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签批信息(Signature):

作者(Originator) : 周 睿 (zhourui) 2018-06-08 13:18:30

审核人(Reviewers) : 刘 小倩 (liuxiaoqian) 2018-06-11 11:06:36

审核人(Reviewers) : 黄 东 (huangdong) 2018-06-08 13:24:30

审核人(Reviewers) : 李 祥 (lixiang1) 2018-06-11 10:01:10

审核人(Reviewers) : 吴 明花 (wuminghua) 2018-06-08 13:34:51

批准人(Approvers) : 夏 欢欢 (xiahuanhuan) 2018-06-14 17:28:47

批准人(Approvers) : 冀 伟 (jiwei) 2018-06-13 14:25:12

SONOTRAX Series

Ultrasonic Pocket Doppler

Service Manual

CE₀₁₂₃



About this Manual

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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 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.

EDAN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by EDAN as repairable by service personnel.

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.

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Chapter 1 Warranty and Service

Standard Service

EDAN provides a one-year-warranty for the warranted products (accessories are included). The warranty period begins on the date the products are shipped to customers. If customer promptly notifies EDAN of customer's warranty claim hereunder, EDAN will either repair, adjust or replace (with new or exchange replacement parts) the EDAN's product. EDAN warrants that any service it provides to customers will be performed by trained individuals in a workmanlike manner.

Limitation of Warranty

Direct, indirect or final damage and delay caused by the following situations for which EDAN are not responsible may void the warranty:

- ✧ Groupware is dismounted, stretched or redebugged.
- ✧ Unauthorized modification or misuse.
- ✧ Damage caused by operating beyond the environmental specifications for the medical product.
- ✧ Change or remove original serial number label or Manufacturer symbol.
- ✧ Improper use.

Service Procedure

(1) Fill in **Service Claim Form (SCF)**.

Fill in the SCF with detailed information including: **Model Name**, **Serial Number (SN)** and **Problem Phenomena**.

EDAN should not have any obligation to take over the case without this information. The form can be downloaded at: <http://www.edan.com.cn> or obtained from EDAN's Service Department.

(2) Send EDAN the SCF and Select a Solution.

Once service department receives the fully filled SCF, EDAN's engineer will offer a solution in three working days. EDAN will follow out the case based on below two conditions:

Within Warranty:

There are two options:

- i) After receiving the **Return Material Authorization (RAM)** form from EDAN service department, customer sends EDAN the defective parts and informs the shipment tracking number. Then we will dispatch new part(s) to your confirmed address with confirmed

shipping invoice.

ii) Customer signs the **Declaration Form** and sends it back by email or fax. This form is legally certificated to make sure the customer or end-user will return the defective parts to EDAN on time. We will, at this option, dispatch the replace one(s) with confirmed shipping invoice.

NOTE:

(1) Both Return Material Authorization Form and Declaration Form are offered by EDAN service department once the SCF is confirmed by service engineer.

(2) Customer is responsible for freight & insurance charges when the equipment is shipped to EDAN for service including custom charges. EDAN is responsible for the freight, insurance & custom charges from EDAN to customer.

Out of Warranty:

After receiving the RMA from service department, customer sends defective parts to EDAN in advance. We will analyze the problems and discuss with customer about either repairing or replacing the part(s). Once the maintenance fee is invoiced and paid, we will make sure to dispatch good part(s) to confirmed address.

NOTE: Customer is responsible for any freight & insurance charge for the returned product.

(3) Obtain RMA Form.

Before the shipment of the materials, customer must obtain a RMA form from our service department, in which the RMA number, description of returning parts and shipping instruction are included. The RMA number should be indicated on the outside of the shipping container.

NOTE: EDAN should not have any obligation to end-user or customer who returns the goods without the notification by EDAN's service department. The sender takes the whole responsibility of accounted fee.

(4) Send the Parts to EDAN.

Follow these recommended instructions:

- ✧ Disassemble the parts with anti-static facility. Do not touch the parts with naked hand.
- ✧ Pack the parts safely before returning.
- ✧ Put the RMA number on the parcel.
- ✧ Describe the returned parts. The total value on the invoice should be less than USD100, and note on the invoice as "sample, no commercial value".
- ✧ Confirm the invoice with EDAN before shipment.

✧ Send back the parts after EDAN's confirmation.

Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, do not hesitate to contact us.

EDAN Instruments, Inc.

TEL: +86-755-26898321, 26899221

FAX: +86-755-26882223, 26898330

E-mail: support@edan.com.cn

Chapter 2 Safety Guide

NOTE: This service manual is written to cover the maximum configuration. Therefore, your model may not have some of the parameters/modules described, depending on what you have ordered.

2.1 Introduction

This service manual is a reference for periodic preventive maintenance and corrective service procedures for the SONOTRAX series ultrasonic pocket Doppler. It provides troubleshooting information, disassembly and assembly procedures, instructions for functional testing and performance verification. It is intended for use only by technically qualified service personnel.

2.2 Safety Precautions

WARNING

- 1** The Doppler must be serviced only by authorized and qualified personnel. EDAN does not assume any responsibility for damage or injury if modifications or repairs are carried out by unauthorized personnel.
 - 2** The service personnel must be familiar with the operation of the Doppler. Refer to the SONOTRAX Series Ultrasonic Pocket Doppler User Manual for details.
 - 3** Do not touch the signal input/output connector and the patient simultaneously.
 - 4** 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. 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. If in doubt, consult our technical service department or your local distributor.
 - 5** Only use the probes provided by the manufacturer. Use and replace the substitutive parts provided or recommended by EDAN only.
 - 6** The device shall only be used when the battery cover is closed.
 - 7** 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. Do not service or maintain the device or any accessory which is in use with a patient.
-


CAUTION

- 1 Do not sterilize the Doppler with autoclave or gas.
 - 2 **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.
 - 3 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.
 - 4 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 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.
 - 5 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.
-

Chapter 3 Installation

3.1 Environment Requirements

Working Environment	
Temperature:	+5 °C ~ +40 °C (+41 °F ~ +104 °F)
Relative Humidity:	25%RH ~ 80% RH (non-condensing)
Atmospheric Pressure:	86kPa ~ 106kPa
Transport and Storage Environment	
Temperature:	-20 °C ~ +55 °C (-4 °F ~ +131 °F)
Relative Humidity:	25% RH ~ 93% RH (non-condensing)
Atmospheric Pressure:	70kPa ~ 106kPa
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: Ordinary equipment (Sealed equipment without liquid proof)
	Probe: 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
Disinfection/Sterilizing Method:	Refer to User Manual for details
EMC:	CISPR 11 Group 1 Class B

3.2 Power Supply Requirements

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: LR6, AA, 1.5 V.

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

NOTE:

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

3.3 Installing Doppler

◆ Putting the Doppler on a Flat Surface

Put the Doppler on a flat surface. Make sure that the surface does not vibrate and is free of corrosive medicine and dust.

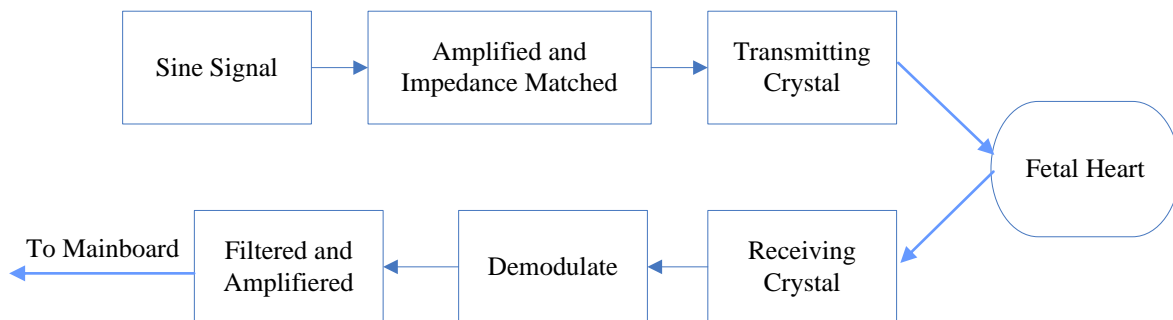
◆ Installing the Doppler on a Trolley

The trolley is optional. If the trolley has been ordered, an Assembly Instruction will be delivered with the trolley. Please refer to the Assembly Instruction for installing the Doppler on the trolley

Chapter 3 Principle

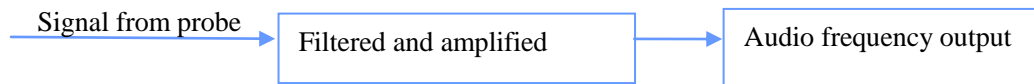
3.1 Principle of Probe

The sine wave signal generated by an oscillator is amplified and matched in impedance by FEFT and transformer, then be sent to the transmitting crystal of probe. The ultrasound emitted from the crystal reflects when meeting an obstacle. The receiving crystal receives the echo signal, after a process of demodulating, filtering and amplifying, this signal can be used by the mainboard.

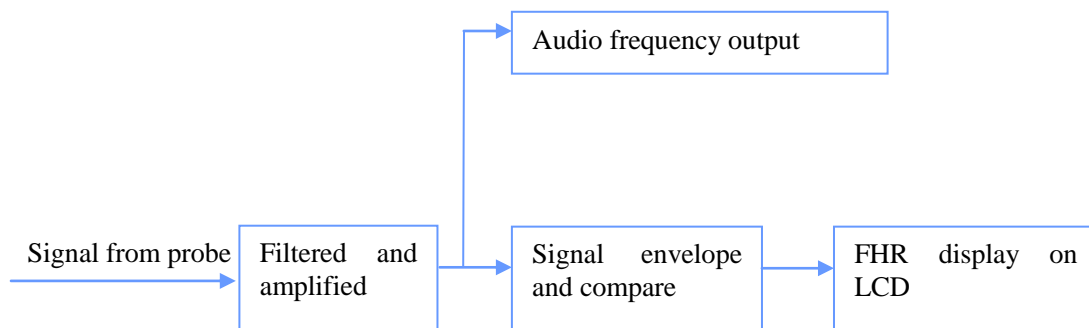


3.2 Principle of the Doppler

Signal framework of SONOTRAX Lite:



Signal framework of SONOTRAX Basic / SONOTRAX Basic A /SONOTRAX Pro / SONOTRAX II/ SONOTRAX II Pro:



f3.3 Introduction of PCBs

3.3.1PCB of SONOTRAX Lite/SONOTRAX Vascular

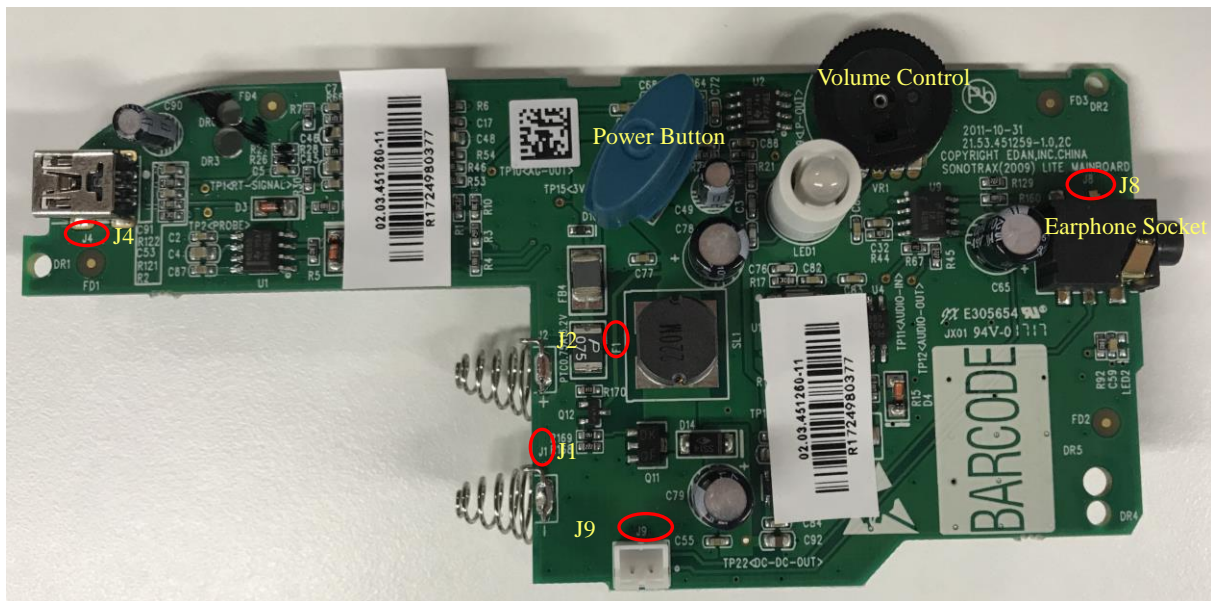
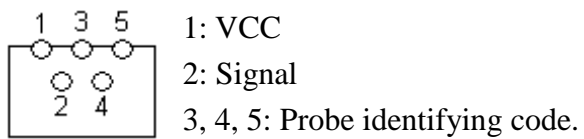


Figure 3-1 PCB of SONOTRAX Lite

J1&J2: socket for connecting with battery

J4: socket for probe mini USB



J8: socket for earphone

J9:socket for speaker

3.3.2 PCB of SONOTRAX Basic

Figure 2-3 PCB Outline of SONOTRAX Basic

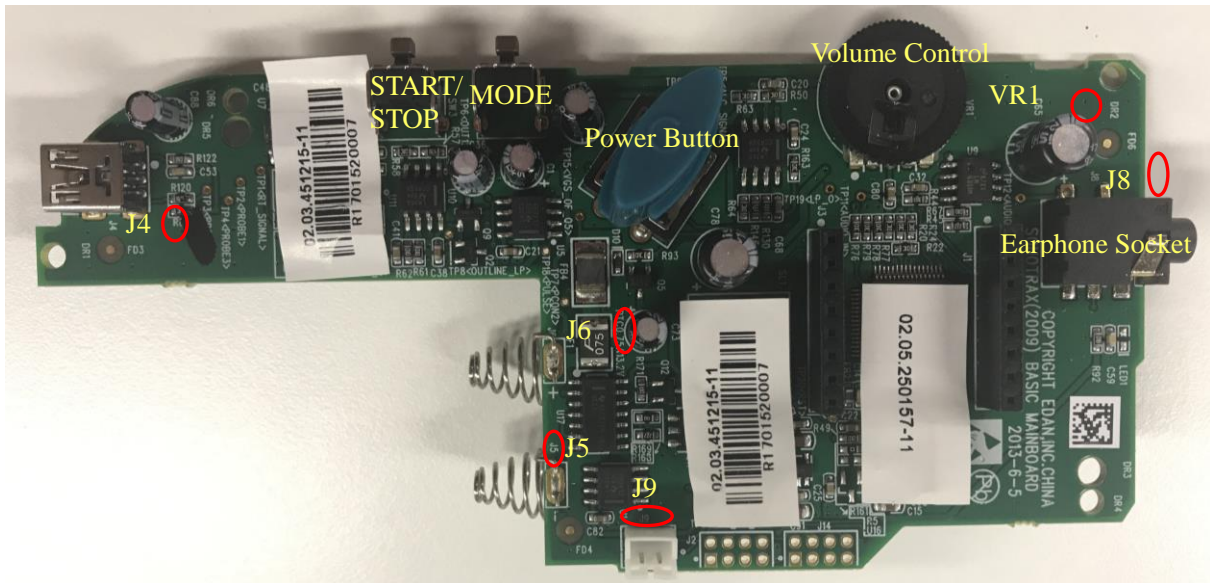
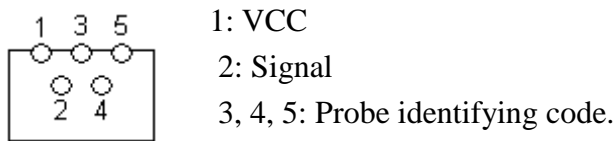


Figure 3-2 PCB of SONOTRAX Basic

VR1: Volume Control.

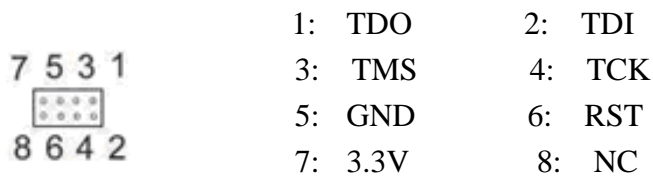
J4: socket for probe mini USB.



J5&J6: socket for connecting with battery.

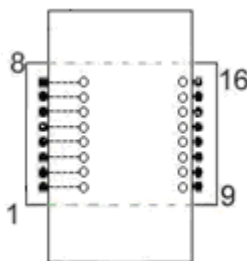
J9: socket for speaker.

JTAG interface: MCU program solidify interface.



J8: earphone socket.

SONOTRAX Basic has a thin LCD with 16 pins:



3.3.3 PCB of SONOTRAX Basic A/Pro/II/II Pro

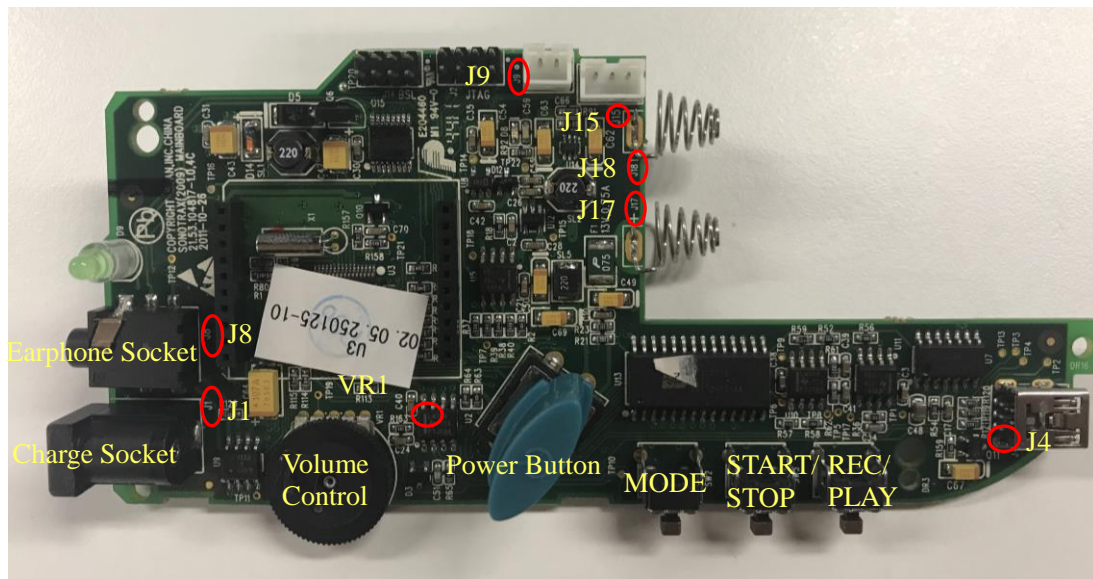
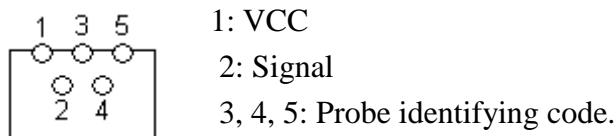


Figure 3-3 PCB of SONOTRAX II Pro

J1: charge socket.

VR1: volume control.

J4: socket for probe mini USB.

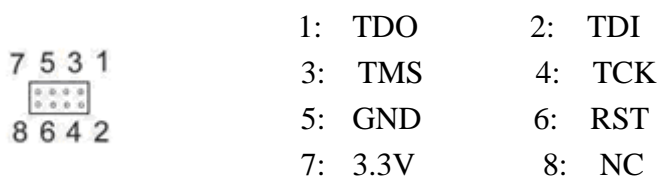


J17&J18: socket for connecting with battery.

J9: socket for speaker.

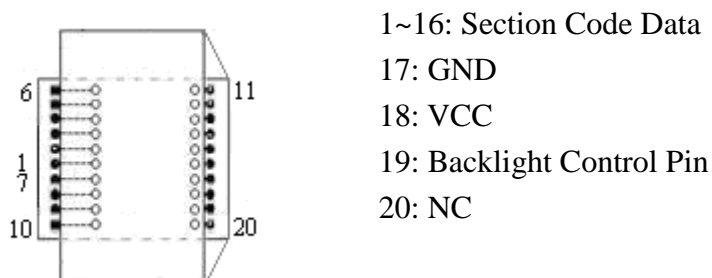
J15: socket for connecting battery interface board

JTAG interface: MCU program solidify interface.



J8: earphone socket.

SONOTRAX Basic A/ Pro/ II/ II Pro has a thick LCD with 20 pins:



Chapter 4 Service

4.1 Disassemble the Doppler

4.1.1 Remove the Probe

Place the probe in the following steps: (Take example for 2.0MHz waterproof probe.)

- 1) Hold the main unit with one hand, and hold the top of the probe with another hand (Figure 4-1).
- 2) Take out the top of the probe (Figure 4-2).
- 3) Take out the whole probe from the frame (Figure 4-3).
- 4) Pull out the plug of the probe from its socket (figure 4-4).

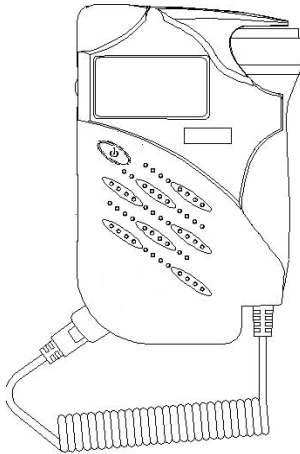


Figure 4-1

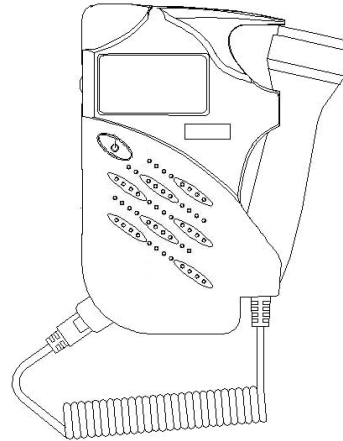


Figure 4-2

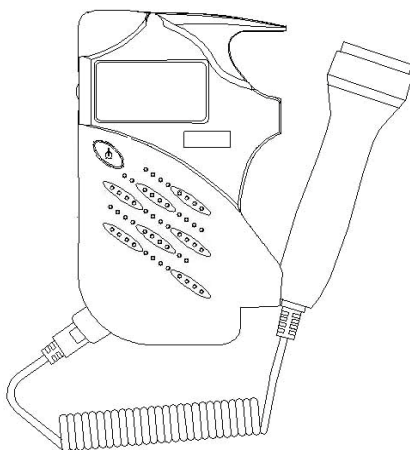


Figure 4-3

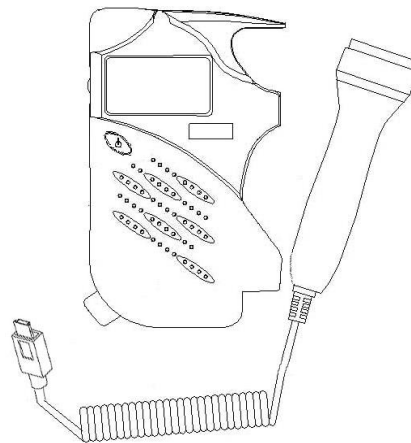


Figure 4-4

4.1.2 Remove the Battery

Remove the battery in the following steps:

- 1) The rear panel is upturned (Figure 4-5);
- 2) Press down the stripe symbols (that without arrowhead) with one thumb, at the same time slide the battery cover out along the direction of arrowhead with the other thumb (Figure 4-6);

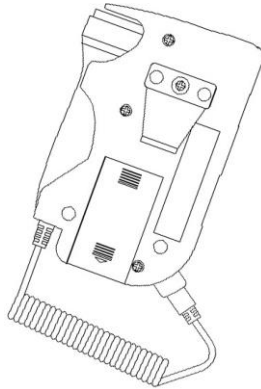


Figure 4-5

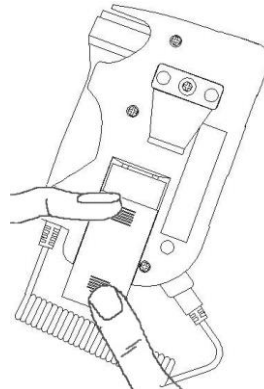


Figure 4-6

- 3) Take out the battery out from the compartment a little and disconnect the battery from the connector (Figure 4-7);

For SONOTRAX Basic, SONOTRAX Basic A, SONOTRAX Pro SONOTRAX II and SONOTRAX II Pro Ultrasonic Pocket Doppler, hold the battery connector cables and pull the plug out from the socket inside the case (figure 4-8).

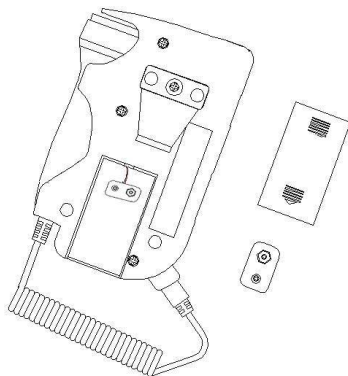


Figure 4-7

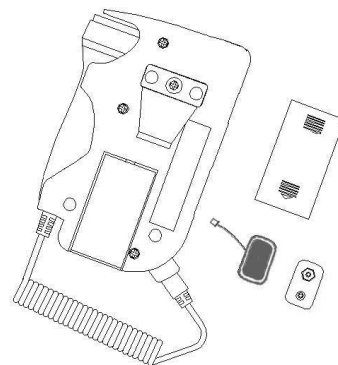


Figure 4-8

4.1.3 Disassemble the Doppler Main Unit

Take SONOTRAX II Pro as an example; disassemble the Doppler main unit in the following steps:

- 1) Peel the information label in the battery compartment off;
- 2) Peel the buttons label on left panel off;

- 3) Remove the three screws as shown in figure 4-9.

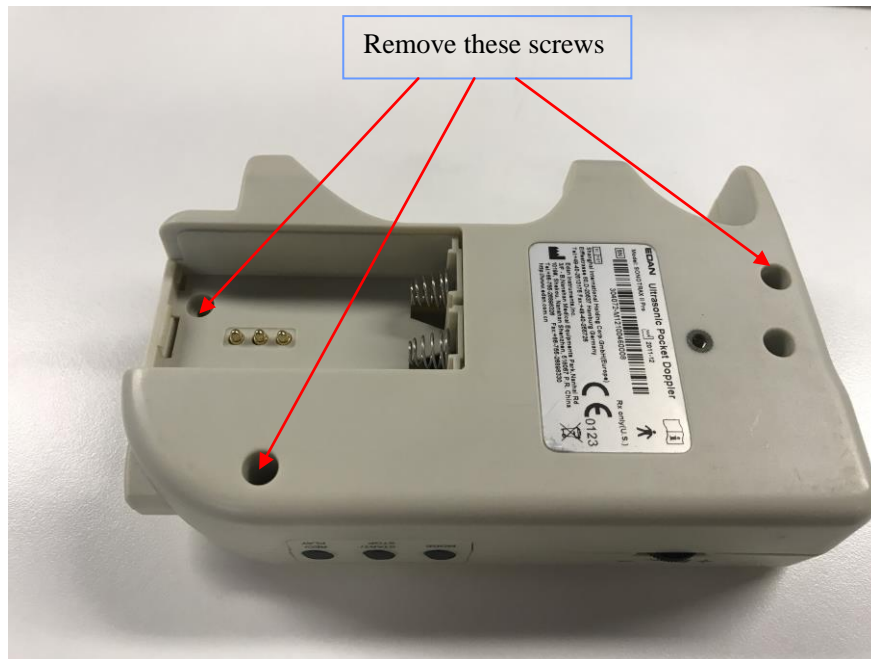


Figure 4-9 Labels and screws need to be removed

- 4) Disjoin the case, the Doppler unit consists of five parts: front panel, rear panel, speaker, LCD and PCB.

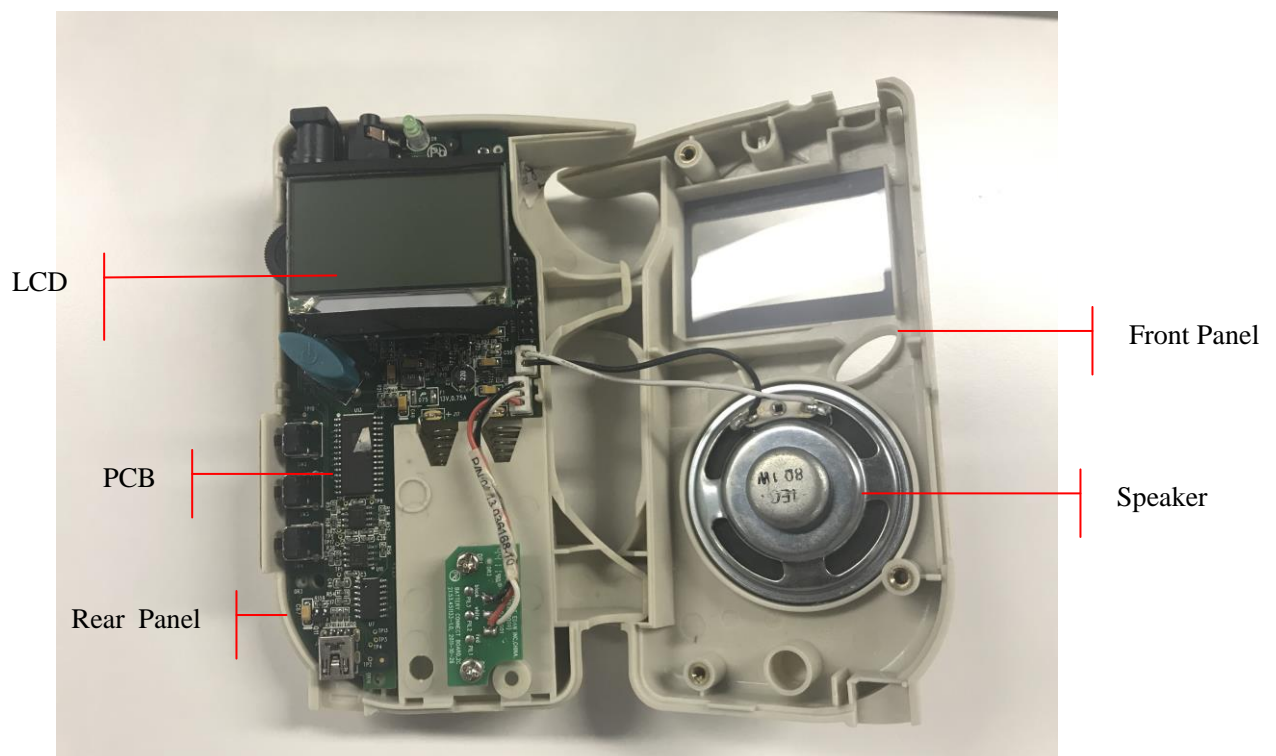


Figure 4-10 Main Parts of the Unit

- 5) Hold the two edges of LCD and unplug it from its socket on the PCB (figure 3-11).

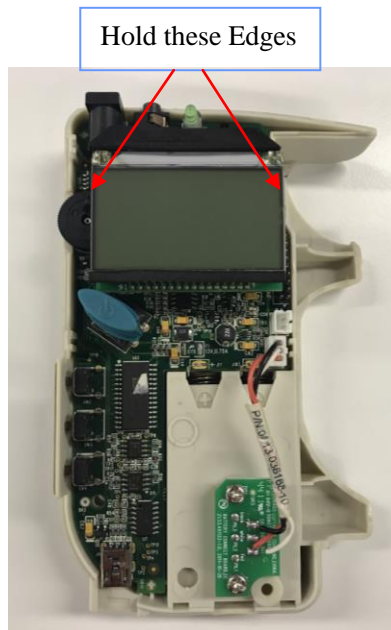


Figure 4-11 Unplugging LCD

- 6) Unplug the speaker connector from the socket on the PCB; Apply a few drops of alcohol to the heat-melting adhesive that sticks the speaker to the front panel (figure 4-12), take out the speaker after the glue is melted.

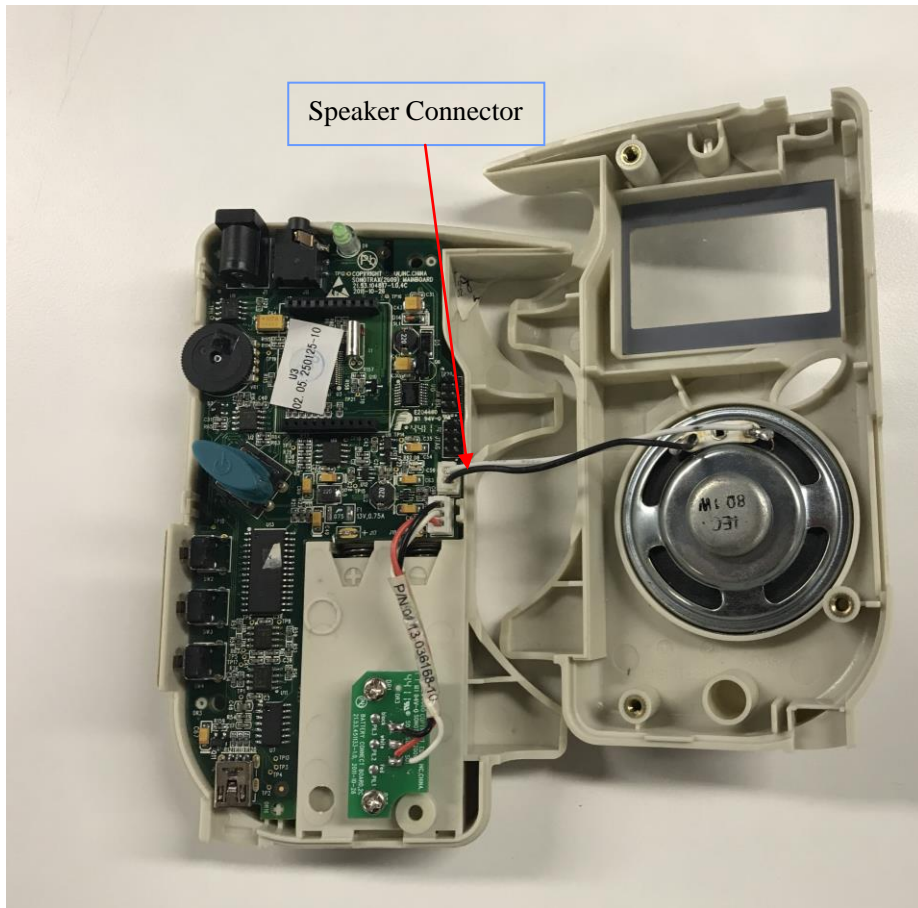


Figure 4-12 Heat-Melting Adhesive on the Speaker and the Speaker Connector

- 7) Unplug the battery plug of SONOTRAX II Pro from its socket on the PCB (figure 4-13).

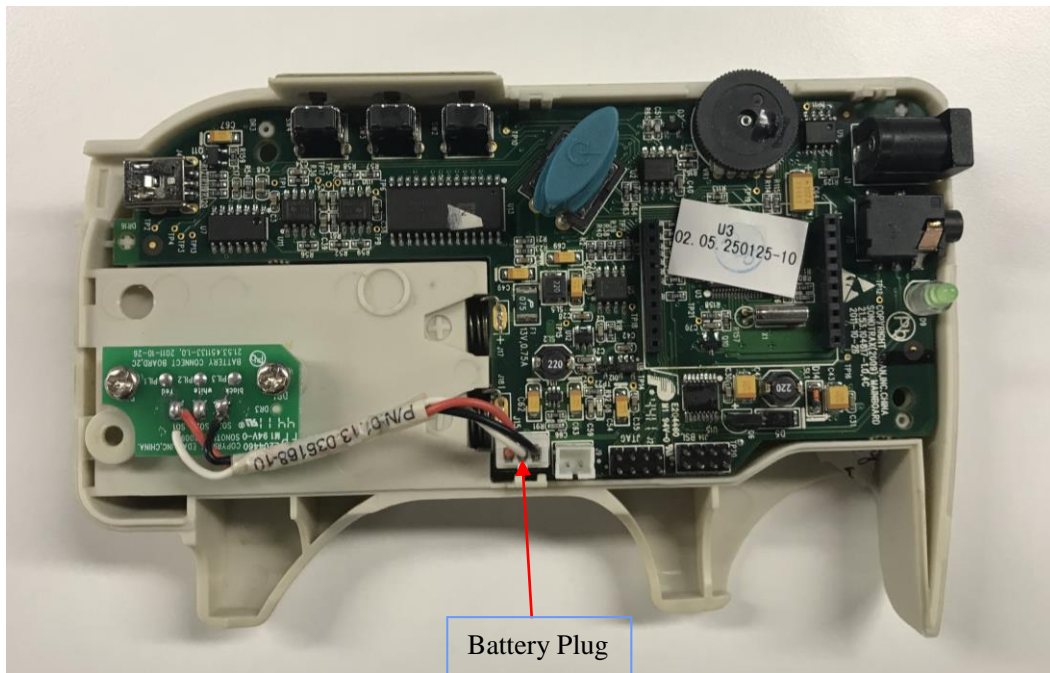


Figure 4-13 The battery plug of SONOTRAX II Pro

8) Take the PCB off from the rear panel carefully.

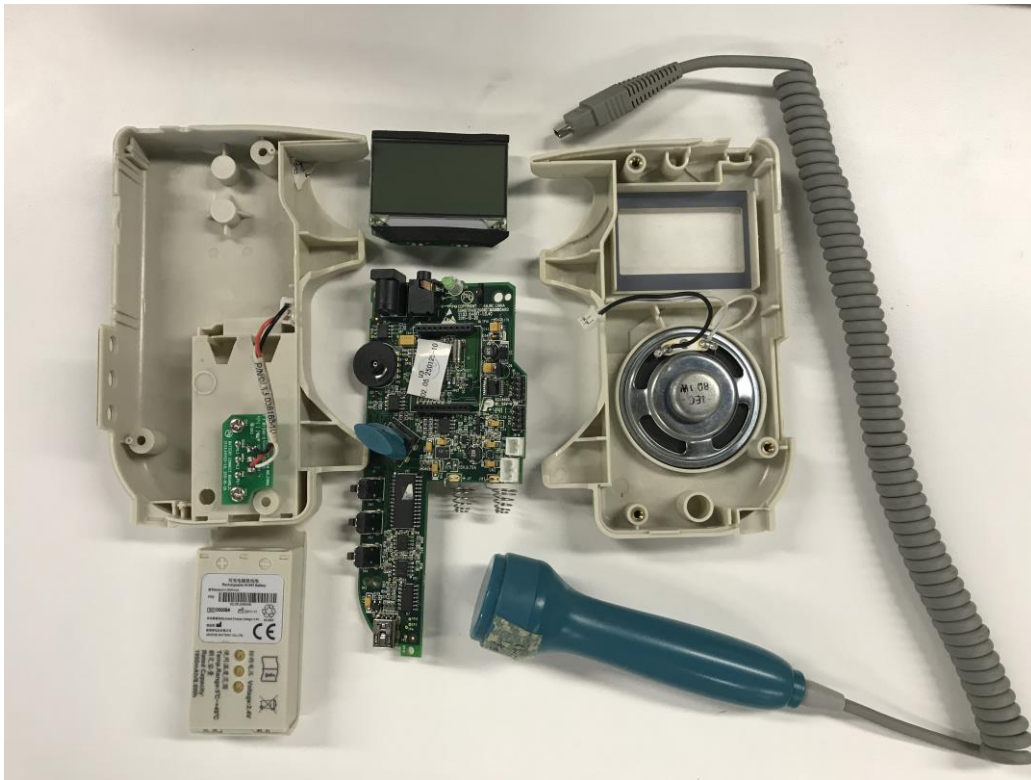


Figure 4-14 Main Parts of the Doppler

4.2 Troubleshooting

4.2.1 Operation failure

Phenomenon	Possible Cause	Solution
None of LED, LCD and speaker works after press the POWER button.	The battery has run down.	Renew or charge the battery.
	The POWER button is damaged.	Renew a POWER button.
	The PCB is damaged.	Renew a PCB.
The volume control doesn't work.	The volume control is damaged.	Renew a volume control.
	The PCB is damaged.	Renew a PCB.
The Doppler can not be shutdown.	The POWER button is damaged.	Renew a POWER button.
	Switch on and shut down the Doppler continuously.	Allow a few seconds intervals between switching on and shut down the Doppler.
	The POWER button is short circuited.	Renew a PCB.

4.2.2 Function Failure

Phenomenon	Possible Cause	Solution
After switched on, the LED/LCD doesn't work while the speaker works.	The LED/LCD is damaged.	Renew the LED/LCD.
	The PCB is damaged.	Renew the PCB.
After switched on, the speaker is soundless while the LED/LCD works.	The speaker is damaged.	Renew the POWER button.
	The volume is turned down.	Turn up the volume.
	The probe is damaged.	Renew a probe.
	The PCB is damaged.	Renew a PCB.
LCD display incorrectly.	The LCD is damaged.	Renew a LCD.
	System error.	Shutdown the Doppler and restart.
	The probe is damaged.	Renew a probe.
	The PCB is damaged.	Renew a PCB.
Sound with noise	Strongly interfered by electromagnetic field.	Avoid using the device in such strong Electromagnetic environment.
	Bad connector of the speaker.	Repair the connector.
	Bad speaker.	Renew a speaker.
No output from earphone.	The earphone socket is damaged.	Renew a socket.
	The PCB is damaged	Renew a PCB.
The LED/LCD is dim, the speaker volume is down.	The battery power is low.	Renew or charge the battery.

4.3 Reassembling the Doppler

4.3.1 Reassemble the Doppler Main Unit

Reassemble the Doppler in the following steps:

- 1) Fix the PCB to the rear panel.
- 2) Plug in the battery connector of SONOTRAX Lite to its socket on the PCB.
- 3) Apply a few drops of heat-melting adhesive to the edge of the speaker and stick it to the front panel, insert the speaker cable plug into its socket on the PCB.
- 4) Hold the LCD on the two edges and plug its connector into the socket on the PCB.

- 5) Join the two panels together tightly and fix them with three M3×6 screws.



Figure 4-15 Fixing screws

- 6) Stick the information label on the bottom of the battery compartment.
- 7) Stick the buttons label to the left panel.

4.3.2 Install the Battery

Install the battery in the following steps:

- 1) For SONOTRAX Basic/ Basic A/ Pro/ II/ II Pro, insert the battery cables plug into the socket inside the case.
- 2) Connect the battery to the battery connector.
- 3) Put them into the battery compartment with the connector inward.
- 4) Slide the battery compartment cover in with the direction opposite to the arrow.

4.3.3 Place the Probe

Place the probe in the following steps:

- 5) Insert the mini USB of the probe into the socket on the main unit.
- 6) Hold the main unit with one hand and hold the probe with the other hand. First place the after body of the probe into the frame (Figure 4-3), then push the top of the probe in (Figure 4-2).

Chapter 5 Tests and Maintenance

5.1 Functional Check

A complete functional check should be performed if the device is suspected of malfunction or each time after service. It is unnecessary to open the device enclosure for functional checks.

WARNING

Qualified service personnel should perform complete functional checks after the device is installed to ensure proper running of the device.

5.1.1 Switching on Check

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., for example,  2 MHz

5.1.2 Screen Check

Check if any symbol or character is missing on the LCD screen, or if there is any especially bright or dark spot. Check if the LCD screen displays symbols normally.

5.1.3 Keys Check

Press the keys on the main unit to check if they work properly.

5.1.4 Probe Check

Switch on the Doppler. Touch the acoustic surface of the probe gently with your hand to check if there is any sound coming from the speaker.

NOTE:

If any failure is detected, refer to *chapter 4* [错误!未找到引用源。](#) for details.

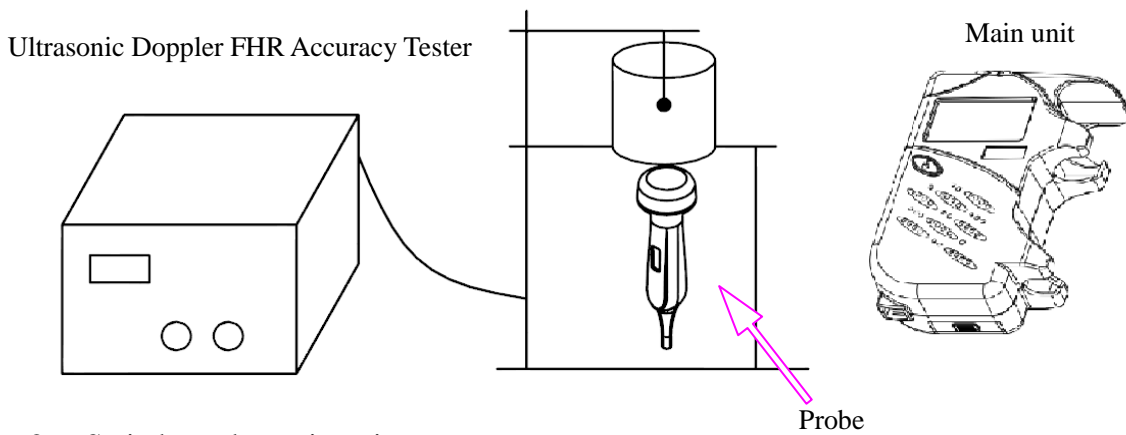
5.2 Performance Test

This test checks the performance of FHR detection.

Required tool: Ultrasonic Doppler FHR Accuracy Tester System

Procedure:

1. Connect the tester and the device as shown below:



2. Switch on the main unit.
3. Generate the heart rate 50 bpm, 90 bpm, 120 bpm, 150 bpm, 180 bpm, 210 bpm and 240 bpm in sequence.
4. Check the FHR value displayed on the screen. If the error is within the range of ± 2 bpm, the test is passed.

5.3 Safety Test

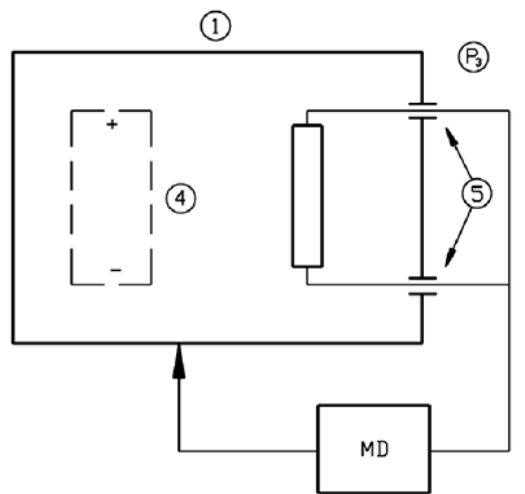
The safety test should be performed by qualified personnel every year and each time after service.

The safety test described here is not a substitute for local safety test where it is required for an installation or a service event. Additional tests may be required by your local standards and regulations.

When performing a safety test, use a standard safety analyzer such as Fluke 601Pro series safety analyzer or the equivalent. Perform the test according to your local regulations, for example, in Europe according to IEC/EN60601-1 and in USA UL60601-1. For the test setup, please refer to the Instructions for Use of the test equipment used.

You are recommended to record the results of the safety test.

5.3.1 Patient Leakage Current Test



① — DUT (Device Under Test) enclosure
part

④ — Power supply

⑤ — Applied

P₃ — Plug, socket, or terminal that will be connected to the patient
device

MD — Measurement

NOTE:

The circuit diagram is based on the Fluke 601Pro series safety analyzer.

This test measures the patient leakage current of the DUT and its applied part located within the patient environment.

Allowable value:

Normal condition (NC): AC: 100 μ A, DC: 10 μ A (IEC/EN60601-1)

5.4 Maintenance

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

Gel must be wiped from the probe after use. These precautions will prolong the life of the unit.

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

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

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

or contact local distributor or manufacturer to get help.

5.4.1 Maintenance of the Main Unit

Check if the equipment has any visible evidence of damage that may affect the patient and the operator's safety or the Doppler's performance before each use. If any damage is detected, replacement is recommended.

The gathering of dew on the screen may occur with abrupt temperature or humidity changes. A stable environment is recommended.

Keep the exterior surface of the main unit clean, free of dust and dirt.

Do not scratch or damage the screen.

5.4.2 Maintenance of the Probe

Handle the probe with care. Avoid contacting the probe with hard or sharp objects. Wipe the remaining gel off the probe after each use.

5.4.3 Maintenance of the Battery

If the Doppler is not used for a long time, please remove the battery, and store the battery in a cool and dry environment at a temperature within the range of 0 °C ~ +45 °C (+32 °F ~ +113 °F).

For rechargeable NI-MH batteries or NI-MH battery pack, which have a service life of more than 300 charge-discharge cycles, we recommend the following:

- Store the battery with about 50% capacity. Do not store the battery in a fully charged or fully discharged state.
- If the battery is stored for more than 6 months, charge it for about 2 hours once every 6 months.

After the Doppler has been stored for a long time, fully charge the battery before using the Doppler.

Chapter 6 Ordering Information

The accessories for normal use supplied or approved by the manufacturer can be used with Ultrasonic Pocket 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

P/N: 01.54.014060

MPN: 01.54.014060014



EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, D-20537 Hamburg Germany

TEL: +49-40-2513175 FAX: +49-40-255726

E-mail: shholding@hotmail.com

EDAN INSTRUMENTS, INC.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District

Pingshan District, 518122 Shenzhen, P.R.China

Email: info@edan.com.cn

TEL: +86-755-2689 8326 FAX: +86-755-2689 8330

www.edan.com.cn