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SONOTRAX Series

Ultrasonic Pocket Doppler

Version 1.2

User Manual

CE 0123

EDAN

About this Manual

P/N: 01.54.457373

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Release Date: November, 2016

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.

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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.

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.

Content

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/Indications for 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.

The 4 MHz, 5 MHz and/or 8 MHz waterproof

vascular probes are indicated 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.

WARNING

3 Placement of the ultrasound transducer on the abdomen is critical to obtaining the fetal heart beat as opposed to maternal heart beat or other abdominal noise. The user should be trained in proper placement techniques either through acceptable Ob/Gyn training and individual state accreditation, or as being prescribed by such a trained clinician and trained in device placement.

4 The device is not protected against defibrillation.

5 Do not use the device with HF surgical equipment.

6 Do not touch the signal input/output connector and the patient simultaneously.

7 Only use the probes provided by the manufacturer.

8 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.

9 Do not heat or throw batteries in fire as this may cause explosion.

WARNING

10 **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.

11 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.

12 Do not short-circuit the batteries or install the batteries reversely.

WARNING

13 Do not attempt to charge normal alkaline batteries. They may leak, catch fire or even explode.

14 Do not solder the leading wire and the battery terminal directly.

15 Do not destroy the battery: Do not pierce the battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.

16 The battery should be charged, used or stored away from the static electricity.

17 Remove the batteries and store them in a cool and dry environment if the device is not used for a long time.

18 If rechargeable batteries are used, charge them fully before initial use by using the method introduced in this manual.

19 The rechargeable NI-MH batteries and battery pack should be charged by using the dedicated adapters recommended or supplied by the manufacturer.

20 Do not mix the battery with metal objects to avoid short-circuit.

WARNING

21 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.

22 Replacement of the battery or charging the battery shall be done at least 1.5 meters away from patients.

23 If the liquid leak from the battery spills onto your skin or clothes, wash well with fresh water immediately.

24 The device shall only be used when the battery cover is closed.

25 If the liquid leak from the battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.

26 Keep away from fire immediately when leakage or foul odor is detected.

27 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Please dispose it according to the local regulations.

WARNING

28 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 those of identical specifications.

29 Do not immerse, throw, or wet the battery in water/seawater.

30 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.

31 Using accessories other than those specified by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

32 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to section A3.4 Recommended Separation Distances.

WARNING

33 The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

34 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.

35 Do not service or maintain the device or any accessory which is in use with a patient.

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 sterilize the Doppler with autoclave or gas.

CAUTION

6 **Electromagnetic Interference** - Ensure that the environment in which the device is operated is not subject to any source of strong electromagnetic emissions, such as radio transmitters, mobile telephones, etc.

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.

CAUTION

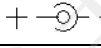
◆ Test the pregnant woman's leakage current according to IEC 60601-1: Limit: d.c 10 μA, a.c 100 μA.

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 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

No.	Symbol	Definition
1	CE 0123	CE marking
2		Disposal method
3	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
4		Operating instructions
5		Caution
6		Current: Direct
7		TYPE B APPLIED PART
8	P/N	Part Number
9	SN	SERIAL NUMBER

10		Date of manufacture
11		MANUFACTURER
12	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
13		General symbol for recovery/recyclable
14		Power adapter connector
15		Headphones
16		Refer to User Manual (Background: Blue; Symbol: White)
17		Warning (Background: Yellow; Symbol&Outline: Black)

NOTE:
The user manual is printed in black and white.

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 char

Model / Function	STA Vascular	STA Lite	STA Basic	STA Basic A	STA Pro	STA II	STA II Pro
LCD Display	-	-	√	√	√	√	√
LCD Backlight	-	-	-	√	√	√	√
Mini USB Probe Socket	√	√	√	√	√	√	√
Probe Detecting	√	√	√	√	√	√	√
Probe Identifying	-	-	√	√	√	√	√
Audio Play	√	√	√	√	√	√	√
Earphone	√	√	√	√	√	√	√

Socket							
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	√	*	*	*	*	*	*

Note: √ = configured - = not available * = available
STA=SONOTRAX

2.2 Main Unit

NOTE:

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

2.2.1 Appearance

Take 2.0 MHz obstetrical probe for example.

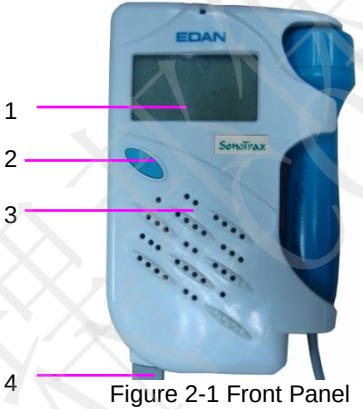


Figure 2-1 Front Panel

Figure 2-2 Rear Panel

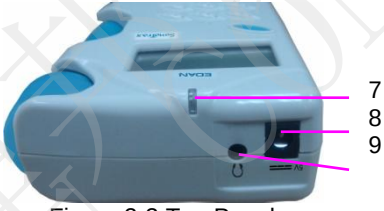


Figure 2-3 Top Panel

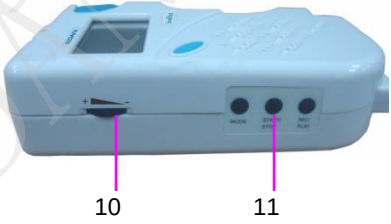


Figure 2-4 Left Panel

1	Display Panel	2	POWER Button		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 Indicator
4		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

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

Function: Select the working mode.

(2) START/STOP Button

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

Function: Start/ stop examining (Mode 3)/Change backlight setting (Mode 4).

(3) 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, or 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 power adapter 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 configuratio 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.

Figure 2-6 Probe socket

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

Connect the 2.0 MHz/3.0 MH
4.0 MHz/5.0 MHz/8.0 MHz 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.

Figure 2-7 Batteries

1. Alkaline Battery
2. Rechargeable NI-MH Battery
3. NI-MH Battery Pack

NOTE:

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

Alkaline battery: LR6, AA, 1.5 V.

Rechargeable NI-MH battery: AA, R6, 1.2 V.

2.3 Probes

2.3.1 Waterproof Obstetrical Probes

The 2 MHz/3 MHz waterproof obstetrical probes can be connected to the main unit for fetal heart examining.

The 2 MHz obstetrical probe features in deep penetration and is designed for use during the third trimester pregnancy. The 3 MHz obstetrical probe features in high sensitivity and is designed for use as early as 10 weeks.

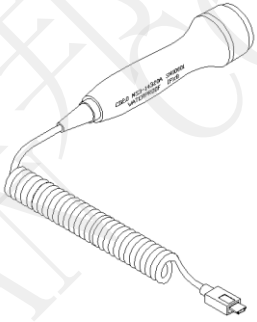


Figure 2-8 2/3 MHz obstetrical probe

The main information on the probe is as follows:

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

Waterproof: The probe is waterproof.

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

2.3.2 Waterproof Vascular Probes

The 4 MHz/5 MHz/8 MHz waterproof vascular probes can be connected to the main unit for artery and vein blood flow examining.

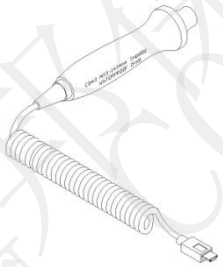


Figure 2-9 4/5/8 MHz Vascular Probes

The main information on the probe is as follows:

4.0 MHz/5.0 MHz/8.0 MHz: The central frequency is 4.0 MHz/5.0 MHz/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 batteries of **SONOTRAX II** and **SONOTRAX II Pro** are fixed in the battery

compartment cover. Start fr
installation.

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

Figure 3-3 Closing 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 displays 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 Working Mode

The Doppler has four working 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 working mode swi[illegible] modes, and the working mode is shown in the top left corner of LCD.

When the doppler is swiched 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**, **S**
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 **SONOTRA 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.


SONOTRA Basic


Other Models

The panes disappear gradually with the energy consumption. When the energy is low, the empty battery symbol flashes. 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 of identical specifications, or charge them with a NI-MH battery charger that meets the following specifications:

   Input: AC 100-240 V, 50 Hz/60 Hz

   Output: DC 1.45 V*2, 500 mA

After the batteries are fully
back to the Doppler.

WARNING

The battery charger should meet the requirements of Standard IEC60950, and it should be placed outside the patient environment when it's working (1.5 m away from the patient).

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 power adapter.

1) Put the plug of the power adapter into the charge socket of the Doppler (on the top panel).

2) Connect the power adapter to a power supply socket. 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 i… battery pack is fully charged (approximately 3 ~ 4 hours are needed). Remove the power adapter plug and the Doppler is ready for examining again.

Figure 3-7 Charging NI-MH Battery Pack

The specifications of the provided power adapter are as follows:

Input: AC 100-240 V, 50 Hz/60 Hz, 0.2 A

Output: DC 5 V, 1 A

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 (1.5 m 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 [illegible] 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 START/STOP 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 START/STOP 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.

5 When applied to the patient, the ultrasound transducer may warm slightly (less than 4°C (7.2°F) above ambient temperature). When

NOT applied, the ultrasc
warm slightly (less than 4°C (7.2°F) above ambient temperature).

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 REC/PLAY 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 REC/PLAY 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 recor

press the REC/PLAY button once, the machine plays the recorded sound, and the LCD reads PLAYING.

When the recorded sound comes to the end or the REC/PLAY 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 sou
Start > Programs > Accessories > Entertainment > Sound Recorder). Refer to figure 4-2.

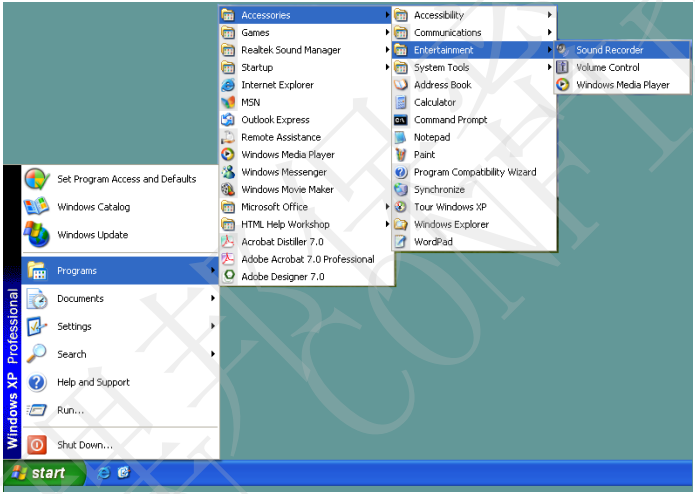


Figure 4-2 Run the sound recorder

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

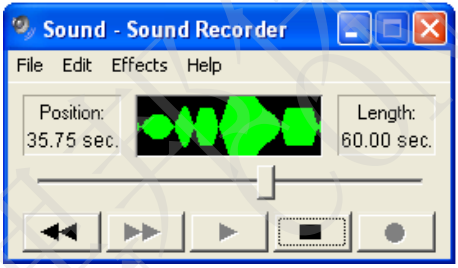


Figure 4-4 Recording

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
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:

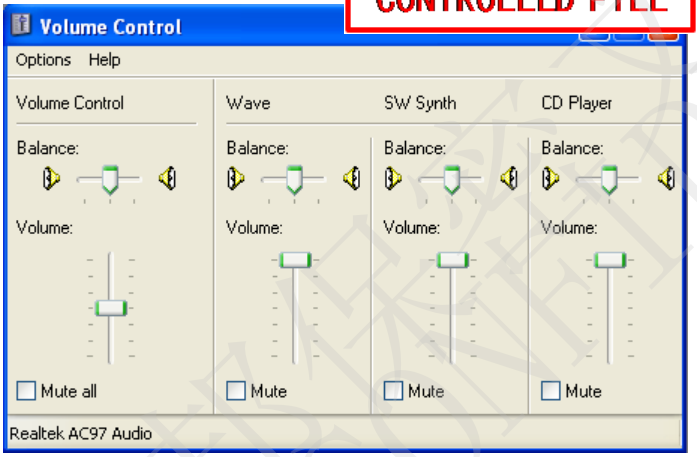


Figure 4-5 Volume control menu

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**:

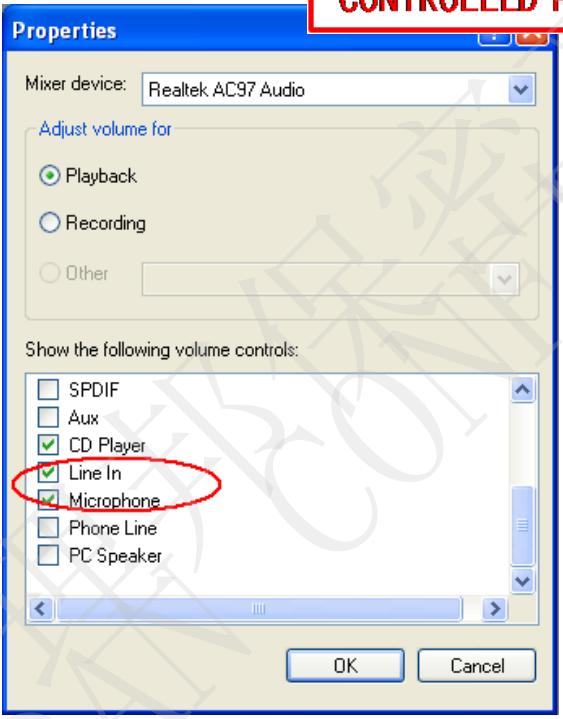


Figure 4-6 Properties

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

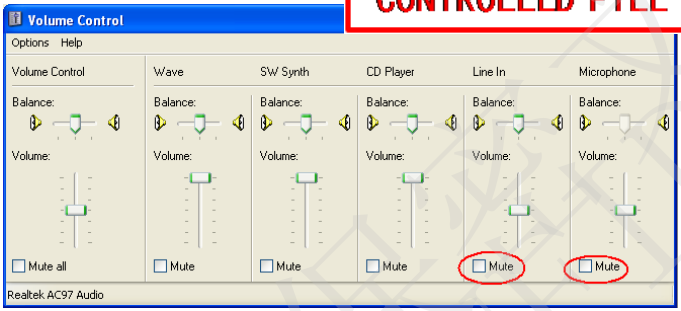


Figure 4-7 Volume Control

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.

4 MHz, 5 MHz or 8 MHz 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 dee[illegible] while the probe with high frequency has better resolution and wider detecting range. The 4 MHz vascular probe is optimized for examining blood vessels; the 5 MHz vascular probe is optimized for examining deeper vessels, and the 8 MHz 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:

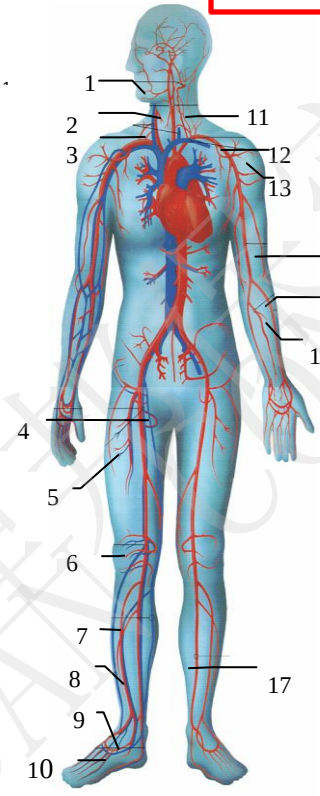


Figure 4-8 Probe sites

Item	[illegible]
1	Vertebral Artery (4/5 MHz)
2	Carotid Artery (4/5/8 MHz
3	Jugular Vein (4/5 MHz)
4	Femoral Artery (4/5 MHz)
5	Femoral Vein (4/5 MHz)
6	Popliteal Artery (4/5 MHz)
7	Great Saphenous Vein (4/5/8 MHz)
8	Small Saphenous Vein (8 MHz)
9	Dorsalis Pedis Artery (8 MHz)
10	Posterior Tibial Vein (8 MHz)
11	Carotid Artery (4/5/8 MHz)
12	Subclavian Artery (4/5 MHz)
13	Subclavian Vein (4/5 MHz)
14	Brachial Artery (8 MHz)
15	Ulnar Artery (8 MHz)
16	Radial Artery (8 MHz)
17	Posterior Tibial Artery (8 MHz)

For best results, keep the probe as still as possible once the optimum position is found. Adjust the

volume as required. High pitch
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 LCD screen always displays the probe frequency.

NOTE:

When applied to the patient, the ultrasound transducer may warm slightly (less than 4°C (7.2°F) above ambient temperature). When NOT applied, the ultrasound transducer may warm slightly (less than 6°C (10.8°F) above ambient temperature).

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 Maintenance

5.1 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.

5.2 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 of the main unit with a dry, soft cloth. If necessary, clean it using a soft cloth dampened with mild near neutral detergent, ethanol (75%) or isopropanol (70%), and then wipe it dry with a dry cloth immediately.

Wipe the remaining coupling gel off the probe. Clean it using a soft cloth dampened with mild near neutral detergent, ethanol (75%) or isopropanol (70%), and then air-dry it or wipe it dry with a dry cloth.

CAUTION

1 Do not use 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.

5.3 Disinfection

In normal use the main unit does not need disinfection. In case of being soiled, clean the main unit case and then disinfect it by wiping it with a soft cloth dampened with ethanol (75%) or isopropanol (70%). Then wipe it dry with a dry cloth.

After each use, clean the probe and then disinfect it by wiping it with a soft cloth dampened with ethanol (75%) or isopropanol (70%). Then wipe it dry with a dry cloth.

CAUTION

Pay attention not to immerse the probe socket into the disinfector.

5.4 Sterilization

Do not sterilize the Doppler, unless this is necessary according to your hospital regulation.

NOTE:

After cleaning or disinfection, check if the Doppler function well. If any problem is detected, please contact the manufacturer for service before reusing it.

Checking Item	**Checking Met**
Visual Check	Inspect the Doppler for any damage.
Function Check	Check if the Doppler can be switched on or off properly (see *3.4 Switching On* and *3.7 Switching Off*). When the Doppler is switched on, check if the display panel works as described in *2.2.2 Display Panel*; touch the probe faceplate gently with your hand and check if the Doppler gives out sound normally.

Chapter 6 Warranty and Service

6.1 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.

6.2 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 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 60601-1:2005, EN 60601-1:2006, IEC 60601-1-2:2007, EN 60601-1-2:2007, IEC/EN 61266, IEC/EN 60601-2-37

Classification:

Anti-electric Shock Type:	Internally powered equipment
Anti-electric Shock Degree:	Type B equipment 
Degree of Protection against Harmful	Main Unit: Ordinary equipment (Sealed equipment without

Ingress of Water:	liquid 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:	CISPR 11 Group 1 Class B

Physical Specifications

Main Unit:

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

Weight: <300 g (including the battery)

Probe

Weight: 100 g

Cable Length: 2.5 m

Size: 112 mm (length) x 32 mm (diameter)

Environment:

Working:	
Temperature:	+5 ℃ ~ +40 ℃ (+41 ℉ ~ +104 ℉)
Humidity:	25% RH~ 80% RH (non-condensing)
Atmospheric Pressure:	86 kPa ~ 106 kPa
Transport Storage	
Temperature:	-20 ℃ ~ +55 ℃ (-4 ℉ ~ +131 ℉)
Humidity:	25% RH~ 93% RH (non-condensing)
Atmospheric Pressure:	70 kPa ~106 kPa

Display:

45 mm x 25 mm LCD display

FHR Performance (Essential Performance):

FHR Measuring Range: 50 bpm ~ 210 bpm

Resolution: 1 bpm

Accuracy: ±3 bpm

Sensitivity: 10 weeks gestation (3 MHz)

Audio Output Power: 1 W

Recording and Playing:

Audio Sampling Frequency: 4 kHz

Recording Length: 240 seconds

White Backlight:

Two Brightness Adjustable: OFF, ON

Auto Shut down:

1 minute after no signal or operation, auto shut down

Recommended Battery Type:

Alkaline battery (AA LR6 1.5 V)

Rechargeable NI-MH battery (AA R6 1.2 V)

Ultrasonic Gel:

pH: 5.5~8.0

Acoustic Impedance:

1.5x106~1.7x106 Pa . s/m (in 35 ℃(95 ℉))

Stand-by Time (hour):

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

Lite			
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:	1800 mAh
Nominal Voltage:	2.4 VDC
Continual Working Time:	8 hr
Necessary Charge Time:	4 hr

Ultrasound

Nominal Frequency	
2.0 MHz Obstetrical Probe	2.0 MHz
3.0 MHz Obstetrical Probe	3.0 MHz
4.0 MHz Vascular Probe	4.0 MHz
5.0 MHz Vascular Probe	5.0 MHz

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

Low Output Summary Table

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

System: SONOTRAX series Ultrasonic Pocket

Doppler

Probes Model (MHz)	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$I_{sppa.3}$ (W/cm^2)
CW 2.0	0.0563	TIS	0.0704	0.021	0.015
		TIB	0.0113		
CW 3.0	1.63	TIS	0.0116	0.0041	0.00163
		TIB	0.0217		
CW 4.0	20.24	TIS	0.0142	0.0125	0.02024
		TIB	0.0589		
CW 5.0	52.593	TIS	0.2055	0.01755	0.04972
		TIB	0.3164		
CW 8.0	48.66	TIS	0.0792	0.0141	0.04866
		TIB	0.1581		

Appendix 2 Ordering Information

CAUTION

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

Parts	Part Number
Probe	
2.0 MHz Obstetrical Probe	02.01.210326
3.0 MHz Obstetrical Probe	02.01.210327
4.0 MHz Vascular Probe	12.01.14346
5.0 MHz Vascular Probe	02.01.104822
8.0 MHz Vascular Probe	12.01.14347
Accessory	

Alkaline Batteries	01.21.064086
Rechargeable NI-MH Batteries	21.21.064180
NI-MH Battery Pack	01.21.064182
Power Adapter (American Standard)	21.21.064158
Power Adapter (European Standard)	01.21.064161
Power Adapter (Brazilian Standard)	21.21.064184
Power Cord (Australian Standard)	01.13.036606
Power Cord (Brazilian Standard)	21.13.036425
Power Cord (English Standard)	01.13.036693
Normal Carry case	01.56.465632

Appendix 3 EMC Information

A3.1 Electromagnetic Emissions

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* *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

Harmonic emissions IEC/EN61000-3-2	Not applicable	power supply ne… buildings used for domestic purposes.
Voltage fluctuations /flicker emissions IEC/EN61000-3-3	Not applicable	

A3.2 Electromagnetic Immunity

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	wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC/EN61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable

Surge IEC/EN61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11	<5%UT(>95% dip in UT) for 0.5 cycle 40%UT(60% dip in UT) for 5 cycles 70%UT(30% dip in UT) for 25 cycles <5%UT(>95% dip in UT) for 5s	Not applicable	Not applicable

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

A3.3 Electromagnetic Immunity

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**
			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.

Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	**Recommende** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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 l… range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 a (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.

A3.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the *SONOTRAX Series Ultrasonic Pocket Doppler*
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.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power r
recommended separation distance d in meters (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 4 Ultrasound Intensity and Safety

A4.1 Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis, including investigation of the human fetus, the question of clinical safety with regards to ultrasound intensity arises.

There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the ALARA (As Low As Reasonably Achievable) principle serves as a rule-of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output.

The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

A4.2 Ultrasound Safety
Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Doppler, it is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, exposure levels should always be limited to As Low As Reasonably Achievable (the ALARA principle).

A4.3 Explanation of MI/TI

A4.3.1 MI (Mechanical Index)

Cavitations will be generated when ultrasound wave passes through and contacts tissues, resulting in instantaneous local overheating. This phenomenon is determined by acoustic pressure, spectrum, focus, transmission mode, and factors such as states and properties of the tissue and boundary. This mechanical bioeffect is a threshold phenomenon that occurs when a certain level of ultrasound output is exceeded. The threshold is related to the type of

tissue. Although no confirme effects on patients or mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined. Generally speaking, the higher the acoustic pressure, the greater the potential for mechanical bioeffects; the lower the acoustic frequency, the greater the potential for mechanical bioeffects.

The AIUM and NEMA formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rarefactional acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3dB/cm/MHz) to the acoustic frequency.

$$MI = \frac{Pr,\ \alpha}{fawf \times CMI}$$

$$CMI = 1\ (MPa / MHz)$$

A4.3.2 TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermophysical properties of the tissue.

In order to indicate the potenti caused by thermal effects, the AIUM and NEMA formulate thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1℃ (1.8℉).

According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.

TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

A4.3.3 Measurement Uncertainties

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The

overall systematic uncertainties as follows:

1. **Hydrophone Sensitivity:** ±23 percent for intensity, ±11.5 percent for pressure. Based on the hydrophone calibration report by ONDA. The uncertainty was determined within ±1 dB in frequency range 1-15 MHz.

2. **Digitizer:** ±3 percent for intensity. ±1.5 percent for pressure.

Based on the stated accuracy of the 8-bit resolution of the Agilent DSO6012 Digital Oscilloscope and the signal-to-noise ratio of the measurement.

3. **Temperature:** ±1 percent

Based on the temperature variation of the water bath of ±1 ℃ (1.8 ℉).

4. **Spatial Averaging:** ±10 percent for intensity, ±5 percent for pressure.

5. **Non-linear Distortion:** N/A.

No effects of nonlinear propagation were observed.

Since all the above error sources are independent, they may be added on an RMS basis, giving a total uncertainty of ±25.1 percent for all intensity values reported, ±12.7 percent for all the pressure values and ±12.6 percent for the Mechanical Index.

A4.4 Prudent Use State

Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

A4.5 References for Acoustic Output and Safety

1. "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993

2. "Medical Ultrasound Safety" issued by AIUM in 1994

3. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment,

Revision 3" issued by AIUM/NEMA in 2004

4. "Standard for real-time display of thermal and mechanical acoustic output indices on

diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004

5. "Information for Ma
Marketing Clearance of Diagnostic
Ultrasound Systems and Transducers" issued in 2008.

6. "Medical electrical equipment—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007.

A4.6 Probe Acoustic Output Parameters List

Acoustic Output Reporting Table for Track 1
Non-scanning Mode

System: SONOTRAX Operating Mode: CW mode
Transducer: CD2.0 Working Frequency: 2.0 MHz

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.021	0.0563	0.015
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	0.031		
	W_0	(mW)		11.8	11.8
	f_c	(MHz)	2.18	2.18	2.18
	Z_{sp}	(cm)	1.85	1.85	1.85
	Beam dimensions	X_{-6} (cm)		0.915	0.915
		Y_{-6} (cm)		1.922	1.922

	PD (μsec)		CW		CW
	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		2.50	
		Ele. (cm)		1.25	
Operating Control Conditions	Fixed				

Acoustic Output Reporting Table for Track 1
Non-scanning Mode

System: SONOTRAX Operating Mode: CW mode
Transducer: CD3.0 Working Frequency: 3.0 MHz

Acoustic Output	MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value	0.0041	1.63	0.00163

Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.007		
	W_0 (mW)			1.2	1.2
	f_c (MHz)		3.0	3.0	3.0
	Z_{sp} (cm)		2.35	2.35	2.35
	Beam dimensions	X_{-6} (cm)		1.7	1.7
		Y_{-6} (cm)		0.532	0.532
	PD (μsec)		CW		CW
	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		1.11	
		Ele. (cm)		2.22	
Operating Control Conditions	Fixed				

Acoustic Output Reporting Table for Track
Non-scanning Mode

System: SONOTRAX Operating Mode: CW mode
Transducer: CD4.0 Working Frequency: 4.0 MHz

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.0125	20.24	0.02024
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.0249		
	W_0 (mW)			0.746	0.746
	f_c (MHz)		4.0	4.0	4.0
	Z_{sp} (cm)		0.975	0.975	0.975
	Beam dimensions	X_{-6} (cm)		0.142	0.142
		Y_{-6} (cm)		0.206	0.206
	PD (μsec)		CW		CW

	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		0.45	
		Ele. (cm)		0.9	
Operating Control Conditions	Fixed				

Acoustic Output Reporting Table for Track 1
Non-scanning Mode

System: SONOTRAX Operating Mode: CW mode
Transducer: CD5.0 Working Frequency: 5.0 MHz

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.01755	52.593	0.04972
Associated Acoustic	$P_{r.3}$	(MPa)	0.03925		
	W_0	(mW)		8.648	8.648

Parameter	f_c (MHz)		4.99999		
	Z_{sp} (cm)		1.2	1.2	1.2
	Beam dimensions	X_{-6} (cm)		0.2484	0.2484
		Y_{-6} (cm)		0.4534	0.4534
	PD (μsec)		CW		CW
	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		0.4	
		Ele. (cm)		0.8	
Operating Control Conditions	Fixed				

Acoustic Output Reporting Table for Track
Non-scanning Mode

System: SONOTRAX Operating Mode: CW mode
Transducer: CD8.0 Working Frequency: 8.0 MHz

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.0141	48.66	0.04866
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.03997		
	W_0 (mW)			2.08	2.08
	f_c (MHz)		8.0	8.0	8.0
	Z_{sp} (cm)		0.64	0.64	0.64
	Beam dimensions	X_{-6} (cm)		0.298	0.298
		Y_{-6} (cm)		0.16	0.16
	PD (μsec)		CW		CW

	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		0.3	
		Ele. (cm)		0.6	
Operating Control Conditions	Fixed				

A4.7 Standard Parameters Equal Contrast Li

parameter specified in TRACK1 of FDA Guidance	
TRACK1 parameter	**NOTE**
$p_{r.3}$	Derated Peak-rare-factional Acoustic Pressure
W_0	Output Power
z_{sp}	$z_{sp} = z_{B.3}$, Depth for Bone Thermal Index
f_c	Center Frequency, Acoustic
x_{-6}	-6dB Beamwidth
y_{-6}	
PD	Pulse Duration

PRF	Pulse Repetition Frequency
MI	Mechanical Index
$I_{SPTA.3}$	Derated Spatial-peak Temporal-average Intensity
$I_{SPPA.3}$	Derated Spatial-peak Pulse-average Intensity
Az.	Aperture X width Y Dimeter
Ele.	
EDS	Entrance Dimensions Of The Scan
EBD	Entrance Beam Dimensions

Appendix 5 Overall Sensitivity

Diameter of Target Reflector (mm)	Distance (d)(mm)	A(dB)	Two-way Attenuation B=∑B_a+B_w ∑B (T: ultrasonic attenuation phantom No. B_a:dB)					B_w (dB)	B (dB)	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
1.58 A=45.7dB@2MHz	50	45.7	T	6#	6#	3#	-	0	57.5	72.15	34.32	6.45	109.6
			B_a	24.9	24.9	7.7	-						
	75	45.7	T	6#	6#	2#	-	0	55.3	70.35	34.83	6.10	107.1
			B_a	24.9	24.9	5.5	-						
	100	45.7	T	6#	6#	1#	-	0	53.5	72.62	35.64	6.30	105.5
			B_a	24.9	24.9	3.7	-						
	200	45.7	T	6#	6#	-	-	0	49.8	75.47	35.86	6.24	101.7
			B_a	24.9	24.9	-	-						
2.38 A=43.2dB@2MHz	50	43.2	T	6#	6#	2#	1#	0	59.0	72.36	34.38	6.46	108.6
			B_a	24.9	24.9	5.5	3.7						
	75	43.2	T	6#	6#	3#	-	0	57.5	74.31	34.83	6.58	107.2
			B_a	24.9	24.9	7.7	-						
	100	43.2	T	6#	6#	2#	-	0	55.3	75.26	35.62	6.49	104.9
			B_a	24.9	24.9	5.5	-						
	200	43.2	T	6#	6#	1#	-	0	53.5	75.42	35.83	6.45	103.2
			B_a	24.9	24.9	3.7	-						
Doppler Frequency (Hz)		333								Velocity of Target (cm/s)		12.5	

Diameter of Target Reflector (mm)	Distance (d)(mm)	A(dB)	Two-way Attenuation $B=\sum B_a+B_w$ ∑B (T: ultrasonic attenuation phantom No. B_a:dB)					B_w (dB)	B (dB)	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	Sensitivity (S=A(d)+B+C) dB
1.58 A=44.5dB @3MHz	50	44.5	T	6#	3#	-	-	0	57.1	112.3	52.44	6.61	108.2
			B_a	43.6	13.5	-	-						
	75	44.5	T	6#	3#	-	-	0	57.1	108.4	52.28	6.34	107.9
			B_a	43.6	13.5	-	-						
	100	44.5	T	6#	3#	-	-	0	57.1	113.8	54.56	6.39	107.9
			B_a	43.6	13.5	-	-						
	200	44.5	T	6#	3#	-	-	0	57.1	112.2	54.82	6.22	103.3
			B_a	43.6	13.5	-	-						
2.38 A=42.0dB @3MHz	50	42.0	T	6#	3#	-	-	0	57.1	109.0	53.46	6.18	105.2
			B_a	43.6	13.5	-	-						
	75	42.0	T	6#	3#	-	-	0	57.1	113.8	52.43	6.73	105.8
			B_a	43.6	13.5	-	-						
	100	42.0	T	6#	3#	-	-	0	57.1	110.4	54.35	6.16	105.2
			B_a	43.6	13.5	-	-						
	200	42.0	T	6#	3#	-	-	0	57.1	112.7	54.46	6.32	105.4
			B_a	43.6	13.5	-	-						
Doppler Frequency (Hz)		500								Velocity of Target (cm/s)		12.5	

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