INSTRUCTION FOR USE FOR OXYGEN FACE MASK

Product Name **:** Oxygen Face Mask
Brand Name **:** Ultramed Oxygen Face Mask (medium concentration with Tube)
Ultramed Oxygen Face Mask (with Nebulizer)
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:

- The oxygen face mask- Medium Concentration is a basic disposable mask, made from clear plastic designed to cover the nose and mouth, held in place by an elastic strap around the back of the head, and it has a metal strip to shape over the nose to allow for a better mask fit for the patient. It consists of exhalation ports (holes on the side of the mask) through which the patient exhales CO2 (carbon dioxide) and allow ambient air to circulate freely into the mask. These holes should always remain open. The mask allows oxygen delivery via either the nose or mouth so it is suitable for nose and or mouth breathers.
- Simple Oxygen face mask is designed to deliver oxygen to patients who need assistance with breathing. Simple Face Masks deliver oxygen concentrations (Approximate *F*IO2 40–60%).The oxygen concentration is influenced by oxygen flow rate and the patient's breathing pattern. The concentration can be changed by increasing or decreasing the flow rate between 5-10 liters per minute (L/min) "British Thoracic Society (BTS, 2017)". when connected to an oxygen source via a star-lumen tube, and is indicated when a moderate amount of oxygen is needed.
- A nebulizer mask is a drug-delivery device used to administer medication in the form of aerosolized inhalation into the lungs. It utilizes oxygen or compressed air to convert the solution into fine aerosol droplets, which are then inhaled by the patient. The mask fits securely on the patient's face with elastic straps and includes vents that allow exhaled air to escape into the atmosphere. The nebulizer chamber has a capacity of 8 cc. According to ISO 27427 the nebulizer liquid container is marked with maximum fill volume of liquid, to indicate its maximum filling level.
- The nebulizer face mask is provided with a specially designed nebulizer chamber that delivers a nebulization rate of approximately 3 cc in 10 minutes.

- The nebulizer transforms liquid medication into a fine mist (aerosol) that can be easily inhaled. It consists of a screw lid (nebulizer cap) that includes an aerosol outlet port, which is the outlet of the nebulizing system through which the generated aerosol is delivered. The lower part is the nebulizer cup (liquid container), which holds the medication to be nebulized. Inside the cup, a funnel-shaped valve is positioned; this component causes the liquid to break into fine droplets by creating impaction and turbulence, thus producing the respirable aerosol.
- According to ISO 27427 A nebulizer is a device that converts a liquid to an aerosol and also known as an aerosol generator while aerosol is suspension of particles in gas. The gas can be the driving gas or ambient air.
- The connections at both ends of the tubing (one end to the flowmeter/source and the other end to the mask or the nebulizer jar) conform to international standards to ensure compatibility with a wide range of medical equipment. These connectors are typically conical in shape to ensure a secure and leak-free connection.
- The mask body connectors are manufactured in accordance with ISO 5356-1 (15 mm) and the nipple of the connector complies with BS EN 13544-2:2002+A1:2009. Tube connectors comply with ISO 17256 and. All connectors meet the requirements of ISO 80369-1, ISO 80369-2, ISO 18190 and ISO 27427 to ensure safe and compatible attachment to respiratory therapy equipment and oxygen delivery systems.
- Oxygen Face Mask available for adult, pediatric, and neonatal patients.
- Oxygen Face Mask individually packed in a Tear pouch.
- Polybag of 10 single units for Oxygen Face Mask - Medium Concentration.
- Polybag of 20 single units for Oxygen Face Mask (with Nebulizer).
- The Oxygen Face Mask – Medium Concentration is intended for short-term use, approximately for a few hours, depending on the medical condition and the prescribed oxygen flow rate.
- This oxygen face mask is intended for single-patient use. Regular monitoring of the patient's oxygen saturation, respiratory rate, and overall clinical status is crucial to ensure adequate oxygenation and to guide any necessary adjustments to the oxygen flow rate or the type of delivery device used.
- The mask should be replaced at least every 24 hours, or sooner if it becomes visibly soiled, discolored, damaged, or causes discomfort. However, the frequency of replacement may also be guided by institutional protocols and specific patient risk factors—such as critical illness or immunocompromised

status—which may necessitate more frequent changes. Timely replacement helps prevent bacterial colonization due to moisture and condensation buildup, which can increase the risk of respiratory tract infections associated with use of oxygen delivery devices.

- The oxygen face mask with nebulizer is intended for transient use, approximately 10–20 minutes per session, depending on the prescribed medication volume
- The product is sterilized using EO (Ethylene Oxide)
- This product is for single use.

Material Used:

-Polyvinyl chloride [PVC]
-High Density Polyethylene [HDPE]
-Polypropylene [PP]
-Polystyrene [PS]
-Aluminum Sheet
-String

Intended purpose:

- **Oxygen face mask (with medium concentration)** is intended to cover the nose and mouth to facilitate the delivery of supplemental medical oxygen to spontaneously breathing patients who require an oxygen concentration higher than that available in ambient air, due to difficulty maintaining adequate blood oxygen levels resulting from certain health conditions.
- **Oxygen face mask (with nebulizer)** is intended to deliver aerosolized medication directly into the patient's respiratory tract while optionally providing supplemental oxygen.

Variants:

Ref Code	Item
2004-01/S	Ultramed Oxygen Face Mask (Medium concentration with Tube) (Adult Standard) [Sterile]
2004-02/S	Ultramed Oxygen Face Mask (Medium concentration with Tube) (Paediatric Standard) [Sterile]
2004-04/S	Ultramed Oxygen Face Mask (Medium concentration with Tube) (Neonates) [Sterile]
2004-01/N	Ultramed Oxygen Face Mask (Medium concentration with Tube) (Adult) (non-Sterile)
2004-02/N	Ultramed Oxygen Face Mask (Medium concentration with Tube) (Paediatric) (non-Sterile)
2004-04/N	Ultramed Oxygen Face Mask (Neonates) (non-Sterile)
2007-01/S	Ultramed Oxygen Face Mask (With Nebulizer)- Adult standard [Sterile]
2007-02/S	Ultramed Oxygen Face Mask (With Nebulizer)- Paediatric standard [Sterile]
2007-03/S	Ultramed Oxygen Face Mask (With Nebulizer)- Neonates [Sterile]
2007-01/N	Ultramed Oxygen Face Mask (With Nebulizer)- Adult standard (Non-Sterile)
2007-02/N	Ultramed Oxygen Face Mask (With Nebulizer)- Paediatric standard (Non-Sterile)
2007-03/N	Ultramed Oxygen Face Mask (With Nebulizer)- Neonates |(Non-Sterile)

Clinical Indications:

- Oxygen Face Mask is widely used for patients suffering from various respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD), asthma, cystic fibrosis, pneumonia, Advanced Cardiac Failure and Myocardial infarction (only if there is hypoxemia), sleep apnea, emphysema and any condition resulting in decreased oxygen levels in the blood
- The Simple Face Mask is suitable for patients with respiratory failure without increased blood carbon dioxide levels 'hypercapnia'.
- Additionally, in emergency situations, Oxygen face mask is administered to relieve acute symptoms, such as shortness of breath and lowered oxygen saturation.
- Oxygen face mask is also commonly administered throughout the hospital setting, such as in the operating room during surgery and during post-operative recovery, and in the intensive care units to critically ill patients.
- A Nebulizer Mask is a crucial medical device designed to deliver aerosolized medication to the respiratory system. It is primarily used for patients with respiratory conditions such as asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, and other lung disorders. and is particularly helpful for administering medications in the form of a fine mist, which can be inhaled directly into the lungs.

Contraindications:

- Do not use in patient with a known allergic reaction to any of the product components.
- Do not use with patients who already have adequate oxygen levels
- Do not use with patients who are not spontaneously breathing
- Do not use in patients with active inflammation, infection, or lesions at the site of mask contact.
- Do not use for patients with facial injuries, trauma, or deformities that prevent an effective mask seal, as this may lead to discomfort or ineffective oxygen delivery.
- Do not use for patients with Severe claustrophobia or intolerance to wearing a face mask
- Do not use in MRI environments as the mask contains a metal strip that may cause magnetic interference or injury.
- Do not use Oxygen Face Masks for patients with hypercapnia respiratory failure because the mask may deliver a high concentration

of oxygen (>50%) which can result in carbon dioxide retention in some patient groups (Kane, 2011). Therefor Simple Face Masks is not advised for patients who require low concentration oxygen therapy because of the risk of carbon dioxide retention.

Device Limitations:

- **Do not use the mask while eating or drinking**, as it covers the mouth and nose.
- **Do not use the mask while attempting to communicate**, since talking is difficult.
- Do not use for patients who require **low concentration oxygen therapy < 5 L** because of the risk of carbon dioxide retention.
- Do not use **with oxygen flow rates exceeding 10–12 L/min, as the mask is not designed for high-flow therapy.**
- For Nebulizer Mask, do not fill the nebulizer chamber beyond 8 cc, as its maximum capacity is 8 cc

Patient Target Group:

- No specific requirements or restrictions on use for patient population or user group defined by the manufacturer.
- Adult, Pediatrics and Neonate.
- It is used for male and female patients.
- For non-intubated, spontaneously breathing patients who are able to breathe on their own, but who may require a higher oxygen concentration than concentration found in ambient air.

Intended User:

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

Application site in the body:

The oxygen face mask is applied over the patient's face, covering the nose and mouth and extending down to the chin. It is secured using an elastic strap positioned below the ears and around the neck, and fitted with an adjustable nose clip contoured to the bridge of the nose to ensure a comfortable and airtight seal for effective delivery.

Replacement Frequency:

- Change the device immediately upon suspected contamination.

- They are designed for single patient use.
- The mask should be replaced at least every 24 hours, or sooner if it becomes visibly soiled, discolored, damaged, or causes discomfort. However, the frequency of replacement may also be guided by institutional protocols and specific patient risk factors—such as critical illness or immunocompromised status—which may necessitate more frequent changes. Timely replacement helps prevent bacterial colonization due to moisture and condensation buildup, which can increase the risk of respiratory tract infections associated with use of oxygen delivery devices.
- The oxygen face mask with nebulizer should be replaced after each treatment session that lasts approximately from 10 to 20 minutes.

Clinical benefits:

- The clinical benefits derived from the device are achieved indirectly. The device functions by establishing a conduit for oxygen delivery or by converting liquid medication into a fine mist (aerosol), allowing it to be effectively inhaled and deposited into the lungs and small airways.

Oxygen Face Mask-Medium Concentration:

- **Delivers Moderate Oxygen Concentration:** Typically provides an inspired oxygen fraction (FiO2) between **40% and 60%** at flow rates of **5 to 10 L/min.**
- **Simple and reliable interface**—easy to fit, adjust, and remove.
- **Reduced CO2 Rebreathing (When Used Correctly):** At flow rates of 5 L/min or more up to 10L/min, the flow is sufficient to flush out exhaled carbon dioxide (CO2) from the mask, minimizing the risk of CO2 rebreathing, which is a key safety feature.

Oxygen Face Mask with Nebulizer:

- **Efficient Drug Delivery:** Converts liquid medication into a fine mist (aerosol), allowing it to be effectively inhaled and deposited into the lungs and small airways.
- **Simultaneous Oxygen Supplementation:** If the nebulizer is driven by oxygen instead of compressed air, the mask provides the dual benefit of delivering the medication **and** supplemental oxygen to support the patient's breathing and correct hypoxemia.

Use Environment:

- Hospital, Emergency Room, Critical care room

- The oxygen face mask is intended for use in both sterile and non-sterile conditions, with the latter applicable when sterilization is not required. Non-sterile environments include general hospital wards, outpatient clinics, emergency medical services (EMS), home healthcare settings, and care facilities. In these settings, the mask is used for non-invasive oxygen delivery, does not enter body cavities, and does not compromise mucosal barriers, making sterile conditions unnecessary. The device is applied directly from its sealed, protective packaging, which preserves cleanliness and product integrity in accordance with standard hygiene practices.
- The non-sterile oxygen face mask should not be used in sterile surgical environments or procedures involving a sterile field, where aseptic conditions are mandatory. In such cases, a sterile oxygen delivery system would be required to maintain procedural sterility and patient safety.
- Sterile conditions may be required in critical care settings like the ICU when used in conjunction with invasive procedures, near surgical sites, or for patients at high risk of infection. The decision to use a sterile or non-sterile mask should be guided by the clinical context, institutional protocols, clinician decision and the patient's condition.

Life time of device:

- The Oxygen Face Mask – Medium Concentration is intended for short-term use, typically for a few hours, depending on the medical condition and the prescribed oxygen flow rate.
- The oxygen face mask with nebulizer is intended for transient use, approximately 10–20 minutes per session, depending on the prescribed medication volume

Sterility status and method of sterilization:

Oxygen face mask, if supplied in sterile state, sterilized using ethylene oxide.

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

The oxygen face mask – medium concentration is designed for use with an oxygen supply source through a flowmeter or regulator to control the flow rate via a funnel-shaped connector, as per ISO 17256.

The Oxygen Face Mask with Nebulizer is designed for use with an oxygen or compressed air source through a flowmeter or regulator to control the flow rate via a funnel-shaped connector, as per ISO 17256.

Performance Characteristics:

- The oxygen face mask is suitable for oxygen therapy.
- While the nebulizer face mask is suitable for oxygen therapy or inhaled medication therapy.
- Elongated face mask to fit under chin.
- Clear and soft mask for patient comfort.
- Adjustable elastic strap and integrated nose strip for proper positioning of mask.
- Side holes allow the inflow of ambient air and the outflow of exhaled gases.
- A star lumen tubing to ensure continuous flow of oxygen.
- Proximal end of the tube is connected with funnel-shape connector for easy connection with Pressure Source "compressed air or oxygen source."
- The nebulizer face mask is provided with a specially designed nebulizer chamber with a capacity of 8 cc that delivers a nebulization rate of approximately 3 cc in 10 minutes.

Instruction for Use:

Action	Rational
- Before Procedure	
- Perform hand hygiene with washing hands with warm soapy water. Dry thoroughly	- This prevents the transmission of microorganisms and reduce risk of infection.
- Apply clean gloves.	- Using gloves decreases the transfer of microorganisms.
- Check the packing carefully, if found damaged, torn or pierced discard the piece. Do not use if pack is damaged	- A damaged or torn package may compromise sterility, increasing the risk of contamination and infection to the patient.
- Tear open the pack & draw out the device with care.	- Careful opening prevents contamination and protects the device from damage, ensuring it remains sterile and safe for patient use.
During Procedure	
In case of Face mask –Medium Concentration - Attach the oxygen supply tubing to the oxygen source and set the prescribed flow between 5-10 Liter per minute using the flow meter. - Avoid setting the Flow below 5 liters	- When using oxygen cylinders, store them upright, chained, position in a well-ventilated area away from any open flame and in appropriate holders so that they will not fall over. - To prevent CO_2 retention

Action	Rational
In case of Nebulizer - Unscrew the nebulizer cap from the top. - Draw the prescribed medication into a graduated syringe using a drawing-up needle for accurate measuring. - Remove the drawing-up needle and immediately dispose of it in a sharps bin, then pour the medication into the nebulizer cup. - Reattach the cap securely to the nebulizer cup.	- To ensure the prescribed medication is correctly placed and securely sealed in the nebulizer cup for effective aerosol delivery during therapy.
- Insert the nebulizer top into the mask connector, ensuring a light and secure fitment.	- To maintain a secure connection between the nebulizer and mask, ensuring optimal aerosol flow and effective patient therapy.
- Attach the tubing at the bottom of the nebulizer cup. - Connect the other end of the tubing to the desired Pressure Source" compressed air or oxygen source."	- This step allows the pressure source to create a mist from the medication so the patient can inhale it easily.
- Set the pressure flow to the prescribed rate as directed by the physician within the range of 5-8 LPM [The Optimum amount of flow may vary between Pressure source]	- Setting the correct flow ensures effective nebulization
- Do not set the Pressure Flow **above 8 L/min**, or **below 5 L/min**,	- To avoid medication wastage, as much of the aerosol may escape into the environment before the patient can inhale it - As the nebulizer may fail to generate adequate mist, resulting in prolonged treatment time, and ineffective drug delivery.
- Check the flow through the device.	- To ensure that the device works efficiently and Access to the maximum benefit of the patient.
- Place the mask on the patient's face with the elastic strap below the ears and around the nick.	- To ensure the correct position of the device on the patient face & the maximum benefit of the patient will be accessed.
- Gently pull the ends of the strap until the mask is secure.	- To ensure the correct position of the device on the patient face & the maximum benefit of the patient will be accessed.
- Mold the metal strip on the mask to fit the nose.	- To ensure the patient's comfort and the correct position of the device on the patient face
- Agree on a signal the patient can use if they wish you to pause during the procedure.	- This procedure can be anxiety-provoking and uncomfortable for many patients. Providing a means for the patient to communicate discomfort and a desire to pause during the procedure helps alleviate anxiety.
In Case of Nebulizer - Ensure The Nebulizer in an Up-right position. - Instruct the patient to inhale slowly and deeply during administration. - Periodically tap the nebulizer to minimize residual volume and ensure continuous medication delivery.	- To prevent spilling and to ensure the medication is correctly distributed. - To maximize the effectiveness of the medication. - Tapping helps the medication flow evenly so the patient receives the full dose.

Action	Rational
- Continuously check skin integrity, abnormal bends in the tubing, proper flow rate, tight connections, and the patient's response to therapy.	- Regular checks ensure safe, effective therapy and help prevent complications.
- After Procedure	
- Perform hand hygiene	- This reduces the transmission of microorganisms.
- Turn off the pressure source—whether oxygen or compressed air, as described above—and disconnect the supply tubing at the end of the procedure.	- This prevents risk of accidents. To ensure safety and prevent unnecessary gas flow.
- Remove device from patient face.	- To ensure Completing the artificial respiration successfully
- Remove gloves and place patient in a comfortable position. Assess patient's level of comfort. Perform hand hygiene.	- This promotes patient comfort and reduces the transmission of microorganisms.

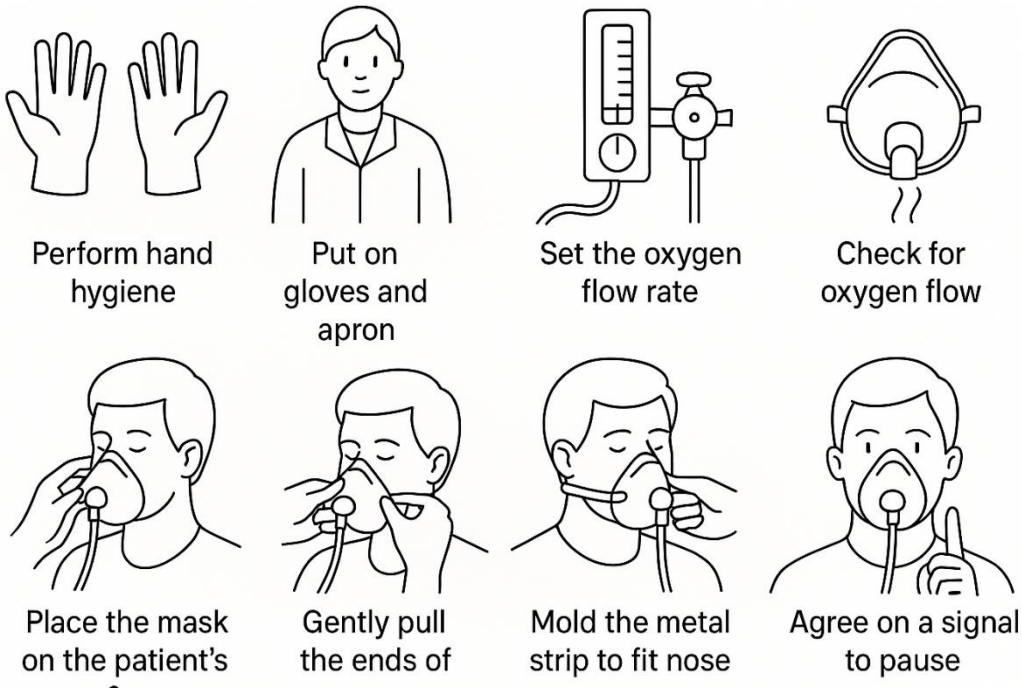

Illustration of using Oxygen Face Mask- Medium concentration

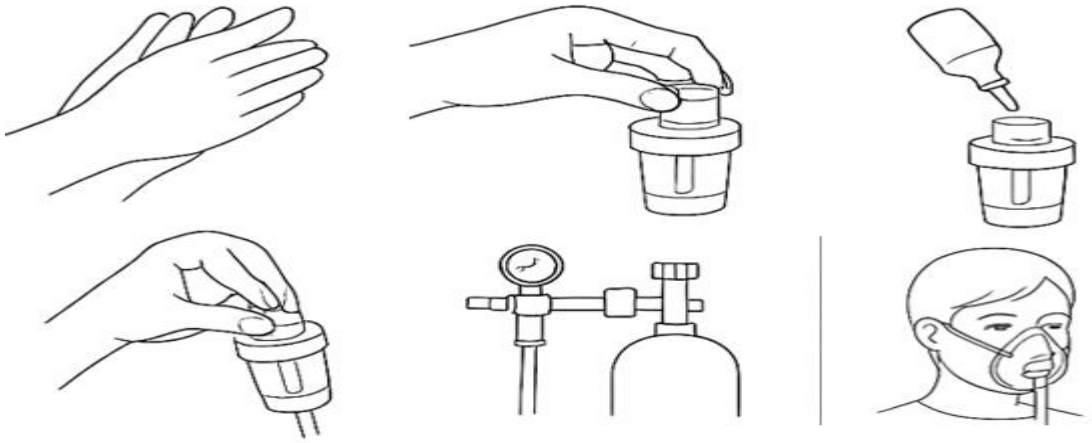

Illustration of using Oxygen Face Mask with Nebulizer

Warnings:

- For Single use.
- Oxygen Face Mask is intended for single patient use and should not be used with more than one patient due to the risk of cross-contamination
- 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 a qualified doctor or paramedic who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Re-use of single use device creates a potential risk. 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.
- Never administer oxygen therapy while smoking or near an open flame.
- Turn off oxygen immediately when not in use
- Storage up to 30º C ± 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 Patient Use Only.
- ❖ Do not use if the package is opened or damaged.
- ❖ Check the integrity and functionality of the oxygen face mask before use.
- ❖ Use the product immediately after opening the individual packing.
- ❖ Do not re-sterilize.
- ❖ This device does not contain phthalates (DEHP FREE); as marked.
- ❖ Determine patient's condition and vitals 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 use the device after the Expiry Date
- ❖ Ensure proper fit of the mask, as the efficiency of oxygen delivery depends on it.
- ❖ Continuously check skin integrity, abnormal bends in the tubing, proper flow rate, tight connections, and the patient's response to therapy.
- ❖ While using the nebulizer mask, do not set the Pressure Flow above 8 L/min, to avoid medication wastage, as much of the aerosol may escape into the environment before the patient can inhale it or below 5 L/min, as the nebulizer may fail to generate adequate mist, resulting in prolonged treatment time, and ineffective drug delivery.

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:

Oxygen toxicity and CO_2 retention (if used incorrectly), pressure sores, discomfort or claustrophobia, cross-contamination or microbial colonization and respiratory infections, and fire or explosion risk due to an oxygen-rich environment, Inadequate oxygenation and/or ventilation resulting in hypoxia and/or hypercarbia, leakage, tube kinking.

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.

Oxygen safety:

Oxygen is not a flammable gas but it does support combustion (rapid burning). Due to this the following rules should be followed:

- Do not smoke in the vicinity of oxygen equipment.
- Do not use aerosol sprays in the same room as the oxygen equipment.
- Turn off oxygen immediately when not in use. Oxygen is heavier than air and will pool in fabric making the material more flammable. Therefore, never leave the mask under or on bed coverings or cushions whilst the oxygen is being supplied.
- Oxygen cylinders should be secured safely to avoid injury.
- Do not store oxygen cylinders in hot places.
- Keep the oxygen equipment out of reach of children.
- Do not use any petroleum products or petroleum byproducts e.g. petroleum jelly/Vaseline whilst using oxygen.

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°C ± 2°C.
- 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 be 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 if supplied sterile.

Shelf life

5 years (from the date of manufacturing)

Basic UDI:

- **For Sterile aspect:** 622300425OFM2004TL
- **For Non-Sterile aspect:** 622300425OFM2004NXA

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 if it is supplied in sterile status:

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.

Symbol	Meaning
	Non- Pyrogenic
	Medical Device
	Unique device Identifier
	Don't use if package is not intact
	Manufacturer’s address
	Phthalate-Free
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 °C ± 2°C
	Cautions
	Latex Free
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Don’t put more than 5 cartons upon each other

Details of symbols used in labels if it is supplied in non-sterile status:

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

Symbol	Meaning
	CE Mark with notified body number 2803 for sterile
	NON-STERILE
	For Single Use Only
	Lot No.
	Date of Manufacturing
	Use by / Expiry date
	Catalogue No.
	Medical Device
	Unique device Identifier
	Don't use if package is not intact
	Manufacturer’s address
	Phthalate-Free
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 °C ± 2°C
	Cautions
	Latex Free
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“

Symbol	Meaning
	Don’t put more than 5 cartons upon each other

ISSUE/REV DATE: 05-11- 2024

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& Fax:002-088-4964222**& Mob:** 002-01001558853, 002-01068832355
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