



WARNING

- This mask is not suitable for providing life support ventilation.
- Use your mask as prescribed by your physician.
- The vent holes associated with the mask should never be blocked for proper exhaling purpose.
- Do not block or seal Anti-Asphyxia Valve or exhalation ports. Occlusion of the exhaust needs to be prevented to avoid having an adverse effect on the safety and quality of the therapy.
- At low CPAP pressure, some exhaled gas may remain in the mask and be re-breathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.
- Some users may have skin redness, irritation, discomfort or other adverse reaction. If this happens, discontinuous to use and contact your health care professional.
- It should be used only together with the appropriate flow generator equipment (CPAP or bi-level system) to ensure optimum therapy.
- Ensured the device is generating airflow before the oxygen supply is turned on. Always turn off the oxygen supply before stopping the airflow from the device. Explanation of the Warning: When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device's enclosure and create a risk of fire.
- Do not wear this mask unless the CPAP or bi-level device is turned on. Explanation of the Warning: CPAP and bi-level devices are intended to be used with special masks (or connectors) which have vent holes to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vents holes. However, when the device is not operating, enough fresh air will not be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bi-level devices.
- This mask should not be used on patients who are uncooperative or taking drug that may cause vomiting.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- Do not overlighten the headgear straps.
- The medical devices which are not intended to be combined with the mask can decrease the safety or alter the performance of the mask.

1. Introduction

This manual should be used for initial set up of the system and saved for reference purpose.

1.1 Intended Use

The Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. These masks are intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. These masks are to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.

1.2 Contraindications

This mask is not for use on patients with the following conditions: recent eye surgery or dry eyes, hiatal hernia, excessive reflux, impaired cough reflex, and impaired cardiac sphincter function. This mask is not for use on patients who are dependent on mechanical ventilation for their life support. This mask is not for use on patient who are taking a prescription drug that induces vomiting, or on patients who are uncooperative, unresponsive or unable to remove the mask by themselves. This mask should not be placed over open wound or skin under risk of decubitus ulcers that are prone to infection.

NOTE: An exhalation port is built into this mask so a separate exhalation port is not required. US Federal law restricts this device to sale by or on the order of a physician

2. Product Description

2.1 Unpacking the Contents

Components include:

- Mask with Headgear
- User manual

Unpack this box by removing the masks and check for any damage, which may have occurred during shipping. If there are damages, please contact your dealer immediately.

2.2 Mask Overview

- Headgear strap
- Headgear clips
- Mask Cushion with Exhalation Ports (Keep clear)
- Mask Frame
- Elbow with Anti-Asphyxia Valve
- Quick release buckles
- Flexible tube

3. Before Use

- Read the instructions completely
- Hand wash the mask
- Inspect the mask and replace it if the cushion silicone side is hardened or if any parts are broken.

4. Use your Mask

- Remove one of the Headgear clips on lower headgear straps
- Hold the mask with the cushion over the nose and pull the headgear on over the head.
- Hook the headgear clips of the lower straps on the mask frame and avoid the headgear to touch bottom of your ears.
- Adjust upper headgear straps to a comfortable fit. The cushion should lightly touch the face.
- Adjust lower headgear straps to a comfortable fit. The lower straps should be kept below the ears.
- Connect the tubing to your flow generator (CPAP or bi-level devices) and turn on the airflow.
- Adjust the headgear to prevent any leaks from the cushion without over-tightening the straps.
- To remove the mask and the headgear, simply unhook one of the headgear clips from the mask frame and pull the upper headgear straps over your head

NOTE: Always read the operating instructions before use.

5. Cleaning Your Mask at Home

- Daily clean mask without headgear and weekly wash headgear after each use
- Detach the flexible tube, unhook both headgear clips, and unthread the upper headgear straps. It is not necessary to remove the headgear clips from the headgear.
- Hand wash mask and headgear in warm water (approximately 30°C/86°F) using mild soap or diluted dishwashing detergent. All facial oils should be removed from the mask.
- Use a soft bristle brush to clean the expiratory port.
- Rinse all parts of mask thoroughly with drinking quality water.
- Air dry completely before use. Lay the headgear flat or line dry.

CAUTION: Do not place the headgear into the dryer.

CAUTION: Do not use bleach, chlorine, alcohol, scented oils or aromatic based solutions. These solutions may damage the mask, cause cracks and reduce the life of the product. Do not iron the headgear.

6. Reprocessing the Mask Between Patients (Multi-Patient Use)

Refer to the Disinfection Guide for Professional Users to reprocess between patients in a clinical setting. Access the latest version of the Disinfection Guide at www.apexmedicalcorp.com

7. Assembling the Mask

- Attach the Cushion by pushing positioning marker on cushion hard side into slot of the frame.
- Place the headgear on a flat surface with the shiny side upside.
- Thread the lower headgear straps through the quick release buckles and ensure the Velcro is outside.
- Thread the upper headgear straps through the hooks on the mask frame and ensure the Velcro is outside.
- Connect quick release buckles to the hooks on the mask frame.

CAUTION: Please check the part number before reassembling the mask after cleaning.

8. Technical Specifications

NOTE: The mask system does not contain latex, PVC or DEHP materials.

Exhaust Flow

The mask has vent holes to protect against rebreathing.

Pressure (cm H₂O) 4 8 12 16 20 24 28 30 32 36 40

Flow (L/Min) 18 26 32 38 45 49 53 57 59 63 66

The Pressure-Flow Curve is as below.

Mask Dead Space

S: 224.8 ml M: 284 ml L: 328 ml

Therapy Pressure Range

4-40 cm H₂O

Resistance with Anti Asphyxia Valve (AAV): closed to atmosphere: Drop in pressure

at 50 L/min: 1.0 cm H₂O at 100 L/min: 2.0 cm H₂O

Resistance with Anti Asphyxia Valve (AAV): open to atmosphere

Inspiration at 50 L/min: 0.9 cm H₂O Expiration at 50 L/min: 1.0 cm H₂O

Anti Asphyxia Valve (AAV) open-to-atmosphere pressure

0.54 cm H₂O

Anti Asphyxia Valve (AAV) closed-to-atmosphere pressure

0.81 cm H₂O

Sound Level

≤ 30 dBA (Pressure setting 10 cm H₂O, at 1 meter position)

Operating Range

+5°C to +35°C [+41°F to +95°F] 15% to 95% relative humidity non condensing

Storage and Transport (Store the mask in a dry place out of direct sunlight)

-15°C to +60°C [+5°F to +140°F] 10% to 90% relative humidity non condensing

Disposal

Dispose of in accordance with local regulations.

Expected Design Life (After Unpacking)

6 months

9. Symbols

	Caution		Temperature limitation
	Consult instructions for use		Humidity limitation
	Reference Number		Not made with natural rubber latex
	Lot Number		Prescription only (In the US, Federal law restricts these devices to safety or on the order of a physician.)
	Use by		Manufacturer
	Date of manufacture		Authorized European representative

10. NOTE, CAUTION, AND WARNING STATEMENTS

NOTE: Indicates information that you should pay special attention to.

CAUTION: Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

11. Limited Warranty

Apex Medical Corp. (hereafter Apex) gives the customer a limited manufacturer warranty on new original Apex products and any replacement part fitted by Apex in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship. To exercise your rights under this warranty, please contact your local, authorized Apex dealer.

NOTE: Warranty is only valid in the country of purchase.

Product	Warranty period
Mask systems	6 months
Disposable products	None