TR–045-13
HyperGrip® (HG)
Product Sterilization

Test Report

	Name	Title	Date
Written by:	Frank Nania	Principal Design Engineer	04/11/2013
Engineering Approval:	Frank Nania	Principal Design Engineer	04/11/2013

Version

Date	REV	Description	ENG
04/11/13	01	INITIAL RELEASE	FN

TR-045-13

Executive Summary

This document details and describes the design validation testing performed on the re-tooled Hypergrip® series plug connector products HG2 (12 position), HG3 (19 position), and HG4 (33 position). The connectors will be subjected to a series of test procedures to validate the design intent.

Scope:
To validate the Hypergrip® connectors configurations from a sterilization standpoint.

Test Procedures:
As defined within this specification.

Test Sample Description:
All test samples utilized in this design validation will be fully loaded mated pair connectors.

Autoclave Sterilization

Scope:
This test determines the effects caused by subjecting electrical connectors to the conditioning action of the autoclave sterilization process.

Goal:
To subject the HG plug connector designs to the autoclave sterilization process and meet the number of cycles (processing) that have been specified.

Sample Size:
3 mated pairs of each connector size.

Test Requirements:

	Steam Autoclave
	Flash
Number of Cycles	20
Sterilizer Type	Gravity
Temperature	135℃ ± 1℃
Full Cycle Time	10 minutes
Dry Time	0 minutes

Acceptance Criteria:
1. The connector must meet the electrical and mechanical requirements of the connector pair.
2. No connector degradation with regards to functionality.

Test Result:
All connectors passed tests as specified above. See Appendix for results.

EtO Sterilization

Scope:
This test determines the effects caused by subjecting electrical connectors to the conditioning action of the EtO sterilization process.

Goal:
To subject the HG plug connector designs to the EtO sterilization process and meet the number of cycles (processing) that have been specified.

Sample Size:
3 mated pairs of each connector size.

Test Requirements:

EtO Process	
Number of Cycles	20
Pre-conditioning	
Temperature	43.3℃ (110ºF)
Relative Humidity	55%
Time	8 hrs minimum
EtO Exposure	
Temperature	54.44℃ (130ºF)
Initial Vacuum	1.30 psia
Steam Addition	0.49 psia rise (23% RH)
Steam Dwell Time	30 minutes
EO gas concentration	590 mg/L of 100% EO
EO Gas Dwell Time	2 hours
Air Washes	3 repeats
Aeration	
Temperature	43.3℃ ± 5℃ (110ºF)
Time	24 hrs minimum

Acceptance Criteria:
1. The connector must meet the electrical and mechanical requirements of the connector pair.
2. No connector degradation with regards to functionality.

Test Result:
All connectors passed tests as specified above. See Appendix for results.

Sterrad Testing

Scope:
This test determines the effects caused by subjecting electrical connectors to the conditioning action of the Sterrad® sterilization process.

Goal:
To subject the HG plug connector designs to the Sterrad® sterilization process and meet the number of cycles (processing) that have been specified.

Sample Size:
3 plug connectors of each size.

Test Requirements:
1. Connectors will be sent to Advanced Sterilization Products in Irvine, California for processing.
2. Connectors will be subjected to 20 cycles of Sterrad® using the **ST100NX system**.
3. Testing after each cycle per Hypertronics HG Latch Testing Procedure.

	Sterrad® ST100NX
Temperature in ℃	Ambient
Exposure holding time in minutes	55 ± 5℃
Dwell time between cycles (cool down)	30 min ± 5 min

Test Sequence:
1. Record lot number if any on samples.
2. Record start time of the test.
3. Subject test samples to one (1) cycle of Sterrad®.
4. Immediately after the one (1) Sterrad® cycle, perform latch retention per the HG Latch Testing Procedure listed below. Record results.
5. Allow the test samples to cool and sit for allotted dwell time listed above.
6. Repeat latch retention test once again per same procedure listed in Step 4, and record results.
7. Allow test samples to sit for 24 hours. After the rest period, perform Steps 2 – 6 once again.
8. Repeat this sequence for a total of twenty (20) Sterrad® cycles.

Acceptance Criteria:
1. The connector must meet the electrical and mechanical requirements of the connector pair.
2. No connector degradation with regards to functionality.

Test Result:
All connectors passed tests as specified above. See Appendix for results.

APPENDIX

Autoclave Test Results

NELSON LABORATORIES

Sponsor:

Hypertronics Corporation
16 Brent Dr.
Hudson MA 01749

Reusable Device Repeat Processing Final Report

Test Article:	HYPERGRIP CONNECTORS numbered 7-9 numbered 13-15 numbered 19-21 numbered 25-27, 31-33 and 37-39
Purchase Order:	
Laboratory Number:	
Study Received Date:	20 Jul 2010
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0159 Rev 01 Protocol Detail Sheet (PDS) Number: 201002368 Rev 01

Summary: This report details the sterilization cycle(s) performed on the test articles.

The test articles were returned to the sponsor. Test articles subject to steam exposure are not for human use. The test articles should only be used for functionality, biocompatibility or other physical evaluations not involving human patients.
All test method acceptance criteria were met. Following the exposure, the test articles were returned to the sponsor.

Procedure:
Steam Exposure: The prepared test articles were placed into the steam sterilizer and sterilized per parameters listed below:

Sterilizer Type:	Gravity
Minimum Temperature:	135°C
Exposure Time:	10 minutes
Dry Time:	0 minutes
Test Article Configuration:	Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554). The wrapped test articles were then individually placed in 5½" x 10" pouches (Cardinal Health)

The test articles were processed through 20 steam sterilization cycles using the above parameters.

EtO Test Results

NELSON LABORATORIES

Sponsor:

Hypertronics Corporation
16 Brent Dr.
Hudson MA 01749

Ethylene Oxide (EO) Exposure (Bier Vessels and STERIS® EO Sterilizers) Final Report

Test Article:	HYPERGRIP CONNECTORS numbered 4-9 numbered 10-15 numbered 16-21 EO: #s 22-24, 28-30 and 34-36
Purchase Order:	
Laboratory Number:	
Study Received Date:	20 Jul 2010
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0107 Rev 03 Protocol Detail Sheet (PDS) Number: 201002503 Rev 01

Summary: This report describes the exposure of the above test articles to EO. The sterilizer was programmed using the set points below and no significant deviations from these set points were observed. All test method acceptance criteria were met. Following the exposure, the test articles were returned to the sponsor.

Test articles subject to EO exposure are not for human use. Because the test articles have not been validated using additional fractional cycles or half cycles, the delivered sterility assurance level (SAL) cannot be determined. The test articles should only be used for functionality, biocompatibility or other physical evaluations not involving human patients.

Number of Test Articles Exposed: 2 boxes

Procedure: The items submitted for EO exposure were processed twenty times using the following set points:

EtO Test Results (continued)

NELSON LABORATORIES

Ethylene Oxide (EO) Exposure
(Bier Vessels and STERIS® EO Sterilizers) Final Report

Preconditioning Phase:

Temperature:	43.3°C
Relative Humidity (RH):	55%
Time:	23 hours 30 minutes (Cycle 1)
	18 hours 14 minutes (Cycle 2)
	18 hours 22 minutes (Cycle 3)
	14 hours 00 minutes (Cycle 4)
	17 hours 15 minutes (Cycle 5)
	19 hours 40 minutes (Cycle 6)
	21 hours 35 minutes (Cycle 7)
	17 hours 20 minutes (Cycle 8)
	16 hours 55 minutes (Cycle 9)
	18 hours 00 minutes (Cycle 10)
	16 hours 42 minutes (Cycle 11)
	20 hours 35 minutes (Cycle 12)
	20 hours 35 minutes (Cycle 13)
	17 hours 45 minutes (Cycle 14)
	11 hours 25 minutes (Cycle 15)
	17 hours 55 minutes (Cycle 16)
	16 hours 05 minutes (Cycle 17)
	18 hours 30 minutes (Cycle 18)
	20 hours 15 minutes (Cycle 19)
	08 hours 10 minutes (Cycle 20)

Conditioning Phase:

Temperature:	54.44°C
Initial Vacuum:	1.30 pounds per square inch absolute (psia)
Humidity Set Point:	1.80 psia
RH:	23%
Steam Dwell Time:	30 minutes

EO Exposure Phase:

Gas Type:	100% EO
Temperature:	54.44°C
Sterilant Set Point:	7.10 psia
EO Concentration:	590 mg/L
EO Gas Dwell Time:	120 minutes

EtO Test Results (continued)

NELSON LABORATORIES

Ethylene Oxide (EO) Exposure
(Bier Vessels and STERIS® EO Sterilizers) Final Report

Aeration Phase:

Temperature:	43.3 ± 5°C
Time:	24 hours 08 minutes (Cycle 1)
	25 hours 12 minutes (Cycle 2)
	54 hours 05 minutes (Cycle 3)
	24 hours 35 minutes (Cycle 4)
	24 hours 05 minutes (Cycle 5)
	48 hours 00 minutes (Cycle 6)
	24 hours 30 minutes (Cycle 7)
	24 hours 25 minutes (Cycle 8)
	30 hours 45 minutes (Cycle 9)
	42 hours 25 minutes (Cycle 10)
	26 hours 15 minutes (Cycle 11)
	28 hours 00 minutes (Cycle 12)
	26 hours 50 minutes (Cycle 13)
	24 hours 20 minutes (Cycle 14)
	26 hours 20 minutes (Cycle 15)
	24 hours 10 minutes (Cycle 16)
	25 hours 00 minutes (Cycle 17)
	25 hours 50 minutes (Cycle 18)
	25 hours 00 minutes (Cycle 19)
	24 hours 12 minutes (Cycle 20)

Sterrad® Test Results

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.

FUNCTIONAL COMPATIBILITY REPORT

SPONSOR:	**HYPERTRONICS CORPORATION**
TEST ARTICLE:	**HYPERGRIP CONNECTORS**
TITLE:	**FUNCTIONAL COMPATIBILITY STUDY OF HYPERGRIP CONNECTORS FROM HYPERTRONICS CORPORATION IN THE STERRAD®100NX™ STERILIZATION SYSTEM**
NUMBER:	

33 Technology Drive, Irvine, CA 92618, Phone: (949) 581-5799, Fax: (949) 450-6804

Sterrad® Test Results (continued)

REPORT

Functional Compatibility Study of HyperGrip Connectors from Hypertronics Corporation in the STERRAD® 100NX™ Sterilization System

1 EXECUTIVE SUMMARY

A compatibility study was performed to evaluate the material and functional compatibility of Hypertronics Corporation HyperGrip (HG) Connectors in the STERRAD® 100NX™ Sterilization System. All testing was done in accordance with AAMI TIR No.12-2004, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."

The Hypertronics Corporation HG Connectors are non-lumen devices. The material composition and design fall within STERRAD® 50/100S/200/NX™/100NX™ Sterilization Systems claims. Additionally, all materials have been evaluated and fall within the claims for the Hypertronics Corporation HG Connectors.

The Hypertronics Corporation HG Connectors were exposed to 20 STERRAD® 100NX™ Standard Cycles per Hypertronics Corporation's request. Each cycle consisted of two identical half-cycles, or exposure phases, consisting of 8 minutes transfer, 30 seconds diffusion and 7.5 minutes plasma. Each cycle received a cassette injection of 5400µL ±216µL of 59% nominal concentration of hydrogen peroxide per exposure phase. Intermediate functionality evaluation of the connectors was carried out prior to, and at the conclusion of all cycles per the testing procedure outlined . Additionally, per Hypertronics Corporation's request, no more than 2 sequential cycles were performed each day during testing.

The samples were returned to Hypertronics Corporation for final functionality evaluation after 20 cycles. Hypertronics Corporation's functionality report states that after exposure to 20 STERRAD® 100NX™ Standard Cycles, the HG Connectors passed functionality testing.

According to Hypertronics Corporation's functionality verification, this study demonstrates that the Hypertronics Corporation HG Connectors are compatible with processing in all STERRAD® Systems up to 20 cycles.

2 EXPERIMENTAL PROTOCOL

2.1 Protocol:

2.1.1 Refer to TP-35119-001 Rev. D: "Functional Compatibility Testing procedure of Medical Devices and Components Intended to be Sterilized in the STERRAD® 100NX™ Sterilization Systems in Health Care Facilities"

2.2 Test Device

2.2.1 Hypertronics Corporation HG Connectors

2.2.1.1 (Qty. 3) ID #1-3

2.2.1.2 (Qty. 3) ID #1-3

2.2.1.3 (Qty. 3) ID #1-3

2.3 Materials and Equipment:

Reference TP-35119-001 and the following:

2.3.1 STERRAD® 100NX™ Sterilization Sterilizer, Product Code(PC): 10104, Serial Number (S/N): 10104001070007, Software Version: 10247102A1

2.3.2 STERRAD® 100NX™ Cassette PC: 10144, Lot: 10D023 Exp#: 2011-06-09

2.3.3 STERRAD® 100NX™ Validation Load Ref: SP-09061 Rev. C

2.3.4 APTIMAX® Tray, PC: 13837

2.3.5 APTIMAX® Instrument Tray Mat, PC: 99213

2.3.6 STERRAD® SealSure® Chemical Indicator Tape, PC: 14202, Lot:30009-B Exp# 2011-08

2.3.7 Kimberly-Clark Kimguard KC400 Wrap, Ref: 68236

Sterrad® Test Results (continued)

REPORT

Functional Compatibility Study of HyperGrip Connectors from Hypertronics Corporation in the STERRAD® 100NX™ Sterilization System

2.4 Laboratory Notebook

2.4.1 #3049: 154 - 188

2.5 Experimental Description:

Testing was performed in accordance with TP-35119-001 Rev. D.

The load consisted of 2 APTIMAX® Trays. One tray consisted of the Hypertronics Corporation HG Connectors, an instrument mat, and the components of a ½ Validation Load. The other tray contained an instrument mat and the components of a ½ Validation Load for the Standard Cycle. The trays were double wrapped with Kimguard KC400 Wrap and secured with STERRAD® Chemical Indicator Tape.

The trays were placed on both shelves of the STERRAD® 100NX™ Sterilization Chamber and processed through a Standard Cycle injecting 5400µL ±216µL of 58-59.6% H_2O_2 per exposure phase. The test devices were processed for 20 cycles without washing in between cycles. Intermediate functionality evaluation of the connectors was carried out prior to, and at the conclusion of all cycles per the testing procedure outlined Additionally, per Hypertronics Corporation's request, no more than 2 sequential cycles were performed each day during testing. During the initial examination, when a change was observed on the device, and at the completion of testing, photographs of the HG Connectors were taken for documentation. After 20 cycles, the devices were returned to Hypertronics Corporation for functionality testing.

2.6 Deviations to Original Protocol:

None.

3 TEST RESULTS AND DISCUSSION

Table 1: Summary of Functionality Results by Hypertronics Corporation

Device	Number of Cycles	Functional Verification Results after 20 STERRAD® 100NX™ Standard Cycles, provided by Hypertronics Corporation
ID #1-3	20	Pass
ID #1-3	20	Pass
ID #1-3	20	Pass

Functional compatibility testing consists of two components: material compatibility (degradation) and retention of functionality post processing. Hypertronics Corporation assessed functionality and material changes, while ASP documented the device appearance via photo documents.

In the US, the STERRAD® 100NX™ Sterilization System is programmed to run two types of sterilization cycles that differ in exposure time, Standard and Flex Cycle. Functional compatibility testing for Hypertronics Corporation HG Connectors used the STERRAD® 100NX™ Standard Cycle.

During the test period, ASP observed no changes.

The samples were returned to Hypertronics Corporation for functionality evaluation after 20 cycles. Hypertronics Corporation's functionality report indicated that after exposure to 20 STERRAD® 100NX™ Standard Cycles, the

Sterrad® Test Results (continued)

REPORT

Functional Compatibility Study of HyperGrip Connectors from Hypertronics Corporation in the STERRAD® 100NX™ Sterilization System

HG Connectors passed functionality evaluation.

4 CONCLUSIONS

After 20 cycles of STERRAD® 100NX™ Sterilization, Hypertronics Corporation has concluded in the post processing functionality verification form that the devices were fully functional in accordance with Hypertronics Corporation Specification. This study demonstrates that the Hypertronics Corporation Connectors are compatible for up 20 cycles when processed in the STERRAD® 100NX™ Sterilization System.

5 RESPONSIBILITIES

5.1 The sponsor is responsible for addressing requirements of regulatory agencies if applicable, and the sponsor and users are responsible for compliance with all regulations regarding labeling claims.

5.2 MDM Testing Program at ASP is responsible for record storage of work it performed. The protocol, report and all raw data including ASP laboratory notebook references are to be retained in ASP's Document Control Center in accordance to ASP Documentation Retention Schedule.

5.3 Hypertronics Corporation performed the functionality testing and is also responsible for retaining the protocol and testing results for work it performed should these be required for a regulatory audit.

6 REFERENCES

6.1 ANSI/AAMI/ISO 14937 (2009), Sterilization of Medical Devices – General Requirements for Characterization of Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process

6.2 AAMI TIR No. 12-2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.

6.3 ASP TP-35119-001 Rev. D, Functional Compatibility Testing procedure of Medical Devices and Components Intended to be Sterilized in the STERRAD® 100NX™ Sterilization Systems in Health Care Facilities

Smiths Connectors
Global Support

AMERICAS

Costa Mesa, CA	1.714.371.110	customerservice@sabritec.com
Hudson, MA	1.978.568.0451	info@hypertronics.com
Kansas City, KS	1.913.342.5544	info@idinet.com

EUROPE

France	33.2.3296.9176	info@hypertac.fr
Germany	49.991.250.120	info@hypertac.de
Italy	39.010.60361	info@hypertac.it
United Kingdom	44.208.236.2400	info@hypertac.co.uk

ASIA

Shanghai, China	86.21.3318.4650	asiacrs@smithsconnectors.com
Singapore	65.6846.1655	asiacrs@smithsconnectors.com
Suzhou, China	86.512.6273.1188	asiacrs@smithsconnectors.com

FOR MORE INFORMATION | smithsconnectors.com