Spirometer Cleaning Instructions

Alpha Order #MD6000
In2itive Order #MD6100
Micro Order #MD6300

Cleaning Instructions 07833
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Applicable to the spirometers using 69130 Fleisch Flowhead

Hygiene Policy

The Alpha, In2itive and Micro spirometers are not designed to be, nor supplied as, sterile.

The manufacturer highly recommends a new viral/bacterial filter be used for every subject to prevent cross contamination. Using a viral/bacterial filter provides a significant level of protection of the patient, 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 manufacturers recommendations, the Alpha, In2itive or Micro spirometers are 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 viral/bacterial filter is used for every subject:

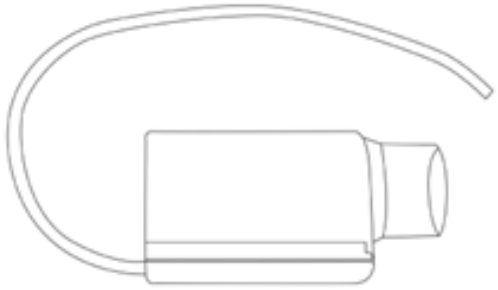

Figure 1: Flowhead Complete + Flowhead Connection Tubing

1. Disconnect both ends of flowhead tubing from the pressure tapping.
2. Use a 70% isopropyl alcohol impregnated cloth to thoroughly clean the case exterior of the flowhead and the flowhead tubing. Alternatively, a peracetic acid disinfectant wipe may be used. Visually inspect and repeat until visibly clean.
3. Reassemble by reconnecting both ends of flowhead tubing to pressure tappings on flowhead carrier and flowhead.
4. It is recommended that a calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in each devices' 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 requirement includes disinfection.

Cleaning of Flowhead Interior

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

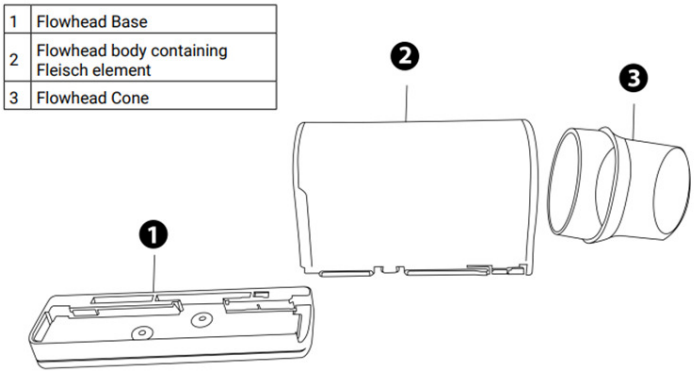

Figure 2: Disassembled Flowhead

2. Remove flowhead base from flowhead body by sliding away from the cone.
3. Remove cone from flowhead body by twisting gently. Examine for damage or contamination. If the mesh is damaged or blocked, discard and replace with a new part.

Cleaning

4. Swill the flowhead body vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at the capillaries of the Fleisch element.
5. Wash the flowhead end cap, flowhead body, flow conditioning meshes and flowhead cone in warm soapy water. Rub surfaces to remove any visible soiling.
6. Ensure all parts are visibly clean. If not visibly clean, repeat the cleaning process.
7. 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 flowhead body is immersed vertically and tap several times to remove air bubbles from the interior.
3. Soak parts for the time recommended by the disinfectant manufacturer.
4. Rinse with potable, clean water.

Table 1: Recommended Disinfectants

Disinfectant	Type of Testing
Revital-Ox® RESERT® High Level Disinfectant (Active germicide; Hydrogen Peroxide)	Vitalograph 2020: Compatibility testing to 35 hours immersion
Revital-Ox Resert High Level Disinfectant- Chemosterilant (Active Germicide; Hydrogen Peroxide)	
Resert XL HLD High Level Disinfectant (Active germicide; Hydrogen Peroxide)	
PeraSafe™ (Active germicide; Peracetic acid)	Vitalograph 2020: Compatibility testing to 44 hours immersion
Korsolex® Extra Aldehyde-Based Disinfectant (5.0% concentration for 15 minutes)	Vitalograph 2023: 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 the flowhead body, flowhead cone and flowhead base to ensure no liquid or particles remain in the holes or grooves.
2. Refer to Fig. 2: Flowhead Assembly.
3. Replace flowhead cone onto flowhead body.
4. Slide the flowhead base back onto the flowhead body toward the flowhead cone.
5. 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 devices 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
69131	Flowhead Cone (5)

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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5. Kendrick, A. H. et al (2003). "Infection control of lung function equipment: a practical approach." Respiratory Medicine 97(11): 1163-1179. DOI: https://doi.org/10.1016/S0954-6111(03)00223-3

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.

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* Available by Request