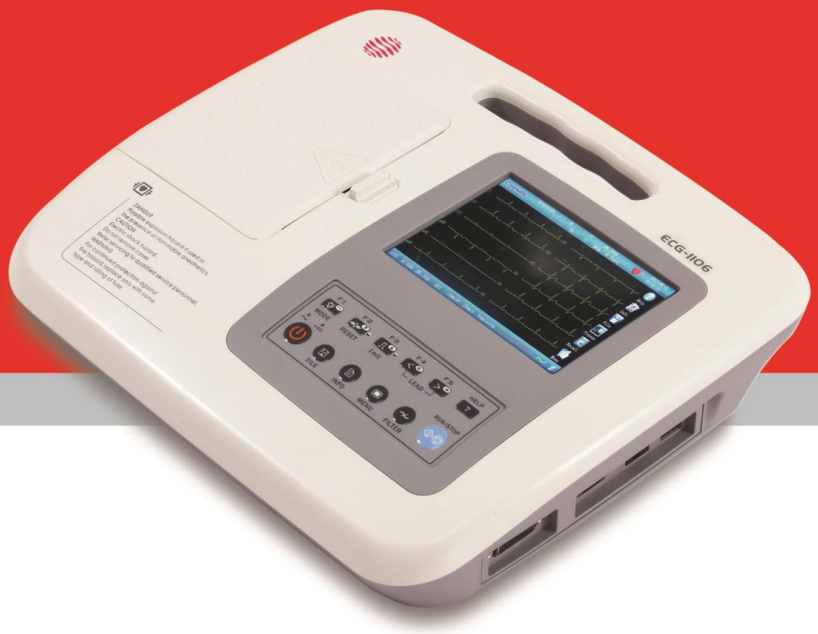
ECG-1106L

Digital Six-channel Electrocardiograph

Operation Manual



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EC-Representative

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80,20537 Hamburg, Germany

Responsibility of the manufacturer

Carewell only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

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

❗NOTE❗:

- This device is not intended for home use.

⚠WARNING⚠:

- This device is not intended for treatment.

Label guide

⚠WARNING⚠

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

❗NOTE❗

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

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Chapter 1 Safety Guidance

1.1 Safety Information

ECG-1106L digital six-channel electrocardiograph (ECG) complies with international standard IEC 60601-1, Medical Electrical Equipment: General Requirements for Safety and IEC 60601-2-25, Particular Requirements for Safety of Electrocardiographs. The classification is Class I, type CF, which means a higher degree of protection against electric shock and the patient connection is fully isolated and defibrillation protected.

ECG-1106L is not explosion-proof. Do not use it in the presence of flammable anesthetics.

ECG-1106L is designed for continuous operation but it is not drip-proof or splash-proof.

Safety classification is listed as below Table 1-1.

Anti-electric-shock type:	Class I with internal power supply
Anti-electric-shock degree:	CF
Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:	Refer to the ***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 A

Table 1-1 Safety Classification

1.1.1 Environment Requirements

Please find in Table 1-2 for environment requirements of transportation, storage and working condition of ECG-1106L.

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

Table 1-2 Environment Requirements

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

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

1.1.2 Power Supply

1) AC Power Supply

Rated voltage: 100-240V~

Rated frequency: 50/60Hz

Rated power: 60VA

2) DC Power Supply

Rated output voltage: 12V

Rated output current: 3A

3) Built-in Lithium Rechargeable Battery

Rated voltage: 14.4V

Rated capacity: 2200mAh

4) Fuse: T2AL250V Ø5×20

1.2 Warnings and Notes

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

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

1.2.1 Safety Warnings

⚠WARNING⚠:

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

⚠WARNING⚠:

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

⚠WARNING⚠:

- Only patient cable and other accessories supplied by Carewell 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 electrode, should not contact with earth or any other conducting objects.
- There is no danger for patients with pacemaker.
- Do not touch the patient, bed, table or the ECG while using defibrillator or pacemaker simultaneously.
- Before defibrillating, make sure the patient is completely isolated and avoid touching any metal part of the ECG in case of electric shock.
- Before defibrillating, remove all electrodes, gel or cloth pieces from the patient in case of any possible burnt.
- Apply patient cable appointed by the manufacturer only. Otherwise there might be electric burnt of the patient or damage of the ECG.
- Electrodes with defibrillator protection should be applied. To avoid any possible electric burn, it is recommended that only the patient cable and electrodes supplied by the manufacturer to be applied while defibrillating.
- In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously. It cannot connect to electric knife and other equipment.

⚠WARNING⚠:

- Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC 60601-1. If in doubt, consult our technical service department or your local distributor.

- The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
- The potential equalization conductor can be connected to that of other equipment when necessary. Make sure the equipment is connected with potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

⚠WARNING⚠:

- Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery' s capacity. It is necessary to read the ***Operation Manual*** carefully and pay more attention to warning messages.
- Opening the battery cover, disassembling or replacing battery should be done according to the ***Operation Manual***, and only battery of same model and specification provided by manufacturer should be used.
- **Danger of explosion** - Do not reverse the anode and cathode when connecting the battery.
- Do not use battery around fire or place over 60℃. Do not heat or splash the battery. Do not throw it into fire or water.
- When leakage or foul smell found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- When the battery' s useful life is over or any abnormal phenomenon is found from the battery, stop using it, and contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

1.2.3 General Notes

NOTE:

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

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

NOTE:

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

1.2.4 Cleaning & Disinfection Notes

NOTE:

- Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be drugged out of the outlet also. Prevent the detergent from seeping into the equipment.
- Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- Any remainder of detergent should be removed from the unit and patient cable after cleaning.

- Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- Do not use high temperature, autoclaving or radiation sterilization processes.

1.2.5 Electro Magnetic Compatibility Information

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

Common sources of interference and solutions:

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

   Solution: Keep the equipment away from the emissive sources.

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

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

3. Direct and indirect influence from electrostatic discharge.

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

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

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

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

Chapter 2 Introduction

ECG-1106L is digital 6-channel physiological function measurement equipment which records the heart waveform during electro-biological movement. It provides sufficient information on the analysis of arrhythmia and cardiovascular disease, helps to know the pathological disorder caused by some drugs and electrolyte, or unbalance of PH value. It is important equipment for cardiac disease examination, and its compact size makes it suitable for use while visiting patients at home.

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

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

NOTE:

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

2.1 Function Features

ECG-1106L has following features:

- 5.7" high bright LCD, real-time display of 12 channel ECG waveforms
- Modern in design, easy to carry
- Light-touch keys & touch screen, contribute to easy and convenient operation
- Simultaneously acquisition of 12-lead ensures reliable data for clinical diagnosis
- Application of digital signal processing technique which can effectively restrict the interference caused by baseline drift, HUM, or EMG
- ECG measurement and analysis function reduce the physician's workload
- Pre-10-second printing function helps the doctor to print out any abnormal ECG waveform

- Three kinds of operation modes: AUTO, MAN, RR ANA. 5 manual print types: 6CH, 3CH, 3CH+1rhy, 3CH+3rhy, Test; 5 automatic print types: 6Tx2, 3x4+3rhy, 3x4+1rhy, 3x4 and Average template;
- Sampling mode: real-time sampling, pre-sampling, period sampling and trigger sampling
- It can connect with laser printer, bar code scanner, magnetic card reader
- It has freeze, print preview and waveforms recall function.
- Clinical information: Patient ID, gender, age, height, weight, technician, doctor, race, bed number, room, blood pressure and hospital information can be edited easily.
- To observe abnormal heartbeat from rhythm lead
- Built-in ECG simulator
- AC (50/60Hz) and battery dual power supply, aptitude protection circuit of over load or over voltage
- High resolution thermal dot-matrix printing system which produces clear and accurate printout of waveforms and characters
- Automatic adjustment of baseline for optimal recording
- Built-in Help Function: electrode positioning, ECG basic knowledge, common trouble-shooting and so on
- 5000 ECG files can be saved in the ECG.
- Flexible saving interface. Saved ECG files can be displayed in image-text or list format, easy for search
- Auto-save function: after printing, the printed ECG file will be automatically saved

2.2 List of Symbols

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

	External output		External input
	Equipment or part of CF type with defibrillator proof		Attention – general warning (see accompanying document)
	Equipotentiality		Mains supply
	Battery recharging indicator		Recovery and recycling
	Refer to instruction manual/booklet NOTE On ME EQUIPMENT “Follow instructions for use”		

Table 2-1 List of Symbols

Chapter 3 General Information

3.1 Front Panel

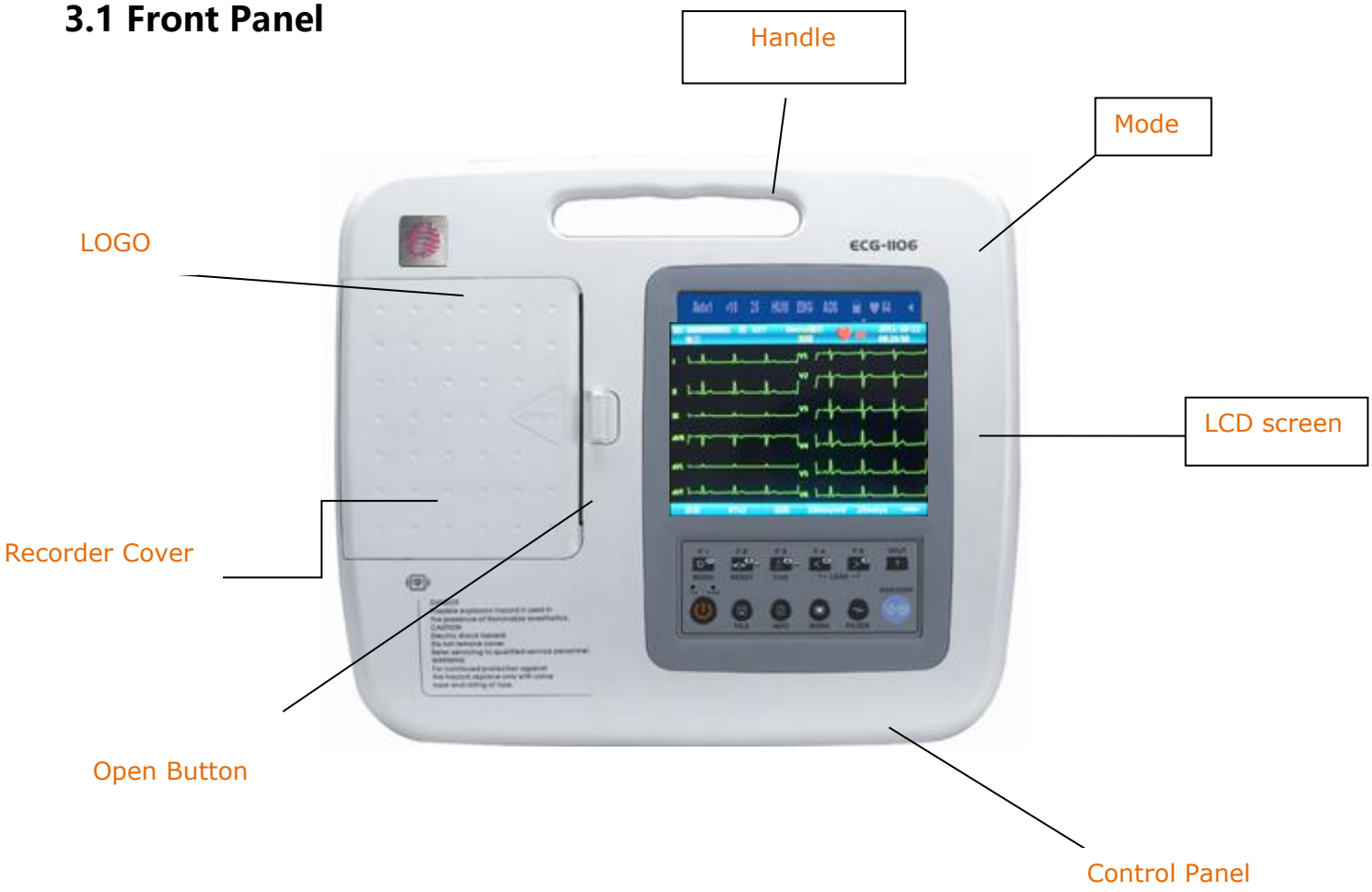


Fig. 3-1 Front Panel of ECG-1106L

3.1.1 Product Information:

1) LOGO

2) Model Series

ECG-1106L

3) Classification Symbol

Equipment of CF type with defibrillator proof

4) Open Button

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

3.1.2 LCD Screen

The display of ECG-1106L is 5.7 inch color LCD.

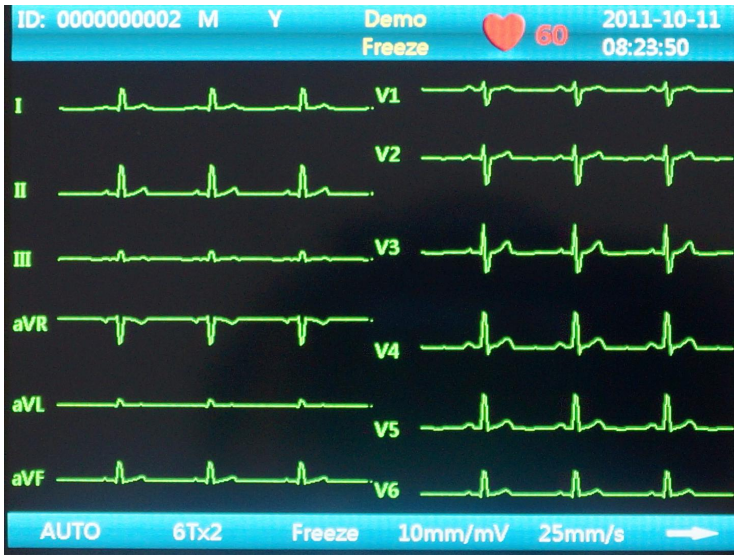


Fig. 3-2a

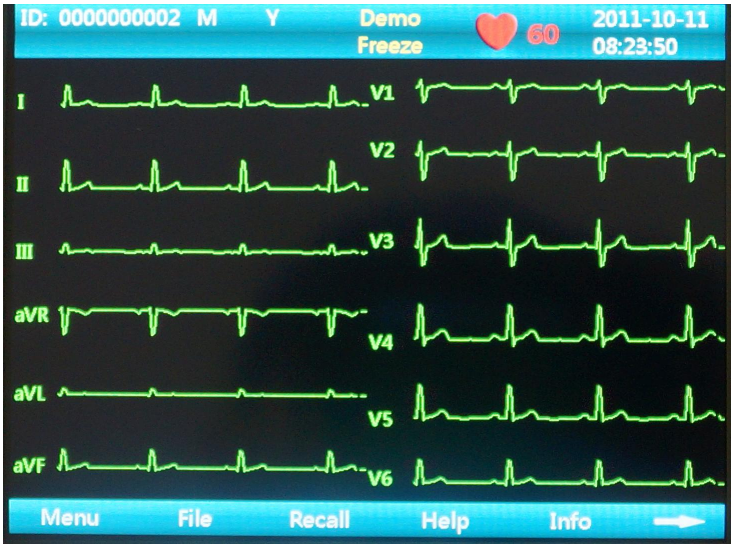


Fig. 3-2b

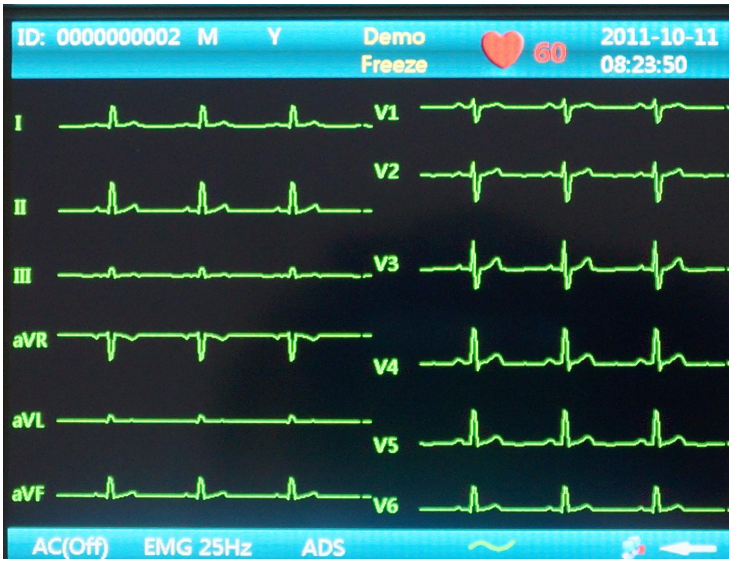


Fig. 3-2c

Normally, the contents displayed in the LCD screen include (from left to right, shown as Fig. 3-2)

Top Row:

- Patient ID (10 digits can be input)
- Gender (Male/Female/Empty)
- Age (3 digits can be input)
- ♥ 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)
- Print Type: 6Tx2, 3x4+3rhy, 3x4+1rhy, 3x4, Average Template
- Freeze
- Sensitivity (Auto, 2.5, 5,10, 20, 40mm/mV)
- Paper Speed: Auto: 25mm/s, 50mm/s

  Manual: 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s

- Page Down
- Menu (edit all parameters)
- File (Storage or open patient data)
- Recall
- Help (ECG basic operation instruction)
- Info (edit patient information)
- 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
- Power indicator (AC or battery)
- Network Connection Status
- Page Up

3.1.3 Control Panel and Keys

Fig. 3-3

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) ON/OFF

Power on or off the ECG. When the ECG is not printing it can be powered off. It need to open AC switch and press the button later when the instrument is in AC status.

3) MODE/F1

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

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

Table 3-1

Under INFO menu, it is an auxiliary key. Press F1 key to move up next ten characters. Press Menu key to move down next ten characters.

4) RESET/F2

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

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

5) 1mV/F3

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

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

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

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

7) RUN/STOP

Start or stop recording.

8) Menu

Press this key to enter menu settings or enter the submenu items.

9) Freeze

In main interface, Press the button to freeze/unfreeze the sampling waveform. The button is used to cancel order or back to last operation under other circumstance.

10) RUN/STOP

Press this key to read helpful information such as electrode positioning, ECG basic knowledge, etc. Press this key again to return to main menu.

11) FILE

Press this key to enter case saving menu to save the patient ECG information. Press again to return to main menu.

12) INFO

Press this key to input patient ID, name, sex, age, Bed NO., height, weight, Drugs, Race, blood pressure. Press again to return to main menu.

See **Chapter 5.7** for specific input methods.

1. 3.2 Connection and Switch of Power

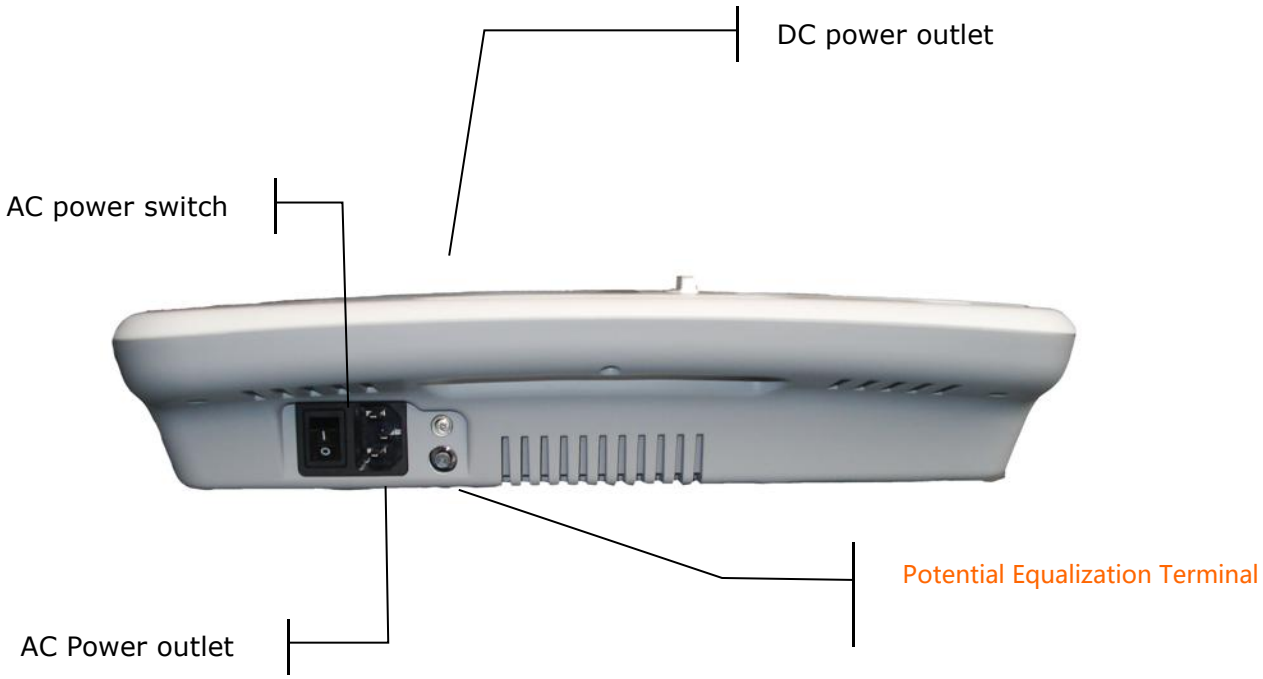


Fig. 3-4

1) AC Power Switch

I : Power on

O: Power off

2) AC Power outlet

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

3) Equipotentiality

NOTE:

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

NOTE:

- Connect one end of the grounding cable to the equipotentiality of the equipment and

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

4) DC Power outlet

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

⚠WARNING⚠:

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

3.3 Patient Cable Socket and Signal Interface

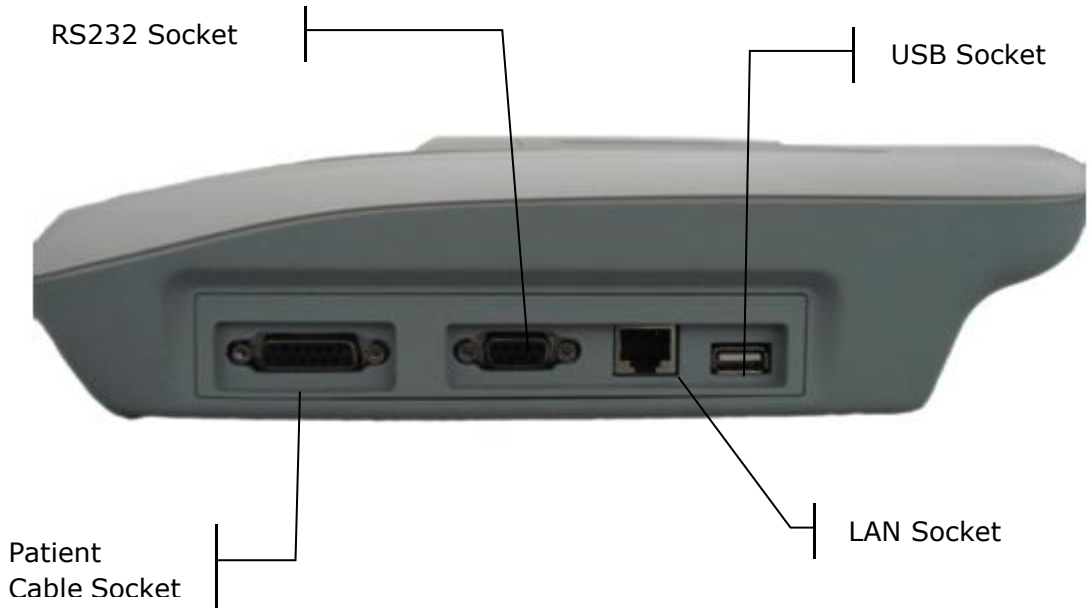


Fig. 3-5

⚠WARNING⚠:

- Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC 60601-1. Therefore anybody, who connects additional equipment to the signal input or

output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult our technical service department or your local distributor.

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

1) Patient Cable Socket

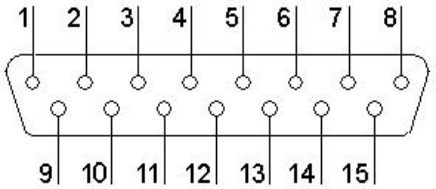


Fig. 3-6 Patient Cable Socket

: Applied part of type CF with defibrillator proof.

Definition of corresponding pins:

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

Table 3-2 Patient Cable Definition of Pins

2) RS232 Socket

⚠WARNING⚠:

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

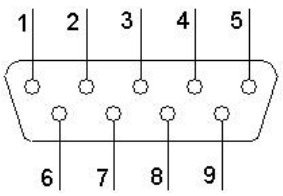


Figure 3-7 RS232 Socket

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

3) USB Interface

After USB device plug in this interface, ECG data can be transferred to USB flash via USB interface. What' s more, laser printer, bar code scanner and magnetic card reader can be plugged in to realize its own functions.

⚠WARNING⚠

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

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

4) LAN interface

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

3.4 Bottom Panel

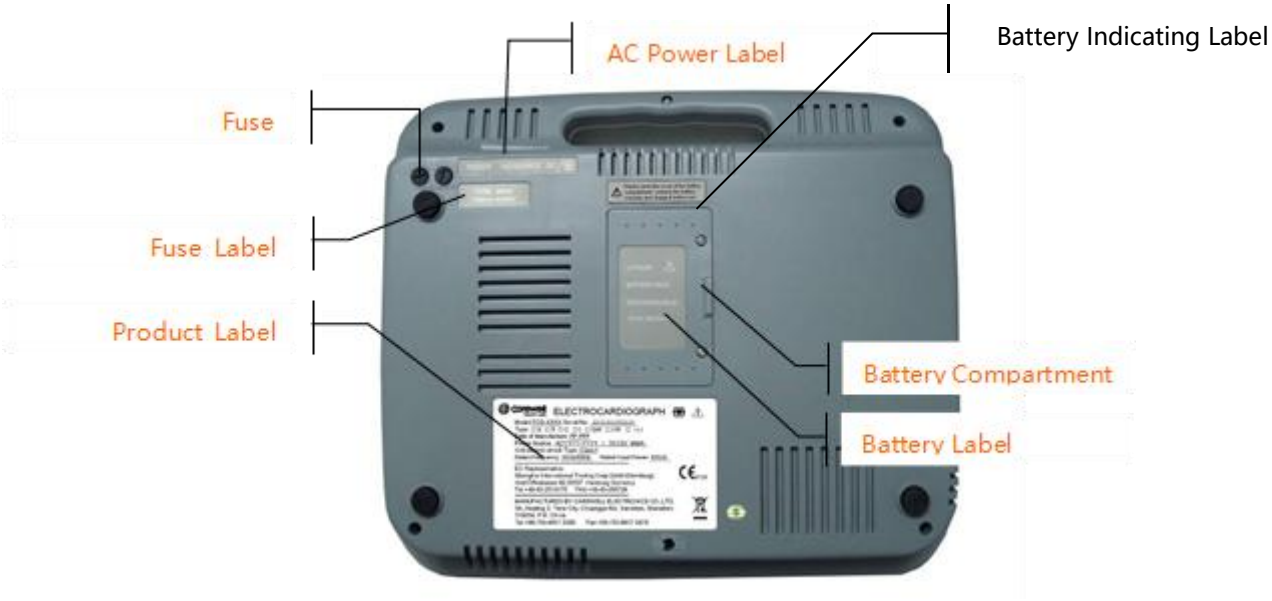


Fig. 3-8 Bottom Panel

1) Battery Compartment

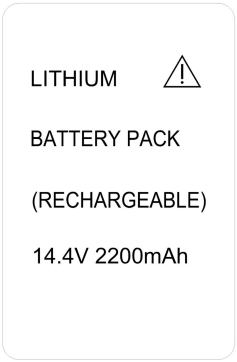


Fig. 3-9

The battery label indicates the rated voltage and rated capacity of rechargeable lithium battery pack. Rated voltage: 14.4V, Rated capacity: 2200mAh.

⚠WARNING⚠:

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

⚠WARNING⚠:

- When leakage or foul smell found, stop using the battery immediately. If the leakage liquid

gets to your skin or cloth, cleanse it with clean water at once. If the leakage liquid gets into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

⚠WARNING⚠:

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

2) Fuse label

Fig. 3-10 Fuse Label

ECG-1106L has equipped with two fuses of same type, their specification is shown as Fig. 3-10.

⚠WARNING⚠:

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

3) Product Label

In the label, there is information of product model, S/N, manufacture date, manufacturer name, etc.

Chapter 4 Operation Preparations

⚠WARNING⚠:

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

4.1 Connecting to AC Power and Grounding

⚠WARNING⚠:

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

⚠WARNING⚠:

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

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

1) AC Power Supply

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

Rated voltage: 100-240V~

Rated frequency: 50/60Hz

Rated input power: 60VA

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

2) Built-in Rechargeable Battery

The built-in rechargeable battery pack is used, because of the consumption during storage and transport, the capacity of battery may not be full. In this case please recharge the battery first. Replace the battery when the battery has been recharged over 300 times.

NOTE:

- The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the ECG, if built-in rechargeable battery is to be used, connect the battery to the socket first.
- Please refer to the Section 7.4.1 for how to recharge the battery. During recharging, the ECG can be powered on by AC power supply and continue operating.
- The battery should be recharged at least 8 hours for first time application.
- The battery’ s recycling life is about 300 times of recharging.
- When the battery is fully charged, the device can work for at least 1 hours continuously.

3) External DC Power Supply

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

Rated output voltage: 12V;

Rated output current: 3A;

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

4) Equipotentiality terminal

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

4.2 Loading Recording Paper

112mm width roll thermal sensitive paper can be applied to ECG-1106L as recording paper. There will be both audio and video alarms when there is no paper or the paper is not properly installed.

Figure 4-1 Loading Roll Paper

Loading Procedures of Rolled Paper:

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

4.3 Patient Cable Connection

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

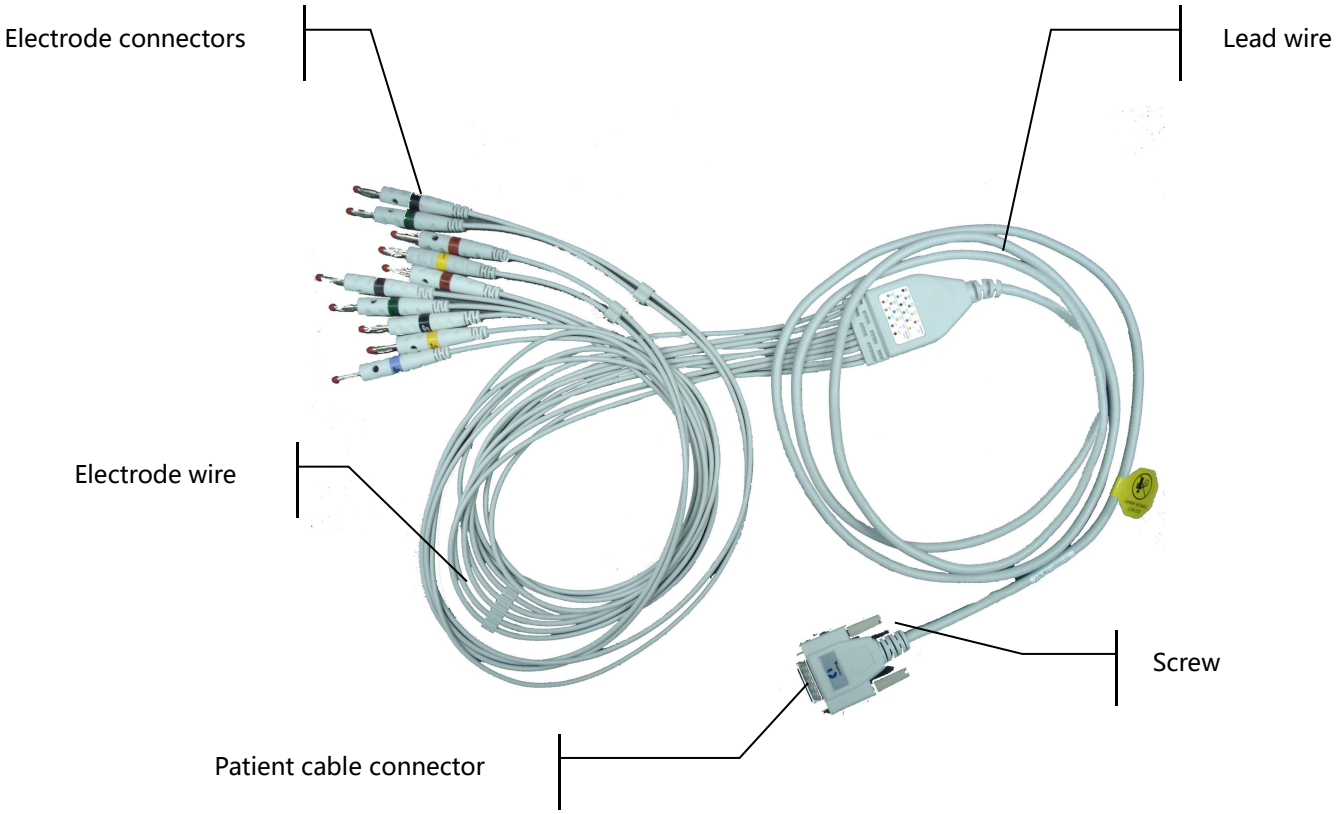


Fig. 4-2 Patient Cable

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

NOTE:

- When the lead wire is not connected or the contact is bad, the lead at the top of the screen indicates that the lead is off and the device is not working properly.

WARNING:

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

4.4 Electrodes Connection (CF Application Part)

Chest Electrode:

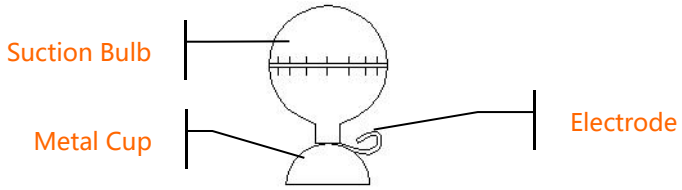


Fig. 4-3 Chest Electrode

Limb Electrode:

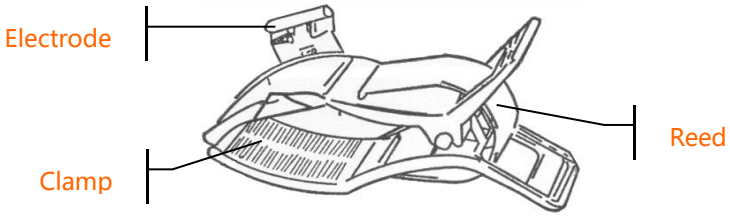


Fig. 4-4 Limb Electrode

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

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

Table 4-1 Electrodes, Identifier and Color Code

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

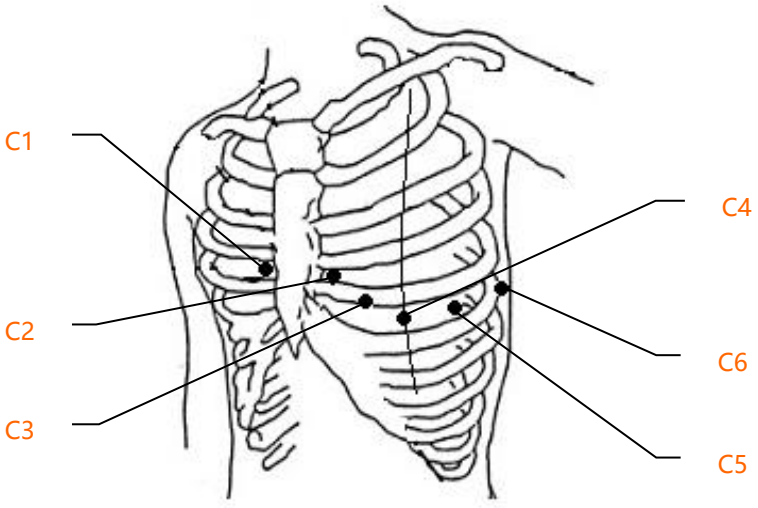


Fig. 4-5 Chest Electrode Positioning

C1: Fourth intercostals space at right border of sternum

C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

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

C6: Left midaxillary line at the horizontal level of C4

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

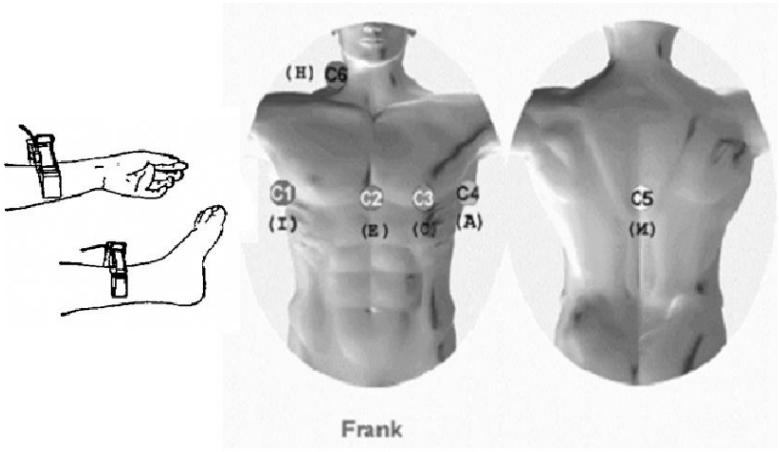
Chest Electrodes Connection:

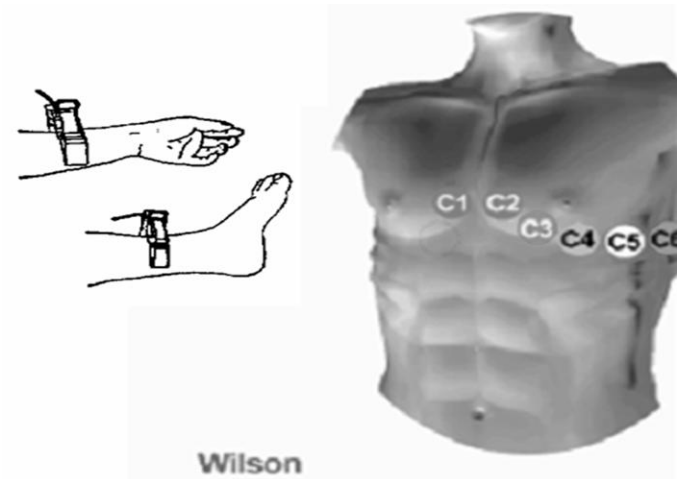
1. Ensure the electrodes are clean;
2. Align all lead wires of patient cable to avoid twisting, and connect the associated electrode connectors with corresponding electrodes according to the color and identifier;
3. Clean electrode area on chest surface with alcohol;
4. Daub the round area of 25mm diameter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

then the electrode is adsorbed on chest. Attach all chest electrodes in the same way.

Limb Electrodes Connection:

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





⚠WARNING⚠:

- Be sure that all electrodes have been connected to the patient correctly before operation.
- Be sure that the conductive parts of electrodes and associated connectors, including neutral

electrode, should not contact with earth or any other conducting objects.

- There is no danger when using the ECG with electrical stimulation equipment. However, the stimulation units should only be used at a sufficient distance from the electrodes. If in doubt, the patient should be disconnected from the device.
- Electrodes with defibrillator protection should be used while defibrillating.
- Do not touch the ECG Shell case during defibrillation.

4.5 Inspection before Startup

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

1) Environment:

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

2) Power Supply:

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

3) Grounding:

- Check the grounding cable is properly connected.

4) Patient Cable:

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

5) Electrodes:

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

6) Recorder Paper:

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

7) Patient:

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

8) AC Filter Frequency

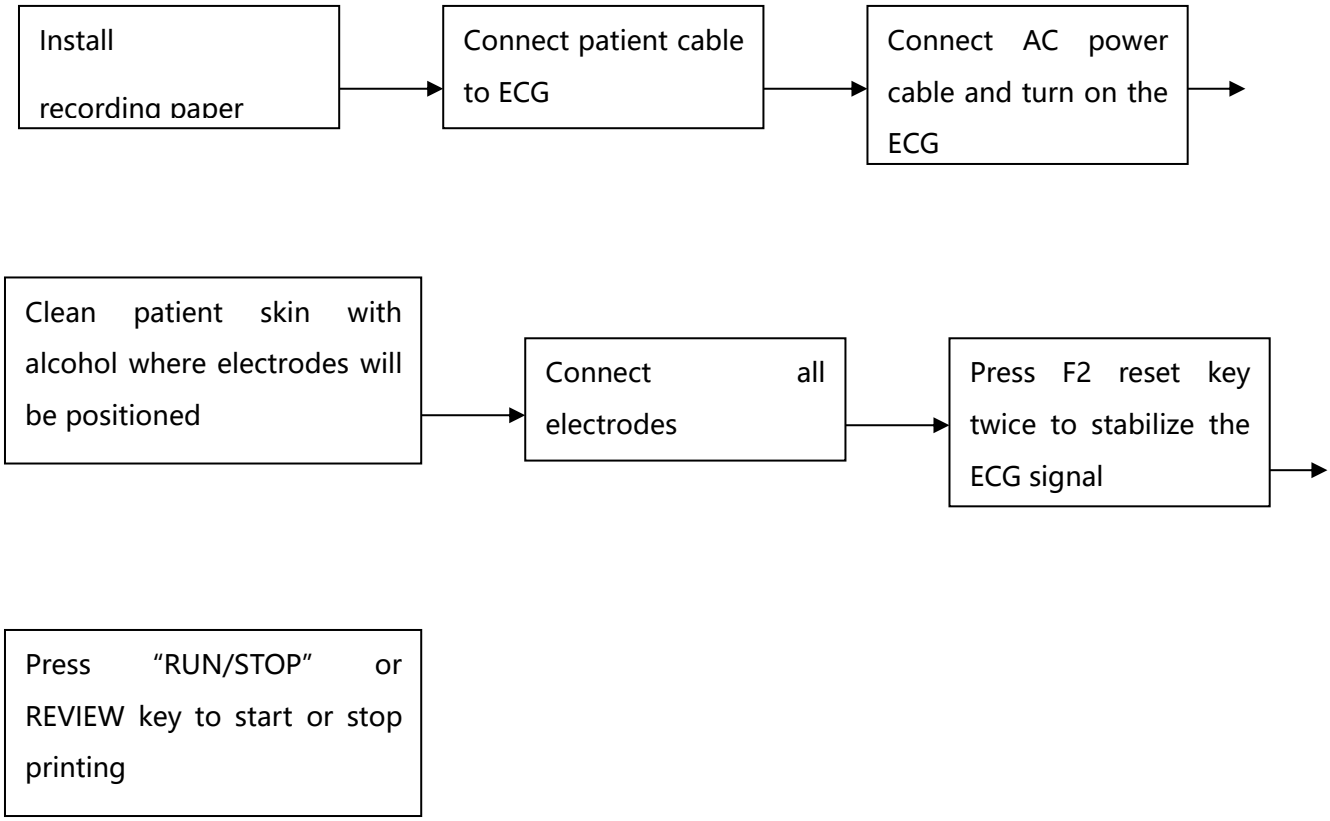
- Check the setup of AC Filter Frequency and make sure is identical with the local regulations, or it will influence the anti-jamming effect.

⚠WARNING⚠:

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

Chapter 5 Operation Instructions

Basic operation procedures



NOTE:

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

5.1 Power ON/OFF

5.1.1 Power ON

- When AC power supply is applied, press the power switch, and the AC power supply indicator (∿) is lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Such information as name, manufacturer and version No. etc., will be displayed in LCD screen after self-test. Then the ECG is ready for examination and recording.
- When external DC power supply is applied, both the two indicator lamps will be constant lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Such information as name, manufacturer and version No. etc., will be displayed in LCD screen after self-test. Then the ECG is ready for examination and recording.
- When using built-in rechargeable lithium battery, press ON/OFF key for about three seconds on the control panel directly to turn on the ECG, and then the AC power supply indicator and the battery indicator are not bright. Equipment information such as name, manufacturer and version No. etc., will be displayed on LCD screen after self-test. The ECG is ready for examination and recording. When the battery symbol becomes "▯", the battery is low, and the equipment will be automatically turned off in 1 minute. In this case, use AC power supply to continue operation and the battery will be simultaneously recharged.

Fig. 5-1 Startup Interface

NOTE:

- LCD back light will be automatically turned off within 1 minute without any operation, and the ECG will be automatically turned off within 3 minutes without any operation when the ECG is powered on by battery.

5.1.2 Power OFF

NOTE

The instrument cannot be switched off when it is in menu interface, it can be switched off only in main interface.

1) When battery is the power supply, Press "  " to switch off after examination.

2) When AC is the power supply, Press "  " after the examination then turn off the AC switch and plug out the AC power cable.

3) When DC is the power supply, Press "  " after the examination then plug out the DC power cable.

4) When battery is the power supply, the backlight will automatically turn off without operation within 60s. If there is no operation within 3 minutes, the ECG will turn off automatically. When AC power is applied, it will enter power-saving mode automatically if there is no operation within 3 minutes.

NOTE:

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

5.2 HELP

Press " 

" or touch " 

" on the screen, and then enter HELP menu. After that, you' ll see the electrode position diagram, basic information about ECG, common trouble shooting and so on. Press " 

"," 

" to scroll the page. Press "ESC" or touch "X" to return to main interface. It has two languages for you to switch, i.e. English and Chinese.

5.3 Info

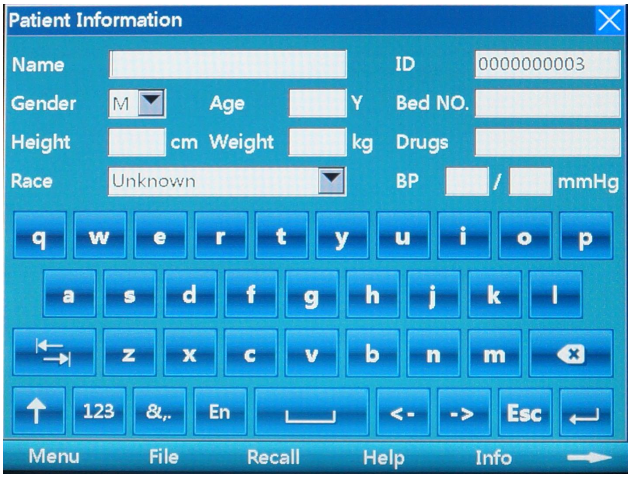


Figure 5-2 Info Interface

Press 

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

Name	Patient’ s Name (20 characters or 10 Chinese words)	**Race**	Asians, White People, Black People, Pacific Island Residents and American Indians, unknown
Gender	Male/Female/Empty	**ID**	Patient’ s ID (10 digits)
Age (Y)	Patient’ s Age (3 digits)	**Bed No.**	6 digits
Height (cm)	000-999 digits	**Drugs**	20 characters or 10 Chinese words
Weight(kg)	Patient’ s Weight (3 digits)	**Blood Pressure (mmHg)**	Patient’ s systolic and diastolic pressure (000-999 digits)

Table 5-1 Items Editable in 1106L

5.4 File

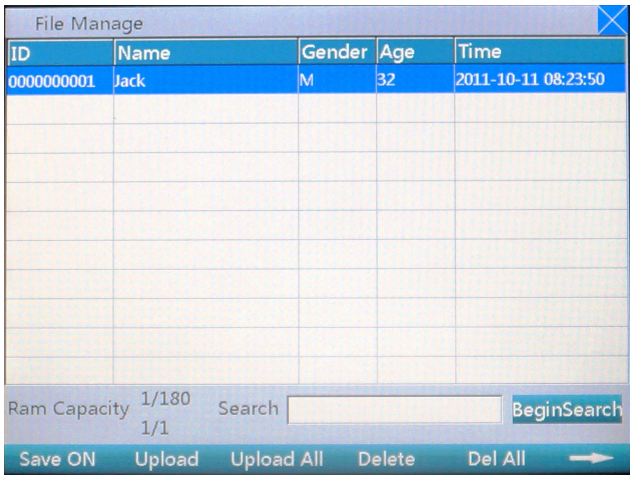


Fig. 5-3a Storage 1

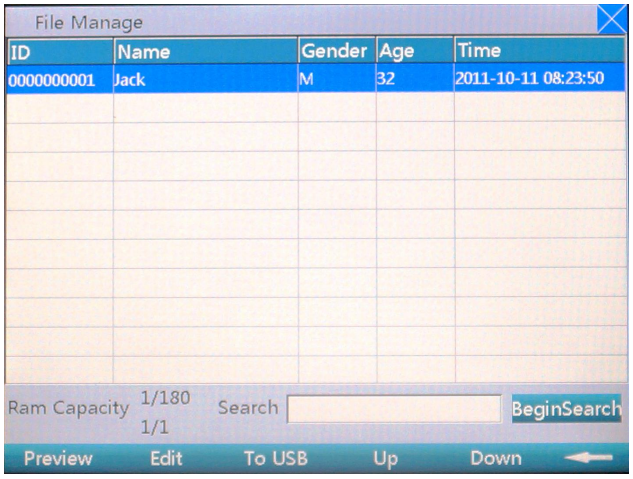


Fig. 5-3b Storage 2

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

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

2. Storage Selection Settings: storage is on the bottom of the "file" interface. From left to right, it is Save ON/OFF, Upload, Upload All, Delete, Delete All and PgDn in order; When press "PgDn", from left to right, you can see Preview, Edit, To USB, Up, Down and PgUp.

- **Save ON/OFF**: It's a storage main switch. Users must turn SAVE on and press "RUN/STOP" in the main interface, then the ECG files will be saved to the Flash of ECG monitor; otherwise, it won't save. The stored ECG files can review under FILE interface.
- **Upload**: Upload the selected case to the PC
- **Upload All:** Upload all the cases to the PC
- **Delete:** Delete the selected case in dark blue background
- **Delete All:** Delete all cases
- **PgDn:** Switch to next function page
- **Preview**: Preview case

- **Edit:** After enter the “File”, users can edit the patient information
- **To ECG:** Import the ECG FILE of USB/SD card to ECG monitor.
- **Up**: Choose up cases
- **Down:** Choose down cases
- **PgUp:** Switch to previous function page

5.5 Freeze

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

5.6 Recall

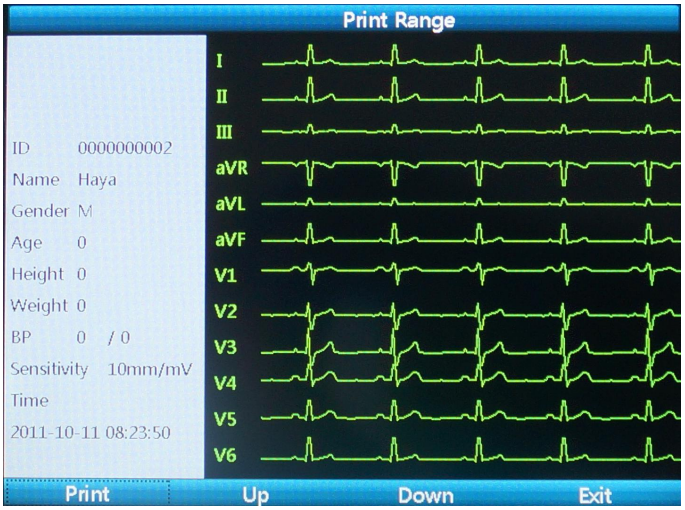


Fig. 5-4 Recall Interface

To recall the previous print-out data. Press the “Recall” key to enter the recall interface and press “Exit” to exit.

The key only functions at the situation which a report has been finished or cases are saved in auto mode.

The recall interface is included preview information display zone and waveform recall display zone, there are 8 setting items, and the display is fixed to 12*1 type.

F1~F4: related to the 4 functional items on the bottom of screen.

5.7 Operation Menu

5.7.1 Menu

Fig. 5-5 Menu Interface

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

As shown in Fig. 5-5, main interface is divided into 10 submenus, Press F1, F2, F3, F4 to select, Press "  " or with touch screen function to select.

5.7.2 Set the Printing Parameters

Fig. 5-6 Print Setting Interface

Choose the **Print Setup** after entering the menu, press F1 or touch the screen to select functional

item. Press F2, F3 to select the sub-item, press F4, F5 to input information in setting item of the cursor flashing. After all is set, press "OK" or  to save and exit to main interface; or Press "Cancel" or  to exit and the settings will not be saved.

NOTE

If the items do not have sub-item, it is item of manual input.

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 Deepen	No
4	Time Marker	ON/OFF
5	Print Grid	Off
6	Print Device	Thermal, HP DJ1000, HP M401D. The default is thermal printer
7	Minnesota Code	ON/OFF
8	Measure	ON/OFF
9	Analysis	ON/OFF
10	Template	ON/OFF
11	R-R Time	60s, 180s
12	Print time	Users enter manually (5~30s)
13	Period Interval	Users enter manually (1~60 minutes)
14	Period Duration	Users enter manually (1~60 minutes)

Table 5-2 Print Setup Table

- 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.

- Please refer to【Period Sample】in **Chapter 5.7.3** for the instruction of Period Interval and Period Duration.

Table 5-3

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 5-7 Work Mode

Table 5-4

No.	Parameter	Options
1	Auto Print Mode	6T×2, 3×4+3rhy, 3X4+1rhy, 3X4, Template
2	Man. Print Mode	6CH, 3CH+3rhy, 3CH+1rhy, 3CH, Test Mode
3	Sensitivity	2.5mm/mv, 5mm/mv, 10mm/mv, 20mm/mv, 40mm/mv, Auto
4	Print Sequence	Sequential, Simultaneous
5	Sample Mode	Pre-Sample, Real-time Sample, Period Sample, Trigger Sample
6	Rhythm mode	Single lead
7	Work Mode	MAN, AUTO, RR ANA
8	Auto Upload	On/Off
9	Demo	On/Off
10	HR Limit	To set the HR value (0~250) manually
11	Preview	Off

1. Work Mode: AUTO-MAN-RR ANA

2. Print Sequence: Sequence, Simultaneous

3. Sample Mode:

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

- **Real-time Sample:** Press "**START/STOP**" **,** it will transmit the real-time 10s ECG information immediately.
- **Period Sample:** First of all, set "**Period Interval**" and "**Period Duration**" in the "**Print Setup**" menu, and then return to the main interface. After that, **"Testing"** will display on the interface. If the "**period interval"** is 2 minutes, 2 minutes later it will start the printing. 2 minutes later, it will start the second printing. It will stop until it reaches the time set in "**Period Duration"** .

NOTE

User can set values of【Period Interval】and【Period Duration】from 1 to 60(minutes) each, and Period Duration should be greater than Period Interval.

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

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

   6Tx2: Print time can be set;

   3x4+3rhy: 12 leads are displaying by 3-channel a row multiply 4 columns, plus 3 rhythm waveforms parallel.

   3x4+1rhy: 12 leads are displaying by 3-channel a row multiply 4 columns, plus 1 rhythm waveforms parallel.

   3x4: 12 leads are displaying by 3-channel a row multiply 4 columns.

   Template: Only analyzing result without waveforms printout.

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

6. 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.

- MAN Print Mode:

  6CH: print 6-channel waveforms parallel;

  3CH+3rhy: 12 leads are displaying by 3-channel a row multiply 4 columns, plus 3 rhythm waveforms parallel.

  3CH+1rhy: 12 leads are displaying by 3-channel a row multiply 4 columns, plus 1 rhythm waveforms parallel.

  3CH: 12 leads are displaying by 3-channel a row multiply 4 columns.

- 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.

5.7.4 Set the Filter Parameters

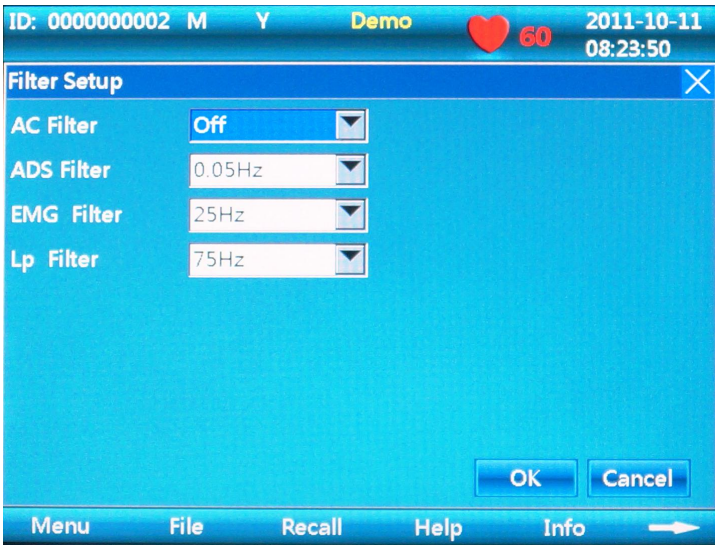


Figure 5-8 Filter Setup

1. Choose the **Filter** setting after entering the menu, and touch the "Cancel" or "X" key to exit.
2. The filter setting concludes following items: AC Filter, EMG Filter, ADS Filter, Low-passed Filter.
3. AC Filter: It has two options: on and off.

   EMG Filter: it has four options: 25Hz, 35Hz, 45Hz and off.

   ADS Filter: it has five options: 0.05Hz, 0.15Hz, 0.25Hz, 0.32Hz, 0.5Hz, 0.67Hz and off.

   Low-passed Filter: it has five options: 75Hz, 90Hz, 100Hz, 165Hz and off.

5.7.5 Lead Sequence

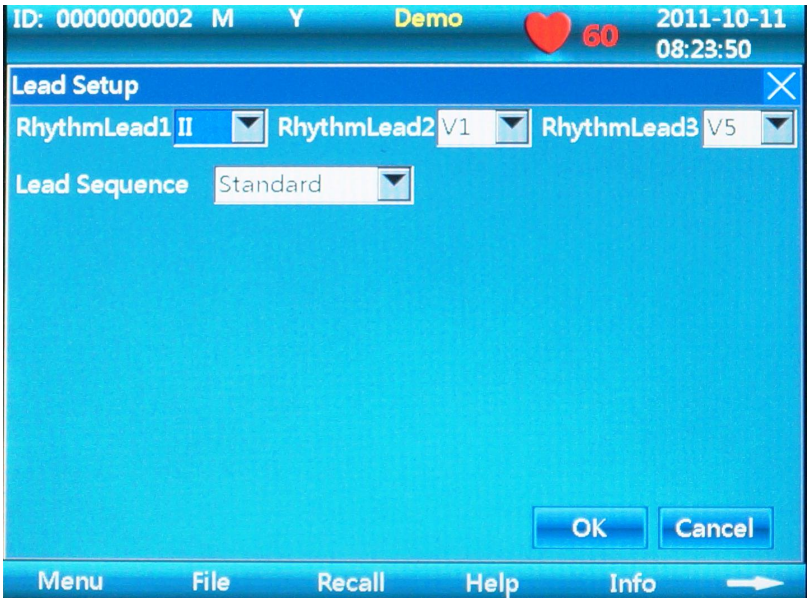


Figure 5-9 Lead Setup

Table 5-5

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 5-10 display& sound

Table 5-6

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

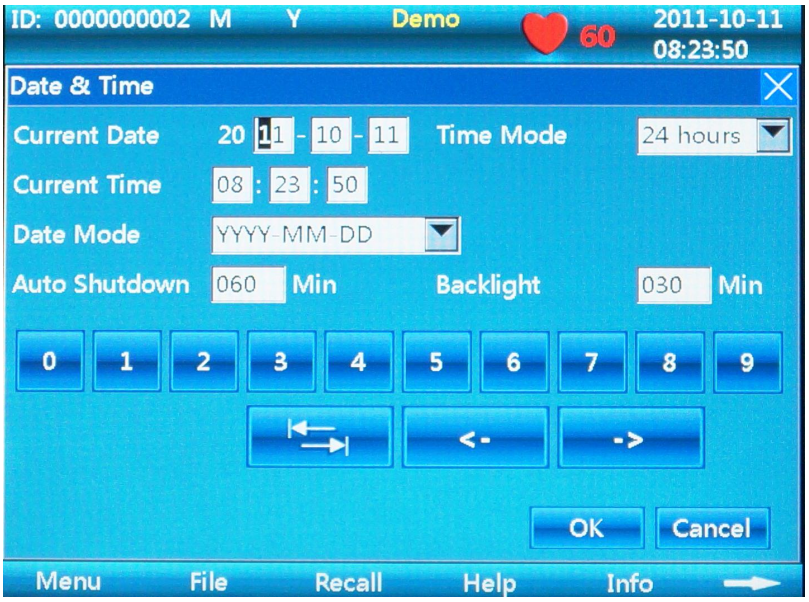


Figure 5-11 data& time

Press “F4”, “F5” to move the cursor, Press “F2”, “F3” to change the number, or you can touch the keyboard on the screen to input.

Table 5-8

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

5.7.8 Set the System Parameter

Figure 5-12 System Setup

Table 5-9

No.	Parameter	Options
1	Language	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

If customer select "Yes" in the "Default" item of system setup, then the content of default is shown as Table 5-10.

Table 5-10 “Default” content

No.	Setting	Default	No.	Setting	Default
1	Speed	25mm/s	25	Auto Upload	Off
2	Print	On	26	Lead Sequence	Standard
3	Print Time	10	27	Rhythm Lead 1	II
4	Print Deepen	No	28	Rhythm Lead 2	V1
5	Time Marker	Off	29	Rhythm Lead 3	V5
6	Print Grid	Off	30	AC Filter	ON
7	Print Device	Thermal	31	ADS Filter	0.05Hz
8	Minnesota Code	On	32	EMG Filter	Off
9	Measure	ON	33	Low Pass Filter	75Hz
10	Analysis	ON	34	All Beeper	Medium
11	Template	ON	35	Brightness	Standard
12	RR Time	60 s	36	Wave Processing	Off
13	Period Interval	001 Min	37	Date Mode	MM/DD/YYYY
14	Period Duration	060 Min	38	Auto shut down	060 Min
15	Work Mode	AUTO	39	Time Mode	24hrs
16	Print Sequence	Simultaneous	40	Backlight	030 Min
17	Sample Mode	Real-time	41	External Input	Off
18	Auto Print Mode	6Tx2	42	External Output	Off
19	DEMO	Off	43	Default	Off
20	Preview	Off	44	Pacemaker Sensitivity	Low
21	Sensitivity	10mm/mv	45	ECG Mode	Resting ECG
22	Rhythm Type	Single lead	46	Comm.Method	Off
23	Man. Print Mode	6CH	47	Storage	Save On
24	HR Limit	150			

5.7.9 Set the Communication

Figure 5-13 Communication Setting Interface

Table 5-11

No.	Parameter	Options
1	Comm. Method	Off, Ethernet, UART
2	Remote IP	Enter it manually
3	Local IP	Enter it manually
4	Gateway	Enter it manually
5	Subnet Mask	Enter it manually
6	Serial Baud Rate	115200 (fixed)

NOTE

When select Ethernet, Remote equipment and local equipment must be in the LAN, then set 2nd~5th items; when select UART, do not need other settings.

5.7.10 Set the Advanced Setting

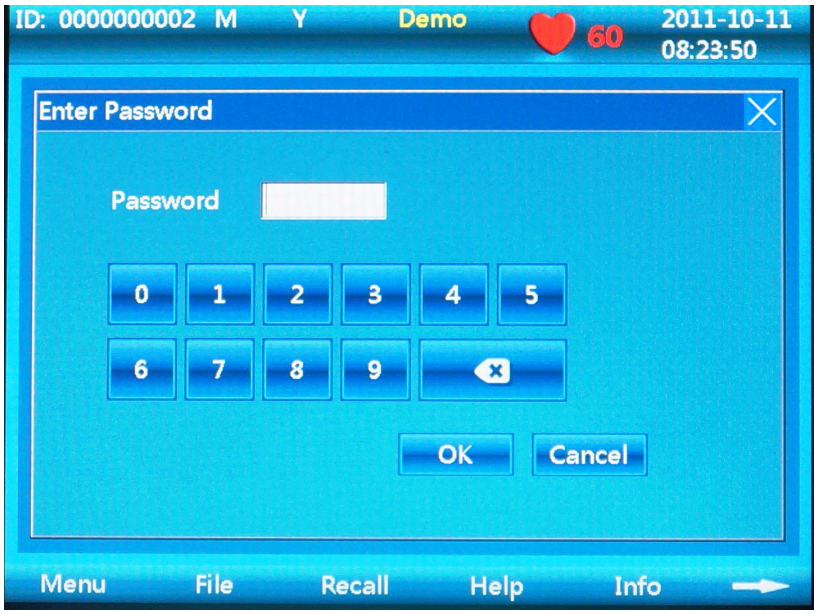


Figure 5-14 Advanced Setting Interface

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

Table 5-12

No.	**Parameter**	**Options**
1	Local ID	Set local ID (16 digits)
2	MAC Address	Set MAC Address
3	Wireless Address	Set wireless address
4	Software Version	V2.0
5	Algorithmic Version	V2.0

5.7.11 Institution

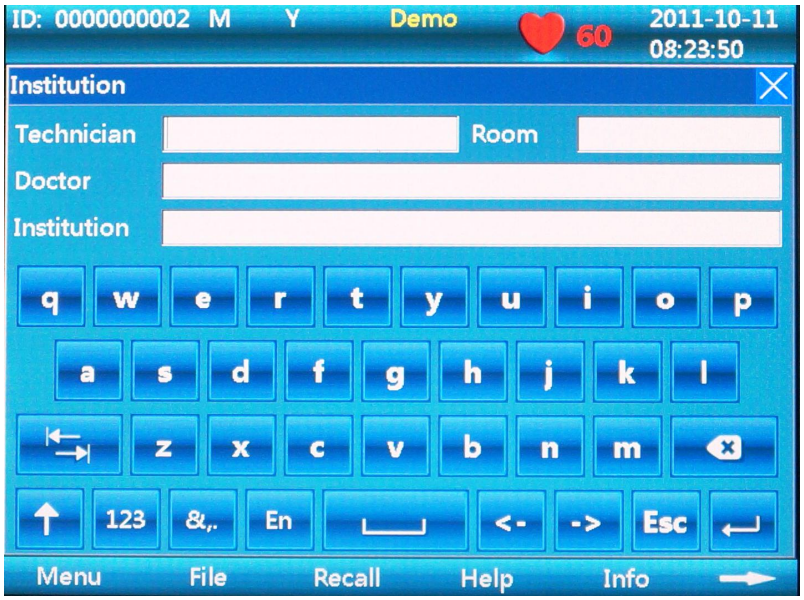


Figure 5-15 Institution setting interface

Table 5-13

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 Function

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 "F1+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.

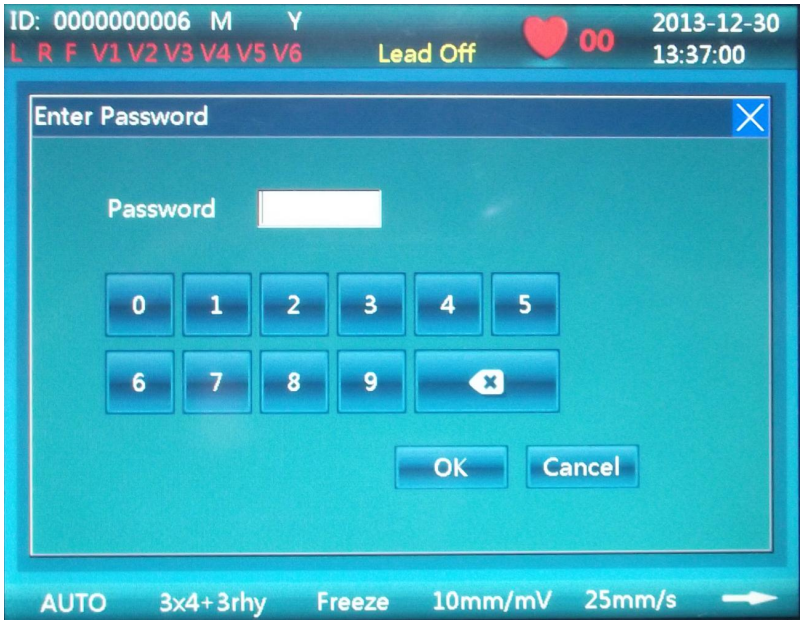


Figure 5-16

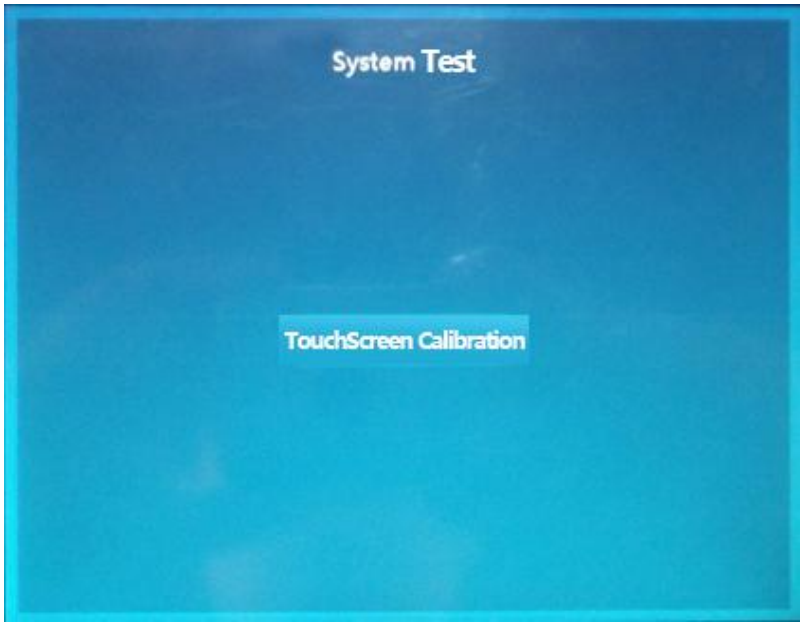


Figure 5-17

NOTE

In the "Enter Password dialog", if touch screen cannot work, there is another way to enter the calibration interface: press F1 first, then press 10 times  .

Chapter 6 Hint Information

Any hint information may appear during operation of ECG-1106L such as "Lead-off", "No Paper", "No battery" is listed in Table 6-1.

Table 6-1

Alarm Information	**Causes**
Lead-off/the corresponding display of lead name turn to red from white	Electrodes fall off from the patient or the patient cable falls off from the unit.
No Paper	Record paper has not been loaded or it has been used out.
Over limit HR beeper	It will beep when HR is out of the value setting
~	No battery
	Low battery

Chapter 7 Cleaning, Care and Maintenance

7.1 Cleaning

NOTE:

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

7.1.1 Cleaning the Main Unit and Patient Cable

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

7.1.2 Cleaning the Electrodes

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

7.1.3 Cleaning the Print Head

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

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

NOTE:

- Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.

- Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- Be sure no cleanser remains on the unit, patient cable or electrodes.

7.2 Disinfection

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

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

NOTE:

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

7.3 Sterilization

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

NOTE:

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

NOTE:

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

7.4 Care and Maintenance

7.4.1 Recharge and Replacement of Battery

1) Capacity Identification

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

: Full capacity

: Not full but enough

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

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

2) Recharge

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

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

3) Replacement

Figure 7-1 Battery Installation

NOTE:

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

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

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

WARNING:

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

7.4.2 Recording Paper

NOTE:

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

Storage Requirements:

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

7.4.3 Main Unit, Patient Cable & Electrodes

1) Main Unit

a. Avoid excessive temperature, sunshine, humidity or dirt.

b. Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.

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

2) Patient Cable

a. Integrity of patient cable, including main cable and lead wires, should be checked regularly. Be sure that it is conductible.

b. Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connect or disconnect the patient cable.

c. Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.

d. Store the lead wires in bigger wheel to prevent any people from stumbling.

e. Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

a. Electrodes must be cleansed after use and be sure there is no remainder gel on them.

b. Keep the suction bulb of chest electrode from sunshine and excessive temperature.

c. After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. In this case, electrodes should be replaced to achieve high-quality ECG.

NOTE:

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

Chapter 8 Common Troubleshooting and Solution

1) Some Lead without Waveform Printout

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

Solution: repeat operation.

2) Vertical Broken Track of Printed Waveform

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

Solution: clean the printer head.

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

3) Failure to turn on the ECG

Possible reason: Fuses burnt

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

⚠Warning⚠:

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

4) Failure to turn off the ECG

Possible reason: menu or Sub-menu not exits

Solution: exit the menu

5) AC Interference (as shown in Figure 8-1)

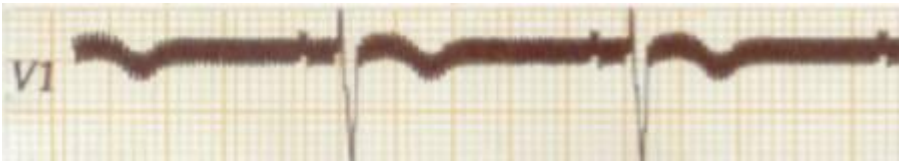


Figure 8-1

Possible reason:

a. Equipment is not properly grounded;

b. Electrode or patient cable is correctly connected;

c. There is not enough cream applied;

d. Patient bed is not properly grounded;

e. Patient bed is not properly grounded;

f. Patient touches metal part of the patient bed;

g. Somebody is touching the patient;

h. There is a powerful equipment operating nearby;

i. The patient is wearing glass or diamond ornaments;

j. AC power frequency.

Solution:

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

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

6) EMG Interference (as shown in Figure 8-2)

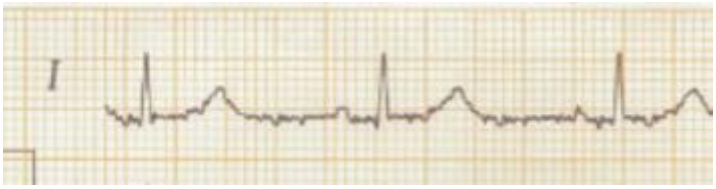


Figure 8-2

Possible reason:

a. The room is uncomfortable;

b. The patient is nervous;

c. The bed is too narrow;

d. The patient is talking;

e. The limb electrodes are tightly attached.

Solution:

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

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

NOTE:

- The isoelectric parts (I-wave) after global QRS-onset or before global QRS-offset (K-wave) are included in the duration measurement of the respective adjacent waveform.

Chapter 9 Service Warranty

1) Workmanship and Raw Material

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

2) Software or Firmware

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

NOTE:

- All services must be finished by engineers authorized by Carewell or its authorized distributor.

3) Exemption of Warranty

The charges of freight and others are excluded under warranty.

The warranty is void in the case of:

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

Service Information

Service Unit: Shenzhen Carewell Electronics, Co., Ltd.

If there is any question, please contact us immediately.

Service Contact

Receiver: Service Center of Shenzhen Carewell Electronics, Co., Ltd

Add: Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District 518108, Shenzhen, P.R. China

Tel: +86-755-8617 0389 Fax: +86-755-8617 0478

E-mail: service-intl@carewell.com.cn Website: http: //www.carewell.com.cn/

Chapter 10 Accessories

⚠WARNING⚠:

Only 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 10-1 Accessories List

NOTE

We advise you tie the touch pen on the handle of the equipment to avoid losing.

Appendix I Technical Specifications

Safety Standards	MDD93/42/EEC	Medical Device Directive
	IEC 60601-1: 2005+A1: 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-2-25: 2011	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs; Amendment 1
	IEC 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

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

Dimensions	345mm×300mm×80mm
Net Weight	2.5kgs
Display	5.7 inches 640×480 color LCD (touch screen)

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

Power Supply	Mains Supply	Rated voltage=100-240V~
		Rated frequency = 50/60Hz
		Rated input power = 60VA
	External DC power supply	Rated output voltage=12V
		Rated output current=3A
	Built-in rechargeable Battery Pack	Rated voltage = 14.4V
		Discharge cut - off voltage≥11V
		Rated capacity = 2200mAh
		Charge mode: Constant current/voltage
		Charge current (standard) < 0.2C5A (400mA)
		Charge voltage (standard) = (16.8±0.1V)
		Charge time ≥ 8h
		Cycle life ≥ 300 times
	Fuse	T2AL250V Ø5×20

Recorder	Record Mode	Thermal dot-matrix printer
	Recording Paper	Rolled thermal-sensitive paper
	Paper Width	Rolled paper: 112 mm
	Effective width	Rolled paper: 104 mm
	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
	Sampling Rate:	8000Hz
	Input Circuit	Floating, protection against defibrillator effect
	A/D Switch:	24 bit
	Time Constant:	≥3.2s
	Frequency Response	0.05Hz ~ 165Hz
	Sensitivity	Auto, 2.5, 5, 10, 20,40 (mm/mV) ±5 %
	Input Impedance	>50MΩ (10Hz)
	Input Circuit Current	≤50nA
	Input Voltage Range	±5mVpp
	Calibration Voltage	1mV±3%
	Depolarization Voltage	±500m V
	Noise	<15μVp-p
	Filter	EMG Filter: 25/35/45Hz
		ADS Filter: Yes/No
		HUM Filter: Yes/No
	CMRR	≥120dB
Patient Leakage Current:		<10μA (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	The 1106L ECG is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group I	The 1106L Electrocardiograph (ECG) 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 A	
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			
The 1106L Electrocardiograph (ECG) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the 1106L ECG 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 a. c. mains voltage prior to application of the test level.			

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

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The 1106L Electrocardiograph (ECG) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications
equipment should be used no closer to any part of the 1106L ECG including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3,5}{V_1}]\sqrt{P}$
$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b
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).
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

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 1106L ECG is used exceeds the applicable RF compliance level above, the 1106L ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 1106L ECG.

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

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

Recommended separation distances between

portable and mobile RF communications equipment and the 1106L ECG

The 1106L Electrocardiograph (ECG) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or 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.

Shenzhen Carewell Electronics Co., Ltd.

Head Office Address: Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park,

Songbai Road, Xili Street, Nanshan District 518108, Shenzhen, P.R. China

Tel: +86-755-8617 0389

Fax: +86-755-8617 0478

Web: www.carewell.com.cn

Email: info@carewell.com.cn