Prymax PM

Measure Volume Set

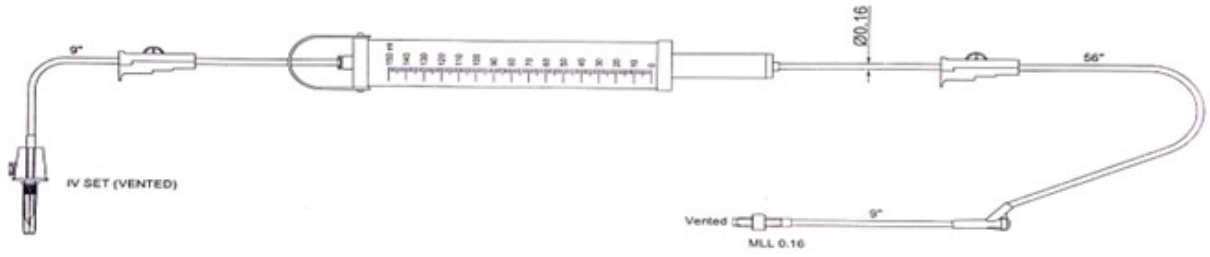
Device Description:

Device is available in measured volume chambers of 110/150 ml with 10 ml overflow limit. Micro drip with drop size of 60 drops per ml. Burette chamber is made of bio-compatible medical grade transparent polymer, suitable for infusion of all types of fluids. Hanger design facilitates the hanging of complete device on the I.V. stand. Floating auto shut off valve acts as floating indicator and automatically shut off the drain path to prevent air in line. Roller controller provides accurate flow control. No-kink device prevents the kinking of tube during transportation. Separate plugs for extra medication and continuous change over. Sterile, individually packed.

Available Sizes:

Product Code	Brand	Variant	Capacity
PMV-110	Prymax PM	Measure Volume Set 110 ml	110ml
PMV-150	Prymax PM	Measure Volume Set 150 ml	150ml

Drawing of product:



MATERIAL USED:

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Poly vinyl Chloride, Polypropylene, Acrylonitrile-butadiene-styrene

INTENDED PURPOSE:

INTENDED USE: The Measure Volume set is a single-use, sterile, consist of a flexible tubing with a luer connector, Drip Chamber & Measuring burette set used to administer iv solution to the body with measuring of solution. The Measure Volume set is used for the infusion of intravenous fluids. Measure Volume set or MV set used to Administered IV solution to the body through veins with measuring of solution.

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:

For intravenous infusion of medications or fluid requiring continuous delivery at controlled infusion rates.

CONTRAINDICATIONS:

- It is not intended for the delivery of whole blood, blood components.
- Administration of highly viscous fluids.
- Blood transfusion.
- Not to be used in patients with known hypersensitivity to any of the materials used.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:

- The accurate measurement and controlled delivery of fluids

Performance Characteristics:

- Roller controller: Helps control the flow
- Soft and kink-resistant tube: Helps ensure the tube doesn't kink

INSTRUCTION FOR USE:

Pre-preparation:

- 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.

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Procedure:

- For infusion, aseptically remove any male luer from the set prior to connection to the female luer port.
- Carefully remove needle protective cap from safety-winged needle and prime set in accordance with recommended procedure
- Perform veni puncture with patient's arm in downward position and assure that the Measure Volume set is securely attached to the patient.
- Begin IV infusion by measuring the fluid. NOTE: Please follow your facility's procedures, however, it is recommended that the device be used for single infusion purposes.
- After completion of infusion, hold the gauze down and terminate the procedure
- After completion place gauze over Infusion site without applying pressure.
- Measured Volume Burette Sets are specially designed floating auto shut- off valve that acts as floating indicator and automatically shuts- off the drain path, when the chamber gets empty to prevent trapping of air in the fluid line
- With one hand, activate the safety mechanism by pressing in the light part on both sides of the hub to engage the lock.
- Slide the safety mechanism backward until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.
- Apply gentle pressure to the puncture site using the gauze pad according to facility protocol.
- Promptly dispose of Measure Volume set in an approved disposal container in accordance with the procedures of your facility

WARNINGS & PRECAUTIONS:

- The device will perform as intended when the instructions are followed accordingly.
- Refrain from carelessly releasing the lock, or forcefully pulling the wing, as such actions may damage the integrity of the device
- Examine individual package for integrity prior to use. If packaging has been damaged, do not use.
- Any used MV set considered contaminated. Discard all used sets together with the holder in biohazard containers approved for their disposal.
- Do not forcefully release or re-activate the safety mechanism after it

has been activated.

- Do not use for subcutaneous infusion or injection.
- A reuse of the product may cause harmful infections, injury.
- Gloves should be worn at all times during venepuncture to minimize exposure hazard.
- Avoid blood leakage and any air in the tubing during infusion procedure.
- Make sure all air is removed by priming prior to use
- The product is guaranteed sterile till the package has not been opened or damaged within the expiry date.
- Sterile, Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.

ADVERSE EFFECTS:
Inadvertent bolus, Siphonage or free-flow, Occlusion, Air entrainment.

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.

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: 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.

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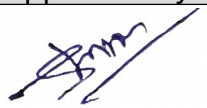
	

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

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 number

Do not resterilize

Catalogue number

Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged

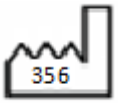
Consult instructions for use

Single Sterile Barrier System

Medical Device

Prepared by:	Approved By:

UDI



UDI Carrier

Country of Manufacturer

Manufactured By:

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53/17,Industrial Area NIT, Faridabad,
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