STERIS
Infection Prevention Technologies

V-PRO External Q&A

The FDA has granted STERIS an Emergency Use Authorization (EUA). This allows STERIS to temporarily provide a distinct option to effectively decontaminate compatible N95 or N95-equivalent Respirators using the **Non Lumen Cycle of the V-PRO® Low Temperature Sterilization System** (Models: 1 Plus, maX and maX 2) **up to 10 times**. Below is a list of questions and answers designed to assist healthcare providers in implementing this process. Please reference the protocol for specific instructions.

General Questions:

Q: Where can I find more information about STERIS Infection Prevention solutions?
A: steris.com is being updated with COVID-19 landing page to address Covid-19 questions

Q: What is an Emergency Use Authorization?
A: The Emergency Use Authorization (EUA) is a process available to the U.S. Food and Drug Administration to allow the unapproved use of a 510k cleared product for certain emergency circumstances.

Q: Did STERIS complete microbiocidal testing to support the use of the cycle to decontaminate compatible N95 or N95-equivalent respirators?
A: Yes. STERIS followed guidelines published by FDA: Enforcement Guideline for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. STERIS completed validation testing with a surrogate virus that is more resistant to inactivation than SARS-CoV-2 virus. Use of the Non Lumen cycle in V-PRO achieved ≥ 3 log reduction of virus in the presence of soil.

Q: Was functional testing completed to support the use of the cycle to decontaminate compatible N95 or N95-equivalent respirators?
A: Yes. The respirator manufacturer completed testing on respirator performance and confirmed up to 10 Non Lumen cycles are not expected to have a detrimental impact on respirator filtration performance.

Q: Did the OEM approve use of the Non Lumen Cycle in V-PRO for reprocessing compatible N95 or N95-equivalent respirator?
A: The U.S. Food and Drug Administration provided STERIS with an Emergency Use Authorization based upon evidence of successful decontamination in the V-PRO Non Lumen Cycle.

Q: What is 3M's stance on the V-PRO compatible N95 or N95-equivalent respirator decontamination protocol?
A: STERIS worked with 3M as we developed the protocol to provide respirator decontamination solutions to healthcare professionals and 3M has evaluated the performance of respirators after processing. Reference the April 2020 Technical Bulletin – 3M Decontamination Methods for 3M N95 Respirators for more information.

Q: Do I need additional/different PPE?
A: No. PPE that is normally used in the decontamination area of sterile processing should be used when preparing the respirators for reprocessing. To prevent contamination of the sterile processing area, hospitals should implement practices to pouch the compatible N95 or N95-equivalent respirators outside the sterile processing departments, for example, at a collection point in each employee work area.

Q: Do I need to write separate policies and procedures for the Non Lumen cycle?
A: No. The decontamination process for compatible N95 or N95-equivalent respirators in the V-PRO units does not change anything about how the staff operates the sterilizer or interprets the results. Therefore, no change would be necessary for existing procedures associated with the use of the sterilizer.

Q: Are there In-Service materials available for the Non Lumen cycle?
A: Yes. STERIS has In-Service materials available at STERIS University (Models: maX, maX 2). Instructions for healthcare personnel are available that identifies how to load the chamber in order to successfully reprocess the compatible N95 and N95 equivalent respirators.

Q: Why are only certain respirators and V-PRO units include in the protocol?
A: Not all respirators are made with equivalent materials or design. STERIS has validated efficacy and functional performance with compatible N95 or N95-equivalent respirators identified in the protocol. Due to incompatibility V-PRO is not authorized with use of respirators or pouches containing cellulose-based or paper materials.

Q: Can the Non Lumen Cycle for V-PRO 60 and V-PRO s2 Sterilizers be used to reprocess compatible N95 or N95-equivalent respirators?
A: No. The V-PRO 60 and V-PRO s2 sterilizers cannot be used to reprocess compatible N95 respirators. STERIS will provide an update if guidance changes.

V-PRO Respirator Decontamination Cycle Questions:

Q: Do I need to modify or change anything to my existing V-PRO?
A: No. There is no need to make any change to the V-PRO sterilizer. The Non Lumen cycle is currently available on the V-PRO 1 Plus, V-PRO maX and V-PRO maX 2.

Q: Do I need STERIS to service the V-PRO prior to utilizing V-PRO for decontamination of compatible N95 or N95-equivalent respirators?
A: No. The V-PRO needs to be fully operational in order to run the cycle. If your unit has been properly maintained, there is no need to perform service to the unit prior to utilizing the sterilizer to reprocess the respirators.

Q: Do I use the same sterilant (VAPROX HC) in the Non Lumen Cycle?
A: Yes. VAPROX HC sterilant (PB007, PB011, PB012, PB028), is used in the Non Lumen cycle. There is no change to the sterilant for use with V-PRO.

Q: How are the compatible N95 or N95-equivalent respirators cleaned before I put them into V-PRO?
A: The respirators do not need to be cleaned prior to putting them into V-PRO. If there is a visibly damaged or heavily soiled respirator, the respirator should be discarded.

Q: How is the compatible N95 or N95-equivalent prepared prior to putting into V-PRO?
A: The respirator is packaged in a Tyvek pouch and sealed prior to initiating the cycle. STERIS provides an 8" x 12" STERIS Vis-U-All pouch 886812 or 885812. Alternatively, any 8"x12" Tyvek pouch would be effective. If desired, pouches may be marked with a sharpie or ink marker for traceability, tracking decontamination cycles, or other purposes. **Cellulose packaging cannot be used.**

Q: Are there other pouch sizes I can use to package the compatible N95 or N95-equivalent respirator?
A: Yes. The minimum size pouch is 8"x12", but larger pouches can be used. Respirators should only be packaged one per pouch regardless of pouch size. Using a larger pouch may impact how many respirators can be processed each cycle.

Q: Are there limitations on how many compatible N95 or N95-equivalent respirators can go in each cycle?
A: Yes. There is a limit of 10 respirators per cycle (5 on each shelf).

Q: Can the compatible N95 or N95-equivalent be stacked in their pouches when placed in the V-PRO?
A: No. In order to achieve appropriate penetration of hydrogen peroxide in the cycle, the respirators cannot be stacked on top of each other.

Q: Do I need to use a STERIS VERIFY HPU Chemical Indicator or Celerity Chemical Indicator when reprocessing the compatible N95 or N95-equivalent respirators in the V-PRO Non Lumen cycle?
A: STERIS recommends that you use a VERIFY HPU Chemical Indicator or the Celerity HP Chemical Indicator to confirm the presence of hydrogen peroxide in the cycle.

Q: Does a biological indicator need to be used within the Non Lumen Cycle for release of the compatible N95 or N-95 equivalent respirators?
A: The use of a biological indicator is not required for the release of reprocessed respirators in the Non Lumen cycle. The healthcare facility should maintain their documented processes for biological monitoring of the V-PRO sterilizer.

Q: Can the compatible N95 or N95-equivalent respirators be stored in the pouch after processing?
A: Yes. The respirators can be stored in the pouch after processing.

Q: Should the compatible N95 or N95-equivalent respirators be processed in V-PRO after each use?
A: Yes. The respirators should be processed after each use up to a maximum of 10 times. The facility needs to implement a method to identify the number of reprocessing cycles of the respirator.

Q: Do I need to reuse my same (per individual) respirator?
A: It is strongly recommended to maintain chain of custody on the respirator to minimize the risk of cross-contamination.

Q: Can I use this cycle forever?
A: No. Reprocessing of compatible N95 or N95-equivalent respirators in V-PRO is only permissible during the pandemic and only if there is insufficient supply of new respirators available to protect healthcare workers.

Q: Can I use steam sterilization or EtO to decontaminate compatible N95 or N95-equivalent respirators?
A: Currently, STERIS is not recommending the use of steam sterilization or EtO as a viable option to decontaminate the respirators.

Q: Can the same compatible N95 or N95-equivalent respirator be reprocessed in both a V-PRO and other equipment (e.g., STERRAD®)?
A: No. None of the EUA, protocol, or compatibility testing contemplate a respirator being reprocessed in two different types of equipment. For example, do not reprocess a respirator two times in a STERRAD unit and then eight times in a V-PRO. There can be no certainty that a respirator will not deteriorate before the 10th cycle in a V-PRO if more than one type of equipment is used. Like the chain of custody for respirator wearers, the healthcare facility should also ensure that each mask reprocessed in V-PRO is reprocessed exclusively in V-PRO units.

Q: Can I use the STERIS protocol for reprocessing compatible N95 or N95-equivalent respirators in non-STERIS systems (e.g., STERRAD®)?
A: No. The protocol developed by STERIS and submitted to the EPA as part of the EUA is applicable only to STERIS V-PRO units. Customers should refer to other manufacturers' EUAs and protocols for processing N95 or N95-equivalent respirators in other equipment.

Q: Can I use the STERRAD® system to decontaminate the compatible N95 or N95-equivalent respirators?
A: Please contact Advanced Sterilization Products for information on the use of the STERRAD® systems.

Q: What is the difference between the STERIS V-PRO compatible N95 or N95-equivalent respirator decontamination protocol and the Battelle® Critical Care Decontamination System?
A: STERIS and Battelle® both use hydrogen peroxide but each solution has a unique process and delivery.