

Instructions for Use & Maintenance

1.

Intended Use

The 7600 V2 Mask is a reusable, multi-patient, multi-use, Oro-Nasal CPAP/BiLevel mask which incorporates a passive, continuous flow exhaust port. It is intended for use with certain CPAP/BiLevel machines for treatment of obstruc-tive sleep apnea, and for use with other similar ventilators that use this exhaust port configuration providing a minimum of 3 cm H<sub>2</sub>O 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 H<sub>2</sub>O 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 mask 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.
5.

Warnings

a.

This CPAP/BiLevel mask should be used only with CPAP/BiLevel systems recommended by your physician or repiratory therapist. This mask should not be used unless the CPAP/BiLevel system is turned on and operating properly. The

- 5
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).

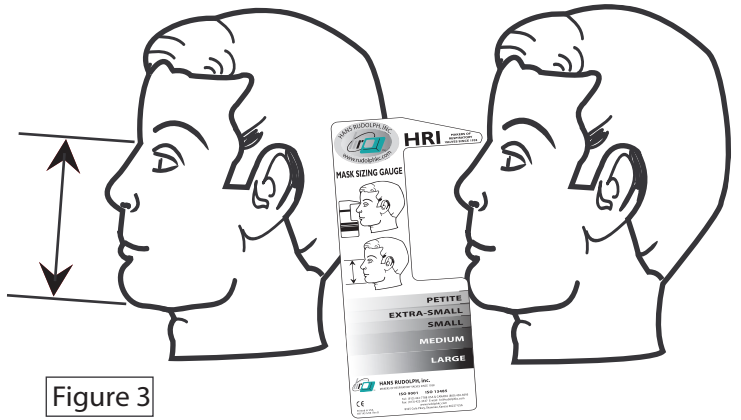


Figure 3

- 2
- b.

vent holes in the mask should never be blocked. These masks are intended to be used only with CPAP/BiLevel systems which require vent holes in the mask to allow continuous air flow out of the mask. 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 mask vent holes. However, when the CPAP/BiLevel machine is not operating properly, 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 cases lead to suffocation.
- c.

This mask is shipped clean but nonsterile. If disinfected or sterile use is required, follow the disinfection of sterilixation procedures described in this document prior to use of the mask.
- d.

Discontinue use of the mask if patient skin or mucous membrane irritation or allergic reaction develops due to the mask.
- e.

Failure to arouse and remove the mask after vomiting could result in aspiration of vomitus.
- f.

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. Oxygen flow must be turned off when the CPAP/BiLevel system is not operating.
6.

Contraindications

a.

a minimum pressure less than 3 cm H<sub>2</sub>O at mask

b.

open wounds that are prone to infection

c.

hemodynamic or cardiorespiratory instability

d.

unconsciousness

e.

claustrophobia, anxiety, or other discomfort with an Oro-Nasal mask

f.

facial or nasopharyngeal deformity, beard, or other inability to fit mask and seal properly

g.

excessive reflux, GI blood or other secretions

- 6
- d.

Fitting the mask
1.

The mask and headgear is supplied fully assembled 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)

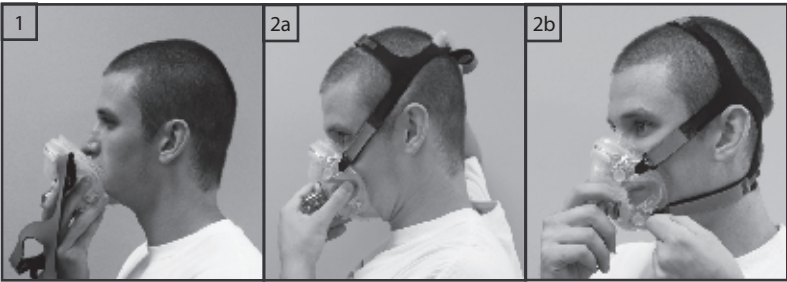
Adjust the tension of the headgear Velcro™ straps by pulling back slightly on the straps. Tighten the lower two straps then the top two to achieve a comfortable fit.

(c)

Finally, adjust the two straps attached by 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.



- 3
- h.

impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions
- i.

upper airway obstruction or facial trauma
- j.

barotrauma
- k.

need for ventilation or ventilatory support more than 12 hours per day
- l.

recent facial, esophageal, or gastric surgery
- m.

patients unable to remove the mask
- n.

patients under medication with a drug that may cause vomiting
- o.

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

8.

Mask Components and Material Descriptions (fig 1)

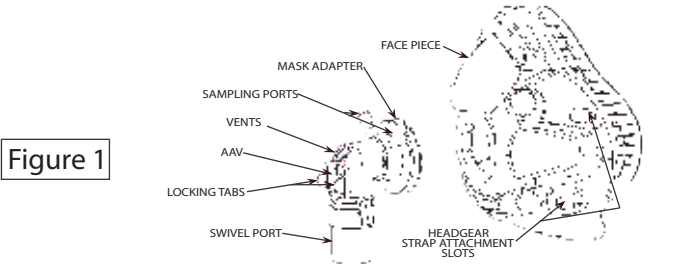
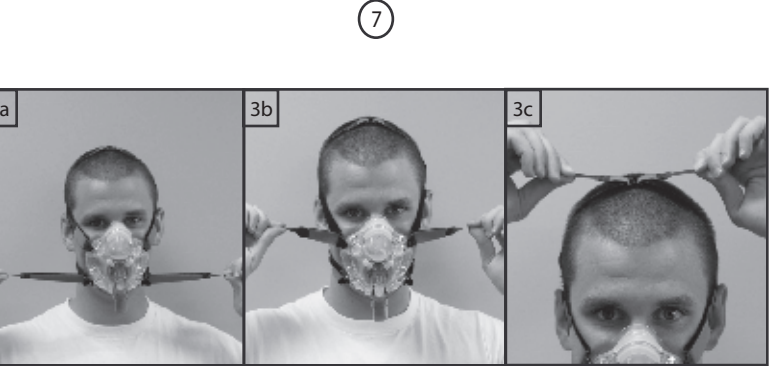


Figure 1



- 7
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.

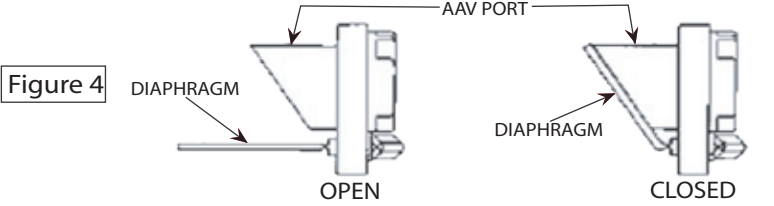


Figure 4

- 8
- 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.

- 4
- 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 two sampling ports, 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.

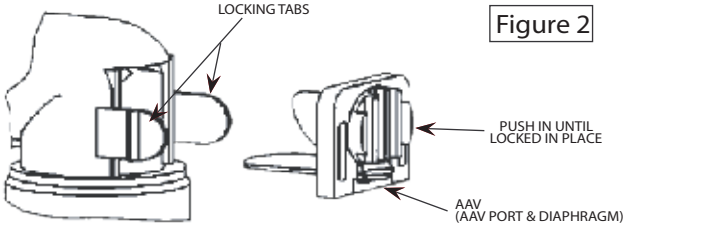


Figure 2

- 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.
- 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.

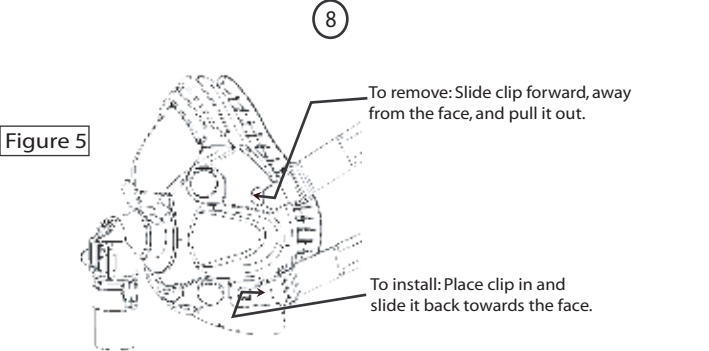


Figure 5

- 8
11.

Removing the Mask:

To remove the mask, slide one of the lower strap quick-release 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

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 plugs from the sampling ports 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

- 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.

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 colution 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.

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 replce 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 H<sub>2</sub>O mask pressure. When there is no CPAP/BiLevel pressure in the mask the diaphragm will OPEN and wallow room qair 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 witht the slots of the AAV.

3.

Press the two rubber cap plugs on to the sampling ports of the mask adapter.

4.

Install the swivel port assembly into the grooved opening of the face mask. Orient the two

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 instruc tions 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

17.

Mask Deadspace

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

Mask Assembly Deadspace Volume ml					
Large	169	Medium	151	Small	125
		Extra Small	114	Petite	104
18.

Mask and Headgear Service Life

Mask and swivel port components are expected to stay in service for minimum of 25 disinfection and steams 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.
21.

Ordering Information

7600 Series Reusable V2 Oro-Nasal Mask with Elbow Swivel Port 22mm OD with AAV, Vents & Headgear (HG)

P/N	Description
	Mask, AAV, Vented, 22mm OD with HG
113485	7600 LARGE
113486	7600 MEDIUM
113487	7600 SMALL
113488	7600 EXTRA SMALL
113489	7600 PETITE

P/N	Description
	Mask, AAV, Vented, 22mm OD LESS HG
113570	7600 LARGE
113571	7600 MEDIUM
113572	7600 SMALL
113573	7600 EXTRA SMALL
113574	7600 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
201523	Swivel Port, Vented, AAV, 22mm OD
201555	HG 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

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



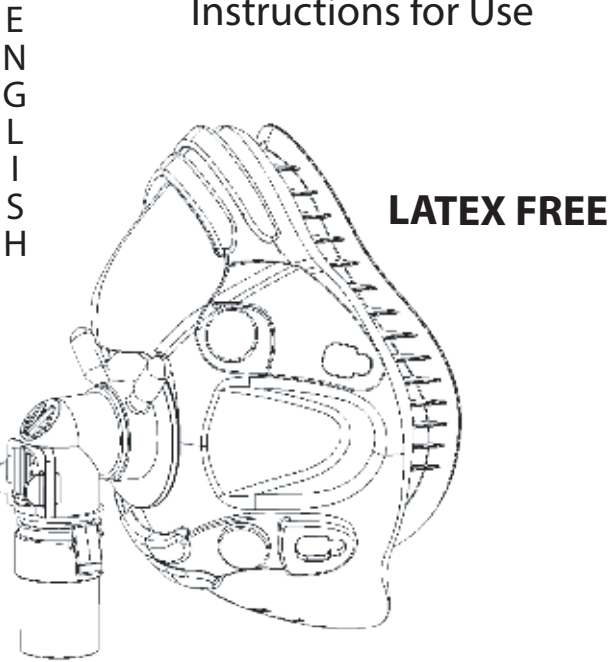
Hans Rudolph, inc.

7600 Series V2 Mask™

Oro-Nasal CPAP/BiLevel Reusable

with Vents & AAV

Instructions for Use



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