DMK-I-15E A/5
2019-06-04
CE 0123
ARTG
DV-2017-MC-13918-1

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

Reference Number	Meanings	
	Type	Length of Cable（cm）
DPT1030	Single-head	30
DPT1120	Single-head	120
DPT1120NT	Single-head，have three-port manifold，no transmission tube	120
DPT1100M	Single-head，have three-port manifold	100
DPT1120M	Single-head，have three-port manifold	120

3. Specifications

Excitation Voltage	6Vdc
Operating Pressure Range	-30~300mmHg
Operating Temperature Range	15℃~40℃
Sensitivity	4.95~ 5.0μV/V/mmHg
Leakage current	＜2μA at 120V RMS 60Hz
Overpressure Tolerance	-400 ~4000 mmHg
Zero Offset	≤±25 mmHg
Zero Thermal Drift	≤±0.3 mmHg /℃
Output Drift	±1 mmHg /8h（after 20 second warm-up）
Signal Impedance	300Ω±5%
Flush valve rate (Only DPT1030 DPT1120)	3mL±1mL/1h/300mmHg

4. Product Structure

This product includes flush set, transducer components, transmission tube, flush valve, cable and stopcock. (Figure 1).

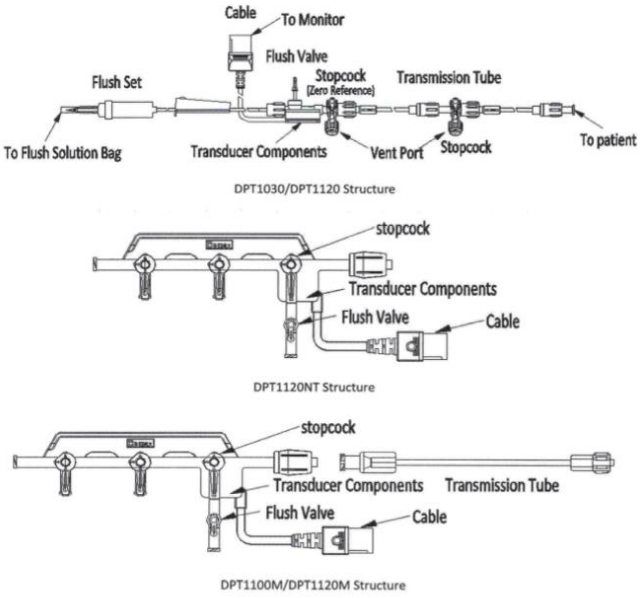


Figure 1:Schematic drawing of disposable pressure transducer.

5. Operational Instructions

5.1 The Operational Instructions of DPT1030 DPT1120

5.1.1 Preparation

1) Using aseptic technique, open the package containing the sterile transducer.

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

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

4) Remove all air from the flush solution bag per hospital policy.
5) 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.
6) Make sure that all connections are tight.
7) Fill the drip chamber halfway on the flush set with flush solution by squeezing the drip chamber. Open the flow regulator.

5.1.2 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.

5.1.3 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.

5.1.4 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.

Caution: Disposable pressure transducer is recommended to be replaced after being used for 72 hours.

5.1.5 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.

5.2The Operational Instructions of DPT1120NT DPT1100M DPT1120M

5.2.1 Preparation

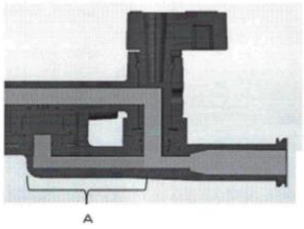
1) Open package containing the sterile Disposable Pressure Transducer. Check all connections for tightness before removing the product from the package.

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.]***



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

Figure2:Cross-sectional side-view of the Transducer port of the Pressure

4) Mount a 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 Transducer plate.
6) Visually examine the entire length of the transmission tube to ensure it is completely fluid filled and bubble free.
7) Once system has been fluid filled and the air is removed, the system is ready to be zero balanced.

5.2.3 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.

5.2.4 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.

Caution: Disposable pressure transducer is recommended to be replaced after being used for 72 hours.

5.2.5 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.

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 integrality 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 Bleed back;
4) Over-infusion(Only DPT1030、DPT1120);
5) Abnormal pressure readings;

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

10. Symbols Explanation

	DO NOT REUSE		CONTENTS
	CAUTION		KEEP AWAY FROM HEAT AND RADIOACTIVE SOURCES
	USE BY DATE		KEEP DRY
	DATE OF MANUFACTURE		THIS SIDE UP
LOT	BATCH CODE		MANUFACTURER
REF	CATALOGUE NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
STERILE EO	STERILIZED USING ETHYLENE OXIDE	CE	CE MARKING OF CONFORMITY
	DO NOT USE IF PACKAGE IS DAMAGED	PHT DEHP	CONTAINS OR PRESENCE OF PHTHALATES

11. 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.

12. Storage

The packaged product should be stored in a dry and cool place with good ventilation. The temperature of storage is -25℃~70℃. The humidity is less than 80%, atmospheric pressure range

from 56.7kPa~113.3kPa.
This product has been sterilized with EO. The use before expiry date is within 2 years.

13. Manufacture Information

Manufacturer: Beijing Demax Medical Technology Co., Ltd.
Registration Address: A13-7, Jingshengnansi Street, Tongzhou District, 101102 Beijing, PEOPLE'S REPUBLIC OFCHINA
Manufacturing Address: A13-7, Jingshengnansi Street, Tongzhou District, 101102 Beijing, PEOPLE'S REPUBLIC OF CHINA
Tel.：0086-10-59771799
Fax：0086-10-59771883
Post code：101102
Email：marketing@demaxmedical.com
After-sales Service：Beijing Demax Medical Technology Co., Ltd.
Address：A13-7, Jingshengnansi Street, Tongzhou District, 101102 Beijing, PEOPLE'S REPUBLIC OF CHINA
Tel.：0086-10-59771799
Fax：0086-10-59771883
Postcode：101102
Email：marketing@demaxmedical.com
European Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel.: 0049-40-2513175
Fax: 0049-40-255726