

Manual



Digital 12CH ECG



Digital 12-channel Electrocardiograph

Operation Manual

Medguard Professional Healthcare

Tel: +353 (0) 1 835 2411

Email: sales@medguard.ie

Fax: 01 969 5009

Website: www.medguard.ie

Unit 6/7, Block 4, Ashbourne Business Park, Ashbourne, Co. Meath, A84 VK52

For your attention

Dear customer,

Thank you for choosing our product.

It's our great honor that you've chosen our product. In order that you can get general and concrete information on operation, installation and troubleshooting of our product, we've released this manual. It is strongly recommended that you read through this manual prior to operating the product to avoid any damage or loss caused by incorrect operation which the company will not be responsible for.

We've tried our best to avoid any man-made mistakes before releasing this manual. However please excuse any mistake in the content of the manual or faults during printing, assembling or recycling.

We may make some minor adjustments to the hardware or software of our product to improve its performance and reliability. Maybe there are some discrepancies between descriptions in this manual and the product you receive. This won't affect your operation of the product. Please be aware of this.

In order that you can get our complete after-sales service, please register your product as soon as possible.

Thank you for your kind cooperation.

Manufacturer's statement

Copyright

We make no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and suitability for a particular purpose. We assume no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the provision, performance or use of this material.

No part of this document can be photocopied, reproduced or translated to another language without our prior written consent.

We will make continuous improvements in features and functions for future release of new equipment without prior notice. We beg your pardon for the inconvenience.

Version

Version: A Release date: November 2013

Responsibility of the manufacturer

We are only 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

Inhalt

| | |
|---|----|
| Chapter 1 Safety Information | 1 |
| 1.1 Safety Information | 1 |
| 1.1.1 Environmental Requirements | 1 |
| 1.1.2 Power Supply | 1 |
| 1.2 Warnings and Notes | 2 |
| 1.2.1 Safety Warnings | 2 |
| 1.2.2 Battery Care Warnings | 3 |
| 1.2.3 General Notes | 3 |
| 1.2.4 Cleaning & Disinfection Notes | 4 |
| 1.2.5 Electromagnetic Compatibility Information | 4 |
| Chapter 2 Introduction | 5 |
| 2.1 Function Features | 5 |
| 2.2 List of Symbols | 6 |
| Chapter 3 General Information | 7 |
| 3.1 Front Panel | 7 |
| 3.1.1 Product Information: | 7 |
| 3.1.2 LCD Screen | 8 |
| 3.1.3 Control Panel and Keys | 9 |
| 3.2 Mains Connection and Switch | 12 |
| 3.3 Patient Cable Socket and Signal Interface | 13 |
| 3.4 Bottom Panel | 15 |
| Chapter 4 Operation Preparations | 18 |
| 4.1 Connecting to AC Power and Grounding | 18 |
| 4.2 Loading Recording Paper | 19 |
| 4.3 Patient Cable Connection | 20 |
| 4.4 Electrode Connection | 20 |
| 4.5 Inspection before Startup | 23 |
| Chapter 5 Operating 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 | 27 |

| | |
|---|----|
| 5.5 Freeze | 29 |
| 5.6 Recall | 29 |
| 5.7 Operating Menu | 29 |
| 5.7.1 Menu | 30 |
| 5.7.2 Set the Printing Parameters | 30 |
| 5.7.3 Set Mode | 33 |
| 5.7.4 Set the FilterParameters | 35 |
| 5.7.5 Lead Sequence | 36 |
| 5.7.6 Display & Sound | 37 |
| 5.7.7 Date & Time | 38 |
| 5.7.8 Set the System Parameters | 39 |
| 5.7.9 Set the Communication | 40 |
| 5.7.10 Set the Advanced Settings | 41 |
| 5.7.11 Institution | 42 |
| 5.7.12 Exit | 42 |
| 5.7.13 Touch Screen calibration | 42 |
| 5.8 How to Use the Battery | 43 |
| 5.9 Operating Mode | 44 |
| 5.9.1 Auto Mode | 44 |
| 5.9.2 Man Mode | 45 |
| 5.9.3 Analysis Mode | 45 |
| 5.10 ECG case | 45 |
| 5.11 ECG Help Information | 45 |
| Chapter 6 Declaration of Auto Measurement & Analysis Report | 47 |
| Chapter 7 Alarm Information | 48 |
| Chapter 8 Cleaning, Care and Maintenance | 49 |
| 8.1 Cleaning | 49 |
| 8.1.1 Cleaning the Main Unit and Patient Cable | 49 |
| 8.1.2 Cleaning the Electrodes | 49 |
| 8.1.3 Cleaning the Print Head | 49 |
| 8.2 Disinfection | 49 |
| 8.3 Sterilization | 49 |
| 8.4 Care and Maintenance | 50 |
| 8.4.1 Recharging and Replacement of Battery | 50 |
| 8.4.2 Recording Paper | 51 |
| 8.4.3 Main Unit, Patient Cable & Electrodes | 51 |

Table of Contents

| | |
|--|----|
| Chapter 9 Common Troubleshooting and Solutions | 53 |
| Chapter 10 Service Warranty | 55 |
| Chapter 11 Accessories | 56 |
| Appendix I Technical Specifications | 57 |
| Appendix II EMC Information | 60 |
| Appendix III Environmental Statement | 64 |

Chapter 1 Safety Information

1.1 Safety Information

KES-121T 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 insulated and defibrillation protected.

KES-121T is not explosion-proof. Do not use it in the presence of flammable anesthetics.

KES-121T 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 class: | Class I with internal power supply |
| Anti-electric-shock type: | CF |
| Degree of protection against harmful water penetration: | Ordinary equipment (Sealed equipment without liquid proof) |
| Disinfection/sterilization method: | Refer to the Operation Manual 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 Environmental Requirements

Table 1-2 indicates environment requirements for transportation, storage and operating conditions of KES-121T.

| | Transportation | 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~1060 hPa | 700hPa~1060 hPa | 700hPa~1060 hPa |

Table 1-2 Environmental Requirements

The transportation conditions must be as stated by the contract. The ECG must be stored where the following requirements are met: the temperature -10°C~+40°C, the relative humidity ≤85%, no corrosive gases and good ventilation.

Be sure that the operating environment is clean, and the ECG is kept away from corrosive materials, high humidity, high temperatures or direct sunlight. Avoid shaking during operation and do not move the equipment when it is switched 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 and avoid possible dangers caused by improper operation, please read through the **Operation Manual** and be sure to familiarize yourself with all functions of the equipment and proper operating procedures before use.

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

1.2.1 Safety Warnings

WARNING :

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

WARNING :

- ◆ **EXPLOSION HAZARD**-Do not use the ECG in the presence of flammable anesthetic mixtures 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 during installation or set-up 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 the patient cable and other accessories supplied by us can be used. Otherwise the performance or electric shock protection cannot 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 electrodes, are not in contact with the ground or any other conducting objects.
- ◆ There is no danger for patients with pacemakers.
- ◆ 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 burn.
- ◆ Only apply the patient cable designated by the manufacturer. Otherwise there might be an electric burn to the patient or damage to 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 are applied while defibrillating.
- ◆ In order to avoid burns, 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 sum of leakage current should never exceed leakage current limits when 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 the potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

 **WARNING** :

- ◆ Improper operation may cause the battery to become hot, ignite or explode, and it may lead to a reduction in the battery's capacity. It is necessary to read the **Operation Manual** carefully and pay particular attention to warning messages.
- ◆ Opening the battery cover, disassembling or replacing the battery should be done according to the **Operation Manual**, and only a 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 the battery around fire or in environments over 60°C. Do not heat or allow liquids to come into contact with the battery. Do not throw it into fire or water.
- ◆ In the event of leakage or a foul smell, stop using the battery immediately. If your skin or clothing comes into contact with any leaked liquid, clean it with clean water at once. If the leaked liquid comes into contact with your eyes, do not rub them. Irrigate them with clean water first and seek medical attention immediately.
- ◆ When the battery's useful life is over or any abnormality regarding the battery is found, stop using it, and contact the manufacturer or local distributor for disposal or disposal of the battery according to local regulations.

1.2.3 General Notes

 **NOTE** :

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

interference.

!NOTE!

- ◆ Check the main unit and its accessories carefully before operating the ECG. It should be replaced if there is any evident defect or signs of aging 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 is used, the power cord should also be disconnected from the outlet. Do not allow detergent to seep into the equipment.
- ◆ Do not immerse the unit or patient cable in liquid under any circumstances.
- ◆ Do not clean the unit and accessories with abrasive materials and avoid scratching the electrodes.
- ◆ Any remaining detergent should be removed from the unit and patient cable after cleaning.
- ◆ Do not use chlorine disinfectant such as chloride and sodium hypochlorite etc.
- ◆ Do not use high temperatures, autoclaving or radiation sterilization processes.

1.2.5 Electromagnetic 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. Adverse electromagnetic interferences should be eliminated 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 systems through the 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 equipment and systems have no direct or indirect electrostatic energy before use. Humid environments 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 contact us or the designated maintenance points.

Chapter 2 Introduction

KES-121T is a digital 12-channel physiological function measurement device which records the heart waveform during electro-biological movement. It provides sufficient information for the analysis of arrhythmia and cardiovascular disease and helps to detect pathological disorders caused by some drugs, electrolytes, or pH imbalances. It is important equipment for cardiac disease investigation, 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!:

- ◆ Patients with 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

KES-121T has the following features:

- 7" high bright TFT screen, real-time display of 12 channel ECG waveforms
- Modern in design, easy to carry
- Light-touch numeric/letter keys for easy and convenient operation
- Touch screen operation
- Simultaneous acquisition of 12 leads 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 physician workload
- Pre-10-second printing function helps the physician to print out any abnormal ECG waveform
- Three kinds of operating 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
- Extended printing function: arrhythmia waveforms can be printed out automatically for 60 seconds in standard 12*1 mode
- Sampling mode: real-time sample, pre-sample, period sample and trigger sample
- It can connect with laser printers, bar code scanners, magnetic card readers
- It has freeze, print preview and waveform recall functions.
- Clinical information: Patient ID, gender, age, height, weight, technician, physician, 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 overload or over voltage
- High resolution thermal dot-matrix printing system which produces clear and accurate printouts of waveforms and characters
- Automatic adjustment of baseline for optimal recording
- Built-in help Function: electrode positioning, ECG basic knowledge, common trouble-shooting etc.

- 180 ECG files can be saved in the ECG, up to 10000 ECG files can be stored in U disk
- Flexible saving interface. Saved ECG files can be displayed in image-text or list format for easy 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 below in Table 2-2.









| | | | |
|---|--|---|--|
|  | External output |  | External input |
|  | Equipment or part of CF type with protection against defibrillator |  | 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 KES-121T

3.1.1 Product Information:

1) Model Series

KES-121T

2) Classification Symbol



Equipment of CF type with protection against defibrillator

3) Open Button

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

4) Hidden handle

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

3.1.2 LCD Screen

The display of the KES-121T is a 7 inch color LCD, 800*480 dpi.

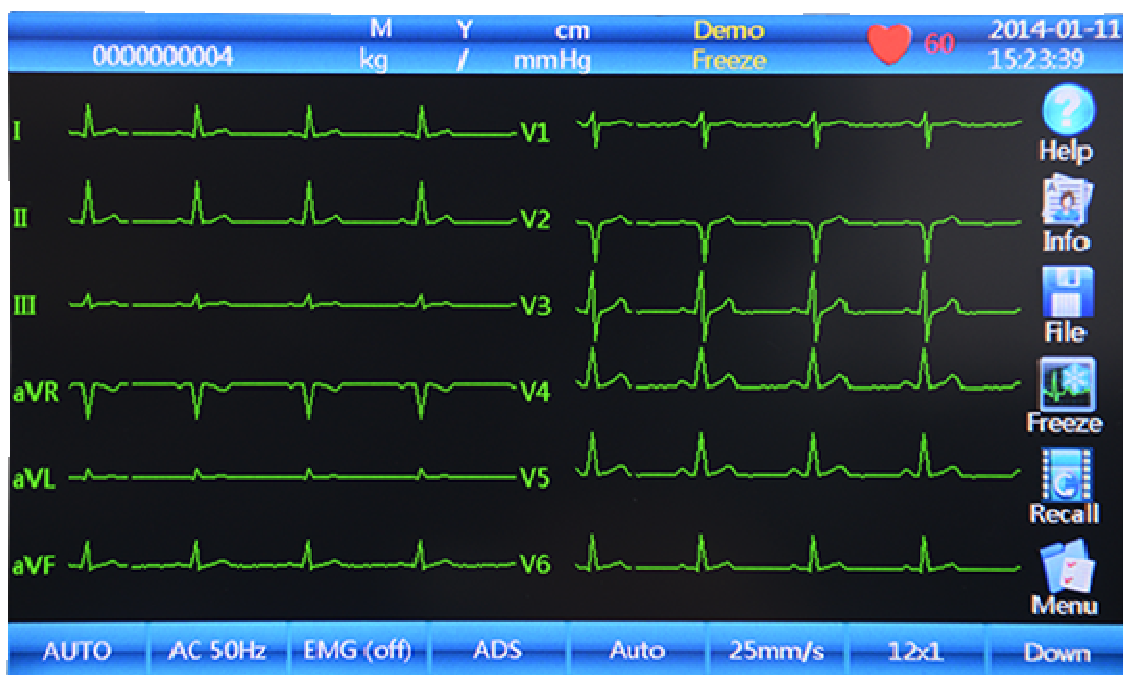



Figure 3-2 LCD Display of KES-121T

Normally, the information displayed in the LCD screen includes (from left to right):

Top Row:

- Name (20 letters or 10 Chinese 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

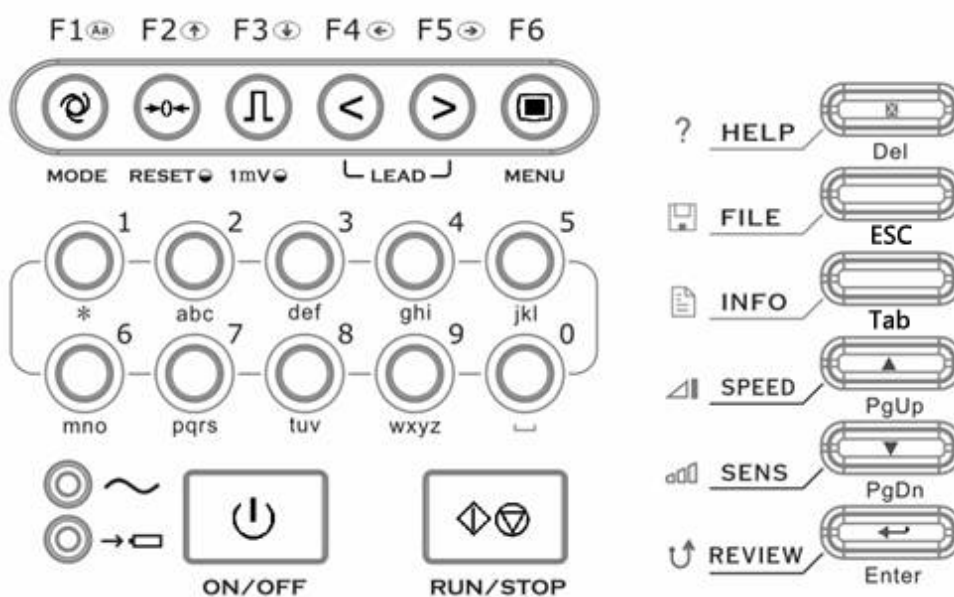



Figure 3-3 Control Panel of KES-121T

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.

2) MODE/F1



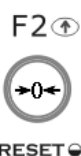
Press this key to switch operating mode between AUTO, MAN, and ANA. The switching order of leads is listed in Table 3-1.

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, press the 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 Basicsubmenu. The Test mode is used by the 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 seconds. The ECG signal will have interference then press **RESET** to reset the signal, if the equipment is connected to a defibrillator.

There is also an up arrow key to be used to select the items and turn pages.

4) 1mV/F3



Under MAN mode, press this key to record a 1mV calibration pulse at any time while recording.

There is also a down arrow key to be used to select items and turn pages.

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



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

There are also left and right arrow keys in the time editing, FILE, INFO interface

6) MENU/F6

F6



MENU

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

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 that the ECG is powered off in main interface.

8) RUN/STOP



RUN/STOP

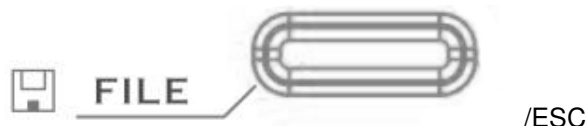
Start or stop recording.

9) HELP/Del





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

10) FILE

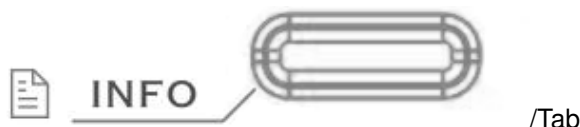


Press this key to enter the "FILE" interface. Press it again to return to the main menu.

In the FILE interface, press   key to delete input information.

When not under the main menu, the key has the same function as "ESC" on the PC keyboard.

11) INFO



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

When not under the main menu, the key has the same function as "Tab" on 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 interfaces, this is the 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 interfaces, this is the PageDown key.

14) Enter

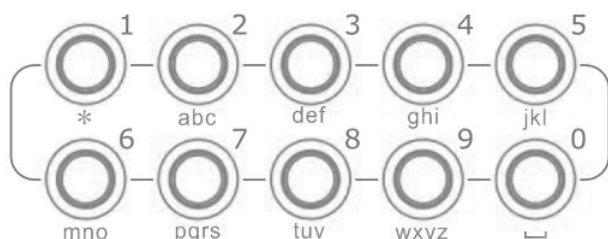


In the main interface, press this key to print pre-10-second ECG data, and press "RUN/STOP" to stop printing;

In the MENU interface, press this key to confirm;

In the FILE interface, press this key to load waveform from the data base;

15) Numeric/letter keys



These keys are numeric symbols.

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

Tips:

1. In the 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 return to the current interface;
Quickly press the MENU, INFO, or FILE key again to return to the main interface;

3.2 Mains Connection and Switch

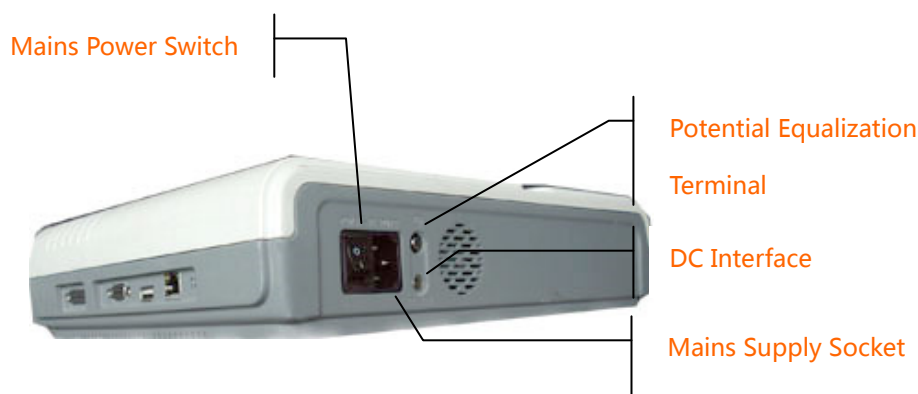


Figure 3-4 Mains Connection and Switch

1) AC PowerSwitch

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 a pipe or the like as a grounding cable, otherwise, the grounding cannot work and there is a potential risk of electric shock to the patient.

4) DC Power Socket

Our ECG can be powered by an external DC power source. When choosing a DC power source, be sure that the output voltage and current meet the equipment requirement and that the interface matches. A vehicle DC power source and the like can be used.

!WARNING!

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

3.3 Patient Cable Socket and Signal Interface

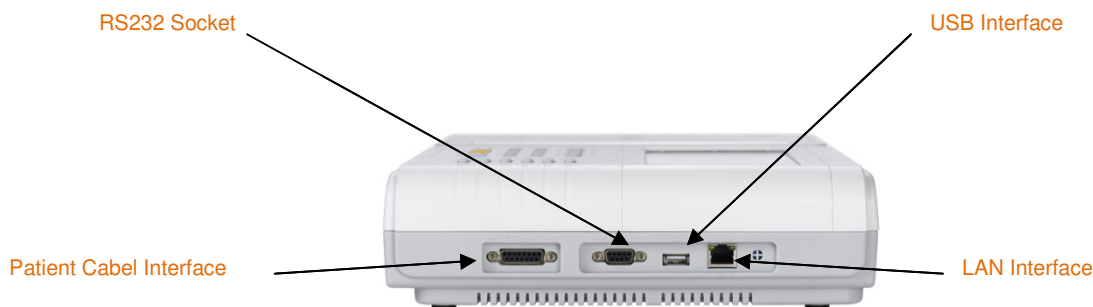


Figure 3-5 Interfaces

⚠ 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 when several other units are used at the same time.

1) Patient Cable Socket

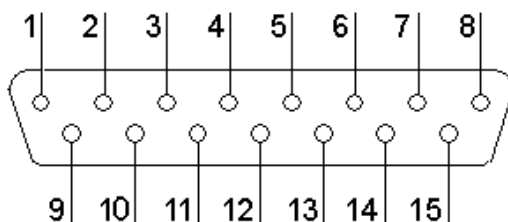


Figure 3-6 Patient Cable Socket

⚡: Applied part of type CF with protection against defibrillator .

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 to the interface cannot exceed +12V.

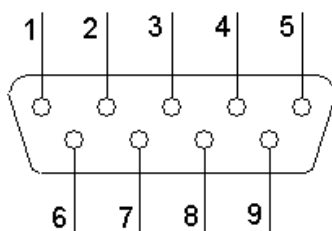


Figure 3-7 RS232 Socket

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 the PC, ECG data can be transferred to the PC via the RS232 interface for display and management.

3) USB Interface

After plugging the USB device into this interface, ECG data can be transferred to a USB flashdrive via the USB interface. Moreover, a laser printer, bar code scanner and magnetic card reader can be plugged in to perform their 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

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

3.4 Bottom Panel

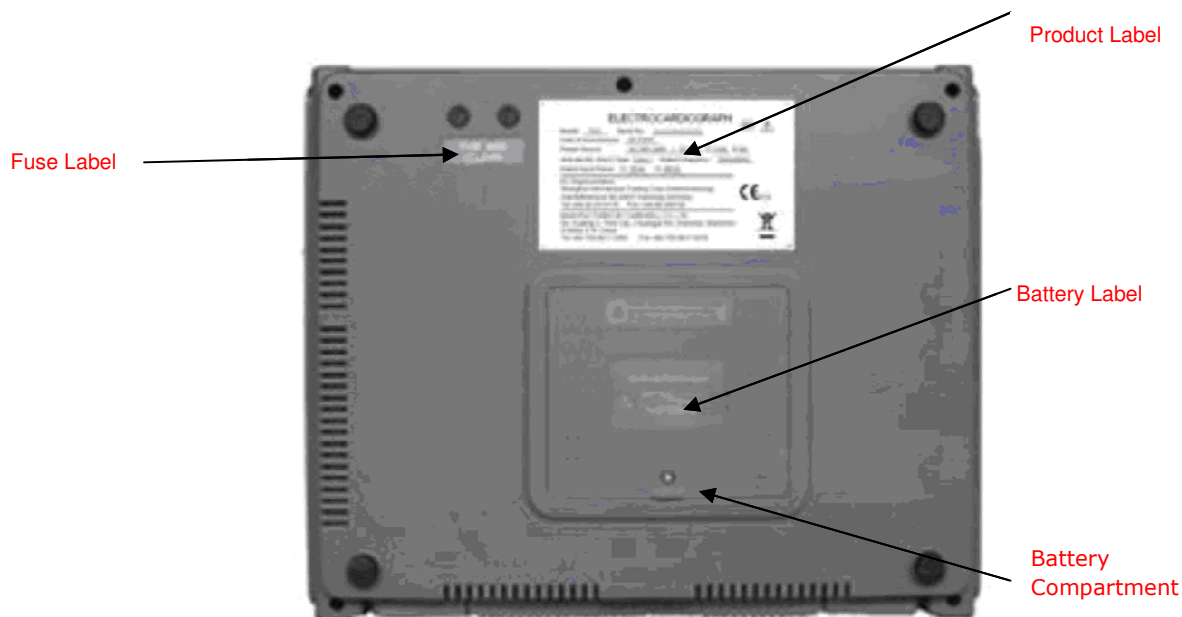


Figure 3-8 Bottom Panel

1) Fuse label

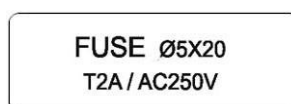


Figure 3-9 Fuse Label

⚠ WARNING ⚠:

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

2) Battery Compartment

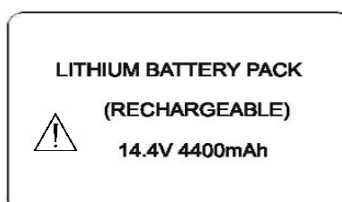


Figure 3-10 Battery Compartment Label

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

⚠ WARNING ⚠:

- ◆ Improper operation may cause the battery to become hot, ignite or explode, and it may lead to a reduction in battery capacity. Therefore, it is necessary to read the Operation Manual carefully and pay particular attention to warning messages.

⚠ WARNING ⚠:

- ◆ If leakage or a foul smell is noted, stop using the battery immediately. If the leaked liquid comes into contact with your skin or clothes, clean it with clean water at once. If the leaked liquid comes into contact with eyes, do not rub them. Irrigate them with clean water first and seek immediate medical attention.

⚠ WARNING ⚠:

- ◆ Opening the battery cover, disassembling or replacing the battery should be done according to the

Operation Manual, and only a battery of same model and specification provided by the manufacturer should be used.

3) Product Label

The label provides information on the product model, S/N, manufacture date, registration no., manufacturer name, etc.

Chapter 4 Operation Preparations

WARNING :

- ◆ Check the main unit and its accessories carefully before operating the ECG. The unit should be replaced if there is any evident defect or sign of aging 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 using a three-phase power cable. Don't open the ECG while it is powered on.

WARNING :

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

The ECG can be powered via AC power supply, DC power supply or the built-in rechargeable lithium battery pack.

1) AC Power Supply

The mains socket is on the upper left-hand 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 switching 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

When the built-in rechargeable battery pack is used, the battery may not be fully charged because of consumption during storage and transport. In this case please charge the battery first. Replace the battery when the battery has been charged over 500 times.

NOTE :

- ◆ The battery is placed 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 **Section 8.4.1** for instructions on recharging the battery. During charging, the ECG can be powered on by AC power supply and continue operating.
- ◆ The battery should be charged at least 8 hours before initial use.
- ◆ The battery's service life is about 500 charges.

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 this equipment with the grounding cable enclosed to protect the patient from electric shock in the event of any possible current leakage from the other equipment.

5) Power on the equipment

Switch on AC power and press the 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 used with the ECG-1112(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.

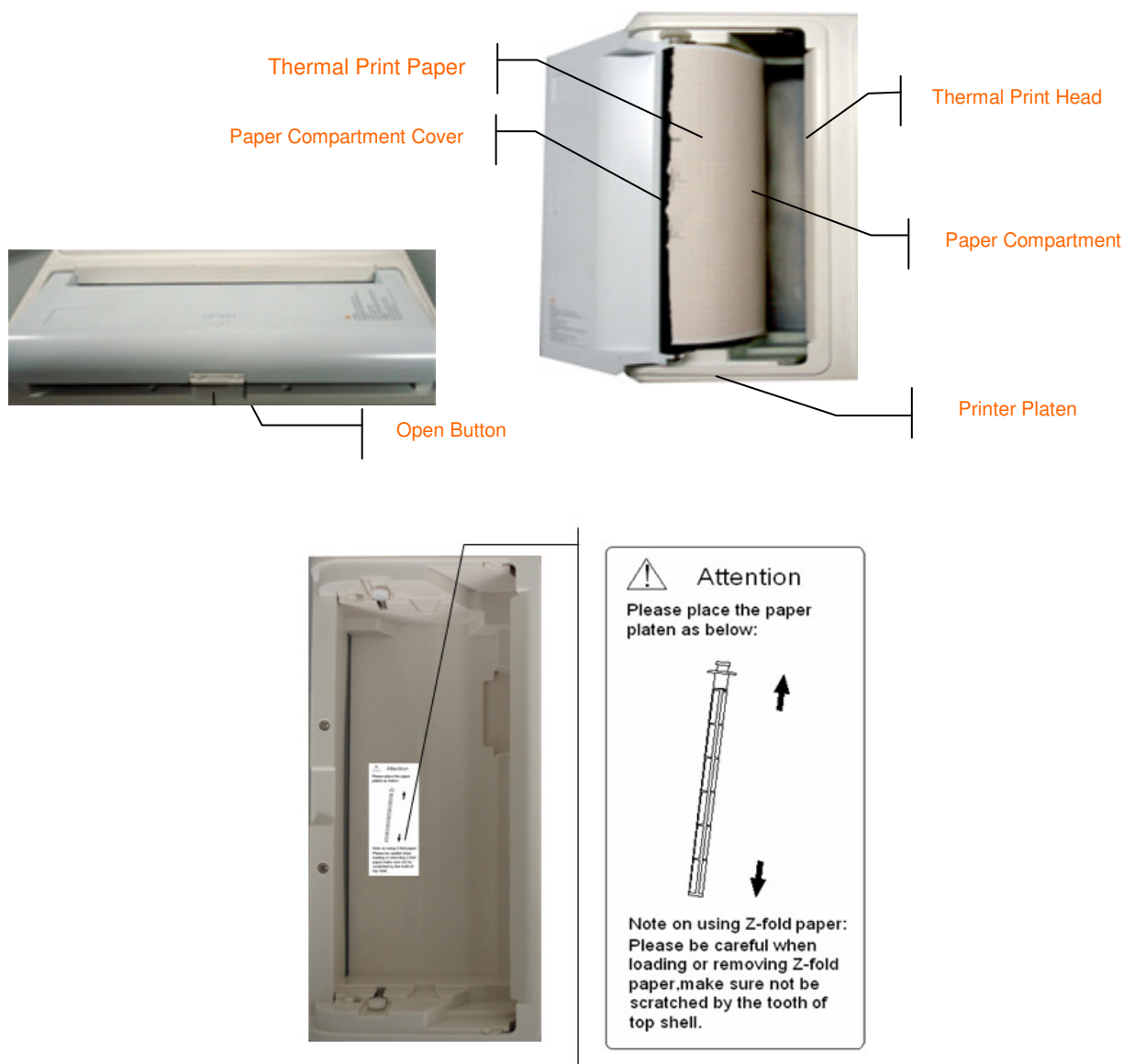


Figure 4-1 Loading Roll Paper

Loading Procedure for 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 of 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 information.

4.3 Patient Cable Connection

The patient cable includes two parts: the main cable and lead wires with associated electrode connectors. The electrode connectors can be distinguished by the color and identifier on them.

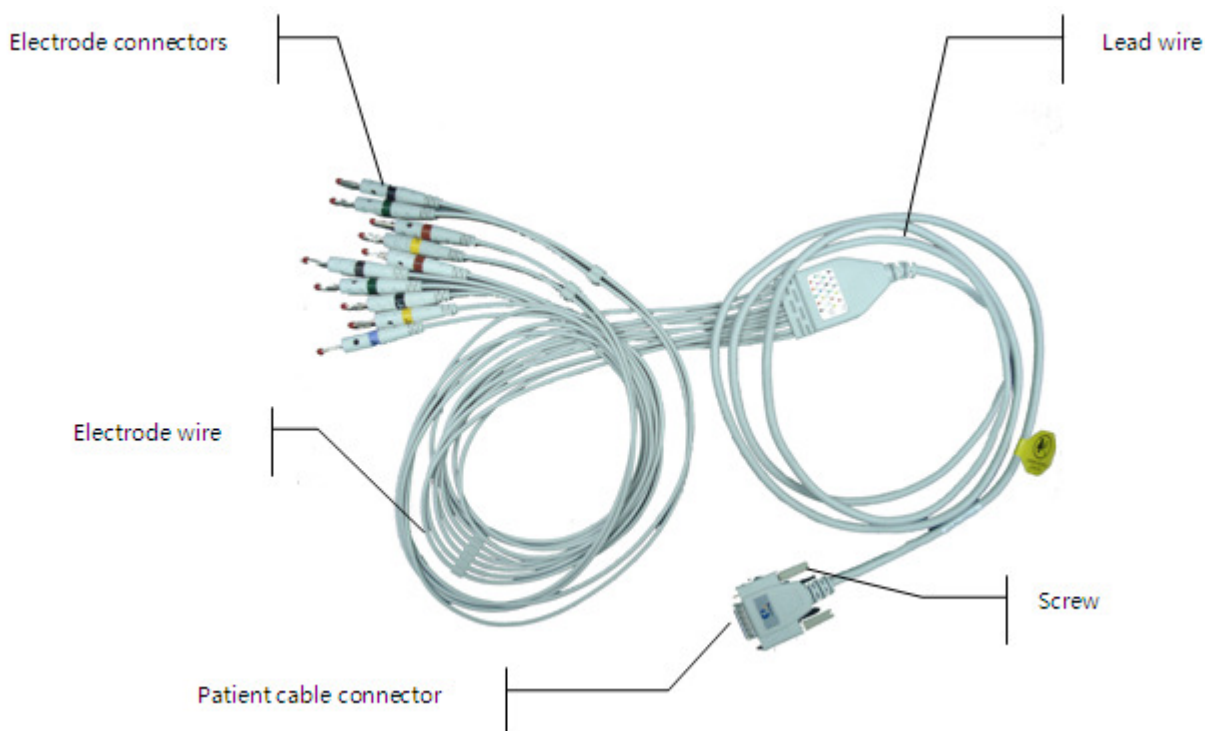


Figure 4-2 Patient Cable

Connect Main Cable: Plug the connector of the 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, remove electrodes before defibrillation, when possible.
- ◆ It is strongly recommended that only our patient cable be used when the ECG is used with high-frequency devices to avoid any possible signal interference.

4.4 Electrode Connection

Chest Electrode:

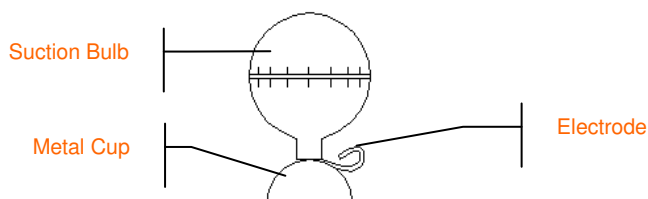


Figure 4-4 Chest Electrode

Limb Electrode:

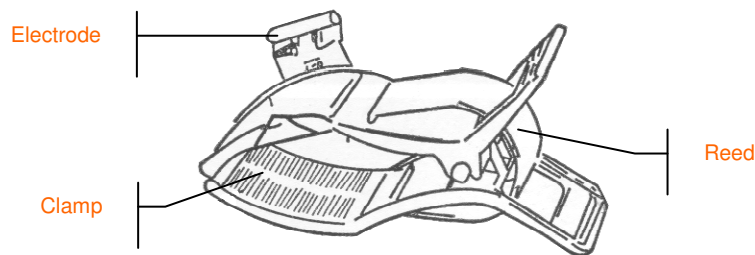


Figure 4-5Limb Electrode

The identifier and color code of the 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 the body surface as shown below.

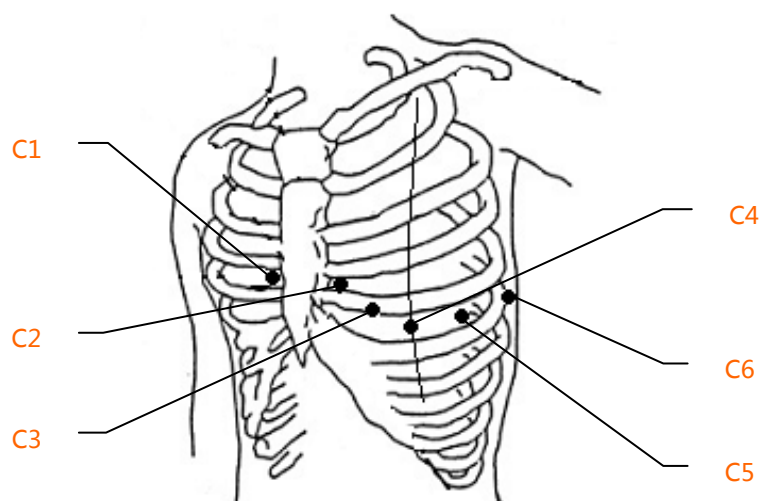


Figure 4-6Chest Electrode Positioning

C1: Fourth intercostal space at right border of sternum

C2: Fourth intercostal space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostal space on left midclavicular line

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

C6: Left midaxillary line at the horizontal level of C4

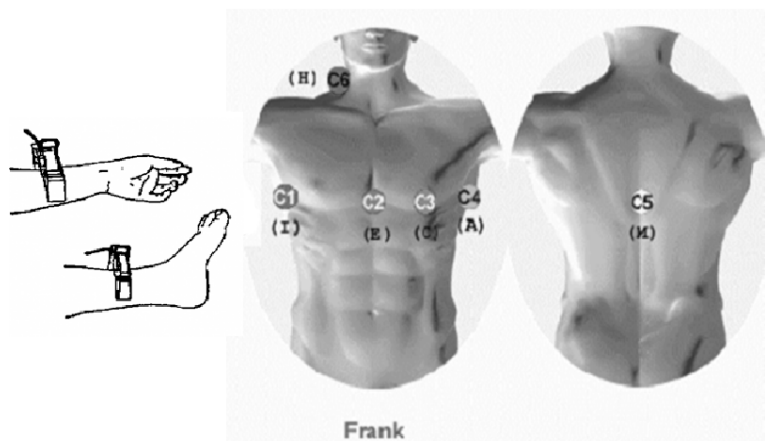
The contact resistance between the patient and the electrode will greatly affect the quality of the ECG waveform. In order to get a high-quality ECG waveform, the skin/electrode resistance must be minimized while connecting electrodes.

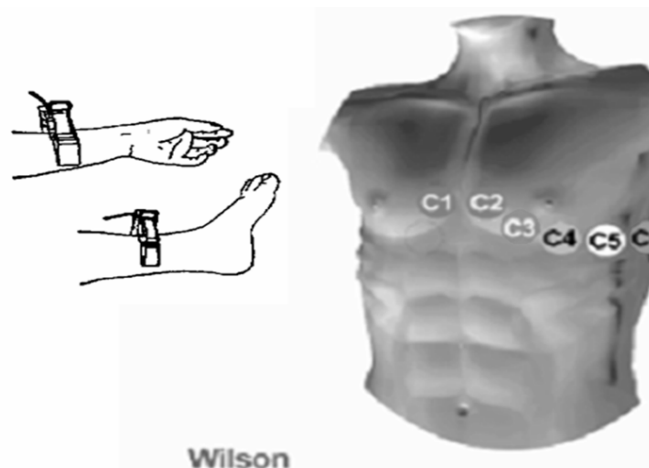
Chest Electrodes Connection:

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, 25mm in diameter, on each electrode site with gel evenly;
5. Place a small amount of gel on the rim 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 adhered to the 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 a short distance above the ankle or wrist with alcohol;
4. Daub the electrode area on the 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 is placed on the electrode area above the ankle or wrist. Attach all limb electrodes in the same way.





⚠️ 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 electrodes, are not in contact with the ground 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 housing during defibrillation.

4.5 Inspection before Startup

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

1) Environment:

- ◆ Check to 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 the ECG signal caused by cold.

2) Power Supply:

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

3) Grounding:

- ◆ Check that the grounding cable is properly connected.

4) Patient Cable:

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

5) Electrodes:

- ◆ Check whether all electrodes have been connected with lead wires of the 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 are not in contact with each other.

6) Recorder Paper:

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

7) Patient:

- ◆ The patient should not be in contact with any conducting object such as the ground and metal parts of the bed etc.
- ◆ Ensure that the patient is warm and relaxed and breathing calmly.

8) AC Filter Frequency

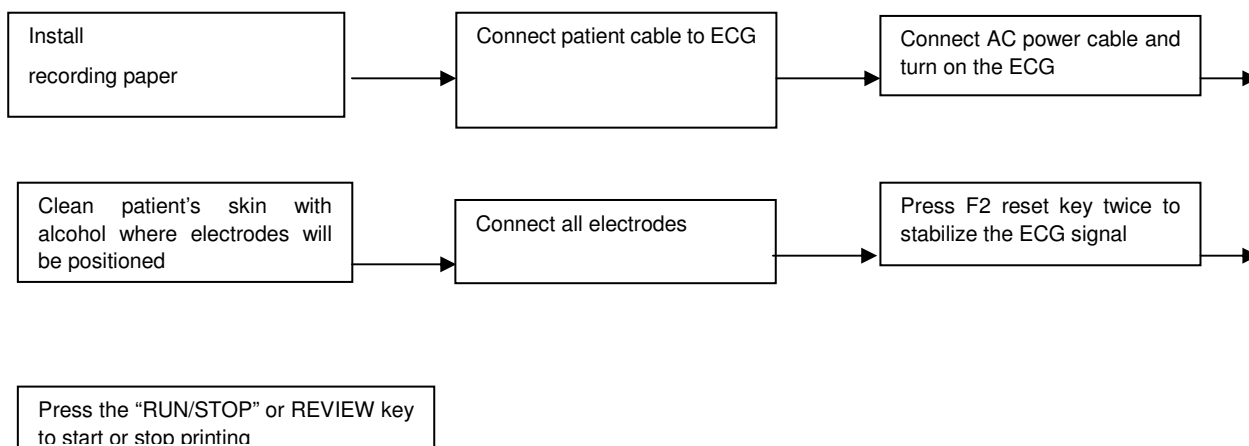
- ◆ Check the setup of AC filter frequency and make sure it complies with the local regulations, or it will impact the anti-jamming effect.

 WARNING :

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

Chapter 5 Operating Instructions

Basic operation procedures




⚠ NOTE ⚠:

- ◆ The battery is put into the battery compartment without connecting to the battery socket at the factory. Upon receipt of the ECG machine, connect the battery to the socket first.
- ◆ Load printing paper with the grid side facing down.
- ◆ Lead wires and electrodes provided by manufacturer should be used.
- ◆ Replace the electrode after cleaning the surface with alcohol, when the lead off alarm sounds.
- ◆ Do not unplug the electrodes 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 (⌚) will be lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Information such as name, manufacturer and version no. etc., will be displayed in the LCD screen after the self-test. Then the ECG is ready for examination and recording.
- When external DC power supply is applied, both indicator lamps will be constantly lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Information such as name, manufacturer and version no. etc., will be displayed in the LCD screen after the self-test. Then the ECG is ready for examination and recording.
- When using a built-in rechargeable lithium battery, press the 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 lit. Equipment information such as name, manufacturer and version no. etc., will be displayed on the LCD screen after the self-test. The ECG is ready for examination and recording.

When the battery symbol switches to “”, 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.

⚠ NOTE ⚠:

- ◆ LCD backlight automatically turns off after 1 minute if there is no activity, and the ECG will be automatically turned off within 3 minutes if there is no activity when the ECG is powered on by battery.

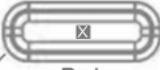

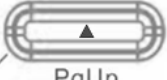
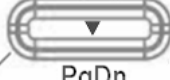
5.1.2 Power OFF

- When the battery is the power supply, hold down the ON/OFF key for 3 seconds to turn off the ECG.
- When AC is the power supply, hold down the ON/OFF key for about three seconds to turn off the ECG, turn off the AC switch, unplug the AC power cable.
- When DC is the power supply, hold down the ON/OFF key for about three seconds to turn off the ECG, then unplug the DC power cable.
- When the battery is the power supply, the backlight will automatically turn off when there is no activity for 30 seconds. If there is no activity for 3 minutes, the ECG will turn off automatically. When AC power is applied, it will enter power-saving mode automatically if there is no activity for 3 minutes.

!NOTE!

- ◆ The ECG can be turned off in any interface. However we recommend turning the ECG off according to normal procedures otherwise the screen will be in confusion when the ECG is powered on next time.

5.2 HELP

Press “**?** **HELP**”  or touch “**Help**”  on the screen and then enter the HELP menu. After that, you’ll see the electrode position diagram, basic information about the ECG, common trouble shooting, etc. Press “**UP**”, “**DOWN**”, “**SPEED**”  and “**SENS**”  to scroll the page. Press “**ESC**” or touch “**X**” to return to main interface. It switches between two languages, i.e. English and Chinese.

5.3 Info

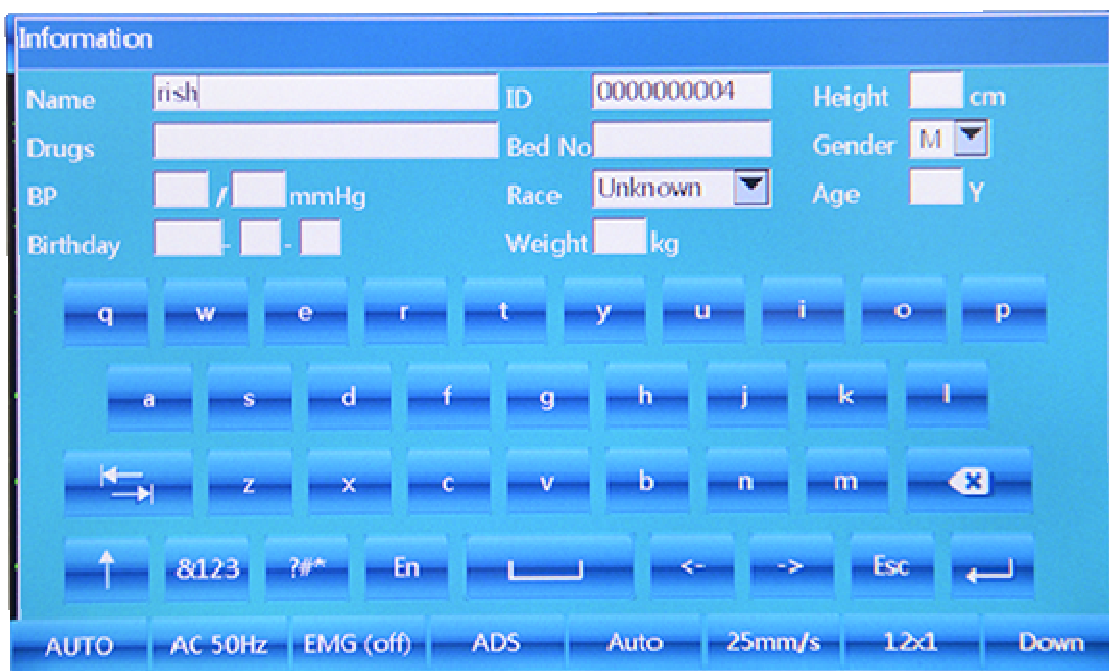


Figure 5-1 Info Interface



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 and press “ESC” key or “X” to return to the main menu as shown in Table 5-1. Press it again to return to the 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 | | |

- ◆ 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

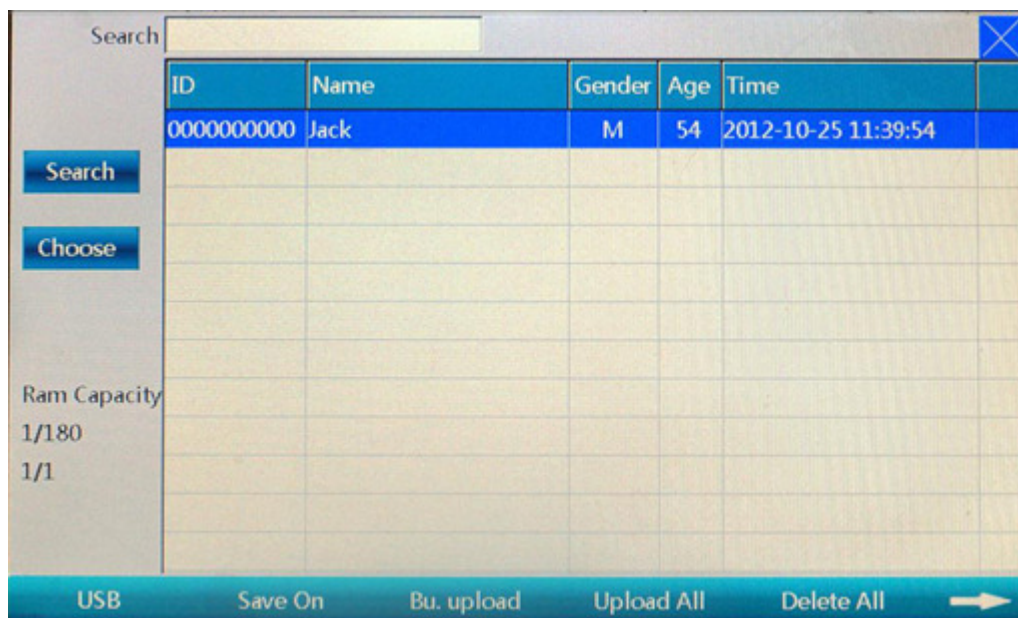


Figure 5-2 Storage 1

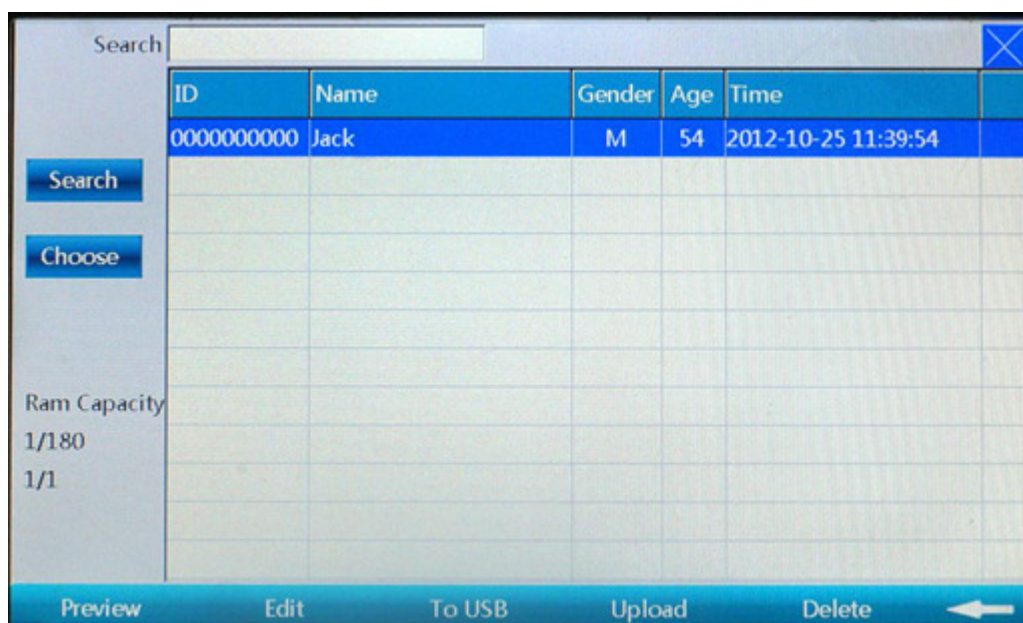



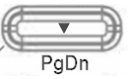


Figure 5-3 Storage 2


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  **SPEED**  and  **SENS**  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, touch this key, it can freeze the waveforms; touch 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.

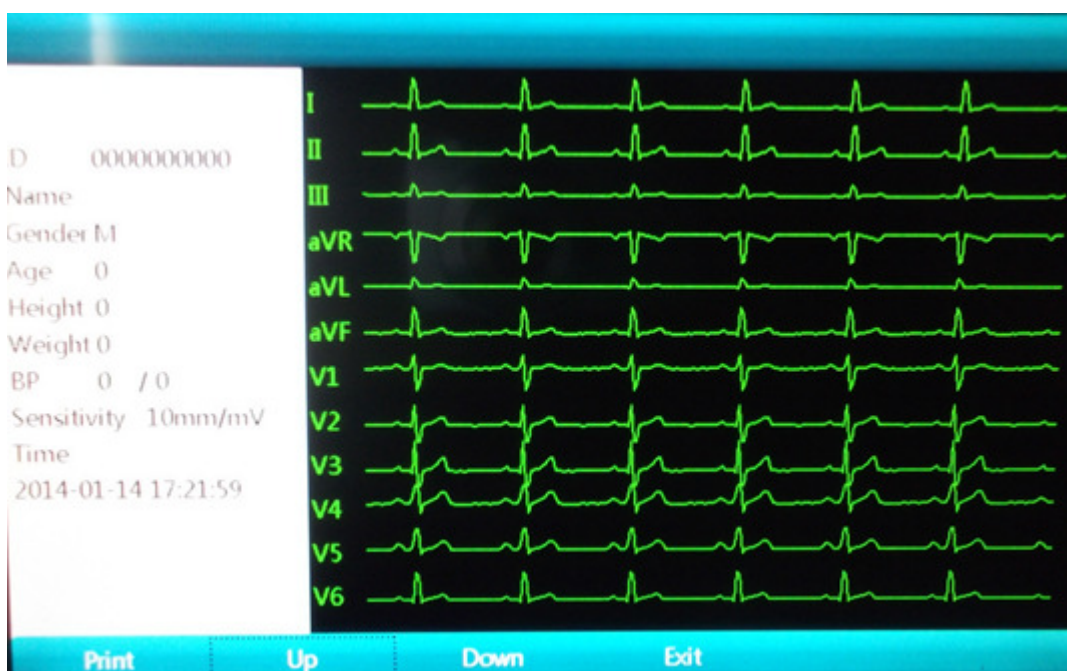


Figure 5-4 Recall Interface

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 Operating Menu



5.7.1 Menu



Figure 5-5 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”  “▲ SENS”  and “Tab” key to choose the sub-menu to be changed and press the **Enter** key to confirm. You can also touch the screen to finish the operation.

5.7.2 Set the Printing Parameters

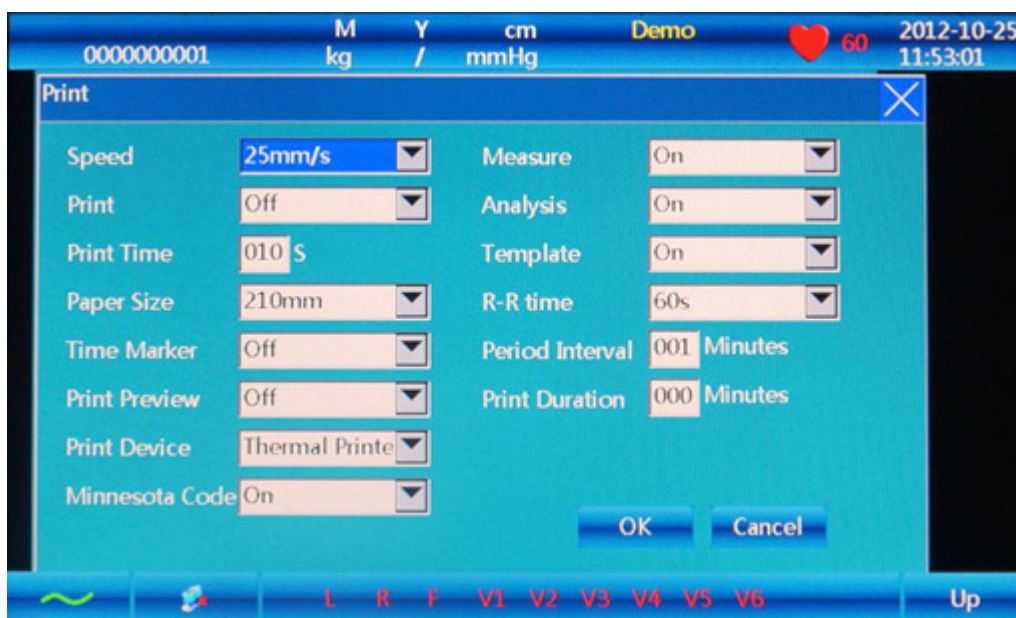


Figure 5-6 Print Setting Interface

1. Choose the **PrintSetting** after entering the menu, and press the **ESC** key to exit.
2. The print setting includes following items: Paper Speed, Acquisition Mode, Auto Print Mode, Man. Print Mode and so on. Press the **Menu** or **Enter** key to select the chosen item, press



“ SPEED” (PgUp), “ SENS” (PgDn) key to select side to side, and press **Tab** to select from top to bottom. Press the **ESC** key to exit and **Confirm or 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

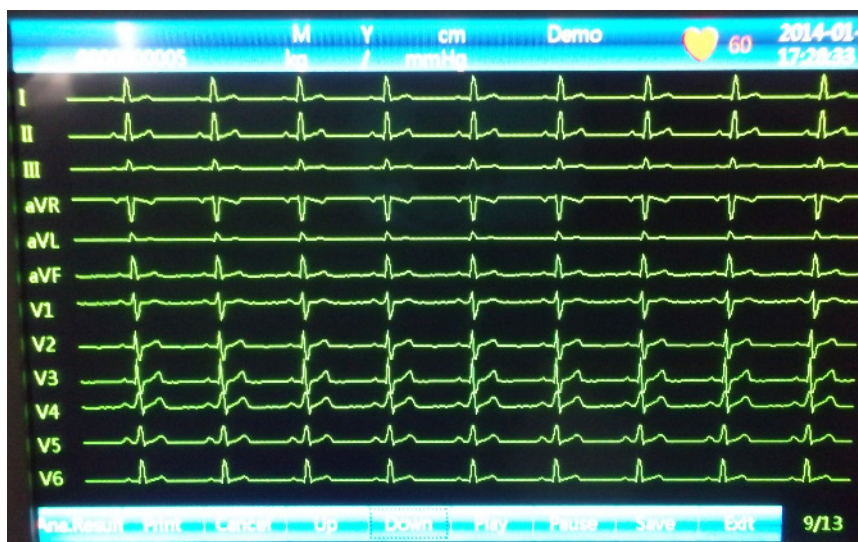


Figure 5-7 Preview

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

From left to right: "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. Touch "Waveform", "Print", "Cancel" and "Exit" to complete 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 have been played.
- ◆ Pause: touch "Pause" to stop waveform replay.
- ◆ Save: analyze and save the current sampling 10s ECG waveforms. The ECG files will be read from the "FILE" interface only when 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

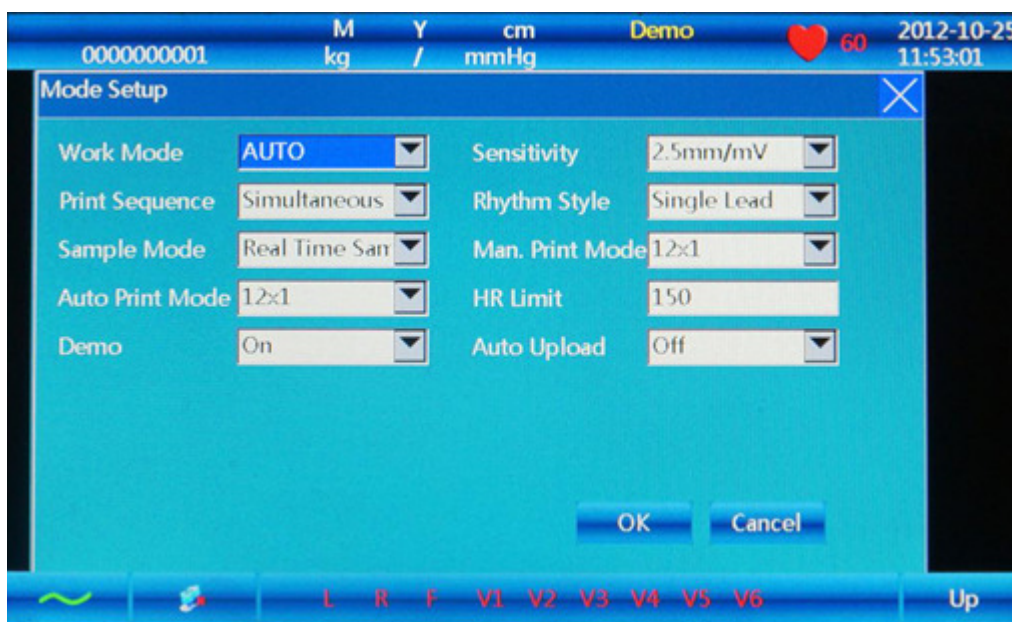


Figure 5-8 Work Mode

| 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 |
| 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: Sequence, Synchronous

3. Acquisition Mode:

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

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

Period Sample: First 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, then 2 minutes after that, it will start the second printing. It will continue until it reaches the periodic continuous time.

Trigger Sample: After choosing trigger acquisition mode, if asystole, ventricular fibrillation, ventricular tachycardia, RonT, missed beats and multiple ventricular premature beats occur, 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 FilterParameters

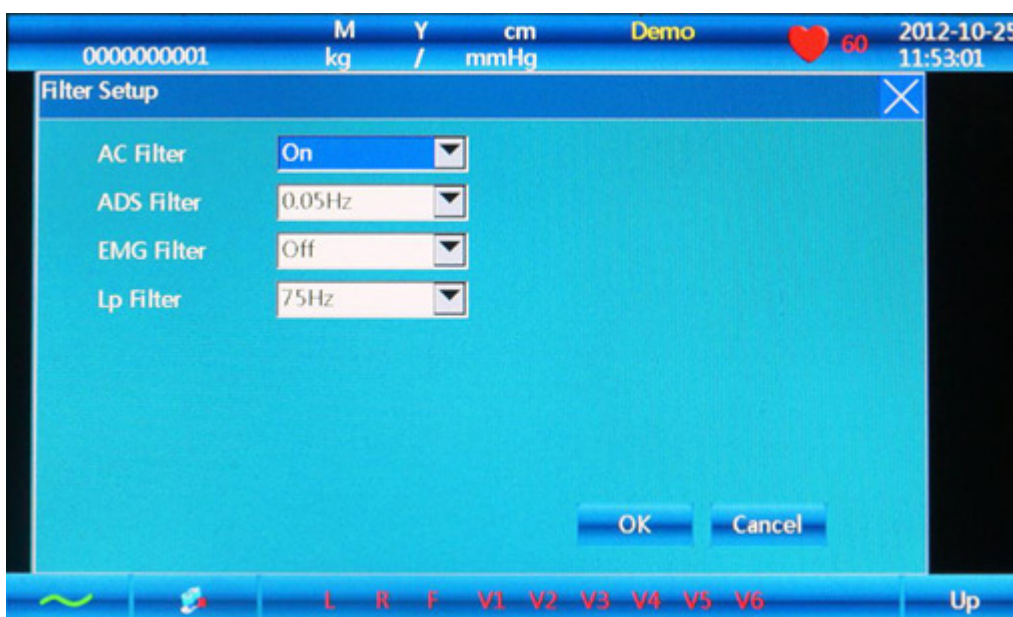


Figure 5-9 Filter Setup

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

5.7.5 Lead Sequence

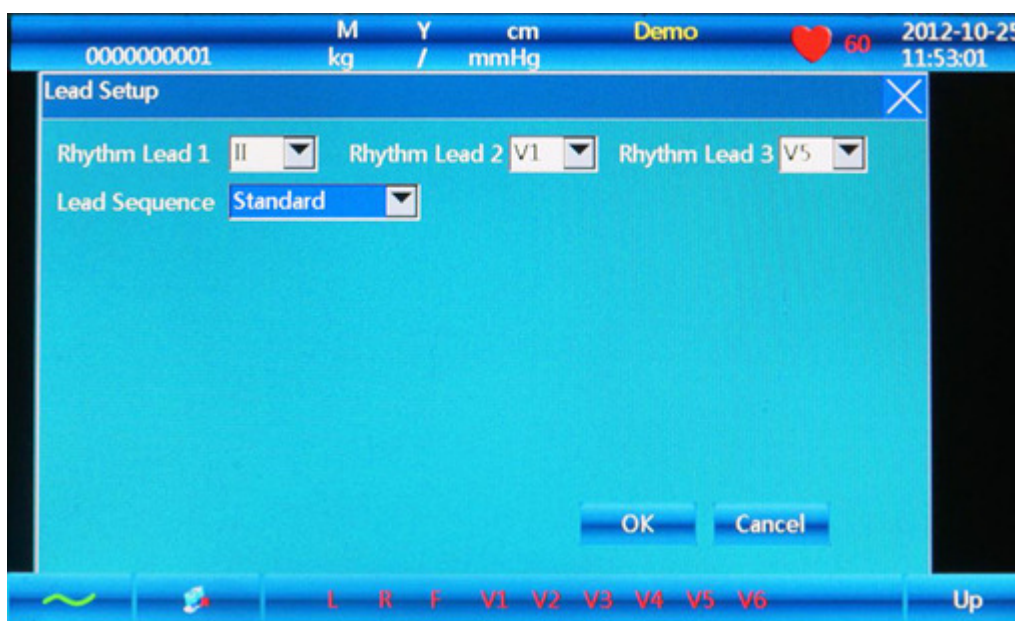


Figure 5-10 Lead Sequence

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 select the chosen item, and

press  SPEED  ” and “  SENS  ” key to select 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

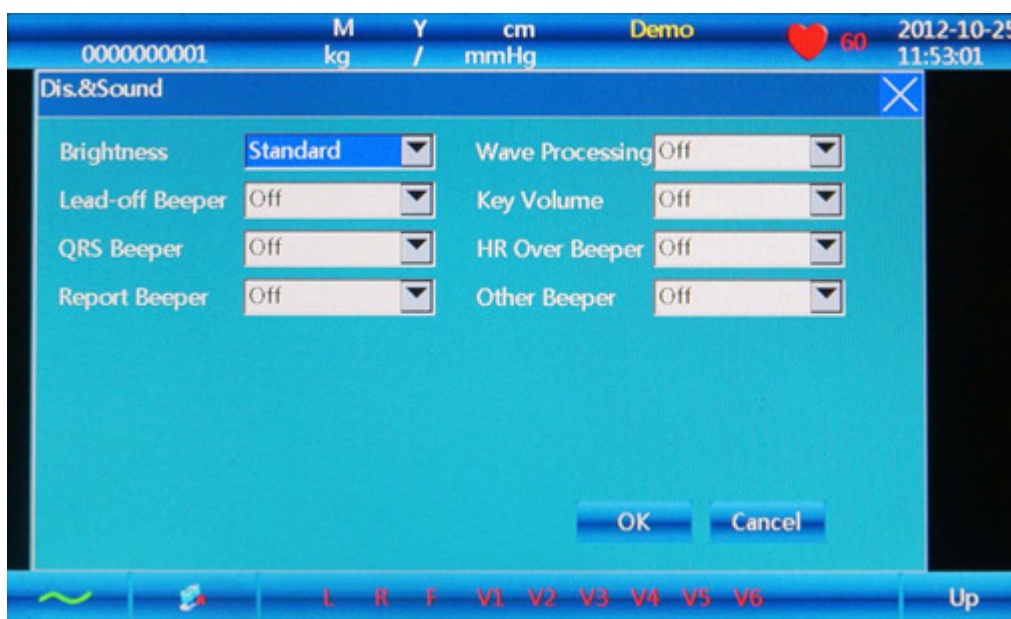


Figure 5-11 Display & sound

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

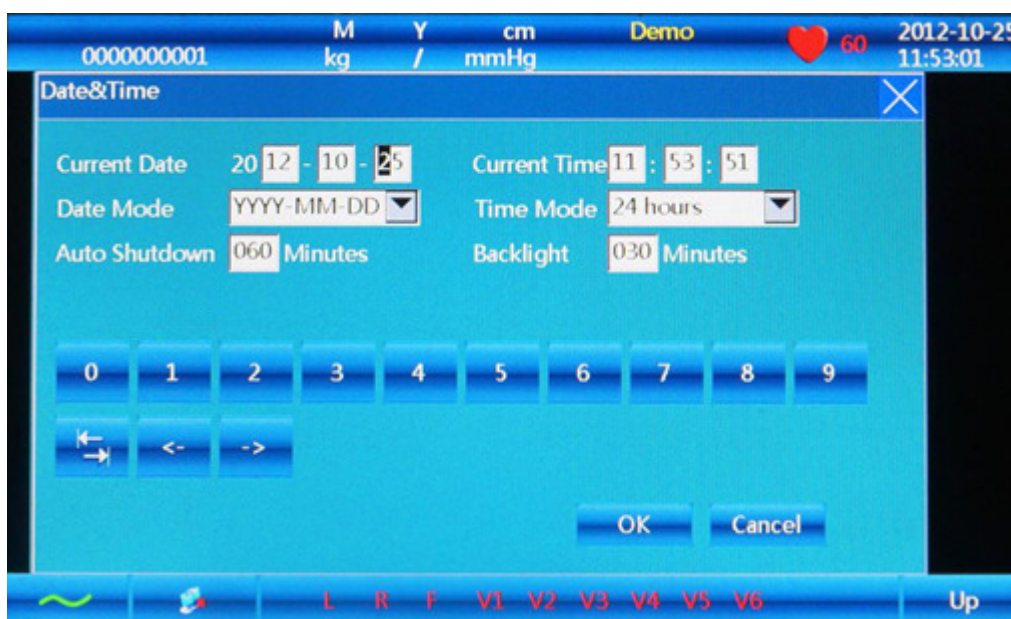


Figure 5-12 Date & time

Table 5-8

| No. | Parameter | Options |
|-----|---------------|---------------------------------------|
| 1 | Current Date | Enter manually |
| 2 | Date Mode | DD-MM-YYYY, MM-DD-YYYY and YYYY-MM-DD |
| 3 | Auto Shutdown | Enter it manually |
| 4 | Current Time | 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 Parameters



Figure 5-13 System Setup

| 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 Mode | Resting ECG |

Table 5-9

| 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 |
| 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 |

Table 5-10 "Default" content

5.7.9 Set the Communication

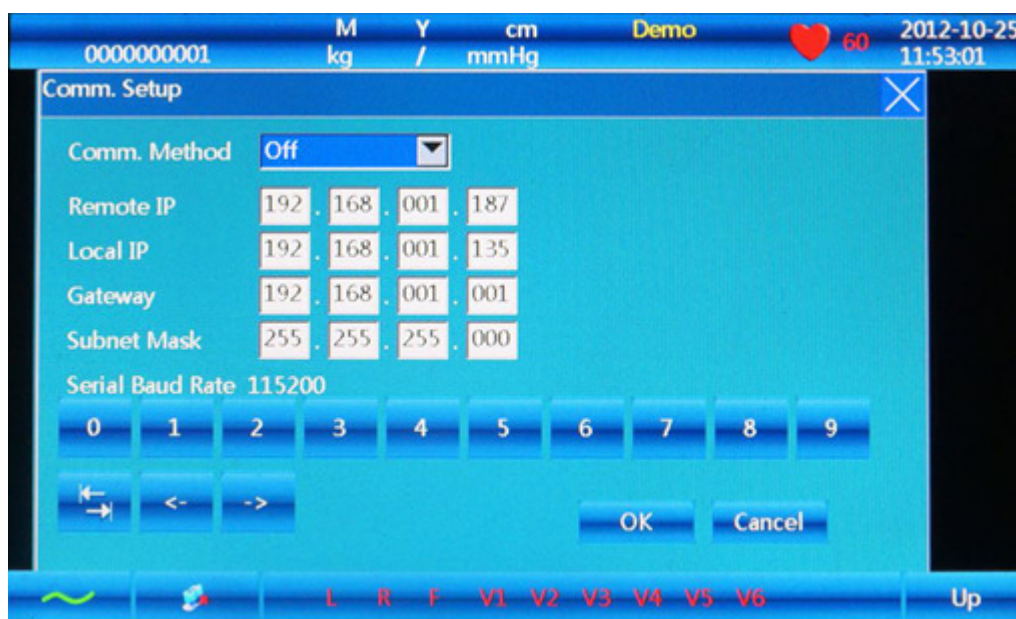


Figure 5-14 Communication Setting Interface

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 connection with ECG) |
| 3 | Local IP | Enter it manually (local ECG IP) |
| 4 | Gateway | Enter it manually |
| 5 | Subnet Mask | Enter it manually |

5.7.10 Set the Advanced Settings

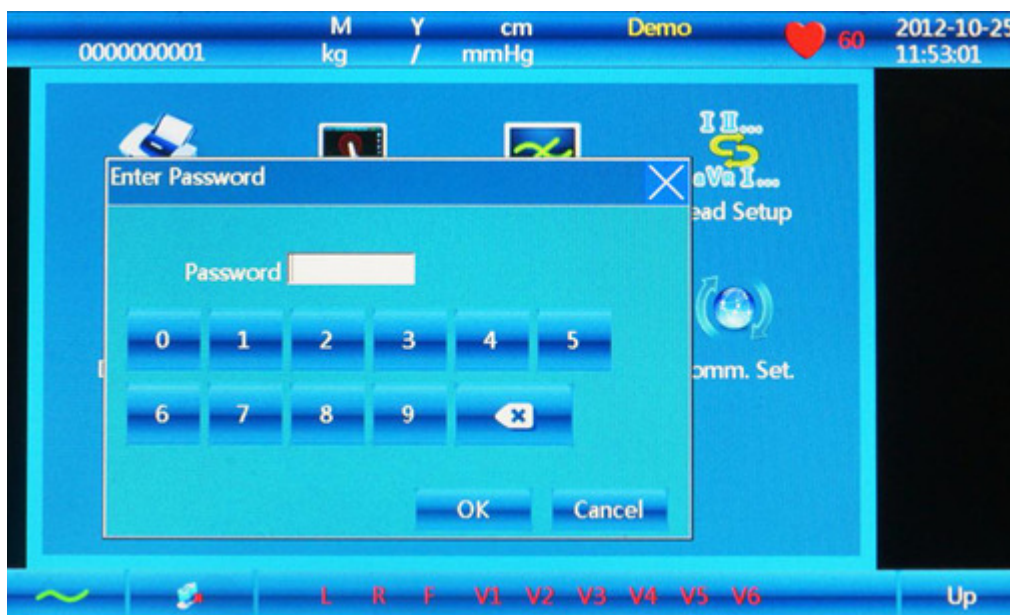


Figure 5-15-1 Advanced Setting Interface



Figure 5-15-2 Advanced Setting Interface

Choose **Advanced** by entering the password: 999999. Users don't need to enter this interface.

5.7.11 Institution

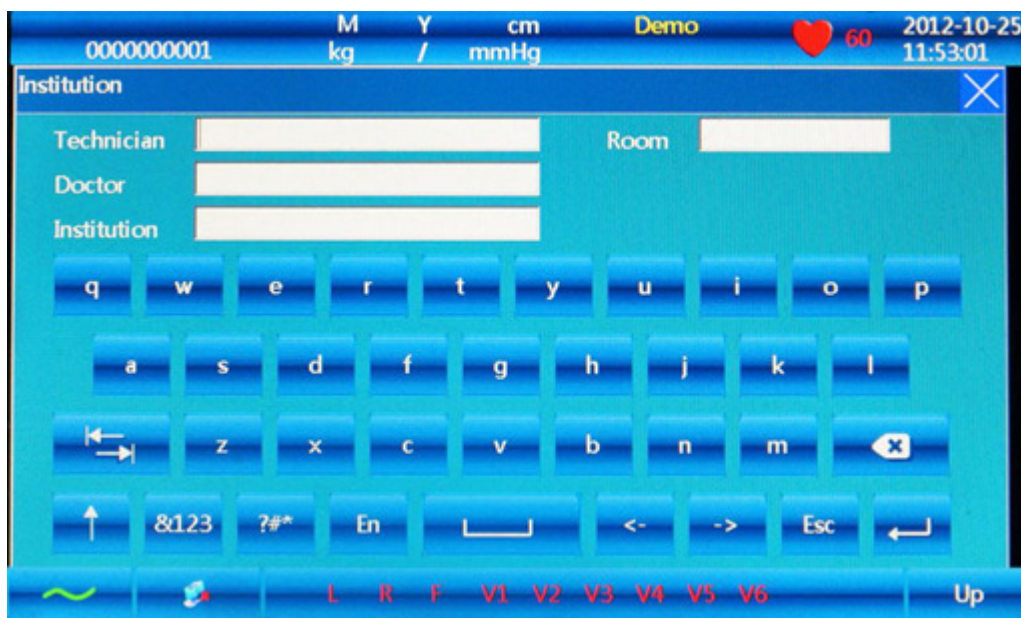


Figure 5-16

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.

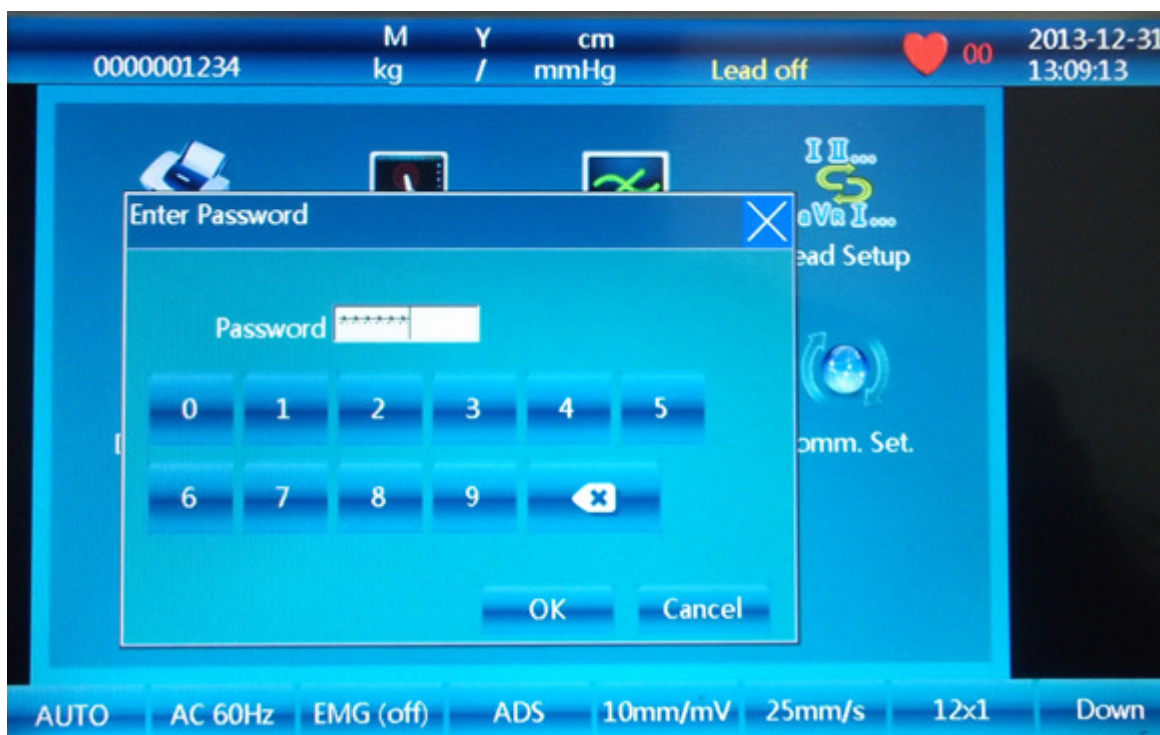


Figure 5-17

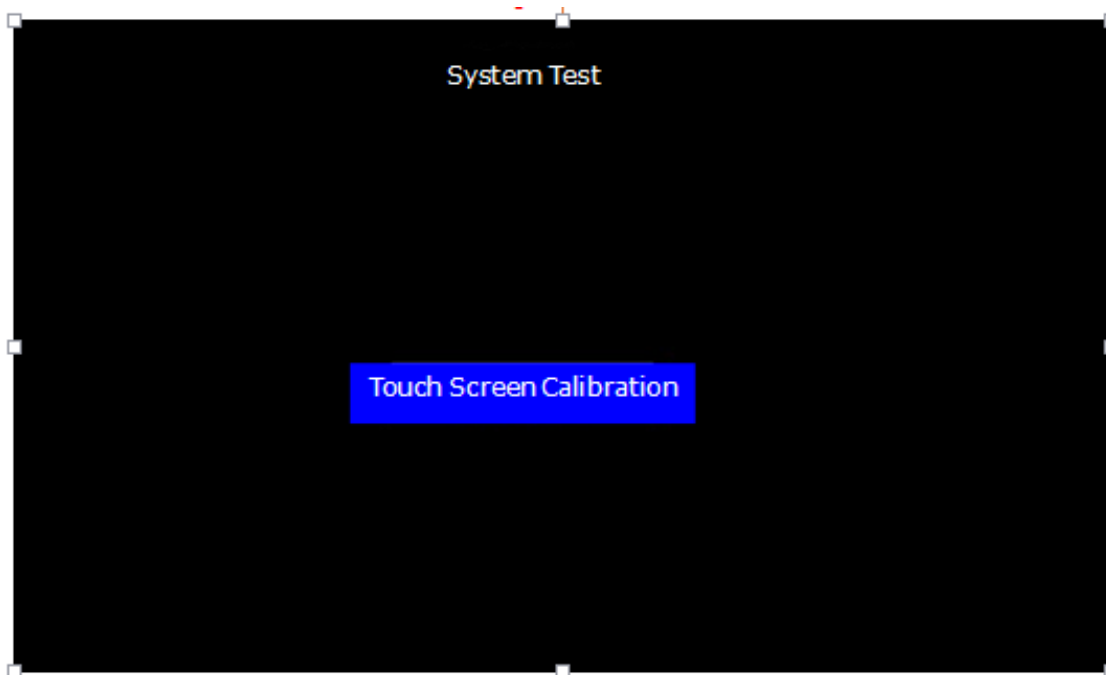


Figure 5-18

5.8 How to Use the Battery

WARNING :

- ◆ Inappropriate operation may cause battery to become hot, ignite, explode, become damaged or lose

capacity. Before using the rechargeable lithium battery, read this manual carefully.

!NOTE!

- ◆ The initial charging of the new battery supplied with the ECG-1112(Class M) should last 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

ECG-1112(Class M) is equipped with a recharging control circuit together with a built-in rechargeable lithium battery. When connected to the AC power supply, the battery will be recharged automatically. Then the battery recharge indicator lamp (→□) will blink and the AC power supply indicator lamp (∞) will be lit. When the capacity of battery is full, the battery recharge indicator lamp (→□) will be lit.

Because of energy consumption during storage and transport, the capacity of battery is not full upon initial use. A new battery should be recharged before use for at least 8 hours.

3) Replacement

!NOTE!

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



Figure 5-19 Battery installation

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

At the end of the battery service life, or if a foul smell and leakage has been noted, please contact the manufacturer or its local distributor for replacement of the battery.

!WARNING!

- ◆ Only qualified service engineers authorized by us can open the battery compartment and replace the battery. And the battery of same model and specification provided by the 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 of the battery according to local regulations.

5.9 Operating Mode

There are 3 kinds of operating modes: 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.

Press RUN/STOP key to start printing, press RUN/STOP again to stop printing. After printing, the patientID will automatically add 1, while patientname and age will not change. Press RUN/STOP key to repeat printing of the same patient. Press INFO key to delete patientinformation (except ID) so that the user can speed up the input of thenext patient's name and age.

5.9.3 Analysis Mode**Operation: press mode key to choose Analysis mode.**

Press the 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 the "Lead Sequence" menu with an analysis report and R-R histogram. During sampling, press RUN/STOP or Enter key to stop sampling.

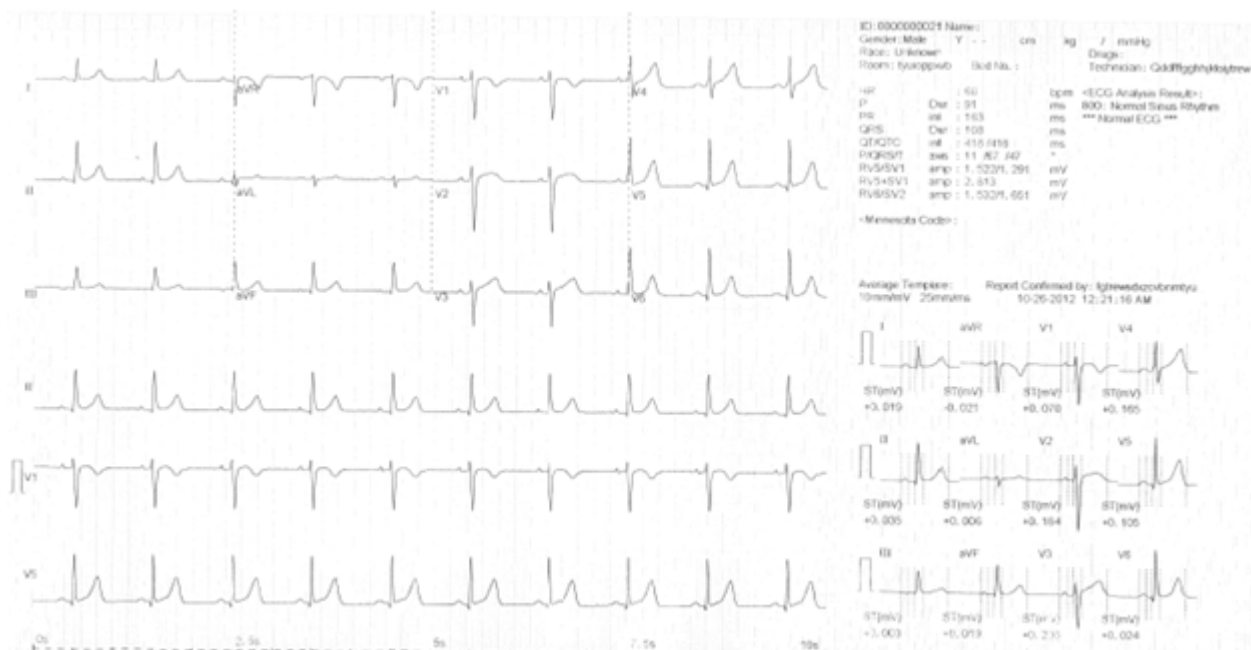
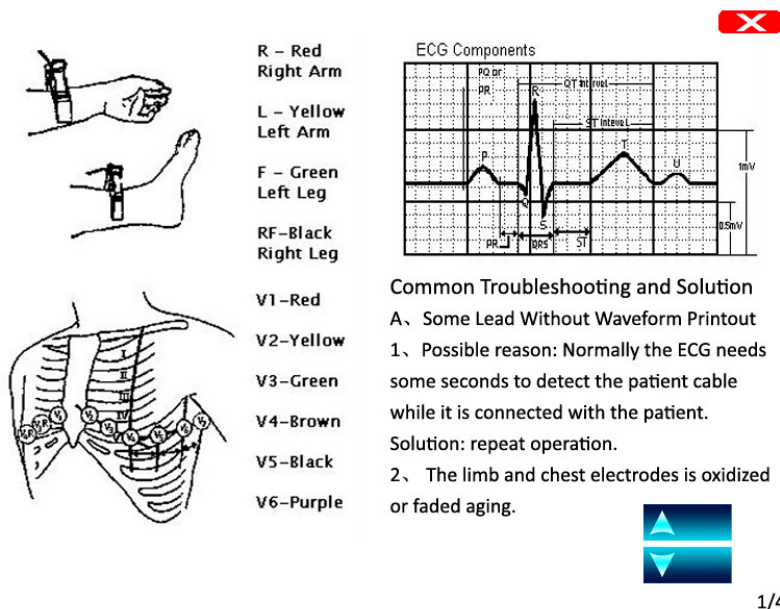
5.10 ECG case

Figure 5-20

As shown in the image, 121T's report includes the following information: sensitivity (10mm/mV), heart rate (80), filters applied (AC50, EMG, ADS), 1mV mark, lead, ECG waveform, recording speed (25mm/s), patient clinical information, print date and time, software version, sampling graph, measurement and analysis result.

5.11 ECG Help Information

Press the **HELP** key to enter the HELP menu. The operator can view information such as electrode positioning, ECG basic knowledge, etc. Press **SPEED** (PgUp) and **SENS** (PgDn) key to scroll up/down to browse the information. Press **HELP** again to return to the main interface. It contains two versions: Chinese and English.



The figure illustrates ECG components and troubleshooting. On the left, diagrams show electrode placement on the limbs (R, L, F, RF) and chest (V1-V6). In the center, a list identifies the colors for each electrode: R (Red, Right Arm), L (Yellow, Left Arm), F (Green, Left Leg), RF (Black, Right Leg), V1 (Red), V2 (Yellow), V3 (Green), V4 (Brown), V5 (Black), and V6 (Purple). On the right, an ECG waveform is shown with labeled components: PQ, PR, Q, R, S, T, U, and ST Interval. A red 'X' icon is positioned above the waveform. Below the waveform, the text 'Common Troubleshooting and Solution' is followed by two points: 1. 'Some Lead Without Waveform Printout' with a possible reason of detection delay and a solution of repeating the operation; 2. 'The limb and chest electrodes is oxidized or faded aging.' A blue double-headed arrow icon is located at the bottom right of the diagram area.

1/4

Figure 5-18 Help Interface

Chapter 6 Declaration of Auto Measurement & Analysis Report

Under Auto mode, after 10 seconds of recording, the following parameters will be automatically recognized and measured by KES-121T:

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

Please pay attention to following factors with 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 to be unreliable.
- ◆ ECG machine only analyzes the waveforms it has acquired, not reflecting the overall status of the patient. This may cause discrepancies with the doctor's diagnosis. A conclusion regarding the final diagnosis can be only made after general evaluation of the analysis report produced by the ECG, the patient's clinical symptoms and other clinical laboratory reports.
- ◆ The analysis report produced by ECG-1112(Class M) can be ONLY used as a clinical reference for the doctor. 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 7 Alarm Information

Alarm information will be displayed on the LCD screen when there is something wrong. Alarm information provided by the ECG and the corresponding cause are listed in Table 7-1.



| Alarm Information | Causes |
|---|---|
|  | Electrodes became disconnected from the patient or the patient cable became disconnected from the unit. |
| NO/PAPER | Recording paper has not been loaded or it has been used up. |
|  | Low battery. |

Table 7-1 Alarm Information and Causes

Chapter 8 Cleaning, Care and Maintenance

8.1 Cleaning

⚠NOTE⚠:

- ◆ Turn off the ECG and unplug the AC power supply cable and 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 moistened with soapy water or non-caustic neutral detergent. After that, remove detergent residues with a clean dry cloth.

8.1.2 Cleaning the Electrodes

First remove the remaining gel from the electrodes with a clean soft cloth. Take the suction bulb and metal 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 remaining 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 heads can decrease the print resolution of the recordings. Clean the print head at least once a month.

Open the recorder housing and remove the paper. Wipe the print head gently with a clean soft cloth moistened in 75% alcohol. For stubborn stains, soak with a little alcohol first and wipe off with a clean soft cloth. After air drying, load the recording paper and shut the recorder housing.

⚠NOTE⚠:

- ◆ Prevent 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 to be necessary according to your hospital's regulations.

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

⚠NOTE⚠:

- ◆ Do not use chlorine disinfectants such as chloride and sodium hypochlorite etc.

8.3 Sterilization

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

!NOTE!

- ◆ Sterilization, if required, cannot be done with high temperatures, autoclaving or radiation.

!NOTE!

- ◆ We are not liable for the effectiveness of infectious disease control by means of the disinfectant or sterilization process. It is recommended that epidemic experts be consulted for advice.

8.4 Care and Maintenance

8.4.1 Recharging and Replacement of Battery

1) Capacity Identification

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

■: Full capacity

▣: Moderately full

□: Capacity is limited, and recharging should be considered

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

2) Recharging

Our ECG device is equipped with a recharging control circuit together with a built-in rechargeable lithium battery. When connected to the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp (→□) will blink and the mains supply indicator lamp (∩) will be lit. When the capacity of battery is full, the battery recharge indicator lamp (→□) will be steadily lit.

Because of the energy consumption during storage and transport, the capacity of battery is not full upon initial use. Battery charging should be considered before first usage.

3) Replacement

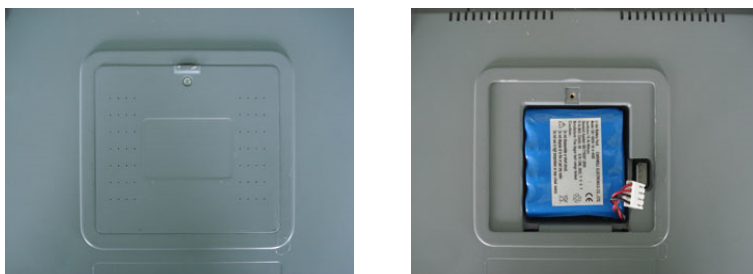


Figure 8-1 Battery Installation

!NOTE!

- ◆ The battery is put into the battery compartment without connecting to the battery socket at the factory. Upon receipt of the ECG machine, if the 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 screwdriver attached;
 - 2) Insert the battery into the battery pack, properly connected;
 - 3) Close the battery cover.

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

!WARNING!

- ◆ Inappropriate operation may cause the battery to become hot, ignite, explode, become damaged or lose capacity. Before using the rechargeable Ni-MH battery, read the **Operation Manual** carefully.
- ◆ Only qualified service engineers 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 service life is over, contact the manufacturer or local distributor for disposal or disposal of the battery according to local regulations.

8.4.2 Recording Paper**!NOTE!**

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

Storage Requirements:

- 4 Recording paper should be stored in a dry, dark and cool area, avoiding excessive temperature, humidity and sunlight.
- 5 Do not expose the paper to fluorescence for a long time.
- 6 Be sure that there is no polyvinyl chloride or other chemicals in the storage environment which will lead to a color change of the paper.
- 7 Do not leave printed recording paper overlapped for a long time, otherwise the printed ECG records may transfer to each other.

8.4.3 Main Unit, Patient Cable & Electrodes**1) Main Unit**

- 8 Avoid excessive temperature, sunlight, humidity or dirt.
- 9 Put on the dustproof cover after use and prevent from shaking violently when moving machine to another place.
- 10 Prevent any liquid from seeping into the ECG machine, as it will affect the safety and performance of the machine.

2) Patient Cable

- 11 Integrity of patient cable, including main cable and lead wires, should be checked regularly. Be sure that it is conductible.
- 12 Do not drag or twist the patient cable with excessive stress during use. Hold the connector plugs instead of the cable when connecting or disconnecting the patient cable.
- 13 Straighten the patient cable to avoid twisting, knotting or kinking in a closed angle during use.

- 14 Keep the lead wires coiled up to prevent any people from tripping on them.
- 15 Once damage or aging of the patient cable has been noted, replace it with a new one immediately.

3) Electrodes

- 16 Electrodes must be cleaned after use; ensure there is no remaining gel on them.
- 17 Protect the suction bulb of the chest electrode from sunlight and excessive temperatures.
- 18 After long-term use, the surface of the electrodes will be oxidized because of erosion and other causes. In this case, electrodes should be replaced to achieve a high-quality ECG.

NOTE :

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

Chapter 9 Common Troubleshooting and Solutions

1) Some Lead with signal delay

Possible reason: Normally the ECG machine needs a few seconds to detect the patient cable while it is connected to 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 persists, there may be damage to the printer head. Please contact our service department or appointed maintenance center.

3) ECG machine cannot be switched on

Possible reason: Fuses burnt out

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

⚠ Warning ⚠:

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

4) ECG machine cannot be switched off

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:

- 19 Equipment is not properly grounded;
- 20 Electrode or patient cable is incorrectly connected;
- 21 There is not enough gel applied;
- 22 Patient bed is not properly grounded;
- 23 Patient touches metal part of the patient bed;
- 24 Somebody is touching the patient;
- 25 There is powerful equipment operating nearby;
- 26 The patient is wearing glass or diamond jewelry;
- 27 AC power frequency.

Solution:

- 28 Ground the equipment properly;
- 29 Connect the electrode and patient cable correctly;
- 30 Apply enough gel;
- 31 Ground the patient bed properly;
- 32 Ask the patient not to touch the metal part of the patient bed;

- 33 Don't touch the patient;
- 34 Wait till the powerful equipment is switched off;
- 35 Remove the glass or diamond jewelry from the patient;
- 36 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:

- 37 The room is uncomfortable;
- 38 The patient is nervous;
- 39 The bed is too narrow;
- 40 The patient is talking;
- 41 The limb electrodes are tightly attached.

Solution:

- 42 Move to a comfortable room;
- 43 Ask the patient to relax;
- 44 Change to a wider patient bed;
- 45 Don't talk to the patient during the procedure;
- 46 Change the limb electrode if it is too tight.

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

Chapter 10 Service Warranty

1) Workmanship and Raw Materials

We warrant that there is no defect in raw material and workmanship. During the warranty period, we will repair or replace the defective part free of charge if the defect has been confirmed to be a raw material or workmanship defect.

2) Software or Firmware

We will replace installed software or firmware free of charge if the defect has been confirmed to be a raw material or workmanship defect within 18 months from the date of shipment. But we cannot guarantee it will not interrupt the use of the ECG.

NOTE :

- ◆ All services must be provided by engineers authorized by us or its authorized distributor.

3) Exemption of Warranty

Freight charges and others are excluded under warranty.

The warranty is void in the case of:

- Assembly, extensions, readjustments of any parts;
- Modification and repair by unauthorized personnel;
- Subsequent damage caused by improper use or maintenance;
- Replacement or removal of serial number labels and manufacturer labels.

Chapter 11 Accessories

⚠️ WARNING ⚠️:

- ◆ Only the patient cable and other accessories supplied by the manufacturer can be used. Otherwise the performance and electric shock protection cannot 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 |
| | IEC60601-2-25:1993 + 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 class: | Class 2 with internal power supply |
| | Anti-electric-shock type: | Type CF with defibrillator protection |
| | Degree of protection against harmful penetration 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) |

| 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) | | |
| | Servicelife ≥500 rechargings | |
| Fuse | T2A/AC 250V Ø5×20 | |

| | | |
|-----------------|-----------------|---|
| Recorder | Record Mode | Thermal dot-matrix printer |
| | Recording Paper | Rolled thermo-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 |

| | | |
|---|---------------------------|--|
| External Input/Output (Optional) | Input (Single ended) | Input impedance ≥100kΩ ; Sensitivity 10mm/V±5%; |
| | Output (Single ended) | Output impedance≤100Ω ; Sensitivity 1V/mV±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 | $\pm 700mV$ |
| | Noise | $< 15\mu V_{p-p}$ |
| | 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 | KES-121T is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment. | | |
| 3 | Emissions test | Compliance | Electromagnetic environment - guidance |
| 4 | RF emissions CISPR 11 | Group I | KES-121 Telectrocardiograph 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 | | | |
|---|---|---|--|
| KES-121T is intended for use in the electromagnetic environment specified below. The user should ensure 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 device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: UT is the AC mains voltage prior to application of the test level. | | | |

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

Guidance and manufacturer’s declaration – electromagnetic immunity

KES-121T is intended for use in the electromagnetic environment specified below. The user should ensure 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 device, 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>80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p>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 propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KES-121T ECG is used exceeds the applicable RF compliance level above, the ECG device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECG device.

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 KES-121T ECG**

KES-121T is 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 pollution control 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 years. 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 normal conditions of use and the use of the product will not cause serious pollution to the environment or serious damage to persons and property when the product is used in the environment-friendly use period.

2. We provide the following table which applies to all parts of the 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 | o | o | o | o | o | o |
| Built-in Connector | o | o | o | o | o | o |
| Sheet Metal | x | o | o | o | o | o |
| Outer Housing | o | o | o | o | o | o |
| Display Block | x | o | o | o | o | o |
| Packing Material | x | o | o | o | o | o |
| Accessories | x | o | o | o | o | o |
| "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 parts of these products is above the limit requirement in SJ/T 11363-2006. | | | | | | |

European Representative:

Shanghai International Trading Corp.GmbH (Hamburg)

Address:

Eiffestrasse 80, 20537 Hamburg German

UMDNS Code: 11407



Notified Body:

TUV SUD Product Service GmbH

Address:

Ridlerstrasse 65, 80339Muenchen, Germany

Certificate No.:G2 12 02 50440 016

ADDITIONAL QUALITY PRODUCTS



KES-301



CARDIOVASCULAR DIAGNOSTICS ECG SYSTEMS

- KES-301** DIGITAL 3-CHANNEL ECG SYSTEM
- KES-601** DIGITAL 6-CHANNEL ECG SYSTEM
- KES-121** DIGITAL 12-CHANNEL ECG SYSTEM



KEC-1000



PC-BASED DIAGNOSTICS ECG RECORDER

- KEC-1000** HIGH-QUALITY 12-CHANNEL PC ECG SYSTEM
WITH USB OR WIFI CONNECTION TO PC OR ANDROID DEVICE

SPIROMETER

- KSP-1000** PC SPIROMETER FOR DIAGNOSTIC TESTING AND
MONITORING OF PULMONARY FUNCTION



KUP-101



DIAGNOSTIC IMAGING ULTRASOUND SYSTEMS

- KUP-101** FULLY DIGITAL B/W ULTRASOUND SYSTEM
- KUT-201** FULLY DIGITAL B/W ULTRASOUND SYSTEM
WITH INNOVATIVE IMAGE-PROCESSING TECHNOLOGY



KLC-101



AESTHETIC MEDICINE LASER SYSTEMS

- KLC-101** THE CO₂ LASER WITH SUPER PULSE

Medguard Professional Healthcare

Tel: +353 (0) 1 835 2411

Email: sales@medguard.ie

Fax: 01 969 5009

Website: www.medguard.ie

Unit 6/7, Block 4, Ashbourne Business Park, Ashbourne, Co. Meath, A84 VK52