HUNTLEIGH

D900

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

Instrucciones de uso

χρήσης

使用方法

Mode d’emploi

Gebruiksaanwijzing

Bruksanvisning

INSTRUCTIONS FOR USE

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HIGH SENSITIVITY POCKET DOPPLERS

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1. Warnings & Safety

WARNING

Do not use the Mini Dopplex® in the presence of flammable gases such as anesthetic agents.

WARNING

This product is not designed for sterile use.

CAUTION

Do not:

- immerse in any liquid.
- use solvent cleaners.
- use high-temperature sterilizing processes (such as autoclaving).
- use E-beam or gamma radiation sterilization.

CAUTION

Federal law restricts this device to sale by or on the order of a licensed practitioner.

IMPORTANT

Before using your **Mini Dopplex**, please study this manual carefully and familiarize yourself with the controls, displays, features and operating techniques.

CAUTION

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 be identified and eliminated.

1.1 Acoustic Safety

Continuous wave Doppler ultrasound instruments such as the Mini Dopplex have been used extensively for medical diagnosis in the United States for over 25 years. Throughout this period, there have been no reports of adverse effects to patients or instrument operators at the acoustic intensities recommended for diagnostic use. Despite this highly favorable safety experience, available data are not conclusive and the possibility remains that unwanted biological effects might be identified in the future.

Authorities therefore recommend that ultrasound procedures be performed in accordance with the "ALARA" principle, which states that the energy delivered to the patient should always be kept As Low As Reasonably Achievable. With the Mini Dopplex, the transmitted acoustic power is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

Acoustic intensity data ($I_{SPTA.3}$) for probes available for use with the Mini Dopplex are summarized in the following table. The values cited are based on measurements in water using a calibrated hydrophone and are stated as the estimated derated intensities. The derated intensity constitutes the most biologically relevant parameter available since true determinations of actual absorbed dose in tissue would require invasive measurement techniques. The derated intensity is therefore calculated mathematically using a derating factor consisting of a constant (the assumed attenuation coefficient) and allowing for the frequency of the probe and the distance from the probe face to the hydrophone.

The calculated derated intensity values for the Mini Dopplex compare very favorably with previously reported acoustic safety data for Doppler ultrasound instruments and are appropriate for all clinical applications recommended in this manual.

As the operating mode of the Dopplex range of probes is continuous wave, I_{SPPA} figures are not applicable.

Acoustic Output Table, Track1, Non-Auto-Scanning Mode						
Model	Max. Value $I_{SPTA.3}$	Wo	f_c	Z_{sp}	A-6, (Z_{sp})	EBD
VP4HS	92	7.5	4.0	0.8	0.14	0.365 x 0.8
VP5HS	92	8.2	5.0	0.8	0.12	0.365 x 0.8
VP8HS	92	4.0	8.0	0.48	0.026	0.215 x 0.5
EZ8	92	14.3	8.0	0.67	0.064	0.635 x 0.22
VP10HS	92	1.4	10.0	0.48	0.022	0.215 x 0.5

NOTES

1. Measurement uncertainty: varies with probe and measurement
   Random - typically ±20% (max. ±32%)
   Systematic - typically ±6.5% (max. ±8%)

2. Intended Uses: Refer to the Recommended Clinical Applications table.

Definition of Terms

$I_{SPTA.3}$	is the derated spatial-peak, temporal-average intensity (milliwatts per square centimeter)
Wo	is the ultrasonic power (milliwatts)
f_c	is the center frequency (MegaHertz)
Z_{sp}	is the axial distance used to calculate the derated intensity (centimeters)
A-6 (Z_{sp})	is (π/4) x (X-6 x Y-6) where X-6, Y-6 are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6dB dimensions in the X-Y plane where Zsp is found (centimeters)
EBD	are the entrance beam dimensions for the azimuthal and elevational planes (centimeters)

2. Introduction

Thank you for purchasing the Huntleigh Healthcare Mini Dopplex® - an innovative product reflecting our expertise and experience gained through many years of engineering excellence and our commitment to customer satisfaction.

Mini Dopplex uses ultrasound techniques to detect vascular blood flow. The unit is ideal for the busy surgeon, doctor, nurse or other medical professional, providing quality sound for vascular examinations.

3. Recommended Clinical Applications

The following table shows recommended uses for the Mini Dopplex and the type of probe that should be used.

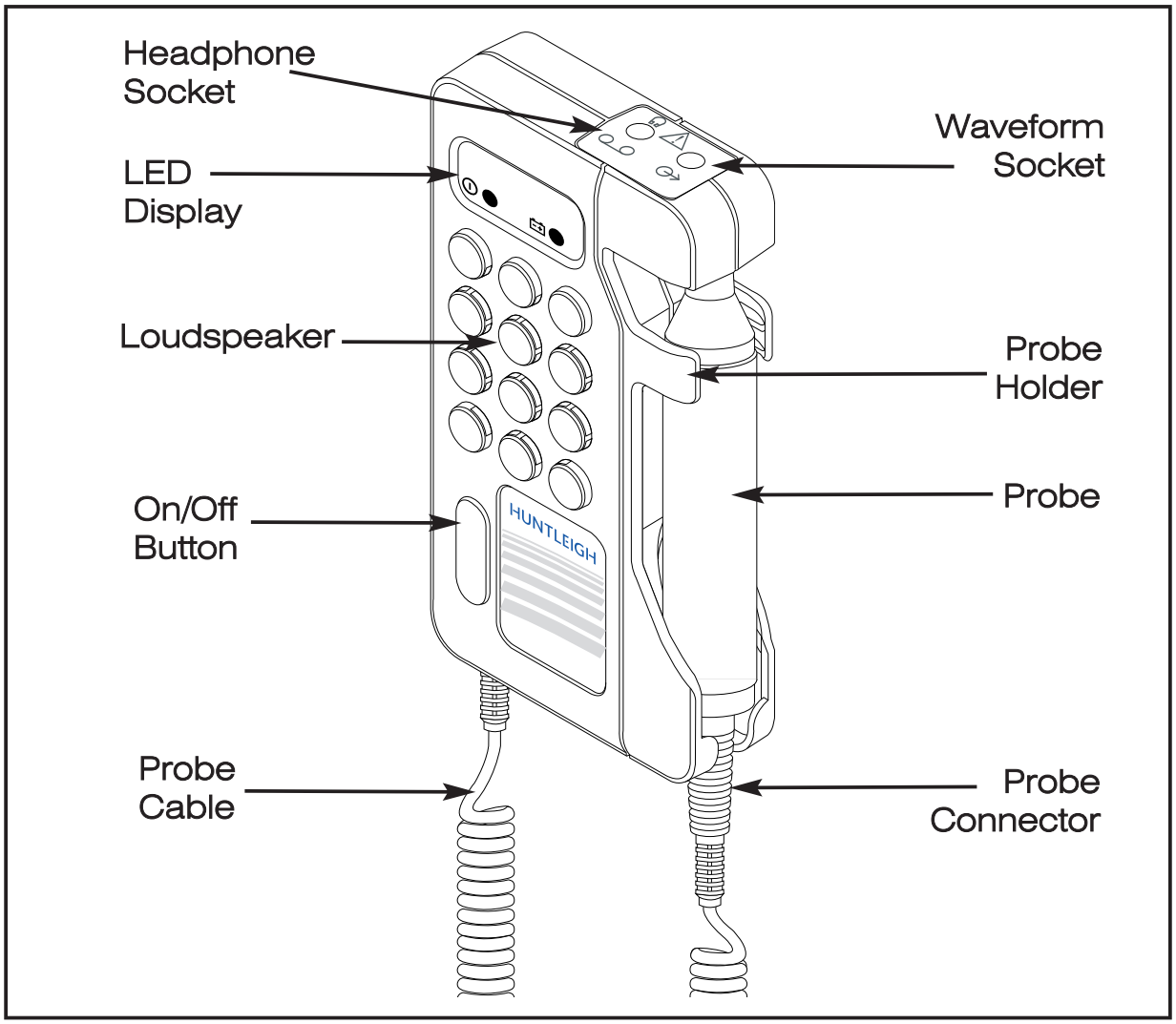
ANATOMIC SITE	PROCEDURE	OBJECTIVE	PROBES
Major arteries: lower and upper limbs.	Pressure studies (segmental gradients & ankle pressure index).	Screening and initial assessment of severity. Localization of occlusions and stenoses.	VP5HS/VP8HS/ EZ8
Major arteries: lower and upper limbs.	Recording of waveforms.	Assessment of occlusions and stenoses.	VP5HS/VP8HS/ VP10HS/EZ8
Major arteries: lower and upper limbs.	Exercise recovery time study. Reactive hyperemia test.	Assessment of occlusions and stenoses.	VP5HS/VP8HS/ EZ8
Major veins: lower limbs.	Evaluation of venous flow patterns using compression.	Screening for venous incompetence.	VP4HS/VP5HS
Carotid arteries.	Recording of waveforms	Detection and assessment of carotid occlusive disease.	VP5HS/VP8HS/ VP10HS/EZ8

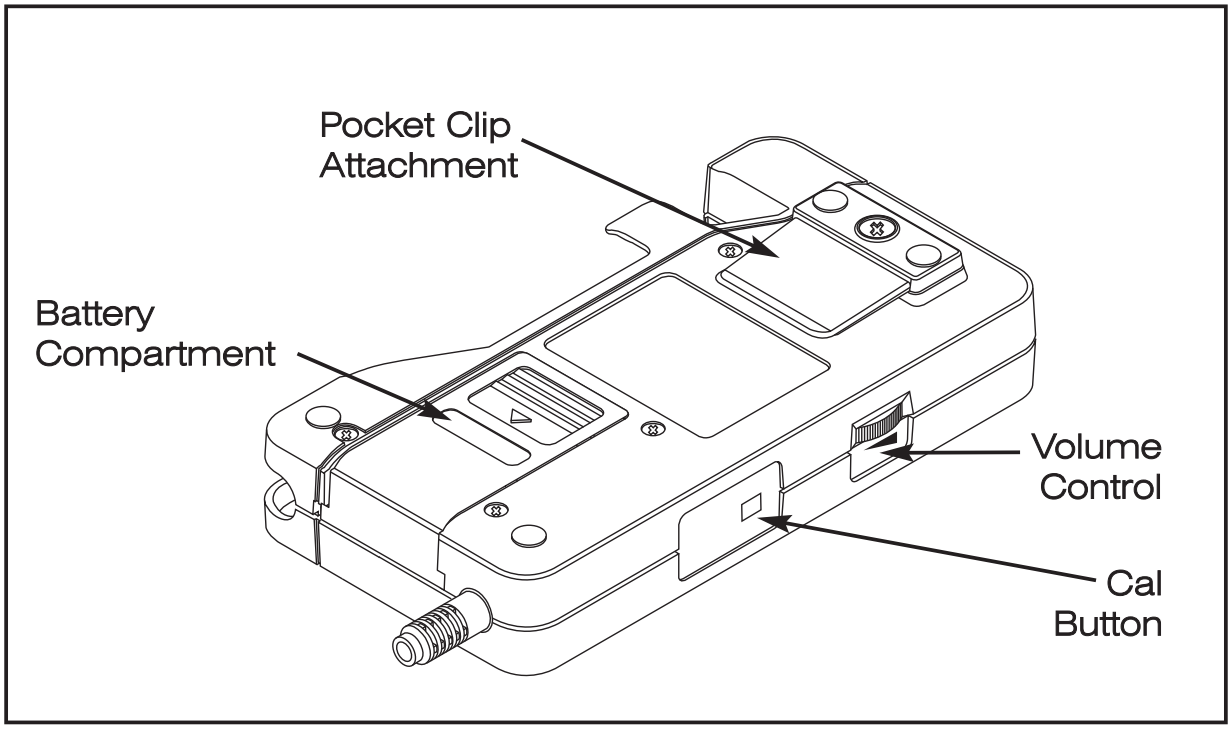
Mini Dopplex is a screening tool to aid the healthcare professional and should not be used in place of normal vascular assessment. If there is doubt as to vascularity after using the unit, further investigations should be undertaken immediately using alternative techniques.

WARNING

The Mini Dopplex should not be used in or around the eye.

4. Product Description





4.1 General

The Mini Dopplex comprises two main parts, connected by a retractile cable.

Probe

The probe contains a sensitive transducer head together with sophisticated electronics to generate the Doppler sounds.

A range of probes is available for the Mini Dopplex : five for vascular applications. See Section 4.2 (Probes).

Main Control Unit

This comprises the battery compartment, LED indicators, microcontroller, audio system and controls.

Doppler signals from the probe are processed, (using a new active noise reduction technique to minimize noise), amplified and output through the integral loudspeaker. Alternatively, an output socket allows private listening with headphones. A volume control provides adjustment of sound level as required.

The LED's provide two status indicators:

Green LED - indicates Power On
Yellow LED - flashes when battery is low.

Battery

Battery life is optimized by an auto shut-off feature after five minutes of continuous use. Efficient battery utilization with Mini Dopplex typically enables 500 one minute obstetric examinations to be performed.

Battery life will vary according to frequency and duration of examinations, volume levels and battery type.

4.2 Probes

A colour coded label around the probe socket denotes its operating frequency.

The probes are fully interchangeable using a push-fit connector. The cable is permanently connected to the control unit.

Vascular Probes

Five probes are available for vascular examinations:

VP4HS	Operates at 4MHz, used for examining deep lying blood vessels: colour code - YELLOW
VP5HS	Operates at 5MHz. This is a general purpose probe: colour code - GREEN
VP8HS	Operates at 8MHz, used for examining peripheral / superficial blood vessels: colour code - GRAY
VP10HS	Operates at 10MHz, used for specialist superficial applications where very high sensitivity is required: colour code - BLUE
EZ8	Operates at 8MHz, "Widebeam" used for peripheral vessels: colour code - GRAY

VP4HS, VP5HS, VP8HS, VP10HS

EZ8

4.3 Modes of Operation

Vascular Mode

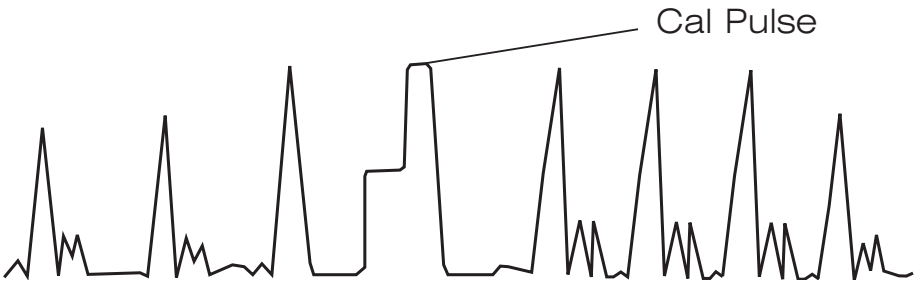
Vascular mode is automatically selected when a vascular probe is connected to the control unit. Blood flow is audible in the loudspeaker or headphones.

Waveform Output

To permit waveform recording during vascular examinations, a chart recorder can be connected to the Waveform jack socket.

Cal Function

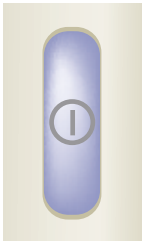
The baseline and sensitivity of the chart recorder can be set up using the **Cal** function. This generates a zero velocity baseline and a sequence of pulses as shown below:



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

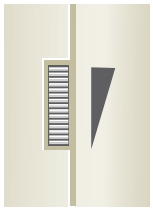
4.4 Controls, Displays and Outputs

Controls



On/Off Button

The ON/Off button is located on the front panel of the **Mini Dopplex**. Press and release to operate.



Volume Control

A rotary control is located on the left-hand side panel of the unit. Clockwise rotation, (towards the top of the unit), increases volume, counter-clockwise rotation, decreases volume.

Cal Button

A membrane push-button is located on the left-hand side panel of the unit.
Press the button to activate the **Cal** function during vascular examinations.

Displays

The GREEN LED indicates that the **Mini Dopplex** is switched ON

When the YELLOW LED flashes, it indicates that the battery charge is low and requires replacement.

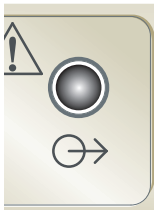
Outputs

The **Mini Dopplex** is fitted with :

Headphone socket

A 3.5mm stereo audio socket* for the connection of suitable headphones. The loudspeaker is muted when headphones are connected.

* Note that the Doppler signal output is mono only.



Waveform Socket

A mono 3.5mm waveform socket for connection to a chart recorder.

5. Installation

5.1 Unpacking

Ensure that the carton contains the items listed:

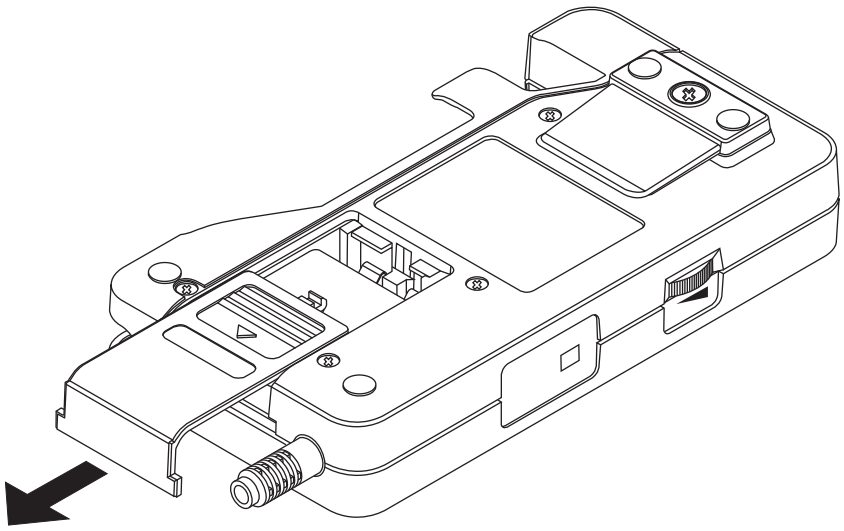
1. Mini Dopplex
2. Warranty card
3. Battery
4. Tube of gel
5. User Manual
6. Probe(s) - as ordered.

If any item is missing or appears to be damaged, contact your supplier.
Note that accessories may vary in certain markets.
Contact your supplier for further information.

5.2 Fitting the Battery

1. Press the cover of the battery compartment, slide it downwards and lift out old battery if replacing.

2. Insert the battery, ensuring the polarity of the new battery corresponds with the + and - signs shown on the battery compartment label.



3. Slide the cover back into position.

If the battery is inserted incorrectly, the Mini Dopplex will not operate, but NO damage to the unit will occur. Simply remove the battery and re-insert with correct polarity.

6. Operating Instructions

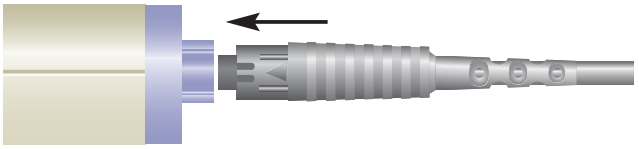
6.1 Preparation

Select Probe

Select the required probe depending on the examination to be performed.

Connect Probe

Connect the probe to the cable. There is an alignment mark on the barrel of the plastic plug at the end of the cable. This corresponds to a mark on the socket in the end of the probe.



To connect the probe, align the two marks, carefully insert the cable plug into the probe socket and push firmly into position.

Apply Gel

Apply a liberal amount of gel on the site to be examined.

Switch ON

Press and release the ON/Off switch, the Green LED will illuminate.

Set Volume

Adjust the volume control to your preferred level.

6.2 Positioning the Probe

Vascular Applications

Place the probe face at 45° to the skin surface over the vessel to be examined. Adjust the position and angle of the probe to obtain the optimum 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.

6.3 Waveform Recording

In vascular assessments, the Mini Dopplex can be connected to a chart recorder, by using a suitable lead, that plugs into the waveform socket on the top panel of the control unit. (For information on the operation of your chart recorder, refer to the appropriate manufacturer's handbook).

6.4 Selecting Cal Function

To calibrate a chart recorder, press the Cal button once while the vascular mode is active, to initiate the Cal sequence. If the button is pressed and held, then the calibration sequence is repeated. When the calibration sequence is complete, normal operation is resumed.

WARNING

The Mini Dopplex waveform output must not be connected to any device at the same time as the headphone output, unless both devices comply with the shock protection requirements of IEC601-1 or equivalent safety standard.

6.5 Battery Management

We recommend that you use a 9 volt alkaline type 6LR61/6LF22 (or equivalent) for cost effective operation, although other battery types, including Ni-Cad rechargeable may be used.

When the battery charge is low, the yellow led will flash, indicating that a new battery will soon be required. If the battery is completely drained, the unit automatically switches off and a new battery must be fitted to restore normal operation.

6.6 Replacing the Battery

Refer to fitting the battery in section 5.2.

WARNING

NEVER dispose of batteries in fire as this can cause them to explode.

NEVER attempt to recharge normal dry-cell batteries. They may leak, cause a fire or even explode.

6.7 After Use

When the examination is finished:

1. Press and release the ON/OFF button. If you forget to switch Mini Dopplex off, the unit will automatically shut-off after 5 minutes to preserve battery life.

2. Refer to the paragraph on Cleaning in Section 7 before storing your Mini Dopplex or using on another patient.

3. Store the Mini Dopplex, together with probes, gel and any accessories in the soft carry case until required.

7. Care of your Mini Dopplex

7.1 Handling

The control unit and the body of the probe are robust and require no special handling. However, the probe faceplate is delicate and must be handled with care. Do not apply excess pressure directly to the probe faceplate. Take great care not to drop the probe or bang the probe tip.

7.2 Maintenance

Other than normal cleaning and replacement of batteries, the Mini Dopplex does not require maintenance.

7.3 Storage

If the Mini Dopplex is to be stored for a long period of time, the battery should be removed.

7.4 Cleaning

Excess gel should always be wiped off after use.

The probe faceplate, probe body and main unit can be cleaned with a damp cloth impregnated with a mild disinfectant or detergent.

Please be sure to check your local control of infection policies or any equipment cleaning procedures.

WARNING

The Mini Dopplex has not been designed for sterile use.

7.3 Coupling Gel

The use of water based gel supplied by Huntleigh Healthcare is strongly recommended. Oil based gels can damage the probe and must not be used. The use of oil based gels will invalidate your warranty.

8. Troubleshooting

Your Mini Dopplex has been designed to a high level of quality and reliability. However, if you should encounter a problem, the table below lists some possible solutions.

SYMPTOM	POSSIBLE CAUSE	REMEDY
No LED illuminated when unit is switched ON	No battery fitted	Fit battery
	Battery dead	Replace Battery
	Battery inserted incorrectly	Remove Battery and replace correctly
No sound from loudspeaker or headphones	Volume control set too low	Re-adjust volume control
	No probe connected	Check probe connection
Excessive frequency of battery replacement	Incorrect battery type	Use alkaline batteries as recommended in Technical Data
Unit shuts down	Battery is dead	Replace battery
	This is normal after 5 minutes use	Refer to After Use in Section 5
No waveform output	Incorrect lead fitted	Replace lead
	Lead connected to wrong socket	Re-insert lead
Headphones not working	Incorrect lead fitted	Replace lead

If the problem persists after trying the above suggestions, please contact your local service center or supplier.

9. Warranty & Service

9.1 Warranty

a) ARJOHUNTLEIGH INC. HEREBY DISCLAIMS ALL EXPRESS OR IMPLIED WARRANTIES (INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND ANY AGREEMENTS, REPRESENTATIONS, AFFIRMATIONS, OR WARRANTIES, WHETHER ORAL OR WRITTEN, MADE BY ANY AGENT, EMPLOYEE OR REPRESENTATIVE OF ARJOHUNTLEIGH INC., UNLESS SPECIFICALLY SET FORTH IN THIS PARAGRAPH. ARJOHUNTLEIGH INC. SHALL NOT BE LIABLE FOR BREACH OF CONTRACT ARISING FROM ANY DEFECT IN MATERIAL OR WORKMANSHIP OF THE GOODS. ALL LEGISLATION RELATING TO EXPRESS AND IMPLIED WARRANTIES OR OTHER OBLIGATIONS ON THE PART OF ARJOHUNTLEIGH INC. THAT MAY BE LAWFULLY EXCLUDED ARE HEREBY EXCLUDED.

b) Notwithstanding the foregoing, ArjoHuntleigh Inc.'s sole warranty is that the Goods shall be free from defects in material and workmanship for a period of three (3) years (excluding probe head and retractile cable which are warranted for one (1) year, following delivery of such Goods to the original purchaser; provided that the Goods were used in an appropriate and reasonable manner during such period and provided further that ArjoHuntleigh Inc. shall be in no event be liable to Customer for defective Goods if: (i) the Goods are damaged in the course of shipping; (ii) any defect is caused wholly or to any material extent by customer's negligence, misuse, failure to use the Goods properly or use of the Goods in conjunction with any accessory not approved for use with the Goods by ArjoHuntleigh Inc.; (iii) the Goods are damaged as a result of improper maintenance, failure to follow manufacturer's instructions, including without limitation those on washing and cleaning, or failure to follow necessary routine maintenance procedures; or (iv) the Goods are altered, repaired or dismantled other than with manufacturer's written authorization using its approved procedures or by any party other than manufacturer's properly qualified and trained technicians.

c) Customer must provide written notice to ArjoHuntleigh Inc., within said warranty period of any defect in the Goods. Upon ArjoHuntleigh Inc.'s written request, Customer must return such Goods adequately packed (in their original packing) and fully insured to ArjoHuntleigh Inc.'s place of business and shall be responsible for all shipping costs incurred therein.

Customer's exclusive remedy and ArjoHuntleigh Inc.'s exclusive liability for any claim for loss, damage or destruction resulting from any defects in materials and workmanship shall be limited to repair, service, adjustment or replacement (at ArjoHuntleigh Inc.'s option) of any nonconforming or defective Goods. ArjoHuntleigh Inc. will have a reasonable time to repair, service or replace such Goods. Any Goods returned to ArjoHuntleigh Inc. which are found not to be defective in breach of the warranty in Subsection (b) above, shall be returned to the Customer in the manner described in this subsection.

d) IN NO EVENT SHALL ARJOHUNTLEIGH INC. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING BUT NOT LIMITED TO ECONOMIC LOSS, LOSS OF PROFITS OR SPECIAL DAMAGES) ARISING OUT OF OR INCURRED BY CUSTOMER IN CONNECTION WITH THE PURCHASE OF ARJOHUNTLEIGH INC.'S GOODS EVEN IF ARJOHUNTLEIGH INC. HAS BEEN ADVISED OR HAS KNOWLEDGE OF THE POSSIBILITY OR EXTENT OF SUCH DAMAGES SUFFERED OR INCURRED BY CUSTOMER OR ANY END USER AS A RESULT OF OR IN CONNECTION WITH ANY BREACH OF THESE TERMS AND CONDITIONS BY ARJOHUNTLEIGH INC. OR ANY TORT (INCLUDING BUT NOT LIMITED TO STRICT LIABILITY OR NEGLIGENCE) COMMITTED BY ARJOHUNTLEIGH INC., ITS AGENTS OR REPRESENTATIVES IN CONNECTION WITH THESE TERMS AND CONDITIONS OR ANY CONTRACT WITH CUSTOMER FOR THE SUPPLY OF GOODS.

e) Customer shall not create, directly or indirectly, any warranty obligations on the part of ArjoHuntleigh Inc. to the customers of Customer, and in particular, without limiting the foregoing, Customer agrees not to pass on to its customers any warranties beyond or in addition to those given by ArjoHuntleigh Inc. to Customer hereunder. Where the Customer is a dealer in the Goods, it shall be responsible for the labor cost of all repairs and ArjoHuntleigh Inc. shall be responsible for providing all repair parts during said three (3) year (excluding probe head and retractivel cable which are warranted for one (1) year). The dealer shall provide written verification of warranty repairs including the original invoice number, date of purchase, description of repairs, name of its customer and date of sale to such customer.

f) Customer shall be deemed to have full knowledge of the nature and properties of the Goods ordered and of any hazards they involve and the proper treatment, storage and handling thereof. Any technical advice furnished by ArjoHuntleigh Inc. or its representatives or agents is given only on the basis that it is followed at the Customer's own risk.

9.2 Service Returns

If for any reason your Mini Dopplex is being returned, please:

1. Clean the product, following the instructions in Section 6.

2. Pack it in suitable packing.

3. Attach decontamination certificate, (or other written statement declaring that the product has been cleaned), to the outside of the package.

4. Mark the package "Service Department - Mini Dopplex".

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

ArjoHuntleigh Inc.
2349 West Lake Street,
Addison,
IL 60101 USA

Tel: (800) 223-1218

or your local distributor.

10. Technical Data

Product Name:	Mini Dopplex
Model Number:	D900
Size - Control Unit:	Height: 140 mm (5.5”) Width: 74 mm (2.92) Depth: 27 mm (1.1”)
Weight:	295 gms (10oz) including one probe & battery
Max Audio Output Power:	500 mW rms typical
Max. Headphones Output Power:	25 mW rms max. (32 Ω headphones) (max. applied voltage +9Vdc)
Waveform Output Scale:	Zero Crosser, 0.5V/kHz (±10%), 3.5V full scale.Cal levels: 1KHz +2KHz (±1%) (max applied voltage +9Vdc)
Auto Shut-off:	After 5 minutes continuous operation
Display:	LED indicators
Case Material:	ABS Polycarbonate alloy
Battery Type Recommended:	9 volt alkaline manganese - 6LR61, 6LF22 or equivalent (e.g. MN1604)
Battery Voltage:	9V nominal
Battery Life:	Typically, 500 x 1 minute examinations (depending on use and battery type)
Probe Transmitter:	Frequencies: VP4HS: 4.0MHz ±1% VP5HS: 5.0MHz ±1% VP8HS: 8.0MHz ±1%: VP10HS: 10.0MHz ±1% EZ8: 8.0MHz ±1%
Effective Area of Active Transmitter Element:	VP4HS, VP5HS: 22mm² (±15%) VP8HS, VP10HS: 8mm² (±20%) EZ8: 16mm² (±15%)
Gel:	Viscous aqueous non-sensitizing, hypo-allergenic and non irritating to skin. Indefinite shelf life, bacteriostatic (non sterile).
Complies With:	BS5724 : PART 1 : 1989 IEC60601-1 : 2005+A1: 2012

IEC601-1 Classification	
Type of shock protection	Internally powered equipment
Degree of shock protection	Type B Equipment
Protection against water ingress	Ordinary equipment
Degree of safety in presence of flammable gases	Equipment not suitable for use in presence of flammable gases

Mode of Operation:	Continuous
Operating Temperature:	10°C to 30°C (50°F to 86°F)
Storage Temperature:	-10°C to +40°C (14°F to 104°F)

10.1 Symbol Identification

CE 2797	This symbol signifies that this product complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745)		
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden		
Manufactured By:		Huntleigh Healthcare Ltd. 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com	
	Applied part is type B		Attention: consult this manual. Refer to safety section.
DI	Device Identifier	**RX Only**	Caution: Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.
REF	Reference number		Waveform Output Socket
	Class II Double Insulated		Headphone Socket
	Power On/Off		Battery
	Volume		Alignment Mark

Manufactured in the UK by Huntleigh Healthcare, Diagnostic Products Division.
Dopplex® and the 'H' logo are registered trademarks of Huntleigh Technology Ltd.

As part of the ongoing development program, the company reserves the right to modify specifications and materials of the Mini Dopplex without notice.

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If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Manufactured in the UK by Huntleigh Healthcare Ltd on behalf of;

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