Cleaning Instructions

Applicable to:

Micro Spirometer Model MD6300

Micro Flowhead P/N 79191
Cleaning Instructions 07799
Issue 1

Flowhead Cleaning Instructions

Applicable to the Micro Spirometer MD6300 using Fleisch Flowhead Assembly P/N 79191.

Hygiene Policy

The Micro 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 Micro Spirometer flowhead does not require decontamination where a new SpiroSafe filter is used for each patient. When used according to Micro Direct recommendations, the Micro 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.

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:

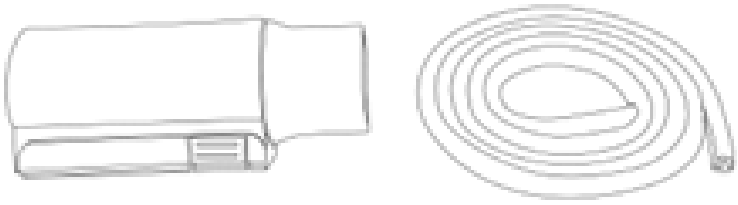

Figure 1: Flowhead and flowhead tubing

1. Use a 70% isopropyl alcohol impregnated cloth to thoroughly clean the case exterior of the flowhead and the body of the device. When cleaning the touchscreen area, wipe left to right or up and down (do not rub in a circular motion).
2. Where the remote flowhead kit has been used, disconnect both ends of flowhead tubing from pressure tappings and wipe the tubing with a 70% isopropyl alcohol wipe.
3. Reassemble by reconnecting both ends of flowhead tubing to pressure tappings on the device 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 Instructions for Use manual provided with the Micro 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 for handheld items includes disinfection.

Cleaning of Flowhead Interior

1. With the screen facing you, remove the flowhead from the body of the device by firmly pressing the button on the front of the flowhead and sliding the flowhead from left to right until it is clear of the device.

***Note**: Ensure the device body is stored in a clean, dust free environment or that the device cap from the remote flowhead adapter kit is applied while the flowhead is detached to protect delicate parts on the top of the device.*

Disassemble the Fleisch flowhead

1	Flowhead body containing Fleisch element
2	Flowhead release button
3	Flowhead cone

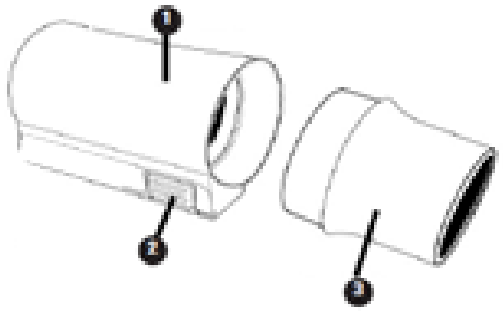

Figure 2: Flowhead Assembly

2. Remove flowhead cone from flowhead body.
3. Examine flow conditioning mesh inside the flowhead cone for damage or contamination. If mesh is damaged or blocked, discard and replace with a new part.
4. Cleaning – Swill Fleisch element vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at the capillaries of the Fleisch.
5. Wash the flowhead body 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 containing the Fleisch element and flowhead cone by immersion in the solution. Ensure the flowhead body is immersed vertically and tap gently to remove air bubbles from interiors of the Fleisch element. Flush all surfaces to remove air bubbles. 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
PeraSafe™ Instrument Sterilant (rely+On™) (Active germicide: 0.2% peracetic acid)	Vitalograph Ltd, 2015: Compatibility[2]
Revital-Ox Resert High Level Disinfectant (Active germicide: Hydrogen Peroxide)	STERIS Corporation, 2016: Compatibility and Efficacy[3]
Revital-Ox Resert High Level Disinfectant - Chemosterilant (Active germicide: Hydrogen Peroxide)	STERIS Corporation, 2016: Compatibility and Efficacy
Resert XL HLD High Level Disinfectant (Active germicide: Hydrogen Perioxide)	STERIS Corporation, 2016: Compatibility and Efficacy

Drying

1. Tap the flowhead body gently several times with the Fleisch element 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 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 and flowhead body to ensure no liquid or particles remain in the holes or grooves.
2. Referring to Fig. 2: Flowhead Assembly, replace the flowhead cone onto the flowhead body.
3. Slide the flowhead into the grooves on the top of the device body. Ensure the flowhead is pushed fully into place.

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 Instructions for Use provided with the Micro Spirometer.

2 Vitalograph (2015) "Testing the disinfecting method using Perasafe – Report Micro & In2itive Flowhead" Dated 21 July 2015. Internal report. Document Number P222_0097.

3 Steris Device Testing (2016) "External Summary Report Device Testing" Dated 20 October 2016. Report for Vitalograph Ireland Ltd. Report Number: 10250035.A Mento, OH. STERIS Corporation.

Consumables and Replacement Parts Ordering Information

Catalog No.	Description
3385	SpiroSafe Viral/Bacterial Filter (Box of 100)
3325	3-Liter Calibration Syringe
79158	Flowhead Cone (10)
79191	Flowhead Complete
79192	Flowhead Connection Tube
79163	Remote Flowhead Adapter Kit

References

1. Steris Device Testing (2016) “External Summary Report Device Testing” Dated 20 October 2016. Internal report for Vitalograph Ireland Ltd. Report Number: 10250035. A Mentor, OH. STERIS Corporation*
2. Vitalograph (2015) “Testing the disinfecting method using Perasafe – Report micro & In2itive Flowhead” Dated 21 July 2015. Internal report. Document Number P222_0097.
3. 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
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

* Data from internal reports and policies may be made available by request