



Shenzhen Hailife Technology Co.,Ltd.

User Manual

Fetal Doppler



About this Manual

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Product information

Product Name: Fetal Doppler

Model: FD-01B, FD-01

Brand: Hailife

Manufacturer: Shenzhen Hailife Technology Co.,Ltd.

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Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.



WARNING

A **WARNING** advises against certain actions or situations that could result in personal injury or death.



CAUTION

A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.



NOTE

A **NOTE** provides useful information regarding a function or procedure.

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Section 1:Instruction

1.1Intended Use

The Fetal Doppler is a hand-held, battery powered audio Doppler device used for detecting the sound of the fetal heartbeat (SFH). FD-01B, the product with Bluetooth feature, can also record the trend line of the fetal heart rate(FHR).

1.2 Product Description

The Fetal Doppler is a lightweight, portable detector. It is designed to meet your detecting and hearing needs by providing advanced detecting functions and a full range of sound of the fetal heartbeat.

The Fetal Doppler is mainly used to detect the fetal heartbeat rate (FHR) and the sound of the fetal heartbeat (SFH).

The growth and development of a fetus can be found out through examination of these indices. It is applicable for department of gynaecology and obstetrics and clinic daily.

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 Operation principle

Ultrasonic wave is transmitted from one piezoelectric ceramic at the front of the probe to the uterus of the pregnant women. Echo is received by the other piezoelectric ceramic at the front of the probe when ultrasonic wave reaches the fatal heart. Then it is converted into voltage. This Doppler signal is detected and demodulated from the received signal. And the Doppler frequency is consistent with the rhythm of the fetal systole and diastole. Once cardiac valves vibrate and a Doppler frequency excursion is formed. It is transmitted an

output signal of cardiac valves vibrating, and it is sent to the headphone for getting a rhythmical sound with the fetal heartbeat. Simultaneously, it is sent to a counter which calculate periods of heartbeat that is fetal heartbeat rate (bpm=beat per minute).

1.4 Contraindications for Use

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

1.5 Adverse effects

No adverse effect

Section 2: Safety Precautions

The Doppler is internally powered equipment, and it is an IEC/EN 60601-1-1 Type BF applied part. Type BF protection means that the connection between the equipment and the personal complies with permitted leakage currents and dielectric strength of IEC/EN 60601-1-1.

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the device.

WARNING














1. Do not transfer or repair the device without permit.
2. The user should read this manual before using this device.
3. Do not use the device with High Frequency surgical equipment.
4. The Doppler is not explosion-proof and can't be used in the presence of flammable anesthetics.
5. Make sure that your hand is clean and dry before touching the power button.
6. Do not connect any equipment or accessories that are not approved by the manufacture
7. Do not heat or throw batteries in fire as this may cause explosion.
8. Do not short-circuit the batteries or install the batteries reversely.

9. Batteries have life cycles. The alkaline batteries are intended to be use once. If the battery life is end, replace them according to the identical specifications.
10. Remove the batteries and store them in a cool and dry environment if the device is not used for a long time.
11. Do not mix the battery with metal objects during storage to avoid short-circuit.
12. The device shall only be used when the battery cover is closed.
13. Stop using the battery if abnormal heat, odor, discoloration, deformation or other abnormal condition is detected during use or storage. Please dispose it according to the local regulations.
14. The Doppler is not intended for treatment
15. The waterproof design is followed to the standard IEC529 and compliance to **IP22**. If the gel or any other liquids are split on or into the product, please wipe it off immediately with a soft dry cloth or clear it up with cotton bud.
16. Do not operate the product in the presence of flammable gases to avoid possible explosion or fire hazard.

CAUTION

1. Keep the Doppler in a clean environment and avoid vibration during storage
2. Clean the surface of the device with non-corrosive detergent.
3. Do not sterilize the Doppler with autoclave or gas.
4. The maximum operational range for Bluetooth connection between the product and a Bluetooth device is approximately 15 meters (45 feet). Out of the range the product may not work normally, please use it in valid range.
5. The Doppler and accessories shall be disposed according to local regulations after their useful lives. Alternatively , they can be returned to manufacture for recycling or proper disposal.
6. Exposing the Product to extreme environmental conditions outside of its operating parameters may compromise the ability of the Product to function properly.
7. It should not be used in life supporting or life sustaining applications
8. Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.
9. **Do not continuous use the Doppler over 20 minutes.**

Section 3: Symbols

No.	Symbol	Definition
1		CE marking
2		Operation instructions
3		Caution
4		RYPE BF APPLIED PART
5		Serial Number
6		Batch code
7		Date of manufacture
8		Manufacturer
9		Authorized Representative in the European Community
10		General symbol for recover/recyclable
11		Refer to User Manual (Background: Blue; Symbol: White)
12		Collect separately from other household waste
13		Federal Communication commission

Section 4: Doppler Introduction

Note:

The pictures and interfaces in this manual are for reference only

4.1. Main Unit

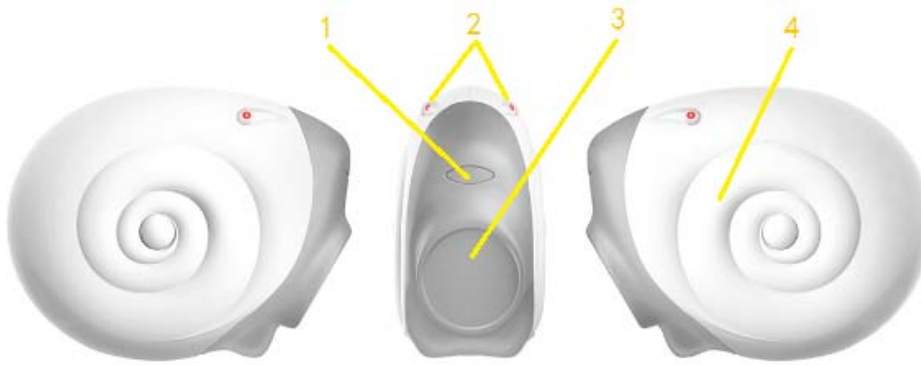


Figure 1 Appearance

1	2	3	4
Power Button	Power Indicate	Probe	Battery Cover

4.2. Features

Feature	FD-01B	FD-01
Bluetooth v4.0	Y	N
APP	Y	N
Power indication	Y	Y
Earphone Output	Y	Y
Record fetal heart beat sound and curve	Y	N
History data sharing	Y	N
Battery low indication	Y	Y
Fetal heart beat detection	Y	Y
Fetal heart sound curve & data display on APP	Y	N

***Note: Y means the product support the feature, N means the product don't have this feature.**

4.3. Accessories

No.	Item	Amount	FD-01B	FD-01
1	User manual	1 pcs	Y	Y
2	Product qualification certificate	1pcs	Y	Y
3	Earphone	1pcs	N	Y
4	Battery , AA LR6 1.5V	2pcs	Y	Y
5	Ultrasound gel	1pcs	Option	Option

***Note: "Y" means the accessory is included in the product, "N" means the accessory is excluded in the product.**

***Note: Ultrasound gel is an option for user, or bought from the local distributor while needed.**

4.4. APP "Mywine"

*** Note: the section is only available for the product with Bluetooth support. Please ignore the section if the product doesn't support the feature.**

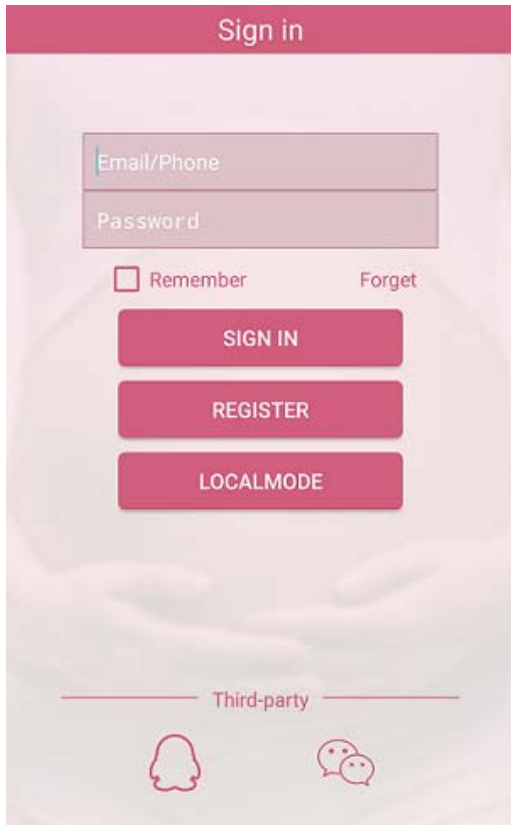


Figure 2

Figure 2: User login page



Figure 3

Figure 3: Home page

Section 5: Operation Instruction

NOTE:

To ensure that the Doppler works properly, please read this chapter and the chapter “ Safety Precautions “ before operation.

The Doppler can detect the fetal heart beats after 16 weeks gestation.

5.1. Open the package and check

Open the package, check for any mechanical damage, check the accessories are all in according to the packing list. If there is any problem, contact us or your local distributor immediately.

CAUTION

Please keep the initial package and do not throw them away, because the initial package has the basic information about the device and manufacturer, which will be the proof when you need a service.

WARNING

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

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.

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

5.2. Install / Replacing Battery

Hold the device, press the battery cover and push it forward following the direction in figure 4. Then the battery cover is open.



Figure 4 Open battery cover

Put the batteries into the device, then put the battery cover back to device, push it forward until it clicks closed. Refer to the figure 5 and figure 6 below.



Figure 5 Put batteries into the device




Figure 6 Put battery cover back to device

CAUTION

- 1.The direction of the batteries should comply with the polar mark on the cover. Reversed connection is forbidden
- 2.If the device is not used for an extended period, take the batteries out and store them in a cool and dry environment.



3.  Please dispose of the device or accessories in accordance with the directive 2002/96/EC-WEEE (Waste Electrical and Electronic Equipment). If you have any queries, please refer to the local authorities responsible for waste disposal.”

5.3. Download APP “Mywine” and install

***Note: The feature is only available for the product with Bluetooth feature support, If the product doesn’t support the feature, please skip to 5.4.**

Download and install “Mywine” application from Google Play or iOS APP store. Or just scan the QR code from the box to install the APP “Mywine”.

NOTE

Make sure your smart phone/tablet with:

Android 4.3 or above, CPU 1.4GHz or above, RAM 512MB or above, Bluetooth V4.0 or above ;

iPhone/iPad with iOS 8.0 or above, CPU 1.0GHz or above, RAM 1GB or above, Bluetooth V4.0 or above.

5.4. Switch on

Press the Power Button on the front of device (as showing in figure 1). The device will be ready for work when the power indicator is green.

If the power indicator is red or not lighted, please check whether the connection of battery is reversed or the battery life is expiration, then adjust or change the battery.

If the power indicator is still red or not lighted after adjust and change the battery, please contact us or your local distributor immediately.

5.5. Open APP

***Note: The feature is only available for the product with BLE feature support, If the product doesn't support the feature, please skip to 5.6.**

Open APP “ Mywine ” in your smart phone or tablet. Choose one type of login : a) sign in with Email/Phone and password, or, b) Local mode. When you choose a), you need to register first.

Then the Doppler will connect to the APP automatically after login the APP.

CAUTION

1. Ensure the Bluetooth setting is “on” on your mobile phone.
2. Ensure the distance between the device and your smart phone/tablet is less than 15 meters.
3. Only the user, who login with Email/Phone and password, can edit and share the recorded fetal heart beat curve to other people by public social media (Facebook and

5.6. Examing

Insert the Earphone as indicated in figure below if the product doesn't support Bluetooth.



Figure 7 Insert the Earphone

Apply a certain amount of gel to probe faceplate and place the probe against the abdomen closely, find the point of fetal heart beat and start monitoring the fetal heart sound. (refer to figure 8 below to look for the point of fetal heart beat).

The best quality records will only be obtained if the probe is placed in the optimum position.

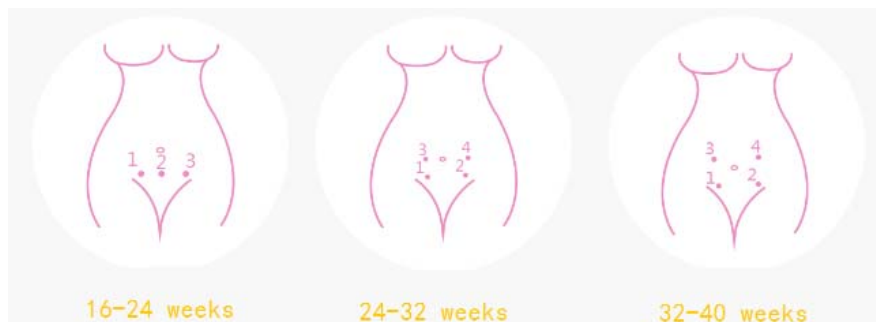


Figure 8 Optimum position for examining

When the fetal heart beat signal is detected, the Power Indicator begin to flash.

And the fetal heart sound can be heard clearly via earphone.

*If the product doesn't support Bluetooth, please ignore below descriptions.

At the same time, rhythmic heart sound is heard from the smart phone/tablet, and numeric FHR is displayed on the Home page of APP.



Figure 9 Numeric FHR on APP

There will be a fetal heart beat curve on the Home page of APP along with the detecting time last.

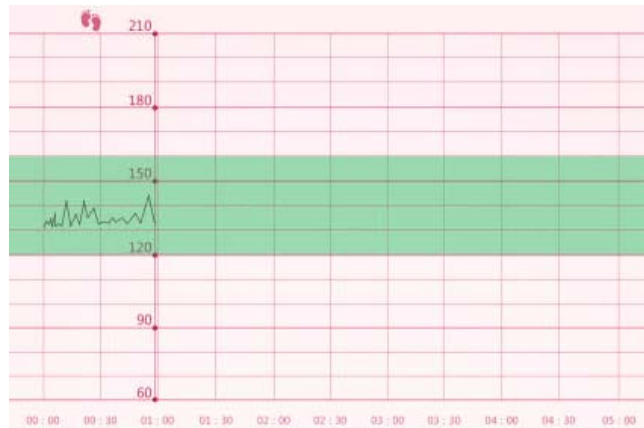






Figure 10 Fetal heart beat curve on APP

5.7. FHR Recording, Playing and Sharing

*the feature is only applicable for the product with Bluetooth supporting. If the product doesn't have this feature, please skip to [5.8](#).

Click record button  on APP “Mywine” while monitoring FHR, the record button


changes to  , APP begins recording the Fetus' fetal heart sound and FHR curve .

Click record button  , it changes to  , then APP stop recording the Fetus' fetal heart sound and FHR curve.

You can view, edit the Fetus' fetal heart sound and FHR curve in record page, and share them to anyone you want. You can upload them to, and download them from Hailife Cloud as well.



Figure 11 Edit your favourite sound and curve

Click Quickening button  on APP “Mywine” when there is a fetal movement of fetus., can record the fetal movement. The fetal movement can be marked and statistic in Quickening page.

Fetal movement will be statistic every 5 minutes, multiple clicking the “quickening” button on main page and circle button in Quickening page within 5 minutes will be regarded as 1 time valid fetal movement. The red digital means valid fetal movement count, the yellow digital is quickening click action count.



Figure 12 Quickening page

You can share the fetal movement to anyone you want.

CAUTION

Only the user, who login with Email/Phone and password, can edit and share the recorded fetal heart beat curve and fetal movement to other people by public social media (Facebook and Twitter.)

5.8. Completing Examing

Switch off the Doppler after examining, clean the probe surface, place the Doppler and accessories back to the initial package, and store them in cool and dry environment.

Section 6: Maintenance

6.1. Maintenance

Please check that the device does not have visible evidence of damage that may affect the operator's safety or the Doppler's capability before each use. Pay special attention to the cracks on the device.

6.2. Cleaning

Please switch off the Doppler before cleaning.

Keep the exterior surface of the device clean and free of dust and dirt.

Clean the exterior of the device with a dry, soft cloth. Clean the device using a soft dampened with mild near neutral detergent, ethanol (75%) or isopropanol (70%), and then wipe the device dry with dry cloth immediately.

CAUTION

1. Do not use strong solvent, such as acetone.
2. Never use an abrasive such as steel wool or metal polish.
3. Do not immerse the device into liquid.

Section 7: Warranty and Service

7.1. Warranty

Hailife warrants that Hailife's Doppler meet the labelled specification of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of :

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) Damage caused by alteration or repair by anyone not authorized by Hailife.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a device covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, Hailife will, at its discretion, repair or replace the defective part free of charge. Hailife will not provide a substitute device for use when the defective device is being repaired.

7.2. Service

If you have any question about maintenance, technical specifications or malfunctions of devices, please contact your local distributor.

Alternatively, you can send an email to Hailife at: service@hailife.com.cn.

Please send the information of product number, serial number, purchase date, purchaser name, telephone number, and your questions to your local distributor or Hailife, so that we can handle you questions in time.

Service center:

Shenzhen Hailife Technology Co., Ltd.

Add: 501, Block 6, Jinghuazhong Industrial Park, No.2, Jinlong Road, Longgang District, Shenzhen, Guangdong Province, China

Telephone Number: +86 755 26928600

Fax: +86 755 26928600

Authorized European Representative:

Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175 Fax: +49-40-255726

Section 8: Product Specifications

8.1 Specifications:

ULTRASOUND	
Ultrasonic emitting frequency	2.5 MHz \pm 10%
Overall sensitivity at the distances 200mm from the face of the probe (Doppler frequency:300 \pm 50Hz, Targe velocity: 10cm/s~40cm/s)	> 90 DB
Ultrasonic emitting power:	\leq 20 mW / c m ²
Effective ultrasonic area	245 m m ²
Space peak time peak sound pressure	P \leq 1 MPa
FHR PERFORMANCE	
FHR Test Range	60 bpm ~ 240 bpm
Resolution	1 bpm
Accuracy	\pm 3 bpm
BATTERY	
Battery Voltage	2x1.5V
Type	AA 1.5V Alkaline

8.2 Operation platform for APP:

android 4.3 or above; iOS 8.0 or above (if the product support this feature)

8.3 PHYSICAL DIMENSIONS AND WEIGHT

Device Size: 98.5mm (W) *47mm (D) *96mm (H)

Device Weight: 159 g (not including battery)

8.4 Environment:

	Working:	Transport and Storage:
Temperature	+5°C ~ +40°C	-20°C ~ +55°C
Humidity	25%~95% RH (non-condensing)	25%~95% RH (non-condensing)
Atmospheric Pressure	700hPa ~ 1060hPa	500hPa ~ 1060hPa

Section 9: Troubleshooting

Phenomenon	Cause	Solution	FD-01B	FD-01
No sound Can be heard	Mobile phone muted, Bluetooth setting is off, or No battery.	Unmute mobile phone, Bluetooth setting to On, or check and install battery.	Y	N
No sound Can be heard	The earphone is not inserted exactly	Check the earphone and make sure the connection is fine.	N	Y
Distorted sound	Low battery	Change battery	Y	Y
Small volume	Gel is not applied.	Apply the gel.	Y	Y

*” Y” herein means the product support this feature, “N” means the product doesn’t support this feature.

Appendix A: 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.

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.

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 %.

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	Compliance level	Electromagnetic environment – guidance

	test level		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any 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</p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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.</p> <p>b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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.			
<p>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.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			
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.

Appendix B: IEC60601-2-37 acoustic output reporting table (IEC60601-2-37, Edition 2.1, 2015-06)

Transducer Model: FD-01B/ FD-01

Nominal Frequency: 2.5M HZ

Operating Model: CW

Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.01621	0.1380		0.2812		n/a
Index component value		0	0	0.1380	0	0.2812	0
Index label		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.02564					
	P (mW)	0	12.62		12.62		n/a
	P_{1x1} (mW)	0	n/a		n/a		0
	z_s (cm)			3.65			
	z_b (cm)					4.75	0
	z_{MI} (cm)	0.65					
	$z_{PII,\alpha}$ (cm)	0.65					
	f_{awf} (MHz)	2.50	2.50		2.50		n/a
Other Information	p_{rr} (Hz)	n/a					
	s_{rr} (Hz)	n/a					
	n_{pps}	n/a					
	$I_{pa,\alpha}$ at $z_{PII,\alpha}$ (W/cm ²)	0.01817					
	$I_{spta,\alpha}$ at $z_{PII,\alpha}$ or $z_{SII,\alpha}$ (mW/cm ²)	18.16					
	I_{spta} at z_{PII} or z_{SII} (mW/cm ²)	20.32					

	p_r at z_{pII} (MPa)	0.02712					
Operating control conditions	Control	Fixed					

$$I_{ob} = I_{sata} = 12.62 / 2.45 = 5.1510 \text{ mW/cm}^2$$



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