





Pressure Monitoring Line

DEVICE DESCRIPTION:

Pressure monitoring line is made of clear and non-toxic PVC that is kink resistant tubing. Pressure monitoring line specifications facilitates optimum dynamic response; it is latex free and available as sterile in non-phylogenetic form. It is highly accurate and monitors the fluent blood pressure as required. Pressure monitoring line is used for observing the pressure through extended medical soft, kink resistant PVC tubing which ensures smooth fluid movement.

Available Sizes:

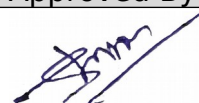
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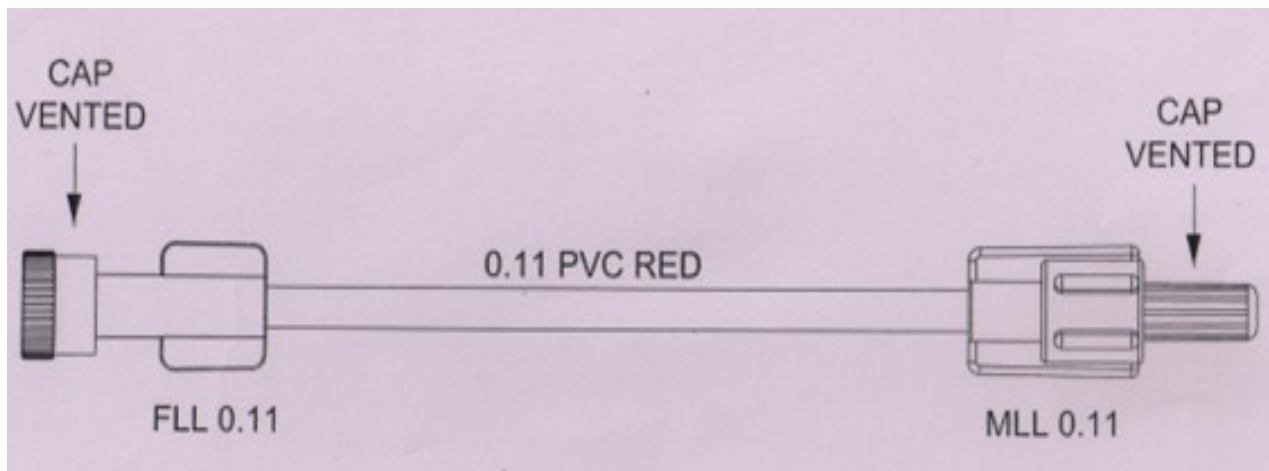
Product Code	Variant description
PPM-04	Pressure Monitoring Line Clear 10 cm M-F
PPM-04M	Pressure Monitoring Line Clear 10 cm M-M
PPM-06	Pressure Monitoring Line Clear 15 cm M-F
PPM-06M	Pressure Monitoring Line Clear 15 cm M-M
PPM-10	Pressure Monitoring Line Clear 25 cm M-F
PPM-10M	Pressure Monitoring Line Clear 25 cm M-M
PPM-12	Pressure Monitoring Line Clear 30 cm M-F
PPM-12M	Pressure Monitoring Line Clear 30 cm M-M
PPM-20	Pressure Monitoring Line Clear 50 cm M-F
PPM-20M	Pressure Monitoring. Line Clear 50 cm M-M
PPM-40	Pressure Monitoring. Line Clear 100 cm M-F
PPM-40M	Pressure Monitoring Line Clear 100 cm M-M
PPM-60	Pressure Monitoring Line Clear 150 cm M-F
PPM-60M	Pressure Monitoring Line Clear 150 cm M-M
PPM-80	Pressure Monitoring Line Clear 200 cm M-F
PPM-80M	Pressure Monitoring Line Clear 200 cm M-M
PPM-100	Pressure Monitoring Line Clear 250 cm M-F
PRPM-40	Pressure Monitoring Line Red 100 cm M-F
PRPM-60	Pressure Monitoring Line Red 150 cm M-F
PRPM-80	Pressure Monitoring Line Red 200 cm M-F
PBPM-40	Pressure Monitoring Line Blue 100 cm M-F
PBPM-60	Pressure Monitoring Line Blue 150 cm M-F
PBPM-60M	Pressure Monitoring Line Blue 150 cm M-M
PBPM-80	Pressure Monitoring Line Blue 200 cm M-F
PBPM-80M	Pressure Monitoring Line Blue 200 cm M-M
PYPM-40	Pressure Monitoring Line Yellow 100 cm M-F
PYPM-60	Pressure Monitoring Line Yellow 150 cm M-F
PYPM-80	Pressure Monitoring Line Yellow 200 cm M-F
PPM-S60	Pressure Monitoring Line Clear Spiral

* M-F stands for: Male Female end connector; M-M stands for Male end connector

Drawing of product:

Approved By:





MATERIAL USED:

Poly Vinyl Chloride (PVC), Poly carbonate (PC), Polypropylene (PP)

INTENDED PURPOSE:

INTENDED USE: PM Lines are used during the Invasive Blood Pressure Measurement. It Carries the Blood/pressure from the patient to the Monitoring System/Device. Pressure monitoring line is used to Increase the pathway between the infusion site & source of infusion.

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:

Pressure Monitoring Line is primarily used in cardiac surgeries for invasive blood pressure monitoring and connection between syringe infusion pump & patient.

CONTRAINDICATIONS:

- Pressure monitoring lines are not suitable for injection or power injection of fluids.
- Not to be used in patients with known hypersensitivity to any of the materials used.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

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Clinical Benefits:

- Monitoring improves BP control
- Improve prevention or regression of organ damage
- Protection from major cardiovascular complications
- Reduced blood pressure
- Improve hypertension control
- (CEC) rate – Clotting of the Extracorporeal circuit – Low

Performance Characteristics:

- Kink resistant
- Dynamic response

INSTRUCTION FOR USE:

- Open the product in sterile environment.
- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Read the Instructions Carefully
- Choose the appropriate size of the device.
- Open the package from the peel-open area and remove the device.
- Check the pressure line and flush it with normal saline before use.
- Connect the luer connector with other devices, and eliminate air in the tube before connection

WARNINGS & PRECAUTIONS:

- 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
- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury
- Do not clean or Re-use the device,
- The product should be used immediately after opening the packing.
- Do not use with a stylet or guide wire
- If the patient is sensitive or allergic to PVC, do not use the device

ADVERSE EFFECTS:


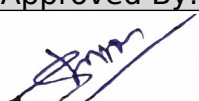
- Formation of an arteriovenous (AV) fistula
- Infection

RE-USE HAZARDS:

Transmission of infection from one patient to another.

PACKAGING:

The device is packed in paper pouch, which is further packed in inner carton & master carton.

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STERILIZATION:

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

STORAGE CONDITION:

Temperature Limit: 15°C to 40°C.

COUNTRY CODE: - 356

DEVICE SHELF LIFE: 5 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
Ethylene Oxide



Do not re-use



Sterilized by



Manufacturing date
Caution



Use-by date



Non-pyrogenic
number



Do not re-sterilize



Catalogue

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Manufacturer
Conformité Européenne



Storage Temperature



Range



Do not use if package is damaged
instructions for use



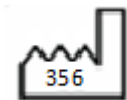
Consult



Single Sterile Barrier System
Medical Device



UDI Carrier



Country of Manufacturer



Manufactured By:

**Prymax Healthcare LLP.,
Management Solutions Europe LTD**

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Petrich, Bulgaria

Haryana, INDIA -121001

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Confidential

Proprietary Information of Prymax Health Care LLP
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