PROFESSIONAL MEDICAL PRODUCTS

GIMASONIC

Use and maintenance book

***ATTENTION:** Operators must read and understand this manual completely before using the product.*

GIMA 29480

CONTEC MEDICAL SYSTEMS CO., LTD
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Made in China

REF **Baby Sound C1**

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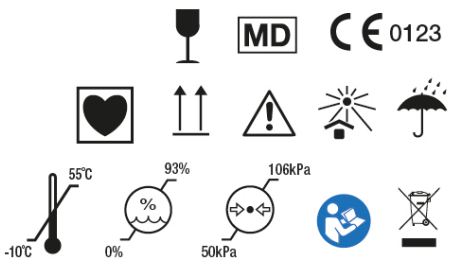

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Attention

This user manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effects on safety, reliability and performance of the equipment if:
Assembly operations, repairs are carried out by persons authorized by the manufacturer, and the device is used in accordance with the instructions for use.

WARNING:

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

Warranty

The unit cannot be repaired by users themselves. All services must be done by the engineers approved by the manufacturer. We guarantee that each product we sell to you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product does not function as specified during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

Using This Label Guide

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 procedure.

CE 0123: This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community

Chapter 1 Safety Guidance

This unit is an internally powered equipment and the degree of shock protection is type CF applied part . Type CF 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.

WARNING: This device is not explosion-proof and can not 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: Do not touch signal input or output connector and the patient simultaneously.
WARNING: This device is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring.
WARNING: Please use the probe provided by the manufacturer.
WARNING: Do not pull the line of probe longer than 2m, to avoid disconnecting the probe from the device connector.
WARNING: Keep out of reach of children - The device contains small parts that can easily be swallowed.
WARNING: Equipment can not be repaired and maintained during use.
WARNING: The patient is an intended operator.
CAUTION: The device must be serviced only by authorized and qualified personnel.
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 sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away.
CAUTION: Before use, care must be taken to ascertain that the equipment is free from damage that may affect patient safety or monitoring capability. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.
CAUTION: The following safety checks should be performed once every two years or as specified in the institution's test and inspection protocol by a qualified person who has adequate training, knowledge, and practical experience to perform these tests:
＊Inspect the equipment for mechanical and functional damage.
＊Inspect the safety relevant labels for legibility.
＊Verify that the device functions properly as described in the instructions for use.
＊Test the patient leakage current according to IEC 60601-1: Limit: 10 uA (CF).
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 must be repaired.
CAUTION: The battery must be properly disposed of, according to local regulation after their use.
CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time.
CAUTION: Patients can replace the battery.
CAUTION: The device shall only be used if the battery cover is closed.
CAUTION: Battery must be stored in a cool and dry place.
CAUTION: Do not set anode and cathode of the battery wrongly.
CAUTION: The typical service life of the new and unused batteries is 300 measurements for the operation time is 60**s.**
CAUTION: The valid period of this product is five years.
CAUTION: After the service life, please return the products to the manufacture or dispose of the products according to local regulations.
CAUTION: This device can not be used with a 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 this device under recommended environmental conditions without strong electromagnetic field, which may influence usage results.
CAUTION: The material of the shell and ultrasound probe of the device is ABS, in line with ISO 10993-5& ISO 10993-10.
CAUTION: Protect the device against extreme moisture, heat, and direct sunlight.

Chapter 2 Introduction

2.1 Overview

Pocket Fetal Doppler is a hand-held obstetrical unit, which can be used in hospital and clinicfor daily self-check by pregnant woman.
The device uses color LCD of high resolution to display the fetal heartbeat waveform, and figure out the FHR to help the doctor diagnose in time.
It contains components of ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, LCD display control unit etc. It has 3 work modes: real-time FHR display mode, averaged FHR display mode, and manual mode. It also has audio output, and can be connected with earphone or recorder with audio input.

2.2 Features

◆Aesthetic design, portable, easy operation.
◆The probe has a flexible structure which is easy to operate and can increase comfort for pregnant women during use, thereby demonstrating the humane care design.
◆Fetal heart rate values, bar graph and heartbeat waveform color screen display.
◆Battery status indicator.
◆2 MHz/3 MHz ultrasound probe can be connected.
◆ Probe inspection.
◆Built-in speaker.
◆Output for headphone.
◆Auto shut off .
◆Two pieces of standard 1.5V alkaline battery available which can work no less than 8 hours.

Chapter 3 Outlook and Configuration

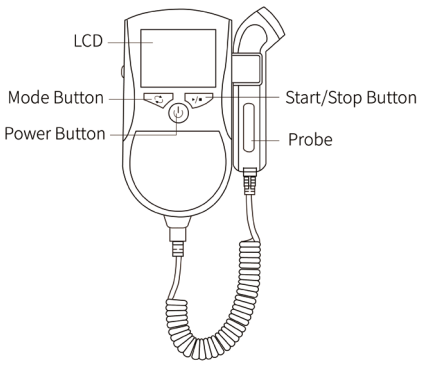

Fig.3-1 Front panel

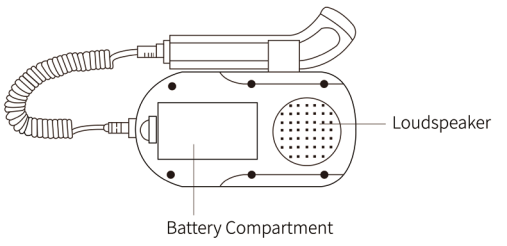

Fig.3-2 Rear panel

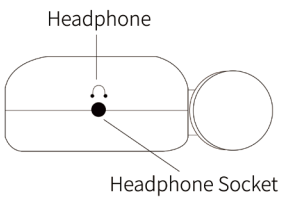

Fig.3-3 Top panel

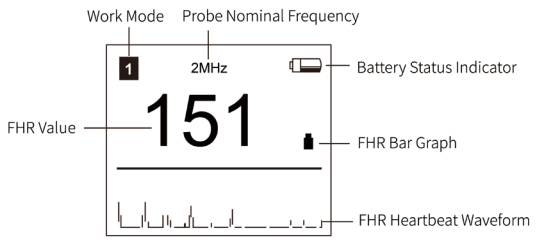

Fig.3-4 LCD display

3.1 Display

The LCD display is as follows:

3.2 Push Button

There are three push buttons **(Power, Mode**, and **Start/Stop)** and a volume control button on Pocket Fetal Doppler. The primary functions are as follows:

3.2.1 Power Button

Function: Power on/off.
Power on: Push the button once.
Power off: Push down the button and hold for 3 seconds to power off.

3.2.2 Mode Button

Function: Mode selection, press once to enter next working mode under working status.
The Fetal Doppler possesses a memory function. When the machine is turned on, it will enter the mode selected before last power off automatically after self-testing.

3.2.3 Start/Stop Button

Function: Start/Stop control.
Under model 3, press this button the fetal heart rate counting starts, press this button again the counting stops.

3.2.4 Volume Control Indicator

Volume adjusting direction indicator.
From left to right means that the sound level is from high to low.

3.3 Headphone Socket

Headphone Socket: a socket for audio output for connection to earphones or recorders with audio input to record.
: The socket, terminal post, or switch that can headphones can be connected to.

3.4 Ultrasound Probe

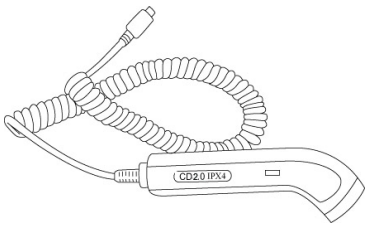

Fig.3-5 Ultrasound probe

The meanings of CD-- IP-- on the label are as follows:
C: The work mode for the probe is continuous wave.
D: The structure form for the probe is cell type.
2.0/3.0: The frequency of the probe is 2 MHz or 3MHz.
IPX4: Harmful Liquid Proof Degree.

Chapter 4 General Operation

4.1 FHR Inspection

① Power on by pressing the Power button.The LCD display is as **Fig.3-4.**
② Find the position of fetus:
To start, feel the position of the fetus by hand. Determine the best direction for inspecting the fetal heart. Apply a liberal amount of gel to the faceplate of probe; place the faceplate of probe at the appropriate position for detecting fetal heart. Adjust the probe to obtain an optimum audio signal, ideally by angling the probe around. Adjust the volume according to requirements.
③ FHR Calculation:
LCD displays fetal heart rate values, bar graph and fetal heartbeat waveform.
④ Turn off the machine:
Keep pressing the power button 3 seconds to turn off.

CAUTION:

① Put the probe on the most appropriate detecting position to get better detecting results.
② Do not put the probe on the position where Placental Blood Sound(PBS) or Umbilical Sound (UMS) is very strong.
③ For pregnant women adopting a horizontal position and the fetus position is normal, position the probe on the lower navel midline to get the clearest FHR sound.
④ Do not measure FHR unless audible fetal sound has been heard.
⑤ Reduce the time of ultrasonic radiation as much as you can.

4.2 Mode Selection

4.2.1 Real-time FHR Display Mode (Mode 1)

The moment when the fetal heart rate signals are detected, the fetal heart rate bar graph on LCD indicates the strength of the fetal heart rate signals, and meanwhile shows the fetal heart rate values and fetal heartbeat waveform.

4.2.2 Averaged FHR Display Mode (Mode 2)

This model is able to acquire more stable fetal heart rate, displaying on LCD the latest acquisition of eight points fetal heart rate on average. When the fetal heart rate is shown, the fetal heart rate bar graph on LCD indicates the strength of the fetal heart rate signals, the shown fetal heart rate values and heartbeat waveform changes slowly.

4.2.3 Manual Mode (Mode 3)

Press the start / stop button starts counting, fetal heart rate reads as "— — —", the moment when the fetal heart rate signals are detected, the fetal heart rate bar graph indicates the fetal heart rate strength. Once again press the start / stop button to stop counting, the equipment will automatically calculate the average fetal heart rate acquired from the beginning to the end, and also the result will be displayed. Numerical fetal heart rate will always remain until a repeated measurements or patterns of change.

4.3 Probe Operation

4.3.1 Inspecting Probe

When the probe is disconnected from the device, the LCD screen displays the "— — —"and displays "Probe fall !".The probe frequency data disappeared. At this moment the probe needs to be reconnected. After connected well, LCD screen will clear away the "Probe fall !"and display the probe frequency data.

4.3.2 Replacing Probe

A probe is connected to the device by the manufacturer. If users need to replace it with another probe, power off the device, then take out the probe from the device before pulling out the plug of the probe from its socket. Afterwards, connect the plug of the probe which needs to be displaced with the socket.
Note: Place the temporarily unused probe carefully and avoid falling off, stress, etc. When the device is not used for a long time, users are recommended to connect the plug of one probe to device socket and put the probe in the parking. Then pack the device with the probe in the wrapping box.

4.3.3 Taking Out Probe and Placing Probe

① Taking Out the Probe

Hold the main unit with one hand, and hold the handle of the probe with another hand to take out the probe. **(See Fig.4-1)**.

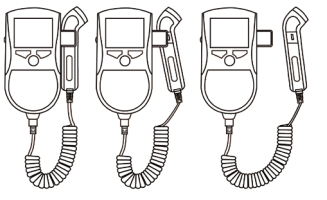

Fig.4-1 Taking out Probe

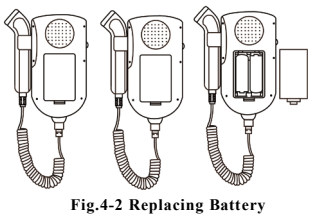

Fig.4-2 Replacing Battery

② Placing Probe

It is opposite to take out probe. Hold the main unit with one hand, and hold the top of the probe with another hand, then push the probe into the probe holder.

4.4 FHR Over Range Remind

The normal fetal heart rate range is 120 BPM ~ 160 BPM, LCD displays the fetal heart rate numerical values as green; when the fetal heart rate is too fast or too slow, beyond the normal range, the fetal heart rate numerical values red to remind pregnant women to go to hospital for further checks to ensure the fetal safety.

4.5 Battery Status Indicator

	Battery power is full
	Battery power is not full
	Battery power is about to run out, it needs replacing batteries.

When it works normally, the LCD screen displays the status of the battery as follows:

When this machine detected the battery power is not able to maintain the normal working of the system, LCD indicates "Low Power!", and meanwhile the battery power state indicative marks is flashing, later the system will automatically shut down.

4.6 Replacing Battery

①The rear panel is upturned. First open the battery compartment, then take out the battery from the battery compartment **(See Fig.4-2)**.
②Put two AA size batteries 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.

Chapter5 Key of Symbols

Symbol	Description	Symbol	Description

	Type CF applied part	CE	Medical Device compliant with Directive 93/42/EEC
	Follow instructions for use		WEEE disposal
	Headphone socket	EU REP	Authorized representative
	Volume adjust	SN	Serial number
	Manufacturer		Recycle
	Manufacture Date		Expiration date
MD	Medical device		Keep away from sunlight
	Keep in a cool, dry place		Atmospheric pressure limit
	Temperature limit		Humidity limit
	Fragile, handle with care	REF	Product code
LOT	Lot number		Imported by
	This way up		Caution: read instructions (warnings) carefully

Chapter 6 Product Specification

Product Name: Pocket Fetal Doppler
Model No.: Baby Sound C1
Classification:
Anti-electroshock Type: Internally powered equipment.
Anti-electroshock Degree: Type CF applied part
Harmful Liquid Proof Degree:
Main unit:Degrees of protection provided by enclosure:IPX0.
Probe: Prevent from water splashing, degree of protection: IPX4.
Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in presence of flammable gases.
Working System: Continuous running equipment.
EMC: Group I Class B.
Suitable Using Range: Suitable for use after the 12th week of pregnancy.
Physical Characteristic
Size: 135 mm (Length) ×92 mm (Width) ×29 mm (Height)
Weight: About 245 g (including batteries)
Environment
Working:
Temperature: +5℃~+40℃
Humidity: ≤80％
Atmospheric Pressure: 70 kPa~106 kPa
Transport and Storage:
Temperature: -10℃~+55℃
Humidity: ≤93％
Atmospheric Pressure: 50 kPa~106 kPa
Display: 1.77"262K TFT display
FHR Performance
FHR Measuring Range: 50 BPM ~ 240 BPM (BPM: beat per minute)
Resolution: 1 BPM
Accuracy: ±2 BPM
Power Consumption:< 1 W
Auto Shut-OFF: After 1 minute no signal, power off automatically.
Battery Type Recommended: Two pieces of 1.5 V DC battery (SIZE AA LR6).
Ultrasound Probe :
Nominal Frequency(2M/3M probe): 2.0 MHz/3.0 MHz
Working Frequency(2M/3M probe): (2.0±10%)MHz/(3.0±10%)MHz
Negative Peak Sound Pressure:P-: <1 MPa
Output Beam Intensity:Iob: <20 mW/cm²
Spatial-peak Temporal-average Derived Intensity:Ispta: <100 mW/cm²
Ultrasonic Output Power: P < 20 mW
Working Mode: Continuous wave doppler
Effective Radiating Area of Transducer: < 157mm²
Note: In all working application modes, mechanical index: MI<1, thermal index: TI<1.

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Chapter 7 Maintenance

7.1 Maintenance
The probe acoustic surface is fragile and must be handled with care.
Gel must be wiped from the probe after use. These precautions will prolong the life of the unit.
The user must check that the equipment does not have visible evidence of damage that may affect patient safety or Pocket Fetal Doppler capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.
The equipment should undergo periodic safety testing to ensure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.
The accuracy of FHR is controlled by the equipment and cannot be adjusted by user. If the FHR result is uncertain, please use other method such as stethoscope to verify immediately or contact local distributor or manufacture to get help.
7.2 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.
Wipe the probe with soft cloth to remove any remaining ultrasound coupling gel. Clean with soap and water only.
CAUTION: Do not use strong solvent, for example, acetone.
CAUTION: Never use an abrasive such as steel wool or metal polish.
CAUTION: Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.
CAUTION: Avoid pouring liquids on the device while cleaning.
CAUTION: Do not leave any cleaning solution on the surface of the device.
Note: Wipe the surface of probe with 70% ethanol, self-air dry, or clean with a clean, dry cloth.
7.3 Disinfecting and Sterilization
Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol infused wipe (70% ethanol).
Wipe the probe with a clean, dry cloth to remove any remaining moisture.
NOTE:
1.The recommended periods of cleaning, sterilization and disinfecting is once per month.
2.After cleaning, sterilization and disinfecting, users must inspect whether have any obvious damage which may affect the patient safety and instrument performance.
WARNING: Never try to sterilize the probe or equipment by low temperature steam or other method.

Chapter 8 Solutions for Possible Problems

If it appears following problems when you use the device, please solve them as below:

Problems	Possible reasons	Solutions
Weak sound	➢Volume is too low ➢Power is low ➢Did not daub the gel	➢Adjust the volume ➢Change the battery ➢Daub the gel
Noise	➢Probe is too close to the main unit ➢Disturbance from the external signal ➢Power is low	➢Make the distance between the probe and the main unit a little further ➢Keep far away from external signal ➢Change the battery
Low sensitivity	➢Position of the probe is not correct ➢Did not daub the gel	➢Adjust the position of the probe ➢Daub the gel

Chapter 9 List for The Device

List for The Device:

Name	Model	Number
Fetal Doppler	Baby Sound C1	1
Doppler Probe	DCD2E10 / DCD3E10	1
User manual	——	1

Appendix 1

The importance of Fetal Domestic Monitor

It is believed that:
FHR is a useful tool in identifying fetal health. By recording FHR changes, users can observe fetal hypoxia, fetal distress, nuchal cord, and other symptoms. Fetal domestic monitor test FHR rate changes by listening to fetal heart sound mainly; Fetal domestic monitor is a powerful support in improving gestational safety.
Fetal heart rate changes most obviously in the following three periods:
1. Within 30 minutes after pregnant women get up
2. Within 60 minutes after pregnant women finish lunch
3. Within 30 minutes before pregnant women go to bed
For the above three periods, because of the change of the body state of pregnant women, the activity of food digesting needs the body to provide more oxygen, relatively, the oxygen for fetus become less. It is easy to stimulate symptoms such as fetus anoxia. Testing the FHR within this period can display the healthy status for the fetus best.
The above three periods can only be tested by pregnant women themselves, so FHR domestic monitor is very important. We advise the pregnant women to measure every day early, mid-day and evening/night time, every time measuring the fetal heart rate and listening to the fetal heart rate for about one minute and recording the measurement results for the medical reference when you go to the hospital.
Generally, the normal fetal heart rate as: 120 BPM~160 BPM; slightly too fast: 161 BPM~180 BPM; too fast: above 181 BPM; slightly too slow: 119 BPM~100 BPM; heavily too slow: below 99 BPM.
This device can detect the fetal heart sound for fetus above twelve weeks and check the LCD display. FHR readings too fast or too slow require a hospital visit for further checks to ensure fetal safety.

Appendix 2

Acoustic Output Reporting Table

Test Mode: CW-mode Transducer Type: CD2.0M

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum index value			0.026	—	—	0.059	0.28	—
Associated	P_{ra}	(MPa)	0.036					
acoustic parameters	P		(mW)		—	—		6.4	—
	Min.of [$P_\alpha(Z_s)$, $I_{zpta,\alpha}Z_s$)]		(mW)				6.24		
	Z_s		(cm)				1.83		
	Z_{bp}		(cm)				1.83		
	Z_b		(cm)					0.2	
	Z at max. $I_{pi,\alpha}$		(cm)	0.6					
	d_{eq} (Z_b)		(cm)					0.48	
	f_{awf}		(MHz)	1.99	—	—	1.99	1.99	—
	Dim of A_{aprt}	X	(cm)		—	—	1.52	1.52	—
		Y	(cm)		—	—	0.77	0.77	—
Other information	t_d		(μsec)	CW					
	prr		(Hz)	CW					
	p_r at max. I_{pi}		(MPa)	0.037					
	d_{eq} at max. I_{pi}		(cm)					0.47	
	$I_{pa,\alpha}$ at max. MI		(W/cm²)	0.31					
	Focal Length	FL_x	(cm)			—	—		
		FL_y	(cm)			—	—		
Operating control conditions	Frequency setting (MHz)			2.0	—	—	2.0	2.0	—

Appendix 3

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The *Pocket Fetal Doppler* is intended for use in the electromagnetic environment specified below. The customer of the user of the *Pocket Fetal Doppler* should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *Pocket Fetal 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 *Pocket Fetal 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.

Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *Pocket Fetal Doppler* is intended for use in the electromagnetic environment specified below. The customer or the user of *Pocket Fetal Doppler* 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%. the manufacturer may recommend the ESD precautionary procedures to user.
Power frequency (50Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *Pocket Fetal Doppler* is intended for use in the electromagnetic environment specified below. The customer or the user of *Pocket Fetal Doppler* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V(0.15 MHz–80 MHz),6 V(in ISM bands between 0.15 MHz and 80 MHz) 10 V/m 80 MHz to 2.7GHz	3 V(0.15 MHz–80 MHz),6 V(in ISM bands between 0.15 MHz and 80 MHz) 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *Pocket Fetal Doppler*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 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:
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 *Pocket Fetal Doppler* is used exceeds the applicable RF compliance level above, the *Pocket Fetal Doppler* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Pocket Fetal Doppler*. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *Pocket Fetal Doppler*			
The *Pocket Fetal Doppler* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Pocket Fetal Doppler* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Pocket Fetal 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 $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.7 GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.67**	**11.67**	**23.33**
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 4

Overall Sensitivity

Overall Sensitivity

Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A(d)	Two-way Attenuation B=ΣBa+Bw (T:mm Ba:dB)					Bw (dB)	B (dB)	Vs (r.m.s.) mV	Vn (r.m.s) mV	$C=20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
1.58 A=45.7dB@ 2MHz	50	45.7	T	20	4.8	4.0	-	0	57.6	186	94	5.93	109.2
			Ba	40	9.6	8.0	-						
	75	45.7	T	20	4.8	3.4	-	0	56.4	175	90	5.78	107.8
			Ba	40	9.6	6.8	-						
	100	45.7	T	20	4.8	3.4	-	0	56.4	174	89	5.82	107.9
			Ba	40	9.6	6.8	-						
	200	45.7	T	20	4.8	-	-	0	49.6	173	90	5.68	100.9
			Ba	40	9.6	-	-						
2.38 A=43.2dB@ 2MHz	50	43.2	T	20	4.8	3.4	2.2	0	60.8	178	89	6.02	110.0
			Ba	40	9.6	6.8	4.4						
	75	43.2	T	20	4.8	3.4	1	0	58.4	170	90	5.52	107.1
			Ba	40	9.6	6.8	2						
	100	43.2	T	20	4.8	3.4	-	0	56.4	165	85	5.76	105.3
			Ba	40	9.6	6.8	-						
	200	43.2	T	20	4.8	1	-	0	51.6	160	85	5.49	100.2
			Ba	40	9.6	2	-						
Doppler Frequency (Hz)	333									Velocity of Target (cm/s)		12.5	

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies