FDA CE 0482

JPD-100S（mini）

Fetal Doppler

AngelSounds®

INSTRUCTION MANUAL

Manual Version: V1.1
Issuing Date: 2012.11.2

Product Information

Product Name: Fetal Doppler

Model: JPD-100S（mini）

Manufacturer: Shenzhen Jumper Medical Equipment Co., Ltd

Address: 5th Floor Building No. 34, Baoyuan Industrial Zone, Xixiang Street, Baoan District, Shenzhen 518102 ,P.R. China

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Statement

Precaution Labels Definition

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.

NOTE: The label indicates what you should attention.

Table of contents

Section 1: Instruction

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

CAUTION: 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.

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

1.1 Contact Information

Manufacturer: Shenzhen Jumper Medical Equipment Co., Limited;
Manufacturer Address: 5th Floor Building No. 34, Baoyuan Industrial Zone, Xixiang Street, Baoan District, Shenzhen 518102 ,P.R. China
Telephone Number: +86-755-26696279
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Web site: http://www.jumper-medical.com

Manufacturing:

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Authorized European Representative:

EC REP

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Tingting Yan
CHINESE LEGAL CONSULTANT, LLC.
2836 rainview dr. san jose, CA 95133
Phone: 408-729-3833
Fax: 408-729-3844
Email: rghtty@sbcglobal.net

Order Entry:
To order additional Ultrasonic Instrument or accessories:
Worldwide
Web site: http://www.jumper-medical.com

Customer Service:
To receive customer support:

U.S. and Canada	Outside U.S. and Canada
408-729-3833	+ 86 755 26696279
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Email: rghtty@sbcglobal.net	Email: info@jumper-medical.com

1.2 Indication for Use

The AngelSounds Fetal Doppler JPD-100S (mini) is a prescription from licensed physician in hospitals, clinics and private offices. It is intended to be used by care professionals including practical nurses, midwives, relative technicians, and physician assistants.
This device can detect the Fetal Heart Rate. Connect the headset allows for hearing the sound of the fetal heartbeat. You can count the fetal heartbeat rate when listening. This device normally is applied to 12 weeks gestation or later, difference in pregnant mater.
The device detects fetal life from early gestation thru delivery, and it can be a general indication of fetal well being. It can also be used to verify fetal heart viability following patient trauma.

1.3 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 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”.

The Product is powered by a 9V internal battery.

1.4 Operating Principle

Fetal Doppler consists of transmitter unit, receiver unit, signal process unit, and signal output unit (such as speaker, headset, display screen etc).

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 signal demodulate unit to get the Doppler frequency signal, and process the signal become the signal that can be heard by human using headset.

1.5 Contraindications for Use

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

1.6 Adverse effects

No adverse effect.

Section 2: Safety Guidance

This product is internal powered equipment, and the degree of shock protection is BF.

It means that these person connections will comply with permitted leakage currents, dielectric strengths of IEC/EN60601.

2.1 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 heed these safety alerts before attempting to operate the Product.

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

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

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

WARNING: Practice the ALARA principle

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

WARNING: Aid healthcare professional tool
The product should not be used in place of normal fetal monitoring. It is a tool to aid the healthcare professional.

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.

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

CAUTION: Systems Statement
Equipment connected to the Product must be certified to the respective IEC Standards (i.e. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. 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 601-1-1. 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 a 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.

CAUTION: Product recycling or disposal
The product could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

2.2 Symbols

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

Consult instructions for use of the Product and/or its accessories.

Warning Information

Authorized Representative in the European Community

CE Mark: The Product system conforms to essential requirements of the Medical Device Directive 93/42/EEC.

Date of manufacture.

Manufacturer

Specifies serial number of the Product

LOT Number

It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.

Section 3: Getting Started

This section presents information on unpacking the Product.
This section contains a list of parts for product. To place an order, contact your representative or distributor.

3.1Unpacking an Inspecting

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify 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 item is packing list:

No.	Item	Quantity	Packed or Unpacked
1	Packing List	1	√
2	Instruction Manual	1	√
3	Main Unit	1	√
4	Line-in Cable	1	√
5	Headset	1	√

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 setup the Product if anything is damaged or defective. Contact Jumper Medical Equipment Co., Limited Ultrasonic Instrument Customer Service immediately if anything is damaged or defective.

3.2Accessories

ACCESSORIES	
Part Number	**Description**
none	

4.2 Indicator

There is an indicating light on JPD-100S(mini).

Function: Power on indicate.

4.3 Knob

There is a knob on JPD-100S(mini).
Power on/off and volume knob

Function: Power on or off the device, change the volume of the speaker.

4.4 Socket

There are one headset socket and one USB interface used as audio out socket at the device.

The headset socket can be connected with headset.
The USB interface is used to connect Line-in Cable (**NOTE:** please refer to accessories).

4.5 Battery

This device is internal powered. The power of JPD-100S (mini) comes from a 9V alkaline battery (IEC type No. 6F22 or equivalent).

Section 5: Operation procedure

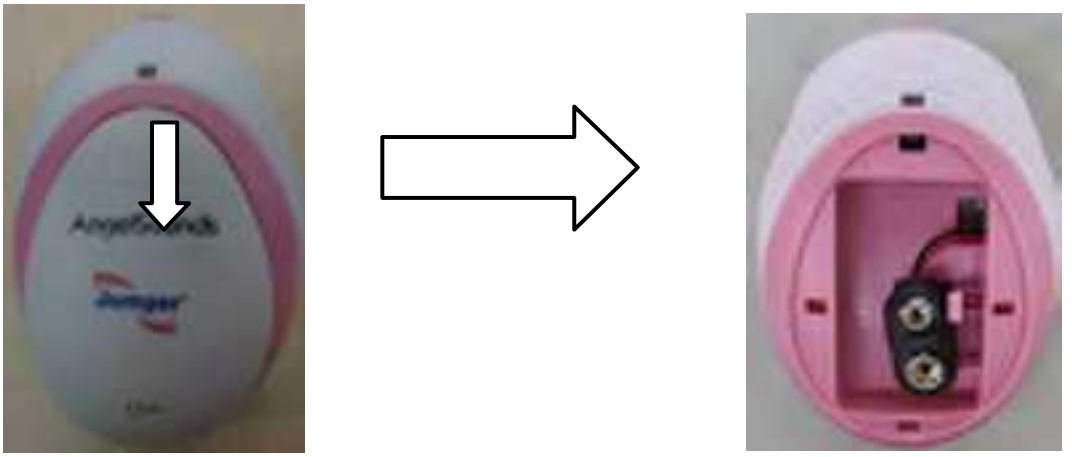
This section provides the description for operation.

5.1 Preparation

Follow these recommendations to preparation for operation:

5.1.1 Install Battery

Open the battery cover, and install the 9V battery. Then, cover the



battery cover.

NOTE：You should push the battery cover backward like the figure upward.

Then you can open the battery cover.

Battery type: Alkaline battery 9V

CAUTION:

Remove the battery if the device is not likely to be used for some time. And keep the battery in cool and dry environment.

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

5.1.2 Connect headset

Before you practice the product, you should prepare an earphone or a headset to hear the fetal heartbeat sound.

We will give you a headset as a present. It can help you to hear the fetal heartbeat sound when you have not bought an earphone.

Insert the headset-plug into headset socket, and wire the handset.

5.1.3 Power on by turning the Power on/off and volume knob

1. On/Off/Volume Knob

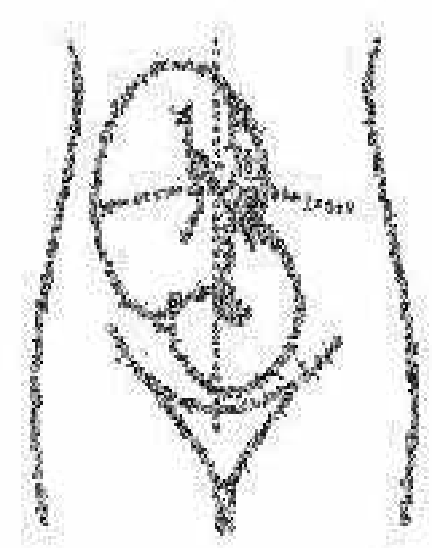
5.1.4 Remove clothes from the pregnant maternal abdomen.

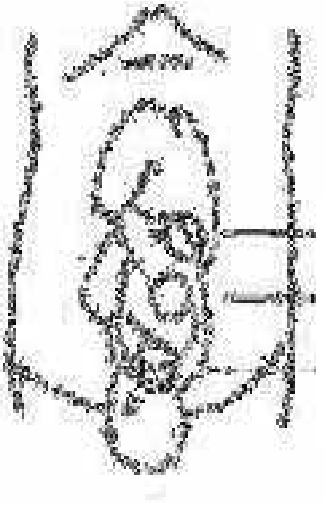
5.1.5 Applying couple gel to the faceplate (4. Transducer) of probe or abdomen of pregnant woman.

5.2 Detecting

5.2.1 Find the fetal heart and listen the fetal heartbeat sound

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





Gestation

Antepartum

Parturition

5.2.2 Calculate the fetal heartbeat rate

Count the fetal heartbeat sound in one minute, the number you counted is the fetal heartbeat rate. Repeat count at least 3 times, you will get the range of fetal heartbeat rate.

5.3 Recording

When you hear the fetal heartbeat sound, you can connect one socket with a headset, and another can connect with computer. You can replay the recorded sound files anytime, and you can send them whoever you want.

Section 6 Preventive maintenance

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.

6.1 Maintenance

WARNING: Failure on 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.

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

2. 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.

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 7 for Temperature Specifications.
- The Product requires no calibration.

6.2 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.
- Verify that the Safety label on back of the product is clearly legible

INSTRUCTION	INSPECT FOR	RECOMMENDED REMEDY
Examine the case connectors and accessories	Foreign substances	Clean the Product and its accessories as described.
	Damage or cracks	Contact Our Customer Service
Examine accessory cables	Foreign substances	Clean the cables as described in the Section 5
	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.

6.3 Cleaning Product and Accessories

Listed below are recommendations for cleaning the Product and its accessories.

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

- Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
- Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
- Do not clean electrical contacts or connectors with bleach.

Cleaning instructions:

1. Before cleaning the Product, turn off the device 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 of dust and dirt, clean exterior surface of the

unit with a dry, soft cloth .if necessary, clean it with a soft cloth soaked in a solution of soap and wipe dry with a clean cloth immediately. Wipe the transducer body with soft cloth to remove any remaining coupling gel .Clean with soap only

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.

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* 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.

6.4 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

6.5 Recycle Batteries

The battery is 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.

6.6 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., Limited Service.

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

Section 7: Technical specifications

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

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

Product name: Fetal Doppler

Mode: JPD-100S(mini)
Safety: Complies with IEC 60601-1: 1990 + A1:1993 + A2:1995, EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996, EN60601-1-2:2001, IEC 61266:1994

Classification:

Anti-electric shock type: Internal powered equipment

Anti-electric shock degree: Type BF equipment

Classification of protection against harmful ingress of water: Ordinary protection IPX0

Methods of sterilization or disinfection: No disinfection required the equipment

Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in the presence of flammable gases

Mode of operation: Continuous operation

EMC: Group I Class B

Technical parameters:

Ultrasound:

Ultrasonic emitting frequency: 3MHz

Ultrasonic emitting power: <10mW/cm^2

Overall sensitivity at the distances 200mm from the face of the probe (Doppler frequency: 500±50Hz, Target velocity: 10cm/s~40cm/s): ≥90dB

Spatial-peak temporal-peak acoustic pressure: ≤1MPa

Output power: <20mW

Effective area of the ultrasonic transducer active element:2.65cm^2±0.3cm^2

The acoustic coupling medium for normal use: ph: 5.5~8, Acoustic impedance: ≤$1.7*10^5$g /cm^2·s

Working mode: Continuous wave Doppler

Audio output:

Audio output power: <0.5 W

Audio out Socket: Φ3.5mm/USB interface

Recommended battery type:

9V DC alkaline battery (IEC Type No. 6F22 or equivalent)

Stand-by Time: >4hours

Suitable gestation: 12 gestational weeks or later, difference in pregnant mater.

Physical Characteristic:

Size: 104.5(length) * 50(width) * 70(height) mm

Weight: 69.5g (only main unit, not including battery)

Environmental Requirements:

Operating Conditions:

Temperature: 5°C to 40°C

Humidity: 0 to 80% RH, non-condensing

Atmospheric pressure: 860hPa to 1060hPa

Storage and Shipping Conditions:

Temperature: -10°C to 60°C

Humidity: 0 to 95% RH, non-condensing

Atmospheric pressure: 500hPa to 1060hPa

CAUTION: Environment of use

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.

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.

NOTE: The device is not user serviceable, and service must be down by authorized persons. Or contact customer service of Jumper Medical Equipment Co., Limited

Appendix A EMC Information

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 %.

A 1.3 Electromagnetic Immunity (not life-supporting)

' is intended for use in the electromagnetic environment specified er or the user of the Fetal Doppler should assure that it is used in nt.

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.

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