

Sip/Puff Cleaning Suggestions

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Origin Instruments Corporation does not guarantee any cleaning method as suitable. It is up to you or your organization to decide what cleaning and sterilization techniques are adequate for your situation.

Components:

1. Head frame Assembly
 - a. Carbon steel music wire, head frame with powder coating and selective PVC heat-shrink tubing
 - b. Neoprene head frame pad
 - c. Two piece acetal homopolymer (Polyoxymethylene or POM) mount for stainless tube
 - d. Stainless steel nut-plate and fastener
 - e. 304 stainless steel tube
 - f. PVC mouth tube with 316 stainless steel forming wire
 - g. PVC head frame tubing with polypropylene, nylon or polycarbonate pneumatic connector
2. Gooseneck (flexible shaft)
 - a. Flexible, carbon, spring steel shaft, lacquer coated and covered with PVC heat shrink tubing
 - b. Aluminum black anodized end fittings bonded with permanent thread-lock adhesive
 - c. Brass hexagonal clamp stud bonded with permanent thread-lock adhesive
 - d. Co-axial PVC tubing with polypropylene, polycarbonate, or nylon pneumatic connectors on each end.
 - e. Multipurpose clamp made of lightweight cast alloy
3. PVC Pneumatic tubing with pneumatic connectors described above between the headset/gooseneck and pressure switch
4. Disposable In-Line filter with expanded, Polytetrafluoroethylene (PTFE) hydrophobic 0.45-micron membrane
5. Pressure Switch Mechanism
 - a. Passive pressure switch enclosure with pneumatic and electrical connectors. Case made of ABS, overlay made of polycarbonate.
 - b. USB pressure switch (Breeze) with PVC tubing pneumatic connectors as described above. Case made of ABS, overlay is polycarbonate and the pressure manifold is made of polylactic acid thermoplastic polymer.

Head Frame

With the head frame, the PVC mouth tube and stainless forming wire form a unit that is designed to be replaced after it becomes soiled or worn. Components of the Sip/Puff system are available for individual replacement.

When mounted on an erect individual, the plastic and stainless mouth tubes and head frame are orientated such that gravity will minimize saliva flow into and past the stainless steel mouth tube. This design and typical usage pattern minimizes tubing obstructions and in general the need for saliva traps.

During continual use by the same individual, replace the plastic mouth tube as needed and clean the remaining tubing with soap and water. For short term use by healthy individuals dispose of the plastic mouth tube after each user.* Cleaning solutions may be flushed through

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the tubing and the tubing blown dry using clean compressed air. For a more complete cleaning, the head frame should be disassembled and the components sanitized as necessary.

If alcohol is used to clean the tubing it must be completely purged and the tubing allowed to dry before returning it to service. Alcohol will interfere with the hydrophobic nature of the PTFE filter.

Gooseneck (Flexible Shaft)

Cleaning solution can be flushed through the co-axial PVC tubing. The exterior of the gooseneck can be cleaned with soap and water, short term application of household cleaning solutions, low concentration hydrogen peroxide (3—6%) or alcohol. **Do not immerse or soak the gooseneck in water.** It is made of carbon steel and will corrode.

To minimize blockage of the filtered mouthpiece and gooseneck tubing, they should be oriented to minimize the flow of saliva into the mouthpiece by gravity. Instead of accumulating in the mouthpiece saliva will flow back into the mouth. The filtered mouthpiece should minimize saliva infiltration into the gooseneck tubing and pressure switch. However, the filtered mouthpiece should be regularly replaced as it becomes soiled or damaged.

Tubing

PVC tubing information provided by the supplier:

- FDA Title 21 Material
- CPSIA Compliant
- EU Directive 2000 / 53 / EC (ELV)
- EU Directive 2011 / 65 / EU (RoHS2)
- EU Directive 2015 / 863 (RoHS3)
- Non-phthalate (less than 1000 ppm)
- Non-DEHP Plasticizer
- BPA-Free
- Lead Free
- Operating Temperature: -45° to +50° C
- Smooth surface prevents lodging of bacteria and sediment buildup. Tubing is easily drained and flushed clean with most available cleaning and sanitizing agents.
- The PVC tubing may be used in a wide variety of medical applications and can withstand EtO (Ethylene Oxide) and autoclave sterilization methods.

Filter

The disposable filters are used to prevent saliva from entering other parts of the sip and puff system. It is NOT designed to prevent the passage of all toxins, bacteria or viruses. However, it uses an expanded PTFE hydrophobic membrane that has a nominal pore size of 0.45-microns. Given that breath is moisture laden, bacteria and viruses will be embedded in moisture and it will be unlikely for them to penetrate the torturous path through the hydrophobic

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filter membrane. The flow rates for puffing to actuate the pressure switch are also minimal so there is a low probability of contaminants passing into the system and later being recovered.

The Sip/Puff pressure switch should always be isolated from the user with a disposable in-line filter. After some period of use the filter will need to be replaced. ***The filter cannot be cleaned.***

Pressure Switch

Internal components of the pressure switch (passive or USB Breeze) cannot be cleaned. It is essential to use the in-line filter to minimize potential damage from saliva and moisture in the user's breath. Outside of the pressure switch (passive or USB Breeze) can be cleaned with a damp cloth or short term application of household cleaning solutions, low concentration hydrogen peroxide (3—6%) or alcohol. Do not immerse, soak or allow liquids to enter the enclosure.

** For applications involving the headset and multiple users we recommend using the MultiUser Sip/Puff Switch with our disposable mouthpiece. The mouthpiece assembly consists of a mouthpiece and aseptic filter that clips to the head frame. The assembly also has a pneumatic connector for quick connection to the switch enclosure. The mouthpiece assemblies are packaged with gloves for sanitary installation and are individually sealed for protection.*