SD5, SD6

Ultrasonic TableTop Doppler

Version 1.1

User Manual

CE 0123

EDAN

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

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

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

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

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 Safety Guide

NOTE:

Familiarize yourself with this user manual before attempting to operate the Doppler. Follow the operation and maintenance instructions to ensure proper use of it.

1.1 Intended Use/Indications for Use

The SD5 Ultrasonic TableTop Doppler (hereinafter called "SD5") and SD6 Ultrasonic TableTop Doppler (hereinafter called "SD6") 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 obstetrical 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.

1.2 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the device.

WARNING

1 SD5/SD6 Ultrasonic TableTop Doppler is a tool to aid healthcare professionals and should not be used in place of normal fetal monitoring. It is not intended for treatment.

2 This device is not explosion-proof and can not be used in the presence of flammable anaesthetics.

3 **SHOCK HAZARD** – In order to protect the patient and the operator, the device case should be grounded. The power receptacle must be a three-slot grounded outlet.

4 **SHOCK HAZARD** – Do not attempt to connect or disconnect a power cord with wet hands. Make sure that your hands are clean and dry before touching a power cord.

5 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.

6 Exposure to ultrasound should be kept as low as reasonably achievable.

WARNING

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

8 Do not apply this device and other ultrasonic equipment simultaneously on the same patient, in case of possible hazard caused by leakage current superposition.

9 Do not apply this device simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on the same patient.

10 The device is not protected against defibrillation.

11 Do not use the device with HF surgical equipment.

12 Only use the probes provided by the manufacturer.

13 Before using the battery, make sure to read the user manual and safety precautions thoroughly.

14 Do not heat or throw the battery into fire as this may cause explosion.

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

16 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.

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

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

19 The battery should be charged at least once a month to prevent overdischarge.

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

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

22 If the device is not used for a long time, please remove the battery and store it as required.

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

24 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.

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

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

27 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.

WARNING

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

29 The appliance coupler or mains plug is used as isolation means from supply mains. Position the device in a location where the operator can easily access the disconnection device.

30 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.

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

32 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to section A2.4 Recommended Separation Distances.

33 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 service personnel.

3 The main unit is designed for continuous operation and is ‘ordinary’. It is not waterproof; do not immerse it in any liquid (i.e. not drip or splash-proof).

4 Keep the device clean. Avoid vibration.

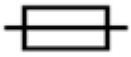
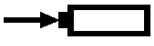
5 Do not sterilize the Doppler with autoclave or gas.

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 Check that the equipment does not have visible evidence of damage that may affect personnel’s safety or examining capability before use. If damage is detected, replacement is recommended.

8 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		Headphones
2		Equipotential grounding
3		Alternating Current
4		Fuse
5		ON/OFF switch
6		Menu
7		Recording and play-back
8		Print control
9		Move the cursor downwards
10		Move the cursor upwards
11		Speaker
12		Decrease
13		Increase
14		Charge battery
15		Push right
16		Caution
17		Operating instructions

18		TYPE BF APPLIED PART
19	CE 0123	CE marking
20		Disposal method
21	IPX4	The device is protected against splashing water. Water splashed against the enclosure from any direction shall have no harmful effects.
22	P/N	Part Number
23	SN	SERIAL NUMBER
24		Date of manufacture
25		MANUFACTURER
26	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
27		General symbol for recovery/recyclable
28	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
29		Refer to User Manual (Background: Blue; Symbol: White)
30		Non-ionizing electromagnetic radiation
31*	FCC ID: SMQSD6PEDAN	Federal Communications Commission: FCC ID: SMQSD6PEDAN
32*	FCC ID: SMQSD6MEDAN	Federal Communications Commission: FCC ID: SMQSD6MEDAN

NOTE:

1 The user manual is printed in black and white.

2 * Applicable to SD6 only.

Chapter 2 Introduction

NOTE:

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

2.1 Main Unit

SD5:

SD6:

1 Probe
2 Probe Cable
3 Main Unit
4 LCD
5 Speakers
6 Probe Socket

Figure 2-1 Overview

7 Probe Holder
8 Handle
9 Probe Sensor Socket
10 Main Unit Control Keys

Figure 2-2 Top View of the Main Unit

WARNING

Please do not touch the probe sensor socket and the patient simultaneously.

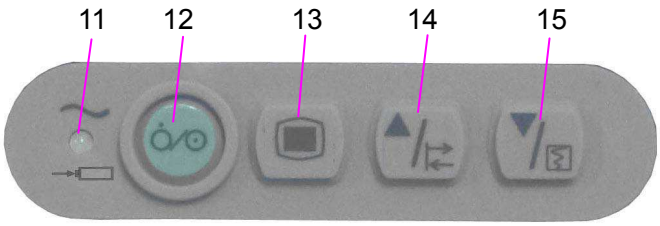


Figure 2-3 Main Unit Control Keys

11 Main Unit Indicator
12 On/OFF Key
13 Setup Key / Confirm Key
14 Up Key /
Record/Play Control Key
15 Down Key /
Print Control Key

Figure 2-4 Back View of the Main Unit

16 Fuses
17 Power Socket
18 Equipotential Grounding Terminal
19 Main Unit Label
20 Earphone Socket

Figure 2-5 Right View of the Main Unit

21 Battery Compartment

NOTE:

The main unit is not waterproof. Do not immerse it in any type of liquid.

2.2 Probes

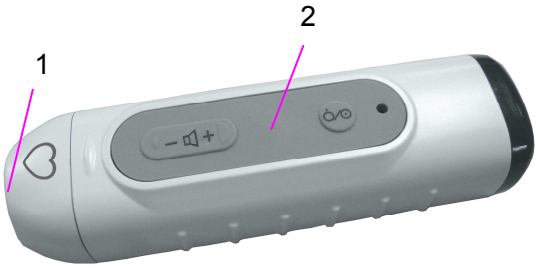
WARNING

Do not touch the charge sockets of the Doppler probe and the patient simultaneously.

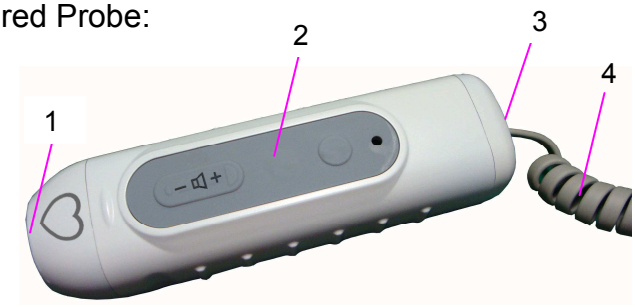
CAUTION

1. Do not immerse the probe (and the probe cable) in any liquid.
2. Do not stretch the probe cable for more than three meters.

Wireless Probe:

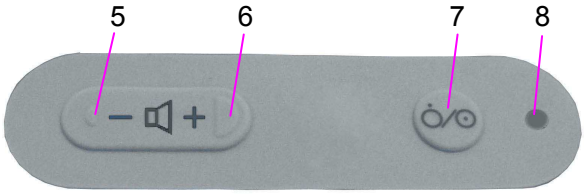


Wired Probe:



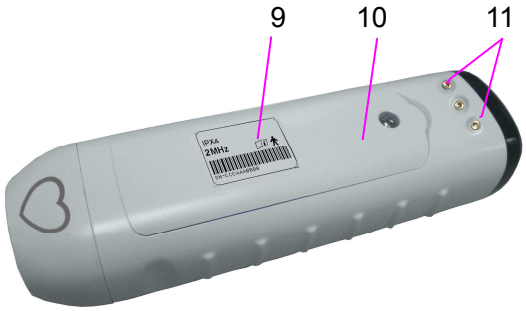
1 Acoustic Face
2 Probe Control Keys
3 Probe Socket
4 Probe Cable

Figure 2-6 Top View of the Probe



5 Volume Decreasing Key
6 Volume Increasing Key
7 Power Key (only available on wireless probe)
8 Probe Indicator

Figure 2-7 Probe Control Keys



9 Probe Type Label
10 Probe Battery Compartment
11 Probe Charge Socket

Figure 2-8 Bottom View of the Probe

Description:

The Doppler supports 2 MHz and 3 MHz probes supplied by the manufacturer. The probe nominal frequency is disclosed on the probe type label.

Probes of SD5 are wired, while probes of SD6 are wireless.

WARNING

SD6 complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) this device may not cause harmful interference, and
2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

1. This equipment (SD6) has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
   - Reorient or relocate the receiving antenna.
   - Increase the separation between the equipment and receiver.
   - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
   - Consult the dealer or an experienced radio/TV technician for help.
2. Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

2.3 Control Keys

Control keys are provided to switch on or off the device, perform the functions and change the settings.

A beep sound will be heard when you press a key of the main unit. Or you can switch off the sound. Refer to section *3.8.2 Switching the Key Sound On and Off* for operation procedures.

(1) Power Key 

Function: Switch on/off the main unit or switch on the probe. Note that if the probe fails to connect the main unit in two minutes, it will power off automatically.

(2) Up Key / Record/Play Control Key 

Function: Move the cursor upwards to the previous item (in the setting mode).

Recording and playing control (in the real-time examining mode).

(3) Down Key / Print Control Key 

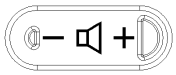
Function: Move the cursor downwards to the next item (in the setting mode).

Printing control (reserved).

(4) Setup Key / Confirm Key 

Function: Enter setup menu (in the real-time examining mode).

Confirm selection (in the setting mode).

(5) Volume Control Keys 

Function: Decrease the FHR volume (). Increase the FHR volume ().

2.4 Indicators

(1) Main unit indicator

The indicator of the main unit indicates the connection status of the main unit and AC power:

The indicator lights up in green – the AC power is connected.

The indicator flashes in green – the main unit is charging the main unit battery.

The indicator goes off – the AC power is not connected.

(2) Probe indicator

The indicator of the probe indicates the status of the probe:

The indicator lights up in green – the probe is switched on.

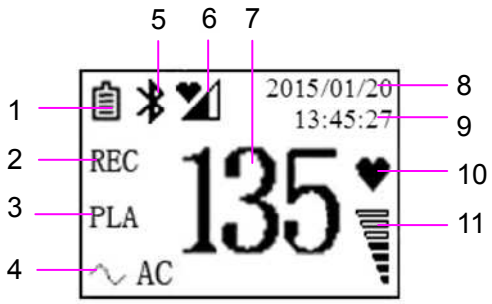
The indicator flashes in yellow when the volume control key is pressed – the volume has been decreased/increased to its minimum/maximum.

For SD6, the indicator lights up continuously in yellow – the probe battery is low; the indicator flashes in green – the probe battery is being charged.

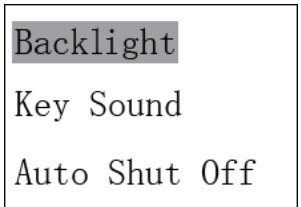
2.5 LCD

The Doppler has four modes: examining mode, recording mode, playing mode and setting mode.

In the former three modes, the LCD displays as follows:



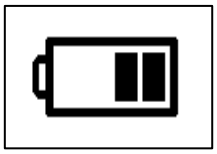
Item	Description	
1	Battery Indicator	The battery is installed and the battery energy is full. The main unit battery is low. The main unit battery is not installed.
2	Recording Indicator: The Doppler is recording fetal heart sound. (Only in the recording mode)	
3	Playing Indicator: The Doppler is playing the recorded fetal heart sound. (Only in the playing mode)	
4	AC Indicator	AC power is connected.
5	Bluetooth Indicator (Only available with SD6)	The wireless probe is switched on and its communication with the main unit is normal. The wireless probe is switched off or its communication with the main unit failed.
	Probe Indicator (Only available with SD5)	The wired probe is well connected. The wired probe is not connected.
6	Fetal heart signal intensity indicator	
7	FHR numeric measurement value	
8, 9	Date and Time	
10	Heart Beat Indicator: When fetal heart signal is received, the heart shape flashes to indicate the FHR refreshing frequency.	
11	Volume Indicator	



In the setting mode, the LCD displays as the right figure shows.

The rectangular mark that moves up and down is called the "cursor". Press the **Up** key or the **Down** key to move it back or forth.

The LCD displays the battery charging icon when the main unit is shut off and charging. During the charging process, the battery charging icon changes as the battery level increases.



Chapter 3 Basic Operation

3.1 Opening Package and Checking

Open the package; take out the Doppler and accessories carefully. Place them on a flat, clean surface.

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 Using Batteries

CAUTION

The fitting of the batteries should be carried out by the manufacturer's authorized personnel.

3.2.1 Fitting Main Unit Battery

The main unit is powered either by alternating current or a Ni-MH battery.

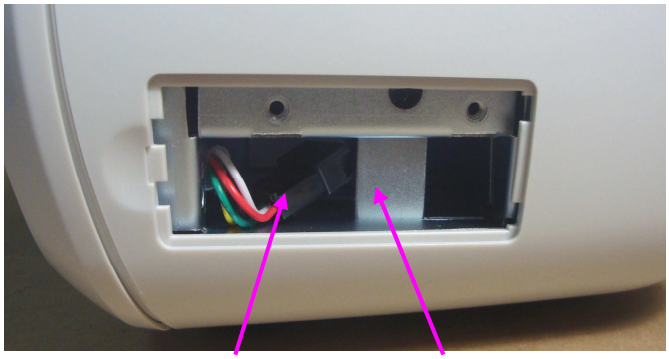
It is recommended to power the main unit solo by a battery during operation. Therefore, charge the battery fully before use to ensure enough power. Connecting to mains power supply will charge the battery no matter if the main unit is on or off.

WARNING

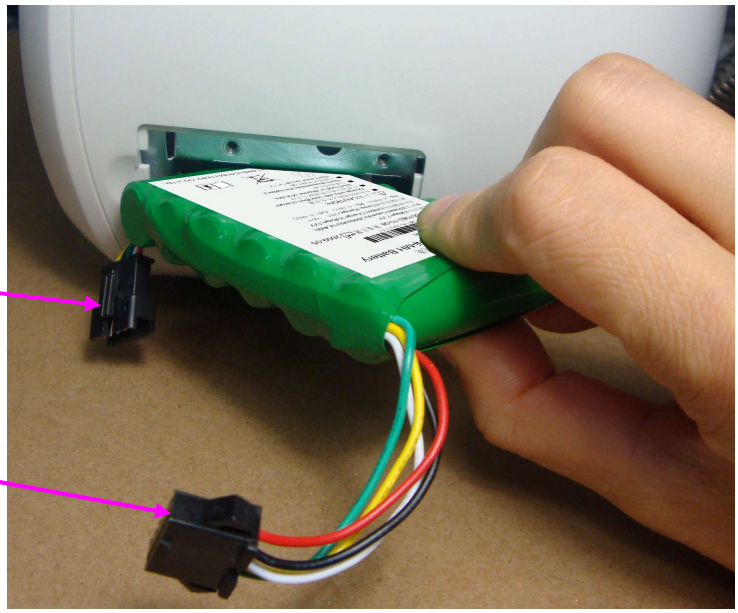
Switch off the Doppler and remove the power cord before fitting the main unit battery.

To fit the battery for the main unit:

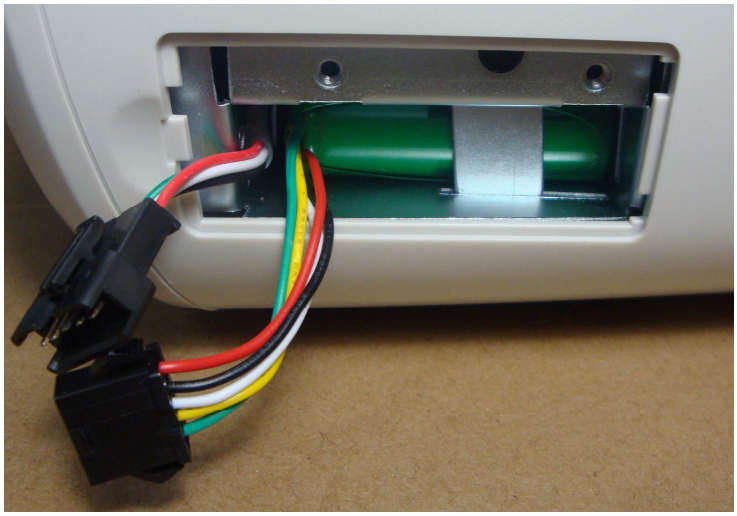
1 Follow the arrow direction to open the battery compartment cover. The battery connecting cable & connector and the metal insert show up.



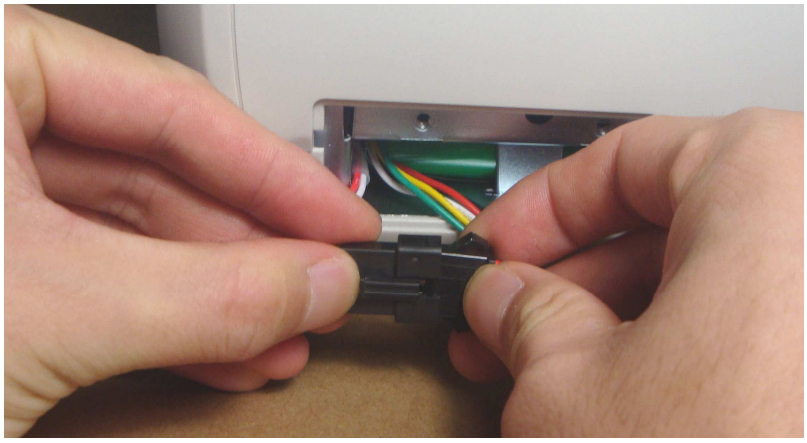
2 Tilt the battery sideways and put its bottom left corner into the battery compartment from the left end of the compartment to the right. Make sure connector ① stays out of the compartment.



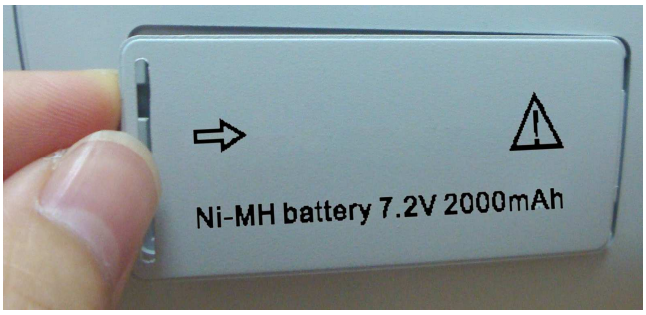
3 Keep pushing the battery into the compartment until the metal insert springs back to lock the battery.



4 Connect the two connectors (①&②) and then put them into the compartment.



5 Close the battery compartment cover.



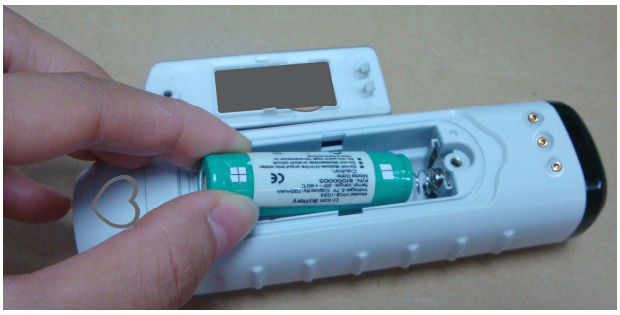
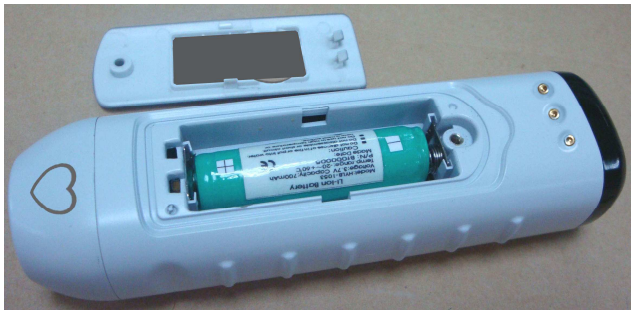
3.2.2 Fitting Wireless Probe Battery

The wireless probe is powered by a lithium battery.

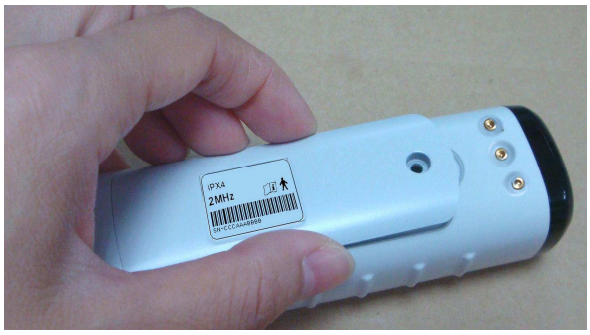
To fit the battery for the probe:

1 Remove the screw on the battery compartment cover with a screw driver and then take the cover away with your hand.

2 Fit the battery. Make sure the polarities correspond with the battery compartment diagram.

3 Close the battery compartment cover and fix it with the screw.




3.2.3 Charging Main Unit Battery

Observe the battery indicator on the LCD, the panes in it indicate the main unit battery electric energy. They go off gradually with the consumption of the battery. When the battery indicator turns into "  ", the battery power is low. You need to switch to outer AC power and charge the battery in time.

To charge the main unit battery, you need to connect the Doppler to 100 V-240 V~ power supply.

Connecting the main unit to the AC power supply will charge the battery, no matter if it is on or off. If the main unit is in the stand-by or switch off state, it takes no more than 5 hours to fully charge the main unit battery. During this period, the main unit indicator flashes in green, and the panes in the battery indicator increase gradually. When the battery is fully charged, the indicator has four panes.

3.2.4 Charging Wireless Probe Battery

When the wireless probe battery is low, the probe power indicator turns into yellow. You need to switch off the probe and charge the battery in time.

To charge the probe battery, you need to place the probe in the probe holder. Then connect the main unit to the AC power supply.

If the probe is in the switch off state, it takes no more than 5 hours to fully charge the probe battery. During this period, both the main unit indicator and the probe indicator will flash in green.

3.2.5 Care of Batteries

WARNING

1 Replacement or charging of batteries shall be done at least 1.5 meters away from the patient.

2 Close the battery compartment before using the main unit or the probe.

3 Do not expose the batteries to high temperature, heat them or dispose of them in fire.

4 Do not disassemble the batteries.

5 Short circuit should be avoided.

CAUTION

1 If the Doppler is not used for an extended period, remove the batteries and keep the batteries in a cool and dry environment. The environment temperature must not exceed the range of -20°C ~ +40°C (-4°F ~ +104°F).

2 If the Doppler is not used for an extended period, charge the batteries at least once a month.

3 The batteries must be properly disposed according to local regulations after their useful life.

3.3 Connecting the Power Cable

Apply the power cable provided with the Doppler. Put the connector of the power cord to the power socket on the Doppler (figure 2-4). Put the plug of the power cord into a grounded 3-slot power output special for hospital usage.

NOTE:

Make sure the AC power supply of the Doppler complies with the following specification: 100 V-240 V~, 50 Hz/60 Hz.

WARNING

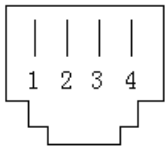
If the protective grounding (protective earth) system is doubtful, the Doppler must be supplied only by inner power.

3.4 Using Wired Probe

3.4.1 Probe Socket

SD5 adopts wired probes. The probe cable is a telephone cable with a standard RJ11 plug on each terminal.

RJ11 Interface:



1	Power
2	GND
3	Signal Wire
4	Signal Wire

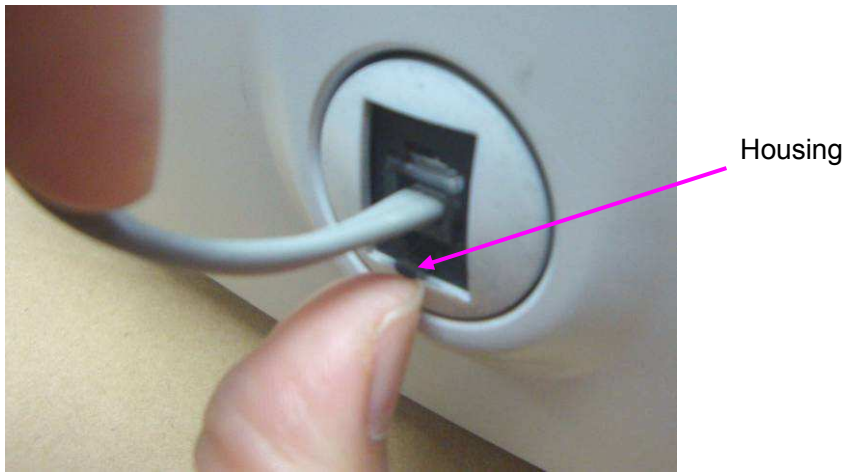
3.4.2 Connecting and Disconnecting a Wired Probe

To connect the wired probe to the main unit:

1 Take out the probe cable from package. Insert one modular plug of the cable into the probe socket of the main unit.

2 Insert the other modular plug into the probe socket of the probe.

To disconnect the probe, press the housing of the modular plug and then pull it out.



3.5 Switching On

WARNING

Make sure all the metal parts are linked to the protective earth cord and the power cord is free of damage before switching on the main unit.

CAUTION

To avoid unwanted noise, do not take out or place the probe when the main unit is on. Remember to take out the probe before switching on the main unit, and place the probe after switching off the main unit.

To switch on the main unit:

Pick up the probe and then press the **ON/OFF** key  on the main unit.

All the real-time examining menu elements light up in a few seconds. A start-up sound (if the key sound is enabled) is heard. The Doppler performs a self test by displaying the FHR numerics in a fast speed.

To switch on the wireless probe:

Press the **Power** key  on the wireless probe. The probe indicator lights up in green.

NOTE:

1 For SD6, the **Power** keys of the wireless probe and the main unit need to be pressed separately. After they are switched on, they will be connected with each other automatically, and the LCD will display ✱ to indicate normal connection. If you touch the acoustic faceplate of the probe gently with your hand, the Doppler will give out sound.

2 For SD6, docking the probe when the main unit is powered on and is in normal connection with the probe, the probe will turn off automatically and begin to charge. If you take up the probe within 3 hours, it will power on automatically and be ready for use.

3 For SD5, the wired probe is ready to use when the main unit is switched on.

3.6 Switching Off

When the examination is finished, switch off the main unit, wipe the remaining gel off the probe with a clean soft cloth and then place the probe back into the holder.

To switch off the main unit, perform any one of these operations:

1) Press the **ON/OFF** key  on the main unit.

2) Put the probe into the probe holder.

3) Auto shut off. If the main unit does not receive signal for a period of time, it will be switched off automatically. The auto-shut-off time is preset in the setup menu. Refer to section *3.8.3 Setting Auto-Shut-Off Time*.

To switch off the wireless probe:

NOTE:

1 If the probe is not to be used over a relatively long period of time, It is recommended to switch off the main unit first, and then put the probe into the probe holder.

2 For SD6, if you switch off the main unit when it is in normal connection with the probe, the probe will also be switched off.

3.7 Using Earphone

In a noisy environment, you are advised to use an earphone to hear fetal heart sound.

Insert the earphone plug into earphone socket on the back of the main unit (figure 2-4). The speakers will be muted when the earphone is connected.

WARNING

Turn down the volume before using earphone to your ears.

CAUTION

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.

3.8 Changing Doppler Settings

3.8.1 Switching Backlight On and Off

1 Press the **Setup** key for about 2 seconds to open setup menu.
2 Press the **Setup** key when the cursor stays at **Backlight**.
3 Press the **Up/Down** key to toggle between **ON** and **OFF**.
4 Press the **Setup** key.

3.8.2 Switching Key Sound On and Off

1 Press the **Setup** key for about 2 seconds to open setup menu.
2 Press the **Up/Down** key to move the cursor to **Key Sound**, press the **Setup** key.
3 Press the **Up/Down** key to toggle between **ON** and **OFF**.

4 Press the **Setup** key.

3.8.3 Setting Auto-Shut-Off Time

The Auto-Shut-Off feature facilitates the economical use of the Doppler. The main unit will switch off automatically after no signal is received and no operation is performed for 1 minute，3 minutes or infinite time.

1 Press the **Setup** key for about 2 seconds to open setup menu.
2 Press the **Up/Down** key to move the cursor to **Auto Shut Off**, press the **Setup** key.
3 Press the **Up/Down** key to move the cursor among options.
4 Press the **Setup** key.

3.8.4 Choosing Language

1 Press the **Setup** key for about 2 seconds to open setup menu.
2 Press the **Up/Down** key to move the cursor to **Language**, press the **Setup** key.
3 Press the **Up/Down** key to select the required language.
4 Press the **Setup** key.

3.8.5 Setting Date and Time

1 Press the **Setup** key for about 2 seconds to open setup menu.
2 Press the **Up/Down** key to move the cursor to **Real Time Clock**, press the **Setup** key.
3 Press the **Setup** key when the cursor stays at **Hour**.
4 Press the **Up/Down** key to choose a number from 00 to 23 and then press the **Setup** key to confirm the choice.
5 In the same way, choose the Minute from 00 to 59. Choose the Year, Month and Day.
6 Move the cursor to **EXIT** and then press the **Setup** key.

3.8.6 Setting Date Format

You can choose to switch the date on or off. When it is on, the date format has three options: DD/MM/YYYY, MM/DD/YYYY and YYYY/MM/DD.

To switch the date on and off or change date format:

1 Press the **Setup** key for about 2 seconds to open setup menu.
2 Press the **Up/Down** key to move the cursor to **Date Format**, press the **Setup** key.
3 Press the **Up/Down** key to toggle between **ON** and **OFF**. If you choose **ON**, the cursor moves to the date format. Select a format.
4 Press the **Setup** key.

NOTE:

If no operation is performed in 30 seconds, the device will exit from the setup menu. The

setting changes will not be effective.

3.9 Replacing Fuses

WARNING

Switch off the main unit and unplug it before replacing the fuses.

Two fuses are located on the rear panel of the device, their specifications are:

Size: Φ5 mm*20 mm; Model: T400mAH250V.

When any one of the fuses is blown, perform the following steps to replace it:

1. Using a flat-head screw driver, push the fuse in for about one millimeter and then rotate it anticlockwise.
2. Remove the old fuse and replace it with a new fuse that is supplied by the manufacturer or of the same specifications.
3. Push the new fuse into the socket for about one millimeter and then rotate it clockwise back into position.

Chapter 4 FHR Examining

WARNING

1 Always check if the main unit and the probe are in good condition prior to use.

2 To avoid inaccurate diagnosis: (a) relocate the probe for the best FHR signal as the fetal position changes; (b) when intrauterine fetal death is doubted by using this examination method, try to verify it with other methods.

CAUTION

Handle the probe with care. Do not drop it on hard surfaces.

The 2 MHz and 3 MHz obstetrical probes are designed for FHR examining. The 2 MHz probe is optimized for deep penetration and is widely used in the third trimester pregnancy. The 3 MHz probe is a general purpose probe. It has better resolution and wider detection range than the 2 MHz probe, therefore is optimized for early fetal heart detection.

Follow these procedures to perform FHR examining:

1 Feel the position of the fetus by hand to find the best position to detect the fetal heart.

2 Switch on the Doppler and the probe.

3 Apply a small amount of coupling gel to the acoustic face of probe; place the probe face at the best position for detecting fetal heart. Angle the probe to obtain an optimum audio signal. Adjust the volume if required.

When an audible fetal heart signal is detected, a clear fetal heart sound will be heard from the speakers/earphone, and numeric FHR value will be displayed on the LCD.

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 not possible to obtain accurate FHR unless an audible fetal heart signal is detected. If the calculated FHR is not in accordance with the beat of the fetal heart sound, the fetal heart sound auscultation result shall prevail.

5 When applied to the patient, the ultrasound transducer may warm slightly (less than 8°C (14.4°F) above ambient temperature). When NOT applied, the ultrasound transducer may reach the highest temperature of 8°C (14.4ºF).

6 Maternal heart will be detected if the probe is strongly placed on maternal vessel.

7 For SD6, the effective transmission distance between the main unit and the wireless probe is 5 meters. It is recommended that they are positioned within this distance in photopic vision.

Chapter 5 Recording and Playing

The built-in recorder of the Doppler allows recording and playing fetal heart sound of 240 seconds (at most).

To record fetal heart sound:

Press and hold the Record/Play control key  for two seconds. The character **REC** on the LCD lights up. Recording starts.

Press the Record/Play control key  again to stop recording and return to the real-time examining mode.

To play the fetal heart sound:

Press the Record/Play control key  in the real-time examining mode. The character **PLA** on the LCD lights up. The Doppler plays the recorded fetal heart sound.

NOTE:

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

Chapter 6 Maintenance and Cleaning

6.1 Inspection

(1) Visual Inspection

Prior to using the device every time, do the following inspections:

- Check the device and accessories to see if there is any visible evidence of damage that may affect patient safety.
- Check the power socket and power cables.
- Check if the device functions properly to make sure it is in good condition.

If any damage is detected, stop using the device on the patient. Replace the damage part(s) or contact the manufacturer for service before reusing it.

(2) Routine Inspection

The overall check of the device, including safety check and function check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to ensure proper patient isolation from live parts. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(3) Mechanical Inspection

Make sure all exposed screws are tight.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

WARNING

Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

CAUTION

The maintenance must be performed by professional personnel.

6.2 Maintenance

Avoid scratching and damaging the LCD. The gathering of dew on the LCD may occur with abrupt temperature or humidity changes. A table environment is recommended for the main unit.

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

Handle the probe with care to avoid damaging the cover, piezoelectric crystals and mechanical movement. Do not contact the probe with hard or sharp objects.

Do not excessively flex the probe cable.

Wipe the remaining gel off the probe after use.

Keep the probes in a dry environment, where the temperature should be lower than 45°C.

6.3 Cleaning

To clean the main unit:

Switch off the Doppler and unplug it from AC power supply. Clean the case 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. The recommended cycle is one week or when needed.

Clean the probe after each use to avoid cross infection and prolong its useful life.

To clean the probe:

Switch off the probe. 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.

CAUTION

1 Do not use strong solvent such as acetone.

2 Do not use an abrasive such as steel wool or metal polish.

3 Neither the main unit nor the probe is waterproof; do not immerse any part of them in liquid. Entry of liquid into the Doppler may destroy the equipment.

4 Do not allow any liquid remain on the surface.

6.4 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.

6.5 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 them.

Checking Item	**Checking Method**
Visual Check	Inspect the Doppler for any damage.
Function Check	Check if the Doppler can be switched on or off properly (see *3.5 Switching On* and *3.6 Switching Off*). When the Doppler is switched on, check if the LCD works as described in *2.5 LCD*; touch the probe faceplate gently with your hand and check if the Doppler gives out sound normally.

Chapter 7 Warranty and Service

7.1 Warranty

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

The warranty is void in cases of:

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

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

7.2 Contact information

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

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

Chapter 8 Product Specifications

8.1 Environmental Specifications

Working	Temperature:	0ºC ~ + 40ºC (+32ºF ~ +104ºF)
	Relative Humidity:	15% RH ~ 95% RH (non-condensing)
	Atmospheric Pressure:	86 kPa ~ 106 kPa
Transport and Storage	Temperature:	-20ºC ~ +55ºC (-4ºF ~ +131ºF)
	Relative Humidity:	15% RH ~ 95% RH (non-condensing)
	Atmospheric Pressure:	70 kPa ~ 106 kPa

8.2 Physical Specifications

Dimensions and Weight	Dimensions:	Main Unit: 265 mm x 155 mm x 180 mm	
		Probes: 140 mm x 40 mm x 32 mm	
	Weight:	Main Unit: 1.7 kg (with battery and probe)	
		Wireless Probe: <140 g (with battery)	
		Wired Probe: <100 g	
Power Supply	Main unit		
	Operating Voltage:	100 V-240 V~	
	Operating Frequency:	50 Hz/60 Hz	
	Input Power:	35 VA	
	Battery:	7.2 V/2000 mAh (Ni-MH Battery)	
	Probe		
	Battery:	3.7 V/800 mAh (Lithium Battery)	
Standards Compliance	IEC 60601-1:2005, EN 60601-1:2006, IEC 60601-1-2:2007, EN 60601-1-2:2007, IEC/EN 60601-2-37		
Anti-electric Shock Type	Class I equipment with internal power supply		
Anti-electric Shock Degree	Type BF applied parts		

Degree of Protection against Harmful Ingress of Water	Main Unit: Ordinary equipment (Sealed equipment without liquid proof)
	Probe: IPX4
Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases
Disinfection/Sterilizing Method	Refer to this user manual for details
EMC	CISPR 11 Group1 Class A
Earth Leakage Current (Limit):	N.C. S.F.C. 500 μA 1000 μA
Enclosure Leakage Current (Limit):	N.C. S.F.C. 100 μA 500 μA
Patient Leakage Current (Limit):	N.C. S.F.C. d.c. 10 μA 50 μA a.c. 10 μA 50 μA
Patient Auxiliary Current (Limit):	N.C. S.F.C. d.c. 10 μA 50 μA a.c. 10 μA 50 μA
Display:	Effective display area: 62.0 mm (W) x 44.0 mm (H) Number of characters: 128*64 Dots Dot size: 0.39 mm (W) x 0.55 mm (H) Dot pitch: 0.44 mm (W) x 0.60 mm (H)
Ultrasonic Gel:	pH: 5.5~8.0 Acoustic Impedance: $1.5x10^6$ Pa.s/m ~$1.7x10^6$ Pa.s/m (in 35°C(95ºF))

8.3 Performance Specifications

FHR Performance (Essential Performance):	FHR Measurement Range: 50 bpm ~ 240 bpm
	Accuracy: ± 2 bpm
FHR Resolution:	1 bpm
Recording and Playing:	Audio Sampling Frequency: 4 kHz
	Recording Length: 240 seconds
White Back Light:	Two Brightness Adjustable: OFF, ON

Audio Output Power:	3 W
Auto Shut off:	1-minute/3-minute no signal and no operation
Bluetooth Transmission Distance:	Photopic vision: >5 m (the indoor distance depends on the building structure and material)
Ultrasound:	
Nominal Frequency:	2 MHz Wired /Wireless Probes: 2 MHz
	3 MHz Wired /Wireless Probes: 3 MHz
Working Frequency:	2 MHz Wired /Wireless Probes: (2.0 ± 10%) MHz
	3 MHz Wired /Wireless Probes: (3.0 ± 10%) MHz
2 MHz Wired/wireless probe:	I_{ob} < 20 mW/cm^2
3 MHz Wired/wireless probe:	
p- < 1 MPa	
I_{spta} < 100 mW/cm^2	
I_{sata} < 20 mW/cm^2	
W0 < 50mW	
Working Mode:	Continuous wave Doppler
Effective Radiating Area of Probe:	2 MHz /3 MHz Wired /Wireless probes: (245±15%) mm^2

8.4 Battery Specifications

	For main unit	**For probe**
Type:	Ni-MH Battery	Lithium Battery
Nominal Capacity:	2000 mAh	800 mAh
Nominal Voltage:	7.2 V	3.7 V
Necessary Charge Time:	≤5 hours (the main unit is in the stand-by or switch off state)	≤5 hours (the probe is in the switch off state)
Expected Battery Life:	≥8 hours (the new battery is fully charged before use, and the fetal heart sound at 1 meter right ahead of the main unit speaker is higher than 80 dB)	≥3 hours (the new battery is fully charged before use)

Circle Life:	≥300 times (after 300 circles, only 90% of the capacity can be restored.)
Storage Temperature:	-20°C ~ +60°C (-4 ºF ~ +140 ºF) (1 month) or -20°C ~ +40°C (-4 ºF ~ +104 ºF) (3 months)

8.5 Low Output Summary Table

Low Output Summary Table

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

System: Ultrasonic TableTop Doppler

Transducer Model (MHz)	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$I_{sppa.3}$ (W/cm^2)
CW 2.0 (SD5)	1.774	TIS	0.0159	0.00628	0.001774
		TIB	0.0301		
CW 3.0 (SD5)	5.867	TIS	0.0969	0.00813	0.005867
		TIB	0.1113		
CW 2.0 (SD6)	3.484	TIS	0.0203	0.00785	0.003484
		TIB	0.0531		
CW 3.0 (SD6)	5.307	TIS	0.1132	0.00763	0.005307
		TIB	0.1141		

Appendix 1 Ordering Information

CAUTION

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

Parts	Part Number
Probe	
2 MHz Wired Probe	02.01.212045
3 MHz Wired Probe	02.01.212046
Probe Cable	01.13.036108
2 MHz Wireless Probe	02.01.212047
3 MHz Wireless Probe	02.01.212048
Accessory	
Ni-MH Battery for Main Unit	01.21.064220
Lithium Battery for Wireless Probe	01.21.064125
Carry Bag	01.56.465630
Power Cord (European Standard)	01.13.036638
Power Cord (American Standard)	21.13.036384

Appendix 2 EMC Information

A2.1 Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacture's declaration- electromagnetic emission</th></tr>
<tr><td colspan="3">The SD5/SD6 is intended for use in the electromagnetic environment specified below. The customer or the user of the SD5/SD6 should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The SD5/SD6 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The SD5/SD6 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC61000-3-3</td><td>Complies</td></tr>
</table>

A2.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The SD5/SD6 is intended for use in the electromagnetic environment specified below. The customer or the user of SD5/SD6 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 Hz/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SD5/SD6 requires continued operation during power mains interruptions, it is recommended that the SD5/SD6 be powered from an uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

A2.3 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The SD5/SD6 is intended for use in the electromagnetic environment specified below. The customer or the user of SD5/SD6 should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment -guidance</th></tr>
<tr><td>Conducted RF
IEC
61000-4-6</td><td>3 Vrms
150z to 80 MHz</td><td>3Vrms

0.1 Vrms
1.995MHz~2.010MHz
2.985MHz~3.015MHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the SD5/SD6 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
d=1.2$\sqrt{P}$
d=35 $\sqrt{P}$ 1.995 MHz to 2.010 MHz
d=35 $\sqrt{P}$ 2.985 MHz to 3.015 MHz</td></tr>
<tr><td>Radiated RF
IEC
61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>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 level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SD5/SD6 is used exceeds the applicable RF compliance level above, the SD5/SD6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SD5/SD6

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

A2.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the SD5/SD6

The SD5/SD6 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SD5/SD6 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SD5/SD6 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$\sqrt{P}$ (d=35 $\sqrt{P}$ 1.995 MHz to 2.010 MHz 2.985 MHz to 3.015 MHz)	**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(3.5)**	**0.12**	**0.23**
0.1	**0.38(11.1)**	**0.38**	**0.73**
1	**1.2(35)**	**1.2**	**2.3**
10	**3.8(111)**	**3.8**	**7.3**
100	**12(350)**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the 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 3 Ultrasound Intensity and Safety

A3.1 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.

A3.2 Ultrasound Safety and the ALARA 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).

A3.3 Explanation of MI/TI

A3.3.1 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 confirmed adverse mechanical 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.

$$MI = \frac{P_{r,\alpha}}{f_{awf} \times C_{MI}}$$

$$C_{MI} = 1 \text{ (MPa / MHz)}$$

A3.3.2 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 potential for temperature rise 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 1ºC.

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.

A3.3.3 Measurement Uncertainties

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The overall systematic uncertainties were determined 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 ±1dB in frequency range 1-15MHz.
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 ºC.
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.

A3.4 Prudent Use Statement

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.

A3.5 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 Manufacturers Seeking 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.

A3.6 Probe Acoustic Output Parameters List

Acoustic Output Reporting Table for Track 1
Non-autoscanning Mode

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

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.02154	30.52	0.03052
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.03047		
	W_0 (mW)			32.09	32.09
	f_c (MHz)		2.00	2.00	2.00
	Z_{sp} (cm)		3.78	3.78	3.78
	Beam dimensions	X_{-6} (cm)		2.449	2.449
		Y_{-6} (cm)		0.1658	0.1658
	PD (usec)		N/A		N/A
	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		Φ1.7678	
		Ele. (cm)		Φ1.7678	
Operating Control Conditions	Fixed				

Acoustic Output Reporting Table for Track 1
Non-autoscanning Mode

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

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.01342	17.45	0.01745
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.02325		
	W_0 (mW)			43.90	43.90
	f_c (MHz)		3.00	3.00	3.00
	Z_{sp} (cm)		5.20	5.20	5.20
	Beam dimensions	X_{-6} (cm)		0.6228	0.6228
		Y_{-6} (cm)		1.372	1.372
	PD (usec)		N/A		N/A
	PRF (Hz)		N/A		N/A
	EBD	Az. (cm)		Φ1.7678	
		Ele. (cm)		Φ1.7678	
Operating Control Conditions	Fixed				

Appendix 4 Overall Sensitivity

A4.1 Overall Sensitivity of SD5 (2MHz Wired Probe)

Diameter of Target Reflector (mm)	Distance (d)(mm)	Reflection Loss A(d)	Two-way Attenuation $B=\sum B_a+B_w$				V_S(r.m.s) mV	V_n(r.m.s) mV	$C=20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
			∑B (T: ultrasonic attenuation phantom No. B_a:dB)		B_w (dB)	B (dB)				
1.58 A=45.7dB@ 2MHz	50	39.8	T	6#6#6#1#	0	78.3	70.06	31.43	6.96	125.06
			B_a	78.3						
	75	43.3	T	6#6#6#	0	74.6	69.39	29.83	7.33	125.23
			B_a	74.6						
	100	45.8	T	6#6#5#4#	0	72.6	69.72	29.66	7.42	125.82
			B_a	72.6						
	200	51.8	T	6#6#4#3#	0	67.6	54.04	29.35	5.30	124.70
			B_a	67.6						
2.38 A=43.2dB@ 2MHz	50	37.2	T	6#6#6#2#	0	80.0	60.47	31.09	5.78	122.98
			B_a	80.0						
	75	40.7	T	6#6#6#1#	0	78.3	58.64	30.32	5.73	124.73
			B_a	78.3						
	100	43.2	T	6#6#6#1#	0	78.3	63.61	30.74	6.32	127.82
			B_a	78.3						
	200	49.2	T	6#6#4#3#	0	67.6	52.58	29.31	5.08	121.88
			B_a	67.6						
Doppler Frequency (Hz)		200					Velocity of Target (cm/s)		10	

A4.2 Overall Sensitivity of SD5 (3MHz Wired Probe)

Diameter of Target Reflector (mm)	Distance (d)(mm)	Reflection Loss A(d)	Two-way Attenuation $B=\sum B_a+B_w$				V_S(r.m.s) mV	V_n(r.m.s) mV	$C=20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
			∑B (T: ultrasonic attenuation phantom No. B_a:dB)		B_w (dB)	B (dB)				
1.58 A=44.5dB@ 3MHz	50	40.9	T	6#5#3#	0	79.4	64.45	31.07	6.34	126.64
			B_a	79.4						
	75	44.4	T	6#5#3#	0	79.4	60.2	29.59	6.17	129.97
			B_a	79.4						
	100	46.9	T	6#4#1#2#	0	77.7	69.53	29.58	7.42	132.02
			B_a	77.7						
	200	52.9	T	6#4#1#	0	68.1	59.84	29.52	6.14	127.14
			B_a	68.1						
2.38 A=42.0dB@ 3MHz	50	39.0	T	6#5#2#1#	0	82.0	61.84	30.32	6.19	127.19
			B_a	82.0						
	75	42.5	T	6#4#3#1#	0	81.6	60.0	30.4	6.01	130.11
			B_a	81.6						
	100	45.0	T	6#4#3#	0	75.1	69.53	30.75	7.09	127.19
			B_a	75.1						
	200	51.0	T	6#4#1#	0	68.1	57.63	29.56	5.80	124.90
			B_a	68.1						
Doppler Frequency (Hz)		380					Velocity of Target (cm/s)		10	

A4.3 Overall Sensitivity of SD6 (2MHz Wireless Probe)

Diameter of Target Reflector (mm)	Distance (d)(mm)	Reflection Loss A(d)	Two-way Attenuation $B=\sum B_a+B_w$				V_S(r.m.s) mV	V_n(r.m.s) mV	$C = 20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
			∑B (T: ultrasonic attenuation phantom No. B_a:dB)		B_w (dB)	B (dB)				
1.58 A=45.7dB@ 2MHz	50	39.8	T	6#6#6#2#	0	80.0	35.80	16.43	6.76	126.56
			B_a	80.0						
	75	43.3	T	6#6#6#1#	0	78.3	36.47	16.04	7.13	128.73
			B_a	78.3						
	100	45.8	T	6#6#5#4#	0	72.6	39.12	18.43	6.54	124.94
			B_a	72.6						
	200	51.8	T	6#6#4#2#	0	65.4	42.0	19.45	6.69	123.89
			B_a	65.4						
2.38 A=43.2dB@ 2MHz	50	37.2	T	6#6#6#2#	0	80.0	46.71	16.37	9.12	126.32
			B_a	80.0						
	75	40.7	T	6#6#6#2#	0	80.0	41.77	17.60	7.51	128.21
			B_a	80.0						
	100	43.2	T	6#6#6#1#	0	78.3	39.95	18.23	6.81	128.31
			B_a	78.3						
	200	49.2	T	6#6#5#4#	0	72.6	40.84	20.54	5.97	127.77
			B_a	72.6						
Doppler Frequency (Hz)		218					Velocity of Target (cm/s)		10	

A4.4 Overall Sensitivity of SD6 (3MHz Wireless Probe)

Diameter of Target Reflector (mm)	Distance (d)(mm)	Reflection Loss A(d)	Two-way Attenuation $B=\sum B_a+B_w$				V_S(r.m.s) mV	V_n(r.m.s) mV	$C=20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
			∑B (T: ultrasonic attenuation phantom No. B_a:dB)		B_w (dB)	B (dB)				
1.58 A=44.5dB@ 3MHz	50	40.9	T	6#5#4#1#	0	90.3	39.57	18.31	6.69	137.89
			B_a	90.3						
	75	44.4	T	6#5#3#1#	0	86.0	38.4	18.59	6.30	136.70
			B_a	86.0						
	100	46.9	T	6#4#3#	0	75.1	45.32	19.96	7.12	129.12
			B_a	75.1						
	200	52.9	T	6#4#3#	0	79.4	40.2	19.36	6.35	138.65
			B_a	75.1						
2.38 A=42.0dB@ 3MHz	50	39.0	T	6#5#4#1#	0	90.3	40.48	18.43	6.83	136.13
			B_a	90.3						
	75	42.5	T	6#5#4#	0	83.8	38.1	19.26	5.93	132.23
			B_a	83.8						
	100	45.0	T	6#4#3#	0	75.1	45.61	18.74	7.73	127.83
			B_a	75.1						
	200	51.0	T	6#4#3#	0	75.1	47.56	19.47	7.76	133.86
			B_a	75.1						
Doppler Frequency (Hz)		377					Velocity of Target (cm/s)		10	

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