

USER MANUAL

o_two controlled™
ventilation



Mesh
NEBULIZER
01CV0330

TABLE OF CONTENTS

1. Device Description	3
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2. Intended Use	3
------------------------	----------

3. Usage	3
-----------------	----------

4. Warnings and Cautions	5
---------------------------------	----------

5. Device Overview	6
---------------------------	----------

6. Operating Instructions	7
----------------------------------	----------

7. Cleaning and Disinfection	13
-------------------------------------	-----------

8. Troubleshooting	15
---------------------------	-----------

9. Service Life	15
------------------------	-----------

1. Device Description

The Mesh Nebulizer is a portable, rechargeable, electrically powered medical device intended for respiratory aerosol therapy. The device uses Active Vibrating Mesh Technology, in which a perforated mesh membrane vibrates at a high frequency to aerosolize physician-prescribed liquid medications for delivery to the respiratory tract.

The lightweight and compact design supports both head-mounted and inline applications. The device is intended for intermittent therapeutic use under the direction of a healthcare professional.

2. Intended Use

2.1 MEDICAL PURPOSE

This device is designed to nebulize the solution into an aerosol for respiratory therapy purposes.

2.2 INTENDED PATIENTS

This device is designed for all ages of patients. Except for those who are unconscious, not breathing spontaneously or having a pulmonary edema.

NOTE

For patients who are unconscious or not breathing spontaneously, the device must be operated only by a healthcare provider and connected in-line with a compatible ventilator circuit during mechanical ventilation.

3. Usage

3.1 PATIENT POPULATION

- Patients of all ages who are conscious and capable of spontaneous breathing.
- Patients receiving (CPAP) or (BPAP) therapy.
- Intubated patients receiving mechanical ventilation when used in-line with a compatible ventilator circuit.

3.2 DO NOT USE:

- In patients who are not breathing spontaneously unless they are mechanically ventilated.
- In patients who are unconscious or unable to maintain airway protection unless the airway is secured and ventilation is provided.
- If the device or medicine cup is damaged, contaminated, or malfunctioning.

3.3 USERS:

- Licensed healthcare professionals
- Emergency medical services (EMS) providers
- Patients and caregivers instructed by a healthcare professional for single-patient use

3.4 ENVIRONMENT OF USE:

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

3.5 OPERATING CONDITIONS:

- Temperature: 10 °C to 40 °C. | Relative humidity: 30% to 85% RH

3.6 STORAGE AND TRANSPORT:

- Temperature: -20 °C to 70 °C | Relative humidity: 20% to 75% RH

NOTE

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

4. Warnings and Cautions



WARNINGS

- Use only physician-prescribed medications approved for nebulization.
- The device is intended for respiratory inhalation therapy only; any other use is improper and may be hazardous.
- The manufacturer is not liable for damage resulting from improper or incorrect use.
- Use a new medicine cup and patient interface for each patient to prevent cross-contamination.
- Clean all components before first use, after each use, and after extended storage.
- Ensure supervision when used with pediatric or dependent patients.
- Do not use in patients unable to maintain airway protection unless appropriately ventilated.
- Do not use the device if any components are damaged, contaminated, or malfunctioning..
- Do not immerse the main unit in water or other liquids or handle the power adapter with wet hands.



CAUTIONS

- Do not attempt to clean the mesh with foreign objects; this may damage the mesh.
- Avoid dropping or subjecting the device to impact; this may affect performance.
- Keep the device away from direct sunlight, excessive heat, or extreme cold to prevent battery damage.
- Do not disassemble, modify, or attempt to repair the device.
- Do not allow liquids to enter the main unit or adapter; if this occurs, wipe dry immediately.
- Follow local laws and recycling plans regarding the disposal or recycling of components, batteries and packaging.

5. Device Overview

5.1.COMPONENTS:

The package contains the following components:



Main Unit



Medicine Cup with
Integrated Vibrating Mesh



USB Charging Cable
and Adapter

5.2. 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.

6. Operating Instructions

6.1. 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's position when possible.

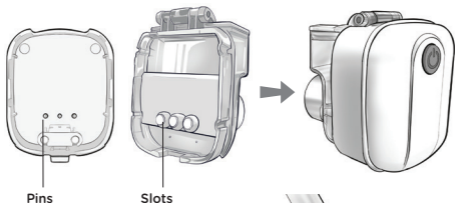
NOTE

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

6.2. ASSEMBLE THE DEVICE

A Align the three slots on the back of the medicine cup with the three pins on the main unit.

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



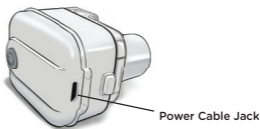
6.3. ADD MEDICATION

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



6.4. CONNECT POWER (IF NEEDED)

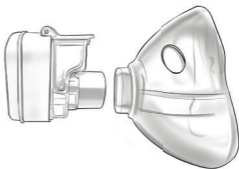
- Connect the USB charging cable to the main unit if battery level is low.
- A blue indicator light confirms that charging is in progress.
- The device may be used while connected to power if necessary.



6.5. ADMINISTER TREATMENT

6.5.1. Use with a Mask

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



- B** Press ON/OFF button (The green indicator 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 button to turn off the device.



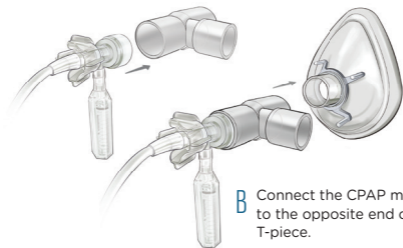
NOTE

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

6.5.2. Use with Disposable CPAP

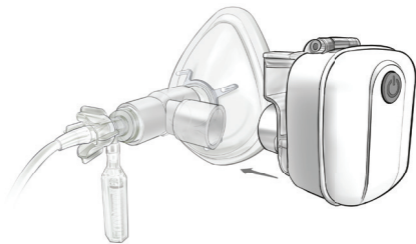
The device can be used during CPAP therapy with disposable CPAP devices, such as the O-Two® Single-Use CPAP system.

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

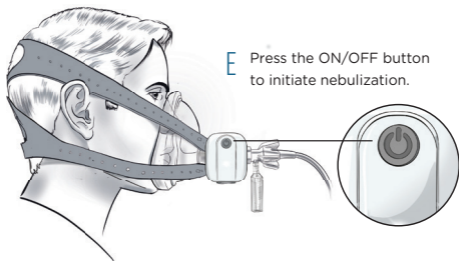
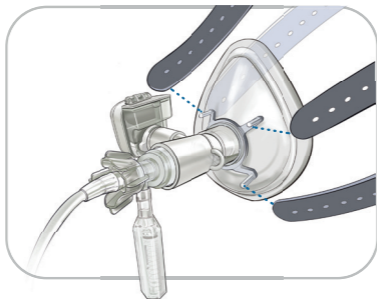


- B** Connect the CPAP mask to the opposite end of the T-piece.

- 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.

6.5.3. In-line Use with Mechanical Ventilator Circuits

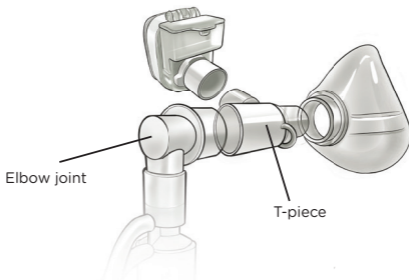
The O-Two® Mesh Nebulizer is suitable for integration into mechanical ventilator circuits in in-hospital, pre-hospital, post-hospital, and patient transport settings.

It is used in:

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

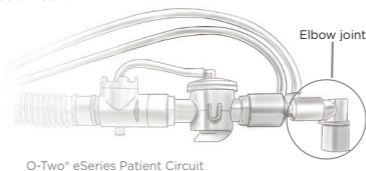


Ventilator Circuit SetUP:



- 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.

7. Cleaning and Disinfection

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

7.1 After Each Treatment (Routine Cleaning):

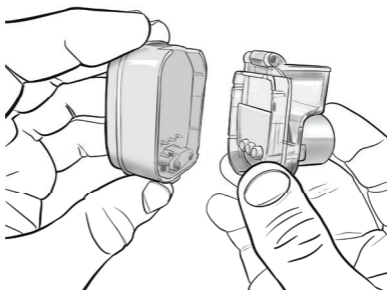
- Turn OFF the device and disconnect from power, if applicable.
- Wipe the exterior surfaces of the main unit using an approved medical-grade disinfectant wipe
- Do not allow liquid to enter electrical ports or device openings.

- Allow the main unit to dry completely before reuse.
- Press release button to remove the medicine cup.
(check figure below)
- Discard the medicine cup in accordance with local protocols and infection control policies.
- Install a new medicine cup before use on the next patient.

A



B



7.2 Replacing the Medicine Cup:

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.

8 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

9. SERVICE LIFE

The expected service life of the main unit is approximately 24 months under normal operating conditions. Service life may vary depending on frequency of use, medication type, cleaning practices, and operating environment.

• **Warranty:** The device is covered by a 12-month warranty against manufacturer's defect from the date of purchase under normal clinical use conditions.

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