HUNTLEIGH

D920/D930

Anwendungshinweise

Kullanım Talimatları

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Instrucciones de uso

; χρήσης

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Anwendungshinweise

HIGH SENSITIVITY POCKET DOPPLERS

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1. Safety

Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operation. Ensure that each user fully understands the safety and operation of the unit, as mis-use may cause harm to the user or patient, or damage to the product.

We recommend that exposure to ultrasound should be kept As Low As Reasonably Achievable - (ALARA guidelines). This is considered to be good practice and should be observed at all times.

This equipment is for use only by suitably qualified healthcare practitioners.

This product may be used in the home healthcare environment by a qualified healthcare practitioner only, and is for indoor use only.

Experience with use of ultrasonic Dopplers is preferable, but for novice users training material is provided with the accompanying documents (CD). This product is not intended for use by the patient.

Please keep these Instructions for Use to hand for future reference.

	General warning
	Attention, consult accompanying documents / Instructions for Use

1.1 Warnings

	Do not use in the presence of flammable gases or oxygen rich environments.
	Do not use in the sterile field unless additional barrier precautions are taken.
	Do Not : • ***immerse in any liquid, (except D920/D930 probe)*** • ***use solvent cleaner,*** • ***use high temperature sterilising processes (such as autoclaving),*** • ***use E-beam or gamma radiation sterilisation.***

	***The main unit is not waterproof and must not be immersed. For underwater use where contamination or cross-infection may occur, additional barrier precautions must be taken.***
	***Do not use on the eye.***
	***Do not dispose of batteries in fire as this can cause them to explode.***
	***Do not attempt to recharge normal dry-cell batteries. They may leak, cause a fire or even explode.***
	***This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it. This will be indicated by unusual sounds from the loudspeaker. We recommend that the source of interference is identified and eliminated***
	***Connect headphones only to the headphone socket.***
	***Dopplex Dopplers are screening tools to aid the healthcare professional and should not be used in place of normal fetal monitoring. If there is doubt as to fetal well-being after using the unit, further investigations should be undertaken immediately using alternative techniques.***
	***This equipment must not be modified.***

1.2 Patient Applied Parts

As defined in IEC60601-1:2005, the patient applied parts of the Sonicaid Dopplers are the ultrasound probes.

1.3 Indications for Use

The D920 and D930 ultrasonic Dopplers are indicated for use by qualified healthcare practitioners in primary, acute and community healthcare, for the detection of the fetal heart, to assist diagnosis.

1.4 Positioning

In normal use, the operator may be standing or seated adjacent to the patient within reach of the device controls and probe, and with the display clearly visible.

2. Introduction

2.1 Unpacking / Preliminary Checks

Contents

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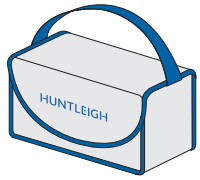
<td> 
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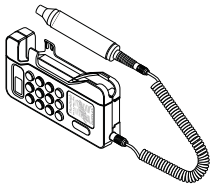
<td>  </td>
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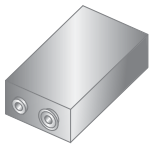
<td>  </td>
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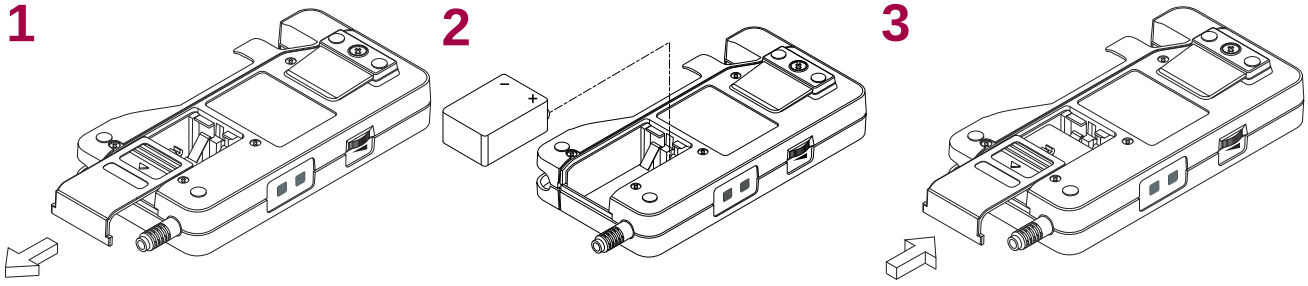
Delivery Inspection

Huntleigh takes every precaution to ensure that goods reach you in perfect condition. However, accidental damage can occur in transit and storage. For this reason we recommend that a thorough visual inspection is made immediately the unit is received. Should any damage be evident or any parts missing, ensure that Huntleigh or your distributor is informed at once.

Storage

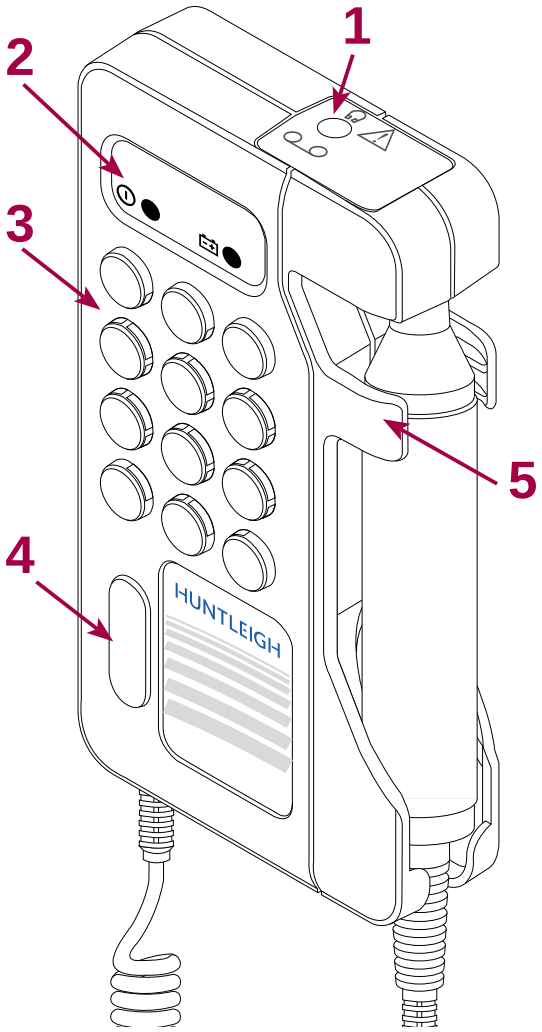
Should the unit not be required for immediate use, it should be re-sealed into its original packing after carrying out the initial delivery inspection, and stored as specified in Section 5.4.

2.2 Battery Insertion / Relacement

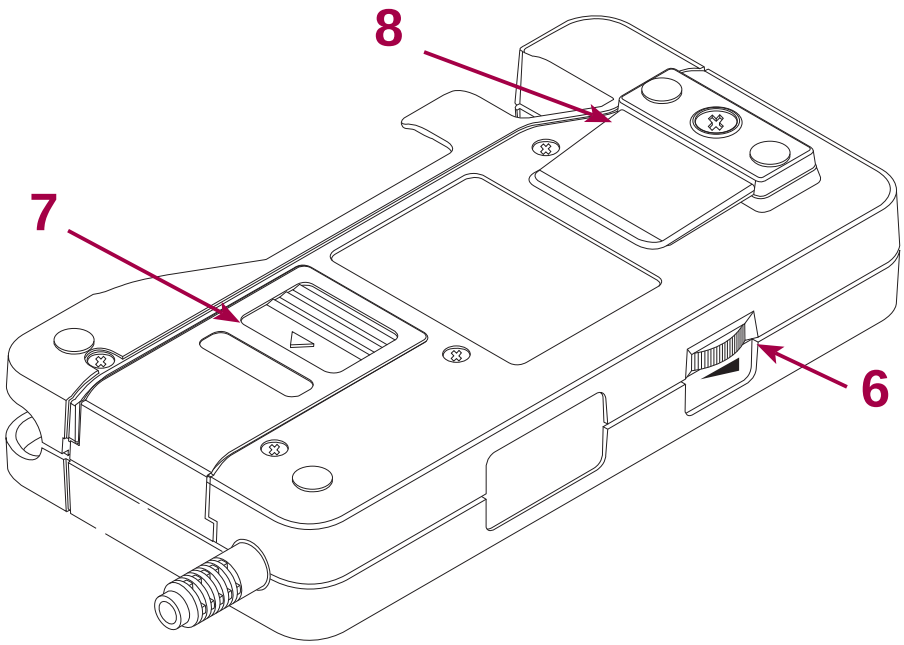


Note: Remove the battery if the unit is not likely to be used for some time.

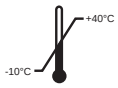
2.3 Product Controls



1	Headphone Socket
2	LED Panel
3	Loud-speaker
4	On/Off Button
5	Probe Holder
6	Volume Control
7	Battery Compartment
8	Pocket Clip



2.4 Product Labelling

	Applied parts (ultrasound probes) are type BF according to the definitions in IEC60601-1:2005		
	This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.		
	General warning Attention, consult accompanying documents / Instructions for Use		
 0088	This symbol signifies that this product complies with the essential requirements of the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC		
Rx Only	Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.		
IP20	Protected against ingress of solid foreign objects >12.5mm diameter. Not protected against ingress of water.		
	Power On/Off		Battery
	Manufacturer	**DI**	Device Identifier
	Volume		Headphone Socket
	Temperature Limitations	**"MAX 93% RH"**	Limits of Relative Humidity
SN	Serial Number	**REF**	Reference Number
	Keep Dry		Do not use hook
	Fragile		Cardboard packaging can be recycled.
	Limits of Atmospheric Pressure		

Note: Product labelling should be read from a distance of no greater than 0.7m.

3. Operation

Note: During use, an automatic noise reduction feature operates on low level signals to improve sound quality.

LED Indicators

Green LED - indicates power ON
Yellow LED - flashes when battery is low

Coupling Gel

Use water based ultrasound gel ONLY.

3.1 Obstetric Mode

Obstetric Probes

Two probes are available for obstetric examinations:

OP2XS	**2MHz ±1%**
OP3XS	**3MHz ±1%**

Audio / Flexi Dopplex (D920/D930)

Both the Audio Dopplex and the Flexi Dopplex have fixed waterproof probes (IPX7) for underwater use.

⚠ ***The D920/D930 main unit is not waterproof and must not be immersed.***

Clinical Use

Apply a liberal amount of gel to the abdomen*. Place the faceplate of the probe flat against the abdomen above the symphysis pubis. Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Avoid sliding it over the skin.

In early pregnancy a full bladder may improve sound detection. In later pregnancy the best signals are generally located higher on the abdomen. The fetal heart sounds like a galloping horse at approximately twice the maternal rate. A wind-like sound is heard from the placenta.

The Dopplex units can detect fetal heart sounds from as early as 9 to 10 weeks gestation.

Note that early detection (9-12 weeks) is highly depedent on operator skill and other factors and may not always be possible.

**Note: For D920/D930 : Gel is not required when probe is used underwater.*

3.2 After Use

1. Press and release the On/Off button. If you forget to switch the unit off, it will automatically shut-off after 5 minutes.

2. Refer to the cleaning section before storing or using the unit on another patient.

3. Store unit together with probe and accessories in the soft carry case provided.

4. Care and Cleaning

4.1 General Care

All Huntleigh products have been designed to withstand normal clinical use, however they can contain delicate components, for example the probe tip, which should be handled and treated with care.

Periodically, and whenever the integrity of the system is in doubt, carry out a check of all functions as described in the relevant section of the IFU. If there are any defects to the housing contact Huntleigh or your distributor for repair or to order a replacement.

⚠	***Please ensure that you check with your facility's local infection control policy and medical equipment cleaning procedures.***
⚠	***Observe warnings and guidance on cleaning fluid labelling regarding use and personal protective equipment (PPE).***
⚠	***Do not use abrasive cloths or cleaners.***
⚠	***Do not use automatic washers or autoclaves.***
⚠	***Phenolic detergent based disinfectants, solutions containing cationic surfactants, ammonia based compounds or perfumes and antiseptic solutions such as Steriscol or Hibiscrub should never be used.***
⚠	***If detergent or disinfectant wipes are used ensure that excess solution is squeezed from the wipe prior to use.***
⚠	***Do not allow any fluid to enter the products and do not immerse in any solution. (Except D920/D930 probes).***
⚠	***Always wipe off disinfectant using a cloth dampened with clean water.***

4.2 General Cleaning and Disinfecting

Always keep the external surfaces clean and free of dirt and fluids using a clean dry cloth.

1. Wipe any fluids from the surface of the product using a clean dry cloth.
2. Wipe with a cloth dampened in 70% Isopropyl Alcohol.
3. Completely dry with a clean, dry lint free cloth.
4. If the product has been contaminated use the methods described for patient applied parts.

4.3 Cleaning and Disinfecting Patient Applied Parts

Clean the probes before examining a patient using low risk cleaning method below.
Following patient examination, clean and/or disinfect the probes by the appropriate method based upon the level of cross contamination risk, as defined below:

Risk	Definitions	Procedure
Low	Normal use or low risk situations include patients having intact skin and no known infection and the probes have not been contaminated with blood.	1. Remove soiling, wipe with a mild neutral detergent and then wipe with a cloth dampened in water. 2. Completely dry with a clean lint free cloth.
Medium	The patient has a known infection, skin is not intact, the part is heavily soiled, or the patient has given birth in a water bath.	1. Follow low risk procedure then wipe with a cloth dampened in Sodium Hypochlorite (1,000ppm). 2. After two minutes wipe with a cloth dampened in water and then dry with a clean lint free cloth.
High	This procedure should only be used when the part has been contaminated by blood.	1. Follow low risk procedure then wipe with a cloth dampened in Sodium Hypochlorite (10,000ppm). 2. After two minutes wipe with a cloth dampened in water and then dry with a clean lint free cloth.

Warning: Sodium Hypochlorite @ 10,000 ppm for disinfecting should only be used in situations described in the High Risk definition. Unnecessary use of this concentrated solution for Low and Medium risk situations may result in damage to the product. Do not allow Sodium Hypochlorite solutions to come into contact with metal parts.

The use of disinfectant materials other than those listed is the responsibility of the user for their efficacy and compatibility with the device.

4.4 Maintenance and Repair

Inspection is recommended each time the product is used, paying particular attention to the tip of the probes, checking for cracks etc., and to the cable and connector. Any crackling or intermittent behaviour should be investigated.

This product does not require periodic maintenance.

Suitable test equipment and a full range of spare parts are also available. Please refer to service manual for further information and part numbers.

A full technical description is provided in the Service Manual 726374.

Warning: Servicing cannot be performed while the unit is in use.

5. Specifications

5.1 Equipment Classification

Type of protection against electric shock.	Internally powered equipment
Degree of protection against electric shock 	Type BF - equipment with an applied part. 
Mode of operation.	Continuous
Degree of protection against harmful ingress of particles and/or water.	Hand Unit: IP20 * D920/D930 probes : IPX7
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE

5.2 Standards Compliance

IEC60601-1: 2005 + C1 + C2
IEC60601-1-11: 2015
IEC60601-2-37: 2007
IEC60601-1-2: 2014
EN 60601-2-37: Thermal Indices (TI) and Mechanical Index (MI) are below 1.0 for all device settings.

**** For homecare use, this can be upgraded to IPX2 by using the Protective Pouch (ACC-OBS-080).***

5.3 General

Max. Audio Output (Loudspeaker)	500mW rms typical
Auto shut-off	After 5 minutes continuous operation
Headphones	Max. output Power: 25 mW rms (32Ω) Connector: 3.5mm stereo jack socket Max. applied voltage: +9Vdc
Battery Type	IEC 6LR61 or IEC 6LP3146
Battery Life	Typically, 500 x 1 minute examinations
Size	Height 140mm, Depth 27mm, Width 74mm
Weight	295g
Service Life	7 years

5.4 Environmental

WARNING: The main unit enclosure does not provide protection from water ingress. For homecare use, we recommend the use of a protective pouch (ACC-OBS-080). However, this will not protect the unit from immersion in liquids.

Operating	
Temperature range	+5°C to +40°C
Relative Humidity	15% to 93% (non condensing)
Pressure	700hPa to 1060hPa

Transport and Storage between uses	
Without relative humidity control	-25°C to +5°C
At a relative humidity of up to 93% non-condensing	+5°C to +35°C
At a water vapour pressure up to 50hPa	>+35°C to +70°C

5.5 Accessories

Item	**Part No**
Protective Pouch	ACC-OBS-080

6. Electromagnetic Compatibility

Make sure the environment in which the Doppler is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, complies with EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

WARNING: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Doppler as replacement parts for internal components, may result in increased emissions or decreased immunity of the Doppler.

WARNING: The Doppler should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Doppler should be observed to verify normal operation in the configuration in which it will be used

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the D920/D930, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the Doppler should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The 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 emissions CISPR 11	Class B	The 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 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	± 8kV contact ± 15kV air	8kV 15kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%, otherwise permanent damage could be caused to the Doppler.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T <95% dip in U_T for 0,5 cycle 40% U_T <60% dip in U_T for 5 cycles 70% U_T <30% dip in U_T for 25 cycles <5% U_T <95% dip in U_T for 5s	N/A	N/A
Power frequency (50/60Hz) 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.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the Doppler should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Doppler, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM bands[a] 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	3V 6V	$d = 1.2\sqrt{P}$ $d = 2.0\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz
			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). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of the 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] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz, to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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 Dopper is used exceeds the applicable RF compliance level above, the Doppler should be observed to verify normal operation. If abnormal performancec is observed, additional measures may be necessary, such as re-orienting or relocating the Doppler.

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

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

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

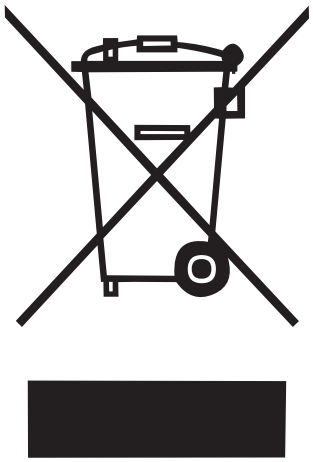
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 80MHz and 800MHz, 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.

7. End of Life Disposal



This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.

8. Warranty & Service

Huntleigh Healthcare Ltd. standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

Service Returns

If for any reason Dopplex unit has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department - D920 / D930'

For further details, refer to NHS document HSG(93)26 (UK only).

Huntleigh Healthcare Ltd reserve the right to return product that does not contain a decontamination certificate.

For service, maintenance and any questions regarding this, or any other Huntleigh Healthcare Dopplex product, please contact:

Service Department.
Huntleigh Healthcare, Diagnostic Products Division,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

Tel: +44 (0)29 20485885
Fax: +44 (0)29 20492520
Email: sales@huntleigh-diagnostics.co.uk
service@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

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The Sonicaid doppler is in conformity with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and has been subject to the conformity assurance procedures laid down by the Council Directive

Manufactured in the UK by Huntleigh Healthcare Ltd.
As part of the ongoing development programme the company reserves the right to modify specifications and materials without notice.

As a proud member of the Arjo family, we have been committed to supporting healthcare professionals in improving outcomes and enhancing patient wellbeing since 1979. We do this through our proven solutions for Vascular Assessment & Treatment and Fetal & Patient Monitoring. With innovation and customer satisfaction as our guiding principles, we strive for clinical excellence and improved performance, for life.

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