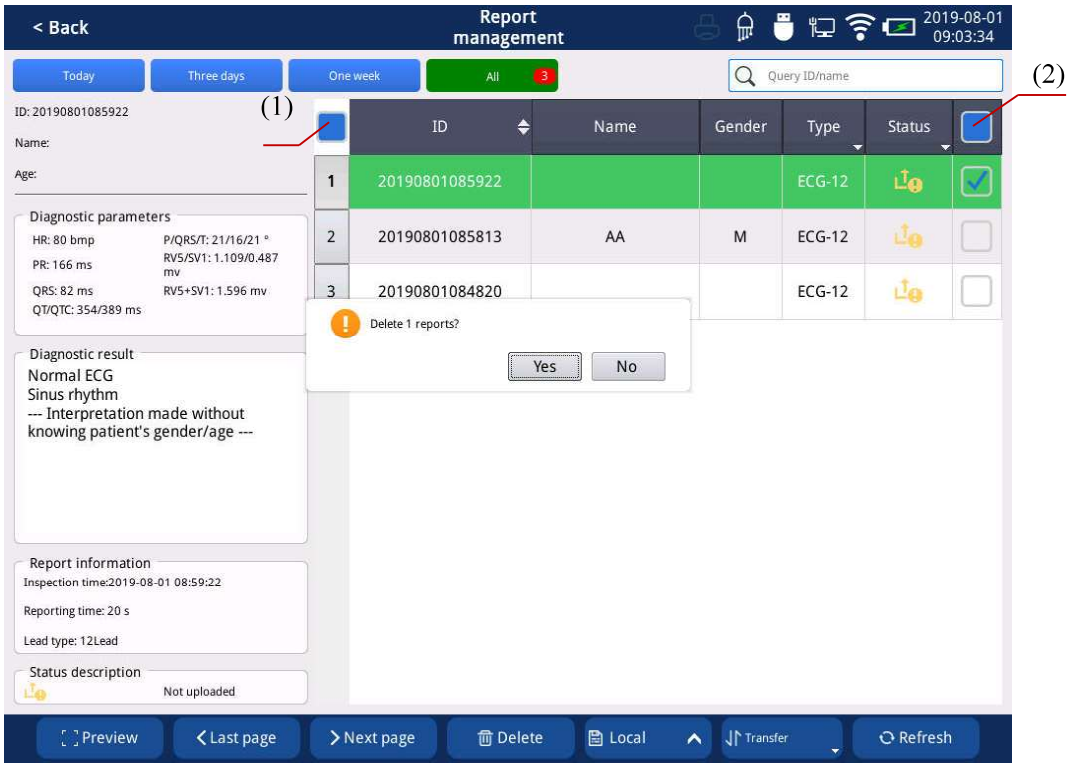


Fig 7.4 Delete Reports

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;

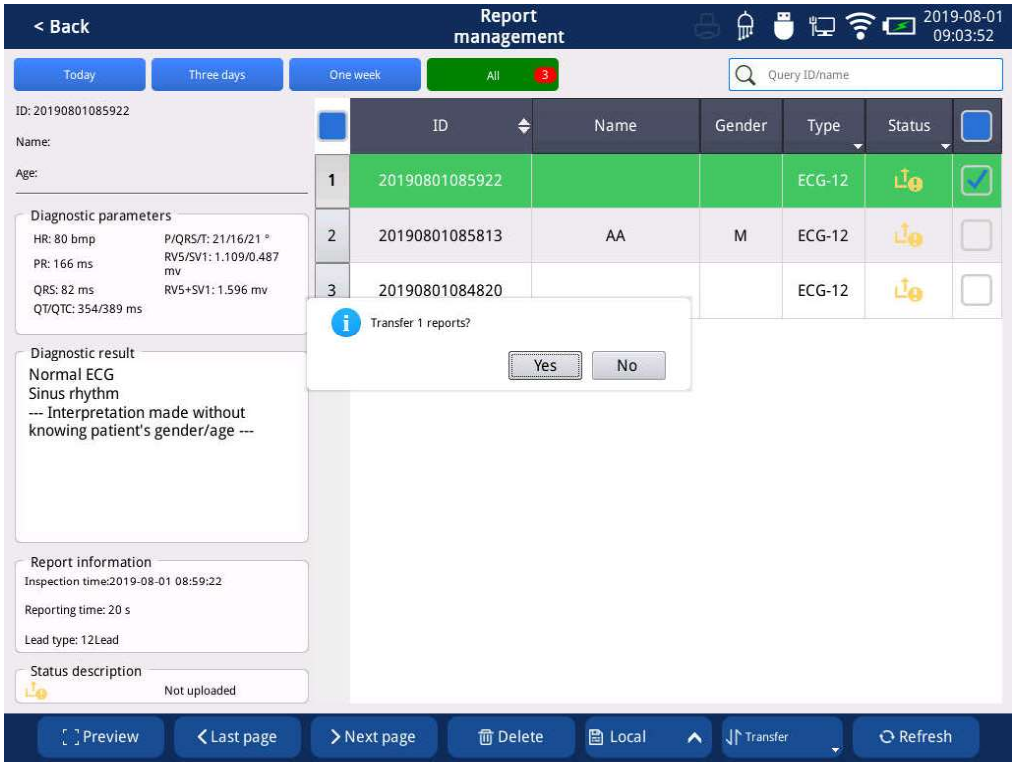


Fig 7.5 Report Transmission

7.4 Report Refresh

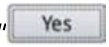
Report brush operation steps:

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

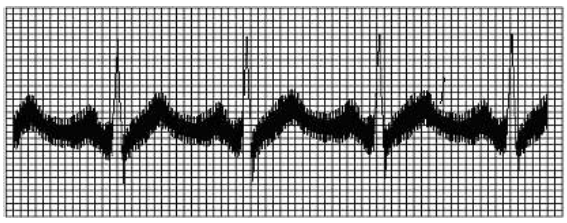


Figure 8.1 ECG with AC interference

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

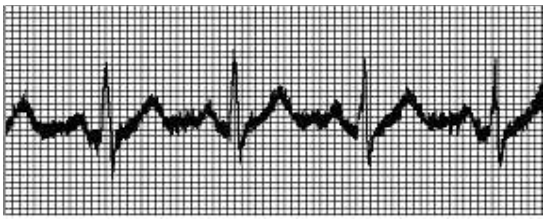


Fig 8.2 EMG Interference

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

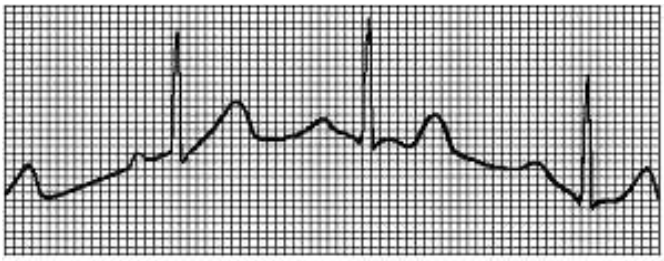


Fig 8.3 Baseline Drift Waveform Graph

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 $\sqrt{P}$

Radio frequency radiation 61000-4-3	3V/m 80MHz ~ 2.5GHz	3 V/m	The recommended isolation distance is calculated as: 80 MHz to 800 MHz: $d = 1.2\sqrt{P}$ 800MHz to 2.5GHz: $d = 2.3\sqrt{P}$ P is the transmitter's rated maximum output rated power, in watts, provided by the transmitter manufacturer; d is the recommended isolation distance in meters. The field strength of the RF transmitter obtained by electromagnetic field measurement must be less than the compliance level in each frequency range. Interference may occur near devices marked  with the following symbols:

Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.

Note 2: The above guidelines may not be applicable in all situations. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and the human body.

Note 3: This equipment is intended to receive RF electromagnetic energy and is exempt from basic performance requirements in the occupied frequency band (2395.825MHz-2487.645MHz), but remains safe.

For fixed-type airports, such as wireless (cellular/cordless) telephones and terrestrial mobile radio base stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts, the field strength is theoretically can not be accurately predicted. In order to assess the electromagnetic environment of a stationary RF transmitter, an electromagnetic field survey should be considered. If the measured field strength of the location where the ECG is located is higher than the RF compliance level of the above application, the ECG should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting the ECG machine and repositioning it.

Recommended isolation distance between portable and mobile RF communications equipment and ECG machines

The electrocardiograph is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (device machine) and the ECG machine as recommended below.

Maximum rated output power of the transmitter (W)	**Isolated distance for different frequency transmitters (m)**		
	150 kHz ~ 80 MHz d= 1.2 $\sqrt{P}$	80 MHz ~ 800 MHz d = 1.2 $\sqrt{P}$	800 MHz ~ 2.5 GHz d = 2.3 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30

100	12.00	12.00	23.00

For the rated maximum output power of the transmitter not listed above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer. Transmitter maximum output rated power in watts (W).

Note 1: Formulas for higher frequency ranges are used at frequencies of 80 MHz and 800 MHz.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

Appendix III Environmental Statement

Names and Contents of Hazardous and Noxious Substances:

Name	Hazardous and Noxious Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (CrVI)	PBB	PBDE
Built-in PCB	○	○	○	○	○	○
plug-in board	○	○	○	○	○	○
Metal parts	○	○	○	○	○	○
Shell	○	○	○	○	○	○
Display part	○	○	○	○	○	○
Package	○	○	○	○	○	○
Accessories	○	○	○	○	○	○
○: It indicates that contents of hazardous substances in the all homogeneous materials of the part are below the limits specified in SJ/T 11363-2006 standard.						

CAUTION	The product and its spare parts should be disposed of in accordance with the local laws and regulations, and shall not be discarded as useless together with household waste.

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.			

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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.

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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: $d = 1.2\sqrt{P}$

Radio frequency radiation 61000-4-3	3V/m 80MHz ~ 2.5GHz	3 V/m	The recommended isolation distance is calculated as: 80 MHz to 800 MHz: $d = 1.2\sqrt{P}$ 800MHz to 2.5GHz: $d = 2.3\sqrt{P}$ P is the transmitter's rated maximum output rated power, in watts, provided by the transmitter manufacturer; d is the recommended isolation distance in meters. The field strength of the RF transmitter obtained by electromagnetic field measurement must be less than the compliance level in each frequency range. Interference may occur near devices marked with the following symbols: 

Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.

Note 2: The above guidelines may not be applicable in all situations. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and the human body.

Note 3: This equipment is intended to receive RF electromagnetic energy and is exempt from basic performance requirements in the occupied frequency band (2395.825MHz-2487.645MHz), but remains safe.

For fixed-type airports, such as wireless (cellular/cordless) telephones and terrestrial mobile radio base stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts, the field strength is theoretically can not be accurately predicted. In order to assess the electromagnetic environment of a stationary RF transmitter, an electromagnetic field survey should be considered. If the measured field strength of the location where the ECG is located is higher than the RF compliance level of the above application, the ECG should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting the ECG machine and repositioning it.

Recommended isolation distance between portable and mobile RF communications equipment and ECG machines

The electrocardiograph is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (device machine) and the ECG machine as recommended below.

Maximum rated output power of the transmitter (W)	**Isolated distance for different frequency transmitters (m)**		
	150 kHz ~ 80 MHz d= 1.2 $\sqrt{P}$	80 MHz ~ 800 MHz d = 1.2 $\sqrt{P}$	800 MHz ~ 2.5 GHz d = 2.3 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30

100	12.00	12.00	23.00

For the rated maximum output power of the transmitter not listed above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer. Transmitter maximum output rated power in watts (W).

Note 1: Formulas for higher frequency ranges are used at frequencies of 80 MHz and 800 MHz.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

Appendix III Environmental Statement

Names and Contents of Hazardous and Noxious Substances:

Name	Hazardous and Noxious Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (CrVI)	PBB	PBDE
Built-in PCB	○	○	○	○	○	○
plug-in board	○	○	○	○	○	○
Metal parts	○	○	○	○	○	○
Shell	○	○	○	○	○	○
Display part	○	○	○	○	○	○
Package	○	○	○	○	○	○
Accessories	○	○	○	○	○	○
○: It indicates that contents of hazardous substances in the all homogeneous materials of the part are below the limits specified in SJ/T 11363-2006 standard.						

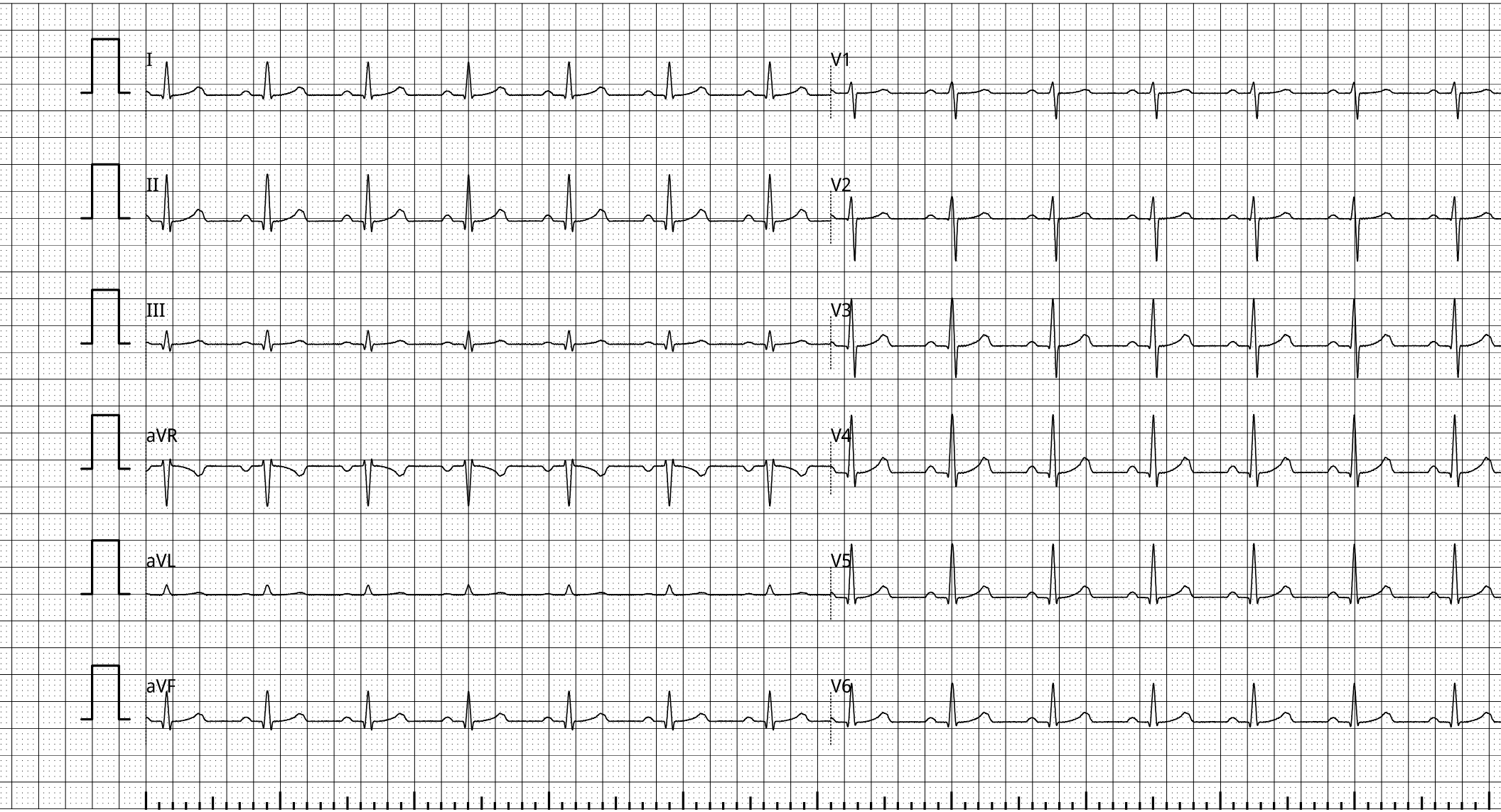
CAUTION	The product and its spare parts should be disposed of in accordance with the local laws and regulations, and shall not be discarded as useless together with household waste.

ECG report

Reporting time : 2021-06-03 11:15:2
Confirm and sign:

ID	: 36212120090	HR	: 80 bpm
Name	: Jonas Jonaitis	PR	: 162 ms
Gender	: M	QRS	: 84 ms
Age	: 59 Years	QT/QTc	: 356/391 ms
Dept	: 92 kg	P/QRS/T	: 51/31/48 °
Bed No	: 180 cm	RV5/SV1	: 0.964/0.461 mv
		RV5+SV1	: 1.425 mv

Interpretations :
Sinus rhythm
Normal ECG



0.30Hz -75Hz - AC 50Hz 25mm/s 10mm/mv iMAC 120 1.0.25 Simultaneous Examination time: 2021-06-03 11:10:02

ECG report

ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm

Reporting time : 2021-06-03 11:15:2
Confirm and sign:

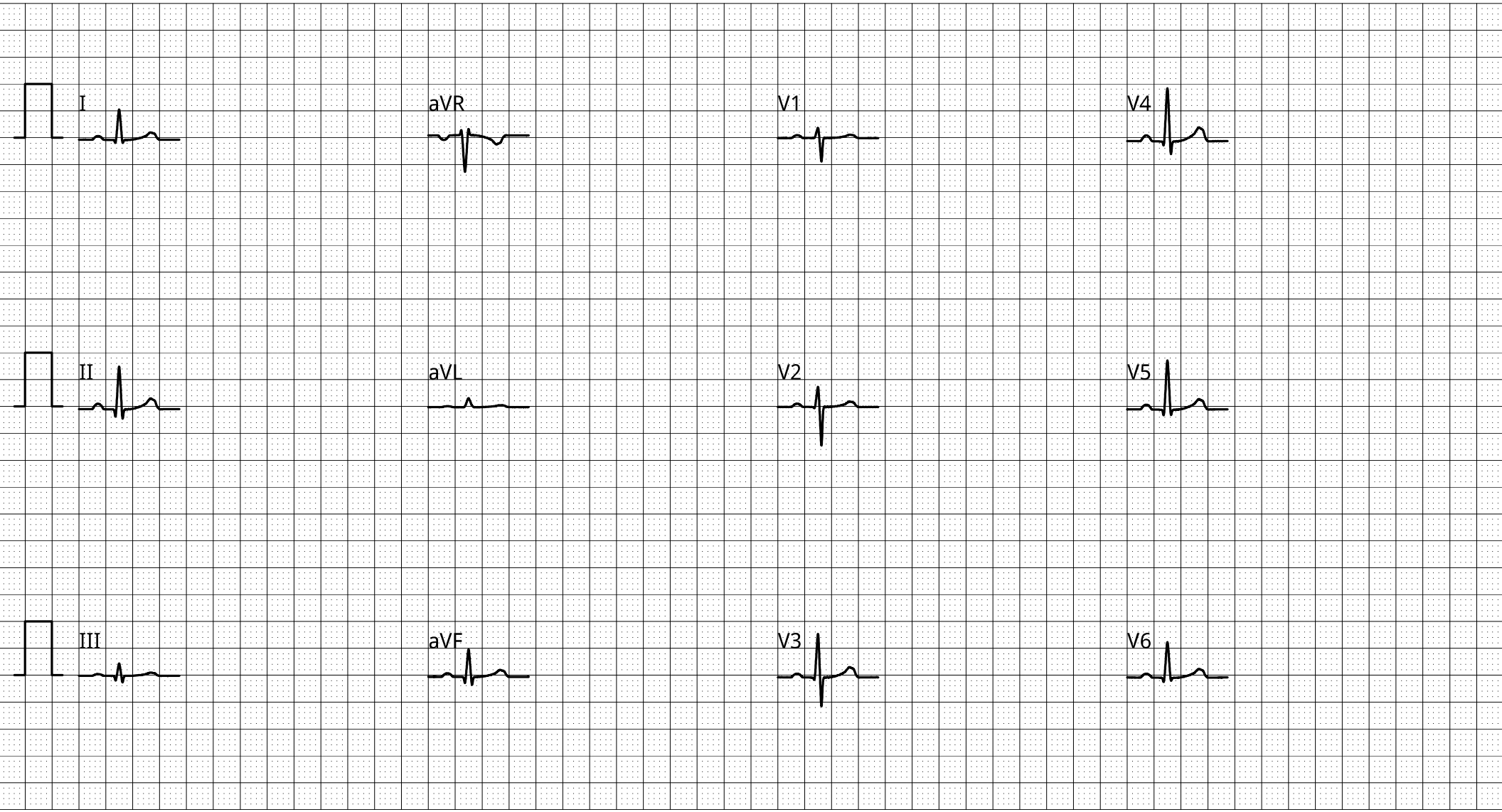
	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P Ons	264	264	264	264	264	264	264	264	264	264	264	264
P Dur	94	94	94	94	94	94	94	94	94	94	94	94
QRS Ons	426	426	426	426	430	426	440	442	428	426	426	426
QRS Dur	60	82	80	78	70	82	68	68	82	84	84	68
Q Dur	16	18	21	0	0	19	0	0	12	15	17	17
R Dur	43	40	34	17	70	38	33	32	39	42	44	50
S Dur	0	23	24	41	0	24	34	35	29	25	22	0
ST Dur	174	128	128	152	172	150	166	156	122	126	144	162
T Ons	660	636	634	656	672	658	674	666	632	636	654	656
T Dur	122	146	148	126	110	124	94	116	150	146	128	126
QRS IntD	36	36	37	62	34	37	22	20	34	39	39	39
Q Amp	-49	-143	-94	0	0	-118	0	0	-35	-73	-103	-80
R Amp	582	834	250	96	166	542	184	381	847	1042	964	687
S Amp	0	-173	-130	-707	0	-151	-461	-768	-571	-236	-86	0
ST Amp	7	14	6	-10	0	11	0	3	9	10	13	7
QRS Area	694	804	109	-747	295	458	-223	-280	526	1085	1103	802
P Area	173	251	77	-211	49	166	108	135	172	291	228	182
T Area	649	951	297	-794	182	630	201	408	882	1215	929	747
P Morph	1	1	1	-1	1	1	1	1	1	1	1	1
T Morph	1	1	1	-1	1	1	1	1	1	1	1	1
STM Amp	3	5	2	-4	0	4	0	1	1	2	4	3
ST60 Amp	7	9	1	-8	3	5	0	3	8	10	9	7
STTMidAmp	2	5	3	-3	0	4	0	3	2	1	4	0

Examination time: 2021-06-03 11:10:0

ECG report

ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm

Reporting time : 2021-06-03 11:15:22
Confirm and sign:

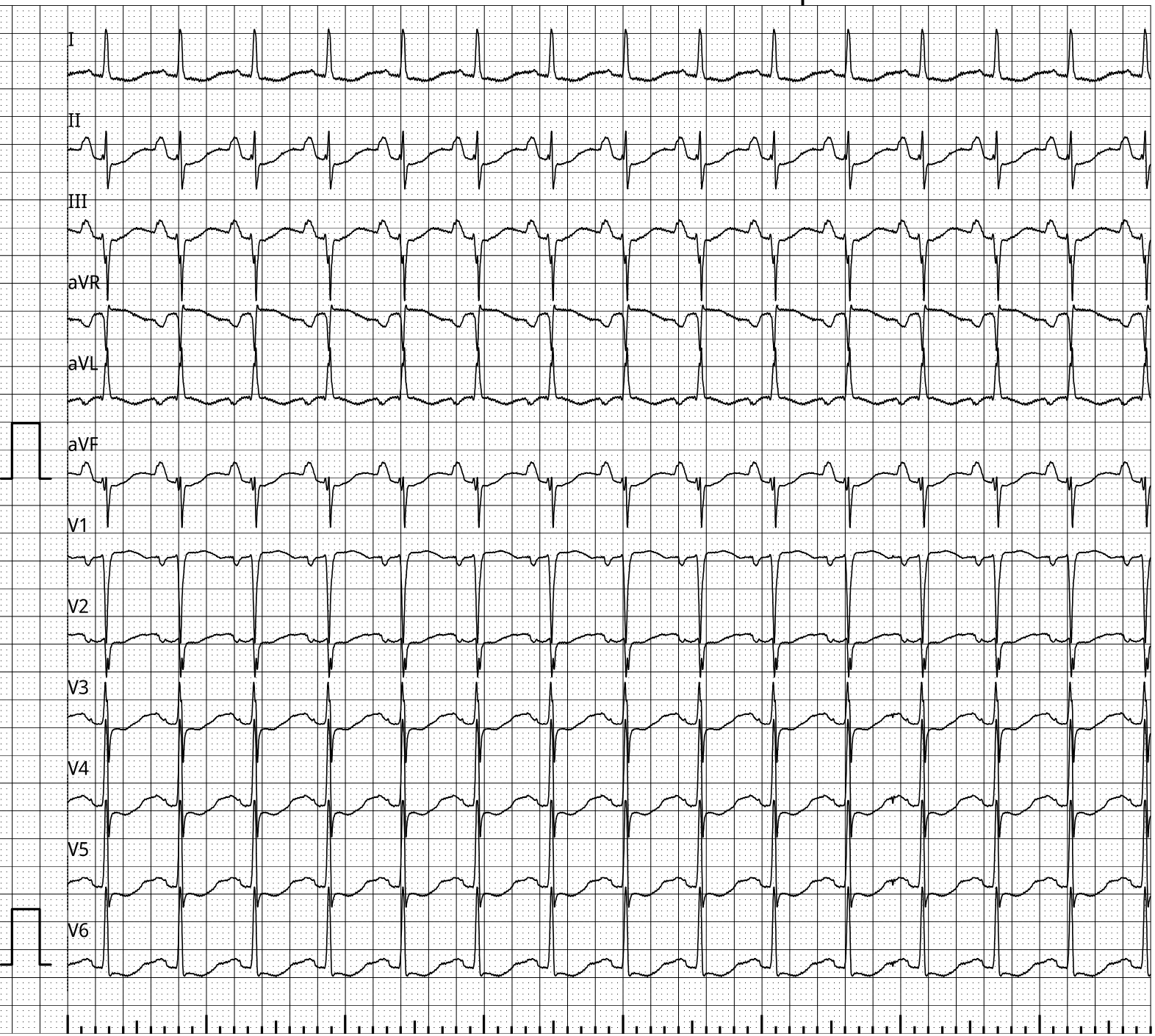


25mm/s 10mm/mv

Examination time: 2021-06-03 11:10:02

ECG report

Reporting time: 2021-06-03 11:15:2



ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm

HR : 113 bpm
PR : 154 ms
QRS : 80 ms
QT/QTc : 290/383 ms
P/QRS/T : 79/-37/109 °
RV5/SV1 : 1.609/1.515 mv
RV5+SV1 : 3.124 mv

Interpretations :
Sinus tachycardia with sinus arrhythmia
Possible right atrial abnormality
Possible left anterior fascicular block
Left ventricular hypertrophy
Widespread ST-T abnormality
~ may be due to the hypertrophy and/or ischemia
Abnormal ECG

Confirm and sign:

0.30Hz -75Hz - AC 50Hz 25mm/s 10mm/mv iMAC 120 1.0.25 Simultaneous Examination time: 2021-06-03 11:08:26

ECG report

Reporting time: 2021-06-03 11:15:2

ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm

	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P Ons	280	280	280	280	280	280	280	280	280	280	280	280
P Dur	106	106	106	106	106	106	106	106	106	106	106	106
QRS Ons	444	434	434	436	436	434	434	444	438	440	440	440
QRS Dur	52	78	76	62	72	76	74	66	74	74	74	46
Q Dur	0	0	0	45	11	0	0	0	0	0	0	0
R Dur	52	40	14	16	60	15	11	13	43	43	44	46
S Dur	0	37	61	0	0	15	62	52	30	30	29	0
ST Dur	150	126	138	148	140	116	140	128	118	120	128	148
T Ons	646	638	648	646	648	626	648	638	630	634	642	634
T Dur	72	82	76	74	76	98	52	70	90	86	78	86
QRS IntD	22	34	10	51	41	32	6	10	24	26	26	28
Q Amp	0	0	0	-633	-28	0	0	0	0	0	0	0
R Amp	790	481	62	181	904	64	28	34	713	1528	1609	1414
S Amp	0	-542	-1117	0	0	-160	-1515	-635	-658	-553	-367	0
ST Amp	-56	-87	-31	71	-18	-59	51	-43	-122	-145	-133	-97
QRS Area	1029	-235	-1240	-385	1128	-736	-1826	-842	158	1280	1480	1456
P Area	1	476	475	-238	-236	474	-266	-434	-347	-158	19	94
T Area	-645	99	963	262	-779	448	749	85	-489	-1159	-1219	-1042
P Morph	1	1	1	-1	-1	1	-1	1	1	1	1	1
T Morph	-1	1	1	2	-1	1	1	1	-2	-1	-1	-1
STM Amp	-46	-83	-36	64	-5	-59	73	-28	-91	-129	-126	-105
ST60 Amp	-66	-55	10	60	-38	-22	75	-27	-98	-143	-140	-118
STTMidAr	-50	-84	-32	64	-1	-62	74	-27	-91	-128	-125	-104

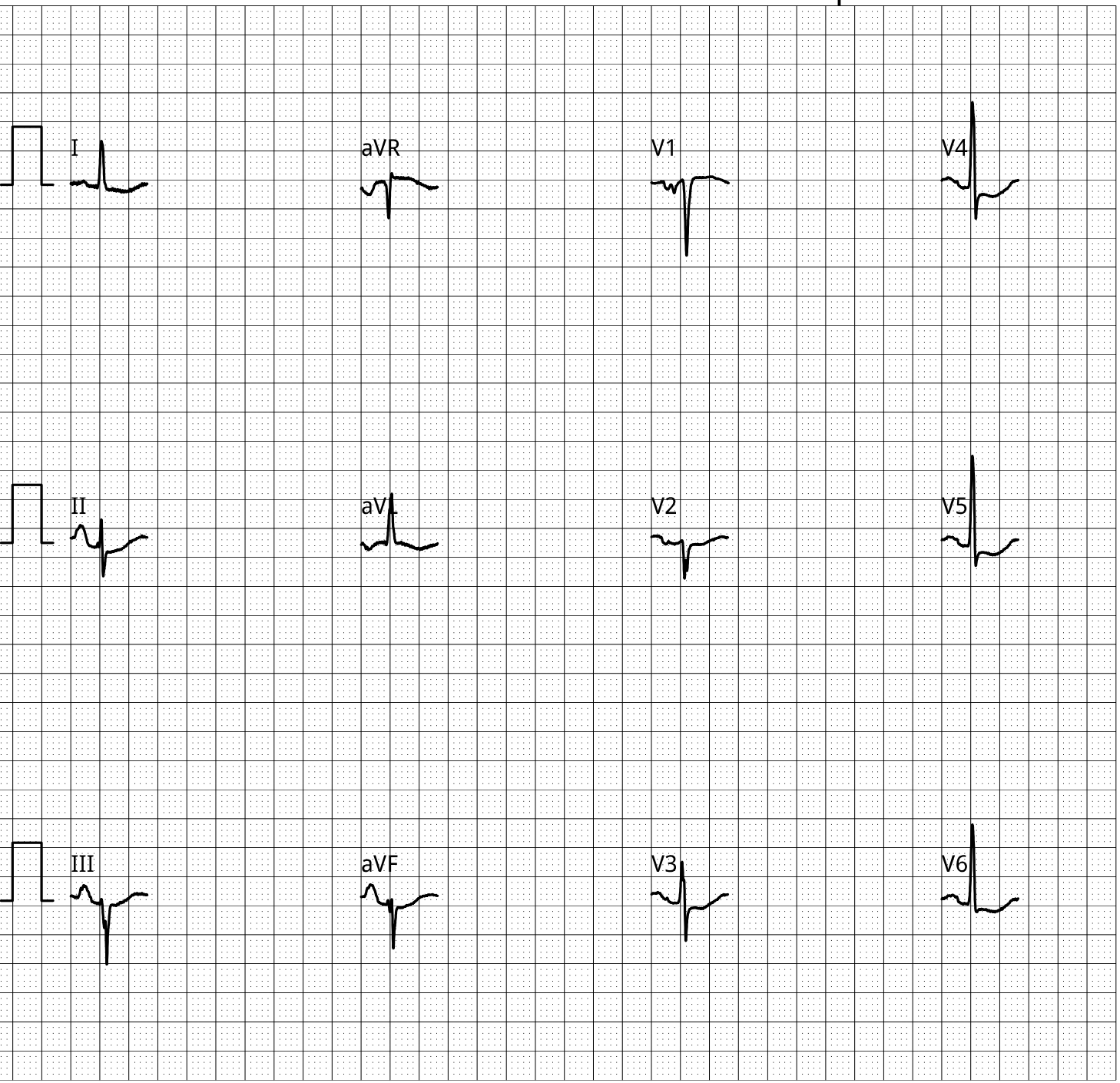
Confirm and sign:

Examination time: 2021-06-03 11:08:26

ECG report

Reporting time: 2021-06-03 11:15:2

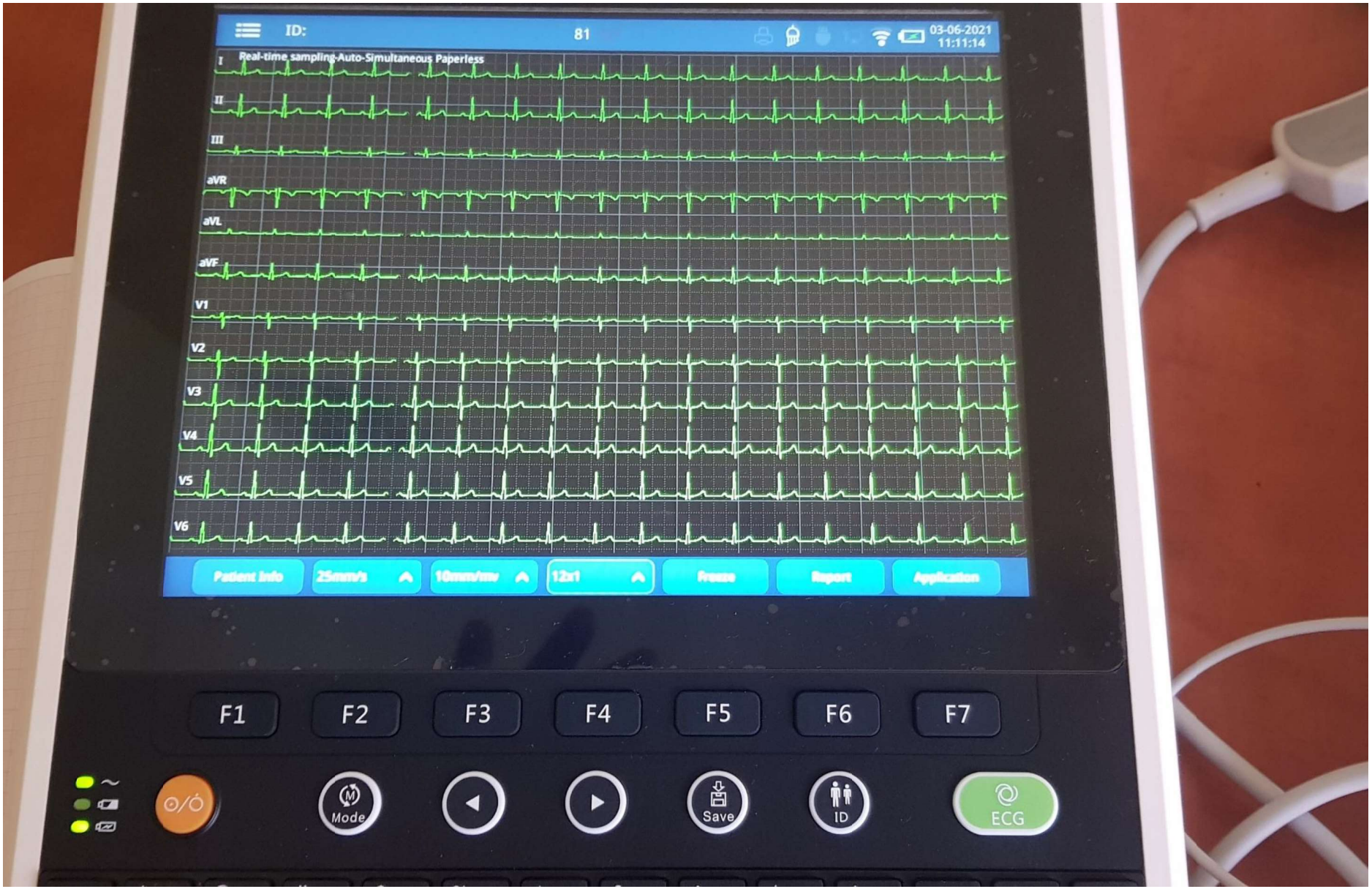
ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm



25mm/s 10mm/mv

Examination time: 2021-06-03 11:08:26

Confirm and sign: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81
03-06-2021
11:11:14
Real-time sampling-Auto-Simultaneous Paperless
I
II
III
aVR
aVL
aVF
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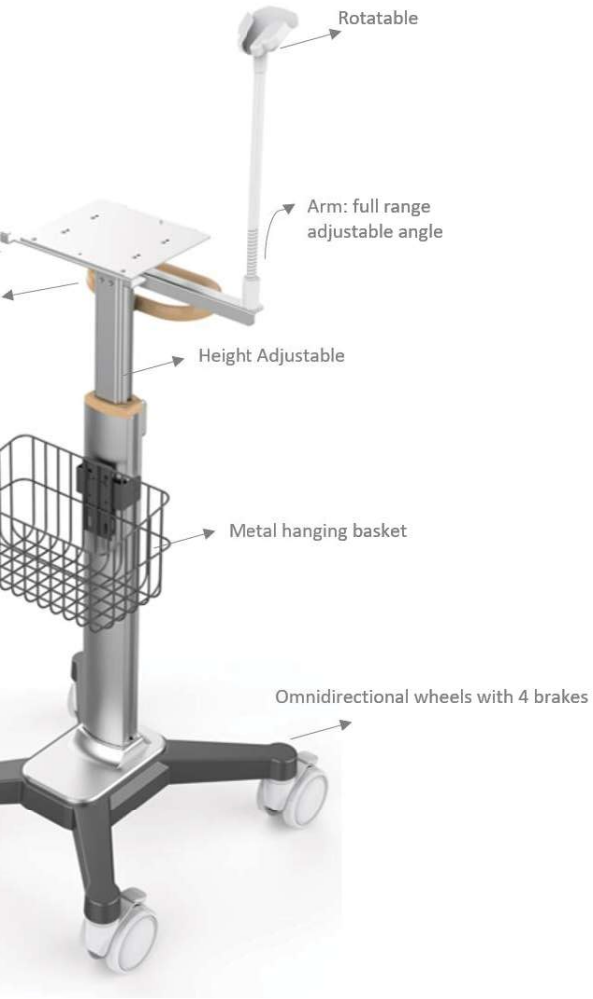
V3
V4
V5
V6
Patient Info
25mm/s
10mm/mv
12x1
Freeze
Report
Application
F1
F2
F3
F4
F5
F6
F7
Mode
Save
ID
ECG

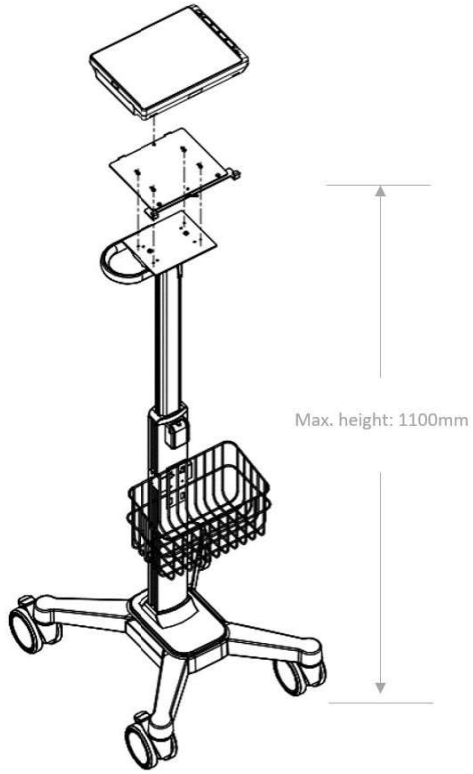
Tel: 86-27-87770203 Email: info@zoncare.com
Fax: 86-27-87770203 Website: www.zoncare.co

iMAC 300/ iMAC 120/ iMAC 12 trolley characteristics and material



10cm

Size

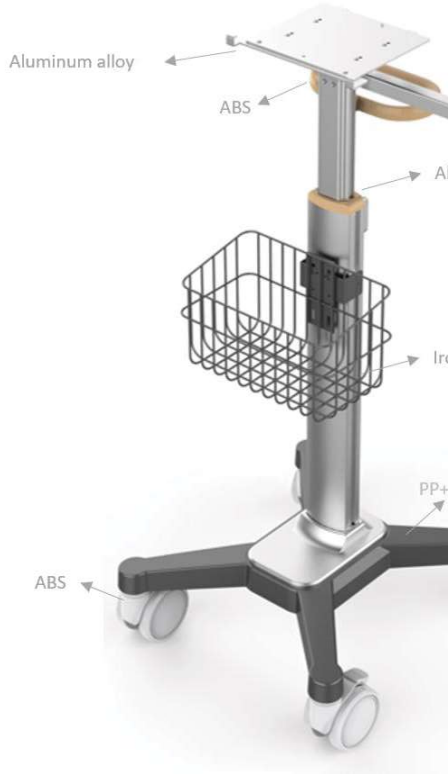


Package size: 750 * 502 * 235 (mm)

G.W.: approx. 7.1 kg

N.W.: approx. 5.6 kg

Material



aybe different with the above one, please refer to the actual received goods.

Wuhan Zoncare Bio-medical Electronics Co., Ltd.
Add: 380, High-tech 2nd road, Eastlake High-tech Development Zone, Wuhan, Hubei (430206), China.
Tel: 86-27-87770581 Email: info@zoncare.com
Fax: 86-27-87770203 Website: www.zoncare.com

DECLARATION OF CONFORMITY

Manufacturer: ***Wuhan Zoncare Bio-Medical Electronics Co., Ltd.***
380, High-tech 2nd road, Eastlake High-tech Development Zone, Wuhan, Hubei (430206), China.

Product: ***Trolley (Medical use)***

UMDNS (Name/Code): ***Carts, Instrument/10641***

Classification: ***Class I, Rule 1 according to Annex IX of the MDD.***

WE HEREWITH DECLARE THAT the ECG Trolley(for models iMAC 300) conform to the safety, reliability and product design criteria referenced in regulations MDD 93/42/EEC and conform with EN 60601-1, 3rd edition.

Place, Date of Issue: WUHAN, Dec 10, 2020

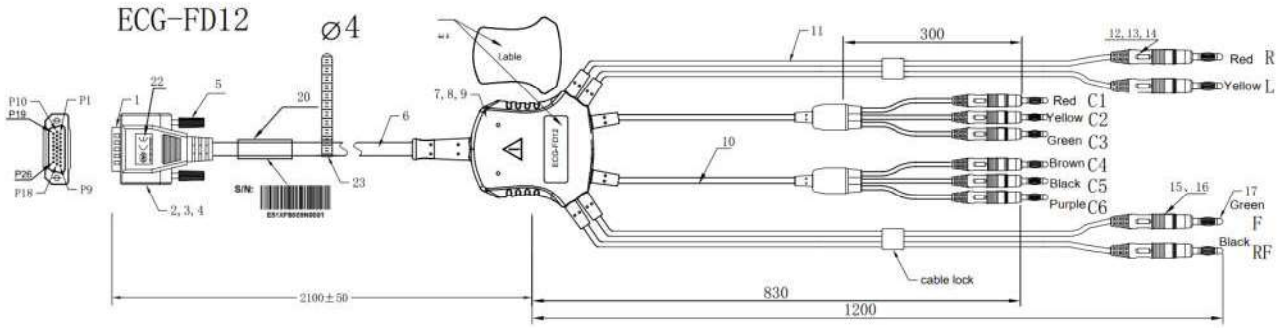
Signature: 蔡海学（Paul Tsai）

Position: Sales Director

Add: 380, High-tech 2nd road, Eastlake High-tech Development Zone, Wuhan, Hubei (430206), China.
Tel: 86-27-87770581 Email: info@zoncare.com
Fax: 86-27-87770203 Website: www.zoncare.com

ECG Cable Specifications

1. Model : ECG-FD12
2. Code : 3902800031
3. Material and specifications :



1	Plug		DB 26P
2	PVC	20g	55P gray-white color PVC
3	Gum	10g	LD-PE natural color
4	Copper foil	1PCS	W30*L60mm
5	Screws	2PCS	Lock bolt
6	Wire	2210mm	⌀6.5
7	Printed board	1SET	PCB Board
8	Gum	50g	
9	Gum	100g	
10	Wire	2*500mm	⌀3.2
11	Wire	2×650mm	⌀3.2
12	Internal mold	5g	PP natural color
13	PVC	4-10g	55P White PVC
14	Resistance	10PCS	Anti-defibrillation resistance
15	PVC	6-10g	55P White PVC
16	Color label set	5g	85P, 10 characters
17	Pins	10PCS	Ø4, H62 nickel plating
18	Clip chain	1PCS	W190*L220*0.1mm

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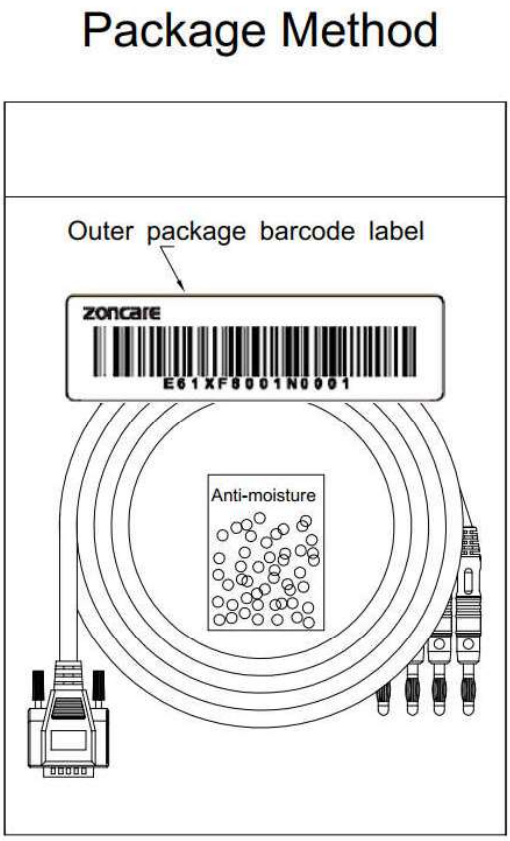
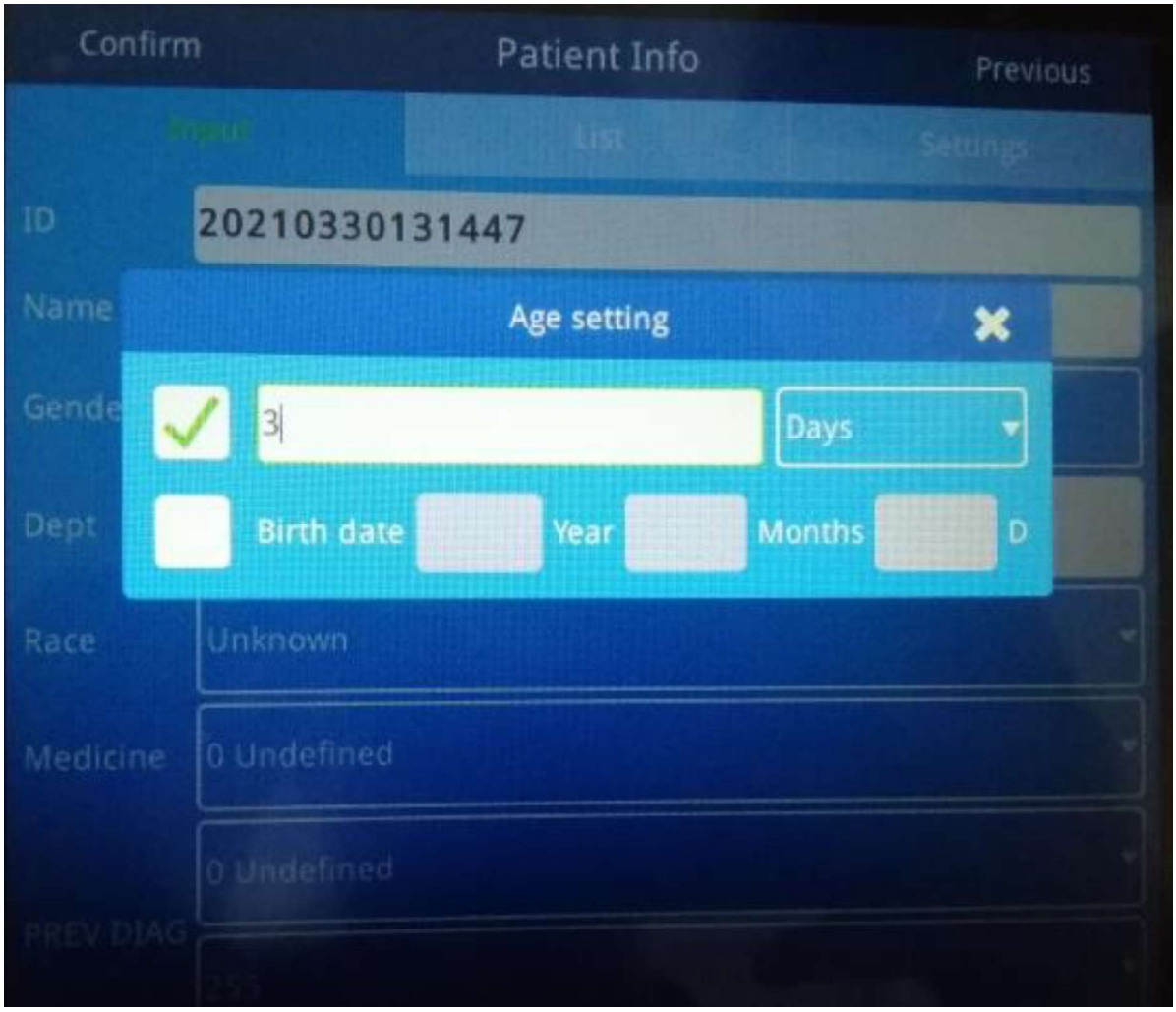
19	Chip	1PCS	DS2431
20	product label	1PCS	Transparent PVC
21	Identification label	1PCS	PVC cold gray 3C
22	CE label	1PCS	
23	Magic cable tie	1PCS	1.5×15 Gray

4. Packing



Limb electrodes, 4 units

Chest electrodes, 6 units


Confirm
Patient Info
Previous
List
Settings
ID
20210330131447
Name
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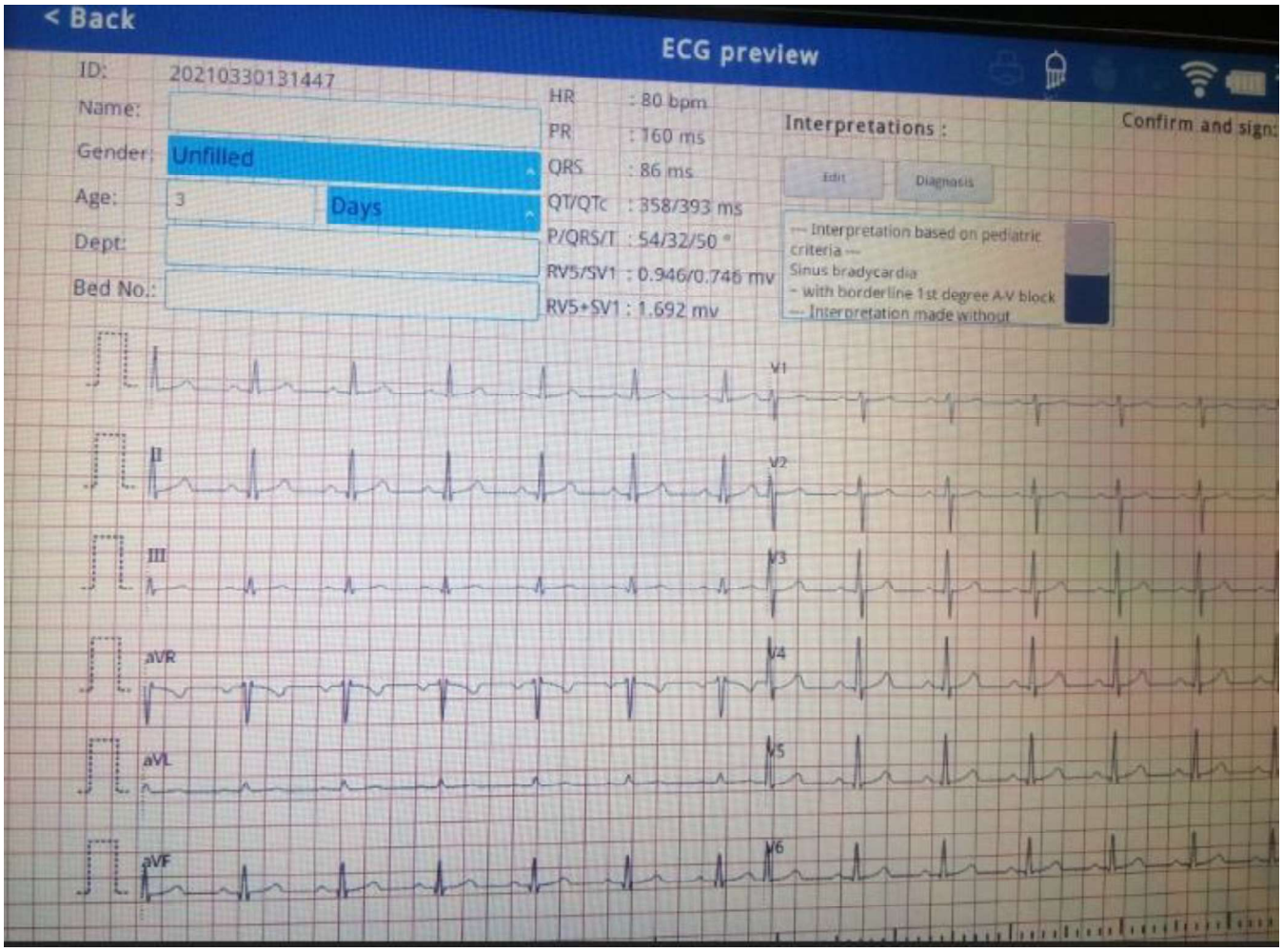
< Back
ECG preview
ID:
20210330131447
Name:
Gender:
Unfilled
Age:
3
Days
Dept:
Bed No.:
HR : 80 bpm
PR : 160 ms
QRS : 86 ms
QT/QTc : 358/393 ms
P/QRS/T : 54/32/50 °
RV5/SV1 : 0.946/0.746 mv
RV5+SV1 : 1.692 mv
Interpretations :
Confirm and sign
Edit
Diagnosis
--- Interpretation based on pediatric criteria ---
Sinus bradycardia
- with borderline 1st degree A-V block
--- Interpretation made without
V1
II
V2
III
V3
aVR
V4
aVL
V5
aVF
V6

Neonatal ECG cable and disposable electrodes

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
12351-2018-CE-RGC-NA-PS Rev. 2.0	PRJC-217612-2010-PRC-CHN	27 May 2024

This is to certify that the quality system of:

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

#380, High-tech 2nd Road, Eastlake high-tech district, Wuhan, Hubei, P. R. China.

For design, production and final product inspection/testing of:
DIGITAL MULTI-CHANNEL ELECTROCARDIOGRAPH

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 06 January 2021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
12351-2018-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2018-04-20
1.0	Extension in scope	2020-06-17
2.0	Recertification	2021-01-06

Products covered by this Certificate:

Product Description	Product Name	Class
Digital Multi-Channel Electrocardiograph	iMAC 120, iMAC 120pro	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Wuhan Zoncare Bio-medical Electronics Co., Ltd.	#380, High-tech 2nd Road, Eastlake high-tech district, Wuhan, Hubei, P. R. China.

EU Representative

Well kang Limited , The Black Church, St. Mary's Place , Dublin 7, Ireland

Certificate No.:	Project No.:	Valid Until:
12351-2018-CE-RGC-NA-PS Rev. 2.0	PRJC-217612-2010-PRC-CHN	27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

1. Declaration of Conformity

Declaration of Conformity

For the following products:

Digital Multi-channel Electrocardiograph

(Product Name)

iMAC 120, iMAC 120A, iMAC 120B, iMAC 120pro

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)
EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, IEC 60601-1:2005/A1:2012, EN 60601-1-2:2015, IEC 60601-2-25:2011, EN 62304:2006/A1:2015, EN 62366-1:2015, EN 60601-1-6:2010/A1:2015.

Conformity Assessment Route:
Annex II excluding section 4 of Medical Device Directive

Notified Body:
DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

The following representative in Europe is responsible for making this declaration:
Company Name: Well kang Limited
Company Address: The Black Church, St. Mary's Place, Dublin 7, Ireland

The following manufacturer is responsible for making this declaration:
Company Name: Wuhan Zoncare Bio-medical Electronics Co., Ltd.
Company Address: #380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China

Qi Wang	General Manager	2020-06-30
(Legal Signature)	(Position/title)	(Date)