About The User Manual

Thank you for purchasing our product!

In order to enable you to skillfully operate our product as soon as possible, a detailed user manual is attached. Please make sure to read all the content when installing and using the product for the first time.

To improve the performance and reliability of its parts, the product (including hardware and software) may be changed from time to time, during which, we will try to modify or add contents. Please forgive us as there may still be inconsistency with some descriptions.

We look forward to your corrections in case of any errors and omissions in this manual.

CE 0123

The CE mark is a protected conformity mark of European Community. The products herewith comply with the requirements of the Medical Device Directive 93/42/EEC

EC REP

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Website: http://www.biocare.com.cn

CAUTION: In US, Federal law restricts this device to sale by or on the order of a physician.Please read the user manual carefully prior to use.

Explanation of key words

WARNING

Indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicate a potentially hazardous situation which, if not avoided, may result in slight personal injury or equipment failure.

EXPLANATION

Other important information besides warning or caution.

Explanation of part symbols

Symbol	Explanation	Symbol	Explanation
~	Alternating Current		Type CF Applied Part
	Direct Current		Type CF applied part including defibrillation-Proof
	Battery Charging		LAN Port
	Equipotential Terminal		USB Port
	Please refer to user manual!		

Conventions

Format	Explanation
”***”	Used to quote the texts in the screen of the machine.
[****]	Used to quote the shortcut buttons or keys in the screen of the machine.
TEXT	Used to quote the referenced chapters or sections in this manual.

Content

Foreword

CAUTION

- This ECG machine shall be used by qualified health professionals in the medical units, who need to analyze the ECG waveforms and give diagnostic results.
- In sequence to use this ECG machine correctly, safely and effectively, please read through the user manual carefully.

★ Safety Information

WARNING

- Avoid using and storing in the places with sulfur, salt, alkaline gas or with risk of gas leakage.
- Avoid using in the places with anesthetic gases, flammable gases such as oxygen, hydrogen or other flammable chemicals, or it may cause explosion or fire.
- Select a room with intact infrastructure (good power supply system and grounding facilities).
- Be cautious when the patient is connected with more than one instrument, because the total leak current may be harmful to the patient. Devices in compliance with the standard of IEC60601-1 are allowed to be connected to this ECG machine, and the equipotential points of all the connected devices should be connected reliability. (The equipotential point and the protection ground of this ECG machine have been connected). Total leak current should be measured by the users to determine that it meets the requirement and can be used after connection.
- All the analog and digital equipment that is connected to this ECG machine in the patient environment has to be in compliance with the standard IEC60601-1; All the analog and digital equipment that is connected to this ECG machine out of patient environment has to be in compliance with other national safety standards (IEC or ISO safety standards); the composition system should be in compliance with the standards of IEC 60601-1-1.
- When the equipment is used simultaneously with cardiac defibrillators, avoid contacting with patients or hospital beds. All the electrodes connected and unconnected to patients as well as patients themselves do not have to be grounded. Do not use other electrical stimulators at the same time. If needed, it should be a professional technician to carry out the operation.

- Chest and limb electrodes along with the device in the packing box could not meet the requirements of defibrillation polarization recovery time (however, they are essential accessories of ECG), should not be used immediately for reliable measurements and diagnostics after defibrillation. To ensure proper defibrillator protection, use only the recommended disposable electrodes (Name: Skintact; Type, RT-34), lead wire and electrode adapters by our company. To ensure the protection of defibrillator discharge, use the lead wire with defibrillation-proof by our company**.**
- When the ECG machine is used together with a defibrillator or other electrical stimulators (like high-frequency surgical devices), we recommend using disposable chest electrodes. Otherwise the patient may get serious injury by using mental electrodes.
- During defibrillation, the device can detect the discharge of defibrillator, and process automatically, and then quickly recover the waveform.
- Keep the ECG machine electrodes away from the electrodes of high-frequency electrosurgical units. Ensure the resistance between the electrosurgical unit and patient body is as low as possible. If necessary, the disposable electrodes can be used because of its larger contact area on the human body, which can keep the high-frequency current density in an acceptable range.
- When the relevant packaging material including, depleted batteries and scrapping products are disposed, please follow the local laws; the user should properly follow requirements of local laws, and recycling laws.

CAUTION

- Avoid contacting with water or other liquids, and avoid using and storing in spaces with too large barometric pressure, humidity and temperature beyond the prescribed standards, poor ventilation, or with excessive dust.
- The ECG machine should be place on the flat horizontal table and avoid strong vibration and mechanical shock while moving.
- The frequency of AC power supply and system voltage should be complied with the requirements. More importantly, the current capacity should be sufficient.
- The instrument should not be surrounded by high-voltage cables, ultrasound equipment, electrotherapy machines and other high-power equipment.
- To more accurately record the ECG, the equipment shall be placed in a quiet and comfortable environment.
- The circuit of application parts works based on floating ground and meets the safety standards in IEC60601-1 CF Type. It can be used in acquiring the body surface ECG signals, but cannot applied to the heart directly.

- Turn off the ECG machine if an accident happens.
- Please clean and disinfect reusable electrodes with medical alcohol before using.
- The conductive parts of electrodes and connectors (including neutral electrodes) on the ECG machine should not in touch with other conductive parts.
- Do not press the buttons with sharp or hard articles or it may cause permanent damage to the buttons.
- Do not make any modifications to this ECG machine.
- Perform regular maintenance and inspection for this ECG machine and all its accessories (at least once every six months).
- The maintenance and repair of this ECG machine should be performed by experienced technicians. When there is any functional abnormality, it should be clearly identified to prevent the ECG machine from running with fault.
- The electrical schematic diagrams and parts listed are only provided to a qualified repair station or technicians recognized by the company.

★ General Operation Precautions

Before operation:

CAUTION

- Make sure the ECG machine is in good condition and the recording paper is sufficient.
- Make sure the temperature and humidity of operating environment comply with the requirements.
- Do not operate ECG machine in a place with X-ray equipment, ultrasound scanner, or other similar equipment. Those equipments may interfere with the ECG machine. If necessary, power off the mentioned equipments or move the ECG machine to an environment without interference.
- Make sure all lead wires are connected correctly and are kept away from the AC power cable.
- Make sure the equipotential cable of the ECG machine is reliable and properly connected.
- Make sure the power cable is properly connected with the ECG machine and is not twisted with other cables or wires.
- Put the lead wires in good order before connecting them to the electrodes.
- Make sure the electrodes are in good contact with skin. Please refer to ***Apply Electrodes*** for details.
- Please install the ECG machine near an AC power outlet. Cut off the power supply immediately when there is an emergency.

- If the patient is nervous, please explain to the patient that ECG examination is easy and no harm.
- Please keep the patient quiet and motionless.
- Use wide hospital beds and keep the patient from touching the metal parts of the hospital bed, which may cause interference in ECG waveform recording.
- Keep the Examination room quiet and comfortable.

WARNING

- All circuits that come in contacting the patient directly should be examined closely.
- When using the battery as the power supply, please check the voltage and condition of the battery first and make sure the battery is fully charged. For new batteries, please discharge and charge it fully before using.
- Use only 3-core power cable when using AC power, otherwise hazard of electric shock to the patient and operator cannot be completely eliminated. If the power cable is not working, only the built-in battery can safely power the ECG machine.
- Make sure equipotential connection is complete and reliable, or else only use the built-in battery.

In operation:

WARNING

- The physician should observe the patients closely without leaving during the operation. If necessary, turn off the ECG machine and remove the electrodes to ensure patient’s safety.
- Prevent the patients from contacting the other parts of the ECG machine or other conductors except for the electrodes.

After operation:

CAUTION

- Please return to the main interface before turning off the ECG machine.
- Remove the electrodes gently and do not pull the lead wires emphatically.
- Clear up the ECG machine and all the accessories for trouble-free operation of next use.

About LCD screen

CAUTION

- Do not place any heavy objects onto the LCD screen or strike it, otherwise it could damage the LCD screen.
- When not using it, please put it away or have a cover on it. Keep it away from water.

About lithium battery

WARNING

- Only the authorized installation or service engineer can open the battery cover and replace the battery; do use the same type of rechargeable lithium battery provided by our company.
- The positive and negative terminals of the batteries cannot be reversed, or it could cause an explosion.
- Do not connect the two polarities of the battery with metal wires. Otherwise, there will be the hazard of fire.
- Do not use the battery near a heat source or in and the environment with temperature up to 60 ℃; do not heat the battery or throw it into the fire.
- Keep the battery away from water; do not drop the battery into the water.
- Do not press any metal into the battery; Do not hammer or beat the battery or use other ways to damage the battery, otherwise it will cause heat, smoke, deform or burn, which is very dangerous.
- When you find battery leakage or its emitting unpleasant odors, please get away from it immediately. If the fluid leaks onto the skin or clothes, wash with clean water at once. If the electrolyte enters the eyes, do not rub the eyes, wash with clean water immediately, and then go to see a doctor.
- The users need to check the battery status regularly. When the battery reaches the end of its lifetime, when it smells, deforms, discolor, contorts, the users should stop using and dispose of it according to local regulations.

★ EMC Considerations

This ECG machine conforms to the IEC60601-1-2, a safety standard for medical electronic devices or systems. However, the electromagnetic environment exceeding the limit or level defined by the standard IEC60601-1-2 will introduce the unwanted interference to the ECG machine, disable its intended functions or it will compromise its intended performance. Thus, if there is any discrepancy with this ECG machine compared to its intended

functions during operation, please do not use it for longer until the adverse affect is identified and eliminated. The appropriate preventing measures are given below by this manual for such cases:

- Influence of radiated electromagnetic wave:

  The use of a mobile phone may affect this ECG machine. Instruct all the people around to turn off their mobile phone or mini-radio devices when any medical electronic device is in use.

- Influence of impact and conductive electromagnetic waves:

  The high frequency noise produced by other devices can be introduced into this ECG machine through the alternating current socket. Please identify the noise source first, and if possible, stop the working of related devices. If they are not allowed to be stopped, measures such as application of noise abatement device should be taken to minimize the influence.

- Influence of static electricity:

  The static electricity in a dry environment (indoor) may affect this ECG machine, especially in winter. Please humidify the indoor air or pre-discharge the static electricity on the cable and the electrocardiogram recording personnel prior to using this ECG machine.

- Influence of thunder and lightning:

  A thunder and lightning strike nearby may cause voltage surge in this ECG machine. You can unplug the power supply and run the ECG machine using its internal battery in case of any danger.

Instrument classification

Methods	**Class**
By Type of Protection Against Electric Shock	Class I, internal power supply
By Degree of Protection Against Electric Shock	Type CF applied part
By Degree of Liquid Proof	Ordinary equipment (enclosed device without liquid proof)
By Level of Protection Against Explosion	This equipment is unsuitable for use in an environment with air, oxygen or nitrous oxide mixed with flammable anesthetic gas.
By Mode of Operation	Continuous operation equipment

Maintenance Warranty

Our company guarantees the new instrument on the material and technological qualification for this product within 18 months and the accessories within 6 months since purchasing day, while consumables are not covered by the guarantee in principle. This guarantee is also inapplicable to the products undergoing any modification, disassembly, refitting or self-repairing without permission of our company, as well as the products damaged by accidents, fire disaster, thunder and lightning, flood and other disaster, intentional damage, improper installation and improper usage.

CAUTION

- For all dated reference documents in this manual, its subsequent amendments (excluding corrections) or revisions do not apply to this manual; for undated reference documents, the latest version applies in this manual.
- Due to product improvement, the content of this User Manual may differ from the product you purchased, which will not affect the usage, please operate according to the actual functions of the product.
- This manual is subject to change without prior notice. We apologize for any inconvenience caused.

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Chapter 1 Introduction

[**Main structure, performance**]

The ECG machine is mainly composed of the main unit, lead wire, limb electrodes and chest electrodes.

[**Scope of application**]

This ECG machine is used to extract the electrocardio complex from the human body for clinical diagnosis and research.

[**Intended Use**]

- The diagnostic applications include: check the cardiac abnormalities of the general population; detect the chest pain in patients with acute myocardial ischemia and myocardial infarction, and evaluate the patients with arrhythmias;
- Suitable for: adults (older than 12 years old), pediatrics (age between 29 days to 12 years old), and neonates (infants born less than 28 days after 37 weeks to 44 weeks of pregnancy);
- Used in: hospitals, clinics;
- The automatic analysis program of this ECG machine focuses on the high sensitivity of detecting high-risk patients with cardiac abnormalities.

1.1 Equipment Overview

1.1.1 Front View

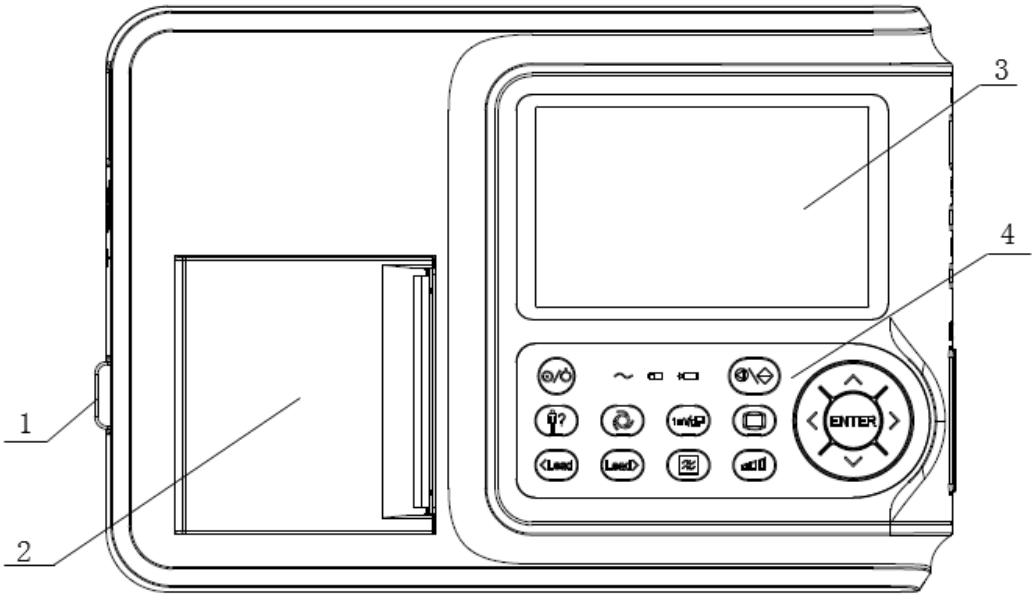


Figure 1-1 Front View

Number	Name	Description
1	Switch Button	Push down to open the Paper Drawer.
2	Paper Drawer	Place the recording paper.
3	Display Screen	Display the waveforms, patients' information and the device status.
4	Operating Buttons	For button operations and inputting methods. Refer to ***Operating Buttons*** for more details.

1.1.2 Left View

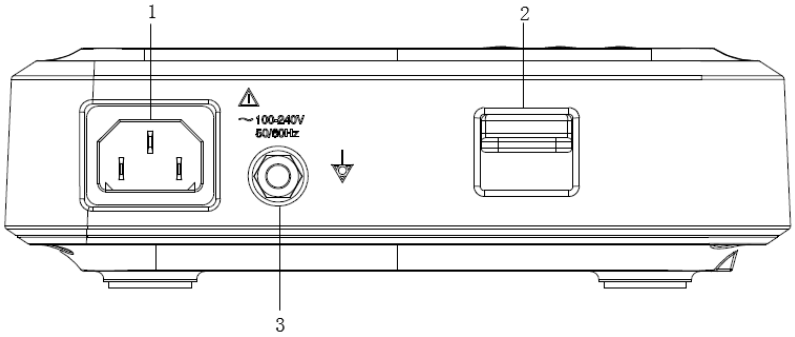


Figure 1-2 Back View

Number	Name	Description
1	Power Supply Socket	Connect to the AC power adaptor.
2	Switch Button	Push down to open the Paper Drawer.
2	Equipotential Terminal	Connect to the equipotential cable.

1.1.3 Right View

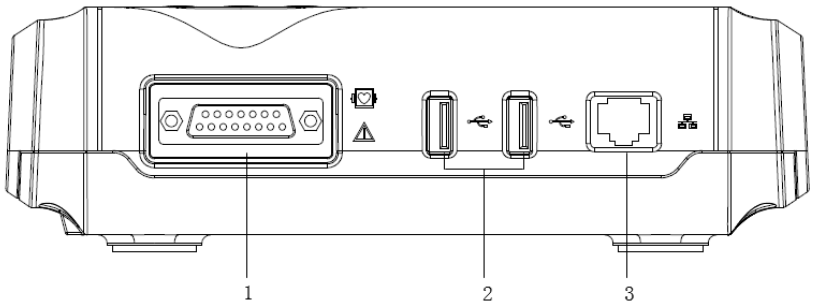


Figure 1-3 Side View

Number	Name	Description
1	ECG Patient Cable Connector	Connect to the Patient Cable.
2	USB Ports	Insert the USB device to save data; Insert the Bar Scanner.
3	LAN Port	Connect to net cable.

1.1.4 Operating Buttons

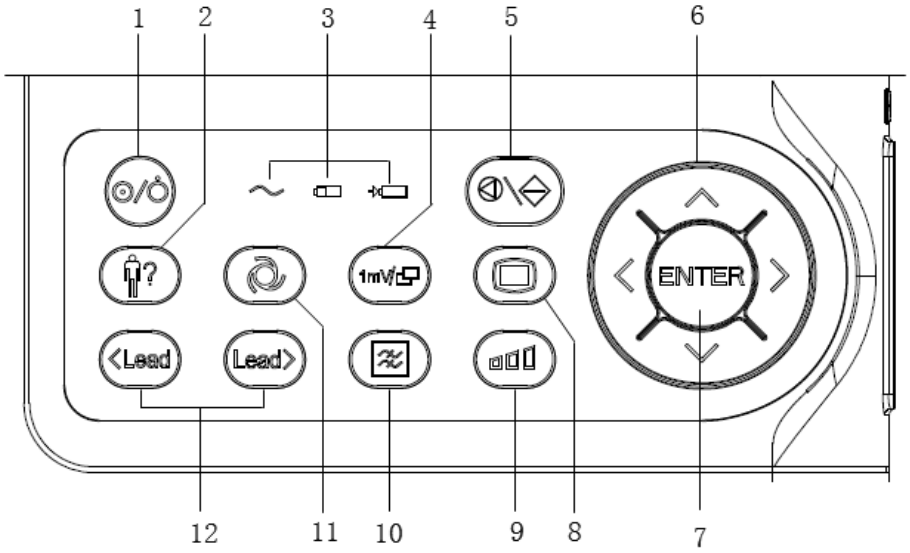


Figure 1-4 Keyboard

Number	Name	Description
1		Press to power on or off the ECG machine.
2		Press to set patient information.
3		Indicate the power status of the ECG machine. From left to right: AC power indicator, battery indicator and charging indicator.
4		1. In Manual Mode, press to print the calibration waveforms of 1mV to check the current sensitivity. 2. In Auto Mode, press to copy the previous report.
5		Press to start or stop printing the ECG waveforms and report.
6 & 7		Press Up/Down/Right/Left button to select a menu or an option. Press **[ENTER]** to confirm, open a submenu, or toggle between two options in a submenu.
8		In Main interface, press to enter configuration Menu. In other interface, press to exit.
9		Press to select a sensitivity.

10		Press to set low-pass filter, baseline wander filter and AC filter.
11		Press to select a record mode and record format.
12	<Lead Lead>	In manual mode, press to switch among different lead groups. In split-screen mode, press to switch among different screens.

1.2 Waveform Display

☞ **EXPLANATION**

Screen display may slightly differ from the product you purchased, which will not affect your usage. Please operate according to the actual functions of the product.

In same screen displayed interface, 12 lead waveforms will be displayed on one interface.

In split-screen displayed interface, 12 lead waveforms will be displayed on several interfaces, which make it possible to show the waveform details more clearly.

Select **[Display**], set the display format and lead format.

1.2.1 Same Screen Display

Waveform display in same screen, 3 X 4 lead format:

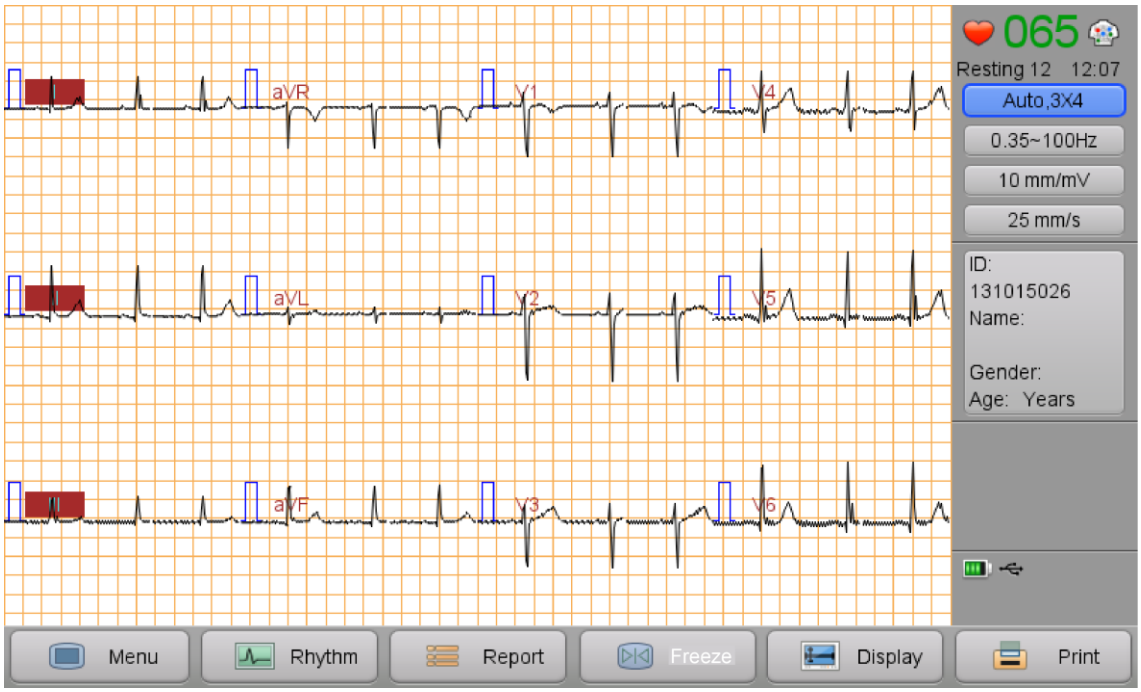


Figure 1- 5 Main Interface

Waveforms display in same screen,

6 X 2 lead format:

I	V1
II	V2
III	V4
aVR	V3
aVL	V5
aVF	V6

Waveforms display in same screen,

12 X 1 lead format:

I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6

1.2.2 Split-screen Display

Waveform under split- screen, 3 X 4 lead format:

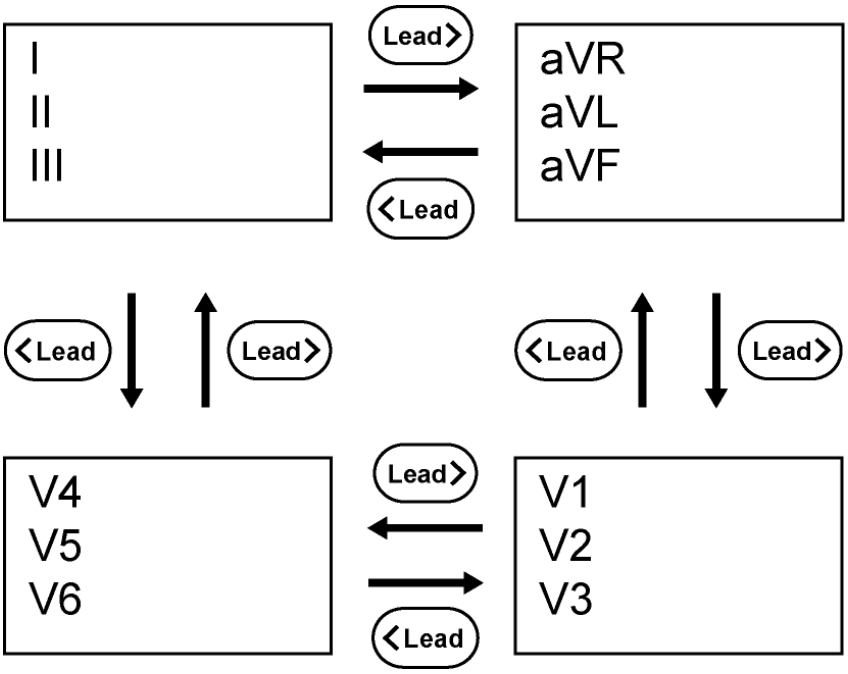


Figure 1- 6 Lead Switch

Press  to change displayed waveforms.

Chapter 2 Preparation

2.1 Locate the ECG Machine

Please refer to ***Foreword***.

2.2 Install Recording Paper

☞ **EXPLANATION**

Installation of the recording paper may slightly differ from the product you purchased, which will not affect your usage, please operate according to the actual feature of the product.

See the descriptions below to install the rolling paper:

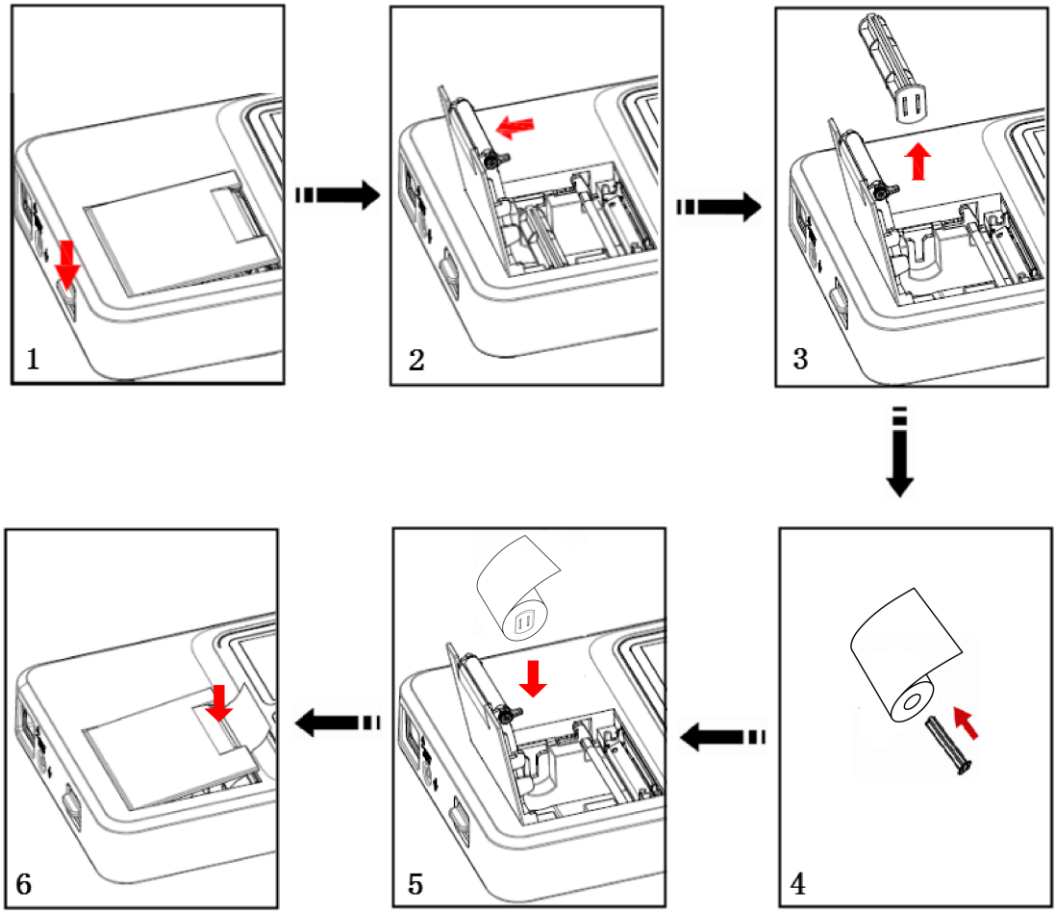


Figure 2- 1 Install the Recording Paper

1. Push the button downwards.
2. Open the Paper Drawer cover.

3. Remove the roller.
4. Insert the roller into the Rolling Paper.
5. Load the recording paper fitly into the Paper Drawer. And make sure the grid side of the paper facing downwards and towards the Thermal Print Head.
6. Pull out the paper about 2cm and press to close the Paper Drawer cover.

CAUTION

- Please make sure the recording paper is installed fitly and straightly, otherwise it may be stuck.
- If paper is absent, or used up, or not placed well, alarm will appear on the main interface and the machine does not print.

2.3 Connect to Power Supply

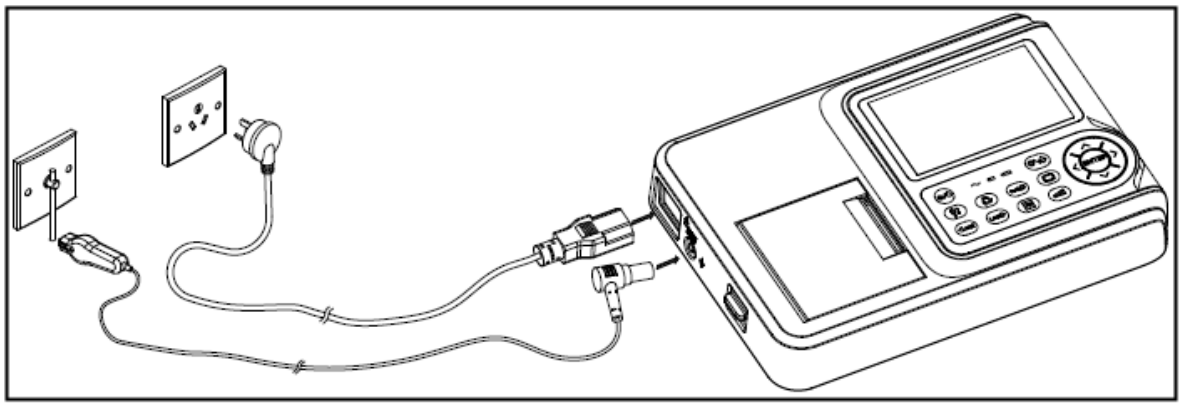


Figure 2- 2 Connect to AC Power Supply

1. Connect the AC Power Cable to the ECG machine and the Power Outlet
2. Connect Equipotential Cable to the ECG machine and the Equipotential Terminal in the room.

EXPLANATION

The ECG machine is equipped with a built-in rechargeable battery and requires no extra installation. The operator needs to check the battery's capacity before usage.

CAUTION

- When the ECG machine is operated together with other medical equipment, please use the accompanying

Equipotential Cable and connect the Equipotential Terminal of the ECG machine altogether with that of the other equipments so as to protect the patient from possible electric shock due to current leakage from those equipments.

- It is forbidden to connect the Equipotential Cable to a conductive water pipe or other pipes. Otherwise, there may be hazard of electric shock to the patient.

2.4 Connect to Patient Cable

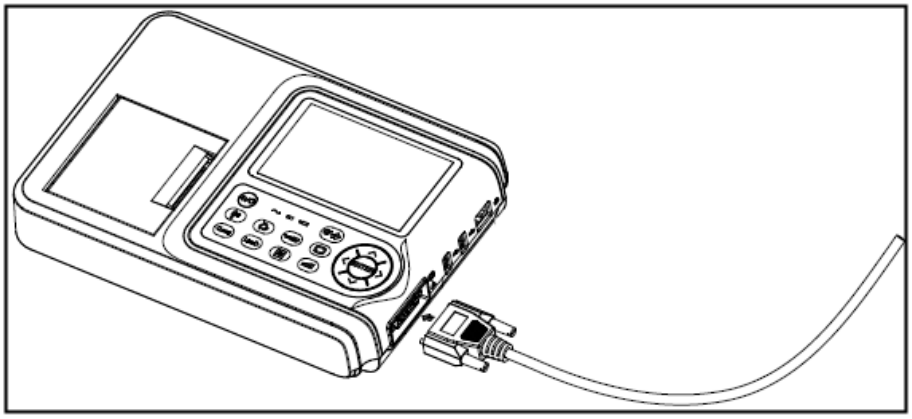


Figure 2- 3 Connect to Patient Cable

Connect the Patient Cable to the ECG machine.

CAUTION

Do not use any other Patient Cable except that supplied one. The ECG Patient Cable Connector is exclusively used for connecting the Patient Cable. Do not use it for other purposes.

2.5 Power On/Off

Press  to power on/off the ECG machine.

The ECG machine enters Standby mode if it is not in use for a setting period. Set the duration in **[System Setting] > [Standby Time]**. To exit standby mode, press any key.

The ECG machine will shut down automatically if it is not in use for a setting period. Set the duration in **[System Setting] > [Auto Power Off]**.

2.6 Connect to Network

CAUTION

In the data transmission, if the ECG machine warns “Network connection failed”, please reconnect to network or reset the network configuration.

1. As shown in the following figure, the cable network system is composed of the ECG machine, the switchboard and the server.
2. Go to **[Menu]** > **[System Setting]** > **[Cable Network]** and set the **[IP address]**, **[Subnet Mask]** and **[Default Gateway]** of the ECG machine. If the IP address is in the same network segment of the server, the subnet mask and gateway shall be as the set value of the server. If the IP address is not within the same network segment of the server, subnet mask and gateway of the **[Cable Network]** shall be set according to actual situations. And make sure the specified gateway does support the data transmission between the two network segments.
3. Select **[Server Setting]** and set the correct **[IP address]** and **[Port]** number of the server.
4. When the machine is connected to network successfully, the icon  will display in the main interface.

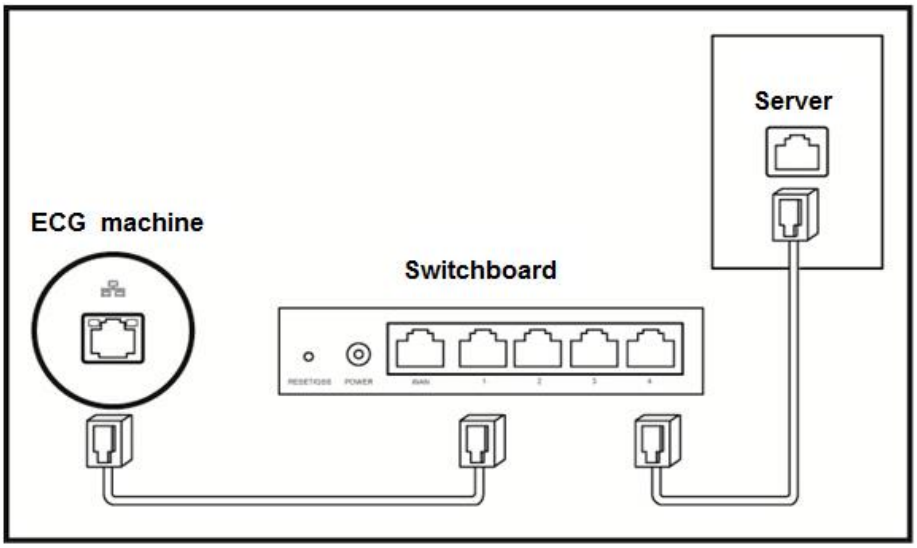


Figure 2- 4 Cable Network Connection

2.7 Apply Electrodes

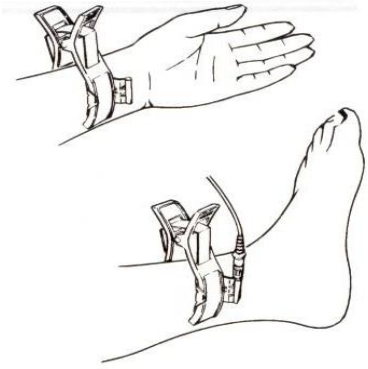
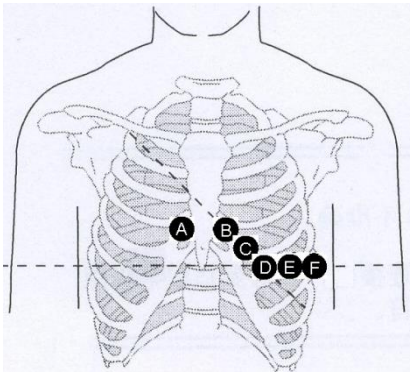
Before attaching the electrodes to patient, wipe the skin where the electrodes attached by using medical alcohol, and then apply ECG gel on the skin. After that, place electrodes to the right position. If using the vacuum ball electrodes, you should apply ECG gel on the electrodes, and then pinch the suction ball to make sure the electrodes are attached to skin tightly.

CAUTION

- Proper electrode attachment is vital for obtaining accurate ECG waveforms; therefore, please ensure good contact between the skin and electrodes.
- Do not use the new electrodes and the used ones at the same time. Replace all electrodes together when any one of them is supposed to be replaced.
- Don’t use disposable electrodes more than one time.
- Confirm the disposable electrodes are within the validity period.
- Use the disposable electrodes as soon as possible after opening the package (generally within 7 days).
- Electrodes or conducting point of lead wires shall not be in contacting with any other metal part or conductor.
- Avoid the electrodes to be dragged by the lead wires.
- Make sure patient’s skin contacted with the electrodes has been well pretreated.
- Clean the stain on the electrodes with medical alcohol whenever the electrodes are contaminated.
- Make sure metal electrodes of limb electrodes touch fully with skin and tightly enough.
- Make sure adjacent electrodes and ECG gel, especially chest ones, are not contacted with each other.
- If the examination involves a short period of time, if ECG gel is unavailable, please wipe the skin with medical alcohol to keep the skin clean and moist, rapidly attach the electrodes.
- It’s not allowed to use saline water as substitute when ECG gel is not available. The saline water will cause corrosion on the electrodes.
- For chest and back application of pediatric, disposable electrodes are suggested.
- Electrodes shall be properly stored. When electrodes have been used for a certain period, they may become corroded and oxidized at the surface. Whenever this happens, the electrodes must be replaced.
- Do not mix electrodes of different types and manufacturers. Do not use re-useable electrodes and disposable ones together, or it will affect the recording.

■ Please use our company's or authorized electrodes to make sure qualified ECG signals.

2.7.1 Electrodes Attachment

<table>
<tr><td colspan="5">Limb Electrodes Placement</td></tr>
<tr><td></td><td>IEC</td><td>AHA</td><td>Description</td><td>Figure</td></tr>
<tr><td rowspan="4"></td><td>R Red</td><td>RA White</td><td>Right Arm</td><td rowspan="4">  </td></tr>
<tr><td>L Yellow</td><td>LA Black</td><td>Left Arm</td></tr>
<tr><td>N Black</td><td>RL Green</td><td>Right Leg</td></tr>
<tr><td>F Green</td><td>LL Red</td><td>Left Leg</td></tr>
<tr><td colspan="5">Standard 12-lead Attachment</td></tr>
<tr><td></td><td>IEC</td><td>AHA</td><td>Description</td><td>Figure</td></tr>
<tr><td>A</td><td>C1 Red</td><td>V1 Red</td><td>Fourth inter-costal space at right sternal border.</td><td rowspan="6"> 
</td></tr>
<tr><td>B</td><td>C2 Yellow</td><td>V2 Yellow</td><td>Fourth inter-costal space at left sternal border.</td></tr>
<tr><td>C</td><td>C3 Green</td><td>V3 Green</td><td>Equidistant between B and D</td></tr>
<tr><td>D</td><td>C4 Brown</td><td>V4 Blue</td><td>Fifth inter-costal space at left mid-clavicles line</td></tr>
<tr><td>E</td><td>C5 Black</td><td>V5 Orange</td><td>Left anterior auxiliary line at the horizontal level of D</td></tr>
<tr><td>F</td><td>C6 Purple</td><td>V6 Purple</td><td>Left mid- auxiliary line at the horizontal level of D</td></tr>
</table>

2.7.2 Lead Signals Formation Scheme

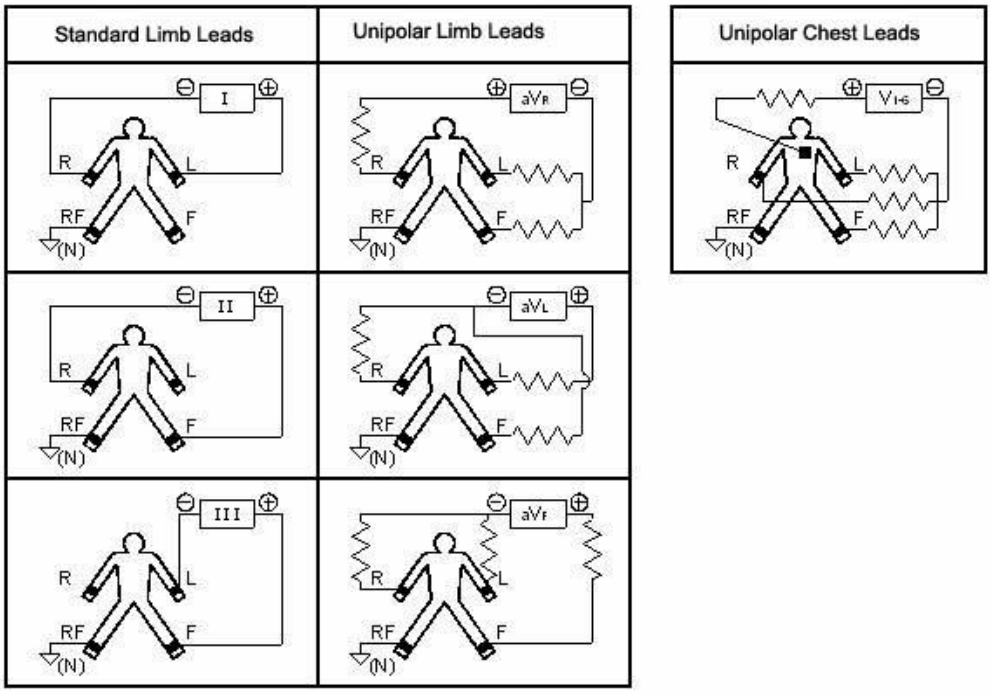


Figure 2- 5 Lead Connection

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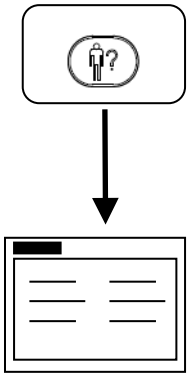
Chapter 3 Entering Patient Information

3.1 Enter Patient Information



Enter the patient information

You can enter patient ID Number, patient name, gender, and age of years. Refer to ***Set Patient Information*** to get more details.

Input ID number:

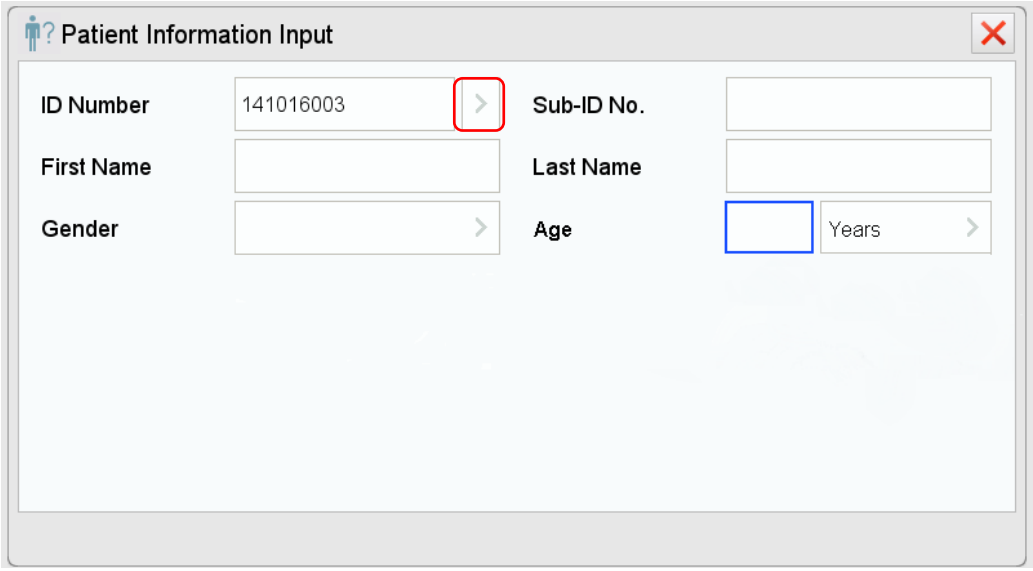


Figure 3- 1 Inputting Patient Information

Select the arrow button and press **ENTER**, and a menu with below three options pops up.

[Automatic Coding]: ID code is automatically generated by ECG machine when admitting a new patient and an ID code will be automatically increased each time when you press **ENTER**.

[Manual Coding]: you can code according to his own demand with numbers and letters.

[Barcode Scanner]: you can directly scan the bar code using the scanner to generate ID code.

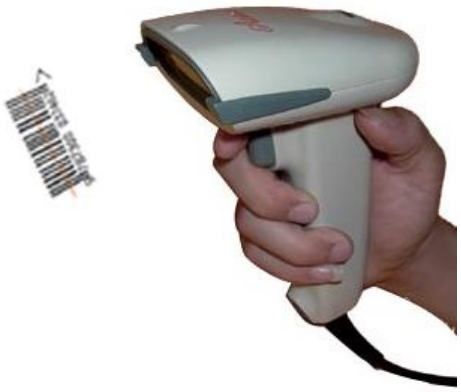


Figure 3- 2 Barcode Scanning

☞ EXPLANATION

When Barcode Scanner is chosen, the onscreen keyboard will be disabled. For the usage of the Barcode Scanner, please refer to the User Manual of your Barcode Scanner.

CAUTION

- Improper patient information may lead to misdiagnose. Please check the information for each new patient carefully.
- Please avoid confusing the patients' ID numbers. Otherwise, it may cause ECG data loss or mistake.

3.2 Introduction of Input Method

3.2.1 Standard Character Keyboard

Select a text box and press **ENTER** to open the onscreen keyboard. Use Up/Down/Right/Left button to select the letters and then press **ENTER** to confirm.

Press  to exit the onscreen keyboard and return to the previous page.

Or, select **End** button on the screen and press **ENTER** to exit the onscreen keyboard.

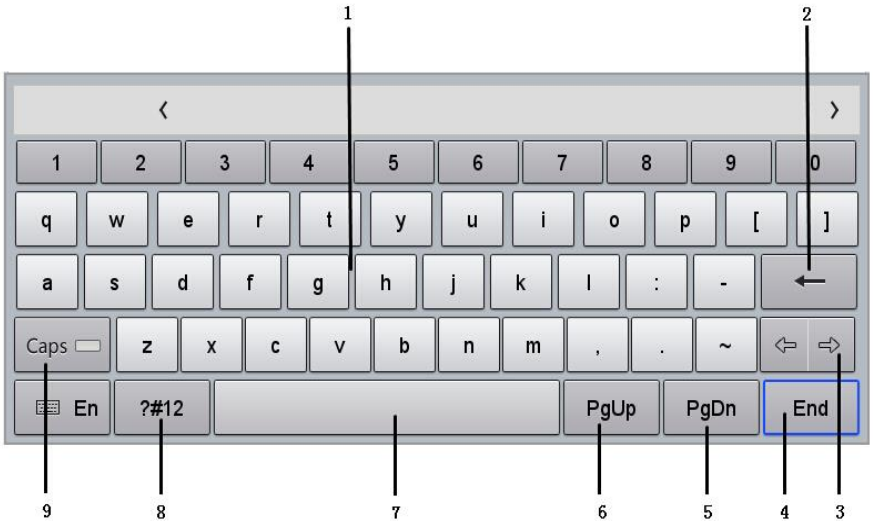


Figure 3- 3 Standard Character Keyboard

Number	Name	Description
1	Characters Area	Input letters or punctuations.
2	Delete	Delete previous inputted character.
3	Cursor Moving	Move the position of cursor on the screen.
4	End	Exit the onscreen keyboard.
5	Page Down	/
6	Page Up	
7	Space	Input null characters.
8	Symbols	Switch to symbols pad to input kinds of symbols.
9	Caps	Switch between uppercase and lowercase letters inputting.

3.2.2 Digital Keyboard

Select a text box and press **ENTER** to open the digital keyboard. Use Right/Left button to select the numbers and then press **ENTER** to confirm. Use Up/Down/ to exit the digital keyboard.

Or, press  to exit the digital keyboard and return to the previous page.

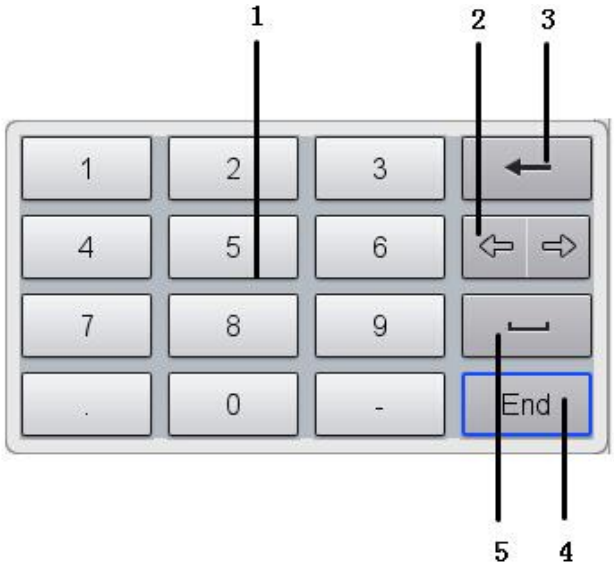


Figure 3- 4 Digital Keyboard

Number	Name	Description
1	Characters Area	Input numbers or punctuations.
2	Cursor Moving	Move the position of cursor on the interface.
3	Delete	Delete previous inputted character.
4	End	Exit the Digital Keyboard.
5	Space	Input null characters.

Chapter 4 ECG Recording

After the ECG machine has been powered on and all the leads are well connected, the following main interface will be displayed. And the ECG machine is ready for recording.

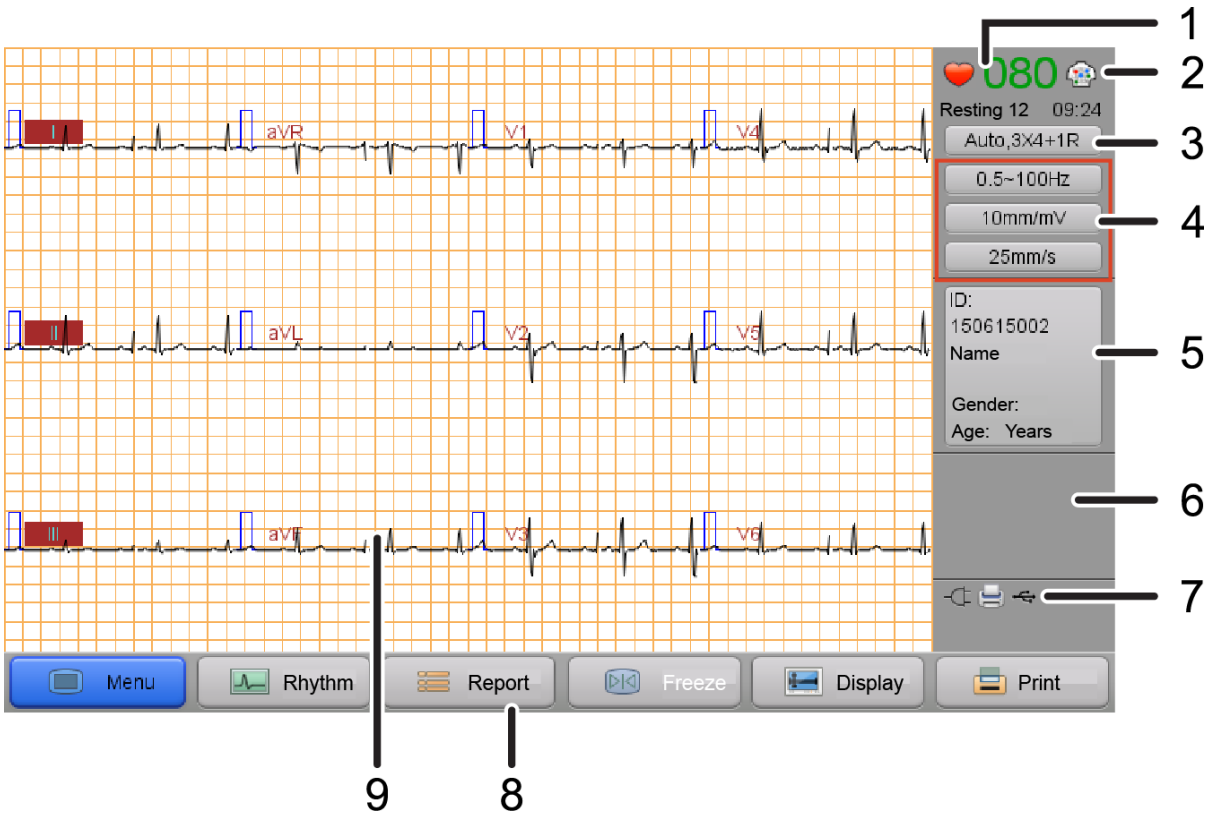


Figure 4 - 1 Main Interface

Number	Name	Description
1	Heart Rate Icon	Display patient's heart rate.
2	Lead Status	Display the location and state of the electrode in the human body. Select for a larger view. If the lead wires are not connected properly, such as electrode falls off, the corresponding electrodes on the view will flash to alarm.
3	Record Setting	Display record mode and record format; Use  to select other record mode and format.
4	Filter, Sensitivity and Print	Display the current Filter, Sensitivity, and Print Speed.

	Speed Status Area	
5	Patient Information	Display patient information;
6	Alarm Area	Display text alarm information, including: system failure about Patient Cable/Print head/Paper, lead off, AC interference, EMG interference, Baseline wander, and Data overflow, etc.
7	System Status	Indicates system status, for example, mute, recording, network, USB connecting, battery, etc.
8	Shortcut Keys	Quick operation to set up parameters and execute functions.
9	Waveform Display	Display real time waveform.

4.1 Introduction of Sensitivities, Filters, Print Speed

Before printing, set the following configuration:

Press  to select the desired sensitivites.

Press  to select the desired Low-pass Filter, Baseline Filter and AC Filter.

On the main interface, use navigation buttons to open the Print Speed Setting Menu and select the desired print speed.

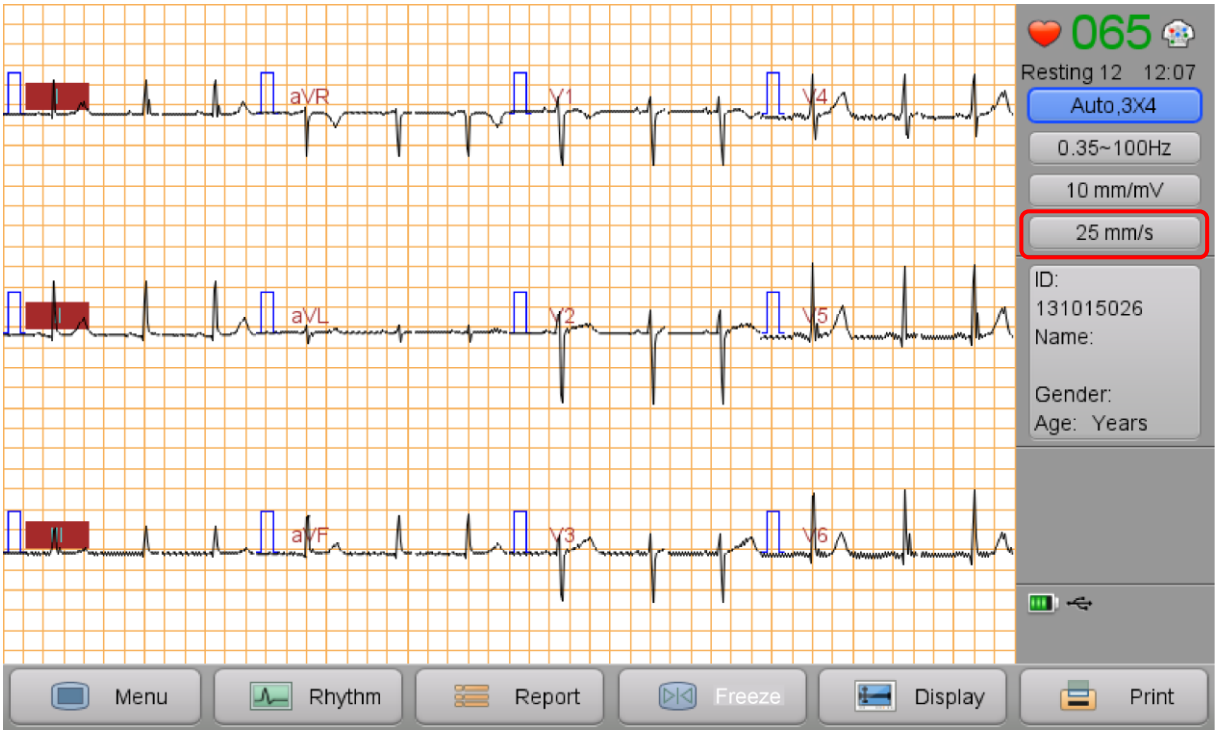


Figure 4- 2 Setup of the Sensitivities, Filters, and Print Speed

☞ **EXPLANATION**

- Noise may affect the quality of the ECG signals. You can change the filter parameters to optimize the displayed or printed ECG waveforms.
- The filters settings affect the displayed and printed ECG waveforms only, not the analysis result.
- In order to reduce baseline interference, a baseline wander filter should be employed. To make sure the ST segment is not distorted, the AAMI standards recommend that cut-off frequency of the baseline wander filter is lower than 0.67Hz.

4.2 Record ECGs

☞ **EXPLANATION**

- Pre-acquisition only works in Auto Mode and Economic mode:

  When the Pre-acquisition mode is enabled, the ECG machine print and upload waveforms automatically; when the Pre-acquisition mode is disabled, press  to print or upload waveform.
- **[Record Format]** is a waveform pattern traced on the recording paper. Please see ***Technical Specification*** for specific recording formats.
- **[Synchronous]** and **[Real Time]** are activated only when waveforms are printed in more than one column.

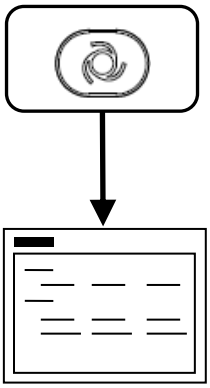
  [Synchronous]: all the start point of the waveforms are the same;

  [Real Time]: the start points of the waveforms in the same columns are the same; but the start points of different column are continuous to the end point of the waveforms in the previous column.

  Set them in **[Print Setting]** > **[Print Data Type]**.
- If you have blank paper, select **[Print Setting]** > **[Print Grid]** > **[Enable]** to print the ECG showing the grids.

  If you have paper with grids, suggest selecting **[Disable]** to print the ECG without showing the grids.

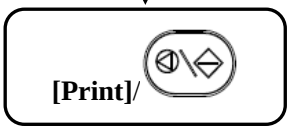
4.2.1 Main Steps to Record ECG



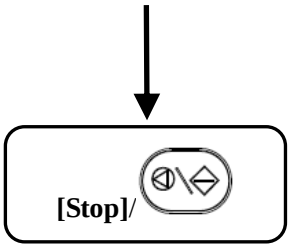
Set up the record mode and record format

Observe the waveforms display

Normal



Record the ECG waveforms



Exit the recording

Abnormal (Lead off, data overflow and etc)

Refer to ***Troubleshooting*** to find solutions.

When the waveforms recording is about to finish (under any record mode except manual mode), the system will carry on the interpretation automatically. Please refer to ***Auto Mode.***

CAUTION

- After the heart rate and waveforms are stable, you can print out the ECG waveforms together with the interpretation.
- This ECG machine can detect the lead connecting status continuously, and if leadoff is detected, the corresponding lead code will flash in the Alarm Area on the main interface, accompanied by sound alarm. When “Lead off” continues, please check carefully the connections from skin to the ECG machine (including electrodes and lead wires). Alarm will disappear when connections become reliable.

4.3 Introduction of Record Mode

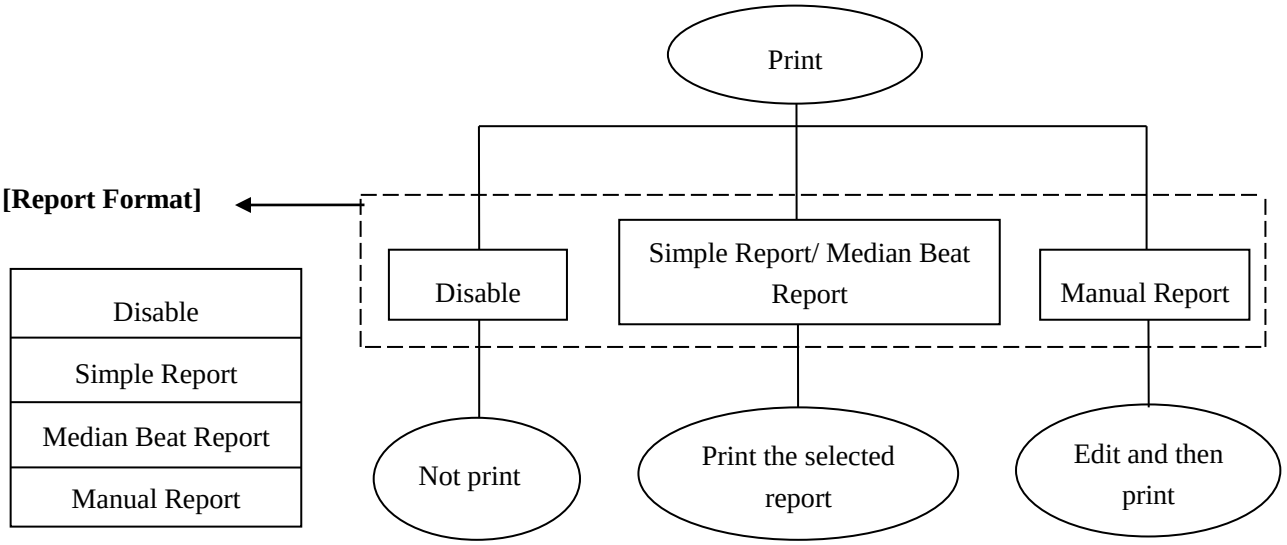
EXPLANATION

- Set up the Waveform length to be printed and uploaded in **[Menu]** > **[ECG Setting] > [Wave Sample Time]**.
- In **[ECG Setting]**, if **[Auto Upload]** is enabled, the ECG machine will automatically upload the waveforms and the reports after printing the waveforms.

  If **[Auto-save]** is enabled, the ECG machine will automatically store the waveforms and reports after printing the waveforms.
- If the waveforms and the reports need to be stored to a specified memory, go to **[System Setting] > [Default Memory]** and select the desired memory: **[Internal Memory]** or **[USB Flash Drive]**.

4.3.1 Auto Mode

In Auto Mode, the ECG machine can automatically print the waveforms and reports.



The ECG machine can analyze the resting ECG and output the measurement data, median beat and analysis result, etc.

Simple Report includes patient information, simple measurement data and Minnesota code;

Median Beat Report includes patient information, simple measurement data, Minnesota code, Median Beat waveform and Rhythm waveforms.

In Manual Mode, the analysis reports include analysis report (1), and analysis report (2).

In **[Print Setting]**, when **[Analysis Output]** is enabled, all the above-mentioned reports will include the analysis results.

After printing waveforms and report, press 

to print waveforms and report of the last patient.

Auto Print

In Economic mode and Automatic mode, select **[Menu] > [Print Setting] > [Auto Print] > [Enable]**, the ECG machine wil automatically print the waveforms and reports when the following 3 conditions are satisfied.

- Lead off does not detected for 2s (none of any electrodes);
- Five or more QRS complex detected;
- Waveform is stable, no EMG interference or Baseline drift.

EXPLANATION

- The ECG machine analyzes the latest 10 seconds waveforms.
- If the age of the patient is not inputted, the ECG machine will assume this patient as adult during analyzing.

WARNING

- In the case for some special populations (such as pregnant women, the user of vascular drugs, etc.) or mixed by obvious interference in the recording process, the analysis result may be inaccurate. Therefore the final conclusion should be drawn by a doctor, based on analysis result, the clinical characterization of patients and other diagnostic test results.
- If there is too much AC and EMG interference, the identification of P wave and Q wave is not reliable sometimes; if there is baseline wander, the identification of ST segment and T wave is not reliable sometimes.
- If the ending points of S wave and T wave are winding and not clear, it might cause measurement error.
- If R wave is undetected because of low voltage for QRS complex, it might cause some deviations in heart rate measurement.
- If QRS complex has low voltage, the electrical axis measurement and the identification of QRS dividing point can be unreliable.
- Occasionally, the frequent (repetitive) ventricular premature beat might be detected as the median beat.
- When several kinds of arrhythmia occur simultaneously, the identification of P wave might be difficult, and the relative parameters might be unreliable.

4.3.2 Manual Mode

In Manual Mode, press  to start or stop printing. You can switch from one column to another by pressing  at any time to control the waveform length of every leads.

4.3.3 Upload Mode

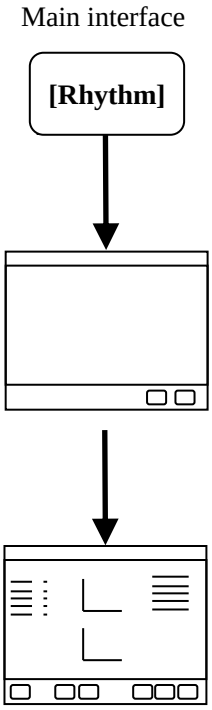
In upload Mode, select **[Upload]** or press  to analyze and then upload the ECG waveforms and reports to ECG workstation.

The Printer is disabled in this mode. You can switch to Auto mode or Manual mode to print the reports.

4.4 Advanced Mode

4.4.1 Rhythm Mode

Operate as follows to enter Rhythm Mode:



Enter Rhythm report interface

In the Rhythm interface, the ECG machine begins collecting waveforms of the Rhythm Lead. In single-rhythm pattern, only one lead is selected as rhythm lead and as long as 300s waveform will be collected and analyzed. After waveforms collecting, the ECG machine will automatically analyze the waveforms and enter report interface.

In rhythm report interface, select **[Page up]** and **[Page down]** to review more information; select **[Print]**, **[Save]**, **[Upload]** to print/save/upload the Rhythm report.

Please refer to ***ECG Setting*** to set **[Rhythm Lead]** and **[Rhythm Time]**.

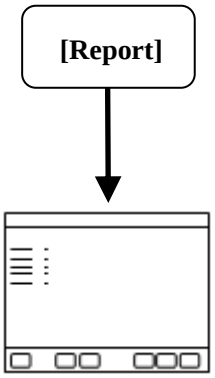
EXPLANATION

During the waveform collection, wait for 8 seconds and then press **[R-R]** to enter report interface.

4.4.2 Analysis Report Mode

Operate as follows to enter analysis report mode:

Main interface



Enter analysis report

Report (1) includes simple measurements, Minnesota code; median beat waveforms, analysis result and rhythm waveforms.

Report (2) includes waveforms of all the leads.

Analysis report interface is as follows:

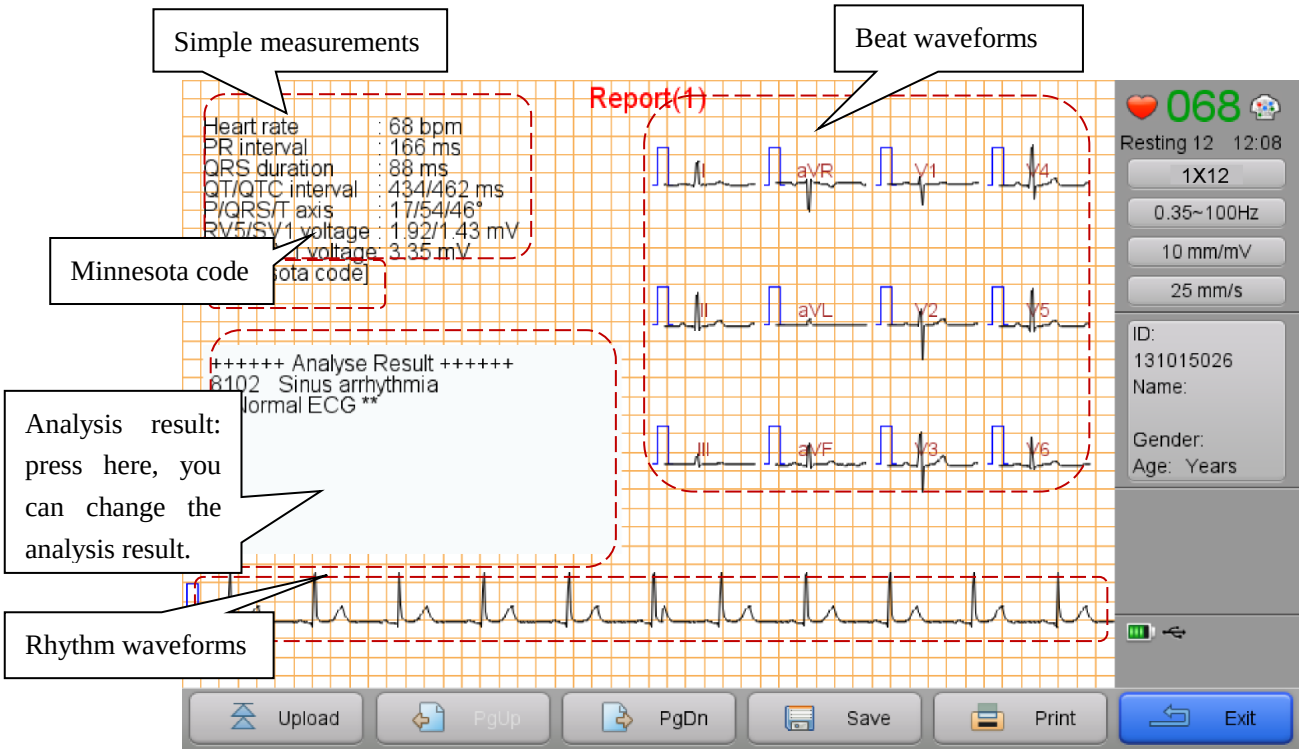


Figure 4- 3 Analysis Report 1

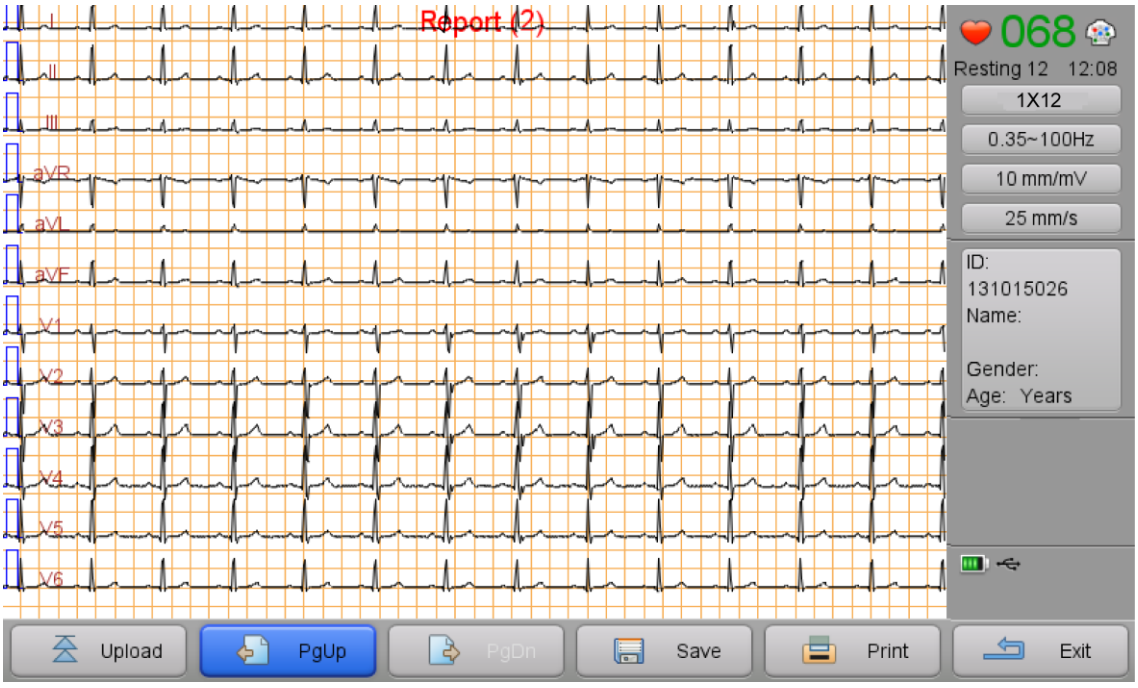


Figure 4- 4 Analysis Report 2

In above two interfaces, you can select to **Upload**, **Save**, and **Print** the report.

In analysis report (1), **Analysis Result** can be manually edited by the user. Please refer to ***List of Interpretation Codes and Corresponding Description*** for the details of the analysis result.

Chapter 5 Setting System Parameters

In the Main interface, select **[Menu]** to enter the configuration menu.

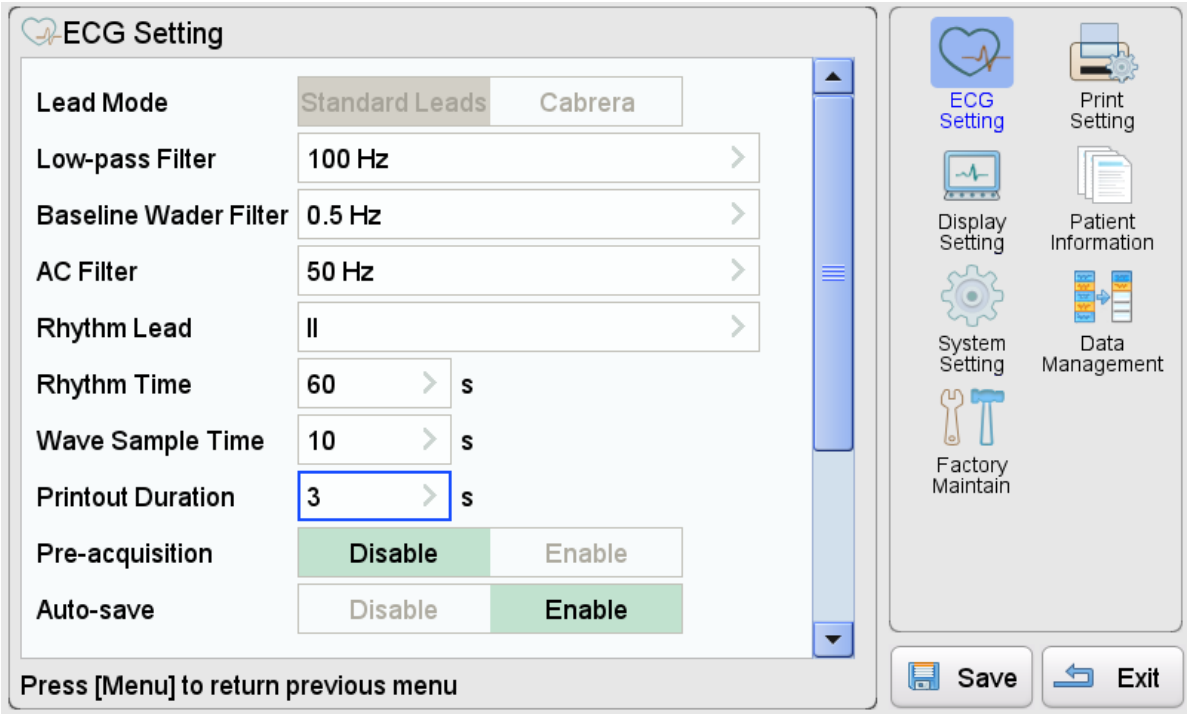


Figure 5- 1 Configration Menu

Press  to return to the previous page; press  step by step to return to the Main interface.

Select **[Save]** before exiting to avoid loss of settings caused by sudden power loss.

5.1 ECG Setting

Enter **[ECG Setting]** to adjust parameters about Electrocardiograph. See following table:

Name	Value	Default	Description
Lead Mode	Standard Leads	Standard Leads	Cabrera is disabled in iE 101/300.
Low-pass Filter	25 Hz, 35 Hz, 75 Hz, 100 Hz, 150 Hz, 250 Hz	100 Hz	Select one option for low-pass Filter, Baseline Wander Filter and AC Filter.
Baseline Wander	0.01 Hz, 0.02 Hz, 0.05 Hz,	0.5 Hz	

Filter	0.35 Hz, 0.5 Hz, 0.8 Hz		
AC Filter	OFF, 50 Hz, 60 Hz	50 Hz	
Rhythm Mode	Single-rhythm	Single-rhythm	Three-rhythm is disabled in iE 101/300.
Rhythm Lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	II	Select a lead as rhythm lead.
Rhythm Time	30 s～300 s	60 s	Select one option for rhythm recording time.
Wave Sample Time	10 s～24 s	10s	Select one option for waveform sampling time.
Printout Duration	3~10s	3s	Select one option for printout duration. Note that this option is only available for iE 101.
Pre-acquisition	Disable, Enable	Disable	Set the pre-acquisition mode. If enabled, it can print out pervious waveforms.
Auto-save	Disable, Enable	Enable	Set whether to automatically save the report.
Data Format	ECG	ECG	The data format for storage.
Auto Upload	Disable, Enable	Disable	Set to upload the waveforms and reports automatically or not after printing.
QTC Formula	Bazett, Fridercia, Framingham, Hodges	Bazett	Select one option for QTC formula.
Examination Type	Normal, Physical Examination	Normal	Select one option for examination type.

☞ **EXPLANATION**

For physical examination of a large population, it is recommended to select **[Examination Type]** > **[Physical Examination]**.

5.2 Print Setting

Enter **[Printer Setting]** to adjust parameters of the Printer. See following table:

Name	Value	Default	Description
Gray Level	1～8	6	Select one option for gray level.
Baseline Width	1～4	2	Select one option for waveform thickness.
Print Speed	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	25 mm/s	Select one option for paper speed.
Report Format	Simple Report, Median Beat Report, Manual Report, Disable	Simple Report	Select one option for report format.
Analysis Output	Enable, Disable	Enable	Select whether to print the interpretation automatically.
Print Grid	Enable, Disable	Disable	Select whether to print the grid on the paper.
Printer	Built-in Thermal Printer, Disable	Built-in Thermal Printer	Select whether to print using built-in printer.
Record Mode	Refer to the ***Appendix B Technical Specification*** and the machine your purchased.	Auto	Select one option for report mode.
Record Format	Refer to the ***Appendix B Technical Specification*** and the machine your purchased.	1 X 12	Select one option for report mode.
Auto Print	Disable, Enable	Disable	Auto Print is disabled in iE 101/300.
Print Data Type	Real Time, Synchronous	Real Time	Select one option for print data type.

5.3 Display Setting

Enter **[Display Setting]** to adjust parameters about display. See following table:

Name	Value	Default	Description
Display Style	Classic White, Classic Black	Classic White	Set the display style of the screen.
Background Grid	Disable, Enable	Enable	Set to display the background gird or not.
Display Format	Same Screen, Split-screen	Same Screen	Select to display all the waveforms in one screen or split the waveforms and display them in different screens.
Lead Format	Refer to ***Appendix B Technical Specification***.	3 X 4	Select one option for lead format.
Lead Standard	IEC Standard, AHA Standard	IEC Standard	Select a lead standard to display.

5.4 Patient Information Setting

Enter **[Patient Information]** to input the patient information.

Input the following information: Sub-ID No., Gender, Age, Date of birth, Height, Weight, BP, Race.

☞ **EXPLANATION**

Age and Date of Birth cannot be selected at the same time.

5.5 System Setting

Enter **[System Setting]** to adjust the system parameters. See following table:

Name	Value	Default	Description
Demo Mode	Normal ECG, Disable	Disable	Select normal ECG to display in the interface as a demo. Or disable the Demo mode.

System Language	English, 中文, etc.	To be determined by the shipping country	Set the system language.
System Version	Version No., Compile Time, Lead Wire Version	/	Display the details of software version.
System Time	Current Time, Date Format, Date, Time	/	Display the details of time and date and to set the date format.
Network Setting	Cable Network	Cable Network	Select one option for network setting.
Transfer Protocol	TCP	TCP	The Default setting is TCP. FTP is disabled in iE 101/300.
Cable Network	IP Address, Subnet Mask, Default Gateway	/	Set the value of IP Address, Subnet Mask, and Default Gateway.
Server Setting	IP Address, Port	/	Input the value of IP Address, Port of server.
Silent Mode	Disable, Enable	Disable	Set to disable or enable the silent mode. If silent mode is enabled, all sound, including alarm tone and key tone will be mute.
QRS Tone	0～10	6	If all three options are zero, a mute icon will be displayed in the Main interface.
Alarm Tone			
Key Tone			
Default Memory	Internal Memory, USB Flash Drive	Internal Memory	Select the default memory way for the saved file.
Memory Format	Internal Memory Formatting	Internal Memory Formatting	Format the specified memory. The files cannot be recovered after formatting.

Standby Time	None, 5 min, 10 min, 30 min, 1 h, 2 h	None	Set the standby time.
Auto Power-Off	None, 30 min, 1 h, 2 h, 3 h	None	Set the auto power off time.
System Password	Disable, Enable	Disable	Select to disable or enable to set a system password.
Password Setting	0～9999	1234	Set the password when the system password is enabled.
General Setting	1～10	1	Select one option, and then set up according to your habit, all your setup will be stored in this option to facilitate your next use. Different doctor or different check up can occupy different options.
Import Setting	Import from USB flash disk	/	Import files from USB flash disk.
Export Setting	Export to USB flash disk	/	Export files to USB flash disk.
Factory Default	/	/	Restore to the factory default settings.
Hospital	/	/	Input the name of hospital.
Device No.	/	/	Input the number of this ECG machine.

CAUTION

Demo mode is designed for representation only. Do not use this mode in clinical analysis, for demo waveforms may be mistaken as that of patient and misdiagnose may happen.

5.6 Factory Maintain

Only the authorized service engineer can enter **[Factory Maintain]**, please contact with our Customer Service Department if necessary.

Chapter 6 Data Management

Select **[Menu]** > **[Data Management]** to enter the Data Management interface. Select one source of storage medium from Local (ECG machine), USB 0, or USB 1, the ECG files will be uploaded.

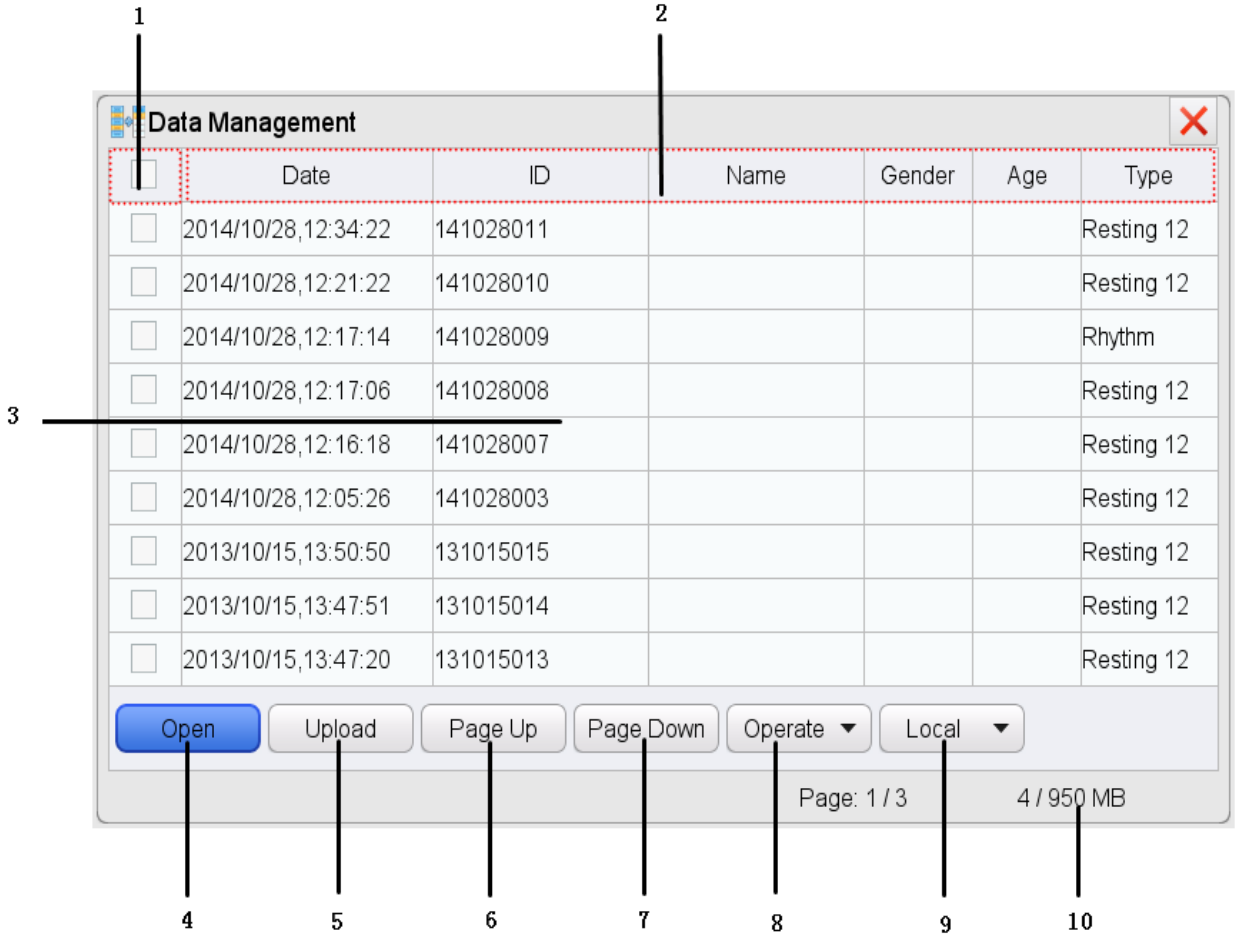


Figure 6- 1 Data Management

No.	Name	Description
1	Select All Shortcut Button	Press to select all the ECG files in the current page.
2	File Attributes Area	Select any file attribute, and sorting files by pressing **ENTER**.
3	ECG Files Display Area	Display basic patient information of all the ECG files.
4	**Open**	Open one patient's ECG file.
5	**Upload**	Upload selected ECG files to ECG workstation or server.
6 and 7	**Page Up/Page Down**	Browse ECG files in previous or next page.
8	**Operate**	Select to **Refresh**, **Copy**, **Move**, **Delete**, or **Search** the ECG files.

		Search ECG files according to ID number, name, age, time and symptom. Search ECG files according to ID number, name, age, time and symptom.
9	Select Storage Medium	Set one option for the storage medium, including local, USB 0 and USB 1.
10	Indication Area	Indicate pages of ECG files and internal memory.

6.1 Open an ECG File

Select an ECG file, select **[Open]** and press **ENTER** to open the file.

☞ **EXPLANATION**

When you select more than one file to open, the default file is the first selected file.

6.2 Edit an ECG File

After opening the ECG file, you can edit the patient information and analysis result, can also upload, save and print the file. You can refer to ***Analysis Report Mode*** to know the content and function of the ECG file.

6.3 Delete ECG Files

Select **[Operate]** > **[Delete]** and press **ENTER** to delete files.

CAUTION

Deleted files cannot be recovered. Please confirm before deleting.

6.4 Copy and Move ECG files

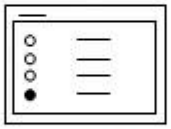
Select one or more ECG files, operate as following to transfer the ECG files.

[Data Management]

Select one or more files

[Operate]

Select **[Copy]** or **[Move]**



Select a storage medium

ECG files are copied or moved to the selected medium

☞ **EXPLANATION**

- Files can be copied or moved between the local ECG machine and external storage medium. ECG files on the local machine will be deleted if the user moves them.
- After selecting files and a path, the files will be copied to the selected path. When copy files to USB device,

the system will create a new folder in the USB device to store the selected files, for example “ecg database”.

- When there is not enough memory, the system will indicate that. You should choose new memory to make files copying or moving successfully.
- Please regularly clear data in a storage medium or the speed of the machine will be slowed down.

CAUTION

- When copying or moving the files, the continuity of power supply must be assured, or the files may be missing.
- When copying or moving the files, it is not allowed to insert or unplug the USB device; otherwise, it may cause abnormality of the ECG machine.

Chapter 7 Maintenance

7.1 Main Unit

CAUTION

- Gently disconnect the Patient Cable and power cable without forcibly pulling the lead wires.
- Clean the ECG machine as well as the accessories and cover the machine from dust.
- Store the machine in a dry and cool environment and avoid excessive shocking and vibration.

7.2 Patient Cable

CAUTION

- The lead wire must be periodically checked. Damage may cause incorrect of ECG waveform at some or all leads.
- The user should avoid twisting the Patient Cable, or the life time of the Patient Cable will be shortened.

7.3 Cleaning and Disinfection

Before cleaning, power off the ECG machine and disconnect it from the AC power.

Do cleaning first before disinfection.

The process to clean and disinfect the ECG machine, cables, lead wires and reusable electrodes are as follows:

1) Use a clean soft cloth absorbing an amount of cleanser or disinfectant to wipe the surface carefully and avoid touching connectors of the ECG machine and accessories.
2) When necessary, wipe the superfluous cleanser or disinfectant with dry cloth.
3) Place in the ventilated and cool environment to dry the ECG machine and accessories.

Sterilization operation for this ECG machine and accessories is not recommended, unless the manual of the accessories has requirement.

CAUTION

- While cleaning and disinfection, do not splash liquid into the ECG machine and the accessories.

- Disinfections may cause damage to the ECG machine or accessories to a certain degree. It is suggested that only when necessary, disinfect the ECG machine and accessories.
- Neutral cleanser or disinfectant is recommended.

7.4 Recording Paper

CAUTION

- To ensure good ECG recording, please use suitable thermal recording paper for the ECG machine. Incorrect recording paper can damage printer head and cause problems such as blurring trace and incorrect paper running. Pay attention to the following comments on recording paper.
- Never use recording paper coated with wax for the ECG machine. It may cause serious problems to the printer head.
- When exposed to high temperature, high humidity and direct sunlight, the recording paper will deteriorate. It is therefore required to store the thermal recording paper in a dry and cool environment.
- When exposed to fluorescent light for long time, the recording paper will deteriorate.
- When stored with polyvinyl chloride (PVC), the recording paper will deteriorate.
- If the thermal recording paper is stored overlapping for a long time, the printing impression will leave traces in other pages, which will cause mislead readings.
- Use suitable size recording paper for the ECG machine. Or, it may cause damage to the printer head and Silicon rubber shaft.

7.5 Battery

The ECG machine is equipped with a built-in rechargeable battery to assure continuous operation when AC power is unavailable. Charging, capacity indication and replacement of the battery are described below:

◆ **Charging**

The ECG machine is designed with a charger and protector for the battery.

- Please turn off the machine first before charging the battery.
- The battery-charging indicator on the operation keyboard will become green when the battery is charged completely.

- Discharge and charge the battery at least once every three months (discharge the battery until the machine turns off automatically, and fully charge the battery).

◆ **Capacity indicator**

When the unit is powered by battery, there will be a symbol of battery capacity indication displayed on the LCD.

For example:

 Full battery capacity, it can work continuously for about 3 hours.

 Battery capacity is sufficient.

 Insufficient battery capacity, charging is required.

 Battery capacity is going to running out, immediate charging is demanded.

 Battery capacity has already run out and blackout may happen at once, immediate charging is demanded.

◆ **Battery replacement**

The battery should be replaced by the professionals according to the following procedures.

1. Power off the ECG machine and disconnect the AC power cable.
2. Flip over the ECG machine and disassemble the battery back cover based on the instruction on the back cover.
3. Disconnect the battery plug and take out the battery.
4. Replace the existing battery with a new one. Pay attention to polarity and connection.
5. Install the battery cover.

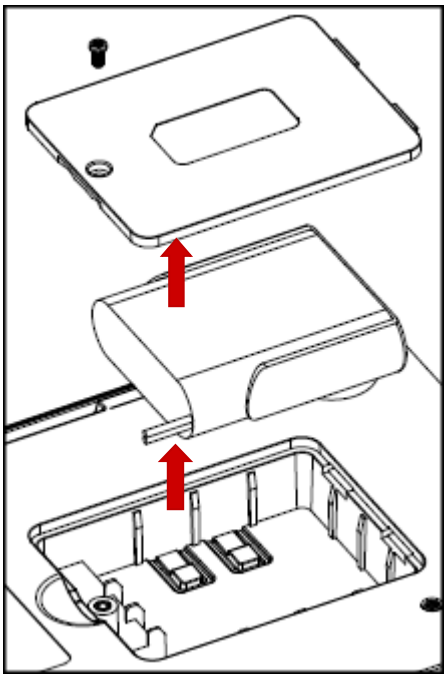


Figure 7- 1 Battery Replacement

☞ **EXPLANATION**

Refer to ***Foreword*** for other warning information of battery.

7.6 Silicon Rubber Shaft for Printing

The silicon rubber shaft shall be kept clean, smooth and free from dirt. Otherwise, the ECG machine may print out unsatisfied ECG trace. To clean the shaft, wipe the shaft with soft cotton moistened with medical alcohol and at the same time rotate shaft until it is clear enough.

7.7 Thermal Print Head

Residue and dirt on the thermal print head could affect the clarity of recorded ECG waveform. To clean the thermal print head, open the paper cover and clean the print head with soft cotton moistened with medial alcohol. It is not permitted to clean the print head with a sharp object, which can cause permanent damage to the print head. Thermal print head maintenance should be done at least once a month.

Chapter 8 Troubleshooting

8.1 Lead Fault

1. Data saturation or overflow happens.

   Solution:

   Ensure that all leads are in good contact, and wait for half a minute or the waveforms on the screen are stable, and then start printing.

2. Straight line is printed in some leads.

   Solution:

   1) Check if the metal piece of limb electrode contacts the body properly; if not, adjust the position of the limb electrode, and adjust the tightness if necessary.
   2) Check if the limb electrodes and chest electrodes are oxidized or faded, and clean the accessories or replace with new ones. Oxidation and aging cause conductive deterioration of the electrode sheet, resulting in poor signal transmission.
   3) Treat the skin of the patient with alcohol; especially in the winter of the North, dry skin causes skin resistance to become larger, which will impact the signal reception.
   4) Please clean the joints of lead wires, suction ball and limb clip, reinstall and tighten all joints. After long-term use, the joints will have dirt or become loose, resulting in poor signal transmission.
   5) Check if the appearance of the lead wires has obvious fracture; if yes, replace with new lead wire. If not, connect a proper lead wire to the device. If the waveform is stable, the lead wires have problem and have to be replaced.
   6) If there is no lead wire available, check if the lead wires conduct with a multimeter. First check if the inner conductors of the lead wires are conductive. Generally speaking, the acceptable resistance shall be about 10 kΩ. Then check if there is a short circuit between the outer shield and inner conductor. The resistance shall be infinity. If the lead wires have a problem, please contact our service department to replace new lead wires.

3. The other reason for lead fault can be caused by failure in signal communication. Please exclude other causes for lead fault problems first, and contact our service technicians if necessary.

8.2 Printer Failure

1. Unclear printing.

   Solution:

   1) Whenever a printer fault occurs, such as poor or incorrect ECG recording, you may try to clean the thermal printer head with soft cotton dipped with medical alcohol.
   2) Please check if the quality of the thermal paper is poor or if the unsealing time is too long, resulting in reduced performance of thermal layers, and replace with provided or specified recording paper.
   3) If the above methods are not applicable, guide the user to test the print head and check if the print head has breaking point; if yes, contact the company service department to replace the thermal print head.

2. Upper half or lower half is blank.

   Solution:

   Check if the bearing on both ends of the rubber shaft of the paper compartment cover is worn, and replace with new bearing if yes.

3. All paper or most part is blank.

   Solution:

   1) Make sure that the thermal recording paper is not installed backwards.
   2) Check if the print head is stuck by dirt (such as adhesive tape); this often occurs when new print paper is replaced.

8.3 Indicator of Lead Off

This ECG machine can detect the lead connecting status continuously. When the leads are not well connected to the main unit, it means that the signals cannot be transferred correctly, thus there is “lead off:*” indication, accompanied by voice alarm. The symbol “*” represents the fault lead, the waveform of which will display as a straight line. Please check carefully whether the connection among the related electrodes, human body, lead wire and the main unit remains well.

8.4 AC Interference

Apparent and regular trembling of ECG waveform in the process of recording due to AC interference is shown as below.

Causes of baseline wander are varied, please do following checks one by one：

1. Make sure the ECG machine is properly grounded according to the instructions.
2. Make sure the lead wires or electrodes are properly connected.
3. Make sure the electrodes and the patient skin have been covered with ECG gel.
4. Make sure the exam bed is properly grounded.
5. Make sure the patient is not in touch with the wall or the metal part of the bed.
6. Make sure the patient is not in touch with anybody else.
7. There shall be no large power electric equipment (such as x-ray machine, ultrasound scanner and so on) operating nearby.
8. The patient shall not be wearing some jewelry like diamond.

CAUTION

Set AC filter to ON if AC interference still exists after the above checks are completed.

8.5 EMG Interference

Irregular trembling of ECG waveform due to EMG interference is shown as below.

Causes of baseline wander are varied; please do following checks one by one:

1. Make sure that the exam room is comfortable for examination.
2. Soothe the patient from irritation or excitement.
3. Make sure the exam bed is in suitable size.
4. Never have talks with the patient during ECG recording.

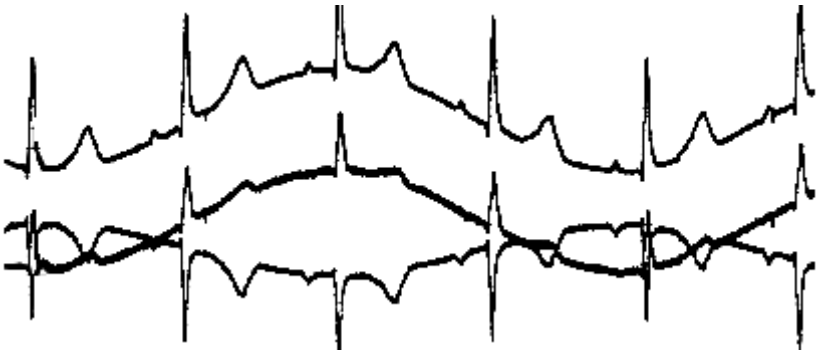
5. Make sure the limb electrode is too tight to make the patient uncomfortable.

CAUTION

Set EMG filter to lower value if EMG interference still exists after the above checks are completed, and keep in mind that the recorded ECG waveform, particularly R wave, will be somewhat attenuated.

8.6 Baseline Wander

Irregular movement of ECG baseline due to baseline drift is shown as below:



Causes of baseline wander are varied, please do following checks one by one：

1. Make sure the electrodes are in good contact with skin.
2. Make sure the connection between the Patient Cable and electrodes is normal.
3. Make sure the electrodes are clean and patient skin contacted with the electrodes has been well pretreated.
4. Make sure the electrodes and skin are covered with ECG gel.
5. Keep the patient silent and motionless, and keep the patient from hyperventilation.
6. Used electrodes shall not be utilized with new ones in patient examination.

CAUTION

If the problem still can’t be cleared, please turn up the baseline wander filter, keep in mind that the recorded ECG waveforms, particularly T wave and ST segment, will be somewhat distorted.

8.7 The ECG Machine cannot be turned on

1. AC power is not working properly and the battery is exhausted.

   Solution:

   First check if the power outlet connects properly, if the power line and the machine connect properly, and then check if local AC voltage is normal. If everything is ok, check if the fuse is good. If everything is

normal after above examination, return the machine to the manufacturer for repair, for it may be damaged.

2. After turning on, the machine turns off automatically after a few minutes.

   Solution:

   While working, if the screen displays the battery power, the machine is using the battery, but the battery power is insufficient, resulting in automatic shutdown. Please supply the machine with AC power, or charge the battery before working; if the user is using AC power and the machine still turns off automatically, please check according to step1.

8.8 Paper Feeding Failure

1. Press  , but paper is not fed.

   Solution:

   Check if the keyboard has been damaged and replace damaged keyboard.

2. Press  , the paper is not fed, and there is abnormal sound from recorder.

   Solution:

   First check if the recording paper is installed properly, and if the gear on the cover of paper magazine is in good condition.

3. Paper feeding isn’t smooth, paper is stuck, or waveforms are compressed.

   Solution:

   First check if the thermal paper complies with the standard, then if the paper is installed properly, or replace a new roll of paper. Finally, replace the paper shaft.

8.9 Battery is quickly Charged and Discharged

If the battery is often not fully charged, the performance will be deteriorated.

Solution:

It is recommended to charge the battery continuously until the battery is fully charged and activated for the first two times. Supply the machine with AC power as far as possible.

8.10 Wrong Analysis Result

For the case for some special populations (such as pregnant women, the user of vascular drugs, etc.) or mixed by obvious interference in the recording process, the analysis result of the resting ECG analysis of this ECG machine

may be inaccurate. The possible reason may be as followings:

1. Poor contact between electrode and patient skin, caused by improper skin treatment and incorrect connection.
2. The patient has relatively large movement in the recording process.
3. Gender or age isn't entered;
4. If there is too much AC, EMG and breathing interference, the identification of P wave and Q wave is not reliable sometimes; if there is baseline wander, the identification of ST segment and T wave is not reliable sometimes.
5. If QRS complex has low voltage, R-wave may be missed, and the electrical axis measurement and the identification of QRS dividing point can be unreliable. Or frequent ventricular contraction occurs or a variety of arrhythmias merge, the relevant detection parameters may be unreliable.
6. The filter settings are incorrect.

   Solution:

   1) Treat as ***Apply Electrode*** and wait until the waveform is stable before reanalyzing.
   2) Enter the patient gender and age correctly.
   3) Exclude the interference as the methods described in ***AC Interference, EMG Interference*** and ***Baseline Wander*** before reanalyzing.
   4) Reset to an appropriate filtering value.

8.11 File Uploading Failure

The most possible reason is that network settings have problems, please check the network connection and refer to ***Network Connection*** to re-set the network.

Appendix A Package and Accessories

A.1 Packing List

Type	Item	Qty
Standard	ECG Machine	1 unit
	Lead Wires	1 set
	Limb Electrodes	1 set
	Chest Electrodes	1 set
	Power Cable	1 piece
	Equipotential cable	1 piece
	Thermal Recording Paper	1 piece
	Paper Roller	1 piece
	User Manual	1 copy
	Warranty Card	1 copy
	Qualified Certificate	1 copy
	Packing List	1 copy
Optional	Electrodes	10 piece
	Pediatric Limb Electrodes	1 set
	Pediatric Chest Electrodes	1 set
	Clips	1 piece
	Cardiograph Cart	1 unit

A.2 Dimensions and Weight

Length × Width × Height	281 mm X 191 mm X 59 mm (iE 101)
	281 mm X 191 mm X 59 mm (iE 300)
Net Weight	About 1.3 kg (iE 101)
	About 1.3 kg (iE 300)

CAUTION

- Please open the package according to instructions on the packing box.
- Enclosed accessories and documents shall be checked according to the packing list before starting checking on the unit.
- Whenever there will be mismatch of the accompanying materials with the packing list, contact our Customer Service Department immediately.
- To ensure good performance and safe operation of the ECG machine, please use the accessories supplied by the manufacturer.
- The package box should be kept well for the regular inspection or maintenance for the machine.

Appendix B Technical Specification

B.1 Specifications

B.1.1 Main Unit

Lead	Standard 12-lead
Acquisition Mode	Simultaneous 12-lead Acquisition
Record Format	1 X 12, 1 X 12+1R (iE 101)
	1 X 12, 1 X 12+1R, 3 X 4, 3 X 4+1R, 3/2 (iE 300)
Record Mode	Auto, Manual, Upload
Display Format	3 X 4, 3 X 4+1R, 6 X 2, 6 X 2+1R, 12 X 1
Rhythm Time	30~300s waveforms acquisition for rhythm analysis
Measurement Parameters	Ventricular Rate, PR Interval, QRS Time Limit, QT/QTC Interval, P/QRS/T Axis, RV5/SV1 Amplitude and RV5+SV1 Amplitude
Filters	AC Filter
	Baseline Wander Filter
	EMG Filter
	High-frequency filter
Input CIR Current	≤0.1 μA
Input Impedance	≥30 MΩ (Full-band)
Time Constant	≥3.2 s
Frequency Response	0.05 Hz～250 Hz
Noise Level	≤12.5 μV_{p-p}
Sensitivity Threshold	≤20 μV_{p-p}
Sensitivity	Auto, 0.625 mm/mV, 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10/5 mm/mV, 10 mm/mV, 20/10mm/mV, 20 mm/mV, and 40 mm/mV
Standard Sensitivity	10 mm/mV ± 2%
Calibration Voltage	1 mV±3 %

Accuracy of input signal reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%; Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample rate and signal rate of the ECG machine, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's and service manuals.
CMRR	＞115 dB
Patient Leak Current	＜10 μA

B.1.2 Recorder Specification

Recorder	Thermal Dot Matrix Word Printing System
Recording Paper	50 mm, roll paper (iE 101) 80 mm, roll paper (iE 300)
Paper Speed	(5, 6.25, 10, 12.5, 25, 50)mm/s ± 5%

B.1.3 Other Specification

Display on LCD	5-inch TFT LCD screen (iE 101)
	5-inch TFT LCD screen (iE 300)
Safety Classification	IEC60601-1, Class I, Type CF
AC Power Supply	100 V-240V, 50 Hz /60 Hz, 80 VA (iE 101)
	100 V-240V, 50 Hz /60 Hz, 80 VA (iE 300)
DC Power Supply	Rechargeable lithium battery, 11.1 V/ 2600mAh. In environment temperature 25 ℃± 5 ℃ and with the machine turning off, the charging time is not more than 2 hours to charge the battery to 90%.
	In environment temperature 25 ℃± 5 ℃, the continuous working time is not less than 3 hours while the ECG device is continuously printing.

B.2 Environment Requirements

1	Transportation	
	Environment Temperature	-20 ℃～+55 ℃
	Relative Humidity	≤95 % (No condensation)
	Air Pressure	70 kPa～106 kPa
	Transportation: avoid direct sunshine and rain.	
2	Storage	
	Environment Temperature	-20 ℃～+55 ℃
	Relative Humidity	≤95 % (No condensation)
	Air Pressure	70 kPa～106 kPa
	The packed ECG should be stored in the well-ventilated room without corrosive gases.	
3	Using	
	Environment temperature	+5 ℃～+40 ℃
	Relative humidity	≤95 % (No condensation)
	Air pressure	70 kPa～106 kPa

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Appendix C Working Principle and Block Diagram

C.1 Power Supply Subsystem

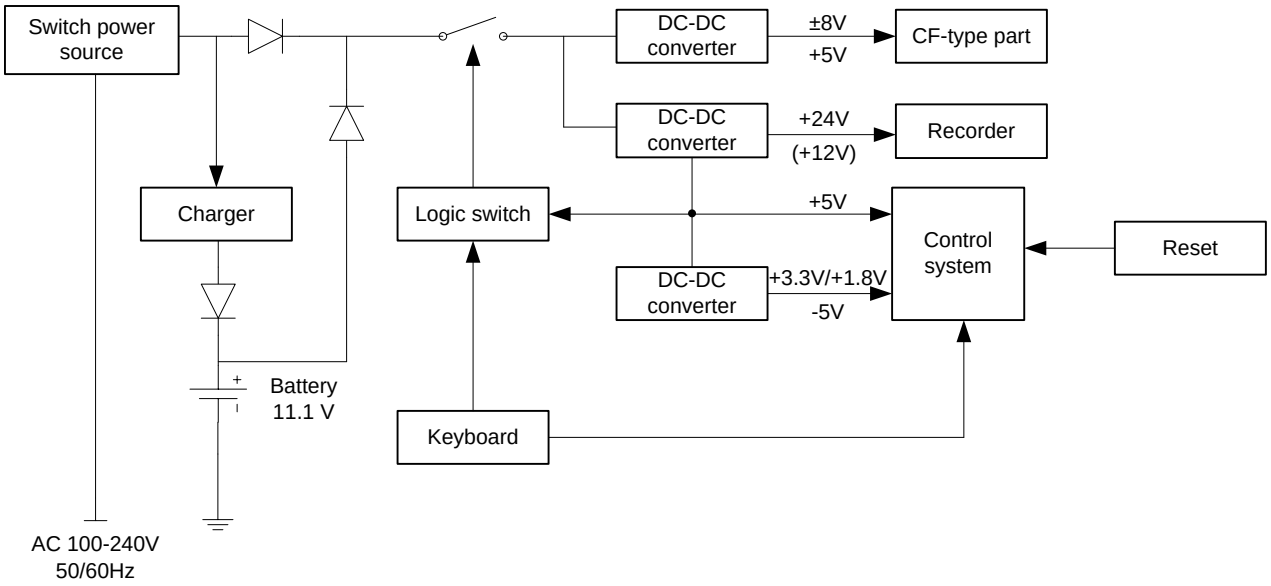
1) Working principle:

By ways of AC to DC high frequency power switching technique, the switching power supply output 20V DC voltage. This voltage works to charge the built-in rechargeable battery at constant voltage and limited current, and at the same time, applies to the power switchover circuitry together with the battery output. If the switchover circuitry is turned on, several stable power outputs will be generated through various switching power technique, including main power supply of +5V and +24 V (+12 V) by the switching power stabilizer, +3.3 V, +1.8 V and -5 V by the power supply transformation.

+5V, +3.3 V, +1.8 V and -5 V supply power for the control system circuitry with the equipotential as reference with 750mA normal load, 3A output current capacity and 3.75A output current limit for short circuit protection.

The +24 V (+12 V) voltage supplies power for the paper driving motor and the thermal printer. The motor is driven by means of width modulation and wave chopping technique in sequence to improve power efficiency. It has about 500mA as normal load, 850mA as output current capacity and 1.2A output current limit for short circuit protection. The self-excitation power switching circuitry transforms the output of the switchover circuitry to several voltages for analog circuitry. The +5V voltage needed by isolated digital circuitry is the direct stabilized output of the switching power supply, of which the normal load is about 150mA and the current capacity is 300mA. The +8V and -8V voltage for the isolated analog circuitry is the un-stabilized output from the switching power supply. Its normal load is about 60mA and has 100mA current capacity.

2) Block diagram (Schematics and parts of list of this unit are only provided for qualified service center under supervision of the manufacturer.)

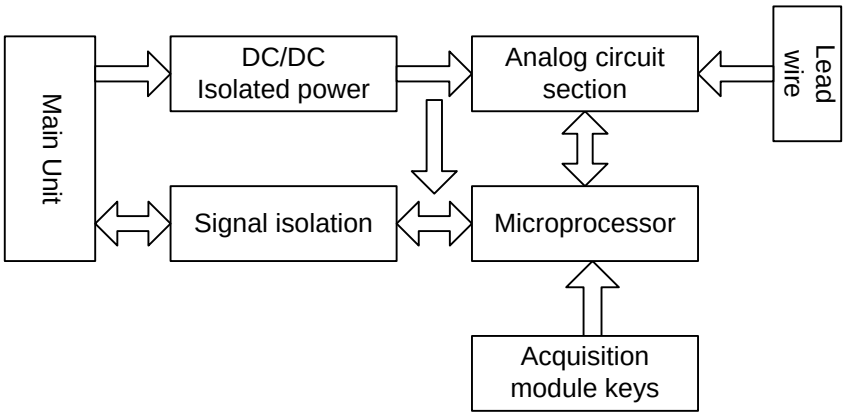


C.2 Acquisition Module

1) Working principle

Acquisition Module is connected to the main unit by ECG port which provides power supply and communication interface. When connecting, the analog circuit and control circuit of acquisition module are powered through the isolated DC/DC switching output. The analog circuit is composed of input protection circuit, anti-aliasing low-pass filter and ECG analog front chips. The electrodes acquire the millivolt electrical signals from human body, which will be converted to digital signals by ECG analog front chips first, then transferred to the processor that controls the converter in the ECG analog circuit, ECG data processing and operation keys on acquisition module. The sampling rate of signals is 8000Hz with 250Hz as bandwidth (-3dB), which meets the standard of AHA and CSE (sampling rate no less than 500Hz). After the signals are processed and filtered, they are sent back to the main unit through optically coupled isolation interface.

2) Block diagram：



3) Leads of acquisition module:

Lead nomenclature	Definition	Name of lead
I II III	I =L-R II =F-R III =F-L	Biopolar limb leads (Einthoven)
aVR aVL aVF	aVR=R- (L+F)/2 aVL=L- (R+F)/2 aVF=F- (L+R)/2	Augmented leads (Goldberger)
V1 V2 V3 V4 V5 V6	V1=C1- (L+R+F)/3 V2=C2- (L+R+F)/3 V3=C3- (L+R+F)/3 V4=C4- (L+R+F)/3 V5=C5- (L+R+F)/3 V6=C6- (L+R+F)/3	Unpolar chest leads (Wilson)

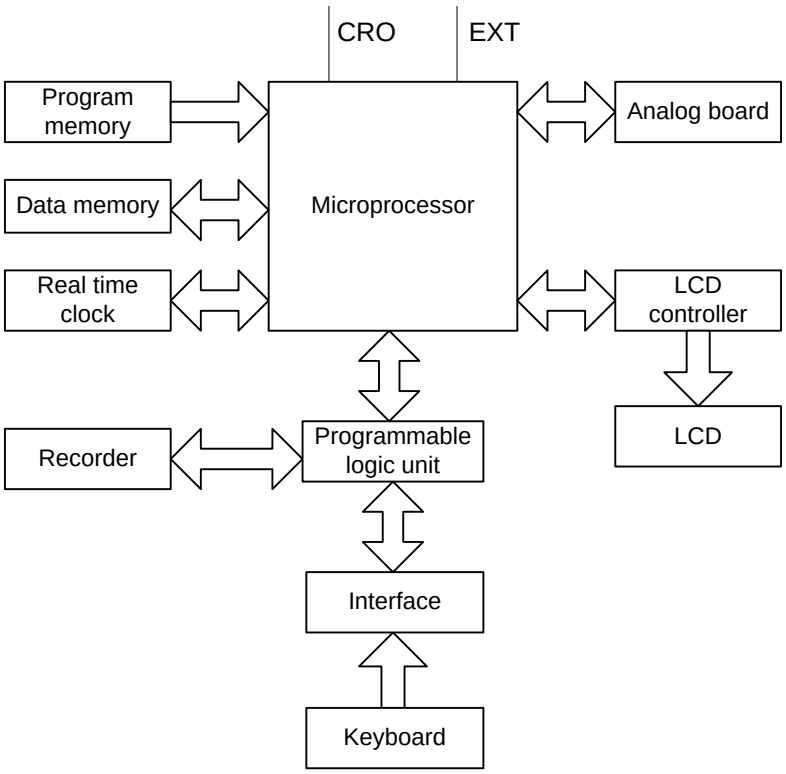
C.3 Control System

1) Working principle

The control system consists of controllers for printer, keyboard, LCD screen and a CPU subsystem. Through high-speed photo-couplers, CPU subsystem receives lead signals from the Data acquisition Subsystem and applies them to the printer controller after digital filtration, gain adjustment and printers driving then

complete the ECG waveforms printing. The lead data will also be measured and interpreted by CPU. In addition to measurement and interpretation on the printed ECG waveform, CPU also receives interruption signals and key codes from the keyboard controller to carry out key interrupt routine. Acquisition and processing of signals for detection of leadoff, out-of-paper detection, battery capacity management, automatic power off, CRO output and EXT input are all managed by CPU. The printer controller receives instructions and data from the CPU, and works to manage the buffering area and generate control signals for the stepping motor and thermal print head to print out ECG waveforms and related information. The keyboard controller works to generate keyboard scan signals, removes key bounces when key is pressed, and sends key codes and interruption signals to CPU for further processing. LCD controller receives instruction s and data from CPU, and works to display the unit's operation status

2) Block diagram



Appendix D List of Interpretation Codes and Corresponding Description

Arrhythmia
Marked rhythm irregularity
Sinus rhythm
Sinus arrhythmia
Marked sinus arrhythmia
Sinus tachycardia
Sinus bradycardia
Atrial rhythm
Atrial fibrillation
Atrial fibrillation with rapid ventricular response
Atrial fibrillation with slow ventricular response
Atrial fibrillation with aberrant conduction, or ventricular premature complexes
Atrial fibrillation with rapid ventricular response with aberrant conduction,or ventricular premature complexes
Atrial fibrillation with slow ventricular response with ventricular premature complexes
Atrial tachycardia
Atrial flutter
Atrial flutter with aberrant conduction or ventricular premature complexes
Cannot rule out atrial flutter
Junctional rhythm
Junctional tachycardia
Supraventricular rhythm
Supraventricular tachycardia
Supraventricular bradycardia
with occasional supraventricular premature complexes
with frequent supraventricular premature complexes
with frequent supraventricular premature complexes in a pattern of bigeminy
Ventricular rhythm

Ventricular tachycardia
with occasional ventricular premature complexes
with frequent ventricular premature complexes
with frequent ventricular premature complexes in a pattern of Bigeminy
Undetermined regular rhythm
Undetermined rhythm
with occasional ectopic premature complexes
with frequent ectopic premature complexes
with frequent ectopic premature complexes in a pattern of Bigeminy
Electronic Atrial pacemaker
Electronic ventricular pacemaker
Dual chamber Electronic pacemaker
Demand pacemaker
Pacemaker failure
Ventricular Fibrillation
AV Conductive Defect
Possible third degree AV block
Second degree AV block, Wenckebach type
Second degree AV block, Mobitz type II
First degree AV block
Short PR interval
Type-A WPW syndrome
Type-B WPW syndrome
Atypical WPW syndrome
Intermittent WPW syndrome
Intraventricular Conductive
Left bundle branch block
Incomplete left bundle branch block
Right bundle branch block, plus RVH
Right bundle branch block
Incomplete right bundle branch block

RSR' in lead V1/V2, consistent with right ventricular conduction delay
Left anterior fascicular block
Left posterior fascicular block
Nonspecific intraventricular conduction block
Nonspecific intraventricular conduction delay
Myocardial
Cannot rule out anterior myocardial infarction, probably old
Cannot rule out anterior myocardial infarction, age undetermined
Possible anterior myocardial infarction, possible acute
Possible anterior myocardial infarction, probably recent
Possible anterior myocardial infarction, probably old
Possible anterior myocardial infarction, age undetermined
Anterior myocardial infarction, possible acute
Anterior myocardial infarction, probably recent
Anterior myocardial infarction, probably old
Anterior myocardial infarction, age undetermined
Cannot rule out anteroseptal myocardial infarction, probably old
Cannot rule out anteroseptal myocardial infarction, age undetermined
Possible anteroseptal myocardial infarction, possible acute
Possible anteroseptal myocardial infarction, probably recent
Possible anteroseptal myocardial infarction, probably old
Possible anteroseptal myocardial infarction, age undetermined
Anteroseptal myocardial infarction, possible acute
Anteroseptal myocardial infarction, probably recent
Anteroseptal myocardial infarction, probably old
Anteroseptal myocardial infarction, age undetermined
Cannot rule out anterolateral myocardial infarction, probably old
Cannot rule out anterolateral myocardial infarction, age undetermined
Possible anterolateral myocardial infarction, possible acute
Possible anterolateral myocardial infarction, probably recent
Possible anterolateral myocardial infarction, probably old

Possible anterolateral myocardial infarction, age undetermined
Anterolateral myocardial infarction, possible acute
Anterolateral myocardial infarction, probably recent
Anterolateral myocardial infarction, probably old
Anterolateral myocardial infarction, age undetermined
Cannot rule out septal myocardial infarction, probably old
Cannot rule out septal myocardial infarction, age undetermined
Possible septal myocardial infarction, possible acute
Possible septal myocardial infarction, probably recent
Possible septal myocardial infarction, probably old
Possible septal myocardial infarction, age undetermined
Septal myocardial infarction, possible acute
Septal myocardial infarction, probably recent
Septal myocardial infarction, probably old
Septal myocardial infarction, age undetermined
Cannot rule out lateral myocardial infarction, probably old
Cannot rule out lateral myocardial infarction, age undetermined
Possible lateral myocardial infarction, possible acute
Possible lateral myocardial infarction, probably recent
Possible lateral myocardial infarction, probably old
Possible lateral myocardial infarction, age undetermined
Lateral myocardial infarction, possible acute
Lateral myocardial infarction, probably recent
Lateral myocardial infarction, probably old
Lateral myocardial infarction, age undetermined
Cannot rule out inferior myocardial infarction, probably old
Cannot rule out inferior myocardial infarction, age undetermined
Possible inferior myocardial infarction, possible acute
Possible inferior myocardial infarction, probably recent
Possible inferior myocardial infarction, probably old
Possible inferior myocardial infarction, age undetermined

Inferior myocardial infarction, possible acute
Inferior myocardial infarction, probably recent
Inferior myocardial infarction, probably old
Inferior myocardial infarction, age undetermined
Cannot rule out inferior myocardial infarction with posterior extension, probably old
Cannot rule out inferior myocardial infarction with posterior extension, age undetermined
Possible inferior myocardial infarction with posterior extension, possible acute
Possible inferior myocardial infarction with posterior extension, probably recent
Possible inferior myocardial infarction with posterior extension, probably old
Possible inferior myocardial infarction with posterior extension, age Undetermined
Inferior myocardial infarction with posterior extension, possible acute
Inferior myocardial infarction with posterior extension, probably recent
Inferior myocardial infarction with posterior extension, probably old
Inferior myocardial infarction with posterior extension, age undetermined
posterior myocardial infarction, possible acute
posterior myocardial infarction, age undetermined
Abnormal Q wave ? [Lat., Inf.]
Abnormal Q wave ? [Ant.]
Abnormal Q wave ? [Ant., Lat.]
Abnormal Q wave ? [Ant., Inf.]
Abnormal Q wave ?
Ventricular Hypertrophy and Atrial
Possible right ventricular hypertrophy
Right ventricular hypertrophy
Right ventricular hypertrophy, probably repolarization abnormality
Minimal voltage criteria for LVH
Possible left ventricular hypertrophy
left ventricular hypertrophy
Left ventricular high voltage (moderate)
Left ventricular hypertrophy, probably repolarization abnormality

Possible left atrial enlargement
Left atrial enlargement
Possible right atrial enlargement
Right atrial enlargement
Biventricular hypertrophy
Biventricular hypertrophy with repolarization abnormality
Axis Deviation
Moderate left axis deviation
Abnormal left axis deviation
S1-S2-S3 pattern
Abnormal right axis deviation
Moderate Right axis deviation
Indeterminate axis
ST-T Abnormality
ST depression, possible digitalis effect
Minimal ST depression
Moderate ST depression
Marked ST depression, possible subendocardial injury
Marked ST depression, possible subendocardial injury or Digitals effect
Marked ST depression, consistent with subendocardial injury
Junctional ST depression, probably normal
Abnormal junctional ST depression
Possible anterior injury or acute infarct
Anterior injury or acute infarct
Possible anteroseptal injury or acute infarct
Anteroseptal injury or acute infarct
Possible anterolateral subepicardial injury
Anteroseptal subepicardial injury
Possible septal subepicardial injury
Septal subepicardial injury
Possible lateral subepicardial injury

Lateral subepicardial injury
Possible inferio injury or acute infarct
Inferio injury or acute infarct
T wave abnormality, possible anterior ischemia
T wave abnormality, possible anterior ischemia or digitalis effect
T wave abnormality, consistent with anterior ischemia
T wave abnormality, possible anterolateral ischemia
T wave abnormality, possible anterolateral ischemia or digitalis effect
T wave abnormality, consistent with anterolateral ischemia
T wave abnormality, possible lateral ischemia
T wave abnormality, possible lateral ischemia or digitalis effect
T wave abnormality, consistent with lateral ischemia
T wave abnormality, possible inferio ischemia
T wave abnormality, possible inferio ischemia or digitalis effect
T wave abnormality, consistent with inferio ischemia
ST elevation, probably early repolarization
Early repolarization
ST elevation, consistent with subepicardial injury, pericardiatis, or Early repolarization
Possible acute percarditis
acute percarditis
Nonspecific ST&T wave abnormality
Nonspecific ST&T wave abnormality, probably digistalis effect
Tall T waves, possible hyperkalemia
Nonspecific T wave abnormality
Nonspecific T wave abnormality, probably digitalis effect
Nonspecific ST elevation
Others
Low voltage
Low voltage in limb leads
Low voltage in chest leads
Long QT interval

Short QT interval
Dextrocardia ?
LIMB LEADS REVERSED
Abnormal QRS-T angle
Consistent with pulmonary disease
Artifacts present
Cannot be analyzed, re-record recommended
Overall Judgment
Normal ECG
Borderline ECG
Atipical ECG
Abnormal rhythm ECG
Abnormal ECG

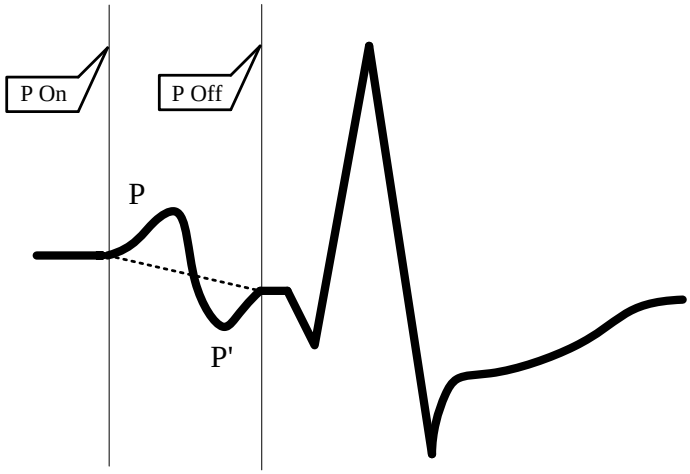
CAUTION

List of Interpretation codes may be subject to changes without notice.

Appendix E Measurement, Diagnosis, Analysis and Assessment of ECG Machine

E.1 Methods to determine the amplitude of P, QRS, ST and T wave

1) P wave amplitude

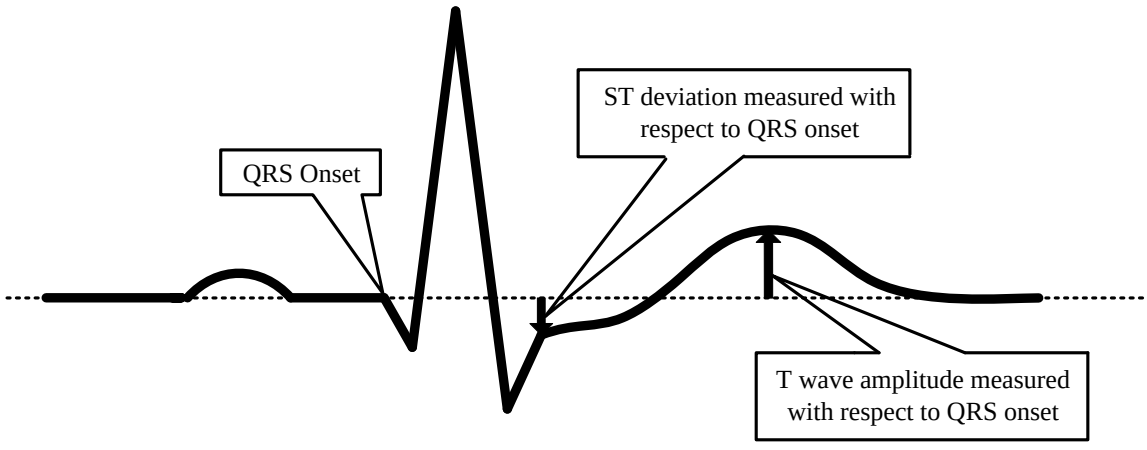


P On is the starting position of P wave, P Off is the ending position of P wave, and dashed line is the reference baseline

To measure P wave amplitude: the line from the starting point to the ending point of P wave is the reference baseline, as shown in above Figure. The positive amplitude is from the reference baseline to top edge of P wave; the negative amplitude is from the reference baseline to bottom edge of P wave.

2) QRS complex, ST segment and T wave amplitude

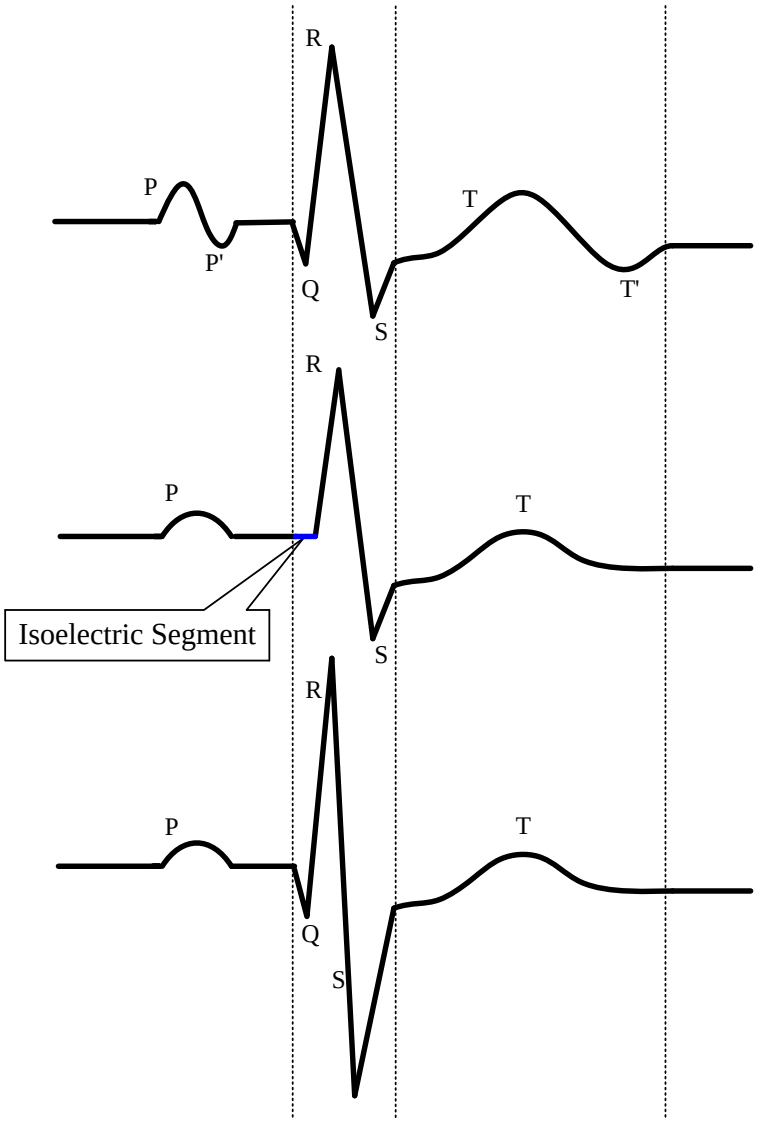
When measuring QRS complex, ST segment and T wave amplitude, the horizontal line of QRS complex beginning part is used as the reference baseline, as shown below:



The measurement of QRS complex, ST segment and T wave amplitude uses the horizontal line of QRS complex

beginning part as the reference baseline QRS Onset is the starting position of QRS wave

E.2 Processing method of isoelectric segment in QRS complex



Isoelectric segment between dash lines are in QRS complex

As shown above, the isoelectric segment beginning from the starting position of QRS complex is processed as a part of QRS complex, but doesn't belong to the meaningful wave later (waveform area is larger than 160 $\mu V \cdot ms$)

E.3 Low incidence heart disease not included in testing and diagnosis database

Test with CSE database, but this database doesn't have sufficient number of acute myocardial infarction and myocardial ischemia ECG.

E.4 ECG diagnosis categories and the number of ECG test of each category

The accuracy of disease diagnosis and non-ECG means used to verify the effectiveness of heart disease diagnosis, as well as the patients statistics data (e.g. age, gender, race) of each group.

Test with CSE database, the following table lists disease diagnostic categories, the number of ECG testing of each category and the accuracy of disease diagnosis.

CSE database sample properties are as follows:

Total number of samples: 1220 (male: 831, female: 389)

Race: White

Age: 52 ± 13

Type of disease	ECG test number	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
Normal	382	92.7	73.9	61.8
Left ventricular hypertrophy	183	60.1	97.0	77.7
Right ventricular hypertrophy	55	32.7	99.9	92.3
Biventricular hypertrophy	53	26.4	99.9	93.3
Anterior wall myocardial infarction	170	80.6	97.7	85.1
Inferior wall myocardial infarction	273	67.0	97.8	89.7
Composite myocardial infarction	73	64.7	99.7	94.0
Hypertrophy and myocardial infarction	31	46.8	100.0	100.0

E.5 The smallest waveform identified by the device and the stability of measurement when noise exists

If the area of certain waveform is greater than or equal to $160\,\mu V \cdot ms$, it is considered as meaningful wave, otherwise it is meaningless. Recognizing meaningful waveforms in area method can effectively reduce the noise. The stability of the measurement when noise exists is shown below

Overall measurement parameter	Type of added noise	Mean difference (ms)	Variance (ms)
P time limit	High frequency	-0.1	0.64
	Power frequency	0.25	1.5
	Low frequency	-2.3	3.8
PR interval	High frequency	1.6	2.4
	Power frequency	-0.1	1.5
	Low frequency	0.38	9.5
QRS time limit	High frequency	0.75	4.0
	Power frequency	-1.1	1.7
	Low frequency	0.3	4.4
QT interval	High frequency	-1.6	3.6
	Power frequency	-0.5	1.2
	Low frequency	4.9	5.6

E.6 Low incidence cardiac rhythm not included in the ECG rhythm test database

The low incidence cardiac rhythms not included in the test database:

1. Grade II conduction block;

2. Grade III conduction block.

E.7 ECG rhythm diagnosis categories and ECG test number of each category

Accuracy of rhythm diagnosis and the patient statistics data (e.g. age, gender, race) of each group

The following able gives the rhythm categories, ECG test number of each category and accuracy of disease diagnosis.

The test database sample properties are as follows:

Total number of sample: 4500 (male: 2847, female: 1653)

Race: Yellow

Age: 48±12

Rhythm type	ECG test number	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
Sinus rhythm	3656	98.0	91.1	97.9
Premature ventricular contractions	351	87.2	98.9	81.2
Supraventricular premature beats	247	68.8	99.6	89.9
Atrial fibrillation	192	89.6	98.7	91.0
Atrial flutter	49	65.3	99.9	88.9
Pacemaker rhythm	5	100.0	100.0	100.0

E.8 Sensitivity regularly test instructions

Inspect ECGs: EGC-1C

Inspection methods:

1) Make ECG machine set in lead I, the sensitivity is set as 10 mm/mV., EGC-1C transmits the U_{in} as 1 mV, frequency 10 Hz sine wave signal to the ECG machine.
2) Test the waveform amplitude h_m on the Inspected ECG machine. Calculate the corresponding to deviations of the sensitivity according to the following formula, should meet the maximum allowable relative deviation of ± 5 %.

$$\delta_S = \frac{S_m - S_n}{S_n} \times 100\%$$

The formula: S_n - nominal value of Sensitivity;

S_m-test value of sensitivity;

h_m-the waveform amplitude of sensitivity ;

U_{in}-input signal amplitude if the inspected ECG machine

3) Make ECG machine set in lead I, the sensitivity is set as 20 mm/mV. EGC-1C transmits the Uin as 0.5 mV, frequency 10 Hz sine wave signal to the ECG machine. Using the same method to test the relative deviation of 20 mm/mV sensitivity.
4) Make ECG machine set in lead I, the sensitivity is set as 5 mm/mV. EGC-1C transmits the Uin as 2 mV, frequency 10 Hz sine wave signal to the ECG machine. Using the same method to test the relative deviation of 5 mm/mV sensitivity.
5) Make ECG machine set in lead I, the sensitivity is set as 2.5mm/mV. EGC-1C transmits the Uin as 4 mV, frequency 10 Hz sine wave signal to the ECG machine. Using the same method to test the relative deviation

of 2.5 mm/mV sensitivity.

6) According to the 1 and 2 steps to change the leads of the ECG machine, and make the ECG-1C's output signals connected to corresponding lead of the ECG machine,to complete all channel's inspect, and then select the largest relative deviation from the test results for each test point, as the result of the inspection.

E.9 Distortion test

The function of ECG machine will not be affected adversely by the running of the pacemaker, which can be verified in the following way:

a) Superimpose the pulse wave of 200 mV peak, rise time less than 100 μs, 1ms pulse width, and 100 beats / min repetition rate with the sine wave signal of 1mV peak-valley value and 40 Hz frequency, and input to the ECG machine (set to standard sensitivity). The time required to restore the sine wave signals recorded by the ECG machine to 70 % of the initial value (when peak-valley value is 1mV and gain is 10 mm/mV, the initial value should be 10 mm) shouldn't exceed 50 ms; in the above test, the maximum baseline drift accumulated in 10 s doesn't exceed 10 mm; both with and without pulse, the amplitude difference recorded by sine wave signals (after waveform is stable) isn't greater than ±1 mm.

b) The filter of ECG machine must be opened for distortion tests.

c) The ECG machine can pass one of the following two tests:

- String the pacemaker pulse wave of 200 mV peak, rise time less than 100 μs, 1ms pulse width, and 120 pulses / min repetition rate together with the symmetrical triangular wave of 2 mV amplitude and 100 ms duration. The starting time of pulse wave should be 40 ms earlier (or later) than the starting time of triangular wave, input such a signal to the ECG machine, record in the standard sensitivity, the triangular wave is clearly visible on the ECG machine records, the difference between recorded amplitude and the original amplitude (the original amplitude of the waveform with 2 mV amplitude should be 20 mm under 10 mm/mV gain) does not exceed 20 %, and the location of the pacemaker pulse can be clearly identified in the ECG machine records.
- String the pacemaker pulse wave of 200 mV peak, rise time less than 100 μs, 1ms pulse width, and 120 pulses / min repetition rate together with the ECG calibration signal CAL20000, and input to the ECG machine. The QRS curve of calibration signal can be clearly identified on ECG machine records, the difference between the recorded amplitude and the original amplitude of QRS curve does not exceed 20%, and the location of the pacemaker pulse can be clearly identified in the ECG machine records.

Appendix F EMC-Guidance and manufacture's declaration

CAUTION

- The use of accessories, sensor and cable which exceed regulations can increase the electromagnetic emissions or decrease the electromagnetic immunity.
- Please don't use the equipment with tightness and pile. The equipment should be detected according to the requirements to make sure it working normally.
- Please make the equipment safety according to the EMC, and install, fix it under the situation required by EMC.
- Even though the other equipments which measure up the CISPR also may cause disturbance.
- When the amplitude of import signal narrow than regulated minimum amplitude may lead to inaccurate measure.
- Portable and mobile communications equipment will affect the performance of the equipment.

F.1 Guidance and manufacturer's declaration – electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emission		
The Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG machine should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The ECG machine 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 CISPR11	Class A	The ECG machine is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

F.2 Guidance and manufacture's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS.

Guidance and manufacture's declaration-electromagnetic immunity			
The ECG machine is intended for use in the electromagnetic environment specified below. The customer of the user of the ECG machine should assure that it is used in such an environment			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±1KV for power supply lines ±1KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1KV differential mode ±2KV common mode	±1KV differential mode ±2KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variation power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT for 0.5 cycle 40% UT for 5 cycle 70% UT for 25 cycles <5% UT for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the ECG machine requires Continued operation during power mains interruptions, it is recommended that the ECG machine be powered from an uninterruptible power supply or a battery.

Power frequency (50Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE: UT is the A.C mains voltage prior to application of the test level.			

F.3 Guidance and manufacture's declaration-electromagnetic immunity for EQUIPMENT and SYSTEMS those are not LIFE-SUPPORTING

Guidance and manufacture's declaration-electromagnetic immunity			
The ECG machine is intended for use in the electromagnetic environment specified below. The customer of the user of the ECG machine should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150kHz -80 MHz 3 V/m 80 MHz -2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ECG machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz-800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz-2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, asdetermined by an

			electromagnetic site survey, range [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: 

NOTE1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 ECG machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECG machine.

b. Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m.

F.4 Recommended separation distance between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distance between portable and mobile RF communications equipment and the ECG machine

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz-80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz-800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz-2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (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.

NOTE1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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