AngelSounds

User Manual

Fetal Doppler

Model:JPD-100S+

Manual Ver.: 1.1
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Thank you for purchasing the Fetal Doppler JPD-100S+ made by Jumper Medical Before using the product, read this manual carefully and operate the product as specified in this manual.

SECTION 1: INTRODUCTION

1.1 PACKING LIST

Main unit X 1;
USB charging cable X 1;
Coupling agent X 1;
User manual X 1.

1.2 PRODUCT DESCRIPTION

The product is mainly used to detect the sound of the fetal heartbeat (SFH).
In accordance with classification criteria in Annex IX on "Medical Device Directive 93/42/EEC", the product is class IIa based on rule 10, "Devices for Direct Diagnosis or Detection on physiological process".

1.3 OPERATING PRINCIPLE

Based on the Doppler's principle, a 2.0MHz ultrasonic probe is used to capture fetal heart signals from the belly of a pregnant woman. After signal processing of the backend circuit, the fetal heart signals are output to the headset socket, and audio signals are wirelessly sent by using the built-in Bluetooth module. A smartphone that has connected to the product receives the data and calculates and displays fetal heart rate information by using specified mobile phone software.

SECTION 2: SAFETY GUIDANCE

2.1 INDICATIONS FOR USE

The product is normally applied to fetus above 20 weeks growth, difference in pregnant mater.

- **Listen to SFH:** Operator can listen to the sound of fetal heartbeat from the headset.
- **Audio record:** The sound of fetal heartbeat can be recorded by a smartphone which is connected with the product.

⚠ *CAUTION:* It should not be used in life supporting or life sustaining applications.

2.2 CONTRAINDICATIONS FOR USE

Normally none, as a particular case, please consult your doctor.

2.3 NOTE FOR HOME USE

Please consult your doctor.

2.4 SAFETY TERMS AND CONDITIONS

The signal words shown below, left, identify the potential hazard categories. The definition of each category is as follows:

⚠ *DANGER:* This alert identifies hazards that will cause serious personal injury or death.

⚠ *WARNING:* This alert identifies hazards that may cause serious personal injury or death.

⚠ *CAUTION:* This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

2.5 SAFETY ALERT DESCRIPTIONS

The following is a list of product safety alerts that appear in this section and throughout this manual. You must read, understand, and pay heed to these safety alerts before attempting to operate the product.

⚠ *DANGER*: Fire and Explosion Hazard
Do not operate the Product in the presence of flammable gases to avoid possible explosion or fire hazard.

⚠ *WARNING:* Use only Approved Equipment
Do not use batteries, gel, cables, or optional equipment other than those approved by Jumper Medical Equipment Co.,Ltd which may cause the product to function improperly during a rescue.

⚠ *WARNING:* Adjacent and/or Stacked Equipment
The Product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Product should be observed to verify normal operation in the configuration in which it will be used.

⚠ *CAUTION:*Temperature/Humidity/Pressure xtremes
Exposing the Product to extreme environmental conditions outside of its operating parameters may compromise the ability of the Product to function properly.

⚠ *CAUTION:* Battery Disposal
Recycle or dispose of the battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

⚠ *CAUTION:* Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause interference with the product. Do not operate wireless radiotelephones in the vicinity of the Product – turn power OFF to the radiotelephone and other like equipment near the Product.

⚠ *CAUTION:* Systems Statement
Equipment connected to the product must be certified to the respective IEC Standards (IEC 60601-1 for medical equipment).

⚠ *CAUTION:* Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

⚠ *CAUTION:* Environment of use
The product is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

⚠ *CAUTION:* Cold Environments
If the product is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.

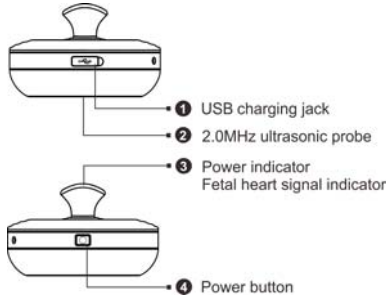
2.6 SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the product, or on its accessories. Some of the symbols represent standards and compliances associated with the product and its use.

	Consult instructions for use of the product and/or its accessories.
	Warning Information.
EC REP	Authorized Representative in the European Community.
CE 0482	CE Mark: The Product system conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer information.
	type BF applied part
SN	Specifies serial number of the Product
LOT	Batch code
5	The environmental protection use period is 5 years.
Ipx4	Waterproofing grade 4
	It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.

SECTION 3: USING THE PRODUCT

This section provides the description for operation.



3.1 PRODUCT STRUCTURE

3.1.1 Power on/off

Power on: Press and hold this button for about 2s and release this button, the power indicator is on, and the instrument is powered on.

Power off: When the instrument is in the power-on state, press and hold this button for about 2s, the power indicator goes out, and the instrument is powered off.

3.1.2 USB charging jack

Charging Requirements

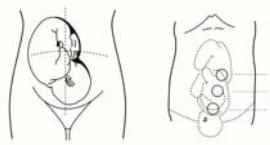
1. Before using the instrument for the first time, if the power indicator blinks or the instrument is automatically powered off due to a low battery level after the instrument is powered on, charge the instrument.
2. Charge the instrument by using a mobile phone charger or a computer USB jack.
3. Charge the instrument for about 2 to 4 hours.

3.4 DESCRIPTIONS OF THE INDICATOR STATES

Indicator type	Indicator state	Instrument working state
Power indicator/Fetal heart signal indicator	Steady green	The instrument is powered on/fully charged.
	Steady orange	The instrument is charging.
	Blink orange evenly	The instrument is in a low voltage state.
	Blink with the fetal heart signal frequency	The instrument is in the working state, and the ultrasonic probe captures a fetal heart signal.

3.5 USING PRODUCT TO DETECT

Locate the position of the fetus by hand touching, firstly to find out the best direction to the fetal heart. Place the faceplate of probe at the best position for detecting fetal heartbeat. Adjust the transducer to obtain an optimum audio signal ideally by angling the transducer around. Generally, the site of heart of fetus is 1/3 below of navel line at its earlier stage, it then moves upward with increasing of gestational period, and the site of heart of fetus will be a little deviation to left or right with different fetus. Pls. make sure that the surface of the probe should be contacted fully with the skin. After the sound become clear, it is the proper functioning. If no coupling gel, water can be used.



Gestation
Antepartum
Parturition

3.6 CONNECTING THE INSTRUMENT TO THE SMARTPHONE VIA BLUETOOTH

Software Downloading:

1. Download and install the mobile phone APP software "AngelSounds" by scanning the QR code on the packing box or searching for the APP in application stores such as APP Store/Google Market.
2. This software supports iOS 7.0 and later versions, and Android 4.3 and later versions. In addition, hardware of the smartphone needs to support Bluetooth 4.0.

Bluetooth connection:

1. Start AngelSounds" on the smartphone, and enable the Bluetooth function of the smartphone to search for a Bluetooth device, find the Bluetooth name of the Fetal doppler, and pair with the instrument.

Software Usage:

Detailed see software operation manual.

SECTION 4: MAINTENANCE & CLEANING AND DISINFECTION

4.1 MAINTENANCE

4.1.1 The transducer acoustic surface is frangible and must be handle with care .Gel must be wiped off from the transducer after use. These precautions will prolong the life of the unit.
4.1.2 The user must check that the equipment does not have visible evidence of damage that may affect patient safety or product's capability before use .The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.
4.1.3 To ensure the product is always functional when required, the following maintenance shall be performed.

- Visual Inspection
- Cleaning the product and its accessories
- Check the battery fuel gauge
- Testing product performance
- If the product is not been used for a long time, charge the product once every three months.
- The product requires no calibration.

4.2 CLEANING PRODUCT AND ACCESSORIES

The following cleaning products may be used to clean the exterior surfaces of the product.

- Isopropyl alcohol (70% solution in water)
- Mild soap and water
- Sodium hypochlorite (chlorine bleach) (3% solution in water).
- Quaternary ammonium compounds (such as Lysol) (10% solution in water).

WARNING: Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
WARNING: Do not use mixing disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
*WARNING:*Do not use acid, alkaline, or corrosive detergent.
WARNING: Do not clean electrical contacts or connectors with bleach.

4.3 CLEANING INSTRUCTIONS

1. Before cleaning the product, turn off the product.
2. Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.
3. When cleaning, do not immerse. Keep the exterior surface of the device clean and free of dust and dirt, clean exterior surface of the unit with a dry, soft cloth .if necessary, clean it with a soft cloth soaked in a solution of soap and wipe dry with a clean cloth immediately.Wipe the transducer body with soft cloth to remove any remaining coupling gel .Clean with soap only.

⚠ *CAUTION:* To prevent damage to the product, do not clean any part of the Product or Accessories with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the Product or accessories.

⚠ *CAUTION:* Cleaning liquids: do not submerge the product in liquids or pour cleaning liquids over, into or onto the product.

4.4 DISINFECTION

Cleaning the unit surface and the transducer as the above mentioned, then wipe the surface of transducer with 75% ethanol or alcohol, clean the transducer surface with a dry, soft cloth.
WARNING: Don't use low temperature steam sterilization or other way to sterilize.
*WARNING:*Don't use high temperature sterilizing process.

SECTION 5: SPECIFICATIONS & TROUBLESHOOTING

This section presents the specifications and safety standards of the Product.

5.1 SPECIFICATIONS

NOTE: The following specifications are subject to change and are only noted as a point of reference.

Technical Specifications
Acoustic working frequency: 2.0MHz±5%
Overall sensitivity : 96 dB
Overall sensitivity at the distances 50,75,100 and 200 mm from the face of the probe:95 dB、98 dB、96 dB、97 dB
Doppler frequency and target velocity, used for the determination of b)(given to two significant figures):300Hz,12cm/s
Spatial-peak temporal-peak acoustic pressure: 20.1kPa
Effective area of the ultrasonic transducer active element: 4.8±0.3cm^2
Output power: 7.9mW
Power working mode: Built-in rechargeable lithium battery 7.4V
Working mode: Continuous working (greater than 6 hours)
Battery capacity: 600mAh
Charging limit: Input 5V 1A
Safety type: Internally powered equipment, type BF applied part
Operating mode: continuous operation
Electromagnetic compatibility: I group, B class
Waterproofing grade: IPX4
Net weight of the main product: 99.5g±5g
Dimension (diameter × thickness): 80mm×50mm
Description of the acoustic coupling medium for normal use, together with its characteristic acoustic impedance: ≤ 1.7×10^{5}g/cm^2.s, fading ≤ 0.02dB/mm
The acoustic output parameter meets the provision freedom from publication in IEC61157 *Requirement for the declaration of the acoustic output of medical diagnostic ultrasonic equipment: P*_<1MPa; I_{ob}<20mW/cm^2; I_{spta}<100mW/cm^2
Product service life: 5 years
Production date: See the label
Operation conditions: Temperature: 5°C to 40°C; Humidity:≤80%RH; non-condensing Atmospheric pressure:70kpa to 106kpa
Transportation & Storage conditions: Temperature: -20°C to 55°C; Humidity:10%RH – 93%RH; non-condensing Atmospheric pressure:50kpa to 106kpa; indoor ventilated place that has no corrosive gas

5.2 Troubleshooting

Symptom	Possible cause	Troubleshooting
Power-on failure	Low battery level	Charge the instrument
No sound	Low volume Insufficient power	Increase the volume Charge the instrument
Fetal heart cannot be found	Low volume The coupling agent is not coated	Increase the volume Coat the coupling agent or water
Low sensitivity	Incorrect probe location The coupling agent is not coated	Adjust the probe location Coat a proper amount of coupling agent

EMC Information

⚠ **CAUTION:**
Fetal Doppler needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided for in the ACCOMPANYING DOCUMENTS.

⚠ **CAUTION:**
Portable and mobile RF communications equipment can affect **Fetal Doppler**.

⚠ **CAUTION:**
The **Fetal Doppler** should not be used adjacent to or stacked with other equipment.

A1.1 Electromagnetic Emissions

The **Fetal Doppler** is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal heart monitor should assure that it is used in such an environment.

Emissions test		**Compliance**
RF emissions CISPR 11	Group 1	The **Fetal Doppler** 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 **Fetal Doppler** 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.

A 1.2 Electromagnetic Immunity

The **Fetal Doppler** is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal Doppler 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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

A 1.3 Electromagnetic Immunity (not life-supporting)

The **Fetal Doppler** is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal Doppler should assure that it is used in such an environment.

Immunity test	IEC 60601 test Level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	part of the **Fetal Doppler** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz a. Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. 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 **Fetal Doppler** is used exceeds the applicable RF compliance level above, the **Fetal Doppler** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Fetal Doppler**.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A 1.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the **Fetal Doppler.**

The **Fetal Doppler** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Fetal Doppler** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Fetal Doppler** 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	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SECTION 6: FCC/ISED CAUTION

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

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.

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

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

- English:
This device complies with Industry Canada licence-exempt RSS standard(s).
Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device mu st accept any interference, including interference that may c ause undesired operation of the device.

- French:
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
(1) l'appareil ne doit pas produire de brouillage, et
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

SECTION 7: CONTACT INFORMATION

7.1 Manufacturer

Shenzhen Jumper Medical Equipment Co., Ltd
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7.2 Authorized European Representative

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AngelSounds

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