Disposable Pressure Transducer

Instructions for Use

Please read the instructions carefully before use.

1. Introduction

Disposable pressure transducer is a sterilized, single use device used for invasive blood pressure measurements. It is composed of a flush set, transducer components, transmission tube, flush valve, cable and stopcock.

2. Reference

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Type</th>
<th>Length of Cable (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPT1030</td>
<td>Single-head</td>
<td>30</td>
</tr>
<tr>
<td>DPT1120</td>
<td>Single-head</td>
<td>120</td>
</tr>
<tr>
<td>DPT1120NT</td>
<td>Single-head, have three-port manifold, no transmission tube</td>
<td>120</td>
</tr>
<tr>
<td>DPT1100M</td>
<td>Single-head, have three-port manifold</td>
<td>100</td>
</tr>
<tr>
<td>DPT1120M</td>
<td>Single-head, have three-port manifold</td>
<td>120</td>
</tr>
</tbody>
</table>

3. Specifications

- Excitation Voltage: 6Vdc
- Operating Pressure Range: -30° to 300mmHg
- Operating Temperature Range: 15°C to 40°C
- Sensitivity: 4.95±0.5μV/V/mmHg
- Leakage current: <2µA at 120V RMS 60Hz
- Over-pressure tolerance: -400° to 4000mmHg
- Zero Offset: ±2±5mmHg
- Zero Thermal Drift: ±0.3±5mmHg/°C
- Output Drift: ±1±1±5mmHg/8h (after 20 second warm-up.)

1) Using aseptic techniques, open the package containing the sterile transducer.
2) Ensure that the transducer cable is compatible with the monitor, otherwise a separate reusable interface cable should be selected.
3) Connect the disposable pressure transducer to the monitor.

Caution: Do not use if package is opened or damaged.
4) Ensure that all connections are tight.
5) Fill the drip chamber halfway on the flush set with flush solution by squeezing the drip chamber. Open the flow regulator.

5.1 The Operational Instructions of DPT1030 DPT1120

5.1.1 Preparation

1) Open package containing the sterile Disposable Pressure Transducer. Check all connections for tightness before removing the product from the package.

Caution: Do not use if package is opened or damaged.
2) Begin the case set-up according to hospital protocol for catheterization pressure monitoring procedures.
3) Arrows on the handles indicate when the lumen is open to the fluid path.
4) Ensure that all electrical connectors are dry. Connect the cable in the correct orientation to the Disposable Pressure Transducer reusable cable for monitor in use. Align the connectors, firmly join the connectors together. For the greatest accuracy allow a minimum of five (5) minutes warm-up time after connecting the transducer before attempting to take readings or zeroing.
5) Prior to use, calibrate the system according to the monitor manufacturer's instructions. Refer to transducer tester manufacturer's instructions manual for proper set-up and use.
6) Fill the drip chamber halfway on the flush set with flush solution by squeezing the drip chamber. Open the flow regulator.

5.2.2 Filling system

1) Attach the male end of the sterile transmission tube to the transducer port. The transducer port is the female luer lock fitting on the lumen from the backside of the transducer and below the Flush Valve. The transducer port is at reference point B of figure 2. Make this connection tight but do not over tighten.
2) Turn the Stopcock so the transducer is open to the saline source. Open the Flush Valve and flush the transducer free of air. Continue fluid filling through the Flush Valve and out the Transmission Tube. Debubble the Transmission Tube. Turn the Stopcock off to the transducer.
3) Caution: the section of lumen between the underside of the sensor and the underside of the stopcock does not need to be fluid filled. (refer to section A in Figure 2.)

5.3 Setting

1) After the system has been primed and mounted, verify that the vent port of the stopcock (zero reference) is positioned at the patient's mid-axillary level.
2) Remove the cap without hole and open the vent port to the atmosphere.
3) Zero the transducer according to the Monitor Manufacturer's Instructions.
4) Close the vent port to the atmosphere and replace the cap without hole.
After finishing the blood pressure monitoring, disconnect the disposable pressure transducer according to relevant operation specifications. 

Caution: Please dispose of the device after use according to local regulations and laws.

6. Indication
Intravascular pressure monitoring.

7. Contraindication
Intracranial pressure monitoring.

8. Warnings
1) This product is sterile. Do not use if package is opened or damaged.
2) Do not allow any air bubbles to enter the system.
3) Abnormal pressure readings should correlate with the patient's clinical manifestations. Verify transducer function with a known amount of pressure before instituting therapy.
4) Use before expiry date.
5) This product should be used only by professional medical staff that should be responsible to check the integrity and validity of the product.
6) Portable and mobile RF communications equipment can affect the product.
7) The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the product as replacement parts for internal components, may result in increased emissions or decreased immunity of the product.
8) The product should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
9) This product is intended for use by healthcare professionals only.
10) The product contains DEHP.
11) This product is connected to the monitor that should conform to standard of IEC 60601-1:2012.

9. Complications include but are not limited to:
1) Infection;
2) Air emboli;
3) Clotted catheter and Blood back;
4) Over-infusion (Only DPT1030, DPT1120);
5) Abnormal pressure readings;

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6) Allergic reactions;
7) Arterial/venous thrombosis;
8) Cardiac or Respiratory arrest;
9) Hemorrhage;
10) Myocardial infarction;
11) Transient ischemic attack (TIA).