INSTRUCTION FOR USE FOR FLOW REGULATOR

Product Name	:	Flow Regulator
Brand Name	:	Ultramed Flow Regulator (Flow range 5 to 250 ml/hr.)
Manufacturer's Name	:	Ultra for Medical Products (ULTRAMED) Co. (U.M.I.C) S.A.E
Manufacturer's Address	:	Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

Description of the Device:

- The **Graduated Flow Regulator (GFR)** is a sterile, single-use medical device intended for use as a subcomponent of sterile gravity-fed intravenous infusion sets. It is designed to manually regulate the flow rate of intravenous fluids and compatible medications administered under gravity feed conditions, ensuring controlled delivery of infusion solutions through the fluid pathway.
- The Graduated Flow Regulator incorporates a graduated control dial with calibrated flow rate markings and clearly identified **OPEN** and **OFF (Closed)** positions, enabling healthcare professionals to accurately select and adjust the desired infusion flow rate. The device is designed to provide consistent flow regulation while minimizing the risk of accidental changes to the selected flow rate, thereby promoting safe and reliable operation.
- The device includes **soft**, **DEHP-free**, **phthalate-free**, **medical-grade PVC** tubing that provides a continuous fluid pathway between the gravity infusion set and the patient's vascular access device (I.V. Cannula). The tubing is **flexible** and **kink-resistant** to help maintain uninterrupted fluid flow and **transparent** to allow visual inspection of the fluid for detection of air bubbles and flow interruption during administration.
- A **female Luer connector** is located at the proximal end of the device for secure connection to the male luer of the infusion set. A **male Luer connector** is positioned at the distal end for secure connection to the female luer of intravenous cannula or three-way stopcock.
- An integrated **Y-site injection port** is incorporated into the tubing to permit the administration of compatible medications without disconnecting the primary infusion line, thereby maintaining a closed fluid pathway and reducing interruptions to the infusion. This design may help reduce the potential risk of contamination associated with repeated disconnection of the infusion system.
- The device is provided with standard **6% Luer** connectors conforming to **ISO 80369-7** to ensure compatibility with standard intravenous administration devices, including gravity infusion sets, intravenous cannulas, and three-way stopcocks, while helping to minimize the risk of leakage or accidental disconnection.
- The device enables healthcare professionals to adjust the infusion rate within a calibrated range according to the prescribed therapy. Once adjusted, the device is designed to maintain the selected flow rate under the specified operating conditions. Periodic monitoring of the infusion remains necessary as factors such as height of the infusion container, solution viscosity, venous pressure, and patient position may influence the actual delivered flow rate.
- The device provides controlled gravity-fed flow regulation within a calibrated range of 5–250 mL/hr. for 10% density liquids and a range of 5 to 200 ml/hr. for 40% density liquids.
- The device fulfills the requirements of ISO 8536-13.
- Flow Regulator individually packed in a sterile peel / Tear pouch.
- Maximum use period not more than 3 days.

- The product is sterilized using EO (Ethylene Oxide).
- This product is for single use.

Product	Quantity per PE Bag	Quantity per Outer Carton	Carton Dimensions
Flow Regulator	25 pcs	400 pcs	51.5*51.5*38

Material Used:

- P.V.C (Poly Vinyl Chloride)
- ABS (Acryl nitrile butadiene styrene)
- Synthetic Rubber
- (H.D.P.E) High-density polyethylene

Intended purpose:

The Graduated Flow Regulator is a sterile, single-use medical device intended to manually regulate the flow rate of intravenous fluids and compatible medications administered through a gravity-fed intravenous infusion system. The device incorporates an integrated Y-site injection port to facilitate the administration of compatible medications into the infusion line without disconnecting the primary infusion line.

Variants:

Ref Code	Item
1010	Flow Regulator Flow range 5 to 250 ml./hr.

Clinical Indications:

- **Intravenous Fluid Administration**: For the controlled administration of intravenous fluids, including crystalloid and colloid solutions, through a gravity-fed intravenous infusion system.
- **Controlled Intravenous Medication Administration**: For the gravity administration of compatible intravenous medications requiring controlled infusion rates, such as antibiotics and other medications intended for gravity infusion.
- **Fluid and Electrolyte Therapy:** For the controlled administration of intravenous fluids used for hydration and electrolyte replacement.
- **Parenteral Nutrition:** The device may be used for the gravity administration of compatible parenteral nutrition solutions when clinically appropriate and in accordance with institutional protocols.

Contraindications:

- Do not use the device in patients with known hypersensitivity or allergic reactions to any materials or components of the device.
- Do not use the device to administer highly viscous fluids, whole blood, or blood components.

Device Limitations:

- Do not use the device for more than 3 days.
- Do not use for the administration of highly viscous fluids.
- Do not use for the administration of whole blood or blood components.
- Do not use with infusion pumps or pressurized infusion systems. The device is intended for gravity-fed infusion only.

Patient Target Group:

- No specific requirements or restrictions on use for patient population or user group.

- ❖ Patients of all ages, including neonatal, pediatric, adult, and geriatric patients.
- ❖ Male and Female patients.
- ❖ Patients requiring gravity-fed, controlled intravenous administration of fluids or compatible medications.
- ❖ It is intended for controlled intravenous infusion, including the administration of small volumes of fluid over extended periods when clinically indicated.

Application site in the body:

- The Graduated Flow Regulator has indirect contact with the patient. It is used as part of a gravity-fed intravenous infusion system and remains external to the patient's body. The device regulates the flow rate of the infusion fluid before it is delivered into the patient's vascular system.

Replacement Frequency:

- Replace the device immediately if contamination, damage, blockage, or loss of integrity is suspected.
- Maximum duration of use: 3 days.

Intended User:

- To be used by an expert qualified medical professional, Skilled or Trained Personnel **(In-Charge).**

Clinical benefits:

- The graduated flow regulators provide a simple and effective method for controlling the flow rate of intravenous fluids and compatible medications in gravity-fed infusion systems. They allow healthcare professionals to easily set and adjust the desired flow rate, reduce the need for manual drip counting, support periodic monitoring and flow adjustment during infusion, and help minimize the risk of over-infusion or under-infusion when used correctly. These features contribute to improved clinical efficiency, enhanced patient safety, and more consistent delivery of intravenous therapy.

Use Environment:

- The device is intended for use in healthcare facilities, including Hospital, Emergency Departments, Intensive Care Units (ICUs), Operating Rooms, and Outpatient Clinics.

Life time of device:

- The Graduated Flow regulator is used for maximum 3 days.

Sterility status and Method of sterilization:

- The Graduated Flow regulator is supplied in sterile state and sterilized using ethylene oxide.

Information on medical device intended to be used with other devices:

- The Graduated Flow Regulator is designed in accordance with ISO 8536-13:2024. It is provided with standard 6% taper male and female Luer connectors conforming to ISO 80369-7. The female Luer connector, located at the proximal end, is intended for secure connection to the male Luer connector of a gravity infusion set, while the male Luer connector, located at the distal end, is intended for secure connection to the female Luer connector of an intravenous cannula or three-way stopcock.

Performance Characteristics:

- ❖ Soft, transparent, medical-grade PVC tubing.
- ❖ Tubing is flexible and kink-resistant.
- ❖ Tubing is DEHP-free and phthalate-free.
- ❖ Tubing dimensions: Inner Diameter (ID): 2.89–3.0 mm & Outer Diameter (OD): 4.1 mm
- ❖ Tube length: 50cm
- ❖ Graduated control dial and clearly marked OPEN and OFF (Closed) positions.

- ❖ Integrated Y-site injection port for intermittent administration of compatible medications.
- ❖ Female Luer connector at the proximal end and male Luer connector at the distal end.
- ❖ Standard 6% Luer connectors conforming to ISO 80369-7.
- ❖ Compatible with standard gravity intravenous administration sets, intravenous cannulas, three-way stopcocks.
- ❖ The product is sterilized using EO (Ethylene Oxide) gas.
- ❖ Manual flow rate adjustment with a calibrated flow range of 5–250 mL/hr.

Risks Associated with reuse

- Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

- ❖ Perform hand hygiene and prepare a clean work area using aseptic technique.
- ❖ Gather all required supplies, including the prescribed I.V. solution or medication, I.V. infusion set, Graduated Flow Regulator, alcohol swabs, syringes (if required), and the patient's vascular access device (cannula).
- ❖ Remove the Graduated Flow Regulator from its sterile package and inspect the device for damage or defects before use.
- ❖ Ensure the Graduated Flow Regulator is in the "OFF" (closed) position.
- ❖ Connect the female Luer connector of the Graduated Flow Regulator securely to the male Luer connector of the I.V. infusion set.
- ❖ Remove the protective cap from the spike of the I.V. infusion set and insert the spike into the I.V. solution container using a twisting motion while maintaining aseptic technique.
- ❖ Hang the infusion container on an appropriate I.V. pole.
- ❖ Gently squeeze the drip chamber until it is approximately one-half to three-quarters full.
- ❖ Open the roller clamp of the I.V. infusion set and gradually open the Graduated Flow Regulator to allow the tubing to prime completely and expel all air from the system. Once priming is complete, close the Graduated Flow Regulator and the roller clamp.
- ❖ Connect the male Luer connector of the Graduated Flow Regulator to the patient's vascular access device (cannula).
- ❖ Open the Graduated Flow Regulator gradually and adjust the dial to the prescribed flow rate (5–250 mL/h), taking into consideration the prescribed therapy and the viscosity of the infused solution.
- ❖ Verify the flow rate by observing the drip rate and adjust the dial as necessary to achieve the prescribed infusion rate.
- ❖ Maintain the infusion container above the level of the patient's vascular access site throughout the infusion to ensure proper gravity flow.
- ❖ Monitor the infusion regularly and recheck the drip rate periodically. Readjust the Graduated Flow Regulator as necessary to maintain the prescribed flow rate.
- ❖ Allow the prescribed I.V. solution or medication to infuse by gravity until the infusion is complete or the solution container is empty.
- ❖ When the infusion is complete or the solution container is empty, turn the Graduated Flow Regulator to the "OFF" (closed) position and disconnect the device in accordance with institutional procedures.
- ❖ Dispose of the used Graduated Flow Regulator in accordance with institutional and local regulation.

Warnings:

- ❖ For Single use.

- Discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- DO NOT re-sterilize 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.
- 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 if packaging is opened, damaged, or compromised; sterility cannot be guaranteed.
- Do not use the device after the expiry date.
- The device should be used only by trained healthcare professionals familiar with the clinical application and operation of the device.
- Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- Do not use the device if the protective Luer cap is missing, loose, or damaged.
- Some organic solvents, alcoholic disinfectants, infusion solutions with high pH-value substances might cause cracking of the device.
- Storage up to 30º C ± 2°C, avoid excessive heat, protect from direct sunlight and moisture.
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.

Precautions:

- 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.
- Check the integrity and functionality of the Flow regulator before use.
- Conduct procedure under strict surgical protocol and ensure complete asepsis.
- Use the device immediately after opening the individual blister packing.
- Ensure all Luer connections are secured prior to start infusion.
- Do not use the device if you observe any damage, kinking, blockage, or foreign bodies in the device as the device may not perform as intended or cause injury to the patient or user.
- Do not use if the sterile package is opened, damaged, or compromised, as sterility cannot be assured, there may be a risk of infection and the device may not perform as intended.
- Storage up to 30º C ± 2°C, avoid excessive heat, protect from direct sunlight and moisture.
- Use the Y-site injection port only for the administration of compatible medications. Do not use it for any other purpose.
- Do not use the device for any infusion method other than gravity-fed intravenous infusion.
- This device does not contain phthalates (DEHP FREE); as marked.
- Determine patient's condition and vitals status during device application / Operation.
- Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- Do not Re-sterilize. Do not Re-use. Single use only.
- Do not use the device after the expiry date.

❖ Remove air from the administration set before use.

❖ Verify the selected flow rate after patient repositioning.

Potential Complications / Risks:

Potential risks and complications associated with the use of the Flow Regulator may result from improper use, incorrect setup, or conditions affecting gravity infusion. These complications include:

Patient-Related Risks

1. Inaccurate Flow Rate (Over- or Under-infusion): May result from incorrect flow setting, changes in IV bag height (hydrostatic pressure), solution viscosity, venous pressure, or improper device adjustment.
2. Air Embolism: May result from failure to remove air from the infusion system before use or from allowing the infusion to continue after the IV container has emptied, permitting air to enter the infusion line.
3. Contamination/Infection: May result from improper aseptic handling, use of damaged packaging, reuse of the device, or contamination during prolonged use of the infusion system.

Device / Infusion System-Related Risks

1. Interruption of Infusion: May result from tube kinking or a closed clamp.
2. Leakage: May result from loose, damaged, or incompatible Luer connections.
3. Device Disconnection: May result from improper connection or excessive tension on the tubing.
4. Occlusion/Blockage: May result from kinked tubing, precipitated medication, blood reflux, or catheter blockage.
5. Y-Site related risks: May result from inadequate disinfection before medication administration, improper injection technique, introduction of air during drug administration, damage to the Y-Site due to repeated or excessive force, or administration of incompatible medication.

General Instructions:

- To be used 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.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartoons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Storage at room temperature up to 30℃ ± 2℃.
- Humidity: Up to RH 65% (± 5)

Safe Disposal of single-use medical devices:

❖ adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.

❖ Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.

❖ Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner. Guidance on the type and color of the container should be sought from the Board Waste

Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility.

Method of sterilization

- Sterilized Using Ethylene Oxide

Shelf life

- 5 years (from the date of manufacturing)

Basic UDI: 622300425FR1010L7

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	For Single Use Only
LOT	Lot No.
	Date of Manufacturing
	Use by / Expiry date
REF	Catalogue No.
	Non- Pyrogenic
MD	Medical Device
UDI	Unique device Identifier
	Don't use if package is not intact
	Manufacturer’s address
PHT NON-DEHP	Phthalate-Free

Symbol	Meaning
	Latex Free
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	Cautions
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Recycle
	Don’t put more than 5 cartons upon each other

ISSUE/REV DATE: 01 -09- 2013 / 20.07.2024

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