



CardioShield[®] PC-ECG System

Operation and Technical Instruction

**(CS-180/CS-181/CS-182/CS-183
CS-280/CS-281/CS-282/CS-283)**

Suzhou Beneware Medical Equipment Co., Ltd.

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The logo for Beneware, featuring the word "BENEWARE" in a bold, blue, sans-serif font. The letters "E" and "A" are stylized with a blue ECG waveform line passing through them.

Modification History

Date	Version	Remarks
September 2011	1.0	Basic version
February 2014	2.0	Upgrade version

Declaration

Thanks for choosing our product. Please read carefully the Operation Instruction before use and observe the safety requirements.

The Instruction is for your reference for the product operation and maintenance. Users should follow strictly the instruction. Where losses are caused by improper installation or operation, Suzhou Beneware Medical Equipment Co., Ltd. will assume no legal responsibilities.

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Product Information

Product name: PC-ECG

Product model: CS-180/CS-181/CS-182/CS-183

CS-280/CS-281/CS-282/CS-283

Manufacturer Responsibility

Only under the following circumstances will Suzhou Beneware Medical Equipment Co., Ltd. be responsible for the safety, reliability and performance of the product: the installation, extension, re-adjustment, improvement and maintenance are

performed by personnel approved by Suzhou Beneware Medical Equipment Co., Ltd. and the electrical installation environment of the room meets national standards and the device is operated as per the Instruction.

Required by users, Suzhou Beneware Medical Equipment Co., Ltd. may charge to provide circuit diagram and other information to enable proper and qualified technicians to maintain the device part that can be maintained by users.

Contents

1 Introduction	1
1.1 Main features	1
1.2 Requirements of safety standards	2
1.3 Instrument symbols and explanation	2
1.4 Environmental requirement	3
2 Precautions	4
3 Structural Feature and Working Principle	6
3.1 Electrical schematic diagram and principle description	6
3.2 CS-28X structure and function	7
3.3 CS-18X structure and function	8
3.4 Description of indicator light	8
4 Operating Instruction	9
4.1 Ward acquisition mode	9
4.2 PC-ECG mode	11
4.3 Relevant setting	12
5 General Operation Procedure	15
5.1 Patient preparatory work	15
5.2 Start acquisition box	15
5.3 Connect electrodes and preview waveform	15
5.4 Start acquisition	15
5.5 Stop acquisition	15
5.6 Take off electrode from patient	15
5.7 Analyze and print data	15
5.8 Electrode connection reference	16
6 Daily Maintenance	17
6.1 Maintenance period	17
6.2 Maintenance measures	17
7 Common Fault and Troubleshooting	19
7.1 Exchange interference	19
7.2 Unstable base line	19
8 Guarantee	21
9 Technical Specifications	23
10 Accessory and List	24
11 After-Sales Service	25
Appendix 1 Electromagnetic Compatibility	26

1 Introduction

PC-ECG is a kind of medical product adopting computers for recording and tracing electrocardiograms, being able to trace regular electrocardiograms, to observe and store 12-lead ECG waveform in real time, and to edit and automatically measure the recorded ECG signals, to carry out waveform analysis, print reports, store data and conduct remote transmission.

The product is composed of host machine (ECG Acquisition Box), ECG lead wire, encryption lock and software disk. The model specifications of PC-ECG of CardioShield[®] series are as below:

Model	CS-180	CS-181	CS-182	CS-183	CS-280	CS-281	CS-282	CS-283
Performance								
Sample frequency(Hz)	10240	10240	4096	4096	10240	10240	4096	4096
Record frequency(Hz)	4096	2048	1024	1024	4096	2048	1024	1024
Resolution(bit)	24	24	24	16	24	24	24	16
Function								
Pace-making detection	Y	Y	Y	Y	Y	Y	Y	Y
Lead-off detection	Y	Y	Y	Y	Y	Y	Y	Y
Sickbed acquisition mode	N	N	N	N	Y	Y	Y	Y
Component								
Touch LCD	N	N	N	N	Y	Y	Y	Y
Lithium cell	N	N	N	N	Y	Y	Y	Y

1.1 Main features

1.1.1 Features of PC-ECG host machine

1. Extremely compact and portable; only 120g for non-LCD, and 168g for LCD; easy for placing and carrying;
2. High-definition LCD facilitating real-time ECG signals of all leads; no more misconnection of lead wires;
3. Optimized filter circuit design filtering the interference signals to the largest extent;
4. Individual pace-making signal detection channel, sample frequency of pace-making signal up to 10240Hz to accurately catch tiny change of signals;

5. Up to 24 digits A/D conversion accuracy, 4096Hz large data size non-compressed synchronous display;
6. Large data storage, up to 200 wards acquisition cases.

1.1.2 Features of analysis software of PC-ECG

1. Easy operation; ECG display interface similar to traditional paper; powerful functions significantly improving working efficiency of doctors;
2. Comprehensive digitization environment supporting paperless workflow;
3. Accessible to all history ECG records for continuous comparison of one patient;
4. Friendly user interface: the latest Ribbon style, quick response to user operation enabling users to rapidly locate the commonly-used functions; flexible interface configuration plan.

1.2 Requirements of safety standards

1. The security type of the product is type II, internal electric source CF-type application equipment.
2. The product is powered by lithium cell or USB.

1.3 Instrument symbols and explanation



CF type applied part



Special attention should be paid and refer to the Operation Instruction



Identification of USB interface



Equipment of type II



The product meets the applicable requirements of European Directive 93/43/EEC.



Serial Number

1.4 Environmental requirement

The environment test of the instrument meets the requirements of the climatic environment test group II and mechanical environment test group II of GB/T14710-93 *Environmental Requirements and Test Method of Medical Electrical Equipment*.

Environmental requirements for using, transporting and storing the instrument:

	Environment temperature	Environment humidity	Atmospheric pressure
Using process	5°C-40°C	< 80%	700hPa-1060hPa
Transportation process	-40°C-+50°C	<93%	560hPa-1060hPa
Storage process	-40°C-+40°C	<93%	560hPa-1060hPa

2 Precautions

⚠ The instrument can only be operated by qualified medical workers.

⚠ Read carefully the Instruction before operation to fully understand the correct operation methods.

⚠ The following measures should be taken when installing or storing the instrument:

a) The instrument is common equipment belonging to type II internal electric cell CF type application part, ready for continuous operation and shall not be used under flammable and combustible environment.

b) Please use lithium cell or USB for power supply and never use any other power supply.

⚠ The product can only work with the specialized cable supplied together with the instrument. Don't pull the ECG lead wire too hard when using the product. Clip-on limb electrode and suction bulb for body surface are supplied with the product. Please correctly link and locate as per the Instruction. Refer to relevant clinicians for the selection of electrodes of other types.

⚠ The PC-ECG can be directly applied to hearts and should be with suitable electrodes.

⚠ When clip-on limb electrode and suction bulb are in loose contact with patient or when the cable and electrodes and host machine are not connected properly, the product may be in non-normal working condition caused by overload or partial saturation of amplifier. At the moment, the indication of off lead may be given on the screen display or indicator light. The indication will disappear when the clip-on limb electrode and suction bulb are checked and correctly connected and the instrument will work normally.


⚠ Avoid interference from high electromagnetic field when using the product. Cell phone near the product may interfere with the ECG signal record. No high-voltage cable, X-ray machine, ultrasonic instrument and electrizer should be located surrounding the product.

⚠ Avoid contacting the instrument with water and avoid using and storing the instrument in places of extreme high air pressure, temperature and humidity exceeding common standards, poor ventilation, high content of dust, or containing sulfur-bearing and saline and alkaline air, or chemicals.

⚠ The product and its accessories should be disinfected with UV disinfection plant periodically.

⚠ Before operation, operators should ensure all components are working well. Special attention should be paid to the screen or the indicator light. Immediately turn off the machine for check when any accidents happen during the use.

⚠ Please don't arbitrarily discard the host machine and the accessories for scrap treatment. Strictly disinfect it and then hand over to qualified company or governmental departments for handling.

	<p>Warning</p>	<p>EXPLOSION HARZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS, OXYGEN, AND HYDROGEN AND COMBUSTIBLE CHEMICALS.</p>
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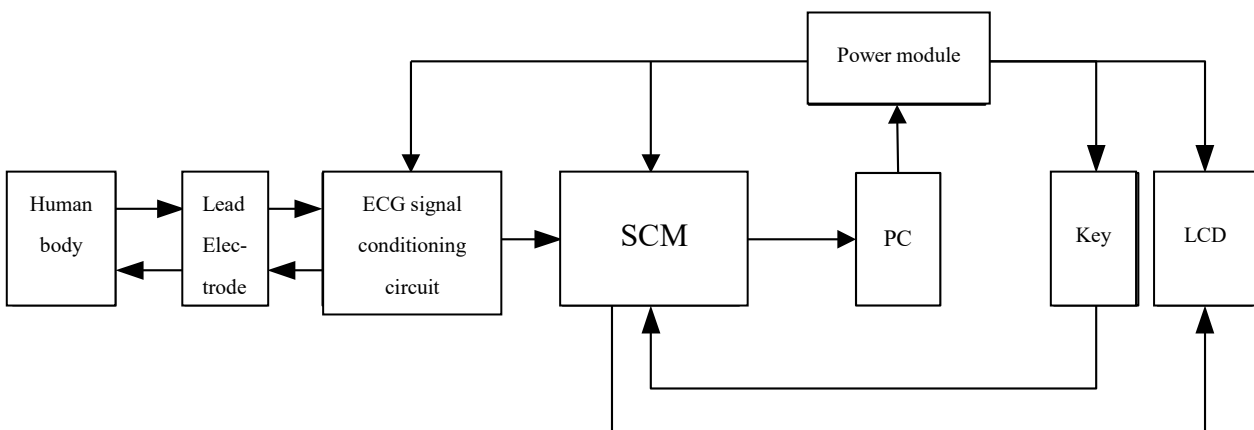
3 Structural Feature and Working Principle

3.1 Electrical schematic diagram and principle description

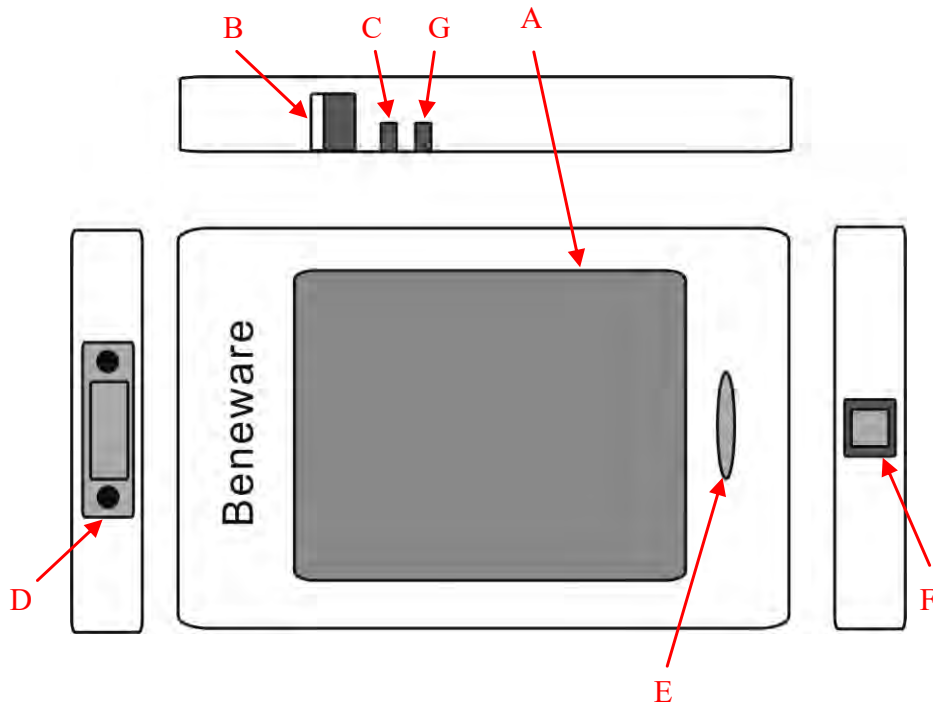
The Electrical schematic diagram and components list are only for qualified maintenance station or personnel approved by the company.

PC-ECG includes lead electrode, ECG signal conditioning circuit, SCM, LCD, keys and power module. Lead electrode is connected with the ECG signal processing circuit and the ECG signal processing circuit, LCD and keys are respectively connected to the SCM. PC supplies power for the power module which powers up the PC-ECG. The body surface ECG signals are transmitted through the lead electrode to the ECG signal conditioning circuit for amplifying and smoothing. SCM acquires the output signal of the ECG signal conditioning circuit, pre-treat them and then transmit to the PC. Through the LCD, users can check in real time the signal waveform and interact with the recorder through the keys. PC-ECG acquisition box is powered by lithium cell or USB. The power module stabilizes the voltage of the power supply and then supplies to the acquisition box.

Electrical schematic diagram is as below:

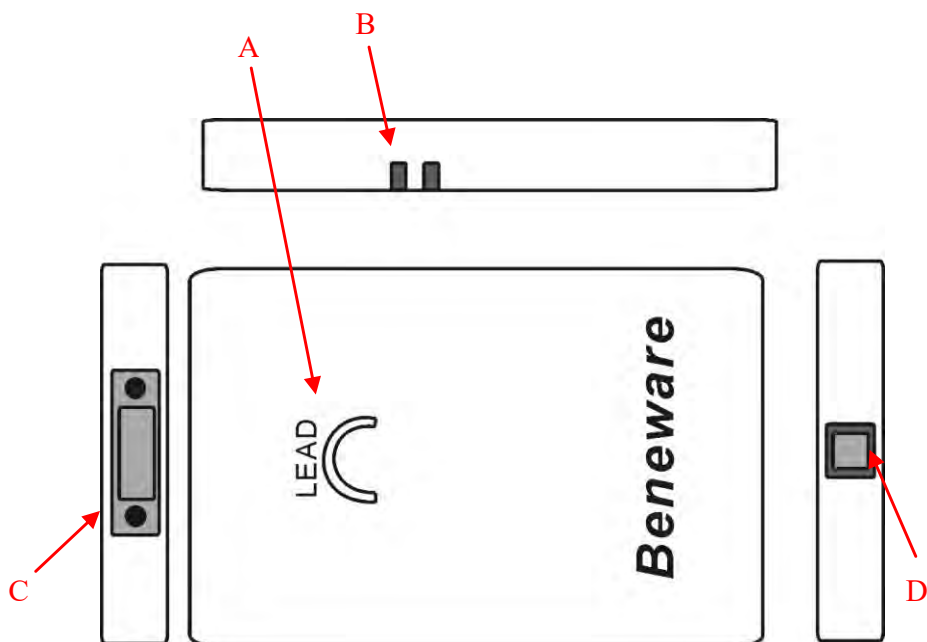


3.2 CS-28X structure and function



Mark No.	Name	Explanation
A	LCD area	User interactive interface for previewing signal waveform of designated channel, and showing information like working status of the device; function of touch key is supported
B	Toggle switch	Turn on and off the machine
C	POWER indicator light	Indicate whether the power is on and whether initialization is successful
D	Lead wire interface	Joint of the host machine and lead wire
E	Function keys	Control key mainly for switching display content
F	USB interface	Joint of the host machine and computer
G	CHARGE indicator light	Indicate the state of charge of the host machine

3.3 CS-18X structure and function



Mark No.	Name	Explanation
A	LEAD indicator light	Indicate the on or off of lead
B	POWER indicator light	Indicate whether the power is on and whether initialization is successful
C	Lead wire interface	Joint of the host machine and lead wire
D	USB interface	Joint of the host machine and computer

3.4 Description of indicator light

Indicator light	Phenomenon	Phenomenon explanation
POWER indicator light	Normally off	Fail to electrify the host machine
	Normally on	Electrify the host machine and successful initialization
LEAD indicator light	Green	All lead wires connect well
	Yellow	Poor connection of the lead of chest
	Red	Poor connection of the lead of limbs
CHARGE indicator light	Normally off	Not being charged
	Normally on	Being charged

4 Operating Instruction

The device supports two modes of operation: ward acquisition mode (only applicable for CS-28X series) and PC-ECG mode.

4.1 Ward acquisition mode

The mode is only applicable for CS-28X series PC-ECG with LCD.

4.1.1 Start up

Start the acquisition box through the toggle switch. After starting up, the acquisition box will carry out self-inspection of the device and initialization. During the initialization, company name, product name, model, serial number and version number and other information will be shown on the display as the Fig. 4.1 shows. After starting up, the device is of the main interface working condition as the Fig. 4.2 shows. Previewed waveforms on the main interface are red.

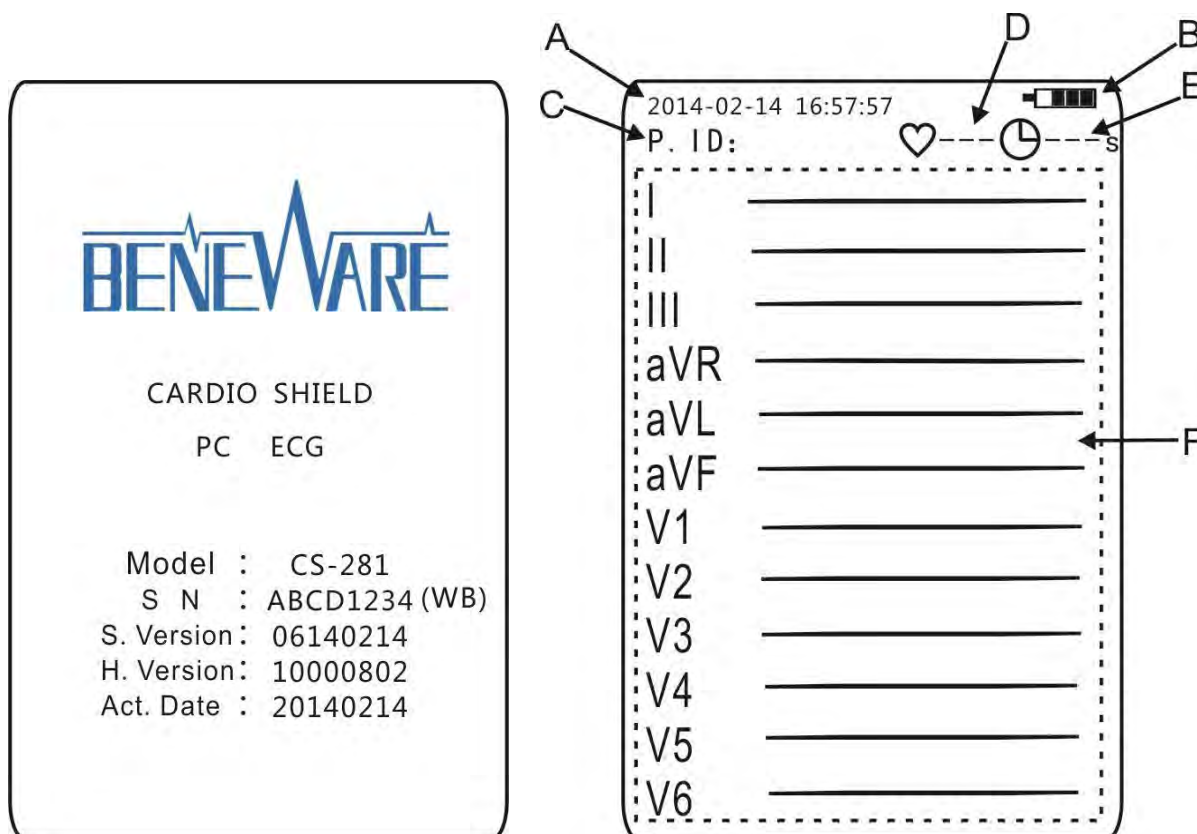


Fig.4.1

Fig.4.2

Marking number of the Fig. 4.2: A stands for the time display area; B is the electric quantity display area; C shows the name; D shows the heart rate; E shows the record time; F shows the real-time ECG waveform.

4.1.2 Start acquisition

Press the screen at any place for a short time to enter the interface of entering information as the Fig. 4.3 shows. After entering the information, press the “next” (or press the key) to go back to the main interface. Connect the lead wire and observe if the waveform is stable through the screen. After it becomes stable, press the key to start acquisition as the Fig. 4.4 shows. During the acquisition, the waveform color on the main interface will become green. Meanwhile, heart rate and acquisition time will be displayed on it.

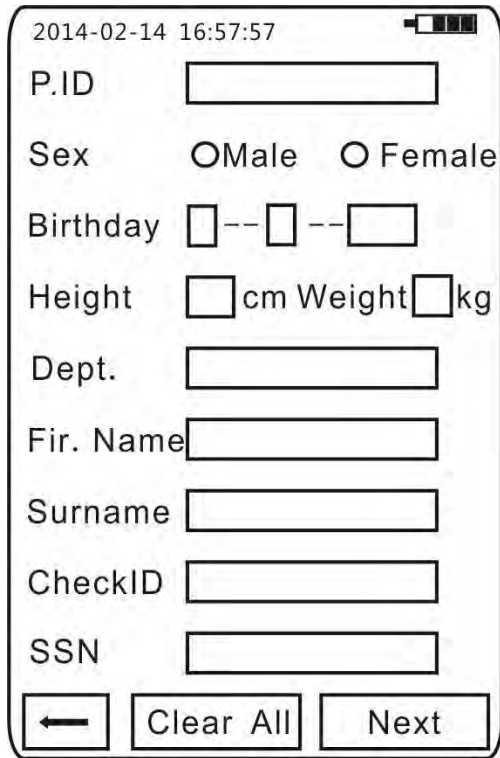


Fig.4.3

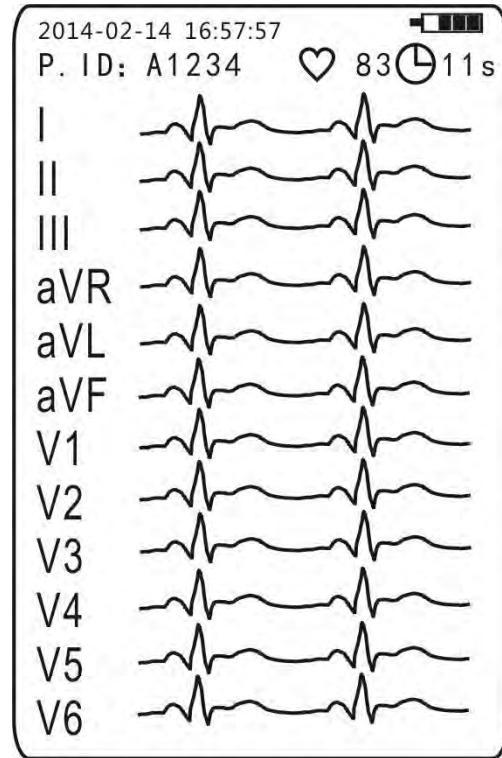


Fig.4.4

4.1.3 Stop acquisition

For manual acquisition, press the key to stop acquisition; for automatic acquisition, it will automatically stop acquisition when the preset time is reached. After acquisition, a prompt will come out as the Fig. 4.5 shows.

Click on the “Finish check” on the screen (or press the key for a short time) and it will remind you of the successful storage as the Fig. 4.6 shows. After acquisition, it will go back to the main interface and the entered patient information will be cleared.

Click the key of “Acquire one more” and it will indicate again successful storage. After it is returned to the main interface, the acquisition box will maintain the information of the current patient. Press the key to acquire other data.

Click the key of “Cancel” to cancel the present acquisition. After it is returned to the main interface, the acquisition box will maintain the information of the current patient. Press the key to re-acquire the data.

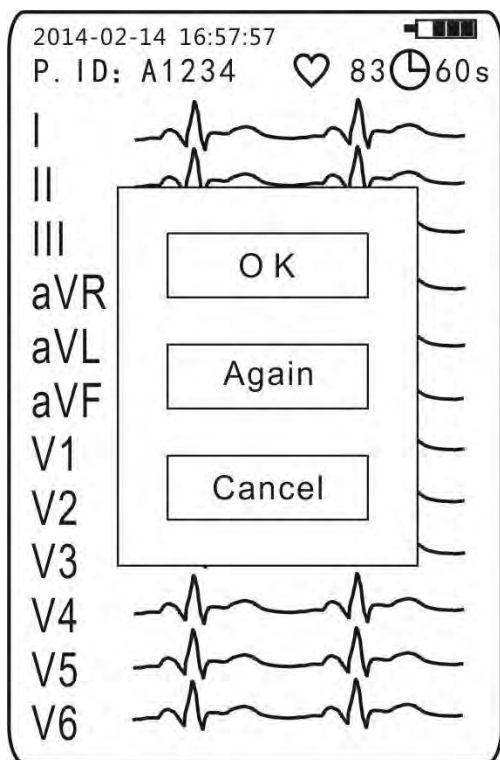


Fig.4.5



Fig.4.6

4.1.4 Shut down

Shut down the acquisition box through the toggle switch.

4.1.5 Simple list of acquisition box operation

Operation	Status of the acquisition box	Procedure
Start up	USB not connected	Switch the toggle switch to start up
Start acquisition	After starting up	Start acquisition through the key
Stop acquisition	Acquisition completed	Stop acquisition through the key
Shut down	After starting up or acquisition stop	Switch the toggle switch to shut down

4.2 PC-ECG mode

4.2.1 Start up

Connect the USB, the CS-18X series PC-ECG will automatically start up; while to start up the CS-28X series PC-ECG, toggle switch is needed; at the time the LCD will not display.

4.2.2 Start acquisition

Connect lead wire and start acquisition through bundled software.

4.2.3 Stop acquisition

Finish the acquisition and stop acquisition through bundled software.

4.2.4 Shut down

Disconnect the USB, the CS-18X series PC-ECG will automatically start up; while to shut down the CS-28X series PC-ECG, toggle switch is needed.

4.2.5 Simple list of acquisition box operation

Operation	Status of the acquisition box	Procedure
Start up	USB not connected	Connect the USB and switch the toggle switch to start up the machine (CS-28X)
Start acquisition	After starting up	Start acquisition through bundled software
Stop acquisition	Acquisition completed	Stop acquisition through bundled software
Shut down	After starting up or acquisition stop	Switch the toggle switch to shut down (CS-28X)

4.3 Relevant setting

Settings here are only for CS-28X series.

4.3.1 Main setting interface

On the main display interface, long press at place of the LCD to enter the main setting interface as the Fig. 4.7 shows. Click the key to enter the corresponding function or setting.

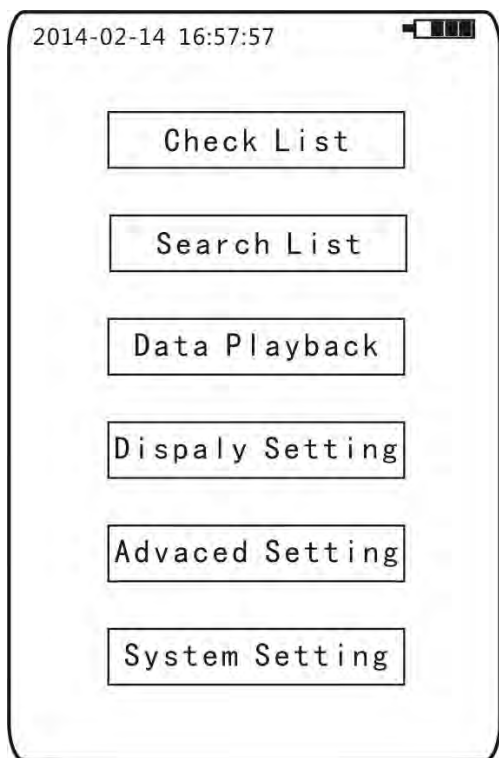


Fig.4.7



Fig.4.8

4.3.2 Data playback list

Click the “Data playback” on the main setting interface to enter the data playback list as the Fig. 4.8 shows. The list records all recorded data in the acquisition box. Click on specific data to playback the recorded patient information and ECG waveform.

4.3.3 Display setting

Click the “Display setting” on the main setting interface to enter the display setting interface as the Fig. 4.9 shows. Click “12×1”, “6×2”, “3×4”, “IP”, “V2” or “V5” to revise the waveform arrangement on the main display interface. The size of waveform on the main display interface and speed of data playback can also be set through the scaling setting and chart speed.

4.3.4 Advanced setting

Click the “Advanced setting” on the main setting interface to enter the advanced setting interface as the Fig. 4.10 shows. Complete automatic acquisition by setting “10s” or “20s”; it can also be set as “manual” and to stop acquisition through the keys. When “lead-off setting” is “on”, and when any lead is off, the corresponding channel will be drawn into a straight waveform to avoid interference of noise and interference signals.

4.3.5 System setting

Click the “System setting” on the main setting interface to enter the system setting interface as

the Fig. 4.11 shows. Change the current system language through the language setting. Click the “About the machine” to read the information of company name, product name, model, serial number and version number on the startup screen.

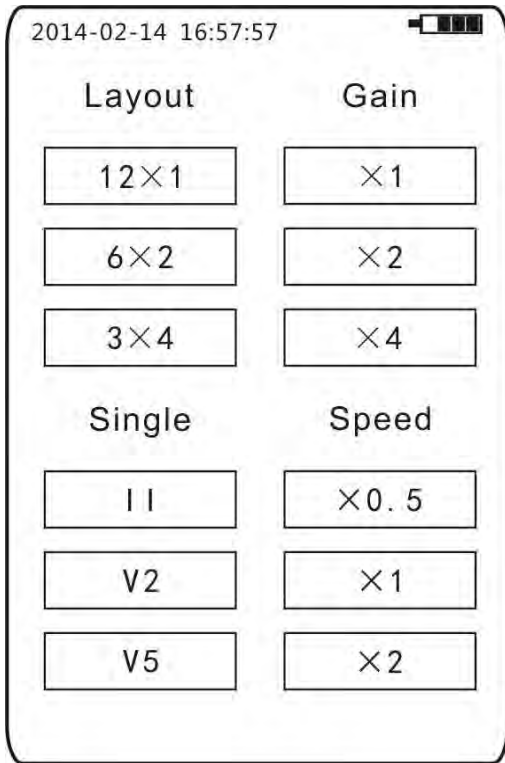


Fig.4.9

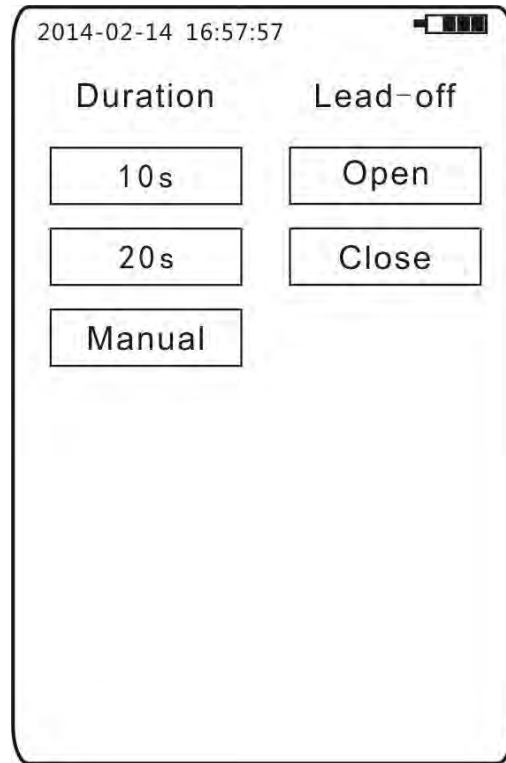


Fig.4.10

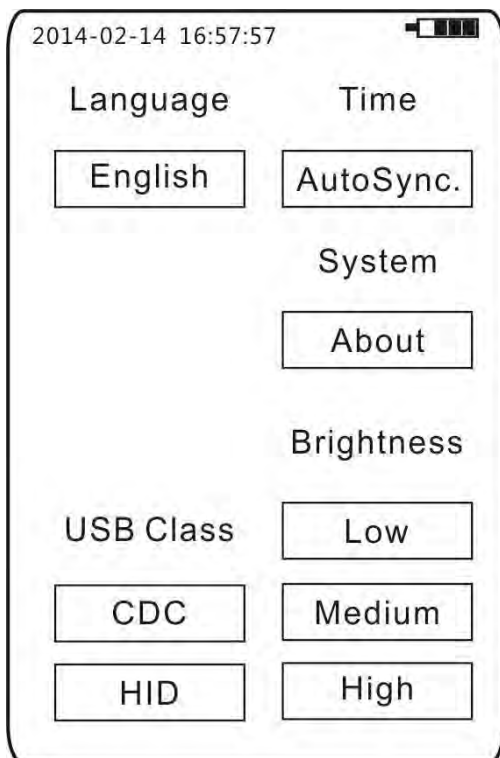


Fig.4.11

5 General Operation Procedure

5.1 Patient preparatory work

Clean the skin of the patient and fix the clip-on limb electrode and suction bulb.

5.2 Start acquisition box

Connect the USB and turn on the acquisition through the toggle switch (CS-28X).

5.3 Connect electrodes and preview waveform

Connect the lead wire of the acquisition box to the clip-on limb electrode and suction bulb on the patient and preview the signal waveform of various channels through the LCD or computer screen and ensure the well connection of the channels.

5.4 Start acquisition

Start acquisition through the key or bundled software.

5.5 Stop acquisition

After acquisition, stop acquisition through the key or bundled software.

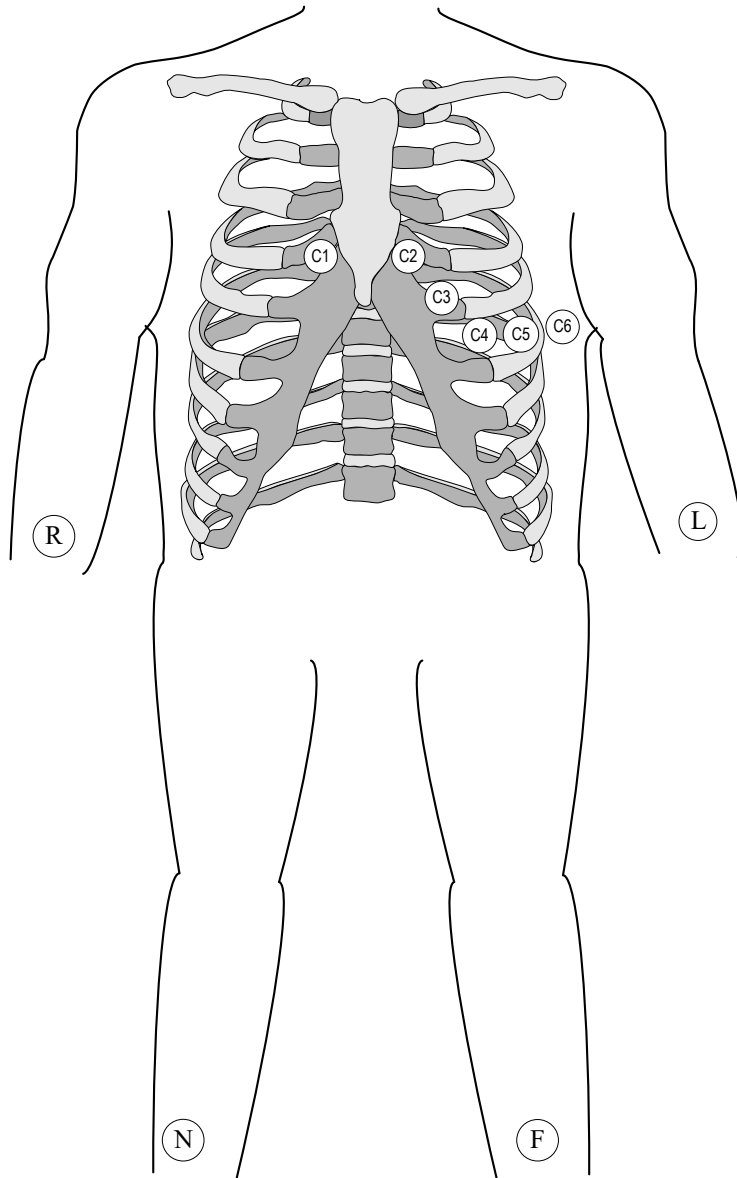
5.6 Take off electrode from patient

Take off the clip-on limb electrode and suction bulb from patient.

5.7 Analyze and print data

Complete through the bundled software.

5.8 Electrode connection reference



Identification	Color	Lead	Location
R	Red	Right hand	Right arm
L	Yellow	Left hand	Left arm
F	Green	Left leg	Left leg
N	Black	Right leg	Right leg
C1	Red	V1	4 th intercostals space at the right sternum
C2	Yellow	V2	4 th intercostals space at the left sternum
C3	Green	V3	Midpoint of the connecting line of C2 and C4
C4	Brown	V4	Joint of left mid-clavicular line and the 5 th intercostals space
C5	Black	V5	Level position of left rib front line C4
C6	Purple	V6	Level position of left rib center line C4

6 Daily Maintenance

6.1 Maintenance period

For the sake of the safety of operators and patients, comprehensive maintenance and safety check on the product once per season is suggested.

Note: lead wire of special parts should be cleaned at least once per month.

6.2 Maintenance measures

6.2.1 Precautions and maintenance for PC-ECG acquisition box

a) Periodically disinfect with UV disinfection equipment the parts of the device such as lead wires which frequently contact patients. The duration of disinfection should not be less than 20 minutes.

b) Periodically check the cable and its connection and replace immediately when there is any abrasion.

6.2.2 Precautions and maintenance for lead wire

a) Periodic check on the completeness of lead wire is required. Damage of any lead wire will cause virtual image of the corresponding lead on the electrocardiogram. Lead wires can be cleaned with water and soap and disinfected with 75% ethyl alcohol. (Immersing lead wire in liquid for disinfection is prohibited).

b) Bending or knot may shorten the service life of lead wire. Straighten out lead wire as far as possible during use.

c) Clip-on limb electrode and suction bulb should be kept well. After a long time use, out of corrosion, oxidation stain may appear on their surfaces which will affect the drawing. Clip-on limb electrode and suction bulb should be replaced at the time.

d) When cleaning the device, notice not to dip it into the detergent and prevent liquid penetrating into the device. The device should be powered off when the housing is cleaned. Don't use detergent and bactericide containing alcohol.

Note: lead wire, clip-on limb electrode and suction bulb for replacing must be the same type of the original one!

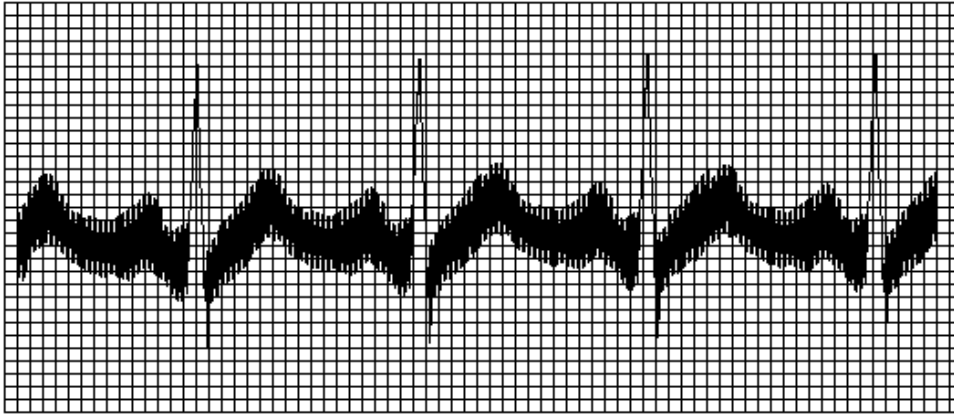
6.2.3 Precautions and maintenance for lithium cell

a) Since the battery will discharge automatically, it may be damaged for this when it is not used for a long period. Therefore, when the product is out of use for a long time (more than half a month), the battery must be charged and placed in dry and cool place to store the acquisition box. Meanwhile, periodically (half a month) charge the acquisition box to prevent the battery being damaged by over discharge.

b) Don't place the acquisition box under environment of high or low temperature: In summer, never place it under the sun or place it directly under air conditioner. During charge, caused by the backflow of battery, slight heating on the back of the acquisition box is normal.

c) Immediately contact the manufacturer for replacing the battery when there is a significant decrease of the battery electric quantity.

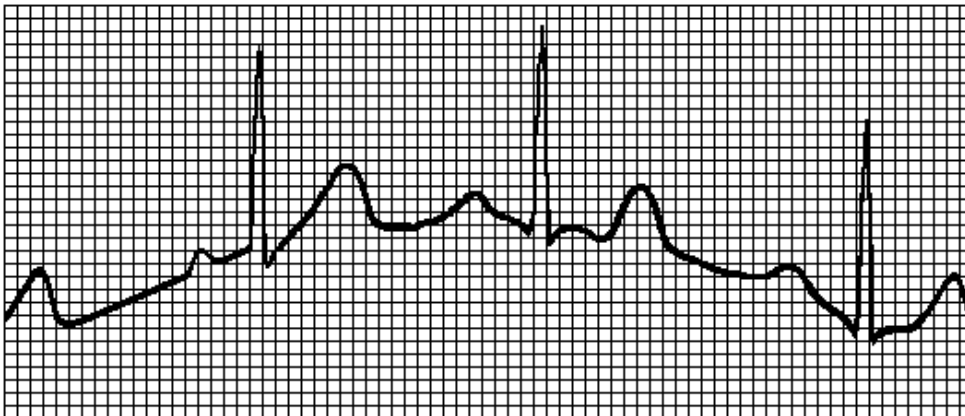
7 Common Fault and Troubleshooting



7.1 Exchange interference

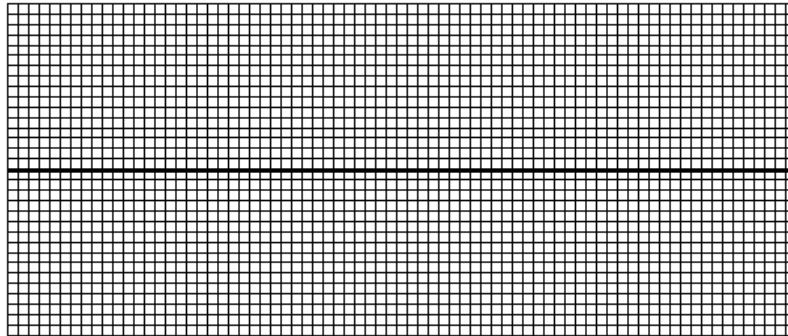
- ① If the clip-on limb electrode and suction bulb or lead wire are connected correctly?
- ② If the contact between the clip-on limb electrode and suction bulb and skin is well?
- ③ Any working electrical equipment of high power like X-ray machine or ultrasonic device around?

7.2 Unstable base line



- ① If the installation of the clip-on limb electrode and suction bulb is stable?
- ② If the connection of the lead wire and clip-on limb electrode and suction bulb is correct?
- ③ If the clip-on limb electrode, suction bulb and patient skin are clean?
- ④ Is it caused by patient movement or respiration?

7.3 No Signal



- ① Is there enough battery capacity?
- ② Is the lead wire drop off from the patient?
- ③ Is the lead wire connected well to the machine?
- ④ Is the lead off detection work well?

7.4 Time is incorrect

- ① Is there enough battery capacity?
- ② You need to connect to computer, and communicate with PC-ECG software to synchronize it.
- ③ If it still not work well, you may consider to replace the battery.

8 Guarantee

1. When starting to use the product of CS series, users should fill in detail the Guarantee Card and timely send back to the company. Based on it, the company will establish the user profile and periodically learn the condition of the use, which facilitates the company to provide users with sustainable and targeted quality service.
2. The PC-ECG and its accessories include no parts that can be repaired by users and users should not arbitrarily disassemble or repair the device; in principle, the company will not provide users with the circuit and working principle and other technical information. However, if it is required, users may contact the Technology Department of the company. Damaged parts may cause dangers and must be repaired or replaced in time. Please contact the technical service center of the company immediately. Users have access to free after service based on the terms and conditions specified in the Guarantee Card.
3. The company may fulfill its obligation through door-to-door visit, instruction through phone and delivery to the company, and other methods.
4. Even in the free guarantee period, the following service will be charged:
 - ① Fault or damage caused by improper use of users;
 - ② Fault or damage caused by transport and falling after purchase;
 - ③ Fault or damage caused by repair, transformation or disassemble in other places beyond the company;
 - ④ Fault or damage caused by fire, earthquake or other force majeure after purchase;
 - ⑤ Fault or damage caused by not using the thermosensitive recording paper designated by the company;
 - ⑥ Fault or damage caused by connecting other equipment.
 - ⑦ The guarantee seal is damaged.
 - ⑧ Users unilaterally revise or change the machine number or lead number.
5. The company will not be responsible for any fault of other connecting equipment caused directly or indirectly by any fault of the product.
6. The guarantee system is only valid in China.

7. If the guarantee label is damaged, the company may be exempted from the obligation of 12-month free maintenance service.
8. For charged maintenance service beyond the guarantee period, users are suggested to use the “Maintenance Contract System”. Refer to the technical service center of the company for details.
9. Please select the accessories of the original factory for replacement.
10. Normally the PC-ECG may serve for five years. The product has no contraindication.

9 Technical Specifications

Function	Parameters
Lead	Synchronic 12 lead
Interactive interface	LCD and key (CS-28X)
Sampling frequency	Up to 10240Hz
USB	USB2.0
Acquisition time	Optional
Pace-making detection	Turn on
Physical specification	
Dimensions	126.5x 75.8 x 24 mm
Weight	Without LCD 120g, with LCD 168g
Housing	Plastic mould
Patient cable	Banana 10 electrode
Work environment	
Operating temperature	5°C ~ +40°C
Storage temperature	-40°C ~ +55°C
Operating humidity	<80%
Storage humidity	<93%
Operational height	-150 to 4500M
Storage height	-150 to 4500M
Strike	The hard surface will continue to work when it is dropped from 20mm at any axial direction
Power supply	
Type	USB or lithium cell (CS-28X)
Electric	
Supply voltage	5V or 3.7V (CS-28X)
Frequency response	-3.0~+1.2dB@1~75Hz
Dynamic range	10mV
Common mode rejection ratio	>89dB

10 Accessory and List

Serial No.	Name	Quantity	Function and explanation	Remark
1	PC-ECG host machine	1 set	PC-ECG acquisition box	
2	ECG lead wire main cable	1	ECG signal acquisition	
3	Clip-on limb electrode	1 box	Connect ECG signal of limbs	
4	Chest electrode connecting ball	1 box	Acquire human chest ECG signal	
5	Softdog	1	Encipherment protection of hardware and software	
6	USB connecting line	1	Data transmission	
7	Disk	1	Install PC-ECG analysis software	
8	Guarantee Card	1 copy	Certificate for product guarantee	
9	Instruction	1 copy	Product operation instruction	
10	Certificate	1 copy	Certificate of compliance	
11	Packing List	1 copy	Packing list of fittings and accessories	

11 After-Sales Service

Please immediately contact the manufacturer or local distributor for any problem during use.

Manufacturer

Address: Floor 7, Building No. 8, Su Gao Xin Software Park, Suzhou New District, Jiangsu Province, China

Post code: 215163

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Appendix 1 Electromagnetic Compatibility

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the CardioShield PC-ECG Recorder according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

Electromagnetic Emissions		
The CardioShield PC-ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the CardioShield PC-ECG Recorder should assure that it is used in such an environment		
Emission Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 1	The CardioShield recorder 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 B	The CardioShield PC-ECG Recorder is suitable for use in all establishments, including domestic establishments. The recorder has no connection to the public low-voltage power supply network.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity			
The CardioShield PC-ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioShield PC-ECG Recorder should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply line +/- 1 kV for input/output lines	N/A	The CardioShield PC-ECG Recorder does not have AC or DC power lines.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	N/A	The CardioShield PC-ECG Recorder does not have AC or DC power lines.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	N/A	The CardioShield PC-ECG Recorder does not have AC or DC power lines.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	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 AC mains voltage prior to application of the test level.			

Electromagnetic Immunity			
The CardioShield PC-ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioShield PC-ECG Recorder should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the CardioShield PC-ECG Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $D = 1.2 \sqrt{P}$ $D = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $D = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people. Additional notes are on following page.</p>			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the CardioShield recorder: for equipment and systems that are not life-supporting

The CardioShield PC-ECG Recorder is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CardioShield PC-ECG Recorder can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CardioShield PC-ECG Recorder 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)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$D = 1.2 \sqrt{P}$	$D = 1.2 \sqrt{P}$	$D = 2.3 \sqrt{P}$
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	12.0	12.0	23.0

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 the absorption and reflection from structures, objects, and people.

BENEWARE

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