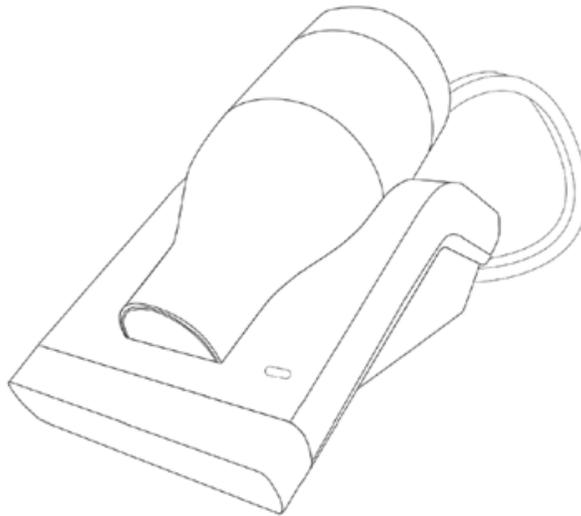




Cleaning Instructions

Applicable to:

Pneumotrac Model MD6800



Pneumotrac MD6800
Cleaning Instructions 07834
Issue 1

Flowhead Cleaning Instructions

Applicable to MD6800 Pneumotrac pictured below.

Hygiene Policy

The Pneumotrac spirometer is not designed to be, nor supplied as, sterile.

Micro Direct highly recommends a new SpiroSafe filter be used for every patient to prevent cross contamination. Using a SpiroSafe 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 SpiroSafe filter is used for each patient. When used according to Micro Direct recommendations, the Pneumotrac spirometer is considered non-critical or low risk regarding infection control. The exterior of the flowhead may be cleaned in line with your facility's requirements for handheld objects¹.

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 SpiroSafe filter is used for every subject:

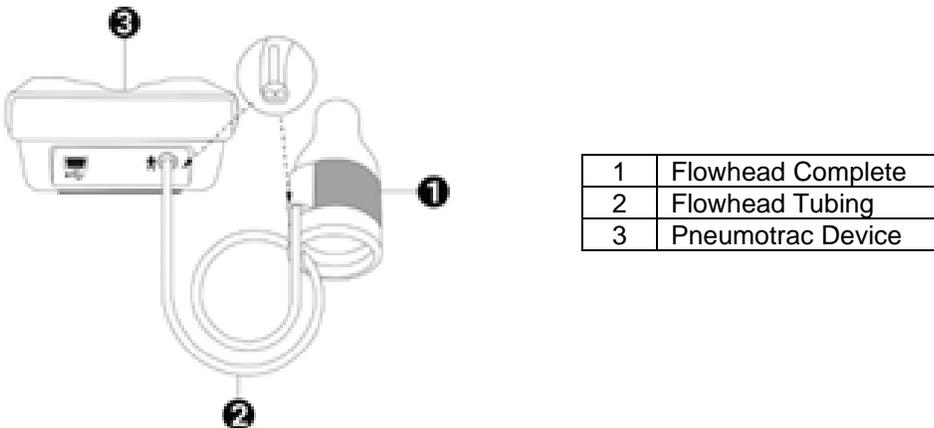


Figure 1: Flowhead Complete, Flowhead Tubing and Pneumotrac Device

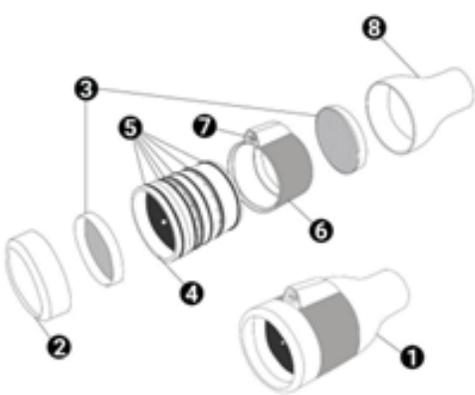
1. Disconnect both ends of flowhead tubing from the pressure ports on the flowhead and the device.
2. Use a 70% isopropyl alcohol impregnated cloth to thoroughly clean the case exterior of the flowhead and the flowhead tubing. Visually inspect and repeat until visibly clean.
3. Reassemble by reconnecting both ends of flowhead tubing to the pressure ports on flowhead and the device.
4. It is recommended that calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in the Spirotrac® software instructions for use provided with the Pneumotrac device.

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 facility requirements include disinfection.

Cleaning of Flowhead Interior

1. Disconnect the flowhead tubing from the flowhead and the device.



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, first remove the 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 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.
5. **Cleaning** – 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 tube, 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 Fleisch element assembly, flowhead end cap, flowhead body tube, flow conditioning meshes and flowhead cone by immersion in the solution. Ensure Fleisch element assembly and flowhead body are immersed vertically and tap to remove air bubbles from interiors. Flush all surfaces to remove air bubbles. Soak parts for the time recommended by the disinfectant manufacturer.
3. Rinse with potable tap water.

Table 1: Recommended Disinfectants

Disinfectant	Type of Testing
Revital-Ox Resert High Level Disinfectant (Active germicide; Hydrogen Peroxide)	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)	2021: Compatibility testing to 44 hours immersion

Drying

1. Tap the Fleisch element gently several times with the capillaries formed by the coil orientated vertically to remove excess water.
2. Arrange disassembled parts separately so any remaining water can drain and air can circulate, e.g., on a drying rack. Drying the Fleisch element assembly may require leaving it in a warm place overnight. If available, a drying cabinet is ideal.
3. Leave to dry completely before reassembling.

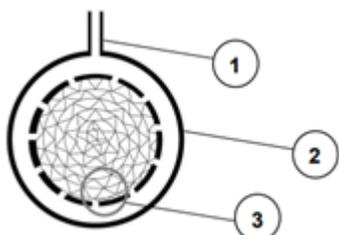
Reassembly of Fleisch Flowhead

1. Examine Fleisch element assembly and flowhead body tube to ensure 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 center O-rings only, 2 end O-rings must **NOT** be greased). Wipe off any visible amounts of grease. Ensure 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 the flowhead end cap was removed from (of the Fleisch element assembly).



Figure 3: Replacing the flowhead body onto the Fleisch element

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



1	Pressure Ports
2	Flowhead Body Tube
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.

Micro Direct recommends a calibration verification be carried out following reassembly to verify correct operation and accuracy. Instructions for calibration verification are contained in the Spirotrac software instructions for use provided with the Pneumotracs device.

Consumables and Replacement Parts Ordering Information

Catalog No.	Description
3385	SpiroSafe Viral/Bacterial Filter (Box of 100)
3325	3-Liter Calibration Syringe
77933	Replacement Flow Conditioning Mesh (Pack of 10)
77934	Replacement Flowhead Complete
77939	Replacement Cone
77938	Replacement End Cap
79192	Replacement Flowhead Connection Tube
2120013	Replacement O-Ring (Pack of 15)
41543	Replacement USB Cable
77935	Replacement Feet
32254SPR	Replacement Silicone Grease Pack

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* Available by Request