



The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-RPT-536

DOCUMENT TITLE: Gray Sumitomo A4 Heat Shrink Design Verification

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Author: TSKINNER

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**Signature Manifest****Document Number:** ENG-RPT-536**Revision:** 001**Title:** Gray Sumitomo A4 Heat Shrink Design Verification

All dates and times are in Mountain Standard Time.

**Gray Insulation Design Verification****Change Request**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		12 Jul 2017, 08:25:46 AM	Approved

**Collaboration**

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		13 Jul 2017, 08:34:53 AM	Complete
Dave Shimkus (DSHIMKUS)		17 Jul 2017, 03:40:56 PM	Complete
Stuart Taylor (STAYLOR)	Sr. Quality Engineer	02 Aug 2017, 04:37:24 PM	Complete
Darlene Hull (DHULL)	Regulatory	11 Aug 2017, 10:36:04 AM	Complete
Christian Crook (CCROOK)		15 Aug 2017, 01:55:27 PM	Complete
Tyler Skinner (TSKINNER)	Project Engineer	17 Aug 2017, 01:48:51 PM	Complete

**Document Review**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)			
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst	18 Aug 2017, 09:54:50 AM	Complete

**RA-Approval**

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	18 Aug 2017, 01:56:59 PM	Approved

**QA-Approval**

Name/Signature	Title	Date	Meaning/Reason
Stuart Taylor (STAYLOR)	Sr. Quality Engineer	22 Aug 2017, 10:16:05 AM	Approved

**ENG-Approval**

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		18 Aug 2017, 10:40:23 AM	Approved

**Training Review**

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		
Lucy Richards (LRICHARDS)		23 Aug 2017, 02:02:17 PM	Approved

Printed on: 21 Jan 2020, 11:12:13 pm; Printed by: .

**Final Release**

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		
Lucy Richards (LRICHARDS)		23 Aug 2017, 02:02:38 PM	Approved

**Quick Approval****Approve Now**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		24 Apr 2018, 11:24:55 AM	Approved

<b>Megadyne Medical Products, Inc.</b>	<b>TEST REPORT</b>	<b>Document Number ENG-RPT-536</b>
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Authored By: Tyler Skinner

## 1. ABSTRACT

After review of DMR requirements for electrosurgical electrode insulation (ENG-DMR-001), it was deemed necessary to perform dielectric testing, bond strength testing, pad print adhesion testing, modified insulation pull testing, and biocompatibility in order to verify the safety and functionality of the new Gray Sumitomo A4 heat shrink insulation (PN: 4100048-06).

This report documents the results gathered while running XENG-PRT-421. This includes dielectric testing, bond strength testing, pad print adhesion testing, and modified insulation pull testing. Biocompatibility testing will be performed per XENG-PRT-422 and results will be found in ENG-RPT-535.

These results demonstrate that the new Gray Sumitomo A4 heat shrink insulation (PN: 4100048-06) met safety and functionality as outlined in ENG-DMR-001. Upon successful completion of biocompatibility testing, it is recommended that the Gray Sumitomo A4 heat shrink insulation (PN: 4100048-06) is ready to be marketed.

## 2. REFERENCES

XENG-PRT-421	Gray Sumitomo A4 Heat Shrink Design Qualification
XENG-PRT-422	Gray Sumitomo A4 Heat Shrink Biocompatibility Protocol
ENG-RPT-535	Gray Sumitomo A4 Heat Shrink Biocompatibility Report
ENG-DMR-001	DMR E-Z Clean
4100048	Tubing, Heat Shrink, Polyolefin, Sumitomo

## 3. OBJECTIVE

The objective of this test report is to document the qualification testing performed on Gray Sumitomo A4 heat shrink (PN: 4100048-06) in compliance with ENG-DMR-001.

## 4. SAMPLE PREPARATION

Samples were sterilized according to the following table. Refer to Appendix I for sterilization data.

Sample - Part #/ Lot #	Sterilization Required
XACE14 / Prototype	2X Gamma & 2X EO

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X6020150 / Gray ACE12	2X Gamma & 2X EO
XACE14M Rev A / Prototype	2X Gamma & 2X EO
Engineering Built – 2.75” Blade w/ 2.5” PTFE Insulation	2X EO

Samples were preconditioned in compliance with the following schedule:

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to 70°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 70°C to 70°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 95%RH	4 hours
Transition from 70°C and 95% RH to 70°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 15%RH	4 hours
Transition to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 23°C and 50%RH	72 hours

Following preconditioning, samples underwent a simulated shipping test as outlined in XENG-PRT-421. This included a drop test, compression test, vehicle vibration and loose load vibration tests, concentrated impact test, and finally a 2nd drop test. Refer to Appendix II for preconditioning and shipping test data.

## 5. RESULTS

### 5.1. Dielectric Testing

#### 5.1.1. Leakage Current Testing

The Leakage Current test was performed as outlined in XENG-PRT-421 using XACE14M Rev. A Lot #: Prototype samples. The high frequency leakage current upper limit was calculated to be 32.9 mA. All electrodes were found to have leakage currents lower than this. Refer to Appendix III for test data.

#### 5.1.2. High Frequency Dielectric Withstand Testing

The High Frequency Dielectric Withstand test was performed as outlined in XENG-PRT-421 using XACE14M Rev. A Lot #: Prototype samples.

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For all samples, at least 6.68 kV was loaded, which exceeded the minimum acceptable value of 4.8 kV, for 20 seconds. Refer to Appendix III for test data.

#### 5.1.3. Mains Frequency Dielectric Withstand Testing

The Mains Frequency Dielectric Withstand test was performed as outlined in XENG-PRT-421 using XACE14M Rev. A Lot #: Prototype samples. For all samples 4,400 Vrms was used, which exceeded the minimum acceptable mains test value of 4,243 Vrms, and this value was maintained for 30 seconds. Refer to Appendix III for test data.

#### 5.2. Bond Strength Testing

Bond Strength testing was performed as outlined in XENG-PRT-421 using X6020150 Rev. A Lot #: GrayACE12. The insulation produced a minimum bond strength value of 19.76 lbf with the mean at 27.67 lbf and a STD of 3.22 lbf. Refer to Appendix IV for test data.

#### 5.3. Pad Print Adhesion Testing

Pad Print Adhesion testing was performed as outlined in XENG-PRT-421. The ink was legible after exposure to 0.9% saline solution and the 70% IPA solution. Refer to Appendix V for test data.

#### 5.4. Modified Insulation Pull Testing

Modified Insulation Pull testing was performed as outlined in XENG-PRT-421 using Engineering built 2.75" ACE Blade test samples with elongated 2.5" PTFE insulation and gray heat shrink insulation see ZIP ACE DHF - Memo Date: 5/24/17 from Tyler Skinner). The insulation produced a minimum pull force value of 5.08 lb with the mean at 6.66 lbf, a STD of 0.84 lb, and a -3  $\sigma$  value of 4.15. Refer to Appendix VI for test data.

### 6. DEVIATION

#### 6.1. Pad Print Adhesion Testing

Instead of XACE14M samples, X6020150 Rev. A Lot #: GrayACE12 samples were used for testing with the 0.9% saline solution. This deviation is considered acceptable as the test area, the interaction between the gray insulation and the pad print, is identical on both the XACE14M and the X6020150 samples.

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## 7. DISCUSSION

### 7.1. Dielectric Testing

#### 7.1.1. Leakage Current Testing

The high frequency leakage current upper limit was calculated to be 32.9 mA. All electrodes were found to have leakage currents lower than this, met the acceptance criteria, and passed the test. Refer to Appendix III for test data.

#### 7.1.2. High Frequency Dielectric Withstand Testing

For all samples, at least 6.68 kV was loaded, which exceeded the minimum acceptable value of 4.8 kV, for 20 seconds. All electrodes met the acceptance criteria passed the test. Refer to Appendix III for test data.

#### 7.1.3. Mains Frequency Dielectric Withstand Testing

For all samples 4,400 Vrms was used, which exceeded the minimum acceptable mains test value of 4,243 Vrms, and this value was maintained for 30 seconds. All electrodes met the acceptance criteria and passed the test. Refer to Appendix III for test data.

### 7.2. Bond Strength Testing

The insulation produced a minimum bond strength value of 19.76 lbf with the mean at 27.67 lbf and a STD of 3.22 lbf. All electrodes met the acceptance criteria and passed the test. Refer to Appendix IV for test data.

### 7.3. Pad Print Adhesion Testing

The ink was legible after exposure to 0.9% saline solution and the 70% IPA solution. All electrodes met the acceptance criteria and passed the test. Refer to Appendix V for test data.

### 7.4. Modified Insulation Pull Testing

The insulation produced a minimum pull force value of 5.08 lb with the mean at 6.66 lbf, a STD of 0.84 lb, and a -3  $\sigma$  value of 4.15. The distribution of the data was normal. Using a process capability analysis with a lower limit of 3.93, (3.93 is the -3  $\sigma$  value of the control group; see XENG-PRT-421) the insulation's pull force is statistically expected to be less than the lower limit in 550.15 PPM. This value indicates that the modified insulation pull force of the test group is expected to be greater than that of the control group 99.95% of the time. This expected overall performance value is acceptable indicating that the test groups pull force is

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statistically greater than the control group and thus all electrodes met acceptance criteria and passed the test. Refer to Appendix VI for test data.

## **8. RISK ASSESSMENT**

8.1. No additional risks were identified during the testing period.

## **9. CONCLUSIONS**

The results demonstrate that the new Gray Sumitomo A4 heat shrink insulation (PN: 4100048-06) met safety and functionality as outlined in ENG-DMR-001.

## **10. RECOMMENDATIONS**

Upon successful completion of biocompatibility testing, it is recommended that the Gray Sumitomo A4 heat shrink insulation (PN: 4100048-06) is ready to be marketed

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## 11. APPENDIX I

### Certificate Of Processing

Prepared for **MEGADYNE MEDICAL PRODUCTS**


Gamma Process Run ID **58248A**

Product Code	Product Lot Number	Quantity	UOM
0009	171858	22	CS
0012A	171835	29	CS
0013M	171843	33	CS
0014	171860	67	CS
0014AMP	171903	25	CS
0016AM	171904	15	CS
0019L	171879	2	CS
0020L	171812	17	CS
0035HL	171881	12	CS
0040-25	171764	40	CS
0040-25	171806	40	CS
0040-25	171830	40	CS
0041-25	171789	20	CS
0041-25	171805	20	CS
0041-25	171861	20	CS
0085	171848	3	CS
0100L	171811	3	CS

Processing Run Start Date/Time: 25-Apr-2017 09:28:46 pm

Approx. Downtime (hours): 0.00

Processing Run End Date/Time: 26-Apr-2017 03:12:47 am



Isomedix Services

Minimum Specified Dose (kGy): 25.0	Minimum Delivered Dose (kGy): 28.5
Maximum Specified Dose (kGy): 40.0	Maximum Delivered Dose (kGy): 38.5

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By  
**Kari Moe (QS/RC Analyst)**  
Document Content Revision: 1

Signed On 4/26/2017 at 10:47 AM  
UTC / GMT Offset (hh:mm): -6:00

Processing Location:  
STERIS Isomedix Services  
9120 South 150 East  
Sandy, UT 84070  
Phone: 801-561-0052  
Fax: 801-255-4074

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

PROC-00034/01354/01369 Last Rev in Rel. 3.6.2.1
Release Date: 02-Apr-2014
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Prepared for **MEGADYNE MEDICAL PRODUCTS**



Gamma Process Run ID **58248A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
0100L	171880	10	CS
0100LS	171810	10	CS
0314A	171859	4	CS
0600	171844	8	CS
0600	171856	8	CS
0600M	171845	8	CS
0605	171862	3	CS
3030HT	171809	20	CS
<b>SAMPLE</b>	<b>XACE14/PROTOTYPE</b>	<b>2</b>	<b>CS</b>

PO Number: 28541

Processing Run Start Date/Time:	25-Apr-2017 09:28:46 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	26-Apr-2017 03:12:47 am		

<b>Minimum Specified Dose (kGy):</b>	<b>25.0</b>	<b>Minimum Delivered Dose (kGy):</b>	<b>28.5</b>
<b>Maximum Specified Dose (kGy):</b>	<b>40.0</b>	<b>Maximum Delivered Dose (kGy):</b>	<b>38.5</b>
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.			

### Signature Manifest

Reviewed and E-Signed By  
**Kari Moe (QS/RC Analyst)**  
Document Content Revision: 1

Signed On 4/26/2017 at 10:47 AM  
UTC / GMT Offset (hh:mm): -6:00

### Processing Location:

STERIS Isomedix Services  
9120 South 150 East  
Sandy, UT 84070  
Phone: 801-561-0052  
Fax: 801-255-4074

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

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STERIS

Isomix Services

STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)

Prepared for MEGADYNE MEDICAL PRODUCTS

Process Run ID 53246A

Date Prepared: 4/26/2017 10:46:58AM

Processing Location: Sandy

Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD

Carrier	Seg	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
1	1	OC7	0BB608000914	TH0059	0528	28.7	28.7
1	2	OCB	0BB608000918	TH0059	0528	28.7	28.7
1	3	1C7	0BB608000912	TH0059	0528	28.5	28.5
1	4	1CEB	0BB608000928	TH0059	0528	29.8	29.8
1	5	2C7	0BB608000869	TH0059	0528	30.2	30.2
1	6	2CEB	0BB608000915	TH0059	0528	30.0	30.0
1	7	27A5	0BB608000974	TH0059	0528	37.7	37.7
1	8	27E5	0BB608000921	TH0059	0528	37.4	37.4
1	9	28A5	0BB608000874	TH0059	0528	38.5	38.5
1	10	28E5	0BB608000860	TH0059	0528	38.0	38.0
1	11	T8A5	0BB608000931	TH0059	0528	38.0	38.0
1	12	T8E5	0BB608000930	TH0059	0528	37.0	37.0
2	1	T8A5	0BB608000868	TH0059	0528	36.9	36.9
2	2	T8E5	0BB608000967	TH0059	0528	36.4	36.4
7	1	OC7	0BB608000916	TH0059	0528	29.9	29.9
7	2	OCB	0BB608000933	TH0059	0528	29.4	29.4
7	3	1CEB	0BB608000961	TH0059	0528	29.8	29.8
7	4	2CEB	0BB608000963	TH0059	0528	30.4	30.4
7	5	27B5	0BB608000960	TH0059	0528	34.4	34.4
7	6	27D5	0BB608000942	TH0059	0528	34.6	34.6
7	7	T8B5	0BB608000862	TH0059	0528	34.6	34.6

On XAGE4/PROTOTYPE

L1 7-6-17

PROC-0074 Last Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date: \*\*Nov-2015

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PROC-00074 Last Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date: 11-Nov-2015

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STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)  
Prepared for MEGADYNE MEDICAL PRODUCTS  
Process Run ID 58248A  
Date Prepared: 4/26/2017 10:46:58AM

Processing Location: Sandy  
Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD




Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
7	8	TBD5	0BB608000896	TH0059	0528	35.5	35.5
8	1	TBB5	0BB608000834	TH0059	0528	30.8	30.8
8	2	TBD5	0BB608000920	TH0059	0528	34.2	34.2
9	1	TBB5	0BB608000923	TH0059	0528	32.2	32.2
9	2	TBD5	0BB608000976	TH0059	0528	33.9	33.9
14	1	OC1	0BB608000866	TH0059	0528	31.6	31.6
14	2	OC3	0BB608000894	TH0059	0528	31.0	31.0
14	3	OC5	0BB608000936	TH0059	0528	31.6	31.6
14	4	OC6B	0BB608000950	TH0059	0528	32.4	32.4
14	5	1CEB	0BB608000925	TH0059	0528	33.8	33.8
14	6	2CEB	0BB608000951	TH0059	0528	34.1	34.1
14	7	TBA5	0BB608000945	TH0059	0528	34.5	34.5
14	8	TBE5	0BB608000848	TH0059	0528	36.2	36.2
15	1	OC6B	0BB608000863	TH0059	0528	32.3	32.3
15	2	TBA5	0BB608000888	TH0059	0528	35.1	35.1
15	3	TBE5	0BB608000919	TH0059	0528	37.0	37.0
Minimum Dose for Record (kGy):						28.5	
Maximum Dose for Record (kGy):						38.5	

PROC-00074 Last Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date: 11/24/2015

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 <b>STERIS</b> IsomediX Services		<b>STERIS IsomediX Services Dosimetry Record (Alanine Dosimetry System)</b> Prepared for MEGADYNE MEDICAL PRODUCTS Process Run ID 58248A Date Prepared: 4/26/2017 10:46:58AM	
Processing Location: <b>Sandy</b> Irradiator / Method: <b>138, Nordion Cobalt-60 Irradiator #138, ON-STD</b>			
Carrier	Seq	Coordinate	Barcode ID
			Insert
		Instrument	Dose (kGy)
			Final Dose (kGy)
Signature Manifest			
Prepared By:  <b>Randy Memmott (Production Supervisor)</b>		Signed On 4/26/2017 at 10:06 AM UTC / GMT Offset (hh:mm): -6:00	
Approved By:  <b>Kari Moe (QS/RC Analyst)</b>		Signed On 4/26/2017 at 10:46 AM UTC / GMT Offset (hh:mm): -6:00	
Document Content Revision: 1			

PROC\*\*\*74 Last Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date: 11-2015

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## Certificate Of Processing

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Gamma Process Run ID **58419A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
0012	172075	65	CS
0013M	172065	34	CS
0014A	172076	61	CS
0014A	172094	57	CS
0016A	172077	8	CS
0028	171990	3	CS
0040-25	172046	40	CS
0040-25	172071	20	CS
0100LS	172093	7	CS
0118	172134	12	CS
0118A	172133	13	CS
0618	172090	4	CS
SAMPLE	2335/165019	6	CS
SAMPLE	2390/165020	14	CS
SAMPLE	2395/165021	13	CS
SAMPLE	X6020150/GrayACE12	2	CS
SAMPLE	XACE14/PROTOTYPE	2	CS

Processing Run Start Date/Time: 09-May-2017 09:14:00 pm      Approx. Downtime (hours): 0.00  
Processing Run End Date/Time: 10-May-2017 02:10:01 am

<b>Minimum Specified Dose (kGy):</b>	<b>25.0</b>	<b>Minimum Delivered Dose (kGy):</b>	<b>28.4</b>
<b>Maximum Specified Dose (kGy):</b>	<b>40.0</b>	<b>Maximum Delivered Dose (kGy):</b>	<b>40.0</b>

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Signature Manifest

Reviewed and E-Signed By  
**LeeAnn McClure (QS/RC Manager)**  
Document Content Revision: 1

Signed On 5/10/2017 at 4:00 PM  
UTC / GMT Offset (hh:mm): -6:00

**Processing Location:**  
STERIS Isomedix Services  
9120 South 150 East  
Sandy, UT 84070  
Phone: 801-561-0052  
Fax: 801-255-4074

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

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Gamma Process Run ID 58419A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
SAMPLE	XACE14M/PROTOTYPE	1	CS


PO Number: 28613

Processing Run Start Date/Time:	09-May-2017 09:14:00 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	10-May-2017 02:10:01 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	28.4
Maximum Specified Dose (kGy):	40.0	Maximum Delivered Dose (kGy):	40.0

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Signature Manifest

Reviewed and E-Signed By  
 **LeeAnn McClure (QS/RC Manager)**  
Document Content Revision: 1

Signed On 5/10/2017 at 4:00 PM  
UTC / GMT Offset (hh:mm): -6:00

**Processing Location:**  
STERIS Isomedix Services  
9120 South 150 East  
Sandy, UT 84070  
Phone: 801-561-0052  
Fax: 801-255-4074

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

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<p>STERIS Isomedia Services</p> <p>STERIS Isomedia Services Dosimetry Record (Alanine Dosimetry System)</p> <p>Prepared for MEGADYNE MEDICAL PRODUCTS Process Run ID 58419A Date Prepared: 5/10/2017 2:59:03PM</p> <p>Processing Location: Sandy Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD</p>									
Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)		
1	1	0C7	0BB608012293	TH0056	0492	29.6	29.6		
1	2	0CEB	0BB608012295	TH0056	0492	29.1	29.1		
1	3	1C7	0BB608012300	TH0056	0492	30.1	30.1		
1	4	1CEB	0BB608012298	TH0056	0492	29.8	29.8		
1	5	2C7	0BB608012338	TH0056	0492	30.1	30.1		
1	6	2CEB	0BB608012291	TH0056	0492	29.4	29.4		
1	7	3C7	0BB608012306	TH0056	0492	30.0	30.0		
1	8	3CEB	0BB608012325	TH0056	0492	30.0	30.0		
1	9	27A5	0BB608012333	TH0056	0492	39.6	39.6		
1	10	27E5	0BB608012311	TH0056	0492	38.5	38.5		
1	11	28A5	0BB608012319	TH0056	0492	39.9	39.9		
1	12	28E5	0BB608012321	TH0056	0492	39.0	39.0		
1	13	TBA5	0BB608012332	TH0056	0492	38.1	38.1		
1	14	TBE5	0BB608012314	TH0056	0492	37.5	37.5		
2	1	0C7	0BB608012290	TH0056	0492	29.2	29.2		
2	2	0CEB	0BB608012373	TH0056	0492	28.4	28.4		
2	3	1C7	0BB608012326	TH0056	0492	29.7	29.7		
2	4	1CEB	0BB608012354	TH0056	0492	29.3	29.3		
2	5	2C7	0BB608012315	TH0056	0492	29.6	29.6		
2	6	2CEB	0BB608012329	TH0056	0492	30.4	30.4		
2	7	27A5	0BB608012409	TH0056	0492	38.8	38.8		

X ACEM / PROTOTYPE  
X AG4M / PROTOTYPE TS 7-6-17  
X 6020150 / GRAY ACEM

WI-007 1st Rev DNA 2.0.1.0 & RT 3.6.5.0

Release Date: \*Nov-2015

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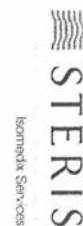


Megadyne Medical Products, Inc.	TEST REPORT		Document Number ENG-RPT-536
	Gray Sumitomo A4 Heat Shrink Design Verification		Revision: 001
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WI-00 1st Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date \*\*Nov-2015

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STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)  
Prepared for MEGADYNE MEDICAL PRODUCTS  
Process Run ID 58419A  
Date Prepared: 5/10/2017 2:59:03PM

Processing Location: Sandy  
Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
2	8	27E5	0BB608012327	TH0056	0492	37.8	37.8
2	9	28A5	0BB608012477	TH0056	0492	40.0	40.0
2	10	28E5	0BB608012307	TH0056	0492	38.5	38.5
2	11	T8A5	0BB608012316	TH0056	0492	38.8	38.8
2	12	T8E5	0BB608012301	TH0056	0492	38.3	38.3
3	1	T8A5	0BB608012328	TH0056	0492	35.4	35.4
3	2	T8E5	0BB608012334	TH0056	0492	35.1	35.1
4	1	T8A5	0BB608012353	TH0056	0492	32.7	32.7
4	2	T8E5	0BB608012352	TH0056	0492	35.3	35.3
5	1	T8A5	0BB608012388	TH0056	0492	33.0	33.0
5	2	T8E5	0BB608012484	TH0056	0492	35.0	35.0
6	1	0C7	0BB608012390	TH0056	0492	29.7	29.7
6	2	0CEB	0BB608012381	TH0056	0492	29.4	29.4
6	3	1CEB	0BB608012335	TH0056	0492	30.2	30.2
6	4	2CEB	0BB608012323	TH0056	0492	31.0	31.0
6	5	27B5	0BB608012341	TH0056	0492	34.2	34.2
6	6	27D5	0BB608012308	TH0056	0492	36.2	36.2
6	7	T8B5	0BB608012356	TH0056	0492	34.3	34.3
6	8	T8D5	0BB608012320	TH0056	0492	34.7	34.7
7	1	T8B5	0BB608012479	TH0056	0492	32.9	32.9
7	2	T8D5	0BB608012358	TH0056	0492	33.8	33.8

Megadyne Medical Products, Inc.	TEST REPORT		Document Number ENG-RPT-536
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Isomedix Services

# STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)

Prepared for MEGADYNE MEDICAL PRODUCTS

Process Run ID 58419A

Date Prepared: 5/10/2017 2:59:03PM

Processing Location: Sandy

Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
8	1	TBA5	0BB608012312	TH0056	0492	33.5	33.5
8	2	TBE5	0BB608012346	TH0056	0492	35.7	35.7
9	1	0CEB	0BB608012322	TH0056	0492	31.2	31.2
9	2	TBA5	0BB608012313	TH0056	0492	32.1	32.1
9	3	TBE5	0BB608012357	TH0056	0492	35.4	35.4
Minimum Dose for Record (kGy):						28.4	
Maximum Dose for Record (kGy):						40.0	

## Signature Manifest

Prepared By:

Jacob Burtleigh (Production Assistant 1)

Approved By:

LeeAnn McClure (QS/RC Manager)

Document Content Revision: 1

Signed On 5/10/2017 at 9:51 AM  
UTC / GMT Offset (hh:mm): -6:00

Signed On 5/10/2017 at 2:59 PM  
UTC / GMT Offset (hh:mm): -6:00

WI-QC

1st Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date

Nov-2015

<b>Megadyne Medical Products, Inc.</b>	<b>TEST REPORT</b>	<b>Document Number ENG-RPT-536</b>
	<b>Gray Sumitomo A4 Heat Shrink Design Verification</b>	<b>Revision: 001</b>
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## Certificate Of Processing

Prepared for **MEGADYNE MEDICAL PRODUCTS**



Gamma Process Run ID **58493A**


<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
0009	172248	21	CS
0012	172155	69	CS
0014	172214	70	CS
0020L	172212	3	CS
0029M	172242	8	CS
0040-10	172153	50	CS
0040-25	172230	40	CS
0041-25	172154	20	CS
0041-25	172190	20	CS
0041-25	172215	20	CS
0100L	172213	4	CS
0600	172253	7	CS
0600M	172254	7	CS
0621M	172255	2	CS
ACE30H	172209	30	CS
C117	172244	21	CS
SAMPLE	2335/22MM TUBING WITH SPONGE GUARD/165019	6	CS

Processing Run Start Date/Time: 17-May-2017 12:42:38 am      Approx. Downtime (hours): 0.40  
Processing Run End Date/Time: 17-May-2017 06:28:44 am

<b>Minimum Specified Dose (kGy):</b>	<b>25.0</b>	<b>Minimum Delivered Dose (kGy):</b>	<b>28.5</b>
<b>Maximum Specified Dose (kGy):</b>	<b>40.0</b>	<b>Maximum Delivered Dose (kGy):</b>	<b>38.3</b>

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Signature Manifest

Reviewed and E-Signed By  
 **Kari Moe (QS/RC Analyst)**  
Document Content Revision: 1

Signed On 5/17/2017 at 10:34 AM  
UTC / GMT Offset (hh:mm): -6:00

**Processing Location:**  
STERIS Isomedix Services  
9120 South 150 East  
Sandy, UT 84070  
Phone: 801-561-0052  
Fax: 801-255-4074

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-536
	Gray Sumitomo A4 Heat Shrink Design Verification	Revision: 001
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## Certificate Of Processing

Prepared for MEGADYNE MEDICAL PRODUCTS



Gamma Process Run ID 58493A

Product Code	Product Lot Number	Quantity	UOM
SAMPLE	2390/LAP TUBING/165020	14	CS
SAMPLE	2395/SPECULUM TUBING/165021	13	CS
SAMPLE	X6020150/GRAY ACE12	2	CS
SAMPLE	XACE14M/PROTOTYPE	1	CS


PO Number: 28645

Processing Run Start Date/Time:	17-May-2017 12:42:38 am	Approx. Downtime (hours):	0.40
Processing Run End Date/Time:	17-May-2017 06:28:44 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	28.5
Maximum Specified Dose (kGy):	40.0	Maximum Delivered Dose (kGy):	38.3

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Signature Manifest

Reviewed and E-Signed By  
 **Kari Moe (QS/RC Analyst)**  
Document Content Revision: 1

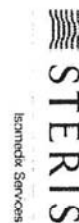
Signed On 5/17/2017 at 10:34 AM  
UTC / GMT Offset (hh:mm): -6:00

**Processing Location:**  
STERIS Isomedix Services  
9120 South 150 East  
Sandy, UT 84070  
Phone: 801-561-0052  
Fax: 801-255-4074

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.



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# STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)

Prepared for MEGADYNE MEDICAL PRODUCTS  
Process Run ID 58493A  
Date Prepared: 5/17/2017 10:33:49AM

Processing Location: Sandy  
Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD

TS 7-6-17  
X60201501 GRAY ACE12  
XACE14M / PROTOTYPE

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
1	1	0C7	0BB608046255	TH0056	0492	28.8	28.8
1	2	0CEB	0BB608046325	TH0056	0492	28.5	28.5
1	3	1C7	0BB608046241	TH0056	0492	28.8	28.8
1	4	1CEB	0BB608046259	TH0056	0492	28.5	28.5
1	5	2C7	0BB608046385	TH0056	0492	29.2	29.2
1	6	2CEB	0BB608046257	TH0056	0492	29.0	29.0
1	7	3C7	0BB608046426	TH0056	0492	29.3	29.3
1	8	3CEB	0BB608046270	TH0056	0492	29.2	29.2
1	9	27A5	0BB608046288	TH0056	0492	38.2	38.2
1	10	27E5	0BB608046334	TH0056	0492	37.4	37.4
1	11	28A5	0BB608046277	TH0056	0492	38.3	38.3
1	12	28E5	0BB608046497	TH0056	0492	38.1	38.1
1	13	28A5	0BB608046295	TH0056	0492	37.7	37.7
1	14	28E5	0BB608046332	TH0056	0492	36.5	36.5
2	1	TBA5	0BB608046323	TH0056	0492	36.0	36.0
2	2	TBE5	0BB608046256	TH0056	0492	35.2	35.2
3	1	TBA5	0BB608046330	TH0056	0492	32.7	32.7
3	2	TBE5	0BB608046329	TH0056	0492	35.5	35.5
5	1	TBB5	0BB608046309	TH0056	0492	32.1	32.1
5	2	TBD5	0BB608046354	TH0056	0492	33.3	33.3
6	1	0C7	0BB608046324	TH0056	0492	29.6	29.6

WI-00074 Last Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date: 14-Nov-2015

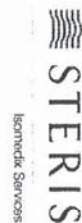
Page 1 of 3

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-536
		Revision: 001
		Page 19 of 32

WI-00074 Last Rev DMA 2.0.1.0 & RT 3.6.5.0

Release Date: 14-Nov-2015

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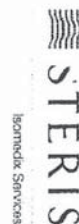
# STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)

Prepared for MEGADYNE MEDICAL PRODUCTS  
Process Run ID 59493A  
Date Prepared: 5/17/2017 10:33:49AM

Processing Location: Sandy  
Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
6	2	0CEB	0BB608046359	TH0056	0492	29.9	29.9
6	3	1CEB	0BB608046284	TH0056	0492	29.9	29.9
6	4	2CEB	0BB608046337	TH0056	0492	29.9	29.9
6	5	27B5	0BB608046289	TH0056	0492	34.1	34.1
6	6	27D5	0BB608046326	TH0056	0492	35.8	35.8
6	7	TB85	0BB608046350	TH0056	0492	34.1	34.1
6	8	TBD5	0BB608046340	TH0056	0492	34.5	34.5
7	1	0C7	0BB608046345	TH0056	0492	28.7	28.7
7	2	0CEB	0BB608046336	TH0056	0492	28.7	28.7
7	3	1CEB	0BB608046380	TH0056	0492	29.2	29.2
7	4	2CEB	0BB608046357	TH0056	0492	29.5	29.5
7	5	27B5	0BB608046349	TH0056	0492	33.6	33.6
7	6	27D5	0BB608046317	TH0056	0492	35.4	35.4
7	7	TB85	0BB608046331	TH0056	0492	34.7	34.7
7	8	TBD5	0BB608046288	TH0056	0492	34.6	34.6
8	1	TB85	0BB608046361	TH0056	0492	34.3	34.3
8	2	TBD5	0BB608046293	TH0056	0492	35.4	35.4
9	1	TBA5	0BB608046346	TH0056	0492	33.3	33.3
9	2	TBE5	0BB608046327	TH0056	0492	35.7	35.7
10	1	TBA5	0BB608046351	TH0056	0492	34.7	34.7
10	2	TBE5	0BB608046253	TH0056	0492	37.5	37.5

Megadyne Medical Products, Inc.	TEST REPORT		Document Number ENG-RPT-536
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STERIS Isomedix Services Dosimetry Record (Alanine Dosimetry System)

Prepared for MEGADYNE MEDICAL PRODUCTS  
Process Run ID 58493A  
Date Prepared: 5/17/2017 10:33:49AM

Processing Location: Sandy  
Irradiator / Method: 138, Nordion Cobalt-60 Irradiator #138, ON-STD

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
11	1	T3B5	0BB608046252	TH0056	0492	32.3	32.3
11	2	T3D5	0BB608046321	TH0056	0492	33.4	33.4
12	1	0CEB	0BB608046341	TH0056	0492	30.6	30.6
12	2	T3A5	0BB608046281	TH0056	0492	32.3	32.3
12	3	T3E5	0BB608046301	TH0056	0492	36.0	36.0

Minimum Dose for Record (kGy): 28.5  
Maximum Dose for Record (kGy): 38.3

Signature Manifest

Prepared By: Randy Memmott (Production Supervisor)  
Approved By: Karl Moe (QS/RC Analyst)  
Document Content Revision: 1

Signed On 5/17/2017 at 9:53 AM  
UTC / GMT Offset (hh:mm): -6:00  
Signed On 5/17/2017 at 10:33 AM  
UTC / GMT Offset (hh:mm): -6:00

WH-00074 Last Rev DMA 2.0, 1.0 & RT 3.6, 5.0

Release Date: 14-Nov-2015

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<b>Megadyne Medical Products, Inc.</b>	<b>TEST REPORT</b>	<b>Document Number ENG-RPT-536</b>
	<b>Gray Sumitomo A4 Heat Shrink Design Verification</b>	<b>Revision: 001</b>
		<b>Page 21 of 32</b>



The Electrosurgical Authority



To: ZIP ACE DHF

From: Tyler Skinner, Project Engineer

Stuart R. Taylor, Sr. Quality Engineer

*Tyler Skinner 7-7-17*  
*Stuart R. Taylor 7/7/17*

Date: 07/06/17

Re: Nelson Laboratories Ethylene Oxide (EO) Exposure – Study Number: 965660-S01

The purpose of this memo is to clarify the test article contents of the three boxes submitted to Nelson Laboratories for ethylene oxide (EO) exposure on May 18, 2017. The three boxes were labeled “Ref: XACE14M Lot: Prototype” and subjected to EO exposure using the following cycle:

Preconditioning Set Points:	
Temperature:	43.3°C
Relative Humidity:	60%
Time (Minimum):	24 hours
Time (Maximum):	n/a
Sterilization Set Points:	
EO Gas Concentration:	804 mg/L (100% EO)
Temperature:	48.9°C
Relative Humidity:	50%
Initial Vacuum:	1.0psia
EO Gas Dwell Time:	240 minutes
Steam Dwell Time:	60 minutes
Aeration Set Points:	
Temperature:	43.3 ± 5°C
Time (Minimum):	24 hours

The EO Exposure GLP report from Nelson Laboratories dated May 18, 2017 documents all test articles as “Ref: XACE14M Lot: Prototype”, consistent with the labelling on the three boxes. However, the three boxes exposed to EO actually contained the following test articles:

Ref (Product Code)	Lot
XACE14M REV A	PROTOTYPE
X6020150 REV A	GrayACE12
Engineering Built – 2.75” Blade w/ PTFE Insulation	NA



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-536
	Gray Sumitomo A4 Heat Shrink Design Verification	Revision: 001
		Page 22 of 32



Sponsor:  
Tyler Skinner  
MegaDyne Medical Products, Inc.  
11506 S. State St.  
Draper, UT 84020-9453

## Ethylene Oxide (EO) Exposure (BIER Vessels and STERIS® EO Sterilizers) GLP Report

Test Article: Ref: XACE14M  
Lot: Prototype  
Description:  
Purchase Order: 28649  
Study Number: 965660-S01  
Study Received Date: 18 May 2017  
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0107 Rev 08  
Customer Specification Sheet (CSS) Number: 201703061 Rev 01

**Summary:** This report describes the exposure of the above mentioned test article(s) to EO. The sterilizer was programmed using the set points below. All test method acceptance criteria were met. Following the exposure process, the test articles were retained at Nelson Laboratories, LLC (NL) for further testing and the remaining test articles were picked up by the sponsor.

The exposed test articles are not for human use. Because the sterilization of the test articles has not been validated using additional fractional 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.

**Test Method Acceptance Criteria:** To be considered a valid cycle, the corresponding cycle record must be assessed and approved according to the cycle review requirements.

**Procedure:** The 3 boxes submitted for EO exposure were processed using the following set points:

Preconditioning Phase:

Temperature: 43.3°C  
Relative Humidity (RH): 60%  
Time: 24 hours 06 minutes (Cycle 1)  
24 hours 19 minutes (Cycle 2)

Conditioning Phase:

Temperature: 48.9°C  
RH: 50%  
Vacuum Set Point: 1.0 pounds per square inch absolute (psia)  
Humidity Set Point: 1.8 psia  
Conditioning Time: 60 minutes  
Vacuum Ramp Rate: 25 psia/minute

Study Director

  
Sammy Diphibane, B.S.

08 Jun 2017  
Study Completion Date



965660-S01

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. • 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.  
www.nelsonlabs.com • Telephone 801 290 7500 • Fax 801 290 7908 • sales@nelsonlabs.com

drf

801-FRT0107-0001 Rev 7  
Page 1 of 3

These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

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Printed on: 21 Jan 2020, 11:12:13 pm; Printed by: .

<b>Megadyne Medical Products, Inc.</b>	<b>TEST REPORT</b>	<b>Document Number ENG-RPT-536</b>
	<b>Gray Sumitomo A4 Heat Shrink Design Verification</b>	<b>Revision: 001</b>
		<b>Page 23 of 32</b>



Study Number 965660-S01  
Ethylene Oxide (EO) Exposure  
(BIER Vessels and STERIS® EO Sterilizers) GLP Report

EO Exposure Phase:

Gas Type: 100% EO  
Gas Concentration: 804.0 mg/L  
Temperature: 48.9°C  
Sterilant Set Point: 8.9 psia  
Exposure Time: 240 minutes  
Vacuum Ramp Rate: 25 psia/minute

Aeration Phase:

Temperature: 43.3 ± 5°C  
Time: 24 hours 37 minutes (Cycle 1)  
25 hours 07 minutes (Cycle 2)

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Study Number 965660-S01  
Ethylene Oxide (EO) Exposure  
(BIER Vessels and STERIS® EO Sterilizers) GLP Report

### Quality Assurance Statement

**Compliance Statement:** The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	19 May 2017
Phase Inspected by Quality Assurance: Exposure	23 May 2017
Audit Results Reported to Study Director	31 May 2017
Audit Results Reported to Management	31 May 2017

Scientists	Title
Dania Cortes-Covington	Supervisor
Tori Dieffenbacher	Study Director

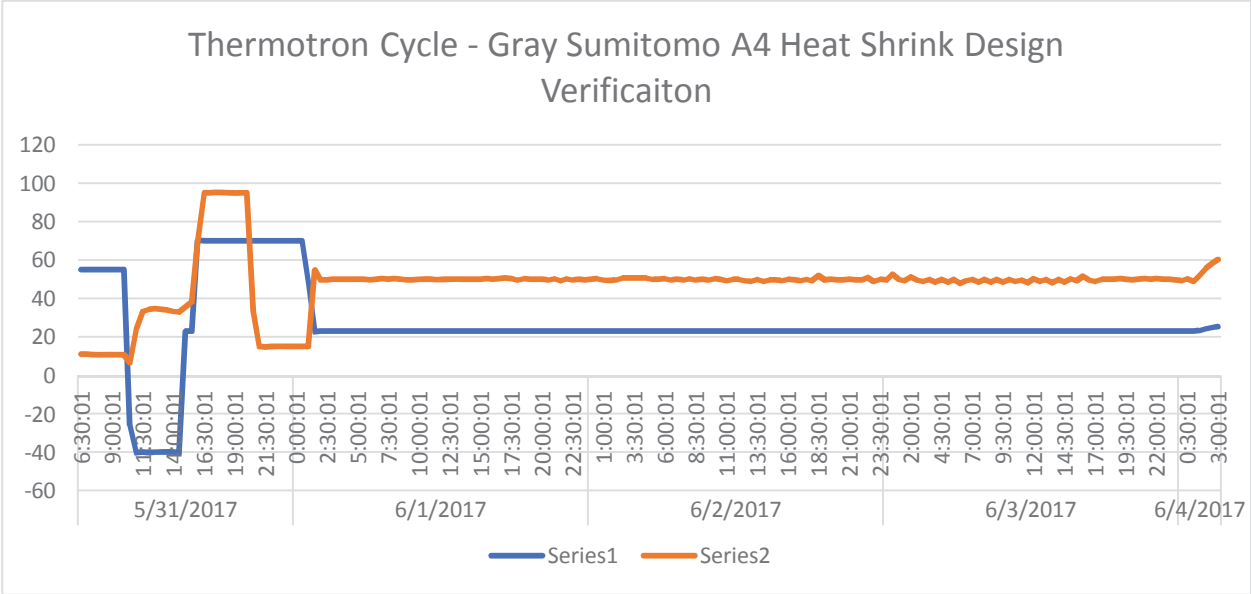
**Data Disposition:** The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

  
Quality Assurance

09 Jun 2017  
Date

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12. APPENDIX II



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# 11. APPENDIX I – SAMPLE PREPARATION

## Preconditioning:

Start Date: 5-31-2017 Chamber Number: 01268  
Completion Date: 6-4-2017 Last Calibration: 5-1-2017  
Signature/Date: Paul Valpreda 6-6-2017 Calibration due: 5-1-2018

## Drop Test:

Catalog Various Weight 2.5 lbs. Drop Height: 15 inches

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV 6-5-2017
2	Edge	Edge 5-3	PV 6-5-2017
3	Edge	Edge 6-3	PV 6-5-2017
4	Corner	Corner 2-3-5	PV 6-5-2017
5	Corner	Corner 4-3-6	PV 6-5-2017
6	Bottom	Face 3	PV 6-5-2017

Comments: Passed.

Signature: Paul Valpreda Date: 6-5-2017

## Compression Test:

Catalog Various Pounds Force 50 lbs.

Comments: Passed.

Signature: Paul Valpreda Date: 6-5-2017

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Appendix I Continued  
Sample Preparation

Vibration:

Low Frequency, 40 minutes, Initials PV

High frequency 10 minutes, Initials PV

Completion Date: 6-5-2017

Signature: Paul Valpreda Date: 6-5-2017

Concentrated Impact Test:

Completion Date: 6-6-2017

Signature: Paul Valpreda Date: 6-6-2017

Second Drop Test:

Catalog Various Weight 2.5 lbs. Drop Height: 15 and 30 inches.

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 6-6-2017
2	Face	Face 4	PV 6-6-2017
3	Face	Face 6	PV 6-6-2017
4	Corner	Corner 2-1-5	PV 6-6-2017
5	Edge	Edge 2-1	PV 6-6-2017
6	Bottom	Face 3, Increase height to 30 inches.	PV 6-6-2017

Comments: Passed all.

Signature: Paul Valpreda Date: 6-6-2017

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### 13. APPENDIX III

#### Electrode Dielectric Withstand Testing Product Tested - XACE14M LOT - Prototype Data Collection Form

Sample	Configuration	d (mm)	L (cm)	LEAKAGE f <sub>test</sub> (kHz)	U <sub>peak</sub> (V <sub>pp</sub> )/2	Measured Leakage Current (mA)	Calculated Leakage	Acceptable P/F	Power (W)
1	XACE14M - Prototype	1.6	14.3	400	400	19.5	32.9	PASS	7
2	XACE14M - Prototype	1.6	14.3	400	400	17.3	32.9	PASS	7
3	XACE14M - Prototype	1.6	14.3	400	400	16.1	32.9	PASS	7
4	XACE14M - Prototype	1.6	14.3	400	400	18.3	32.9	PASS	7
5	XACE14M - Prototype	1.6	14.3	400	400	16.2	32.9	PASS	7
6	XACE14M - Prototype	1.6	14.3	400	400	17.4	32.9	PASS	7
7	XACE14M - Prototype	1.6	14.3	400	400	17.2	32.9	PASS	7
8	XACE14M - Prototype	1.6	14.3	400	400	17.5	32.9	PASS	7
9	XACE14M - Prototype	1.6	14.3	400	400	16.0	32.9	PASS	7
10	XACE14M - Prototype	1.6	14.3	400	400	17.0	32.9	PASS	7
11	XACE14M - Prototype	1.6	14.3	400	400	17.1	32.9	PASS	7
12	XACE14M - Prototype	1.6	14.3	400	400	17.9	32.9	PASS	7
13	XACE14M - Prototype	1.6	14.3	400	400	17.5	32.9	PASS	7
14	XACE14M - Prototype	1.6	14.3	400	400	17.4	32.9	PASS	7
15	XACE14M - Prototype	1.6	14.3	400	400	17.1	32.9	PASS	7
16	XACE14M - Prototype	1.6	14.3	400	400	17.6	32.9	PASS	7
17	XACE14M - Prototype	1.6	14.3	400	400	17.4	32.9	PASS	7
18	XACE14M - Prototype	1.6	14.3	400	400	17.2	32.9	PASS	7
19	XACE14M - Prototype	1.6	14.3	400	400	18.3	32.9	PASS	7
20	XACE14M - Prototype	1.6	14.3	400	400	17.5	32.9	PASS	7
21	XACE14M - Prototype	1.6	14.3	400	400	16.9	32.9	PASS	7
22	XACE14M - Prototype	1.6	14.3	400	400	19.5	32.9	PASS	7

d = smallest measured outer dimension of insulation

L = length of insulation up to a max. of 300 mm

f<sub>test</sub> = frequency of the pure out signal

U<sub>peak</sub> = Oscilloscope test p-p voltage

Leakage Calculation -

$$I_{\text{leakage}} = 9.0 \times 10^{-6} d \cdot L \cdot f_{\text{test}} \cdot U_{\text{peak}} \text{ (mA)}$$

Sample	Configuration	HIGH FREQUENCY		MAINS	
		Max V <sub>pk</sub> (kV)	P/F	P/F	P/F
1	XACE14M - Prototype	6.68	PASS	PASS	PASS
2	XACE14M - Prototype	6.75	PASS	PASS	PASS
3	XACE14M - Prototype	6.68	PASS	PASS	PASS
4	XACE14M - Prototype	6.75	PASS	PASS	PASS
5	XACE14M - Prototype	6.68	PASS	PASS	PASS
6	XACE14M - Prototype	6.68	PASS	PASS	PASS
7	XACE14M - Prototype	6.68	PASS	PASS	PASS
8	XACE14M - Prototype	6.68	PASS	PASS	PASS
9	XACE14M - Prototype	6.68	PASS	PASS	PASS
10	XACE14M - Prototype	6.68	PASS	PASS	PASS
11	XACE14M - Prototype	6.68	PASS	PASS	PASS
12	XACE14M - Prototype	6.68	PASS	PASS	PASS
13	XACE14M - Prototype	6.68	PASS	PASS	PASS
14	XACE14M - Prototype	6.68	PASS	PASS	PASS
15	XACE14M - Prototype	6.75	PASS	PASS	PASS
16	XACE14M - Prototype	6.68	PASS	PASS	PASS
17	XACE14M - Prototype	6.68	PASS	PASS	PASS
18	XACE14M - Prototype	6.68	PASS	PASS	PASS
19	XACE14M - Prototype	6.68	PASS	PASS	PASS
20	XACE14M - Prototype	6.68	PASS	PASS	PASS
21	XACE14M - Prototype	6.68	PASS	PASS	PASS
22	XACE14M - Prototype	6.68	PASS	PASS	PASS

PV

PV

Mains Test Value Calculation:			
(Rated Accessory V <sub>test</sub> = 1000V <sub>max</sub> ) / √2			
Rated Accessory V <sub>test</sub>	5.000	V <sub>test</sub>	
Minimum Mains Test Value	4.243	V <sub>min</sub>	
Actual Mains Test Value	4.400	V <sub>act</sub>	

Paul Valpreda

Operator Name

*Paul Valpreda*

Operator Signature

#### CALIBRATION INFORMATION

##### Multimeter

Fluke 179 True RMS Multimeter

Serial Number 33660168

Megadyne Number 01507

Calibration Date 1/17/2017

Calibration Due 1/31/2018

##### Generator

Mega Power 1000

Serial Number 10353001

Megadyne Number N/A

Calibration Date N/A

Calibration Due N/A

##### Oscilloscope

Tektronix DPO 3012

Serial Number C0104/1

Megadyne Number 01420

Calibration Date 10/4/2016

Calibration Due 10/31/2017

##### Hipot Test Generator

Hipotronics Model HD 100 Series

Megadyne Number 01037

Calibration Date 8/15/2016

Calibration Due 8/31/2017

##### High Voltage Probe

Tektronix P6015A High Voltage Probe

Serial Number B032485

Megadyne Number 01023

Calibration Date 2/13/2017

Calibration Due 2/28/2018

##### Inductive Current Coil

Pearson Current Monitor Model 2100

Serial Number 109555

Megadyne Number 01288

Calibration Date 1/17/2017

Calibration Due 1/31/2018

##### RMS Voltmeter

Fluke 8920A True RMS Voltmeter

Serial Number 4220005

Megadyne Number 01254

Calibration Date 10/17/2016

Calibration Due 10/31/2017

##### Digital Calipers

Starrett

Serial Number MMP-1003

Megadyne Number 01039

Calibration Date 5/18/2016

Calibration Due 5/31/2018

6/12/2017

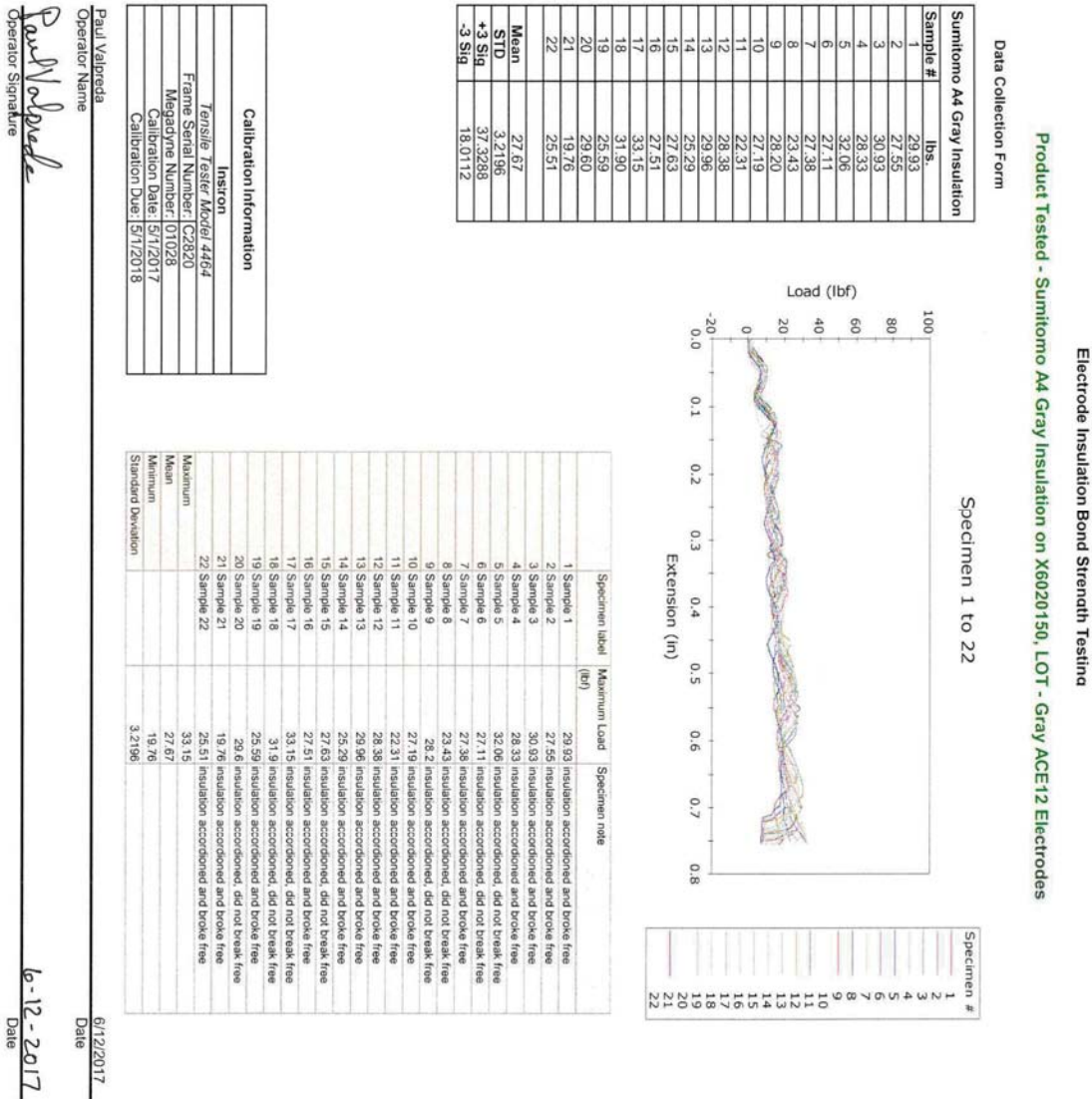
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14. APPENDIX IV





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## 15. APPENDIX V

Pad Print Adhesion Testing		
Sample #	P(Pass) / F(Fail) 0.9% Saline	P(Pass) / F(Fail) 70% IPA
1	PASS	PASS
2	PASS	PASS
3	PASS	PASS
4	PASS	PASS
5	PASS	PASS
6	PASS	PASS
7	PASS	PASS
8	PASS	PASS
9	PASS	PASS
10	PASS	PASS
11	PASS	PASS
12	PASS	PASS
13	PASS	PASS
14	PASS	PASS
15	PASS	PASS
16	PASS	PASS
17	PASS	PASS
18	PASS	PASS
19	PASS	PASS
20	PASS	PASS
21	PASS	PASS
22	PASS	PASS

Saline used: Baxter 0.9% Sodium Chloride Injection USP - LOT Number C901777, Exp. Date: 08/17

Alcohol used: Texwipe TX 167 - LOT Number: 171204, Exp. Date: 03/20

Electrodes used in the saline testing - X6020150, LOT - Gray ACE12

Electrodes used in the alcohol testing - XACE14M, LOT - Prototype

Performed by: Paul Valpreda

6/16/2017

*Paul Valpreda*

Date

6-16-2017

Signature

Date

## 16. APPENDIX VI

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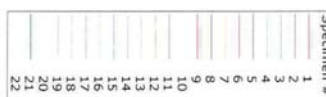
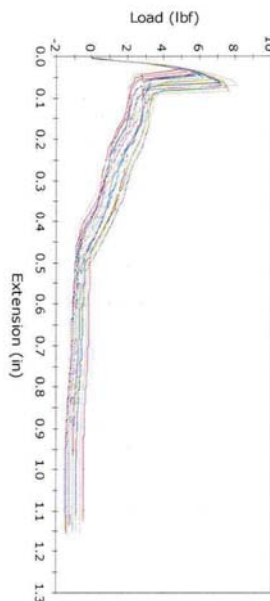
Megadyne Medical Products, Inc.	<b>TEST REPORT</b>		<b>Document Number</b> <b>ENG-RPT-536</b>
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PTFE Modified Sleeve Extraction Force

Product Tested - PTFE Sleeve With Sumitomo A4 Gray Insulation on XACE14M, LOT - Prototype Electrodes

Data Collection Form

Specimen 1 to 22



Sample #	lbs.
1	5.52
2	5.92
3	7.63
4	7.00
5	6.05
6	5.97
7	7.44
8	6.25
9	5.08
10	7.12
11	7.25
12	6.93
13	8.19
14	6.60
15	7.80
16	6.88
17	6.28
18	7.66
19	5.16
20	6.17
21	7.18
22	6.67
Mean	6.66
STD	0.83563
+3 Sig	9.16689
-3 Sig	4.15311

Calibration Information	
Instron	
Tensile Tester Model 4464	
Frame Serial Number: C2820	
Megadyne Number: 01028	
Calibration Date: 5/17/2017	
Calibration Due: 5/17/2018	

Specimen Label	Maximum Load (lbf)	Description
1 Sample 1	5.52	PTFE pulled from new grey insulation
2 Sample 2	5.92	PTFE pulled from new grey insulation
3 Sample 3	7.63	PTFE pulled from new grey insulation
4 Sample 4	7.00	PTFE pulled from new grey insulation
5 Sample 5	6.05	PTFE pulled from new grey insulation
6 Sample 6	5.97	PTFE pulled from new grey insulation
7 Sample 7	7.44	PTFE pulled from new grey insulation
8 Sample 8	6.25	PTFE pulled from new grey insulation
9 Sample 9	5.08	PTFE pulled from new grey insulation
10 Sample 10	7.12	PTFE pulled from new grey insulation
11 Sample 11	7.25	PTFE pulled from new grey insulation
12 Sample 12	6.93	PTFE pulled from new grey insulation
13 Sample 13	8.19	PTFE pulled from new grey insulation
14 Sample 14	6.6	PTFE pulled from new grey insulation
15 Sample 15	7.5	PTFE pulled from new grey insulation
16 Sample 16	6.88	PTFE pulled from new grey insulation
17 Sample 17	6.28	PTFE pulled from new grey insulation
18 Sample 18	7.66	PTFE pulled from new grey insulation
19 Sample 19	5.16	PTFE pulled from new grey insulation
20 Sample 20	6.17	PTFE pulled from new grey insulation
21 Sample 21	7.18	PTFE pulled from new grey insulation
22 Sample 22	6.67	PTFE pulled from new grey insulation
Maximum	8.19	
Mean	6.66	
Minimum	5.08	
Standard Deviation	0.83563	

Paul Valpreda  
Operator Name  
*Paul Valpreda*  
Operator Signature  
6-12-2017  
Date

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