Hans Rudolph 7600 Series V2 Mask
Oro-Nasal CPAP/BiLevel Reusable with Vents & AAV

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 obstructive sleep apnea, and for use with other similar ventilators that use this exhaust port configuration providing a minimum of 3 cm H2O pressure measured at the mask.

2. Environment of Use

This mask is intended 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 mask as well as the device to which the mask is 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 mask vents 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.

d. Facial or nasal hair may need to be shaved to assure mask effectiveness.

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.

g. Some slight discomfort after prolonged use.

5. Warnings

a. 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. The vent holes in the mask should never be blocked.

b. 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 relined, 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 cleaned nonsterile. If disinfected or sterilized use is required, follow the disinfection or sterilization 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. Excessive, facial hair may need to be shaved to assure mask effectiveness.

6. Contraindications

a. a minimum pressure less than 3 cm H2O 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 nasal hair may need to be shaved to assure mask effectiveness.

g. gagging

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.

g. Some slight discomfort after prolonged use.

7. Complications

a. a. infection due to improved 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 regurgitated air

g. some slight discomfort after prolonged use.

d. decreased secretions clearance especially during upper respiratory tract infections

h. aspiration of secretions

5. Apply and Fitting Mask

a. Mask sizes: L (large), (medium), (small), ES (extra small), P (petite)

b. Headgear sizes: L (large), M (medium), S (small)

Recommended Headgear Sizes for each Mask Size

<table>
<thead>
<tr>
<th>Mask</th>
<th>L</th>
<th>M</th>
<th>S</th>
<th>ES</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headgear</td>
<td>L</td>
<td>M</td>
<td>S</td>
<td>ES</td>
<td>P</td>
</tr>
</tbody>
</table>

c. Determine mask size of patient with a Mask Sizing Guide (fig. 1) provided to measure the patient’s face and select 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).

d. Fitting the mask

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. 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. Reconnect the headgear strap clip after the headgear is in place. The bottom strap should be positioned below the ears and the top strap above the ears and below the eyes.

c. 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. Lastly, adjust the strap across the crown of the head.

4. Connect the mask to the ventilator patient circuit by following the ventilator operating instructions.

5. Turn on the ventilator. If you or the patient detects a leak around the mask sealing area, reposition the mask and adjust the strap tension to eliminate the leak. If the leak continues regardless of your adjustments try another mask size.

8. Mask Components and Material Descriptions (fig 1)

a. Anti-Asphyxia Valve (AAV) (fig 2) snaps into the elbow and the flexible components are silicone rubber. The plastic components are acrylic from the face, and pull it out.

c. Anti-Asphyxia Valve (AV) (fig 2) snaps into the elbow of the swivel port assembly using the "locking tabs" for engagement. The function of the AV is to allow the patient to breath room air when the CPAP/BiLevel machine is not operating or turned off.

b. AAV PORT & DIAPHRAGM

d. Strap quick-release Clips snap easily into and out of the mating slots on the face mask for easy mounting and disinfecting of the headgear. The strap quick-release clips allow quick removal of the mask from the patient.

10. Verification of Safety Features

a. Anti-Asphyxia Valve (AV) (fig 4) The AV allows room air breathing for the patient if the ventilator device should stop for some reason. The AV diaphragm closes the large bore air port in the mask when the ventilator machine is turned off and opens the mask to room air breathing when the ventilator device is off. Mask should not be used if the AV 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.

c. Mask plate is molded of a biocompatible thermoplastic elastomer. There are four slots openings in the mask acrylate plastic braces for the attachment of the headgear strap mounting quick-release clips.

a. Soak all the components for 5 minutes in warm water with a mild detergent (neutral pH)

b. Rinsing with warm water Place the components in a bath of warm water and agitate for two minutes.

c. Rinse with warm water Place the components in a clean, lint free cloth

1. To remove: Slide clip forward, away from the face, and pull it out.

2. To install: Place clip in and slide it back towards the face.

3. a. Detach mask from the ventilator

b. Separate the headgear from the mask

c. Separate the swivel port assembly from the mask, AV from the swivel port (squeeze two locking tabs and pull AV 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

11. Removing the Mask: To remove the mask, slide one of the lower strap quick-release clips slightly forward toward 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. Mask face piece is molded of a biocompatible thermoplastic elastomer. There are four slots openings in the mask acrylate plastic braces for the attachment of the headgear strap mounting quick-release clips.

b. Swivel Port assembly consists of two sampling ports, micro vent and anti-asphyxia valve (AV) and detachable 22mm swivel port. The plastic components are acrylic and the flexible components are silicone rubber.

c. Anti-Asphyxia Valve (AV) (fig 2) snaps into the elbow of the swivel port assembly using the "locking tabs" for engagement. The function of the AV 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 polyurethane foam laminate with a nylon loop on the outer surface for Velcro™ hook attachment and a soft nylon fabric surface on the patient contact surface for comfort.

1. Place mask on a flat surface (fig 3)

2. From the face, and pull it out.

3. Slide clip forward, away from the face, and pull it out.
d. Steam Sterilization cycles
- Pre-vacuum cycles
  1. Temperature: 132.2 ± 3°C
  2. Sterilization time: 30 minutes
  3. Packaging: Tyvek® sterilization pouch
  4. Dry time: 10 minutes
  5. Sterilization time: 2 minutes
  6. Temperature: 132.2 ± 3°C
  7. Sterilization time: 4 minutes
  8. Packaging: Double pouched or wrapped in CSR
  9. Dry time: 10 minutes
  10. Sterilization time: 4 minutes

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 should be completely cleaned and disinfected
      according to instructions before each use.

15. Steam Sterilization (Face Mask assembly less Headgear)
   a. Wash the parts using warm soapy water until all signs
      of debris or stains are removed. Rinse in clean tap water
      and sterile distilled water.
   b. AAV is installed completely in the port, locking tabs fully engaged
      and the diaphragm flexes freely without any obstruction.
   c. Swivel port assembly is completely engaged in the mask face piece.

16. Mask Vent Pressure Flow Curve
   This graph illustrates the air flow leak rate through the mask vent holes
   at a full range of mask pressures.

17. Mask Deadspace
   Values measured using a facial profile include the face mask
   and swivel port assembly (22mm OD swivel port)
   Headgear SMALL
   Headgear MEDIUM
   Headgear LARGE

18. Mask and Headgear Service Life
   Mask and swivel port components are expected to stay in service
   for minimum of 25 disinfection and steam sterilization cycles or 6 months
   of use under normal conditions, whichever occurs first. The headgear
   is expected to stay in service for 8 months.

19. Operational Temperature and Humidity ranges for the Mask assembly and Headgear
   Temperature: 5–40°C
   Humidity range: 6–95% 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 CPAP/BiLevel Reusable
   with Vents & AAV

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
    Toll-free: (800) 456-6695

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

LATEX FREE