



Little Martin's Fetal Sound Amplifier

User Manual

For Model BFD1609

In order to ensure you and your baby's safety, please be sure to read this manual before using this product, and use it correctly.

- Please keep this manual in a safe place.
- When attaching the extra parts, please be sure to carefully read manual before doing so.
- When giving this away as a gift, please be sure to include this manual.

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Before Using

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

The product normally detects fetuses starting from 9 weeks, but can take up to 12-14 weeks depending on each individual.

Normally there are no contraindications for use. For specific cases, please consult your doctor.

Please consult your doctor about how to use at home.

Caution

It should not be used in life supporting or life sustaining applications.

About The Product

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".

How The Product Works

Little Martin's Fetal Sound Amplifier consists of a probe (transmitter and receiver) and signal process unit. Ultrasonic waves are 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 the ultrasonic waves reach 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. It is transmitted as an output signal of cardiac valves vibrating, and is then sent to the loudspeaker for getting a rhythmical sound with the fetal heartbeat. Simultaneously, it is sent to a counter which calculates the fetal heartbeat rate. (bpm=beat per minute)

Listen To The Sound Of The Fetal Heartbeat

The sound of the fetal heartbeat can be played through earphones or speakers.

Record The Sound Of The Fetal Heartbeat

When the device is connected to record devices with USB cable, it can transmit the sound of the fetal heartbeat to record devices, such as cellphones or computers, and save it into the record devices.

Playback The Sound Of The Fetal Heartbeat

Operator can playback the sound of the fetal heartbeat saved in the record devices.

Transit The Fetal Heartbeat Rate

The instrument automatically displays the value according to the fetal heartbeat detected by the probe instantly.

Average Fetal Heartbeat Rate

The detected fetal heartbeat signal will be calculated once every five seconds for the average FHR and the result will be displayed.

Audio Record

The sound of the fetal heartbeat can be recorded by a device which is connected with the product.

As a safety advisement, this product can only be connected with a recorder compliant with the safety requirements of IEC 60601-1.

Safety Terms & Conditions

The signal words shown below 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.

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 follow 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, cables, or optional equipment other than those approved by Little Martin's Drawer 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, if necessary, first turn power OFF prior to use of the radiotelephone or other similar equipment.

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 to the respective IEC Standards (i.e. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all configurations should comply with the system standard IEC 601-1-1. If you choose to connect additional equipment to the signal input part or signal output part, please ensure 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 required operating temperature before using.

Name Of Parts

Every attempt is made to ensure your accurate and complete order. However, to ensure the correct order, please make sure to verify the contents of the box against your packing slip.

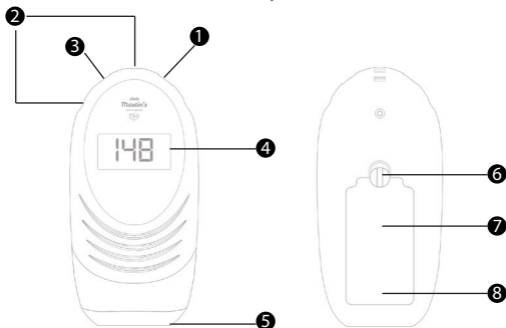
The product is designed for simple operation and set-up, requiring minimal assembly. The following items are included in your box:

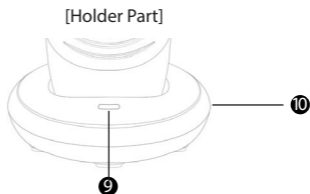
- 1 x Main Unit
- 1 x Holder (Speaker)
- 1 x Audio Cable
- 1 x USB Cable
- 1 x 9V Alkaline Battery
- 1 x Lanyard
- 1 x User Manual

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 Little Martin's Drawer Customer Service immediately if anything is damaged or defective.

[Main Body Part]





① Switch/Volume

Turn on or off the device, change the volume.

② Earphone Jack

Connect to earphones to play fetal heartbeat or connect to record devices, such as your computer or cellphone, to record heartbeat sound and save it on the record devices.

Note: The 'Earphone Jack' socket can be connected to headset or recorder. A socket for audio output can only be connected with a recorder complied with the requirements of IEC 60601-1

③ USB Socket

Play the heartbeat sound through the speaker when the USB speaker sockets on both main body and base are connected with a USB cable.

④ LCD

Display heartbeat rate on it.

⑤ Probe

Detect fetal heartbeat.

⑥ Battery Cover Lock

Lock the Battery Cover.

⑦ Battery Cover

Hold the battery.

⑧ Label

Information about model, manufacturer, agent and so on.

⑨ Indicator

Indicate that the USB Speaker Socket is connected to USB Socket with a USB cable.

⑩ USB Speaker Socket

Connects the USB socket in Main body with USB cable, then the heartbeat sound can be played through the speaker in Base.

Caution

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

Warning

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

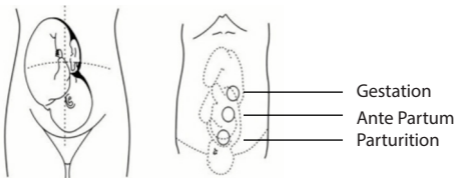
How To Use The Fetal Sound Amplifier

STEP 1. Rotate the battery cover locker(6) in the proper direction before using it for the first time, take off battery cover(7), and insert 9V battery.

STEP 2. Plug earphones into Earphone Jack(2) (Using unmatched earphones may reduce sound quality).

STEP 3. Rotate Switch/Volume to power on the device, the LCD (4) displays"- -"at this moment. Put on the earphones, adjust the volume to desired level.

STEP 4. Locate the position of the fetus first by touching gently with hands to find out the best direction to the fetal heart. Place the faceplate of the probe at the best position for detecting fetal heartbeat. Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Generally, fetus' heart is 1/3 below the navel line at its earlier stage, it then moves upward with increasing of gestational period, and from there, will deviate slightly to the left or right depending on the fetus. Please make sure that the surface of the probe is in full contact with the skin. After the sound becomes clear and stable for a few seconds, the FHR value will appear on the LCD in real time. If coupling gel is not available, water can be used.



[Positions of fetus heart in different periods]

STEP 5. Plug one end of the record cable into Earphone Jack (2), the other end into the record device, the computer, in order to record the fetal heart beat. Move the Probe (5) to the user's left breast to record the heart beat, replaying it can calm down the baby after the fetus is born.

STEP 6. Rotate the Switch/Volume to power off the device.

STEP 7. Connect the USB Socket(3) of the main body to the USB Speaker Socket(10) with the Base with a USB cable if you want to use the speaker in the Base, then the Indicator(9) will turn on after you power on the device.

Note: abnormal FHR values may appear while searching for the fetal heart.

Product Maintenance

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

The transducer acoustic surface is frangible and must be handled with care. 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.

To ensure the product is always functional when required, the following maintenance should be performed:

- Visual Inspection
- Cleaning the product and its accessories
- Checking the battery
- Testing product performance

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

Important Tips

- 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.
- The product requires no calibration.

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.

 **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 for repair. The accessories should be disposed of appropriately and replacement parts shall be ordered.

Cleaning The Product

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)

When you clean the product,

- 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.

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
	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.

- Before cleaning the product, turn the device off and disconnect the power cord.
- Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.
- 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.
- Avoid pouring fluids on the device, and do not allow fluids to penetrate the exterior surfaces of the device.
- 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 phenol compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the product or accessories.
- Cleaning liquids: Do not submerge the device in liquids or pour cleaning liquids over, into or onto the device.
- Do not use strong solvents such as acetone.
- Never use an abrasive cleaning tool 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.
- Do not leave any cleaning solution on the surface of the device.
- Wipe the surface of the sensor of transducer with 70% ethanol or alcohol, self-air dry or clean with a clean, dry cloth.

Disinfection

Clean the unit surface and the transducer according to the method mentioned above, then wipe the surface of transducer with 70% ethanol or alcohol. Clean the transducer surface with a dry, soft cloth.

- Do not use low temperature steam sterilization or other sterilization methods.
- Do not use high temperature sterilizing process.

Recycling The Battery

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 cause hazards to health and environment.

Specifications

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

DISPLAY

LCD Size	34mm X 16mm
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ULTRASOUND

Ultrasonic emitting frequency:	2.5MHz±3%
Overall sensitivity at distances 200mm from the face of the probe (Doppler frequency: 300±50Hz, Target velocity: 10cm/s~40cm/s)	≥90dB
Spatial-peak temporal-peak acoustic pressure	<8.6kPa
Output power	<20mW
Effective area of the ultrasonic transducer active element	1.57cm ²
The acoustic coupling medium for normal use:	ph: 5.5~8, Acoustic impedance: ≤1.7×10 ⁵ g/cm ² .s

FHR PERFORMANCE

FHR Test Range:	30 bpm ~240 bpm (Beat/Minute)
Resolution:	1 bpm
Accuracy:	± 1% ± 1 bpm

AUDIO OUTPUT

Audio Output Power:	<0.5 W
Audio Out Socket:	Ø3.5mm

BATTERY

Battery Voltage:	9V
Type:	9V Alkaline

Environmental Requirements

Conditions	Operating	Storage and Shipping
Temperature:	5°C to 40°C	-10°C to 60°C
Humidity:	<80% RH, non-condensing	10% - 95% RH, non-condensing
Atmospheric pressure:	86kPa to 106kPa	50kPa to 106kPa

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 required operating temperature prior to use.

Symbol Descriptions

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 its accessories



Serial number of the product



Warning information



LOT Number



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



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



Authorized representative in the European Community



Ingress Protection. IPX4 offers protection from dust 1mm or larger from entering the casing.



100% Recyclable

Troubleshooting

Common problems	Possible causes	Solutions
There is no reaction after pressing power on button or product powers off too soon.	<ol style="list-style-type: none"> 1. Battery is low. 2. Battery is in bad contact. 3. Placement of the battery is incorrect. 4. Device failures. 	<ol style="list-style-type: none"> 1. Change battery. 2. Ensure battery is in good contact. 3. Insert the battery correctly. 4. Send the device back to manufacturer for repair.
There are values on LCD but no sound.	<ol style="list-style-type: none"> 1. Volume is at the minimum. 2. Earphones or speaker incorrectly inserted. 	<ol style="list-style-type: none"> 1. Adjust the volume to the proper level. 2. Plug the earphones or speaker correctly.
Too much noise while using the device.	<ol style="list-style-type: none"> 1. There is no coupling agent. 2. Moving the probe on the skin of abdomen causes noise. 3. Probe is not placed at the optimal position. 	<ol style="list-style-type: none"> 1. Use coupling agent. 2. Do not allow the probe to come in contact with the skin while searching for the fetal heart. Find the right angle between probe facet and skin of the abdomen to get the clearest fetal heartbeat sound. 3. Look for the right position of the fetal heart again.
There is sound but no values on LCD, difficult to find the position of the fetal heart.	<ol style="list-style-type: none"> 1. There is no coupling agent between probe facet and abdomen skin. 2. Gestation period is the short, fetal heartbeat is weak. 	<ol style="list-style-type: none"> 1. Make sure that there is enough coupling agent between the probe facet and abdomen skin. 2. Use the device after longer gestation period, fetus is bigger.
Random values appear frequently on the LCD when using the device.	<ol style="list-style-type: none"> 1. The friction between the probe and abdomen skin causes the wrong random values during looking for right position of fetal heart. 2. There is electromagnetic interference around, such as high frequency generator machines which create electrical spark, and cellphones. 3. There is fetal movement, which means the position of fetal heart may have changed. 	<ol style="list-style-type: none"> 1. Find the position where the fetal heartbeat sound is the loudest, keep the probe static for 10 seconds, then the values on LCD are real instant fetal heart rate. 2. Use the device in a place without interferences. 3. Adjust the position of the probe, making sure that the probe is where the fetal heartbeat sound is the loudest.



Warranty Certificate

This certificate promises our customers that they will receive free repair. If you notice any problems listed below within the warranty period, please contact our customer service with this certificate.

1. Once you have used this product, we basically will not offer exchangement.
2. When the product is damaged (after proper use) within the warranty period which is a year from the purchase date, we will repair it for free. Contact us via email support@littlemartinsdrawer.com, and send the product over to our customer center.
3. Even within the warranty period, in the following situation the repair process will come with a fee.
 - a. Natural discoloration of the plastic area.
 - b. Damage due to misuse of the product.
 - c. Damage due to fire, water, earthquake and other natural disasters.
 - d. Damage due to commercial or business usage.
 - e. The shipping fee for paid repair.
4. This service will apply only inside United States.
5. Once the product is out of production and certain parts are out of stock, we will not be able to offer certain repairs.

LOT

BATCH CODE
SEE THE LOT NUMBER ON THE BACK
OF THE MOTOR UNIT



CONSULT INSTRUCTIONS FOR USE



100% RECYCLEABLE



WASTE FROM
ELECTRICAL AND
ELECTRONIC
EQUIPMENT (WEEE)

