ULTRA FOR MEDICAL PRODUCTS CO.

F/UM-QD-OP-35-01Rev0

INSTRUCTION FOR USE

Burette set measured volume fluid administration set

Product Name : Burette set

Brand Name : Ultramed measured volume fluid administration set

Manufacturer's Name : Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E

Manufacturer's Address : Part no. (304 : 310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.

- ***Description of the Device:***

❖ Burette set is a medical device used to deliver specific amount of intravenous fluid and medication.
❖ Burette set consists of:
❖ Sharp piercing spike for easy insertion in container of solution.
❖ C-clamp to control the pass of the solution from container.
❖ Cylinder Tube (made of medical grade poly vinyl chloride compound (rigid PVC) to permit observation of fluid in the chamber with graduated scale (100 ml or 150 ml) that is accurate and clearly legible.
❖ Floater: it floats on solution surface, highlight scaling values for the visualization of fluid level. Once chamber is empty, float valve shuts off automatically to prevent air flowing into patient's body.
❖ Injection port (on the top cap of burette set) is used for an intermittent injection of medication.
❖ hanger at top cap for suspending the cylinder.
❖ Cylindrical collapsible drip chamber to visualize the Drip Rate.
❖ Air vent is provided with hydrophobic filter (0.45 µm) for allowing air to enter and to give no permission for micro-organisms entrance.
❖ filter (Disc type 15 µm fluid filter at the bottom of drip chamber filters any particulate matter in the I.V fluid.
❖ Microneedle provide 60 Drops of solution equivalent to 1 ml ± 0.1 ml.
❖ Super smooth kink resistant flexible tube (phthalate free and DEHP free) for unobstructed flow.
❖ Efficient roller clamp controller to control the flow of the infusion fluid from zero to the maximum.
❖ bulb for manual control of fluid flow by squeezing or releasing it, and used for intermittent administration of medication.
❖ Luer lock (6% luer taper) for secure connection to all standard devices (Cannula, Extension tube, Flow regulator or Three-way Stop Cock).
❖ Burette set may be provided with "Y" site injection port for administration of medication.
❖ Burette set may be provided with / without needles.

- ❖ Burette sets are specially designed to administer measured volume of infusion fluid through gravity.
- ❖ Maximum duration of use is not more than 3 days for normal fluids and nutrition.
- ❖ Maximum duration of use of Burette Set for lipid containing fluids is not more than 24 hours to minimize the risk of bacterial contamination.
- ❖ The device is Sterile, disposable, non-pyrogenic, individually packed.
- ❖ Burette set is individually packed in a Peel pouch (medical pouch)
- ❖ It is packed in Medical pouch of 12 single units in polybag, 10 polybags in carton so there is 120 single units in the carton.
- ❖ Product is conventional Product and fully equivalent with many products in market.
- ❖ The product is approved by the Ministry of Health.
- ❖ This product is CE marked since 2008.
- ❖ The product is sterilized using EO (Ethylene Oxide)
- ❖ This product is for single use.

- ***Material Used:***
  - High Density Polyethylene [H.D.P.E.]
  - Polypropylene (P.P) + Master Batch (Blue)
  - Poly Vinyl Chloride [P.V.C.] non phthalate and DEHP free.
  - Stainless Steel.
  - Low Density polyethylene (L.D.P.E)
  - Acryl nitrile butadiene styrene ABS
  - Class fiber
  - Synthetic rubber for Y site injection port.
  - Natural rubber(latex) for latex bulb & Latex floater.

- ***Intended purpose:***

❖ The product is used to administer Intravenous fluid and medicines into human circulating system by using intravenous catheter or cannula. Burette Sets are specially designed to administer measured volume of infusion fluid through gravity.

- ***Variants:***

Ref Code	**Item**
1016-150	Burette Set (measured volume fluid administration set) 150 ml
1016-100	Burette Set (measured volume fluid administration set) 100 ml

- ***Clinical Indications:***

❖ Pediatric Fluid Administration: In children, especially infants, it is crucial to administer small, precise volumes of fluids to avoid fluid overload or dehydration. The burette set allows for the controlled infusion of fluids in measured amounts, making it ideal for this patient population.

❖ Fluid Therapy in Critically Ill Patients: In cases of severe dehydration, shock, or other critical conditions, it is important to carefully control fluid volume to avoid complications like fluid overload. The burette set ensures accurate volume control.

❖ Medications and Infusion Therapy: Burette sets are used when administering medications that require precise dosing and timing, such as in cases of intravenous antibiotics, pain

management (e.g., morphine), or other critical medications where slight variations in volume can lead to adverse effects.

- ❖ IV Nutrition or Electrolyte Administration: It is also useful in administering total parenteral nutrition (TPN) or electrolyte solutions in a controlled manner to patients who cannot take oral nutrition, ensuring precise fluid administration
- ❖ Prevention of Fluid Overload: In patients with heart failure, kidney disease, or other conditions where fluid balance is critical, a burette set ensures that only the required amount of fluid is administered, helping to prevent complications like pulmonary edema.
- ❖ Post-Surgical Care: It is used post-surgery to provide controlled intravenous fluid therapy and medications, ensuring the patient does not receive excessive amounts of fluids that could lead to complications like edema or fluid overload

- ***Contraindications:***
  - ❖ Do not use for patients with known allergies (hypersensitivity) to any materials used in the burette set
  - ❖ Do not use for administration of chemotherapy
  - ❖ Do not use for administration of highly viscous fluids.
  - ❖ Do not use for Blood transfusion.
  - ❖ Do not use for patients who have anatomy that poses a risk for fluid extravasation or inadequate flow and peripheral IVs should be avoided in these situations.
  - ❖ Examples include extremities that have massive edema, burns or injury.
  - ❖ Do not use for the patient with severe abdominal trauma it is preferable to start the IV in an upper extremity because the veins of upper extremities are more prominent and easier to access than veins of lower extremities and because of the potential for injury to vessels between the lower extremities and the heart.
  - ❖ Do not use for the patient with cellulitis of an extremity, the area of infection should be avoided when starting an IV because of the risk of inoculating the circulation with bacteria. Also, extremities on the side of a mastectomy or that have an indwelling fistula should be avoided because of concerns about adequate flow.
- ***Device Limitation:***
  - ❖ Do not use for Administration of highly viscous fluids.
  - ❖ Do not use for Blood transfusion.
  - ❖ Do not use with chemotherapy
- ***Patient Target Group:***

❖ No specific requirements or restrictions on use for patient population or user group defined by the manufacturer.

❖ Adult & Pediatrics.

❖ It is used for male and female patients (all Ages).

❖ Intravenous therapy is an effective and fast-acting way to administer fluid or medication treatment in an emergency situation

❖ For patients who are unable to take medications orally. Approximately 80% of all patients in the hospital setting will receive intravenous therapy

- ***Intended User:***

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

- ***Application site in the body:***

- The medical device burette set establishes a conduit for venous access into the vein.
- Intravenous route.
- The burette Set is in-direct contact with patients' blood.

- ***Replacement Frequency:***
  - Maximum duration of use is not more than 3 days for normal fluids and nutrition.
  - Maximum duration of use of Burette Set for lipid containing fluids is not more than 24 hours to minimize the risk of bacterial contamination.
  - Change the device immediately upon suspected contamination.

- ***Clinical benefits:***
  - Burette sets allow healthcare providers to administer precise volumes of fluids, such as medications or IV solutions, ensuring that patients receive the correct dose. This is especially important in pediatric care or for patients with specific fluid restrictions.
  - It has the ability to carefully control the infusion of medications and fluids helps reduce the likelihood of medication errors. This is particularly helpful when administering high-risk drugs or when there are multiple medications being infused simultaneously.
  - In clinical situations requiring complex drug regimens (e.g. intensive care), a burette set can help ensure that multiple fluids or medications are administered according to protocol without contamination or incorrect ratios.
  - Burette sets are ideal for administering smaller volumes of fluids that require more precise measurement, making them suitable for neonates, pediatric patients, or those requiring very specific fluid management.
  - Filter (Disc type 15 µm fluid filter at the bottom of drip chamber filters any particulate matter in the I.V fluid.
  - The graduated markings on the burette set offer an immediate visual indication of the fluid volume.

- ***Use Environment:***
  - Hospital, Emergency Room, Critical care room

- ***Sterility status and Method of sterilization:***
  - The burette set is supplied in sterile state and sterilized using ethylene oxide.

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

- Burette set is designed to be connected with IV Cannula, extension tube, flow regulator or Three-way stop cock for connection with other devices, Distal end of the Burette Set is provided with a 6% taper male luer as per ISO 80369-7.

- ***Performance Characteristics:***
  - Clear, transparent & flexible drip chamber.
  - Transparent cylinder with graduated scale for measuring the level of the fluid.
  - Soft and kink-resistant tube.
  - flow controller.
  - Tube (Phthalate free and DEHP free)

- 60 drops equal to 1±0.1ml of distilled water for burette Set
- Tube length: 150cm

- *Instruction for Use:*

- Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece
- Wash-up and scrub hands and preferably use sterile protective gloves.
- Peel open the pouch and take out the device aseptically.
- Close all the controllers.
- Remove the spike cover and insert the spike into solution container.
- Suspend the solution container with the attached set and open the upper clamp. To allow burette to fill required level of The solution then Close the upper clamp.
- Gently squeeze and release the drip chamber until it is two third full.
- Remove the needle cover or remove the luer lock & slightly open lower clamp to remove air from the tube and vein needle. Then Close the lower clamp
- Open the upper clamp & allow solution to flow into graduated chamber until the desired volume is obtained. After that Close the upper clamp.
- Make vein puncture or connect the Burette Set to IV Catheter.
- Gradually open the lower clamp. Adjust drip rate & control infusion with the clamp.
- Make sure that the upper clamp is closed during infusion of solution from the Burette.
- The floater will shut off the flow when solution level in graduated chamber is zero.
- When more solution is required, close the lower clamp & open the upper clamp to fill graduated chamber until desired level. Close the upper clamp and squeeze the drip chamber a little to float the valve up and restart infusion.
- Medication may be added through injection site on the top cap of the Burette, Y- site injection port.
- If medication is being given for the first time, stay with the patient for the first 5 minutes to monitor for any potential adverse effects.
- Encourage patient to notify the health care provider if IV site becomes red, painful, or swollen, or if patient notices any adverse effects from the medication.

- *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.

- The product should be used only by qualified doctors or paramedics who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Do not attempt to re-insert a partially or completely withdrawn needle.
- Use Y-site (If applicable) only for injecting the medicine intermittently using aseptic technique.
- Some organic solvents, alcoholic disinfectants, infusion solutions with high PH value substances might cause cracking of the device.
- Reuse and cleaning of products may alter their structural and mechanical properties. It may lead to infection or other illness/injury.
- 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.
- Store in room temperature up to 30 ℃ ± 2 ℃, avoid excessive heat, protect from direct sunlight and moisture.
- The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- 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.
- The device is for Single Use Only.
- Do not use if package is open or damaged.
- Use Y-Site only for injecting the medicines.
- Do not fill the chamber beyond the maximum capacity.
- Check the integrity and functionality of the Burette sets before use.
- Do not use if protective cap is loose or missing.
- Infusion of fluid or solution is by gravity
- Use the product immediately after opening the individual blister packing.
- Close the air-vent during periods of interrupted infusion therapy.
- Do not re-sterilize.
- Discard the set after single use.
- This device does not contain phthalates (DEHP FREE); as marked.
- Determine patient's condition and vital status during device application / Operation.
- Conduct procedure under strict surgical protocol and ensure complete asepsis.
- 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

- ***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.
- ***Potential Complications / Risks:***

❖ Risk from improper fitment due to faulty 6% luer taper, any broken / cracked part / less clear drip chamber and tubing /components, kinking, un-proper tip of piercing spike, uncontrolled flow, malfunction due to leakage or blockage, Allergic reactions, tissue necrosis, Infiltration, Hematoma, Extra Vascular drug administration, Phlebitis, Septicemia, Pulmonary Edema/ Embolism, Air embolism, Under-infusion lead to inadequate therapeutic effect, Over-infusion lead to fluid Imbalance and electrolyte Imbalance.

- ***General Instructions:***
  - ❖ To be used by an expert qualified medical professional. Use maximum 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 cartons on each other.
  - ❖ Nice Ventilated place.
  - ❖ Out of Sunlight.
  - ❖ Storage at room temperature up to 30°C ± 2°C.
  - ❖ Humidity: 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: 622300425BUS1016UU

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
EC 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
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 °C ± 2°C
	60 drops/ml
	This product contains latex
	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

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