Intended Use and Indications

The DIOP8 surgical Doppler is indicated for use by qualified healthcare practitioners in a sterile condition in the operating theatre for the assessment of vascular blood flow by direct application to the vessel wall.
The DIOP8 is suitable for use on all patient populations.

Contraindications

- Do not use the DIOP8 on the eye.
- Do not use in the presence of flammable gases or oxygen rich environments.
- Do not apply the DIOP8 to the patient when using high frequency (HF) surgical equipment. Make sure when using such equipment that the DIOP8 is not in contact with the patient.

Note. No pressure should be applied to the vessel wall.

Complications

The following are possible complications from using the DIOP8. These should always be recognised when considering use of the DIOP8, and balanced against the benefits.

- There is an additional risk of infection when using the DIOP8. To minimise this risk, always check that the packaging is intact and undamaged.
- Ultrasound devices can cause cavitation within the blood. The DIOP8 ultrasound intensity levels are below the limits specified for intraoperative use in applicable international standards. The DIOP8 should only be applied for as short a time as possible in order to achieve the clinical objective.

Warnings/Cautions & Safety

⚠ **The sterile Intraoperative Probes are delicate and should be handled with care. Do not drop or strike against hard surfaces. Avoid excessive tension on the probe cable.**

⚠ **These probes are supplied STERILE. Always ensure that the packaging is intact and undamaged before opening.**

⚠ **The DIOP8 is a screening tool to aid the healthcare professional and can not provide a diagnosis. If there is doubt as to the status of the vessel after using the unit, further investigations should be undertaken immediately using alternative techniques.**

⚠ **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.**

⚠ **The DIOP8 is for single use only. DO NOT REUSE. DO NOT STERILISE. Failure to follow this advice may result in failure of the product, compromised sterility and potential harm to the patient.**

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

⚠ **This equipment must not be modified.**

Note. The control unit and adaptor are NOT sterile. Refer to the hand-held Doppler IFU for details of cleaning.

Operation

Connect the probe adaptor to the Dopplex cable, using the alignment mark on the barrel.

Locate the probe adaptor into the probe holder at the side of the Dopplex control unit. The Dopplex control unit can then be mounted onto an IV pole using the clamp as shown in Fig.1.

Using aseptic procedure, remove the DIOP8 probe from its packaging and insert plug into adaptor. Always maintain sterility of the probe.

Note: The Dopplex control unit will automatically switch off at a predetermined time after switching the unit on. See control unit IFU for more information.

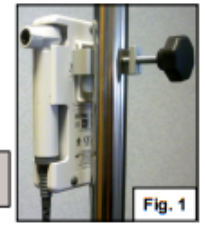

Fig. 1

The Dopplex control unit can be switched on by a member of staff positioned outside the sterile field.

Adjust the volume control accordingly.

Ensure that the probe connector is fully engaged in the socket on the probe adaptor.

Correct operation of the system should be confirmed by placing the DIOP8 tip wetted with patient's body fluid in light contact with an artery which is known to have blood flowing through it. A clearly audible pulsatile Doppler sound should be heard. The audibility and amplitude of the signal will be optimised when the probe is at an angle of approximately 45° ±15° to the vessel.

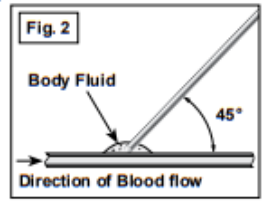

Fig. 2

The probe can now be used to assess blood flow in other vessels.
Aiming the probe proximally along the line of the vessel at an angle of 45° ±15° and ensuring that the tip is fully wetted at all times (Fig.2.) will enable the optimal audio signal to be obtained.
(If you are using a DMX, Multi Dopplex II or Super Dopplex II, an indication of the blood velocity and its direction will be shown on the LCD display.)

Operation

The probe can then be moved along the length of the vessel, noting any change in pitch of the Doppler signal or height of the Doppler waveform. This may be indicative of a change in the lumen area.

The same procedure can then be carried out after a graft has been inserted to confirm that adequate blood flow has been restored. By placing the probe on the vessel distal to the anastamosis, confirmation of distal run off is provided.

Product Labelling

	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)		
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB, Hans Michelsensgatan 10 211 20 Malmö, Sweden	**Shelf Life**	3 year from date of manufacture.
Manufactured by:	**Huntleigh Healthcare Ltd.** 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com		

	Sterile Barrier System (non sterile protective outer layer with an internal sterile barrier)			Rx Only	Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.		
	Attention, consult accompanying documents / Instructions for Use				Single patient use		Do Not Reuse
	Applied part is type CF	⚠	Warning		Do not resterilise	STERILE EO	Sterilised using ethylene oxide
MD	Medical Device	REF	Catalogue Number	LOT	Batch Code		Date of Manufacture
DI	Device Identification code		Cardboard packaging can be recycled.		Do not use if packaging is damaged		Atmospheric Pressure Limitation
	Contents can be recycled		Does not contain Latex		Use By date		Fragile, handle with care
	Temperature Limitations		Humidity Limitations		Keep Dry		

Technical Specifications - IEC60601-1 Classification

Type of shock protection	Internally powered equipment (Dopplex control unit)
Degree of shock protection	Type CF equipment
Protection against ingress of liquids	**Probe Adaptor**: Ordinary Equipment **DIOP8**: Suitable for use in contact with body fluids.
Degree of safety in presence of flammable gases	Equipment not suitable for use in presence of flammable gases or oxygen rich environments
Mode of Operation	Continuous

Ultrasound

P_r	< 1 MPa
I_{ob}	< 20 mW/cm²
$I_{spta.3}$	< 100 mW/cm²

Thermal Indices and Mechanical Index are 1.0 or less for all device settings.

Standards

Complies With	IEC60601-1 :2012
EMC	IEC60601-1-2: 2014

Environmental

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

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