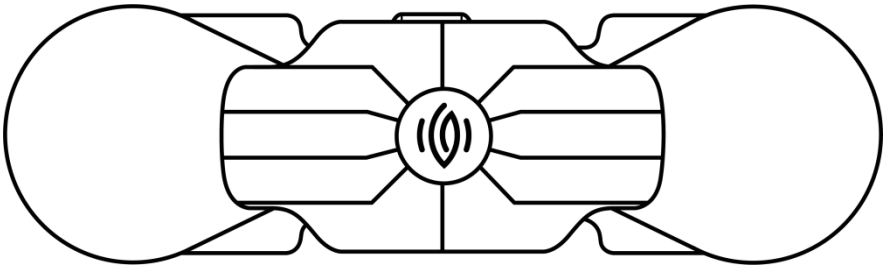
Cardiac Monitor

(Model:HR-0542F)



Contents

1. Product Introduction

1.1 Introduction

The device is designed for medical professionals to collect, record, store and automatically analyze patients' single lead dynamic ECG(electrocardiograms) and heart sound signals. The system includes a wearable patch device collecting synchronized PCG (phonocardiogram) and ECG readings, a smartphone application (App), and a web application. The data collected from the wearable patch are sent to a cloud based data center for further analysis. AI and other advanced data processing methods, such as wavelets, are used for data analysis.
The system features audio and ECG data transmission via Bluetooth that allows the users to open and play back heart sound and visualize PCG and ECG in a mobile application on compatible iOS and Android smartphones and tablets. The APP provides the ability to save audio recordings and waveforms (PCG and ECG) within Electronic Health Record (EHR) systems, and share recording s with other medical practitioners. The device is intended for use on pediatric and adult patients.

1.2 For Help and Assistance

For product related questions, or report any adverse event, please use any of the contact information listed below.

Fuzhou Wenxin Electronics Technology Co.,Ltd.
General Assistance and FAQs: https://wenxintech.com/contact
Direct Contact：support@wen-xintech.com
Phone Support：+86 0510-83592511
Product Reference and Information：https://wenxintech.com/

1.3 Safety Related Labels and Symbols

Symbol	Significance
	Consult instruction for use.
	This product contains an intentional RF radiator certified by the FCC.
	CF Type Application Part
	Serial Number
	This product uses wireless Bluetooth communication
	Manufacturer
	Date of manufacture

1.4 Signal Word Consequences

⚠ Indicates a hazardous situation, which if not avoided, could result in injury and/or property damage and/or damage to the device.

1.5 Caution ⚠

- To reduce the risk of device interference, keep the device at least one meter away from all RF emitters.
- To reduce the risks associated with infection, follow the cleaning and disinfecting procedures included in this manual.
- To reduce the risks associated with inaccurate data acquisition, store and operate this device only as instructed in this manual.
- Do not immerse the device in a liquid.
- To reduce the risks associated with very strong electromagnetic fields, do not use the device near strong radio frequency (RF) signals or mobile RF devices.
- Please follow all safety instruction in this manual while using this device.
- This device contains a Bluetooth Class 2 wireless data link. The maximum radio frequency field strength generated by the device is below three volts per meter.
- To reduce the risks associated with environmental contamination, follow applicable regulations when disposing of this device. This device contains a lithium-ion polymer rechargeable battery; please dispose of the device as mandated by local regulations.
- No modification of this device is allowed. There are no repairable parts inside the device.
- Disperse any static electricity before using the unit.
- Do not expose the device to a magnetic resonance (MR) environment.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes.
- Do not use the device on the body with too much body hair; a successful recording may not be possible.
- Do not store the device in extremely hot, cold, humid or wet conditions.
- Do not expose to strong electromagnetic fields.
- Do not use the device over broken skin or wound areas.
- The product is only used for daily ECG and heart sound signal recording. It is not suitable for intensive care and cannot be directly applied to the heart.
- The product cannot be used together with the defibrillator.
- Do not use on patients with cardiac pacemakers or other electronic implanted devices.
- The conductive part of the electrode and its connector shall not contact other conductor parts, including earth.
- Dispose in the category of Universal Waste Electronic Devices.

1.6 EMC Compliance

FCC Intentional Radiator Certification
Contains FCC ID:2AWXN0542

FCC Warning

15.19 Labeling requirements.
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.

15.21 Information to user.
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.105 Information to the user.
Note: 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.

RF Exposure information

- This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- This device complies with RF radiation exposure limits set forth for an uncontrolled environment, this device should be installed and operated with minimum distance 5mm between the radiator and your body.

1.7 Indication for Use

This device is intended to be used by healthcare professionals for diagnostic decision support. It can electronically amplify, filter, and transfer body sound and single-channel electrocardiogram (ECG) waveforms. This device displays ECG waveforms and heart sounds waveforms on the accompanying mobile application for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of cardiac, vascular, pulmonary, or abdominal organ systems, The device can be used on adults and pediatrics.

1.8 Patient Privacy

The privacy of patient health information may be protected by state, federal, or international/foreign laws that regulate how such information can be used, stored, transmitted, and disclosed. The device employs security features that are compliance with HIPAA policies. Third party access may be prohibited to such information without obtaining written authorization from the patient.

The user is fully responsible for understanding and following all laws that regulate storage, transmission, and disclosure of any electronic patient data through the use of software. If the user becomes unable to comply with a law or restriction that applies to use and disclosure of such data, the user should not proceed to collect or save such information.

The application may require entry of individually identifiable health information in order to function. Records are stored and recalled through the use of patient name, date of birth, and/or patient ID number. By entering this information, the user assumes any and all risks of and liabilities incurred with using or transmit such information.

1.9 Contraindications

- Chest skin defect.
- People who are allergic to hydrogel.

1.10 Technical Specifications

1) Use Environment

- Ambient temperature: 10℃ ~45℃.
- Relative humidity: 10%~95% (no condensation).
- Atmospheric pressure range: 700hPa ~1060hPa.
- Power supply: built-in 3.7V lithium polymer battery, voltage value allowable fluctuation range of ± 10%.
- The electromagnetic environment meets the requirements.
- No simultaneous equipment with serious electromagnetic interference (such as high-frequency electric knife, ultra-short-wave treatment instrument, RF treatment instrument, high-power microwave treatment equipment or equipment prone to serious arc generation).

2) Basic, performance, and parameters

- ECG lead: single lead; ECG channel: single lead.
- Heart rate range: 30 to 300 b p m, the maximum error of ± 10% or the larger in 5bpm.
- Dynamic input signal range: For differential mode voltage of 10mV DC offset voltage according to 125mV / s.
- Input impedance: For all channels, the input impedance shall be above 10M at the specified test frequency (10Hz).This requirement shall also be met within the specified DC bias range (± 300mV).
- Common mode suppression ratio: for the sinusoidal signal at the network power frequency, B of common mode suppression is at least 60dB and 45dB for signals at 2 times the network power frequency.When the network power frequency signal of the signal generator is 4V (peak-valley), the output of each test shall not exceed 4mV (peak-valley).For 1.422V (peak-valley) signals at twice the grid power frequency, the output of each test shall not exceed 4mV (peak-valley).
- Gain stability: After 1min, the gain change cannot exceed 3% at 24h.
- Frequency response: The response amplitude to the 1.5mV 40ms triangular wave pulse group used to simulate a series of R-wave narrow waves should be between 80% and 110% of the response amplitude to the 1.5mV 200ms triangular wave pulse group.
- Minimum detection signal: When the travel speed is set to 25 mm/s and the gain is set to 10mm / mV, a 10Hz, 50 V (peak-valley) sinine signal shall be applied to produce a clearly visible deflection.
- Timing accuracy: the total error within 24h should not exceed 30s.

1.11 Contents

The package includes

(1) Main device, one
(2) User Manual, one

For full functionality, the system requires users to connect the device with an internet-enabled smart mobile device using the APP. The APP supports many Apple and Android mobile device.

System Requirements
The mobile app software can be used on Apple devices with iOS 11.0 and higher. The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0 and above) and Android 6.0 and above.

1.12 Product Cleaning and Disinfection

- The surface of the product can be wiped and cleaned with dry flannelette (such as lens cloth).
- If there are stains on the surface of the product, it can be wiped with flannelette dipped in non-solvent cleaning agent.
- Use alcohol (75% concentration) to clean and disinfect the device before each use;
- After use, clean and disinfect according to the same method.

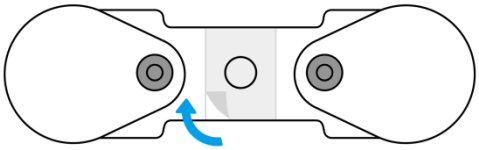
⚠Caution:

- Please turn off the power before cleaning process.
- The cleaned device can only be used after drying.
- Do not wipe the device or accessories with corrosive liquid or water.
- When wiping, the device should be placed flat. Do not drop debris and stains into the device.
- Do not immerse the device in any liquid or subject it to any high-pressure/autoclave sterilization process.

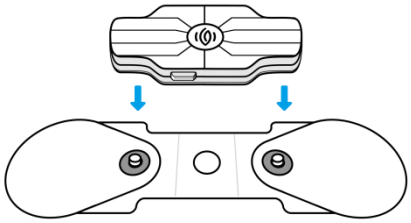
2. Operation Method

2.1 Patch Installation and Operation

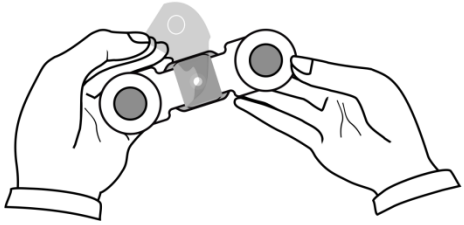
1) Remove the blue protective film in the middle.



2) Fasten the patch with the device to ensure that the device and patch are fit together smoothly.



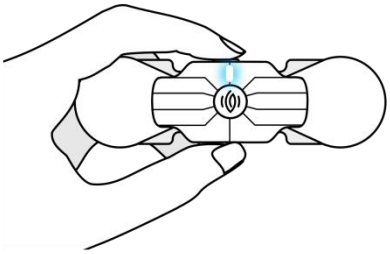
3) Remove the transparent protective film on the back of the patch before use.



⚠Caution: After removing the transparent protective film, please place it on the chest skin promptly. Prolonged exposure to the air will reduce the viscosity and affect the use effect.

2.2 Start the Device

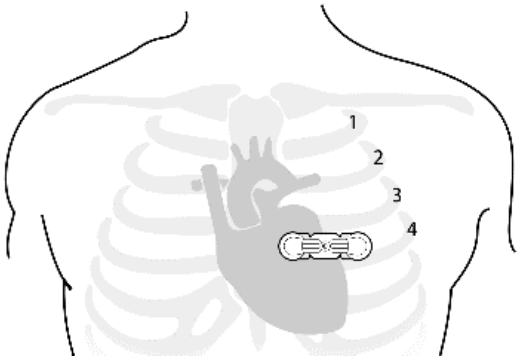
Press and hold the switch button for 2 seconds to turn on / off the device. After turning on, the blue light is on, and Bluetooth is connected.



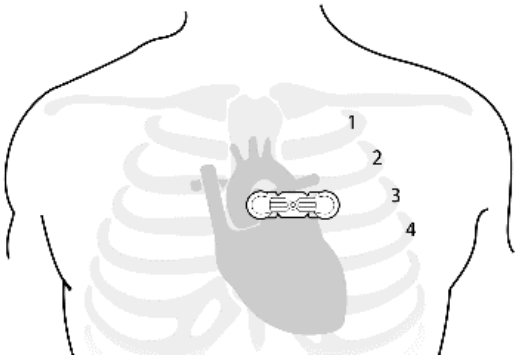
2.3 Device Placement Position

Before the initial use, please try test points A and B to find your own best test point (the waveform is the most stable and strongest) and keep it consistent in future use.

- **Test point A**(Left of sternal border in fourth intercoatal space)



- **Test point B**(Left of sternal border in second intercostal space)



⚠Caution:
Keep skin clean. If there is too much hair on the chest, shave before use to ensure that the patch can be fully attached to the chest. Do not use if there is skin injury or allergy.

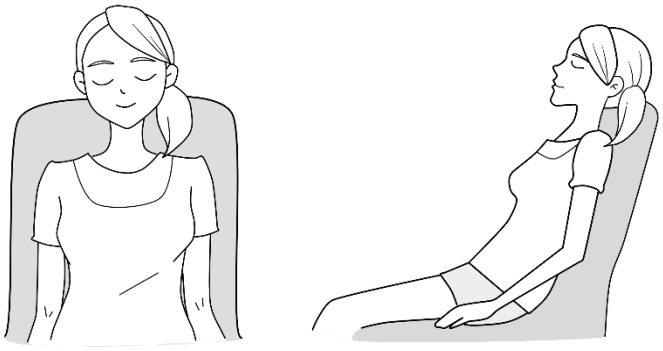
Downward from the clavicle bulge, and the first transverse bone is the second rib, which is downward in turn. The intercostal between second and third ribs is the concave part that could be felt by fingers.

2.4 Test Posture and Environment

1) Find a quiet environment. Keep body relaxed, half lying or half leaning. Do not lean or bend the body. Keep hands and feet relaxed

2) It is recommended to unbutton the clothes, try to avoid the pressure on the device during the test, and keep the body quiet and stable to reduce the interference caused by clothing friction.

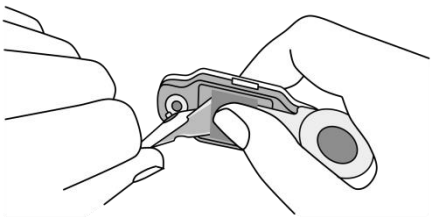
3) During the test, please keep quiet, avoid talking, coughing or breathing deeply, and keep hands and feet relaxed. It is recommended to hold the breath for about 10 seconds to obtain the best heart sound data.



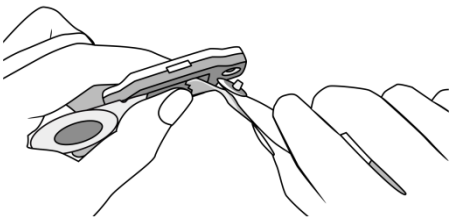
2.5 Remove the Disposable Patch

First remove both sides, then peel off the middle

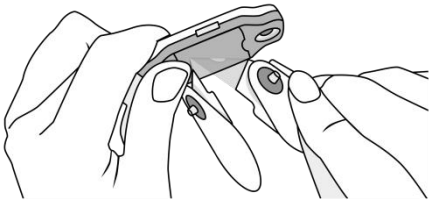
1) Press and hold the middle of the device with one hand, hold one side of the patch with the other hand, and break the snap button.



2) Break the snap button on the other side of the patch.



3) Finally, remove the integrated patch completely.



⚠Caution: Do not use excessive force when removing the button. If you feel it is too tight to break, you can hold the patch, slowly rotate the button part, and try to break it from other angles.

2.6 Software Operation Restrictions

• User login: must use an account that has been successfully registered.

• User creation: required fields are name, age and gender.

• Blood pressure input range: systolic blood pressure (0, 300), diastolic blood pressure (0, 200).

• Blood glucose input range: fasting, two hours after meal and glycosylated hemoglobin (1, 20).

• User height input range: (100, 250), unit: cm.

• User's weight input range: (20, 200), unit: kg.

• Length limit of user's disease history: Character length (0, 300)

• Length limit of user medication: Character length (0, 300)

2.7 APP use

1) Sign in

[Login]: enter the account name and password, and click [Log in] to enter the data collection page.

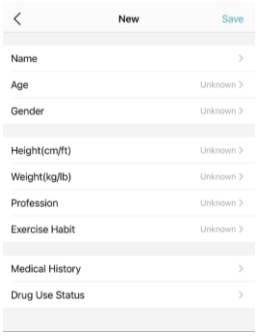
2) User list

On the data collection page, click the photo icon in the upper left corner to enter the user list page. The user list page displays all users under the current account. You can switch, add, edit users.

① Switch user: click [Set] as current user, and the collected data belongs to the current user.

② Add new user: click the symbol [+] in the upper right corner to enter the add user page, enter user information and click [✓] in the upper right corner to save. Name, age and gender are required, and other information is optional.

③ Edit user: click Edit to enter the modify user page. After modification, click [✓] in the upper right corner to save.



3) Data collection and playback

- Input of body parameters:

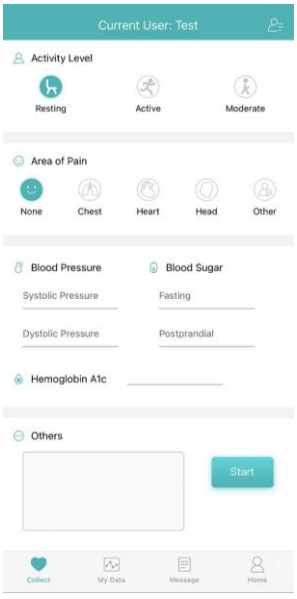
① Physical state: single choice, choose from after exercise, calm and mild activity.
② Subjective feelings: multiple choices, choose from comfort, chest discomfort, heart discomfort, head discomfort and others.
③ Blood pressure and systolic blood pressure can be input in the range (0, 300) and diastolic blood pressure can be input in the range (0, 200).
④ Blood glucose, including fasting, two hours after meal and glycosylated hemoglobin, the input range is (0, 20).

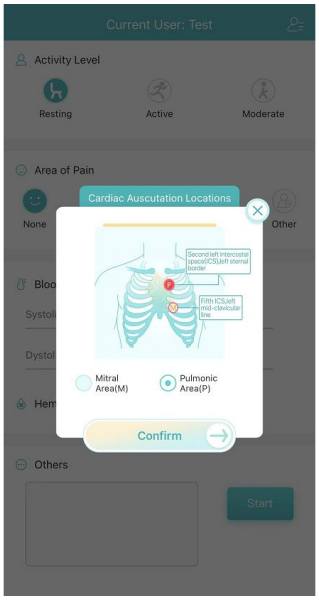
- Data collection:

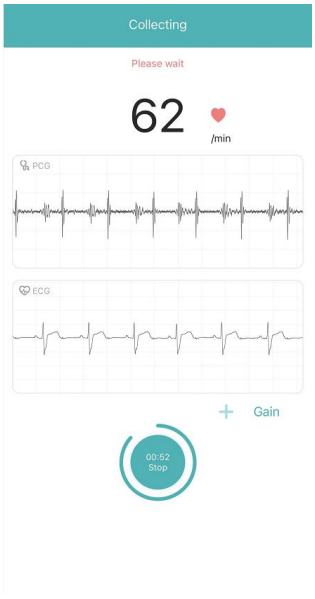
After inputting body parameters, click [Start] go to the test page, which displays real-time heart rate, ECG waveform, heart sound waveform, remaining power of device and data collection time. Click [Adjust heart sound amplitude] to adjust the heart sound amplitude according to the actual heart sound waveform, and click [End] to stop data collection.

- Data playback:

On the record page, click to view the recorded date, and click [review] to enter the data details page. On this page, you can drag the progress bar to view ECG waveform, heart sound waveform and play heart sound.

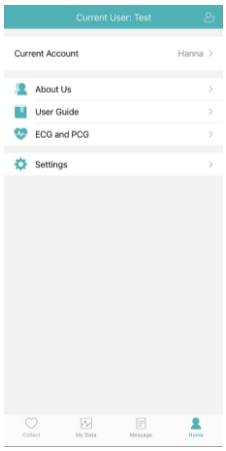


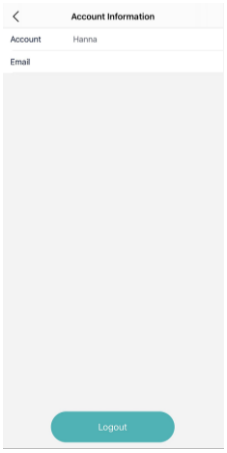




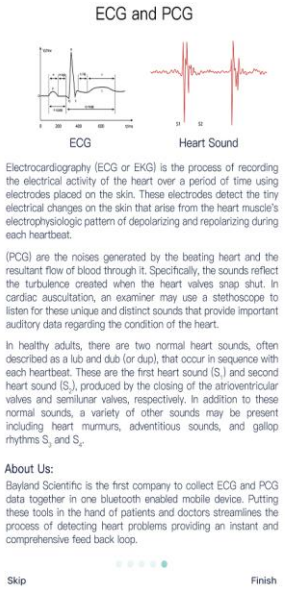
4) Current User

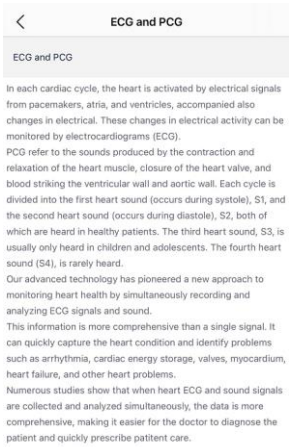
- Current account: display the current login account information, click the account name to enter the account information page, and click [Exit] to exit the current login account.





- Heart sound and ECG: concepts related to ECG and heart sound.





- App version: displays the current series number of the software.

3. Electrical Safety

Guidance and Manufacturer's Declaration – Electromagnetic Emission

The system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Applicable Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR11	Group 1	The system uses RF energy only for internal function. Therefore its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The system is suitable for use in all establishments.
Harmonic emissions IEC 61000 -3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.			
Immunity Test	IEC60601Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for supply lines ±1kVfor input/output lines	±2 kV for supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical commercial or hospital

			environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	＜5% UT （＞95% dip in UT) for 0.5 cycles 40% UT （60% dip in UT) for 5 cycles 70% UT （30% dip in UT) for 25 cycles ＜5% UT （＞95% dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency （50/60Hz） IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field should be at levels characteristic of typical places in typical commercial magnetic field or hospital environment.
Note ： U_T is the a.c. mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.			
Immunity Test	IEC60601Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 V 150 kHz ～ 80 MHz	Not Applicable	
Radiated RF IEC 61000–4-3	3V/m 80MHz～2.7GHz	3V/m 80MHz～2.7GHz	d =1.2 $\sqrt{P}$ d =1.2 $\sqrt{P}$ 80MHz～800MHz ； d = 2.3$\sqrt{P}$ $\sqrt{P}$ 800MHz～2.7GHz P--- the maximum output power rating of the transmitter in watts (W) d---the recommended separation distance in meters (m)

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

Note1：At 80 MHz 和 800 MHz，the higher frequency range applies.

Note 2 ：These guideline may not apply in all situations. Electromagnetic propagation is affected by absorption and is affected by absorption and reflection from structure, objects and people.

[a] Field strength 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 address 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures maybe necessary, such as re-orienting or relocating the device.

[b] Between the frequency range150kHz~80MHz，field strengths should be less than 3V/m。

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Device

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150kHz～80MHz $d=1.2\sqrt{P}$	80MHz～800MHz $d=1.2\sqrt{P}$	800MHz～2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* is meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum 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.