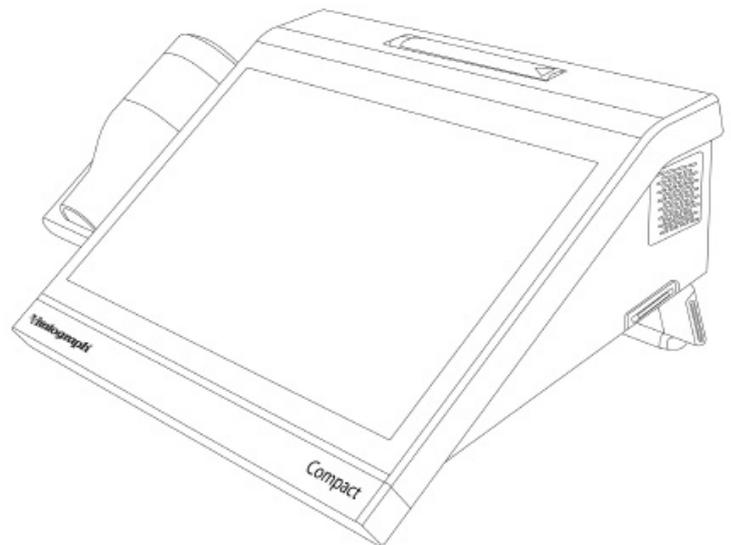
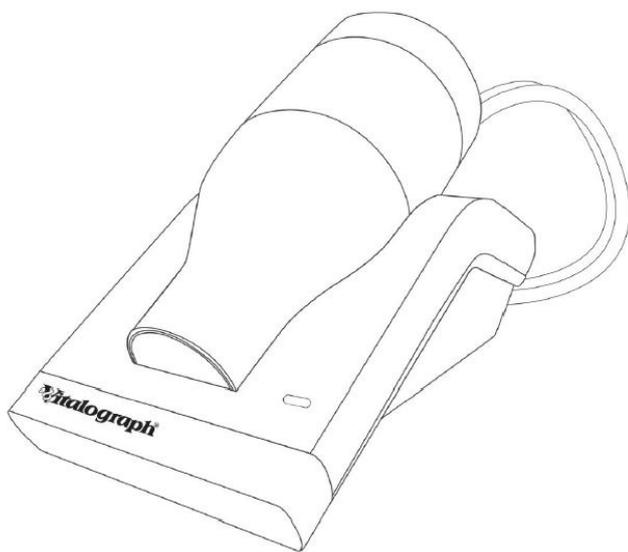




Cleaning Instructions

Applicable to Vitalograph
Model 6800 Pneumotrac,
Model 6600 Compact



Flowhead Cleaning Instructions

Applicable to Vitalograph Model 6800 Pneumotrac, Model 6600 Compact using Vitalograph Number 4 Fleisch Flowhead Assembly PN 77930

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:

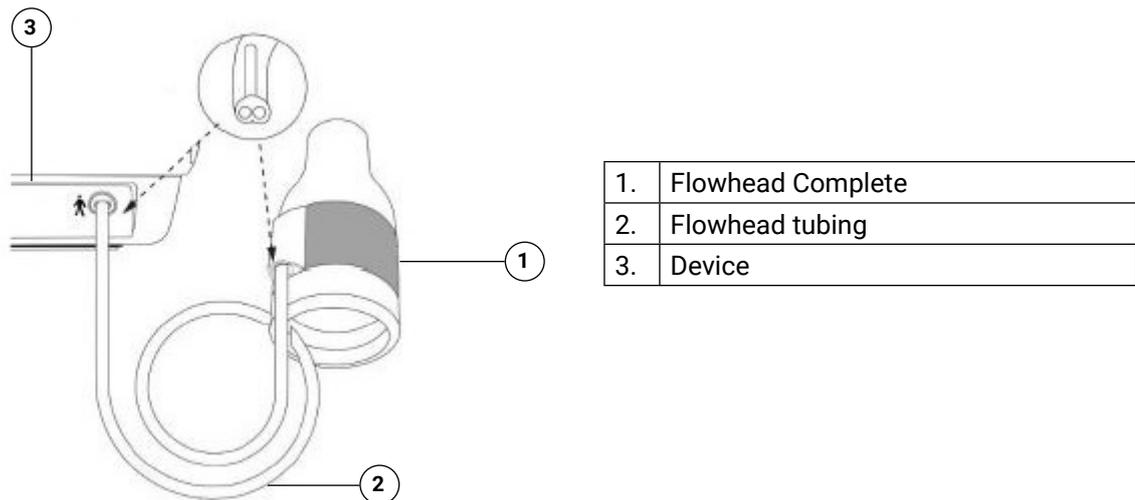


Figure 1: Flowhead Complete, Flowhead Connection Tubing and Device

1. Disconnect both ends of flowhead tubing from the pressure ports on the flowhead and the device.
2. Use a 70% isopropyl alcohol impregnated cloth to thoroughly clean the case exterior of the flowhead and the flowhead tubing. Visually inspect and repeat until visibly clean.
3. Reassemble by reconnecting both ends of flowhead tubing to the pressure ports on flowhead and 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.

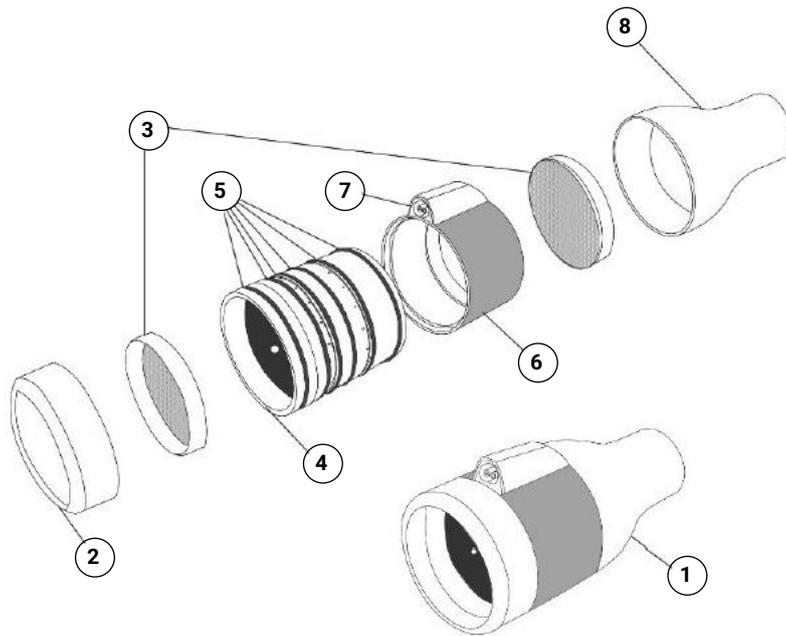
Decontamination by Cleaning and Disinfection

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 Alpha.

Disassemble the Fleisch flowhead:



1.	Flowhead Complete
2.	Flowhead End Cap
3.	Flow Conditioning Mesh (x2)
4.	Fleisch Element Assembly
5.	O-Ring (x6)
6.	Flowhead Body Tube
7.	Pressure Ports
8.	Flowhead Cone
	Lubrication: Silicone Grease

Figure 2: Flowhead Assembly

2. Remove flowhead cone and flowhead end cap.
3. Remove flow conditioning meshes from inside the cone and end cap. Examine for damage or contamination. If meshes are damaged or blocked, discard and replace with new parts.
4. Remove flowhead body tube from Fleisch element assembly. To do this, firstly remove O-Ring from the smaller diameter side of the fleisch element assembly (same side the flowhead cone was removed from) and then place the Fleisch element assembly on a hard, flat surface with the largest diameter at the top (this is the end that the flowhead end cap was removed from). Push down on the flowhead body tube with thumbs and forefingers until it reaches the flat surface. A final pulling and twisting action will separate the parts.

Cleaning:

5. Swill Fleisch element assembly vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at capillaries.
6. Wash the flowhead end cap, 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.

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 the flowhead body is immersed vertically and tap several times to remove air bubbles from the interior. Soak parts for the time period recommended by the disinfectant manufacturer.
3. 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 2021: 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 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.

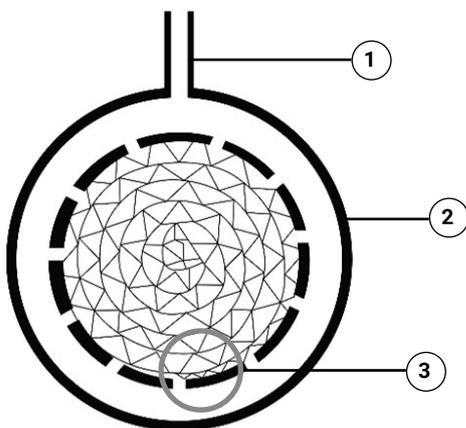
Reassembly of Fleisch Flowheads

1. Examine Fleisch element assembly and flowhead body tube to ensure that no liquid or particles remain in the holes or grooves.
2. Check O-rings for damage and ensure correct positioning within the grooves.
3. Apply a very small amount of silicone grease to the O-Rings (4 centre o-rings only, 2 end o-rings must **not** be greased). Wipe off any visible amounts of grease. Ensure that the tiny annular holes on the outside of the Fleisch element assembly are not blocked.
4. Refer to Figure 2: Flowhead Assembly to view placement of parts for reassembly.
5. Replace flowhead body tube onto Fleisch element assembly. Ensure the pressure ports on the flowhead body tube are nearest to the largest diameter (this is the end that the flowhead end cap was removed from) of the Fleisch element assembly.



Figure 3: Replacing the flowhead body onto the Fleisch element

6. Ensure that flowhead body tube is pushed fully home, and rotate it so that the pressure ports are approximately 180° opposite the end of the Fleisch element coil.



1.	Port Pressure Tappings
2.	Flowhead Body
3.	End of the Fleisch Element Coil

Figure 4: Orientating the Fleisch element coil at 180° to the pressure ports

7. Fit flow conditioning meshes to both flowhead cone and flowhead end cap as shown in Figure 2.
8. Re-fit the end O-ring that was removed from the smaller diameter side of the fleisch element assembly (same side the flowhead cone was removed from) which was specified in step 4 of disassembly of flowhead.
9. Push flowhead end cap onto the larger diameter of the Fleisch element assembly and push flowhead cone onto the smaller diameter.
10. 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

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)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip and Disposable Nose Clip (75)
36020	3-L Precision Syringe
77933	Flow Conditioning Mesh (10) (Replacement)
77934	Flowhead Complete (Replacement)
77939	Flowhead Cone (Replacement)
77938	Flowhead End Cap (Replacement)
79192	Flowhead Connection Tube (Replacement)
2120013	O-Ring (15) (Replacement)
41543	USB Cable (Replacement)
77935	Feet (Replacement)
32254SPR	Silicone Grease Pack (Replacement)

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

