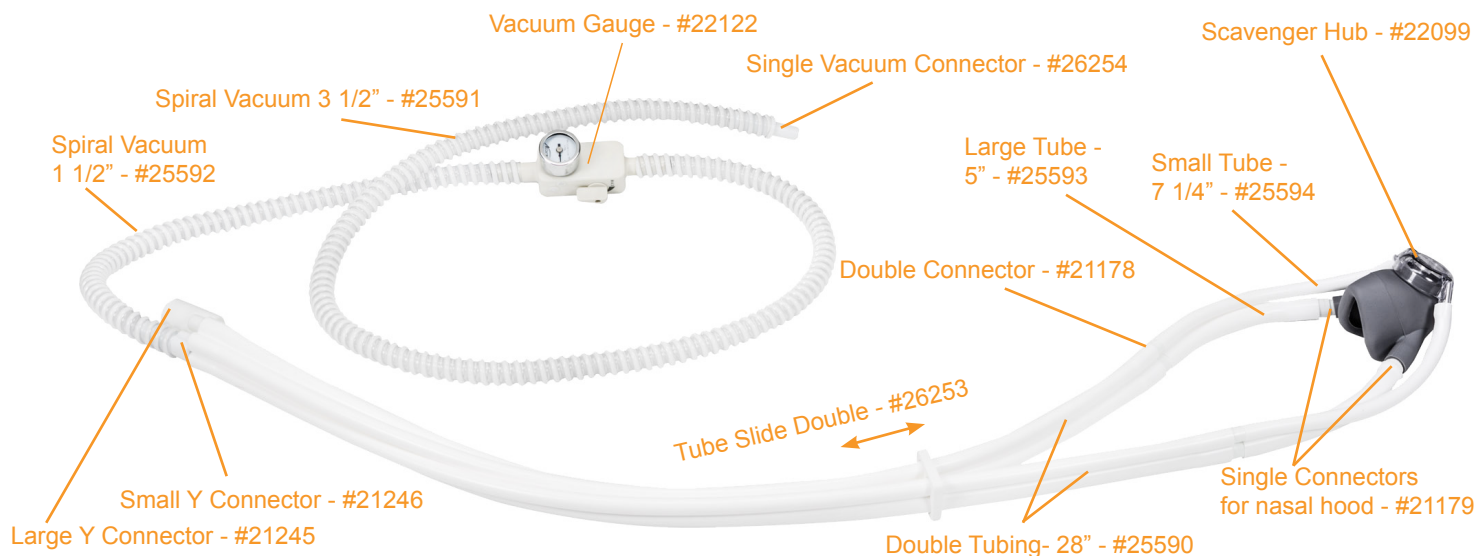


PIP+™ Scavenging Circuit Instructions

Sample Hood

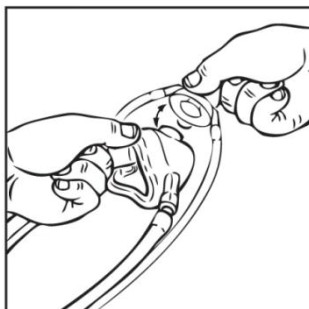
Scavenger inhaler sent with complimentary sample large orange scented disposable hood attached. The included grey hood is reusable and autoclaveable (see autoclaving instructions). Additional Accutron disposable hoods are available through your dealer.

Scavenger Parts List



Changing Your Nasal Hood

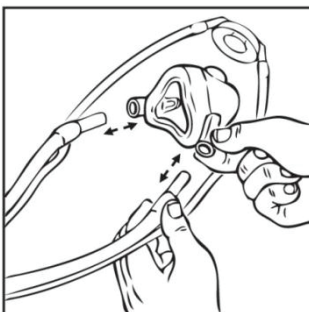
Step 1



To attach fresh nasal hood:

- Attach two white tubes containing the ridged connectors at either side of the nasal hood.
- Complete the circuit by connecting clear hub with attached tubes to the exhalation valve on the nasal hood.
Example: Place one or two fingers inside the top portion of hood and gently push hub ring into exhalation valve groove.

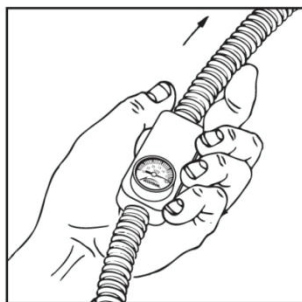
Step 2



To remove used nasal hood:

- Disconnect the hood at scavenging hub by "unsnaping" clear hub (white tubes should remain attached to clear hub).
- Detach the two white tubes from either side of nasal hood (rigid connectors need to remain inside white tubing).

Step 3



To initiate vacuum flow and begin patient administration of N₂O:

- Initiate vacuum flow by turning control knob on the vacuum gauge until gauge needle is in the green zone, which is between 5 and 10inHg.
- Place nasal hood on patient and check for comfortable fit.
- Turn on flowmeter and adjust oxygen and nitrous gases to desired level.
- Recheck vacuum flow and, if necessary, adjust to the appropriate setting. Periodically verify vacuum setting.
Note: the vacuum controller requires a minimum of 10inHg vacuum source pressure from system vacuum pump. At this source pressure, controller will vacuum gases at approximately 45lpm when gauge needle is between 5 and 10inHg on the gauge.

Reprocessing of Accutron scavenging circuits and multi-use nasal hoods

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 hoods.

| | |
|---|--|
| WARNINGS | <p>Reprocess scavenging circuit and multi-use nasal hoods prior to each reuse per following instructions.</p> <p>Do not exceed 134°C (273.2 deg F)</p> <p>Do not autoclave spiral vacuum tubing or vacuum gauge. Do not submerge vacuum gauge in liquid solutions.</p> <p>Do not reprocess single use nasal hoods. (Note: these are marked “Single Patient Use” on bottom of hood.)</p> |
| Recommended Sterility Levels and General Methodology | <p>Current CDC guidelines require only high-level disinfection for dental items that touch mucous membranes or nonintact 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.</p> |
| Limitations on reprocessing | <p>Accutron multi-use hoods and non-vacuum components have been autoclaved up to 250 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.</p> |

| Instructions | |
|---|--|
| Point of Use | Remove excess contamination with disposable cloth/paper wipe. |
| Disassembly | <p>Detach the spiral vacuum tubing containing the vacuum gauge from the scavenging circuit before reprocessing. 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.</p> <p>If any contamination or fluid is visible inside the vacuum gauge, it must be replaced.</p> <p>Detach the large corrugated tube from the white scavenging circuit.</p> <p>Detach the nasal hood from the scavenging circuit. Dispose of any single use nasal hoods. Gray reusable “multi-use” hoods may be reprocessed along with the circuit. These have black leafs and do not say “Single Patient Use”.</p> <p>Multi-use hoods 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.</p> |
| Pre-cleaning | <p>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.</p> <p>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.</p> <p>Remove excess moisture from the components with a clean absorbent, lint- free wipe. Sterilize per next step.</p> |
| Sterilization*: | <p>Validated Packaging and Chamber loading: Loop circuit to prevent kinking. Individually wrap in 2 layers of 1-ply polypropylene wrap such as (Kimguard KC600) using sequential envelope folding technique. Load only one scavenging circuit per chamber load. Multi-use hoods can be placed in open space between tubing loops.</p> <p>Option 1: Gravity autoclave, 132°C (273.2°F), 15 min steam cycle, 30 min dry cycle</p> <p>Option 2: Pre-vacuum autoclave, 132°C (273.2°F), 4 min steam cycle, 30 min dry cycle</p> <p>Option 3: Pre-vacuum autoclave, 134°C (273.2°F), 3 min steam cycle, 30 min dry cycle</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 Kimguard KC600 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> |

These instructions have been validated to achieve a sterility level of SAL 10⁻⁶ level and follow guidelines from ISO 17664:2004.