

# PADECG

PC ECG

(iOS) Version 2.1



# User Manual

CE<sub>0123</sub>

## **About this Manual**

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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 the manufacturer. (hereinafter called the manufacturer) cannot be held liable.

The manufacturer owns the copyrights of this manual. Without prior written consent of the manufacturer, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of the manufacturer.

The manufacturer holds the rights to modify, update, and ultimately explain this manual.

## **Responsibility of the Manufacturer**

The manufacturer 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 the manufacturer, and

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

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

## **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.

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# 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.

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### **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.
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## 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

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#### **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.
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**WARNING**

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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. Disposable electrodes must be used during defibrillation.
  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 ECG workstation, 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. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1 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.
  15. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
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**WARNING**

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16. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
  17. 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. 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. If in doubt, consult our technical service department or your local distributor.
  18. 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.
  19. 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.
  20. You are recommended to purchase the iPad from the manufacturer. Otherwise, the manufacturer will not be held responsible for the maintenance of the hardware, operating system and other accessories.
  21. 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.
  22. Connecting to other devices may decrease the antistatic gradation of the system during operation.
  23. 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 3 meters between DX12(iOS) Transmitter and the iPad.
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**WARNING**

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24. Do not open the battery cover of DX12(iOS) Transmitter when using the wireless system of PADECG.
  25. The iPad 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 iPad shall be charged outside the patient environment, and no operations are permitted during the charging.
  26. The device shall not be serviced or maintained while in use with a patient.
  27. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC information.
  28. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
  29. 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.
  30. Assembly of the ECG workstation and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
  31. Check the gain and speed of the report thoroughly when confirming diagnosis.
  32. The device is MR unsafe. It is not intended for use in an MRI environment.
  33. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
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## 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.
9. Replace the depleted battery before use.

## 1.2.3 General Cautions







### **CAUTION**










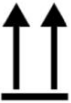

1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 °C and 40 °C during operation, and it should be kept between -20 °C and 55 °C during transportation and storage.
2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.








**CAUTION**

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**

No.	Symbol	Description
1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		Caution
3		Consult operating instructions
4		General warning sign (Background: Yellow; Symbol&Outline: Black)
5		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
6		Non- ionizing electromagnetic radiation

7		General symbol for recovery/recyclable
8	P/N	Part Number
9		SERIAL NUMBER
10		Date of manufacture
11		MANUFACTURER
12		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
13		CE marking
14		Disposal method
15	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
16	FCC ID: SMQDX12TREDAN	Federal Communications Commission: FCC ID: SMQDX12TREDAN
17		MR Unsafe
18	ETL CLASSIFIED  Intertek 4005997	Conforms to AAMI Std. 60601-1, IEC Std. 60601-2-25 Certified to CSA Std. C22.2 No 60601-1, CSA Std. C22.2 No 60601-2-25
19		This way up
20		Fragile, handle with care

21		Keep dry
22		Stacking limit by number
23		Handle with care
24		Do not step on
25		Front
26		Medical Device
27		Unique Device Identifier

**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 iPad.

- ◆ DX12(iOS) Transmitter
- ◆ Patient Cable
- ◆ Electrodes

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

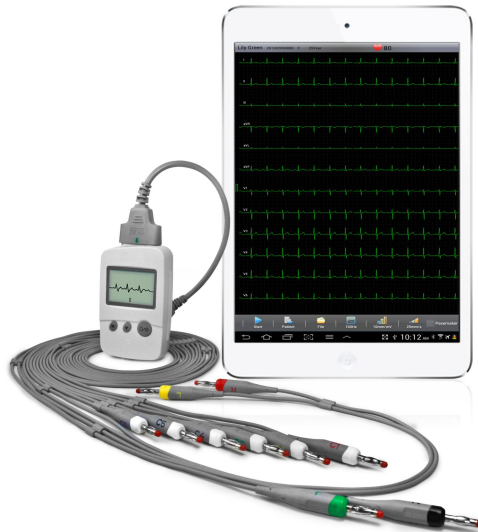
### 2.1 Assembling the System

#### 2.1.1 PADECG System



#### **WARNING**

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



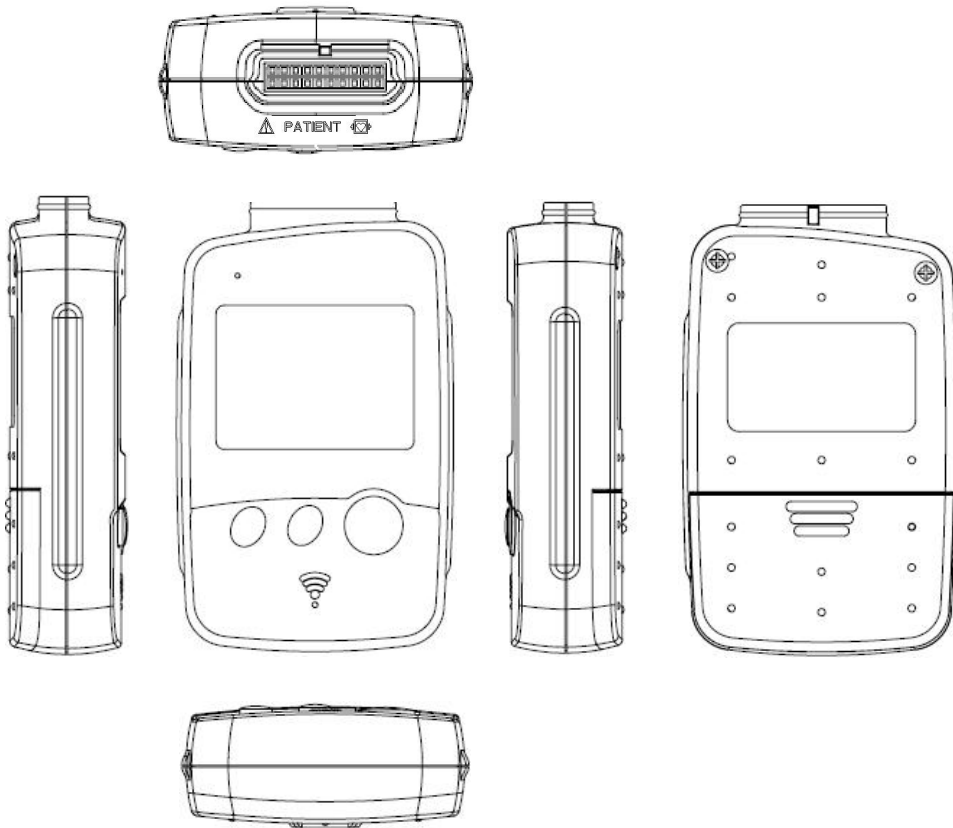
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**WARNING**

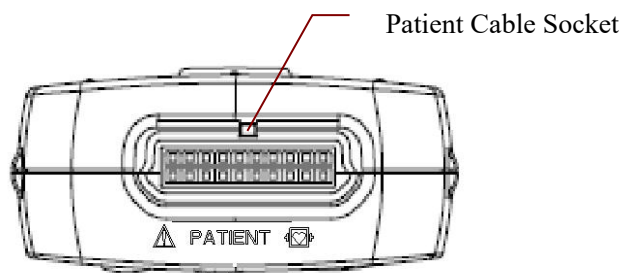
1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard IEC/EN 60601-1. 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. 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 DX12(iOS) Transmitter

### DX12(iOS) Transmitter Appearance

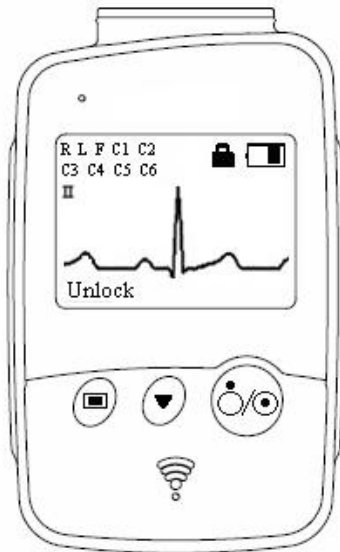


### Front Panel

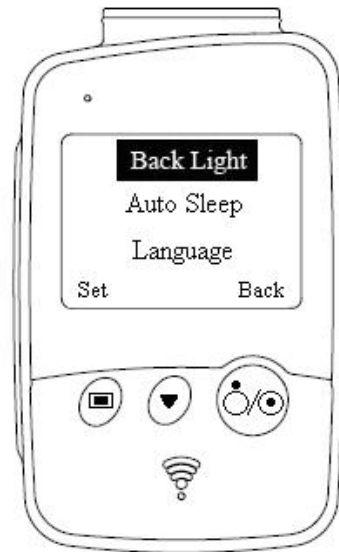




### 2.1.2.1 Keys and Icons



Main Screen



Menu Screen

Keys/Icons	Description
	After batteries are installed, press this key to turn on/off DX12(iOS) 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 App.

**NOTE:** ECG waveforms displayed on the DX12(iOS) Transmitter only indicates whether the electrodes are attached properly. Diagnosis and evaluation of the ECG should be done based on the display on the iPad.

### 2.1.2.2 Setting the Menu

Menu	Description
Back Light	Select <b>On</b> to turn on the backlight of LCD screen. Select <b>Off</b> to turn off the backlight of LCD screen.
Auto Sleep	Select <b>On</b> to display <b>Sleeping</b> on the screen and make DX12(iOS) Transmitter be in low power consumption mode after lead off for 5 minutes. Select <b>Off</b> to turn off auto sleep function.
Language	You can set the system language.
Lead Electrode	You can select <b>IEC</b> or <b>AHA</b> .
Bluetooth Device	You can see the Bluetooth name and address of the DX12(iOS) Transmitter.
Device Information	You can see the related information, such as software version, ID, address of the device, manufacture and release time about the device. <b>NOTE:</b> The device information is for reference only.

## 2.2 Installing the PADECG App

**NOTE:** This section is only for reference when the operating system of the iPad needs to be reinstalled or DX12(iOS) Transmitter is broken.

### 2.2.1 System Running Environment

<b>Applicable iPads:</b>	IPad(6th generation), iPad8 or iPad mini 5 Note: iPad models running iOS 14, iOS 16, and iOS 17 are also available, not just the three recommended iPad models.
<b>Operating System:</b>	iOS 14, iOS 16 and iOS 17
<b>CPU:</b>	Apple A8 or above
<b>Capacity:</b>	16 G or above
<b>Transmission</b>	Built-in Bluetooth and WIFI

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**WARNING**

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1. Use the PADECG system only on the iPad that is installed with the official operating system (iOS) released by Apple.
  2. Please consult the manufacturer's service engineer for PADECG App compatibility before you upgrade the iOS system.
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## 2.2.2 About Installation

Enter the App Store of the iPad, input *PADECG* to search for the application. The installation is the same as that of other applications available in the iPad.

**NOTE:**

1. To uninstall the application, exit the application first. Local data will be lost after uninstalling the application.
2. Please upgrade the application in time when a new version is available.

## 2.2.3 Matching DX12(iOS) Transmitter with iPad

For the first time to match the transmitter with the iPad, perform the following operations:

1. Start the DX12(iOS) Transmitter and the iPad.
2. Enable the Bluetooth function in *iPad>Settings>Bluetooth*.
3. Click the required DX12(iOS) Transmitter for connection.

In later use, when turned on, the transmitter will automatically search for and connect with the iPad of the previous match in 10s. If connection with DX12 requires passwords, the system will prompt a dialog box. Enter the PIN (12345678) to the box so that the tablet is connected to DX12.

Operation for viewing device information of the required transmitter: turn on DX12(iOS)

Transmitter → press  → press  to display **Device Information** in black → press .

**NOTE:**

1. Before matching DX12(iOS) Transmitter and the iPad, ensure batteries of DX12(iOS) Transmitter and iPad are full.
2. You need to reconnect the DX12(iOS) Transmitter to the iPad after changing system language.
3. Before matching the transmitter, please ensure that the iPad Bluetooth is in unconnected state.

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## **WARNING**

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This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
  - 2) this device must accept any interference received, including interference that may cause undesired operation.
- 
- 

### **NOTE:**

1. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.
2. Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

## **2.3 Features**

- ◆ Reliable and handy data recording, suitable for doctors' inspections and visits
- ◆ iOS operating system, user friendly interfaces and easy operation
- ◆ Supporting order downloading function
- ◆ Perfect data management, sampled ECG data can be transmitted to SE-1515 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 Cleaning 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 clean 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

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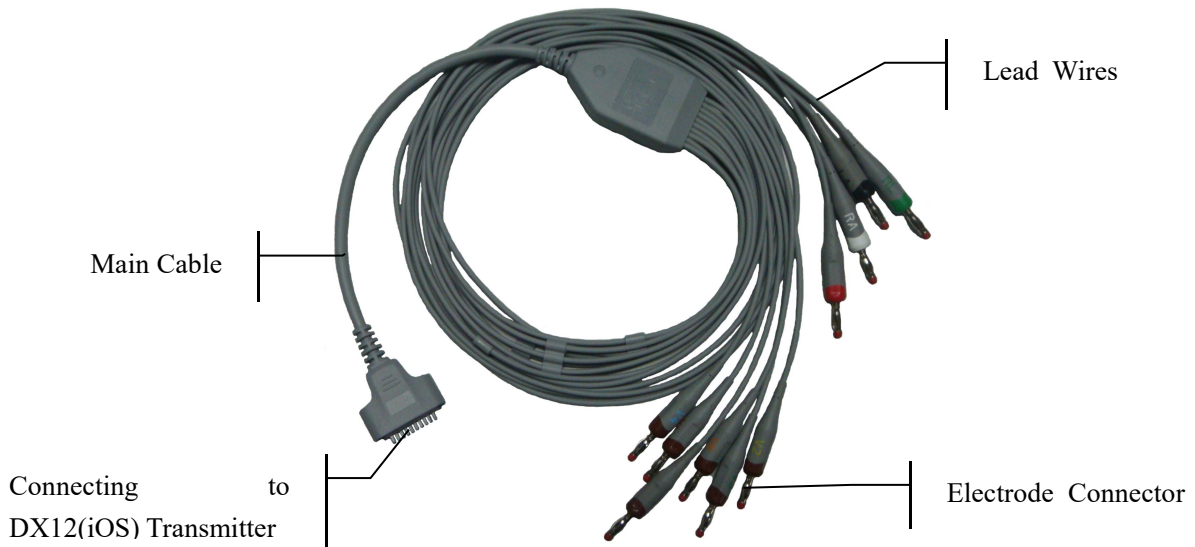
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#### **WARNING**

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

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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(iOS) 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.

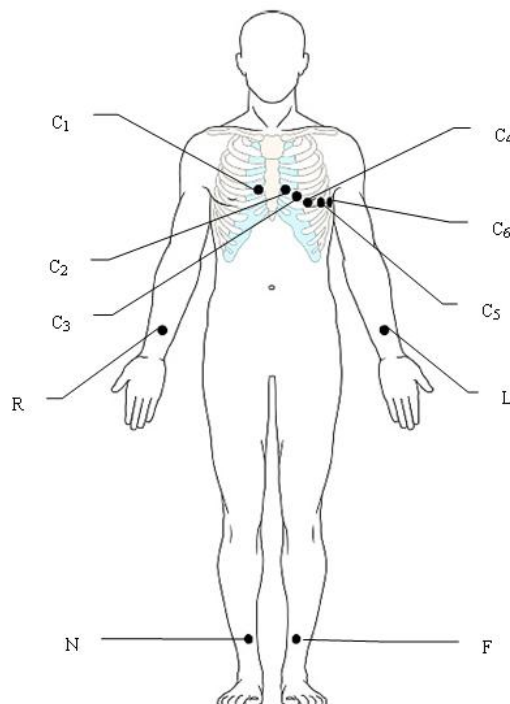
The identifiers and color codes of electrodes used comply with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifiers and color codes are specified in the following table. Moreover the equivalent codes according to American requirements are given in the following table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

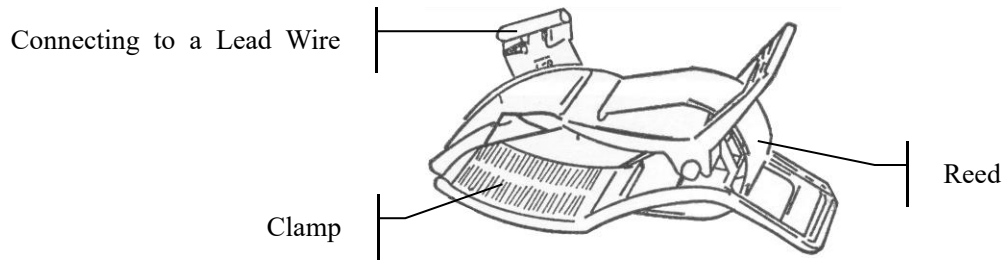


IEC	AHA	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4	V4	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal level of C4
C6	V6	Left midaxillary line at the horizontal level of C4
L	LA	Left arm
R	RA	Right arm
F	LL	Left leg

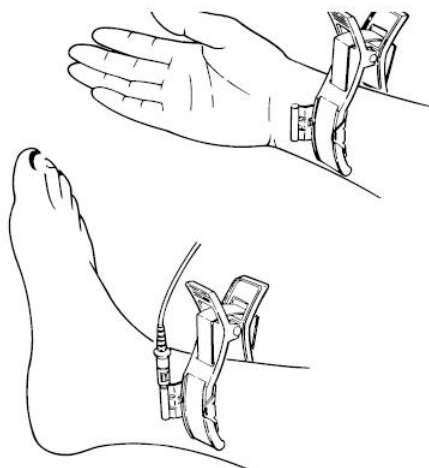
N	RL	Right leg
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### 3.3.2 Attaching the Reusable Electrodes

#### 3.3.2.1 Attaching the Limb Electrodes



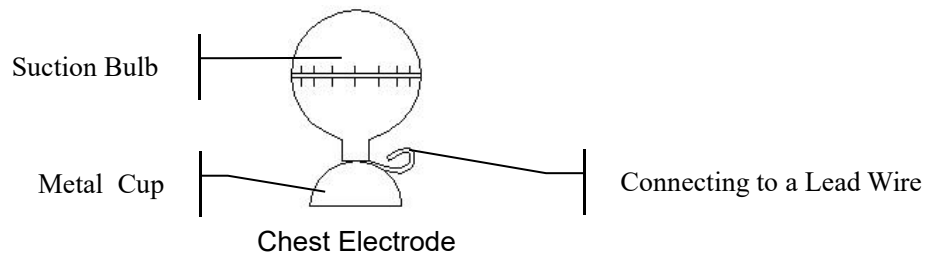
Limb Electrode



#### 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



**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

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**CAUTION**

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The disposable electrodes can only be used for one time.

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Connect the snap socket adapter to the disposable electrode.

Proper skin preparation (abrasion if necessary), proper electrodes, and patient cables in fixed position are very important for a good signal quality.

## Chapter 4 Operation Instructions

1. Turn on the iPad and enable the Bluetooth function in *iPad>Settings>Bluetooth*.
2. Connect to the required DX12(iOS) Transmitter.
3. Start the PADECG App.
4. Input the user name and password, and then click **Login**.

The default password is *ecg* (case sensitive). Click **Setting**, you can change the password, or enable or disable the Remember Password function.


If no DX12(iOS) Transmitter 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.

**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.

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 by patient name is supported.

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

### 3. Description for buttons

Key	Description
STAT ECG	Press to enter the ECG sampling screen directly.
	Options: <b>Delete, Scan, Download, Download Setting</b> <ul style="list-style-type: none"> <li>◆ <b>Delete:</b> Press to delete one or multiple orders.</li> <li>◆ <b>Scan:</b> Press to input patient information by scanning a bar code.</li> <li>◆ <b>Download:</b> Press to download patient orders.</li> <li>◆ <b>Download Setting:</b> Press to set the filter conditions for downloading patient information from the server.</li> </ul>
	Press to load orders from the server (SE-1515). For details about the order settings, please refer to "Order Server" in Section 4.6.4 "Transmission Setting". <p><b>NOTE:</b></p> <ol style="list-style-type: none"> <li>1. 1000 patient records can be displayed in the information list, and 200 latest created orders in the server can be loaded at one time.</li> <li>2. This item only applies to the local mode.</li> <li>3. Not all options related to SE-1515 are available.</li> </ol>
	If the number of orders exceeds the maximum of a page, press these keys to turn pages. <p><b>NOTE:</b> Each page contains 50 orders.</p>
File	Press to enter the file manager screen. For details about the file manager screen, refer to section 4.5 "Processing Patient Records".
System Setting	Press to enter the system setting screen. For details about the system setting screen, refer to section 4.6"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 enabled, click on **OK** and click on the patient record in the patient list to

enter the pre-sampling screen.

Key	Description
Start/Stop	Press this button to start/stop sampling ECG data. <b>NOTE:</b> At most 180s ECG data can be sampled.
100Hz	Choose from: 25 Hz,35 Hz,45Hz,75 Hz,100 Hz,150Hz <b>NOTE:</b> 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
25mm/s	Speed: 5mm/s, 12.5mm/s, 25mm/s or 50mm/s
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 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.

If more than 10s ECG data has been sampled, a scrollbar will appear above the ECG waveforms. You can slide the scrollbar to adjust the time period of the waveforms to be displayed. During sliding, the start time and end time of the displayed 10s ECG waveforms will be shown. You can click "+" or "-" to view the 10s ECG waveforms 5s later or earlier.

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
PR (ms)	P-R interval
QRS (ms)	QRS complex duration
QT/QTc (ms)	Q-T interval /Normalized QT interval
P/QRS/T (°)	The axis of P wave, QRS complex, and T wave in the frontal plane
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. Hiding or displaying measure information and diagnosis results

On the ECG Analysis screen, you can slide the ECG waveforms upward to hide measure information and diagnosis results or downward to display them again.


## 7. 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) Add an Email account.


If no Email account is set, add one in the following directory: *iPad>Mail, Contact, Calendars*.

- 2) Set default Email information in the following directory: *PADECG>System Settings>Transmission Setting>Email Settings*.

- 3) Click  on the ECG analysis screen and select **Sending Email**.


If no default Email information is set, a dialog box requiring report format selection will be displayed. 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.

## 8. Print


Click  on the ECG analysis screen and select **print** button to print report, which is very simple to operate.

Note: Make sure the network and printer is working.

## 9. Share

Click  on the ECG analysis screen, and then you can click share button to share the report of the current patient.

## 10. Edit

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

## 4.4 Printing Reports

We suggest that the report be printed out on a printer to diagnose and sign.

To print a report, the tablet should be connected to a PC which is installed with the SE-1515 analysis software or an FTP server by setting the IP address and FTP parameters of the PADECG App. For details, please refer to "FTP Setting" in section 4.6.4"Transmission Setting".

To use the FTP server, configure it before connecting to the PC. For details please contact the

local distributor or the manufacturer.

**NOTE:**


1. This function is available only under network connection.
2. Not all options related to SE-1515 are available.

**WARNING**

The printouts need to be done with no scaling or sizing done to fit the page.

## 4.5 Processing Patient Records

### 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 by patient name 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, modify, delete or print.

**NOTE:**

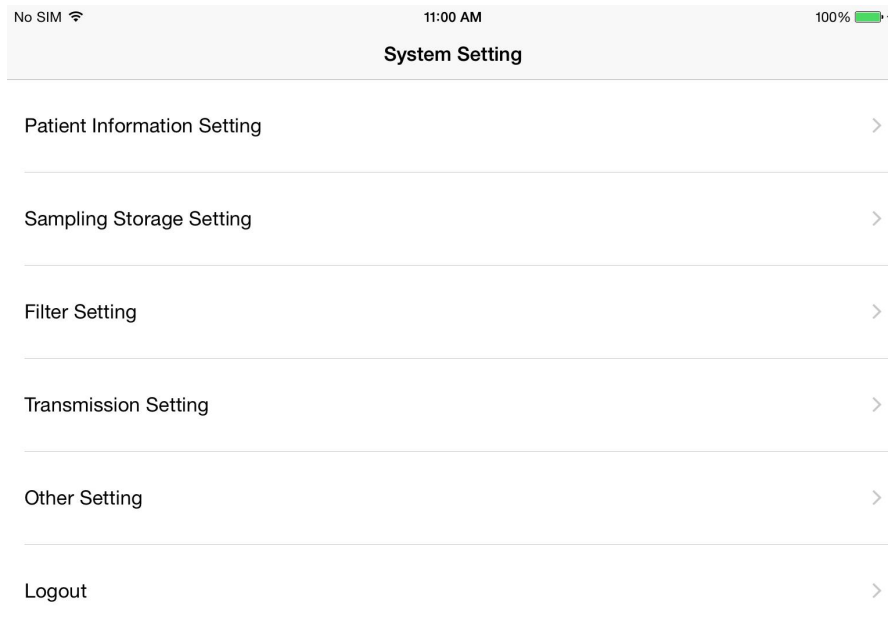
1. The patient ID cannot be modified.
2. The modification on the patient name and gender will be synchronized to other data of the same patient ID.

If you need to delete or upload records in bulk, press  and choose **Upload** or **Delete**.

Key	Description
	Press this button to enter submenu.
	Press this button to upload the selected examination records to the server.
	If the checkbox before <b>Select All</b> is ticked, pressing this button can clear the examination record list.
	Set the search criteria for the records to be displayed.

## 4.6 Configuring the System

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



### 4.6.1 Patient Information Setting

Item	Description
ID Generating Method	Choose from: <u>Auto</u> or <b>Manual Input</b> Select <b>Auto</b> , the patient ID can be automatically generated according to the examination date. Select <b>Manual Input</b> , you should enter the patient ID manually on the <b>New Patient</b> screen.
Patient Info Auto Clear	<ul style="list-style-type: none"> <li>● Enabled: The system automatically clears the current patient information except Gender, Exam.Room, Technician, and Physician. If ID Input Method is set to Manual Input, the patient ID will also be cleared.</li> <li>● Disabled: If <b>disabled</b>, the current patient information remains when creating a new patient.</li> </ul>
First/Last Name	If enabled, the <b>Name</b> textbox on the <b>New Patient</b> screen will change into



		the <b>First Name</b> and <b>Last Name</b> textboxes.
Age		Choose from: <b>Manual</b> or <b>Date of Birth</b>
Other Settings	Display	You can configure the items to be displayed on the <b>New Patient</b> 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.
Barcode Setting		<b>NOTE:</b> 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 <b>OK</b> button confirm.

## 4.6.2 Sampling Storage Setting

Item		Description
Sampling Mode		Choose from: <b><u>Real-time Sample</u></b> , <b>Pre-sample</b> <ul style="list-style-type: none"> <li>➤ Select <b>Pre-Sample</b>, 10s ECG data before pressing the <b>Start</b> key will be saved.</li> <li>➤ Select <b>Real-time Sample</b>, 10s ECG data sampled after pressing the <b>Start</b> key will be saved.</li> </ul>
Rhythm lead		Choose from: I 、 II 、 III、 aVR、 aVL、 aVF、 V1、 V2、 V3、 V4、 V5、 V6.
Sampling Setting	Time	It can be set to a value between 10s and 180s.
Auto Diagnosis		If selected, the system automatically generates diagnosis results after sampling finishes.
Warning of Serious diseases		If selected, The system will identify and prompt serious disease information in the ECG analysis interface.  For serious diseases, see Appendix 3 List of Serious Diseases.
Enter the Analysis screen when sampling finishes		If selected, the system automatically enters the wave analysis screen after sampling finishes.

File Format	Choose from: <b>SCP, FDA-XML, DICOM, PDF, JPG, BMP</b> . If selected, files in the selected format will be generated when sampling finishes. <b>NOTE:</b> This item only applies to the local mode.
File Naming	Choose from: <b>ID, Name, Date of Birth, Exam. Time</b> , and blank. The file name is “Name-Date of Birth-Exam. Time” by default. But users can set the file name themselves by tapping the drop-down box and choosing what they want to display in the file name. If the above items are all blank, the system will use the examination time to name the file.
Auto JPG Export	If selected, the system will automatically export an examination record in JPG format to the tablet album when ECG data is sampled. Or when measure information or diagnosis is modified, the updated data will be exported in JPG format to the tablet album.
Report Format	Choose from: <b>12*1, <u>6*2+1</u>, 3*4+1</b> .
Print Speed	Choose from: 25mm/s、 50mm/s.

### 4.6.3 Filter Setting

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: <b>0.05Hz, 0.32Hz</b> or <b>0.67Hz</b> 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 <b>Off, 25Hz, 35Hz</b> or <b>45Hz</b> .
Lowpass Filter	Lowpass Filter restricts the bandwidth of input signals. The cutoff frequency can be set to <b>75Hz, 100Hz</b> or <b>150Hz</b> . All the input signals whose frequency is higher than the set cutoff frequency will be attenuated. <b>NOTE:</b> The Lowpass Filter is effective only when the <b>EMG Filter</b> is set to <b>Off</b> .
AC Filter	AC filter suppresses AC interference without attenuating or distorting ECG signals. Choose from: <b>Off, 50Hz</b> and <b>60Hz</b> .

**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.

#### 4.6.4 Transmission Setting

Item	Description
Device No.	Type the Device No., within 30 ASCII characters.
Auto Upload	Select this item, the system will automatically upload files to the server when sampling finishes.  <b>NOTE:</b> This item only applies to the local mode. Under the network mode, the system automatically uploads files when sampling finishes.
Delete file after uploading	Select this item, the system will automatically delete files from the examination record list after they are uploaded.
Order Server Address	Set it to IP address of the order server.  <b>NOTE:</b> For more information on configuring network settings, consult your Network Administrator.
FTP Setting	Set the FTP address, port, user name, and password of the FTP server.
Email Settings	Set the default recipient, subject, and file format.

#### 4.6.5 Other Setting

Item	Description
DEMO mode	Choose from: <b><u>Off</u></b> , <b>Normal</b> or <b>Abnormal</b>
Lead Electrode	Choose from: <b><u>IEC</u></b> , <b>AHA</b>  If <b>IEC</b> is selected, the hint information on the sampling screen will show the IEC electrode name upon lead off.  If <b>AHA</b> is selected, the hint information on the sampling screen will show the AHA electrode name upon lead off.
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 <b>System Setting</b> screen.
Restore to factory	Press to restore the factory settings.

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defaults

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Device Info

View or edit the information of sampling devices.

**NOTE:** If a DX12(iOS) Transmitter is connected, its information (name and address) will be displayed on the screen, otherwise, the hint "*No sampling device is connected*" will be displayed.

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## 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 DX12(iOS) Transmitter.
Lead wire reversal	The limb leads are reversed.
Order server connection fails!	The order server is not enabled or the network connection is abnormal.
FTP connection fails!	The FTP server is not enabled or the network connection is abnormal.
Battery of sampling device is weak, please change the battery after the test!	Battery of DX12(iOS) Transmitter is low.
Battery is weak, and the sampling device will be powered off!	Battery of DX12(iOS) Transmitter runs out.

## Chapter 6 Cleaning, Care and Maintenance

Use only the manufacturer-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.

The manufacturer 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 DX12(iOS) Transmitter 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 DX12(iOS) Transmitter and reusable accessories after they are cleaned and disinfected.

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#### **CAUTION**

1. If you spill liquid on the equipment or accessories, or they are accidentally immersed in liquid, contact your service personnel or the manufacturer's service engineer.
  2. The equipment is chemically resistant to most cleaning agents, disinfectants and non-caustic detergents used in hospital, but cleaning agents or disinfectants that are not listed in this manual are not recommended. For example, didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt, may corrode the equipment and accessories.
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### 6.2 Cleaning

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

The validated cleaning agents for cleaning the DX12(iOS) Transmitter 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 DX12(iOS) Transmitter

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#### **WARNING**

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

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1. Switch off the DX12(iOS) Transmitter 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 DX12(iOS) Transmitter 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.

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#### **CAUTION**

Any remainder of cleaning solution should be removed from the DX12(iOS) Transmitter and the patient cable after cleaning.

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### 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

If the equipment or accessory has been in contact with the patient, then disinfection is required.

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 DX12(iOS) Transmitter 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 DX12(iOS) Transmitter

#### **WARNING**

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

1. Switch off the DX12(iOS) Transmitter 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 DX12(iOS) Transmitter 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 enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100  $\mu$ A, SFC 500  $\mu$ A.
- e) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10  $\mu$ A, d.c. 10  $\mu$ A; SFC a.c. 50  $\mu$ A, d.c. 50  $\mu$ A.
- f) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10  $\mu$ A, d.c. 10  $\mu$ A; SFC a.c. 50  $\mu$ A, d.c. 50  $\mu$ A.
- g) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50  $\mu$ A (CF).
- h) 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.

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**WARNING**

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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.

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**1) iPad and DX12(iOS) Transmitter**

- ◆ Avoid excessive temperature, sunshine, humidity and dirt.
- ◆ Put the dustproof coat on the DX12(iOS) Transmitter 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 ECG workstation 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.

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**CAUTION**

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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.

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## 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

<b>Accessory</b>	<b>Part Number</b>
ECG Cable, DX12 Patient Cable (IEC)	01.57.471030
ECG Cable, DX12 Patient Cable (AHA)	01.57.471055
ECG Cable, Patient Cable (IEC)	01.57.471278
ECG Cable, 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
Adult Disposable Adhesive Electrodes	01.57.471858
Pediatric Disposable Adhesive Electrodes	01.57.471859
Clip/Snap/Banana Socket Adapter	01.57.040172
Alligator Clip/Banana Socket Adapters	01.57.040173
Snap/Banana Socket Adapters	01.57.471864
Disposable Resting Tab electrodes	01.57.471863

#### **NOTE:**

1. The chest electrodes and limb electrodes are not available in the U.S.
2. The part name may vary depending on context, but the part number is constant.

## **Chapter 8 Warranty and Service**

### **8.1 Warranty**

The manufacturer warrants that the manufacturer'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 the manufacturer.
- 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, the manufacturer will, at its discretion, repair or replace the defective part(s) free of charge. The manufacturer 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.

## Appendix 1 Technical Specifications

### A1.1 Safety Specifications

Comply with:	IEC 60601-1:2015+A1:2012+A2:2020 EN 60601-1:2006/A2:2021 IEC 60601-1-2:2014+A1:2020 EN 60601-1-2:2015/A1:2021 IEC 60601-2-25	
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	<10 $\mu$ A (AC) / <10 $\mu$ A (DC)
	SFC	<50 $\mu$ A (AC) / <50 $\mu$ A (DC)
Patient Auxiliary Current:	NC	<10 $\mu$ A (AC) / <10 $\mu$ A (DC)
	SFC	<50 $\mu$ A (AC) / <50 $\mu$ A (DC)

### A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	-20°C (-4°F) ~ +55°C (+131°F)	+5°C (+41°F) ~ +40°C (+104°F)
Relative Humidity:	15%RH - 95%RH Non-Condensing	15%RH - 95%RH Non-Condensing
Atmospheric Pressure:	70 kPa - 106 kPa	70 kPa - 106 kPa

## A1.3 Physical Specifications

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

## A1.4 Power Supply Specifications

Power Supply:	DX12(iOS) Transmitter: Input Power: 2×1.5V Excell Alkaline AA IEC LR6;Operation life of battery≥12 hours
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## A1.5 Performance Specifications

<b>HR Recognition</b>	
HR Range:	30 bpm ~300 bpm
Accuracy:	1 bpm
*Filter (PADECG App)	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
<b>DX12(iOS) Transmitter Performance</b>	
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 (mm/mV) (±5%)
Speed:	5mm/s, 12.5mm/s, 25mm/s or 50mm/s

*Defibrillation protection	Defibrillation voltage: $\pm 5$ kV
	Recovery time after defibrillation: $< 5$ s
*Amplitude measurements	Fulfil the subclause 201.12.1.101 of IEC60601-2-25:2011
Input Impedance:	$\geq 20\text{M}\Omega$ (10Hz)
Input Circuit Current:	$\leq 0.05\mu\text{A}$
Input Voltage Range	$< \pm 5\text{mVp-p}$
Calibration Voltage:	$1\text{mV} \pm 2\%$
DC Offset Voltage:	$\pm 500\text{mV}$
Minimum Amplitude:	$20\mu\text{Vp-p}$
Noise:	$\leq 15\mu\text{Vp-p}$
Recovery Time After Defibrillation	$< 5$ s
CMRR	$\geq 100$ dB
<b>Pacemaker Detection (Single Channel Detection)</b>	
Amplitude	$\pm 2$ mV to $\pm 500$ mV
Width	0.1 ms to 2.0 ms
Sampling Frequency	10,000/sec/channel, rhythm lead
<b>DX12(iOS) Transmitter Bluetooth</b>	
Transmitting Frequency	2402 MHz ~2480 MHz
Frequency Band	2402 MHz ~2480 MHz
Modulation Type	FHSS, GFSK, DPSK, DQPSK
Transmitting Power	$\geq 0$ dBm

**NOTE:**

1. \*Indicates the essential performance of this device.
2. Operation of the equipment below the minimum amplitude may cause inaccurate results.

## Appendix 2 EMC Information

### Electromagnetic Emissions

<b>Guidance and manufacture's declaration - electromagnetic emission</b>		
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.		
<b>Emission test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
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/EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Not applicable	

### Electromagnetic Immunity

<b>Guidance and manufacture's declaration - electromagnetic immunity</b>			
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.			
<b>Immunity test</b>	<b>IEC/EN 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact (only for PADECG) ±15 kV air (only for PADECG)	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/EN 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Not applicable	Not applicable
Surge IEC/EN 61000-4-5	$\pm 1$ kV line to line $\pm 2$ kV line to ground	Not applicable	Not applicable
Power frequency (50Hz/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IMMUNITY to proximity magnetic field	65A/m, Modulation: Pulse modulation, 2.1KHz Test frequency: 134.2KHz; 7.5A/m, Modulation: Pulse modulation, 50KHz Test frequency: 13.56MHz;	65A/m, Modulation: Pulse modulation, 2.1KHz Test frequency: 134.2KHz; 7.5A/m, Modulation: Pulse modulation, 50KHz Test frequency: 13.56MHz;	/
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % $U_T$ ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles ) Single phase: at 0°  0 % $U_T$ ; 250/300 cycle	Not applicable	Not applicable

NOTE  $U_T$  is the a.c. mains voltage prior to application of the test level.

### Electromagnetic Immunity

<b>Guidance and manufacture's declaration - electromagnetic immunity</b>			
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.			
<b>Immunity test</b>	<b>IEC/EN 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC/EN 61000-4-6	3 V <sub>rms</sub>  150 kHz to 80 MHz 6V <sub>rms</sub> <sup>c)</sup> in ISM bands between 0.15 MHz and 80 MHz	3 V <sub>rms</sub>  150 kHz to 80 MHz 6V <sub>rms</sub> <sup>c)</sup> in ISM bands between 0.15 MHz and 80 MHz	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.  <b>Recommended separation distance</b>  $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m  80 MHz to 2.7 GHz  See Table 1	3 V/m  80 MHz to 2.7 GHz  See Table 1	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz  $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz  $d = 6\sqrt{P} / E$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the

		<p>PADECG, including cables specified by the manufacturer).</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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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.

<sup>a</sup> 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.

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

<sup>c</sup> The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

**Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment**

Test Frequency (MHz)	Brand <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM <sup>c)</sup> ±5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Brand 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
5500						
5785						

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50% duty cycle square wave signal.
- c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

**Recommended separation distances between portable and mobile  
RF communications equipment and the EQUIPMENT or SYSTEM**

<b>Recommended separation distances between portable and mobile RF communications equipment and the PADECG</b>			
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.			
<b>Rated maximum output power of transmitter (W)</b>	<b>Separation distance according to frequency of transmitter (m)</b>		
	<b>150 kHz to 80 MHz</b> $d = 1.2\sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = 1.2\sqrt{P}$	<b>800 MHz to 2.7 GHz</b> $d = 2.3\sqrt{P}$
0.01	<b>0.12</b>	<b>0.12</b>	<b>0.23</b>
0.1	<b>0.38</b>	<b>0.38</b>	<b>0.73</b>
1	<b>1.2</b>	<b>1.2</b>	<b>2.3</b>
10	<b>3.8</b>	<b>3.8</b>	<b>7.3</b>
100	<b>12</b>	<b>12</b>	<b>23</b>
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 List of Serious Diseases

<b>Serious Diseases</b>
Second-degree Atrioventricular Block (Mobitz type II)
Third-degree Atrioventricular Block
Marked ST Depression
Marked ST Elevation
Acute Anterior Myocardial Infarction
Acute High Lateral Myocardial Infarction
Acute Inferior Myocardial Infarction
Extensive Anterior Myocardial Infarction
Occlusion of the First Septal Branch of LACA
Occlusion of the Left Anterior Descending Coronary Artery (LACA)
Occlusion of the Left Main Coronary Artery Stenosis
Occlusion of the Right Coronary Artery (RCA)
Occlusion of Ostium Right Coronary Artery
Occlusion of the Left Circumflex Coronary Artery (LCx)
Atrioventricular Dissociation
Asystole
Ventricular Fibrillation
Marked Sinus Bradycardia
Ventricular Tachycardia

## Appendix 4 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 / Normalized QT Interval
P/QRS/T	The Axis of P Wave, QRS Complex, and T Wave in the Frontal Plane
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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