



MAKERS OF RESPIRATORY VALVES SINCE 1938

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Data Sheet & Instructions for Use...

6450 Series V2 Mask™ ORO-NASAL SINGLE PATIENT USE Face Mask and Headgear for Custom Adapter & Valve Applications

Large, Medium, Small, Extra Small, Petite

Intended Use - Environment for Use:

The 6450 series face mask is a single patient 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.

Mask and Headgear Service Life:

Mask and headgear assembly may be cleaned and re-used on a single-patient basis for several test sessions as long as the fit continues to be leak free and comfortable.

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:

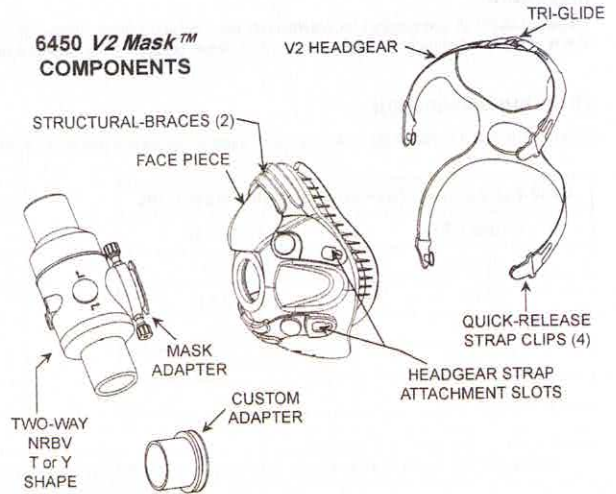
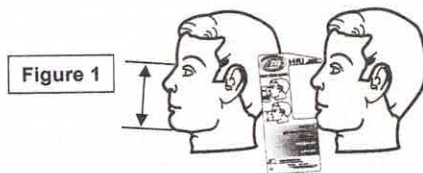
1. Shipped clean, non-sterile.
2. To avoid skin irritation, never use any cleaning solutions or chemicals on this mask or headgear other than a mild detergent and water. Discontinue use if irritation or allergic reaction develops due to the mask.
3. Patients with facial hair may experience leakage
4. 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

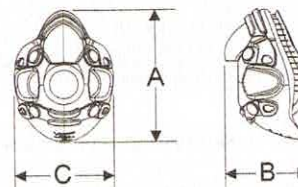
Mask	L	M	S	XS	P
Headgear	L	M	M	S	S

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



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)	106	96	84	74	70



Safety Information

Safety or technical information regarding this product can be obtained from Hans Rudolph, inc.
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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.

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.

Ordering Information

Enquire with Hans Rudolph for Two-Way Non-Rebreathing Valves and other mask adapters for use with this mask series.

6450 Series Face Mask and Headgear Assembly	
Order REF.	Description
201575	Large (L)
201576	Medium (M)
201577	Small (S)
201578	Extra Small (XS)
201579	Petite (P)

6450 Series Face Mask, Mask Adapter to MGC Prevent® Flow Sensor and Headgear Assembly		
Order REF.	Description	
113871	Large (L)	
113872	Medium (M)	
113873	Small (S)	
113874	Extra Small (XS)	
113875	Petite (P)	

6450 Series Face Mask, Mask Adapter to Vyair Flow Sensors and Headgear Assembly	
Order REF.	Description
113820	Large (L)
113821	Medium (M)
112822	Small (S)
112823	Extra Small (XS)
112824	Petite (P)

Custom Mask Adapters MATE all sizes of the 6450 V2™ Series Face Masks

(Flexible types are molded of Silicone Rubber others are machined from Polycarbonate Plastic)

Ordering Part Number	Device Description that Custom Adapter MATES TO: (for direct connection to face mask)
602048	Adapter, Flexible Type, CAREFUSION VmaxMFS, Oxycon/Masterscreen DVT & Vyntus DVT Flow Sensor
602068	Adapter, Flexible Type, MEDICAL GRAPHICS Corp Prevent™ Flow Sensor
201519	Adapter to SCHILLER Flow Sensor (includes female luer sample port)

Please contact HRI for Order Numbers and Prices for other custom adapters to HRI face masks or to specify a custom adapter for your device.

6450 V2™ Series Face Mask Adapters to connect to 2700 or 2730 Non-Rebreathing Valves (NRBV) or Rudolph Linear PNTs

(ID O-ring SSF (slip-sealing fit) or Medical Taper create a firm but rotational leak-free fit to the mating PNT or other device)

Ordering Part Number	Device Description that Adapter MATES TO: (polycarbonate material for direct connection to face mask)
200583	Adapter to 2700 or 2730 Two-Way NRBV & 6450 V2™ Series Face Mask (includes 2 female luer sample ports)
612738	Adapter to 2700 or 2730 Two-Way NRBV & 6450 V2™ Series Face Mask (no sample ports)
CC1748	Adapter with 35mm ID O-ring SSF, will mate with 3813 or 3830C PNT (includes 2 female luer sample ports)
CC1265	Adapter with 35mm ID O-ring SSF, will mate with 3813 or 3830C PNT (no sample ports)
CC1734	Adapter with 28.6mm ID O-ring SSF, will mate with 3830A PNT (includes 2 female luer sample ports)
CC1267	Adapter with 28.6mm ID O-ring SSF, will mate with 3830A PNT (no sample ports)
201144	Adapter with 22mm ID Medical Taper, will mate with 3700 or 3500 PNT (includes 2 female luer sample ports)
612462	Adapter with 22mm ID Medical Taper, will mate with 3700 or 3500 PNT (no sample ports)

Please contact HRI for Order Numbers and Prices for other 2-Way NRBV adapters to HRI face masks or to specify a different material or custom adapter.

Replacement Parts

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

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

Disposal

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

Credits

Velcro™ is a Trademark of Velcro USA