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SD1 Ultrasonic Pocket Doppler User Manual

About this Manual

P/N: 01.54.457693

MPN: 01.54.457693012

Release Date: Jul. 2018

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)cannot be held liable.

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Responsibility of the Manufacturer

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

Assembly operations, 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.

Product Information

Product Name: Ultrasonic Pocket Doppler

Model:SD1

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.

● Safety Precautions

CAUTION

Federal (U.S.) Law restricts this device to sale by or on the order of a physician

NOTE:

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

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

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

WARNING

1 It is to be used by health care professionals and patients on the order of a physician.
2 Before the SD1 is prescribed for home use, the user (patient) must be instructed/trained in proper use of the equipment.
3 Home fetal heart rate detection has not been shown to prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.
4 The Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal detection. It is not intended for treatment.
5 Placement of the ultrasound transducer on the abdomen is critical to obtaining the fetal heart beat as opposed to maternal heart beat or other abdominal noise. The user should be trained in proper placement techniques either through acceptable Ob/Gyn training and individual state accreditation, or as being prescribed by such a trained clinician and trained in device placement.
6 This device is not explosion-proof and cannot be used in the presence of flammable anesthetics.
7 Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of this device comply with the relevant EMC requirements. X-ray equipment and magnetic resonance imaging (MRI) devices can emit high levels of electromagnetic radiation.
8 We recommend that exposure to ultrasound should be kept as low as reasonably achievable. This is considered to be good practice and should be observed at all time.
9 Do not use the device with HF surgical equipment and do not use it in an MRI environment.
10 The device is not protected against defibrillation.
11 **SHOCK HAZARD** - Do not attempt to replace batteries with wet hands.
12 Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC 60601-1 approved to the device. The operation or use of non-approved equipment or accessories with the device is not tested or supported, and device operation and safety are not guaranteed.
13 Using accessories other than those specified by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.
14 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.
15 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
16 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to section **Recommended Separation Distances**.
17 Do not service or maintain the device or any accessory which is in use with a patient.

CAUTION

1 Refer servicing to qualified personnel.
2 Keep the device in a clean environment and avoid vibration during storage.
3 Do not sterilize the Doppler with autoclave or gas.
4 **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.
5 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.
6 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.
◆ Inspect the equipment for mechanical and functional damage.
◆ Inspect the safety relevant labels for legibility.
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.
7 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. .

● Introduction

Intended Use/Indications for Use

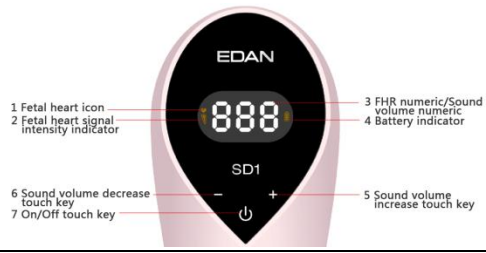
SD1 is intended for the detection of fetal heart rate. It is intended to be used by professionally trained health care personnel or pregnant women in hospitals, clinics or at home.

Features

◆ FHR detection and display
◆ FH sound
◆ Switching off when no signal received for 2 Min
◆ Sound volume adjustment
◆ Bluetooth connection (Optional)
◆ FH signal intensity indicator
◆ FH icon
◆ Battery indicator
◆ Low battery warning
◆ Sound volume levels

Appearance（Above pictures are just for reference）

LCD Display& Touch Keys



Item	Description	
1	Fetal heart icon	Indicates fetal heart beat and flickers to the fetal heart beat.
2	Fetal heart signal intensity indicator	This indicator displays on the left side of the screen and has three status: empty, half empty and full, which respectively represents low, medium and high fetal heart signal intensity.
3	FHR numeric/Sound volume numeric	Displays fetal heart rate within the range from 50 bpm to 240 bpm. When fetal heart rate is out of the range, it displays "---".
	Sound volume numeric	Sound volume numeric is displayed in the center of the screen, the same area as the FHR numeric. When you adjust sound volume, the sound volume numeric will display for 0.5 second before switching back to display FHR numeric. Sound volume ranges from level 0 to 7.
4	Battery indicator	Battery indicator displays on the right side of the screen. There are 5 battery levels, represented by 0 to 4 panes in the icon. When battery is empty, battery empty icon will be displayed and flickering, and the battery needs replacing.
5	Sound volume increase touch key	Touch the key for a little while to increase sound volume.
6	Sound volume decrease touch key	Touch the key for a little while to decrease sound volume.
7	On/Off touch key	When the Doppler is off, touch this key for a little while to switch it on; When the Doppler is on, touch this key for a little while to switch it off.

Battery

SD1 is powered by two AA alkaline batteries. Battery specification: LR6, AA, 1.5 V;

Note:

You can use AA alkaline batteries of the same specification purchased locally.

● Basic Operation

NOTE:

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

Opening the Package and Checking

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

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

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

Installing the Battery

a) Unscrew the screw with a cross screwdriver and remove the battery compartment cover.
b) Insert the battery into the compartment carefully. Ensure its anode and cathode terminals are aligned with the anode and cathode marks on the compartment.
c) Install the compartment cover and secure it with the screw.

Removing/ Replacing the Battery

a) Unscrew the screw with a cross screwdriver and remove the battery compartment cover.
b) Take out the used battery. You can also replace it with a new one. Ensure the new battery's terminals are placed in the right direction as indicated by the anode and cathode marks.
c) Install the compartment cover and secure it with the screw.

WARNING

1 Turn off the Doppler before removing or replacing the battery.
2 Replace alkaline batteries with those of identical specifications provided by the manufacturer or purchased locally. See Chapter ***Product Specifications*** for details about battery specifications.
3 If the batteries have been inserted incorrectly, the Doppler will not function or it will be damaged.
4 Do not disassemble or short-circuit batteries.
5 Do not recharge batteries.
6 Do not dispose of batteries in fire or water.
7 Do not allow metal objects to contact the battery terminals.
8 Do not mix with used or other battery type (such as alkaline with carbon zinc).
9 Do not solder the batteries directly. If soldering or welding connection to the battery is required, consult our engineer for proper methods.
10 Do not over-discharge batteries.
11 To install or remove batteries, follow the equipment manufacturer's instructions.
12 Keep battery away from small children. If swallowed, consult a physician at once.
13 Store the battery in cool, dry place before use. Do not keep batteries at temperature of 45°C or above, or at humidity of 75% or above.
14 Dispose the battery according to the local regulations. Refer to IEC61429 for standard disposal when necessary.
15 Remove the battery and store it at a cool and dry environment if the Doppler is not used for a long time.
16 Batteries have life cycles. If the time that the Doppler using battery becomes much shorter than usual, the battery life is at an end. Replace the battery with a new one of the same specification as the one provided or recommended by the manufacturer.

Switching On

Touch the On/Off touch key for about 1second when the Doppler is off, and the Doppler will display the switching on interface before switching to display the test interface.

Switching Off

Touch the On/Off touch key for about 1second when the Doppler is on, and the Doppler will be switched off.

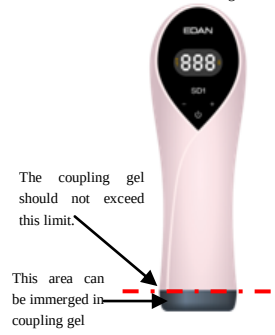
If the Doppler is not in operation or no signal is received for 2 minutes, the Doppler will switch off automatically.

● FHR Detection

Before applying the Doppler to inspect FHR, you should always check whether the Doppler is in good condition and whether there is evident damage that might affect patient's safety and the device's function. If evident damage is found, stop using it at once and replace it with a good one.

Procedures to Detect FHR:

a) Have the patient lie on her back.
b) Apply appropriate amount of coupling gel to the ultrasonic transducer head of the Doppler and switch on the Doppler.
c) Palpate the patient's abdomen gently to confirm the fetus's position.
d) Place the Doppler on the patient's abdomen, and move it around the fetus's position or tilt it until a clear and rhythmic heart sound is heard and FHR numeric is stably displayed.

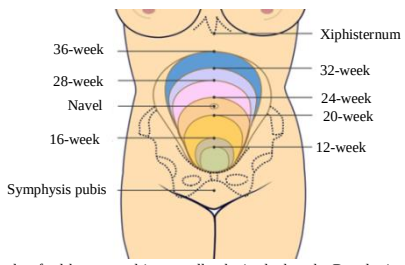


Note:

1 Do not mistake the maternal heart rate for fetal heart rate.
2 Do not wear gloves to touch the keys. If there's water and coupling gel on the fingers, please clean them first or the touching effect will be influenced.

How to Find the Best FH Signal:

1) The easiest way: take the position the doctor last detected for FHR as a reference and move the Doppler around the position slowly until the best FH signal is found.
2) The fetal heart position may change as the fetus moves inside the uterus. You can confirm the fetal position first according to the position of the uterus fundus in different gestational weeks.
➢ At the end of the 12-week gestation, the uterus fundus is about 2-3 fingers' breadth (about 2-3 cm) above the symphysis pubis.
➢ At the end of the 16-week gestation, the uterus fundus is in the middle between the navel and the symphysis pubis.
➢ At the end of the 20-week gestation, the uterus fundus is about 1 finger's breadth (about 1 cm) below the navel.
➢ At the end of the 24-week gestation, the uterus fundus is about 1 finger's breadth (about 1 cm) above the navel.
➢ At the end of the 28-week gestation, the uterus fundus is about 3 fingers' breadth (about 3 cm) above the navel.
➢ At the end of the 32-week gestation, the uterus fundus is in the middle between the navel and the xiphisternum.
➢ At the end of the 36-week gestation, the uterus fundus is about 2 fingers' breadth (about 2 cm) below the xiphisternum.



The clearest and loudest fetal heart sound is generally obtained when the Doppler is placed on the fetus's back. Fetal movement is usually the movement of fetal limbs. So, if frequent fetal movement occurs at the right side of the abdomen, the fetus's back is probably at the left side and vice versa. You can find the fetus's back according to fetal movement's position.

If the fetus is in cephalic delivery position, the fetal heart is either on the right side or on the left side below the navel; if the fetus is in breech delivery position, the fetal heart is either on the right side or on the left side above the navel.

Steps to Find Fetal Heart:

Have the patient lie on back and relax >> confirm fetal position by hand >> apply coupling gel to the Doppler>> place the Doppler on patient's abdomen and start looking for the fetal heart >> the fetal heart is found when the Doppler gives out a continuing thumping sound "boom-boom-boom".

CAUTION

1 The Doppler's degree of protection against harmful ingress of water is IP22. Do not immerse it in water.
2 The Doppler is delicate and sensitive. Please handle it with care and try to avoid dropping on to the ground or any hard surfaces. Any damage caused by dropping is not covered by the warranty.
3 Keep the coupling gel away from children. If swallowed, consult a physician at once.

Note:

1 The best quality of fetal heart signal is obtained only when the Doppler is placed in the best detection position.
2 Do not place the Doppler near positions where placental sound or umbilical blood flow sound is loud.
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 navel. During detection, the pregnant woman's prolonged lying in the supine position should be avoided to reduce the possibility of supine hypotension. Putting a pillow or cushion under the patient's head or feet can be of help.
4 It is not possible to obtain accurate FHR unless a clear 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 Doppler may warm slightly (less than 2°C (35.6°F) above ambient temperature). When NOT applied, the Doppler may slightly (less than 5°C (41°F) above ambient temperature).

After Detection

1) Switch off the Doppler.
2) Wipe the remaining gel off the patient and the probe with a clean soft cloth or tissue.

● Mobile Application Software (APP)

SD1 can connect to mobile phones with its Bluetooth function (optional). The SD1 APP has both Android and iOS versions.

iOS APP operating environment:
A) hardware environment
Processor: dual-core Apple A6
RAM: ⩾1GB
B) software environment: iOS 8.0 and above operating system
C) network environment: support Bluetooth

Android APP operating environment:
A) hardware environment
CPU: frequency⩾1.0GHz
RAM: ⩾1GB
B) software environment: Android 4.3 and above operating system
C) network environment: support Bluetooth

Scan either of the following QR codes to download the SD1 APP, and install and run it as prompted.

Android Version　　iOS Version

Note:

1 Your mobile phone may prohibit the installation of "applications from unknown sources". Enter **Settings** to allow the installation first.
2 For normal functioning of the APP, please give the APP function-related permissions.
3 For how to use the APP, read the instructions in the **About** sub-interface under the **Settings** interface of the APP.

● Maintenance and Cleaning

Maintenance

Before each use, check if the equipment has visible evidence of damage that may affect the patient and the operator's safety or the Doppler's functioning. If the damage is evident, contact the manufacturer for service or replace it.

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

The accuracy of FHR is determined by the Doppler and cannot be adjusted by user. If you have doubt concerning the accuracy of FHR, verify it with other methods such as using a stethoscope, or contact local distributor or the manufacturer for help.

The Doppler is frangible and must be handled with care. Wipe the remaining gel off the Doppler after each use. These measures can help prolong the Doppler's life.

Replace the accessories such as the battery according to use. If any of the accessories are damaged, refer to chapter **Ordering Information** for details and order new ones.

Cleaning

Before cleaning, switch off the Doppler.

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

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

CAUTION

1 Do not use strong solvent, such as acetone.
2 Never use an abrasive such as steel wool or metal polish.
3 The Doppler's degree of protection against harmful ingress of water is IP22. Do not immerse it in water.
4 Do not remain any solution on the surface after cleaning.

Disinfection

In normal use the Doppler 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 Doppler and then disinfect it by wiping it with a soft cloth dampened with ethanol (75%) or isopropanol (70%). Then wipe it dry with a dry cloth.

CAUTION

Do not immerse the Doppler into the disinfector.

Sterilization

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

NOTE:

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

Checking Item	Method
Visual Check	Inspect the Doppler for any damage.
Functional Check	Check if the Doppler can be switched on and off normally (see **Switching On** and **Switching Off**).When the Doppler is switched on, check if the display panel works as described in **LCD Display &Touch Keys**; touch the ultrasonic transducer head gently with your hand and check if the Doppler gives out sound normally.

● Product Specifications

Product Information

Product Name	Ultrasonic Pocket Doppler
Model	SD1

Complied Standards

IEC 60601-1:2005/A1:2012, EN 60601-1:2006/A1:2013, IEC 60601-1-2:2014, IEC 60601-2-37:2015, IEC 60601-1-11:2015, IEC 61266:1994

Classification

Anti-electric Shock Type:	Internally powered equipment
Anti-electric Shock Degree:	Type BF equipment
Degree of Protection against Harmful Ingress of Water:	IP22 Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
Degree of Safety in Presence of Flammable Gases:	Equipment not suitable for use in presence of flammable gases
Working System:	Continuous running equipment
EMC:	CISPR 11 Group 1 Class B

Physical Specifications

Size:	Length*Width* Height: (48±2) mm×(39±2) mm×(147±3) mm		
Weight:	< 180g		
LCD:	Size:	(24±2) mm×(13±2) mm	
	Display:	◆FHR ◆Battery level ◆Signal intensity	◆Sound volume level ◆FH icon
Coupling Gel:	pH: 5.5~8.0 Acoustic Impedance: $1.5x10^6$ Pa.s/m ~$1.7x10^6$Pa.s/m (35 ℃/95 ℉)		

Environment

Working:	Temperature:+5 ℃ ~ +40 ℃ (+41 ℉ ~ +104 ℉) Humidity:15% RH ~ 95% RH(non-condensing) Atmospheric Pressure:70 kPa ~ 106 kPa
Transport and Storage:	Temperature:-25 ℃ ~ +70 ℃ (-13 ℉ ~ +158 ℉) Humidity:15% RH ~ 95% RH (non-condensing) Atmospheric Pressure:70 kPa ~106 kPa

Note: The time required for the Doppler to warm from the minimum storage temperature between uses until it is ready for intended use is at least 2 hours; the time required for the Doppler to cool from the maximum storage temperature between uses until it is ready for intended use is at least 2 hours

Performance Specifications

FHR (Essential Performance):	FHR Measuring Range: 50 bpm ~ 240 bpm Accuracy: ±2 bpm Note: FHR measurement result may not be accurate if the equipment is measuring beyond its measuring range.
FHR Resolution:	1bpm
Audio Output:	Output Power: 2w Background noise: ≤45dBA
Overall Sensitivity:	>110dB
Auto Power-off:	Power off when the Doppler receives no signal or operation for 2 minutes.
Bluetooth:	Transmission Range (Without Obstacles) :>5m (Indoor range depends on the building's structure and material.)
Ultrasound:	Nominal Frequency: 3MHz
	Working Frequency: 3MHz
	p_<1 MPa
	Iob<10 mW/cm2
	Ispta<100 mW/cm2

	Isata<10 mW/cm2
	Isppa.3<190 W/cm2
	Ispta.3<94 mW/cm2
	Effective Radiating Area: 490mm2 ±15%
	Working Mode: pulse wave

Battery Specifications

Specification:	Two AA 1.5V alkaline batteries (AA, LR6, 1.5V)
Working Duration:	◆≥6h

Bluetooth Specifications

Modulation:	GFSK π /4-DQPSK 8DPSK
Frequency:	2400-2483.5MHz
Tolerance Frequency:	≤20ppm
RF output power:	≤20dBm (EIRP)
Occupied Channel Bandwidth:	≤2MHz
Transmitter Unwanted Emissions:	≤﹣30dBm

Low Output Summary Table

(For systems whose global maximum value does not exceed 1.0)

System: SD1 Ultrasonic Pocket Doppler

Model (MHz)	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$I_{sppa.3}$ (W/cm^2)
SD1 CD3.0	5.69	TIS	0.05	0.01	0.02
		TIB	0.01		

● Ordering Information

CAUTION

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

Parts	Part Number
Main Unit	
SD1 Doppler(Non-Bluetooth version)	02.06.262535
SD1 Doppler(Bluetooth version)	02.06.262639
Accessories	
AA Alkaline Battery	01.21.064086
Normal Carry Case	01.56.465616
Coupling Gel	01.57.14019

● Ultrasound Intensity and Safety

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.

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).

Explanation of MI/TI

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 0.3 dB/cm/MHz) to the acoustic frequency.

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

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

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 1℃ (1.8℉).

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

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

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

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

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: ± 12 percent for intensity, ± 6 percent for pressure. Based on the hydrophone calibration report by ONDA. The uncertainty was determined within ±1 dB in frequency range 1-15 MHz.

2. Digitizer: ±0.3 percent for intensity. ± 0.15 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: ±2.4 percent for intensity uncertainty, ±1.2 percent for pressure uncertainty.

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

4. Spatial Averaging: ± 3.5 percent for intensity, ± 1.75 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 ± 12.73 percent for all intensity values reported, ± 6.37 percent for all the pressure values,, ± 12.6 percent for the Mechanical Index, uncertainty of ±12.73% percent for power, ±0.15 percent for center frequency, ±6.87% for the MI.

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.

Reference 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 detection equipment" issued by IEC in 2007.

Acoustic Output Reporting Table for Track 1 Acoustic output reporting table for IEC60601-2-37 (IEC60601-2-37, Edition 2.1, 2015-0, table 201.103)

Transducer Model: SD1, Operating Mode: PW mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At Surface	Below Surface	At surface	Below Surface	
Maximum index value		0.01	0.05		0.01		N/A
Index component value			N/A	0.05	NA	0.01	
Acoustic Parameters	*pr.aat zMI (MPa)*	0.02					
	P (mW)		7.35		7.35		N/A
	P1x1 (mW)		N/A		N/A		
	zs (cm)			3.50			
	zb (cm)					3.70	
	zMI (cm)	3.70					
	zPII.α (cm) $_{\alpha}$	3.70					
	fawf (MHz)	3.00	3.00		3.00		N/A
Other information	*prr (Hz)*	5000					
	srr (Hz)	N/A					
	npps	1					
	Ipa.α at zPII.α (W/cm2)	0.02					
	Ispta.α at zPII.α or zSII.α(mW/cm2)	5.69					
	Ispta at zPII or zSII (mW/cm2)	12.26					
	pr. at zPII (MPa)	0.04					
Operating control conditions		Fixed					

Acoustic Output Reporting Table for Track1(Non-autoscanning Mode)

Transducer Model: SD1 , Operating Model: PW

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.01	5.69	0.02
Associated Acoustic Parameter	Pr.3	(MPa)	0.02		
	W0	(mW)		7.35	8.97
	fc	(MHz)	3.00	3.00	3.00
	Zsp	(cm)	3.70	3.70	3.70
	Beam dimensions	X-6 (cm)		2.50	2.50
		Y-6 (cm)		2.50	2.50
	PD	(usec)	72.25		72.25
	PRF	(Hz)	5000		5000
	EBD	Az. (cm)		2.50	
		Ele.		2.50	
		(cm)			
Operating Control Conditions			Fixed		

Standard Parameter Equal Contrast List

IEC60601-2-37 Standard Parameters				
Parameter	**Note**	**Parameter**	**Note**	
$p_{r.\alpha}$	Attenuated Peak-rare-factional Acoustic Pressure	f_{awf}	Center Frequency, Acoustic Working Frequency	
p_r	Peak-rare-factional Acoustic Pressure	X	-12dB Output Beam Dimensions	
P	Output Power	Y		
z_s	Depth for Soft Tissue Thermal Index	t_d	Pulse Duration	
$P_\alpha(Z_s)$	Attenuated Output Power	prr	Pulse Repetition Frequency (Pulse Repetition Rate)	
$I_{ta.\alpha}(Z_s)$	Attenuated Temporal-average Intensity	d_{eq}	Equivalent Beam Diameter	
z_{bp}	Break-point Depth	$I_{pi.\alpha}$ at max MI	Attenuated Pulse-average Intensity at the point of Maximum MI	
z_b	Depth for Bone Thermal Index	A_{aprt}	-12dB Output Beam Area	
$I_{pi.\alpha}$	Attenuated Pulse-intensity Integral	MI	Mechanical Index	
I_{pi}	Pulse-intensity Integral	TIS	Soft Tissue Thermal Index	
$d_{eq}(Z_b)$	Equivalent Beam Diameter at the point of Z_{sp}	TIB	Bone Thermal Index	
		TIC	Cranial-bone Thermal Index	

● EMC Information

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emission

The SD1 Ultrasonic Pocket Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The *SD1Ultrasonic Pocket Doppler* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The *SD1 Ultrasonic Pocket Doppler* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC/EN61000-3-3	Not applicable	

Electromagnetic Immunity

Guidance and manufacture's declaration–electromagnetic immunity

The *SD1 Ultrasonic Pocket Doppler* is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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/EN61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Not applicable
Surge IEC/EN61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11	<5%UT(>95% dip inUT) for 0.5cycle 40%UT(60%dip in UT) for 5 cycles 70%UT(30%dip in UT) for 25 cycles <5%UT(>95% dip in UT) for 5s	Not applicable	Not applicable
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity

The *SD1 Ultrasonic Pocket Doppler* is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC61000-4-6	3 V_{rms} 150 kHz ~ 80 MHz 6Vrmsc)in ISM bands between 0,15 MHz and 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the *SD1 Ultrasonic Pocket Doppler*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Radiated RF IEC61000-4-3	10V/m 80 MHz ~ 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P/E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SD1 Ultrasonic Pocket Doppler, including cables specified by the manufacturer). 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:

NOTE 1:At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *SD1 Ultrasonic Pocket Doppler* is used exceeds the applicable RF compliance level above, the *SD1Ultrasonic Pocket Doppler* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *SD1 Ultrasonic Pocket Doppler*.

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

[c] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz,21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table-Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Brand 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the *SD1 Ultrasonic Pocket Doppler*

The *SD1 Ultrasonic Pocket Doppler* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the*SD1 Ultrasonic Pocket Doppler* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *SD1 Ultrasonic Pocket Doppler* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7\sqrt{P}$
0.01	/	**0.035**	**0.07**
0.1	/	**0.11**	**0.22**
1	/	**0.35**	**0.7**
10	/	**1.11**	**2.21**
100	/	**3.5**	**7**

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.

● Overall Sensitivity

D	d	A	B ∑Ba		B	B	V_S	V_n	C	S
1.58 3MHz	50	40.9	T	5#4#	0	77.0	140	75	5.42	123.32
			B_a	77.0						
	75	44.4	T	5#3#	0	68.4	80	40	6.02	118.82
			B_a	68.4						
	100	46.9	T	5#3#	0	69.6	180	90	6.02	122.52
			B_a	69.6						
	200	52.9	T	5#3#	0	68.4	83	42	5.92	127.22
			B_a	75.1						
2.38 3MHz	50	39.0	T	5#4#	0	77.0	130	69	5.50	121.50
			B_a	77.0						
	75	42.5	T	5#4#	0	77.0	115	55	6.41	125.91
			B_a	77.0						
	100	45.0	T	5#3#	0	68.4	130	65	6.02	119.42
			B_a	68.4						
	200	51.0	T	5#4#	0	77.0	78	43	5.17	133.17
			B_a	75.1						
Doppler Frequency (Hz)			505				Velocity of Target			10
Note	D: Diameter ofTarget Reflector(mm)		A: Attenuation A(dB))				S：Overall Sensitivity (S=A+B+C)dB			
	d: Distance (d)(mm)		V_S: Signal RMS (mV)				C:Signal to Noise Ratio (dB) $C = 20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$			
	B:Two-wayAttenuation(dB) B=∑Ba+Bw		V_n: Noise RMS (mV)							

● Troubleshooting

Problem	Possible Cause	Solution
Fail to power on, or shut down shortly after switching on	Battery level is very low.	Replace the battery.
	Battery is not installed properly.	Re-install the battery.
	Fail to switch on the Doppler as instructed.	Touch the On/Off touch key for a while to power on the Doppler.
	The Doppler has malfunctions.	Contact service personnel.
Loudspeaker does not work.	Sound volume has been turned down to the lowest level.	Adjust sound volume to appropriate level.
	If the Doppler is configured with Bluetooth, fetal heart sound can be played by mobile phone.	Set to play fetal heart sound by mobile phone or the Doppler on the APP.
	The Doppler has malfunctions.	Contact service personnel.
FHR cannot be displayed stably.	There is strong interference source such as high frequency machines and mobile phones nearby.	Use the Doppler away from strong interference sources.
	The fetal heart position has changed because of fetal movement.	Relocate the Doppler to the best fetal heart rate detection position.
	Friction between the Doppler and patient's abdomen causes false displaying.	Find the best fetal heart rate detection position.
Sensitivity is low and noise is too much.	There is strong interference source such as high frequency machines and mobile phones nearby.	Use the Doppler away from strong interference sources.
	The Doppler is not applied with coupling gel.	Apply coupling gel to the Doppler.
	The Doppler is not placed at the best detection position.	Relocate the Doppler to the best fetal heart rate detection position.
	The Doppler has malfunctions.	Contact service personnel.

● Warranty and Service

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.

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.

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● Definition of Symbols

No.	Symbol	Definition	No.	Symbol	Definition
1	CE 0123	CE marking	9		Manufacturer
2		Disposal method	10	EC REP	Authorized Representative in the European Community
3		Operating instructions	11		General symbol for recovery/recyclable
4		Caution	12		Refer to User Manual (Background: Blue; Symbol: White)
5		Type BF applied part	13	MR	MR Unsafe–Keep away from magnetic resonance imaging (MRI) equipment
6	P/N	Part Number	14		Non-ionizing electromagnetic radiation
7	SN	Serial Number (Start with H on battery compartment cover)	15	IP22	IP22 Protected against solid foreign objects of 12,5 mm ⌀ and greater，Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
8		Date of Manufacture	16	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.