

Hans Rudolph 7500 Series V2 Mask
Oro-Nasal NIV Reusable
No Vents – No AAV

LATEX FREE

Instructions for Use & Maintenance

1. **Intended Use**
 The 7500 V2 Mask is a reusable, multi-patient, multi-use, Oro-Nasal NIV mask intended to provide a patient interface for applications of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure and which are intended to administer positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency.
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 30kg weight) who are appropriate candidates for noninvasive ventilation.
4. **Cautions**
 - a. Federal law restricts this device to sale by or on the order of a physician.
 - b. 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. do not block mask or patient circuit flow, watch for flow blockages or restrictions
 - b. This mask does not include an Anti-Asphyxia Valve (AAV) that would allow a patient to breathe if the ventilator failed.

- 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 place 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.

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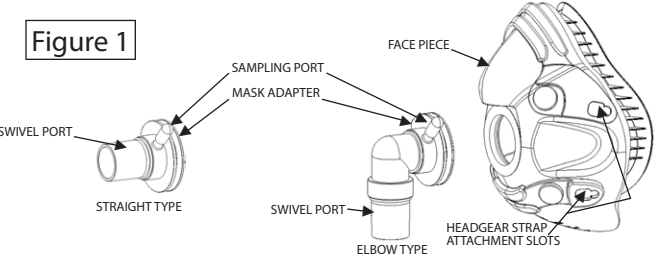
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- c. In the event of ventilator failure, use of this mask requires the same level of attention and assistance as the use of a tracheal tube.
- d. This mask must be used with ventilators which have adequate alarms and safety systems for ventilator failure.
- e. 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.
- f. 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.
- g. Discontinue use of the mask if patient skin or mucous membrane irritation or allergic reaction develops due to the mask.
- h. Failure or inability to arouse and remove the mask after vomiting could result in aspiration of vomitus.
- i. Do not use this mask with single-limb constant-flow ventilation or CPAP devices that require either an added exhalation valve, vent holes and or an anti-suffocation valve built into the mask in order to allow the patient to breath.
- j. Do not use this mask with a ventilation device that does not have a built-in anti-suffocation mechanism.

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

8. **Mask Components and Material Descriptions (fig 1)**

 - a. Mask face piece is molded of 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 (Elbow or Straight Type) consists of a sampling port and 22mm OD or ID swivel port connected

- c. directly to the mask adapter (Straight type) or to an Elbow. The plastic components are polycarbonate and the flexible sampling port cap plug is silicone rubber.
 - c. 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.
 - d. 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 2) 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).



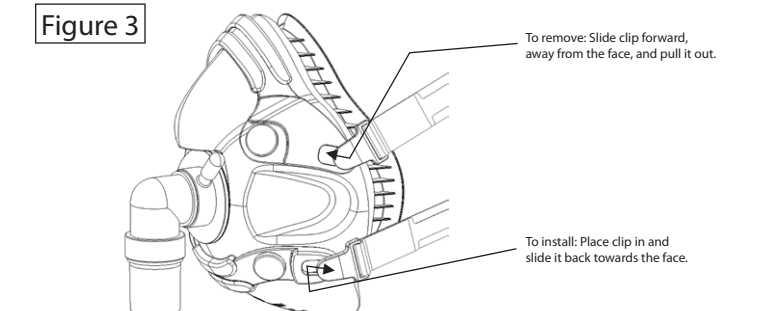
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10. **Verification of Safety Features**
 - a. Quick-Release Headgear (fig 3): Unsnapping one of the lower headgear strap quick-release clips from the mask will allow complete removal of the mask assembly.



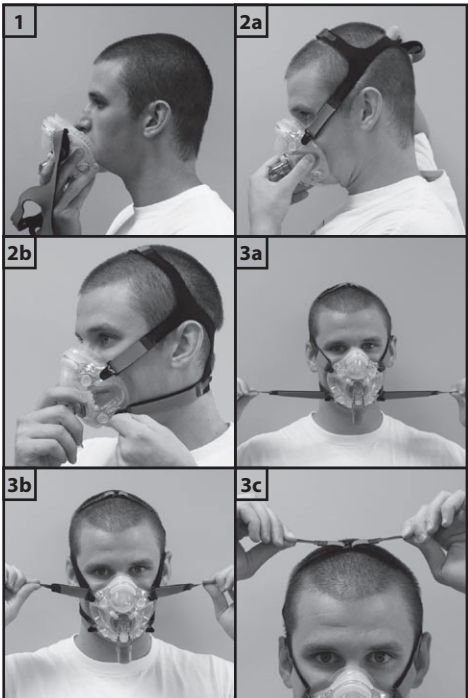
11. **Removing the Mask:**
 To remove the mask, slide one of the lower strap clips slightly forward towards the front of the mask and it will disconnect from the mask, pull the mask and headgear to the opposite side or up over the patient's head.
12. **Disassembly for Cleaning, Disinfection or Sterilization**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

- Mask face piece 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 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



9

- 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 replace all defective parts
- g. Reassemble
 1. Press the rubber cap plug on to the sampling port of the mask adapter
 2. 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.
 3. 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. 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

12

Commonly Ordered Items Continued

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
201532	Swivel Port Elbow Type 22mm ID
201537	Swivel Port Straight Type 22mm ID
201531	Swivel Port Elbow Type 22mm OD
201536	Swivel Port Straight Type 22mm OD
201555	HG Strap Clips package of four
211022	Cap Plugs for sampling port package of two

Other Ordering Options Available but Uncommon

P/N	Description
	Mask, 22mm ID Straight Type with Headgear
113520	7500 LARGE
113521	7500 MEDIUM
113522	7500 SMALL
113523	7500 EXTRA SMALL
113524	7500 PETITE

10

- 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 cycle
 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
- 16. **Mask Resistance to Flow**
The resistance to flow through the mask assembly is less than 0.5 cm H2O 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 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 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

13

P/N	Description
	Mask, 22mm OD Elbow Type with Headgear
113505	7500 LARGE
113506	7500 MEDIUM
113507	7500 SMALL
113508	7500 EXTRA SMALL
113509	7500 PETITE
	Mask, 22mm OD Straight Type with Headgear
113515	7500 LARGE
113516	7500 MEDIUM
113517	7500 SMALL
113518	7500 EXTRA SMALL
113519	7500 PETITE

- 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

11

- 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**
7500 Series Reusable V2 Oro-Nasal Mask with Straight or Elbow Type Swivel Port 22mm OD or ID & Headgear (HG)

Commonly Ordered Items

P/N	Description
	Mask, 22mm ID Elbow Type with Headgear
113510	7500 LARGE
113511	7500 MEDIUM
113512	7500 SMALL
113513	7500 EXTRA SMALL
113514	7500 PETITE
	Accessories
691143	Mask Sizing Gauge for V2 Oro-Nasal Masks
669353	METRO™ NG Tube Seal Disposable package of 1

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PRINTED IN U.S.A.
 691271 02/10 Rev. D

US Pat D573,709S, EC Reg'd Des.No.000780556-0001 and Patents Pending
 ISO 9001 / ISO 13485
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ENGLISH

7500 Series V2 Mask
 Oro-Nasal NIV
Reusable
NO Vents - NO AAV
 Instructions for Use

LATEX FREE

