Digital Electrocardiograph

Operation Manual

Model: ECG-3306G

Date: 2014-03-01

File No.: MNU-ECG3306G-01-Rev.C1

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Statement of the Manufacturer

Thank you for choosing the electrocardiograph produced by our company. This manual refers to the working principle, safety precautions, operation and use methods, maintenance and repairing, packaging, storage and transportation of this machine. Please read this manual carefully before use.

The preparation of this manual complies with the relevant standards of IEC60601-1 "General Instructions for the Use of Industrial Products" and the "Management Regulations on the User Manual and Labels of Medical Devices" in National Code for Quality Management of the Production of Medical Devices. The company has the non-public publishing copyright of this manual. No individual or organization should modify, copy or translate part or the entirety of the use manual without written permission of our company.

The contents of this manual have been closely checked. We keep the right to revise this Operation Manual and to change the product description at any time.The content may be subject to change without previous notice.

Responsibility of After-Sales Service

The company is only responsible for the performance and reliability of the instrument under the following conditions:
® Assembly, commissioning, and repairing are performed by personnel approved by the company.
® The relevant electrical equipment complies with national standards.
® Using the instrument in accordance with the operation manual.

Information of the Operation Manual

Version	=== Revision Description ===	Date
C1	First release (in compliance with the latest standards)	2014/03/01
Language	English, Chinese, Spanish, French, Portuguese (Please specify before ordering.)	

NOTE: This device is not intended for home use.

WARNING: This device is not intended for treatment.

WARNING: This instrument is intended for use by trained professionals or medical institutions.

Content

Section 1 Safety Guidance

The design of the Electrocardiograph (ECG) complies with IEC 60601-1 / GB 9706.1-2007 (Medical Electrical Equipment: General Requirements for Safety) and IEC 60601-2-25 / GB10793-2000 (Medical Electrical Equipment: Particular Safety Requirements for Electrocardiographs). The classification of this equipment 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. The device is not water-proof type. Please avoid water splashing when using. It is also not explosion-proof. Please do not use it in the presence of flammable anesthetics.

The device complies with the standards of IEC 60601-1-2 / YY0505-2012 about the electromagnetism compatibility. When in the environment where the electromagnetism is beyond the limit of the standard, the device may not work properly. When the abnormal interference appears, please check and clear all the electromagnetism interference before the operation.

About Power Supply and Environment Requirements of the device please refer to [Appendix A : Specification and Electrical Characteristics]

1.1 Warning

✧ The user of the device must be qualified with professional training and should be very familiar with the content of this manual.

✧ Before using the device, the user must check the equipment, cables and accessories carefully to ensure that they can work properly and safely.

✧ Do not use the ECG in the presence of flammable anesthetic mixture with oxygen or other flammable agents.

✧ Avoid electric shock hazard. While using the device, please connect the device to the ground port to ensure good grounding. Please use the socket with protective grounding and ensure the protective grounding of the socket in good situation.

✧ Before connecting or disconnecting the power cord to the device, please make sure the device is power off and the power cable is disconnected to the AC power socket. Or it may cause electric shock or other harm to patient or operator.

✧ If there is any doubts about the integrity of the protective grounding cable, please disconnect the AC power and use the built-in rechargeable battery.

✧ When using an electrocardiograph, there should be no high-power equipment around, such as high-voltage cables, X-ray machines, ultrasound equipment and electrotherapy machines. It is also should not be used in the environment with high static. Otherwise the normal performance and work of the device may be affected by electromagnetic interference.

✧ Do not open the shell of the device, otherwise there may be a danger of electric shock. Repairing or upgrading the device requires professional after-sales personnel.

✧ The electrocardiograph should avoid contact with water and avoid storage or using in site with excessive atmospheric pressure,over -standard temperature and humidity, poor ventilation situation, excessive dustiness, or with gas mixed with sulfur or saline-alkali, or with chemicals.

✧ The electrocardiograph should be placed in a flat place while, and should be handled gently when moving in avoid of excessive vibration and drop.

✧ The ECG machine only allow to connect with other equipment of Class I which comply with the standards of IEC60601-1. The total patient leakage current caused by using several devices at the same time may bring harm to patients. The monitoring of patient leakage current should be carried out by the person who connects the devices and he should take responsibility. The operator should pay more attention in correct connection in avoid of wrong diagnosis or other problems. Please consult the technical staff if necessary.

✧ Using ECG machine and other ECG monitor to monitor the same patient may cause mutual interference.

✧ The electrodes and connectors of the electrocardiograph can only be in contact with the patient and should not touch other conductor components, including not touching the ground.

✧ When the machine is working, the medical staff should not leave the working site and should pay attention to the patient. If necessary turn off the power or remove the electrodes to ensure the safety of patients. If any abnormality occurs during the usage, please shut down the machine and check immediately.

✧ Chemicals released from a broken LCD may cause poison. Please carefully deal with the device which the LCD is broken.

✧ The ECG machine is an anti-defibrillation internal power supply Type CF device. The application part of the device can not be directly applied to the human heart.

✧ If the ECG machine is used with defibrillator or other electric stimulation devices, the users should use the anti-defibrillation patient cable and electrodes supplied by our company. If the defibrillation time is over 5 seconds or using with a high-frequency surgical knife, the disposable electrodes must be used to prevent the metal electrodes burning the skin of patients. If the ECG machine is used with other electronic stimulators, there should be professional technical staff in present to instruct.

✧ When the ECG machine is used with a pacemaker or other electrical stimulators, professional technical staff should be in present to instruct and there should be enough safety measures, in avoid of serious injury or death.

✧ An instantaneous high voltage will e released from the defibrillator during the operation of defibrillation. Do not touch the patient, otherwise it may cause serious injury or death.

✧ To prevent the spread of infection, the following precautions should be taken: (1) Take regular cleaning of all parts in contact with the patient; (2) Avoid making electrocardiogram examination of patients with open infectious ulcers.

✧ The quality of the ECG signal acquisition can be affected by specific environmental conditions, the user's misuse, and certain conditions of the patient. For the relevant safety information, please refer to the corresponding section of this Operation Manual.

✧ The patient cable, limb electrodes and chest electrodes equipped with the ECG machine are consumables.Their high usage frequency is easy to cause component consumption, which may lower the anti-interference capacity of ECG machine. The performance of the patient cable and the electrodes is required to be examined regularly. It is recommended to check at least one time per month.

✧ Using unspecified ECG recording paper may shorten the usage life of the printing parts of the ECG machine and it may result in unclear waveform.

✧ The ECG machine is only an auxiliary measure of diagnosis. It must be used in conjunction with the clinical manifestations and symptoms, as well as doctors' diagnosis.

✧ Accuracy of input information reconstruction: Test method for system error and frequency response, please refer to the descriptions of IECG60601-2-25. Due to the sampling characteristics of the system and the asynchronousness of the sampling rate and the signal rate, the digital system may produce an appreciable modulation effect from one cycle to the next, especially in the case of electrocardiogram measurement in children.

✧ When the device is connected to any external equipment powered by the network power supply, it should ensure the connection comply with the safety requirements of medical electric system stipulated in IECG60601-1. If necessary, the external equipment should be powered by the isolation transformer. Any medical equipment connected to the device must comply with the safety requirements stipulated in IECG60601-1. Any non-medical equipment connected to the device must comply with relevant product safety standards. If in doubt, please consult the manufacturer or the local distributor.

✧ Connecting any accessory (such as an external printer) or equipment (such as a computer) to an ECG machine can form a medical system. Additional safety measures should be taken when installing the system, and the system should:

a) In the patient environment, meet the equivalent safety level of medical electrical equipment required by IECG60601-1, and

b) Outside of the patient environment, meet the relevant safety level of non-medical electrical equipment required in other national safety standards (or IEC or ISO safety standards).

1.2 Safety warnings for battery

⚠ **WARNING**

✧ Improper usage may cause the battery become hot, catch fire, explode, destroy or the attenuate of the battery capacity. Please read this manual and precautions carefully before using the built-in rechargeable battery (hereinafter named as 'battery').

✧ Only professionally trained service engineers are allowed to replace the battery. The replaced battery must be with the same specification as the one configured in factory.

✧ It is forbidden to use metal to cut into the battery or violently hit the battery. Otherwise, the battery will be heated, smoked, deformed or burned, and will pose a danger.

✧ If the built-in battery is not used for a long time, please charge and discharge the battery at least every six months.

✧ While install or taking off the battery, it must keep the ECG machine power off. Otherwise white screen or system crash will happen.

✧ If the device is not used for long time, please take out the battery and store it separately, to prevent battery leakage corroding the device.
✧ Warning: Do not disassemble the battery without the guidance of a professional technical personnel.
✧ Warning: Prevent the battery being splashed by water and do not throw the battery into water.
✧ Warning: Do not place the battery near an open flame, otherwise there is a danger of explosion.
✧ Warning: Do not directly connect the positive and negative terminals of the battery. Otherwise there is a danger of fire.
✧ Warning: The battery should be handled gently and must not fall on the ground or collide with other items.
✧ If the electrolyte of the battery leaks onto your skin or clothing, wash it off with water immediately. If the electrolyte gets into your eyes, do not rub your eyes, wash them immediately with clean water, and ask a professional doctor.
✧ When the battery reaches the end of life (such as capacity reduced, not able to be charged, etc.), or if the battery leaks, emits an odor, and is deformed, please stop using the battery and dispose of the used battery according to local regulations.
✧ The transportation of the ECG machine with built-in battery should comply with the relevant regulations. Please refer to the requirements of the latest version of Section 3 Item 38.3 (UN38.3) (Currently Rev.6) of the 'United Nations Handbook on Transport Tests and Standards for Dangerous Goods'.

⚠ **WARNING**
✧ This device should avoid environment of high pressure, high temperature and high humidity. Please pay attention to ventilation, and avoid contact with dust, sulfur/salt/alkaline gas.
✧ Please prevent the device being splashed by water and avoid using, transportation and storage in high temperature environment. The proper temperature range is stipulated in this manual.
✧ Make sure that there is no strong source of electromagnetic interference, such as wireless transmitters or mobile phones, in the installation and use environment of this device. Please note: Large electrical equipment such as electrosurgical equipment, ultrasound equipment, radiology machines, and magnetic resonance imaging equipment may cause electromagnetic interference.
✧ To avoid being scalded, do not touch the print head immediately after printing, at which point the print head temperature may be high.
✧ To avoid malfunctions, please do not press the buttons and touch screen with sharp or hard objects. It only allows fingertips to press.
✧ If the device has any abnormality during the usage, it should be maintained by a qualified service engineer.
✧ Before turning the device on, make sure that the voltage and frequency of the power supply meet the requirements on the label of the device or the requirements specified in this manual.
✧ When the fuse needs to be replaced, it only allows to use the fuses supplied by the manufacturer.
✧ Please use the patient cable and other accessories supplied by the manufacturer, otherwise it may affect the performance and safety of the device.
✧ Please use the electrode specified in this manual. It is forbidden to use isometallic electrodes, otherwise it will cause excessive polarization voltage.
✧ Using unspecified recording paper may shorten the use life of print parts and make the recording waveform unclear.
✧ The ECG machine is a measuring device. The users should send the device to legal measurement department to calibrate according to the relative requirements of IEC60601-2-25 about electrocardiograph verification regulations'. The verification period must not exceed 1 year.
✧ Radio receivers (such as televisions and radios) will bring electromagnetic interference. Please keep the device away from radio receivers.
✧ The communication cable (USB/RS232) connected to other equipment should have good electrical isolation and electromagnetic shielding, and the length should not exceed 3 meters. The communication cable configured by the manufacturer is suggested.
✧ Please do not maintain the ECG machine during usage
✧ The ECG machine disconnect from the grid by means of a connector or a power plug. The ECG machine should be placed in a position where the user can easily disconnect the grid.
✧ Indicator for abnormal operation of ECG machine including ECG signal overload indication, filter indication added to suppress interference, overheat indication caused by continuous work of print head, etc., and description of other phenomena.

✧ The inner and outer packaging materials of the device are in compliance with environmental protection requirements, and the packaging materials, the device and its accessories should be properly disposed of at the end of the life to meet the requirements of environmental protection regulations. After the end of its use life, the device and recyclable parts can be returned to the manufacturer for recycling or disposed of in accordance with local regulations.

1.3 Symbols about the device

	Output		DC Power		Potential Equalization
	Input		Charging Indicator		Filter
	Defibrillation-Protected Type CF		Recording Mode		INST
	Attention! Should refer to the Operation Manual.		AC Power		1mV Calibration
	Refer to the Operation Manual.		Menu		ECG File Management
PATIENT	Patient Cable Socket		Sensitivity		Run/Stop
	USB Interface		Patient		Power On / Off
SD	SD Card slot		Network port		Help
	Recycling		File	EC REP	Authorized European Representative
SN	Serial Number		Equipment Grounding End		Non-ionizing radiation
CE 0123	CE Certification		Refer to the Operation Manual		Lack of paper

Section 2 Product Description

2.1 Model configuration

Lead	Record format	Paper width	LCD	Touch Screen	Number of keys	Battery	Cases Storage	Bar Code Scan	USB
12 leads	3ch+, 3ch+++, 6ch	112mm	7inch	Yes	10	14.4V, 2200mAh	250	Optional	Optional

Remark: In the recording format,3ch+ means the waveform of three channels plus the waveform of one rhythm lead. 3ch+++ means the waveform of three channels plus the waveform of three rhythm leads, and so on so forth.

2.2 Software version

Main software release version	MAIN-V2.30
Acquisition software release version	AMP12-V2.5 (12 leads)

2.3 Structure and composition

The device consists of a host, an ECG patient cable, a ground wire, limb electrodes clip and chest electrodes.

2.4 Scope of application

The device is used to extract the electrocardiograph waveform group to make morphology and rhythm analysis for clinical diagnosis and research.

2.5 Software description

	Main Software	Acquisition Software
Hardware Configuration	LPC1788 Processor (NXP) + K4S561632N (32M SDRAM)+ SST25VF032 (4MB SPI FLASH)+ K9F2G08 (256MB NAND FLASH)	LPC1114 Processor (NXP) + MCP3208 12bitADC (AMP12)

This device is an embedded system. It does not require other software environments and network conditions, and does not need to install anti-virus software and firewall.

⚠ **WARNING**

The update of the software (hardware) requires special software / hardware supplied by the company. The end user cannot update the software (hardware).

2.6 Communication description

2.6.1 Interface description

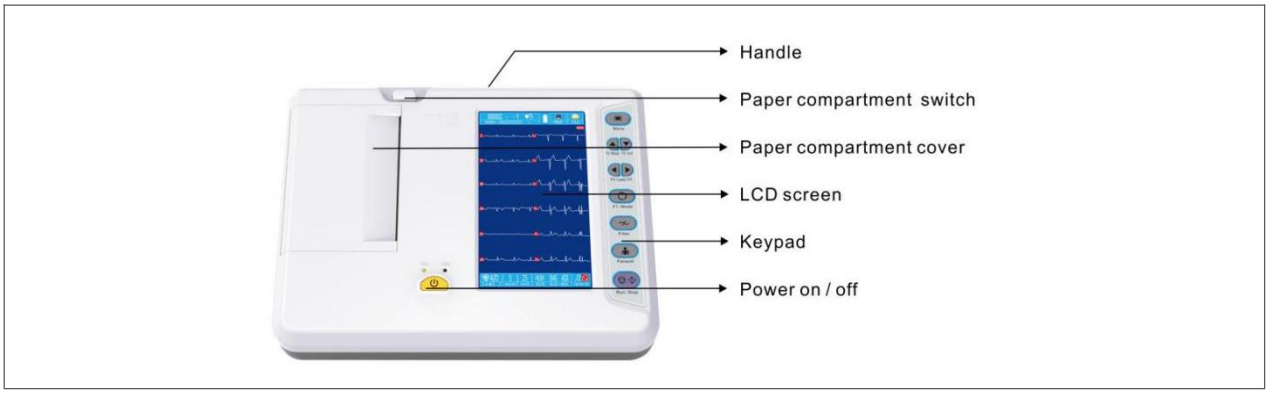
Data communication type	Transfer Protocol	Storage format
USB	USB2.0	U-disk (FAT32format)
UART	UART	115KBPS (3.3V level)

2.6.2 User access control

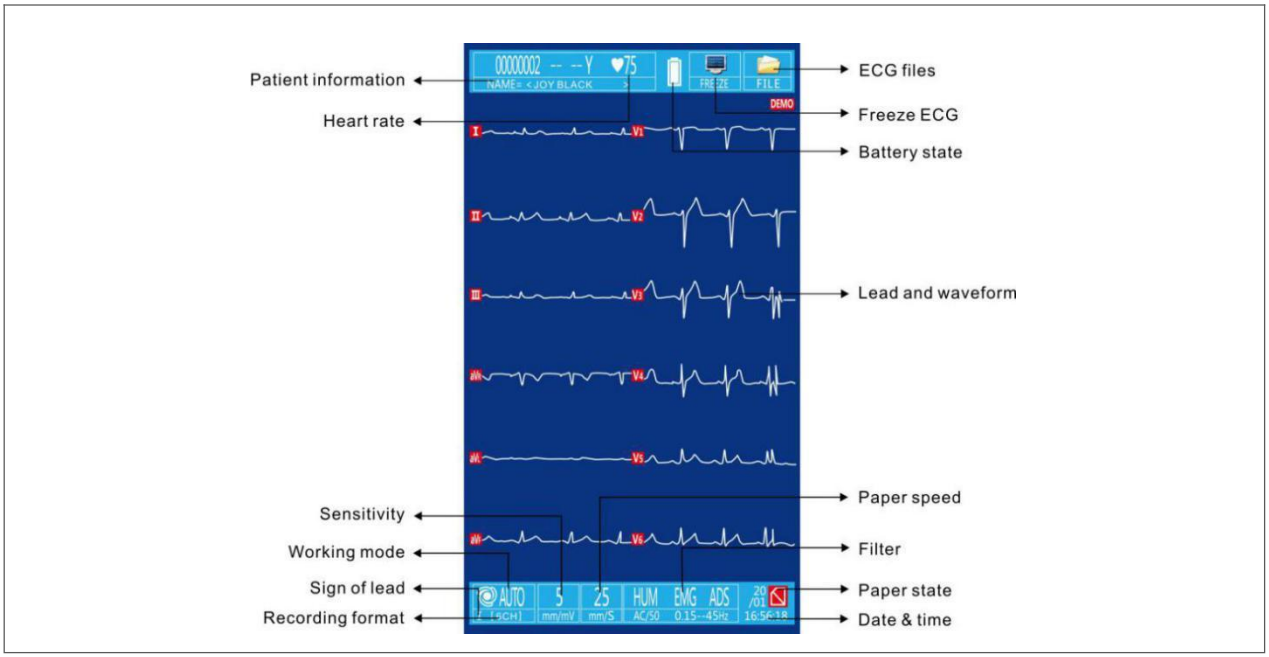
When special software is required to communicate with the ECG machine, the user is authenticated by the special software and the user type and authority are provided.

Section 3 Structure & Function

3.1 Front panel



3.2 LCD display



3.3 Bottom / Lateral panel

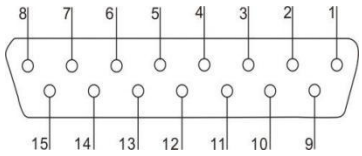
3.4 Keypad panel and functions

	≃	Power Indicator.
	⇥□	Battery Charging Indicator.

	⏻	Power on / off. Press it to turn on the device; Press it for 2 to 3 seconds, power-off.
	Menu	To enter the main menu, file menu or ECG review menu.
	F2/Reset	Move the cursor up to select item. / Reset the baseline. / When inputting the patient age, height, weight, diastolic and systolic value, press the key Menu and F2 at the same time, the value will decrease by 10.
	F3/1mV	Move the cursor down to select item. / 1mV calibration. / When inputting the patient age, height, weight, diastolic & systolic value, press the key Menu and F3, the value will increase by 10.
	F4	To execute the operation command. / Switch the lead or lead group when recording ECG under Manual Mode. / Hold the key F4 to prolong the current lead of lead group recording under Auto. Mode. / Move the cursor to the left in the interface of 'Patient'. / When inputting the patient I.D.,age, height, weight, diastolic and systolic value, press the key Menu and F4 at the same time, the value will decrease by 1. / Switch the time of stored ECG for checking ECG of different time.
	F5	To execute the operation command. / Switch the lead or lead group when recording ECG under Manual Mode. / Hold the key F5 to prolong the current lead or lead group recording under Auto.Mode. / Move the cursor to the right in the interface of 'Patient'. / When inputting the patient I.D., age, height, weight, diastolic and systolic value, press the key Menu and F5 at the same time, the value will increase by 1. / Switch the time of stored ECG for checking ECG of different time .
	F1/Mode	Press it to confirm operation or to return to previous page (see prompt on screen) / To select working modes.
	Filter	To activate the filter (The icon will show on the screen).
	Patient	To input and edit patient information. Press it again to return.
	Run/Stop	Start or Stop sampling or recording ECG.

3.5 (DB15) Patient cable interface(DB15)

PIN	NAME	PIN	NAME	PIN	NAME
1	C2	6	SHIELD	11	F
2	C3	7	NC	12	C1
3	C4	8	NC	13	NC
4	C5	9	R	14	RF(N)
5	C6	10	L	15	NC

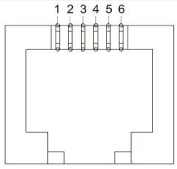


3.6 UART port (RJ11)

Analog I/O and UART Interface (RJ11) : Used for

- ✧ Connect to external bar-code scanner : Scan the bar-code of patient file to fast input patient code.
- ✧ Factory debugging mode: Debugging and update the ECG hardware and etc. (need special software)

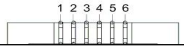
PIN	Instruction	PIN	Instruction
1	GND (COMMON)	4	UART receive (3.3V)
2	NC	5	UART Send (3.3V)
3	NC	6	NC



- ✧ Record analog External Input In [TEST] lead of [MAN] mode.
- ✧ Export the Rhythm Lead of the [BASIC] menu to Analog External Output.
- ✧ Communicate with personal computer for 12 lead real-time ECG transmission and ECG files transmission.

(Need optional ECG Archive Software and UART/USB cable).

PIN	Remark	PIN	Remark	



1	GND (COMMON)	4	UART-Rxd (3.3V)	
2	Ext..In: 10mm/V [±5％]	5	UART-Txd (3.3V)	
3	Ext.Out: 1V/mV [±5％]	6	NC	

3.7 RJ45 port (Optional)

=== Not valid ===

3.8 USB host port (Optional)

USB Host Port (Optional) : Used for

✧ Transmit ECG file stored in ECG machine to ECG Management Software installed in personal computer. Please refer to the ECG Software Operation Manual for more information.

✧ Save ECG files stored in ECG machine to an external USB disk (FAT File Format). The files can be imported into ECG Management Software. Please refer to the User Manual for more information.

✧ ECG files stored in ECG machine can be printed on normal A4 paper through a USB printer (Now it only supports printer with HP PCL5 control language). For details about the supported USB printer models, please contact our service department.

⚠ **CAUTION:** Signal output or input part only allow to connect with equipment with relevant certificates.

⚠ **CAUTION:** The USB cable should be well shielded and can not be longer over 3 meters, It's better to use the manufacturer's recommended USB cable.

Section 4 Operation Preparation

4.1 Power supply and grounding

The device can be powered by mains supply and built-in rechargeable battery. Protective grounding and potential balancing functions are offered.
Mains Supply: Please make sure the AC power strictly meet the requirements on the label of the device. Input one head of the 3-core power cord to the power port of the device and input the other head of the 3-core power cord to the socket of main supply. The socket of main supply must be grounded. Thus the device will ground automatically.
Please keep away from the mains supply when using the internal DC power, in order to reduce the AC interference. Please note the battery symbol on the screen. When the power capacity of the battery is not enough, please charge the battery in time. (For details please refer to 4.2)
Use protective grounding and equipotentiality terminal : When using AC power, please make sure the 3-core AC socket with safety grounding are used, in order to effectively reduce the patient leakage and to protect the patient. When this device is used with several other equipment, the grounding terminal on this device and the grounding cable offered with the device connected with other grounding cables of other equipment can ensure the equipotentiality work of several equipment.
The device can be powered by mains supply and built-in rechargeable battery. When the main supply interrupt, the built-in battery will power automatically.

⚠ **Note:** Connecting the grounding cable with this device and the earth can enhance the reliability of grounding. Do not use water pipe as grounding cable, otherwise it will cause danger of electric shock.

4.2 Use battery to power

The device is equipped with big capacity rechargeable battery. AC power supply is preferred in this device. When there is no AC power supply, the device will automatically start battery power. The battery capacity symbol will be shown on the LCD. In battery-powered mode, the device will power off automatically if there is no operation for a certain period of time. When the capacity of the battery is too low, the device will be power off automatically to protect the battery.

4.3 Load the recording paper

This device requires to use roll thermal paper. About the specification of recording paper please refer to Appendix A.2. The way of loading the recording paper is as follows :

✧ Open the paper compartment cover and take out the paper shaft.
✧ Insert the paper roll to the paper shaft and pull out about 10cm and then load them into the paper compartment. Keep the grid downward (towards the direction of the printing head).
✧ Close the paper compartment cover and make sure everything in right position and situation.

⚠ **Note:** If the device shows the icon of ‘Lack of paper‘, it means there is no paper in the paper box or the paper is not well loaded. The device will not able to print. It is suggested to load the paper again according to the above method.

4.4 Connect the patient cable

Connect the patient cable to the patient cable port and tighten it in right direction.

4.5 Connect the electrodes

Correct connecting the electrodes is very important to record ECG. The following points should be noted:

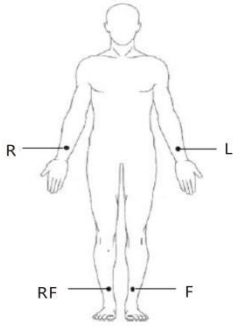
✧ New and old electrodes or reusable and disposable electrodes can not be used at the same time.
✧ The human body, electrode or patient cable plug must not be touched with any conductors such as other metal surfaces or metal beds.
✧ Clean the skin where the electrodes will be placed with alcohol and apply a small amount of conductive gel on the cleaned skin.
✧ Place the electrodes on the right positions of human body and ensure good connection and contact.

The mark and color code of electrodes are as follows :

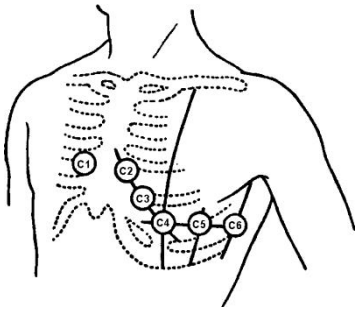
Electrodes	**European Standards**		**American Standards**	
	Mark	**Color**	**Mark**	**Color**
Right arm	R	Red	RA	White

Left arm	L	Yellow	LA	Black
Left leg	F	Green	LL	Red
Right leg	N or RF	Black	RL	Green
Chest	C1	Red	V1	Red
	C2	Yellow	V2	Yellow
	C3	Green	V3	Green
	C4	Brown	V4	Blue
	C5	Black	V5	Orange
	C6	Violet	V6	Violet

The connection between the electrodes and the thoracic electrodes is shown in the schematic diagram below.



Limb electrodes position diagram



Chest electrodes position diagram

⚠ **Note:** Do not mix the conductive gel together. Do not make one chest electrodes contact another to prevent short circuit.

⚠ **Note**: If there is no conductive gel, 5% normal saline can be used for short-time ECG examination.

Please use accessories, replaceable parts and materials approved by our company to replace. Using other parts or materials will reduce the minimum safety. Electrodes of ECG and other conductive part of connector (including neutral electrodes) must not contact other conductive part, especially contact the earth.

Section 5 Operation Instructions and Setting

5.1 Check the device before start

In order to ensure the safe operation of the device and to get high quality ECG waveform, please make the following inspection before start the device:

5.1.1 Check the grounding :

Make sure the ground wire is properly connected. Ensure good contact between the grounding wire connector and the grounding post of the unit.

5.1.2 Check the working environment :

The working environment should be clean and dry. The temperature is suitable and there should be no radio equipment such as X-ray machine or ultra-short wave device nearby.

5.1.3 Check the power supply :

The AC power supply should meet the power supply requirements of the unit, and the power cord must not be entangled with other patient cables.

5.1.4 Check the patient cable :

Keep the connecting wires away from other AC cables. The lead wires and plugs should be properly connected to the corresponding electrodes.

5.1.5 Check the electrodes:

✧ Wipe off the grease on the patient's skin where the electrodes will be placed, and and apply a conductive gel as required.

✧ The electrodes should be kept clean. If the surface is smudged, wash it off with alcohol or soapy water. Being sanded with sandpaper can be done if necessary.

✧ Old and new electrodes, different types of electrodes must not be mixed (such as clip electrodes, adsorption electrodes and disposable electrodes). If a different type of electrode is used in combination, it will result in a large polarization voltage and the ECG waveform cannot be displayed and printed.

✧ The electrodes, especially between the chest electrodes, must not touch each other.

5.1.6 Check the patient :

✧ If the patient is too nervous, the operator should explain to him that the ECG examination is simple and non-invasive, making it psychologically relaxed.

✧ Patient should be relaxed and should not move and speak during the examination.

✧ The environment of the examination room should be as comfortable as possible. Beds used for ECG should not be too narrow.

✧ The body of the patient cannot touch the metal part of the bed, otherwise AC interference may occur.

5.1.7 Check the recording paper installation:

After the above checks, make sure that the machine and the patient are connected properly and the recording paper is sufficient before recording.

5.2 Working modes

The working modes of this model are: Manual / Automatic / R-R / Storage. The default boot-up mode is Automatic.The default setting of sensitivity is Automatic. The Drift / AC filter and analog hot pen print are set to On by default.

Remark 1: For Manual Mode : Switch the leads and sensitivity by manual.

Remark 2: For Automatic Mode : Automatically switch the leads and sensitivity.

5.2.1 Manual mode: manual real-time recording

✧ Press the key Mode to select the ‘MAN’ mode.

✧ Set the recording format of ‘Manual Mode’ in the menu ‘Basic ’.

✧ According to the actual situation, make necessary adjustments to the sensitivity and filter before recording.

✧ Press the key Run/Stop to start recording the ECG

✧ Press the key F4 or F5 to switch the lead (or lead group) if needed.

✧ Press the key Run/Stop again to stop printing.

✧ When the lead is set to [TEST], it is used to print the test triangle waveform (print head test).

Under the ‘MAN’ mode, the ECG won’t give automatic interpretation result.

5.2.2 Automatic mode: ‘Review’ recording and automatic real-time recording

The automatic mode has two modes: ‘Review’ recording and automatic real-time recording. When the ‘Automatic Mode’ is set to ‘Review’ in the menu ‘Basic’, it is the ‘Review’ recording format, and the other is the automatic real-time recording format.

< 1 > Review recording mode: Press the key Mode to select ‘AUTO’ mode. Set the recording format of ‘Auto Mode’ in the menu ‘Basic’ as ‘Review’.Then set the filter state and observe the LCD waveform display. After the waveform is stable, press the the key Run/Stop. The electrocardiogram of 10-12 seconds is recorded. The report will be printed automatically (if the ECG waveform stabilization time is insufficient, it will automatically prompt [==Please wait ==], then automatically start printing) .

< 2 > Automatic real-time recording mode: When the automatic mode is automatic real-time recording, the operation steps are as follows:

✧ Press the key Mode to select 'AUTO' mode.

✧ Set the recording format of 'Auto Mode' in the menu 'Basic'.

✧ After the waveform and heart rate are stable, press the key Run/Stop to start printing the ECG.

✧ In auto mode, during the printing process, the sensitivity and baseline position are automatically adjusted according to the waveform amplitude.

✧ The lead is automatically switched in the automatic mode. You can also keep pressing the key F4 or F5 to extend the recording time of the current lead.

✧ When the last set of leads is printed, the printing stops automatically. The user can also stop printing by pressing the key Run/Stop at any time.

Tip: After the automatic mode printing stops automatically, if in the menu 'Advance' it is set to automatically prompt to save the ECG, the prompt [press F1 to confirm saving] will show up. Press the key F1 to save the ECG (press other keys to give up the saving).

5.2.3 R-R mode: Rhythm lead record

✧ Press the key Mode to select the 'R-R' mode.

✧ Select the Rhythm lead in the menu 'Basic'.

✧ Press the key Run/Stop to start sampling the ECG. When the sampling time exceeds 60 seconds, the sampling will stop automatically. (Press the key Run/Stop at any time to stop sampling .)

✧ When the ECG sampling is completed, the ECG machine automatically starts to print the ECG. If In the menu 'Advance' it is set to automatically prompt to save the ECG, the prompt [press F1 to confirm saving] will show up. Press the key F1 to save the ECG (press other keys to give up the saving).

5.2.4 Storage mode : Under this mode, the ECG won't print out ECG, but only save ECG data. It is also optional for printing ECG through USB printer.

✧ Press the key Mode to select the 'STOR' mode.

✧ Press the key Run/Stop start the ECG sampling (maximum 90 seconds). During the period, users can press the key F1 to stop sampling.

✧ When the sampling time is less than 12 seconds, the storage operation will be abandoned. If in the menu 'Advance' it is set to automatically prompt to save the ECG, prompt [press F1 to confirm saving], press the key F1 to save the ECG (press other keys to give up the saving). If in the menu 'Basic' it is set to allow USB printing, the device will automatically check the USB printer of the USB/HOST interface and print out the ECG report on the normal A4 paper.

In the automatic mode, after pressing the key Run/Stop to complete the recording and the recording automatically stops, the patient ID is automatically incremented. If the user stops the operation by pressing the key Run/Stop, the patient ID is not automatically incremented. In manual mode, the patient ID is not automatically incremented.

5.3 Menu Settings

5.3.1 Menu items

The system menu is divided into four main menu items: CLOCK, BASIC, ADVANCE, and TOOLS. Press the key Menu to switch the main menu items. Press the key F2 or F3 to select the menu items. Press the key F4 or F5 to modify the selected items. Press the key F1/Mode to return. Or touch the icons on the screen to select menu or execute the operation command.

5.3.2 Set the menu of [CLOCK]

[CLOCK]	BASIC	ADVANCE	TOOLS
1. Local Date		YYYY-MM-DD	
2. Local Time		HH:MI:SE	
3. Date Format		Y-M-D	
4. Color Theme		Theme1 / 2 / 3 / 4	
5. LCD Backlight		Level 1 / 2 / 3 / 4 / 5	
6. Auto Pow-off Time		5min., 10min.	

[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

1. Local Date: Set current date (Year-Month-Date). It will be recorded on the recording paper.
2. Local Time: Set current time (Hour-Minute-Second). It will be recorded on the recording paper.
3. Date Format: Set the date format as Year-month-date or date-month-year.
4. Color Theme: 4color theme can be set ‘ Theme 1 / 2 / 3 / 4 ’.
5. LCD Backlight: 5 brightness level can be set ‘ Brightness 1 / 2 / 3 / 4 / 5 ’.
6. Auto Pow-off Time: Set the automatic power-off time when no operation as 5min, 10min .....50min.

5.3.3 Set the menu of [BASIC]

CLOCK	[BASIC]	ADVANCE	TOOLS
1. Sensitivity (mm/mV)		Auto	
2. Speed(mm/s)		25	
3. Man. Mode		3ch+++	
4. Auto. Mode		6ch	
5. Rhythm Lead		II, V1, V5	
6. Auto Rec. Length		Normal	
7. Lead Mode		CABERA	
8. AC Filter Freq.		50Hz	
9. EMG Filter Freq.		25Hz	
10. Report Print Format		All Param	
11. Store Mode Timer		12ch/18S	
12. STOR/Storage Mode		SAVE-ECG	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

1. Sensitivity (mm/mV): Set the sensitivity as 2.5 / 5 / 10 / 20 / 40mm/mV, and Auto (Default).
2. Paper Speed (mm/s): Set the paper speed as 6.25 / 12.5/ 25/ 50mm/s. .
3. Man.Mode: Set the record format as 3ch+, 3ch+++, 6ch. 3ch+ means the waveform of three channels plus the waveform of one rhythm lead. 3ch+++ means the waveform of three channels plus the waveform of three rhythm leads, and so on so forth.
4. Auto. Mode: Set the record format as 3ch+, 3ch+++, 6ch or Review. 3ch+ means the waveform of three channels plus the waveform of one rhythm lead. 3ch+++ means the waveform of three channels plus the waveform of three rhythm leads, and so on so forth.

Explication: The manual and automatic mode rhythm leads (also known as long leads) are convenient for doctors to observe and contrast ECG rhythm changes during lead switching.

5. Rhythm leads: To select the rhythm lead. It is used to specify the rhythm leads (any one of the 12 leads).
If the the rhythm lead is set as +++, it is used to specify the first rhythm lead, and the second and third rhythm leads are fixed to V1 and V5.
6. Auto Rec. Length: Set the recording time in automatic mode. There are 4 options: short, normal, longer, and long+ (see the description in the table below).

Auto Recording Length of Different Record Format

FORMAT	Short	Normal	Long	Long+
3ch (or plus rhythm lead)	10 Sec.	15 Sec.	20 Sec.	25 Sec.
6ch (or plus rhythm lead)	7.5 Sec.	10.5 Sec.	14.5 Sec.	18 Sec.

7. Lead Mode: Two options for lead mode: Standard lead (WILSON) and European lead (CABERA).The lead mode is defined as follows:

Lead Mode Definition

No.	1	2	3	4	5	6	7	8	9	10	11	12
WILSON	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
CABERA	aVL	I	-aVR	II	aVF	III	V1	V2	V3	V4	V5	V6

8. AC Filter Freq.: Two options for AC filter frequency: AC50Hz or AC60Hz.

⚠ **Note**: The AC filter frequency must comply with the AC grid frequency, otherwise AC interference may not be effectively suppressed.

9. EMG Filter Freq.: Two options for myoelectric filtering frequency: EMG25Hz or EMG45Hz. The default EMG filtering frequency is 45Hz. When the myoelectric interference is serious and cannot be eliminated, EMG25Hz can be used. At this time, the amplitude of the QRS wave of the ECG is attenuated.
10. Report Print Format: There are three options for Report Print Format: Print all parameters, print parameters and print without parameters.
11. Store Mode Timer: To set the recording time under Storage Mode.
12. STOR/Storage Mode: To set to save the ECG report or not after printing under Auto and R-R modes.

5.3.4 Set the menu of [ADVANCE]

DATE	BASIC	[ADVANCE]	TOOLS
1. Pen Heater		[X]	
2. QRS Beeper		[X]	
3. Keypad Beeper		[√]	
4. Lead-off Beeper		[X]	
5. Enable Ext. Input		[√]	
6. ADS Filter		[√]	
7. Stylus Printing		[√]	
8. ECG Simulator		[X]	
9. Local Language		[√]	
10. View of 12 Lead ECG		[√]	
11. Prompt to Save ECG		[X]	
12. Grid(mm) Printing		[X]	
13. 210mm Thermal Paper		[X]	
14. Auto Z-fold Paper		[X]	
15. ECG Aux.Analysis		[X]	
16. Prompt Repeated Patient ID		[X]	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

1. Pen Heater: To deepen the print tracks. When the ECG machine is after long time use or the thermal paper is lower quality, users can set it on. It is not suggest to use this function when the machine is in good state. Good quality thermal paper is necessary to ensure the normal performance and using life of the machine. The default setting is off.
2. QRS Beeper: When a QRS heartbeat is detected, internal beep sounds to remind. The default setting is off.
3. Keypad Beeper: When there is operation of pressing the key or touch the soft key, an internal beep sounds to remind.The default setting is on.
4. Lead-off Beeper: When the lead is detected to fall off, the screen displays abnormal tracks and an internal beep sounds to remind. The default setting is on.
5. Enable Ext. Input: Display / print analog signal of the external input in the TEST status of the manual mode. The default setting is on.
6. ADS Filter: Automatically suppresses ECG baseline drift & optimizes print position. The default setting is on.
7. Stylus Printing: Locally bold print ECG waveform, simulate hot pen printing effect.The default setting is on.
8. ECG Simulator: A simulated electrocardiogram is generated in the machine for testing or demonstration. The default setting is off.
9. Local Language: Select [English] or [Local Language]. The default one is decided by the version of the operation software.
10. View of 12 Leads ECG: Select to display format of all 12 leads ECG waveform on screen. The default setting is on.
11. Prompt to Save ECG: Under automatic mode, it prompts to save the ECG after printing (press F1 to confirm). The default setting is off.
12. Grid (mm) Printing: Print a millimeter grid when printing to use plain thermal paper without a grid. The default setting is off.
13. 210mm Thermal Paper: This item is only for 12 / 15 / 18ch ECG. The default setting is off.

14. Auto Z-fold Paper: This item is only for 12 / 15 / 18ch ECG. The default setting is off.
15. ECG Aux. Analysis : When this function is on, the ECG analysis interface will come out automatically after printing the waveform and before the ECG parameters and interpretation is printed. The default setting is off.
16. Prompt Repeated Patient ID: This item to remind the user to pay attention when the patient ID is repeated before each recording / sampling. The default setting is off.

5.3.5 Set the menu of [TOOLS]

CLOCK	BASIC	ADVANCE	[TOOLS]
1. Load Default--AC50Hz		◄►	
2. Load Default--AC60Hz		◄►	
3. ECG File(s)		◄►	
4. Last Record Review		◄►	
5. UART/Real-time ECG		◄►	
6. Touch Screen Calibration		◄►	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

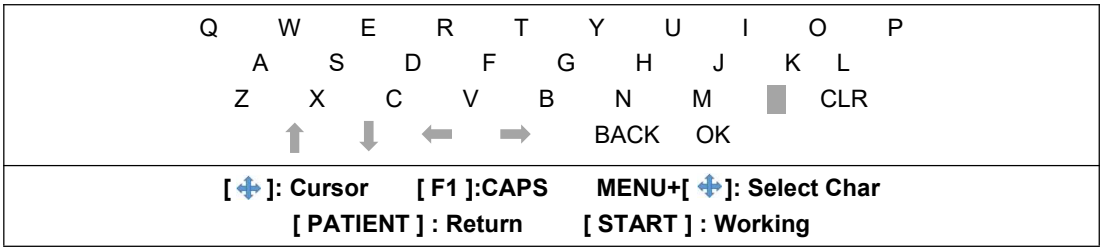
1. Load Default-AC50Hz: Restore the default factory settings (the AC power frequency defaults to 50Hz).
2. Load Default-AC60Hz: Restore the default factory settings (the AC power frequency defaults to 60Hz).
3. ECG Files: ECG files stored. Refer to [5.7 File Management and Playback] for details.
4. Last Record Review: The last recorded ECG waveform is played back on the screen. Press the key Menu to enter the interface of operation to save, save to U disk, copy to USB printer or thermal printer. This function should be performed immediately after recording, otherwise other operations (such as ECG playback) may clear the last recorded data. Note: This function can only play back the last 12 seconds of the last recorded ECG data.
5. UART/Real-time ECG: This function is to activate the UART interface to transfer real-time ECG.
6. Touch Screen Calibration: Press the button F4 or F5 to activate this function. The four icons of (1) (2) (3) (4) will display on the screen. Click on the four points in order, the icon [OK] appears. Click on [OK] to complete the touch screen correction.

Explanation: The resistive touch screen configured on this unit needs to apply appropriate pressure when tapping the touch screen. The click time should not be too short. Therefore, it is recommended to click the touch screen with your fingertips.

5.4 Input patient information

Before examination the ECG, users can input patient information. Press the key Patient, the interface of patient information will come out (Press the key Patient again to get back). The keys F2 and F3 is for selecting different items. The keys F4 and F5 is for moving the cursor to the left or to the right. The key F1 is for selecting between upper case, lower case, numbers, punctuation and symbols.
The patient bar-code number is displayed on the right side of the title bar. If the ECG machine is equipped with a bar-code scanner, the patient number can be quickly entered by scanning the bar-code. The patient bar-code number can be up to 16 ASCII characters.

---------- **Clinical** ---------- IIIIIIIIIIIIIII	
Name	XXXXXXXXXXXXXXXX
I.D.	000000000001
Gender / Age	M/F/--; 0-199 (Years)
Height / Weight	0-255 (cm / kg)
Diastolic / Systolic	0-255 (mmHg)
Hospital Name	XXXXXXXXXXXXXXXX



The ECG machine is equipped with touch screen. Users can select items or input letters or digit, or execute other operation commands by clicking on the touch screen.

✧ Name: Press the key F1 to switch between upper / lower case. Click on the letter keys or the indication keys on the touch screen to input or edit patient name.

✧ I.D.: Up to12 digits. Press the key F4 or F5 to move the cursor. Click on the digit on the touch screen to input digit. Or press the key Menu and F4 or F5 at the same time to decrease the numerical value or increase the numerical value. All set to 0 means no number. The record number is automatically incremented each time.

✧ Gender: Click on the key F or M on the touch screen to input patient gender. Or press the key Menu and F4 or F5 at the same time to select different gender between Male, Female and None.

✧ Age: The value is 0-199 years. Click on the digit on the touch screen to input patient age. Or press the key Menu and F2 or F3 at the same time, the digit will decrease or increase by 10 (from 0, 10, 20, 30 ...); Press the key Menu and F4 or F5 at the same time, the digit will decrease or increase by 1 (from 0, 1, 2, 3 ...).

✧ Height / Weight: The value is 0-255cm and 0-255kgs. The operation is same as inputting patient age.

✧ Diastolic / Systolic: The value is 0-255Kpa. The operation is same as inputting patient age.

✧ Hospital Name: Up to 16 characters. The operation is same as inputting patient name.

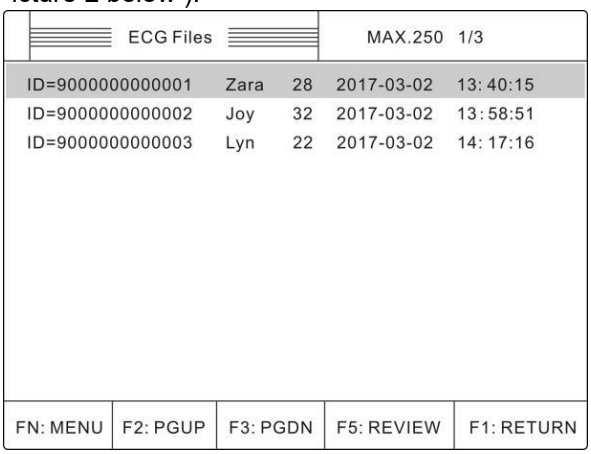
5.5 Record ECG

Press the key Run/Stop to start recording the ECG waveform. Press the key Run/Stop again to stop recording. In the working mode of [Storage], press the key Run/Stop to start sampling the ECG (not recorded), and then prompt whether to save the ECG will show up (Press F1 to confirm the save).

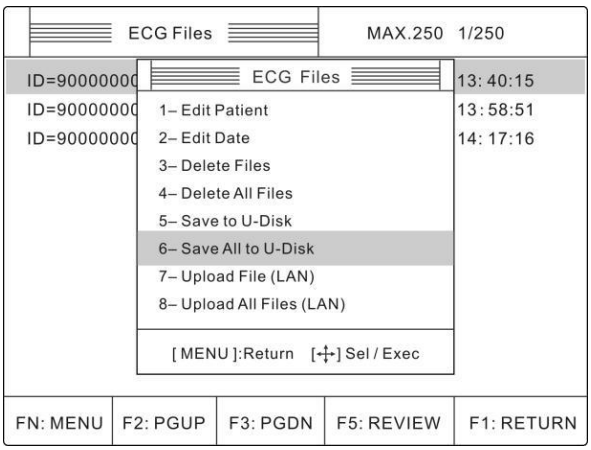
5.6 File management and playback

5.6.1 File Management

The ECG machine can store 250 patient cases in internal memory card. (If necessary, users can choose add an internal SD card to extend the storage). Click on the icon ‘File’ on the screen to enter the ECG file interface. Or Press the key Menu to the menu ‘Tools ’. Press the key F2 or F3 to select the item ‘ECG File(s)’ . Press the key F4 or F5 to enter the ‘ECG Files’ interface (See Picture 1 below). Press the key F2 or F3 to move the cursor to select an ECG case. Press the key Menu to enter the interface of ‘ECG Files’ management (See Picture 2 below).



Picture 1



Picture 2

Press the key F2 or F3 to move the cursor to select different operation items. Press the key F4 or F5 to execute the operation. Press the key F1 or Menu to get back to the upper interface.

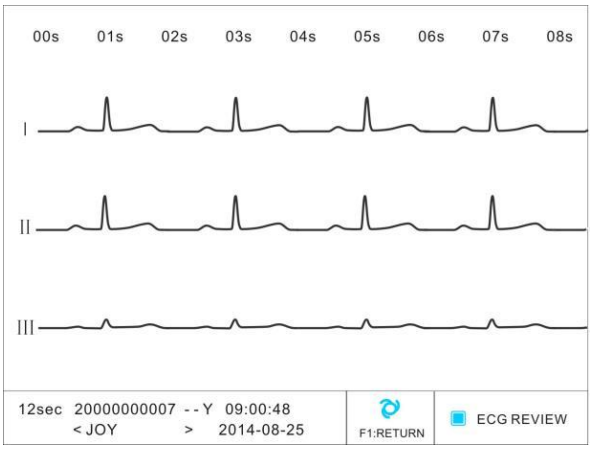
Note: For ECG which are not equipped with optional USB function, the functions of Item 5-Save to U-Disk and

Item 6-Save All to U-Disk are invalid. The functions of Item 7-Upload File (LAN) and Item 8-Upload All Files (L AN) is for future software upgrade. For all current ECG models, the functions are not valid now.

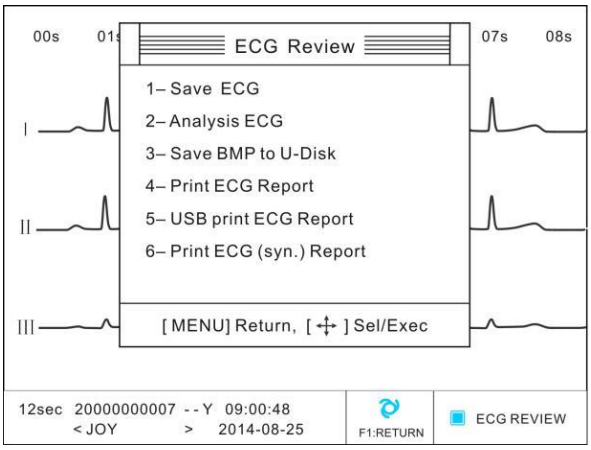
1-- Edit Patient: To modify the patient information of the selected patient case. The detailed operation is the same as [5.4 Input Patient information] .
2-- Edit Date: To modify the date/time of the ECG record.
3-- Delete File: To delete the selected ECG file.
4-- Delete All Files: To delete all ECG files stored.
5-- Save File to U-Disk : To transmit the selected ECG file to U-Disk (Optional function).
6-- Save All Files to U-Disk: To transmit all the ECG files to U-Disk (Optional function).
7-- Upload File (LAN) : Not valid now.
8-- Upload All Files (LAN) : Not valid now.

5.6.2 Playback ECG

Press the key F2 or F3 to move the cursor to select an ECG case.Press the key F4 or F5 to playback the stored ECG. Press the key F4 or F5 to check the ECG of different time (See picture 1 below). Press the key Menu to enter the interface of 'ECG Review' (See picture 2 below). (Press F1 to get back to the upper interface).



Picture 1



Picture 2

1-- Save ECG: Save the ECG data frozen or recorded in last time to the internal flash memory (or SD card). The data will not be lost after the data is stored. The patient information, date / time and ECG parameters will be saved as well.
1-- Analysis ECG : To check the auto interpretation result on the screen.
3-- Save BMP to U-Disk: Save the ECG report (BMP format) to the USB flash drive (external) through the USB/HOST interface of the unit. (Only for ECG configured with USB functions).
4-- Print ECG Report: Copy the ECG report to the built-in thermal printer to print out.
5-- USB print ECG Report: Copy the ECG report to the USB printer (external) through the USB/HOST interface of this unit to print out. (Only for ECG configured with USB functions).
6-- Print ECG (syn.) Report: Copy the synchronized ECG report to the built-in thermal printer.

⚠ Precautions for using USB flash drive and USB printer:

✧ The external USB flash drive must be formatted (FAT16/FAT32 format). There is no U disk formatting function on this unit.

✧ If the prompt [Read and Write Failure (Timeout)] is prompted, it may be because the U disk file system error / too many files and directories / old-fashioned slow U disk. It is recommended to reformat or replace the U disk (recommended to use the manufacturer's recommended U disk).

✧ Please confirm that the U disk is read and written after the U disk is read and written. If the U disk is unplugged during reading and writing, it may cause data loss due to a U disk file system error. Therefore, please note: back up the user data on the USB flash drive before using the USB flash drive.

✧ This function is an optional function of the ECG machine, not a standard configuration. Please consult your dealer for machine configuration.

Section 6 Cleaning, Disinfection and Maintenance

6.1 Recording paper

To ensure the quality of printing results, please make sure to use the recording paper attached to the machine or the same specifications. Otherwise, it will cause problems such as shortened service life of the thermal head, blurred waveform, and poor paper feed. At the same time, users should keep in mind the following notes on recording paper:

✧ Do not use surface-waxed, gray-black recording paper, otherwise the wax will stick to the print head and will not work properly.

✧ Store the recording paper in a dry, cool place. Exposing to high temperatures, humidity, and sunlight can fade the recording paper.

✧ Do not leave the recording paper under fluorescent light for a long time, otherwise it will affect the recording effect.

✧ Do not store the recording paper with polyvinyl chloride, as this may cause discoloration of the recording paper.

✧ The specifications of the recording paper should be given special attention. Failure to meet specifications may damage the thermal print head or silicone rubber shaft.

✧ When the recording paper is placed over a long period of time, the recorded waveform may be transferred to each other.

6.2 Maintenance after use

After using the ECG machine, please pay attention to the following items:

✧ Press the power key to turn off the ECG machine, then turn off the main power switch.

✧ Gently disconnect the lead wire and power cord, and do not pull the cable part with force.

✧ Clean the machine and cover it with a dust cover. Neutral detergent should be used for cleaning and the machine should not be immersed in detergent.

✧ Place the unit in a cool, dry environment and avoid severe vibration when moving.

✧ Bending or knotting will shorten the service life of the lead wire. When using it, please straighten the lead wire as much as possible.

✧ After long-term use, the electrode shall be replaced if its surface is affected by corrosion, oxidative discoloration, etc.

6.3 Cleaning and maintenance for patient cable

Regularly check the integrity of the patient cable and use a multimeter to check the continuity of each lead (Its resistance should be less than 50Ω). Any damage will result in no waveform for the corresponding lead or all leads. The patient cable can be cleaned with water and soap and disinfected with 75% alcohol (the patient cable must not be immersed in the liquid). A small angle of bending / knotting / stretching will shorten the service life of the lead wire. When using it, please straighten the lead wire and connect it to the electrode.

6.4 Cleaning and maintenance for electrodes

The electrodes must be well preserved. The electrodes can be sterilized with 75% alcohol. After prolonged use, the electrode shall be replaced if it is affected by corrosion, surface oxidative discoloration, etc.

6.5 Cleaning the silicone rubber shaft

The silicone rubber shaft should be cleaned regularly to keep it smooth and free of smudging, otherwise it will affect the ECG recording effect. The cleaning method is as follows: clean the soft cotton swab with alcohol, wipe it in the longitudinal direction, and wipe it while turning the silicone rubber shaft in the direction of the paper discharge until it is wiped clean.

6.6 Cleaning the print head

Smudges and dirt on the surface of the thermal print head can affect the clarity of the printed waveform. The print head should be cleaned regularly. The specific method is: open the paper compartment cover and gently wipe the surface of the print head with a clean soft cloth dampened with alcohol. If there is residue, first infiltrate with a little alcohol, then wipe with a soft cloth. Do not scratch the surface of the print head with a sharp object, as this may cause damage. The paper compartment cover can only be closed after the alcohol has completely evaporated. The print head is recommended to be cleaned once a month.

⚠ **Note**: Do not clean the print head immediately after printing. At this time, the print head has a high temperature and be careful of burns.

6.7 Replacing the fuse

When the AC power is supplied, if the power indicator is off and the battery capacity symbol is displayed after the power is turned on, the AC fuse may be damaged. Replace it as follows:

✧ Remove the AC power cord and turn off the power switch.

✧ Press the fuse cover with a screwdriver. The fuse cover will pops out;

✧ Remove the burnt fuse and replace the fuse of the specified specification;

✧ Push and fasten the fuse cover and make sure the fuse cover is locked.

⚠ **Warning**: If the fuse is blown again after replacing the fuse, there may be other malfunctions in the machine. Please turn off the power, and contact the after-sales service department or the designated service agent.

6.8 Maintenance for the battery

This unit is equipped with a rechargeable DC battery. For the voltage, capacity, and charging time of the DC battery, please see Appendix A.5 Product Model and Product Specifications. When AC power is supplied, the

battery is charged when the machine is in standby. During the charging process, the charging indicator on the control panel is always on, and when the battery is full, the indicator changes from blinking to off. To ensure that the battery is fully charged, it will continue to be charged for 1-2 hours.

⚠ **Note**: When using the battery for the first time, it must be charged for more than 5 hours. If you do not use the battery for a long time, you should charge and discharge the battery at least once every three months.
The screen displays the battery capacity symbol during DC battery operation. The symbol flashes empty, indicating that the battery capacity is seriously insufficient, and the machine will automatically turn off the power to protect the battery. Battery replacement must be carried out by a qualified person according to the prescribed procedures. When the battery is defective, there will be insufficient battery capacity or power failure, and it should be replaced at this time.

⚠ Warning: Do not disassemble the battery without the guidance of a professional.

⚠ Warning: Do not place the battery near an open flame as there is a danger of explosion.

⚠ Warning: Do not directly connect the positive and negative terminals of the battery. Otherwise there is a danger of fire.

⚠ Warning: The battery should be handled gently and must not fall on the ground or collide with other item

Section 7 Common Faults and Troubleshooting

7.1 No waveform displaying

During the printing process, the reasons why individual lead waveform are not displayed are as follows:

✧ Do not start recording immediately after connecting the patient cable. Since the baseline drift and amplitude detection requires a stabilization time of about 2 seconds, the individual leads are not shown. At this point, you can press the “Reset” button to quickly stabilize each lead waveform or re-record it again.

✧ If the patient cable is not in good contact or the internal wire breakage is faulty, the individual lead will not be displayed. Check the patient cable as described in ‘6.3 Cleaning and maintenance for patient cable’. If you are sure that the patient cable is faulty, please contact our after-sales service department or designated service point.

After eliminating the above two reasons, if the unit still has a fault, it is usually caused by the fault of the signal channel amplification unit. At this time, you must contact our after-sales service department or the designated service agent.

7.2 Print head failure

The main problem of the print head failure is that the printed ECG waveform or character has a break-point in

the vertical direction. Generally, it is because the surface of the thermal print head is contaminated with dust or smudges. It must be cleaned to eliminate the malfunction(Refer to 6.6 Cleaning the print head) . After cleaning, if there is still this phenomenon, it indicates that the heating unit of the print part of the device may be damaged. Please contact our after-sales service department or designated service agent.

7.3 AC interference

The AC interference is manifested by the fact that the recorded electrocardiogram is regularly superimposed with a certain amplitude of 50 Hz/60 Hz sinusoidal interference waveform, and the baseline exhibits significant shake. The possible causes of AC interference are as follows. Please check the exclusion in order:

- ✧ The ECG machine is not reliably grounded.
- ✧ There is no conductive gel on the electrode and the corresponding part of the patient's body surface.
- ✧ The patient touches the metal part of the wall or bed, or touches someone else.
- ✧ There are X-ray machines, ultrasonic instruments and other high-power electrical equipment in the vicinity.
- ✧ The setting of [AC Filter Frequency] is inconsistent with the frequency of the local AC power supply.
- ✧ The patient wears jewelry.

If the above measures still cannot clear the AC interference, please use the AC filter, and the recorded waveform will be slightly attenuated.

7.4 Myoelectric interference

Myoelectric interference is manifested by an irregular spike in the printed ECG baseline. The possible causes of myoelectric interference are as follows. Please check the exclusion in order:

- ✧ The room temperature is too low and the patient feels uncomfortable.
- ✧ The bed is small and the patient is mentally or physically nervous .
- ✧ The patient is talking with others during the recording process.
- ✧ The limb electrode or the chest electrode is too tightly clamped.

If the above measures still do not remove the interference, please use the myoelectric filter. At this time, the recorded ECG waveform will be attenuated, and the attenuation of the R wave is more obvious.

7.5 Baseline drift

The ECG baseline is unstable and exhibits irregular up and down fluctuations. The possible causes of this phenomenon are as follows. Please check, exclude, or correct them in order:

- ✧ The electrode is not installed securely.
- ✧ During the recording process, the patient's body moves or breathes.
- ✧ The patient's skin is not clean or has no conductive gel.
- ✧ The old electrode is mixed with the new electrode.

If the above measures still can not clear the baseline drift, please use the baseline drift filter (ADS).

Section 8 Product Warranty

The company guarantees the use of raw materials and processes that meet the requirements to manufacture the device. In the normal use and maintenance state, if it proves to be a manufacturing process and raw material failure, the company will offer the service of repairing or replacing the hardware.
For the software or firmware installed in the hardware of the machine, if it proves to be a software or firmware failure, the software or firmware media will be replaced . Although fully tested, the company cannot guarantee the use of hardware, software or firmware won't be interrupted or error free.

Note: The company's obligations under this warranty do not include freight and other charges. The company is not responsible for any direct, indirect or eventual damage or delay caused by:

- ✧ The components are disassembled, stretched, and re-commissioned;
- ✧ Not authorized by the company to repair or modify the device;
- ✧ Damage caused by abnormal use beyond the specified conditions of use;
- ✧ This product serial number label nameplate or manufacturing mark is replaced or removed;
- ✧ The user is not using it properly.

Section 9 Information about Accessories

No.	Description	Quantity	Remark
1	Patient cable	1 pc	
2	Limb electrode (4pcs/set)	1 set	
3	Chest electrodes (6pcs / set)	1 set	
4	Grounding cable	1 pc	
5	Paper axis	1 pc	
6	Thermal paper	1 pc	
7	Fuse	2 pcs	
8	Power cord	1 pc	Different type, please specify before order.

If there is any questions or comments during usage, please contact your local dealer or our customer service department.

Section 10 Appendix

Appendix A1 Technical Characteristics

Main Unit	Lead	Standard 12 leads
	lead acquisition	12 leads synchronously acquisition
	Work mode	MAN, AUTO, R-R, STOR
	Filter	AC Filter : 50Hz / 60Hz / Off EMG Filter : 25Hz / 45Hz / Off
	CMRR	≥120dB (with AC Filter)
	Input circuit	Floating; Protection against Defibrillator effect
	Input Impedance	≥50MΩ (10Hz)
	Electrode DC current	≤0.1μA
	Input dynamic range	±5mVp-p DC bias voltage ≥±620mV
	Patient current leakage	<10μA
	Calibrating voltage	1mV±5%

	Lag	<0.5mm
	Sensitivity	2.5,5, 10, 20, 40, mm/mV (±3%)
	Paper speed	6.25, 12.5, 25, 50mm/s（±3%）
	System error	< ±5% or < ±40μV
	Impulse and frequency response	Method A and Method D system test method
	Inter-channel Interference	<2%
	System Noise	<30μ Vp-p
	HR range	30 - 300 BPM (±1 BPM)
Pacing pulse display capability	Amplitude	2mV - 250mV
	Width	0.1ms - 2.0ms
	Sampling rate	4000Hz / channel
Recorder	Recording way	Thermal dot matrix recording
	Recording format	3ch+, 3ch+++, 6ch,
	Paper Specification	112mmx27m, Roll paper
Others	LCD display	800x480 graphic 7 inch color touch LCD
	Patient cases storage	250 patient cases (internal SD card is optional)
	Communication interface	USB , UART
	AC Power	100V-240V (±10%), 50/60Hz (±1Hz), power 60VA
	DC Power	Rated voltage / capacity: 14.4V / 2200mAh (Li-ion battery) Rated charging current: 1300mA (constant voltage constant current) Rated charging cycle number: not less than 500 times (Li-ion battery)
	Fuse specification	TZAH/250W, ф5x20
	Measurement and weight	300mm x 230mm x 75mm, 2.8kgs.

Appendix A2 Product Type

Type of anti electric shock	Type I, internal power supply equipment
Degree of anti electric shock	CF type application part, with anti-defibrillation function
Degree of anti Immersion in liquid	Ordinary equipment, does not have anti waterproof immersion ability
Degree of safety of being in presence with flammable gases	It is not suitable for use in environments with flammable gases
Working mode	Continuously work
Electromagnetic compatibility	CISPR 11 Group 1 Class A

Appendix A3 Environmental Requirements

Transportation and storage environment	Working environment
Ambient temperature: -20 ° C ~ +55 ° C Relative humidity: 25% to 93% Atmospheric pressure: 700hPa~1060hPa	Ambient temperature: +5°C～+40°C Relative humidity: 25% to 80% (no condensation) Atmospheric pressure: 700hPa ~ 1060hPa

Appendix A4 Product Configuration

Lead	Record format	Paper width	LCD	Touch Screen	Number of keys	Battery	Cases Storage	Bar Code Scan	USB
12 leads	3ch+, 3ch+++, 6ch	112mm	7inch	Yes	10	14.4V, 2200mAh	250	Optional	Optional

Appendix A5 Product EMC Performance

⚠ **Note:**

Digital electrocardiograph meets the requirements of IEC60601-2-25/YY5050 standard electromagnetic compatibility;

Users should install and use the device according to the electromagnetic compatibility information provided in the files attached with device provided by manufacturer;

Portable and mobile RF communication equipment may affect the performance of digital electrocardiographs, avoiding strong electromagnetic interference when used, such as near mobile phones, microwave ovens, etc.

The guide and the statement of manufacturer are detailed in the attachment.

⚠ **Warning:**

Digital electrocardiographs should not be used close to or stacked with other equipment. If they must be used close to or stacked, they should be observed to operate properly in the configuration in which they are used.

Class A equipment is intended for use in industrial environments. Due to the conducted disturbance and radiated disturbance of digital electrocardiographs, it may be potentially difficult to ensure electromagnetic compatibility in other environments.

In addition to cables sold by manufacturers of digital electrocardiographs as spare parts for internal components, the use of extra-standard accessories and cables may result in increased emissions or reduced immunity of the digital electrocardiograph

Digital electrocardiograph operation below the minimum amplitude or minimum may result in inaccurate consequences

Cable Information :

Name	Length (m)	Shield for not	Remark
Power Cable	1.8	No	/
Patient Cable	2.6	Yes	Magnetic ring
Grounding Cable	1.5	No	/

Manufacturer's Statement

Manufacturer's Statement —— Electromagnetic Emission		
The digital electrocardiograph is expected to be used in the electromagnetic environment specified below, and the user should ensure that it is used in this electromagnetic environment:		
Emission Test	**Compliance**	**Electromagnetic Environment - Guide**
Radio frequency emission GB 4824	Group I	Digital electrocardiographs use RF energy only for their internal functions. Therefore, its RF energy is very low and it is unlikely to cause interference to nearby electronic equipment.
Radio frequency emission GB 4824	Class A	The digital electrocardiograph is suitable for use in all facilities that are not home and are not directly connected to the residential public low voltage power supply network for domestic use.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation / flicker emission GB 17625.2	Not applicable	

Manufacturer's Statement

Manufacturer's Statement —— Electromagnetic Immunity
The digital electrocardiograph is expected to be used in the electromagnetic environment specified below, and the user should ensure that it is used in this electromagnetic environment:

Immunity test	Test level	Compliance level	Electromagnetic environment - Guide
Radio frequency conduction GB/T 17626.6 Radio frequency radiation GB/T 17626.3	3V（valid value） 150kHz～80MHz 3V/m 80MHz～2.5GHz	3V(valid value) 3V/m	Portable and mobile RF communications equipment should not be used closer to any part of the digital electrocardiograph, including cables, than the recommended isolation distance. This distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz～800MHz $d=2.3\sqrt{P}$ 800MHz～2.5GHz Explain: *P*——According to the transmitter's maximum rated output power from the transmitter manufacturer. The unit is (W); d——The recommended isolation distance. The unit is meters (m). The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field (a), and each frequency range (b) should be lower than the compliance level. Interference may occur near devices marked with the following symbols: 

Remark 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.
Remark 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

(a) Fixed transmitters, such as base stations for wireless (cellular/cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, their field strength are not theoretically predictable. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic field should be considered. If the field strength of the measured digital electrocardiograph is higher than the applicable RF compliance level above, the digital electrocardiograph should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting the position or position of the digital electrocardiograph.
(b) The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80MHz.

Recommended isolation distance between portable and mobile RF communications equipment and digital electrocardiographs

Digital electrocardiographs are expected to be used in electromagnetic environments where radio frequency disturbances are controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (transmitter) and the digital electrocardiograph as recommended below.

The rated maximum output power of the transmitter /W	Corresponding distance to different frequencies of the transmitter /m		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz～ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the rated maximum output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmission provided by the transmitter manufacturer. Maximum output rated power in watts (W).
Note 1: At frequencies of 80 MHz and 800 MHz, the formula for the higher frequency range is used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

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