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Wherever you are

Electronic Stethoscope User's Manual

Contents

Introduction

Thank you for chossing the Smartho-D2 Electronic Stethoscope.

The Model Smartho-D2 brings you the very latest in advanced auscultation and wireless electronics technology in a highly ergonometric and easy-to-use format.

Whether you are auscultating infant, pediatric or adult patients, in quiet or noisy environments, or picking up difficult-to-hear heart and body sounds, you'll appreciate the technology that's been built into this latest electronic stethoscope bearing the Smartho-D2 brand.

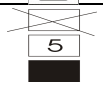
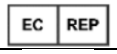
Don't miss the sounds you need to hear.

Safety Information

Please read, understand, and follow all safety information in this user manual before using this electronic stethoscope, keep this users manual for future reference.

U.S.A. Only

Caution: Federal laws restrict the sale by or on the order of a physician.

Safety-related Labels and Symbols Description	
	Fragile -do not drop, to reduce the impact of the stethoscope components.
	This side up, Do not put the stethoscope upside down.
	Stacking layer limit, in order to reduce the risk, do not exceed the stacking layer number.
	Keep dry, do not place in a humid and rainy environment.
	Keep from sunlight, do not expose to the sun.
	This product contains electrical and electronic components, standard handling and garbage collection are not permitted. Refer to local instructions for disposal of electrical and electronic equipment.
	Name and address of manufacturer
	Product serial number
	date of manufacture
	Please refer to the manual
	BF application part
IP22	Level of protection of electrical equipment housing against foreign body intrusion
	EC Representative
	CE mark
Rx Only	For prescription use only
	MR unsafe
Explanation of Signal Word Consequences	
CAUTION	Indicates a dangerous situation, may result in minor injury and/or adverse damage if unavoidable
NOTICE	In dangerous situations, may result in property losses if unavoidable.

CAUTION

Before using the device, please pay attention to and follow all safety & security instructions in these instructions, keep these instructions so that you can refer to them.

Safety：

1.External equipment intended for connection to cable for charging, shall comply with relevant IEC standard (e.g.,IEC 60601 series for medical electrical equipment). If, in doubt, contact qualified technician or your local representative.

2.Please charge it firstly before your first use. And any operation is not allowed when being charged.

3.Do not drop but handle it with care. Otherwise damages or measuring errors will occur.

4.While in use, please use it strictly as instructed in this manual.

5.Please test in the quite environment, stay as much calm as possible during measuring to have steady monitoring and reliable record data.

6.If stethoscope is not used for several days or months, please turn off the power supply of stethoscope. If the battery power is blank or 0%, please use if after charging; In order to maintain the battery performance of the product, it is recommended to charge it once a month when it is not used for a long time.

7.If any problem with the electronic stethoscope, do not attempt to repair it, don't disassemble the main unit. Please inform us of the after-sales hotline. The after-sales service will give instructions.

8.Never throw the device into the fire, or battery will explode.

9.Incorrect battery replacement will cause battery damage, damage (or even explosion), the user is forbidden to replace the battery itself. If necessary, please contact our consultant and will be trained by our qualified personnel for battery maintenance or replacement.

10.In order to prolong the life of the stethoscope, avoid high temperatures, low temperatures, humidity, solvents and grease.

11.Adapter with EMC accreditation is recommended.

12.The device do not need regular maintenance, please contact our customer services department for our technical and business support.

13.Check before each use: Check whether the equipment is damaged or stained, and clean it in time; check whether the base of the device is removed; check whether the connected mobile phone or tablet speaker or media volume is turned on.

14.If the headset is lost or damaged, you can contact the sales service personnel to purchase the original charging cable, you can purchase the mid-bass headset by yourself. If the USB charging cable is lost, you can contact the sales service personnel to purchase the original cable or purchase the charging cable by yourself.

15.In order to reduce the risk associated with infection, please follow all instructions contained in this manual for cleaning, the system and the schedule for cleaning.

16.In order to reduce the risk associated with strong electromagnetics, avoid using stethoscopes close to strong radio frequency signals or portable/or mobile radio frequency devices. If you listen to unusual sounds, stay away from any radio transmitting antenna.

17.In order to reduce the risk associated with incorrect result storage, simply follow the instruction in this manual to operate the stethoscope. The stethoscope has a sound amplification mode (three gears) which can be adjusted by sound button. Please charge the battery in time if the battery grid on the OLED display is empty, do not immerse the stethoscope in the liquid, and do not disinfect the stethoscope.

18.In order to reduce the risk associated with electric shock, do not disassemble the stethoscope unit and do not use the disassembled stethoscope for the user.

19.Do not to press the device by a force bigger than 10N to avoid any damage, and any patients' discomfort.

20.Store the device out of strong sunlight or any substances which causes corrosion and in a good ventilated space.

21.Properly handle the device to avoid dropping from the table or pocket.

22. This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

23.The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Security：

1. Before using the application, please choose the appropriate device and deploy network configuration for security.

2. The phone with the application installed is recommended to install anti-virus software, and open the system automatic patch upgrade.

3. In order to ensure data security, the phone with the application installed is recommended to set the access password.

4. When using the application, please pay attention to the privacy protection.

5. When sending or sharing auscultation data, please pay attention to the protection of private data and ensure the facticity of the person.

6. When not using the application anymore, please delete the sensitive data stored in the idle or scrapped application device.

Notice
In order to reduce the risk associated with the environment, the stethoscope and battery should be properly disposed of or recycled in accordance with the local regulations.

This device is not allowed to be disassembled and modified. Only the authorized service personnel of Hefei Mintti Medical Technology Co., Ltd can repair the stethoscope. Read, understand, and follow all the safety information on the package.

EMC Compliance
This device complies with Part 15 of the FCC Rules, the operation of this device complies with the following two conditions:
(1) The equipment shall not cause toxic interference.
(2) This device must accept any interference received, including interference that may lead to poor operation.

The equipment shall not be modified without the written consent of the Mintti company. Unauthorized modifications may invalidate the authority granted by the Federal Communications Commission rules to allow the device to operate.

EMC conforms to Europe
The device complies with electromagnetic compatibility requirements of the international standard IEC60601-1-2.

Indications for Use/Intended Use
The Electronic Stethoscope is intended for the detection and amplification of sounds from the heart, lungs and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment for medical diagnostic purposes only.

Brief Introduction
The smartho-D2 Electronic stethoscope adopts acoustic sensor to convert the analog signal into a digital signal of auscultation, improve the quality of auscultation signal by increasing signal amplification to achieve the sounds described in the intended use section.
This manual provides complete information on how to operate smartho-D2 electronic stethoscope, so no additional operational training is required.

Function Description
The smartho-D2 electronic stethoscope can receive voices, such as heart and lung sounds from the patient's body, after amplification and filtering, transmit the sound by headset to the user.
The user interface of the stethoscope consists of five buttons and one OLED display screen, the sound processor is carried out with the help of a digital signal processor, the power supply of the stethoscope is provided by the rechargeable built-in lithium battery, including power management system to extend battery life, stethoscope can transmit auscultation data to external devices (such as personal mobile phones, computers) by the reserved Bluetooth wireless connection.

Serial Number
Each smartho-D2 electronic stethoscope has a unique serial number for easy identification, please record the serial number in this manual for future reference: _____

Chapter 01 Instructions for Use

1.Turn on/off

Manual Turn on: When the device is off, press the power button, OLED display will be activated, which indicates the device is on, and will enter the home interface.

Manual Turn off: When the device is on, press the power button for two seconds, OLED display will shut off, which indicates the device is off.

2.Monitor battery information

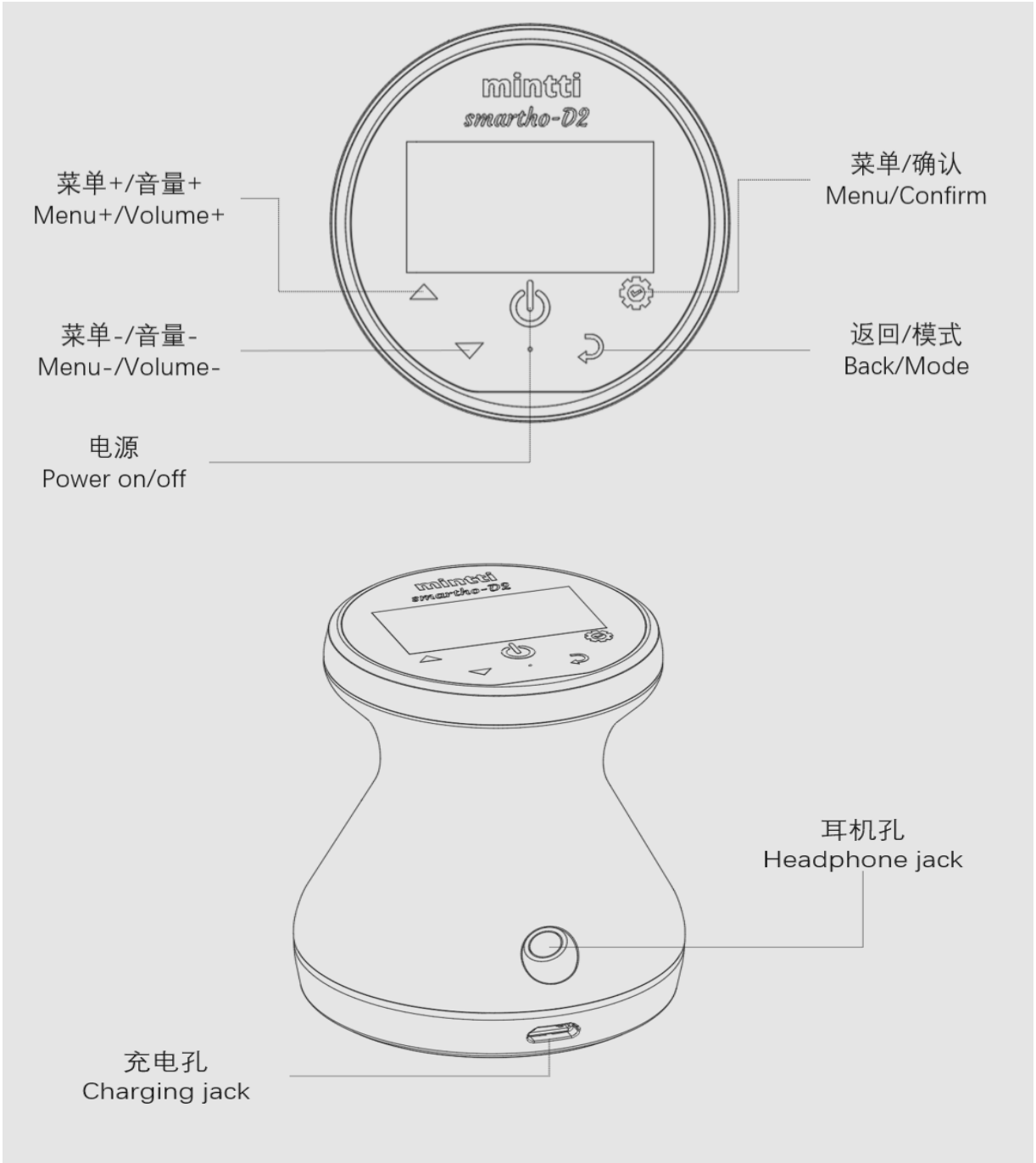
The battery information is displayed by the OLED frame, it is black if the battery is full, the blank in the battery grid indicates that there is no electricity, it needs to be charged in time. smartho-D2 electronic stethoscope use the rechargeable lithium battery, which can be continuous used for more than 48 hours after each full charge, when charging, place the device on the base, plug in the USB cable, plug the 5V adapter on the other end or directly plug into the computer USB interface, the device will jump to the charging interface.

3.Battery charging

When charging, place the device on the base. Then plug one end of the charging cable into the charging hole and the other end to connect to an external electronic device for charging, when the device will switch over to the charging interface.

When full charged, the charging interface will be off and the device enters into the shutdown status.

When the battery is used up or the battery grid is blank or 0%, the stethoscope can’t work, please charge in time. Keep the equipment dry and clean when charging to prevent electric shock.



4.**Mode Switch**

There are two kinds of auscultation modes (heart sound mode, lung sound mode), the switch of auscultation mode can be realized in two ways:

1) under the main interface, by pressing "return / mode key", the mode can be switched; 2) under the menu interface, the mode sub-menu can select the auscultation mode, and the current auscultation mode can be seen as the mode icon under the main interface.

5.Adjust Volume

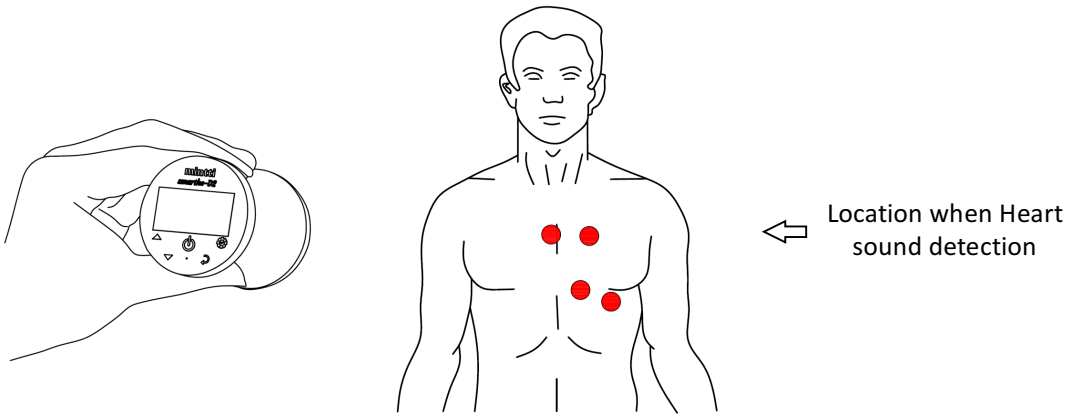
The volume of the auscultation signal could be adjusted. There are two ways to adjust the volume: 1) On the home interface, adjust by "Menu +/Volume" "Menu-/Volume-"; 2) adjust the volume by sub-menu on the menu page.

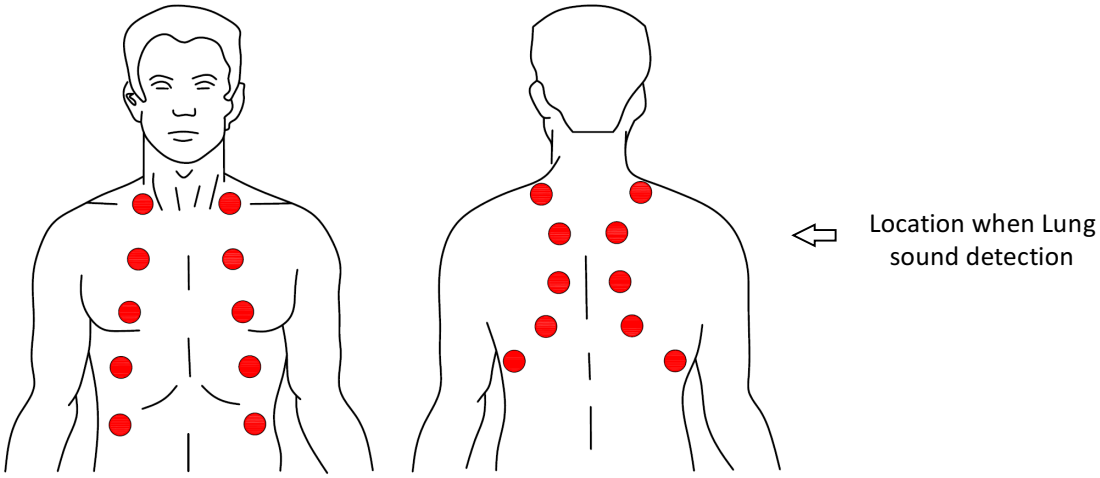
6.Adjust Display Brightness

The backlight under the menu page adjusts the brightness of the display. The factory default is 80%. The OLED displays the backlight brightness for a long time during long standby time.

7. Monitor Patient Heart Rate

The hand-held stethoscope is placed in the red circle of the human body to mark the position to hear the sounds of lungs, heart, each time the auscultation time should be more than 30 seconds (as shown below)



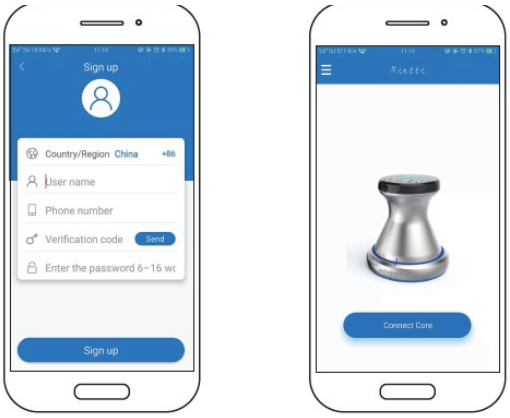


8. Data Storage and Review

Please refer to the Application designated by the Mintti for data storage and review. The device cannot store any data without the Application.

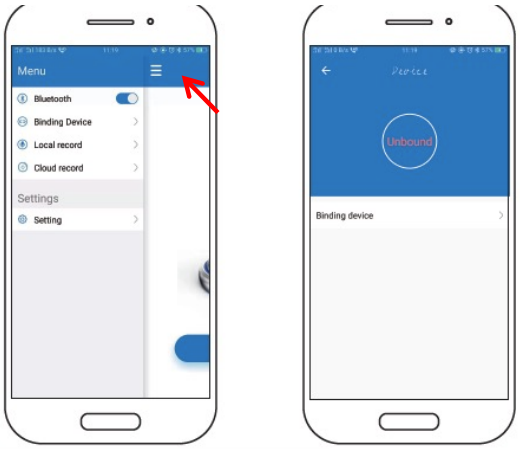
8.1 Download the application named “Mintti” in the phone or other electronic device, and installed following the instructions in the phone.

8.2 Open the Application and registration.



8.3 Device binding

When the device is connected for the first time, device binding should be finished before use. Click the Setting icon in the upper left corner of the Application to enter the setting interface. Select “Binding Device”. When the “Bound” is displayed, the binding is successful. After the binding is successful. It will be automatically bound the next time when connect.



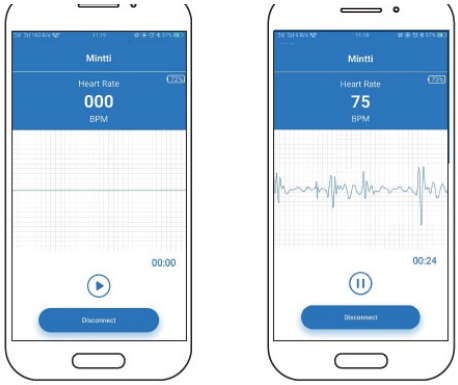
Note:

1.Bluetooth can be turned on by the phone's settings, or you can open it by tapping the Bluetooth button directly on the application.

2.The connection process is slow and requires a few seconds. When the application and the device fail to connect, restart both the application and the device and try again until the connection is successful.

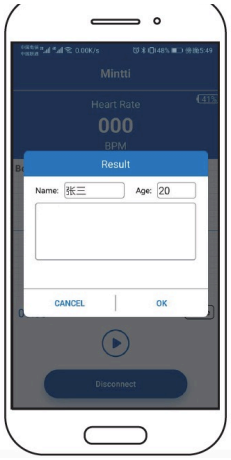
8.4 Connection with smartho-D2

Go back to the main interface and click ”Connect Core” to connect the device. After the connection is successful, it will automatically jump to the playback interface. The upper right corner of the playback interface will display the device power in real time. After clicking the play button, you can hear the signal collected by the device and see the detection time, and display the waveform and heart rate in real time on the software.



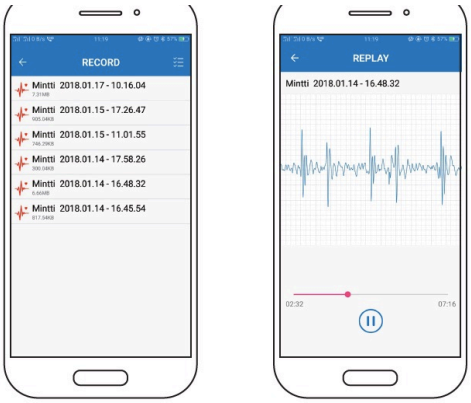
8.5 Data Filling

Fill in the information and save it after detection.



8.6 Data Review

The data collected by smartho-D2 will be saved in real time on the mobile phone, and all the data can be reviewed under the “Local Record” on the “Setting”. Click on the data files to play back the historical data. During playback, drag the progress bar of the playback file to perform fast forward and backward operations. All the data files can be found in the "Mintti" folder of your mobile phone.



Chapter 02 Product Specification

ITEM	Parameter
Battery Specifications	
Battery Type	3.7V/2000mAh lithium ion polymer battery
Battery Operation Time	60 Hours
Battery Use-life	300 cycles
Charging Time	4 hours
Technical Specifications	
Binaural headset	YES
Chest-piece	YES
Sound processing	Digital signal processor
Display Screen	1.3’ Color OLED
Low Battery Indicator	YES
Automatic Power Off	No
Volume Control	1-3 level
Sound Amplifier	Amplifies up to 4X
Signal Sampling Rate	8 kHz
Frequency Response	Heart Sound Mode:20-500Hz
	Lung Sound Mode: 200-2000Hz
Total harmonic distortion	＜3%
*Sound Attenuation	100-500 Hz: ≦12dB 500-1000 Hz: ≦20dB
Intuitive keypad	NO
Direct Listening	Only transferred via headset
Recording and Playback	Not on the device itself
Wireless Technology	Bluetooth® at 2.4GHz
Dimension	Ø58mm×78mm
Safety Classification	
Electric Shock Protection Type	Internal power supply equipment (A rechargeable 3.7V/2000mAh lithium ion polymer battery), or Input 0.2A/5VDC
Electric Shock Protection Level	BF
Liquid Access Proof Level	IP22
Bluetooth Specification	
Version	Bluetooth® 4.0
RF frequency	2.4GHz
Maximum Output Power	-20-4dBm
Frequency Range	2402-2480 MHz
Transmission rate	1M/S
Single-channel bandwidth	1Mbps
Transmission Distance(Max.)	3 m

* Note:The Sound Attenuation is the essential performance.

Chapter 03 Maintenance and Warranty

1.Cleaning

The stethoscope should be cleaned every time after use.

Cleaning method: Under normal circumstances, it is not necessary to disassemble the stethoscope base and the upper cover for cleaning. The contact parts of the stethoscope outer casing are wiped clean with alcohol.

Use the edge of the alcohol cotton swab to sliding wipe the myra, top cover, the outer casing and silicone rubber sleeve of the stethoscope.

Note: The stethoscope should not be invaded into any solution, nor should it be disinfected. Excessive liquid during cleaning may cause moisture to enter the internal components, wipe dry and use again.

2.Service and Warranty

This device is guaranteed for 12 months from the date of purchase.
The smartho-D2 electronic stethoscope provides excellent service and warranty policies. If the product quality problems are found during the warranty period, except the detailed damage or accidental damage, the device will be repaired free of charge when it is returned to Mintti.

Please put your name, address, email address and phone number in it together with the stethoscope.

Please send the stethoscope directly to the Hefei Mintti Medical Technology Co., Ltd. Or the local authorized distributor for maintenance and repair information.

Maintenance & Service Card			
Model		Products name	
Serial No.		Manufacturer	
Price		Acceptance	
Date of manufacture		Date of purchase	
Date of Maintenance & Service	Maintenance Instructions	Maintenance Cost	Maintenance Person

3.Trouble Shooting

No.	Fault Type	Occurrence	Solutions
1	Battery Exhausted	No response while press the on/off key.	Charging the device
2	Poor Battery	The battery indicator in the device is blank or the battery indicator in the APP is 0%	Charging the device
3	Charging Problem	The charging indicator icon is shown in the device	Normal
4	Full Battery	No charging indicator icon, device power off.	Turn off the device and connect the charging dock

Appendix EMC Declarations

Guidance and manufacturer´s declaration – electromagnetic emission		
The model smartho-D2 is intended for use in the electromagnetic environment specified below. The customer or the user of the model smartho-D2 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Model smartho-D2 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 emissions CISPR 11	Class B	
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 Model smartho-D2 are intended for use in the electromagnetic environment specified below. The customer or the user of the Model smartho-D2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The smartho-D2 is intended for use in the electromagnetic environment specified below. The customer or the user of the smartho-D2 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Models smartho-D2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a 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.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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 smartho-D2 is used exceeds the applicable RF compliance level above, the smartho-D2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the smartho-D2.

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

Recommended separation distances between portable and mobile RF communications equipment and the model smartho-D2

The Model smartho-D2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model smartho-D2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model smartho-D2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (M)		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Recommended separation distances between RF wireless communications equipment

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

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E=\frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, 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: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Hefei Mintti Medical Technology Co., Ltd

Address: C309, National University Science Park, 602 Huangshan Road, High-tech Zone, Hefei City, 230088, Anhui Province, China

Contact: 86 0551-63638810

FCC Statement

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.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

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.

RF Exposure Information

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.