



MAKERS OF RESPIRATORY VALVES SINCE 1938

HANS RUDOLPH, inc.

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Data Sheet...

6500 Series V2 Mask™
ORO-NASAL NIV DISPOSABLE
No AAV - No 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.
- **Elbow shaped or Straight Swivel Ports** in both 22mm outside diameter or 22mm inside diameter allow for improved patient freedom of movement. Color coded translucent green.
- **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 Green
Headgear	Polyurethane Foam Black, Nylon UBL Black and Blue
Headgear Hook	Nylon, Black
Headgear Strap Clips (4), Tri-glide	Polypropylene, Black

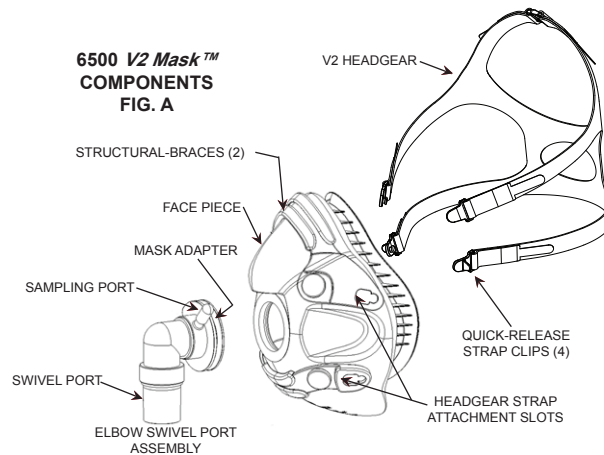


Oro-Nasal NIV V2 Mask™ with Headgear
 Elbow and Straight Type Swivel Port Shown

GENERAL INFORMATION

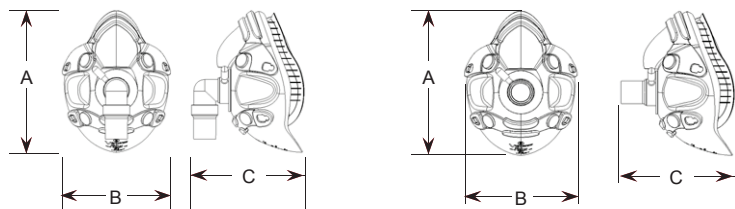
- **Intended Use:** The 6500 Series V2 Masks™ are disposable, single-patient-use, adult oro-nasal masks intended to provide a patient interface for application of noninvasive ventilation. The masks are to be used as an accessory to continuous ventilators which have adequate alarms and safety systems for ventilator failure.
- **Indications for Use & Environment:** The masks are specifically indicated for use on adult patients (greater than 30 kilograms weight) to administer positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency. They are intended for use on patients who are appropriate candidates for noninvasive ventilation, in the hospital, or other clinical settings by individuals that have received at least minimal instruction or training on the use of the masks as well as the device and system to which the masks are intended to connect.
- **Cautions:**
 - a.) Federal law restricts this device to sale by or on the order of a physician.
 - b.) Patients with facial hair, especially beards, may experience mask leakage which may require shaving the hair.
- **Warnings:** Refer to: Instructions for Use, Document No. 691274, shipped with product.
- **Contraindications & Complications:** Refer to: Instructions for Use, Document No. 691274, shipped with product.

6500 V2 Mask™ COMPONENTS FIG. A

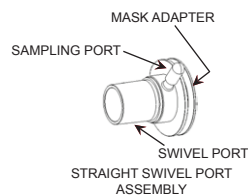


PHYSICAL CHARACTERISTICS

Face Mask Dimensions



MASK SIZE WITH OVERALL DIMENSIONS - inches (mm)						
	Elbow Swivel Port			Straight Swivel Port		
	A	B	C	A	B	C
Large	5.9 (150)	4.2 (107)	4.71 (120)	5.9 (150)	4.2 (107)	4.53 (115)
Medium	5.5 (140)	4.16 (105)	4.46 (113)	5.5 (140)	4.16 (105)	4.28 (109)
Small	5.2 (132)	4.05 (103)	4.31 (109)	5.2 (132)	4.05 (103)	4.12 (105)
X-Small	4.8 (122)	3.95 (100)	4.21 (107)	4.8 (122)	3.95 (100)	4.04 (103)
Petite	4.6 (117)	3.9 (99)	4.05 (103)	4.6 (117)	3.9 (99)	3.92 (100)



MASK SIZING GAUGE

MASK SIZING GAUGE

For Hans Rudolph, inc. Oro-Nasal Vmask™ and V2mask™ Series Face Masks. Dimensions: Length measurements are used to determine the size of the Hans Rudolph Oro-Nasal mask that will best fit the patient. For measurements the patient's facial features should be relaxed and not stretched. Measure the Gauge Tip in the deepest part of the nasal root. Angulate 30° and use the dimension in the bottom of the circle. The color band will indicate the size range. (This gauge is a reference to aid in sizing and not an exact measurement in other facilities may need to be taken before use.)

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

PETITE
EXTRA-SMALL
SMALL
MEDIUM
LARGE

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Mask Deadspace Volume (ml) With 22mm ID Elbow Swivel Port				
Large 169	Medium 151	Small 125	Extra Small 114	Petite 104

Commonly Ordered Items

Elbow Style Swivel Ports

P/N Description

18 Mask Pack	Mask, No AAV, Non-Vented 22mm ID Elbow Type & HG
114501	6500 Large
114502	6500 Medium
114503	6500 Small
114504	6500 Extra Small
114505	6500 Petite

Accessories

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

Other Ordering Options Available But Uncommon

Elbow Style Swivel Ports

P/N Description

18 Mask Pack	Mask, No AAV, Non-Vented 22mm OD Elbow Type & HG
114506	6500 Large
114507	6500 Medium
114508	6500 Small
114509	6500 Extra Small
114510	6500 Petite

Straight Style Swivel Ports

P/N Description

18 Mask Pack	Mask, No AAV, Non-Vented 22mm ID Straight Type & HG
114511	6500 Large
114512	6500 Medium
114513	6500 Small
114514	6500 Extra Small
114515	6500 Petite

18 Mask Pack	Mask, No AAV, Non-Vented 22mm OD Straight Type & HG
114516	6500 Large
114517	6500 Medium
114518	6500 Small
114519	6500 Extra Small
114520	6500 Petite