Prymax PM

Pressure Monitoring Kit

DEVICE DESCRIPTION:
Pressure Monitoring Kits are a combination of Medical grade PVC Tubing's, Drip Chambers, Transducers, Flush device & Stop cocks, sampling devices, connectors, roller clamps & caps assembled together as a functional unit to monitor the invasive blood pressure. This functional unit is sterilized by Ethylene Oxide, as a "single unit sterile pack".

Available variants:

Model Number	Variant description	Transducer Connector type
PMK-S01	Pressure Monitoring Kit Single	Abbott
PMK-S01ED	Pressure Monitoring Kit Single	Edwards
PMK-S02	Pressure Monitoring Kit Single with needle free connector	Abbott
PMK-S03	Pressure Monitoring Kit Single with sampling device	D
PMK-S04	Pressure Monitoring Kit Single with needle free connector	Edwards
PMK-S05	Pressure Monitoring Kit Single with 2 needle free connector	Abbott
PMK-S06	Pressure Monitoring Kit Single Arterial with Sampling Port with needle free connector	Abbott
PMK-S07	Pressure Monitoring Kit Single Venous with Sampling Port with needle free connector	Abbott
PMK-S08	Pressure Monitoring Kit Single with Sampling Port and Red & Blue PM Line	Abbott
PMK-S09	Pressure Monitoring Kit Single with Red Line & Stopcock	Abbott
PMK-D01	Pressure Monitoring Kit Double	Abbott DPT
PMK-D01ED	Pressure Monitoring Kit Double	Edwards DPT
PMK-D02	Pressure Monitoring Kit Double EHIRC Delhi	Abbott

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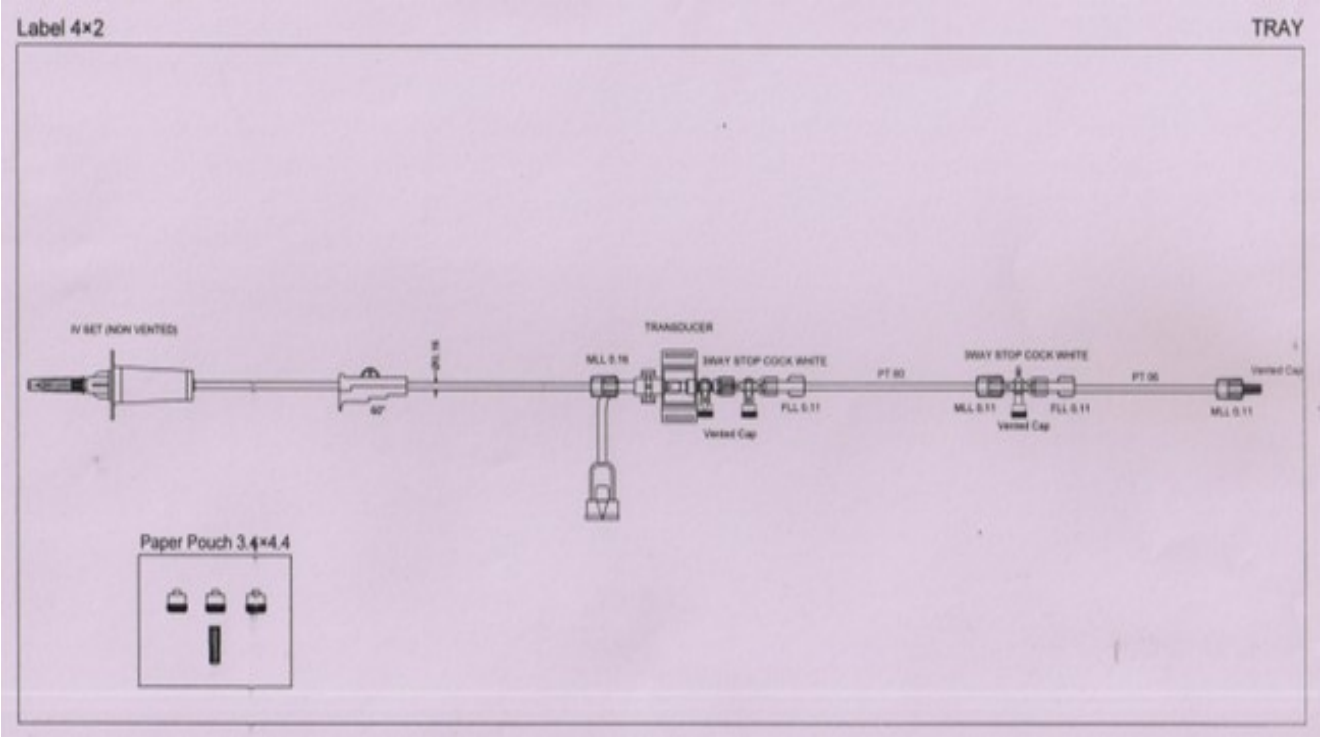
PMK-D03	Pressure Monitoring Kit Double with 2needle free conn.	BD
PMK-D04	Pressure Monitoring Kit Double	Abbott
PMK-D05	Pressure Monitoring Kit Double KPUG	Abbott
PMK-D06	Pressure Monitoring Kit Double Max Art CVP EL	Abbott
PMK-D07	Pressure Monitoring Kit Double with 2needle free connector	Abbott
PMK-D08	Pressure Monitoring Kit Double with 2needle free connector	Edwards
PMK-D09	Pressure Monitoring Kit Double Batra Hospital	Abbott
PMK-D10	Pressure Monitoring Kit Double	D
PMK-D11	Pressure Monitoring Kit Double Aurbindo Hospital	Abbott
PMK-D12	Pressure Monitoring Kit Double Artemis	Abbott
PMK-T02	Pressure Monitoring Kit Triple	Abbott

Drawing of product:



MATERIAL USED:

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Poly vinyl chloride (PVC), Polypropylene (PP), Polycarbonate (PC), High density poly ethylene (HDPE), acrylonitrile butadiene styrene (ABS), Poly ethylene (PE), Thermoplastic poly urethane (TPU)

INTENDED PURPOSE:

INTENDED USE: Device is intended to be used for an invasive blood pressure measurement. This set will typically connect directly to the applied invasive catheter, and the transducer will provide the electrical signals for display by a patient monitoring system.

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:

- Monitoring include traumatic brain injury (TBI), hydrocephalus or conditions at high risk of developing hydrocephalus (e.g. space-occupying lesions or subarachnoid hemorrhage), idiopathic intracranial hypertension, or Reye's syndrome

CONTRAINDICATIONS:

- Pressure monitoring should not be monitored without using an air-eliminating filter to clear air passage between solution source and flush device.
- High viscous liquid and large blood transfusion.
- Not to be used in patients with known hypersensitivity to any of the materials used.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- Allows continuous 'beat-to-beat' blood pressure monitoring. This is useful in patients who are likely to display sudden changes in blood pressure (e.g. vascular surgery).
- Allows accurate blood pressure readings at very low pressures, for example in shocked patients.
- Allows close blood pressure monitoring for a long period of time e.g. ICU patients. IBP monitoring avoids the trauma of repeated cuff inflations.

Performance Characteristics:

- Pressure sensor sensitivity

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	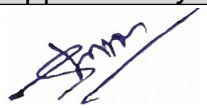

- Pressure sensor resolution

INSTRUCTION FOR USE:
Pre-application

- 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.
- Set the ZERO-IN in the Monitor by activating flushing.

Application

- Prime the Lines and the kit to ensure bubble-free fluid path
- Check that all connections are properly fixed including the stopcock and luer caps.
- Hang the IV bottle through the IV pole mount. Pressurize IV source to 300mmHg.
- Prepare the drape and Puncture the Radial artery & introduce Arterial line.
- Prepare the drape and Puncture the IJV or Sub-Clavion Vein and Introduce the Venous line.
- Connect the Arterial & Venous Line to the IV Fluid through the IV set.
- Flush the Line with the help of Flush device.
- Repeat priming steps if required.
- Check for leakage, if any. Ensure complete purging of air from line.
- Check for flow of IV solution intermediately to ensure proper working of flush device.
- Check the ABP & CVP Plethysmograph and reading.
- Withdraw the line and remove the whole kit once procedure is over.

Zeroing, Leveling and Calibration of Pressure Transducer

- After the system has been primed and mounted on the pole mount, zero the transducer. The following procedure should be completed periodically.

  a) At this stage, the pressure transducer and the zero-reference stopcock (the one integrally formed with the transducer) is in its original position
  b) Turn zero-reference stopcock "off" to the patient and remove the white, vented cap from the side port thus opening the stopcock to air.
  Important note: The air-fluid interface at the side port of the zero-reference stopcock should be at or near the level of the right arterial (mid-axillary).

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	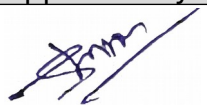

c) Zero the transducer according to the monitor manufacturer's instructions.

d) Turn zero-reference stopcock "off" to the side port, replace by non-vented cap

WARNINGS & PRECAUTIONS:

- Do not use the product if the package is damaged or open.
- 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
- 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 resterilized. 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 kit

ADVERSE EFFECTS:

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

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^{o}C to 40^{o}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:

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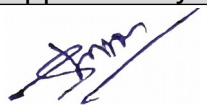
	

In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.

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

Non-pyrogenic

Do not resterilize

Catalogue number

Prepared by:	Approved By:

Manufacturer

Storage Temperature Range

Conformité Européenne

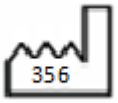
Do not use if package is damaged

Consult instructions for use

Single Sterile Barrier System

Medical Device

UDI Carrier



Country of Manufacturer

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