INSTRUCTIONS FOR USE

Re-Sterilisable 8MHz Surgical Doppler Probe
**Clinical Applications**

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<th>Application</th>
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<td>Carotid Endarterectomy</td>
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<td>Femoral-Popliteal Bypass</td>
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<tr>
<td>In-situ Femoral-Distal Bypass</td>
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<tr>
<td>Detection of Arterio-Venous (AV) Fistula</td>
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<td>Coronary Artery Bypass Grafts</td>
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<td>Renal and Hepatic Transplantation</td>
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<tr>
<td>Real Blood Flow Confirmation Post Aortic Aneurysm Repair</td>
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<td>Intraoperative Blood Flow Monitoring</td>
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</table>
WARNING/CAUTIONS & SAFETY

WARNING!

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

IMPORTANT

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

- Do not use the Intraoperative Probe in the presence of flammable gases such as anesthetic agents.
- The Intraoperative Probe (IOP8) and the Probe Adaptor must only be connected to the Multi Dopplex® II, Super Dopplex® II, Rheo Dopplex® II or Mini Dopplex®, manufactured by Huntleigh Healthcare.
- The Multi Dopplex® II, Super Dopplex® II, Rheo Dopplex® II or Mini Dopplex®, when used with these probes, must only be connected to equipment which complies with EN60601-1 or EN60950.
- Do not use the Intraoperative Probe in the eye.
- This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it. This will be indicated by unusual sounds from the loudspeaker in the main unit. We recommend that the source of interference be identified and eliminated.
- The 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.
- Do not sterilize any part of the Multi Dopplex® II, Super Dopplex® II, Rheo Dopplex® II, Mini Dopplex® or Probe Adaptor (PA8).
- These probes are supplied NON STERILE. Always clean and sterilize before use, in accordance with the Recommended Cleaning and Sterilization instructions.
- The Intraoperative Probe is a screening tool to aid the healthcare professional and should not be used in place of normal vascular monitoring. If there is doubt as to vascularity after using the unit, further investigations should be undertaken immediately using alternative techniques.
Acoustic Safety

Doppler ultrasound instruments such as the MD2/SD2/D900/RD2, have been used extensively for medical diagnosis in the United States for over 25 years. Throughout this period, there have been no reports of adverse effects to patients or instrument operators at the acoustic intensities recommended for diagnostic use. Despite this highly favorable safety experience, available data are not conclusive and the possibility remains that unwanted biological effects might be identified in the future. Authorities therefore recommend that ultrasound procedures be performed in accordance with the “ALARA” principle, which states that the energy delivered to the patient should always be kept As Low As Reasonably Achievable. With the Intraoperative Probe, the transmitted acoustic power is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

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

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

<table>
<thead>
<tr>
<th>Acoustic Output Reporting Table for Track 1 - Non-Auto-scanning Mode</th>
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</thead>
<tbody>
<tr>
<td>Operating Mode: PW-Mode</td>
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<tr>
<td>Application(s): Vascular Monitoring</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acoustic Output</th>
<th>MI</th>
<th>Ispta.3 (mW/cm²)</th>
<th>Isppa.3 (W/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Value</td>
<td>0.036 (± 9%)</td>
<td>73 (± 17%)</td>
<td>0.31 (± 17%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Associated Parameters</th>
<th>Pr.3 (MPa)</th>
<th>Wo (mW)</th>
<th>Ic (MHz)</th>
<th>Zsp (cm)</th>
<th>Beam Dimensions</th>
<th>PD (μS)</th>
<th>PRF (kHz)</th>
<th>EBD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.101 (± 9%)</td>
<td>1 (± 20%)</td>
<td>8 (± 1%)</td>
<td>0.54</td>
<td>x-6 (cm)</td>
<td>0.12</td>
<td>62.5</td>
<td>Az (cm) 0.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>y-6 (cm)</td>
<td>0.12</td>
<td>62.5</td>
<td>Ele (cm) 0.3</td>
</tr>
</tbody>
</table>
NOTES

1. Measurement uncertainty:
   - Random - ±20%
   - Systematic - ±7.0%

Definition of Terms

- **ISPPA.3**: is the derated spatial-peak, pulse-average intensity (Watts per square centimeter)
- **ISPTA.3**: is the derated spatial-peak, temporal-average intensity (milliwatts per square centimeter)
- **Wo**: is the ultrasonic power (milliwatts)
- **fc**: is the center frequency (MegaHertz)
- **Zsp**: is the axial distance used to calculate the derated intensity (centimeters)

**A-6 (Zsp)** is \( \frac{\pi}{4} \times (X-6 \times Y-6) \) where X-6, Y-6 are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6dB dimensions in the X-Y plane where Zsp is found (centimeters)

**EBD**: are the entrance beam dimensions for the azimuthal and elevational planes (centimeters)

Cleaning of Adaptor (PA8)

- Clean with a damp cloth impregnated with mild detergent. Do not allow fluid to seep into the adaptor.
- For disinfection use a soft cloth with Sodium Hypochlorite 1000ppm or alcohol.
- Please be sure to check your local control of infection policies, or any equipment cleaning procedures.
- Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the adaptor or Dopplex control unit.

⚠️ Attention! Consult this manual.
Refer to Warnings / Cautions and Safety Section.
### RECOMMENDED CLEANING AND STERILIZATION

#### NON STERILE - PRE-CLEAN AND STERILIZE BEFORE USE

#### WARNINGS

| Limitations on Reprocessing | Only use 1 sterilization method.  
If probe is damaged Do Not re-use.  
Do not exceed 278.6°F (137°C).  
Do Not exceed the number of uses.  
6 Autoclave Cycles  
30 ETO Cycles |

#### Pre-cleaning Instructions

Prior to pre-cleaning, remove a cut-out from the tracking label.  
Pre-clean the IOP8 prior to sterilization by any of the following techniques:

| Automatic Washer Disinfector | A typical operating cycle is:  
Wash at ~ 149°F (65°C) with detergent (pH 5 - 13.2)  
Rinse at ~ 140°F (60°C) - rinse aid (pH 2.0±0.5) may be added  
Disinfection cycle - 199.4°F (93°C) (max) held for 1 min. or 159.8°F (71°C)  
(min) held for 3 mins  
Heat assisted drying cycle - 179.7°F (82°C) (max) |
| Ultrasonic Bath | Follow manufacturer’s instructions. |
| Manual Cleaning / Washing | Only undertake when other mechanical methods are unavailable.  
Take necessary precautions when manual cleaning / washing.  
Use hand hot water with detergent (pH 5 - 5.5). Use bottlebrush if necessary. |

#### Sterilization

Always use established temperatures, pressures and holding periods.

<table>
<thead>
<tr>
<th>Method</th>
<th>Temperature (min/max)</th>
<th>Pressure (min/max)</th>
<th>Holding Period (min/max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum Autoclaving - 1</td>
<td>273.2 / 278.6°F (134 / 137°C)</td>
<td>2.0 / 2.2 bar</td>
<td>3.0 / 3.5 minutes</td>
</tr>
<tr>
<td>Vacuum Autoclaving - 2</td>
<td>249.8 / 253.4°F (121 / 123°C)</td>
<td>1.1 / 1.2 bar</td>
<td>15.0 minutes</td>
</tr>
<tr>
<td>ETO</td>
<td>131°F (55°C)</td>
<td>Atmospheric pressure</td>
<td>6 hours cycle duration</td>
</tr>
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</table>

**Inspection**  
Visually inspect for damage.

**Packaging**  
Pack each probe individually. Use suitable container for sterilization technique.

**Storage**  
No particular requirements.

#### Instructions - After Use

**After Use** | Remove gross debris, place in an enzyme solution or tap water.

**Containment and Transportation** | Reprocess as soon as possible.

**Preparation for Cleaning** | IOP8 has no removable parts.

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The instructions provided above have been validated as being CAPABLE of preparing a device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided, should be properly evaluated for effectiveness and potential adverse consequences.
Refer to inside front cover for Clinical Applications.

**During Use**

An automatic diathermy noise reduction feature operates on high level signals to reduce interference.

**After Use**

The control unit and the body of the probe are robust and require no special handling. However, the probe tip is delicate and must be handled with care.

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**OPERATING INSTRUCTIONS**

Connect the Probe Adaptor to the Dopplex® cable, using the alignment mark on the barrel.

Place 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.

Following sterilization, remove the 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 user manual for more information.

After use, the probe should be disconnected from the main unit by carefully gripping the connector and pulling it from the Probe Adaptor.

**DO NOT PULL ON THE PROBE CABLE.**
The **Dopplex®** control unit can be switched on by a member of staff who is outside the sterile field. The volume control should be adjusted until a background hiss can be heard.

Ensure that the probe connector is fully inserted into the socket on the Probe Adaptor.

Correct operation of the system should be confirmed by placing the probe tip wetted with patient’s body fluid on an artery which is known to have blood flowing through it. A clearly audible pulsatile Doppler sound should be heard when the probe is at an angle of approximately 45° to the vessel. (Fig. 2).

![Fig. 2](image)

The probe can now be used to assess blood flow in other vessels maintaining an angle of 45° and ensuring that the tip is fully wetted.

Point the probe along the length of the vessel until the maximum audio signal is heard. If you are using a Multi Dopplex® II, Super Dopplex® II or Rheo Dopplex® II an indication of the blood velocity and its direction will be shown on the LCD display.

![Fig. 3](image)

The probe can then be moved along the length of the vessel noting any change in pitch of the Doppler signal, as this may be indicative of a change in lumen area (Fig. 3).

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.
**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) months, or the number of sterilization cycles, as defined in the user manual, whichever is sooner, (excluding probe adaptor which is warranted for three (3) years), 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 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, cleaning and sterilization, 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 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.
Service Returns

There are NO USER SERVICEABLE PARTS inside the Probe Adaptor or probe.

If for any reason your Intraoperative Probe or Probe Adaptor is being returned, please:

1. Clean the product, as described in the cleaning section.
2. Pack in suitable packing.
3. Attach the decontamination certificate, (or other written statement declaring that the product has been cleaned), to the outside of the package.
4. Call Huntleigh Service Dept. in Eatontown, NJ, for a return authorization number.

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

Service Department
ArjoHuntleigh Inc.
40 Christopher Way
Eatontown, NJ 07724-3327
Tel: (888) 223-1218
Local: (732) 578-9898
Fax: (732) 578-9889

Or your local distributor.

Manufactured in the UK by Huntleigh Healthcare.
As part of the ongoing development program, the company reserves the right to modify specifications and materials of the IOP and Probe Adaptor without notice.

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## TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th><strong>Product Name:</strong></th>
<th>Intraoperative Probe</th>
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</thead>
<tbody>
<tr>
<td><strong>Model No.:</strong></td>
<td>IOP8</td>
</tr>
</tbody>
</table>
| **Physical Characteristics:** | Length: 5.1”  
                    Tip Diameter: 0.2”  
                    Cable Length: 98.4” |
| **Complies With:** | EN60601-1 :1990  
                    UL2601-1 :1997 |

### IEC601-1 Classification:

- **Type of shock protection**: Internally powered equipment (control unit)
- **Degree of shock protection**: Type CF equipment
- **Protection against ingress of liquids**: Probe Adaptor: Ordinary Equipment
  - IOP8: Suitable for use in contact with body fluids and liquid sterilants.
  - Equipment not suitable for use in presence of flammable gases
- **Degree or safety in presence of flammable gases**
- **Mode of Operation**: Continuous

### Measurement accuracy when using Dopplex Reporter

- **Heart Rate**: 1.9% over range 60-240bpm
- **Doppler Shift Frequency**: ±16% over range 1-4KHz