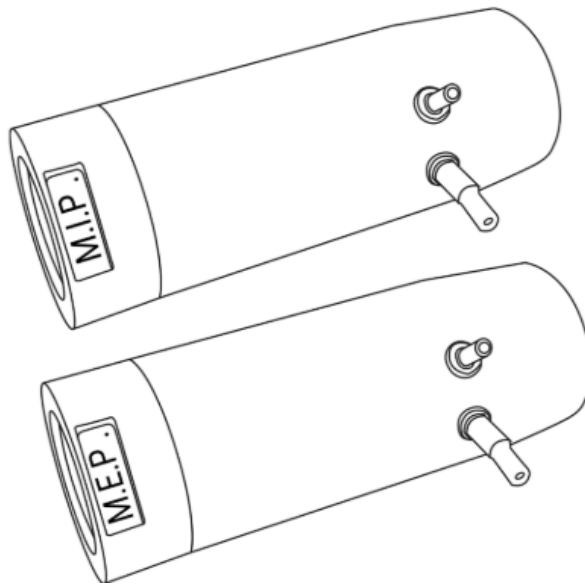




Spirometer Cleaning Instructions

Applicable to

MIP and MEP Flowheads as used with the Pneumotrac
Spirometer



Cleaning Instructions 07832
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Flowhead Cleaning Instructions

Applicable to the devices using order #MD6850 MIP/MEP Flowhead

Hygiene Policy

The Pneumotrac w/RMS is not designed to be, nor supplied as, sterile.

The manufacturer highly recommends a new viral/bacterial filter be used for every subject to prevent cross contamination. Using a viral/bacterial filter provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry maneuvers.

The interior of a flowhead does not require decontamination where a new viral/bacterial filter is used for each subject. When used according to the manufacturer's recommendations, Pneumotrac w/RMS is considered non-critical or low risk regarding infection control. The exterior of the flowhead may be cleaned in line with your local requirements for handheld 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 viral/bacterial filter is used for every subject:

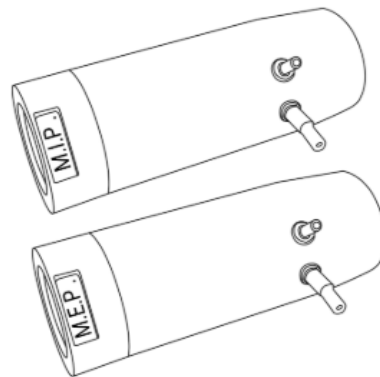


Fig 1: MIP and MEP Flowhead Assemblies Complete

1. Disconnect both ends of flowhead tubing from the 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 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 base.

Decontamination by Cleaning and Disinfection

This is the recommended cleaning method where the user suspects the flowhead interior may have become contaminated or if the 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 the parts is recommended on a routine basis.

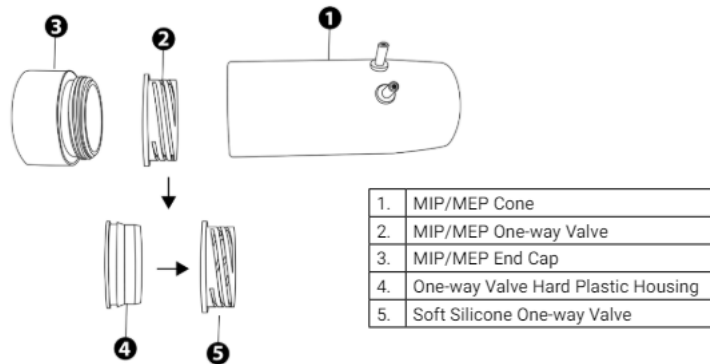


Fig 2: Disassembled MIP or MEP Flowhead

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.
3. Soak parts for the time period recommended by the disinfectant manufacturer.
4. Rinse with potable, clean water.

Table 1: Recommended Disinfectants

Disinfectant	Type 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™ (Active germicide; Peracetic acid)	Vitalograph 2021: Compatibility testing to 44 hours immersion
Korsolex® Extra Aldehyde-Based Disinfectant (5.0% concentration for 15 minutes)	Vitalograph 2023: Compatibility testing to total 65 hours immersion

Drying

1. Arrange disassembled parts separately so 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 Fleisch Flowhead

1. 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 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.

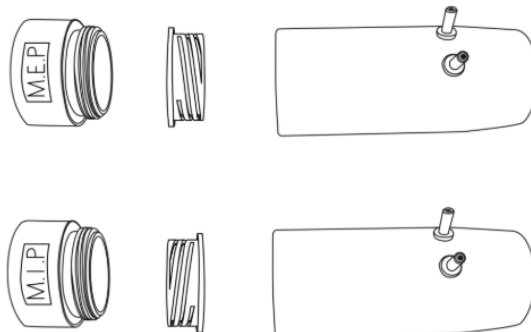


Figure 3: Orientation of one-way valve in MIP and MEP flowheads

2. Screw the MIP/MEP end cap to the cone. Ensure this is fully screwed home and hand tightened.
3. Attach the white end of the flowhead connection tube to the silver pressure tapping on the MIP/MEP flowhead.
4. The clear end of the flowhead connection tube is connected to the push in connector adjacent to the spirometry connector on the base.

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

1. 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.
2. 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 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.

Consumables and Replacement Parts Ordering Information

Catalog No.	Description
28551	Eco BVF Bite On DNC (60/box)
3325	3-Liter Calibration Syringe
NPROBE02	Nasal Probe, Small (Pack of 10)
NPROBE03	Nasal Probe, Medium (Pack of 10)
NPROBE04	Nasal Probe, Large (Pack of 10)
77652	MIP MEP Flowheads (Replacement)
77651	MIP MEP Connection Tube (Replacement)
77653	Silicone One-Way Valve (Pack of 2) (Replacement)

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* Available by Request