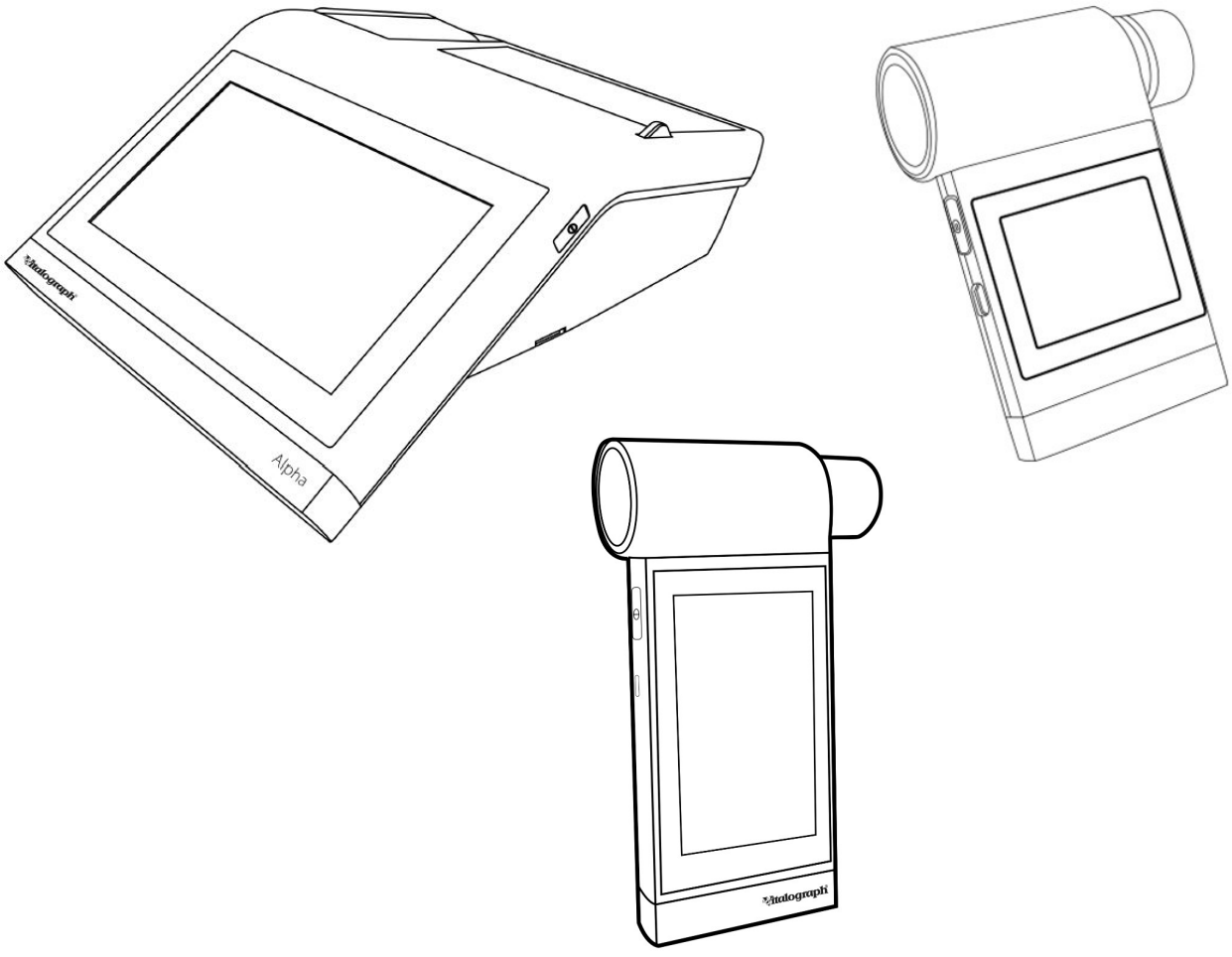
Cleaning Instructions

Applicable to
Model 6000 Alpha,
6300 micro
& 2120 In2itive, In2itive eDiary



Flowhead Cleaning Instructions

Applicable to the Vitalograph 6000 Alpha, 6300 micro and 2120 In2itive and In2itive eDiary using 83126 Vitalograph Fleisch Flowhead

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 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 BVF is used for every subject:

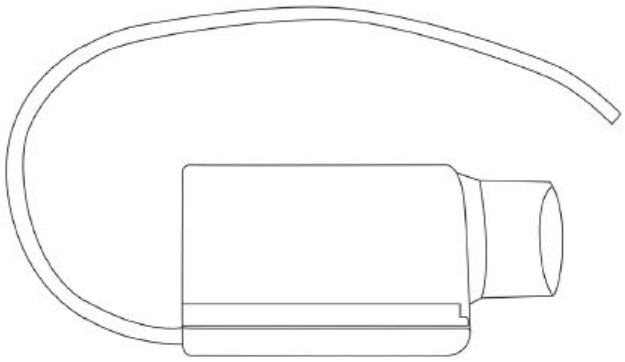


Fig 1: Flowhead Complete + Flowhead Connection Tubing – Alpha, or with remote flowhead adaptors for micro, In2itive and In2itive e-Diary. For direct connection on micro, In2itive and In2itive e-Diary the flowhead body slides onto the device body.

1. If tubing is present to connect to device (Alpha, or remote flowhead for micro, In2itive) disconnect both ends of flowhead tubing from pressure tapping.
   If connected directly to a micro or In2itive, In2itive e-Diary slide the Flowhead off by holding the device in one hand (screen facing up) and sliding the flowhead to the right with the other hand, off the device.
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 device and Flowhead base, if tubing is present. If connected directly to a micro or 2120 slide the Flowhead back on to the device.
4. Vitalograph recommends that a 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.

1 Vitalograph (2019), "Hygiene Policy". Internal Vitalograph policy. Document number: SOP_0523.

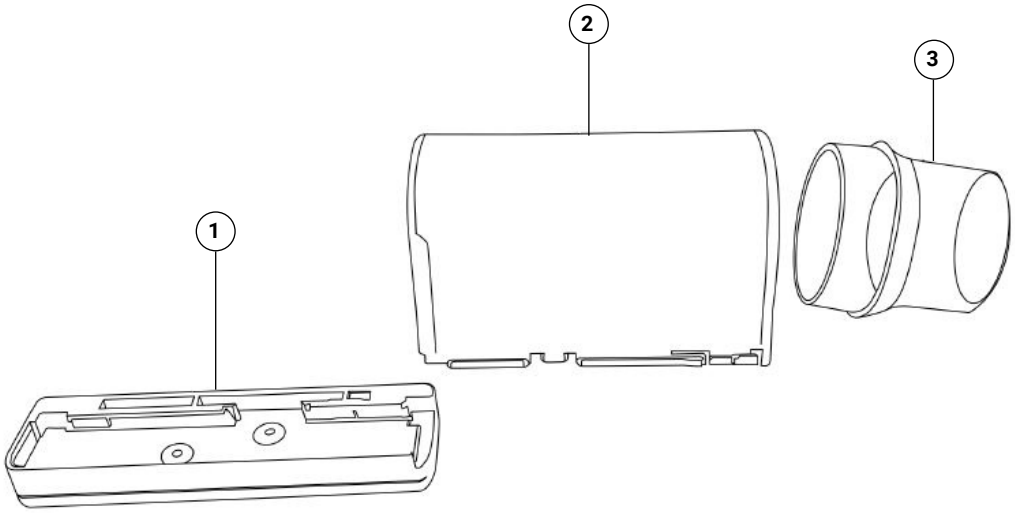
Decontamination by Cleaning and Disinfection

This is the recommended cleaning method where the user suspects that the flowhead interior may have become contaminated or if a user's local requirement includes disinfection.

Cleaning of Flowhead Interior

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

Disassemble the Fleisch flowhead:



1.	Flowhead Base – Alpha, remote Flowhead connector for micro, In2itive, In2itive e-Diary Or direct connection to device – micro, In2itive, In2itive e-Diary
2.	Flowhead body containing Fleisch element
3.	Flowhead Cone

Figure 2: Disassembled Flowhead

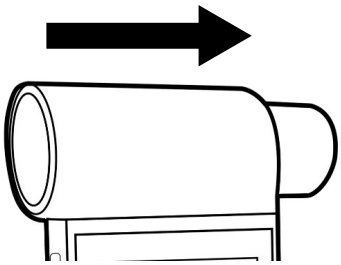


Figure 3: Removing Flowhead from micro, In2itive, In2itive eDiary

2. For connection with tubing on Alpha, remote Flowhead for micro, In2itive, In2itive e-Diary, remove the Flowhead base by sliding away from the cone.
3. For direct connection to the device, remove the flowhead by holding the device in one hand (screen facing up) and sliding the flowhead to the right with the other hand, off the device in the direction of the arrow shown in figure 3.
4. 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:

5. Swill the flowhead body vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at the capillaries of the Fleisch element.
6. 6. Wash the flowhead base (if present), flowhead body, 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.

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 vertically and tap several times to remove air bubbles from the interior.
3. Soak parts for the time period recommended by the disinfectant manufacturer.
4. Rinse with potable, clean water.

Table 1: Recommended Disinfectants

Disinfectant	**Type and level 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™ Instrument Sterilant (Rely+On™) (Active germicide: 0.2% peracetic acid)	Vitalograph 2020: Compatibility testing to 44 hours immersion
Korsolex® Extra Aldehyde-Based Disinfectant (5.0% concentration for 15 mins)	Vitalograph 2023: Compatibility testing to total 65 hours immersion

Drying

1. Tap and shake the flowhead body up and down firmly several times with the 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 Fleisch Flowheads

1. Examine the Flowhead body, Flowhead cone and and if present, Flowhead base to ensure that 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. 4. Slide the Flowhead base back onto the Flowhead body, towards the Flowhead cone (for Alpha or remote flowhead on micro, In2itive, In2itive e-Diary) or slide Flowhead body directly onto device (for micro, In2itive, In2itive e-Diary).
5. Reconnect flowhead tubing.

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
28553	Eco BVF with Bite-Lip and Disposable Nose Clip (75)
28350	BVF - Bacterial/Viral Filters (50)
28501	Eco BVF – Bacterial/Viral Filters (100)
28572	Eco BVF and Disposable Nose Clip (80)
36020	3-L Precision Syringe
69131	Flowhead cone (5)

References

1. 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
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.
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*