BeneHeart R3/BeneHeart R3A

Electrocardiograph

Operator's Manual

CE 0123

For this Operator's Manual, the issue date is April 2015.

⚠ WARNING

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

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

WARNING

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

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- Others not caused by instrument or part itself.

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Preface

Manual Purpose

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

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

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

Intended Audience

This manual is geared for clinical professionals who are expected to have 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 in this manual to quote the referenced chapters or sections.
- [ ] is used to enclose screen texts.
- → is used to indicate operational procedures.

Contents

1 Safety

1.1 Safety Information

⚠ DANGER

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

⚠ WARNING

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

⚠ CAUTION

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

NOTE

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

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific "Danger" statements may be given in the respective sections of this manual.

1.1.2 Warnings

⚠ WARNINGS

- **This equipment is used for 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.**
- **The equipment must be connected to a properly installed power outlet with protective earth contacts only. 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 to be in use with high frequency surgical units.**
- **Do not come into contact with patients 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 risk of entanglement or strangulation by patients or personnel.**
- **Properly dispose of the package material according to applicable waste control regulations and keeping it out of children's reach.**

1.1.3 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.**

1.1.4 Notes

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 obtained conveniently 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. Your equipment may not have all of them.**

1.2 Equipment Symbols

	Caution (Attention, consult accompanying documents)		ON/OFF for part of equipment
	Battery indicator		Alternating current (AC)
	DEFIBRILLATION-PROOF TYPE CF APPLIED PART		Equipotentiality
	Network connector		USB connector
	DATE OF MANUAFACTURE		Serial number
	Dispose of in accordance to your country's requirements		Environment-friendly Used Period per Chinese Standard SJ/T11363-2006
	Authorized representative in the European Community		China Metrology Certification
	Manufacturer		
	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.		

NOTE

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

2 The Basics

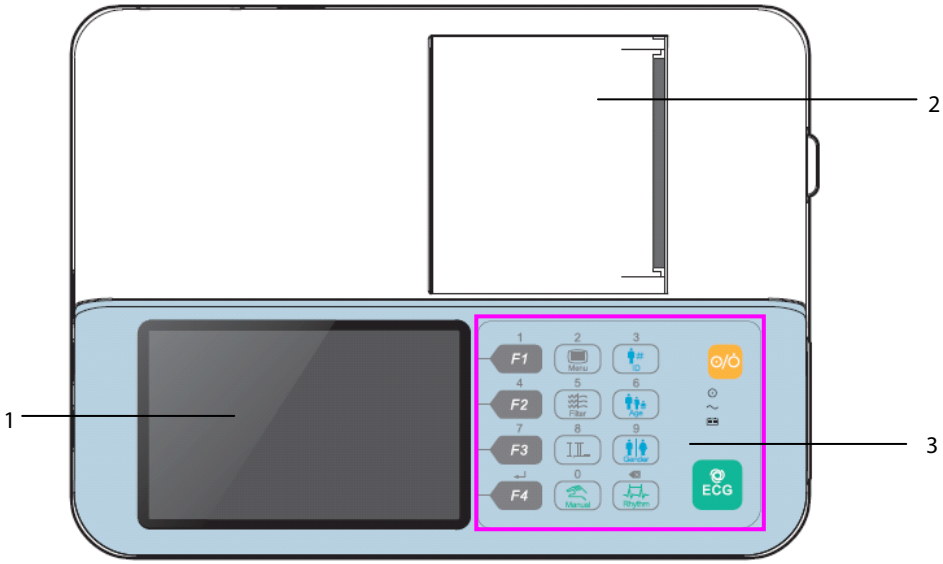
2.1 Intended Use

BeneHeart R3/ BeneHeart R3A Electrocardiograph (hereafter referred to as "the equipment" or "the system") is intended to acquire, analyze, display, store, and record the patient's electrocardiographic information 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 Main Unit

2.2.1 Front View

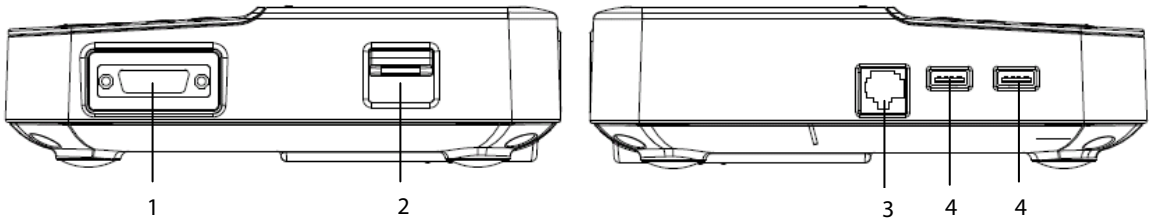


1. Display screen: presents waveforms and texts
2. Recorder: print reports
3. Operating panel: see the table below for details

Key	Function
F1 (Numerical key "1")	Function key, select the option that appears at the right side of the screen. In numeric keypad mode, enter the number "1".
F2 (Numerical key "4")	Function key, select the option that appears at the right side of the screen. In numeric keypad mode, enter the number "4".
F3 (Numerical key "7")	Function key, select the option that appears at the right side of the screen. In numeric keypad mode, enter the number "7".
F4 (Enter key)	Function key, select the option that appears at the right side of the screen. In numeric keypad mode, confirm the input or selection.
 Menu (Numerical key "2")	Access the main menu. Exit the menu when a menu is opened. In numeric keypad mode, enter the number "2".
 Filter (Numerical key "5")	Switch the frequency of muscle artifact filter. In numeric keypad mode, enter the number "5".
 (Numerical key "8")	Switch the leads to be recorded in manual measurement mode. In numeric keypad mode, enter the number "8".
 Manual (Numerical key "0")	Start recording real-time ECG report. Stop recording. In numeric keypad mode, enter the number "0".
 ID (Numerical key "3")	Press this key, and then press numeric keys to enter patient's ID. When [**Detailed Patient Info**] is enabled, enter the Patient Info menu. In numeric keypad mode, enter the number "3".
 Age (Numerical key "6")	Press this key, and then press numeric keys to enter patient's age. When [**Detailed Patient Info**] is enabled, press this key to enter the Patient Info menu. In numeric keypad mode, enter the number "6".
 Gender (Numerical key "9")	Switch patient's gender. When [**Detailed Patient Info**] is enabled, enter the Patient Info menu. In numeric keypad mode, enter the number "9".
 Rhythm (Backspace)	Record a rhythm report. Stop recording. In numeric keypad mode, delete characters.
	Power on/off switch Turn on the equipment. Turn off the equipment by pressing and holding this key for 0.5 second. Forcefully shut down the equipment by pressing and holding this key for 10 seconds when it could not be shut down normally or under some special situations.
 ECG	Start recording auto ECG report. Stop recording.

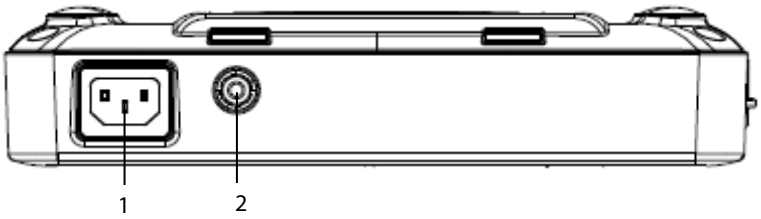
Indicator	Description
⊙	Power indicator On: when the equipment is powered on. Off: when the equipment is powered off.
- +	Battery indicator Green: when the equipment operates on battery power or the battery is being charged. Yellow: when the equipment operates on battery power and the battery is low. Yellow, 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 AC mains is connected. Off: when AC mains is not connected.

2.2.2 Side View



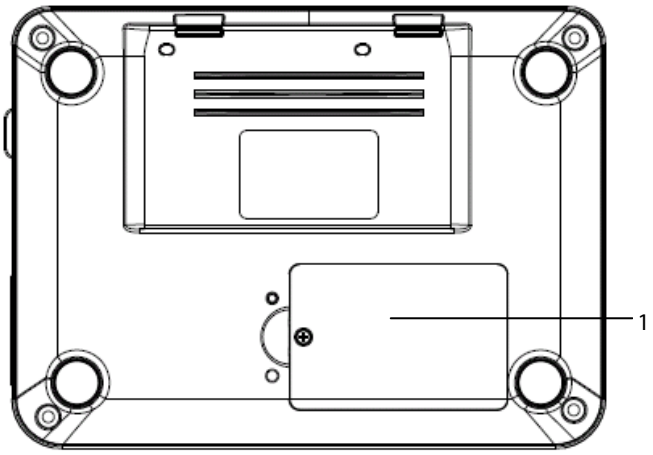
1. Patient cable connector: connects the patient cable for ECG acquisition
2. Recorder door latch: opens the recorder door
3. Network connector: connects the equipment to the network for software upgrade
4. USB connector: connects USB disc for data transfer

2.2.3 Back View



1. AC power input
2. Equipotential Grounding Terminal: When the equipment and other devices are to be used together, their equipotential grounding terminals should be connected together to eliminate the potential difference between them.

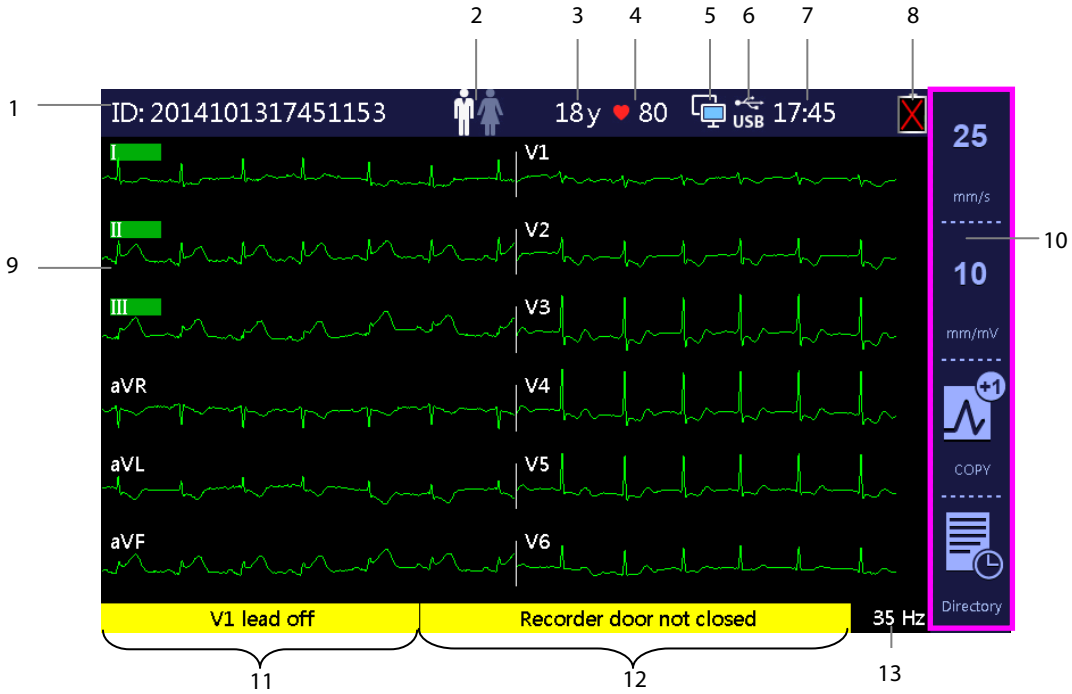
2.2.4 Bottom View



1. Battery compartment

2.3 Display Screen

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

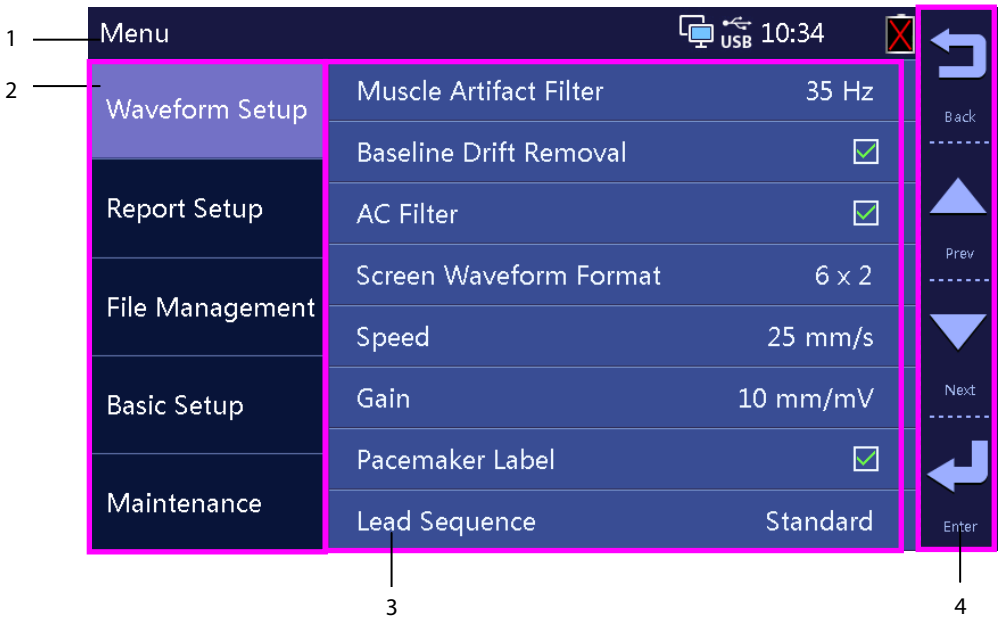
   If successfully connected,  is displayed. If not, this area is left blank.

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 labels of Function Keys located rightwards.
11. Message area 1: displays lead off and noise information.
12. Message area 2: displays messages except lead off and noise.
13. Muscle artifact filter setting: displays the setting of muscle artifact filter. If the filter is disabled, the display is 150Hz.

Main Menu



1. Heading: shows system information
2. Options of main menu
3. Options of submenu
4. Function Key labels area
   - Pressing F1 returns to previous menu.
   - Pressing F2 and F3 selects the previous or next option, or toggles between settings when an option is selected.
   - Pressing F4 confirms the selection.

2.4 Operating Mode

2.4.1 Normal Mode

The equipment enters Normal Mode after being turned on.

In Normal Mode, you can acquire the patient's electrocardiographic information, record ECG waveforms, measurements, and diagnoses. You can also perform system setup and export data.

2.4.2 Standby Mode

In the case that any of the limb leads is detached, the equipment automatically enters Standby Mode if there is no operation within the defined time.

To set the time,

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

In Standby Mode, the screen is off. This helps reduce power consumption and extend the life of the equipment.
To returns to Normal Mode, press any key.

2.4.3 Demo Mode

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

To enter Demo Mode,

1. Press the [**Menu**] key to enter the main menu.
2. Select [**Maintenance**] →enter the required password→[**Demo Mode 1**] or [**Demo Mode 2**].
3. Enter the password.

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

⚠ WARNING

- **The Demo mode is for demonstration purpose only. To avoid that the simulated data are mistaken for the measurements, you must not enter Demo mode during ECG acquisition.**

2.4.4 Maintenance Mode

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

FOR YOUR NOTES

3 Basic Operations

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 juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1-1 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 60601-1-1. 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 within the patient environment.
The operating environment of the equipment must meet the requirements specified in this manual.

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

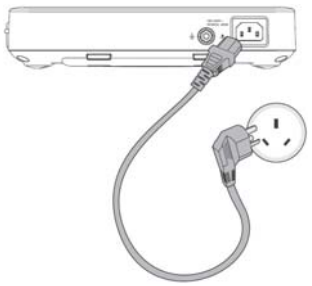
NOTES

- **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 obtained conveniently when needed.**

3.2 Getting Started

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

3.2.1 Connecting AC Mains



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

⚠WARNING

- **Use only power cord we supplied.**
- **Where the integrity of the external protective conductor in the insatllation 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 a 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 be installed by service personnel trained and authorized by our company only. No battery is installed when the equipment leaves the factory. Please contact your service personnel to install the battery before the equipment is first put into use.

To prevent the data from losing 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.**

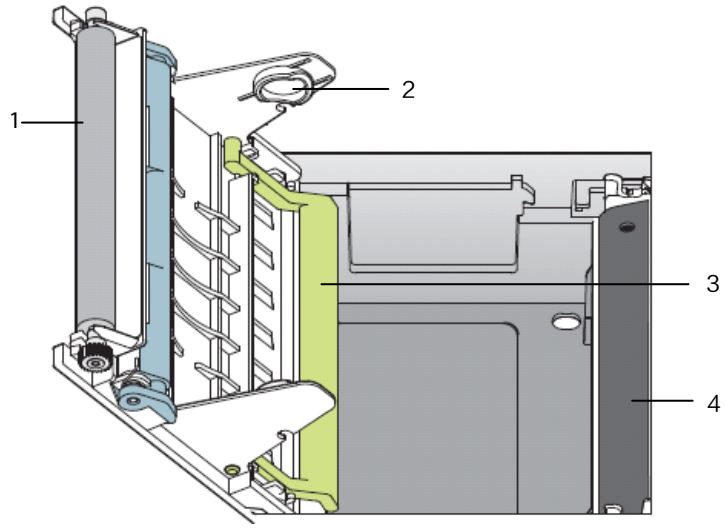
3.2.3 Loading Paper

Before printing ECG reports, ensure that thermal recording paper is loaded. The equipment supports both roll paper and Z-fold paper.

NOTE

- **The setting of [Paper Type] in the [Maintenance] Menu must correspond with the paper used.Otherwise, the system will prompt "Paper Type Error".**

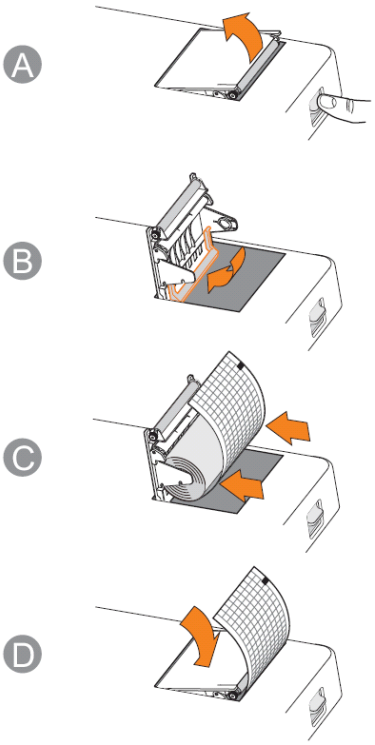
The picture below shows the inside of the recorder.



1. Platen
2. Paper roll holder
3. Paper jam protector (for Z-fold paper only)
4. Thermal print head

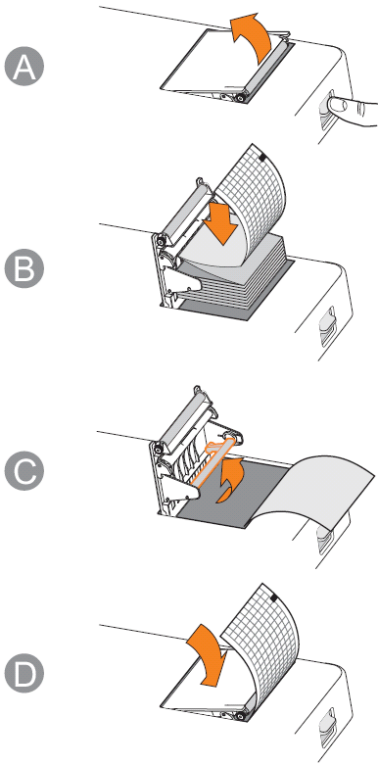
To load roll paper,

1. Press down the recorder door latch to open the recorder door.
2. Check that the paper jam protector is released from the little openings at the bottom of the paper roll holder.
3. Insert a new paper roll, with the print side (grid side) facing the thermal print head, into the paper roll holder on the recorder door.
4. Unroll the beginning of the paper and close the recorder door.
5. Overlap the unrolled paper on the recorder door. Make sure the grid side is facing up.
6. Check that [**Paper Type**] is set to [**Roll**] by selecting [**Menu**]→[**Maintenance**]→enter the required password.



To Load Z-fold paper,

1. Press down the recorder door latch to open the recorder door.
2. Place the Z-fold paper pack into the paper compartment.
3. Lift the paper jam protector and click it into the little openings at the bottom of the paper roll holder.
4. Unfold the first page of the Z-fold paper pack. Make sure the print side (grid side) faces the thermal print head. Close the recorder door.
5. Overlap the unfolded paper on the recorder door. Make sure the grid side is facing up.
6. Check that [**Paper Type**] is set to [**Z-Fold**] by selecting [**Menu**]→[**Maintenance**]→enter the required password..



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 mains power is used. Use only power socket that is properly grounded.

Check that a battery is installed and fully charged if battery is used.

- 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 to be in 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 on/off switch.

⚠ WARNING

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

3.2.8 Configuring the Equipment

Use the following procedures to configure your equipment before it first put into use.

1. Press the [**Menu**] 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 is finished.
2. Disconnect the electrodes from the patient.

Then press and hold the power on/off switch for approximately 0.5 second to turn off the equipment.

⚠ CAUTION

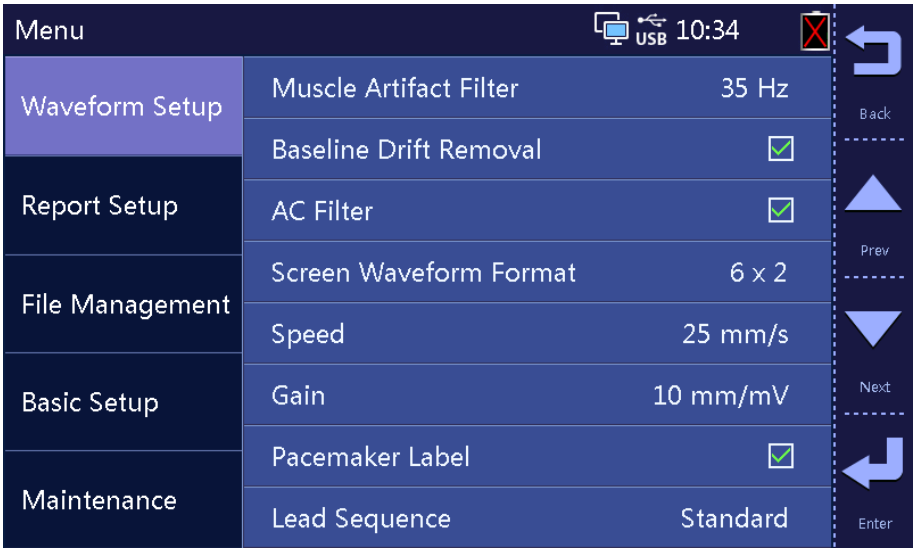
- **Although not recommended, you can press and hold the power on/off switch for 10 seconds to forcibly shut down the equipment when it could not be shut down normally or under some special situations. This may cause loss of data.**

4 System Setup

4.1 Accessing the Main Menu

1. Press the [**Menu**] key to access the main menu.
2. Press F2 or F3 to select the desired menu item.
3. Press F4 to confirm the selection.

You can return to previous menu by pressing F1.



In the main menu, you can

- Configure waveforms
- Configure recordings
- Manage files
- Customize patient information, and
- Perform system setup

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

4.2 Waveform Setup

Menu item	Option	Default	Description
Muscle Artifact Filter	20 Hz , 35 Hz, Off	35 Hz	Set the 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 will be displayed. Signals exceeds 35 Hz will be attenuated. [**20 Hz**]: Only signals at 20 Hz or less will be displayed. Signals exceeds 20 Hz will be attenuated. [**Off**]: Signals at 150 Hz or less will be displayed.
Baseline Drift Removal	Selected, not selected	Selected	Select BDR (baseline drift removal) process or 0.05-Hz filter. Selected: BDR is enabled. This process suppresses most baseline drift interference and also is able to preserve the fidelity of the ST-segment level. Not selected: BDR is disabled and the 0.05-Hz filter is used. **NOTE**: BDR or 0.05-Hz selection applies to 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	Select whether you want to filter electrical interference from AC line voltage. Selected: AC filter is enabled to filter electrical interference from AC line voltage. Not selected: AC filter is disabled. The AC filter should be on. Turn off only if necessary.
Screen Waveform Format	3×1, 6×2	6×2	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. [**6×2**]: displays 12-lead ECG waveforms in one page in two columns, with 6 lines in each column.
Speed	5 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	25 mm/s	Select default recording speed of ECG waveforms.

Menu item	Option	Default	Description
Gain	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, Auto	10 mm/mV	Select default amplitude of ECG signal. The measurement is in millimetre per millivolt. The larger the setting is, the larger the waveform size. However, only the appearance of the waveform changes. The signal strength is not affected. If [**Auto**] is selected, the system automatically selects the gain as per the amplitudes of ECG waves.
Pacemaker label	Selected, not selected	Selected	Choose whether you want to place a mark on each ECG waveform when a pace pulse is detected. Selected: A pace pulse mark "|" is placed on each ECG waveform when a pace pulse is detected. Not selected: No mark is placed when a pace pulse is detected.
Lead Sequence	Standard, Cabrera	Standard	Select ECG lead sequence for displaying and recording. [**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
Thermal Report Format	3×4, 3×4＋1, 3×4 Compact	3×4	Select the format of ECG report generated by auto measurement. [**3×4**]: ECG waveforms are displayed in 3 lines and 4 columns, followed by Median Complex, Measurement Matrix, measurements, and diagnoses, if enabled. [**3×4+1**]: [**3×4**] format plus a line of rhythm lead. If this option is selected, you cannot set [**Print Out Sequence**] to [**Simultaneous**]. [**3×4 Compact**]: The arrangement of ECG waveforms is the same with that of [**3×4**] format, but the measurements and diagnoses, if enabled, are above the waveforms. If this option is selected, Median Complex and Measurement Matrix will not be included in the ECG report even if enabled and you cannot set [**Print Out Sequence**] to [**Simultaneous**].
Standard Report Format	3×4+1, 6×2, 6×2+1, 12×1	3×4+1	Selects the format of standard ECG report generated by auto measurement. [**3×4+1**]: ECG waveforms are displayed in 3 lines and 4 columns. Additionally there is a rhythm lead at the bottom. [**6×2**]: 12-lead ECG waveforms are displayed in 6 lines and 2 columns [**6×2＋1**]: 12-lead ECG waveforms are displayed in 6 lines and 2 columns. Additionally there is a rhythm lead at the bottom. [**12×1**]: 12-lead ECG waveforms are displayed in 12 lines.

Menu item	Option	Default	Description
Printout Sequence	Sequential, Simultaneous	Sequential	Set the recording method of ECG report generated by auto measurement. [**Simultaneous**]: Record simultaneous 12-lead ECG data. [**Sequential**]: 12-lead ECG data are recorded sequentially and displayed in 3 lines and 4 columns with 2.5 seconds of ECG data for each column.
Printout Duration	2.5 s, 5 s, 7.5 s, 10 s	2.5 s	Set duration of ECG data to be recorded. This option is available only when [**Print Out Sequence**] is set to [**Simultaneous**].
Rhythm Lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	II	Select the lead to be recorded in the report generated by rhythm measurement.
Manual	1 Channel, 3 Channel	3 Channel	Set the number of channels to be recorded in the report generated by manual measurement. The recorded channel(s) are those highlighted on the screen. [**3 Channel**]: Simultaneously record three real-time ECG channels. [**1 Channel**]: Record one real-time ECG channel.
Paperless Recording	Selected, not selected	Not selected	Select whether you want to print ECG report during auto measurement. Selected: ECG report is not printed out. Not selected: The system automatically prints ECG report 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	In auto measurement mode, select whether the ECG data before or after the [**ECG**] key is pressed you want to record. Selected: The equipment records 10 seconds of ECG data before the [**ECG**] key is pressed. In the case that the equipment has not acquired 10 seconds of data when the [**ECG**] key is pressed, a message "ECG Data Insufficient" is shown at the bottom of the screen and the equipment will start recording till 10 seconds of ECG data has been acquired. Not selected: The equipment immediately start recording as soon as the [**ECG**] key is pressed.
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.

Menu item	Option	Default	Description
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	Select whether you want to include Median Complex as part of ECG report generated by auto measurement. Selected: Median Complex, which is displayed in 3x4+1 format with a median complex waveform for each lead and a lead II waveform of 10 seconds, is included in ECG report. Not selected: Median Complex is not included in ECG report.
Measurement Matrix	Selected, not selected	Not selected	Select whether you want to include Measurement Matrix as part of ECG report generated by auto measurement. Selected: 32 measurements for each lead are included in ECG report. 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 (μ V), P-amp (μ V), QRSp2p (μ V), Qamp (μ V), Ramp (μ V), Samp (μ V), R'amp (μ V), S'amp (μ V), STamp (μ V), 2/8STT (μ V), 3/8STT (μ V), T+amp (μ V), T-amp (μ V), QRSarea (μ V*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms). Not selected: Measurement Matrix is not included in ECG report.
Measurement	Selected, not selected	Selected	Select whether you want to include measurement result as part of ECG report generated by auto measurement. Selected: Measurement result, including Vent. Rate, PR Interval, QRS Duration, Qt/QTc Interval, P-QRS-T Axis, are included in ECG report. Not selected: Measurement result is not included in ECG report. **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	Select whether you want to include diagnoses as part of ECG report generated by auto measurement. Selected: The diagnoses interpreted by the ECG algorithm are included in ECG report. Not selected: The diagnoses are not included in ECG report.

Menu item	Option	Default	Description
Tachy	80-130	100	Set tachycardia threshold. Heart rate above the setting are labelled Tachycardia. Only apply to patients whose age exceeds180 days.
Brady	40-60	50	Set bradycardia threshold. Heart rate below the setting are labelled Bradycardia. Only for patients whose age exceeds 2191 days.
QTc Formula	Hodges, Bazett, Fridericia, Framingham	Hodges	Select 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.
Search by date	Year: 2012-2099 Month: 01-12 Day: 01-31	/	By selecting this option, and then setting start date and end date, you can find all the files that meet the search criteria.
Search by ID	/	/	By selecting this option and entering the desired ID, you can find all the files that meet the search criteria.

Menu item	Option	Default	Description
Auto Save	Selected, not selected	Selected	Select whether you want to save patient archive at the completion of each auto measurement. Selected: The equipment automatically saves patient archive at the completion of each auto measurement. Not selected: The equipment does not save patient archive.
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.
Delete The Oldest Report	Selected, not selected	Selected	Select whether you want the equipment automatically deletes the earliest patient archive when the memory of defined path is full. Selected: The system automatically deletes the earliest report when the memory is full. Not selected: When the memory at defined destination is full in the case [**Auto Save**] is enabled, the system will give a prompt and ask if you want to delete the earliest report and save the latest one.
File Format	Mindray, PDF, XML	PDF	Select the format of the report sent to the USB drive or the target FTP server. When set to [Mindray], the report will be sent to the FTP server in XML format.
PDF Grid	Selected, not selected	Selected	Select if there is a grid behind the waveforms on ECG report. Selected: There is a grid behind the waveforms and the footer. Not selected: There is no grid.
Record File List	/	/	Print a list of all patient archives stored in the directory.

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.
Brightness	1-5	3	Adjusts the display brightness. 1 is the dimmest; 5 is the brightest.

Menu item	Option	Default	Description
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***.
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 item	Option	Default	Description
Patient Info Required	Selected, not selected	Not selected	Choose whether entering patient information is compulsively required. Selected: You are required to enter patient information. The Patient Info menu pops up each time the [**ECG**] key is pressed to start auto measurement. Not selected: Patient information is not compulsory.
Detailed Patient Info	Selected, not selected	Not selected	Detailed patient information includes the patient's secondary ID, DOB, race, medication, class, V3 electrode placement, and department. You can edit detailed patient information only when this option is selected.
Secondary ID	Selected, not selected	Not selected	Selected: You can set the patient's secondary ID from the [**patient Info**] menu. Not selected: You cannot set the patient's secondary ID from the [**patient Info**] menu.

Menu item	Option	Default	Description
DOB	Selected, not selected	Selected	Selected: You can set the patient's date of birth from the [**patient Info**] menu. Not selected: You cannot set the patient's date of birth from the [**patient Info**] menu.
Race	Selected, not selected	Not selected	Selected: You can select the patient's race from the [**patient Info**] menu. Not selected: You cannot select the patient's race in the [**patient Info**] menu.
Medication	Selected, not selected	Not selected	Selected: You can select the medicine the patient has used from the [**patient Info**] menu. Not selected: You cannot select the medicine the patient has used in the [**patient Info**] menu.
Class	Selected, not selected	Not selected	Selected: You can select the patient's class from the [**patient Info**] menu. Not selected: You cannot select the patient's class from the [**patient Info**] menu.
V3 Electrode Placement	Selected, not selected	Not selected	Selected: You can select the patient's V3 placement from the [**patient Info**] menu. Not selected: You cannot select the patient's V3 placement from the [**patient Info**] menu.
Department	Selected, not selected	Not selected	Selected: You can set the patient's department from the [**patient Info**] menu. Not selected: You cannot set the patient's department from the [**patient Info**] menu.

4.6 Maintenance

Menu item	Option	Default	Description
Network Type	LAN, WLAN	LAN	Selects the type of network through which the equipment is connected.
Network Name (SSID)	/	/	When connects WLAN, enters the SSID.
Password	/	/	Enters the password to connect the WLAN.
IP Address	0-255	192.168.0.100	Set the equipment's IP address.
Subnet Mask	0-255	255.255.255.0	Set subnet mask.
Default Gateway	0-255	192.168.0.101	Set the default gateway's IP address.
Server IP Address	0 - 255	192.168.0.101	Enters the IP address of the FTP server.
FTP Communication Setup	/	/	Enters the **[FTP Communication Setup**] menu.

Menu item	Option	Default	Description
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	/	/	Restore the factory default configuration. Restoring factory defaults does not change the current setting of [**Language**].
Load Configuration	/	/	Import the configuration file stored in the USB memory into the equipment's internal memory.
Export Configuration	/	/	Export the configuration file stored in the equipment's internal memory to the USB memory.
Print Configuration	/	/	Print the current configuration.
Paper Type	Roll, Z-fold	Roll	Select currently used paper type.
Language	ENGLISH, SIM. CHINESE, FRENCH, GERMAN, ITALIAN, POLISH, SPANISH, PORTUGUESE, RUSSIAN, CZECH, TURKISH, HUNGARIAN, ROMANIAN	ENGLISH	Select 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	/	/	The equipment provides Maintenance Mode for service personnel to check and test the equipment. Maintenance Mode is password protected.

FTP Communication Setup

Menu item	Option	Default	Description
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, and Department. **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.

FOR YOUR NOTES

5 Patient Information

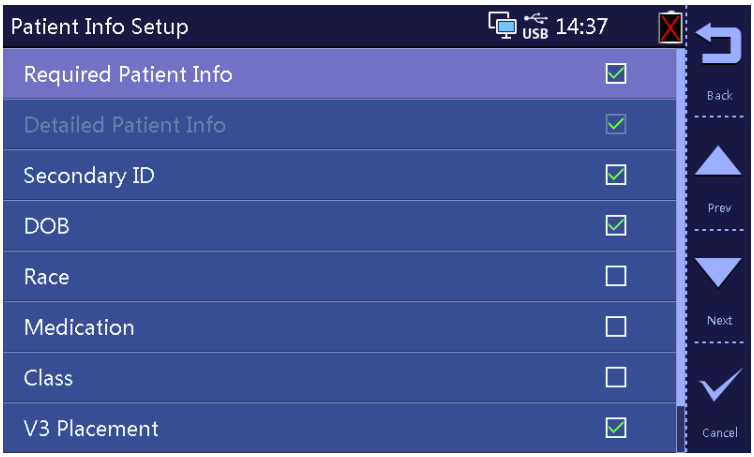
5.1 Setting Patient Information

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 basic information and detailed information. The basic information are those included in the [**Patient Info**] menu by default, including ID, name, gender and age. The detailed information helps you to know more about the patient.

You can follow the steps below to select the items to be included in the [**Patient Info**] menu, and whether to prompt the menu before each time performing ECG recording:

1. Press the [**Menu**] 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

You can quickly enter patient information by pressing the [**ID**] key, [**Age**] key, or [**Gender**] key. You can also enter patient information from the [**Patient Info**] screen when [**Detailed Patient Info**] is enabled, see ***4.5 Basic Setup***. If configured, you can also input the patient information with a barcode reader.

5.2.1 Quickly Entering Patient Information

Entering Patient ID

1. Press the [**ID**] key.
2. Enter the patient ID.
3. Press F4 to confirm the selection.

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.**

Entering the Patient's Age

1. Press the [**Age**] key.
2. Enter the patient's age.
3. Press F4 to confirm the selection.

Entering the Patient's Gender

Repeatedly press the [**Gender**] key to select the patient's gender.

5.2.2 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 F4 to save the patient information.

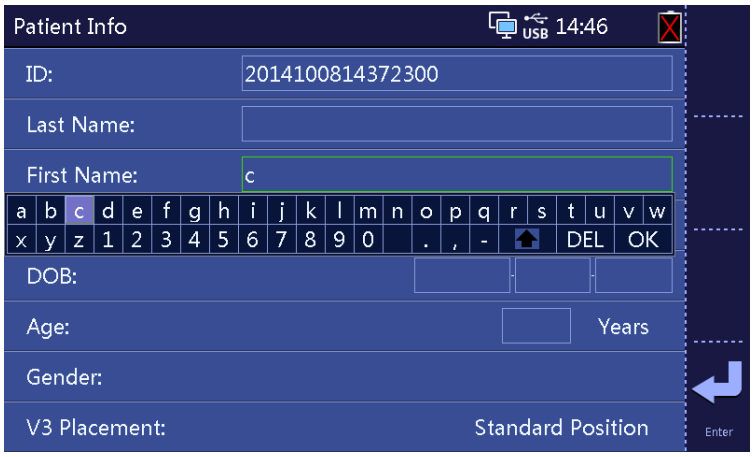
NOTE

- **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.**

5.2.3 Entering Patient Information from Patient Info Screen

You can also enter patient information from the [**Patient Info**] screen when [**Detailed Patient Info**] is enabled, see ***4.5 Basic Setup***.

1. Press the [**ID**] key, or [**Age**] key, or [**Gender**] key to access the [**Patient Info**] menu.
2. Input the information in the corresponding entry field.



NOTE

- **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 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.**

FOR YOUR NOTES

6 Patient Preparation

6.1 Relaxing a 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 the 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 aqcquisition of ECG signal.**

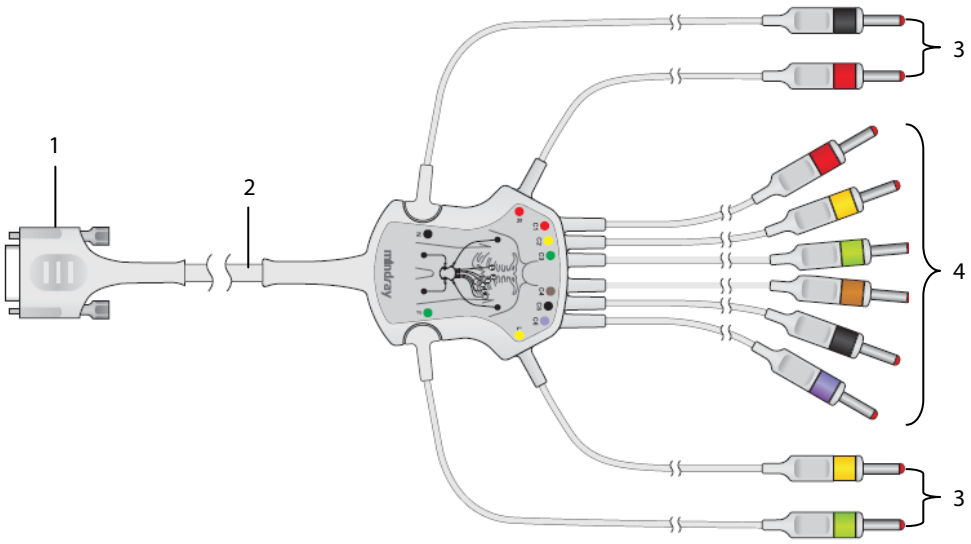
⚠CAUTION

- **Never mix patient electrode types or brands. Dissimilar metals or other incompatibilities may cause considerable baseline drift and may increase trace covery time after defibrillation.**
- **Do not reuse disposable electrodes. Reuse may cause a risk of contamination and affect measurement accuracy.**
- **Reusable electrodes shall be cleaned and disinfected before applying to the patient.**
- **Use disposable electrodes when the equipment is in use with a defibrillator.**

6.3.1 ECG Accessories

Patient Cable

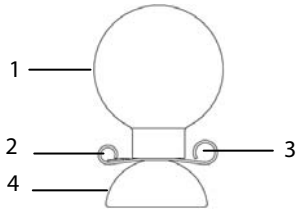
The patient cable consists of a connector, a trunk cable, 4 limb lead wires and 6 chest lead wires. The lead wires are colour-coded. Refer to ***6.4.3 Lead Wire Colour Code***.



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

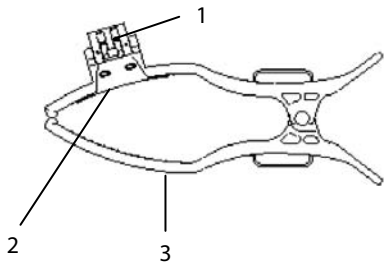
The chest electrode consists of a bulb and a metal electrode. On the metal electrode, there are two lead wire connectors, one for lead wire with Φ 3.0 mm connector, another for lead wire with Φ 4.0 mm connector.



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, another 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

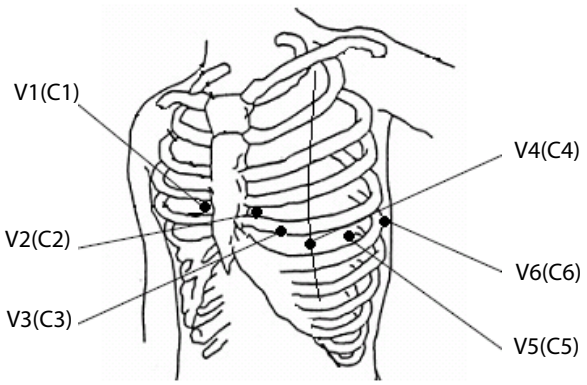
Respectively plug the limb lead wires into the lead wire connectors of the 4 limb electrodes. Adjust each lead wire to make sure the electrode and lead wire properly come into contact.

Note

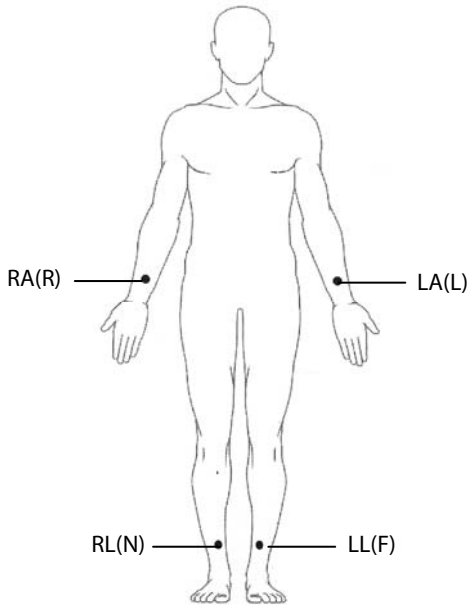
- **The limb electrodes are colour coded. Make use limb lead wire and limb electrode of the same colour are connected.**

6.4 Applying Electrodes

6.4.1 Electrode Placement



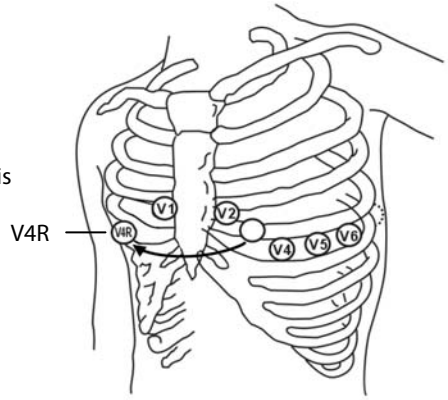
AHA	IEC	Electrode placement
V1	C1	Fourth intercostal space at the right sternal border
V2	C2	Fourth intercostal space at the left sternal border
V3	C3	Midway between V2 (C2) and V4 (C4) electrode positions
V4	C4	Fifth intercostal space at the left midclavicular line



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 sensor 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 Colour Code

Lead	IEC		AHA	
	Label	**Colour**	**Label**	**Colour**
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 colour. 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 bulb of the chest electrode contains latex, a material that can cause skin irritation. Monitor the elctrode 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 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 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 will prompt 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 will respectively prompt "LA Lead Off"("L Lead Off"), "LLead Off" ("F Lead Off"), or "RA Lead Off"("R Lead Off").
- When any of chest electrodes or leads is detached, the system will respectively prompt "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 will prompt "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 to be in use with high frequency surgical units.**
- **Do not come into contact with patients 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 the 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 risk of entanglement or strangulation by patients or personnel.**
- **The bulb of the chest electrode contains latex, a material that can cause skin irritation. Monitor the elctrode 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 Setting ECG Waveforms

In the normal screen,

- Repeatedly press F1 to select the current waveform speed.
- Repeatedly press F2 to select the current waveform gain.
- Press the [**Filter**] key to set the the current frequency of muscle artifact filter.
- Press the [**lead**] key to select the lead for manual recording.

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

7.2 Setting ECG Report

The contents and format of ECG report is configurable. Refer to ***4.3 Report Setup***.

7.3 Recording an ECG

7.3.1 Auto Measurement

In auto measurement mode, the equipment automatically acquires 10 seconds of 12-lead ECG, starts analyzing at the completion of ECG acquisition, and then prints ECG report as per system setup.

To start an auto measurement:

1. Prepare the patient as described in ***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 [**Menu**] → [**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:

- Press F1 to discard the report and return to the normal screen.
- Press F2 to send the report to the external device.
- Press F3 to print the report.
- Press F4 to display the next page of the report, if there is any.

The equipment automatically stops recording when the ECG report has been printed. You can also press F4 to interrupt printing.

7.3.2 Manual Measurement

In manual measurement mode, the equipment continuously records the ECG waveforms of selected lead(s) in real time. You can select the [**Lead**] key to switch the lead(s) to be recorded. The label(s) of selected lead(s) are highlighted with green background on the screen.

To generate a manual report:

1. Prepare the patient as described in ***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 [**Menu**] → [**Waveform Setup**] and [**Report Setup**].
6. Press the [**Manual**] key to start recording.
7. Press F4 to stop recording.

In manual measurement mode, you can press F3 to place a 1 mV square wave on the printout.

7.3.3 Rhythm Measurement

In rhythm measurement mode, the equipment acquires 60 seconds of 12-lead ECG and prints the waveforms of the rhythm lead. In the rhythm ECG report, ECG waveforms are displayed in 3 cascade lines, with each line including 10 seconds of waveforms.

You can change the lead to be recorded in the rhythm report by selecting [**Menu**] →[**Report Setup**]→[**Rhythm Lead**].

To generate a rhythm report:

1. Prepare the patient as described in ***6 Patient Preparation***.
2. Enter patient information as described in ***5.2 Entering Patient Information***.
3. Set the [**Rhythm lead**] by selecting **Menu** → [**Report Setup**].
4. Check other waveforms and report settings by selecting [**Menu**] → [**Waveform Setup**] and [**Report Setup**].
5. Press the [**Rhythm**] 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 mode automatically stops when the report is finished. You can also press the [**Rhythm**] 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 [**Menu**] → [**Report Setup**].

The equipment supports HP LaserJet P1606dn and LaserJet M401n.

Before printing a report, check that the paper is properly loaded. Refer to ***3.2.3 Loading 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 an Report

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

To print another copy of the latest auto or rhythm ECG report, press F3. You can copy the report using the current configuration, or you can also change the settings before printing another copy.

7.6 Saving Patient Report

If [**Auto Save**] is enabled from the [**File Management**] menu, the system will automatically create and save a patient archive at the completion of each auto measurement. You can search, send, review, print or delete historic patient archives. Refer to ***8.2 Managing Patient Archives*** for detail.

7.7 Resting 12-lead ECG Analysis

The equipment incorporates the University of Glasgow algorithm to provide an interpretation of the resting 12-lead ECG in all situations. The system 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 value, including
  - Consider Acute STEMI
  - Acute MI/Ischemia
  - Extreme Tachycardia
  - Extreme Bradycardia
  - Significant Arrhythmia
  - Prolonged QTc Interval
- Diagnoses
- Median Complexs

  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).

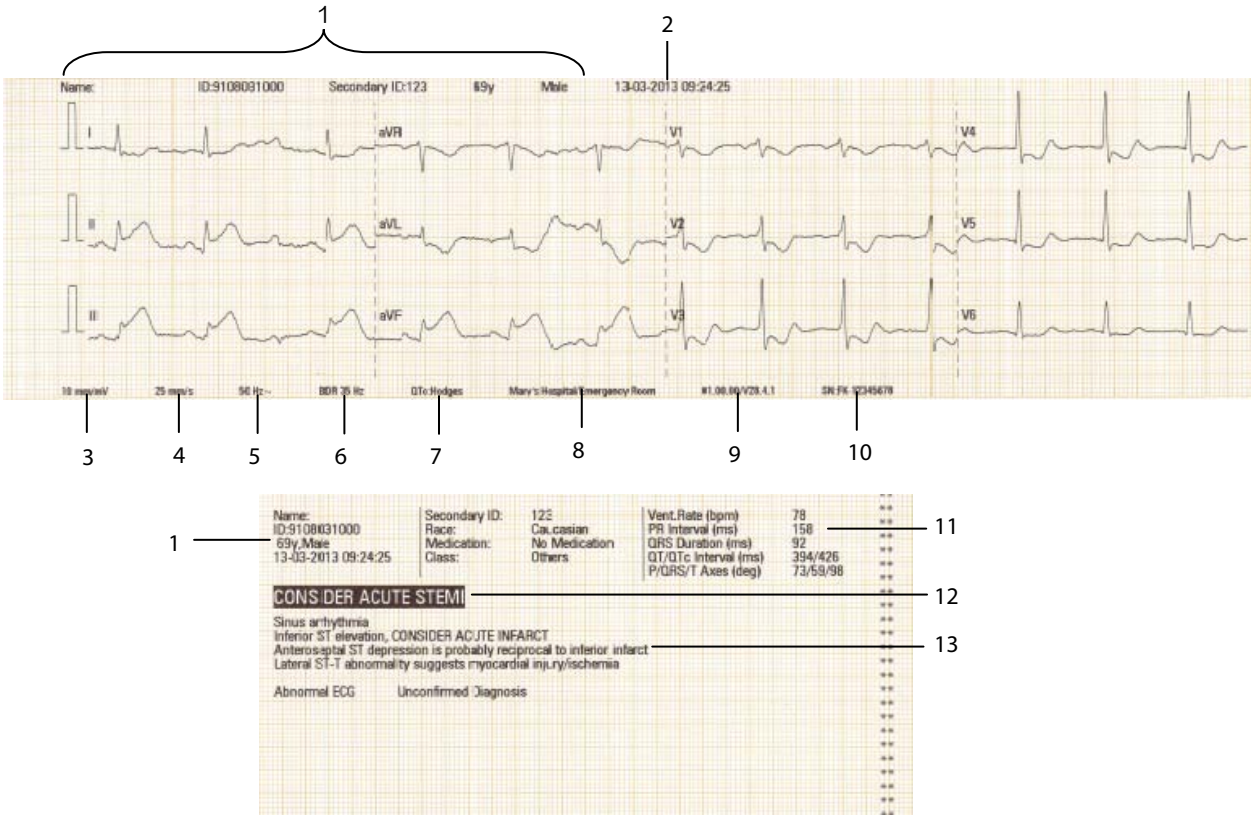
The diagnoses of 12-lead ECG analysis is included in the ECG report by default, see the setting of [**Interpretation**] as described in ***4.3 Report Setup***.

Resting 12-lead ECG analysis is not intended for the manual measurement mode and rhythm measurement mode. 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 ECG report are configurable. Refer to ***4.3 Report Setup*** for details.

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



1. Patient information
2. Time of acquisition
3. Gain
4. Paper speed
5. AC filter setting
6. Frequency range
7. QTc formula
8. Hospital/Department name

9. System software version/algorithm version
10. Equipment ID
11. Global measurements
12. Critical value
13. Diagnosis statement

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

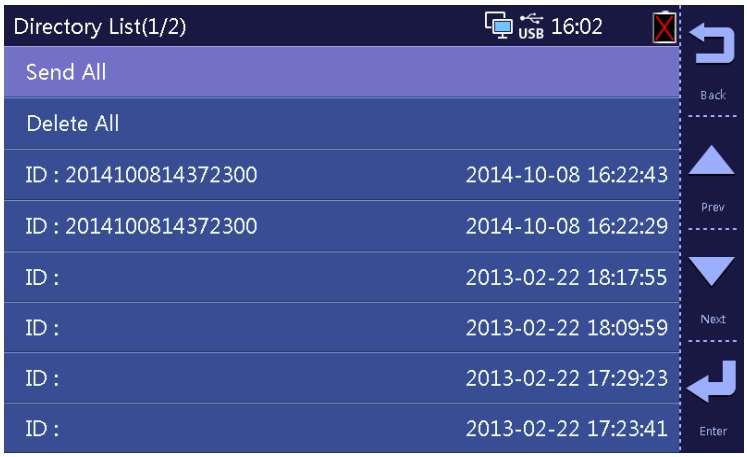
Refer to ***4.4 File Management*** for detail.

8.2 Managing Patient Archives

If you have enabled [**Auto Save**] in the [**File Management**] menu, the system automatically creates and saves a patient file at the completion of each auto measurement. You can search, review, export, delete and print historic archives.

8.2.1 Accessing the Directory Screen

In normal screen, press F4 to enter the Directory screen, in which all the patient archives are listed in time sequence with the latest on the top.



In the Directory screen, you can

- Select [**Send All**] to export all the files in the Directory list.
- Select [**Delete All**] to delete all the files in the Directory list.

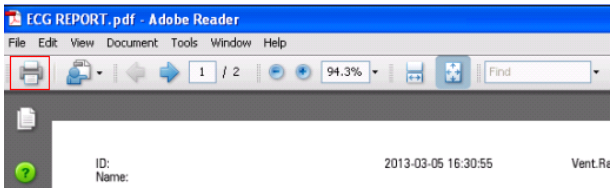
By selecting a file, you can

- Select F1 to return.
- Select F2 to delete this file.
- Select F3 to review this file.
- Select F4 to print this file as per the current configuration.

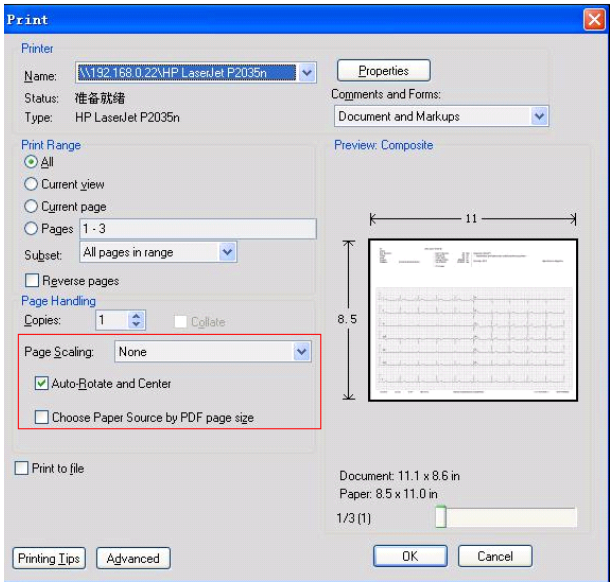
You can view the exported PDF format reports on a PC running a PDF reader. You can also print the exported reports.

When printing a PDF format ECG report, properly set the printer. Taking HP LaserJet P2035n as an example, follow this procedure to set the printer:

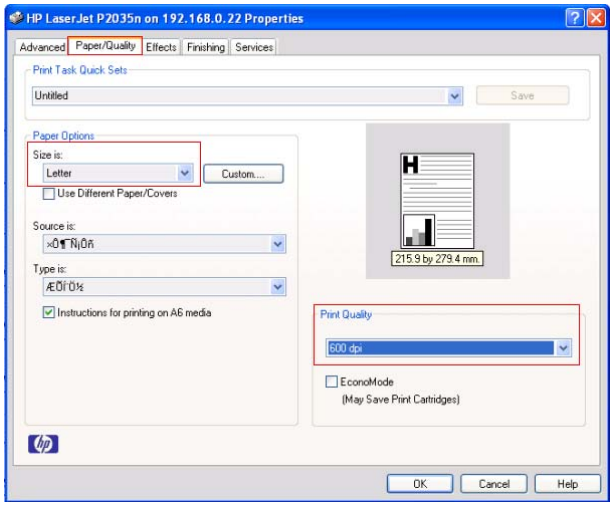
1. Open the PDF file to be printed through PDF reader.
2. Select the Print button on the tool bar, or select [**Files**]→[**Print (P)**] to access the [**Print**] menu.



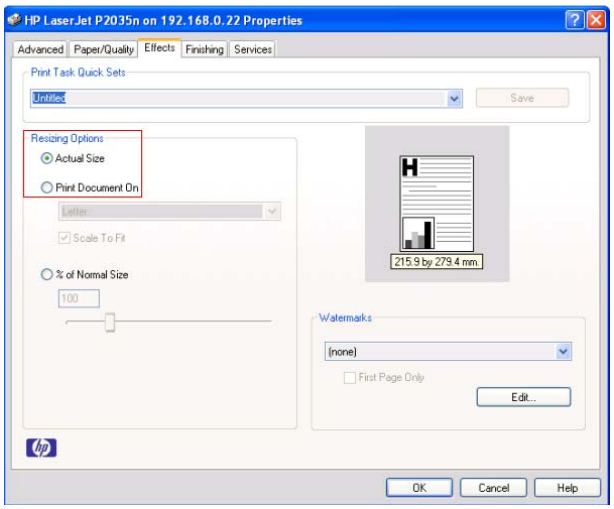
3. Set [**Page Scaling**] to [**None**], and enable [**Auto-Rotate and Center**].



4. Select the [**Properties**] button to access the Properties screen.
5. Select the [**Paper/Quality**] tab, and set paper size to [**Letter**] and [**Print Quality**] to [**600 dpi**].



6. Select the [**Effects**] tab, and select [**Actual Size**].



7. Select [**Ok**] to start printing.

We recommend that Adobe Reader 8.0 is used to open the PDF format ECG report.

8.2.2 Searching the Patient's Archives

The equipment has the function of searching patient archives. You can search the archives by date or by patient ID.

1. Press the [**Menu**] key to access the main menu.
2. Select [**File Management**]→[**Search by Date**] or [**Search by ID**].
3. Set search criteria.
   - ◆ If you select [**Search by Date**], set [**Start Date**] and [**End Date**].
   - ◆ If you select [**Search by ID**], enter the patient's ID or part of patient ID.
4. Select [**Search**] to start searching.

Then the system will find all the patient archives that meet the search criteria.

8.3 Managing Configuration

Select [**Menu**] →[**Maintenance**] → enter the required password→ [**System Setup**], you can:

- ■ Load configuration
- ■ Export configuration
- ■ Print configuration
- ■ Restore default configuration

8.3.1 Loading Configuration

You can import the configuration file stored in the USB memory into the equipment's internal memory.

1. Insert the USB memory storing the configuration file into the USB connector on the left side of the equipment.
2. Select [**Menu**]→[**Maintenance**]→[**Load Config**].
3. Follow the on-screen instructions.

8.3.2 Exporting Configuration

You can export the configuration file stored in the equipment's internal memory to a USB memory.

1. Insert a USB memory into the USB connector on the left side of the equipment.
2. Select [**Menu**]→[**Maintenance**]→[**Export Config**].
3. Follow the on-screen instructions.

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

  During auto measurement, the equipment automatically sends out the current report 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 manually 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, please contact your service personnel.

Symptom	Possible Cause	Corrective actions
The equipment does not power up.	1. The equipment is not connected to AC mains. 2. Battery is not installed or has no charge.	1. Check that the power cord is securely connected. 2. Check that the battery is installed and has sufficient charge. Otherwise, connect the equipment to AC mains to run the equipment and charge the battery.
ECG data displays unacceptable noise.	1. Patient movement. 2. Improper filter setting. 3. Poor skin preparation. 4. Electrode problem. 5. Patient cable problem. 6. Wrong accessories are used or mix electrode types and brands.	1. Tell the patient not to move during ECG acquisition. 2. Check the settings of the filters are appropriate. 3. Prepare the patient before ECG acquisition. 4. Verify the electrodes are applied correctly. Check for defective or expired electrodes. 5. Check for defective, broken or disconnected patient cable. 6. Use specified accessories. Do not mix electrode types or brands.
The recorder does not work.	1. Paperless recording is enabled. 2. Recording paper is not loaded. 3. Recorder door is not properly closed. 4. Print head is too hot. 5. Recorder is disabled due to depleted battery.	1. Select [**Menu**]→[**Report Setup**] and check [**Paperless Recording**]. 2. Verify recording paper is properly loaded. 3. Verify recorder door is properly closed. 4. Wait till the print head cools down. 5. Connect the equipment to AC mains to run the equipment and charge the battery.
Paper jammed or misaligned.	1. Unapproved paper is used. 2. Recording paper is not properly loaded.	1. Use approved recording paper. 2. Take out the paper and tear off the jammed part. Reload the paper as described in ***3.2.3 Loading Paper***.
Partially missing printout or printout not clear.	1. Dirty print head. 2. Some thermal points on print head are damaged.	1. Clean the print head. 2. If the problem persists, contact your service personnel.

Symptom	Possible Cause	Corrective actions
The equipment automatically shuts down.	1. Auto shutdown is enabled. 2. The battery is depleted when the equipment runs on battery power.	1. Check the setting of [**Auto Shut Down**] by selecting [**Menu**]→[**Basic Setup**]. In the case that any of limb leads is off, the equipment automatically shut down if there is no operation when the defined time is reached. 2. Connect the equipment to AC mains to run the equipment and charge the battery.
The display is completely blank.	Auto Standby is enabled.	In the case that any of limb leads is off, the equipment automatically turns off the display to save power if there is no operation when the defined time is reached. To exit the standby mode, press any key.
The screen display is too dark to be seen clearly.	The setting of brightness is low.	Adjust screen brightness.

9.2 Messages

The equipment prompts messages to indicate the current system status.

Some messages, see **Message List 1**, are more 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 messages or wait till the triggers disappear.

Some messages, see **Message List 2**, are less important. 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*** **错误!未找到引用源。**.

However, the equipment always gives a notification tone when some messages occur regardless of the setting of [**Notification tone**]. Refer to the messages followed by an asterisk in the Messages Lists below.

9.2.1 Message List 1

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

Message	Trigger	Action
Battery depleted!*	The battery is too low.	Connect the equipment to AC mains to run the equipment and charge the battery.

Message	Trigger	Action
Recorder unavailable!*	1. When recording is needed or a measurement is started. In this case a dialog box pops up. You can press any key to close the dialog box. It does not affect the function. 2. Recorder communication error or does not work.	1. Verify that recording paper is properly loaded. 2. Verify the platen of the print head is in position. 3. Verify that the recorder does not stop due to hot print head. 4. If the message persists after above actions have taken, contact your service personnel.
Paper type error *	The setting of [**Paper Type**] is different with the used paper type.	Verify the setting of [**Paper Type**] is correct by selecting [**Menu**]→[**System Setup**].
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, press F4.
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 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 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.
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 F4.	/

Message	Trigger	Action
Configuration loaded successfully*	The configuration is successfully loaded.	/
Loading configuration failed*	Main control software or hardware fails.	Contact your service personnel.
Configuration file not found*	Configuration file is not found in the USB memory when [**Load Configuration**] is selected.	1. Verify that correct configuration file is stored in the USB memory. 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 and a correct option is select. 2. Check that USB memory is properly inserted and file system is not damaged. 3. Check that the USB memory has sufficient space.
Failed to create file(s)	The system failed to create files when file(s) are being exported.	Check whether the USB memory is properly plugged. If yes, the file system might be damaged. Format the USB memory and try again.
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	A single file or all files are successfully deleted.	/
Deleting failed	Deleting file(s) failed.	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
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 memory.	Delete useless files stored in the USB memory to release the memory space.
USB memory not found	The system fails to find the USB memory.	1. Verify the USB memory is properly plugged. 2. If the message persists, format the USB memory and try again.
Save failed	Files failed to be saved.	Try again. If the problem persists, contact your service personnel.
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.	/
Shutting down...	The system is shutting down.	/
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.
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.

Message	Trigger	Action
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	Action
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 the patient.
Printing…	The thermal recorder or the external printer is printing a report.	Wait till printing finishes.
Analyzing...	The algorithm is analyzing acquired ECG data.	/
Analyzing Failed	The algorithm fails to analyze acquired ECG data and is unable to give disagnoses.	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.
Acquiring...	The equipment is acquiring 60-second	Wait till 60 seconds of countdown is reached.

Message	Trigger	Action
	ECG data when rhythm measurement is started.	To stop acquisition, press the [**Rhythm**] key.
Recorder out of paper	The thermal recorder runs out of paper.	Load the paper as described in ***3.2.3 Loading Paper.***
Recorder door not closed	Paper tray is open.	Push the paper tray to snap in position. Try again.
Recorder head hot *	Print head has heated up do 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	Battery charge is low.	Connect the equipment to AC mains to run the equipment and charge the battery.

FOR YOUR NOTES

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 AC power as primary power source. In case of power failure, the equipment will automatically run 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 battery works correctly. The solid green portion represents the current battery charge level. Each block represent a charge of approximately 20% capacity.
-  Indicates that the battery has low charge level and needs to be charged. In this case, the LED turns to be yellow and the messag [**Low Battery]** is shown 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!],** and the battery indicator flashes in yellow, and the recorder is disabled. At this moment, connect the equipment to 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. For more aggressive use models, 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:

- The battery performance test must be performed once a year, before equipment repairs, or whenever the battery is suspected as being the source of the problems.
- Condition a 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.
- The shelf life of a Lithium Ion battery is about 6 months when the battery is stored with the battery power being 50% of the total power. After 6 months fully charge the battery. Then run the equipment on this fully charged battery .When its battery power becomes 50% of the total power, take out 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. If batteries are stored for an extended period of time, they should be placed in a cool place. Storing batteries in a cool place slows the aging process. Ideally the battery should be stored at a temperature of 15°C. Storing batteries at high temperature for an extended period of time will significantly shorten the life expectancy of a battery. Do not store the battery at a temperature beyond -20°C-60°C.

⚠ WARNING

- **Keep the battery out of children's reach.**
- **Use only specified batteries.**
- **If the battery shows signs of damage or signs of leakage, replace it immediately. Do not use a faulty battery in the equipment.**

10.5 Battery Maintenance

10.5.1 Conditioning a Battery

A battery should be conditioned before it is used for the first time. 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 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 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 will decrease over time with use of batteries. For old batteries, 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. The battery performance test must be performed 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, follow this procedure:

1. Disconnect the equipment from the patient.
2. Connect the equipment to 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.

The operating time of the batteries reflects their performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, 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

A battery should be replaced 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 for proper disposal.

⚠ 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.**
- **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 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

- **If you spill liquid on the equipment or accessories, contact us or your service personnel.**

11.1.1 Cleaning

Recommended cleaning agents for the equipment are:

- sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (75%)
- Isopropanol (70%)

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

To clean your equipment, follow these rules:

1. Shut down the equipment and disconnect the power cord, accessories, and other devices that are connected with the equipment.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaning agent.
4. Wipe off excess moisture with a dry cloth.
5. Dry your equipment in a ventilated, cool place.

⚠ CAUTION

- **When cleaning, avoid the patient cable connector and other connectors.**

Cleaning Patient Cables and Lead Wires

Remove cable and lead wires from the equipment before cleaning.

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

Cleaning Reusable Electrodes

Clean reusable electrodes immediately after use on a patient.

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

Cleaning Thermal Print head

Dirty print head will deteriorate 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, follow this procedure:

1. Turn off the equipment.
2. Press the recorder door latch to open the recorder door. Take out the recording paper.
3. Gently wipe the print head with cotton swabs dampened with ethanol to remove the dust and foreign particles.
4. Wipe off excess moisture with dry cotton swabs.
5. Reload the recording paper and close the recorder door when 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 disinfectants for the equipment include: ethanol 75%, isopropanol 70%, perform® classic concentrate OXY. 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 specfied in the instructions for using an accessory, do not sterilize the equipments and the accessories.

11.2 Regular Check

Perform a visual inspection before the equipment's first use everyday. In case of any damage or abnormity, remove the equipment from use. Contact the hospital's biomedical engineers or your service personnel immediately.

Verify that the equipment meets the following requirements:

- The housing and display screen are free from cracks and other damages.
- All keys funtions 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 electrods 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 batteries meet 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.

11.3 Maintaining the Battery

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

11.4 Storing Thermal Recording Paper

To store thermal paper, follow these rules:

- Store in a cool, dark, and dry place, avoiding high temperature, moisture and direct sunlight.
- Avoid long-term exposure to fluorescent.
- Do not store thermal paper with polyvinyl chloride or other chemicals which cause yellowing and fading.
- Do not overlap used thermal paper for a long time.

NOTE

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

11.5 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.

11.6 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.**
- **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.**

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.
EC6401	AHA, 12-lead, Φ4, banana connector, defibrillation-proof	040-001582-00
EC6404	AHA, 12-lead, Clip, defibrillation-proof	040-001583-00
EC6405	IEC, 12-lead, Φ4, banana connector, defibrillation-proof	040-001579-00
EC6407	IEC, 12-lead, Clip, defibrillation-proof	040-001584-00
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
022-000122-00	Lithium battery, 11.1 V, 2500 mAh, LI13S001A
1000-21-00122	Grounding cable
M002-10-69954	Recording paper, roll
095-002708-00	Recording paper, Z-fold
023-000217-00	USB memory, 4GB, Transcend
023-000218-00	USB memory, 4GB, Apacer
DA8K-10-14452	Three-wire power cord (America)
DA8K-10-14453	Three-wire power cord (Britain)
DA8K-10-14454	Three-wire power cord (Europe)
0000-10-10775	Conductive gel
048-003791-00	BeneHeart R3/R3A carrying case

A Product Specifications

A.1 Classifications

The equipment is classified, according to IEC60601-1:

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
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 (℃)	**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	60 VA
Frequency	50 Hz/60 Hz (±3 Hz)
Fuse	T2A 250V

Battery

Battery Type	Rechargeable lithium-ion battery
Run time	When powered by a new fully-charged battery and at ambient temperature 25 ℃±5 ℃, ≥500 auto measurement reports, or 2 hours of continuous recording, or 6 hours of measurement without recording
Charge time	With equipment power off and at ambient temperature 25 ℃±5 ℃, ≤3 h to 90% capacity ≤3.5 h to 100% capacity
Shutdown delay	at least 5 minutes (after a low battery message first occurs)

A.4 Physical Specifications

Weight	**Size (Length×Width×Height)**
1.28 kg (including main unit, battery, and recorder, excluding accessories)	260 mm×194 mm×56 mm

A.5 Hardware Specifications

A.5.1 Display

Screen type	Colour TFT LCD
Screen Size	5 inch
Resolution	800×480 pixels

A.5.2 Equipment Connector

Patient cable connector	1, connects patient cable for ECG acquisition
USB connector	2, connects USB disc for data transfer
Network connector	1, standard RJ45 connector, connects the equipment to the network for software upgrade

A.5.3 Indicators

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

A.5.4 Audio Indicator

Buzzer	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. 4
Paper speed	5 mm/s, 12.5 mm/s, 25mm/s, 50 mm/s Accuracy: ±5%
Recording paper	Roll: 80 mm×20 m Z-fold: 80 mm×70 mm, 200 pcs
Resolution	Vertical resolution: ≥8 dots/mm Horizontal resolution: 32 dots/mm (with paper speed 25 mm/s), 16 dots/mm (with paper speed 50 mm/s)

A.6 Measurement Specifications

ECG	
Standards	IEC 60601-2-25, IEC 60601-2-51, EC11
Measurement mode	Auto, manual, rhythm
Lead type	12-lead
ECG standard	AHA, IEC
ECG size	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, Auto 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
Line frequency suppression	≥20 dB
Sampling rate	1000 samples/s (A/D) 500 samples/s (ECG algorithm) Accuracy: 1 μV/LSB
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 equipments 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/℃ within operation temperature range
Pace pulse	
PACE pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: 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

FOR YOUR NOTES

B EMC and Radio Regulatory Compliance

B.1 EMC

The device meets the requirements of IEC 60601-1-2. All the accessories listed in ***12 Accessories*** also meet the requirements of IEC 60601-1-2 when in use with this device.

Note

- **Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the patient monitoring equipment.**
- **The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.**
- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may interfere with this monitor 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.**
- **Portable and mobile communication equipment may affect the performance of this monitor.**
- **Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).**

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment - guidance**
Radio frequency (RF) emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device 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 emissions IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

⚠ WARNING

- **This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.**

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	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, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	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.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conduced RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Recommended separation distances: 80 MHz–800 MHz: $d = 1.2\sqrt{P}$ 800MHz-2.5GHz: $d = 2.3\sqrt{P}$ Where, *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80 MHz to 800 MHz, the separation distance for 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. Note 3: The device that intentionally receives RF electromagnetic energy at the exclusion band (2395.825MHz-2487.645MHz) is exempt from the essential performance requirements, but remains safe.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM]. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than3 V/m.			

⚠ WARNING

- **The device is configured with a wireless network connector to receive wireless signal. Other devices may interfere with this device even though they meet the requirements of CISPR.**

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance in meters (m) according to frequency of the transmitter**		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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 separation distance for 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

Item	Description		
	IEEE 802.11b	**IEEE 802.11g**	**IEEE 802.11n**
Operating Frequency Band (MHz)	2412 - 2472	2412 - 2472	2412 - 2472
Modulation	DSSS and CCK	OFDM	OFDM
Transmitter Output Power (dBm)	<20	<20	<20

CE

The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive).

⚠ WARNING

- **Keep a distance of at least 20cm away from the device when Wi-Fi function is in use.**

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

C.3 Abbreviations and Acronyms

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
LCD	liquid crystal display
LED	light emitting diode
LL	left leg
MDD	Medical Device Directive

MRI	magnetic resonance imaging
N/A	not applied
Neo	neonate
OR	operating room
Ped	pediatric
R	right
RA	right arm
Rec	record, recording
RL	right leg
UPS	uninterruptible power supply
USB	universal serial bus
VAC	volts alternating current

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.**

PN: 046-004651-00 (6.0)