UltraTec PDI

Series Pocket Doppler
Operating Manual
Issue 2.01

CONTENTS

This user manual provides instructions for the operation of UltraTec PD1 series pocket Dopplers hereafter refered to generically as the UltraTec PD1.

It is recommended that personnel study this manual before attempting to operate any UltraTec PD1 device. The safe and effective use of this equipment requires understanding of, and compliance with, all warnings, cautionary notices, and instructions marked on the product, and included in this manual.

Typical users of UltraTec PD1 are trained medical professionals including, but not limited to, Midwives, Clinicians and other health professionals.

If you have any queries regarding the operation of the UltraTec PD1 or understanding the information provided in this manual please contact:

Ultrasound Technologies Ltd.,
Lodge Way,
Portskewett,
Caldicot, NP26 5PS,
South Wales, United Kingdom.

Tel +44 (0) 1291 425425
Fax +44 (0) 1291 427093
e-mail service@doppler.co.uk

2. ABOUT THE ULTRATEC PD1 SERIES

The UltraTec PD1 series features two classes of Doppler, obstetric Dopplers for use in the detection of fetal heart signals and vascular Dopplers for use in routine blood flow detection.

2.1 Obstetric Doppler

Intended Use

The PD1 and PD1+ pocket Dopplers are designed for the use of the Midwife, Doctor or General Practitioner for the detection of the fetal heart during all stages of pregnancy.

Description

The PD1 is a dedicated fetal heart detector with integral 2MHz transducer and audio presentation of the fetal signal.

The PD1+ adds digital fetal heart rate detection and rate display to the PD1 and is supplied with an integral 2MHz transducer. The built-in loudspeaker provides audio presentation of the fetal signal and the fetal heart rate (FHR) is displayed on the LCD display. The PD1+ also has an RS232 data port for the transfer of data to a PC to review the fetal heart rate traces.

The PD1 dŵr water birth Doppler provides fetal heart rate detection and rate display with the addition of a sealed probe for immersion in water for water birth FHR monitoring. The PD1 dŵr also has an RS232 data port for the transfer of data to a PC to review the fetal heart rate traces.

2.2 Vascular Doppler

Intended Use

The PD1v and PD1cv pocket Dopplers are designed for the use of the General Practitioner, Vascular Specialist, Podiatrist and Chiropodist for the detection of blood flow in the body, particularly for the treatment of Peripheral Vascular Disease by measurement of ABI.

Description

The PD1cv includes an integral vascular probe and provides the user with an audio presentation of the vascular flow signal.

The PD1v includes an integral pencil or flat vascular probe and provides the user with an audio presentation of the vascular flow signal and an analogue waveform output for connection to a suitable printer.

2.3 Multipurpose Doppler

The PD1 Combi and PD1+ Combi interchangable probe Dopplers can connect to either obstetric or vascular probes for use by General Practitioner, Midwife, Vascular Specialist, Podiatrist or Chiropodist.

Probes for the PD1 Combi are identified by a coloured ring around the connector. The following probes are available for the PD1 Combi and PD1+ Combi Dopplers:

Type	Frequency	Colour
Obstetric	2MHz	Red
	3MHz	Orange
Vascular	5MHz	Green
	8MHz	Grey

2.4 Accessories

The following accessories are supplied with every UltraTec PD1 series Doppler:

9V Battery (MN1604 6LR61)
Operating Manual
Coupling Gel 0.25ltr (Aquasonic 100)
Soft Carry Case

3. SAFETY

The UltraTec PD1 range of Dopplers are screening tools to aid the healthcare professional and should be used in conjunction with normal vascular or fetal monitoring. If there is doubt as to the result obtained by using the unit, further investigations should be undertaken immediately using alternative techniques.

We would recommend that to maintain the standard of performance of the UltraTec PD1, whenever possible, the device is included in a scheduled maintenance scheme (see section 8 for details).

Fluids should not be allowed to enter the device as this may result in damage to the system. Only the PD1 dŵr probe may be immersed in water.

Regular inspection and testing of PD1 Dopplers is recommended. The PD1 dŵr probe must be checked for cracks that may allow water to enter the probe.

Do not use the device if there is damage to either the probe or probe cable.

The UltraTec PD1 contains no user servicable parts, all service requirements should be referred to an Ultrasound Technologies Ltd. authorised representative.

WARNING: No modification of this equipment is allowed.

WARNING: Replacement batteries must meet the specified type and rating.

WARNING: UltraTec PD1 series pocket Dopplers are not to be used in the presence of flammable anaesthetics, flammable gases or in an oxygen rich environment.

WARNING: US Federal Law restricts this device for sale on or by order of a physician.

3.1 Prudent Use Statement

The UltraTec PD1 has been designed to minimise the ultrasound exposure to the patient. It is recommended that exposure to ultrasound should be kept As Low As Reasonably Acheivable (ALARA guidelines). Avoid unnecessary prolonged exposure. This is considered to be good practice and should be observed at all times.

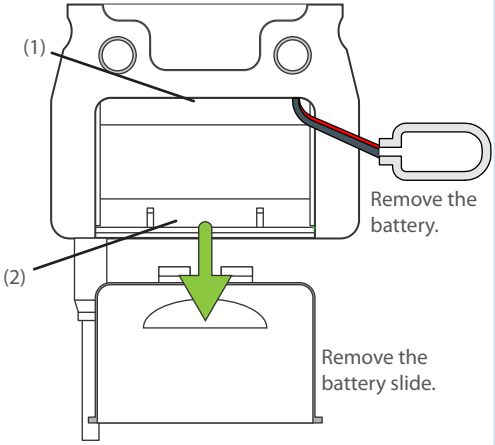
Symbol Definitions

The following symbols have been used on the front and rear labels of the UltraTec PD1 and are here defined according to EN60601-1.

	Unit On/Off Control (Standby).
	Type B Equipment Unit Classification.
	Refer to operating manual
	Attention, consult accompanying documents. Associated with auxiliary connections, see operating manual.
	This symbol on the product or on it's packaging indicates that this product must not be disposed of with your normal waste.
	Battery Low.
	Fetal Pulse Indicator
	Product Manufacturer.

Product Serial Number

The product serial number (1) and manufacture date (2) can be found in the battery compartment by removing the battery.



5. CONTROLS AND INDICATORS

5.1 UltraTec PD1 and PD1+

The PD1 and PD1+ are powered from a single 9 volt alkaline battery (type MN1604 6LR61). To insert or change the battery, slide off the battery cover (A) and withdraw the battery and connector. Carefully remove the battery from the connector and snap the new battery into position taking care to ensure correct orientation. Place the battery and connector back into the battery compartment and refit the battery cover.

To switch on the PD1 or PD1+ press the centre of the membrane switch located on the front of the unit (B).

The PD1 will stay on for approximately 5 minutes or until the on/off switch is pressed again.

The PD1+ system micro-controller monitors the detected signal and turns the unit off when no signal has been detected for approximately 2 minutes.

With the unit on, the volume can be adjusted by the rotary volume control on the edge of the unit (D).

The fetal heart signal is detected using the 2MHz fetal transducer (E).

On the PD1, the condition of the battery is indicated by a yellow LED (C). When this LED is illuminated constantly, battery replacement is recommended. The LED will flash momentarily when the unit is first turned on.

The PD1+ displays battery the condition on the LCD. A battery icon (H) is displayed when the battery requires changing.

On the PD1+ the fetal heart rate (F) is displayed on the LCD. The fetal pulse icon (G) flashes at approximately the same rate as the detected fetal heart.

Serial RS232 connection can be made by attaching the optional serial link cable to socket (I) - contact supplier for further details.

NOTE: The PD1 dŵr functions are identical to those of the PD1+.

5. CONTROLS AND INDICATORS

5.2 UltraTec PD1cv and PD1v

The PD1cv and PD1v are powered from a single 9 volt alkaline battery (type MN1604 6LR61). To insert or change the battery, slide off the battery cover (A) and withdraw the battery and connector. Carefully remove the battery from the connector and snap the new battery into position taking care to ensure correct orientation. Place the battery and connector back into the battery compartment and refit the battery cover.

To switch on the PD1cv or PD1v press the centre of the membrane switch located on the front of the unit (B). The unit will stay on for approximately 5 minutes or until the on/off switch is pressed again.

With the unit on, the volume can be adjusted by the rotary volume control on the edge of the unit (D).

The blood flow signals are detected using the probe (E or F).

A yellow LED (C) indicates the condition of the battery, when illuminated constantly, battery replacement is recommended. The LED will flash momentarily when the unit is first turned on.

Velocity signals can be printed on a suitable printer or ECG with an analogue input by attaching the unit optional printer cable to socket (I) - contact supplier for further details (not available on PD1cv).

5.3 UltraTec PD1 Combi and PD1+ Combi

The PD1 Combi and PD1+ Combi units can be connected to either Obstetric (G) or Vascular (H) probes. Connect the selected probe to the unit using the fixed cable connector (J). Align the red dots on the plug and socket and push together. Ensure that the connector clicks securely into place.

Once connected, operation of the PD1 Combi or PD1+ Combi is identical to the standard PD1 or PD1+ unit.

NOTE: The probe is disconnected from the connector by pulling back on the connector body. Do not twist the connector as this can damage the probe.

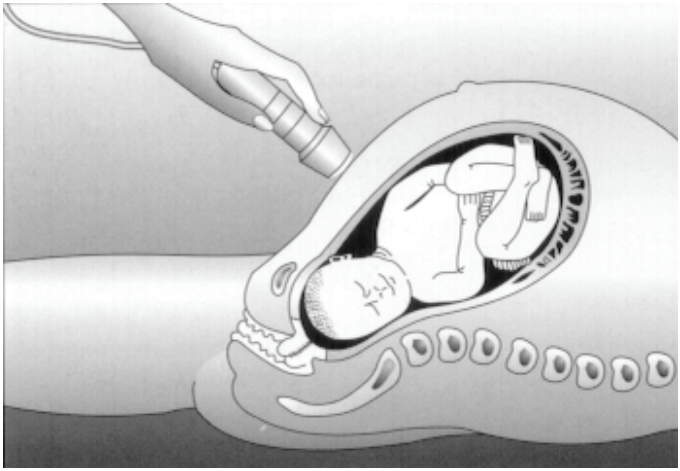
6. FETAL HEART DETECTION

The UltraTec PD1 can be used to detect the beating fetal heart from approximately the 10th week of gestation, though this will vary between patients.

Apply a liberal amount of coupling gel to the area just above the symphysis pubis and position the transducer face flat against the abdomen. Tilt the transducer slowly until the fetal heart is heard in the loudspeaker or headset (in early pregnancy the headset helps to eliminate ambient noise making it easier to detect the weaker signals).

Later on in pregnancy the best signals are generally found higher up the abdomen.

Avoid sliding the transducer over the abdomen as this results in an increase in the background noise and makes it more difficult to detect the fetal heart sounds.



The UltraTec PD1 may be used to locate the position of the placenta, thus aiding in the early diagnosis of placenta praevia or eliminating placental site where amniocentesis is to be performed.

The sound from the placenta is an indistinct swishing, caused by blood flow in many vessels. There is no distinct beat pattern to the sound.

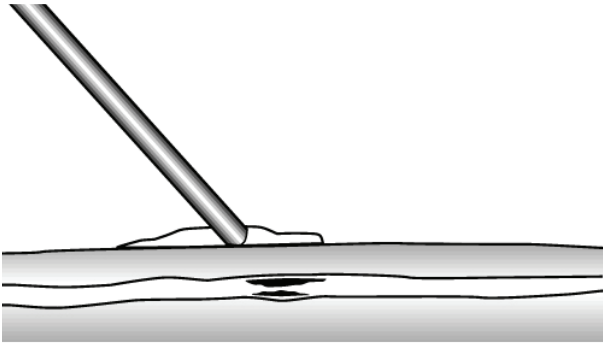
The vessels of the umbilical cord give rise to a higher pitched sound than the normal fetal heart, with pulsations at the fetal rate.

7. VASCULAR FLOW DETECTION

The UltraTec PD1 can be used to detect both surface vessels, deeper arteries and veins using either the 5MHz or 8MHz transducers.

To obtain the best signal, apply a liberal amount of coupling gel to the area of the vein or artery under investigation. Tilt the transducer at approximately 45 degrees to the vessel. Arteries give a high pitched pulsatile sound, with veins giving a sound like a roaring wind.

The optional headset helps to eliminate ambient noise, making it easier to detect the weaker signals.



It is also usual for the UltraTec PD1 to be used in association with a pressure cuff and sphygmomanometer to indicate the location and extent of arterial occlusion in the form of ankle/brachial pressure index and segmental pressures.

Due to the variation of leg blood pressure over a wide range with the systemic pressure, the actual values are less useful than the pressure index, which relates the ankle pressure to the pressure obtained at the brachial artery. Using the PD1 to measure both pressures will ensure compatibility. In cases where patients have peripheral arterial disease using the UltraTec PD1, due to its high sensitivity, can be the only technique suitable for the measurement of leg blood pressure.

$$\text{Pressure Index} = \frac{\text{Ankle systolic pressure}}{\text{Brachial systolic pressure}}$$

Normal

Ankle systolic pressure > Brachial pressure
Normal pressure index >1
Abnormal pressure index <1

8. PREVENTATIVE MAINTENANCE

To ensure continued accuracy and reliability from your Doppler you should regularly perform the following routine maintenance tasks:-

8.1 Cleaning

- Maintain a clean environment for the Doppler.
- Remove all coupling gel, blood, saline, etc. as soon as possible after use.
- After each use carefully wipe excess coupling gel from the probe with a soft tissue.
- NEVER clean probes with alcohol or any other solvent as these may cause damage.
- If the probe or unit require disinfection then wipe with a damp cloth moistened with a mild dilution of Milton* or equivalent product. Recommended dilution is 1 part Milton* 2% (20,000ppm of available chlorine) to 20 parts water.
- DO NOT IMMERSE any UltraTec PD1 device or probe in any liquid (with the exceptio of the PD1 dŵr probe, which can be immersed in water).
- NEVER Autoclave the transducers. The transducers should be cleaned with a sterile non-abrasive cloth dampened with an aqueous disinfectant. If, in extreme cases, it is considered necessary to sterilize the transducer this should be done using gas sterilization methods at pressure and at elevated temperature in accordance with hospital practice. Note that out-gassing periods should be adhered to.

8.2 General Maintenance

- The transducer face is very delicate and may be damaged by dropping. Always store the unit and transducer in the soft carry bag.
- Regularly inspect the unit for damage. Pay particular attention to the probe and probe cable.
- Refer damaged units to an Ultrasound Technologies Ltd. authorised service reprasentative as soon as any damage is identified.

*Milton is a solution of 2% Sodium Hypochlorite.

In the unlikely event of instrument failure, the following simple checks may be made before contacting your service agent for further advice.

Functional Checks

- Turn the volume control to maximum.
- Turn the unit on and observe the battery low indicator, if it does not illuminate, replace the battery and try again.
- If the battery low indicator remains on, replace the battery again.
- If the battery low indicator illuminates and then goes out (normal operation) stroke the transducer face.
- If no audio signal is heard in the loudspeaker, with the volume turned up, consult your supplier.

Operational Checks

- Make sure all connectors are firmly plugged in, that the transducers are correctly positioned and the audio volume set to the desired level.
- Observe that the fetal pulse icon flashes with each heart beat (PD1+ only).

If the Doppler does not perform as described above then contact your service agent.

NOTE: Be ready to provide the model, serial number and the nature of the problem. The serial number can be found inside the unit by removing the battery.

There are no user serviceable parts inside the UltraTec PD1. A service manual, which includes circuit diagrams, parts lists and test procedures, is available and may be purchased from your supplier or directly from Ultrasound Technologies Ltd.

10. EQUIPMENT SPECIFICATION

10.1 UltraTec PD1 Series Doppler Specifications

Ultrasound	
Frequency (Obstetric)	2 or 3MHz continuous wave.*
Frequency (Vascular)	5 or 8MHz continuous wave.**
Probe	2 crystal narrow beam.
Audio	Response 300Hz to 1KHz (4KHz with vascular).
Range	50 to 210 bpm.
Power output	<15m W/cm^2 SATA.
Indicators	LCD heart rate and pulse indication.
Heart Rate Processing	Digital multipoint autocorrelator.
Controls and Indicators	
Control	Rotary volume control and power on/off button.
Indicators (PD1)	Yellow battery low LED.
Indicators (PD1+)	3 digit FHR LCD display, FHR pulse icon, battery low icon.
Outputs	
Headset	Audio output to optional headset.
Serial (PD1+ range)	RS232 interface to optional UltraTrace 2 PC software.
Recorder (PD1v)	Voltage output proportional to velocity of flow.
Power Supply	
Battery	MN1604 6LR61 (PP3) 9V Alkaline Manganese.
Expected Battery Life (PD1)	>9 hours.
Expected Battery Life (PD1+)	>6 hours.
Enclosure	
Material	ABS.
Weight	295g typically, including probe.
Size	150 x 75 x 35 (mm).
Safety	
Classification	Class 1 Type B - IEC 60601-1:2006.

*3MHz only available for PD1combi. **The PD1cv is supplied with a fixed probe. The frequency must be specified at the time of ordering.

10.2 Environmental Requirements

Operating	
Ambient Temperature	+10°C to +40°C.
Relative Humidity	30 – 70% non-condensing.
Ambient Pressure	700 kPa to 1060 kPa.
Transit and Storage	
Ambient Temperature	-40°C to +70°C.
Relative Humidity	10% to 100%, including condensation.
Ambient Pressure	500kPa to 1060kPa.

10.3 Ultrasound Output Specification

	Maximum Index Value	Index Component Values		Acoustic Parameters			
		At Surface	Below Surface	P (mW)	P_{1x1} (mW)	z_b (cm)	f_{awf} (MHz)
Obstetric	0.291	0.291	0.229	6.6	5.9	10	2.0

Thermal indices and the mechanical index are 1.0 or less for all device settings.

10.4 FHR Display Performance

Range	Resolution	Accuracy
50 - 210 bpm	1 bpm	± 1 bpm

10.5 Electromagnetic Compatibility Tables

As detailed in the Specifications, this product is classified as a Class A Group 1 type of product according to EN55011. This product is allowed in a domestic establishment under the jurisdiction of a Healthcare professional.

The UltraTec PD1 is designed to comply with EN60601-1, Medical Electrical Requirements for Safety and is a Class 1 device.

10.5.1 Manufacturers Declaration and Guidance : Emissions

Care has been taken through the design and manufacturing process to minimize the electromagnetic (EM) emissions which may be produced by this equipment. However, in the unlikely event that the unit causes an EM disturbance to adjacent equipment, we suggest that the procedure is performed out of range of the affected equipment.

Electromagnetic Emission		
The UltraTec PD1 is intended for use in the electromagnetic environment specified below. The user of the UltraTec PD1 should assure that it is used in such and environment.		
Emission Test	Compliance	Electromagnetic Environment
RF Emissions CISPR II	Group 1	The PD1 series pocket Doppler uses RF energy only for it's internal function. Therefore, it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR II	Class B	The PD1 series 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 61000-3-4	Not Applicable	
Voltage Fluctuations / Flicker Emissions IEC61000-3-3	Not Applicable	

10. EQUIPMENT SPECIFICATION

10.5.2 Manufacturers Declaration and Guidance : Immunity

If the user has any doubt regarding the unit's EM immunity during routine operation, we suggest that the source of EM disturbance is identified and its emissions reduced.

Electromagnetic Immunity			
The UltraTec PD1 is intended for use in the electromagnetic environment specified below. The user of the UltraTec PD1 should assure that it is used in such and environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If the floor is covered in sythetic material the relative humidity should be at least 30%.
			Portable and mobile RF communications equipment should be used no closer to any part of the UltraTec PD1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d=1.2\sqrt{P}$ (80MHz to 800MHz) $d=2.3\sqrt{P}$ (800MHz to 2.5GHz)
			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 meters (m). Field strengths from fixed RF transmitters, as determined by an electomagnetic 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 80MHz and 800MHz, 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/or 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 UltraTec PD1 device is used exceeds the applicable RF compliance level above, the UltraTec PD1 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

10.5.3 Manufacturers Declaration and Guidance : Separation Distances

Recommended separation distances between portable and mobile communications equipment and a UltraTec PD1			
The UltraTec PD1 is intended for use in an electromagnetic environment in which RF disturbances are controlled. The user of the UltraTec PD1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UltraTec PD1 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)		
	150KHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1**: At 80MHz and 800MHz, 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/or people.			

This equipment complies with the essential requirements of the European Council Directive 93/42/EEC + 2007/47/EC relating to Medical Devices.

11. WARRANTY

11.1 Terms and Conditions

1. The Warranty

Ultrasound Technologies Ltd. warrants the product, when new, to be free of defects in material and workmanship and to perform in accordance with the manufacturer's specification for a minimum period of three years from the date of purchase from Ultrasound Technologies Ltd.

2. Replacement of Product or Components

Ultrasound Technologies Ltd. will repair or replace any components found to be defective or at variance from manufacturer's specification at no cost during the warranty period.

3. Return of a Faulty Product

It shall be the purchaser's responsibility to return the product, at their cost, directly to Ultrasound Technologies Ltd. or to an authorized Ultrasound Technologies Ltd. distributor, agent or service representative.

4. Procedure for Return

In order to return the product directly to Ultrasound Technologies Ltd. the purchaser must first obtain a return authorization from Ultrasound Technologies Ltd.'s Service Centre.

5. Condition of Products for Return

All products must be returned in a clean, decontaminated condition and with a decontamination certificate. Ultrasound Technologies Ltd. reserves the right to refuse to service equipment returned without a suitable decontamination certificate or in a contaminated condition. Ultrasound Technologies Ltd. will not be responsible for units damaged during return due to poor packing.

6. Exclusion from the Warranty

This warranty does not include breakage or failure due to tampering, misuse, neglect, accident or shipping, nor the effects of normal wear and tear.

7. Negating the Warranty

This warranty is also void if the product is not used or serviced in accordance with the manufacturer's instructions or has been repaired by any person other than a Ultrasound Technologies Ltd. authorized agent.

8. Commencement of Warranty Period

The purchase date determines the period of the warranty.

9. Limitation of Warranty

No other express or implied warranty is given. Ultrasound Technologies Ltd. will under no circumstances be liable for loss from any indirect or consequential damage.

11. WARRANTY

11.2 The Ultrasound Technologies Ltd. CUSTOMER CARE PROMISE

When you bought this quality product you also bought a commitment from Ultrasound Technologies Ltd. to support the product throughout it's lifetime, and the supply of spare parts, where possible, for up to 10 years.

11.3 Meeting Expectations

The Ultrasound Technologies Ltd. Service Centre is only a phone call away, whether the product is under warranty, covered by a service agreement or the repair is to be paid for. This applies whether the product was bought directly from Ultrasound Technologies Ltd. or through an authorized distributor.

We will:

Respond promptly to any call made with regard to service.

If required, we will provide you with written estimates of the work to be carried out and the costs before commencing work.

A comprehensive service manual for this equipment, including circuit diagrams, parts lists, and test procedures, is available and may be purchased from your supplier or directly from Ultrasound Technologies Ltd.

For any service-related query contact:

Ultrasound Technologies Ltd.,
Lodge Way,
Portskewett,
Caldicot, NP26 5PS,
South Wales, United Kingdom.

Tel	+44 (0) 1291 425425
Fax	+44 (0) 1291 427093
e-mail	service@doppler.co.uk

Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC)

There is an increasing interest in the proper disposal of used electronic equipment. The European Union (EU) has developed the WEEE (Waste Electrical and Electronic Equipment) Directive to ensure that systems for collection, treatment and recycling of electronic waste will be in place throughout the European Union.

Ultrasound Technologies Ltd. Position with Regard to the WEEE Directive

Product recycling is nothing new and Ultrasound Technologies have implemented processes in each member state where the Company has a presence. Ultrasound Technologies will comply with the provisions of the WEEE Directive and national implementing legislation.

Instructions for Disposal of Waste Equipment

This symbol on the product or on its packaging indicates that this product must not be disposed of with your general waste.

For users of Ultrasound Technologies Ltd. equipment, Ultrasound Technologies Ltd. will provide free recycling of equivalent medical electronic equipment once a customer has returned the equipment to Ultrasound Technologies Ltd., with all transport and importation costs paid, and where a replacement product is being supplied by Ultrasound Technologies Ltd. Where a replacement product is not being supplied, recycling services may be provided on request at additional cost.

RoHS

The RoHS (Restriction of Hazardous Substances) directive (2002/95/EC), compliments the WEEE Directive by banning the presence of specific hazardous substances in the products at the point of manufacture.

At Ultrasound Technologies Ltd. we take our responsibilities to the environment very seriously and 100% of our entire manufacturing process and parts meet the RoHS directive and are fully compliant.

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Ultrasound Technologies Ltd.,
Lodge Way,
Portskewett,
Caldicot, NP26 5PS,
South Wales, United Kingdom.

Tel +44 (0) 1291 425425
Fax +44 (0) 1291 427093
e-mail service@doppler.co.uk

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