



MAKERS OF RESPIRATORY VALVES SINCE 1938
HANS RUDOLPH, inc.

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Intended Use - Environment for Use:

The 7450 series face mask is a reusable, multi-patient, multi-use mask intended for use with two-way non-rebreathing valves or other mask adapters for connection with flow measuring instruments used in lung function testing procedures with spontaneous breathing adults (>30 kg) in hospitals and other clinical settings by individuals that have at least minimal training or instructions on the use of the mask as well as the devices to which the mask is intended to connect. Applications are for pulmonary function testing, exercise testing and respiratory research. The masks, valves, adapters and headgear are supplied clean, non-sterile.

Service Life:

Mask, mask adapter and headgear when maintained and reprocessed per these instructions are expected to stay in service for minimum of 25 disinfection or steam sterilization cycles and the headgear 25 cleaning cycles. Visual inspection of the components during reprocessing will identify any defects. If defects are identified dispose of and do not use.

Operational Temperature and Humidity Ranges for the Mask:

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

Cautions:

Federal law restricts this device to sale by or on the order of a physician

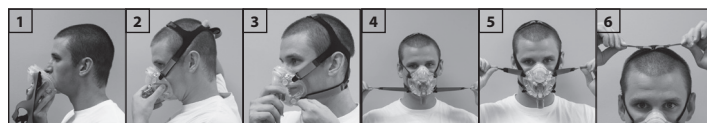
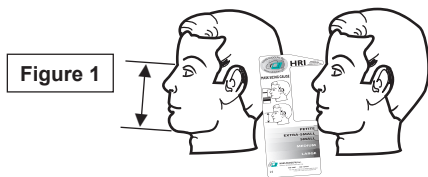
Warnings:

1. Shipped clean, non-sterile. If disinfected or sterile use is required, follow the procedures in this document prior to use of the mask.
2. To avoid skin irritation, never use any cleaning solutions or chemicals on this mask or headgear other than a mild detergent and water. Discontinue use if irritation or allergic reaction develops due to the mask.
3. Patients with facial hair may experience leakage
4. Do not use these masks, valves and or adapters in a life support system such as a ventilator circuit.

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

Application & Fitting:

1. Determine patient mask size with optional Mask Sizing Gauge (fig1)
2. Place mask over patient's nose and mouth (1). Chin should fit into mask chin cup portion with top of mask sealing area on the bridge of the nose.
3. Slide headgear over patient's head (2) with one of the lower quick release strap clips disconnected. Reconnect headgear strap clip after headgear is mounted (3). Bottom straps should be positioned below ears and top straps above ears and below eyes.
4. Adjust headgear strap tension by pulling slightly away from the face on strap end hook sections until tension is evenly distributed at all four straps with mask snug but comfortable (4 & 5). The strap clips lock and hold the position of the strap. To loosen the straps pull up on the back of the clip. Attach hook ends to the headgear fabric to keep the ends attached and out of the way. Adjust straps at crown of head by pulling each in opposite direction until reaching the required tension then connect Velcro™ (6).
5. Push the flow meter patient side into the port opening in the flexible mask adapter

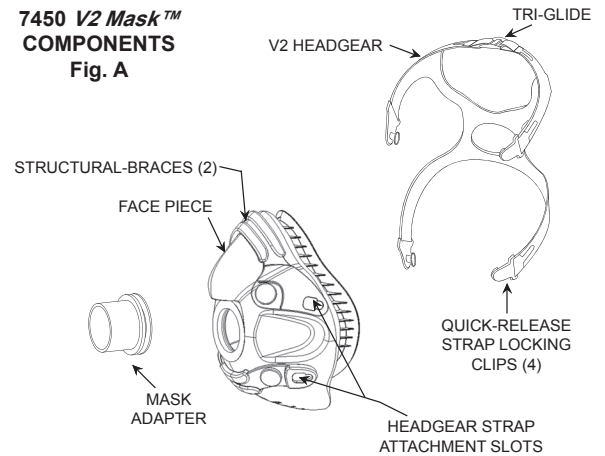


Data Sheet & Instructions for Use...

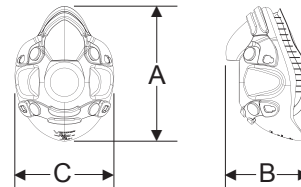
7450 Series V2 Mask™
ORO-NASAL REUSABLE
Face Mask, Mask Adapter and Headgear
 for use with Vyair Medical Flow Meters
Vmax MFS, Oxycon/Masterscreen DVT
& Vyntus DVT

Large, Medium, Small, Extra Small, Petite

7450 V2 Mask™
COMPONENTS
 Fig. A



Characteristic	Mask face Piece Sizes				
	Large (L)	Medium (M)	Small (S)	Extra Small (XS)	Petite (P)
A (inches)	5.9	5.6	5.2	4.8	4.6
B (inches)	3.7	3.4	3.2	3.1	3.0
C (inches)	4.2	4.2	4.0	3.9	3.9
Deadspace (ml)	143	125	99	88	78
Weight (gm)	128	118	100	89	83



MATERIALS (See Fig. A)	
Face Piece with Structural Braces	Silicone Rubber Blue, Polycarbonate Thermoplastic
Headgear	Polyurethane Foam Black, Nylon UBL Gray and Nylon Fabric Red
Headgear Strap Clips (4), Tri-glide	Polypropylene, Black
Vyair Medical Mask Adapter	Silicone Rubber

Safety Information

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

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Disassembly for Cleaning

1. Separate headgear from mask
2. Separate mask adapter from mask
3. Do not remove the upper and lower plastic braces (headgear attachment) from the mask face piece

Cleaning Mask face piece and Mask Adapter

1. Soak components for 5 minutes in warm water with mild detergent (neutral pH)
2. Hand wash components with sponge or soft brush; then rinse with warm tap water
3. Place components in warm water bath and agitate for two minutes
4. Rinse in clean tap water for at least 1 minute
5. Allow components to completely air dry or dry with clean, lint free cloth

Cleaning Headgear

1. Submerge headgear in warm soapy tap water; gently rub all areas
2. Rinse in clean tap water for 1 minute or until all soap is removed; air dry
3. Precaution: Do not use bleach, chlorine or alcohol based solutions to clean mask or headgear. These solutions can damage components. Direct sunlight exposure on mask and headgear components can cause deterioration and reduce product life.

High Level Disinfection (Mask & Mask Adapter only)

1. Thoroughly clean and dry the mask and mask adapter prior to disinfection or sterilization
2. For high level disinfection use liquid glutaraldehydes (Cidex™) or hot water pasteurization.
3. Do not use any alcohol or chlorine based solutions.

Liquid Chemical Disinfection

1. Soak the device components in the liquid chemical solution per the manufacturer's instructions.
2. Remove the components and soak in 1500 ml of water (preferably sterile) for a minimum of 1 minute.
3. Repeat step 2 and then dry the device with a clean lint free cloth (preferably sterile)

Hot Water Pasteurization

1. Immerse all device components surfaces in hot water temperatures 71.1° C – 76.6° C for 30 minutes.
2. Dry the components with a clean lint free cloth (preferably sterile)

Steam Sterilization (Silicone Rubber Face Mask & Silicone Rubber Mask Adapter less Headgear)

1. Thoroughly clean and dry the mask and mask adapter prior to disinfection or sterilization.
2. Mask and mask adapter should be assembled

Steam Sterilization Pre-Vacuum Cycle

1. Temperature: 132° C
2. Sterilization Time: 4 minutes
3. Dry Time: 10 minutes
4. Type of Load: Wrapped method

Steam Sterilization Gravity Displacement Cycle

1. Temperature: 132° C
2. Sterilization Time: 30 minutes
3. Dry Time: 10 minutes
4. Type of Load: Wrapped method

Inspection

Visually inspect all components for cleanliness, function and defects. If there are any residues, stains or organic debris then repeat the previous steps. Dispose of all defective parts.

Reassemble

1. Install flexible mask adapter into face mask port opening with the mask adapter flanges placed on the inside and outside of the mask port opening. This may require some stretching and pulling to completely install the mask adapter such that the flanges are fully engaged and not disfigured.
2. Mount headgear to the face piece with the snap-in quick release clips.

Functional Check

1. Mask adapter flanges should be stretched to fit snug without disfiguration on either side of the mask port opening. Do not use if the mask adapter is not completely engaged in the mask port opening.
2. For function test hold palm of hand over the outlet of the mask adapter and create a slight positive pressure inside the mask by exhaling gently. If you detect a leak, reposition the mask or adjust straps tension. If leak continues regardless of adjustments try the next smaller size mask.
3. Push the patient port side of the flow meter into the flexible mask adapter. It should fit snug and not fall out without significant pulling.
4. Do not use if it is non-functional

Storage

1. Components should be completely dry prior to storage in a sealed poly bag.
2. Label the poly bag with disinfection/clean status, mask description, date and initials

Disposal

Treat as conventional solid waste in accordance with local and federal regulations

Credits

Velcro™ is a Trademark of Velcro USA
Cidex™ is a Trademark of Johnson & Johnson Co.

Ordering Information

7450 Series Face Mask, Mask Adapter and Headgear Assembly	
Order REF.	Description
113812	Large (L)
113813	Medium (M)
113814	Small (S)
113815	Extra Small (XS)
113816	Petite (P)

Replacement Parts

7450 Face Piece Only	
Order REF.	Description
669195	Large (L)
669196	Medium (M)
669197	Small (S)
669198	Extra Small (XS)
669199	Petite (P)

7450 Headgear Only (Strap Locking Clips)	
Order REF.	Description
201494A	Large (L) ref L Mask
201493A	Medium (M) ref M & S Mask
201492A	Small (S) ref XS & P Mask

Replacement Parts

Mask Adapter Flexible type mates Vyaire Medical Flow Meters	
Order REF.	Description
602048	Mask Adapter Flexible (CF)

Brace Set (Top & Bottom 2 pc) for 7450 Face Pieces	
Order REF.	Description
201607	Large (L)
201608	Medium (M)
201603	Small (S)
201609	Extra Small (XS)
201610	Petite (P)

Mask Sizing Gauge	
Order REF.	Description
691143	Mask Sizing Gauge V2 Masks