

Hygiene and Cleaning of the Vitalograph Alpha III

General Recommendation

To reduce the risk of cross infection the use of SafeTway mouthpieces for expiratory only testing, or Bacterial Viral Filters for Inspiratory/Expiratory testing, is recommended.

A Risk Assessment should be carried out to assess the risks presented to both operator and subject, and an action plan devised by the facility to minimise the chance of cross infection occurring, particularly where known-infectious or immuno-deficient subjects are being tested.

An assessment should be made of methods of decontamination available to the operator, and their effectiveness against potential risks - a table of materials used in the Vitalograph ALPHA is provided below to assist in this.

It is recommended that in cases of high risk with no effective disinfection methods available, that the contaminated parts are disposed of. For this device, the Flowhead Assembly: FLOWHEAD COMPLETE and the FLOWHEAD CONNECTION TUBE.

Routine Practice

A new mouthpiece (either SafeTway or Bacterial Viral Filter) should be used for each subject. A delay of at least 5 minutes should be allowed between subjects to allow settling of previously aerosolised particles in the measuring device.

It is recommended that the Flowhead Assembly be regularly cleaned according to the guidelines of the user's facility.

In the event of visible contamination to the FLOWHEAD CONES or FLOWHEAD ELEMENT - these should be cleaned and disinfected.

The FLOW CONDITIONING MESHES should be replaced regularly. The frequency of this is dependent on the Facilities' Risk Assessment, usage, and test environment, but should be at least monthly or every 100 subjects (500 blows). They should also be replaced in the event of damage, or if visibly contaminated.

It is recommended to replace the complete Flowhead Assembly: FLOWHEAD COMPLETE and FLOWHEAD CONNECTION TUBE at least annually.

All parts of the Vitalograph Alpha require **cleaning**, i.e. the removal of visible particulate contamination. The parts of the Vitalograph Alpha that make up the flowhead also require **disinfecting**.

Hygiene

It is vital for the user to set guidelines for protective hygiene measures whilst performing spirometry testing. There are three main potential sources of cross contamination, skin contact; aerosolised particles and saliva/body fluids. By far the most important is the last item – a minimum requirement is to use a new disposable mouthpiece for each subject tested. We recommend using the SafeTway mouthpiece for expiratory tests or the Bacterial/Viral Filter for testing involving inspiratory and expiratory manoeuvres. We also recommend that a delay of at least 5 minutes be allowed between subjects. This allows aerosolised organisms to be removed by gravitational sedimentation between tests. (*Am J Respir Crit Care Med* Vol 159, pp 610-612, 1999)

Cleaning Instructions

All parts of the Vitalograph Alpha require regular **cleaning**, i.e. the removal of visible particulate contamination. The parts of the Vitalograph Alpha that make up the flowhead also require **disinfecting**. Vitalograph recommends that cleaning and disinfecting should normally be carried out on a weekly basis. In addition to a weekly cleaning and disinfection cycle, Vitalograph recommends cleaning and disinfection of equipment to be carried out after use on infected subjects or prior to use on immuno-compromised subjects. The user must determine what level of disinfection is appropriate and acceptable in any particular circumstance.

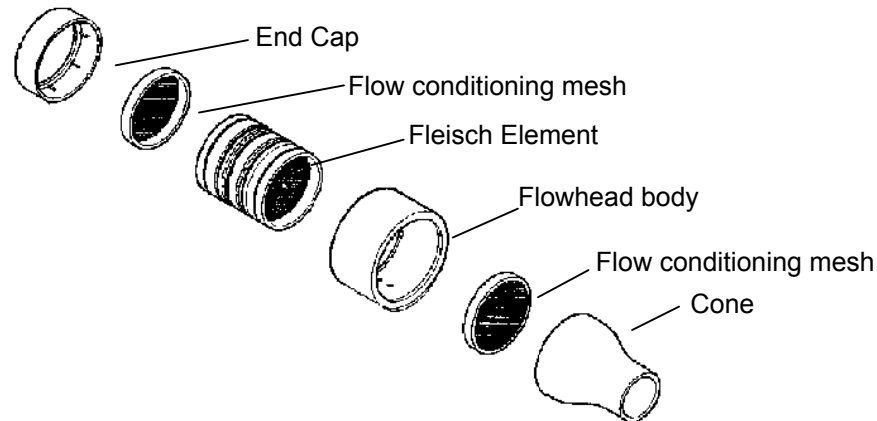
Cleaning/Disinfecting- Recommendations Chart

Part	Material	Clean/Disinfect	Autoclave Possible?	Recommended Disinfectants
Case Exterior	Polystyrene high density foam with epoxy paint	Clean	No	Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection.
Display	Glass	Clean	No	
Screen Surround	ABS	Clean	No	
Keypads	ABS	Clean	No	
Flowhead Tubing	Silicone Rubber	Clean	Viable	
Flowhead Body	Aluminium	Clean	Viable	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes. (see recommended cleaning/disinfection method for the Vitalograph Alpha Flowhead) The flowhead will also withstand autoclaving at 134°C for 3 minutes.
Fleisch Element Assembly	Aluminium, Stainless Steel, Acetal	Clean & Disinfect	Viable	
Flowhead Cone	TPX	Clean & Disinfect	Viable	
Flowhead Mesh Housing	Anodised Aluminium	Clean & Disinfect	Viable	
'O' Rings	Viton	Clean & Disinfect	Viable	
Flowhead Conditioning Mesh	Acetal and Polyester	Disinfect Dispose	No	
Flowhead End Cap	TPX	Clean & Disinfect	Viable	

Definitions of cleaning and disinfection are as defined in "Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, 1996" Recommendations for chemical disinfectants are derived from the PHLS publication "Chemical Disinfection In Hospitals" 1993.

Disassembling the Flowhead for Cleaning and Disinfecting

1. Remove the cone and the end cap from the flowhead.
2. Remove the flow conditioning meshes from inside the cone and the end cap, and either clean or discard them.
3. Hold the unit case with one hand and the exposed part of the Fleisch element with the other. Pull and twist the Fleisch element to remove it entirely from the case.



- ▶ Clean each separate part of the flowhead by washing in a mild detergent to remove particulate contamination. To clean the Fleisch element, swill vigorously in water with mild detergent. Do not attempt to "rub" or "scrub" at capillaries. If the flow conditioning meshes appear dirty or blocked they should be thrown away and replaced. The flowhead body does not require disinfection, but may be disinfected with the rest of the flowhead for convenience.
- ▶ Rinse with clean water.
- ▶ Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes. Prepare disinfectant solution as directed in the manufacturer's guidelines.
- ▶ Rinse with hot water to aid drying.
- ▶ Leave to dry completely before reassembling. Drying the Fleisch element assembly may require placing it in a warm place overnight. A drying cabinet is ideal, alternatively another heat source could be used.
- ▶ Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection for the case exterior, display, screen surround, flowhead tubing, flowhead body and keypads. Repeat at least weekly to prevent build-up of grime from normal handling and use.

Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals or equipment.

Reassembling the Fleisch Flowhead

1. Ensure that no liquid remains in the holes, grooves or pressure tappings of the Fleisch element assembly.
2. If replacing the sealing rings, check for damage and very lightly grease each ring before replacing them in the housing grooves. (Molycote 55 silicone grease or its equivalent is recommended.)
Make sure you remove excess grease as it can cause blockage of the holes in the flowhead body, resulting in false readings.
3. Place cleaned or new flow conditioning meshes into the cone and the end cap.
4. When re-assembling ensure that the BLUE PRESSURE TAPPING is closest to the wider end of the element assembly. Also ensure that the flowhead body is pushed fully home.
5. When attaching the FLOWHEAD CONNECTION tubing ensure that the matching coloured pressure tappings on the FLOWHEAD and the Vitalograph-ALPHA are connected to each other. When connecting the double tubing from the flowhead to the ports on the side of the unit it is very important that the tubing is pushed fully home over the ports. This is critical to obtain accurate results from the unit.
6. When the flowhead is reassembled, an accuracy check must be performed.