OKDentale

CE 0123

Sonoline C1
Pocket Fetal Doppler

User Manual

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Attention

This user manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The manufacturer makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. The manufacturer assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

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The information contained in this document is subject to change without notice.

Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, repairs are carried out by persons authorized by the manufacturer, and the device is used in accordance with the instructions for use.

⚠WARNING⚠:

This device is not intended for treatment. The intended use is for detecting Fetal Heart Rate. If the fetal heart rate (FHR) result is distrustful, please use other methods such as stethoscope to verify immediately.

Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by manufacturer. We warrant that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

⚠WARNING⚠:

A WARNING label advises against certain actions or situations that could result in personal injury or death.

◇CAUTION◇:

A CAUTION label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Note: A NOTE provides useful information regarding a function or procedure.

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Chapter 1 Safety Guidance

This unit is internally powered equipment and the degree of shock protection is type B applied part.

Type B protection means that these patient connections will comply with permitted leakage currents, dielectric strengths of IEC 60601-1.

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the device.

⚠**WARNING**⚠**:** This device is not explosion-proof and can not be used in the presence of flammable anaesthetics.

⚠**WARNING**⚠**:** Do not throw batteries in fire as this may cause them to explode.

⚠**WARNING**⚠**:** Do not attempt to recharge normal dry-cell batteries, they may leak, and may cause a fire or even explode.

⚠**WARNING**⚠**:** Don't touch signal input or output connector and the patient simultaneously.

⚠**WARNING**⚠**:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult our technical service department or your local distributor.

⚠**WARNING**⚠**:** Pocket Fetal Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring.

⚠**WARNING**⚠**:** Replacing battery shall only be done outside the patient environment (1.5m away from the patient).

CAUTION: The device must be serviced only by authorized and qualified personnel.

CAUTION: The main unit is designed for continuous operation and is 'ordinary'. Do not immerse in any liquid (i.e. not drip or splash- proof).

CAUTION: Keep the device clean. Avoid vibration.

CAUTION: Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

CAUTION: Electromagnetic Interference-Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away.

CAUTION: The user must check that the equipment does not have visible evidence of damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended

before use.

**CAUTION: The following safety checks should be performed once every two years or as specified in the institution's test and inspection protocol by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

* Inspect the equipment for mechanical and functional damage.

* Inspect the safety relevant labels for legibility.

* Verify that the device functions properly as described in the instructions for use.

* Test the patient leakage current according to IEC 60601-1: Limit: 100 uA (B).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

**CAUTION: The battery must be properly disposed according to local regulation after their use.

**CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time.

**CAUTION: The device shall only be used if the battery cover is closed.

**CAUTION: Battery must be stored in cool and dry place.

**CAUTION: If use rechargeable battery, to insure capability and life, please fully charge batteries before first use, normally, batteries must be continuously charged over 14 hours or charged according to the guidance displayed on the battery.

**CAUTION: Please don't set anode and cathode of the battery wrongly.

**CAUTION: The valid period of this product is five years.

**CAUTION: After the service life, please return the products to the manufacture or disposal the products according to local regulations.

When cleaning the machine:

**CAUTION: Don't use strong solvent, for example, acetone.

**CAUTION: Never use an abrasive such as steel wool or metal polish.

**CAUTION: Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.

**CAUTION: Avoid pouring liquids on the device while cleaning.

**CAUTION: Don't remain any cleaning solution on the surface of the device.

When disinfecting the machine:

**WARNING: Never try to sterilize the probe or equipment by low temperature steam or other methods.

: Attention, Refer to accompanying documents.

Chapter 2 Introduction

2.1 Overview

Pocket Fetal Doppler is a hand-held obstetrical unit, which can be used in hospital, clinic and home for daily self-check by pregnant woman.

It contains components of ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, LCD display control unit etc.It has 3 work modes: real-time FHR display mode, averaged FHR display mode, and manual mode. It also has audio output, and can be connected with earphone or recorder with audio input.

2.2 Features

- Beautiful shape, portable, easy operation.
- The probe has bending structure which is easy to operate and can increase the ease of the pregnant women, embodies the humane care design.
- Battery status indicator.
- The probe can be changeable.
- Probe inspection.
- Built-in speaker.
- Output for headphones.
- Backlight.
- Auto shut off .
- Two pieces of standard 1.5V alkaline battery available which can work no less than 8 hours.

Chapter 3 Outlook and Configuration

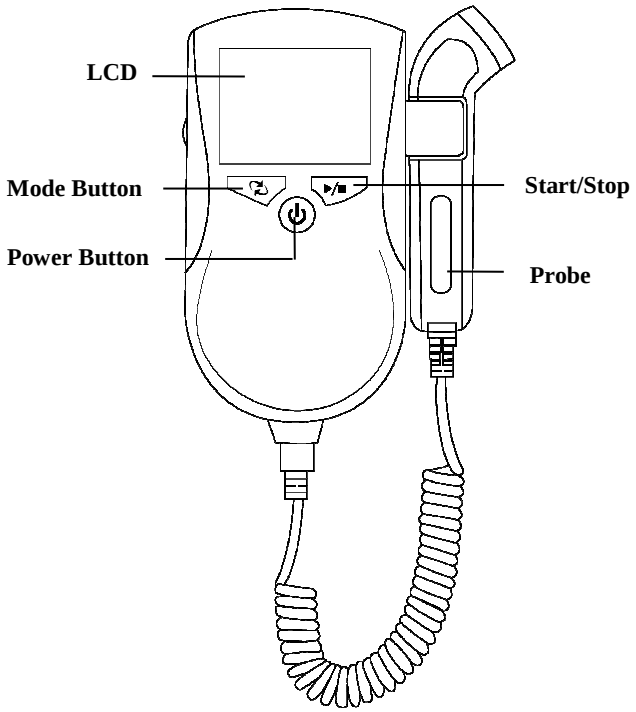

Fig.3-1 Front Panel

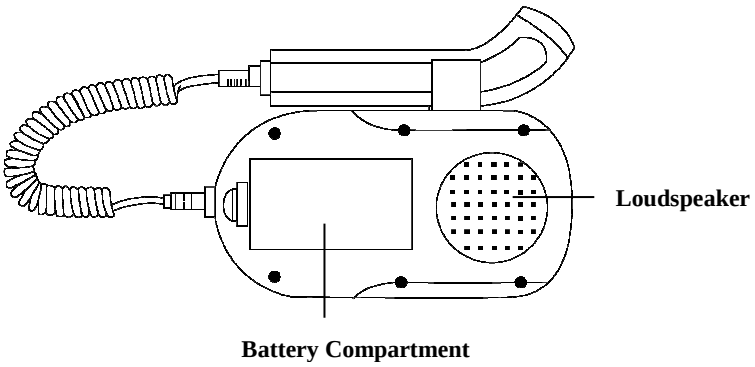

Fig.3-2 Rear Panel

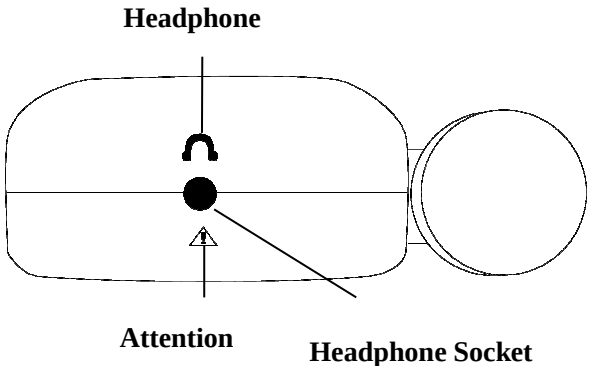

Fig.3-3 Top Panel

3.1 Display

The LCD display is as follows:

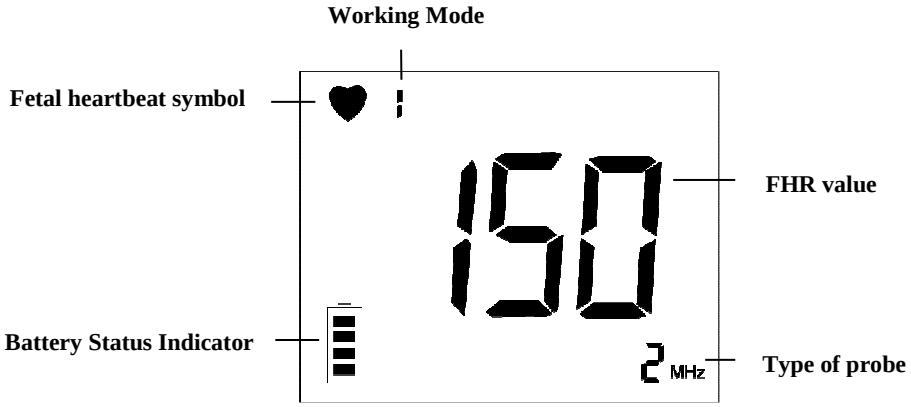

Fig.3-4 LCD Display

3.2 Push Button

There are three push buttons (**Power**, **Mode,** and **Start/Stop**) and a volume control button on Pocket Fetal Doppler. The primary functions are as follows:

3.2.1 Power Button

Function: Power on/off.

Power on: Push the button once.

Power off: Push down the button and hold 3 seconds to power off.

3.2.2 Mode Button

Function: Mode selection, press once to enter next working mode under working status.

For the Fetal Doppler has memory function, when turning on the machine, it will enter the mode selected before last power off automatically after self testing.

3.2.3 Start/Stop Button

Function:**Fout! Verwijzingsbron niet gevonden.**Under mode 1 and mode 2, press the button to turn on /off backlight.

Fout! Verwijzingsbron niet gevonden. Under model 3, press this button the fetal heart rate counting starts, press this button again the counting stops.

3.2.4 Volume Control Indicator

Volume adjusting direction indicator.

From left to right means that the sound level is from high to low.

3.3 Headphone Socket

Headphone Socket: a socket for audio output, and can be connected with earphone or recorder with audio input to record.

: The socket, terminal post, or switch that connected with the headphones.

⚠: Attention. Refer to the accompanying documents.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC60601-1-1. If in doubt, consult our technical service department or your local distributor.

Headphone Socket Signal Interface:

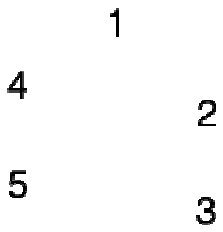

Fig.3-5 Headphone Socket for Audio Output

Headphone socket showed as **Fig.3-5**, the definition of pins showed as below:

Pin	Definition
1	GND
2	Signal
3	Signal
4	Signal
5	Signal

Chapter 4 General Operation

4.1 FHR Inspection

Fout! Verwijzingsbron niet gevonden. Power on by pressing the Power button.The LCD display is as **Fig.3-4**.

Fout! Verwijzingsbron niet gevonden. Find the position of fetus:

At first, please feel the position of the fetus by hand .Find out the best direction for inspecting the fetal heart. Apply a liberal amount of gel to the faceplate of probe; place the faceplate of probe at the best position for detecting fetal heart. Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Adjust the volume according to requirements.

Fout! Verwijzingsbron niet gevonden. FHR Calculation:

The FHR result will be showed on LCD screen.

Fout! Verwijzingsbron niet gevonden. Turn off the machine:

Keep pressing the power button 3 seconds to turn off.

⚠CAUTION⚠:

 Put the probe on the best detecting position to get better detecting effect.

 Don't put the probe on the position where have strong Placental Blood Sound(PBS) or strong Umbilical Sound (UMS).

 If pregnant woman adopts horizontal position and the fetus position is normal, put the probe on the position of lower navel midline to get the clearest FHR sound.

 Do not measure FHR unless audible fetal sound has been heard.

⑤ Please reduce the time of ultrasonic radiation as possible as you can.

4.2 Mode Selection

4.2.1 Real-time FHR Display Mode (Mode 1)

At the moment of detecting FHR signal, the LCD will display the flashing heart symbol, and display real-time FHR simultaneously.

4.2.2 Averaged FHR Display Mode (Mode 2)

This model is able to acquire more stable fetal heart rate, displaying on LCD the latest acquisition of eight points fetal heart rate on average. The LCD displays the flashing heart symbol when displaying FHR.

4.2.3 Manual Mode (Mode 3)

When entering into mode 3, the system will automatically counts the audible beats, FHR will be showed in "— — —" Format, and the LCD flashes heart symbol. Press the start / stop button to stop calculating.The unit will automatically calculate the derived FHR averaged over the caculating time and display the result. If measure FHR again, press the start / stop button to start. Repress it, it will stop calculating .This rate value is retained until the measurement is repeated or

the mode is changed.

4.3 Probe Operation

4.3.1 Inspecting Probe

When the probe falls away from the device, the LCD screen displays the flickering “— — —”and the probe frequency indication data disappeared.At this moment the probe needs to be reconnected. After connected well, LCD screen will stop flickering and display the probe frequency data.

4.3.2 Replacing Probe

There has been a probe connected to device while packaged by the manufacturer. If users need to replace it with another probe, power off the device at first, then take out the probe from the parking of device. And then pull out the plug of the probe from its socket. Then connect the plug of the probe which needs to be displaced with the socket.

Note: Place the temporarily unused probe carefully and avoid falling off, stress, etc. When the device is not used for a long time, users are recommended to connect the plug of one probe to device socket and put the probe in the parking. Then pack the device with the probe in the wrapping box.

4.3.3 Taking Out Probe and Placing Probe

Fout! Verwijzingsbron niet gevonden. **Taking Out The Probe**

Hold the main unit with one hand, and hold the handle of the probe with another hand to take out the probe. (See **Fig.4-1**).

Fig.4-1 Taking Out Probe

Fout! Verwijzingsbron niet gevonden. **Placing Probe**

It is opposite to take out probe. Hold the main unit with one hand, and hold the top of the probe with another hand, then push the probe into the probe holder.

4.4 Battery Status Indicator

When it works normally, the LCD screen displays the status of the battery, and the number of the

grid in the status represents how much power is left; when the power of the battery is low, the power of the battery displays grid 0 to remind the customer to change another new battery or charge the battery (only the chargeable battery can be charged).

4.5 Replacing Battery

Fout! Verwijzingsbron niet gevonden. The rear panel is upturned. First open the battery compartment, then take out the battery from the battery compartment (see **Figure 4-2**).

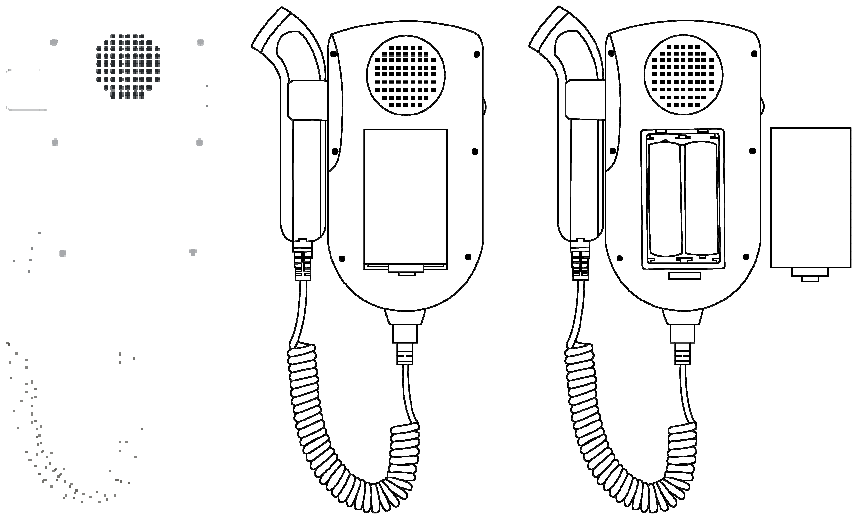

Fig.4-2 Replacing Battery

Fout! Verwijzingsbron niet gevonden. Put two AA size batteries into the battery compartment (as for the direction of battery, please refer to the instruction inside the battery compartment), at last close the battery compartment.

CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time.

Chapter 5 Product Specification

Product Name: Pocket Fetal Doppler

Safety: Complies with: IEC 60601-1:1988＋A1:1991＋A2:1995

Classification:

Anti-electroshock Type: Internally powered equipment.

Anti-electroshock Degree: Type B applied part

Harmful Liquid Proof Degree:

Main Unit :Ordinary equipment (sealed equipment without liquid proof).

Probe: Prevent from water splashing, degree of protection: IPX4.

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

Working System: Continuous running equipment.

EMC: Group I Class B.

Suitable Using Range: Suitable for use after the 12th week of pregnancy.

Physical Characteristic

Size: 135 mm (Length) × 92 mm (Width) × 29 mm (Height)

Weight: About 245 g (including batteries)

Environment

Working:

Temperature: +5℃ ~ +40℃

Humidity: ≤ 80%

Atmospheric Pressure: 70 kPa ~ l06 kPa

Transport and Storage:

Temperature: -10℃ ~ +55℃

Humidity: ≤ 93%

Atmospheric Pressure: 50 kPa ~ l06 kPa

Display: 38 mm × 28 mm LCD display

FHR Performance

FHR Measuring Range: 50 BPM ~ 240 BPM (BPM: beat per minute)

Resolution: 1 BPM

Accuracy: ± 2 BPM

Power Consumption:< 0.8 W

Auto Shut-OFF: After 1 minute no signal, power off automatically.

Battery Type Recommended: Two pieces of 1.5 V DC battery (SIZE AA LR6).

Probe:

Nominal Frequency: 2.0 MHz

Working Frequency: 2.0 MHz ±10%

P-: < 0.5 MPa

I_{ob}: < 10 mW/cm^2

I_{spta}: < 50mW/cm^2

Ultrasonic Output Intensity: I_{sata} < 5 mW/cm^2

Ultrasonic Output Power: P <10 mW

Working Mode: Continuous Wave Doppler

Effective Radiating Area of Transducer: 157 mm^2 ± 15%

Chapter 6 Maintenance

6.1 Maintenance

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

Gel must be wiped from the probe 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 Pocket Fetal Doppler capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

The accuracy of FHR is controlled by the equipment and can not be adjusted by user. If the FHR result is distrustful, please use other method such as stethoscope to verify immediately or contact local distributor or manufacture to get help.

6.2 Cleaning

Before cleaning, switch off and take out the batteries.

Keep the outside surface of the device clean and free of dust and dirt, clean exterior surface (display screen included) of the chassis with a dry, soft cloth. If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.

Wipe the probe with soft cloth to remove any remaining ultrasound coupling gel. Clean with soap and water only.

CAUTION: Don't use strong solvent, for example, acetone.

CAUTION: Never use an abrasive such an steel wool or metal polish.

CAUTION: Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.

CAUTION: Don't remain any cleaning solution on the surface of the device.

Note: Wipe the surface of probe with 70% ethanol, self-air dry, or clean with a clean, dry cloth.

6.3 Disinfecting and Sterilization

Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol impregnated wipe (70% ethanol).

Wipe the probe with a clean, dry cloth to remove any remaining moisture.

NOTE:

1) The recommended periods of cleaning, sterilization and disinfecting is once per month.
2) After cleaning, sterilization and disinfecting, users must inspect whether have any obvious damage which may affect the patient safety and instrument performance.

⚠**WARNING**⚠**:** Never try to sterilize the probe or equipment by low temperature steam or other method.

Chapter7 Solutions for Possible Problems

If it appears below problems when you use the device, please solve them as below:

Problems	Possible reasons	Solutions
Weak sound	⊙volume is too low ⊙power is low ⊙did not daub the gel	⊙adjust the volume louder ⊙change the battery ⊙daub the gel
Noise	⊙probe is too near from the main unit ⊙disturbance from the outside signal ⊙power is low	⊙make the distance between the probe and the main unit a little further ⊙keep far away from the outside signal ⊙change the battery
Low sensitivity	⊙position of the probe is not correct ⊙did not daub the gel	⊙adjust the position of the probe ⊙daub the gel

Appendix 1

Essentiality of Fetal Domestic Monitor

Modern medicine think that:

FHR is an important gist to identify fetal health, by recording FHR changes can observe fetal hypoxia, fetal distress and the umbilical cord around the neck, and other symptoms. Fetal domestic monitor test FHR rate changes by listening to fetal heart sound mainly; Fetal domestic monitor is a powerful guarantee to improve generational safety.

Fetal heart rate changes most obviously in the following three periods:

1. Within 30 minutes after pregnant women get up

2. Within 60 minutes after pregnant women finish lunch

3. Within 30 minutes before pregnant women go to bed

For the above three periods, because of the change of the body status of pregnant women, the activity of food digesting needs the body to provide more oxygen, relatively, the oxygen for fetus become less. It is easy to arose symptoms such as fetus anoxia. Testing the FHR at this time can display the healthy status for the fetus best.

The above three periods can only be tested at home by pregnant women themselves, so FHR domestic monitor is very important. We advise the pregnant women to measure every day respectively at early, middle and late time, every time measuring the fetal heart rate and listening to the fetal heart rate for about one minute, and recording the measurement results for the medical reference when go to the hospital.

Generally, the medicine deems the normal fetal heart rate as: 120BPM~160BPM; slightly too fast: 161BPM~180BPM; heavily too fast: above 181BPM; slightly too slow: 119BPM~100BPM; heavily too slow: below 99BPM.

This device can hear the fetal heart sound for fetus above twelve weeks, and check the LCD display. Finding too fast or too slow should go to hospital for further checks to ensure safety.

Appendix 2

Overall Sensitivity

Overall Sensitivity														
Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A(d)	Two-way Attenuation $B=\Sigma B_a+B_w$							V_s (r.m.s.) mV	V_n (r.m.s) mV	$C=20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
			ΣB_a (T:mm B_a:dB)					B_w (dB)	B (dB)				
1.58 A=45.7dB@ 2MHz	50	45.7	T	20	4.8	4.0	-	0	57.6	186	94	5.93	109.2
			B_a	40	9.6	8.0	-						
	75	45.7	T	20	4.8	3.4	-	0	56.4	175	90	5.78	107.8
			B_a	40	9.6	6.8	-						
	100	45.7	T	20	4.8	3.4	-	0	56.4	174	89	5.82	107.9
			B_a	40	9.6	6.8	-						
	200	45.7	T	20	4.8	-	-	0	49.6	173	90	5.68	100.9
			B_a	40	9.6	-	-						
2.38 A=43.2dB@ 2MHz	50	43.2	T	20	4.8	3.4	2.2	0	60.8	178	89	6.02	110.0
			B_a	40	9.6	6.8	4.4						
	75	43.2	T	20	4.8	3.4	1	0	58.4	170	90	5.52	107.1
			B_a	40	9.6	6.8	2						
	100	43.2	T	20	4.8	3.4	-	0	56.4	165	85	5.76	105.3
			B_a	40	9.6	6.8	-						
	200	43.2	T	20	4.8	1	-	0	51.6	160	85	5.49	100.2
			B_a	40	9.6	2	-						
Doppler Frequency (Hz)		333								Velocity of Target (cm/s)		12.5	