Technical Data Monograph

Verify® SixCess® 270 FP Challenge Pack

(Class 6 Emulating Indicator)
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Introduction

This Technical Data Monograph illustrates the principles of operation and the performance of the Verify® SixCess® 270FP Challenge Pack.

Steam Sterilization and Extended Cycle Times

Whether it is for a standard cycle or an extended cycle, steam sterilization is the predominant sterilization process employed in healthcare facilities to sterilize instruments, linens and other medical devices. Steam sterilization is a moist heat process in which items are heated through the condensation of steam to a temperature sufficient to cause the death of microorganisms. The ability for a steam sterilization process to be effective is dependent on the ability of steam to reach all surfaces of a device and condense on those surfaces in order to maintain the correct temperature for the necessary period of time.

The rate at which microorganisms die when exposed to steam is dependent on the temperature and condition of the steam. Microorganisms will die at a predictable rate for a given temperature in saturated steam. The predictability of the process allows for use of the “over-kill” method of sterilization. The over-kill method of sterilization seeks to achieve a one-in-a-million chance that a medical device would contain a surviving organism. This is referred to as the Sterility Assurance Level (SAL). The sterilization process is designed to deliver a minimum SAL of $10^{-6}$. To accomplish the SAL, the steam sterilization process must ensure that steam penetrates each pack and reaches the instrumentation for the required amount of time and at the right temperature to achieve the SAL.

Steam sterilization uses many methods to achieve the common goal of sterility. Whether prevacuum, gravity or steam-flush pressure-pulse sterilization, all steam cycles (standard or non-standard) are designed to achieve a sterility assurance level (SAL) of $10^{-6}$. Why then do these cycles all have different exposure times even when using the same sterilization temperature? Simple: different sterilization methods, medical devices and containment devices affect the ability to effectively remove air and penetrate device surfaces with steam.

Medical devices and device containment systems have become increasingly more complex. The complex nature of the new devices and containment systems are known to impede air removal and steam penetration. To ensure air removal and steam penetration, device manufacturers have used exposure times beyond the standard times. Cycles with extended sterilization exposure times are becoming more common with orthopedic and neurological instrument sets that contain dense instrumentation or difficult to sterilize medical devices, which have FDA clearance for these claims. The device design or containment device creates a greater challenge to air removal and steam penetration than standard instrument sets. This has created the need of healthcare facilities to extend the exposure time beyond the validated cycles recommended by the steam sterilizer manufacturers.

The Association for the Advancement of Medical Instrumentation provides recommended sterilization times and exposures in the guidance ANSI/AAMI ST79 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”. However, these recommendations are based on the validated cycles of steam sterilizers. The advent of extended cycles has created a dilemma with the multitude of sterilization exposure times and temperatures utilized by medical device manufacturers. In 2008, AAMI’s sterilization working group published Technical Information Report AAMI TIR31:2008 “Process challenge devices/test packs for use in health care facilities”. Medical device manufacturers, sterilizer manufacturers and users from around the country collaborated and proposed “standard” extended cycles. The Verify SixCess 270FP Challenge Packs are used to monitor dynamic air removal (pre-vacuum and SFPP) in steam sterilization cycles operating at 270°F (132°C) with exposure times of 4, 10, or 20 minute cycles as cleared by the FDA.
Use Application:
The Verify® SixCess® 270FP Challenge Packs are cycle specific challenge packs designed to monitor steam sterilization cycle performance. These packs may be used to monitor and release loads, consistent with hospital policy, for the specific cycle for which they are labeled.

The Verify SixCess 270FP Challenge Packs are not cleared as a substitute for biological indicators and are not intended to release loads that contain implantable devices.

Interpretation of Challenge Packs:
The indicator sheet is composed of three indicator ink figures. Each figure is calibrated for a specific exposure time. When the indicator ink figure has been exposed to the time and temperature required, the yellow indicator figure becomes blue/purple. Any color other than blue/purple is a failed result.

4, 10 and 20 minute unprocessed

4 minute section

10 minute section

20 minute section
4 minute Pass

10 minute Pass

20 minute Pass

4 minute Fail

10 minute Fail

20 minute Fail
**PRECAUTIONS:**

- While the sheet may demonstrate variations of the blue/purple color, this is still a passing result.
- Sterilizer performance may vary between sterilizer models, manufacturers, age, etc. The indicator inks have been timed to pass when the conditions have been met. It is possible for an indicator ink to show passing conditions in a sterilization cycle with a programmed shorter exposure time due to the sterilizer's performance.
- The indicator ink reaction occurs quickly, changing from yellow through green until blue/purple. The green transitional color must be recorded as a fail and may demonstrate a reversion to yellow over time.

**Device Description:**

The Verify SixCess 270FP Challenge Pack consists of approximately 198 sheets of paper barrier material surrounded by a wrap. The indicator sheet centrally located within the pack is 125 mm x 125 mm (4 7/8" x 4 7/8") with three geometric chemical indicator ink figures printed on one side. The ink used with the Verify SixCess 270FP Challenge Pack employs the same proprietary ink formulation as the Verify SixCess Challenge Packs and the Verify SixCess Chemical Indicator Strips. The barrier material challenges the air removal and steam penetration process. Upon exposure to saturated steam at the labeled time and temperature, the corresponding ink figure on the indicator sheet within the Verify SixCess 270FP Challenge Pack changes from its start color of yellow to a blue/purple color if air removal / steam penetration is adequate.

The Verify SixCess 270FP Challenge Pack has been cleared to monitor a 4 minute 270°F/132°C SFPP (Steam-Flush Pressure-Pulse) and 4, 10 or 20 minute pre-vacuum steam sterilization cycles.
Regulatory Status:
The Verify SixCess 270FP Challenge Packs are Class 2 medical devices as defined by the U.S. Food and Drug Administration that have been cleared for the indications for use specified in Table 1.

When used according to its instructions for use, the Verify SixCess 270FP Challenge Packs may be used to release loads processed during a sterilization cycle, consistent with hospital policy, for the specific sterilization cycles for which they are labeled, i.e. 4 minute 270°F/132°C SFPP and 4, 10 or 20 minute pre-vacuum steam sterilization cycles.

Table 1: 510(k) Clearance for the Verify SixCess 270FP Challenge Packs

<table>
<thead>
<tr>
<th>Reorder Number</th>
<th>Description</th>
<th>Indications for Use</th>
<th>510(k) Number</th>
</tr>
</thead>
</table>
| LCC019         | Verify® SixCess® 270FP Challenge Pack | • The Verify 270 FP Challenge Pack is a test pack consisting of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier, intended for use in SFPP (steam-flush-pressure-pulse) and pre-vacuum steam sterilization. The Verify 270 FP Challenge Pack indicators change color from yellow to blue/purple when exposed to the following conditions:  
- 4 minute indicator – SFPP and Pre-vacuum steam sterilization for 4 minutes  
- 10 minute indicator – Pre-vacuum steam sterilization for 10 minutes  
- 20 minute indicator – Pre-vacuum steam sterilization for 20 minutes | K103053       |

The challenge packs are not cleared as a substitute for biological indicators and are not intended to release loads that contain implantable devices.

3 Resistometer Vessel Performance Testing Summary

Class 6 Emulating Indicator Performance Verifications to ANSI/AAMI/ISO 11140-1:2005:
The Verify SixCess steam indicators were tested to demonstrate performance to Class 6 emulating indicator standards included in the ANSI/AAMI/ISO 11140-1:2005 Sterilization of health care products - Chemical Indicators - Part 1: General Requirements. This included:

• Class 6 emulating indicator standards according to ANSI/AAMI/ISO 11140-1:2005 using a steam resistometer meeting requirements specified in ANSI/AAMI/ISO 18472. See Table 2.

• Dry heat test requirements according to ANSI/AAMI/ISO 11140-1:2005. See Table 2.

Definition: Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs (stated values) are generated from the critical variables of the specified sterilization process according to ANSI/AAMI/ISO 11140-1:2005.
Table 2: Performance Requirements of Class 6 Emulating Steam Indicators as Identified by ANSI/AAMI/ISO 11140-1

<table>
<thead>
<tr>
<th>Test Point</th>
<th>Test Time</th>
<th>Test Temperature</th>
<th>Test Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Passing Condition</td>
<td>SV*</td>
<td>SV*</td>
<td>Saturated steam</td>
</tr>
<tr>
<td>Steam Failing Condition</td>
<td>SV* - 6%</td>
<td>SV* – 1°C</td>
<td>Saturated steam</td>
</tr>
<tr>
<td>Dry Heat Test (Indicator Must Fail)</td>
<td>30 minutes (+1/-0)</td>
<td>137°C (+1/-0ºC)</td>
<td>Dry heat</td>
</tr>
</tbody>
</table>

*SV (Stated Value): selected based upon the critical variables required for a specified sterilization cycle.

**Test Objective:** Three lots of the Verify SixCess 270FP Challenge Pack were tested at the passing and failing points identified in ANSI/AAMI/ISO 11140-1 by testing them in a steam resistometer and a dry heat resistometer.

**Test Articles:** Three lots of the following Verify SixCess Steam indicator test sheets with the following inks:
- 4 minute indicator ink section
- 10 minute indicator ink section
- 20 minute indicator ink section

**Test Results:** All three lots from each indicator demonstrated passing conditions for all PASS tests and failing results for all FAIL tests. See Table 3. The indicators met the steam and dry heat performance criteria for Class 6 emulating indicators as defined by ANSI/AAMI/ISO 11140-1.

Table 3*: Resistometer Performance Verification of the Verify SixCess 270FP Challenge Pack Class 6 Emulating indicator test sheet to ANSI/AAMI/ISO 11140-1

<table>
<thead>
<tr>
<th>Sterilization Cycle Parameters</th>
<th>Verify SixCess 270FP Indicator Ink Section</th>
<th>Stated Values</th>
<th>Test Conditions</th>
<th>Result (# pass / # tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 minute SFPP/prevacuum sterilization cycles at 270°F</td>
<td>4 minute indicator ink section</td>
<td>132°C 4 minutes</td>
<td>Steam Pass Condition 132°C, 4.00 minutes</td>
<td>27/27</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Steam Fail Condition 131°C, 3.76 minutes</td>
<td>0/27</td>
</tr>
<tr>
<td>10 minute prevacuum sterilization cycle at 270°F</td>
<td>10 minute indicator ink section</td>
<td>132°C 10 minutes</td>
<td>Steam Pass Condition 132°C, 10.00 minutes</td>
<td>27/27</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Steam Fail Condition 131°C, 9.40 minutes</td>
<td>0/27</td>
</tr>
<tr>
<td>20 minute prevacuum sterilization cycle at 270°F</td>
<td>20 minute indicator ink section</td>
<td>132°C 20 minutes</td>
<td>Steam Pass Condition 132°C, 20.00 minutes</td>
<td>27/27</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Steam Fail Condition 131°C, 18.80 minutes</td>
<td>0/27</td>
</tr>
<tr>
<td>Dry heat tests</td>
<td>4 minute indicator ink section</td>
<td>Not applicable</td>
<td>Dry Heat Condition 137°C, 30.00 minutes (Indicator Must Fail)</td>
<td>0/27</td>
</tr>
<tr>
<td></td>
<td>4 minute indicator ink section</td>
<td></td>
<td></td>
<td>0/27</td>
</tr>
</tbody>
</table>

*Testing performed by STERIS Corporation test laboratories
Compliance to FDA Defined Chemical Integrators and Process Challenge Devices (PCDs)

The Food and Drug Administration defines 3 types of chemical indicators. These include Process Indicators, Chemical Integrators and Air Removal Indicators. The Verify SixCess 270FP Challenge Packs fall into the categories of Chemical Integrators and Process Challenge Devices.

Chemical Integrator: A chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles. *

Process Challenge Device (PCD): Item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process, and used to assess the effective performance of the process. *

*Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Chemical Indicators issued December 19, 2003

This guidance indicates that test data must be presented that identifies the critical parameters of the sterilization process and the pass/fail criteria that the chemical integrator meets. This was completed using the FDA recognized consensus standard ANSI/AAMI/ISO 11140-1 for Class 6 emulating indicators. In accordance with the FDA guidance, testing must demonstrate that the indicator sheet is less of a challenge than the indicator sheet within its challenge pack.

Side-by-Side of Indicator Sheets and Challenge Packs:
Test Objective: To demonstrate that the challenge pack presents a greater challenge in the sterilization cycle than the indicator sheet alone.

Test Method: Side-by-Side testing was completed using a commercially available steam sterilizer. Verify SixCess 270FP Challenge Packs were placed in a sterilizer. Verify SixCess 270FP Challenge Pack indicator test sheets were placed within a tray within the same sterilizer. Six cycles were run for each indicator section, three at full exposure time and three at an abbreviated cycle time.

Test Articles:
• Three test lots for each Verify SixCess 270FP Challenge Packs
• Three lots of Verify SixCess 270FP Challenge Pack indicator test sheets

Test Results: The Verify SixCess 270 FP Challenge Pack required more time than the corresponding test sheet in the sterilization cycle to demonstrate passing conditions. See Table 4.
### Table 4: Side-by-Side Testing of Verify SixCess 270FP Challenge Packs and indicator test sheets in a Commercially Available Steam Sterilizer

<table>
<thead>
<tr>
<th>Indicator Ink Section</th>
<th>Sterilizer Test Conditions</th>
<th>4 Minute Indicator Ink Section (# pass / # tested)</th>
<th>10 Minute Indicator Ink Section (# pass / # tested)</th>
<th>20 Minute Indicator Ink Section (# pass / # tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Challenge Pack indicator test sheet</td>
<td>Challenge Pack indicator test sheet</td>
<td>Challenge Pack indicator test sheet</td>
</tr>
<tr>
<td>4 minute 270°F/132°C (prevacuum conditioning)</td>
<td>4.00 min exposure 270°F/132°C pre-vacuum</td>
<td>27/27</td>
<td>27/27</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>2.00 min exposure 270°F/132°C pre-vacuum</td>
<td>0/27</td>
<td>26/27</td>
<td>NA</td>
</tr>
<tr>
<td>10 minute 270°F/132°C (prevacuum conditioning)</td>
<td>10.00 min exposure 270°F/132°C pre-vacuum</td>
<td>NA</td>
<td>NA</td>
<td>27/27</td>
</tr>
<tr>
<td></td>
<td>5.50 min exposure 270°F/132°C pre-vacuum</td>
<td>NA</td>
<td>NA</td>
<td>0/27</td>
</tr>
<tr>
<td>20 minute 270°F/132°C (prevacuum conditioning)</td>
<td>20.00 min exposure 270°F/132°C pre-vacuum</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>12.00 min exposure 270°F/132°C pre-vacuum</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

### Environmental Considerations

**Recycle:**
Verify SixCess 270FP Challenge Packs are composed of 95% recycled material by weight.

Verify SixCess Extended Timing Challenge Packs are free of lead and other heavy metals.

The paper barrier material and wrapper can be safely recycled.
Reuse:
The Verify SixCess 270 FP Challenge Pack barrier paper has many hidden uses, including scrap paper, children's art paper and physical rehabilitation origami sheets.

References

Guidance Documents and Standards
- ANSI/AAMI/ISO 18472 Sterilization of health care products - Biological and chemical indicators - Test Equipment
- Guidance for Industry and FDA Staff Premarket Notifications [510(k)] Submissions Sterilizers Intended for Use in Health Care Facilities March, 1993
- Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use In Health Care Facilities September 15, 1995
- Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submission for Chemical Indicators December 19, 2003

STERIS Corporation Test Reports
- RDP.164-VTP4 Performance of Verify SixCess 270FP Class 6 Challenge Pack
- RDP.164.VTP6 Simulated Use Testing of Verify 270FP Class 6 Challenge Pack
- RDP.164.VTP5 Challenge Verification Testing of 270FP Class 6 Challenge Pack