



MAKERS OF RESPIRATORY VALVES SINCE 1938

HANS RUDOLPH, inc.

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Data Sheet...

7600 Series V2 Mask™ ORO-NASAL CPAP/BiLevel REUSABLE with AAV & Vents

Large, Medium, Small, Extra Small, Petite

PRODUCT FEATURES

- Five Sizes to cover a wide range of patient sizes.
- Face Piece with new Facial Sealing Flange is a single piece mask, made of clear soft Silicone Rubber.
- Anatomically Contoured Face Mask Design with ribbed support for a leak free comfortable fit.
- Anti-Asphyxia Valve (AAV) for patient safety - allows patient to breathe room air if the flow device malfunctions. Valve opens at mask pressures less than 3cm H₂O.
- Swivel Port Micro Vent Holes dissipate CO₂.
- 360° Dual Swivel Elbow Port with Detachable Swivel Port for improved patient freedom of movement. Color coded translucent blue.
- Easily adjustable, light weight, 4 strap Headgear for patient comfort, available in three sizes.
- New Quick-Release Strap Clips for quick & simple mounting & dismounting of headgear.
- Lightweight, easy to use, high quality mask & headgear.
- Reusable masks; steam autoclaveable, cold chemical, pasteurization safe & dishwasher safe.

SPECIFICATIONS

MATERIALS (See Fig. A)	
Face Piece with Structural Braces	Silicone Rubber, Polycarbonate Thermoplastic
Swivel Port - Mask Adapter, Elbow, 22mm Port	Polycarbonate Thermoplastic, Translucent Blue
Swivel Port - AAV Port	Polycarbonate Thermoplastic Translucent
Diaphragm	Silicone Rubber
Headgear	Polyurethane Foam, Nylon UBL and Elastane Fabric, Black
Headgear Hook	Nylon, Black
Headgear Strap Clips (4)	Polypropylene, Black

GENERAL INFORMATION

Intended Use: The Hans Rudolph 7600 V2 Mask™ series are reusable, multi-patient use, adult Oro-Nasal CPAP/BiLevel mask which incorporates passive, continuous flow exhaust ports built into the mask. It is intended for use with certain CPAP/BiLevel 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 cmH₂O pressure measured at the mask.

Indications for Use: The V2 Mask™ are for use on adult patients (greater than 30 kilograms weight) for treatment of Obstructive Sleep Apnea or any other conditions requiring CPAP/BiLevel or non-invasive ventilatory support at pressures greater than or equal to 3.0 cmH₂O at the mask in homes, hospitals and other clinical settings.

Environment of Use: The V2 Masks™ are for use in homes, hospitals and other clinical settings by individuals that have at least minimal instructions or training on the use of the mask as well as the device to which the mask are intended to connect.

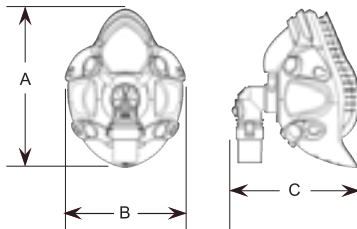
Cautions:

- Federal law restricts this device to sale by or on the order of a physician.
- At low CPAP/BiLevel pressures the flow through the mask vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Patients with facial hair, especially beards, may experience mask leakage which may require shaving the hair.

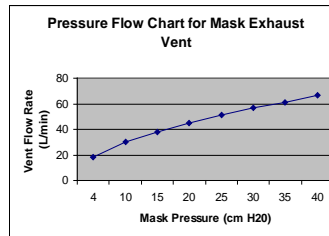
Warnings: Refer to: Instructions for Use, Document No. 691270, shipped with product.

Contraindications & Complications: Refer to: Instructions for Use, Document No. 691270, shipped with product.

PHYSICAL CHARACTERISTICS Face Mask Dimensions



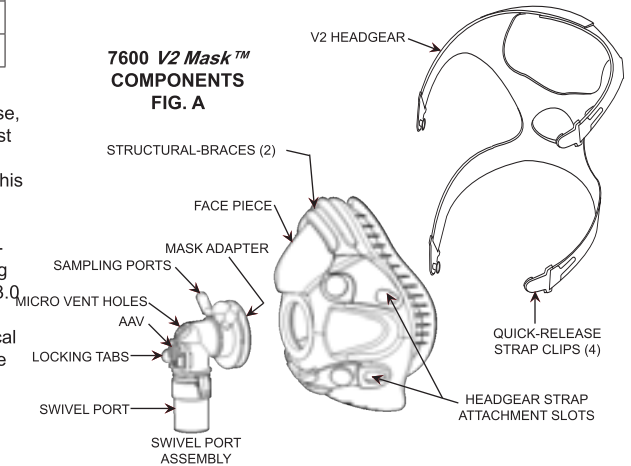
Mask DeadSpace Volume (ml) Measured up to vent in Swivel Port				
Large 154	Medium 136	Small 110	Extra Small 99	Petite 89



MASK SIZE WITH OVERALL DIMENSIONS - inches (mm)					
	LARGE	MEDIUM	SMALL	EXTRA SMALL	PETITE
A	5.9 (150)	5.5 (140)	5.2 (132)	4.8 (122)	4.6 (117)
B	4.2 (107)	4.16 (105)	4.05 (103)	3.95 (100)	3.9 (99)
C	4.7 (119)	4.46 (113)	4.32 (110)	4.2 (107)	4.04 (103)



Oro-Nasal CPAP/BiLevel V2 Mask™
with Headgear



7600 V2 Mask™
COMPONENTS
FIG. A



MASK SIZING GAUGE

MASK SIZING GAUGE

For Hans Rudolph, Inc. Oro-Nasal V2mask™ and V2mask™ Series Face Masks. Distances (length measurements) are used to determine the size of the Hans Rudolph Oro-Nasal mask that will best fit the patient. For measurement, the patient's facial features should be relaxed and are moist. Place the Gauge to the bridge point of the nose and depress it down and over the indication at the bottom tip of the chin. The blue band width indicates the size range. This gauge is reference tool in sizing and not an exact measurement as other factors may need to be taken into account.

If between sizes, we recommend you use the smaller size.

PETITE
EXTRA-SMALL
SMALL
MEDIUM
LARGE

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ISO 9001 ISO 13485
18101-2015/2016 ISO 13485:2016
18101-2015/2016 ISO 13485:2016
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• Specifications subject to change without notice •

ORDERING INFORMATION - 7600 Series Reusable V2 Oro-Nasal Mask with Elbow Swivel Port 22mm OD Vented with Anti-Asphyxia Valve (AAV) & Headgear (HG)

P/N Description

Mask, AAV Valve, Vented 22mm OD Elbow with HG	
113485	7600 Large
113486	7600 Medium
113487	7600 Small
113488	7600 Extra Small
113489	7600 Petite

Mask, AAV Valve, Vented 22mm OD Elbow LESS HG	
113570	7600 Large
113571	7600 Medium
113572	7600 Small
113573	7600 Extra Small
113574	7600 Petite

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
201523	Swivel Port, Vented, AAV, 22mm OD
201555	HG Strap Clips package of four
201521	AAV Port assembly

Accessories	
691143	Mask Sizing Gauge for V2 Oro-Nasal Masks
669353	METRO™ NG Tube Seal Disposable Package of 1