

• ABOUT US •

Driven by the passion for innovation, we at Dr Trust endeavour to provide our customers with the latest medical inventions with an objective to promote good health and wellness all around the world. All the medical devices and health monitors provided by Dr Trust are supported by accurate, latest and ground breaking technologies, innovated at our headquarter in NY, USA. All our products adhere to the most stringent CE and FDA guidelines and are strongly recommended by doctors and health practitioners. Our products are designed in the utmost exemplary ways to ensure that their accuracy and convenience are unrivalled. The ease of their use and operation makes them even more suitable for users of all age groups.

Dr Trust strives to enhance the quality of lifestyle by providing with the most trusted and innovative health care and wellness products. Being a renowned global leader in health care products, Dr Trust ensures that our technically efficient team works dynamically and tirelessly to provide the best of the medical devices to our clients. The products that we have to offer are suitably designed for use at homes, laboratories and hospitals.

Our ground breaking solutions allow you to monitor your health in the easiest ways possible. In today's era when all of our lives are too hassled to handle, it becomes a bit difficult to pay attention to our health. But it has now become easier with the coming of the monitoring devices which can be conveniently used at homes and even on the go.

We bring to you a variety of best self medical devices, trusted and used by Doctors, medical professionals and home users all over the world.

Dr Trust[®] USA Fetal Doppler-1202



• QUICK STARTUP GUIDE •

Step 1

Get into a resting position, laying down on your backside. Turn on your Fetal Doppler.

Step 2

Determine what listening option you will be using (i.e., speaker or headphones) and adjust the volume accordingly.

Step 3

Expose your stomach and then apply ultrasound gel to the lower abdomen region.

Step 4

Place the device on the area you have applied gel and slowly start to move it from the lower abdomen upwards.

Step 5

To locate your baby, continue to adjust the position of your device, changing both your angle of approach and covering different areas.

Step 6

When you are finished, clean the device and your tummy by wiping off the gel with a dry cloth.



1202

⚠ WARNING

This device is not intended for treatment. The intended use is for detecting Fetal Heart Rate. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately.

⚠ Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

⚠ WARNING

A WARNING label advises against certain actions or situations that could result in personal injury or death.

⚠ CAUTION

A CAUTION label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

⚠ NOTE

A NOTE provides useful information regarding a function or a procedure.

TABLE OF CONTENTS

1. Safety Guidance	4
1.1 Safety Precautions	
1.2 Symbols	
2. Introduction	8
2.1 Intended Use	
2.2 Features	
2.3 Main Units	
3. Basic Operation	12
3.1 Switch ON/OFF	
3.2 Obtaining Doppler Signals	
3.3 Volume Controller	
3.4 Display Mode	
3.5 Probe Operation	
3.6 Battery	
4. Product Specifications	17
5. Maintenance & Cleaning	18
6. Troubleshooting	20
7. Appendix A	21
7.1 Electromagnetic Emissions—for all Equipment and Systems	
7.2 Electromagnetic Immunity—for all Equipment and Systems	
7.3 Electromagnetic Immunity- for all Equipment and Systems that are not Life-supporting	
7.4 Recommended Separation Distances	
8. Accessories	24
9. Contact Us	25
10. About Us	26



1. SAFETY GUIDANCE

This unit is internally powered equipment; the degree of shock protection is type BF applied part.

Type BF applied part protection means that these patient connections will comply with permitted leakage currents, dielectric strengths of IEC 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.

1.1 Safety Precautions

WARNING: This device is not explosion-proof and cannot be used in the presence of flammable anesthetics.

WARNING: Do not throw batteries in fire as this may cause them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak, and may cause a fire or even explode.

WARNING: Don't touch signal input or output connector and the patient simultaneously.

WARNING: Pocket Fetal Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring. This is not intended for fetal use.

WARNING: Please use the probe provided by the manufacturer.

WARNING: Do not pull the line of probe longer than 2 meters, or else the probe may break away from the connector.

CAUTION: The device must be serviced only by authorized and qualified personnel.

CAUTION: The device is designed for continuous operation and is 'ordinary'. Do not immerse in any liquid (i.e. not drip or splash-proof).

CAUTION: Keep the device clean. Avoid vibration.

CAUTION: Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

CAUTION: Electromagnetic Interference-Ensure that the environment in which the device is operated is not subject to any source of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away.

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

CAUTION: The battery must be properly disposed according to local regulation after use.

CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time.

CAUTION: The device shall only be used if the battery cover is closed.

CAUTION: Battery must be stored in cool and dry place.

CAUTION: If use rechargeable battery, to insure capability and life, please fully charge batteries before first use, normally, batteries must be continuously charged over 14 hours or charged according to the guidance displayed on the battery.

CAUTION: Please don't set anode and cathode of the battery wrongly.

CAUTION: The valid period of this product is five years.

CAUTION: After the service life, please return the products to the manufacture or disposal the products according to local regulations.

CAUTION: This device cannot be used with defibrillator or high frequency surgical unit.

CAUTION: Please choose the accessories authorized by our company or the device may be damaged.

CAUTION: Please keep the probe from edge tool.

CAUTION: Please use machine under the environment without strong electromagnetic field, which may influence results.

Remove the battery if the EQUIPMENT is not likely to be used for some time.

The device requires no calibration.

The device contains no user serviceable parts.

The user must check that the equipment functions safely and see that it is in proper working condition before being used.


No modification of this equipment is allowed.




Disposal: Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being. Strong electromagnetic field, which may influence measure result.











Battery Disposal: Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Recycling the batteries: When the battery no longer holds a charge, it should be replaced. The batteries are recyclable. Remove the old battery from the battery cover and follow your local recycling guidelines.

 Magnetic and electrical fields are capable of interfering with the proper performance of the Fetal Doppler. For this reason, make sure that all external devices operated in the vicinity of the Fetal Doppler comply with the relevant EMC requirements. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

 Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (See IEC 60601-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements.

1.2 Symbols

Mark	Summary	Mark	Summary
	Caution, consult accompanying documents		Up button
	Type BF		Down Button
	Serial Number		Date of manufacturing
	Manufacturer		ON/OFF
	Refer to user manual		
IPX2	Protected against access to hazardous parts with a finger and against vertically falling water drops when enclosure tilted up to 15°		
IPX1	Protected against access to hazardous parts with a finger and against vertically falling water drops.		
	The symbol indicates that the device should be sent to the special agencies according to local regulation for separate collection after its useful life.		



• 2. INTRODUCTION •

2.1 Intended use

Dr Trust Fetal Doppler is a hand-held obstetrical unit, which can be mainly used to detect the Fetal Heartbeat Rate (FHR) and the Sound of the Fetal Heartbeat (SFH).

2.2 Features

	LCD Display	TFT Display	Probe Socket	Headphone Socket	Powered by Alkaline battery	Power by Lithium batteries (Have Micro USB)
Dr Trust Fetal Doppler	✘	✓	✓	✓	✘	✓

✓ means it has this function

✘ means it doesn't have this function

2.3 Main Unit

2.3.1 Appearance

NOTE:

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

This device is a non-invasive handheld Fetal Doppler with an internal speaker. This device has the following special description that will enhance your product use, refer Figure 1, 2, 3, 4.

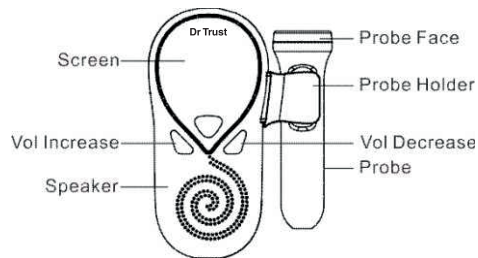


Figure 1 Front Panel of the Device

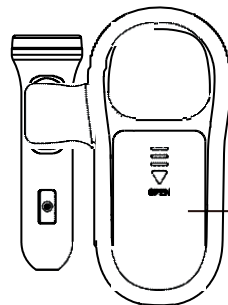


Figure 2 Rear Panel of the Device

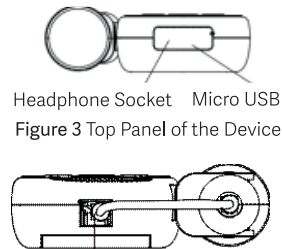


Figure 3 Top Panel of the Device

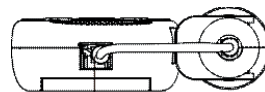


Figure 4 Bottom Panel of the Device



2.3.2 Display

This has a TFT screen with below showing readings.

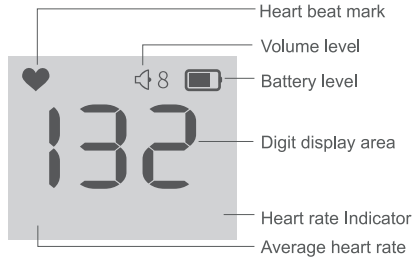


Figure 5 Digit Display Mode of TFT

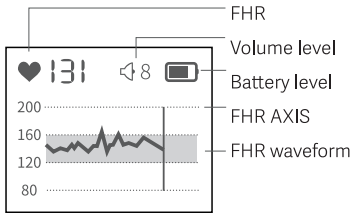


Figure 6 Waveform Mode of TFT

2.3.3 Buttons

Power Button

Function: Power on/off, change digit display mode of TFT into waveform display mode of TFT


Power on: Push the button once.


Change mode: Push the button once after power on.

Power off: Push down the button and hold 3 seconds to power off.

Volume Button

Function: adjust volume

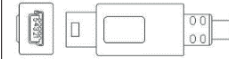
: Push the button to increase the volume

: Push the button to decrease the volume

Earphone socket

Function: for audio signals, the earphone or line-in cable connects to the Doppler via this socket.

Probe Socket



Connect the 2.5MHz obstetrical probes or supplied by the manufacturer to the Doppler through the probe socket.

CAUTION

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



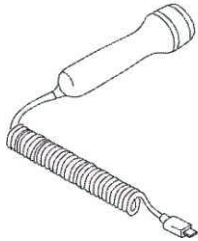


Figure 7 2.5 MHz obstetrical probe

3. BASIC OPERATION

3.1 Switch ON/OFF

- Turn the device on by pressing the On/Off button for 1 second. TFT display will be switched on to indicate the power status.
- Push down ON/OFF button and hold 3 seconds to power OFF. The device automatically shuts itself off after 2 minutes if it is not being used. Complete power shutdown preserves the life of the batteries and ensures the device will be ready for operation in case it was accidentally left on.

3.2 Obtaining Doppler Signals

NOTE

In some cases, fetal heart beats at 12 weeks gestation cannot be detected due to the maternal physical difference and the operator's technique.

Perform fetal heart examination using the following procedures:

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

⚠ CAUTION:

Put the probe on the best detecting position to get better detection effect. Positions with strong placental sounds or umbilical blood flow sound should be avoided.

If pregnant woman adopts horizontal position and the fetus position is normal, put the probe on the position of lower navel midline to get the clearest FHR sound. It is impossible to examine FHR unless a fetal heart sound is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

3.3 Volume controller

The audio level can be adjusted using the "▲" "▼" buttons. Push the "▲" "▼" button will increase the volume, while push the "▼" button will decrease it.

3.4 Display mode

There are two display modes (Digit Display and Waveform Display) which can be changed if short press the On/Off button "⏻" (less than 1 second).



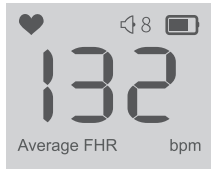


Figure 8 Digit Display

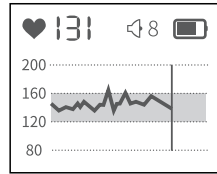
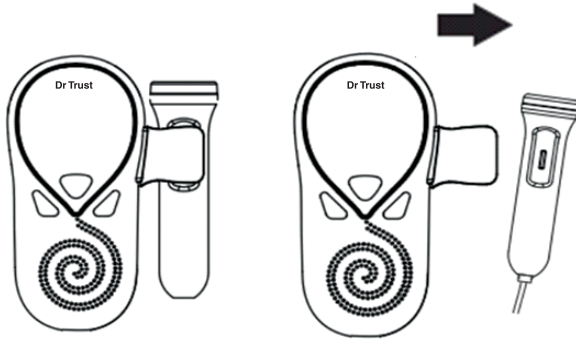


Figure 9 Waveform Display

3.5 Probe Operation

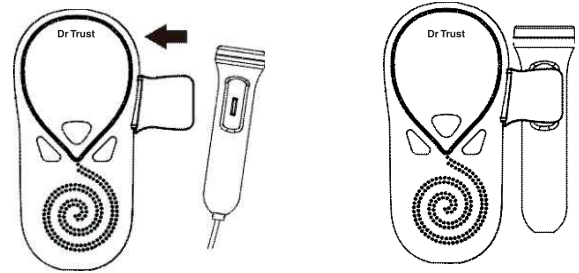
3.5.1 Taking out the probe

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



3.5.2 Placing the probe

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



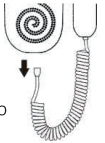
CAUTION

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

3.5.3 Replacing the Probe

Remove the old probe:

- Switch off the Doppler, hold the main unit with one hand and pinch the jacket of the mini registered jack. Lift the jacket up slightly and pull it out with mild force; take out the probe.
- Replace it with a new probe: Put the registered jack of new probe into the probe interface of the Doppler.



NOTE



Place the temporarily unused probe carefully and avoid falling off, splash or stress, etc. When the Doppler is not used for a long time, it's recommended to connect the probe to the Doppler and keep them safely in the package.

3.6 Battery

3.6.1 Battery

Dr Trust Fetal Doppler is powered by one 14500 Lithium battery (DC3.7V)

3.6.2 Battery Energy Indication

There is a battery symbol  in the top right corner of TFT. When the power is low, the empty battery symbol  flashes, to remind to change another new battery or charge the battery (only the chargeable battery can be charged).

3.6.3 Replacing the Batteries

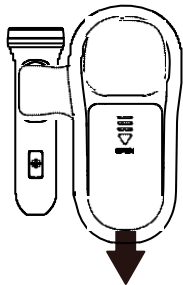
CAUTION

Make sure the Doppler is shut down before opening the battery compartment. The rear panel is upturned. First open the battery compartment, then take out the battery from the battery compartment.

Put 2 alkaline batteries/one lithium battery into the battery compartment (as for the direction of battery, please refer to the instruction inside the battery compartment), at last close the battery compartment.

CAUTION

The battery must be taken out from the battery compartment if the device will not be used for a long time.



4. PRODUCT SPECIFICATIONS

Product Name: Dr Trust Fetal Doppler

Display: 35mm x 28mm (1.77") Color TFT display

Doppler Probe: 2.5MHz

Safety:

Complies with: IEC60601-1

Classification: Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BFEquipment 

Liquid Proof Degree:

Main unit: Degree of protection: IPX1.

Probe: Prevent from water splashing, degree of protection: IPX2. The probe is treated as the applied part.

Degree of Safety in Presence of Flammable Gases: Equipment is not suitable for use in presence of flammable gases

Working System: Continuous running equipment

EMC: Group I Class B

Physical Characteristic

Size: 140 mm (Length) x 30 mm (Width) x 100 mm (Height)

Weight: about 160g (including probe, excluding battery)

Environmental Specifications

Temperature range: 0 °C ~ 40 °C

Humidity range: 30% to 90%

Atmospheric pressure range: 60.0kPa ~ 110.0kPa

Transportation and Storage

Temperature range: -10 °C ~ 60 °C

Temperature range: 10% to 93%

Atmospheric pressure range: 50.0kPa ~ 110.0kPa



FHR Measuring Range: 50 BPM ~ 240 BPM (BPM: beat per minute)

Resolution: 1 BPM

Accuracy: ± 2 BPM Power Consumption :< 0.8 W

Auto Shut-OFF: After 2 minute no signal, power off automatically.

Battery Type Recommended: one piece 14500 Lithium Battery (DC 3.7V).

Standard Configuration: 2.5 MHz Ultrasound Probe

Nominal Frequency: Continuous wave Doppler

Working Frequency: 2.5 MHz \pm 5%

Audio bandwidth and power: 250Hz ~1.25kHz, 1.5W

Ultrasonic output power :< 40mW

Space peak time peak sound pressure :< 0.35MPa

Effective ultrasonic transmitting/receiving area: 2.45cm $2 \pm$ 30%

Operating Frequency: 2.5MHz \pm 5%

Size: 140 x100x30mm (H x W x D)

Weight: 160g (including probe, excluding battery)

Comprehensive sensitivity shall not be less than 90dB at a distance of 200mm from the probe surface

Table 1. Sound output level technical data of ultrasonic probe

Index Label	MI	TIS		TIB		TIC
		At surface	Below surface	At surface	Below surface	
Maximum index	0.016	0.121		0.957		(a)
Index component value		0.105	0.121	0.957	0.235	
Acoustic Parameters	$P_{r,a}$ at ZMI (MPa)	0.026				
	P (mW)		21.66	21.66		#
	P ₁₋₁ (mW)		8.84	8.84		
	Z _s (cm)		3.8			

	Z _b (cm)				3.8	
	Z _{MI} (cm)	2.7				
	Z _{p_{ii,a}} (cm)	2.7				
	f _{awf} (MHz)	2.501	2.501		2.501	#
Other Information	p _{rr} (Hz)	1				
	s _{rr} (Hz)	--				
	n _{pps}	1				
	I _{pa,a} at Z _{p_{ii,a}} (W/cm ²)	0.01				
	I _{spta,a} at Z _{p_{ii,a}} or Z _{s_{ii,a}} (mW/cm ²)	10.19				
I _{spta} at Z _{p_{ii}} or Z _{s_{ii}} (mW/cm ²)	16.23					
P _r at Z _{p_{ii}} (WPa)	0.032					
Operating Control Conditions	Frequency		2.5MHz			

NOTE 1 : Only one operating condition per index.

NOTE 2 : Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.

NOTE 3: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 : If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 : If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 : The depths zp_{ii} and zp_{ii,a} apply to NON-SCANNING MODES, while the depths zs_{ii} and zs_{ii,a} apply to SCANNING MODES.

(a) Intended use does not include cephalic so TIC is not computed

No data reported



5. MAINTENANCE & CLEANING

5.1 Maintenance

This device requires very little maintenance. However, it is important to continuing function of the unit and the health of the patients that the unit is cleaned and examined regularly as per the following guidelines:

Annually inspect the main unit and probe for signs of cracks or breaks in the mechanical housing. Inspect cables and connectors for signs of wear or failure. The user should discontinue use of the unit with any sign of loss of housing integrity. Contact Manufacturer or us for instructions.

It is recommended that the internal rechargeable battery be replaced every two years.

5.2 Cleaning

Before cleaning, switch off and take out the batteries.

Keep the outside surface of the device clean and free of dust and dirt, clean exterior surface (display screen included) of the chassis with a dry, soft cloth. If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.

CAUTION

- Don't use strong solvent, for example, acetone.
- Never use an abrasive such as steel wool or metal polish.
- Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.
- Avoid pouring liquids on the device while cleaning.
- Don't remain any cleaning solution on the surface of the device.

NOTES

Wipe the surface of probe with 70% ethanol, self-air dry, or clean with a clean, dry cloth.

6. TROUBLESHOOTING

Poor Sound Quality

- Inadequate gel use
- Try and relocate the probe for a better signal
- Interference from other equipment

Heart Rate Inaccurate

- Try and relocate the probe for a better signal
- Ensure maternal sounds are not mixing with fetal sounds

Battery Indicator Flashing

- Battery is old - place the new battery.

7. WARRANTY

The unit cannot be repaired by users themselves. All services must be done by the professionals/engineers.

After the instrument is out of the service life, it should be disposed of in time. The disposal of the scrap should follow the relevant regulations of the country or region for the management of such products to prevent environmental pollution. If there is any technical problem, please contact us/manufacturer directly.



● 8. APPENDIX A ●

EMC Information-Guidance and Manufacture's Declaration
A.1 Electromagnetic Emissions - for all Equipment and Systems

Guidance and manufacture's declaration—electromagnetic emission

The instrument is intended to be used in the electromagnetic environment specified below, and the user should ensure that it is used in this electromagnetic environment:

Emission test	Compliance	Electromagnetic environment - guide
Radio-frequency emission CISPR 11	Group 1	The instrument uses Radio-frequency energy only for its internal functions. Therefore, its Radio-frequency emissions are low and there is little possibility of interference with nearby electronic equipment.
Radio-frequency emission CISPR 11	Class B	The instrument is suitable for use in all facilities, including domestic facilities and direct connection to residential public voltage supply networks
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuation /flicker emission IEC 61000-3-2	Not applicable	

A.2 Electromagnetic Immunity - for all Equipment and Systems

Guidance and Declaration—Electromagnetic Immunity

The Device is suitable 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	IEC60601 Test Level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV Air	±6KV contact ±8KV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at Least 30%
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	The power frequency magnetic field should have the characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment.

A.3 Electromagnetic Immunity - for all Equipment and Systems that are not Life-Supporting



Guidance and Declaration — Electromagnetic Immunity

The Device is suitable for use in the electromagnetic environment Specified below. The customer or the user of the device should as sure that it is used in such an environment

Immunity test	IEC60601 Test Level	Compliance level	Electromagnetic environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms I	Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ <p style="text-align: center;">80MHz to 800MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: center;">80MHz to 2.5GHz</p> <p>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: </p>

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 device is used exceeds the applicable RF compliance level above, the devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

A.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Fetal Doppler.

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

Rated Maximum Output power of Transmitter (W)

Separation Distance (m) Corresponding to Frequency of Transmitter



1202

	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334

For transmitter at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: From 80 MHz to 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 structure, objects and people.

9. ACCESSORIES

1	Main unit	1
2	2.5MHz probe	1
3	Manual	1
4	Battery	1 piece 14500 Lithium battery

10. CUSTOMER SUPPORT

CONTACT ADDRESS

USA

Nureca INC.USA
276 5th Avenue, Suite 704-397,
New York (NY) - 10001, USA

INDIA

Corporate Office (Mumbai)

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