5.3.2 Electrode Selection

The ECG machine is equipped with reusable chest bulbs and limb clamps. For your convenience, you can also purchase disposable electrode slices from the manufacturer. Use chest bulbs or disposable electrode slices to connect the chest leads (C1 ~ C6), while use limb clamps or disposable electrode slices to connect the limb leads (R, F, L, RF).

5.3.2.1 Chest Bulb

The chest bulb is composed of suction bulb and metal electrode. There is a connection hole on metal electrode, which is used to connect the lead wire of Φ4.0 mm connector.

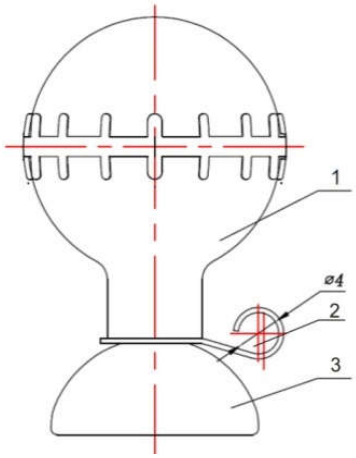


Figure 5.1 Chest Bulb

1. Suction bulb;
2. Connection hole (Φ4.0mm);
3. Metal electrode;

Placing Chest Electrodes

- Check the chest electrodes, and verify that they are clean;
- Respectively connect 6 chest electrodes with its corresponding lead wire. Straighten out the lead wires, and avoid twisting and twining;
- Unsnap the patient's chest button to expose electrode sites;
- Prepare the skin;
- Apply a thin layer of conductive cream on the surface of electrode sites.
- Evenly apply a thin layer of conductive cream on the edges of chest bulbs,;

- Well place the electrodes: squeeze the chest suction bulb to make the lower edge of the metal electrode tightly connected with the skin. Loosen the bulb to make the electrode adsorbed on the patient's skin;
- Ensure that the ECG machine and its cable, electrodes and lead wires are firmly connected.

5.3.2.2 Limb Clamp

The limb clamp is composed of the clamp and metal electrode. There is a connection hole on the metal electrode, which is used to connect the lead wire of Φ4.0 mm connector.

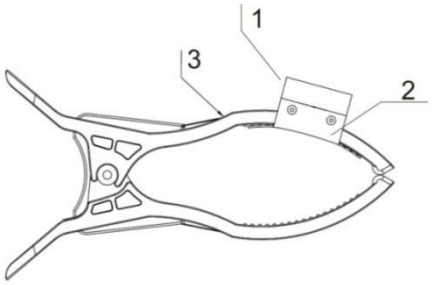


Fig 5.2 Limb Clamp

1. Connection hole (Φ4.0mm);
2. Metal electrode;
3. Clamp

Placing Limb Clamps

Limb electrodes should be placed above the forearm wrist joint and the calf ankle joint medial to make them closely contact with skin, bypassing the bones.

- Check the electrodes to verify that they are clean,
- The four limb electrodes are respectively connected with the corresponding lead wire. Straighten out the lead wires, and avoid twisting,
- Roll up sleeves and trousers to expose electrode sites.
- Prepare the skin,
- Apply a thin layer of conductive cream on the surface of electrode sites;
- Apply a thin layer of conductive cream on metal electrodes,
- Well place the electrodes: clamp the prepared sites by limb clamps;

- Ensure the ECG machine and its patient cable, the electrodes and the lead wires are firmly connected.

5.3.2.3 Disposable Electrode Slice

Disposable electrode slices are not accompanied with this ECG machine. Please contact the manufacturer or authorized representatives if needed.

Steps of placing disposable electrode slices:

- Roll up the patient's sleeves and trousers, and loosen his or her chest button to expose electrode sites,
- Prepare the skin,
- Attach the electrodes in correct position. Limb electrodes should be placed above the forearm wrist joint and the calf ankle joint medial to make them closely contact the skin, bypassing the bones.
- Straighten out the lead wires, and avoid twisting and twining. Connect the lead wires with electrode slices;
- Ensure the ECG machine and its patient cable, the electrodes and lead wires are firmly connected.

- *Please don't mix up electrodes of different types and brands. Otherwise it may cause large baseline drift or longer baseline recovery after defibrillation.*
- *Disposable electrodes can be used only once, repeated use may result in performance degradation or cross infection.*
- *Reusable electrodes must be cleaned and disinfected before use.*
- *Suction bulb of chest electrode contains natural rubber, which may cause allergy. Please pay close attention to the electrode sites, if allergy occurs, please change another type of electrodes.*
- *If reusable electrodes are damaged after long-term use, please contact our after-sale service in time for purchase and replacement. We receive order of*

electrodes only by set. Old and new electrodes cannot be mixed up.

⚠ *CAUTION*

- *In order to achieve satisfactory ECG recording results, metal electrodes must be closely contacted with the skin evenly.*
- *Metal electrodes must be clean. And the prepared sites contacting metal electrodes must be clean, free of grease and perspiration.*
- *When placing chest electrodes, don't let metal electrodes contact with each other, or the conductive cream zone of adjacent electrodes overlap.*
- *When placing the four limb electrodes, don't injury the patient' hands and feet. After placement, check whether the electrodes are too loose or too tight.*
- *Frequent plugging and unplugging may cause the metal plates of limb electrodes moving or loosening, which need adjustment during use.*
- *Reusable electrodes should be immediately cleaned after each use.*

5.4 Electrode Placement

5.4.1 ECG Patient Cable

Contrast Table of Electrodes and Lead Wires:

Placement	Symbol	Color Code
Right Arm	R	Red
Left Arm	L	Yellow
Left Foot	F	Green
Right Foot	RF	Black
Chest	C1	Red
Chest	C2	Yellow
Chest	C3	Green
Chest	C4	Brown
Chest	C5	Black
Chest	C6	Purple

5.4.2 Limb Lead Placement

R ——Right Arm

L ——Left Arm

RF——Right Foot

F ——Left Foot

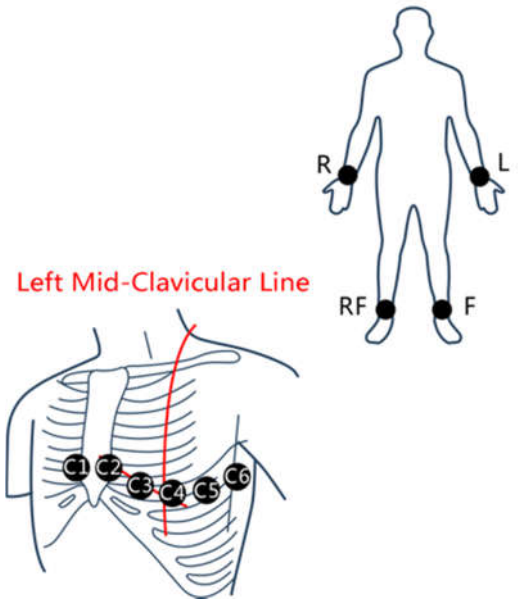


Fig 5.3 Chest & Limb Lead Electrode Placement

5.4.3 Chest Lead Placement

C1: Fourth intercostal space at the right sternal border.

C2: Fourth intercostal space at the left sternal border

C3: Midway between location C2 and C4.

C4: Left mid-clavicular line in the fifth intercostal space.

C5: Left anterior axillary line on the same horizontal level as C4.

C6: Left mid-axillary line on the same horizontal level as C4.

5.4.4 Pediatric Electrode Placement

When acquiring pediatric ECG, C3 lead should be placed in C4R position rather than the site where standard C3 lead is placed, as shown in right figure.

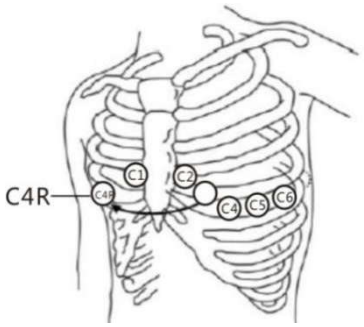


Fig 5.4 Pediatric Chest Lead Electrode Placement

5.5 Electrode Connection

Plug chest lead wires and limb lead wires respectively into connection holes of the chest electrode bulbs and limb electrode clamps. Adjust the contact sites to guarantee compact connection. Pay attention to the electrode placement.

5.6 Lead-off Handling

When the electrode is loose, or the electrode is not properly connected to the lead wire, or the ECG cable is loose from the machine side, the lead name on the ECG display will be red. The "  " icon is illuminated (white) after all leads are connected.

5.7 Entering Patient Information

Some of the patient's information directly affects ECG measurements. Patient information must be checked before starting ECG acquisition. The user can enter into Patient Information page with **F1** key on panel or hotkey 

at bottom right of numeric keyboard. Enter patient information by keyboard; select the desired blank by direction key. For details, please refer to *Chapter 2*. After filling out the information, please confirm and exit.

Chapter 6 ECG Acquisition and Recording

6.1 Acquisition Preparation

To secure the patient and to record stable accurate electrocardiogram (ECG), please carefully check the following items before you power on the machine for measurement.

1）Check whether the exam room is appropriate;

- Whether there are apparatuses such as X-ray machine, ultrasound system and so forth in the patient room, as they may interfere with each other;
- Whether the ground is well connected;
- Whether room temperature and humidity are suitable; temperature would better be in the range of 20 ～ 25℃, ambient humidity would better be in the range of 30% ～ 60%.

2） Whether the power is well connected.

- Whether the power plug is loose;
- Whether the power cord is intertwined;
- Whether the power is sufficient if supplied by battery.

3）Whether the lead wires are well connected.

- Whether the plug is loose;
- Whether the patient cable stays too close to the power cord;
- Whether the lead wires and electrodes are well connected;
- Whether electrodes are installed loosely, or adjacent electrodes have contact with each other.

4）How is the patient?

- Whether the patient is too nervous; whether he or she moves or talks
- Whether the patient’s hands or feet contact metal objects such as bed edges.

5）Whether instruments are in good condition.

- Whether the ECG machine is damaged;
- Whether ECG machine is inspected and maintained regularly:
- Whether recording paper is sufficient.

6.2 Acquisition and Recording

6.2.1 Recording Setup

After the checks are all right, power on the ECG machine, it enters into Waveform Acquisition interface, and then you can observe the waveforms after they become stable. Set the sampling mode, layout, gain, and paper speed on actual needs, and then press 

key to print ECG waveforms. On Waveform Acquisition interface, you can set the ECG machine with **F1~F7** key or by clicks on touchscreen. Press the key 

to switch between auto mode and manual mode. In manual mode, you can change leads with "  " key. If you select a layout with rhythm lead, set it in **12-Lead**. For details, please refer to *Chapter 2*.

CAUTION

- *When ECG signal is just connected or the machine receives overload noise, waveforms will be chaotic, baseline drift will be severe, and waveform amplitude may exceed the maximum width. At this moment, please wait until the machine is connected, the patient calms down, and waveforms displayed on the interface become stable, then start measuring and recording.*
- *When the ECG machine is overloaded or any part of the amplifier is saturated, or ECG machine works abnormally, at this moment, only baseline is displayed on the interface. In order to achieve accurate results, please wait until the machine is connected, the patient calms down, and waveforms displayed on the interface become stable, then start measuring and recording.*
- *During the process of ECG signal acquisition, if waveforms become cluttered or unstable, please refer to Chapter 8.*

6.2.2 Recording Report

The following are the reports printed in real-time auto-simultaneous mode:

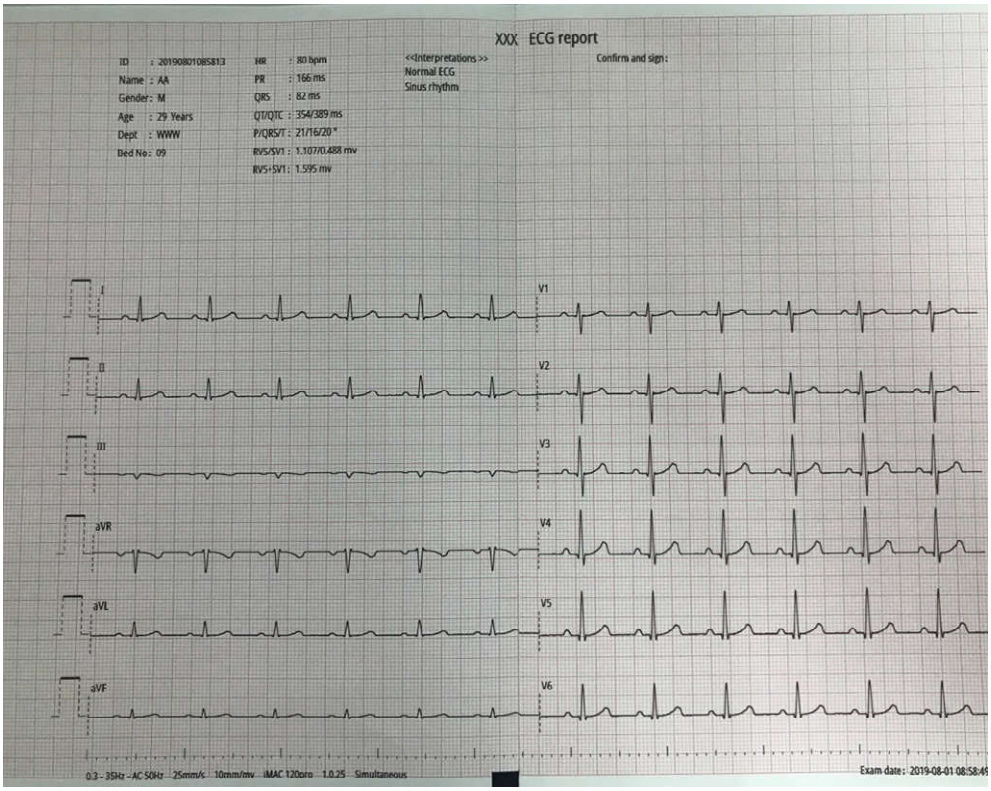


Fig. 6.1 ECG Recording Report(a)

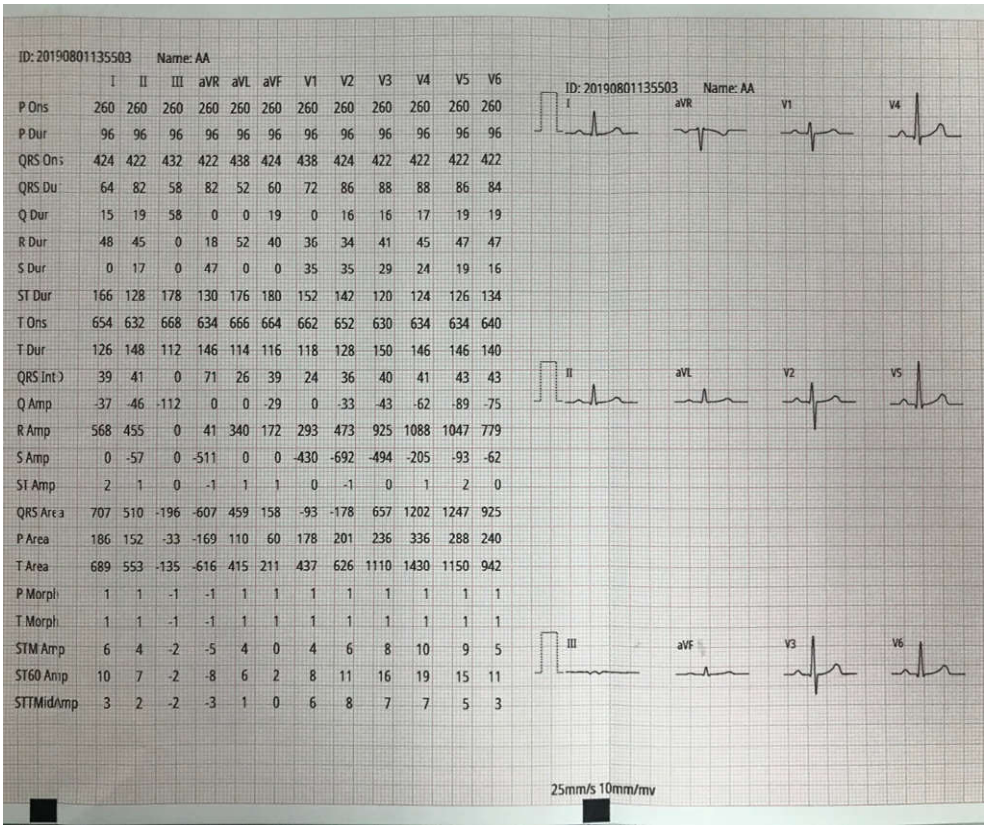


Fig. 6.1 ECG Recording Report(b)

The ECG report above consists of two parts (a) and (b) with a print layout of 6×2.

This ECG report contains the following information: The ECG waveform 6×2 layout, patient information, date of inspection, and measurement information.

Measurement information:

HR: heart rate

P duration: average value of the P-wave duration of the average heart beat of each lead

PR interval: average value of the PR interval of the average heart beat of each lead

QRS duration: average value of the QRS duration of the average heart beat of each lead

QT/QTc interval: average/normalized value of the QT interval of the average heart beat per lead of each lead

P/QRS/T electric axis: the dominant direction of the average integrated ECG vector on the frontal plane.

RV5/SV1 amplitude: the maximum amplitude of the R and R' waves in the average heart beat on the lead V5 / The maximum value of the absolute amplitude of the S and S' waves in the average heart beat on the lead V1

RV5+SV1 amplitude: RV5 and SV1 sum

Minnesota code (optional) ECG code

Average template (optional) : multiple periodic waveform for each lead will be combined into an average of a single periodic waveform

Measurement matrix (optional) : the horizontal display shows 12 leads; the vertical display shows the parameters of each lead, such as PQRST wave start and end points, P, QRS, T wave group interval, etc.

The dotted line on the ECG waveform is the position marker, which marks the start and end points of the P wave, the start and end points of the QRS wave, and the T wave end point.

Diagnostic results: the diagnostic results show the results of the automated diagnosis.

Top information; name of medical institution

Bottom information: 0.6~35Hz (0.6Hz baseline drift filter, 35Hz low pass filter)

AC50 (50Hz AC filter)

25mm/s (paper feed speed)

10mm/mV (gain)

iMAC 120pro (machine model)

1.0.25 (software version)

Simultaneous (recording order)

Inspection date

Confirm report and sign

WARNING

- *This machine's auto-measurement precision conforms to the measurement standard of ECG machine (please refer to Appendixes). Diagnostic structure is made of related parameters in each wave segment. The interpretations are for doctors' reference only, which cannot be used as the basis of clinical treatment.*

6.2.3 ECG Waveform Description

Standard ECG waveform is shown as follows:

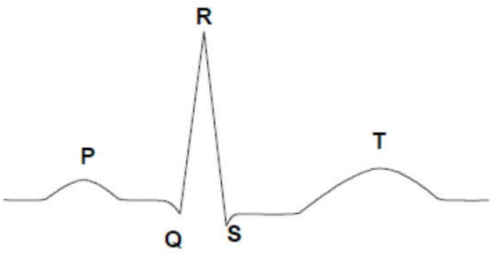


Fig 6.2 Standard ECG Waveform

Meaning and description of each segment of ECG waveform:

- P wave is of blunt round shape, and its amplitude is lower than T wave's.
- PR interval: time from the start point of P wave to the start point of QRS wave group. It represents the depolarization time from atrial to ventricle. The older the patient is or the slower the heart rate is, the longer PR interval will be. Abnormally-prolonged PR interval indicates atrioventricular conduction disturbance.
- QRS waveform group: it indicates the changes of potential and time during ventricular

muscle depolarization. R wave is high and narrow without notch, and its segments are completely above or below the base point.

- S-T segment: a horizontal line from the end point of QRS wave group (J point) to the start point of T wave is called S-T segment. Down deviation of any normal lead's S-T segment should not exceed 0.05mV. When S-T segment's down deviation exceeds the standard range, it is common in myocardial ischemia or strain. Normally, if S-T segment deviates upwards, limb lead and precordia leads of V4-6 should not exceed 0.1mV and precordia leads of V1-3 should not exceed 0.3mV. When S-T segment's up deviation exceeds the standard range, it is common in acute myocardial infarction or pericarditis.
- T wave is of blunt round shape. Its amplitude is lower than 1/3 of R wave's. But it takes longer time. The direction of T wave is usually the same as that of the main wave of QRS wave group. Ⅰ, Ⅱ, V4-6 leads are upright while aVR is upside down. Other leads can be upright, bidirectional or upside down. If V1 is upright, V3 could not be upside down. In the leads of QRS wave group whose main wave is up, when T wave is low and smooth or upside down, it is common in myocardial ischemia or hypokalemia.

CAUTION

- *Here is a simple description of ECG waveforms. For details, please see relevant references.*

6.3 Freeze

Before ECG signal acquisition, please set the freeze time on Standard ECG interface. For details, please refer to *Section 2.3.2.1*. On Freeze interface, use the real-time hotkeys to observe ECG waveforms as needed.

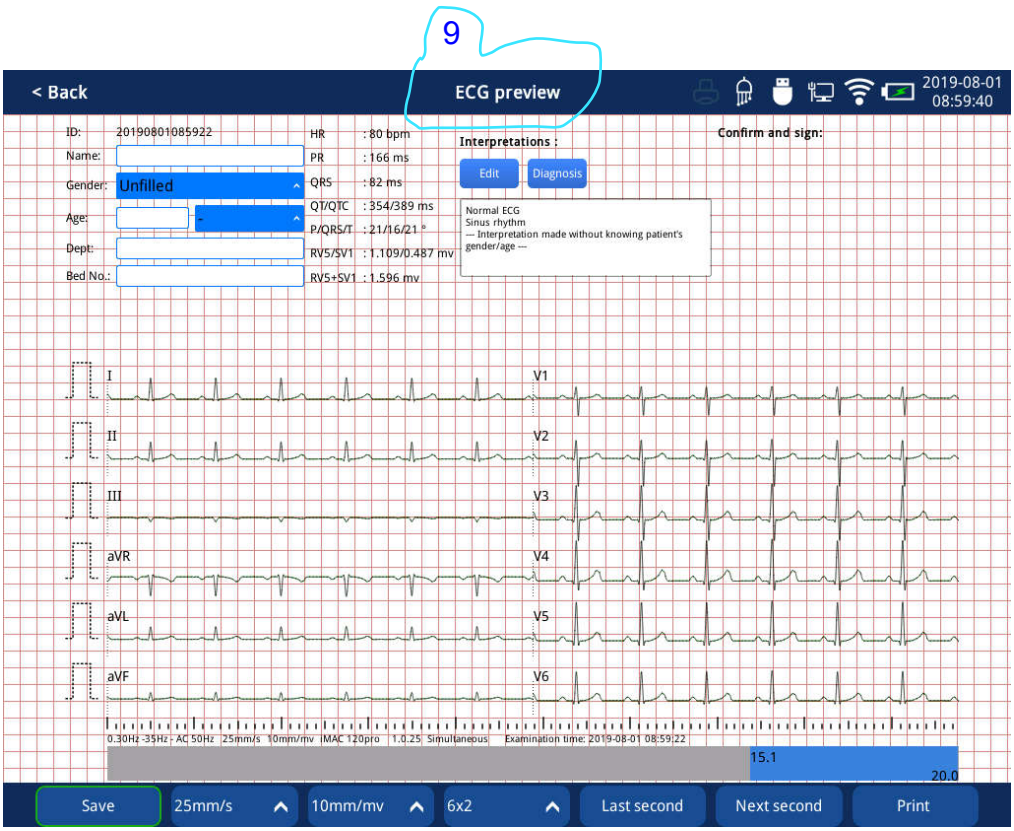


Fig 6.3 Freeze Interface

6.4 Report Storage

6.4.1 Report Storage Location

Configure the report storage location in Application→ Convention→ General with options such as Local/SD card/U disk.

Local: When sampling time is 10s, and layout is 6×2, you can store no less than 1500 reports.

When sampling time is 2.5s, and layout is 6×2, you can store no less than 2000 reports.

U disk (SD card): you can select U disk (SD card) only when it is inserted. Reports are stored in .ECG format and can be viewed from this ECG Machine or dedicated software workstation.

CAUTION

- *Local storage has limited capacity, thus U disk (SD card) is recommended to store the reports.*

6.4.2 Report Storage Mode

In the [Report Management] interface, you can set the report save mode to automatic / manual.

Auto Storage

In auto recording mode, after each measurement, the system will automatically store the current report to designated location.

When freezing the ECG waveforms, the system will automatically generate the report and store it in designated location.

CAUTION

- *In auto recording mode, the system will store the report only when the measurement is finished. If it stops recording abnormally, the report will not be saved.*

- *In manual recording mode, reports are automatically saved every 10s.*
- *When a lead is off the patient, freezing loses its effect, still it can print, but the system cannot store the recording results automatically.*

Manual Storage

When the save mode is set to manual, when the recording ends, the system will pop up the "Save the ECG file?" dialog box .

After freezing the ECG waveform, click the Back button on the Freeze interface. The system will pop up the "Save the ECG file?" dialog box .

Chapter 7 Report Management

7.1 Report Storage

The report is default to be saved locally, but the local storage capacity is limited. It is recommended to use USB storage. The USB has large storage capacity, which is convenient for category management and storage.

To avoid damage or loss of external storage devices, you can back up the reports in the storage device to a dedicated computer server.

7.2 Report Management

In the waveform acquisition interface directly click the " 

" button at the bottom of the screen or click **F6** key enter into the **[Report Management]** interface. For the layout of the interface, see section 2.3.7.

The general setting interface has a locking function. Pressing the key combination "CTRL+ALT+L" will pop up a lock dialog box, which can lock the functions of report printing, report transmission, report deletion and so on. After locking, the option button is grayed out; if you need to change the option settings, press the key combination "CTRL+ALT+L" again to unlock the option.

7.2.1 Selecting Reports

Ways of selecting reports:

- Select a storage device to view reports;
- Touch select the desired report or control it by an external USB mouse;
- Select all reports on the current page;
- Check the Select All button to select all reports.

7.2.2 Searching Reports

Enter relevant information (such as ID number, name) in the "  " query dialog box to query related reports. After the query, the list area only displays the reports that meet the requirements, which is convenient for finding and operating. Figure 7.1.

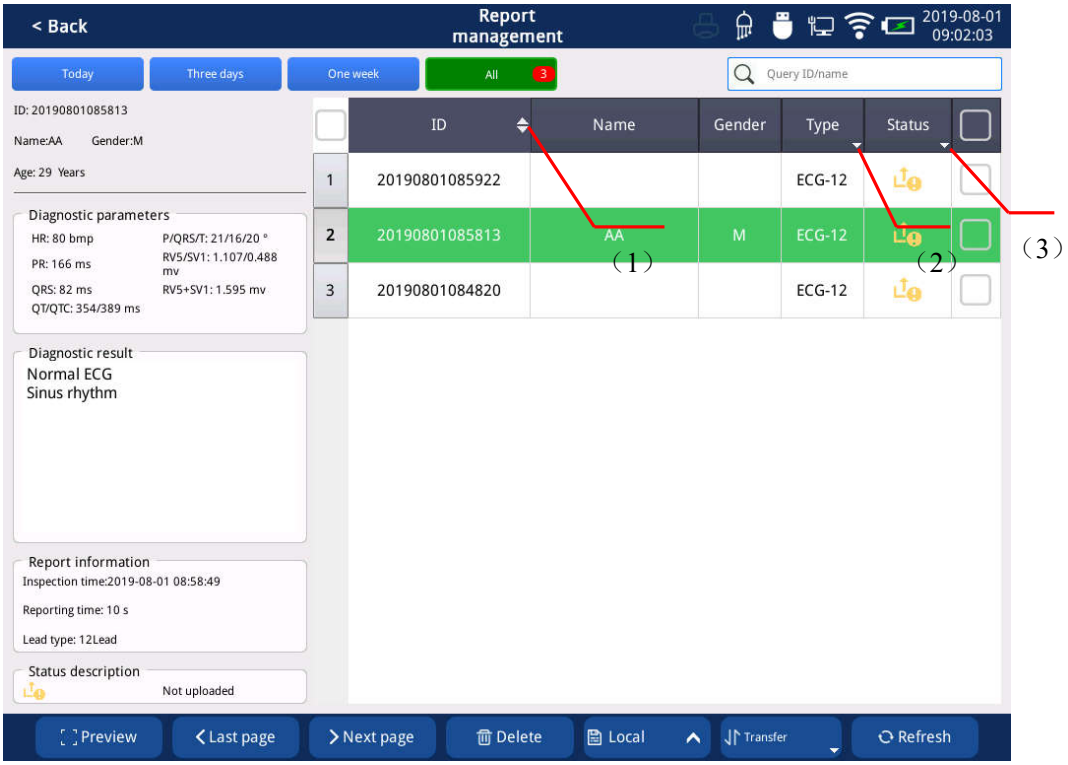


Fig 7.1 Searching Reports

After the query is completed, the query information is deleted, and the content of the report list before the query can be restored.

You can also filter the report in the following ways:

(1) Click the up arrow next to the "ID" button, all reports will be sorted in ascending order by ID number; click the down arrow, all reports will be sorted by ID number in descending order; click the "ID" button, all reports will be sorted in descending order of report modification time.

(2) Click the "Type" button to filter the report by report type. They are: all, standard 12 leads, rhythm, etc.

(3) Click the "Status" button to filter the report by report upload status. They are: all, not uploaded, uploaded, failed to upload, diagnosed, etc.

7.2.3 Editing Reports

After selecting the report, click the “ Preview ” button to enter the ECG report preview interface, you can edit the patient information in the report, edit or re-analyze the diagnostic parameters and diagnosis results in the report. Click the " Edit " button, the "Case dictionary" page will pop up, and the diagnosis result can be quickly edited; the medical record can also be customized and added to the "Case dictionary". Click the “ Diagnosis ” button, the “Previous diagnosis” and “Current diagnosis” comparison pages will pop up. Click the “ Reanalysis ” button to give the diagnosis parameters and diagnosis results of the ECG waveform displayed on the current ECG preview interface. After editing, click the “ Save ” button to save and return to the report management interface.

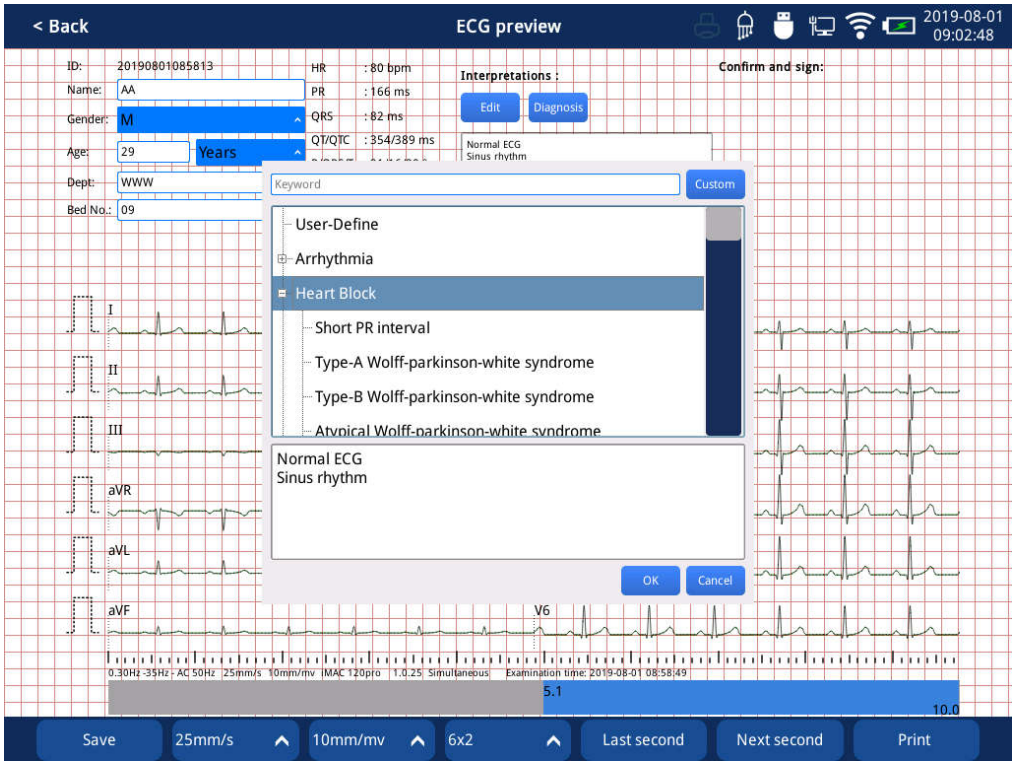


Fig 7.2 Editing Reports

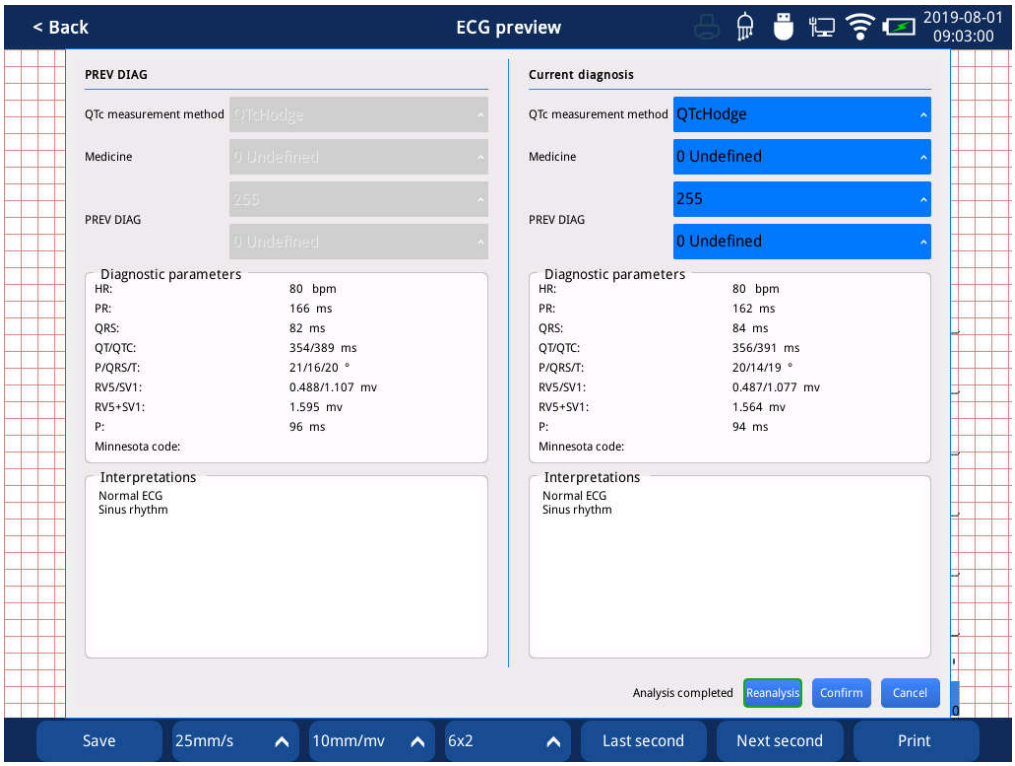


Fig. 7.3 Reanalysis report

7.2.4 Printing Reports

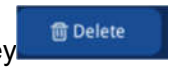
When preview a report, you can print it with 

key.

CAUTION

- *When preview and edit the report, you can select only one report.*

7.2.5 Deleting Reports

Select a report and press the key 

to delete it.

(1) Check to select all the reports in **[Report Management]**

(2) Check to select all the reports in the current page.

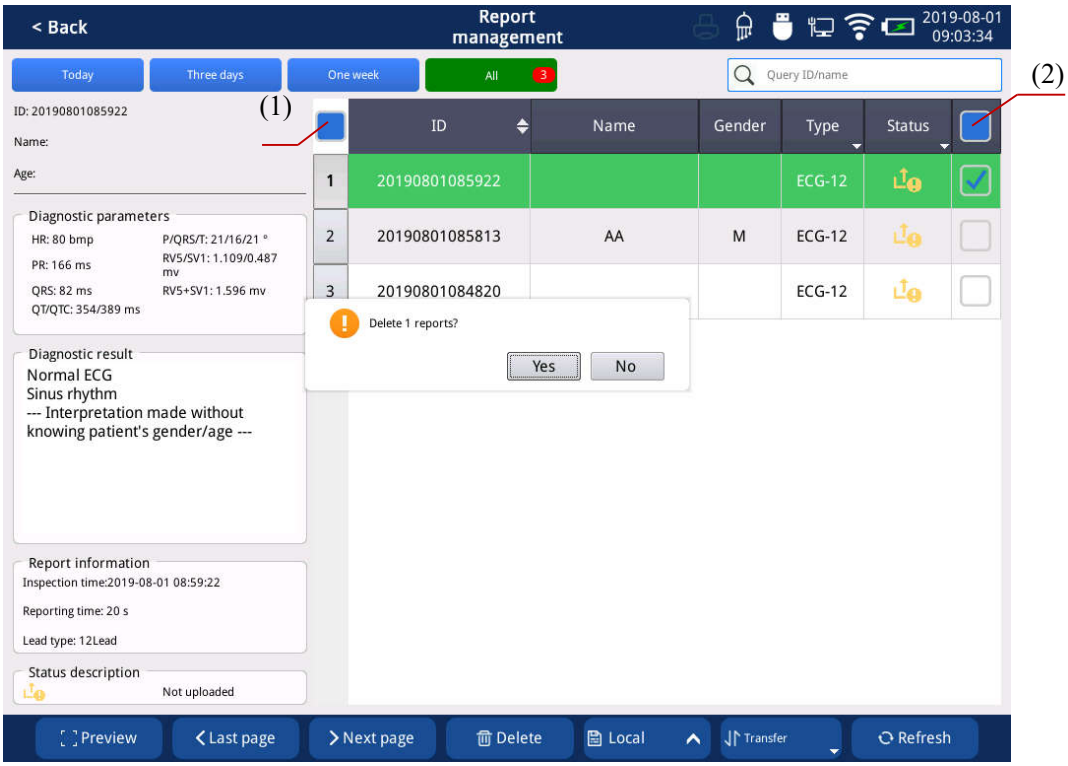


Fig 7.4 Delete Reports

7.3 Report Transmitting

Here are steps of transmitting reports:

1. Click the key 

at bottom of **Report Management** interface.
2. Select a time option (today, three days, one week, all)
3. Select the report to be transmitted
4. Click the " 

" button on the report transmission interface to select the transfer mode (FTP/HTTP/SAMBA/DICOM/USB/SD card/local); (see 4.2.8 [General Setting – Transfer Settings] section and 4.2.9 for details). **[General Settings – DICOM Settings]** section. Note: The transfer mode FTP/HTTP/SAMBA/DICOM can only be used in the [Report Management] interface transmission after the settings interface is enabled.)
5. Continue to click the " 

" button to complete the report transmission. (Support multi-page PDF transmission. For example, if the report template is set to select all, upload the report PDF document, the first page displays the waveform, the second page

displays the measurement matrix, and the third page displays the average template. The PNG format only supports a single report template options.)

6. Status bar：  means not uploaded ;

 means upload successful ;

 means upload failed ;

 means report reload successful;

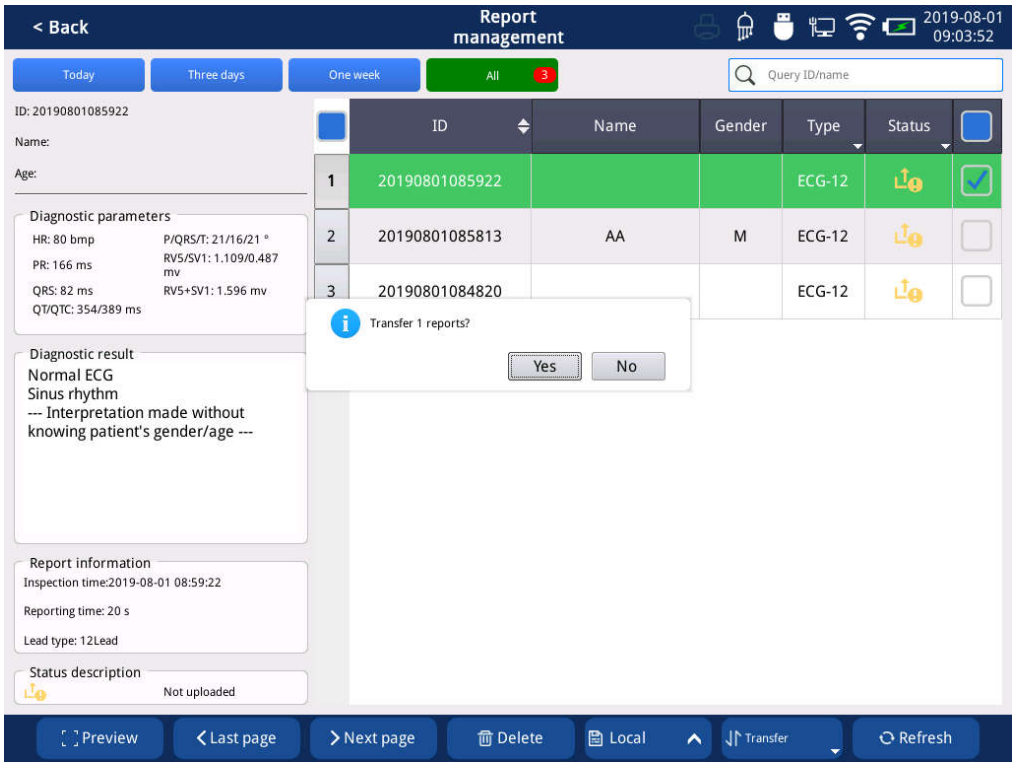


Fig 7.5 Report Transmission

7.4 Report Refresh

Report brush operation steps:

1) Successfully enable HTTP and remote diagnosis on the [**General Settings - Transfer Settings]** screen. (For details, see section 4.2.8 **[General Settings - Transfer Settings]**);

2) Select the report that needs to be transmitted;

3) Click the " 

" button on the report management interface to select the HTTP transmission mode;

4) Continue to click the " 

" button to complete the report transmission.

5) After the remote diagnosis is completed, click the " 

" button to return the ECG report after the diagnosis has been updated.

Chapter 8 Troubleshooting

To record a stable and accurate ECG, when a failure occurs, please find out its cause, and solve it with effective solutions.

WARNING

- *ECG machine cover should be opened only by qualified service personnel. There are no user-serviceable parts inside the ECG machine.*

8.1 Interference Problem

During use, ECG machine will inevitably be disturbed by the environment, itself, human static electricity etc. The ECG machine is desired with functions of myoelectric filter, baseline drift filter, and frequency filter. As the filter band is limited, interference signals cannot be filtered out completely. Therefore, please avoid the interferences caused by the environment or non-standard operation during use.

8.1.1 AC Interference

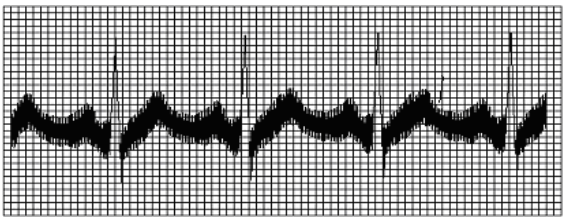


Figure 8.1 ECG with AC interference

1）Environment Cause:

- Both ECG machine and metal bed are properly grounded.
- Avoid electrical devices of large power working in the vicinity of the ECG machine, such as X-Ray machine or ultrasound instrument etc.

2）Patient Cause:

Inform the patient of no touching the wall or metal bed edges. Don’t let other people contact the patient.

3）Electrode Cause:

- Check whether the electrodes or lead wires are connected correctly,

  Electrodes and skin are well applied with conductive cream, clean the patient's electrode sites with medical alcohol, apply conductive cream on the sites evenly, conductive cream on each electrode can't be cross-linked
- Check whether the patient cable is too close to or intertwined with the power cord.
- Check whether the metal part on the connection of lead wire and electrode is rusty or dirty, if it is, please clean it.
- Check whether the patient cable has poor contact, please replace a new cable and try again.

If the interference can't be cleared out by the solutions above, please make sure whether frequency filter is activated.

8.1.2 EMG Interference

Fig 8.2 EMG Interference

1）Environment Cause:

- Check whether the exam room is comfortable,
- Check whether the indoor temperature is too low,
- Check whether the bed is small and narrow.

2）Patient Cause:

- Explain to the examinee that ECG examination is very simple, which will not injury his or her body, or have sequelae;
- Make the patient relax physically and mentally, and breathe gently.
- Do not let the patient move or talk.

3）Electrode Cause:

- Check whether limb electrodes are installed too tightly, which makes the patient

feel uncomfortable,

- Check the metal part on the connection of the lead wire and electrode is rusty or dirty, if it is, please clean it.

8.1.3 Baseline Drift

Fig 8.3 Baseline Drift Waveform Graph

1）Environment Cause:

- Check whether the exam room is comfortable,
- Check whether the indoor temperature is too low,
- Check whether the bed is small and narrow.

2）Patient Cause:

- Explain to the patient that ECG examination is very simple, which will not injury his or her body, or have sequelae;
- Make the patient relax physically and mentally, and breathe gently.
- Let the patient not move or talk.

3）Electrode Cause:

- Check whether limb electrodes are installed too tightly, which makes the patient feel uncomfortable,
- Check whether the electrode is loose or poorly connected.
- Check whether the metal part on the connection of the lead wire and electrode is rusty or dirty.
- Make sure that all electrodes are of the same specification; mixed use of new and old batteries will also cause interference.

If the interference can't be cleared out by the solutions above, please make sure whether frequency filter is activated.

8.2 Recorder Failure

Failure	Possible Cause	Solutions
The paper feeds slowly and unevenly.	As the paper-feeding device has been used for a long time, its transmission ability is degraded by worn gear or loose connector.	Tighten the transmission unit, and apply some lubricating oil on the gear and both ends of paper shaft.
	As the paper-feeding device has been used for a long time, its transmission resistance increases.	Contact our service department for maintenance or replacement.
	The recorder is deformed by external force collision, thus affecting the paper speed.	Contact our service department for maintenance or replacement.
	The paper is out of specification, thus the resistance becomes over-large.	Select and use the specified paper.
	The paper has been installed for a long time, it gets heated or moistened, which makes local viscosity increase, thus affecting the paper speed.	Replace the paper
	ECG machine is not well cleaned and maintained. The recorder's transmission unit is dusty, thus degrading the transmission ability.	Inspect and clean the ECG machine to remove moisture and dust.
The paper doesn't feed, while paper is detected.	The motor is damaged.	Contact our service department for replacement.
	Main control board failure.	Return to depot maintenance.
The printer works with noises but the paper doesn't feed.	Transmission gear is stuck by some hard object.	Clear out the hard object
	Transmission gear teeth are damaged.	Contact our service department for replacement.
It's detected lack of paper.	Recording paper is not well placed or the recorder's printer door is not well closed.	Place the paper again and well close the printer door.
	Paper detector transducer is dusty.	Clear the transducer with Anhydrous ethanol.

Failure	Possible Cause	Solutions
It prints unclear or with breakpoints	Recording paper is out of specification.	Replace it with our paper or with better paper of the same specification.
	Paper shaft is dusty.	Clean the paper shaft.
	Print head is dusty.	Clean the print head.
After pressing "**Stop**", the recorder still works, but prints nothing.	Recording paper is installed backwards. Black label direction is wrong	Reinstall the recording paper.
	Recording paper is out of specification.	Select the recording paper with black label.
	Black label detection sensor head is dusty.	Clean the transducer head with a cotton swab dipped in medical alcohol.
It prints empty	Recording paper is installed backwards	Properly install the recording paper, with grid side right facing to the print head.

The solutions above can solve common printing failures. If there are still some issues unsolved, please contact our service department, or return the ECG machine to us for maintenance or replacement.

Chapter 9 Maintenance

9.1 Cleaning and Disinfection

Please keep the ECG machine and its accessories clean. And in order to avoid damaging the ECG machine, please follow the regulations below:

- Please dilute the cleaner and disinfectant according to the manufacturer's instructions, or use the cleaner and disinfectant whose concentration is as low as possible;
- Do NOT immerse the device into liquid;
- Do NOT dump any liquid onto the device or its accessories;
- Do NOT let any liquid enter into the device ;
- Do NOT use abrasive materials such as steel wool or silver polisher, or any strong solvents such as acetone or acetone detergent.

- *You must turn off the power, and disconnect the power cord and the outlet before cleaning and disinfecting the machine;*

WARNING

- *The ECG machine can be cleaned or disinfected only by the materials and methods listed in this chapter. We will not provide warranty for any damage or accident caused by using other materials or methods;*
- *We will not assume any responsibility for the effectiveness of using the listed chemicals or methods as infection control ways. For ways of infection control, please consult the infection prevention department in hospitals or epidemiologists.*

CAUTION

- *If you accidentally dump liquid onto the equipment or its accessories, cause damage, please contact our service department.*

9.1.1 Cleaning

Available detergents for cleaning the host are listed as follows:

NaClO (Bleaching)

Oxydol (3%)

Ethanol (75%)

Isopropyl alcohol (70%)

It is recommended to clean the accessories with 75% ethanol.

Cleaning the host:

The ECG machine should be cleaned regularly. In those areas where the environment is seriously polluted or the sand blows heavily, it should be cleaned more frequently. Please consult or know about the hospital regulations for cleaning the ECG machine before you clean it.

While cleaning the machine:

- *Turn off the power. Disconnect the power cord, accessories and other devices connected to this ECG machine before cleaning;*
- *Use a soft cotton ball to wipe the LCD screen with some detergents;*
- *Use a soft cloth to clean the surface of the machine with some detergents. Avoid the ports at the sides and rear of the machine;*
- *Wipe off the remaining detergents with a dry cloth when necessary;*
- *Put the machine in a place with cool ventilation to dry it naturally.*

Cleaning ECG cables and lead wires:

- *Please remove the cables from ECG machine before cleaning them and the lead wires.*
- *Use a soft cloth with some 75% ethanol to wipe the surface of the cables and lead wires. Avoid the metal connection parts;*
- *Wipe off the remaining detergent with a dry cloth if necessary;*
- *Put the cables and lead wires in a place with cool ventilation to dry them naturally.*

Cleaning reusable electrodes:

- *Reusable electrodes must be cleaned after each use.*
- *Use a soft cloth with some 75% ethanol to wipe the surface of the electrodes;*
- *Wipe off the remaining detergent with a dry cloth if necessary;*
- *Put the electrodes in a place with cool ventilation to dry them naturally.*

Cleaning the recorder head:

Stains and dirt on the surface of thermosensitive recorder head will influence the record's definition. Therefore the recorder head should be cleaned regularly (at least once a month). If you find that characters on the report are light or the recorder doesn't work, it indicates that the recorder head needs cleaning.

Please follow the steps below to clean the recorder head:

- *Turn off the ECG machine;*
- *Push the button to open the print door, and take out the paper;*
- *Clear out the stains and dirt on the surface of thermosensitive recorder head with a cotton swab dipped with 75% alcohol;*

- *Dry the recorder head gently with a clean cotton swab;*
- *Dry the recorder head naturally, reinstall the recording paper and close the printer door.*

CAUTION

- *Please don't clean the recorder head immediately after recording as the head might be extremely hot at this time.*

9.1.2 Disinfection

Disinfection may cause some damage to the ECG machine or its accessories. It's recommended to perform disinfection only when it is necessary for the service plan in your hospital. Perform cleaning before disinfection.

Disinfectants recommended for the host contain 75% ethanol, 70% isopropyl alcohol, Shu US sterilization agent (C/D-level) with R active oxygen. It is recommended to disinfect the accessories with 75% ethanol.

9.1.3 Sterilization

It is not recommended to sterilize the ECG machine and its accessories unless otherwise required in the manual for accessories.

9.2 Routine Inspection and Test

9.2.1 Daily Inspection

Before the first use each day, the machine appearance should be inspected. Once the ECG machine is found damaged, please stop using it immediately, and contact the engineers in your hospital or our maintainers.

Inspection items include:

- No stain is on ECG machine shell; the panel and LCD screen is not broken or damaged;

- All buttons are in good condition;
- Ports, plugs and cables are not damaged or twined;
- The power cord and ECG cable are firmly and respectively connected with the machine;
- The recording paper is installed correctly, and sufficient for use;
- The battery is installed and fully charged;
- Chest bulbs are free of cracks, and limb clamps clamp well with adequate force.

9.2.2 Regular Inspection

When used continuously for 6 to 12 months, or after maintenance or upgrading, the ECG machine should be tested completely by the qualified service personnel, ensuring that the ECG machine works normally.

Inspection items are listed as follows:

- The environment and power meet the requirements;
- The ECG machine and it accessories are not mechanically damaged;
- The power cord, ECG cable and lead wires are not worn;
- The battery performance is in good condition;
- Function test: used for inspecting the inside of the ECG machine. This test needs to be performed by our professionals or by the authorized personnel under the guidance of our technicians.

CAUTION

- *For accidents or equipment damage caused by lack of necessary maintenance, we will not assume any responsibility.*

9.3 Battery Usage & Maintenance

9.3.1 Overview

ECG machine is configured with rechargeable lithium-ion battery so as to ensure that it works normally while moving in the hospital or when the power fails. When the power fails suddenly, the system will automatically enable the battery to supply the ECG machine, thus the machine won't stop working. .

The rechargeable lithium-ion battery used in the machine has over-charge protection circuit, so it will not get over charged. Its output voltage is related to its power. When its power is low, its output voltage will decrease, but it will not affect ECG machine's normal running. There is a battery detection system inside the machine. If the battery is short of power, it will not be used in order to prevent its over-discharging. The battery plug corresponds to its socket, which could prevent misconnection of battery polarity. The battery is well sealed itself, which will not leak electrolyte or dangerous gas during use.

WARNING

- *Be sure to use and maintain the battery according to the contents in this chapter.*
- *If the battery has sign of damage or leakage, please replace it immediately. Do not install faulty battery into ECG machine.*

CAUTION

- *In order to prevent the machine from working interruption caused by sudden power failure, we suggest the user always install a full-charged battery in it.*
- *When ECG machine is supplied by battery, if the battery is short of power, the machine will crash with black screen. This is a normal phenomenon, which could be eliminated by connection with AC power or charging the battery.*

Battery icons on the screen indicate its status:

Those two icons   indicate that the battery works normally. The white grid shows the power capacity.

This icon  indicates that the battery power is extremely low. When battery power is extremely low, ECG machine will pop out a message “Extremely Low Battery Power”, and the recorder cannot work. At this moment, please immediately connect the machine with AC power to charge the battery. Otherwise it will power off automatically.

9.3.2 Battery Charging

When the ECG machine is connected with AC power, no matter it is turned on or off, the battery will be charged. When the battery is being charged, its light will be lit. Once fully charged, the light will go out

When charging the battery with the ECG machine turned off, in an environment with temperature range of 25℃±5℃, the battery is charged to 90% in no more than 3 hours, and charged to 100% in no more than 3.5 hours.

9.3.3 Battery Replacement

The battery installed in this ECG machine should be replaced by authorized service engineers. Please contact our service engineers if it is demanded for battery replacement.

9.3.4 Battery Guidance

The battery’s life depends on its usage frequency and time. If the lithium-ion battery is properly maintained and stored, its life will last for about 2 years. If used improperly, its life will be shortened. We recommend replacing the battery every two years.

In order to guarantee the battery’s life, please pay attention to the following guidance:

- Battery performance must be inspected once half a year. Besides, you also need to inspect the battery performance before maintenance of the ECG machine or when the battery is suspected to be faulty.

- When the battery has been used or stored for three months or when its working time obviously shortens, perform an optimization on it.
- Before the ECG machine is delivered or when it will not be used for more than 3 months, please take out the battery.
- If the ECG machine has not been used for a long time with the battery installed in it, the battery's life will shorten. The battery should be charged and discharged at least once every three months.
- When the lithium battery is laid aside with 50% of its full power, it can be stored for about 6 months. After 6 months, the battery must be charged again to full power, and then use it to supply ECG machine. When its power reduces to 50% of the full power, take it out of ECG machine and lay it aside again.
- When storing the battery, please make sure that its electrodes do not touch mental objects. If the battery needs to be stored for a long time, put it in a cool environment, which can delay battery aging. Ideally, the battery should be stored in a cool environment whose temperature is 15℃. If the battery is placed in high heat for a long time, its life will obviously shorten. Do not store the battery in the environment whose temperature is not within the range of -20℃～60℃.

CAUTION

- *Place the battery in a place out of reach of children.*
- *Only use the battery designated by the manufacturer.*

9.3.5 Battery Maintenance

Battery Performance Optimization

The battery should be optimized for its initial use. A complete optimization period is continuously charging the battery to full capacity. Then discharge it until the ECG machine is power off. During use, the battery should be optimized annually to sustain its life.

Please optimize the battery by following steps:

1. Disconnect ECG machine with the patient;

2. Connect ECG machine with AC power, continuously charge the battery to its full capacity, and then the indicator light goes out.
3. Disconnect AC power, and supply ECG machine with battery power until it is power off.
4. Connect ECG machine with AC power again, and continuously charge the battery to full capacity, then the light goes out.

CAUTION

- *As the time of using the battery increases, its actual power capacity will decrease. For the used battery, full-capacity icon indicates that neither its power capacity nor supply time could still meet the manufacturer's specification. When optimizing the battery, if you find that its supply time shortens obviously, please replace it.*

Battery Performance Inspection

Battery performance will degrade as times of using the battery increase, thus it should be inspected once a year. Besides, it also needs inspection before servicing the ECG machine or when the battery is suspected to be faulty.

Please inspect the battery according to the following steps:

1. Disconnect ECG machine with the patient
2. Connect ECG machine with AC power, and constantly charge the battery to full power, then the light goes out.
3. Disconnect AC power, supply ECG machine by battery until it is power off.

The Battery's supply time reflects its performance. After announced charging time, if its actual supply time is obviously lower than the time declared in specification, please contact the maintainer to replace the battery.

CAUTION

- *Battery supply time depends on configuration and operation of the machine..*
- *If the battery's supply time is too short after fully charged, obviously less than*

stated in the specification, it might be damaged or faulty. Please contact the maintenance staff to replace the battery.

9.3.6 Battery Recycling

If the battery is obviously damaged or cannot be charged, it should be replaced and recycled properly. When disposing of the used battery, please follow relevant laws and regulations. .

WARNING

- *Do not disassemble the battery or throw it into fire or short it out. Its burning, explosion or leakage may cause personal injury.*

9.4 Usage and Maintenance of Recording Paper

Please follow the rules below when storing the recording paper：

- Store it in cool dry environment free from high temperature, humidity and direct sunlight.
- Do not put it in fluorescent light for a long time.
- Do not let it contact polyvinyl chloride (PCC), which will cause its color change.
- Do not overly the used paper while storing, which may cause its printout transferring with each other.
- Using the paper provided by the manufacturer or of specification dedicated by the manufacturer. Otherwise it may shorten thermosensitive recorder head's life, recorded waveforms will become fuzzy and the paper will feed poorly.

9.5 Maintenance of Electrodes and Lead Wires

Conduction of each lead wire will directly affect ECG traces. If it conducts poorly (any one lead conducts poorly), it will cause virtual image of corresponding lead wire on ECG traces. Therefore the conduction must be inspected regularly, at least once a month.

Slightly bending or entangling the lead wire will shorten its life. Please put it in as good order as possible before use.

Electrodes must be properly stored. After long-term use, their surfaces may become oxidized and discolored because of corrosion, at this moment, it’s better to replace them.

Chapter 10 After-sale Service information

1. When users begin to use the ECG machine, they should fill the details in warranty card and send it back to the manufacturer by mail or email in time, the manufacturer will build the users' profiles and regularly contact them to know about the usage, which will help provide targeted first-rate services constantly.
2. During normal use per the manual and operation notes, once the machine breaks down, please contact the manufacturer's after-sale service center immediately. Users can enjoy free service within the stipulated time on warranty card since the purchase day.
3. The manufacturer after-sale service team or local support partners may fulfill its warranty promise by ways of visiting your place, telephone guidance or delivery back to the manufacturer. .
4. Even within warranty period, the following services will be charged:

   ①Fault and damage caused by improper operation of users;

   ②Fault or damage caused by falling down while moving the machine after purchase;

   ③Fault and damage caused by repairing, transforming or decomposing the machine without the manufacturer's authorization.

   ④Fault and damage caused by fire or natural disaster after purchase;

   ⑤Fault and damage caused by using thermal paper unspecified by the manufacturer;

   ⑥Fault and damage caused by connection with other devices;

   ⑦Warranty seal is broken. Users privately alter and replace the serial numbers of the machine and lead wires. .
5. If the product fails within three months and it is not caused by article 4, the company will replace the main unit free of charge, but the accessories, worn parts and consumables will not be replaced.
6. The company shall not be responsible for the failure of other connected devices directly or indirectly caused by the failure of the product.This warranty system is only valid in China.

7. If warranty label is damaged, the manufacturer has rights to exempt free service within stipulated time on warranty card.
8. For chargeable services out of warranty period, it’s recommended to continue “Service Contract Rules”. For details, please consult the customer service center of the manufacturer.

Chapter 11 Accessories

WARNING

- *Use the accessories stipulated in this manual only. Other accessories may damage this ECG machine or cannot meet the specification declared in this manual.*
- *Disposable accessories can be used only once; Reuse will cause performance degradation or cross infection.*
- *If the accessories or their packages are found damaged, please do not use the accessories.*

Accessories:

Name	Type
Patient Cable	Pinning fibrillation-proof ECG cable
Chest Bulbs	ECG chest electrodes(ф4)
Limb Electrodes	ECG limb electrodes (ф4)
Power Cord for Adapter	Power cord of European standard

I.4 Appearance Parameters

Size	(L × W × H) 285mm×360mm×94mm
Weight	about 3.7 kg

I.5 Environmental Conditions

Operation

Ambient Temperature	+ 5℃～ + 40℃
Ambient Humidity	20%~85%(no condensation)
Atmospheric Pressure	570hPa～1060hPa

Shipment and Storage

Ambient Temperature	－20℃～+55℃
Ambient Humidity	10%～95%
Atmospheric Pressure	500hPa～1060hPa

I.6 Adherence to Standards

EN ISO 13485:2016	Medical devices-quality management system-Requirements for regulatory purpose;
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
~~ISO 10993-5:2009~~	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
~~ISO 10993-10:2010~~	Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization

EN 1041:2008	Information supplied by the manufacturer of medical devices
IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-25: 2011	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance of Electrocardiographs;
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility-Requirements and tests;
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 60601-1-6:2015	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability

Appendix II Electromagnetic (EMC)

Electromagnetic compatibility (EMC) is defined as the ability of a product, device, or system to function properly in its electromagnetic environment without posing unacceptable electromagnetic disturbances to anything in the environment.

Anti-electromagnetic interference is the ability of a product, device, or system to function properly in the presence of electromagnetic interference (EMI).

It is designed and manufactured in accordance with existing electromagnetic compatibility standards and related requirements. Use in the presence of an electromagnetic field may cause performance degradation such as output anomalies. If this happens frequently, it is recommended to check the environment in which the ECG is used to determine possible sources of disturbance. These harassments may come from other electrical equipment used in the same room or in a nearby room, or from portable and mobile RF communications equipment such as cell phones, walkie-talkies, or from nearby radios, televisions, or microwave transmission equipment. If electromagnetic interference (EMI) interferes with the ECG, it may be necessary to move the ECG to another location or take appropriate electromagnetic interference suppression measures.

This product complies with the requirements of the EMC standard IEC 60601-1-2.

Warning

- *It will not be used for the lead wire and power cord of the electrocardiograph for the electrocardiograph, which may result in an increase in the emission of the electrocardiograph or a decrease in the immunity.*
- *The electrocardiograph should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed that it will function properly in the configuration in which it is used.*

Note

- Medical equipment has special precautions for EMC and needs to be installed and used according to the EMC information provided in the

documentation provided with the ECG.

- This section includes information on electromagnetic radiation and immunity to electromagnetic systems. Ensure that the operation of the electrocardiograph meets the conditions specified in the reference information. Operating an electrocardiograph in an environment that does not meet these conditions may degrade the performance of the system.
- To ensure electromagnetic compatibility when installing and using an electrocardiograph, follow the information and warnings contained in this and other sections.

Description

- If you operate and use an electrocardiograph in the electromagnetic environment described in "Anti-Electromagnetic Interference" below, it will work safely and provide the following basic properties:

  1 button works normally;

  2 The host continuously collects signals and displays the waveform and measured value results on the display.

Electromagnetic radiation		
The electrocardiograph is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.		
Launch Test	Compliance	Electromagnetic Environment - Guide
Radio frequency emission CISPR 1	Group 1	The ECG uses RF energy only for its internal functions. Therefore, its RF emissions are low and there is little chance of interference with nearby electronic equipment.

Radio frequency emission CISPR 11	Class A	The electrocardiograph is suitable for use in all facilities that are not directly connected to the home and to the public low voltage power supply network of the home.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fluctuation/ flicker emission IEC61000-3-3	Not applicable	

Approved accessories that meet electromagnetic standards

Accessories for electrocardiographs may affect their amount of radiation. The accessories listed in this section have been tested in accordance with international standards when used in electrocardiographs to confirm compliance with radiation standards. Please use only the attachments listed in this section.

When connecting the accessories to the ECG machine, the user should ensure the electromagnetic compatibility of the ECG machine. Unless otherwise stated, use only EMC-compliant equipment.

No.	Name	Cable length (m)	Shielding or Not
1	power cord	1.6	NO
2	Patient cable	< 3	NO

Anti-electromagnetic interference

The electrocardiograph is designed for use in the electromagnetic environment specified herein. The user or user of the electrocardiograph should ensure that it is used in such an environment.

Electromagnetic Immunity Guidelines and Statements			
The electrocardiograph is expected to be used in a defined electromagnetic environment and the purchaser or user should ensure that it is used in such an electromagnetic environment.			
Anti-interference test	**IEC60601Test level**	**Compliance level**	**Electromagnetic environment- guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The floor must be wood, concrete or tile. If the floor is covered with synthetic material, the relative humidity is at least 30%.
Electrical fast transient (EFT)/burst IEC 61000-4-4	±2kV power cord ±1 kV I/O cables (Length >3m).	±2kV power cord ±1 kV input/output cables (>3m)	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The network power supply should have the quality used in a typical commercial or

			hospital environment.
Voltage dip, short interruption and voltage change on the power input line IEC 61000-4-11	＜5％UT（drop＞95％UT）0.5cycle 40％UT（drop 60％UT 5cycle 70％UT（drop 30％UT 25cycle ＜5％UT（drop＞95％UT）5sec	＜5％UT（drop＞95％UT）0.5cycle 40％UT（drop 60％UT 5cycle 70％UT（drop 30％UT 25cycle ＜5％UT（drop＞95％UT）5sec	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the ECG machine needs to run continuously during a power outage, it is recommended that the ECG machine be powered by an uninterruptible power supply or battery.
Power frequency magnetic field (50/60Hz) EC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should have a power frequency magnetic field level characteristic typical of a typical commercial or hospital environment.
Note 1: UT is the A.C. mains voltage prior to application of the test level.			

Electromagnetic interference

Electromagnetic interference can occur on the electrocardiograph in a variety of ways. These disturbances depend on the immunity of the device. In the presence of interference, be careful when continuing to use the ECG machine.

Electromagnetic Immunity Guidelines and Statements			
The electrocardiograph is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such an electromagnetic environment.			
Immunity test	**IEC60601 Test level**	**Compliance level**	**Electromagnetic environment - guide**
Radio frequency conduction 61000-4-6	3 Vrms 150k ~ 80MHz	3Vrms	Portable and mobile RF communications equipment should not be used closer to any part of the electrocardiograph, including cables, than the recommended isolation distance. This distance is calculated by a formula corresponding to the transmitter frequency. The recommended isolation distance is calculated as: d = 1.2 $\sqrt{P}$