












Document #: CO-7	 Standard Operating Procedure (SOP)	Status: v 0.0 Revised: June 01, 2020 Owner: Shared Health
Reprocessing Single Use N95 Respirators due to COVID-19 using AMSCO STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers		Page 1 of 5

Purpose	<p>To disinfect single use N95 respirators using STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers to a maximum of ten (10) reprocessing cycles. These will be stored and used as a backup supply to regular inventory on the direction of the Provincial Ministry or Health Authority.</p>						
Background	<p>There are 3 different models of STERIS sterilizers that can be used to disinfect N95 respirators.</p> <table border="0" data-bbox="289 625 1485 976"> <tr> <td data-bbox="289 625 690 724"> AMSCO V-PRO 1 PLUS LOW TEMPERATURE STERILIZATION SYSTEM </td> <td data-bbox="706 625 1107 724"> AMSCO V-PRO MAX LOW TEMPERATURE STERILIZATION SYSTEM </td> <td data-bbox="1123 625 1485 724"> V-PRO MAX 2 LOW TEMPERATURE STERILIZATION SYSTEM </td> </tr> <tr> <td data-bbox="289 745 422 976">  </td> <td data-bbox="706 745 839 976">  </td> <td data-bbox="1123 745 1256 976">  </td> </tr> </table> <p>The STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 sterilizers must be operated in Non-Lumen Cycle to disinfect compatible N95 respirators. When the Non-Lumen Cycle starts the load is processed by automatic moisture checks in order to ensure the removal of moisture from the load. Vaporized Hydrogen Peroxide (VHP) is injected four times during each sterilization cycle (pulse). The load automatically aerates after the last segment and the chamber exhausts through a catalytic converter that decomposes VHP into water and oxygen.</p> <ul style="list-style-type: none"> • All compatible N95 respirators used in the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers must be free of visible damage and visual soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids). • Compatible N95 respirators should be discarded after ten (10) reprocessing cycles. • Disinfected compatible N95 respirators are not sterile. • N95 respirators may be safely stored in pouches. • Refer to STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 User Manuals and supplemental documentation for complete operating instructions. • Follow existing policies and CSA standards for proper operating documentation. 	AMSCO V-PRO 1 PLUS LOW TEMPERATURE STERILIZATION SYSTEM	AMSCO V-PRO MAX LOW TEMPERATURE STERILIZATION SYSTEM	V-PRO MAX 2 LOW TEMPERATURE STERILIZATION SYSTEM			
AMSCO V-PRO 1 PLUS LOW TEMPERATURE STERILIZATION SYSTEM	AMSCO V-PRO MAX LOW TEMPERATURE STERILIZATION SYSTEM	V-PRO MAX 2 LOW TEMPERATURE STERILIZATION SYSTEM					
							
Types of N95 Respirators:	<ul style="list-style-type: none"> • N95 respirators that do not contain cellulose-based or paper materials are compatible. <ul style="list-style-type: none"> ○ Refer to CO-4 N95 Respirator Content Information from Vendors. • N95 respirators that have either not been reprocessed before or have been reprocessed using the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers are compatible. 						
Required Materials	<ul style="list-style-type: none"> • Black permanent marker (e.g. Sharpie) that conforms to ASTM D-4236 (avoid fine points). • Tyvek and compatible pouches/rolls identified for use in STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers (for example 8" x 12" STERIS Vis-U-All pouch 886812 or 885812, Tyvek roll 6"x 228" and 8" x 228") 						

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	<ul style="list-style-type: none"> Type 1 chemical indicator for vaporized hydrogen peroxide: STERIS Celerity Chemical Indicator PCC075 or VERIFY H2O2 Indicator Tape PCC071.
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The Process:



Step	1) Collecting N95 Respirators
1.1	Refer to <i>CO-1 N95 Respirator and Eye Protection Collection for Sterilization and Reuse</i> .

Step	2) Sorting
2.1	Refer to <i>CO-3 Sorting Compatible N95 Respirators for Reprocessing</i> .

Step	3) Packaging for Reprocessing
3.1	Use PPE (gown, gloves, mask, eye protection) when packaging respirators for reprocessing.

3.2	<p>Confirm that there is no visible damage or soil/contamination prior to prepping the N95 respirator for reprocessing.</p> <p>Use a black permanent marker (e.g. Sharpie) that conforms to ASTM D-4236 (avoid fine points) for all labelling on respirator.</p> <ul style="list-style-type: none"> Respirators that are unmarked have not been reprocessed. <ul style="list-style-type: none"> Place an “N” on the respirator to indicate this is being reprocessed through the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2. Place a small line on the N95 respirator to indicate the current reprocessing cycle in order to maintain the reprocessing cycle count. If the respirator has an “N” and one (1) to nine (9) cycle count lines marked on it, <ul style="list-style-type: none"> Place another small line on the N95 respirator to indicate the current reprocessing cycle in order to maintain the reprocessing cycle count. A second line indicates the respirator has gone through two (2) reprocessing cycles, a third line indicates three (3) cycles, etc. If the respirator already has an “N” and ten (10) cycle count lines marked on it, the respirator has already reached the maximum
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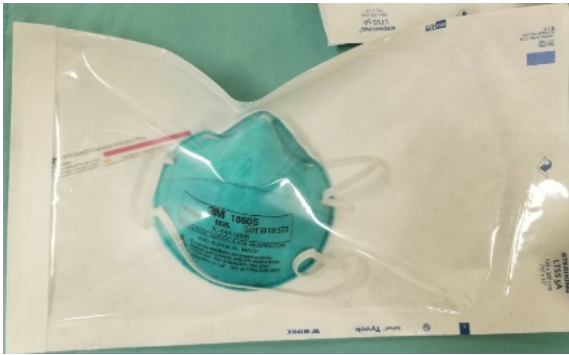

number of reprocessing cycles and should be discarded.

- Respirators labelled with a “C”, “A”, or “X” have been reprocessed through other equipment and should be returned to sites that have the appropriate equipment for reprocessing.
 - Place respirators into clearly labelled bins for possible return to a site that has the equipment to reprocess the respirator.
 - “C” = Clēan Flow Health Care Mini
 - “A” = STERRAD 100S, NX, 100NX Sterilization Systems
 - “X” = STERIZONE VP4
- If labelling is not legible or does not follow labelling conventions, place the respirator aside for further review and consideration of reprocessing.


NOTE: The respirator may be disinfected up to a maximum of ten (10) times through the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers. Respirators already reprocessed to the maximum ten (10) times will be discarded.

3.3 Using Tyvek pouches/roll or equivalent product compatible with STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers place one N95 respirator in each pouch.

3.4 Place one STERIS V-PRO compatible chemical indicator in each pouch and seal the opening





3.5 Label the pouch with the decontamination cycle count, and seal it.

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<p>Step</p>	<p>4) Reprocessing using STERIS V-Pro 1 Plus, V-Pro maX, and V-Pro maX2 Sterilizers</p>
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<p>4.1</p>	<p>Place compatible N95 respirators into the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 sterilizers for decontamination.</p> <ul style="list-style-type: none"> • A maximum of 10 pouched, compatible N95 respirators (5 pouches per shelf) can be processed in a Non-Lumen Cycle in the sterilizer. • Caution: Do not combine any other load with the 10-pouched N95 respirator load. • A specific orientation of the mask in the Tyvek pouch or pouches in the sterilizer is not required, however, pouches should not overlap or cover other pouches. <p>Note: N95 respirators will be processed using the Non-Lumen Cycle</p>	
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<p>4.2</p>	<p>A Type 1 chemical indicator for vaporized hydrogen peroxide (for example, a chemical indicator or chemical indicator tape) may be used to monitor the cycle.</p> <ul style="list-style-type: none"> • The indicators may be placed on the pouch, inside a pouch, or within the chamber to provide an indicator that sterilant has been delivered. One indicator per pouch is recommended.
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<p>4.3</p>	<p>Place a compatible Biological Indicator on the top shelf of the loading rack, as per STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 User Manuals.</p>
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<p>4.4</p>	<p>Use the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 sterilizers Operator Manual instructions on how to initiate the Non-Lumen Cycle and to verify a successful cycle completion.</p>
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<p>4.5</p>	<p>After the Non-Lumen Cycle in the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 sterilizers is complete:</p> <ul style="list-style-type: none"> • Following completion of the Non-Lumen Cycle in the Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color. If the indicator color matches the reference color or is lighter, the respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirator should not be considered disinfected and either repackaged and disinfected through another Non-Lumen Cycle in the STERIS Sterilization System or discarded. Please note that successful completion of the cycle and passing chemical indicator signifies appropriately disinfected compatible N95 respirators. These results do not indicate sterility of the disinfected, compatible N95 respirators.
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<p>4.6</p>	<p>Once cycle is complete, inspect each respirator and discard any damaged ones.</p>
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<p>4.7</p>	<p>Disinfected compatible N95 respirators that match the “PASS” criteria are ready for use.</p>
<p>4.8</p>	<p>Healthcare facilities should report any discoloration or other signs of degradation with a disinfected, compatible N95 respirator to Shared Health Logistics and STERIS, and the healthcare facility should discard the respirator.</p>

<p>Step</p>	<p>5) Re-issue of N95 respirators</p>
<p>5.1</p>	<p>Return disinfected N95 respirators to Materials Management for entry into inventory, secure storage and re-issue according to PPE policies.</p>