

User's Manual



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The purpose of this manual is to guide the user in the operation and care of the Digital Doppler. Every reasonable effort has been made to present accurate information. Stork Radio hereby disclaims and makes no warranty with respect to any diagnosis, clinical condition or interpretation made based on the information presented herein.



Warning: This product is not intended for use on or around the eyes. This product is not intended for use on non-intact skin.

LIMITATIONS

The theory of Doppler ultrasound is beyond the scope of this manual, but is covered in many recent publications. The Digital Doppler is designed to be reliable, but as with all medical instruments, should be treated with care. While the Digital Doppler augments the user's skills, it is not a substitute for medical training and knowledge.

NOTE: The Digital Doppler provides the listener with information about the fetal condition. Under poor signal conditions, the fetal heart sounds and readings may not be accurate. (Refer to the Troubleshooting section at the end of this manual for a description of sensitivity problems and solutions.) If there is any doubt about the fetal condition after using the Doppler, further investigation should be initiated immediately.

PRODUCT DESCRIPTION

The Digital Doppler is a non-invasive hand-held Doppler with a speaker. The Digital Doppler has the following special features that will enhance your product use:

On/Off: ①

Pressing the "On/Off" button on the front panel of the unit turns on the Digital Doppler. The Digital Doppler is turned off by again pressing the "On/Off" button.



Heart Rate/Low Battery Indicator: ♥

The digital display shows heart rate. The display flashes when batteries are low.

Probe Connector: ②

Disconnect the probe by holding the probe in one hand, grasping the connector at the bottom of the probe in the other hand, firmly depressing the clear tab on the connector, and pulling the connector from the probe.

Warning



THE DIGITAL DOPPLER IS NOT EXPLOSION PROOF. DO NOT USE THE DIGITAL DOPPLER OR PROBES IN THE PRESENCE OF FLAMMABLE OR EXPLOSIVE GASES. DO NOT IMMERSE THE UNIT OR PROBES IN FLUIDS AND DO NOT AUTOCLAVE.

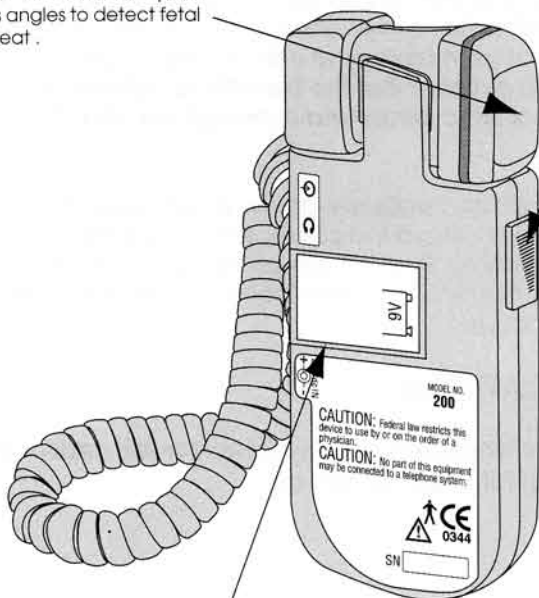
Probe Face:

Place 3MHz probe flat on skin. There is no need to tip at various angles to detect fetal heartbeat.

Volume control:



Volume is adjusted by sliding the "Volume" control button on the side of the unit. Slide the button up to make the sound louder. Slide the button down to make the sound quieter.



Battery Replacement:



To replace a battery, remove the battery compartment door and remove the old battery. Carefully install the new battery with the connector end as shown on the label. Replace the battery compartment door.

SAFETY OF ULTRASOUND

The American Institute of Ultrasound in Medicine (AIUM) has addressed the concerns relating to the safety of ultrasound and has issued the following statement as of March 1993:

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the AIUM herein addresses the clinical safety of such use:

"No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present."

Stork Radio's policy is to always use as low an ultrasound power as practical. The level of ultrasound power emitted by the Digital Doppler is not adjustable. Prudent use on the operator's part would include minimizing the length of time that the patient is undergoing the ultrasound exposure.

CONTRAINDICATIONS

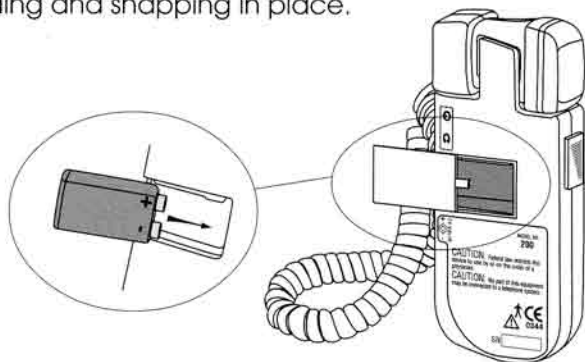
The Digital Doppler is not for invasive use, not for use near or on non-intact skin and not for use near the eyes.

OPERATION

Remove the probe from the main unit by grasping the probe and pulling it straight up and away from the unit. Turn on the unit by pressing the "On/Off" button.

1. Make sure the probe cable is connected at both the probe and the main unit.
2. Apply gel to the face of the probe and begin the Doppler examination.
3. Adjust the volume on the main unit as needed, by sliding the slider up to increase the volume or down to decrease the volume.

4. When finished with the exam, turn the unit off by pressing the "On/Off" button.
5. Refer to cleaning instructions to clean the probe.
6. To replace the battery, firmly push down on the battery door and slide the door off. Remove the existing battery. To replace with a new battery, align the battery as indicated on the battery door and in the diagram. Replace the battery door by sliding and snapping in place.



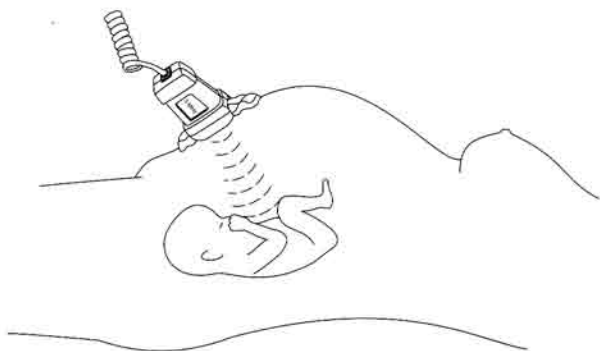
Obstetrical Exams

Doppler ultrasound in an obstetrical application is used primarily to reassure the mother of the presence of fetal viability. In some patients the fetal heart can be heard as early as 8 to 12 weeks. It should be audible 95% of the time in 12-week pregnancies and nearly 100% after 14 weeks.

The 3 MHz probe is designed to be used early in pregnancy.

The exam is most easily done with the mother supine, although it may also be accomplished in a sitting or standing position. Expose the abdomen and apply a generous amount of coupling gel to the face of the probe. It is important to maintain good coupling at all times with no air bubbles between the probe and the abdomen.

The key to the examination is to intercept the fetal heart with the beam from the probe. The beam travels in a relatively straight direction much like a flashlight beam.



In the first trimester, the best technique is to start with the probe on the midline of the abdomen and aimed downward behind the pubic bone. The probe should be moved very slowly to search the most likely areas. Because the fetal heart sounds are faint at this time, be careful not to scan too quickly or the sounds may be missed.

It is often difficult to find the fetal heartbeat during the first trimester and this by itself is not a cause for alarm. A full bladder may make finding the heartbeat a little easier.

The fetal heartbeat sounds like a galloping horse and is about twice the speed of the mother's heart rate. The heart rate will be displayed in the LCD display. The placental blood flow sounds more like a whirlwind.

NOTE: The Digital Doppler provides the listener with information about the fetus; however if there is any doubt about fetal condition after using the Doppler, further investigation must be initiated immediately.

When you have completed the exam, press the "On/Off" button to turn off the Digital Doppler. Then wipe the gel off the face of the probe. Return the probe to the top of the unit for protection.

GENERAL HINTS

Use plenty of coupling gel. Ultrasound is almost completely stopped by any air or bubbles between the skin and the probe. Use the ultrasound gel liberally for best results.

Move the probe slowly. When searching for the fetal heart, a slow rocking and rotating motion will minimize noise and help avoid missing the heartbeat. Rest your hand on the patient to stabilize the probe and to avoid unwanted motion and noise.

Maintain probe contact. It is important to keep the entire probe face in contact with the skin surface. Holding the probe in this manner allows you to obtain the best possible sounds.

Angling. The 3 MHz probe is designed to achieve optimum results without angling - lay the probe face down against the skin.

Carrying the unit. Always check the probe to make sure it is completely seated in the holding clips. Never presume the probe is lodged tightly.

Care of the Instrument

Main Unit



Keep the instrument clean by wiping it periodically with a damp cloth and mild disinfectant cleaner. DO NOT immerse in fluids or use solvent cleaners.

Doppler Probes



Caution: DO NOT USE organic cleaning agents or alcohol. DO NOT immerse the probes in liquid.

Note: The following steps are recommended for the cleaning and disinfecting of Stork Radio probes before each use. The procedure renders clean probes which are neither sterile nor pyrogen free. When carried out according to standard clinical practice, it should help prevent the transfer of infectious agents, through the elimination of significant microbiological contamination between uses.



The probe should be wiped clean with a soft non-abrasive cloth or disposable wipe soaked in an aqueous disinfectant. Avoid aerosol preparations of disinfecting agents, since they may contain alcohol or organic solvents.

The probe should then be wiped with a non-abrasive cloth moistened with water.

Clean, dry probes should be packaged in clean bags, covered trays, or other suitable systems for storage and transport.



If sterilization of the probes is desired, it can be done with cold gas sterilization (such as ethylene oxide at less than 140° F), or the Sterrad™ System. The user is responsible for verification of sterility. Follow the manufacturer's instruction for your model.



Note: Only sterilize the probe with these methods. Do not sterilize the main unit in this manner.



Battery

Remove battery if the Digital Doppler will not be in use for an extended period. Do not expose to temperatures greater than 65°C (149°F).

Transport and Storage

Temperature: -20°C to 60°C

Humidity: 15% to 90% (non-condensing)

Pressure: 500 hPa to 1060 hPa


Product Compatibility

The Digital Doppler was not designed to be compatible with other products. Stork Radio recommends using only Stork Radio-brand accessories that have been approved for use with the Digital Doppler.



Warning: No part of the Digital Doppler is to be connected to a telephone system.

SPECIFICATIONS

Dimensions:	17cm x 7.5cm x 2.5cm (6.8" x 2.9" x 1.0")
Weight (with one probe):	Approximately 0.25 kg (.60 lb.)
Doppler Technology:	Continuous Wave (CW) Unfocused.
Battery Type:	9 volt alkaline
Operational Temperature:	10 to 32 degrees C (50 to 90 degrees F)
Speaker:	2.25", 8 Ω (Ohms)
Audio Output:	1/4 watt typical
Frequency Response:	-3dB @ 391 Hz and 1.2 K
Safety Standards:	IEC 601-1 and IEC601-1-2 (if applicable and only when using the appropriate recharger)
Classification:	Internally Powered Equipment, Type B 
Display Rate (BPM):	60-199 \pm 2 for OB Probe

Acoustic Output Reporting Table

Transducer Model: Digital Doppler 3MHz

Operating Mode: Continuous Wave (cw)

Application(s): Continuous Fetal Heart Monitoring

Acoustic Output		MI	I _{SPTA.3} (mW/cm ²)	I _{SPPA.3} (W/cm ²)	
Global Maximum Value		.028	55.4	.055	
Associated Acoustic Parameter:	P _{f,3} (MPa)	.116			
	W ₀ (mW)		20.0	20.0	
	f _c (MHz)	3.04	3.04	3.04	
	Z _{sp} (cm)	0.9	0.9	0.9	
	Beam dimensions	x ₋₆ (cm)		1.01	1.01
		y ₋₆ (cm)		0.85	0.85
	EBD	Az. (cm)		1.02	
Ele. (cm)			1.40		



When in the presence of audible interference the heart rate display may be inaccurate.

- $I_{SPTA,3}$ - The **derated spatial-peak, temporal-average intensity** (milliwatts per square centimeter).
- $I_{SPPA,3}$ - The **derated spatial-peak, pulse-average intensity** (milliwatts per square centimeter).
- MI - The **Mechanical Index**.
- $P_{r,3}$ - The **peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported under MI.
- W_0 - The total time-average **ultrasonic power** (milliwatts).
- f_c - The probe **center frequency** (MHz).
- z_{sp} - The axial distance at which the reported parameter is measured (centimeters).
- x_{-6} & y_{-6} - The -6dB beam dimensions in the x-y plane where z_{sp} is found (centimeters).
- EBD** - the **entrance beam dimensions** (centimeters). These dimensions are the same as the dimensions of the transmit crystal.

Operating Conditions: There are no user controls which affect the ultrasound output.

Measurement Uncertainties:	Power:	+29% -42%
	Pressure:	+17% -23%
	Intensity:	+18% -29%
	Frequency:	+1% -1%

Additional Information for IEC-1157

The output beam intensity $I_{00} = 48 \text{ mW/cm}^2$

This transducer is intended for direct patient contact.

The probe face has a liquid ingress level of IPX4.

Troubleshooting Digital Doppler Problems

Problem:

Unit will not turn on

Heart rate display flashes

Main unit is on, but no audio

Static

Weak or no fetal signal detected

Solution:

a. Battery is discharged. Replace battery.

a. Main unit battery is low and should be replaced.

a. Probe is not plugged in.

a. Use an ample supply of ultrasonic coupling gel. Hold the probe steady once a signal has been detected.

b. Some coupling agents, such as baby oil, may cause extra static.

c. Reduce the volume level.

a. Fetus is too young. Wait a few weeks before trying the test again.

b. Use plenty of coupling gel.

c. Try turning up the volume.

No fetal heart rate displayed with audible tones	<ul style="list-style-type: none"> a. Fetal heart rate is outside of display range. See Specifications Section. b. The detected signal is blood flow or placental flow. The characteristics of placental flow sounds produce a smooth Doppler envelope. A very smooth envelope will not correlate well, so no rate is displayed. Reposition the probe.
Unit shuts off during use	<ul style="list-style-type: none"> a. The unit shuts off after approximately 3 minutes if not in use. Large signals are used to reset the power-off-timer. Faint signals may not reset the timer. b. Battery is low. Replace.
Unstable fetal heart rate display	<ul style="list-style-type: none"> a. Fetus is too young. Wait a few weeks before trying the test again, or try a manual method for determining heart rate. b. Fetus is moving. Wait a few minutes to see if the fetus settles down. c. Excessive static. Some probe movement patterns may cause erroneous heart rate displays. Refer to the above section on static for recommendations. d. Probe is detecting blood flow sounds. Reposition the probe.
Inaccurate fetal heart rate display	<ul style="list-style-type: none"> a. The detected signal is maternal or maternal mixed with fetal sounds. A maternal sound, usually one half of the fetal sound, may produce harmonics which are in the fetal range. Reposition the probe to detect only fetal sounds. b. Excessive static. Some probe movement patterns may cause erroneous heart rate displays. Refer to the above section on static for recommendations. c. Fetal heart rate is out of the display range. Harmonics may cause doubling of the displayed fetal heart rate.
Audible hum or feedback with no signal present.	<ul style="list-style-type: none"> a. Replace battery.