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Data Sheet ...

7600 Series *V2 Mask™*ORO-NASAL <u>CPAP/BiLevel</u> 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, pastuerization safe & dishwasher safe.

SPECIFICATIONS

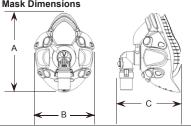
| MATERIALS (See Fig. A) | | |
|--|--|--|
| Face Piece with Structural Braces | Silicone Rubber, Polycarbonate Thermoplastic | |
| Swivel Port - Mask Adapter, Elbow, 22mm Port | Polycarbonate Thermoplastic, Translucent Blue | |
| Swivel Port - AAV Port | Polycarbonate Thermoplastic Translucent | |
|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

GENERAL INFORMATION

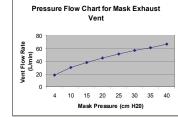
- Intended Use: The Hans Rudolph 7600 V2 Mask™ series are reusable, multi-patient use, adult Oro-Nasal CPAPBiLevel mask which incorporates passive, continuous flow exhaust ports built into the mask. It is intended for use with certain CPAP/BiLevel machines for treatment of obstructive sleep apnea, and 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 SAMPLING CPAP/BiLevel or non-invasive ventilatory support at pressures greater than or equal to 3.0 CMH2O at the mask in homes, Nospitals and other clinical settings.

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

PHYSICAL CHARACTERISTICS Face Mask Dimensions



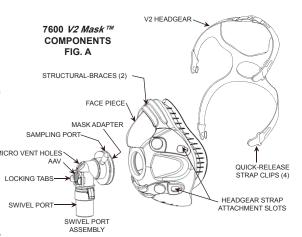
| Mask Deadspace Volume (ml) Measured up to vent in Swivel Port | | | | I |
|--|--------|-------|-------------|--------|
| Large | Medium | Small | Extra Small | Petite |
| 154 | 136 | 110 | 99 | 89 |

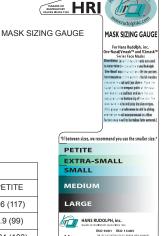


| | MASK SIZE WITH OVERALL DIMENSIONS - inches (mm) | | | | | |
|---|---|-----------|------------|------------|-------------|------------|
| 1 | | LARGE | MEDIUM | SMALL | EXTRA SMALL | PETITE |
| | Α | 5.9 (150) | 5.5 (140) | 5.2 (132) | 4.8 (122) | 4.6 (117) |
| | В | 4.2 (107) | 4.16 (105) | 4.05 (103) | 3.95 (100) | 3.9 (99) |
| | С | 4.7 (119) | 4.46 (113) | 4.32 (110) | 4.2 (107) | 4.04 (103) |



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





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 |
| 211022 | Cap Plugs for sampling port package of two |

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