Doc. No.:	RGI/IFU-09/3058
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons® MEASURED VOLUME INFUSION SET

(BURETTE TYPE MEASURED VOLUME INFUSION SET)

REF **GS-3058**

℞ ONLY

INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic , Phthalate Free, Latex Free, Sterile, Single Use

⚠ **Caution :** Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.Failure to do so may result in complications.This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Device Description: Burette type measured volume chamber of 100 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.Patent design hanger 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.

Population of use: Adult & Paediatrics**.**

Intended User : To be administered by an expert qualified medical professional.

Intended Use: Device is intended for use in the administration of fluids from a container into a patient's vascular system through a vascular access device.

Preferred Route of Administration: Intravenous.

Contents: Sterile, single use Measured Volume Infusion Set packed in a peel open pouch.

Size: 100ml & 150ml, 60 Drops of distilled water equivalent to 1 ml Tolerance: (± 4 % of Nominal capacity)

Material of Construction: PVC, PP, PE, ABS, Acrylic , Nylon , SS ,Isoprene & Master Batch.

Storage: Store in a cool & dry place.

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

Contra-indications: Use in patient with a known allergic reaction to any of the product components, Administration of highly viscous fluids, It is not intended for the delivery of whole blood, blood components.

Potential Complications / Risks: Risk from improper fitment due to faulty 6% luer taper, Leakage & Blockage, any broken / cracked part / components/less clear drip chamber and tubing /un-proper tip of piercing spike, faulty air passage in vented piercing spike, bent & blunt of SS needle, uncontrolled flow.

Warnings: Warnings: This device is intended for Single use only.

DO NOT resterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.

Do not attempt to re-insert a partially or completely withdrawn needle.

Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.

Contamination and / or limited functionality of the device may lead to injury, illness of the patient. Do not use on injured or interacted surface. Do not use with light sensitive or photo sensitive drugs & paclitaxel type of chemotherapeutic drugs. Do not use for vasopressor drugs/ vasoconstrictor medications

Precautions:

(i) Check the integrity and functionality of the Infusion sets before use. Do not use if the Unit Pack is open or damaged.

(ii) Determine patient's condition and vitals status During device application / Operation.

(iii) Conduct procedure under strict surgical protocol and ensure complete asepsis.

(iv) Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.

(v) Do not Re-sterilize. Do not Re-use. Single use only.

(vi) Do not put the Device to Use after the Use by Date or Date of Expiry.

Adverse Events: Malfunction due to leakage or blockage, Embolism, Allergic reactions, tissue necrosis, Phlebitis, Thrombophlebitis & blistering, Phlebitis, Infiltration, Hematoma, Extra Vascular drug administration.

To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration Dispose the device after use as bio-medical waste as per applicable laws.

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Use Instructions:

1.Peel open the pouch & take out the burette type infusion set.
2.Close all controllers. Remove both anti-kink fixture from the set.
3.Remove Piercing spike protector and insert firmly into closing stopper of infusion container.

4. Suspend infusion container with attached set. Open air vent of piercing spike & graduated chamber, do not use needle to puncture the air vent. open upper clamp and allow approximately 30ml. Solution to flow into the graduated chamber. Close upper clamp.
5.Gently squeeze & release drip chamber till it is approximately one third full.
6.Remove luer lock cap. Slightly open flow regulator to clear air from tubing and luer lock. Close the flow regulator.
7.Open upper clamp & allow solution to flow into the graduated chamber till the desired volume is obtained. Close the upper clamp.
8.Attach the infusion Set to the vein puncture device. Gradually open the flow regulator. Adjust drop rate & control the solution flow with the flow regulator.

9. Hang the complete set with the help of the hanger on the other side of the I.V. stand, to prevent accidental fall of the Measure Volume IV Set.
10.The floating valve shall shut-off the flow when solution level in the graduated chamber comes to zero.
11 When more solution is required close flow regulator & open upper clamp to fill graduated chamber upto desired level.
12.Close upper clamp and squeeze the drip chamber gently to float the shut-off valve and then restart infusion as in step-8.
13.Close air vent caps during periods of interrupted infusion therapy.

Mfr.: **Romsons International** (Unit-II), 59J(C) & 9, Noida Special Economic Zone, Noida Dadri Road, Phase-II, Noida-201305 (INDIA) CE 2460

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Basic UDI DI : 8902120C014RX

REF	**Catalogue Number**	MD	**Medical Device**		**Do not Re-use**		**Consult instructions for Use**
LOT	**Batch Code**	IN	**Country of Manufacture**		**Do Not Resterilize**		**Keep away from sunlight**
	Date of Manufacture	STERILE EO	**Sterilized Using Ethylene oxide**	UDI	**Unique device Identifier**		**Keep Dry**
	Use by date		**Non-pyrogenic**		**Do Not Use if Package is Damaged & consult instructions for use**		**Caution**
	Manufacturer	EC REP	**Authorized Representative in the European Union**		**Single Sterile barrier system**		**Temperature Limit**
	Gravity Feed	15 µm	**Liquid Filter with Pore Size**		**Fluid Path**	60 ml	**Drops per millilitre**