



SONOTRAX
Ultrasonic Pocket Doppler
Release 1.1



About this Manual

P/N: 01.54.455405-11

Release Date: July 2012

© Copyright EDAN INSTRUMENTS, INC. 2012. All rights reserved.

Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Edan Instruments, Inc. (hereinafter called EDAN) can not be held liable.

EDAN owns the copyrights of this manual. Without prior written consent of EDAN, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.

EDAN holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

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

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Product Information

Product Name: Ultrasonic Pocket Doppler

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

Terms 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 a procedure.

Table of Contents

| | |
|---|-----------|
| Chapter 1 Safety Guide..... | 1 |
| 1.1 Intended Use..... | 1 |
| 1.2 Safety Precautions..... | 1 |
| 1.3 Symbols..... | 4 |
| Chapter 2 Doppler and Accessories..... | 5 |
| 2.1 Features..... | 5 |
| 2.2 Main Unit..... | 6 |
| 2.2.1 Appearance..... | 6 |
| 2.2.2 Display Panel..... | 7 |
| 2.2.3 Buttons..... | 8 |
| 2.2.4 Socket..... | 8 |
| 2.2.5 Probe Socket..... | 9 |
| 2.2.6 Batteries..... | 10 |
| 2.3 Probes..... | 10 |
| 2.3.1 Waterproof Obstetrical Probes..... | 10 |
| 2.3.2 Waterproof Vascular Probes..... | 11 |
| Chapter 3 Basic Operation..... | 12 |
| 3.1 Opening the Package and Checking..... | 12 |
| 3.2 Installing/Replacing Battery..... | 12 |
| 3.3 Probe Operation..... | 14 |
| 3.4 Switching on..... | 16 |
| 3.5 Selecting Work Mode..... | 16 |
| 3.6 Enabling or Disabling Backlight..... | 16 |
| 3.7 Switching Off..... | 17 |
| 3.8 Replacing/Charging the Battery..... | 17 |
| 3.8.1 Battery Energy Indication..... | 17 |
| 3.8.2 Replacing Alkaline Batteries..... | 17 |
| 3.8.3 Charging the NI-MH Batteries..... | 18 |
| 3.8.4 Charging NI-MH Battery Pack..... | 19 |
| Chapter 4 Examining..... | 20 |
| 4.1 FH Examining..... | 20 |
| 4.2 FH Sound Recording and Playing..... | 21 |
| 4.3 FH Sound Recording by PC..... | 22 |
| 4.3.1 Recording Sounds..... | 22 |
| 4.3.2 Playing Sound Files..... | 24 |
| 4.3.3 Burning CD or Sending in Email..... | 24 |
| 4.3.4 Record Troubleshooting..... | 24 |
| 4.4 Vascular Examining (Optional)..... | 26 |
| 4.5 Completing Examining..... | 28 |

| | |
|--|-----------|
| Chapter 5 Product Specifications | 29 |
| Chapter 6 Maintenance | 33 |
| 6.1 Maintenance | 33 |
| 6.2 Cleaning | 33 |
| 6.3 Disinfection of the Probe..... | 33 |
| Chapter 7 Warranty and Service..... | 35 |
| 7.1 Warranty..... | 35 |
| 7.2 Contact information..... | 35 |
| Appendix 1 Ordering Information | 36 |
| Appendix 2 EMC Information-Guidance and Manufacture’s Declaration | 37 |
| A2.1 Electromagnetic Emissions - for all Equipment and Systems..... | 37 |
| A2.2 Electromagnetic Immunity - for all Equipment and Systems | 37 |
| A2.3 Electromagnetic Immunity - for all Equipment and Systems that are not Life-supporting..... | 38 |
| A2.4 Recommended Separation Distances | 39 |
| Appendix 3 Overall Sensitivity..... | 40 |

Chapter 1 Safety Guide

NOTE:

This user manual is written to cover the maximum configuration. Therefore, your model may or may not have some of the parameters and functions described, depending on what you have ordered.

1.1 Intended Use

The SONOTRAX Series Ultrasonic Pocket Dopplers (hereinafter called “the Doppler”) are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz waterproof probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability following patient trauma.

The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

1.2 Safety Precautions



This unit is internally powered equipment, and it is an IEC/EN 60601-1 Type B applied part. Type B protection means that the connection between the equipment and personnel complies with permitted leakage currents and dielectric strength of IEC/EN 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

- 1 The Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring. It is not intended for treatment.
- 2 This device is not explosion-proof and can not be used in the presence of flammable anaesthetics.
- 3 Do not touch the signal input/output connector and the patient simultaneously.
- 4 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.
- 5 Only use the probes provided by the manufacturer.
- 6 Do not throw batteries in fire as this may cause explosion.

WARNING

- 7 Do not attempt to charge normal alkaline batteries. They may leak, catch fire or even explode.
 - 8 Remove the batteries and store it at a cool and dry environment if the monitor is not used for a long time.
 - 9 If the rechargeable batteries are stored alone and not used for a long time, we recommend that the batteries should be charged at least once every 6 months to prevent overdischarge.
 - 10 The rechargeable NI-MH batteries and battery pack should be charged by using the dedicated adapters supplied by the manufacturer.
 - 11 **SHOCK HAZARD** - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
 - 12 Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC 60601-1 approved to the device. The operation or use of non-approved equipment or accessories with the device is not tested or supported, and device operation and safety are not guaranteed.
 - 13 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
 - 14 Replacement or charging of the battery shall be done at least 1.5 meters away from patients.
-
-

CAUTION

- 1 Federal (U.S.) law restricts this device to sale by or on the order of a physician.
 - 2 Refer servicing to qualified personnel.
 - 3 The main unit is designed for continuous operation and is 'ordinary'. Do not immerse it in any liquid (i.e. not drip or splash-proof).
 - 4 Keep the device in a clean environment and avoid vibration during storage.
 - 5 Do not disinfect or sterilize the Doppler.
 - 6 **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.
-
-





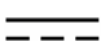






CAUTION

- 7 Prior to examination using the Doppler, check for visible damages of the main unit and the probe that may endanger the patient/operator or machine performance. If the damage is found, replace them with good ones at once.
- 8 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 the pregnant woman's leakage current according to IEC 60601-1: Limit: d.c 10 μ A, a.c 100 μ A.

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.

- 9 When the battery is charged, used or stored, keep it away from objects or materials with static electric charges.
 - 10 If rechargeable batteries are used, charge them fully before initial use by using the method introduced in this manual.
 - 11 Do not short-circuit the batteries or install the batteries reversely.
 - 12 Store the batteries in a cool and dry environment.
 - 13 Do not mix the batteries with metal objects to avoid short-circuit.
 - 14 The device shall only be used when the battery cover is closed.
 - 15 Batteries have life cycles. The alkaline batteries are intended to be used once. If the time that the Doppler using NI-MH battery becomes much shorter than usual, the battery life is at an end. Replace them with a new same one provided or recommended by the manufacturer.
 - 16 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
-
-

1.3 Symbols

| | |
|---|--|
|  | The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices. |
|  | The symbol indicates that the device should be sent to the special agencies according to local regulation for separate collection after its useful life. |
|  | Consult Instructions for Use |
|  | Attention. |
|  | Direct current |
|  | Type B applied part. |
| P/N | Part Number |
|  | Serial Number |
|  | Date Of Manufacture |
|  | Manufacturer |
|  | Authorized Representative in the European Community |
|  | General symbol for recovery / recyclable |
| Rx only (U.S.) | Federal (U.S.) Law restricts this device to sale by or on the order of a physician |

Chapter 2 Doppler and Accessories

2.1 Features

There are seven different models available: **SONOTRAX Lite**, **SONOTRAX Basic**, **SONOTRAX Basic A**, **SONOTRAX Pro**, **SONOTRAX II**, **SONOTRAX II Pro** and **SONOTRAX Vascular**.

SONOTRAX Lite and **SONOTRAX Vascular** are for simple auscultation (intermittent listening). **SONOTRAX Basic**, **SONOTRAX Basic A**, **SONOTRAX Pro**, **SONOTRAX II**, and **SONOTRAX II Pro** not only detect fetal heart sound; they also display the fetal heart rate on a LCD screen.

The features of the Dopplers are listed in the following chart:

| Model Function | SONOTRAX Vascular | 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 | - | - | √ | √ | √ | √ | √ |
| Audio Play | √ | √ | √ | √ | √ | √ | √ |
| Attached Earphone | √ | √ | √ | √ | √ | √ | √ |
| Volume Adjustable | √ | √ | √ | √ | √ | √ | √ |
| Modes Switching | - | - | √ | √ | √ | √ | √ |
| Audio Recording and Playing | - | - | - | - | √ | - | √ |
| Powered by Alkaline Batteries | √ | √ | √ | √ | √ | - | - |
| Powered by Rechargeable NI-MH Batteries | * | * | * | * | * | - | - |
| Powered by NI-MH Battery Pack | - | - | - | - | - | √ | √ |
| Low Battery Detecting & indicating | √ | √ | √ | √ | √ | √ | √ |
| Auto Shutdown | - | - | √ | √ | √ | √ | √ |
| Vascular Examining | √ | * | * | * | * | * | * |

√ = configured - = not available * = available

2.2 Main Unit

NOTE:

The pictures and interfaces in this manual are for reference only.

2.2.1 Appearance

Take 2.0MHz obstetrical probe for example.

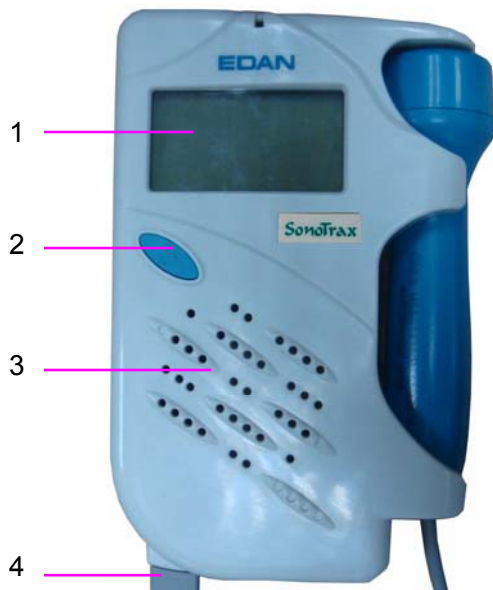


Figure 2-1 Front Panel

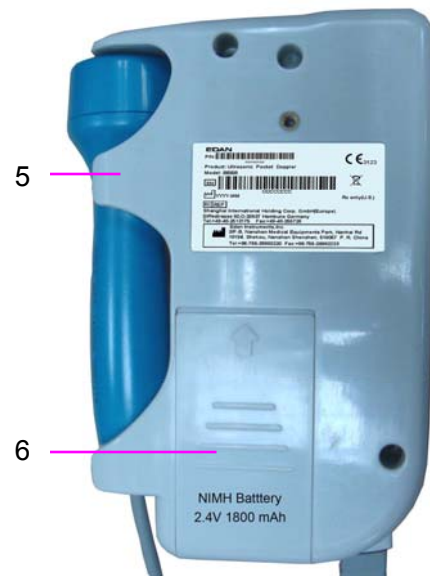


Figure 2-2 Rear Panel

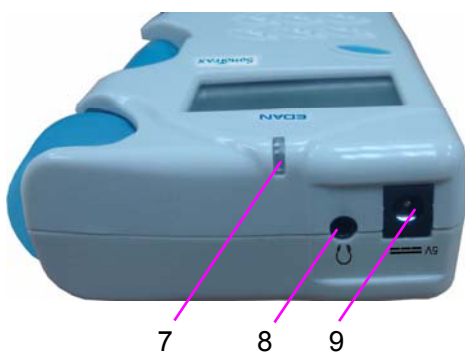


Figure 2-3 Top Panel



Figure 2-4 Left Panel

| | | | | | |
|----|--------------------------------------|----|-----------------|---|---------------------|
| 1 | Display Panel | 2 | POWER Button | 3 | Speaker |
| 4 | Probe Socket | 5 | Probe Holder | 6 | Battery Compartment |
| 7 | Charge Indicator/ Power Indicator | 8 | Earphone Socket | 9 | Charge Socket |
| 10 | Volume Control | 11 | Buttons | | |




2.2.2 Display Panel



SONOTRAX Lite and **SONOTRAX Vascular** have a LED in the bottom left corner of its display panel area. When powered on, the LED turns green. If the LED flashes in green, it indicates that the probe is disconnected or poorly connected. If the LED flashes in orange, it indicates that the battery is too low to support working. Change for a new battery or charge the rechargeable battery in time.

For **SONOTRAX Basic**, **SONOTRAX Basic A**, **SONOTRAX Pro**, **SONOTRAX II** and **SONOTRAX II Pro**, the LCD is shown as follows:



Figure 2-5 LCD

| Item | Screen Element | Description |
|------|---|-----------------------|
| 1 |  | FHR Refresh Frequency |
| 2 |  | Working Mode |
| 3 | PLAYING | Playing Indicator |
| 4 | RECORDING | Recording Indicator |
| 5 |  | Battery Indicator |

| | | |
|---|---|-------------|
| 6 |  | Numeric FHR |
| 7 |  | Probe Type |

2.2.3 Buttons

At most there are three push buttons (**MODE**, **START/STOP** and **REC/PLAY**) and a volume control button on the main unit of the Doppler. Their primary functions are as follows:

(1) **MODE Button**  **MODE**

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

Function: Select the working mode.

(2) **START/STOP Button**  **START/STOP**

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

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

(3) **REC/PLAY**  **REC/PLAY**

(Only for **SONOTRAX Pro/ SONOTRAX II Pro**)


Function: Start/ stop recording or playing fetal heart sound.

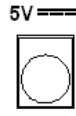
(4) **Volume Control Indicator** 


Function: Adjust volume. Rotate the volume gear toward “+” to turn up the volume, while rotate it toward “-” to turn down the volume.

2.2.4 Socket

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

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



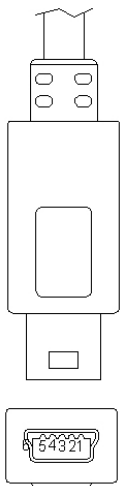
(2) **Charge socket** : for charging the NI-MH battery pack, the dedicated charger connects to the Doppler via this socket. (For **SONOTRAX II** and **SONOTRAX II Pro** only)

NOTE:

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

2.2.5 Probe Socket

The probe socket is as shown in figure 2-6.



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

Figure 2-6 Probe socket

Connect the 2.0MHz/3.0MHz obstetrical probes or 4.0MHz/5.0MHz/8.0MHz vascular probes supplied by the manufacturer to the Doppler through the probe socket.

CAUTION

- 1 Do not try to connect any other plug to the probe socket except the plug of the probes mentioned above.
- 2 Do not stretch the probe cable for more than two meters long.

2.2.6 Batteries

SONOTRAX Lite, **SONOTRAX Basic**, **SONOTRAX Basic A**, **SONOTRAX Pro** and **SONOTRAX Vascular** are powered either by two alkaline batteries or two rechargeable NI-MH batteries.

SONOTRAX II and **SONOTRAX II Pro** are powered by a NI-MH battery pack supplied by the manufacturer.



Alkaline Battery

Rechargeable NI-MH Battery

NI-MH Battery Pack

Figure 2-7 Batteries

NOTE:

The alkaline battery and rechargeable NI-MH battery can be replaced by those of identical specifications purchased locally.

Alkaline battery: LR6, AA, 1.5V.

Rechargeable NI-MH battery: Ni-MH, AA, 1.2V.

2.3 Probes

2.3.1 Waterproof Obstetrical Probes

2.0MHz/3.0MHz waterproof obstetrical probes can be connected to the main unit for fetal heart examining.

The 2MHz obstetrical probe features in deep penetration and is designed for use during the third trimester pregnancy. The 3MHz obstetrical probe features in high sensitivity and is designed for use during the entire pregnancy.

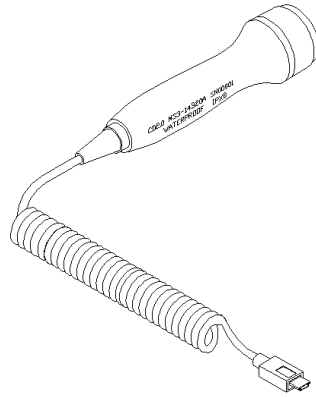


Figure 2-8 2.0/3.0MHz obstetrical probe

The main information on the probe is as follows:

2.0MHz/3.0MHz: means central frequency is 2.0MHz/3.0MHz.

Waterproof: The probe is waterproof.

IPX8: Water Ingress Protection Code. It indicates that this probe does not get soaked under water within 1 meter deep for five hours.

2.3.2 Waterproof Vascular Probes

The 4.0MHz/5.0MHz/8.0MHz waterproof vascular probes can be connected to the main unit for artery and vein blood flow examining.

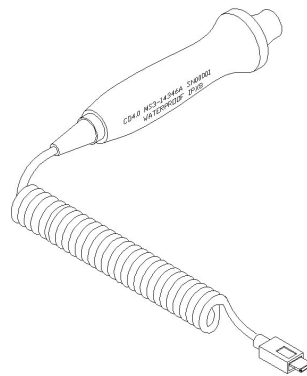


Figure 2-9 4.0/5.0/8.0MHz Vascular Probes

The main information on the probe is as follows:

4.0MHz/5.0MHz/8.0 MHz: means the central frequency is 4.0/5.0/8.0 MHz.

Waterproof: The probe is waterproof.

IPX8: Water Ingress Protection Code. It indicates that this probe does not get soaked under water within 1 meter deep for five hours.

Chapter 3 Basic Operation

NOTE:

To ensure that the Doppler works properly, please read this chapter and *Chapter 1 Safety Guide* before operation; follow the steps when connecting all the components.

3.1 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.

- ◆ Check for any mechanical damage.
- ◆ Check all the cables and accessories.

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

3.2 Installing/Replacing Battery

NOTE:

The battery pack of **SONOTRAX II** and **SONOTRAX II Pro** is fixed in the battery compartment cover. Start from step 3 when installing it.

1) Open the battery compartment.

Turn the Doppler upside down. Hold the main unit with one hand; press the thumb of the other hand on the cover notch and push it upward and forward. The compartment cover is open.



Figure 3-1 Opening battery compartment

2) Install the battery.

Put the alkaline batteries or NI-MH batteries into the battery compartment cover.

CAUTION

The direction of the batteries should comply with the polar mark on the cover. Reversed connection is forbidden.



Figure 3-2 Putting batteries into the compartment cover

3) Close the compartment.

Put the batter compartment cover back into the compartment, push it forward and downward until it clicks closed.

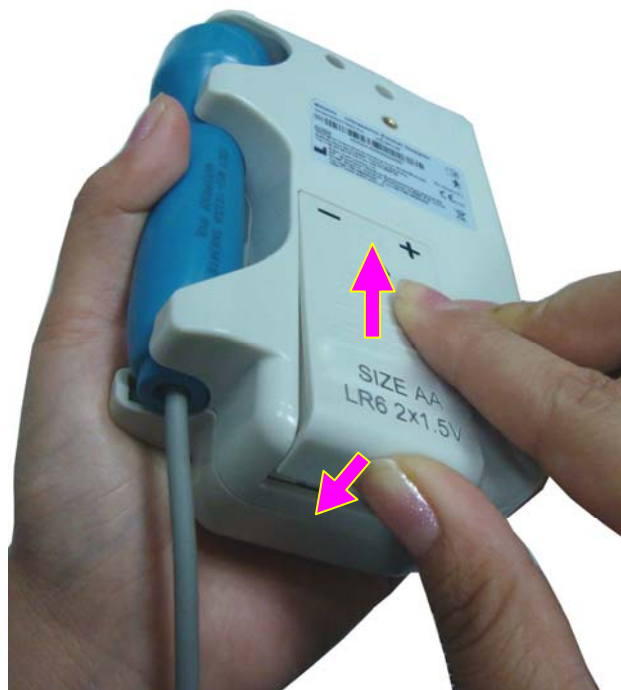


Figure 3-3 Close the battery compartment

CAUTION

- 1 If the Doppler is not used for an extended period, take the alkaline/NI-MH batteries out and store them in a cool and dry environment.
 - 2 Do not remove the NI-MH battery pack frequently after initial installation.
 - 3 If the Doppler is not used for an extended period, charge the NI-MH batteries or the NI-MH battery pack at least every three months.
-

3.3 Probe Operation

(1) Taking out the probe

Hold the main unit with one hand. Pinch the probe and pull it outwards using mild force.



Figure 3-4 Taking out the probe

(2) Placing the probe

Hold the main unit with one hand. Pinch the probe and align it with the probe holder. Push the probe inwards using mild force until it clicks in position.



Figure 3-5 Placing the probe

CAUTION

Do not take out or place the probe when the Doppler is on. Remember to take out the probe before switching on the Doppler, and place the probe after switching off the Doppler.

(3) Replacing the Probe

Remove the old probe:

Switch off the Doppler; hold the main unit with one hand and pinch the jacket of the mini USB socket. Lift the jacket up slightly and pull it out with mild force; take out the probe.

CAUTION

Do not pull the probe cable directly.



Figure 3-6 Removing the probe

Replace it with a new probe:

Put the USB socket of new probe into the probe interface of the Doppler.

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.

3.4 Switching on

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

If the probe is not connected or poorly connected, the LCD display a flashing “--- MHz” sign. You should reconnect the probe properly.


When the probe is well connected, the LCD stops flashing and shows the probe frequency in the bottom right corner.



3.5 Selecting Work Mode

The Doppler has four work modes. They are:

- Mode 1: Real-time FHR Display Mode
- Mode 2: Averaged FHR Display Mode
- Mode 3: Manual Counting Mode
- Mode 4: Backlight Brightness Setting Mode



Press the  **MODE** button on the left panel, the doppler work mode switches among these modes, and the work mode is shown in the top left corner of LCD.



When the doppler is switched on, it enters mode 1 automatically.

3.6 Enabling or Disabling Backlight

SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II and **SONOTRAX II Pro** have backlight. You can enable or disable it.

Keep pressing the  **MODE** button until the working mode on LCD displays **4**. Press the  **START/STOP** button. The backlight is enabled when the LCD reads “ON”, and it is disabled when the LCD reads “OFF”.

The setting in this mode is saved automatically after the mode is changed or normal power-off.

3.7 Switching Off

Press the **POWER** button on the front panel to switch off the Doppler.

For **SONOTRAX Basic**, **SONOTRAX Basic A**, **SONOTRAX Pro**, **SONOTRAX II** and **SONOTRAX II Pro**, it switches off automatically if there is no input signal or no operation is performed for 60 seconds.

3.8 Replacing/Charging the Battery

3.8.1 Battery Energy Indication

After switched on, the Doppler gives indication of battery energy.

For **SONOTRAX Lite** and **SONOTRAX Vascular**, the LED in the bottom left corner of the display panel lights up in green. When it flashes in orange, the battery power is low.

For **SONOTRAX Basic**, **SONOTRAX Basic A**, **SONOTRAX Pro**, **SONOTRAX II** and **SONOTRAX II Pro**, there is a battery symbol in the bottom left corner of LCD. The panes in it indicate the battery electric energy.



SONOTRAX Basic



Other Models

The panes disappear gradually with the energy consumption. When the energy is low, the empty battery symbol flashes and the Doppler gives sharp alarm sounds (NOTE: **SONOTRAX Basic** does not give alarm sound). Approximately five minutes later, the Doppler shuts down automatically.

You should replace the batteries or charge the rechargeable batteries.

3.8.2 Replacing Alkaline Batteries

CAUTION

Make sure the Doppler is shut down before charging the battery or opening the battery compartment.

When the alkaline batteries are low in energy, they should be removed from the main unit, by using the procedures described in section 3.2 *Installing/Replacing Battery*. Dispose of them according to local regulations.

New alkaline batteries with identical specifications are required. Install them to the Doppler as introduced in section 3.2.

WARNING

DO NOT CHARGE THE ALKALINE BATTERY.

3.8.3 Charging the NI-MH Batteries

When the rechargeable NI-MH batteries are low in energy,

- 1) Take the NI-MH batteries out from the main unit by using the procedures described in section 3.2 *Installing/Replacing Battery*.
- 2) Replace them with new batteries with identical specifications, or charge them with the provided charger.

To charge the rechargeable NI-MH batteries,

- 1) Fit the NI-MH batteries in the charger slot properly. Make sure the direction of the batteries complies with the polar marks in the slot.
- 2) Plug the charger into an AC power supply socket. During charging, the indicators in the charger slot lights up in red.
- 3) When the charging indicators go off, the batteries are fully charged (approximately 10 hours are needed). Take the batteries out from the charger and reinstall them to the Doppler.

WARNING

1. Make sure the batteries are not connected reversely before plugging the charger into the power socket.
 2. The battery charger meets the requirements of Standard IEC60950, and it should be placed outside the patient environment when it's working (1.5m away from the patient).
-
-



Figure 3-7 Charging NI-MH battery

3.8.4 Charging NI-MH Battery Pack

When the NI-MH battery pack is low in energy, charge the battery pack with the provided charger.

- 1) Put the plug of the charger into the charge socket of the Doppler (on the top panel).
- 2) Connect the charger to a power supply socket (100V-240V~, 50Hz/60Hz). During charging, a battery sign appears on the LCD with continuous changing energy sign, and the charging indicator on the Doppler lights up.
- 3) When the charging indicator goes off, the battery pack is fully charged (approximately 3 ~ 4 hours are needed). Remove the charger plug and the Doppler is ready for examining again.



Figure 3-8 Charging NI-MH Battery Pack

WARNING

The AC-DC power adapter meets the requirements of Standard IEC60950, and it should be placed outside the patient environment when it's working (1.5m away from the patient). The Doppler is not available for examining during charging.

Chapter 4 Examining

4.1 FH Examining

Before applying the Doppler for fetal heart (FH) examining, a proper probe should be chosen. The 2.0 MHz obstetrical probe is optimized for deep penetration and late pregnancy. The 3.0 MHz obstetrical probe has higher sensitivity and is optimized for early pregnancy (after 10 weeks gestation).

NOTE:

In some cases, fetal heart beats at 10 weeks gestation can not be detected due to the maternal physical difference and the operator's technique.


Perform fetal heart examining using the following procedures:


- 1) Confirm the fetus's position by hand.
- 2) Determine the probable probe location for optimal FHR examining.
- 3) Take out the probe and switch on the Doppler.
- 4) Apply a certain amount of coupling gel to the probe faceplate and place the probe against the abdomen at the predetermined location. Move the probe around or tilt it until clear and rhythmic heart sound is heard from the headphone or speaker. At the same time, a numeric FHR is displayed on the LCD (except **SONOTRAX Lite**).



If the Doppler works in mode 1, the numeric is the real-time heart rate, it changes continuously.

If the Doppler works in mode 2, the numeric is the average of every 8 heart beats, it changes slowly.

If the Doppler works in mode 3, press the  button once and start counting immediately, viz. count one at the moment when the button is pressed. The LCD shows a flashing heart shape

symbol and “---”. Press the  button again on the 10th count (after nine beat intervals). The Doppler calculates and displays the average FHR over the 10 beats. This rate value will not disappear until another measurement starts or the mode is changed.


NOTE:


- 1 The best quality records will only be obtained if the probe is placed in the optimum position.
- 2 Positions with strong placental sounds or umbilical blood flow sound 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 examining, the pregnant woman's 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.
- 4 It is impossible to examine FHR unless a fetal heart sound is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

4.2 FH Sound Recording and Playing

This function is only available with **SONOTRAX Pro** and **SONOTRAX II Pro**.

Recording:


In mode 1, 2 or 3, press and hold the  button for three seconds, the machine starts recording, and the LCD reads **RECORDING**.


The longest record time is 240 seconds. When the time is up or the  button is pressed again, the Doppler stops recording and returns to the real-time status.

NOTE:

Only the last set of recorded fetal heart sounds is saved in the Doppler. It is cleared when new sounds are recorded.

Playing:

When the machine is not recording in mode 1, 2 or 3, press the  button once, the machine plays the recorded sound, and the LCD reads **PLAYING**.

When the recorded sound comes to the end or the  button is pressed again, the Doppler stops playing and returns to the real-time status.



NOTE:

Observe the LCD, pay attention not to mistake the recorded fetal heart sound for the real-time sound.

4.3 FH Sound Recording by PC

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

4.3.1 Recording Sounds

Insert one plug of the special line-in cable supplied by the manufacturer to the audio input socket (the socket with the symbol “”) of the PC, refer to figure 4-1. If the PC has no audio input socket, insert the plug into the microphone socket (the socket with the symbol “”).

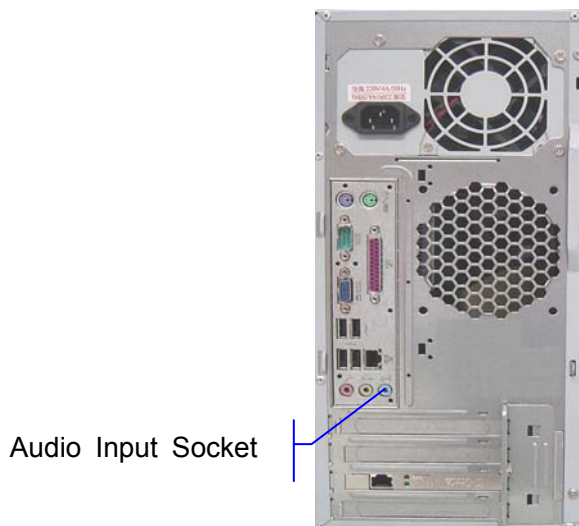


Figure 4-1 Audio Input Socket on the PC

Turn on PC and run the sound recorder (Click on **Start** > **Programs** > **Accessories** > **Entertainment** > **Sound Recorder**). Refer to figure 4-2.

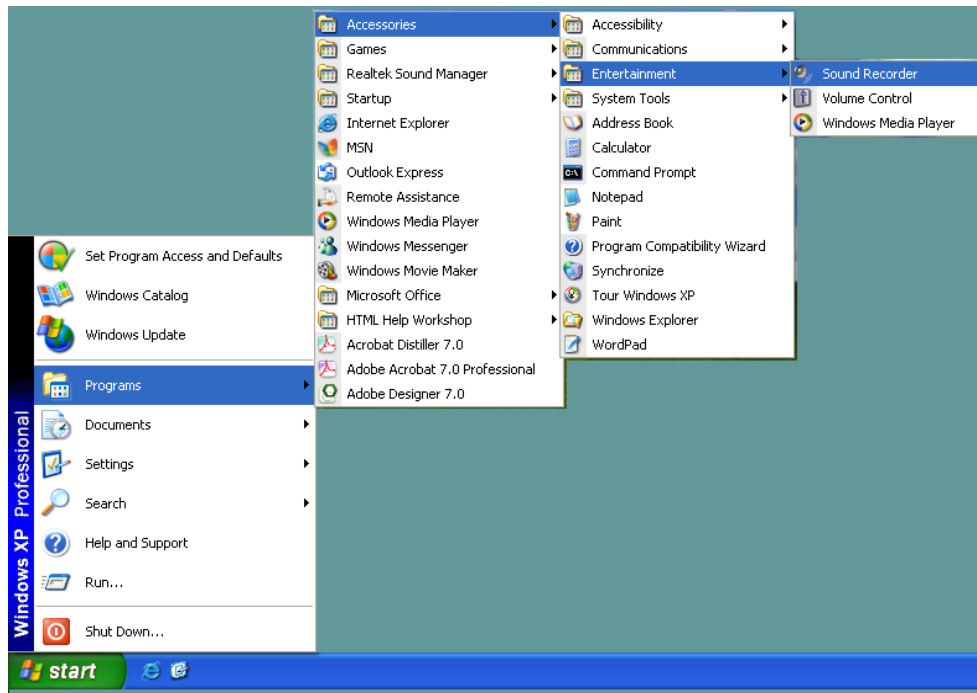


Figure 4-2 Run the sound recorder


Perform FHR examination with the method described in section 4.1. When the ideal signal is detected, unplug the earphone (if it's connected) and insert the other plug of the audio cable into the earphone socket on the Doppler.




Figure 4-3 Sound Recorder



Figure 4-4 Recording

Click on the start key  to start recording, refer to figure 4-3.

You can record 60 seconds each time. When the time is up, click on the start key again to keep on recording.


Click on the stop key  to stop recording, refer to figure 4-4.

Click on **File** > **Save**, input the file name, select a folder and click on **Save** to save the signals in a “.wav” file.

To start a new recording, click on **File** > **New**.

4.3.2 Playing Sound Files

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

You can play the waveform file with the sound recorder. Run the sound recorder, click on **File > Open**, search for the folder and select the file, click on **Open** to load the file, and then click on the play key .

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

4.3.3 Burning CD or Sending 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.

4.3.4 Record Troubleshooting

If there is audio output from the speaker or earphone, but the PC recorder does not have any input. (The green line recording area has no waveform.) The reason could be:

1. Poor connection of the audio cable between the Doppler and the PC.
 - Check the plugs of the cable and re-connect it if any poor connection is detected.
2. The audio cable has been plugged to the wrong socket of the PC, instead of the audio input socket or the microphone socket.
 - Insert the plug to the right socket.
3. The Line in or microphone is muted on PC.
 - Change the setting of the PC in these steps:
 - a) Double-click on the volume symbol in the bottom right corner of your desktop;



- b) The volume control menu pops up:

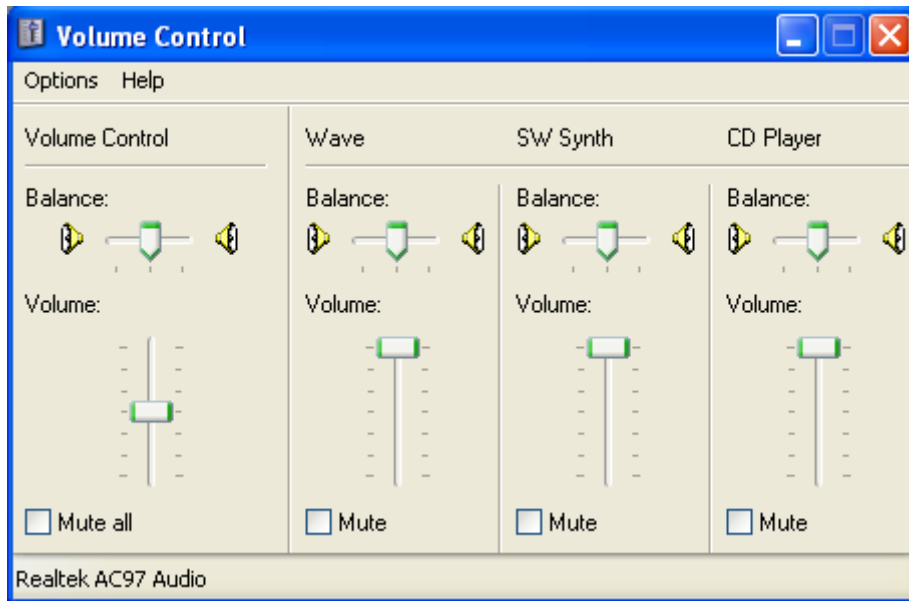


Figure 4-5 Volume control menu

- c) If the line in or/and microphone volume control is/are not shown in the Volume Control menu, click on **Options** > **Properties**, tick **Line In** and **Microphone** as shown in figure 4-6, click on **OK**:

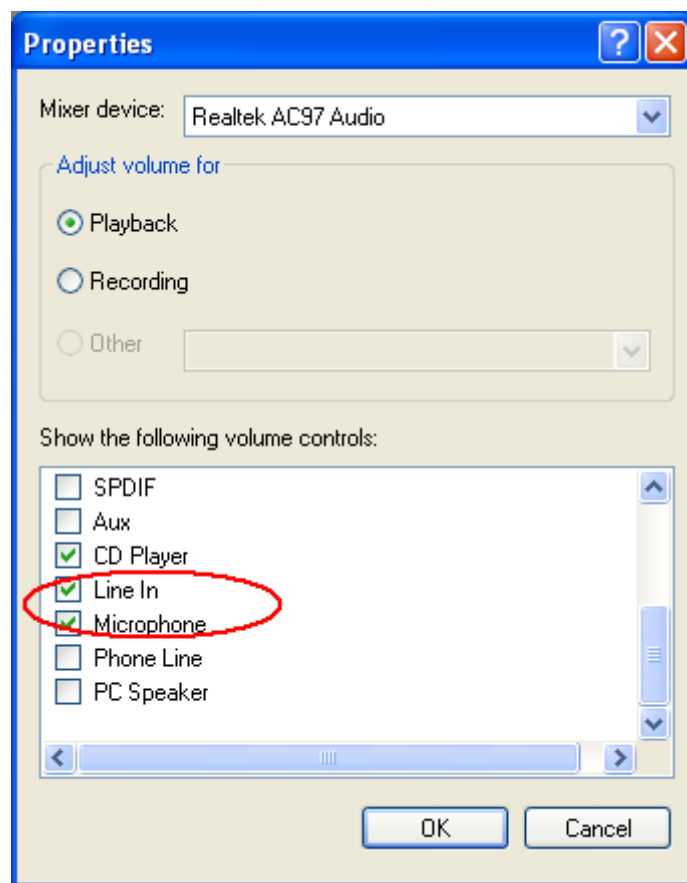


Figure 4-6 Properties

- d) Make sure **Line In** and **Microphone** is not mute, click on  to exit.

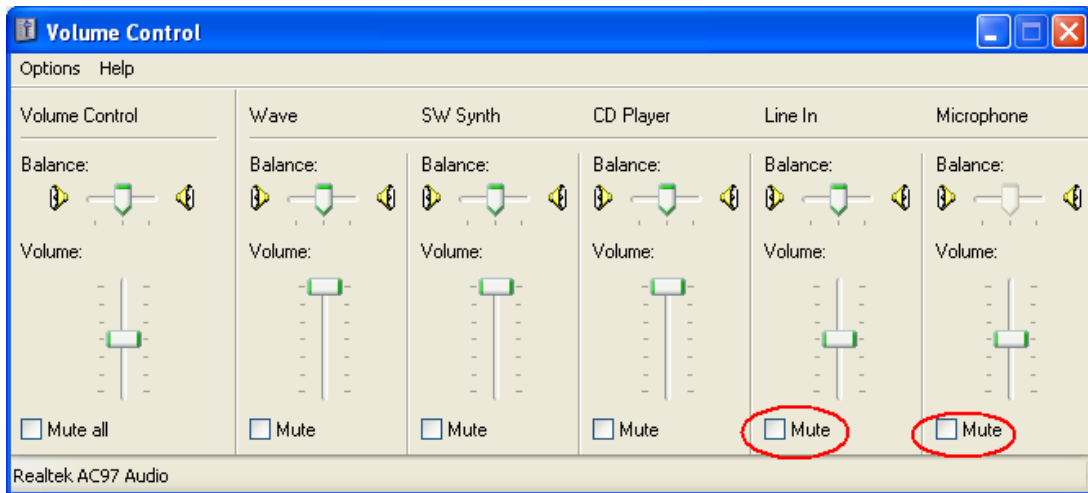


Figure 4-7 Volume Control

e) Start a new recording.

4.4 Vascular Examining (Optional)

WARNING

The Doppler is not intended for ophthalmic use. Do not use it for examining ophthalmic vessels, or any other procedures which may cause the ultrasound beam to pass through the eye.

4MHz, 5MHz or 8MHz vascular probes are to be connected to the Doppler to perform vascular examination.

Choose the appropriate probe as required. The probe with low frequency has a deeper penetration depth, while the probe with high frequency has better resolution and wider detecting range. The 4MHz vascular probe is optimized for examining blood vessels; the 5MHz vascular probe is optimized for examining deeper vessels, and the 8MHz vascular probe is optimized for examining surface vessels.

Apply a liberal amount of gel on the site to be examined. Place the probe at a 45° angle on the skin over the vessel to be examined. Adjust the position of the probe to obtain the loudest blood flow sound. Refer to figure 4-8 for the probe sites:

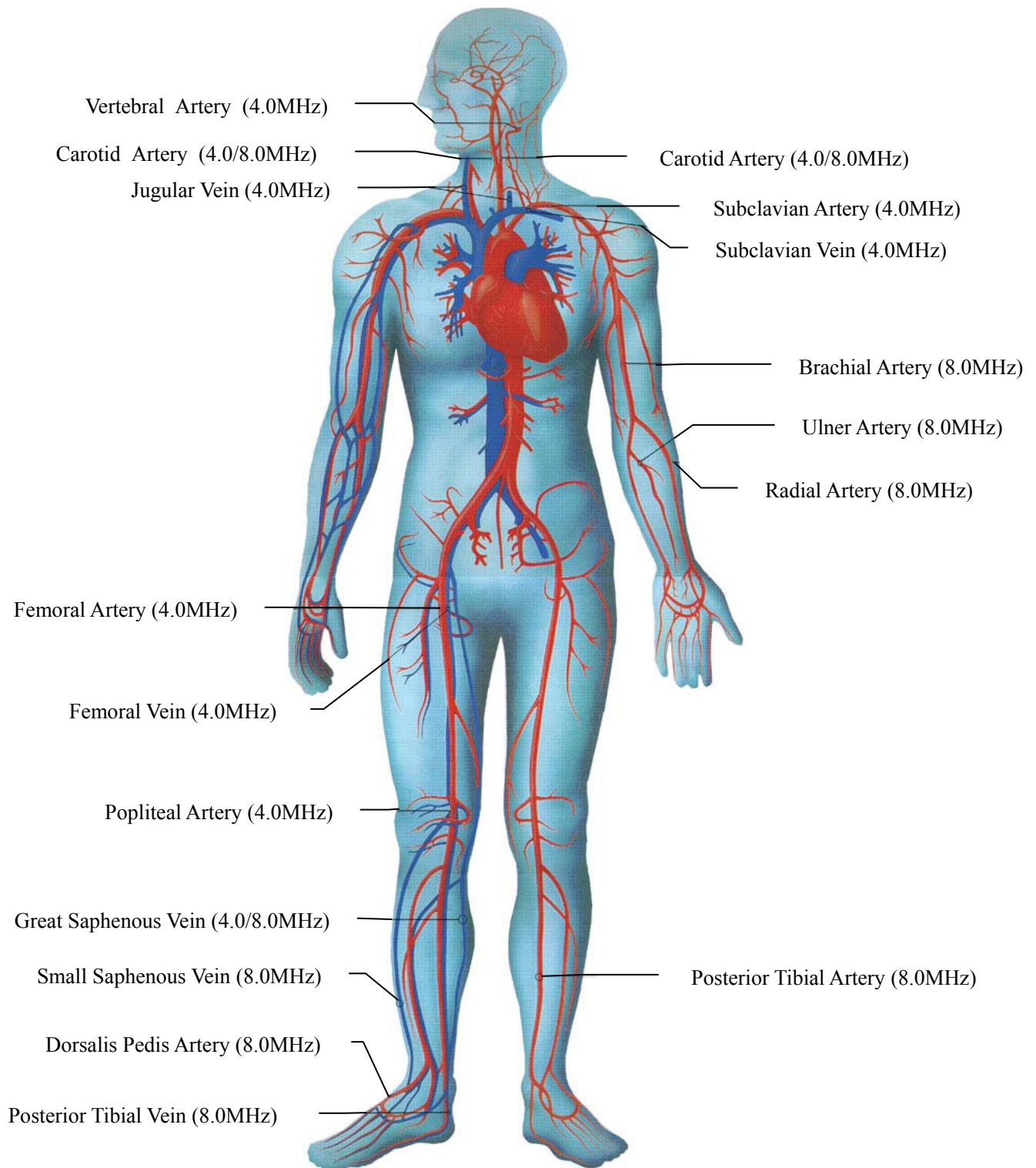


Figure 4-8 Probe sites

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

Vascular examination only provides audio signals of arteries and veins. The figure displayed on the LCD screen is null.

4.5 Completing Examining

After examining,

- 1) Switch off the Doppler.
- 2) Wipe the remaining gel off the patient and the probe with a clean soft cloth or tissue.
- 3) Place the probe back to the holder.

Chapter 5 Product Specifications

Product Name: Ultrasonic Pocket Doppler

Model:


SONOTRAX Lite, SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro, SONOTRAX II, SONOTRAX II Pro, SONOTRAX Vascular

Safety:

Complies with: IEC/EN 60601-1, IEC/EN 60601-1-2, IEC/EN 61266

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: Not-protected

Probes: IPX8 Water Ingress Protection Code, indicating this probe does not get soaked under water within 1 meter deep for five hours.

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 1 Class B

Physical Characteristic:

Main Unit

Size: 34 mm × 89 mm × 141 mm (Depth×Width×Height, ±1mm)

Weight: <300 g (including the battery)

Probe

Weight: 100g

Cable Length: 2.5m

Size: 88mm (diameter)×35mm (thickness)

Environment:

Working:

Temperature: +5°C ~ +40°C (+41 °F ~ +104 °F)

Humidity: 25% ~ 80% (non-condensing)

Atmospheric Pressure: 860hPa ~ 1060hPa

Transport and Storage:

| | |
|-----------------------|--------------------------------|
| Temperature: | -20°C ~ +55°C (-4°F ~ +131 °F) |
| Humidity: | 25% ~ 93% (non-condensing) |
| Atmospheric Pressure: | 700hPa ~1060hPa |

Display:

45mm*25mm LCD display

FHR Performance:

| | |
|----------------------|---------------------------|
| Sensitivity: | 10 weeks gestation (3MHz) |
| FHR Measuring Range: | 50bpm ~ 210bpm |
| Resolution: | 1bpm |
| Accuracy: | ±3bpm |

Audio Output Power: 0.5W

Recording and Playing:

Audio Sampling Frequency: 4KHz
Recording Length: 240s

White Backlight:

Two Brightness Adjustable: OFF, ON

Auto Shut down:

1 minute after no signal or operation, auto shut down

Recommended Alkaline Battery Type:

Alkaline battery (IEC 60086, LR61/AA)

Ultrasonic Gel:

Weight: 60g
Acoustic Impedance: $1.533 \times 10^6 \text{Pa} \cdot \text{s/m}$

Stand-by Time (hour):

| Model | Alkaline Batteries | Rechargeable NI-MH Batteries | NI-MH Battery Pack |
|--------------------------|--------------------|---------------------------------|--------------------------|
| SONOTRAX Vascular | 9 hr | 8 hr | |
| SONOTRAX Lite | 9 hr | 8 hr | / |
| SONOTRAX Basic | 9 hr | 8 hr | / |

| | | | |
|-------------------------|------|------|------|
| SONOTRAX Basic A | 9 hr | 8 hr | / |
| SONOTRAX II | / | / | 8 hr |
| SONOTRAX Pro | 9 hr | 8 hr | / |
| SONOTRAX II Pro | / | / | 8 hr |

Rechargeable NI-MH Battery

| | |
|-------------------------|----------|
| Nominal Capacity: | 1800m Ah |
| Nominal Voltage: | 2.4 VDC |
| Continual Working Time: | 8 hr |
| Necessary Charge Time: | 4 hr |

Ultrasound

| | | |
|--|--------------------------|---------------------------|
| Nominal Frequency | 2.0MHz Obstetrical Probe | 2.0MHz |
| | 3.0MHz Obstetrical Probe | 3.0MHz |
| | 4.0MHz Vascular Probe | 4.0MHz |
| | 5.0MHz Vascular Probe | 5.0MHz |
| | 8.0MHz Vascular Probe | 8.0MHz |
| Working Frequency | 2.0MHz Obstetrical Probe | (2.0±10%) MHz |
| | 3.0MHz Obstetrical Probe | (3.0±10%) MHz |
| | 4.0MHz Vascular Probe | (4.0±10%) MHz |
| | 5.0MHz Vascular Probe | (5.0±10%) MHz |
| | 8.0MHz Vascular Probe | (8.0±10%) MHz |
| p- < 1MPa | | |
| $I_{ob} < 10 \text{ mW/cm}^2$ | | |
| $I_{spta} < 100\text{mW/cm}^2$ | | |
| Working Mode | Continuous wave Doppler | |
| Effective Radiating Area of Transducer | 2.0MHz Obstetrical Probe | (245±15%) mm ² |
| | 3.0MHz Obstetrical Probe | (245±15%) mm ² |
| | 4.0MHz Vascular Probe | (32±15%) mm ² |
| | 5.0MHz Vascular Probe | (32±15%) mm ² |
| | 8.0MHz Vascular Probe | (14±15%) mm ² |

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)

System: SONOTRAX series Ultrasonic Pocket Doppler

| Transducer Model (MHz) | $I_{\text{spta.3}}$ (mW/cm ²) | TI Type | TI Value | MI | $I_{\text{sppa.3}}$ (W/cm ²) |
|---------------------------|--|---------|----------|----------|---|
| CW 2.0 | 47.227 | TIS | 0.20 | 0.03498 | N/A |
| | | TIB | 0.19 | | |
| CW 3.0 | 1.423 | TIS | 0.014 | 0.0038 | 0.001423 |
| | | TIB | 0.17 | | |
| CW 4.0 | 17.297 | TIS | 0.01 | 0.0116 | 0.017297 |
| | | TIB | 0.13 | | |
| CW 5.0 | 44.25 | TIS | 0.3031 | 0.008475 | 0.04425 |
| | | TIB | 0.2876 | | |
| CW 8.0 | 45.44 | TIS | 0.08 | 0.0133 | 0.04544 |
| | | TIB | 0.33 | | |

Chapter 6 Maintenance

6.1 Maintenance

You must check that the equipment does not have visible evidence of damage that may affect the patient and the operator's safety or the Doppler's capability before each use. Pay special attention to the cracks on the probe and the cable before immersing them into conductive fluid. If the damage is evident, replacement is recommended.

The probe is frangible and must be handled with care.

Wipe the remaining gel after use to prolong the probe life.

The overall check of the Doppler, including safety check and function check, should be performed by qualified personnel every 12 months, and each time after service. Besides the above requirements, comply with local regulations on maintenance and measurement.

6.2 Cleaning

Before cleaning, switch off the Doppler.

Keep the exterior surface of the device clean and free of dust and dirt.

Clean the exterior surface (display screen included) of the main unit with a dry, soft cloth. If necessary, clean it with a soft cloth soaked in soap water and then wipe it dry with a dry cloth immediately.

Wipe the remaining coupling gel off the probe. Clean it with a soft cloth dampened in solution (soap water, 70% ethanol or isopropanol alcohol) and then air-dry it or wipe the moisture with a soft dry cloth.

CAUTION

- 1 Clean the main unit with soap and water only. Avoid strong solvent, such as acetone.
 - 2 Never use an abrasive such as steel wool or metal polish.
 - 3 The main unit is not waterproof. Do not immerse any part of it into liquid.
 - 4 Avoid pouring liquids on the main unit while cleaning.
 - 5 Do not remain any solution on the surface after cleaning.
 - 6 Only the body and cable of the probe are waterproof. Do not immerse the probe socket into any liquid.
-

6.3 Disinfection of the Probe

Clean the probes as above. Immerse them into the solutions of Benzalkonium Bromide, 0.5% Chlorhexidine, 2% Glutaraldehyde or 75% ethanol, and then wipe them with a clean, dry cloth to remove the remaining moisture.

CAUTION

- 1 Pay attention not to immerse the probe socket into the disinfectant.
 - 2 The main unit is not waterproof, do not disinfect it.
 - 3 Never try to sterilize the probe or the main unit.
-
-

Chapter 7 Warranty and Service

7.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) damage caused by alteration or repair by anyone not authorized by EDAN.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

7.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Ordering Information

CAUTION

Only the parts supplied by the manufacturer should be used with the Doppler.

| Parts | Part Number |
|---|--------------------|
| Probe | |
| 2.0MHz Obstetrical Probe | 02.01.210326 |
| 3.0MHz Obstetrical Probe | 02.01.210327 |
| 4.0MHz Vascular Probe | 12.01.14346 |
| 5.0MHz Vascular Probe | 02.01.104822 |
| 8.0MHz Vascular Probe | 12.01.14347 |
| Accessory | |
| Alkaline Batteries | 01.21.064086 |
| Rechargeable NI-MH Batteries | 21.21.064180 |
| NI-MH Battery Charger (American Standard) | 01.21.064113 |
| NI-MH Battery Charger (European Standard) | 01.21.064112 |
| NI-MH Battery Pack | 01.21.064182 |
| NI-MH Battery Pack Charger (American Standard) | 21.21.064158 |
| NI-MH Battery Pack Charger (European Standard) | 01.21.064161 |
| NI-MH Battery Pack Charger (Brazil) | 21.21.064184 |
| Line-in Cable | 11.13.36032 |
| Earphone | 01.14.104751 |
| Normal Carry case (DPVC) | 01.56.104581 |
| Blue Carry Case (EVA) | 01.56.14268 |
| Consumable | |
| Coupling Gel | 11.57.14019 |

Appendix 2 EMC Information-Guidance and Manufacture's Declaration

A2.1 Electromagnetic Emissions - for all Equipment and Systems


| Guidance and manufacture's declaration–electromagnetic emission | | |
|---|------------|---|
| The <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> 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 <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> 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 <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> 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. |

A2.2 Electromagnetic Immunity - for all Equipment and Systems

| Guidance and manufacture's declaration–electromagnetic immunity | | | |
|---|----------------------------|----------------------------|--|
| The <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> 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%. |

| | | | |
|--|-------|-------|---|
| Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
|--|-------|-------|---|

A2.3 Electromagnetic Immunity - for all Equipment and Systems that are not Life-supporting

| Guidance and manufacture's declaration – electromagnetic immunity | | | |
|---|---|--------------------|--|
| The <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> 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 |
| Conducted RF IEC 61000-4-6 | 3 V _{rms} 150 kHz to 80 MHz | 3 V _{rms} | Portable and mobile RF communications equipment should be used no closer to any part of the <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ 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). 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 Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

- ^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*.
- ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A2.4 Recommended Separation Distances

| Recommended separation distances between portable and mobile RF communications equipment and the <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> | | |
|--|---|--|
| The <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> 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 <i>SONOTRAX Series Ultrasonic Pocket Doppler</i> as recommended below, according to the maximum output power of the communications equipment. | | |
| 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 |
| 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. | | |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. | | |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | |

Appendix 3 Overall Sensitivity

| Overall Sensitivity (2MHz Probe) | | | | | | | | | | | | | |
|-----------------------------------|-------------------|----------------------|---|----|-----|-----|------------|--------|---------------------------|-------------------|-------------------|--|-------------------------------------|
| Diameter of Target Reflector (mm) | Distance (d) (mm) | Reflection Loss A(d) | Two-way Attenuation $B = \sum B_a + B_w$ | | | | | | | 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 |
| | | | $\sum B_a$ (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 $B = \sum B_a + B_w$ | | | | | 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 | | |
| | | | $\sum B_a$ (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 | | | | |

P/N: 01.54.455405-11

EDANUSA
www.edanusa.com

4901 Morena Blvd., Suite 505
San Deigo, CA 92117
Tel: 888.850.4597