

firstMED



Model: **ECG-100**

ELECTROCARDIOGRAPH

EKG CİHAZI

ELECTROCARDIOGRAPHIE

ЭЛЕКТРОКАРДИОГРАФ

AMÈRA EKG'YÊ















جهاز تخطيط القلب

اللكتروكارديوغرافي

EN Instruction Manual

www.firstmed-health.com

Symbols

	CE mark		Keep the carton straight.
	Read the instructions carefully before using this device.		Fragile, handle with care.
	Waste Electrical and Electronic Equipment Directive		Storage temperature limit.
	Manufacturer		Type CF equipment
	Caution-Consult accompanying documents.		Class I equipment
	Keep away from sunlight.		Manufacturing date
	Keep dry.		Serial number

Instructions to User

Dear User, thank you very much for purchasing our product.

This Manual is written and compiled in accordance with the council directive 93/42/EEC for medical devices and harmonized standards. The Manual is written for the current ECG-100 Electrocardiograph. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the ECG-100 Electrocardiograph's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this equipment. These instructions describe the operating procedures to be followed strictly; Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

WARNING:

- ☛ **All the electrodes connected to the patients directly must be correct and tried.**
- ☛ **Make sure the battery voltage is normal when choosing the UPS**
- ☛ **The AC power cable and the patient cable could not be enlaced.**
- ☛ **Please peruse the relative content about the clinical restrictions and caution.**
- ☛ **This device is not intended for treatment.**

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1 Main Technical Specifications

1.1 Work environment

a) Temperature: $+10^{\circ}\text{C}\sim+40^{\circ}\text{C}$

b) Relative humidity: $\leq 85\%$

c) Power supply: Main unit $220\text{V}\pm 22\text{V}$, $50\text{Hz}\pm 1\text{Hz}$

Under direct current as power supply, the device can work for half an hour

d) Atmospheric pressure: $50\text{kPa}\sim 106\text{kPa}$

1.2 Noise level: $\leq 15\mu\text{Vp-p}$

1.3 CMRR: $> 60\text{dB}$

1.4 Range frequency character: 10Hz is reference mark, $1\text{Hz}\sim 75\text{Hz}$ (-3dB , $+0.4\text{dB}$)

1.5 Low frequency character: Time constant $\geq 3.2\text{s}$

1.6 Sensitivity: standard sensitivity is 10mm/mV , $\pm 0.2\text{mm/mV}$.

1.7 Sensitivity control: 5、10、20mm/mV, $\pm 5\%$

1.8 Paper speed: 25mm/s、50mm/s, $\pm 5\%$

1.9 Safety Standard: Class I, Type CF

1.10 Input power: $\leq 150\text{VA}$

1.11 Fuse specification: alternating current 220V/2A

2 Security Notice

2.1 Make sure the instrument grounding properly during installation.

2.2 If the ground cable is not integrated, please run the device with battery.

2.3 Please pull out power supply plug before change the fuse.

2.4 This device must be operated and preserved by professional doctor,

2.5 The operator must read this user manual carefully before operation, and operate the device according to operation regulation strictly.

2.6 The design of this device with mature consideration of security, but operator should never neglect attention to device state and patient's situation.

2.7 Please dismantle the battery and pull out power supply plug before cleanout and disinfection of this device.

2.8 Please don't operate this device in environment contain flammable anesthesia gas.

3 Device Characteristics

3.1 Recording system: Thermal-array (8 dots/mm), it needs not be adjusted.

Frequency Response: 150Hz (IEC).

3.2 The device can record exact single ECG waveform and remark. The remark includes: lead sign, sensitivity, paper speed, filter state.

3.3 Under automatic mode, just press the button once, it starts record procedure, which can enhance your work efficiency.

3.4 The language of operation interface include: Chinese/English.

3.5 The keyboard is convenient to operate, and the LCD can display the operation state, which is convenient and readable.

3.6 Security standard: Class: I, type: CF.

3.7 The power supply includes both AC/DC. This device includes built-in lithium chargeable, which can record 80 piece of ECG waveform.

3.8 The figure of whole device is elegancy and gliding.

3.9 According to defencence degree of deleterious fluid, this device is belong to common device.

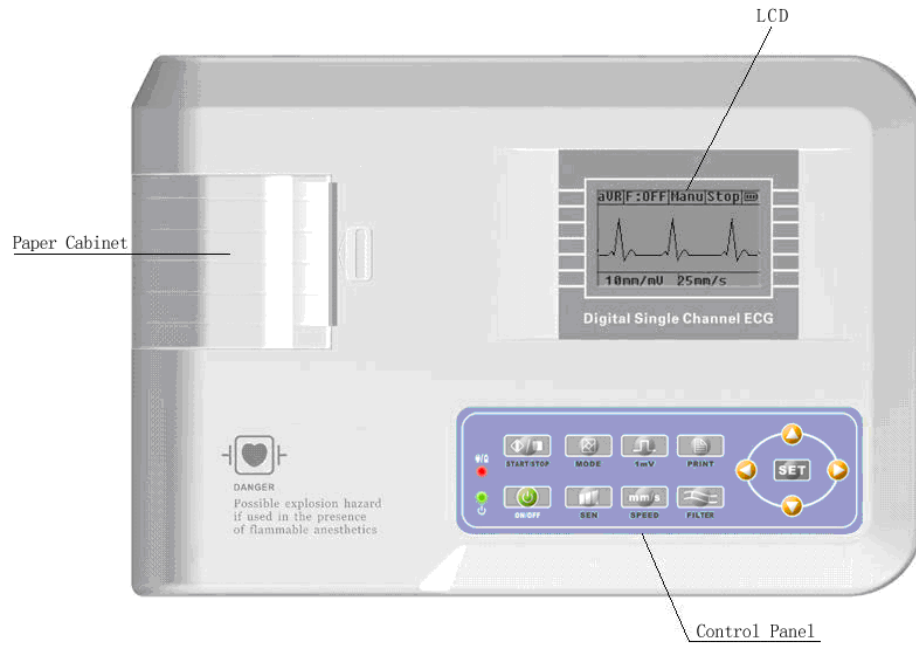
3.10 The device can't be used in the environments which contain flammable anesthetic gas mixed with air.

3.11 According the working mode class, this device is not suit to continuous work state.

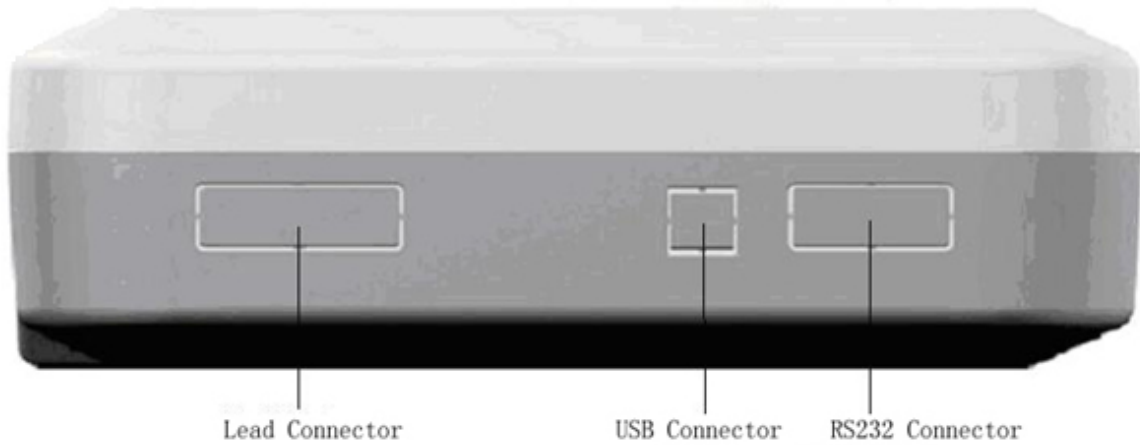
4 ECG-100 View

A – Device View

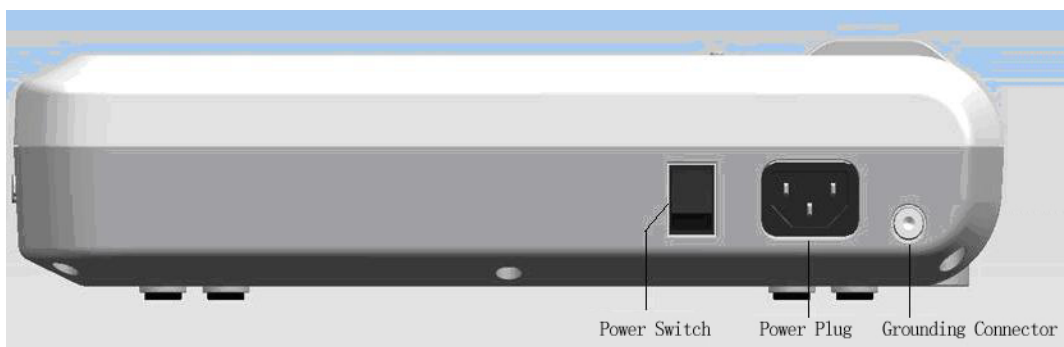
Front view



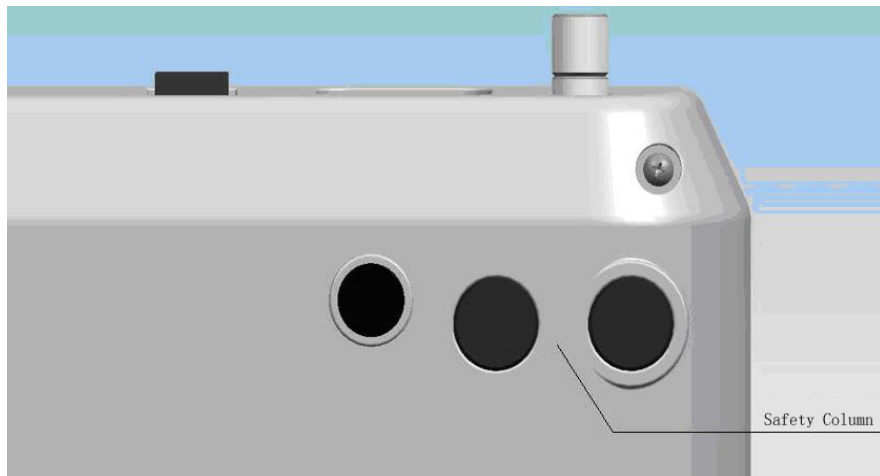
Side view



Rear view




Bottom view





B - Button definition


 Function button: ON/OFF & time display

 Function button: plus adjust

 Function button: paper speed adjust


 Function button: filter function select


 Function button: pause/on


 Function button: switch work mode


 Function button: marker


 Function button: print

 Function button: system menu

 Function button: upwards

 Function button: downwards

 Function button: leftwards

 Function button: rightwards

5 Operation Direction

5.1 You are required to read the following so as to ensure taking proper operation of the instrument.

5.2 Installation and maintenance of the instrument shall be carried out as the following

5.2.1 Install and keep the instrument away from splashing water.

5.2.2 Do not install the instrument in the place where it might be affected by bad humidity and ventilation, direct sunlight, as well as air containing dust, salt, and sulphur, etc.

5.2.3 Do protect the instrument from tilting and possible vibration or shock.

5.2.4 Do not install the instrument in a chemical storage or gas generation area.

5.2.5 Check the power source for voltage and frequency.

5.2.6 Do the instrument grounding properly during installation.

5.3 You are suggested to report the problem to a technician whenever it occurs.

5.4 Carry out periodical maintenance on the machine and related parts.

5.5 Do not make any modifications on the instrument.

5.6 Environmental temperature:

Operation: 10 ~ 40°C; 0 ~ 85% humidity, non-condensing.

Storage: -10 ~ 55°C; 0 ~ 95% humidity, non-condensing.

5.7 Pay attention to the following description

DANGER: Possible explosion hazard if used in the presence of flammable anesthetics.

CAUTION: Avoid electric shock hazard.

Do not remove cover.

Refer to qualified personal for service.

Grounding continuity should be checked periodically.

WARNING: For continuous protection against fire hazard, replace fuse only with same type and rating.

5.8 AC frequency and voltage value should be $220V \pm 22V$, $50Hz \pm 1Hz$, and the current capacity should be enough..

5.9 If this device use with cardiac defibrillator or other electric stimulate devices at same time, please use our company's Ag-AgCl chest electrode and ECG lead, if the electric stimulate device use over 55 seconds, please choose one-off chest electrode. We suggest ECG-100 not be used with other electric stimulate device, if it is compulsory, there should be professional technician guide be on the scene.

6 Preparation Before Operation

6.1 Check that the instrument properly grounded and that cable connections safe or not.

6.2 Check the instrument working properly or not.

6.3 Check the electrode which connected with patient safe or not

6.4 When power supply is direct current (UPS), please check the voltage of battery before use.

6.5 The chest electrodes should be separated from gel coats, this operation can avoid short circuit.

6.6 When the instrument is used with other equipment, you'd better invite assistance from a specialist.

6.7 The AC power supply cable and leads should be separated.

7 Attention Points of During Operation

7.1 Keep close observation of the patient and instrument. If any abnormality occurs.

To ensure patient' safty, stopping operation of the instrument should be immediately taken.

7.2 Make sure the patient does not touch the instrument or any other electric devices.

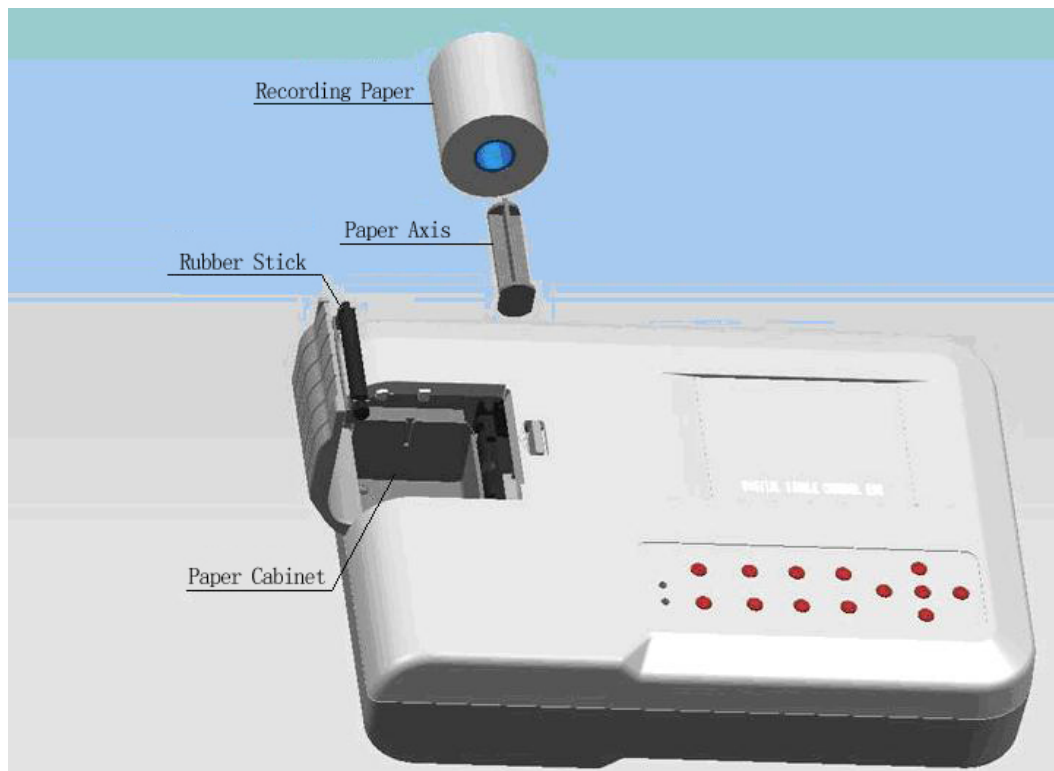
7.3 The device and patient can't be moved during working.

7.4 Turn off device after operation.

7.5 Pull out the power supply plug, then move the leads lightly.

7.6 Tidy up the devices and accessories for next use.

7.7 The installation recording paper.



7.7.1 This device use 50mm single trace roll record paper.

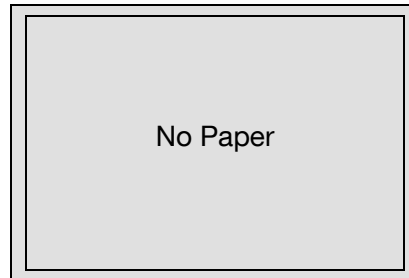
7.7.2 First, open the paper cabinet, take out the paper axis, then put the paper axis in recording paper, then put it in the relevant position of paper cabinet.

7.7.3 Cover the paper cabinet with paper cabinet cover, 2cm of the beginning of paper should be left out of the cabinet exit.

7.7.4 Be sure the paper fixer of paper cabinet works well in order to avoid paper choking result in breakdown of the instrument.

8 Paper Loading

8.1 If the recording paper is used up during the recording process, the paper record will over, and a notice as following will be displayed on the LCD screen as following:



8.2 There is a line at the verge of paper at the last two meters of the recording paper, this line means the paper is not enough, please change the paper immediately. We suggest you choose our company's print paper, as for its detailed information, please consult with our company or agency.

8.3 The possible reason which will make the recording paper disable includes: high temperature, humidity, and sunshine irradiation. The recording paper which needs long time stock should be deposit in dry, dark and cool environment.

8.4 The instance which may contaminate the recording paper.

8.5 The materials that may cause the record wave disappear: the folder contain soft PVC; plastic; the demagnetize ware and tape contain elasticizer; the high-lighter pen, stamp-pad ink, and so on.

9 Electrode Placement

9.1 Chest electrode(As the following figure)

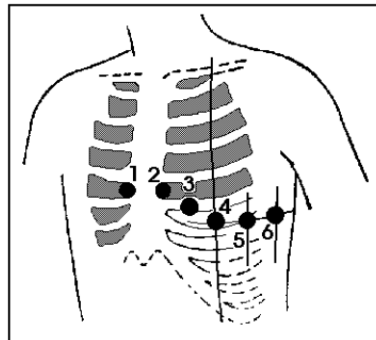


Figure: chest electrode locations

Attach the chest electrodes to the locations as following after cleaning with alcohol and applying of ECG cream in the similar way as mentioned limb electrode placement. Keep in mind that the electrodes' coming into contact with each other or cream's overlap from one position to another is not allowed.

V1: Fourth inter-costal space at right border of sternum.

V2: Fourth inter-costal space at left border of sternum.

V2: Fourth inter-costal space at left border of sternum.

V3: Midway between V2 and V4.

V4: Fifth inter-costal space at left mid-clavicular line.

V5: Left anterior axillary line at the horizontal lever of V4.

V6: Left mid-axillary line at the horizontal lever of V4.

9.2 Limb electrode

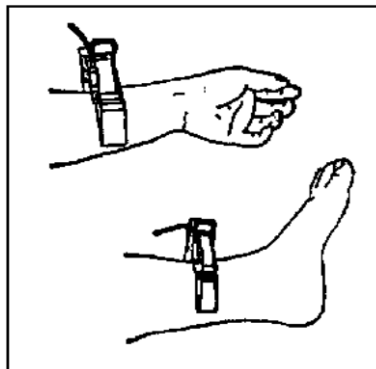


Figure : Limb electrode locations

Clean all the limb electrodes and the positions around to which limb electrodes are to be attached with alcohol before applying ECG cream to them, then firmly attach the electrodes to the positions.

Attention: the fix knob should be screwed down tightly after lead connected with main unit.



9.3 Electrode connection definitions of color code

Electrode Location	Electrode Code	Line Color	Electrode Color	Socket Number
Right arm	R	Black	Red	9
Left arm	L	Black	Yellow	10
Right leg	F	Black	Black	11
Left leg	RF	Black	Green	14
Chest 1	V1/C1	White	Red	12
Chest 2	V2/C2	White	Yellow	1
Chest 3	V3/C3	White	Green	2
Chest 4	V4/C4	White	Brown	3
Chest 5	V5/C5	White	Black	4
Chest 6	V6/C6	White	Purple	5

10 Grounding And Power Connection

Make sure the instrument be properly grounded through a 3-prong outlet, a grounding cable may be utilized to connect the grounding terminal of the instrument. The ground cable can not be connected with water pipe or other pipe. A proper grounding ensures security and reduce AC and electromagnetic wave interference.








11 Battery Operation Direction

11.1 This device includes built-in hermetical chargeable lithium battery, which needn't maintenance. This battery is with perfect automatic charge and discharge monitoring system. When you connect power supply adapter with alternating current, the charge will be start automatically. When this device be open, an icon  be displayed on top right corner of LCD screen.  means the battery is charging. The whole charge process needs four hours.


11.2 When the battery is full, the device can be operated for one hour, when the battery be used as power supply, An icon of battery will be displayed in the LCD screen of front panel, this icon includes five degree indicates power of battery. When the battery is power off, the device will turn off automatically, this setting is for avoiding permanent damage on battery caused by excessive discharge.

11.3 Please charge the battery after power off. When this device be deposit for long time, the battery should be charge once every six months, this operation will prolong the use –pan of battery.

11.4 The icon of seven different state of power supply as following:

	The alternating current is power supply & the battery is full or no battery
	The battery is only power supply and its power is full.
  	The battery is only power supply and its power is not full
	The battery is only power supply and its power is exhausted.
	Charge up


11.5 If the battery is full, but the power of battery is exhausted within 10 minutes. Please change new battery. If the battery is can't be charged, please change new battery.

11.6 When the icon  display on screen. Please charge the battery immediately, or the device will turn off.

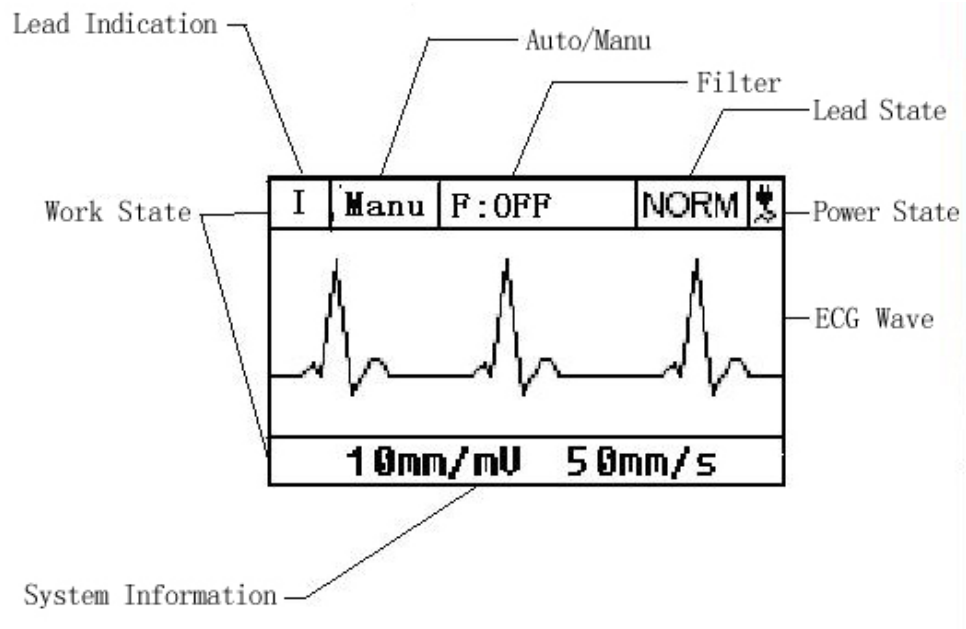
Warning!!!

- Please don't connect the anode and cathode with lead of battery directly, it will cause danger.
- Please don't put the battery on fire. It may cause explosion.
- The battery should be take gently.



12 Keypad and Controls

12.1 Press power supply key  for several seconds, the device will enter auto-check mode, at this time, the display will be boot-strap menu.

12.2 After auto-check mode, the display as following:



(1) The operation of lead indicate column

By press button  , choose relevant lead, the device will switch to appointed lead check state, it switch among according following order: I II III aVR aVL aVF VI V2 V3 V4 V5 V6.

(2) The operation of system state information column:

Switch by press relevant function key(The function key as following)

Sensitivity: 5mm/mV、10mm/mV、20mm/Mv, three kinds of sensitivity in all.

Switch Mode: MANU, AUTO.

Under AUTO-MODE, the device will note 12 leads, 3 second ECG signal every lead.

Filter: OFF、50Hz、60Hz、50Hz+、60Hz+、35Hz, six filter mode in all.

The mode of 50Hz+ & 60Hz+ mean open 35Hz EMG filter.


Speed: 25mm/s、50mm/s. two kind of paper speed in all.

(3) Leads state instruction.



When the leads state is NORM mode, you can print the ECG, when the leads state is


OVER, you can't print the CEG, please check whether the electrode is fall off.

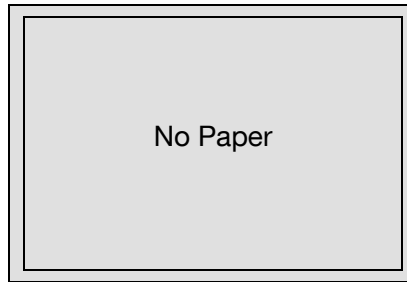
(4) Print operation

Press  under this state, you can start print system setup and ECG wave, press


 again the device will be turn off.

Attention: when the paper cabinet is empty, press  or , the device will

display as following figure, please put in the paper then press .



(5) Mark operation

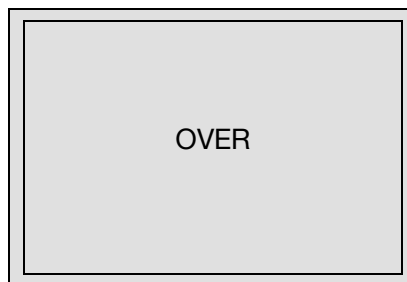
Press  you can print a 1mv standard voltage marker, which is helpful to know

current sensitivity, during marking procedure, the LCD displays as following:

be marking:





the marking procedure is over:





Attention: the marking procedure is automatically, after this procedure you need not press any key, the interface will be back automatically.


(6) Operation of waveform frozen

Press  you can freeze current waveform in LCD screen, which is helpful for preview. Press  again, back to previous interface.

(7) Operation of Time display

Under normal boot-strap mode, press  displays current time. press  again back to operation interface.







(8) Operation of turn off

Press  for several seconds, the device will be turn off.

12.3 System menu

Menu	
Backlight	99s
Contrast	10
Language	English
Demo	ON

(1) Operation of menu

Press  enter above interface, you can choose relevant item by press  , then you can press   adjust the content, after setup, press  back.

(2) Introduction of every item

Backlight: 0-99seconds, back light start time, when choose 0s, the back light will be turn off, when choss 99s, the backlight will be turn on for 99s.

Contrast: 00-20, please choose different contrast degree according to different device state.

Language: you can choose between English and Chinese version.

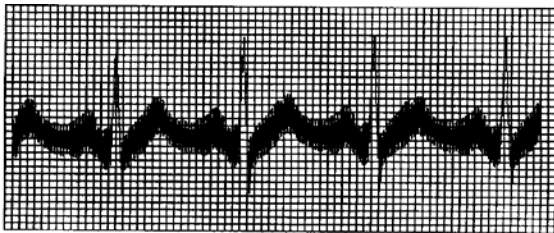
Demo: ON、OFF, if you need not inspection practice, just choose ON for demo.

13 Troubleshooting

13.1 Automatic Switch off

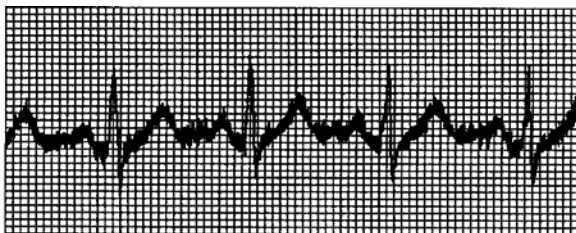
- ① Please check whether the power of battery is used up. Turnoff is for protecting circuit.
- ② Please check whether the alternating current voltage is too high, Turnoff is for protecting circuit.
- ③ Please check whether the alternating current disturb too high, whether the fix knob of lead plug too tight. shut automatically is for protecting circuit when overload.

13.2 AC interference



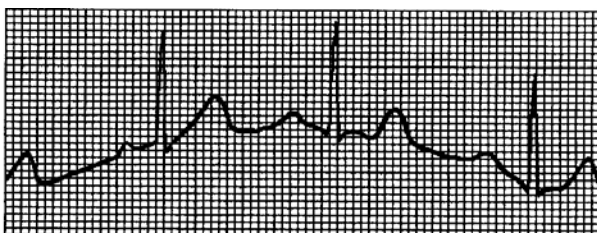
- ① Is the ECG device ground cable proper?
- ② Is the electrode and leads' ground cable proper?
- ③ Is the electrode and skin covered with enough Gel?
- ④ Is the metal bed grounding proper?
- ⑤ Does the patient touch the wall or metal sickbed?
- ⑥ Does other people touch the patient?
- ⑦ Whether there is powerful electric device working beside ECG device? For example: X radial device or B-Ultrasound devices.

13.3 EMG interference



- ① Whether the patient room is comfortable.
- ② Is the patient nervous?
- ③ Is the sickbed too narrow?

13.4 Baseline drift



- ① Verify the electrode attachment and lead wire performance.

- ② Check the connection between patient cable and electrodes.
- ③ Check the cleaning of electrode and patient skin. Is the electrode and skin covered with enough Gel?
- ④ Keep the patient from motion or hyperventilation.
- ⑤ Is the connection between lead and electrode proper?

13.5 Troubleshooting List

Phenomenon	Reason	Resolve method
Disturbance too big, the waveform is in disorder	1-Whether the ground cable proper. 2-The connection of leads is not stable. 3-Whether there is disturbance from alternating current. 4-Patient is nervous	1-Please check the lead, ground cable and power supply. 2-Please dispose the patient in proper state.
Baseline is rough	1-Disturbance from alternating current too strong. 2-Patient is nervous and the disturbance of EMG too strong	1-Change a comfortable environment for patient 2-If the sickbed is metal, please change it. 3-The power line and lead is not parallel or too close.
Wave form is not regular, with too great wave or beeline	1-The conductivity of electrode is not well. 2-Power of battery is used up 3-Contact between electrode and skin is not proper. 4- The plug between lead and main unit is not tight. 5-The contact between lead and electrode is not proper.	1-Use alcohol of high quality. 2-Clean the electrode and patient's skin where touch the electrode 3-Charge the battery
Baseline draft	1-Power of battery is used up 2-Patient is moving	1-Charge the battery 2-Keep patient hold still
Waveform is not clear.	1-The printer head is dirty 2-The paper is not right	1-Clean the printer head with alcohol when the power is off, use the printer head after the alcohol is volatiled. 2-Use the appointed thermal print paper.

14 Maintenance and Storage

Maintenance:

- ECG-100 is designed to work free from maintenance for many years. It contains no repairable parts. Customer is not permitted to open it.
- Paper scraps and dust may accumulate around or on the document feeder and paper shaft due to long time operation. Such steep can be cleaned with a soft-bristled brush or be carefully vacuumed. In extreme case, the shaft must be cleaned with a damp (not wet) lint-free cloth. Solvents, alcohol, and detergent are not allowed to be used to clean the aforementioned because they may cause damage. It is also of importance to disconnect the cables with the instrument before attempt of cleaning. The above-mentioned detail holds true for the exterior of the machine.
- Please pull out the power supply plug when power cut. If the device out of use for long time, please put the device in a shady cool dry place, and the device need be charge once every three months.
- Warranty covers a period of 24 months.
- Within this period, we provide free service on any machine failure through our service center or sales representatives.
- We charge for reparation after the expire of the warranty period.
- We charge for reparation in case of failure resulted from user's neglect, natural disasters, or accidents, whatever the warranty period is.
- Spare parts for warranty service exclude accessories including power cable, recording paper, user's manual and packing material.
- Contact our service center or sales representatives for professional repair service.

Storage

- The temperature of preservation should be $-10^{\circ}\text{C}\sim+55^{\circ}\text{C}$, the relative humidity should less than 95%, The room for preservation should be ventilative and without causticity gas.





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CONTEC MEDICAL SYSTEMS CO., LTD

No.112 Qinhuang West Street, Economic & Technical
Development Zone, 066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA



Shanghai International Holding Corp. GmbH (Europe)
EiffestraÙe 80, 20537 Hamburg Germany

İthalatçı/Distributor:

Trimpeks İth.İhr.Tur.ve Tic.A.Ş.

Sultan Selim Mah. Yunus Emre Cad. No:1/11

Kağıthane 34415, İSTANBUL TÜRKİYE

Tel +90 212 319 50 00 | Fax +90 212 319 50 50

Read the instructions carefully
before using this device.



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