Instructions

For Use

HANS RUDOLPH, INC TWO WAY NON-REBREATHTING VALVES
INSTRUCTIONS FOR USE

RÜCKATEMSCHUTZ-ZWEIWEGEVENTILE, HANS RUDOLPH, INC.
Gebrauchsanweisung

VALVES BIDIRECTIONNELLES SANS REINSPIRATION, HANS RUDOLPH, INC
INSTRUCTIONS D'UTILISATION

VALVOLE NON A REINSPIRAZIONE BIDIREZIONALI, HANS RUDOLPH, INC
ISTRUZIONI PER L'USO

V ÁLVULAS DE DOBLE DI RECCIÓN SÓLO PARA INHALAR 0 EXHALAR, HANS RUDOLPH, INC.
INSTRUCCIONES DE USO

BIDIRECTIONEEL NIET-HERADEMEND VENTIEL, HANS RUDOLPH, INC
INSTRUCTIES VOOR HET GEBRUIK

TVÅVÄGS ICKE-ÅTERANDNINGSVENTIL, HANS RUDOLPH, INC
BRUKSANVISNING

REFER TO LAST PAGE FOR PARTS LIST

Step 10 Reassembly
Punkt 10 Zusammenbau
10 é etape Réassemblage
Fase 10 Rimontaggio
Paso 10 Rarmado
Stap 10 Terug monteren
Steg 10 Hopsättning

• Specifications subject to change without notice •
A. Intended Use
Two-Way Non-Rebreathing valves are intended for use as a component of a respiratory circuit for spontaneously breathing patients to enable two-way non-rebreathing. The direction of flow through the valve is indicated with arrows marked on the valve body. These valves are indicated for use in pulmonary function testing, exercise testing, respiratory research and custom applications involving adults and pediatric patients. These valves are not intended for use in any type of therapeutic application, especially those involving critical care or life support, ventilation or anesthesia.

B. Directions for Use, Installation, Operation & Safety
Two-way non-rebreathing valves have three ports a mouth port, inhalation and exhalation port for installation in the breathing circuit. A flexible mouthpiece is typically attached to the mouth port for the patient connection. Flexible tubing or rigid connectors connecting the measurement system to the valve are connected to the inspiratory and expiratory ports. The valve ports are designed to fit snugly with standard tubing systems or standard medical tapered connectors. The direction of flow through the valve is indicated with arrows marked on the valve. Proper use of these valves will ensure their effectiveness. Confirm with a simple test that the valve diaphragms open and close allowing flow in the desired direction. See Step 9 Functional Test for more information. Contact Hans Rudolph for further information and data sheets on these products.

C. Reprocessing Instructions
Product Classification
These valves are classified as reusable devices
These valves are supplied clean, non-sterile
These valves are respiratory devices categorized by the CDC as semi-critical with respect to potential risk of infection. High Level Disinfection has been validated using CIDEX® liquid glutaraldehyde disinfectant.

D. Cleaning and High Level Disinfection Methods
Step 1 Preparation at Point of Use
Cleaning of reusable devices should begin soon after use. Soil is wiped from the device surfaces with a moist sponge or cloth. The soiled components are then contained for transport to reduce the risk of personnel exposure to pathogens.

Step 2 Inspection
Inspect valve components for damage at all stages of handling. If damage is detected on any of the components it should be identified and documented. Complete the disinfection process and contact Hans Rudolph for guidance on replacement components.

Step 3 Presoak
Soak and rinse the device in warm tap water (40 C). If an enzymatic cleaner is required, soak the components for two minutes. Remove and inspect, extend the soak time for components with dried-on matter. Prolonged soaking may be detrimental to the valve materials so inspect frequently.

Step 4 Disassembly
Refer to the valve diagrams.

Tools/Supplies
a. Phillips head screw driver may be required on some assemblies
b. Silicone lubricant (REF 660170) may be required on assemblies where orings are used.

Instructions
1 Separate the mouth port, inhalation port and exhalation port from the valve main body unthreading the ports counterclockwise.
2 Remove the two rubber diaphragm and ring subassemblies. Observe how these diaphragm and ring subassemblies are assembled in the valve body. Separate the diaphragm from the ring gently by pulling them apart. The open flange end of the diaphragm fits into the groove of the diaphragm ring. Series 7200 has additional diaphragm discs that contain the diaphragm and ring subassemblies and these require three screws for disassembly.
3 Remove the diaphragm stop from the exhalation port groove. Squeeze the wire form diaphragm stop and it should easily pop out of the groove. Some of the smaller valves do not have diaphragm stops. Refer to the diagrams for details.
4 Remove orings from mating components where applicable.
5 Installed hose barbs should not be disassembled.
6 Care should be observed with the rubber diaphragm legs as these are very delicate and can tear easily.
7 Always replace damaged components.
8 Series 6900 saliva trap mouth port assembly is an accessory that replaces the standard mouth port tube. Unthread the tightening ring counterclockwise until the entire mouth port assembly disconnects from the two-way valve. The threaded adapter can be removed from the valve body by unthreading it counterclockwise with the spanner wrench provided. The saliva collector tube unthreads from the mouth port tube.

Step 5 Manual Cleaning
1 Manual cleaning of the valve components should be done in warm water (40 C). Use a neutral pH (7) mild detergent. Refer to the detergent manufactures instructions for dilution ratios with water. Use a small soft brush to scrub the component parts. The rubber diaphragms should be washed gently by rubbing the surfaces with gloved fingers.
2 Valve components should be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components. Use a flowing triple rinse cycle at a minimum with tap water.
3 Dry all components thoroughly using a lint free soft clean cloth or disposable paper towel.

Step 6 Manual High Level Disinfection with liquid Glutaraldehyde
High Level Disinfection of all respiratory valve components should be performed after each use. The disinfecting solution must contact all surfaces to assure disinfection. Hans Rudolph has validated High Level Disinfection for these valves using CIDEX® glutaraldehyde disinfectant solution.
1 Determine the required soak time and temperature of the disinfectant and assure these requirements are met. Typical high level disinfection soak time is 45 minutes.
2 Activate the glutaraldehyde solution by mixing the components per the manufacturer’s instructions. Use the concentration testing devices sold by the manufacturer to determine the solution is effective.
3 Completely immerse the valve components in the solution assuring that all surfaces are in contact with the liquid chemical.
4 Rinse 1: Remove the valve components from the disinfecting solution and submerge in 7-8 liters of water (preferably sterile water) and thoroughly rinse for one minute.
5 Rinse 2: Remove the components from the first rinse and submerge in another 7-8 liters of water (preferably sterile water) and thoroughly rinse for one minute.
6 Dry the components thoroughly using a clean (preferably sterile) lint free cloth or disposable paper towels.

**Step 7 Inspection, Preventive Maintenance & Repair**

All components should be visually inspected for cleanliness, proper function and free of defects. Visual inspection provides evidence of thorough cleaning and proper functioning of all valve components. Valves in poor working condition are hazardous to personnel and patients. There are no maintenance or repair procedures that are specified for these valves in the field. Contact Hans Rudolph for Return Authorization for valves that require repair or replacement components.

1 Visually inspect all components for cleanliness. If there are signs of residue from the detergent or disinfectant repeat the previous steps. If there are any signs of remaining stains or organic debris repeat the previous steps. If the cleaning and disinfection steps have been repeated with no improvement eliminating the stains or residues then dispose of and replace the components.
2 Visually inspect all components for defects. Check the rubber parts for tears, nicks, hardening or stiffening, deformation or distortion. Check the plastic parts for crazing, cracking or stripped threads. Any defective parts should be discarded and replaced.
3 Visually inspect all metal parts for corrosion. Replace any metal parts showing rust, discolored or chipped plated surfaces.

**Step 8 Reassembly**

Refer to the previous valve diagrams. Use appropriate personal protective clothing to assure that you do not recontaminate the components.

1 Install rubber diaphragms on the rings. Mating grooves on the diaphragms and rings should fit together. Make sure the diaphragms are completely fitted into the groove on the rings. The flat diaphragm face should contact the ring sealing edge evenly with no visible gaps.
2 Snap the diaphragm stop into the exhalation port groove by collapsing one end of the wire stop while placing the opposing end into the groove.
3 Insert a diaphragm/ring subassembly into the inhalation port of the valve body. Orientation of the diaphragm/ring assembly is very important. Identify the inhalation port by the arrows on the valve body. One arrow points to the mouth port from the inhalation port. The diaphragm should open with air flow into the body. Make sure the flange of the open end of the diaphragm sits squarely in the counter bore of the valve body.
4 With the diaphragm/ring assembly mounted in the valve body thread the inhalation port tube into the valve body. Hand tighten only. Do not over tighten, this could damage the threads.
5 Insert a diaphragm/ring assembly into the exhalation port of the valve body. Orientation of the diaphragm/ring assembly is very important. Identify the exhalation port by the arrows on the valve body. The diaphragm/ring assembly is mounted into the exhalation port of the valve body open flange end first. Make sure the flange of the open end of the diaphragm sits squarely in the counter bore of the valve body. The diaphragm should open with air flow out of the body.
6 With the diaphragm/ring assembly mounted in the valve body thread the exhalation port tube into the exhalation port of the valve body. Hand tighten only. Do not over tighten, this could damage the threads.
7 Thread the mouth port tube into the mouth port of the valve body. Hand tighten only. Do not over tighten.
8 Series 7200 two-way non-rebreathing valve has additional diaphragm discs. The diaphragm/ring assemblies are placed between the discs with three screws holding the assembly together, one of the diaphragm discs has the counter bores that mate the open flange end of the diaphragm/ring assembly. The diaphragm/ring assemblies should sit squarely in the counter bores of the discs.
9 All o-rings should be lubricated with approved silicone lubricant (HRI P/N 660170). Apply a light film of lubricant with your fingers to all surfaces of the o-ring.
10 Series 6900 saliva mouth port assembly replaces the standard mouth port tube on the valve body. Thread the adapter clockwise into the mouth port position of the valve body. Use the spanner wrench provided to hand tighten the adapter. Do not over tighten. Push the mouth port tube o-ring end into the threaded adapter engaging the o-ring and adapter. Rotate the saliva collector tube to the desired position. Thread the tightener ring onto the threaded adapter clockwise hand tight only.

**Step 9 Functional Test**

Confirm that the two-way non-rebreathing valve functions as intended before storage.

1 Attach an appropriate sized volume calibration syringe to the valve mouth port with the piston rod at the mid stroke position.
2 Push and pull the syringe piston rod slowly, visually checking the valve function. Air should enter the valve through the inhalation port and exit the valve through the exhalation port. Visually inspect the diaphragm opening and closing functions. The diaphragms should open and close easily without interference.
3 Block the inhalation port tube with your hand while you easily pull on the calibration syringe piston rod. You should not be able to pull air through the valve into the syringe. If the syringe is filling with air this indicates an air leakage at the exhalation port diaphragm/ring assembly. Inspect the diaphragm/ring assembly and replace if necessary. The same functional test should be performed for the inhalation diaphragm/ring assembly by blocking the exhalation port with your hand and pushing easily on the syringe piston rod. If you are able to push air through the valve then this indicates air leakage at the inhalation port diaphragm/ring assembly. Inspect the diaphragm/ring assembly and replace if necessary.

**Step 10 Storage**

Confirm that the valve is completely dry prior to storage. Valves should be stored in a way that prevents recontamination or damage between uses.

1 Place valve in a clean plastic bag and heat seal the opening.
2 Label the bag documenting that it has been disinfected, date, initials, valve part number and description.

**E. Service Life/Reuse Life**

Hans Rudolph two-way non-rebreathing valves when maintained properly and reprocessed per these instructions should function within specification for 100 cleaning and high level disinfection cycles or one year of service (whichever occurs first). Visual inspection of all the components during each reprocessing cycle will identify any defects. The functional tests as described in Section D, Step 9 will determine if the valve is functioning properly.

**F. Ambient Conditions**

1 Temperature: 5°C to 40° C
2 Relative Humidity: 0% to 95% (non-condensing)

**G. Warnings: (Indicates possible harm to persons)**

1 Glutaraldehyde solutions can be hazardous to humans
   a. Do not get into eyes, on skin or on clothing
   b. Use in well ventilated area in closed containers
   c. For emergency, safety or technical information about the glutaraldehyde solution contact the manufacturer.
2. Appropriate personal protective clothing should be worn when cleaning and disinfecting soiled devices.
3. Contaminated, reusable devices must be thoroughly cleaned prior to disinfection, since residual contamination will decrease effectiveness of the glutaraldehyde solution.
4. It's the user's responsibility to validate any deviations from this recommended method of processing.

H. Cautions: (indicates possible harm to device)
1. Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Do not ethylene oxide, steam sterilize or pasteurize these valves.
3. Use only approved liquid glutaraldehydes (see Section D, Step 6). Do not use alcohol, bleach or chlorine solutions.

I. Risks
Valves that function ineffectively can cause delays in a procedure and increase the risk of infection and injury. However, the risk of any harm to patients, clinicians, and bystanders caused by the use of these valves is remote. Steps have been taken in their design to greatly reduce the probability of occurrence of these existing potential hazards:
1. External valve leakage
2. Inoperative valve diaphragm (leakage or blockage)
3. Valve contaminants (particulates or microbes)
4. Biosensitivity to valve materials
5. Excessive valve dead space
6. Excessive breathing resistance
7. Exposure to toxic disinfectant agents

J. Safety Information
Safety or technical information regarding Hans Rudolph two-way non-rebreathing valves can be obtained from Hans Rudolph inc., 913-422-7788, USA & Canada 800-456-6695, Fax 913-422-3337, or by contacting your Hans Rudolph representative.

K. Recommendation for Disposal
Treat as conventional solid waste in accordance with local and federal regulations.

L. Credits
1. Cidex® is a registered trademark of Advanced Sterilization Products
2. CDC is an abbreviation for the Centers for Disease Control