PRODUCT NAME

Measured Volume Set (MV Set)

BRAND NAME

UMA-DRIP-110 ML

UMA-DRIP-150 ML

VARIANTS

- Measured Volume Set (MV Set)-110 ML
- Measured Volume Set (MV Set)-150 ML

GENERAL DEVICE DESCRIPTION

The Measured Volume Set (MV Set) is a device used to inject fluid into the human body through veins. It consists of a PVC tube, drip chamber, spike, roller control and safety shut-off valve. The floating auto shut-off valve prevents air in line, while a roller controller ensures accurate flow. Spike at one end to allow the inlet of solution into the measured burette and hypodermic needle on another end. Drip formation rate is 60 drops = 1.0 ± 0.1 ml (1.0 + 0.1 g). This can also be used in conjunctions with IV Cannula.

INTENDED PURPOSE

Measured Volume Set (MV Set) is intended for used in the administration of fluids or medications from a container into the patient's vascular system through a vascular access device

MATERIAL OF CONSTRUCTION

Components	Material
Needle Cover	Polypropylene(PP)
Needle	SS304
Injection Site	Latex

Components	Material
Injection Port ("Y" Connector)	Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC), Rubber
PVC Tubing	Non-Toxic Polyvinyl Chloride (PVC)
Reel	Polypropylene (PP), Acrylonitrile Butadiene Styrene (ABS), High-Density Polyethylene (HDPE)
Regulator	Polypropylene (PP), Acrylonitrile butadiene styrene (ABS)
C Clamp	Polypropylene (PP)
D Clamp	Polypropylene (PP)
PVC Chamber	Nontoxic Polyvinyl chloride(PVC)
Fluid Filter	High-Density Polyethylene (HDPE)
Micro Drip	SS-304
Floater	Latex Free Rubber
Measuring Cylinder	Non-Toxic Polyvinyl Chloride (PVC)
TOP & Bottom Cylinder Cap	Acrylonitrile butadiene styrene (ABS)
Air vent	Polyvinyl Chloride (PVC)
Air vent Filter	Polypropylene (PP)
Spike	Acrylonitrile butadiene styrene (ABS)
Spike Cover	Polypropylene (PP)
Adopter (Regular), Adopter (Luer Lock)	Polypropylene (PP) & Acrylonitrile butadiene styrene (ABS)

INDICATIONS

The Measured Volume Set (MV Set) is used to administer Intravenous fluid and medicines into human circulating system at controlled infusion rates to treat electrolyte imbalance, dehydration.

MEDICAL CONDITIONS

- Dehydration
- Electrolyte imbalance

- Specialized medication delivery

DURATION OF CONTACT

Short Term (Intended to be used for less than 24 Hours)

POINT OF CONTACT

Indirect contact with blood

USAGE FREQUENCY

Single use device

INTENDED PATIENT POPULATION

This device is used for any patient population (such as neonates, pediatrics, adults and old age patients) with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

INTENDED USER

The device is intended to be used by Healthcare professional.(Generalist medical practitioners, Specialist medical practitioners, Nursing professionals, Paramedical practitioners, emergency room staff and critical care staff)

USE ENVIRONMENT

Healthcare Setting

PERFORMANCE CHARACTERISTICS

- Measured Volume Set (MV Set) is intended for continuous delivery of IV fluids at controlled infusion rates by gravity fluid.
- 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.
- Soft, clear and flexible tubing promotes smooth flow of fluids.

- The fluid filter in Measured Volume Set (MV Set) is intended to filter particulates.
- Efficient roller controller for better flow control and ensures accurate flow.

CLINICAL BENEFITS

- Measured Volume Set (MV Set) is used to measure and deliver the exact amount of medication to the patient.
- Measured Volume Set (MV Set) assist in precise fluid management i.e. preventing fluid overload or dehydration.
- Measured Volume Set (MV Set) is efficient in delivering small and accurate doses so it can be beneficial for pediatric and neonatal care where higher doses are not recommended.
- Measured Volume Set (MV Set) is use for precise and controlled fluid delivery directly into a patient's bloodstream, ensuring that the accurate amount of fluid or medication is administered.

CLINICAL SAFETY

- The device is sterile single use, Non-toxic, Non-pyrogenic, cylinder type measured volume chamber.
- The medical-grade PVC tubings provide a soft, transparent, and flexible means for users to detecting any air bubbles.
- The flow controller provides accurate and controlled infusion from Measured Volume Set (MV Set) reduces the risk of medication errors, ensuring patient safety.
- The device is made of materials which are not leachable ensuring fluids is safely administered and the fluid filter of the device filters off the unwanted substances during infusion.
- The needle cap protects the user from needle injury.
- DEHP Free (Applicable only for DEHP free variants)

PRINCIPLE OF OPERATION

The device is used for to administer IV fluids or medications to a patient's vascular system by gravity-controlled flow.

- **Gravity-controlled flow:** Gravity-controlled flow in an infusion set relies on the force of gravity to deliver fluids or medications from an elevated reservoir (typically an IV bag or bottle) to a patient's bloodstream. The container (usually a bag or bottle) is hung above the patient's level, creating a height difference between the container and the patient. The greater the height difference, the faster the flow rate, as it increases the gravitational force. The flow rate is controlled by adjusting the height of the container or by using a flow rate regulator. Higher placement of the container increases the flow rate, while lowering it decreases the flow rate.

CONTRAINDICATIONS

- The device must not be used in patients hypersensitivity to any of the materials used.
- The device is not used for administration of highly viscous fluids.(e.g. Lipid emulsion)
- It is not intended for the delivery of whole blood, blood components.
- Measured Volume Set (MV Set) which contains DEHP should not be used for the treatment of pregnant or nursing women, infants, or children.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- Blockage of filter or air vents.
- Any infectious disease can transfer
- Tube kink

LIMITATION

The device is not intended to be used with blood or blood components.

WARNINGS

- For single use only
- Read instructions before use.
- Check expiry date prior to use.
- Re-use may lead to contamination and/or limited functionality of the device may lead to infection, injury or illness.

- Attached needle to be used for puncture of bottle and shall not be inserted into circulating blood /veins

PRECAUTIONS

- Do not store in direct sunlight, at extreme temperature or in high humidity.
- Do not use if packaging or product is damaged or contaminated
- Do not use if protective cap are loose or missing.
- Device should be immediately used after the opening of the package.
- Use rubber part only for Injecting medicine.
- Monitor all connections for tightness over the whole infusion procedure.
- This product is sterilized for single use only, discard after single use. Please do not repeat sterilization, do not clean, do not reuse.
- Burette must be in a complete vertical position at times to ensure the performance of the floating safety shut off valve.

DIRECTIONS FOR USE

1. Close all controllers
2. Remove spike protector and insert the spike firmly into solution container
3. Suspend the solution container with attached set. Open upper clamp and allow approx. 30 ml solution to flow chamber. Close upper clamp.
4. Gently squeeze and release drip chamber until it is approximately one third full.
5. Remove vein needle protector, slightly open flow regulator to clear air from tubing and needle. close lower clamp flow regulator.
6. Open upper clamp and allow solution to flow into scaled chamber until the desired volume is obtained. Close upper clamp.
7. Make vein puncture. Firmly open flow regulator, adjust drip rate & control infusion of solution with the flow regulator.
8. Hang the complete set with the help of the hanger on the other side of the IV stand, to prevent accidental fall of the UMA drip.

9. The floating valve shut-off the flow when solution level in the graduated chamber come to zero.
10. When more solution is required, close flow regulator & open upper clamp to fill scaled chamber until desired level. Close upper clamp and squeeze the drip chamber a little bit to float the valve up and then restart infusion as step 7.
11. Close air vent caps during periods of interrupted infusion therapy.

POTENTIAL SIDE EFFECTS / POTENTIAL ADVERSE EVENTS

- Air Embolism
- Allergic reactions
- Tissue necrosis
- Phlebitis
- Thrombophlebitis & blistering
- Hematoma
- Infiltration
- Malfunction due to leakage or blockage
- Extra Vascular drug administration
- Infection

STERILIZATION

The device is a single use device supplied in a sterile condition and it is sterilized by ETO Sterilization Method.

PACKAGING

For Primary Packaging: HM Bag, Ribbon Pouch, Paper Pouch

For Secondary Packaging: LD bag ,FBB inner Box

For shipper Packaging: Corrugated Box

STORAGE CONDITION

Store in cool and dry place, away from moisture, direct sunlight and extreme temperature.

Humidity Limit: 40% to 60%

Temperature Limit : 10℃ to 45℃

SHELF LIFE

5 years

DISPOSAL METHOD/ INSTRUCTIONS

Dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

NOTICE TO THE USER AND/OR PATIENT

In the event of malfunction of the device or changes in its performance that may affect safety, or any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

FOR FURTHER INFORMATION

For Further Information, please contact:

ROYAL SURGICARE PRIVATE LIMITED,

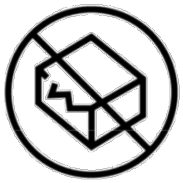
Plot No.832 Nr. Ganesh Rubber, Prima Automation Lane, Tal: Kalol, Dist.: Gandhinagar, Santej, Gujarat-382721, India

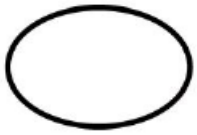
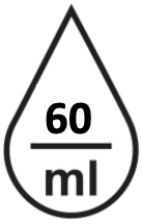
Email ID: royalsurgicare@gmail.com

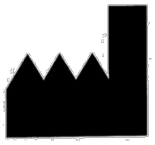
Website: www.umaflowindia.com

SYMBOLS AND DESCRIPTION

Symbol	Description	Symbol	Description
MD	**Medical Device** Indicates the item is a medical device	ROYAL SURGICARE PVT. LTD.	**Manufacturers Company Logo**

Symbol	Description	Symbol	Description
	**Consult Instructions For Use** Note: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.		**Do not re-use** Single use or use only once
	**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.		**Batch Code** Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.
	**Do Not Use If Package Is Damaged** Do not use, if the packaging is compromised.		**Caution** This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels
	**Use-by date** Indicates the date after which the medical device is not to be used.	 MM/YYYY	**Country of Manufacture** Note: This symbol is accompanied by the date that the device was manufactured. The date could be year, year and month, or year, month and day, as appropriate.
	**Unique device Identifier**		**Sterilized using ETO**

Symbol	Description	Symbol	Description
	Indicates a carrier that contains Unique Device Identifier information		Indicates a medical device that has been sterilized using Ethylene Oxide.
	**Single sterile barrier system** Indicates Single sterile barrier system		**Single sterile barrier system with protective packaging outside** To indicate that there is a single sterile barrier system with protective packaging outside.
	**Drops per Millilitre** Indicates the number of drops per millilitre.		**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed.
	**Liquid filter with pore size** Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.		**Non-pyrogenic** Indicates a medical device that is non-pyrogenic.
	**Keep Away from Sunlight** The symbol denotes the medical device that needs protection from light sources.		**Keep Dry** Indicates a medical device that needs to be protected from moisture.

Symbol	Description	Symbol	Description
	**Do not resterilize** Indicates a medical device that is not to be resterilized.		**ROYAL SURGICARE PRIVATE LIMITED** Plot No.832 Nr. Ganesh Rubber, Prima Automation Lane, Tal: Kalol, Dist.: Gandhinagar, Santej, Gujarat-382721, India **Customer Care No.:** +91 - 9724312823 +91 - 97268665503 **Email ID:** royalsurgicare@gmail.com **Website:** www.umaflowindia.com
CE 0123	CE marking with Notified Body Number		**Authorized Representative in the European Community** MED DEVICES LIFESCIENCES B.V. **Address:** Keizersgracht 482 1017 EG Amsterdam, The Netherlands **Contact No.:** +31-202254558 **Email ID:** info@meddevices.net
	**Does not contain DEHP** Contains less then 0.1% Phthalates—DEHP		**DEHP** Contains or presence of phthalate plasticizers DEHP.

Symbol	Description	Symbol	Description
	**Contains or presence of natural rubber latex**		**Latex free** (Indicates a medical device that is Latex free)
	**Temperature limit** Indicates the temperature limits to which the medical device can be safely exposed. Storage Conditions: Temperature: 10℃ to 45℃		