



MAKERS OF RESPIRATORY VALVES SINCE 1938  
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# Data Sheet & Instructions for Use...

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

Large, Medium, Small, Extra Small, Petite

### 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

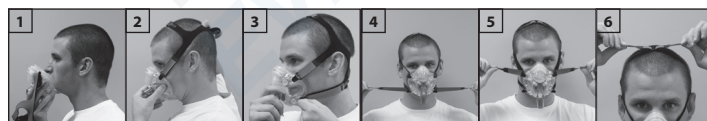
### Warnings:

- Shipped clean, non-sterile. If disinfected or sterile use is required, follow the procedures in this document prior to use of the mask.
- 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.
- Patients with facial hair may experience leakage
- Do not use these masks, valves and or adapters in a life support system such as a ventilator circuit.

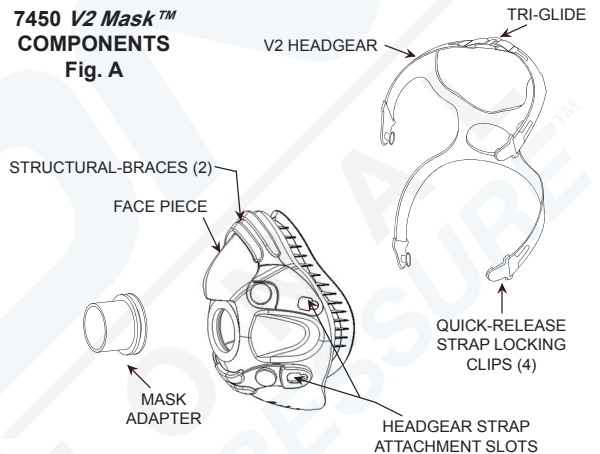
| Recommended Headgear Sizes for each Mask Size |   |   |   |    |   |
|---|---|---|---|----|---|
| Mask  | L | M | S | XS | P |
| Headgear                                      | L | M | M | S  | S |

### Application & Fitting:

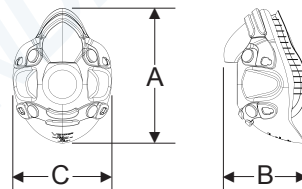
- Determine patient mask size with optional Mask Sizing Gauge (fig1)
- Place mask over patient's nose and mouth (1). Chin should fit into mask chin cup portion with top of mask sealing area on the bridge of the nose.
- Slide headgear over patient's head (2) with one of the lower quick release strap clips 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.
- 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).
- Push the flow meter patient side into the port opening in the flexible mask adapter



### 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   |
| CAREFUSION 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

EC REP **M.Devices Group**  
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 Riding Street  
 Southport PR8 1EW, UK  
 P: 44 1704 544 944  
 F: 44 1704 544 050

## 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 CareFusion 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 |