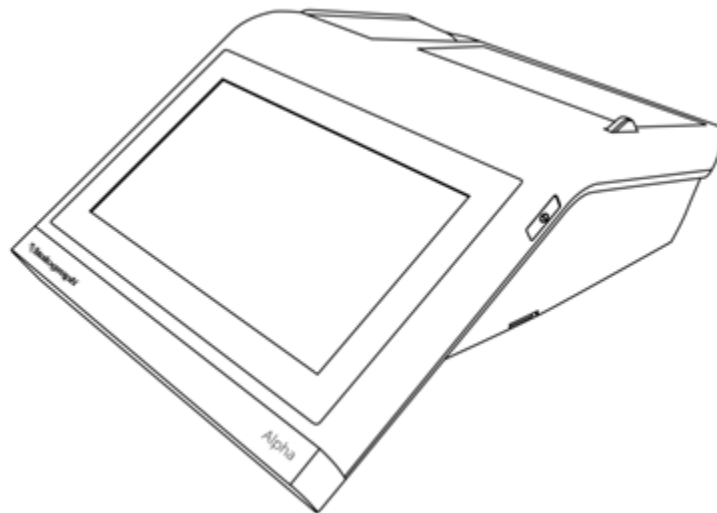




Cleaning Instructions

Applicable to:

Alpha Model MD6000



Alpha MD6000
Cleaning Instructions 07833
Issue 1

Flowhead Cleaning Instructions

Applicable to the Alpha MD6000 using 69130 Fleisch Flowhead

Hygiene Policy

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

Micro Direct highly recommends a new SpiroSafe filter be used for every patient to prevent cross contamination. Using a SpiroSafe 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 SpiroSafe filter is used for each patient. When used according to Micro Direct recommendations, the Alpha 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 objects¹.

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:



Figure 1: Flowhead Complete

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 the Alpha Instructions for Use provided with the Alpha spirometer.

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 Alpha Flowhead Interior

1. Disconnect both ends of flowhead tubing from flowhead and Alpha.

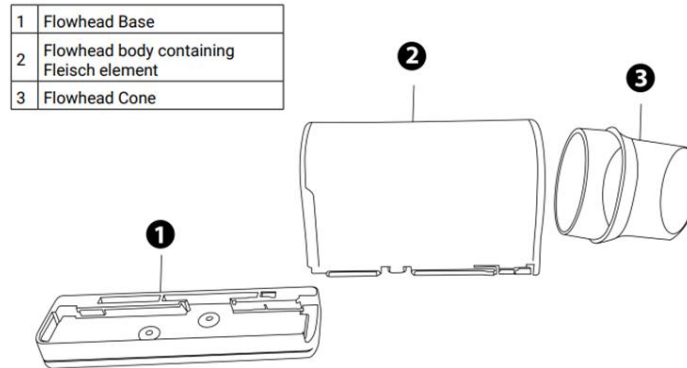


Figure 2: Disassembled Flowhead

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.
4. **Cleaning** – 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 cone and flowhead base 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

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.

Micro Direct recommends a calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in the Alpha Instructions for Use provided with the Alpha Spirometer.

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

1. Bracci, M. et al (2011). "Risk of bacterial cross infection associated with inspiration through flow-based spirometers". American Journal of Infection Control 39(1): 50-55. DOI: <https://doi.org/10.1016/j.ajic.2010.04.215>.
2. Dunne, C (2019). "Calibrated Flow Bioburden testing of Vitalograph Alpha Flow Heads" Dated 16 July 2019. Internal report for Vitalograph Ireland Ltd.*
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.
4. FDA (2018). "What are Reusable Medical Devices?" U.S. Food & Drug Administration. Accessed 4 July 2019, from <https://www.fda.gov/medical-devices/reprocessing-reusablemedical-devices/what-are-reusable-medical-devices>
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](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](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