

Dieble Surgical LLC

Dieble Instrument Organizer

**Steam Sterilization Cycle
Validation
(Re-usable Device)**

Final Report


SVS-DSL-01

October 5, 2023



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Executive Summary

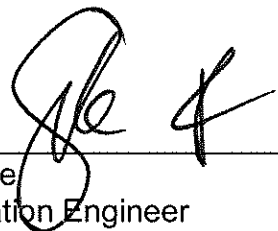
A study was successfully performed by LSO on behalf of Dieble Surgical LLC to validate indicated steam sterilization and dry time instructions for their Dieble Instrument Organizer. All acceptance criteria to establish a SAL of 10^{-6} with the indicated dry time were met. Therefore, the indicated steam sterilization cycles and dry time for the Dieble Instrument Organizer are validated. Details of the study are followed in this report.

Report written by:

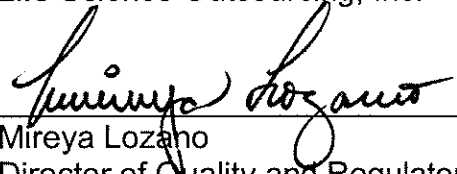

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10-5-23
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Reviewed By:


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 Life Science Outsourcing, Inc.

October 9, 2023
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Approved By:


 Diane Lyons
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Oct 09, 2023
 Date

THERE IS NO WARRANTY EXPRESSED OR IMPLIED WITH THE SUBMISSION OF THIS REPORT AND CUSTOMER ASSUMES ALL LIABILITIES FOR USE OF DATA CONTAINED HEREIN. FOR COMPLETE WARRANTY INFORMATION, REFER TO LSO SOP-F-14.

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Final Analysis:

Summary of Procedure

1. Biological Indicators (BIs) were installed in the part per the Protocol, Attachment 2: Load Configuration and BI Placement. **(See Tabbed Section 2: Protocol to this report.)**
2. Three half cycles at 134°C for 2 minutes were performed and the BI's were cultured for 7 days. **(See Tabbed Sections 3 and 4 to this report.)**
3. One full cycle at 134°C for 4 minutes followed by a 30-minute dry time was performed and the BI's were cultured for 7 days, the part was inspected for dryness with the results recorded. **(See Tabbed Sections 3 and 4 to this report.)**
4. Two additional full cycles at 134°C for 4 minutes followed by a 30-minute dry time were performed for dryness verification only. Upon cycle completion, the part was inspected for dryness with the results recorded. **(See Tabbed Sections 3 to this report.)**

Biological Indicator Results

All biological indicators for the cycles validated tested negative for growth except the positive control, which, as required, tested positive.

Exposure Time Results

Cycle exposure times are confirmed to be in accordance with the Protocol cycle parameters.

Dry Time Results

The part was confirmed dry after the full cycles.

NCR's and Deviations

None.

Conclusion

Based on these results, the steam sterilization and dry time cycle performed is validated. Detailed results follow in this report.

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Cycle Records

(See Tabbed Section 3)

Performed at: Life Science Outsourcing

Reference to Section: LSO Protocol SVS-DSL-01, Sections 4.0 and 5.0

Reference to Standard: ANSI/AAMI ST79:2017 and ANSI/AAMI/ISO 17665-1:2006/(R)2013

Acceptance Criteria (Protocol Section 5.0):

- | | |
|---|--------|
| 5.1 Process must meet specified parameters. | Passed |
| 5.3 Temperature must be within -1°C and +3°C. | Passed |
| 5.3 Exposure Time must be within ±10% of setting. | Passed |

Results: The following cycles met Acceptance Criteria 5.1 and 5.3 from Protocol SVS-DSL-01, Rev A01.

A. Pre-Vac, Wrapped 134°C half cycle at 2 minutes Passed

Lot numbers of each cycle: E043-23, E044-23, E045-23

B. Pre-Vac, Wrapped 134°C full cycle at 4 minutes Passed

Lot number of dry cycles: E042-23, E049-23, E050-23

Device History Record: WO 90467-1

Deviation: None.

Processed By: Trino Perales, LSO

Conclusion: The cycles meet the acceptance criteria listed in the protocol.

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Biological & Dryness Test Results

(See Tabbed Section 4 for BI Results)

Performed at: Life Science Outsourcing

Reference to Section: LSO Protocol SVS-DSL-01, Sections 4.0 and 5.0

Reference to Standard: ANSI/AAMI ST79:2017 and ANSI/AAMI/ISO 17665-1:2006/(R)2013

Acceptance Criteria (Protocol Section 5.0):

- | | |
|---|--------|
| 5.2 No BI positives in half cycles; Controls must grow | Passed |
| 5.4 No BI positives in first full cycle; Controls must grow | Passed |
| 5.4 Full cycle tray and instruments must be visually dry | Passed |

Results: The following cycles met Acceptance Criteria 5.2 and 5.4 from Protocol SVS-DSL-01, Rev A01 .

A. Pre-Vac, Wrapped 134°C half cycle at 2 minutes Passed

Lot numbers of each cycle: E043-23, E044-23, E045-23

B. Pre-Vac, Wrapped 134°C full cycle at 4 minutes Passed

Lot number of dry cycles: E042-23, E049-23, E050-23

Device History Record: WO 90467-1

Deviation: None

Processed By: Trino Perales, LSO

Conclusion: The cycles meet the Acceptance Criteria listed in the protocol.

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NCR's and Deviations

(See Tabbed Section 5)

During the performance of this study, there are no NCR's and one Deviation to report:

- 1. None**



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Dieble Surgical LLC

Dieble Instrument Organizer

Steam Sterilization
Cycle Validation Protocol
(Re-usable Device)

SVS-DSL-01

September 19, 2023

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1.0 Scope

This document applies to the steam sterilization process recommended for use with the re-useable surgical instrument set described herein.

- 1.1 Objective:** To validate the recommended steam sterilization cycles for the reusable instruments to a Sterility Assurance Level (SAL) of and verify the drying cycle as specified in Instructions for Use (IFU) provided to health care providers using the product.
- 1.2 Sponsor:** Dieble Surgical LLC, North Lawrence, OH.
- 1.3 Project Manager:** Life Science Outsourcing, Inc. ("LSO") Brea, California
- 1.4 Sterilizer Location:** LSO, Brea, California
- 1.5 Test Lab:** LSO, Brea, California
- 1.6 Product:** Dieble Instrument Organizer(D10K6)
- 1.7 Strategy:** Half-cycle overkill validation by inactivation of biological indicators with a 10^6 population.

2.0 Reference Documents

2.1 Primary:

- 2.1.1 ANSI/AAMI/ISO 17665-1:2006/(R)2013** Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- 2.1.2 ISO 17664-1:2021** Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices.
- 2.1.3 AAMI TIR12:2010**, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
- 2.1.4 AAMI ST77:2013/(R)2018**, Containment devices for reusable medical device sterilization.
- 2.1.5 ANSI/AAMI ST79:2017**, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

2.2 Secondary:

- 2.2.1 ISO 11737-2:2019(E)** Sterilization of health care products - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process.
- 2.2.2 ISO 11138-1:2017(E)** Sterilization of health care products - Biological Indicators - Part 1: General Requirements.

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- 2.2.3 **ISO 11138-3:2017(E)** Sterilization of Healthcare products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes.
- 2.2.4 **ISO 11138-7:2019(E)** Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use, and interpretation of results.
- 2.2.5 **ISO/TS 17665-2:2009(E)** Sterilization of health care products-Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1.
- 2.2.6 Premarket Notification [510(K)] Submission for Medical Sterilization Packaging Systems in Health care Facilities; Draft Guidance for Industry and FDA. Office of Device Evaluation, draft released for comment on March 7, 2002.

2.3 LSO Quality Documents:

- 2.3.1 Life Science Outsourcing Work Instruction **WI-LSO-MSI-062**, for *Sterility Testing of Biological Indicators*

2.4 Relevant Project Documents:

- 2.4.1 Form 7-31-F-04, BI Test Report (Validation)
- 2.4.2 Form 7-31-F-10, Sterilization Cycle Record Form

3.0 Resources

3.1 Test Load Materials

- 3.1.1 See Attachment 1: Product Description; Attachment 2: Load Configuration and BI placement.

3.2 Equipment

- 3.2.1 Sterilizer: Amsco Steam Sterilizer, LSO-469T, of the type available in healthcare facilities.
- 3.2.2 Biological Safety Cabinet, LSO-118T
- 3.2.3 Laminar Flow Hood, LSO-490T
- 3.2.4 Incubator Oven, LSO-305T, (55-60°C)
- 3.2.5 HEPA Test Bench, LSO-118T

3.3 Supplies

- 3.3.1 Biological Indicator spore strip (**BI,SVS-STM-001**), *Geobacillus stearothermophilus*, of the type cleared by the FDA for use in healthcare facilities. The spore strip used is certified by the indicator manufacturer to have a minimum population of 10⁶ and the Certificate of Analysis will be included in the final report.

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3.3.2 Microbiological culture media, **SVS-STM-013**, is of the type cleared by the FDA for use in healthcare facilities.

3.3.3 CSR Wrap, **SVS-MIS-002**, 36" x 36", of the type cleared by the FDA for use in healthcare facilities.

3.4 **External Laboratory Tests: None**

4.0 Validation Process

4.1 Pre-cycle Tasks

4.1.1 Calibration

4.1.1.1 All instrumentation used in the validation requiring calibration will be calibrated. Records will be included in the final report.

4.1.1.2 BI lot population will be verified by the certificate of population from the BI supplier, the certificate will be included in the final report.

4.2 Cycle Tasks

4.2.1 Biological Indicator Preparation

4.2.1.1 **Half Cycles:** Five (5) BI's will be numbered and be placed per Attachment 2: Load Configuration and BI placement. One (1) BI will be marked as the positive control and set aside for testing with the sample BI's.

4.2.1.2 **Full Cycles:** Only the first cycle will require BI's, five (5) BI's will be numbered and be placed per Attachment 2: Load Configuration and BI placement. One (1) BI will be marked as the positive control and set aside for testing with the sample BI's.

4.2.2 Load Preparation:

4.2.2.1 See Attachment 2 : Load Configuration and BI Placement.

4.2.2.2 Wrap the tray with CSR wrap in accordance with **ANSI/AAMI ST79:2017**.

4.3 **Half Cycles:** Perform three (3) half cycles at the following Cycle number parameters:

Cycle #	Cycle Type	Temp (C°)	Exposure Time (Minutes)	Dry Time (Minutes)
1	Pre-Vac, Wrapped	134	2	0

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4.4 Full Cycles: Perform three (3) full cycles at the following Cycle number parameters:

Note: Only the first full cycle will contain BI's, the two additional full cycles will be for dryness verification only with no BI's. Upon completion of the full cycles, the Instrument Organizer will be inspected for dryness, results will be reported and documented on the Autoclave Drying Inspection Form (7-31-F-02).

Cycle #	Cycle Type	Temp (C°)	Exposure Time (Minutes)	Dry Time (Minutes)
2	Pre-Vac, Wrapped	134	4	30

4.5 BI Testing

4.5.1 After each half cycle, collect and test BI's per **WI-LSO-MSI-062**. Incubate for 7 days and perform inspection and record the results from each workday. BI's will not be used during the full cycle drying tests.

4.5.2 Sample Size Justification: Samples will be re-used for all cycles throughout this study. The device sample will primarily be used as a means for BI placement and involves no functionality testing or to its efficacy for re-use. This study is solely addressing sterility assurance.

4.5.3 Note: the AMSCO Eagle Steam Sterilizer (LSO-469T) located at the LSO facility (the "Equipment") has a chamber dimension of 16" X 16" X 26" and capacity of 0.1 cubic meter. Per ANSI/AAMI ST79:2017, the number of BI's used within each product test sample will depend on the size and configuration of the pack being tested and the product test samples should be placed throughout the load at the points most difficult to sterilize. For this study, a minimum of five (5) biological indicators (BI's) / PCD's will be used based on a useable chamber volume of $\leq 1 \text{ m}^3$.

5.0 Acceptance Criteria

5.1 All sterilization processes must meet the specified parameters and loading instructions herein. All printed data results from validation equipment and recorders are to be complete, legible, reviewed, signed, and dated.

5.2 There must be no BI positives in the half cycles. The positive controls must have growth. All data sheets with BI, Sterilization Indicator, or any other test results will be reviewed, signed, and dated.

5.3 Temperature and time data must be analyzed to identify any cycle abnormalities. The acceptable temperature range will be from 1 degree below to 3 degrees above the parameter temperature setting. The acceptable time range will be $\pm 10\%$ of the parameter time settings.


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- 5.4** There must be no BI positives in the full cycle. After the full cycle, the test load must be dry with no visible condensate moisture upon removal of the product from the full cycle. Instruments with lumens will be tapped on a dry cloth to confirm no visual moisture comes from the inside of the lumen.
- 5.5** Any deviations are to be documented for review by the sponsor.
- 5.6** The final report must be approved by LSO and the sponsor.

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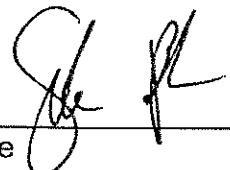
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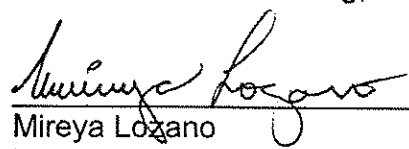
9-20-23
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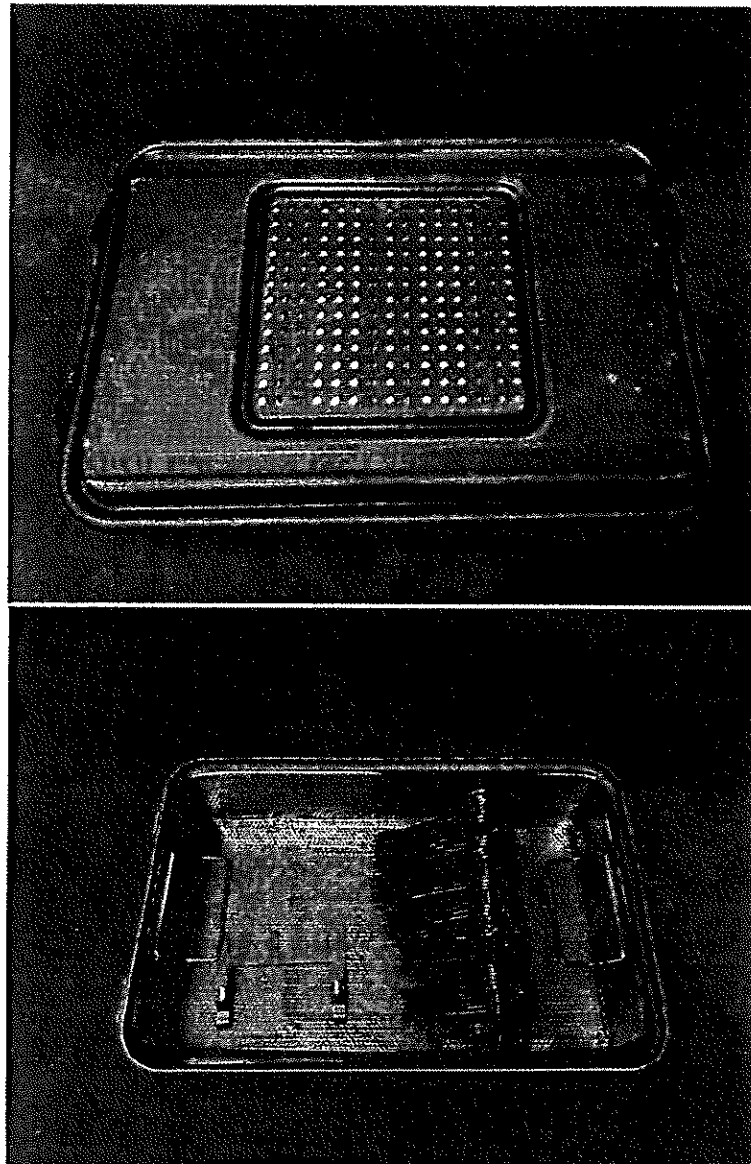
9/21/2023
Date

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Attachment 1: Product Description

The Dieble Instrument Organizer is a multipurpose instrument stringer used in Central Processing to organize and string ring handle instruments and an instrument stand used in surgery to transfer instrument to and from the field. After the case instruments can be restrung back onto the stand and returned to Central Processing in a safe and organized manner. See Figure 1: Dieble Instrument Organizer and Table 1 for the components .

Figure 1: Dieble Instrument Organizer



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Table 1: List of Components

Quantity	Reference Part Number	Description
1	BDC	Mesh Tray
1	6Q6	Stand
2	S10	Stinger Rod
5	QC50	Clips
1	QACL	Holder W/Clips
33	HDC	Hemostats

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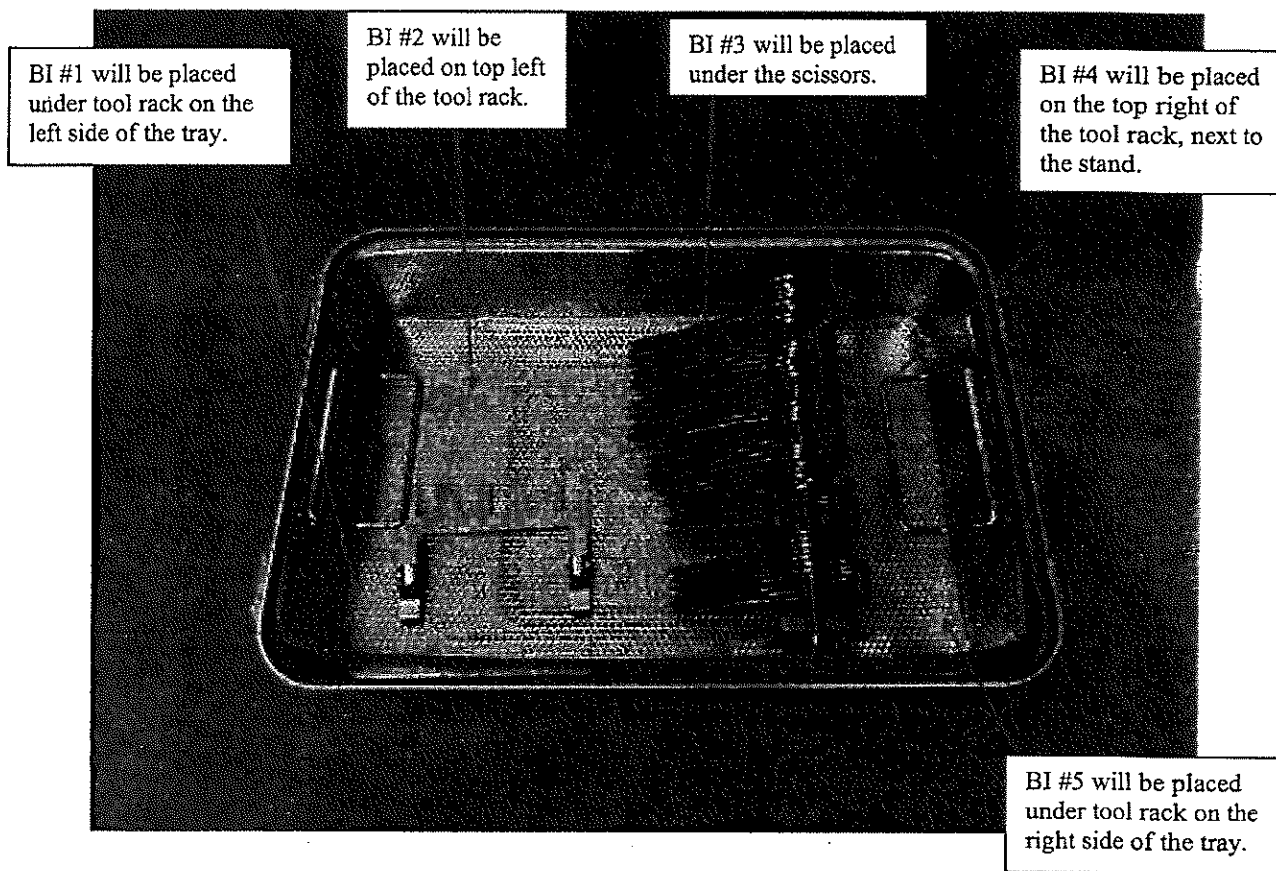
Attachment 2: Load Configuration and BI Placement

The Dieble Instrument Organizer was assessed to determine the Worst Case location(s) for steam penetration. This assessment considered the complexity of the devices, the size, the mass, through holes, blind holes, use within surgery, and overall difficulty to Sterilize. Based on this assessment the location(s) shown below are determined to be the Worst Case

The load will consist of:

1. A single Dieble Instrument Organizer will be double wrapped with CSR Wrap(SVS-MIS-002).
2. BI's (SVS-STM-001) will be placed as shown below in Figure 2:

Figure 2: BI Placement



END OF PROTOCOL



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Steam Sterilization Line Clearance

Customer Code: <u>DSL</u>	W/O No.: <u>90467-1</u>	Run Date: <u>9-22-23</u>
Sterile Lot No.: <u>E043-23</u>	Run No.: <u>02697</u>	Product Lot No.: <u>N/A</u>
No.	Pre-Sterilization Steps	Initial/Date
1	<p style="text-align: center;">Lancer Sterilizer LSO-434T Startup</p> <p>a) On the general boiler LSO-621T: open/close the following water valves, #1 open, #1A DI water open, #2 close, #3 open, #4 close, #5 close, #6 open, #7 close, #8 open, #9 open, #10 open.</p> <p>b) Turn power on, breaker located at main power panel (B siemens switch board 150 amps).</p> <p>c) Turn 3 switches on, located at the right side of boiler.</p> <p>d) Verify the pump comes on and level of the water in the sight glass on the right of the boiler is between "L" and "H".</p> <p>e) Allow the boiler pressure to come up to 60 psi.</p> <p>f) Open air valve #11</p> <p>g) Verify there is enough printer paper to complete the cycle.</p> <p>h) Run a test at the beginning of the day, prior to running any product.</p> <p>i) Verify sterilizer clocks are correct prior to run.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-22-23
2	<p style="text-align: center;">Primus Sterilizer LSO-532T Startup</p> <p>a) Use the Lancer boiler startup instructions 1a-1c to turn on boiler.</p> <p>b) Close the Lancer steam valve #6.</p> <p>c) Open the Primus valve #7.</p> <p>d) On the Primus open valve #1 and valve #2.</p> <p>e) Turn on Primus control switch to the left on top of control panel.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-22-23
3	<p style="text-align: center;">Getinge Sterilizer LSO-113T Startup</p> <p>a) On the Pacific boiler LSO-116T-01: open/close the following water valves, #1 open, #2 closed, #3 open, #4 closed, #5 closed, #6 open, #7 close, #8 open, #9 open and #10 open.</p> <p>b) Verify there is enough printer paper to complete cycle.</p> <p>c) Turn on power #9 on, #10 on, #11 on, boiler switch #12 on, control power #13 on, located on the right side of the boiler.</p> <p>d) NOTE: if an alarm sound sounds for low steam generator pressure, push P4 on the front of sterilizer to turn off the alarm</p> <p>e) In 15-20 minutes, check that the pressure gauge to the left and above the clean steam generator is reading a minimum of 40 psi.</p> <p>f) Check if the ready light is lit on the front of the sterilizer.</p> <p>g) NOTE: If the pressure is reading 40 psi and yellow light is not lit, push P4. The sterilizer will now be ready to start. Refer to the work order for further processing instruction.</p> <p>h) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	N/A TP 9-22-23
4	<p style="text-align: center;">Amsco Sterilizer LSO-469T Startup</p> <p>a) Use Getinge boiler startup instructions 3a, 3c-3e to turn on boiler.</p> <p>b) The Amsco valve #1 open, #2 open, #3 open, #4 open.</p> <p>c) Verify there is enough printer paper to complete the cycle.</p> <p>d) Turn on the control switch on the sterilizer, located on the front of the sterilizer under the top panel. The steam will go to the steam generator at this time.</p> <p>e) Before starting the cycle, ensure that the jacket pressure is at the following: 19-20 psi for 121 °C cycle, 29-30 psi for 132 °C cycle, for other temperature settings refer to WI-LSO-468T.</p> <p>f) In 15-20 minutes, check the pressure gauge above the generator for a minimum reading of 40 psi.</p> <p>g) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>h) Check to make sure the water knob and the steam knob are turned to the left.</p> <p>i) Verify there has been 30 minutes cool down since the last cycle run.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	TP 9-22-23
5	<p>Verified by:</p>	TH 9-22-23

Sterilization Cycle Record

Work Order#: <u>90407-1</u>	Sterile Lot#: <u>E043-23</u>	Run#: <u>02692</u>
-----------------------------	------------------------------	--------------------

=====
 ===== P R E V A C =====
 =====
 CYCLE START AT 12:06:56P
 ON 9/22/23

CYCLE COUNT 02692
 OPERATOR T. Renalis
 STERILIZER Eagle

STER TEMP = 134.0°C
 CONTROL TEMP = 135.2°C
 STER TIME = 0:02:00
 DRY TIME = 0:00:00

OCT 03 2023

- TIME	T=°C	P=bar
		U=bar
C 12:06:56P	75.9	0.0P
C 12:07:57P	116.5	0.9P
C 12:09:15P	83.7	0.5U
C 12:09:27P	115.5	1.0P
C 12:10:40P	80.3	0.7U
C 12:10:55P	116.3	1.0P
C 12:12:10P	86.3	0.8U
S 12:13:21P	134.1	2.2P
S 12:14:22P	135.1	2.2P
S 12:15:22P	134.9	2.2P
E 12:15:22P	134.6	2.1P
E 12:15:44P	104.8	0.1P
E 12:15:44P	103.3	0.1P
Z 12:15:54P	102.2	0.1P

Q.C.
9

LOAD 92202

TEMP MAX=135.1°C
 TEMP MIN=134.1°C

CONDITION = 6:25
 STERILIZE = 2:01
 EXHAUST = 0:32
 TOTAL CYCLE = 8:58

Steam Sterilization Line Clearance

Customer Code: <u>DSL</u>		W/O No.: <u>90467-1</u>	Run Date: <u>9-22-23</u>
Sterile Lot No.: <u>E044-23</u>		Run No: <u>02693</u>	Product Lot No: <u>N/A</u>
No.	Pre-Sterilization Steps	Initial/Date	
1	<p align="center">Lancer Sterilizer LSO-434T Startup</p> <p>a) On the general boiler LSO-621T: open/close the following water valves, #1 open, #1A DI water open, #2 close, #3 open, #4 close, #5 close, #6 open, #7 close, #8 open, #9 open, #10 open.</p> <p>b) Turn power on, breaker located at main power panel (B siemens switch board 150 amps).</p> <p>c) Turn 3 switches on, located at the right side of boiler.</p> <p>d) Verify the pump comes on and level of the water in the sight glass on the right of the boiler is between "L" and "H".</p> <p>e) Allow the boiler pressure to come up to 60 psi.</p> <p>f) Open air valve #11</p> <p>g) Verify there is enough printer paper to complete the cycle.</p> <p>h) Run a test at the beginning of the day, prior to running any product.</p> <p>i) Verify sterilizer clocks are correct prior to run.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	<p align="center">N/A TP 9-22-23</p>	
2	<p align="center">Primus Sterilizer LSO-532T Startup</p> <p>a) Use the Lancer boiler startup instructions 1a-1c to turn on boiler.</p> <p>b) Close the Lancer steam valve #6.</p> <p>c) Open the Primus valve #7.</p> <p>d) On the Primus open valve #1 and valve #2</p> <p>e) Turn on Primus control switch to the left on top of control panel.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	<p align="center">N/A TP 9-22-23</p>	
3	<p align="center">Getinge Sterilizer LSO-113T Startup</p> <p>a) On the Pacific boiler LSO-116T-01: open/close the following water valves, #1 open, #2 closed, #3 open, #4 closed, #5 closed, #6 open, #7 close, #8 open, #9 open and #10 open.</p> <p>b) Verify there is enough printer paper to complete cycle.</p> <p>c) Turn on power #9 on, #10 on, #11 on, boiler switch #12 on, control power #13 on, located on the right side of the boiler.</p> <p>d) NOTE: if an alarm sound sounds for low steam generator pressure, push P4 on the front of sterilizer to turn off the alarm</p> <p>e) In 15-20 minutes, check that the pressure gauge to the left and above the clean steam generator is reading a minimum of 40 psi.</p> <p>f) Check if the ready light is lit on the front of the sterilizer.</p> <p>g) NOTE: If the pressure is reading 40 psi and yellow light is not lit, push P4. The sterilizer will now be ready to start. Refer to the work order for further processing instruction.</p> <p>h) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	<p align="center">N/A TP 9-22-23</p>	
4	<p align="center">Amsco Sterilizer LSO-469T Startup</p> <p>a) Use Getinge boiler startup instructions 3a, 3c-3e to turn on boiler.</p> <p>b) The Amsco valve #1 open, #2 open, #3 open, #4 open.</p> <p>c) Verify there is enough printer paper to complete the cycle.</p> <p>d) Turn on the control switch on the sterilizer, located on the front of the sterilizer under the top panel. The steam will go to the steam generator at this time.</p> <p>e) Before starting the cycle, ensure that the jacket pressure is at the following: 19-20 psi for 121 °C cycle, 29-30 psi for 132 °C cycle, for other temperature settings refer to WI-LSO-468T.</p> <p>f) In 15-20 minutes, check the pressure gauge above the generator for a minimum reading of 40 psi.</p> <p>g) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>h) Check to make sure the water knob and the steam knob are turned to the left.</p> <p>i) Verify there has been 30 minutes cool down since the last cycle run.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	<p align="center">TP 9-22-23</p>	
5	<p>Verified by:</p>	<p align="center">JH 9-22-23</p>	

Sterilization Cycle Record

Work Order#: <u>90467-1</u>	Sterile Lot#: <u>E044-23</u>	Run#: <u>02693</u>
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 ===== P R E V A C =====
 =====
 CYCLE START AT 12:40:24P
 ON 9/22/23

CYCLE COUNT 02693
 OPERATOR T. Renales
 STERILIZER Eagle

STER TEMP = 134.0°C
 CONTROL TEMP = 135.2°C
 STER TIME = 0:02:00
 DRY TIME = 0:00:00

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- TIME	T=°C	P=bar V=bar
C 12:40:24P	80.0	0.0P
C 12:41:25P	115.2	0.8P
C 12:42:39P	80.9	0.5U
C 12:42:48P	110.9	1.0P
C 12:43:59P	94.9	0.8U
C 12:44:13P	116.3	1.0P
C 12:45:27P	93.0	0.8U
S 12:46:35P	134.1	2.2P
S 12:47:36P	135.1	2.2P
S 12:48:36P	134.5	2.2P
E 12:48:36P	134.4	2.0P
E 12:48:57P	105.4	0.1P
E 12:48:58P	103.7	0.1P
Z 12:49:08P	102.3	0.1P

LOAD 92203

TEMP MAX=135.1°C
 TEMP MIN=134.1°C

CONDITION = 6:11
 STERILIZE = 2:01
 EXHAUST = 0:32
 TOTAL CYCLE = 8:44

Steam Sterilization Line Clearance

Customer Code: <u>DSL</u>	W/O No.: <u>90467-1</u>	Run Date: <u>9-22-23</u>
Sterile Lot No.: <u>E045-23</u>	Run No.: <u>02694</u>	Product Lot No.: <u>N/A</u>
No.	Pre-Sterilization Steps	Initial/Date
1	<p style="text-align: center;">Lancer Sterilizer LSO-434T Startup</p> <p>a) On the general boiler LSO-621T: open/close the following water valves, #1 open, #1A DI water open, #2 close, #3 open, #4 close, #5 close, #6 open, #7 close, #8 open, #9 open, #10 open.</p> <p>b) Turn power on, breaker located at main power panel (B siemens switch board 150 amps).</p> <p>c) Turn 3 switches on, located at the right side of boiler.</p> <p>d) Verify the pump comes on and level of the water in the sight glass on the right of the boiler is between "L" and "H".</p> <p>e) Allow the boiler pressure to come up to 60 psi.</p> <p>f) Open air valve #11</p> <p>g) Verify there is enough printer paper to complete the cycle.</p> <p>h) Run a test at the beginning of the day, prior to running any product.</p> <p>i) Verify sterilizer clocks are correct prior to run.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-22-23
2	<p style="text-align: center;">Primus Sterilizer LSO-532T Startup</p> <p>a) Use the Lancer boiler startup instructions 1a-1c to turn on boiler.</p> <p>b) Close the Lancer steam valve #6.</p> <p>c) Open the Primus valve #7.</p> <p>d) On the Primus open valve #1 and valve #2.</p> <p>e) Turn on Primus control switch to the left on top of control panel.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-22-23
3	<p style="text-align: center;">Getinge Sterilizer LSO-113T Startup</p> <p>a) On the Pacific boiler LSO-116T-01: open/close the following water valves, #1 open, #2 closed, #3 open, #4 closed, #5 closed, #6 open, #7 close, #8 open, #9 open and #10 open.</p> <p>b) Verify there is enough printer paper to complete cycle.</p> <p>c) Turn on power #9 on, #10 on, #11 on, boiler switch #12 on, control power #13 on, located on the right side of the boiler.</p> <p>d) NOTE: if an alarm sound sounds for low steam generator pressure, push P4 on the front of sterilizer to turn off the alarm</p> <p>e) In 15-20 minutes, check that the pressure gauge to the left and above the clean steam generator is reading a minimum of 40 psi.</p> <p>f) Check if the ready light is lit on the front of the sterilizer.</p> <p>g) NOTE: If the pressure is reading 40 psi and yellow light is not lit, push P4. The sterilizer will now be ready to start. Refer to the work order for further processing instruction.</p> <p>h) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	N/A TP 9-22-23
4	<p style="text-align: center;">Amsco Sterilizer LSO-469T Startup</p> <p>a) Use Getinge boiler startup instructions 3a, 3c-3e to turn on boiler.</p> <p>b) The Amsco valve #1 open, #2 open, #3 open, #4 open.</p> <p>c) Verify there is enough printer paper to complete the cycle.</p> <p>d) Turn on the control switch on the sterilizer, located on the front of the sterilizer under the top panel. The steam will go to the steam generator at this time.</p> <p>e) Before starting the cycle, ensure that the jacket pressure is at the following: 19-20 psi for 121 °C cycle, 29-30 psi for 132 °C cycle, for other temperature settings refer to WI-LSO-468T.</p> <p>f) In 15-20 minutes, check the pressure gauge above the generator for a minimum reading of 40 psi.</p> <p>g) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>h) Check to make sure the water knob and the steam knob are turned to the left.</p> <p>i) Verify there has been 30 minutes cool down since the last cycle run.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	TP 9-22-23
5	<p>Verified by:</p>	JH 9-22-23

Sterilization Cycle Record

Work Order#: <u>90467-1</u>	Sterile Lot#: <u>E045-23</u>	Run#: <u>02694</u>
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===== P R E U A C =====
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CYCLE START AT 1:20:56P
                ON 9/22/23
  
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CYCLE COUNT      02694
OPERATOR T. Perales
STERILIZER Eagle
  
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STER TEMP = 134.0°C
CONTROL TEMP = 135.2°C
STER TIME = 0:02:00
DRY TIME = 0:00:00
  
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- TIME	T=°C	P=bar	U=bar
C 1:20:56P	62.1	0.0P	
C 1:21:57P	115.1	0.8P	
C 1:23:14P	86.9	0.5U	
C 1:23:25P	113.0	1.0P	
C 1:24:37P	80.9	0.7U	
C 1:24:54P	116.4	1.0P	
C 1:26:09P	79.7	0.7U	
S 1:27:20P	134.1	2.2P	
S 1:28:21P	134.7	2.2P	
S 1:29:21P	134.5	2.2P	
E 1:29:21P	134.3	2.0P	
E 1:29:43P	104.8	0.1P	
E 1:29:43P	103.1	0.1P	
Z 1:29:54P	101.7	0.1P	

LOAD 92204

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TEMP MAX=134.8°C
TEMP MIN=134.1°C
  
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CONDITION = 6:24
STERILIZE = 2:01
EXHAUST = 0:33
TOTAL CYCLE = 8:58
  
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Steam Sterilization Line Clearance

Customer Code: <u>DSC</u>	W/O No.: <u>90467-1</u>	Run Date: <u>9-22-23</u>	
Sterile Lot No.: <u>E092-23</u>	Run No: <u>02691</u>	Product Lot No: <u>N/A</u>	
No.	Pre-Sterilization Steps	Initial/Date	
1	<p style="text-align: center;">Lancer Sterilizer LSO-434T Startup</p> <p>a) On the general boiler LSO-621T: open/close the following water valves, #1 open, #1A DI water open, #2 close, #3 open, #4 close, #5 close, #6 open, #7 close, #8 open, #9 open, #10 open.</p> <p>b) Turn power on, breaker located at main power panel (B siemens switch board 150 amps).</p> <p>c) Turn 3 switches on, located at the right side of boiler.</p> <p>d) Verify the pump comes on and level of the water in the sight glass on the right of the boiler is between "L" and "H".</p> <p>e) Allow the boiler pressure to come up to 60 psi.</p> <p>f) Open air valve #11</p> <p>g) Verify there is enough printer paper to complete the cycle.</p> <p>h) Run a test at the beginning of the day, prior to running any product.</p> <p>i) Verify sterilizer clocks are correct prior to run.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-22-23	
2	<p style="text-align: center;">Primus Sterilizer LSO-532T Startup</p> <p>a) Use the Lancer boiler startup instructions 1a-1c to turn on boiler.</p> <p>b) Close the Lancer steam valve #6.</p> <p>c) Open the Primus valve #7.</p> <p>d) On the Primus open valve #1 and valve #2.</p> <p>e) Turn on Primus control switch to the left on top of control panel.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-22-23	
3	<p style="text-align: center;">Getinge Sterilizer LSO-113T Startup</p> <p>a) On the Pacific boiler LSO-116T-01: open/close the following water valves, #1 open, #2 closed, #3 open, #4 closed, #5 closed, #6 open, #7 close, #8 open, #9 open and #10 open.</p> <p>b) Verify there is enough printer paper to complete cycle.</p> <p>c) Turn on power #9 on, #10 on, #11 on, boiler switch #12 on, control power #13 on, located on the right side of the boiler.</p> <p>d) NOTE: if an alarm sound sounds for low steam generator pressure, push P4 on the front of sterilizer to turn off the alarm</p> <p>e) In 15-20 minutes, check that the pressure gauge to the left and above the clean steam generator is reading a minimum of 40 psi.</p> <p>f) Check if the ready light is lit on the front of the sterilizer.</p> <p>g) NOTE: If the pressure is reading 40 psi and yellow light is not lit, push P4. The sterilizer will now be ready to start. Refer to the work order for further processing instruction.</p> <p>h) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	N/A TP 9-22-23	
4	<p style="text-align: center;">Amsco Sterilizer LSO-469T Startup</p> <p>a) Use Getinge boiler startup instructions 3a, 3c-3e to turn on boiler.</p> <p>b) The Amsco valve #1 open, #2 open, #3 open, #4 open.</p> <p>c) Verify there is enough printer paper to complete the cycle.</p> <p>d) Turn on the control switch on the sterilizer, located on the front of the sterilizer under the top panel. The steam will go to the steam generator at this time.</p> <p>e) Before starting the cycle, ensure that the jacket pressure is at the following: 19-20 psi for 121 °C cycle, 29-30 psi for 132 °C cycle, for other temperature settings refer to WI-LSO-468T.</p> <p>f) In 15-20 minutes, check the pressure gauge above the generator for a minimum reading of 40 psi.</p> <p>g) Run a test cycle at the beginning of the day, prior to running any product</p> <p>h) Check to make sure the water knob and the steam knob are turned to the left.</p> <p>i) Verify there has been 30 minutes cool down since the last cycle run.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	TP 9-22-23	
5	<p>Verified by:</p>	JH 9-17-23	

Sterilization Cycle Record

Work Order#: <u>90467-1</u>	Sterile Lot#: <u>E042-23</u>	Run#: <u>G2C691</u>
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 ===== P R E V A C =====
 =====
 CYCLE START AT 9:12:54A
 ON 9/22/23

CYCLE COUNT 02691
 OPERATOR J. Pineda
 STERILIZER Eagle

STER TEMP = 134.0°C
 CONTROL TEMP = 135.2°C
 STER TIME = 0:04:00
 DRY TIME = 0:30:00

OCT 03 2023

- TIME	T=°C	P=bar	U=bar	Q.C.
C 9:12:54A	65.2	0.0P		
C 9:13:55A	114.5	0.8P		
C 9:15:14A	80.9	0.5U		
C 9:15:27A	115.8	1.0P		
C 9:16:41A	76.8	0.6U		
C 9:16:57A	116.2	1.0P		
C 9:18:11A	66.6	0.8U		
S 9:19:25A	134.1	2.2P		
S 9:20:26A	135.0	2.2P		
S 9:21:26A	134.8	2.2P		
S 9:22:26A	134.6	2.2P		
S 9:23:26A	134.7	2.2P		
E 9:23:26A	134.7	2.0P		
E 9:23:49A	104.4	0.1P		
E 9:53:47A	48.9	0.8U		
Z 9:54:04A	56.6	0.0P		

LOAD 92201

TEMP MAX=135.1°C
 TEMP MIN=134.1°C

CONDITION = 6:32
 STERILIZE = 4:01
 EXHAUST = 30:39
 TOTAL CYCLE = 41:12

Steam Sterilization Line Clearance

Customer Code: <u>DSL</u>	W/O No.: <u>90467-1</u>	Run Date: <u>9-27-23</u>
Sterile Lot No.: <u>E049-23</u>	Run No.: <u>02098</u>	Product Lot No.: <u>N/A</u>
No.	Pre-Sterilization Steps	Initial/Date
1	<p align="center">Lancer Sterilizer LSO-434T Startup</p> <p>a) On the general boiler LSO-621T: open/close the following water valves, #1 open, #1A DI water open, #2 close, #3 open, #4 close, #5 close, #6 open, #7 close, #8 open, #9 open, #10 open.</p> <p>b) Turn power on, breaker located at main power panel (B siemens switch board 150 amps).</p> <p>c) Turn 3 switches on, located at the right side of boiler.</p> <p>d) Verify the pump comes on and level of the water in the sight glass on the right of the boiler is between "L" and "H".</p> <p>e) Allow the boiler pressure to come up to 60 psi.</p> <p>f) Open air valve #11</p> <p>g) Verify there is enough printer paper to complete the cycle.</p> <p>h) Run a test at the beginning of the day, prior to running any product.</p> <p>i) Verify sterilizer clocks are correct prior to run.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	<p align="center">N/A</p> <p align="center">TP</p> <p align="center">9-27-23</p>
2	<p align="center">Primus Sterilizer LSO-532T Startup</p> <p>a) Use the Lancer boiler startup instructions 1a-1c to turn on boiler.</p> <p>b) Close the Lancer steam valve #6.</p> <p>c) Open the Primus valve #7.</p> <p>d) On the Primus open valve #1 and valve #2.</p> <p>e) Turn on Primus control switch to the left on top of control panel.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	<p align="center">N/A</p> <p align="center">TP</p> <p align="center">9-27-23</p>
3	<p align="center">Getinge Sterilizer LSO-113T Startup</p> <p>a) On the Pacific boiler LSO-116T-01: open/close the following water valves, #1 open, #2 closed, #3 open, #4 closed, #5 closed, #6 open, #7 close, #8 open, #9 open and #10 open.</p> <p>b) Verify there is enough printer paper to complete cycle.</p> <p>c) Turn on power #9 on, #10 on, #11 on, boiler switch #12 on, control power #13 on, located on the right side of the boiler.</p> <p>d) NOTE: if an alarm sound sounds for low steam generator pressure, push P4 on the front of sterilizer to turn off the alarm</p> <p>e) In 15-20 minutes, check that the pressure gauge to the left and above the clean steam generator is reading a minimum of 40 psi.</p> <p>f) Check if the ready light is lit on the front of the sterilizer.</p> <p>g) NOTE: If the pressure is reading 40 psi and yellow light is not lit, push P4. The sterilizer will now be ready to start. Refer to the work order for further processing instruction.</p> <p>h) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	<p align="center">N/A</p> <p align="center">TP</p> <p align="center">9-27-23</p>
4	<p align="center">Amsco Sterilizer LSO-469T Startup</p> <p>a) Use Getinge boiler startup instructions 3a, 3c-3e to turn on boiler.</p> <p>b) The Amsco valve #1 open, #2 open, #3 open, #4 open.</p> <p>c) Verify there is enough printer paper to complete the cycle.</p> <p>d) Turn on the control switch on the sterilizer, located on the front of the sterilizer under the top panel. The steam will go to the steam generator at this time.</p> <p>e) Before starting the cycle, ensure that the jacket pressure is at the following: 19-20 psi for 121 °C cycle, 29-30 psi for 132 °C cycle, for other temperature settings refer to WI-LSO-468T.</p> <p>f) In 15-20 minutes, check the pressure gauge above the generator for a minimum reading of 40 psi.</p> <p>g) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>h) Check to make sure the water knob and the steam knob are turned to the left.</p> <p>i) Verify there has been 30 minutes cool down since the last cycle run.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	<p align="center">TP</p> <p align="center">9-27-23</p>
5	<p>Verified by:</p>	<p align="center">JH</p> <p align="center">9-27-23</p>

Sterilization Cycle Record

Work Order#: <u>90467-1</u>	Sterile Lot#: <u>E049-23</u>	Run#: <u>02698</u>
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 ===== P R E V A C =====
 =====
 CYCLE START AT 10:13:41A
 ON 9/27/23

CYCLE COUNT 02698
 OPERATOR T. Renales
 STERILIZER Eagle

STER TEMP = 134.0°C
 CONTROL TEMP = 135.2°C
 STER TIME = 0:04:00
 DRY TIME = 0:30:00

OCT 03 2023

- TIME	T=°C	P=bar U=bar
C 10:13:41A	60.2	0.0P
C 10:14:42A	115.8	0.9P
C 10:16:02A	79.5	0.5U
C 10:16:15A	115.6	1.0P
C 10:17:29A	73.7	0.6U
C 10:17:45A	116.3	1.0P
C 10:18:59A	73.3	0.7U
S 10:20:16A	134.1	2.2P
S 10:21:17A	134.6	2.2P
S 10:22:17A	134.4	2.2P
S 10:23:17A	134.1	2.1P
S 10:24:16A	134.4	2.2P
E 10:24:17A	134.2	2.0P
E 10:24:39A	104.5	0.1P
E 10:54:38A	48.6	0.8U
Z 10:54:55A	56.7	0.0P

LOAD 92702

TEMP MAX=134.7°C
 TEMP MIN=134.1°C

CONDITION = 6:35
 STERILIZE = 4:01
 EXHAUST = 30:39
 TOTAL CYCLE = 41:15

Steam Sterilization Line Clearance

Customer Code: <u>DSL</u>	W/O No.: <u>90467-1</u>	Run Date: <u>9-27-23</u>	
Sterile Lot No.: <u>E050-23</u>	Run No.: <u>02699</u>	Product Lot No.: <u>N/A</u>	
No.	Pre-Sterilization Steps	Initial/Date	
1	<p style="text-align: center;">Lancer Sterilizer LSO-434T Startup</p> <p>a) On the general boiler LSO-621T: open/close the following water valves, #1 open, #1A DI water open, #2 close, #3 open, #4 close, #5 close, #6 open, #7 close, #8 open, #9 open, #10 open.</p> <p>b) Turn power on, breaker located at main power panel (B siemens switch board 150 amps).</p> <p>c) Turn 3 switches on, located at the right side of boiler.</p> <p>d) Verify the pump comes on and level of the water in the sight glass on the right of the boiler is between "L" and "H".</p> <p>e) Allow the boiler pressure to come up to 60 psi.</p> <p>f) Open air valve #11</p> <p>g) Verify there is enough printer paper to complete the cycle.</p> <p>h) Run a test at the beginning of the day, prior to running any product.</p> <p>i) Verify sterilizer clocks are correct prior to run.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-27-23	
2	<p style="text-align: center;">Primus Sterilizer LSO-532T Startup</p> <p>a) Use the Lancer boiler startup instructions 1a-1c to turn on boiler.</p> <p>b) Close the Lancer steam valve #6.</p> <p>c) Open the Primus valve #7.</p> <p>d) On the Primus open valve #1 and valve #2.</p> <p>e) Turn on Primus control switch to the left on top of control panel.</p> <p>NOTE: DO NOT OPERATE THE LANCER AND PRIMUS STERILIZERS AT THE SAME TIME AS THEY SHARE THE SAME BOILER.</p>	N/A TP 9-27-23	
3	<p style="text-align: center;">Getinge Sterilizer LSO-113T Startup</p> <p>a) On the Pacific boiler LSO-116T-01: open/close the following water valves, #1 open, #2 closed, #3 open, #4 closed, #5 closed, #6 open, #7 close, #8 open, #9 open and #10 open.</p> <p>b) Verify there is enough printer paper to complete cycle.</p> <p>c) Turn on power #9 on, #10 on, #11 on, boiler switch #12 on, control power #13 on, located on the right side of the boiler.</p> <p>d) NOTE: if an alarm sound sounds for low steam generator pressure, push P4 on the front of sterilizer to turn off the alarm</p> <p>e) In 15-20 minutes, check that the pressure gauge to the left and above the clean steam generator is reading a minimum of 40 psi.</p> <p>f) Check if the ready light is lit on the front of the sterilizer.</p> <p>g) NOTE: If the pressure is reading 40 psi and yellow light is not lit, push P4. The sterilizer will now be ready to start. Refer to the work order for further processing instruction.</p> <p>h) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	N/A TP 9-27-23	
4	<p style="text-align: center;">Amsco Sterilizer LSO-469T Startup</p> <p>a) Use Getinge boiler startup instructions 3a, 3c-3e to turn on boiler.</p> <p>b) The Amsco valve #1 open, #2 open, #3 open, #4 open.</p> <p>c) Verify there is enough printer paper to complete the cycle.</p> <p>d) Turn on the control switch on the sterilizer, located on the front of the sterilizer under the top panel. The steam will go to the steam generator at this time.</p> <p>e) Before starting the cycle, ensure that the jacket pressure is at the following: 19-20 psi for 121 °C cycle, 29-30 psi for 132 °C cycle, for other temperature settings refer to WI-LSO-468T.</p> <p>f) In 15-20 minutes, check the pressure gauge above the generator for a minimum reading of 40 psi.</p> <p>g) Run a test cycle at the beginning of the day, prior to running any product.</p> <p>h) Check to make sure the water knob and the steam knob are turned to the left.</p> <p>i) Verify there has been 30 minutes cool down since the last cycle run.</p> <p>NOTE: DO NOT OPERATE THE GETINGE AND AMSCO STERILIZERS AT THE SAME TIME AS THEY SHARE ONE BOILER.</p>	TP 9-27-23	
5	<p>Verified by:</p>	JA 9-27-23	

Sterilization Cycle Record

Work Order#: <u>90467-1</u>	Sterile Lot#: <u>E650-23</u>	Run#: <u>02699</u>
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=====
===== P R E V A C =====
=====
CYCLE START AT 11:16:37A
ON 9/27/23

CYCLE COUNT 02699
OPERATOR T. Revales
STERILIZER Eagle

STER TEMP = 134.0°C
CONTROL TEMP = 135.2°C
STER TIME = 0:04:00
DRY TIME = 0:30:00

- TIME T=°C P=bar V=bar **OCT 03 2023**

C 11:16:37A	60.5	0.0P
C 11:17:37A	116.5	0.9P
C 11:18:58A	80.0	0.5V
C 11:19:11A	115.6	1.0P
C 11:20:25A	78.8	0.7V
C 11:20:41A	116.4	1.0P
C 11:21:56A	82.3	0.8V
S 11:23:07A	134.1	2.2P
S 11:24:08A	134.5	2.2P
S 11:25:08A	134.3	2.1P
S 11:26:08A	134.1	2.1P
S 11:27:08A	134.2	2.2P
E 11:27:08A	134.0	2.0P
E 11:27:30A	104.7	0.1P
E 11:57:28A	52.0	0.9V
Z 11:57:45A	60.6	0.0P

LOAD 92703

TEMP MAX=134.6°C
TEMP MIN=134.1°C

CONDITION = 6:31
STERILIZE = 4:01
EXHAUST =30:38
TOTAL CYCLE =41:10



**Life Science
Outsourcing**

4

PME Services, Inc.

1584 N. Batavia Suite 1
Orange, CA 92867
Phone: (714) 418-1444

Calibration Report



Life Science Outsourcing (9488)

830 Challenger St.
Brea, CA 92821

Asset Number: LSO-469T
Manufacturer: Amsco
Model Number: MGS-GDS-1 EAGLE 3013
Description: Sterilizer
Serial Number: 0116381-010
Cal. Procedure: CP/035
PO Number: 27474


Ambient Temperature: 75° F
Ambient Humidity: 43% RH
Condition As Found: In Tolerance
Condition As Left: In Tolerance - No Adjustment
Calibration Date: 06/23/2023
Calibration Due Date: 06/23/2024
Calibration Interval: 12 Months

Remarks:

Calibrated at Life Science Outsourcing.

Standards Utilized

I.D. No.	Mfg.	Model No.	Description	Cal. Date	Due Date
PME-0407	Heise	HQS-2	Pressure Module	05/16/2023	11/16/2023
PME-0464	Heise	PTE-1	Handheld Pressure Calibrator	08/25/2022	08/25/2023
PME-0551	Heise	HQS-2	Pressure Module	09/22/2022	09/22/2023
PME-0665	ThermoWorks	PT100	Reference Thermometer	02/22/2023	02/22/2024
PME-0668	ThermoWorks	3004	Dry Well	03/21/2023	03/21/2024

REVIEWED BY: 
DATE: 7-5-23

Calibration Performed By:	Quality Reviewer:
Brown, Johnathan  Name Title Metrologist (714) 418-1444 Phone	 Name Date 06-28-2023 Date

All instruments used in this calibration are traceable to the International System of Unit (SI), through a recognized National Metrology Institute (NMI) such as the National Institute of Standards and Technology (NIST), a natural physical constant, or radiometric techniques, and were performed in accordance with ISO17025:2017. This Report may not be reproduced, except in full, without written permission of PME Services, Inc. The results stated in this certificate relate only to the item(s) calibrated.

PME Services

Steam Sterilizer Data Sheet

ID# LSO-469T Model MGS-GDS-1 Eagle 3013 Serial 0116381-010
 Tech 3 Mfr Amsco Date 6/23/2023

Function	Set Point	As Found	As Left	OOT	Low Limit	High Limit
Temperature	121 °C	121.77	Same		120.0	122.0
	132	132.61	Same		131.0	133.0
	135	135.75	Same		134.0	136.0
Vacuum	0.0 bar	0.0000	Same		-0.2	0.2
	-0.5	-0.4995	Same		-0.7	-0.3
	-0.9	-0.8896	Same		-1.1	-0.7
Pressure	0.0 bar	0.000	Same		-0.2	0.2
	0.5	0.419	Same		0.3	0.7
	1.0	0.906	Same		0.8	1.2
	1.5	1.420	Same		1.3	1.7
	2.0	1.924	Same		1.8	2.2
	2.5	2.433	Same		2.3	2.7
	3.0	2.957	Same		2.8	3.2

Note: OOT is an out-of-calibration condition.



**Life Science
Outsourcing**

5

**Biological Indicator Test Report
(Validation)**

Protocol No.:	SUS-DSL-01	Cycle Type(s):	<input type="checkbox"/> Fractional <input checked="" type="checkbox"/> Half <input type="checkbox"/> Full <input type="checkbox"/> Development
Run Date:	9-22-23	Sterile Lot No.:	E043-23
		Run No.:	02692

Customer Code:	DSL	WO Number:	90467-1
Product Description:	STEAM STER. VAL	Lot Number:	N/A
IPCD BI Lot Number:	RUI28.2	IPCD BI Exp. Date:	4-30-24
EPCD BI Lot Number:	N/A	EPCD BI Exp. Date:	N/A
TSB Lot Number:	3081058	TSB Exp. Date:	9-19-24
Date on Test:	9-22-23	Date Due Off Test:	9-29-23
Total Number of Samples (Not including control samples):			<u>5</u> IPCD <u>0</u> EPCD

Tested By: T. Renales Date: 9-22-23

BI Sample #	Incubation Day										Acc. Criteria
	1	2	3	4	5	6	7	8	9	10	
1.											See protocol
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10.											
Positive Control	+		+	+	+	+	+				+
Negative Control	-		-	-	-	-	-				-
Total # Positive	0		0	0	0	0	0				See protocol
Inspected By Initials/Date	JH 9-13-23		JH 9-25-23	JH 9-26-23	JH 9-27-23	JH 9-28-23	TP 9-29-23				

Key: "+" : Positive, Growth; "-" : Negative, No Growth; "N/A" : Not applicable

**Biological Indicator Test Report
(Validation, continued)**
(Attach more copies of this page as necessary)

Protocol No.:	SUS-DSL-01	Sterile Lot No.:	E043-23	Run No.:	02692
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BI Sterility Results (continued)

N/A the table below

IPCD, Description (if applicable): _____

EPCD, Description (if applicable): _____

BI Sample #	Incubation Day										Acc. Criteria	
	1	2	3	4	5	6	7	8	9	10		
												See protocol
Positive Control												+
Negative Control												-
Total # Positive												See protocol
Inspected By Initials/Date												

N/A
TP
9-22-23

Key: "+" Positive, Growth; "-" Negative, No Growth; "N/A": Not applicable

Test Result (circle one): Pass Fail / For Information Only

Comments: N/A TP 9-29-23

Completed By: T. Renales Date: 9-29-23

Quality Review by: A. Ramos Date: 9-29-23

**Biological Indicator Test Report
(Validation)**

Protocol No.:	SUS-DSL-01	Cycle Type(s):	<input type="checkbox"/> Fractional <input checked="" type="checkbox"/> Half <input type="checkbox"/> Full <input type="checkbox"/> Development
Run Date:	9-22-23	Sterile Lot No.:	E044-23
		Run No.:	02693

Customer Code:	DSL	WO Number:	90467-1
Product Description:	STEAM STER. VAL.	Lot Number:	N/A
IPCD BI Lot Number:	RUI28.2	IPCD BI Exp. Date:	4-30-23
EPCD BI Lot Number:	N/A	EPCD BI Exp. Date:	N/A
TSB Lot Number:	3081058	TSB Exp. Date:	9-19-23 ^{TP 9-22-23}
Date on Test:	9-22-23	Date Due Off Test:	9-29-23
Total Number of Samples (Not including control samples):		5 IPCD	0 EPCD

Tested By: T. Penales Date: 9-22-23

BI Sterility Results

IPCD, Description (if applicable): SUS STM-001 EPCD, Description (if applicable): N/A

BI Sample #	Incubation Day										Acc. Criteria
	1	2	3	4	5	6	7	8	9	10	
1.	-		-	-	-	-	-				See protocol
2.	-		-	-	-	-	-				
3.	-		-	-	-	-	-				
4.	-		-	-	-	-	-				
5.	-		-	-	-	-	-				
6.	-		-	-	-	-	-				
7.	-		-	-	-	-	-				
8.	-		-	-	-	-	-				
9.	-		-	-	-	-	-				
10.	-		-	-	-	-	-				
Positive Control	+		+	+	+	+	+				+
Negative Control	-		-	-	-	-	-				-
Total # Positive	0		0	0	0	0	0				See protocol
Inspected By Initials/Date	JH 9-23-23		JH 9-25-23	JH 9-26-23	JH 9-27-23	JH 9-28-23	TP 9-29-23				

Key: "+" : Positive, Growth; "-" : Negative, No Growth; "N/A" : Not applicable

**Biological Indicator Test Report
(Validation, continued)**
(Attach more copies of this page as necessary)

Protocol No.: <u>SUS-DSC-01</u>	Sterile Lot No.: <u>E044-23</u>	Run No.: <u>02693</u>
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BI Sterility Results (continued) N/A the table below

IPCD, Description (if applicable): _____ EPCD, Description (if applicable): _____

BI Sample #	Incubation Day										Acc. Criteria	
	1	2	3	4	5	6	7	8	9	10		
												See protocol
Positive Control												+
Negative Control												-
Total # Positive												See protocol
Inspected By Initials/Date												

Key: "+" : Positive, Growth; "-" : Negative, No Growth; "N/A" : Not applicable

Test Result (circle one): Pass / Fail / For Information Only

Comments: N/A TP 9-29-23

Completed By: T. Perales Date: 9-29-23

Quality Review by: D. Ramos Date: 9-29-23

**Biological Indicator Test Report
(Validation)**

3rd

Protocol No.:	SUS-DSL-01	Cycle Type(s):	<input type="checkbox"/> Fractional <input checked="" type="checkbox"/> Half <input type="checkbox"/> Full <input type="checkbox"/> Development
Run Date:	9-22-23	Sterile Lot No.:	E045-23
		Run No.:	02694

Customer Code:	DSL	WO Number:	90467-1
Product Description:	STEAM STER. VAL.	Lot Number:	N/A
IPCD BI Lot Number:	RU129.2	IPCD BI Exp. Date:	4-30-23
EPCD BI Lot Number:	N/A	EPCD BI Exp. Date:	N/A
TSB Lot Number:	3081058	TSB Exp. Date:	9-19-24
Date on Test:	9-22-23	Date Due Off Test:	9-29-23
Total Number of Samples (Not including control samples):		<u>5</u> IPCD	<u>0</u> EPCD

Tested By: T. Revales Date: 9-22-23

BI Sterility Results

IPCD, Description (if applicable): SUS-STM-001 EPCD, Description (if applicable): N/A

BI Sample #	Incubation Day										Acc. Criteria
	1	2	3	4	5	6	7	8	9	10	
1.	-	-	-	-	-	-	-	-	-	-	See protocol
2.	-	-	-	-	-	-	-	-	-	-	
3.	-	-	-	-	-	-	-	-	-	-	
4.	-	-	-	-	-	-	-	-	-	-	
5.	-	-	-	-	-	-	-	-	-	-	
6.	-	-	-	-	-	-	-	-	-	-	
7.	-	-	-	-	-	-	-	-	-	-	
8.	-	-	-	-	-	-	-	-	-	-	
9.	-	-	-	-	-	-	-	-	-	-	
10.	-	-	-	-	-	-	-	-	-	-	
Positive Control	+	+	+	+	+	+	+	+	+	+	+
Negative Control	-	-	-	-	-	-	-	-	-	-	-
Total # Positive	0	0	0	0	0	0	0	0	0	0	See protocol
Inspected By Initials/Date	JH 9-23-23	JH 9-25-23	JH 9-26-23	JH 9-27-23	JH 9-28-23	JH 9-28-23	TP 9-29-23	TP 9-29-23	TP 9-29-23	TP 9-29-23	

Key: "+" : Positive, Growth; "-" : Negative, No Growth; "N/A" : Not applicable

**Biological Indicator Test Report
(Validation, continued)**
(Attach more copies of this page as necessary)

Protocol No.: <u>SUS-DSL-01</u>	Sterile Lot No.: <u>E045-23</u>	Run No.: <u>02094</u>
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BI Sterility Results (continued) N/A the table below

IPCD, Description (if applicable): _____ EPCD, Description (if applicable): _____

BI Sample #	Incubation Day										Acc. Criteria	
	1	2	3	4	5	6	7	8	9	10		
												See protocol
Positive Control												+
Negative Control												-
Total # Positive												See protocol
Inspected By Initials/Date												

Key: "+": Positive, Growth; "-": Negative, No Growth; "N/A": Not applicable

Test Result (circle one): Pass / Fail / For Information Only

Comments: N/A TP 9-29-23

Completed By: T. Renales Date: 9-29-23

Quality Review by: D. Ramos Date: 9-29-23

**Biological Indicator Test Report
(Validation)**

Protocol No.:	SUS-DSL-01	Cycle Type(s):	<input type="checkbox"/> Fractional <input type="checkbox"/> Half <input checked="" type="checkbox"/> Full <input type="checkbox"/> Development
Run Date:	9-22-23	Sterile Lot No.:	E042-23
Run No.:	022691		

Customer Code:	DSL	WO Number:	90467-1
Product Description:	STEAM STER. VAL.	Lot Number:	N/A
IPCD BI Lot Number:	RUI28.2	IPCD BI Exp. Date:	4-30-24
EPCD BI Lot Number:	N/A	EPCD BI Exp. Date:	N/A
TSB Lot Number:	3081058	TSB Exp. Date:	9-19-24
Date on Test:	9-22-23	Date Due Off Test:	9-29-23
Total Number of Samples (Not including control samples):	5 IPCD		0 EPCD

Tested By: T. Renales Date: 9-22-23

BI Sterility Results

IPCD, Description (if applicable): SUS-STM-001 EPCD, Description (if applicable): N/A

BI Sample #	Incubation Day										Acc. Criteria
	1	2	3	4	5	6	7	8	9	10	
1.	-	-	-	-	-	-	-	-	-	-	See protocol
2.	-	-	-	-	-	-	-	-	-	-	
3.	-	-	-	-	-	-	-	-	-	-	
4.	-	-	-	-	-	-	-	-	-	-	
5.	-	-	-	-	-	-	-	-	-	-	
6.	-	-	-	-	-	-	-	-	-	-	
7.	-	-	-	-	-	-	-	-	-	-	
8.	-	-	-	-	-	-	-	-	-	-	
9.	-	-	-	-	-	-	-	-	-	-	
10.	-	-	-	-	-	-	-	-	-	-	
Positive Control	+	+	+	+	+	+	+	+	+	+	+
Negative Control	-	-	-	-	-	-	-	-	-	-	-
Total # Positive	0	0	0	0	0	0	0	0	0	0	See protocol
Inspected By Initials/Date	JH 9-23-23	JH 9-25-23	JH 9-26-23	JH 9-27-23	JH 9-28-23	JH 9-29-23	TP 9-29-23	N/A 9-29-23 TP			
Key:	"+": Positive, Growth; "-": Negative, No Growth; "N/A": Not applicable										

**Biological Indicator Test Report
(Validation, continued)**
(Attach more copies of this page as necessary)

Protocol No.:	<u>SUS-DSL-01</u>	Sterile Lot No.:	<u>E042-23</u>	Run No.:	<u>02691</u>
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BI Sterility Results (continued) N/A the table below

IPCD, Description (if applicable): _____ EPCD, Description (if applicable): _____

BI Sample #	Incubation Day										Acc. Criteria	
	1	2	3	4	5	6	7	8	9	10		
												See protocol
Positive Control												+
Negative Control												-
Total # Positive												See protocol
Inspected By Initials/Date												

Key: "+": Positive, Growth; "-": Negative, No Growth; "N/A": Not applicable

Test Result (circle one): Pass / Fail / For Information Only

Comments: N/A TP 9-29-23

Completed By: T. Remles Date: 9-29-23

Quality Review by: D. Ramos Date: 9-29-23



Autoclave Drying Inspection

Sterilization Lot No.: E042-23 Customer Code: DSL WO: 90467-1

Pouched Inspection Record
~~Outer Pouch Dry Wet A TP 9-22-23 Inner Pouch Dry Wet~~

CSR Wrap Inspection Record
 Outer wrap Dry Wet Inner Wrap Dry Wet

Rigid Container Inspection Record
 Lid / Seal area Dry Wet Corners / Base: Dry Wet

(Empty section)

Product Inspection Record

Part No.	Description	Outside	Lumens (tap test)
<u>D10K6</u>	<u>Dieble Instrument Organizer</u>	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input checked="" type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
	<u>N</u>	<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
	<u>A</u>	<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
	<u>TP 9-22-23</u>	<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A

Comments: N/A TP 9-22-23

Sterilizer used: LSO-113T LSO-399T LSO-469T Other _____

Cycle Used: 121C Other 134C Gravity Drying time 30 min minutes
 132C Pre-Vac

Performed By: T. Perales Date: 9-22-23

Quality Reviewed By: C. Ibarra Date: 9-22-23



Autoclave Drying Inspection

Sterilization Lot No.: <u>E049-23</u>	Customer Code: <u>DSC</u>	WO: <u>90467-1</u>
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Pouched Inspection Record

Outer Pouch Dry Wet Inner Pouch Dry Wet

N/A TP 9-27-23

CSR Wrap Inspection Record

Outer wrap Dry Wet Inner Wrap Dry Wet

Rigid Container Inspection Record

Lid / Seal area Dry Wet Corners / Base: Dry Wet

Product Inspection Record

Part No.	Description	Outside	Lumens (tap test)
<u>D10K6</u>	<u>Dieble Instrument Organizer</u>	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input checked="" type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A

N/A TP 9-27-23

Comments: N/A TP 9-27-23

Sterilizer used: LSO-113T LSO-399T LSO-469T Other _____

Cycle Used: 121C Other 134C Gravity Drying time 30 min minutes

132C Pre-Vac

Performed By: T. Renales Date: 9-27-23

Quality Reviewed By: C. Ibarra Date: 9-27-23



Autoclave Drying Inspection

Sterilization Lot No.: <u>E050-23</u>	Customer Code: <u>DSL</u>	WO: <u>90467-1</u>
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Pouched Inspection Record

Outer Pouch Dry Wet *N/A TP 9-27-23* Inner Pouch Dry Wet

CSR Wrap Inspection Record

Outer wrap Dry Wet Inner Wrap Dry Wet

Rigid Container Inspection Record

Lid / Seal area Dry Wet Corners / Base: Dry Wet

Product Inspection Record			
Part No.	Description	Outside	Lumens (tap test)
<u>D10K Le</u>	<u>Dieble Instrument Organizer</u>	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input checked="" type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A
		<input type="checkbox"/> Dry <input type="checkbox"/> Wet	<input type="checkbox"/> Dry <input type="checkbox"/> Wet <input type="checkbox"/> N/A

Comments: N/A TP 9-27-23

Sterilizer used: LSO-113T LSO-399T LSO-469T Other _____

Cycle Used: 121C Other 134C Gravity Drying time 30 min minutes

132C Pre-Vac

Performed By: T. Perales Date: 9-27-23

Quality Reviewed By: C. Young Date: 9-27-23



CERTIFICATE OF ANALYSIS

PRODUCT NAME: Biological Indicator Spore Strips

PRODUCT CODE: BS-106

QUANTITY: 100 strips

ORGANISM: *Geobacillus stearothermophilus*, Cell Line 7953

FOR USE IN MONITORING: Steam

This lot of product meets, where applicable, the accepted performance criteria recommended in the USP, ISO 11138-1, and ISO 11138-3.

LOT: RU128	2024-04-30 (YYYY-MM-DD)	POPULATION¹: 1.7 x 10 ⁶	z VALUE^{2,4}: 7.2°C
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Performance Characteristics				
PROCESS	PARAMETERS	D VALUE ²	SURVIVAL TIME ³	KILL TIME ³
Steam	121.1°C	1.9 minutes	8.1 minutes	19.4 minutes

¹After a preliminary heat treatment of 95-100°C for 15 minutes

²Determined using fraction negative procedures (e.g. Stumbo-Murphy-Cochran) in an AAMI/ISO compliant test vessel. The D value is reproducible only under the exact conditions under which it was determined. Users may not necessarily obtain the same results.

³Calculated using USP, AAMI and ISO survival and kill time formulas

⁴Based upon D values determined at 118.1°C, 121.1°C, 126.1°C.

Purity: No evidence of contamination present in sufficient numbers to adversely affect the finished product.

Storage and Shelf Life

+15°C to +30°C	15°C to 30°C		Keep away from sunlight
20% to 70%	20% to 70% Relative Humidity		Keep dry
Shelf Life	24 Months from the date of manufacture		Protect from heat and radioactive sources
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Strips. Do not use damaged Spore Strips. Do not use after the expiration date. The Spore Strips contain live cultures and should be handled with care.		

Dispose: Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

Keaton Candace 5/25/2022
 QUALITY ASSURANCE APPROVAL

REVIEWED BY: TP
 DATE: 10-5-23



REVIEWED BY: TP
 DATE: 10-5-23

Certificate of Analysis

Becton Dickinson and Company
 BD Diagnostic Systems
 PO Box 999
 Sparks MD 21152-0999 US

Page: 1 of 3

Product Name : Tube Trypticase Soy Broth 8 Ml 100 Ea
Catalog Number : 221093 **Manufacture Date**: 2023/04/18
Batch Number : 3081058
Expiration Date : 2024/09/19

- 01 Broth Appearance: Light yellow to medium tan yellow; clear to trace hazy.
- 02 Biological Performance: Samples were inoculated with 1000 CFU's or less of *S. pneumoniae* and 100 CFU's or less of the remaining test organisms, incubated as noted below and gave responses as indicated:

CULTURE	ATCC®	INCUBATION	RESULT
Bacillus subtilis subspecies spizizenii	6633	20-25°C, 3 days	Growth*
Candida albicans	10231	20-25°C, 5 days	Growth*
Aspergillus brasiliensis	16404	20-25°C, 5 days	Growth*
Streptococcus pneumoniae	6305	30-35°C, 1 day	Growth*
Escherichia coli	25922	30-35°C, 2 days	Growth*
Staphylococcus aureus	25923	30-35°C, 2 days	Growth*

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		7.3	7.1	7.5

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Porcine	USA	III	III	IB

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 13485:2016 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA)



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Page: 2 of 3

Product Name : Tube Trypticase Soy Broth 8 Ml 100 Ea
Catalog Number : 221093 **Manufacture Date:** 2023/04/18
Batch Number : 3081058
Expiration Date : 2024/09/19

typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at www.bd.com/regdocs. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD. See "COA Animal Origin Information Position Statement" located at www.bd.com/regdocs under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Diagnostics - Diagnostic Systems, Animal Origin Position Statement", at www.bd.com/regdocs under "Position Statements".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see www.bd.com/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information.

A satisfactory result corresponds with light to heavy growth for (*)organism(s) and moderate to heavy growth of the remaining organisms per Becton Dickinson Standard Test Method for this product. Representative samples of this lot were tested for microbial viability or the Fo value for parametric release was examined and found to be acceptable.

Stability data for this product is on file.

The pH stated was obtained at the time of release, the pH may vary depending on the age of the product and the type of pH meter and probe used.

Samples meet CLSI (NCCLS) requirements for recovery, where applicable.

Creation Date: 2023/05/02 17:38:41



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Page: 3 of 3

Product Name	: Tube Trypticase Soy Broth 8 Ml 100 Ea	
Catalog Number	: 221093	Manufacture Date: 2023/04/18
Batch Number	: 3081058	
Expiration Date	: 2024/09/19	

A large, stylized handwritten signature in black ink, appearing to read 'Zuleika Vargas'.

Zuleika Vargas
Director, Quality Management
Signature Date: 2023/05/02



**Life Science
Outsourcing**

6



Deviations & NCR's

1. None.



**Life Science
Outsourcing**

7

Parent part: SVS-DSL-VAL-S VALIDATION SCHEDULE

Type : N

Level	Component	Description	Qty Required	UM	T	Scrap	Seq	RtNum	Reference	Lin
.1	SVS-DSL-01	STEAM STERILIZATION VALIDATION	0.00000000	EA	N	0.00	0	0	COMPLETED 10/23	1
.1	SVS-DSL-01-XX	STEAM REVALIDAITON	0.00000000	EA	N	0.00	0	0	DUE 10/24	2

Remks: NOTE: PLEASE REVIEW THE ABOVE STERILIZATION VALIDATION REPORTS THAT HAVE BEEN PERFORMED FOR YOUR PRODUCTS FOR COMPLETENESS. IF YOU CHOOSE TO NOT PERFORM A SCHEDULE EVENT COMING OR PAST DUE, PLEASE PROVIDE THE JUSTIFICATION FOR OUR RECORDS. *JUSTIFICATION FOR NOT PERFORMING A REVALIDATION IS LOCATED AT CUSTOMER COMPANY IN THEIR QUALITY FILES.

Notes : THE SYMBOL "XX" INDICATES A STUDY AND THE NUMBER HAS NOT BEEN AUTHORIZED AND ASSIGNED.

LSO REVIEWED BY: *J. Renales* DATE: 10-9-23