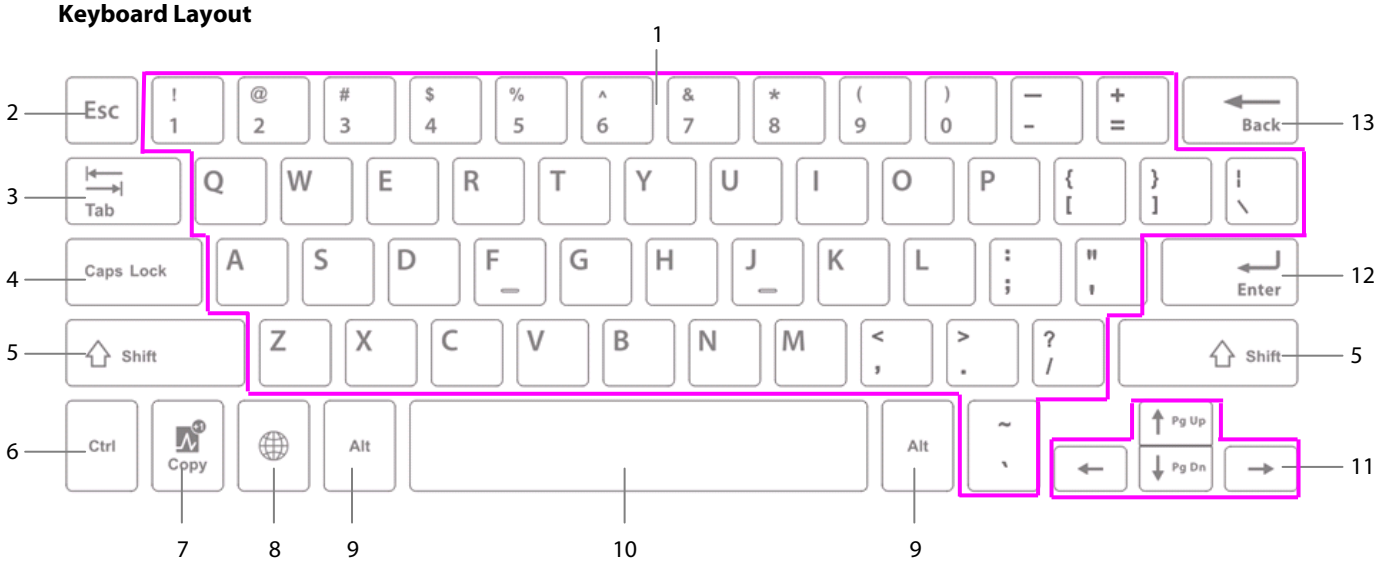
   Soft key labels: for the equipment not configured with a touchscreen.

   See ***Soft Keys*** below.
6. Soft keys: only for equipment not configured with a touchscreen. The soft keys illuminate when the equipment is powered on. Press the soft keys to select the options that appear on the right side of the screen. For the equipment configured with a touchscreen, there are no keys in this area.
7. USB connector: connects USB devices, such as a USB drive, external printer, or barcode reader.
8. Patient cable connector: connects the patient cable for ECG acquisition.
9. Keyboard: see ***Keyboard Layout*** below.

Hard Keys and Indicators

Key	Function
Power switch 	Turns on the equipment when the equipment is powered off. Turns off the equipment by pressing and holding this key for 0.5 second when the equipment is powered on. Forcefully shuts down the equipment by pressing and holding this key for 10 seconds when it cannot be shut down normally.
Setup key 	Accesses the main menu. Exits a menu and returns to the normal screen when the menu is open.
Leads key 	Switches the format and leads to be displayed. Switches leads to be printed during a manual measurement.
ID key 	Enters the [**Patient Info**] menu.
ECG key 	Starts an auto measurement. Stops the ongoing auto measurement when the preview option is disabled.
Indicator	**Description**
Power indicator 	On: when the equipment is powered on. Off: when the equipment is powered off.
Battery indicator 	Green: when the equipment operates on battery power or the battery is being charged. Yellow: when the equipment operates on battery power and the battery is low. Yellow and blink: when the equipment operates on battery power and the battery is depleted. Off: when no battery is installed or the battery is fully charged.
AC indicator 	On: when the AC mains is connected. Off: when the AC mains is not connected.

Keyboard Layout



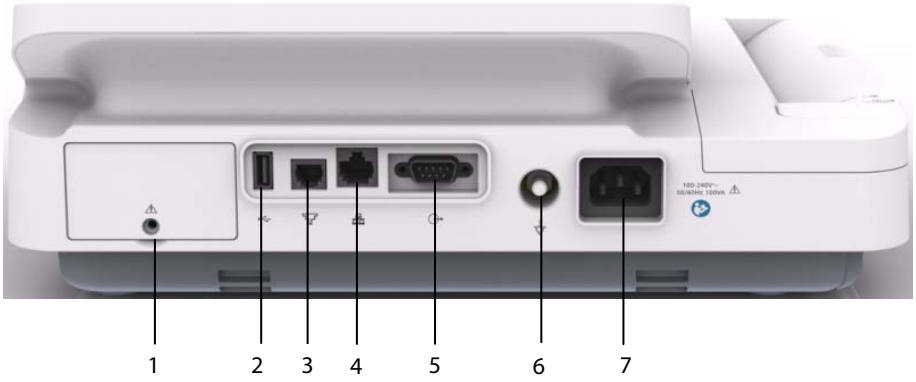
No.	Key	Description
1	Alphanumeric keys	Enters corresponding letters, digits, and symbols.
2	**Esc** key	Returns to the previous screen.
3	**Tab** key	Moves the cursor to the next item.
4	**Caps Lock** key	Locks the capital letters and upper case symbols.
5	**Shift** key	Uses in conjunction with alphanumeric keys to enter the upper case characters. For example, press **Shift** + **a** to enter a capital **A**, and press **Shift** + **=** to enter the symbol **+**.
6	**Ctrl** key	Not currently used.
7	Copy key	Prints the latest auto or rhythm report.
8	key	Switches input method.
9	**Alt** key	Not currently used.
10	Space bar	Enters a space.
11	Arrow keys	Moves the cursor left, right, up, or down.
12	**Enter** key	Confirms the selection.
13	**Back** key	Deletes the character in front of the cursor.

Soft Keys

Key	Function
	Adjusts the current waveform speed.
	Adjusts the current waveform size.
	Adjusts the current frequency of the muscle artifact filter.
	Enters the Directory List.
	Starts a manual measurement.
	Starts a rhythm measurement.
	Switches the rhythm leads.
	Returns to the previous menu.
	Moves to the previous menu item.
	Moves to the next menu item.
	Selects the highlighted menu item.
	Cancels the highlighted selection.
	Confirms the selection.
	Returns to the normal screen.
	Sends the selected files to an external device.
	Sends the selected files through the network.
	Sent the selected files to a USB drive.
	Reviews the highlighted report.
	Reviews the next page of the current report.
	Reviews the next report.

Key	Function
	Deletes the selected files.
	Starts printing.
	Stops printing.
	Searches for patients.
	Edits patient information.
	Saves patient information to the internal memory.
	Places a 1 mV square wave on the manual report.

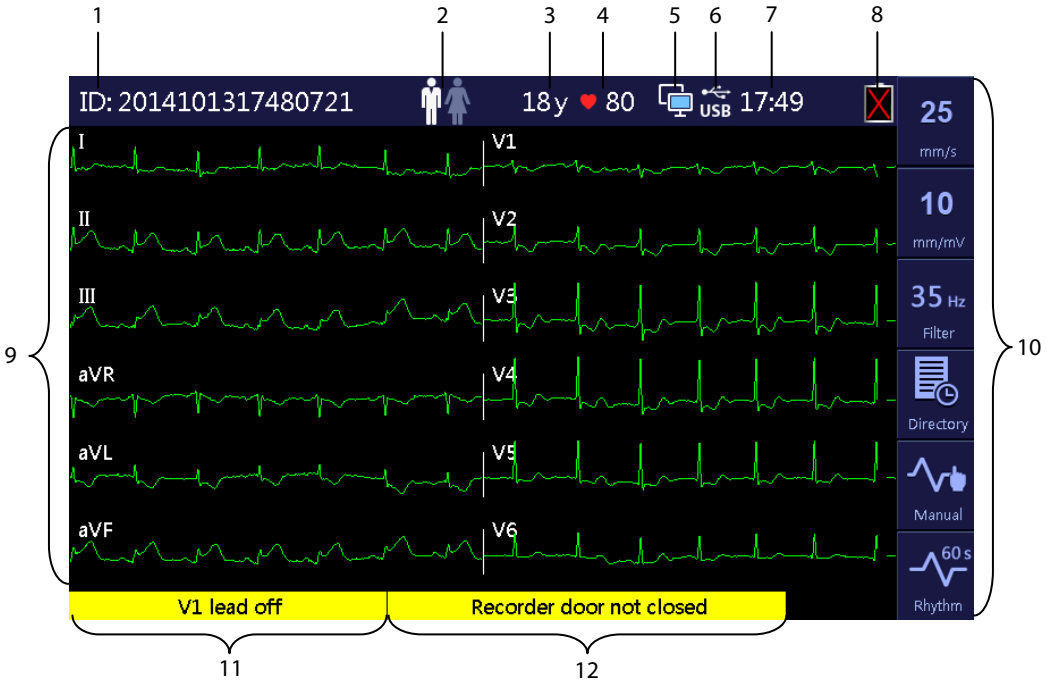
2.4.2 Back View



1. Battery compartment
2. USB connector: connects USB devices, such as a USB drive, external printer, or barcode reader.
3. Telephone line connector: for future external devices. Do not use.
4. Network connector: a standard RJ45 connector for software upgrade and sending ECG data.
5. Analog output connector: for future external devices. Do not use.
6. Equipotential Grounding Terminal: when using the monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential differences between them.
7. AC power input: connects the power cord to run the equipment on AC power supply.

2.5 Screen Layout

Normal Screen



1. Patient ID: displays the ID of the patient

   You can input up to 20 digits. If not inputted, the ID information is left blank.

2. Gender icon: indicates the gender of the patient

   If set to [**Male**],  is displayed. If set to [**Female**],  is displayed. If not set,  is displayed.

3. Age: displays the age of the patient

   The unit can be set to [**Years**], [**Months**], or [**Days**]. The input range is 0 to 199 for [**Years**], 0 to 2400 for [**Months**], and 1 to 73050 for [**Days**], If not set, the age area is left blank.

4. Heart rate: displays the heart rate and heartbeat symbol 

5. Network status icon: indicates the current status of network connection

   -  indicates that the equipment is connected to a wire network successfully.
   -  indicates that the equipment is disconnected from a wire network.
   -  indicates that the equipment is connected to a wireless network successfully.
   -  indicates that the equipment has failed to connect a wireless network.
   -  indicates that the equipment is connected to the CardioVista ECG viewer with a network cable.
   -  indicates that the equipment is connected to the CardioVista ECG viewer via a wireless network.

6. USB device connecting status icon: indicates the connection status of an external USB device

   If successfully connected,  is displayed. If not, this area is left blank.

7. System time: displays the set system time in 12 hour format or 24 hour format
8. Battery status icon: indicates the battery status. For details, refer to chapter ***10 Battery***.

   -  Indicates that the battery works properly. The solid green portion represents the current battery charge level. Each block represents a charge of approximately 20% capacity.
   -  Indicates that the battery has low charge level and needs to be charged. In this case, the LED turns yellow and the message "**Low Battery**" shows at the bottom of the screen.
   -  Indicates that the battery is almost depleted and needs to be charged immediately.
   -  Indicates that no battery is installed or charging battery fails.

9. Waveform area: displays ECG waveforms.
10. Soft key area: shows the soft keys. For the equipment not configured with a touchscreen, this area shows the labels of the soft keys located rightward.
11. Message area 1: displays lead off and noise related messages.
12. Message area 2: displays other messages.

Main Menu

1. Heading: shows the menu heading and system information including network and USB device connecting status, system time, battery status; etc.
2. Options of the main menu
3. Options of the highlighted submenu

4. Soft keys: for the equipment configured with a touchscreen.

   Soft key labels: for the equipment not configured with a touchscreen.

2.6 Operating Mode

2.6.1 Normal Mode

The equipment enters the Normal mode after being turned on.

In the Normal mode, you can acquire the patient's electrocardiographic information, record ECG waveforms, measurements, and diagnoses. You can also configure the equipment and export data.

2.6.2 Standby Mode

When any of the limb leads is detached, the equipment automatically enters the Standby mode if the equipment is inactive for a predefined time limit. The Standby mode helps reducing power consumption and increases the life of LCD.

To set the time to automatically enter the Standby mode,

1. Press the **Setup** key to enter the main menu.
2. Select [**Basic Setup**] → [**Auto Standby**].
3. Set the time to automatically enter the Standby mode.

In the Standby mode, the screen is off.
To exit the Standby mode, press any key or touch the touchscreen, if configured. The equipment automatically exits the Standby mode if:

- ECG signal is received.
- Information from the barcode reader is received.

2.6.3 Demo Mode

In the Demo mode, the equipment can demonstrate its major functions when a patient or patient simulator is not connected. The Demo mode is password protected.

To enter the Demo mode,

1. Press the **Setup** key to enter the main menu.
2. Select [**Maintenance**], and then select [**Demo Mode 1**] or [**Demo Mode 2**].
3. Enter the password.

To exit the Demo mode, turn off the equipment and restart it.

⚠ WARNING

- **The Demo mode is for demonstration purpose only. To avoid the potential risk of the simulated data being mistaken for the patient data, do not enter the Demo mode during ECG acquisition.**

2.6.4 Maintenance Mode

In the Maintenance mode, you can change network and configuration related settings. You can also change UI language.

Accessing the [**Maintenance**] menu is password protected.

⚠ CAUTIONS

- **The maintenance settings can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.**

3 Setting up the Equipment

3.1 Installation

⚠ WARNING

- **The equipment shall be installed by personnel authorized by us.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
- **The software copyright of the equipment is solely owned by us. 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 us.**
- **If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.**

3.1.1 Unpacking and Checking

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

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. Contact us in case of any problem.

⚠ WARNING

- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**

NOTE

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

3.1.2 Environmental Requirements

The equipment is suitable for use in the patient environment.
The operating environment of the equipment must meet the requirements specified in this manual.

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

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

⚠ WARNING

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **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.**
- **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 phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **The mains plug is used to isolate the equipment circuits electrically from the SUPPLY MAINS. Do not position the equipment so that it is difficult to operate the plug.**
- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**

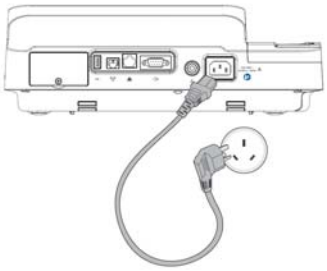
NOTES

- **Put the equipment in a location where you can easily see the screen and access the operating controls.**
- **Keep this manual in the vicinity of the equipment so that it can be conveniently referenced when needed.**

3.2 Setting up the Equipment

Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

3.2.1 Connecting the AC Mains



You can run this equipment either on AC power supply or battery power.

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

To use the AC power source,

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

⚠WARNING

- **Use only the supplied power cord.**
- **Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the equipment shall be operated from the battery. Otherwise the patient or operator might be shocked.**

3.2.2 Using the Battery

You can run this equipment on a rechargeable lithium battery. When a battery is installed, the equipment will automatically run power from the battery in case of AC power failure.

Installing the Battery

The battery must only be installed by service personnel trained and authorized by our company. No battery is installed when the equipment leaves the factory. Contact your service personnel to install the battery before putting the equipment into use.

To prevent data loss in case of sudden power failure, we recommend you always install a fully charged battery in the equipment.

Charging the Battery

The battery is charged whenever the equipment is connected to an AC power source regardless of whether or not the equipment is currently turned on.

When the battery is being charged, the battery indicator is illuminated in green. The on-screen battery symbol dynamically shows the charging status if the equipment is powered on.

NOTE

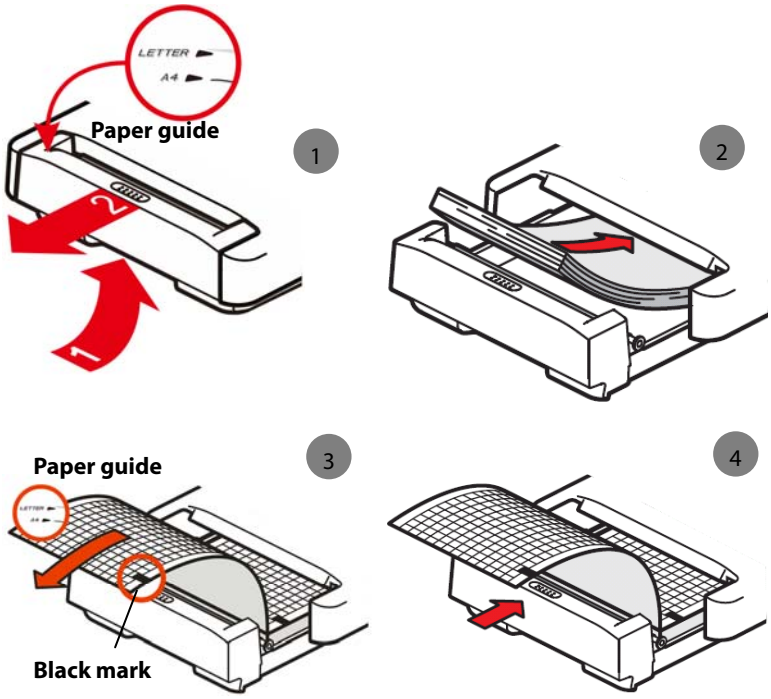
- **Charge the battery before it is first put into use.**

3.2.3 Loading the Paper

You can print reports either through the thermal recorder or through an external printer. Before printing reports, ensure that the paper is loaded.

The thermal recorder supports Z-fold paper. To load the paper:

1. Lift the level at the bottom of the paper tray and pull out the paper tray until it stops.
2. Place a stack of paper in the tray.
3. Lift the first sheet of paper, flip it over the roller holder, and align the upper edge of the paper with the paper guide. Make sure that the print side (grid side) faces up and the black mark on the lower left corner of the paper is visible
4. Firmly push the paper tray until it snaps back into place.



The equipment can print either on A4 (295 mm × 210 mm) or US Letter (8.5" × 11") paper. The paper tray is configured to meet the appropriate paper size for the destination location when the equipment leaves the factory.

To change the paper size, move the white plastic spacer bar in the paper tray to limit the paper tray.

- For A4 sized paper, insert the spacer in the slot at the top of the paper tray.
- For US Letter sized paper, insert the spacer in the slot at the bottom of the paper tray.

NOTE

- **Use only thermal recording paper we supply.**

3.2.4 Connecting the Patient Cable

1. Plug the patient cable to the connector on the right side of the equipment. Ensure the connector on the cable is arrow-side up.
2. Tight the screws to securely attach the patient cable to the equipment.

3.2.5 Connecting the Barcode Reader

If your equipment is configured with a barcode reader, connect it to the equipment's USB connector. You can enter patient information through the barcode reader.

NOTE

- **Restore the barcode reader to factory default configuration before using it.**

3.2.6 Checking the Equipment before Power On

Before powering on the equipment, check the following:

- Operating environment

  Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.

  Keep the examination room warm (no less than 18 °C) to avoid muscle action voltages in ECG signal caused by cold.

- Power supply

  Check that power supply specification is met and the power cord is securely connected if the mains power is used. Use only power socket that is properly grounded.

  Check that a battery is installed and fully charged if you want to run the equipment on battery power.

- Patient cable

  Check that the patient cable is firmly connected to the equipment.

- Recording paper

  Check that recording paper is correctly loaded.

⚠ WARNING

- **This equipment is not intended for use with high frequency surgical units.**

3.2.7 Turning On the Equipment

Once the equipment has been installed and checked, you can get ready for measurement and recording:

1. Connect the equipment with AC mains. If you run the equipment on battery power, ensure that the battery is sufficiently charged.
2. Press the **Power** switch.

⚠ WARNING

- **Do not use the equipment on a patient if you suspect that it is not working properly, or if it is mechanically damaged. Contact your service personnel or us.**

3.2.8 Configuring the Equipment

Configure your equipment before the first use:

1. Press the **Setup** key to access the main menu.
2. Select [**Basic Setup**].
3. Respectively set [**Date**], [**Time**], and [**Brightness**].

You can also set other items as needed. Refer to ***4 System Setup*** for details.

3.2.9 Turning off the Equipment

Before turning off the equipment:

1. Confirm that patient measurement and recording are finished.
2. Disconnect the electrodes from the patient.

Then press and hold the **Power** switch for approximately 0.5 second to turn off the equipment.

⚠ CAUTION

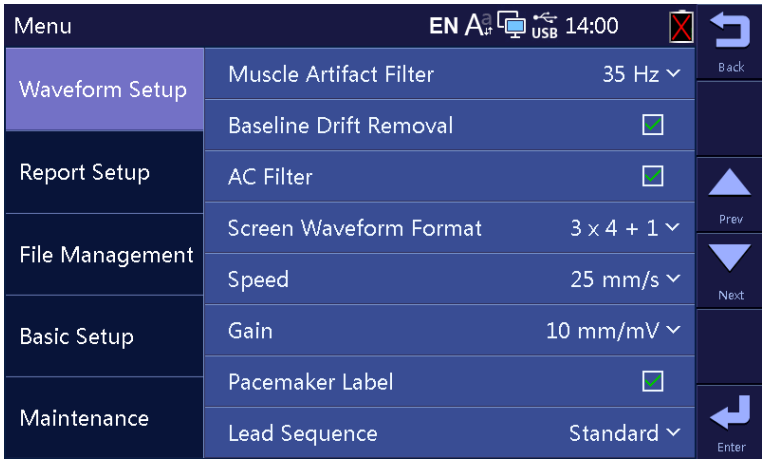
- **Although not recommended, you can press and hold the Power switch for 10 seconds to forcibly shut down the equipment when it could not be shut down normally or under some special situations. This may cause loss of data.**

4 System Setup

4.1 Accessing the Main Menu

Press the **Setup** key to access the main menu. To configure the equipment:

- Press the arrow keys on the keyboard to select a menu option.
- Press the [**Prev**] or the [**Next**] soft key to move to the previous or the next menu item.
- Press the [**Back**] soft key or the [**Esc**] key on the keyboard to return to the previous menu.
- Press the [**Select**] or the [**Cancel**] soft key to select or deselect a menu item.
- Press the [**Enter**] soft key or the **Enter** key on the keyboard to confirm the selection.



The settings in the main menu are saved as user defaults and remain effective even after the equipment is turned off and restarted.

4.2 Waveform Setup

Menu item	Option	Default	Description
Muscle Artifact Filter	20 Hz , 35 Hz, Off	35 Hz	Sets the default frequency of muscle artifact filter. Muscle artifact filter attenuates noise in the waveform by restricting the frequencies that are included. The muscle artifact filter is a low-pass filter. That is to say signals that exceed the set frequency are filtered out. [**35 Hz**]: only signals at 35 Hz or less display. Signals exceeds 35 Hz are attenuated. [**20 Hz**]: only signals at 20 Hz or less display. Signals exceeds 20 Hz are attenuated. [**Off**]: signals at 150 Hz or less display.

Menu item	Option	Default	Description
Baseline Drift Removal	Selected, not selected	Selected	Select whether the baseline drift removal (BDR) process or 0.05-Hz filter is used. If selected, BDR is enabled. This process suppresses most baseline drift interference and also is able to preserve the fidelity of the ST-segment level. If not selected, BDR is disabled and the 0.05-Hz filter is used. **NOTE:** BDR or 0.05-Hz selection applies to the displayed ECG, printed report, and analyzed and stored data. BDR introduces around 1-second delay. We recommend use of BDR except when the delay is unacceptable. Both BDR and 0.05-Hz selections meet requirements of the 1990 American Heart Association Recommendations for Standardization and Specifications in Automated Electrocardiography: Bandwidth and Signal Processing pertaining to lower-frequency response in electrocardiography.
AC Filter	Selected, not selected	Selected	Selects whether electrical interference is filtered from AC line voltage. If selected, the AC filter is enabled to filter electrical interference from AC line voltage. **Note:** The AC filter should be on. Turn off only if necessary.
Screen Waveform Format	3×1, 6×1, 3×4+1, 3×4+3, 6×2, 6×2+1, 12×1	3×4+1	Selects the default format of ECG waveforms displayed on the screen. [**3×1**]: displays 12-lead ECG waveforms in four pages, with 3 waveforms in one column in each page. [**6×1**]: displays 12-lead ECG waveforms in two pages, with 6 waveforms in one column in each page. [**12×1**]: displays 12-lead ECG waveforms in one page in one column. [**6×2**]: displays 12-lead ECG waveforms in one page in two columns, with 6 lines in each column. [**3×4+1**]: displays 12-lead ECG waveforms in one page in 4 columns, with 3 lines in each column, and one rhythm lead waveform at the bottom. So it is with [**3×4+3**] and [**6×2+1**].
Speed	5 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	25 mm/s	Selects the default printing speed.
Gain	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, Auto, L＝10 C＝5, L=20 C=10	10 mm/mV	Select the default amplitude of 1mV ECG signal. The larger the setting is, the larger the waveform size. However, only the appearance of the waveform changes. The signal strength is not affected. [**L=10 C=5**]: displays the limb lead waveforms at an amplitude of 10 mm/mV; displays chest lead waveforms at an amplitude of 5 mm/mV. [**L=20 C=10**]: displays the limb lead waveforms at an amplitude of 20 mm/mV, displays chest lead waveforms at an amplitude of 10 mm/mV. [**Auto**]: automatically selects the gain as per the amplitude of ECG waveforms.

Menu item	Option	Default	Description
Pacemaker Label	Selected, not selected	Selected	Selects whether a mark is placed on each ECG waveform when a pace pulse is detected. If selected, a pace pulse mark "|" is placed on each ECG waveform when a pace pulse is detected. If not selected, no mark is placed when a pace pulse is detected.
Lead Sequence	Standard, Cabrera	Standard	Select ECG lead sequence for displaying and printing. [**Standard**]: the sequence is I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. [**Cabrera**]: the sequence is aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6.

4.3 Report Setup

Menu item	Option	Default	Description
Rhythm Format	One lead, Three Leads	One lead	Selects how many rhythm leads are recorded during rhythm measurement.
Standard Report Format	3×4+1, 3×4+3, 6×2, 6×2+1, 12×1	3×4+1	Selects the format of standard ECG report generated by auto measurement. [**3×4+1**]: displays 12-lead ECG waveforms in 3 lines and 4 columns followed by the first rhythm lead waveform. So it is with other formats.
Rhythm Lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	II	Selects the first rhythm lead to be recorded during auto measurement and rhythm measurement.
Rhythm Lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	V2	Selects the second rhythm lead to be recorded during auto measurement and rhythm measurement.
Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	V5	Selects the third rhythm lead to be recorded during auto measurement and rhythm measurement.
Paperless Recording	Selected, not selected	Not selected	Selects whether ECG report is printed during auto measurement. If selected, ECG report is not printed. If not selected, ECG report is automatically printed at the completion of ECG acquisition and analysis.
Reanalysis	Selected, not selected	Selected	Selects whether the ECG data is reanalyzed when the patient's age, date of birth, gender, race, medication, type or V3 placement is changed. Modifying patient information may change diagnostic statements produced by the algorithm. Consider to enable reanalyzing process.
Pre-acquisition	Selected, not selected	Selected	During auto measurement, selects whether the ECG data acquired before pressing the **ECG** key is recorded. If selected, the equipment records 10 seconds of ECG data acquired before the **ECG** key is pressed. If less than 10 seconds of data is acquired, the message "**ECG Data Insufficient**" displays at the bottom of the screen. If not selected, the equipment records 10 seconds of ECG data acquired after the **ECG** key is pressed.

Menu item	Option	Default	Description
Extend Record	Selected, not selected	Not selected	Select whether the equipment automatically performs a rhythm measurement and print a rhythm report if critical values "**Extreme Tachycardia**", "**Extreme Bradycardia**", or "**Significant Arrhythmia**" are detected at the completion of auto measurement.
Report Analysis Setup	/	/	Enters the [**Report Analysis Setup**] menu.
Printing Device	Thermal Recorder, External Printer	Thermal Recorder	Selects what printing device is used to output the reports.
Printer Resolution	High Quality, Standard	Standard	Selects the quality of reports produced by the external printer. [**Standard**]: the printout resolution is 300 dpi. [**High Quality**]: the printout resolution is 600 dpi.
Printout Grid	Selected, not selected	Selected	Selects whether a grid is printed behind the waveforms on the ECG report produced by the external printer. A grid may make reading ECG waveforms easier.

Report Analysis Setup

Menu item	Option	Default	Description
Median Complex	Selected, not selected	Not selected	Selects whether Median Complex is included on the ECG report generated by auto measurement. Median Complex displays a median complex waveform for each lead and a lead II waveform of 10 seconds in 3x4+1 format.
Measurement Matrix	Selected, not selected	Not selected	Selects whether Measurement Matrix is included on the ECG report generated by auto measurement. 32 measurements for each lead are provided. The measurements are: Pon (ms), Pdur (ms), QRSon (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (μV), P-amp (μV), QRSp2p (μV), Qamp (μV), Ramp (μV), Samp (μV), R'amp (μV), S'amp (μV), STamp (μV), 2/8STT (μV), 3/8STT (μV), T+amp (μV), T-amp (μV), QRSarea (μV*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms).
Measurement	Selected, not selected	Selected	Selects whether measurement result is included on the ECG report generated by auto measurement. Measurement result includes Vent. Rate, PR Interval, QRS Duration, QT/QTc Interval, P/QRS/T Axes, RV5/SV1 and RV5+SV1. **Note:** To include the RV5/SV1 and RV5+SV1 information in the measurement result, both [**Measurement**] and [**RV5/SV1**] shall be selected.
Interpretation	Selected, not selected	Selected	Selects whether diagnoses are included on the ECG report generated by auto measurement.

Menu item	Option	Default	Description
Interpretation Summary	Selected, not selected	Selected	Selects whether interpretation summary is included on the ECG report generated by auto measurement. **Note:** If the [**Interpretation**] option is not enabled, interpretation summary is not included on the report even if [**Interpretation Summary**] is selected.
Tachy	80-130	100	Adjusts tachycardia threshold. Heart rates above the setting are labelled Tachycardia. Only applies to patients whose age exceeds 180 days.
Brady	40-60	50	Adjusts bradycardia threshold. Heart rates below the setting are labelled Bradycardia. Only applies to patients whose age exceeds 2191 days.
QTc Formula	Hodges, Bazett, Fridericia, Framingham	Hodges	Selects QTc formula. Hodges: $QTc = QT + 1.75 \times (HeartRate - 60)$ Bazett: $QTc = QT \times \left(\frac{HeartRate}{60}\right)^{\frac{1}{2}}$ Fridericia: $QTc = QT \times \left(\frac{HeartRate}{60}\right)^{\frac{1}{3}}$ Framingham: $QTc = QT + 154 \times \left(1 - \frac{60}{HeartRate}\right)$
RV5/SV1	Selected, not selected	Not selected	Selects whether the RV5/SV1 and RV5+SV1 information is included on the ECG report generated by auto measurement.

4.4 File Management

Menu item	Option	Default	Description
Preview	Selected, not selected	Not selected	During auto measurement selects whether the ECG report is previewed before being printed.
Auto Send	Selected, not selected	Not selected	During auto measurement selects whether the ECG report is automatically sent out through the network after measurement finished. You can enable Auto Send only when the Preview function is disabled.
Send Destination	FTP, CardioVista	FTP	Select the destination of currently generated ECG report. If [**Auto Send**] is selected, when an ECG report is generated, it will be sent to the selected destination automatically. If [**Preview**] is selected, you can select [**Send**] in the preview window to send the generated report to the selected destination.
Auto Save	Selected, not selected	Selected	During auto measurement selects whether the ECG report is automatically saved on the internal storage after measurement finishes.
Auto Delete after Transmission	Selected, not selected	Not selected	Selects whether ECG report is automatically deleted from the internal storage after being sent out through the network.

Menu item	Option	Default	Description
Delete the Oldest Report	Selected, not selected	Selected	Selects whether the earliest report is deleted when the internal storage is full. If selected, the earliest report is automatically deleted when a new report is saved. If not selected, prompts whether the earliest report is deleted and the current report is saved.
File Format	MR RAW, FDA XML, PDF, MR XML	PDF	Selects the format of the report sent to the USB drive or the target FTP server. When set to [**MR RAW**], the report will be sent to the FTP server in MR XML format.
PDF Grid	Selected, not selected	Selected	Select whether there is a grid behind the waveforms when a PDF format report is printed.
Record File List	/	/	Starts printing the Directory List.

4.5 Basic Setup

Menu item	Option	Default	Description
Patient Info Setup	/	/	Enters the [**Patient Info Setup**] menu.
Date	Year: 2012-2099 Month: 01-12 Day: 01-31	Year: 2012 Month: 01 Day: 01	Sets the current date.
Time	Hour: 00-23 (24 h) 12 am-11 pm (12 h) Minute: 00-59 Second: 00-59	Hour: 00 Minute: 00 Second: 00	Sets the current time.
Date Format	yyyy-mm-dd, mm-dd-yyyy, dd-mm-yyyy	yyyy-mm-dd	Selects the date format.
Time Format	12 h, 24 h	24 h	Selects the time format.
Lead Notation	AHA, IEC	AHA	Sets lead notation.
Institution Name	/	/	Enters the name of the institution.
Calibrate Touchscreen	/	/	Accesses touchscreen calibration. **Note**: only equipment configured with the touchscreen has this option.
Brightness	1-5	3	Adjusts the display brightness. 1 is the dimmest; 5 is the brightest.
Notification Tone	Selected, not selected	Not selected	Selects whether a notification tone sounds when a message occurs. However, the equipment always gives a notification tone when some messages occur regardless of the setting of [**Notification tone**]. Refer to ***9.2 Messages***.

Menu item	Option	Default	Description
Heart Beep	Selected, not selected	Not selected	Selects whether the heartbeat tone is enabled.
Auto Standby	5 Minutes, 10 Minutes, 15 Minutes, 20 Minutes, 25 Minutes, 30 Minutes, Off	5 Minutes	Sets the time after which the equipment automatically enters the Standby mode. When any of the limb leads is detached, the equipment automatically enters the Standby mode if the equipment is inactive for a predefined time limit. [**Off**]: The equipment does not automatically enter the Standby mode. **Note**: the setting of [**Auto Standby**] should not exceed the setting of [**Auto Shut Down**].
Auto Shut Down	5 Minutes, 10 Minutes, 15 Minutes, 20 Minutes, 25 Minutes, 30 Minutes, Off	Off	Sets the time after which the equipment automatically shuts down. When any of the limb leads is detached, the equipment automatically shuts down if the equipment is inactive for a predefined time limit. [**Off**]: The equipment does not automatically shut down.

[Patient Info Setup] Menu

Required patient information

You should enter the required information for a new patient.

Menu item	Option	Default	Description
ID	Selected, not selected	Not selected	Selects whether the patient ID is defined as required patient information.
Last Name	Selected, not selected	Not selected	Selects whether the patient's last name is defined as required patient information.
First Name	Selected, not selected	Not selected	Selects whether the patient's first name is defined as required patient information.
Age	Selected, not selected	Not selected	Selects whether the patient's age is defined as required patient information.
Gender	Selected, not selected	Not selected	Selects whether the patient's gender is defined as required patient information.

Detailed Patient Info

The detailed information helps you to know more about the patient.

Menu item	Option	Default	Description
Secondary ID	Selected, not selected	Not selected	Selects whether the patient's secondary ID is included on the ECG report as patient information.
DOB	Selected, not selected	Not selected	Selects whether the patient's date of birth is included on the ECG report as patient information.
Race	Selected, not selected	Not selected	Selects whether the patient's race is included on the ECG report as patient information.

Menu item	Option	Default	Description
Medication 1	Selected, not selected	Not selected	Selects whether the medication taken by the patient is included on the ECG report as patient information.
Medication 2	Selected, not selected	Not selected	Selects whether the medication taken by the patient is included on the ECG report as patient information.
Class 1	Selected, not selected	Not selected	Selects whether the patient's class is included on the ECG report as patient information.
Class 2	Selected, not selected	Not selected	Selects whether the patient's class is included on the ECG report as patient information.
V3 Placement	Selected, not selected	Not selected	Selects whether the setting of V3 placement is included on the ECG report as patient information.
Physician	Selected, not selected	Not selected	Selects whether the physician who supervises the ECG is included on the ECG report as patient information.
Technician	Selected, not selected	Not selected	Selects whether the technician who conducts the ECG measurement is included on the ECG report as patient information.
Department	Selected, not selected	Not selected	Selects whether the patient's department is included on the ECG report as patient information.
Room	Selected, not selected	Not selected	Selects whether the patient's room number is included on the ECG report as patient information.
Bed	Selected, not selected	Not selected	Selects whether the patient's bed number is included on the ECG report as patient information.
Keep Previous Input Information	/	/	Select which required patient information is kept for the next patient.

4.6 Maintenance

⚠ CAUTIONS

- **Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.**
- **Always set the wireless network according to local wireless regulations.**
- **Data communication must be performed within a closed network or within a virtually isolated network provided by a hospital for all network functions. The hospital is responsible for ensuring the security of the virtually isolated network.**
- **Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.**
- **Do not connect non-medical devices to the wireless network system.**
- **If wireless network signal is poor, there may be a risk of data loss on the wireless network system.**
- **RF interference may result in wireless network disconnection. The equipment may fail to send files due to the network disconnection.**
- **Ensure that the IP address setting on the equipment is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.**

Menu item	Option	Default	Description
Network Type	LAN, WLAN	LAN	Selects the type of network through which the equipment is connected.
Network Name (SSID) (not for the equipment with a 5G module)	/	/	When connects WLAN, enters the SSID.
Password (not for the equipment with a 5G module)	/	/	Enters the password to connect the WLAN.
IP Address	0 - 255	192.168.0.100	Enters the IP address of the equipment.
Subnet Mask	0 - 255	255.255.255.0	Enters the subnet mask of the equipment.
Default Gateway	0 - 255	192.168.0.254	Enters the IP address of the default gateway.
WIFI Setup (for the equipment with a 5G module)	/	/	Enters the **[WIFI Setup]** menu. You can change wireless network and WLAN related settings, or maintain certificates by selecting a desired item.
FTP Communication Setup	/	/	Enters the **[FTP Communication Setup]** menu.
CardioVista Communication Setup	/	/	Enters the **[CardioVista Communication Setup]** menu to set the [**CardioVista IP Address**].
ADT Communication Setup	/	/	Enters the **[ADT Communication Setup]** menu.
Demo Mode 1	/	/	Enters the password to access Demo Mode 1. To exit the Demo mode, turn off the equipment and restart it.
Demo Mode 2	/	/	Enters the password to assess Demo Mode 2. To exit the Demo mode, turn off the equipment and restart it.
Restore Default Configuration	/	/	Restores the factory default configuration. This does not change the current language setting.
Load Configuration	/	/	Imports the configuration file on the USB drive to the internal memory.
Export Configuration	/	/	Exports the configuration file on the internal memory to the USB drive.
Print Configuration	/	/	Prints the current configuration.
Language	ENGLISH, SIM. CHINESE, FRENCH, GERMAN, ITALIAN, POLISH, SPANISH, PORTUGUESE, RUSSIAN, CZECH, TURKISH, HUNGARIAN, ROMANIAN	ENGLISH	Selects UI language.
AC Filter	50 Hz, 60 Hz	50 Hz	Selects the frequency of the AC power line filter.
Modify Password	/	/	Modifies the password to access the Maintenance mode.
Factory Maintenance	/	/	Enters the password to access Factory Maintenance.

FTP Communication Setup

Menu item	Option	Default	Description
Server IP Address	0 - 255	192.168.0.101	Enters the IP address of the FTP server.
FTP Port	0 - 65535	21	Enters FTP port.
FTP Username	/	/	Enters FTP username.
FTP Password	/	/	Enters FTP password.

ADT Communication Setup

Menu item	Option	Default	Description
ADT Query Enable	Selected, not selected	Not selected	To select whether to enable the ADT query function. If the ADT query function is enabled and the equipment is successfully connected to the ADT database, when you input a patient ID, the equipment can automatically obtain other patient information of this ID from the ADT database, including Last Name, First Name, DOB, Gender, Race, Physician, Department, Room and Bed. **Note**: If [**ADT Query Enable**] is selected, [**Detailed Patient Info**] will be selected automatically.
ADT IP Address	0 - 255	192.168.0.98	Enters the ADT IP address.
ADT Port	0 - 65535	3502	Enters the ADT port.

Wireless Network Setup

Menu item	Option	Default	Description
Network Name (SSID)	/	/	When connects WLAN, enters the SSID.
Security	/	WEP OFF	Selects the security method.
Password	/	/	Enters the password to connect the WLAN.

WLAN Setup

Menu item	Option	Default	Description
WLAN Band	Auto, 2.4G, 5G	AUTO	Selects automatically identifies the WLAN band
AUT. Server Type	ACS, SBR	ACS	Selects the type of authentication server.
BG Channel	ALL, NONE, SPCIALS	ALL	Selects the type of B and G channels.
A Channel	ALL, NONE, SPCIALS	ALL	Selects the type of A channels.

Certificates Maintenance

Menu item	Option	Default	Description
Import Certificates	/	/	Import the certificate file stored in the USB memory into the equipment's internal memory.
Delete Certificates	/	/	Export the certificate file stored in the equipment's internal memory to the USB memory.

FOR YOUR NOTES

5 Patient Information

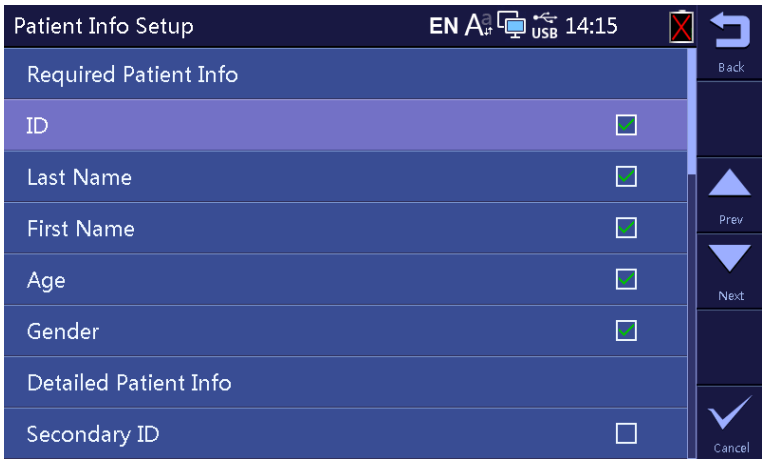
5.1 Setting Patient Information

Some patient information may directly affect ECG analysis. Complete and correct patient information is helpful for accurate diagnosis and treatment of the patient. For a new patient, enter patient information before taking an ECG measurement.

Patient information is classified as required information and detailed information. The required information must be entered. In the [**Patient Info**] menu, an asterisk (*) is placed before the required information. The detailed information helps you to know more about the patient.

To set patient information:

1. Press the **Setup** key to access the main menu.
2. Select [**Basic Setup**] → [**Patient Info Setup**] to enter the [**Patient Info Setup**] menu.
3. Select the required patient information and detailed patient information as necessary. For details about the menu items, refer to ***4.5 Basic Setup***.



5.2 Entering Patient Information

Before taking an ECG measurement, enter patient information.

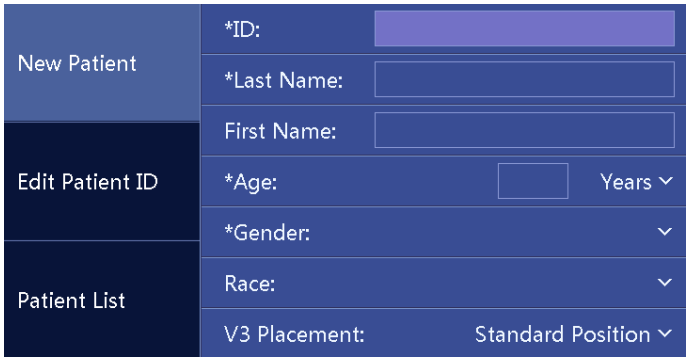
You can:

- Manually enter patient information.
- Read patient ID with a barcode reader.
- Select the patient from the Patient List.

Manually Entering Patient Information

To manually enter the patient information:

1. Press the **ID** key to enter the [**Patient Info**] menu.
2. In the [**New Patient**] sheet, enter the patient information.
3. Press the [**Save**] soft key to save the patient information.



NOTE

- **You can save patient information only when all the required patient information is entered.**
- **We recommend using pediatric lead placement V4R, V1, V2, V4 - V6 if the patient is under 16 years of age. Please record V4R using the V3 electrode. Also set [V3 Electrode Placement] to [V4R]. This is a normal practice for a patient of this age.**
- **If the ADT query function is enabled and the equipment is successfully connected to the ADT database, when you input a patient ID, the equipment can automatically obtain other patient information of this ID from the ADT database.**

Reading Patient ID Using the Barcode Reader

To read the patient ID with a barcode reader:

1. Check that the barcode reader is connected to the USB connector.
2. Press down the button on the reader handle, and target the reader to the barcode.

   Then the [**Patient Info**] menu pops up with the patient ID entered.
3. Enter other patient information as necessary.
4. Press the [**Save**] soft key to save the patient information.

NOTE

- **If the ADT query function is enabled and the equipment is successfully connected to the ADT database, when you input a patient ID, the equipment can automatically obtain other patient information of this ID from the ADT database.**

Selecting a Patient from the Patient List

1. Press the **ID** key to enter the [**Patient Info**] menu.
2. Select [**Patient List**] to enter the [**Patient List**] sheet.
3. Select a patient and edit the patient information as necessary.
4. Press the [**Save**] soft key to save the patient information.

After the patient's information is saved, the patient is added to the Patient List. The Patient List can include up to 500 patients.

5.3 Editing Patient Information

You can edit the information of the current patient.

To edit the patient information:

1. Press the **ID** key to enter the [**Patient Info**] menu.
2. Select [**Edit Patient ID**] to enter the [**Edit Patient ID**] sheet.
3. Modify or enter the patient information as necessary.
4. Press the [**Save**] soft key to save the patient information.

Editing patient information updates the information of corresponding patient in the Patient List.

FOR YOUR NOTES

6 Patient Preparation

6.1 Relaxing the Patient

Before applying electrodes, greet the patient and explain the procedure. Explaining the procedure decreases anxiety and informs the patient about what to expect.

- Assure the patient that there is no danger or discomfort involved. Explain that full cooperation will produce a valuable diagnostic record.
- Lay the patient on a bed with arms rest at the side and legs lying flat and not touching. Ensure the patient is comfortable and relaxed.

Once the electrodes and lead wires are applied, instruct the patient to:

- Remain still and do not talk.
- Breathe normally.
- Try not to shiver.
- Do not chew or clench teeth.

The more relaxed the patient is, the less the ECG will be affected by noise.

6.2 Preparing the Skin

Careful skin preparation is the key to high-quality ECG signals. To prepare the skin:

1. Expose the chest and electrode sites on the limbs.
2. Shave hair from each electrode site.
3. Degrease each electrode site with alcohol and abrade slightly with dry gauze to remove dead skin cells.
4. Dry the skin completely.

6.3 Connecting Lead Wires and Electrodes

Before acquiring the patient's ECG, check that all electrodes are correctly connected to the lead wires and the patient cable is plugged securely into the connector on the right side of the equipment.

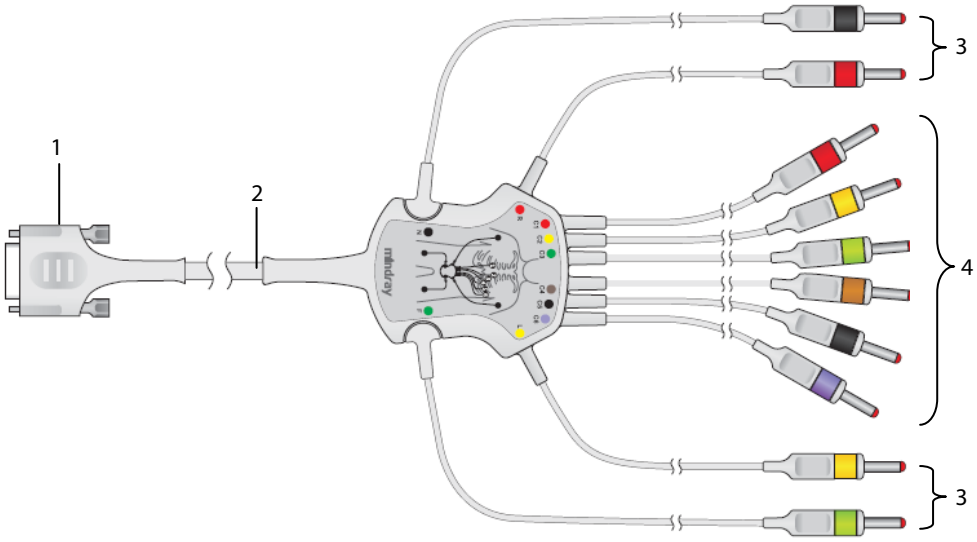
⚠CAUTION

- **Ensure that all leads are connected and all electrodes are applied to correct sites. Ensure the conductive parts of the patient cable and electrodes, including the neutral electrode, do not contact other conductive parts, including earth.**
- **Polarizing electrodes may cause the electrodes to retain a residual charge after defibrillation. Residual charge will block the acquisition of ECG signal.**
- **Never mix patient electrode types or brands. Dissimilar metals or other incompatibilities may cause considerable baseline drift and may increase trace recovery time after defibrillation.**
- **Do not reuse disposable electrodes. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **Reusable electrodes shall be cleaned and disinfected before applying to the patient.**
- **Use defibrillator-proof ECG cables during defibrillation.**
- **Use disposable electrodes when the equipment is in use with a defibrillator.**

6.3.1 ECG Accessories

Patient Cable

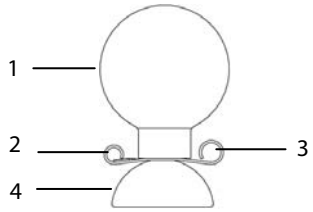
The patient cable consists of a connector, a trunk cable, 4 limb lead wires and 6 chest lead wires. The lead wires are color-coded. Refer to 6.4.3 Lead Wire Color Code.



1. Connector: connects to the electrocardiograph
2. Trunk cable
3. Limb lead wires: connect limb electrodes
4. Chest lead wires: connect chest electrodes

Chest Electrode

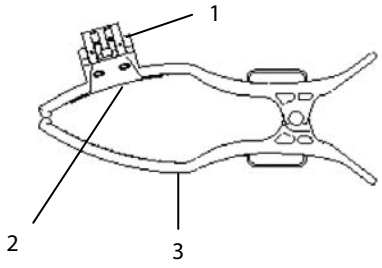
The chest electrode consists of a bulb and a metal electrode. On the metal electrode, there are two lead wire connectors: one for lead wire with Φ 3.0 mm connector; the other for lead wire with Φ 4.0 mm connector.



1. Bulb
2. Lead wire connector (Φ3.0)
3. Lead wire connector (Φ4.0)
4. Metal electrode

Limb Electrode

The limb electrode consists of a plastic clamp and a metal electrode. On the metal electrode, there are two lead wire connectors: one for lead wire with Φ 3.0 mm connector; the other for lead wire with Φ 4.0 mm connector.



1. Lead wire connectors
2. Metal electrode
3. Clamp

6.3.2 Connecting Chest Lead Wires with Chest Electrodes

Respectively plug the chest lead wires into the lead wire connectors of the 6 chest electrodes. Adjust each lead wire to make sure the electrode and lead wire properly come into contact.

6.3.3 Connecting Limb Lead Wires with Limb Electrodes

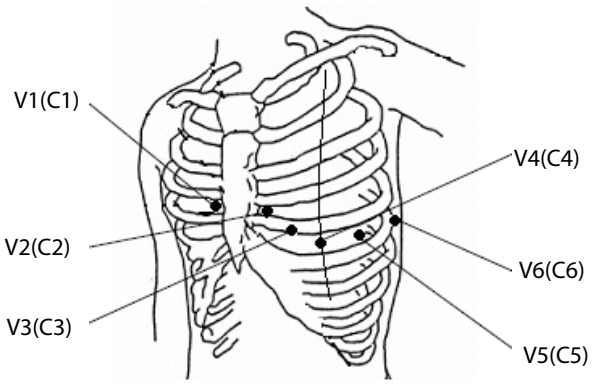
Respectively plug the limb lead wires into the lead wire connectors of the 4 limb electrodes. Adjust each lead wire to make sure the electrode and lead wire properly come into contact.

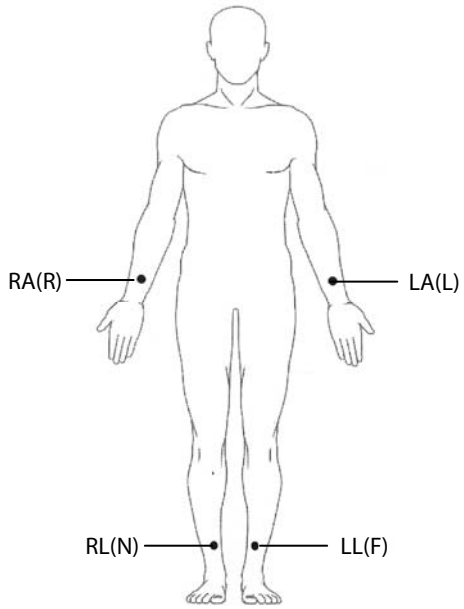
Note

- **The limb electrodes are color coded. Make use limb lead wire and limb electrode of the same color are connected.**

6.4 Applying Electrodes

6.4.1 Electrode Placement

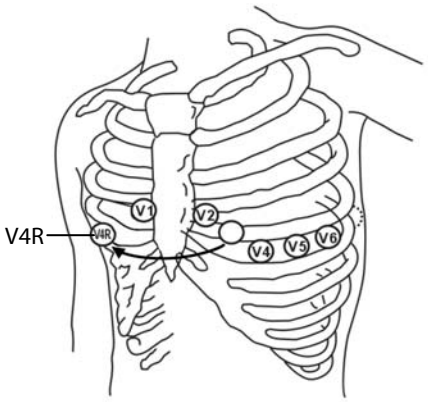




AHA	IEC	Electrode placement
V1	C1	Fourth intercostal space at the right sternal border
V2	C2	Fourth intercostal space at the left sternal border
V3	C3	Midway between V2 (C2) and V4 (C4) electrode positions
V4	C4	Fifth intercostal space at the left midclavicular line
V5	C5	Left anterior axillary line, horizontal with the V4 (C4) electrode position
V6	C6	Left midaxillary line, horizontal with the V4 (C4) electrode position
RA	R	Above right wrist
LA	L	Above left wrist
RL	N	Above right ankle
LL	F	Above left ankle

6.4.2 Pediatric Lead Placement

When acquiring a pediatric ECG, an alternative to the standard V3 (C3) placement may be used. Place the electrode in the V4R (C4R) position, which is on the right side of the chest in a position corresponding to V4 (C4).



6.4.3 Lead Wire Color Code

Lead	IEC		AHA	
	Label	Color	Label	Color
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg (neutral)	N	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/Red	V1	Brown/Red
Chest 2	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C3	White/Green	V3	Brown/Green
Chest 4	C4	White/Brown	V4	Brown/Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Violet	V6	Brown/Violet

6.4.4 Applying Reusable Electrodes

Applying Limb Electrodes

Limb electrodes should be placed on fleshy areas above the inside wrists and ankles, not on the bone.

1. Check that the electrodes are clean.
2. Connect the four limb electrodes with corresponding lead wires as indicated by the color. Route the lead wires to avoid twisting.
3. Expose the patient's arms and legs.
4. Prepare the skin as describe in ***6.2 Preparing the Skin.***
5. Apply a thin layer of conductive gel on each electrode site.
6. Apply a thin layer of conductive gel on each metal electrode.
7. Place the electrodes on the limb sites above the inside ankles and wrists.
8. Make sure the patient cable is tightly connected to the equipment and electrodes are correctly connected with the lead wires.

Applying Chest Electrodes

1. Check that the electrodes are clean.
2. Connect the six chest electrodes with the chest lead wires. Route the lead wires to avoid twisting.
3. Expose the patient's chest.
4. Prepare the skin as describe in ***6.2 Preparing the Skin***.
5. Apply a thin layer of conductive gel on each electrode site. Ensure the gel from one site does not touch another site.
6. Apply a thin layer of conductive gel on the metal electrodes.
7. Apply the electrodes by squeezing the rubber bulb and allowing suction to hold the electrodes in place.
8. Make sure the patient cable is tightly connected to the equipment and electrodes are correctly connected with the lead wires.

⚠WARNING

- **The bulbs of the chest electrode contain latex, a material that can cause allergic reactions. Monitor the electrodes site and, if irritation occurs, use an alternate electrode.**
- **The reusable electrodes contain nickel, a material that can cause skin irritation. Monitor the electrode sites and, if irritation occurs, use an alternate electrode.**

NOTE

- **To obtain high-quality ECG signal, make sure that the metal electrodes firmly contact the skin.**
- **The metal electrodes and placement sites must be clean.**
- **When placing the chest electrodes, ensure that the metal electrodes do not touch each other and the conductive gel from one application site does not touch another site.**
- **The metal plate of the limb electrode may be loose due to frequently plugging and unplugging the lead wire. Make sure the lead wire is firmly connected with the electrode.**
- **Reusable electrodes must be cleaned and disinfected after each use.**

6.4.5 Applying Disposable Electrodes

1. Expose the patient's chest.
2. Prepare the skin as describe in ***6.2 Preparing the Skin***.
3. Place the electrodes firmly on the correct sites.

   Limb electrodes should be placed on fleshy areas above the inside wrists and ankles, not on the bone.
4. Route the lead wires to avoid twisting. Connect the lead wires with the electrodes.
5. Make sure the patient cable is tightly connected to the equipment and electrodes are correctly connected with the lead wires.

6.5 When Lead Off Occurs

The system prompts lead off when electrodes are detached, or any of the lead wires is poorly connected with the electrode, or patient cable detaches the equipment.

- When any of the electrodes on the patient's left arm, left leg, or right arm is detached, or any of LA/L, LL/F, RA/R lead is off, the system respectively prompts "LA Lead Off" ("L Lead Off"), "LL Lead Off" ("F Lead Off"), or "RA Lead Off" ("R Lead Off").
- When any of the chest electrodes or leads is detached, the system respectively prompts "V (X) Lead Off" ("C (X) Lead Off"), in which X represents 1 - 6.
- When RL/N electrode or lead is off, or two or more limb leads are detached, or the patient cable detaches the equipment, the system prompts "Limb Lead Off".

In this case, check that the electrodes are firmly attached to the skin, the lead wires are properly connected with the electrodes, and the patient cable is tightly connected to the equipment.

7 Acquiring an ECG

⚠WARNING

- **This equipment is not intended for use with high frequency surgical units.**
- **Do not contact the patient during defibrillation. Otherwise serious injury or death could result.**
- **For paced patients, the equipment may mistake a pace pulse for a QRS complex if several adverse conditions exist simultaneously. Always keep these patients under close surveillance.**
- **Ensure that all leads are connected and all electrodes are applied to correct sites. Ensure the conductive parts of the patient cable and electrodes, including the neutral electrode, do not contact other conductive parts, including earth.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess part to reduce the risk of entanglement or strangulation by patients or clinical personnel.**
- **The bulb of the chest electrode contains latex, a material that can cause skin irritation. Monitor the electrode site and, if irritation occurs, use an alternate electrode.**
- **The reusable electrodes contain nickel, a material that can cause skin irritation. Monitor the electrode sites and, if irritation occurs, use an alternate electrode.**
- **The auto measurements and diagnoses are for reference only and cannot be directly used for patient treatment.**

7.1 Configuring the ECG Waveforms

Before starting an ECG measurement, configure the ECG waveforms:

- Press the first soft key to adjust the current waveform speed.
- Press the second soft key to adjust the current waveform size.
- Press the third soft key to adjust the current frequency of the muscle artifact filter.

You can also configure the ECG waveforms by accessing the [**Wave Setup**] menu. Refer to ***4.2 Waveform Setup*** for detail.

7.2 Configuring the ECG Reports

The contents and format of the ECG reports are configurable. You can configure the ECG reports by accessing the [**Report Setup**] menu. Refer to ***4.3 Report Setup***.

7.3 Recording an ECG

7.3.1 Auto Measurement

During the auto measurement, the equipment automatically acquires 10 seconds of 12-lead ECG waveforms, analyzes the ECG data, and then prints a report as per system setup.

To start an auto measurement:

1. Prepare the patient as described in ***Chapter 6 Patient Preparation***.
2. Enter patient information as described in ***5.2 Entering Patient Information***.
3. Adjust waveform speed, waveform size, and the frequency of muscle artifact filter.
4. Check other waveform and report settings by selecting **Setup** → [**Waveform Setup**] and [**Report Setup**].
5. Press the **ECG** key to start an auto measurement.

If the preview option is disabled, the equipment automatically prints the ECG report after ECG data is acquired and analyzed.

If the preview option is enabled, the preview of the ECG report displays. You can:

- Select the [**Home**] soft key or the [**Esc**] hard key to discard the report and return to the normal screen.
- Select the [**Send**] soft key to send the report to the external device.
- Select the [**Edit**] soft key to edit the patient information.
- Select the [**Next Page**] soft key to display the next page of the report, if there is any.
- Select the [**Print**] soft key to print the report.
- If the auto save function is disabled, select the [**Save**] soft key to manually save the report to the internal storage.

The equipment automatically stops recording when the ECG report has been printed. You can also press the [**Stop**] soft key to interrupt printing.

7.3.2 Manual Measurement

During the manual measurement, the equipment continuously prints the waveforms of selected leads in real time. The manual measurement provides only printed report. There are no measurement results and diagnoses. You cannot save the report or send it to the external device.

To generate a manual report:

1. Prepare the patient as described in ***Chapter 6 Patient Preparation***.
2. Enter patient information as described in ***5.2 Entering Patient Information***.
3. Press the **Leads** key to switch the leads to be recorded.
4. Adjust waveform speed, waveform size, and the frequency of muscle artifact filter.
5. Check other waveforms and report settings by selecting **Setup** → [**Waveform Setup**] and [**Report Setup**].
6. Select the [**Manual**] soft key to start recording.
7. Select the [**Stop**] soft key to stop recording.

During a manual measurement, you can:

- Select the [**1 mV**] soft key to place a 1 mV square wave on each waveform.
- Press the **Leads** key to switch the leads to be recorded.

7.3.3 Rhythm Measurement

During the rhythm measurement, the equipment acquires 60 seconds of 12-lead ECG and prints the waveforms of the rhythm lead.

The rhythm measurement provides only printed report. There are no measurement results and diagnoses. You cannot save the report or send it to the external device.

To generate a rhythm report:

1. Prepare the patient as described in ***Chapter 6 Patient Preparation***.
2. Enter patient information as described in ***5.2 Entering Patient Information***.
3. Set [**Rhythm Format**], [**Rhythm lead 1**], [**Rhythm Lead 2**], and [**Rhythm Lead 3**] by selecting **Setup** → [**Report Setup**].
   - If you set [**Rhythm Format**] to [**One Lead**], the waveform of the selected rhythm lead displays in 6 cascade lines, with each line including 10 seconds of waveforms on the report.
   - If you set [**Rhythm Format**] to [**Three Leads**], the waveforms of the selected rhythm leads display in 3 cascade lines, with each line including 20 seconds of waveforms on the report.
4. Check other waveforms and report settings by selecting **Setup** → [**Waveform Setup**] and [**Report Setup**].
5. Select the [**Rhythm**] soft key to start a rhythm measurement.

Then the equipment starts acquiring ECG data and a countdown displays. When 60 seconds are reached, printing starts.

The rhythm measurement automatically stops when the report is finished. You can also select the [**Stop**] soft key to manually interrupt it.

NOTE

- **Do not touch the metal electrodes or connectors when acquiring and recording an ECG. Otherwise inaccurate measurements may results.**

7.4 Printing a Report

The equipment is configured with a thermal recorder to output the ECG reports. You can also print auto ECG reports and rhythm ECG reports through an external printer.

To use an external printer, set [**Printing Device**] to [**External printer**] by selecting **Setup** → [**Report Setup**].

The equipment supports HP LaserJet P1606dn, LaserJet M401n and LaserJet M202DW.

Before printing a report, check that the paper is properly loaded. Refer to ***3.2.3 Loading the*** Paper for loading the paper for the thermal recorder. To load the paper for the external printer, refer to the printer's accompanying instructions for use.

NOTE

- **For LaserJet M401n, on the printer select [System Setup] → [Paper Setup] → [Tray 1]/[Tray 2], set [Paper Size] to [Any Type]..**

7.5 Copying a Report

The equipment has the function of copying the latest auto report and rhythm report.

To print another copy of the latest auto or rhythm ECG report, press 

on the keyboard.
You can copy the report using the current configuration, or change the settings before printing another copy.

7.6 Saving a Patient Report

If you have enabled [**Auto Save**] from the [**File Management**] menu, a patient record is automatically created and saved at the completion of each auto measurement. You can search, send, review, print or delete the historic patient records from the Directory List. Refer to ***8.2 Managing Patient Records*** for detail.

If auto save is disabled, you can manually save a report when a preview of the report is generated.

7.7 Resting 12-lead ECG Analysis

The equipment incorporates the Glasgow algorithm, developed by the University of Glasgow, to provide an interpretation of the resting 12-lead ECG in all situations. The equipment automatically starts analysis at the completion of ECG acquisition.

Resting 12-lead ECG analysis provides:

- Measurements, including:
  - Vent. Rate (bpm)
  - PR Interval (ms)
  - QRS Duration (ms)
  - QT/QTc Interval (ms)
  - P/QRS/T Axes (°)
  - RV5/SV1 (mV, available only when [**RV5/SV1]** is selected)
  - RV5+SV1 (mV, available only when [**RV5/SV1]** is selected)
- Critical values, including:
  - Consider Acute STEMI
  - Acute MI/Ischemia
  - Extreme Tachycardia
  - Extreme Bradycardia
  - Significant Arrhythmia
  - Prolonged QTc Interval
- Diagnoses
- Median Complex

  Gives the median complex of each lead.
- Measurement Matrix

  Gives 32 measurements of each lead, including:

  Pon (ms), Pdur (ms), QRSon (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (μV), P-amp (μV), QRSp2p (μV), Qamp (μV), Ramp (μV), Samp (μV), R'amp (μV), S'amp (μV), STamp (μV), 2/8STT (μV), 3/8STT (μV), T+amp (μV), T-amp (μV), QRSarea (μV*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms).

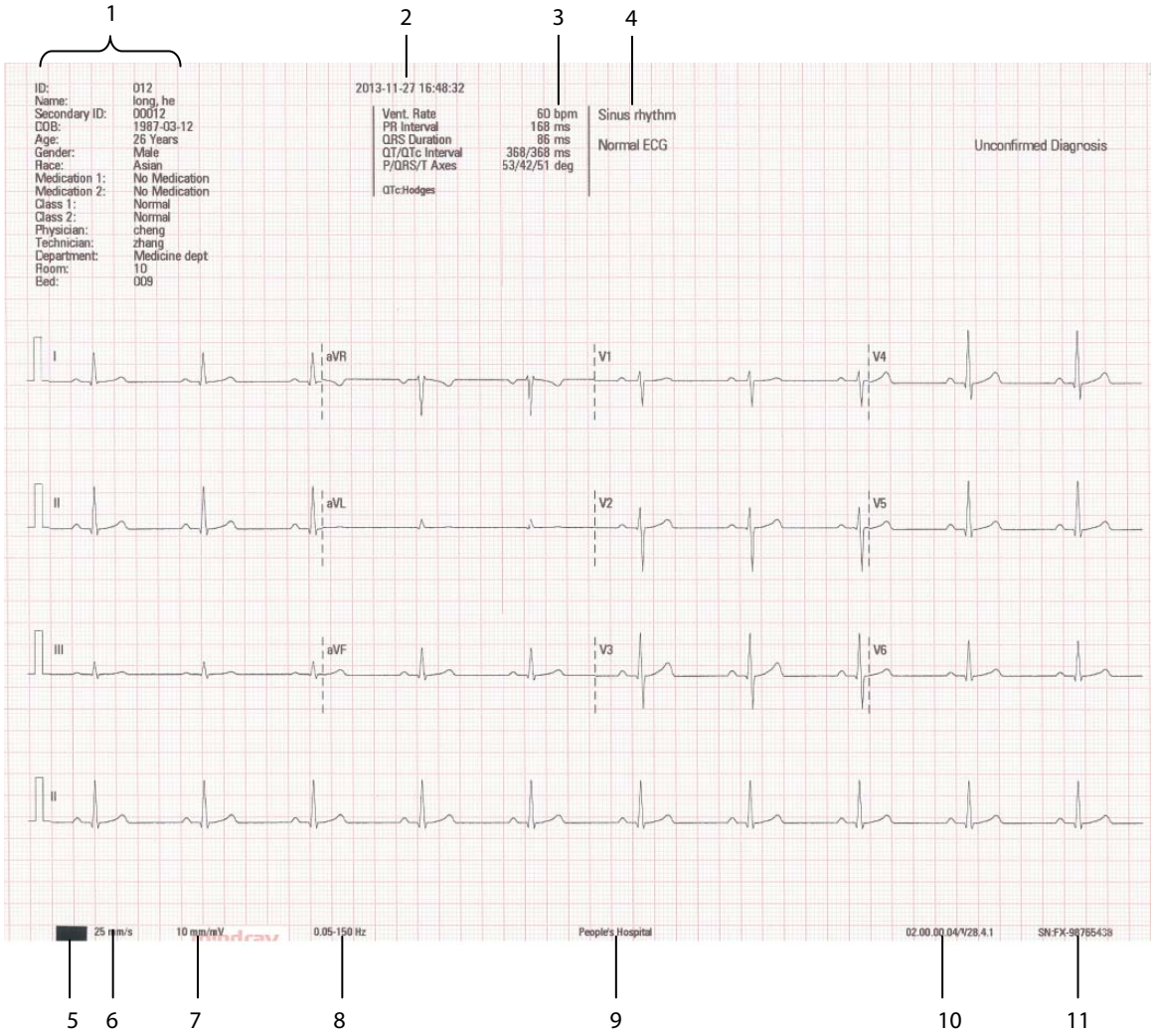
The diagnoses of 12-lead ECG analysis is included on the ECG report by default, see ***Report Analysis Setup*** in ***4.3 Report Setup***.

Resting 12-lead ECG analysis is not intended for the manual measurement and rhythm measurement.
Refer to***12-Lead ECG Interpretive Program Physician's Guide*** (PN: ***046-004817-00***) for details.

7.8 ECG Report

The format and contents of the ECG reports are configurable. Refer to ***4.3 Report Setup*** for details.

The following is a sample of the standard auto measurement recording with default configuration.



1. Patient information
2. Time of acquisition
3. Measurements
4. Diagnosis statement
5. Black mark
6. Paper speed
7. Gain
8. Frequency range
9. Institution name
10. System software version/algorithm version
11. Equipment ID

⚠ CAUTION

- **Do not touch the print head after long-time recording. It might burn the skin.**

8 File Management

8.1 Accessing File Management

1. Press the **Setup** key to access the main menu.
2. Select [**File Management**].
3. Set the options as desired.

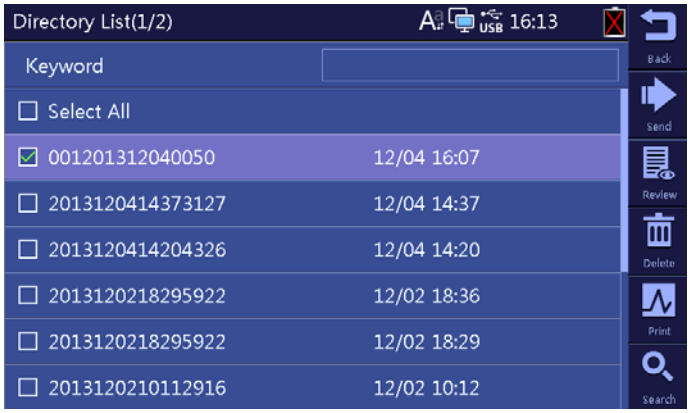
Refer to ***4.4 File Management*** for detail.

8.2 Managing Patient Records

If you have enabled [**Auto Save**] from the [**File Management**] menu, a patient record is automatically created and saved at the completion of each auto measurement. You can search, send, review, print or delete the historic patient records from the Directory List.

8.2.1 Accessing Directory List

In normal screen, select the [**Directory**] soft key to enter the [**Directory List**]. The [**Directory List**] lists all patient records in time sequence with the latest on the top.



In Directory List, select one or more records to:

- Send the selected records to an external device.
- Review the highlighted record.
- Delete the selected records.
- Print the selected records.

You can search patients from the Directory List.

1. Select the [**Search**] soft key and enter a keyword.
2. Select [**Search**] again to start searching.

Then you can find all the patients that meet the search criteria.

8.3 Managing the Configuration

Select **Setup** → [**Maintenance**], enter the required password to enter the [**Maintenance**] menu. You can:

- Select [**Load Configuration**] to load a configuration stored in the USB drive.
- Select [**Export Configuration**] to export the current configuration to the USB drive.
- Select [**Print Configuration**] to print the current configuration.
- Select [**Restore Default Configuration**] to restore the default configuration.

8.4 Sending Files

The equipment can be connected with the hospital's FTP server or CardioVista ECG viewer through the wired or wireless network to send the patient's ECG reports.

To connect the FTP server or CardioVista ECG viewer:

1. Select **Setup** → [**Maintenance**], enter the required password to enter the [**Maintenance**] menu.
2. Select [**Network Type**].
3. If you select [**WLAN**], set [**Network Name (SSID)**] and [**Password**].
4. Set the network related information of the equipment:
   - [**IP Address**]: the IP address of the equipment.
   - [**Subnet Mask**]: the subnet mask of the equipment.
   - [**Default Gateway**]: the IP address of the default gateway.
5. Set the destination information:
   - FTP communication setup, including the IP address, port, user name and password of the FTP server; or,
   - CardioVista communication setup, namely the CardioVista IP address.

The format of the files sent to the FTP server can be MR XML, FDA XML or PDF. Refer to [**File Format**] as described in ***4.4 File Management***.

You can send the patient's reports in either of the following ways:

- Automatically

  Select **Setup** → [**File Management**] → [**Auto Send**] and then [**Send Destination**].

  During auto measurement, the equipment automatically sends the current report to the set destination through the network after the measurement is finished.

- Manually

  1. Select the [**Directory**] soft key to enter the [**Directory List**].
  2. Select the files to be sent
  3. Select the [**Send**] soft key.

Then you can send the selected files to the FTP server or the CardioVista ECG viewer through the network, or send them to the USB drive connected to the equipment.

If you have problems to send out the patient's reports, contact your service personnel.

9 Troubleshooting

9.1 General Problems

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

Symptom	Possible Cause	Corrective actions
The equipment does not power up.	1. The equipment is not connected to the AC mains or the power cord is poorly connected. 2. External power supply problems, such as damaged power cord or AC power outlet. 3. Battery is not installed or has no charge when the AC mains is not connected.	1. Verify the equipment is turned on. 2. Verify the equipment is properly connected to the AC mains. 3. Verify the equipment receives power from the AC mains. Replace the power cord or AC power outlet if necessary. 4. Verify the battery is installed and has sufficient charge. Otherwise, connect the equipment to the AC mains to run the equipment and charge the battery.
The display is completely blank.	1. The equipment is in the Standby mode. 2. The equipment is power off.	1. Press any key to exit Standby. 2. Press the power switch to turn on the equipment.
The display is frozen.	Software failure.	1. Press and hold the **Power** switch for 10 seconds to forcibly shut down the equipment. 2. Restart the equipment.
Wrong characters are entered.	Wrong entering method.	Verify the entering method is correct.
No response to keystroke.	1. One or more keys on the keyboard are being pressed and held. 2. Software failure.	1. Verify no other key is pressed and held. 2. Press and hold the **Power** switch for 10 seconds to forcibly shut down the equipment. 3. Restart the equipment.
The barcode reader cannot read the patient ID.	The barcode reader is not properly connected to the equipment.	Properly connect the barcode reader to the equipment's USB port.

Symptom	Possible Cause	Corrective actions
The recorder does not work.	1. Paperless recording is enabled. 2. Recording paper is not loaded. 3. The paper tray is not snap in place. 4. Print head is too hot. 5. The thermal recorder is disabled due to low battery.	1. Select **Setup** → [**Report Setup**] and disable [**Paperless Recording**]. 2. Verify the recording paper is properly loaded. 3. Verify the paper tray is snap in place. 4. Wait till the print head cools down. 5. Check whether the message "**Battery depleted! Recorder disabled**." is presented. If yes, connect the equipment to the AC mains to run the equipment and charge the battery.
Paper jammed or misaligned.	1. Unspecified paper is used. 2. Recording paper is not properly loaded. 3. The paper tray spacer is not properly placed.	1. Verify specified paper is used. 2. Take out the paper and tear off the jammed part. Reload the paper as described in ***3.2.3 Loading the Paper***. 3. Verify the paper tray spacer is placed appropriately for the paper size. Refer to ***3.2.3 Loading the Paper*** for detail.
Some or all leads have no waveforms.	1. Defective or broken ECG cable. 2. ECG cable is not connected. 3. Electrodes are not applied, or leadwires are dragged or pressed.	1. Replace the ECG cable with a new one. 2. Check the ECG cable is properly connected. 3. Verify electrodes are correctly applied as described in ***6.4.1 Electrode Placement***.
Baseline drift for one or more leads.	1. Unspecified electrodes are used or mix electrode types and brands. 2. Poor skin preparation. 3. Electrode problems.	1. Use specified accessories. Do not mix electrode types or brands. 2. Prepare the patient skin before ECG acquisition as described in ***6.2 Preparing the Skin***. 3. Verify electrodes are correctly applied as described in ***6.4.1 Electrode Placement***. Check for defective or expired electrodes. Replace with disposable electrodes if necessary.

Symptom	Possible Cause	Corrective actions
ECG data displays unacceptable noise.	1. Patient movement. 2. AC interference from external devices or improper AC filter setting. 3. Muscle artifact or improper muscle artifact filter setting. 4. Poor skin preparation. 5. Electrode problems.	1. Ensure the patient remains motionless during ECG acquisition. 2. Turn of the adjacent devices or move the electrocardiograph away from the interference if possible. Properly set the AC filter. 3. Properly set the muscle artifact filter. 4. Prepare the patient before ECG acquisition as described in ***6.2 Preparing the Skin***. 5. Verify electrodes are correctly applied as described in ***6.4.1 Electrode Placement***. Check for defective or expired electrodes. Replace with disposable electrodes if necessary.
The equipment automatically shuts down.	1. Auto shutdown is enabled and the equipment is inactive for the predefined time. 2. The battery is depleted when the equipment runs on battery power.	1. Enable or disable [**Auto Shutdown**] by selecting **Setup** → [**Basic Setup**] as desired. 2. Connect the equipment to AC mains to run the equipment and charge the battery.

9.2 Messages

The equipment prompts messages to indicate the current system status.

Some messages, see ***9.2.1 Message List 1***, are important and urgent, and need you to acknowledge or take actions in time. The system pops up a dialog box when these messages happen. In this case, you cannot operate the equipment unless you press any key to clear the pop-up message or wait till the triggers disappear.
Some pop-up messages also display in the message area and disappear till the triggers disappear.

Some messages, see ***9.2.2 Message List 2***, are less urgent. These messages are shown in the message area. They disappear automatically when the triggers disappear.

The equipment can give a notification tone when a message is presented. The notification tone is switched off by default. You can enable it by accessing the [**Basic Setup**] menu. Refer to ***Notification Tone*** in ***4.5 Basic Setup***.

9.2.1 Message List 1

Note: * means that the equipment always gives a notification tone when the message occurs.

Message	Trigger	Action to be taken
Battery depleted!*	The battery is too low.	Connect the equipment to the AC mains to run the equipment and charge the battery.
Recorder unavailable!*	Communication with the recorder fails or the recorder does not work.	1. Verify that recording paper is properly loaded. 2. Verify that the print head is not too hot. 3. If the problem persists after the above actions have taken, contact your service personnel.
Paper type error *	1. Unspecified paper is used. 2. The black mark on the paper cannot be detected.	1. Verify specified paper is used. 2. Verify the paper tray spacer is placed appropriately for the paper size as described in ***3.2.3 Loading the Paper***.
Recorder head hot *	Print head becomes too hot due to heavy use.	Stop printing and wait till the print head cools down.
Printer unavailable! *	1. The printer is not turned on. 2. The electrocardiograph does not support the printer. 3. The printer automatically shuts down. 4. The function of smart drive installation is enabled. 5. Communication with the external printer fails.	1. Turn on the printer. 2. Check the printer model. Make sure supported printer is used. 3. Disable the auto shutdown function. 4. Disable the smart drive installation function. 5. Check that the printer is properly connected with the cardiograph and the connection cable is not damaged. 6. If the problem persists, contact your service personnel.
ECG module error*	Damaged ECG board or software failure causes ECG communication error or communication stops.	Contact your service personnel.
Printing...	The report is being printed.	Wait till the printing finishes. To stop printing, select the [**Stop**] soft key.
Generating preview...	The equipment is generating a preview of the ECG report.	Wait till the preview is generated.
Recorder out of paper	The thermal recorder runs out of paper.	Load the paper as described in ***3.2.3 Loading the Paper.***
Recorder is out of paper. Please load paper	The thermal recorder runs out of paper when printing a report.	Load the paper as described in ***3.2.3 Loading the Paper.***
Recorder door not closed	Paper tray is open.	Push the paper tray back to snap in position and try again.
Printer out of paper	The external printer runs out of paper.	Load the paper and try again.

Message	Trigger	Action to be taken
Please check printer	Problems, such as paper tray not closed, no paper, paper jam, or cartridge running out of ink, occur to the external printer.	Check the printer, remove the errors as indicated, and try again.
Printing stopped	The printing task is interrupted by pressing the [**Stop**] soft key.	/
Configuration loaded successfullly*	Configuration is loaded successfully.	/
Loading configuration failed*	Main control software or hardware failed.	Contact your service personnel.
Configuration file not found*	Configuration file is not found in the USB drive when loading configuration.	1. Verify that correct configuration file is stored in the USB drive. 2. Check whether the file system is damaged. If yes, contact your service personnel.
Export configuration successfully	Configuration is successfully exported.	/
Export failed	Exporting patient data failed.	1. Check that the settings are correct 2. Check that the USB drive is properly inserted and file system is not damaged. 3. Check that the USB drive has sufficient space.
Failed to create file(s)	Creating files failed when exporting configuration.	Try again. If the problem persists, contact your service personnel.
Sending data. Please wait…(X/Y)	Files are sending to the external device. X refers to the number of files having been sent; Y refers the total number of files to be sent.	Wait till all files have been sent.
Sending data successfully	The files are successfully sent to the external device.	/
Sending data failed	The files fail to be sent to the external device.	Check network connection and network related settings. Try again. If the problem persists, contact your service personnel.
Deleting...	File(s) are being deleted.	/
Deleted successfully	Selected files are successfully deleted.	/
Deleting failed	The selected files failed to be deleted.	Check that deleting option is selected. You can format the internal memory if you want to delete all the files.
There's no report to copy. Please acquire ECG data first.	No auto ECG report or rhythm report is available when you try to copy the latest report.	Take an auto measurement or rhythm measurement.
Reanalyzing…	The equipment is reanalyzing ECG data.	Wait till reanalysis finishes.

Message	Trigger	Action to be taken
Modifying patient information may cause difference in the diagnostic statements produced by the software. Consider to enable reanalyzing process.	If the reanalysis option is disabled, saving the change to the patient's age, date of birth, gender, race, medication, or V3 placement setting pops this message.	Enable reanalysis if necessary.
Connection failed. Please check your network.	When you try to manually send reports to an external device, the equipment is not connected to the network or cannot connect to the network due to network problem	Check network connection and network related settings. Try again. If the problem persists, contact your service personnel.
Connecting server failed.	The equipment cannot connect to the FTP server when you send files.	Check network connection and network related settings. Try again. If the problem persists, contact your service personnel.
Incorrect FTP username or password. Please try again.	Wrong FTP user name or password is entered when you try to manually send the reports to an external device.	Enter the correct user name and password.
USB memory low	The USB memory has insufficient space when patient data or configuration is to be exported to the USB drive.	Delete useless files stored in the USB drive to release the memory space.
USB memory not found	The system fails to find the USB drive.	1. Verify the USB drive is properly plugged. 2. If the problem persists, format the USB drive and try again.
Save failed	Files failed to be saved.	Try again. If the problem persists, contact your service personnel.
Save successfully	When auto save is disabled, a report is manually saved by pressing the [**Save**] soft key.	/
Formatting failed	Formatting memory failed.	Internal memory might be damaged. Contact your service personnel.
Formatting completed	The memory is successfully formatted.	/
Formatting. Please wait...	The memory is being formatted.	Wait till formatting finishes.
Shutting down...	The system is shutting down.	/
Touchscreen Calibration Completed!	The touchscreen is calibrated successfully.	/
ADT service is abnormal, please contact administrator	The equipment failed to communicate with the ADT database through eGateway.	1. Make sure the eGateway has been installed on the PC. 2. Make sure the network cable is properly connected between the equipment and the PC. 3. Check the ADT communication setup, and make sure the port and IP address are correct.

Message	Trigger	Action to be taken
No matched patient information	The equipment cannot find any patient information that matches the input patient ID.	Check if the input patient ID is correct. If so, this ID does not exist in the ADT database.
Excessive query results. Please provide more information to query.	The input patient ID is incomplete and too many results are found.	Input the complete patient ID.

9.2.2 Message List 2

Note: * means that the equipment always gives a notification tone when the message occurs.

Message	Trigger	Actions to be taken
Data memory unavailable*	Data memory is unavailable or cannot detect the data memory.	Contact your service personnel.
Data memory error*	Unable to read or write the data memory.	Contact your service personnel.
RT clock need reset*	The real-time clock displays the initial value because button cell failed and reset, or button cell is not available.	Contact your service personnel.
RT clock error*	Unable to read the real-time clock register.	Contact your service personnel.
Battery error *	Failure is detected when the battery is being charged.	Contact your service personnel.
Device abnormal voltage *	The voltage of PCBA power supply is abnormal.	Contact your service personnel.
Limb lead off	1. RL lead off or more than one limb lead off. 2. Patient cable is detached from the equipment.	1. Check corresponding electrodes and lead wires. Re-apply the electrodes or reconnect the lead wires if necessary. 2. Check that patient cable is properly connected to the equipment.
XX Lead off (XX refers to LA/L, LL/F, V1-V6/C1-C6)	The referred lead is off.	Check corresponding electrodes and lead wires. Re-apply the electrodes or reconnect the lead wires if necessary.
Noise	Noise or artifacts from lead I, II, V1, V2, V3, V4, V5, V6 is detected.	Check that the patient is relaxed, patient skin is properly prepared, and the electrodes are properly connected.
Printing…	The thermal recorder or the external printer is printing a report.	Wait till printing finishes.
Analyzing...	The algorithm is analyzing acquired ECG data.	Wait till analyzing finishes.
Analyzing Failed	The algorithm fails to analyze acquired ECG data and is unable to give diagnoses.	Refer to"***12-Lead ECG Interpretive Program Physician's Guide***" ***(PN: 046-004817-00).***
ECG data insufficient	In the situation that pre-acquisition is enabled, the equipment has not acquired 10 seconds of ECG data when auto measurement is started.	Wait till sufficient data is acquired.

Message	Trigger	Actions to be taken
Acquiring...	The equipment is acquiring 60-second ECG data when a rhythm measurement is started.	Wait till 60 seconds of countdown is reached. To stop acquisition, press the [**Stop**] soft key
Recorder out of paper	The thermal recorder runs out of paper.	Load the paper as described in ***3.2.3 Loading the Paper.***
Recorder door not closed	Paper tray is open.	Push the paper tray to snap in position. Try again.
Recorder head hot *	Print head becomes too hot due to heavy use.	Stop printing and wait till the message disappears.
IP address conflict	IP address conflict.	Contact your service personnel.
Insufficient memory space	The left memory space is less than 10 files.	Delete useless historic files.
Low battery	The battery charge is low.	Connect the equipment to the AC mains to run the equipment and charge the battery.

10 Battery

10.1 Overview

The equipment is designed to operate from battery power during intra-hospital patient transfer or whenever AC power supply is not available. The equipment uses the AC power as primary power source. In case of power failure, the equipment automatically runs power from the battery. So we recommend you always install a fully charged battery in the equipment.

On-screen battery symbols indicate battery status as follows:

 Indicates that the battery works properly. The solid green portion represents the current battery charge level. Each block represents a charge of approximately 20% capacity.

 Indicates that the battery has low charge level and needs to be charged. In this case, the LED turns yellow and the message "**Low Battery**" shows at the bottom of the screen.

 Indicates that the battery is almost depleted and needs to be charged immediately.

 Indicates that no battery is installed or charging battery fails.

When the battery is depleted, the system pops up the message "**Battery Depleted"**, the battery indicator flashes in yellow, and the recorder is disabled. At this moment, connect the equipment to the AC mains to run the equipment and charge the battery. Otherwise the equipment will shut down.

10.2 Charging the Battery

The battery is charged whenever the equipment is connected to an AC power source regardless of whether or not the equipment is currently on.

When the battery is being charged, the battery indicator is illuminated in green. The on-screen battery symbol dynamically shows the charging status if the equipment is powered on.

10.3 Replacing the Battery

The battery must be installed by service personnel trained and authorized by our company only. To replace the battery, contact your service personnel.

10.4 Battery Guidelines

Life expectancy of a battery depends on how frequent and how long it is used. For a properly maintained and stored lithium ion battery, its life expectancy is about 3 years. Under more aggressive use, life expectancy can be less. We recommend replacing lithium ion batteries every 3 years.

To get the most out of the battery, observe the following guidelines:

- Perform the battery performance test once a year, before equipment repairs, or whenever the battery is suspected as being the source of the problems.
- Condition the battery once when it is used or stored for 3 months, or when its operating time becomes noticeably shorter.
- Take out the battery before the equipment is transported or will not be used for more than 3 months.
- Store the battery with battery power about 50% of the full charge. Every 6 months, fully charge the battery, and then run the equipment on this battery till its power becomes 50% of the full charge. Remove the battery from the equipment and store it.
- When storing batteries, make sure that the battery terminals do not come into contact with metallic objects. Store the batteries in a cool place, ideally at a temperature of 15 ºC. Storing batteries in a cool place slows the aging process, while storing batteries at high temperature for an extended period of time will significantly shorten battery life. Do not store the battery at a temperature beyond -20 ºC – 60 ºC.

⚠ WARNING

- **Keep the battery out of children's reach.**
- **Use only the specified batteries.**
- **If the battery shows signs of damage or signs of leakage, replace it immediately.**

10.5 Battery Maintenance

10.5.1 Conditioning a Battery

The battery should be conditioned before the first use. A battery conditioning cycle is one uninterrupted charge of the battery, followed by an uninterrupted battery discharge and charge. Batteries should be conditioned regularly to maintain their useful life.

To condition a battery, follow this procedure:

1. Disconnect the equipment from the patient.
2. Connect the equipment to the AC mains. Allow the battery to be charged uninterrupted till the battery is full and the battery indicator is off.
3. Disconnect the AC mains and allow the equipment to run from the battery until it shuts off.
4. Again connect the equipment to the AC mains. Allow the battery to be charged uninterrupted till the battery is full and the battery indicator is off.

NOTE

- **The actual battery capacity decreases over time. For an old battery, the full capacity battery symbol does not indicate the capacity and operating time of this battery can still fulfill battery specifications in the operator's manual. Please replace the battery if its operating time is significantly lower than the specified time.**

10.5.2 Checking a Battery

The performance of a rechargeable battery may deteriorate over time. Perform the battery performance test once a year, before equipment repairs, or whenever the battery is suspected as being the source of the problems.

To check the performance of a battery:

1. Disconnect the equipment from the patient.
2. Connect the equipment to the AC mains. Allow the battery to be charged uninterrupted till the battery is full and the battery indicator is off.
3. Disconnect the AC mains and allow the equipment to run from the battery until it shuts off.

Battery operating time directly reflects its performance. If the operating time of a battery is noticeably shorter than that stated in the specifications, contact your service personnel.

NOTE

- **Battery operating time depends on the device configuration and operation. The battery might be damaged or malfunctioned if its operating time is too short after being fully charged.**
- **When a battery has visual signs of damage, or no longer holds a charge, it should be replaced.**

10.6 Battery Recycling

Replace the battery if there are visual signs of damage, the battery fails, or the battery has been used for more than three years. To dispose of the batteries, follow local laws.

⚠ WARNING

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

11 Care and Maintenance

Regular maintenance is essential to ensure that the equipment functions properly. This chapter contains information on basic care and periodic maintenance.

⚠ WARNING

- **Failure for the responsible individual, hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
- **This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **If you discover a problem with any of the equipment, contact your service personnel or us.**

11.1 Cleaning and Disinfecting

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

- Always dilute the cleaning and disinfecting agent according to the manufacturer's instructions or use the lowest possible concentration.
- Do not immerse any part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

⚠ WARNING

- **Be sure to shut down the system, disconnect power cord and other cables before cleaning the equipment.**
- **Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.**
- **We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.**

⚠ CAUTION

- **Remove the equipment from use if liquid is spilled on the equipment or accessories. Contact your service personnel.**

11.1.1 Cleaning

Recommended cleaning agents for the equipment are:

- Water
- Mild soap

Do not use any of the following materials to clean the equipment because equipment damage may result.

- Organic solvents except ethanol
- Ammonia-based solvents
- Acid or alkaline cleaning agents such a sodium hypochlorite and peroxide solvents
- Abrasive cleaning agents

For the recommended cleaning agents for the reusable accessories, refer to the instructions for use delivered with the accessories.

Cleaning the Equipment

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

To clean your equipment:

1. Shut down the equipment and disconnect the power cord, accessories, and other devices that are connected with the equipment.
2. Dilute the mild soap in water to make a cleaning solution.
3. Soak a clean and soft cloth in the solution and wring out excess solution.
4. Thoroughly wipe the surface of the equipment with the damp cloth, avoiding the connectors.

   Do not drip the solution or any liquid on the keyboard and the opening of the thermal recorder.
5. Dry the surface with a clean cloth or paper towel.

Cleaning Patient Cables and Lead Wires

Remove the cables and lead wires from the equipment before cleaning.

1. Gently wipe the cables and lead wires with a soft cloth dampened with the cleaning agent, avoiding the metal connectors.
2. Wipe off excess moisture with a dry cloth.
3. Dry the cables and lead wires in a ventilated and cool place.

Cleaning Reusable Electrodes

Clean the reusable electrodes immediately after use on a patient.

1. Gently wipe the electrodes surface with a soft cloth dampened with 75% ethanol, avoiding the metal connectors.
2. Wipe off excess moisture with a dry cloth.
3. Dry the electrodes in a ventilated and cool place.

Cleaning the Thermal Print Head

Dirty print head deteriorates printing quality. Clean the print head at least once per month or as needed. Check the printout to ensure the printing is legible and dark. Light printing may indicate a dirty print head.

To clean the thermal print head:

1. Turn off the equipment.
2. Pull out the paper tray. Take out the recording paper.
3. Gently wipe the print head with cotton swabs dampened with water or ethanol to remove the dust and foreign particles.
4. Wipe off excess moisture with dry cotton swabs.
5. Reload the recording paper and push back the paper tray after the print head is completely air dry.

⚠ CAUTION

- **The print head gets hot when recording. Do not clean the print head immediately after recording.**

11.1.2 Disinfecting

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

The recommended disinfectant for the equipment is 75% ethanol. For the recommended disinfectant agents for the reusable accessories, refer to the instructions for use delivered with the accessories.

11.1.3 Sterilization

Unless otherwise specified in the instructions for using an accessory, do not sterilize the equipment or the accessories.

11.2 Regular Check

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

- The housing and display screen are free from cracks or other damages.
- All keys funtion properly.
- Connectors are not loose, cracked, or bent and cables have no cuts, nicks, or fraying.
- Power cord and patient cable are securely connected with the equipment.
- Recording paper is properly loaded and sufficient.
- Battery is installed and has sufficient charge.
- Chest electrode bulbs are free from cracks and limb electrodes can properly clamp.

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

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect power cord, patient cable and lead wires for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Make sure that the battery meets the performance requirements.
- Make sure that the recorder functions correctly and the recorder paper meets the requirements.
- Make sure that the equipment is in good working condition.

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

11.3 Calibrating the Touchscreen

For the equipment configured with a touchscreen, calibrate the touchscreen when necessary.

1. Select **Setup** → [**Basic Setup**] → [**Calibrate Touchscreen**].

   Then the symbol  appears at the top left corner of the screen.
2. Tap the center of the symbol to align the touchscreen. Then the symbol moves to the next position.
3. Tap the center of the symbol in turn.

The equipment automatically exits touchscreen calibration and displays the message "**Touchscreen Calibration Completed**" after the calibration is completed. You can press the **Setup** key to interrupt touchscreen calibration.

11.4 Maintaining the Battery

Refer to ***10.5 Battery Maintenance*** for detailed information.

11.5 Storing Thermal Recording Paper

To store the thermal paper:

- Store in a cool, dark, and dry place, avoiding high temperature, moisture and direct sunlight.
- Avoid long-term exposure to bright light and ultraviolet sources.
- Avoid contact with cleaning fluids and solvents, such as alcohols, ketones, esters, ether, and so on.
- Do not store thermal paper with polyvinyl chloride or other chemicals which cause yellowing and fading.
- Store each report separately in a paper bag. Avoid long-term overlapping or pressing by weight.

NOTE

- **Use only specified thermal paper. Using other paper may result in print head wearing out prematurely or recording of poor quality.**

11.6 Storing Cables and Lead Wires

To ensure that cables and lead wires work properly, follow these rules to store them:

- Store in a dry and well-ventilated place.
- Hang cables and lead wires vertically or around a big wheel, avoiding twisting or sharp-angle bending.
- Do not coil cables or lead wires around the equipment.

11.7 Electrical Safety Tests

The users cannot perform electrical safety tests by themselves. Contact the service personnel if these tests are required.

Refer to ***D Electrical Safety Inspection*** for details.

FOR YOUR NOTES

12 Accessories

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.**
- **Use disposable electrodes when the equipment is in use with a defibrillator.**
- **Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **The accessories shall be disposed of according to hospital's regulations.**
- **The accessory material that contacts the patients has undertaken the biocompatibility tests and is verified to be in compliance with ISO 10993-1.**
- **Use the accessories before the expiry date if indicated.**

12.1 ECG Accessories

ECG Electrodes

Model	Description	Patient Category	Part No.
31499224	10 pcs/pack	Adult	0010-10-12304
2245	50 pcs/pack	Pediatric	9000-10-07469
2258-3	3 pcs/pack	Neonate	900E-10-04880
EC6402	Chest electrode	Adult	040-001585-00
EC6403	Limb electrode, AHA	Adult	040-001586-00
EC6406	Limb electrode, IEC	Adult	040-001587-00
5400	Tab electrode	Adult and pediatric	040-001908-00

Patient Cable

Model	Description	Part No.
EC6408	AHA, 12-lead, Φ4, banana connector, defibrillation-proof, Mindray	040-001642-00
EC6409	AHA, 12-lead, Clip, defibrillation-proof, Mindray	040-001643-00
EC6410	IEC, 12-lead, Φ4, banana connector, defibrillation-proof, Mindray	040-001644-00
EC6411	IEC, 12-lead, Clip, defibrillation-proof, Mindray	040-001645-00

Adapter

Part No.	Description	Patient category
040-001646-00	Multifunction-electrode adapter	Adult and pediatric

12.2 Others

Part No.	Description
022-000008-00	Lithium battery, 11.1 V, 4500 mAh, LI23S002A
024-000534-00	External printer, HP LaserJet P1606dn
023-000254-00	Barcode reader, LS2208-SR
1000-21-00122	Grounding cable
095-002775-00	Recording paper, A4, 100 pages
095-002773-00	Recording paper, A4, 150 pages
095-002776-00	Recording paper, Letter, 100 pages
095-002774-00	Recording paper, Letter, 150 pages
023-000217-00	USB memory, 4GB, Transcend
023-000218-00	USB memory, 4GB, Apacer
DA8K-10-14452	Power cord, American
DA8K-10-14453	Power cord, UK
DA8K-10-14454	Power cord, European
0000-10-10903	Power cord, Indian
009-001791-00	Power cord, South African
0000-10-10775	Conductive gel
049-000739-00	Keyboard protector

A Product Specifications

A.1 Classifications

According to IEC60601-1, the equipment is classified as follows:

Type of protection against electrical shock	CLASS I EQUIPMENT, equipment energized from an external and internal electrical power source.
Degree of protection against electrical shock	DEFIBRILLATION-PROOF TYPE CF AAPPLIED PART
Mode of operation	CONTINUOUS OPERATION
Degree of protection against harmful ingress of water	IPX0, non-protected against ingress of liquid
Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
Degree of mobility	Portable

A.2 Environmental Specifications

	Temperature (°C)	Relative humidity (noncondensing)	Barometric (kPa)
Operating conditions	0-40	15%-95%	57.0-107.4
Storage conditions	–20- + 60	10%-95%	16.0-107.4

A.3 Power Supply Specifications

AC power

Input voltage	100-240V ~ (±10%)
Input power	100 VA
Frequency	50 Hz/60 Hz (±3 Hz)

Battery

Battery type	Rechargeable lithium-ion battery, 4500 mAh, 11.1 V
Run time	For equipment in standard configure and with default setting, when powered by a new fully-charged battery and at ambient temperature 25 °C±5 °C: ≥400 auto reports, or no less than one hour of continuous paper recording, or no less than 3.5 hours of paperless recording
Charge time	With the equipment power off: ≤6 h to 90% capacity ≤7 h to 100% capacity
Shutdown delay	at least 5 minutes after the low battery message first occurs

A.4 Physical Specifications

Weight	Size (Length × Width × Height)
4.8 kg, including the main unit, battery, and thermal recorder, excluding recording paper and other accessories	305 mm × 365 mm × 128 mm

A.5 Hardware Specifications

A.5.1 Display

Screen type	Color LCD with LED backlight
Screen Size	8 inches
Resolution	800 × 480 pixels

A.5.2 Equipment Connector

Patient cable connector	One, connects patient cable for ECG acquisition
USB connector	Two, connects the USB drive, external printer or barcode reader
Network connector	One standard RJ45 connector for LAN, connects the equipment to the network for data transmission and software upgrade
	One standard RJ45 connector for Wi-Fi , connects the equipment to the network for data transmission

A.5.3 Indicators

Power indicator	1 (green)
AC indictor	1 (green)
Battery indictor	1 (two colors: yellow and green)

A.5.4 Audio Indicator

Sounder	Gives notification tone, heartbeat tone, and power-on self-check tone

A.5.5 Recorder

Recorder type	Build-in thermal recorder
Number of waveform channels	Max. 12
Paper speed	5 mm/s, 12.5 mm/s, 25mm/s, 50 mm/s Accuracy: ±5%
Recording paper	Z-fold Paper size: A4 or US Letter
Resolution	Vertical resolution: ≥8 dots/mm Horizontal resolution: 40 dots/mm (with paper speed 25 mm/s)

A.6 System Specifications

Boot time	≤7 s

A.7 Wireless Network

Protocol	IEEE 802.11a/b/g/n
Modulation mode	BPSK, QPSK, 16-QAM, 64-QAM
Operating frequency	IEEE 802.11b/g/n (2.4G): 2.4GHz to 2.495GHz IEEE 802.11a/n (5G): 5.15GHz to 5.25GHz, 5.725GHz to 5.85GHz
Wireless baud rate	IEEE 802.11a: 6 Mbps to 54 Mbps IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 72.2 Mbps
Output power	<20dBm (CE requirement, detection mode: RMS) <30dBm (FCC requirement: detection mode: peak power)
Operating mode	Infrastructure
Data security	Standards: WPA-PSK, WPA2-PSK, WPA-Enterprise,WPA2-Enterprise EAP method: EAP-FAST. EAP-TLS, EAP-TTLS, PEAP-GTC, PEAP- MSCHAPv2, PEAP-TLS, LEAP Encryption: TKIP, AES

A.8 Measurement Specifications

ECG	
Standards	EC11, IEC 60601-2-51
Measurement mode	Auto, manual, rhythm
Lead type	12-lead
ECG standard	AHA, IEC
ECG size	2.5 mm/mV (× 0.25), 5 mm/mV (× 0.5), 10 mm/mV (× 1), 20 mm/mV (× 2), Auto, L=10 C=5, L=20 C=10 Accuracy: ±5%
Sweep speed	5 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s Accuracy: ≤±5%
Baseline drift removal (BDR)	0.56 Hz
Muscle artifact filter	20/35 Hz
Frequency response	0.05 Hz-150 Hz ($^{+0.4dB}_{-3.0dB}$)
Accuracy of input signal reproduction	Overall system error is tested using the method described in AAMI EC11 3.2.7.1. Overall system error is±5%. Frequency response is tested using the method described in AAMI EC11 3.2.7.2 methods A and D.

Common mode rejection ratio	≥110 dB
AC filter	50/60 Hz
ECG sampling rate	1 kHz (A/D) Accuracy: 1μV/LSB
Pacer detection sampling rate	16 kHz/channel, two channels
Input signal range	±10 mV (peak-to-peak value)
Input impedance	≥50 MΩ @10 Hz, any two electrodes
DC offset voltage range	±600 mV, Sensitivity: ±5%
Defibrillation proof	5000 V, 360 J
Baseline recovery time	<5 s after defibrillation
Electrode polarization recovery time	<10 s
Defibrillation energy reduction	≤10% (100Ω load)
Calibration signal	1 mV Accuracy: ±5%
Noise level	≤15 μV (p-p)
AC overload protection	Apply for 10 seconds. The equipment meets the requirements of EC11 after a 10-second application of 50Hz/60Hz, 1Vp-p differential voltage.
Channel crosstalk	≤0.5mm at normal sensitivity
Lead-off detection current	Measuring electrode: ≤0.1 μA Drive electrode: ≤1 μA
Minimum signal	10Hz sinusoidal signal, with 20μVp-p deflection
Baseline stability	Baseline drift ≤1 mm Average baseline drift ≤0.5mm/°C within operation temperature range
Pace pulse	
PACE pulse markers	Pace pulses meeting the following conditions are labelled with a PACE mark: Amplitude: ±2 mV - ±250 mV Width: 0.1 ms - 2 ms Rise time: < 100 μs
	Amplitude: ≥0.2 mV RTI
Resting 12-lead ECG analysis	
Method	12 lead simultaneous analysis
Interpretation algorithm	Glasgow 12-lead resting ECG interpretive program
Applicable patient	Adult, pediatric, neonate
Measurements	Vent. Rate (bpm), PR Interval (ms), QRS Duration (ms), QT/QTc Interval (ms), P/QRS/T Axes (°)

B EMC and Radio Regulatory Compliance

B.1 EMC

BeneHeart R12/BeneHeart R12A meets the requirements of IEC 60601-1-2: 2014. All the accessories listed in ***12 Accessories*** also meet the requirements of IEC 60601-1-2: 2014 when in use with BeneHeart R12/BeneHeart R12A.

⚠ WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of BeneHeart R12/BeneHeart R12A could result in increased electromagnetic emissions or decreased electromagnetic immunity of BeneHeart R12/BeneHeart R12A and result in improper operation.**
- **Use of BeneHeart R12/BeneHeart R12A adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, BeneHeart R12/BeneHeart R12A 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 BeneHeart R12/BeneHeart R12A, including cables specified by the manufacturer. Otherwise, degradation of the performance of BeneHeart R12/BeneHeart R12A could result.**
- **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
- **BeneHeart R12/BeneHeart R12A is intended for use in professional healthcare facility environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**

Guidance and Declaration - Electromagnetic Emissions		
BeneHeart R12/BeneHeart R12A is intended for use in the electromagnetic environment specified below. The customer or the user of BeneHeart R12/BeneHeart R12A should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
Conducted and radiated RF EMISSIONS CISPR 11	Group 1	BeneHeart R12/BeneHeart R12A 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 device.
Conducted and radiated RF EMISSIONS CISPR 11	Class A	BeneHeart R12/BeneHeart R12A is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC 61000-3-2	Class A	BeneHeart R12/BeneHeart R12A 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.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

Note

- **BeneHeart R12/BeneHeart R12A needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided above.**
- **Other devices may affect BeneHeart R12/BeneHeart R12A 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.**
- **The EMISSIONS characteristics of BeneHeart R12/BeneHeart R12A make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) BeneHeart R12/BeneHeart R12A might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting BeneHeart R12/BeneHeart R12A.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the monitor and contact the service personnel.**

If BeneHeart R12/BeneHeart R12A is operated within the electromagnetic environment listed in Table **Guidance and Declaration —Electromagnetic Immunity**, the system will remain safe and provide the following essential performance:

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

Guidance and Declaration - Electromagnetic Immunity			
BeneHeart R12/BeneHeart R12A is intended for use in the electromagnetic environment specified below. The customer or the user of BeneHeart R12/BeneHeart R12A should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
BeneHeart R12/BeneHeart R12A is intended for use in the specified electromagnetic environment. The customer or the user of BeneHeart R12/BeneHeart R12A should assure that it is used in such an environment as described below.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted disturbances induced by RF fields IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of BeneHeart R12/BeneHeart R12A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the
	6 Vrms in ISM bands[a] between 0,15 MHz and 80 MHz	6 Vrms	

<table>
<tr><td>Radiated RF
IEC61000-4-3</td><td>3V/m
80 MHz to 2.7 GHz</td><td>3V/m</td><td rowspan="4">transmitter. Recommended separation distance:
$d = \left[\frac{3.5}{V}\right]\sqrt{P}$ 150k to 80 MHz
$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E}\right]\sqrt{P}$ 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).
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:  .</td></tr>
<tr><td>Radiated RF EM fields
IEC61000-4-3</td><td>3V/m
80 MHz to 2.7 GHz</td><td>3V/m</td></tr>
<tr><td rowspan="3">Proximity fields from RF wireless communications equipment
IEC61000-4-3</td><td>27 V/m
380–390 MHz</td><td>27 V/m</td></tr>
<tr><td>28 V/m
430–470 MHz,
800–960 MHz,
1700–1990 MHz,
2400–2570 MHz</td><td>28 V/m</td></tr>
<tr><td>9 V/m
704–787 MHz,
5100–5800 MHz</td><td>9 V/m</td></tr>
<tr><td colspan="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.</td></tr>
<tr><td colspan="4">[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 BeneHeart R12/BeneHeart R12A is used exceeds the applicable RF compliance level above, BeneHeart R12/BeneHeart R12A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating BeneHeart R12/BeneHeart R12A.
[c] Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.</td></tr>
</table>

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 BeneHeart R12/BeneHeart R12A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BeneHeart R12/BeneHeart R12A 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 $d = \left[\frac{3.5}{V}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	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.			

B.2 Radio Regulatory Compliance

RF parameters

Type of Radio	**IEEE 802.11b/g/n (2.4G)**	**IEEE 802.11a/n (5G)**
Operating frequency	2.4 GHz to 2.495GHz ETSI: 2.4GHz to 2.4835GHz FCC: 2.4GHz to 2.4835GHz (channel1-11) MIC (Japan): 2.4GHz to 2.495GHz	5.15GHz~5.85GHz ETSI: 5.15GHz to 5.35GHz, 5.47GHz to 5.725GHz FCC: 5.15GHz to 5.35GHz, 5.47GHz to 5.725GHz, 5.725GHz to 5.82GHz MIC (Japan): 5.15GHz to 5.35GHz, 5.47GHz to 5.725GHz
Modulation mode	BPSK, QPSK, 16-QAM, 64-QAM	BPSK, QPSK, 16-QAM, 64-QAM
Output power	< 30 dBm (Peak Power) < 20 dBm (Average Power)	

CE

BeneHeart R12/BeneHeart R12A comply with the essential requirements and other relevant provisions of Directive 2014/53/EU.

⚠ WARNING

- **Keep a distance of at least 20cm away from BeneHeart R12/BeneHeart R12A when Wi-Fi function is in use.**

B.3 Cable Information

No.	Name	Cable Length	Cable Shielded
1.	Power input	2.5m	N
2.	ECG cable	3.3m	N
3.	Scanner cable	1.5m	N

C Symbols and Abbreviations

C.1 Units

µA	microampere
µV	microvolt
µs	Microsecond
A	ampere
Ah	ampere hour
bpm	beat per minute
bps	bit per second
°C	centigrade
cm	centimeter
dB	decibel
°F	fahrenheit
g	gram
GHz	gigahertz
h	hour
Hz	hertz
in	inch
k	kilo
kg	kilogram
kPa	kilopascal
L	litre
m	meter
mAh	milliampere hour
Mb	mega byte
mg	milligram
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeters of mercury

ms	millisecond
mV	millivolt
mW	milliwatt
MΩ	megaohm
s	second
V	volt
VA	volt ampere
Ω	ohm
W	watt

C.2 Symbols

–	Minus sign, negative, or hyphen
%	percent
/	per; divide; or
+	plus or positive
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

C.3 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
AHA	American Heart Association
ANSI	American National Standard Institute
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
CCU	cardiac (coronary) care unit
CE	Conformité Européenne
CIS	clinical information system
CISPR	International Special Committee on Radio Interference
CMS	central monitoring system
DC	direct current
ECG	electrocardiograph
EEC	European Economic Community
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ESU	electrosurgical unit
FCC	Federal Communication Commission
FDA	Food and Drug Administration
HIS	hospital information system
ICU	intensive care unit
ID	identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IP	internet protocol
LA	left arm
LAN	local area network
LCD	liquid crystal display
LED	light emitting diode
LL	left leg
MDD	Medical Device Directive

MR	magnetic resonance
MRI	magnetic resonance imaging
N/A	not applied
R	right
RA	right arm
RAM	random access memory
RL	right leg
SSID	service set identifier
UPS	uninterruptible power supply
USB	universal serial bus
VAC	volts alternating current
WLAN	wireless local area network

D Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe such as Fluke, Metron, or Gerb may require modifications to the procedure. Follow the instructions of the analyzer manufacturer.

The electrical safety inspection should be periodically performed every two years. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

D.1 Power Cord Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

D.2 Device Enclosure and Accessories

D.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

D.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

D.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

D.4 Protective Earth Resistance

1. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
2. Test the earth resistance with a current of 25 A.
3. Verify the resistance is less than limits.

LIMITS

ALL COUNTRIES R = 0.2 Ω Maximum

D.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test.

- normal polarity(Normal Condition),
- reverse polarity(Normal Condition),
- normal polarity with open neutral(Single Fault Condition),
- reverse polarity with open neutral(Single Fault Condition)

LIMITS

For UL60601-1,

- 300 μA in Normal Condition
- 1000 μA in Single Fault Condition

For IEC60601-1,

- 500 μA in Normal Condition
- 1000 μA in Single Fault Condition

D.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity(Normal Condition);
- reverse polarity(Normal Condition),
- normal polarity with open neutral(Single Fault Condition);
- reverse polarity with open neutral(Single Fault Condition).
- normal polarity with open earth(Single Fault Condition);
- reverse polarity with open earth(Single Fault Condition).

LIMITS

For CF  applied parts

- 10μA in Normal Condition
- 50μA in Single Fault Condition

D.7 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity

LIMITS

- For CF applied parts: 50 µA

D.8 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connector s. All measurements may have a true RMS only response.

The following outlet conditions apply when performing the Patient Auxiliary Current test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition);
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition).
- normal polarity with open earth (Single Fault Condition);
- reverse polarity with open earth (Single Fault Condition).

LIMITS

For CF applied parts,

- 10µA in Normal Condition
- 50µA in Single Fault Condition

NOTE

- **Make sure the safety analyzer is authorized comply with requirement of IEC60601-1.**
- **Follow the instructions of the analyzer manufacturer.**

E Declaration of Conformity

Declaration of Conformity-V3.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Electrocardiograph (Including Accessories)
Model:	BeneHeart R12/BeneHeart R12A

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

☒ EN 60601-1:2006/A1:2013	☒ IEC 60601-1-2: 2014
☒ EN 62311:2008	☒ ETSI EN 301 489-1 V2.2.3
☒ ETSI EN 301 489-17 V3.2.0	☒ EN 300 328 V2.1.1
☒ ETSI EN 301 893 V2.1.1	

Start of CE-Marking:	**2017-6-13**
Place, Date of Issue:	Shenzhen
Signature:	Guan Zhiyong, 2020.3.9
Name of Authorized Signatory:	Mr. Guan Zhiyong
Position Held in Company:	General Manager, Central R&D Department

FOR YOUR NOTES

P/N: 046-004836-00(14.0)