

# Instruction for Use

# iPeX



## Pressure Monitoring Kit

Variants	: Single, Double, Triple- with/without Sampling Device/Sampling Stopcock
Product Class as per REGULATION (EU) 2017/745	: IIa
Product Class as per Medical Device Rule	: B
Duration of use	: Short Term

## **DESCRIPTION**

PM Kit, 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.

The major components of the Pressure Monitoring Kit are;  
PVC Tubing-PVC, Luer Lock-ABS/Co-polyester/PVC, Vented Cap/Non-Vented Cap-HDPE, Stopcock- PC.

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells, or their derivatives, of human origin
- tissues or cells of animal origin, or their derivatives.

Patient Target Group: All Age groups.

## **INTENDED USE**

Pressure Monitoring kit are used for blood pressure sensing during clinical invasive procedures without interfering with blood flow and/or pressure. Open the pack containing sterile disposable pressure monitoring kit. Check all fittings to assure tight connection. Connect the Transducer to the Monitor through the Interface cable. Use aseptic technique.

## **MODE OF ACTION**

Pressure Monitoring Kits are a combination of Medical grade PVC Tubings, 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".

The Sensor is a hydraulic communication with the blood stream to detect the patient's pulse. The flush device allows continuous flow of 3 ml/hr. when addressed when, operated it allows high flow, that is required for flushing blood remains from the monitoring line. The stopcock is used for Zeroing the pressure monitor before operation. It also assists in Blood samplings procedure.

Pressure transducers are placed on the base plate which is usually mounted on IV stand. Transducers should be positioned at the level of the patient's heart to get accurate reading.

The whole apparatus is primed with saline solution & then connected to the site of monitoring (Radial Artery in the wrist via a catheter or cannula).

Saline is connected into the pressure bag & inflated up to 300 mm hg to prevent backflow of blood from monitoring site.

Note: The catheter or cannula is not the part of BL's PM Kit.

## **INDICATION FOR USE**

### **Pre-application**

- 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.

### **INTENDED USERS:**

- Product is recommended to use by qualified medical/paramedic staff.

## **CONTRAINDICATION**

- The device is not designed, sold, or intended for use except as indicated.
- 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.
- The Patient is known or is suspected to be allergic to materials contained in the device.

## **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.

## **CAUTION/WARNING**

- 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 kit.

**RISKS OF RE-USE**

- A device designated, as ‘single-use’ must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
  - Anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.
  - Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer’s specifications and, therefore, the performance may be compromised.

**STORAGE**

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 15 °C to 40 °C and maintaining the relative humidity condition 50 to 75%. In case of any tempering in the packaging, the product condition may be affected even incase store at above defined condition. Product Sterility is valid for three years, from the manufacturing of the product.

**DISCLAIMER**

The condition of the device must be verified prior to use. BL is not responsible for any damage to person, property, etc. from any inappropriate or recommended use of the device, including reuse. Reuse could cause infection or serious health issues.

**DISPOSITION**

Dispose off/Discard the used Device, in accordance with your country’s health care and safety regulations.















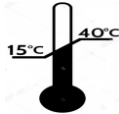
**GOODS RETURN POLICY**








Refer to the company’s return good policy.

Please contact the branch office or customer service at [bls@bllifesciences.com](mailto:bls@bllifesciences.com) or call +91 11 45100100.

Company Website Link to product IFU: <https://www.bllifesciences.com>

**SYMBOLS USED ON PRODUCT LABEL**

Symbol			
Meaning	Caution	Conformity of European Norm with Notified Body Number	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in the European Community	Sterilized using ethylene oxide Single sterile barrier system
Symbol			
Meaning	Do not resterilize	Consult Instruction for use	Non-pyrogenic
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit

<b>Symbol</b>			
<b>Meaning</b>	Fragile, handle with care	Keep dry	This way up
<b>Symbol</b>			
<b>Meaning</b>	Keep away from sunlight	Stacking limit by number	
<b>Symbol</b>			
<b>Meaning</b>	Medical device	Unique Device Identifier	



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