

Reprocessing of Accutron Axess™ scavenging tubing circuits

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

Products: Accutron Axess™ reusable scavenging tubing circuit and components

WARNINGS	Reprocess scavenging tubing circuit prior to each re-use per following instructions. Do not exceed 134°C Do not autoclave spiral vacuum tubing or vacuum gauge. Do not submerge vacuum gauge in liquid solutions. Do not reprocess single use nasal hoods.
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: <i>Guidelines for Infection Control in Dental Health-Care Settings – 2003, MMWR Recommendations and Reports - December 19, 2003 / Vol. 52 / No. RR—17.</i> Based on these opinions, Accutron recommends the higher level Steam Sterilization with appropriate pre-cleaning steps and/or Automated Washer/Disinfectors.
Limitations on re-processing	Accutron Axess™ scavenging tubing circuits have been autoclaved up to 1,000 times with no loss of essential function. Accutron does not recommend exceeding this number of cycles. Visually inspect for damage, wear, distortion, cracks, pits or any other irregularity. If any of these conditions reach a point where flow is reduced or leakage occurs, discard and replace with new components.

Instructions	Note. For cleaning prior to sterilization, where possible use the automated procedures.
Point of Use	Remove excess contamination with disposable cloth/paper wipe.
Disassembly	Detach the spiral vacuum tubing containing the vacuum gauge from the scavenging circuit before re-processing. Disinfection of these items is not necessary since they are far enough downstream in vacuum flow to make any relevant migration back to patient highly unlikely. 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. Detached the nasal mask from the Axess™ scavenging tubing circuit. Dispose of the single use nasal mask. The Axess™ Clear tubing set and connections leading to Nasal Hood can be removed from the administration set and is subject to the Pre-Cleaning and Sterilisation steps as follows.
Manual Cleaning	Completely submerge/soak the reusable scavenging circuit components in an enzymatic detergent solution (prepared per detergent manufacturer's label instructions), and allow them to soak for a minimum time per detergent manufacturer's label instructions. Scrub using a soft bristled nylon brush until all visible soil is removed. 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. Remove excess moisture from the components with a clean absorbent, lint-free wipe. Sterilize per next step.
Automated Washer/Disinfectors	Place Axess™ Clear tubing set in suitable washer/disinfectors basket and process through a standard instrument washer/disinfectors cycle. The following minimum parameters are recommended for thorough cleaning and disinfection.

Typical US automated Washer/Disinfectors Cycle	
Step	Description
1	2 min prewash with cold water
2	20 min enzyme spray with hot water
3	1 min enzyme soak
4	15 sec hot tap water rinse
5	2 min detergent water with hot water 64-66°C
6	15 sec hot water rinse
7	2 min thermal rinse 80-93°C
8	7-30 min hot air drying 116°C

Typical European automated Washer/Disinfectors Cycle	
Step	Description
1	2 min pre-cleaning prewash with cold water, draining
2	5 min alkaline cleaning at 55°C, draining
3	3 min neutralization rinse with cold water draining
4	2 min rinse with cold water, draining
5	5 min thermal disinfection, 90°C hot demineralised water
6	30 min hot air drying

Instructions	
Sterilization *	<p>Validated Packaging and Chamber loading: Loop circuit to prevent kinking. Individually wrap in 2 layers of 1-ply polypropylene wrap (such as CSR Sterilization Wrap) using sequential envelope folding technique. Do not over-stack per chamber load if sterilizing multiple circuits.</p> <p>Option 1: Gravity autoclave, 132°C (273.2°F), 15 min steam cycle, plus drying cycle Option 2: Pre-vacuum autoclave, 132°C (273.2°F), 4 min steam cycle, plus drying cycle Option 3: Pre-vacuum autoclave, 134°C (273.2°F), 3 min steam cycle, plus drying cycle</p> <p>Note. Sterilizer manufacturer recommendations should always be followed.</p> <p>Note. The hospital/physician is responsible for the reassembly, inspection and packaging of the devices after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying.</p> <p>* The instructions have been validated to achieve a sterility level of SAL 10⁻⁶ and follow guidelines from ISO 17664:2004</p>
	<p>Caution. The integrity of the reusable Axess™ scavenging tubing circuit may be adversely affected by exceeding sterilization temperatures of 137°C</p>
Maintenance, Inspection and Testing	<p>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 hood. Replace any damaged components.</p>
Packaging	<p>Standard packaging material such as CSR Sterilization Wrap may be used. Ensure that the packaging is large enough to contain the scavenging circuit without kinking the tubing.</p>
Storage	<p>Use normal asepsis containers and locations.</p>
	<p>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 maximum storage period of the sterile reusable Axess™ scavenging tubing circuit.</p> <p>Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.</p> <p>Note. Maintenance of sterile package integrity is generally event related. If a sterile wrap is worn, perforated, or shows any evidence of tampering or has been exposed to moisture, the device must be cleaned, repackaged and sterilized.</p>