USER MANUAL

Ultrasonic Fetal Doppler

Model: P612

Shenzhen Jamr Technology Co., Ltd

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INTRODUCTION

Thank you for purchasing the Jamr Ultrasonic Fetal Doppler. Please read this manual carefully before using the device and save the manual to inspect at any time.

The P612 ultrasonic fetal doppler is a hand-held,battery powered doppler fetal heartrate detector. It is intended to detect and display fetal heart rate,and used by health care professionals in hospital,clinic, community and home for singleton pregnancies after 16 weeks gestation.

The following symbols appear in the manual or device,understand what these symbol means help you to use the device correctly.

Symbol	Description	Symbol	Description
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.	CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.
	Type BF	DISPOSAL	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Refer to instruction manual / booklet	IP22	Degree of protection against harmful ingress of particulate matter and water.
	Manufacturer		Date of manufacture
SN	Serial number	CE 0123	CE Mark: conforms to Medical Device Directive 93/42/EEC
	Type BF applied part	EC REP	EU Authorized Representative

SAFETY INFORMATION

WARNING Indicates a potentially hazardous situation , if not avoided, which could result in death or serious injury.

WARNING The device is is not intended for treatment.

WARNING The device is not explosion-proof and can not be used in the presence of flammable anaesthetics.

WARNING Do not throw batteries in fire as this may cause them to explode.

WARNING Do not attempt to recharge normal dry-cell batteries, they may leak, and may cause a fire or even explode.

⚠ WARNING Don’t touch signal input or output connector and the patient simultaneously.

⚠ WARNING Do not use the device during the process of surgical equipment (including high-frequency surgical equipment) and MRI examinations to avoid jeopardizing physician or patient safety.

⚠ WARNING Don’t dismantle or fix the device by yourself, or use not authorized parts and accessories , otherwise it may result in detection error or damage the device.

⚠ WARNING If the electrolyte in the battery gets into your eye, please immediately flush with a great deal of clear water, or it will result into to blindness or other harmful danger.

⚠ CAUTION **Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.**

⚠ CAUTION Operate the device only as intended,do not use for any other purse. Remove batteries if the device is not likely to be used for 3 month or longer time.

⚠ CAUTION Don’t use a cell phone for calling near the device, or it may influence the normal function of the device .

⚠ CAUTION Dispose of device,component and optional accessories according to applicable local regulations. Unlawful dispose may cause environment pollution.

⚠ CAUTION Don’t subject the device to strong shock like dropping it on the floor, otherwise it may lead to the measurement value of the product incorrect.

⚠ CAUTION DO NOT disassemble or attempt to repair repair this device or other components by yourself,this may cause an inaccurate reading.

⚠ CAUTION DO NOT use this device in a moving vehicle such as in a car.

⚠ CAUTION DO NOT drop or subject this device to strong shocks or vibrations.

⚠ CAUTION During .

⚠ CAUTION DO NOT use this device in high-use environments such as medical clinicsor physician offices.

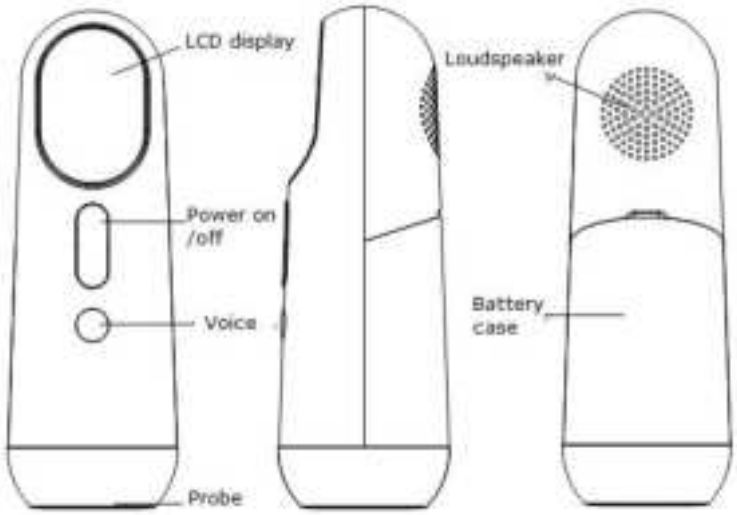
⚠ CAUTION DO NOT insert batteries with their polarities incorrectly aligned.

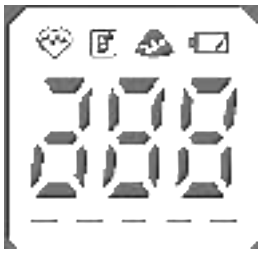
⚠ CAUTION Remove batteries if this device will not be used for a long period of time.

⚠ CAUTION DO NOT use batteries after their expiration date.

COMPONENTS OF THE DEVICE

The following components are including with the package, make sure all the components are complete when you open your new purchase.





The symbols on the LCD display

No.	Explanation		
1	Fetal heartbeat symbol		Indicate fetal heartbeat information, flashing with the fetal heart beat
2	Fetal heart signal quality		Fetal heart signal quality is divided into three grades: average, good,very good
3	Fetal heartbeat value		display range is 60 to 240,when the fetal heart rate is not between 60 and 240, it will display "OL".
4	Voice		The voice level display range is from 1 to 6.
5	Low power		When the battery is low, the battery symbol keeps flashing, indicating that the battery needs to be replaced as soon as possible
6	Bluetooth symbol		Bluetooth is waiting for connection, the symbol keeps flashing, the Bluetooth connection is successful, and the symbol is always on.
7	Probe symbol		Indicates that the probe is on.

BATTERY INSTALLATION

⚠ CAUTION Use only 1.5V”AA”alkaline batteries with the device.

STEP1-Press the ▲ indicator on the battery cover and slide the cover off in the direction of the arrow.

STEP2-Install two ”AA” size batteries so the +(positive) and –(negative) polarities match the polarities of the battery compartment as indicated.

STEP3- Close the battery cover.

BATTERY REPLACEMENT

Battery Indicator

When appears on the display, turn the device off and remove all the batteries.

Replace with four new 2 “AA” size batteries at the same time.

⚠ CAUTION Don’t replace other model AA alkaline battery, otherwise may arouse breakdown.

⚠ CAUTION Do not mix use new and old batteries , otherwise may cause leakage, fever, fracture of the battery to damage the product.

⚠ CAUTION Turn the device off before replacing batteries .

⚠ CAUTION When the batteries are replaced or taken out ,you need to reset the date and time .

⚠ CAUTION To prevent the damage of device from leaked battery fluid, please take out of battery if the device unused in a long time(generally more than 3 months). If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.

⚠ CAUTION Dispose the useless batteries according to local environment protection regulation

TAKING A DETECTION

Before detection

Check whether the device is in good condition and whether there is obvious damage that may affect the safety of pregnant women or the performance of the device; if any damage is found, please stop using it immediately and replace the damaged parts.

Detection Procedure

Follow the steps below for fetal heart rate detection:

1）The pregnant woman lying on bed;

2）Apply an appropriate amount of couplant to the acoustic surface of the ultrasound fetal Doppler;

3）Turn on the power switch;

4）Touch the pregnant woman's abdomen to determine the position of the fetal;

5）Place the device on the pregnant woman's abdomen and move or tilt the device slowly within the range of the fetal until hearing clear and rhythmic fetal heart sounds and see a stable fetal heart rate value;

6）After the detection, turn off the device first, and then use a clean soft cloth or paper to wipe off the remaining couplant on the surface of the pregnant woman's abdomen and the ultrasound head of the device.

⚠ CAUTION Do not mistake maternal heart rate as fetal heart rate.

⚠ CAUTION Do not take gloves to operate the buttons. If there is water, couplant and other substances on the surface of the fingers, please clean them first, otherwise the test results will be affected.

Look for the fetal heart rate

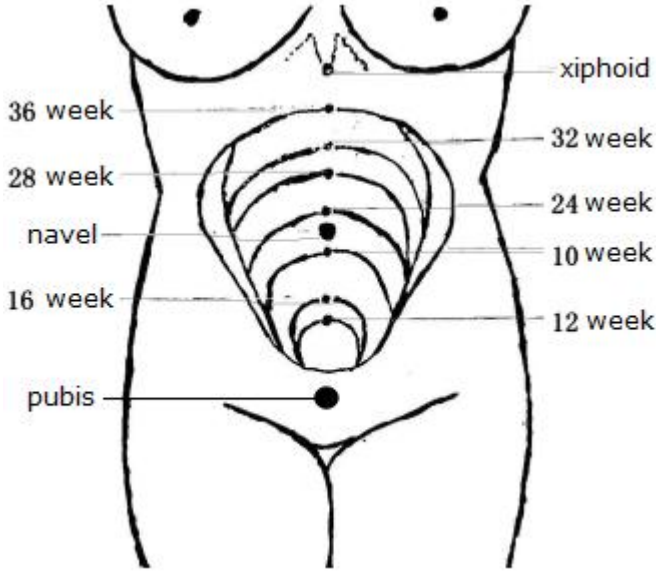
Since the fetus moves at any time in the abdomen, the position of the fetal heart is not fixed. You can refer to the uterine fundus height of the following different pregnancy cycles to determine the approximate range of the fetus:

- At the 12th week of pregnancy, the height of the uterine fundus is 2-3 transverse fingers above the pubic symphysis (about 2-3cm).
- At the 16th week of pregnancy, the height of the fundus is between the navel and the pubic bone.
- At the 20th week of pregnancy, the height of the fundus of the uterus is 1 finger

below the navel (about 1cm).

- At the 24th week of pregnancy, the height of the fundus of the uterus is 1 finger above the navel (about 1cm).
- At the 28th week of pregnancy, the height of the fundus of the uterus is 3 fingers above the navel (about 3cm).
- At the 32th week of pregnancy, the height of the fundus of the uterus is between the navel and the xiphoid process.
- At the 36th week of pregnancy, the height of the fundus of the uterus is 2 fingers below the xiphoid process (about 2cm).

See the position picture of the fetal heart below:



CARE AND MAINTENANCE

To keep your ultrasonic fetal doppler in the best condition and protect the unit from damage, follow the directions listed below:

Maintenance

• Before each use, the device must be checked whether has obvious damage that could affect the safety of pregnant women or the performance of the device. If damage is found, make necessary repairs or replacements.

• The accuracy of the fetal heart rate is controlled by the device and cannot be adjusted by oneself. If the fetal heart rate result is not reliable, use other methods such as using a stethoscope to verify, or contact your local agent or manufacturer for assistance.

• The device is a precision instrument and must be handled with care.the excess couplant on the ultrasonic probe must be wiped off after the instrument is used.

Cleaning

• Shut down before cleaning.

• Do not use any abrasive or volatile cleaners.

• Use a soft cloth moistened with neutral soap or 70% isopropyl alcohol to clean the surface of device, and then wipe them with a dry cloth.

• Wipe off excess couplant from the ultrasound probe, clean the ultrasound probe with a soft cloth soaked in mild neutral detergent or 70% isopropyl alcohol, then dry the ultrasound probe with a dry soft cloth.

• Do not wash or immerse your device in water.

Storage

Keep your device in the storage case when not in use.

• Store your device in a clean, safe location.

Do not store your device:

• If your device is wet.

• In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.

• In locations exposed to vibrations or shocks.

Disposal

Dispose of your device and other components according to applicable local regulations.Unlawful disposal may cause environmental pollution.

BLUETOOTH CONNECTION

a) Install the App from Google play store or Apple app store.

Open Bluetooth on smart phone, and then Turn on the App.

b) Bluetooth pairing for the first time

Press the power button to turn on the device and the Bluetooth symbol will flash,then operate bluetooth pairing according to the settings on the APP,The bluetooth symbol will stop flashing after the connection is successful.

c)Bluetooth paired successfully

Bluetooth will be automatically searched and connected when it is powered on.

TROUBLESHOOTING

Due to operation or other problems, you may not be able to achieve the expected results, please refer to the following troubleshooting measures to solve.

SYMBOL	CAUSE	CORRECTION
Can't turn on or turn off immediately after turning on	The battery is low	Replacement battery
	Switch on and off the device without following the instructions	Long press the switch button to turn on and off
	Device malfunction	Contact customer service to resolve
After power on, the LED shows, but there is no sound from the loudspeaker	The probe did not start working	The device needs to touch the skin probe to start for working
	the volume is minimum and no sound	Voice adjustment
	Device malfunction	Contact customer service to resolve
Fetal heart rate jumps when detecting fetal heart sounds	Some strong interference sources, such as high-frequency device, mobile phones, etc	Avoid using in environments with strong electromagnetic interference sources
	Pregnant women experience fetal movement and the position of the fetal heart changes	Readjust the position of the ultrasound fetal Doppler to find the best position
	Device and belly friction misidentification	Find the best fetal heart position and hear stable fetal heart sounds
When used, the sensitivity is low and the noise is too large	Some strong sources of interference	Avoid using in environments with strong electromagnetic interference sources
	No couplant applied	Add coupling agent
	Device was not placed in the optimal fetal heart position	Adjust the position and angle of the ultrasound fetal Doppler on the belly of pregnant women
	Device malfunction	Contact customer service to resolve

TECHNICAL SPECIFICATIONS

Model	P612
Intended patient	Pregnant woman
Contacting location	Abdomen surface
Operation Principle	Pulsed Wave
fetal heart rate range	60bpm-240bpm
Accuracy	±2bpm
Display screen	LCD
Unit	bpm
Sensitivity	≥90dB
Ultrasound working frequency	2.5MHz
Power supply	d.c.3.0V AA battery
Life time	3 years
Degree of Ingress Protection	IP22
Anti-electric shock degree	Type BF
Anti-electric shock type	Internally powered equipment
Operating Environment	Temperature: 5℃ to 40℃
	Humidity: 10% to 80% RH
Storage Environment	Temperature: -20℃ to 55℃
	Humidity: ⩽93% RH
Weight	98.3g
Size	141x45x45mm
Conformance standard	IEC 60601-1, IEC 60601-1-2,IEC60601-1-11,IEC 60601-2-37,IEC6126

EMC DECLARATION

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning：Don’t near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or

provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ultrasonic fetal doppler,model:P612, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The "Ultrasonic Fetal Doppler P612" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Ultrasonic Fetal Doppler" should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The P612 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 P612 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 Voltage	Not application	
fluctuations/ flicker emissions IEC 61000-3-3	Not application	

Table2

Guidance and manufacturer's declaration – electromagnetic immunity			
The "Ultrasonic Fetal Doppler P612" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Ultrasonic Fetal Doppler" should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2,4,8,15 kV air± 6KV indirect	± 8 kV contact ± 2,4,8,15 kV air ± 6KV indirect	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	Signal ports:±1 kV Input a.c. power ports:±2 kV Input d.c. power ports:±2 kV	Not application	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±1kV, Line to ground: ±2 kV	Not application	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%*U*T (>95 % dip in *U*T) for 0,5 cycle 40%*U*T (60 % dip in *U*T) for 5 cycles 70%*U*T (30 % dip in *U*T) for 25 cycles <5%*U*T (>95 % dip in *U*T) for 5 sec	Not application	Mains power quality should be that of a typical commercial or hospital environment. If the user of the"Ultrasonic Fetal Doppler P612" requires continued operation during power mains interruptions, it is recommended that the "Ultrasonic Fetal Doppler " be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table3

Guidance and manufacturer's declaration – electromagnetic immunity			
The "Ultrasonic Fetal Doppler P612" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Ultrasonic Fetal Doppler" should ensure that it is used in such an environment.			
Immunity test	**IEC60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the " Ultrasonic Fetal Doppler P612", 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 800MHz** **$d=2.3\sqrt{P}$ 800MHz to 2.5 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	10V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land a 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 "Ultrasonic Fetal Doppler P612" is used exceeds the applicable RF compliance level above, the Ultrasonic Fetal Doppler P612 should be observed to verify b normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "Ultrasonic Fetal Doppler P612".Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [*V*1] V/m.			

Table4

Recommended separation distances between portable and mobile RF communications equipment and the Ultrasonic Fetal Doppler P612	
The "Ultrasonic Fetal Doppler P612" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ultrasonic Fetal Doppler can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the"Ultrasonic Fetal Doppler" as recommended below, according to the maximum output power of the communications equipment.	
Rated maximum output power of	**Separation distance according to frequency of transmitter** m

transmitter W	**150 kHz to 80** $d = [\frac{3,5}{V_1}]\sqrt{P}$ **MHz**	**80 MHz to 800** $d = [\frac{3,5}{E_1}]\sqrt{P}$ **MHz**	**800 MHz to 2,5** $d = [\frac{7}{E_1}]\sqrt{P}$ **GHz**
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 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.

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.

WARRANTY

Your Jamr Ultrasonic Fetal Doppler is guaranteed for 2 years against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.

Warranty only applies to the instrument. All accessories including the cuff are guaranteed for one year, USB charging cable is not included.

There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.

Note: According to international standards, your monitor should be checked for accuracy every year.

	Faults	Reasons	What is repaired
The First Repair			
	Date:	Repaired By:	

	Faults	Reasons	What is repaired
The Second Repair			
	Date:	Repaired By:	

CONTACT INFORMATION

Ultrasonic Fetal Doppler P612 is manufactured by:

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Eiffestrasse 80, 20537 Hamburg, Germany.
Telephone: +49-40-2513175 /2513178
FAX: +49-40-255726
E-mail: shholding@hotmail.com

FCC Statement:

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.

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 guarant ee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

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

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environm ent. This transmitter must not be co - located or operating in conjunction with any other antenna or transmitter.