ibiomedi

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衛部醫器製字第007411號

User Manual

ES-2020

Electronic Stethoscope

ibiomedi Electronic Stethoscope

EN

Before use, please read the Instruction Manual of the original manufacturer and follow the instructions.

Product Application

After selecting a specific frequency response mode, this product can be used for the detection and amplification of sounds, arteries, veins, breathing sounds from the anterior/posterior/lateral chest cavity, and throat sounds in the neck. The electronic stethoscope is designed specifically for medical professionals . This product can be used in any medical clinics or hospitals to perform auscultation for children, adolescent and adults.

Functions

This product is an amplifying device that detects the heart, arteries, veins, anterior/posterior/lateral chest breathing sounds, and neck throat sounds. After amplifying and filtering the sounds, the sounds will be transmitted to the user through the earphones, providing excellent sounds quality.
This product provides users with additional functions, such as wireless transmission and speakers to play auscultation sounds to increase the convenience of diagnosis.

Product Introduction

This product has simple operation interface, allowing medical personnel to perform auscultation for patients with one hand. The three frequency response mode selection button and volume adjustment button can be used for quick adjustment according to the needs of patients, helping users to quickly perform diagnosis.
This product uses two AAA alkaline batteries. The sounds detected by the electronic stethoscope can be recorded through wireless transmission by using external devices such as notebook computers.
Earphones that are comfortable to wear and be used to reduce ambient noise, providing users with high-quality sounds.

Safety Information

Before using this product , please read, understand, and follow all the safety related information and instructions in this Instruction Manual. Please keep this Instruction Manual for future reference.

Prohibited use

Do not use in flammable environments
Use in such environments could lead to spark or explosion.

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Description of safety related labels and signs

	Warning.
	Please refer to the instruction manual.
	Type BF (Body Floating) instrument label: This product provides protection against electric shock and leakage. The applied part is a complete chestpiece with diaphragm.
	This product has limitation on the ambient temperature for operation.
	This product contains electrical and electronic parts, and must not be discarded as general waste. Please refer to the local regulations on the disposal of electrical and electronic equipment for its disposal.
	This product uses wireless transmission.
	Please try to avoid contacting this product with object that contains static electricity.
	This product contains an intentional RF radiator certified by the FCC.
RX only	Federal (USA) law restricts this device to sale to or on the order of a clinician.

Description of word signs

NOTICE	It suggests to pay attention to the situation. If not avoided, it may cause property loss or damage.
WARNING	It suggests that the situation is dangerous. If not avoided, it may cause minor injuries and/or property loss or damage.

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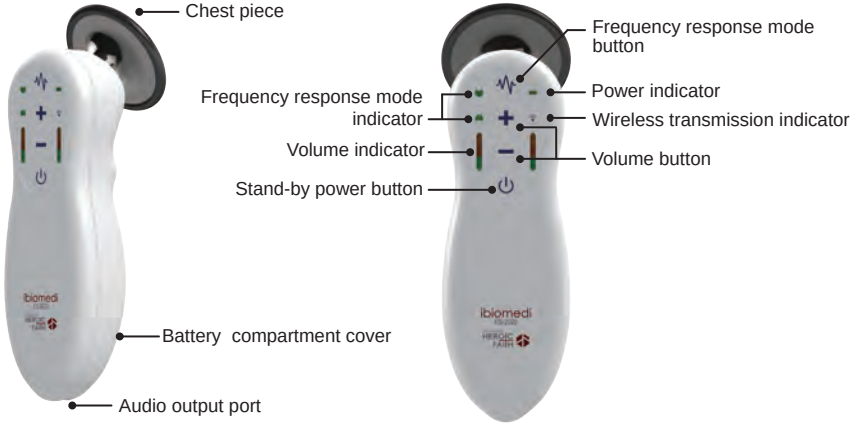
Stethoscope Interface



Stand-by power button	Turn on the power or enter stand-by.
Volume button	The "+" and "-" keys are used to increase/decrease the volume, and The volume indicator will change a light according to the volume press twice.
Frequency response mode button	In "heart sounds mode", the heart sounds indicator will show green light; in the “lung sounds mode”, the lung sounds indicator will show green light; in the “full frequency mode”, both indicators are off.
Audio output	The auscultation sounds can be played through the earphones/speaker connected to the audio source line. Note: This device is not suitable for street pairing Bluetooth speakers and Bluetooth headsets.
Wireless transmission	Class II Bluetooth wireless transmission is adopted. By connecting to a wireless device through Bluetooth , the sounds detected by the electronic stethoscope can be recorded in the device.

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Operation Instruction

1.Check Chest piece

- Replace the chest piece immediately if it is broken or dirty.
- Confirm that the chest piece has been installed before use.

2.Chest piece replacement

Please hold the instrument body tightly when replacing the chest piece. Rotate counterclockwise to remove the ches tpiece and place it in a safe place to avoid falling and damage.

Insert the new chest piece into the main unit and rotate it clockwise until the arrow on the chest piece reaches the marked line on the main unit.

Prohibited use

Means that usage exceeding the performance range or improper use could result in death or severe injury.

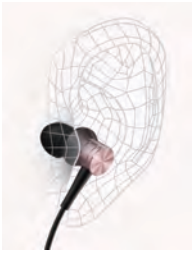
Warning

Means that wrongful use could result in death or severe injury.

Precautions

Means that wrongful use could result in injury or product damage.

3.Audio output



Insert the earphones plug into the audio output port and place the earbud into your ear canal. It is recommended to replace the earbud tip if you feel uncomfortable. Auscultation can be performed by using earphones.
Plug the audio line into the audio output port, and then connect the other end of the audio line to the microphone port of the computer. Users can then perform auscultation by using communication software.

WARNING：
To avoid ear damage, do not hit the chestpiece or rub the chestpiece diaphragm when operating the electronic stethoscope with earphones, while the power is turned on.

4.Stand-by power button (turn on/stand-by the instrument)

- Press the power button for three seconds to start the instrument or enter Stand-by.
- When the power indicator lights green, it means the power is on.

NOTICE:
When the battery is low, the power indicator will flash and the function will be turned off.
Be sure to replace the battery.

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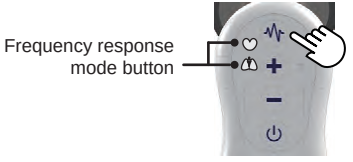
5.Frequency response mode

Press the button to change the frequency response mode. The switching sequence is: heart sounds mode → lung sounds mode → full frequency mode. Users can choose three different frequency response modes.

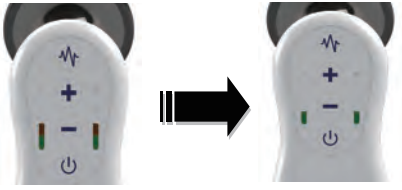


Heart sounds mode: the sounds in the frequency range of 20~200 Hz will be emphasized and amplified. The heart sounds indicator will show green light.

Lung sounds mode：the sounds in the frequency range of 100~1000 Hz will be emphasized and amplified. The lung sounds indicator will show green light.

Full frequency mode：the sounds within the frequency of 1200 Hz will be amplified. Both indicators are off.

6.Volume adjustment



Press the "+" key to increase the volume, and press the "-" key to decrease the volume. There is a limit to the volume level; the maximum volume is level 8, and the minimum volume is to mute the sounds. Please adjust to proper volume for auscultation.

NOTICE：
Sequentially displayed when increasing the volume:
Every time you press the volume button twice to change the light.
green→green→orange→orange
Displayed in order when the volume is reduced:
Every time you press the volume button twice to change the light.
green←green←orange←orange

7.Wireless connection

When the ES-2020 electronic stethoscope is connected to a notebook computer or wireless device, the wireless transmission indicator will show blue light.
The following sequence explains the Bluetooth connection steps:
1.Connect your smart phone with ES-2020 Bluetooth.
2.After wireless device pairing is successful, the ES-2020 electronic stethoscope can support auscultation sound recording via notebook computer, or perform direct auscultation via communication software.
3. Open the built-in voice memo program of smart phone.
4.Press the record button to start recording.
(The sound signal will be reflected on the voice memo with the sound captured by the ES-2020.
If you use a Bluetooth to connect to the computer, you need to set the system device as a microphone, and use recording software to record auscultation sounds.)
5.When using a wireless device to connect to a communication device (such as a smart phone), you need to use the communication software to dial the other party for direct auscultation.

WARNING:
The device cannot directly connect to Bluetooth speakers via Bluetooth wireless transmission.
WARNING:
To avoid pairing errors, please re-pair before each use.

8.Recommendation about speakers

Computer by default usually is not equipped with a subwoofer or a low-tone audio.
Heart sounds contain very low audio frequencies, about 20 Hz. Only speakers or subwoofers with corresponding audio capabilities can reproduce true heart sounds.

The sounds collected by the ibiomedi electronic stethoscope ES-2020 may be different from the reference sound mostly due to the differences in recording conditions or recording equipment such as personal computers.

NOTICE：
For personal use, please use earphones.
For public demonstration, it is recommended to use speakers with a subwoofer.

How to replace the batteries

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When do the batteries need to be replaced?

- When the battery indicator is flashing green.
- When nothing happens after the power switch is pressed.

AAA (No. 4) 1.5V
alkaline batteries

Battery notes

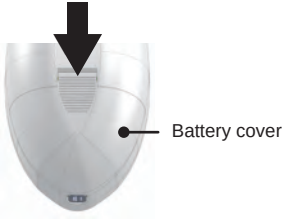
- Alkaline batteries can be used for about 7~8 hours, if the Bluetooth is turned on, it can only be used for about 4 hours.
- When the power level is low, the indicator will flash green. This may mean a low battery level; please replace the battery. Insufficient voltage may affect functioning or result in mis-diagnosis.
- When the power is off. The bluetooth inducator will flash. Indicates that the battery is low. Please replace battery.

- When first inserting and when changing batteries, the device must be turned off to avoid malfunction or damage.
- The battery will gradually decrease when the power is turned off. It is recommended to remove the battery when not in use.

Precautions

Do not use non-specified batteries.
Use otherwise could lead to malfunction.
Do not stack batteries.
Doing otherwise could lead to heating or fire.
Do not dispose of batteries in a fire.
Waste batteries should be disposed of according to local recycling regulations.

Battery replacement



- Open the battery compartment cover by pushing down the cover and remove the old batteries.
- Replace the old batteries with two new AAA alkaline batteries.
- Note that batteries may spring out when being removed.
- Insert the new battery in the correct direction. After replacing the battery, close the battery compartment cover.
- After battery replacement, the volume setting will be reset to the original factory setting.

NOTICE：Please turn off the instrument before removing the batteries.
The power will gradually decrease when the power is turned off.
It is recommended to remove the battery when not in use.

WARNING：Please do not use the battery if it is broken or damaged.

Product Introduction

Features

This product can detect sounds from the heart, arteries, veins, breathing sounds from the anterior/posterior/lateral chest and throat sounds in the neck. The auscultation sounds can be played through earphones/speakers.
The product has three frequency response modes to perform auscultation depending on the parts of the patient.
In addition, the auscultation sounds can be recorded by a notebook computer or wireless device through wireless transmission and remote auscultation can also be performed.

Product description

This product detects sounds from the heart, arteries, veins, breathing sounds from the anterior/posterior/lateral chest, and throat sounds in the neck of patients. The sounds is transmitted to the user's ears through accessories such as earphones.

User interface includes
A: Power button, frequency response mode button, volume button
B: Power indicator, wireless transmission indicator, frequency response mode indicator, volume indicator.

Turn on this product and connect to the wireless device via Bluetooth to transmit and store sounds. This product and the connected wireless device have walls, human bodies and other barriers, the effective range of Bluetooth transmission will be affected. It is recommended to reduce the distance between this product and the connected wireless device to improve Bluetooth connection.

Power to the device is provided by two AAA 1.5V batteries.

Indications for use

The ES-2020 electronic stethoscope is used to detect sound from the heart, arteries, veins, breathing sound from the anterior/posterior/lateral chest, and throat sound in the neck.
The chest piece is designed for children who are over two years old, teenagers and adults.
It can be applied to any body type and can only be used for the purpose of medical diagnosis in clinics or hospitals.

Contraindications for use

There are no known contraindications for ES-2020, although care should be taken when considering using the device according to the warnings and precautions below.
Do not use the device over open wound or on infected skin.
ES-2020 is not life-supporting or life sustaining.

Specifications

Product name : ibiomedi Electronic Stethoscope

Model No.: ES-2020

Color：White

Battery：AAA 1.5V alkaline battery * 2

Operation current：90mA

Chestpiece：Replaceable chestpiece (child/adult)

Dimension：139 X 48 X 34 mm

Weight：180g

Clinical application：For auscultation

Ingress Protection (IP) Rating：IPX2

Frequency response mode：heart sounds / breathing (lung) sounds / full frequency

Frequency range of frequency response mode：
heart sounds (20~200Hz) lung sounds (100~1000Hz) full frequency (20~1200Hz)

Volume adjustment：+ / -

Audio output：earphones / speakers

Volume level：8 increments up to 50X amplification

Digital wireless transmission

Bluetooth (Receiver) : Bluetooth v4.2 specification compliant.2.402GHz ~ 2.480GHz unlicensed ISM band, π/4 DQPSK, 8DPSK . EDR(3MB)

Bluetooth (Transmitter) : Bluetooth v4.2 specification compliant. 2.402GHz ~ 2.480GHz unlicensed ISM band, 9 dBm (typ)=7.9433mW RF transmit power with level control, π/4 DQPSK and 8DPSK modulation,EDR(3MB)

Bluetooth Specifications : Operation Frequency: 2402MHz~2480MHz
Average speed bit rate > 327 kbps bit pool:53bits
Delay: < 200ms
Bluetooth transmission distance:10m
Bluetooth transmission power: 9 dBm (typ)=7.9433mW

Accessories

- Small chest piece (For children with diaphragm) ×1
- Large chest piece (For adult with diaphragm) ×1
- Audio line (PVC 1 meter) ×1
- Earphones (1MORE Earphones) ×1
- Battery (1.5V Alkaline AAA battery) ×2
- Instruction Manual ×1

WARNING：Do not use unauthorized accessories to avoid accidents. Please use the accessories specified by the original manufacturer and comply with safety regulations.

Cleaning Method

Before cleaning, please check whether the structure of the battery compartment cover and the chest piece is stable to avoid liquid infiltration.

Cleaning chest piece

Under normal conditions, there is no need to remove the diaphragm for cleaning. The diaphragm can be sprayed on a cotton cloth with 75% alcohol solution, and then cleaned and wiped with a cotton cloth.
If it is required or the diaphragm is damaged, please replace the diaphragm with a new one. Please operate carefully following the instructions given below.

(1) Remove the chest piece: turn off the power and remove the chest piece.
(2) Remove the diaphragm: use your thumb to lift the lower part of the diaphragm from the chest piece groove, and then pull it away from the chest piece. After removing the diaphragm, the edge of the chest piece groove can be cleaned with alcohol, and the entire chest piece can be wiped with alcohol.
(3) Diaphragm installation: When the diaphragm is completely dry, insert it into the chest piece groove. Starting from a single point, move your finger around the chest piece groove until the diaphragm fits into the groove.

Earphones: Alcohol-containing cloth can be used to wipe the earphones. For more thorough cleaning, please remove the ear bud tip for deep cleaning.

ES-2020: We strongly recommend spraying 75% alcohol onto a cotton cloth, and then use it to wipe the instrument.

When cleaning is complete, if there is still dirt remaining on visual inspection, be sure to repeat the cleaning one at a time until the dirt is removed.

WARNING：To reduce the risk of infection, the electronic stethoscope must be cleaned after each use.
WARNING：Please do not immerse the electronic stethoscope in liquid or perform any high temperature autoclave sterilization process. It may damage the instrument.
WARNING：Do not spray alcohol toward the earphone plug hole, which may cause damage to the device.

Expected Service Life

If it is operated normally in accordance with the manual, the service life is one year, unless improper operation may shorten the service life.

Maintenance and Repair

If you need maintenance or repair services, or have any questions or comments, please feel free to contact the customer service center. We will do our best to provide you with assistance and solve your problems.

NOTICE：Please do not disassemble this instrument without authorization. This product can only be repaired by authorized maintenance personnel; if unauthorized modification of the instrument is carried out by the user, the user will take full responsibility for any damage.

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Transportation, Storage and Disposal

Transportation and storage

The transportation and storage of the instrument should comply with the conditions described in the "Other Operational Precautions" section of this Manual.

This product should be delivered to an authorized customer service center for inspection and repair. The storage must comply with the conditions described in the "Other Operational Precautions" section of this Manual.

Disposal

You should properly dispose of the electronic stethoscope in accordance with local regulations. Alkaline batteries must be disposed of or recycled separately from general waste.

Note: To reduce the risks associated with environmental pollution, we follow the applicable local regulations when disposing of the electronic stethoscope . Alkaline batteries must be disposed of and recycled separately from general waste.

Troubleshooting

Q：Unable to turn on the power

A： 1. Please check whether the batteries are placed correctly, and try again after re-placing the batteries.
2. Please place new batteries and then check again.

Q：There is no auscultation sounds or abnormal sounds is noticed after power on.

A： 1. Please check whether the chestpiece is installed correctly, and check again after adjustment is made.
2. Please use the "volume button" to adjust to an appropriate volume level.
3. Please confirm whether the headphones cable is completely inserted into the audio output interface.

Q：The instrument is not working and the indicator flashes abnormally.

A： 1. Please remove the batteries from the battery compartment and placing them into the battery compartment again. Press the power button to restart.
2. Please place new batteries and then check again.

Q：Bluetooth connection fails.

A： 1. Please restart the instrument and then check again.

NOTICE：If you have tried all the solutions but still unable to solve the problem, please call your local customer service center for help.

WARNING

- **To reduce the risk of incorrect results, personal injury, and equipment damage,** please follow the instructions provided in this Manual to operate this product.
- **To reduce the risk of damaging the chestpiece,** please do not place the chestpiece near an intense sounds.
- To reduce the risk of infection, please follow the cleaning instructions provided in this Manual, establishing and implementing a cleaning.
- **To reduce the risk of strong magnetic fields,** please avoid using this product near strong radio frequency signals or portable and/or mobile radio frequency equipment. If a sudden or unexpected sound is noticed, stay away from any radio frequency antennas.
- **To reduce the risk of electric shock,** please do not use an electronic stethoscope without a covering film on patient.
- **Do not immerse the stethoscope in liquid or any sterilizing solution,** which may damage the instrument.
- **This product is not suitable for children under two year old because** its chestpiece is designed for children who are over two year old, teenagers and adults.
- **To avoid battery electrolyte leakage to damage the product,** please follow the battery usage instructions carefully.
- **If the battery electrolyte solution gets into your eyes,** please rinse them with clean, cold running water immediately and seek medical assistance right away.
- **Please do not use this product near or together with other instruments.**
- That portable RF communications equipment can effect medical electrical equipment. We recommend a safety distance no closer than 30 cm to any part for sensitive equipment.
- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

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Precautions

- To reduce environmental pollution related risks, please follow the local regulations to discard this product and the used batteries should be properly disposed of or recycled.
- Un authorized modification of this product is forbidden. This product should be repaired by authorized service personnel. Users who carry out any improper modification or repair of this product shall be held responsible for the resulted loss.
- It is not safe to use this product in a magnetic resonance imaging environment. Do not use this product in a magnetic resonance imaging environment.
- Before using AAA alkaline batteries, please make sure that both ends of the battery electrodes are clean. Put them in the battery holder correctly.
- To extend the battery life, remember to turn off the power of the instrument when it is not in use.
- The power will gradually decrease when the power is turned off.It is recommended to remove the battery when not in use.

Other Operational Precautions

- The operating environment temperature range must be between 41º to 104ºF (5º to 40ºC), the relative humidity should be 15 to 93%, and the atmospheric pressure range should be between 1002hpa and 1008hpa.
- The storage and transportation temperature must be between -4ºF to 158ºF (-20ºC to 70ºC), and the relative humidity must be between 0% to 93%.
- To extend the lifetime of the electronic stethoscope, avoid operating in extremely cold or hot environment, and contacting with solvents or oil.
- If the electronic stethoscope will not be operated for several months, please remove its batteries.
- Failure to follow the instructions on maintaining this product may cause damage to its internal parts. Internal damage may lead to product failure, ranging from decrease of auscultation performance to total damage.
- If you encounter any problems while using the electronic stethoscope, please do not try to fix it by yourself. Please contact the customer service center for consultation or repair.
- The power will gradually decrease when the power is turned off.It is recommended to remove the battery when not in use.
- When using this product, medical personnel recommend wearing medical gloves.

EMC Compliance and electrical safety

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EMC Compliance

EMC Compliance Europe
This equipment complies with the EMC requirements ofthe IEC60601-1-2.

Electromagnetic Emissions and Immunity

Emissions test	Compliance	Electromagnetic Environment - Guide
RF emissions CISPR 11	Group 1	The ES-2020 only utilises RF energy for its internal function. Therefore, their Rf emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 6100-3-2	Non applicable	The ES-2020 is suitable for use in all establishments including domestic establishments and those directly connected to the public lowvoltage power supply network that powers buildings used for domestic purposes.
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Non applicable	

Using the device

The use of accessories that have not been supplied by us may result in non-compliance with the safety levels of the ES-2020, reducing the safety level, increasing the level of emissions, and reducing immunity. The manufacturer has foreseen most of the possible faults of the device, which have been included in the internal monitoring system. However, if the patient depends on this system, it is recommended to have an alternative system.
The user must read and understand this manual before using any device in the ES-2020. This manual has been written to provide the necessary information for the use of any device in the ES-2020, but should not be considered a substitute for medical instructions essential for the adjustment of the ES-2020 to adapt it to the needs of the patient.

Manufacturer's declaration-electromagnetic emissions		
The ES-2020 is intended for use in the electromagnetic environment (for Professional healthcare environments) specified below. The customer or the user of the ES-2020 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for Professional healthcare environments)**
RF emissions CISPR 11	Group 1	The ES-2020 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 A	The ES-2020 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distance between portable and mobile RF communications equipment and the ES-2020

The ES-2020 is intended for use in an electromagnetic environment (for Professional healthcare environments) in which radiated RF disturbances are controlled. The customer or the user of the ES-2020 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ES-2020 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\xi\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\xi\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2{,}3\xi\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Manufacturer's declaration-electromagnetic immunity			
The ES-2020 is intended for use in the electromagnetic environment (for Professional healthcare environments) specified below. The customer or the user of the ES-2020 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for** Professional healthcare environments**)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	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	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical Professional healthcare environments
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical Professional healthcare environments
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical Professional healthcare environments. If the user of the ES-2020 requires continued operation during power mains interruptions, it is recommended that the ES-2020 be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The ES-2020 power frequency magnetic fields should be at levels characteristic of a typical location in a typical Professional healthcare environments.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity

The ES-2020 is intended for use in the electromagnetic environment (for Professional healthcare environments) specified below.
The customer or the user of the ES-2020 should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for Professional healthcare environments)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz	Not applicable Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the** ES-2020 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 % AM at 1 kHz e) 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2\xi \overline{P}$ $d = 1,2\xi \overline{P}$ 80MHz to 800 MHz $d = 2,3\xi \overline{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The ES-2020 is intended for use in the electromagnetic environment (for Professional healthcare environments) specified below. The customer or the user of the ES-2020 should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for Professional healthcare environments)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ☒±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. 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 to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

FCC and NCC regulations statement

FCC Part 15.19This 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.
(2) this device must accept any interference received, including interference that may cause undesired operation FCC Part 15.21 information for user You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment. FCC Section 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.

IMPORTANT NOTE:FCC Radiation Exposure Statement :This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

IMPORTANT NOTE: This medical device complies with the FCC Bluetooth Transmission Security Specification. (AAMI TIR69: 2017/(R)2020, ANSI C63.27-2017)

FCC ID : 2AYQY-ES-2020

EN

NCC Regulation Statement:

According to the regulations of NCC low-power radio wave radiant motors:
Please note that for certified low-power radio frequency equipment, companies, trade names, or users are not allowed to change the frequency, increase power, or change the features and functions of the original design without permission.
The use of low-power radio frequency equipment must not affect flight safety and interfere with legal communications; if interference is found, immediately stop using it and improve it to be interference-free before continuing to use it.
The aforementioned legal communications refer to radio communications operated in accordance with the provisions of the Telecommunications Administration Law.
Low-power radio frequency equipment must endure interference from legal communications or industrial, scientific, and medical radio wave radiation electrical equipment.

NCC form certification number： CCAM21LP0370T7

好音電子聽診器
ibiomedi Electronic Stethoscope

衛部醫器製字第007411號

使用前請務必詳閱原廠之使用說明書並遵照指示使用

CH

產品用途

本產品用於在選擇特定的頻響模式後，可使用於檢測和擴大來自心臟、動脈、靜脈、前/後/側邊胸腔之呼吸音，頸部喉音等聲音。電子式聽診器為醫事人員使用而設計，本產品可在任何診所或醫院為兒童、青少年及成人聽診。

功能介紹

本產品為偵測心臟、動脈、靜脈、前/後/側邊胸腔之呼吸音，頸部喉音等聲音的擴大裝置。經過擴大及過濾聲音後，聲音會透過耳機傳送給使用者，提供優良的聲音品質。本產品提供用戶額外的功能，例如無線傳輸功能、揚聲器播放聽診聲音，以增加診斷的便利性。

產品介紹

本產品具有簡易的操作介面，讓使用者可用單手為病人聽診。三段頻響模式按鍵、音量調整按鍵，可依照患者的需求快速調整，幫助使用者快速的聽到聽診音。

本產品使用兩顆AAA四號鹼性電池，聽診器可通過無線傳輸與個人筆記型電腦等外部設備擷取聽診聲音。耳機配件以求穿戴舒適，並降低環境噪音，提供使用者良好的音質。

安全性資訊

請於使用本產品前，詳細閱讀、理解，並遵循此操作手冊內所有安全資訊指示。

請保留此操作手冊供日後參考用。

⚠ 禁忌.禁止

請勿在可能起火的環境使用

否則可能引發火苗或爆炸

CH

安全性相關標示及符號說明

	警告。
	請參照使用說明書。
	BF型儀器標示：本產品提供防電擊和漏電的保護。應用部分為具薄膜的完整聽頭。
	本產品有使用環境溫度限制。
	本產品包含電力及電子零件，不得以一般垃圾回收標準丟棄。 請參閱當地電力及電子設備丟棄之相關規定。
	本產品使用無線傳輸。
	請盡量避免含靜電物品接觸本產品。

文字符號說明

NOTICE	表示注意情況，如不避免，可能導致財產損失。
WARNING	表示危險情況，如不避免，可能導致輕微傷害，亦/或財產損失。

聽診器介面

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電源鍵	開啟電源或進入休眠模式。
音量鍵	“+” 和” - “鍵用於調整音量增加/減少， 音量指示燈會依音量按壓兩次變化一個燈號。(綠→綠→橘→橘)
頻響模式鍵	“心音模式” 時心音指示燈會亮綠燈、 “肺音模式” 時肺音指示燈會亮綠燈、 “全頻模式” 時沒有燈亮指示。
音訊輸出	可透過接口與音源線連接之耳機/揚聲器播放聽診聲音。 註：本產品不適用於直接配對藍牙喇叭及藍牙耳機。
無線傳輸	使用Bluetooth HFP (Hands-free Profile)無線傳輸， 透過藍牙與無線設備 連接後可以傳輸、擷取聲音。

操作說明

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1.聽診頭的確認

- 當破裂、污損時，請立即更換聽診頭。
- 使用前請確認有裝聽診頭。

2.更換聽診頭

請在更換聽診頭時緊緊握住裝置主體。逆時針旋轉並取下聽診頭。請將聽診頭放在安全的位置，避免墜落造成損壞。

將新聽診頭套入主體並順時針旋轉，聽診頭的箭頭落入標示線的範圍。

⚠ 禁忌/禁止

表示若使用方法超過性能範圍或不適當，可能導致死亡或重傷發生。

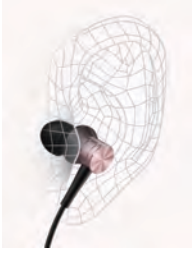
⚠ 警 告

表示若使用錯誤，可能導致死亡或重傷發生。

⚠ 注 意

表示若使用錯誤，可能導致受傷，或物品損壞發生。

3.音訊輸出



將耳機插頭插入音訊輸出接口，將耳機放入耳道內，如覺不適時建議更換耳套。可透過耳機進行聽診。
將音源線插入音訊輸出接口，再將音源線與電腦音源的麥克風接口連接，可以擷取聽診音。

CH

WARNING：
為避免損傷耳朵，請勿在聽診器開機的情況下用力拍打聽診頭或摩擦聽診頭膜片。

4.開機(裝置開機/休眠)

- 按下電源鍵三秒啟動儀器或進入休眠模式。
- 電源指示燈亮綠燈時表示電源已打開。

WARNING：
當電量不足時，電源指示燈會閃爍，並且關閉功能。請務必更換電池。

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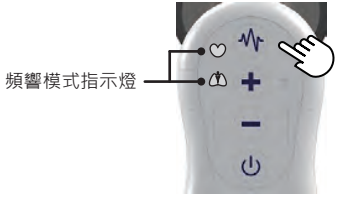
5.頻響模式

按下按鍵切換頻響模式。依序為：心音模式→肺音模式→全頻模式。使用者可選擇三種不同的頻響模式。

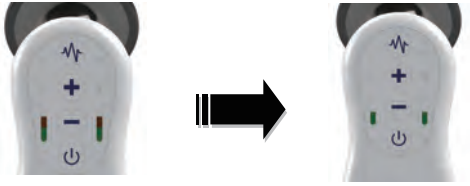


心音模式：可放大並強調頻率於20~200Hz區間的聲音。心音指示燈會亮綠燈。

肺音模式：可放大並強調頻率於100~1000Hz區間的聲音。肺音指示燈會亮綠燈。

全頻模式：可放大頻率於1200Hz以內的聲音。沒有燈亮指示。

6.音量控制



按”+”鍵時增加音量，按”-“鍵時減小音量。
音量大小有限制最大只有到放大8級，最小則為靜音。
請調整到適當音量進行聽診。
(增加音量時依序顯示 每次段音量改變燈號 綠→綠→橘→橘)
(降低音量時依序顯示 每次段音量改變燈號 綠←綠←橘←橘)

7.無線連線

當本產品與筆記型電腦或無線設備連接時，無線傳輸指示燈亮藍燈。
當無線裝置配對成功後，本產品可支援筆記型電腦或智慧型手機擷取聽診音。
使用無線連接電腦時，需至系統裝置設定為麥克風以擷取聽診音。
使用無線連接智慧型手機時，可以擷取聽診音。

CH

WARNING ：
本產品無法直接透過藍牙無線傳輸連接藍牙揚聲器。

8.關於揚聲器的建議

安裝有揚聲器的電腦通常很少擁有一個低音喇叭。
心臟音含有非常低的音頻，大約為20Hz。只有帶相應音頻能力的揚聲器或低音揚聲器才能夠重現真實的心臟音。
本產品如使用揚聲器時，建議使用音量在5以下，揚聲器會有產生正回授的問題。

聽診器採集的聽診音可能與參照聽診音有所不同，多半是由於擷取條件或個人電腦等設備的不同造成。

NOTICE：個人使用，可帶耳機。
公開演示，建議使用帶有低音喇叭的揚聲器。

CH

電池更換方式

什麼時後需要更換電池?

- 當電池標記閃綠燈時。
- 按下電源，無動作時。

AAA 1.5V
四號鹼性電池 x 2

有關電池

- 鹼性電池約可使用7~8小時，如果在藍牙開啟的狀態下只能使用約4小時。
- 電源不足時會閃綠燈，可能是電池沒電，請更換電池。電壓不足會影響功能或誤診。
- 當電源關閉時，藍芽指示燈會閃爍，表示電池電量不足，請更換電池。
- 當安裝或更換電池時，請務必關閉本機，防止故障和損壞。
- 電源關閉時也會漸漸的減少電量，不使用時建議將電池取出。

⚠ 注意

請勿使用非指定的電池 否則可能導致故障。
電池請勿重疊放置 可能導致發熱、起火。
請勿將電池投入火中
廢舊電池請依當地回收規定處理。

更換電池

CH

- 通過下推蓋子打開電池盒蓋，取出舊電池。
- 使用兩顆AAA鹼性電池更換舊電池。
- 取出舊電池時，請注意電池容易彈出。
- 請確保將新電池插入正確的方向，然後在更換後將電池盒蓋重新蓋回。
- 更換電池後，音量自動回復購買時設定。

NOTICE：取出電池前請先關機。
電源關閉時也會漸漸的減少電量，
不使用時建議將電池取出。

WARNING：如果電池破裂或損壞，請勿使用。

產品介紹

特　點

心臟、動脈、靜脈、前/後/側邊胸腔之呼吸音、頸部喉音之聽診用途、可透過耳機/揚聲器播放聽診聲音。
三段頻響模式，可針對病患部位進行聽診。
另外具備藍牙可將聽診聲音儲存至外部設備。

產品序述

本產品從病患身體中聽取心臟、動脈、靜脈、前/後/側邊胸腔之呼吸音、頸部喉音等聲音。聲音透過配件耳機傳遞到使用者的耳朵。

使用者介面包括
A: 電源鍵、頻響模式鍵、音量鍵
B: 電源指示燈、無線傳輸指示燈、頻響模式指示燈、音量顯示燈

開啟本產品並透過藍牙與無線設備(iOS 12.1或以上版本)連接後可以傳輸、儲存聲音。本產品與連接的無線設備之間有例如牆壁、人體和其他屏障時，藍牙傳輸的有效範圍將受到影響，建議減少本產品與連接的無線設備之間的距離可改善藍牙連接。

本產品僅可使用兩顆AAA 1.5V四號鹼性電池。

使用目的

本產品用於檢測來自心臟、動脈、靜脈、前/後/側邊胸腔之呼吸音，頸部喉音的聲音。
聽診頭的設計用於兩歲以上兒童、青少年和成人病患。
可適用於任何體型，僅用於診所或醫院的醫療診斷目的。

規　格

銷售名稱 : 好音電子聽診器
型號 : ES-2020
顏色 : 白色
電池規格：AAA 1.5V 四號鹼性電池 * 2
使用電流 ：90mA
聽診頭類型：可更換式聽診頭(兒童/成人)
外觀尺寸 : 139 X 48 X 34 mm
重量 : 180g
臨床領域：聽診用
防水等級：IPX2
頻響模式：心音 / 呼吸 / 全頻
頻響模式頻率範圍：心音(20~200Hz) / 肺音(100~1000Hz) / 全頻(20~1200Hz)
音量控制：+ / -
音訊輸出：耳機/揚聲器
音量級別：8級 最大放大50倍
藍牙無線傳輸
藍牙（接收器）：Bluetooth v4.2 specification compliant.2.402GHz ~ 2.480GHz unlicensed ISM band, π/4 DQPSK, 8DPSK . EDR(3MB)
藍牙（發射器）：Bluetooth v4.2 specification compliant. 2.402GHz ~ 2.480GHz unlicensed ISM band,9 dBm (typ)=7.9433mW RF transmit power with level control, π/4 DQPSK and 8DPSK modulation,EDR(3MB)

附　件

- 小聽診頭(兒童用含膜片) x 1
- 大聽診頭(成人用含膜片) x 1
- 音源線 PVC(1米) x 1
- 耳機 (1 More) x 1
- 電池 1.5V鹼性AAA四號 x 2
- 使用說明書 x 1

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WARNING：
請勿使用未經授權的配件以免導致意外危險。 請使用原廠指定、符合安規之配件。

清潔方式

在開始清潔之前，請檢查電池盒蓋和聽診頭結構是否穩定，以避免液體滲入。

清潔聽診頭

在正常條件下，無需拆下膜片進行清潔，膜片可使用75%酒精溶液噴灑於棉布上，再以棉布進行清潔擦拭。如有必要或是破損時，請更換新膜片，請仔細按照以下說明進行操作。

(1) 移除聽診頭：關閉電源並將聽診頭取下。

(2) 移除膜片：用拇指將膜片下側部分從聽筒槽中提起，然後將其從聽診頭上剝離，取下膜片後，聽筒槽可以使用酒精在邊緣進行清潔，聽診頭所有部分均可使用酒精擦拭。

(3) 膜片安裝：膜片完全乾燥的狀態下，將膜片插入聽筒槽中，從一個點開始，將手指沿聽筒槽環繞，直到膜片貼合凹槽中。

耳機：可以用含酒精擦拭布清潔配件，如欲進行更徹底的清潔，請將耳套取下進行深度清潔。

主機：建議用75%酒精溶液噴灑於棉布上，再以棉布進行清潔擦拭。

WARNING：為減少感染風險，每位病患使用完畢後電子聽診器均須清潔。
WARNING：請勿將聽診器浸入液體中或進行任何高溫高壓滅菌過程。可能導致裝置損壞。
WARNING：請勿將酒精溶液噴向耳機孔，否則可能會損壞設備。

使用壽命

如有依照使用手冊正常操作的話，使用壽命為一年，除非有操作不當可能會縮短使用壽命。

維護修理

如需維護或維修服務，或有任何問題或意見，請隨時聯繫原廠客戶服務中心。
我們將盡最大的努力為您提供協助及解決您的問題。

NOTICE：請勿擅自拆解本產品。只有經過授權的維修人員才能修理此產品；
如果設備被使用者修改，使用者將承擔全部責任。

運輸，儲存和棄置

運輸和儲存

設備的一般運輸應符合本手冊”其他操作注意事項”部分所述的條件。

本產品需要送到授權服務中心進行檢查和維修。儲存環境條件必須符合本手冊的”其他操作注意事項”部分。

棄置

您應按照當地法規妥善處理電子聽診器。鹼性電池必須與一般廢棄物分開處理或分開回收。

注意：為減少與環境汙染相關的風險，在處理此聽診器時，我們遵循當地的適用規範。鹼性電池必須與一般廢棄物分開處理或分開回收。

疑難排解

Q : 無法開機。
A : 1. 請檢查電池極性是否安裝正確，並在重新安裝電池後再試。
2. 請安裝新電池，並在安裝後重新測試。

Q : 開機後沒有聽診音或聲音異常。
A : 1. 請檢查聽診頭是否安裝正確，重新整後再測試。
2. 請使用”音量鍵”調整適宜地音量級別。
3. 請確認耳機連接線是否有完整插入音訊輸出接口。

Q : 裝置發生當機，亮燈閃爍異常。
A : 1. 請取下電池並重新安裝，按下電源鍵重新開機。
2. 請安裝新電池，並在安裝後重新測試。

Q : 藍牙無法連線。
A : 1. 請關機後，再開機後，重新測試。

NOTICE：如果嘗試了所有問題的解決方案，但仍未能解決問題，請致電原廠當地服務部門尋求幫助。

⚠ WARNING

- **為降低不正確結果、人身傷害以及設備損壞之風險**，請遵循本手冊之建議指示進行儲存和操作本產品。
- **為降低損壞聽診頭之風險**，請勿讓聽診頭靠近強烈聲源。
- **為降低感染之風險**，請遵照手冊內清潔與消毒指示，設立及遵循一個清潔及消毒計畫。
- **為了降低極強力磁場之風險**，使用本產品時，請避免靠近強大的射頻訊號或攜帶式亦/或移動式射頻設備。如果您聽到突然性或非預期的聲音，請遠離任何無線電發射天線。
- **為了降低電擊之風險**，請勿使用沒有覆蓋薄膜的電子聽診器於病人身上。
- 請勿使用未經授權的配件，以免造成危險。
- **請勿將聽診器浸入液體**，或將其浸入任何消毒液中，可能導致設備損壞。
- **本產品不適用於兩歲以下幼兒**，因聽診頭設計是針對超過兩歲的兒童、青少年與成人病患。
- **為了避免電池液體漏出損壞終端產品**，請謹慎遵循電池使用的指示。
- **如果電池液體濺入眼睛**，請立刻用乾淨、流動的冷水沖洗並立刻尋求醫療協助。
- **本產品請勿靠近或堆疊於其他儀器使用。**
- **為了避免影響醫療電器設備**，本產品具有藍牙無線通訊功能，對請避免靠近之電子醫療設備，建議保持使用安全距離30釐米。
- 本產品不適用於居住環境，因其可能無法針對此環境下的無線電接收提供充分的保護。

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⚠ 注意事項

- 為降低與環境汙染有關之風險，請遵循當地法規丟棄本產品。並妥善處理或回收廢舊電池。
- 不得任意修改本產品之設計。請透過授權的服務人員維修產品。任何不當的修改或維修之行為，須由使用者自行承擔變更後的結果。
- 本產品在磁振造影環境使用是不安全的。請勿在磁振造影環境下使用。
- 使用AAA四號鹼性電池前，請確認電極兩端無髒污後，再依正負極指示正確放入電池座內。
- 為延長電池使用壽命，切記不用時請關閉電源。
- 電源關閉時也會漸漸的減少電量，不使用時建議將電池取出。

⚠ 其他操作注意事項

- 操作環境溫度範圍須介在41°至104°F（5°至40°C），相對濕度為15 至93%，大氣壓力範圍須介在1002hPa至1008hPa。
- 儲存和運輸溫度範圍須介在-4°至158°F（-20°至70°C），相對濕度為0 至93%。
- 為延長聽診器的使用年限，避免極度的冷、熱、接觸溶劑或油污。
- 如數月不使用聽診器，請取出電池。
- 如未遵循照護及維修建議指示可能導致本產品的內部零件損壞。內部損壞可能導致產品故障，受損範圍從輕微的聽診效果下降到完全損壞。
- 如果您在使用電子聽診器時遇到任何問題，請勿嘗試自行維修。請通知原廠的客戶服務中心，聯絡後續處理事宜。
- 電源關閉時也會漸漸的減少電量，不使用時建議將電池取出。
- 使用本產品時，醫事人員建議配戴醫療手套。

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