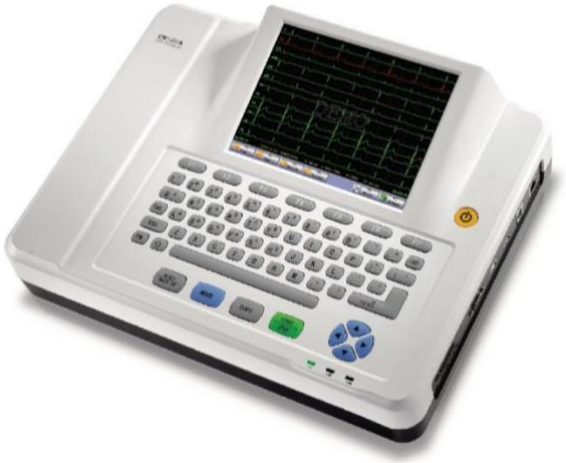
Specification: CM1200A

SHENZHEN COMEN MEDICAL INSTRUMENT CO.,LTD
Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106,P.R. China
Tel: +86-755-26408879
Fax: +86-755-26431232
Email: info@szcomen.com
Web: en.comen.com

2021 V 1.4

12-channel Electrocardiograph CM1200A



Safety Standards:

ISO 13485:2016 approved, CE marking according to MDD93/42/EEC, IEC60601-1, IEC 60601-2-25, IEC 62304, ANSI/AAMI EC-11, Class I, with internal power supply, CF type, with defibrillation proof function

Physical Characteristics:

Product Size:	410mm×316mm×135.8mm
Net Weight:	5.2kg

Operation Environment:

Working Temperature:	0-40°C
Humidity:	≤93%
Power Supply:	100-240V~, 50/60Hz±1Hz
Battery Type:	Rechargeable Lithium-ion battery
Battery Capacity:	4400mAh
Battery Recharging Time:	Maximum 6 hours for charging;
Battery backup:	2 hours for continuous working
Display:	8.4” color LCD touch screen
Resolution:	800*600
Trace:	12 waveforms

Indicator:

Power indicator
Battery indicator
QRS beep
Operating key sound
Key backlight

Interface:

Parameter cable interface
AC power input socket
Two USB port
RJ45 port

Data storage

Standard 8G micro SD card for 40000 ECGs internal memory 300 patient case

Power-off storage：	Yes
Network:	Connected to PCECG by hardwire/wireless

Display:

Parameter:	Patient ID, gender, age, waveforms, recording/sweep speed, gain, EMG filter, HR, leads status, clock, information message,
Format:	3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 1×12, 1×12+T
Timing Power off:	OFF, 1min, 5min, 10min, 30min
Keyboard:	Available

Recorder:

Type:	Built-in; thermal array
Record width:	216mm/210mm
Speed:	5mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s
Printer Format:	3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 1×12, 1×12+T
External printer Format:	3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 1×12, 1×12+T
Print information:	Off, Basic, Detailed
Diagnostic Review:	2 min review for all 12 leads waveform info.

ECG:

Lead Type：	CardioTec^{TM}12-leads ECG Analysis
Lead selection	12-Lead I; II; III; aVR; aVL; aVF; V1-V6.
Gain Selection	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 20/10mm/mV, 10/5mm/mV and AGC， the error is ± 2%.
Sweep Speed：	5mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s
Heart Rate Range：	30-300bpm
Resolution:	1 bpm
Accuracy:	±1% or ±1bpm (whichever is greater)
Drift Filter:	OFF, 0.05Hz, 0.10Hz, 0.20Hz, 0.50Hz
EMG Filter:	OFF, 25Hz, 35Hz, 45Hz
Low Pass Filter:	OFF, 75Hz, 100Hz, 150Hz
AC Filter:	OFF, 50Hz, 60Hz
Protection:	Withstand 4000VAC/50Hz voltage in isolation; Against electrosurgical interference and defibrillation;
Arrhythmia analysis:	122 Types

Processing:

Acquisition Mode:	Real-time, Pre-sample
Frequency Response:	0.05Hz-150Hz: $\begin{pmatrix} +0.4dB \\ -3.0dB \end{pmatrix}$
CMRR:	≥105dB
Input Impedance:	≥50MΩ
Digital Sampling Rate	1000（Single channel） 8000（Eight Channel）
AD Conversion:	24Bits

***Notice: Specifications subject to changes without prior notice.**

Copyright

Shenzhen Comen Medical Instruments Co., LTD.

Version: B00

Date: 2024/06

Part No: 046-001158-06

Product name: Electrocardiograph

Product model: CM1200A

Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Tel: + 86-755-26431236 Fax: +86-755-26431232 Http://en.comen.com

Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel: +31644168999

Email: peter@lotusnl.com

UK Responsible Person

Company: Lotus Global Co Ltd

Tel: 0044-20-70961611

E-mail: peter@lotusglobaluk.com

Address: 23 Maine Street, Reading, RG2 6AG, England, United Kingdom.

Australia sponsor

Company name: Wiselink Group Pty. Ltd.

Address: Suite31, 427-441 Victoria Avenue, Chatswood NSW2067, Australia.

Tel.: +61 401 607 270

Web: https://www.wiselink.com.au/

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The version number of this manual may be subject to upgrade without notice due to changes of software, technical specifications or other reasons.

This manual is applicable to the CM1200A Electrocardiograph produced by Comen Company.

Guarantee

When all of the following conditions are satisfied, Comen Company shall be responsible for the safety, reliability and performance of the product:

- The product is used according to the User Manual.
- The installation, maintenance and upgrading of the product are conducted by the personnel recognized or authorized by Comen Company.
- The storage environment, working environment and electrical environment of the product comply with the product specifications.
- The serial number label or manufacturing mark of the product is clear and identifiable. It is verified that this product is manufactured by Comen Company.
- The damages are caused by non-human factors.

The products that are within the warranty scope of Comen Company shall enjoy free service. As for the products that are beyond the warranty scope, Comen Company shall charge for the service. If the products are transported to Comen Company for maintenance, the user shall bear the freight (including the customs expenses).

Return

If the products need to be returned to Comen Company, please follow the following steps:

Acquisition of the right to return the goods: Contact the after-sales department of Comen Company, tell it the SN of the instrument made by Comen which is printed on the equipment nameplate; if this SN is not legible, the goods returned shall not be accepted. Please specify the SN and production date, and briefly describe the reason for returning the goods.

Preface

This Manual provides the performance information, operating instructions and safety information regarding the CM1200A Electrocardiograph and can serve as the start guide for new users.

This manual is applicable to the professional clinical medical staff or the persons who are experienced in using the electrocardiographing equipments for reading. The readers shall have the knowledge and working experience in medical procedure, practice and terms necessary for examining the patients.

In order to use the equipment effectively and avoid the possible damages, please read the user manual in detail before using and be familiar with the equipment to know the correct operation methods and cautions thoroughly.

Figures

All the figures provided in this User Manual are for your reference only. The menus, options, values and functions in the figures may not be entirely consistent with what you see from the electrocardiograph.

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Contents

Chapter 1 Safety Guidance

1.1 Safety Information

The design of this electrocardiograph complies with the international standard IEC 60601-1 Medical Electrical Equipment: General Requirements for Safety and IEC 60601-2-25 General Requirements of the Electrocardiograph. The classification of this equipment is class I and type CF which complies with IEC 60601-1 Regulations of the Protection against Electric Shock and it has the function of defibrillation protected.

This electrocardiograph is continuous operation equipment which is ordinary and it should be protected from water; this equipment is not explosion-proof and it cannot be used in the presence of flammable anesthetics.

CM1200A electrocardiograph has wide screen (8.4 inch screen).

Before using of the equipment, check the equipment, ECG cable and electrode to find whether there is damage which may affect the patient safety, if obvious damage or aging is found, this part should be replaced before using. The replaced part should be the same as the original one.

This equipment should be maintained by the authorized and qualified engineers. If the modification and maintenance are not conducted by the personnel authorized by Comen Company, Comen Company will not be responsible for the safety, reliability and performance of the equipment.

1.1.1 Guide to Labels in the Manual

⚠Warning

- **To warn you of the conditions where serious consequence, disadvantageous matters or danger may occur. Failure to comply with the warning will result in severe personal injury or death of the user or the patient.**

⚠Caution

- **To indicate potential danger or unsafe operation. If not avoided, it may lead to mild personal injury, product malfunction, damages or property loss. It may also give rise to more severe harm.**

⚠Note

- It emphasizes primary warnings or provides descriptions or explanations so that this product can be used in a better way.

1.1.2 Operating the equipment

⚠Warning

- This equipment is not intended for treatment.
- This equipment can only be used by one patient at the same time.
- This equipment cannot be used directly for the cardiac surgery.
- If it is used in the presence of flammable anesthetics, there is risk of explosion.
- Do not place the power cord and plug connecting the cut-off device to the network power supply where the operator is difficult to operate.
- Do not use the equipment in the presence of high voltage equipment or high electrostatic capacity; otherwise spark may be produced due to instantaneous discharge.
- Avoid the electric shock risk——The shell of the equipment should be grounded and the earthing connection should be kept well; use the three-phase socket with protective grounding and the earthing of the socket should be kept well.
- This equipment should be installed by the qualified maintenance engineer; only the authorized maintenance engineer can open the shell of the equipment.
- If there is doubt for the integrality of the protective earthing line, please use the built-in battery for the power supply and do not use the AC power supply.
- The accessories connected to the analog and digital interfaces should be validated according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations should comply with the valid version of the IEC 60601-1. Therefore anybody, who connects additional equipment to the signal input connector or signal 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. If there is any problem, consult us or your local agent.
- In order to ensure the patient safety, the summation of leakage current should never exceed leakage current limits while several other units are connected to the patients at the same time.
- When the defibrillator or cardiac pacemaker is used at the same time, do not contact the patient, bed, table or equipment.
- In order to avoid burning, please keep the electrode far away from the electro surgery knife while using electrosurgical equipment at the same time.

- **Patient cable or other accessories provided by Comen Company must be used, if accessories of other types are used, the equipment many be damaged and the performance and safety of the equipment may be affected. Different metal electrodes shall not be used as the electrodes used on the patient.**
- **Please ensure that all the electrodes are connected to the correct positions on the patient body; the contact of electrodes (include neutral electrodes) and patients to any other conductive parts or the ground.**
- **The operation personnel of this equipment should have qualified professional training and at the same time ensure that they have understanding the content of this user manual before using thoroughly.**

⚠**Note**

- **This equipment is not intended for home use.**
- **This equipment is for examine use instead of diagnosis use, and it is only responsible for indicators regulated by relevant national standards.**

⚠**Caution**

- **Avoid liquid splash of the equipment.**
- **Avoid high temperature and the equipment should be used under +5℃~+40℃.**
- **Avoid using this equipment in the environment with high pressure, bad ventilation, and full of dust or include salt, sulfuric gas and chemical medicines.**
- **Ensure that there is no intense electromagnetic interference source around the installation and use environment of the equipment, such as radio transmitter or mobile phone etc. Attention: Large medical electrical equipment such as electrosurgical equipment, ultrasonic equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to cause electromagnetic interference.**
- **Before using, the equipment, patient cable and electrodes should be checked to find whether there is damage which may affect the safety of the patient. If obvious damage or aging is found, the part should be replaced before using.**
- **Safety tests should be conducted periodically for the equipment, the test period is at least once a year. The test should be conducted by the trained and qualified personnel with safety test knowledge and experiences and the test results should be recorded. If there is any problem for the equipment in the above tests, it should be maintained.**
- **The service life of this equipment is 5 years.**
- **When the service life is over, the equipment and reusable accessories should be sent back to the manufacturer for recycling or disposal properly according to the local regulations.**

1.1.3 Using of the Rechargeable Lithium Battery

⚠Warning

- Improper operation may cause the battery to be hot, ignited or exploded or it may lead to the declination of the battery's capacity. It is necessary to read the user manual carefully and the warnings and cautions before using of the rechargeable lithium battery (hereinafter called "Battery").
- Do not reverse the anode and cathode when connecting the battery, otherwise explosion may be caused.
- Do not use the battery near the fire source or in the environment with temperature higher than 45 ℃. Do not heat the battery or throw it into the fire. Avoid the battery to be splashed by water and do not throw the battery into water.
- Do not penetrate the battery with metal, hammer or beat the battery or use other methods to damage the battery, otherwise battery heating, smoking, distortion or burning may be caused and risk occurs.
- When leakage or foul smell is found, keep far away from the battery immediately. If your skin or clothes comes into contact with the leakage electrolyte, rinse it with clean water at once. If the electrolyte splashes into your eyes, do not rub them. You should irrigate them with clean water first and go to see a doctor immediately.
- Only authorized installation or maintenance engineer can open the battery compartment and replace the battery; and the rechargeable lithium battery of the same mode provided by Comen Company should be used.
- When the service life of the battery is over, or there is peculiar smell, deformation, discoloration or distortion, the battery should be stopped to use immediately and disposed of the battery according to the local regulations.

1.1.4 Clean, Disinfection and Maintenance

⚠Caution

- Turn off the power before the cleaning. If the AC power supply is used, the AC power supply should be cut off and the power cord and patient cable should be removed.
- Pay attention not to prevent the liquid from entering the inner of the equipment. Do not immerse the equipment and patient cable into the liquid in any case.
- It is prohibited to use abrasive material to conduct cleaning and avoid scratching the electrodes.

- **Any residual detergent in the instruments and on the surface of the patient cable should be avoided after cleaning.**
- **Do not use high temperature, autoclaving or ionizing radiation methods to conduct disinfection. Do not use chloric disinfectants such as bleaching powder, sodium hypochlorite and so on.**

1.2 Symbol Description

(1) Symbols of Instruments

Symbol	Description	Symbol	Description
	External Output		Tab Key
	External Input		Esc Key
NETWORKS	Network		FN Key
	USB		Shift Key
COM	Serial Port		SLEEP/WAKE UP Key
	CF Equipment(parts), with defibrillation protected function		MODE Key
	Attention! Please refer to theca companying document.		COPY Key
	Equipotential grounding		START/STOP Key
	Power Switch Key		Up/Down/Left/Right Arrow Key Group
	AC		Conformité Européenne Complies with medical device

			directive 93/42/EEC
	Working State of the Battery		Refer to instruction manual/booklet
	Recharging State of the Battery		Separate collection for electrical and electronic equipment
	Space key		Enter Key
	Delete Key	IPX0	Ingress protection rating
	Environment-friendly use period		

Illustration: Refer the detailed key symbol and its corresponding function of the keyboard in chapter 4.

(2) Symbols of Packing

Symbol	Description	Symbol	Description
	Up		Stacking layers limit
	Fragile		Keep dry

Chapter 2 Patient Safety

2.1 Power Supply

1) Alternating Current:

Rated Voltage: 100-240V ～

Rated Frequency: 50Hz/60Hz

Rated Power: 95VA

2) Built-in Rechargeable Lithium Battery:

Rated Voltage: 11.1V

Rated Capacity: 4400 mAh

⚠**Note**

- **Use a medical grade power strip.**
- **When a battery is provided, the battery must be charged after transportation or storage. If the battery is low, startup of the electrocardiograph may fail without connecting an AC power supply.**
- **Once connected to an AC power supply, the battery will be charged until it is fully charged.**

2.2 Environment Requirements

The environment requirements for the transportation, storage and normal operation of this electrocardiograph are as shown in the following table

	Temperature:	Relative Humidity	Atmospheric pressure
Normal Operation	5℃～40℃	≤93%（No Condensation）	700hPa～1060hPa
Storage	Packed ECG must be stored in well ventilated rooms with -20℃～+60℃ temperature, relative humidity no more than 93%, and without corrosive gases. Leave at least 2 inches (5cm) free space around the electrocardiograph for air circulation.		
Transportation	Must avoid severe shock ,vibration, rain and snow during transport		

Note

- **The surrounding environment of the electrocardiograph should be clean and far away from the places with corrosives, high humidity, high temperature and direct sunlight, in the using vibration should be avoided and it is prohibited to move the equipment under the electriferous state.**

2.3 Protective Earthing

To protect both the patient and the operator, the housing of the electrocardiograph must be earthed. The electrocardiograph is supplied with a detachable 3-prong power cord, which shall be inserted into a grounded power outlet to connect the electrocardiograph to the earth. If grounded power outlet is not available, contact the electrician in your hospital.

Warning

- **It is forbidden to connect the 3-prong power cord to a 2-prong power outlet.**

Connect the earth wire to the equipotential connector of the electrocardiograph. If you have doubt about whether devices used together involves any electrical risks, such as risk caused by accumulation of leakage current, consult an expert in this field to ensure the safety of all devices.

2.4 Equipotential Earthing

The electrocardiograph must be connected to a power supply with protective earthing. For cardiac examination, the electrocardiograph must be separately connected to an equipotential earthing system. Connect one end of the equipotential conductor (potential equalization conductor) to the equipotential connector on the rear panel of the electrocardiograph, and connect the other end to a connector of the equipotential earthing system. In the event that the protective earthing system is damaged, the equipotential earthing system can provide protection to the electrocardiograph.

Cardiac examination can only be performed in a room installed with a protective earthing system. Before each use, check whether the electrocardiograph is in normal working status. Cables connecting the patient to the electrocardiograph cannot be tainted with electrolyte.

Warning

- **If the protective earthing system is not stable, use the built-in battery to supply power to the electrocardiograph.**

2.5 Condensation

Ensure that the electrocardiograph is free from condensation during operation. When the electrocardiograph is moved from one room to another, condensation may be formed due to exposure to damp air and temperature difference. In this case, do not use the electrocardiograph until it gets dry.

Chapter 3 Introduction

3.1 Product Performance, Structure and Composition

This instrument is mainly composed of the main unit, lead wire, limb electrode and chest electrode.

3.2 Product Application

This instrument is applicable to clinic units to detect and record people's routine ECG signals.

3.3 Brief Introduction

1) Brief introduction to conventional 12-lead ECG

Conventional 12-lead ECG is the physiological function detecting equipment to record waveform of electric activity of the heart. It can provide the basic information of various heart diseases for diagnosis and treatment use. It is helpful to the analysis and cognition of various arrhythmias and the understanding of the influence on the cardiac muscle exerted by certain drugs, electrolyte disorder and acid-base imbalance, therefore this equipment plays an important role in heart disease examination.

This ECG is a digital ECG gathering the records of 12 leads simultaneously. It has the function of ECG waveform display and automatic analysis. By installing with advanced thermal dot-matrix output system, high-performance 32-bit processor and large storage built-in memory, the performance and reliability of this ECG are improved greatly. The operation is easy and convenient, the functions are abundant and useful, and it is very suitable for the routine diagnosis of ECG in various medical departments, especially for physical examination, clinic emergency, ward and so on.

3.4 Principle of Operation

（1）Principle of operation for conventional 12-lead ECG

ECG is the waveform of bioelectrical changes on the skin which are caused by the successive stimulation from pacemaker to atrium and to ventricle in each cardiac cycle and which are detected and displayed by the electrocardiograph. ECG is the objective indicator of the generating, conduction and recovery process of

cardiac stimulation. The synchronous electrocardiograph is highly praised as the machine of detecting ECG by the clinic medicine at home and abroad, which can synchronously gather the ECG signal on skin from multiple channels and realize inputting multi-channel signals synchronously, and therefore the electrophysiological characteristics of every part of the heart during each cardiac pulse can be observed easily, which is conducive to the diagnosis of diseases concerning cardiac nerve conduction and cardiac dynamics.

3.5 Function Features

1) 8.4 inch color LCD (resolution 800×600), optional touch screen display.
2) Support many languages, such as: English, Spanish, French
3) The patient information can be input in English and other languages
4) The patient information report can be printed.
5) The printing preview function can be set before printing.
6) Supporting external laser printer (optional) , A4 paper showing 1:1,For now, the brand for printer supported including: PANTUM P3255DN.
7) With the conventional 12 leads ECG.
8) 300 cases can be saved and recalled (standard configuration). Built-in 8GB SD card (optional) can save 40000 cases.
9) Support program update by USB flash disk, the brand supported including Kingston, PNY, ADATA, Apacer. The storage of such USB flash disk should be 2G～8G
10) Supporting far distance ECG data-transformation between ECG machine and PC.
11) Multiple channel formats: 3×4, 3×4 +1R,， 3×4+3R, 6×2, 6×2 + 1R, 12×1, 12×1 + T.
12) The 12 lead waveforms are gathered, magnified, displayed, analyzed and printed synchronously, full-digital design and all float-ground design.
13) It has many output printing formats and supports the folded paper and rolled paper with the specification of 210mm and 216mm. It can record the detailed information such as correct uncompressed ECG waveform, lead marker, wave gain, paper driving speed, patient information and analytical reports clearly.
14) The ratio between the ECG waveform displayed on the screen and the printed one is 1:1, the grid displayed on the screen is the same as that on the record paper.
15) AC/DC, built-in environmental friendly and durable lithium battery can work continuously for more than 2 hours.
16) It can store the 12 lead waveforms for recent 2 minutes.
17) Large keyboard design and individual numbers and letters key.
18) Automatic measurement function and automatic diagnosis function can be selected.
19) It can analyze as many as 122 types of arrhythmia.

20) There are three working modes such as manual, automatic and rhythm to choose.
21) The main interface can display or close the lead status map and it can judge the bad electrode on the lead status map correctly and prompt the falling off information of each lead.
22) It adopts unique high precision digital filter to eliminate the baseline drift and other interferences, it does not cause distortion for the ECG waveform and it has enhanced the ability against baseline drift greatly and it is convenient for the waveform judging.
23) Security standard: European CE certificate.
24) When the thermosensitive record paper is skewed, this equipment can adjust the print paper automatically.

Chapter 4 Appearance Description

4.1 Top Panel of the Main Unit

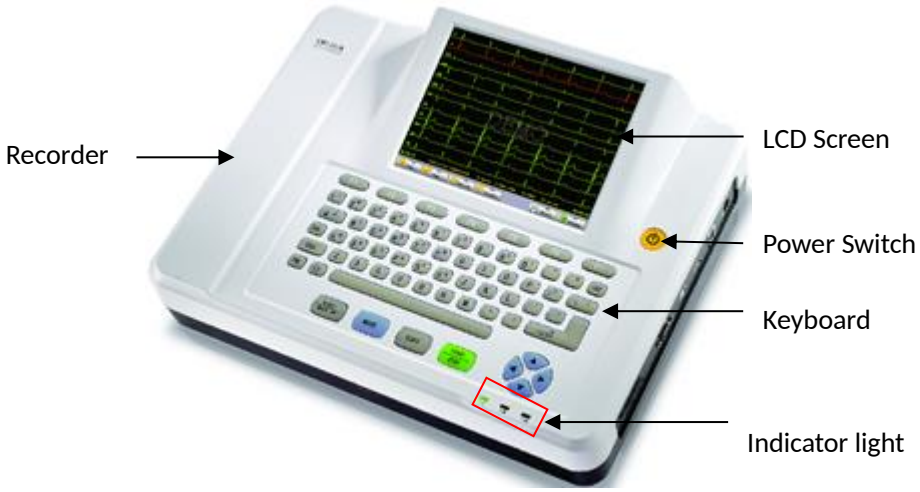

Figure 4-1Top Panel

Working State Indicators:

As shown in the above figure, the working state indicators from left to right are: AC Indicator lamp, Battery Working Indicator Lamp and Battery Recharging Indicator Lamp.

	Symbol	Name	Explanation
A	~	AC Indicator Lamp	When the AC power supply is used, this indicator lamp is light.
B		Battery Working Indicator Lamp	When the built-in rechargeable lithium battery is used, this indicator lamp is light.
C		Battery Recharging Indicator Lamp	When the battery is recharging, this indicator lamp and the AC indicator lamp are light at the same time.

4.1.1 LCD Main Screen

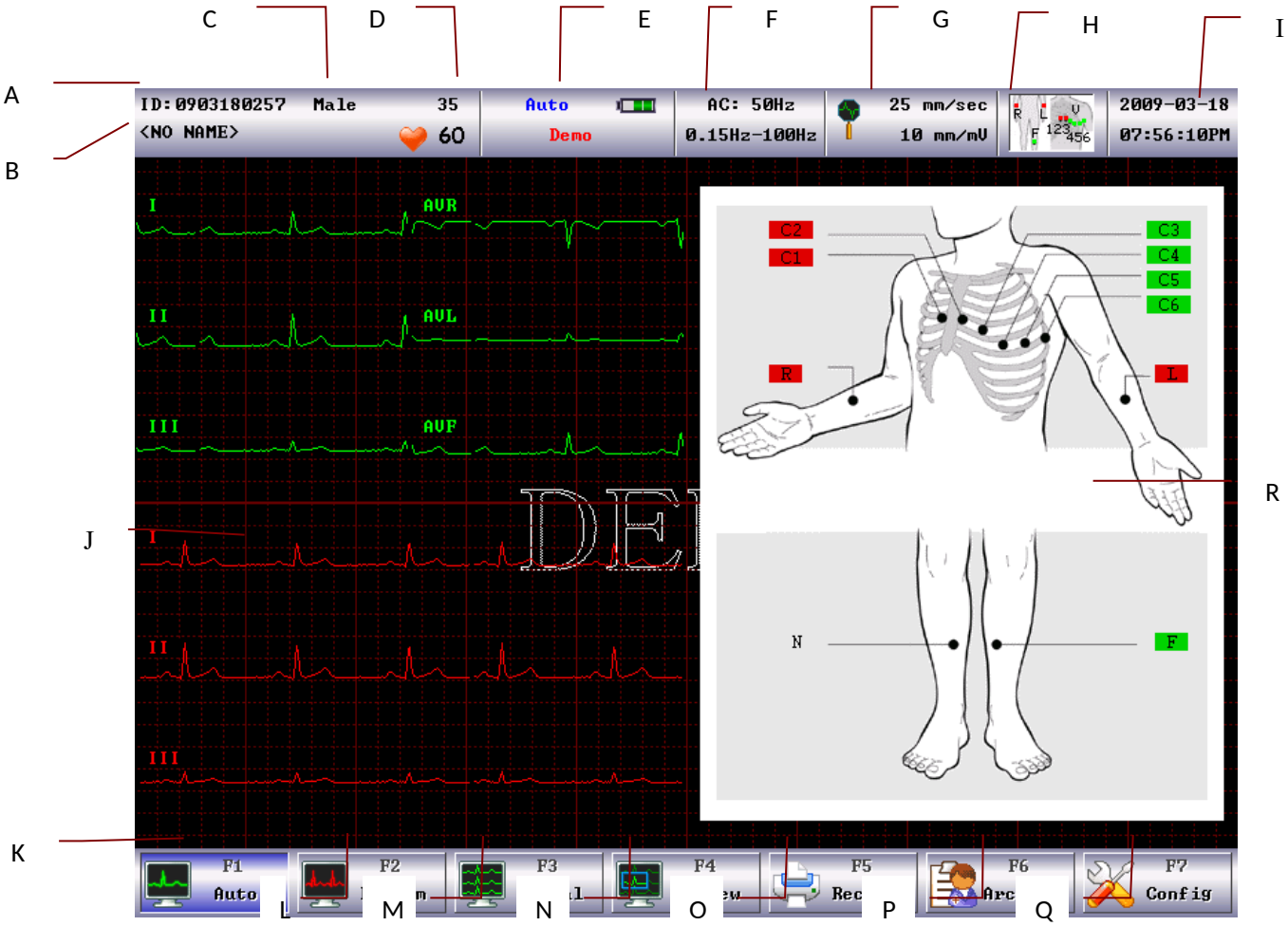

Figure 4-2 Main Interface

No.	Name	Explanation
A	Number	Patient number: less than 10 characters (click here to enter the “Register” settings.)
B	Name	Patient name: less than 20 English letters (click here to enter the “Register” settings.)
C	Sex	Sex: Male/Female (click here to enter the “Register” settings.)
D	Age， Heart Rate	Patient age， heart rate values
E	Working Model, Battery and Prompt Information	Display the current working model, battery capacity and prompt information (prompt “Demonstrate, lead off, printing, analyzing, sampling” and so on.)

F	Filter Options	Display the settings of the current AC filter, EMG filter, drift filter and lowpass filter，from here enter the “Filters” Setting.
G	Printing Speed, Gain Options	Display the current printing speed and gain, from here enter the “Print” Setting.
H	Leads Status Map	Show the falling off state of the lead, green color shows that the lead is connected and red color shows the falling off state of the lead. Click here to turn on and off “Leads Status Map” rapidly.
I	Time	Current Time Display，from here enter the “System” Setting.
J	Waveform Area	Current Waveform Display
K	F1 Automatic	Automatic Printing Option Key
L	F2 Rhythm	Rhythm Lead Mode Option Key
M	F3 Manual	Manual Printing Option Key
N	F4 Review	Patient Information Storage Review
O	F5 Print	Waveform Printing Key
P	F6 Archive	Patient File Information Management
Q	F7 Configuration	System Settings Menu(include in register options, lead options, filter options, printing options, system options and net options) After entering Settings Menu, "F7" is used as the return key.
R	Diagram Area	Leads Status Map

4.1.2 Keyboard

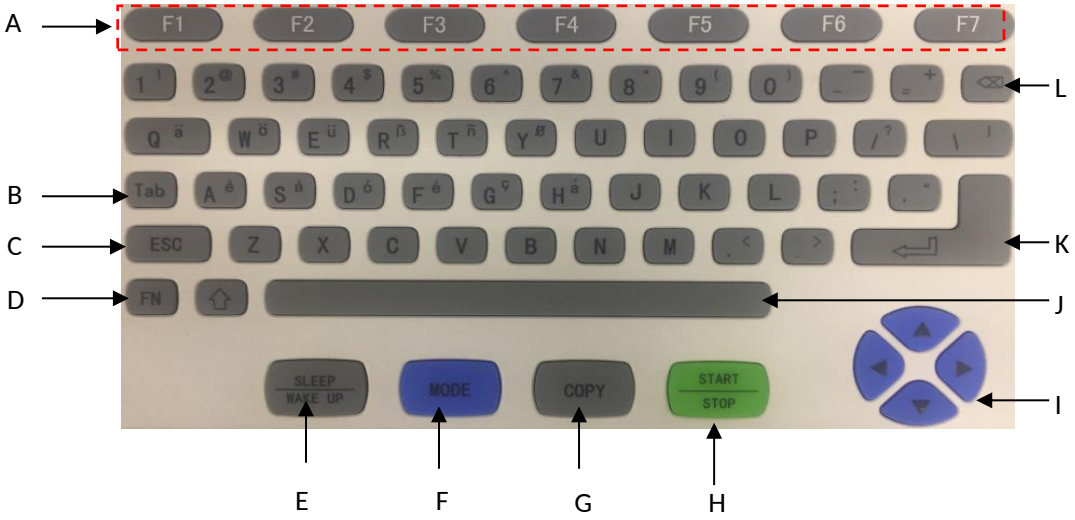

Figure 4-3 Keyboard

No.	Name	Explanation
A	Function Key	Select screen menu function.
B	Tab	Cursor Movement Key. (Reserved)
C	Esc	Cancel the operation. (Reserved)
D	FN	Used to generate special characters. (Reserved)
E	SLEEP/WEAK UP	Sleep/Wake Up Key.
F	MODE	Printing Mode Switching Shortcut Key (Manual, Automatic, Rhythm). And can be used as the switching key for capital letter and lower case of English in the keyboard window of register settings.
G	COPY	Review and record the latest ECG data recorded under the automatic working mode.
H	START/STOP	Start and stop the recorder.
I	Arrow Keys Group	Move the cursor to upper, lower, left and right. Under the manual working mode, press the left and right key to converse the lead group.
J	Space Bar	Insert space between the input characters.
K	Enter Key	Confirm the input character.
L	Delete Key	Delete the input character.

4.2 Back Panel of the Main Unit

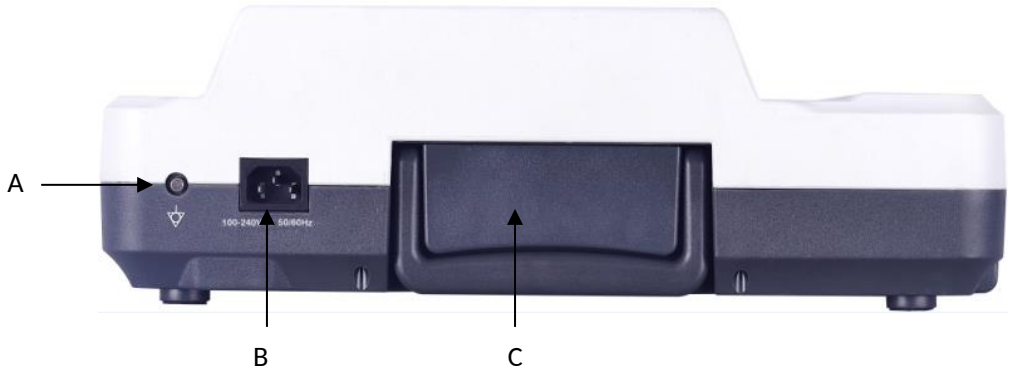

Figure 4-4 Back Panel

No.	Name	Explanation
A	Equipotential grounding terminal	When the equipotential line needs to be grounded in order to ensure the safety of electricity, connect this equipotential terminal and the earthing line port with earthing line.
B	AC Socket	AC SOURCE: AC Power Cable Socket
C	Handle	For the hand grip.

4.3 Right Panel of the Main Unit

Warning

- **The accessories connected to the analog and digital interfaces should be validated according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations should comply with the valid version of the IEC60601-1. Therefore anybody, who connects additional equipment to the signal input connector or signal 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. If there is any problem, consult us or your local agent.**
- **In order to ensure the patient safety, the summation of leakage current should never exceed leakage current limits while several other units are connected to the patients at the same time.**

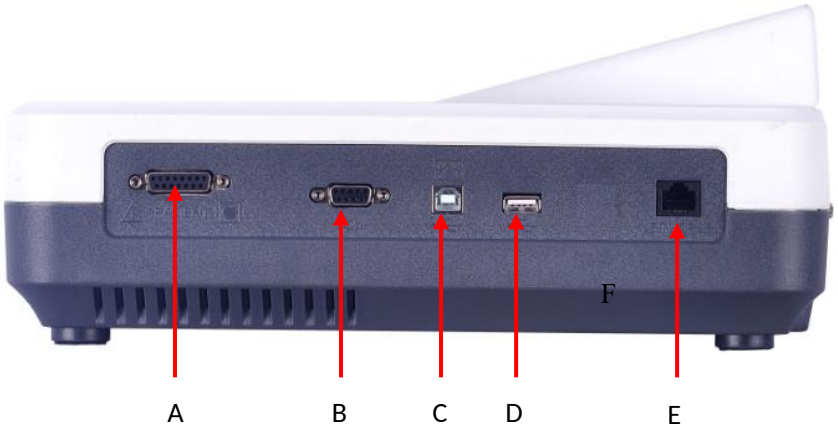

Figure 4-5 Right Panel

No.	Name	Explanation
A	Patient Cable Socket	Connect the patient cable.
B	External Input and Output Interfaces	Connect other equipment.
C	USB Connector1	Standard USB connector, connect the special USB and special USB printer. （For now, the brand for printer supported including: PANTUM P3255DN）
D	USB Connector 2	Standard USB connector, connect the PC.
E	Network Connector	Standard network connector, connect the network cable.

1) Patient Cable Socket

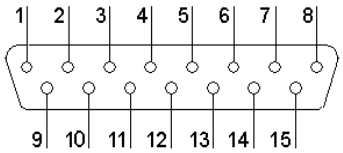

Figure 4-6 Patient Cable Socket

Definition of corresponding pins:

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

2) External Input and Output Interfaces

⚠Warning

- **The insulation strength of the external input and output interfaces is AC 1500V, the maximum DC voltage at this port is not more than +15V.**

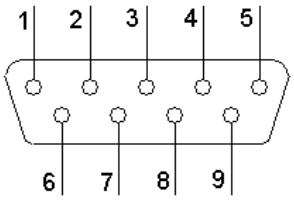

Figure 4-7 External input/ output interface

Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	ECG signal (input)	4	NC	7	NC
2	RxD (input)	5	GND	8	+12V
3	TxD(output)	6	NC	9	ECG signal (output)

3) USB Connector 1/ USB Connector 2（Reserved）

⚠Warning

- **Two USB connectors can only be connected to the special USB equipment designated by Comen Company.**

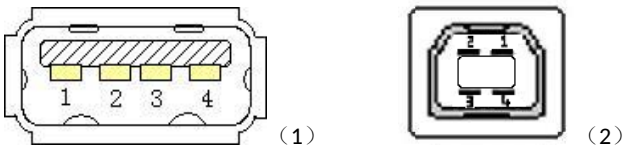

Figure 4-8 USB connector

Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	+5V	**3**	D+
2	D-	**4**	GND

4.4 Bottom Panel of the Main Unit

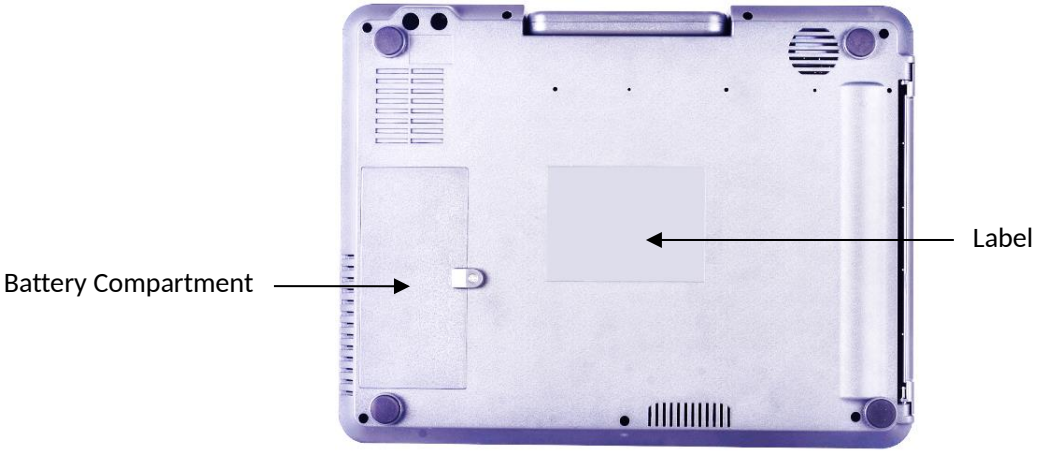

Figure 4-9 Bottom Panel

Chapter 5 Operation Preparations

⚠Warning

- **The patient cable and other accessories provided by our company should be used, if accessories of other types are used, the equipment may be damaged and the performance and safety of the equipment may be affected.**

5.1 Connect the Power and Earthing Line

⚠ Warning

- **Avoid the electric shock risk— — the three-phase socket with the protective ground should be used and the earthing of the socket should be kept well; the shell of the equipment can not be open when the power supply is connected.**
- **If there is doubt for the integrality for the protective earthing line, please use the built-in battery for the power supply and do not use the AC power supply.**

1) Use the AC Power Supply

First check whether the AC power supply complies with the requirements:

Rated Voltage: 100-240V ～

Rated Frequency: 50Hz/60Hz

Rated Power: 95VA

Then plug the power cable connector into the AC socket on the back of the equipment, plug the power cable into the three-phase AC power socket.

2) Use the Built-in Battery

When this electrocardiograph is delivered to the user, the built-in rechargeable lithium battery has been installed and which can be used directly. For the power loss in the storage and transportation, for the initial use the electric quantity of the lithium battery may be inadequate and at this time the battery should be recharged. When the shelf life of the battery is over (cycle life ≥300 times) or the using time after the recharging has been shortened obviously, the battery should be replaced in time. The detailed instruction of the recharging and replacement of the battery please refer to section 7.3 Daily Care and Maintenance.

3) Connect the Earthing Line

Connect one end of the earthing line to the equipotential grounding terminal at the back of the

equipment and connect another end to the public earthing of the hospital.

5.2 Loading the Record Paper

This electrocardiograph supports two kinds of record paper: rolled thermosensitive record paper and folded thermosensitive record paper. When there is no record paper loaded or it reaches the end of the record paper, “Paper?” will be displayed on the LCD screen to remind the user of loading or replacing the record paper.

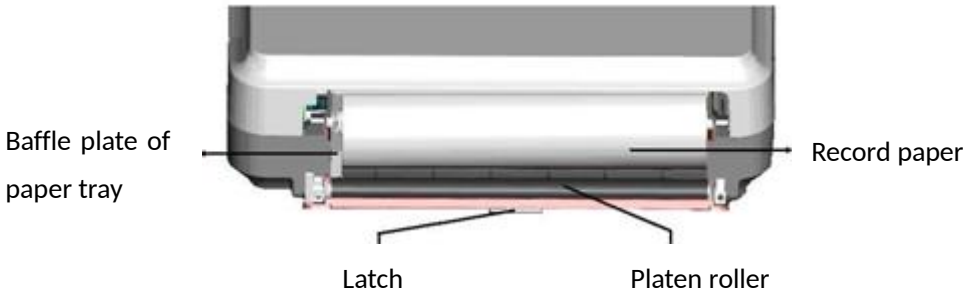

Figure 5-1 Recorder

5.2.1 Loading the Rolled Thermosensitive Record Paper

1) Press the latch on the left of the recorder with one hand and open the recorder with another hand forced down;
2) Take out the paper roller, and remove remaining paper from the left of roller if necessary;
3) Unwrap the new rolled record paper and put it into the paper tray; make sure that the grid surface should face upward
4) Place the record paper and roller gently in the paper tray with the roller pin
5) Pull about 2cm paper out from the paper exit on the right of the recorder and close the recorder cover

5.2.2 Loading the Folded Thermosensitive Record Paper:

1) Press the latch on the left of the recorder with one hand and open the recorder with another hand forced down;
2) Take out the remaining folded record paper;
3) Take off the package of the new folded record paper and place it into the paper tray, pay attention to that when the free end of the record paper is vertical, the grid surface of the

record should be forward right;

4) Pull about 2cm paper out from the paper exit on the right of the recorder and close the recorder cover.

⚠Warning

- **When 210mm folded or rolled print paper is used, please install the baffle plate in Appendix I into paper case to avoid print deviation, paper jam and so on.**

5.3 Patient Cable Connection

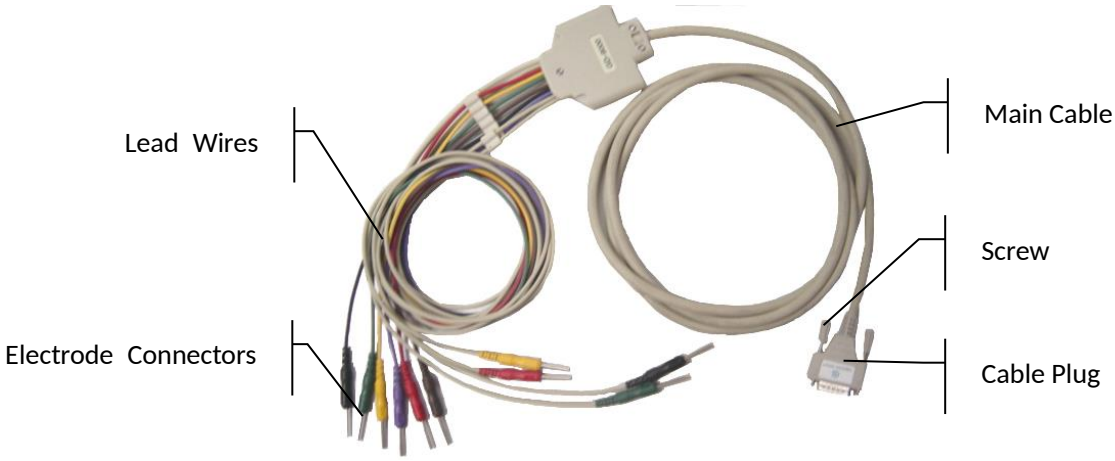

Figure 5-2 Patient Lead Lines

Patient cables include two parts: main cables which are connected to the electrocardiograph and the lead wires which are connected to the patient. Lead wires include 6 chest lead wires and 4 limbs lead wires, the user can distinguish the chest leads and limb leads from the color of the lead wires and the label on the connector.

Patient Cable Connection: Plug the patient cable into the cable socket on the right side of the electrocardiograph; rotate the screws at the two sides of the plug.

5.4 Electrodes Connection

5.4.1 Electrodes and Identifiers

⚠Warning

- **Please ensure that all the electrodes are connected to the correct positions on the patient body; avoid the contact of electrodes (include neutral electrodes) and patients to any other conductive parts or the ground.**

The contact resistance between the patient and electrodes exerts great influence on the quality of the ECG; therefore in the connection of electrodes, the contact resistance should be minimized as possible to obtain better ECG.

Electrode identifiers and color codes (European Standard) are shown in Table 5-1. The code and color are different for the electrodes with different standards, the corresponding American standard identifiers and color codes are shown in Table 5-1 too.

	European Standard		**American Standard**	
Lead	Identifier	Color	Identifier	Color
Right Arm	R	Red	RA	White
Left Arm	L	Yellow	LA	Black
Right Foot	N or RF	Black	RL	Green
Left Foot	F	Green	LL	Red
Chest 1	C1	White/Red	V1	Brown /Red
Chest 2	C2	White/Yellow	V2	Brown /Yellow
Chest 3	C3	White/Green	V3	Brown /Green
Chest 4	C4	White/Brown	V4	Brown /Blue
Chest 5	C5	White/Black	V5	Brown /Orange
Chest 6	C6	White/Purple	V6	Brown /Purple

Table 5-1 Electrode Identifiers and Color Codes

5.4.2 Limb Electrodes and Chest Electrodes

(1) Limb Electrodes (Clamp Type):

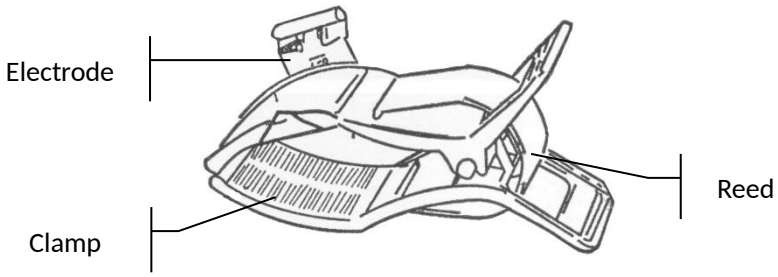

Figure 5-3 Limb Electrodes

The limb electrodes are placed above the wrist joint of the forearm and above the inner side of the ankle joint of the lower leg, on those parts the electrodes and skin contact tightly.

Connect the limb electrodes:

1) Check whether the electrodes are clean;
2) Align all lead wires and avoid twisting and connect the electrode connector and electrode well;
3) Clean electrode area on chest surface with alcohol;
4) Daub conductive gel on the skin evenly;
5) Daub a thin layer of gel on the surface of the limb electrode;
6) Place the electrodes on the skin surface well.

(2)Chest Electrode (suction bulb type):

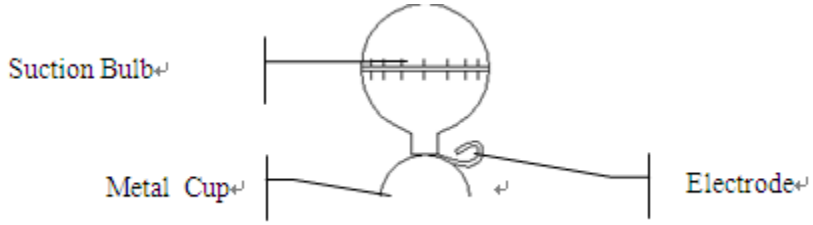

Figure 5-4 Suction Bulb

Chest Electrodes Connection:

1) Check whether the electrodes are clean;
2) Align all lead wires and avoid twisting and connect the electrode connector and electrode well;
3) Clean electrode area on chest surface with alcohol;
4) For each electrode position on the chest, daub evenly conductive gel with the diameter range of about 25 mm;
5) Daub a thin layer of conductive gel on the brim of chest electrode’s suction bulb;
6) Place the electrodes on the skin and squeeze the suction bulb. Unclench the suction ball and then the electrodes are absorbed on the chest.

⚠Note

- **Do not daub too much conductive gel and the layer should be separated, otherwise it may cause short circuit between electrodes and the errors of the ECG signal record.**

5.4.3 WILSON Standard Leads

Wilson leads system, proposed by Wilson, is the central terminal connection leads system. Taken European Standard as an example, its connection method is as follows:

1. Electrode R --- right arm;
2. Electrode L --- left arm;
3. Electrode N --- right leg;
4. Electrode F --- left leg;
5. C1: Fourth intercostals space at right border of sternum
6. C2: Fourth intercostals space at left border of sternum
7. C3: Middle of C2 and C4
8. C4: Fifth intercostals space on left midclavicular line
9. C5: Left anterior axillary line at the horizontal level of C4
10. C6: Left middle axillary line at the horizontal level of C4

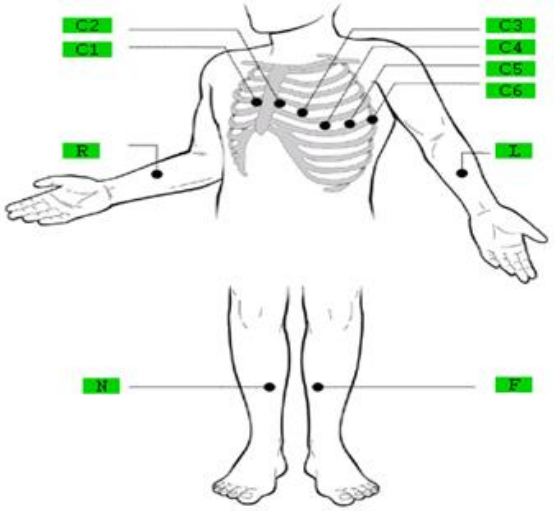

Figure 5-5 WILLSON lead system connection method

5.5 Inspection before Power On

Before using this electrocardiograph please read the user manual carefully to be familiar with the performance of the equipment and the operation methods must be mastered and the cautions and

warnings; following inspection procedures are recommended before power on.

1) Environment:

   Check whether there is other electric equipment in the surrounding environment, such as electrosurgical equipment, ultrasonic equipment radiological equipment and so on, these equipments may cause interference and switch off these equipments when necessary;

   The room is required to keep warm (5℃～40℃) to avoid the EMG interference caused by cold.

2) Power Supply:

   When the AC power supply is used, please check whether the power cable has been connected to the unit well, and the grounded three-phase socket should be used;

3) Earthing:

   Whether the earthing lines have been connected correctly and tightly;

4) Leads:

   Check whether the pins of the leads have been connected well and avoid the lead wires being close to the AC power cord; check whether the lead wires have been connected with the corresponding electrodes correctly;

5) Electrodes:

   Check whether the electrodes have been connected well; whether the electrodes and particular the chest electrodes contact with each other;

6) Record Paper:

   Ensure that the record paper is adequate and the loading is correct.

7) Examinee:

   Check whether the hand and foot of the examinee contact with the metal parts of the bed, whether the environment of the examination room is comfortable, whether the examinee is too nervous, require the examinee to relax the body and keep quiet respiration.

Chapter 6 Operation Instruction

6.1 Switch On

When AC power supply is used, first connect the power cord and the AC indicator lamp (⏦) is light. Then press the ON/OFF key on the keyboard to turn on the unit, after some information is displayed on the equipment, the equipment enters the working state;

When AC power supply is used, if the electric quantity of the built-in rechargeable battery is insufficient, the battery will be recharged at the same time and at this time the AC power indicator lamp(⏦) and battery recharging indicator lamp () are light at the same time.

When the built-in rechargeable battery is used, press the ON/OFF key on the keyboard to turn on the unit, and the battery indicator lamp () is light, after some information is displayed on the equipment, the equipment enters the working state;

6.2 Basic Operation Introductions

The ECG waveform recording, parameters settings, ECG data managements and all operations can be conducted through the keyboard.

For the CM1200A, the user can conduct the operations by pressing the touch key on the LCD screen.

⚠Warning

- **It is prohibited to touch the screen with sharp substances, such as pencil or pen, otherwise it may cause damage.**

6.2.1 Register

Press F7 key to enter “Configuration” setting Menu, select the “Register” setting window to edit patient’s information, as shown in the following figure:

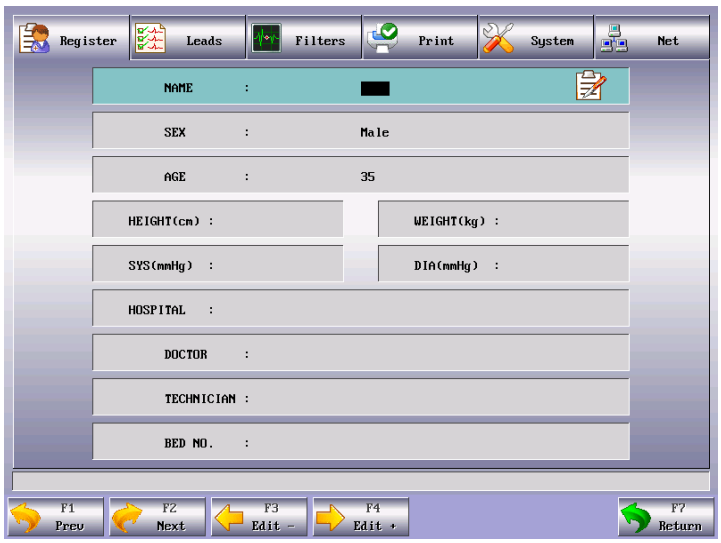

Figure 6-1 Register Interface

(1) Select the Sub-item of the Register Setting Window

Press the F1/F2 key to select the six options settings of “Register Options, Lead Options, Filter Options, Print Options, System Options and Net Options”. Press the F3/F4 key to set a submenu.

(2) Input the Characters

Input the patient information on the “Register” setting interface:

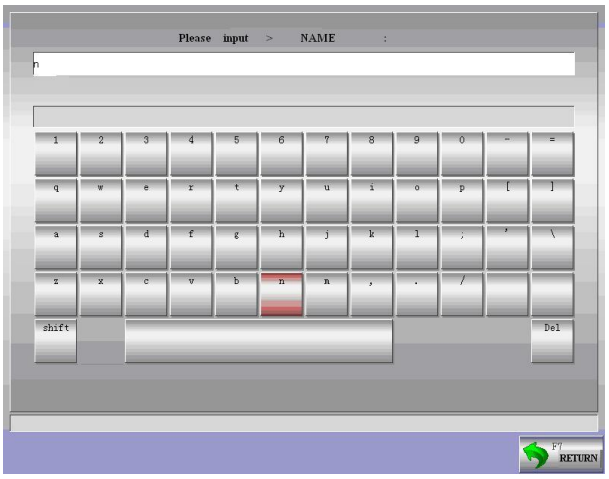

Figure 6-2 Lead Options

- Press the up and down arrow key of the combination keys to move the cursor to “Name” menu, then press the left and right key of the combination keys to enter the edit interface, as shown in the above figure;
- Press “-”or “=”to search characters, press the left and right key of combination keys to select the corresponding character and then press the enter key to confirm or enter the related information on the keyboard of the panel, if the user needs to delete all the original information,

press the delete key to delete;

- Press the MODE key to switch the input method or the capital letter and lowercase of the English;
- Press the F7 key to return to the previous menu.

Edit the hospital, doctor, parameters or other items in the setting window of the “Register” setting window, the methods of parameters setting and characters input are the same as described above.

Note

- **In the recording process, the patient information can not be modified.**

- Name: Patient’s Name (within20 characters)
- Sex: Sex of the Patient (Male/Female)
- Age: Patient’s Age (Range: 0~99)
- Height (cm): Patient’s Height (Range: 0~999)
- Weight (kg): Patient’s Body Weight (Range: 0~999)
- SYS(Systolic Pressure) (mmHg): Patient’s Systolic Pressure
- DIA(Diastolic Pressure) (mmHg): Patient’s Diastolic Pressure
- Hospital: Hospital Name within 40 characters)
- Doctor: Doctor’s Name (within 20 characters)
- Technician: Technician’s Name (within 20 characters)
- Bed No.: Bed No. (within 20 characters)
- Division: the division patient registered in (within 20 characters)
- Hospital No.: within 10 numbers or letters

6.2.2 Lead Options

Press the “F7” key to enter the “Configuration” menu, select the “Leads” as shown in the following figure:

Figure 6-3 Lead Options

1. Channel Format: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 12×1, 12×1+1T.
   - When it is set as 3×4, 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence.
   - When it is set as 3×4+1R, 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence and add 1 channel of rhythm lead waveform.
   - When it is set as 3×4+3R, 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence and add 3 channels of rhythm lead waveform.
   - When it is set as 6×2, 12 leads are recorded in 6 channels and 2 sequences, record 5 seconds for each sequence.
   - When it is set as 6×2+1R, 12 leads are recorded in 6 channels and 2 sequences, record 5 seconds for each sequence and add 1 channel of rhythm lead waveform.
   - When it is set as 12×1, 12 leads are recorded in 12 channels, record 10 seconds at the same time.
   - When it is set as 12×1+T, 12 leads are recorded in 12 channels, record 5 seconds for each sequence from I to V3 and record 10 seconds for each sequence from V4 to V6. Patient's information and patient's diagnosis information are printed on one recorder paper.
2. Lead Sequence: Standard, Cabrera

   Lead Order: as shown in the following table

Lead Order	Lead Group 1	Lead Group 2	Lead Group 3	Lead Group 4
Standard	I, II, III	aVR, aVL, aVF	V1, V2, V3	V4, V5, V6
Cabrera	aVL, I, -aVR	II, aVF, Ш	V1, V2, V3	V4, V5, V6

3. Leads Status Map: On, Off and Auto.
   - When the leads status map is on, the leads status map on the right of the screen can be used as a reference schematic diagram of one kind of leads connection, and the lead connection and falling off state information can be observed. Red color shows the falling off state of the lead and green color shows that the leads have been connected well.
   - When the leads status map is off, there is no leads status map on the right of the screen.
   - When the leads status map is auto, leads status map will display only when leads are falling off, and the leads status map will disappear once leads wires are connected well.

⚠Note

- **On the basis of the male and female sex settings in the "Patient Parameters", the corresponding male and female lead state diagrams will be shown.**

4. Sample Mode: Real time and Pre-sampling.
   - When the sample mode is set as real time, the user press the "F5 Print" key or "START/STOP" key, then ECG data of 10 seconds after pressing of the key will be recorded and output.

- When the sample mode is set as pre-sampling, once the leads connect with the patient the ECG data will be collected and it is not necessary to wait for the user to press the START/STOP key to collect the ECG data. After the user press the START/STOP key, ECG data of 10 seconds after pressing of the key will be recorded and output.

5. Sample Order: Simultaneous and Sequential.

   In the sequential sampling of each group, " ¦ " shows in the place of printing lead waveform; and in the simultaneous sampling of each group, "¦¦ " shows in the place of the printing lead waveform. As shown in the following figure:

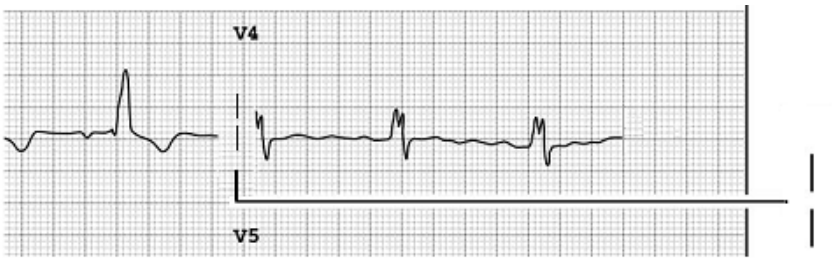

Figure 6-4 Sequential Sampling of Each Group

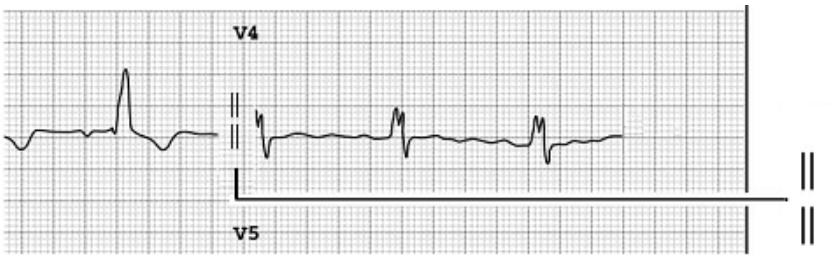

Figure 6-5 Simultaneous Sampling of Each Group

6. Rhythm Lead Type: 1 channel and 3 channel.

   This lead type is only for the rhythm model. Under other models, the user can select the number of the channel to print according to the channel format.

   - When 1 channel is selected, only anyone channel of the "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" of "Rhythm Lead 1" can be set as the rhythm lead; when 3 channel is selected, any one channel of the "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" of "Rhythm Lead 1, Rhythm Lead 2 and Rhythm Lead 3" can be set as the rhythm lead.
   - Under the rhythm working mode, when the rhythm mode is set as 1 channel, the ECG record process will record and output the rhythm waveform for 60 seconds of the rhythm lead selected in the rhythm lead 1; when the rhythm mode is set as 3 channel, in the ECG record process the rhythm waveform for 60 seconds of the three rhythm leads selected in rhythm lead 1, rhythm lead 2 and rhythm lead 3.

7. Rhythm Lead 1: select any one of the "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" as the rhythm lead.
8. Rhythm Lead 2: select any one of the "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" as the rhythm lead.
9. Rhythm lead 3: select any one of the "I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6" as the rhythm lead.

⚠Note

- **The red waveform on the screen shows the waveform of the rhythm lead.**

6.2.3 Filter Options

Press the F7 key to enter the “Setting” menu, select the “Filters” as shown in the following figure:

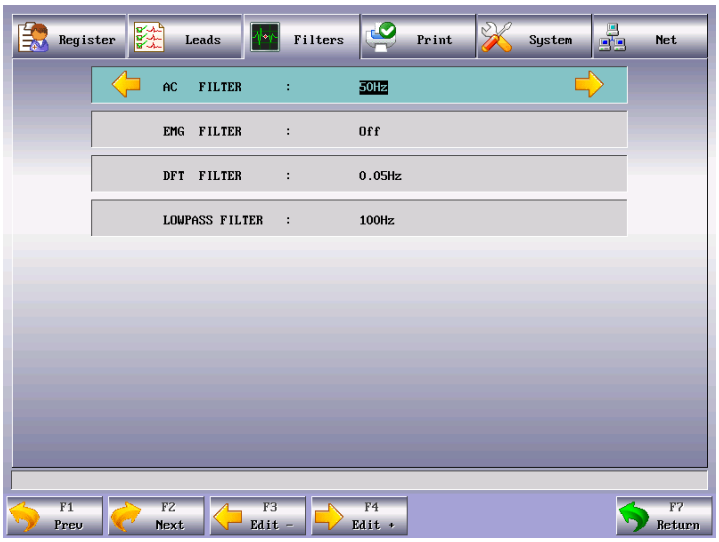

Figure 6-6 Filter Options

Filter setting menu includes 4 filter settings: AC filter, EMG filter, DFT filter and lowpass filter.

(1) AC Filter: 50HZ, 60HZ and Off

AC filter is used to resist the interference of the AC power supply to avoid the reducing or distortion of the ECG signal.

(2) EMG（Electromyography）Filter: 25HZ, 35HZ, 45HZ and Off

EMG filter is used to resist the interference on the ECG signal caused by strong muscle vibration. The cutoff frequencies the user can select are 25Hz, 35Hz, and 45Hz or off.

(3) DFT （Drift） Filter: 0.05Hz, 0.10Hz, 0.20Hz and 0.50Hz

DFT filter is used to resist the drift of the baseline and ensure the ECG signal is on the baseline in the recording process. The set option values are the lower limits of the frequency range which include four options such as 0.05Hz, 0.10Hz, 0.20Hz and 0.5Hz.

(4) Lowpass Filter: 75HZ, 100Hz, 150Hz and Off.

Lowpass filter is used to limit the bandwidth of the input signal and reduce the signal with the frequency higher than the set cutoff frequency. The cutoff frequencies the user can select are 75Hz, 100Hz, 150Hz and Off.

⚠Note

- **Among these four filter modes above, "DFT FILTER" has the greatest influence on the waveforms imputed. Higher level could better filter out low frequency interference like movement, but ECG signals would have more distortion like ST segment too high, and therefore only the experienced clinicians can use the high level of drift filter. The "DFT FILTER" should be set as 0.05Hz to get the undistorted ECG signals. "AC FILTER" is used to resist the interference of the AC power supply, 50Hz for 220V and 60Hz for 110V. "EMG FILTER" is used to resist the interference on the ECG signals caused by strong muscle vibration. In the process of clinical use, the clinicians will ask the patients to relax first, so this option is usually set as "off". "LOWPASS FILTER" is a filter mode that the signals below a certain frequency (75Hz, 100Hz, 150Hz and off) can pass through, and it is suggested that it be set as 100Hz.**
- **This instrument is detection equipment instead of diagnosis equipment. It is suggested that clinicians conduct the detection and analysis according to actual situation and their clinic experience.**

6.2.4 Print Options

Press the F7 key to enter the "Configuration" menu, select the "Print" as shown in the following figure:

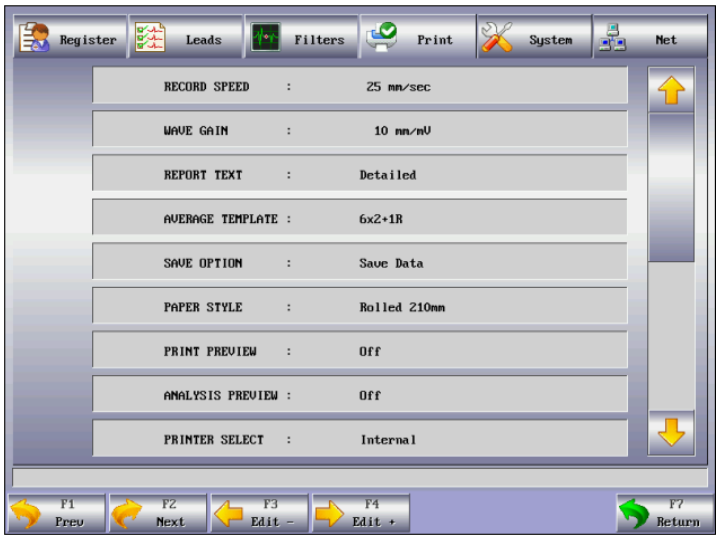

Figure 6-7 Print Options Interface

(1) Record Speed: the paper driving speed of the recorder, there are five options for the user to set such as 5mm/sec, 10mm/sec, 12.5mm/sec, 25mm/sec and 50mm/sec. For the rhythm mode and automatic mode, the print only supports the paper driving speed of 25mm/s and 50mm/s.

(2) Wave Gain: 2.5mm/mV, 5mm/mV, 10mm/mV, AGC(automatic gain), 20mm/mV, 10/5mm/mV, (grade gain, the former represents the limb lead gain and the latter represents the chest lead gain)

and 20/10mm/mV(grade gain, the first represents the limb lead gain and the former represents the chest lead gain).

(3) Report Text: Off, Basic, Detailed.

- When it is set as “Off”, there is only information set in the “Register”;
- When it is set as “Basic”, the print information includes: information set in the “Register”, interval, electrical axis, amplitude, etc;
- When it is set as “Detailed”, the print information include: information set in the “Register”, interval, electrical axis, amplitude, Minnesota code, diagnosis information, etc.

(4) Average Template: 3×4+1R, 6×2+1R, Off.

- When it is set as 3×4+1R, 12 leads of average template waveforms are recorded in 3 channels and 4 sequences and add 1 average template waveform of the rhythm lead.
- When it is set as 6×2+1R, 12 leads of average template waveforms are recorded in 6 channels and 2 sequences and add 1 average template waveform of the rhythm lead.
- When it is set as “off”, there is no average template output.

(5) Save Option: Save Data, Off.

- When the save option is set as “Save Data”, under automatic working mode the waveform and data of patient cases whether chosen to print by internal printer or external printer are all saved in the document management “File” interface.
- When the save option is set as “Off”, the ECG data recorded under the automatic working mode will not be stored in the document management “File” interface.

(6) Paper Style: Rolled 210mm,Rolled 216mm;Folded 140×210mm, Folded 140×216mm, Folded 295×210mm, Folded 295×216mm.

There are two kinds of record paper supported by this electrocardiograph: rolled thermosensitive record paper and folded thermosensitive record paper. When no record paper is loaded or the record paper is used up, “Paper?” will be displayed on the LCD screen to remind the user of loading or replacing the record paper.

⚠**Note**

- **If incorrect paper type is selected, the equipment may not print normally.**
- **When rolled paper 210mm or folded paper 140×210 mm, 295×210mm is used, the baffle plate in the Appendix I should be used to avoid print paper being skewed.**

(7) Print Preview: On, Off.

Before the automatic printing, set the print preview as “On”, press the “Print” key, the related waveform, patient information can be previewed， then select whether to print.

(8) Analysis Preview: On, Off.

Set analysis preview as “on” before automatic print, press the print key and a preview window will pop up after sampling. In this preview window, doctors can judge patient’s diagnosis information

and modify it through their clinic experience, or they can print patient's information directly.

(9) Printer select: Internal, External, Picture, Close.

- Select "Internal" to use the built-in thermosensitive dot-matrix printer;
- Select "External" to use an external printer, like PANTUM P3255DN
- Select "Picture" not to use the internal or external printer, but to save the patient's waveforms and information as an image file identified by ID+"G";
- When select "Close", there is no print and no save.

⚠Note

- **The external printer is optional.**
- **Only use the external printer supplied or recommended by us, or it may fail to be recognized by the ECG machine or cause damage to reduce the performance and safety of the machine**
- **Currently our ECG machine CM1200 supports such external printers as PANTUM P3255DN.**

(10) Printer Test: Off, Testing. When test of print head is normal, triangle wave will be printed.

⚠Warning

- **When the printer is out of order, the maintenance should be conducted by authorized and qualified engineers. If the maintenance is not conducted by those engineers authorized by Comen Company, Comen Company will not be responsible for the security, reliability and performance of this equipment.**

6.2.5 System Options

Press the F7 key to enter the "Configuration" menu, select the "System" as shown in the following figure:

Figure 6-8 System Options Interface

1) Language: The user can set the language set on the display screen in the electrocardiograph and the language used in the ECG records.

2) Demo Mode: On, Off.

⚠Warning

- **Waveform demonstration is the simulated demonstrate waveform set by the manufacturer to show the equipment performance and help the user to conduct training. In the practical clinical application, demonstration waveform is forbidden to use, because it is easier to mislead the medical personnel to consider it as the electrocardiographed patient waveform and parameters and which may affect the patient care and delay the diagnosis and treatment of the disease.**

3) Key Beep: On, Off.

Key beep is the brief “Di” sound sent out by the equipment when the user presses the keys on the keyboard. When it is set as “Off”, there will be no sound when pressing the key.

4) QRS BEEP: On, Off.

QRS beep is the brief “Di” sound sent out by the equipment when the R wave is detected. When the QRS beep is set as “Off”, there will be no sound.

5) LCD Brightness: Bright, Dark.

6) Extern In/Out: Input, Output, Off.

When it is set as “Input”, external ECG signals can be displayed through the “input and output” interface. When it is set as “output”, the ECG signals can be output to oscilloscope and other instruments through the “input and output” interface.

7) Default configuration: The user can select whether to recover the default value.

8) Automatic power off: Off, 1min、5min、10min、30min.

This function is the time selection of automatic power-off for ECG. When 1min is selected, this equipment will shut down automatically 1 minute after no operation.

9) Date and Time Setup

Set the current date and time to be displayed on the thermosensitive record paper.

6.2.6 Network Parameter

Press [F7] to enter the menu "Setup" and select "Net" as below:

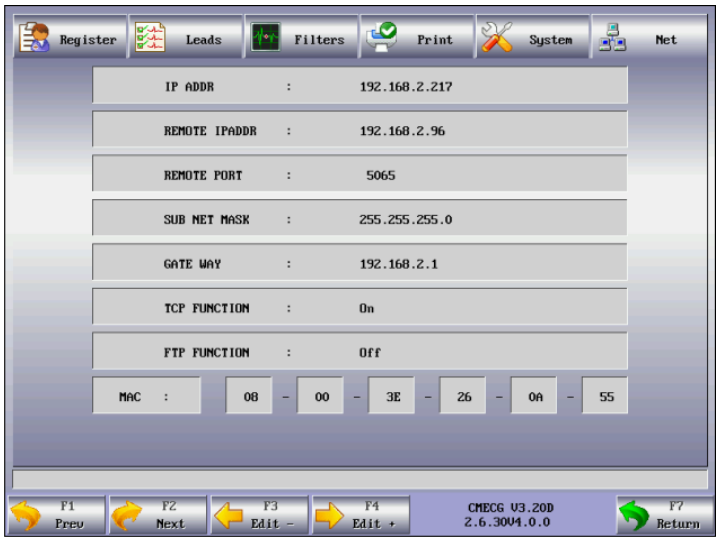

Figure 6-9 Network Parameters Interface

1. IP ADDR: 192.168.2.217, IP address of the ECG machine.
2. Remote IP ADDR: 192.168.2.96, IP address of the computer connected.
3. Remote Port: 5065, remote port connected to the ECG workstation.
4. Sub Net Mask: 255.255.255.0, subnet mask of the computer connected.
5. Gateway: 192.168.2.1, default gateway of the computer connected.
6. TCP FUNCTION: On, Off. Select On to connect to the ECG workstation.

   TCP (Transmission Control Protocol) is a connection-oriented reliable transport layer communication protocol based on bytes stream.
7. FTP FUNCTION: On, Off. Select On to connect to the computer and view the case data record on the computer. Refer to the section 6.6 File Management.

   FTP (File Transfer Protocol) allows one computer to acquire files from or transfer files to another computer. You can connect the ECG machine to a computer and designate a user name and password to use the computer in a safe way. Whenever the computer accesses the files on the data management window of the ECG machine, FTP will be run and you can only copy the files to your computer to use.

Note: The network connection function is optional.

8. MAC address: 08-00-3E-26-0A-55, MAC address of the ECG machine.

⚠Warning

- **Only connect this machine to the ECG workstation system of Shenzhen Comen Medical Instruments Co., LTD. .**

6.3 ECG Review

The user can review the ECG waveform to observe. If the ECG data before the review is less than 10s, the user need to wait until the electrocardiograph has gathered data for 10s to freeze the operation.

Specific Operation Methods:

Press the “F4” key on the keyboard and start to review the ECG, as shown in the following figure;

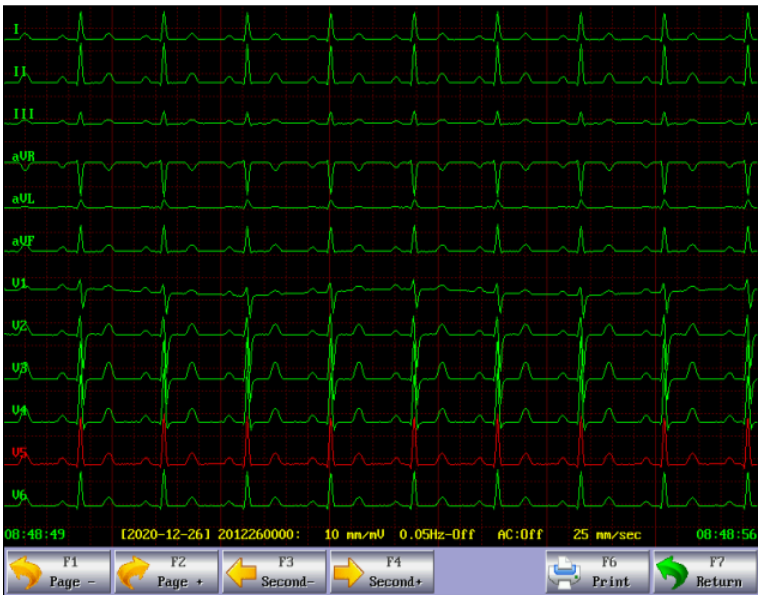

Figure 6-10 ECG Review Interface

1) Press the function key F1/F2 to turn to the previous page/next page;
2) Press the function key F3/F4 to see the ECG of the previous second/next second;
3) Press F6 key to print the current selected ECG.
4) Press the F7 key to return the previous menu.

6.4 Printing preview & analysis preview

Print the ECG waveform under the automatic working model. Press “print” menu option and select the “print preview”& “analysis Preview” function “On”, it could display the current waveform and diagnosis information. The doctor could diagnose and modify patient’s information in “analysis preview” interface. Pressing the “F4”key could “Edit” the selected diagnosis information.

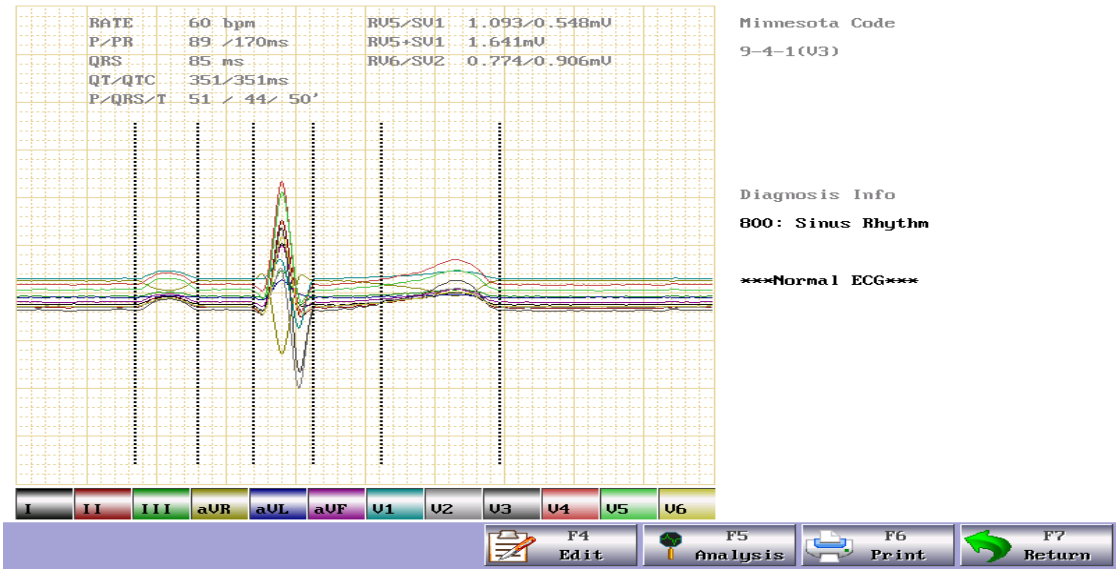

Figure 6-11 ECG Analysis Preview Interface

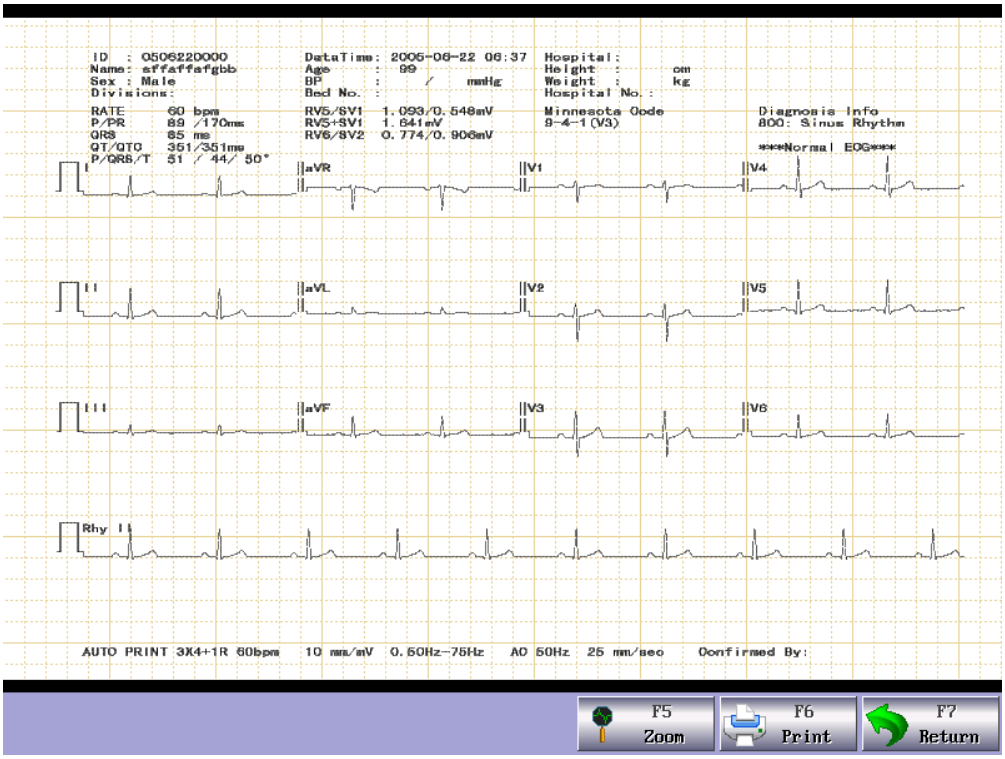

Figure 6-12 Print Preview Interface

Note

- **Set the "analysis preview"option as "on " and "save " option as "Save data " as well, and press the "F6 Print "after press preview interface poping up, then the current case could be saved.**

6.5 File Management

Press [F6] to enter the file management interface as below:

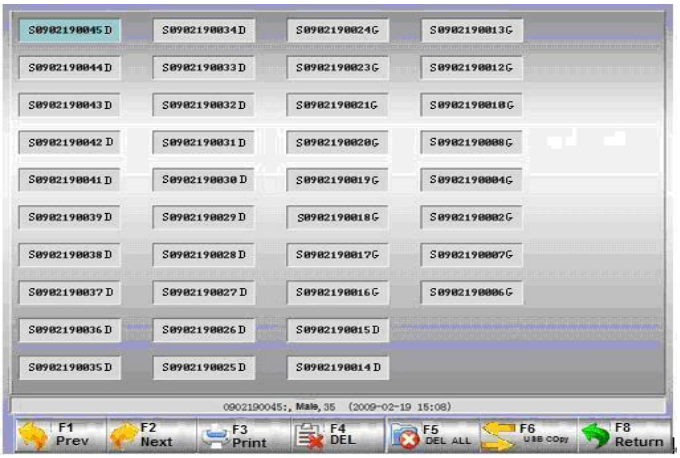

Figure 6-13 File Management Window

Press the “File” function key to enter the case file management window to record or delete the patient data. The file management window can store 300case data records. It will be a blank window in case of no data record.

6.5.1 What is the Case ID?

E.g.: S 090219 0045 D

1) S: the patient data is stored in the SD card (“F” for Flash memory);
2) 090219:the patient’s arrival date;
3) 0045: the 45th patient on that day;
4) D: the data was printed by the internal or external printer. “G” for data saved as an image file. Upload this type of files to a computer and all the information and waveforms of cases can be viewed on the computer.

⚠Note

- **Any data saved as an image file can not be printed by the internal or external printer. You can connect the ECG machine to the computer and upload this image file to the computer to print.**

6.5.2 How to View, Save, or Print the Data in the Form of Image?

1) Print: Select a case data record, press [F3] to pop up the dialogue box as below. Select Yes (F1) to print this data record or select No (F7) to cancel printing.

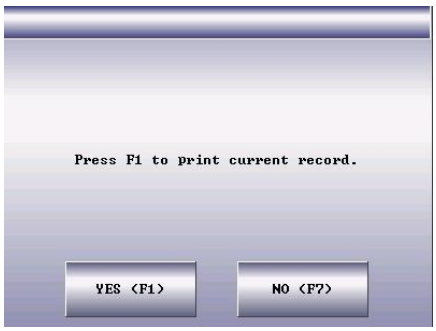

Figure 6-14 Printing dialog box

Select Yes (F1) to start printing. Enable “Print Preview” in the window “Print Options” to pop up the waveforms and patient information within the preview range.

⚠Note

- **Press [F3] to stop printing in recording.**

2) Delete: Select a case data record, press [F4] to pop up a dialogue box, and select Yes (F1) to delete this record or select No (F7) to cancel deleting.
3) Delete All: Press the delete function key to pop up a dialogue box and select Yes (F1) to delete all the case data records or select No (F7) to cancel deleting.
4) USB Copy: Press [F6] to pop up a dialogue box and select Back (F1) to copy all the case data records to the USB Flash Drive or select Restore (F7) to restore all the case data from the USB Flash Drive to the data management window of the ECG machine or select Cancel to cancel USB copy.

⚠Note

- **USB Connection is a standard function.**
- **You are recommended to use the USB Flash Drive supplied or designated by us, like Kingston, PNY, ADATA or Apacer, or it may fail to be recognized by the ECG machine or cause damage to reduce the performance and safety of the machine.**
- **Our ECG machine can only recognize the USB Flash Drive of FAT or FAT32 format. Please format it to FAT or FAT32 before using your USB Flash Drive. FAT and FAT32 are respectively available for the USB Flash Drive in a capacity of 0~2G and 2G~8G.**

6.5.3 Connection to the Computer

1) Use the network cable to connect the ECG machine to your computer.

Note

- **If the ECG machine is connected to your computer via a switch, please use the straight network cable; if it is directly connected to your computer, please use the cross network cable.**

2) Set the firewall of your computer: Start → Setup → Control Panel → Network Connection → Local Connection (or directly double click the local connection icon "  " at the bottom right corner of the desktop) → General (on the popup window "Local Connection Status") → Attributes → Advanced → Setup → Disable (on the window "Windows Firewall") → Save.

3) Set the TCP/IP address of your computer: Follow the above steps → Attributes → Internet Protocol (TCP/IP) (double click) → Advanced → Advanced TCP/IP Setup → IP Setup → IP Address → Add → input the IP address. If the remote address of the ECG machine is 192.168.2.40, please input the IP address 192.168.2.40 and subnet mask 250.250.250.0 on your computer as below:

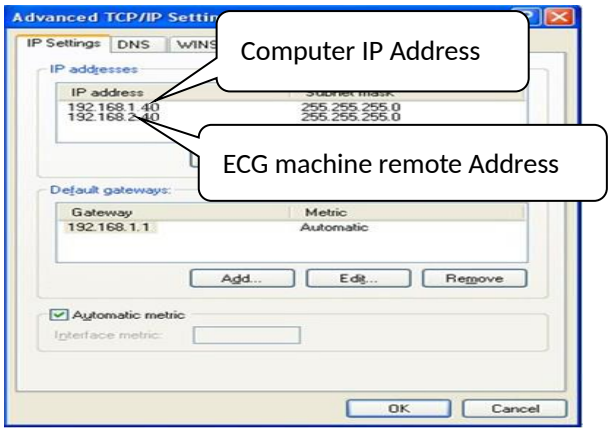

Figure 6-15 Computer IP Setup

Note

- **If your computer is connected to WAN or LAN, please set the IP address as shown in Fig. 5-18. Either IP number should not conflict with that of any other computer. If the ECG machine is connected to an off-line computer, they can share the same IP number. Follow the steps in above (3) → Internet Protocol (TCP/IP) → Use the IP Address Below (S) → input the remote IP number of the ECG machine.**

4) Set the FTP view protocol: Internet Explorer (double click, Fig. 6-16) → Tools → Internet Options → Advanced → Browse → uncheck "Use Passive FTP (Compatibility of the Firewall and DSL Modem)"→ check "Enable Folder View for FTP Websites" (Fig. 6-17 in red) → Save.

Figure 6-16 IE Browser

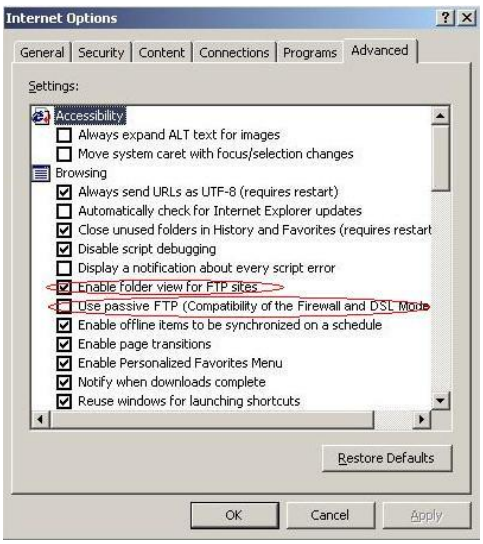

Figure 6-17 FTP protocol option

5) Double click “My Computer”, input ftp://root:comen@192.168.2.217 as the IP address, and press [Enter] to view the case data displayed on the window “File” of the ECG machine.

⚠Note

- **The IP number in ftp://root:comen@192.168.2.217 is the same as the local IP number of the ECG machine. If the local IP number of the ECG machine is 192.168.2.217, please input ftp://root:comen@192.168.2.217 as the IP address in “My Computer”.**
- **This IP number should not conflict with that of any other computer connected to LAN or WAN, or the system could be halted.**

6) Use the printer connected to your computer to print the case data saved as an image file: connect the ECG machine to your computer, select a case data and copy it to a new folder in another disk of the computer, and right click this image file to select “Open” or “Open With”→“ACDSee Viewer” or “Windows Image and Fax Viewer" →“Print”.

⚠Note

- **In this way you can only print the case data identified with ID+“G”.**
- **Please select “System Setup” → “Printer Selection” → “Picture” of the ECG machine.**

Suggestion:

You are suggested to use the ACDSee Viewer to print the image file so that you can set the width of the printed page more flexibly as shown in Fig. 6-18.

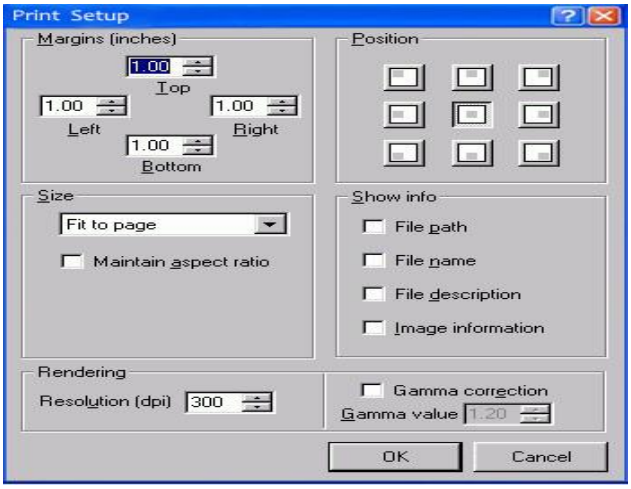

Figure 6-18 Print Setting in ACDSee Viewer

⚠ **Note**

- **To print the image file, the computer accesses the window "File Management" of the ECG machine and copies the image file to its own disk.**
- **The case data copied from the USB Flash Drive and the data from computer should be stored in two files with different file names, or there could be ID confusion, resulting in failure to be recognized by the ECG machine.**

6.6 Print ECG under Automatic Mode

Under the automatic working mode, the lead groups will be switched in order automatically in the recording of ECG, which means that when the ECG signal of one lead group has been recorded in the set period, it will be switched to the next lead group automatically and start to record the ECG signal of the next lead group. Before the recording of the ECG signal, 1mV calibration will be conducted automatically and marked on the record paper.

Specific Operation Methods:

1) Press "F7 Configuration" to enter setting window; press F1 or F2 to enter "Register" window to input patient's detailed information.
2) Press F1 or F2 to enter other setting windows to set other parameters according to the need, such as channel format, filters, wave gains, print speed, print text, average template, save options, paper style, print preview, analysis preview and printer select and so on.
3) After fishing the settings, press "F7 Configuration" to return to waveform area
4) Press the F1 key to select the automatic print and then press the F5 key to start printing. Here, below the working model on the above of the screen and the battery display following items will

be displayed: sampling, analyzing and processing, then the printing will start. Turn on the “Print Preview” in the “Print Options” window and the related visible ECG and patient information to be printed will pop up after pressing F5.The doctors can modify the diagnosis results if they judge that the diagnosis information doesn’t confirm to actual clinic situation according to their clinic experience. Choose the “diagnosis information” needs to be modified and press F4 to edit.

⚠Note

- **This equipment is detecting equipment instead of diagnosis equipment, and it is only responsible for those indicators regulated by relevant national standards. The diagnosis information selected and printed by doctors, the adjunctive and optional software function of this equipment can only be the reference for diagnosis use. The doctor should sign after diagnosis and confirmation according to actual ECG waveform. The doctor should be responsible for printed reports.**

6.7 Rhythm Mode

Under the rhythm mode, the user can select the rhythm lead according to the need and record the rhythm waveform of the lead.

1) Press F7 key to enter the “Configuration” interface, press F1 or F2 to enter “Register” window and input detailed information of the patient.
2) Press F7 key to enter the “Configuration” interface, press F1 or F2 to enter “Lead” window and select the rhythm type: 1 channel or 3 channel. 1 channel mode just displays one rhythm lead and 3 channel mode can select three rhythm leads. The red waveform is the waveform of the rhythm lead.
3) When the 1 channel rhythm is selected, enter the rhythm lead 1 to select the rhythm waveform;
4) When the 3 channel rhythm is selected, enter the rhythm lead 1, rhythm lead 2, rhythm lead 3 to select the rhythm lead;
5) Set other parameters as you need and when the setting finishes, press F7 to exit the “Configuration” setting menu;
6) Press F2 to select rhythm mode, the red waveform represents rhythm lead.
7) Press the F2 key to select the rhythm print, then press the F5 key to start to print, “Sampling” will appear in the message prompt area.
8) You can press the START/STOP or F5 key to stop in the recording process if necessary.

6.8 Manual Mode

Under the manual working mode, the user can select the lead group to record the ECG according to the need. When the user needs to record the ECG signal of another lead group, it needs to be switched manually.

Under the manual working mode, the user can select the “Channel Format” according to the need and set the record parameters or other parameters according to different channel modes.

Specific Operation Methods:

1) Press F7 key to enter the “Configuration” interface, press F1 or F2 to enter “Register” window and input detailed information of the patient.
2) Press F7 key to enter the “Configuration” interface, press F1 or F2 to select other configuration window to set the parameters such as channel format, filters options, print speed and so on.
3) Set other parameters according to your need, when the setting finishes press F7 to exit the configuration window and return to the waveform area;
4) Press the “F3 Manual” key to select the “Manual” print, then press the “F5 Print” key to print. At this time, below the working model on the above of the screen and the battery display prompt information will display, like sampling and printing.
5) You can press the START/STOP or F5 key to stop in the recording process if necessary.

6.9 ECG Report

1) Automatic print ECG report

Automatic print: take the ECG records of 6×2 channel mode and 6×2+1R average templates as an example, which is composed of part (a) and part (b):

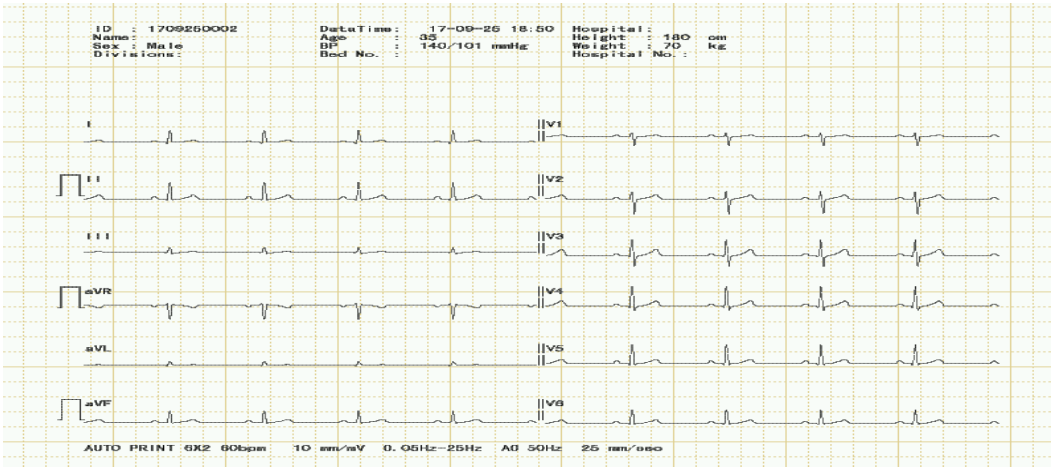

Figure 6-19(a) Automatic Print Channel Mode 6×2

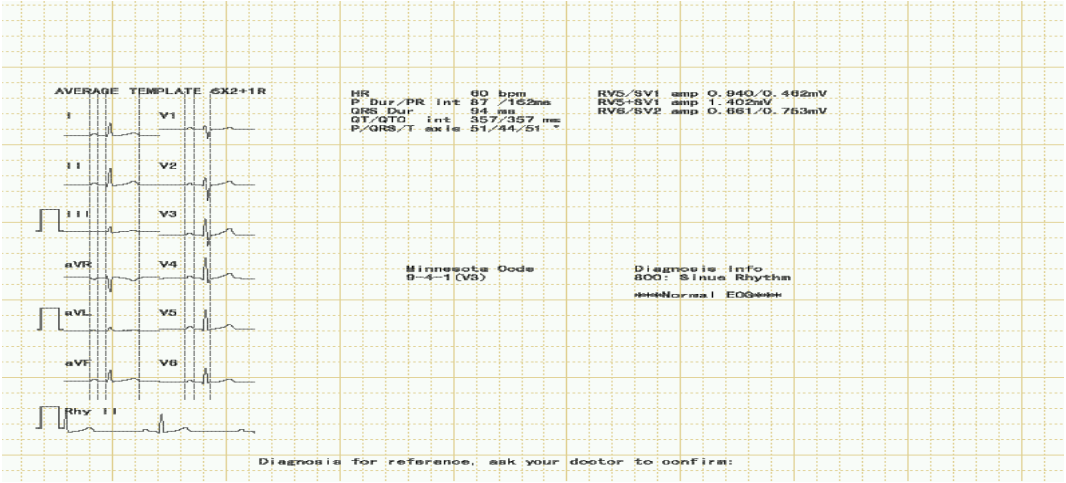

Figure 6-19(b) Automatic Print Average Template 6×2+1R

The contents of figures (a), (b) include:

- ID: Patient ID
- Name: Patient's Name
- Height: Patient's Height)
- Time: Current Date, Current Time)
- Sex: Male (Patient's Sex)
- Weight: 70 kg (Patient's Weight)
- Age: 35 (Patient's Age)
- Blood Pressure: (Patient's Diastolic Pressure as High Pressure)
- Hospital Name: (Hospital Name)
- Doctor: (Doctor's Name)
- Heart Rate: 60 bpm (Heart Rate Value of the Patient)
-  (Calibration Signal of the 1mV)
- I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 (12 Standard Lead Mark Symbol and ECG)
- 0.05~25Hz (0.05Hz Baseline Drift Filter, 25Hz Lowpass Filter)
- AC (50Hz AC Filter)
- 25mm/s (Print Speed)
- 10mm/mV (Gain)
- Automatic Print: 6×2(Print Mode and Channel Mode)
- Average Templates 6×2+1R
- Template: The template is the average value of the sampling signal of 10 seconds of each lead; the dashed line in the template ECG is the mark of location.
- Measurement information includes:
  - Interval:
  - P Time Limit (Average Value of the Average Cardiac Beat P Wave Time Limits of Many

Leads)

- PR Interval (Average Value of the Average Cardiac Beat PR Intervals of Many Leads);
- QRS Time Limit (Average Value of the Average Cardiac Beat QRS Wave Time Limits of Many Leads);
- QT/QTC Interval (Average Value of the Average Cardiac Beat QT Intervals of Many Leads/Normalized QT Intervals);
- Electric Axis:
- P/QRS/T Electric Axis (ECG Axis is the Main Direction of the Average Synthetic Vector on the Frontal Plane);
- Amplitude:
- RV5/SV1 Amplitude (Maximum Amplitude in the Average Cardiac Beat R and R' Waves of the Lead V5/Maximum Amplitude Absolute Value in the Average Cardiac Beat S and S' Waves of Lead V1);
- RV5+SV1Amplitude (Sum of RV5 and SV1);
- RV6/SV2 Amplitude (Maximum Amplitude in the Average Cardiac Beat R and R' Waves of the Lead V6/Maximum Amplitude Absolute Value in the Average Cardiac Beat S and S' Waves of Lead V2);

◆ Minnesota Code: The code of various diagnosis and diagnostic basis

◆ Diagnosis Information: The diagnosis information shows the results of the automatic diagnosis.

◆ Confirmed By: Doctors sign here after confirmation

2) Manual print ECG report

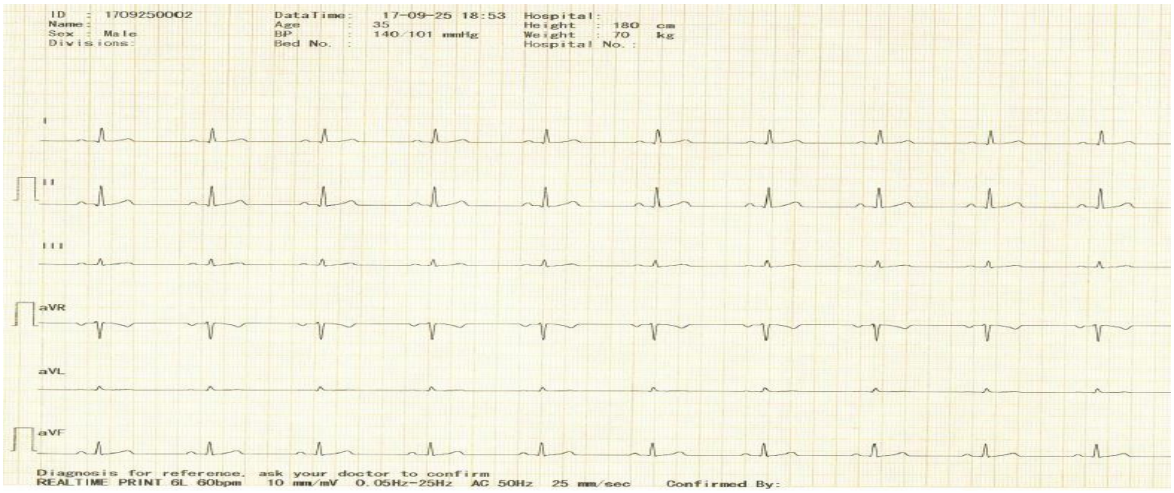

Figure 6-20 Channel Mode 6×2 Manual Print

6.10 Calibration of the LCD Screen

The LCD screen of the CM1200A equipment has the function of touch. Therefore, if an insensitive phenomenon appears on the touch screen of the CM1200A equipment, it can be calibrated to repair well. The procedures are as follows:

1. Press the “F7 Configuration” key to enter the setting window, and then select the “System” Options menu;
2. Press the “F6” key in the “System” Options menu, then a “small red dot” and “press here” message appear;
3. Click the “small red dot” with forefinger gently to calibrate, after the calibration the “OK” pops up;
4. Then another “small red dot” and “press here” pop up on the top right corner of the screen and click the “small red dot” with forefinger gently to calibrate, after the calibration the screen will return to the previous menu automatically.

6.11 Switch Off

When the built-in battery is used, after the examination, press the power switch to switch off.

When the AC power supply is used, after the examination, press the power switch to switch off; pull out the plug.

Chapter 7 Cleaning, Disinfection and Maintenance

7.1 Cleaning

⚠Caution

- **Before the cleaning, the power of the equipment should be cut off, if AC power supply is connected, it should be cut off and the power cable and patient cable should be removed.**

1) Cleaning of the Main Unit and Patient Cable:

Soak the soft and clean lint free cloth in mild soapsuds or in the non-corrosive washing solution after dilution, wipe the surface of the electrocardiograph and patient cable and use the clean and dry soft cloth to clean.

2) Cleaning of the Electrodes:

After the using of electrodes, erase the conductive ointment with the clean soft cloth; disconnect the suction bulb and metal cup of the chest electrode and the electrode plate and the clamp, wash them with clean warm water (lower than 35℃) and make sure that there is no residual conductive ointment; natural drying or clean with clean and dry soft cloth.

3) Cleaning of the Print Head:

Dirty and soiled thermosensitive print head will affect the definition of the record; therefore the user should clean the surface of the print head periodically (at least once a month):

Open the recorder casing and remove the paper. Wipe the print head gently with a clean soft cloth damped in a little75% alcohol. For the stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth; after natural drying, load the record paper and shut the casing of the recorder.

⚠ Caution

- **Prevent the detergent from infiltrating into the electrocardiograph while cleaning; do not immerse the equipment or its accessories into liquid in any case.**
- **It is prohibited to clean the equipment with abrasive material and avoid the scratching of the electrodes.**
- **Avoid any residual detergent on the surface of the equipment and patient cable after cleaning.**

7.2 Disinfection

In order to avoid permanent damage to the equipment, we suggest you should only perform the disinfection when it has been considered as necessary according to the regulations of your hospital; we also suggest that you clean the product first before disinfection.

⚠ **Caution**

- **Do not use high temperature, autoclaving or ionizing radiation methods to conduct disinfection.**
- **Do not use chloric disinfectants such as bleaching powder, sodium hypochlorite and so on.**

7.3 Daily Care and Maintenance

7.3.1 Capacity, Recharge and Replacement of the Battery

⚠**Warning**

- **Improper operation may cause the battery to be hot, ignited or exploded or it may lead to the declination of the battery's capacity. It is necessary to read the user manual carefully and the warnings and cautions before using of the rechargeable lithium battery (here in after called Battery).**

1) Battery Capacity identification:

Current capacity of the rechargeable battery can be identified according to the battery symbol in the top right corner on the LCD screen:

For 1200A:

 : Full capacity

 : The capacity is low and recharge should be taken into account.

 : Capacity is critically too low, it should be recharged immediately; and now "Low Capacity" will be displayed in the prompt information area.

 : Absence or damage of the battery.

2) Recharge:

This electrocardiograph is equipped with built-in rechargeable lithium battery and its recharge control circuit. For the power loss in the storage and transportation, for the initial use the capacity of the lithium battery may be inadequate and the battery should be recharged first before using.

When connect with the AC power supply, the rechargeable lithium battery can be recharged. And then

the AC indicator lamp (~) and battery recharge indicator lamp () will be light at the same time which shows that the battery is recharging. When the capacity of the battery is full, the battery recharged indicator lamp () will off.

3) Replacement:

When the service life of the battery is over, or there is peculiar smell, liquid leakage, contact with the local maintenance engineer or the manufacturer immediately to replace the battery.

⚠Warning

- **Only authorized installation or maintenance engineer can open the battery compartment and replace the battery; and the rechargeable lithium battery of the same typeprovided by Comen Company should be used.**
- **Do not reverse the anode and cathode when connecting the battery, otherwise explosion may be caused.**
- **The waste battery should be sent back to Comen Company or dealt with according to the local regulations.**

7.3.2 Recorder and Record Paper

⚠Note

- **The record paper provided by the manufacturer should be used, other wise the life of the thermosensitive print head will be shortened and problems such as fuzzy record waveform or unsmooth paper driving may appear.**

For the storage of the record paper please pay attention to the requirements as follows:

- ♦ The record paper should be placed in the dry and cool place and protected from high temperature, dampness and direct sunlight;
- ♦ It should avoid to be placed under the fluorescent light for long time;
- ♦ There should be no polyvinyl chloride plastic in the storage place of the record paper, otherwise the color of the record paper will change;
- ♦ Do not lap over the record paper with waveforms for long time, otherwise the waveforms may be transfer printed to each other.

7.3.3 Maintenance of the Main Unit, Lead and Electrode

⚠ Caution

- **Safety tests should be conducted periodically for the equipment, the test period is at least once a year and the test mainly includes:**
  - **a) Check whether there is mechanical and functional damage of the main unit and accessories.**
  - **b) Check whether there is damage of the safety mark;**
  - **c) Validate the functions of the equipment as described in the instructions of use;**

Main Unit:

- The main unit of the electrocardiograph should be protected from high temperature, isolation, damp, dust or impact and the dust shied should be covered well if the equipment is not used; when moving the intense vibration should be avoided;
- Liquid should be protected from entering the equipment which may affect the performance and safety of the equipment;
- The performance of the electrocardiograph should be tested periodically by the medical Instruments maintenance department.

Lead:

- The integrality of the patient cable and lead wire should be examined periodically and confirm the conduct situation is well;
- The lead wires should be aligned to avoid knotting and blending of small angle;
- The core wire or shielding layer are easier to be damaged, especially the places near the plug of the two ends, do not pull or wrest forcibly when using, nip the plug parts with hand;
- The cables and leads should be coiled into a disk with larger diameter in storage or be hung, wresting or sharp angle folding should be avoided;
- If the cables and lead wires are found to be damaged or aging, new cable and lead wires should be replaced.

Electrode:

- After the using of the electrode, it should be cleaned and avoid the residual conductive gel;
- The suction bulb of the chest electrode should avoid the direct sunlight or being too hot;
- After long time of using and for the reasons of corrosion and so on, the surface of the electrode may be oxidized and the color will change, then new electrode should be replaced to obtain good ECG records.

 **Discarding of the Equipment and Accessories:**

Do not disposal the waste electric or electronic equipment and accessories as the unclassified civil waste. Collect it separately so as to reuse, disposal, recycle or recover safely and properly.

Chapter 8 Service Warranty

Manufacture Process and Materials:

Comen Company warrants the adopted materials and manufacture process comply with the requirements, under the normal using or maintenance state, if the report that the failure is proved to be caused by the manufacture process and materials has been received by Comen Company, Comen Company will maintain or replace the hardware products.

Software or Firmware:

For the software or firmware installed in the hardware, Comen Company will replace the software or firmware if the report that if the report that the failure is proved to be caused by the software or firmware failure, but Comen Company do not warrant there is no interruption or mistake in the using process of the hardware, software or firmware products.

Note: Comen **Company does not responsible for the freight charge or other charges under this warranty.**

Comen Company is not responsible for the direct, indirect or final damage and delay caused by the following situations:

- ✘ Assembly, extensions, readjustments of any parts;
- ✘ Modification and repair by unauthorized persons;
- ✘ The damage caused by the non-normal using under the improper using conditions
- ✘ The original serial no. label or manufacture mark has been replaced or removed
- ✘ Improper operation

⚠**Note**

- **At present, under users requests, Comen Company will conditionally provide circuit diagram, calibration methods and other information to help users maintain those intrument parts which are classified by Comen Company and can be maintained by usersthrough proper and qualified technicians**

Appendix I Accessories and Ordering Information

When using this electrocardiograph, following accessories acre recommended by the manufacturer to use:

⚠Warning

- **The ECG cables and other accessories provided Comen Company must be used, accessories of other types may damage the equipment and affect the performance and safety of the equipment.**

No.	PN.	Model	Type	Name
1	040-000688-00	TD-15PK-J/IEC10/Q	Banana	12-lead; IEC Standard;Φ4.0
2	040-000151-00	TD-15PK-B/IEC10/Q	Banana	12-lead; IEC Standard;Φ3.0
3	040-000682-00	TD-15Pk-J/AHA10/Q	Banana	12-lead; AHA Standard;Φ4.0
4	040-000683-00	TD-15Pk-I/O/AHA10/Q	Banana	12-lead; AHA Standard;Φ3.0
5	040-000466-00	P26-ST30-21/GI6+2	/	Chest Electrodes
6	040-000098-00	B23-B30-17/GN6+2	/	Chest Electrodes
7	040-000465-00	P28-H30/40-21/GN6+2	/	Suction chest electrodes/child
8	040-000227-00	G32-G40-24/BL6	/	Adult suction chest electrodes
9	040-000143-00	B30-(RY)-GND/1*4	/	Limb clamp electrodes
10	040-000099-00	D40-89*4/ IEC4	/	Limb clamp electrodes/child
11	040-000228-00	C40-140*4/ IEC4	/	Limb Clamp Electrodes/Adult
12	040-000464-00	B30/40-115×2+142×2/IEC4	/	Clamp Electrodes

Appendix II Accessory Service Life

Testing and maintenance items	Frequency
ECG lead	It is recommended to replace once every two years.
Electrode clamp	It is recommended to replace once a year.

Appendix III Prompt Information

Prompt information appears in the using of this electrocardiograph is as shown in the following table:

Prompt Information	**Causes**
LEAD OFF	Electrodes fall off from the patient or the patient cable falls off from the unit.
Low Battery	The built-in battery is low battery.
Sampling/Printing	ECG signal is being sampled/ printed.
Copy	The ECG data is ready to be recalled.
Process	The ECG data is being processed.
Mem Full	No more patient cases can be saved in “RECALL” interface.
Paper？	There is no paper loaded or it is used up.
USB printer?	The USB printer is not connected or is not connected properly.
USB Printer Paper?	There is no paper loaded in the USB printer or it is used up.
Printer close	The “Printer Select” is set as “Close”.
Overload	The electrodes are not connected correctly.

Appendix IV Technical Specifications

Safety Standards	MDD93/42/EEC	Medical Device Directive
	IEC60601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
	IEC 60601-2-25	Medical Electrical Equipment-Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
	ANSI/AAMI EC-11	Diagnostic ECG Record Device

Classification	Anti-electric-shock type:	Class I, with internal power supply
	Anti-electric-shock degree:	CF type, with defibrillation proof function
	Degree of protecting against harmful ingress of liquid:	Ordinary equipment, without the ability of water proof
	Safely degree in the presence of flammable gas :	It is not suitable to use in the presence of flammable gas.
	Working Mode:	Continuous Operation
	Electromagnetic Compatibility :	Group I Class A

Size	CM 1200A:410mm×316mm×135.8mm
Weight	CM 1200A: about 5.2kg
Display	(8.4inch screen) 800 × 600 Color LCD Display

Work Environment	Temperature	5℃~40℃
	Relative Humidity	≤93%
	Atmospheric Pressure	700hPa ～1060hPa

Transport:	Must avoid severe shock ,vibration, rain and snow during transport
Storage	Packed electrocardiographs must be stored in well ventilated rooms with -20℃～+60 ℃ temperature, relative humidity no more than 93%, and without corrosive gases

Power Supply	AC Power Supply	Rated Voltage＝100-240V ～
		Rated Frequency＝50Hz/60Hz
		Rated Power＝95VA

	DC Power Supply (Built-in Rechargeable Lithium Battery)	Rated Capacity:4400mAh
		Rated Voltage:11.1V
		Discharging Final Voltage ≥11V
		Recharge Mode: Constant Current/ Constant Voltage
		Recharge Current (Standard)＝$0.2C_5A$ (320mA)
		Recharge Voltage(Standard)＝(16.8±0.1V)
		Cycle Life ≥300 times
	Power Consumption	95VA(Maximum)

Recorder	Record Mode	Thermosensitive Dot-Matrix Record
	Specifications of the Record Paper	Rolled Thermosensitive Record Paper/ Folded Thermosensitive Record Paper
	Width of the Record Paper	216mm/210mm
	Effective Record Width	200mm/195mm
	Paper Driving Speed	5 mm/s, 10 mm/s, 12.5 mm/s, 25mm/s, 50mm/s（±2%）
	Accuracy of Record	±5%(X axis), ±5% (Y axis)

Calculation of the Heart Rate	Calculation Method	Peak Value Test
	Range of the Heart Rate	30bpm~300bpm
	Calculation Accuracy	±1% or ±1 bpm (whichever is greater)

ECG Main Unit	Input Mode	Floating ground, defibrillation protection and pacing pulse inhibition
	Lead	Standard 12 leads sample synchronously.
	Sampling Mode	Sequential sampling of each group, simultaneous sampling of each group.
	Rhythm Lead Mode	1 channel and 3 channel for choice, 12 leads can be selected for each channel.
	A/D Switching	No less than 12 bits
	Measurement Range	>±5mV

	Time Constant	≥5s
	Baseline Control	Adjust automatically
	Frequency Response	0.05Hz ~ 150Hz($^{+0.4dB}_{-3.0dB}$)
	Gain	AGC(auto), 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 20/10 mm/mV, 10/5mm/mV, totally seven options, AGC(auto) is defaulted as10 mm/mV, the error is ±2%.
	Input Impedance	≥50MΩ.
	Input Circuit Current	≤50nA
	Stand Voltage	±650mV±5%
	Calibration Voltage	1mV±1%
	Noise Level	≤15 μ Vp-p
	Interference between Channels	≤0.5mm
	Patient Leakage Current	<10 μ A (100V～240V 50Hz/60Hz)
	Patient Auxiliary Leakage Current	<0.1 μ A (DC)
	Dielectric strength	4000V rms
	Filter:	AC Filter:50Hz/60Hz/Off
		Drift Filter: 0.05Hz/0.10Hz/0.20Hz/0.50Hz
		EMG Filter: 25Hz/35Hz/45Hz/Off
		Lowpass Filter: 75Hz/100Hz/150Hz/Off
	CMRR	≥105dB
	Baseline stability	When the supply voltage is stable: baseline drift shall not be more than 1mm; When the supply voltage waves transiently: baseline drift shall not be more than 1mm; When sensitivity changes (no signal input), its displacement does not exceed 2mm; When temperature drift is in the 5 ℃ ~ 40 ℃, the baseline drift should not exceed 0.5mm/℃

	50Hz / 60Hz interference suppression filter	≥20db
	Accuracy of input signal reconstruction	System error: ± 5% or ± 40μV, both take the maximum. The frequency response of the system is determined according to the method A and method D or method A, method B and method C used in EC11.
	Reproduction of calibration voltage	Add an external step voltage (rise time is not more than 5ms, and amplitude is 1mV ± 0.01mV) to Lead I, II and V1 ~ V6, and record the waveform according to IEC 60601-2-25. Error of the reproduced calibration voltage error is within 5%.

External Input and Output (Optional)	Single End Input	≥100 kΩ; Sensitivity10mm/V±5%
	Single End Output	≤100 Ω; Sensitivity 1V/mV/ 0.5 V/mV±5%

Appendix V EMC

Note

- **The electrocardiograph CM1200A complies with the applicable EMC requirements in IEC60601-1-2.**
- **CM1200A meets the requirement of Group I Class A in CISPR 11/EN 55011.**
- **Please follow the EMC instructions in the User's Manual to install and use the Electrocardiograph.**
- **Portable and mobile RF communication equipment may affect the performance of the electrocardiograph CM1200A. To protect the Electrocardiograph against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.**
- **Refer to the attached guide and manufacturer's statement.**

Warning

- **Do not stack this product on/under or get it close to any other equipment. If you have to use it this way, observe and verify whether it works properly in such condition first.**
- **Class-A equipment are intended to work in industrial environments. Considering this product's conduction disturbance and radiation disturbance, it may be difficult to ensure its EMC in non-industrial environments.**

Table 1

Guidance and manufacturer´s declaration - electromagnetic emission		
CM1200A Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of CM1200A Electrocardiograph should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	CM1200A 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.
RF emissions CISPR 11	Class A	CM1200A 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.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer´s declaration - electromagnetic immunity			
CM1200A Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of CM1200A Electrocardiograph should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tie. 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 ± 1 kV for input/ output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/ output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° >95 % U_T; 1 cycle and 30 % U_T; 25/30 cycles Single phase: at 0° 95 % U_T; 250/300 cycles	>95 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° >95 % U_T; 1 cycle and 30 % U_T; 25/30 cycles Single phase: at 0° 95 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CM1200A Electrocardiograph requires continued operation during power mains interruptions, it is recommended that the CM1200A Electrocardiograph be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">CM1200A Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of CM1200A Electrocardiograph should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V RMS
0.15 MHz to 80 MHz
6 V RMS in ISM and between 0.15 MHz and 80 MHz</td><td>3 V RMS
0.15 MHz to 80 MHz
6 V RMS in ISM and between 0.15 MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of CM1200A Electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ 150 KHz to 80 MHz
$d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m
80 MHz to 2.7 GHz</td><td>3V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

a	Field strengths from fixed RF 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 CM1200A Electrocardiograph is used exceeds the applicable RF compliance level above, CM1200A Electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating CM1200A Electrocardiograph.
b	Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and CM1200A Electrocardiograph			
CM1200A Electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of CM1200A Electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and CM1200A Electrocardiograph, as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	0.15 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For 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.			

Table 5

declaration - IMMUNITY to proximity fields from RF wireless communications equipment
CM1200 Electrocardiograph is intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.

Immunity test	IEC60601 test level				Compliance level	Electromagnetic environment - guidance
	Test frequency	Modulation	Maximum power	Immunity level		
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m	
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m	
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m	
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.						

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