

## **N95 Decontamination: Non Lumen Cycle of V-Pro Low Temperature Sterilization Systems 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 respirators using the Non Lumen Cycle of the V-PRO® Low Temperature Sterilization System (Models: 1 Plus, maX, maX2, 60 and s2 up to 4 times. Below is a list of questions and answers designed to assist healthcare providers in implementing this process. This Q&A is effective as of February 7, 2021 and supersedes any previous versions. 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: [Can I use the Non Lumen Cycle in the V-PRO Low Temperature Sterilization System \(Models: 1 Plus maX, maX2, 60 and s2\) to decontaminate compatible N95 respirators outside of a healthcare facility?](#)**

**A:** No. The intended use of V-PRO is in health facilities only,

**Q: [What defines compatible N95 respirators?](#)**

**A:** The U.S. Food & Drug Administration has further defined compatible N95 respirators to include:

Respirators that do not contain cellulose-based material, exhalation valves, antimicrobial agents, or duckbilled designs and that are either NIOSH-approved and authorized under the EUA or are authorized by the non-NIOSH-approved FFR EUA for FFRs not manufactured in China.

**Q: [Did STERIS complete microbiocidal testing to support the use of the cycle to decontaminate compatible N95 respirators?](#)**

**A:** Yes. STERIS followed 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-CoV2 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 respirators?](#)**

**A:** Yes. The respirator manufacturer completed testing on respirator performance and confirmed up to 4 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 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 respirator decontamination Protocol?**

**A:** STERIS worked with 3M as we developed the protocol to provide respirator decontamination solutions to health professionals and 3M has evaluated the performance of respirators after processing. Reference the 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 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 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, maX2, 60 and s2). Instructions for healthcare personnel are available that identifies how to load the chamber in order to successfully reprocess the compatible N95 respirators.

**Q: What are the residual levels thresholds of H2O2 after decontaminating a compatible N95 respirator in the Non Lumen Cycle in the V-PRO Low Temperature Sterilization System?**

**A:** The safe use of decontaminating compatible N95 respirators in the Non Lumen Cycle in the eV-PRP Low Temperature Sterilization System has been established in accordance with ISO 10993-17 (Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substance). STERIS has verified that, following decontamination of compatible N95 respirators, sterilant residues are significantly less than the levels determined as safe for dermal contact (>1100-fold less) and mucosal contact (>30-fold less). The residual level threshold was developed in conjunction with a 3<sup>rd</sup> party toxicologist in accordance with ISO 10993-17.

**Q: Will STERIS be conducting further use/real world evident (RWE) testing for fit, filtration and marking of respirators?**

**A:** STERIS is currently working with FDA to appropriately update the EUA based on their condition for maintaining authorization.

#### **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, maX, maX2, 60 and s2.

**Q: Do I need STERIS to service the V-PRO prior to utilizing V-PRO for decontamination of compatible N95 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 process 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 or use with V-PRO.

**Q: How are the compatible N95 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 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 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 respirators can go in each cycle?**

**A:** Yes. For V-PRO models 1 Plus, maX, maX2, there is a limit of 10 respirators per cycle (5 on each shelf). For V-PRP models 60 and s2, there is a limit of 6 respirators per cycle (3 on each shelf).

**Q: Can the compatible N95 respirators 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 STERIS VERIFY HPU Chemical Indicator or the CELERITY HP Chemical Indicator to when reprocessing the compatible N95 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 with the Non Lumen Cycle for release of the compatible N95 respirators?**

**A:** The use of a biological indicator is not required for the release of reprocessing 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 respirator be stored in the pouch after processing?**

**A:** Yes. The respirators can be stored in the pouch after processing.

**Q: Should the compatible N95 respirators be reprocessed in V-PRO after each use?**

**A:** Yes. The respirators should be processed after each use up to a maximum of 4 times. The facility needs to implement a method to identify the number of reprocessing cycles of the respirator.

**Q: What is the "Hierarchy of Decontamination and Bioburden Reduction System for Surgical Masks and/or Respirators"?**

**A:** In May of 2020, The U.S. Food and Drug Administration released Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators during the Coronavirus Diseases 2019 Public Health Emergency. These recommendations included guidance to sponsors (e.g. STERIS) to provide evidence in their submissions that the critical parameters are controlled and follow the hierarchy levels, or tiers, of resistance of microorganisms to germicidal chemicals.

**Q: What tier of decontamination is the use of the Non Lumen Cycle to reprocess compatible N95 respirators in V-PRO?**

**A: Based on evidence submitted by STERIS to the U.S. Food and Drug Administration, the use of the Non Lumen Cycle to reprocess compatible N95 respirators in V-PRO is considered Tier 1: Decontamination of Surgical Masks and/or Respirators for Single- or Multiple- Users.**

**Q: Do I need to reuse may same (per individual) respirator?**

**A: Though the use of Non Lumen Cycle to reprocess compatible N95 respirators in V-PRO is considered Tier 1, it is strongly recommended to maintain a single-user approach and chain of custody on the respirator to minimize the risk of cross-contamination. STERIS labeling authorized by FDA identifies a single-user reuse process.**

**Q: Can I use this cycle forever?**

**A: No. Reprocessing of compatible N95 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 EtO to decontaminate compatible N95 respirators?**

**A: Currently, STERIS is not recommending the use of EtO as a viable option to decontaminate the respirators.**

**Q: Can the same compatible N95 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 two times in a V-PRO. There can be no certainty that a respirator will not deteriorate before the 4th 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 respirators in non-STERIS systems (e.g. STERRAD®)?**

**A: No. The protocol developed by STERIS and submitted to the FDA 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 respirators in other equipment**

**Q: What is the difference between the STERIS V-PRO compatible 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.**