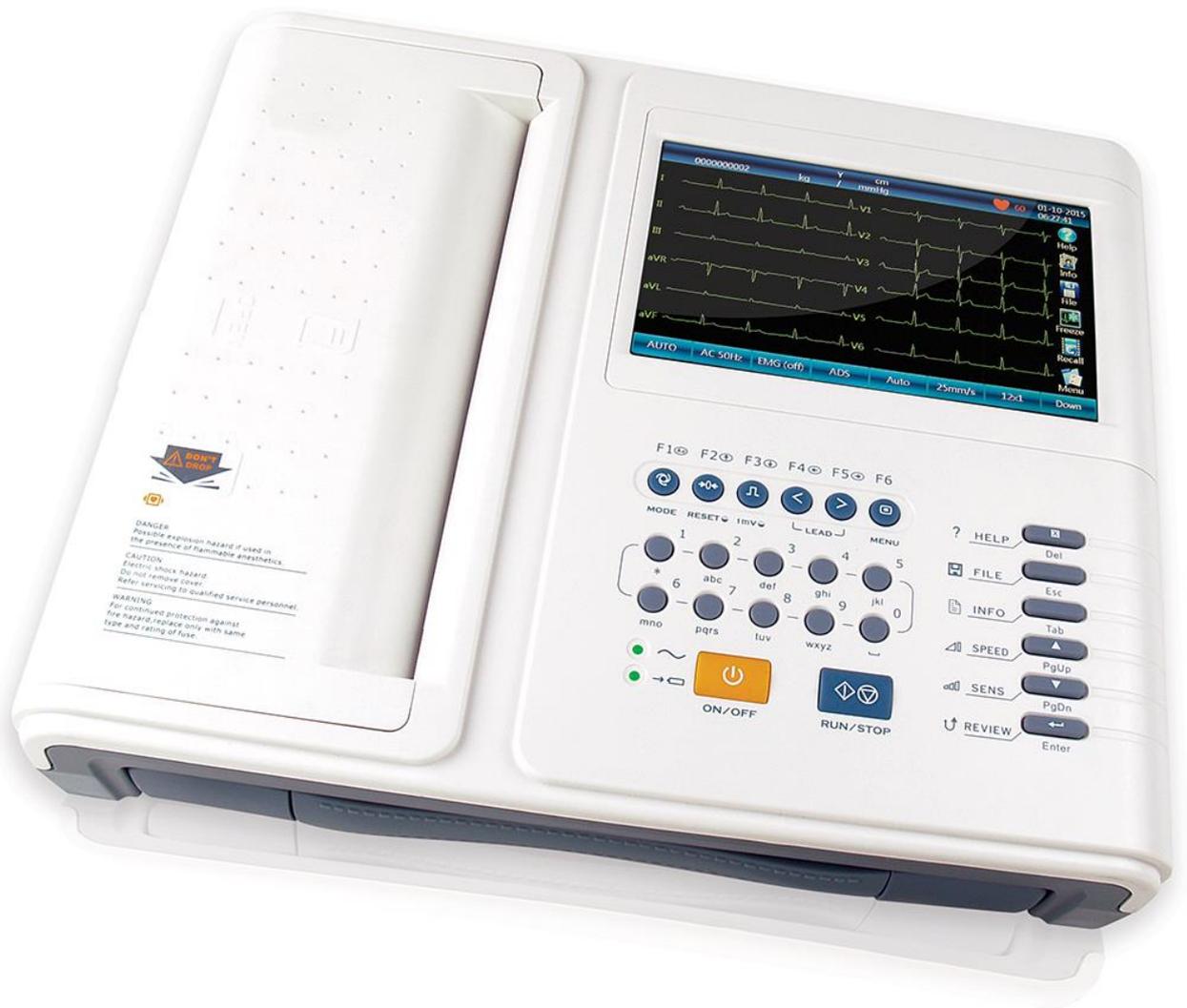




QRS-12
Operators Manual



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Version

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P/N No.: 24000348

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Responsibility of the manufacturer

Infinium Medical Inc. only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorized by us, and the electrical installation of the relevant room complies with safety standards.

ⓘNOTEⓘ:

- ◆ This device is not intended for home use.

⚠WARNING⚠:

- ◆ This device is not intended for treatment.

Label guide

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

NOTE

A **NOTE** label advises against certain actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Table of Contents

CHAPTER 1 SAFETY GUIDANCE	1
1.1 SAFETY INFORMATION	1
1.1.1 Environment Requirements.....	1
1.1.2 Power Supply.....	2
1.2 WARNINGS AND NOTES.....	2
1.2.1 Safety Warnings.....	2
1.2.2 Battery Care Warnings.....	3
1.2.3 General Notes.....	4
1.2.4 Cleaning & Disinfection Notes.....	4
1.2.5 Electro Magnetic Compatibility Information.....	5
CHAPTER 2 INTRODUCTION	6
2.1 FUNCTION FEATURES.....	6
2.2 LIST OF SYMBOLS	6
CHAPTER 3 GENERAL INFORMATION	8
3.1 FRONT PANEL.....	8
3.1.1 Product Information:.....	8
3.1.2 LCD Screen.....	9
3.1.3 Control Panel and Keys.....	10
3.2 MAINS CONNECTION AND SWITCH.....	13
3.3 PATIENT CABLE SOCKET AND SIGNAL INTERFACE	14
3.4 BOTTOM PANEL.....	16
CHAPTER 4 OPERATION PREPARATIONS	17
4.1 CONNECTING TO AC POWER AND GROUNDING.....	18
4.2 LOADING RECORDING PAPER.....	19
4.3 PATIENT CABLE CONNECTION	20
4.4 ELECTRODES CONNECTION	20
4.5 INSPECTION BEFORE STARTUP	23
CHAPTER 5 OPERATION INSTRUCTIONS	25

5.1 POWER ON/OFF.....	25
5.1.1 Power ON.....	25
5.1.2 Power OFF.....	26
5.2 HELP.....	26
5.3 INFO	26
5.4 FILE.....	28
5.5 FREEZE.....	29
5.6 RECALL.....	29
5.7 OPERATION MENU.....	30
5.7.1 Menu.....	30
5.7.2 Set the Printing Parameters.....	31
5.7.3 Set Mode	34
5.7.4 Set the Filter Parameters.....	36
5.7.5 Lead Sequence.....	37
5.7.6 Display & Sound.....	38
5.7.7 Date & Time.....	39
5.7.8 Set the System Parameter.....	40
5.7.9 Set the Communication.....	41
5.7.10 Set the Advanced Setting.....	42
5.7.11 Institution.....	43
5.7.12 Exit.....	43
5.7.13 Touch Screen calibration	43
5.8 HOW TO USE THE BATTERY	44
5.9 OPERATION MODE.....	45
5.9.1 Auto Mode.....	46
5.9.2 Man Mode.....	46
5.9.3 Analysis Mode.....	46
5.10 ECG CASE.....	46

CHAPTER 6 HINT INFORMATION	48
CHAPTER 7 DECLARATION OF AUTO MEASUREMENT & ANALYSIS REPORT	49
CHAPTER 8 CLEANING, CARE AND MAINTENANCE	50
8.1 CLEANING.....	50
<i>8.1.1 Cleaning the Main Unit and Patient Cable.....</i>	<i>50</i>
<i>8.1.2 Cleaning the Electrodes.....</i>	<i>50</i>
<i>8.1.3 Cleaning the Print Head.....</i>	<i>50</i>
8.2 DISINFECTION.....	50
8.3 STERILIZATION	51
8.4 CARE AND MAINTENANCE.....	51
<i>8.4.1 Recharge and Replacement of Battery.....</i>	<i>51</i>
<i>8.4.2 Recording Paper.....</i>	<i>52</i>
<i>8.4.3 Main Unit, Patient Cable & Electrodes.....</i>	<i>52</i>
CHAPTER 9 COMMON TROUBLESHOOTING AND SOLUTION.....	54
CHAPTER 10 SERVICE WARRANTY	56
CHAPTER 11 ACCESSORIES	57
APPENDIX I TECHNICAL SPECIFICATIONS	58
APPENDIX II EMC INFORMATION	61
APPENDIX III ENVIRONMENTAL STATEMENT	65

Chapter 1 Safety Guidance

1.1 Safety Information

QRS-12 digital twelve channel electrocardiograph (ECG) complies with international standard IEC 60601-1, Medical Electrical Equipment: General Requirements for Safety and IEC 60601-2-25, Particular Requirements for Safety of Electrocardiographs. The classification is Class I, type CF, which means a higher degree of protection against electric shock and the patient connection is fully isolated and defibrillation protected.

QRS-12 is not explosion-proof. Do not use it in the presence of flammable anesthetics.

QRS-12 is designed for continuous operation but it is not drip-proof or splash-proof.

Safety classification is listed as below Table 1-1.

Anti-electric-shock type:	Class I with internal power supply
Anti-electric-shock degree:	CF
Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:	Refer to the <i>Operation Manual</i> for details
Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
Working Mode:	Continuous operation
EMC:	Group I, Class B

Table 1-1 Safety Classification

1.1.1 Environment Requirements

Please find in Table 1-2 for environment requirements of transportation, storage and working condition of QRS-12.

	Transportation	Storage	Working
Temperature	-20°C~+55°C	-10°C~+40°C	+5°C~+40°C
Relative Humidity	25%~95%	25%~85%	25%~85%
Atmosphere Pressure	700hPa~1060 hPa	700hPa~1060 hPa	700hPa~1060 hPa

Table 1-2 Environment Requirements

The transportation condition must be as stated by the contract. The ECG must be stored in the place which need meet the following requirements: the temperature being -10°C~+40°C, the relative humidity being ≤85%, there being no corrosive gases and it being well-ventilated.

Be sure that the operation environment is clean, and the ECG is kept away from corrosive, high humidity, high temperature or direct sunshine. Avoid shaking during operating and do not move the equipment when it is power on.

1.1.2 Power Supply

- 1) AC Power Supply
 - Rated voltage: 100V-240V
 - Rated frequency: 50Hz/60 Hz
 - Rated power: 75VA
- 2) DC Power Supply
 - Rated output voltage: 19V
 - Rated output current: 3.5A
- 3) Built-in Lithium Rechargeable Battery
 - Rated voltage: 14.4V
 - Rated capacity: 4400mAh
- 4) Fuse: T2A/AC250V Ø5×20

1.2 Warnings and Notes

In order to use the ECG safely and effectively, avoid possible dangers caused by improper operations, please read through the ***Operation Manual*** and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

Please pay more attention to the following warning and note information.

1.2.1 Safety Warnings

WARNING :

- ◆ Infinium Medical Inc. ECG is provided for the use of qualified physicians or personnel professionally trained. The operator is supposed to be familiar with the contents of this ***Operation Manual*** before operation.
- ◆ Only qualified service engineer can install the ECG. And only service engineer authorized by Infinium Medical Inc. can open the shell.
- ◆ Only qualified installation or service engineer can shift the mains shift switch (100V-240V) according to local mains supply.
- ◆ The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it can not substitute for regular checking.

WARNING :

- ◆ **EXPLOSION HAZARD** - Do not use the ECG in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- ◆ **SHOCK HAZARD** - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
- ◆ If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.
- ◆ Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
- ◆ This equipment is not designed for internal use and direct cardiac application.

 **WARNING** :

- ◆ Only patient cable and other accessories supplied by Infinium Medical Inc. can be used. Otherwise the performance or electric shock protection can not be guaranteed.
- ◆ Be sure that all electrodes have been connected to the patient properly before operation.
- ◆ Be sure that the conductive parts of the electrodes and associated connectors, including neutral electrode, should not contact with earth or any other conducting objects.
- ◆ There is no danger for patients with pacemaker.
- ◆ Do not touch the patient, bed, table or the ECG while using defibrillator or pacemaker simultaneously.
- ◆ Before defibrillating, make sure the patient is completely isolated and avoid touching any metal part of the ECG in case of electric shock.
- ◆ Before defibrillating, remove all electrodes, gel or cloth pieces from the patient in case of any possible burnt.
- ◆ Apply patient cable appointed by the manufacturer only. Otherwise there might be electric burnt of the patient or damage of the ECG.
- ◆ Electrodes with defibrillator protection should be applied. To avoid any possible electric burn, it is recommended that only the patient cable and electrodes supplied by the manufacturer to be applied while defibrillating.
- ◆ In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.

 **WARNING** :

- ◆ Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of IEC 60601-1. If in doubt, consult our technical service department or your local distributor.
- ◆ The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
- ◆ The potential equalization conductor can be connected to that of other equipment when necessary. Make sure the equipment is connected with potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

 **WARNING** :

- ◆ Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery' s capacity. It is necessary to read the *Operation Manual* carefully and pay more attention to warning messages.
- ◆ Opening the battery cover, disassembling or replacing battery should be done according to the *Operation Manual*, and only battery of same model and specification provided by manufacturer should be used.
- ◆ **Danger of explosion** - Do not reverse the anode and cathode when connecting the battery.

- ◆ Do not use battery around fire or place over 60°C. Do not heat or splash the battery. Do not throw it into fire or water.
- ◆ When leakage or foul smell found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- ◆ When the battery's useful life is over or any abnormal phenomenon is found from the battery, stop using it, and contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

1.2.3 General Notes

⚠NOTE⚠:

- ◆ Avoid liquid splash and excessive temperature. The temperature must be kept between 5°C to 40°C while working, and between -20°C to 55°C during transportation, and between -10°C to 40°C during storage.
- ◆ Do not use the ECG in dusty environment with poor ventilation or in the presence of corrosive.
- ◆ Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc.

Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

⚠NOTE⚠:

- ◆ Check the main unit and its accessories carefully before operating the ECG. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.
- ◆ Fuses must only be replaced with the same type and rating as the original.
- ◆ The equipment and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.

1.2.4 Cleaning & Disinfection Notes

⚠NOTE⚠:

- ◆ Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be drugged out of the outlet also. Prevent the detergent from seeping into the equipment.
- ◆ Do not immerse the unit or patient cable into liquid under any circumstances.
- ◆ Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- ◆ Any remainder of detergent should be removed from the unit and patient cable after cleaning.
- ◆ Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- ◆ Do not use high temperature, autoclaving or radiation sterilization processes.

1.2.5 Electro Magnetic Compatibility Information

The equipment must comply with IEC 60601-1-2 for medical electronic equipment or EMC standards. The electromagnetic environment which exceeds the limits of the IEC 60601-1-2 standard will generate harmful interference or degrade the performance. Please exclude adverse electromagnetic interference before using.

Common sources of interference and solutions:

1. Strong electromagnetic interference generated by the nearby emissive sources, such as: broadcasting station, transformer substation and cell phone.

Solution: Keep the equipment away from the emissive sources.

2. RF interference generated by other equipment or system through electric knife line.

Solution: Determine the causes of interference and remove possible ones. If not, please change the power supply.

3. Direct and indirect influence from electrostatic discharge.

Solution: Make sure that all equipments and systems have no direct or indirect electrostatic energy before use. Humidor room can effectively reduce such interference.

4. Electromagnetic interference generated by radio receiver such as TV and radio.

Solution: Try to keep this equipment away from the radio receiver.

If these methods cannot solve the problem, please connect us or the designated maintenance points.

Chapter 2 Introduction

QRS-12 digital 12-channel physiological function measurement equipment which records the heart waveform during electro-biological movement. It provides sufficient information on the analysis of arrhythmia and cardiovascular disease, helps to know the pathological disorder caused by some drugs and electrolyte, or unbalance of PH value. It is important equipment for cardiac disease examination, and its compact size makes it suitable for use while visiting patients at home.

Standard Configuration: main unit and accessories, including patient cable, chest electrodes, limb electrodes, thermo-sensitive print paper and power cord etc.

Intended use: The cardiogram and heart rate recorded by the ECG can help doctors to analyze and diagnose heart disease or arrhythmia in hospitals. Its compact size makes it suitable for use while visiting patients at home.

⚠NOTE⚠:

- ◆ The patient who has a heart disease may have a normal electrocardiogram, so other tests are required for a full heart appraisal. This equipment cannot be connected to the heart directly.

2.1 Function Features

QRS-12 has following features:

- 7" high brightness TFT screen, real-time display of 12 channel ECG waveforms
- Modern in design, easy for carry
- Light-touch numeric/letter keys contribute to easy and convenient operation
- Touch screen operation
- Simultaneously acquisition of 12-lead ensures reliable data for clinical diagnosis
- Real-time age-analyze software package produces accurate analysis report
- Application of digital signal processing technique which can effectively restrict the interference caused by baseline drift, HUM, or EMG when measuring heart rate
- ECG measurement and analysis function reduces doctor' s work strain
- Pre-10-second printing function helps the doctor to print out any abnormal ECG waveform
- Three kinds of operation modes: AUTO, MAN, RR ANA. 5 manual print types: 12x1 , 6Tx2 , 6x2+1rhy, 3x4+3rhy, Test Mode; 8 manual print types : 12x1, 12x1+P, 6Tx2, 6x2+1rhy, 6x2+1rhy+P, 3x4+3rhy, 3x4+1rhy+P and template +P
- Sampling mode: real-time sample, pre-sample, period sample and trigger sample
- It can connect with laser printer, bar code scanner, magnetic card reader
- It has freeze, print preview and waveforms recall function.
- Clinical information: Patient ID, gender, age, height, weight, technician, doctor, race, bed number, room, blood pressure and hospital information can be edited easily.

- To observe abnormal heartbeat from rhythm lead
- Built-in ECG simulator
- AC (50/60Hz) and battery dual power supply, aptitude protection circuit of over load or over voltage
- High resolution thermal dot-matrix printing system which produces clear and accurate printout of waveforms and characters
- Automatic adjustment of baseline for optimal recording
- Built-in Help Function: electrode positioning, ECG basic knowledge, common trouble-shooting and so on
- 180 ECG files can be saved in the ECG, up to 10000 ECG files can be stored in U disk
- Neat saving interface. Saved ECG files can be displayed in image-text or list format, easy for search
- Auto-save function: after printing, the printed ECG file will be automatically saved

2.2 List of Symbols

Symbols in this *Operation Manual* are listed as below Table 2-2.

	External output		External input
	Equipment or part of CF type with defibrillator proof		Attention – general warning(see accompanying document)
	Equipotentiality		Mains supply
	Contrast adjustment		Battery recharging indicator

Table 2-1 List of Symbols

Chapter 3 General Information

3.1 Front Panel



Figure 3-1 Front Panel of QRS-12

3.1.1 Product Information:

1) LOGO

2) Model Series

QRS-12

3) Classification Symbol



Equipment of CF type with defibrillator proof

4) Open Button

Push this button to open the recorder cover. See Chapter 4.2 for details

5) Hidden handle

When necessary, the handle can be pulled out for carrying the machine.

3.1.2 LCD Screen

The display of QRS-12 is 7 inch color LCD, 800*480 dip.

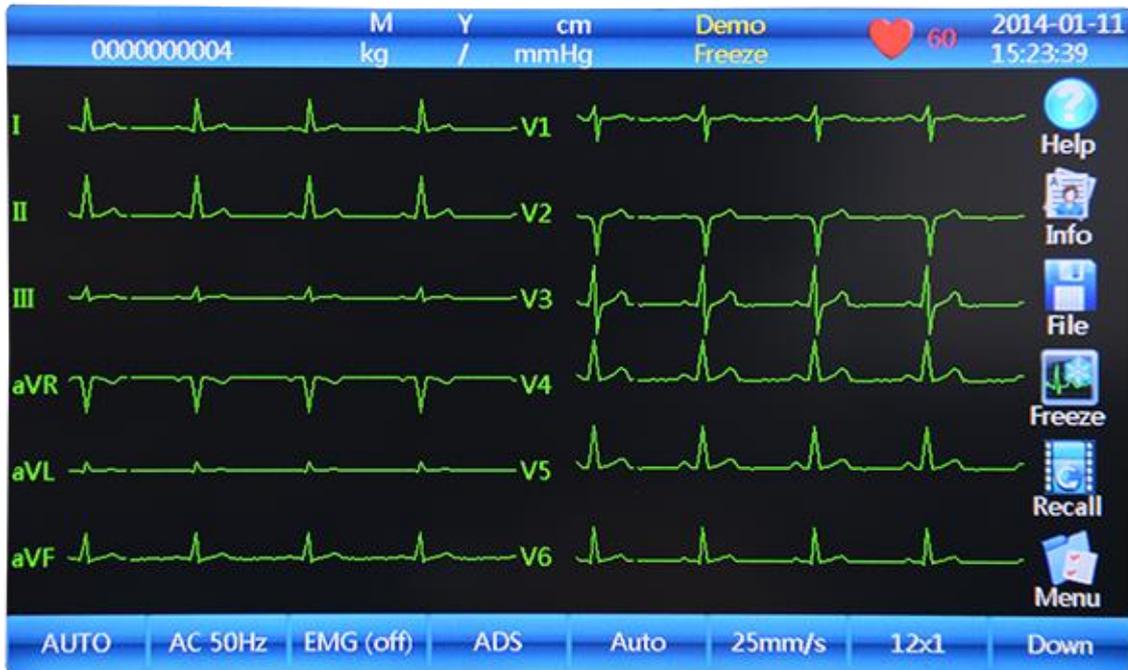


Figure 3-2 LCD Display of QRS-12

Normally, the contents displayed in the LCD screen include (from left to right):

Top Row:

- Name (20 letters or 10 characters)
- Patient ID (10 digits can be input)
- Gender (Male/Female/Empty)
- Weight Kg (000-999)
- Age Y (000-999)
- Blood pressure mmHg (000-999, can input systolic and diastolic)
- Height cm (000-999)
- Operation status: DEMO, sampling, analyzing and printing
- Hint information: Freeze , Lead off or blank
-  Heart rate (Actual heart rate, the refreshing speed of the dynamic icon is the same as the heart beating speed)
- Current date& time (YYYY/MM/DD; HH:MM:SS)

Bottom Row:

- Mode (AUTO, MAN, ANA)

- AC Filter (AC OFF, AC 50Hz, AC 60Hz), AC 50Hz and AC 60Hz must be selected in the system setting.
- EMG Filter (EMG OFF, EMG 25Hz, EMG 35Hz, 45Hz)
- ADS Filter (OFF, 0.05Hz , 0.15Hz , 0.25, 0.32Hz , 0.5Hz, 0.67Hz, it can be selectable in Filter setup)
- Sensitivity (Auto, 2.5, 5,10, 20, 40mm/mV)
- Paper Speed: 25mm/s, 50mm/s (other speed can be set in Print setup)
- Print Type: 12x1, 12x1+P, 6Tx2, 6x2+1rhy, 6x2+1rhy+P, 3x4+3rhy, 3x4+3rhy+P, Template+ P
- Page down
- Status of power source
- Network Connection Status (LAN)
- Rhythm Lead display: L, R, F, V1, V2, V3, V4, V5, V6.
- Page up

Right-hand Column (from top to bottom):

- Help (basic knowledge of how to operate the ECG)
- Info(to edit the patient information)
- File (to save or open up the patient data and edit the hospital information)
- Freeze
- Recall
- Menu (to set up different parameters)

3.1.3 Control Panel and Keys

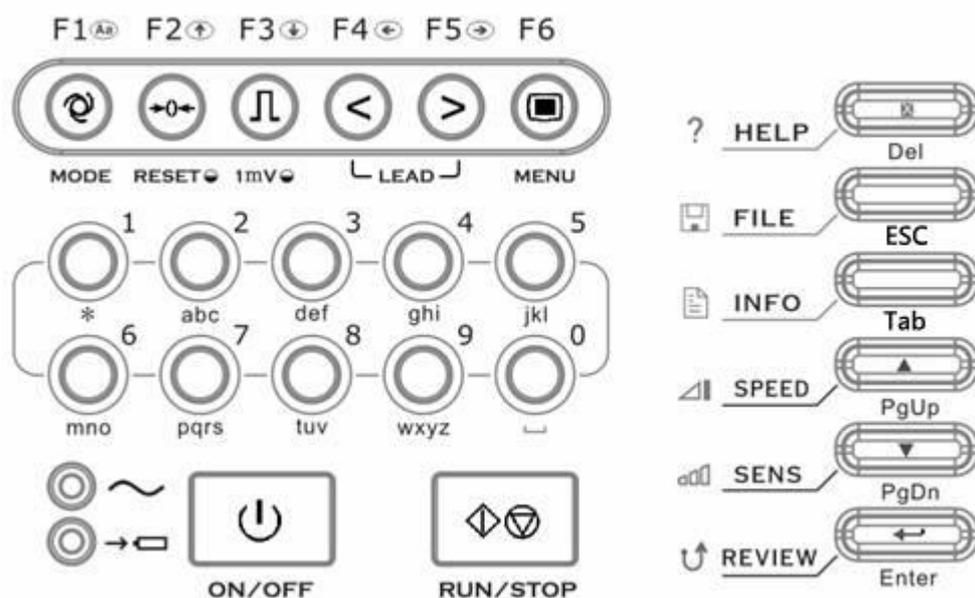


Figure 3-3 Control Panel of QRS-12

1) Indicator Lamp

- ~ Mains supply indicator lamp: when mains supply is used, the lamp is on.
- ➔☐ Battery recharging indicator lamp: when the battery is recharged, this lamp flashes.
When the battery is full charged, this lamp will be off.

2) MODE/F1



Press this key to select operation mode between AUTO, MAN, and ANA. The switching order of leads is listed in Table 3-1.

When inputting patient name or hospital name, press this key to change between capital and small letters. In FILE menu, press this key to change between image-text and list modes.

Mode		Switching Order (from left to right)											
AUTO	AUTO (Standard)	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
	AUTO (Cabrera)	aVL	I	aVR	II	aVF	III	V1	V2	V3	V4	V5	V6
MAN		In this mode, you need to press Lead (F4/F5) Key to change the lead. For the lead switching order, refer to that of AUTO (Standard) or AUTO (Cabrera) above, which can be set in the Basic submenu. The Test mode is used for manufacturer to test the print head and the paper shift.											
ANA		After around 1 minute of self-sampling, the compressed lead of any one of the above 12 leads waveform, report and its R-R histogram will be printed out.											

Table 3-1 Switching order of Leads

3) RESET/F2



Press **RUN/STOP** to start recording, then press **RESET** to reset signal lead. After that, the corresponding wave is a line. The locked lead will unlock itself after 0.4 second. The ECG signal will have interference and press **RESET** to reset the signal, if the equipment is connected with a defibrillator.

It is also a direction key upward to be used to choose the items and page turning.

4) 1mV/F3



Under MAN mode, press this key to record a 1mV calibration pulse at any time while recording. It is also a direction key downward to be used to choose the items and page turning.

5) LEAD (Lead Switch Keys)/F4, F5

F4 ← F5 →



Under AUTO mode, press the keys to switch the lead group.

They' re also direction keys leftward or rightward in time editing, FILE, INFO interface

6) MENU/F6

F6



MENU

Press this key to enter MENU interface, press it again to exist.

7) ON/OFF



ON/OFF

Power on or off the ECG. When the ECG is not printing it can be powered off. However we strongly recommend the ECG is powered off in main interface.

8) RUN/STOP



RUN/STOP

Start or stop recording.

9) HELP/Del



Press this key to read helpful information such as electrode positioning, ECG basic knowledge, etc. Press this key again to turn back to main menu. In "INFO" interface, it can be used to delete input information.

10) FILE



/ESC

Press this key to enter "FILE" interface. Press it again to return to main menu.

11) INFO



/Tab

Press this key to input patient ID, name, sex, age, height, weight, and blood pressure, etc.

If it' s not under main menu, it has the same function like "Tab" of the PC keyboard.

12) SPEED



Choose required printing speed from 25mm/s, 12.5mm/s, 10 mm/s, 6.25mm/s, 5mm/s or 50mm/s.

In FILE and HELP interface, this is a PageUp key.

13) SENS



Choose required sensitivity from AUTO, X2.5mm/mV, x5mm/mV, x10mm/mV, x20mm/mV, or x40mm/mV.

In FILE and HELP interface, this is a PageDown key.

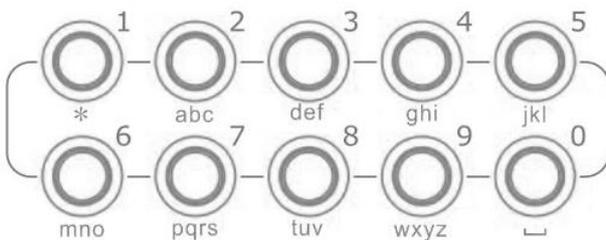
14) Enter



In main interface, press this key to print pre-10-second ECG data, and press "RUN/STOP" to stop printing;

In MENU interface, press this key to confirm;

15) Numeric/letter keys



These keys are numeric symbols.

In FILE or INFO interface, press these keys to input patient name, hospital name, patient ID, age, height, weight, blood pressure.

Tips:

1. In MENU interface, efficiency can be improved by directly pressing the numeric key;
2. Press MENU, INFO, FILE to enter the desired interface, no need to retreat the current interface; Quickly press MENU, INFO, or FILE key again to return to main interface;

3.2 Mains Connection and Switch

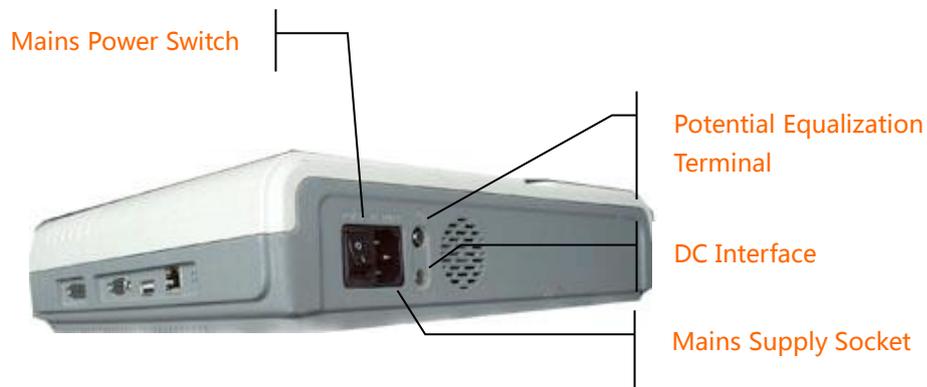


Figure 3-4 Mains Connection and Switch

1) AC Power Switch

- I : Power on
- : Power off

2) AC Power Socket

The equipment is well grounded when connected to a 3-phase power supply.

3) Equipotentiality



!NOTE !:

- ◆ When used with other medical equipment, connect the equipotentiality of the ECG to the grounding ends of the equipment with the grounding cable provided, to protect patients from any possible electric shock caused by other equipment.

!NOTE !:

- ◆ Connect one end of the grounding cable to the equipotentiality of the equipment and connect the other end to the ground to enhance reliability of grounding. Do not use pipe or the like as grounding cable, otherwise, the grounding cannot work and the patient has potential risk of electric shock.

4) DC Power Socket

Infinium Medical Inc. ECG can be powered by external DC power source. When choosing DC power source, be sure that the output voltage and current meet the equipment requirement and the interface matches. Car DC power source and the like can be used.

!WARNING !:

- ◆ Be sure that the safety specification of the DC power source meets the requirement of valid version of IEC 60601-1.

3.3 Patient Cable Socket and Signal Interface

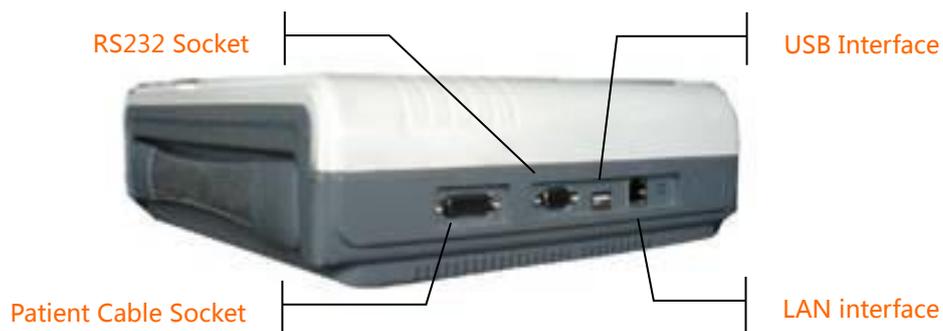


Figure 3-5 Interfaces

!WARNING !:

- ◆ Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of IEC 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult our technical service

department or your local distributor.

- ◆ Total current leakage should not exceed current leakage limit while several other units are used at the same time.

1) Patient Cable Socket

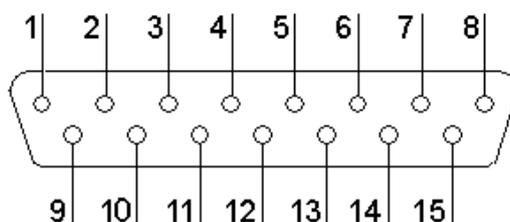


Figure 3-6 Patient Cable Socket

: Applied part of type CF with defibrillator proof.

Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)	6	SH	11	F (input)
2	C3 (input)	7	NC	12	CI(input)
3	C4 (input)	8	NC	13	NC
4	C5 (input)	9	R (input)	14	RF
5	C6 (input)	10	L (input)	15	NC

Table 3-2 Patient Cable Definition of Pins

2) RS232 Socket

 **WARNING** :

- ◆ The dielectric strength of RS232 interface is AC 1500V, therefore the maximum DC voltage applied on the interface can not exceed +12V.

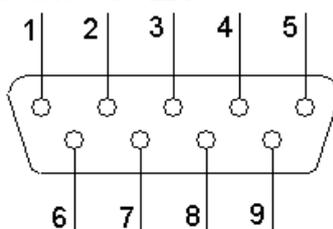


Figure 3-7 RS232 Socket

Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	EXT/OUT	4	NC	7	NC
2	RxD (input)	5	GND	8	NC
3	TxD (output)	6	NC	9	EXT/IN

Table 3-3 RS232 Definition of Pins

After the ECG Workstation Software is installed in PC, ECG data can be transferred to the PC via RS232 interface for display and management.

3) USB Interface

After USB device plug in this interface, ECG data can be transferred to USB flash via USB interface.

What's more, laser printer, bar code scanner and magnetic card reader can be plugged in to realize its own functions.

⚠️WARNING⚠️

The laser printer should be connected to power source first, after its initialization is down, then connect to ECG, or the laser printer will not work.

HP Printer setup flow: Power on → select [service] → select [USB speed] → select [Full] → back to [service] → select [HP Smart Install] → select [Off] →connect ECG and print

4) LAN interface

LAN interface can be used as communication port between ECG and workstation, and upload the ECG files to workstation directly. If you choose LAN interface to be the communication port, please set the IP, subnet mask, etc, according to PCECG-500 operation manual.

3.4 Bottom Panel



Figure 3-8 Bottom Panel

1) Fuse label

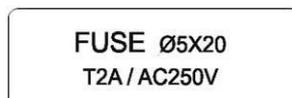


Figure 3-9 Fuse Label

⚠️WARNING⚠️:

- ◆ Fuse must only be replaced with the same type and rating as the original one.

2) Battery Compartment

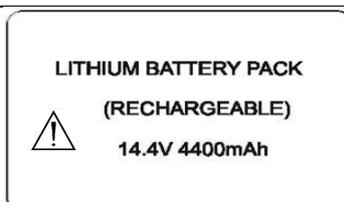


Figure 3-10 Battery Compartment Label

The battery label indicates the rated voltage and rated capacity of rechargeable lithium battery pack. Rated voltage: 14.4V, Rated capacity: 4400mAh.

⚠️WARNING⚠️:

- ◆ Improper operation may cause the battery hot, ignited or exploded, and it may lead to the decrease of battery capacity. Therefore, it is necessary to read the **Operation Manual** carefully and pay more attention to warning messages.

⚠️WARNING⚠️:

- ◆ When leakage or foul smell found, stop using the battery immediately. If the leakage liquid gets to your skin or cloth, cleanse it with clean water at once. If the leakage liquid gets into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

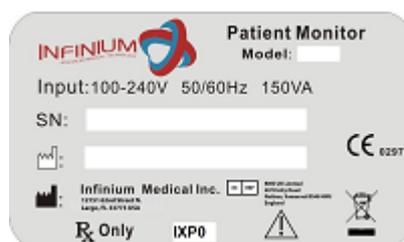
⚠️WARNING⚠️:

- ◆ Opening the battery cover, disassembling or replacing battery should be done according to the **Operation Manual**, and only battery of same model and specification provided by the manufacturer should be used.

3) Product Label

In the label, there is information of product model, S/N, manufacture date, register No., manufacturer name, etc.

Figure 3-11 Product Label



Chapter 4 Operation Preparations

WARNING :

- ◆ Check the main unit and its accessories carefully before operating the ECG. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance. Make sure that the equipment is in proper working condition.

4.1 Connecting to AC Power and Grounding

WARNING :

- ◆ To avoid any possible electric shock, please connect the ECG with AC power by a three-phase power cable. Don't open the ECG while it is powered on.

WARNING :

- ◆ If the integrity of external protective conductor in installation or arrangement is in doubt, the ECG should be operated from the built-in rechargeable battery.

We ECG can be powered on by AC power supply, DC power supply or built-in rechargeable lithium battery pack.

1) AC Power Supply

The mains socket is on the left upper side of the ECG. Properly connect the ECG with mains supply.

Rated voltage: 100V-240V

Rated frequency: 50Hz/60Hz

Rated input power: 75VA

Make sure the AC power supply meets the above requirements before power on. Then press the AC power switch to turn on the ECG. The AC power supply indicator lamp (⌚) will be lit.

2) Built-in Rechargeable Battery

The built-in rechargeable battery pack is used, because of the consumption during storage and transport, the capacity of battery may not be full. In this case please recharge the battery first. Replace the battery when the battery has been recharged over 500 times.

NOTE :

- ◆ The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the ECG, if built-in rechargeable battery is to be used, connect the battery to the socket first.
- ◆ Please refer to the **Section 8.4.1** for how to recharge the battery. During recharging, the ECG can be powered on by AC power supply and continue operating.
- ◆ The battery should be recharged at least 8 hours for first time application.
- ◆ The battery's recycling life is about 500 times of recharging.

3) External DC Power Supply

Make sure the DC power supply meets the requirements as below:

Rated output voltage: 19V;

Rated output current: 3.5A;

Output terminal plug must match the DC socket in the ECG.

4) Equipotentiality terminal

When used with other medical equipment, connect the equipotentiality of the ECG to the grounding ends of these equipment with the grounding cable enclosed to protect patient from electric shock in case any possible current leakage of other equipment.

5) Power on the equipment

Switch on AC power and press ON/OFF key to power on the equipment. Or just press ON/OFF to power on the equipment when using battery.

4.2 Loading Recording Paper

216mm/210mm width roll thermal sensitive paper can be applied to QRS-12(Class M) as recording paper. There will be both audio and video alarms when there is no paper or the paper is not properly installed.

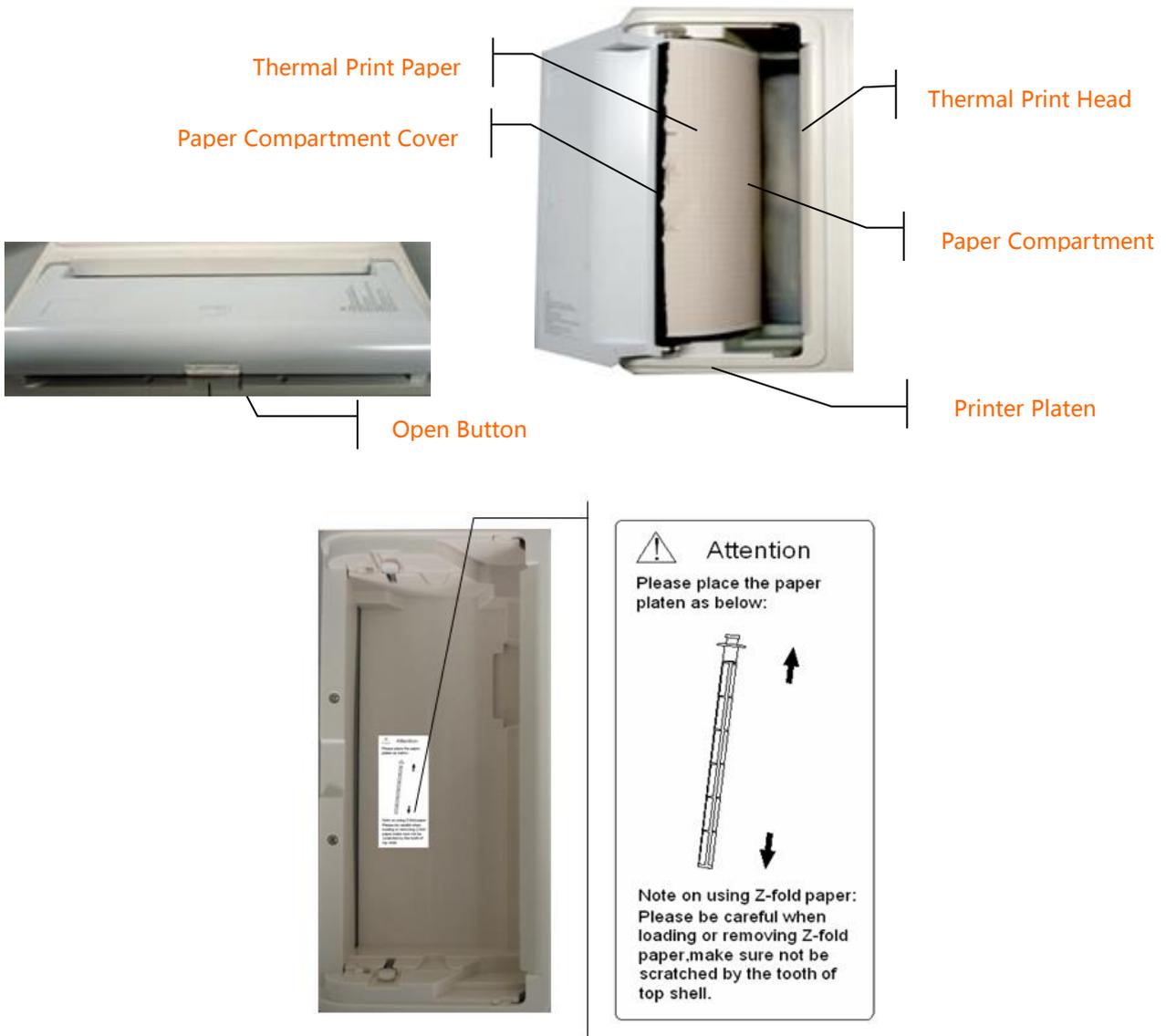


Figure 4-1 Loading Roll Paper

Loading Procedures of Rolled Paper:

1. Push the Open Button to open the paper compartment cover.
2. Take out the paper rollers, remove remaining paper if necessary. Insert the rollers into the new roll paper and put the paper with rollers back into the paper compartment. Be sure that the paper is installed with the paper's grid side facing downward.
3. Pull about 2cm of the paper out, and close the cover gently.

!NOTE!:

- ◆ Print record before the press "INST" key to reset and wait until stable and then print the ECG ECG information.

4.3 Patient Cable Connection

Patient cable includes two parts, main cable and lead wires with associated electrode connectors. The electrode connectors can be distinguished from the color and identifier on them.

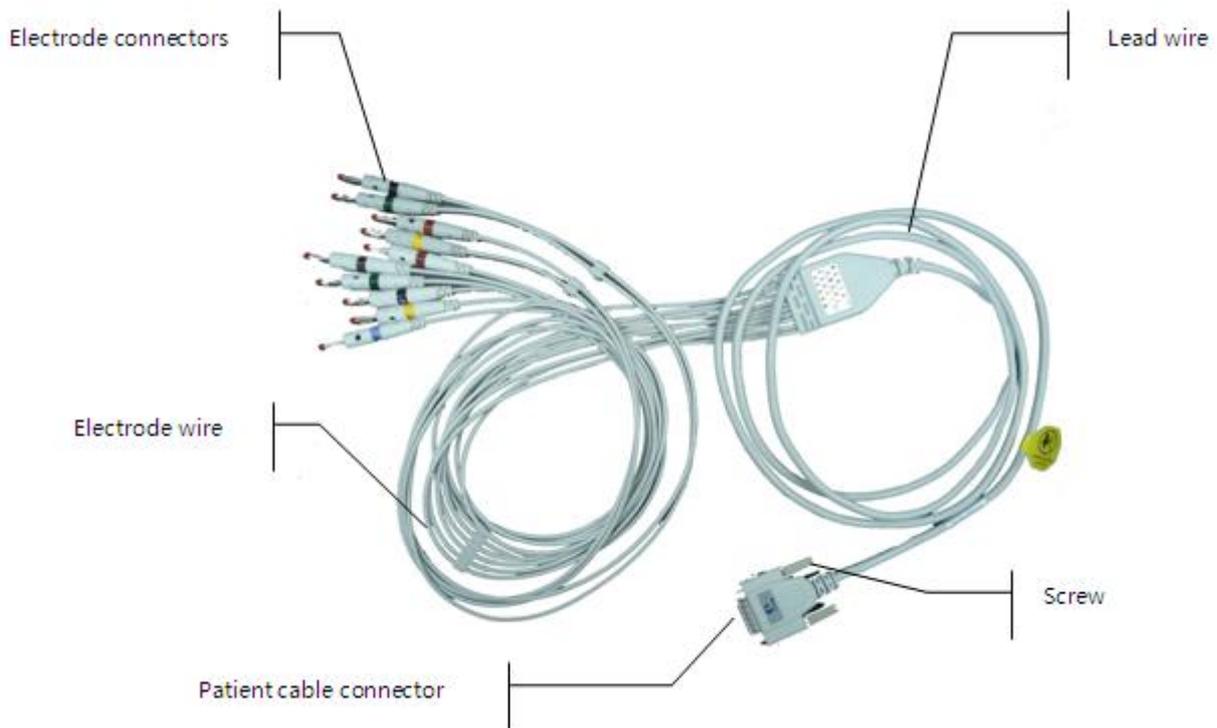


Figure 4-2 Patient Cable

Connect Main Cable: Plug the connector of main cable into the patient cable socket on the right side of the ECG. Secure the knobs on sides of the socket.

!WARNING!:

- ◆ This product is CF classified and defibrillation protected only when the original patient cable is used. However, as a safety precaution when possible, remove electrodes before defibrillation.
- ◆ It is strongly recommended that only Infinium Medical Inc. patient cable be used when the ECG is using with high frequency devices to avoid any possible signal interference.

4.4 Electrodes Connection

Chest Electrode:

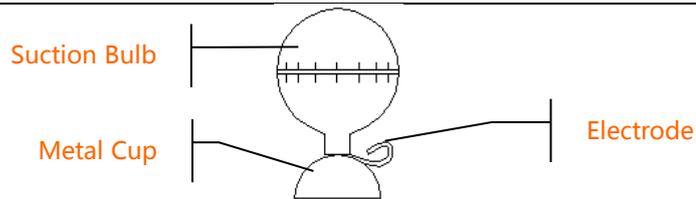


Figure 4-3 Chest Electrode

Limb Electrode:

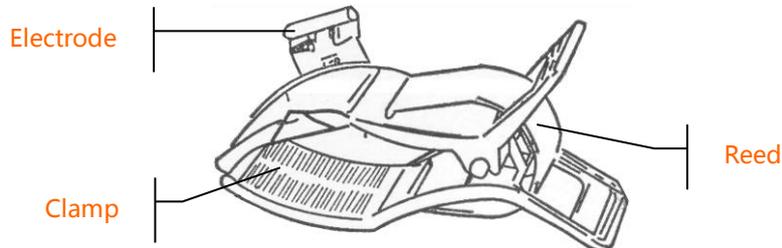


Figure 4-4 Limb Electrode

The identifier and color code of electrodes used comply with IEC requirements. In order to avoid incorrect connections, the electrode identifier and color code are specified in Table 4-1. The equivalent code of American standard is given too.

Electrodes	European		American	
	Identifier	Color code	Identifier	Color code
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/red	V1	Brown/red
Chest 2	C2	White/yellow	V2	Brown/yellow
Chest 3	C3	White/green	V3	Brown/green
Chest 4	C4	White/brown	V4	Brown/Blue
Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/violet	V6	Brown/violet

Table 4-1 Electrodes, Identifier and Color Code

The chest electrode should be placed on body surface as shown below.

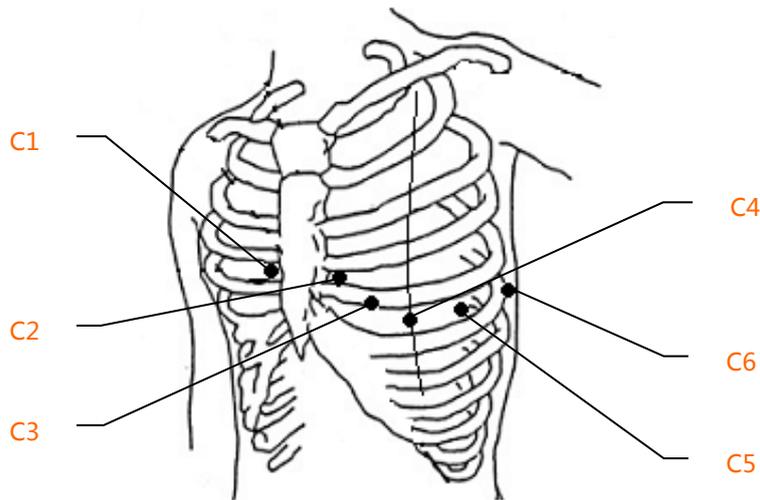


Figure 4-5 Chest Electrode Positioning

C1: Fourth intercostals space at right border of sternum

C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

C5: Left anterior auxillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4

The contacting resistance between the patient and the electrode will affect the quality of ECG waveform greatly. In order to get a high-quality ECG waveform, the skin/electrode resistance must be minimized while connecting electrodes.

Chest Electrodes Connection:

1. Ensure the electrodes are clean;
2. Align all lead wires of patient cable to avoid twisting, and connect the associated electrode connectors with corresponding electrodes according to the color and identifier;
3. Clean electrode area on chest surface with alcohol;
4. Daub the round area of 25mm diameter on each electrode site with gel evenly;
5. Place a small amount of gel on the brim of chest electrode' s metal cup;
6. Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the electrode is adsorbed on chest. Attach all chest electrodes in the same way.

Limb Electrodes Connection:

1. Ensure the electrodes are clean;
2. Align lead wires of patient cable to avoid twisting, and connect the electrode connectors to corresponding electrodes according to the color and identifier;
3. Clean electrode area on a short distance above the ankle or wrist with alcohol;
4. Daub the electrode area on limb with gel evenly;
5. Place a small amount of gel on the metal part of limb electrode clamp;
6. Connect the electrode to limb, and be sure that the metal part be placed on the electrode area above the ankle or wrist. Attach all limb electrodes in the same way.

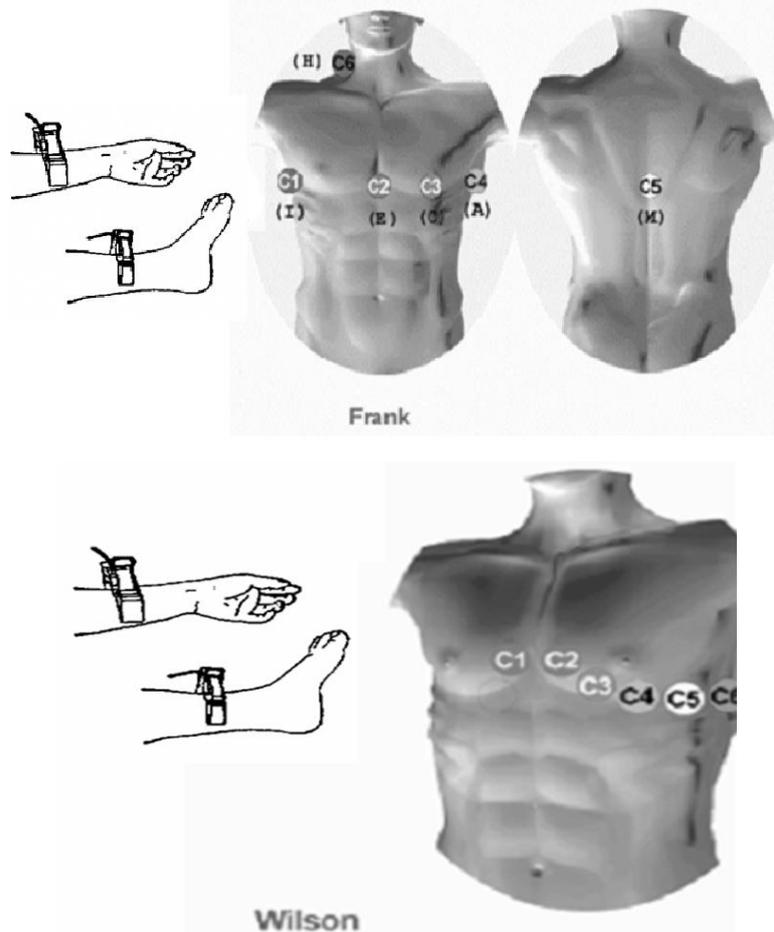


Figure 4-6

⚠️WARNING⚠️:

- ◆ Be sure that all electrodes have been connected to the patient correctly before operation.
- ◆ Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with earth or any other conducting objects.
- ◆ There is no danger when using the ECG with electrical stimulation equipment. However, the stimulation units should only be used at a sufficient distance from the electrodes .If in doubt, the patient should be disconnected from the device.
- ◆ Electrodes with defibrillator protection should be used while defibrillating.
- ◆ Do not touch the ECG Shell case during defibrillation.

4.5 Inspection before Startup

In order to avoid safety hazards and get good ECG record, the following inspection procedures are recommended before turning on the ECG and beginning operation.

1) Environment:

- ◆ Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.
- ◆ Keep the examination room warm to avoid muscle action voltages in ECG signal caused by cold.

2) Power Supply:

- ◆ If mains power used, please check whether the power cord has been connected to the ECG and it is properly grounded.
- ◆ Recharge the battery first before use when the battery capacity is low.

3) Grounding:

- ◆ Check the grounding cable is properly connected.

4) Patient Cable:

- ◆ Check whether the patient cable has been connected to the ECG firmly, and keep it far away from the power cord.

5) Electrodes:

- ◆ Check whether all electrodes have been connected with lead wires of patient cable correctly according to the identifier and color.
- ◆ Be sure that all electrodes have been connected to the patient correctly.
- ◆ Ensure that the chest electrodes haven't contacted with each other.

6) Recorder Paper:

- ◆ Ensure that there is enough recording paper loaded.
- ◆ Make sure the case of the recorder has been secured.

7) Patient:

- ◆ The patient should not contact with conducting object such as earth, and metal part of bed etc.
- ◆ Ensure the patient is warm and relaxed, and breathe calmly.

8) AC Filter Frequency

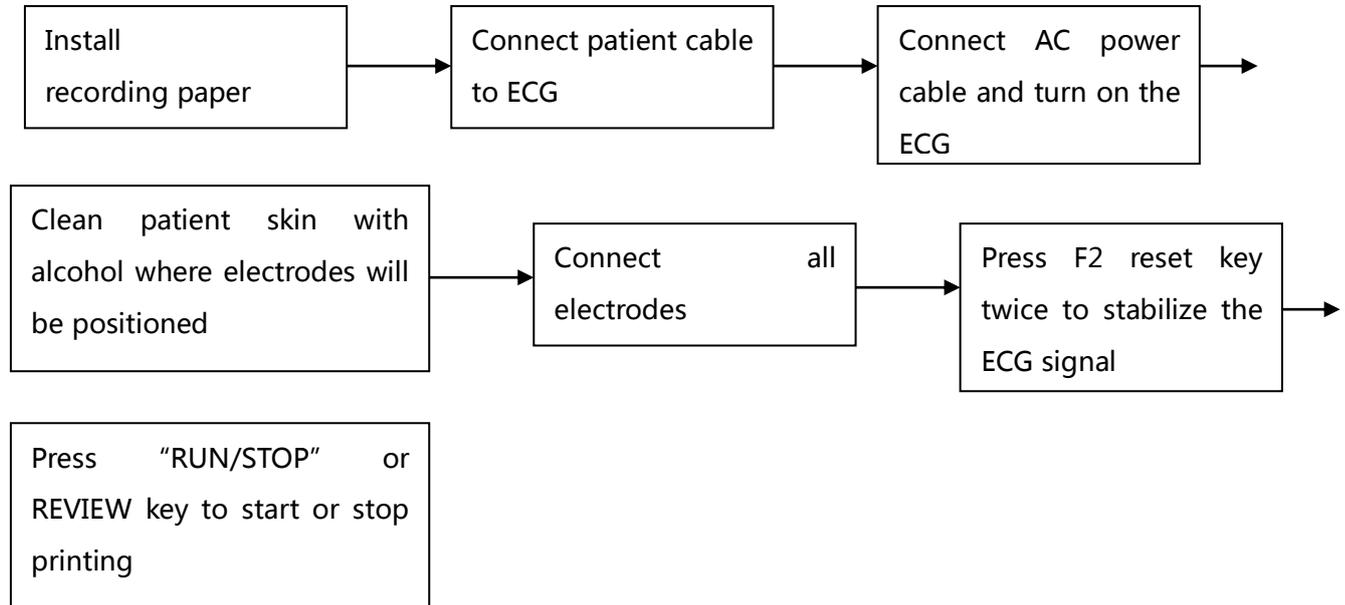
- ◆ Check the setup of AC Filter Frequency and make sure is identical with the local regulations, or it will influence the anti-jamming effect.

 **WARNING** :

- ◆ The ECG is provided for the use of qualified physicians or personnel professionally trained. The operator is supposed to be familiar with the contents of this *Operation Manual* before use.

Chapter 5 Operation Instructions

Basic operation procedures



⚠NOTE⚠:

- ◆ The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the ECG machine, connect the battery to the socket first.
- ◆ The side with grid faced down when loading the print paper.
- ◆ Lead wires and electrodes provided by manufacturer should be used.
- ◆ Replace the electrode after cleaning the surface with alcohol, when there is alarm information for lead off.
- ◆ Do not plug the electrodes off when doing the ECG analysis.

5.1 Power ON/OFF

5.1.1 Power ON

- When AC power supply is applied, press the power switch, and the AC power supply indicator (⌚) is lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Such information as name, manufacturer and version No. etc., will be displayed in LCD screen after self-test. Then the ECG is ready for examination and recording.
- When external DC power supply is applied, both the two indicator lamps will be constant lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Such information as name, manufacturer and version No. etc., will be displayed in LCD screen after self-test. Then the ECG is ready for examination and recording.
- When using built-in rechargeable lithium battery, press ON/OFF key for about three seconds on

the control panel directly to turn on the ECG, and then the AC power supply indicator and the battery indicator are not bright. Equipment information such as name, manufacturer and version No. etc., will be displayed on LCD screen after self-test. The ECG is ready for examination and recording. When the battery symbol becomes "  ", the battery is low, and the equipment will be automatically turned off in 1 minute. In this case, use AC power supply to continue operation and the battery will be simultaneously recharged.

5.1.2 Power OFF

- When battery is the power supply, continuously press ON/OFF key for about three seconds for 3 seconds to turn off the ECG.
- When AC is the power supply, press ON/OFF key for about three seconds to turn off the ECG, turn off the AC switch, plug out the AC power cable.
- When DC is the power supply, press ON/OFF key for about three seconds to turn off the ECG, then plug out the DC power cable.
- When battery is the power supply, the backlight will automatically turns off without operation within 30s. If there is no operation within 3 minutes, the ECG will turn off automatically. When AC power is applied, it will enter power-saving mode automatically if there is no operation within 3 minutes.

⚠NOTE⚠:

- ◆ The ECG can be turned off in any interface. However we'd recommend the ECG is turned off accordingly to the normal procedures in case there is any chaos in the screen when the ECG is powered on next time.

5.2 HELP

Press " ? HELP  " or touch "  " on the screen, and then enter HELP menu. After that, you'll see the electrode position diagram, basic information about ECG, common trouble shooting and so on. Press " UP", " DOWN", "  PgUp " and "  PgDn " to scroll the page. Press "ESC " or touch "X" to return to main interface. It has two languages for you to switch, i.e. English and Chinese.

5.3 Info

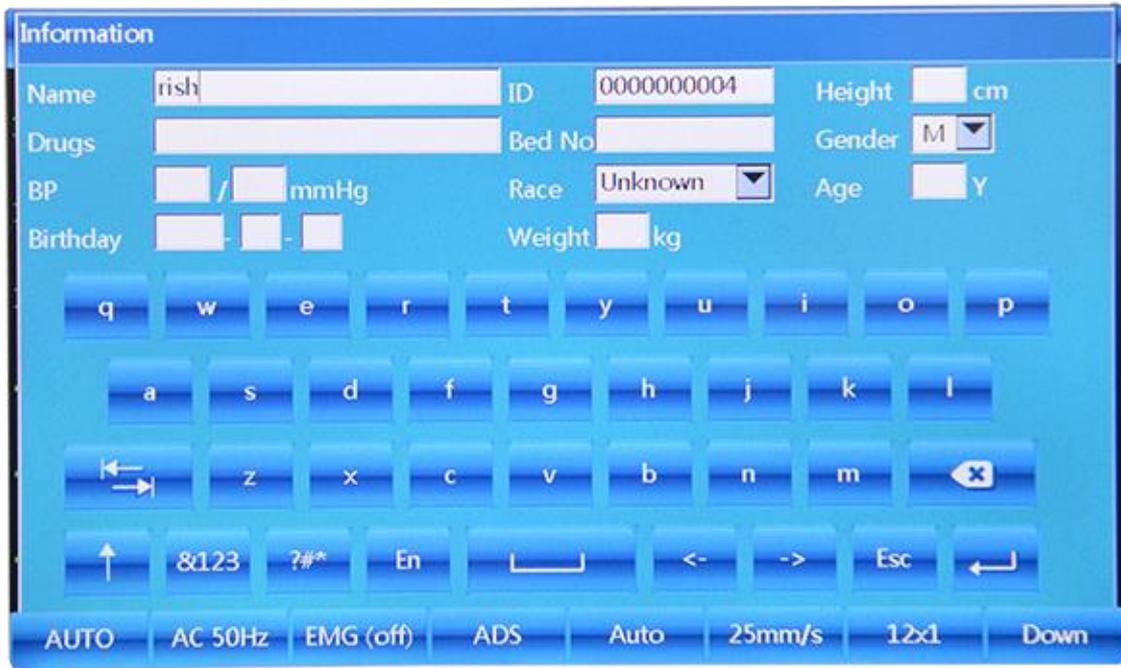


Figure 5-2 Info Interface

Press  **INFO**  /Tab key to input clinical information, including patient name, technician, drugs, doctor, Institution, ID, bed No., race, room, blood pressure, height, gender, age and weight. Press  to save and confirm but press **"ESC"** key or **"X"** to turn back to main menu as Table 5-1. Press it again to return to main menu.

Name	Patient's Name (20 characters or 10 Chinese characters)	Race	Asians, White People, Black People, Pacific Island Residents and American Indians , unknown
Drugs	20 characters or 10 Chinese characters	Weight(kg)	Patient's Weight (3 digits)
BP (mmHg)	Patient' s systolic and diastolic pressure(000-999 digits)	Height (cm)	000-999 digits
Birthday	YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY (data format chosen from "Date" of main menu)	Gender	Male/Female/Empty
ID	Patient's ID (10 digits)	Age (Y)	Patient's Age (3 digits)
Bed No.	10 digits		

Table 5-1

- ◆ Touch “↑” key on the keyboard of the touch screen to shift from small letter to capital letter. Press “TAB” key to the next blank in order. Touch “X” key on the keyboard of the touch screen .

5.4 File

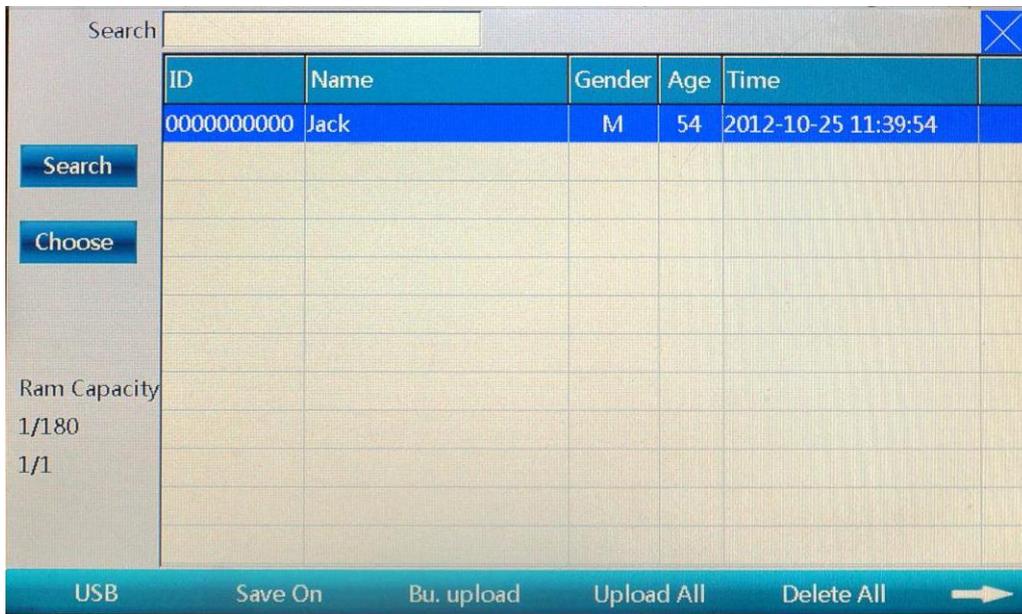


Figure 5-3 Storage 1

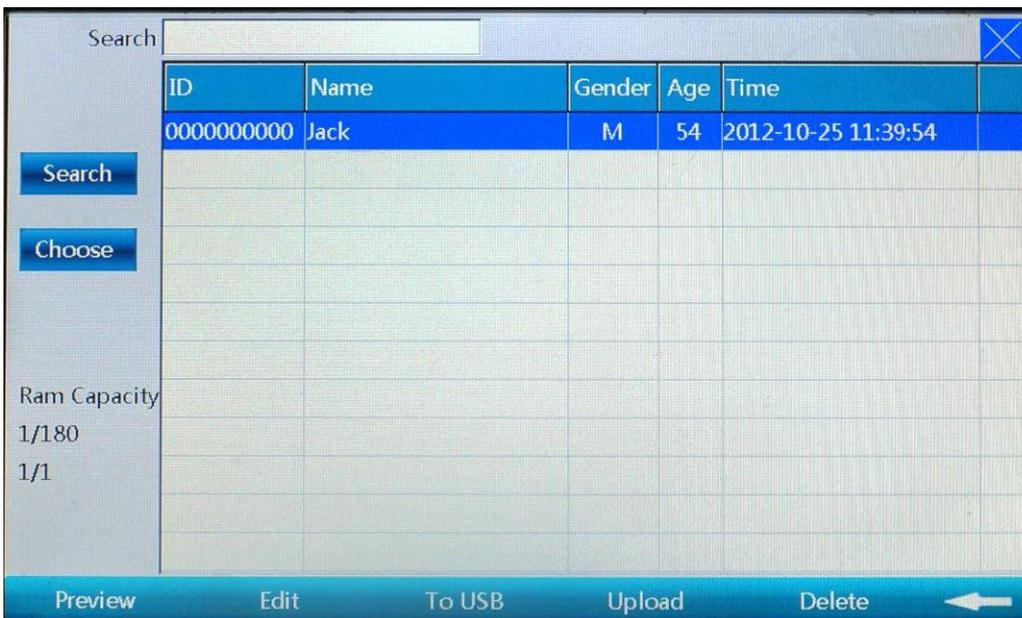


Figure 5-4 Storage 2

1. This function mainly focuses on the storage and search for the patient information and ECG waveforms.

Operation Method : As the above Figure 5-3 and Figure 5-4 shows, from F1 to F6, there are 6 keys to select. And touch screen will be much easier for operation.

- ◆ **Search:** click the blank frame to input searching information through soft keyboard, then touch the “Search” button.

- ◆ **Exit Search:** To return file interface.

- ◆ **Choose:** Press  and  to move the cursor to the case you need, then touch the **【Choose】** on the left screen, then there is a "*" in the last column of the case, which indicates the case has been selected (touch the **【Choose】** again to cancel select). With this operation, you can select several cases, then touch the **【Bu.upload】** on the bottom of screen to upload.

Storage function setup(down in the interface, left to right):

- ◆ **USB :** Users can choose to save patient information in USB . ECG files will be automatically saved in internal flash, when printing.
- ◆ **Save On/Off :** When the equipment is in "save on " status, the case will be automatically saved in the flash after printing, or cases will not be saved.
- ◆ **Bu.Upload :** Upload cases selected to the PC
- ◆ **Upload All:** Upload all cases to the PC
- ◆ **Delete All:** Delete all cases
- ◆ : Switch to next function page
- ◆ **Preview :** Preview case
- ◆ **Edit:** After enter the "File" , users can edit the patient information
- ◆ **To USB:** Export the selected case to the "ECGFILE" file of U disk
- ◆ **Upload:** Upload the selected case to the PC
- ◆ **Delete:** Delete the selected case in dark blue background
- ◆ : Switch to previous function page

5.5 Freeze

In the main interface, press this key, it can freeze the waveforms; press this again, it returns to the real-time sampling mode.

5.6 Recall

Touch "Recall" , the previous print-out data will show; press ESC, then users can exit. It only functions after printing results under the AUTO and RR ANA mode.

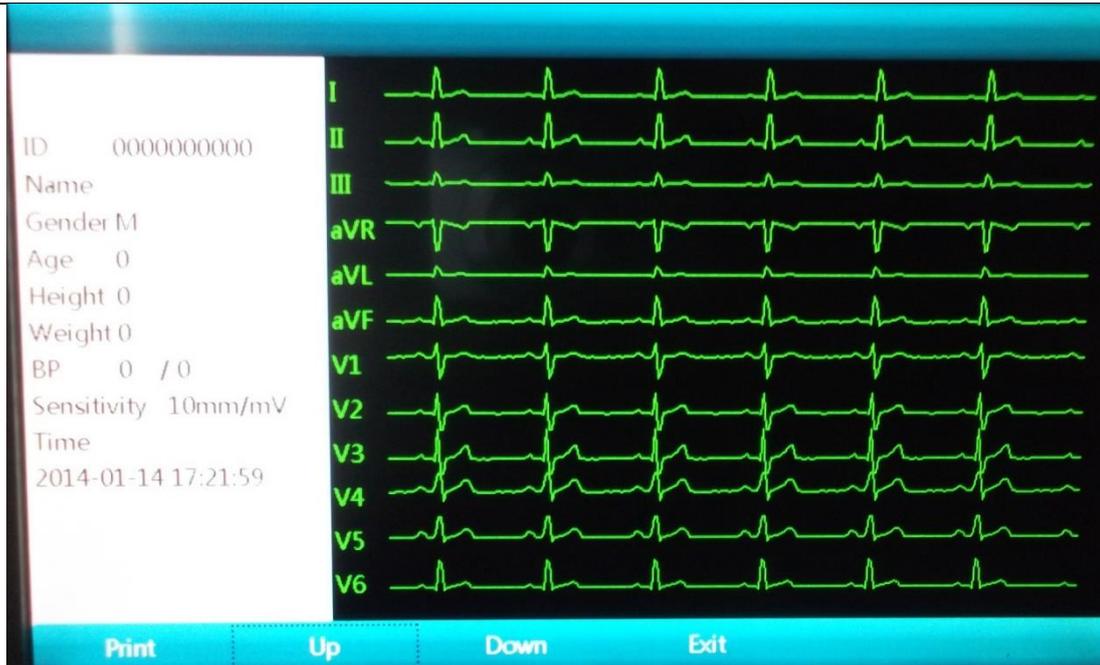


Figure 5-5 Recall Interface

1. Touch **Recall** key to enter the recall interface.
2. Press **F1** key of the panel to print out this ECG waveform. Press the **F4** key to exit. Press the **F2** and **F3** key to turn page up/down. Or you can operate by touch relative button on the bottom of the interface.
3. The recall function only works after finishing a report in auto mode.

5.7 Operation Menu

5.7.1 Menu

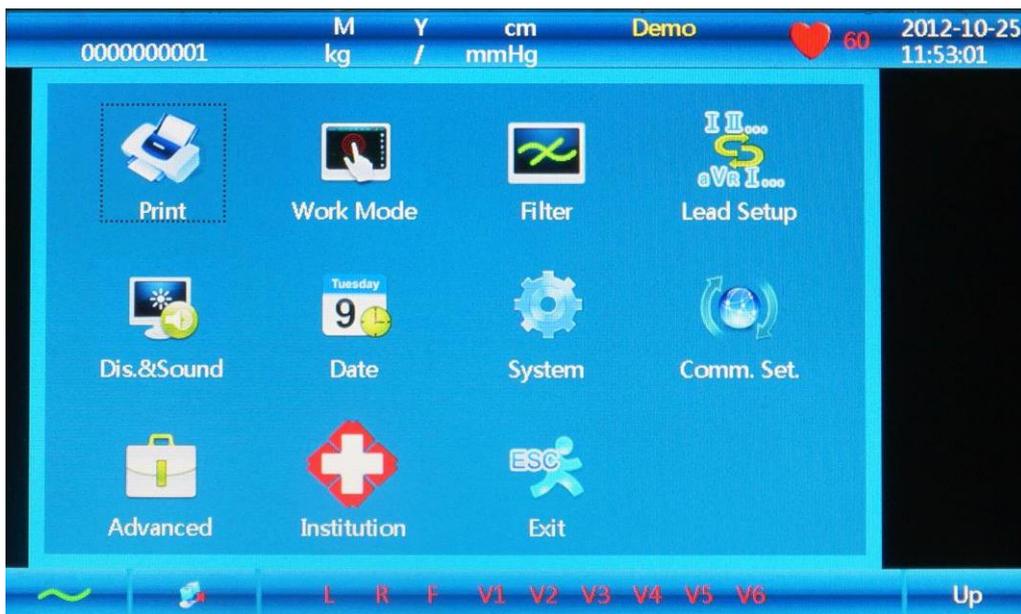


Figure 5-7 Menu Interface

Press **MENU** to enter the **MENU** interface. Press the **Exit** key of the menu interface to exit.

There are 10 sub-menus under the MENU interface as the figure 5-7 shows, press the "▲ SPEED PgUp", "▼ SENS PgDn" and "Tab" key to choose the sub-menu you need to change, and press **Enter** key to make a confirmation. What's more, you can also touch the screen to finish operation.

5.7.2 Set the Printing Parameters

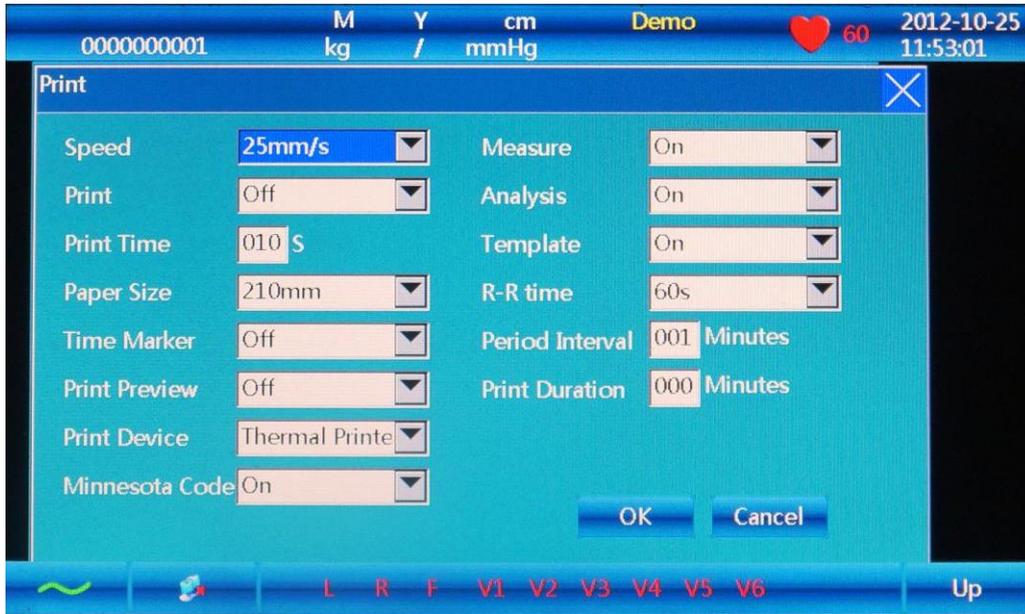


Figure 5-8 Print Setting Interface

1. Choose the **Print Setting** after entering the menu, and press the **ESC** key to exit.
2. The print setting concludes following items: Paper Speed, Acquisition Mode, Auto Print Mode, Man. Print Mode and so on. Press the **Menu** or **Enter** key to set the chosen item, press "▲ SPEED PgUp", "▼ SENS PgDn" key to choose side to side, and press **Tab** to choose from top to bottom. Press the **ESC** key to exit and Press **Enter** to confirm.

Table 5-2

No.	Name	Options
1	Speed	5mm/s , 6.25mm/s , 10mm/s , 12.5mm/s , 25mm/s , 50mm/s
2	Print	ON/OFF
3	Print Time	User enter manually (5~30s)
4	Paper Size	210mm/216mm
5	Time Marker	On/Off
6	Print Preview	On/Off
7	Print Device	Thermal, HP DJ1000, HP M401D. The default is thermal printer
8	Minnesota Code	ON/OFF

9	Measure	ON/OFF
10	Analysis	ON/OFF
11	Template	ON/OFF
12	R-R Time	60s, 180s
13	Period Interval	Users enter manually (1~60 minutes)
14	Print Duration	Users enter manually (1~60 minutes)

- ◆ Paper Speed: 25mm/s or 50mm/s is generally selected in clinical use. 5mm/s , 6.25mm/s , 10mm/s , 12.5mm/s are for test purpose or special acquisition and ECG recall.
- ◆ Print: It has two options: On and Off. If you want to print the results, you must turn it on.
- ◆ Minnesota code: On or Off. If you turn it on, it will print Minnesota code on the printing results; otherwise, it won' t.
- ◆ **HP Printer setup flow: Power on → select [service] → select [USB speed] → select [Full] → back to [service] → select [HP Smart Install] → select [Off] →connect ECG and print**

NOTE

The laser printer should be connected to power source first, after its initialization is down, then connect to ECG, or the laser printer will not work.

Print Preview

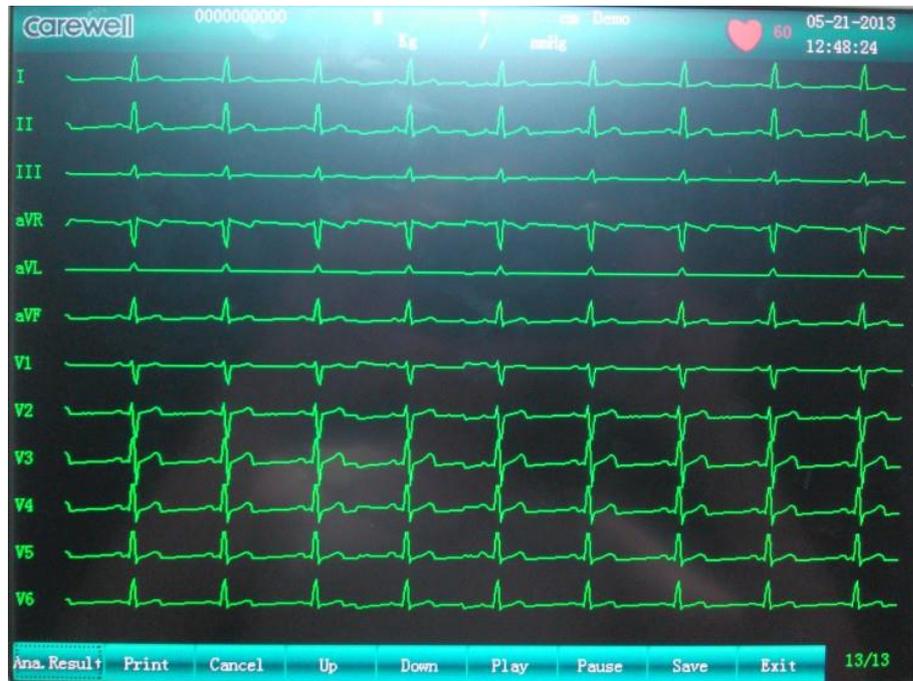


Figure 5-9 Preview

Under AUTO mode, if "Print Preview" turns on, press "RUN/STOP " to enter preview interface.

From left to right, it's "Analysis Result", "Print", "Cancel", "Up", "Down", "Play", "Pause", "Save" and "Exit".

- ◆ Analysis result: Press "F1" or touch "Ana. Result" to enter analysis result preview interface. You can touch "Waveform", "Print", "Cancel" and "Exit" to fulfill the function.
- ◆ Print: Press "F2" or touch "Print" to print the current 10S ECG waveforms.
- ◆ Cancel: Press "F3" or touch "Cancel" to stop printing.
- ◆ Up/Down : Press "F4" or "F5" or touch "Up/Down" to scroll the pages.
- ◆ Play: Press "F6" or touch "Play" to replay the previous 120S waveforms. It will stop playing automatically after the 120s waveforms completely replayed
- ◆ Pause: touch "Pause" to stop waveforms replay.
- ◆ Save: analyze and save the current sampling 10s ECG waveforms. The ECG files will be read from the "FILE" interface, only when the SAVE in the "FILE" interface is on.
- ◆ Exit: Press <ESC> to exit freeze interface.

Table 5-3 13 arrhythmia

Arrhythmia	
2nd Degree Type II AV Block	Atrial premature contraction (Bigeminy)
2nd Degree Type I AV Block	Atrial premature contraction (Trigeminy)
2nd Degree AV Block (2:1)	Occasional Ventricular premature contraction
Possible 3rd Degree complete AV Block	Frequent ventricular premature contraction
Sinus pause	Ventricular premature contraction (Bigeminy)
Atrial escape beat	Ventricular premature contraction (Trigeminy)
Atrial escape beat rhythm	Paroxysmal tachycardia (Ventricular)
Junctional escape beat	Paroxysmal tachycardia (Supraventricular)
Junctional escape beat rhythm	Atrial fibrillation
Ventricular escape beat	Atrial fibrillation (Bradycardia)

Ventricular escape beat rhythm	Atrial fibrillation (tachycardia)
Possible junctional premature contraction	Atrial fibrillation, with aberrant ventricular conduction
Occasional supraventricular premature contraction	Atrial fibrillation, with long R-R interval
Frequent supraventricular premature contraction	Atrial fibrillation with 2nd degree AV block
Supraventricular premature contraction (Bigeminy)	Atrial flutter
Supraventricular premature contraction (Trigeminy)	Possible atrial flutter
Occasional atrial premature contraction	Atrial fibrillation+ atrial flutter
Frequent atrial premature contraction	

5.7.3 Set Mode

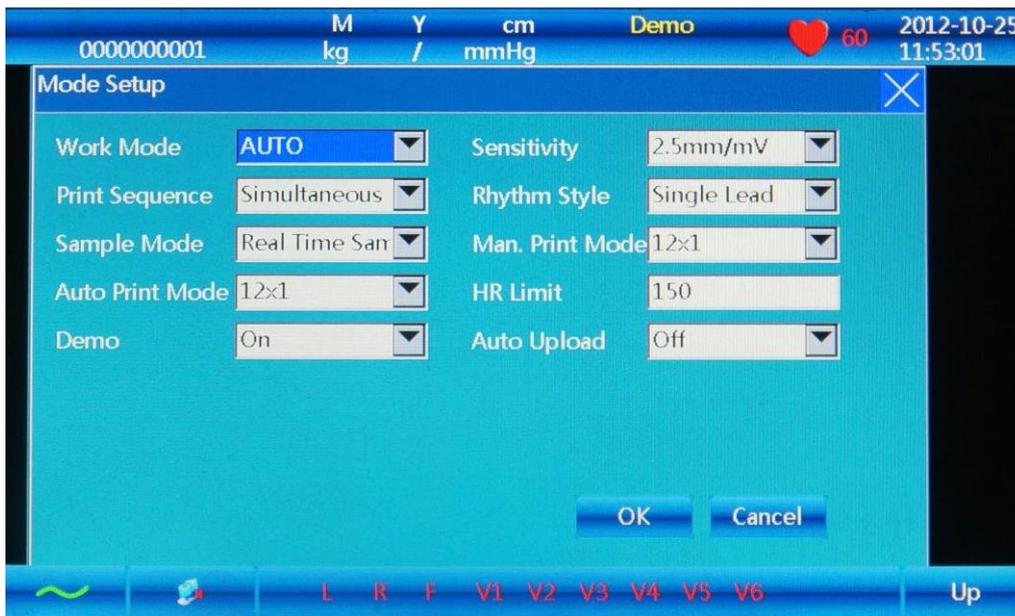


Figure 5-9 Work Mode

No	Parameter	Options
1	Work Mode	MAN, AUTO, RR ANA
2	Print Sequence	Sequential, Simultaneous
3	Sample Mode	Pre-Sample, Real-time Sample, Period Sample, Trigger Sample
4	Auto Print Mode	12x1 , 12x1+P , 6Tx2 , 6x2+1rhy , 6x2+1rhy+P , 3x4+3rhy , 3x4+1rhy+P and Template+P

Chapter 5 Operation Instructions

5	DEMO	ON/OFF
6	Sensitivity	Auto , 2.5mm/mV , 5mm/mV , 10mm/mV , 20mm/mV , 40mm/mV
7	Rhythm style	Single lead
8	MAN. print mode	12x1 , 6Tx2, 6x2+1rhy , 3x4+3rhy , test mode
9	HR Limit	To set the HR value (0~250) manually
10	Auto Upload	ON/OFF

1. Work Mode: AUTO-MAN-RR ANA
2. Print Sequence: Sequential, Simultaneous
3. Acquisition Mode:

Pre-sample: Press "**START/STOP**" and it can print the previous 10s waveform under pre-sampling mode.

Real-time Sample: Press "**START/STOP**", it will transmit the real-time 10s ECG information immediately.

Period Sample: First of all, set "**Period Interval**" and "**Period Time**" in the "**Date& Time**" menu, and then return to the main interface. After that, "**Testing**" will display on the interface. If the period interval is 2 minutes, 2 minutes later it will start the printing. 2 minutes later, it will start the second printing. It will last until it reaches the periodic continuous time.

Trigger Sample: After choosing trigger acquisition mode, if asystole, ventricular fibrillation, ventricular tachycardia, Ront, missed beat and multiple ventricular premature happens, it will trigger the ECG to print the abnormal waveform automatically, which makes it easy to identify the disease.

4. Auto Print Mode: Set print-forms of ECG waveform. The modes are as follows:

12x1: print 12-channel waveforms parallel;

12x1+P: print 12-channel waveforms parallel in the A4 size;

6Tx2: print 6-channel waveforms parallel;

6x2+1rhy: print 6-channel parallel plus one rhythm waveforms;

6x2+1rhy+P: print 6-channel parallel plus one rhythm waveforms parallel in the A4 size;

3x4+3rhy: print 3-channel plus 3 rhythm waveforms parallel.

3x4+1rhy+P: print 3-channel parallel plus one rhythm waveforms parallel in the A4 size;

Template+P: There is no waveform but only analysis in printing report.

5. MAN Print Mode:

6x2: print 6-channel waveforms parallel;

12x1: print 12-channel waveforms parallel;

6x2+1rhy: print 6-channel parallel plus one rhythm waveforms;

3x4+3rhy: print 3-channel plus 3 rhythm waveforms parallel.

Test Mode: it is used for the manufacturer to test the print head and paper skip are in good condition and the external input situation. It is used to test the triangle waveforms.

The auto and manual print mode also can be set up by the shortcut key F1 of the panel, while for the lead mode change is the F4/F5 key.

6. Sensitivity : AUTO , 2.5mm/mV , 5mm/mV , 10mm/mV , 20mm/mV , 40mm/mV ;

Under MAN mode, users can choose any of the 6 above sensitivity to get the best ECG signal; under AUTO mode, it is auto gain control, so it will adjust automatically.

5.7.4 Set the Filter Parameters

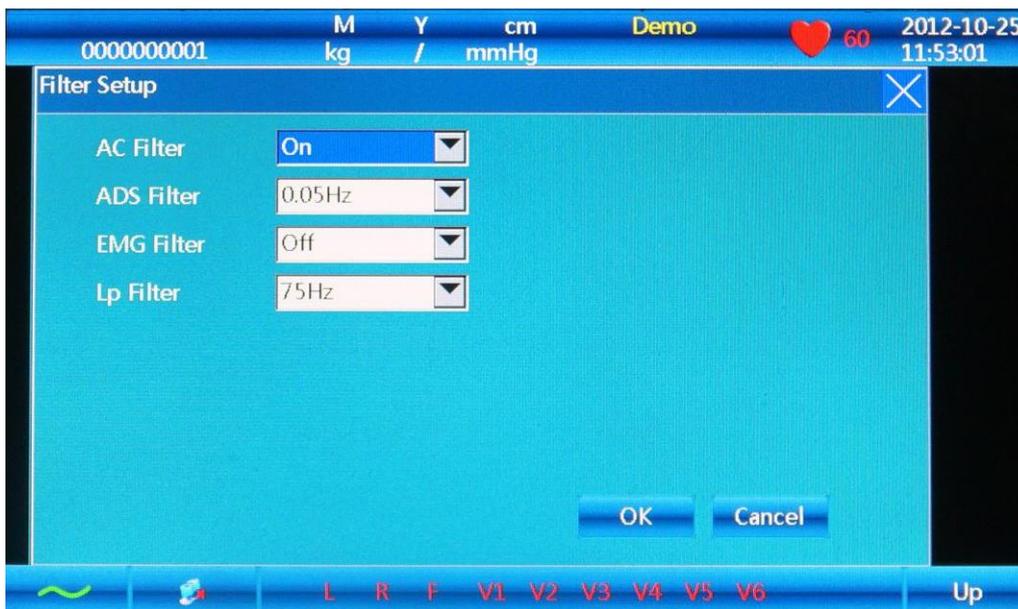


Figure 5-10 Filter Setup

1. Choose the **Filter** setting after entering the menu, and touch the "Cancel" or "X" key to exit.
2. The filter setting concludes following items: AC Filter, EMG Filter, ADS Filter, Low-passed Filter, Auto Position.
3. AC Filter: It has two options: on and off.
 EMG Filter: it has four options: 25Hz , 35Hz , 45Hz and off.
 ADS Filter: it has five options: 0.05Hz , 0.15Hz , 0.25Hz , 0.32Hz , 0.5Hz , 0.67Hz and off.
 Low-passed Filter: it has five options: 75Hz , 90Hz , 100Hz , 165Hz and off.

5.7.5 Lead Sequence

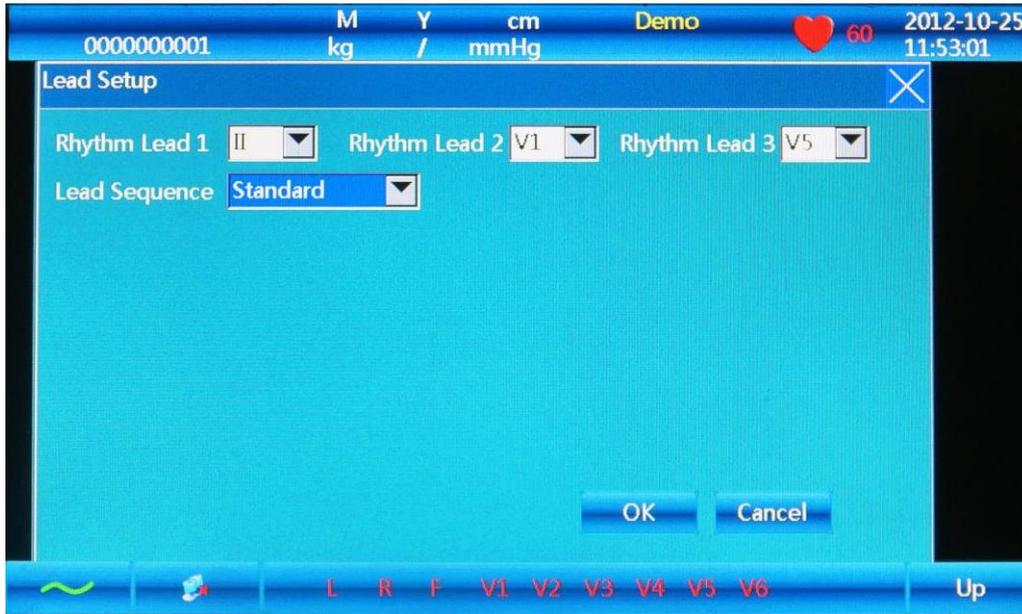


Figure 5-11 Lead Sequence

1. Choose the **Lead Sequence** setting after entering the menu, and touch the “X” key or press “ESC” to exit.
2. The submenu has two options: Standard and Cabrera. Press the **Tab** key to set the chosen item, and

press SPEED PgUp " and " SENS PgDn " key to set the parameter.

Table 5-6

No.	Parameter	Options
1	Lead sequence	standard , Cabrera
2	Rhythm Lead 1	I , II , III , aVR , aVL , aVF , V1 , V2 , V3 , V4 , V5 , V6
3	Rhythm Lead 2	I , II , III , aVR , aVL , aVF , V1 , V2 , V3 , V4 , V5 , V6
4	Rhythm Lead 3	I , II , III , aVR , aVL , aVF , V1 , V2 , V3 , V4 , V5 , V6

5.7.6 Display & Sound

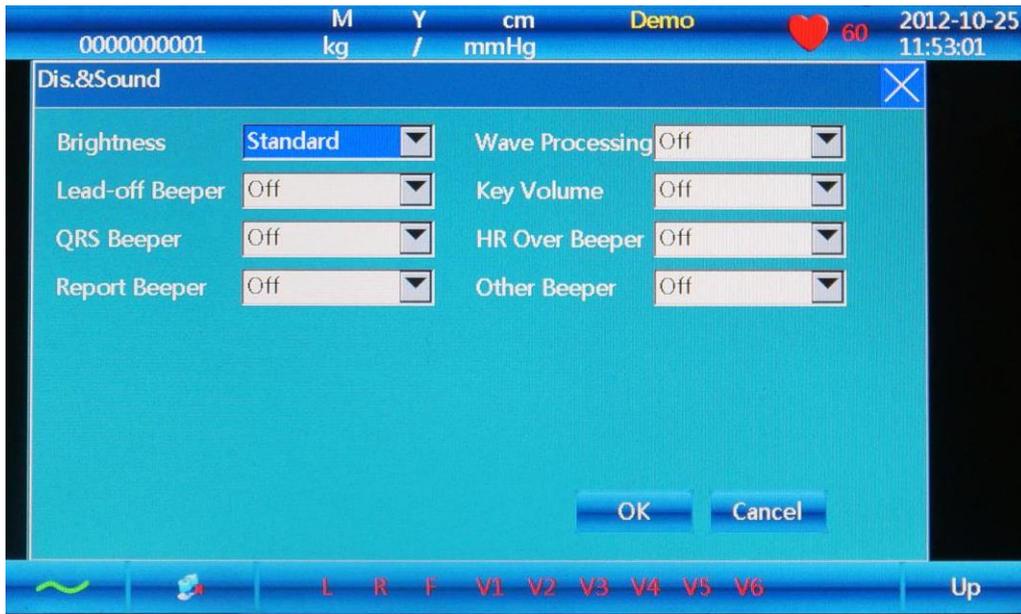


Figure 5-12 display& sound

Table 5-7

No.	Parameter	Options
1	Brightness	Standard, darker, brighter
2	Lead-off Beeper	On/off
3	QRS Beeper	On/off
4	Report Beeper	On/off
5	Waveform Processing	On/off
6	Key Volume	On/off
7	HR Over Beeper	On/off
8	Other Beeper	On/off

5.7.7 Date & Time

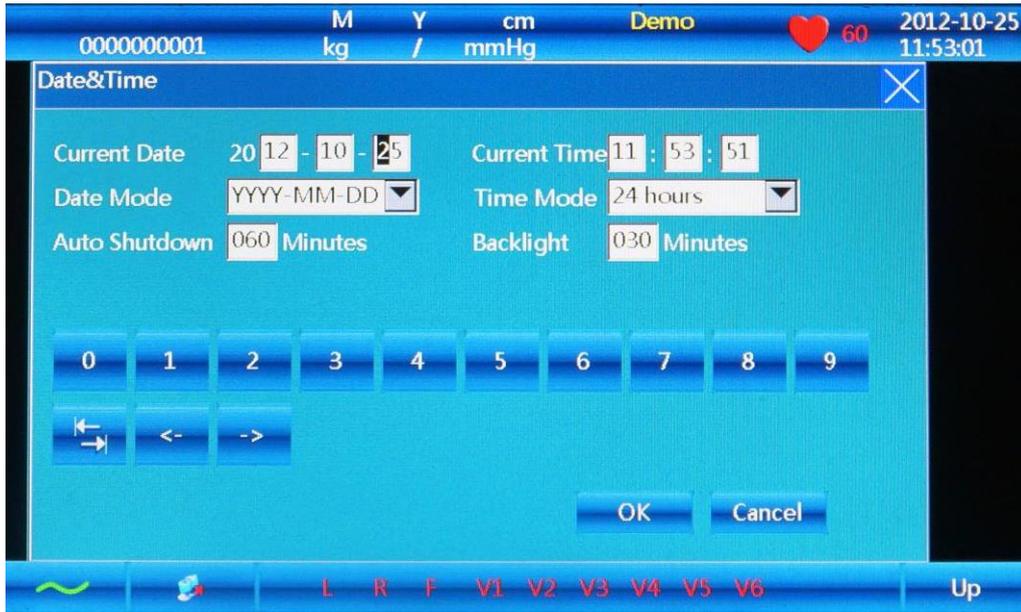


Figure 5-13 data& time

Table 5-8

No.	Parameter	Options
1	Current Date	Enter manually
2	Current Time	Enter it manually
3	Date Mode	DD-MM-YYYY , MM-DD-YYYY and YYYY-MM-DD
4	Auto Shutdown	Enter it manually (0~60 Min)
5	Time Mode	12 hours , 24 hours
6	Backlight	Enter it manually (0~60 Min)

5.7.8 Set the System Parameter

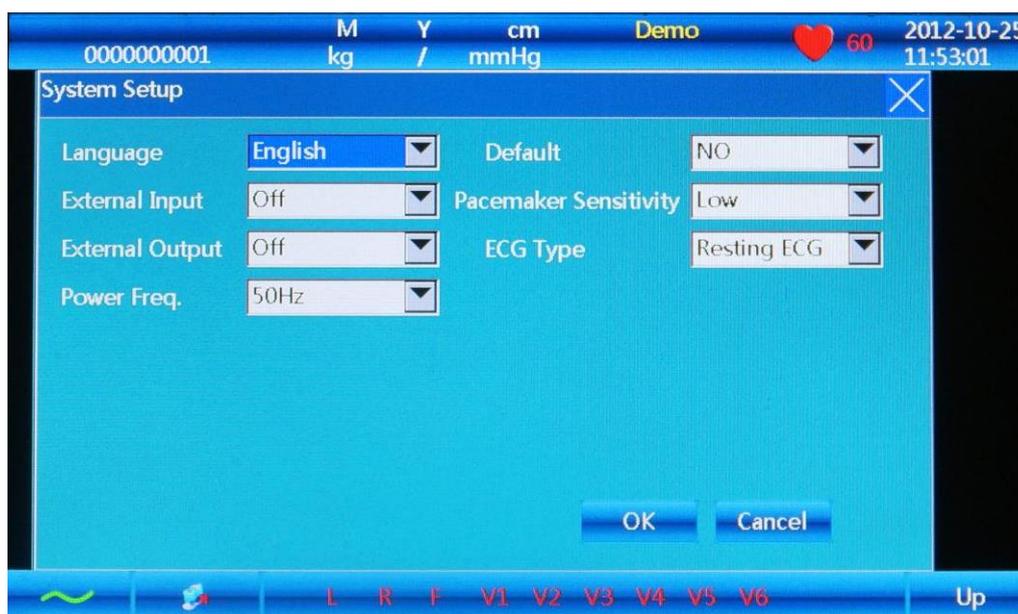


Figure 5-15 System Setup

Table 5-9

No.	Parameter	Options
1	Language	Chinese , English
2	External Input	ON/OFF
3	External Output	ON/OFF
4	Power Freq.	50Hz , 60Hz
5	Default	YES/NO
6	Pacemaker Sensitivity	Low/high
7	ECG Type	Resting ECG

Table 5-10 "Default" content

No.	Setting	Default	No.	Setting	Default
1	Speed	25mm/s	23	HR Limit	150
2	Print	On	24	Auto Upload	Off
3	Print Time	10s	25	Lead Sequence	Standard
4	Time Marker	Off	26	Rhythm Lead 1	II
5	Print Device	Thermal Printer	27	Rhythm Lead 2	V1
6	Minnesota Code	On	28	Rhythm Lead 3	V5
7	Measure	ON	29	AC Filter	ON
8	Analysis	ON	30	ADS Filter	0.67Hz
9	Template	ON	31	EMG Filter	Off
10	Acq. Time	60 s	32	Low Pass Filter	75Hz
11	Period Interval	1 min	33	All Beeper	On

Chapter 5 Operation Instructions

12	Print Duration	60 min	34	Brightness	Standard
13	Paper Size	216mm	35	Wave Processing	Off
14	Work Mode	AUTO	36	Date Mode	MM-DD-YYYY
15	Print Sequence	Simultaneous	37	Auto shut down	60 min
16	Sample Mode	Real-time	38	Time Mode	24hrs
17	Auto Print Mode	12×1	39	Backlight	30 min
18	DEMO	Off	40	External Input	Off
19	Preview	Off	41	External Output	Off
20	Sensitivity	Auto	42	Default	Off
21	Rhythm Style	Single Lead	43	Pacemaker Sensitivity	Low
22	Man. Print Mode	12×1	44	Comm. Method	Low

5.7.9 Set the Communication

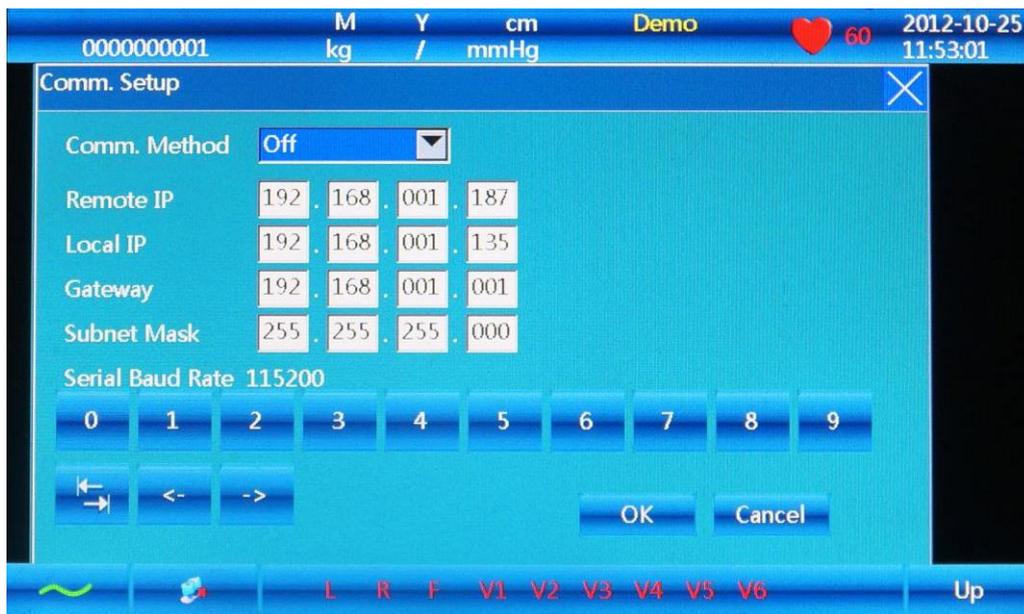


Figure 5-15 Communication Setting Interface

1. Choose the **Comm. Setup** after entering the menu, and press the **ESC** key to exit.

Table 5-11

No.	Parameter	Options
1	Comm. Method	OFF , Ethernet, UART
2	Remote IP	Enter it manually (IP of PC connecting with ECG)
3	Local IP	Enter it manually (local ECG IP)
4	Gateway	Enter it manually

5	Subnet Mask	Enter it manually
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5.7.10 Set the Advanced Setting

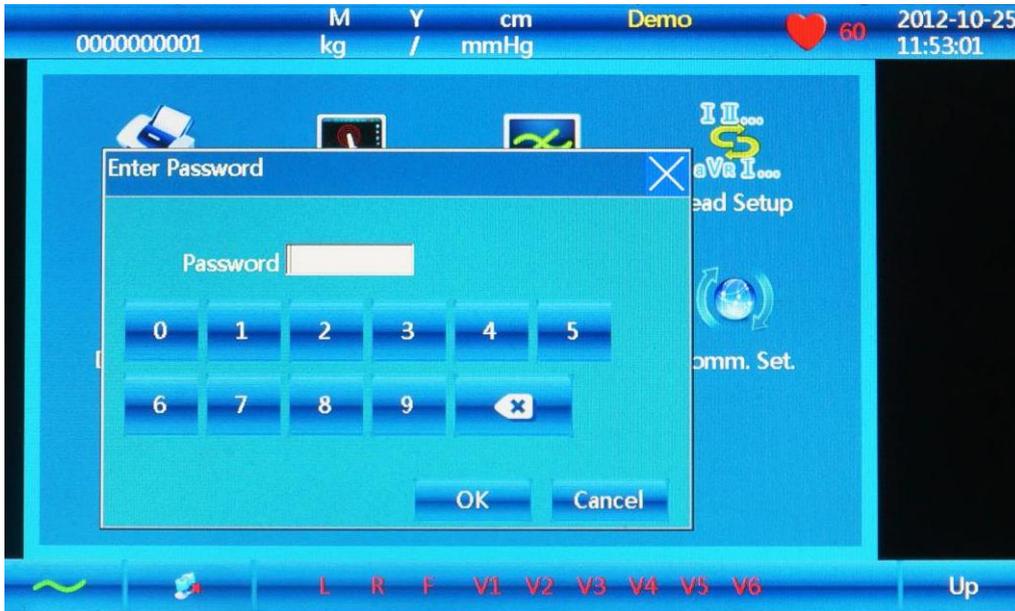


Figure 5-16-1 Advanced Setting Interface

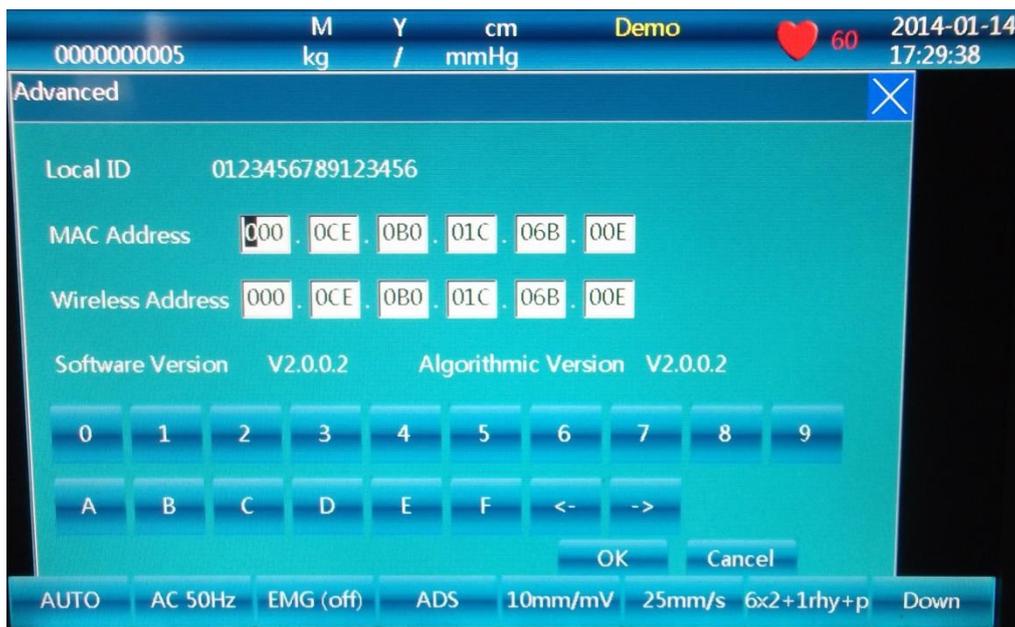


Figure 5-16-2 Advanced Setting Interface

Choose the **Advanced** by entering the password. Users don't need to enter this interface.

5.7.11 Institution

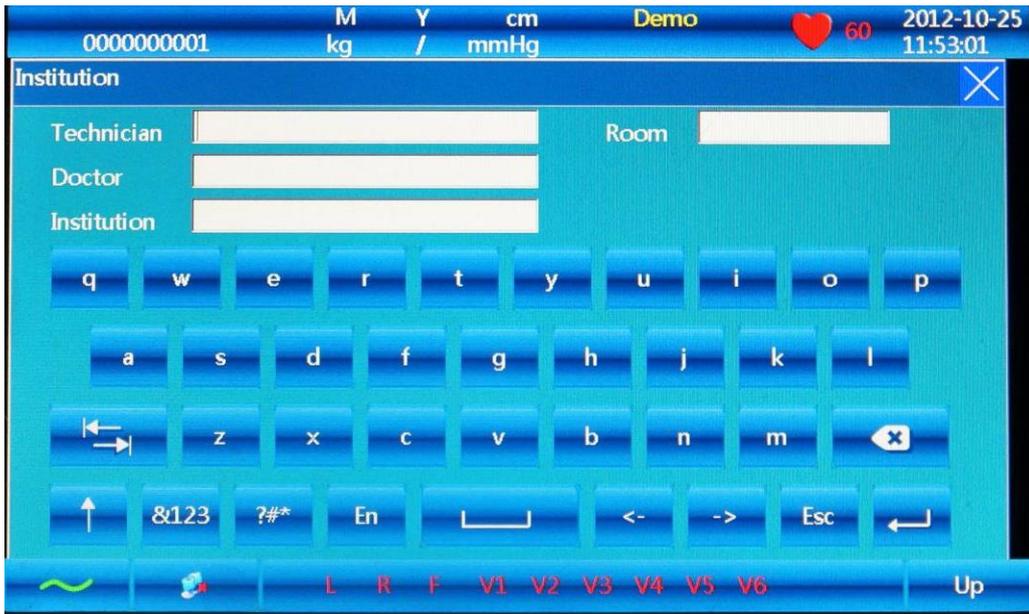


Figure 5-17

Table 5-12

No.	Parameter	item
1	Technician	Input information of technician
2	Room	Input room information
3	Doctor	Input doctor information
4	Institution	Input information of institution

5.7.12 Exit

This icon is used to exit menu interface and return main interface, there is another way

to press   .

5.7.13 Touch Screen calibration

If touch screen is not sensitive enough, you can do the touch screen calibration again.

Method: in menu interface, press "F2" button, there will be a "Enter Password" dialog, input password "999999" , the calibration interface will appear. To calibrate by touching five points

appearing on the screen one by one, after the calibration, press   to exit.

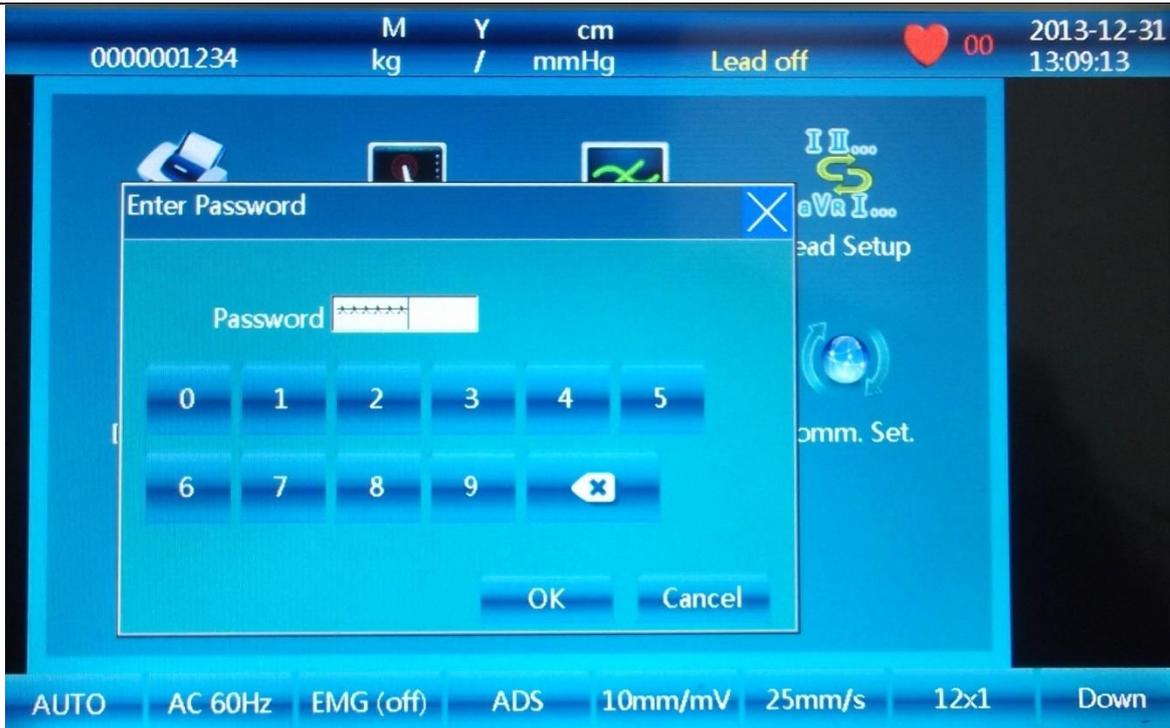


Figure 5-19

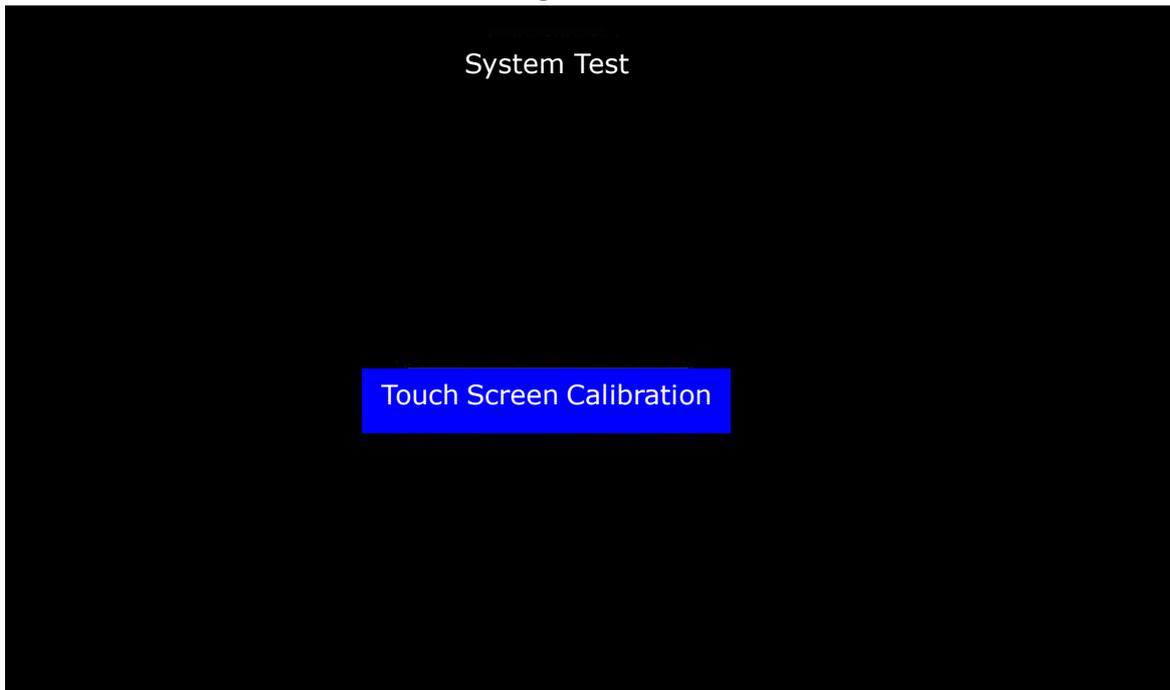


Figure 5-20

5.8 How to Use the Battery

⚠️ WARNING ⚠️:

- ◆ Inappropriate operation may lead battery to be hot, ignited, exploded, damaged or capacity fade. Before using the rechargeable lithium battery, read this manual carefully.

ⓘ NOTE ⓘ:

- ◆ The first time recharging of new battery coming with QRS-12(Class M) should be at least 8

hours.

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol in the screen.

2) Recharge

QRS-12(Class M) is equipped with recharging control circuit together with built-in rechargeable lithium battery. When connect with the AC power supply, the battery will be recharged automatically. And then the battery recharge indicator lamp (→□) will flicker and the AC power supply indicator lamp (∞) will be lit. When the capacity of battery is full, the battery recharge indicator lamp (→□) will be bright.

Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at the first time. New battery should be recharged before use for at least 8 hours.

3) Replacement

⚠NOTE⚠:

- ◆ The battery is put into the battery compartment without connectin4g to the battery socket at factory. After receiving the ECG, if built-in rechargeable battery is to be used, connect the battery to the socket first. See Figure 7-1 for installation.

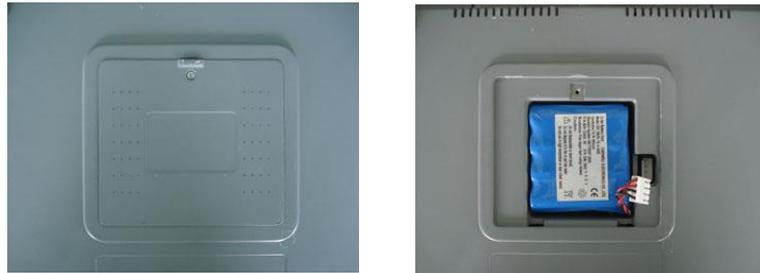


Figure 5-21 Battery installation

1. Open the battery compartment cover with the screw-driver enclosed;
2. Insert the battery into the battery pack, properly connected;
3. Close the battery cover.

When the cycling life of battery is over, or foul smell and leakage has been found, please contact the manufacturer or its local distributor for replacement of battery.

⚠WARNING⚠:

- ◆ Only qualified service engineer authorized by us can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.
- ◆ **Danger of explosion** - Do not reverse the anode and cathode when connecting the battery.
- ◆ When the battery' s useful life is over, contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

5.9 Operation Mode

There are 3 kinds of operation mode: Auto, Manual and Analysis.

5.9.1 Auto Mode

Mode description: print according to preset printing mode, change leads automatically, printout with measurement value and analysis report.

Operation: press Mode key to choose Auto mode.

Press RUN/STOP key to start printing and press RUN/STOP twice to stop. After printing, the examinee ID will automatically add 1, while examinee name and age will be cleared.

Tips: printing mode can't be changed during printing.

5.9.2 Man Mode

Mode description: print according to preset printing mode, change leads manually, printout without measurement value and analysis report.

Operation: press Mode key to choose Manual mode.

Press LEAD key, then move the cursor to the left or right to choose the expected lead. Press RUN/STOP key to start printing. During printing, press LEAD key to change lead, or 1mV key to calibrate. Press RUN/STOP key to stop printing.

5.9.3 Analysis Mode

Operation: press mode key to choose Analysis mode.

Press RUN/STOP key and the ECG will start sampling for 1 minute, and then print out the compressed waveform of the lead from "Rhythm Lead 1" in "Lead Sequence" menu with analysis report and R-R histogram. During sampling, press RUN/STOP or Enter key to stop sampling.

5.10 ECG case

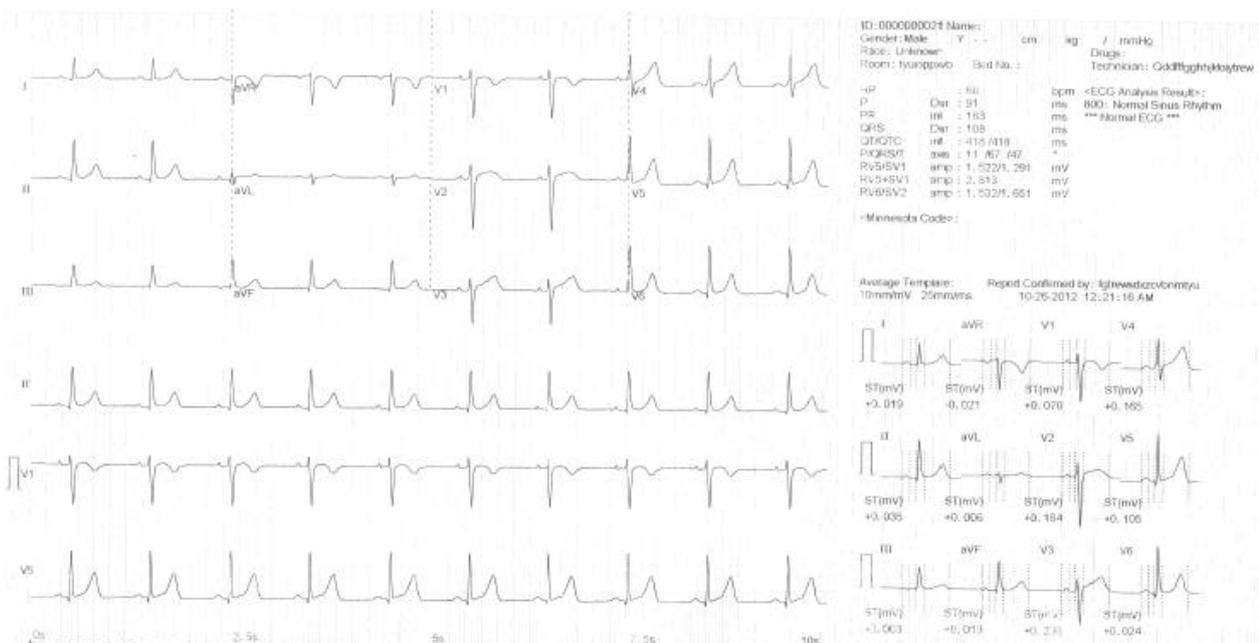


Figure 5-22

As shown in Figure 5-22, content of QRS-12' s report includes: Sensitivity (10mm/mV), HR, filter(AC/50Hz, EMG, ADS), calibration signal (1mV), lead, ECG waveforms, speed (25mm/s), clinic information of patient, date, time, software version, waveform template, measurement data and analysis results.

Chapter 6 Hint Information

Any hint information may appear during operation of QRS-12 such as “Lead-off”, “No Paper”, “No

Alarm Information	Causes
	Electrodes fall off from the patient or the patient cable falls off from the unit.
No Paper	Record paper has not been loaded or it has been used out.
	Low battery.

battery” is listed in Table 6-1.

Table 6-1

Chapter 7 Declaration of Auto Measurement & Analysis

Report

Under Auto mode, after 10 seconds' recording, following parameters will be automatically recognized and measured by QRS-12(Class M):

HR, PR In., QRS In., QT/QTc In., P/QRS/T Axis, RV1/SV5 Amp., RV5/SV1 Amp..

Please pay attention to following factors as regard to automatic measurement.

- ◆ Possible misreading of P/Q/T waveform and ST segment caused by severe baseline drift
- ◆ Possible error of measurement result due to undefined start/stop position of P/T waveform
- ◆ Heart rate measurement value differs each time when R waveform is not detected due to low voltage.
- ◆ Calculation of electrical axis of heart or definition of QRS waveforms maybe unreliable due to low voltage
- ◆ Difficult definition of P waveform caused by multi-arrhythmia may cause the related parameters unreliable.
- ◆ ECG machine only analyzes the waveforms it has acquired, not reflecting all-round status of the patient. This may cause discrepancy with doctor' s diagnosis. Final diagnosis conclusion can be only made after general evaluation of the analysis report produced by the ECG, patient clinical symptom and other clinical laboratory reports.
- ◆ The analysis report produced by QRS-12(Class M) can be ONLY applied for the doctor' s clinical reference. It CAN' T be used as final evidence for diagnosis conclusion. Otherwise the company takes no legal liability for any medical treatment dispute thus caused.

Chapter 8 Cleaning, Care and Maintenance

8.1 Cleaning

⚠NOTE⚠:

- ◆ Turn off the ECG and plug off the AC power supply cable, patient cable before cleaning and disinfection.

8.1.1 Cleaning the Main Unit and Patient Cable

The surface of the main unit and patient cable can be wiped with a clean soft cloth damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

8.1.2 Cleaning the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. Take the suction bulb and mental cup of chest electrodes apart, and take the clamp and the metal part of the limb electrodes apart. Clean them in warm water and be sure there is no remainder gel. Dry the electrodes with a clean dry cloth or air dry naturally.

8.1.3 Cleaning the Print Head

Dirty and soiled thermal print head can deteriorate the record definition. Clean the print head at least once a month regularly.

Open the recorder casing and remove the paper. Wipe the print head gently with a clean soft cloth damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the recording paper and shut the casing of the recorder.

⚠NOTE⚠:

- ◆ Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.
- ◆ Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- ◆ Be sure no cleanser remains on the unit, patient cable or electrodes.

8.2 Disinfection

To avoid permanent damage to the ECG, disinfection can be performed only when it has been considered as necessary according to your hospital' s regulations.

Before disinfection clean the equipment first. Then wipe the surface of the ECG and patient cable with hospital standard disinfectant.

⚠NOTE⚠:

- ◆ Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

8.3 Sterilization

To avoid permanent damage to the ECG, sterilization can be performed only when it has been considered as necessary according to your hospital's regulations. The equipment should be cleaned before sterilization.

! NOTE !:

- ◆ Sterilization, if required, can not be done with high temperature, autoclaving or radiation.

! NOTE !:

- ◆ Infinium Medical Inc. will not bear the responsibility for the effectiveness of infectious diseases control measure by using the disinfectant or sterilization process. It would be better to consult epidemic experts for advices.

8.4 Care and Maintenance

8.4.1 Recharge and Replacement of Battery

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol in the screen.

■: Full capacity

▣: Not full but enough

◻: Capacity is limited, and recharge should be taken into account

□: Battery is weak; and warning message will be displayed on LCD screen. The battery should be recharged immediately

2) Recharge

Infinium Medical Inc. ECG is equipped with recharge control circuit together with built-in rechargeable lithium battery. When connect with the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp (→□) will flicker and the mains supply indicator lamp (∞) will be lit. When the capacity of battery is full, the battery recharge indicator lamp (→□) will be lit all the time.

Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at the first time. Battery recharge should be considered before first usage.

3) Replacement

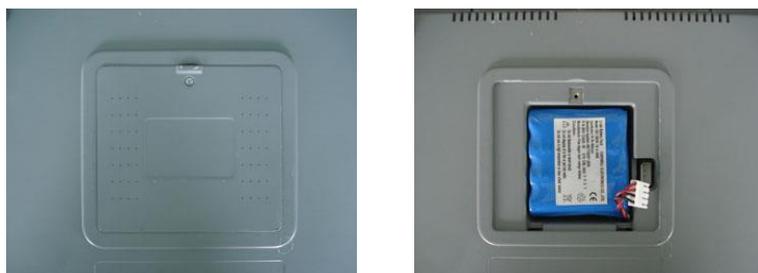


Figure 8-1 Battery Installation

!NOTE!

- ◆ The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the ECG machine, if built-in rechargeable battery is to be used, connect the battery to the socket first. See Figure 8-1 for installation:
 - 1) Open the battery compartment cover with the screw-driver attached;
 - 2) Insert the battery into the battery pack, properly connected;
 - 3) Close the battery cover.

When the useful life of battery is over, or foul smell and leakage has been found, please contact with manufacturer or local distributor for replacement of battery.

!WARNING!

- ◆ Inappropriate operation may lead battery to be hot, ignited, exploded, damaged or capacity fade. Before using the rechargeable Ni-MH battery, read the *Operation Manual* carefully.
- ◆ Only qualified service engineer authorized by Infinium Medical Inc. can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.
- ◆ **Danger of explosion** - Do not reverse the anode and cathode when connecting the battery.
- ◆ When the battery' s useful life is over, contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

8.4.2 Recording Paper

!NOTE!

- ◆ Recording paper provided by manufacturer should be used. Other paper may shorten thermal print head' s life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper etc.

Storage Requirements:

- Record paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the paper under fluorescence for long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not overlap the recorded paper long time. Otherwise the ECG record may trans-print each other.

8.4.3 Main Unit, Patient Cable & Electrodes

1) Main Unit

- a. Avoid excessive temperature, sunshine, humidity or dirt.
- b. Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.

- c. Prevent any liquid from seeping into the ECG, as it will affect the safety and performance of the ECG.

2) Patient Cable

- a. Integrity of patient cable, including main cable and lead wires, should be checked regularly. Be sure that it is conductible.
- b. Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connect or disconnect the patient cable.
- c. Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- d. Store the lead wires in bigger wheel to prevent any people from stumbling.
- e. Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- a. Electrodes must be cleansed after use and be sure there is no remainder gel on them.
- b. Keep the suction bulb of chest electrode from sunshine and excessive temperature.
- c. After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. In this case, electrodes should be replaced to achieve high-quality ECG.

⚠NOTE⚠:

- ◆ The ECG and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.

Chapter 9 Common Troubleshooting and Solution

1) Some Lead without Waveform Printout

Possible reason: Normally the ECG needs some seconds to detect the patient cable while it is connected with the patient.

Solution: repeat operation.

2) Vertical Broken Track of Printed Waveform

Possible reason: This may be caused by dirt on the printer head.

Solution: clean the printer head.

If the problem still exists, there may be damage of the printer head. Please contact with our service department or appointed maintenance center.

3) Failure to turn on the ECG

Possible reason: Fuses burnt

Solution: Unscrew the fuse holder and install the fuses enclosed.

Warning :

- ◆ AC power cable must be plugged out from AC power source when replacing the fuse to avoid any possible electric shock.

4) Failure to turn off the ECG

Possible reason: menu or Sub-menu not exits

Solution: exit the menu

5) AC Interference (as shown in Figure 9-1)



Figure 9-1

Possible reason:

- Equipment is not properly grounded;
- Electrode or patient cable is correctly connected;
- There is not enough cream applied;
- Patient bed is not properly grounded;
- Patient bed is not properly grounded;
- Patient touches metal part of the patient bed;
- Somebody is touching the patient;
- There is a powerful equipment operating nearby;
- The patient is wearing glass or diamond ornaments;

j. AC power frequency.

Solution:

- Ground the equipment properly;
- Connect the electrode and patient cable correctly;
- Apply enough cream;
- Ground the patient bed properly;
- Ask the patient not touch the metal part of the patient bed;
- Don't touch the patient;
- Wait till the powerful equipment stops;
- Remove the glass or diamond ornaments from the patient;
- Reset AC frequency accordingly to local AC frequency.

If interference still exists, please apply HUM filter. The waveform will be weakened a little.

6) EMG Interference (as shown in Figure 9-2)



Figure 9-2

Possible reason:

- a. The room is uncomfortable;
- b. The patient is nervous;
- c. The bed is too narrow;
- d. The patient is talking;
- e. The limb electrodes are tightly attached.

Solution:

- Move to a comfortable room;
- Ask the patient to be relaxed;
- Change a wider patient bed;
- Don't talk with the patient during operating;
- Change the limb electrode if it is too tight.

If interference still exists, please apply EMG filter. The waveform will be weakened a little.

Chapter 10 Service Warranty

1) Workmanship and Raw Material

Infinium Medical Inc. warrant there' s no defect in raw material and workmanship. During warranty period, Infinium Medical Inc. will repair or replace the defective part free of charge if the defect has been confirmed as raw material or workmanship defect.

2) Software or Firmware

For the software or firmware installed, Infinium Medical Inc. will replace them free of charge if the defect has been confirmed as raw material or workmanship defect within 18 months from the date of shipment. But Infinium Medical Inc. can not warrant it will not interrupt the use of the ECG.

⚠NOTE⚠:

- ◆ All services must be finished by engineers authorized by Infinium Medical Inc. or its authorized distributor.

3) Exemption of Warranty

The charges of freight and others are excluded under warranty.

The warranty is void in the case of:

- 4 Assembly, extensions, readjustments of any parts;
- 5 Modification and repair by unauthorized personnel;
- 6 Subsequent damage caused by improper use or maintenance;
- 7 Replacement or remove of serial number label and manufacturer label.

Service Information

Service Unit: Infinium Medical Inc. Electronics, Co., Ltd.

If there is any question, please contact us immediately.

Service Contact

Infinium Medical
12151 62ns st N
Largo FL USA
1-727-531-8434 fax 1-727-531-8436
e-mail: sales@infiniummedical.com

website: www.infiniummedical.com

Chapter 11 Accessories

⚠️ WARNING ⚠️:

- ◆ Only patient cable and other accessories supplied by the manufacturer can be used. Otherwise the performance and electric shock protection can not be guaranteed.

No.	Accessory	Quantity
1	Power cord	1
2	Patient cable	1
3	Chest electrodes	6 pcs
4	Limb electrodes	4 pcs
5	Paper roller	1
6	Thermal sensitive paper	1
7	Ground lead	1
8	Fuse	2 pcs
9	Small flat-head screwdriver	1
10	Dust Cover	1
11	Touch pen	1

Table 11-1 Accessories List

Appendix I Technical Specifications

Safety Standards	MDD93/42/EEC	Medical Device Directive
	IEC 60601-1: 1988 +A1:1991+A2: 1995	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-2-25:1993 + A1:1999	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs; Amendment 1
	IEC 60601-1-2: 2007	Medical electrical equipment Part 1: General requirements for safety -2 Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN 60601-1-4 :1996/A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
	EN ISO14971-2009	Medical devices - Application of risk management to medical devices
	YY1139:2000	Single and multichannel electrocardiograph

Classification	Anti-electric-shock type:	Class I with internal power supply
	Anti-electric-shock degree:	Type CF with defibrillator protection
	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
	Working Mode:	Continuous operation
	EMC:	Group I , Class B

Dimensions	338mm×280mm×85mm
Net Weight	3.5kgs
Display	7.0 inches 800×480 color LCD (touch screen)

Appendix I Technical Specifications

Environment		Transport	Storage	Operation
	Temperature	-20°C~+55°C	-10°C~+40°C	+5°C~+40°C
	Relative Humidity	25%~95%	25%~85%	25%~85%
	Atmospheric Pressure	700hPa~1060hPa	700hPa~1060hPa	700hPa~1060hPa

Power Supply	Mains Supply	Rated voltage=100V~240V
		Rated frequency = 50/60Hz
		Rated input power = 75VA
	External DC power supply	Rated output voltage=19V
		Rated output current=3.5A
	Built-in rechargeable Battery Pack	Rated voltage = 14.4V
		Discharge cut - off voltage≥11V
		Rated capacity = 4400mAh
		Charge mode: Constant current/voltage
		Charge current (standard) < 0.3C5A(1320mA)
		Charge voltage (standard) = (16.8±0.1V)
		Cycle life ≥500 times
	Fuse	T2A/AC 250V Ø5×20

Recorder	Record Mode	Thermal dot-matrix printer
	Recording Paper	Rolled thermal sensitive paper
	Paper Width	Rolled paper: 210/216 mm
	Effective width	Rolled paper: 200/206mm
	Paper Speed	5 mm/s, 6.25 mm/s, 10mm/s, 12.5 mm/s, 25mm/s, 50mm/s(±3%)

HR Recognition	Technique	Peak-peak detection
	HR Range	30BPM~250BPM
	Accuracy	±1BPM

Appendix I Technical Specifications

External Input/Output (Optional)	Input (Single ended)	Input impedance $\geq 100k \Omega$; Sensitivity 10mm/V $\pm 5\%$;
	Output (Single ended)	Output impedance $\leq 100 \Omega$; Sensitivity 1V/mV $\pm 5\%$;
Communication Interface	RS232 serial port/USB/LAN	

ECG Unit	Leads:	12 standard leads, lead change, manually/automatically
	Acquisition Mode:	12 lead acquisition simultaneously
	Input Circuit	Floating, protection against defibrillator effect
	A/D switch:	24 bit
	Time Constant:	$\geq 3.2s$
	Frequency Response	0.05Hz ~ 165Hz
	Sensitivity	Auto, 2.5, 5, 10, 20,40 (mm/mV) $\pm 5 \%$
	Input Impedance	$> 50M \Omega$ (10Hz)
	Input Circuit Current	$\leq 50nA$
	Input Voltage Range	± 5 mVpp
	Calibration Voltage	1mV $\pm 2\%$
	Depolarization Voltage	$\pm 700m V$
	Noise	$< 15 \mu Vp-p$
	Filter	EMG Filter: 25/35/45Hz
		ADS Filter: Yes/No
HUM Filter: Yes/No		
CMRR	$\geq 120dB$	
Patient Leakage Current:	$< 10 \mu A$ (a.c.)	
Dielectric Strength:	4000V rms	

Appendix II EMC Information

Guidance and manufacturer' s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer' s declaration – electromagnetic emission		
2	QRS-12is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group I	QRS-12electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

**Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS**

Guidance and manufacturer' s declaration – electromagnetic immunity			
QRS-12is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the ECG be powered on from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

**Guidance and manufacturer' s declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING**

Guidance and manufacturer' s declaration – electromagnetic immunity

QRS-12 is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the ECG including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ <p align="right">80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p align="right">800 MHz to 2,5 GHz</p> <p>where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range (b).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the QRS-12 ECG is used exceeds the applicable RF compliance level above, the ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECG.

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

**Recommended separation distances between portable and mobile
RF communications equipment and the EQUIPMENT or SYSTEM -
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the QRS-12ECG			
QRS-12is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and as recommended below, according to the maximum output power of the communications equipment			
	Separation distance according to frequency of transmitter m		
Rated maximum output of transmitter W	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix III Environmental Statement

1. Identification

The mark for control of pollution caused by electronic information products in this diagnosis system is as the following picture shows:



The number "50" in the mark is environmental protection use period ("EPUP"), of which the unit is year. It means the environmental protection use period ("EPUP") is fifty years from its production. The mark gives the following information: the hazardous substances will not leak or mutate under the normal conditions of use and the use of the product will not cause serious pollution to the environment or serious damage to their personal and property, when the product is used in the environment-friendly use period.

2. Infinium Medical Inc. provides the following table which applies to all parts of its products.

Hazardous Substances Table						
Parts of Product	Hazardous Substances					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr(VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Built-in Breadboard	○	○	○	○	○	○
Built-in Connector	○	○	○	○	○	○
Sheet Metal	×	○	○	○	○	○
Outer Casing	○	○	○	○	○	○
Display Block	×	○	○	○	○	○
Packing Material	×	○	○	○	○	○
Accessories	×	○	○	○	○	○

"O" indicates that this hazardous substance, for the corresponding part of these products, is below the limit requirement in SJ/T 11363-2006.

"X" indicates that this hazardous substance contained in at least one of the corresponding part of these products, is above the limit requirement in SJ/T 11363-2006.

