

USER MANUAL

o_two controlled™
ventilation



Mesh
NEBULIZER
01CV0330

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1. Device Description

The O-Two® Mesh Nebulizer is a portable, electrically powered medical device designed to aerosolize prescribed liquid medications for inhalation therapy.

The device uses vibrating mesh technology, in which a perforated mesh membrane vibrates at high frequency to generate a fine aerosol suitable for delivery to the lower respiratory tract.

The lightweight, compact, and head-mounted design allows the device to be used in hospitals, emergency medical services, clinical settings, and patient transport. It is intended for intermittent therapeutic use as prescribed by a healthcare professional.

2. Intended Use

INTENDED USE AND PATIENT POPULATION:

The device is intended to nebulize prescribed liquid medications for delivery to the respiratory tract during inhalation therapy in:

- Adult and pediatric patients capable of spontaneous breathing.
- Patients receiving continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BPAP) therapy.
- Intubated patients receiving invasive mechanical ventilation when used inline with a compatible ventilator circuit.

DO NOT USE:

- In patients who are not breathing spontaneously unless connected to a mechanical ventilator.
- In patients who are unconscious or unable to protect their airway unless managed with an appropriate artificial airway and ventilation support.
- If the device is damaged or malfunctioning.

INTENDED USERS:

This device is intended for use by

- Licensed healthcare professionals
- Emergency medical services (EMS) providers
- Trained caregivers in supervised homecare settings
- Patients or caregivers who have received instruction from a healthcare professional for single-patient use in homecare.

INTENDED ENVIRONMENT OF USE:

- Hospitals and acute care facilities
- Emergency departments
- Prehospital and patient transport settings
- Physician offices and outpatient clinics
- Supervised homecare settings
- Covered outdoor medical environments

OPERATING CONDITIONS:

For safe operation, use the device within the following conditions:

- Temperature: 10°C to 40°C;
- Humidity 30% to 85% RH.

STORAGE AND TRANSPORT:

- Temperature: -20°C to 70°C
- Humidity 20% to 75% RH

NOTE

Allow the device to return to room temperature before use if stored in extreme conditions.

3. Warnings and Cautions



WARNINGS

- Use only prescribed medications for inhalation therapy.
- Do not use in patients unable to protect their airway unless properly ventilated.
- Do not use if damaged, malfunctioning, or contaminated.
- Use a new medicine cup and interface for each patient to prevent cross-contamination.
- Do not immerse the main unit in water or liquids.
- Ensure adult supervision for pediatric or dependent patients.
- During ventilation, monitor patient and device continuously and have a backup available.
- Do not use oily, high-viscosity, or non-approved solutions (may damage mesh and affect therapy).



CAUTIONS

- Do not touch or probe the mesh; this may damage the medicine cup.
- Avoid dropping or impact; handle the device carefully.
- Do not disassemble, modify, or attempt to repair the device.
- Prevent liquid from entering the main unit or power port.



CAUTIONS

- Clean the main unit before first use and after each treatment.
- Keep the device upright during operation to ensure proper aerosol delivery.
- Ensure medication does not exceed 6 mL and is suitable for nebulization.
- Do not reuse the medicine cup in multi-patient or EMS settings. Dispose of after use according to local regulations.

4. Device Overview

4.1. COMPONENTS:

The package contains the following items:



Main Unit



**Medicine Cup with
Integrated Vibrating Mesh**



**USB Charging Cable
and Adapter**

4.2. CONTROLS AND INDICATORS



Controls:

A single ON/OFF Button
Located on the top of the main unit.
Press to start or stop nebulization.

Indicator Lights:

- Green Light: Nebulization in progress
- Red Flashing Light: Low battery or malfunction (e.g., mesh obstruction)
- Blue Light: Charging in progress

NOTE

If the red indicator light remains ON after charging, inspect the medicine cup and mesh for obstruction or damage.

5. Operating Instructions

5.1. PRE-USE CHECK AND PREPARATION

- Ensure all components are present and free from damage or contamination. Do not use the device if any part is missing, damaged, or malfunctioning.
- Confirm all components are clean and completely dry.
- Verify the prescribed medication and dosage. Do not exceed 6 mL total volume.
- Inspect the medicine cup for damage, blockage, or residue.
- Ensure the battery is sufficiently charged or connect to a power source.
- Ensure the battery is sufficiently charged or connect to a power source.
- Position spontaneously breathing patients upright or in a semi-fowler position when possible.

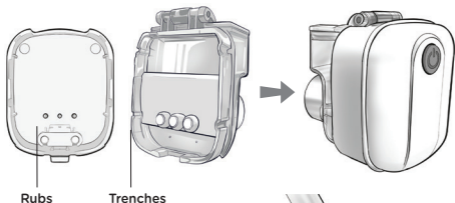
NOTE

The medicine cup is a patient-contact component and must be replaced between patients in clinical or multi-patient environments.

5.2. ASSEMBLE THE DEVICE

A Align the three rubs on the back of the medicine cup with three trenches of the main unit.

B Insert the medicine cup firmly into the main unit until it clicks, confirming it is securely seated.



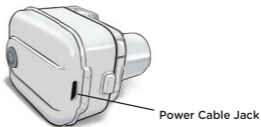
5.3. ADD MEDICATION

- Open the medicine cup cap.
- Fill with the prescribed medication (Do not exceed 6 mL).
- Close the cap securely to prevent leakage.



5.4. CONNECT POWER (IF NEEDED)

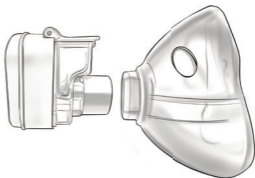
- Connect the USB charging cable to the main unit if battery level is low.
- A blue indicator light confirms that charging is in progress.
- The device may be used while connected to power if necessary.



5.5. ADMINISTER TREATMENT

5.5.1. Use with a Mask

- A** Attach the mask to the medicine cup outlet.



- B** Press the ON/OFF button (green light confirms operation).
- C** Instruct the patient to breathe normally during treatment, with periodic slow deep breaths if tolerated.
- D** Continue treatment until the prescribed dose has been delivered or aerosol output has stopped
- E** Press ON/OFF to turn off the device.



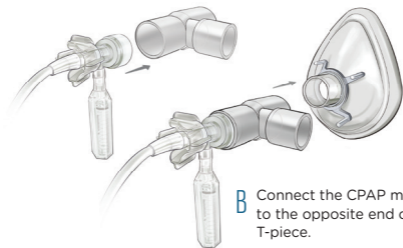
NOTE

Patient Positioning should be upright or semi-Fowler's whenever possible.

5.5.2. Use with Disposable CPAP

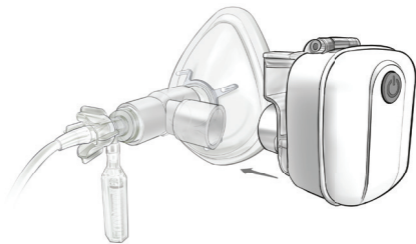
The device can be used during CPAP therapy with disposable CPAP devices, such as the O-Two® Single-Use CPAP system.

- A** Insert one end of a T-piece adapter into the outlet of the disposable CPAP device.

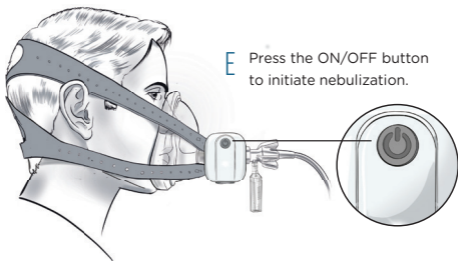
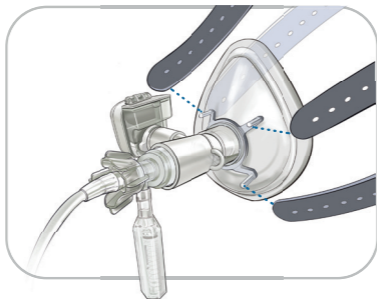


- B** Connect the CPAP mask to the opposite end of the T-piece.

- C** Attach the nebulizer to the side port of the T-piece adapter.



- D** Once CPAP flow is established, place the mask securely on the patient's face and apply the head harness. Ensure the mask seal is secure and that no air leaks are present



- E** Press the ON/OFF button to initiate nebulization.

NOTE

Maintain the nebulizer in an upright position during operation to ensure proper aerosol generation and optimal medication delivery.

5.5.3. Inline Use with Mechanical Ventilator Circuits

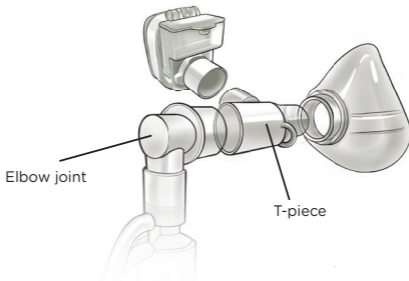
The O-Two® Mesh Nebulizer is suitable for integration into mechanical ventilator circuits in in-hospital, pre-hospital, post-hospital, and patient transport settings.

It is used in:

- Spontaneously Breathing Patients receiving CPAP or BPAP therapy.
- Intubated patients receiving invasive mechanical ventilation

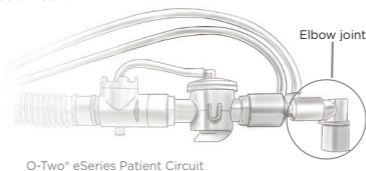


Ventilator Circuit SetUP:



- A** Connect one side of the T-piece adapter to the elbow joint of the patient circuit.

- B** Connect the opposite side of the T-piece to the patient interface:
- o Mask for CPAP/BPAP
 - o Endotracheal tube for invasive ventilation
- C** Attach the O-Two® Mesh Nebulizer to the side port of the T-piece adapter.
- D** Before initiating nebulization, confirm that the elbow joint, T-piece, nebulizer, and all circuit connections are secure and free of leaks.



NOTE

Do not remove the elbow joint when connecting the T-piece, as it helps maintain circuit integrity and reduce the risk of leaks or interruption of ventilation.

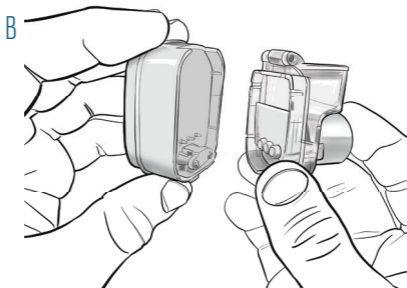
6. Cleaning and Disinfection

Proper cleaning and disinfection are necessary to reduce the risk of contamination and maintain device performance.

6.1. After Each Treatment (Routine Cleaning):

- Turn OFF the device and disconnect from power, if applicable.
- Wipe the exterior surfaces of the main unit using an approved medical-grade disinfectant wipe
- Do not allow liquid to enter electrical ports or device openings.

- Allow the main unit to dry completely before reuse.
- Press release button to remove the medicine cup.



- Discard the medicine cup in accordance with local protocols and infection control policies.
- Install a new medicine cup before use on the next patient.

NOTE

The main unit must never be immersed in liquid.

IMPORTANT

The medicine cup is a single-use, patient-contact component intended for use on one patient only. Discard the cup after each patient treatment and replace it with a new one. Do not reuse between patients, as exposure to exhaled breath, coughing, and mask leakage may contaminate the cup and increase the risk of cross-contamination.

7. Troubleshooting

PROBLEM	POSSIBLE CAUSE	ACTION
Weak output	Mesh obstruction	Clean medicine cup
No mist, no light	Power connection issue	Check power and battery
Light on, no mist	Cup not seated	Reinstall medicine cup
Red flashing light	Low battery or device/cup malfunction	Recharge device and inspect the medicine cup
Persistent malfunction	Mesh damaged	Replace medicine cup

Your Representative is:

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SERIAL N°:	
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