HANS RUDOLPH, INC. PNEUMOTACHOMETER (PNT) INSTRUCTIONS FOR USE

DE PNEUMOTACHOMETER (PNT) VON HANS RUDOLPH, INC. GEBRAUCHSANWEISUNG

FR PNEUMOTACHOMETRES (PNT), HANS RUDOLPH, INC INSTRUCTIONS D'UTILISATION

IT PNEUMOTACHIMETRO, HANS RUDOLPH, INC ISTRUZIONI PER L'USO

ES NEUMOTACÓMETRO (PNT), HANS RUDOLPH, INC. INSTRUCCIONES DE USO

NL PNEUMATISCHE TACHOMETER (PNT), HANS RUDOLPH, INC INSTRUCTIES VOOR HET GEBRUIK

SV PNEUMOTACHOMETER (PNT), HANS RUDOLPH, INC BRUKSANVISNING

Models: 8410A, 8420A, 8430A

Models: 8410B, 8420B, 8430B

Models: 8300, 3719

Models: 3500, 3700, 3830, 3813

PARTS LIST ON PAGE 4
All Hans Rudolph Pneumotachs require complete or partial disassembly for cleaning and disinfection. It is the responsibility of the user (health care personnel) for ensuring that the cleaning methods recommended by Hans Rudolph can be duplicated in their environment, that appropriate tools, and replacement parts are available and that Hans Rudolph instructions are followed correctly.

C. Cleaning Assistance

Prepare and assemble Hans Rudolph pneumotachs for use. These PNT’s are classified as reusable devices. Mild detergents with a neutral pH(7) are recommended for cleaning Hans Rudolph Pneumotachs. Greece cutting dishwashing detergent is helpful in removing the silicone lubricant found on many components. Use warm water (22°-43°C) with the mild detergent. To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device. Cleaning agents should be used in the correct dilution and concentration and at the correct temperature in accordance with the cleaning agents manufacturer's directions. It is ultimately the user's responsibility to choose the correct cleaning agent, based on the instructions of the device manufacturer and any recommendations of the cleaning manufacturer. Certain cleaning agents can damage metal or other device materials. Do not use cleaning agents containing bleach or alcohol.

Cleaning supplies are very basic, usually consisting of a surgical scrub brush, chenille pipe cleaners, cotton or foam tipped applicators, soft brushes, and soft cloths. Cleaning supplies should be cleaned and disinfected or sterilized daily.

2. Silicone lubricant (P/N 660170) may be required on assemblies where orings are used.
3. Unload orings and seals from mating components where applicable.
4. Installed hose barbs should not be disassembled.
5. Care should be taken to ensure that all small parts (orings, pressure tape seals, pressure taps, screens) are contained to prevent loss. Pneumotach assemblies are calibrated devices and their components are noninterchangeable with other PNT's. Keep the components of each assembly together to ensure correct assembly.
6. Always replace damaged components.

8. Remove orings and seals from mating components where applicable.
9. Installed hose bars should not be disassembled.
10. Care should be taken to ensure that all small parts (orings, pressure tape seals, pressure taps, screens) are contained to prevent loss. Pneumotach assemblies are calibrated devices and their components are noninterchangeable with other PNT's. Keep the components of each assembly together to ensure correct assembly.

Step 5 Manual Cleaning

Protective attire is required for personnel handling contaminated devices. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

1. Manual cleaning of the PNT components should be done under water in cool to Luke warm water (43°C maximum). Use a neutral pH(7) mild detergent. Typical concentration of detergent is one ounce to 3.9 liters of water. Water hardness, temperature and the type of soil affect the effectiveness of the detergent; the detergent manufacturer's instructions should be consulted. Use a small soft brush to scrub all detachable parts. Visually inspect the screen assemblies for debris build up. If this is the case soak the screen assembly in a mild detergent followed by a gentle brush cleaning (toothbrush). Use an enzymatic detergent (neutral pH) so if the mild detergent does not break down the debris buildup. Abrasive cleaning compounds and implements can damage these PNT components and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.

Scope

This guidance is directed to personnel responsible for decontamination of Hans Rudolph pneumotachs.

These recommended practices provide guidelines to assist the health care personnel in the decontamination, cleaning, maintenance, handling, storage and/or sterilization of Hans Rudolph Pneumotach components.

Decontamination is a multi-step process that includes preparation at point of use, thorough cleaning and rinsing and a microbicidal process. Thorough cleaning and rinsing are the first and most important steps in the decontamination of any reusable medical device. Without thorough cleaning and rinsing it may not be possible to achieve high level disinfection or sterilization of the device. The purpose of cleaning and rinsing is to remove all adherent visible soil, to reduce the number of particulates and microorganisms, and to reduce the amount of pyrogenic and antigenic material. Any organic material, lubricants, or residual cleaning agents remaining on a device can inactivate liquid chemical disinfectants/sterilants as well as protect microorganisms from destruction.

The second step in decontamination is the microbial process which is defined as a process to provide a particular level of microbial lethality (kill). Hans Rudolph Pneumotachs are classified as "semi-critical" items which come into contact with intact mucous membranes. Properly performed disinfection and sterilization is recommended by using liquid glutaraldehyde disinfectants approved as sterilants/disinfectants by the Environmental Protection Agency and cleared for marketing in use on medical instruments by the Office of Device Evaluation. The U.S. Food and Drug Administration. High level disinfectants are simply sterilants used at a shorter exposure time.

A. Intended Use

Pneumotachometers (PNT) are designed for use as a component of a respiratory flow measurement system. The pneumotach converts the flow of gas into a proportional linear signal of differential gas pressure for input into a differential gas pressure transducer. The output from the differential pressure transducer is used for flow and volume measurements. The end user is required to design and assemble the additional instrumentation required to integrate the PNT into the flow system. PNT’s are available in a wide range of sizes as specified by the flow range and volume dead space. Applications range from pulmonary function testing to biofluidics and respiratory research. Heater controllers are available for these PNT’s. WARNING: This pneumotach is not intended for long term continuous flow monitoring in a humidified ventilator circuit. Moisture can occlude the screen. Never leave PNT in the ventilator circuit unattended by qualified personnel.

B. Directions for Use

For detail information contact Hans Rudolph for the PNT Service and Instruction Manual 691038 and Data sheet 691037. Connect the port tubes (inlet, outlet) to the gas flow circuitry. Complete the pressure connection between the differential pressure taps on the PNT and the appropriate ports of the differential pressure transducer. The flow will then be detected by pressure changes recorded in the transducer amplifier recording system. A heater controller is recommended for the PNT’s that are used in a humid respiratory circuit. The heater controller reduces condensation on the screens (resistive element) of the PNT which would affect the differential pressure output to the transducer. Heated PNT’s should be evaluated first in humidified circuits prior to use by visual inspection of the screens. WARNING: If humidity collects on the screens do not use the PNT in this flow circuit.

C. Reprocessing Instructions

Step 5 Manual Cleaning

Protective attire is required for personnel handling contaminated devices. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

1. Manual cleaning of the PNT components should be done under water in cool to Luke warm water (43°C maximum). Use a neutral pH(7) mild detergent. Typical concentration of detergent is one ounce to 3.9 liters of water. Water hardness, temperature and the type of soil affect the effectiveness of the detergent; the detergent manufacturer's instructions should be consulted. Use a small soft brush to scrub all detachable parts. Visually inspect the screen assemblies for debris build up. If this is the case soak the screen assembly in a mild detergent followed by a gentle brush cleaning (toothbrush). Use an enzymatic detergent (neutral pH) so if the mild detergent does not break down the debris buildup. Abrasive cleaning compounds and implements can damage these PNT components and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.

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2. PNT components must 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 soft cloths or disposable paper towels. Components should be dry to prevent dilution of the disinfectant used in subsequent steps.
4. The heater shell and cable assembly are not in communication with the patient and therefore do not require high level disinfection. To clean this assembly spray and wipe with a mild detergent or disinfectant solution.

Step 6 Manual Disinfection
High level disinfection of all pneumotach components must be performed after each use. The disinfectant/sterilizing agent must contact all surfaces to ensure disinfection or sterilization. High level disinfection of Pneumotach components ensures patient safety and minimizes the risk of infection.

6. Soak the PNT components for the time specified by the disinfectant solution manufacturer to achieve high level disinfection. Use a timer to ensure adequate soaking time.
7. Repeat the same process with the three dot screen assembly. Note: the screen assembly must be placed in flat to avoid binding. If the screen assembly binds, tap lightly on the body assembly until the screen lays flat. Do NOT PUSH ON THE SCREEN MESH.
8. Insert o-ring in the groove above the stacked screen assemblies within the body.
9. Screw the large flange port tightly (hand tighten only) to the body.

Step 7 Rinse After Manual Disinfection
Adequate rinsing must follow disinfection to remove all traces of the toxic substances of the disinfectant left on the PNT components. Sterile water rinse is preferred over tap water. Tap water may contain a variety of microorganisms which could contaminate the valve components.

1. Rinse: Fill a basin with 7-8 liters of water (preferably sterile water). Place the PNT components into the basin and thoroughly rinse all the components for a minimum of one minute. Empty basin.
2. Rinse: Fill a basin with 7-8 liters of water (preferably sterile water). Place the PNT components into the basin and thoroughly rinse all the components for a minimum of one minute. Empty basin.

Step 8 Drying
To prevent the growth of waterborne organisms, the PNT components should be thoroughly dried prior to reassembly and storage.

8. Insert oring in the groove above the stacked screen assemblies within the body.
9. Screw the large flange port tightly (hand tighten only) to the body.
10. Place the heater or non-heated shell assembly onto the body.
11. Screw the small flange port onto the body (hand tighten only).
12. Screw the precision screws into the body until the tap o-ring is compressed 1/2 turn.

Step 11 Functional test
The PNT should be inserted into the flow measurement system and a recalculation procedure should be performed. If the PNT calibrates accurately and meets the system specification then it is functioning acceptably.

1. Flow measurements or calibration errors
2. Relative Humidity: 0% to 95% (non-condensing)
3. Dry thoroughly using a soft cloth (preferably sterile) or disposable paper towels.
4. Application of the disinfectant solution.