




Document #: CO-9	 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 CLEAN WORKS Clēan Flow Health Care Mini		Page 1 of 4

Purpose	To disinfect single use N95 respirators using Clēan Flow Health Care Mini to a maximum of ten (10) reprocessing cycles. These will be stored and used as a backup supply to new inventory on the direction of the Provincial Ministry or Health Authority.
Background	<p>The Clēan Flow Health Care Mini exposes personal protective equipment (PPE) to an atmosphere that quickly and effectively inactivates a wide range of pathogens by mixing together three (3) ingredients: Ozone gas, Clēan Flow Solution, and UV-C Light.</p>  <ul style="list-style-type: none"> • All compatible N95 respirators used in the Clēan Flow Health Care Mini must be free of visible damage and visual soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids). • Clēan Works Medical recommends respirators may be reprocessed a maximum of ten (10) times. • Any disinfected item that becomes wet, is dropped or is otherwise mishandled should be considered contaminated and must be reprocessed. • Disinfected N95 Respirators are not sterile. • Refer to Clēan Flow Health Care Mini User Manual and supplemental documentation for complete operating instructions. • Follow existing policies and CSA standards for proper operating documentation.
Types of N95 Respirators:	<ul style="list-style-type: none"> • N95 respirators that do not contain cellulose, latex, natural rubber, or activated charcoal are compatible for reprocessing using the Clēan Flow Health Care Mini. <ul style="list-style-type: none"> ○ Refer to <i>CO-4 N95 Respirator Content Information from Vendors.</i> • N95 respirators that have either not been reprocessed before or have already been reprocessed using the Clēan Flow Health Care Mini are compatible for reprocessing using the Clēan Flow Health Care Mini.
Required Materials	<ul style="list-style-type: none"> • Black permanent marker (e.g. Sharpie) that conforms to ASTM D-4236 (avoid fine points). • Clēan Works Medical Respirator Tray • Clēan Flow Solution

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>


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


Step	3) Preparation for Reprocessing
3.1	Use PPE (gown, gloves, mask, eye protection) when handling respirators for disinfection.
3.2	<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"> If the respirator does not have any labelling or markings on it, it is the first time the respirator is being reprocessed, <ul style="list-style-type: none"> Place an “C” on the respirator to indicate this was reprocessed through the Clēan Flow Health Care Mini. 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 a “C” and one (1) to nine (9) 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) sterilization cycles, a third line indicates three (3) cycles, etc. If the respirator already has a “C” and ten (10) lines marked on it, <ul style="list-style-type: none"> The respirator has already reached the maximum number of sterilization cycles and should be placed into a bin marked “NRC” for separate reprocessing and shipping (once disinfected) to the National Research Council Canada (NRC) (as per contract, if NRC study is active). If NRC study is no longer active, discard. If labelling is not legible, place the respirator aside for further review and consideration of reprocessing. <p>NOTE: The respirator may be reprocessed up to a maximum of ten (10) times through the Clēan Flow Health Care Mini. Respirators already reprocessed to the maximum ten (10) times will be placed into a bin marked “NRC” for separate reprocessing and shipping (once disinfected) to the National Research Council Canada (NRC) (as per contract, if NRC study is active). If NRC study is no longer active, discard.</p>



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Step	4) Reprocessing using Clēan Flow Health Care Mini	
4.1	<p>The Clēan Flow Health Care Mini must be loaded in the following manner to ensure sterilant contact and penetration:</p> <ul style="list-style-type: none"> • The respirator must be placed on the tray supplied by Clēan Works Medical with the inside facing down and outside facing up. • A maximum of six (6) respirators may be placed on each tray. • The respirators must be placed with the interior portion of the respirator facing the conveyor. • Respirators must not be over-lapping, nesting or stacked. • Folding styled respirators must be opened. • The tray is to be placed in the center of the belt. 	
4.2	<ul style="list-style-type: none"> • Using the Clēan Flow Health Care Mini standard procedures, respirators will be disinfected by a 3% hydrogen peroxide solution delivered at 40 ml/min with a UV-C dose of 59 mJ/cm² and ozone in a 30s treatment. • Refer to Clēan Flow Health Care Mini User Manual for full operating instructions, start up checks and correct cycle parameters. 	
4.3	<ul style="list-style-type: none"> • Place tray on centre of the conveyor belt and allow it to pass through the Clēan Flow Health Care Mini. 	

Step	5) Unloading the Clēan Flow Health Care Mini	
5.1	Perform hand hygiene and use appropriate PPE when unloading the Clēan Flow Health Care Mini.	
5.2	<p>Upon completion of the cycle, the operator on the “clean” side responsible for unloading the sterilizer must,</p> <ul style="list-style-type: none"> • Review the sterilizer parameters to verify that the correct cycle parameters have been met and document the cycle time and date. • Ensure respirators have maintained open, upright position. If not, respirator must be reprocessed, and cycle count must be increased by one. • Empty the metal tray, placing the disinfected N95 respirators into a clean bin. 	
5.3	Once bin is full, place lid on bin and move bin to clean area for storage, sorting and packaging for distribution. Replace full bin with disinfected clean empty bin.	
5.4	Move empty metal trays to designated location for transport to dirty area for re-loading.	
5.5	Healthcare facilities should report any discoloration or other signs of degradation with a disinfected N95	

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respirator to Shared Health Logistics and CLEAN WORKS, and the Healthcare facility should discard the respirator.

Step	6) Packaging N95 Respirators for Distribution
6.1	Perform hand hygiene and use appropriate PPE when handling disinfected respirators for packaging.
6.2	<p>For each respirator, conduct respirator integrity check prior to packaging.</p> <ul style="list-style-type: none"> • Ensure respirator is free from any visible sign of damage. <ul style="list-style-type: none"> ○ If damaged, log results, place respirator into clean bin labelled “NRC Integrity Check” for shipping to NRC. Results will be reported to NRC as per contract. • Ensure straps are secure by performing gentle tug on straps. <ul style="list-style-type: none"> ○ If straps are not secure, log results, place respirator into clean bin labelled “NRC Integrity Check” for shipping to NRC. Results will be reported to NRC as per contract. • Respirators free of damage with secure straps to proceed to packaging for distribution.
6.3	Sort respirators in appropriate type and size.
6.4	Place respirators into bags according to Materials Management distribution polices for PPE.
6.5	Enter disinfected respirators into inventory.
6.6	Prepare bagged respirators for shipping to sites.

Step	7) Collection of Disinfected N95 Respirators for Shipping to NRC (as per contract, if NRC study is active)
7.1	Perform hand hygiene and use appropriate PPE when handling disinfected respirators for shipping.
7.2	<p>For each of five (5) N95 models (or as many as possible if fewer than five (5) models are in use), collect ten (10) respirators from disinfected stock and ship to NRC for laboratory testing as follows:</p> <ul style="list-style-type: none"> • After first (1) reprocessing event – respirator has one (1) line • After second (2) reprocessing event – respirator has two (2) lines • After three (3) reprocessing events – respirator has three (3) lines • After five (5) reprocessing events – respirator has five (5) lines • After ten (10) reprocessing events – respirator has ten (10) lines • An additional twenty (20) N95 respirators at end of life regardless of the number of cycle count lines recorded on it. <ul style="list-style-type: none"> ○ Note: End of life respirators will be from discarded stock as per Sorting Step 2.4 and must be disinfected prior to shipping to NRC.

