




<p><b>Document #:</b></p> <p><b>CO-14</b></p>	 <p><b>Standard Operating Procedure (SOP)</b></p>	<p>Status: 1.0</p> <p>Revised: Mar 4, 2021</p> <p>Owner: Shared Health</p>
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<p><b>Collection and Reprocessing of Precision AIR Respirator due to COVID-19 using <b>Medical Device Reprocessing (MDR)</b></b></p>	<p>Page 1 of 4</p>
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<p><b>Purpose</b></p>	<p>To collect and reprocess Precision Air reusable N95 respirators.</p>
<p><b>Background</b></p>	<p>Precision AIR respirator is Health Canada approved as a medical device and was designed and manufactured in Manitoba. The Precision AIR respirator offers our healthcare system the following benefits:</p> <ul style="list-style-type: none"> <li>▪ reusable - 30 uses</li> <li>▪ designed for comfort and safety of health-care workers</li> <li>▪ allows for clear communication between staff and patients</li> <li>▪ ability to clean and disinfect manually and washer/disinfector equipment</li> <li>▪ N95 respirator supply chain reliability</li> </ul> <p><math>A_0</math> is a theoretical measurement of microbiological lethality delivered by a moist heat disinfection process, expressed in terms of the equivalent time in seconds and temperature.</p> <p>An <math>A_0</math> value of 600 is a sufficient level of disinfection for respiratory devices according to <i>CAN/CSA-Z314-18</i> (section 11, table 11.1).</p> <p>Disinfection is the inactivation of disease-producing microorganism apart from bacterial spores. Hospital-grade disinfectants are used on inanimate objects and require a drug identification number (DIN) for sale in Canada.</p> <div style="text-align: center;">  </div>
<p><b>Supplies</b></p>	<ul style="list-style-type: none"> <li>• PPE</li> <li>• Washer/Disinfector</li> <li>• Detergent</li> <li>• Clean and Soiled bins</li> <li>• Extra head straps</li> </ul>


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**Procedure:**

Step	1) Collecting the Precision AIR Respirator
1.1	Ensure collection bins are labeled as "SOILED Precision AIR respirators".
1.2	Disinfect collection bin and lid and place in the designated location in each unit. The designated location <b>cannot</b> be in a patient's room.
1.3	Wearer to place used Precision AIR respirator into the designated bins. Do not mix Precision AIR respirators with any other PPE being collected.
1.4	Once collection bins are 2/3 full, immediately move to the designated 'dirty' area in your facility following site processes.

Step	2) Disassemble Respirators in Designated Area (Use Soiled One Way Workflow Where Possible)
2.1	Wear correct PPE as required for all item decontamination (level IV gown, nitrile gloves, standard mask, eye protection, head covering) when handling respirators for disinfection.
2.2	In MDR decontamination area, sort bins containing used Precision AIR respirators.
2.3	Disassemble respirators: <ul style="list-style-type: none"> <li>• Remove filters cartridge and dispose them into garbage.</li> <li>• Do not disassemble the head halo and straps.</li> <li>• During disassembly, inspect each section for damage.</li> <li>• Place damaged items into a separate bin for reprocessing.</li> <li>• Damaged masks may be used for spare parts.</li> </ul>



Step	3) Cleaning & Reprocessing of Respirators in MDR
3.1	Wear correct PPE (level IV gown, nitrile gloves, standard mask, eye protection, head covering) when handling respirators for disinfection.
3.2	Immerse entire respirator in a prepared cleaning solution. Detergents should have a neutral PH. Detergents that remove grease work well, e.g., Getinge Manual High Foam Detergent.

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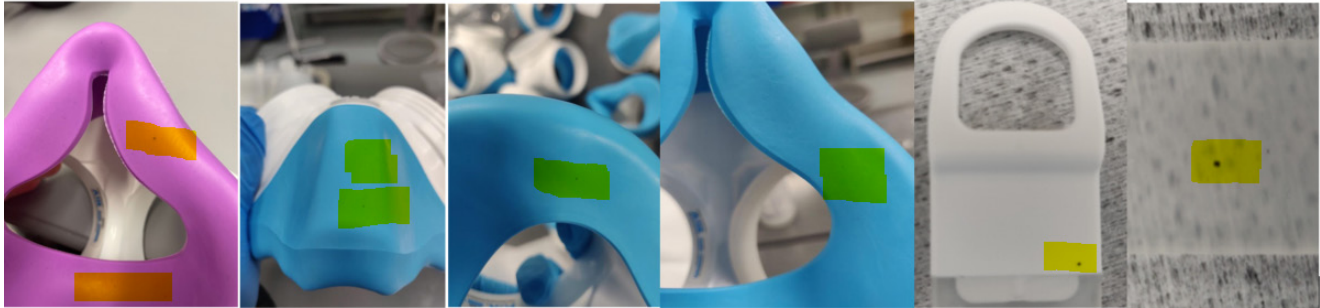
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3.3	Using a low lint wipe or soft-bristled brush, remove all gross visible soil. Skin secretions, makeup, lotion, and petroleum jelly are commonly found on the respirator. Pay attention to the lip of the respirator, including the underside.
3.4	Rinse the respirator thoroughly using potable water.
3.5	Place head halo assembled, and respirators face up in stainless steel baskets.
3.6	<p>Place loaded stainless steel baskets into the washer/disinfector. Wash the respirators using a parameter set that achieves A<sub>600</sub> disinfection (i.e., Pasteurization, Respiratory, Anaesthesia or Instrument cycle).</p> <p>Pasteurization conditions require immersion in water at a minimum 71 °C for 30 minutes; however, washer/disinfectors using spray nozzles that achieve an A<sub>600</sub> can be used as an alternative to pasteurization at 80 degrees C for 10 min. These thermal conditions are adequate to ensure the respiratory equipment is safe to use.</p>
3.7	<p>Perform hand hygiene. Wearing correct PPE (mask, gloves, head covering) upon completion of washing:</p> <ul style="list-style-type: none"> <li>• Empty any residual pooled water from the respirators</li> <li>• Move the baskets to the clean drying area</li> <li>• Use a dryer if available</li> <li>• Place the mask in the dryer so the <u>inside of the respirator is face up</u></li> <li>• Allow the masks to dry completely</li> <li>• If using a dryer, operate according to the dryer manufacturer’s instructions</li> </ul>
3.8	Respirator must be thoroughly dry before proceeding to step 9.
3.9	Wearing correct PPE (mask, gloves, head covering) place disinfected respirators in the reassembly area utilizing aseptic process.

<b>Step</b>	<b>4) Reassembly of Precision AIR Respirators</b>
4.1	Wear correct PPE (gloves, mask, head covering) when handling clean Precision AIR respirators and head halo for reassembly.

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<p>4.2</p>	<p>Inspect the respirator for damage, wear and missing parts based on the model. If present, confirm all straps, buckles and fasteners are present and in good working order.</p> <p><b>NOTE: there may be black, purple, or dark blue specks the raw material during manufacturing not contamination.</b></p> 
<p>4.3</p>	<p>Reassemble the head halo and barrel according to site processes. Consider 2 person check for additional safety.</p>
<p>4.4</p>	<p>Place into clear sealable bag (e.g., Ziploc® bag).</p>
<p>4.5</p>	<p>Seal the bag and label the size. Use additional markings per site process. Such markings may include but are not limited to:</p> <ul style="list-style-type: none"> <li>- Indication that this product has been disinfected</li> <li>- The initials of the person who assembled the respirator</li> <li>- The date of reprocessing</li> </ul>
<p>4.6</p>	<p>Place reprocessed Precision AIR respirator in designated clean storage area.</p>