DFMX User Manual		
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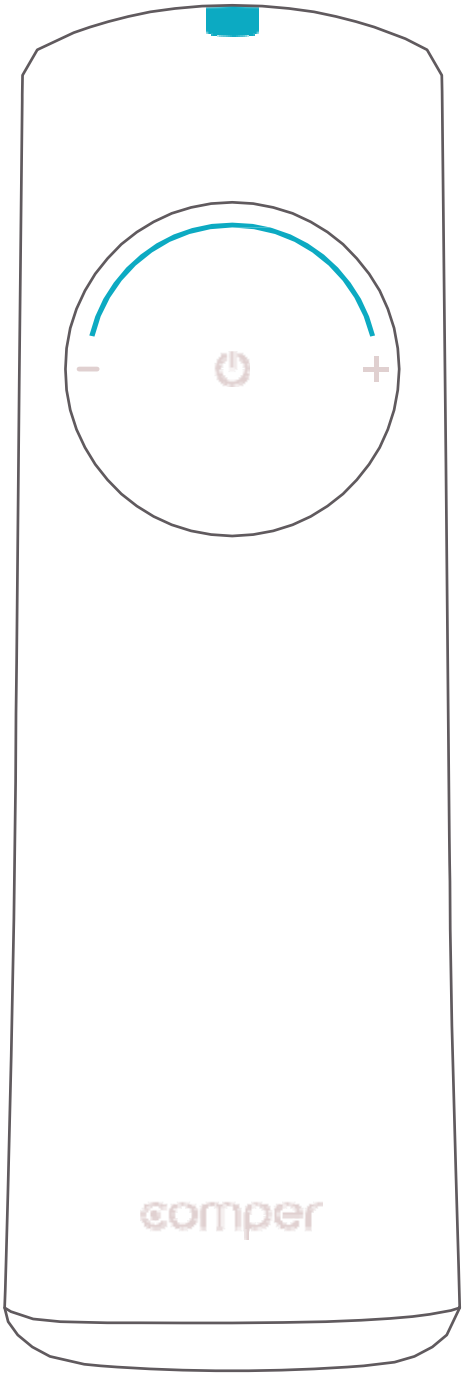
Product Name: COMPER SMART DOPPLER FETAL MONITOR

Product Model: DFMX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Content

Dear customers,

Thank you for purchasing COMPER SMART DOPPLER FETAL MONITOR. Please read the user manual to ensure safe operation and accurate outcome before use. Keep this manual readily available for reference.

Basic function of the product

Fetal Monitor is hand-held detection instrument, intended to be used by health care professionals including obstetrician, nurse in hospitals, clinics and pregnant women at home.

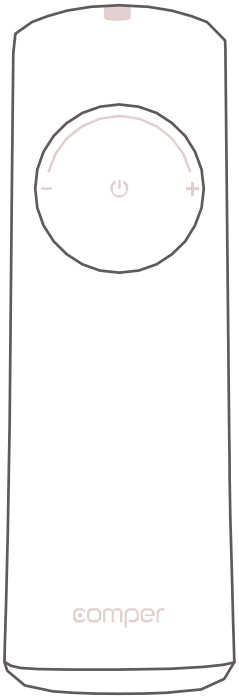
Application scope: monitor fetal heart sound and the range of heart rate during antepartum.

Working principle

Adopting the principle of non-focused ultrasound continuous wave Doppler, when in use, the ultrasonic transducer generates an ultrasonic beam directing to the fetus. A portion of the incoming ultrasonic beam will reach the surface of fetal heart movement, due to the Doppler effect, the frequency shift of the ultrasonic occurs, which can be detected by receiving transducer. The low-frequency signal related to the fetal heart can be separated by signal processing, and to be identified.

Overview

1



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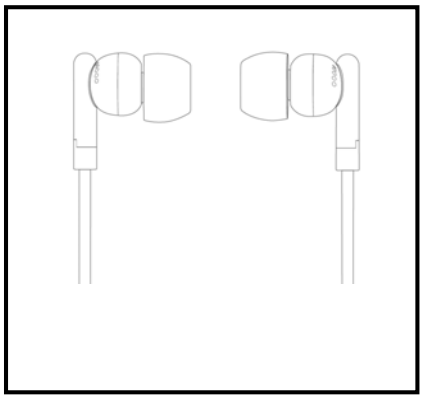

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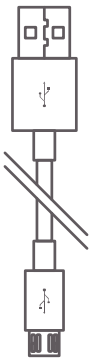

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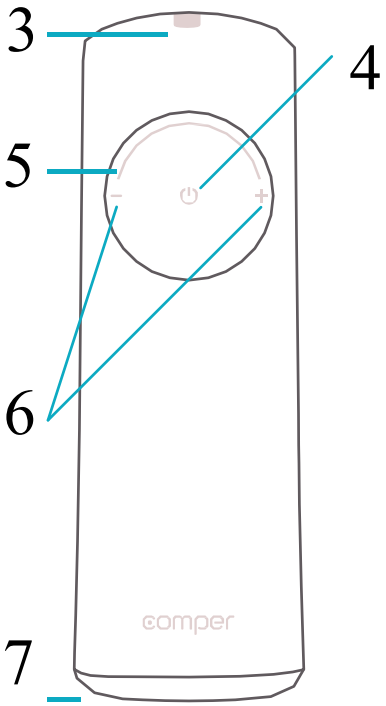
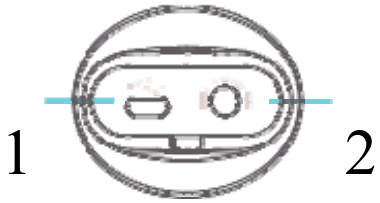
Manual

5

Qualification certificate

Parts list:
1. One Fetal Monitor
2. One pair of 3.5mm earphone
3. One USB charging cable
4. One manual
5. One qualification certificate





Instruction of parts:

1. Charging socket
2. Earphone socket
3. Status indicator lamp
4. Power key
5. FH reading lamp
6. Volume keys
7. Doppler ultrasound probe

Power switch

Volume down

Volume up

Charging socket

Earphone socket

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Precautions, warnings and caution

All possible harms or damages caused by error operations have been indicated in this manual, please read these instructions.

Please be aware and understanding that, for all human health and property damage due to error operations specified in the Manual or deviating from the designed purpose of the product, the Company shall not bear any responsibility.

Prohibition

It represents absolutely not allowed
There may risk caused by operation that is out of the performance of the product.

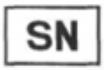
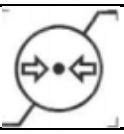
Warning

Represent matters that require special attention
May damage personal safety for the wrong purpose

Caution

Represent general considerations in using
If misused, it may cause personal injury or property damage

Explanation of Symbol

	Consult instruction for use
	Storage temperature limitation
	Serial Number
	Non-sterile
	Do not use if package is damaged
	Atmospheric pressure limitation
	Caution, consult accompanying document
	Type BF applied part
	non-ionizing radiation

Warning!

The device is intended for detecting Fetal Heart Rate not intended for clinical treatment. If the result is distrustful, please use other methods to check the fetal well-being immediately.

Environment conditions, operators and pregnant woman health conditions vary during device use, synthetic judgment are recommended in complex situation.

Clean ultrasonic probe before use, it is high recommended for singe use to avoid cross - infection.

Keep out reach of infants and young children.

This product is ultrasonic product, and do not use it at the part other than the abdomen.

Use the product matching earphone and charging cable. Using non-matching accessories may lead to security risks of the product.

Use the product supporting medical ultrasonic coupling agent, or similar products with a valid legal qualification of medical devices, otherwise it may cause the risk of biohazard or performance degradation.

Caution!

If the product breaks down during use, please shut down the power and turn to contact customer service for trouble shooting.

Please inspect the bottom and surrounding of the ultrasonic probe before use and make sure there is no obvious damage which may affect the patient safety and instrument performance possibly.

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Do not use the product close to strong electromagnetic fields, electromagnetic wave and magnetic environment
* There is possibility of measurement errors or damage to the product

Avoid severe shock, falling from the height or stomping.
* There is possibility of causing damage to the product.

On the premise of clinical requirement, it is recommended that users should minimize ultrasound exposure time.

Do not place the product into boiling water for sterilization
* There is possibility of product breakdown or product failure.

The product IP Rating is IPX4 (including ultrasound head) is a splash-proof device, it can immerse in saline and water, but please do not soak in hot water.

Except ultrasound head, other parts are designed of non-anti-soak, please do not flush the product. Please wipe the product with a run-out cloth to wipe the surface.

Please do not wipe the product with disinfectant or alcohol or other organic solvent.

Please wipe away the water with a dry cloth to keep maintenance.

Please do not conduct ultrasonic cleaning, or it may cause a failure.
Do not use a dryer, electric hair drier, otherwise it will cause a failure.

Warnings and Cautions about Potential Electromagnetic Interference

Warning!

In addition to the supporting earphone and charging cable, using unspecified accessories and cables may cause the increase of product radiation or the decline of immunity.

This product should not be used closely to or stacked with other equipment, or if the close use or stacked use cannot be avoided, should observe and verify whether the product can operate normally in its configuration.

Caution!

Interference may occur in the vicinity of equipment marked with the symbol

Warnings and cautions about chargeable lithium battery

The device is built-in rechargeable lithium battery, not removable, please do not dismantle, damage the battery, heat the battery or throw it in fire. There is possibility of a battery explosion.

Caution!

Please shut down the product after- use to avoid unnecessary consumption of battery power.

If the product is not to be used for more than 3 months, please store it in the environment of -10 ° C - +40 ° C, otherwise there is a risk of damage to the battery.

Product disposal

Caution!

Please clean the remaining coupling agent after use, and wipe the product with cloth, twist dry come not to drip the dishcloth of water
If the product becomes dirty, use a cloth or tissue paper with a small amount of water to wipe it clean.

At the end of product life, please deal with the product according to the relevant local environmental protection laws and regulations.

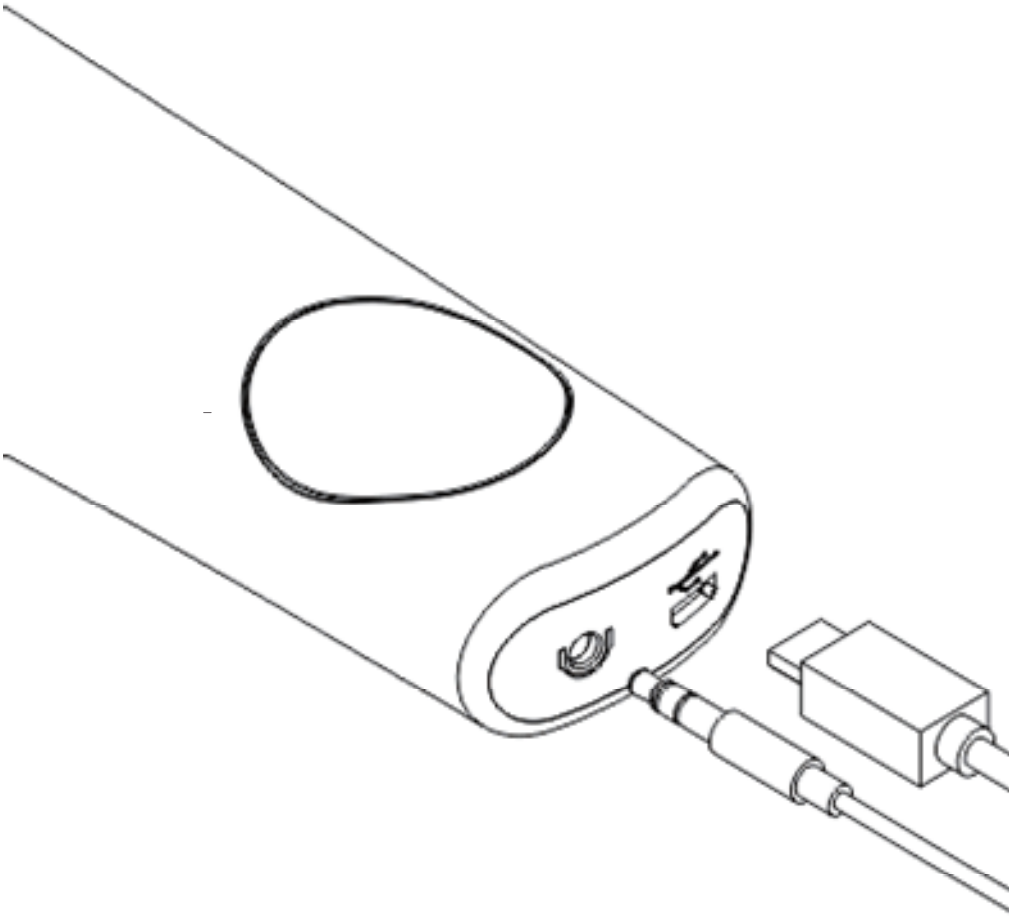
Caution!
Please conduct charging for at least 3 hours in the initial use of the Fetal Monitor.
The product should be used with coupling agent.
The product is equipped with the function of Bluetooth transmission

The connection and remove of detachable components

Insert the plug of earphone into the earphone socket of Fetal Monitor;

In the process of charging, please insert the plug of USB charging cable into the charging socket of Fetal Monitor;

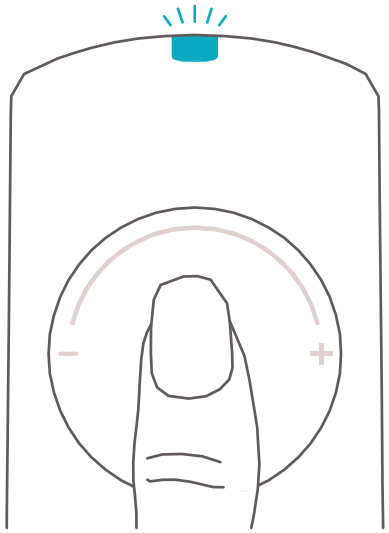
Make sure that the plug is fully inserted when connecting with the socket, and keep straight direction when removing.



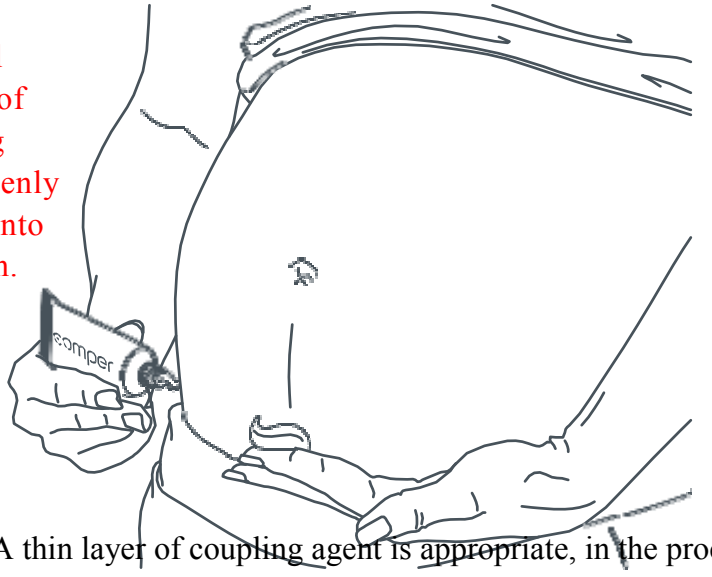
Usage schematic diagram of fetal heart sound detector

Starting up

1. Long press the power button, when the status indicator lamp shows white, indicating the starting up.



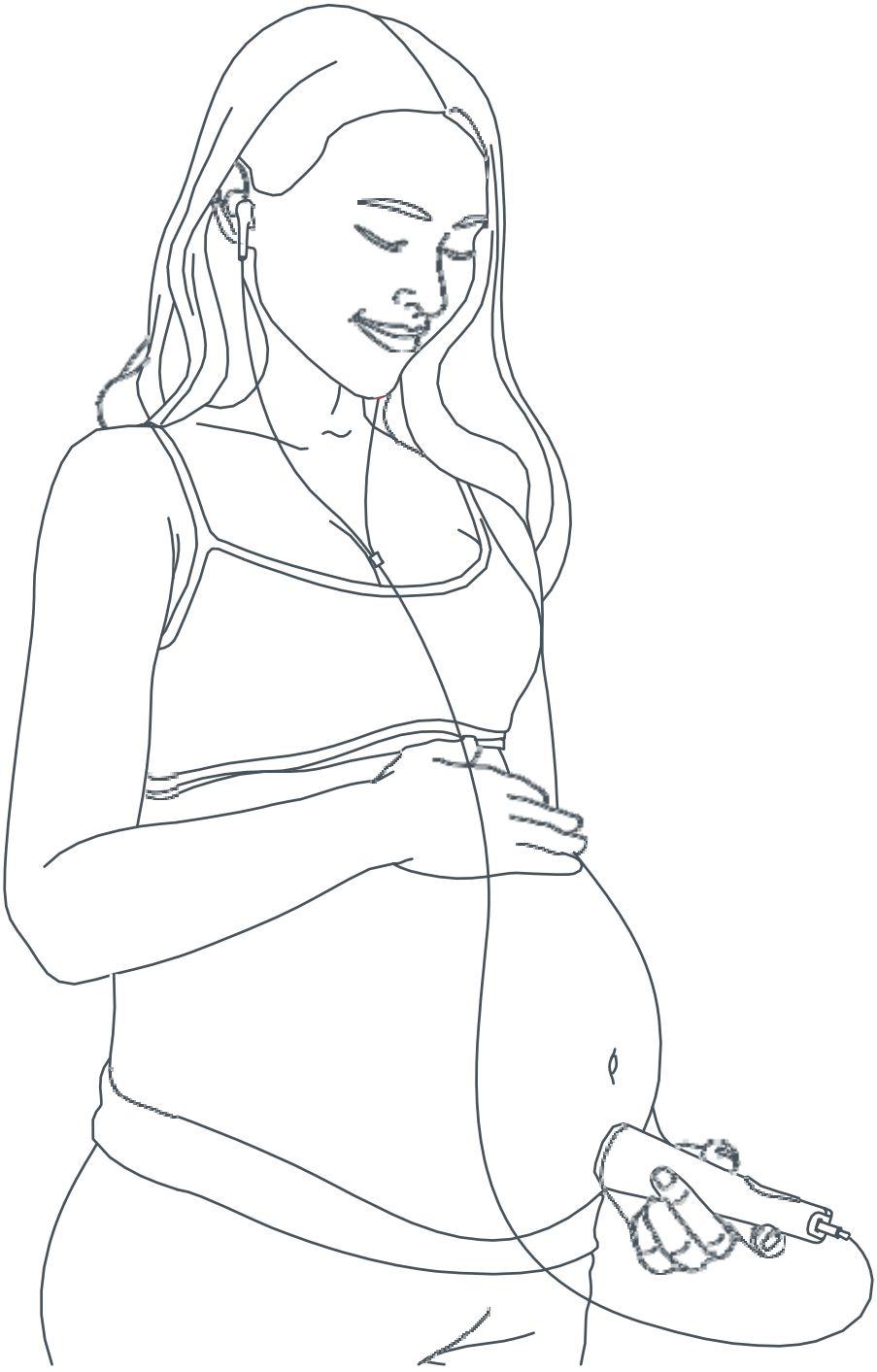
2. A liberal amount of coupling agent evenly spread onto abdomen.



Prompt:

A thin layer of coupling agent is appropriate, in the process of searching fetal heart sound, if the coupling agent becomes drying or coagulating, it can be appropriately added.

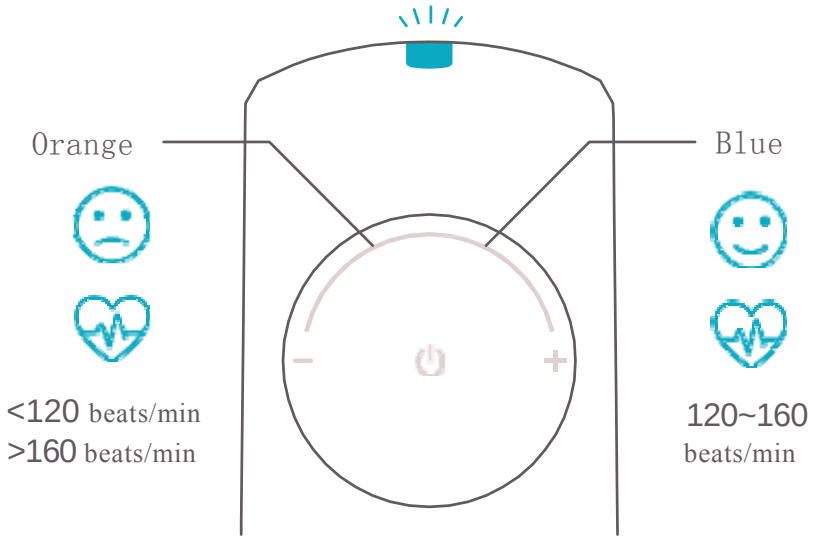
Usage schematic diagram of fetal heart sound detector



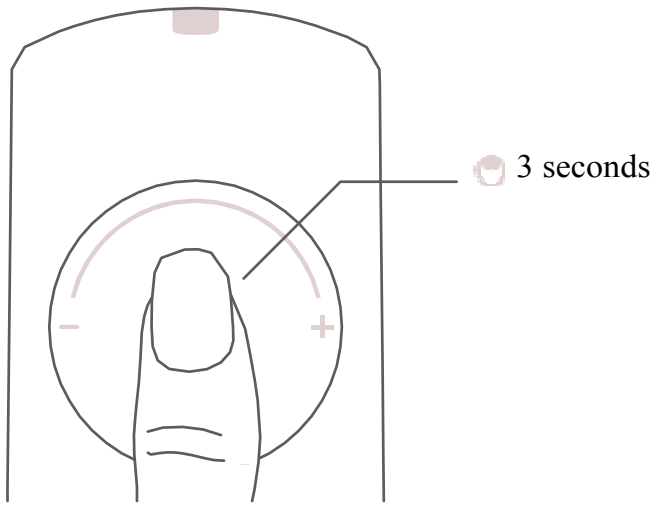
3. The schematic diagram of listening to the fetal heart sound: please put on earphones, and then slowly move the Fetal Monitor to detect fetal heart rate, and the continuous regular heartbeat indicates the position of fetal heart, try to keep the unchanged position of Fetal Monitor (volume keys can be used to adjust the sound volume).

Usage schematic diagram of fetal heart sound detector

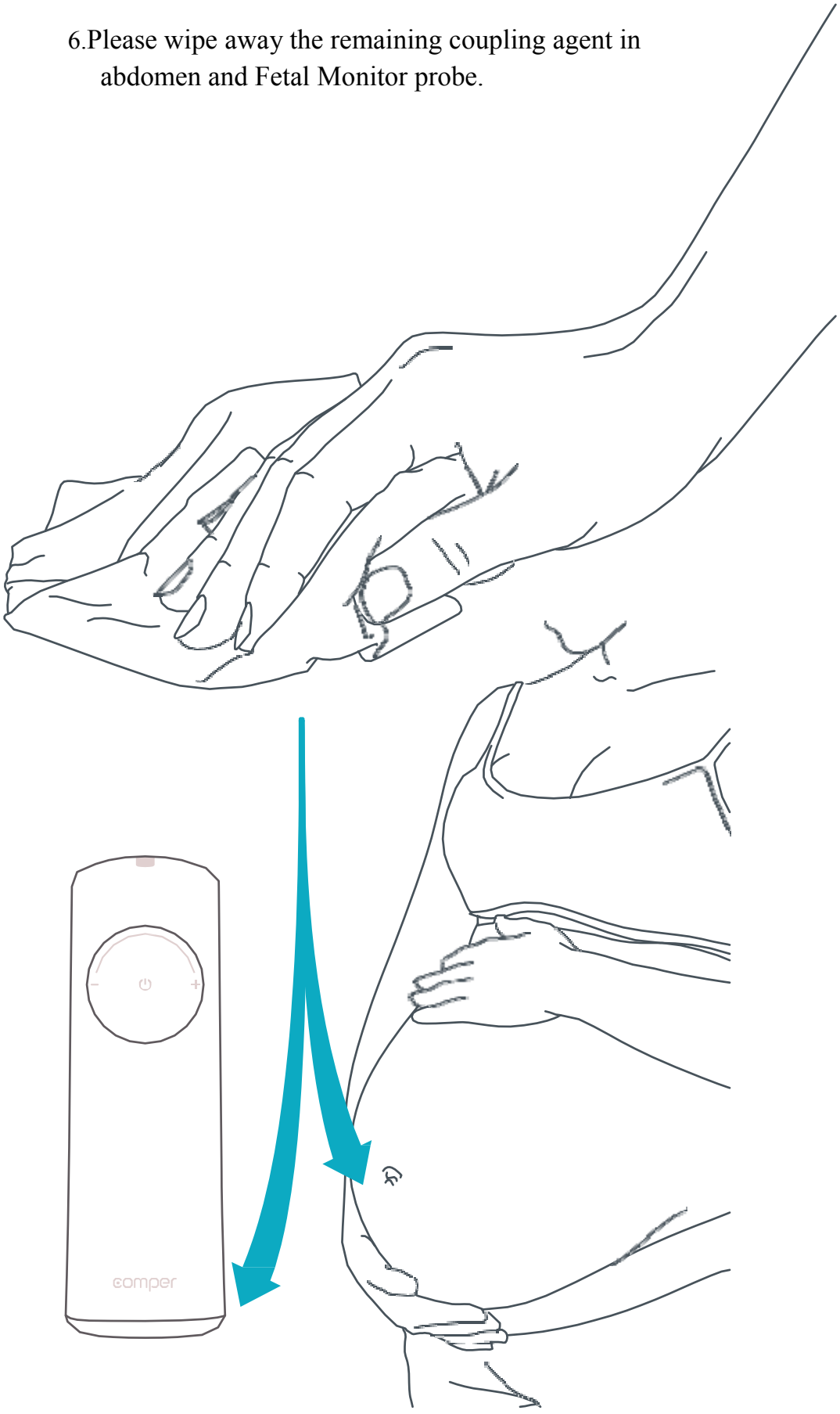
4. After a period of continuous monitoring of fetal heart sound, the different color of fetal heart sound reading lamp indicates the range of fetal heart rate, blue indicates the range of 120-160 beats/min, and orange indicates other ranges.



5. After measurement, press the power button for 3 seconds, and extinction of light indicates power off.



6.Please wipe away the remaining coupling agent in abdomen and Fetal Monitor probe.

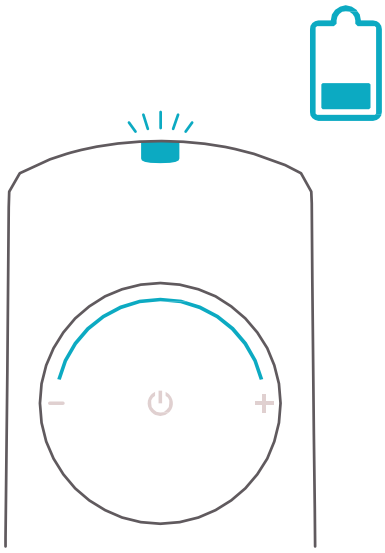


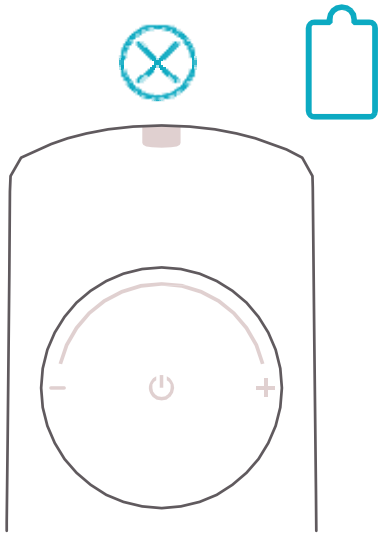
Charging tips

Charging reminder

When start up the product, the status indicator lamp blinks orange light, right after white light, alerting the low power, and please charge as soon as possible.

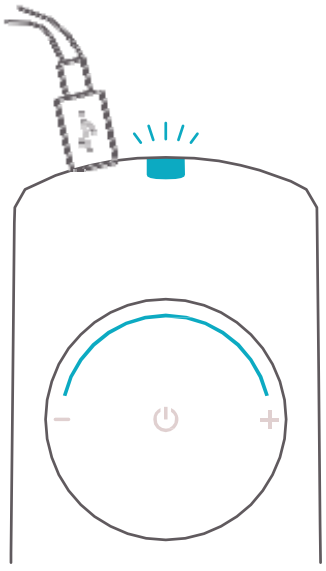
If device won't turn on, please charge as soon as possible.

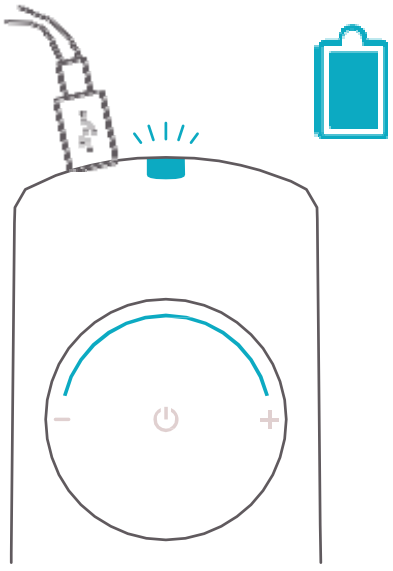




The charging cable is inserted into the charging socket, and the status indicator lamp shows orange light, which means the product enters into the state of charging.

After the charging is completed, the status indicator lamp shows blue light.





Fetal monitoring knowledge

1. In general, fetal heart sound can be monitored after 12 weeks of pregnancy, but because of individual differences, the gestational week that the fetal heart sound can be monitored may be different.

2. In general, the fetal heart rate is in the range of 120 to 160 beats / min, when the fetal heart rate is less than 120 beats / min or more than 160 beats / min, consult with your physician depending on the individual situation.

3. When the pregnant woman finds that fetal heart sound cannot be found in the original location, but fetal movement can be felt, it indicates the fetal position may change. Slowly move the probe in small extent to find the fetal heart carefully. If you confirm that you cannot listen to the fetal heart sound or the fetal movement is not obvious, please go the hospital for consultation immediately.

Problems and Troubleshooting

Problem/failure	Possible reason
Cannot hear sound	The volume is adjusted to the weakest Earphone is not inserted into the device
Noise is big	•No coupling agent is applied on the abdomen •Noise is generated by the dragging of probe on the abdominal wall • Incorrect placement of probe
Can hear the sound but it is relatively weak, and cannot find the fetal heart position	• No coupling agent is applied on the abdomen •Gestational age is short and fetal heart sound is too weak

Problem/failure	Possible reason
The power switch turns on, but it is silent when rubbing the probe	• Plug in your headphones and increase the volume
Noise is big	• Apply the coupling agent to the abdominal detection zone • Find the fetal heart sound, lift up the probe and avoid dragging, and try to change the angle to get clear fetal heart sound
Can hear the sound but it is relatively weak, and cannot find the fetal heart position	• Apply the coupling agent to the abdominal detection zone • Use the product when the gestational stage is a little longer
Other failure	• Please contact with Comper customer service

Cleaning and maintenance

Cleaning of Fetal Monitor

Wipe away the remaining coupling agent on the ultrasonic probe. Be careful not to let the coupling agent, BB oil or other liquid get into the interior in order to avoid damage to the device.

If there is a lot of dirt on the ultrasonic detector probe, please wipe the probe with a wringed cloth with neutral detergent or water, and then use a soft cloth to wipe it dry.

Please disinfect the ultrasound probe, wipe gently with immersed medical cotton pad with 75% rubbing alcohol.

Please comply with the following precautions to avoid breakdown or failure

Do not remove dirt by using volatile agents, diluent or gasoline, etc.

Do not immerse the product into in water or wash it with water.

Do not use hot water to conduct sterilization (over 50 ˚C).

Turn off the power before cleaning; please keep it dry after cleaning

Do not store the product in the following environments, or otherwise it will cause a breakdown or failure

Humid environment

High temperature, direct sunlight, dusty environment, or salt environment

Environment with chemicals or corrosive gas

Storage and Shipping Condition

Storage environment

Temperature: -10°C to +40°C
Humidity: ≤85% RH
Ventilated room without corrosive gases

Transportation environment
Temperature: -40°C to + 55°C
Humidity: ≤90% RH
Atmospheric pressure: 50 to 101.3kPa
Method: air, sea, rail transport or coach transport

Basic Parameters and Specifications

Battery: Rechargeable lithium battery (3.7V)
Battery life: continuous use of 12 hours, more than 300 times of charge-discharge
Charging power supply: Micro USB (DC 5.0 V 160mA)

The charging power supply should be checked or replaced regularly.

Category of product
Electric shock protection type: internal power supply
Electric shock protection type: BF product
Water proof level:
IPX4 (ultrasound probe)
IPX1 (for the other part of housing)
The degree of safety of combustible gas: not suitable for using in environment with flammable gas

Operating mode: continuous operation
Size of product: 46 x 39 x 135 mm
Net weight: 150 g
Communication: Ultra-low-power consumption Bluetooth 4.0

Standard Compliance

AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC));

AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3). (General II (ES/EMC));

IEC 60601-1-11 IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [including: technical corrigendum 1 (2011)]. (General II (ES/EMC))

IEC 60601-2-37-2007Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

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Basic Parameters and Specifications

Working environment
Temperature: + 15°C to + 35°C
Humidity: 30%~90%
Atmospheric pressure: 70 to 106 kPa

Product performance
Rated sound working frequency: 2.0 MHz ± 10%
Ultrasonic output power: <10 mW
Effective ultrasound emission area: <2.0 cm²
Comprehensive sensitivity: ≥ 90 dB
Fetal heart monitoring range: 65 ~210 beats / min
Fetal heart monitoring error: ≤ ±2 times / min
Continuous working time ≥ 2 hours
(Low battery or too large volume will shorten the working hours)
Peak negative sound pressure: <0.2 MPa
Sound intensity of output beam: 20 mW / cm²
Spatial peak time average output sound intensity: <100 mW / cm²
Service life: 3 years

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Beijing

US Agent Contact:
Name:
Contact number

Manual version: JS02114DFMX V1.0

Table for acoustic output level

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How the best is done

Federal Communications Commission (FCC) Statement

15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)
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.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
1) this device may not cause interference and
2) this device must accept any interference, including interference that may cause undesired operation of the device.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The procedures necessary for safe operation shall be provided, drawing attention to the safety hazards that may occur as a result of an inadequate electrical installation when the APPLIED PART of the ULTRASONIC DIAGNOSTIC EQUIPMENT is a TYPE B APPLIED PART.

A notice shall be provided if the ULTRASONIC DIAGNOSTIC EQUIPMENT or parts thereof are provided with protective means against burns to the PATIENT when used with high frequency(HF) surgical equipment. If no such means are incorporated, notice shall be given in the ACCOMPANYING DOCUMENTS and advice shall be given regarding the location and use of the TRANSDUCER ASSEMBLY to reduce the hazard of burns in the event of defect in the HF surgical neutral electrode connection.

A recommendation calling the OPERATOR'S attention to the need for regular testing and periodic maintenance including inspection of the TRANSDUCER ASSEMBLY for cracks that allow the ingress of conductive fluid shall be provided.

Instructions shall be provided regarding the avoidance of unintended control settings and acoustic output levels.

Guidance and manufacturer's declaration-electromagnetic emissions		
The ___DFMX is intended for use in the electromagnetic environment specified below. The customer or the user of the ___DFMX should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The ___DFMX 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 ___DFMX 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	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The (DFMX) is intended for use in the electromagnetic environment specified below.

The customer or the user of the (DFMX)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	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in	Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the (model) requires continued operation

	UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable	during power mains interruptions, it is recommended that the DFMX be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The DFMX 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 ____(DFMX) is intended for use in the electromagnetic environment specified below. The customer or the user of the ____(DFMX) should assure that is used in such and 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	Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the ____ DFMX** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\ \sqrt{P}$ $d = 1,2\ \sqrt{P}$ 80MHz to 800 MHz $d = 2,3\ \sqrt{P}$ 800MHz to 2,5 GHz Where *P* is the maximum output
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	

			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:

			

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.

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

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

Recommended separation distance between

portable and mobile RF communications equipment and the DFMX

The DFMX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DFMX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DFMX 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 $\sqrt{P}$	**80 MHz to 800 MHz** d =1,2 $\sqrt{P}$	**800 MHz to 2,5 GHz** d =2,3 $\sqrt{P}$
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.