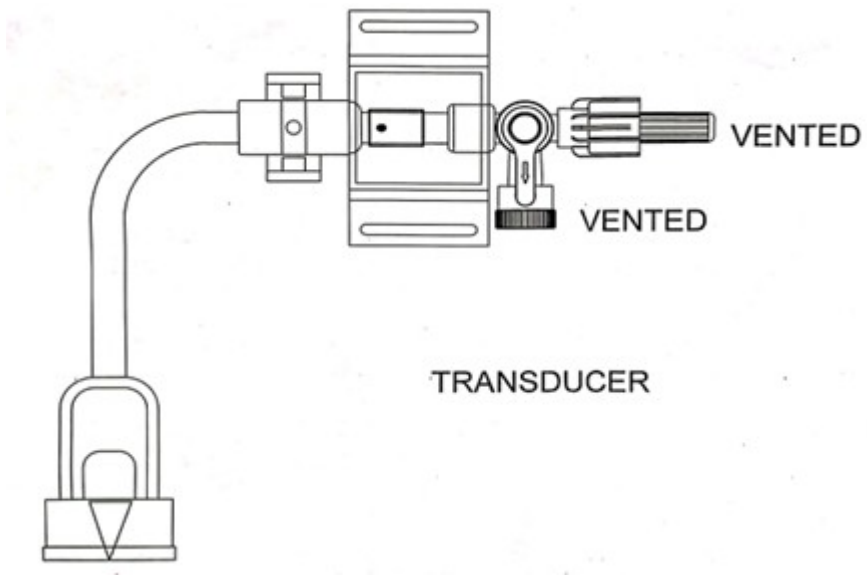
Prymax PM

Disposable Pressure transducer

DEVICE DESCRIPTION:

Disposable Blood Pressure Transducer composed of Pressure Transducer and Configuration accessories. The main component of Pressure Transducer consists of Protective cap, Perfusion valve, Zero Tee and Cable Connector. This functional unit is sterilized by Ethylene Oxide, as a “single unit sterile pack”.

Drawing of product:



MATERIAL USED:

Poly vinyl chloride (PVC), Polypropylene (PP), Polycarbonate (PC), Poly ethylene (PE), Silicone rubber

INTENDED PURPOSE:

INTENDED USE: Device is used for traumatic arterio-venous pressure monitoring. Device is also used as an accessory during hemodynamic pressure monitoring procedure.

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INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender.

INDICATIONS:

- All kinds of critically patients and surgery patients who are circulatory insufficiency and maybe massive bleeding under the extracorporeal circulation of heart surgery and large blood vessels surgery.
- Patients with Serious hypotension, shock and other blood flow mechanics unstable, and having difficulty by using the indirect method to measure pressure or difficult to measure because of pulse pressure narrow.

CONTRAINDICATIONS:

- It is prohibited to measure the pressure of left atrium in case that the air filter is not installed between the cannula and the persistent infusion valve
- Not to be used in patients with known hypersensitivity to any of the materials used

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- Accurate measurements: Pressure transducers can provide precise measurements of a patient's blood pressure, which can help clinicians understand cardiovascular function and monitor vital signs.
- Improved patient safety: Disposable pressure transducers are designed for single-patient use, which reduces the risk of cross-contamination and healthcare-associated infections (HAIs).
- Clinical diagnosis: Pressure transducers can be used to monitor a variety of pressures, including arterial, central venous, pulmonary artery, and left coronary artery pressures. This information can help with diagnosis, treatment, and prognosis estimates.
- Treatment of diseases: Pressure transducers can be used to help clinicians safely titrate vasoactive medications to achieve the desired blood pressure effect.
- Bedload monitoring: Pressure transducers can be used to monitor bedload.
- Infusion pumps: Pressure transducers can be used with infusion pumps for drug delivery.

Performance Characteristics:

- Pressure sensor sensitivity

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- Pressure sensor resolution

INSTRUCTION FOR USE:

Setup program

1. Open the product in sterile environment.
2. Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
3. Open the monitor, choose disposable sterile pressure Transducer and accessories and sterile flushing liquor (commonly use 0.9% normal saline, with 1 ~ 2 unit's heparin per ml), check the outer packing is complete.
4. Open the disposable sterile pressure transducer and accessories, pay attention to keep sterile operation, and can use the packing which have be opened as sterile plate. Check and verify if all the connectors are connecting reliable and the core are spun to the designated position. Don't screw the Luer Lock connector too tightly.
5. Connect the reusable monitoring instrument cables and transducer cable connector together, to avoid liquid flowing into connector.

Product Main Features

1. Electric Properties

a) Transducer incentive voltage: 1V ~ 6V;
b) Incentive voltage rate: 5 KHz;
c) Transducer input impedance: 300Ω ~ 400Ω;
d) Transducer output impedance: 250Ω ~ 350Ω.

2. Physical Properties:

a) Under the normal temperature and 200Kpa water pressure, sustain for 15 seconds without the overflowing phenomenon;
b) The connect power of Components ≥15N.

Note: All three-way bye hole on Transducer tube both have protection of exhaust sealing cap, to avoid accidental contact pollution. This sealing cap should keep to the bubbles, and then use the airtight sealing cap which is in the inside bag of Transducer and components instead it.

Fluid Pipeline Preflush

1. Insert the stopper puncture of the transfusion set into the infusion bag, upside downs the infusion bag to release the air. Open the rolling clamp, gently squeeze the infusion bag, at the same time pull the cleaning valve till the infusion bag is fully exhausted.

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	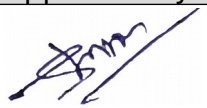

2. Close the rolling clamp put the infusion bag into the pressurization bag, and hang onto the intravenous infusion bracket around 2 feet higher than patient's heart.
   Note: Do not pressure the infusion bag at this moment; infuse the pipeline system by gravity force to reduce the possibility of air bubble during the pre-flush process.
3. Under the condition of the rolling clamp closing, extrusion drops tube make the liquid fill to one third
4. when pressure bag pressure, liquid water surface in the drop tube will rise.
   Note: Liquid surface of drop tube cannot pass drop tube, otherwise it will not through the liquid dripping speed to calculate flow.)
5. Open rolling clamp, press or pull flush valve, using liquid gravity to make the flushing
   liquor filled the whole pipeline completely.

Note: Opening cap which is easy to exhaust should be upwards and put in a peak.

6. Tap the dropper lower part lightly, make bubbles rising and press or pull flush valve at
   the same time, in order to help the bubble educt.
7. Close rolling clamp, Pipeline pre-flush finished.

Technique on Eliminating the Air Bubble

1. After eliminating the air from the infusion bag, make the ringent cap of the pressure transducer facing upward and put it on the highest point. Open the rolling valve of the venous infusion channel, press or pull the infusion valve, make sure the washing fluid fills in the transducer and the initializing three-way stopcock. Then unscrew the ringent cap loose (instead of getting rid of it), the washing fluid will drop from the ringent cap when pre- washing. Rotate the tap so that “OFF” faces the ringent cap, and screw it tight again. Continue to pre-wash the other channels and three-way stopcocks.
2. Check whether the air bubbles in the pressure transducer are completely eliminated or not. If there are any air bubbles left, gently flip the pressure transducer with hand, and rotate the pressure transducer so that the air bubbles rise. Then press or pull the infusion valve so as to help eliminate the remaining air bubbles.
3. Raise the pressure to 300mmHg with the pressure- adding bag, watch carefully to decide whether the air bubbles in the channel system are eliminated or not. If there are any air bubbles, wash again following the steps mentioned above result in the air bubbles are eliminated completely.

Adjusting the Plane of Transducer

1. Substitute the closed caps for the ringent caps on the side ports and pressure monitoring ports of all three-way stopcocks
2. Install the pressure transducer on the supporting stand of venous infusion rod, put the initializing three-way stopcock on the highest point so that it is on the same level of the center of heart. Or directly fix the pressure transducer on the patient's arm, corresponding to the horizontal level of the center of heart.
3. Connect the pressure monitoring tube in which the air bubbles are eliminated with the intra venous cannula in the patient, and wash off the patient's blood in the intra venous cannula by fast infusion.

Initializing the Transducer

a) The initializing three-way stopcock of the pressure transducer is on the same level of the center of heart.
b) "OFF" on the tap of the initializing three-way stopcock of the pressure transducer face the patient.
   Unscrew the closed caps loose so that they can rotate freely, instead of getting rid of them.
c) Initialize the monitoring instrument complying with the Instruction for Operation ofit.
d) Turn the tap of the three-way stopcock so that "OFF" face the closed cap. And screw the closed cap tight.
e) Check the wave form of pressure.
f) It takes about one minute for the system to become balanced.
   Then calculate the flow rate, make sure the flow rate of infusion keeps at 2 ~ 5ml/h

WARNINGS & PRECAUTIONS:

- Do not use the product if the package is damaged or open.
- The procedure must be performed by trained personnel, well versed in anatomical landmark, trained for safe Techniques and aware of potential complications.
- The physician should be aware of possible complications may occur during Arterial and Venous insertion.
- Product must not be re-sterilized. The re-sterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device
- Do not alter or modify any part of the device
- Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death

ADVERSE EFFECTS:

Thrombosis, infections, air embolisms, and trauma are potential complications.

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RE-USE HAZARDS:
Transmission of infection from one patient to another.

PACKAGING:
The device is packed in blister pack sealed with Tyvek paper, which is further packed in inner carton & master carton.

STERILIZATION:
Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:
Temperature Limit: 15^{0}C to 40^{0}C.

COUNTRY CODE: - 356

DEVICE SHELF LIFE: 3 Year

DISPOSAL
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:
In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY
Refer to the company's return goods policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide


Manufacturing date


Use-by date


Caution

Prepared by:	Approved By:

Non-pyrogenic

Do not resterilize

REF

Catalogue number

CE 0297

Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged and

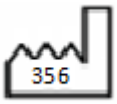
consult Instructions for Use

MD

Single Sterile Barrier System

Medical Device

UDI



UDI Carrier

Country of Manufacturer

Manufactured By:

Prymax Healthcare LLP.,
Management Solutions Europe LTD

EC REP:

Compliance

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