

Ray Non-Vented Pediatric NIV Mask

REF CM061L-NV Large • CM061XL-NV Extra Large

Using This Guide

Please read the entire guide before use. When following instructions, refer to the images at the front and back of the guide.

Intended Use

The mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency.

The mask is for single patient use in the hospital/institutional environment only.

The mask is to be used on patients 7 years or older (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation.

Contraindications

This mask may not be suitable for patients with the following conditions: impaired cardiac sphincter function, excessive reflux, impaired cough reflex and hiatal hernia. It should not be used if the patient is unresponsive, obtunded, unable to remove the mask, or uncooperative. Do not use if patient is experiencing nausea, vomiting, or taking a prescription that may cause vomiting.

Caution US federal law restricts this device to sale by or on the order of a physician.

Warnings

The Ray NIV Mask is a non-vented device and must only be used with a patient breathing circuit that incorporates an external exhalation valve to prevent CO₂ rebreathing and ensure patient safety.

Note: The external exhalation valve must be positioned proximal to the patient, placed between the ventilator tubing and the L-Connector/Corrugated Tubing assembly included with the mask. Never place the valve distal to the ventilator tubing. The mask assembly itself, including the L-Connector and Corrugated Tubing, contains no integrated exhalation valves.

This product is used in conjunction with the bi-level system in accordance with the recommendations of physician or respiratory therapists.

• Do not use this mask unless the NIV system is turned on and operating properly.

Note: When ventilator is not operating, enough fresh air will not be provided through the mask and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. If oxygen is used with the NIV system, the oxygen flow must be turned off when the ventilator is not in operation.

Note: When the ventilator is not in operation and the oxygen flow is left on, oxygen delivered into the ventilation tubing may accumulate within the ventilator enclosure and create a risk of fire.

Note: At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary depending on the pressure setting, patient pattern and leak rate.

- Do not smoke if oxygen is in use.
- Contact a health care professional if chest discomfort, shortness of breath, stomach distention, belching, or severe headache are experienced.
- Avoid eating or drinking three hours before using this mask to minimize the risk of vomiting during treatment.
- Not suitable for life support.
- Do not use on patients without a spontaneous respiratory drive.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Technical Specifications

RESISTANCE TO FLOW @ 50 L/min: 0.7 cmH₂O
Pressure drop through mask @100 L/min: 2.9 cmH₂O

MAXIMUM WORKING PRESSURE 20 cmH₂O

OPERATING TEMPERATURE 5-40°C

MASK DEAD SPACE With Large Cushion:
Empty volume from the end of the mask to the end of the swivel
• CM061L-NV: 116mL (±10%)
• CM061XL-NV: 148mL (±10%)

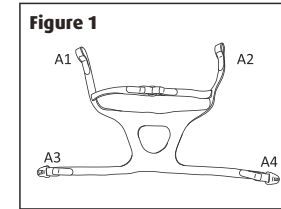
Caution

- The mask is designed to provide a stable, effective air seal with minimum headgear tension. Excessive headgear tension may lead to facial deformities with long-term use. Regular clinical checks are recommended.
- If skin irritation or any other adverse reaction develops, discontinue use.

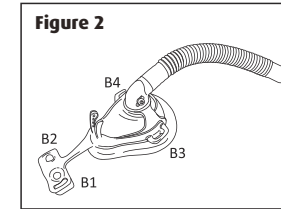
Warning

- Do not use the Mask with baseline pressure less than 5 cm H₂O or greater than 20 cm H₂O
- The mask does not have exhalation holes and must be used with a patient circuit that incorporates an exhalation valve.
- At low baseline pressure, the flow through the exhalation valve may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. If symptoms occur, discontinue using the mask.
- Do not use the device if damaged. Before each use, visually inspect all mask components. If any visible deterioration (such as cracking, crazing, or tears) is apparent, the component should be discarded and replaced immediately.
- Before starting therapy, ensure the mask is properly fitted and free of leaks. After assembling and fitting the mask according to the Assembling Instructions section of this manual, perform a mask fit check following the ventilator or system's Instructions for Use. Adjust the headgear or mask position as needed to achieve a proper seal. Significant unintentional leak may occur without properly fitting the mask.
- Children should be attended at all times during therapy.
- This product is designed for single patient use, using this product for multiple patients will cause risk of infection and contamination.

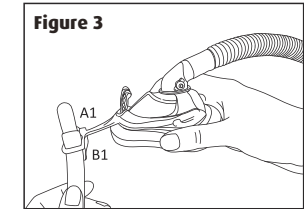
If headgear is included, follow assembly instructions below:



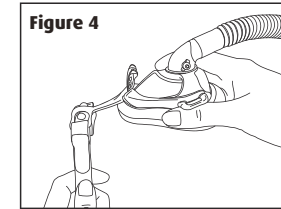
Place headgear with Velcro side down on a flat surface, detach 2 Velcro tapes on A1 & A2.



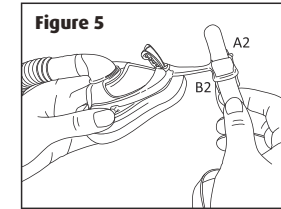
Identify headgear fastening positions on the mask.



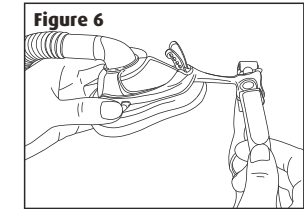
Pull the upper headgear strap A1 through the slot B1 on the mask, making sure the Velcro faces outward.



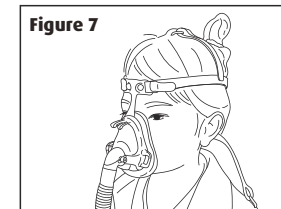
Fasten the Velcro tape.



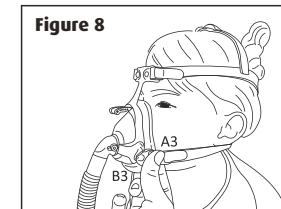
Pull the upper headgear strap A2 through the slot B2 on the mask, making sure the Velcro faces outward.



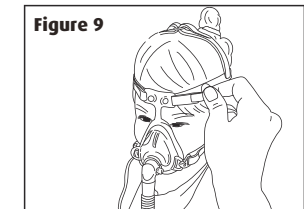
Fasten the Velcro tape.



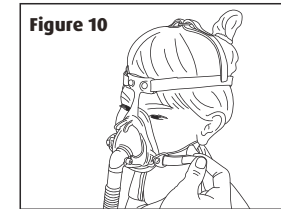
Place the headgear over your head and adjust both upper headgear straps to a comfortable tension.



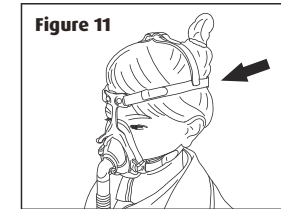
Hook the plastic buckle A3 onto B3 and A4 onto B4 on mask frame.



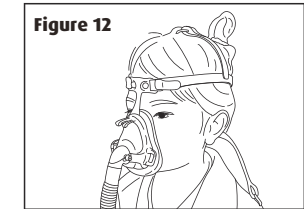
Adjust again both upper headgear straps A1 & A2 to a comfortable tension.



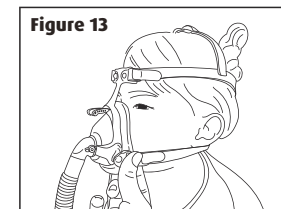
Adjust both lower headgear straps A3 & A4 to a comfortable tension.



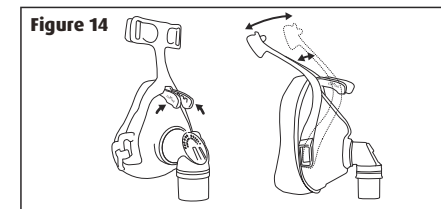
Making sure the overhead strap is in proper position to avoid slipping down.



To remove the mask, simply unbuckle one side of bottom buckles and pull up the mask.



To put the mask back on, simply put on the mask and hook up the buckle.













To further conform to the patient's face, adjust the Fin Tek levers by squeezing them together and swiveling back or forth. When the desired fit is reached, let go to lock in place.

Troubleshooting

Problem	Possible Cause	Solution
Mask is uncomfortable	Headgear straps are too tight.	The cushion membrane is designed to inflate against your face to provide a comfortable seal with low headgear tension. Adjust straps evenly. Ensure that the headgear straps are not too tight and that the cushion is not crushed or creased.
	Mask could be the wrong size.	Talk to your clinician to have your face size checked against fitting template. Note that sizing across different masks is not always the same.
Mask leaks around the face	Cushion membrane is creased or folded.	Refit your mask according to the instructions. Ensure that you position the cushion correctly on your face before pulling headgear over your head. Do not slide the mask down your face during fitting as this may lead to folding or curling of the cushion.
	Mask could be the wrong size.	Talk to your clinician to have your face size checked against fitting template. Note that sizing across different masks is not always the same.

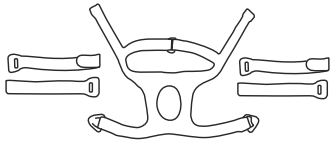
Symbol Glossary

The following symbols may appear on your product or packaging:

 REF	Catalogue Number	 LOT	Batch Code
	Manufacture Date		Expiration Date
 MD	Medical Device		Do not Re-Use
	Consult Instructions for Use		Manufacturer
	Caution or Warning		Unique Device Identifier

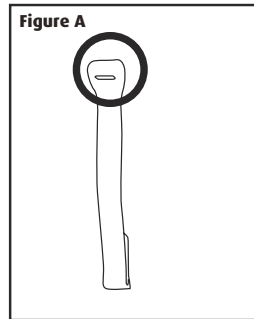
How to add Extender Straps

Each Sunset Ray Mask includes headgear, four extender straps, and mask.

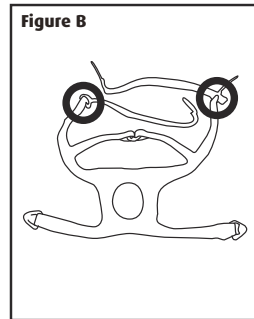


To Attach Extender Straps:

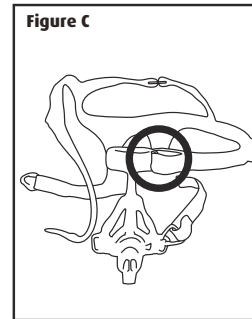
1. Remove extender straps from packaging.



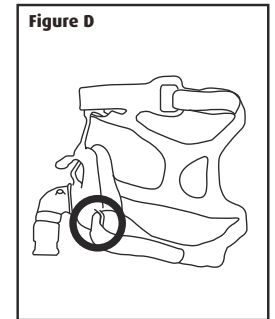
2. Locate the slits on the extender straps. (fig. A)



3. Thread the headgear strap through the slits. (fig. B)



4. Adjust as needed and secure the headgear. (fig. C & D)



5. Verify proper attachment before use.