

Vitalograph 4000 Series Products Used for in Clinic Testing Cleaning and Disinfecting the Respiratory Monitor

Daily Procedures

A new mouthpiece (either SafeTway[®] or BVF[™]) should be used for each subject. A delay of at least 5 minutes should be allowed between subjects to allow settling of previously aerosolized particles in and around the measuring device.

Monthly Procedures

It is recommended that the device be regularly cleaned according to guidelines set by the user's facility. The disinfection materials and procedures applied in the users' facility may be more appropriate than the methods outlined below. In the event of visible contamination of the flowhead element, it should be cleaned or disinfected as described in the accompanying table. The device should be replaced in the event of damage, or if visibly contaminated.

The frequency of cleaning and disinfecting is dependent on the facility's risk assessment, usage, and test environment, but it should be at least monthly or every 100 subjects (300 blows).

Annual Procedures

It is recommended that the device be replaced annually or test and calibration serviced at least annually. There is no planned preventive maintenance for this medical device.

Table of Materials Used & Cleaning/Disinfection Methods

This listing of materials used is given to provide clinical users with information to allow the assessment of other cleaning and disinfecting procedures available in the facility on this device.

| Part | Material | Clean/ Disinfect | Autoclave Possible? | Recommended Disinfectants |
|----------------------------------|--------------------|-------------------------|------------------------|--|
| SafeTway mouthpiece or BVF | Cardboard / ABS | Dispose – single use | No | Dispose – single use |
| Case Exterior | ABS | Clean | No | Wiping with a 70% isopropyl alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection. This may be preceded by cleaning with an anti-static foam cleaner if necessary. |
| Fascia | PMMA/PET | Clean | No | |
| Removable flowhead | ABS, | Clean | No | Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes (see following section for recommended cleaning/disinfection method for the |

All external parts of the Respiratory Monitor require **cleaning**, i.e. the removal of visible particulate contamination. The parts of the device that make up the flowhead, which comes into contact with the breath of the subjects being tested, also require **disinfecting**. This device is not designated as a 'sterile' device.

Removing the Flowhead for Cleaning and Disinfecting

1. Remove the flowhead from the body with a sharp pulling motion.
2. Clean the flowhead by washing in a mild detergent to remove particulate contamination, taking care not to touch the moving vanes. Swill vigorously in water with mild detergent. Do not attempt to “rub” or “scrub” in the area of the vanes. Rinse with clean water.
3. 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 warm water for faster drying.
4. Leave it to dry completely before reassembling. Drying the flowhead may require placing it in a warm place overnight. A drying cabinet is ideal.



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 and keys. Repeat this at least weekly to prevent a 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.

Reassemble the flowhead by pushing back on until it ‘clicks’ into position. Ensure that the flowhead is pushed fully home.

When the flowhead is reassembled, it is good practice with any respiratory measuring device for an accuracy check be performed using a Precision Syringe, with the volume delivered in less than one second. An accuracy of +/- 3% should be achieved.



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.

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