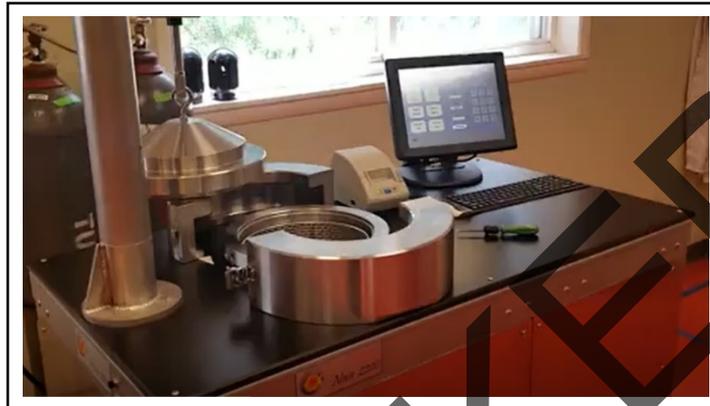


Nova2200 Equipment Platform for NovaClean decontamination process

Instructions for Decontamination Personnel (DP)



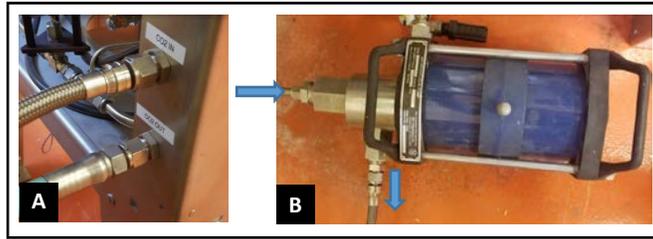
The U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of the Nova2200 with NovaClean decontamination process (“Nova2200”) for use in decontaminating 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for single-user reuse by healthcare personnel.

The Nova2200 has been authorized by FDA under an EUA for decontamination of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The Nova2200 has not been FDA cleared or approved for this use. The Nova2200 is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices unless the authorization is terminated or revoked sooner.

Respirators that are NIOSH-approved before decontamination (<https://wwwn.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer.

Installation Guidelines and Requirements:

1. Install the Nova2200 with the venting of the machine piped to an external vent. A window can be adapted to accept the vent plumbing; however, this is to be performed during installation by NovaSterilis personnel to ensure proper venting and operator safety.
2. Carbon Dioxide (CO₂) Supply:
 - a. The CO₂ supply is piped through a booster pump where the CO₂ is boosted from the tank pressure to 1425 psi. The CO₂ ports (A) and the direction of flow through the pump (B) are shown in the images below.



- b. Four CO₂ tanks have the capability to complete 7 runs, depending on the number of respirators to be decontaminated.

Note: If a tank is run empty during operation, pump seal damage may occur as the liquid CO₂ acts as a lubricant.

Decontamination of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators using the Nova2200:

- a. Before powering up the unit, ensure all connections on the back of the machine are appropriately seated and tightened, and that the unit is vented properly via an external vent.
- b. Turn on the power to the machine using the red and yellow switch located on the front of the unit.
- c. Open the valves to all four CO₂ cylinders by turning the hand knobs counter clockwise at least two full turns (image C). Actual configuration of tanks and gas manifold may vary depending on installation location.

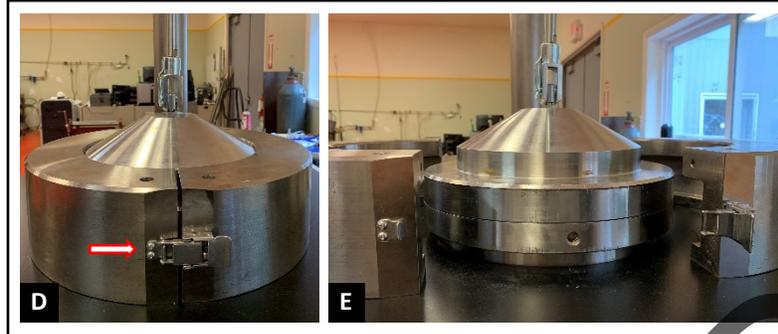


- d. Turn on the air compressor or pneumatic supply (location of the power switch is dependent on installation location and equipment type). Verify that the compressor is providing 80 psi of pressure.

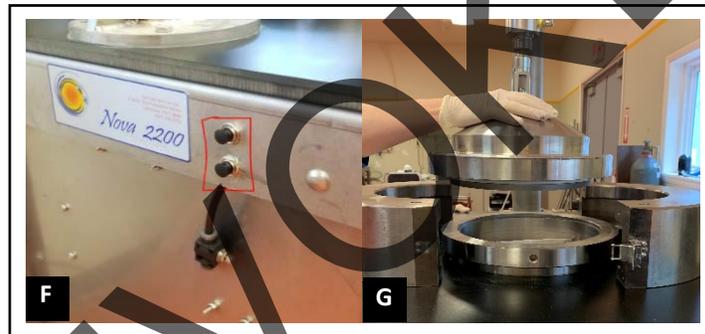
3. Installing/Removing the Vessel Lid

- a. Remove the lid locking rings by unlatching the locking clasps on either side of the rings (image D).

- b. Slide the locking rings away from the vessel body to give clearance to the vessel lid (image E).



- c. Remove the lid using the pneumatic buttons located on the left side of the machine (image F). The upper button raises the lid, the lower button lowers the lid. A hand can be placed on the top of the lid to steady it if desired (image G). When raising or lowering the lid, ensure that the locking rings and lid do not contact each other, otherwise damage to the lid or locking rings may occur.

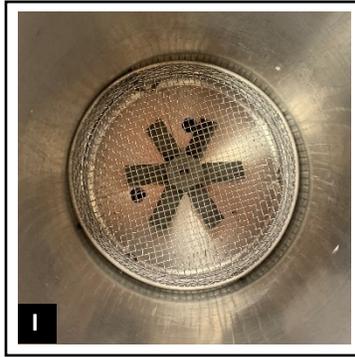


- d. Once open, swing the lid over the rear locking ring and “park” the lid by lowering it onto the ring (H).



4. Loading the vessel:

- a. Place the stand in the bottom of the vessel and set the 1” additive basket on top of the stand as pictured below (image I). If the basket and stand are not properly installed, contact with the impellor is possible, which may damage the impellor or the basket.



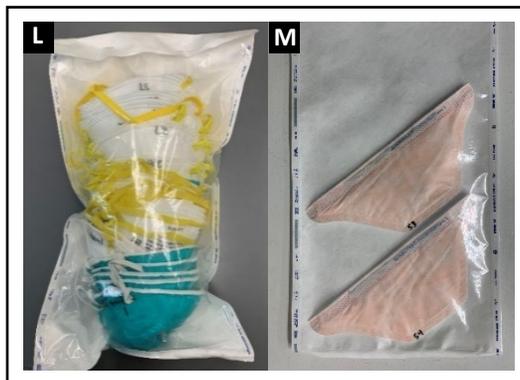
5. Placing Items in the Vessel

Note: DP is solely responsible for attaching the pre-packaged biological indicator (3M Attest 1295 Biological Indicator) to one of the two pouches containing the N95 respirators to be decontaminated in the vessel for each load.

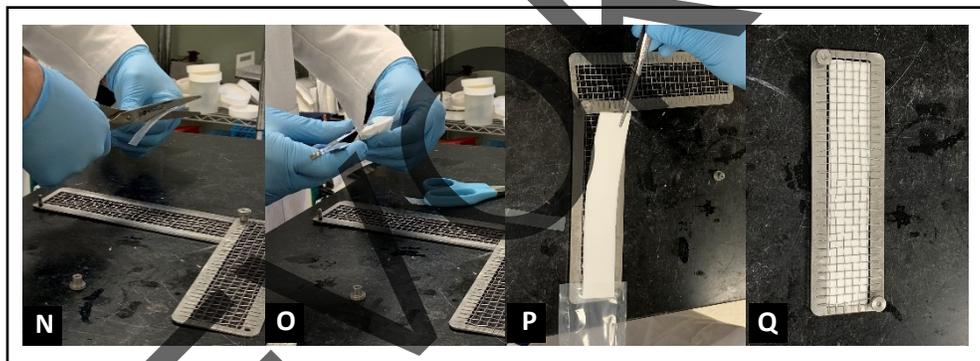
- a. Healthcare facility staff must wear the appropriate personal protective equipment (PPE) (e.g., gown, gloves, and N95 respirator (or equivalent face protection) while handling contaminated N95 respirators, as required by their institutional policies.
- b. Verify that the used respirators are labeled with the wearer's name, a single tick mark, and the location identifier (e.g., department identification). Respirators can safely undergo one (1) decontamination cycle. Discard any used respirators that have previously undergone a decontamination cycle in accordance with the institutional policies.
- c. Place the used respirators to be decontaminated into NovaPouches.
3M Model 1860 N95 respirators are to be nested with the nose bridges aligned and placed facing the white side of the NovaPouch (image L). A maximum of 25 3M Model 1860 respirators can be placed in each NovaPouch. Halyard FLUIDSHIELD N95 respirators must be stacked (not nested) and placed in the NovaPouches as shown in image M below. Two NovaPouches containing 25 of either respirator style, for a total of 50 respirators, can be decontaminated per run. Label the NovaPouch with the date, time, and the location identifier using a permanent marker. To seal the pouch, fold over the end of the pouch and staple to close as shown in image L below.

NOTE: The 3M Model 1860 and Halyard FLUIDSHIELD N95 respirators must not be combined in a single NovaPouch. Each N95 respirator model must be packaged with the like N95 respirator model in a NovaPouch.

- d. DP ensure that the sleeve containing the biological indicator is attached to the outside of one of the pouches containing N95 respirators to be decontaminated. DP must not remove the biological indicators from their pre-packaged sleeve.

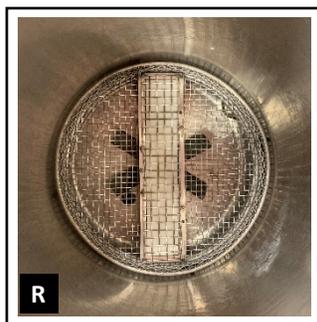


- e. Using scissors, DP carefully open a pouch containing a NovaKill additive pad (image N). Remove the NovaKill additive pad with tweezers and place it in the NovaKill additive pad holder (images O and P). Close the lid and tighten the bolts to secure the additive pad (image Q). Discard the NovaKill additive pad packaging in accordance with internal EHS policies. Refer to the safety data sheet (SDS) and instructions provided with the NovaKill additive pads for guidance in proper handling. Gloves and eye protection must be worn while handling the NovaKill additive pad.



WARNING: Make sure a fresh NovaKill pad is used for each decontamination cycle. NovaKill pads are required to achieve decontamination.

- f. Position the NovaKill additive pad holder in the additive basket centered over the inlet port on the bottom of the vessel as shown below (image R).



- g. Insert the packaged respirators to be decontaminated into the vessel above the 1” additive basket. The additive basket must be placed in the bottom of the vessel in order to prevent contact between the packages and the impellor. Packaged respirators must be placed such that the face-side of the respirator is towards the top of the vessel (orientation shown in images L and M).

WARNING: Respirators may be damaged if the face side of the respirator is facing towards the bottom of the chamber. Ensure that care is taken to be sure the face side of the respirators are pointing toward the top of the chamber.

- h. NovaPouches must be placed in an alternating manner so that the white sides are together as shown in image S below.



- i. Using scissors, open a reverse osmosis (RO) water pouch. Pour the contents of the RO pouch into the vessel on top of the NovaPouches.

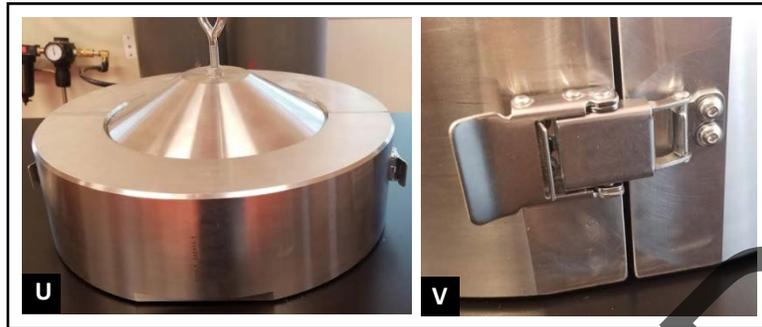
6. Close and seal the vessel

- a. Swing the lid over the vessel body and use the pneumatic switches on the side of the unit to lower the lid onto the vessel body. Ensure that the lid seats into the groove of the vessel body (image T). Pressing downward onto the lid from above may help the lid seat properly.



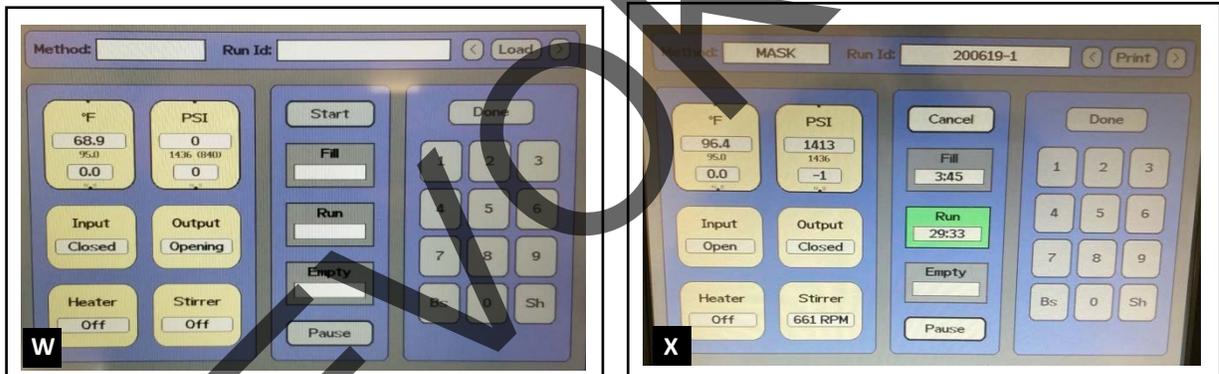
- b. Position the locking rings over the lidded vessel as shown in image U below. If the lid is seated properly, the locking rings will slide onto the lid easily.

- c. Secure the locking rings by latching the locking clasps on both sides of the locking rings (image V).



7. Initiating a Run

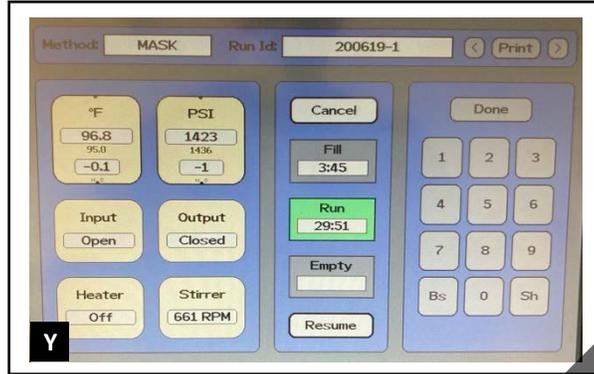
- a. The 10" display is a touch screen interface (image W). The numerical keypad on the screen can be used for alpha input by pressing the SH key. A keyboard can be attached to the USB port, if desired.



- b. Enter a run ID by pressing the "Run Id" box. Enter the desired run ID using the touch screen or keyboard, then press "Done" (image X).
- c. Select the cycle named "MASK" (image X).
- d. Verify that the vessel lid is seated properly and that the locking rings are latched securely.
- e. Press start to begin the run. Once pressurized, the unit will be operating at 1400-1600 psi and $35^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

8. Pausing/Cancelling a Run

- a. To pause a run, press the pause button on the touch screen (image X). The run can be restarted again by pressing the resume button (image Y).



Note: Pausing a run will not cause depressurization of the vessel. The vessel will remain under pressure and serious injury can occur if the lid is removed while the vessel is under pressure.

- b. To completely cancel a run and depressurize the unit, press the cancel button on the touch screen (image Y). This option is only available on the touch screen once a run has been started. **Note: Do not attempt to open the vessel until it is fully depressurized, and the pressure level reads 0 psi.**
 - c. If noises are occurring from inside the vessel, the stirrer may be in contact with the additive basket and the run must be stopped to prevent damage to the unit.
9. Finishing a Run
- a. At the end of the 1 hour and 30-minute run, the unit will start a 15-30 minute depressurization cycle.
 - b. During the depressurization cycle, a run report will be printed indicating the performance of the run. A “PASS” report indicates that the unit performed the run within the stirring, temperature, and pressure specifications. A “FAIL” report indicates that the run operated outside the stirring, temperature, and/or pressure parameters required. If a “FAIL” report is given, the out of specification parameter will be highlighted on the report in bold text. If the cycle parameters are not met and a “FAIL” report is generated, the N95 respirators from that cycle must be discarded. Follow steps c – h below, and discard the respirators instead of allowing the respirators to aerate. If the cycle parameters are met and a “PASS” report is generated, follow steps c – h below.
 - c. When the depressurization cycle is complete, the unit is safe to open once the pressure reading is **0 psi**. **Attempting to open the unit prior to fully releasing the pressure can result in serious injury.**
 - d. Open the unit by unlocking the clasps on the sides of the locking rings and sliding the rings away from the vessel body.
 - e. Use the pneumatic button on the side of the unit to raise the lid off the vessel and “park” the lid by resting it on top of the rear locking lid.
 - f. Remove the decontaminated NovaPouches. **Note: There may be dry ice in the vessel after the run. If there is dry ice in the vessel upon completion, remove the pouches without touching the dry ice and let the vessel aerate for 5 minutes before starting the next run.**
 - g. Place the decontaminated NovaPouches on a flat surface with the white side of the pouch up and the transparent side contacting the flat surface. Allow the decontaminated NovaPouches to aerate for at least four hours prior to using the respirators. Although not necessary, the

aeration process can be augmented by applying direct air flow over the NovaPouches using a fan.

- h. Remove the NovaKill additive pad from the vessel and additive pad holder and discard the pad in a trash receptacle.
10. Turning off the Machine
- a. After all runs are complete, the machine can be shut down using the red and yellow switch located on the front of the unit.
 - b. Turn off the air compressor or pneumatic supply.
 - c. Close the valves of all of the CO₂ tanks by turning the hand knobs clockwise until tightened.

After the Nova2200 Cycle is Complete:

1. Healthcare facility staff must verify successful cycle completion on the run printout. A “PASS” report indicates that the unit performed the decontamination run within the stirring, temperature, and pressure specifications, whereas a “FAIL” report indicates that the run operated outside the required parameters. If the run “FAILS”, the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator must not be considered decontaminated and must be discarded.
2. Healthcare facility staff must verify successful cycle completion by reading the 3M Attest 1295 Biological Indicator in the 3M Attest Auto-reader. Remove the decontaminated NovaPouches containing 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators from the vessel. Remove the 3M Attest Biological Indicator from the NovaPouch and activate the Biological Indicator. Place the Biological Indicator into the 3M Attest Auto-reader. Confirm that the Biological Indicator is negative for growth by reading a minus “-“ sign on the reader.
3. Decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators that “PASS” the run printout, which verified the stirring, temperature, and pressure specifications, and whose biological indicators were confirmed to be negative for growth are ready for use after aeration. Allow the decontaminated NovaPouches with the N95 respirators to aerate for at least 4 hours prior to use. 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators can be stored in the NovaPouches for up to 1 week. **3M Model 1860 or Halyard FLUIDSHIELD N95 respirators may be decontaminated a maximum of 1 time.**
4. After aeration, in a clean area, the HCP with clean PPE (e.g., gown, gloves, and N95 respirator (or equivalent face protection)) remove the decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators from NovaPouches. HCP individually place decontaminated respirators in a clean, sealable transparent plastic bag to assist with visualization of original wearer's name to help with chain of custody return at originating site, and seal the bag. The sealed bags are loaded back in decontaminated totes or containers and placed in a closed case cart following the healthcare facility’s policy for identifying/labeling processed loads. The healthcare facility must follow a similar protocol for identifying processed loads to transport to the operating room for surgical cases. The documentation needs to include a clean copy of the location identifier to ensure return of the respirators to the original location in the facility for distribution to healthcare workers.
4. DP must wait for clearance of biological indicator results of each load before transferring decontaminated N95 respirators from the decontamination facility. Biological indicators are required with each cycle. If the biological indicator is negative after each cycle, the decontaminated N95 respirators can be released.
5. The healthcare facility must ensure that the chain of custody is maintained to minimize the risk of cross-contamination. Upon return of the decontaminated, 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators to the appropriate individuals, the respirator must be checked for the following:

- a. The decontaminated respirator is received in a sealed, transparent plastic bag.
- b. Ensure that the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator is returned to its previous user.
- c. Ensure the name or other identifier is still legible. Any 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator whose traceability was lost must be discarded. If the labeling is not legible, return the respirator to the healthcare facility for quarantine.
- d. Any 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator that is visually soiled or contaminated must be discarded.
- e. Perform a user seal check of the decontaminated N95 respirator prior to use – If a successful user seal check cannot be performed, return the respirator to the healthcare facility for quarantine.

Reporting:

Report any problems with the decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators to your healthcare facility.

Healthcare facilities must report any discoloration or other signs of degradation with a decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator to NovaSterilis. After contacting NovaSterilis and providing the requested information, the healthcare facility must quarantine the N95 respirator until instructed by NovaSterilis to dispose of it. During the monthly maintenance visits, NovaSterilis staff may collect quarantined N95 respirators for further investigation.

Healthcare facilities will report adverse events of which they become aware related to the Nova2200 and the decontaminated, 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators. This includes monitoring personnel using the Nova2200 and HCP using the decontaminated, 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. Report Adverse events to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088.

Any problems must be immediately reported to NovaSterilis

NovaSterilis Contact: 1-607-330-2772 or Team@NovaSterilis.com