STERIS
Healthcare

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

The U.S. Food and Drug Administration has issued 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, maX2, 60, and s2 Sterilizers (hereafter referred to as the "STERIS Sterilization Systems") for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. The STERIS Sterilization Systems contain five models: V-PRO 1 Plus, maX, maX2, 60, and V-PRO s2. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to decontaminate compatible N95 respirators using the STERIS Sterilization Systems.

The STERIS Sterilization Systems have neither been cleared or approved by the FDA, but have been authorized for emergency use by FDA under an EUA for decontamination of compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 pandemic. The emergency use of the STERIS Sterilization Systems is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is 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 and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

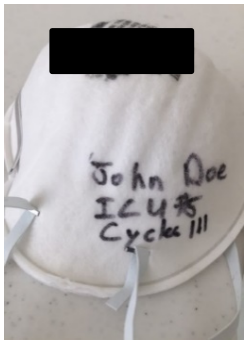
- **The STERIS Sterilization Systems are not authorized for use with the following:**
  - **Respirators or pouches containing cellulose-based materials;**
  - **Respirators containing exhalation valves;**
  - **Respirators containing antimicrobial agents;**
  - **Respirators with duck-billed designs; and**
  - **Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.**
- **All compatible N95 respirators used in the STERIS Sterilization Systems must be free of visible damage and visual soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).**
- **Do not collect compatible N95 respirators that are visually soiled or damaged, and discard such respirators.**
- **Discard compatible N95 respirators after exceeding 4 decontamination cycles.**
- **Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.**
- **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 must 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 will 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 will 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 will 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 will create a collection station at the point of generation (i.e., hospital floor/unit). Each station will 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) 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 will have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
3. The case cart will 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 will adhere to the healthcare facility's policies for documenting load contents for and use of the STERIS Sterilization System.
2. In the Non-Lumen Cycle of the V-PRO 1 Plus, maX, and maX2 sterilizer, a maximum of 10 pouched, compatible N95 respirators (5 pouches per shelf) can be processed. (**Caution:** Do not combine any other load with the 10-pouched N95 respirator load).
3. In the Non-Lumen Cycle of the V-PRO 60 and s2 sterilizer, a maximum of 6 pouched, compatible N95 respirators (3 pouches per shelf) can be processed. (**Caution:** Do not combine any other load with the 6-pouched N95 respirator load).

4. A specific orientation of the mask in the Tyvek pouch or pouches in the sterilizer is not required, however, pouches cannot overlap or cover other pouches.
5. A Type 1 chemical indicator for vaporized hydrogen peroxide (for example, a chemical indicator or chemical indicator tape) must be used to monitor the cycle. The indicators must 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.
6. Use the STERIS V-PRO Sterilizer Operator Manual instructions on how to initiate the Non Lumen Cycle and to verify a successful cycle completion.
7. Upon completion of the cycle, the decontaminated, compatible N95 respirators are ready for use. **Compatible N95 respirators may be decontaminated a maximum of 4 times**.

<u>After the Non-Lumen Cycle in the STERIS Sterilization Systems is complete:</u>

1. Following completion of the Non-Lumen Cycle in the Sterilizer, compare the chemical indicator's color 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 will not be considered decontaminated and either repackaged and decontaminated through another Non-Lumen Cycle in the STERIS Sterilization Systems 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 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 are 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 must 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 will be checked for the following:
    a. Ensure that the name or other identifier and number of decontamination cycles is still legible. Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.
    b. Discard any compatible N95 respirator that is visually damaged or soiled.
    c. Discard any compatible N95 respirator that has exceeded 4 decontamination cycles.
    d. Ensure that the compatible N95 respirator is returned to its previous user.
5. The healthcare facility must make available the "Fact Sheet for Healthcare Personnel: STERIS Sterilization Systems for Decontaminating Compatible N95 Respirators" upon return of the decontaminated, compatible N95 respirators.

Additional Information:

1. Prior to use, healthcare personnel will inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil). Discard respirators that are damaged or contain visible soil.
2. Do not decontaminate N95 respirators or pouches containing cellulose-based materials in the V-PRO Sterilizers. Do not decontaminate respirators containing exhalation valves, antimicrobial agents, or duck-billed design. Do not decontaminate respirators identified in the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
3. N95 respirators may be safely stored in pouches.
4. Maintain chain of custody on the compatible N95 respirator to minimize the risk of cross-contamination between individuals.

Reporting to STERIS:

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

Healthcare facilities will report adverse events of which they become aware related to the STERIS Sterilization Systems and the decontaminated, compatible N95 respirators. This includes monitoring personnel using the STERIS Sterilization Systems and healthcare personnel using the decontaminated, compatible 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.**

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 (V-PRO 1 Plus, maX, and maX2):

1. Select “Options”

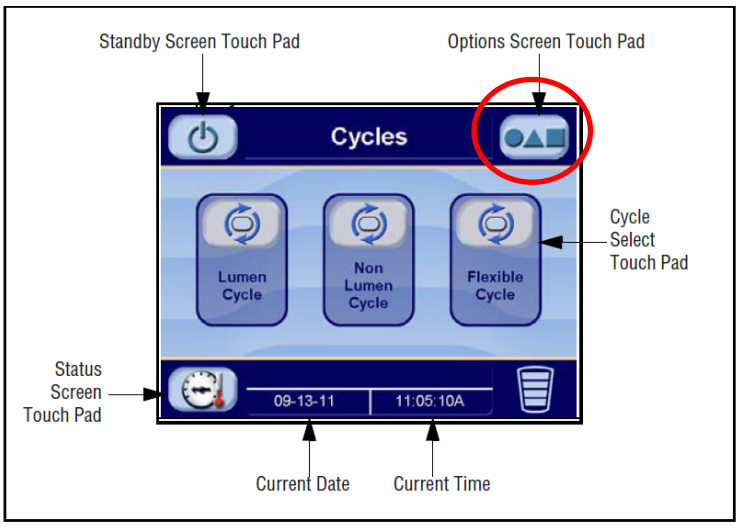
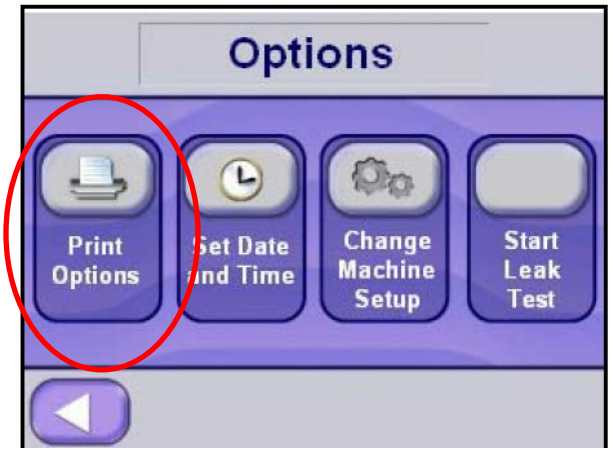


Figure 6-3. Start CYCLES or Ready Screen

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.

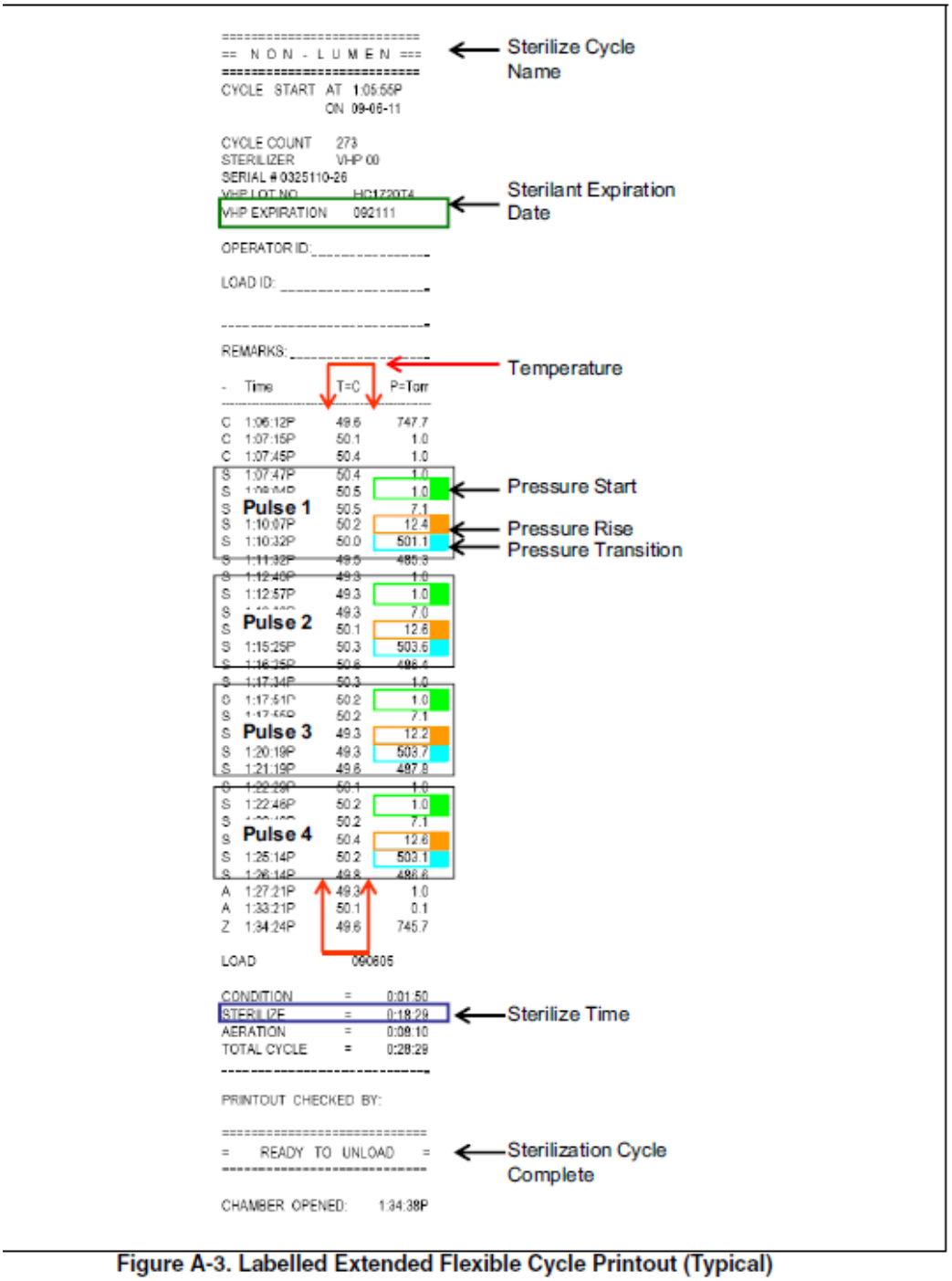


Figure A-3. Labelled Extended Flexible Cycle Printout (Typical)

Parametric Instructions (V-PRO 60 and s2):

1. Select “Options”

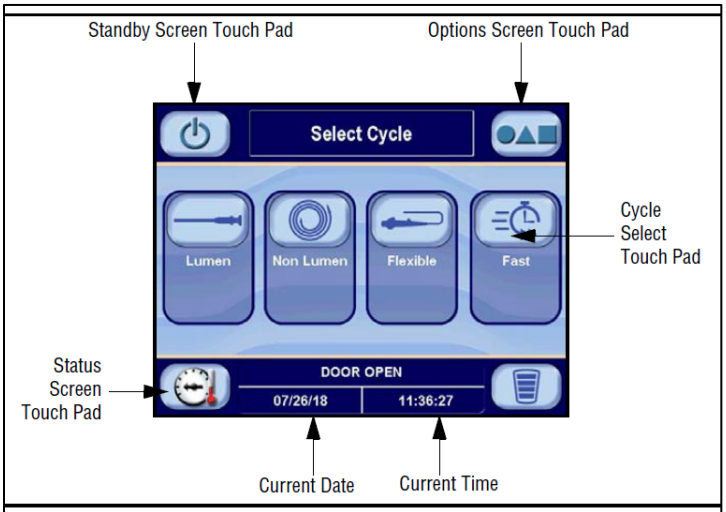
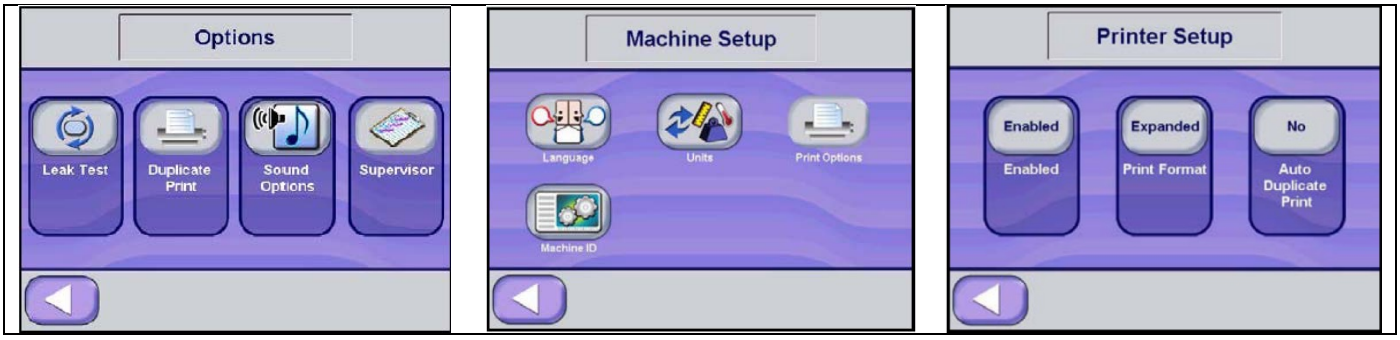


Figure 6-13. Start CYCLE or Ready Screen

2. Select Supervisor, Machine Setup, then Print Options



3. Select Printer Format and toggle to “Expanded 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 labeled 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 nine minutes:

❑ YES

❑ NO

4. Verify pressure reading for all four sterilization pulses. Pressure started at 1.0 Torr, rises to between 6.0 - 17.6 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.

In addition, when **Cycle Pass** appears on the Sterilization Cycle printout in *Sterilize Cycle Complete* section, it indicates the critical cycle parameters were met.

NOTE: The control numbers each load as follows:

- *LOAD xxyyzz*

  Where xx = month

  Where yy = day

  Where zz = cycle number/load run that day

- *EXAMPLE: For Figure A-3, the load was 21st run on December 30th.*

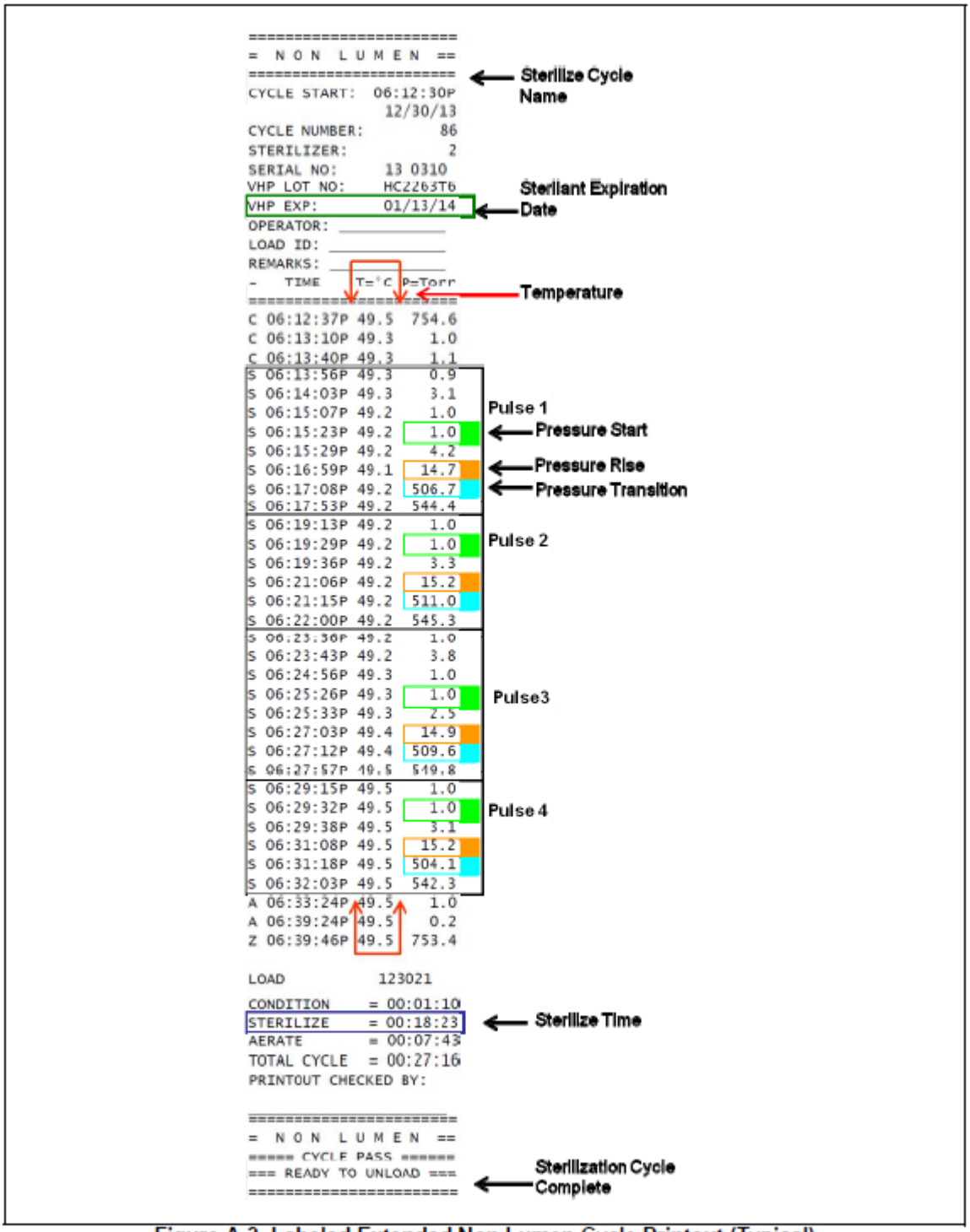


Figure A-3. Labeled Extended Non Lumen Cycle Printout (Typical)

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