



Infection Control Suggestions for Nitrous Oxide/Oxygen Delivery Systems

v3.0





1733 W. Parkside Ln. Phoenix, AZ 85027 623-780-2020 Office 623-780-0444 Fax

The ADA has released a document *"Return To Work Interim Guidance Toolkit"*, which provides a new approach to cross-contamination and sterilization of Nitrous Oxide/Oxygen equipment and scavenging components.

Accutron has prepared some informative data for dental offices who are looking for guidance in selecting the best equipment, new parts for their systems, and best practice for processing the scavenging systems.

Table of ContentsPo	age
Introduction & Sterilization Basics	2
Return to Work Interim Guidance Toolkit	4
Reprocessing Instructions	5
Axess [™] Kits & Parts Information	7
ClearView [™] Kits & Parts Information	8
PIP+ [™] Kits & Parts Information	.9
Scavenging Parts Page	10
Parts Listing	

Accutron-2020-Product-Catalog



Infection Control for Nitrous Oxide/Oxygen Delivery Systems

June 2020

Sterilization Basics:

a) Preparation:

- Be sure to wash off any chemicals from hoses before preparing to sterilize.
- Wash with a mild detergent & warm water.
- Ultrasonic or Instrument Washers can be used to clean and prepare.

b) Dry in & dry out:

- Ensure that after washing & rinsing processing, that all components are dry, inside & out before wrapping & placing in the sterilizer.
- Do not remove or touch sterilized pouches/wrap until completely dry.
- NOTE: Some sterilizer doors open to start the drying cycle, not before drying is complete.
- NOTE: Contents should never touch the walls of the sterilization chamber. It is important to place hoses in a pouch or wrap to prevent uncoiling inside the sterilizer.

c) Sterilize:

- Cold Sterilization:
 - Do not process only in Cold Sterile
- Dry Sterilizers:
 - Do not process in a "dry" sterilizer
- Chemical Sterilizers:
 - Do not process in a "chemical" sterilizer
- Steam Sterilizers: (Autoclave)
 - Refer to IFU, Reprocessing, Pages 4-5

d) What Can I Sterilize?

- All the solid white tubings & fittings
- Plus, the clear hub on the PIP+[™] system.

e) What Shouldn't I Sterilize?

 The corrugated mixed gas hose, the reservoir bag, and the clear/white spiral scavenging tubing.

f) Storage:

- Keep the hoses stored in the sterilization packaging until ready to be used.
- Unwarp in front of the patient





Infection Control for Nitrous Oxide/Oxygen Delivery Systems Accutron is #1 in Cross-Contamination Prevention



Single-Use Nasal Masks
Disposable after every patient
3 Styles to fit every need

Color & Scent Match



Sterilizeable Hoses
White Hose easily Sterilized
Use as "extension sets"



Digital Flowmeters:

- Flat Screen
 - Easy to Barrier
 - Easy to Clean

The Accutron approach to cross-contamination is incorporated throughout our whole product line, not just the mask and hoses.

The system starts with the Digital Ultra Flowmeter, featuring a sealed, flat screen for easy cleaning or barriers. Complete bagging of the flowmeter is the best approach for other products.

The system rounds out with the 3 scavenging systems with sterilizeable hoses and single use, disposable masks.

Some Processing Considerations:

- Flowmeter Maintenance:
 - Flat Screen Flowmeter:
 - Barrier or wipe down, if sealed
 - Analog Flowmeter: (knobs, levers, dials, switches, etc.)
 - Bag over the whole flowmeter
 - NOTE: there is no effective way to properly clean these flowmeters.
- Disinfectants & Wipes
 - Accutron product surfaces are the most durable materials, designed to hold up under the dental surface disinfectants.
 - Please follow all Instructions For Use by the manufacturer.
 - Suggested Cleaners:
 - <u>SaniTex Plus[™] Surface Disfectent</u>
 - <u>Advantaclear®</u> <u>Surface Disinfectant</u>

Breathing Circuit Sterilization

- See page 1, "Select Your Mask"
- See page 6, 7, or 8 according to your selection
- Frequency of Circuit Sterilization
- Note the "Return To Work Recommendations" ... all components that can be sterilized should be sterilized after each patient use. (refer to page 4)
- How Do We Accomplish Sterilization between every patient?
 - Purchase extra "sterilization circuits" from pages 6, 7, or 8

Breathing Circuit Sterilization

- See page 1, select the mask you're using
- See page 6, 7, or 8 according to your selection

• Mask Maintenance:

- Mask Type:
 - Single Use (Disposable)
 - Dispose after each patient
 - Sterilizeable (Reusable)
 - Sterilize between patients?
 - NOTE: Refer to ADA Recommendations to Dispose





Return to Work Interim Guidance Toolkit

□ Use professional judgment to employ the lowest aerosol-generating armamentarium when delivering any type of restorative or hygiene care.

ADA

- As an example, use hand scaling rather than ultrasonic scaling when appropriate.
- o High velocity evacuation should be employed whenever possible.
- Use of nitrous oxide: use disposable nasal hood; tubing should either be disposable or if reusable, sterilized according to the manufacturer's recommendations.
- □ Shock your dental unit water lines if you are returning from an extended break in practice. Consult your manufacturer for proper product recommendations.
- □ Use professional judgment on mask removal and replacement between patients.
 - o If you are removing your mask, do so outside the treatment room.
 - o If the mask is soiled, damaged, or hard to breathe through, it must be replaced.
 - Resource: CDC Strategies for Optimizing the Supply of Facemasks
- Clean the operatory while wearing gloves, a mask, and face shield or goggles.
 - o Dispose of surface barriers after each patient.
 - o If surfaces are dirty, they should be cleaned using a detergent or soap and water prior to disinfection.
 - For disinfection, use products that meet EPA's criteria for use against SARS-CoV-2 (the cause of COVID-19) and are appropriate for the surface, following manufacturer's instructions.
 - Replace surface barriers.
 - Limit paperwork in operatory.
 - Include other evacuation systems.

Resources:

- American Dental Association and Organization for Safety, Asepsis, and Prevention (OSAP)
 webinar: COVID-19 Infection Control Protocols and Procedures Webinar
- A second webinar was presented on April 24 by the ADA and OSAP on PPE. Visit ADA.org <u>COVID-19 Digital Events page</u> to view the on-demand version.





Reprocessing of scavenging circuits and multi-use nasal masks

Manufacturer: Accutron - 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.						
	Failure to follow these instructions could lead to patient or user infection and an adverse health impact.						
	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 single use nasal masks. (Note: these are marked "Single Patient Use" on bottom of mask.)						
Recommended Sterility Levels and General Methodology	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: 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 has approved both Steam Sterilization with appropriate pre-cleaning steps and Automated Washer/Disinfectors.						
Limitations on reprocessing	Accutron multi-use masks 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.						

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	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 <u>exterior</u> 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.						
	Detach the nasal mask from the scavenging circuit. Dispose of any single use nasal masks. Gray reusable "multi-use" masks may be reprocessed along with the circuit. These have black leafs and do not say "Single Patient Use".						
	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 hare-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/disin- fector 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.						





5





Reprocessing

Accutron, Inc. MASTER

Typical US automated Washer/Disinfector Cycle]	Typical European Automated Washer/Disinfector Cycle		
Step	Description]	Step	Description	
1	2 min prewash with cold tap water]	1	2 min pre-cleaning with cold tap water, draining	
2	20 min enzyme spray with hot tap water 1 min enzyme soak 15 sec hot tap water rinse		2	5 min alkaline cleaning at 55°C, draining	
3			3	3 min neutralization rinse with cold tap water, draining	
4			4	2 min rinse with cold tap water, draining	
5	2 min detergent wash with hot tap water (64-66°C/146-150°F)]	5	Thermal disinfection, 90°C with hot demineralized water, 5 min	
6	15 sec hot tap water rinse]	6	30 min hot air drying	
7	2 min thermal rinse (80-93°C/176-200°F)]			
8	7-30 min hot air dry (116°C/240°F)]			

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.

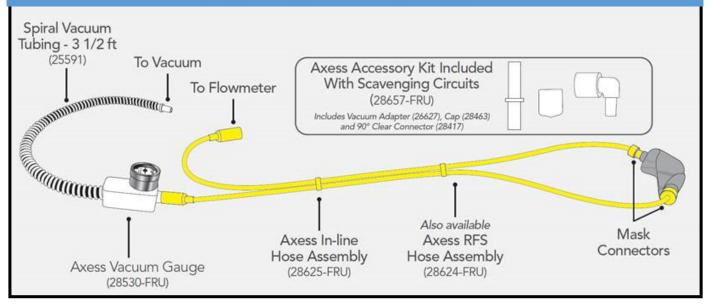
Sterilization:*	Validated Packaging and Chamber loading: Loop circuit to prevent kinking. Individually wrap in 2 layers of 1-ply polypropylene wrap such as (Kimguard KC600) using sequential envelope folding technique. Load only one scavenging circuit per chamber load. Multi-use masks can be placed in open space between tubing loops.							
	Option 1: Gravity autoclave, 132°C (273.2°F), 15 min steam cycle, 30 min dry cycle							
	Option 2: Pre-vacuum autoclave, 132°C (273.2°F), 4 min steam cycle, 30 min dry cycle							
	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 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 ⁴ 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 ex sterilization temperatures of 137° C or 278.6° F.								
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 Kimberly Clark Kimguard KC600 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, perfor shows any evidence of tampering or has been exposed to moisture, the device must be cleaned, repack and sterilized.								





p/n 28624-FRU p/n 28625-FRU \$100 \$75

Items Highlighted in yellow represent the sterilizeable components



- Above: are the 2 AxessTM scavenging circuits:
 - The "RFS" and the "In-Line" assemblies. They are found on pages 32-33 of the 2020 Catalog.
 - How to distinguish which you have?
 - IF both of the tubes are the same length = RFS
 - IF one tube is shorter than the other = In-Line
- The items highlighted in yellow represent what is sterilizeable.
- NOTE: The ClearView masks are "single use", Disposable.
 - ADA recommendations (see the FDA page 3 of this document)
 - Their advise: use only "single use" nasal hoods, and dispose of them after use.



NOTE:

- Sterilization Bag Suggestion
- Crosstex, SCL2, 7.5" x 14"

Instructions For Use:

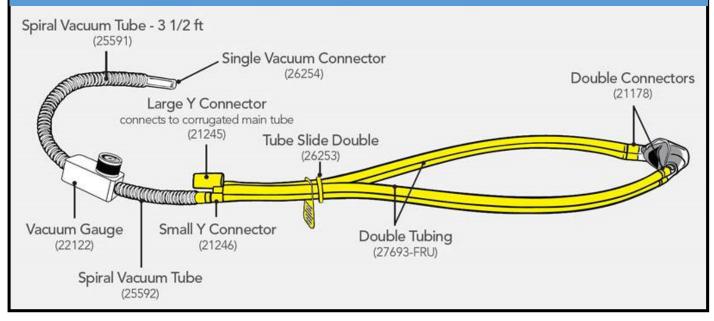
Axess-In-line-Scavenging-Circuit-IFU Axess-RFS-Scavenging-Circuit-IFU



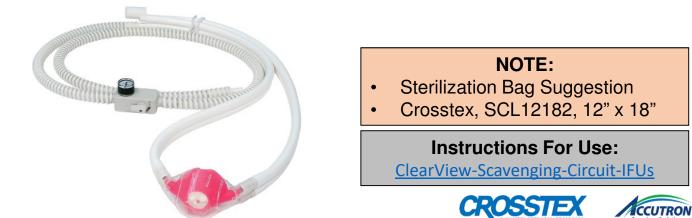


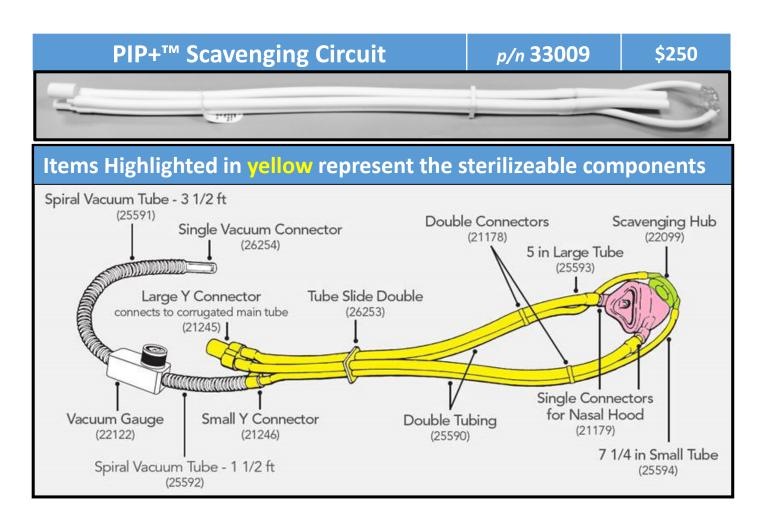
ClearView™ Scavenging Circuit p/n 43009 \$250

Items Highlighted in yellow represent the sterilizeable components



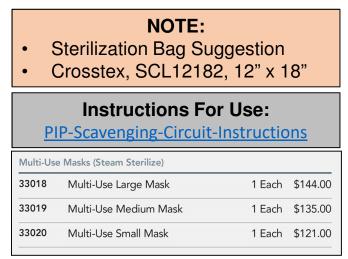
- Above: is the ClearView[™] Scavenging System, found on pages 34-35 of the 2020 catalog.
- The items highlighted in yellow represent what is sterilizeable.
- NOTE: The ClearView masks are "single use", Disposable.
- ADA recommendations (see the FDA page 3 of this document)
 - Their advise: use only "single use" nasal hoods, and dispose of them after use.
- The ClearView is single use for the whole mask assembly. (Inner & Outer Masks)
- NOTE: Be alert, there are other mask brands that feature removable inners in their masks, you must dispose of the inner mask & sterilize the outer mask.





- **Above: is the PIP+**TM Scavenging System, found on pages 36-37 of the 2020 catalog.
- The items highlighted in yellow represent what is sterilizeable.
- The scavenging hub (Green) cannot be steam sterilized, only cold sterilized.
- NOTE: the nasal hood is highlighted a different color, and that is because most PIP hoods are "single use", but there are sterilizeable/reusable hoods seen below and also on page 36 of the catalog).
- ADA recommendations (see the FDA page 3 of this document)
 - Their advise: use only "single use" nasal hoods, and dispose of them









2020 Accutron Nitrous Catalog, Page 38

Scavenging C	ircuit Components				
Ref. #	Description	Retail List			
21178	Double Connectors for PIP+™ Nasal Mask (2/pkg.)	\$34.00			
21179	Single Connectors for PIP+™ Nasal Mask (2/pkg.)	\$34.00			
21245	Large Y Connector	\$34.00			
21246	Small Y Connector	\$34.00			
22099	Scavenging Hub for PIP+™ Nasal Masks (clear disk)	\$57.00			
22122	22 Vacuum Controller w/ Gauge (for standard bag tee) for ClearView™ and PIP+™ Nasal Masks				
28530-FRU	Vacuum Controller w/ Gauge for Axess™ In-line Scavenging Circuit	\$170.00			
28657-FRU	Axess™ Accessory Kit (Includes: 90° Outspot Adapter, White Cap, Matrx Scavenger Adapter, Porter In-line Scavenger Adapter and Porter AVS Scavenger Adapter)	\$51.00			
28463-FRU	Vinyl Cap (7/8" x 1")	\$6.20			
28624-FRU	Axess™ RFS Hose Assembly	\$204.00			
28625-FRU	Axess™ In-Line Hose Assembly	\$204.00			
25590	Double Tubing for PIP+™ Scavenging Circuit (order 2)	\$34.00			
53004	Axess™ Extension Tube (tubing that extends the Axess™ Scavenging Circuit by 32″)	\$33.00			
28559-FRU	Axess™ Scavenging Circuit to Accu-Vac™ Adapter	\$37.00			
25591	Spiral Vacuum Tube – 3 1/2'	\$19.00			
25592	Spiral Vacuum Tube – 1 1/2'	\$19.00			
25593	5" Large Tube for PIP+ [™] Scavenging Circuit (order 2)	\$19.00			
25594	7 1/4" Small Tube for PIP+ ™ Scavenging Circuit (order 2)	\$19.00			
26252	PIP+ ™ Scavenging Plug	\$24.00			
26253	Tube Slide Double	\$34.00			
26254	Single Vacuum Connector	\$19.00			
26255-FRU	90° Elbow (creates 90° angle off flowmeter for attachment of scavenging circuit)	\$27.00			
27132	6' Spiral Vacuum Tube (for RFS™ Scavenging Circuit)	\$34.00			
27693-FRU	Double Tubing for ClearView [™] Scavenging Circuit (order 2)	\$34.00			

