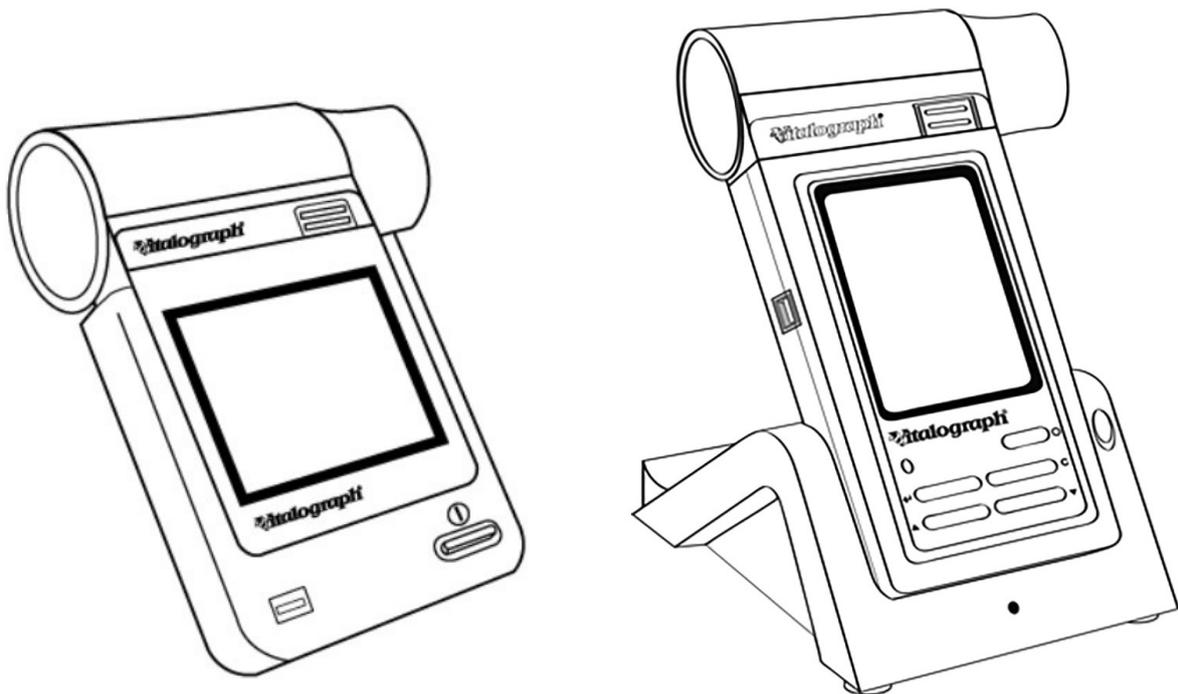




micro/In2itive Flowhead Cleaning Instructions

P/N 79191



Flowhead Cleaning Instructions

**Applicable to devices using Vitalograph Fleisch Flowhead Assembly P/N 79191
Including antecedent versions of the In2itive and micro.**

Hygiene Policy

Vitalograph spirometers are not designed to be, nor supplied as, sterile.

Vitalograph intends that a new Bacterial Viral Filter(BVF™) be used for every subject to prevent cross contamination. Using a BVF provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry manoeuvres.

The interior of a Vitalograph flowhead does not require decontamination where a new BVF is used for each subject. When used according to Vitalograph recommendations, Vitalograph spirometers are considered non-critical or low risk with regard to infection control. The exterior of the flowhead may be cleaned in line with local requirements for hand held 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 BVF is used for every subject:

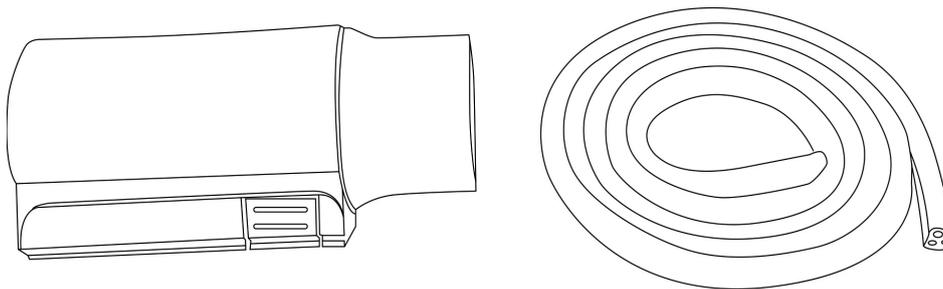


Figure1: Flowhead and flowhead tubing

1. Use a 70% isopropyl alcohol impregnated cloth to 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% IP wipe.
3. Reassemble by reconnecting both ends of flowhead tubing to pressure tappings on the device and flowhead.
4. Vitalograph recommends 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 that the flowhead interior may have become contaminated or if a user's local requirements for hand held 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 adaptor kit is applied while the flowhead is detached to protect delicate parts on the top of the device.

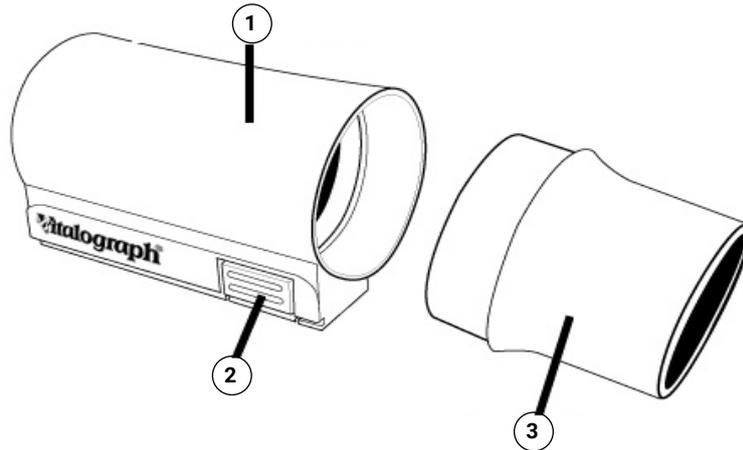


Figure 2: Flowhead Assembly

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

Disassemble the Fleisch flowhead.

1. Remove flowhead cone from flowhead body.
2. 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.

Cleaning.

3. Swill Fleisch element vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at the capillaries of the Fleisch.
4. Wash the flowhead body and flowhead cone in warm soapy water. Rub surfaces to remove any visible soiling.
5. Ensure all parts are visibly clean. If not visibly clean repeat the cleaning process.
6. 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 Peroxide)	STERIS Corporation, 2016: Compatibility and Efficacy
Korsolex® Extra Aldehyde-Based Disinfectant (5.0% concentration for 15 mins)	Vitalograph 2023: Compatibility testing to total 65 hours immersion

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 that 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 the Flowhead and Device

1. Examine Fleisch element and flowhead body to ensure that 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.

Vitalograph recommends that calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in the device instructions for use.

Consumables Ordering Information

Cat.No	Description
28350	BVF-Bacterial/ViralFilters (50)
28501	Eco BVF–Bacterial/ViralFilters (100)
28572	Eco BVF and Disposable Nose Clip (80)
36020	3-L Precision Syringe
79158	Flow Cone (10)
79191	Flowhead Complete
79192	Flowhead Connection Tube
79163	Remote Flowhead Adaptor Kit

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 Mentor, OH. STERIS Corporation.

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. Bentz, J. R. (2019). "Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final" Study Number 1138681-SGI; "Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final" Study Number 1138680-S01. Internal reports for Vitalograph Ireland Ltd dated 17 January 2019. Nelson Laboratories, Salt Lake City.*
 2. Bracci, M. et al (2011). "Risk of bacterial cross infection associated with inspiration through flowbased spirometers." American Journal of Infection Control 39(1): 50-55. DOI: <https://doi.org/10.1016/j.ajic.2010.04.215>.
 3. Dunne, C (2019). "Calibrated Flow Bioburden testing of Vitalograph Alpha Flow Heads" Dated 16 July 2019. Internal report for Vitalograph Ireland Ltd.*
 4. 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.
 5. 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/whatare-reusable-medical-devices>
 6. 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)
 7. 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).
 8. 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/>
 9. 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*