

# User guide

**Product name:** CPAP Masks

**Product model:** NM50

**Specification:** Large (L), Medium (M), Small (S)

**In order to ensure safe operation, please read the entire guide before use.**

## Instructions:

This manual provides guidance on the installation, use, and daily maintenance of the CPAP Nasal Mask.

The nasal mask contains a vent that can provide continuous vent access in the patient's breathing circuit, eliminating the need for an additional independent vent system.

## Intended use

It is an interface connection device through nasal airway. The nasal mask is to be used by patients who has chronic respiratory insufficiency, Improving ventilation and sleep therapy with non-invasive ventilation support.

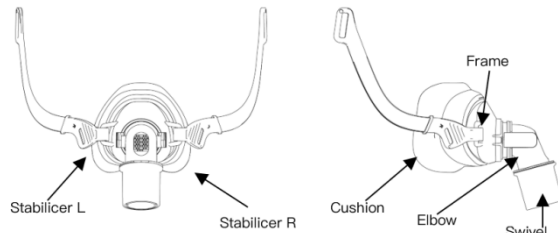
## Contraindications

It is not intended for use by children, or by users who are physically, sensibly, or intellectually incapable of safe use without assistance or supervision.

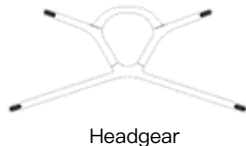
Disturbance of consciousness; Weak or stopped breathing, cardiac arrest; Inability to clean the airway or a high risk of aspiration, serious organ dysfunction; Undrained pneumothorax or mediastinal emphysema; Severe abdominal distension and intestinal obstruction; Upper respiratory tract obstruction due to upper airway or maxillofacial injury, postoperative or malformation; Can not match NPPV(non-invasive positive pressure ventilation) or nose (face) mask discomfort; Recent esophageal or gastrointestinal surgery or bleeding. Cardiac sphincter dysfunction, massive reflux, impaired cough reflex and esophageal hiatus xenon; Slow to act or react.

## Product structure

CPAP Nasal Mask is consisted of nasal mask body (frame, stabilizer L\R, elbow, cushion, swivel) and headgear. The nasal mask is available in large (L), medium (M) and small (S) sizes.



Picture 1 CPAP Nasal Mask



Picture 2 Headgear of CPAP Nasal Mask

## Connect the nasal mask to the device

The nasal mask is intended to be connected to the device and the patient via a breathing tube. Before using the device, ensure that the device is dry, the breathing tube is clear, and the outlet of the nasal mask is smooth. Only after the device is opened and operated normally can the nasal mask be used.

## ⚠ WARNING

- The nasal mask is not intended to provide life support ventilation and is intended for use in adults.
- Do not use oxygen when smoking or in the presence of an open flame.
- Do not block or try to close the vent hole of the nasal mask during use to avoid adverse effects on the safety and quality of treatment.
- The safety valve group has a specific safety function. When the safety valve assembly is damaged, twisted or torn, the CPAP Nasal Mask should be stopped and the nasal mask or related accessories should be replaced in time.
- The following cases should be used with caution: claustrophobic patients; Chest X-ray or CT examination reveals pulmonary bulla; Significantly lower blood pressure (blood pressure less than 90/60 mmHg), or when in shock; Hemodynamic index of acute myocardial infarction patients was unstable; Cerebrospinal fluid leakage, craniocerebral injury or intracranial gas; When acute otitis media, rhinitis, sinusitis infection is not controlled; Green eyes; Recent eye surgery or dry eyes.

## CAUTION

- This nasal mask is suitable for the positive airway pressure devices (non-invasive ventilator) recommended by medical professionals, and is used in combination with non-invasive ventilator. Do not wear the nasal mask until the device is turned on and in normal operation. The nasal mask can only be worn when the device works properly.
- Do not use oxygen when smoking or in the presence of an open flame.
- Follow all precautions when using supplemental oxygen.
- In the case of a fixed supplemental oxygen flow, the inhaled oxygen concentration would be different due to pressure settings, patient breathing patterns, choice of nasal mask, wearing position, and degree of leakage.
- Some users may experience redness, irritation, or discomfort of the skin; if these symptoms occur, stop use immediately and should contact medical professionals.
- Using nasal mask may cause pain on your teeth, gums or jaw, even worse dental conditions. If these symptoms occur, please consult medical professionals.
- Contact your doctor immediately if you experience any of the following symptoms while using the nasal mask or after removing it: abnormal chest discomfort, shortness of breath, stomach dilation, hiccups, or severe headaches; Dry eyes, eye pain or eye infection; Blurred vision. (If the symptoms persist, please consult an ophthalmologist.)
- Continuous positive airway pressure or Bilevel positive airway pressure devices have the potential to re-inhale the exhaled

exhaust gas. The device should be combined with a CPAP Nasal Mask (or connector) with a vent hole or exhaust gear. When the device is working normally, fresh air can blow out the exhaled exhaust gas from the vent hole; When the pressure of the device is low or not working, the exhaled exhaust gas may be re-inhaled. In some cases, breathing in and out the exhaust gas again for more than a few minutes can lead to asphyxiation.

- When using this nasal mask, it is necessary to maintain at least 3cmH<sub>2</sub>O pressure.
- The nasal mask should be used by patients who are unable to cooperate, move or react slowly, or who are unable to remove the nasal mask on their own under qualified supervision.
- The nasal mask is not recommended if the patient is taking prescribed medications that may cause vomiting.
- Do not use solutions containing bleach, chlorine, alcohol, aromatics, humidifiers, antibacterial agents, or scented oils to clean any part of the nasal mask. Some cleaning products may damage the mask, or leave harmful residual vapours that could be inhaled if not rinsed thoroughly.
- Do not expose any part of the nasal mask or the air tube to direct sunlight, or it will age.
- Replace the nasal mask if the component has any obvious signs of aging (such as cracks and tears).
- The nasal mask does not contain latex, polyvinyl chloride or dioctyl phthalate materials.
- Use the nasal mask with other medical devices that are not intended to be used may reduce the safety of the nasal mask or alter the performance of the nasal mask.
- Before use, check whether the package is intact, confirm the production date, and prohibit the use of damaged packaging and products beyond the expiration date.

## Unpacking list

Nasal mask, headgear,user guide.

## Fitting



1. The adhesive buckle of the headgear is inserted into the hole of the nasal mask stabilizer respectively. And bond them together.

2. Fasten one side of the stabilizer on the nasal mask frame, and combine the frame with the nasal mask body.

3. Press the nasal mask on your face and pull the headgear over your head. Attach the other stabilizer to the frame.

4.



Adjust the tightness of the headgear by connecting the band. Do not adjust the headgear too tight.

5.



Adjust the nasal mask by hand until it is worn in the most comfortable position. Do not adjust the headgear too tight while keeping the air tight.

6.



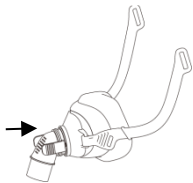
Connect the swivel to one end of the breathing tube, and connect the other end of the breathing tube to the ventilator.

**Removal**

The stabilizer is removed from the nasal mask body, then take the nasal mask and headgear from the head.

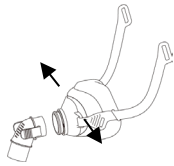
**Disassembly**

1



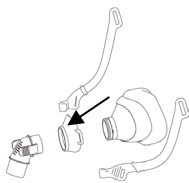
1. Detach the elbow from the nasal mask body

2



2. Separate the stabilizer from the frame

3



3. Separate the frame from the nasal mask body

**Cleaning your mask at home**

The nasal mask should be cleaned by hand before first use and should be cleaned daily with removing the headgear during cleaning. The headgear should be cleaned once a week, or as needed.

Clean the nasal mask and headgear in warm soapy water and avoid soaking for more than 10 minutes. Please use a soft bristle brush if you want to clean the vent hole.

Clean the components except the headgear with drinking water and dried naturally in a dark place. Make sure the nasal mask is dry before each use.

Rinse the headgear with water after cleaning, and allow it to dry out of direct sunlight.

Do not expose the nasal mask and breathing tube to direct sunlight, which will accelerate the aging of the mask.

After cleaning, use a clean towel to dry the nasal mask, and then use a clean towel dipped in 75% medical alcohol or 75% medical alcohol wipes to wipe the inner and outer surfaces of the nasal mask to ensure that all components are wiped, and then wipe each

component repeatedly for about 1 minute to disinfect, and then wait for natural air drying.

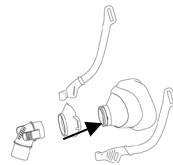
Before using the nasal mask, check whether it is damaged or worn (cracked, craze, torn, etc.), discard and replace the corresponding parts if necessary.

**CAUTION:** Excessive cleaning may cause damage to the product and affect the expected service life. Failure to follow the prescribed cleaning frequency, cleaning method, detergent use, or exceeding the number of treatment cycles may adversely affect the silicone cushion, ultimately affecting the safety and quality of the treatment, resulting in product damage or patient respiratory infection. Do not use volumetric cleansers containing bleach, chlorine, alcohol, aromatics, humidifiers, antibacterial agents, or aromatic oils. These solutions may damage or reduce the service life of the product.

**Do not cross use between different patients for avoiding infection.**

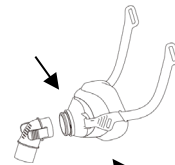
**Assemble**

1



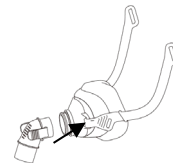
1. Combine the frame with the nasal mask body

2



2. Combine the stabilizer and frame

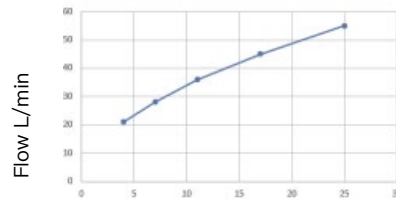
3



3. Attach the elbow to the nasal mask body

**Product technical parameters**

Pressure flow curve



	Pressure cmH <sub>2</sub> O			
Pressure (cmH <sub>2</sub> O)	4	11	17	25
Flow (L/min)	22	36	46	57

**Therapy Pressure** 4–25 cmH<sub>2</sub>O

**Noise:** According to the ISO 17510:2015 standard, The A-weighted sound pressure power of the nasal mask should be ≤43dB, and the A-weighted sound pressure level at A distance of 1m should be ≤35dB.

**Flow resistance (pressure drop)** Nasal mask gas resistance (pressure drop) compliance: 0.8cmH<sub>2</sub>O when the flow rate is 100L/min; When the flow rate is 50L/min, it is 0.5cmH<sub>2</sub>O.

**Environmental condition**

Operating temperature: 5°C~40°C

Operating humidity: 15% ~ 95% relative humidity, non- condensing

Storage and transport temperature: -20°C~60°C

Storage and transport humidity: Maximum relative humidity not exceeding 95%, non-condensing

**Storage and disposal**

**Storage**

Before storage, the nasal mask should be thoroughly cleaned and kept dry regardless of the length of storage. And the nasal mask should be stored in a dry place out of direct sunlight.

**Disposal**

The nasal mask does not contain any hazardous substances and can be disposed of as general household waste.

**Symbols**

	Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device. Please read the entire guide before use.		
	Not made with natural rubber latex		Humidity limitation
	Temperature limitation		Nonsterile mark

**Quality Assurance**

CPAP Nasal Mask includes: CPAP Nasal Mask x1, headgearx1,user guide x1

Warranty period: 90 days from the date of purchase

Production date and expiration date: See product label

Service life: It is recommended to replace it every 6 months, if the nasal mask is damaged or aged during use, it should be replaced immediately, and the mask can be washed no more than 180 times.

Version number: V1.1

Revision Date: December 6, 2024