

Instructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators Using the STERIS Sterilization Systems

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the STERIS N95 Respirator Decontamination Cycle (Non-Lumen Cycle) in STERIS V-PRO 1 Plus, maX, and maX2 Sterilizers (hereafter referred to as the “STERIS Sterilization System”) for use in decontaminating compatible N95 or N95-equivalent respirators (“compatible N95 respirators”) for single-user reuse by healthcare personnel in healthcare facilities. The STERIS Sterilization System contains three models: V-PRO 1 Plus, V-PRO maX, and V-PRO maX2. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to decontaminate compatible N95 respirators using the STERIS Sterilization System.

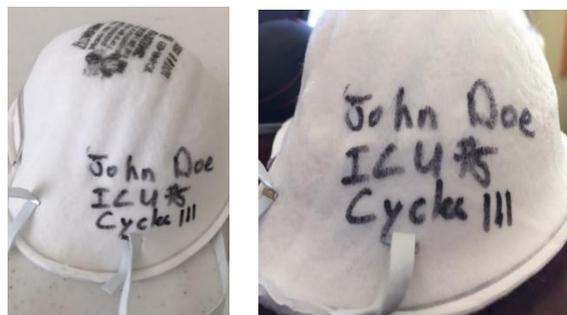
- **Due to incompatibility, the STERIS Sterilization System is not authorized for use with respirators or pouches containing cellulose-based or paper materials.**
- **All compatible N95 respirators used in the STERIS Sterilization System must be free of visible damage and visual soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).**
- **Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and should be discarded by healthcare providers.**
- **Compatible N95 respirators should be discarded after 10 decontamination cycles.**
- **Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.**
- **Decontaminated compatible N95 respirators are not sterile.**

Materials Needed:

- Tyvek pouch identified for use in vaporized hydrogen peroxide, for example an 8” x 12” STERIS Vis-U-All pouch 886812 or 885812.
- Type 1 chemical indicator for vaporized hydrogen peroxide: STERIS Celerity Chemical Indicator PCC075 or VERIFY H2O2 Indicator Tape PCC071. In the event of Chemical Indicator Shortage, please see the [Parametric Instructions](#) section below.

Compatible N95 Respirator Marking:

The healthcare facility should ensure that the chain of custody is maintained to minimize risk of cross-contamination. Prior to collection by the healthcare facility personnel, the healthcare personnel should label their own individual compatible N95 respirator with their name and/or identifier, and number of decontamination cycles (as shown below) with a permanent marker. The healthcare personnel should pouch the compatible N95 respirator in a Tyvek pouch, label the pouch with the decontamination cycle count, and seal it. The compatible N95 respirator in the Tyvek pouch should be placed at a designated collection station. See the “*Instructions for Healthcare Personnel*” for details.



Compatible N95 Respirator Collection and Transportation:

1. The healthcare facility should create a collection station at the point of generation (i.e., hospital floor/unit). Each station should have a tray or container provided by the healthcare facility to collect the pouches containing the compatible N95 respirators for decontamination with the following note:
NOTE: Only compatible N95 respirators in Tyvek pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.
2. The healthcare personnel who are assigned to decontamination (i.e., those with training for collection/transport of such materials) should collect the Tyvek pouches containing the compatible N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. The case cart should have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
3. The case cart should be transported to healthcare facility's decontamination area.

Use of the Non-Lumen Cycle in the STERIS Sterilization System:

1. Unload the pouched, compatible N95 respirators and place them into the STERIS Sterilization System for decontamination. Healthcare facility staff should adhere to the healthcare facility's policies for documenting load contents for and use of the STERIS Sterilization System.
2. A maximum of 10 pouched, compatible N95 respirators (5 pouches per shelf) can be processed in a Non-Lumen Cycle in the sterilizer. **(Caution: Do not combine any other load with the 10-pouched N95 respirator load).**
3. A specific orientation of the mask in the Tyvek pouch or pouches in the sterilizer is not required, however, pouches should not overlap or cover other pouches.
4. A Type 1 chemical indicator for vaporized hydrogen peroxide (for example, a chemical indicator or chemical indicator tape) may be used to monitor the cycle. The indicators may be placed on the pouch, inside a pouch, or within the chamber to provide an indicator that sterilant has been delivered. One indicator per cycle is recommended.
5. Use the STERIS V-PRO Sterilizer Operator Manual instructions on how to initiate the Non-Lumen Cycle and to verify a successful cycle completion.
6. Upon completion of the cycle, the decontaminated, compatible N95 respirators are ready for use. **Compatible N95 respirators may be processed a maximum of 10 times.**



After the Non-Lumen Cycle in the STERIS Sterilization System is complete:

1. Following completion of the Non-Lumen Cycle in the Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color. If the indicator color matches the reference color or is lighter, the respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirator should not be considered decontaminated and either repackaged and decontaminated through another Non-Lumen Cycle in the STERIS Sterilization System or discarded. Please note that successful completion of the cycle and passing chemical indicator signifies appropriately decontaminated compatible N95 respirators. These results do not indicate sterility of the decontaminated, compatible N95 respirators.

2. Healthcare facilities should utilize existing processes to decontaminate the case carts and sterilize the transport trays or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.
3. Decontaminated, compatible N95 respirators that match the “PASS” criteria should be loaded back in sterilized trays or containers and placed in a closed case cart following the healthcare facility’s policy for identifying/labeling processed loads. The healthcare facility should follow 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. The healthcare facility should ensure that the chain of custody is maintained to minimize risk of cross-contamination. Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, the respirator should be checked for the following:
 - a. Ensure that the name or other identifier and number of decontamination cycles is still legible. Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
 - b. Any compatible N95 respirator that is visually damaged or soiled should be discarded.
 - c. Any compatible N95 respirator that has exceeded 10 decontamination cycles should be discarded.
 - d. Ensure that the compatible N95 respirator is returned to its previous user.
5. The healthcare facility should make available the “Fact Sheet for Healthcare Personnel: STERIS Sterilization System for Decontaminating Compatible N95 Respirators” upon return of the decontaminated, compatible N95 respirators.

Additional Information:

1. Prior to use, healthcare personnel should inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (i.e., blood, dried sputum, makeup, soil). Respirators that are damaged or contain visible soil should be discarded.
2. N95 respirators or pouches containing cellulose or paper should not be processed in the V-PRO Sterilizer.
3. N95 respirators may be safely stored in pouches.
4. It is strongly recommended to maintain chain of custody on the compatible N95 respirator to minimize the risk of cross-contamination between individuals.

Reporting to STERIS:

Healthcare facilities should report any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator to STERIS, and the healthcare facility should discard the respirator.

Healthcare facilities using the decontaminated, compatible N95 respirators should monitor healthcare personnel who use such respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to STERIS, so that STERIS can provide a weekly report to FDA. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

Advisories on Chemical Indicators:

In the event of Chemical Indicator shortage, the following Parametric Instructions should be followed to determine proper decontamination of the compatible N95 respirators in the Non-Lumen Cycle of the STERIS Sterilization Systems.

Parametric Instructions:

1. Select "Options"

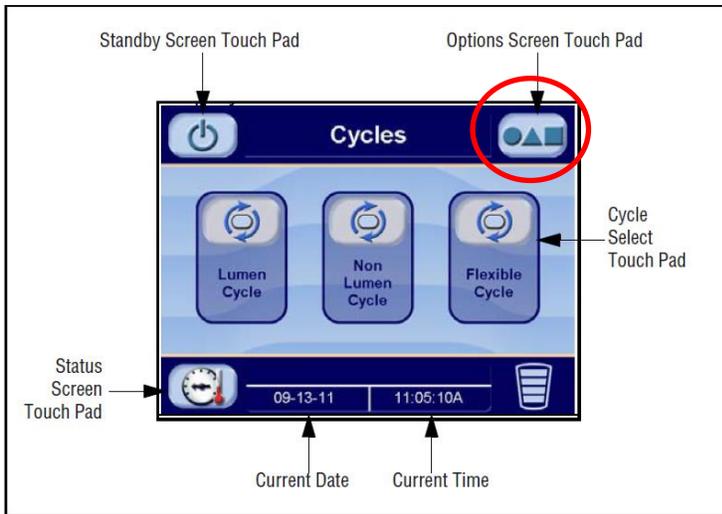
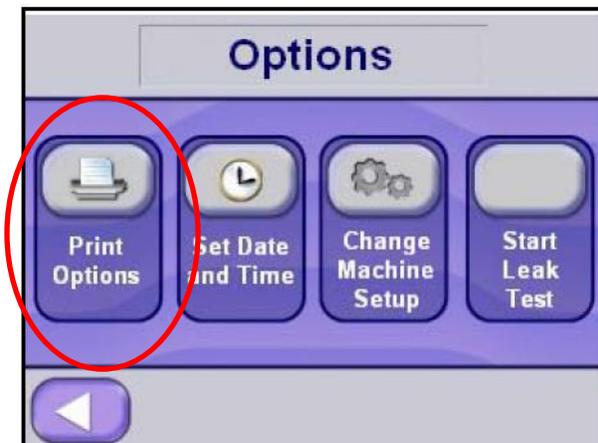


Figure 6-3. Start CYCLES or Ready Screen

2. Select "Print Options"



3. Select Printer Format and toggle to “Extended Printout”

Using the extended printout and in accordance with STERIS V-PRO Sterilizer Operator Manual (Appendix A), users can verify the pressure and temperature in each cycle. Specific instructions on how to do so are provided for the Non-Lumen Cycle in Appendix A.

A.4 Extended Non Lumen Cycle Printout Evaluation

Refer to Figure A-3 for an example of an Extended Non Lumen Cycle Printout with major sections labelled for ease of understanding. To confirm cycle parameters are within specification for the cycle, verify the following:

1. Verify VAPROX HC Sterilant is within expiration date:
 - YES
 - NO
2. Verify temperature is 48.5 - 51.5°C (119 - 125°F):
 - YES
 - NO
3. Verify sterilize time is greater than 12 minutes:
 - YES
 - NO
4. Verify pressure reading for all four sterilization pulses. Pressure started at 1.0 Torr, rises to between 6.3 - 15 Torr, and transitions at greater than 500 Torr:
 - **Pulse 1**
 - YES
 - NO
 - **Pulse 2**
 - YES
 - NO
 - **Pulse 3**
 - YES
 - NO
 - **Pulse 4**
 - YES
 - NO

If a YES answer is marked for each of the previous four steps, the cycle met all specified parameters.

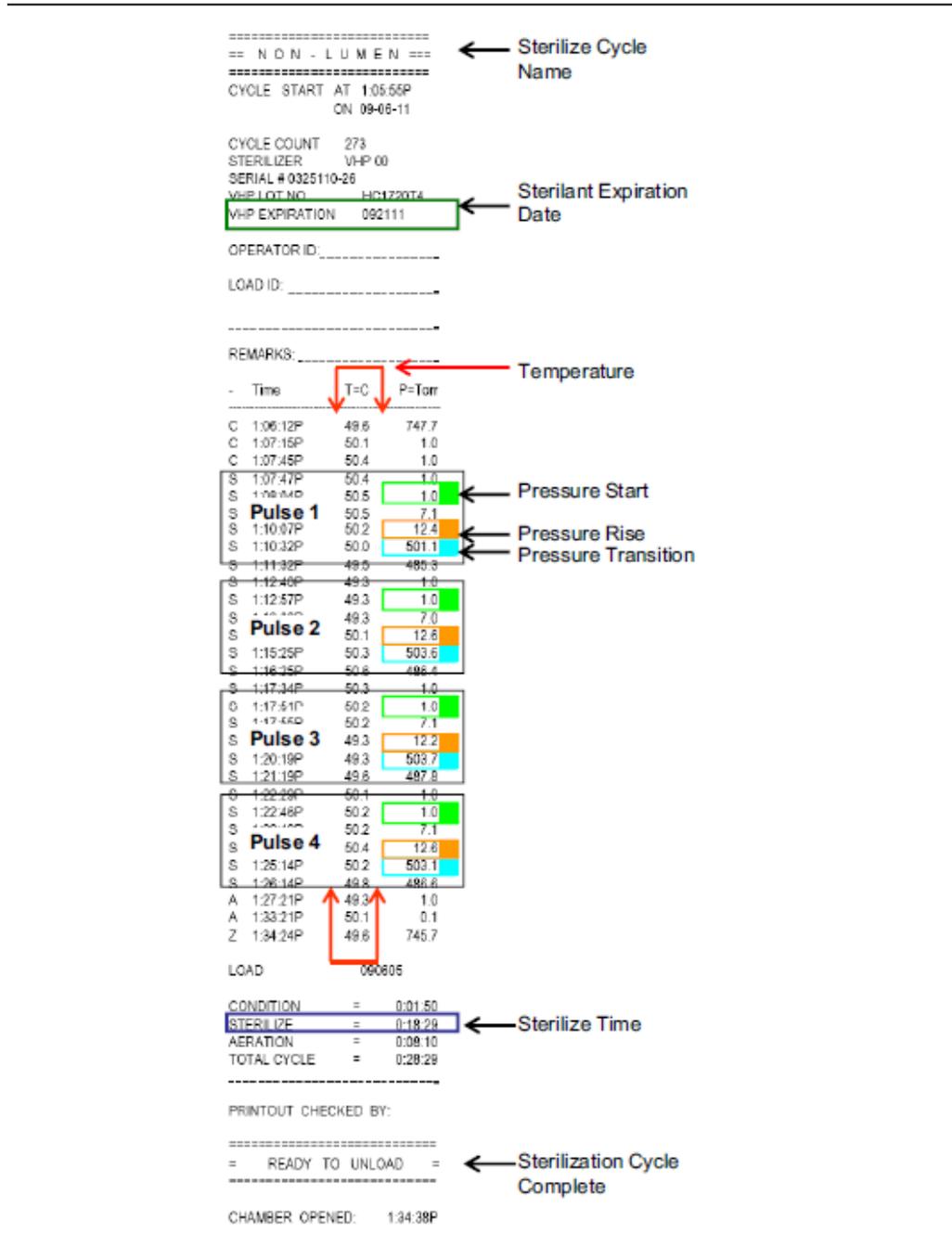


Figure A-3. Labelled Extended Flexible Cycle Printout (Typical)

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