



MAKERS OF RESPIRATORY VALVES SINCE 1938

HANS RUDOLPH, inc.

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Data Sheet...

6500 Series V2 Mask™ ORO-NASAL NIV - No AAV - No Vents SINGLE PATIENT USE

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



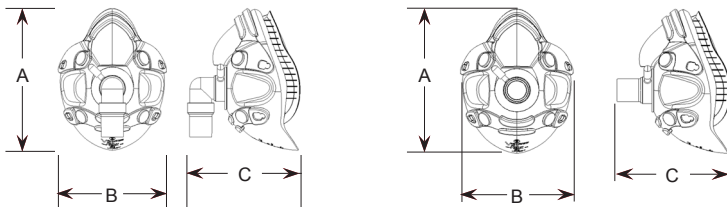
Oro-Nasal NIV V2 Mask™ with Headgear
Elbow and Straight Type Swivel Port Shown

GENERAL INFORMATION

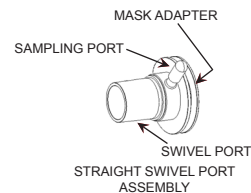
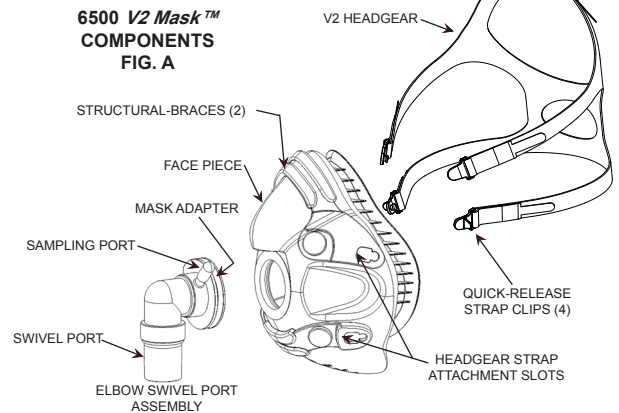
- **Intended Use:** The 6500 Series V2 Masks™ are disposable, single-patient-use, adult oro-nasal masks intended to provide a patient interface for application of noninvasive ventilation. The masks are to be used as an accessory to continuous ventilators which have adequate alarms and safety systems 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.

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

Directions: 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 structure should be relaxed and jaw closed. Place the Gauge to the deepest point of the nasal root depression (indicated and note the size indicator where the bottom of the eye sets the gauge). The gray band within indicates the size range.

This gauge is a reference to, not a device and not intended for measurement of other features. Use only for mask fit assessment.

IF BETWEEN SIZES, WE RECOMMEND YOU USE THE SMALLER SIZE.

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- PETITE (P)
- EXTRA-SMALL (XS)
- SMALL (S)
- MEDIUM (M)
- LARGE (L)

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



Commonly Ordered Items

Elbow Style Swivel Ports

P/N	Mask, No AAV, Non-Vented 22mm ID Elbow Type & HG
113530	6500 Large
113531	6500 Medium
113532	6500 Small
113533	6500 Extra Small
113534	6500 Petite
MINIMUM ORDER REQUIRES 18 EACH OF ONE P/N	

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	Mask, No AAV, Non-Vented 22mm OD Elbow Type & HG
113525	6500 Large
113526	6500 Medium
113527	6500 Small
113528	6500 Extra Small
113529	6500 Petite

MINIMUM ORDER REQUIRES 18 EACH OF ONE P/N

Straight Style Swivel Ports

P/N	Mask, No AAV, Non-Vented 22mm ID Straight Type & HG
113540	6500 Large
113541	6500 Medium
113542	6500 Small
113543	6500 Extra Small
113544	6500 Petite

P/N	Mask, No AAV, Non-Vented 22mm OD Straight Type & HG
113535	6500 Large
113536	6500 Medium
113537	6500 Small
113538	6500 Extra Small
113539	6500 Petite

