

3-Channel Digital ECG Machine

Operator's Manual

Venni Instruments, Inc.

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Warranty

VI-3300E ECG machine is warranted for 18 months of free charge from the date of the purchase, while the ECG cable and other accessory parts are warranted for 6 months. The consumables are excluded from the scope of this warranty.

The following situations are not included in the scope of the warranty:

- The serial number of the main unit was ripped off or unreadable; or
- The main unit was damaged due to improper connection with other equipment; or
- The main unit was damaged due to accident; or
- The main unit was modified by user without the written authorization from Venni Instruments, Inc.

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ⓘNOTEⓘ:

- ◆ 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.

ⓘNOTEⓘ

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 VI-3300E digital 3-channel ECG machine complies with international standard IEC 60601-1, IEC 60601-2-25, and medical industry standard YY1139. The equipment is classified as Class I, type CF, which indicates a higher degree of protection against electric shock.

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

The equipment is designed for continuous operation and is 'ordinary' (i.e. not drip or splash-proof).

Safety classification is listed as below Table 1-1.

Anti-electric-shock type	Class I with internal power supply
Anti-electric-shock degree	CF
Degree of protection against harmful ingress of water	Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method	Refer to the Operator 's Manual 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

Please find in table 1-2 for environmental requirements for transportation, storage and working condition of the unit.

	Transportation	Storage	Working
Temperature	-4 °F ~ +131°F	+14 °F ~ +104 °F	+41 °F ~ +104 °F
Relative Humidity	25%~95%	25%~85%	25%~85%
Atmosphere Pressure	700hPa~1060 hPa	700hPa~1060 hPa	700hPa~1060 hPa

Table 1-2 Environment Requirements

The transportation condition must be as stated by the table. The ECG must be stored in the place which meets the following requirements: 1) temperature in between +14 °F and +104 °F; 2) relative humidity must be ≤85%; 3) not exposed to corrosive gases; 4) well-ventilated.

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

1.1.2 Power Supply

1) AC Power Supply

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

Rated frequency: 50Hz/60 Hz

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: 2000mAh

4) Fuse: T400mA/ AC 250V Ø5×20

T800mA/ AC 125V Ø5×20

1.2 Warnings and Notes

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

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

1.2.1 Safety Warnings

WARNING .

- ◆ ECG is provided for the use of qualified physicians or personnel professionally trained. The operator is supposed to be familiar with the contents of this **Operation Manual** before operation.
- ◆ Only qualified service engineer can install the ECG. And only service engineer authorized by us can open the shell.
- ◆ Only qualified installation or service engineer can shift the mains shift switch (100V-120V/220V-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 can not substitute for regular checking.

WARNING .

- ◆ **EXPLOSION HAZARD** - Do not use the ECG in the presence of flammable anesthetic mixture 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 in installation or arrangement 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 patient cable and other accessories supplied by us can be used. Otherwise the performance or electric shock protection can not 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 electrode, should not contact with earth or any other conducting objects.
- ◆ There is no danger for patients with pacemaker.
- ◆ 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 burnt.
- ◆ Apply patient cable appointed by the manufacturer only. Otherwise there might be electric burnt of the patient or damage of 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 to be applied while defibrillating.
- ◆ In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.

 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 summation of leakage current should never exceed leakage current limits while 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 potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

 WARNING .

- ◆ Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery's capacity. It is necessary to read the **Operation Manual** carefully and pay more attention to warning messages.
- ◆ 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 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 place over 60°C. Do not heat or splash the battery. Do not throw it into fire or water.
- ◆ When leakage or foul smell found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage

liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

- ◆ When the battery's useful life is over or any abnormal phenomenon is found from the battery, stop using it, and contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

1.2.3 General Notes

NOTE :

- ◆ Avoid liquid splash and excessive temperature. The temperature must be kept between 5°C to 40°C while working, and between -20°C to 55°C during transportation, and between -10°C to 40°C during storage.
- ◆ Do not use the ECG in dusty environment with poor ventilation or in the presence of corrosive.
- ◆ Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc.

Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

NOTE :

- ◆ Check the main unit and its accessories carefully before operating the ECG. Replacement should be taken if there is any evident defectiveness or aging symptom 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 used, the power cord should be plugged out of the outlet also. 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 fabric and avoid scratching the electrodes.
- ◆ Any remainder of detergent should be removed from the unit and patient cable after cleaning.
- ◆ Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- ◆ Do not use high temperature, autoclaving or radiation sterilization processes.

1.2.5 Electro Magnetic 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. Please exclude adverse electromagnetic interference 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 phone.

Solution: Keep the equipment away from the emissive sources.

2. RF interference generated by other equipment or system through 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 equipments and systems have no direct or indirect electrostatic energy before use. Humidor room 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 can not solve the problem, please connect us or the designated maintenance points.

Chapter 2 Introduction

VI-3300E Series ECG is a digital three channel ECG recorder with high performance. It has three kinds of LCD (liquid crystal display). ECG waveform can be recorded by high-quality thermal printer on thermal sensitive paper. AC power, DC power or built-in rechargeable battery can be used as power supply.

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.

!NOTE!:

- ◆ The patient who has a 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

VI-3300E Series ECG can be divided into VI-3300EB/1103B(I), VI-3300EG/1103G(I), VI-3300EGW/1103GW(I), VI-3300EL/1103L(I) and VI-3300ELW/1103LW(I) accordingly to functions, LCD specification, Rated voltage, Waveform and printing paper width, detailed as below Table 2-1.

VI-3300E Series	LCD Type	Rated voltage	Wave -form	Paper Width	INFO	HELP	FILE
VI-3300EB	192×64 monochrome	220V-240V	3	63mm	Yes	No	No
VI-3300EB(I)	192×64 monochrome	100V-120V	3	63mm	Yes	No	No
VI-3300EG	3.8inch monochrome	220V-240V	12	63 mm	Yes	Yes	Yes
VI-3300EG(I)	3.8inch monochrome	100V-120V	12	63 mm	Yes	Yes	Yes
VI-3300EGW	3.8inch monochrome	220V-240V	12	80 mm	Yes	Yes	Yes
VI-3300EGW(I)	3.8inch monochrome	100V-120V	12	80 mm	Yes	Yes	Yes
VI-3300EL	5.7inch monochrome	220V-240V	12	63 mm	Yes	Yes	Yes
VI-3300EL(I)	5.7inch monochrome	100V-120V	12	63 mm	Yes	Yes	Yes
VI-3300ELW	5.7inch monochrome	220V-240V	12	80 mm	Yes	Yes	Yes
VI-3300ELW(I)	5.7inch monochrome	100V-120V	12	80 mm	Yes	Yes	Yes

Table 2-1 features and Functions of VI-3300E Series ECG

Unless otherwise specified, VI-3300E Series ECG has following features:

- Light in weight, compact in size

- Touch key for easy operation
- Three kinds of operation 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 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 VI-3300EB/1103B(I))
- Clinical information such as patient ID, sex, age can be edited (available in VI-3300EB/1103B (I)). Besides ID, sex and age, name, height, weight, blood pressure and hospital name can also be edited (not available in VI-3300EB/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 VI-3300EB /1103B(I))

2.2 List of Symbols

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

	External output		External input
	Equipment or part of CF type with defibrillator proof		Attention – general warning(see accompanying document)
	Potential equalization	POWER	Power switch
~AC SOURCE	Connect the AC power		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

Table 2-2 List of Symbols

2.3 Operational Principle Overview and Functional Block Diagram

See the functional block diagram at Appendix IV.

The operational principle is as follow:

A faint twelve lead electro-cardio signal about 1mV detected through electrode, which is connected with the human body, accompanied with the polarizing voltage approaching to direct current about $\pm 300\text{mV}$ and strong AC interference about 1V. The faint electro-cardio signal will first barrage the AC interference through the 8-channel low noise differential amplifier circuit, and then eliminate the polarizing voltage via the time constant circuit, and finally be transformed into digit synchronization ECG signal via low-pass filter, level switch and A/D circuit. The digital ECG signal and the detection signal of Lead Off will be sent to the CPU of the control section.

The CPU can recognize the ECG signal, calculate the heart rate, rectify the baseline drift and other functions then save the data to the data storage device. After the record, it will analyze the P/QRS/T wave group to calculate the parameters of the ECG and form a diagnosis report. It also need to translate the keyboard orders and to show the electrocardiogram, status quo, the battery capacity, lead off etc in the LCD. The electrocardiogram and the analysis report of the ECG will be sent to the thermal print head for printing.

The thermal record head of the recorder is a thermal component. The width of the record is 63/80 millimeters, in which it has 504/640 heating elements. It also means there are 8 heating elements integrated in a millimeter. The recorder has an accurate control program to make the paper move with a constant speed and control the heating elements whether to be heated. That is why the recorder can take notes of every curve, image and letter in the thermal record paper.

The power supply section feeds the electricity to all the circuits. It is controlled by the switch of the power. The power supply section has the switchover function, switching between AC and DC or between bidding your time and working. The AC power supply has priority. The built-in charging circuit can protect the battery by its over-voltage, over-current and under-voltage detection functions.

Contact the company for further information.

Chapter 3 General Information

3.1 Front Panel



Figure 3-1 Front Panel of VI-3300EG /1103G (I)

3.1.1 Product Information

1) LOGO

2) Model Series

VI-3300E

3) Classification Symbol



Equipment of CF type with defibrillator proof

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 VI-3300E Series ECG:

- 3.8 inches monochrome graphic LCD for VI-3300EG/1103G(I) and 1103GW/1103GW(I);
- 5.7 inches monochrome LCD Screen for VI-3300EL/1103L(I) and 1103LW/1103LW(I);

- 192×64 monochrome graphic LCD for VI-3300EB/1103B (I).

3.1.2.1 LCD Screen of VI-3300EG/1103G(I) and VI-3300EGW/1103GW(I) (3.8 Inch monochrome graphic)

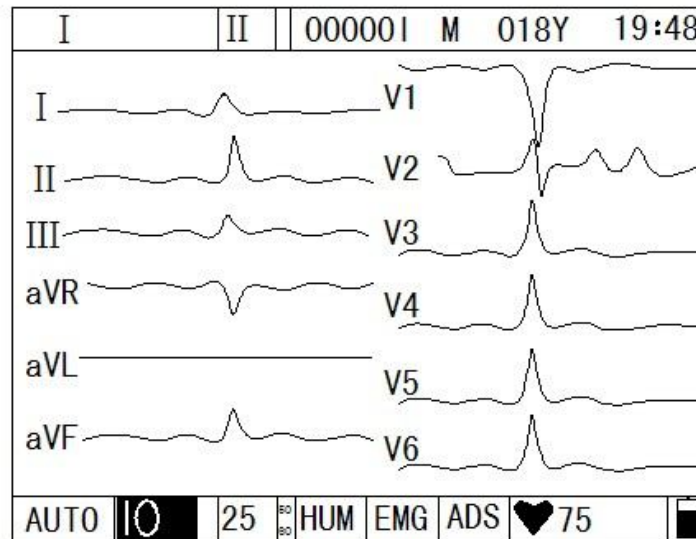


Figure 3-2 LCD Display of VI-3300EG/1103G (I) and 1103GW/1103GW (I)

Normally, the contents displayed on the LCD screen include (from left to right):

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
- Sex (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 (5mm/s, 6.25mm/s, 10mm/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 VI-3300EB/1103B (I) (192×64)

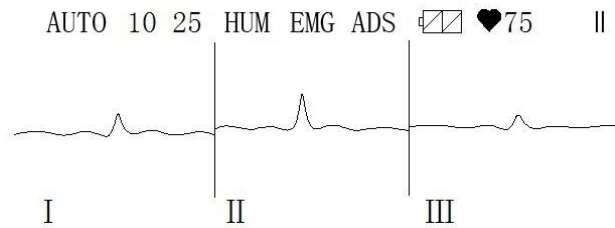


Figure 3-3 LCD Display of VI-3300EB/1103B (I)

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 (5mm/s, 6.25mm/s, 10mm/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 VI-3300EG/1103G(I), 1103GW/1103GW(I),
1103L/1103L(I) and 1103LW /1103LW(I)

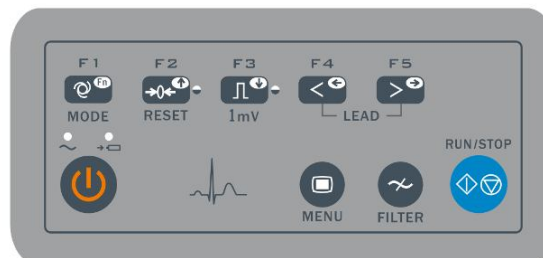


Figure 3-5 Control Panel of VI-3300EB/1103B (I)

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 select operation 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	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
	AUTO (Cabrera)	aVL	I	aVR	II	aVF	III	V1	V2	V3	V4	V5	V6
MAN		In this mode, you need to press 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 for manufacturer to test the print head and the paper shift.											
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, it is an auxiliary key. Press F1 key to move up next ten characters. Press Menu key to move down next ten characters.

! NOTE !:

- ◆ 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 **RUN/STOP** to start recording, then press **RESET** to reset signal lead. After that, the corresponding wave is a line. The locked lead will unlock itself after 0.4 second. The ECG signal will have interference and press **RESET** to reset the signal, if the equipment is connected with a defibrillator.

It is also a direction key upward to be used to choose the items and page turning.

4) 1mV/COPY



Under MAN mode, press this key to record a 1mV calibration pulse at any time while recording. It is also a direction key downward to be used to choose the items and page turning.

5) LEAD (Lead Switch Keys)



Under MAN mode, press the keys to switch the lead group. Under AUTO mode, press the (→) 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



Turn on or off the ECG. When the ECG is connected to mains, turn on the mains first.

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 VI-3300EB/1103B (I))



Press this key to read helpful information such as electrode positioning, ECG basic knowledge, etc.

Press this key again to return to main menu (not available in VI-3300EB/1103B (I)).

11) FILE (not available in VI-3300EB/1103B (I))



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

12) INFO (not available in VI-3300EB/1103B (I))



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

! NOTE !:



- ◆ Press **FILTER** key to delete all information except hospital name.



- ◆ Press **RUN/STOP** key to delete all information in the current editing line.
- ◆ VI-3300EB/1103B (I) can be input patient sex, 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)
Sex	Patient Sex (male/female/empty)	Hospital	Hospital (sixteen digits)

Table 3-2 Items Editable in VI-3300EG/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, sex, height, etc can be input the same. Press INFO again to return to upper menu.

y	z	blank	#	*	-	.	/	:	,
0	1	2	3	4	5	6	7	8	9
A	B	C	D	E	F	G	H	I	J
K	L	M	N	O	P	Q	R	S	T
U	V	W	X	Y	Z	a	b	c	d
e	f	g	h	i	j	k	l	m	n
o	p	q	r	s	t	u	v	w	x

Table 3-3 Order of Character to Be Input

3.1.4 F1-F5 key function

keystroke	interface	The 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.

Chapter 3 General Information

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 Mains Connection and Switch

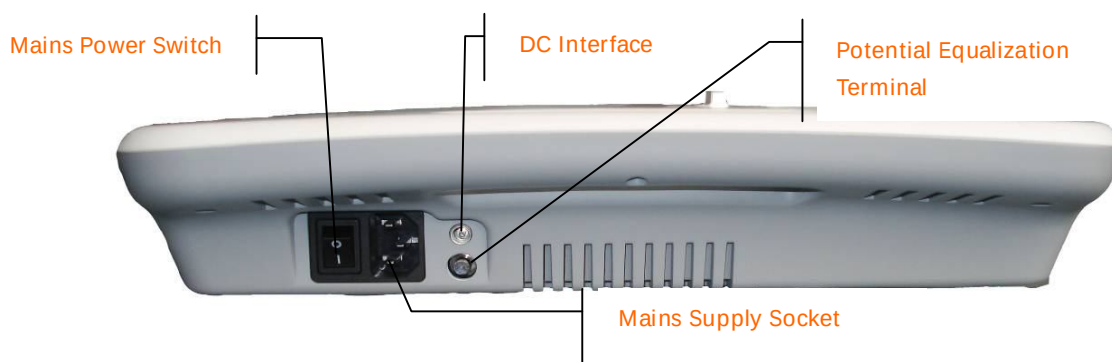


Figure 3-6 Mains sockets

1) AC Power Switch

I : Power on

○ : 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 pipe or the like as grounding cable, otherwise, the grounding cannot work and the patient has potential risk of electric shock.

4) DC Power Socket

ECG can be powered by external DC power source. When choosing 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 requirement of 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 while several other units are used at the same time.



Figure 3-7 Interfaces

1) Patient Cable Socket

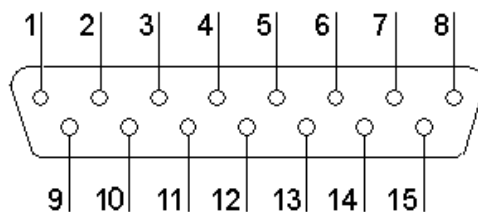


Figure 3-8 Patient Cable Socket

††: Applied part of type CF with defibrillator proof.

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	Cl(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

WARNING :

- ◆ The dielectric strength of RS232 interface is AC 1500V, therefore the maximum DC voltage applied on the interface can not exceed +12V.

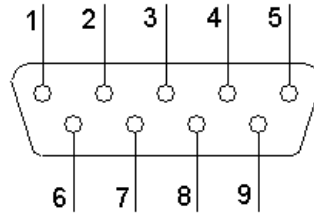


Figure 3-9 RS232 Socket

Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	EXT/OUT	4	NC	7	NC
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 our ECG Workstation Software is installed in PC, ECG data can be transferred to PC via USB interface for management. Please refer to **our ECG Workstation Software Operation Manual** for more information on ECG data management.

4) LAN Interface (Optional)

3.4 Bottom Panel



Figure 3-10 Bottom Panel

1) Battery Compartment

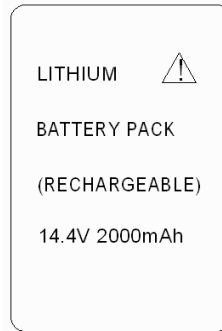


Figure 3-11 Battery Compartment Label

The battery label indicates the rated voltage and rated capacity of rechargeable Lithium battery pack. Rated voltage: 14.4V, Rated capacity: 2000mAh.

WARNING .

- ◆ Improper operation may cause the battery hot, ignited or exploded, and it may lead to the decrease of battery capacity. Therefore, it is necessary to read the **Operation Manual** carefully and pay more attention to warning messages before operation.

WARNING .

- ◆ When leakage or foul smell found, stop using the battery immediately. If the leakage liquid gets to your skin or cloth, cleanse it with clean water at once. If the leakage liquid gets into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

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:

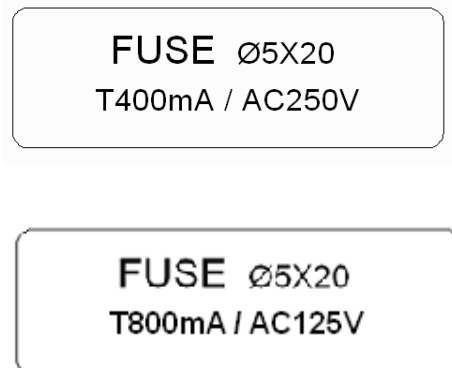


Figure 3-12 Fuse Label

 WARNING .

- ◆ Fuse must only be replaced with the same type and rating as the original one (T400mA 250V Ø5×20/ T800mA 125V Ø5×20).

3) Product Label

In the label, there is information of product model, S/N, manufacture date, register No., manufacturer name, etc.

Chapter 4 Operation Preparations

WARNING :

- ◆ Check the main unit and its accessories carefully before operating the ECG. Replacement should be taken if there is any evident defectiveness or aging symptom 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 with 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 in installation or arrangement is in doubt, the ECG should be operated from the built-in rechargeable battery.

ECG can be powered on by AC power, DC power or 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: 50Hz/60Hz

Rated input power: 35A

Make sure the mains supply meets the above requirements before power on.

2) Built-in Rechargeable Battery

The built-in rechargeable battery pack is used, because of the consumption during storage and transport, the capacity of battery may not be full. In this case please recharge the battery first. Replace the battery when the battery has been recharged over 500 times.

NOTE :

- ◆ The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the ECG, if built-in rechargeable battery is to be used, connect the battery to the socket first.
- ◆ Please refer to the Section 7.4.1 for how to recharge the battery.

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 is used as recording paper for VI-3300EB /1103B (I), VI-3300EG/1103G (I), and VI-3300EL/1103L (I); 80mm width for VI-3300EGW/1103GW (I) and VI-3300ELW/1103LW (I). If the paper is unloaded or used up, the ECG will remind the operator to replace paper.

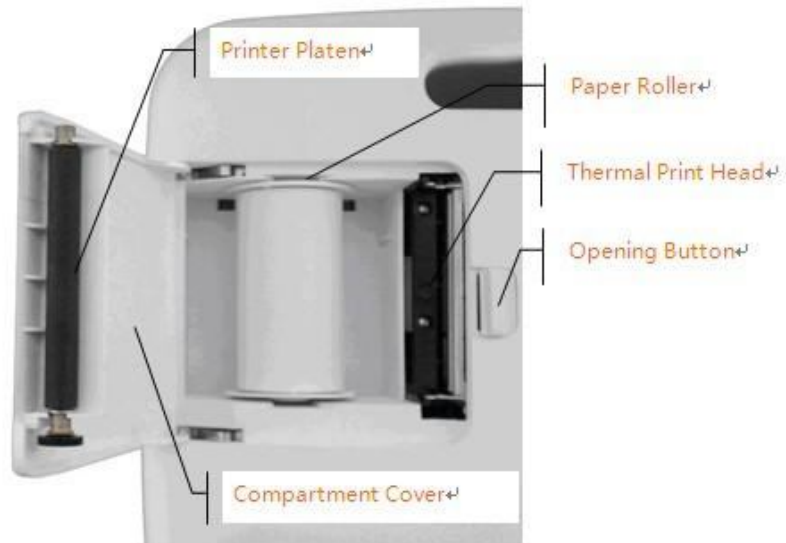


Figure 4-1 80mm Width Roll Paper



Figure 4-2 63mm Width Roll Paper

Loading Procedures of 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 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.

!NOTE!:

- ◆ 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 from the color and identifier on them.

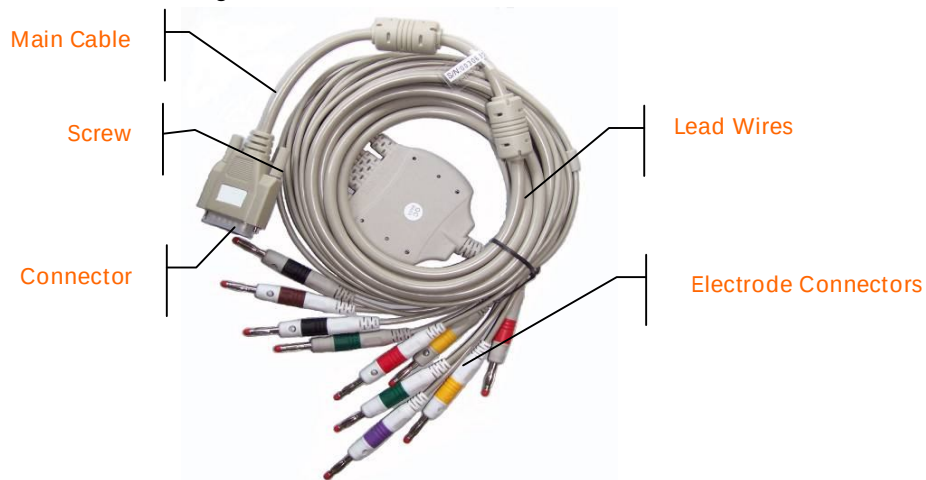


Figure 4-3 Patient Cable

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.

!WARNING!:

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

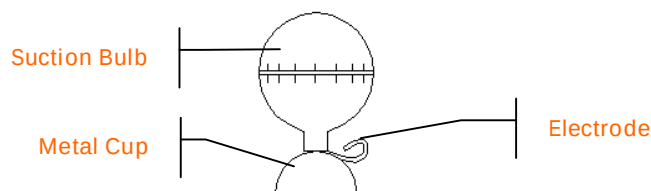
4.4 Electrodes Connection**Chest Electrode:**

Figure 4-4 Chest Electrode

Limb Electrode:

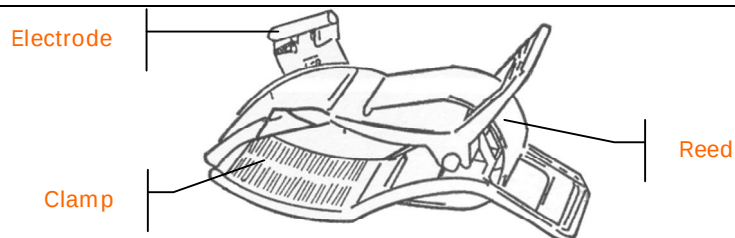


Figure 4-5 Limb Electrodes

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.

Electrodes	European		American	
	Identifier	Color code	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	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 surface as shown below.

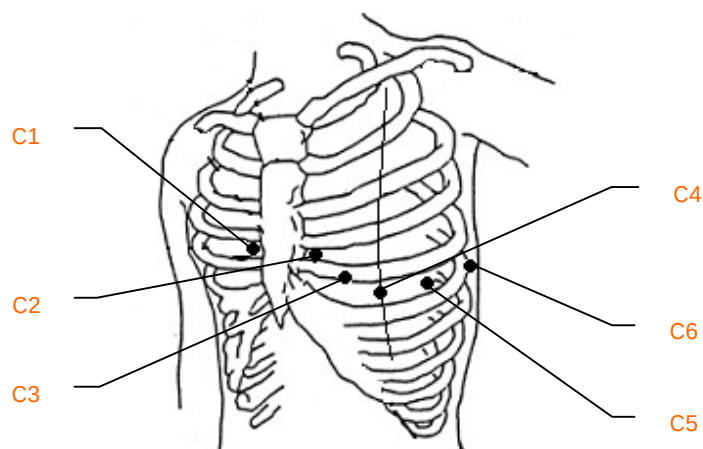


Figure 4-6 Chest Electrode Positioning

C1: Fourth intercostals space at right border of sternum

C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

C5: Left anterior auxillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4

The contacting 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 Electrodes 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 of 25mm diameter on each electrode site with gel evenly;
5. Place a small mount of gel on the brim 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 adsorbed on 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 on a short distance above the ankle or wrist with alcohol;
4. Daub the electrode area on limb with gel evenly;
5. Place a small amount of gel on the metal part of limb electrode clamp;
6. Connect the electrode to limb, and be sure that the metal part be 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 electrode, should not contact with earth 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 Shell case during defibrillation.

4.5 Inspection before Startup

In order to avoid safety hazards and get good ECG record, 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 ECG signal caused by cold.

2) Power Supply:

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

3) Grounding:

- ◆ Check the grounding cable is properly connected.

4) Patient Cable:

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

5) Electrodes:

- ◆ Check whether all electrodes have been connected with lead wires of 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 haven't contacted 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 contact with conducting object such as earth, and metal part of bed etc.
- ◆ Ensure the patient is warm and relaxed, and breathe calmly.

8) AC Filter Frequency

- ◆ Check the setup of AC Filter Frequency and make sure is identical with the local regulations, or it will influence the anti-jamming effect.

 WARNING :

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

Chapter 5 Operation Instructions

5.1 Startup

!NOTE!:

- ◆ 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.
- When external DC power supply is applied, both two indicator lamps will be normal 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 using built-in rechargeable lithium battery, press  key on the control panel directly to turn on the ECG, then the mains supply indicator and the battery indicator are not bright. Equipment information such as name, manufacturer and version No. etc., will be displayed on LCD screen after self-test. The ECG is ready for examination and recording. When the battery symbol become "□", the battery is low, and the equipment will be automatically turned off in 1 minute. In this case, use mains supply to continue operation and recharge the battery as soon as possible.

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 waveform. 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 VI-3300EB /1103B (I), patient information (including ID, sex 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 can not 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 VI-3300EB/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.

ECG Files			000/014
0000.	000093	2007-12-12	13:55
0001.	000094	2007-12-12	13:59
0002.	000095	2007-12-12	14:00
0003			
0004			
0005			
0006			
0007			
0008			
0009			

[F1]+[F2/F3]: Select [F4/F5/Run]: Replay/Save/Delete

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.

Replay	000095	M	002Y	2007-12-12	14:00
I _____					
II _____					
III _____					
[Menu] Esc, F2/F3 Lead, F4/F5 Copy/Comm					

Figure 5-2 ECG Case Recall

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

Replay	000095	M	002Y	2007-12-12	14:00
I _____					
---Press[F1]Confirm---					
III _____					
[Menu] Esc, F2/F3 Lead, F4/F5 Copy/Comm					

Figure 5-3 ECG Case Copy

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 our 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 our ECG Workstation Software, and select “USB” in the software to start communication.

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

5.6 ECG Help Information (not available in VI-3300EB/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.

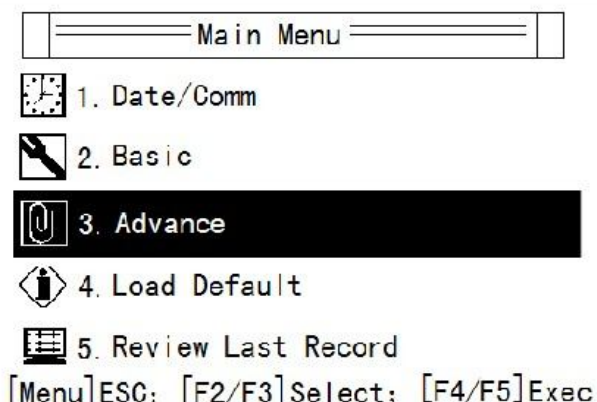


Figure 5-4 Main Menu

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.

Date/Comm	
1. Local Date	2007-12-11
2. Local Time	15: 51: 57
3. Date Format	Y-M-D
4. Wireless Addr	170-187-018-052
5. LAN Local IP	
6. LAN Remote IP	
7. LAN Mask	
8. LAN Gate IP	
[Menu] Esc, [F2/F3] Select, [F4/F5] Change	

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, 5, 6.25, 10, 12.5
3	Man. Mode	Wide paper: <u>3ch</u> , 3ch+, 1ch+ Narrow paper: <u>1ch</u> , 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	<u>Standard</u> , 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: 5mm/s, 6.25mm/s, 10mm/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, <u>No</u>
2	Beeper	No, QRS, <u>Key</u> , All
3	Lead-off Beeper	<u>Yes</u> , No
4	Auto LCD Backlight	<u>Yes</u> , No
5	Enable Ext. Input	<u>Yes</u> , 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, <u>No</u>
9	Local Language	<u>Yes</u> , No
10	View 12 Lead ECG	<u>Yes</u> , 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 VI-3300EB/1103B (I)), choose "No" to display one lead waveform plus rhythm lead.

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.

! NOTE !:

- ◆ 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

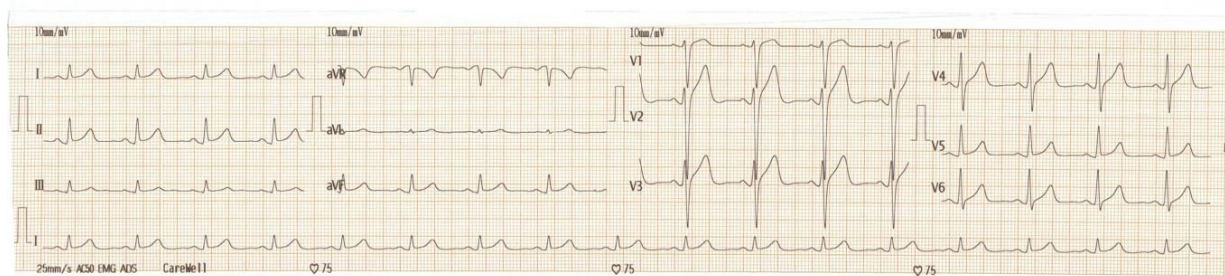


Figure 5-6 ECG Printout (1)

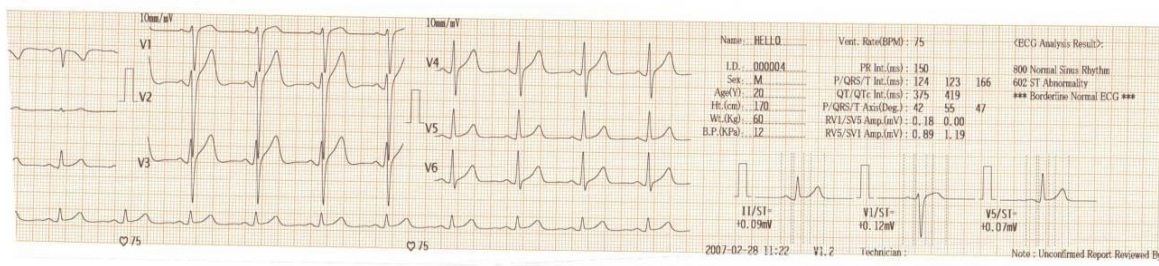


Figure 5-7 ECG Printout (2)

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.

5.10 Turn off the ECG

After finishing ECG recording, hold down the **ON/OFF** key a few seconds until hearing a long "beep".

When built-in battery pack used, press  key directly to turn off the ECG after recording. When there is no operation within 1 minute, the LCD backlight will be turned off automatically, no operation within 3 minutes; the ECG will turn off automatically.

When mains supply used, press  key after finishing ECG recording and then switch off the mains supply by pressing the switch on the left side of the ECG. Plug off the power cable for long-term no use.

When external DC power supply used, press  key first after finishing ECG recording and then plug off the DC power cable.

!NOTE!

- ◆ When switching off the ECG, please operate it according to the sequence above strictly. Otherwise there will be some abnormal characters displayed in the screen next time when the ECG is turned on.

Chapter 6 Alarm Information

Alarm information will be displayed on the LCD screen when there is something wrong. Alarm information provided by the ECG and corresponding cause is listed in Table 6-1.

Alarm Information	Causes
 V6	Electrodes fall off from the patient or the patient cable falls off from the unit. (Not available in VI-3300EB/1103B (I))
ESC	Electrodes fall off from the patient or the patient cable falls off from the unit. (Available in VI-3300EB/1103B (I))
	Record paper has not been loaded or it has been used out. (Not available in VI-3300EB/1103B (I))
	Record paper has not been loaded or it has been used out. (Available in VI-3300EB/1103B (I))
HI	The heart rate is over 215BPM.
LOW	The heart rate is below 30BPM.
	No battery. (Not available in VI-3300EB/1103B (I))
	Low battery.

Table 6-1 Alarm Information and Causes

Chapter 7 Cleaning, Care and Maintenance

7.1 Cleaning

⚠NOTE⚠:

- ◆ Turn off the ECG and plug off the AC power supply cable, 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 damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

7.1.2 Cleaning the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. Take the suction bulb and mental 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 remainder 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 head can deteriorate the record definition. 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 damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, 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 fabric and avoid scratching the electrodes.
- ◆ Be sure no cleanser remains on the unit, patient cable or electrodes.

7.2 Disinfection

To avoid permanent damage to the ECG, disinfection can be performed only when it has been considered as 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 chloric disinfectant such as chloride and sodium hypochlorite etc.

7.3 Sterilization

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

!NOTE!

- ◆ Sterilization, if required, can not be done with high temperature, autoclaving or radiation.

!NOTE!

- ◆ We will not bear the responsibility for the effectiveness of infectious diseases control measure by using the disinfectant or sterilization process. It would be better to consult epidemic experts for advices.

7.4 Care and Maintenance

7.4.1 Recharge and Replacement of Battery

1) Capacity Identification

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

2) Recharge

ECG is equipped with recharge control circuit together with built-in rechargeable lithium battery. When connect with the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp (→□) will flicker and the mains supply indicator lamp (∞) will be lit. When the capacity of battery is full, the battery recharge indicator lamp (→□) will be lit all the time. Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at the first time. Battery recharge should be considered before first usage.

3) Replacement

!NOTE!

- ◆ The battery is put into the battery compartment without connecting to the battery socket at 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:



Figure 7-1 Battery Installation

- 1) Open the battery compartment cover with the screw-driver 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 with manufacturer or local distributor for replacement of battery.

 WARNING .

- ◆ Inappropriate operation may lead battery to be hot, ignited, exploded, damaged or capacity fade. Before using the rechargeable Ni-MH battery, read the **Operation Manual** carefully.
- ◆ Only qualified service engineer authorized by us can open the battery compartment and replace the battery. And the battery 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 with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

7.4.2 Recording Paper

 NOTE .

- ◆ Recording paper provided by manufacturer should be used. Other paper may shorten thermal print head's life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper etc.

Storage Requirements:

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

7.4.3 Main Unit, Patient Cable & Electrodes

1) Main Unit

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

2) Patient Cable

- Integrity of patient cable, including main cable and lead wires, should be checked regularly. Be sure that it is conductible.

- Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connect or disconnect the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- Store the lead wires in bigger wheel to prevent any people from stumbling.
- Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- Electrodes must be cleansed after use and be sure there is no remainder gel on them.
- Keep the suction bulb of chest electrode from sunshine and excessive temperature.
- After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. In this case, electrodes should be replaced to achieve high-quality ECG.

NOTE :

- ◆ 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 Solution

1) Some Lead without Waveform Printout

Possible reason: Normally the ECG needs some seconds to detect the patient cable while it is connected with 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 exists, there may be damage of the printer head. Please contact with our service department or appointed maintenance center.

3) Failure to turn on the ECG

Possible reason: Fuses burnt

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

Warning .

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

4) Failure to turn off the ECG

Possible reason: menu or Sub-menu not exits

Solution: exit the menu

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



Figure 8-1

Possible reason:

- Equipment is not properly grounded;
- Electrode or patient cable is correctly connected;
- There is not enough cream applied;
- Patient bed is not properly grounded;
- Patient touches metal part of the patient bed;
- Somebody is touching the patient;

- There is a powerful equipment operating nearby;
- The patient is wearing glass or diamond ornaments;
- AC power frequency.

Solution:

- Ground the equipment properly;
- Connect the electrode and patient cable correctly;
- Apply enough cream;
- Ground the patient bed properly;
- Ask the patient not touch the metal part of the patient bed;
- Don't touch the patient;
- Wait till the powerful equipment stops;
- Remove the glass or diamond ornaments 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:

- The room is uncomfortable;
- The patient is nervous;
- The bed is too narrow;
- The patient is talking;
- The limb electrodes are tightly attached.

Solution:

- Move to a comfortable room;

- Ask the patient to be relaxed;
- Change a wider patient bed;
- Don't talk with the patient during 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 there's no defect in raw material and workmanship. During warranty period, we will repair or replace the defective part free of charge if the defect has been confirmed as raw material or workmanship defect.

2) Software or Firmware

For the software or firmware installed, we will replace them free of charge if the defect has been confirmed as raw material or workmanship defect within 18 months from the date of shipment. But we can not warrant it will not interrupt the use of the ECG.

⚠NOTE⚠:

- ◆ All services must be finished by engineers authorized by us or its authorized distributor.

3) Exemption of Warranty

The charges of freight and others 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 remove of serial number label and manufacturer label.

Chapter 10 Accessories

 WARNING :

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

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

Table 10-1 Accessories List

Appendix I Technical Specifications

Safety Standards	MDD93/42/EEC	Medical Device Directive
	IEC 60601-1: 1988 +A1:1991+A2: 1995	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-2-25:1993 + A1:1999	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs; Amendment 1
	IEC 60601-1-2: 2007	Medical electrical equipment Part 1: General requirements for safety -2 Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN 60601-1-4:1996/A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
	EN 60601-2-51: 2003	Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multi-channel electrocardiograph
	EN ISO14971-2009	Medical devices - Application of risk management to medical devices
	YY1139:2000	Single and multi-channel electrocardiograph

Classification	Anti-electric-shock type:	Class I with internal power supply
	Anti-electric-shock degree:	Type CF with defibrillator protection
	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
	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

Appendix I Technical Specifications

Dimensions	345mm×300mm×80mm
Net Weight	2.5kgs
Display	VI-3300EB/1103B (I): 192×64 monochrome LCD Screen VI-3300EG/1103GW (I): 3.8 inch 320×240 monochrome LCD Screen VI-3300EL/1103LW (I): 5.7 inch 320×240 monochrome LCD Screen

Environment		Transport	Storage	Working
	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

Power Supply	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 power supply	Rated output voltage=12V
		Rated output current=2.5A
	Built-in rechargeable Battery Pack	Rated voltage = 14.4V
		Discharge cut - off voltage≥11V
		Rated capacity = 2000mAh
		Charge mode: Constant current/voltage
		Charge current (standard) < 0.2C5A(400mA)
		Charge voltage (standard) = (16.8±0.1V)
		Cycle life ≥500 times
	Fuse	T800mA/AC 125V Ø5×20: (1103B(I) /1103G(I) /1103L(I) /1103GW(I) /1103LW(I)) T400mA/AC 250V Ø5×20: (1103B / 1103G / 1103L / 1103GW /1103LW)

Recorder	Record Mode	Thermal dot-matrix printer
	Recording Paper	Rolled or folded thermo-sensitive paper
	Paper Width	80mm or 63mm

Appendix I Technical Specifications

	Recording Width	72mm or 56mm
	Paper Speed	5 , 6.25, 10 , 12.5, 25, 50mm/s ($\pm 3\%$)
	Accuracy of data	$\pm 5\%$ (X- axis), $\pm 5\%$ (Y- axis)

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

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

External Input/Output (Optional)	Input (Single ended)	Input impedance $\geq 100k\Omega$; Sensitivity 10mm/V $\pm 5\%$;
	Output (Single ended)	Output impedance $\leq 100\Omega$; Sensitivity 1V/mV $\pm 5\%$;
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 VI-3300E 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	VI-3300E 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 VI-3300E 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 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 VI-3300E Series ECG be powered from an uninterruptible power supply or 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 commercial 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 VI-3300E 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 test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the VI-3300E Series ECG including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ 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 metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
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 VI-3300E Series ECG is used exceeds the applicable RF compliance level above, the VI-3300E Series ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VI-3300E 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 VI-3300E Series ECG			
The VI-3300E 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 W	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix III Environmental Statement

1. Identification

The mark for control of pollution caused by electronic information products in this diagnosis system is as the following picture shows:

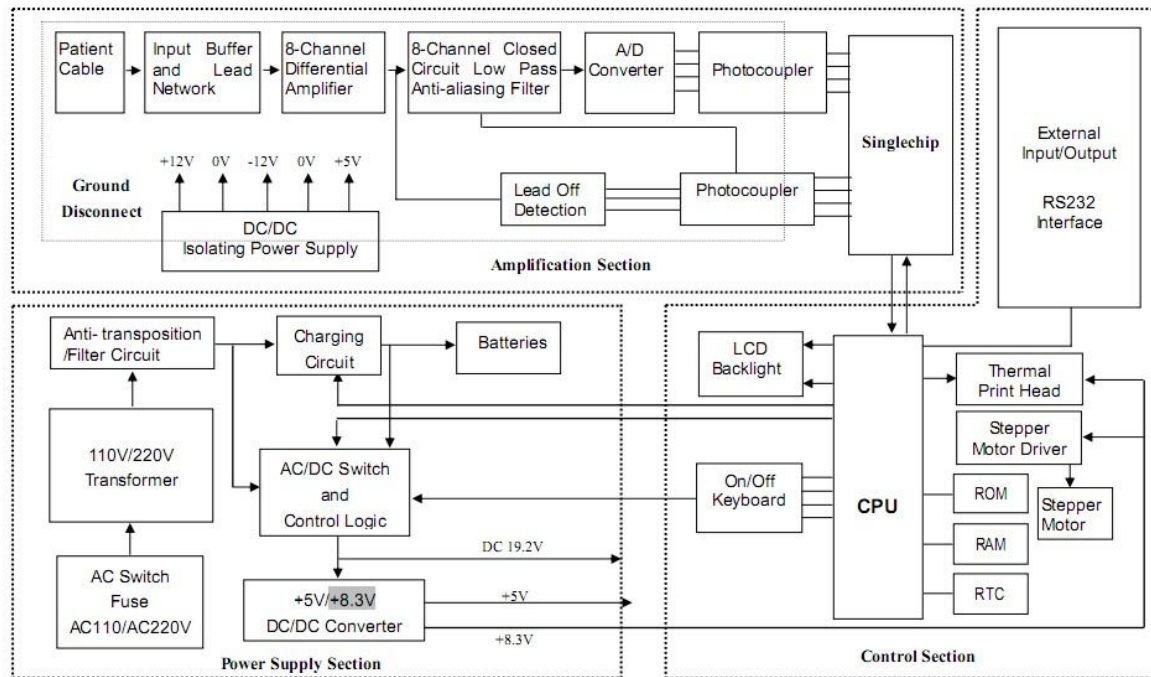


The number “ 50 ” in the mark is environmental protection use period ("EPUP"), of which the unit is year. It means the environmental protection use period ("EPUP") is fifty years from its production. The mark gives the following information: the hazardous substances will not leak or mutate under the normal conditions of use and the use of the product will not cause serious pollution to the environment or serious damage to their personal and property, when the product is used in the environment-friendly use period.

2. provides the following table which applies to all parts of its products.

Hazardous Substances Table						
Parts of Product	Hazardous Substances					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr(VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Built-in Breadboard	○	○	○	○	○	○
Built-in Connector	○	○	○	○	○	○
Sheet Metal	×	○	○	○	○	○
Outer Casing	○	○	○	○	○	○
Display Block	×	○	○	○	○	○
Packing Material	×	○	○	○	○	○
Accessories	×	○	○	○	○	○
"O" indicates that this hazardous substance, for the corresponding part of these products, is below the limit requirement in SJ/T 11363-2006. "X" indicates that this hazardous substance contained in at least one of the corresponding part of these products, is above the limit requirement in SJ/T 11363-2006.						

Appendix IV Functional Block Diagram



Version: A

P/N No.: 24000003