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PADECG

PC ECG

(Android) Version 1.5

User Manual

CE 0123

EDAN

About this Manual

P/N: 01.54.455973

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Release Date: August. 2015

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) cannot 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 PADECG.

1.1 Intended Use/Indications for Use

The intended use of PADECG is to acquire resting ECG signals from adult and pediatric patients through body surface ECG electrodes. It is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by PADECG can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only. It is mainly used in ECG inpatient department of hospitals or healthcare facilities.

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 cannot 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. Otherwise, safety hazards may happen.
3. **EXPLOSION HAZARD** - Do not use the system in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection cannot 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.
5. Make sure that all electrodes are connected to the patient correctly before operation.
6. 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.
7. 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.
8. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.
9. The disposable electrodes can only be used for one time.
10. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
11. Do not touch accessible parts of electrical equipment and the patient simultaneously.
12. 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.
13. Fix attention on the examination to avoid missing important ECG waves.
14. **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

15. **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.
16. 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.
17. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
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 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.
20. 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.
21. Connecting any accessory (such as external printer) or other device (such as the computer) to this system 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.
22. 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

23. You are recommended to purchase the Android tablet from the manufacturer. Otherwise, the manufacturer will not be held responsible for the maintenance of the hardware, operating system and other accessories.
24. 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.
25. Connecting to other devices may decrease the antistatic gradation of the system during operation.
26. Make sure that there is no intense electromagnetic interference source around when using the wireless system of PADECG. Furthermore, Keep a unobstructed distance of at most 6 meters between DX12 transmitter and the Android tablet.
27. Do not open the battery cover of DX12 transmitter when using the wireless system of PADECG.
28. The Android 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 Android tablet shall be charged outside the patient environment, and no operations are permitted during the charging.
29. The device shall not be serviced or maintained while in use with a patient.
30. The appliance coupler or mains plug is used as isolation means from supply mains. Position the ECG workstation in a location where the operator can easily access the disconnection device.
31. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC information.
32. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
33. The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
34. Assembly of the ECG workstation and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

1.2.2 Battery Care Warnings

WARNING

1. Improper operation may cause the internal 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.
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.

CAUTION

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

No.	Symbol	Description
1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		Caution
3		Operating instructions
4		General symbol for recovery/recyclable
5	P/N	Part Number
6	SN	SERIAL NUMBER
7		Date of manufacture
8		MANUFACTURER
9	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

10	CE 0123	CE marking
11		Disposal method
12	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
13		Refer to User Manual (Background: Blue; Symbol: White)
14		Warning (Background: Yellow; Symbol&Outline: Black)
15		Non- ionizing electromagnetic radiation

NOTE: The user manual is printed in black and white.

Chapter 2 Introduction

PADECG as mobile ECG Workstation has similar functions with an ordinary ECG Workstation. ECG data can be sampled, analyzed and stored in a Pad, ECG waves can be reviewed. Auto measurement and diagnosis are available, and the diagnosis template can be edited.

PADECG includes the following equipment, you can also purchase the Android tablet.

- PADECG software
- ECG Sampling Box (DX12 transmitter)
- Patient Cable
- Electrodes

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

2.1 Assembling the System

2.1.1 PADECG System

WARNING

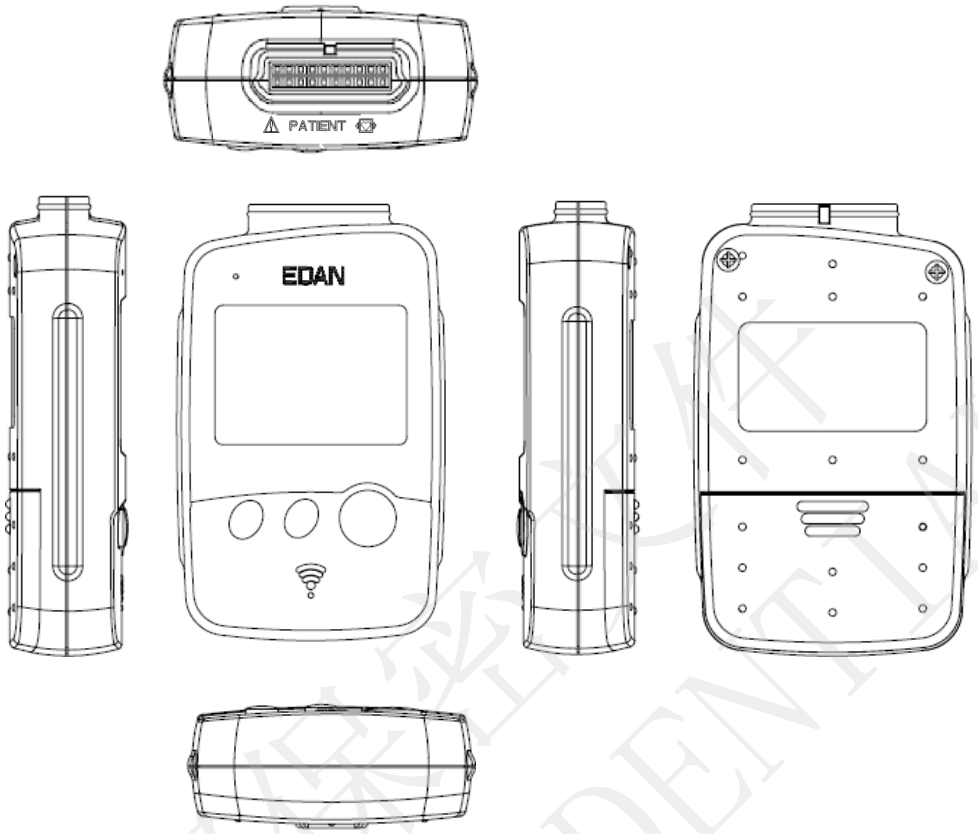
DX12 transmitter of the wireless system uses the Bluetooth technology, which could make the patient with the pacemaker uncomfortable. Keep DX12 transmitter far away from the pacemaker when using the wireless system of PADECG, Android.

WARNING

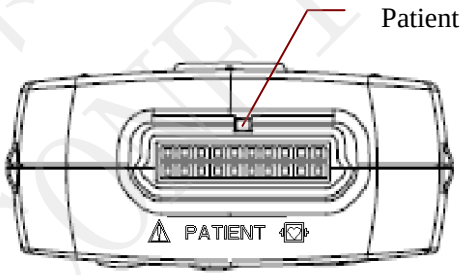
1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard 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 ECG Sampling Box

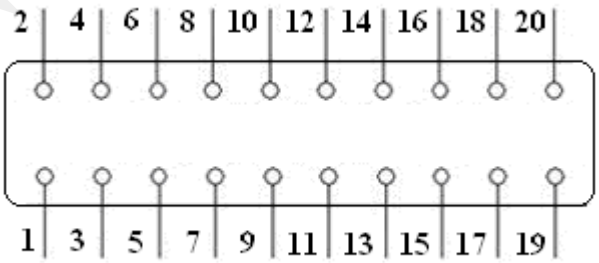
DX12 Transmitter Appearance



Front Panel



Patient Cable Socket



: Applied part of type CF with defibrillator proof

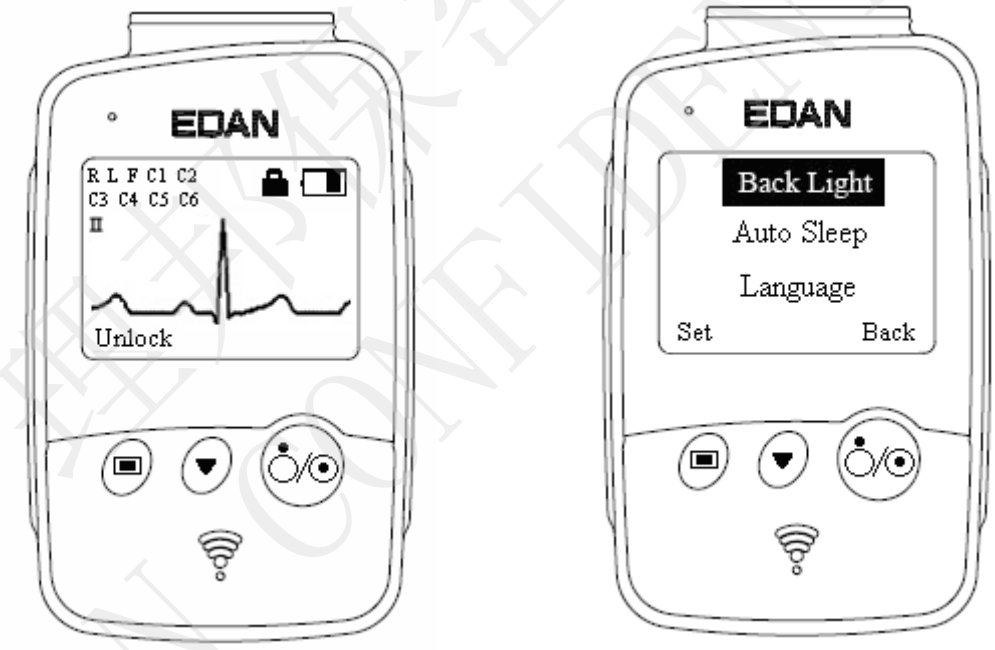
: Caution

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.

2.1.2.1 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 Menu 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 PADECG software.

2.1.2.2 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 set the system language.
Lead Electrode	You can select **IEC** or **AHA**.
Match Device	**Searching Bluetooth device…**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.
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 Installing the Software

NOTE:

1. Before the delivery, the operating system has been installed in the Android tablet; If you purchase the wireless system of PADECG, the Android tablet 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 Android tablet needs to be reinstalled or DX12 transmitter is broken.

2.2.1 System Running Environment

Operating System	Android 4.0 ICS
CPU:	Dual core 1.5GHZ or above
System Memory (RAM):	1G or above
Hard Disk:	8G or above
Display:	7” TFT (Resolution: 1024*600) or 10.1” TFT (Resolution: 1280*800)
Wireless Network Card:	Built-in WIFI, IEEE802.11B/G/N
External Interface:	USB2.0
Bluetooth:	Bluetooth 3.0 or above

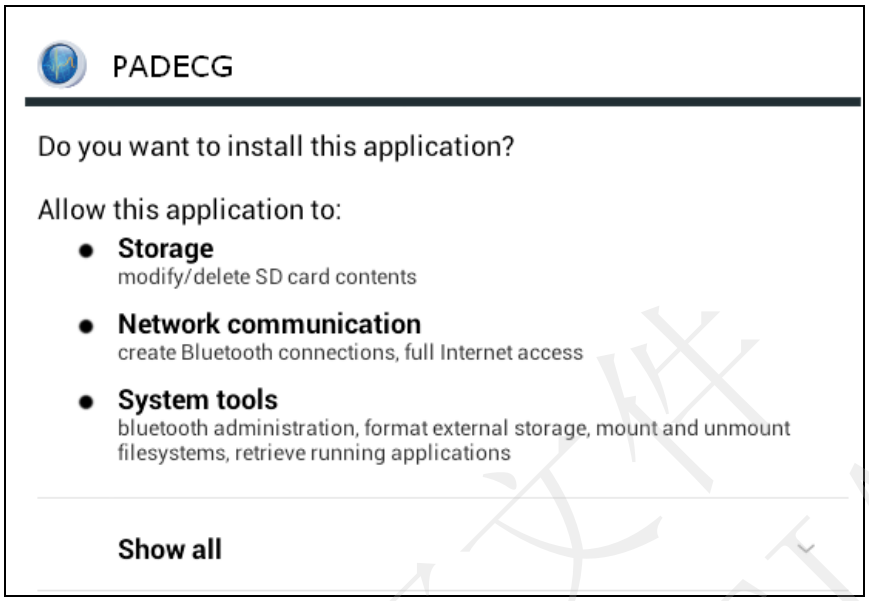
NOTE: Please use the SAMSUNG tablets recommended by the manufacturer, including GT-P5210 and P3110.

WARNING

1. Using tablets of other companies may cause software incompatibility. If necessary, contact the local distributor.
2. Use the PADECG system only on the tablet that is installed with the official operating system (OS) versions released by the tablet's manufacturer.
3. When upgrading the tablet OS, consult EDAN service engineer if necessary.

2.2.2 About Installation Window

Click on the installation folder to open the following installation window.



Click on the **Install** button, and then perform as the hint information prompted by the system. Click on the **Finish** button to complete the installation.

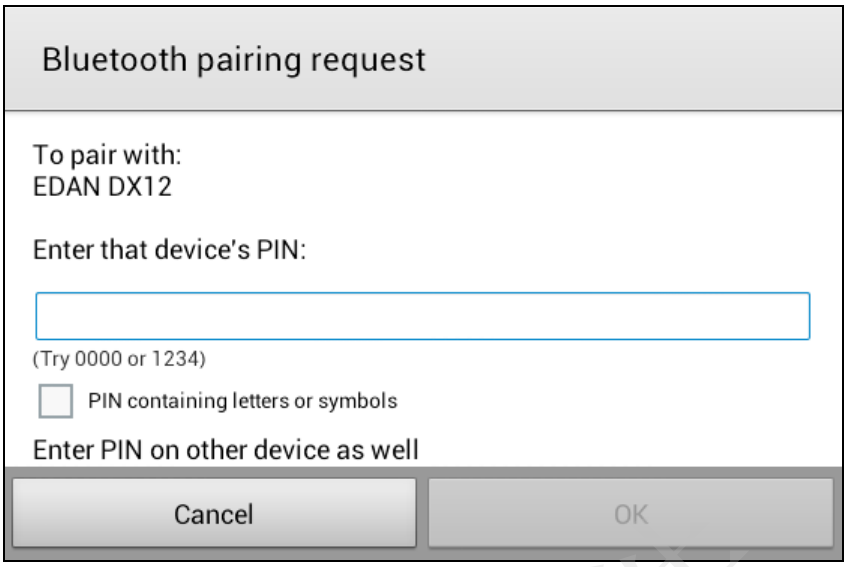
NOTE:

1. Ensure you exit and uninstall the software before the reinstallation; otherwise, data will be lost.
2. If a lower version of PADECG is installed, uninstall it before installing V1.2, and then delete folder ***ecgdata*** and ***edan*** under the root directory of the device memory. If you want to save the history data, backup the two folders before uninstallation. Otherwise, data will be lost.

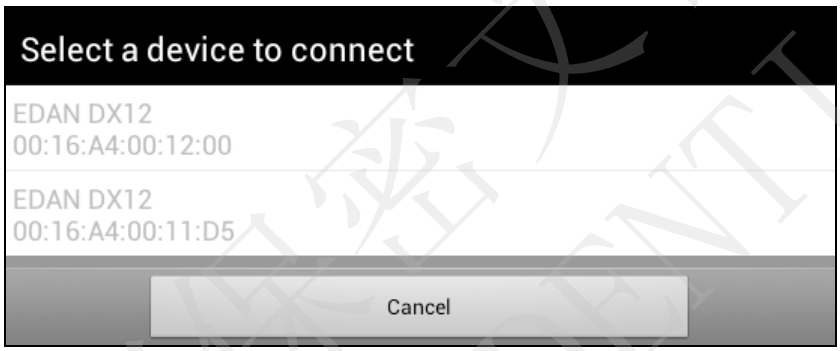
2.2.3 Matching DX12 Transmitter with Android Tablet

The system will automatically enter the **Login** dialogue after you turn on the Android tablet. Enter the correct name and password, and then the following window pops up.

Enter the device's PIN (12345678), and then click on the **OK** button.



If more than one DX12 transmitter is around, you can select the required one in the following window.



Operation for viewing device information of the required transmitter: turn on DX12 transmitter → press → press to display **Device Information** in black → press .

NOTE:

1. Before matching DX12 transmitter and the Android tablet, ensure batteries of DX12 transmitter and Android tablet are full.
2. When selecting the required DX12 transmitter, ensure the required one is powered on.
3. You can also match DX12 transmitter by configuring the Android tablet.

2.3 Features

- Reliable and handy data recording, suitable for doctors' inspections and visits
- Android operating system, friendly windows and easy operation
- Supporting Worklist function
- Perfect data management, sampled ECG data can be transmitted to Smart ECG Viewer or Smart ECG Net system over LAN
- 3-/6-/12-channel ECG waves are displayed simultaneously
- Supporting amplifying ECG waves, providing manual measurement with an electronic ruler of high precision
- 0.32 Hz/0.67Hz DFT filter greatly reduces the baseline fluctuations without affecting ECG signals
- Supporting auto measurement and diagnosis
- Supporting editing the Diagnosis Template
- 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 the main cable and lead wires which can be connected to electrodes.

1. Connect the patient cable to the socket of DX12 transmitter.
2. Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the electrodes. Firmly attach them.

3.3 Attaching Electrodes

WARNING

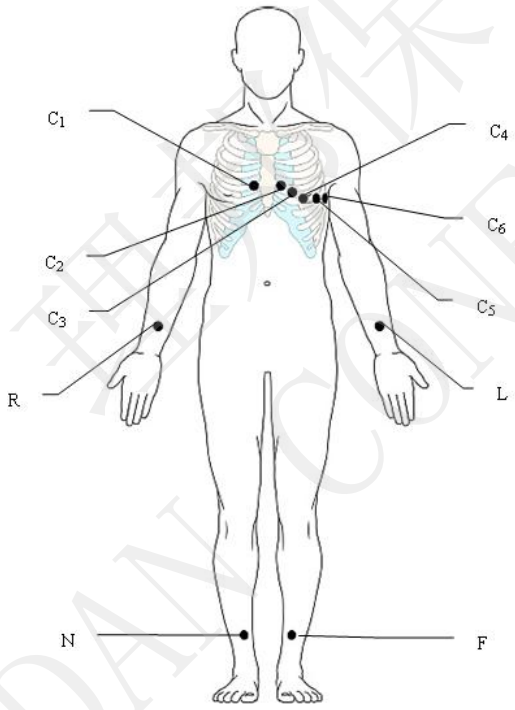
Make sure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

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.

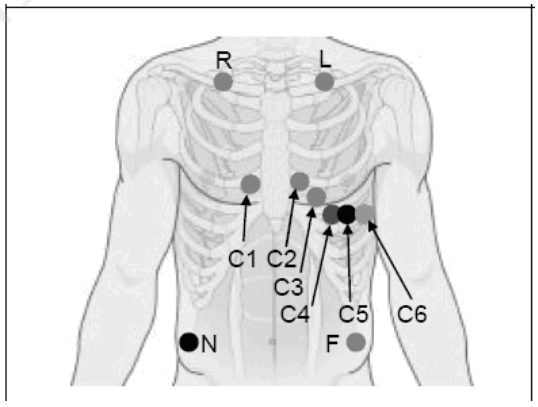
Table 3-1 Electrodes and Their Identifiers and Color Codes

		IEC		AHA	
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/Yello	V2	Brown/Yello
Chest 3	C	C3	White/Green	V3	Brown/Green
Chest 4	A	C4	White/Brow	V4	Brown/Blue
Chest 5	M	C5	White/Black	V5	Brown/Orang
Chest 6	H	C6	White/Violet	V6	Brown/Violet

3.3.1 Electrode Placement



Only for the Reusable Electrodes

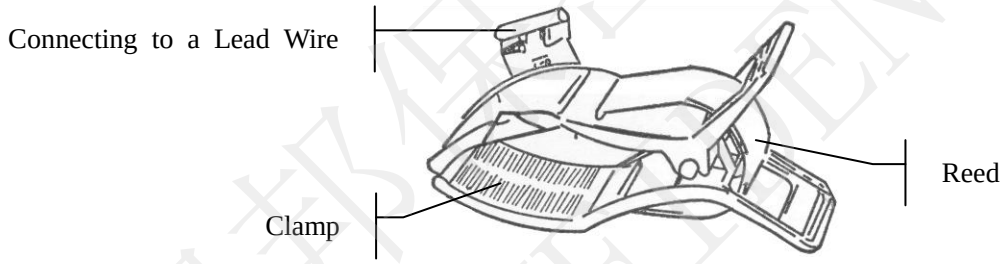


Only for the Disposable Electrodes

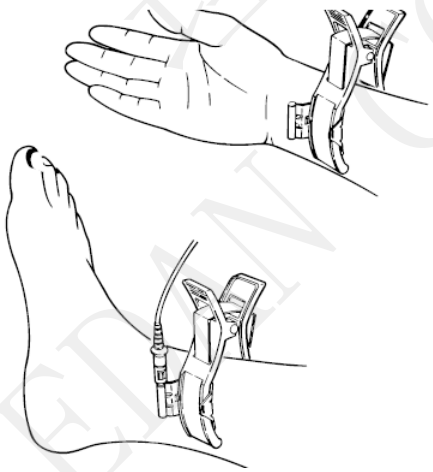
IEC	AHA	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4	V4	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal 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



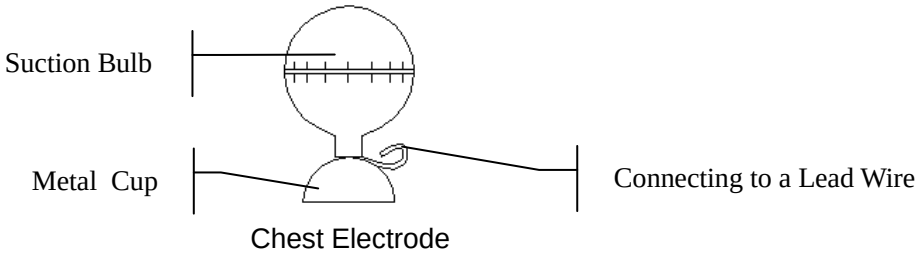
Limb Electrode



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:

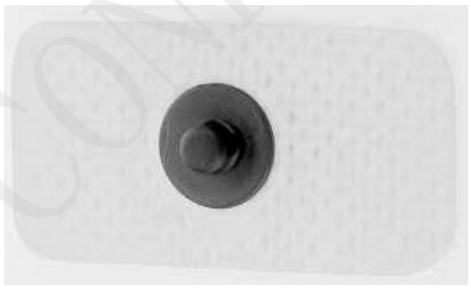
1) Ensure that the electrodes are clean;
2) Clean the electrode area on the chest surface with 75% alcohol;
3) Daub the round area of 25mm in diameter on each electrode site with gel evenly;
4) Place a small amount of gel on the brim of the chest electrode's metal cup;
5) Place the electrode on the chest 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 Operation Instructions

Turn on the Android tablet, the system will automatically start and detect for sampling box.

If no sampling box is detected and no data exists on the file screen, a dialog box requiring password will be displayed. Enter the correct password and you will enter the login screen. You can choose to log in in the **Local** mode or **Network** mode.

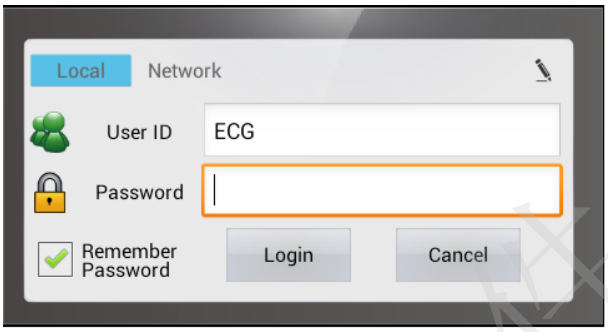


Figure 4-1 Login Screen-local Mode

 : Click this button and you can set the user password.

If Network mode is selected, you should set the network address before login.

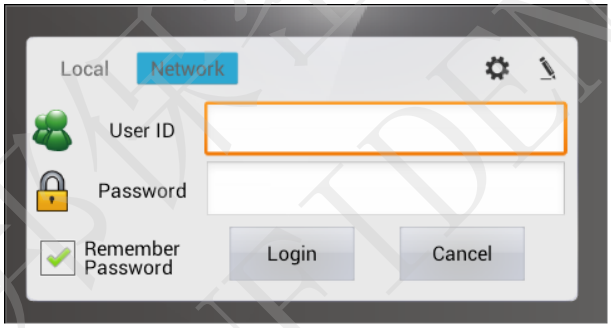


Figure 4-2 Login Screen-network Mode

 : Click this button and you can set the login password.

 : Click this button and you can modify the network address.

If the software is started for the first time or the first time after initialization, the following window will be displayed after login.

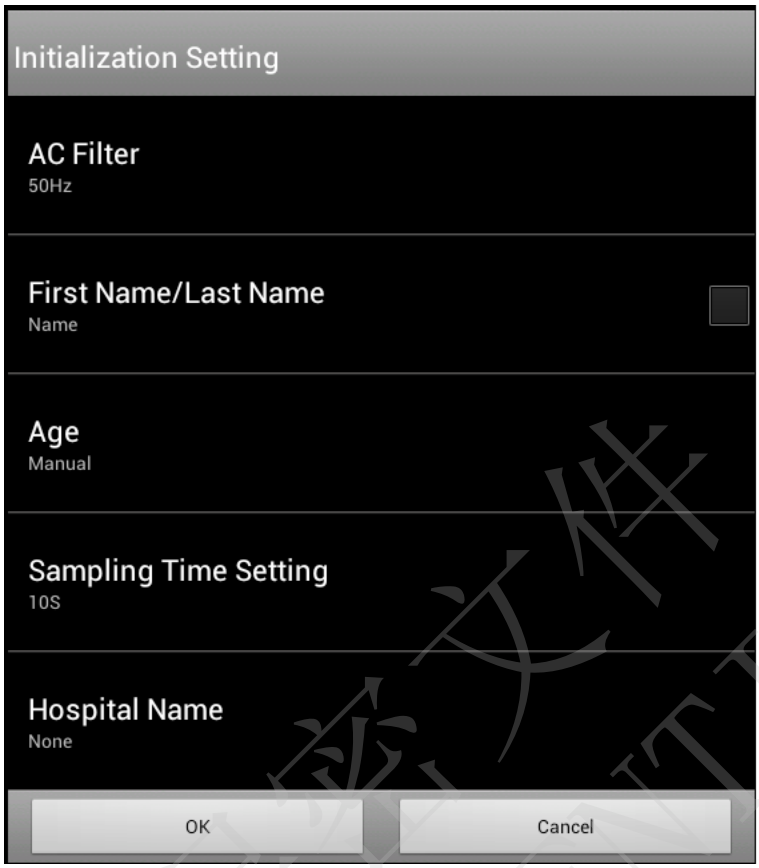


Figure 4-3 Initialization Window

Make the related settings, click on the **OK** button, and then the system will automatically enter the Patient screen.

NOTE: Do not run other applications when running PADECG, or the system response speed will be affected.

4.1 Entering Patient Information

On the Patient screen, you can view or create patient orders.

1. **Entering patient information**

   Press  on the patient screen, and then the system will automatically enter the **New Patient** screen.

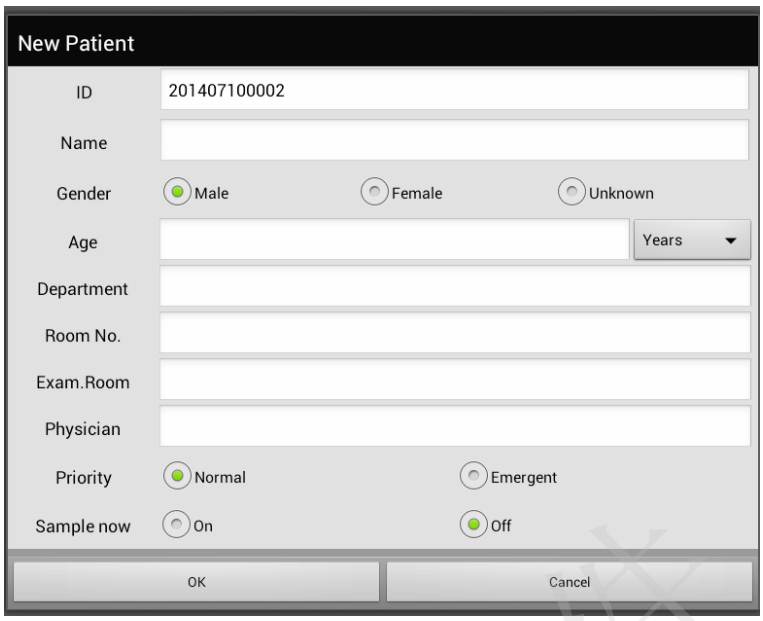


Figure 4-4 New Patient Screen

Input the related patient information in the inputting area, click **OK** and the new patient record will be listed on top of the information list.

If **Sample now** is enabled, the system will automatically enter the pre-sampling screen after you click on the **OK** button.

NOTE: Patient ID is a must when entering patient information. You can use the number generated by the system or input a number manually. Patient ID can be a random character string excluding '/', '\', ':', '*', '?', '<', '>' ,'|', '%' and Chinese characters.

2. Searching, modifying and deleting patient information

Input the patient name in the search area, click on  , and all the patient information which meet the conditions will be displayed in the information list. Patient records in emergent state will always be listed on the top.

NOTE: Fuzzy search is supported in the search area.

Long press the patient information in the information list, you can modify or delete patient information.

3. Description for buttons

 (Upper right corner)	Options in the local mode: **Delete, Scan, Sequence Setting, Download Setting** Options in the network mode: **Delete, Scan, Sequence Setting, Query Setting** ♦ **Delete**: Press to delete one or multiple orders. ♦ **Scan**: Press to input patient information by scanning a bar code.

	♦ **Sequence Setting**: Press to set the sequencing conditions. ♦ **Download Setting**: Press to set the filter conditions for downloading patient information from the server. ♦ **Query Setting**: Press to set the filter conditions for searching patient information.
	Press to load orders from Smart ECG Viewer or Smart ECG Net system. For details, please refer to Section 4.5.4. **NOTE:** 1. 1000 patient records can be displayed in the information list, and 200 latest created orders in Smart ECG Viewer or Smart ECG Net system can be loaded at one time. 2. This item only applies to the local mode.
	Press to refresh the file list. **NOTE**: This item only applies to the network mode.
	Press this button to cancel operations.
 (From the device)	No response is provided for this button on the current screen.
	If the number of orders exceeds the maximum of a page, press these keys to turn pages.
File	Press to enter the file manager screen. For details about the file manager screen, refer to section 4.4 "Processing Patient Records".
System Setting	Press to enter the system setting screen. For details about the system setting screen, refer to section 4.5 "Configuring the System".

4.2 Sampling ECG Data

Enable **Sample now** and then click **OK** on the **New Patient** screen, the system will automatically enter the pre-sampling screen. If **Sample now** is not disabled, click on **OK** and click on the patient record in the patient list to enter the pre-sampling screen.

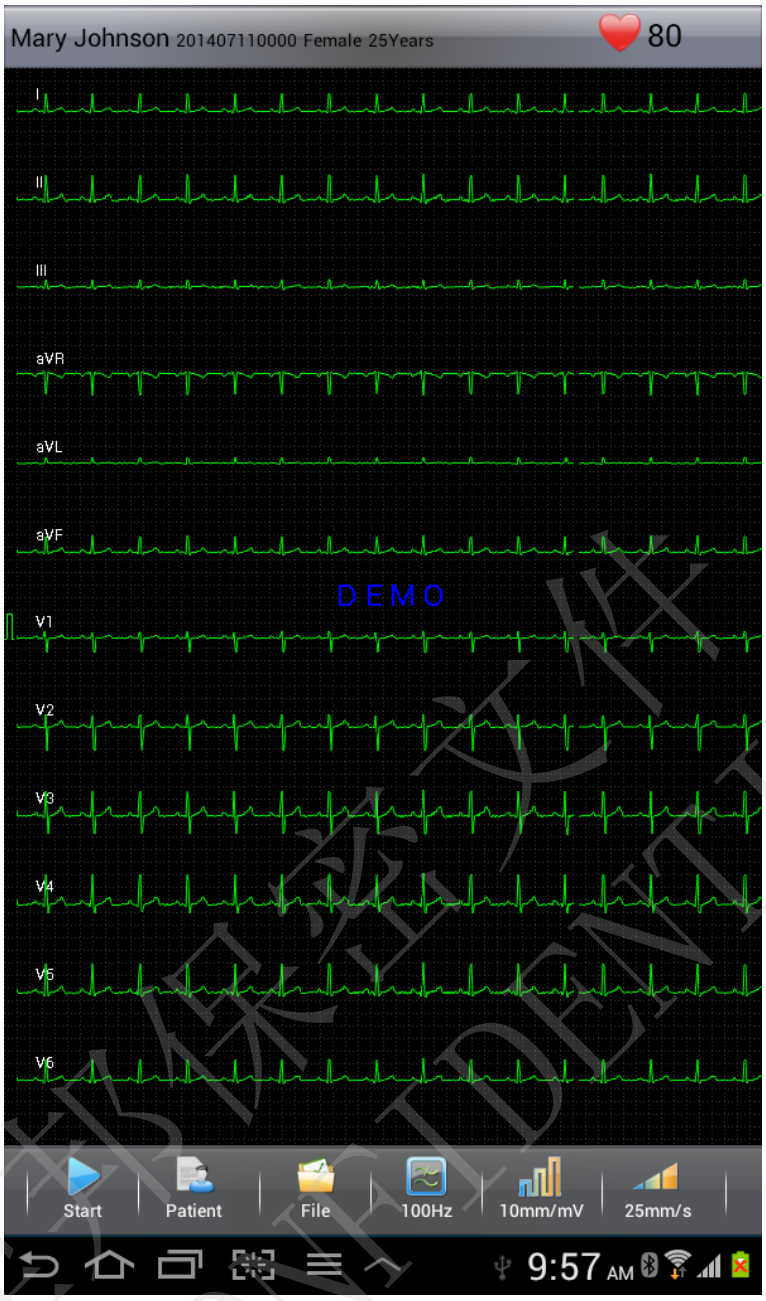


Figure 4-5 Pre-sampling Screen

Start/Stop	Press this button to start/stop sampling ECG data. **NOTE:** At most 10s ECG data can be sampled.
File	Press this button to enter the File Manager screen. For details, please refer to Section 4.4.

100Hz	EMG Filter: Off, 25Hz, 35Hz or 45Hz Lowpass Filter: Off, 75Hz, 100Hz or 150Hz **NOTE:** This setup modified on the pre-sampling screen is only effective for the current patient.
10mm/mV	Gain: 2.5 mm/mV, 5 mm/mV, 10 mm/mV or 20 mm/mV **NOTE:** This setup modified on the pre-sampling screen is only effective for the current patient. The system automatically remembers the last modification.
25mm/s	Speed: 5mm/s, 12.5mm/s, 25mm/s or 50mm/s **NOTE:** This setup modified on the pre-sampling screen is only effective for the current patient. The system automatically remembers the last modification.
	No response is provided for this button on the current screen.
Patient	Press to enter the patient screen.
File	Press to enter the file manager screen.

NOTE: Long press the tablet screen during ECG data pre-sampling, the display mode of 12-channel ECG waves will be switched among 12×1, 6×2+1 and 3×4+1.

4.3 Analyzing ECG Data

The system will automatically enter the ECG Analysis screen after sampling 10s ECG data. ECG data can be displayed with the following style: **12×1**, **6×2+1**, and **3×4+1**.

1. Viewing ECG waveform

Long press the rhythm waveform to display the **Rhythm Lead** window on the 6×2+1 or 3×4+1 ECG Analysis screen. You can view other rhythm waveform by selecting one lead in the pop-up window.

You can view other waveforms by dragging or clicking on the rhythm waveform on the 6×2+1 or 3×4+1 ECG Analysis screen.

2. Amplifying and measuring ECG waveform

Multi-touch on the ECG waveforms of the ECG Analysis screen can be used to amplify or minify the ECG waveforms.

Long pressing the waveform on the ECG Analysis screen can amplify the ECG waveform.

Press  on the Amplified Waveform screen to measure the ECG waveform. Press this button again to cancel measuring.

3. Modifying measure information

Long press one parameter in the top left corner of the ECG Analysis screen, and the **Modify measure information** window pops up. Make the related settings, and then click on the **OK** button to save the modifications.

The common parameters are displayed as follows.

Designation	Description
HR (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 (°)	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

4. Modifying diagnosis results

Long press one diagnosis result in the top right corner of the ECG Analysis screen, and the **Auto Diagnosis** window pops up.

Select one diagnosis result from the **Diagnosis List** or input diagnosis information directly in the textbox, and click on the **OK** button to save the modifications.

5. Modifying Diagnosis List

Long press one diagnosis result in the **Diagnosis List**, and you can add, delete, or modify the diagnosis result.

NOTE: If **Diagnosis List** is modified, you should click on the **Save** button in the **Auto Diagnosis** window to save the related modifications.

6. Email

Click on  on the analysis screen, and then you can Email files by clicking on the **Send Email** button. The procedure is as follows:

1) Click on **Send Email** and a file format selection window will be displayed.
2) Select a file format in the displayed window.

   Options provided are: **PDF**, **JPG**, and **BMP**. The default value is **PDF**.
3) After the file format is selected, the current file will be added to the mail editing window as an accessory. Input the receiver address before sending it.

7. Edit

Click on  on the analysis screen, and then you can click on **Edit** to modify patient information.

8. Print

Click on  on the analysis screen, and then you click on **Print** to print the current examination record.

If it is the first time that the print function has been used, you have to configure the WIFI connection with the printer before printing.

Printer recommended: ML-2166W

NOTE: For more detailed information about configuring the WIFI connection with the printer, please contact the manufacturer or the local distributor.

4.4 Processing Patient Records

4.4.1 Local Mode

1. Search

Input the patient name in the search area, click on  , and all the examination records which meet the conditions will be displayed in the examination record list.

NOTE: Fuzzy search is supported in the search area.

2. Upload and Delete

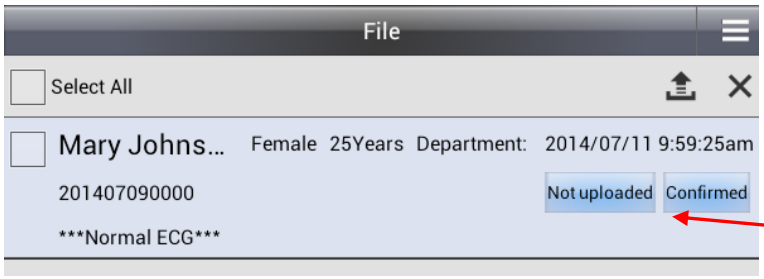
Long press one examination record in the examination record list, and you can perform the following operations on the selected record: view, upload, print, modify, or delete.

NOTE:

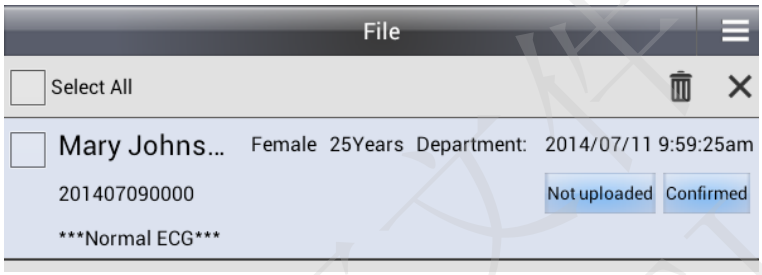
1. The patient ID cannot be modified.
2. The modification on the patient name and gender will be synchronized to other data of the same patient ID.

If you need to delete or upload records in bulk, press  on the upper right corner and choose **Upload** or **Delete**.

Press **Upload**, and the following screen will be displayed:



Press **Delete**, and the following screen will be displayed:



Description for buttons

	Press this button to enter submenu.
	Press this button to cancel operations.
	Press this button to upload the selected examination records to Smart ECG Viewer or Smart ECG Net system.
	If the checkbox before **Select All** is ticked, pressing this button can clear the examination record list.
	Press this button to cancel operations.

4.4.2 Network Mode

Long press on a patient record and you can analyze, edit or print its information.

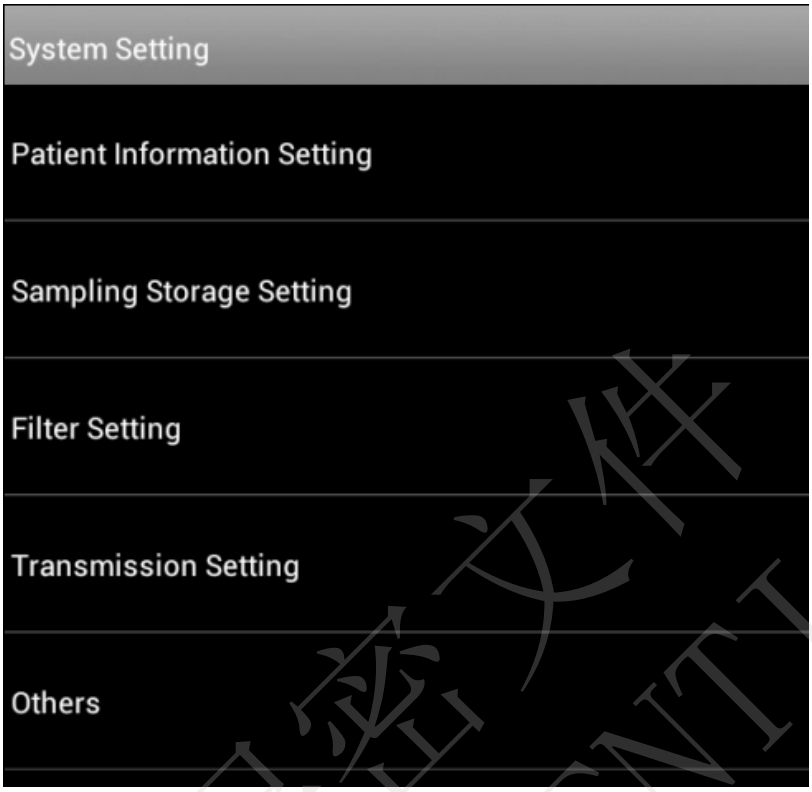
Press on  the upper right screen to enter the Query Setting window.

On the Query Setting window, you can set the conditions for searching required patient records.

NOTE: State **Consulted** and **Consulting** cannot be selected simultaneously.

4.5 Configuring the System

The system will automatically save the modifications after you make the related settings.



4.5.1 Patient Information Setup

Item	Description
ID Generating Mode	Choose from: **Auto** or **Manual** Select **Auto**, the patient ID can be automatically generated according to the examination date. Select **Manual**, you should enter the patient ID manually on the **New Patient** screen.
Default Patient ID	No more than 4 letters or numbers can be entered. The total length of the patient ID and default patient ID must be within 30 ASCII characters.
First Name/ Last Name	Select this item, the **Name** textbox on the **New Patient** screen will change into the **First Name** and **Last Name** textboxes.
Age	Choose from: **Manual** or **Date of Birth** Select **Manual**, you can enter the age manually on the **New Patient** screen.

	Select **Date of Birth**, the **Date of Birth** textbox appears on the **New Patient** screen. You can enter the birthday of the patient, and the system will calculate the patient age automatically.
Other Display Settings	You can configure the items to be displayed on the **New Patient** window, including: height, weight, blood pressure, race, medication, department, room number, request number, exam. room, technician, physician, and priority. You can also add other items to be displayed by editing the customization options. **NOTE**: Under the network mode, Exam. Room is selected by default and cannot be modified.
Barcode Setting	**NOTE:** 1. The barcode settings only apply to two-dimensional barcode. 2. If unset, the scanned results may be incorrect. Enter the start and end addresses, the male and female codes and encoding mode, and then click on the **OK** button confirm.

4.5.2 Sampling Storage Setup

Item	Description
Sampling Mode	Choose from: **Real-time Sample, Pre-sample** ➢ Select **Pre-Sample**, 10s ECG data before pressing the **Start** key will be saved. **NOTE:** When **Sampling Mode** is set to **Pre-Sample**, if you press the **Start** key before the electrocardiograph samples for 10s, the recorder will not respond. ➢ Select **Real-time Sample**, 10s ECG data sampled after pressing the **Start** key will be saved.
Sampling Time Setting	It can be set to a value between 10s and 180s. **NOTE**: The pre-sample time is a fixed value of 10s.
Auto Diagnosis	If selected, the system automatically generates diagnosis results after sampling finishes.
Enter the Analysis screen when	If selected, the system automatically enters the wave analysis screen after sampling finishes.

sampling finishes	
File Format	Choose from: **SCP**, **FDA-XML**, **DICOM**, **PDF**, **JPG**, **BMP**. If selected, files in the selected format will be generated when sampling finishes. **NOTE**: This item only applies to the local mode.
Speed	Options: 25mm/s, 50 mm/s It is used to set the print speed.
Report Format	Choose from: **12*1**, **6*2+1**, **3*4+1**.
Rhythm Lead Definition	It can be set to any one of the leads. The default value is **II**.
Edit Analysis Result Locally	If selected, you can modify the measurement information and diagnosis results locally.
Saving Path	Choose from: **Built-in SD Card**, **External SD Card**

4.5.3 Filter Setup

Item	Description
DFT Filter	DFT filter greatly reduces the baseline fluctuations without affecting ECG signals. The purpose of this filter is to keep the ECG signals on the baseline of the printout. Choose from: **0.05Hz**, **0.32Hz** or **0.67Hz** The set value is the low limit of the frequency range.
EMG Filter	EMG filter suppresses the disturbance caused by strong muscle tremor. The cutoff frequency can be set to **Off**, **25Hz**, **35Hz** or **45Hz**.
Lowpass Filter	Lowpass Filter restricts the bandwidth of input signals. The cutoff frequency can be set to **Off**, **75Hz**, **100Hz** or **150Hz**. All the input signals whose frequency is higher than the set cutoff frequency will be attenuated. **NOTE**: The Lowpass Filter is effective only when the **EMG Filter** is set to **Off**.
AC Filter	AC filter suppresses AC interference without attenuating or distorting ECG signals. Choose from: **Off**, **50Hz** and **60Hz**.

NOTE: To pass the distortion test, the ECG workstation has to be configured with the highest bandwidth in filter settings. Otherwise, ECG signal may be distorted.

4.5.4 Transmission Setup

Item	Description
Device No.	Type the Device No., within 30 ASCII characters.
Auto Upload	Select this item, the system will automatically upload files to Smart ECG Viewer or Smart ECG Net system when sampling finishes. **NOTE:** This item only applies to the local mode. Under the network mode, the system automatically uploads files when sampling finishes.
Delete file after uploaded	Select this item, the system will automatically delete files from the examination record list after they are uploaded. **NOTE:** This item only applies to the local mode.
Web Browser Integration	Select this item, the system automatically generates a PDF report after sampling in the network mode, and then uploads the report to Smart ECG Viewer or Smart ECG Net. In this way, the user can view the report with a web browser.
Refresh Interval	It is used to set the interval of refreshing the order or file list. **NOTE:** This item only applies to the network mode.
WebService Address	Set the web server address. **NOTE:** This item only applies to the network mode.
Automatic Synchronization	Choose from: **Off,10s, 20s, 30s, 1min, 2min, 3min, 5min** After the synchronization interval is set, the system automatically sends a request to the server for data synchronization over the set interval.
Order Server Address	Set it to IP address of the order server. **NOTE:** For more information on configuring network settings, see your Network Administrator.
FTP Setting	Set the FTP address, port, user name, and password of the FTP server.

4.5.5 Other Setup

Item	Description
DEMO mode	Choose from: **Off**, **Normal** or **Abnormal**
UI style	Choose from: **Classical** or **Bright**

Hospital Name	Enter the hospital name, within 20 Chinese characters or within 60 English characters. The configured hospital name will appear in the PDF/JPG/BMP report.
System Password	Type a password that allows you to access the **System Setting** screen.
Restore the default setting	Press to restore the factory settings.
Bluetooth Device Address	Display the information of Bluetooth devices. **NOTE**: If a DX12 sampling box is connected, its information will be displayed on the screen, otherwise, the hint "*Unconnected to any Bluetooth device*" will be displayed.

Chapter 5 Hint Information

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

Table 5-1 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.
Network unavailable!	3G/WIFI is disabled.
Network connection timeout, please check the network.	The network signal is poor, and fails to be connected.
Order server connection fails!	The order server address is not configured.
FTP connection fails!	FTP information is unset.
Searching Bluetooth device….	The system is searching DX12 Bluetooth device
No sampling device is detected, please make sure the device is on!	Fail to find DX12 transmitter or it is not turned on.
Unable to connect to the sampling device!	DX12 transmitter fails to be matched with the Android tablet.
Battery of sampling device is weak, please change the battery after the test!	Battery of DX12 transmitter is low.
Battery is weak, and the sampling device will be powered off!	Battery of DX12 transmitter is low.
Are you sure to stop sampling?	Click on  when sampling ECG data.
The account has been cancelled!	The account has been cancelled on the server.
The account has been forbidden!	The account has been forbidden on the server.
Not authorized to perform the operation!	The user does not have the right to perform the operation.

Chapter 6 Cleaning, Care and Maintenance

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Edan Instruments has validated the cleaning and disinfection instructions provided in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

6.1 General Points

Keep your sampling box and accessories free of dust and dirt. To prevent the device from damage, please follow the instructions:

- Use only the recommended cleaning agents and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the equipment.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the sampling box and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

6.2 Cleaning

If the equipment or accessory has been in contact with the patient, then cleaning and disinfection is required after each use.

The validated cleaning agents for cleaning the sampling box and patient cable are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

The validated cleaning agent for cleaning the reusable electrodes is:

- Mild near neutral detergent

Cleaning agents should be applied or removed using a clean, soft, non-abrasive cloth or paper towel.

6.2.1 Cleaning the Sampling Box

WARNING

Turn off the power and take out the battery before cleaning.

1. Switch off the sampling box and take out the battery.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the sampling box in a ventilated and cool place.

6.2.2 Cleaning the Patient Cable

1. Wipe the patient cable with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
3. Wipe off with a dry cloth to remove residual moisture.
4. Leave the patient cable to air dry.

CAUTION

Any remainder of cleaning solution should be removed from the sampling box and the patient cable after cleaning.

6.2.3 Cleaning the Reusable Electrodes

1. Wipe off with a soft cloth to remove residual gel.
2. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.

4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the suction bulbs and clamps to air dry.

6.3 Disinfection

To avoid permanent damage to the equipment, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital' regulations.

Clean the equipment and reusable accessories before they are disinfected. The validated disinfectants for disinfecting the sampling box and patient cable are:

- Ethanol (75%)
- Isopropanol (70%)

The validated disinfectant for disinfecting the reusable electrodes is:

- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

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. Clean and disinfect reusable electrodes after each use.

6.3.1 Disinfecting the Sampling Box

WARNING

Turn off the power and take out the battery before disinfection.

1. Switch off the sampling box and take out the battery.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
3. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
4. Dry the sampling box for at least 30 minutes in a ventilated and cool place.

6.3.2 Disinfecting the Patient Cable

1. Wipe the patient cable with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the patient cable to air dry for at least 30 minutes.

6.3.3 Disinfecting the Reusable Electrodes

1. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the suction bulbs and clamps to air dry for at least 30 minutes.

6.4 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).
i) Test the essential performance according to IEC/EN 60601-2-25, or methods recommended by the hospital or local distributor.

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) Android Tablet and Sampling Box

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put the dustproof coat on the sampling box after use and prevent shaking it violently when moving it to another place.
- Prevent any liquid from seeping into the equipment; otherwise the safety and the performance of the electrocardiograph cannot 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 7 Accessories

WARNING

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

Table 7-1 Accessory List

Accessory	Part Number
Wireless Sampling Kit	02.06.260163
PADECG Software	02.01.211058
Patient Cable (IEC)	01.57.471278
Patient Cable (AHA)	01.57.471279
Chest electrodes	01.57.040163
Limb electrodes	01.57.040162
Excell Alkaline AA LR6 1.5V	01.21.064086
Portable Bag	01.56.465623
Disposable Resting Snap Electrodes	01.57.471056
Disposable Resting Snap Electrodes	01.57.471057
Disposable Frosting Film for Skin Preparation	01.57.107418
Multi-Function Electrode Adapters	01.57.040172

NOTE:

1. The chest electrodes and limb electrodes are not available in the U.S.
2. The part name may differ in documents, but the part number shall prevail for all purposes.

Chapter 8 Warranty and Service

8.1 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.

8.2 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 60601-1:2005 EN 60601-1:2006 IEC 60601-1-2:2007 EN 60601-1-2:2007 IEC 60601-2-25:2011
Anti-electric-shock type:		Internally powered equipment
Anti-electric-shock degree:		Type CF with defibrillation-proof
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
Degree of protection against falling:		Handheld device
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:		CISPR 11, 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:	-20 ℃ (-4 ℉)~+55 ℃ (+131 ℉)	+5 ℃ (+41 ℉) ~ +40 ℃ (+104 ℉)
Relative Humidity:	25%RH~93%RH Non-Condensing	25%RH~80%RH Non-Condensing
Atmospheric Pressure:	70 kPa ~106 kPa	86 kPa ~106 kPa

A1.3 Physical Specifications

Dimensions	DX12 transmitter: 63mm(L)×107mm(W) ×23mm(H) (2.5in×4.2in×0.9in)
Weight	DX12 transmitter: Approx. 113g (not including battery)

A1.4 Power Supply Specifications

Power Supply:	DX12 transmitter: Input Power: 2x1.5V Excell Alkaline AA IEC LR6; Operation life of battery≥12 hours

A1.5 Performance Specifications

HR Recognition	
HR Range:	30 bpm ~300 bpm
Accuracy:	1 bpm
ECG Sampling Box Performance	
Leads Mode:	12 standard leads
Acquisition Mode:	Simultaneously 12 leads
A/D:	18 bits
Resolution:	2.52uV/LSB
Sample Frequency:	10,000 /sec/channel (sampling) 500 /sec/channel (analysis)

Time Constant:	≥3.2 s
Frequency Response:	0.05Hz ~ 150Hz
Gain:	2.5, 5, 10, 20, AGC (mm/mV) (±5%)
Input Impedance:	≥50MΩ (10Hz)
Input Circuit Current:	≤10nA
Input Voltage Range	<±5mVp-p
Calibration Voltage:	1mV±2%
DC Offset Voltage	±500mV
Minimum Amplitude:	20 μVp-p
Noise:	≤15μVp-p
Filter	AC Filter: 50Hz/60Hz/Off
	DFT Filter: 0.32Hz (weak) /0.67Hz (strong) /0.05Hz
	EMG Filter: 25Hz/35Hz/45Hz/Off
	Lowpass Filter: 150Hz/100Hz/75Hz/Off
CMRR	≥100 dB
Pacemaker Detection (Single Channel Detection)	
Amplitude	±2 mV to ±500 mV
Width	0.1 ms to 2.0 ms
Sampling Frequency	10,000Hz, rhythm lead
DX12 Bluetooth	
Transmitting Frequency	2402 Hz ~ 2480Hz
Frequency Band	2402 Hz ~ 2480Hz
Modulation Type	FHSS
Transmitting Power	4.65dBM
Effective Radiated Power	2.65dBM

NOTE: Operation of the equipment below the minimum amplitude may cause inaccurate results.

Appendix 2 EMC Information

Electromagnetic Emissions

Guidance and manufacture's declaration - electromagnetic emission		
The PADECG is intended for use in the electromagnetic environment specified below. The customer or the user of the PADECG should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PADECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The PADECG 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The PADECG is intended for use in the electromagnetic environment specified below. The customer or the user of the PADECG 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	±4 kV contact (only for system with Android tablet) ±6 kV air (only for system with Android tablet)	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 ±1kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	Not applicable
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 IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The PADECG is intended for use in the electromagnetic environment specified below. The customer or the user of the PADECG 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 the PADECG, 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 the PADECG is used exceeds the applicable RF compliance level above, the PADECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PADECG.

[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

Recommended separation distances between portable and mobile RF communications equipment and the PADECG

The PADECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PADECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PADECG 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	**0.37**	**0.37**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.7**	**3.7**	**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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