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Decontamination of N95 respirators using
the STERIS V-PRO Low Temperature
Sterilization Systems

Instructions for use

Introduction

The U.S. Food and Drug Administration has granted STERIS a temporary Emergency Use Authorization for decontaminating compatible N95 and N95-equivalent respirators by utilizing V-PRO maX, V-PRO maX2, V-PRO 60 or V-PRO S2

This is a temporary process: decontaminating N95 masks in the V-PRO is only permissible during the pandemic and only if there is insufficient supply of new respirators available to protect healthcare workers.

Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare N95 respirators for decontamination using the STERIS V-PRO maX, V-PRO maX2, V-PRO 60 or V-PRO S2.

WARNING!

- A N95 or N95-equivalent respirator must be placed in the V-PRO in a Tyvek pouch. No paper-based materials or other types of pouches/bags can be used.
- All compatible N95 respirators that are to be processed must be free of visible damage and soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).
- A N95 or N95-equivalent respirators that are visibly soiled or damaged should not be decontaminated and should be discarded.
- N95 or N95-equivalent respirators should be discarded after 10 decontamination cycles.
- Each used N95 or N95-equivalent respirator must be traceable to the single wearer of the mask and the number of times it has been processed must be recorded. If this information is missing the mask should not be processed.
- Decontaminated, compatible N95 or N95-equivalent respirators are not sterile.

Procedure for Decontaminating N95 or N95-equivalent respirator

1. To minimize the risk of cross-contamination each N95 or N95-equivalent respirator should be allocated to a single wearer.
2. It should be labelled with a name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside OR inside of each N95 or N95-equivalent respirator, as shown below.
3. It is not necessary to clean or disinfect the N95 or N95-equivalent respirator before processing it in the V-PRO maX, V-PRO maX2, V-PRO 60 or V-PRO S2.
4. Place a tick mark on the N95 or N95-equivalent respirator each time to maintain the decontamination cycle count. NOTE: the N95 or N95-equivalent respirator may be decontaminated up to a maximum of 10 times.
5. Confirm that the labeling is legible, and that there is no visible damage or soil/contamination prior to pouching the compatible N95 or N95-equivalent respirator.
6. Pouch and seal the N95 or N95-equivalent respirator in Tyvek pouches at the end of use. Wear appropriate PPE when handling the used mask.
7. Load only five N95 or N95-equivalent respirators on each shelf of the V-PRO maX or V-PRO maX2 units. There can only be a total of ten N95 or N95-equivalent respirators in each load.
8. Load only three N95 or N95-equivalent respirators on each shelf of the V-PRO 60 or V-PRO S2 units. There can only be a total of six N95 or N95-equivalent respirators in each load.
9. Select & run the 28 minute Non-Lumen cycle of the V-PRO maX, V-PRO maX2, V-PRO 60 or V-PRO S2.
10. Before wearing the decontaminated N95 or N95-equivalent respirator the individual wearer must ensure that they have received the correct (i.e. their own) N95 or N95-equivalent respirator and check that there is no visible damage.