

Electrocardiograph

User Manual

Model: EM-301/EM-601



Statement

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1 Safety Guidance



This 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.



This is applicable for ECG signal acquisition, recording and analysis.

1.1 Installation and storage

- Avoid contact with water. Don't install and store in the high air-pressure, humidity and temperature, poor ventilation and dusty environment;
- Put the ECG in the stable place to avoid vibration;
- Don't install and store it in the environment including sulphur, salt and soda and other chemicals;
- Be sure there is no intense electromagnetic interference source around the equipment, such as high-voltage cable, radiological equipment and magnetic resonance imaging equipment.
- Make sure the integrity of the external protective earth conductor in the room

1.2 Before operation

- Check if the equipment is in good condition;
- Check if the equipment is placed properly;
- Check if all the lead wires are well connected and the equipment is properly grounded;
- When the instrument is used with other instruments, special attention should be paid to safety, misdiagnosis and other problems;
- All circuits which directly contact patients need to be inspected more carefully;
- The voltage and frequency of the AC power must match the requirements on the user manual and the battery capacity must be sufficient when battery is applied.

1.3 During operation

- During the operation, the doctors cannot leave alone the patients. Watch the patient carefully and turn off the power or remove the electrodes if necessary to ensure the safety of patients;
- Except electrodes, patients should not contact other parts of the instrument or other conductors

1.4 After operation

- Reset all the function setup to the initial state and shut down the power;
- Gently remove the electrodes, and do not harshly drag the wires;
- Clean the instrument and accessories for the later use.

1.5 EMC and relevant notes

This instrument complies with IEC60601-1-2 standard about the medical electronic equipment safety standards on electromagnetic compatibility. But in an electromagnetic environment exceeding the limitation of IEC60601-1-2 standard, the instrument might suffer from harmful interference and will not provide expected function or get worse performance. If the performance of the instrument is degraded while working, please check and eliminate possible adverse effects before any further use. This manual provides the following preventive procedures.

1.5.1 The influence of electromagnetic radiation

Mobile phone may affect the operation of this equipment. Once this equipment is used, be sure to remind people to turn off mobile phones and small wireless devices.

1.5.2 The influence of Impact and electromagnetic waves

The high frequency noise made by other instruments may bring electromagnetic interference to the instruments via entering AC outlet. Please identify the noise source and stop using the corresponding equipment. If it can not be stopped then use de-noising equipment to reduce the influence.

1.5.3 Electrostatic affect

The static electricity in a dry room may affect the operation of this instrument, especially in the winter. Before using this instrument, humidify the air in the room, or discharge the static electricity from cables or the ECG patients.

1.5.4 Impact of lightning

Nearby lightning may cause high-voltage surge. If worried about this issue, please disconnect the AC power and use the battery power.

1.6 Device classification

- Protection against electric shock: Class I, Type CF internally powered
- Protection against ingress of hazardous liquid : Normal equipment (no protection against ingress of hazardous liquid)

- Combustible gas safety: Not suitable for use under the presence of flammable gas
- Mode of operation: Continuous
- EMC: Class B













1.7 Measurement requirement





ECG belongs to measurement instrument. The users are suggested to send the instrument to authorized Measurement Institutes for verification at least once a year according to the state ECG and EEG metrological verification regulations.

1.8 Discarding the equipment


Discard electronic materials, packing materials, battery and other declared waste according to the local laws. Support the sorting recycling work of the local administration.


1.9 Symbols

Symbols	Function	Symbols	Function
	USB		Alternating current
	Battery recharging indicator		Product serial number
	Manufacturer		Date of manufacture
	Recycle		Storage temperature range
	Avoid direct light		Keep dry
	Tier limitation		Equipment of type CF with defibrillator proof

	Battery indicator		Note (general warning): the information you should know to avoid possible damage to patients or operators.
	Note: the information you should know to avoid possible damage to the equipment		Potential equalization


Remark:

 Note (general warning): the information you should know to avoid possible damage to patients or operators.

 Note: the information you should know to avoid possible damage to the equipment

1.10 Recording paper


To guarantee the record quality of the ECG waveforms, please use the high speed thermal paper supplied or appointed by ECGMAC. Other paper may shorten print head's life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper etc


 Please do pay attention to the following aspects:


- (1) Never use wax-coated recording paper. Otherwise wax may stick to the heater of the print head and damage it;
- (2) Record paper should be stored in dry and cool area, avoiding excessive temperature, humidity and sunshine;
- (3) Avoid exposure to fluorescent for a long time, it will influence the recording quality;
- (4) Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper;
- (5) Do not overlap the recording paper, otherwise the ECG record may trans-print each other;
- (6) Pay attention to the size of the paper. Improper size may damage the printer head or Roller shaft.


2. Safety Information


2.1 Safety Warning


 Use three core power cord and protective grounding socket when mains supply is applied, in order not to cause electric shock to patient and operator.


 Be sure that the installation room has stable power supply system which is reliable and grounding.


 When the system is not complete and reliable, cut off the A/C power and use internal D/C supply directly


 Do not use the instrument near anesthetic gases, oxygen, hydrogen or other flammable and corrosive chemicals.


 Do not use the instrument near high-voltage, high- static, X ray, ultrasonic, electrosurgical equipment and other strong magnetic wave environment.


 Only qualified service engineers can install this equipment. And only service engineers authorized by ECGMAC can open the shell case.


 Auxiliary equipments connected to the digital and analog interfaces must be certified according to IEC standards (e.g. IEC950 for data processing equipment and IEC60601-1 for medical equipment). 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 IEC60601-1-1. If any questions, please consult our service department or the local agent on your side.


 When defibrillator is used simultaneously with the instrument, the operator should not touch patient, bed, table or instrument. All the electrodes (whether connected to the patient or not) and the patient do not need to be grounded. When the instrument is operated simultaneously with defibrillator or other electrical stimulation equipment, it is recommended to use disposable plate chest electrodes to avoid skin burns by metal electrodes.


 Be careful when patient is connected to multiple equipments, the total leakage current might cause the injury. Only type I equipment compliant with GB9706 is allowed to connect with this instrument, when it is connected with other equipments. Meanwhile, reliable connection between the potential equalization needs to be carefully considered. After the connection, the users must measure the total leakage current by themselves to determine whether it meets the requirements or usage condition.


 The pacemaker (if installed) may influence the accuracy and analysis result. Under this situation, it is suggested that the doctors should identify and analyze it according to the waveform.

 To prevent burns, high frequency electric knife contact point must be kept away from the electrodes. If necessary, plate electrodes can be chosen. Its larger contact area can limit high-frequency current density to an acceptable range.

 The total leakage current should never exceed leakage current limits while several other instruments are used at the same time.


 The operator should not touch patient, patient bed, table or instrument when it use simultaneous with the defibrillator or pacemaker.


 Please use the patient cable and other accessories supplied by ECGMAC. Otherwise, it will affect the performance and function, even damage the ECG.


 Be sure that all electrodes have been connected to the correct position of human body before operation. Avoid electrodes (including neutral electrodes) and patient to be contacted with any conducting parts or earth.


2.2 Warnings for rechargeable lithium battery


Improper operation might cause the rechargeable lithium battery to become hot, ignited, exploded, and it may lead to declination of battery capacity. It is necessary to read the Operation Manual carefully and pay more attention to warning messages.


 Danger of explosion- Do not reverse the anode and cathode when connecting the battery.


 Do not use the battery near fire or place over 60°C. Don't heat or splash the battery. Do not throw the battery into fire or water.


 Do not ruin the battery by hammering, beating, chiseling a metal into it or other else, which will cause the battery to be deformation, heat, to smoke, burn and other danger.

 When leakage or foul smell found, stop using the battery immediately. If the leakage liquid gets to your skin or cloth, cleanse it when 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.


 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.


 When the shelf life of battery is due, or foul smell and leakage has been found, stop using it, and contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.


 Do not pull in or take out the battery when the equipment is powered on, which will cause white screen, crash, etc.

 Take out the battery when not using the equipment for long time

2.3 General Notes

 In order to record ECG data accurately, the instrument should be placed in a horizontal table to avoid excessive vibration and shock during movement. The environment should be quiet and comfortable.

 Avoid liquid splash and excessive temperature. The temperature must be kept between 5°C to 40°C while working.

 Do not use the equipment in dusty environment with poor ventilation or in the presence of corrosive, such as salt, sulphur and chemicals.

! 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.

! Check the main unit and its accessories carefully before operating the ECG for patients. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.

! The frequency and voltage of the AC power should conform to it requires. This ECG uses mains supply and built-in rechargeable lithium battery. For mains supply, rated voltage: 220V, frequency: 50Hz; power: 50VA. For battery, rated voltage: 14.8V, capacity: 4400mAh, power: 50VA. When using, please follow the requests to supply power.

! Safety test should be applied on the instrument regularly (at least once every two years), tests should include

- a) Check if the instrument and accessories has mechanical and functional damage;
- b) Check if the safety ID is broken;
- c) Check the fuse whether it fulfills the requirement the rated current and short circuit characteristic
- d) Check the function of the instrument according to its operation manual
- e) Perform the following safety test according to IEC60601-1 standard:

Protection ground impedance, Limit Value 0.1Ω .

Earth leakage current, Limit Value: NC 500uA, SFC 1000uA.

Patient current leakage, Limit Value: 10uA. (Type CF equipment)

When AC power is applied, limit value patient current leakage is 50 uA (Type CF equipment) in single trouble status. The test results have to be recorded and performed by the authorized staff. If the equipment failed in any of the tests, it has to be repaired.

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

! If any accident happens during use, please turn off the ECG immediately.

2.4 Cleaning, Disinfection, Maintenance

- ❗ Turn off the main unit and remove power supply cable and patient cable before cleaning and disinfection.
- ❗ Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the main unit or patient cables 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.
- ❗ Disinfection, if required, can not be done with high temperature, autoclaving or radiation.
- ❗ Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- ❗ Maintenance and repair should be applied on the main units and accessories regularly (at least once every half year)
- ❗ ECG machines are classified into Measuring Instrument, so users should send it to Official Measurement Administrative to test and certify according to national metrological calibration regulation of electro-cardiograph and electroencephalogram machine every year.
- ❗ The instrument signal input/output connector (when needed) must be connected with Class I equipment which is GB9706.1-compliant, and the total leakage current should be tested to be available by users themselves.
- ❗ Electrical schematic diagram and parts lists are only available to qualified repair stations or staff of ECGMAC authorized.

2.5 Intended Use

The intended use is to acquire ECG signals from human through body surface ECG electrodes. The ECG recorded by the electrocardiograph can help users to analyze and diagnose heart disease.

2.6 Contraindication

Absolute Contraindication

1. Acute myocardial infarction (within 2days)
2. High risk unstable angina
3. Hemodynamic disorder caused by uncontrolled arrhythmia
4. Active endocarditis
5. Symptomatic severe aortic stenosis
6. Decompensated symptomatic heart failure
7. Acute pulmonary embolus or pulmonary infarction
8. Acute noncardiac disorder that may affect exercise performance or be aggravated by exercise (eg, infection, renal failure, thyrotoxicosis)
9. Acute Myocarditis or Pericarditis
10. Serious Physical Disability which disable to make safe and effective test
11. Without acquiring patient's permission

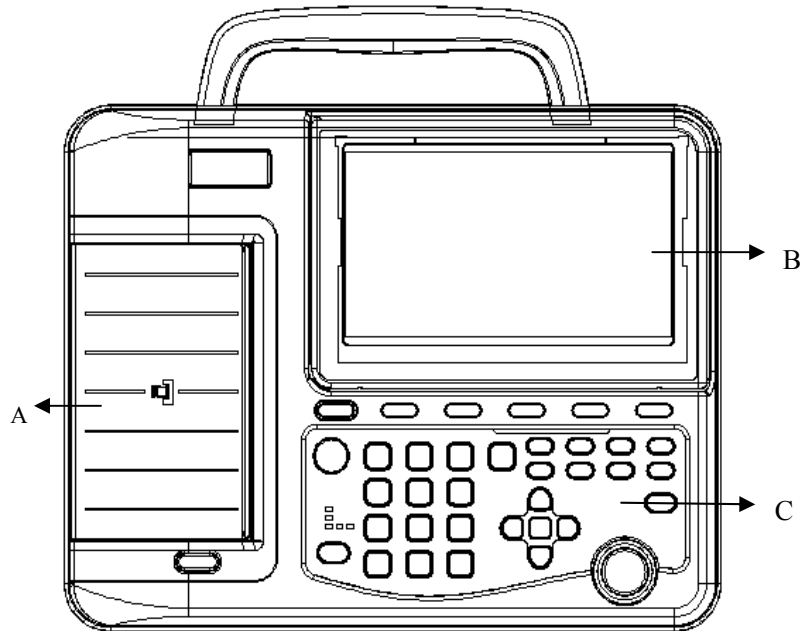
Relative contraindications

1. Left main coronary stenosis or its equivalent
2. Moderate stenotic valvular heart disease
3. Electrolyte abnormalities
4. Tachyarrhythmias or bradyarrhythmias
5. Atrial fibrillation with uncontrolled ventricular rate
6. Hypertrophic Cardiomyopathy
7. Patients can not cooperate because of mental impairment
8. High-degree AV block

3 Structure and principle

3.1 Product structure

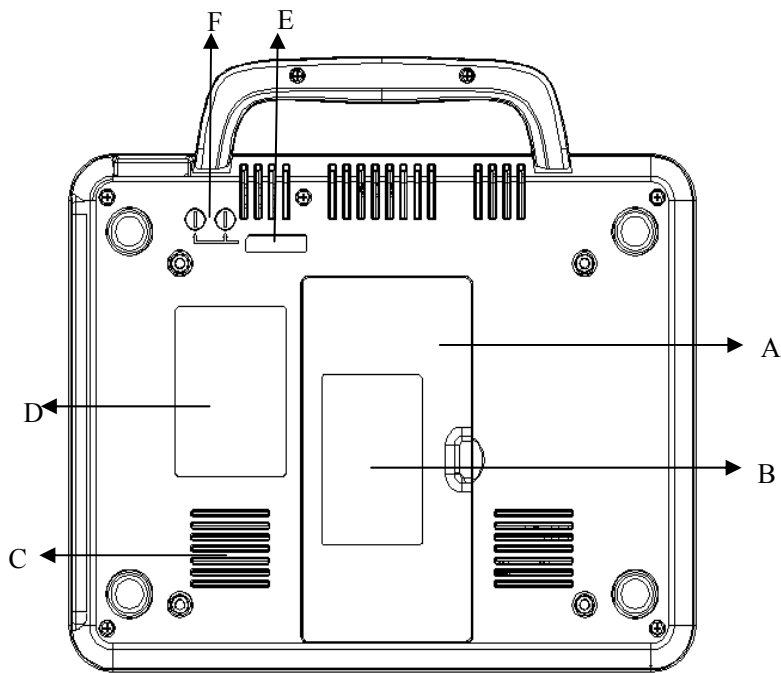
3.1.1 Top view



Sign	Name	Description
A	Recorder	Load recording paper, print ECG report
B	LCD screen	Display operation interface and contents
C	Keyboard	Function buttons, input of numbers and letters

- ❗ The LCD screen can be damaged if place heavy object on it or hit it.
- ❗ Please fold the screen to prevent accidental damage after use.

3.1.2 Bottom Panel



Signal	Name	Function description
A	Battery compartment	Lithium battery installed inside
B	Battery label	Battery group label
C	Vents	Internal heat dissipation channel
D	Product label	Product information label
E	Fuse label	Fuse specification label
F	Fuse compartment	AC fuse installation

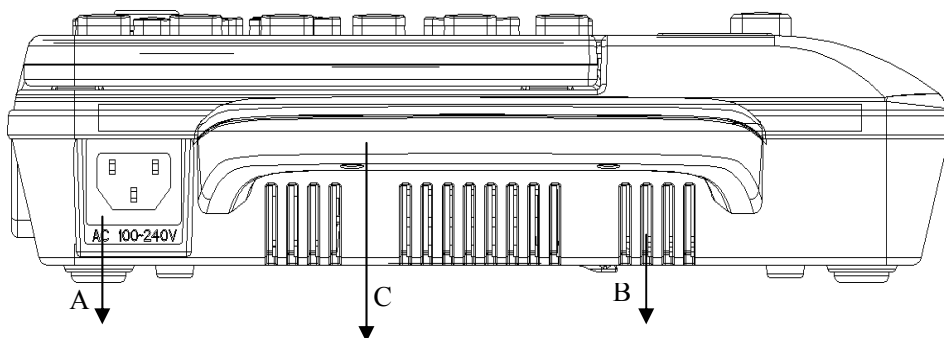
1) Battery compartment

The rated output voltage and capacity of built-in rechargeable lithium batteries are as follow:

Rated output voltage: 14.8V

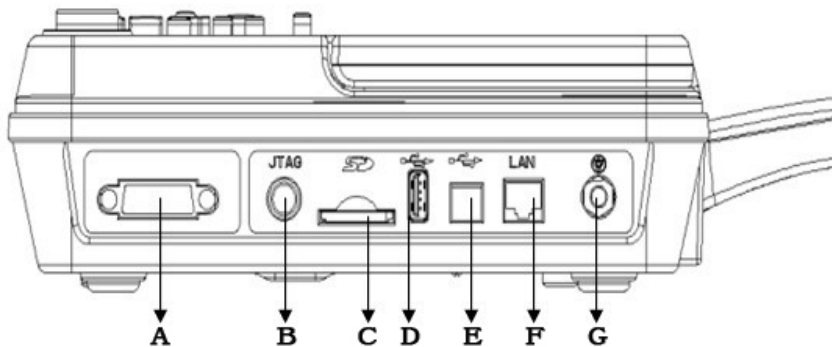
Rated capacity: 4400mAh

3.1.3 Rear View



Sign	Name	Function description
A	AC power socket	Connect with AC power cord
B	Vents	Internal cooling channels
C	Handle	Easy to carry

3.1.4 Side view

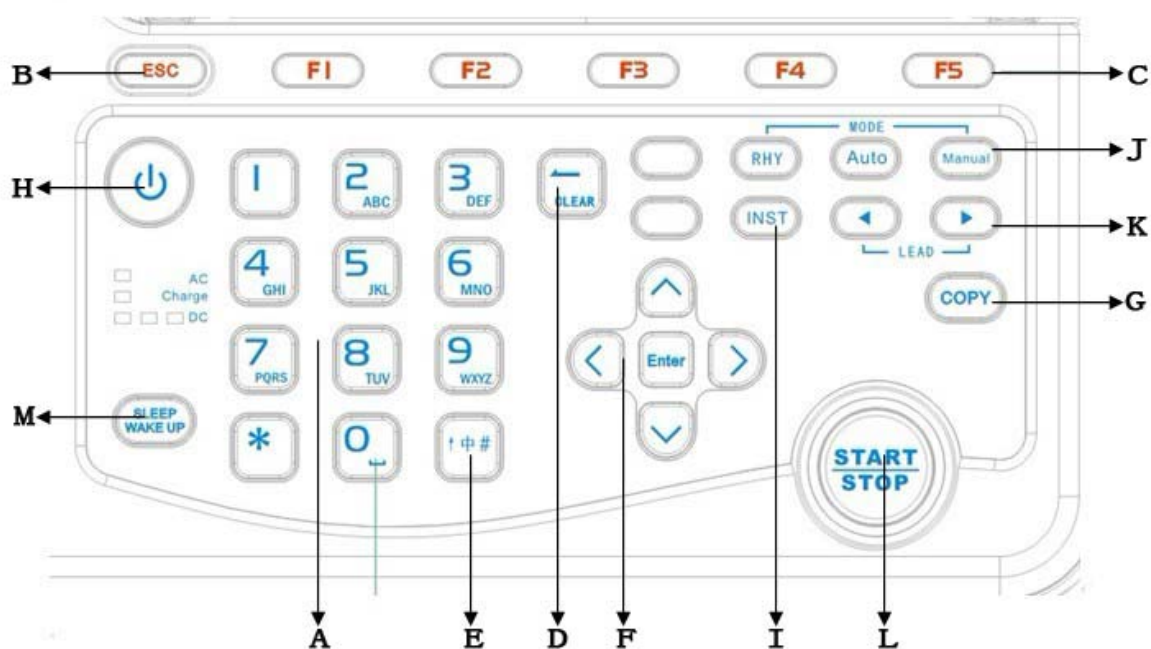


Sign	Name	Function description
A	Patient cable socket	Connect patient cable.
B	Test interface	Testing by manufacturer
C	SD card slot	For SD card insert
D	USB Slave Port	Standard USB 2.0 port to connect external printer support PCL6
E	USB Master Port	Standard USB 2.0 port to connect PC
F	LAN socket	Standard LAN port, connect with network cable
G	Potential equalization	When need to use potential equalization grounding cable to protect the security of electricity, use grounding cable to connect this potential equalization terminal with the grounding cable which is already connected to the walls



Test interface B list above is for manufacturer use only

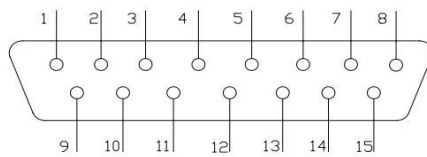
3.1.5 Keyboard and its functions



Sign	Button name	Function description
A	Numbers and letters input	Enter numbers, letters and signs
B	ESC	Cancel operation
C	Function buttons	Select screen menu functions
D	Backspace	Delete the character to the left of the cursor
E	Input method	Choose the input methods: English / Numbers
F	Five-way navigation buttons	Up, down, left, right and action.
G	Copy button	Copy the last ECG signals when the system works in automatic model.
H	ON/OFF	Turn on or off the ECG.
I	Reset	Make lead input fast and stable and reset lead print output
J	Recording mode	Select recording modes: manual, automatic and

		rhythm.
K	Lead Select	Lead switch in manual mode.
L	START/STOP	Start and stop print
M	Sleep/wake up	System enters sleep mode or back to work mode

3.1.6 Patient Cable Socket and definition for plug pins

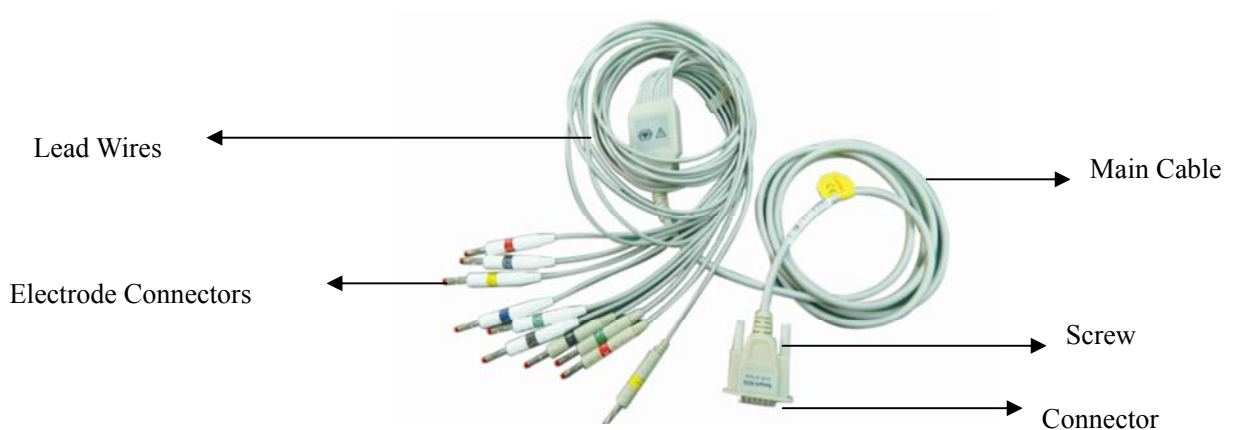


Applied part of type CF with defibrillator proof

Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)	6	SH	11	F (input)
2	C3 (input)	7	NC	12	NC
3	C4 (input)	8	NC	13	C1 (input)
4	C5 (input)	9	R(input)	14	NC
5	C6 (input)	10	L(input)	15	N or RF (input)

3.1.7 Patient cable



Patient cable includes main cable and lead wires. The lead wires include 6 chest lead wires

and 4 limb lead wires. The user can identify them through the colors and the identifiers on the connectors.

3.1.8 Chest electrodes



3.1.9 Limb electrodes (clamp style)



3.2 Electrodes connection

The installation of electrodes is critical for accurate record of ECG signals. Please ensure electrodes are well-connected. Disposable electrodes cannot be used together with reusable electrodes (old or new). Different models cannot be used together otherwise it will seriously affect the accuracy of ECG record. Electrodes or lead wire socket cannot touch other conductors, such as metal beds. All electrodes need to be replaced together during replacement.

3.2.1 Limb electrodes connection

Limb electrodes should be installed on the soft skin of hands and legs. Clean the skin where electrodes will be installed with medical alcohol; Apply a small amount of electrode gel on the skin.

The connection is shown in the following figure:

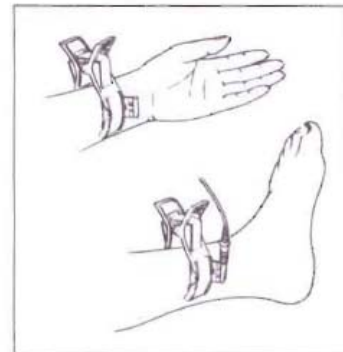
The location for Limb electrodes are:

R (RA) connect right hand

L (LA) connect left hand

RF (RL) connect right leg

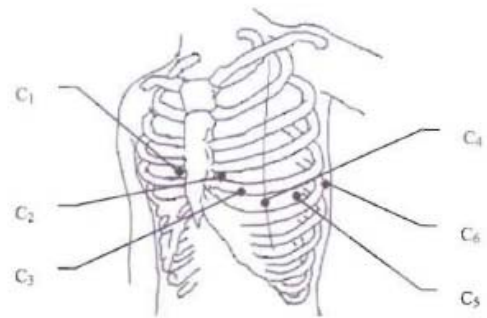
F (LL) connect left leg



3.2.2 Chest electrodes connection

Clean the skin where electrodes will be connected with alcohol; Apply about 25mm diameter electrode gel on the skin where the electrodes contacted; Apply a small amount of

electrode gel on the edge of the sucker ball of the chest electrodes; Press the suction ball of the chest electrodes; attach them to C1-C6. The connection is shown in the following figure



C1 (V1): Fourth inter-costal space at right border of the sternum.

C2 (V2): Fourth inter-costal space at left border of the sternum.

C3 (V3): Midway between locations C2 and C4.

C4 (V4): Mid-clavicular line in the fifth inter-costal space.

C5 (V5): Left anterior axillary line on the same horizontal level as V4.

C6 (V6): Left mid-axillary line on the same horizontal level as V4.

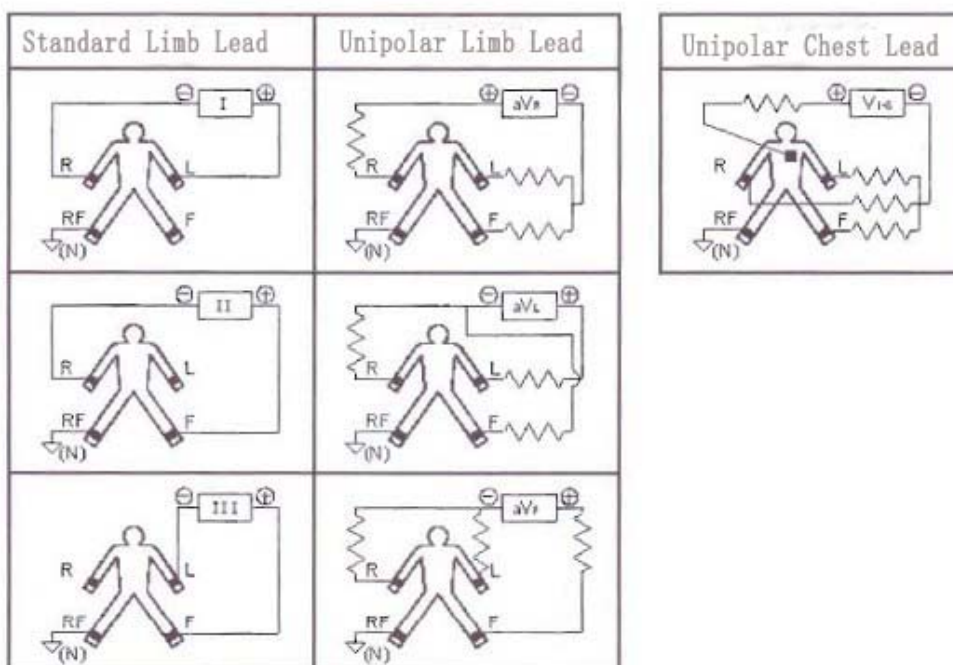


Electrode gel coating should be separated from each other. Chest electrodes should not touch with each other to avoid short circuit. If no electrode gel is available, apply a small amount of 75% alcohol instead. Place the electrodes right away to make sure it is adequately wet at the contact area. Do not use physiological saline to replace electrode gel. Otherwise, it will cause electrode corrosion.

3.2.3 Electrode identification and connection color table:

Electrode Position	Electrode identifier	Lead wire color	Electrode color code
Right arm	R	Grey	Red
Left arm	L	Grey	Yellow
Right foot	RF	Grey	Black
Left foot	F	Grey	Green
Chest	C1	White	Red
	C2	White	Yellow
	C3	White	Green
	C4	White	Brown
	C5	White	Black
	C6	White	Purple

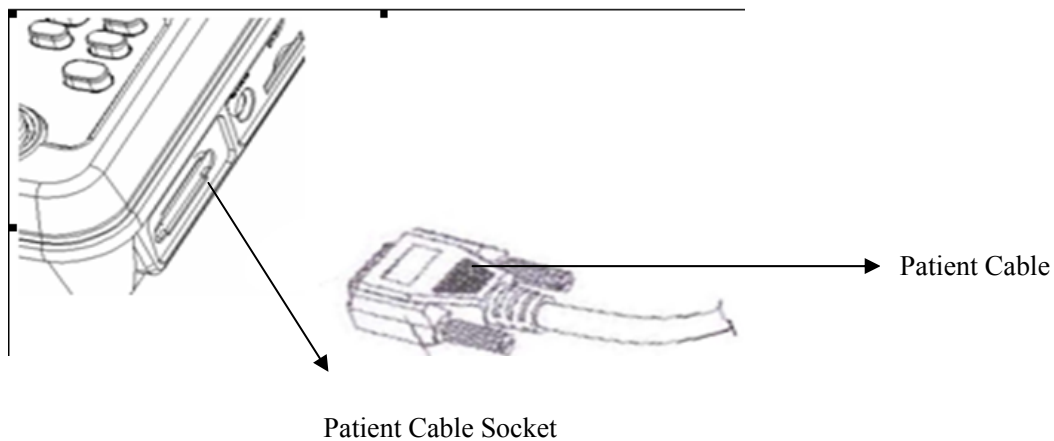
3.2.4 Lead method and system diagram



3.3 Patient cable connection

Plug the patient cable connector into the socket on the right side of ECG machine as shown

below, and lock the screw on both sides.



❗ Only use the designated patient cables. Do not use any other models.

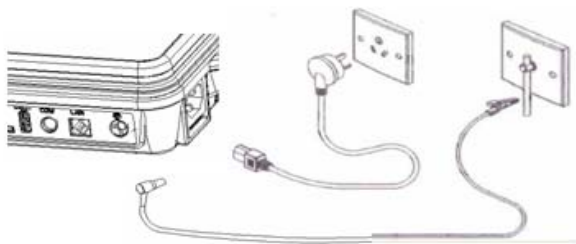
❗ Patient cables socket is designed for ECG signal input only. Do not use it for other Purpose

❗ The instrument has built-in defibrillator protection circuit with supporting non defibrillation protection cables

3.4 Power connection

3.4.1 AC power

Plug one end of three-core power cord to the power socket on the ECG and the other end to the socket on the wall as shown below:



3.4.2 DC Battery

The battery is not put into the battery compartment when it is dispatched with the machine, it needs installation after receive it. After receiving the ECG, if built-in rechargeable battery is to be used, check the battery capacity and condition.

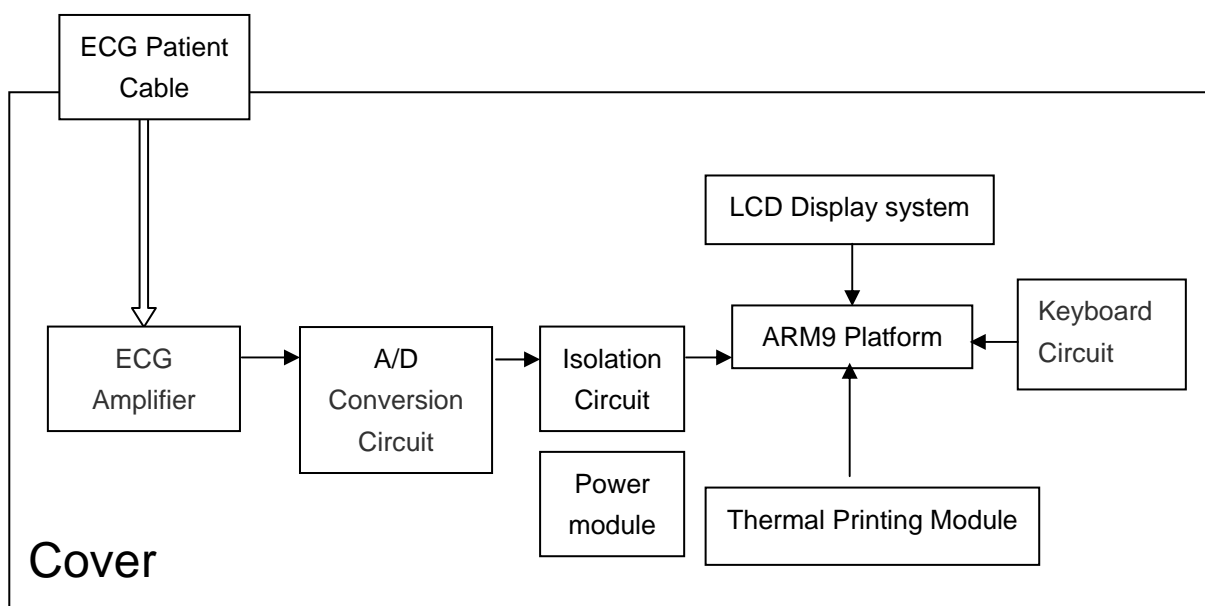
⚠ Connect one end of the grounding cable to the instrument's potential equalization and connect the other end to the ground. It can enhance the reliability of ground connection. It is forbidden to use water pipe or other pipes as grounding cable. Otherwise, the first-class safety protection will fail and patients may get electric shock.

3.5 Principle and Schematic diagram

3.5.1 Principle

Multi-channel ECG is made up of amplifier circuit, print controller, keyboard controller, LCD controller, CPU system and other parts. Lead signals from optical coupler are received by CPU. After digital filter, sensitivity adjustment and print driver, then the signals are sent to print controller for the waveform printing. When printing finished, the measurement and analysis will be processed by the CPU system. Besides, the CPU system will receive the interrupt signal and button codes to finish the interrupt processing. And CPU system will handle lead-off signal, no paper detection, auto power off of batter voltage management, sampling and print of CRO simulation output and EXT input. Keyboard controller produces scanning signals, finishes the key anti-vibration, generate keypad number and interruption signals, which are processed by the CPU system. LCD controller receives the data and orders from the CPU system and achieves the display for the ECG control state.

3.5.2 Schematic diagram



3.6 Features

- Three operating modes: Automatic, Manual and Rhythm; AC/ DC Power supply
- Multiple language options, convenient and flexible system setting and data management
- Simultaneous 12 leads ECG acquisition, amplification, display and recording; ECG analysis software can analyze ECG reports and data according to 5 judgment types and 241 cases.
- Built-in 4G SD card, save up to 10,000 groups of 12 leads ECG waveforms every 10sec., which can be transmitted to PC by connecting USB network interface.
- High-resolution thermal matrix printing system, recording frequency response is not more than 150Hz,
- Big keyboard with independent numeric key, big printing key; 7 inch color LCD.

4. Operation Preparations

4.1 Applicable fields

EM301&EM601 are applicable for hospitals, clinics, group checkup and other outdoor activities.

4.2 Environmental operating conditions

Please make sure the temperature and humidity meets the requirement for use.

Temperature 5°C ~ 40°C

Relative humidity 25% ~ 95%

4.3 Inspection before operation

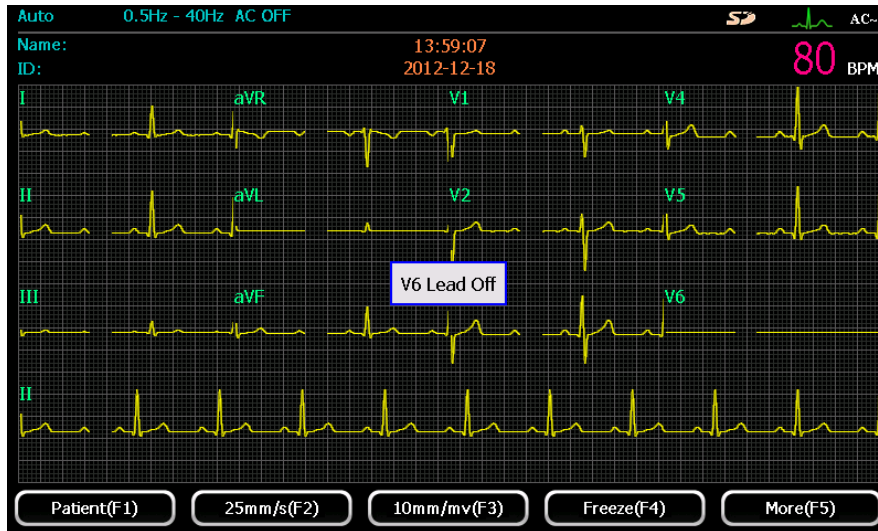
- Check if the instrument, Socket and grounding cable are well connected.
- Confirm no high voltage cable, X ray, ultrasonic, electrosurgical machine and other high power equipment around the instrument.
- Check if the plug pin is connected with corresponding electrodes; No twisting with other cable.
- Check if the electrodes are well-connected. No contact with each other
- Check if the patient is nervous or talking or moving or contacting the metal part of the bed
- Check if the environment is comfortable and if the bed is too small



To ensure the patient safety and ECG reliability, please check the above and start operation.

4.4 Lead off indication

The instrument constantly checks the lead connection status. If the instrument detects the lead off, it will display the corresponding information on the LCD screen as shown below, it shows C3 and C6 lead off.



When lead off, the waveform will not be displayed. Pressing "record" button is ineffective. Please check the loose electrodes or electrode leads according to the prompt message and reconnect them.

1) Electrodes fall off

① When the lead wires are not connected to the patient or the instrument stably, ECG signals can not be transmitted correctly, this message will be displayed for reminding;

② When the polarization voltage exceeds the limit value, the message will be displayed for reminding.

2) If the “electrodes off” message is shown, handle it according to the following method:

① Press “reset” button to eliminate the influence of the polarization voltage to amplifier. It will get the amplifier back to normal quickly;

② If pressing “reset” button does not eliminate the alarm, check the corresponding electrode and its connection.

4.5 Battery Installation

See Figures below for installation:

1. Turn the electrocardiograph upside-down, unscrew and remove the battery door as A enclosed;



2. Put out the battery from accessories box; make sure the leads are all in order as Picture B.



C



D

3. Tidy the leads, and put the battery into the battery pack horizontally (as Picture C)
4. Close the battery cover and screw it tightly clockwise. (As picture D)

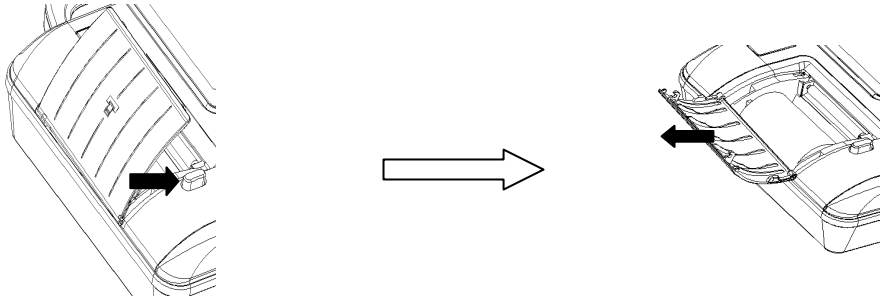
4.6 Recording paper

EM-301: 80mm width*20M thermal rolled paper

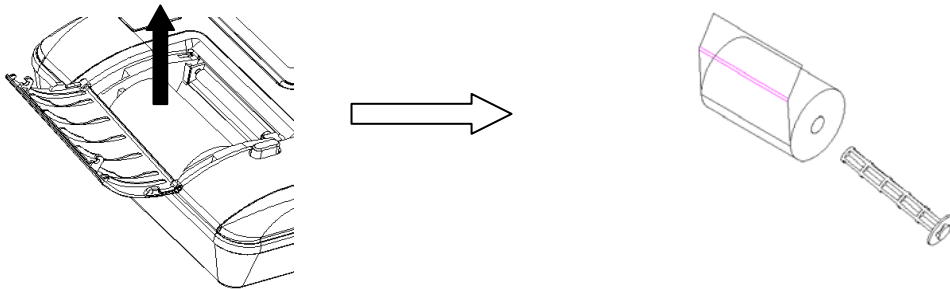
EM-601: 110mm width*20M thermal rolled paper

4.7 Loading recording paper

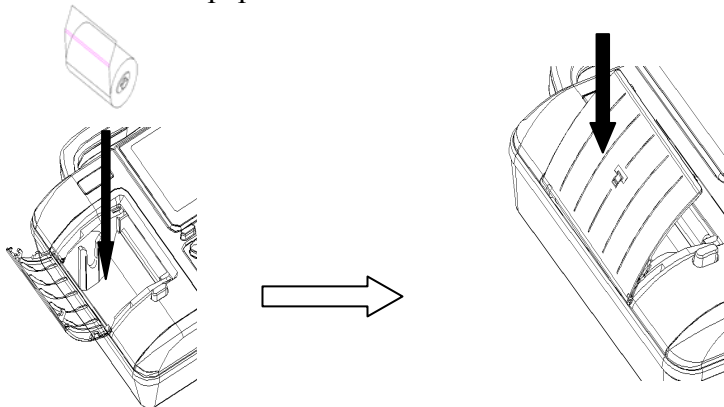
- 1) Press the Open Button to open the paper compartment cover according to the arrow shown in the figure.



- 2) Take out the paper rollers from the paper compartment. Insert the rollers into the rolled paper as shown below



- 3) As shown in the figure below, put the paper with rollers back into the paper compartment. After that, pull about 2cm of the paper out and close the cover.



5 Operation Instructions

5.1 Startup and shutdown

5.1.1 Startup with the mains supply

When power cord and grounding cable are well connected, and the AC supply indicator is lit. Press

“ON/OFF” key (about 3 seconds) and wait 15 seconds for system initialization. After the ECG beeps and starts working, the ECG is ready for operation.

5.1.2 Shutdown with the mains supply

Press “ON/OFF” key (about 3 seconds) in the working state. After the LCD screen display is off, pull the power cord and grounding cable out.

5.1.3 Startup and shutdown with the battery

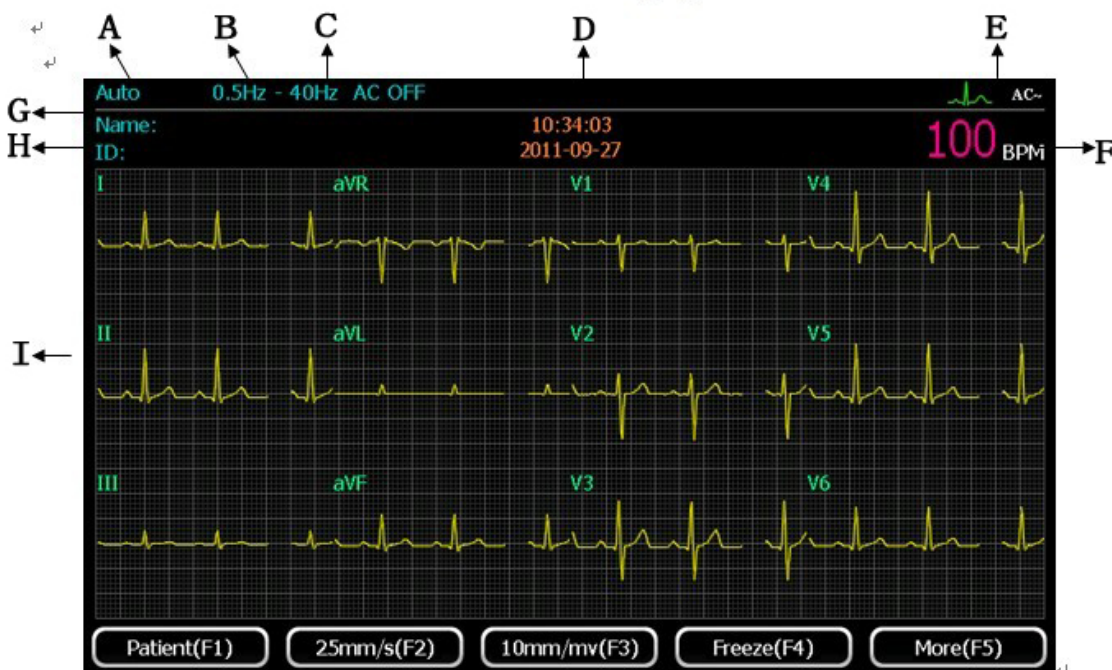
When power cord is disconnected, the ECG will use the built-in battery. And the DC indicator is lit. Then the same startup and shutdown operation with the mains supply.

5.1.4 Battery charge

- ❗ If the built-in rechargeable battery is weak when mains supply is used, it will be recharged automatically at the same time.
- ❗ Please exactly follow the above instruction. Otherwise, disordered messages will be displayed on the screen. When the shutdown prompt message is displayed, do not press the “ON/OFF” button continuously.

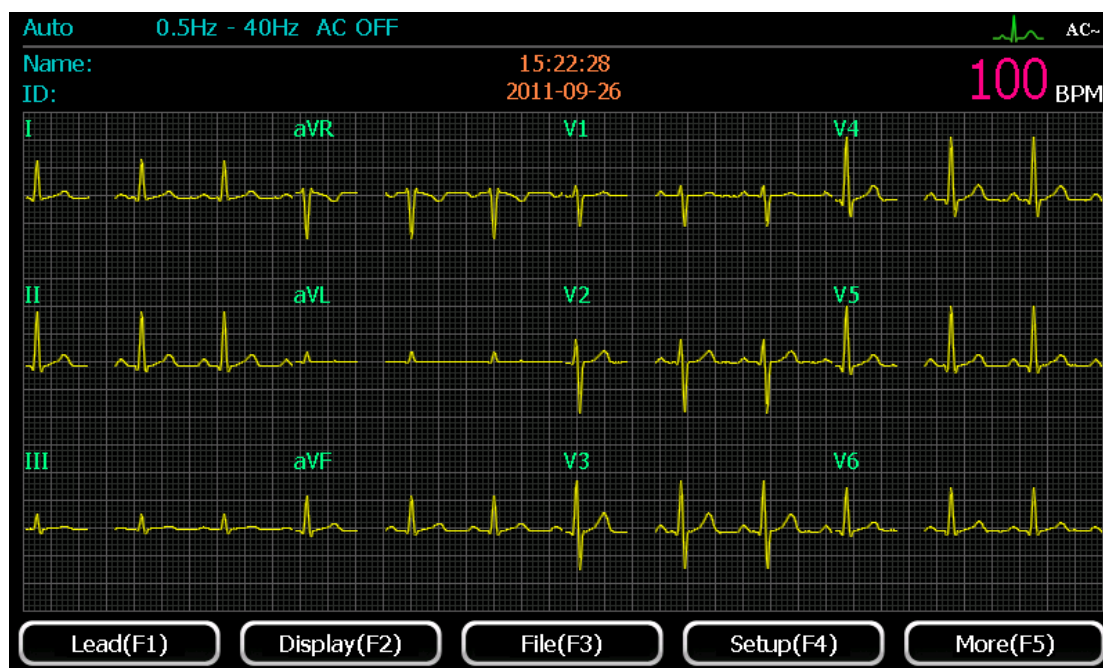
5.2 The ECG main interface

Press “ON/OFF” key (about 3 seconds) to turn on. After system initialization, the first page of the main interface will be shown as the following figure:



Identifier	Name	Description
A	Operation mode	Select Rhythm, AUTO and Manual mode from the keyboard
B	Baseline drift filter	Select it in the filter setup interface, refer to Chapter 5.5.6
C	EMG filter	Select it in the filter setup interface, refer to Chapter 5.5.6
D	Time and date	Set it in the time and date setup interface, refer to Chapter 5.5.7
E	Power supply mode	Indicate the current power supply mode, AC or battery
F	Heart rate	Current Heart rate value
G	Name	Patient name: no more than 20 characters
H	ID	Patient ID: no more than 10 digits
I	Leads and waveform display	Display the waveforms
F1	Patient	Press 【F1】 ,enter patient information setup interface
F2	Paper speed setup	Press 【F2】 ,choose paper speed within 6.25mm/s, 12.5mm/s,25mm/s,50 mm/s
F3	Sensitivity setup	Press 【F3】 ,choose sensitivity within 2.5mm/mV. 5mm/mV,10mm/ mV,20mm/mV
F4	Save	Press 【F4】 ,save current patient test waveforms
F5	More	Press 【F5】 ,enter the second page of the main interface

Press **【F5】** in the first page, the second page will be shown as the following figure on the LCD screen:



Identifier	Name	Description
F1	Lead(F1)	Press 【F1】 to enter the lead system and rhythm lead interface
F2	Display setup(F2)	Press 【F2】 to enter display setup interface
F3	File (F3)	Press 【F3】 to enter file management interface
F4	System setup(F4)	Press 【F4】 to enter system setup interface, refer to chapter 5,6
F5	More(F5)	Press 【F5】 to return to the first page of the main interface

5.3 Operation mode

This ECG has three operation modes: Manual mode, AUTO mode and Rhythm mode. Users can press **【manual】** , **【automatic】** or **【rhythm】** button to select.

Manual mode: under manual mode, users can select lead group need to be recorded. When the users need to record another ECG lead group, manual switch is required.

AUTO mode: under auto mode, the lead groups switch automatically. When one group's ECG is recorded within the period of time which defaulted by system, it will automatically switch to the next group and start recording the waveforms from it.

Rhythm mode: under rhythm mode, users can select rhythm lead group and record its rhythm waveforms.

5.3.1 Manual Mode

Under manual mode, “Manual 1”, “Manual 2”, “Manual 3” and ”Manual 6” (“Manual 6” is applicable for EM-601 only) can be selected by pressing **【manual】** button.

Manual1: ECG is set to display single lead. The users can record the ECG waveforms for a single lead;

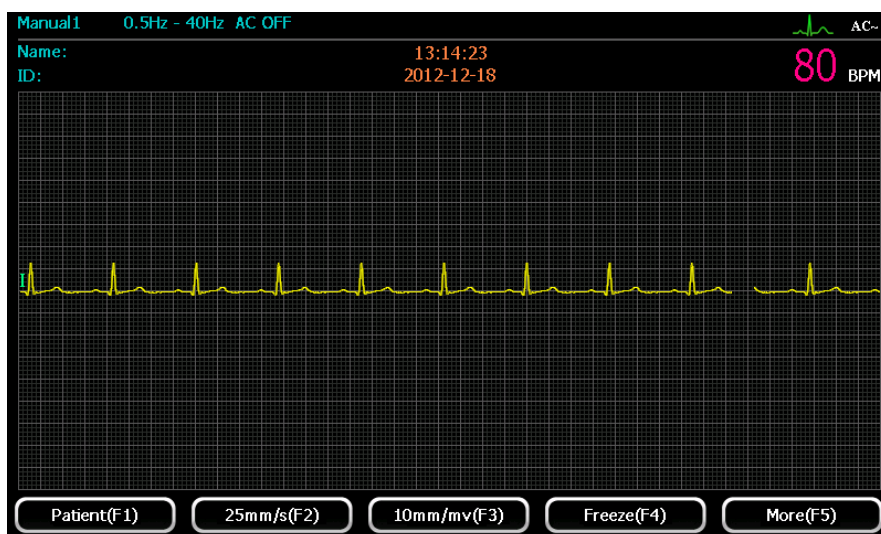
Manual 2: ECG is set to display two leads simultaneously. The users can record the ECG waveforms for two leads;

Manual 3: ECG is set to display three leads simultaneously. The users can record the ECG waveforms for three leads;

Manual six leads: ECG is set to display six leads simultaneously. The users can record the ECG waveforms for six leads; (Note: “Manual 6” is applicable for EM-601)

◆ Manual1

Select “Manual 1” mode by pressing **【manual】** button. Users can select one lead in 12 leads to display. The display interface is shown as the below:



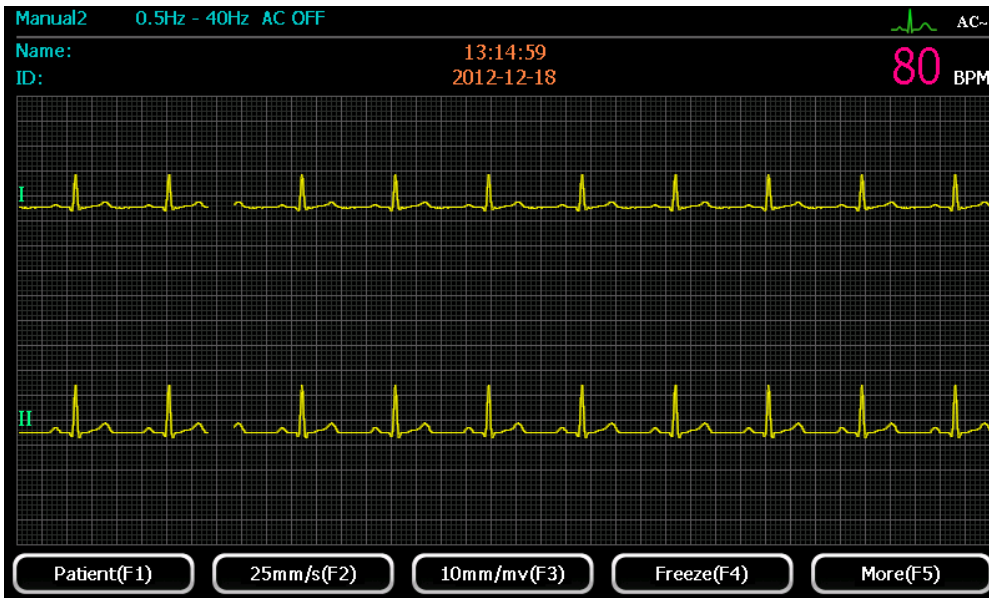
- 1) Press **【F2】** to set required paper speed. Four kinds of speed are available for selection: 6.25mm/s, 12.5mm/s, 25mm/s and 50 mm/s;
- 2) Press **【F3】** to set sensitivity level. Four kinds of sensitivity are available for selection: 2.5mm/mV, 5mm/mV, 10mm/mV and 20mm/mV;
- 3) When waveforms are stable, press **【START/STOP】** button to start printing records (record

time is depend by users). If needing to pause or stop the print, just press **【START/STOP】** button.

4) During the recording, press **【Lead>】** and **【Lead<】** button to switch to another lead's recording.

◆ Manual 2

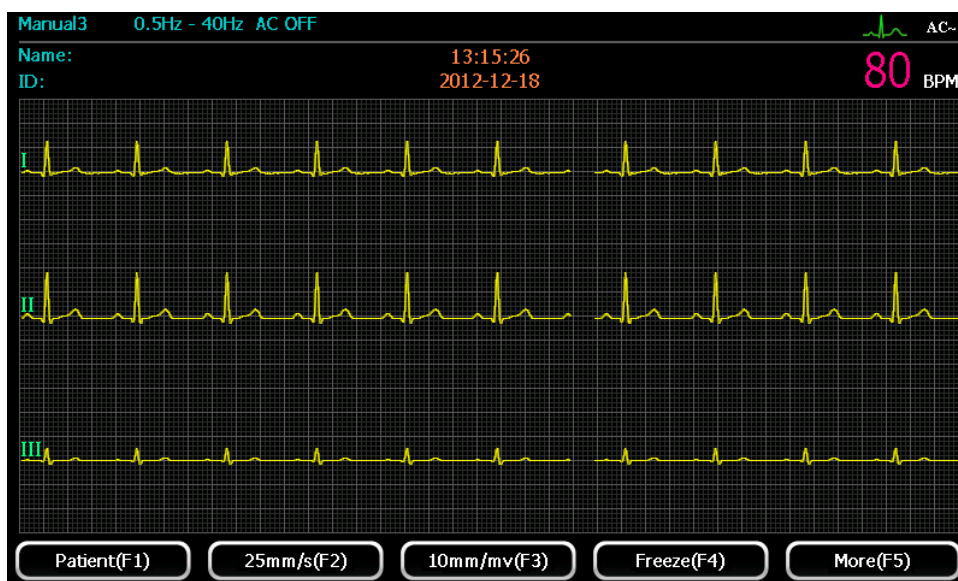
Select “Manual 2” mode by pressing **【manual】** button. Users can choose any one lead in 12 leads and rhythm lead to display. The display interface is shown as below:



For detailed operation, please refer to “Manual 1” mode.

◆ Manual 3

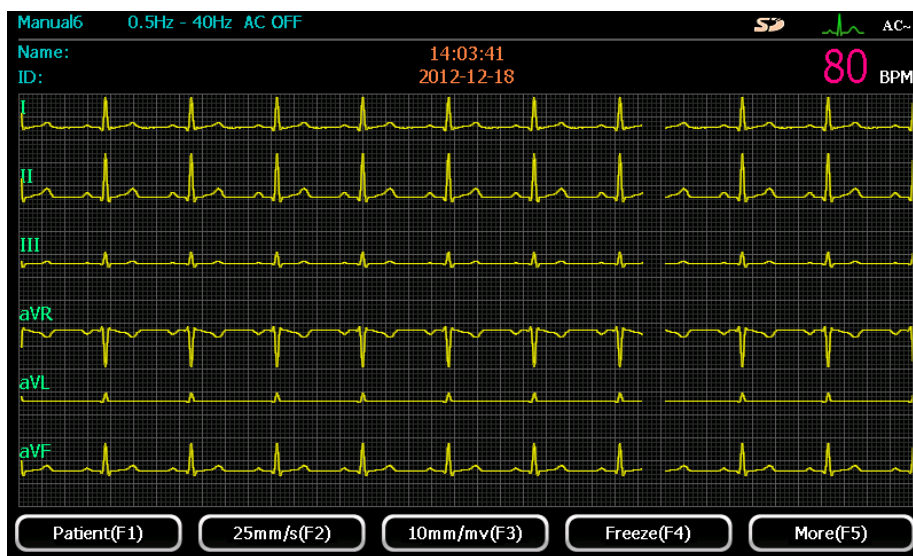
Select “Manual 3” mode by pressing **【manual】** button. Users can choose any three leads in 12 leads to display. The display screen is shown as the following figure.



For detailed operation, please refer to “Manual 1” mode.

◆ Manual 6(For EM-601 only)

Select “Manual 6” working mode by pressing **【manual】** button Users can choose any six leads to display. The display screen is shown as the following figure



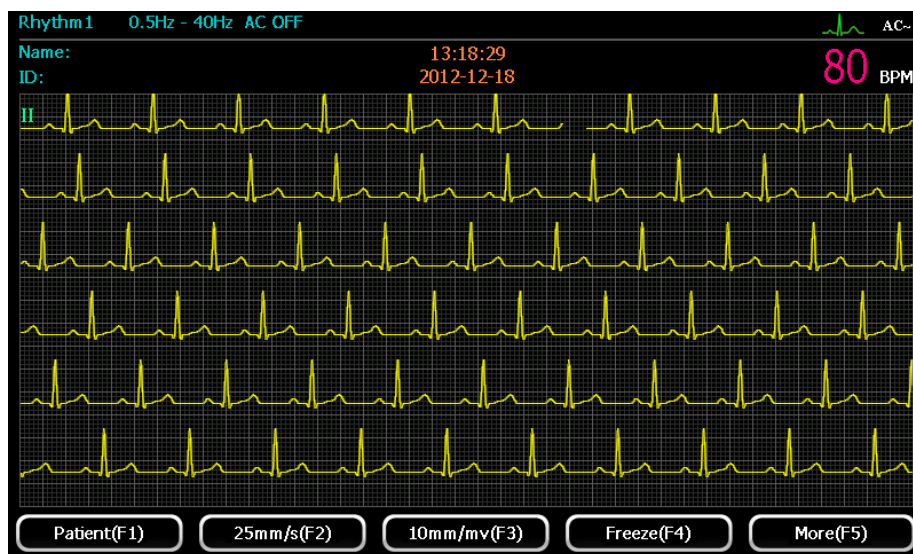
For detailed operation, please refer to “Manual 1” mode

5.3.2 Rhythm Mode

This mode is rhythm lead record mode. Under the mode, the ECG can acquire users defined rhythm. Press **【Start/Stop】** for recording, and the record length is 0~60 seconds, the ECG rhythm lead waveform with rhythm analysis will printed out.

To select rhythm, please refer to chapter 5.4.

Select “rhythm” mode by pressing **【RYH】**button. The ECG will connect data about the defined rhythm lead. The display screen is shown as the following figure:



- 1) Press **【F2】** to set paper speed. Four kinds of speed are available for selection: 6.25mm/s, 12.5mm/s, 25mm/s and 50 mm/s;
- 2) Press **【F3】** to set sensitivity . Four kinds of sensitivity are available for selection: 2.5mm/mV, 5mm/mV, 10mm/mV and 20mm/mV;
- 3) When waveforms become stable, press **【Start/Stop】** for recording, and the record length is 0~60 seconds, the ECG rhythm lead waveform with rhythm analysis will printed out. If needing to pause or stop the print, just press **【START/STOP】** button.

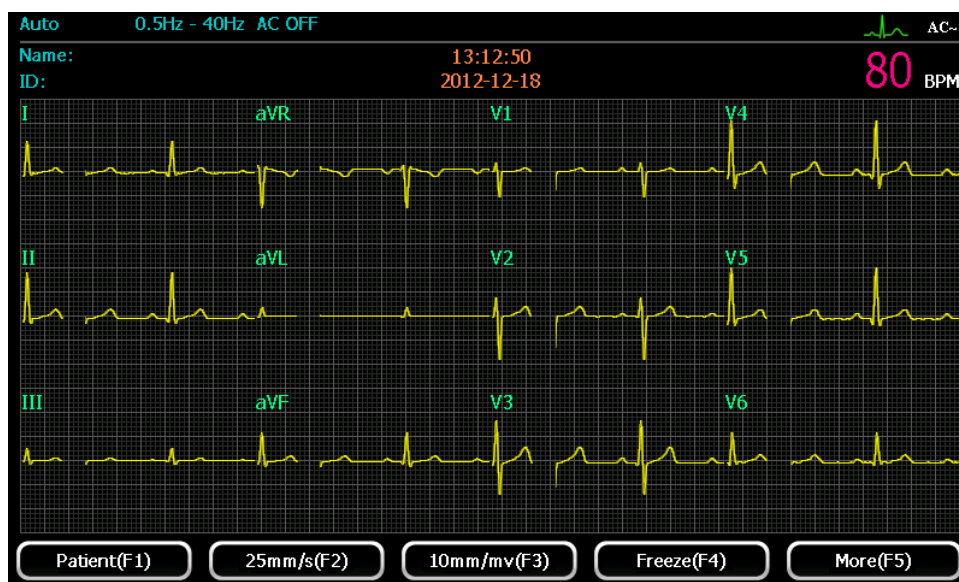
5.3.3 Auto Mode

Under Auto Mode, select 6 automatic display formats through “display setup” screen:

3CH×4, 3 CH×4+1R, 3 CH×4+3R, 6 CH×2, 6 CH×2+1R and 12 CH×1.

- 3 CH×4 3rows ×4 columns
- 3 CH×4+1R 3rows ×4 columns+ 1 rhythm lead
- 3 CH×4+3R 3 rows×4 columns+ 3 rhythm leads
- 6 CH×2 6 rows×2 columns
- 6 CH×2+1R 6 rows×2 columns+1 rhythm lead
- 12 CH×1 12 rows×1 column

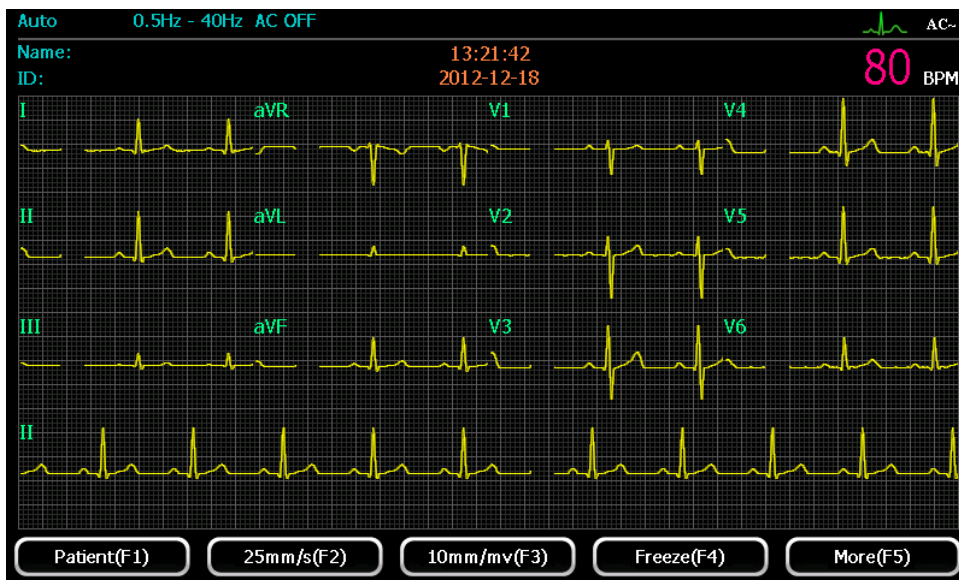
◆ 3×4format



- 1) Press **【F2】** to set paper speed. Four kinds of speed for selection: 6.25mm/s, 12.5mm/s, 25mm/s and 50 mm/s;
- 2) Press **【F3】** to set sensitivity. Four kinds sensitivity of for selection: 2.5mm/mV, 5mm/mV, 10mm/mV and 20mm/mV;

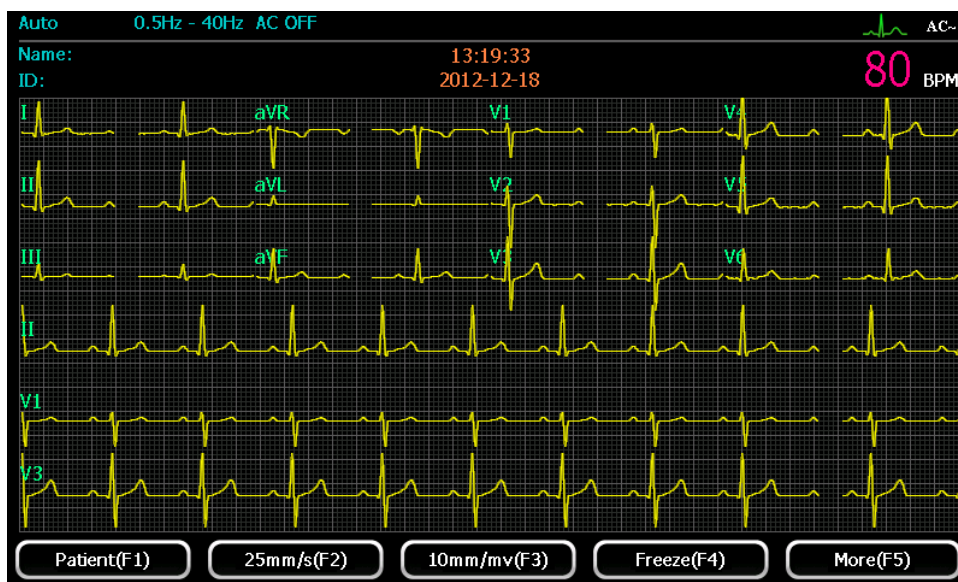
3) After waveforms become stable, press **【START/STOP】** button to start printing records (record time is depend on Users control). If needing to pause or stop the print, just press **【START/STOP】** button.

◆ 3CH×4+1R format



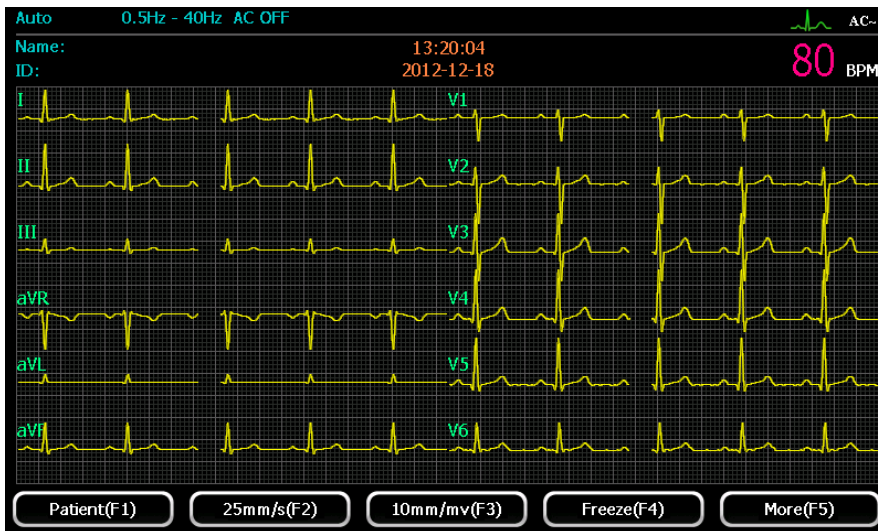
Detailed operation, please refer to “3×4 format”

◆ 3CH×4+3R format



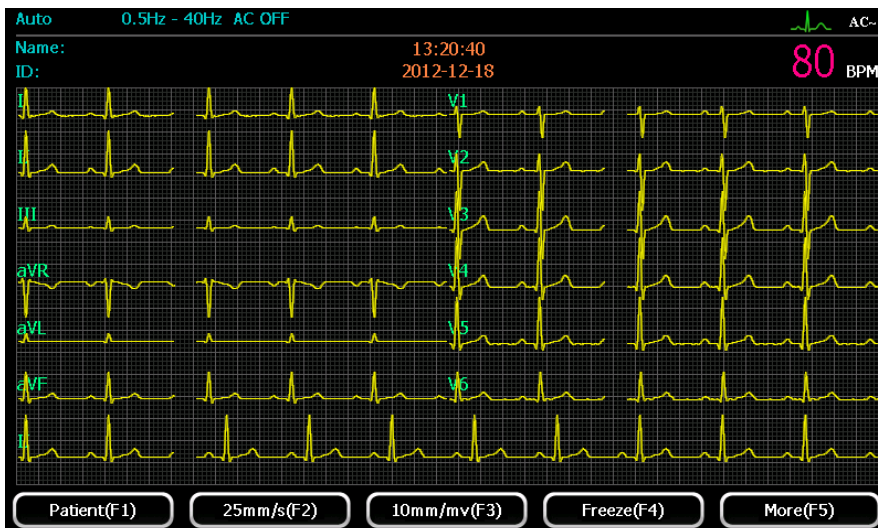
Detailed operation, please refer to “3×4 format”

◆ 6CH×2 format



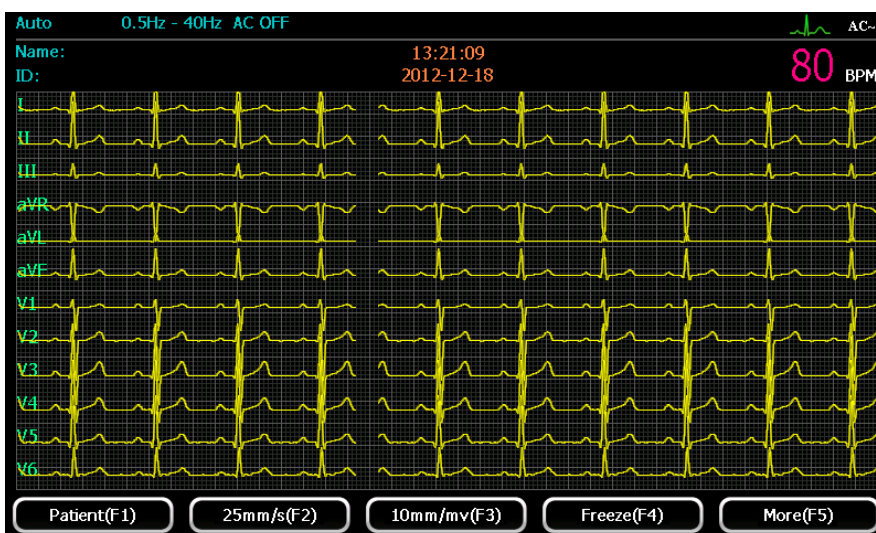
Detailed operation, please refer to “3×4 format”.

◆ 6CH×2+1R format



Detailed operation, please refer to “3×4 format”.

◆ 12CH×1 format

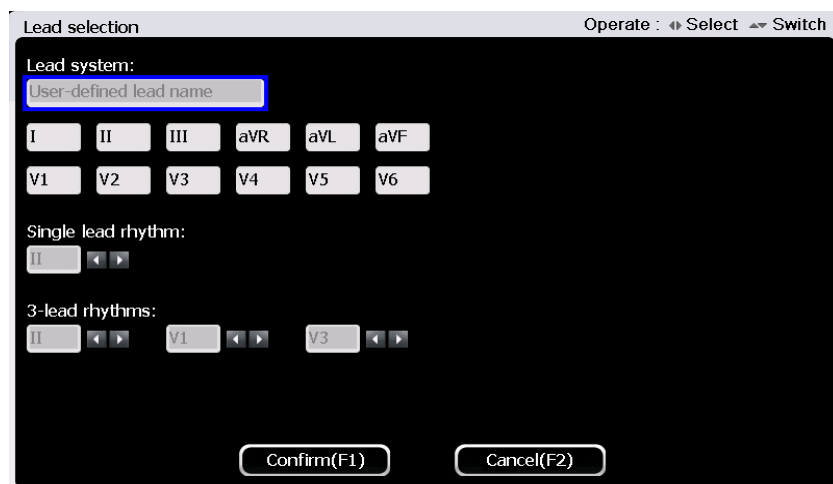


Detailed operation, please refer to “3×4 format”

5.4 Leads setup

On the second page of main interface, press **【F1】** button to enter lead setup interface. There are 8 lead systems for selection. For lead rhythm, you can choose either single lead or 3 lead rhythms as shown below.

There are 8 lead setup systems available for selection. Users can select required lead system through **【↔】** and **【↔】** button. The lead systems are defined as:



No	Lead Setup System	Electrode label
1	Standard lead system	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
2	Posterior wall of the lead system	I, II, III, aVR, aVL, aVF, V1, V2, V3, V7, V8, V9
3	Right chest lead system	I, II, III, aVR, aVL, aVF, V1, V2, V3R, V4R, V5R, V6R
4	left chest lead system	I, II, III, aVR, aVL, aVF, V3R, V4R, V5R, V7, V8, V9
5	Previous intercostal lead system	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, , V6
6	Next intercostal lead system	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
7	FRANK lead system	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
8	CUBRERA lead system	aVL, I,-aVR, II, aVF, III, V1, V2, V3, V4, V5, V6

Users can set single lead rhythm and three lead rhythms here. Select any lead rhythm from the 12 leads by pressing **【▲】** and **【▼】** button.

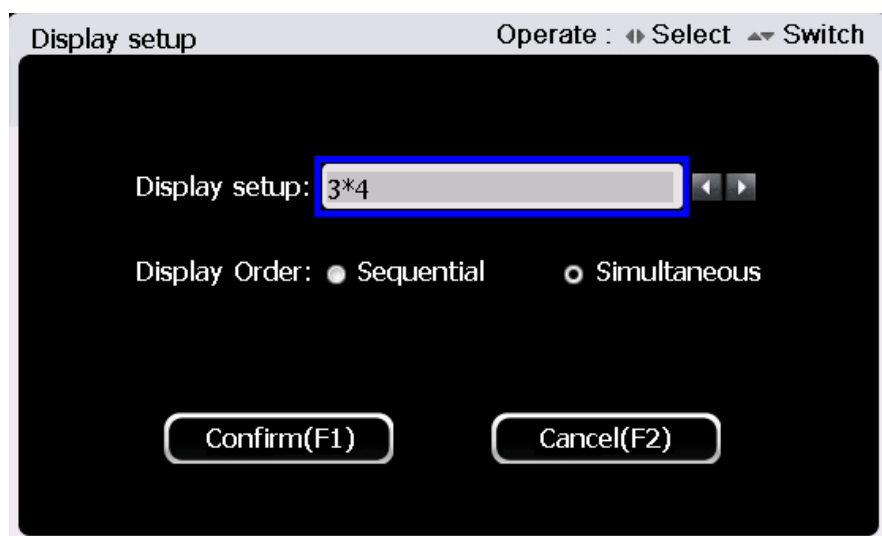
Single lead rhythm: Users can set any single lead as lead rhythm. In auto mode, if 3CH×4+1R or 6CH×2+1R are selected, the single lead rhythm displayed is the lead set here.

Three lead rhythms: Users can set any 3 leads as lead rhythms in the 12 leads. Under auto mode, if 3CH×4+3R is selected, the lead rhythm recorded as the rhythm leads set here.

When lead selection finished, press **【F1】** button to save and return, or press **【F2】** button to cancel setup and return.

5.5 Display setup

In second page of the main interface, press **【F2】** to enter display setup interface. The interface is shown as the figure below:



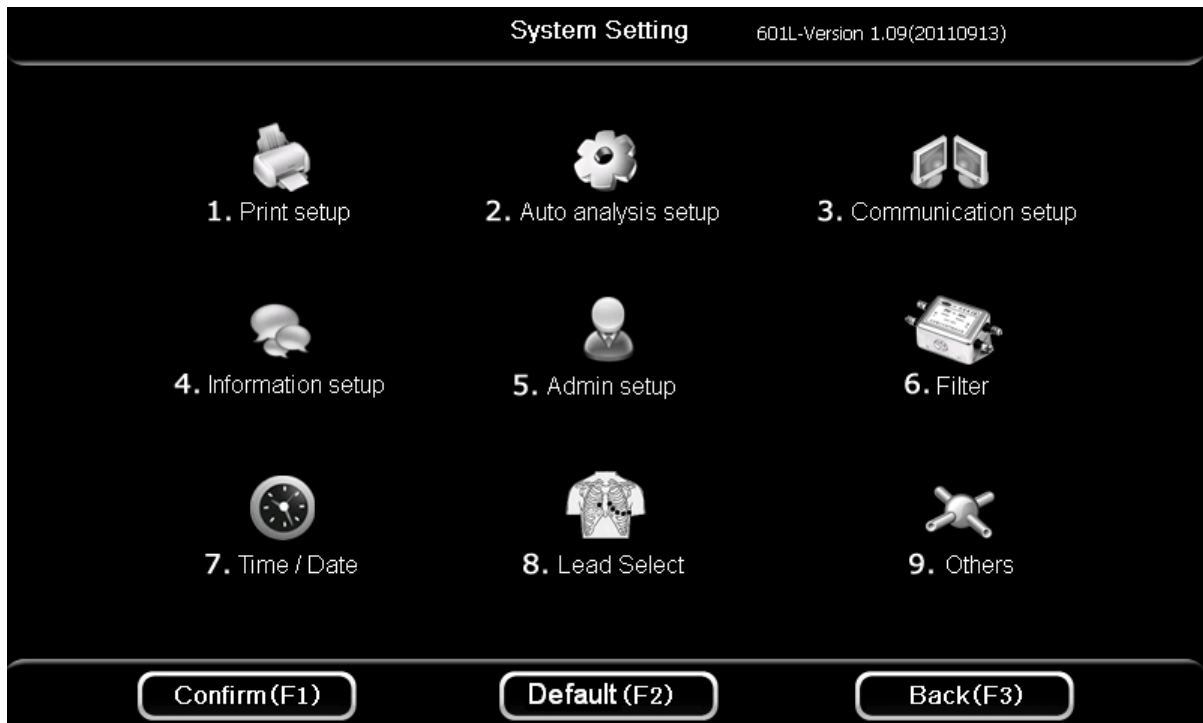
Under display setup interface, select setting item between “display format” and “display order” through **【▲】** and **【▼】** button. After selecting the setting item, use **【↔】** and **【↔】** button to choose setting contents

- ◆ There are 6 display formats as following: 3CH×4, 3CH×4+1rhythm, 3CH×4+3rhythm, 6CH×2, 6CH×2+1rhythm and 12CH×1.
- ◆ Display sequence: sequential mode or simultaneous mode. In sequential mode, the waveforms will be displayed one group after another group. In simultaneous mode, all waveforms will be displayed at the same time.

After display setup, press **【F1】** button to save and return, or press **【F2】** button to cancel setup and return.

5.6 System setting

On the second page of the main interface, press **【F4】** to enter system setup interface. The interface is shown as the figure below:

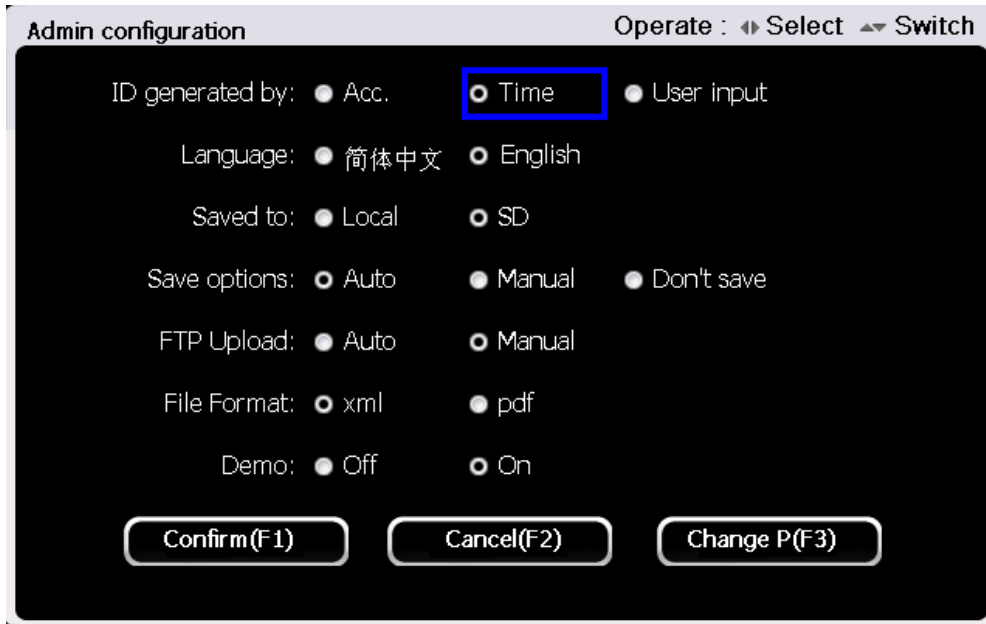


Press **【F1】** button to save system setting and return, press **【F3】** button to cancel setting and return, or press **【F2】** button to return to the default setup.

Press button **【1】 ~ 【9】** to enter different items settings menu:

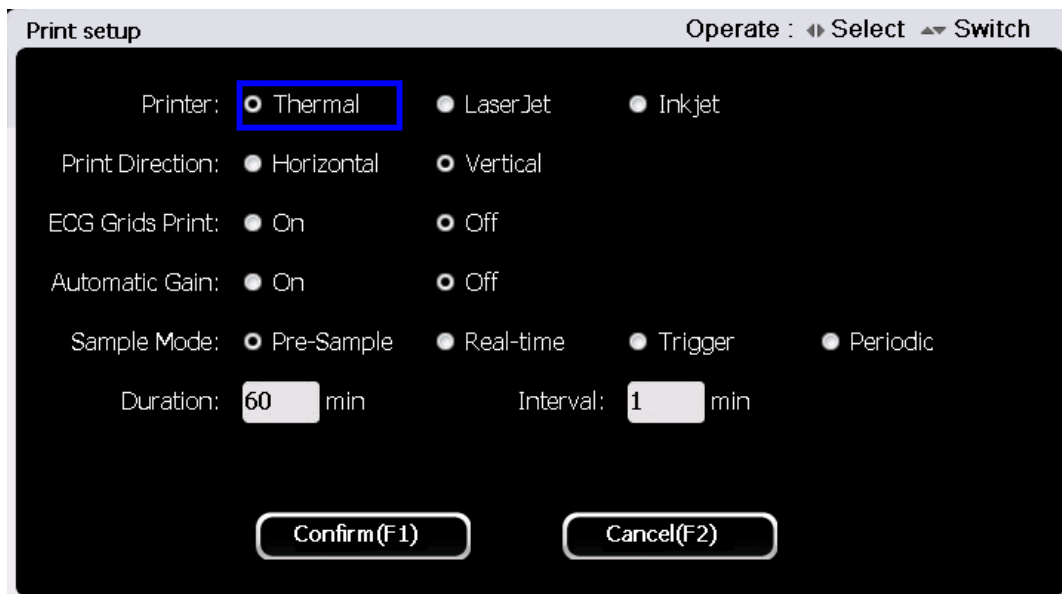
- 【1】** Print setup
- 【2】** Auto analysis setup
- 【3】** Communication setup
- 【4】** Information setup
- 【5】** Administrator setup
- 【6】** Filter
- 【7】** Time and date
- 【8】** Lead setup
- 【9】** Others

5.6.1 Management Setup



5.6.2 Print setup

Press button **【1】** to enter print setup interface in the system setup interface. The interface is shown as the figure below:



At the print setup interface, use **【▲】** and **【▼】** button to select setting items among Printer, Record order and ECG grids print, and then use **【↔】** and **【↵】** to set

Printer: Thermal Printer, Laser Printer and Ink Printer.

Record order: sequential and simultaneous.

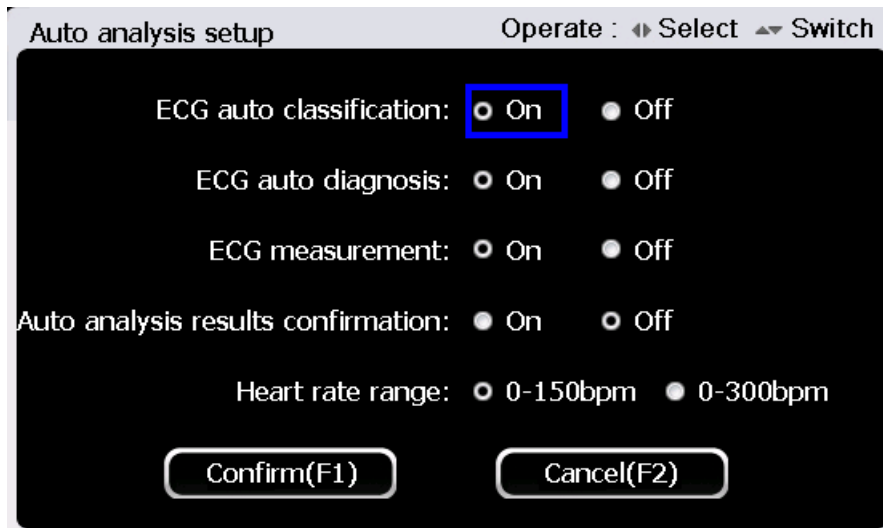
ECG grid print: enable and disable grid printing on the recording paper

- 1) When the record order is set to be sequential, the leads will acquire data sequentially.
- 2) When the record order is set to be simultaneous, the leads will acquire data simultaneously.

Press **【F1】** button to save print setup and return, or press **【F2】** button to cancel and return.

5.6.3 Auto analysis setup

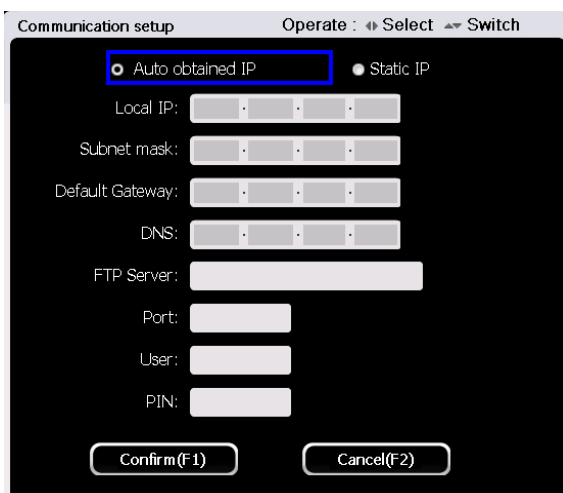
Press button **【2】** to enter auto analysis setup at the system setup interface. The interface is shown as below:



In auto analysis setup interface, use **【▲】** and **【▼】** button to select setting items among “ECG auto classification”, “ECG auto analysis function”, “ECG measurement”, “Auto analysis results confirmation” and “Heart rate range”. use **【→】** and **【←】** to “enable” and “disable”. Press **【F1】** button to save auto analysis setup and return, or press **【F2】** button to cancel and return.

5.6.4 Communication setup

Press **【3】** to enter communication setup at the system setup interface. The interface is shown as figure below:



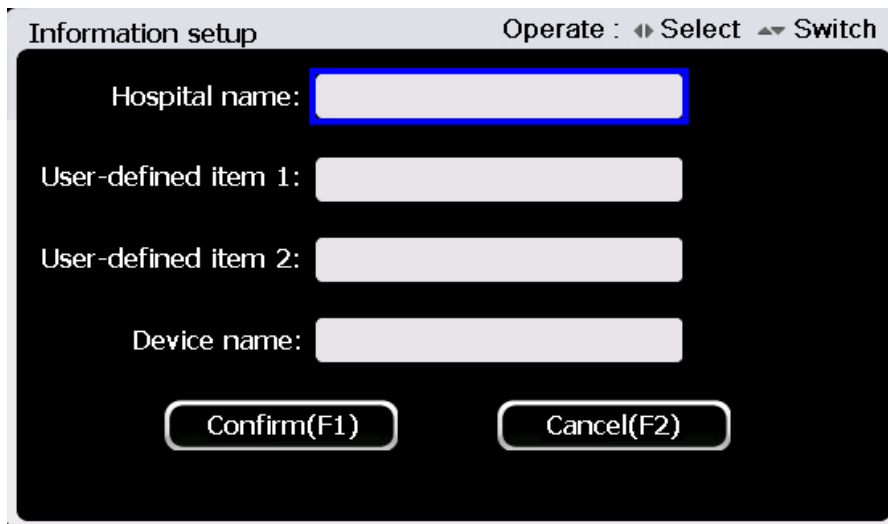
At the communication setup interface, use **【▲】** and **【▼】** button to select setting items, and use

【↔】 and **【↵】** number keys and letter keys to set and input.

Press **【F1】** button to save communication setup and return, or press **【F2】** button to cancel and return.

5.6.5 Information setup

Press button **【4】** to enter information setup in the system setup interface. The interface is shown as below:

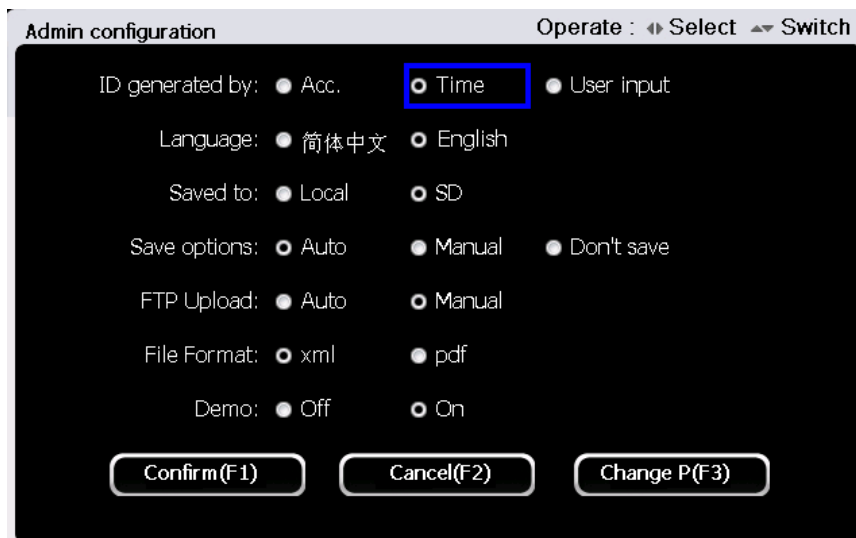


At the information setup interface, use **【▲】** and **【▼】** button to select setting items, and use number keys and letter keys to select and input.

Press **【F1】** button to save information setup and return, or press **【F2】** button to cancel and return.

5.6.6 Admin setup/configuration

Press button **【5】** to enter Admin setup/configuration at the system setting interface. Type in password 123456 and press **【F1】** to enter. The interface is shown as figure below:

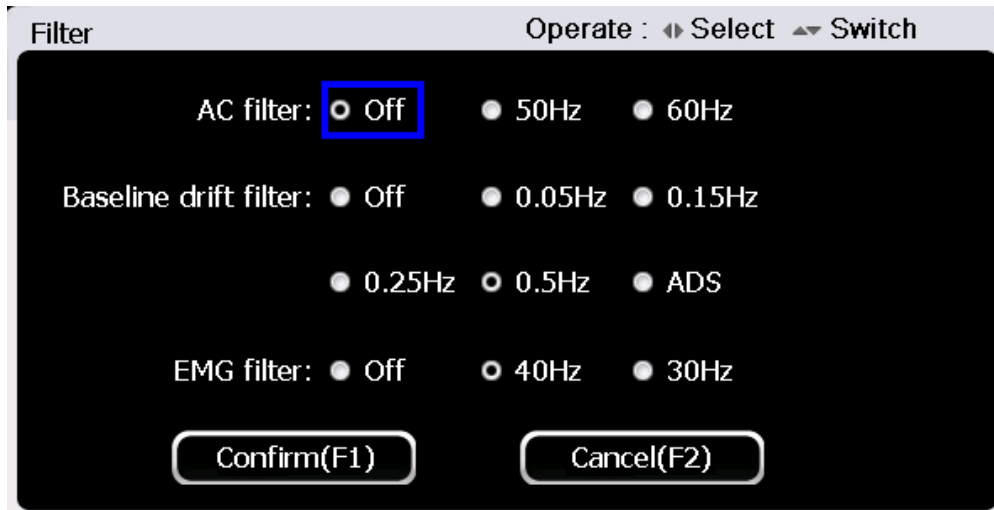


Use **【▲】** and **【▼】** button to select setting items of “ID generated by”, “Screen color” “language” “Saved to” and “Save options”, and use **【↔】** and **【↵】** to set.

After administrator setup, press **【F1】** button to save and return, or press **【F2】** button to cancel and return.

5.6.7 Filter setup

Press button **【6】** to enter filter setup at the system setup interface. The interface is shown as figure below:



In the filter setup interface, use **【▲】** and **【▼】** button to select setting times among “AC filter”, “Baseline drift filter” and “EMG Filter”, use **【↔】** and **【↔】** to set.

Baseline Drift Filter: 0.05Hz/ 0.15Hz/ 0.25Hz/0.5Hz /ADS/OFF;

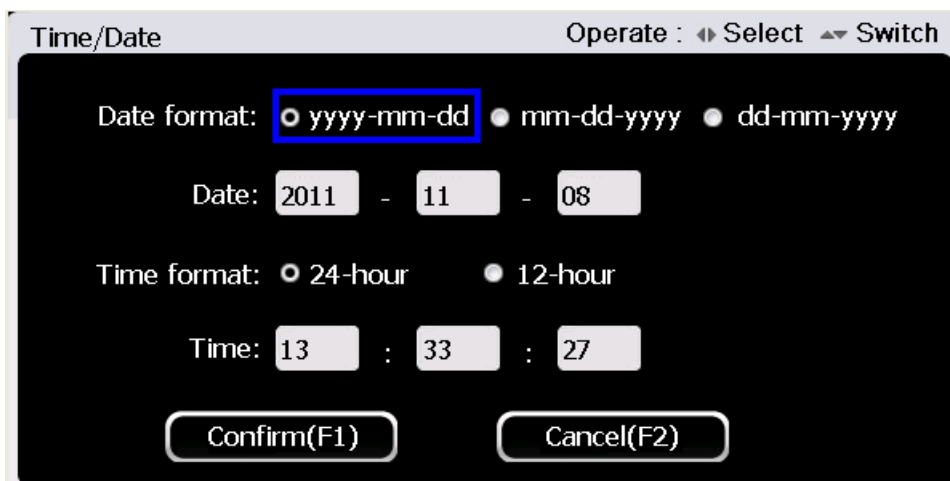
EMG Filter: 30Hz/40Hz/OFF

AC Filter: 50Hz/60Hz/OFF

Press **【F1】** button to save filter setup and return, or press **【F2】** button to cancel and return.

5.6.8 Time and date setup

Press button **【7】** to enter time and date setup at the system setup interface. The interface is shown as figure below:



At the time and date setup interface, use **【▲】** and **【▼】** button to select setting items of “date format”, “date”, “time format” and “time”, and use **【↔】** and **【↵】** button and number key to set and input.

Date/Time: users can set current date and time. Date and time will be displayed on the main User interface;

Date format: yyyy—mm—dd, mm—dd—yyyy and dd—mm—yyyy;

Time format: 24-hour and 12-hour

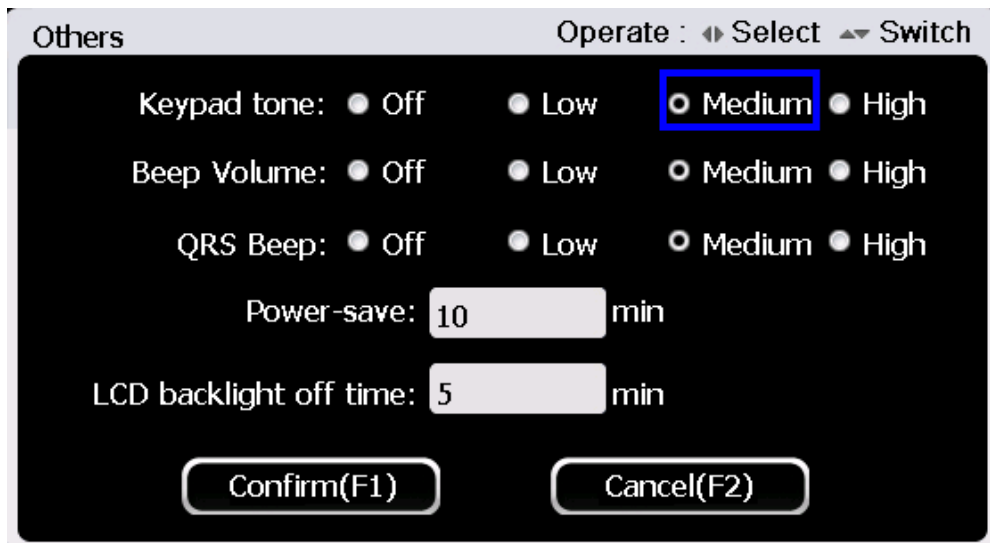
Press **【F1】** button to save time and date setup and return, or press **【F2】** button to cancel and return.

5.6.9 Lead selection setup

Press button**【8】**to enter lead selection setup at the system setup interface. For details, please refer to chapter 5.4.

5.6.10 Others

Press button **【9】** to enter other setup at the system setup interface, the interface is shown as below:



At the other function setup interface, use **【▲】** and **【▼】** button to select setting items among “keypad tone”, “Beep volume”, “QRS Beep”, “Power-save” and “LCD backlight off time”, and use **【↔】** and **【↵】** button and number key to select and input.

Press **【F1】** button to save others setup and return, or press **【F2】** button to cancel and return.

File

File--SD		Operate : ◀ Select ▶ Switch			
ID	Name	Sex	Age	Time	Record mode
123	john	Male	23	20121115145944	Auto
124	lilei	Male	36	20121116095433	Auto
125	lili	Female	24	20121126150007	Auto
				20121215133207	Auto

Transmit(F1) Delete(F2) Print(F3) Preview(F4) More(F5)

Transmit: transmit the file via Network.

Delete, Delete the patient data selected

Print, print the file selected.

Preview, preview the patient file selected

Press more to next page

File--SD		Operate : ◀ Select ▶ Switch			
ID	Name	Sex	Age	Time	Record mode
123	john	Male	23	20121115145944	Auto
124	lilei	Male	36	20121116095433	Auto
125	lili	Female	24	20121126150007	Auto
				20121215133207	Auto

Edit(F1) Query(F2) Exit(F3) More(F5)

Edit: Edit the patient information here, it is able to edit the name, ID etc.

Patient		Operate : ◀ Select ▶ Switch	
ID:	<input type="text"/>	Item1:	<input type="text"/>
Name:	<input type="text"/>	Item2:	<input type="text"/>
Age:	<input type="text"/>	Weight:	<input type="text"/> kg
Sex:	<input type="text"/>	Height:	<input type="text"/> cm
Hospital:	<input type="text"/>	BP:	<input type="text"/> / <input type="text"/> mmHg
Department:	<input type="text"/>		

Confirm(F1) Cancel(F2) Clear(F3)

Query, query the patient data by ID, Name, Sex, Age, time.

Query Operate : ◀ Select ▶ Switch

ID:

Name:

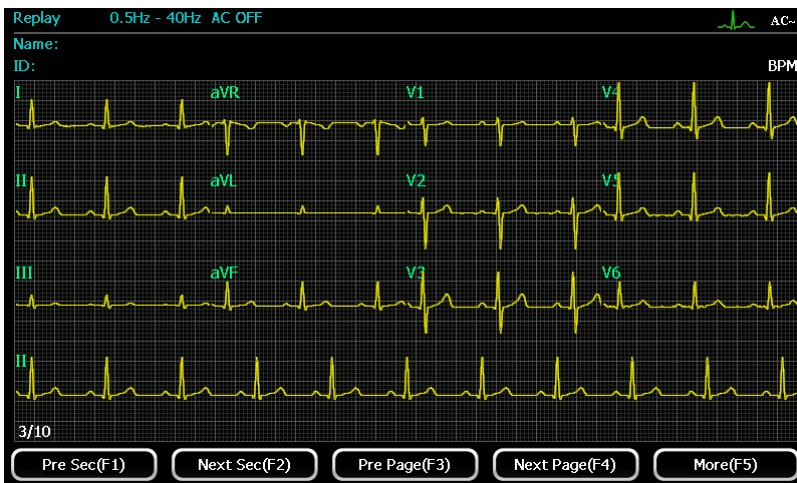
Sex: ◀ ▶ Age:

Time: Off On

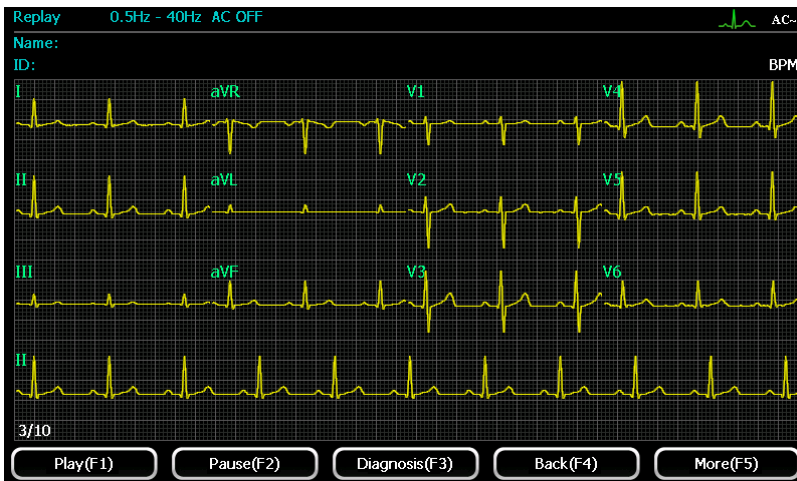
/ / -- / /

Replay

Press F4 to Freeze the waveform displayed on the main interface.



Press MORE to next page.



It is able to freeze up to 120 seconds ECG waveform, 10 seconds ECG waveform at least.(the figure showed above is the data freeze for 10 seconds, ECG waveform is displayed from the 3rd second.)

Pre Sec: Display from previous second.

Next Sec: Display from next second.

Pre Page: Display from previous page

Next Page: Display from next page.


Play: Play from the current displayed waveform

Pause: Pause in the play process

Diagnosis: make diagnosis for the 10 seconds ECG waveform current displayed

6 Cleaning, Disinfection and Maintenance

6.1 Cleaning

 Turn off the ECG and remove the patient cable. Unplug the power cord from the AC outlet if main supply applied.

1) Cleaning the main unit and patient cable

Wipe the exterior of the main unit and patient cable with a damp cloth using mild (non-caustic neutral) detergent diluted in water. Then wipe it with a dry cloth.

2) Cleaning the electrodes

Remove the residual gel from the electrodes with a clean soft cloth first. Take off the clip and suction ball from electrodes connectors. Immerse them soap water (less than 35 Celsius) to remove the gel, then use clean water to wash again, air dry or use a clean cloth to dry.

3) Cleaning the printing head


Dirty thermal printing head can deteriorate the record result. Clean the printing head at least one time monthly.

Open the recorder cabinet and take out recording paper when the ECG is power off. Wipe the printing head gently with a clean soft cloth damped in 75% alcohol. Do not use hard objects to scratch the printing head. Otherwise the printing head will be damaged. Load the recording paper and close the cover when all traces of alcohol are evaporated.


4) Cleaning the silicon glue alloy Shaft


Silicon glue alloy Shaft should be flat, smooth and free-of-dirt. Otherwise the ECG records will be influenced. Wipe the shaft with damped soft cloth. Close the cover when it is air dried.

 Prevent the liquid from leaking into the main unit while cleaning

 Do not clean the unit and accessories with hard materials and avoid scratching the electrodes.


6.2 Disinfection

 It is recommended that disinfection should be only performed under the regulation of medical situations or under other proper situations; Disinfecting equipment must be disinfected before cleaning the ECG machine. Do not use high-temperature, high-pressure steam, ionizing radiation methods for disinfection.

 Do not use chlorine-containing disinfectant for disinfection, such as chlorinated lime and sodium hypochlorite etc.

6.3 Care and Maintenance

6.3.1 Battery capacity, charging and replacement

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

1) Charge

ECGMAC ECG is equipped with recharge control circuit together with built-in rechargeable lithium battery. Because of the capacity consumption during storage and transport, the capacity of battery is not full while using the first time. Battery-recharging should be suggested before first usage.

When connect with the mains supply, the battery will be recharged automatically. Then the battery recharge indicator light and mains supply indicator light on. When the capacity of battery is full, the battery recharge indicator light will be off.

2) Battery capacity indicator

When using the battery, there is a sign representing the battery capacity on the LCD screen. As shown in the following figures,



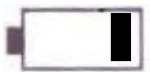
Battery is full



Battery is sufficient



Battery is low. Need charging




Battery is not sufficient. Need charging




Battery is completely empty. Need charging immediately.

3) Replacement

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

 Danger of explosion— Do not reverse the anode and cathode when connecting the battery

 Only authorized maintenance engineers can open the battery compartment and replace the battery. Only the battery of same model and specification provided by manufacturer should be used

 Battery has to be disposed and recycled according to the local regulation.

6.3.3 Maintenance of Main Unit, Patient Cable & Electrodes

1) Main Unit

Make sure the instrument is powered off.

Clean the instrument and accessories. Put on the dustproof cover after use.

Place the instrument in a dry and cool environment. Prevent from shaking violently when moving it to another place.

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

Handle over the medical instrument to maintenance departments to check the ECG instrument regularly.

2) Patient Cable

1) Check the patient cable is well-collected according to the following table. The resistor between the electrode plug and plug pin of the patient cable plug should be less than 10Ω ;

Note: the resistance of patient cable with the function of defibrillating protection is around $10K\Omega$.

Wire plug symbol	R	L	F	RF	C1	C2	C3	C4	C5	C6
Plug pin location	9	10	11	14	12	1	2	3	4	5

2) Integrity of patient cable, including main cable and lead wires, should be checked regularly.

3) Knotting or crooking in closed angle will shorten the patient cable's life, so please align the patient cable and then collect the electrodes

4) 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

5) Storing the lead wires in bigger wheel or swinging to avoid twisting or folding


6) Once damaged or aged patient cable has been found, replace it with new one immediately

7) Electrodes

- Electrodes must be cleaned after use and be sure there is no remaining gel on them
- Keep the suction ball of chest electrodes from sunshine and excessive temperature.
- After long time 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

6.3.4 Fuse exchange

After AC power cord is well connected, if the AC power indicator light is off, the battery is working and the AC power supply from the socket is normal, it might indicate the fuse is burned and need to be replaced.

 If the same model fuse is broken again after changing the fuse, it might indicate other failure in the instrument. In this condition, turn off the machine and contact the maintenance agent designated by ECGMAC.

7 Common troubleshooting and solution

7.1 Some lead without waveform printout

This phenomenon might be caused by following issues:

- When the patient cable is connected with patient, if the instrument start record before ECG waveforms and data become stable, it might leads to data value saturation or overflow in the baseline stable software.

Solution: repeat operation.

- There is failure with patient cable. Check the patient cable by the methods in chapter 7.3.3. Contact our after-sale service department or appointed maintenance center if it is broken.
- If the instrument still has this problem, normally the problem is caused by the signal channel failure, contacts our after-sale service department or appointed maintenance center.

7.2 Vertical breakpoint of printed waveform

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

Solution: Clean the printer head.

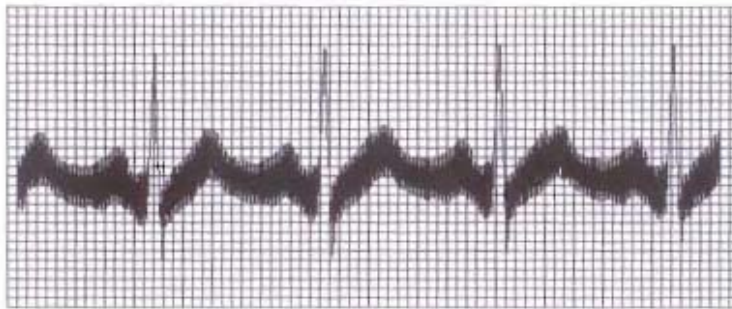
If not due to dust or dirt, maybe the heating unit of print head gets damaged. Please contact with our service department or appointed maintenance center.

7.3 Buttons on the control panel not working

Possible reason: The control panel and circuit board are not well connected due to the vibration in transportation. Solution: Open the instrument cover and connect them again, if the problem still exists, contact with our after sale service department or appointed maintenance center.

7.4 AC interference

AC interference is interference which arises from super positioning of ECG wanted signal with sinusoidal voltages with the mains frequency. Phenomenon shown as below:

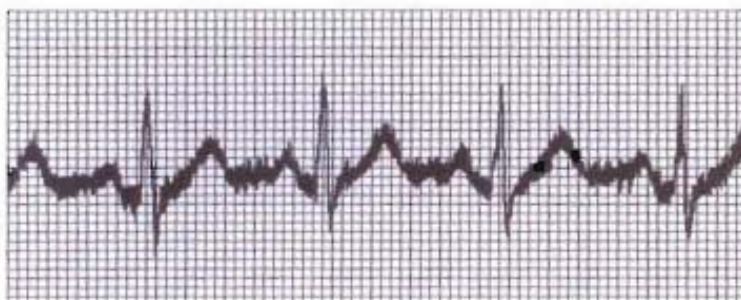


Solutions:

- Make sure the instrument is properly grounded
- Electrode or patient cable is correctly connected
- Applied electrode gel is enough
- The metal bed is properly grounded
- Keep the patient from physical contact with the surroundings.
- There is no powerful equipment operating nearby, such as X ray or ultrasonic machine
- The patient don't wears jewelry such as glass or gem
- If interference still exists, please reset AC filter according to local AC frequency

7.5 EMG interference

Phenomenon: Recorded ECG base line has irregular vibration, as shown in the following ECG waveforms.



Solutions:

- Move to a comfortable room if the room is uncomfortable
- Let the patient to be relaxed
- Make sure the bed is not too small.
- The patient should keep quiet
- Change the limb electrodes if it is too tight.
- If the EMG interference still exists, please apply EMG filter .The waveform will be weakened a little and have obvious effect for the weakening of R wave.

7.6 Baseline Drift

Phenomenon: The baseline of the recorded ECG waveforms wandering as shown in the following ECG waveforms.



Solutions:

- Make sure the electrodes are well connected
- The lead wire and electrodes are well connected
- Check the cleaning of the electrode and patient skin
- Electrode gel is applied on the electrodes and skin
- Keep the patient from motion or hyperventilation
- The old electrodes and new ones are mix use
- If the problem still exists, please apply baseline filter.

8 Warranty and after-sale service

8.1 Warranty

ECGMAC warrants that ECGMAC's products meet the labeled specifications of the products and will be free from defects in materials and workmanship occur within warranty period.

ECGMAC warrants main unit of product against all defects or deficiency in material, workmanship under normal use for a period of two (2) years from the date of the products shipped to distributors. The accessories used with the main unit are warranted for six months from the date of the accessories shipped to distributors. Such accessories include: patient cable, power cord, grounding wire, electrodes and battery. If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, ECGMAC will, at its discretion, repair or replace the defective part(s) free of charge. ECGMAC will not provide a substitute product for use when the defective product is being repaired.

The service claimer is responsible for freight, insurance and customs duties for the returned products to ECGMAC, ECGMAC responsible for the freight, insurance and customs duties to service claimer within the warranty. The service claimer is responsible for any freight, insurance & custom charges for the product out of warranty.

This warranty does not cover damage caused by:

- a) Damage caused by alteration or repair by anyone not authorized by ECGMAC.
- b) Replacement or removal of serial number label and manufacture label.
- c) Subsequent damage caused by improper operations, storage or transportation.
- d) Damage caused by accidents.

8.2 Customer service

If the user has any questions, please contact your local distributor or manufacturer.

After-sales service agent: Shenzhen ECGMAC Medical Electronics Co., Ltd

Company address: 2nd Floor of Block 2 , Haoye Industrial Park, Tiegang Road, Xixiang Street,

Baoan District, 518102 Shenzhen, China

Postal code: 518102

Telephone: +86-755-27697821 Fax: +86-755-27697823-616

E-mail: Info@ecgmac.com

Appendix A Packaging and Accessories

A.1 Packing

When the product is dispatched from the factory, completed package should contain the following accessories:

ECG Main Unit	1
Patient Cable	1
Limb electrodes (clamp)	4
Chest electrodes (suction ball)	6
Power Cord	1
Grounding Wire	1
Thermal Rolled Paper	1
Warranty Card	1
Verification Certificate	1
Quality Certificate	1
Packing List	1
User Manual	1

A.2 Caution

- 1) Open the box from the top;
- 2) After opening the box, check the accessories and files according to the packing list, and then check the instrument;
- 3) If the package does not match the packaging list or the instrument does not work properly, contact the sales department or customer service department;
- 4) Please use the accessories supplied by ECGMAC. Accessories from other suppliers may damage the instrument and affect its performance and safety. Before using the accessories from other suppliers, please consult our customer service first;
- 5) To enable us to serve you in time, please fill out the warranty card (copy) and mail it to us;
- 6) Please keep the instrument package for periodic testing or equipment maintenance.

Appendix B Product Performance

B.1 External Output

1.1 Sensitivity 1V/mV, Tolerance: $\pm 5\%$ or 0.5V/mV.

1.2 Impedance of External Output $\leq 100 \Omega$.

1.3 Output short circuit shall not damage the ECG machine.

B.2 External DC signal Input

1.4 Sensitivity 10mm/V. Tolerance: $\pm 5\%$

1.5 Input Impedance $\geq 100k \Omega$

1.6 Input Impedance Attenuation. By Paralleling impedance of 4700PF capacitor and 620K Ω is connected to each lead electrode. When achieving the specified value, the impedance should be near to 2.5M Ω , each uniform resistance should be no less than 600 k Ω .

1.7 Input circuit current: all input circuit current should be less than 0.1uA

1.8 Calibration Voltage: 1mV, tolerance $\pm 5\%$

1.9 Sensitivity

1.9.1 Sensitivity control: At least three grade: 5, 10, 20mm/mV. Tolerance $\pm 5\%$ by shifting

1.9.2 Anti-polarization Voltage : Applying $\pm 300mV$ DC polarization Voltage, the tolerance of sensitivity is $\pm 5\%$

1.9.3 Minimum testing signal: Testing the energy of deviated sine signal of 10Hz, 20 μV (summit)

1.10 Noise Level

By paralleling impedance of 0.047 μF capacitor and 51k Ω resistance which is connected between input terminal and neutral electrode. Within the frequency range of regulation 4.2.10. The noise level should be no more than 15 μV (peak to peak value)

1.11 Anti-interference

1.11.1 The CMRR of each lead should be no less than 89db

1.11.2 ECG represents 10V rejection of common mode signal on patient, according to picture 5 simulation test, each lead is connected with simulation electrode --- Skin none-balance impedance(paralleling impedance of 51k Ω resistance and 0.047 μF capacitor) . The recording amplitude should be less than 10mm

1.12 50Hz Anti-interference filter $\geq 20dB$

Table 1 Input Impedance

Lead Position	Lead Electrode		The summit value of deflection front traced by K open circuit (mm)	
	Connecting to P1	Connecting to P2	Single Channel ECG	Multi-channel ECG
I, II, aVR, aVL, aVF, V1	R	All other Lead electrodes	8	8
I, III, aVL, aVR, aVF, V2	L	All other Lead electrodes		
II, III, aVF, aVR, aVL, V3	F	All other Lead electrodes		
V _i (i is 1~6)	C _i	All other Lead electrodes		
V _x , V _y , V _z	A, C, F, M	I, E, H	—	

1.13 Features of Amplitude Frequency

When the filter is shut off, take 10Hz sine wave as reference.

From 0.5 to 50Hz, the tolerance of amplitude of frequency is -10%~+5%.

From 50 to 70Hz, the tolerance of amplitude of frequency is -30%~+5%

1.14 Features of Low Frequency .Time Constant no less than 3.2s

1.15 Baseline stability

1.15.1 Stable Power: baseline drifting should be no more than 1mm

1.15.2 Unstable Power: baseline drifting should be no more than 1mm

1.15.3 Sensitivity (no signal input) : baseline drifting should be no more than 2mm

1.15.4 Temperature Drift: From 5~40℃, baseline drifting should be no more than 0.5mm/℃

1.16 Paper Speed

6.25 mm/s 12.5 mm/s 25mm/s and 50mm/s , tolerance : ±5%

1.17 The impact of AC to DC conversion

The DC indicator should be lit when changing AC to DC conversion. All operation should be normal.

1.18 Printing resolution (Thermal matrix printing)

Y axis ≥8 dots/mm;

X axis ≥32 dots/mm (Paper speed 25 mm/s) 、 ≥16 dots/mm (Paper speed 50 mm/s) .

1.19 Request of Thermal matrix printing

Printer can record letters and marks. When recording, the printer could print out lead, paper speed, gain and etc.

- 1.20** The range of voltage input
Each lead should no less than 0.03 to 5mV and the waveform should be correct.
- 1.21** Tolerance of Weighted parameters
Should be no more than $\pm 10\%$.
- 1.22** Waveform identification and amplitude-time parameters measurement
Should match with the waveform shown in A.1,A.2 and A.3 in appendix JJG 1041-2008.
The testing result comply with the value range of A.1.1~A.1.4, A.2.1~A.2.2 in appendix JJG 1041-2008.
- 1.23** Voltage measurement tolerance
Should not exceed the value range of table A.1.1~A.1.4 in appendix JJG 1041-2008
- 1.23.1** Measurement tolerance of time interval
Should not exceed the error range of table A.2.1, A.2.2 in Appendix JJG 1041-2008

Appendix C Specification

C.1 Technical Index

1) Main Machine

Lead	Standard 12 Leads
Sampling Method	12 leads simultaneously
Measurement Parameter	HR, PR interval, QRS duration, QT/QTc, R/QRS/T electric axis, RV5/SVI amplitude
Input Method	Floating Ground input with defibrillator protection
Recording Mode	Manual Mode (Manual 1 lead, Manual 2 Lead, Manual 3 Lead, Manual 6 Lead)
	Rhythm Mode
	Auto Mode (3CH × 4, 3CH × 4+1 rhythm, 3CH × 4+3rhythm, 6CH × 2, 6CH × 2+1rhythm)
Filter	AC Filter: 50 Hz /60 Hz/ Off EMG Filter: 30 Hz /40Hz/ Off DFT Filter:0.05 Hz /0.15 Hz /0.25 Hz /0.5Hz/ Off
Input Circuit Current	$\leq 0.1 \mu\text{A}$
Input Impedance	$\geq 50 \text{ M}\Omega$ (10 Hz)

Patient Leakage Current	$< 10\mu\text{A}$
Time Constant	$\geq 3.2\text{ s}$
Frequency Response	0.05~150 Hz (-3 dB)
Noise Level	$\leq 15\ \mu\text{Vp-p}$
Paper Speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, Tolerance $\leq \pm 5\%$
Standard Sensitivity	10 mm/mV $\pm 0.2\text{ mm/mV}$
Sensitivity	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, Tolerance $\pm 5\%$
Internal calibration voltage	1 mV $\pm 5\%$
Polarization Voltage	$\pm 500\text{ mV}$
CMRR	$> 98\text{ dB}$

2) Recorder

Recording Method	Thermal matrix printing
Resolution	$\geq 8\text{ dots/mm}$ (Vertical) $\geq 32\text{ dots/mm}$ (25 mm/s) ; $\geq 16\text{ dots/m}$ (50 mm/s) (Horizontal)
Recording Paper	EM-601: 110mm width rolling paper EM-301: 80mm width rolling paper

3) Display

Display	7 inches color LCD screen, display resolution: : 800×480
Display information	Paper Out, Lead Off Alarm, Operation Manual, Patient Information, Battery Volume, Date and Time, Heart Rate, Working Mode, Paper Speed, Gain, Filter

4) Others

Leads	Standard 12 leads with defibrillator protection
Safety Level	GB9706.1 I Classification, CF Type
Power Supply	AC: 100~240 V, 50/60Hz, 30 VA~100 VA DC: 14.8 V/4400 mAh, built in rechargeable lithium battery
Fuse Specification	2- ϕ 5x20 mm AC Time-delay Fuse T1 A/250 V

C.2 Dimension and weight

Dimension	310mm×244mm×65mm
Package Size	380 mm×330 mm×230mm
Net weight	2.25KGS
Gross weight	4.1KGS

C.3 Environment conditions

- Transportation
 - Temperature -20°C ~+50°C
 - Relative humidity 25%~95% (Non-condensing)
 - Atmospheric pressure 500hPa~1060hPa
- Storage
 - Temperature -20°C ~+50°C
 - Relative humidity 25%~85%
 - Atmospheric pressure 500hPa~1060hPa
- Usage
 - Temperature +5°C ~+40°C
 - Relative humidity 25%-80%
 - Atmospheric pressure 700hPa~1060hPa

Appendix D Applied standards

1	EN 980:2008	Symbols for use in the labeling of medical devices
2	EN 1041:2008	Information supplied by the manufacturer of medical devices
3	EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)
4	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
5	EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002, including Amd 1:2006)
6	EN ISO 13485:2003/AC2007	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
7	EN ISO 14971:2007	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
8	EN 60601-1:1990+A1:1993+A2:1995	Medical electrical equipment -- Part 1: General requirements for safety IEC 60601-1:1988 +A1:1991+A2:1995
9	EN60601-1:2006	Medical electrical equipment --Part1: General requirements for basic safety and essential performance IEC 60601-1:2005
10	EN 60601-1-2:2001+A1:2006	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

		IEC 60601-1-2:2001+A1:2004
11	EN 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2007 (Modified)
12	EN 60601-1-4:1996+A1:1999	Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems IEC 60601-1-4:1996 +A1:1999
13	EN 60601-1-6:2004	Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability IEC 60601-1-6:2004
14	EN 60601-1-6:2007	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC 60601-1-6:2006
15	EN 60601-1-8:2004+A1:2006	Medical electrical equipment -- Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2003 +A1:2006
16	EN 60601-1-8:2007	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006
17	EN 60601-2-25:1995+A1:1999	Medical electrical equipment -- Part 2-25: Particular requirements for the safety of electrocardiographs IEC 60601-2-25:1993+A1:1999
18	EN 60601-2-51:2003	Medical electrical equipment -- Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs IEC 60601-2-51:2003
19	EN 62304:2006	Medical device software - Software life-cycle processes IEC 62304:2006
20	EN 62366:2008	Medical devices - Application of usability engineering to medical devices IEC 62366:2007
21	MEDDEV.2.7.1	Evaluation of clinical data: A guide for manufacturers and notified bodies
22	MEDDEV 2.12-1 rev 5	Guidelines on a medical devices vigilance system



A warning label indicates conditions or practices that could lead to injury to patients or operators



A note label indicates conditions or practices that could damage the equipment)

Appendix E EMC information

EMC guidance and manufacturer's declarations - Electromagnetic emissions -For all the equipments and systems

EMC guidance and manufacturer's declarations - Electromagnetic emissions		
EM-301 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or user of EM-301 electrocardiograph should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	EM-301 electrocardiograph 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. EM-301 electrocardiograph is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	


EMC guidance and manufacturer's declarations - Electromagnetic emissions - For all the equipments and systems

EMC guidance and manufacturer's declarations –Electromagnetic immunity			
EM-301、EM-601 electrocardiograph is intended for use in the electromagnetic environment specified below.			
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%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply 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.
Power frequency (50HZ) IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in 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 0.5 cycle 40%U 60% dip in 5 cycles 70%U 30% dip for 25 cycles) < 5%UT >95% dip in 5 seconds	< 5%UT >95% dip in 0.5 cycle 40%UT 60% dip in 5 cycles 70%UT 30% dip for 25 cycles) < 5%UT >95% dip in 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the user of EM-301 electrocardiograph requires continued operation during power mains interruptions, it is recommended that EM-301 electrocardiograph be powered from an uninterruptible power supply or battery.
Note: U AC voltage before test voltage is applied			

EMC guidance and manufacturer's declarations –Electromagnetic immunity – For non-life-support equipment

EMC guidance and manufacturer's declarations –Electromagnetic immunity			
EM-301、EM-601 electrocardiograph is intended for use in the electromagnetic environment specified below.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150KHz-80MHz 3V/m 80MHz-2.5GHz	3Vrms 1V/m	Portable and mobile RF communications equipment should be used no closer to any part of EM-301 electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{v1} \right] \sqrt{p}$

			$d = \left[\frac{3.5}{E1} \right] \sqrt{P}$ <p style="text-align: right;">80MHz-800MHz</p> $d = \left[\frac{7}{E1} \right] \sqrt{P}$ <p style="text-align: right;">800MHz-2.5GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which EM-301、EM-601 electrocardiograph is used exceeds the applicable RF compliance level above, the electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the electrocardiograph.

B Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and equipments or systems

- For non-life-support equipment and system

Recommended separation distances between portable and mobile RF communications equipment and EM-301、EM-601 electrocardiograph	
EM-301、EM-601 electrocardiograph s intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of EM-301、EM-601 electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and EM-301、EM-601 electrocardiograph h as recommended below, according to the maximum output power of the communications equipment.	
Rated max. output power of	Separation distance according to frequency of transmitter (m)

transmitter(W)	150KHz-80MHz	80MHz-800MHz	800MHz-2.5GHz
	$d = \left[\frac{3.5}{v1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E1} \right] \sqrt{P}$	$d = \left[\frac{7}{E1} \right] \sqrt{P}$
0. 01	0. 1167	0. 35	0. 7
0. 1	0. 3689	1. 107	2. 214
1	1. 1667	3. 5	7
10	3. 6893	11. 07	22. 14
100	11. 6667	35	70

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Appendix F Manufacturer information

Manufacturer: Shenzhen ECGMAC Medical Electronics Co., Ltd

Factory Address: 2nd Floor of Block 2 ,Haoye Industrial Park, Tiegang Road,Xixiang Street, Baoan District, 518102 Shenzhen,China

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