Freeplay FHRM

Fetal Doppler/Monitor
Operating Manual
Issue 1.08

CONTENTS

1. ABOUT THIS MANUAL

This user manual provides instructions for the operation of the Freeplay FHRM Fetal Doppler/Monitor, hereafter refered to generically as the FHRM.

It is recommended that personnel study this manual before attempting to operate the FHRM Fetal Doppler. 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 FHRM Fetal Dopplers 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 FHRM Fetal Doppler or understanding the information provided in this manual please contact your local distributor or authorised Freeplay Representative

2. ABOUT THE FHRM

The Fetal Heart Rate Monitor (FHRM) is a portable hand-held, robust device with a probe that uses Doppler ultrasound waves to detect the fetal heart rate.

The FHRM uses internal rechargable batteries to enable health professionals to count the fetal heart rate in conditions where a reliable source of mains electricity may not be available.

There are a number of options to recharge or power the device, with the wind- up/ self-powered being the most obvious.

The fetal heart can be "heard" on the loudspeaker while the fetal heart rate is shown on the display screen.

2.1 Intended Use

The FHRM Fetal Doppler is intended for use in conventional Fetal Heart detection and monitoring during antenatal and intrapartum care.

This device should only be used by trained medical personnel with a background in obstetric care.

It should not be used for any other application or patient examination procedure.

If its use is in doubt, contact your local distributor or authorised Freeplay Representative directly.

2.2 Accessories

The following accessories are supplied with every FHRM series Doppler:

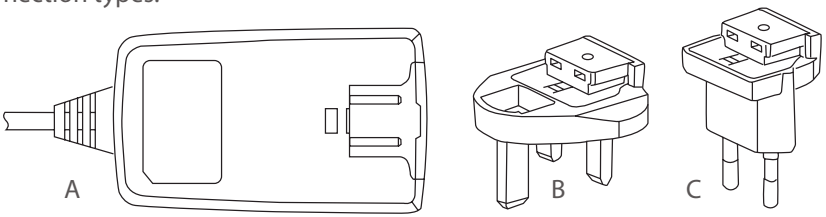
AC Mains Adapter
Operating Manual

2.3 AC Mains Adaptor

The FHRM Fetal Doppler is supplied with a universal Mains AC to 12VDC mains adaptor for charging the internal batteries of the FHRM Fetal Doppler.

The FHRM is disabled while charging and therefore can not be used on a Patient .

The AC Mains adaptor (A) is supplied with 2 plug heads , for UK (B) and EU (C) connection types.



Select the appropriate plug head for your main connection. Align the plug head connector with the mains adapter socket and slide together. Ensure that the plug head clips into place and is securely attached before use.

WARNING: The device must only be used with the supplied power supply unit.

3. SAFETY

The FHRM Fetal Doppler is a screening tool to aid the healthcare professional and should be used in conjunction with normal 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 FHRM, whenever possible, the device is included in a scheduled maintenance scheme (see section 10 for details).

Fluids should not be allowed to enter the device as this may result in damage to the system.

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

The FHRM contains no user servicable parts, all service requirements should be referred to your local distributor or authorised Freeplay Representative.

The FHRM contains a rechargable NiMH battery pack that is not user replaceable. Attempts to replace this battery pack could lead to damage to the unit, environment and/or human health in incorrectly fitted, handled or disposed of improperly.

The FHRM battery pack must only be replaced by your local distributor or authorised Freeplay Representative.

WARNING: No modification of this equipment is allowed.

WARNING: FHRM Fetal 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 FHRM 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 FHRM 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.
	Direct Current
	Connector Polarity (Tip Positive)

Product Serial Number

The product serial number can be found on the rear label of the product, beneath the winding handle.

5. CONTROLS AND INDICATORS

5. CONTROLS AND INDICATORS

The FHRM is powered from an internal battery, which can be charged using the windup mechanism built into the unit or using the included AC power adapter.

To switch on the FHRM press the centre of the switch located on the front of the unit (A).

The FHRM will stay on for approximately 2 minutes after the last FHR is detected or until the on/off switch is pressed again.

The fetal heart signal is detected using the 2MHz ultrasound probe (F).

The FHRM displays battery condition on the LCD. A battery icon (B) is displayed when the battery requires re-charging.

The fetal heart rate (D) is displayed on the LCD. The fetal pulse icon (E) flashes at approximately the same rate as the detected fetal heart and the fetal heart sound is presented from the built in loudspeaker.

On the rear of the unit there is the charging handle and a green LED that indicates when the unit is charging.

The fetal probe (F) is permanently attached to the unit and no attempt must be made to disconnect it.

6. CHARGING THE FHRM

This fetal heart rate monitor runs off rechargeable batteries that are inside the device. The batteries may be recharged from three different power sources.

Mains electricity

The batteries can be charged from a mains electric power supply using a power adaptor:

Plug the adaptor into a standard wall electricity plug and insert the cable into the power socket of the fetal monitor. Switch on the wall plug. Check that the green light on the fetal monitor is flashing. This means that the batteries are now charging from the electric power supply.

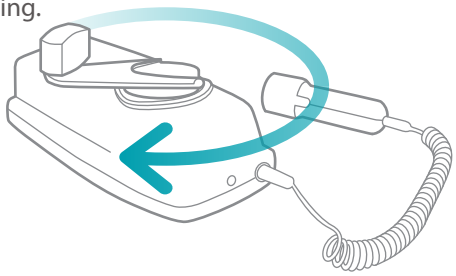
It takes approximately 2 hours to fully charge the batteries. When they are fully charged the green light on the fetal monitor will flash on and off slowly. Now the fetal monitor will operate for approximately 7 hours continuously before the batteries need recharging again.

Wind-up power

The batteries can also be recharged with power created by turning the wind-up handle on the back of the fetal monitor:

Turn the wind-up handle fast in any direction. The green light next to the power socket will come on brightly if you are winding the handle fast enough to create power. If the light does not come on, you are winding the handle too slowly and are not storing power in the batteries.

If you wind the device for 60 seconds, it will function and show a reading for approximately 8 to 10 minutes, depending on the speed of winding. The longer and faster you wind the longer the fetal monitor will function without the need for further winding. You can store wind-up power by winding for any length of time. All power created by winding is stored in the batteries.



First choose the power supply you will use to charge the batteries and make sure you have enough power stored in the batteries to complete your examination.

Clean the ultrasound probe by wiping it with a cloth and disinfectant agent such as chlorohexidene or sodium hypochlorite, NEVER use alcohol on the FHRM.

Switch the fetal monitor on by pressing the on/off button.

Put a gel, or water, on the ultrasound probe/or mother's abdomen and place the probe on the mother's abdomen and move it around until the fetal heart is heard well.

It is important NOT to use a mineral oil based gel (eg: KY jelly) between the probe and the skin. An aqueous (water based) gel must be used, or water alone is quite adequate. Mineral oil based gels can penetrate the plastic and cause damage to the faceplate assembly. This will result in the device failing to function. Water is adequate to create an air-free seal between the Doppler head and skin if an aqueous gel is unavailable.

Keep the probe in that position when a good signal is heard.

The flashing heart symbol on the display screen indicates that a readable heart rate is detected and the fetal heart rate per minute is shown on the screen.

The power source must be disconnected from the monitor before it can be used. You will not be able to switch the monitor on if it is still attached to the power.

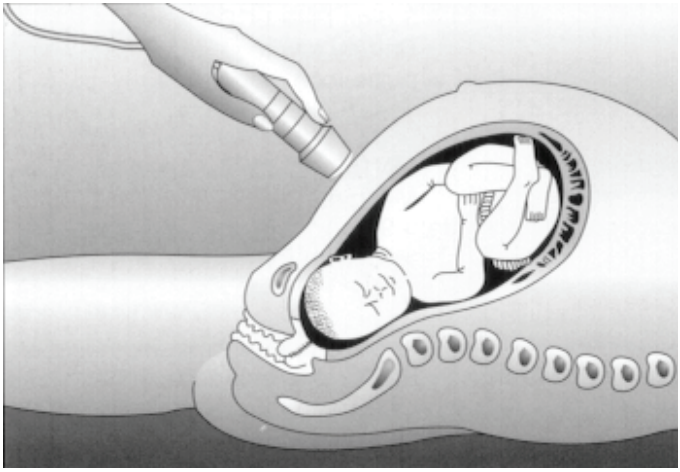
8. FETAL HEART DETECTION

The FHRM 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 probe face flat against the abdomen. Tilt the probe slowly until the fetal heart is heard in the loudspeaker.

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

Avoid sliding the probe 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 FHRM 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.

9. FREQUENTLY ASKED QUESTIONS

Q: *What if the fetal monitor turns off unexpectedly?*
A: There is no power left. Choose your power option and charge the batteries before switching on the fetal monitor again.

Q: *Can you damage the fetal monitor by turning the handle too fast?*
A: No. The faster you turn the handle the more power you will store in the batteries.

Q: *What happens if you turn the handle in the wrong direction?*
A: It does not matter in which direction you turn the handle. Either direction will generate power.

Q: *Is it safe to use the fetal monitor near other electrical equipment?*
A: Yes. The fetal monitor will not affect or be affected by other electrical equipment.

Q: *Can the operator or patient receive an electric shock from the fetal monitor?*
A: No. It is specially designed so that it cannot give an electric shock.

Q: *Will the device be damaged if it is dropped?*
A: It may be damaged, especially if the probe is dropped. However it has been designed to be robust and is not easily damaged.

Q: *When do you know that the fetal heart rate reading on the display screen is accurate?*
A: The reading is only reliable if there is a heart icon shown and if the heart rate does not change frequently on the display screen. If the icon is not shown or the heart rate changes all the time, reposition the probe on the mother's abdomen and make sure that she remains still, as movement can interfere with the reading. If the heart rate is less than 100, make sure you are not measuring the mother's pulse rate by comparing the reading on the display screen with the mothers' wrist pulse rate.

A self-learning programme for professionals on fetal heart rate monitoring during intrapartum care can be accessed free on:
http://bettercare.co.za/learning-programmes/intrapartum-care/

10. PREVENTATIVE MAINTENANCE

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

10.1 Cleaning

- Maintain a clean environment for the FHRM.
- 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 FHRM device or probe in any liquid.
- NEVER Autoclave the probe. The probe 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 probe 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.

10.2 General Maintenance

- The probe face is very delicate and may be damaged by dropping. Always store the unit carefully and protect the probe.
- Regularly inspect the unit for damage. Pay particular attention to the probe and probe cable.
- Refer damaged units to your local distributor or authorised Freeplay Representative 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 local distributor or authorised Freeplay Representative for further advice.

Functional Checks

- Turn the unit on and observe the display, if it does not illuminate, charge the battery and try again.
- If the battery low indicator remains on, then call your local distributor or authorised Freeplay Representative.
- If the battery low indicator is off (normal operation) stroke the probe face.
- If no audio signal is heard in the loudspeaker, consult your local distributor or authorised Freeplay Representative.

Operational Checks

- Make sure that the probe are correctly positioned.
- Observe that the fetal pulse icon flashes with each heart beat.

If the FHRM does not perform as described above then contact your local distributor or authorised Freeplay Representative.

NOTE: Be ready to provide the model, serial number and the nature of the problem. The serial number can be found on the rear of the unit beneath the charging handle.

There are no user serviceable parts inside the FHRM.

12. EQUIPMENT SPECIFICATION

12.1 FHRM Series Doppler Specifications

Ultrasound	
Frequency	2 MHz continuous wave.
Probe	2 crystal narrow beam.
Audio	Response 300Hz to 1KHz.
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	Power on/off button.
Indicators	3 digit FHR LCD display, FHR pulse icon, battery low icon, charge indicator on rear
Power Supply	
Hand Crank	60 seconds of winding for 8 to 10 minutes of use
Battery	Rechargeable NiMH internal battery
Expected Battery Life	>6 hours. (when fully charged)
Mains Battery Charger	
Output Voltage DC	12V
Input Voltage AC	80 - 264 VAC
Mains Frequency	47 - 63Hz
Output Current	1.25A
Input Power	36W max
Enclosure	
Material	ABS.
Weight	590g typically, including probe.
Size	180 x 90 mm.
Safety	
FHRM Device Classification	Internally Powered ME Equipment - IEC 60601-1:2006.
Mains Charger Classification	Class II ME Equipment

12.2 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.

12.3 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

12.4 FHR Display Performance

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

12.5 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 FHRM is designed to comply with EN60601-1, Medical Electrical Requirements for Safety.

12.5.1 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 FHRM is intended for use in the electromagnetic environment specified below. The user of the FHRM should assure that it is used in such and environment.		
Emission Test	Compliance	Electromagnetic Environment
RF Emissions CISPR II	Group 1	The FHRM Fetal 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 FHRM 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.
Harmonic Emissions IEC 61000-3-4	Not Applicable	
Voltage Fluctuations / Flicker Emissions IEC61000-3-3	Not Applicable	

12. EQUIPMENT SPECIFICATION

12.5.2 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.

<table>
<tr><th colspan="4">Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The FHRM is intended for use in the electromagnetic environment specified below.
The user of the FHRM should assure that it is used in such and environment.</td></tr>
<tr><td>Immunity test</td><td>IEC60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Electrostatic Discharge (ESD) IEC61000-4-2</td><td>±6KV contact
±8KV air</td><td>±6KV contact
±8KV air</td><td>Floors should be wood, concrete or ceramic tile. If the floor is covered in synthetic material the relative humidity should be at least 30%.</td></tr>
<tr><td colspan="3"></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the FHRM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3V/m 80MHz to 2.5GHz</td><td>3V/m</td><td>$d=1.2\sqrt{P}$ (80MHz to 800MHz)
$d=2.3\sqrt{P}$ (800MHz to 2.5GHz)</td></tr>
<tr><td colspan="3" rowspan="2"></td><td>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).</td></tr>
<tr><td>Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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 FHRM device is used exceeds the applicable RF compliance level above, the FHRM 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.</td></tr>
</table>

12.5.3 Manufacturers Declaration and Guidance : Separation Distances

Recommended separation distances between portable and mobile communications equipment and a FHRM			
The FHRM is intended for use in an electromagnetic environment in which RF disturbances are controlled. The user of the FHRM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FHRM 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√P	80MHz to 800MHz d=1.2√P	800MHz to 2.5GHz d=2.3√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.

13. WARRANTY

13.1 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.

14. WEEE AND ROHS

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.

CE
0120

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

Printed in United Kingdom

Document Date: 22/09/2018