

Digital Electrocardiograph  
Operation Manual

for ECG-3301G / ECG-3303B / ECG-3303G

**Date : 2013-03-26**

**File No. : MNU-ECG3303B-USR-Rev.A1**

## Statement of the Manufacturer

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The company only considers itself 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 the company, and the electrical installation of the relevant room complies with safety standards.

## Responsibility of User

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This product will perform in conformity with the description thereof contained in this Operation Manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. **This product must be checked periodically for its safety and accuracy.** A defective product should not be used. This product or any of its parts should not be repaired other than in accordance with instructions provided by the trained personnel by the manufacturer.



**WARNING** :The machine uses environmentally friendly packaging materials, the machine and its accessories in the use of end of life can return to the manufacturer for recycling; or are to be properly handled to comply with local regulations.

## Using Labels Guide

A circular icon containing an exclamation mark, used to denote a note.	Note	This label advises against certain actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.
A triangular icon containing an exclamation mark, used to denote a warning.	Warning	This label advises against certain actions or situations that could result in personal injury or death.



**NOTE** : **This device is not intended for home use.**



**WARNING** : **This device is not intended for treatment.**

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# 1. Safety Guidance

THE design of the electrocardiograph (ECG) complies with IEC 60601-1 / GB 9706.1-2007 (Medical Electrical Equipment: General Requirements for Safety) and IEC 60601-2-25 / GB10793-2000 ( Particular Requirements for Safety of Electrocardiographs ). The classification of this equipment 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 not drip or splash-proof.

THE device also strictly follows the standard IEC 60601-1-2/YY0505-2005 about the electromagnetism compatibility of medical instrument. When the electromagnetism is beyond the margin of the standard, the device may not work properly. When the abnormal situation appears, please check and clear all the influence before the operation starts again.

POWER Supply and Environment Requirements of the equipment please refer to [Appendix A : Specification and Electrical characteristics ]

## 1.1. Application environment and connection

### **WARNING :**

- ◆ 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.
- ◆ EXPLOSION HAZARD - Do not use the ECG in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- ◆ If the integrity of external protective conductor in installation or arrangement is in doubt, the ECG should be operated by the built-in rechargeable battery.
- ◆ Do not use 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.
- ◆ Only patient cable and other accessories supplied by the manufacturer 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.
- ◆ Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of IEC 60601-1-1. 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, to make sure that all these equipment are connected with the potential equalization bus bar of the electrical installation.

## 1.2. Application simultaneously with defibrillator, pace-maker and high-frequency electrosurgical unit

- ◆ Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, do 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 equipment while using defibrillator or pacemaker simultaneously.
- ◆ Before defibrillating, make sure the patient is completely isolated and avoid touching any metal part of the ECG machine in case of electric shock.
- ◆ Before defibrillating, remove all electrodes, gel or cloth pieces from the patient in case of any possible burning.
- ◆ Apply patient cable appointed by manufacturer only. Otherwise there might be electric burn of the patient or damage of ECG machine.
- ◆ 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.

## 1.3. Battery maintenance

### **WARNING :**

- ◆ Improper operation may cause the battery hot, ignited or exploded, and it may lead to declination of battery capacity. It is necessary to read the Operation Manual carefully.
- ◆ 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 the battery into fire or water.
- ◆ When leakage or foul smell found, stop using the battery immediately. If skin or cloth contact with the leakage liquid, cleanse it with clean water at once. If splashed into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- ◆ When the battery's cycle life is over, stop using it, and contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

## 1.4. Cleaning & Disinfection

### **NOTE :**

- ◆ Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be pulled out from the outlet, too. Prevent 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 after cleaning.
- ◆ Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- ◆ Do not use high temperature, autoclaving or radiation sterilization processes.

 **WARNING :**

- ◆ To prevent the spread of infection , the following precautions should be taken : (1) use the disposable electrodes ; (2)regular cleaning of all components contacting with the patient ; (3) avoid to examine ECG for the patients with infectious ulcers etc.

## 1.5. EMC declaration

 **NOTE :**

- ◆ Powerful electromagnetic interference produced by radio station, transformer substation, X-ray machine, CT-scanner, micro-waver, high-frequency treatment equipment, mobile phone, wireless receiver, etc.

**Solution:** keep enough distance from this equipment.


- ◆ AC interference caused by other equipment nearby

**Solution:** activate HUM filter, change power cable or use built-in battery

- ◆ Static interference

**Solution:** make sure the operator and other equipment contacting with the patient has no static. Tip: a moisture room will be helpful reducing such interference.

If the interference can't be eliminated through all above ways, please contact our service department or the nearby appointed maintenance center.

 **WARNING :** Possible explosion or fire hazard if used in the presence of flammable anesthetics, oxygen, hydrogen or other chemicals.

## 2. Introduction







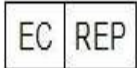

ECG machine is digital 12 channel physiological function measurement equipment which records the heart waveform during electro-biological movement. It provides sufficient information on the analysis of arrhythmia and cardiovascular disease, helps to know the pathological disorder caused by some drugs and electrolyte, or unbalance of PH value. It is important equipment for cardiac disease examination, 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.



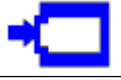












### 2.1. Intended for use :

The digital electrocardiograph is medical electrical equipment intended for the production of detachable electrocardiograms for diagnosis purposes.

### 2.2. Symbols on the device body :

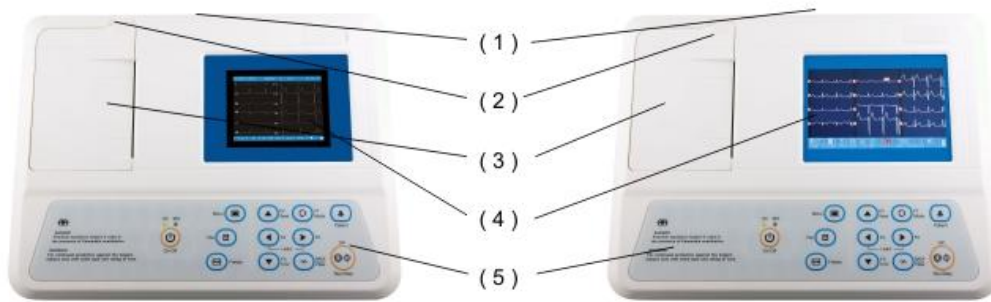
	Defibrillation-Protected Type CF Equipment.
	Potential equalization
	Equipment grounding end
	Attention! Should See the User Manual
	External Input
	External Output
	Information of European Representative
	Meets or exceeds Council Directive 93/42/EEC, MDD, Class IIa.

### 2.3. Symbols on the keypad panel :

	DC Power		AC Power
	Recharging indicator		Menu
	Mode		Sensitivity
	Filter		Patient
	INST		FILE
	1mV		Help
	ECG File		Power On/Off
	Run/Stop		

### 3. Structure & Function

#### 3.1. Front Panel



ECG-3301G , 3303B

ECG-3303G

(1) Handle (2) Paper Switch (3) Paper Cover (4) LCD (5) Keypad

#### 3.2. LCD display



ECG Lead  
Working Mode  
Sensitivity  
Paper Speed  
Filter  
Time  
Paper State  
Patient Information  
Battery State

#### 3.3. Bottom/Lateral Panel

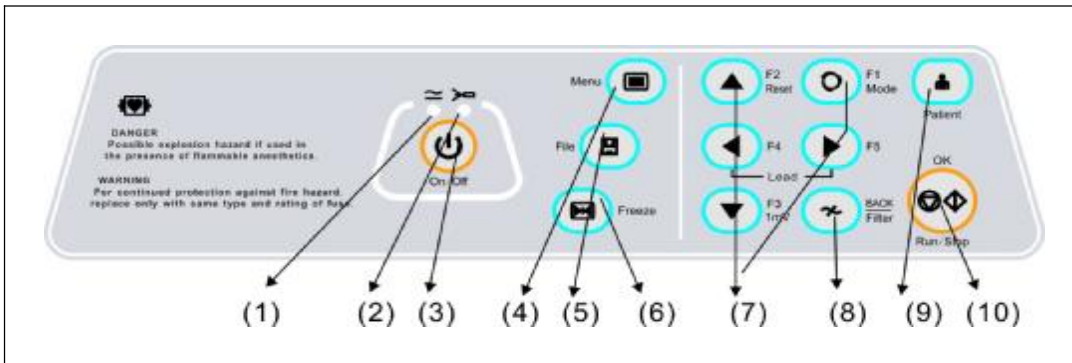


(1) Handle  
(2) AC/SLOT  
(3) GND  
(4) Name Plate  
(5) UART  
(6) USB  
(7) USB/HOST  
(8) Patient Cable  
(9) Battery Box



### 3.4. Control Keypad Panel

The functions of keypad are as following :



- (1) Power Indicator, (2) Charge Indicator;
- (3) [POWER] : Power-on, Press 2-3sec. power-off;
- (4) [MENU] : Main Menu、 File Menu、 ECG Review Menu;
- (5) [FILE] : ECG File Management, Press again to return;
- (6) [FREEZE] : freeze 12 second ECG waveform for ECG review;
- (7) [F1/F2/F3/F4/F5] : SELECT in MENU/PATIENT, else is FUNCTION;

In [PATIENT] mode, Press[MENU+F2/F3/F4/F5] to select and input digital or alphabetic;

- (9) [FILTER] : default is [FILTER].
- (8) [PATEINT] : edit Patient Info., Press again to return;
- (10) [RUN/STOP] : default is [RUN/STOP] to capture/record ECG;

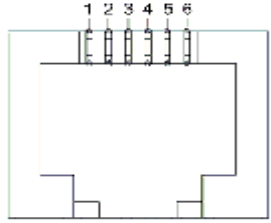
### 3.5. Patient Cable Interface(DB15)

PIN	NAME	PIN	NAME	PIN	NAME
1	C2	6	SHIELD	11	LF
2	C3	7	NC	12	NC
3	C4	8	NC	13	C1
4	C5	9	RL	14	NC
5	C6	10	LL	15	RF(N)

### 3.6. Analog I/O and UART Interface (RJ11) : Used for

- ◆ Record analog External Input In [TEST] lead of [MAN] mode.
- ◆ Export the Rhythm Lead of the [BASIC] menu to Analog External Output.
- ◆ Communicate with personal computer for 12 lead real-time ECG transmission and ECG files transmission.(Needs optional ECG Archive Software and UART/USB cable).

PIN	Remark	PIN	Remark
1	GND (COMMON)	4	UART-Rxd (3.3V)
2	Ext..In : 10mm/V[±5%]	5	UART-Txd (3.3V)
3	Ext.Out: 1V/mV[±5%]	6	NC



### 3.7. USB/Host Interface (Optional) : Used for

- ◆ Transmit ECG file to ECG Archive software based on personal computer, Please refer to the ECG Software Operation Manual for more information.
- ◆ Save ECG files to a external USB disk via USB/Host interface; the files can be imported into ECG Archive software, Please refer to the User Manual for more information.
- ◆ Print ECG report to a external USB printer (PCL command) via USB/Host interface; details about the supported USB printer, please contact our service department.

**CAUTION:**The USB cable should be well shielded and can not be longer over 3 meters, It's better to use the manufacturer's recommended USB cable.

### 3.8. USB or LAN Interface (USB/RJ45,Optional) : Used for

- ◆ Communicate with personal computer system (This need a optional ECG Archive software, Please refer to the ECG Software Operation Manual for more information) .

**CAUTION:**The USB or LAN cable should be well shielded and can not be longer over 3 meters, It's better to use the manufacturer's recommended USB cable.

## 4. Operation Preparation

### 4.1. Power supply and grounding

The ECG can be powered on by mains supply or built-in rechargeable battery pack.

#### 4.1.1. Mains Supply : Rated Main Supply : 100V~230V, 50Hz/60Hz, 60VA

Properly connect the ECG with mains supply. Make sure the mains supply meets the above requirements before power on. Then press the mains power switch to turn on the ECG. The mains supply indicator lamp will be lit as well as the battery recharging indicator .

If the built-in rechargeable battery is in low capacity, it will be recharged automatically when the ECG

is powered on by mains supply. Both the mains supply indicator lamp and the battery recharging indicator lamp will be lit.

### 4.1.2. Built-in Rechargeable Battery

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.

NOTE : Please refer to Section 4.2 for how to recharge the battery. During recharging, the ECG can be powered on by mains supply and continue operating.

NOTE : The battery should be recharged at least 5 hours for first time application.

NOTE : The battery's recycling life is about 500 times.

### 4.1.3. Equipotentiality Terminal

When used with other medical equipment, connect the equipotentiality of the ECG to the grounding ends of these equipment with the grounding cable enclosed to protect patient from electric shock in case any possible current leakage of other equipment.



**WARNING** : To avoid any possible electric shock, please use a three-slot electrical outlet properly grounded. Don't open the ECG while it is powered on.



**WARNING** : If the integrity of external protective conductor installation or arrangement is in doubt, the ECG should be powered on by built-in rechargeable battery.

## 4.2. Using Rechargeable Battery

### 4.2.1. Capacity Identification

The battery capacity can be identified according to the battery symbol in the screen.



**Full capacity.**



**Not full but enough.**



**Capacity is limited, and recharge should be taken into account.**



**Battery is weak; Note : The battery should be recharged immediately.**

### 4.2.2. Recharge

The ECG is equipped with recharge circuit together with built-in rechargeable battery. When connected with the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp on the control panel 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 gone out all the time. Because of the capacity consumption during storage, the capacity of battery is not full while using at the first time. Battery recharge should be considered before first usage.

### 4.2.3. Replacement

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.

- ◆ Open the battery compartment cover with the screw-driver enclosed;
- ◆ Insert the battery into the battery pack, properly connected;
- ◆ 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 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.

### 4.3 Loading Recording Paper

Roll or Z-fold thermo-sensitive paper is used as recording paper. If the paper is unloaded or used up, the ECG will remind the operator to replace paper.

#### **4.3.1. Loading Procedures of Roll Paper:**

- ◆ Lift up the two ears of paper cover to open the paper compartment cover;
- ◆ Take out the paper roller; Insert the roller into the new roll paper and put the roller with paper back into the paper compartment. Be sure the paper is placed upside down.
- ◆ Pull about 2cm of the paper out, and close the cover gently.

#### **4.3.2. Loading Procedures of Z-fold Paper:**

- ◆ Push the Open Button to open the paper compartment cover;
- ◆ Put the Z-fold paper to the paper compartment. Be sure the paper is placed upside down.
- ◆ Pull about 2cm of the paper out, and close the cover gently.

### 4.4. Connecting Patient Cable

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.

### 4.5 Connecting Electrodes (as following)

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	Identifier		Color code	
	European	American	European	American
Right arm	R	RA	Red	White
Left arm	L	LA	Yellow	Black
Left leg	F	LL	Green	Red
Right leg	N/RF	RL	Black	Green
Chest	C1	V1	White/Red	Brown/Red
	C2	V2	White/Yellow	Brown/Yellow
	C3	V3	White/Green	Brown/Green
	C4	V4	White/Brown	Brown/Blue
	C5	V5	White/Black	Brown/Orange
	C6	V6	White/Violet	Brown/Violet

The Limb/Chest electrode should be placed on body surface shown as following:

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

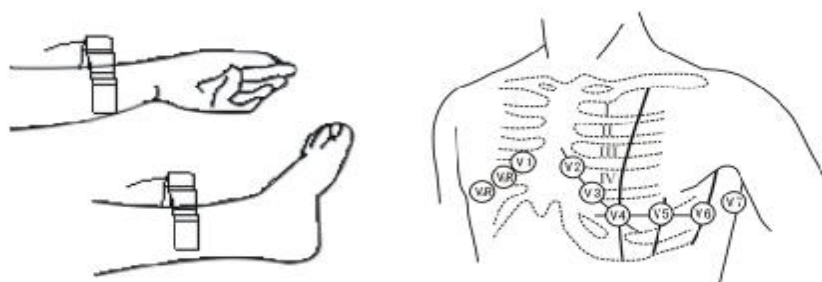
V2 : Fourth inter-costal space at left border of sternum.

V3 : Fifth rib between V2 and V4.

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

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

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



**NOTE : Tangling of electrodes or overlap from one place to another of ECG cream is not allowed.**

## 5. Operation Instructions and Setting

### 5.1. Power On

5.1.1. When mains supply is applied, the mains supply indicator is lit. Press POWER key to turn on the ECG, a logo information will be displayed on LCD screen after self-testing, Then the ECG is ready for examination and recording.

5.1.2. When using built-in rechargeable battery, press the key on the control panel directly to turn on the ECG, then the mains supply indicator and the battery indicator are not bright. Logo information will be displayed on LCD screen after self-testing. The ECG is ready for examination and recording. When the battery symbol is low, and the equipment will be automatically turned off in 1 minute. In this case, use mains supply to continue operation and the battery will be simultaneously recharged.



**NOTE : LCD back light will be turned off within 30 second without any operation, and the device will be automatically turned off within 3 minutes without any operation to save battery.**

### 5.2. Recording Mode

MAN/AUTO/R-R/STOR Mode can be used to record ECG. When the power is turned on, AUTO mode is the default mode, and the sensitivity is set as [Auto], **anti-drift-filter** and **stylus-printing** is set as [On].

#### 5.2.1. Manual Mode

Under MAN Mode, the operator can choose which lead group needs to be recorded and determine the record length. There is no automatic measurement or interpretation function under this mode.

Operation procedure as follows:

Press MODE key to choose MAN mode, Press Left or Right lead key to select 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 is not changed in MAN mode.

#### 5.2.2. Auto Mode

AUTO Mode have review recording mode and real-time recording mode; if REVIEW is set in "Auto Mode" of the BASIC Menu, Auto Mode is review recording mode, the others is real-time recording mode.

#### ◆ **Review Recording Mode:**

In Review recording mode, user can verify the ECG waveform displayed on the screen before starting recording, When the “Run/Stop” key is pressed, 10 seconds ECG can be recorded and saved before the RUN/STOP key is pressed.

#### ◆ **Real-time Recording Mode:**

In Real-time recording mode, the lead is switched automatically while recording, and the 1mV calibration mark is printed on the 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, 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. When the last lead group is printed out, printing is paused to wait ECG measurement or interpretation for several second, the ECG report can be printed automatically.

If “Prompt to save ECG” in [ADVANCE] menu is set, [Press F1 to save ECG] is shown on LCD screen after printing, User can press F1 to save ECG file, or press other key to abort saving, Patient ID number will change automatically accordingly.

### **5.2.3. R-R Mode**

Under R-R Mode, press RUN/STOP key to start ECG sampling for about 60 seconds, then print out the all 60 seconds ECG waveform of Rhythm Lead pre-set in the BASIC menu, including arrhythmia analysis result and R-R histogram.

If “Prompt to save ECG” in [ADVANCE] menu is set, [Press F1 to save ECG] is shown on LCD screen after printing, User can press F1 to save ECG file, or press other key to abort saving, Patient ID number will change automatically accordingly.

### **5.2.4. STOR Mode**

Under STOR Mode, press RUN/STOP key to start ECG sampling for 12-90 second, if the operator press F1 to stop the sampling and the sampling time is greater than 12 second, [Press F1 to save ECG] will be shown on LCD screen, User can press F1 to save ECG file, or press other key to abort saving, Patient ID number will change automatically accordingly. Nothing is printed in the STOR mode.

## **5.3. Operation Menu Setting**

### **5.3.1. Main Menu :**

Main Menu has four items as DATE / BASIC / ADVANCE / TOOLS. Press MENU key to select item, Press [F2/F3] to select sub-menu item, Press[F4/F5] to change the set menu, Press [F1/MODE] to return;

**5.3.2. Date/Time** : 5 items of the sub-menu shown as following:

[ DATE ]	BASIC	ADVANCE	TOOLS
1. Local date		YYYY-MM-DD	
2. Local Time		HH:MI:SE	
3. Date Format		Y-M-D	
4. Color Theme		Theme 1/2/3/4	
5. LCD back-light		Level 1/2/3/4/5	
[MENU]Item, [F2/F3]Select, [F4/F5]Change, [F1]Return			

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. Color Theme : color theme for GUI.
5. LCD Back-light : brightness of LCD display.

**5.3.3. Basic** : 12 items of the sub-menu shown as following:

DATE	[ BASIC ]	ADVANCE	TOOLS
1. Sensitivity (mm/mV)		2.5, 5, 10, 20, 40, [Auto]	
2. Speed(mm/s)		6.25, 12.5, [25], 50	
3. Man. Mode		see Appendix A.4	
4. Auto. Mode		see Appendix A.4	
5. Rhythm Lead		I, [II], III, aVR/L/F, V1-V6	
6. Auto Rec. Length		Short, [Normal], Long, Long+	
7. Lead Mode		[Standard], Cabera	
8. AC Filter Freq.		50Hz, 60Hz	
9. EMG Filter Freq.		25Hz, [45Hz]	
10. Report Print Mode		None, Param, [Par+Ana]	
[MENU]Item, [F2/F3]Select, [F4/F5]Change, [F1]Return			

1. Sensitivity : 2.5/5/10/20/40mm/mV, and Auto[Default].
2. Speed : select paper speed at 6.25/12.5/25/50mm/s. .
3. Man.Mode : select Record format of Man Mode.
4. Auto.Mode : select Record format of Auto Mode.
5. Rhythm Lead : select Rhythm Lead for 1ch+/3ch+/6ch+/3ch+++format.
6. Auto.Rec Length : Recording Length for each Lead(s) in Auto Mode as following.



**Auto Rec. Length in Sec. Of different Record Format**

<b>FORMAT</b>	<b>Short</b>	<b>Normal</b>	<b>Long</b>	<b>Long+</b>
1ch/1ch+	18Sec.	27 Sec.	36 Sec.	45 Sec.
3ch/3ch+/3ch+++	10 Sec.	15 Sec.	20 Sec.	25 Sec.
6ch/6ch+	8 Sec.	12 Sec.	16 Sec.	24 Sec.
12ch	5 Sec.	7.5 Sec.	10 Sec.	12.5 Sec.

7. Lead Mode : Standard or Cabera Mode; shown as following.

**Lead Mode Definition**

<b>No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>
<b>Standard</b>	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
<b>Cabera</b>	aVL	I	-aVR	II	AVF	III	V1	V2	V3	V4	V5	V6

8. AC Filter Freq. : AC filter frequency : 50Hz or 60Hz.

9. EMG Filter Freq. : EMG filter frequency : 25Hz or 45Hz.

10. Report Print Mode : None, Parameters, Parameters+Interpretation Report Mode.

R-R/Rhythm Mode : None, Parameters, Parameters+Interpretation Report Mode.

STOR/Storage Mode : None, Parameters, Parameters+Interpretation Report Mode.



**NOTE : AC Filter Freq. : 50Hz or 60 Hz should comply with local power supply. Otherwise, anti-interference effect will be seriously impacted.**

**5.3.4. Advance** : 15 items of the sub-menu shown as following:


DATE	BASIC	[ADVANCE]	TOOLS
1.	Pen Heater	[No], Yes	
2.	QRS Beeper	[No], Yes	
3.	Keypad Beeper	No, [Yes]	
4.	Lead-off Beeper	No, [Yes]	
5.	Enable Ext. Input	No, [Yes]	
6.	ADS Filter	No, [Yes]	
7.	Stylus Printing	No, [Yes]	
8.	ECG Simulator	[No], Yes	
9.	Local Language	No, [Yes]	
10.	View of 12 Lead ECG	No, [Yes]	
11.	Prompt to save ECG	[No], Yes	
12.	Grid(mm) printing	[No], Yes	
13.	210mm Z-Fold paper	[No], Yes	
14.	ECG Aux.Analysis On	[No], Yes	
15.	Prompt repeated patient ID	[No], Yes	
[MENU]Item, [F2/F3]Select, [F4/F5]Change, [F1]Return			

1. Pen Heater : to print thick waveforms. It is not recommend when the ECG is new.
2. QRS Beeper : when QRS is detected, the machine will give a short Beep sound.
3. Keypad Beeper : when Keypad is pressed, the machine will give a short Beep sound.
4. Lead-off Beeper : If any electrode loose from patient body, beep will sounds and corresponding indication on the screen will be generated to alarm.
5. Enable Ext. Input : external analog signals can be input under MAN mode TEST.
6. ADS Filter : ADS(Anti-Drift-System) is used to restrain the ECG baseline drifting.
7. Stylus Printing : This option makes ECG printout more clear like stylus ECG recording.
8. ECG Simulator : Demonstration of ECG waveform.
9. Local Language : The default local language is English.
10. View 12 Lead ECG : choose "Yes" to display 12 lead ECG waveform.
11. Prompt to save ECG: Prompt to save ECG file after the ECG report is printed.
12. Grid(mm) printing: Printing millimeter grids in the empty thermal paper.
13. 210mm Z-Fold paper: The option is for 210mm Z-Fold paper in 12-channel ECG.
14. ECG Aux.Analysis On: The option will preview the ECG Analysis report.
15. Prompt repeated patient ID.: The option will prompt user repeated patient ID found.

**5.3.5. TOOLS** : 6 items of the submenu as shown as following:

DATE	BASIC	[ADVANCE]	TOOLS
1.	Load Default--AC50Hz	◀▶	
2.	Load Default--AC60Hz	◀▶	
3.	ECG File(s)	◀▶	
4.	Last Record Review	◀▶	
5.	UART/Real-time ECG	◀▶	
6.	Touch screen calibration	◀▶	
[MENU]Item, [F2/F3]Select, [F4/F5]Change, [F1]Return			

1. Load default-AC50Hz : The default setting for 50Hz AC frequency.
2. Load default-AC60Hz : The default setting for 60Hz AC frequency.
3. ECG File(s) : Show ECG file(s) of the machine, See 5.7、 ECG File Management.
4. Last Record Review : Review the last printed ECG record, user can preview/analysis ECG waveform, then save or print as ECG report. This function should be executed immediately after recording, otherwise the last ECG record may be cleared by the other operation . For details, please refer to the ECG Software Operation Manual. --CAUTION---: Only the last 12 second ECG recorded waveform can be reviewed.
5. UART/Real-time ECG : Transmit real-time ECG to UART (RJ11) interface. If a optional UART/USB cable is connected the personal computer, ECG can be displayed and saved in the computer (A optional ECG Archive software installed in computer is needed).
6. Touch screen calibration : Touch label (1)(2)(3)(4) point of LCD screen in the order, A [OK] button will be shown, then touch the [OK] button to confirm Touch Screen Calibration. This resistor touch-screen need proper pressure on it when clicking, so cilcking the touch-screen with a fingernail is recommended. The calibration is not necessary for the models which touch screen is not present.

	<b>NOTE : AC Filter Freq. : 50Hz or 60 Hz should comply with local power supply. Otherwise, anti-interference effect will be seriously impacted.</b>
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## 5.4. Patient Info. Setting

Press "PATIENT" key to setup Patient Information.

-----Clinical-----	
1. Name	XXXXXXXXXXXXXXXXXX
2. I.D.	0-999999999999
3. Sex	M/F/Empty
4. Age(Y)	0-255, 0 is Empty
5. Height (cm)	0-255, 0 is Empty
6. Weight (Kg)	0-255, 0 is Empty
7. Diastolic (KPa)	0-255, 0 is Empty
8. Systolic (KPa)	0-255, 0 is Empty
9. Hospital Name	XXXXXXXXXXXXXXXXXX
[Q] [W] [E] [R] [T] [Y] [U] [I] [O] [P] [A] [S] [D] [F] [G] [H] [J] [K] [L] [F1] [Z] [X] [C] [V] [B] [N] [M] [ ] [CLR] [F2/UP] [F3/DN] [F4/L] [F5/R] [BACK] [OK]	
<b>[*] : Cursor, [F2/F3/F4/F5] : Select, [Filter] : Back</b> <b>Touch [CLR] or Press [Fn]+Z clear patient info.</b>	

1. for NAME/HOSPITAL: Press [F1] to alter a-z/A-Z, next keep pressing [MENU], then press [F2 or F3 or F4 or F5] key to select the Alphabet key;
2. for ID : 12 bit Patient ID, if >0, ID will auto increase after printing(High 8 Bit is fixed).
3. for SEX : Male/Female/Empty, Press [MENU]+[F2/F3] to change the value.
4. for Age/Ht./Wt./B.P. : 0-255, Press [MENU]+[F2/F3/F4/F5] to change the value.

**CAUTION** : Setting ID/Sex/Age/Ht./Wt./B.P. zero means Null or Empty(no printing out).

**CAUTION** : Interpretation for ECG classification and judgments is based on the patient **SEX** and **AGE**. Empty **SEX** default is **MALE**, Zero **AGE** default is **18-YEARS-OLD**.

## 5.5. Record ECG

Press [Run/Stop] to start ECG sampling or printing after filling the patient's NAME/ID/SEX/AGE(see SECTION 5.4 patient info.) , Press the [Run/Stop] key again to stop recording in MAN and AUTO mode.

## 5.6. Freeze ECG (\*\*\*\*\*some model only\*\*\*\*\*)

Touch [Freeze] button of keypad to start freezing ECG, this function freeze and preview the 8 seconds after 4 second ECG sampling, user can preview/analysis ECG waveform, then save or copy the ECG report to built-in thermal printer or external USB printer via USB/Host interface.

The saved ECG file can be opened in ECG file function(see SECTION 5.7 ECG file management) .

## 5.7. ECG File Management

**5.7.1** Press or touch [File] key shows the ECG Files Management window as below. The ECG files can be previewed, edited, deleted or save as USB disk file. Press MENU to select menu function, press F2/F3 to select file, press F4/F5 to preview ECG waveform, press F1 return to MAIN windows.

-----ECG Files				=====ECG File Menu=====
ID=0000000001113	M	28Y	2012-10-02 09	Edit Patient
ID=0000000001123	F	22Y	2012-10-02 09:	Delete File
ID=0000000001124	F	29Y	2012-10-02 11:	Delete All Files
ID=0000000001125	M	44Y	2012-10-02 13	Save File To U-Disk
ID=0000000001128	M	61Y	2012-10-02 15	Save All Files To U-Disk
				Upload File
				Upload All Files
				-----
				[Fn]Rtn,[F2/3]Select,[F4/5]Exec
[Fn]MENU, [F2]PgUp, [F3]PgDn, [F4/F5]Review, [F1]Return				

### ◆ Edit Patient Info

Edit patient information(NAME,ID,SEX,AGE etc.) (see SECTION 5.4 Patient Info.) .

### ◆ Delete ECG file

Delete the choosen ECG file, Press F1 to delete this file.

### ◆ Save file To USB disk

Save ECG file as external USB disk file(FAT32) via USB/Host interface.

### ◆ Upload File

Upload ECG file to our ECG Archive software based on Personal Computer System.

## 5.7.2 . ECG Review

Press F4/F5 to review the set ECG data to REVIEW window, user can cine-loop, save, analysis, save ECG report as bitmap to external USB disk, or copy ECG report to built-in thermal printer or external USB printer via USB/Host interface.

### ◆ Save ECG

Save ECG wave of FREEZE or LAST PRINT REVIEW to the built-in flash memory.

◆ **Analysis ECG**

Calculate/Interprete the ECG waveform.

◆ **Save BMP To USB disk**

Save ECG bitmap report as external USB disk file (FAT32) via USB/Host interface.

◆ **Print ECG Report**


Print ECG Report to the built-in thermal printer.

◆ **USB Print ECG Report**

Print ECG Report to external USB printer via USB/Host interface.

◆ **Print Sync. ECG Report**

Print synchronous ECG Report to the built-in thermal printer.

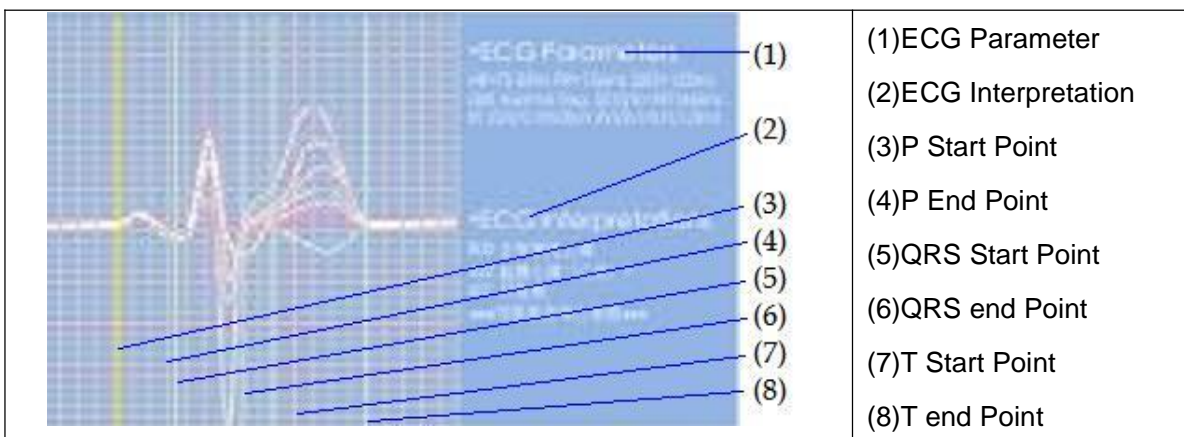
	<b>-----Using the USB disk and USB printer-----</b>
	◆ The USB disk MUST be formatted as FAT32 file system before using;
	◆ [-----R/W failure(Time Out)-----] will be shown if something wrong, it can be caused by bad file system or low speed( old USB disk or too many disk file or low disk space), so user should re-format or change a new USB disk.
	◆ Do not pull out the USB disk in working, Otherwise the file system of USB disk may be damaged; <b>CAUTION : Backup the USB disk data before using.</b>
	◆ This USB/HOST function is optional, Please check the machine configuration to your distributor.

**5.8. UART/USB communication**

UART/USB Interface(RJ11) is used for transmitting real-time ECG and ECG file to personal computer system.

**Note :** The UART / USB function needs the company’s optional UART/USB cable connecting the ECG machine with personal computer and ECG Archive software ( Optional ) installed in personal computer .

**5.9. ECG Explanation on measurement**



If setting [MENU]->[ADVANCE]->ECG Aux. Analysis is ON, a ECG ANALYSIS windows will shown when ECG interpretations is completed. User can change the ECG parameters and interpretations by pressing [F2/F3/F4/F5] to select/move P/QRS/T point.

The machine will measure the HR、 PR Interval、 QRS Interval、 QT/ QTC Interval、 P/QRS/T Axis、 RV1/SV5 Amp、 RV5/SV1 Amp. after ECG recording. Pay attention to the following in measurement and interpretations:

- ◆ AC and EMG Interference might cause mistakes in reading P Wave and Q Wave; baseline drift might cause misunderstanding in reading ST Segment and T Wave.
- ◆ Measuring error might occur due to blur endings of S Wave and T Wave.
- ◆ Low voltage might cause the measurement result of HR not reliable.
- ◆ Low voltage might cause the ECG coordinate axes calculation or QRS not reliable.
- ◆ Multi arrhythmia might make it difficult to recognize P Wave and the relative parameters might be unreliable.

## **6. Cleaning, Sterilization and Maintenance**

### **6.1. Recording Paper**

Please use the recommended recording paper or similar to ensure smooth move of paper, clear printing and extend the thermal printer's usage life.

- ◆ Avoid use of greyish and blackish paper;
- ◆ High temperature, high humidity and direct sunshine will cause paper color change.

Please keep the paper in a dry and cool place;

- ◆ Do not expose the paper in fluorescent light for a long time;
- ◆ Do not store the paper with PVC to avoid color change;
- ◆ Do not pile up the recorded paper for a long time to avoid waveform transfer.

### **6.2. Points to be notified after operation**

- ◆ Press "START/STOP" to stop the device, then turn off the power;
- ◆ Do not drag the patient cable with force;
- ◆ Clean the main unit and accessories then put the device in a dust-free cover;
- ◆ Keep the device in a dry and cool place;
- ◆ Avoid sharp shock while moving the device.

### **6.3. Patient cable function check and cleaning**

The patient cable can be checked by a multi-meter. The impedance should be less than 50Ω. The patient cable must be checked at a certain time interval as any damage of the cable will interfere ECG wave-forms. Soap and water can be applied to clean the patient cable, and 75% alcohol can be used for disinfection. Don't immerse the patient cable into water.

#### **6.4. Patient cable's usage life**

Zigzag or knot the patient cable may shorten its usage life.

#### **6.5. Electrodes**

Electrodes must be carefully kept. Longtime application may cause color change due to corrosion and oxidation and the electrodes must be changed.

#### **6.6. Cleaning the device**

The device must be powered off before cleaning. Remember not to immerse the device into cleaning solution. Don't use alcohol or disinfectant for cleaning.

#### **6.7. Maintenance of the rubber axis**

The rub axis should be kept level off, smooth, and dust free. Apply a soft cotton cloth with a little alcohol to wipe the axis softly and vertically for cleaning.

#### **6.8. Cleaning the thermal printer head**

Dirt and dust on the printer head may affect printing quality. Open the paper cabinet, apply a clean soft cotton cloth with a little alcohol, gently wipe the printer head. After the volatilization of the alcohol, close the cabinet. The printer head should be cleaned monthly. Remember no metal tools to be applied for cleaning the printer head

.

#### **6.9. Replacement of fuse**

Switch on AC power but the power indicator doesn't light up. This may be caused by a burnt fuse. Plug out the power cord from the power socket, unscrew the fuse cover at the bottom of the device and replace a new fuse.



NOTE: If a newly replaced fuse is burnt again, please power off the device and contact our service department or appointed maintenance center.

#### **6.10. Battery recharge and replacement**

The device is configured with a recharge circuit and a protection circuit. When the device is connected with AC power, turn on the power and the battery will be recharged. The battery should be recharged or discharged every 3 months. The battery should be recharged for at least 6 hours before working for the first time.

When the device uses DC power supply, the battery symbol will be displayed on the LCD. Flash of battery indicates the battery is in low volume and needs to be recharged. Replacement of battery : Open the battery box in the bottom panel by trained service personnel.



## 7. Troubleshooting and solution

### 7.1. Some lead without waveform

When the cables connected with the patient, usually needs several seconds to get ready.

Solution: press RESET and start recording after 2~3 seconds.

### 7.2. Vertical broken track of printed waveform

This may be caused by dirt on the printer head.

Solution: clean the printer head. If the problem still exist, there may be damage of the printer head.

Please contact our service department or appointed maintenance center.

### 7.3. Keypad doesn't work

This may be caused by loose connection between the keypad and the main unit.

Solution: a trained technician may open the panel and tighten the connection. If the problem still exist,

Please contact our service department or appointed maintenance center.

### 7.4. AC interference

AC interference may cause regular 50Hz sine wave repeat and apparent wobble of baseline.



Solution: check the following:

- 【×】 The machine is properly grounded;
- 【×】 Electrodes or patient cable are correctly connected;
- 【×】 Enough cream applied;
- 【×】 Metal bed properly grounded;
- 【×】 Patient disconnects metal part of bed;
- 【×】 Other person detach the patient;
- 【×】 Close powerful equipment operating nearby;
- 【×】 Patient with no glass or diamond ornaments.

If still exist, please apply AC filter. The QRS waveform will be weakened a little.

### 7.5. EMG interference

EMG interference may cause irregular wobble of waveform.



Solution: check the following:

- 【×】 The room is too cold;
- 【×】 The patient is nervous;
- 【×】 The bed is too narrow;
- 【×】 The patient is talking or moving;
- 【×】 The limb electrodes are too tightly attached

If still exist, please apply EMG filter. The QRS waveform will be weakened a little more.

## 7.6. Unstable baseline



Solution: Check the following:

- 【×】 Electrodes properly placed;
- 【×】 Patient cable and electrodes properly connected;
- 【×】 Electrodes and patient skin applied enough cream;
- 【×】 Patient moving or irregular breath;
- 【×】 Old electrodes and new ones mixed up;

If still exist, Please contact with our service department or appointed maintenance center.

## 7.7. Print nothing after a long time printing

When the device continue printing for long time( about 2 hours), the thermal unit of printer may be in high temperature, it cause the over-heat-protection to stop printing. Stop printing for about 15 minutes, the device will be all right.

# 8. Service Warranty

## 8.1. Workmanship and Raw Material

The warranty period for the main unit is 18 months and, 9 months for the accessories from the date of shipment. The company warrants that there's no defect in raw material and workmanship. During warranty period, The Company will repair or replace the defective part free of charge if the defect has been confirmed as raw material or workmanship defect.

## 8.2. Software or Firmware

For the software or firmware installed, The Company 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 The Company can not warrant it will not interrupt the use of the ECG.

NOTE : All services must be finished by engineers authorized by the company or its authorized distributor.

### 8.3. Exemption of Warranty

The charges of freight and others are excluded under warranty. The Exemption 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.

## 9. Accessories

<b>№</b>	<b>Description</b>	<b>Quantity</b>	<b>Comment</b>
<b>1</b>	Patient cable	1 unit	
<b>2</b>	Limb electrode	4 pcs/set	
<b>3</b>	Chest electrodes	6 pcs/set	
<b>4</b>	Grounding cable	1 pc	
<b>5</b>	Paper axis	1 pc	
<b>6</b>	Thermal paper	1 roll	
<b>7</b>	Fuse	2 pcs	
<b>8</b>	3-cord power cord	1 pc	
<b>Option 1</b>	UART/USB cable	1 pc	Cable connecting ECG and PC
<b>Option 2</b>	ECG Archive Software	1 pc	Personal computer software disc.

## Appendix A.1 : Product Standards

MDD93/42/EEC	Medical Device Directive
IEC60601-1 GB9706.1-2007	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-2-25 GB10793-2000	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
EN 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
EN 60601-2-51	Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multi-channel electrocardiographs
EN ISO14971	Medical devices - Application of risk management to medical devices
ANSI/AAMI EC-11	Diagnostic Electrocardiographic Devices
YY1139-2000	single channel and multi-channel ECG

## Appendix A.2 : 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, type A

## Appendix A.3 : Technical characteristics

Items	Specification	
Lead	standard 12 leads	
lead acquisition	12bit/1000Hz (synchronously 12 leads )	
Work mode	MAN、 AUTO、 R-R、 STOR Modes	
Filter	AC Filter : 50Hz / 60Hz EMG Filter : 25Hz / 45Hz Anti-Drift Filter : 0.15Hz (Adaptive)	
CMMR	≥120dB (with AC FILTER)	
Input circuit	Floating; Protection against Defibrillator effect	
Input Impedance	≥50MΩ	
Input circuit current	≤0.05μA	
Input dynamic range	±10mVp-p	
Patient current leakage	< 10μA	
Calibrating voltage	1mV±2%	
Voltage tolerance	≥±500mV	
Time constant	≥3.2s	
Frequency response	0.05 ~ 160Hz(-3db)	
Noise level	< 15μVp-p	
Sensitivity valve	≤20μV	
Sensitivity	5, 10, 20, 40mm/mV, Auto	
Inter-channel Interference	≤0.5mm	
Paper speed	6.25, 12.5, 25, 50mm/s (±3%)	
IEC 60601-1/UL60601-1 EN 60601-1-2 Safety classification	Class I, Type CF, IPX0 Applied Parts : Patient Cable Not suitable for use in the presence of a flammable anesthetic mixture (No AP/APG Protection) Continuous operation	
Storage	Temperature	-20°C ~ +55°C
	Relative Humidity	25% ~ 95%
	Atmospheric Pressure	700hPa ~ 1060hPa
Operation	Temperature	+5°C ~ +40°C
	Relative Humidity	25% ~ 80%
	Atmospheric Pressure	860hPa ~ 1060hPa
External In	Input impedance	>100kΩ
	Input Sensitivity	10mm/V±5%
	Output impedance	≤100Ω
	Output Sensitivity	1V/mV±5%

## Appendix A.4 : Model and Specification

Items	Specification
Recording mode	ECG-3301G : 1ch、 1ch+ ECG-3303B/G : 1ch+、 3ch、 3ch+
Recording method	Thermal Array printing
Paper specifications	ECG-3301G : 50mm Roll ECG-3303B/G : 80mm Roll
LCD display	ECG-3301G : 320x240 LCD(3.5 inch) ECG-3303B : 320x240 LCD(3.5 inch) ECG-3303G : 800x480 LCD(5.0 inch)
Case Storage	250 ECG cases (Expandable)
Communication	USB/UART Port, LAN(not present)
Power supply	AC 110 ~ 230V (±10%) , 50/60Hz(±1Hz) ; 40VA DC : Built In Rechargeable Battery ; 12V/1500mAh
Fuse	T2A/250V, φ5x20
Dimension/Weight	ECG-3301G : 300mm×230mm×72mm, 2.8Kg ECG-3303B/G : 300mm×230mm×72mm, 2.8Kg