AngelSounds®

FETAL DOPPLER
ANGELSOUNDS JPD-100S
BEDIENUNGSANLEITUNG

Fetal Doppler AngelSounds JPD-100S – Instruction manual

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Product Information

Product Name: Fetal Doppler
Model: JPD-100S
Manufacturer: Shenzhen Jumper Medical Equipment Co., Ltd

Statement

⚠ Please read the User Manual carefully to ensure safe and proper use of this Fetal Doppler. Please read and fully understand the Safety Precautions before use.

1. INTRODUCTION

1.1 OVERVIEW

Become familiar with the controls and how to use the product properly before operating the product.

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

⚠ **CAUTION: It cannot replace the professional fetal monitor. When the fetal heart rate is abnormal, the fetal heart cannot be found , or no fetal movement can be felt, pregnant woman should immediately go to the hospital to seek the doctor's help.**

Intended use

The Fetal Doppler JPD-100S is a hand-held, battery powered audio Doppler device used for detecting fetal heartbeats.

1.2 PRODUCT DESCRIPTION

The product 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 product is mainly used to detect 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 gynecology and obstetrics and clinic daily.
In accordance with classification criteria in Annex IX on “Medical Device Directive 93/42/EEC”, the product is class II based on rule 10, “Devices for Direct Diagnosis or Detection on physiological process”.
The product is powered by an internal battery.

1.3 OPERATING PRINCIPLE

Fetal Doppler consists of probe (transmitter and receiver) and signal process unit.
Ultrasonic wave is transmitted from a 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 fetal 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. The output signal of the cardiac valves vibrating is transmitted, and it is sent to the loudspeaker to get the rhythmical sound of the fetal heartbeat.

2. SAFETY GUIDANCE

2.1 INDICATIONS FOR USE

The product is normally applied to fetus above 16 weeks growth, difference in pregnant mater. The

normal range of fetal heart rate: 110bpm-160bpm.

Listen to SFH:

Operator can listen to the sound of fetal heartbeat from the headset.

Audio record:

The sound of fetal heartbeats can be recorded by a recorder which is connected with the product. Safety advisement: only recorders can be connected that comply with the safety requirements of IEC 60601-1.

2.2 CONTRAINDICATIONS FOR USE

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

2.3 NOTE FOR HOME USE

This device cannot replace a professional fetal monitor. If the fetal heart rate is abnormal or cannot be located by using this monitor, the pregnant woman should immediately go to the hospital to seek the doctor's help.If fetal movement is not felt by the pregnant woman, immediately go to the hospital to seek the doctor's help.

2.4 SAFETY TERMS AND CONDITIONS

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

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

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

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

2.5 SAFETY ALERT DESCRIPTIONS

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

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

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

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

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

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

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

⚠ **CAUTION**: Systems Statement
Equipment connected to the product must be certified according to the respective IEC Standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1. The product service port is only intended for use during

maintenance by authorized service personnel.

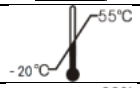
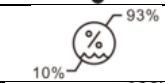
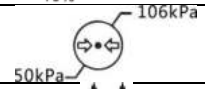
⚠ **CAUTION**: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

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

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

2.6 SYMBOL DESCRIPTIONS

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

	Consult instructions for use of the product and/or its accessories.
	Warning Information
	Authorized Representative in the European Community
CE 0482	CE Mark: The Product system conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
	Storage Temperature
	Humidity
	Atmospheric Pressure
	Upward
	Non-hook
SN	Specifies serial number of the Product
LOT	Batch code
	It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.
	Type B applied part
IPX4	Ingress Protection.

SECTION 3: USING THE PRODUCT

This section provides the description for operation.

3.1 UNPACKING AND INSPECTING

Every attempt is made to ensure your accurate and complete order. However, to be sure that your correct order, verifying the contents of the box against your packing slip.

The product is designed for simplicity of operation and set-up and requires minimal assembly. The following items are included in your box:

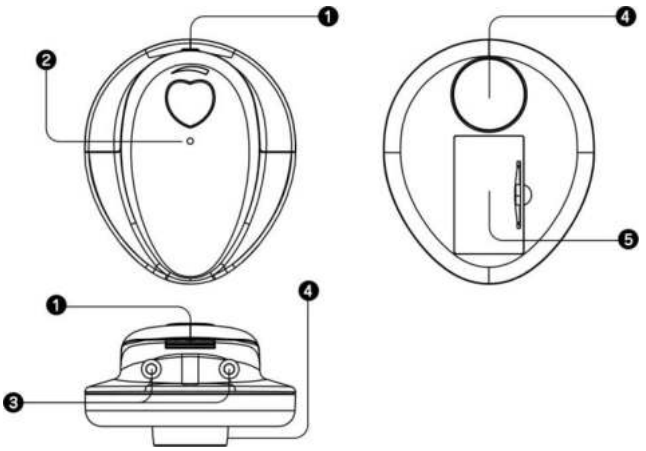
1 (one) Product, 1 (one) Headset, 1 (one) Recording Cable, 1 (one) Operator's manual, 1 (one) Battery (9V).

Carefully inspect each item as it is unpacked for any signs of damage which may have occurred during shipment.

- Check the components according to the packing list.
- Check for any damage or defects. Do not attempt to assemble the product if anything is damaged or defective. Contact Shenzhen Jumper Medical Equipment Co., Ltd Customer Service immediately if anything is damaged or defective.

3.2 SETTING UP THE PRODUCT

Controls and indicators



1. Power On/Off/Volume Knob
2. Working Indicator Light
3. Headset Socket(two)
4. Transducer
5. Battery Compartment Cover

3.3 BUILD IN BATTERY

1. Open the battery cover:

The rear panel is upturned. First, open the cover (5) of battery compartment.

2. Install the battery:

Take out the battery connector. Then plug the battery to connector, after that put them into the battery compartment.

3. Close the battery cover:

First, along the left of battery compartment latch, put the cover at the right place. Then close the cover (5).

⚠ ***CAUTION:***

Remove these batteries if the device is not likely to be used for some time.

⚠ ***WARNING:*** Irregular treatment of batteries may be result in hazards to health and environment.

3.4 OPERATE KNOB AND INDICATOR LIGHT

There has an 'Power on/off/volume knob (1)', it's easy to operate. And working indicator light (2) shows working condition.

3.4.1 POWER ON

When the product is not in use, turn the 'Power on/off/volume knob (1)' to right for switching on the product. Indicator light (2) is on.

3.4.2 POWER OFF

When in use, turn the 'Power on/off/volume knob (1)' to the end of left for switching off the product. Indicator light (2) is off.

3.4.3 VOLUME ADJUSTMENT

Turn the 'Power on/off/volume knob (1)' to right; the sound volume will increase. Contrary, Turn the 'Power on/off/volume knob (1)' to left, the sound volume will decrease.

3.4.4 AUDIO OUT

A socket for audio output can only be connected with a recorder complied with the requirements of IEC 60601-1.

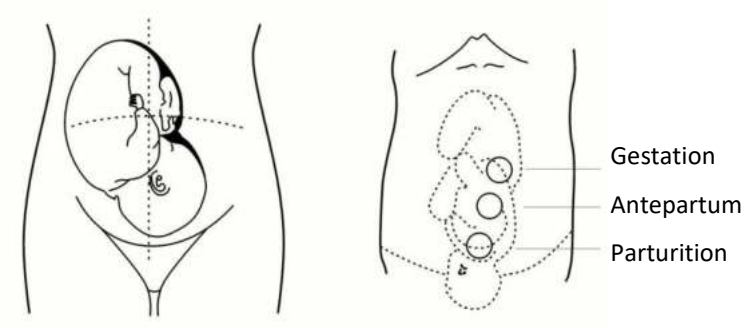
3.5 PREPARATION

Follow these recommendations to prepare for operation:

- Switching on by turning the 'Power on/off/volume knob (1)'.
- Apply coupling gel to the faceplate of probe or abdomen.
- Move the transducer slowly over the lower part of the abdomen.

3.6 USING PRODUCT TO DETECT

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



4. MAINTENANCE & AFTER-SALES SERVICE

Proper maintenance of the product is very simple, yet it is an important factor of its reliability. The section describes the maintenance and service required for the product and its accessories.

4.1 MAINTENANCE

⚠ ***WARNING:*** Failure of the part of all responsible individuals, hospitals or institutions, employing the use of product, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the product.

3. The transducer acoustic surface is frangible and must be handle with care .Gel must be wiped off from the transducer after use. These precautions will prolong the life of the unit.
   The user must check that the equipment does not have visible evidence of damage which may affect patient's safety or product's capability before use .The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.
4. To ensure the product is always functional when required, the following maintenance shall be performed.
   - Visual Inspection
   - Cleaning the product and its accessories
   - Check the battery fuel gauge
   - Testing product performance

Correction: manually calculate the FHR with hearing fetal heartbeat sound for qualification.

4.2 RECOMMENDED MAINTENANCE AND CARE

- It is important that the product is stored at the operating temperature range if it is expected to be used. Optimal battery life will be obtained if stored and operated at room temperature. See Section 5 for temperature specifications.
- The product requires no calibration.

4.3 VISUAL INSPECTION

The product and its accessories should be carefully inspected prior to installation, once every 12 months thereafter and each time the equipment is serviced.

- Carefully inspect the equipment for physical damage
- Inspect all external connections for loose connectors or frayed cables.
- Inspect the graphics display for marks, scratches, or other damage.
- Verify that the safety label on back of the product is clearly legible

INSTRUCTION	INSPECT FOR	RECOMMENDED REMEDY
Examine the case connectors and	Foreign substances	Clean the product and its accessories as described.

accessories	Damage or cracks	Contact Our Customer Service
Examine accessory cables	Foreign substances	Clean the cables as described in the Section 4
	Broken parts, cracks, damage, or extreme wear, broken or bent connectors and pins, after bending and flexing the cable	Replace cable if any abnormalities are found.
Examine disposable accessories	Expired product or Product pads	Replace any products approaching or past their expiration dates.

⚠ ***WARNING:*** After the visual inspection, if the product and/or its accessories are damaged please contact our Customer Service. The product will need to be returned back to us for repair. The accessories should be disposed of appropriately and replacement parts shall be ordered.

4.4 CLEANING PRODUCT AND ACCESSORIES

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

- Isopropyl alcohol (70% solution in water)
- Mild soap and water
- Sodium hypochlorite (chlorine bleach) (3% solution in water).
- Quaternary ammonium compounds (such as Lysol) (10% solution in water).
- Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
- Do not use mixing disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
- Do not clean electrical contacts or connectors with bleach.

4.5 CLEANING INSTRUCTIONS

1. Before cleaning the product, turn the device off and disconnect the power cord.
2. Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.
3. When cleaning, do not immerse. Keep the exterior surface of the device clean and free from dust and dirt, clean exterior surface of the unit with a dry, soft cloth .if necessary, clean it with a soft cloth soaked in a solution of soap and wipe dry with a clean cloth immediately.
   Wipe the transducer body with soft cloth to remove any remaining coupling gel .Clean with soap only.
4. Wring any excess moisture from the cloth before cleaning.
5. Avoid pouring fluids on the device, and do not allow fluids to penetrate the exterior surfaces of the device.
6. To prevent scratching the display, the use of a soft cloth is recommended.

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

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

* Don’t use strong solvent, for example, Acetone.
* Never use an abrasive such as steel wool or metal polish.
* Do not allow any liquid to enter the product, and do not immerse any parts of the device into and liquids.
* Avoid pouring liquids on the device while cleaning.
* Don’t remain any cleaning solution on the surface of the device.

Wipe the surface of sensor of transducer with 70% ethanol or alcohol, self-air dry or clean with a clean, dry cloth.

4.6 DISINFECTIONS

Cleaning the unit surface and the transducer as the above mentioned, then wipe the surface of transducer with 70% ethanol or alcohol, clean the transducer surface with a dry, soft cloth.

* Don’t use low temperature steam sterilization or other way to sterilize.

* Don't use high temperature sterilizing process.

4.7 RECYCLING THE BATTERIES

The batteries are recyclable. Remove the old battery from the Product and follow your local recycling guidelines or Refer to local regulations.

⚠ ***WARNING:*** Irregular treatment of batteries may be result in hazards to health and environment.

4.8 AUTHORIZED REPAIR SERVICE

The Product has no user-serviceable internal components. Try to resolve any maintenance issues with the Product by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Jumper Medical Equipment Co., Ltd Service department.

☞ ***NOTE:*** The warranty will be void upon unauthorized disassembly or service of the product.

5. SPECIFICATIONS AND SAFETY

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

ULTRASOUND	
Ultrasonic emitting frequency:	3MHz
Overall sensitivity at the distances 200mm from the face of the transducer (Doppler frequency:300±50Hz,Targe velocity: 10cm/s~40cm/s)	≥90dB
Spatial-peak temporal-peak acoustic pressure:	<1MPa
Output power:	<20mW
Effective area of the ultrasonic transducer active element:	4.92cm2
The acoustic coupling medium for normal use:	ph :5.5~8, Acoustic impedance: $1.5*10^6$~$1.7*10^6$Pa·s/m
AUDIO OUTPUT	
Audio Output Power:	<0.2 W
Audio out socket:	Φ3.5mm
BATTERY	
Battery Voltage:	9V
Type:	IEC6F22 9V alkaline

5.2 MODE OF OPERATION

Continuous operating

5.3 PHYSICAL DIMENSIONS

104mm (W) x 120mm (D) x 61mm (H), Wt: 0.14kg (including battery)

W –4.1 in, D –4.7in, H –2.4 in, Wt: 31lbs (including battery)

5.4 ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS

Temperature: 5°C to 40°C

Humidity: <80% RH, non-condensing

Atmospheric pressure: 86kPa to 106kPa

STORAGE AND SHIPPING CONDITIONS

Temperature: -20°C to 55°C

Humidity: 10% - 93% RH, non-condensing

Atmospheric pressure: 50kPa to 106kPa

6. ACCESSORIES

6.1 OVERVIEW

This section contains a list of parts and software accessories for Product. To place an order, contact your representative or distributor.

6.2 PRODUCT ACCESSORIES

Product is available in more than twenty languages, with others being added on a regular basis. For a complete list of those available, contact your sales representative or Shenzhen Jumper Medical Equipment Co., Ltd Customer Service.

ACCESSORIES

Part Number	Description
JP100S-HS13B	Headset Φ3.5mm
JP100S-RC1.2M	Recording cable Φ3.5mm

7. TROUBLESHOOTING

What appears to be a malfunction may not always serious, if your product does not perform as expected, consult the table below to see if the problems can be corrected before seeking help from your dealer or service representative.

Symptom	Cause	Remedy
Audio scream	• Audio volume too high • Too much gel on the probe surface • Battery is exhausted	• Turn down the volume • Use less gel • Replace the batteries
Weak sound output	• Audio volume too low • Insufficient gel • Battery is exhausted	• Turn up the volume • Add gel • Replace the battery
Low sensitivity	• Incorrect probe position • Insufficient gel	• Locate the correct position • Add gel

8. WARRANTY AND SERVICE

We provide 1 year warranty for material and manufacturing defects of the product.
The warranty does not apply:
- in case of damage caused by improper operation
- for wearing parts
- for defects that were already known to the customer at the time of purchase
- in case of the customer's own fault

The statutory warranties of the customer remain unaffected by the guarantee.
For the assertion of a warranty claim within the warranty period, the customer must provide proof of purchase.
The guarantee is valid for a period of 1 year from the date of purchase against
Novidion GmbH, Fuggerstr. 30, 51149 Cologne, Germany
to assert its rights. The customer has the right to have the goods repaired by us in case of a warranty claim or at workshops authorised by us.
The customer is not granted any further rights based on the warranty.

Vertrieb durch/ Distribution by/ Distribución por/ Distribué par/ Distribuito da:
Novidion GmbH, Köln

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EC Representative
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Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Bei Fragen wenden Sie sich bitte an/If you have any questions, please contact:/Si tiene alguna pregunta, póngase en contacto con nosotros/Si vous avez une question s'il vous plaît contacter/Se si dispone di una domanda si prega di contattare:
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WEEE: DE24355330

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https://www.pulox.de/Anleitungen-Datenblaetter-Retouren

APPENDIX

Appendix A: EMC Information-Guidance and Manufacture's Declaration

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

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

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

A1.1 Electromagnetic Emissions

The **Fetal Doppler** is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal heart monitor should assure that it is used in such an environment.		
Emissions	**test**	**Compliance**
RF emissions CISPR 11	Group 1	The **Fetal Doppler** uses RF energy only for its internal function. Therefore, its RF emissions are very low, and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **Fetal Doppler** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

A 1.2 Electromagnetic Immunity

The **Fetal Doppler** is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal Doppler should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field lEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

A 1.3 Electromagnetic Immunity (not life-supporting)

The **Fetal Doppler** is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal Doppler should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	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 $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz a. Where P is the maximum output power

			rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Fetal Doppler** is used exceeds the applicable RF compliance level above, the **Fetal Doppler** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Fetal Doppler**.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A 1.4 Recommended Separation Distances

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

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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