SAMPLE PROCEDURE
Routine Monitoring of V-PRO® Low Temperature Sterilization Systems with Celerity™ 20 HP Biological Indicators

Product Numbers:
LCB044 Celerity™ 20 HP Biological Indicator
LCB046 Celerity™ HP Incubator
PCC061 VERIFY® HPU Chemical Indicator

This document contains sample procedures for the routine monitoring of V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 Low Temperature Sterilization Systems. The procedures contained in this document are only intended to provide a foundation for your development of specific policies and procedures for your facility. It is the responsibility of the health care facility to ensure compliance with applicable laws, regulations, standards, and industry-recommended practices. The health care facility should seek expert advice and consultation for guidance with compliance issues. STERIS Corporation makes no representation, express or implied, with respect to compliance with local or federal laws, regulations, standards, or industry-recommended practices. STERIS Corporation shall not be responsible for any loss, injury, damage, or claim arising from use of this document or the sample policies and procedures contained in it.

Definitions:

Mechanical Monitor: Sterilizer time, temperature, and pressure recording devices.

Biological Indicator: Test system containing viable microorganisms providing a defined resistance to a specified sterilization process (ANSI/AAMI ST58:2013). A biological indicator does not verify that an item is sterile.

Biological Indicator “Control”: An unprocessed biological indicator used to ensure viable organisms are present in the indicator lot and to monitor the operation of the incubator.

Chemical Indicator: System that shows exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the variables required for sterilization process. (ANSI/AAMI/ISO 11140-1)

Routine Monitoring of V-PRO® Low Temperature Sterilization Systems

Procedure:
Prior to initiating a cycle examine the BI for expiration date, ensure media-filled cap is not fully seated on the top of the vial and the foil seal is intact. Verify there
is no evidence of media in the vial and the process indicator has NOT changed from magenta to orange/yellow.

NOTE: Routine microbial challenges shall be conducted daily utilizing the cycle with the shortest cycle time to be run that day.

- The Non Lumen Cycle is the shortest cycle followed by the Flexible Cycle ending with the Lumen Cycle.

Initiating the cycle:

1. Load the V-PRO Sterilizer with items to be processed according to the sterilizer Operator Manual.

2. Take one Biological Indicator (BI), remove the lot label and place in record keeping documentation.

3. Verify that the BI and CI are within expiration dates. Place the BI into a Vis-U-All Low Temperature Sterilization Pouch. Insert one VERIFY HPU Chemical Indicator (CI) into the pouch so that the indicator ink is visible through the clear side of the pouch and seal the pouch.

4. Place the pack in the middle of the top shelf. If the top shelf is not installed, place the pack on the bottom shelf near the door.

   NOTE: Where space is limited, pouch may be placed along the outside edge of the top rack along the side of the items being sterilized. Never place the pouch on top or beneath items being sterilized.

5. Close the chamber door.

6. Initiate the appropriate sterilization cycle.

Upon completion of the cycle:

1. Review the cycle printout to verify that cycle did not abort and that process parameters were met (i.e. sterilant within expiration, temperature, sterilize time and pressure are correct).
   a. If any parameter was not met, the sterilization cycle was not successful. The processed items may not be released for use. Follow departmental procedures for investigating suspected sterilization failures.
   b. Dispose of BI per manufacturer's instructions for use.

2. Don gloves and remove the pouch from the shelf. Look for any leakage of the media within the pouch or in the BI’s vial. If no leakage detected, proceed to step 3.
a. Pouches which show leakage must be placed in a steam compatible container for sterilization prior to disposal. Refer to the product instructions for disposal recommendations.

3. Remove the chemical indicator strip. Observe the strip for a “Pass” color change.
   a. The chemical indicator passes if the indicator ink changes from magenta to yellow. Continue to step 4.
   b. The chemical indicator ink fails if any color other than yellow is seen. Determine the root cause of the cycle failure. Follow departmental procedures for investigating suspected sterilization failures.
   c. If indicator demonstrates a failure, dispose of BI per manufacturer’s instructions for use.

4. Remove the BI and check the process indicator on the BI vial label for a color change from magenta to orange/yellow.
   a. If the process indicator is orange/yellow, proceed to step 5.
   b. If the process indicator is not orange/yellow, determine the root cause of the cycle failure. Follow departmental procedures for investigating suspected sterilization failures.
   c. Dispose of BI per manufacturer’s instructions for use.

5. To activate the BI, twist the cap clockwise and transfer the media from the cap to the vial by holding the BI firmly by its cap and flicking the wrist down.

6. Label the BI with pertinent process information, ensuring the label is not placed on the side of the vial.

7. Place the activated BI in a Celerity HP Incubator and press the corresponding well number to start reading. The well light will blink red during incubation.

**Control Biological Indicator**

A control must be performed each day a microbial test is performed, and when a new lot is used.

1. Obtain a BI from the same lot as used in the test pack.

2. Activate, and incubate the BI as described in Steps 5 through 7 above.
   Note: Use an unprocessed BI as the control.
   Note: The process indicators on the label will remain magenta.

**Interpretation of Biological Indicator Test Results**

1. The Incubator will display results for the “Test” and “Control” BIs when incubation is completed (within 20 minutes).
a. A Negative response (no organisms present) is confirmed when the Celerity HP Incubator demonstrates a solid green light with no audible alarm.

b. A Positive response (organism present) is confirmed when the Incubator demonstrates a solid red light with an audible signal.

2. Record the BI “Test” and “Control” results.

3. The test passes when the “Test” BI demonstrates a negative response (no increase in fluorescence signal) and the “Control” BI demonstrates a positive response (increase in fluorescence signal).

4. The test fails if the “Test” BI demonstrates a positive response (increase in fluorescence signal) and the “Control” BI demonstrates a positive response (increase in fluorescence signal). Follow departmental procedures for reporting and investigating suspected sterilization failures.
   a. Recall sterilized loads back to the last negative BI.

5. The test is invalid whenever the “Control” BI demonstrates a negative response (no increase in fluorescence signal). All tests performed since the last positive control must be repeated using a different box of BIs.
   a. Do not release the load
   b. Repackage with all new materials and rerun the load.
   c. Dispose of BI and Control per manufacturer’s instructions for use
   d. Recall sterilized load back to the last positive control BI.