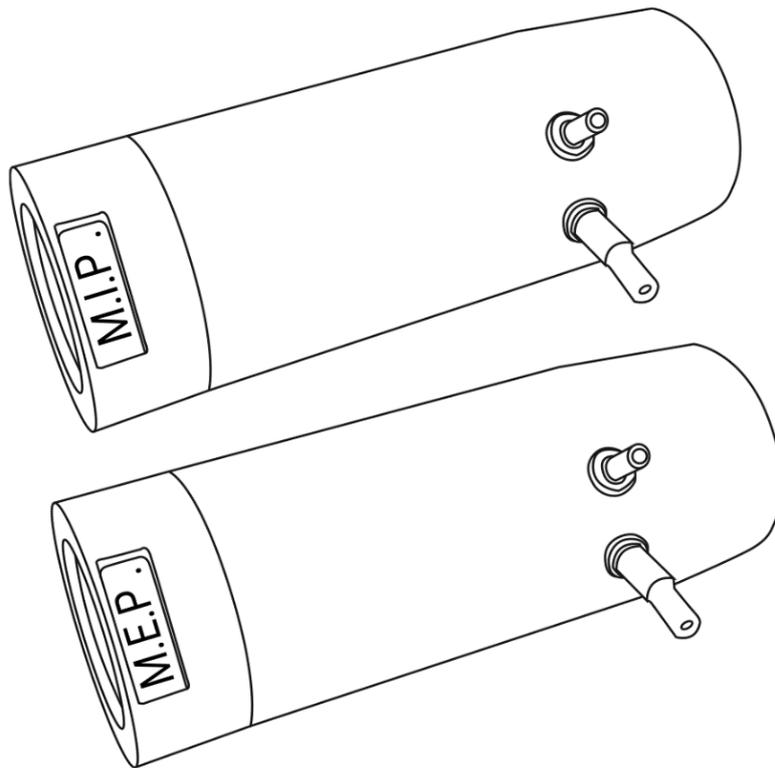




Cleaning Instructions

Applicable to:

MIP and MEP Flowheads as used with
Vitalograph Pneumotrac™ and COMPACT™



MIP and MEP Flowhead Cleaning Instructions

Applicable to devices using 77652 Vitalograph MIP/MEP 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 objects¹.

If a higher level of decontamination is required, then cleaning may be followed by disinfection as outlined below.

Cleaning the MIP and MEP Flowhead Exterior

Recommended cleaning method where a new BVF is used for every subject:

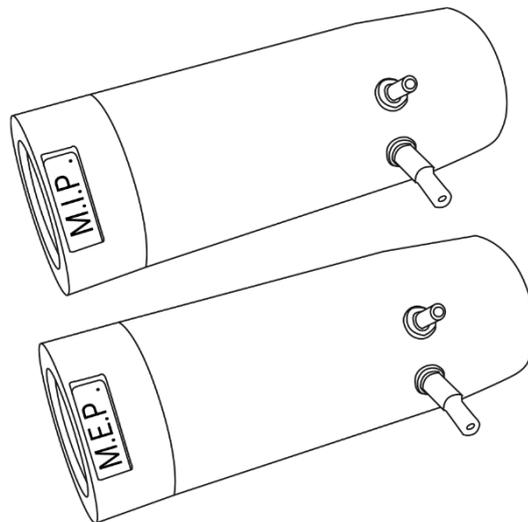


Fig 1: MIP and MEP Flowhead Assemblies Complete

1. Disconnect both ends of flowhead connection tube from pressure tapping.
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 visually clean.
3. Reassemble by reconnecting both ends of the flowhead connection tube. Attach the white end of the Flowhead connection tube to the silver pressure tapping on the MIP/MEP Flowhead. The clear end of the Flowhead connection tube is connected to the push in connector adjacent to the spirometry connector on the Pneumotrac or COMPACT device body.

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: Applicable to MIP and MEP Flowhead

Disassemble the flowhead(s):

1. Unscrew the MIP or MEP end cap from the cone.
2. Remove the One-Way valve from the cone and examine it for damage. If it is damaged, discard and replace with a new part (Reference Consumables and Accessories).
3. Carefully separate the hard plastic housing from the soft silicone one-way valve.
4. Visual inspection of all parts is recommended on a routine basis.

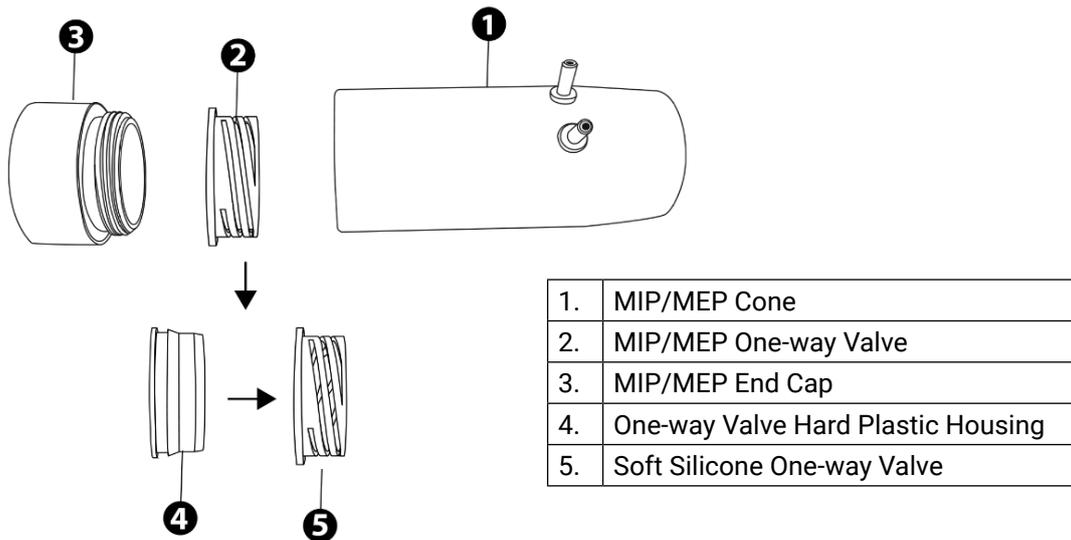


Fig 2: Disassembled MIP or MEP Flowhead

Cleaning:

5. Swill the soft silicone one-way valve in warm soapy water. Do not attempt to "rub" or "scrub" the delicate silicone.
6. Wash the MIP or MEP flowhead cone, end cap and one-way valve hard plastic housing in warm soapy water. Gently rub surfaces to remove any visible soiling.
7. Ensure all parts are visually clean. If not visually 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 the MIP or MEP flowhead cone, end cap, one-way valve hard plastic housing and soft silicone one-way valve by immersion in the solution. 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 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™ (Active germicide; Peracetic Acid) | Vitalograph 2021: 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. Arrange disassembled parts separately so that any remaining water can drain and air can circulate, e.g. on a drying rack. Drying the flowhead parts may require leaving it in a warm place overnight. If available, a drying cabinet is ideal.
2. Leave to dry completely before reassembling.

Reassembly of MIP and MEP Flowheads

- Carefully re-assemble the Soft Silicone One-way Valve with the Hard Plastic Housing, taking care not to damage the Soft Silicone One-way Valve. **Note: It is important that the Soft Silicone One-way Valve is fitted to the Cone in the correct orientation for the different MIP and MEP flowheads. Refer to the images below for the correct orientations.** The version of the flowhead is marked on the End Cap. Ensure the Soft Silicone One-way Valve is fully seated and centered into the groove on the Cone.

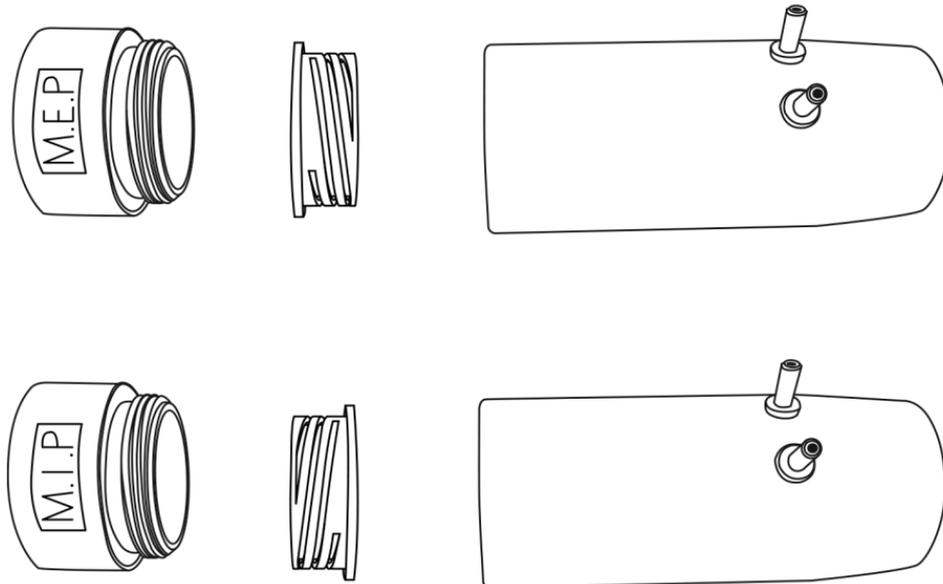


Figure 3: Orientation of one-way valve in MIP and MEP flowheads

- Screw the MIP/MEP end cap to the cone. Ensure this is fully screwed home and hand tightened.
- Attach the white end of the Flowhead connection tube to the silver pressure tapping on the MIP/MEP Flowhead.
- The clear end of the Flowhead connection tube is connected to the push in connector adjacent to the spirometry connector on the Vitalograph Pneumotrac or COMPACT device.

To ensure the MIP or MEP Flowhead has been correctly re-assembled, attach a new BVF to the flowhead that has been cleaned and check the flowhead as detailed below:

- For the MEP Flowhead, fully inhale through the Flowhead. The Soft Silicone One-way Valve should open, and no resistance should be felt. Then attempt to exhale through the flowhead. The Soft Silicone One-way Valve should close and a significant resistance should be felt. The only air escaping should be through the MIP/MEP Pressure Vent on the Flowhead.
- For the MIP Flowhead, fully exhale through the Flowhead. The Soft Silicone One-way Valve should open, and no resistance should be felt. Then attempt to inhale. The Soft Silicone One-way Valve should close and a significant resistance should be felt. The only air entering should be through the MIP/MEP Pressure Vent on the Flowhead.

Consumables Ordering Information

| Cat. No | Description |
|---------|--|
| 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 |
| 77652 | MIP MEP Flowheads (Replacement) |
| 77651 | MIP MEP Connection Tube (Replacement) |
| 77653 | Silicone One-way Valve (Pack of 2) (Replacement) |

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