

Instructions for Use & Maintenance

1. **Intended Use**
The 7700 V2 Mask is a reusable, multi-patient use, Oro-Nasal CPAP/BiLevel mask that does NOT incorporate a passive, continuous flow exhaust port built into the mask. It is intended for use with certain CPAP/BiLevel machines for treatment of obstructive sleep apnea, and for use with other similar ventilators that incorporate the patient vent (exhaust port) into the patient circuit instead of the mask and provide a minimum of 3 cm H2O pressure measured at the mask.
2. **Environment of Use**
This mask is for use in homes, hospitals and other clinical settings by individuals that have received at least minimal instruction or training on the use of the masks as well as the device to which the masks are intended to connect.
3. **Indications for Use**
This mask is indicated for use on adult patients (greater than 30 kg weight) for treatment of Obstructive Sleep Apnea or any other conditions requiring CPAP/BiLevel or non-invasive ventilatory support at pressures greater than or equal to 3 cm H2O at the mask in homes, hospitals and other clinical settings.
4. **Cautions**
 - a. Federal law restricts this device to sale by or on the order of a physician.
 - b. At low CPAP/BiLevel pressures the flow through the patient circuit exhalation vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
 - c. Patients with facial hair may experience mask leakage even though all fitting instructions are followed. If mask leakage is excessive, facial hair may need to be shaved to assure mask effectiveness.

- e. Strap quick-release Clips snap easily into and out of the mating slots on the face mask for easy mounting and dismounting of the headgear. Unsnapping one of the lower strap clips allows quick removal of the mask assembly from the patient.
9. **Apply and Fitting Mask**
 - a. Mask sizes: L (large), M (medium), S (small), ES (extra small), P (petite)
 - b. Headgear sizes: L (large), M (medium), S (small)

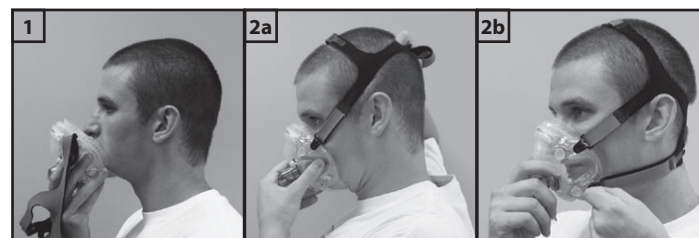
Recommended Headgear Sizes for each Mask Size					
Mask	L	M	S	ES	P
Headgear	L	M	M	S	S

- c. Determine mask size of patient with a Mask Sizing Gauge (fig 3) provided to measure the patient's face and aid in selecting the best mask size. For sizing the patient's facial muscles should be relaxed and jaw closed. Fit the patient's chin in the chin cup section of the mask and slightly press the mask onto the face. The top of the mask should be slightly below the nasal root depression (where the nose meets the forehead).

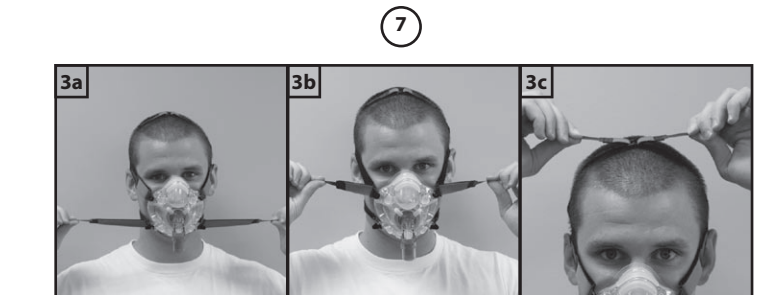


5. **Warnings**
 - a. Do not block mask or patient circuit flow, watch for flow blockages or restrictions
 - b. Not for use with ventilators that require double-limb patient circuits for separate inhaled and exhaled gases
 - c. Not for use with CPAP/BiLevel devices which require a mask with built-in vent holes
 - d. This mask requires a separate exhalation venting device included as part of the patient circuit
 - e. This CPAP/BiLevel mask should be used only with CPAP/BiLevel systems recommended by your physician or respiratory therapist. This mask should not be used unless the CPAP/BiLevel system is turned on and operating properly.
 - f. This mask is intended to be used only with CPAP/BiLevel systems which require separate exhalation vents included as a part of the patient circuit to allow continuous air flow out of the patient circuit. When the CPAP/BiLevel machine is turned on and functioning properly, new air from the CPAP/BiLevel machine flushes the exhaled air out through the exhalation vent holes. However, when the CPAP/BiLevel machine is not operating properly, enough fresh air will not be provided through the mask or patient circuit, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some cases lead to suffocation.
 - g. This mask is shipped clean but nonsterile. If disinfected or sterile use is required, follow the disinfection or sterilization procedures described in this document prior to use of the mask.
 - h. Discontinue use of the mask if patient skin or mucous membrane irritation or allergic reaction develops due to the mask.
 - i. Failure to arouse and remove the mask after vomiting could result in aspiration of vomitus.
 - j. If a fixed flow rate of supplemental oxygen is used, the inhaled percent oxygen will vary depending upon the pressure settings, patient breathing pattern, mask size and leak rate.

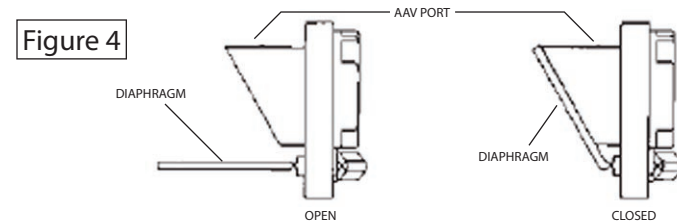
- d. **Fitting the mask**
The mask and headgear is supplied fully assembled
 1. Place the mask over the patient's nose and mouth. The patient's chin should fit into the chin cup portion of the mask with the top of the mask sealing area on the bridge of the nose.
 2. (a) Slide the headgear over the patient's head. It may be easier for some patients if one of the lower headgear quick-release strap clips is disconnected before putting the headgear on the patient. (b) Reconnect the headgear strap clip after the headgear is placed on. The bottom straps should be positioned below the ears and the top straps above the ears and below the eyes.
 3. (a & b) Adjust the tension of the headgear Velcro™ straps by pulling back slightly on the straps. Tighten the lower two straps then the top two to achieve a comfortable fit. (c) Finally, adjust the two straps attached to the tri-glide connection at the crown of the head by pulling each in opposing directions until reaching the required tension and then reconnecting the velcro. Overtightening can cause leaks.
 4. Connect the mask to the ventilator patient circuit by following the ventilator operating instructions.
 5. Turn the ventilator on. If you or the patient detects a leak around the mask sealing area, reposition the mask and or adjust the strap tension to eliminate the leak. If the leak continues regardless of your adjustments try another mask size.



6. **Contraindications**
 - a. open wounds that are prone to infection
 - b. hemodynamic or cardiorespiratory instability
 - c. unconsciousness
 - d. claustrophobia, anxiety, or other discomfort with an Oro-Nasal mask
 - e. facial or nasopharyngeal deformity, beard, or other inability to fit mask and seal properly
 - f. excessive reflux, GI blood or other secretions
 - g. impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions
 - h. upper airway obstruction or facial trauma
 - i. barotrauma
 - j. recent facial, esophageal, or gastric surgery
 - k. patients unable to remove the mask
 - l. patients under medication with a drug that may cause vomiting
 - m. patients requiring immediate intubation
7. **Complications**
 - a. infection due to improper use over open wounds
 - b. skin irritation after prolonged use caused by rubbing of the mask
 - c. nasal or dental pain or deformity
 - d. drying of pharyngeal and nasal mucosa
 - e. eye irritation or conjunctivitis
 - f. gastric distention and abdominal pain or flatulence from ingested air
 - g. some slight discomfort after prolonged use
 - h. decreased secretion clearance especially during upper respiratory tract infections
 - i. aspiration of secretions

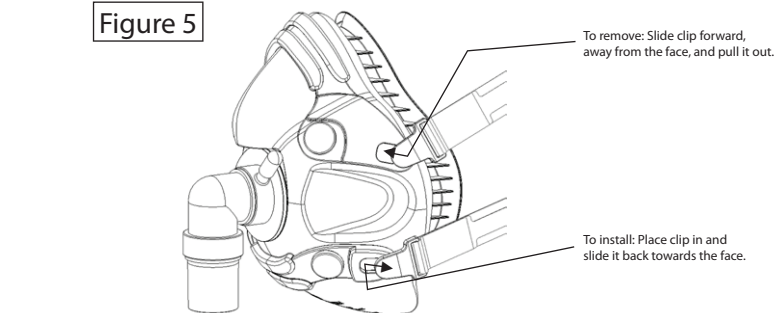


10. **Verification of Safety Features**
 - a. Anti-Asphyxia Valve (AAV) (fig 4): The AAV allows room air breathing for the patient if the ventilator device should stop for some reason. The AAV diaphragm CLOSES the large bore room air port in the mask swivel port during CPAP/BiLevel ventilation and OPENS the mask to room air breathing when the ventilator device is off. Mask should not be used if the AAV is missing, damaged or not functioning properly.



- b. Quick-Release Headgear (fig 5): Unsnapping one of the lower headgear strap quick-release clips from the mask will allow complete removal of the mask assembly.

8. **Mask Components and Material Descriptions (fig 1)**
 - a. Mask face piece is molded of a silicone rubber. There are four slot openings in the mask polycarbonate plastic braces for the attachment of the headgear strap mounting quick-release clips.
 - b. Swivel Port assembly consists of a sampling port, anti-asphyxia valve (AAV) and detachable 22mm swivel port. The plastic components are polycarbonate and the flexible components are silicone rubber.
 - c. Anti-Asphyxia Valve (AAV) (fig 2): snaps into the elbow of the swivel port assembly using the "locking tabs" for engagement. The function of the AAV is to allow the patient to breath room air when the CPAP/BiLevel machine is not operating or turned off.
 - d. Headgear is a breathable, stretchable polyurethane foam laminate with a nylon loop on the outer surface for Velcro™ type hook attachment and a soft Lycra type surface on the patient contact surface for comfort.



11. **Removing the Mask:** To remove the mask, slide one of the lower strap clips slightly forward towards the front of the mask and it will disconnect from the mask, pull the mask and headgear to the opposite side or up over the patient's head.
12. **Disassembly for Cleaning, Disinfection or Sterilization**
 - a. Detach mask from the ventilator.
 - b. Separate the headgear from the mask.
 - c. Separate the swivel port assembly from the mask, AAV from the swivel port (squeeze two locking tabs and pull AAV out) and rubber cap plug from the sampling port of the mask adapter.
13. **Cleaning Mask face piece, swivel port components and headgear**

- Mask and swivel port assembly**
 - a. Soak all the components for 5 minutes in warm water with a mild detergent (neutral pH).
 - b. Hand wash the components with a sponge or soft brush.
 - c. Rinse with warm tap water. Place the components in a bath of warm water and agitate for two minutes.
 - d. Rinse in clean tap water for at least 1 minute.
 - e. Allow the components to air dry or dry them with a clean, lint free cloth.

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Headgear

- a. Submerge the headgear in warm soapy tap water and gently rub all the areas
- b. Rinse in clean tap water for 1 minute or until all signs of the soap are removed
- c. Air dry
- d. Caution: Fabric dye in the headgear material may run the first couple times during cleaning. We recommend washing the headgear before first time use.
- e. Precaution: Do not use bleach, chlorine or alcohol based solutions to clean any of the mask and headgear components. These solutions can damage this product. Direct sunlight exposure with the mask and headgear components can cause deterioration and reduce product life.

14. High Level Disinfection (Mask and Swivel port components only)

- a. The mask assembly should be disinfected or sterilized between multiple patient uses
- b. The mask must be thoroughly cleaned in accordance with the cleaning instructions prior to disinfection or sterilization. For disinfection use Cidex™ liquid glutaraldehyde solution or hot water pasteurization method.
- c. For disinfection use Cidex™ liquid glutaraldehyde solution or hot water pasteurization method.
- d. Liquid Chemical Disinfection
 - 1. Submerge and soak the device components in the liquid solution according to manufacturers recommendations
 - 2. Remove the device from the solution and submerge in 1500 ml of sterile water for at least 1 minute
 - 3. Repeat the previous step a second time
 - 4. Dry the device with a clean (preferably sterile) lint free cloth
- e. Hot Water Pasteurization
 - 1. Completely immerse the device components in a hot water bath. All surfaces should be in direct contact with the hot water for 30 minutes at temperatures set between 71.1 C and 76.6 C.

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16. Mask Resistance to Flow

The resistance to flow through the mask assembly is less than 0.5 cm H20 at 50 L/min

17. Mask Deadspace

Values measured using a facial profile include the face mask and complete swivel port assembly (22mm ID swivel port)

Mask Assembly Deadspace Volume ml				
Large 170	Medium 152	Small 126	Extra Small 115	Petite 105

18. Mask and Headgear Service Life

Mask and swivel port components are expected to stay in service for minimum of 25 disinfection or steam sterilization cycles or 6 months of use under normal conditions, whichever occurs first. The headgear is expected to stay in service for 6 months of use.

19. Operational Temperature and Humidity ranges for the Mask assembly and Headgear

Temperature range: 5-40 C
Humidity range: 0-95% RH

20. Recommendations for Mask Disposal

All components of this product can be treated as conventional solid waste and disposed of in accordance with your local and federal regulations.

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- 2. Dry the device with a clean (preferably sterile) lint free cloth
- f. Inspect all Components for Cleanliness, Function and Defects
 - 1. If there are any signs of residues, stains or organic debris then repeat the previous steps. If these signs remain following further cleaning and disinfection then replace with new components.
 - 2. Visually inspect all components for defects. Check rubber parts for nicks, tears, deformation or distortion. Check plastic parts for crazing and cracking.
 - 3. Dispose of and replace all defective parts
- g. Reassemble
 - 1. Check AAV diaphragm function: with the mask installed the diaphragm should flex instantly to CLOSE the room air breathing port with a minimum CPAP/BiLevel of 3 cm H20 mask pressure. When there is no CPAP/BiLevel pressure in the mask the diaphragm will OPEN and allow room air breathing directly through the room air port opening.
 - 2. Snap the AAV into the elbow of the swivel port assuring the elbow locking tabs are fully engaged with the slots of the AAV.
 - 3. Press the rubber cap plug on to the sampling port of the mask adapter
 - 4. Install the swivel port assembly into the grooved opening of the face mask. Orient the sampling port on either side of the nose portion of the face mask. The flange of the swivel port mask adapter mates with the groove of the mask. Start with placing one portion of the adapter into the mask groove then continue completely around stretching it and working it into the mask groove until completely installed.

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21. Ordering Information

7700 Series Reusable V2 Oro-Nasal Mask with Elbow Swivel Port 22mm ID, No Vents with AAV & Headgear (HG)

P/N	Description
	Mask, AAV, Vented, 22mm ID with Headgear
113500	7700 LARGE
113501	7700 MEDIUM
113502	7700 SMALL
113503	7700 EXTRA SMALL
113504	7700 PETITE

P/N	Description
	Replacement Parts
669180	Face Piece LARGE
669181	Face Piece MEDIUM
669182	Face Piece SMALL
669183	Face Piece EXTRA SMALL
669184	Face Piece PETITE
201494	Headgear LARGE
201493	Headgear MEDIUM
201492	Headgear SMALL
201528	Swivel Port, AAV, Non-Vented, 22mm ID
201555	Headgear Strap Clips (package of four)
201521	AAV Port Assembly
211022	Cap Plugs for sampling port package of two

P/N	Description
	Accessories
691143	Mask Sizing Gauge for V2 Oro-Nasal Masks
669353	METRO NG Tube Seal Disposable package of 1

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- 5. Mount the headgear to the face piece. Snap the strap quick-release clips into the appropriate plastic slots on the mask.
 - h. Functional Check
 - 1. All swivel port joints should swivel freely
 - 2. AAV is installed completely in the port, locking tabs fully engaged and the diaphragm flexes freely without any obstruction.
 - 3. Swivel port assembly is completely engaged in the mask face piece
 - i. Storage
 - 1. All components should be completely dry before storage
 - 2. Place complete assembly in clear plastic bag and seal the bag
 - 3. Label the bag with disinfection/clean status, mask description, date and initials
- 15. Steam Sterilization (Face Mask assembly less Headgear)**
- a. Mask must be cleaned and dry in accordance with instructions prior to sterilization
 - b. The mask should be completely assembled (less headgear)
 - c. It is the user's responsibility to validate any deviations from these methods
 - d. Steam Sterilization cycles
 - Pre-vacuum cycles
 - 1. Temperature: 132.2 +3/-1 C
 - 2. Sterilization time: 4 minutes
 - 3. Dry time: 10 minutes
 - 4. Packaging: Double pouched or wrapped in CSR
 - Gravity Displacement cycle
 - 1. Temperature: 132.2 +3/-1 C
 - 2. Sterilization time: 30 minutes
 - 3. Dry time: 10 minutes
 - 4. Packaging: Tyvek® sterilization pouch

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22. Safety Information

Safety or technical information regarding this product can be obtained from Hans Rudolph inc. Phone 913-422-7788 Fax 913-422-3337 hri@rudolphkc.com

23. Credits

Velcro™ is a Trademark of Velcro, U.S.A. Cidex™ is a Trademark of Johnson & Johnson Medical Products, Inc. Tyvek® is a Trademark of DuPont

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7700 Series V2 Mask™
 Oro-Nasal CPAP/BiLevel
Reusable
with AAV & No Vents
 Instructions for Use

LATEX FREE

