HUNTLEIGH

DMX / SRX

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

Instrucciones de uso

χρήσης

使用方

Mode d'emploi

Gebruiksaanwijzing

Bruksanvisning

INSTRUCTIONS FOR USE

使用方法

Käyttöohjeet

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Istruzioni per l'uso

Anwendungshinweise

Οδηγίες χρήσης

Anwendungshinweise

Digital Handheld Dopplers

Contents

Measurement Sites and Recommended Probes

1 Jugular Vein
VP4XS, VP5XS

2 Subclavian Vein
VP4XS, VP5XS

3 Fetus
OP2XS, OP3XS

4 Femoral Vein
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5 Great Saphenous Vein
VP5XS, VP8XS,
EZ8XS

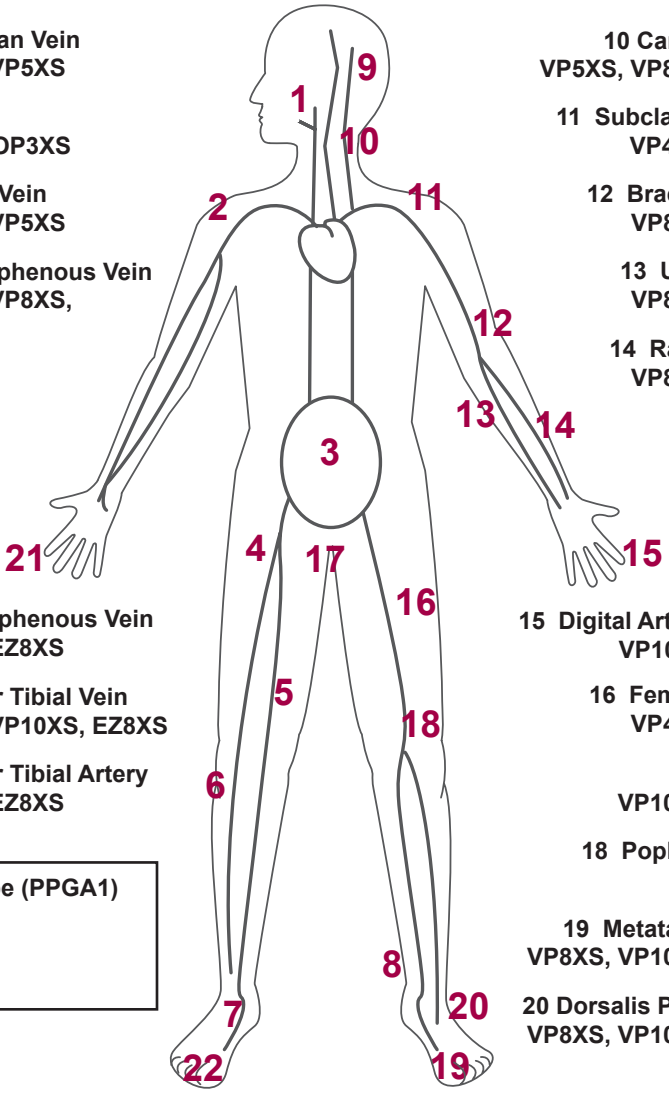
6 Small Saphenous Vein
VP8XS, EZ8XS

7 Posterior Tibial Vein
VP8XS, VP10XS, EZ8XS

8 Posterior Tibial Artery
VP8XS, EZ8XS

PPG Probe (PPGA1)

21 Digits
22 Toes



9 Vertebral Artery
VP4XS, VP5XS

10 Carotid Artery
VP5XS, VP8XS, EZ8XS

11 Subclavian Artery
VP4XS, VP5XS

12 Brachial Artery
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15 Digital Artery VP8XS,
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VP10XS, EZ8XS

18 Popliteal Artery
VP5XS

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VP8XS, VP10XS, EZ8XS

20 Dorsalis Pedis Artery
VP8XS, VP10XS, EZ8XS

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.

Symbols

	General Warning Attention, consult this manual.		Attention, consult accompanying documents / Instructions for Use
Rx Only	Caution: Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.		

1.1 Warnings

Do not use in the presence of flammable gases.

Do not sterilize the product or its accessories.* The product will be damaged, and there is a risk of patient and user harm.

Do not use in the sterile field unless additional barrier precautions are taken.

Do not immerse in any liquid. (Except waterproof probes - fitted on models SR2 and SR3).

⚠	***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 dispose of batteries in fire as this can cause them to explode.***
⚠	***If this product is connected to another item of electrical equipment, it is important that the system is fully compliant with IEC 60601-1 :2005.***
⚠	***This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it, e.g. mobile phones. This will be indicated by unusual sounds from the loudspeaker. We recommend that the source of interference is identified and eliminated. (Refer to Section 9).***
⚠	***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.***
⚠	***Do not expose the Doppler to excess heat, including prolonged exposure to sunlight.***
⚠	***Connect headphones only to the headphone socket.***
⚠	***This equipment must not be modified.***
⚠	***The main unit enclosure does not provide protection from water ingress. For homecare use, the protective pouch (ACC-OBS-080) must be used. However, this will not protect the unit from immersion in liquids.***

**** Note:*** ***Does not apply to IOP8 Intraoperative Probe. Refer to Intraoperative Probe IFU for details on cleaning/sterilization processes.***

1.2 Patient Applied Parts

As defined in IEC 60601-1:2005, the patient applied parts of the Digital Handheld Doppler are the ultrasound probes, PPG sensors and cuffs.

2. Introduction

This manual is your introduction to the Dopplex® and Sonicaid® Doppler products.

The Doppler is a multi-function, battery powered, hand-held Doppler intended for both vascular and obstetrics use. It is compatible with Huntleigh's full range of 'XS' interchangeable probes (depending on model).

The DMX Vascular Doppler is indicated for the examination of blood flow in a range of vessel depths, from peripheral / superficial blood vessels down to deep vessels and vessels in oedematous limbs. It provides an indication of blood flow and direction by audible and visual means.

By the addition of a Photo Plethysmography 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) in patients with intermittent claudication (walking pain) which is the first line assessment for suspected PAD.

The SRX, SR2, SR3 Fetal Doppler are indicated for the detection of fetal life, at early gestation, from as early as 8 to 10 weeks and for fetal screening from early gestation through to delivery. It provides an audible fetal heart sound and a numeric/graphical display of fetal heart rate.

You must read, fully understand and comply with the instructions given in this manual before using the Doppler.

Use this manual to initially set up the Doppler, and keep it as a reference for day-to-day routines and as a guide to cleaning and maintenance.

If you have any difficulties in setting-up or using the Doppler, contact your local Huntleigh sales representative.

The model (REF) number of your Doppler is shown on the front and rear panel labels.

Note: ***Screen shots and product images are shown for illustration purposes only. These may vary from the actual product.***

This manual applies to the following products:

VASCULAR DOPPLER	MODEL	FUNCTIONALITY
	**DMX**	**Vascular -** Full Visual and audio functionality if a suitable vascular probe* is attached. **Obstetric -** Full Visual and audio functionality if a suitable obstetric probe* is attached. (Not suitable for underwater monitoring). **PPG** - PPG functionality if a PPG probe* is attached.

OBSTETRIC DOPPLER	MODEL	FUNCTIONALITY
	**SRX**	**Obstetric -** Full Visual and audio functionality if a suitable obstetric probe* is attached. (Not suitable for under water monitoring). **Vascular -** *Audio functionality only* if a suitable vascular probe* is attached. Screen will display date/time, probe frequency and battery status only. **PPG - *No functionality.***
	SR2	**Obstetric -** Full Visual and audio functionality. 2MHz hard wired waterproof probe **suitable for underwater monitoring**. ***No Vascular or PPG functionality as probe is hard wired and cannot be changed.***
	SR3	Same as for SR2 model but with 3MHz hard wired probe.

** Please see relevant sections for full details of functionality and probe /sensor options and accessories.*

2.1 Intended Use & Indications

The DMX & SRX range of handheld Dopplers are intended for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the assessment of vascular blood flow and/or fetal heart rate, to assist in diagnosis.

2.2 Contraindications

The Doppler is not intended to be used on broken or fragile skin.

Do not use on the eye or scrotum.

The (Fetal) Doppler provides just one indicator of fetal condition. This should be assessed as part of an holistic approach to obstetric care together with other factors. A complete assessment must be made before taking appropriate action. If there is any doubt concerning the accuracy of any measurement, an alternative method should be used.

The (Vascular) Doppler is a screening tool to aid the healthcare professional and should be used with clinical judgement before interventional procedures are undertaken. If there is doubt as to vascularity after using the unit, further investigations should be undertaken immediately using alternative techniques.

2.3 Battery Requirements

All models in the DMX and SRX range are compatible with the following battery types:

- Alkaline LR6 (non-rechargeable)
- NiMH NR06 (rechargeable)

Refer to Section 4.3.1 to set the battery type on the Doppler.

NiMH batteries can be charged by connecting the Doppler to the charger provided via the USB port (refer to Section 3.1).

Do not attempt to recharge normal dry-cell batteries. They may leak, cause a fire or even explode.

Do not mix non-rechargeable and rechargeable batteries.

2.4 Unpacking / Preliminary Checks

Contents

Item	Item	Item
1 x Digital Handheld Doppler	1 x Instructions for Use CD	Batteries
Charger *	USB lead *	Ultrasound Gel
Quick Reference Guide	Carry bag	

* Depending on model

Delivery Inspection

Huntleigh Healthcare Ltd 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 Healthcare Ltd is informed at once.

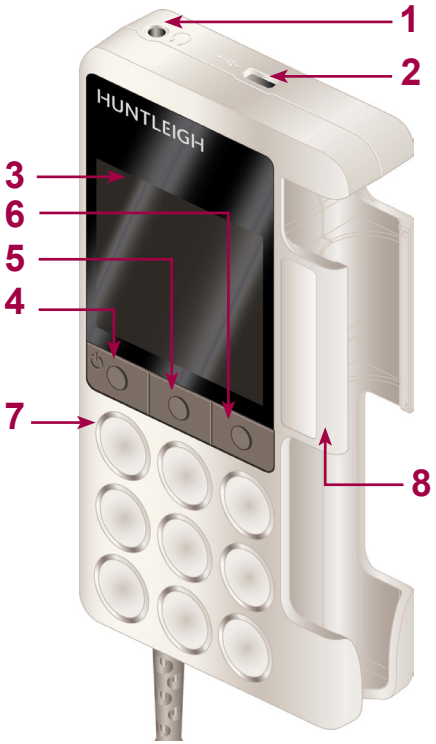
Storage

Refer to Section 5.8 and 8.8.

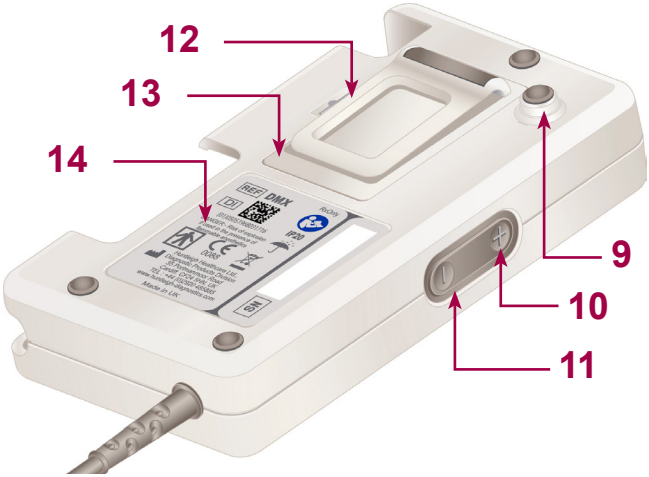
Note: Remove the batteries if the unit is not likely to be used for some time.

3. Product Identification

3.1 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

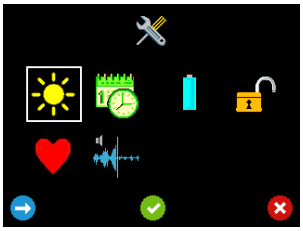
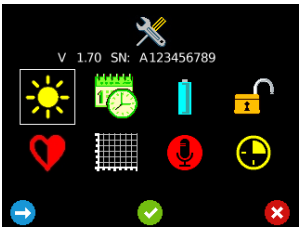


3.2 Product Labelling

	Patient applied parts (ultrasound probes) are type BF according to the definitions in IEC 60601-1:2005.		
	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.		
	Attention, consult this manual. Attention, consult accompanying documents / Instructions for Use		
CE 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.		
	Power On/Standby		Manufacturer
-25°C 50°C	Temperature Limitations	% Max 90% RH	Limits of Relative Humidity
SN	Serial Number	**REF**	Model Number
	Keep Dry	**DI**	Device Identifier
	Fragile		Contents can be recycled
	Headphone Socket		Cardboard packaging can be recycled.
	USB Port		Alignment mark
	Volume Up		Volume Down
PVC	PVC FREE Does not contain PVC	LATEX	LATEX FREE Does not contain Latex
	Limits of Atmospheric Pressure	**IP20**	Protected against ingress of solid foreign objects >12.5mm diameter. Not protected against ingress of water.

3.3 Display

3.3.1 Setup Screen

Vascular Setup Screen		Obstetric Setup Screen	
			
	Date and Time Setup		Brightness
	Lock screen		Battery Selection
	Heartrate Display Selection (Vascular)		FHR Averaging Mode (Obstetric)
	DDNR Hiss suppression (Vascular)		Trace Options (Obstetric)
	Audio Recording (Obstetric)		Timer (Obstetric)
	Move Highlight		Select
	Exit Setup		

3.3.2 *Status Bar*

The Status Bar is visible at the top of the display on most screens, (not available in Setup). The information displayed differs depending on the operating mode of the Doppler.

- Status Bar (Vascular shown)

All Modes

	Battery Level Low	27/01/2015 14.30	Date / Time
	USB Connected		USB Transmitting
	USB Receiving		

Vascular Mode

	Forward Flow (Flow towards probe)		Reverse Flow (Flow away from probe)
	Arterial Mode		Venous Mode
5MHz	Probe Type		

Obstetric Mode

	Standard Mode - FHR outside user set range		Standard Mode - FHR within user set range
	Smooth Mode - FHR outside user set range		Smooth Mode - FHR within user set range
0:10	Manual Mode		Signal Strength

Note: ***Other Display icons will be explained throughout the manual in their respective sections.***

4. Setup

4.1 Battery Insertion / Replacement & Micro SD Card Insertion

Disconnect unit from any other equipment before removing the battery cover.

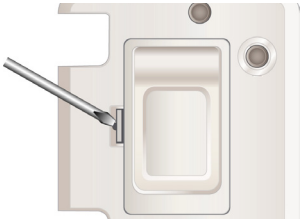
If you are fitting a Micro SD Card into the Doppler, this must be done BEFORE inserting the batteries.

Use Huntleigh recommended Micro SD cards only.

The Doppler is supplied with the batteries removed. Insert as shown below.

Note: ***Refer to section 8.4 for the specifications of suitable batteries.***

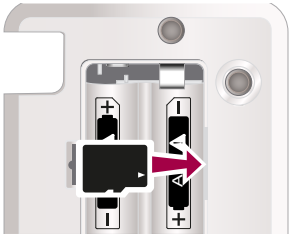
1



Remove the battery cover :

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

2

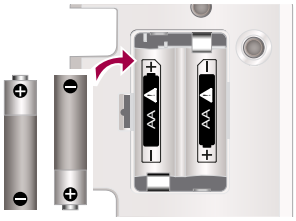


Insert the Micro SD Card. (If fitting).

Ensure card clicks into place.

(To remove the Micro SD card, press it in to release and pull gently to remove.)

3



Insert batteries in accordance with the diagram, positive terminal first, ***ensuring correct polarity.***

Replace the battery cover.

Note: ***We recommend the Doppler is charged prior to first use. (Charge ONLY if Doppler is fitted with rechargeable batteries - See Section 5.6).***

4.2 Probe Connection

Note: ***Models SR2 and SR3 are fitted with hard wired probes which cannot be removed.***

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

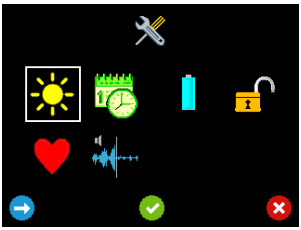
To disconnect the probe, pull the connector. DO NOT pull the cable.

4.3 Setup Screen

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

Press  to turn the unit ON.

Press and hold Button 3 to access the Setup screen. (The screen shown is with a vascular probe attached).



Use the 3 buttons below the screen to navigate and select each function.

Press Button 1  to move the highlight to each option .

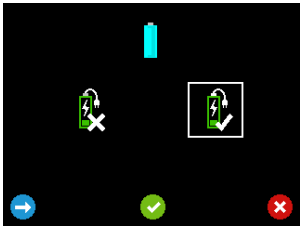
Press Button 2  to accept your selection.

4.3.1 Battery Selection

The Doppler can operate from either alkaline or rechargeable NiMH batteries, but it is important that the correct battery type is selected in the settings menu to correspond with the battery type fitted.

In the Setup menu, press  to move the highlight to Battery Selection  .

Press  to accept your selection.



Press  to move highlight between selections.

 - Select for **Alkaline** batteries.

 - Select for **NiMH rechargeable** batteries.

Press  to confirm and return to Setup screen.

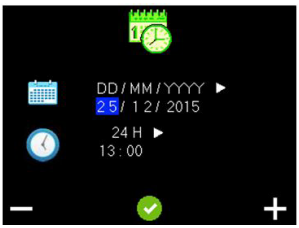
4.3.2 Date and Time

When the Doppler is switched on for the first time, you will need to set the time and date.

Highlight the Date and TIme option  in the Setup menu and press  .

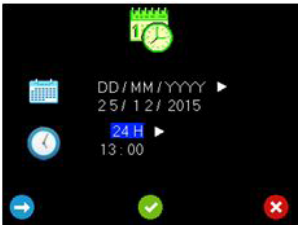
Press  to cycle through the Date format options.

Press  to confirm and enter Date Edit Mode.



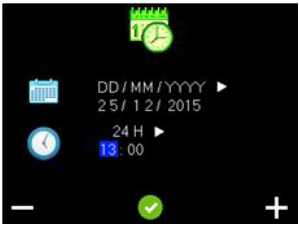
Press  or  to change the values

Press  to Accept the value and move to next item .
When the final item of the date has been accepted, Time Format Selection mode is entered.



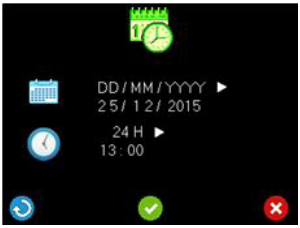
Press to cycle through the Time format options. (i.e. 12H or 24H).

Press to confirm and enter Time Edit Mode.



Press or to change the values

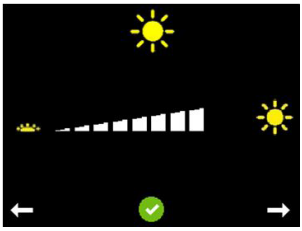
Press to Accept the value and move to next item .
When the final item of the Time has been entered, Date and Time Confirmation mode is entered.



Press to return to the Date Format Selection screen.

Press accept and save the changes or to discard the changes and return to the Setup screen.

4.3.3 Brightness



Press Button 1 to decrease Brightness and Button 3 to increase brightness.

Press Button 2 to confirm and return to the Setup screen.

4.3.4 Vascular, PPG and Obstetric Setup

Depending on whether a Vascular or Obstetric probe is attached, the Setup screen allows you to access the Heartrate Display Selection Screen and DDNR Hiss Suppression Screen (Vascular), and FHR Averaging Mode screen and Trace Options screen (Obstetric). If a PPG probe is attached, this screen will allow access to PPG monitoring functionality (Vascular). ATP and ABI kits are available to purchase as optional extras.

These functions will be explained in the Operation section.

Note: ***The Setup screen can be accessed by pressing and holding Button 3 in the main monitoring screens, i.e. Vascular Live Waveform screen, APPG Home screen and Obstetric Numeric/ Trace mode screens.***

4.4 System Connection

WARNING: These requirements must be met when the Doppler is connected to any other electrical equipment, such as a PC.

1 Non-medical equipment must comply with the relevant IEC or ISO safety standard. For Information Technology equipment, this standard is EN60950.

2 The configured system must comply with the requirements of IEC 60601-1:2005; clause 16.

3 If non-medical equipment (e.g. the PC or printer) with enclosure leakage currents greater than those allowed by IEC 60601-1 is to be used in the patient environment (within 1.5m of the patient), the enclosure leakage currents must be brought within the limits laid down by IEC 60601-1. This may be achieved by using a medical grade isolating transformer. Suitable types are available via Huntleigh sales agents.

4 Anyone who connects additional equipment to signal input or signal output parts of the system is configuring a medical system, and is therefore responsible for ensuring that the system complies with the requirements of IEC 60601-1:2005; clause 16. If there is any doubt as to whether your system complies, consult the technical service department or your local Huntleigh representative.

5. Operation

Refer to diagram on Page 4 for Doppler Measuring sites and Recommended Probes.

Please note: All functions and screen displays are model dependent. Please see table in 'Introduction' section for details on the functionality available on each model.

Please note: The Setup screen can be accessed by pressing and holding Button 3 in the main monitoring screens, i.e. Vascular Live Waveform screen, APPG Home screen and Obstetric Numeric/Trace mode screens.

Coupling Gel

Use water based ultrasound gel ONLY.

5.1 Switching On

Press to turn the unit ON.

5.2. Vascular Mode

If a vascular probe is inserted into the SRX model Doppler, there will be audio functionality only. The Doppler screen will display date/time, probe frequency and battery status but no waveform or button details.

The Vascular Live Waveform screen is displayed automatically if a vascular probe is detected when the device is powered on, or when a vascular probe is subsequently inserted into the device.

Vascular Probes

Six probes are available for vascular examinations:

VP4XS	**4MHz for deep lying vessels**
VP5XS	**5MHz for deep lying vessels and oedematous limbs**
VP8XS	**8MHz for peripheral vessels**
VP10XS	**10MHz for specialist superficial applications.**
EZ8XS	**8MHZ "Widebeam" for peripheral vessels.**
IOP8 / PA8XS	**Intraoperative Probe and adaptor**

Patient Preparation

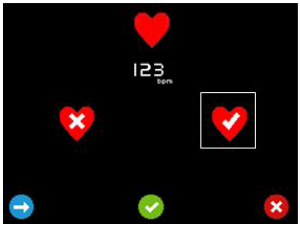
The patient must lie supine, be relaxed, remain still, and refrain from talking, coughing etc.

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 and point the probe tip towards the heart. 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.

5.2.1 Vascular Setup

Heartrate Display Selection Screen

This selection determines if the heartrate figure is displayed when the trace is frozen.



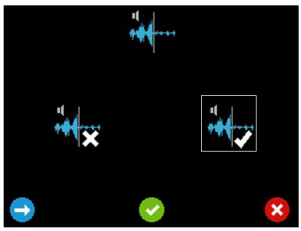
Press to move the highlight between displaying the heartrate and not displaying the heartrate .

The sample heartrate figure appears and disappears accordingly.

Press to accept your selection or to discard the changes and return to Setup.

DDNR Hiss Suppression Selection Screen

This selection determines if the DDNR applies hiss suppression to the audio signal.



To disable hiss suppression select .

To enable hiss suppression select .

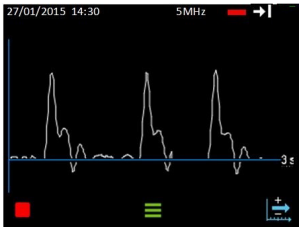
Press to move the highlight between selections.

Press to accept your selection or to discard the changes and return to Setup.

5.2.2 *Vascular Monitoring*

Vascular Live Waveform Screen

On the Vascular Live Waveform screen, the trace displays from left to right, then begins overwriting again from the left hand axis. The time taken to traverse the screen depends on the current time base and can be set to 3, 6 or 12 seconds. The currently selected time base is displayed to the right of the chart level with the X axis (3 seconds in the example shown).



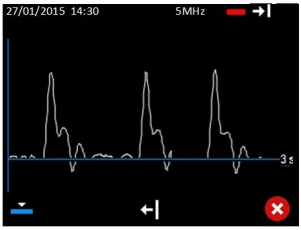
Press  to freeze the trace and display the Frozen Options screen.

Press  to display the Trace options.

Press  To cycle through the Time base options (3s > 6s > 12s > 3s).

 Vascular Waveform Options

The trace continues to update when the trace options are displayed. The soft key icons will display the available options depending on the current settings. The status bar displays the current settings.



If currently in Arterial Mode, button 1 will show Set Venous Mode  and if in Venous Mode, it will show Set Arterial Mode  .

Press button 1 to toggle between Venous and Arterial modes and restore the live waveform soft keys.

Venous mode centres base line and defaults timebase to 12s.
Arterial mode offsets base line and defaults timebase to 3s.

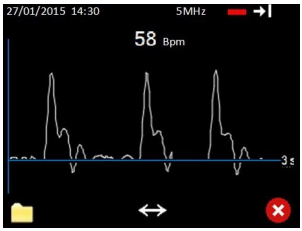
If currently displaying Forward Flow, button 2 will show Set Reverse Flow  and if displaying Reverse Flow, it will show Set Forward Flow  .

Press button 2 to toggle between Forward and Reverse Flow and restore the live waveform soft keys

Press  to restore the live waveform soft keys without making any changes to the running state.

Vascular Frozen Waveform Options

When the waveform is frozen, the heartrate is displayed. (If the option has been selected in setup - See Heartrate Display Selection Screen in Vascular Setup section). Once the trace is stopped the time base cannot be changed, so this must be selected beforehand.

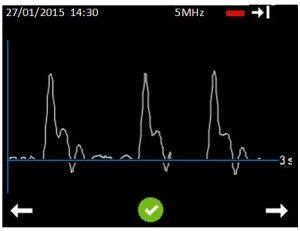


Press to display the File Options.

Press to show the scroll options. (This button will only be displayed if more than a screen of data has been captured).

Press to exit and return to Live Waveform screen.

Vascular Scroll Options



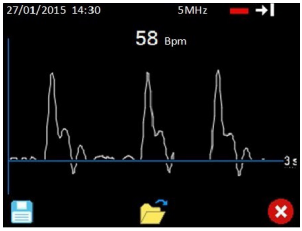
Press to scroll left / back or to scroll right / forward through the trace.

Press to accept the displayed portion of the trace and return to the Frozen Waveform Options screen.

Heartrate is not shown while scrolling.

Vascular File Options (If Micro SD card fitted)

From this screen, the user can choose to save a waveform or open the folder containing previously stored waveforms for review. If there is insufficient memory to save a waveform, the save option is unavailable and the save icon is hidden. In this case the user should go to the review files screen and delete one or more stored files to free up memory.
The filename will be generated automatically and a popup temporarily displayed to acknowledge that the file has been saved. Data is stored on the Micro SD card.



Press to save the ***visible portion*** of the waveform to permanent storage.

Press to open the folder containing stored waveforms for review.

Press to exit back to the Frozen Waveform Options screen.

5.2.3 *Measuring Doppler Pressures*

Refer to diagram on Page 4 for Doppler Measuring sites and Recommended Probes.

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

Brachial Systolic Pressure

Rest the patient in supine position in a quiet warm room for at least 10 minutes.

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

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

Apply a liberal amount of gel on the site of the brachial artery.

Place the probe at 45° to the skin surface over the vessel to be examined and keep the probe tip in line with the vessel.

Adjust the position of the probe to obtain the loudest audio.

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

Adjust the audio volume as required.

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 (2 mm/ sec) and note the pressure on the sphygmomanometer at which the arterial sounds return.

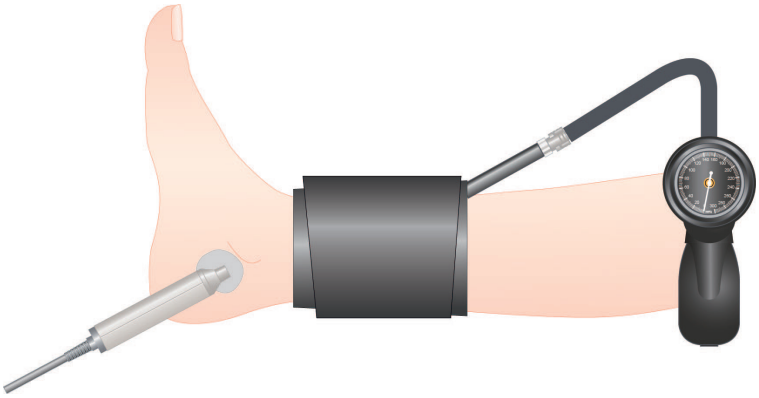
Deflate the cuff completely.

Ankle Systolic Pressure

Place the appropriately sized cuff 1-3 cm above the lateral malleolus.

Connect the sphygmomanometer to the cuff.

Repeat the procedure described above, only this time monitoring the desired foot artery (e.g. Posterior Tibial shown).



5.3 PPG Mode

This function is only available on the DMX model.

The PPG Home Screen is displayed automatically if an PPG module is detected when the device is powered on, or when an PPG module is subsequently connected to the device. (Available as an optional accessory).

APPG Probes

An arterial PPG probe is available for arm, ankle and toe systolic pressures and PPG waveforms:

PPGA1	**Photo Plethysmography Probe**

Systolic pressure measurements rely on a a bulb inflation / valve deflation system in combination with a tube and cuff attachment as shown overleaf. The Photo plethysmography 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.
The cuff is wrapped around the patient's extremity, and the pressure in the cuff is recorded by a pressure sensor located inside the PPGA1 module. The pressure transducer records the cuff pressure values as a function of time. These readings are presented graphically on the display, allowing the user to make the determination of which pressure reading is the actual systolic pressure.

Connect the cuff, sphyg, APPG adaptor and probe as shown:

Patient Preparation

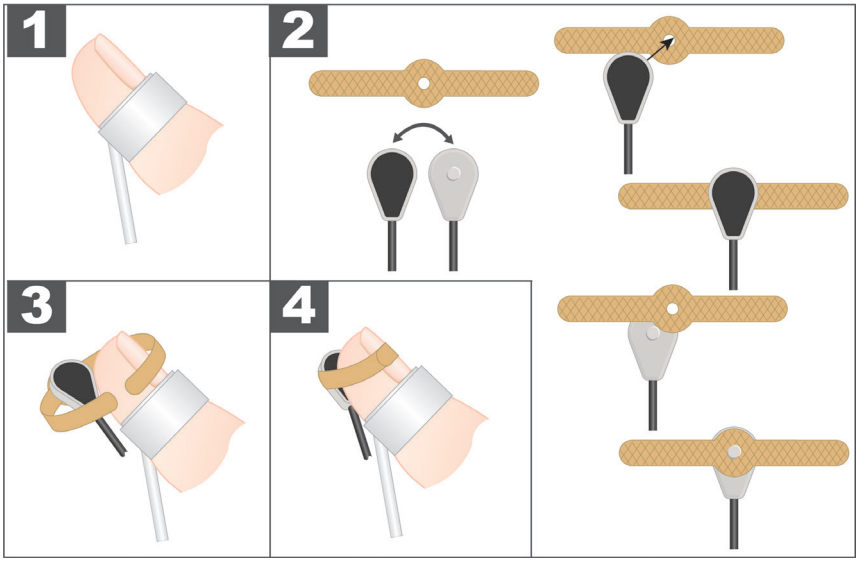
Patient must rest for 10 minutes in a warm room (> 24°C).

Patient must be supine with stockings and footware removed.

Temporarily cover feet to keep them warm until measurement is made.

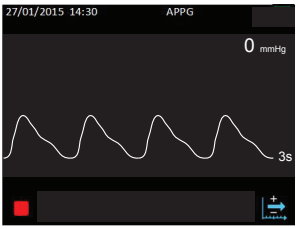
Fit the sensor & toe cuff as shown.

NOTE: ***Select cuff size appropriate for the patient's toe/digit.***



APPG Home Screen

The PPG trace runs in real time at the selected time base and is auto scaled to optimise the display height. The time base can be set to 3, 6 or 12 seconds. The currently selected time base is displayed to the right of the chart level with the X axis (3 seconds in the example shown).



Press  to freeze the trace and display the APPG Trace Only screen.

Press  to cycle through the time base options: 3s > 6s > 12s > 3s.

 APPG Trace Only Screen

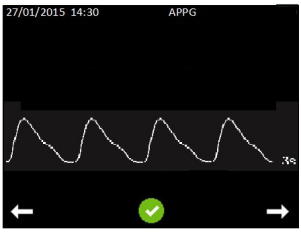
The required time base should be selected before freezing the trace.

Press  to display the File Options.

Press  to show the scroll options. (This button will only be displayed if more than a screen of data has been captured).

Press  to exit the APPG Trace Only screen, return to the APPG Home Screen and restart the trace.

 APPG Scroll Options

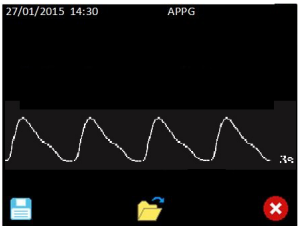


Press  to scroll back or  to scroll forward through the trace.

Press  to accept the displayed portion of the trace and return to the APPG Trace Only screen.

APPG File Options (If Micro SD card fitted)

From this screen, the user can choose to save a waveform or open the folder containing previously stored waveforms for review. If there is insufficient memory to save a waveform, the save option is unavailable and the save icon is hidden. In this case the user should go to the review files screen and delete one or more stored files to free up memory.
When saving a waveform, only the portion of the waveform displayed on the screen is actually saved. The user should scroll the desired portion of the waveform into view before saving. The filename will be generated automatically and and a popup temporarily displayed to acknowledge that the file has been saved.



Press to save the visible portion of the waveform to permanent storage

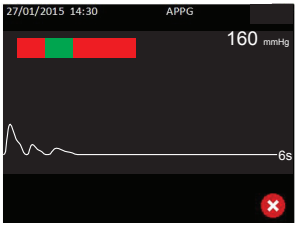
Press to open the folder containing stored waveforms for review.

Press to exit back to the APPG Trace Only screen.

Measuring a Toe Systolic Pressure

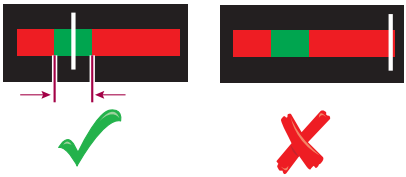
This screen shows the PPG waveform and the instantaneous cuff pressure in real time.
Inflate the cuff and stop at a target pressure approximately 30 mmHg above that at which blood flow is totally occluded.

It is the responsibility of the user to note the pressure at which blood flow is totally occluded and continue inflating for a further 30mmHg.

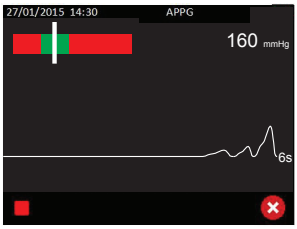


Press to exit back to the APPG Home screen.

The user will now aim to reduce the pressure by pressing the vent button on the sphyg to achieve a constant rate of 2 – 4 mmHg per second. To assist the user, the deflation bar indicates the current calculated deflation rate. If it is between 2 – 4 mmHg, the white line will be over the green band. The red bands either side correspond to rates that are either too low or too high.



Cuff pressure is plotted in the Right Hand upper corner.
When the returning pulses are detected, the screen is frozen, and the Pressure Adjust screen is entered.



Press  to Freeze trace and display Pressure Adjust screen.

Press  to exit back to the Pressure Inflate screen.

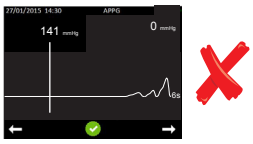
Always deflate the cuff pressure to zero after the trace stops.

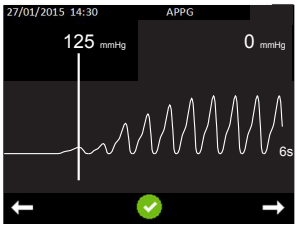
NOTE: ***If the cuff pressure remains above 10mmHg the displayed cuff pressure will turn orange and flash.***

NOTE: ***If the cuff pressure exceeds the nominal range shown in Section 8, it will be displayed as '- - - ' mmHg.***

APPG Systolic Pressure Adjust Screen

The first pulse detected will be aligned with the vertical line. If this is not the case, the user can manually adjust the detected systolic pressure using the  or  buttons .This may be useful if the user believes the first detected pulse to be random noise. The trace can be moved in either left or right directions, with the vertical line remaining static. The pressure shown above the vertical line is updated accordingly.
Ensure that the first pulse is aligned with the vertical line.





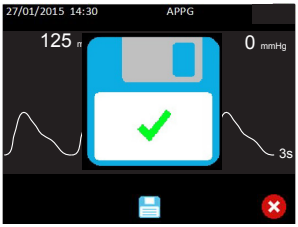
Press ⬅ to scroll back or ➡ to scroll forward through the trace.

Indicated pressure reduces or increases.

Press ✓ to accept the selected systolic pressure.

APPG Final Review and Save Screen

The detected or adjusted systolic pressure is displayed at the top left hand corner of the display. The APPG waveform that was saved when the pressure icon was pressed in the APPG Home screen is displayed.



Press 💾 to save the screen information.

A popup will be displayed momentarily to confirm successful save 💾.

If data has been saved, press ✖ to exit to APPG Home Screen.

If the data has not been saved, the Data Will Be Lost Screen is displayed.

APPG Data Will Be Lost Screen

This screen prompts the user to reconsider exiting the Final Review and Save Screen without saving the record.

Press ✓ to exit to APPG Home screen without saving.

Press ✖ to return to Final Review and Save screen.

5.4 Obstetric Mode

The Obstetric FHR Numeric screen is displayed automatically if an obstetric probe is detected when the device is powered on, or when an obstetric probe is subsequently inserted into the device.

Obstetric Probes

Two probes are available for obstetric examinations:

OP2XS	**2MHz ±1%**	**OP3XS**	**3MHz ±1%**

Doppler Signal Strength

The strength of the Doppler signal is displayed in the status bar at the top of the display.

Underwater Monitoring - SR2 and SR3 models only!

Models SR2 and SR3 are fitted with hard wired waterproof probes suitable for underwater monitoring. Other probes are not waterproof and must not be used in water.

For underwater use where contamination or cross-infection may occur, refer to Section 6 for Cleaning Instructions.

The main unit is not waterproof and must not be immersed.

Patient Preparation

Make the patient comfortable in a semi-recumbent or sitting position.
Apply a liberal amount of gel* to the abdomen. Where practical, palpate first to determine fetal position - best probe position is over the fetal left scapula. 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 while maintaining firm pressure. Avoid sliding it over the skin.

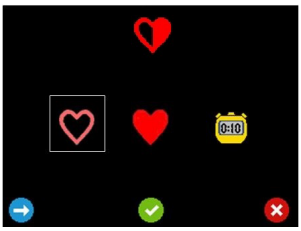
In early pregnancy a full bladder may improve sound detection. In later pregnancy the best signals are generally located higher on the abdomen. The fetal heart sounds like a galloping horse at approximately twice the maternal rate.
Best heart rate performance is from the fetal heart itself, characterised by ‘slapping’ valve sounds, rather that umbilical artery or placental sounds.

*Note: For SR2/SR3 Models : Gel is not required when probe is used underwater.

5.4.1 *Obstetric Setup*

FHR Averaging Mode Selection Screen

This selection determines the method used to calculate the Fetal Heartrate.



- Selects Standard Averaging Mode over 4 beats.

- Selects Smooth Averaging Mode over 8 beats.

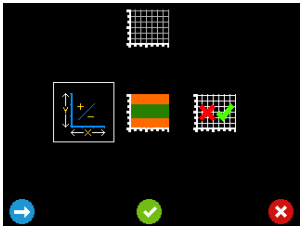
- Selects Manual mode where the user times 10 beats

Press to move the highlight between selections.

Press to accept your selection or to discard the changes and return to Setup.

Trace Options Screen

This screen provides a submenu of option screens to define the properties of the trace display.



- Go to the Chart Speed / Y Axis Scale Selection screen.

- Go To the Threshold Limit Selection screen.

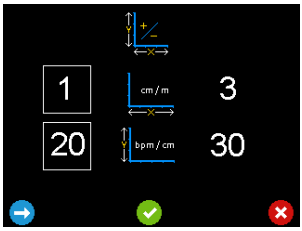
- Go to the FHR Trace Mode Enable / Disable screen.

Press to move the highlight between selections.

Press to accept your selection or to discard the changes and return to Setup.

Chart Speed / Y Axis Scale Selection Screen

This screen allows the Obstetric trace chart speed and Obstetric trace chart Y Axis scale to be set.*



Press to move the highlight between selections.

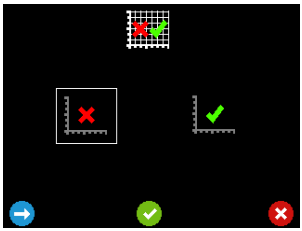
Press to accept your selection and return to the Trace Options screen.

Press to return to the Trace Options screen without saving the changes.

NOTE:** **Each grid division on the chart represents one centimetre equivalent.

FHR Trace Mode Enable / Disable Screen

This screen allows the FHR Trace Mode Screen to be enabled or disabled .



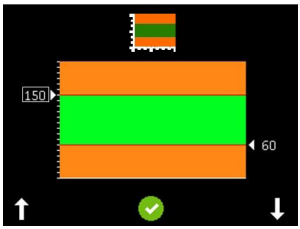
Press to move the highlight between selections.

Press to accept your selection and return to the Trace Options screen.

Press to return to the Trace Options screen without saving the changes.

Threshold Indication Limits Selection Screen

On entering this screen, the current upper limit (left) and lower limit (right) are displayed (upper limit is shown selected). The area of the chart in green represents heartrate levels within the user set range. The areas in orange represent rates outside the user set levels. When the heart rate is outside these user set levels, the heart symbol changes from green to amber.



Press ⬆ to increase or ⬇ to decrease the selected level by 5.

As the levels change, the new values are displayed and the areas of the graph change accordingly.

Press ✓ to move the selection from upper level to the lower level. Adjust the selected level with ⬆ and ⬇ .

Press ✓. Confirmation softkey functions will be displayed giving the options to Redo ↻, Accept ✓ or cancel ✗ the changes.

Accept or Cancel will return to Trace Options screen.

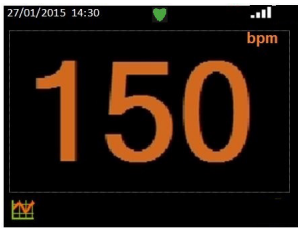
Fetal Heart Audio Record Screen- *Refer to Section 12*

Timer Function Screen - *Refer to Section 12*

5.4.2 Obstetric Monitoring

Obstetric FHR Numeric Mode Screen

In this Mode, the FHR is displayed (in beats per minute) in large digits and is continually updated. When the rate cannot be determined, 3 x dashes are displayed.



Press 📈 to switch to FHR Trace Display.

Obstetric FHR Numeric Mode Screen (Manual)

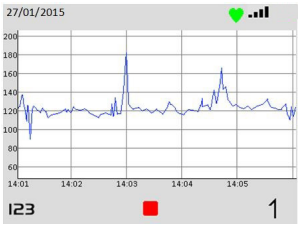
In manual mode (selected from setup), the display initially shows three dashes in place of the digits. This mode allows a 10 beat average heart rate to be measured, where the user can hear a weak or noisy heart beat but the Doppler is unable to calculate FHR.

Press 10 (Button 1), count 10 beats then press again. The Doppler will calculate and display the FHR based on the time taken. The FHR will remain on screen until the operation is repeated or the mode is changed.

Obstetric FHR Trace Mode Screen *

Trace display mode is for indication only and is not a replacement for conventional fetal monitoring. If any concern arises from viewing this trace, alternative means (e.g. full CTG) must be used to determine fetal condition.

This screen displays the FHR as a trace on a graph. The horizontal and vertical scales are determined in setup**. The trace displays from left to right until it fills the screen then scrolls to the left as each new data point is added.



Press 123 to switch to numeric display mode.

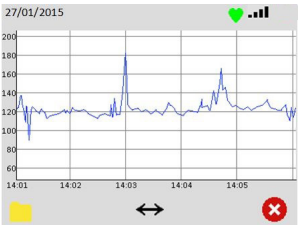
Press 1 to register fetal movement and place a marker on the graph at the corresponding position.

Press ■ to stop the trace and display the FHR frozen trace option.

** Trace scaling is equivalent to 1 or 3 cm/min and 20 or 30 beats per cm, scaled down to screen size, maintaining the same aspect ratio to avoid distortion of the trace for easy visual interpretation.

**** NOTE:*** ***These options are only available if the FHR Trace Mode screen has been enabled (see Section 5.4.1 - FHR Trace Mode Enable / Disable Screen).***

Obstetric Frozen Trace Options *



Press to display the File Options.

Press to show the scroll options. (This button will only be displayed if more than a screen of data has been captured).

Press to display the Resume or Restart trace options.

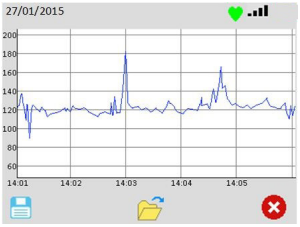
Obstetric Scroll Options *

Press to scroll left / back or to scroll right / forward through the trace.

Press to select the displayed portion of the trace and return to the Frozen Trace Options screen.

Obstetric File Options *

From this screen, the user can choose to save a trace or open the folder containing previously stored traces for review. If there is insufficient memory to save a trace, the save option is unavailable and the save icon is hidden. In this case the user should go to the review files screen and delete one or more stored files to free up memory. Memory capacity can be increased as required by installing an appropriate Micro SD card.
The filename will be generated automatically and and a popup temporarily displayed to acknowledge that the file has been saved.



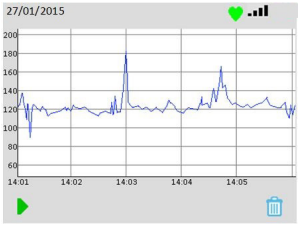
Press to save the visible portion of the waveform to permanent storage.

Press to open the folder containing stored waveforms for review.

Press to exit back to the Frozen Trace Options screen.

Obstetric FHR Trace Resume or Restart Options *

While the FHR trace is stopped / frozen, no further data is recorded. On exiting the frozen state, the user can resume the current recorded trace or start a new trace.

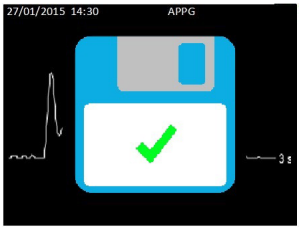


Press to resume the current trace.
There will be a gap in the trace for the time period corresponding to the frozen state.

Press to discard the current trace data and start a new trace.
Note that discarding the current trace does not delete any saved data files.

5.5 Stored file Access

Saved File Confirmation Popup



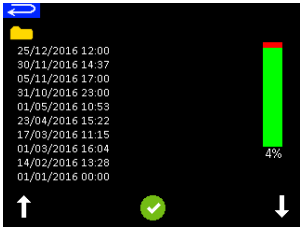
Whenever a file is saved, a popup is temporarily overlaid.

File Saving	File Saved	File Save Failed

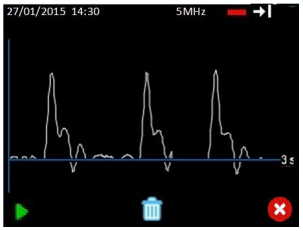
Soft keys are removed while the popup is on screen.

Stored File Review Screen

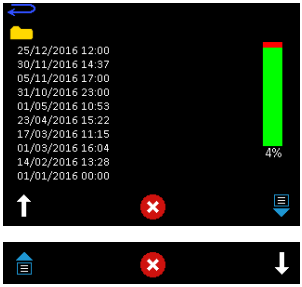
A list of stored files is displayed with the most recent file at the top. A bar to the right displays the amount of memory in use.



Press or to scroll through the file list.
Press to select the required file.



Press to view the selected waveform.
Press to delete selected waveform.
Press to confirm delete or to cancel and return to File options.



Press  or  to scroll through the pages of files.

Press  to return to Live Trace screen.

Highlight  and press  to return to Live Trace screen.

Highlight  and press  to enter the Demo Files screen.

Demo Files

Demo files have been pre-programmed onto the SD Card.

Vascular Demo Files

Obstetric Demo Files

Press  and  to scroll through the file list and  to select the required file.

Highlight  and press  to return to File Review screen.

Note: When any Demo file is displayed, the auto switch off timeouts are disabled.

5.6 Battery Charging

⚠	***Only rechargeable batteries can be recharged. Confirm battery type before connecting to charger. (See Section 4.3.1).***
⚠	***Only use charger and lead supplied by Huntleigh. (See Section 8.4).***
⚠	***Do not use the Doppler on patients when connected to the charger.***

Insert the supplied charger lead into the USB socket at the top of the Doppler.

Connect to mains supply and switch on mains power.

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

During charging, a  symbol will be displayed on the screen. Once fully charged, the symbol will change to  .

Note: ***The Doppler must be switched off for battery charging.***

5.7 Battery Status

Approximately 500 x 1 minute examinations can be performed with fully charged batteries, depending on use.

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

When the battery is fully depleted, the Doppler will switch itself off.

5.8 Battery Care

If the Doppler is not to be used for some time, the following guidance should be followed:

Non-rechargeable Batteries (Alkaline)

Remove the batteries from the unit. If the batteries are not removed, there is a risk of battery leakage causing product damage.

Rechargeable Batteries (NiMH)

Fully charge the batteries following the instructions in Section 5.6, then remove the batteries from the unit. Store the batteries in a dry location within a temperature range of 10°C to 30°C for up to six months.

For longer storage periods, the batteries should be re-fitted to the Doppler, fully charged and removed every six months.

If the batteries are not periodically re-charged, they can be irreversibly damaged.

5.9 Data transfer to an external device

The stored waveform/trace and data can be transferred to an external PC via a USB connection.

Insert the supplied USB lead into the USB socket at the top of the Doppler and connect to the computer.

5.10 After Use

1. Press and hold the On/Off button. If you forget to switch the unit off, it will automatically switch off after 1 minute obstetric or 3 minutes vascular.
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.

6. Care and Cleaning

6.1 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.***
⚠	***Do not use Phenolic detergent based disinfectants, solutions containing cationic surfactants, ammonia based compounds or perfumes and antiseptic solutions.***
⚠	***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.***
⚠	***Do not allow any fluid to enter the products and do not immerse in any solution.***
⚠	***Always wipe off disinfectant using a cloth dampened with clean water.***

6.2 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 cloth.
4. If the product has been contaminated use the methods described for patient applied parts.

6.3 Cleaning and Disinfecting Patient Applied Parts

Probes *

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.	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.

**** Note:*** ***Does not apply to IOP8 Intraoperative Probe. Refer to Intraoperative Probe IFU for details on cleaning/sterilization processes.***

Warning: 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, as defined below:
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 high risk situations is not practical. Therefore, we recommend to dispose of according to local procedures

	Do not iron		Do not use phenol or phenol-derivative disinfectant.
	Do not dry clean		Do not machine wash. Do not immerse tubeset in water.
	Do not tumble dry		

CAUTION: Do not allow any fluid to enter the cuff tubing.

CAUTION: Do not use alternative cleaning agents or methods as permanent damage is likely.

CAUTION: 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.

6.4 Maintenance and Repair

There are no user serviceable parts inside the Doppler unit or probes.

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 772490.

7. Troubleshooting

This section gives some of the more common problems encountered during use together with possible causes. If the problem cannot be located after consulting the table in this section, the Doppler should be switched off and a qualified technician should be consulted.
Before attempting trouble-shooting, verify 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 Insufficient Gel
No Signal	Damaged probe / sensor Incorrect probe / sensor
Screen displays: 	Damaged probe / sensor No Probe
Screen displays: 	Incompatible probe / sensor Incorrect Probe / sensor
Screen displays: 	Incorrect battery fitted

8. Specifications

8.1 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.	Main Unit: IP20 Doppler Probes: IPX1 (Excluding connector) PPGA1 module : IPX0 SR2/SR3 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

8.2 DMX / SRX Ultrasound Transducers' Global Maximum Values

Transducer Model	Ispta .3 (mW/cm2)	TI Type	TI Value	MI	Ipa .3@ MImax
OP2XS	20	Soft Tissue Bone	0.11 0.29	0.017	N/A
OP3XS	13	Soft Tissue Bone	0.09 0.19	0.016	N/A
VP4XS	30	Soft Tissue Bone	0.062 0.21	0.014	N/A
VP5XS	20	Soft Tissue Bone	0.08 0.16	0.0103	N/A
VP8XS	10	Soft Tissue Bone	0.039 0.1	0.005	N/A
EZ8XS	60	Soft Tissue Bone	0.17 0.37	0.015	N/A
VP10XS	20	Soft Tissue Bone	0.029 0.08	0.0069	N/A

8.3 SRX FHR Performance*

Standard Mode	Range - 60-210bpm Averaging - 4 beats	Resolution - 1bpm Accuracy - ±3bpm
Smoothed Mode	Range - 60-210bpm Averaging - 8 beats	Resolution - 1bpm Accuracy - ±3bpm
Manual Mode	Range - 60-210bpm Averaging - 10 beats	Resolution - 1bpm Accuracy - ±3bpm

**(excluding user error)*

8.4 DMX Vascular Doppler Performance

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

**Heart rate indications may be unreliable if the signal is weak or irregular*

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	110 to 7,400 Hz

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

***Measured using a Doppler string phantom in water*

8.5 ABI and TBI Calculations

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

8.6 APPG Systolic Pressure Performance

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

8.7 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 (Loudspeaker)	500mW rms typical
Auto shut-off	1 minute obstetric, 3 minutes vascular
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) NR06 (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	Length: 5.5" (140mm) Height: 1.3" (33mm) Width: 3" (75mm)
Weight	9.9oz (280g)
Service Life	7 years

8.8 Environmental

Operating	
Temperature range	+41°F to 104°F (+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	-13°F to +41°F (-25°C to +5°C)
At a relative humidity of up to 93% non-condensing	+41°F to +95°F (+5°C to +35°C)
At a water vapour pressure up to 50hPa	>+95°F to +122°F (>+35°C to +50°C)

8.9 Standards Compliance

IEC 60601-1: 2005 +A1:2012 (Edition 3.1)	**JIS T 060606-1:2012**
ANSI/AAMI ES 60601-1:2005.	**IEC 60601-1-2:2007**
CAN/CSAC22.2 No 601.1-M90 (R2005)	**IEC60601-1-11: 2015**
IEC 60601-1:1998+A2:1995 (2nd Edition)	**BS EN 81060-1:2012**
EN 60601-2-37:2008+A11:2011 - Thermal Indices (TI) and Mechanical Index (MI) are below 1.0 for all device settings.	

8.10 Accessories

Use only recommended accessories listed in this manual.

Item		Part No
ATP Kit (DMXR, Battery charger, EZ8XS, APPG probe and adaptor, Pack of Adhesive strips (ACC179), 2 x Toe cuffs (1 large + 1 small), Arm/Ankle cuff (23-33cm), Large Arm/ankle cuff (31-40cm), DS-65 sphygmomanometer, tubes, Gel, Neuropen, Box of Neuropen tips, Carry Case)		ATP KIT
ABI Kit (DMXR, VP5XS, EZ8XS, Arm/Ankle cuff (23-33cm), Large Arm/ankle cuff (31-40cm), DS-65 sphygmomanometer, Gel, Carry Case)		ABI KIT
Vascular Probes :	VP4XS VP5XS VP8XS VP10XS EZ8XS PPG Adaptor PA8XS Adaptor	VP4XS VP5XS VP8XS VP10XS EZ8XS PPGA1 PA8XS
Intraoperative Probe Starter pack		ISP3XS
Obstetric Probes:	OP2XS OP3XS	OP2XS OP3XS
Aquasonic 100 Gel		ACC24
Support Stand		ACC52-2
Micro SD Card		ACC227
Mains Charger Kit		ACC226
Carry Pouch		ACC34
Headphones		ACC21
Protective Pouch (IP22)		ACC-OBS-080

9. 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 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:

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

Guidance and Manufacturer's declaration - electromagnetic emissions DMX and SRX with OP2XS, OP3XS, VP4XS, VP5XS, VP8XS, EZ8, VP10XS, SR2 and SR3		
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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration - electromagnetic emissions - DMX with IOP8		
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 A	The Doppler is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Doppler or shielding the location
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

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%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	2kV 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	1kV 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_r ; 0.5 cycles: At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_r ; 1 cycle: and 70% U_r ; 25/30 cycles, single phase at 0° 0% U_r ; 250/300 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Doppler requires continued operation during power mains interruptions, it is recommended that the Doppler is powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_r is the a.c. mains voltage prior to the 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 2.7MHz	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 Doppler is used exceeds the applicable RF compliance level above, the Doppler should be observed to verify normal operation. If abnormal performance 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.

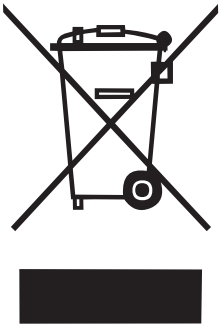
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12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

10. 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.

11. 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 retractile 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.

12. Service

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.
- Call Huntleigh in Addison, IL for a return authorization number.

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

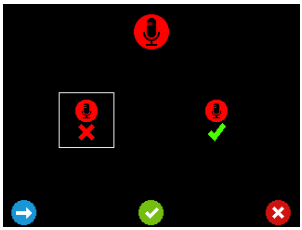
T: 1-800-323-1245 option 2

W: www.ArjoHuntleigh.com

13. Additional Obstetric Features

Fetal Heart Audio Record Screen

This screen allows Fetal Heart audio recording to be enabled or disabled .



Press to move the highlight between selections.

Press to accept your selection and return to the Setup screen.

Press to return to the Setup screen without saving the changes.

Record Function

Press to start recording sound.

Press to stop recording sound.

Press to playback sound.

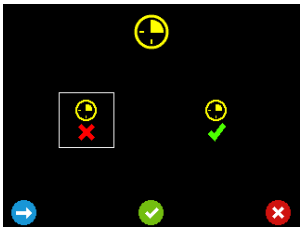
Press to save the recording.

Press and to access stored recordings.

Press to delete the recording.

Timer Selection Screen

This screen allows a 15 minute timer to be enabled or disabled .



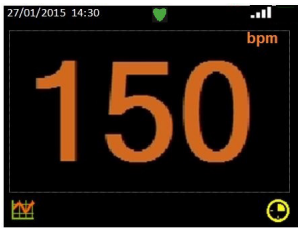
Press to move the highlight between selections.

Press to accept your selection and return to the Setup screen.

Press to return to the Setup screen without saving the changes.

Timer Function

A timer is available to remind the clinician to repeat auscultation after 15 minutes if required.



Press to set or to cancel the timer.

When the timer expires, press to acknowledge and silence the 15 minute timer.

Press to switch the Doppler off.

NOTE: ***The timer will repeat every 15 minutes until cancelled, even if the Doppler has been switched off.***

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The 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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