

**INSTRUCTIONS FOR USE & RECOMMENDATIONS FOR CLEANING, DISINFECTION,
STERILIZATION AND MAINTENANCE**
HANS RUDOLPH MODEL 7600 VMASK MULTI-PATIENT MULTI-USE ORO-NASAL MASK

1. Intended Use

The Hans Rudolph 7600 Vmask Series is a reusable, multi-patient, multi-use, adult Full-Face CPAP/NPPV mask which incorporates a passive, continuous flow exhaust port at the patient connection. It is intended for use with certain CPAP 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

The Masks are 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 and system to which the masks are intended to connect.

3. Indications for Use

The Masks are indicated for use on adult patients (greater than 30 kilograms weight) for treatment of Obstructive Sleep Apnea or any other conditions requiring CPAP or non-invasive ventilatory support at pressures greater than or equal to 3.0 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 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, especially beards, may experience mask leakage even though all fitting instructions are followed. If mask leakage is excessive, the beard or other facial hair may need to be shaved to assure mask effectiveness.

5. Warnings

- a. This CPAP mask should be used only with CPAP systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP system is turned on and operating properly. The vent holes associated with the mask should never be blocked.
- b. CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask vent holes. However, when the CPAP machine 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. This warning applies to most models of CPAP systems.
- c. Masks are shipped clean but nonsterile. If disinfected or sterile use is required, follow the disinfection or sterilization procedures described in this document prior to initial use of the mask.
- d. The masks will not remain sterile between repeated single-patient uses and should not be placed over open wounds that are prone to infection. Cleaning, disinfection, and sterilization procedures are included as part of these Instructions for Use.
- e. To prevent the growth and spread of infectious microbes, replace the mask if it is uncleanable.
- f. Discontinue use of the mask if patient skin or mucous membrane irritation or allergic reaction develops due to the mask.
- g. The mask should not be worn unless the CPAP/bi-level system or other ventilation device is connected and operating properly.
- h. Failure to arouse and remove the mask after vomiting could result in aspiration of vomitus.
- i. To minimize the risk of aspiration during sleep, avoid eating or drinking for three hours prior to sleep.
- j. Any unusual chest discomfort, shortness of breath, stomach distention, belching or severe headache during or immediately after use should be immediately reported to your physician.
- k. 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.
- l. The mask should not be used if the Anti-Asphyxia Valve or the Headgear Pull-String Release Mechanism are missing or damaged.
- m. In situations where the risk of contamination between the patient and the ventilation device is high (e.g., rental units, patients with respiratory infections), a low resistance main flow bacteria filter should be placed in-line between the ventilation device and the patient.

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 full-face mask
- f. facial or nasopharyngeal deformity, beard, or other inability to fit mask & seal properly
- g. excessive reflux, GI blood, or other secretions
- 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 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 & Materials Description

- a. **Face piece** (fig 3) is one piece molded of silicone rubber. Integrally molded label on the face piece indicates the size. The main port opening (fig 3) mates with a groove in the mask adapter of the swivel port assembly (fig 4). There is a series of air vent holes in the nose section for flushing of exhaled air. There are four integral nibs (mounting posts) on the face piece for attachment of the headgear (fig 5) strap clips (fig 8).
- b. **Swivel port assembly** (fig 4) consists of a mask adapter with two sampling ports with cap plugs, elbow, 22mm swivel port, anti-asphyxia valve (AAV) port and diaphragm. The mask adapter, elbow and 22mm swivel port are permanently assembled and rotate 360 degrees at both joints. The diaphragm is permanently mounted in the diaphragm AAV port (fig 4A & B). The plastic components of the swivel port assembly are molded of polysulfone thermoplastic. The cap plugs are molded of silicone rubber.

- c. **Anti-Asphyxia Valve (AAV)** (fig 4A, B, & C). The AAV port snap fits into the elbow of the swivel port assembly using the “locking tabs” (fig 4C). The AAV port is molded of polysulfone thermoplastic and the diaphragm is molded of silicone rubber. The function of the AAV diaphragm (fig 4A) is to “close-off” the room air opening when the CPAP machine is “on” and to “open” the room air opening when the CPAP machine is “off”. This allows the patient to breathe room air when the CPAP machine is not operating or turned “off”.
- d. **Headgear** (fig 2 & 5) has a pull-string quick release mechanism which when pulled allows the mask to quickly fall from the patient’s face. Each of four elastic straps has a plastic clip that mates to a nib on the face piece. When the strap is pulled correctly (straight back away from the face) through the clip, (fig 8) the clip will lock and hold the strap position. To release the strap tension lift the rear of the clip. The clip can be removed quickly from the face piece by rotating it 90 degrees off the nib. The straps are an elastic Velcro™ loop material and have a Velcro™ hook section next to the pull-tab that will attach to the loop of the strap in order to keep the strap ends out of the way of the patient’s face.
- e. **Easy-Release (two-piece) Clips** (fig. 8) are assembled on each of the four straps on the Headgears. These (grey colored) Clips allow easy mounting and dis-mounting of the headgear and mask without re-adjusting the straps or removing the Clip from the mask nib.
To disconnect the clips; simply squeeze the sides of the clip with two fingers and pull back.
To connect the clips; simply press the male half into the female half and it will snap in place. (Photo F)

9. Safety Features

- a. **Anti-Asphyxia Valve** (fig 4A,B) allows the patient to breathe room air in the case that the CPAP device connected to the mask is not operating or turned “off”.
- b. **Pull-String Quick-Release Mechanism** (fig 1,2,5) allows the patient to quickly remove the mask assembly in an emergency. If the Quick-Release Mechanism does not function properly, then the Strap Clips can be released from the mask nibs by simply rotating the Strap Clip 90 degrees away from the face.

10. Applying and Fitting Mask

- a. **Mask and Headgear Sizing:**
 - 1.) Mask sizes: L(Large), M(Medium), S(Small), ES(Extra Small) and P(Petite)
 - 2.) Headgear sizes: Large and Small. The Large headgear is recommended for the L, M & S face piece and the Small headgear for the ES and P face pieces.
- b. **Determining mask size of patient:** A MSC (Mask Sizing Caliper) (fig 7) is available to help determine the best face mask size although the best method is to place the actual face mask(s) on the patient’s face and observe the fit. For mask sizing the patient’s facial muscles should be relaxed and jaw closed. Fit the patient’s chin in the chin cup section (fig 6) of the mask and slightly press the mask onto the face. The top of the mask (nose section) should be slightly below the nasal root depression (where the nose meets the forehead).
- c. **Application of mask and headgear:**
 - 1. Extend the length of the four straps (where the pull-tabs meet the clips) without pulling them completely through the clips.
 - 2. Slip each of the clips onto the correct face piece nib (mounting post) (fig 8). Note the bottom straps are the ones that mount at the quick-release section on the back of the headgear.
 - 3. With the face piece in one hand and the headgear in the other, place the headgear (polynet section) on the crown of the head and pull the mask face piece down over the patient’s face. The top headgear straps should be located above the ears and below the eyes and the bottom straps below the ears. (Photos A & B)
 - 4. Place the face piece on the patient (locate patient’s chin in the mask chin cup) and begin pulling the straps straight back away from the face. Tighten the four straps equally until the assembly is slightly snug on the face. The locking type strap clips will maintain the tightened strap position when pulled snug. To loosen the strap tension lift the rear of the strap clip. (Photos C & D)
 - 5. Communicate with the patient to adjust the mask position and tightness for a comfortable secure fit.
 - 6. Connect the air tube from the blower device to the 22mm swivel port (fig 4).
- d. **Checking mask seal:** If you or the patient detects a leak around the sealing flange of the mask attempt to reposition the mask or adjust strap tension to eliminate the leak. If the leak continues regardless of your adjustments try another size mask.
- e. **Verification of the Anti-Asphyxia Valve (AAV).** The AAV consists of a plastic port (AAV port) and rubber diaphragm (fig 4, 4A, B). When there is flow from the CPAP machine the diaphragm’s hinge area flexes so the diaphragm’s face section will seal off the room air opening in the AAV port (“closed” fig 4A). When there is no flow from the CPAP machine the diaphragm recoils to its natural position and opens the Anti-Asphyxia Valve port to room air (“open” fig 4A). The diaphragm is permanently installed in the AAV port at the factory. Check the installation of the diaphragm in the AAV port by flexing the diaphragm’s “sealing face” to the “closed” position and insure complete sealing off of the room air port (fig 4A “closed”). The AAV port and diaphragm subassembly snap fit into the opening of the elbow adapter of the swivel port assembly (fig 4C). Push the AAV port and diaphragm into the elbow opening until both locking tabs snap-lock with the AAV port locking in place. To release the AAV port and diaphragm subassembly from the elbow adapter “squeeze” the two locking tabs of the elbow together (fig 4C) and pull the AAV port from the elbow.
- f. **Verification of pull-string quick release mechanism:** With the mask and headgear assembled pull on the pull-string and the headgear should separate at the Velcro™ hook and loop section (quick-release section) at the rear of the head (fig 2). This should completely release the mask and headgear from the patient’s face. The pull-string should only be used to release the mask and headgear for verification or emergencies in order to extend the life of this hook and loop connection. (Photo E)

11. Removing Mask and Headgear (includes storage)

- a. **Removing the mask and headgear: Easy-Release (two-piece) Clips** (fig. 8) are assembled on each of the four straps on the Headgears. These (grey colored) Clips allow easy mounting and dis-mounting of the headgear and mask without re-adjusting the straps or removing the Clip from the mask nib.
To disconnect the clips; simply squeeze the sides of the clip with two fingers and pull back.
To connect the clips; simply press the male half into the female half and it will snap in place. (Photo F)
- b. **Storage:** Masks should be stored in a way that prevents contamination or damage between uses.

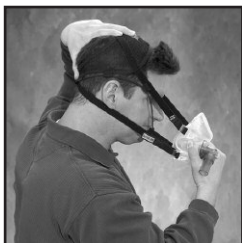


Photo A



Photo B



Photo C

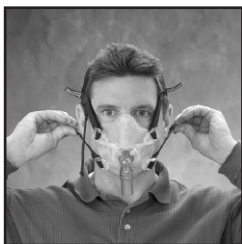


Photo D



Photo E



Photo F

12. Disassembly for Cleaning and Disinfection or Sterilization

It is recommended that personnel handling contaminated devices wear gloves and other protective attire. The mask assembly must be completely disassembled to expose all surfaces to the cleaning process.

1. Detach the air tube of the CPAP machine from the mask assembly (fig 1).
2. Detach the headgear from the mask assembly by sliding the strap clips off the nibs (mounting posts).
3. Detach the swivel port assembly from the face piece main port opening. Hold the two sides of the mask together with one hand and twist the mask adapter of the swivel port assembly with the other hand and it will pop out of the mask easily.
4. Remove the AAV port and diaphragm subassembly from the elbow of the swivel port assembly. Squeeze the two tabs of the elbow together (fig 4C) and pull the AAV port from the elbow at the same time.
5. Remove the rubber cap plugs from the sampling ports of the mask adapter (fig 4).

13. Cleaning (Home or Institution)

- a. It is recommended that the mask assembly be thoroughly cleaned after each use and in accordance with these instructions prior to disinfection or sterilization.
- b. Immediately separate and contain soiled devices at the point of use and transport to the decontamination area so as to minimize risk of personal contact with contaminants.
- c. **Cleaning technique of the mask face piece and swivel port components**
 1. Submerge all the components of the device in a mild neutral pH detergent. Prepare the detergent according to the manufacturer's recommendations. Soak the device for five (5) minutes in the mild detergent.
 2. Scrub the submerged device with a soft bristled brush. Agitate the device in the solution while scrubbing. Use a small cytology type brush to clean the internal channels of the mask face piece and swivel port assembly.
 3. Rinse the device with warm (38-49 C) tap water. Place the device into a bath containing warm (38-49 C) water. Agitate the device by hand for at least one (1) minute. Repeat this process two (2) additional times.
 4. Rinse the device with clean, tap water for at least one (1) minute.
 5. Dry the exterior of the device with a clean, lint free cloth.
- d. **Cleaning technique of the headgear**
 1. Submerge the headgear in soapy warm tap water (38-49 C) and gently rub all the areas.
 2. Rinse the headgear in clean, tap water for one (1) minute or until all signs of the soap are removed.
 3. Air dry
 4. **Caution:** the black dye of the straps and headgear material may run the first couple times during cleaning.
- e. Always inspect the mask components for damage at all stages of handling. If damaged components are found they should be replaced.
- f. **Do not use bleach, chlorine or alcohol based solutions** to clean any of the mask and headgear components.
- g. It is the user's responsibility to validate any deviations from these recommended methods.

14. High Level Disinfection (HLD) (face mask and AAV swivel port assembly)

- a. The mask assembly should be disinfected (high level) or sterilized between multiple patient uses.
- b. The mask must be thoroughly cleaned in accordance with the cleaning instructions prior to disinfection.
- c. The disinfectant/sterilizing agent/hot water must contact all surfaces to ensure disinfection or sterilization.
- d. For high level disinfection use CIDEX™ Liquid Glutaraldehyde disinfection solution or hot water pasteurization method.
- e. Adequate ventilation of glutaraldehyde chemical vapors is required. Use lidded containers for the disinfection solution when appropriate. The inhalation and direct skin contact of the disinfectant chemicals can be hazardous to personnel. Gloves should be worn made of butyl or nitrile rubber.
- f. **Liquid disinfection technique:**
 1. Submerge the device components in the liquid chemical (CIDEX™ glutaraldehyde) solution. Prepare the solution according to manufacturer's recommendation.
 2. Soak the device for 45 minutes.
 3. Remove the device from the solution and submerge in 1500 ml of sterile water for at least one (1) minute (first rinse).
 4. Remove the device from the sterile water and submerge in 1500 ml of sterile water for at least one (1) minute (second rinse).
 5. Dry the device with a clean (preferably sterile), lint free cloth.
- g. **Hot Water Pasteurization**
 1. Separate mask body from swivel port assembly during pasteurization HLD.
 2. Completely immerse the disassembled device components in a hot water bath. Be sure that all surfaces are in direct contact with hot water.
 3. Immerse the devices for 30 minutes at temperature set between 71.1°C (160°F) and 76.6°C (170°F).
 4. Remove all components from the water and dry exterior with lint-free cloth.
- h. **Inspect all components for cleanliness, proper function and freedom of defects.**
 1. If there are any signs of residues, stains or organic debris from the detergents or disinfectants then repeat the previous steps. If these signs remain following repeating the steps then dispose of the components and replace with new ones.
 2. Visually inspect all components for defects. Check rubber parts for nicks, tears, hardening or stiffening, deformation or distortion. Check the plastic parts for crazing or cracking.
 3. Dispose of and replace all defective parts.
- i. **Reassemble**

Use appropriate personal protective clothing to assure that you do not recontaminate the components.

 1. Check the diaphragm in the AAV port by flexing the diaphragm's "sealing face" to the "closed" position and insure complete sealing off of the room air port (fig 4A "closed").
 2. Install the AAV subassembly (port & diaphragm) in the elbow of the swivel port assembly (fig 4C). The AAV subassembly snaps into the elbow opening with the two elbow locking tabs snap fitting with the two side slots in the AAV port. To check the installation you should not be able to remove or dislodge the AAV from the elbow without squeezing the two tabs together releasing the AAV port.
 3. Press the two rubber cap plugs onto the sampling ports of the mask adapter (fig 4). Push them on as far as possible. This will assure that the caps will not accidentally fall off during mask usage.
 4. Install the complete swivel port assembly into the mask main port opening (fig 3). Orient the two sampling ports of the mask adapter on either side of the nose section of the face piece during this installation. The flange and groove of the mask adapter (fig 4) mate with an identical flange and groove of the mask main port opening. Start by placing a portion of the mask adapter into the mask opening and then work your way around by stretching the mask rubber opening into the adapter groove. Following this installation the swivel port assembly should not easily pull out or rotate in the mask face piece.
 5. Mount the headgear to the mask face piece. Pull the straps through the mounting clips extending the strap length as long as possible until the pull-tabs are located at the clips. Slip each of the clips onto the correct face piece nib (mounting posts) (fig 8). The bottom straps are the ones that mount at the quick-release section on the back of the headgear (fig 2).

j. Functional check

1. The two swivel port joints should rotate easily (fig 4).
2. The AAV diaphragm should move freely inside the elbow without interference with any surfaces. Visually check this by confirming that the diaphragm is positioned flat and undistorted.
3. The AAV port should be completely engaged with the tabs of the elbow opening. Check this by pulling on the AAV port. It should not become dislodged with out squeezing the two tabs together.
4. There should be complete engagement of the mask adapter in the mask port opening. Check this by slightly pulling and twisting on the elbow of the swivel port assembly.

k. Storage

1. All components of the mask and headgear assembly should be completely dry prior to storage. They should be stored in a way that prevents recontamination or damage between uses.
2. Place the mask assembly in a clean plastic bag and heat seal or twist tie the end.
3. Label the bag that it has been disinfected with part numbers, dates and initials.

15. Steam Sterilization (face mask and AAV swivel port assembly)

- a. The mask assembly should be disinfected (high level) or sterilized between multiple patient uses.
- b. The mask must be thoroughly cleaned and dry in accordance with the cleaning instructions prior to sterilization.
- c. The mask must be completely assembled as described above (detach the headgear). The headgear cannot be steam sterilized.
- d. Gloves should be worn to prevent contamination of sterile packages.
- e. It is the user's responsibility to validate any deviations from this recommended method of processing.

f. Steam sterilization cycle parameters (Pre-vacuum & Gravity)

Pre-vacuum Cycle type

1. Sterilization temperature: 132.2 +3/-1 C
2. Sterilization time: 4 minutes
3. Dry time: 10 minutes
4. Packaging: Double pouched or wrapped in CSR (Cellulose Sterilization Wrap)

Gravity Displacement Cycle type

1. Sterilization temperature: 132.2 +3/-1 C
2. Sterilization time: 30 minutes
3. Dry time: 10 minutes
4. Packaging: Tyvek® sterilization pouch

g. Packaging system should:

1. allow adequate air removal and steam penetration of the package
2. adequate barrier to microorganisms and resist tearing and puncturing
3. proven seal integrity and low linting
4. provide removal of the contents without contamination

h. Loading/Unloading the sterilizer

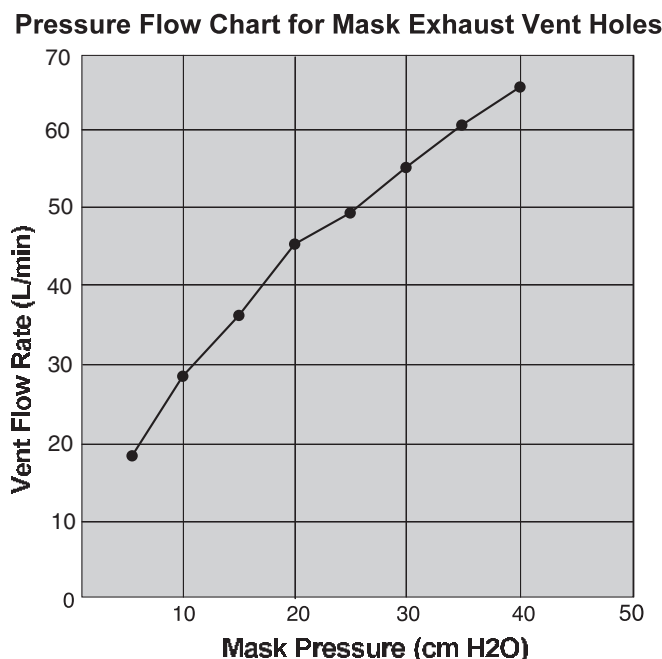
1. Allow for free circulation of steam around each package.
2. Position devices to allow for adequate air elimination and draining of condensate without wetting other items.
3. Items removed from the sterilizer should not be touched until adequately cooled otherwise they can absorb moisture-carrying bacteria.
4. Visually inspect for torn packaging, compressed packaging, or wet packaging. These packages should be returned for reprocessing.
5. Sterilizers differ in design and each manufacturer's written instructions should be carefully followed.

i. Storage

1. Plastic dust covers should be applied soon after sterilization but only to packages that are thoroughly cool and dry.
2. Dust cover should be sealed to be an effective barrier to moisture.
3. Label the package (dust cover) with the appropriate identity and traceability information.

16. Pressure/Flow Curve

The graph (below) illustrates the air flow leak rate through the mask vent holes (fig 1,3) at a full range of mask pressures.



17. Mask and Headgear Service Life

All reusable device subassemblies (Face Piece and Swivel Port Assembly) are expected to stay in service for a minimum of 100 high level disinfection cycles or 50 auto-clave (steam sterilization) cycles or 2 years of operation under normal operational and environmental conditions, whichever occurs first. The service life of the disposable Head Gear is a minimum of 6 months within the range of operational environmental conditions.

18. Operational Temperature and Humidity Ranges for mask assembly and headgear

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

19. Recommendations for Mask Disposal

All the components of this device are considered non-critical and should be treated as conventional solid waste disposed of in accordance with your local and federal regulations.

20. Ordering Information - 7600 Series Oro-Nasal Mask with Elbow Swivel Port 22mm OD or 22mm ID with Anti-Asphyxia Valve (AAV) & Quick-Release (Q-Rel) Headgear (HG)

P/N	Description	Replacement Parts
	Mask, AAV Valve, 22mm OD Elbow & Headgear	
113237	7600 Large , AAV, 22mm OD Elbow with Lg Q-Rel HG	669130 Face Piece, Large, 7600 Series
113238	7600 Medium , AAV, 22mm OD Elbow with Lg Q-Rel HG	669131 Face Piece, Medium, 7600 Series
113239	7600 Small , AAV, 22mm OD Elbow with Lg Q-Rel HG	669132 Face Piece, Small, 7600 Series
113240	7600 Extra Small , AAV, 22mm OD Elbow with Sm Q-Rel HG	669133 Face Piece, Extra Small, 7600 Series
113241	7600 Petite , AAV, 22mm OD Elbow with Sm Q-Rel HG	669134 Face Piece, Petite, 7600 Series
	Mask, AAV Valve, 22mm OD Elbow Less Headgear	201418 Headgear Large
113300	7600 Large , AAV, 22mm OD Elbow, No HG	201419 Headgear Small
113301	7600 Medium , AAV, 22mm OD Elbow, No HG	201388 22mm OD Elbow Swivel Port complete with AAV
113302	7600 Small , AAV, 22mm OD Elbow, No HG	201454 22mm ID Elbow Swivel Port complete with AAV
113303	7600 Extra Small , AAV, 22mm OD Elbow, No HG	201476 Easy-Release Clips for Q-Rel or Standard Headgear package of four
113304	7600 Petite , AAV, 22mm OD Elbow, No HG	201452 AAV Port with Diaphragm
	Mask, AAV Valve, 22mm ID Elbow & Headgear	211022 Cap Plugs for sampling ports, package of two
113380	7600 Large , AAV, 22mm ID Elbow with Lg Q-Rel HG	
113381	7600 Medium , AAV, 22mm ID Elbow with Lg Q-Rel HG	
113382	7600 Small , AAV, 22mm ID Elbow with Lg Q-Rel HG	
113383	7600 Extra Small , AAV, 22mm ID Elbow with Sm Q-Rel HG	
113384	7600 Petite , AAV, 22mm ID Elbow with Sm Q-Rel HG	
	Mask, AAV Valve, 22mm ID Elbow Less Headgear	
113373	7600 Large , AAV, 22mm ID Elbow, No HG	
113374	7600 Medium , AAV, 22mm ID Elbow, No HG	
113375	7600 Small , AAV, 22mm ID Elbow, No HG	
113376	7600 Extra Small , AAV, 22mm ID Elbow, No HG	
113377	7600 Petite , AAV, 22mm ID Elbow, No HG	
		Accessories
		691141 Mask Sizing Caliper for 7600/7500 Full Face Masks & 7800 Nasal Masks
		Sensa Seal™ - optional silicone rubber sealing flange Accessory
		669160 Large Sensa Seal™
		669161 Medium Sensa Seal™
		669162 Small Sensa Seal™
		669163 Extra Small Sensa Seal™
		669164 Petite Sensa Seal™
		(For User Instructions refer to doc # 691247.)
		Metro Seal™ - NG Tube & Catheter Seal
		201478 Box of 20 Metro Seals™ (five trays individually poly bagged with four Metro Seals™ per tray).
		(For User Instructions refer to doc # 691246.)

21. Safety Information

Safety or technical information regarding Hans Rudolph mask assemblies can be obtained from Hans Rudolph, inc., phone 816-363-5522, USA & Canada 800-456-6695, fax 816-822-1414, email: hri@rudolphkc.com or by contacting your Hans Rudolph representative.

22. References

1. "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance", Rockville, MD, FDA Center for Devices and Radiological Health, Office of Device Evaluation. April 1996.
2. Association for the Advancement of Medical Instrumentation. "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers". AAMI TIR NO. 12-1994 Arlington (Vir.) AAMT, 1194c. AAMI Technical Information Report.
3. Association for the Advancement of Medical Instrumentation. "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Noncritical Settings", ANSI/AAMI 5T35-1196, Arlington (Vir.) AAMI. 1996 American National Standards.
4. Centers for Disease Control. "Guidelines for Handwashing and Hospital Environmental Control". Section 2: "Cleaning, Disinfecting, and Sterilizing Patient Care Equipment". Atlanta, CDC, 1985.
5. Centers for Disease Control. "Guidelines for Prevention of Nosocomial Pneumonia". Infection Control and Hospital Epidemiology 1194; 15:587-627.
6. Rutala, WA. APIC "Guidelines for Selection and Use of Disinfectants". American J. INFEC. Control, 1190. Vol. 18 No. 2. PP 99-117.

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.