

MAKERS OF RESPIRATORY VALVES SINCE 1938 HANS RUDOLPH, inc. www.rudolphkc.com

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PRODUCT FEATURES

- Five Sizes to cover a wide range of patient sizes. Face Piece with new Facial Sealing Flange is a single piece mask, marle 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 & dismounling of headgear. Lightweight, easy to use, high quality mask & headgear.

SPECIFICATIONS

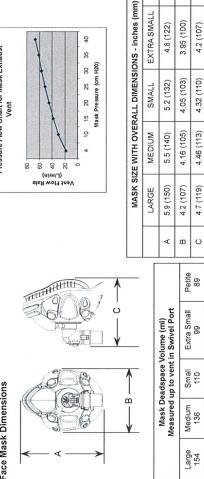
MATERI	MATERIALS (See Fig. A)
Face Piece with Structural Braces	Thermoplastic Elastomer, Polycarbona (3 Thermoplastic
Swivel Port - Mask Adapter, Elbow, 22mm Port Polycarbonate Thermoplastic, Translucient Blue	Polycarbonate Thermoplastic, Translucent Blue
Swivel Port - AAV Port	Polycarbonate Thermoplastic Translucent
Diaphragm	Silicone Rubber
Headgear	Polyurethane Foam Black, Nylon UBL and Fabric Gray
Headgear Hook	Nylon, Black
Headgear Strap Clips (4), Tri-glide	Polypropylene, Black

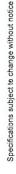
GENERAL INFORMATION

- Intended Use: The Hans Rudolph 6860 *Quest^{Tim} Mask*series are single patient use, adult Oro-Nasal CPAF/BiLevel mask which incorporates passive, continuous flow exhaust ports built into the mask. It is intended for use with 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 *Quest™ 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 requiring CPAP/BiLevel or non-invasive ventilatory support at pressures greater than or equal to 3.0 cmH2O at the mask in the home care setting only. Environment of Use: The *Quest™ Mask* are for use in the home care setting by individu-als 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.
- a.)
- 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. 691284, shipped with product. Contraindications & Complications: Refer to: Instructions for Use, Document No.
 - 691284, shipped with product

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PHYSICAL CHARACTERISTICS Face Mask Dimensions





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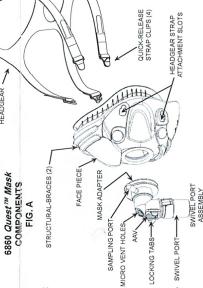


ORO-NASAL CPAP/BiLevel with AAV &Vents Large, Medium, Small, Extra Small, Petite Home Care Setting Only Single Patient Use



with Headgear

HEADGEAR





Pressure Flow Chart for Mask Exhaust Vent

8 8 9 8 Vent Flow Rate (L/min)



PETITE 4.6 (117)

EXTRA SMALL

SMALL 5.2 (132)

MEDIUM

9

35 H20) 8

15 20 25 3 Mask Pressure (cm H

0

US Pat No's D573,709 & 8,136,523 and EC Req d Design No. 000786556-0001 $C \in C = 0001 / 1500 = 0010 / 1000 = 0001 / 1000 = 0000 / 1000 / 1000 = 0000 / 1000$

4.04 (103) 3.9 (99)

4.2 (107)

4.46 (113)

3.95 (100) 4.8 (122)

> 4.05 (103) 4.32 (110)

4.16 (105) 5.5 (140)