EN

INSTRUCTIONS FOR USE

DMX

Digital Handheld Doppler

Instructions for Use

772637-05 2026-03

HUNTLEIGH

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INSTRUCTIONS FOR USE DMX

Contents

1. Introduction

The DMX is a multi-function, battery powered, hand-held Doppler intended for vascular use. It is compatible with Huntleigh's full range of 'XS' interchangeable probes.

By the addition of a Photo Plethysmography (PPG) Probe, the Doppler can be used in determining the Ankle Brachial Pressure Index (ABPI), or Toe Brachial Pressure Index (TBI), for the detection of Peripheral Artery Disease (PAD).

This equipment is for use only by suitably qualified healthcare practitioners and is not intended for use by the patient.

Before using this equipment, study this manual carefully and familiarise yourself with the controls, display features and operation.

Experience with use of ultrasonic dopplers is preferable, but for novice users training material is provided with the online documents. Exposure to ultrasound should be kept As Low As Reasonably Achievable - (ALARA guidelines).

Scan the QR code on the rear cover of this IFU with a smartphone, or visit the Huntleigh website for electronic copies of user literature. All documents are available to download as PDF files. To read them, you must have a PDF reader installed on your device. Alternatively paper copies are available upon request.

1.1 Unpacking / Preliminary Checks

On receipt of your Doppler, check that all items are present and undamaged. If items are missing or have been damaged in transit, inform Huntleigh Healthcare immediately.

Digital Handheld Doppler	IFU (this document)	Batteries
Charger & USB lead*	Ultrasound Gel	Carry bag

*selected Dopplers

2. Safety ⚠

2.1 Warnings

- Dopplers are screening tools to aid the healthcare professional. If there is doubt as to vascular status, further investigations should be undertaken immediately using alternative techniques.
- Do not use in the presence of flammable gases.
- Do not use in a sterile field* unless additional barrier precautions are taken.
- Do not sterilise the product or its accessories*. The product will be damaged.
- Do not expose to excessive heat, including prolonged exposure to sunlight.
- Do not dispose of batteries in fire as this can cause them to explode.
- The Doppler is not waterproof and must not be immersed.
- This product contains sensitive electronics, which are susceptible to interference, this will be indicated by unusual sounds.
- Any equipment connected to the USB port must be compliant with IEC 60601-1.
- This equipment must not be modified.

*Note: *Does not apply to Intraoperative Probe. Refer to Intraoperative Probe IFU for details on cleaning/ sterilisation processes.*

2.2 Patient Applied Parts

As defined in IEC 60601-1, the patient applied parts of the DMX Doppler are the ultrasound probes, PPG sensors and cuffs.

2.3 Intended Use & Indications

The Doppler is intended for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the assessment of vascular blood flow, to assist in diagnosis.

It is indicated for the assessment of blood flow and direction, within veins and arteries, by audible and visual means.

2.4 Contraindications

- Do not use on broken or fragile skin.
- Do not use on the eye.

2.5 Patient Population

The DMX is suitable for use on all patient populations.

3. Warranty & Service

Huntleigh Healthcare Diagnostic Products Division 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: To return the Doppler:

- 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. (Huntleigh Healthcare Ltd reserve the right to return product that does not contain a decontamination certificate).
- Mark the package ‘Service Department‘.

3.1 Service Life

This is defined as the period during which the device is expected to remain safe and suitable to meet its intended use, and all risk control measures remain effective.

The service life for this device is seven years.

3.2 Maintenance and Repair

There are no user serviceable parts inside the Doppler unit or probes. This product does not require periodic maintenance. 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. Any unusual sounds or intermittent behaviour should be investigated.

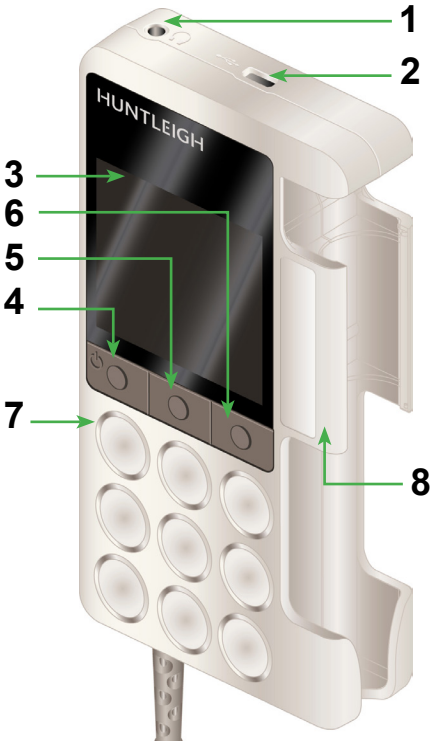
Spare parts are available. Please refer to service manual for further information and part numbers.
A full technical description is provided in the Service Manual 772490.

Caution ⚠

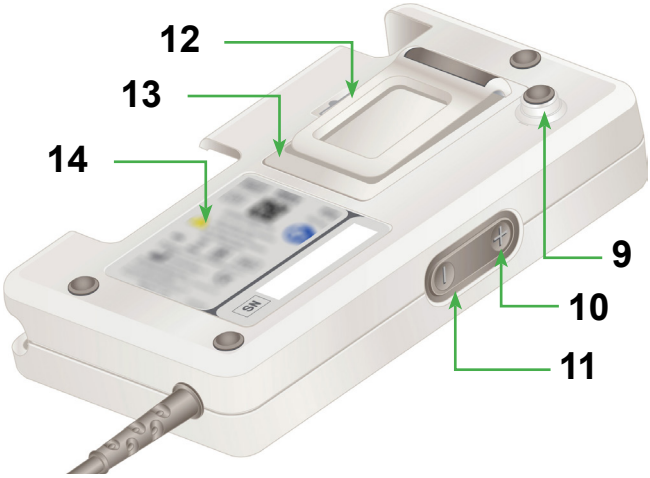
Servicing cannot be carried out while the Doppler is in use.

4. Product Identification

4.1 Product Controls



1	Headphone Socket
2	USB Port
3	LCD Panel
4	Function Button 1 / On/Off Button
5	Function Button 2
6	Function Button 3 / Setup
7	Loudspeaker
8	Probe Holder
9	Trolley Mount
10	Volume Up
11	Volume Down
12	Pocket Clip
13	Battery Compartment + Micro SD Card Slot
14	Rear Panel Label



4.2 Symbol Identification

	Applied parts are type CF (As defined by IEC60601-1)		Applied parts are type BF (As defined by IEC60601-1)
	General Warning		Attention, consult accompanying documents / Instructions for Use
	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.		
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).		
RxOnly	Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.		
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden		
IP20	Protected against ingress of solid foreign objects >12.5 mm diameter. Not protected against ingress of water.		
IPX1	Protected against vertically falling water drops.		
	Power On/Standby		USB Port
DI	Device Identifier	SN	Serial Number
REF	Reference Number	MD	Medical Device
	Fragile		Keep Dry
	Atmospheric Pressure Limitations		Relative Humidity Limitations
	Temperature Limitations		Cardboard packaging can be recycled
	LATEX FREE Does not contain Latex		PVC FREE Does not contain PVC
	Headphone Socket		Alignment mark
	Volume Up		Volume Down
	Contents can be recycled		

Note: Product labelling should be readable from a distance of up to 0.7m.

4.3 Display Status Bar

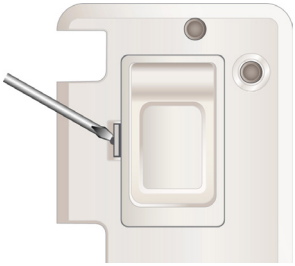
The Status Bar appears at the top of most screens, the information displayed depends on the operating mode.

Status Bar Icons			
	Battery Level Low		Date / Time
	USB Connected		Probe Type
	Forward Flow (Flow towards probe)		Reverse Flow (Flow away from probe)
	Arterial Mode		Venous Mode
	Heart Rate Indicator		

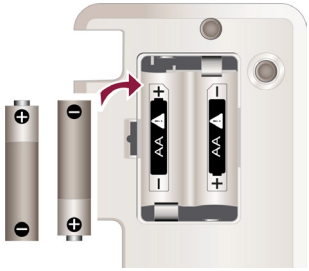
5. Prepare the Doppler for Use

5.1 Battery Insertion / Replacement

Disconnect the Doppler from other equipment before removing the battery cover.



Insert a suitable tool into the recess, release the clip and gently lever off the battery cover.



Insert the batteries according to the diagram, observing polarity.

- **Use either alkaline LR6 (non-rechargeable) or NiMH HR6 (rechargeable) batteries.**
- **Do not mix rechargeable and non-rechargeable batteries.**

Note: If the Doppler will not be used for an extended period, remove the batteries.

5.2 Probe Connection

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

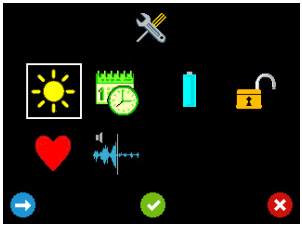
To disconnect the probe, pull the connector from the probe. DO NOT pull the cable.

5.3 Change the Doppler Settings

5.3.1 Setup Screen

Note: A probe must be connected before the Setup Screen can be accessed.

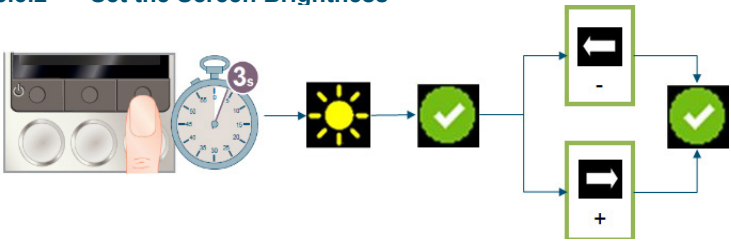
Press  to turn the unit ON, then press and hold button 3 to enter Setup mode.



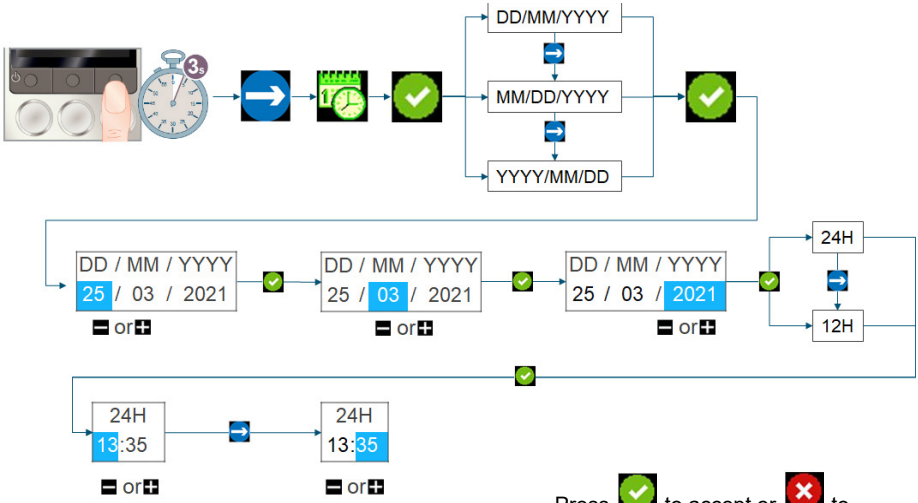
Setup Screen Icons			
	Brightness		Date and Time Setup
	Battery type Selection		Lock screen

Press Button 1  to move the selection, Button 2  to accept, Button 3  to exit menu.

5.3.2 Set the Screen Brightness

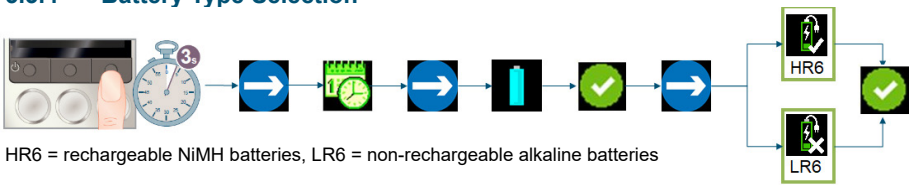


5.3.3 Set the Date and Time



Press to accept or to discard the changes.

5.3.4 Battery Type Selection



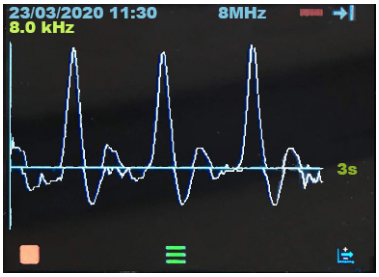
HR6 = rechargeable NiMH batteries, LR6 = non-rechargeable alkaline batteries

6. Operation

Press  and hold for one second to turn the unit ON.

6.1 Clinical Use

Apply a liberal amount of water based ultrasound 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. Additional icons appear in the Setup mode.

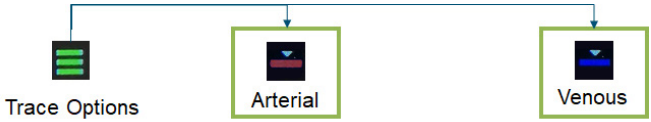


Setup Screen Icons	
	Freeze Trace
	Trace Options
	Set Timebase

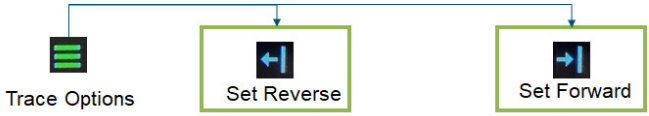
6.1.1 Waveform Options

1. Freeze Live trace screen (refer to Frozen Trace section 6.3)

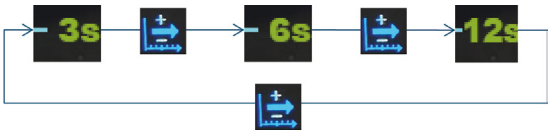
2. Switch between Venous and Arterial Modes



3. Switch between Forward and Reverse Flow

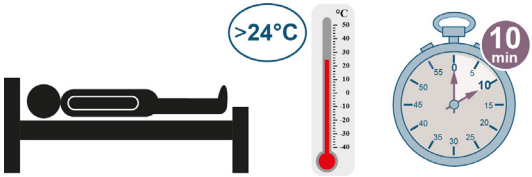


4. Select Timebase



6.1.2 Measure Doppler Pressures

Patient Preparation

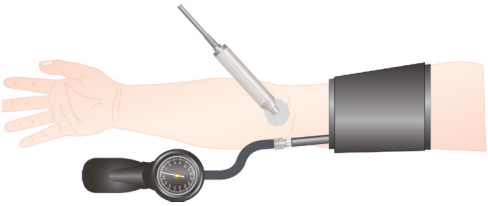


Pressure measurements rely on a bulb inflation / valve deflation system in combination with a tube and cuff attachment as shown below.

Brachial Systolic Pressure

Place the cuff on the upper arm approximately 1 - 2 cm above the antecubital fossa. Connect the sphygmomanometer to the cuff.

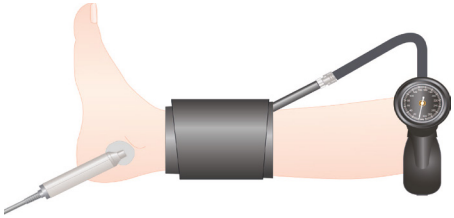
Note: Select a cuff size appropriate for the patient's limb. Ensure that the index marker on the cuff falls within the range marker.



- Palpate the artery.
- Apply a liberal amount of ultrasound gel.
- Place the probe over the vessel at an angle of 45°.
- Move the probe laterally across the limb to locate the strongest audio signal.

- Inflate the BP cuff by compressing the bulb of the sphygmomanometer until the pulse sound disappears and then further inflate by 10 – 20 mmHg.
- Gradually deflate the cuff at a rate of about 2 – 3 mmHg/s. Note the pressure displayed on the sphyg as soon as the Doppler signal is heard.
- For best results, keep the probe as still as possible after the optimum position has been found.

Ankle Systolic Pressure

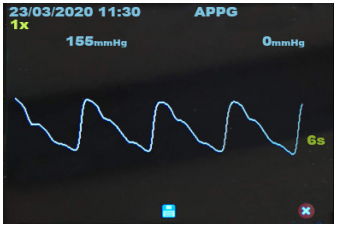


- Place the appropriately sized cuff 1-3 cm above the lateral malleolus
- Connect the sphygmomanometer to the cuff
- Repeat the inflation procedure described above, but this time monitor the desired foot artery (e.g. Posterior Tibial shown).

6.2 Photoplethysmography (PPG) Mode

An arterial PPG probe is available for arm, ankle and toe systolic pressures and PPG waveforms.The PPG probe is attached to the arm, ankle or toe as appropriate, and uses infra-red light to make a relative measurement to detect the return of bloodflow.

6.2.1 APPG Home Screen



APPG Home Screen Icons	
	Freeze Trace
	Change Timebase

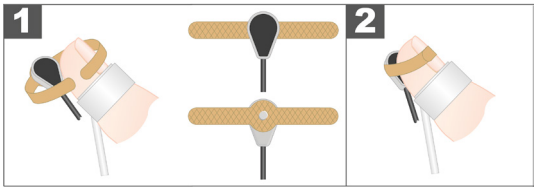
Waveform Options

5. Freeze Trace (Refer to Frozen Trace section 6.3)

6. Select Timebase (Refer to Vascular Timebase section 6.1.1)

6.2.2 Measuring Pressures with PPG

Prepare the patient as described in section 5.1.2. Connect the cuff, sphyg, APPG adaptor and probe as shown:



Once a full screen of regular pulses is displayed, inflate the Cuff slowly.

- As soon as the cuff pressure exceeds 30 mmHg, a deflate bar appears at the top of the screen.

- When no regular traces are visible on the screen, begin to deflate the cuff by lightly squeezing the trigger release valve.

- Keep the deflate line within the green range.

To measure brachial pressure, the cuff is positioned 2-3cm above the antecubital fossa while the ppg probe is placed on any digit of the same arm. Carry out the procedure as described above.

6.2.3 Trace Scroll section

Make sure that the first pulse is aligned with the vertical line.

Note that the left and right arrows move the trace, not the marker line.

Use the arrows to scroll back and forward.

In PPG mode, as the trace moves, the recorded pressure indicator is updated.

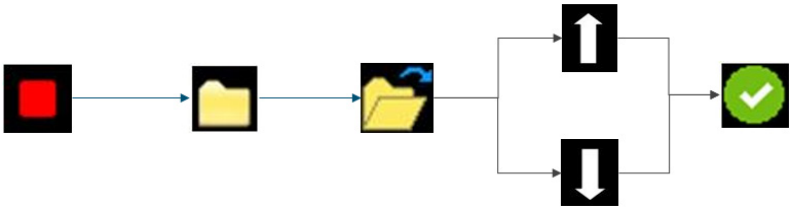
Press Tick when the desired information is displayed.

6.3 Frozen Trace

Press  at any time to return to the live trace screen.

To Save a trace:

To Open a Saved trace:



6.4 Battery Charging

- **Only HR6 (NiMH) batteries can be charged. Check the battery type before connecting the charger.**
- **Do not attempt to recharge normal alkaline batteries. They may leak, cause a fire or even explode.**
- **Only use the charger and USB lead supplied by Huntleigh.**
- **Switch off the Doppler before charging.**
- **Do not use the Doppler on patients when the charger is connected.**

- Insert the supplied charger lead into the USB socket on top of the Doppler.
- Connect the charger and switch on mains power.

Charging will take approximately 5 - 6 hours, depending on battery status.

If the battery level is low, a  symbol will appear on the Status bar.

During charging, a  symbol will be displayed on the screen.

When fully charged, the symbol will change to  .

6.5 Data transfer to a PC

The Doppler does not contain patient information however, stored waveforms and data can be transferred to a PC running Huntleigh reporting software, via the same USB socket as for battery charging. Consult your local sales representative for details.

Note: Please observe the safety warnings in the Huntleigh software IFU.

6.6 After Use

Press and hold the On/Off button for one second to switch the unit off.

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

7. Care and Cleaning

7.1 General Care

The Doppler contains 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 this IFU. If there are any defects, contact Huntleigh or your distributor for repair or to order a replacement.

Caution

- **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).**
- **If detergent or disinfectant wipes are used ensure that excess solution is squeezed from the wipe prior to use.**
- **Always switch off the Doppler and disconnect from the AC supply before cleaning and disinfecting.**
- **Always wipe off disinfectant using a cloth dampened with clean water.**
- **Do not allow any fluid to enter the products and do not immerse in any solution.**
- **Do not use abrasive cloths or cleaners.**
- **Do not use automatic washers or autoclaves.**
- **Do not use Phenolic detergent based disinfectants, solutions containing cationic surfactants, ammonia based compounds or perfumes and antiseptic solutions.**

7.2 Cleaning and Disinfecting the Doppler

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

- **Wipe any fluids from the surface of the product using a clean dry cloth.**
- **Wipe with a cloth dampened in 70% Isopropyl Alcohol.**
- **Completely dry with a clean, dry cloth.**
- **If the product has been contaminated use the methods described for probes.**

7.3 Cleaning and Disinfecting Probes

(Does not apply to IOP8/DIOP8 Intraoperative Probe. Refer to Intraoperative Probe IFU for details on cleaning/sterilisation processes).

Clean the probes before examining a patient using the 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.	1. Remove soiling, wipe with a mild neutral detergent and then wipe with a cloth dampened in water. 2. Completely dry with a clean cloth.
Medium	The patient has a known infection, skin is not intact, the part is heavily soiled.	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 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 cloth.

Caution

Repeated and unnecessary use of concentrated solutions will 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.

Cuffs: Clean the cuffs before examining a patient using the low risk cleaning method below. Following patient examination, clean and/or disinfect the cuffs by the appropriate method based upon the level of cross contamination risk. Before fitting the cuffs to the patient, evaluate the cross-contamination risk according to the definitions in the tables below:

Risk	Definitions	Procedure
Low	Normal use or low risk situations including patients with intact skin and no known infection.	1. Clean with soft cloth and a mild, neutral detergent @ 40°C (104°F) 2. Disinfect using a 70% isopropyl alcohol wipe or chlorine releasing agent @ 1000ppm available chlorine 3. Wipe with a cloth dampened in clean water. 4. Completely dry with a clean lint-free cloth
Medium/ High	The patient has a known infection, or skin is not intact.	Because of the nature of the cuff materials, effective cleaning and disinfection in medium/high risk situations is not practical. Therefore, we recommend to dispose of according to local procedures

Refer to the cuff IFU for cleaning guidance and restrictions.

Caution

- **Do not allow any fluid to enter the cuff tubing.**
- **Do not use alternative cleaning agents or methods as permanent damage is likely.**
- **Inspect cuffs after cleaning and prior to use.**

Cuff Inspection: Cuffs should be regularly inspected. Examine the outer cuff surfaces for material damage, splitting, fraying etc. Make sure that labelling is clearly legible. Check the cuff tubing and connections for damage, splits etc. If in any doubt as to the condition, the cuff(s) should be replaced. In any case, cuffs should be replaced every two years.

Caution

After using chemicals ALWAYS rinse off / remove the chemical with absorbent material, dampened in clean water and dry with a clean cloth.

8. Troubleshooting

This table lists some of the common problems found during use, with possible solutions. If the problem cannot be located after consulting this table, turn off the Doppler and consult a qualified technician.

Before attempting trouble shooting, make sure that the batteries are charged.

SYMPTOM	POSSIBLE CAUSE / REMEDY
Doppler will not turn on.	Replace / re-charge batteries.
Audio Only	Doppler model does not support visual functionality
No Audio signal	Incorrect volume setting
Poor Signal	Probe / sensor incorrectly positioned, or Insufficient Gel
No Signal	Damaged probe / sensor, or Incorrect probe / sensor
Screen displays: 	Damaged probe / sensor, or No Probe
Screen displays: 	Incompatible probe / sensor, or Incorrect Probe / sensor
Screen displays: 	Incorrect battery fitted

9. Specifications

9.1 Equipment Classification

Type of protection against electric shock.	Internally powered equipment	
Degree of protection against electric shock 	 Type BF - equipment with an applied part	 Type CF - equipment connected to PA8XS/ DIOP8 applied part
Mode of operation.	Continuous	
Degree of protection against harmful ingress of particles and/or water.	Main Unit: IP20*, Probes: 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	

*For home use, this can be upgraded to IPx2 when using the protective pouch (ACC-OBS-080).

9.2 DMX Vascular Doppler Performance

Doppler bandwidth (+0; -3 dB)	
VP4XS, VP5XS	170 to 4,600 Hz
VP8XS, EZ8XS	270 to 6,000 Hz
VP10XS	270 to 8,000 Hz
IOP8/DIOP8	110 to 7,400 Hz

Doppler Shift Maximum Frequency Display Error*
Typically < 5%; maximum 10%

Doppler Heart Rate**	
Range	40 – 200 ± 3 bpm

**Measured using a Doppler string phantom in water,*
***Heart rate indications may be unreliable if the signal is weak or irregular*

9.3 ABI and TBI Calculations

Right ABI	$\frac{\text{Highest Pressure in Right Foot}}{\text{Highest Brachial Systolic Pressure}}$	**Right TBI**	$\frac{\text{Highest Pressure in Right Toe}}{\text{Highest Brachial Systolic Pressure}}$
Left ABI	$\frac{\text{Highest pressure in Left Foot}}{\text{Highest Brachial Systolic Pressure}}$	**Left TBI**	$\frac{\text{Highest pressure in Left Toe}}{\text{Highest Brachial Systolic Pressure}}$

9.4 APPG Systolic Pressure Performance

Range	0 - 260 ± 3 mmHg
Resolution	1 mmHg
Indication Type	On-Screen digital numeric display
Pressure Generation / Reduction	Bulb / Manual air release valve

9.5 General

Charger- 'R' models only **(Part No. 772559)**	Protection : Class II ⧈ Input Voltage : 100-240 V AC ±10% Output Voltage : 5VDC ± 5% Input Frequency : 50 - 60Hz Standby power consumption: 230V AC ≤ 0.1W		
Max. Audio Output	500 mW rms typical (loudspeaker)		
Auto shut-off	3 minutes		
Headphone output	Max. output Power: 25 mW rms (32Ω) Connector: 3.5mm stereo jack socket		
USB Port	Micro USB	**SD Card Slot**	Micro SD
Real Time clock battery	RENATA CR1025, 3V Lithium		
Battery Type	LR6 (Alkaline cells 1.5V), HR6 (NiMH rechargeable 1.2V)		
Battery Life	Typically, 500 x 1 minute examinations Note: Battery life is typically 2 years or 500 charge/discharge cycles		
Size	140 x 33 x 75 mm	**Weight**	280 g

9.6 Environmental

Operating	
Temperature range	+5°C to +40°C
Relative Humidity	15% to 90% (non condensing)
Pressure	700 hPa to 1060 hPa
Transport and Storage between uses	
Without relative humidity control	-20°C to +5°C
At a r.h. of up to 90% non-condensing	+5°C to +35°C
At a water vapour pressure up to 50 hPa	>+35°C to +50°C

9.7 Standards Compliance

IEC 60601-1	**IEC 60601-1-11**
EN 60601-2-37 Thermal Indices (TI) and Mechanical Index (MI) are below 0.7 for all device settings.	
BS EN 81060-1	**IEC 60601-1-2**

9.8 Accessories

Use only the recommended accessories.

10. 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). 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 IEC 60601-1-2, 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:

- Reorient the equipment
- Relocate the equipment with respect to the source of interference
- Move the equipment away from the device with which it is interfering

Warnings

- **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.**
- **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.**
- **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 Doppler including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**