

HUNTLEIGH

D900/D920/D930

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

Instrucciones de uso

χρήσης

使用方

Mode d'emploi

Bruksanvisning

Gebruiksaanwijzing

aanwijzing

INSTRUCTIONS FOR USE

Bruksan

alimatları

使用方法

Käyttöohjeet

Instruções de Utilização

Istruzioni per l'uso

Anwendungshinweise

Οδηγίες χρήσης

Anwendungshinweise

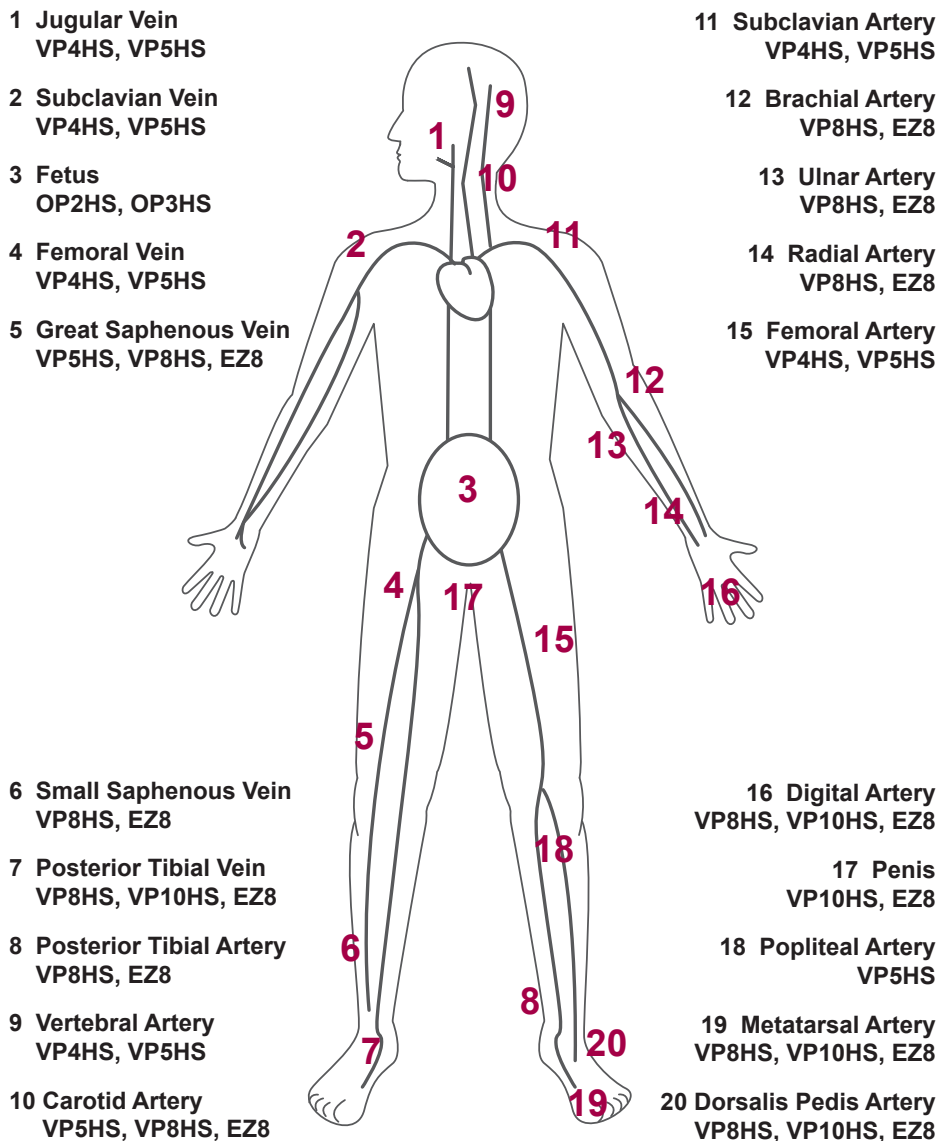
HIGH SENSITIVITY POCKET DOPPLERS

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Doppler Measurement Sites and Recommended Probes



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.

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



Attention, consult this manual. Refer to safety section.



Attention, consult accompanying documents / Instructions for Use

1.1 Warnings



Do not use in the presence of flammable gases such as anaesthetic agents.



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



Any equipment connected to the waveform output socket must be compliant with IEC60601-1:2005.



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 vascular or fetal monitoring. If there is doubt as to vascularity or fetal well-being after using the unit, further investigations should be undertaken immediately using alternative techniques.







1.2 Patient Applied Parts

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

2. Introduction

2.1 Unpacking / Preliminary Checks

Contents

		D900 Only 
		

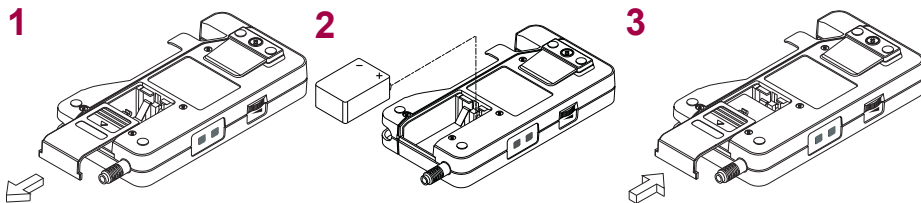
Delivery Inspection

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

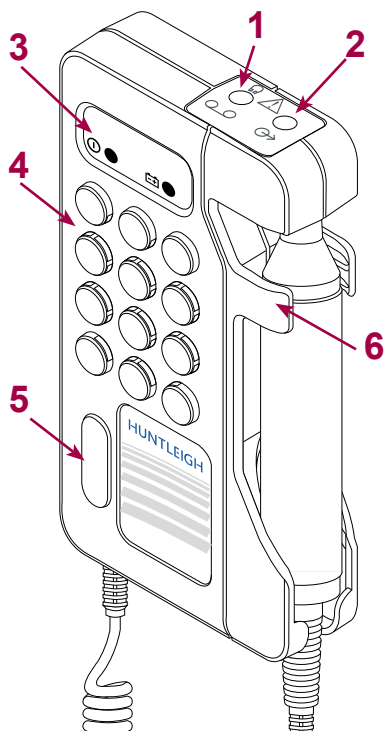
Should the unit not be required for immediate use, it should be re-sealed into its original packing after carrying out the initial delivery inspection, and stored under covered conditions at a temperature between -10°C to $+40^{\circ}\text{C}$, and relative humidity of 10% to 93% non-condensing.

2.2 Battery Insertion / Relacement

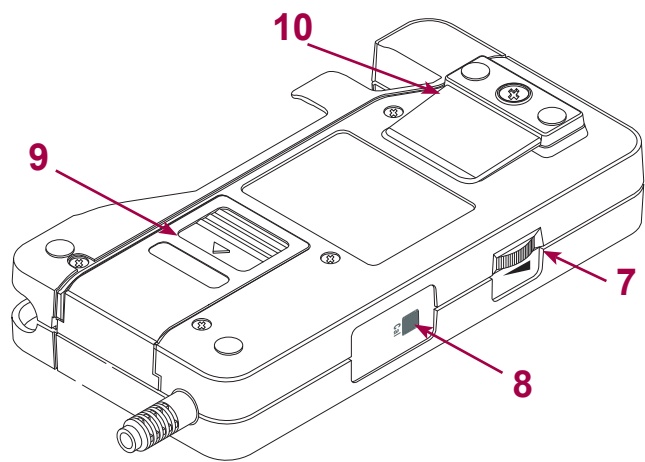


Note: Remove the battery if the unit is not likely to be used for some time.



















2.3 Product Controls



	D900	D920 D930	
1	•	•	Headphone Socket
2	•		Waveform Socket
3	•	•	LED Panel
4	•	•	Loud-speaker
5	•	•	On/Off Button
6	•	•	Probe Holder
7	•	•	Volume Control
8	•		Cal Button
9	•	•	Battery Compartment
10	•	•	Pocket Clip



2.4 Product Labelling

	Applied parts (ultrasound probes are type B according to the definitions in IEC60601-1:1988)		
	Power On/Off		Battery
	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.		
	Attention, consult this manual. Refer to safety section.		
	Attention, consult accompanying documents / Instructions for Use		
	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		
	Alignment mark		Waveform Output Socket
	Volume		Headphone Socket
	Temperature Limitations	"MAX 93% RH"	Limits of Relative Humidity
	Serial Number		Reference Number
	Keep Dry		Do not use hook
	Fragile		Cardboard packaging can be recycled.

3. Operation



Refer to diagram on page 3 for Doppler Measuring sites and Recommended Probes.

To connect the probe, align the arrow on the connector with the slot on the probe and push firmly.

To disconnect the probe, pull the connector sharply. DO NOT pull the cable.

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 Vascular Mode (D900 Only)

The D900 will select vascular mode when a vascular probe is connected to the control unit.

Vascular Probes

Five probes are available for vascular examinations:

VP4HS	4MHz $\pm 1\%$ for deep lying vessels
VP5HS	5MHz $\pm 1\%$ for deep lying vessels and oedematous limbs
VP8HS	8MHz $\pm 1\%$ for peripheral vessels
VP10HS	10MHz $\pm 1\%$ for specialist superficial applications.
EZ8	8MHZ $\pm 1\%$ "Widebeam" for peripheral vessels.

Clinical Use

Apply a liberal amount of gel on the site to be examined. Place the probe at 45° to the skin surface over the vessel to be examined. Adjust the position of the probe to obtain the loudest audio signal. High pitched pulsatile sounds are emitted from arteries while veins emit a non-pulsatile sound similar to a rushing wind.

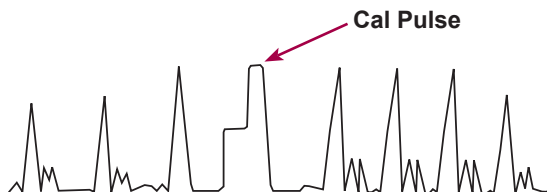
For best results, keep the probe as still as possible once the optimum position has been found. Adjust the audio volume as required.

Waveform Recording - D900 Only

The D900 can be connected to a chart recorder by using a suitable lead that plugs into the Waveform socket. (For more information on the chart recorder, refer to the manufacturer's handbook).

Cal Function

The baseline and sensitivity of the chart recorder can be set up using the Cal function. This generates a zero velocity baseline and a sequence of pulses as shown below:



Two levels of calibration pulses are provided. While Cal is active, calibration tones synchronised to the calibration pulses are superimposed on the audio signal.

If the button is pressed and held, then the calibration sequence is repeated. When the calibration sequence is complete, normal operation is resumed.

3.2 Obstetric Mode

D900 only

Obstetric mode is automatically selected when an obstetric probe (OP2HS/OP3HS) is connected to the control unit.

In this mode the waveform output and Cal function are disabled.

Obstetric Probes

Two probes are available for obstetric examinations:

OP2HS	2MHz $\pm 1\%$
OP3HS	3MHz $\pm 1\%$

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 dependent 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.*

3.3 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.

5. Specifications



5.1 Equipment Classification

Type of protection against electric shock.	Internally powered equipment
Degree of protection against electric shock 	Type B - equipment with an applied part. 
Mode of operation.	Continuous
Degree of protection against harmful ingress of particles and/or water.	Hand Unit: Ordinary Equipment D920/D930 probes : IPX7 All other probes (Tip only): IPX1
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: 1988 + A1:1991 +A2:1995

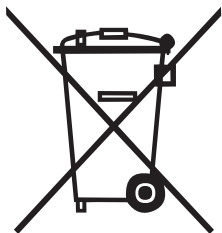
5.3 General

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
Waveform Output (D900 only) 	Zero crosser, 0.5V/kHz, 3.5V full scale Cal levels: 1kHz + 2kHz, Max. applied voltage +9Vdc Connector: 3.5mm mono socket
Battery Type	IEC 6LR61 or IEC 6LP3146
Battery Life	Typically, 500 x 1 minute examinations
Size	Height 140mm, Depth 27mm, Width 74mm
Weight	295g

5.4 Environmental

Operating		Storage
+10°C to +30°C	Temperature range	-10°C to +40°C
10% to 90% (non condensing)	Relative Humidity	93% maximum
860mb to 1060mb	Pressure	860mb to 1060mb

6. 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.

7. 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 - D900 / 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:

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

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The Dopplex 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

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