User Manual

EDAN

SE-1010

PC ECG

Version 1.0

CE 0123

About this Manual

P/N: 01.54.455698-10

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

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

CAUTION

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

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Table of Contents

Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of SE-1010 PC ECG.

1.1 Intended Use

SE-1010 PC ECG is a PC-based diagnostic tool intended to acquire, process and store ECG signals from adult and pediatric patients undergoing stress exercise test or resting test. SE-1010 PC ECG is intended to be used only in hospitals and healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

WARNING

1. This system is not designed for intracardiac use or direct cardiac application.
2. This system is not intended for home use.
3. This system is not intended for treatment or monitoring.
4. This system is intended for use on adult and pediatric patients only.
5. The results given by the system should be examined based on the overall clinical condition of the patient, and they can not substitute for regular checking.

1.2 Warnings and Cautions

To use the system safely and effectively, firstly be familiar with the operation method of Windows and read the user manual in detail to be familiar with the proper operation method for the purpose of avoiding the possibility of system failure. The following warnings and cautions must be paid more attention to during the operation of the system.

1.2.1 General Warnings

WARNING

1. The system is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.

WARNING

2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell.
3. **EXPLOSION HAZARD** - Do not use the system in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. **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.
5. Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed. The system has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the system is operated with cardiac pacemakers or other stimulators.
6. Make sure that all electrodes are connected to the patient correctly before operation.
7. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.
8. If reusable electrodes with electrode gel are used during defibrillation, the system recovery will take more than 10 seconds. The manufacturer recommends the use of disposable electrodes at all times.
9. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.
10. The disposable electrodes can only be used for one time.
11. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
12. Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.
13. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.
14. Fix attention on the examination to avoid missing important ECG waves.
15. **SHOCK HAZARD** - Don’t connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.

WARNING

16. **SHOCK HAZARD** - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
17. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1-1 approved to the system. The operation or use of non-approved equipment or accessories with the system is not tested or supported, and system operation and safety are not guaranteed.
18. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
19. Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.
20. Multiple portable socket-outlets shall not be placed on the floor.
21. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.
22. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard IEC/EN 60601-1-1. 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/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
23. Connecting any accessory (such as external printer) or other device (such as the computer) to this electrocardiograph makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
    a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
    b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
24. All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

WARNING

25. You should purchase computer, printer, and bar code reader from the manufacturer. Otherwise, the manufacturer will not be held responsible for the maintenance of the PC hardware, operating system and other accessories.
26. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.
27. Connecting to other devices may decrease the antistatic gradation of the system during operation.
28. Make sure that there is no intense electromagnetic interference source around when using the wireless system of PC ECG.
29. Do not open the battery cover of DX12 transmitter when using the wireless system of PC ECG.
30. The tablet shall comply with the valid version of the standard IEC 60950 and be used outside the patient environment (at least 2 meters away from the patient). The tablet PC shall be charged outside the patient environment, and no operations are permitted during the charging.

1.2.2 Li-ion Battery Care Warnings

WARNING

1. Improper operation may cause the internal li-ion battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
2. Batteries of the same model and specification as manufacture configuration should be used.
3. **DANGER OF EXPLOSION** -- Do not reverse the anode and the cathode when installing the battery.
4. Do not heat or splash the battery or throw it into fire or water.
5. Do not destroy the battery; do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.

WARNING

6. When leakage or foul smell is 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.
7. Properly dispose of or recycle the depleted battery according to local regulations.
8. Remove the battery from the transmitter if the system won't be used for a long time.

1.2.3 General Cautions

CAUTION

1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.
2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.
3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
4. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
5. Federal (U.S.) law restricts this device to sale by or on the order of a physician.

1.3 List of Symbols

	Equipment or part of CF type with defibrillator proof
	Caution
	Consult Instructions for Use
	Recycle
P/N	Part Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	It indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
Rx only (U.S.)	Federal (US) law restricts this device to sale by or on the order of a physician
	Class Ⅱ

Chapter 2 Introduction

SE-1010 PC ECG is a mobile PC ECG workstation, which has similar functions with an ordinary electrocardiograph. ECG data can be sampled, analyzed and stored in a PC, and it can be saved in PDF, Word, BMP or JPG format. ECG waves can be frozen and reviewed. Auto measurement and diagnosis are available, and the diagnosis template can be edited. Moreover, SE-1010 PC ECG can transmit ECG data to Smart ECG Net system over LAN.

With a large capacious built-in battery, a portable and compact size, SE-1010 PC ECG is suitable for doctors' inspections and visits and can perform a reliable data recording anywhere at any time.

SE-1010 PC ECG includes the following equipment, you can also purchase the tablet PC.

- DP12 ECG sampling box
- PC ECG software
- ECG Sampling Box (wired or wireless system)
- Patient Cable
- Electrodes
- Sentinel
- USB Cable

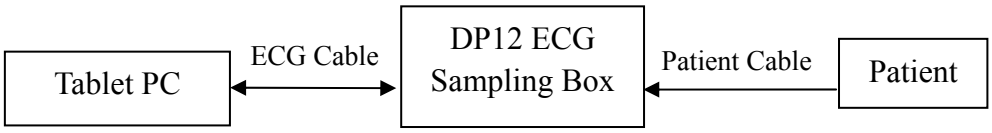
NOTE: The pictures and windows in this manual are for reference only.

2.1 Assembling the System

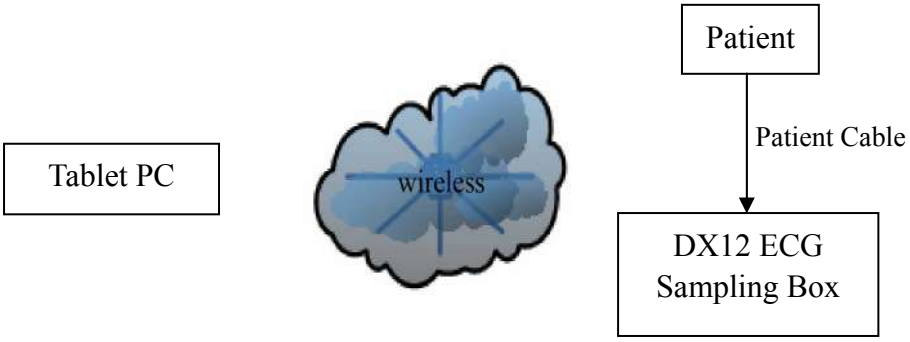
2.1.1 SE-1010 PC ECG System

The docking station configured with the tablet PC includes 3 USB interfaces, 1 net port and 1 HDMI port. You can connect the printer, keyboard or mouse by using the USB interfaces.

1. The Wired System



2. The Wireless System



WARNING

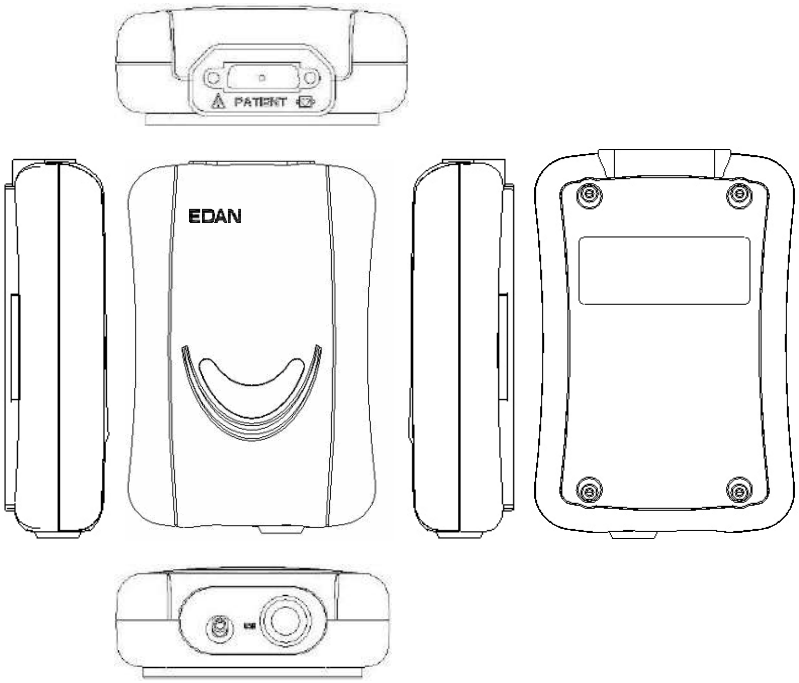
DX12 transmitter of the wireless system uses the Bluetooth technology, which could make the patient with the pacemaker uncomfortable. Keep DX12 transmitter far away from the pacemaker when using the wireless system of PC ECG.

WARNING

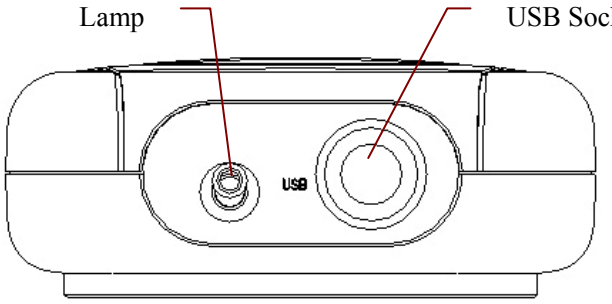
1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard IEC/EN 60601-1-1. 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/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
2. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

2.1.2 DP12 ECG Sampling Box of the Wired System

DP12 ECG Sampling Box Appearance

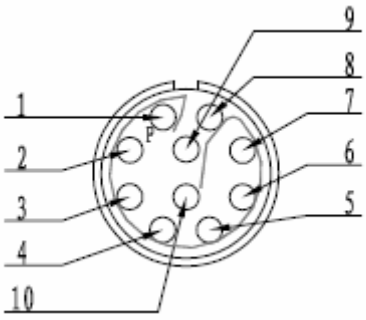


Front Panel



Name	Explanation
Lamp	When the ECG sampling box is powered by the PC, the lamp will be lit.
USB Socket	Connecting to the USB socket of the PC with a USB cable

USB Socket



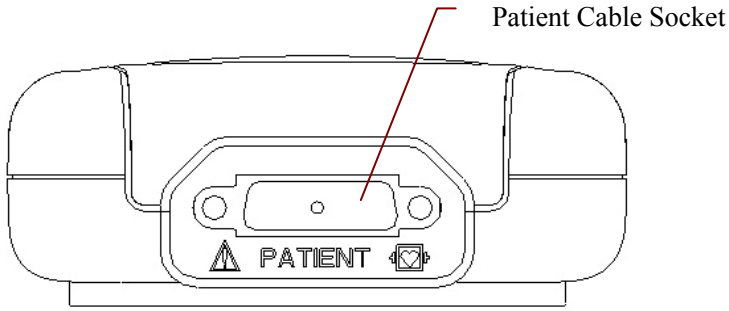
Definitions of corresponding pins:

Pin	Signal	Pin	Signal
1	GND	**6**	GND
2	VCC	**7**	GND
3	QRS	**8**	GND
4	GND	**9**	D-
5	GND	**10**	D+

WARNING

1. When the computer connected to the USB cable is powered on, do not connect the USB cable to the DP12 ECG sampling box; when the system is powered on, do not disconnect the USB cable from the ECG sampling box.
2. It is not necessary or recommended to regularly disconnect the USB cable from the DP12 ECG sampling box. Disconnect the USB cable from the PC if necessary.

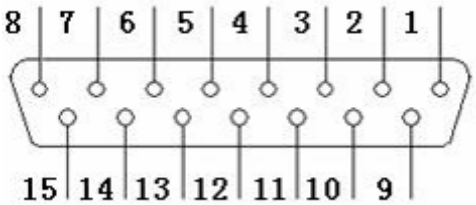
Back Panel



: Applied part of type CF with defibrillator proof

: Caution

Patient Cable Socket

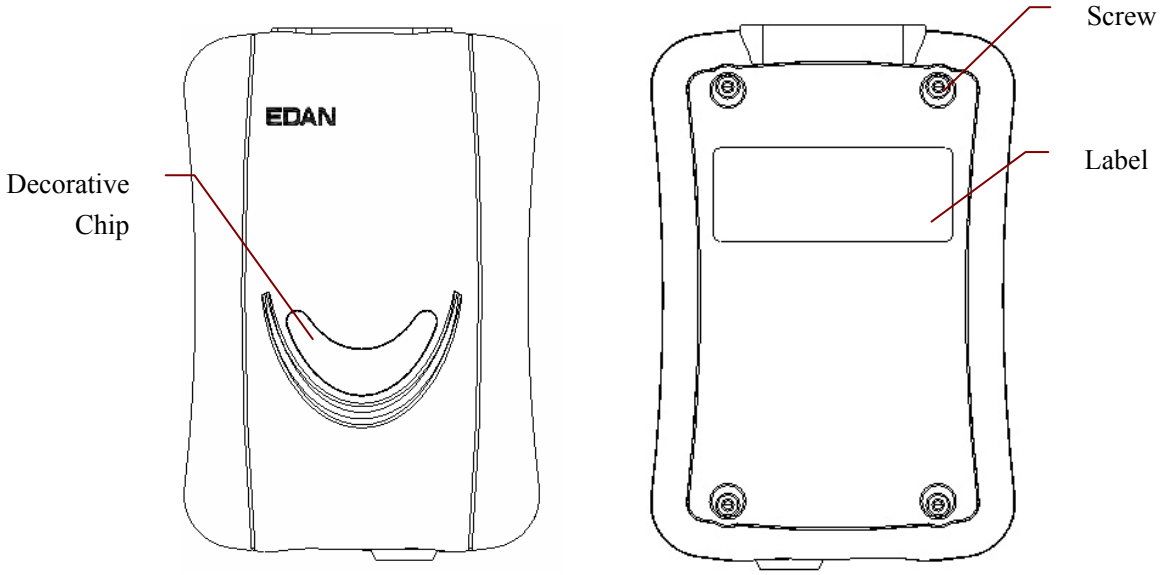


Definitions of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 / V2	**6**	SH	**11**	F / LL
2	C3 / V3	**7**	NC	**12**	C1 / V1 or NC
3	C4 / V4	**8**	NC	**13**	C1 / V1
4	C5 / V5	**9**	R / RA	**14**	RF (N) /RL or NC
5	C6 / V6	**10**	L / LA	**15**	RF (N) / RL

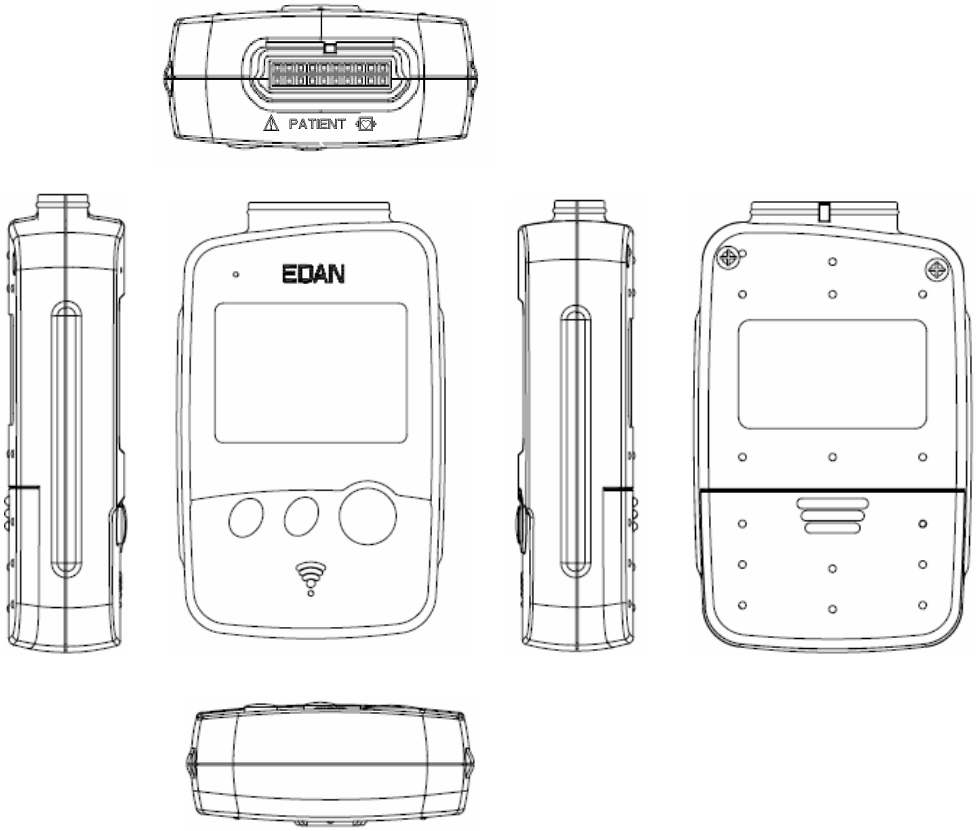
NOTE: The left side of "/" is European standard, and the right side is American standard.

Top Panel and Bottom Panel

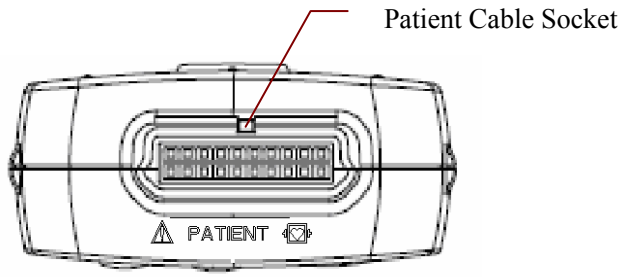


2.1.3 DX12 ECG Sampling Box of the Wireless System

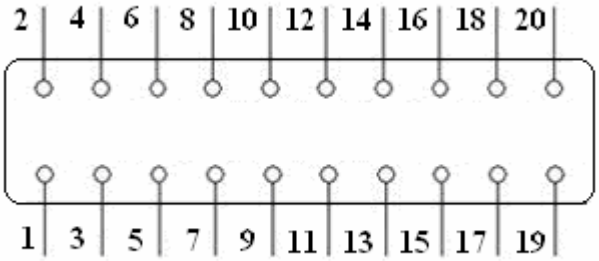
DX12 Transmitter Appearance



Front Panel



Patient Cable Socket



: Applied part of type CF with defibrillator proof

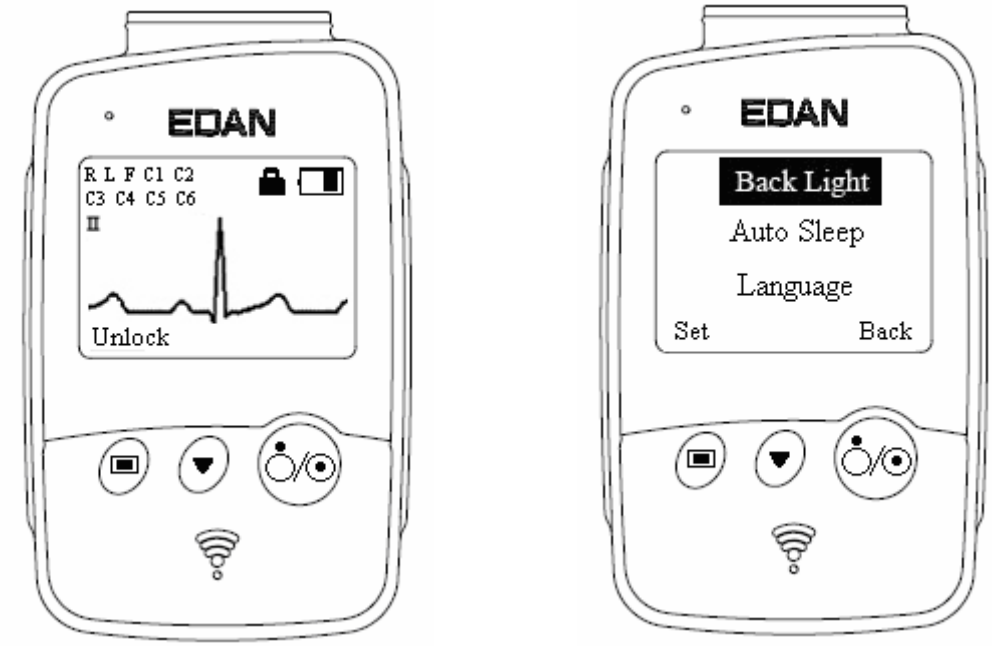
: Caution

Definitions of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal	Pin	Signal
1	NC	**6**	C5/V5	**11**	NC	**16**	L/LA
2	F/LL	**7**	NC	**12**	C2/V2	**17**	NC
3	NC	**8**	C4/V4	**13**	NC	**18**	R/RA
4	C6/V6	**9**	NC	**14**	C1/V1	**19**	NC
5	NC	**10**	C3/V3	**15**	NC	**20**	N/RL

NOTE: The left side of "/" is European standard, and the right side is American standard.

2.1.3.1 Keys and Icons



Main Screen Menu Screen

Keys/Icons	Description
	After batteries are installed, press this key to turn on/off DX12 transmitter. When the Menus screen is displayed, press this key to return to the previous screen.
	When the Main or Menu screen is displayed, press this key to enter the next menu. Press this key, and then press  in 1.2 seconds to lock / unlock the keypad.
	When the Main screen is displayed, press this key to switch the lead. When the Menu screen is displayed, press this key to display an item in black.
	Icon for Bluetooth Connection If this icon is not displayed on the main screen, you need to match the device manually.

	Icon for Keypad Locked If no operation is taken, the Main screen will be displayed and the keyboard will be locked automatically in 8 seconds.
	Icon for Battery Capacity When the battery is weak, a hint will be displayed in SE-1010 PC ECG software.

2.1.3.2 Setting the Menu

Menu	Description
Back Light	Select **On** to turn on the backlight of LCD screen. Select **Off** to turn off the backlight of LCD screen.
Auto Sleep	Select **On** to display **Sleeping** on the screen and make DX12 transmitter be in low power consumption mode after lead off for 5 minutes. Select **Off** to turn off auto sleep function.
Language	You can select **English** or **Chinese**.
Lead Electrode	You can select **IEC** or **AHA**.
Match Device	**Inquiring……**will be displayed (for 10 seconds) to search the device. The address of the device will be displayed (for 8 seconds) if a matching device is found. **No device found. Try again later** will be displayed (for 1 second) if no matching device is found.
Device Information	You can see the related information, such as software version, ID, address of the device, manufacture and release time about the device. **NOTE:** The device information is for reference only.

2.2 Assembling the Software

NOTE:

1. Before the delivery, the operating system has been installed in the tablet PC; If you purchase the wireless system of PC ECG, the tablet PC has been matched with the corresponding DX12 transmitter, extra installations or configurations are not needed.
2. This section is only for reference when the operating system of the tablet PC needs to be reinstalled or DX12 transmitter is broken.

2.2.1 System Running Environment

Operating System	Windows7 ultimate
CPU:	Dual core 1.5GHZ or above
System Memory (RAM):	1G or above
Hard Disk:	32G or above
Display:	10.1” TFT (Resolution: 1280*800)
Wireless Network Card:	Built-in WIFI, IEEE802.11B/G/N
External Interface:	USB2.0
Bluetooth:	Bluetooth 2.1 or 3.0 (Bluetooth 4.0 is not supported)

2.2.2 About Installation Window

Double-click on **Setup.exe** 

in the installation folder to open the following installation window.

Click on the **Install** button to install PC ECG. Click on the **Next** button continually during installation.

After installing PC ECG, click on the **Install** button in the installation window. Then the **Environment Detection** window pops up. Check the installing status of all the components. If the **Environment Detection** window shows that a certain component needs to be installed, please install it manually.

NOTE: During the installation of SQL Server 2005 Express in Windows 7, only if **Add user to the SQL Server Administrator role** is selected, can the database be available.

Click on the **Help** button to see the installation guide.

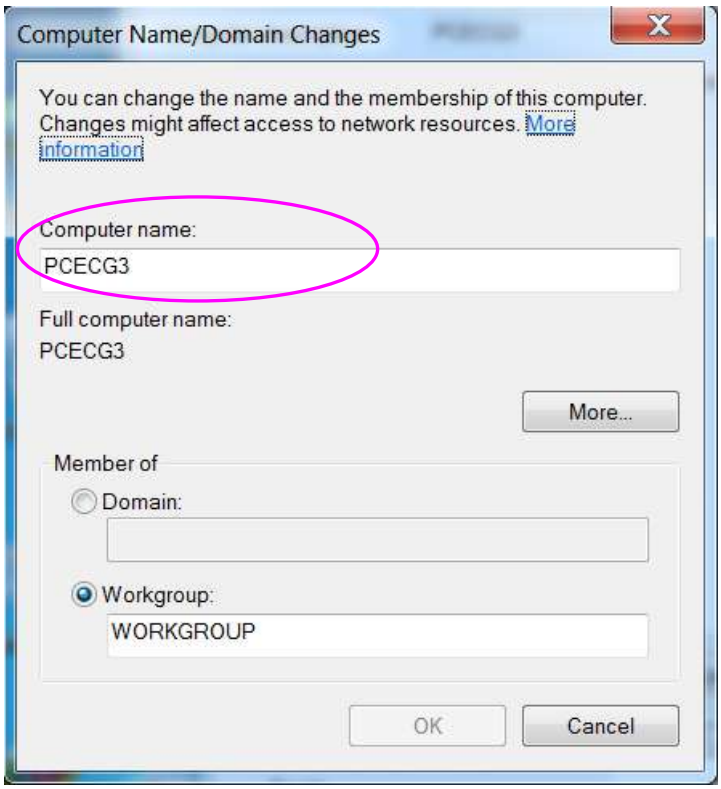
For details on installing PC ECG software, please refer to *SE-1010 PC ECG Installation Guide.*

2.2.3 Matching DX12 Transmitter with Tablet PC

NOTE: Ensure batteries of DX12 transmitter and tablet PC are full, the tablet PC is powered on and enter the operating system before matching DX12 transmitter and the tablet PC.

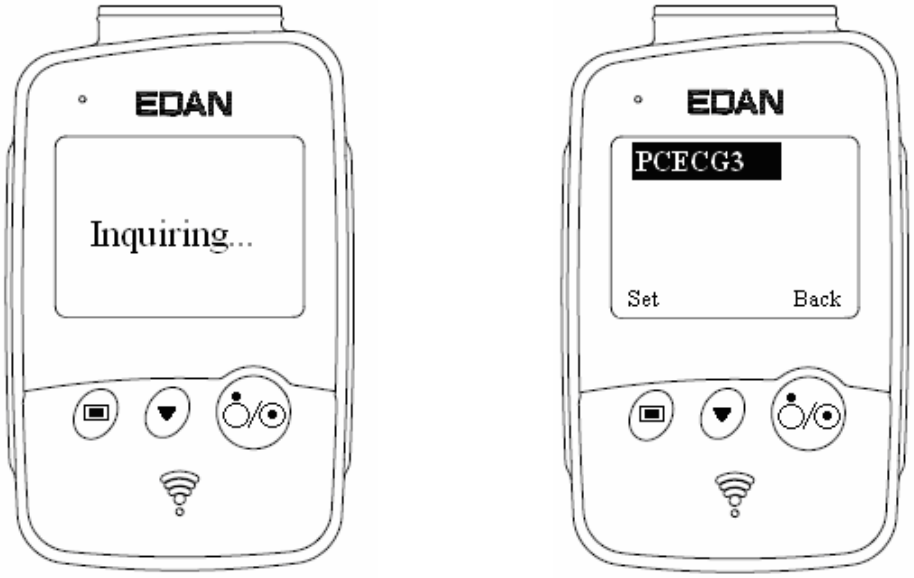
1. Press the icon for **My Computer** for a while, choose **Prosperities** -> **Change Settings** -> **Change (C)…,** input **PCECG** in the **Computer name** textbox, and then click on the **OK** button.

   If more than one tablet PC is around, you can input **PCECG1**, **PCECG2** or **PCECG3** in the **Computer name** textbox. The maximum number after **PCECG** can be set to **999**.



2. Display **Match Device** item in black on the Menu screen, and then press  to open the following screen.

   Inquiring… will be displayed for 8s, and then the computer names (such as, **PCECG1**, **PCECG2** or **PCECG3**) of the power-up tablet PCs will displayed on the screen of DX12 transmitter.

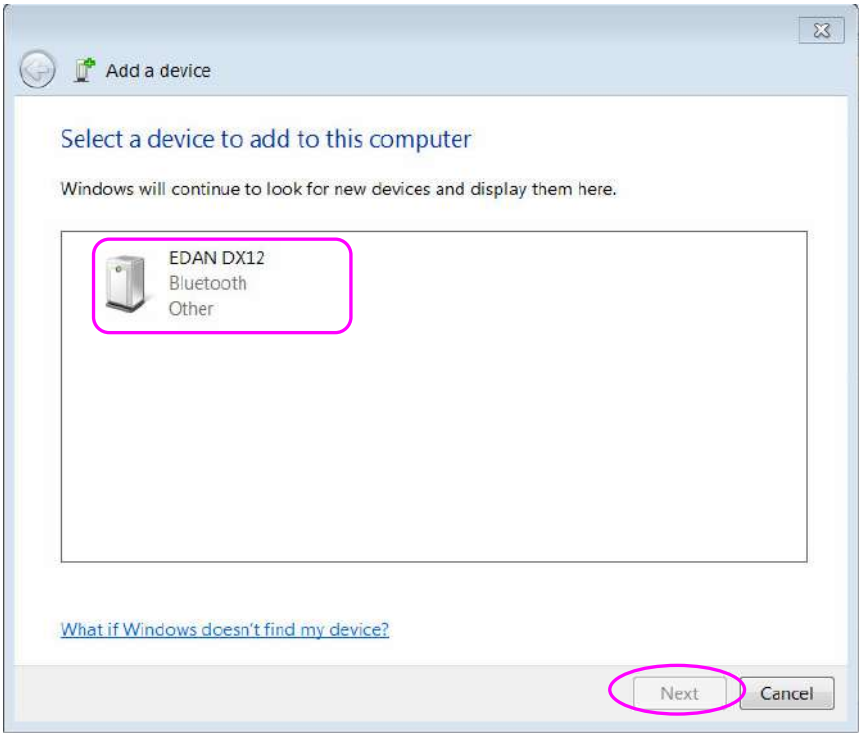


3. Select the computer name for the required tablet PC on the screen of DX12 transmitter, and then press  to confirm.

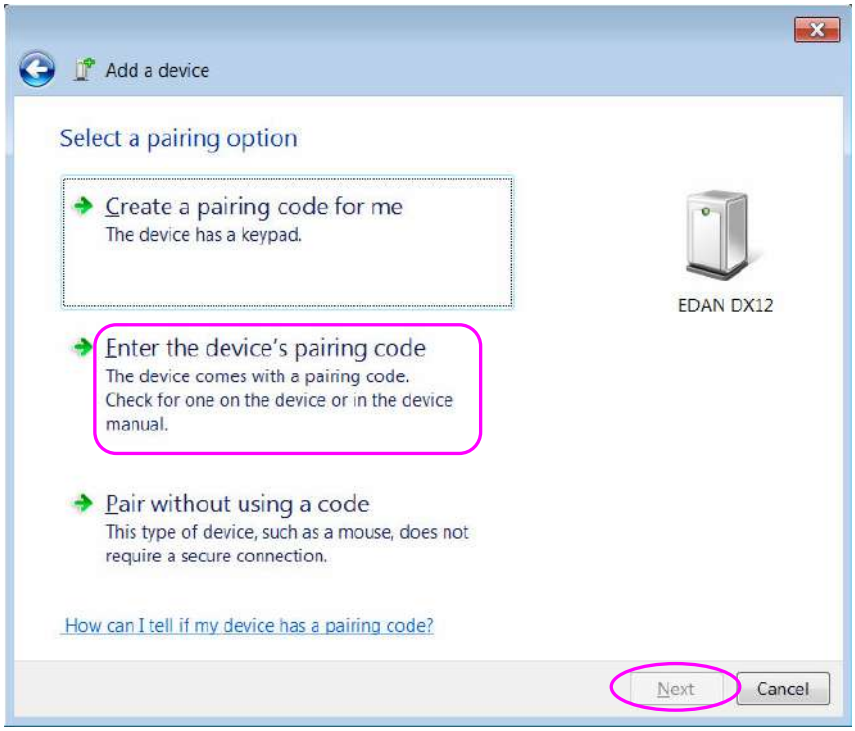
   Initializing… will be displayed for 8s, and then **Initialization is completed，the system will restart in 5s.** will be displayed on the screen of DX12 transmitter.

4. After DX12 transmitter restarts, choose  -> **Devices and Printers** -> **Add a Device**, select the required device and click on the **Next** button.

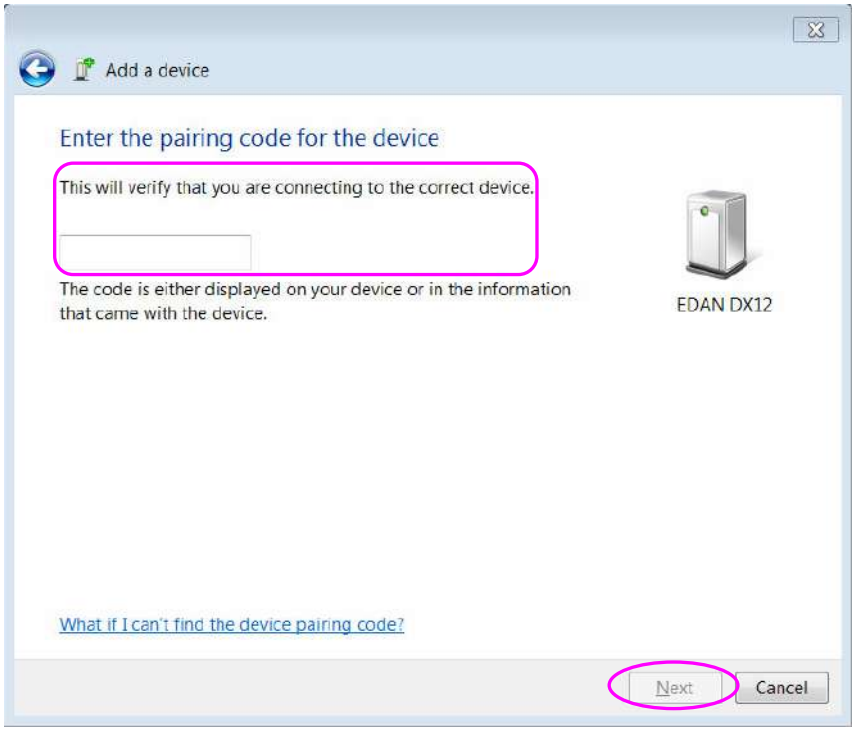
   NOTE: When selecting the required DX12 transmitter, ensure the required one is powered on, and the others are powered off.



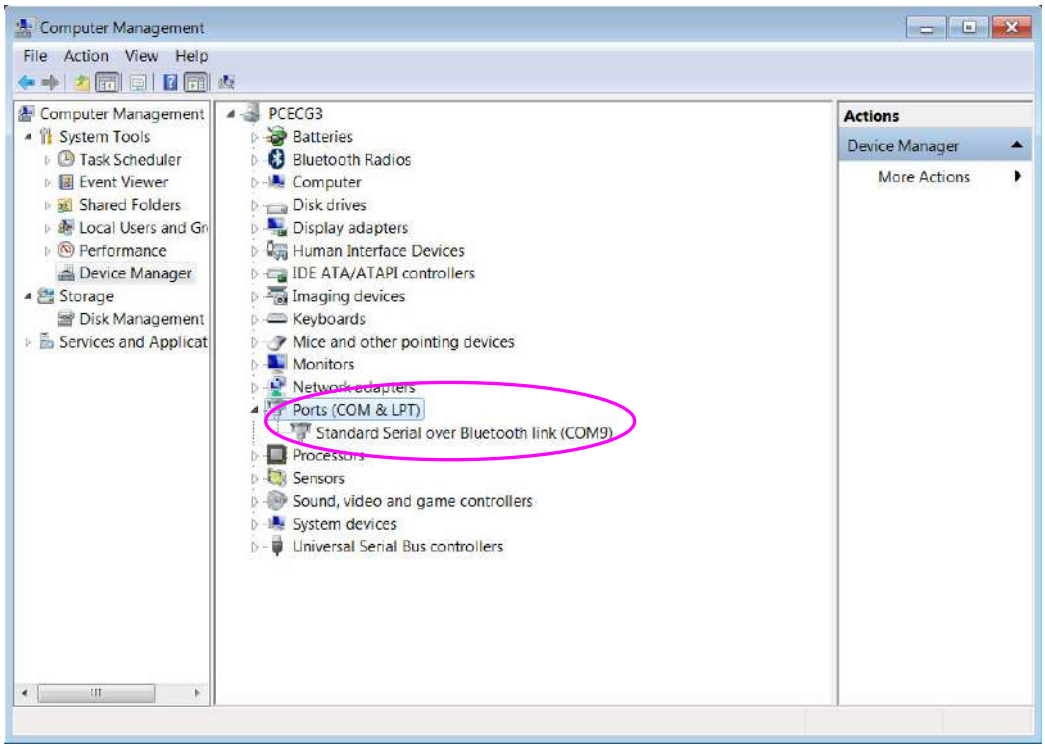
5. Click on **Enter the device's pairing code**, and then click on the **Next** button.



6. Input the default password (12345678), and then click on the **Next** button to confirm.



7. After a successful match, you can view the port on the **Device Manager** screen.



2.3 Features

- ♦ Supporting order function
- ♦ Transmitting ECG data to Smart ECG Net system over LAN
- ♦ Powerful functions, friendly windows and easy operation
- ♦ 3/6/12-channel ECG waves are displayed and printed simultaneously
- ♦ ECG waves can be frozen and reviewed
- ♦ Supporting auto measurement and diagnosis
- ♦ Measurement point adjustment and re-analysis, manual measurement with an electronic ruler of high precision
- ♦ Perfect data management and processing functions
- ♦ Reports can be printed in PDF, Word, JPG or BMP format
- ♦ Automatic baseline adjustment for optimal printing
- ♦ High performance filters guarantee stable ECG waveforms
- ♦ Real-time analysis, real-time displaying and printing 12-lead simultaneous ECG waveforms
- ♦ 12-lead normal ECG analysis

Chapter 3 Preparations Before Operation

3.1 Preparing the Patient

3.1.1 Instructing the Patient

Before attaching the electrodes, greet the patient and explain the procedure. Explaining the procedure decreases the patient's anxiety. Reassure the patient that the procedure is painless. Privacy is important for relaxation. When possible, prepare the patient in a quiet room or area where others can't see the patient. Make sure that the patient is comfortable. The more relaxed the patient is, the less the ECG will be affected by noise.

3.1.2 Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifacts that distort the ECG signals. By performing methodical skin preparation, you can greatly reduce the possibility of noise caused by muscle tremor and baseline drift, ensuring high-quality ECG waves. There is natural resistance on the skin surface due to dry, dead epidermal cells, oils and dirt.

To prepare the skin

1. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.
2. Wash the area thoroughly with soap and water.
3. Dry the skin to increase capillary blood flow and to remove the dead, dry skin cells and oils.
4. Use the disposable frosting film in the standard accessory list to get good ECG waveform.

NOTE: Rub the skin with a gauze pad to increase capillary blood flow if you don't operate the steps above.

3.2 Connecting the Patient Cable

WARNING

The performance and electric shock protection can be guaranteed only if the original patient cable and electrodes of the manufacturer are used.

The patient cable includes main cable and lead wires which can be connected to electrodes according to the colors and identifiers.

Patient Cable for Wired System

Connect the patient cable to DP12 ECG sampling box of the wired system, and then secure them with two screws.

Patient Cable for Wireless System

Insert the patient cable into the socket of DX12 transmitter for the wireless system.

3.3 Attaching Electrodes

WARNING

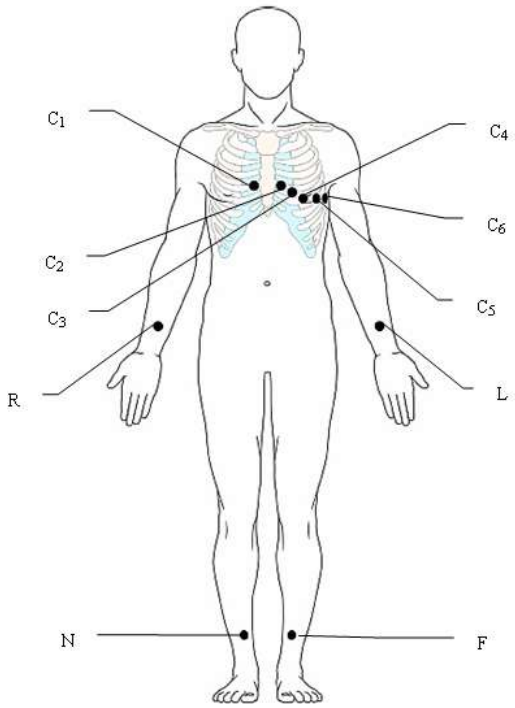
Make sure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

The identifiers and color codes of electrodes used comply with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifiers and color codes are specified in the following table. Moreover the equivalent codes according to American requirements are given in the following table too.

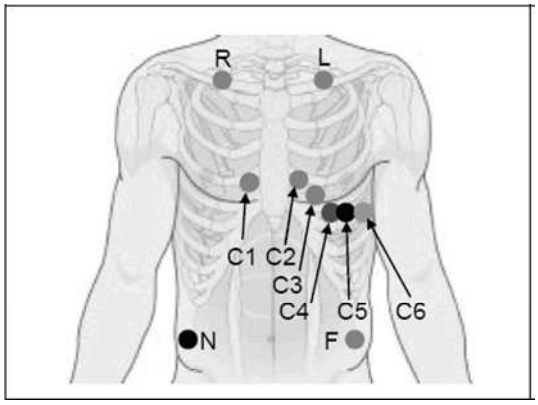
Table 3-1 Electrodes and Their Identifiers and Color Codes

		European		American	
WILSON	**FRANK**	**Identifier**	**Color Code**	**Identifier**	**Color Code**
Right arm	Right arm	R	Red	RA	White
Left arm	Left arm	L	Yellow	LA	Black
Right leg	Right leg	N or RF	Black	RL	Green
Left leg	Left leg	F	Green	LL	Red
Chest 1	I	C1	White/Red	V1	Brown/Red
Chest 2	E	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C	C3	White/Green	V3	Brown/Green
Chest 4	A	C4	White/Brown	V4	Brown/Blue
Chest 5	M	C5	White/Black	V5	Brown/Orange
Chest 6	H	C6	White/Violet	V6	Brown/Violet

3.3.1 Electrode Placement



Only for the Reusable Electrodes

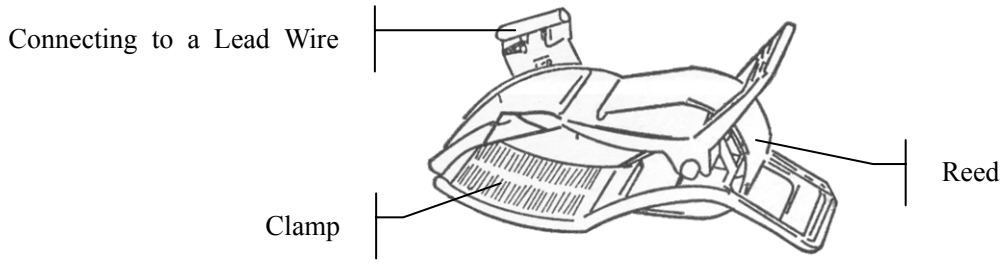


Only for the Disposable Electrodes

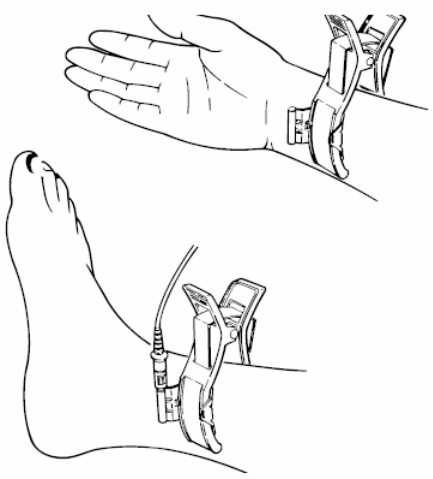
European Label	American Label	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4	V4	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal level of C4
C6	V6	Left midaxillary line at the horizontal level of C4
L	LA	Right arm/Right deltoid
R	RA	Left arm/Left deltoid
F	LL	Right leg/Upper leg as close to torso as possible
N	RL	Left leg/Upper leg as close to torso as possible

3.3.2 Attaching the Reusable Electrodes

3.3.2.1 Attaching the Limb Electrodes



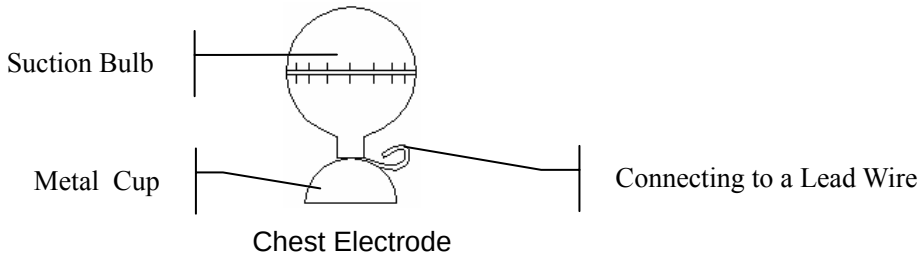
Limb Electrode



Limb Electrode Connection:

1) Ensure that the electrodes are clean;
2) Clean the electrode area which is a short distance above the ankle or the wrist with 75% alcohol;
3) Daub the electrode area on the limb with gel evenly;
4) Place a small amount of gel on the metal part of the limb electrode clamp;
5) Connect the electrode to the limb, and make sure that the metal part is placed on the electrode area above the ankle or the wrist;
6) Attach all limb electrodes in the same way.

3.3.2.2 Attaching the Chest Electrodes



Chest Electrode Connection:

1) Ensure that the electrodes are clean;
2) Clean the electrode area on the chest surface with 75% alcohol;
3) Daub the round area of 25mm in diameter on each electrode site with gel evenly;
4) Place a small amount of gel on the brim of the chest electrode's metal cup;
5) Place the electrode on the chest electrode site and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest;
6) Attach all chest electrodes in the same way.

NOTE: Long-time measurement with a strong negative pressure on the suction bulb may cause reddening of the skin. When using the electrode on kids or patients with delicate skin, squeeze the suction bulb lightly.

3.3.3 Attaching the Disposable Electrodes

CAUTION

The disposable electrodes can only be used for one time.

Connect the snap socket adapter to the disposable electrode.

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

Chapter 4 Sampling Resting ECG

Double-click on 

on the desktop to display the main screen.

NOTE: Do not use other software when using PC ECG software.

Figure 4-1 Toolbar of Main Screen

If you use PC ECG software for the first time, the following window will be displayed.

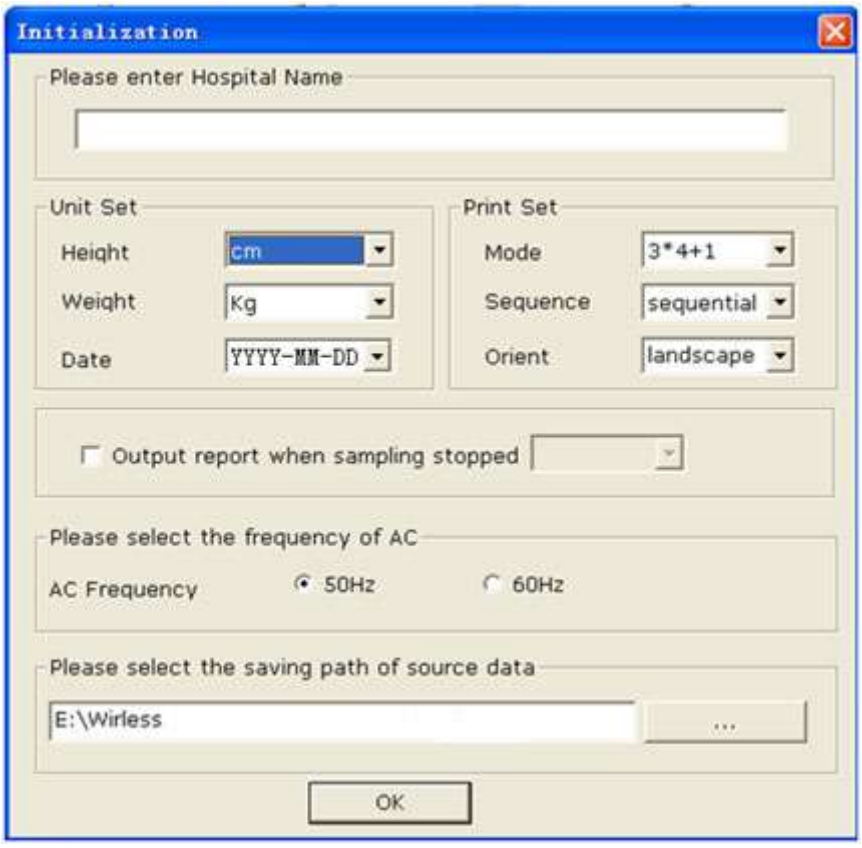


Figure 4-2 Initial Window

You can set the unit, print, frequency of AC and the saving path of source data based on your needs. Click on the **OK** button after setup, the system will enter the main screen automatically.

NOTE: You should install the software to the saving path of source data after the uninstallation and reinstallation; otherwise, the software needs a new configuration.

4.1 Viewing Lead Placement Information

Click on 

on the main screen, and then click on **Wilson lead system** to view the lead placement information.

4.2 Viewing Patient Information

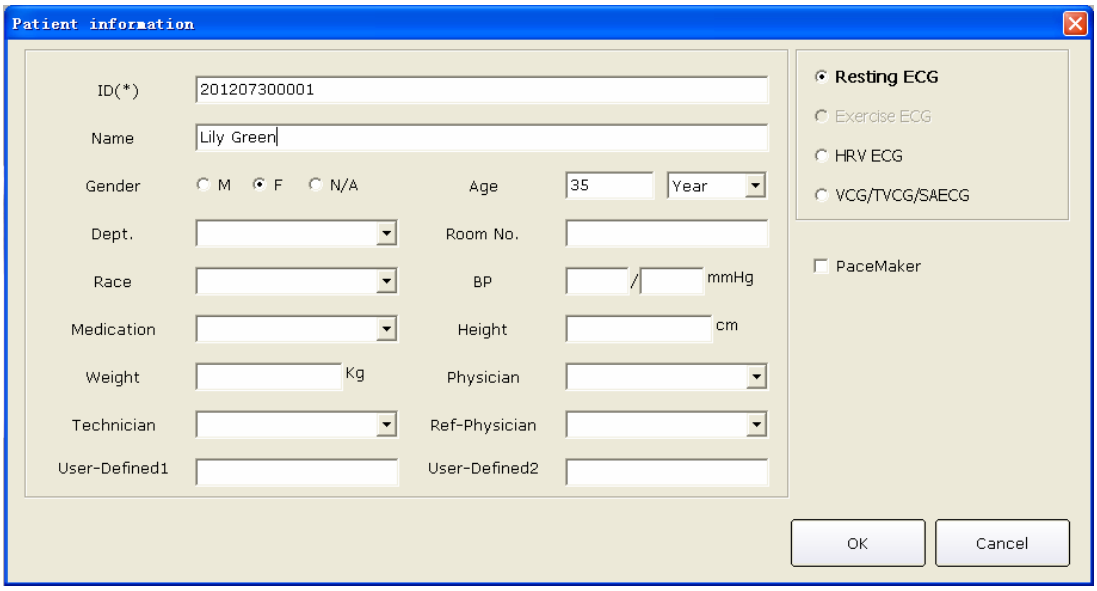
You can view the patient information in one of the following two ways:

1. Click on an order in the **Order Manager** window, and then click on the **Examine** button. Or, double-click on an order
2. Click on a patient record in the patient information list, and then click on the **Select** button.

4.3 Entering Patient Information

Click 

on the main screen to display the **Patient Information** window.



4.3.1 Entering Patient Information Manually

NOTE: User-defined 1/2 can be set in the **Basic Information** window, items of **Pacemaker** and specific patient information can be selected in the **Print Setting** window. Before setting them, these items in the **Patient Information** window are unavailable. For details, please refer to Section 8.1 and Section 8.5.

Basic Information	Including patient ID, name, sex, age, user-defined 1/2. **NOTE:** In the **Patient information** window, patient ID is a must. You can use the number generated by the system or input a number manually. Patient ID can be a random character string excluding '/', '\', ':', '*', '?', '<', '>' and '|'.
Physician and Department Information	Including information of physician, technician, Req. physician Input the information of physician or department in the corresponding textboxes in the **Patient Information** window, and then click on the **OK** button to confirm. Or, 1. Click on the  pull-down list, and then click on the **Edit…** button. Input the information of physician or department in the **Add** textbox, and then click on the **Add** button. 2. Click the information in **List**, and then click on the **Delete** or **Modify** button to delete or modify the selected information of physician or department. 3. Click on the **OK** button in the **Edit** window to confirm.
Additional Information	Including information of BP, height, weight, medication, race
Pacemaker Information	Select **Pacemaker** to detect very small pacemaker pulses. However, when pacemaker pulse enhancer is on, the system is very sensitive, and should not be close to equipment emitting high frequency radiation. High frequency radiation can interfere with pacemaker pulse detection and normal ECG acquisition. **NOTE:** **Pacemaker** is recommended to be deselected unless it is known that the majority of the electrocardiograph usage will be on patients with pacemakers.

4.3.2 Entering Patient Information by Using a Bar Code Reader

Operation procedures are as follows:

1. Configure the bar code

   For more detailed information about configuring the bar code, please refer to Section 8.4.

   NOTE: If the two-dimensional bar code reader is used, you should install Symbol COM Port Emulation Drive manually. For details, please refer to *SE-1010 PC ECG Installation Guide.*

2. Connect the bar code reader to the tablet PC.
3. Log into the PC ECG software.
4. When the main screen or the **Patient Information** window is displayed, scan the patient's bar code with the bar code reader, and then the patient information will appear in the corresponding boxes of the **Patient Information** window.

NOTE:

1. Only bar code readers recommended by the manufacturer can be used.
2. Only the basic information of the patient can be scanned by the bar code reader.
3. If you purchase the wired system of PC ECG, you can assemble the wired system after using a bar code reader.

4.3.3 Entering Patient Information by Acquiring Orders

Operation procedures are as follows:

1. Load orders from Smart ECG Net system.

   For details, please refer to Section 6.1.

2. Enter the patient ID manually in the **ID** textbox or connect a bar code reader, click on the **Acquire** button in the **Patient Information** window, and then the related information will be displayed in the corresponding textboxes.

4.4 Sampling ECG Data

After inputting the patient information, click on the **OK** button in the **Patient information** window to open the ECG pre-sampling screen.

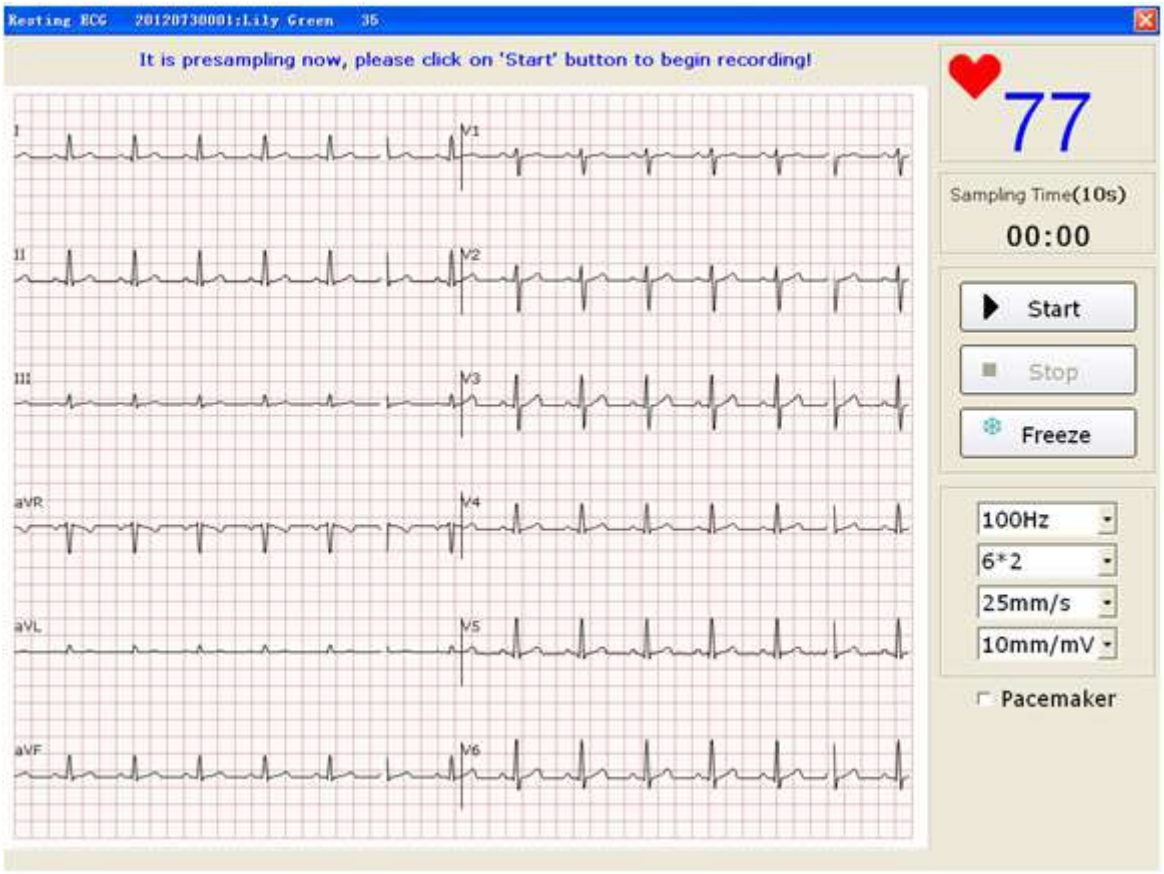


Figure 4-3 Pre-Sampling Screen

Start Click on this button to save the sampled ECG data to the designated directory. For details, please refer to Section 8.1.

NOTE: After you click on the **Start** button, the system will save the sampled ECG data.

Stop Click on this button to stop sampling ECG data.

The system will stop sampling ECG data and display the ECG analysis screen automatically after the ECG sampling time is over. For details, please refer to Section 8.2.

NOTE: Only after you click on the **Start** button, can the **Stop** button be available.

Freeze Click on this button to display the **Wave review** window.

You can review the waveform by dragging the scrollbar in the **Wave review** window, or you can print the current waveform by clicking on the **Print** button.

The system can review a 3-minute (at least) waveform (counted 3 minutes before clicking on the **Freeze** button).

NOTE: The display modes in the **Wave review** window are the modes you select on the ECG sampling screen. 3*1 and 6*1 display modes are displayed in 3*4 and 6*2 modes.

You can set the display mode, the lowpass filter, the gain and the speed from 

.

4.5 Sampling STAT ECG

Click on 

on the main screen to sample normal ECG directly without entering the patient information or selecting an existing patient record before sampling. The system will automatically distribute a new patient ID.

Chapter 5 Analyzing ECG Data

You can open the ECG analysis screen in one of the following three ways:

1. Click on the **Start** button, and then the system will stop sampling ECG and display the ECG analysis screen automatically after the ECG sampling time is over.
2. Or, click on the **Stop** button to stop sampling after clicking on the **Start** button, and the system will display the ECG analysis screen automatically.

Or, double-click on an examination record in the examination record list on the **Data**

5.1 Analyzing Normal ECG

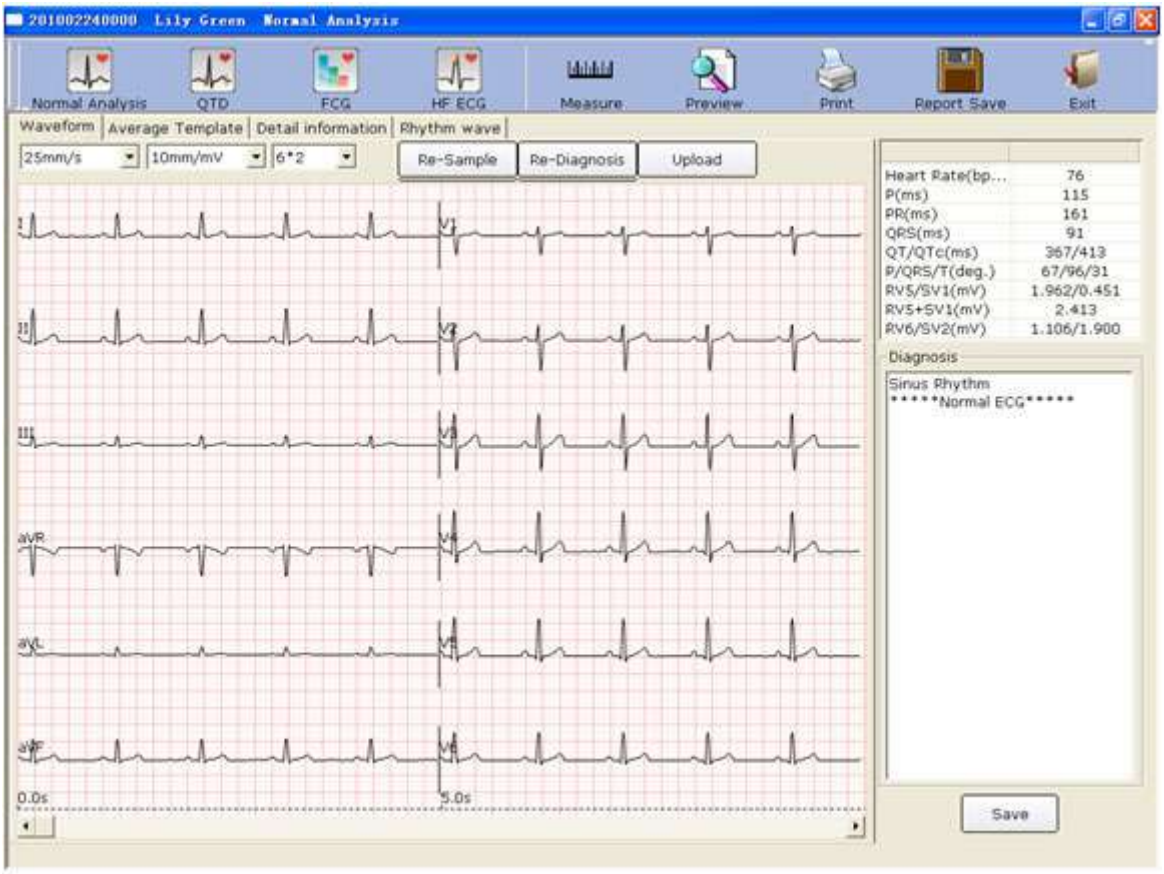


Figure 5-1 Normal Analysis Screen

1. About the Waveform Window

Click on the **Waveform** tab to open the **Waveform** window.

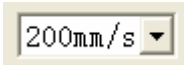
Click on the **Re-Sample** button to re-sample ECG data.

Click on the **Re-Diagnosis** button to re-diagnose the 10s ECG data automatically.

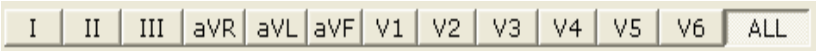
Click on the **Upload** button to upload 10s ECG data to Smart ECG Net system.

2. About the Average Template Window

Click on the **Average Template** tab to open the **Average Template** window.

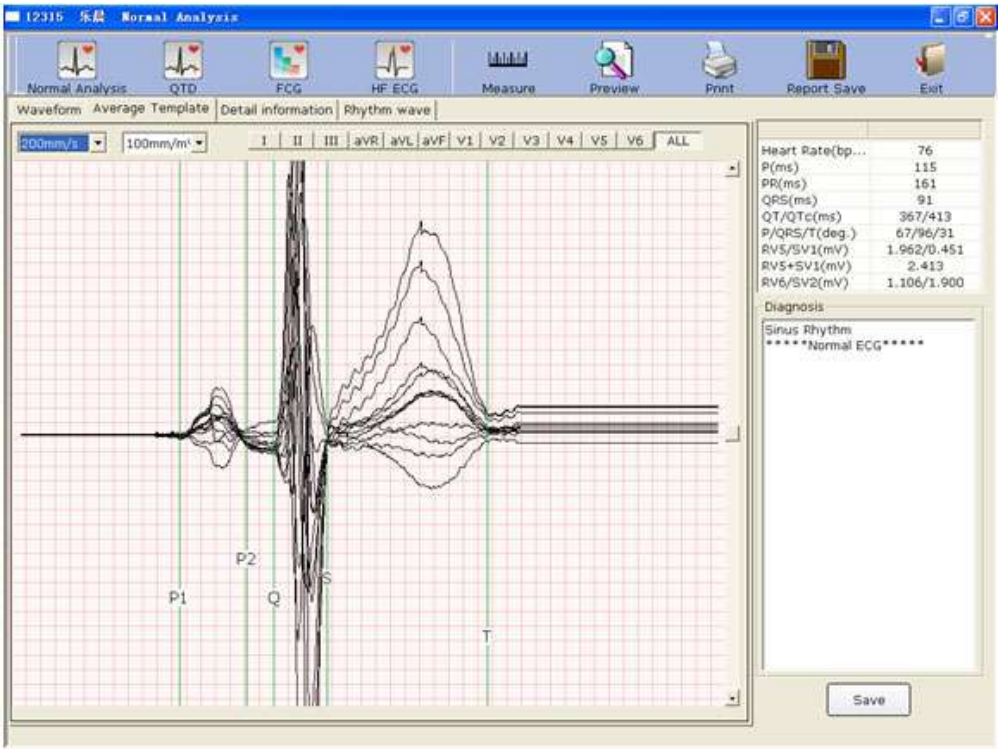
Set the speed and the gain in 

and .

Click on a lead button in 

to display magnified average templates of this lead. Click on more than one lead button to display magnified average templates of these leads overlapped with the same central axis.

When you click on the **ALL** button, magnified average templates of all leads will be overlapped with the same central axis.



You can drag marker lines of P1, P2, Q, S and T on average templates.

P1 is the start point of P wave, P2 is the end point of P wave, Q marks the position of Q point, S marks the position of S point, and T is the end point of T wave. You can move these lines by dragging on the mouse and the mouse will turn to a hand pointer when it is put on these marks. You can also use the arrows key on the keyboard to move these marks, and the corresponding parameter values will change.

3. About the Detail Information Window

Click on the **Detail information** tab to open the **Detail information** window.

Click on the **Export Excel** button to export an Excel file.

4. About the Rhythm Wave Window

Click on the **Rhythm Wave** tab to open the **Rhythm wave** window.

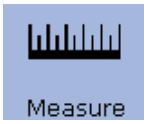
Set the gain, the speed and the lead of the displayed ECG waves in 

.

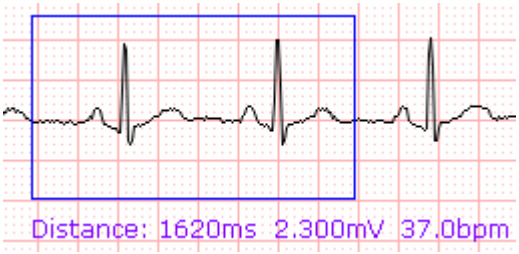
Click on the **Previous Page** or **Next Page** button to display the waves of the previous or next page.

Click on one point on the wave, and then drag the mouse to another point. Then click on **Print** to print the selected wave field.

5.2 Measuring ECG

Click on 

in the **Waveform** or **Average Template** window. Click on one point on the wave, and then drag the mouse to another point. The distance, amplitude difference and heart rate between the two points will be displayed.



NOTE:

1. You can measure the distance between any two points more than once after running the ruler. The last measure track and data will be displayed after the measurement.
2. Only ECG waves can be measured.

5.3 Viewing Parameters and Diagnosis

Double-click on a parameter, and then you can modify it. Then click on the **Save** button to save the modifications.

These parameters are as follows.

Designation	**Description**
Heart Rate (bpm)	Heart Rate
P (ms)	P-wave duration of the current lead
PR (ms)	P-R interval of the current lead
QRS (ms)	QRS complex duration of the current lead
QT/QTc (ms)	Q-T interval of the current lead/Normalized QT interval
P/QRS/T (deg.)	Dominant direction of the average integrated ECG vectors
RV5/SV1 (mV)	The amplitude of R wave of V5 lead/the amplitude of S wave of V1 lead
RV5+SV1 (mV)	The amplitude of R wave of V5 lead plus the amplitude of S wave of V1 lead
RV6/SV2 (mV)	The amplitude of R wave of V6 lead/the amplitude of S wave of V2 lead

Enter your own opinions in the **Diagnosis** textbox, and then click on the **Save** button.

If the Integration function is activated, the data can be uploaded to Smart ECG Net system after you click on the **Save** button.

5.4 Previewing ECG Report

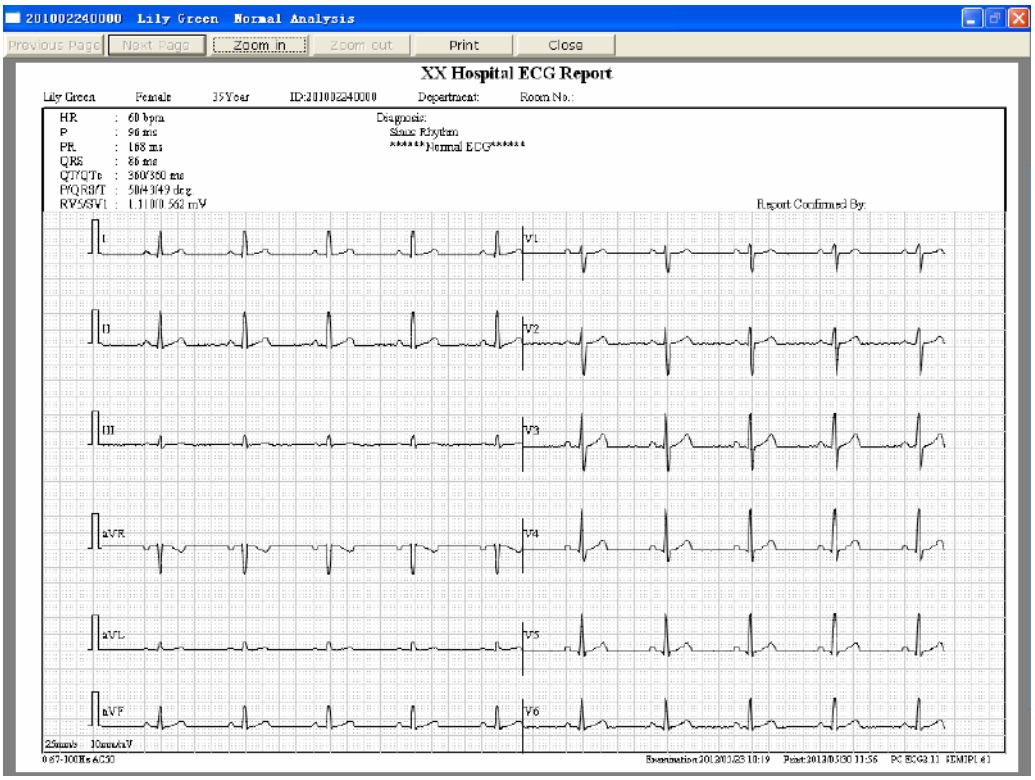
Click on 

to display the normal ECG preview screen.

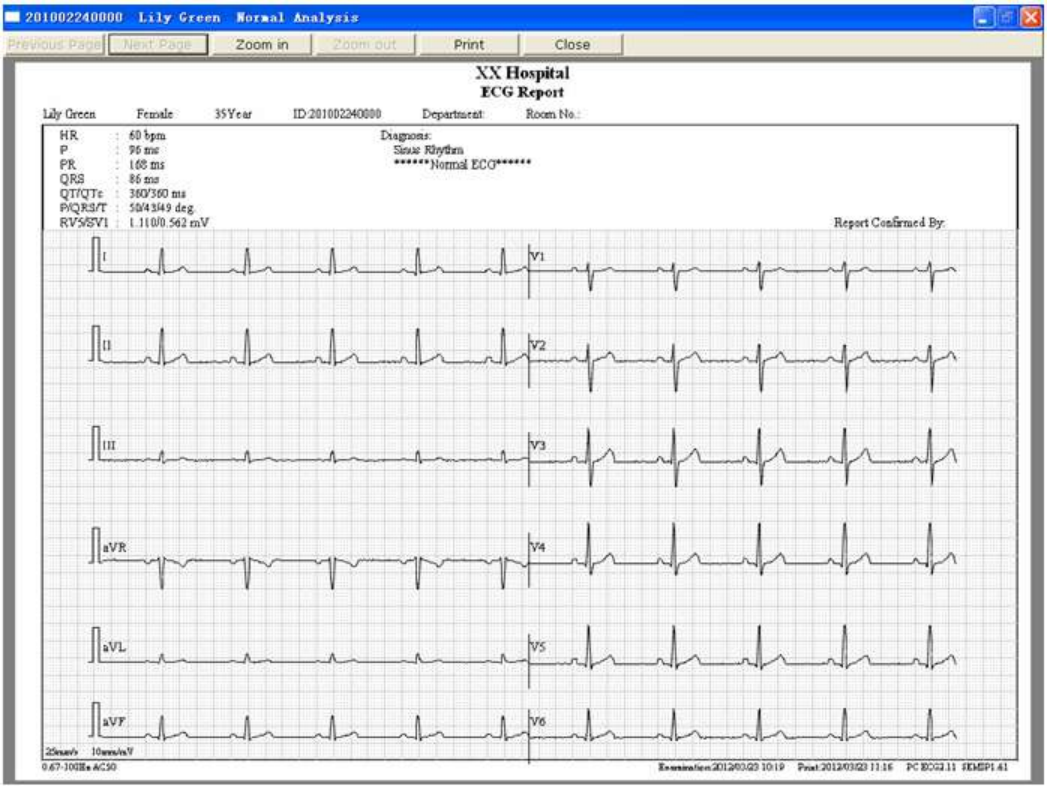
1. Click on **Previous Page/Next Page** to switch to the previous/next preview page.
2. Click on **Zoom In**/ **Zoom Out** to magnify/minify the preview page.
3. Click on **Print** to print the report.
4. Click on **Close** to close the normal ECG preview screen and return to the previous screen.

NOTE: The report title is in one line by default, you can also change the line to two lines. Find the text named **PCECG.ini** in the installation path, modify **LineofTitle=0** to **LineofTitle=1**, and then save the text to change the line to two lines.

Effect pictures of report title are as shown below:



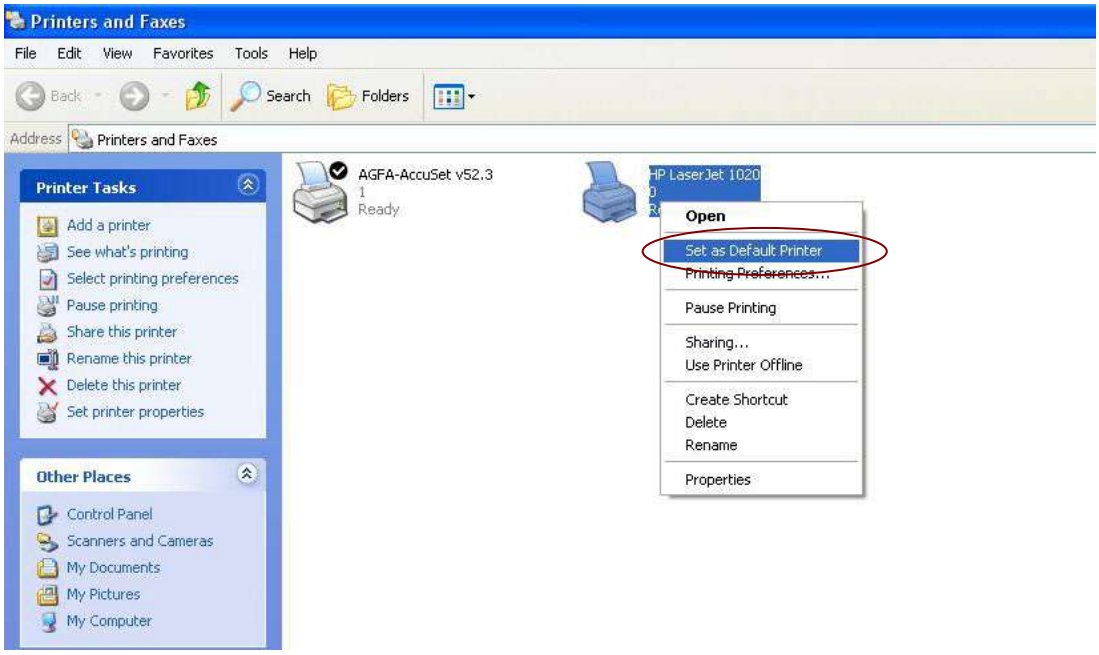
Report Title in One Line



Report Title in Two Lines

5.5 Printing ECG Reports

1. Choose **Start** > **Printers and Faxes**, and then right-click on the icon of the printer used, and select **Set as Default Printer**. Then close the **Printers and Faxes** window.



2. Click on 

on the analysis screen, or click on the **Print** button on the preview screen to print an ECG report.

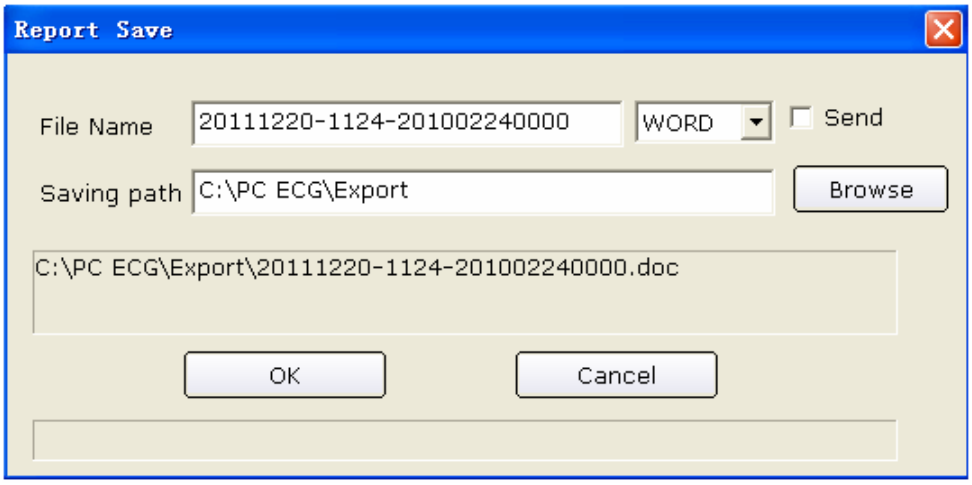
NOTE: You can set the printer type on the **Printer and Faxes** screen. The report color is defined by setting the printer type and can be observed on the preview screen. For details, please refer to Section 8.5.

5.6 Saving ECG Reports

Click on 

on the Normal Analysis screen to save ECG reports.

The report format includes **PDF**, **WORD**, **JPG** and **BMP**. Click on the **Browse** button to choose the save path and click on **OK** to save the sampled data to the designated directory.



If you select **Send**, the sampled data will be sent by Window Live Mail (Windows 7) when it is saved to the designated directory. During the saving and sending course, the system will give the hint information.

NOTE: In Windows 7, only if Window Live Mail is installed, can the report be sent by email.

Chapter 6 Processing Orders

Click on 

on the main screen to display the **Order Manager** window.

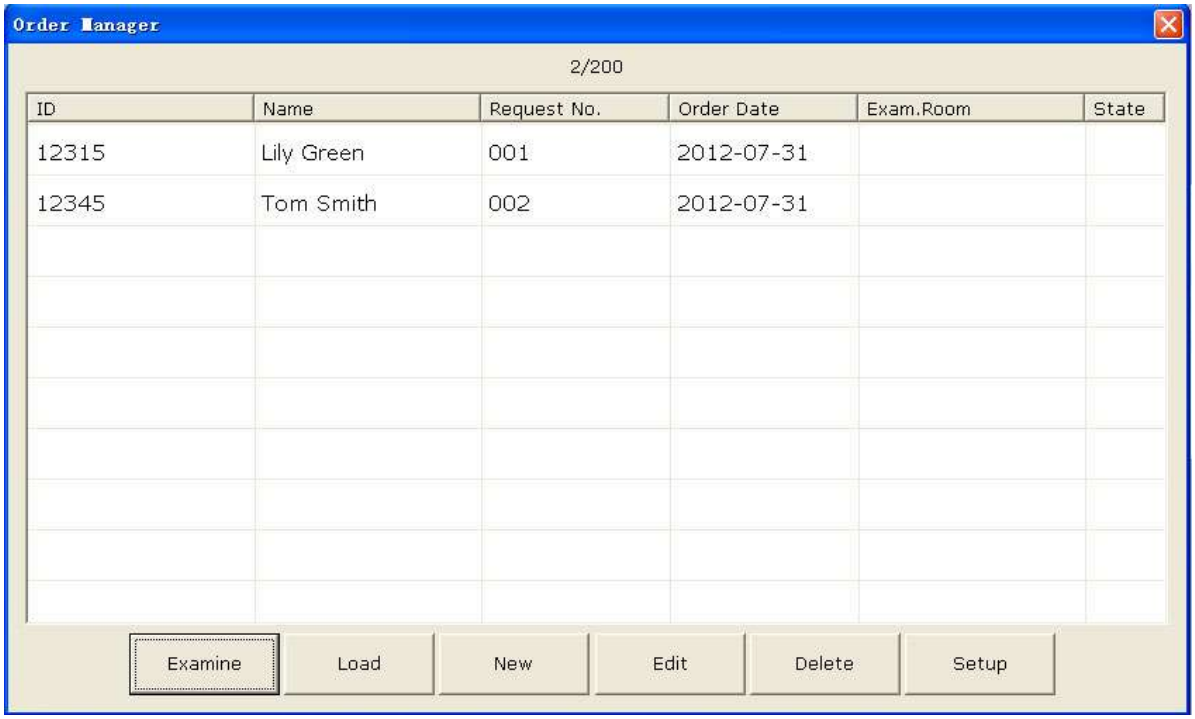


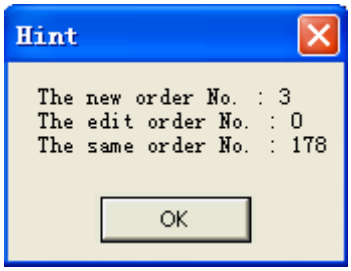
Figure 6-1 Order Manager Window

6.1 Loading Orders

Before loading orders, please configure the **Order Setup** window. For details, please refer to Section 6.5.

Operation procedures are as follows:

1. Click on the **Load** button in the **Order Manager** window to load orders from Smart ECG Net system, and then a hint will be displayed as follows.



NOTE:

1) If orders are modified in Smart ECG Net system, the corresponding orders existing in the **Order Manager** window will be refreshed after you load orders from the system.
2) Ensure the software of Smart ECG Net is stared up when you load orders from the system.

2. If you select **Exam.Room Filter** in the **Order Setup** window, orders will be filtered after you click on the **Load** button.
3. If 200 orders already exist in the **Order Manager** window, a hint ***The max data of order is 200!*** pops up after you click on the **Load** button.

6.2 Creating and Editing Orders

Click on the **New** button in the **Order Manager** window, enter patient information manually, and then click on the **OK** button to create an order.

NOTE: If you select **Examine after orde**r in the **Patient Information** window, after you click on the **OK** button to create an order, the system will automatically examine this patient.

Select an order in the **Order Manager** window, click on the **Edit** button to modify the select order.

For details on entering patient information, please refer to Section 4.3.

6.3 Examining Orders

Select an order in the **Order Manager** window, and then click on the **Examine** button to start an examination.

NOTE: If you select **Delete After Examination** in the **Order Setup** window, the order will be deleted from the **Order Manager** window after you examine the selected order. Otherwise, the order will be marked by **Y** in the **Order Manager** window after you examine the selected order.

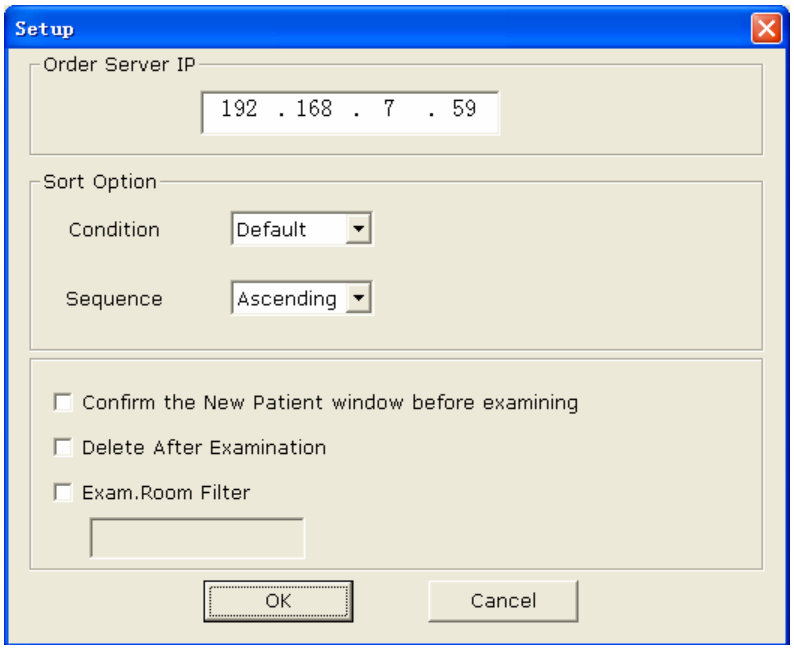
6.4 Deleting Orders

Pressing **Del All** on the **Order Manager** screen can delete all the orders from the electrocardiograph.

Or, you can select an order on the **Order Manager** screen, select **Delete** to delete the selected order from the electrocardiograph.

6.5 Setting Orders

Click on the **Setup** button in the **Order Manager** window to make settings of orders.



Item	Description
Order Server IP	Set this item to Server IP of Smart ECG Net Client. **NOTE:** For more information, see your Network Administrator.
Condition	Choose from: **Default**, **ID, Order Date, Request No.** or **State** Select **Default**, orders will be displayed in sequence of the time when the orders are loaded from Smart ECG Net system. Select **ID, Order Date, Request No.** or **State**, orders will be displayed in sequence of the selected condition in the **Order Manager** window.
Sequence	Choose from: **Ascending** or **Descending** **NOTE:** 1. When **Condition** is set to **State** and **Sequence** is set to **Ascending**, orders without examination will be displayed on the top of the **Order Manager** window. 2. When **Condition** is set to **State** and **Sequence** is set to **Descending**, orders with examination will be displayed on the top of the **Order Manager** window.
Confirm the New Patient window before examining	Select this item, every time you click on the **Examine** button to start an examination for the patient, the **Patient Information** window pops up.

Item	Description
Delete After Examination	Select this item, the order will be deleted from the **Order Manager** window after the order is examined.
Exam.Room Filter	Select this item, and enter an exact exam.room in the textbox, such as Electrocardiograph. Then all the orders which meet the requirements will be searched and displayed in the **Order Manager** window. Deselect this item or enter nothing in the textbox, all the orders will be searched and displayed on the **Order Manager** window.

Chapter 7 Processing Records

Click on 

on the main screen to display the **Data Manager** screen.

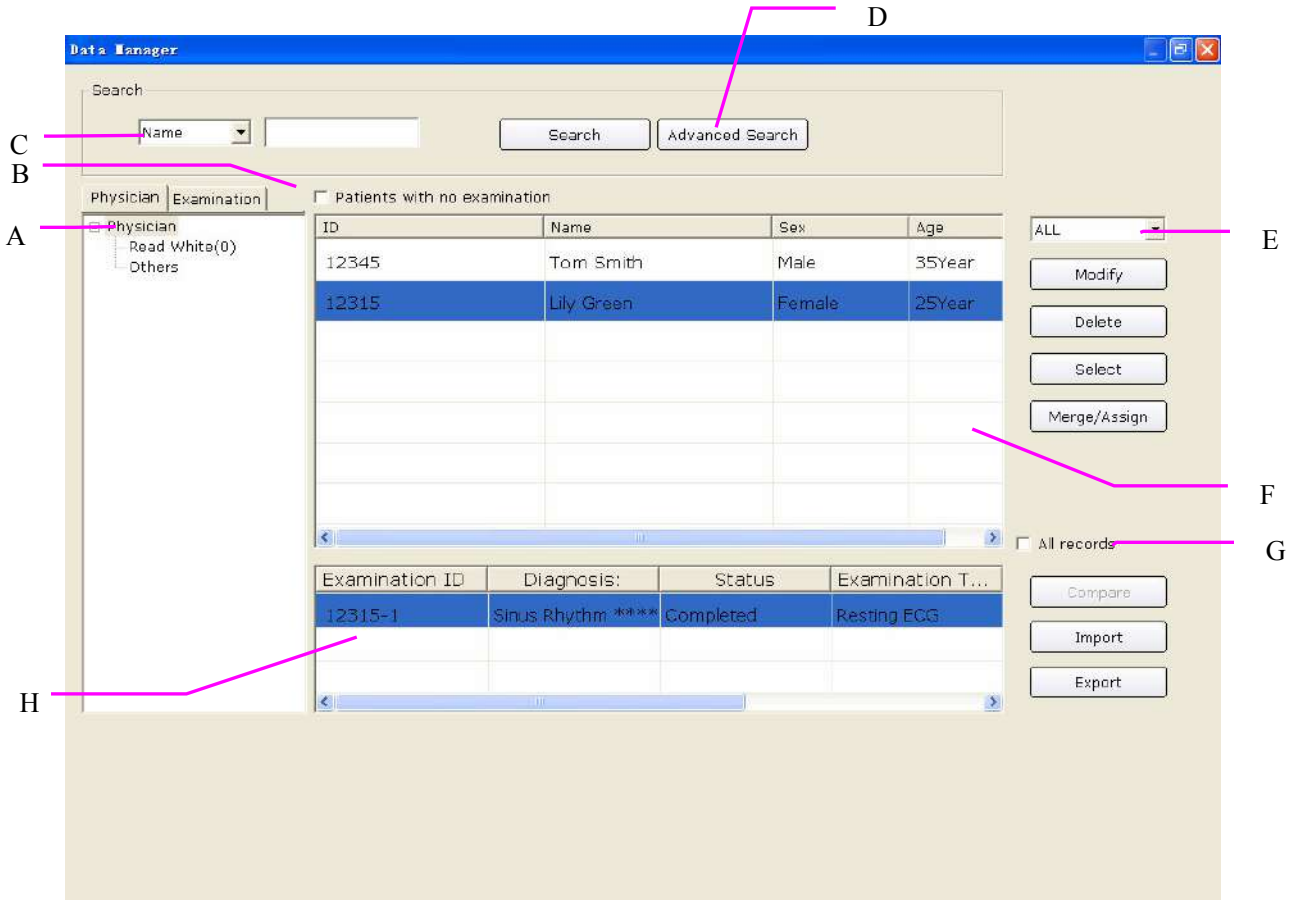


Figure 7-1 Data Manager Screen

A All names of the physicians are displayed in this column.

Click on one physician, all the patient records examined by this physician will be displayed in the patient information list.

B Select this item, all the patient records which are registered but not examined, will be displayed in the patient information list.

C Select a search item from this pull-down list, enter the corresponding information in the right textbox, and then click on the **Search** button. All the patient records which meet the conditions will be displayed in the patient information list.

D Click on this button to display the **Search Condition** window, and then enter the search conditions. Click on the **Search** button, and all the patient records which meet the conditions will be displayed in the patient information list.

NOTE: User-defined 1/2 is available after it is set in the **Basic Information** window.

E Select a search item from this pull-down list, and then all the patient records which meet the search condition are listed in the patient information list.

F Patient Record list

Click on a patient record in this list, and then all the examination records of the patient will be displayed in the examination record list.

Click on an option in the patient information list, such as ID, name, etc, and then all the patient records will be arranged in sequence.

G Select this item, all the patient records will be displayed in the patient information list.

H Examination Record list

This list includes the information of **Examination ID**, **Diagnosis**, **Status**, **Examination Type**, **ExamTime** and **Physician**.

7.1 Selecting and Modifying Patient Records

Click on a patient record in the patient information list, and then click on the **Select** button to display the **Patient Information** window. The system will sample ECG data after you click on the **OK** button in the **Patient Information** window.

Click on a patient record in the patient information list, and then click on the **Modify** button to display the **Patient Information** window. Then you can modify the information of the patient in the **Patient Information** window. If the patient has more than one record, the modification is only for the selected record. Click on the **OK** button to save these modifications.

7.2 Viewing an Examination Record

Double-click on an examination record in the examination record list to display the **Normal Analysis** screen.

Status of examination record includes **Completed** and **Unconfirmed**.

Examination record in **Completed** status means that you click on the **Save** button in the **Waveform** window.

Examination record in **Unconfirmed** status means that you do not click on the **Save** button in the **Waveform** window.

7.3 Deleting Records

NOTE: The deletion of records is permanent, and you can't restore the records deleted. Please use this operation cautiously.

Click on a patient record in the patient information list, and then click on the **Delete** button to delete the selected patient record. At the same time, all the examination records of the patient will be deleted.

Or, you can click on the first patient record to be deleted and press the **Shift** button on the keyboard, and then click on the last patient record to be deleted in the patient information list; You can also press the **Ctrl** button on the keyboard and then select the patient records one by one. After selecting all the patient records to be deleted, click on the **Delete** button to delete all the selected patient records.

The operation methods of deleting examination records are similar to those of deleting patient records. The deletion of an examination record cannot delete the corresponding patient information.

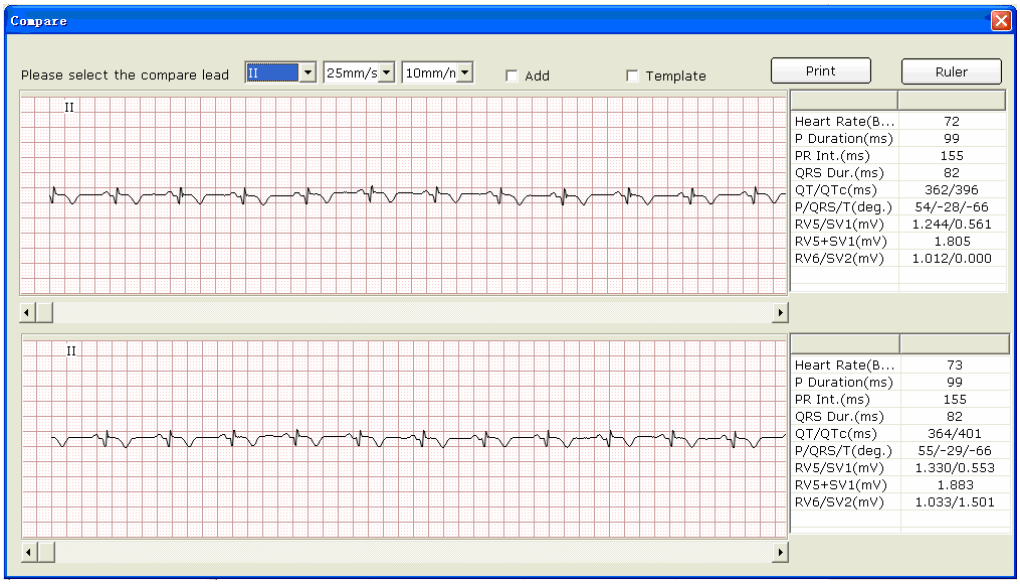
7.4 Merging Examination Records

Click on one or more examination records in the examination record list, and then click on the **Merge/Assign** button to display the **Patient Information** window. Input a patient ID and click on the **OK** button to assign the examination record selected to this patient.

7.5 Comparing Two Examination Records

Press the **Ctrl** button on the keyboard and select two examination records of one patient, and then click on the **Compare** button to display the **Compare** window.

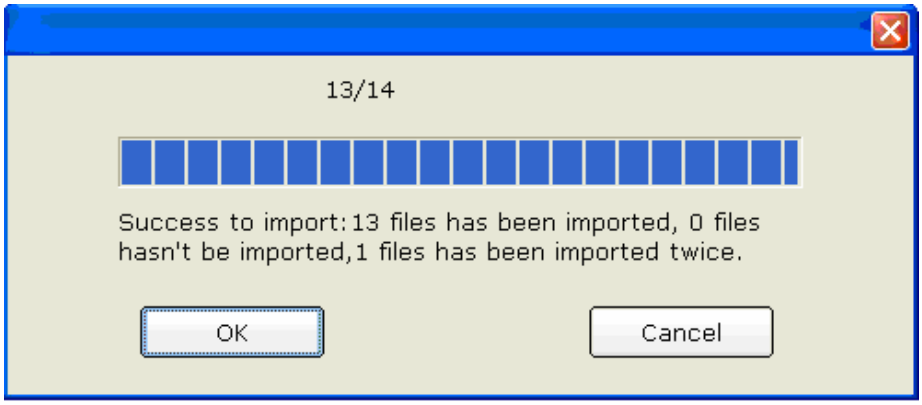
NOTE: Please select two examination records of one patient to compare.



Item	Description
	Select the leads, and set the speed and gain to be compared from the this pull-down list.
Add	Select this item to display the waves of the two examination records. The black wave is the original wave and the blue wave is the compared wave.
Template	Select this item to display the templates of the two examination records.
Print	Click on this button to print the current window.
Ruler	Click on this button, click on one point on the wave, and then drag the mouse to another point. The distance, amplitude difference and heart rate between the two points will be displayed.

7.6 Importing ECG Data into the Data Manager Screen

Click on the **Import** button on the **Data Manager** screen, select the data to be imported, and then click on the **Select** button to import the data.



To import multiple examination records simultaneously, you can click on the first examination record to be imported and press the **Shift** button on the keyboard, and then click on the last examination record to be imported. You can also press the **Ctrl** button on the keyboard and then select the examination records one by one. After selecting all the examination records to be imported, click on the **Select** button to import all the examination records.

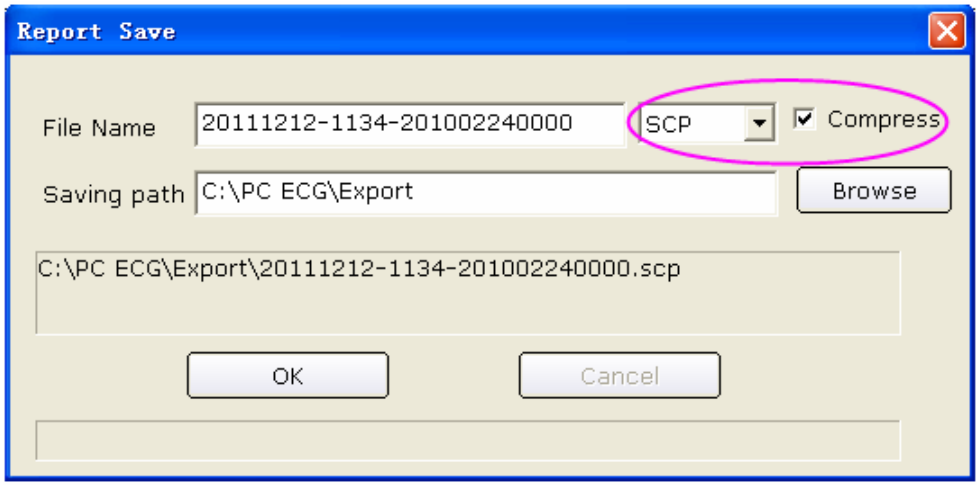
If the data to be imported exists on the **Data Manager** screen, the system will give a hint.

NOTE: Only ECG data in DAT format can be imported.

7.7 Exporting ECG Data from the Data Manager Screen

Select examination records and click on the **Export** button on the **Data Manager** screen to display the **Report Save** window. Assign the file name, saving path and export file format (SCP, FDA-XML, DICOM, dat, pdf), and then click on the **OK** button to export the data into the selected path. At the same time, the patient information of these records will be exported.

If you select **SCP** and **Compress**, the compressed SCP file will be exported.



NOTE: Only if the export file format is set to **SCP**, can the **Compress** check box be displayed.

Chapter 8 Configuring the System

Click on 

on the main screen to open the **System Setting** window.

After you modify some information in the **System Setting** window,

1. Click on the **OK** button to save these modifications and exit.
2. Or, click on the **Cancel** button to cancel these modifications and exit.

8.1 Basic Information Setup

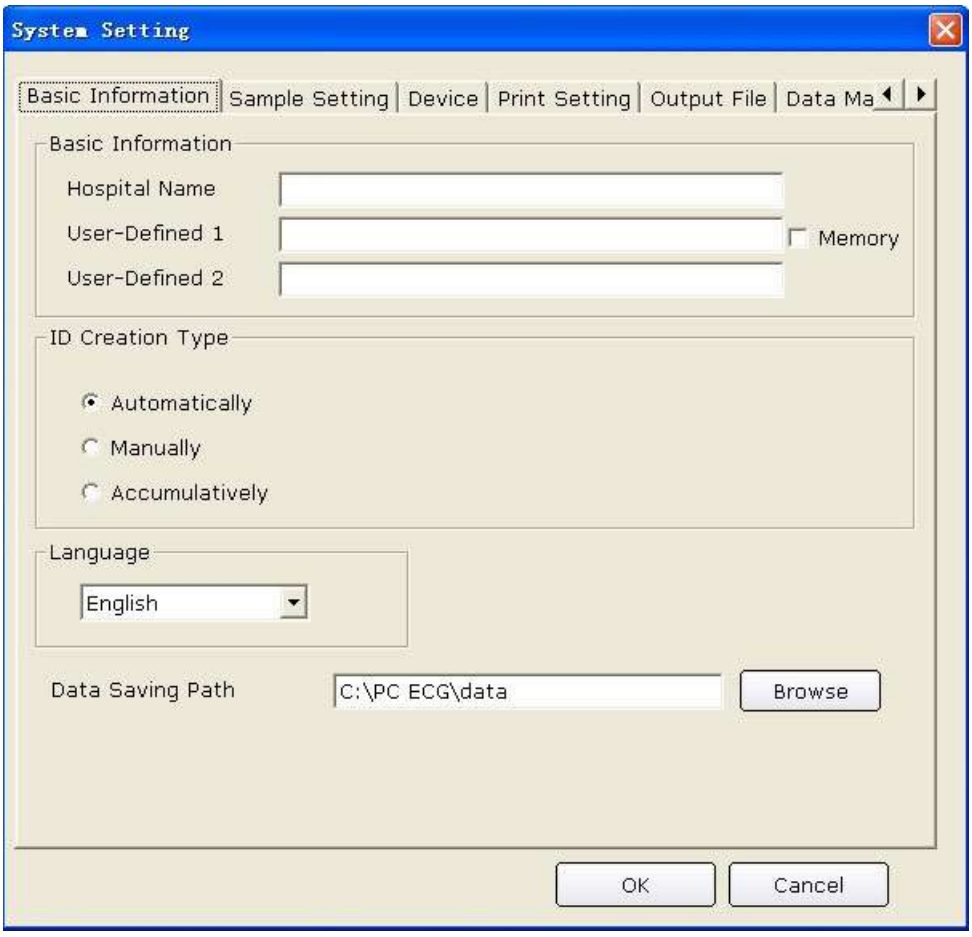


Figure 8-1 Basic Information Setup Window

Item	Description
Hospital Name	Enter hospital name.
User-defined 1/2	Input information in this textbox, the **Patient Information** and **Search Condition** windows will display the defined items.

Item	Description
Memory	Select this item, the content of **User-Defined 1** in the **Patient Information** or **Search Condition** windows is the information you input last time. Deselect this item, the content of **User-Defined 1** is empty when you open the **Patient Information** or **Search Condition** windows every time.
ID Creation Type	Choose from: **Automatically**, **Manually** or **Accumulatively** Select **Automatically**, the patient ID can be automatically generated according to the examination date. Select **Manually**, you should enter the patient ID manually in the **Patient Information** window. Select **Accumulatively**, the patient ID can be increased by one automatically. You need to set the format and the starting number for ID.
Language	Choose from: **Chinese** or **English**. **NOTE**: To validate the language setup, after setting, you should restart the system.
Data Saving Path	Click on the **Browse** button to assign the storage path.

8.2 Sample Setup

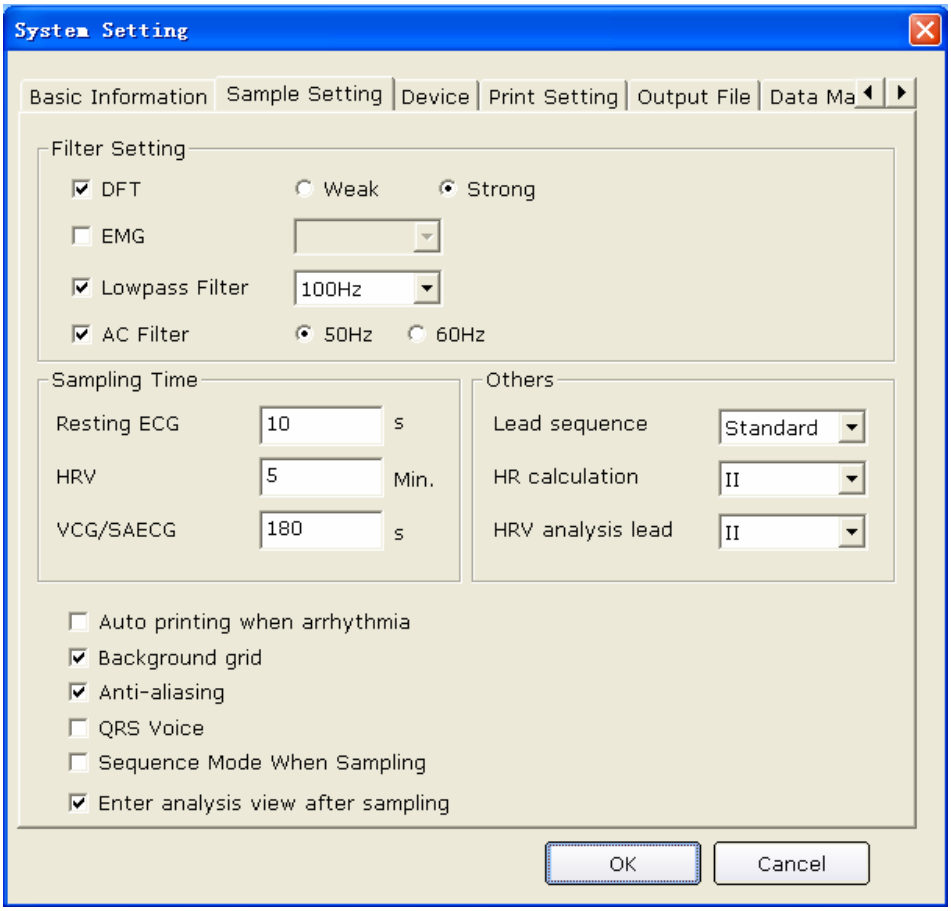


Figure 8-2 Sample Setup Window

<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Filter Setting</td><td>
♦ DFT Filter: DFT filter greatly reduces the baseline fluctuations without affecting ECG signals.
Choose from: Weak and Strong.
NOTE: If DFT filter is set to Strong, the ECG data displayed on the screen is 0.85 seconds later than the real-time ECG data; if DFT filter is set to Weak, the ECG data displayed on the screen is 1.8 seconds later than the real-time ECG data.
♦ EMG Filter: EMG filter suppresses the disturbance caused by strong muscle tremor.
Choose from: 25Hz, 35Hz or 45Hz.
♦ Lowpass Filter: Lowpass filter restricts the bandwidth of input signals. All the input signals whose frequency is higher than the setting cutoff frequency will be attenuated.
Choose from: 75Hz, 100Hz or 150Hz
♦ AC Filter: AC filter suppresses AC interference without attenuating or distorting ECG signals.
Choose from: 50Hz and 60Hz.
</td></tr>
<tr><td>Sampling Time</td><td>Set the sampling time of Resting ECG to 10-600s.</td></tr>
<tr><td>Others</td><td>
♦ Lead Sequence
Set Lead sequence to Standard or Cabrera, and the lead groups are displayed or printed in the corresponding sequence listed in the following table.
<table>
<tr><th>Lead Sequence</th><th>Lead group 1</th><th>Lead group 2</th><th>Lead group 3</th><th>Lead group 4</th></tr>
<tr><td>Standard</td><td>I, II, III</td><td>aVR, aVL, aVF</td><td>V1, V2, V3</td><td>V4, V5, V6</td></tr>
<tr><td>Cabrera</td><td>aVL, I, -aVR</td><td>II, aVF, III</td><td>V1, V2, V3</td><td>V4, V5, V6</td></tr>
</table>
♦ HR Calculation
Set the HR calculation to one of the 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6.
♦ HR Analysis Lead
Set the HR Analysis Lead to one of the 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6.
</td></tr>
</table>

Item	Description
Auto printing when arrhymia	Select this item, if Arrhythmia ECG data, including Ventricular Tachycardia, 5>PVCS>=3, Paired PVCS, Bigeminy, Trigeminy, R ON T, single PVC and Missed Beat, is detected during the sampling course, printing will be triggered automatically.
Background grid	Select this item, the ECG waveforms will be displayed with a background grid.
Anti-aliasing	Select this item, the system will automatically make the waveform smooth.
QRS Voice	Select this item, there will be a beep when an R wave is detected.
Sequence mode when sampling	Select this item, groups of waves will be displayed in succession.
Enter analysis view after sampling	Select this item, the system will automatically enter the Normal Analysis screen after the sampling.

8.3 Device Setup

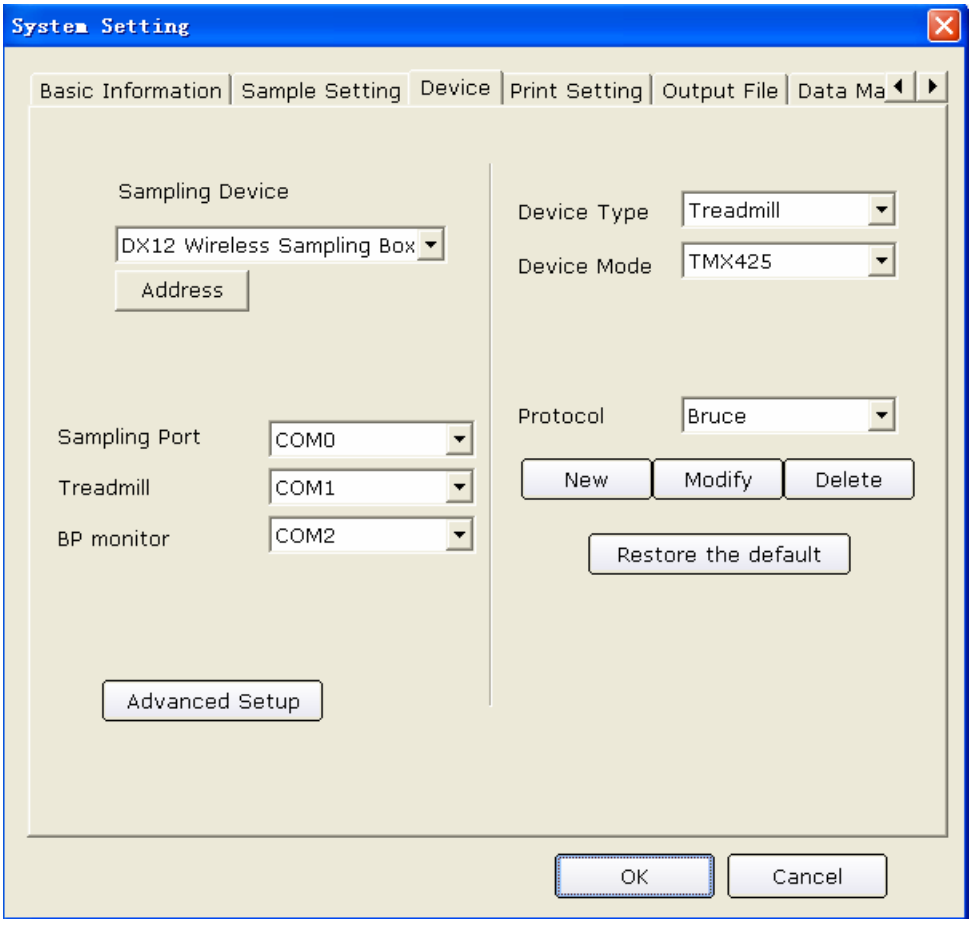


Figure 8-3 Device Setup Window

Item	Description
Sampling Device	Choose from: **DP10 Wired Sampling Box**, **DP12 Wired Sampling Box**, **DX12 Wireless Sampling Box**, **SE Serial Machine** or **DEMO** Select **DX12 wireless sampling box**, you can click on the **Address** button to view the address. Select the viewed address on the screen of DX12 transmitter to match DX12 transmitter with tablet PC.

8.4 Advanced Setup

Click on **Advanced Setting**, input the correct password in the pop-up textbox, and then click on the **OK** button.

Click on the **Access Network Setting** tab to open the **Access Network Setting** window.

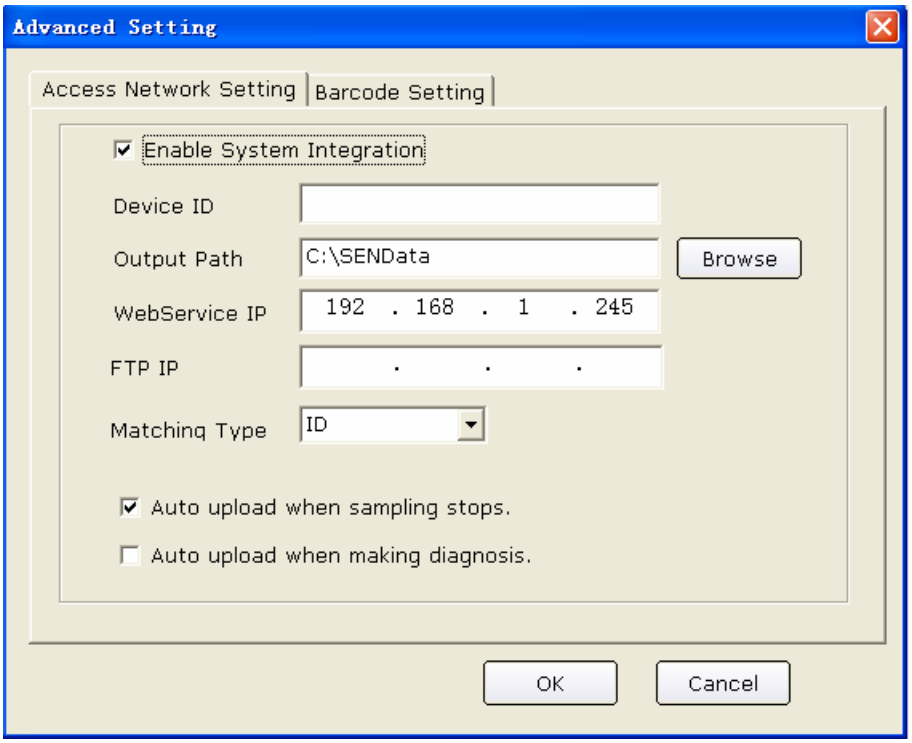


Figure 8-4 Access Network Setup Window

Item	Description
Enable System Integration	Select this item to enable system integration features. Meanwhile, the **Acquire** button appears in the **Patient Information** window.
Device ID, Output Path, WebService IP and FTP IP	Set **Device ID**, **Output Path**, **WebService IP** and **FTP IP** to the Device ID, Output Path, WebService IP and FTP IP of Smart ECG Net system. Otherwise, ECG data cannot be uploaded to Smart ECG Net system normally.

Item	Description
Auto upload when sampling stops	Select this item, the system will automatically upload files to Smart ECG Net system when sampling finishes.
Auto upload when making diagnosis	Select this item, the system will automatically upload files to Smart ECG Net system when making diagnosis.

Click on the **Barcode Setting** tab to open the **Barcode Setting** window.

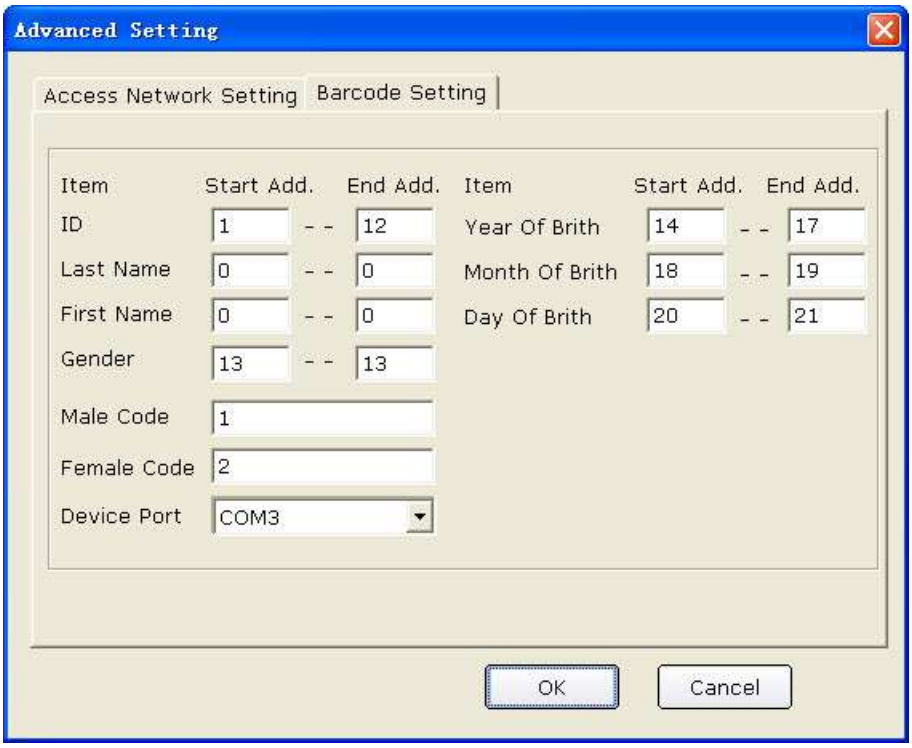
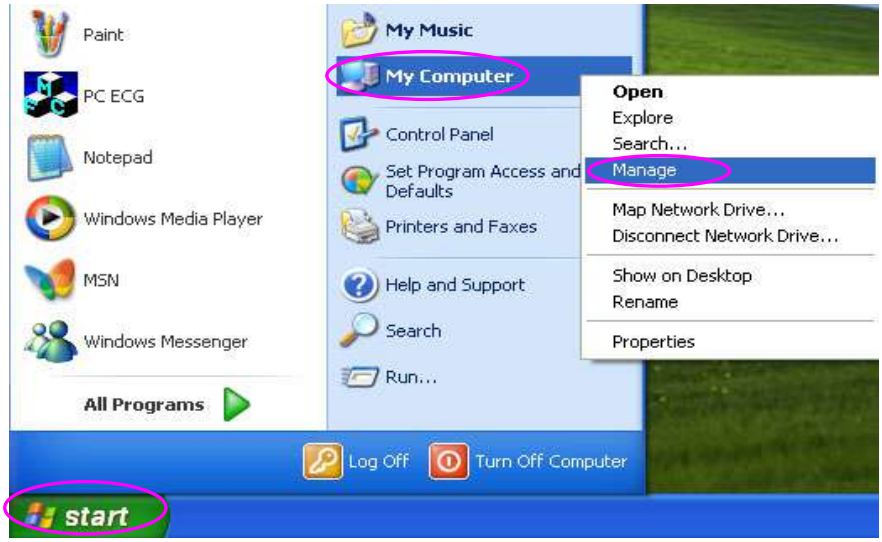


Figure 8-5 Barcode Setup Window

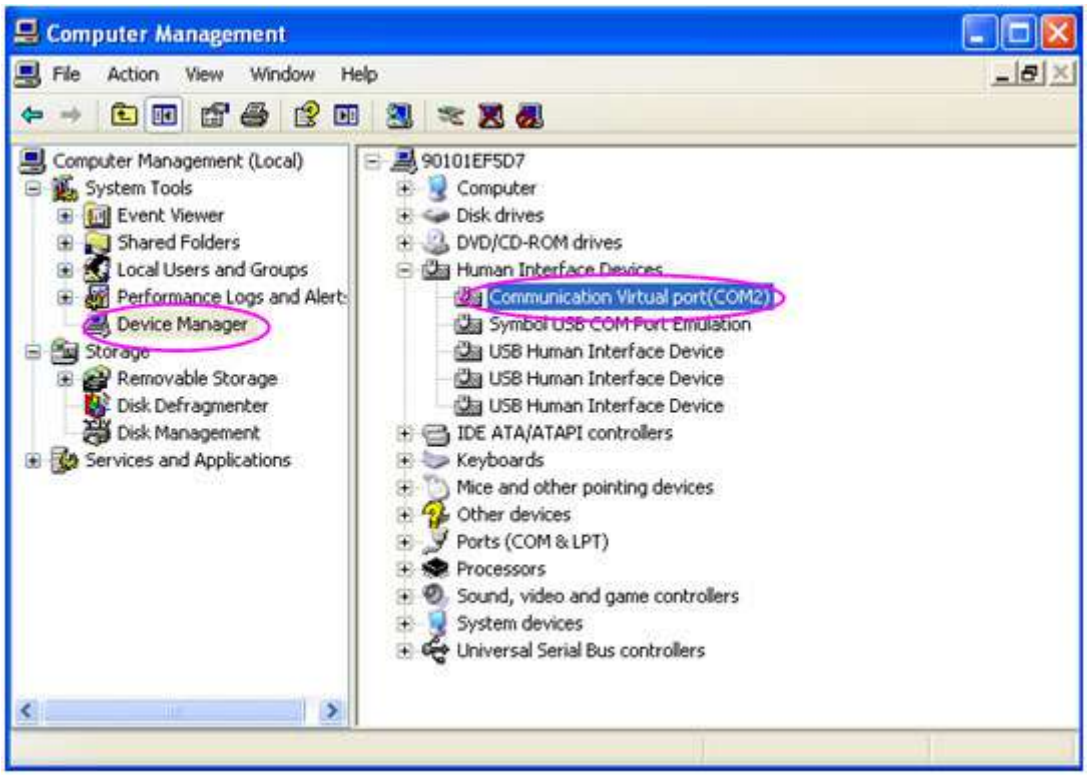
Item	Description
Barcode Setting	Enter the start and end addresses, the male and female codes and the device port, and then click on the **OK** button confirm. **NOTE:** Only bar code readers recommended by the manufacturer can be used.

If the bar code reader cannot be automatically detected, you can make related settings as the following procedures show:

1. Connect the bar code reader to the PC
2. Click on **start**, right-click on **My Computer**, and then select **Manage** in the pop-up menu to display the **Computer Management** screen.



3. Click on **Device Manager** on the **Computer Management** screen, and then click on **Human Interface Devices** to view port information.



4. In the **Barcode Setting** window, set **Device** to the port you view on the **Computer Management** screen, and then click on the **OK** button to confirm.
5. Restart the SE-1010 PC ECG software.

8.5 Print Setup

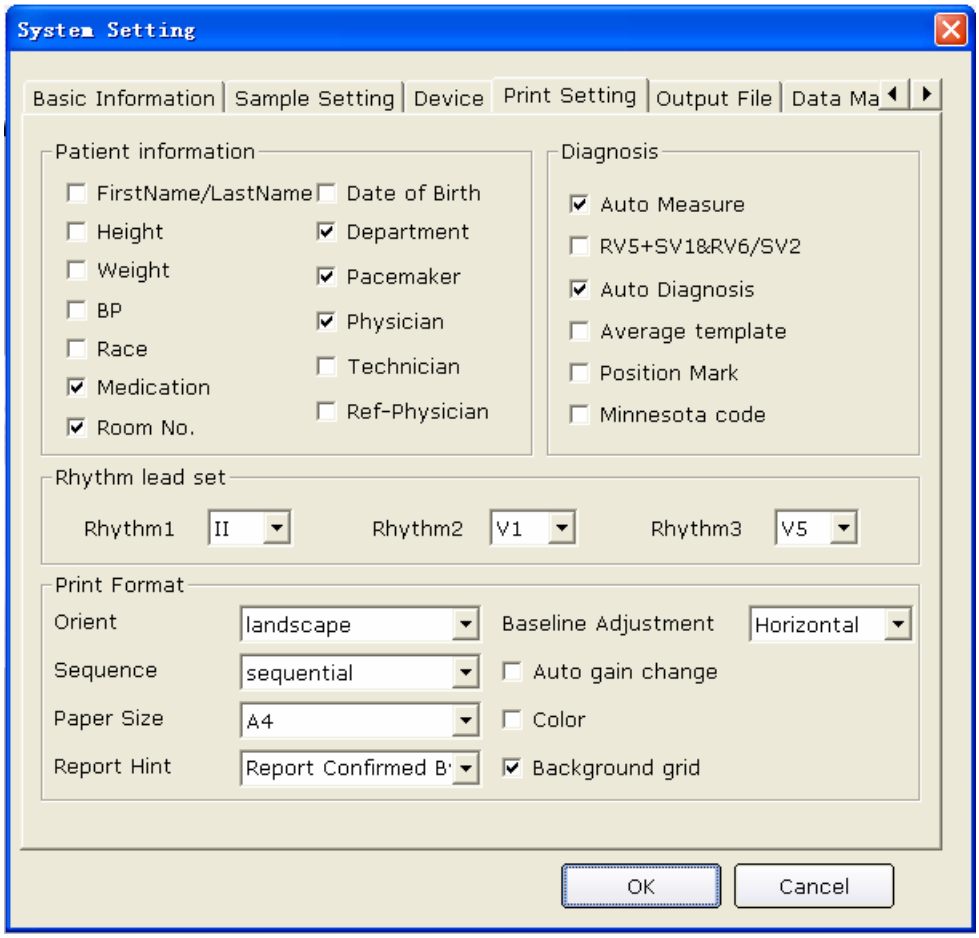


Figure 8-6 Print Setting Window

Item	Description
Patient Options	Select the item displayed in the **Patient Information** window and the report printed out. Select **First Name/Last Name**, the **Patient Name** textbox in the **Patient Information** window will change into the **First Name** and **Last Name** textboxes. Select **D.O.B**, the D.O.B textbox appears in the **Patient Information** window, and the **Age** textbox becomes unavailable. **NOTE:** 1. **Pacemaker** appears in the **Patient Information** window after it is selected in the **Patient Information Setup** window. Set **Pacemaker** to **Yes** in the **Patient Information** window, and the **Pacemaker** information will be displayed on the report printed out. 2. **Pacemaker** is recommended to be set to **No** unless it is known that the majority of the electrocardiograph usage will be on patients with pacemakers.

Item	Description
Diagnosis	Select the diagnosis item displayed on the preview screen and in the report printed out. **NOTE: Position Mark** should be selected together with **Average template**, because the position mark is only used to mark the position of ECG waves in the average template.
Rhythm Lead Set	Set the rhythm lead to one of 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6. When the printing mode is set to **3×4+1** or **6×2+1**, the rhythm lead selected in the **Rhythm1** list box will be printed out. When the printing mode is set to **3×4+3**, 3 rhythm leads selected in the **Rhythm1**, **Rhythm2** and **Rhythm3** list boxes will be printed out.
Print Format	♦ Set **Orient** to **landscape** or **portrait**. ♦ Set **Sequence** to **sequential** or **synchronous**. Select **sequential**, the lead group is printed one by one in a certain sequence. The start time of a lead group is just the end time of the previous lead group. Select **synchronous**, all leads are printed simultaneously. The start time of each group is the same. ♦ Set **Paper Size** to **A4** or **Letter**. ♦ Set **Report Hint** to **Report confirmed by:** or **Unconfirmed Report**. ♦ Set **Baseline Adjustment** to **OFF, Horizontal** or **Auto.** ♦ Select **Auto gain change**, and the gain will be changed automatically and **Baseline Adjustment** automatically**.** ♦ Select **Color**, the background grid of report will be printed in color. **NOTE**: If the printing color is set to color, but a black-and-white printer is used, the report printed will be illegible. ♦ Select **Background grid**, and the background grid will be printed in the report.

8.6 Output File Setup

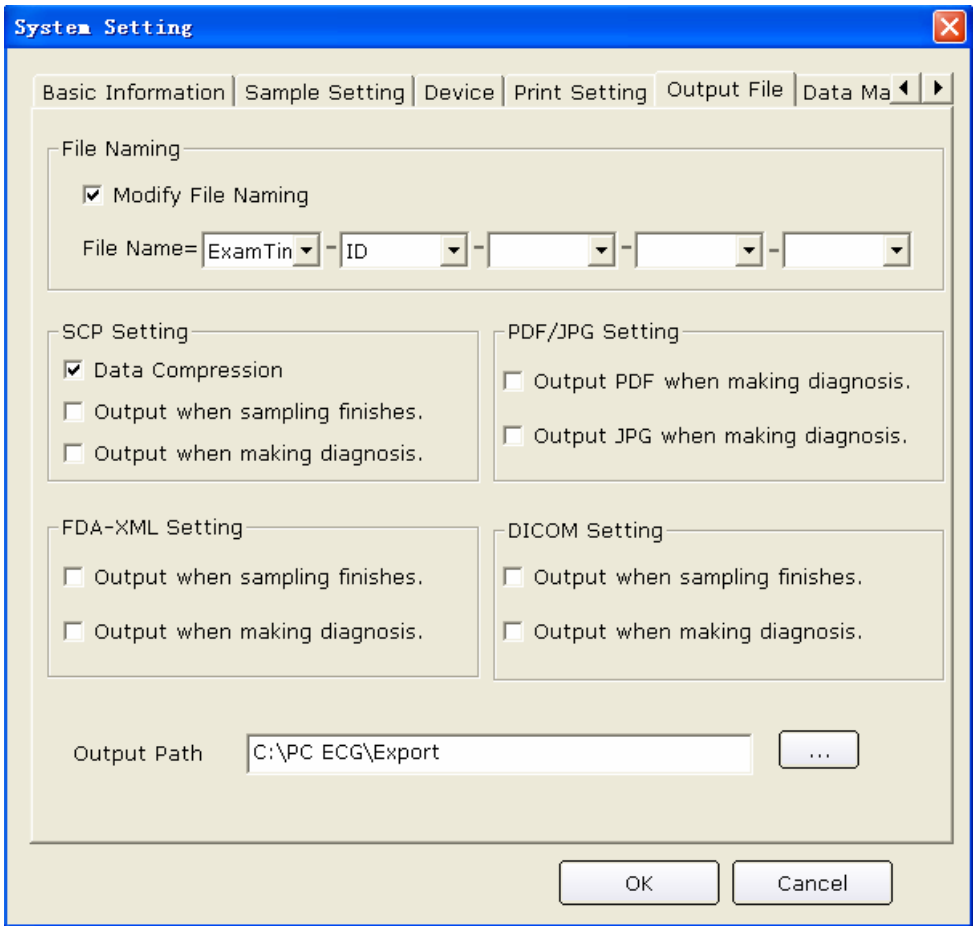


Figure 8-7 Output File Setup Window

Item	Description
File Naming	Each field of **File Name** includes **ID**, **Name**, **ExamTime**, **Age** and **Sex** items. Deselect **Modify File Naming**, **File name** is set to Exam Time-ID by default. Select **Modify File Naming**, you can also modify the file name manually, such as Name-ID-Exam Time. **NOTE:** Select at least one item as a file name when you select **Modify File Naming**.
SCP Setting	Select **Data Compression,** the system will automatically output compressed SCP files. Select **Output when sampling finishes,** the system will automatically output SCP files when sampling finishes. Select **Output when making diagnosis,** the system will automatically output SCP files when making diagnoses.

Item	Description
PDF/JPG Setting	Select **Output PDF when making diagnosis,** the system will automatically output PDF files when making diagnoses. Select **Output JPG when making diagnosis,** the system will automatically output JPG files when making diagnoses.
FDA-XML Setting	Select **Output when sampling finishes,** the system will automatically output FDA-XML files when sampling finishes. Select **Output when making diagnosis,** the system will automatically output FDA-XML files when making diagnoses.
DICOM Setting	Select **Output when sampling finishes,** the system will automatically output DICOM files when sampling finishes. Select **Output when making diagnosis,** the system will automatically output DICOM files when making diagnoses.
Output Path	Click on the **…** button to assign the output path.

8.7 Data Maintenance Setup

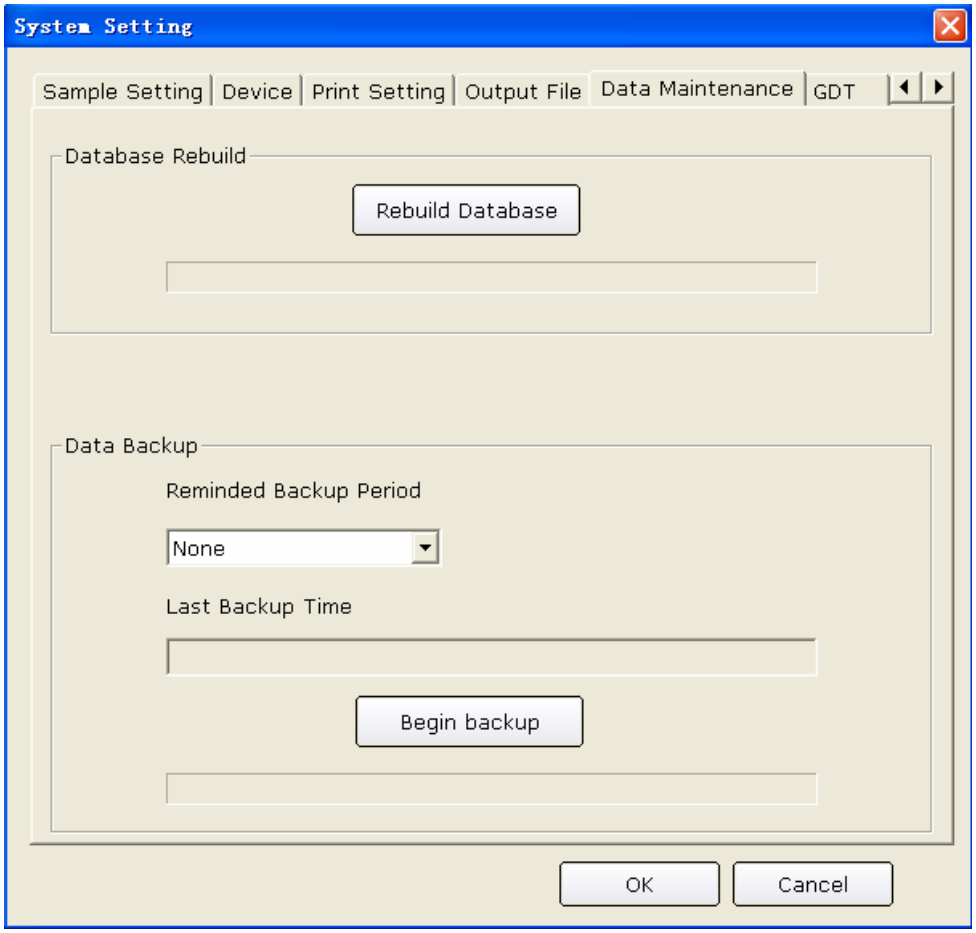


Figure 8-8 Data Maintenance Window

Item	Description
Database Rebuild	Click on the **Rebuild Database** button, click on **…** button in the Database-rebuild Setting window to select the path, and then click on the **OK** button to rebuild database.
Database Backup - Begin Backup	Click on the **Begin backup** button to display the **Backup Setting** window. ♦ Click on the **…** button to assign the backup path. ♦ Select **Select Time** to back up the data files during the set time range. ♦ Deselect **Select Time** to back up all the data files. ♦ Click on the **OK** button in the **Backup Setting** window, the system will begin backup. The system will back up the data files of the latest time if you do not change the path.
Database Backup - Reminded Backup Period	Choose from: **None**, **7 days**, **14 days**, **30 days** or **User Defined…** Select **User Defined…**, you can define the backup period manually.

8.8 GDT Setup

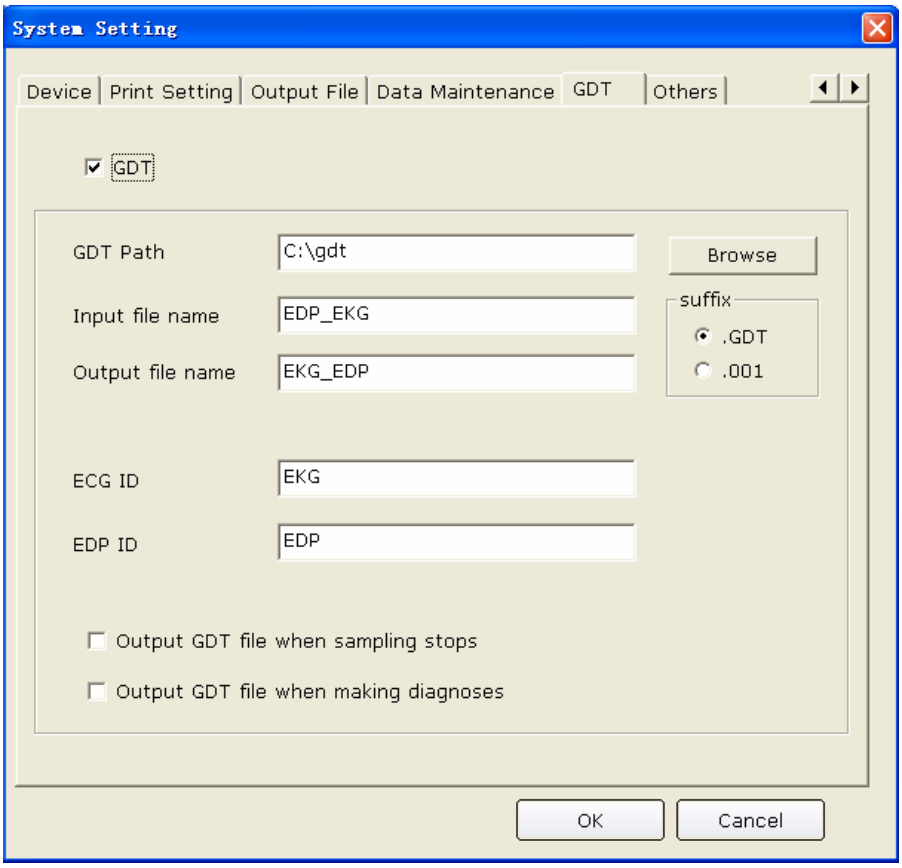


Figure 8-9 GDT Setup Window

Item	Description
GDT	Select this item to enable GDT features.
GDT Path	Click on the **Browse** button to design the path to exchange files with EDP.
Input file name	Enter information in this textbox to set command file name assigned by EDP to the PC ECG system.
Output file name	Enter information in this textbox to set data file name that is used by the PC ECG system to transmit the result data to EDP.
ECG ID	Enter information in this textbox to set GDT ID assigned to the system which will be entered in field 8315 or 8316 in the GDT protocol.
EDP ID	Enter information in this textbox to set GDT ID of the EDP system which will be entered in field 8315 or 8316 in the GDT protocol.
Output GDT file when sampling stops	Select this item, the system will automatically output GDT files when sampling stops.
Output GDT file when making diagnoses	Select this item, the system will automatically output GDT files when making diagnoses.

8.9 Other Setup

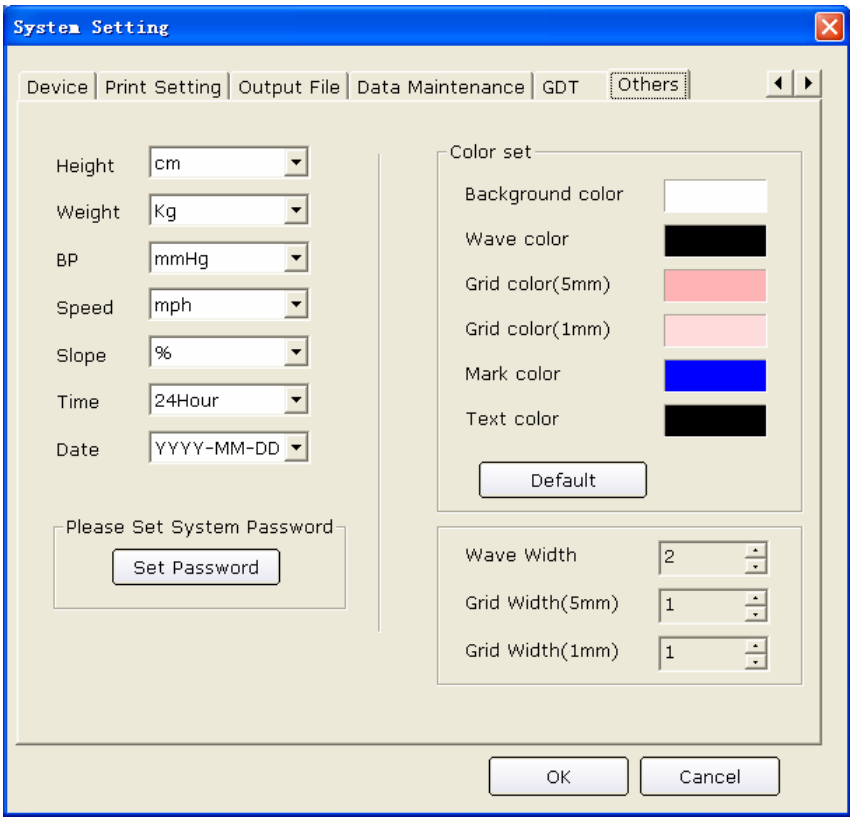


Figure 8-10 Other Setup Window

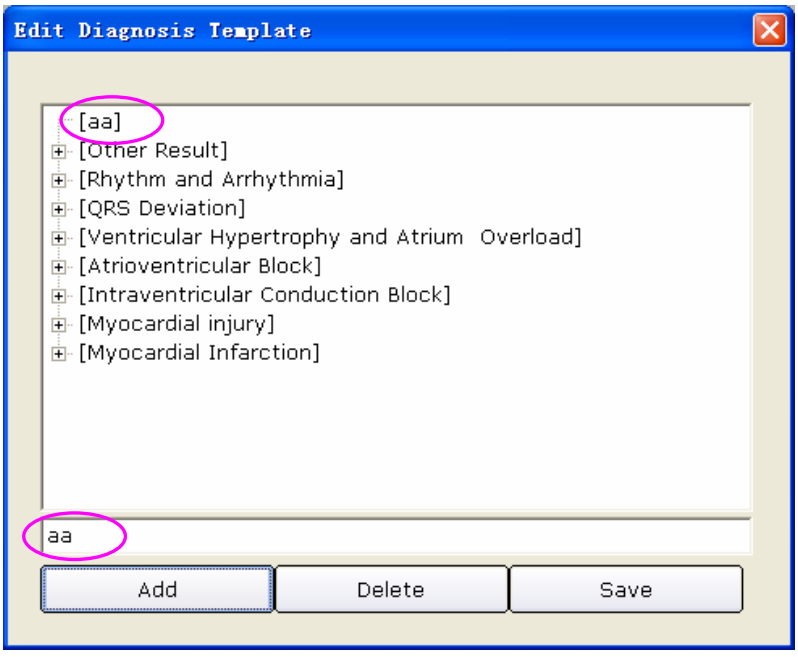
Item	Description
Unit	You can set the units of **Height**, **Weight**, **BP**, **Slope**, **Speed**, **Time** and **Date**.
Color	You can set the colors of the background, waves, grid (5mm), grid (1mm), mark and text. Double-click on the color block to display the **Color** window, and then you can select your favorite color. Click on the **Default** button to restore the default colors.
System Password	Click on the **Set Password** button, enter the same password for twice in the **System Password Setting** window, and then click on the **OK** button to set the system password. After a successful password setting, you should have a correct password to enter the **System Setting** window.
Wave Width and Grid Width	You can adjust **Wave Width, Grid Width (5mm)** and **Grid Width (1mm)** of report by using the up or down arrow. The adjustable range is: 1~5. **NOTE**: The width may vary with the type of printer.

8.10 Modifying the Glossary

Choose **Tool (F)** -> **Edit Diagnosis Template** on the main screen to display the **Edit Diagnosis Template** window.

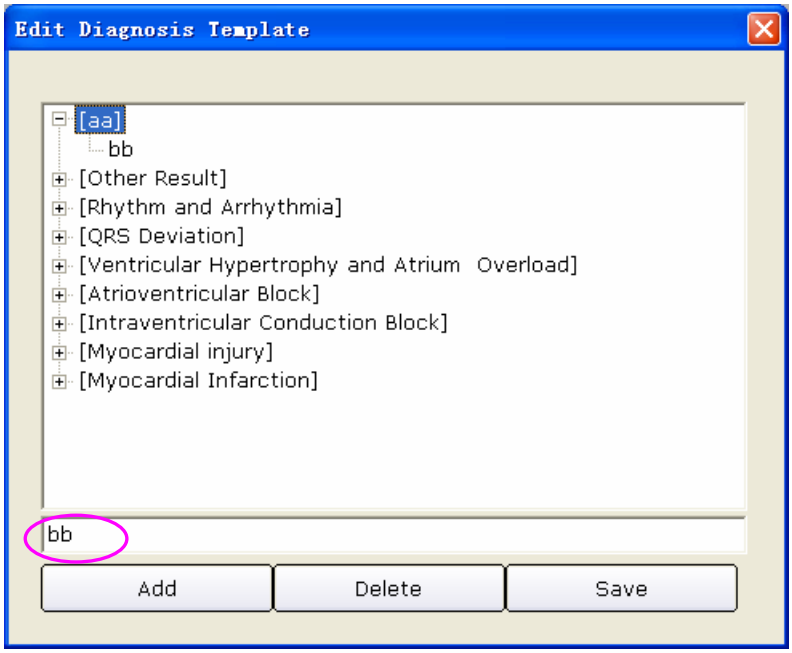
1. Adding an item

   Enter a diagnosis item, such as **aa** in the textbox, and then click on the **Add** button. The added item will be displayed in the **Edit Diagnosis Template** window.



2. Adding a subitem

Click on the item you wanted to add a subitem, enter a diagnosis subitem, such as **bb** in the textbox, and then click on the **Add** button. The added subitem will be displayed under **aa**.



3. Deleting an item

Click on the item you wanted to delete from the **Edit Diagnosis Template** window, and then click on the **Delete** button to delete this item.

4. Save the settings

Click on the **Save** button to save these modifications.

Chapter 9 Hint Information

Hint information and the corresponding causes provided by the system are listed as follows.

Table 9-1 Hint Information and Causes

Hint Information	**Causes**
Lead off: X	Electrodes fall off the patient or the patient cable falls off the ECG sampling box.
It is pre-sampling now, please click on 'Start' to begin recording.	During the pre-sampling course
Resting ECG is sampling now!	During the sampling course of Resting ECG
Hint: Please make sure the USB line has been connected. If possible, please re-connect it!	The USB cable is disconnected or the communication between the ECG sampling box and the serial port is interrupted. 1. Reconnect the ECG sampling box to the PC. 2. Click on the **Device** tab in the **System Setting** window of the PC ECG system, and check whether the sampling device is set correctly.
Communication error! Please check the USB cable!	The USB cable falls off the PC during the sampling process.
It is connecting now, please wait…	DX12 transmitter is connecting to DX12 receiver.
Can't find the corresponding Bluetooth sampling device, please make sure the device is on.	Fail to connect with DX12 receiver.
Battery of sampling device is weak, please change the battery after the test.	Battery of DX12 transmitter is low.
Battery is weak, the sampling device is closing.	Battery of DX12 transmitter is low.
Sampling Device is in sleep mode, please press "Power" to wake it up.	DX12 transmitter is in sleep mode.
Overload	The direct current offset voltage on an electrode is too high.

Sorry, Can not Connect to the Database!	MSDE 2000 or SQL Server 2005 Express is not started up.
Fail to create database!	The system fails to create database.

Chapter 10 Cleaning, Care and Maintenance

10.1 Cleaning

CAUTION

Turn off the tablet PC before cleaning. The mains supply must be switched off when using the adapter to charge the tablet PC.

10.1.1 Cleaning Tablet PC and the Patient Cable

1. Wipe the external surfaces of the tablet PC and the patient cable with a soft cloth dampened in any of the approved cleaning solutions listed below.
2. Wring excess moisture from the cloth before cleaning.

Recommended Cleaning Solutions

- ♦ Mild soap and water
- ♦ 75% alcohol

10.1.2 Cleaning the Reusable Electrodes

1. Remove the remainder gel from the electrodes with a clean soft cloth first.
2. Take suction bulbs and metal cups of chest electrodes apart, and take clamps and metal parts of limb electrodes apart.
3. Clean them in warm water and make sure there is no remainder gel.
4. Dry the electrodes with a clean dry cloth or air dry naturally.

CAUTION

1. Prevent the detergent from seeping into the tablet PC while cleaning. Do not immerse the tablet PC or the patient cable into liquid under any circumstances.
2. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
3. Any remainder of detergent should be removed from the tablet PC and the patient cable after cleaning.

10.2 Disinfection

Disinfection of the main unit is not necessary need in daily maintenance, it is only necessary in operating room. In that case, please use hospital standard disinfectant.

NOTE: Clean and disinfect the chest and limb electrodes after each use.

CAUTION

1. Do not use high-temperature, high-pressure vapour or ionizing radiation as disinfection methods.
2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.
3. Always clean and disinfect reusable electrodes after patient use.

10.3 Care and Maintenance

CAUTION

Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.

b) Inspect the safety related labels for legibility.

c) Verify that the device functions properly as described in the instructions for use.

d) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1 ohm.

e) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100 μA, SFC 500 μA.

f) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10 μA, d.c. 10 μA; SFC a.c. 50 μA, d.c. 50 μA.

g) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10 μA, d.c. 10 μA; SFC a.c. 50 μA, d.c. 50 μA.

h) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50 μA (CF).

The data should be recorded in an equipment log. If the equipment is not functioning properly or fails any of the above tests, the equipment has to be repaired.

WARNING

Failure on the part of the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.

1) Tablet PC

- Avoid excessive temperature, sunshine, humidity and dirt.
- Prevent any liquid from seeping into the tablet PC; otherwise the safety and the performance of the electrocardiograph can not be guaranteed.

2) Patient Cable

- Integrity of the patient cable, including the main cable and lead wires, should be checked regularly. Make sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using it. Hold the connector plug instead of the cable when connecting or disconnecting the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in a closed angle while using it.
- Store the lead wires in a big wheel to prevent any people from stumbling.
- Once damage or aging of the patient cable is found, replace it with a new one immediately.

3) Reusable Electrodes

- Electrodes must be cleansed after use and make sure there is no remainder gel on them.
- Keep suction bulbs of chest electrodes away from sunshine and excessive temperature.
- After long-term use, the surfaces of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high-quality ECG records.

CAUTION

The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Chapter 11 Accessories

WARNING

Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed.

Table 11-1 Standard Accessory List for Wired System

Accessory	Part Number
DP12 ECG Sampling Box	02.01.210039
Resting ECG External USB Cable	01.13.036134
DP12 Patient Cable / European Standard	01.57.106902
DP12 Patient Cable / American Standard	01.57.107048
Limb Electrode	01.57.040162
Chest Electrode	01.57.040163
Hasee Tablet PC	02.04.240844
Portable Bag	01.56.465280-10

Table 11-2 Standard Accessory List for Wireless System

Accessory	Part Number
PC ECG&Stress ECG (DX12) Transmitter	02.06.260163
DX12 Patient Cable / European Standard	01.57.471030-10
DX12 Patient Cable / American Standard	01.57.471055-10
Excell Alkaline AA LR6 1.5V	01.21.064086
Disposable electrodes	11.57.471046
Hasee Tablet PC	02.04.240844
Portable Bag	01.56.465280-10

Table 11-3 Optional Accessory List

Accessory	Part Number
MSB1212 Disposable Electrode	01.57.040171
Disposable Frosting Film for Skin Preparation	01.57.107418
Bar Code Reader Z-3152SR（U）	01.18.052267
Bar Code Reader LAB 1000	11.23.068003

Chapter 12 Warranty & Service

12.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.
b) subsequent damage caused by improper use or maintenance.
c) damage caused by alteration or repair by anyone not authorized by EDAN.
d) damage caused by accidents.
e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

12.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC/EN 60601-1+A1+A2, IEC/EN 60601-1-2+A1, IEC/EN60601-2-25, ANSI/AAMI EC11, IEC/EN60601-2-51
Anti-electric-shock type:		Class II
Anti-electric-shock degree:		Type CF with defibrillation-proof
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:		Refer to the user 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 1, Class A
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	DP12 ECG sampling box: -40ºC (-40ºF) ~ +55ºC (+131ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)
	DX12 Transmitter: -20℃ (-4ºF)~+55℃ (+131ºF)	
Relative Humidity:	25%~93% Non-Condensing	25%~80% Non-Condensing
Atmospheric Pressure:	700hPa ~1060hPa	860hPa ~1060hPa

A1.3 Physical Specifications

Dimensions	DP12 ECG sampling box: 148 mm (L) ×100 mm (W) × 40 mm (H) (5.8in×3.9in×1.6in)
	DX12 transmitter: 63mm(L)×107mm(W) ×23mm(H) (2.5in×4.2in×0.9in)
Weight	DP12 ECG sampling box: Approx. 210g
	DX12 transmitter: Approx. 113g (not including battery)

A1.4 Power Supply Specifications

Power Supply:	DP12 ECG Sampling Box:	DC 5V, 1W
		Input Power: 1 VA(MAX), 0.5 VA(MIN)
	DX12 transmitter	Input Power: 2x1.5V Excell Alkaline AA IEC LR6; Operation life of battery≥12 hours

A1.5 Performance Specifications

Display	
Display Content	System name, Patient ID, Patient name Hear rate, Display mode, Printing mode Speed, Gain, Lowpass Filter Hint information ECG waves
Recording	
Recording Paper:	A4, Letter
Paper Width:	210*295mm (A4)，216*279mm (Letter)
Paper Speed:	5 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s（±3%）
Record message:	Date, Time, Printing Speed, Filter, Symbol, Heart Rate, Patient ID, Sex, Age, Lead Mark, Lead Wave, Average Template Wave or Rhythm Lead Wave, Measurement Result and Interpretation Information Result (option) etc.
Channel:	3 / 6 / 12 channels, auto baseline adjustment

HR Recognition	
Technique:	Peak-peak detection
HR Range:	30 BPM ~300 BPM
Accuracy:	±1 BPM
Memory	
Memory:	Storage amount depends on PC machine
ECG Sampling Box Performance	
Leads Mode:	12 standard leads/ Cabrera leads
Acquisition Mode:	simultaneously 12 leads
Sample Frequency:	DP12 ECG sampling box: 1,000 Hz / lead
	DX12 transmitter: 10,000 Hz / lead (sampling) 500 Hz / lead (analysis)
A/D Resolution:	DP12 ECG sampling box: 24 bits
	DX12 transmitter: 18 bits
Time Constant:	≥3.2 s
Frequency Response:	0.05 Hz ~ 150 Hz (-3 dB)
Gain:	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV
Input Impedance:	DP12 ECG sampling box≥50 MΩ (10Hz)
	DX12 transmitter≥20 MΩ (10Hz)
Input Circuit Current:	≤0.05 μA
Input Voltage Range	<±5 mVpp
Calibration Voltage:	1 mV± 2%
DC Offset Voltage	DP12 ECG sampling box: ±600mV
	DX12 transmitter: ±500mV
Noise:	DP12 ECG sampling box≤12.5μVp-p
	DX12 transmitter≤15μVp-p
Filter	Work Frequency
	DFT Filter: weak/strong
	LOWPASS Filter: 25 Hz / 35 Hz / 45 Hz / 75 Hz / 100 Hz / 150 Hz

CMRR	DP12 ECG sampling box≥110 dB
	DX12 transmitter≥100 dB
Pacemaker Detection	
Amplitude	DP12 ECG sampling box: ±2 to ±700 mV
	DX12 transmitter: ±2 to ±500 mV
Width	0.1 to 2.0 ms
Sampling Frequency	DP12 ECG sampling box:10,000 Hz / rhythm lead DX12 transmitter: 10,000 Hz / lead

NOTE: Test the accuracy of input signal reproduction according to the methods described in clause 4.2.7.2 in ANSI/AAMI EC11:1991/(R) 2001/(R) 2007, and the result complies with clause 3.2.7.2 in ANSI/AAMI EC11:1991/(R) 2001/(R) 2007.

Appendix 2 EMC Information

Guidance and manufacture's declaration - electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

<table>
<tr><td colspan="3">Guidance and manufacture's declaration - electromagnetic emission</td></tr>
<tr><td colspan="3">SE-1010 PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1010 PC ECG should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>SE-1010 PC ECG 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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">SE-1010 PC ECG is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and manufacture's declaration - electromagnetic immunity -
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration - electromagnetic immunity			
SE-1010 PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1010 PC ECG 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 ±2 kV contact (only for system with tablet PC) ±2 kV air (only for system with tablet PC)	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to groud	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of SE-1010 PC ECG requires

IEC 61000-4-11	for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec		continued operation during power mains interruptions, it is recommended that SE-1010 PC ECG be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration - electromagnetic immunity -

for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration - electromagnetic immunity			
SE-1010 PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1010 PC ECG should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	$3V_{rms}$ 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of SE-1010 PC ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[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 SE-1010 PC ECG is used exceeds the applicable RF compliance level above, SE-1010 PC ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating SE-1010 PC ECG.

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

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

Recommended separation distances between portable and mobile RF communications equipment and SE-1010 PC ECG

SE-1010 PC ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of SE-1010 PC ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and SE-1010 PC ECG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 3 Abbreviation

Abbreviation	Statement
ECG	Electrocardiograph/Electrocardiogram
BP	Blood Pressure
HR	Heart Rate
P	P-wave Duration
PR	P-R Interval
QRS	QRS Complexes Duration
QT/QTc	Q-T Interval of the Current Lead / Normalized QT Interval
P/QRS/T	Dominant Direction of the Average Integrated ECG Vectors
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
LA	Left Arm
LL	Left Leg
RA	Right Arm
RL	Right Leg
ID	Identification
AC	Alternating Current
USB	Universal Serial Bus
NC	Normal Condition
SFC	Single Fault Condition

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