

User's Manual  
and useful information



Baby's  Beat™



BabyBeat uses Doppler ultrasound to listen to the wonderful sounds of your baby's heartbeat within the womb – beginning at 10-12 weeks. This product can help you form a special bond with your baby. The BabyBeat requires approval of your healthcare provider before use.

## Thank you for choosing BabyBeat®!

*Read entire manual before operating unit.*

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bbm0311

## Introduction

Ultrasonic Dopplers create little sound waves, about 3 million per second, and then listen for them to return much like dolphins “see” in the open ocean. Just like a dolphin, if the sound waves touch something moving, they become slightly distorted on the return trip. Those distortions are what the BabyBeat Doppler unit magnifies into the speaker for you to hear. It is much more precise and sensitive than just a plain microphone or even a doctor's stethoscope.

Since the 1950's, doctors have used Dopplers to listen to babies' heartbeats. That history, combined with the FDA's clearance to use the BabyBeat for home use, should make you feel very comfortable and confident throughout the rest of your pregnancy.

## Baby Sounds vs. Maternal Sounds

Your baby's heartbeat is about two times faster than yours. Late in your first trimester and early in your second trimester, it may take several attempts to find it.

In addition to the sounds that the baby is making, you will also hear sounds of your own heart, blood flow and the placenta. As you get further along in your pregnancy, the increased flow of blood through the placenta will sound like wind moving through trees. Also, you can expect to hear some instrument noise as you slide and move the Doppler probe across your stomach.

## Other Doppler Technology Uses

While BabyBeat can only “listen” to your baby's heartbeat, this same technology creates the pictures you see at your doctor's office during sonogram imaging. Prized for its safety, ease of use and accuracy, Doppler technology is an excellent choice to monitor your unborn baby.

## Your Baby Moves Around

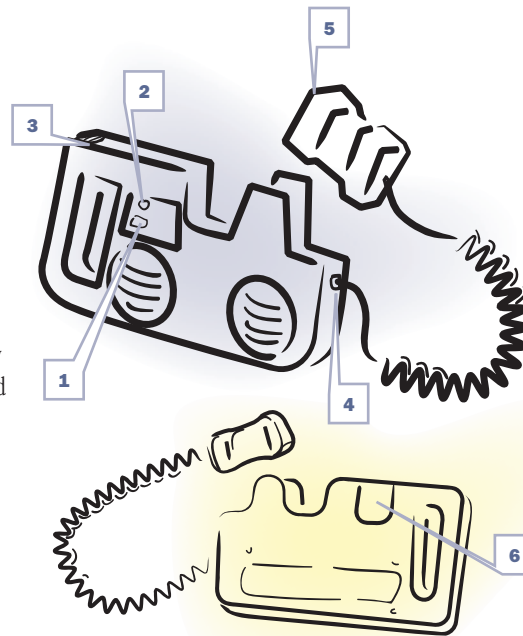
While you will become very good at using the BabyBeat Doppler quickly, remember, the heartbeat may not always be in the same place and you may have to hunt around. Refer to the General Hints and Troubleshooting section if you have questions or concerns.

BabyBeat is not intended for self diagnosis.

## Product Description

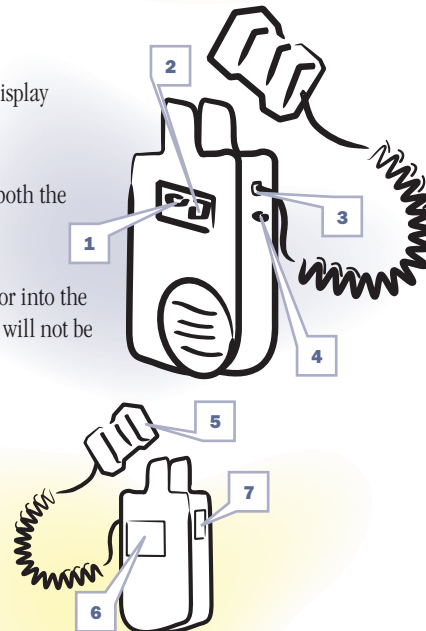
### Model BB100 – Audio Only

1. On/Off
2. Power
  - Green - Unit is on.
  - Flashing Green - Battery is low.
  - Red - Battery needs to be replaced.
3. Volume Control
4. Probe Connector
  - Be certain the cord is securely inserted in both the probe and in the main unit.
5. Probe Face
  - place the flat end on the skin.
6. Battery Door



### Model BB200 – Display

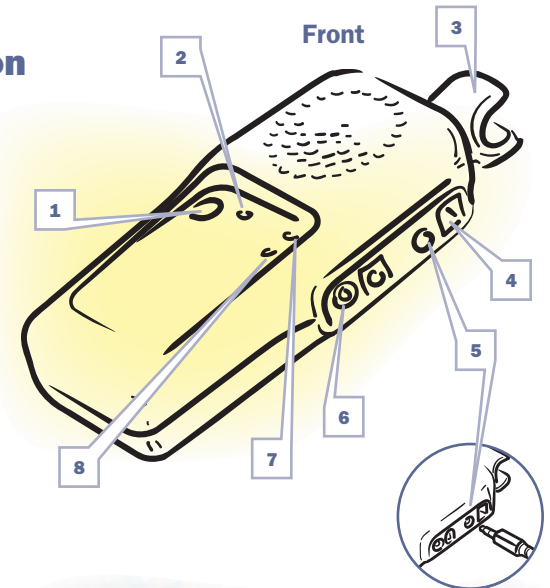
1. On/Off
2. Heart Rate/Low Battery Indicator
  - The digital display shows heart rate. The display flashes when batteries are low.
3. Probe Connector
  - Be certain the cord is securely inserted in both the probe and in the main unit.
4. Headphone Connector
  - To use optional headphones, plug connector into the hole on the edge of the unit. Main speaker will not be heard when headphones are plugged in.
5. Probe Face
  - Place flat end on skin
6. Battery Door
7. Volume Control



## Product Description

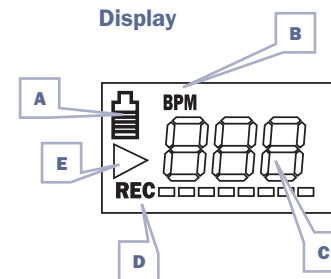
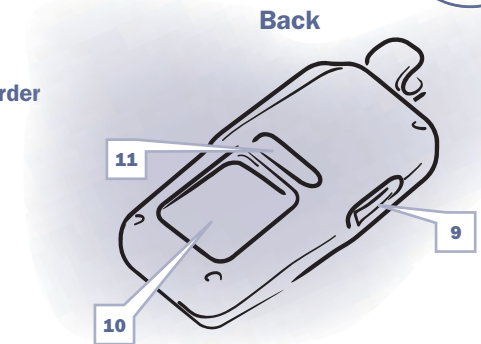
### Model BB150 – Audio 150A – Audio/Recorder

1. On/Off Button
2. Power/Battery LED
3. Probe Clip
4. Probe Connector
5. Headphone/REC Connector
6. Play/Record Button
7. Play LED
8. Record LED
9. Volume Slider
10. Battery Door
11. Model Serial Number



### Model BB250A – Display/Recorder

- A. Battery Charge Level
- B. Heart Rate Indicator
- C. 3 Digit Display Area
- D. Recording Indicator
- E. Playing Indicator



• = only Model BB150A/250A recording units

## Product Description

Model BB300A – Audio/Recorder  
350A – Display/Recorder

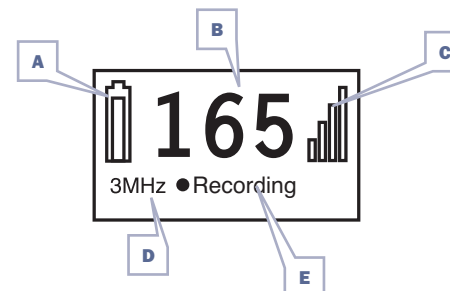
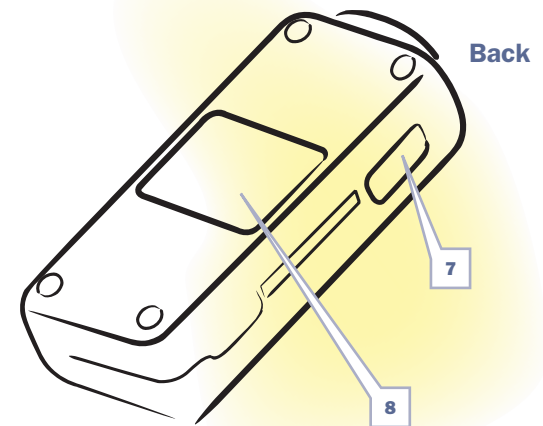
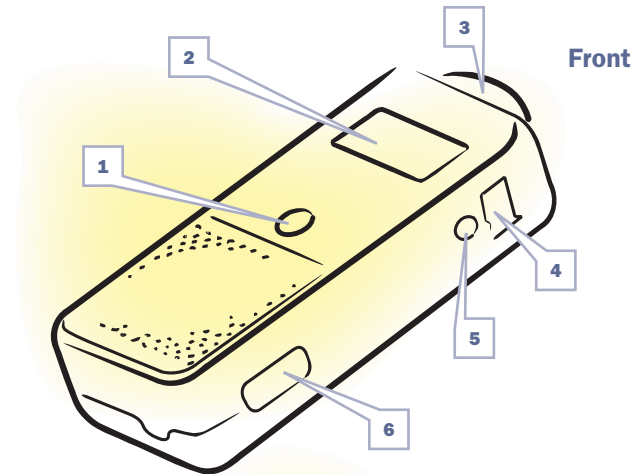
### Turning Unit On/Off

1. On/Off
2. Heart Rate/Battery Indicator
3. Probe Cradle
4. Probe Connector
5. REC Connector
6. Play/Record Button
7. Volume Slider
8. Battery Door

### Display Model Only

- A. Battery Charge Level
- B. Heart Rate Indicator
- C. Signal Strength Indicator
- D. Probe ID Indicator
- E. Record/Play Indicator

**WARNING:** Do not attempt to recharge alkaline batteries.



## Operation and Use

Upon receiving your BabyBeat, we recommend that you take the unit with you to your next prenatal visit. Your caregiver can use the BabyBeat during your exam, provide tips on using it at home and discuss any issues or concerns.

1. Turn the unit on by pressing the On/Off button. LED or LCD indicators (depending on the model) indicate power status.
2. Make sure the cord is plugged into the main unit and the probe.
3. Remove the probe from the main unit and apply ultrasound gel to the face of the probe. It is important to use plenty of gel at all times to insure that there are no air bubbles between the probe and the stomach.
4. You can adjust the volume by moving the Volume Slider on the unit (see drawings on page 4-5).
5. The exam is most easily done with the mother lying down. However, it can also be done sitting or standing.
6. Place the probe on the middle of the stomach below the navel. The probe should be rocked and moved around the stomach very slowly to search for the heartbeat. Be careful not to scan too quickly or the sounds may be missed. Slight pressure may be applied.
7. A full bladder may make finding the heartbeat a little easier.
8. The baby's heartbeat sounds like a galloping horse and is typically about 120-180 beats per minute which is twice the speed of the mother's heart rate
9. With display units a fetal heartbeat must be heard and distinguished before a reliable display reading can be determined.



## Auto Shut-off *(excludes model BB100)*

The BabyBeat automatically shuts itself off after 3 minutes if it is not being used. This complete power shutdown preserves the life of the batteries and ensures the unit will be ready for operation in case it was accidentally left on.

## Battery Monitoring

These BabyBeat Doppler units perform continuous battery monitoring and give a visual indication of battery level.

**BB250A/BB350A** use a multiple level battery shaped icon that indicates the voltage level of the battery. The battery outline will flash when the battery level is very low indicating that the user should change the batteries soon after the current examination is complete.

**BB300A** will flash the LED in the power button to signal low battery level

**BB150/150A** use the On/Off LED as a battery indicator by flashing at a low rate (approximately once per second) when the battery level is low. Several exams can still be performed in this state of operation. The battery indicator will flash at a higher rate (approximately twice per second) when the battery level is very low. The user should change the batteries soon after the current exam is complete.

**BB200** display readout will flash when battery level is low.

**BB100** Light will flash green when low and turn to red when battery is dead and needs to be changed.

## Play and Record

### Models BB150A /BB250A

**Caution:** To distinguish between live audio and playback audio refer to the Play arrow on the display unit or Play light on the standard unit. If the indicator is on, the sound is coming from a recorded signal.

#### Record

To record a new audio file on the BabyBeat Doppler, obtain the desired Doppler signal and press and hold the Play/Record button until the Record icon on display, or Record light on standard comes on (approximately 4 seconds). Once the icon has turned on and the button is released, the Doppler signal will be stored for 32 seconds or until the Play/Record button is pressed again. Either of these events will stop the recording audio mode.

Recording a new audio file automatically overwrites any previous recording.

#### Play

To listen to a pre-recorded audio file on the BabyBeat Doppler, press and release the Play/Record button on the side of the unit. For display units, the Play icon is on during playback. For standard units, the Play light is on during playback. The recorded audio files are not re-processed for heart rate calculation - heart rates must be determined manually in the play mode.

The unit will continue to play the recorded audio until either the end of the stored data, or until the Play/Record button is pressed again. This will stop the playback audio and the unit switches back to real time audio when the indicators turn off. Volume control remains functional during playback.

### Models BB300A /BB350A

#### Record

Press and hold red button. Red light on front of unit will light up. Must hold red button down the whole time. Record time is 30 seconds. Release button to end recording.

For display units, “recording” will also show on LCD display.

#### Play

To listen to a pre-recorded audio file, press and release the play/record button on the side of the unit. Green light on front of unit will light up. For display units, “playing” will also show on LCD display.

## Download to Personal Computer *(Sound Card Required)*

**Warning:** The audio/headphone output should only be connected to external line powered accessories that comply with recognized safety standards such as IEC601-1, IEC60065, UL2601-1 or UL544.

**Warning:** The BabyBeat Doppler is not specified for connection to any line powered accessories while it is being used on a patient.

## For use with Personal Computers (PC)

To download the audio to a PC for permanent storage, connect one end of the provided 3.5 mm audio cable into the Audio Out jack on the side of the BabyBeat. Connect the other end of the cable into your PC sound card “Audio In” port or “Microphone In” port\*.

Using operating system Windows 98 or higher, on your PC select the Sound Recorder Application by selecting: START MENU, PROGRAMS, ACCESSORIES, ENTERTAINMENT, SOUND RECORDER.

Click on the highlighted RECORD icon in the Sound Recorder Application to start recording.

Press the Play button on the side of the BabyBeat Doppler. The audio should now be playing and the PC downloading the audio information as indicated by the graphical sound waveform.

If the sound waveform is a flat line while you are hearing the audio from the BabyBeat, then the recorder input is not selected properly. To choose the proper input, open the Volume Control Application by selecting: START MENU, PROGRAMS, ACCESSORIES, ENTERTAINMENT, VOLUME CONTROL.

Click on Options and then Properties. Click on Recording and ensure that the LINE IN or MICROPHONE box is checked\*\*, then click OK. In the Recording Control Screen, click the Select Box for LINE IN or MICROPHONE and then exit. The recorder is now set up to use the audio as an input. Restart the Sound Recorder Application and record as directed above.

When the audio playback is finished, click on the STOP icon in the Sound Recorder. The file can be played back on the PC by clicking the PLAY icon in the Sound Recorder or the file can be stored by selecting FILE, SAVE AS to locate and name the file.

Refer to your PC User’s Manual for problems associated with the sound card or Sound Recorder Application.

\*The Microphone-In tends to give the best recording results.

\*\* Your selections need to be consistent, ie. if you choose “Microphone In” as the connection on your PC, then you also need to choose “Microphone” in your computer software options.

Continued on next page



## For use with Macintosh

*(Please note: SimpleSound is a program associated with OS 9 or earlier operating systems. For OS X or later operating systems SimpleSound is not needed.)*

To download the audio to a Macintosh for permanent storage, connect one end of the provided 3.5 mm audio cable into the Audio Out jack on the side of the BabyBeat. Connect the other end of the cable into your Mac sound card "Audio In" (microphone) port.

On your Macintosh, open the SimpleSound Application that is usually found in the Apple Menu. If you are unable to locate the application in the Apple Menu, do a FIND for "SIMPLESOUND".

Once you open SimpleSound, an AlertSounds box may be shown. Select File and then New to open a new audio file.

Click on the highlighted RECORD icon in the application to start recording.

Press the Play button on the side of the BabyBeat Doppler. The audio should now be playing and the Macintosh downloading the audio information as indicated by the graphical waveform from the Speaker icon.

If there is no graphical waveform from the Speaker icon while you are hearing the audio from the BabyBeat, then the recorder input is not selected properly. To choose the proper input, return to the Apple Menu and open the Control Panel. Open the Sound Application and select Input. Set "External Mic" as the built in sound source.

The recorder is now set up to use the audio as an input. Restart the SimpleSound Application and record as directed above.

When the audio playback is finished, click on the STOP icon in the recorder. The file can be played back by clicking the PLAY icon in the recorder or the file can be stored by selecting SAVE to locate and name the file.

Refer to your Macintosh User's Manual for problems associated with the sound card or Simple Sound Application.

## Accessories

Contact Medical Equipment Direct at 888-758-8822 to order by phone, or order on-line on our website [www.babybeat.com](http://www.babybeat.com)

## General Hints

For any Doppler examination, it is essential that an adequate supply of ultrasound gel or lotion is used to transmit the ultrasound energy from the probe to the surface of the skin. Re-apply more gel if it starts to dry out or spread so thinly that an air gap occurs between the probe and the skin. It is not necessary to cover the entire surface of the probe, only the probe face. Applying too much gel makes the unit difficult to clean and does not aid in the performance of the probe.

### Volume Slider

The audio level can be adjusted using the Volume Slider. Moving the slider up will increase the volume, while moving it down will decrease it.

### Obstetrical

For early term fetal detection, start the probe at the pubic bone, often right around the top of the pubic hair line and slowly move along the midline – rocking the probe slowly from side to side until a heart beat is heard. For mid to late term fetal detection the best chance of finding the heart sounds is to start slightly above the pubic hair line and move toward the navel and from one side of the abdomen to the other, slowly rocking the probe until the heart beat is heard. The fetal heart reminds many people of a galloping horse and can vary in tone from a distant swishing sound to a hard clapping sound depending on the position of the baby and probe.

Many times when attempting to detect the fetal heart, the mother's sounds are heard instead of (or in some cases, in addition to) the fetal sounds. These maternal sounds can come from one of the major arteries, the placenta or the umbilical cord. The maternal vascular sounds are typically higher in frequency at a lower rate. The heart rate calculation will display either the mother's heart rate (normally between 60-90 beats per minute) or the baby's heart rate (normally between 120-180 beats per minute), whichever portion of the signal is stronger. It is important that a fetal heartbeat be heard and distinguished before a reliable display reading can be determined.

## Maintenance and Cleaning

**Warning:** The BabyBeat is not designed for liquid immersion. Do not soak or drop the Doppler main unit or probe in liquids.

**Warning:** The BabyBeat is not designed for sterilization processes such as autoclaving or gamma radiation.

**Warning:** The BabyBeat is not intended to be used on open skin. If there is evidence of open wound contamination, disinfect the probe before using again as described below.

The BabyBeat Doppler requires very little maintenance. However, it is important to the continuing function of the unit and the health of the patients that the unit is cleaned and examined regularly per the following guideline:

After every examination:

Excess gel should be wiped off prior to docking the probe. You can wipe the probe with a slightly damp cloth.

Store unit in a clean area free from dust and debris. Follow temperature and humidity guidelines as specified at the end of this manual.

**Warning:** If the unit is to be stored for longer than 90 days without use, remove the batteries prior to storage.

## Troubleshooting

**Warning:** Call Medical Equipment Direct if the probe or main unit malfunctions.

### Poor sound quality

Inadequate gel use – may be too much or too little gel.

Try and relocate the probe for a better sound signal.

Unit may be picking up interference from other equipment or radio.

### Heart rate inaccurate

Try and relocate the probe for a better signal.

Be sure that mother's sounds are not mixing with fetal sounds.

Count the heart rate and be sure that the rate is between about 120 and 180 beats per minute.

### Battery indicator flashing

Consult Battery Monitoring, replace batteries as described in Replacing Batteries.

## Replacing Batteries

**Warning:** The battery compartment only accepts AA size batteries (150, 150A, 250A, 300A, 350A), 9 volt batteries required for BB100 and BB200.

Open the battery compartment by depressing the tab and pulling outward on the battery door. Remove the existing drained batteries by pushing on the end of the battery that compresses the battery contact spring and lift upwards. It is acceptable to carefully use a simple tool, such as a pen, to assist in lifting the batteries out.

Replace the batteries by paying close attention to the polarity indicators on the battery and the polarity indicators on the battery holder in the compartment. Positive (+) aligns with positive (button) and negative (-) aligns with negative (spring). Insert the battery such that the spring contacts are loaded first and then press the battery firmly into place. After all three have been inserted, replace the battery door.

**Warning:** If the batteries have been inserted incorrectly, the unit will not function but the BabyBeat will not be damaged.

## Intended Use

BabyBeat (models bb100/150/150A/200/250A/300A/350A) should not be used in any way for diagnostic or medical purposes by anyone other than a medical professional.

BabyBeat should not be used as a substitute for regular prenatal care by a medical practitioner. Any concerns about your pregnancy should be addressed to your care provider.

Fetal heartbeat is not the only indicator of fetal well being, if you have any concerns please consult with your care provider.

## Caution and Safety Statements

**FDA:** Federal law restricts this device to sale by or on the order of a physician.

**Warning:** The ultrasound probes are not to be used on or near the eyes.

**Warning:** The device is for use only on intact skin.

**Warning:** Do not plug any part of this device into a telephone or modem system.

If there are questions or concerns regarding these warnings or contraindications, please do not hesitate to contact Medical Equipment Direct for further clarification.

## Safety of Ultrasound

BabyBeat Dopplers were designed with patient safety in mind. In early design phases all potential hazards were eliminated or reduced to As Low As Reasonably Achievable (ALARA) by adhering to good design practices and industry wide safety standards. Ultrasound procedures should be performed with the ALARA principle in mind when delivering ultrasound energy into the body.

The following official statement from the American Institute of Ultrasound Medicine (AIUM) is provided for your general information regarding the safe use of ultrasound.

### Clinical Safety

*Approved March 1997, October 1982*

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

*There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. 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.*



## Specifications

Level of protection against electric shock:



Type B Applied part



Class II Equipment

Safety tested to meet:

BB100/200: IEC 601-1, IEC601-1-2, IEC60601-2-37

BB150/150z/250A: IEC601-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-37, EN5011-A

BB300A/350A: IEC60101-1, IEC60601-2, IEC60601-2-37

### BB150/150A/250A

Dimensions (h w l): 140 x 70 x 35 mm; 5.5 x 2.76 x 1.38 inches

Weight: 320 grams; 11.29 ounces

### BB300A/350A

Dimensions (h w l): 152 x 64 x 32 mm; 6 x 2.5 x 1.25 inches

Weight: 370 grams; 13 ounces

### BB100

Dimensions (h w l): 190 x 110 x 30 mm; 7.6 x 4.5 x 1.1 inches

Weight: 400 grams; 14.4 ounces

### BB200

Dimensions (h w l): 170 x 70 x 25 mm; 6.8 x 2.9 x 1 inches

Weight: 250 grams; 9.6 ounces

Operating temperature: 10 to 40 C; 50 to 104° F

Operating humidity: 30 to 75 %

Transport/Storage temperature: -20 to 50 C; -4 to 122° F

(beyond 30 days, battery to be stored between -20 and 30 C; -4 to 86° F)

Transport Storage humidity: 5 to 90%, non-condensing

Battery voltage, type: 3 – AA Alkaline 1.5 volt (non-rechargeable) Model

BB150/150A/BB250A/300A/350A

1 – 9v Alkaline Model BB100/BB200

Battery life:

Batteries provided: 750 1-minute exams – Model BB300A/350A

1250, 1-minute exams – Model BB150/150A, BB250A

250, 1-minute exams – Model BB100/200

Audio bandwidth and power: 350 Hz – 2 KHz, 0.5 W (150, 150A, 250A)

100 Hz – 3000 Hz, 1.0 W (300A, 350A)

Record sampling rate, duration: 4 KHz, 32 seconds

Heart rate calculation accuracy: Model BB350A +/- 3 BPM over range 50 to 220 BPM

Model BB250A +/- 3 BPM over range 50 to 220 BPM

Model BB200 +/- 2 BPM over range 60 to 199 BPM

Audio cable pin out: 3.5 mm stereo plug

(record versions only) Tip – Audio out

Ring – Audio out

Shaft – Ground

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



Attention: Consult Accompanying Documents

*Additional technical information is available upon customer request.*

## Obstetrical Probe Information:

	Model Number		
	150/150A/250A	300A/350A	100/200
With 3 MHz Probe			
$I_{SATA (max)}$ (mW/cm <sup>2</sup> )	16.3	12.6	
$P_o$ (mW)	16.3	14.2	20.0
Effective Radiating Area (cm <sup>2</sup> )	1.0	1.125	.9
Ultrasound Frequency (MHz)	3.2	2.96	3.04
Pulse Duration	CW	CW	CW

Acoustic Output Parameters are measured in water. Derated values, denoted by the subscript “3”, take into account a conservative level of attenuation that would be encountered in the human body. The derated intensity values ( $I_3$ ) are obtained from water values of intensity ( $I_w$ ) at a depth of z calculated by:

$$I_3 = \exp(-0.23*0.3*f*z)*I_w$$

(where f is the probe frequency in MHz and z is the depth in centimeters)

The derated peak rarefactional pressure is calculated from the value of measure water (pr) by:

$$P_{r3} = \exp(-0.115*0.3*f*z)*p_r$$

(where pressure is given in megapascals)

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## For Moms and Dads...

Please know that we want to take care of your needs and don't consider serving you anything to be taken lightly. We're parents ourselves and when we became the first suppliers of Dopplers for home use, nobody was looking out for parents who wanted or needed Doppler equipment.

Listening to your baby's heartbeat is exciting. But for some parents, it's essential. BabyBeat knows that for many, using our Doppler equipment is a life preserving capability for their baby. That's why you can count on us to provide you with the best service and equipment available. We know there is more at stake than just novelty and entertainment.

We hope that you are looking forward to "listening inside" and developing that indescribable bond with your child as they grow within. Thank you for letting us be a part of your life in this very special way.

*Tom and Stacie Hansen*

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*Thank you for  
working with  
BabyBeat!*

# BabyBeat



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