Demax

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# Disposable Pressure Transducer

# Instructions for Use

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.**

**Description**

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

**Information of Basic UDI-DI**

Basic UDI-DI is available in the European database on medical devices (Eudamed), URL to the Eudamed public website: https://ec.europa.eu/tools/eudamed

Basic-UDI-DI: 69437182DPT5B

**Intended Purpose**

The Disposable Pressure Transducer is intended for monitoring intravascular blood pressure in humans, such as Arterial Pressure, Venous Pressure. The device with stopcocks can be used with normal saline, heparinized saline solution and contrast media.

**Intended user**

The Disposable Pressure Transducer is meant to be used by experienced physicians trained.

**Target Population**

Disposable Pressure Transducer are intended for patients who are in need of human intravascular blood pressure monitoring.

**Operating conditions**

The product shall be operated under the following conditions:

1) operating temperatures: 15°C～40°C;
2) humidity: 10%～90%, noncondensing;
3) atmospheric pressure: 56.7kPa～113.3kPa.

**Storage**

The packaged product should be stored in a dry and cool place with good ventilation. The temperature of storage is 10℃～30℃. The humidity is less than 80%, atmospheric pressure range from 56.7kPa～113.3kPa.

After sterilization by ethylene oxide, the shelf-life is 3 years from the date of sterilization under the conditions of abiding by the storage rules.

**Transportation condition**

keep away from heavy and sunshine, keep dry

Temperature limit: -18℃~55℃

Humidity limitation: 0~85%

**Indications for Use**

The Disposable Pressure Transducer for patients in need of invasive blood pressure monitoring.

**Clinical benefit**

The clinical benefits of the Disposable Pressure Transducer are to contribute to the success of patient management by providing accurate blood pressure information to the healthcare professionals involved in the patient's treatment.

**Contraindication**

Contraindicated in patients with severe infections.

**Warnings**

- This product is a sterile product. Do not use if the package is opened or damaged.
- This product should be used with monitors that comply with IEC 60601 electrical safety standards. If this product is used with components from other manufacturers, you must also check their instructions for use.
- Do not reuse.

Note: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

**Precautions**

- Please read the IFU before use.
- Luer connector must be well connected, incorrect connection or lose connection may cause leaking.
- Do not inject air into the blood vessel.
- For qualified physicians use only.
- Please use it before the expiration date.
- The safety and effectiveness of the use of Disposable Pressure Transducer have not been tested in pregnant women, in breastfeeding women and in pediatric population

**Adverse Event**

-Infection

-Blood loss

-air emboli

-Contrast-induced AKI

**Performance Characteristics**

Disposable Pressure Transducer is a sterilized, single use device used for invasive blood pressure monitoring. It is composed of a flush set, transducer components, blood pressure transmission line, flush valve, cable and stopcock. Disposable Pressure Transducer, including three product structure types. The first type of Disposable Pressure Transducer mainly includes: flush set, flush valve (flush rubber plug), stopcock, and transducer components. The second type of Disposable Pressure Transducer mainly includes: stopcock, valve, transducer components, manifolds, etc. The third type of Disposable Pressure Transducer mainly includes a flush valve (for rapid flush only). Among the first and second type of structure type products, there are seven different types of cable connector design available, the user can choose according to the use of the monitors.

**Guidance and Manufacturer's Declaration**

Below cables information are provided for EMC reference.

| Cable | Max. cable length, Shielded/unshielded | | Number | Cable classification |
|---|---|---|---|---|
| AC Power Line | 1.5m | Unshielded | 1 Set | AC Power |
| DC Power Line (USB Cable) | 0.67m | Unshielded | 1 Set | DC Power |
| HDMI Cable | 0.67m | shielded | 1 Set | Signal |

**Important information regarding Electro Magnetic Compatibility (EMC)**

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014+A1:2020 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

The equipment with following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active

**Essential Performance**

Working pressure range: -30 ~ 300 mmHg (-4kPa to +40kPa)

Excitation voltage: 6VDC, Compliant with IEC 60601-1.

Sensitivity: 4.95~5.05μV/V/ mmHg

Excitation impedance: 1800~3300Ω

Signal Impedance: 300Ω±5%

Zero drift: ≤±25 mmHg

Zero Temperature Drift: ≤±0.3 mmHg /℃

Sensitivity temperature drift: ≤±0.1%/℃

Inherent frequency: 40Hz (Standard set)

Shock resistance: 3 free falls from a distance of 1m high can be tolerated

Light sensitivity: ＜1 mmHg

ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally".

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

WARNING: EUT is not intended to be used with HF SURGICAL EQUIPMENT, therefore the clause 202.6.2.101 Electrosurgery interference from IEC 60601-2-34 is excluded from this evaluation.

When the AC input voltage is interrupted, it could be recovered automatically/by operator manually, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance

**EMI Compliance Table (Table 1)**

**Table 1 - Emission**

| Phenomenon | Compliance | Electromagnetic environment |
|---|---|---|
| RF emissions | CISPR 11<br>Group 1, Class A | Professional healthcare facility environment |
| Harmonic distortion | IEC 61000-3-2<br>Class A | Professional healthcare facility environment |
| Voltage fluctuations and flicker | IEC 61000-3-3<br>Compliance | Professional healthcare facility environment |

**NOTE** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

**EMS Compliance Table (Table 2-6)**

**Table 2 - Enclosure Port**

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| | | Professional healthcare facility environment |
| Electrostatic<br>Discharge | IEC 61000-4-2 | ±8 kV contact<br>±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 3V/m<br>80MHz-2.7GHz<br>80% AM at 1kHz |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | Refer to table 3 |

| | | |
|---|---|---|
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30A/m<br>50Hz or 60Hz |
| Proximity magnetic fields | IEC 61000-4-39 | Frequencies 30 kHz, 8A/m, CW<br>Modulatio<br>Frequencies 134,2 kHz, 65A/m<br>Pulse modulation 2,1 kH<br>Frequencies 13,56 MH, 7.5A/m<br>Pulse modulation 50 kHz |

**Table 3 – Proximity fields from RF wireless communications equipment**

| Test frequency (MHz) | Band (MHz) | Immunity test levels |
|---|---|---|
| | | Professional healthcare facility environment |
| 385 | 380-390 | Pulse modulation 18Hz, 27V/m |
| 450 | 430-470 | FM, ±5kHz deviation, 1kHz sine, 28V/m |
| 710 | 704-787 | Pulse modulation 217Hz, 9V/m |
| 745 | | |
| 780 | | |
| 810 | 800-960 | Pulse modulation 18Hz, 28V/m |
| 870 | | |
| 930 | | |
| 1720 | 1700-1990 | Pulse modulation 217Hz, 28V/m |
| 1845 | | |
| 1970 | | |
| 2450 | 2400-2570 | Pulse modulation 217Hz, 28V/m |
| 5240 | 5100-5800 | Pulse modulation 217Hz, 9V/m |
| 5500 | | |
| 5785 | | |

**Table 4 – Input a.c. power Port**

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| | | Professional healthcare facility environment |
| Electrical fast transients/burst | IEC 61000-4-4 | ±2 kV<br>100kHz repetition frequency |
| Surges<br>Line-to-line | IEC 61000-4-5 | ±0.5 kV, ±1 kV |
| Surges<br>Line-to-ground | IEC 61000-4-5 | ±0.5 kV, ±1 kV, ±2 kV |
| Conducted disturbances induced by RF fields | IEC 61000-4-6 | 3V, 0.15MHz-80MHz<br>6V in ISM bands between 0.15MHz and 80MHz<br>80%AM at 1kHz |
| Voltage dips | IEC 61000-4-11 | 0% $U_T$; 0.5 cycle<br>At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º |
| | | 0% $U_T$; 1 cycle<br>and<br>70% $U_T$; 25/30 cycles<br>Single phase: at 0º |

| | | |
|---|---|---|
| Voltage interruptions | IEC 61000-4-11 | 0% $U_T$; 250/300 cycles |

**Table 5 – Signal input/output parts Port**

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| | | Professional healthcare facility environment |
| Electrical fast transients/burst | IEC 61000-4-4 | ±1 kV<br>100kHz repetition frequency |
| Conducted disturbances induced by RF fields | IEC 61000-4-6 | 3V, 0.15MHz-80MHz<br>6V in ISM bands between 0.15MHz and 80MHz<br>80%AM at 1kHz |

**Table 6 – PATIENT coupling PORT**

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| | | Professional healthcare facility environment |
| Electrostatic Discharge | IEC 61000-4-2 | ±8 kV contact<br>±2kV, ±4kV, ±8kV, ±15kV air |
| Conducted disturbances induced by RF fields | IEC 61000-4-6 | 3V, 0.15MHz-80MHz<br>6V in ISM bands between 0.15MHz and 80MHz<br>80%AM at 1kHz |

**Electrical Safety Tips**

The location of the chip outer cover of the Disposable Pressure Transducer may exceed 41℃during use, but will not exceed 43° C. Since the chip outer cover will not be in contact with the skin for a long time, there will be no risk, so please feel free to use it. (IEC 60601-1:2005+AMD1:2012+AMD2:2020)

**Instructions for Use**

The Disposable Pressure Transducer can be used with normal saline and heparinized saline solution, it is recommended to replace the transducer every 96hrs (4 days) to reduce risk of infection

**The Operational Instructions of DPT1030/ DPT1120/ DPT1030B /DPT1120B/ DPT1030C/ DPT1120C/ DPT1030E/ DPT1120E/ DPT1030F/ DPT1120F/ DPT1030G/ DPT1120G/ DPT1030H/ DPT1120H**

**1. Preparation**

Using aseptic technique, open the package containing the sterile product.

***Caution: Do not use if package is opened or damaged.***

1) Ensure that the cable is compatible with the monitor, otherwise a separate reusable interface cable should be selected.
2) Connect the disposable pressure transducer to the monitor.

***Caution: Care must be taken to keep electrical connections on the cable extension dry, otherwise it may cause unstable readings.***

Remove all air from the flush solution bag per hospital policy.

3) Close the flow regulator on the flush set and connect the flush set to the flush solution bag. Hang the bag approximately 60cm above the patient.
4) Make sure that all connections are tight.

***Caution: Do not over-tighten the joint, as this may cause the joint to crack and leak together, resulting in bubble embolism or loss of blood pressure waveform.***

5) Fill the drip chamber halfway on the flush set with flush solution by squeezing the drip chamber. Open the flow regulator.

**2. Filling system**

1) Pull the flush valve, turn the appropriate stopcocks and make sure all tubing of the disposable pressure transducer are filled with infusion solution. Remove all air bubbles from the system.

***Caution: Significant distortion of the pressure waveform or air emboli can result from air bubbles in the system.***

2) Replace all caps on the stopcocks with caps without holes.
3) Turn stopcock "OFF" to the side of the vent port.
4) Mount the transducer either on the patient's body per hospital procedure or on an infusion stand.
5) Recheck whether all connections are tight. Make sure that caps without hole have been screwed.
6) Pressurize the flush solution bag to 300mmHg.

***Caution: Fluid input line pressure greater than 300 mmHg will result in an average fluid infusion rate greater than 3mL±1mL/hour. This may result in a potentially harmful increase in blood pressure and fluid overdose.***

7) Connect transmission tubing to the catheter on the patient per manufacturer's instructions.
8) Flush system per hospital policy.
9) Test whether the Disposable Pressure Transducer product provides a color code to identify the intended monitoring site of the blood pressure transmission line.
   The color code is as follows:
   Red: ARTERIAL;
   Blue: central venous pressure (RA/CVP);
   Yellow: pulmonary artery pressure (PA);
   Green: atrial pressure (AL);
   White or colorless: Other.

**3. Zeroing**

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.

**4. Blood pressure monitoring**

***Caution: Rezeroing of the transducer is required if the zero reference point is moved relative to the pressure monitoring site.***

***Caution: The system should be checked periodically for bubbles or leaks.***

After finishing the blood pressure monitoring, disconnect the disposable pressure transducer according to relevant operation specification.

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

**The Operational Instructions of DPT1120IB**

**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. Arrows on the handles indicate when the lumen is open to the fluid path.
3) 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.
4) 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.

5) Fill the drip chamber halfway on the flush set with flush solution by squeezing the drip chamber. Open the flow regulator.

**2. Filling system**

1) Connect the the female luer of the transducer to the corresponding position of the catheter, open the Flush Valve, so that the liquid flows from the catheter to the transducer, and after flush the transducer free of air, close the Flush Valve.
2) Mount a Disposable Pressure Transducer compatible mounting bracket on a pole. Place a transmission tube mounting plate in the bracket so that the slots of the plate are facing up. Adjust the bracket on the pole so that the top of the slots are at patient heart level.
3) Visually examine the entire lumen to ensure it is completely fluid filled and bubble free.
4) Once system has been fluid filled and the air is removed, the system is ready to be zero balanced.

**3. Zeroing**

1) Balance the system according to the monitor manufacturer's instructions.
2) Once the system is balanced and you have begun monitoring pressures, changes in elevation of the Pressure Transducer manifold will not affect the continued accuracy of pressure readings. To monitor patient pressure, close the Flush Valve off to atmosphere.

**4. Blood pressure monitoring**

1) Turn the stopcock so that the transducer lumen is open to the catheter. (Inspect carefully for air bubbles and re-flush the manifold lumen if necessary.)
2) If the patient position is changed, adjust the height of the transducer mounting Bracket so that the slots for the compensator line are maintained at patient heart level.

***Caution: Rezeroing of the transducer is required if the zero reference point is moved relative to the pressure monitoring site.***

***Caution: The system should be checked periodically for bubbles or leaks.***

**5. After finishing the blood pressure monitoring, disconnect the disposable pressure transducer according to relevant operation specification.**

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

**The Operational Instructions of all (Except DPT1030/ DPT1120/ DPT1030B /DPT1120B/ DPT1030C/ DPT1120C/ DPT1030E/ DPT1120E/ DPT1030F/ DPT1120F/ DPT1030G/ DPT1120G/ DPT1030H/ DPT1120H/ DPT1120IB)**

**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. Arrows on the handles indicate when the lumen is open to the fluid path.
3) 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.
4) 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.
5) Fill the drip chamber halfway on the flush set with flush solution by squeezing the drip chamber. Open the flow regulator.

**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 1. Make this connection tight but do not over tighten.

2) Turn the Stop cock 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 1.]***

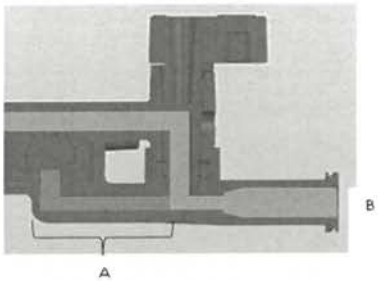


Figure 1: Cross-sectional side-view of the Transducer port of the Pressure

A-This area of the lumen does not need to be fluid filled.

B-Transducer port

4) Mount a Disposable Pressure Transducer compatible mounting bracket on a pole. Place a transmission tube mounting plate in the bracket so that the slots of the plate are facing up. Adjust the bracket on the pole so that the top of the slots are at patient heart level.

5) Place the female luer fitting of the transmission tube into one of the slots in the Pressure Transducerplate. Visually examine the entire length of the transmission tube to ensure it is completely fluid filled and bubble free.

6) Once system has been fluid filled and the air is removed, the system is ready to be zero balanced.

**3. Zeroing**

1) Balance the system according to the monitor manufacturer's instructions.

2) Once the system is balanced and you have begun monitoring pressures, changes in elevation of the Pressure Transducer manifold will not affect the continued accuracy of pressure readings. To monitor patient pressure, close the Flush Valve off to atmosphere.

**4. Blood pressure monitoring**

1) Turn the stopcock so that the transducer lumen is open to the catheter. (Inspect carefully for air bubbles and re-flush the manifold lumen if necessary.)

2) If the patient position is changed, adjust the height of the transducer mounting Bracket so that the slots for the compensator line are maintained at patient heart level.

***Caution: Rezeroing of the transducer is required if the zero reference point is moved relative to the pressure monitoring site.***

***Caution: The system should be checked periodically for bubbles or leaks.***

**5. After finishing the blood pressure monitoring, disconnect the disposable pressure transducer according to relevant operation specification.**

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

**eIFU**

The exact same pdf version e-IFU can also be found on the website of Demax Medical:
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Note: When the manufacturer's instruction for use is updated, it will be uploaded timely. For it is di cult to trace to every end user to inform the change, so we advise the customer to browse and check it regularly.

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**Symbol Identification**

| | | | |
|---|---|---|---|
|  | **Do Not Reuse** |  | **Contents** |
|  | **Caution** |  | **Keep Away From Sunlight** |
|  | **Use By** |  | **Keep Dry** |
|  | **Date Of Manufacture** |  | **Sterlized Using Ethylene Oxide** |
| LOT | **Batch Code** |  | **Manufacturer** |
| REF | **Catalogue Number** | EC REP | **Authorised Representative In The European Community** |
|  | **Do Not Use If Package Is Damaged** | CE | **CE Marking Of Conformity** |
|  | **Consult Instruction For Use** | MD | **Medical device** |
|  | **Do Not Resterilize** | $\mathbb{R}_{\text{Only}}$ | **PRESCRIPTION ONLY** |
| UDI | **Unique device identifirer** |  | **Defibrillation-proof type CF applied part** |
|  | **Humidity limitation(0%-80%)** |  | **Temperature limit(10℃-30℃)** |
| UK CA | UK Conformity Assessed | UK REP | **UK Responsible Person (UKRP)** |

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