

SONOTRAX Series

Ultrasonic Pocket Doppler

User Manual

EC Declaration of Conformity

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Product: Ultrasonic Pocket Doppler

Model: SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II, SONOTRAX II Pro

Classification (MDD, Annex IX): IIa

We herewith declare that the above mentioned product(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices - as amended by Directive 98/79/EC on in vitro diagnostic medical devices.

All supporting documentation is retained at the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards applied: EN ISO 9001, ISO13485, EN ISO14971, EN ISO10993-1, IEC 601-1, EN 60601-1-1, BS EN 60601-1-4, IEC 60601-1-2, EN 61157, EN 1041, EN 60417-2-2000, IEC/TR 60878-2003, EN 980, EN 55011, ISO 1000, YY 0111-93, EN 61266, EN ISO 780 , GB/T 14740, GB/T 15464

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr 65, D-80339 München, Germany.

Identification number



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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, repairs are carried out by persons authorized by EDAN, 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 clinical use. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately.

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 a procedure.

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Chapter 1 Safety Guidance



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







Type B protection means that these person 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 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 charge normal alkaline batteries, they may leak, and may cause a fire or even explode.



 **WARNING** : Charge the lithium-ion polymer battery with the special charger supplied by EDAN.

 **WARNING** : Don't touch signal input or output connector and the person 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 IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. 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** : SONOTRAX Series Ultrasonic Pocket Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring.

 **WARNING** : We recommend that exposure to ultrasound should be kept as low as reasonably achievable. This is considered to be good practice and should be observed at all time.



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



 **WARNING** : Please use probes provided by EDAN.



 **WARNING** : The stretching length of probe cable should be less than 2m in order to avoid the cable breaking away from the probe socket.



 **CAUTION** : Federal law restricts this device to be used by or on the order of a physician.



 **CAUTION** : Refer servicing to qualified personnel.



 **CAUTION** : The main unit of the SONOTRAX Series 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 source 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 personnel's 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.



Z Inspect the equipment for mechanical and functional damage.



Z Inspect the safety relevant labels for legibility.



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



Z Test the the pregnant woman's leakage current according to IEC 60601-1/1988: 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** : If the rechargeable buttony battery is used, please charge it fully before use in order to protect its performance and life. Under normal temperature, the battery should be charged for 14 hours continuously at standard charge circuit.

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


 **CAUTION** : The device could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

1.2 Symbols




This item is compliant with Medical Device Directive 93/42/EEC of 14 June 1993, a directive of the European Economic Community.



: Attention. Refer to accompanying documents.



 This symbol consisting of two parts, see below.



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



It indicates that the equipment is put on the market after 13 August 2005.

Chapter 2 Introduction

2.1 Overview

SONOTRAX Series Ultrasonic Pocket Doppler is an advanced obstetrical unit, which can meet routine examination requirements of obstetricians. They can also be used for vascular monitoring (optional).

There are six different models available: SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and SONOTRAX II Pro.

SONOTRAX Lite is for simple auscultation (intermittent listening). SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and SONOTRAX II Pro are not only used to listen in the fetal heart, they also display the fetal heart rate on a LCD screen.

2.2 Features

Different models have different features, refer to the chart below for details:

Function Model	SONOTRAX Lite	SONOTRAX Basic	SONOTRAX Basic A	SONOTRAX Pro	SONOTRAX II	SONOTRAX II Pro
LCD Display		√	√	√	√	√
LCD Backlight			√	√	√	√
Mini USB Probe Socket	√	√	√	√	√	√
Probe Detecting	√	√	√	√	√	√
Probe Identifying		√	√	√	√	√
Built-in Speaker	√	√	√	√	√	√
Attached Earphone	√	√	√	√	√	√
Volume Adjustable	√	√	√	√	√	√
Modes Switching		√	√	√	√	√
Audio Recording and Playing				√		√
Alkaline Battery (9V)	√	√	√	√		
Lithium-ion Polymer Battery					√	√
Charge in Machine					√	√

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Low Detecting	Battery	√	√	√	√	√	√
Low Indicating	Battery	√	√	√	√	√	√
Auto Shutdown			√	√	√	√	√
Vascular Monitoring		√	√	√	√	√	√

2.3 Ordering Information

The accessories for normal use supplied or approved by EDAN can be used with SONOTRAX Series Ultrasonic Pocket Doppler.

Accessory	Manufacturer and Part Number
Coupling Gel (0.06litre/0.25litre bottle)	Parker Aquasonic 100 or equivalent, MS2-14019
2.0MHz Waterproof Probe	EDAN, MS3-14320
3.0MHz Waterproof Probe	EDAN, MS3-14321
4.0MHz Waterproof Vascular Probe	EDAN, MS3-14346
8.0MHz Waterproof Vascular Probe	EDAN, MS3-14347
Alkaline Battery (9V)	NANFU, M21-64048
Lithium-ion Polymer Battery (900mAh)	Xwoda Electronics Co. Ltd, M21R-64083
Lithium-ion Polymer Battery (500mAh)	HYENERGY, M21R-64084
Line-in Cable	EDAN, M13-36032
Lithium-ion Polymer Battery Charger	HYENERGY, M21R-64082
Earphone	EDAN, M13-36041
Carry Bag	EDAN, MS1-14268

Chapter 3 Doppler and Accessories

3.1 Appearance

Take example for 2.0MHz waterproof probe.

Figure 3-1 Front Panel

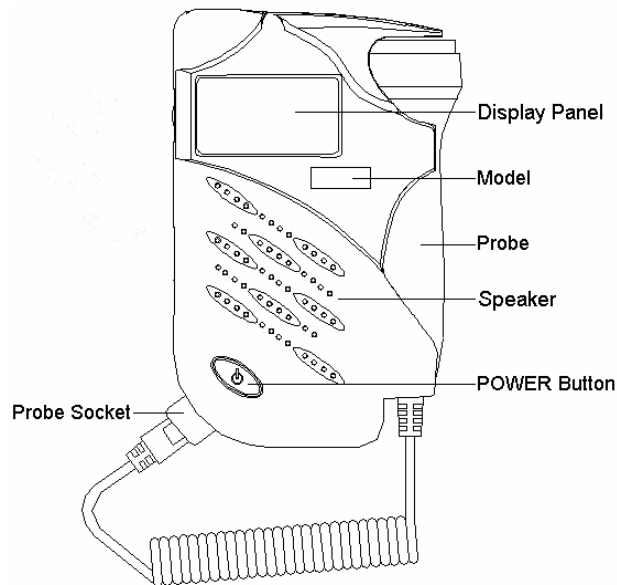


Figure 3-2 Rear Panel

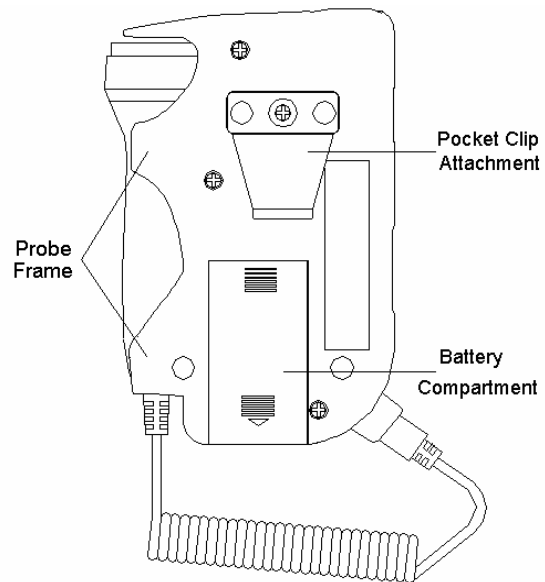


Figure 3-3 Top Panel

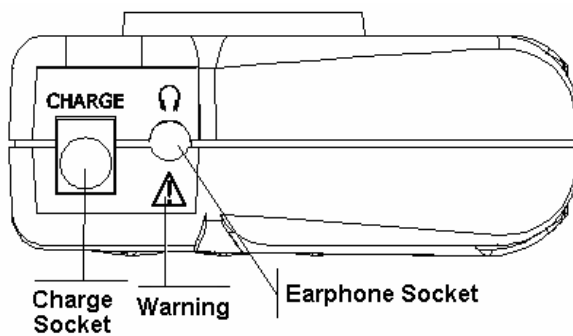
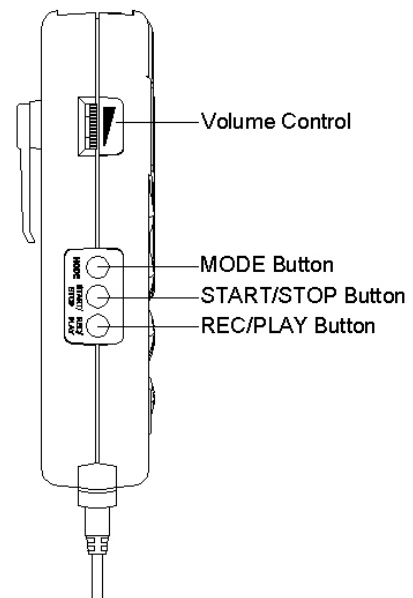


Figure 3-4 Left Panel

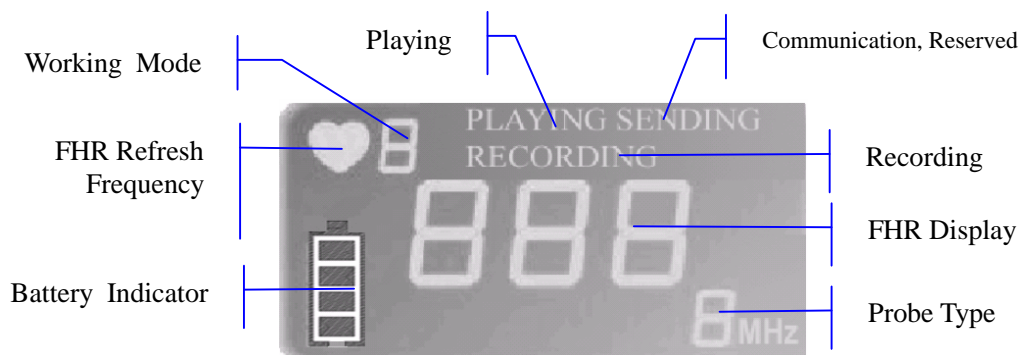


3.2 Display Panel

There is a LED at the left-bottom corner of the display panel area of SONOTRAX Lite. When powered on, the LED turns into green. If the green LED flashes, it indicates that the probe is disconnected or bad connected. If the LED turns into orange and flashes, it indicates that the battery is too low to support working. Change for a new battery or charge the chargeable battery in time.

For SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and SONOTRAX II Pro Ultrasonic Pocket Doppler, while self-testing, the LCD display is as follows:

Figure 3-5 LCD display status while self-testing



Working Mode:

Here shows which working mode is the Doppler working on.

FHR Refresh Frequency:

When monitor starts, the heart shape flashes, its frequency indicates the FHR refreshing frequency.

Battery Indicator:

For SONOTRAX Basic, a battery symbol appears on the LCD after powered on, when battery is low, this symbol flashes; the Doppler will shut down automatically after 7 seconds.

For SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and SONOTRAX II Pro, there are several green panes in the battery symbol on the LCD, which indicates the battery electric energy. The green panes disappear gradually with the energy consumption. When battery is low, the empty symbol flashes for 3 times then the Doppler shuts down automatically.

PLAYING:

PLAYING is highlighted when the Doppler is playing the recorded audio signals.

RECORDING:

RECORDING is highlighted when the Doppler is recording.

FHR Displaying:

Here displays the fetal heart rate value, whose unit is bpm (beat per minute).

Probe Type:

The Doppler can detect and identify the probe: when the probe is not connected or not well connected to the Doppler, the “---” symbol and “MHz” symbol on the LCD screen flash; when the probe is well connected, the flashing stops, the probe type displays on the LCD screen.

Communication

The Doppler can communicate with PC. This function is reserved.

3.3 Buttons

At most there are four push buttons (**Power**, **MODE**, **START/STOP** and **REC/PLAY**) and a volume control button on the SONOTRAX Series Ultrasonic Pocket Doppler. Their primary functions are as follows:

(1) Power Button

Function: Switch on or off the Doppler.

(2) MODE Button

(Only for SONOTRAX Basic / SONOTRAX Basic A/ SONOTRAX Pro/ SONOTRAX II/ SONOTRAX II Pro)

Function: Select the working mode.

(3) START/STOP Button

(Only for SONOTRAX Basic/ SONOTRAX Basic A/ SONOTRAX Pro/ SONOTRAX II/ SONOTRAX II Pro)

Function: Start/ stop monitoring (Mode 3)/ setting (Mode 4 and Mode 5).

(4) REC/PLAY

(Only for SONOTRAX Pro/ SONOTRAX II Pro)

Function: Start/ stop recording or playing.

(5) Volume Control Indicator

Function: Adjust volume. Rotate the volume gear clockwise to turn up the volume, while rotate it anti-clockwise to turn down the volume.

3.4 Socket

The two sockets are located on the top panel of the Doppler.


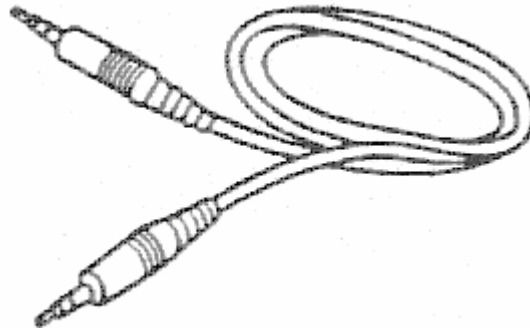
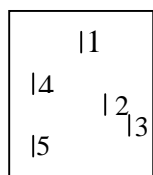
- (1) **Earphone socket** : the earphone or line-in cable connects to the Doppler via this socket.

Figure 3-6 Line-in Cable



: Attention. Refer to the accompanying documents.


Signal Interface



- | | | | |
|---|--------|---|--------|
| 1 | GND | 2 | Signal |
| 3 | Signal | 4 | Signal |
| 5 | Signal | | |

CHARGE



- (2) **Charge socket** : the special lithium-ion polymer battery charger connects to the Doppler via this socket. (For SONOTRAX II and SONOTRAX II Pro only)

NOTE: 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 IEC 60601-1-1. 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.

3.5 Probes

3.5.1 Waterproof Probes

2.0MHz/3.0MHz waterproof probe can be connected with the main unit of the SONOTRAX Series.

Figure 3-7 2.0MHz waterproof probe

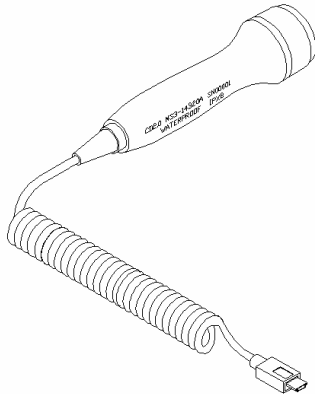
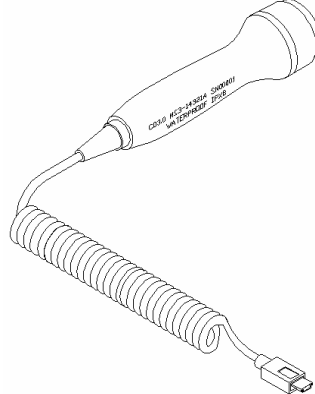


Figure 3-8 3.0MHz waterproof probe



The main information on the probe is as follows:

CD2.0/3.0: CD means continuous wave Doppler, 2.0/3.0 means central frequency is 2.0 MHz/3.0MHz.

MS3-14320: Part number of the 2.0MHz waterproof probe.

MS3-14321: Part number of the 3.0MHz waterproof probe.

A: Version number of the probe.

SNxxxxx: Serial number of the probe.

Waterproof: The probe is waterproof.

IPX8: Water Ingress Protection Code, which indicates this probe can work continuously for 5 hours when being immersed into water within 1 meter depth.

3.5.2 Waterproof Vascular Probes

The 4.0MHz (optional) and the 8.0MHz waterproof vascular probes are used for monitoring arteries and veins.

Figure 3-9 4.0MHz Waterproof Vascular Probes

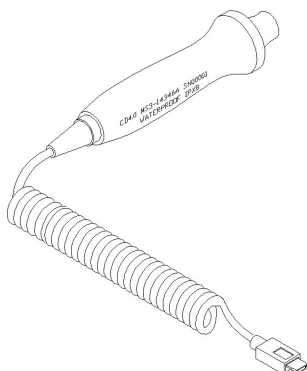
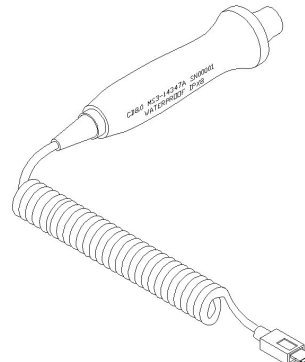


Figure 3-10 8.0MHz Waterproof Vascular Probes



The main information on the probe is as follows.

CD 4.0/CD8.0: CD means continuous wave Doppler, 4.0/8.0 means the central frequency is 4.0/8.0 MHz.

MS3-14346: EDAN part number of 4.0MHz waterproof vascular probe.

MS3-14347: EDAN part number of 8.0MHz waterproof vascular probe.

A: the version number of this vascular probe.

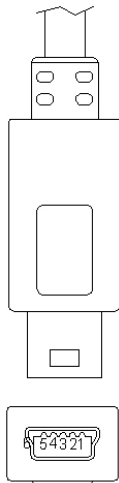
SNxxxxx: Serial number of this vascular probe.

Waterproof: The probe is waterproof.

IPX8: Water Ingress Protection Code, which indicates this probe can work continuously for 5 hours when being immersed into water within 1 meter depth.

3.5.3 Probe Socket

Figure 3-11 Probe socket



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

The probe socket is shown as Figure 3-11.

Connect the 2.0MHz waterproof probe, 3.0MHz waterproof probe, 4.0MHz waterproof vascular probe or 8.0MHz waterproof vascular probe developed by EDAN to the SONOTRAX Series according to real requirements.

⚠ WARNING ⚠: Do not try to connect any other plug to the probe socket except the plug of the probes mentioned above.

⚠ WARNING ⚠: In case of disengaging from the probe interface, the connecting cable of the probe can not be dragged for more than 2 meters.

3.6 Battery

Power of the SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A and SONOTRAX Pro Doppler comes from a 9V alkaline battery (IEC Type No. 6LR61/6LF22 or equivalent).

Power of the SONOTRAX II and SONOTRAX II Pro Doppler comes from a lithium-ion polymer battery supplied by EDAN.

Chapter 4 Operation

NOTE: To ensure that the Doppler would work properly, please read this chapter and **Chapter 1 Safety Guidance** before operating; follow the steps when connecting all the components.

4.1 Opening the Package and Checking

Open the package; take out the Doppler and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

Z Check for any mechanical damage.

Z Check all the cables and accessories.

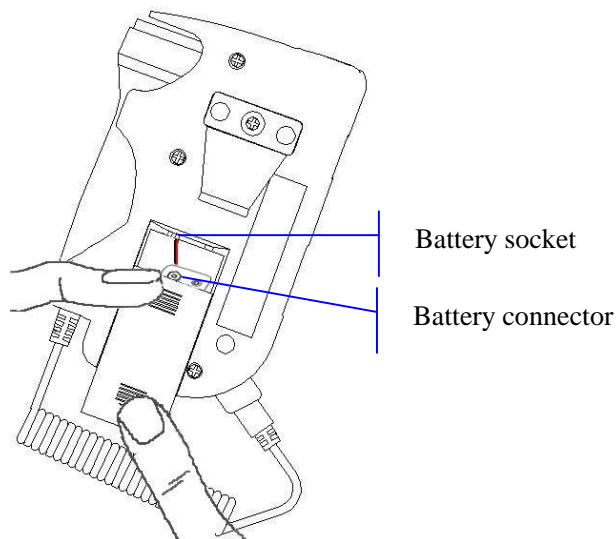
If there is any problem, contact us or your local distributor immediately.

4.2 Installing Battery

1. Open the battery compartment.

Turn the rear panel up. Press the top stripe symbols of the compartment cover hard with one thumb. Meanwhile slide the cover out along the direction of arrowhead with the other thumb (figure 4-1).

Figure 4-1 Remove the compartment cover



2. Place the battery.

For SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A and SONOTRAX Pro Doppler, there is a battery connector that has been inserted to the battery socket in the compartment. Take out a new battery and connect the battery to the connector; put the assembly back into the compartment with the connector inward.

For SONOTRAX II and SONOTRAX II Pro Doppler, insert the plug of the lithium-ion polymer battery into the battery socket and put them into the compartment with the wires inward.

3. Slide the compartment cover back to close the compartment.

⚠ CAUTION ⚠: Take out the battery and keep it in cool and dry environment if the Doppler will not be used for a long time.

⚠ CAUTION ⚠: For the lithium-ion polymer battery, charge it in the machine with the special charge when its power is low. Do not charge it with other charges or remove it frequently.

4.3 Probe Operation

(1) Taking out Probe

Hold the Doppler main unit with one hand, and hold the top of the probe with another hand (Figure 4-2). First take out the top of the probe (Figure 4-3). Then take out the whole probe from the probe frame (Figure 4-4).

(2) Placing Probe

Follow the opposite steps to take out the probe.

Hold the main unit with one hand, and hold the top of the probe with another hand (Figure 4-4). Place the probe from the middle of the unit (at the right) into the probe holder (Figure 4-3), then push the top of the probe (Figure 4-2).

Figure 4-2

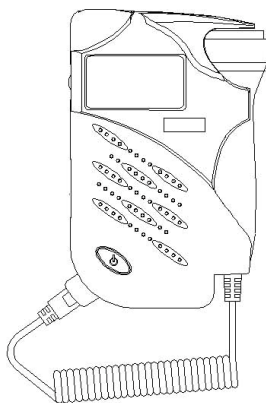


Figure 4-3

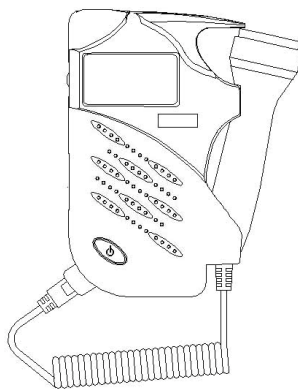
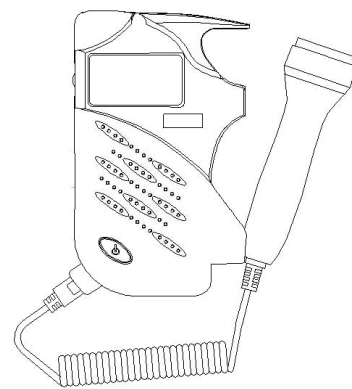


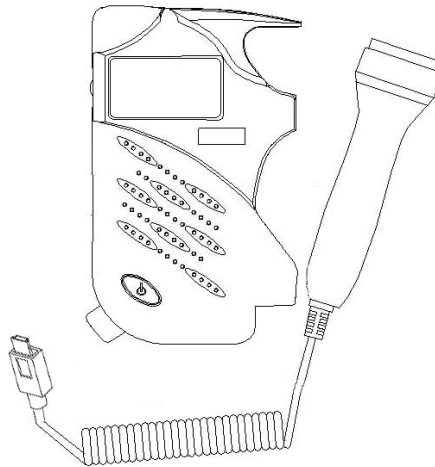
Figure 4-4



(3) Removing and Connecting a Probe

One probe has been connected to SONOTRAX Series ultrasonic pocket Doppler while packed by the manufacturer. If the user needs to replace it with another probe, take out the probe first; then pull out the plug of the probe from its socket (figure 4-5). Connect the plug of another probe to the socket and then the probe can be used.

Figure 4-5 Remove the Probe



NOTE: Place the temporarily unused probe carefully and avoid falling off, splash or stress, etc. When the Doppler is not used for a long time, it's recommended to connect the probe to the Doppler and keep them safely in the package.

4.4 Turn on the Doppler

Press the **POWER** button on front panel to turn on the Doppler.

4.5 Modes Setting

SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and SONOTRAX II Pro Dopplers have a number of mode options. Press the **MODE** button to switch to the next mode.

If the SONOTRAX Basic/ SONOTRAX Basic A/ SONOTRAX Pro/ SONOTRAX II/ SONOTRAX II Pro Doppler worked on Mode1/ Mode 2/ Mode 3 last time before shutdown, after self-testing, the Doppler will enter the same mode automatically. If its last mode is Mode 4/ Mode 5, it will enter Mode 1 after self-testing.

4.5.1 Real-time FHR Display Mode (Mode 1)

When the Doppler works on this mode, the Working Mode on LCD displays 1.

As soon as a fetal heart signal is detected, the heart shape on LCD flashes, the FHR display area displays the real-time FHR value.

4.5.2 Averaged FHR Display Mode (Mode 2)

When the Doppler works on this mode, the Working Mode on LCD displays 2.

The heart shape on LCD flashes when fetal heart signal is detected, the FHR value indicates the average value of 8 beats, which changes slowly.

4.5.3 Manual Mode (Mode 3)

When the Doppler works on this mode, the Working Mode on LCD displays 3.

Press **START/STOP** button once and immediately start counting, count 1 on the moment when the button is pressed. The LCD displays the flashing heart shape symbol and “---”. Press the button again on the 10th count (after 9 beat intervals).

The Doppler automatically calculates the derived FHR averaged over the 10 beat periods and displays the result. This rate value will not disappear until another measurement starts or the mode is changed.

4.5.4 Back Light Brightness Setting Mode (Mode 4)

This mode is only for SONOTRAX Basic A/ SONOTRAX Pro/ SONOTRAX II/ SONOTRAX II Pro.

When the Doppler works on this mode, the Working Mode on LCD displays 4.

Press **START/STOP** button to set the brightness of white back light. “OFF” displayed at the LCD means the white back light is disabled, while “ON” means the white back light is enabled.

NOTE: The setting under this mode will be saved automatically after mode switching or normal power off.

4.5.5 Record Sampling Frequency Setting Mode (Mode 5)

SONOTRAX Pro/ SONOTRAX II Pro Doppler have the build-in function of recording and playing audio signals, this mode is used to set the record sampling frequency.

When the Doppler works on this mode, the Working Mode on LCD displays 5.

Press **START/STOP** button, the sampling frequency switches between 4 and 8 on the LCD. “4” means the frequency is 4KHz, the longest record time is 480 seconds; while “8” means 8KHz, the longest record time is 240 seconds.

NOTE: (1) The setting under this mode will be saved automatically after mode switches or normal power off.

(2) After changing frequency, the records related to the original frequency will be cleared automatically.

4.6 Fetal Heart (FH) Monitoring

FH monitoring with 2.0MHz waterproof probe or 3.0MHz waterproof probe

Feel the position of the fetus by hand firstly to find out the best direction to 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. Refer to figure 4-6.

Figure 4-6 FH monitoring



The audio fetal heart beat is sent out via the built-in speaker or attached earphone; the FHR value is displayed on the LCD (except SONOTRAX Lite).

NOTES:

- 1) **The best quality records will only be obtained if the probe is placed in the optimum position.**
- 2) **Positions with strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate) should be avoided.**
- 3) **If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable to the mother.**
- 4) **It is not possible to FHR unless an audible fetal heart signal is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.**

4.7 Build-in Recording and Playing

This function is only for SONOTRAX Pro/ SONOTRAX II Pro.

Recording: Press the **REC/PLAY** button and hold for 3 seconds under mode 1, 2 or 3, the machine starts recording, "RECORDING" will appear on the LCD. The longest record time depends on the recording sampling frequency set in mode 5. The machine records 480 seconds with 4KHz frequency and 240 seconds signal with 8KHz frequency.

The machine will stop recording and return to monitoring status when the limited time is over or when the user presses the **REC/PLAY** button again.

Playing: Press the **REC/PLAY** button under mode 1, 2 or 3 when the machine is not recording, “PLAYING” will appear on the LCD, the machine plays the recorded signals. When playing is over or the user presses the **REC/PLAY** button again it will return to the monitoring status.

4.8 Record Fetal Heart Sounds

The fetal heart sound signal can be transferred to a personal computer (PC) and recorded by its Sound Recorder. You can play the recorded sound files, burn them into CDs or e-mail them to whomever you want.

4.8.1 Record Sounds



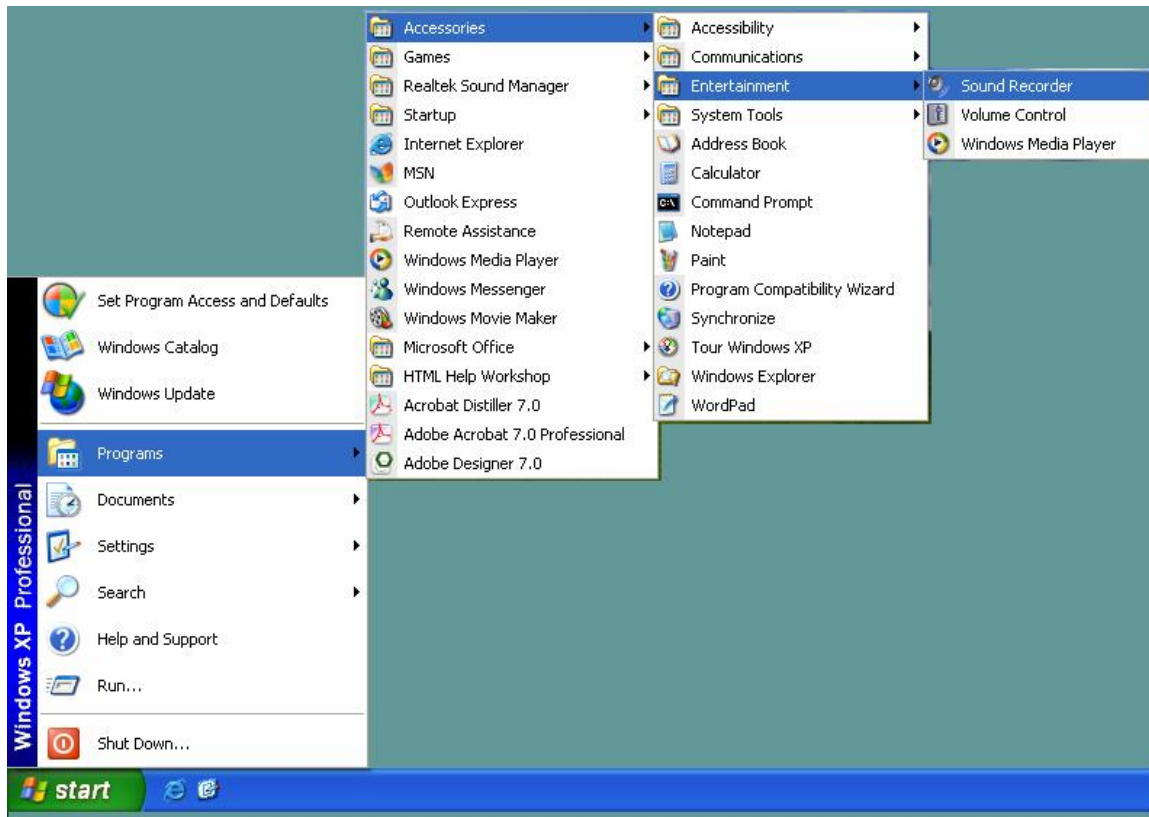
Insert one plug of the special audio cable supplied by the manufacturer to the audio input socket (socket with the symbol “”) of the PC, refer to figure 4-7. If the PC has no audio input socket, insert the plug into the microphone socket (socket with the symbol “”).

Figure 4-7 The Audio Input Socket on the PC



Turn on the PC; startup the sound recorder (Click “Start” → “Programs” → “Accessories” → “Entertainment” → “Sound Recorder”). Refer to figure 4-8.


Figure 4-8 Startup the Sound Recorder




Monitor the FHR with the method described in section 4.6. When the ideal signal is detected, unplug the earphone first if it's connected; insert the other plug of the audio cable into the earphone socket on the Doppler.

Figure 4-9 The Sound Recorder



Click **Start**  to start recording, refer to figure 4-9.

You can record 60 seconds every time, when time is up, click **Start** again to keep on recording.

Click **Stop**  to stop recording, refer to figure 4-10.

Click "**File**" → "**Save**", input the file name, select a folder and click **Save**.

To start a new recording, click "**File**" → "**New**".

Figure 4-10 Recording



4.8.2 Play Sound Files

The recorded sounds are saved as a waveform (.wav) file in your computer.

You can play the waveform file in Sound Recorder. Startup the Sound Recorder, click “**File**” → “**Open**”, search for the folder and select the file, click **Open** to load the file, click **Play**



If you have any other program that supports waveform (.wav) files installed on your PC, double click the file to play it.

4.8.3 Burn CD or Send in Email

The waveform files saved in your PC are normal audio data files. You can burn them into CDs or e-mail to whomever you want.

4.8.4 Record Troubleshooting

If there is audio output from the speaker or earphone, but when recording starts, no sound is input. (The green line recording area has no waveform.) The reason could be:

1. The plug of audio cable is not well connected to the Doppler or the PC socket.

Re-connect the cable if this condition is detected.

2. The plug of audio cable has been inserted to the wrong socket of the PC, instead of the audio input socket or the microphone socket.

Insert the plug to the right socket if this condition is detected.

3. The Line in or microphone is muted on PC.

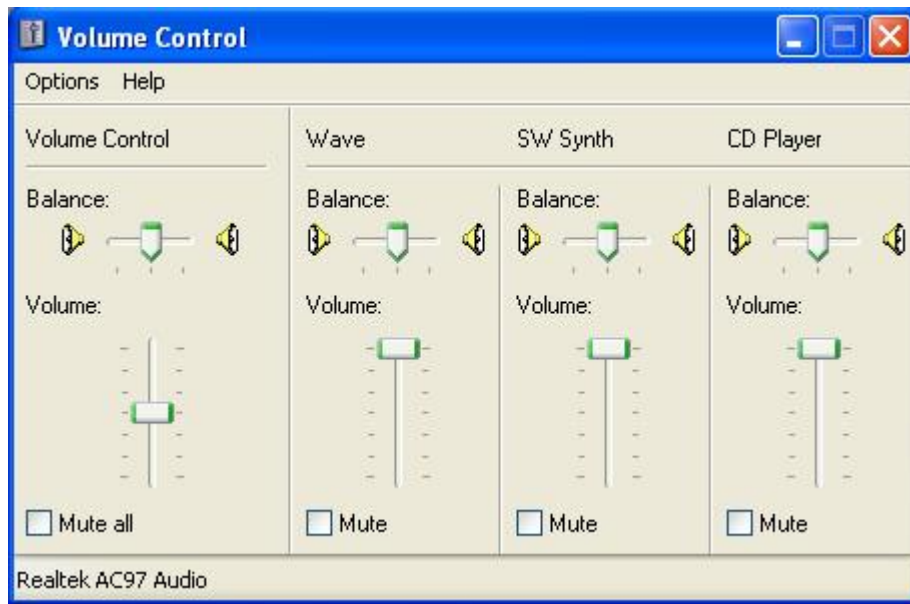
If this condition is detected, change the setting of the PC in these steps:

- a) Double click the volume symbol on the right bottom corner;



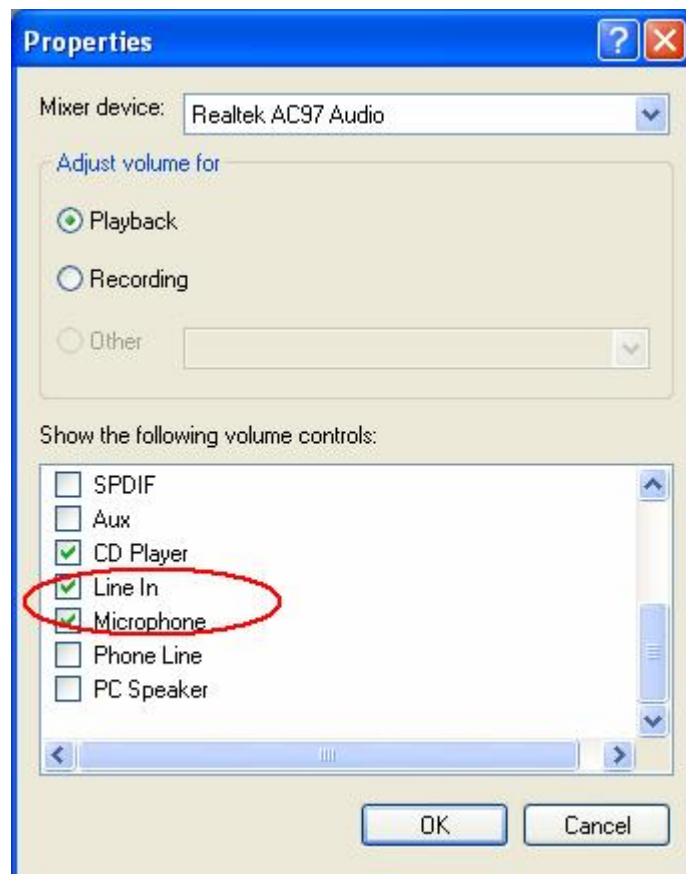
- b) The Volume Control menu pops up:

Figure 4-11 Volume Control

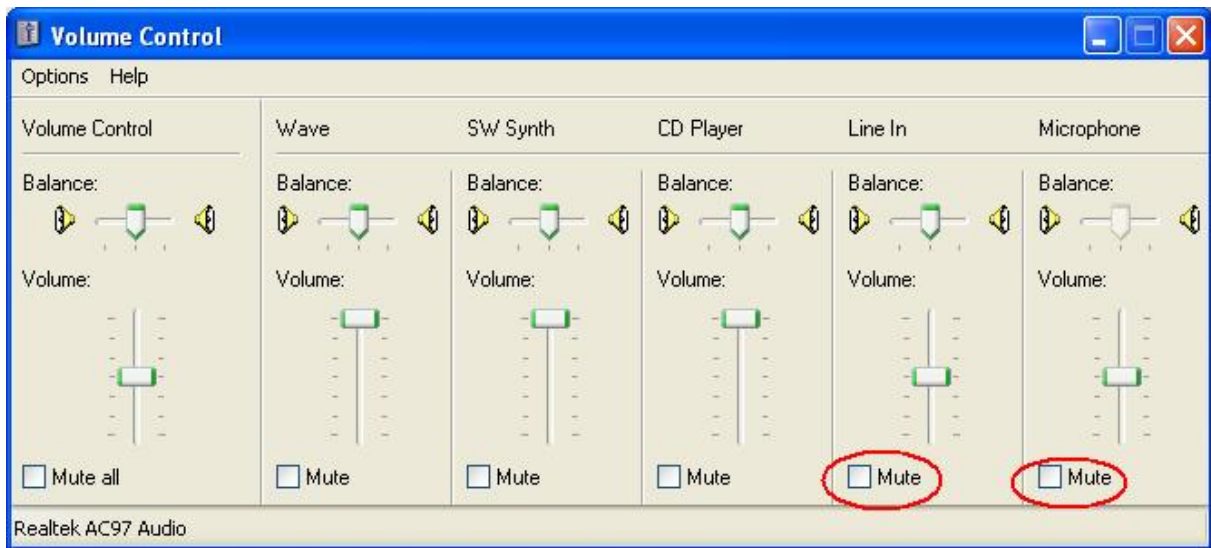


- c) If the Line In or microphone volume control is not shown in the Volume Control menu, click “Options” → “Properties”, tick the Line In and Microphone as shown in figure 4-12, click **OK**:

Figure 4-12 Properties



d) Undo the tick of Line In and Microphone Mute, click  to exit.



e) Start a new recording.

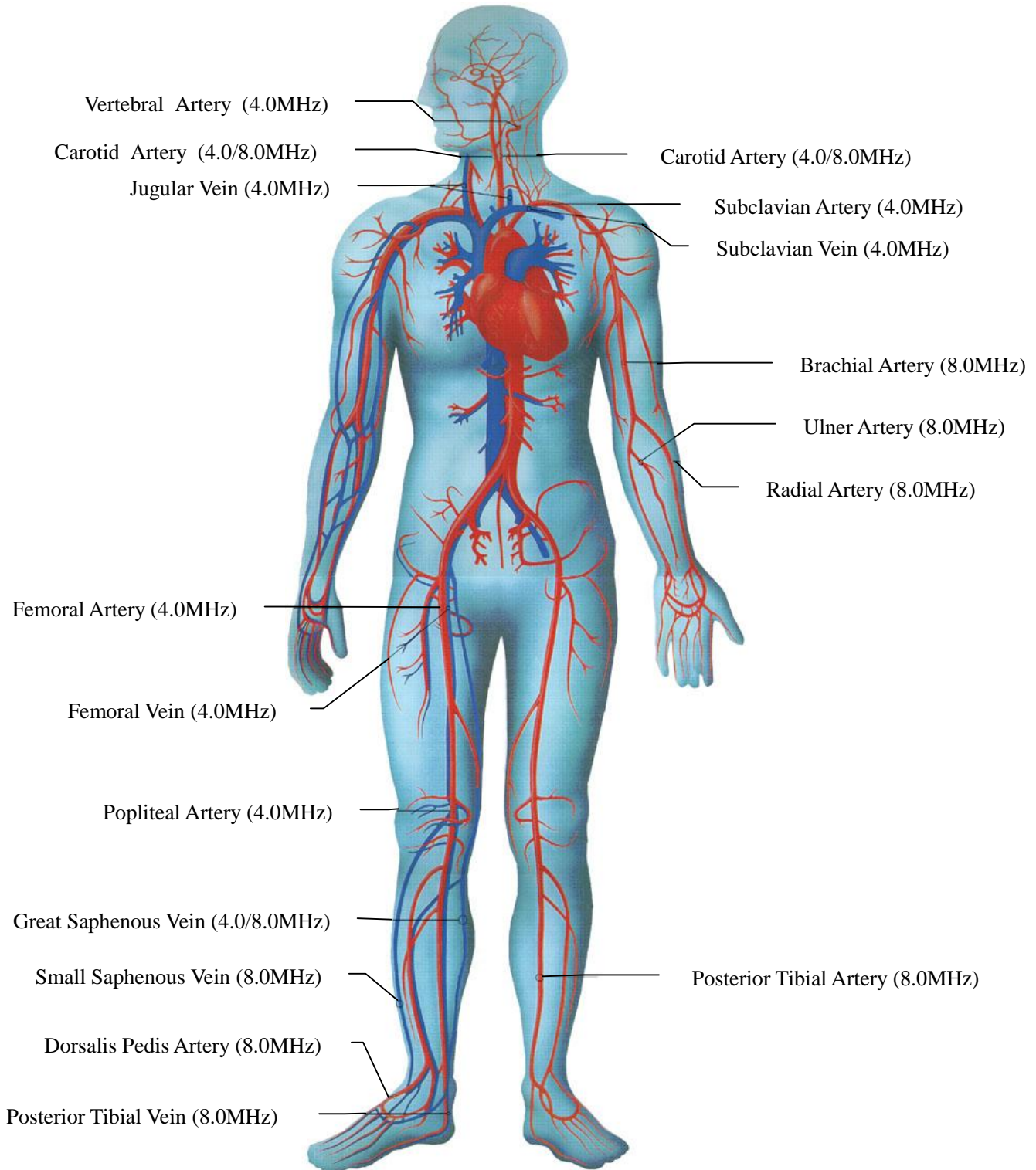
4.9 Vascular Monitoring (Optional)

If the SONOTRAX Series Ultrasonic Pocket Dopplers are connected with 4MHz or 8MHz probes, they can be used to do vascular monitoring, which meets most arterial and venous assessment applications, including helping to detect arterial and venous disease, arterial and venous flow studies and other application where detection of blood flow is important.

Choose appropriate probe as needed. The 8MHz probe has better resolution and wider detecting range than the 4MHz probe, but the 4MHz has a deeper detecting depth.

Apply a liberal amount of gel on the site to be examined. Place the probe at 45° to the skin surface over the vessel to be examined. Adjust the position of the probe to obtain the loudest audio signal. Refer to figure 4-13 for the probe sites:

Figure 4-13 Probe sites



For best results, keep the probe as still as possible once the optimum position has been found. Adjust the audio volume as required. High pitched pulsatile sounds are emitted from arteries while veins emit a non-pulsatile sound similar to a rushing wind.

Vascular monitoring provides audio signals of arteries and veins. If it is done with SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II or SONOTRAX II Pro, the figure displayed on the LCD screen is null.

4.10 Shut down the Doppler

When the monitor is finished, wipe off the remaining gel off the probe with a clean soft cloth, then put the probe back into the probe frame.

Press the **POWER** button on the SONOTRAX Lite again to shut it down.

If there is no signal input or no operation done to SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and SONOTRAX II Pro for 60 seconds, it will automatically shut down. Or the users can press and hold the **POWER** button for 3 seconds to shut it down manually.



4.11 Replacing or charging the battery



When the Doppler gives out alarm indicating the battery power is low, you have to shut down the Doppler to replace or charge the battery.

For SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A and SONOTRAX Pro Doppler, follow the reverse order of installing a battery described in section 4.2 to replace the battery.

For SONOTRAX II and SONOTRAX II Pro Doppler, charge their lithium-ion polymer battery in the machine by inserting the DC plug of the special charger supplied by EDAN in to the charge socket on the Doppler and connecting the AC plug of it to the a.c.110-240V, 50/60 Hz power supply.

It takes about 4 hours to fully charge the battery. When charging, the LED of the charger is orange; when the battery is fully charged, the LED turns to green.

 **CAUTION** : Make sure the Doppler is shutdown before charging the battery or opening the battery compartment.

 **CAUTION** : Only charge the lithium-ion polymer batter of SONOTRAX II and SONOTRAX II Pro in the machine. Do not use the Doppler for monitoring until the charger is disconnected with the Doppler.

Chapter 5 Product Specifications

Product Name: Ultrasonic Pocket Doppler


Model No.: SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II, SONOTRAX II Pro

Safety:

Complies with: EN 60601-1/1990

Classification:

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type B equipment 

Degree of Protection against Harmful Ingress of Water:

Main Unit: Non-protected

2.0MHz Waterproof Probe, 3.0MHz Waterproof Probe, 4.0MHz Waterproof Vascular Probe, 8.0MHz Waterproof Vascular Probe: IPX8 Water Ingress Protection Code, which indicates this probe can work continuously for 5 hours when being immersed into water within 1 meter depth.

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

Physical Characteristic:

Size: 32 (Depth) x 85 (Width) x 138 (Height) mm

Weight: 290±5g (including a battery and a probe)

Environment:

Working: Temperature: +5°C ~ +40°C
 Humidity: ≤80%
 Atmospheric Pressure: 860hPa ~ 1060hPa

Transport and Storage: Temperature: -10°C ~ + 55°C
 Humidity: ≤93%
 Atmospheric Pressure: 860hPa ~1060hPa

Display: 45*25mm LCD display

FHR Performance:

FHR Measuring Range: 50bpm ~ 210bpm

Resolution: 1bpm

Accuracy: ±3bpm

Recording and Playing:

Audio Sampling Frequency: 4KHz / 8KHz

Recording Length: 480s / 240s

Recording can be played

White Back Light:

Two Brightness Adjustable: OFF, ON

Audio Output Power: 0.5W

Auto Shut down:

After 1 minute no signal or no operation, auto shut down

Battery Type Recommended:

9 volt DC alkaline battery (IEC Type No. 6LR61/6LF22 or equivalent).

Stand-by Time (hour):

9V Alkaline Battery	SONOTRAX Lite	>10 hours
	SONOTRAX Basic	>13 h
	SONOTRAX Basic A	>8 h (with backlight), >13 h (without backlight)
	SONOTRAX Pro	>8 h (with backlight), >13 h (without backlight)
Lithium-ion Polymer Battery	500mAh	>8 h (with backlight), >13 h (without backlight)
	900mAh	>15 h (with backlight), >24 h (without backlight)

Lithium-ion Polymer Battery

Type:	Lithium-ion Polymer Battery
Nominal Capacity:	≥500mAh
Nominal Voltage:	7.4V
Charge Mode:	Constant current / Constant voltage
Charge Current (Standard):	300mA
Charge Voltage (Standard):	8.4V
Storage Temperature:	-20°C ~ 40°C (3 months)
	-20°C ~ 60°C (1 month)
Circle Life:	≥500 times

Ultrasound

Nominal Frequency	2.0MHz Waterproof Probe	2.0MHz
	3.0MHz Waterproof Probe	3.0MHz
	4.0MHz Waterproof Vascular Probe	4.0MHz
	8.0MHz Waterproof Vascular Probe	8.0MHz
Working Frequency	2.0MHz Waterproof Probe	2.0MHz±10%
	3.0MHz Waterproof Probe	3.0MHz±10%
	4.0MHz Waterproof Vascular Probe	4.0MHz±10%
	8.0MHz Waterproof Vascular Probe	8.0MHz±10%
$P_{-} < 1\text{MPa}$		
$I_{ob} < 10\text{ mW/cm}^2$		
$I_{spta} < 100\text{mW/cm}^2$		
Working Mode	Continuous wave Doppler	
Effective Radiating Area of Transducer	2.0MHz Waterproof Probe	$245\text{mm}^2 \pm 15\%$
	3.0MHz Waterproof Probe	$245\text{mm}^2 \pm 15\%$
	4.0MHz Waterproof Vascular Probe	$32\text{mm}^2 \pm 15\%$
	8.0MHz Waterproof Vascular Probe	$14\text{mm}^2 \pm 15\%$

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 the pregnant woman's safety or SONOTRAX Series 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 personnel 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 manufacturer to get help.

6.2 Cleaning



Before cleaning, switch off the power and take out the batteries.

Keep the exterior surface of the device clean and free of dust and dirt, clean exterior surface (display screen included) of the unit with a dry, soft cloth. If necessary, clean it 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 coupling gel. Clean with soap and water only.

 **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 part of the device into any liquid.

 **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 or isopropanol alcohol, self-air dry, or clean with a clean, dry cloth.

6.3 Disinfection

Clean the equipment exterior surface, probe, etc. as above. For the disinfecting of 2.0MHz waterproof probe/ 3.0MHz waterproof probe, immerse the probe into the solutions of Benzalkonium Bromide, 0.5% Chlorhexidine, 2% Glutaraldehyde or 75% ethanol to disinfect. Wipe the probe with a clean, dry cloth to remove any remaining moisture.

NOTE: Please pay attention to the height when the probe is immersed in order to prevent the sterilant from entering the probe socket.

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

Chapter 7 Warranty and Service

Warranty

EDAN warrants 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.

EDAN provides a one-year-warranty for the products (accessories are included). The warranty period begins on the date the products are shipped to distributors. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge.

The product can not be repaired by users. All services must be done by the engineers approved by EDAN. Misuse, improper maintenance may void the warranty.

After Service

Upon request, EDAN can provide technical documentation or schematic diagram to the qualified engineer approved by EDAN. If you require, please contact us.

For service any question regarding this device, please contact EDAN or your local distributor. Get service details from EDAN website: <http://www.edan.com.cn>.

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Appendix A EMC Information-Guidance and Manufacture's Declaration


A1.1 Electromagnetic Emissions - for all Equipment and Systems

Guidance and manufacture's declaration–electromagnetic emission		
The SONOTRAX Series Ultrasonic Pocket Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment–guidance
RF emissions CISPR 11	Group 1	The SONOTRAX Series Ultrasonic Pocket Doppler uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The SONOTRAX Series Ultrasonic Pocket Doppler is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

A1.2 Electromagnetic Immunity - for all Equipment and Systems

Guidance and manufacture's declaration–electromagnetic immunity			
The SONOTRAX Series Ultrasonic Pocket Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

A1.3 Electromagnetic Immunity - for all Equipment and Systems that are not Life-supporting

Guidance and manufacture's declaration – electromagnetic immunity			
The SONOTRAX Series Ultrasonic Pocket Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the SONOTRAX Series Ultrasonic Pocket Doppler, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SONOTRAX Series Ultrasonic Pocket Doppler is used exceeds the applicable RF compliance level above, the SONOTRAX Series Ultrasonic Pocket Doppler should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SONOTRAX Series Ultrasonic Pocket Doppler.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

A1.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the SONOTRAX Series Ultrasonic Pocket Doppler		
<p>The SONOTRAX Series Ultrasonic Pocket Doppler is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SONOTRAX Series Ultrasonic Pocket Doppler as recommended below, according to the maximum output power of the communications equipment.</p>		
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distances in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>		

Appendix 2 Overall Sensitivity

Overall Sensitivity (2MHz Probe)													
Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A(d)	Two-way Attenuation B=Σ B _a +B _w							V _s (r.m.s.) mV	V _n (r.m.s) mV	C = 20log ₁₀ $\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
			Σ B _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		

Overall Sensitivity (3.0 MHz Probe)													
Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A(d) (dB)	Two-way Attenuation B=ΣB _a +B _w						V _s (r.m.s.) mV	V _n (r.m.s) mV	C = 20log 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=44.5dB@ 3MHz	50		T	10	4	-	-	0	61.5	179	90	5.97	111.9
			B _a	43.6	17.9	-	-						
	75		T	10	3	-	-	0	57.2	186	94	5.93	107.63
			B _a	43.6	13.5	-	-						
	100		T	10	3	-	-	0	57.2	173	88	5.87	107.5
			B _a	43.6	13.5	-	-						
	200		T	10	1	-	-	0	50.2	171	89	5.67	100.3
			B _a	43.6	6.5	-	-						
2.38 A=42.0dB@ 3MHz	50		T	10	4	-	-	0	61.5	194	88	6.73	110.2
			B _a	43.6	17.9	-	-						
	75		T	10	3	-	-	0	57.2	172	87	5.92	105.1
			B _a	43.6	13.5	-	-						
	100		T	10	2	-	-	0	53.2	165	85	5.76	100.9
			B _a	43.6	9.6	-	-						
	200		T	10	1	-	-	0	50.2	160	84	5.59	97.8
			B _a	43.6	6.5	-	-						
Doppler Frequency (Hz)		500							Velocity of Target (cm/s)		12.5		



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