

MAKERS OF RESPIRATORY VALVES SINCE 1938

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Data Sheet...

6600 Series V2 Mask™
ORO-NASAL CPAP/BiLevel DISPOSABLE
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 Thermoplastic Elastomer.
- **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.
- **Low Cost. Disposable mask.**

SPECIFICATIONS

MATERIALS (See Fig. A)	
Face Piece with Structural Braces	Thermoplastic Elastomer, 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 Black, Nylon UBL Black and Blue
Headgear Hook	Nylon, Black
Headgear Strap Clips (4), Tri-glide	Polypropylene, Black



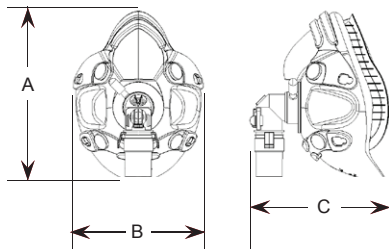
**Oro-Nasal CPAP/BiLevel V2 Mask™
with Headgear**

GENERAL INFORMATION

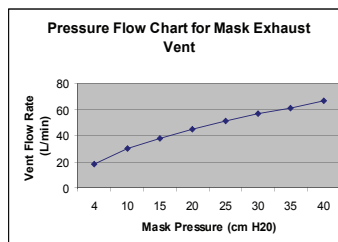
- **Intended Use:** The Hans Rudolph 6600 *V2 Mask™* series are disposable, single-patient use, adult Oro-Nasal CPAP/BiLevel mask which incorporates passive, continuous flow exhaust ports built into the mask. It is intended for use with certain CPAP/BiLevel machines for treatment of obstructive sleep 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 hospitals and other clinical settings.
- **Environment of Use:** The *V2 Masks™* are for use in 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:**
 - a.) Federal law restricts this device to sale by or on the order of a physician.
 - b.) 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.
 - c.) Patients with facial hair, especially beards, may experience mask leakage which may require shaving the hair.
- **Warnings:** Refer to: Instructions for Use, Document No. 691273, shipped with product.
- **Contraindications & Complications:** Refer to: Instructions for Use, Document No. 691273, shipped with product.

PHYSICAL CHARACTERISTICS

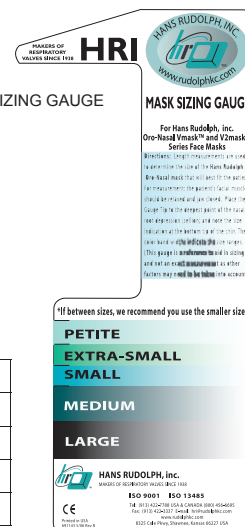
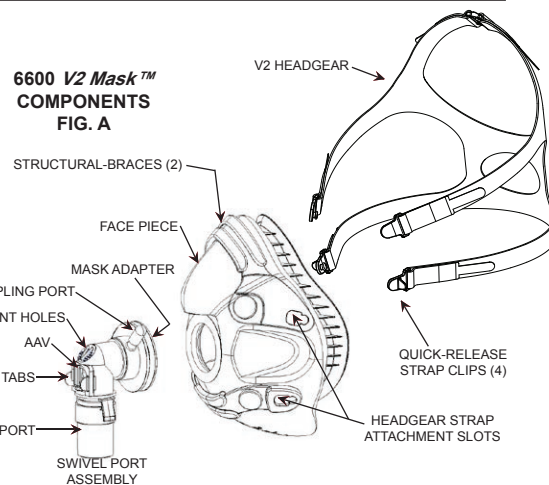
Face Mask Dimensions



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)



ORDERING INFORMATION - 6600 Series Disposable V2 Oro-Nasal Mask with Elbow Swivel Port 22mm OD Vented with Anti-Asphyxia Valve (AAV) & Headgear (HG)

P/N	Description
18 Mask Pack	Mask, AAV Valve, Vented 22mm OD Elbow & HG
114601	6600 Large
114602	6600 Medium
114603	6600 Small
114604	6600 Extra Small
114605	6600 Petite

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