Reprocessing of scavenging circuits and multi-use nasal masks

Manufacturer: Accutron, Inc. 1733 W. Parkside Lane, Phoenix, AZ, USA [www.accutron-inc.com] (+1) 800.531.2221

Products: Accutron reusable scavenging circuit components and multi-use nasal masks.

WARNINGS	Reprocess scavenging circuit and multi-use nasal masks prior to each reuse per following instructions. Do not exceed 134°C (273.2 deg F) Do not autoclave spiral vacuum tubing or vacuum gauge. Do not submerse vacuum gauge in liquid solutions. Do not reprocess any masks other than multi-use PIP which are gray with black leaf. All others are single use only.
Recommended Sterility Levels and General Methodology	Current CDC guidelines require only high-level disinfection for dental items that touch mucous membranes or non-intact skin (i.e. semi-critical items such as breathing circuits). These guidelines also recommend heat sterilization for dental items that are not heat sensitive. See: *Guidelines for Infection Control in Dental Health-Care Settings – 2003, MMWR Recommendations and Reports - December 19, 2003 / Vol. 52 / No. RR—17.* Based on these opinions, Accutron recommends the higher level Steam Sterilization with appropriate pre-cleaning steps.
Limitations on reprocessing	Accutron multi-use masks and non-vacuum components are able to be autoclaved up to 250 times without loss of essential function. Do not exceed 250 cycles. Always visually inspect for damage, wear, distortion, cracks, pits or other irregularities before each use. Such checks are the responsibility of the User. If such damage is discovered, replace damaged components with new. Note: Some discoloration may occur in some components over time but will not degrade performance unless additional physical damage is found.

Instructions	A manual and automated procedure using a washer/thermal disinfector are detailed. When possible, use the automated procedure.
Point of Use	Remove excess contamination with disposable cloth/paper wipe.
Disassembly	Inline circuits; detach the spiral vacuum tubing containing the vacuum gauge from the scavenging circuit before reprocessing. Disinfection of these items is not allowed. The spiral vacuum tubing and the exterior of the vacuum gauge may be cleaned with a mild detergent and warm water. Do not submerge vacuum gauge. If any contamination or fluid is visible inside the vacuum gauge, it must be replaced. Detach the large corrugated tube from the white scavenging circuit (ClearView/PIP). Detach the nasal mask from the scavenging circuit. Dispose of single use nasal masks. Only specified reusable "multi-use" masks (PIP) may be reprocessed along with the circuit. These are gray with black leafs. Multi-use masks and scavenging circuit components (other than spiral vacuum tubing, vacuum flow gauge, and Corrugated hose) may now be reprocessed. It is recommended that these components be reprocessed as soon as reasonably practical following use.
Manual Cleaning	Completely submerge/soak the reusable scavenging circuit components in an enzymatic detergent solution (prepared per detergent manufacturer's instructions), and allow them to soak per manufacturer's instructions. Scrub using a soft bristled nylon brush until all visible soil is removed. Particular attention must be given to crevices, lumens, connectors and other hard-to-clean areas. Remove the components from the enzyme soak and rinse in clean warm tap water for a minimum of 3 minutes. Thoroughly flush all internal surfaces (lumen) and difficult to reach areas to ensure removal of any contamination/detergent residuals. Repeat as necessary. Remove excess moisture from the components with a clean absorbent, lint- free wipe. Carefully inspect the device to ensure that all visible foreign matter has been removed.
Automated washer/dis-infector cycle	Place device in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Typical US automated Washer/Disinfector Cycle	
Step	**Description**
1	2 min prewash with cold tap water
2	20 min enzyme spray with hot tap water
3	1 min enzyme soak
4	15 sec hot tap water rinse
5	2 min detergent wash with hot tap water (64-66°C/146-150°F)
6	15 sec hot tap water rinse
7	2 min thermal rinse (80-93°C/176-200°F)
8	7-30 min hot air dry (116°C/240°F)

Typical European Automated Washer/Disinfector Cycle	
Step	**Description**
1	2 min pre-cleaning with cold tap water, draining
2	5 min alkaline cleaning at 55°C, draining
3	3 min neutralization rinse with cold tap water, draining
4	2 min rinse with cold tap water, draining
5	Thermal disinfection, 90°C with hot demineralized water, 5 min
6	30 min hot air drying

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. CE mark, validation according to ISO 15883) should be used.

Sterilization:*	Validated Packaging and Chamber loading: Loop circuit to prevent kinking. Individually wrap in 2 layers of 1-ply polypropylene wrap such as (Crosstex CSR Sterilization Wrap) using sequential envelope folding technique. Load only one scavenging circuit per chamber load. Multi-use masks can be placed in open space between tubing loops. Option 1: Gravity autoclave, 132°C (269.6°F), 15 min steam cycle, 30 min dry cycle (not allowed in Europe) Option 2: Pre-vacuum autoclave, 132°C (269.6°F), 4 min steam cycle, 30 min dry cycle (not allowed in Europe) Option 3: Pre-vacuum autoclave, 134°C (273.2°F), 3 min steam cycle, 30 min dry cycle Note: Sterilizer manufacturer recommendations should always be followed. Note: The hospital/physician is responsible for in-house procedures for the re-assembly, inspection for kinks, cracks, degradation and packaging of the devices after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. * These instructions have been validated to achieve a sterility level of SAL 10-6 level and follow guidelines from ISO 17664:2004
Caution:	The integrity of the reusable Scavenging Circuit and nasal mask materials may be adversely affected by exceeding sterilization temperatures of 137° C or 278.6° F. • Clear Axess tubing will turn white after autoclave cycle but will become clear again after cooling (4-6 hours). • Axess tubing must be coiled without kinking. Do not ball up and place in pouch.
Maintenance, Inspection and Testing:	Prior to use, visually inspect for damage, wear, or any distortion of the scavenging circuit components that could restrict air flow or cause leaks or poor fitting of the patient nasal mask. Replace any damaged components.
Packaging:	Standard packaging material such as Crosstex CSR Sterilization Wrap may be used. Ensure that the packaging is large enough to contain the scavenging circuit without kinking the tubing.
Storage:	Use normal asepsis containers and locations
	Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes. It is the responsibility of the hospital/physician to define the maximal storage period for sterile reusable scavenging circuits. Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. **Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the device must be cleaned, repackaged and sterilized.**