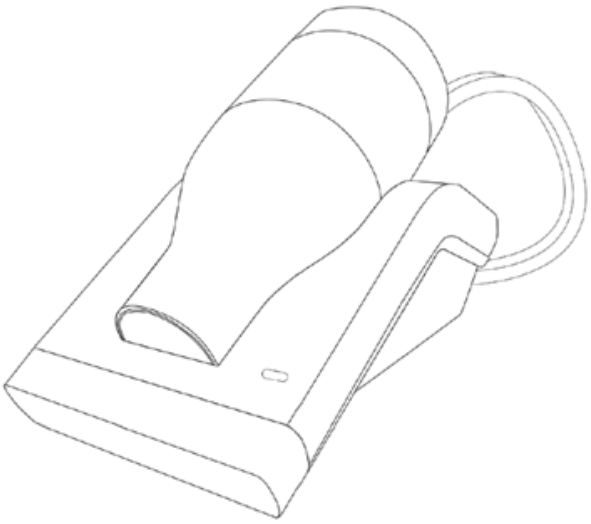
# Cleaning Instructions

**Applicable to:**

Pneumotrac Spirometer
Order #MD6800



Pneumotrac
Cleaning Instructions 07834
Issue 2 March 29, 2023

# Flowhead Cleaning Instructions

*Applicable to Pneumotrac pictured below.*

Hygiene Policy

The Pneumotrac spirometer is not designed to be, nor supplied as, sterile.

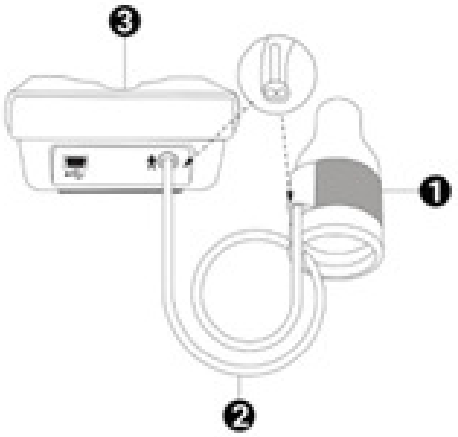
The manufacturer highly recommends a new viral/bacterial filter be used for every patient to prevent cross contamination. Using a viral/bacterial filter provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry maneuvers.

The interior of a flowhead does not require decontamination where a new viral/bacterial filter is used for each subject. When used according to the manufacturer's recommendations, the Pneumotrac spirometer is considered non-critical or low risk regarding infection control. The exterior of the flowhead may be cleaned in line with your facility's requirements for handheld objects[1].

If a higher level of decontamination is required, then cleaning may be followed by disinfection as outlined below.

## Cleaning the Flowhead Exterior

Recommended cleaning method where a new SpiroSafe filter is used for every subject:




| | |
|---|---|
| 1 | Flowhead Complete |
| 2 | Flowhead Tubing |
| 3 | Pneumotrac Device |

*Figure 1: Flowhead Complete, Flowhead Tubing and Pneumotrac Device*

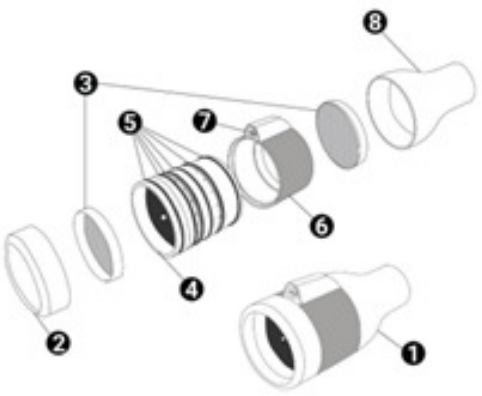
1. Disconnect both ends of flowhead tubing from the pressure ports on the flowhead and the device.
2. Use a 70% isopropyl alcohol impregnated cloth to thoroughly clean the case exterior of the flowhead and the flowhead tubing. Visually inspect and repeat until visibly clean.
3. Reassemble by reconnecting both ends of flowhead tubing to the pressure ports on flowhead and the device.
4. It is recommended that calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in each device's instructions for use.

# Decontamination by Cleaning and Disinfection

This is the recommended cleaning method where the user suspects the flowhead interior may have become contaminated or if the user's local requirements include disinfection.

## Cleaning of Flowhead Interior

1. Disconnect both ends of flowhead tubing from flowhead and the device.




| | |
|---|---|
| 1 | Flowhead Complete |
| 2 | Flowhead End Cap |
| 3 | Flow Conditioning Mesh (x2) |
| 4 | Fleisch Element Assembly |
| 5 | O-Ring (x6) |
| 6 | Flowhead Body Tube |
| 7 | Pressure Ports |
| 8 | Flowhead Cone |
| | Lubrication: Silicone Grease |

*Figure 2: Flowhead Assembly*

2. Remove flowhead cone and flowhead end cap.
3. Remove flow conditioning meshes from inside the cone and end cap. Examine for damage or contamination. If meshes are damaged or blocked, discard and replace with new parts.
4. Remove flowhead body tube from Fleisch element assembly. To do this, first remove the O-Ring from the smaller diameter side of the fleisch element assembly (same side the flowhead cone was removed from) and then place the Fleisch element assembly on a hard, flat surface with the largest diameter at the top (this is the end the flowhead end cap was removed from). Push down on the flowhead body tube with thumbs and forefingers until it reaches the flat surface. A final pulling and twisting action will separate the parts.

**Cleaning**

5. Swill Fleisch element assembly vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at capillaries.
6. Wash the flowhead end cap, flowhead body tube, flow conditioning meshes and flowhead cone in warm soapy water. Rub surfaces to remove any visible soiling.
7. Ensure all parts are visibly clean. If not visibly clean, repeat the cleaning process.
8. Rinse with potable tap water.

**If disinfection is required, proceed to disinfection steps after rinsing, otherwise proceed straight to drying.**

## Disinfection

1. Prepare disinfectant solution as per the disinfectant manufacturer's recommendation.

   **Always follow the safety guidelines given by the manufacturer of the disinfectant chemicals.**

2. Disinfect flowhead body, flowhead base and flowhead cone by immersion in the solution. Ensure the flowhead body is immersed vertical and tap several times to remove air bubbles from the interior. Soak parts for the time period recommended by the disinfectant manufacturer.
3. Rinse with potable tap water.

Table 1: Recommended Disinfectants

| Disinfectant | Type of Testing |
|---|---|
| Revital-Ox Resert High Level Disinfectant<br>(Active germicide; Hydrogen Peroxide) | Vitalograph 2021:<br>Compatibility testing to 35 hours immersion |
| Revital-Ox Resert High Level Disinfectant- Chemosterilant<br>(Active Germicide; Hydrogen Peroxide) | |
| Resert XL HLD High Level Disinfectant<br>(Active germicide; Hydrogen Peroxide) | |
| PeraSafe™ Instrument Sterilant (Rely+On™)<br>(Active germicide: 0.2% peracetic acid) | Vitalograph 2020:<br>Compatibility testing to 44 hours immersion |
| Korsolex® Extra Aldehyde-Based Disinfectant<br>(5.0% concentration for 15 minutes) | Vitalograph 2023:<br>Compatibility testing to total 65 hours immersion |

## Drying

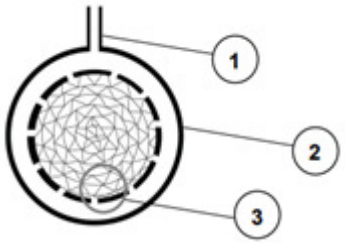
1. Tap and shake the flowhead body up and down several times with the capillaries orientated vertically to remove excess water.
2. Arrange disassembled parts separately so any remaining water can drain and air can circulate, e.g., on a drying rack. Drying the Fleisch element assembly may require leaving it in a warm place overnight. If available, a drying cabinet is ideal.
3. Leave to dry completely before reassembling.

## Reassembly of Fleisch Flowhead

1. Examine Fleisch element assembly and flowhead body tube to ensure no liquid or particles remain in the holes or grooves.
2. Check O-rings for damage and ensure correct positioning within the grooves.
3. Apply a very small amount of silicone grease to the O-Rings (4 center O-rings only, 2 end O-rings must **NOT** be greased). Wipe off any visible amounts of grease. Ensure the tiny annular holes on the outside of the Fleisch element assembly are not blocked.
4. Refer to Figure 2: Flowhead Assembly to view placement of parts for reassembly.
5. Replace flowhead body tube onto Fleisch element assembly. Ensure the pressure ports on the flowhead body tube are nearest to the largest diameter (this is the end the flowhead end cap was removed from (of the Fleisch element assembly.

*Figure 3: Replacing the flowhead body onto the Fleisch element*

6. Ensure the flowhead body tube is pushed fully home and rotate it so the pressure ports are approximately 180º opposite the end of the fleisch element coil.




| | |
|---|---|
| 1 | Pressure Ports |
| 2 | Flowhead Body Tube |
| 3 | End of the Fleisch Element Coil |

*Figure 4: Orientating the Flesich element coil at 180º to the pressure ports*

7. Fit flow conditioning meshes to both flowhead cone and flowhead end cap as shown in Figure 2.
8. Re-fit the end O-ring that was removed from the smaller diameter side of the fleisch element assembly (same side the flowhead cone was removed from) which was specified in step 4 of disassembly of flowhead.
9. Push flowhead end cap onto the larger diameter of the Fleisch element assembly and push flowhead cone onto the smaller diameter.
10. Reconnect flowhead tubing.

**The manufacturer recommends a calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in the device instruction for use.**

**Consumables and Replacement Parts Ordering Information**

| Catalog No. | Description |
|---|---|
| 3385 | SpiroSafe Viral/Bacterial Filter (Box of 100) |
| 3325 | 3-Liter Calibration Syringe |
| 77933 | Replacement Flow Conditioning Mesh (Pack of 10) |
| 77934 | Replacement Flowhead Complete |
| 77939 | Replacement Cone |
| 77938 | Replacement End Cap |
| 79192 | Replacement Flowhead Connection Tube |
| 2120013 | Replacement O-Ring (Pack of 15) |
| 41543 | Replacement USB Cable |
| 77935 | Replacement Feet |
| 32254SPR | Replacement Silicone Grease Pack |

## References

1. Vitalograph (2019), “Hygiene Policy”. Internal Vitalograph policy. Document number: SOP_0523. *

## Bibliography

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3. FDA (2015) “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff” U.S. Food & Drug Administration.

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6. Loveday, H. P. et al (2014). “epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England.” Journal of Hospital Infection 86: S1-S70. DOI: https://doi.org/10.1016/S0195-6701(13)60012-2.

7. NHS (2017). Community Infection Prevention and Control Guidance for General Practice. Infection Prevention Control. UK. Accessed 28 May 2019, from https://www.infectionpreventioncontrol.co.uk/

8. Rutala, W. A., D. J. Weber and HICPAC (2008). “Guideline for Disinfection and Sterilization in Healthcare Facilities.” CDC Infection Control Accessed 28 May 2019, from https://www.cdc.gov/infectioncontrol/guidelines

* Available by Request