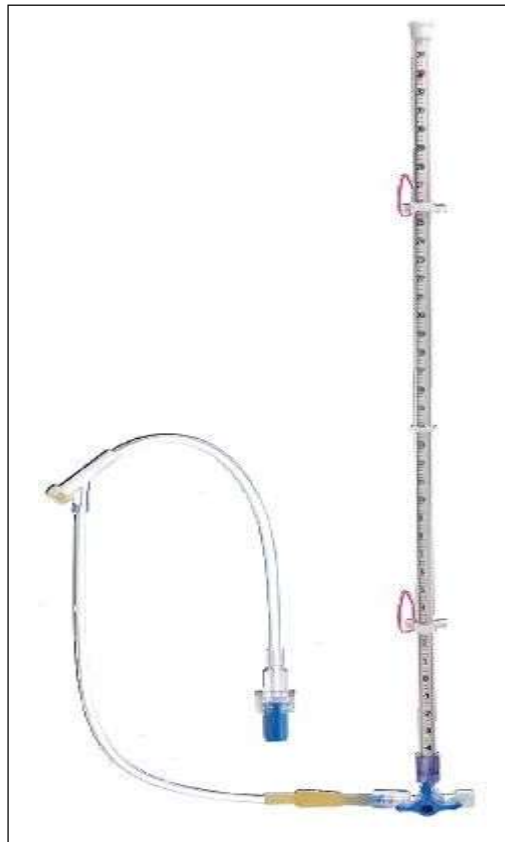


DETAILED SPECIFICATION

CVP MANOMETER

Product Reference	Product Description
13350	POLYMED CVP Manometer with Latex bulb and without Y port
13351	POLYMED CVP Manometer with luer lock and Y port

Product Photograph



GENERAL INFORMATION

Intended Use: The CVP Manometers are used for continuous or intermittent monitoring of central venous pressure during infusion. Central venous pressure is defined as the pressure of blood in the central venous system which is essentially just prior to entry into the right atrium.

Legal Manufacturer-

POLY MEDICURE LIMITED

Plot No.: 104-105, Sector 59, HSIIDC Industrial Area, Ballabgarh,
Faridabad, HARYANA, INDIA - 121004

Production Site-

POLY MEDICURE LIMITED

Plot No.:104-105, Sector 59, HSIIDC Industrial Area, Ballabgarh,
Faridabad, HARYANA, INDIA – 121004

European Authorized Representative- Name and address

OBELIS S.A.

Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium,

Certification:

Certification	Notified Body
CE Certificate Medical Device Directives 93/42/EEC- Annex II <u>CE Certificate No.: G1 041938 0007</u>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany <u>Notified Body Number: 0123</u>
EN ISO 13485:2016/DIN-EN ISO 13485:2016 <u>Certificate No.: Q5 041938 0001</u>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany

Classification:

Device Class

- As per the "Classification criteria" Annexure- IX of the Council Directive 93/42/EEC as amended by 2007/47/EC the CVP Manometer is used for more than 60 minutes and less than 30 days. Hence this device is for „short term use“ as per the description in the 1.1 of Annexure- IX.
- This device doesn't penetrate inside the surface of body, hence are "Non - Invasive device" as per 1.2 of Annexure- IX.
- As per Rule- 2 for Classification, all non-invasive devices intended for channeling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified in Class- IIa. Hence CVP Manometer is classified as **Class-IIa** Medical device.

Device Description:

Central Venous Pressure is an accurate indicator of the amount of blood returning to the heart from the head, body and limbs via the superior and inferior vena cava. If and when there is blood loss, then the CVP reading will be altered (will fall) almost immediately as the amount of blood returning to the heart will have decreased. Central Venous Pressure is also an accurate indicator of the ability of the heart (myocardial pump strength) to pump out blood to maintain normal blood pressure and tissue perfusion. CVP is an accurate indicator of right ventricular end diastolic volume. In most institutions CVP is measured in cm of water (H₂O).

- Specially designed to measure and monitor continuous or intermittent central venous pressure.
- CVP manometer is a tube with graduations marked from -4cm to +34cm and attached to three way stop cock.
- Extra soft kink-resistant frosted 120cm long extension tube is fitted with female luer lock on one end and male luer lock on the other end for safe connection to central venous catheter.
- Sliding indicator is provided to record reading.
- Molded clamps with latex rubber strings are provided for easy fixation to IV Stands.
- Y-injection site/Latex rubber flash bulb is provided for extra medication.
- The manometer is manufactured from non-toxic Polypropylene & Poly Vinyl Chloride.
- Individually packed in peelable pouch.
- The product is sterilized using EO (Ethylene Oxide) gas.
- The product & product packaging doesn't contain any constituents of animal origin.

Sterilization Method/Shelf Life:

Sterilization Method: Ethylene Oxide Sterilization.

Shelf Life: Five years from the date of manufacturing.

Packaging Characteristics:**Unit**

Quantity	1 No.
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Duplex

Quantity	01 Nos.
Dimensions-L x H x W (mm)	90 x 560 x 35

Carton

Quantity	50 Nos.
Dimensions-L x H x W (mm)	845 x 460 x 260

Storage Conditions:

Between 5°C to 35°C

Materials of Concern:

Material	Present (No/Yes)
DEHP free	Yes
Latex free	Yes
Free from Substances of animal origin BSE/TSE	Yes