The Rudolph Mouth Breathing Face Mask is primarily designed for Stress/Exercise Testing, Metabolic Measurements, and Pulmonary Function Studies. This is a mouth breathing only mask where the nose chamber of the mask does not communicate in the breathing circuit.

The lower rebreathing volume dead space improves the analytical quality of the breath by breath measurement. This lower dead space is created by dividing the mask cavity into a separately sealed nose chamber. This nose chamber being sealed, is not a part of the rebreathing volume dead space of the mask. The nose chamber is separated from the mouth chamber by a partition, which engages the subjects face and forms a seal between the upper lip and the nose. This design technique of eliminating the nose chamber volume from the mask rebreathing volume is one of the most significant advantages of this New Mouth Breathing Face Mask.

These Two-Way Non-Rebreathing Masks are especially useful with subjects who have difficulty in using a mouthpiece and noseclip with a Two Way Non-Rebreathing Valve. Subject comfort and the secure fit afforded with this New Mouth Breathing Face Mask will result in more accurate test results. As compared to a mouthpiece / noseclip technique, this mask design has the advantage of eliminating jaw fatigue, saliva build up, dry mouth, and throat irritation.

This Adult Size Series has Large, Medium and Small Mask Face Pieces available adapted with Hans Rudolph Y-Shape™ and T-Shape™ Two Way Non-Rebreathing Valves. The user can select from these valve sizes to meet the optimum test parameters such as dead space and flow characteristics.

INTENDED USE
The Hans Rudolph 7900 series Mask face piece is designed for use with the Hans Rudolph two way non-rebreathing valves and other mask connectors designed for respiratory circuits with spontaneously breathing patients where the application requires a valve to separate the patient’s inspiratory and expiratory flows or a special connector to mate directly to a respiratory flow meter or other device. The typical mouthpiece and nose clip is replaced by this face mask assembly and headgear. The masks and valves are supplied clean, non-sterile. Typical applications are for pulmonary function testing, exercise testing and respiratory research. These mask valves are classified as reusable and can be high level disinfected.

ENVIRONMENT OF USE
This mask series is 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 masks are intended to connect.

MASK AND HEADGEAR SERVICE LIFE
The Mask when maintained properly and reprocessed per instructions is expected to stay in service for 25 disinfection and sterilization cycles under normal conditions. The Headgear is expected to stay in service for 6 months of use.

AMBIENT CONDITIONS
1. Temperature range: 5°- 40°C
2. Humidity range: 0-95% RH (Non-Condensing)

CLEANING AND DISINFECTION
For cleaning and disinfection care be sure you fully comprehend our cleaning Data Sheet 691195.

CAUTIONS
• Federal Law restricts this device to sale by or on the order of a physician.
• Patients with facial hair, especially beards, may experience mask leakage which may require shaving the hair.
• Do not use these valves in a life support system such as a ventilator circuit.

SPECIAL FEATURES
• This Head Cap Design ensures that the mask has a secure fit to the subject's face and head overcoming the problem of slipping during exercise testing.
• The adult size head cap fits all three sizes of the mask face pieces in this series.
• Sampling Ports, Couplers & Tubing - (Gas and Pressure)
• Two plastic nylon Female Luer Lock Type Sampling Ports with plugs are located 180° apart from one another on the circumference of the valve adapter to face piece.
• A set of three couplers is supplied with each mask. One end connects to the sampling port Female Luer Lock, the other end is a hose barb which fits in to the bore of flexible plastic tubing. These three hose barb sizes provide the user flexibility in tube size usage.
• Tubing for Sampling Ports (Gas & Pressure) is available in .062" (1.6mm) P/N 666060 & .093"(2.4mm) P/N 666061 & .125"(3.2mm) P/N 666062 Bore sizes to match the Coupler Hose Barb.
• Face Mask sizes #00, #0, #1, #2, #3, #4, #5, #6 represent a commonly designated size configuration with anesthesia face masks. To help the end user relate to these different sizes, this series of numbers will be shown on this series of the Rudolph Face Mask product line.

GENERAL INFORMATION
Valving - Utilizes one inhalation port and one exhalation port.
• Uses Hans Rudolph, inc. time proven, low resistance to flow Spiral-Type™ Diaphragms.
• Diaphragm sizes used in the inhalation / exhalation ports are shown in the tabulation.
GENERAL INFORMATION (continued)

Rebreathing Volume Dead Space:
Includes the sum of face piece mouth chamber, which has some variance because of users facial differences, plus the Two-Way Non-Rebreathing Valve chamber and adapter, which is the passageway volume between the inhalation and exhalation One-Way Valve Spiral-Type™ Diaphragms. Refer to Physical Characteristics.

Mask Face Piece - Molded of silicone rubber, which is durable, resilient, comfortable to facial skin, resistant to oxidation and chemical degradation.
• Low Volume Dead Space - the geometry of the inside of the mask separates and seals the nose chamber from the mouth chamber and places the subjects mouth directly at the mouth port of the valve.
• Leak Free Facial Seal - the wide face sealing flange conforms to face contour without creating pressure points.
• Chin Nest - prevents slipping, especially when perspiring during exercise testing.
• Four buttons are an integral part of the mask face piece. Two buttons are positioned on each side of the mask such that the straps pull the mask against the subjects face along the chin and the upper lip.

Head Cap Design - The one adult size and two pediatric sizes include an open crown cap, four elastic velcro straps with four locking type clips that attach to the four buttons (Nibs) on the mask face piece.
• Cap - Fabricated of quality, polyester net material which is light in weight and allows for greater heat loss during exercise testing. The open crown polynet cap allows for a snug fit around the upper portion of the head evenly distributing the pulling force from the straps and face mask.
• Straps - Fabricated of elastic velcro, this hook and loop type of fastener is well recognized by users as a convenient and secure method of fastening. The four straps (with adjustable locking clips) vary in length depending on cap application size and can be adjusted to mount and dismount on subjects head and to secure a leak free snug fit. Perspiration and moisture will not affect the performance of this stretch velcro and locking clip.
• Clips - Made of rigid plastic, are assembled to be a removable part of the strap assembly. They are specifically designed to mate with the mask buttons (Nibs). The clip is designed to lock in position when assembled on the stretch velcro strap and pulled tight laying parallel to the strap so as it would in a mounted position on the subject’s head. The clip can be loosened easily by pulling forward the top of the clip allowing the strap to move freely through the clip. It is a Two-Piece Easy-Release type, set of four to mate the four straps on headgear.

MOUNTING AND DISMOUNTING MASK INSTRUCTIONS
• Mounting
  First - attach all four strap & clip assemblies to buttons on mask. Extend the length of the four straps to obtain the maximum distance between the poly net cap and the face piece.
  Second - while holding face piece and valve assembly in one hand, use other hand to seat head cap on crown of head so that it fits snugly around head.
  Third - while holding head cap in a secure position on head, bring face piece down in front of face allowing the lower straps to position themselves below the ear lobes.
  Fourth - place and push mask face piece on holding in a snug position.
• Fifth - hold the tab and pull velcro straps out away from face to free them from the locked position in the clip. Also by lifting up on the back of the clip, you will allow the strap to move freely.
• Sixth - pull back on straps bringing face mask to a snug fit on face. Balance and adjust each strap until the best leak free seal is accomplished. The locking type clip will not allow the strap to slip.

Leak Test - for seal of mask face piece
• Hold palm of hand over outlet of exhalation valve port tube.
• Create a slight positive pressure inside mask face piece by exhaling gently.
• If air leakage occurs around facial seal, readjust face piece and velcro straps and retest until leak tight.

Note: It is emphasized to exhale with only a slight positive pressure as this simulates the low pressure of spontaneous breathing common with normal applications of this mask.

• Dismounting - The Two-Piece Easy Release Clips allow you to easily separate the Straps & Head Cap from the Face Mask by disconnecting 2 Clips from the same side. Thus the whole Mask Assembly is free to come off the face.
**TABULATION FOR EXPLODED ASSEMBLY DRAWINGS** describes the models and components, replacement part numbers with material description, protective finish and appearance.

<table>
<thead>
<tr>
<th>Item</th>
<th>Req’d</th>
<th>Replacement Part Description &amp; Order Number (P/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>One</td>
<td>Mask Face Piece Only (Silicone)</td>
</tr>
<tr>
<td>2</td>
<td>One</td>
<td>Head Cap (Straps/Clips)</td>
</tr>
<tr>
<td>3</td>
<td>One</td>
<td>Adapter Assembly to face piece (Two sampling ports &amp; plug included)</td>
</tr>
<tr>
<td>4</td>
<td>One</td>
<td>2 Piece Easy Release Clips - Package of 4</td>
</tr>
<tr>
<td>5</td>
<td>Two</td>
<td>Sampling Port - Female Luer Lock</td>
</tr>
<tr>
<td>6</td>
<td>Two</td>
<td>Male Luer Plug - to seal Female Luer Lock</td>
</tr>
<tr>
<td>7</td>
<td>One</td>
<td>Coupler - Male Luer Lock/Hose Barb for .062&quot; (1.6mm) Bore Tube</td>
</tr>
<tr>
<td>8</td>
<td>One</td>
<td>Coupler - Male Luer Lock/Hose Barb for .093&quot; (2.4mm) Bore Tube</td>
</tr>
<tr>
<td>9</td>
<td>One</td>
<td>Coupler - Male Luer Lock/Hose Barb for .125&quot; (3.2mm) Bore Tube</td>
</tr>
<tr>
<td>10</td>
<td>One</td>
<td>Inflation Port Tube</td>
</tr>
<tr>
<td>11</td>
<td>Two</td>
<td>Diaphragm Ring (Seat)</td>
</tr>
<tr>
<td>12</td>
<td>Two</td>
<td>Diaphragm, Spiral-Type™</td>
</tr>
<tr>
<td>13</td>
<td>One</td>
<td>Housing (Body)</td>
</tr>
<tr>
<td>14</td>
<td>One</td>
<td>Diaphragm Stop</td>
</tr>
<tr>
<td>15</td>
<td>One</td>
<td>Exhalation Port Tube</td>
</tr>
<tr>
<td>NA</td>
<td>One</td>
<td>Mask Face Piece, Head Cap, Straps &amp; Clips Assembly</td>
</tr>
<tr>
<td>NA</td>
<td>One</td>
<td>Two-Way Non-Rebreathing Valve Part (P/N)</td>
</tr>
<tr>
<td>NA</td>
<td>One</td>
<td>Two-Way Non-Rebreathing Valve Model No.</td>
</tr>
<tr>
<td>NA</td>
<td>One</td>
<td>Y or T-Shape Two-Way Valve</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

**NOTE:** Velcro straps are not sold separately. They are attached to the head cap and available with the Head Cap P/N 200525.

* The **Req’d** column represents the quantity of each replacement part that is required to assemble a specific Mouth Breathing face mask.

**PHYSICAL CHARACTERISTICS**
Port tube size: The 15mm & 22mm Diameters are tapered. All other size diameters are straight.

<table>
<thead>
<tr>
<th>Inflation/Exhalation Port Tubes:</th>
<th>(mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside Diameter</td>
<td></td>
</tr>
<tr>
<td>Inside Diameter</td>
<td></td>
</tr>
<tr>
<td>Size of Mask-Identified on chin.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight:</th>
<th>(gm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Assembly (Mask, Valve Adapter, Head Cap Assembly &amp; Clips)</td>
<td></td>
</tr>
<tr>
<td>Head Cap, Straps &amp; Clips Only</td>
<td></td>
</tr>
<tr>
<td>Mouth Breathing Face Mask Face Piece Only</td>
<td></td>
</tr>
<tr>
<td>Two-Way Non-Rebreathing Valve &amp; Adapter Only</td>
<td></td>
</tr>
<tr>
<td>Rebreathing Volume Dead Space:</td>
<td>(ml)</td>
</tr>
<tr>
<td>Total Assembly (Mask, Adapter &amp; Valve)</td>
<td></td>
</tr>
<tr>
<td>Mouth Breathing Face Piece Only (Less Adapter)</td>
<td></td>
</tr>
<tr>
<td>Adapter Assembly Only (For Adult Masks)</td>
<td></td>
</tr>
<tr>
<td>Two-Way Valve Only (Less Mouth Port Tube)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material Description, Protective Finish and Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1 - Acetal Plastic (white), G1 - Elastic, Velcro, P1-Nylon Plastic (Transparent/Yellow Tinted, White &amp; Black) Q1 - PET, Thermoplastic Polyester Plastic (white), V1 - Silicone Rubber (Royal Blue, Medium Blue, Beige, Yellow, Red, White, Gray, Translucent), X1 - Stainless Steel (Electro Polished), B2 - Polyester Net</td>
</tr>
</tbody>
</table>

****Measured by water displacement on a typical face. Values will change with different face geometries.
The nose chamber being sealed, is not a part of the Breathing Face Mask 112864-7941 Rudolph Mouth Breathing Face Mask, Adult, 112848-7931 Rudolph Mouth Breathing Face Mask, Adult with your choice of the appropriate size.

ORDERING INFORMATION
112852-7935 Rudolph Mouth Breathing Face Mask, Adult, Medium with 2730 Large T-Shape™ Valve (2WNRBV).
112853-7936 Rudolph Mouth Breathing Face Mask, Adult Medium with 1410 Small T-Shape™ Valve (2WNRBV).
112851-7934 Rudolph Mouth Breathing Face Mask, Adult Medium with 2600 Medium T-Shape™ Valve (2WNRBV).

The Two-Way Non-Rebreathing Valve Model is part of the mouth breaching face mask assembly & shown as an aid in your selection process. (E) is expired and (I) is inspired.

COUPLERS For Sampling Ports to Tubing
- Couplers adapt the Female Luer Lock Sampling Port to different bore sizes of Flexible Plastic Tubing.

Right End Hose Barb for use with flexible Plastic Tubing
P/N 171210-Barb for .062” (1.6mm) Bore Tubing.
P/N 171212-Barb for .125” (3.2mm) Bore Tubing.
P/N 171215-Barb for .177” (4.5mm) Bore Tubing.

Refer to items 7, 8, and 9 of the Exploded Assembly Drawing & Tabulation for additional information.

This set of three couplers is supplied with each Rudolph Mouth Breathing Face Mask.

For ordering Replacement Parts & mating Tubing to Hose Barb, refer to the Detailed Price List Section "Sampling Ports, Couplers & Tubing (Gas & Pressure)*."

ORDERING INFORMATION - Rudolph Adult size Mouth Breathing Face Mask with your choice of the appropriate size T-Shape™ or Y-Shape™ Two-Way Non-Rebreathing Valve (2WNRBV).

For ordering information and part number of replacement components, refer to Exploded Drawings & Tabulation of part numbers (P/N).

P/N-Model No. Adult Small Series 7940 Size #2
112864-7941 Rudolph Mouth Breathing Face Mask, Adult, Small with 2730 Large Y-Shape™ Valve (2WNRB).
112865-7942 Rudolph Mouth Breathing Face Mask, Adult Small with 2700 Large T-Shape™ Valve (2WNRBV).
112854-7943 Rudolph Mouth Breathing Face Mask, Adult Small with 2630 Medium Y-Shape™ Valve (2WNRBV).
112855-7944 Rudolph Mouth Breathing Face Mask, Adult Small with 2600 Medium T-Shape™ Valve (2WNRBV).
112856-7945 Rudolph Mouth Breathing Face Mask, Adult Small with 1420 Small Y-Shape™ Valve (2WNRB).
112857-7946 Rudolph Mouth Breathing Face Mask, Adult Small with 1410 Small T-Shape™ Valve (2WNRBV).

Adult Medium Series 7930 Size #5
112848-7931 Rudolph Mouth Breathing Face Mask, Adult Medium with 2730 Large Y-Shape™ Valve (2WNRB).
112849-7932 Rudolph Mouth Breathing Face Mask, Adult Medium with 2700 Large T-Shape™ Valve (2WNRBV).
112850-7933 Rudolph Mouth Breathing Face Mask, Adult Medium with 2630 Medium Y-Shape™ Valve (2WNRBV).
112851-7934 Rudolph Mouth Breathing Face Mask, Adult Medium with 2600 Medium T-Shape™ Valve (2WNRBV).

Adult Large Series 7920 Size #6
112822-7921 Rudolph Mouth Breathing Face Mask, Adult, Large with 2730 Large Y-Shape™ Valve (2WNRBV).
112839-7922 Rudolph Mouth Breathing Face Mask, Adult, Large with 2700 Large T-Shape™ Valve (2WNRBV).
112840-7923 Rudolph Mouth Breathing Face Mask, Adult, Large with 2630 Medium Y-Shape™ Valve (2WNRBV).
112841-7924 Rudolph Mouth Breathing Face Mask, Adult, Large with 2600 Medium T-Shape™ Valve (2WNRBV).

REFERENCES
For a validation study of the large Rudolph Mouth Breathing Face Mask compared to the historic mouthpiece/noseclip technique refer to abstract titled "Comparison of the Rudolph Face Mask with the standard Mouthpiece/Noseclip Apparatus in measuring Respiratory Variables." G.W. Danhoff & T.E. Dohmeier, W.L. Lake Human Performance Lab, Western Illinois University, Macomb, IL & Condell Medical Center, Medical Center Health Institute, Libertyville, IL. Medicine and Science in Sports and Exercise. Volume 24, Number 5, Supplement.


For additional information on the advantages of using the Rudolph Mouth Breathing Face Mask to collect expired air in spontaneously breathing patients refer to "Nutritional Assessment in Critical Care: A Training Handbook" by Donald C. Zavala, M.D., First Edition, Chapter 3, pages 51 & 55.

For information on the effects of breathing patterns comparing the face mask with mouthpiece technique, refer to "Human breathing patterns on mouthpiece of face mask during air, CO2 or Low O2" by Judith Ann Hirsch and Beverly Bishop, Journal of Applied Physiology, No. 1982 - Vol. 53, No. 5, pages 1281-1290. The mask discussed in the article is not this Rudolph Mouth Breathing Face Mask Series 7900 or the Rudolph Nasal & Mouth Breathing Face Mask Series 8900.