Ultrasound Technologies

PD1+

fetal pocket doppler with FHR display

PD1

fetal pocket doppler
INTRODUCTION

The UltraTec PD1 and PD1+ are Pocket Doppler fetal heart detectors designed to suit the needs of the General Practitioner or Midwife for routine antenatal heart rate detection.

The PD1 is a dedicated fetal heart detector with integral 2 MHz 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 2 MHz 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 instrument is supplied complete with the following:
- Doppler Instrument with integral 2MHz transducer
- 9V battery (6LR61)
- Operating instructions
- Coupling gel 0.25ltr
- Soft carry case

The following symbols have been used on the instrument and are defined according to BS EN 60601-1:2006

- Type B Equipment, Unit Classification
- Unit On/Off control
- Attention. Consult accompanying documents
- This symbol on the product or its packaging indicates that this product must not be disposed of with your normal waste. WEE Directive (2002/96/EC)

Before using your Pocket Doppler for the first time, please read these operating instructions carefully.
The **PD1** is powered from a single 9 volt alkaline battery (type 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** press the switch located on the front of the **PD1** unit (B).

The **PD1** 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 fetal heart signal is detected using the 2MHz fetal transducer (E).

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.
CONTROLS AND INDICATORS - PD1+

The PD1+ operates in a similar manner to the PD1. The unit is turned on by pressing the on / off control (B), the system micro-controller monitors the detected signal and turns the unit off when no signal has been detected for approximately 2 minutes.

The LCD displays battery condition and fetal heart rate (F). A battery icon (C) is displayed when the battery requires changing. 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 (H) - contact supplier for further details.
SPECIFICATIONS

**Ultrasound**
- **Frequency**: 2 MHz continuous wave
- **Transducer**: 2 crystal narrow beam
- **Output Power**: <10mW/cm² SATA
- **Audio Response**: 300Hz – 1KHz
- **Fetal Heart Rate**: Multipoint real time Autocorrelator (PD1+ only)

**Unit Controls**
- **Keys**: 1 Key (for unit on / off)
- **Controls**: Rotary volume
- **Indicators**: PD1 - Yellow battery low LED
  PD1+ - 3 digit FHR LCD display, Battery low icon and FHR pulse icon

**Power Supply**
- **Battery**: MN1604 (PP3) 9V Alkaline Manganese
- **Expected battery life**: > 9 hours of use PD1
  > 5 hours PD1+

**Output**
- **Headset**: Audio output to optional headset.
- **Serial**: (PD1+only) RS232 interface to optional UltraTrace 2 PC software

**Enclosure**
- **Material**: ABS
- **Size**: 150mm by 75mm
- **Weight**: 290gms typical

**Safety**
- **Classification**: Type B - IEC 60601-1:2006

The following Consumables are available for use with the PD1, PD1+
- Coupling gel 0.25ltr
- Alkaline battery (6LR61)
FETAL HEART DETECTION

The PD1 / 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. The same procedure should be adopted as above.

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.
PLACENTA AND UMBILICAL CORD

The PD1 / 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 bloodflow 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.

PD1+ FETAL HEART RATE RECORDING

The optional UltraTrace2 software runs under Windows XP and provides a fetal monitor style real time chart recording and patient database where the traces can be printed on most Windows supported printers. Details of the use of UltraTrace2 are included in the UltraTrace2 operating manual. For more information contact your supplier.

CARE OF YOUR PD1 OR PD1+ DOPPLER

After each use carefully wipe excess coupling gel from the transducer with a soft tissue. Never use alcohol or any other solvent to clean any part of the Pocket Doppler, as these may cause damage. If cleaning becomes necessary wipe the Pocket Doppler with a damp cloth moistened with a mild detergent.

The transducer face is very delicate and may be damaged by dropping. Always clip the transducer in its holder when not in use.

WARNINGS

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

If in any doubt of the Fetal Heart Rate from the PD1 series pocket dopplers always use another method to establish the well being of the Fetus.
SIMPLE FAULT FINDING

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

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 and try 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 consult your supplier.

When contacting your supplier with a problem please have available the instrument type and serial number. The serial number can be found inside the battery compartment.

SERVICE

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

WARRANTY

Your PD1 Pocket doppler is guaranteed for a period of 3 years against defects in material and workmanship. Any instrument that proves to be defective within that period will be repaired or replaced free of charge, provided that:

i) the instrument has not been damaged accidentally or by misuse or mishandling.

ii) no unauthorised attempts at repair have been made.

iii) the goods are returned to Ultrasound Technologies Ltd or its authorised representative freight pre-paid.
Under no circumstances whatsoever shall Ultrasound Technologies Ltd have any liability for loss or for any indirect or consequential damage.

This Equipment complies with the essential requirements of the European Council Directive 93/43/EEC + 2007/47/EC

Manufactures Declaration and Guidance. Electromagnetic Emissions and Immunity

<table>
<thead>
<tr>
<th>Electromagnetic Emission</th>
<th>Compliance</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The PD1 series pocket doppler is intended for use in the electromagnetic environment specified below. The User of the PD1 series doppler should assure that it is used in such an environment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions CISPR 11 Group 1</td>
<td>The PD1 series 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.</td>
<td></td>
</tr>
<tr>
<td>RF emissions CISPR 11 Class B</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-4 Not Applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3 Not Applicable</td>
<td></td>
<td></td>
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</tbody>
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Electromagnetic Immunity

The PD1 series pocket doppler is intended for use in the electromagnetic environment specified below. The User of the PD1 series doppler should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 61000-4-2</td>
<td>±6KV contact ±8KV air</td>
<td>±6KV contact ±8KV air</td>
</tr>
</tbody>
</table>

Electromagnetic Environment - guidance

Floors should be wood, concrete or ceramic tile. If the floor is covered in synthetic 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 PD1series pocket doppler, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

<table>
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<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>3V/m 80MHz to 2.5GHz</td>
<td>3V/m</td>
</tr>
</tbody>
</table>

Electromagnetic Environment - guidance

d=1.2√P (80MHz to 800MHz)
d=2.3√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 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 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 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 PD1 series pocket doppler is used exceeds the applicable RF compliance level shown above, the PD1 series pocket doppler should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orientating or relocating the PD1 series pocket doppler.

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

If the user has any doubt regarding the identification and resolution of adverse EM conditions, they may contact the following to seek advice:

**Service Department**
Ultrasound Technologies Ltd
Lodge Way, Portskewett, Caldicot, NP26 5PS, South Wales. UK

Tel: +44 (1291) 425425
Fax: +44 (1291) 427093
Email: service@doppler.co.uk
Website: www.doppler.co.uk
The PD1 series pocket doppler is intended for use in an electromagnetic environment in which RF disturbances are controlled. The user of the PD1 series pocket doppler can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PD1 series pocket doppler as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150KHz to 80MHz, d=1.2√P</td>
<td>80MHz to 800MHz, d=1.2√P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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 people.