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Suzhou Melodicare Medical Technology Co., Ltd.



Electronic Stethoscope User Manual

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Foreword

Thank you for choosing the smartho-D2 Electronic Stethoscope.

The Model smartho-D2 gives you the best experience of auscultation and wireless electronics technology which is also easy to use.

It works well no matter you are using it to auscultate infant, young kid or adult; no matter you are in quiet or noisy environments.

The cutting-edge technologies that have been built into the Model smartho-D2 will guarantee you the best quality.









Don't miss out the wonderful 'sound' you need to hear.

Safety Information







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

U.S.A. Only

Caution: Federal laws restrict the sale from the 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. |

Safety-related Labels and Symbols Description

| | |
|---|---|
|  | 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 Words | |
| CAUTION | Indicates a dangerous situation, there might be minor injury and/or adverse damage. |
| NOTICE | There might be property losses in dangerous situations. |

CAUTION

Before using the device, please have a careful look at the user manual and follow the safety instructions.

- 1.External equipment intended for charging shall comply with relevant IEC standard (e.g., IEC 60601 series for medical electrical equipment). If not, please contact qualified technician or your local representatives.
- 2.Charge before the first use. No other operation is allowed when being charged.
- 3.Handle it with care. Otherwise, there might be damages or other errors.
- 4.Use it strictly as instructed in the manual.
- 5.Test the model in a quite environment, stay as calm as possible during measurement to have reliable data.
- 6.Power down the stethoscope if unused. If it runs out of battery, please recharge before use. It is recommended to charge once a month to maintain the battery life.
7. Do not repair the stethoscope by yourself if there is any problem. Please ask for the professional advice from our customer service department, the consultant will be able to provide further examination or replacement.
8. Do not throw the device into the fire, otherwise the battery may explode.

9. Avoid extreme temperatures, humidity, solvent, and grease to prolong the battery life.
10. Adapter with EMC accreditation is recommended.
11. No regular maintenance is needed. If necessary, please contact our customer services department for technical support.
12. Check before use and make sure the equipment is safe to use.
13. If some parts are damaged or lost, you can contact the customer service department to purchase the part that you need.
14. Follow instructions in the manual for cleaning and disinfecting advice.
15. Avoid using stethoscopes close to strong radio frequency signals or mobile radio frequency devices.
16. If you heard abnormal noise, stay away from any radio transmitting antenna.
17. In order to reduce the risk associated with incorrect result, please follow the instruction in the manual. There is a sound amplification mode (three gears) which can be adjusted by the sound button in the stethoscope.
18. Do not press the device by a force larger than 10N to avoid damage.
19. Store the device out of strong sunlight or any substances which may cause corrosion and keep it in a ventilated space.
20. Avoid dropping the device from the table or pocket.
21. Do not use the device when you are close to other electronic equipment such as cell phone, transceiver, or radio control products.
22. Only use verified accessories and replacement parts sold by the manufacturer of the equipment.

Security:

- 1.Choose the secured network for privacy.
- 2.Download anti-virus software and open the system automatic patch upgrade.
- 3.Set the access password to ensure data security.
- 4.Pay attention to private data when sharing with others.
- 5.Delete the local data if you don't use the APP anymore.

Notice

To reduce the risk associated with the environment, the stethoscope and battery should be properly disposed or recycled in accordance with the local regulations.

This device is not allowed to be disassembled and modified. Only companies authorized by Suzhou Melodicare Medical Technology Co., Ltd. can repair the stethoscope. Read and follow all the safety information in the user manual.

EMC Compliance

This device complies with Part 15 of the FCC Rules, the operation of this device complies with following two conditions:

- (1)The equipment will 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 consent of our company. Unauthorized modifications may result in inaccurate results.

EMC conforms to Europe

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

Intended Use

The Electronic Stethoscope is used for the detection and amplification of sounds from the heart, lungs and other internal organs within selective frequencies.

It can only be used for people who undergo a physical assessment for medical diagnostic purpose.

Patient Profile: There is no age limit.

User Profile: There is no user identification for the device. It can be used by experts or non-specialists.

Brief Introduction

The smartho-D2 Electronic stethoscope uses acoustic sensor to convert the analog signal into the digital signal of auscultation which will improve the quality of auscultation results by increasing signal amplification.

This manual provides detailed information on how to operate smartho-D2 electronic stethoscope, no additional training is required.

Function Description

The smartho-D2 electronic stethoscope can be used to auscultate sounds, such as heart and lung sounds after amplifying the sound by headset.

The stethoscope consists of five buttons and an OLED display screen. The sound system uses a digital signal processor, and the stethoscope is powered by the rechargeable built-in lithium battery including power management system to extend battery life. The stethoscope can transmit auscultation data to external devices (such as mobile phones, computers) via Bluetooth and wireless connection.

Serial Number

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

Instructions for Use

1. Turn on/off

Manual Turn on: When the device is off, press the power button. The OLED display will be activated which means the device is on, and you will see the home interface.

Manual Turn off: When the device is on, press the power button for two seconds. When the OLED display shuts off, it means the device is off.

2. Monitor battery information

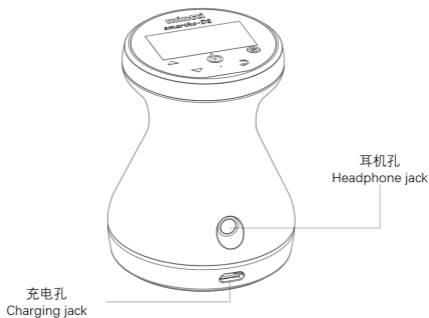
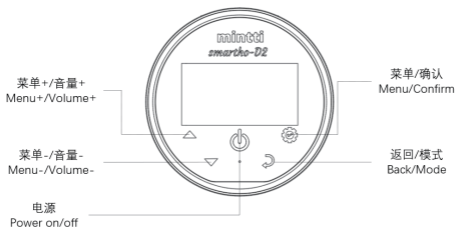
The battery information is displayed by the OLED screen. The screen is black if the battery is full. The blank in the battery grid indicates that the device is running out of battery and will need to be charged in time. The smartho-D2 electronic stethoscope uses the rechargeable lithium battery which can be continuously used for more than 60 hours after each full charge. When the device is charging, place the device on the base and use the USB cable to plug the 5V adapter on the other end or directly plug into the computer USB interface. Then, you will see the charging interface of the device.

3. Battery charging

When charging, place the device on the base, plug in the charging cable on one end, plug in 5V adapter on the other end or directly plug into the charging port of computer.

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

When the device is running out of battery, the stethoscope can't work. Please charge in time and keep the equipment dry and clean when charging.



4.Mode Switch

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

- 1) In the main interface, press "return / mode key", the mode can be switched;
- 2) In the menu interface, select the auscultation mode and you will see the current mode under the main interface.

5.Adjust Volume

The volume of the auscultation signal could be adjusted. There are two ways to adjust the volume:

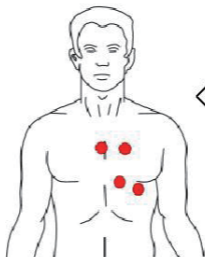
- 1) On the home interface, press "Menu +/Volume+" "Menu-/Volume-";
- 2) Or press sub- menu button on the menu page.

6.Adjust Display Brightness

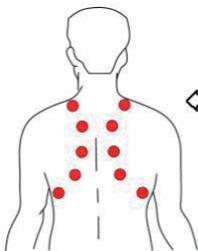
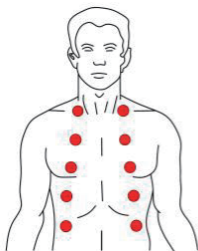
The backlight under the menu page adjusts the brightness of the display. The factory default is 80%. The OLED system will have the backlight brightness during long standby time.

7. Monitor Patient Heart Rate

The hand-held stethoscope should be placed in the marked red circle of the body picture to hear lungs, heart sounds. (as shown below) Each time the auscultation time should be longer than 30 seconds.



Location when
Heart sound
detection



Location when
Lung sound
detection

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' 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 | 100-500Hz: $\leq 12\text{dB}$ |
| | 500-1000Hz: $\leq 20\text{dB}$ |

| | |
|------------------------|------------------------------|
| 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 | 1Mbps |
| Single -channel bandwidth | 1Mbps |
| Transmission Distance(Max.) | 3m |
| Normal working conditions | Ambient temperature: +5°C ~+40°C; Relative humidity: 0%RH~80%RH; Atmospheric pressure: 860hPa~1060hPa |
| Storage and transportation conditions | Ambient temperature: -40°C ~+55°C; Relative humidity: 0%RH~93%RH; Atmospheric pressure: 860hPa~1060hPa |

Note:The Sound Attenuation is the essential performance.

Maintenance and Warranty

1. Cleaning

The stethoscope should be cleaned every time after use.

Cleaning method: It is not recommended to disassemble the stethoscope base and the upper cover for cleaning. The contact parts of the stethoscope outer casing should be wiped clean with alcohol pads.

You can use alcohol pads to wipe the mylar, top cover, the outer casing and silicone rubber sleeve of the stethoscope.

Note: The stethoscope should not be disinfected by yourself. Excessive liquid during cleaning may cause liquid entering the internal components. Please keep it dry and clean before each use.

2. Service and Warranty

The quality of the device is guaranteed for 12 months from the date of purchase. The smartho-D2 electronic stethoscope provides excellent service and warranty policies. If there are quality problems during the warranty period, the device will be repaired free of charge. (Except the accidental damage)

Please send the stethoscope directly to the Suzhou Melodicare Medical Technology Co., Ltd. or the local authorized distributor for maintenance and repairment 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 | he 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 | The Model smartho-D2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | Not applicable |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Not applicable | 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% U_T (100% dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T (100% dip in U_T) for 1 cycle at 0° 70% U_T (30% dip in U_T) for 25/30 cycles at 0° 0% U_T (100% dip in U_T) 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. |

| | | | |
|--|--|---------------|--|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bands</p> | <p>N/A</p> | <p>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</p> |
| | | | $d = \frac{3.5}{V_1} \sqrt{P}$ |
| | | | $d = \frac{3.5}{E_1} \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ |
| | <p>10 V/m 80MHz to 2.7 GHz</p> | <p>10 V/m</p> | $d = \frac{7}{E_1} \sqrt{P} \quad 800\text{MHz to } 2.7\text{GHz}$ <p>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 meter(m).</p> <p>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</p> |
| | | | <p>following symbol: </p> |

NOTE 1: U_i is the a. c. mains voltage prior to application of the test level.

NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3: 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 $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ | 800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ |
| 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 meter(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 | IEC60601 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 $E = \sqrt[6]{d^3 P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be |
| 450 | 2 | 0.3 | 28 | 28 | |
| 710 | | | | | |
| 745 | 0.2 | 0.3 | 9 | 9 | |
| 780 | | | | | |
| 810 | | | | | |
| 870 | 2 | 0.3 | 28 | 28 | |
| 930 | | | | | |
| 1720 | | | | | |
| 1845 | 2 | 0.3 | 28 | 28 | |
| 1970 | | | | | |
| 2450 | 2 | 0.3 | 28 | 28 | |

| | | | | | |
|--|-----|-----|---|---|---|
| 5240 | 0.2 | 0.3 | 9 | 9 | less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  |
| 5500 | | | | | |
| 5785 | | | | | |
| <p>Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | | | |

| Packaging Information | | |
|-----------------------|------------------------------------|------|
| No. | Items | QTY. |
| 1 | Electronic Stethoscope | 1 |
| 2 | Stethoscope base | 1 |
| 3 | Headphone (Gifts) | 1 |
| 4 | USB charger (Gifts) | 1 |
| 5 | Electronic Stethoscope User manual | 1 |
| 6 | APP User manual | 1 |
| 7 | Maintenance & Service card | 1 |
| 8 | QC Certificate | 1 |

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