USER MANUAL

Ultrasonic Fetal Doppler

Model: M523

Shenzhen Jamr Technology Co., Ltd.

Caution: Federal law restricts this device to sale by or on the order of a physician

CONTENTS

1 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.

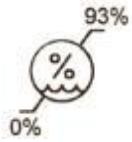
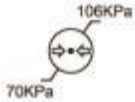
The ultrasonic fetal doppler is a hand-held,battery powered doppler fetal heartrate detector. It is intended to detect and display fetal heart rate,and used by health care professionals in hospital,clinic, community and home for singleton pregnancies after 16 weeks gestation.

Contraindications

None.

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

Symbol	Description	ISO/IEC symbol number and registration date	Symbol	Description	ISO/IEC symbol number and registration date
 WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.	N/A	 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.	ISO 7000-0434A 2004-01-15
	indicates a carrier that contains unique device identifier information	N/A, conform to ISO 15223-1-2021		Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.	N/A, conform to EN 50419:2022

	Refer to instruction manual / booklet	N/A, ISO 7010-M002	IP22	Degree of protection against harmful ingress of particulate matter and water.	N/A, conform to IEC 60529
	Manufacturer	ISO 7000-3082 2011-10-02		Solids: Date of manufacture	ISO 7000-2497 2004-01-15
	Serial number	ISO 7000-2498 2004-01-15		Type BF applied part	N/A, conform to IEC 60417-5333
	Indicate the item is a medical device	N/A, conform to ISO 15223-1-2021	**Rx only**	Caution: Federal law restricts this device to sale by or on the order of a physician.	N/A
	This device has not been tested for use in an MR environment and should not be used exposed to MR environments. Keep it outside the MRI scanner room.	N/A, conform to Testing and Labeling MedicalDevices for Safety in the Magnetic Resonance (MR) Environment		Humidity limitation	ISO 7000-2620 2004-01-15
	Temperature limit	ISO 7000-0632 2014-06-04		Atmospheric pressure limitation	ISO 7000-2621 2004-01-15
	This way up This is the correct upright position of the distribution packages for transport and/or storage.	ISO 7000,No.0623		Fragile, handle with care	ISO 7000-0621 2014-06-04

	Keep away from sunlight	ISO 7000-0624 2014-06-04		Keep dry	ISO 7000-0626 2014-06-04
	Stacking limit by number Maximum number of identical transport packages/items which may be stacked on the bottom package, where "n" is the limiting number.	ISO 7000, No.2403		The device complies with part 15 of the FCC rules	N/A

Packing List

No.	Name	Quality
1	Main unit	1
2	User manual	1
3	Bluetooth User manual	1
4	AA battery	2

2 SAFETY INFORMATION

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

WARNING The device and the APP are for use by healthcare professionals only.

The device is **WARNING** not intended for treatment.

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

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 clearwater, or it will result into to blindness or other harmful danger.

⚠ WARNING Contraindication for women with multiple fetuses

⚠ WARNING Device not for use in water

⚠ WARNING Device interference (e.g., performing ultrasound imaging or doppler flow measurements together with ultrasound fetal monitoring may cause false FHR readings, and the trace recording may deteriorate.)

⚠ WARNING We recommend that exposure to ultrasound should be kept as low as reasonably achievable. This is considered to be good practice and should be observed at all time.

⚠ WARNING Precaution to perform the ultrasound procedure prudently using the principle of ALARA

⚠ 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 purpose. 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 this device or other components by yourself, this may cause an inaccurate reading.

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

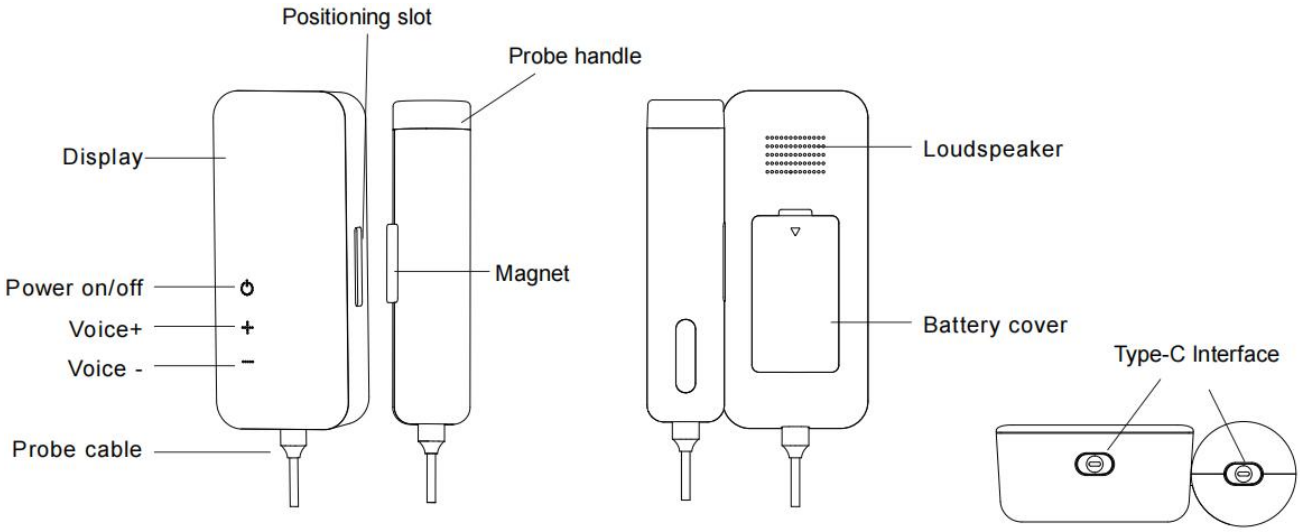
⚠ CAUTION DO NOT insert batteries with their polarities incorrectly aligned.

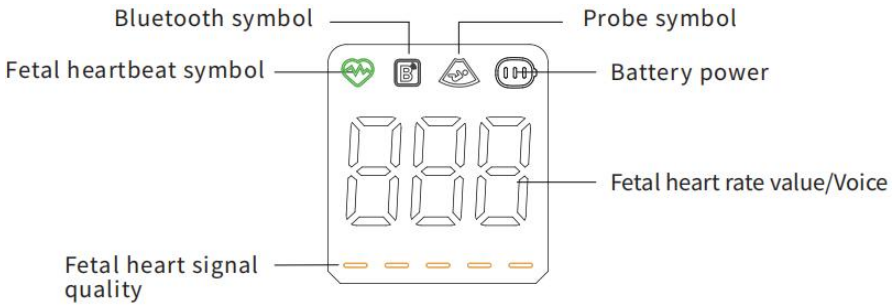
⚠ CAUTION Remove batteries if this device will not be used for a long period of time.

⚠ CAUTION DO NOT use batteries after their expiration date.

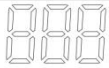
3 COMPONENTS OF THE DEVICE

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		1.Fetal heartbeat symbol indicates fetal heartbeat information. It flashes with fetal heart beat. 2.When the fetal heart rate is between 110 and 160 bpm, the green one flashes.When the fetal heart rate is out of this range, the red one flashes.
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 "  ".
4	Voice		Voice level: The Voice level and fetal heart rate value display use the same area, when there is a voice controloperation, display voice level and then recover to display the current values of fetal heart rate .The voice level shows the range of 0 to 6. 0 represents mute.

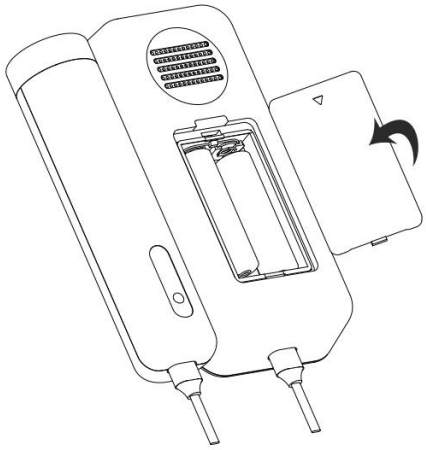
5	Battery power symbol		 indicates full battery;  indicates approximately 70% remaining battery;  indicates approximately 40% remaining battery;  indicates approximately 10% remaining battery. When the battery level is critically low, the low battery indicator  will flash 10 times before automatically shutting down. (Please replace the battery promptly when this  occurs.)
6	Bluetooth symbol		In standby mode, Bluetooth is awaiting connection, and the Bluetooth symbol will flash. Once the connection is successful, the Bluetooth symbol will remain steady.
7	Probe symbol		Indicates that the probe is on.

4 Product Usage Introduction

BATTERY INSTALLATION

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

Follow the device's instructions to open the battery cover. Insert two AA size batteries into the battery compartment, ensuring that the positive and negative terminals of the batteries align with the corresponding markings inside the compartment. Place the batteries flat and then close the battery cover.



BATTERY REPLACEMENT

Low Battery Indicator

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

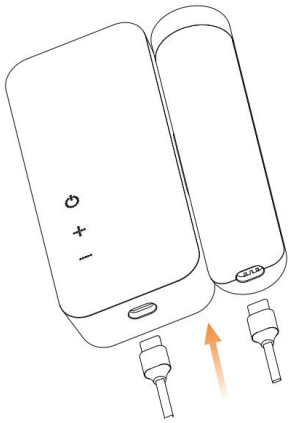
⚠CAUTION When the batteries are replaced or taken out, you need to reset the date and time.

⚠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.

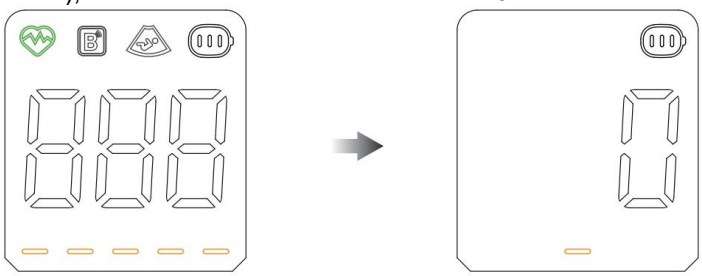
⚠CAUTION Dispose the useless batteries according to local environment protection regulation

Powering On and Off

1. Insert one end of the probe cable into the Type-C port at the rear of the main unit and the other end into the Type-C port at the rear of the handle, ensuring a proper connection between the main unit and the probe handle.



2. To power on the device from the off state, press and hold the power button for approximately 2 seconds. During the screen initialization, a full-screen display will appear for 1 second (the heart-shaped symbol alternates between red and green on the full-screen display, with each color displayed for 0.5 seconds), and then the device will enter the "0" detection screen.



Power-on display interface detection display interface

3. In the initial state, the voice defaults to level 3. Regardless of the voice level adjusted during usage, the device will remember the voice level from before it was powered off.

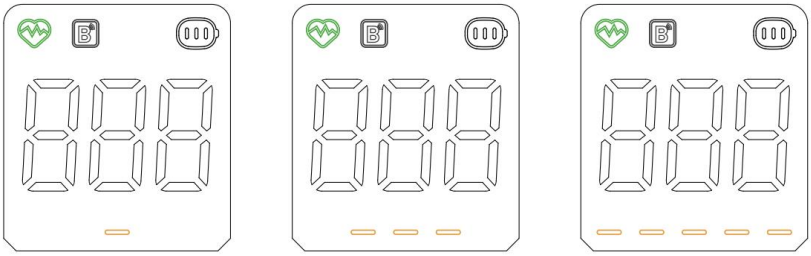
4. Press the side voice + and - keys briefly to adjust the device's speaker volume, which ranges from 0 to 6 levels, with 0 representing mute.

5. To power off the device, press and hold the power button for approximately 2 seconds. A short press does not initiate any operational commands.

6. To prolong battery life, if there is no operation and no signal input within 3 minutes (the display remains at "0"), the fetal heart monitor will automatically power off.

7. Fetal Heart Signal Quality Indicator

The fetal Doppler will display three levels based on the recognized signal strength: Level one, level two, and level three represent weak fetal heart signal strength, moderate fetal heart signal strength, and strong fetal heart signal strength, respectively. See the illustration below for reference:



Fetal heart detection procedure

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.

Note: We recommend you to use the couplant manufactured by Hony Medical Co., Ltd., the number of 510(k) is K221999. You can order this couplant from the manufacturer. Manufacturer's product website:http://www.yafho.com/product/222.html.

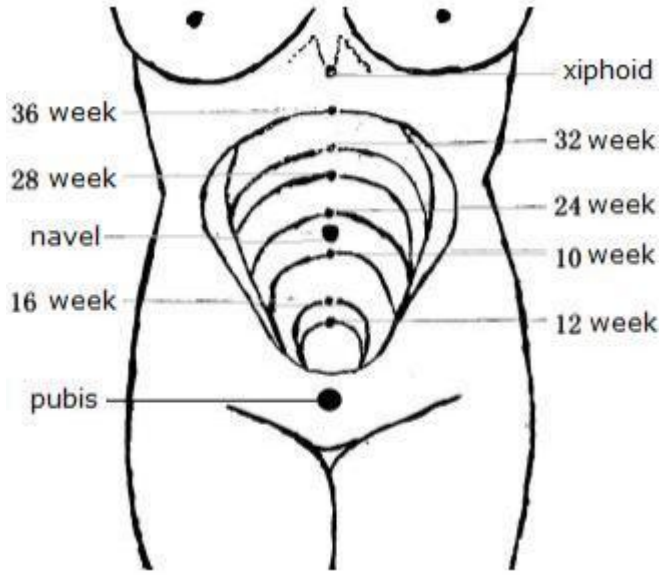
Look for the fetal heart rate

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:



5 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

We recommend thorough cleaning of the device.

Monitor/Main Unit should be wiped down with a clean paper towel, soft cloth, or damp cloth with clean, warm water after each use. If a damp cloth or wipe is used, the monitor should be dried with a clean dry paper towel or cloth. The fetal monitor should never be put into water or other liquids for cleaning.

Visual inspection for residual soil and an additional repeat previous cleaning steps in the event that residual soil is visible on the device.

Probe:

1. Ensure that any acoustic coupling gel is completely wiped off the probe.
2. Use a moistened soft cloth or wipe to remove any remaining contaminants that remain on the probe.
3. Do not re-use cloths or wipes.
4. Soap, detergents, or enzymatic cleaners should be used in accordance with the manufacturer's instructions.
5. Use a lint-free soft and clean dry cloth or wipe to thoroughly dry the probe.

Disinfection

Re-usable fetal dopplers should be cleaned and disinfected after each use. Re-usable fetal dopplers can be disinfected by being wiped down with a low-level disinfectant such as Ethyl or isopropyl alcohol (70-90%).

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 the device in accordance with the regulations applicable at the place of operation.

If you have any queries, please refer to the local authorities responsible for waste disposal.

NOTES:

- Handing of battery and wastes method, please act according to the native law to proceed to handle.

To protect the environment, dispose of empty battery at your retail store or at appropriate collection sites according to national or local regulations.

6 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.

For details, please refer to the Bluetooth APP user manual

Note: Only the health care professionals can use the APP.

7 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	The probe did not start working	The device needs to touch the skin probe to start for working

there is no sound from the loudspeaker	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 ultrasonic couplant applied	Apply ultrasonic couplant
	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

8 TECHNICAL SPECIFICATIONS

Model	M523
Intended patient	Pregnant woman
Contacting location	Abdomen surface
Operation Principle	Continuous wave
fetal heart rate range	60bpm-240bpm
Accuracy	±2bpm
Ultrasound frequency	3.0MHz
Display screen	LED
Unit	bpm
Sensitivity	≥90dB
Ultrasound working frequency	3.0MHz ± 10%
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
	Atmospheric pressure: 80Kpa~105Kpa
Storage Environment	Temperature: -20℃ to 55℃
	Humidity: ≤93% RH
	Atmospheric pressure: 80Kpa~105Kpa
Weight	169.2g
Size	Main Unit:138.6× 59.6× 29.8mm Probe Handle:132.1× 31.7× 31.7mm Probe Cable:0.8m
Conformance standard	IEC 60601-1, IEC 60601-1-2, IEC60601-1-11, IEC 60601-2-37

9 Ultrasound Intensity and Safety

Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis, including investigation of the human fetus, the question of clinical safety with regards to ultrasound intensity arises. There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the ALARA (As Low As Reasonably Achievable) principle serves as a rule-of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output. The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Doppler, it is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, exposure levels should always be limited to As Low As Reasonably Achievable (the ALARA principle).

Explanation of MI/TI

MI (Mechanical Index)

Cavitations will be generated when ultrasound wave passes through and contacts tissues, resulting in instantaneous local overheating. This phenomenon is determined by acoustic pressure, spectrum, focus, transmission mode, and factors such as states and properties of the tissue and boundary. This mechanical bioeffect is a threshold phenomenon that occurs when a certain level of ultrasound output is exceeded. The threshold is related to the type of tissue.

Although no confirmed adverse mechanical effects on patients or mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined. Generally speaking, the higher the acoustic pressure, the greater the potential for mechanical bioeffects; the lower the acoustic frequency, the greater the potential for mechanical bioeffects.

The AIUM and NEMA formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rarefactional acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3 dB/cm/MHz) to the acoustic frequency.

$$MI = Pr, \alpha$$

$$fawf \times CMI$$

$$CMI = 1 \ (MPa / MHz)$$

TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermo physical properties of the tissue.

In order to indicate the potential for temperature rise caused by thermal effects, the AIUM and

NEMA formulate thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1ºC (1.8°F).

According to different thermo physical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.

TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

Measurement Uncertainties

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The overall systematic uncertainties were determined as follows:

1. Hydrophone Sensitivity: ±12percent for intensity, ±6 percent for pressure. Based on the hydrophone calibration report by ONDA. The uncertainty was determined within ±1 dB in frequency range 1-15 MHz.
2. Digitizer: ±0.3 percent for intensity. ±0.15 percent for pressure. Based on the stated accuracy of the 8-bit resolution of the Agilent DSO6012 Digital Oscilloscope and the signal-to-noise ratio of the measurement.
3. Temperature: ±2.4 percent for intensity uncertainty, ±1.2 percent for pressure uncertainty. Based on the temperature variation of the water bath of ±1ºC (1.8°F).
4. Spatial Averaging: ±3.5 percent for intensity, ±1.75percent for pressure.
5. Non-linear Distortion: N/A.

No effects of nonlinear propagation were observed.

Since all the above error sources are independent, they may be added on an RMS basis, giving a total uncertainty of ±12.73 percent for all intensity values reported, ±6.37 percent for all the pressure values, ±12.6 percent for the Mechanical Index, uncertainty of ±12.73% percent for power, ±0.15 percent for center frequency, ±6.87%for the MI.

Prudent Use Statement

Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

Reference for Acoustic Output and Safety

1. “Bioeffects and Safety of Diagnostic Ultrasound” issued by AIUM in 1993

2. “Medical Ultrasound Safety” issued by AIUM in 1994

3. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004

4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004

5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in 2008.

6. “Medical electrical equipment—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007.

Acoustic Output Reporting Table for Track 1 Acoustic output reporting table for IEC60601-2-37(IEC 60601-2-37 (ed.2), am1 for use in conjunction with IEC60601-1 (ed.3), am1 with Corr1 and Corr2, table 201.103)

Transducer Model: M523, Operating Mode: CW mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.00418	0.03064		0.09		n/a
Index component value				0.02976	0.03064	0.09	0.06904	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.00661					
	P	(mW)		9		9		n/a
	P_{1x1}	(mW)		2.5		2.5		
	z_s	(cm)			3.85			
	z_b	(cm)					3.85	
	z_{MI}	(cm)	3.6					
	$z_{pii,\alpha}$	(cm)	3.6					
	f_{awf}	(MHz)	2.5	2.5		2.5		n/a
Other Information	prr	(Hz)	n/a					
	srr	(Hz)	n/a					
	n_{pps}		n/a					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	0.0008646					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	0.8646					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	5.005					
	p_r at z_{pii}	(MPa)	0.01392					
Operating control conditions	n/a							

Acoustic Output Reporting Table for Track 1 (non-autoscanning Mode)

System Model: M523 SN: 20211224P612000001|

Transducer Model: /

Nominal Frequency:3.0MHz

Operating Mode: CW Mode

Acoustic Output			MI	I_{sapa}(mW/cm²)	$I_{sppa.3}$(W/cm²)
Global Maximum Value			0.0112	6.9694	0.008759
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.02308		
	P_0 (mW)			13	13
	f_c (MHz)		2.505	2.505	2.505
	z_{sp} (cm)		n/a	n/a	n/a
	Beam dimensions	x_{-6} (cm)		0.78	0.78
		y_{-6} (cm)		0.78	0.78
	PD (usec)		5.001		5.001
	PRF (Hz)		5714		5714
	EBD	Az. (cm)		ϕ 2.5	
		Ele. (cm)		ϕ 2.5	
Operating Control Conditions	Focus (mm)		Fixed		
	Depth (mm)		Fixed		
	Frequency (MHz)		2.5		

Acoustic Output Reporting Table for Track 1 (non-autoscanning Mode)

System Model: M523 SN: 20211224P612000002

Transducer Model: /

Nominal Frequency:3.0MHz

Operating Mode: CW Mode

Acoustic Output			MI	I_{sapa}(mW/cm²)	$I_{sppa.3}$(W/cm²)
Global Maximum Value			0.01052	6.4332	0.007908
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.01972		
	P_0 (mW)			12	12
	f_c (MHz)		2.504	2.504	2.504
	z_{sp} (cm)		n/a	n/a	n/a
	Beam dimensions	x_{-6} (cm)		ϕ 2.5	ϕ 2.5
		y_{-6} (cm)		ϕ 2.5	ϕ 2.5
	PD (usec)		4.907		4.907
	PRF (Hz)		5555		5555
	EBD	Az. (cm)		ϕ 2.5	
		Ele. (cm)		ϕ 2.5	
Operating Control Conditions	Focus (mm)		Fixed		
	Depth (mm)		Fixed		
	Frequency (MHz)		2.5		

Acoustic Output Reporting Table for Track 1 (non-autoscanning Mode)

System Model: M523 SN: 20211224P612000003

Transducer Model: /

Nominal Frequency:3.0MHz

Operating Mode: CW Mode

Acoustic Output			MI	I_{sapa}(mW/cm^2)	$I_{sppa.3}$(W/cm^2)
Global Maximum Value			0.01217	5.8971	0.006574
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.02007		
	P_0 (mW)			11	11
	f_c (MHz)		2.496	2.496	2.496
	z_{sp} (cm)		n/a	n/a	n/a
	Beam dimensions	x_{-6} (cm)		ϕ 2.5	ϕ 2.5
		y_{-6} (cm)		ϕ 2.5	ϕ 2.5
	PD (usec)		4.907		4.907
	PRF (Hz)		5655		5655
	EBD	Az. (cm)		ϕ 2.5	
		Ele. (cm)		ϕ 2.5	
Operating Control Conditions	Focus (mm)		Fixed		
	Depth (mm)		Fixed		
	Frequency (MHz)		2.5		

10 Cybersecurity related information

. A description of all interfaces and communication protocols available on the device.

Bluetooth devices use the serial port and Bluetooth gatt layer encapsulated profile port for communication with the app, the serial port is the use of baud rate of one megabit, and the app docking profile is part of the public standard 32bit public protocol, and 128bit private protocol combination of the profile

. Instructions on how to maintain the device cybersecurity and how to update the firmware/software for the device.

Software update can only be done by way of serial port burn-in and Jieli private protocol for over-the-air upgrade, does not support ota upgrade on the app

. Instructions for any security actions that the user or user facility are expected to take/implement to ensure secure use of the device.

The device does not involve any security issues, and there is no docking with the gateway, so it only does the work of verification of the transmitted data

. Inform users of any cloud/networking/connection dependencies and provide instructions for users if the dependencies are unavailable.

1. APP establishes communication with the device through Bluetooth and receives the data transmitted by the device; APP can store the data in the cloud server through the Internet to facilitate the user's view of the history;

2. Bluetooth connection status, users use APP to connect with the device via Bluetooth, after successful connection, during the measurement process, once APP detects the disconnection of Bluetooth connected with the device, it will give a reminder and try to reconnect the Bluetooth of the device, users can also choose to reconnect the Bluetooth device via manual way;

3. network connection status, after the user has registered and logged in successfully through the APP, in the process of using the APP, once the APP detects that the current network connection is abnormal, it will give a reminder and try to reconnect the network;

Description of cybersecurity events that can be detected by the device and a description of how users will be informed of such events.

For some common network security events, APP will try to circumvent and remind. For example, anti-interface hijacking, in key interfaces such as login window or user privacy input, APP detects whether the foremost active application is itself, and gives a reminder if it is not its own system to avoid malware stealing user privacy information.

Instructions for what a user should do if a cybersecurity event is detected or suspected

In the User Agreement, "VII. Rights and Obligations" gives some suggestions and instructions, such as: the user is responsible for the safety of the registered account information and account password, the user needs to take legal responsibility for the registered account and the actions under the password. The user agrees not to disclose the account and password information to others under any circumstances, and to notify JAMR immediately if the user suspects that others are using the user's account.

11 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.

12 EMC DECLARATION

The ME EQUIPMENT or ME SYSTEM with following ESSENTIAL PERFORMANCE is intended used in home and healthcare environment facility environment.

ESSENTIAL PERFORMANCE:

Device-Specific Function	Device-Specific Pass/Fail Criteria	Detection/Testing Method
Fetal heart rate range	60bpm-240bpm	IEC 60601-2-37:2007/AMD1:2015
Accuracy	±2bpm	

If Essential Performance is lost or degraded due to electromagnetic disturbances, this may result in loss of product function, please read below important information before to avoid possible electromagnetic disturbances.

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: M523, 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 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

Harmonic emissions IEC 61000-3-2 Voltage	Not application	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 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

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The “Ultrasonic Fetal Doppler P612” is intended for use in the electromagnetic environment specified below. The user of the “Ultrasonic Fetal Doppler” should ensure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC60601 Test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">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√P
d=1.2√P 80MHz to 800MHz
d=2.3 √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 meters (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’s
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,7 GHz</td><td>10V/m</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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 [V1] V/m.</td></tr>
</table>

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 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 transmitter W	**Separation distance according to frequency of transmitter (m)**		
	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.			

13 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.

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

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