POCKET FETAL DOPPLER

USER MANUAL

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TORONTEK FETAL MONITOR

ATTENTION!

ToronTek fetal monitor is a hand-held, battery powered audio capturing device. It can pick up fetal heartbeat and any sounds in the womb during pregnancy. The use of this device is for the purpose of making emotional connection between unborn baby and family by listening to the baby's heartbeats.

This device in not intended to be used to diagnose, treat, cure or prevent any medical condition unless used by or under the direct supervision of a licensed health provider. Using this device is not a substitute for your own healthcare provider's professional advice. You should never delay seeking medical advice, disregard medical advice or discontinue medical treatment because of using this product. If you think you or your baby may be suffering from any medical conditions you should seek immediate medical attention. While using the device, expecting mom's heartbeat could be possibly heard also. Never make a decision on your baby's health, in case you feel something is wrong even though you could be hearing a heartbeat by using this device, seek immediate medical attention.

No part of this document may be photocopied, reproduced or translated to another language without prior written consent of the manufacturer.
No liability is accepted for injury, loss or damage incurred by use or mis-use of this product

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

⚠ WARNING ⚠

This device is not intended for treatment. The intended use is for detecting Fetal Heart Rate. If the FHR result is not meaningful and reliable, please use other methods such as a stethoscope to verify immediately.

WARRANTY

The unit cannot be repaired by users themselves. All services must be done by the engineers approved by the 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. The term of warranty coverage is specified by the assigned distributor in the country of purchase. Please contact the entity you purchased the unit from to inquire about the warranty period. Any misuse, improper maintenance may void the warranty.

LABELS USED IN THIS MANUAL:

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.

Section 1 Safety Guidance

This unit is internally powered equipment; the degree of shock protection is type CF applied part.
Type CF applied part protection means that these patient connections will comply with permitted leakage currents, dielectric strengths of IEC 60601-1.

1.1 Safety Precautions

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 cannot 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 as they may leak, and may cause a fire or even explode.
⚠**WARNING**⚠ : Do not touch the signal input/output connectors 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). Furthermore, all configurations shall comply with the valid version of the system standard IEC60601-1-1. Any user 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** ⚠: This device in not intended to be used to diagnose, treat, cure or prevent any medical condition unless used by or under the direct supervision of a licensed health provider . It should not be used in place of normal fetal monitoring.

⚠ **WARNING** ⚠: Replacing batteries shall only be done away from pregnant' s mother environment (1.5 m away)

⚠ **WARNING** ⚠: Please use the probe provided by the manufacturer.

⚠ **WARNING** ⚠: Do not pull the line of the probe longer than 2 m, or else the probe may break away from the connector of the device.

⚠ **WARNING** ⚠: Keep the device and probe away from small children and pets to avoid strangulation or choking hazards.

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

⚠ **CAUTION** ⚠: The main unit is not waterproof or resistant, Do not immerse in any liquid or water while using.

⚠ **CAUTION** ⚠: Keep the device in a clean within the recommended storing temperature while not using.

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

⚠ **CAUTION** ⚠: The batteries must be taken out from battery compartment if the device is not used for a long time. (More than one month). In order to avoid battery leakage and damage to the unit.

⚠ **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.

⚠ **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.

⚠ **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: 10 uA (CF).

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 batteries should be deposed according to local regulations after the use.

⚠ **CAUTION** ⚠: Make sure the battery cover is closed before using the device.

⚠ **CAUTION** ⚠: Batteries must be stored in a cool, dry place.

⚠ **CAUTION** ⚠: If using rechargeable batteries, fully charge the batteries before the use to avoid damaged to the unit.

⚠ **CAUTION** ⚠: Insert batteries in right directions as indicated in the battery compartment.

⚠ **CAUTION** ⚠: This product shelf life is 5 years from manufacturing date.

⚠ **CAUTION** ⚠: After the service life, dispose the product according to local regulations.

⚠ **CAUTION** ⚠: Do not use the device with a defibrillator or high frequency surgical unit.

⚠ **CAUTION** ⚠: Choose the accessories authorized by our company only, or the device maybe damaged.

⚠ **CAUTION** ⚠: Keep the probe line away from sharp edges.

⚠ **CAUTION** ⚠: The material of the shell and probe is ABS, in line with ISO10993-5:1999&ISO10993-10:2002

⚠ **CAUTION** ⚠: Protect the device against extreme moisture, heat, direct sunlight

When cleaning the machine:

⚠ **CAUTION** ⚠: Do not use strong solvents 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. Do not immerse any parts of the device into any liquids.

⚠ **CAUTION** ⚠: Avoid pouring liquid on the device while cleaning.

⚠ **CAUTION** ⚠: Do not leave any cleaning solution on the surface of the device.

When disinfecting the machine:

⚠ **WARNING** ⚠ : Never try to sterilize the probe or equipment using high temperature steam.

: Refer to accompanying documents.

Section 2 Introduction

2.1 Overview

ToronTek Fetal Doppler is a hand-held, battery powered audio device. It can even pick up the slightest sound in the womb. It is fun to listen to baby's heartbeats or listen to mom's heartbeats. This unit included a power button, mode button and volume control. It is also equipped with built-in speaker, headphone jack and a display screen. On display screen, battery level, volume level, current working mode, Heart beat Per Minute (BMP) as well as probe type in use is shown.

This device in not intended to be used to diagnose, treat, cure or prevent any medical condition unless used by or under the direct supervision of a licensed health provider. Using this device is not a substitute for your own healthcare provider's professional advice. You should never delay seeking medical advice, disregard medical advice or discontinue medical treatment because of using this product. If you think you or your baby may be suffering from any medical conditions you should seek immediate medical attention. While using the device, expecting mom's heartbeat could be possibly heard also. Never make a decision on your baby's health, in case you feel something is wrong even though you could be hearing a heartbeat by using this device. Seek immediate medical attention.

No liability is accepted for injury, loss or damage incurred by use or mis-use of this product

2.2 Features

- Battery status and low battery indicator
- Built-in speaker
- Volume adjust button
- Audio output socket for headphone, earphones or recording cable
- 2/3 Mhz probe can be connected
- Probe inspection
- Backlit LED display with bar graph and waver form display of FHR.
- Auto shut off (The device shuts off automatically is no signal received for a certain period of time)
- Operates on two replaceable 1.5 V AA Alkaline batteries.

Section 3 main unit, buttons and display info

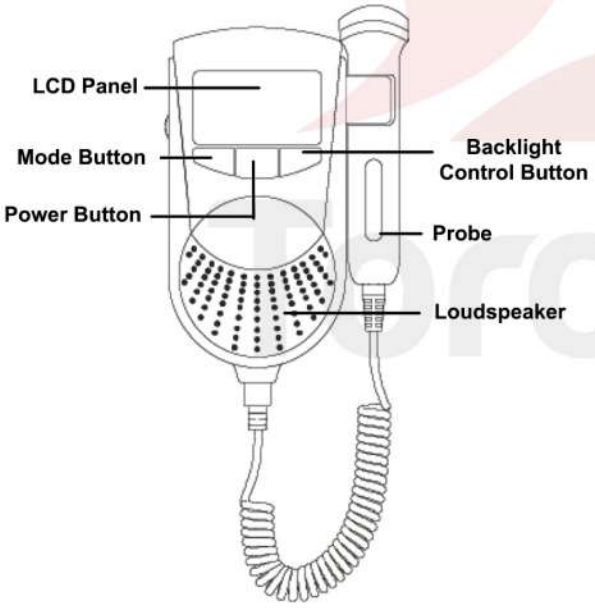


Fig.3-1 Front Panel

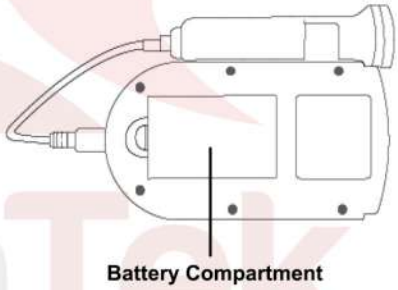


Fig.3-2 Rear Panel

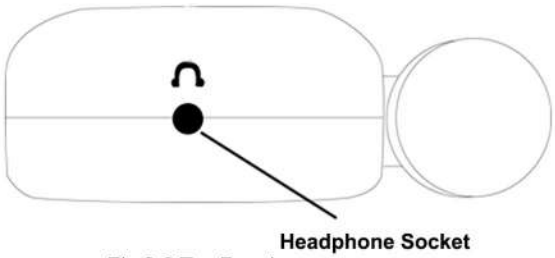
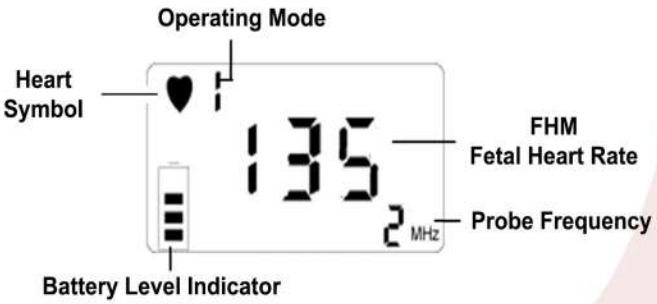


Fig.3-3 Top Panel

3.1 Display Screen

3.1.1 Display

In 3 seconds after turning on the device, the display is as followed:



After the device is ON for 3 seconds, the display is as followed:

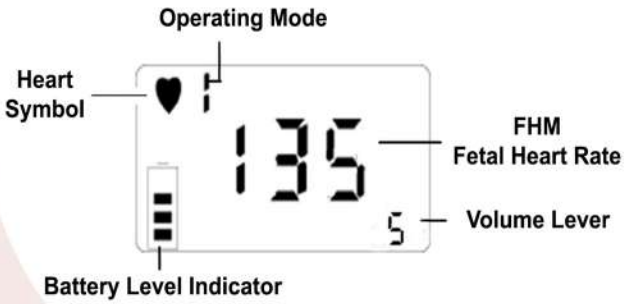


Fig.3-4 and 3-5 Screen Displays

3.1.2 Probe Socket

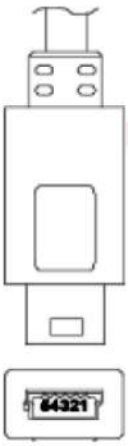


Fig.3-6 Probe Socket

The probe socket is shown as Fig.3-6 above. The definition of the jacks of the socket is shown below:

Pin	Definition
1	Power Supply
2	Signal
3	Probe Coding 1
4	Probe Coding 2
5	Probe Coding 3
6	(Shell) GND

⚠ **WARNING** ⚠ : Do not attempt to connect probes not manufactured by ToronTek

3.1.3 Probe

ToronTek-Fetal Doppler is compatible with both with 2 or 3 MhZ probes.

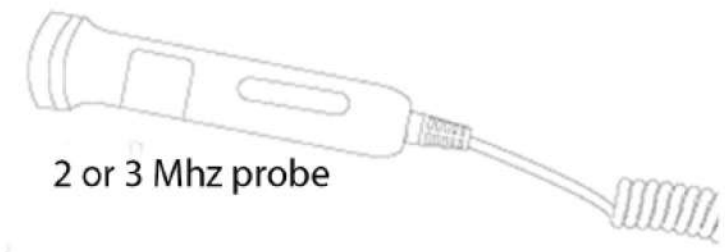


Fig.3-7 Probe

3.2 Push Buttons

There are three push buttons POWER, MODE, and BACKLIGHT CONTROL The primary functions are as follows:

3.2.1 Power Button

Function: Power on/off.

Power on: Press the button once.

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

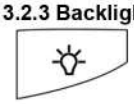
3.2.2 Mode Button

Function: Mode selection button.

Press once to enter next working mode while the device is ON.

The device will resume on the current mode, the next time you switch it on.

3.2.3 Backlight Control Button



Function:

1. While on mode 1 and mode 2, press the button to turn backlight on/off.
2. While on mode 1, the button is for start/stop operation. Please refer to manual mode (Mode 3)

The button is for start/stop of the measurement on mode 3. Please refer to manual mode (Mode 3)

3.2.4 Volume Control Indicator

Function: Adjusting the volume

Turn the volume button to increase or decrease the volume.

3.3 Audio Jack

Headphone Jack: A socket for audio output which can be connected to earphones, headphone or audio recording cable.

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

: 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). Furthermore, all configurations shall comply with the valid version of the system standard IEC60601-1-1. Anybody 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.

3.3.1 Signal Interface

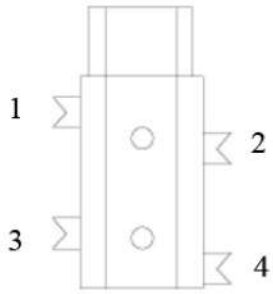


Fig.3-8 Headphone Socket for Audio Output

Headphone socket showed as figure 3-6, the definition of pins showed as below:

Pin	Definition
1	Signal
2	Signal
3	Signal
4	Signal

Section 4 Using the device:

4.1 Powering on the device and spotting the heartbeat:

This device is capable of spotting fetal heartbeat from12th weeks of pregnancy although it's possible at earlier weeks to spot the fetal heartbeat however to avoid the anxiety is better to wait till week 12th.

NOTE: As a general rule, the bigger the baby gets, the easier it will be to hear his or her heartbeat. The sound you hear will also depend on your size and the position of the fetus. Before you use your doppler, consider that some women report hearing the heartbeat easier in the morning since that's when the belly is typically the least bloated. Using the doppler while you have a full bladder can also make the heartbeat easier to hear.

1. To start; lie with your back down on a flat surface. Expose your abdomen like you would during a regular ultrasound.
2. Apply a blob of ultrasound gel or other non-thick lubricant to your lower belly. Since the gel will reduce static, use a generous amount. (To give and approximate amount: assume a circle of gels with diameter of 3- cm or 1.2 inch)
3. Power on by pressing the power button.The device will self-test to verify if the probe is well inserted in the socket. When the device is ON the LCD display is as Fig 3-4 and 3-5
4. Place the doppler probe in the gel. Starting from your pubic bone, gently glide the probe upwards towards your belly button. Slowly rock the probe, covering every part of your stomach so that you find the fetus.
5. If you hear a heart beat and the display shows a heart beat per minute (BPM) of about 120 or higher, you've likely found your fetus.
6. If after a few minutes you cannot find your baby, shut the device off and try another time. You may need to wait for the baby to grow bigger or switch positions.
7. After you're finished; hold down the power button for 3 seconds to turn off the device. Clean off the probe to avoid build up. You may choose to wipe it with 70% ethanol and let air dry or simply wipe it with a clean, dry cloth. Do not submerge the device in water or apply cleaning chemicals.

4.2 Mode Selection

This device is capable of calculating FHR (Fetal Heart Rates) in three different modes. You can see the current operating mode on the top left side of the LCD display. When you change the mode remember the next time you turn on the device it will resume on the current existing mode.

4.2.1 Real-time FHR Display Mode (Mode 1)

This mode detects and displays the exact simultaneous FHR which is been detected and transmitted by the probe.

4.2.2 Averaged FHR Display Mode (Mode 2)

It is used to obtain more stable heart rate readings. In this mode, FHR is averaged over the 8 heart-beats. The LCD displays the flashing heart symbol when displaying FHR.

4.2.3 Manual Mode (Mode 3)

When entering mode 3, the system counts the audible beats based upon the user instruction to start and stop. After entering this mode the FHR will be showed in "— — —" format, and the LCD flashes a heart symbol and the device starts the count. Press the start/stop button to stop the count. The device will automatically calculate the derived FHR averaged over the calculating time and display the result. To measure FHR again, press the Backlight Control button to start. Press it again and 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 the Probe

If the probe disconnects from the ToronTek Doppler, the LCD screen flickers and displays "— — —" and the probe frequency indication data will disappear. The probe needs to be reconnected. Once reconnected, the LCD screen will stop flickering and display the probe frequency data.

4.3.2 Replacing the Probe

If the user needs to replace it with another probe, power off the Pocket Fetal Doppler, then remove the probe from the packaging of the Pocket Fetal Doppler. Pull out the plug of the probe from its socket, and then connect the plug of the new probe.

Note: Always store the probe carefully. Avoid dropping the probe or putting extra pressure or weight on the probe while packing it and storing it. If you store the doppler for a long time it is recommended to store the probe and device while the probe is inserted in the main unit so the connectors stay in better status for next use.

4.4 Low Power Indication

When the device is working normally, the LCD screen displays the status of the battery on the bottom right hand corner of the display, and the number of the grid in the status represents the level of the battery left. When you see the battery bar empty of the indicating grids it is time to replace the batteries with new ones.

4.5 Replacing the Batteries

4.5.1 Removing the Batteries

Open the battery compartment on the back of the device and then remove the batteries from the compartment (see Figure 4-1).

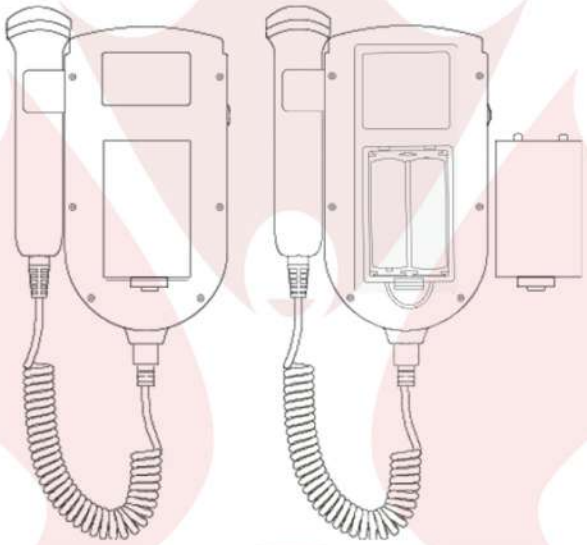


Fig.4-1 Replacing the Batteries

4.5.2 Replacing the Batteries

Insert two AA batteries into the battery compartment then replace the cover.

⚠ **CAUTION** ⚠: Always remove the batteries if the device will not be in use for a long time.

Section 5 Symbols:

Symbol	Description
	Type CF
	Refer to instruction manual/booklet
	Headphone socket
	Volume adjust
	WEEE (2002/96/EC)
EC REP	European Representative
SN	Serial number

Section 6 Product Technical Specification

Product Name: Pocket Fetal Doppler

Safety: Complies with: IEC 60601-1:2005

Classification:

Anti-electroshock Type: Internally powered equipment.

Anti-electroshock Degree: Type CF applied part

Harmful Liquid Proof Degree:

Main unit: Degrees of protection provided by enclosure:IPX0:

2M/3M straight probe: No prevention against any water or liquid exposure. IPX4 2M/3M straight probe:: Prevents from splashing water or liquids, IPX8

2M/3M straight probe: Waterproof

Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in the 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: 135mm (Length) ×95mm (Width) ×35 (Height) mm

Weight: About 180g (including batteries)

Environment

Working:

Temperature: +5℃~+40℃

Humidity: ≤80%

Atmospheric Pressure: 70 kPa~l06kPa

Transport and Storage:

Temperature: -10℃~+55℃

Humidity: ≤93%

Atmospheric Pressure: 50 kPa~l06kPa

Display: 45mm×25mm LCD display

Backlight: with control to switch on and off the back light

FHR Performance

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

Resolution: 1BPM

Accuracy: ±2BPM

Power consumption: < 1 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-: <1 MPa

Iob: <20 mW/cm2

Ispta: <100 mW/cm2

Ultrasonic Output Power: P < 20 mW

Working Mode: Continuous wave doppler

Effective Radiating Area of Transducer: < 208mm2

Note: In all working application modes, mechanical index: MI<1, thermal index: TI<1.

Section 7 Maintenance

7.1 Maintenance

IMPORTANT: The probe acoustic surface (The round end of the probe wand) is very sensitive and must be handled with care. Any hitting, dropping or extra pressure on this part can damage the device and also void the warranty.

- The gel must be wiped from the probe after use.
- The user must check that the equipment does not have visible evidence of damage that may affect patient safety or the device performance before use.
- The equipment should undergo periodic safety testing to ensure 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. (For professional use)
- The algorithm of FHR calculation is controlled by the equipment and cannot be adjusted by the user. If the user finds the FHR result is unreliable other methods such as a stethoscope should be used immediately to verify the results
- Always store the device in a clean, dry and dust free environment. If you are not using the device for a long period of time, it is recommended to remove the batteries, insert the probe in the device socket and store it in the original box.

7.2 Cleaning

Before cleaning, switch the device off and remove the batteries.

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

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

⚠ **CAUTION** ⚠: Do not use strong solvents (e.g acetone).

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

⚠ **CAUTION** ⚠ Do not allow any liquid to enter the device. Do not immerse any parts of the device into any liquids.

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

⚠ **CAUTION** ⚠: Do not leave any cleaning solution on the surface of the device.

Note: Wipe the surface of the probe with 70% ethanol and leave to air-dry. Otherwise, clean with a dry cloth.

7.3 Disinfecting

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.

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

Chapter 8 Troubleshooting

If the problems listed below arise while using ToronTek Fetal Doppler, Please follow the steps recommended below:

Problems	Possible Reasons	Solutions
No Sound	☐ Volume is too low ☐ Power is low	☐ Adjust the volume ☐ Change or recharge the batteries
Weak sound	☐ Volume is too low ☐ Power is low ☐ No gel has been used	☐ Adjust the volume ☐ Change or recharge the batteries ☐ Apply gel
Noise/Statics	☐ Probe is too close to the main unit ☐ Disturbance from an outside signal ☐ Power is low	☐ Keep the probe apart from the main unit while operating. ☐ Keep far away from outside signals like cell phones ☐ Change or recharge the batteries

Additional info

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	

SAFETY NOTE:

This unit in NOT intended to be used to diagnose, treat, cure or prevent any medical condition unless used by or under the direct supervision of a licensed health provider. Using this device is not a substitute for your own healthcare provider's professional advice. You should never delay seeking medical advice, disregard medical advice or discontinue medical treatment because of using this product. If you think you or your baby may be suffering from any medical conditions you should seek immediate medical attention. While using the device, expecting mom's heartbeat could be possibly heard also. Never make a decision on your baby's health, in case you feel something is wrong even though you could be hearing a heartbeat by using this device. Seek immediate medical attention.