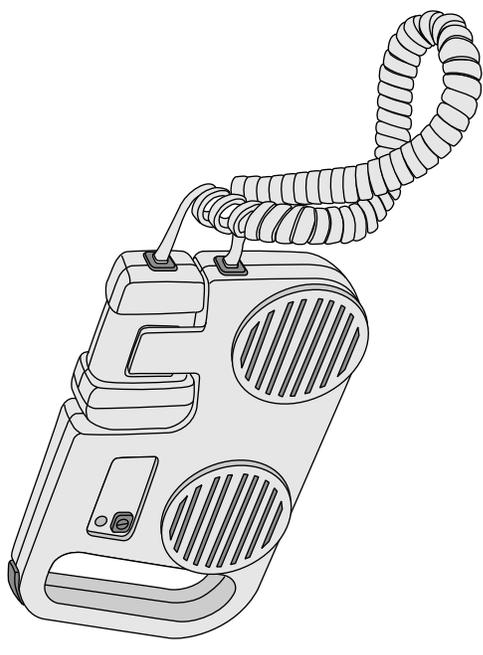


Heartbeats at Home Fetal Doppler User's Manual



SERVICE

It is recommended that all repairs be performed by a qualified service representative only. Service information and assistance is available on the Heartbeats at Home Fetal Doppler by phoning (321) 303-7643 Toll-Free (866) 851-BABY, or visit our website at www.HeartbeatsAtHome.com

Prior to shipping, please contact Heartbeats at Home, LLC to arrange method of shipment.

Attn: Service

Heartbeats at Home, LLC

14402 Stamford Circle

Orlando, FL 32826

Date of Manufacture

To determine the year this product was manufactured go to the back of the unit and look at the third digit of the serial number. Example: CKD; The product was produced in 2003. Refer to the following for the alpha-numeric designation of the year of manufacture:

C=2002 E=2004 G=2006 I=2008 K=2010

D=2003 F=2005 H=2007 J=2009 L=2011 and so on through...Z=2025.

INDICATIONS/CONTRAINDICATIONS

The Heartbeats at Home Fetal Doppler is indicated for the following conditions:

2 MHz + 3 MHz: Determination of fetal viability.

 Do not use on eyes; do not use invasively. Not for use near or on non-intact skin.

INTENDED USES

The Heartbeats at Home Fetal Doppler is used for:

2 MHz: The detection of fetal life.

3 MHz: The early detection of fetal life.

Congratulations on your choice of the

Heartbeats at Home Fetal Doppler

The Heartbeats at Home Fetal Doppler provides the features which have made it a world leader in Doppler technology: reliability, quality, sensitivity and value.

CAUTION: Federal law (USA) restricts this device to use by or on the order of a physician.



The  Mark identifies compliance with the Medical Device Directive 93/42/EEC.

Distributor

Heartbeats at Home, LLC

14402 Stamford Circle

Orlando, FL 32826

www.heartbeatsathome.com

Phone: (321) 303-7643

Toll-Free: (866) 851-BABY

Manufacturer

Nicolet Vascular

Madison, WI USA

European Authorized

Representative:

VIASYS Healthcare

Wellton Road

Warwick, CV345PZ U.K.

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The purpose of this manual is to guide the user in the operation and care of the Heartbeats at Home Fetal Doppler. Every reasonable effort has been made to present accurate information. Heartbeats at Home, LLC hereby disclaims and makes no warranty with respect to any diagnosis, clinical condition or interpretation made based on the information presented herein. Refer to the Limited Warranty sent with your Heartbeats at Home Fetal Doppler for the equipment warranty.

Troubleshooting Heartbeats at Home Fetal Doppler Problems

Note: If the system is not functioning properly, do not operate until all necessary repairs are made and the unit is tested for proper functioning in accordance with Heartbeats at Home, LLC published specifications. It is recommended that all repairs be performed by a qualified service representative only.

Problem	Solution
Unit will not turn on.	a. Battery is dead.
Unit is on, but no audio signal is present.	a. Headphones interrupt the internal speakers. b. Probe not plugged in.
Static.	a. Use an ample supply of ultrasonic gel. Hold the probe steady once a signal has been detected. b. Some coupling agents, such as baby oil, may cause extra static.
LED is red.	c. Reduce the volume level. a. Battery is OK. b. Probe is unplugged. c. Probe cable is defective.
LED flashes.	a. Battery is low. b. Probe is unplugged. c. Probe cable is defective.
Weak or no fetal signal detected.	a. Fetus is too young. b. Be sure to use the 3 MHz probe for fetal use. c. When in the presence of radio frequency interference, blood flow sounds may become diminished.
Weak blood flow signal.	a. The long side of the probe face should be aligned with the blood vessel. b. Use an ample amount of coupling gel. c. When in the presence of radio frequency interference, blood flow sounds may become diminished.

SPECIFICATIONS (continued)

- Global Maximum** values are the maximum expected values based on statistical analysis of one production lot:
- The **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter), $I_{SPTA,3}$
 - The **derated spatial-peak pulse-average intensity** (watts per square centimeter), $I_{PPA,3}$
 - The **mechanical index**, MI
 - The **peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported for MI , P_r
 - The total time-average **ultrasonic power** (milliwatts), W_o
 - The probe **center frequency** (MHz), f_c
 - The axial distance at which the reported parameter is measured (centimeters), Z_o
 - The -6 dB beam dimensions in the x-y plane where Z_o is found (centimeters), X_o, Y_o
 - The entrance beam dimensions (centimeters). These dimensions are the same as the dimensions of the transmit crystal, **EBD**

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 IEC1157 Requirements:

- 3 MHz: This probe is exempted from labeling requirements of IEC1157 because the following inequalities are met:
 - Spatial-peak temporal-average intensity (I_{SPTA}) < 100 mW/cm²
 - Output beam intensity (lob) < 20 mW/cm²
 - Peak negative acoustic pressure (P) < 1MPa

BATTERY:

9V Alkaline IEC: 6LR61
NEMA: 1604A

Headphone Type:

8 to 32 Ohm, 3.5 mm mono plug

Audio Output:

0.5 watt typical

Speakers:

two 2.25 inch (5.7 cm), 0.3 watt each

Cord:

telephone handset style

Battery Life (1 minute exams):

3 MHz 250 minimum

Frequency Response:

-3 dB @ 330 Hz and 950 Hz

Safety Standards:

IEC601-1-1, IEC601-1-2

PRODUCT DESCRIPTION

The Heartbeats at Home Fetal Doppler is a non-invasive hand-held Doppler with dual speakers. The Heartbeats at Home Fetal Doppler has the following special features which will enhance your use of the product.

Volume Control

Volume is easily adjusted by sliding the volume control slider on the edge of the unit's handle. Slide the button up toward the large part of the arrow to make the volume louder. Slide the button down toward the small part of the arrow to make the volume quieter.

Probe Face

Place the flat end on the skin. There is no need to tip at various angles to detect fetal heartbeat.

Power Indicator/Low Battery Indicator

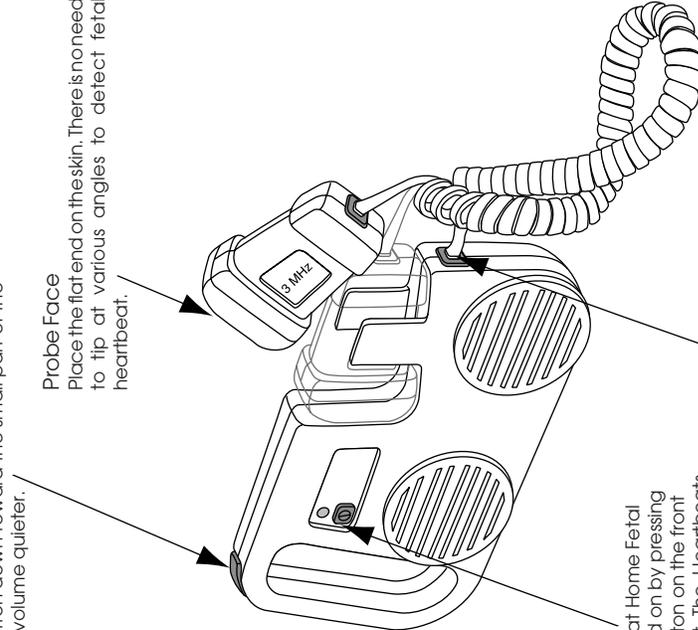
The green light turns on to indicate that the unit is turned on. It flashes green to indicate that the battery is low. It turns red when the battery is low enough that the integrity of operation cannot be guaranteed and the battery needs to be replaced.

Easy ON/OFF

The Heartbeats at Home Fetal Doppler is turned on by pressing the ON/OFF button on the front panel of the unit. The Heartbeats at Home Fetal Doppler is turned off by again pressing the on/off button.

Probe Connector

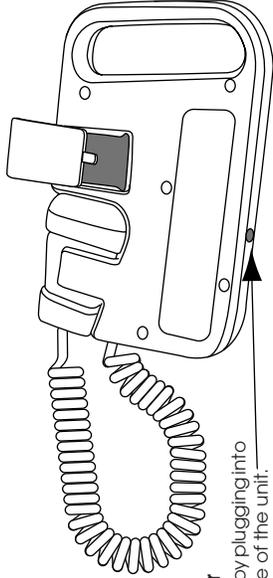
Disconnecting the probe is a simple matter of holding the probe in one hand, grasping the connector at the bottom of the probe in the other hand, firmly depressing the clear tab on the connector, and pulling the connector from the probe.



Warning

The Heartbeats at Home Fetal Doppler is not explosion proof. Do not use the Heartbeats at Home Fetal Doppler or probes in the presence of flammable or explosive gases. Do not immerse the unit or probes in fluids and do not autoclave.

PRODUCT DESCRIPTION, continued



Headphone Connector

Headphones can be used by plugging into this connector on the edge of the unit.

ACCESSORIES

Catalog

- N200 2MHz Probe
- N300 3MHz Probe
- NW20 2MHz Waterproof Probe

LIMITATIONS

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

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."

Heartbeats at Home, LLC has always strived to use as low an ultrasound power as practical. The level of ultrasound power emitted by the Heartbeats at Home Fetal 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.

SPECIFICATIONS

- Dimensions:** 7.6" x 4.5" x 1.1" (19 x 11 x 3 cm)
- Weight (with one probe):** 0.9 lb (0.4 kg)
- Doppler Technology:** Continuous Wave (CW) Unfocused.

Acoustic Output Tables

Transducer Model: Heartbeats at Home Fetal Doppler 2MHz
 Operating Mode: Continuous Wave (cw)
 Applications: Continuous fetal heart monitoring

ACOUSTIC OUTPUT		MI	I _{sp1a,3}	I _{sp0a,3}
Global Maximum Value		.031	42.6	.043
Associated Acoustic Parameter	R (Mpa)	.043		
	W ₀ (mW)		13.6	13.6
	f _c (MHz)	2.0	2.0	2.0
	Z ₀ (cm)	1.62	1.62	1.62
Beam Dimensions				
	x ₋₆ (cm)		0.8	0.8
	y ₋₆ (cm)		0.4	0.4
	Az (cm)		0.79	
EBD				
	Ele. (cm)		1.58	

Transducer Model: Heartbeats at Home Fetal Doppler 3MHz
 Operating Mode: Continuous Wave (cw)
 Applications: Continuous fetal heart monitoring

ACOUSTIC OUTPUT		MI	I _{sp1a}	I _{sp0a}
Global Maximum Value		.028	55.4	.055
Associated Acoustic Parameter	Pr (Mpa)	.116		
	W ₀ (mW)		20.0	20.0
	f _c (MHz)	3.04	3.04	3.04
	Z ₀ (cm)	0.9	0.9	0.9
Beam Dimensions				
	x ₋₆ (cm)		1.01	1.01
	y ₋₆ (cm)		0.85	0.85
	Az (cm)		1.02	
EBD				
	Ele. (cm)		1.40	

CARE OF THE INSTRUMENT

Main Unit

Keep the main unit clean by wiping it periodically with a damp cloth and mild disinfectant cleaner. **DO NOT IMMERSE** in fluids. **DO NOT AUTOCLAVE!**

Doppler Probes

⚠ Caution: Do not use organic cleaning agents or alcohol. Do not immerse the probe in liquids. Do not allow detergent solutions to seep into the electronic portions of the system.

Note: The following steps are recommended for the cleaning and disinfection of Heartbeats at Home 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 soaked in water.

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

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

Battery

Remove battery if not in use for extended period.

Transport and Storage

Temperature: -10°C to 60° C
Humidity: 15% to 90% humidity (non-condensing)
Atmospheric Pressure: 500 hPa to 1060 hPa

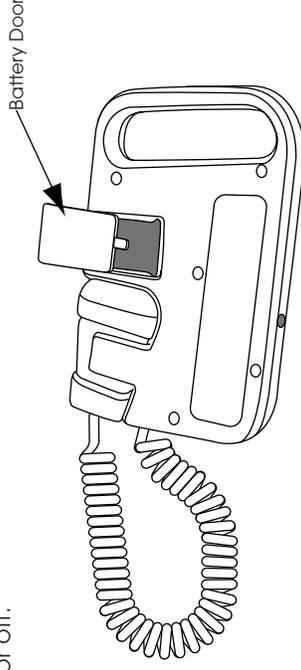
PRODUCT COMPATIBILITY

The Heartbeats at Home Fetal Doppler was not designed to be compatible with other products. Heartbeats at Home, LLC recommends using only Heartbeats at Home-brand accessories that have been approved for use with the Heartbeats at Home Fetal Doppler.

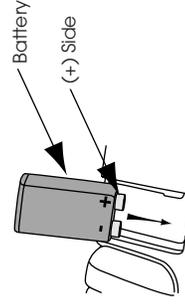
⚠ WARNING: No part of the Heartbeats at Home Fetal Doppler is to be connected to a telephone system.

OPERATION

1. 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.
2. Make sure the probe cable is connected at both the probe and the main unit.
3. Apply gel to the face of the probe and begin the Doppler examination.
4. Adjust the volume of the main unit handle as needed, by sliding the slider up to increase the volume and down to decrease the volume.
5. When you have finished the exam, turn the unit off by pressing the ON/OFF button.
6. Refer to the cleaning instructions to clean the probe.
7. To replace the battery, 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 door and shown below. Replace the battery door by sliding and locking into place.



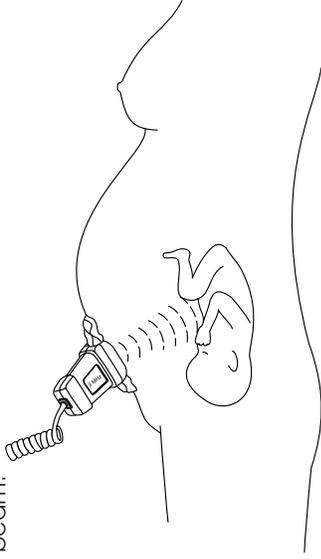
OBSTETRICAL EXAMS

Doppler ultrasound in an obstetrical application is primarily used to reassure the mother of the presence of fetal life. 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% of the time after 14 weeks.

The exam is most easily done with the patient 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 rocked 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 placental blood flow sounds more like a whirlwind.

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



GENERAL HINTS

Use plenty of couplant. Ultrasound is almost completely stopped by any air or bubbles between the skin and the probe. Liberally use the ultrasound gel 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 skin surface. Holding the probe in this manner allows you to obtain the best possible sounds.

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

PRODUCT SAFETY

⚠ CAUTION: Read and understand the User's Manual before use.

CLASSIFICATION ACCORDING TO IEC-601-1:

⚡ Protection against electric shock: Type B
Protection against spill: Ordinary Equipment
Internally Powered Equipment
Mode of Operation: Continuous Operation

WARNING: Equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

WARNING: No part of the Heartbeats at Home Fetal Doppler is to be connected to a telephone system.