ECG-1103B/G/GW/LW

Digital Three-channel Electrocardiograph

Operation Manual









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We will make continuous improvements in features and functions for future release of new equipment without prior notice. We beg your pardon for the inconvenience.

Version

Version: E

P/N: SZ09.24300003-05 Release date: Sep. 2018

EC-Representative

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Responsibility of the manufacturer

We are only responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorized by us, and the electrical installation of the relevant room complies with safety standards.

DNOTE:

This device is not intended for home use.

△WARNING△:

This device is not intended for treatment.

Label guide

△WARNING△

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.



A **NOTE** label advises against certain actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure

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Chapter 1 Safety Guidance

1.1 Safety Information

The design of ECG-1103 Series ECG digital three channel electrocardiograph (ECG) complies with international standard IEC 60601-1, Medical Electrical Equipment: General Requirements for Safety and IEC 60601-2-25, Particular Requirements for Safety of Electrocardiographs. The classification is Class I, type CF, which means a higher degree of protection against electric shock and the patient connection is fully isolated and defibrillation protected.

The equipment is not explosion-proof. Do not use it in the presence of flammable anesthetics.

The equipment is designed for continuous operation but it is not drip-proof or splash-proof.

Safety classification is listed as below Table 1-1.

palety classification is listed as below fable in	-1.			
Anti-electric-shock class:	Class I with internal power supply			
Anti-electric-shock type:	CF			
Degree of protection against harmful penetration	Ordinary equipment (Sealed equipment without liquid proof)			
Disinfection/sterilization method:	Refer to the <i>Operation Manual</i> for details			
Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas			
Working Mode:	Continuous operation			
EMC:	Group I, Class B			

Table 1-1 Safety Classification

1.1.1 Environmental Requirements

Table 1-2 indicates environmental requirements for transportation, storage and operating conditions of ECG-1103 Series ECG.

	Transportation	Storage	Operation
Temperature	-20°C~+55°C	-10°C~+40°C	+5°C~+40°C
Relative Humidity	25%~95%	25%~85%	25%~85%
Atmospheric Pressure	700hPa~1060hPa	700hPa~1060hPa	700hPa~1060hPa

Table 1-2 Environmental Requirements

The transportation conditions must be as stated by the contract. The ECG must be stored where the following requirements are met: the temperature -10°C~+40°C, the relative humidity ≤85%, no corrosive gases and good ventilation.

Be sure that the operating environment is clean, and the ECG is kept away from corrosive materials, high humidity, high temperatures or direct sunlight. Avoid shaking during operation and do not move the equipment when it is powered on.

1.1.2 Power Supply

1) AC Power Supply

Rated voltage: 100V-120V/220V-240V

Rated frequency: 50/60Hz Rated power: 35VA 2) DC Power Supply

Rated output voltage: 12V Rated output current: 2.5A

3) Built-in Lithium Rechargeable Battery

Rated voltage: 14.4V Rated capacity: 2200mAh 4) Fuse: T400mAL250V Ø5×20 T800mAL125V Ø5×20

1.2 Warnings and Notes

In order to use the ECG safely and effectively and avoid possible dangers caused by improper operation, please read through the *Operation Manual* and be sure to become familiar with all functions of the equipment and proper operating procedures before use.

Please pay particular attention to the following warning and note information.

1.2.1 Safety Warnings

⚠WARNING⚠:

- Our ECG is provided for use by qualified physicians or personnel professionally trained. The operator is supposed to be familiar with the contents of this **Operation Manual** before operation.
- Only a qualified service engineer can install the ECG and only a service engineer authorized by us can open the shell.
- Only a qualified installation or service engineer can shift the mains shift switch (100V-240V) according to local mains supply.
- The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it cannot substitute for regular checking.

⚠WARNING⚠:

- ◆ **EXPLOSION HAZARD** Do not use the ECG in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
- ◆ SHOCK HAZARD The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
- If the integrity of external protective conductor during installation or set-up is in doubt, the equipment should be operated from the built-in rechargeable battery.
- Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
- This equipment is not designed for internal use and direct cardiac application.

⚠WARNING⚠:

- Only the patient cable and other accessories supplied by us can be used. Otherwise the performance or electric shock protection cannot be guaranteed.
- Be sure that all electrodes have been connected to the patient properly before operation.
- ♦ Be sure that the conductive parts of the electrodes and associated connectors, including neutral electrodes, are not in contact with the ground or any other conducting objects.
- There is no danger for patients with pacemakers.
- Do not touch the patient, bed, table or the ECG while using defibrillator or pacemaker simultaneously.
- Before defibrillating, make sure the patient is completely isolated and avoid touching any metal part of the ECG in case of electric shock.
- Before defibrillating, remove all electrodes, gel or cloth pieces from the patient in case of any possible burn.
- Only apply the patient cable designated by the manufacturer. Otherwise there might be an electric burn to the patient or damage to the ECG.
- ♦ Electrodes with defibrillator protection should be applied. To avoid any possible electric burn, it is recommended that only the patient cable and electrodes supplied by the manufacturer are applied while defibrillating.
- In order to avoid burns, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously. It cannot connect to electric knife and other equipment.

⚠WARNING⚠:

- Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment).
 Furthermore, all configurations shall comply with the valid version of IEC 60601-1. If in doubt, consult our technical service department or your local distributor.
- The sum of leakage current should never exceed leakage current limits when several other units are used at the same time.
- The potential equalization conductor can be connected to that of other equipment when necessary.

 Make sure the equipment is connected with the potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

⚠WARNING⚠:

- ◆ Improper operation may cause the battery to become hot, ignite or explode, and it may lead to a reduction in the battery's capacity. It is necessary to read the *Operation Manual* carefully and pay particular attention to warning messages.
- Opening the battery cover, disassembling or replacing battery should be done according to the
 Operation Manual, and only a battery of the same model and specification provided by manufacturer
 should be used.
- Danger of explosion Do not reverse the anode and cathode when connecting the battery.
- ◆ Do not use battery around fire or in environments over 60°C. Do not heat or allow liquids to come into contact with the battery. Do not throw it into fire or water.
- ♦ In the case of leakage or foul smell, stop using the battery immediately. If your skin or clothing comes into contact with any leaked liquid, clean it with clean water at once. If the leaked liquid comes into contact with your eyes, do not rub them. Irrigate them with clean water first and go to see a doctor immediately.
- When the battery's useful life is over or any abnormality regarding the battery is found, stop using it, and contact the manufacturer or local distributor for disposal or dispose of the battery according to local regulations.

1.2.3 General Notes

NOTE!

- ◆ Avoid liquid splashes and excessive temperature. The temperature must be kept between 5°C to 40°C while operating, and between -20°C to 55°C during transportation, and between -10°C to 40°C during storage.
- Do not use the ECG in a dusty environment with poor ventilation or in the presence of corrosive materials.
- ◆ Be sure that there is no intense electromagnetic interference source around the equipment, such as a radio transmitter or mobile phone etc.
 - **Attention:** large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to cause electromagnetic interference.

NOTE:

- Check the main unit and its accessories carefully before operating the ECG. It should be replaced if there is any evident defect or signs of aging which may impair the safety or performance.
- Fuses must only be replaced with the same type and rating as the original.
- ♦ The equipment and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.

1.2.4 Cleaning & Disinfection Notes

NOTE():

- Turn off the power before cleaning and disinfection. If mains supply is used, the power cord should also be disconnected from the outlet. Prevent the detergent from seeping into the equipment.
- Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive materials and avoid scratching the electrodes.
- Any remaining detergent should be removed from the unit and patient cable after cleaning.
- Do not use chlorine disinfectants such as chloride and sodium hypochlorite etc.
- Do not use high temperatures, autoclaving or radiation sterilization processes.

1.2.5 Electromagnetic Compatibility Information

The equipment must comply with IEC 60601-1-2 for medical electronic equipment or EMC standards. The electromagnetic environment which exceeds the limits of the IEC 60601-1-2 standard will generate harmful interference or degrade the performance. Adverse electromagnetic interference should be eliminated before using.

Common sources of interference and solutions:

1. Strong electromagnetic interference generated by the nearby emissive sources, such as: broadcasting station, transformer substation and cell phones.

Solution: Keep the equipment away from the emissive sources.

2. RF interference generated by other equipment or systems through the electric knife line.

Solution: Determine the causes of interference and remove possible ones. If not, please change the power supply.

3. Direct and indirect influence from electrostatic discharge.

Solution: Make sure that all equipment and systems have no direct or indirect electrostatic energy before use. Humidity can effectively reduce such interference.

4. Electromagnetic interference generated by radio receiver such as TV and radio.

Solution: Try to keep this equipment away from the radio receiver.

If these methods cannot solve the problem, please contact us or the designated maintenance points.

Chapter 2 Introduction

ECG-1103 Series ECG are digital three channel ECG recorder with high performance. It provides sufficient information for the analysis of arrhythmia and cardiovascular disease and helps to detect pathological disorders caused by some drugs, electrolytes, or imbalance of PH value. It is important equipment for cardiac disease investigation, and its compact size makes it suitable for use while visiting patients at home.

Standard Configuration: main unit and accessories, including patient cable, chest electrodes, limb electrodes, thermo-sensitive print paper and power cord, etc.

Intended use: The cardiogram and heart rate recorded by the ECG can help doctors to analyze and diagnose heart disease or arrhythmia in hospitals. Its compact size makes it suitable for use while visiting patients at home. It is suitable for Adults.

NOTE:

• Patients with heart disease may have a normal electrocardiogram, so other tests are required for a full heart appraisal. This equipment cannot be connected to the heart directly.

2.1 Function Features

ECG-1103 Series ECG can be divided into ECG-1103B/1103B(I), ECG-1103G/1103G(I), ECG-1103GW/1103GW(I), ECG-1103L/1103L(I) and ECG-1103LW/1103LW(I) accordingly to functions, LCD specification. Rated voltage. Waveform and printing paper width, detailed as below in Table 2-1.

ECG-1103 Series	LCD Type	Rated voltage	Wave- form	Paper Width	INFO	HELP	FILE
ECG-1103B	192×64 monochrome	220V-240V	3	63mm	Yes	No	No
ECG-1103B(I)	192×64 monochrome	100V-120V	3	63mm	Yes	No	No
ECG-1103G	3.8inch monochrome	220V-240V	12	63 mm	Yes	Yes	Yes
ECG-1103G(I)	3.8inch monochrome	100V-120V	12	63 mm	Yes	Yes	Yes
ECG-1103GW	3.8inch monochrome	220V-240V	12	80 mm	Yes	Yes	Yes
ECG-1103GW(I)	3.8inch monochrome	100V-120V	12	80 mm	Yes	Yes	Yes
ECG-1103L	5.7inch monochrome	220V-240V	12	63 mm	Yes	Yes	Yes
ECG-1103L(I)	5.7inch monochrome	100V-120V	12	63 mm	Yes	Yes	Yes
ECG-1103LW	5.7inch monochrome	220V-240V	12	80 mm	Yes	Yes	Yes
ECG-1103LW(I)	5.7inch monochrome	100V-120V	12	80 mm	Yes	Yes	Yes

Table 2-1 features and Functions of ECG-1103 Series ECG

Unless otherwise specified, ECG-1103 Series ECG has following features:

- Light in weight, compact in size
- Touch key for easy operation
- Three kinds of operating modes: AUTO, MAN, ANA
- Alarm information for lead-off
- Built-in ECG simulator
- > Built-in rechargeable lithium battery with high capacity
- > Thermal dot-matrix printer for high-resolution printout
- > Automatic adjustment of baseline for optimal recording
- > Standard RS232 communication interface
- Optional USB interface

- Optional wireless communication interface for sending 12 channel ECG to PC and setting up ECG Database via Carewell ECG Workstation Software
- Display of ECG waveforms on LCD
- ➤ Built-in Help Function: electrode positioning, ECG basic knowledge, common trouble-shooting and so on (not available in ECG-1103B/1103B(I))
- Clinical information such as patient ID, gender, age can be edited (available in ECG-1103B/1103B (I)). Besides ID, gender and age, name, height, weight, blood pressure and hospital name can also be edited (not available in ECG-1103B/1103B(I))
- > Standard lead mode or Cabrera lead mode available
- Case Storage function: 15 cases can be saved in the machine or as much as 250 cases in an SD card. Saved ECG waveforms can be cine-looped, printed out or transferred to PC (available in ECG-1103B /1103B(I))

2.2 List of Symbols

Symbols in this *Operation Manual* are listed as below in Table 2-2.

ymbols in this operation manual are listed as below in Table 2-2.								
\rightarrow	External output	⊕	External input					
1 9 1	Equipment or part of CF type with proof of defibrillator connection	\triangle	Attention – general warning (see accompanying document)					
	Potential equalization	POWER	Power switch					
~AC SOURCE	Connect the AC power	2	Mains supply					
→□	Battery recharging indicator	PATIENT	Lead wire interface					
←	USB interface	OPEN	Open the upper case of the print					
DC 12V	Connect the DC power	LAN	Internet interface					
	Refer to instruction manual/booklet NOTE On ME EQUIPMENT "Follow instructions for use"		Recovery and recycling					

Table 2-2 List of Symbols

Chapter 3 General Information

3.1 Front Panel



Figure 3-1 Front Panel of ECG-1103G /1103G (I)

3.1.1 Product Information

1) LOGO



2) Model Series ECG-1103

3) Classification Symbol



Equipment of CF type with proof of defibrillator connection

4) Open Button

Push this button to open the recorder cover. See Chapter 4.2 for details.

3.1.2 LCD Screen

There are three kinds of LCD specifications for ECG-1103 Series ECG:

- 3.8 inches monochrome graphic LCD for ECG-1103G/1103G(I) and 1103GW/1103GW(I);
- ➤ 5.7 inches monochrome LCD Screen for ECG-1103L/1103L(I) and 1103LW/1103LW(I);
- > 192×64 monochrome graphic LCD for ECG-1103B/1103B (I).

3.1.2.1 LCD Screen of ECG-1103G/1103G(I) and ECG-1103GW/1103GW(I) (3.8 Inch monochrome graphic)

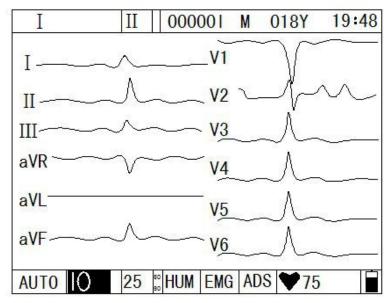


Figure 3-2 LCD Display of ECG-1103G/1103G (I) and 1103GW/1103GW (I)

Normally, the information displayed on the LCD screen includes (from left to right, shown as Figure 3-2)

Top Row:

- ➤ Current lead (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6)
- > Rhythm lead (selectable from I to V6)
- > Patient ID
- Gender (Male/Female/Empty)
- ➤ Age
- Current time

Under Row:

- > Operation mode (AUTO, MAN and ANA)
- Sensitivity (Auto, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40mm/mV)
- ➤ Paper speed (6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s)
- > AC Filter Freq.: 50Hz, 60Hz
- ➤ HUM Filter (ON/OFF)
- ➤ EMG Filter (EMG OFF, EMG 25Hz, EMG 45Hz)
- ➤ ADS Filter (ON/OFF)
- ➤ Heart rate ♥ (Actual heart rate)
- > Battery capacity (Only when the built-in battery is used)

5.7 inch LCD and 3.8 inch LCD are basically the same content, refer to the above information.

3.1.2.2 LCD display of ECG-1103B/1103B (I) (192×64)

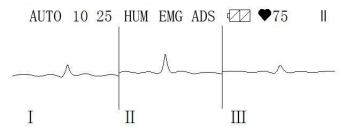


Figure 3-3 LCD Display of ECG-1103B/1103B (I)

From top left to bottom right:

- > Operation mode (AUTO, MAN, ANA)
- Sensitivity (Auto, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40mm/mV)
- Paper Speed (6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s)
- > AC Filter Frequency: 50Hz, 60Hz
- ➤ HUM Filter (ON/OFF)
- ➤ EMG Filter (EMG OFF, EMG25Hz, EMG45Hz)
- ➤ ADS Filter (ON/OFF)
- ➤ Battery Capacity (Only when the built-in battery is used)
- ➤ Heart Rate ♥ (Actual heart rate)
- Print Status (printing/not print)

3.1.3 Control Panel and Keys



Figure 3-4 Control Panel of ECG-1103G/1103G(I), 1103GW/1103GW(I), 1103L/1103L(I) and 1103LW /1103LW(I)



Figure 3-5 Control Panel of ECG-1103B/1103B (I)

1) Indicator Lamp

Mains supply indicator lamp: when mains supply is used, the lamp is on. Battery recharging indicator lamp: when the battery is recharged, this lamp flashes.

2) MODE/F1



Press this key to switch operating mode between AUTO, MAN, and ANA. The switching order of leads is listed in Table 3-1.

	Mode	Switching Order (from left to right)											
AUTO	AUTO (Standard)	I	п	Ш	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
AUTO	AUTO (Cabrera)	aVL	I	aVR	П	aVF	Ш	V1	V2	V3	V4	V5	V6
	In this mode, press the Lead (F4/F5) key to change the lead. For the lead-switching order, refer to that of AUTO (Standard) or AUTO (Cabrera) above, which can be set in the Basic submenu. The Test mode is used by the manufacturer to test the print head and the paper shift.							rera)					
	ANA	After around 1 minute of auto-sampling, the compressed waveform of lead II and its R-R histogram will be printed out.											

Table 3-1 Switching order of Leads

Under INFO menu is an auxiliary key. Press F1 key to move up the next ten characters. Press Menu key to move down the next ten characters.



♦ The keys F1- F6 have a hint in the bottom of the LCD under the menu/data save/info interface, do as the hint shows.

3) RESET/F2



Press **RESET** to reset signal lead. After that, the corresponding wave is a line. The locked lead will unlock itself after 0.4 second. If the ECG signal has interference, press **RESET** to reset the signal, if the equipment is connected to a defibrillator.

There is also an up arrow key to be used to select items and turn pages.

4) 1mV/COPY



Under MAN mode, press this key to record a 1mV calibration pulse at any time while recording.

There is also a down arrow key to be used to select items and turn pages.

5) LEAD (Lead Switch Keys)



Under MAN mode, press the keys to switch the lead group. Under AUTO mode, press the (\rightarrow) key to extend the record of the current lead.

Under case saving interface, F4 can be used to recall the saved ECG waveforms, and F5 can be used to save the printing ECG data. When under the interface of data-recall/copy/delete, F4 can be used to print the recalling ECG waveforms. F5 can send the ECG data to PC by RS232 or USB.

Under Menu interface, press the keys to change the parameters. Under Info interface, press the keys to input characters.

6) RUN/STOP



Start or stop recording.

Under case saving interface, it can delete the saved ECG waveforms.

7) ON/OFF



Power the ECG on or off. When the ECG is not printing it can be powered off. Activate the AC switch and then press the button when the instrument is in AC status.

8) MENU



Press this key to enter menu settings.

9) FILTER



Switch among No Filter, EMG, HUM, or ADS filters. The filter status can be seen on the LCD.

10) HELP (not available in ECG-1103B/1103B (I))



Press this key for helpful information such as electrode positioning, ECG basic knowledge, etc. Press this key again to return to main menu. (not available in ECG-1103B/1103B (I)

11) FILE (not available in ECG-1103B/1103B (I))



Press this key to enter the case-saving menu to save the patient ECG information. Press again to return to main menu.

12) INFO (not available in ECG-1103B/1103B (I))



Press this key to input patient ID, name, gender, age, height, weight, blood pressure and hospital name as Table 3-2. The current item to be edited is **Gender**. Press again to return to main menu. See Table 3-3 for the order of characters to be input.

① NOTE①:

Press FILTER

Press FILTER key to delete all information except hospital name.



Press RUN/STOP key to delete all information in the current editing line.

♦ ECG-1103B/1103B (I) can be input patient gender, ID and age information.

ID	Patient's ID (six digits)	Height (cm)	Patient Height (three digits)
Name	Patient Name (eight characters)	Weight (kg)	Patient Weight (three digits)
Age	Patient Age (three digits)	B.P. (KPa)	Patient Blood Pressure (three digits)
Gender	Patient Gender (male/female/empty)	Hospital	Hospital (sixteen digits)

Table 3-2 Items Editable in ECG-1103G/1103G (I), 1103 GW/1103GW (I), 1103L/1103L (I) and 1103LW /1103LW (I)

NOTE:

- ♦ F2, F3, F4, F5 only works in the menu screen. Press **F2/F3** to select up/down; press **F4/F5** to confirm. Press **F1** key to move up next ten characters.
- ◆ Press **INFO** to enter information management menu, then press **F2/F3** to highlight Name. Press **F4/F5** to input patient name. Characters can be input are listed as Table 3-3. Other items such as patient ID, gender, height, etc can be input the same. Press INFO again to return to upper menu.

у	Z	blank	#	*	-		1	:	,
0	1	2	3	4	5	6	7	8	9
Α	В	С	D	Е	F	G	Н	I	J
K	L	М	N	0	Р	Q	R	S	Т
U	V	W	Х	Υ	Z	а	b	С	d
е	f	g	h	i	j	k	i	m	n
0	р	q	r	s	t	u	V	w	Х

Table 3-3 Order of Character to Be Input

3.1.4 F1-F5 Key Function

Keystroke	Interface	Function of F1 ~ F5
key [MENU]	Settings menu interface	Press key [MENU] to enter settings menu interface, press key F2 or F3 up/down to choose the Submenu, press key F4/F5 to enter submenu interface, press key [MENU] to exit. When entering submenu, press key F2 or F3 up/down to choose the Options you need to modify, press key F4/F5 to modify, press key [MENU] to turn back. Press key F4/F5 to modify, press key [MENU] to exit.
key [INFO]	Clinic information input interface	Press key [INFO] to Clinic information input interface, press key F2 or F3 up/down to choose the Options you need to modify, press key F4/F5 to modify, press Menu key to move down next ten characters. Press key [INFO] to exit.
key [FILE]	ECG data management interface	Press key [FILE] to enter ECG data management interface, press key F2 or F3 up/down to choose the Options you need. press key F1+F2/F3(press key F1 first, then press key F2/F3 up/down to choose every Ten-line information. press key [FILE] to exit. When executing ECG Case Storage, Record an ECG waveform of 10-16 seconds, then press key [FILE] , press key F2 or F3 up/down to choose a file name and press F5 to save the data, press key [MENU] to exit. When executing ECG Case Recall and Copy, press key [FILE] to enter ECG data management interface, press key F2 or F3 up/down to choose the file name and press key F4 to recall ECG data, press key F2 or F3 up/down to choose the lead, press F4 to copy the ECG case, Press F1 to print out this ECG waveform. When executing ECG Case Delete, press key [FILE] to enter ECG Data Management interface, press key F2 or F3 up/down to choose a file, then press RUN/STOP . The ECG will remind the operator "Waiting, press F1 to confirm". Press key F1 to delete this file.
key [HELP]	Help interface	Press HELP key to enter HELP menu. Press F2/F3 key to move to next page. Press HELP to return to upper menu.

3.2 Connection and Switching Power Source

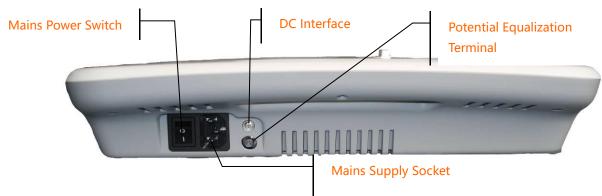


Figure 3-6 Mains sockets

- 1) AC Power Switch
 - I: Power on
 - O: Power off
- 2) AC Power Socket

The equipment is well grounded when connected to a 3-phase power supply.

3) Equipotentiality



NOTE:

When used with other medical equipment, connect the equipotentiality of the ECG to the grounding ends of this equipment with the grounding cable provided, to protect patients from any possible electric shock caused by other equipment.

NOTE(!):

• Connect one end of the grounding cable to the equipotentiality of the equipment and connect the other end to the ground to enhance reliability of grounding. Do not use a pipe or the like as a grounding cable, otherwise the grounding cannot work and there is a potential risk of electric shock to the patient.

4) DC Power Socket

Carewell ECG can be powered by an external DC power source. When choosing a DC power source, be sure that the output voltage and current meet the equipment requirement and the interface matches. Car DC power source and the like can be used.

⚠WARNING⚠:

• Be sure that the safety specification of the DC power source meets the requirements of the valid version of IEC 60601-1.

3.3 Patient Cable Socket and Signal Interface

⚠WARNING⚠:

- Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC 60601-1. Therefore, anybody who connects additional equipment to the signal input or output connector to configure a medical system must make sure that it complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult our technical service department or your local distributor.
- Total current leakage should not exceed current leakage limit when several other units are used at the same time.



Figure 3-7 Interfaces

1) Patient Cable Socket

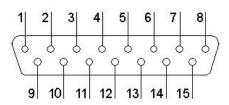


Figure 3-8 Patient Cable Socket

Applied part of type CF with proof of defibrillator connection.

Attention — see accompanying document. Definition of corresponding pins:

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

Table 3-4 Patient Cable Definition of Pins

2) RS232 Socket

MARNING:

◆ The dielectric strength of RS232 interface is AC 1500V, therefore the maximum DC voltage applied to the interface cannot exceed +12V.

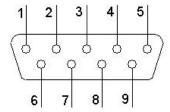


Figure 3-9 RS232 Socket

Definition of corresponding pins:

	Pin	Signal	Pin	Signal	Pin	Signal
	1	EXT/OUT	4	NC	7	NC
Ī	2	RxD (input)	5	GND	8	NC
	3	TxD (output)	6	NC	9	EXT/IN

Table 3-5 RS232 Definition of Pins

3) USB Interface (Optional)

After USB device is plugged into this interface, ECG data can be transferred to USB flash drive via USB interface. Moreover, the laser printer, bar code scanner and magnetic card reader can be plugged in to perform their own functions.

4) LAN Interface (Optional)

A LAN interface can be used as a communication port between the ECG and workstation, and to upload the ECG files to the workstation directly. If you choose a LAN interface to be the communication port, please set the IP, subnet mask, etc. according to PCECG-500 operation manual.

3.4 Bottom Panel

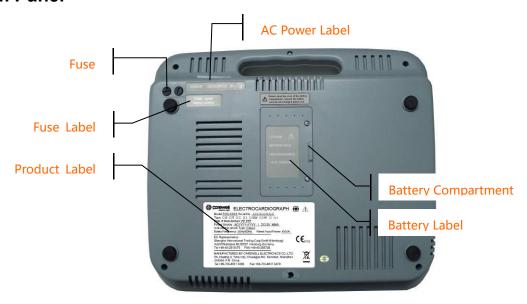


Figure 3-10 Bottom Panel

1) Battery Compartment



Figure 3-11 Battery Compartment Label

The battery label indicates the rated voltage and rated capacity of rechargeable Lithium battery pack. Rated voltage: 14.4V, Rated capacity: 2200mAh.

⚠WARNING⚠:

◆ Improper operation may cause the battery to become hot, ignite or explode, and it may lead to a reduction in battery capacity. Therefore, it is necessary to read the *Operation Manual* carefully and pay particular attention to warning messages.

⚠WARNING⚠:

◆ If a leak or foul smell is noted, stop using the battery immediately. If leaked liquid comes into contact with your skin or clothing, clean it with clean water at once. If the leaked liquid comes into contact with your eyes, do not rub them. Irrigate them with clean water first and go to see a doctor immediately.

⚠WARNING⚠:

• Opening the battery cover, disassembling or replacing battery should be done according to the **Operation Manual**, and only battery of same model and specification provided by the manufacturer should be used.

2) Fuse

There are two same fuses installed on the bottom of the main unit. The specification is showed on the fuse label:



Figure 3-12 Fuse Label

⚠WARNING⚠:

◆ Fuse must only be replaced with the same type and rating as the original one (T400mAL250V Ø5×20/ T800mAL125V Ø5×20).

3) Product Label

The label provides information on product model, S/N, manufacture date, manufacturer name, etc.

Chapter 4 Operation Preparations

⚠WARNING⚠:

• Check the main unit and its accessories carefully before operating the ECG. The unit should be replaced if there is any evident defect or sign of aging which may impair the safety or performance. Make sure that the equipment is in proper working condition.

4.1 Connecting to AC Power and Grounding

⚠WARNING⚠:

◆ To avoid any possible electric shock, please connect the ECG to AC power by a three-phase power cable. Don't open the ECG while it is powered on.

⚠WARNING⚠:

- If the integrity of external protective conductor during installation or set-up is in doubt, the ECG should be operated from the built-in rechargeable battery.
- Carewell ECG can be powered on by AC power, DC power or the built-in rechargeable lithium battery pack.

1) Mains Supply

The mains socket is on the left upper side of the ECG. Properly connect the ECG with mains supply.

Rated voltage: 100V-120V/220V-240V

Rated frequency: 50/60Hz Rated input power: 35A

Make sure the mains supply meets the above requirements before powering on. Then press the AC power switch to turn on the ECG. The AC power supply indicator lamp (\sim) will be lit.

2) Built-in Rechargeable Battery

When the built-in rechargeable battery pack is used, the battery may not be fully charged because of consumption during storage and transport. In this case please charge the battery first. Replace the battery when the battery has been charged over 500 times.

NOTE!:

- The battery is put into the battery compartment without connecting to the battery socket at the factory. After receiving the ECG, if a built-in rechargeable battery is to be used, connect the battery to the socket first
- ◆ Please refer to Section 7.4.1 for instructions on recharging the battery. During charging, the ECG can be powered on by AC power supply and continue operating.
- The battery should be charged at least 8 hours before initial use.
- The battery's service life is about 500 charges.
- When the battery is fully charged, the device can work for at least 1 hours continuously.

3) External DC Power Supply

Make sure the DC power supply meets the requirements as below:

Rated output voltage: 12V; Rated output current: 2.5A;

Output terminal plug must match the DC socket in the ECG.

4) Potential equalization conductor

Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading Recording Paper

Rolled or folded thermo-sensitive paper of 63mm width can be used as recording paper for ECG-1103B /1103B (I), ECG-1103G/1103G (I), and ECG-1103L/1103L (I); 80mm width for ECG-1103GW/1103GW (I) and ECG-1103LW/1103LW (I). If the paper is unloaded or used up, the ECG will remind the operator to replace paper.

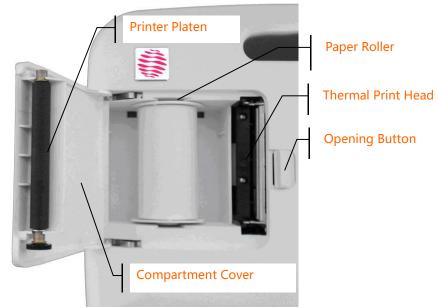


Figure 4-1 80mm Width Roll Paper



Figure 4-2 63mm Width Roll Paper

Loading Procedures for Rolled Paper:

- 1. Push the Open Button to open the paper compartment cover.
- 2. Take out the paper rollers, remove remaining paper if necessary. Insert the rollers into the new roll of paper and put the paper with rollers back into the paper compartment. Be sure that the paper is installed with the paper's grid side facing downward.
- 3. Pull about 2cm of the paper out, and close the cover gently.

Loading Procedures of Folded Paper:

- 1. Push gently the button on the right of the paper compartment to the left to pop up the cover.
- 2. Load the paper to the paper compartment. Be sure that the paper is installed with the paper's grid side facing downward.
- 3. Pull about 2cm of the paper out, and close the cover gently.



• Rollers are not required when using folded paper.

4.3 Patient Cable Connection

Patient cable includes two parts: main cable and lead wires with associated electrode connectors. The electrode connectors can be distinguished by the color and identifier on them.

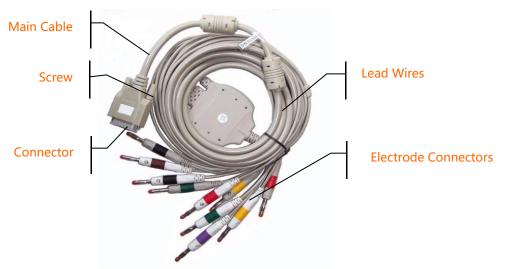


Figure 4-3 Patient Cable

Connect Main Cable: Plug the connector of main cable into the patient cable socket on the right side of the ECG. Secure the knobs on sides of the socket.

NOTE:

• When the lead wire is not connected or the contact is bad, the lead at the top of the screen indicates that the lead is off and the device is not working properly.

⚠WARNING⚠:

- This product is CF classified and defibrillation-protected only when the original patient cable is used. However, as a safety precaution, remove electrodes before defibrillation, when possible.
- It is strongly recommended that only our patient cable be used when the ECG is used with high frequency devices to avoid any possible signal interference.

4.4 Electrodes Connection (CF Application Part)

Chest Electrode:

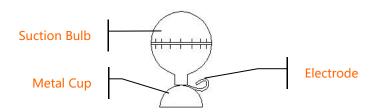


Figure 4-4 Chest Electrode

Limb Electrode:

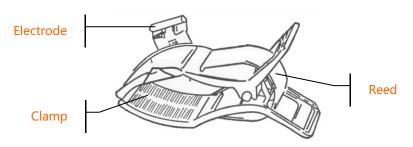


Figure 4-5 Limb Electrodes

The identifier and color code of electrodes used comply with IEC requirements. In order to avoid incorrect connections, the electrode identifier and color code are specified in Table 4-1. The equivalent code of American standard is given too.

	European Electrodes Identifier Color code		American	
Electrodes			Identifier	Color code
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/red	V1	Brown/red
Chest 2	C2	White/yellow	V2	Brown/yellow
Chest 3 C3	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/violet	V6	Brown/violet

Table 4-1 Electrodes, Identifier and Color Code

The chest electrode should be placed on body surfaces as shown below.

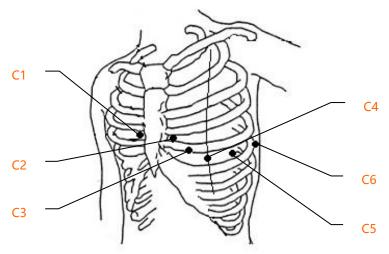


Figure 4-6 Chest Electrode Positioning

- C1: Fourth intercostal space at right border of sternum
- C2: Fourth intercostal space at left border of sternum
- C3: Fifth rib between C2 and C4
- C4: Fifth intercostal space on left midclavicular line
- C5: Left anterior auxiliary line at the horizontal level of C4
- C6: Left midaxillary line at the horizontal level of C4

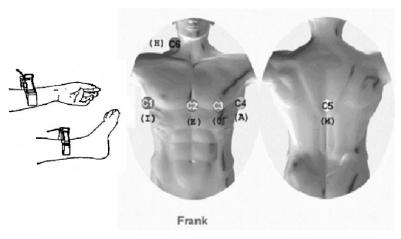
The contact resistance between the patient and the electrode will affect the quality of ECG waveform greatly. In order to get a high-quality ECG waveform, the skin/electrode resistance must be minimized while connecting electrodes.

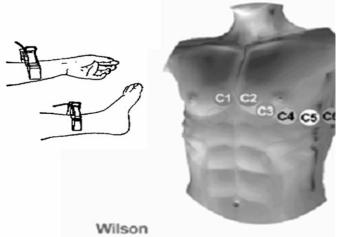
Chest Electrode Connection:

- 1. Ensure the electrodes are clean:
- 2. Align all lead wires of patient cable to avoid twisting, and connect the associated electrode connectors with corresponding electrodes according to the color and identifier;
- 3. Clean electrode area on chest surface with alcohol;
- 4. Daub the round area, 25 mm in diameter, on each electrode site with gel evenly;
- 5. Place a small amount of gel on the rim of chest electrode's metal cup;
- 6. Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the electrode is adhered to the chest. Attach all chest electrodes in the same way.

Limb Electrodes Connection:

- 1. Ensure the electrodes are clean;
- 2. Align lead wires of patient cable to avoid twisting, and connect the electrode connectors to corresponding electrodes according to the color and identifier;
- 3. Clean electrode area a short distance above the ankle or wrist with alcohol;
- 4. Daub the electrode area on the limb with gel evenly;
- 5. Place a small amount of gel on the metal part of limb electrode clamp;
- 6. Connect the electrode to the limb, and be sure that the metal part is placed on the electrode area above the ankle or wrist. Attach all limb electrodes in the same way.





⚠WARNING!:

- Be sure that all electrodes have been connected to the patient correctly before operation.
- Be sure that the conductive parts of electrodes and associated connectors, including neutral electrodes, are not in contact with the ground or any other conducting objects.
- ♦ There is no danger when using the ECG with electrical stimulation equipment. However, the stimulation units should only be used at a sufficient distance from the electrodes. If in doubt, the patient should be disconnected from the device.
- Electrodes with defibrillator protection should be used while defibrillating.
- Do not touch the ECG housing during defibrillation.

4.5 Inspection before Startup

In order to avoid safety hazards and get good ECG records, the following inspection procedures are recommended before turning on the ECG and beginning operation.

1) Environment:

- Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.
- Keep the examination room warm to avoid muscle action voltages in the ECG signal caused by cold.

2) Power Supply:

- If mains power is used, please check whether the power cord has been connected to the ECG and whether it is properly grounded.
- Recharge the battery first before use when the battery capacity is low.

3) Grounding:

Check that the grounding cable is properly connected.

4) Patient Cable:

 Check whether the patient cable has been connected to the ECG securely, and keep it far away from the power cord.

5) Electrodes:

- Check whether all electrodes have been connected with lead wires of the patient cable correctly according to the identifier and color.
- Be sure that all electrodes have been connected to the patient correctly.
- Ensure that the chest electrodes are not in contact with each other.

6) Recorder Paper:

- Ensure that there is enough recording paper loaded.
- Make sure the case of the recorder has been secured.

7) Patient:

- The patient should not be in contact with any conducting object such as the ground and metal parts of the bed, etc.
- Ensure that the patient is warm and relaxed and breathing calmly.

8) AC Filter Frequency

 Check the setup of AC filter frequency and make sure it complies with the local regulations, or it will impact the anti-jamming effect.

⚠WARNING⚠:

The ECG is provided for use by qualified physicians or professionally trained personnel. The operator should be familiar with the contents of this *Operation Manual* before use.

Chapter 5 Operating Instructions

5.1 Power ON/OFF

DNOTED:

- ♦ Whether boot or shutdown should hold down the **ON / OFF** key a few seconds. Hold the boot until the display shows information on manufacturers, equipment model and version, shut down until the screen display closed.
- ➤ When mains supply is applied, press the power switch, and the mains supply indicator (~) is lit. Press key on the control panel to turn on the ECG. Equipment information such as name, manufacturer and version No. etc., will be displayed on LCD screen after self-test. Then the ECG is ready for examination and recording.
- When only the mains supply is applied, the mains supply indicator lamp (<) will be normal lit as well as the battery recharging indicator (→□). If the built-in rechargeable battery is weak when mains supply used, it will be recharged automatically at the same time. The mains supply indicator lamp (<) will be normal lit while the battery recharging indicator lamp (→□) will flash. The indicator lamp will stop flashing and become normal lit until the battery is full.</p>
- When external DC power supply is applied, both indicator lamps will be constantly lit. Press ON/OFF key for about three seconds on the control panel to turn on the equipment. Information such as name, manufacturer and version no. etc., will be displayed in the LCD screen after the self-test. Then the ECG is ready for examination and recording.
- When using a built-in rechargeable lithium battery, press the ON/OFF key for about three seconds on the control panel directly to turn on the ECG, and then the AC power supply indicator and the battery indicator are not lit. Equipment information such as name, manufacturer and version no. etc., will be displayed on the LCD screen after the self-test. The ECG is ready for examination and recording. When the battery symbol switches to "\[\int \]", the battery is low, and the equipment will be automatically turned off in 1 minute. In this case, use AC power supply to continue operation and the battery will be simultaneously recharged.

5.2 AUTO Mode

Under Auto Mode, the leads switch and calibrate automatically while recording, and the 1mV calibration mark is printed on the thermal-sensitive paper. Recording time of each lead can be preset in "Auto Rec. Length (Sec.)" in the Basic menu.

Operation procedures as follows:

Press **MODE** key to choose AUTO, which will be displayed in the lower left corner of the LCD screen, then press "**RUN/STOP**" to print a complete ECG waveform. There is a Beep sound after printing a group of waveforms. During printing, the operator can press "**RUN/STOP**" key to stop recording any time. Press "**RUN/STOP**" again to continue printing. Patient ID number will change automatically accordingly. If the ID number needs to be unchanged, the operator should adjust patient ID before continuing recording.

NOTE:

- For ECG-1103B /1103B (I), patient information (including ID, gender and age) will pop up after pressing RUN/STOP key. Press F1, F2, F3, F4, or F5 key as necessary to finish editing and press RUN/STOP key again to start printing. To neglect editing patient information, press RUN/STOP key to start printing directly. For other procedures, refer to the operation above.
- ♦ Whether under AUTO or MAN mode, recording mode cannot be changed during recording. Stop recording before choosing recording mode.

5.3 Manual Mode

Under MAN Mode, the operator can choose which lead group needs to be recorded and determine the record length.

Operation procedure as follows:

Press MODE key to choose MAN

Press **LEAD** Left or Right arrow key to select 3 leads to be recorded;

Press RUN/STOP to start recording;

1mV key can be pressed to print out 1mV mark while recording;

Press RUN/STOP during recording to stop recording at any time;

Patient ID will be changed automatically if the recording is interrupted. If the ID number needs to be unchanged, the operator should adjust patient ID before continuing recording.

5.4 Analysis Mode

Under ANA Mode, press **RUN/STOP** key, the ECG will sample for around 1 minute, and then print out the compressed waveform of Lead II, including measurement data and R-R histogram. Press F1 to stop sampling and start printing. The operator can't operate the ECG during printing.

5.5 ECG Data Management (not available for ECG-1103B/1103B (I))

Press **FILE** key to enter ECG Data Management interface. Patient data can be saved, deleted or cine-looped. Press F2 or F3 to move the cursor up/down, or press F1 plus F2/F3 to move the cursor every 10 lines.

5.5.1 ECG Case Storage

Record an ECG waveform of 10-16 seconds, then press **FILE**, move the cursor to choose a file name and press F5 to save the data, as shown in Figure 5-1.

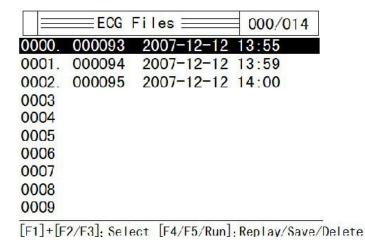
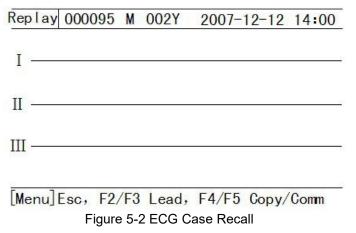


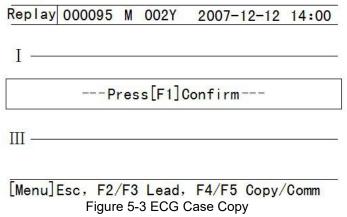
Figure 5-1 ECG Case Storage

5.5.2 ECG Case Recall and Copy

Move the cursor to the file name and press F4 to recall ECG data, as shown in Figure 5-2.



Press F2 or F3 to choose the lead, press F4 to copy the ECG case as shown in Figure 5-3.



Press F1 to print out this ECG waveform.

5.5.3 ECG Case Delete

Press **FILE** key to enter ECG Data Management interface, press F2 or F3 to choose a file, then press **RUN/STOP**. The machine will remind the operator "____Waiting, press F1 to confirm". Press F1 to delete this file

5.5.4 ECG Case Transferring to PC (Optional)

Connect the ECG and PC through RS232 interface, start Carewell ECG Workstation Software in PC and choose "RS232" to start transferring ECG data to PC.

If USB communication function is available, you can start communication via USB interface. Connect the ECG and PC via USB cable, start Carewell ECG Workstation Software, and select "USB" in the software to start communication.

For details, please refer to Carewell ECG Workstation Software Operation Manual.

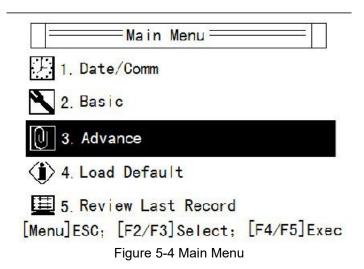
5.6 ECG Help Information (not available in ECG-1103B/1103B (I))

Press **HELP** key to enter HELP Menu. The operator can read such information as electrode positioning, basic ECG knowledge, etc. Press F2/F3 key to move the cursor. Press **HELP** to return to upper menu.

5.7 Operation Menu

5.7.1 Enter and Exit Menu

Press **MENU** to enter MENU interface as shown in Figure 5-4. There are 5 sub-menus in MENU.



5.7.2 Move Cursor among Sub-menus

Press F2 or F3 to move the cursor among the sub-menus.

5.7.3 Change Parameter

Press F4 or F5 to change parameter as required.

5.8 Menu Settings

5.8.1 Date/Comm.

There are 8 items under Date/Comm. interface as shown in Figure 5-5.

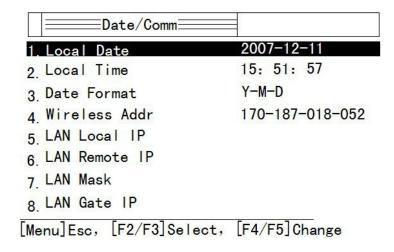


Figure 5-5 Date/Comm. Settings

- 1. Local date: Set current date. It will be recorded on the recording paper.
- 2. Local time: Set current date and time. It will be recorded on the recording paper.
- 3. Date format: year-month-date or date-month-year.
- 4. Wireless Addr.
- 5. LAN local IP: Optional.
- 6. LAN remote IP: Optional.
- 7. LAN mask: Optional.
- 8. LAN Gate IP: Optional.

5.8.2 Basic Settings

There are 10 basic settings as shown in Table 5-1.

No.	Parameter	Options
1	Sensitivity (mm/mV)	<u>AUTO</u> , 2.5, 5,10, 20, 40,
2	Speed (mm/s)	<u>25</u> , 50, 6.25, 12.5
3	Man. Mode	Wide paper: 3ch, 3ch+, 1ch+ Narrow paper: 1ch, 1ch+, 3ch
4	Auto. Mode	Wide paper: 3ch, <u>3ch+</u> , 1ch+ Narrow paper: 1ch, 1ch+ <u>, 3ch</u>
5	Rhythm Lead	I, <u>II</u> , III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
6	Auto Rec. Length (Sec.)	Short, normal, long, longer
7	Lead Mode	Standard, Cabrera
8	AC Filter Freq.	<u>50Hz</u> , 60Hz
9	EMG Filter Freq.	<u>45Hz</u> , 25Hz
10	Report Print Mode	Param, Par+Ana, None

Table 5-1 Basic Settings

Underlined items are default settings.

Sensitivity: adjustable 6 levels: Auto, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40mm/mV. Under MAN Mode, press "Sensitivity" to choose the appropriate sensitivity to achieve optimal ECG record according to the signal range. "Auto" means the sensitivity will be adjusted automatically. If the signal range changes greatly, "Auto" is usually chosen.

Speed: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s.

25mm/s or 50mm/s is generally selected in clinical use. 6.25mm/s and 12.5mm/s are for test purpose or special acquisition and ECG recall.

MAN Mode: switch between ch and ch+ modes.

3ch: print three channel waveform;

3ch+: print three channel waveform plus rhythm lead;

1ch: print single waveform;

1ch+: print single channel waveform plus rhythm lead;

Auto mode: switch between ch and ch+ modes.

Rhythm lead: 12 leads.

Auto Rec. length: recording time of 12-lead ECG waveform under Auto Mode

Lead mode:

Lead Mode	
Standard	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Cabrera	aVL, I, aVR, II, aVF, III, V1, V2, V3, V4, V5, V6

Table 5-2 Lead Mode

AC Filter Freq.: 50Hz or 60Hz accordingly to local AC power frequency.

EMG Filter Freq.: 25Hz or 45Hz

Report Print Mode: If select "Param", besides ECG waveform, the report includes ECG voltage range, axis, and interphase of each waveform. If select "Par+Ana" besides ECG waveform and measurement data, auto analysis is generated in the report. If select "None", only ECG waveform is printed.

5.8.3 Advanced Settings

There are 10 items to be set as shown in Table 5-3. Choose "Yes" or "No" to activate or deactivate the functions.

No.	Parameter	Options
1	Print curves deepen	Yes, No
2	Beeper	No, QRS, <u>Key</u> , All
3	Lead-off Beeper	Yes, No
4	Auto LCD Backlight	Yes, No
5	Enable Ext. Input	Yes, No
6	ADS Filter/Auto Position	No, Base, ADS, <u>All</u>
7	Low-pass Filter	75Hz,90Hz, <u>100Hz</u> ,165Hz
8	ECG Simulator	Yes, No
9	Local Language	Yes, No
10	View 12 Lead ECG	Yes, No

Table 5-3 Advanced Settings

Print curves deepen: to print thick waveforms on the thermal-sensitive paper.

Beeper: If QRS beeper on, when R wave is detected, the machine will give a short Beep sound. During recording, regular short Beep sounds can be heard.

Lead-off Beeper: During use, if there is electrode fall off from patient body or cable loose from equipment, beep sounds and corresponding indication on the screen will be generated to alarm lead-off.

Auto LCD Backlight: When there is no operation within one minute, the ECG will turn off LCD backlight automatically to save battery capacity.

Enable Ext. Input: RS232 interface is preset in standard configuration. Through this interface, external ECG signals can be input; internal ECG signals can be transferred to PC.

ADS Filter/Auto Position: "No": turn off automatic baseline positioning and drift filtering; "base": open baseline automatic positioning function; "ADS": open drift filtering; "All": to locate and open the automatic baseline drift filtering.

Low-pass Filter: Users can choose low-pass filter cut-off frequency of 75Hz, 90Hz, 100Hz or 165Hz; filter out high frequency interference signals.

ECG Simulator: Demonstration of ECG waveform. **Local Language:** The default local language is English.

View 12 Lead ECG: Choose "Yes" to display 12-lead ECG wave (not available in ECG-1103B/1103B (I)), choose "No" to display one lead waveform plus rhythm lead.



◆ The isoelectric parts (I-wave) after global QRS-onset or before global QRS-offset (K-wave) are included in the duration measurement of the respective adjacent waveform.

5.8.4 Return to Default Settings

The default setting for AC frequency can be 50Hz or 60Hz. Please choose accordingly as per local power frequency and press F1 to confirm.

DNOTE:

♦ AC filter frequency should comply with local power frequency. Otherwise, anti-interference effect will be seriously impacted.

5.8.5 Review Last Waveform

Choose "Review Last Record" to cine-loop, copy or transfer the last recorded waveform to PC.

5.9 ECG Printout

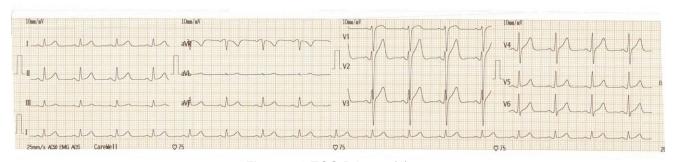


Figure 5-6 ECG Printout (1)

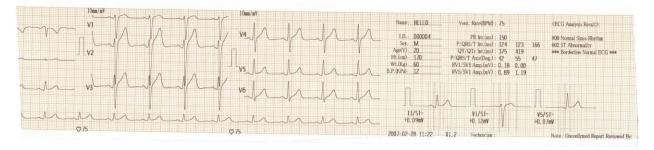


Figure 5-7 ECG Printout (2)

In printout (1), there are heart rate, sensitivity, filters applied, hospital name, 1mV mark, lead, ECG waveform (rhythm lead waveform not available in 63mm width paper), and recording speed.

In printout (2), there is patient information, print date and time, software version, sampling graph (sampling graph not available in 63mm width paper), measurement and analysis result.

Chapter 6 Information Messages

Information messages may appear when operating ECG-1103 Series ECG, such as "Lead-off", "No Paper", "No battery" as listed in Table 6-1

Alarm Information	Causes	
V6	Electrodes fell off from the patient or the patient cable fell off from the unit (Not available in ECG-1103B/1103B (I))	
ESC	Electrodes fell off from the patient or the patient cable fell off from the unit. (Available in ECG-1103B/1103B (I)	
	Record paper has not been loaded or it has been used up. (Not available in ECG-1103B/1103B (I))	
20	Record paper has not been loaded or it has been used up. (Available in ECG-1103B/1103B (I)	
HI	This will beep when HR is beyond the set value	
LOW	The heart rate is below 30BPM.	
7	No battery. (Not available in ECG-1103B/1103B (I))	
	Low battery.	

Table 6-1 Alarm Information and Causes

Chapter 7 Cleaning, Care and Maintenance

7.1 Cleaning

DNOTED:

 Turn off the ECG and unplug the AC power supply cable and patient cable before cleaning and disinfection.

7.1.1 Cleaning the Main Unit and Patient Cable

The surface of the main unit and patient cable can be wiped with a clean soft cloth dampened in soapy water or non-caustic neutral detergent. After that, remove detergent residue with a clean dry cloth.

7.1.2 Cleaning the Electrodes

First remove the remaining gel from the electrodes with a clean soft cloth. Take the suction bulb and metal cup of chest electrodes apart, and take the clamp and the metal part of the limb electrodes apart. Clean them in warm water and be sure there is no remaining gel. Dry the electrodes with a clean dry cloth or air dry naturally.

7.1.3 Cleaning the Print Head

Dirty and soiled thermal print heads can cause poor resolution of the recordings. Clean the print head at least once a month regularly.

Open the recorder casing and remove the paper. Wipe the print head gently with a clean soft cloth dampened in 75% alcohol. For stubborn stains, soak with a little alcohol first and wipe it off with a clean soft cloth. After air drying, load the recording paper and shut the casing of the recorder.

NOTE:

- Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive materials and avoid scratching the electrodes.
- Be sure no cleaner remains on the unit, patient cable or electrodes.

7.2 Disinfection

To avoid permanent damage to the ECG, disinfection can be performed only if it is considered necessary according to your hospital's regulations.

Before disinfection, clean the equipment first. Then wipe the surface of the ECG and patient cable with hospital standard disinfectant.

NOTE():

• Do not use chlorine disinfectants such as chloride and sodium hypochlorite etc.

7.3 Sterilization

To avoid permanent damage to the ECG, sterilization can be performed only if it is considered necessary according to your hospital's regulations. The equipment should be cleaned before sterilization.

(NOTE():

Sterilization, if required, cannot be performed at high temperatures or via autoclaving or radiation.

PNOTED:

• We are not responsible for the effectiveness of infectious disease control measures by using disinfectants or a sterilization process. It would be better to consult epidemic experts for advice.

7.4 Care and Maintenance

7.4.1 Recharging and Replacement of Battery

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol on the screen.

- : Fully charged
- : Partially charged
- : Charge is limited, and recharging should be considered
- Battery is weak; and warning message will be displayed on LCD screen. The battery should be recharged immediately

2) Recharging

Our ECG is equipped with a recharging control circuit together with a built-in rechargeable lithium battery. When connecting with the mains supply, the battery will be recharged automatically. Then the battery recharge indicator lamp ($\rightarrow \Box$) will flicker and the mains supply indicator lamp (\bigcirc) will be lit. When the battery is fully charged, the battery recharge indicator lamp (\bigcirc) will be continuously lit.

Because of the capacity consumption during storage and transport, the battery does not retain a full charge when being used for the first time. Battery recharging should be considered before first usage.

3) Replacement





Figure 7-1 Battery Installation

()NOTE():

- ◆ The battery is put into the battery compartment without connecting to the battery socket at the factory. After receiving the ECG machine, if built-in rechargeable battery is to be used, connect the battery to the socket first. See Figure 7-1 for installation:
 - 1) Open the battery compartment cover with the screwdriver attached;
 - 2) Insert the battery into the battery pack, properly connected;
 - 3) Close the battery cover.

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

MARNING:

- Inappropriate operation may cause battery to become hot, ignite, explode, become damaged or have reduced capacity. Before using the rechargeable Ni-MH battery, read the *Operation Manual* carefully.
- Only qualified service engineers authorized by us may open the battery compartment and replace the battery. Batteries of same model and specification provided by manufacturer must be used.
- Danger of explosion Do not reverse the anode and cathode when connecting the battery.
- When the battery's useful life is over, contact the manufacturer or local distributor for disposal or dispose
 of the battery according to local regulations.

7.4.2 Recording Paper



• Recording paper provided by the manufacturer should be used. Other paper may shorten the life of the thermal print head. And the deteriorated print head may lead to illegible ECG recordings and prevent paper advancement, etc.

Storage Requirements:

- Record paper should be stored in dry, dark and cool area, avoiding excessive temperatures, humidity and sunshine.
- Do not put the paper under fluorescence for a long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment which will lead to a color change of the paper.
- Do not overlap recorded paper for a long time, otherwise print may transfer from one ECG record to another.

7.4.3 Main Unit, Patient Cable & Electrodes

1) Main Unit

- a. Avoid excessive temperature, sunshine, humidity or dirt.
- b. Put on the dustproof cover after use and prevent from shaking violently when moving it to another place.
- c. Prevent any liquid from seeping into the ECG, as it will affect the safety and performance of the ECG.

2) Patient Cable

- a. The integrity of the patient cable, including main cable and lead wires, should be checked regularly. Be sure that it is conductible.
- b. Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connecting or disconnecting the patient cable.
- c. Align the patient cable to avoid twisting, knotting or tightly kinking while using.
- d. Keep the lead wires coiled up to prevent anyone from tripping on them.
- e. Once damage or aging of the patient cable has been noted, replace it with a new one immediately.

3) Electrodes

- a. Electrodes must be cleaned after use; ensure there is no remaining gel on them.
- b. Protect the suction bulb of the chest electrode from sunshine and excessive temperatures.
- c. After long-term use, the surface of the electrodes will be oxidized because of erosion and other causes. In this case, electrodes should be replaced to achieve a high-quality ECG.



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

Chapter 8 Common Troubleshooting and Solutions

1) Some delay without Waveform Printout

Possible reason: Normally the ECG needs some seconds to detect the patient cable while it is connected to the patient.

Solution: repeat operation.

2) Vertical Broken Track of Printed Waveform

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

Solution: clean the printer head.

If the problem still persists, there may be damage to the printer head. Please contact our service department or appointed maintenance center.

3) ECG cannot be switched on

Possible reason: Fuses burnt out

Solution: Unscrew the fuse holder and install the fuses enclosed.

⚠Warning⚠:

◆ AC power cable must be unplugged from AC power source when replacing the fuse to avoid any possible electric shock.

4) ECG cannot be switched off

Possible reason: menu or sub-menu not exited

Solution: exit the menu

5) AC Interference (as shown in Figure 8-1)



Figure 8-1

Possible reason:

- a. Equipment is not properly grounded;
- b. Electrode or patient cable is incorrectly connected;
- c. There is not enough gel applied;
- d. Patient bed is not properly grounded;
- e. Patient touches metal part of the patient bed;
- f. Somebody is touching the patient;
- g. There is powerful equipment operating nearby;
- h. The patient is wearing glass or diamond jewelry;
- i. AC power frequency.

Solution:

- Ground the equipment properly;
- Connect the electrode and patient cable correctly;
- Apply enough gel;
- Ground the patient bed properly;
- Ask the patient not to touch the metal part of the patient bed;
- Don't touch the patient;
- Wait till the powerful equipment is switched off;
- Remove the glass or diamond jewelry from the patient;
- Reset AC frequency accordingly to local AC frequency.

If interference still exists, please apply HUM filter. The waveform will be weakened a little.

6) EMG Interference (as shown in Figure 8-2)

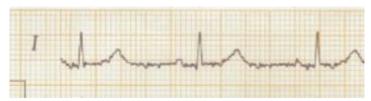


Figure 8-2

Possible reason:

- a. The room is uncomfortable;
- b. The patient is nervous;
- c. The bed is too narrow;
- d. The patient is talking;
- e. The limb electrodes are tightly attached.

Solution:

- Move to a comfortable room;
- Ask the patient to relax;
- Change to a wider patient bed;
- Don't talk with the patient while operating;
- Change the limb electrode if it is too tight.

If interference still exists, please apply EMG filter. The waveform will be weakened a little.

Chapter 9 Service Warranty

1) Workmanship and Raw Material

We warrant that there is no defect in raw material and workmanship. During the warranty period, we will repair or replace the defective part free of charge if the defect has been confirmed to be a raw material or workmanship defect.

2) Software or Firmware

We will replace installed software or firmware free of charge if the defect has been confirmed to be a raw material or workmanship defect within 18 months from the date of shipment. But we cannot guarantee it will not interrupt the use of the ECG.



All services must be provided by engineers authorized by us or its authorized distributor.

3) Exemption of Warranty

The charges of freight and other charges are excluded under warranty.

The warranty is void in the case of:

- Assembly, extensions, readjustments of any parts;
- Modification and repair by unauthorized personnel;
- Subsequent damage caused by improper use or maintenance;
- Replacement or removal of serial number labels and manufacturer labels.

Service Information

Service Unit: Shenzhen Carewell Electronics, Co., Ltd.

If there is any question, please contact us immediately.

Service Contact

Receiver: Service Center of Shenzhen Carewell Electronics, Co., Ltd

Add.: Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District

518108, Shenzhen, P.R. China

Tel: +86-755-8617 0389 Fax: +86-755-8617 0478

E-mail: service-intl@carewell.com.cn Website: http://www.carewell.com.cn/

Chapter 10 Accessories

⚠WARNING:

• Only patient cable and other accessories supplied by the manufacturer can be used. Otherwise the performance and electric shock protection cannot be guaranteed.

No.	Accessory	Quantity
1	Power cord	1
2	Patient cable	1
3	Chest electrodes	6 pcs
4	Limb electrodes	4 pcs
5	Paper roller	1
6	Thermo sensitive paper	1
7	Ground lead	1
8	Fuse	2 pcs
9	Small flat-head screwdriver	1
10	Dust cover	1

Table 10-1 Accessories List

DNOTE

• We advise you secure the touch pen to the handle of the equipment so that it does not get lost.

Appendix I Technical Specifications

	MDD93/42/EEC	Medical Device Directive
	IEC 60601-1: 2005+A1 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential
		performance
Safety Standards	IEC 60601-2-25: 2011	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
	IEC 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

	Anti-electric-shock class:	Class I with internal power supply
	Anti-electric-shock type:	Type CF with defibrillator protection
Classification	Degree of protection against harmful penetration of water:	Ordinary equipment (Sealed equipment without liquid proof)
Classification	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
	Working Mode:	Continuous operation
	EMC:	Group I , Class B

Dimensions	345mm×300mm×80mm	
Net Weight	eight 2.5kgs	
Display	ECG-1103B/1103B (I): 192×64 monochrome LCD Screen ECG-1103G/1103GW (I): 3.8 inch 320×240 monochrome LCD Screen ECG-1103L/1103LW (I): 5.7 inch 320×240 monochrome LCD Screen	

		Transport	Storage	Operation
	Temperature	-20℃~+55℃	-10℃~+40℃	+5℃~+40℃
Environment	Relative Humidity	25%~95%	25%~85%	25%~85%
	Atmospheric Pressure	700hPa~1060hPa	700hPa~1060hPa	700hPa~1060hPa

	Mains Supply	Rated input voltage =100V~120V (1103B (I)/1103G (I)/ 1103L (I)/1103GW (I)/1103LW (I)) =220V~240V (1103B /1103G / 1103L /1103GW /1103LW)
		Rated frequency = 50/60Hz
		Rated input power = 35VA
	External DC	Rated output voltage=12V
	power supply	Rated output current=2.5A
		Rated voltage = 14.4V
Power		Discharge cut - off voltage≥11V
Supply	Built-in rechargeable Battery Pack	Rated capacity = 2200mAh
		Charge mode: Constant current/voltage
		Charge current (standard) < 0.2C5A(400mA)
		Charge voltage (standard) = (16.8±0.1V)
		Charge time ≥ 8h
		Cycle life ≥500 times
	Fuse	T800mAL125V Ø5×20: (1103B(I) /1103G(I) /1103L(I) /1103GW(I) / 1103LW(I)) T400mAL250V Ø5×20: (1103B / 1103G / 1103L / 1103GW / 1103LW)

	Record Mode	Thermal dot-matrix printer
	Recording Paper	Rolled or folded thermo sensitive paper
Boordon	Paper Width	80mm or 63mm
Recorder	Recording Width	72mm or 56mm
	Paper Speed	6.25, 12.5, 25, 50mm/s (±3%)
	Accuracy of data	±5% (X- axis), ±5% (Y- axis)

HR Recognition	Technique	Peak-peak detection
	HR Range	30BPM~215BPM
	Accuracy	±1BPM

Appendix I Technical Specifications

	Leads:	12 standard leads, lead change manually/automatically
	Acquisition Mode:	12 lead acquisition simultaneously
	Sampling Rate:	8000Hz
	Input Circuit	Floating, protection against defibrillator effect
	A/D Switch:	12 bit
	Time Constant:	≥3.2s
	Frequency Response	0.05Hz ~ 165Hz
	Sensitivity	Auto, 2.5, 5, 10, 20,40 (mm/mV) ±5 %
ECG Unit	Input Impedance	≥50M Ω (10Hz)
	Input Circuit Current	≤50nA
	Input Voltage Range	±5 mVpp
	Calibration Voltage	1mV±2%
	Depolarization Voltage	±500m V
	Noise	<15 ^{μ} Vp-p
		EMG Filter: 25/45Hz
	Filter	ADS Filter: Yes/No
		HUM Filter: Yes/No
	CMRR	≥100dB
Patient Leakage Current:		<10 ^{μ} A (a.c.)
Dielectric Strength:		4000V rms

External Input/Output (Optional)	Input (Single ended)	Input impedance ≥ 100k Ω Sensitivity 10mm/V±5%
	Output (Single ended)	Output impedance ≤ 100 Ω Sensitivity 1V/mV±5%
Communication Interface	RS232 serial port/USB	

Appendix II EMC Information

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer's declaration – electromagnetic emission				
2		The ECG-1103 Series ECG is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
3	Emissions test	Compliance	Electromagnetic environment - guidance		
4	RF emissions CISPR 11	Group I	ECG-1103 Series ECG 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.		
5	RF emissions CISPR 11	Class B			
6	Harmonic emissions IEC 61000-3-2	Class A			
7	Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies			

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity

The ECG-1103 Series ECG is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

the user 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	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.		
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.		
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the ECG-1103 Series ECG be powered from an uninterruptible power supply or a battery.		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercia or hospital environment.		

NOTE: UT is the a. c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity

The ECG-1103 Series ECG is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity testIEC 60601 test levelCompliance levelElectromagnetic environment - guidancePortable and mobile RF communications equipment should be used no closer to any part of the ECG-1103 Series ECG including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distanceConducted RF IEC 61000-4-6 $d = [\frac{3}{N}]\sqrt{P}$ BO MHz to 800 MHz $d = [\frac{3}{N}]\sqrt{P}$ Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).bField 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:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ECG-1103 Series ECG is used exceeds the applicable RF compliance level above, the ECG-1103 Series ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECG-1103 Series ECG.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the ECG-1103 Series ECG

The ECG-1103 Series ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter m				
Rated maximum output of transmitter	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$		
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		

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.





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