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ENG-RPT-558 Zip Verif Rpt

Change Request

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Authored By: Mallory Schroeder

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1. REFERENCES

| | |
|-------------|---|
| ENG-PRT-451 | Zip Pen Requirement Verification Protocol |
| MKT-CMR-029 | MEGADYNE Smoke Evacuation Product Line CMR |
| MKT-US-002 | Usability Requirements Specification, Smoke Evacuation Pencils, Extension Nozzles and Universal ULPA Filter |
| ENG-PS-007 | Product Specification, Smoke Evacuation Pencil and Accessories |
| ENG-PS-010 | Product Specification, Disposable Electrosurgical Pencil |
| ENG-IOM-014 | Input/Output Conformance Test Matrix: Disposable Electrosurgical Pencil |

2. ABSTRACT

Zip Pen samples were subjected to a testing outlined in ENG-PRT-451. The samples passed the acceptance criteria described in ENG-PRT-451, verifying customer and marketing level (MKT-CMR-029), usability (MKT-US-002) and product specification (ENG-PS-007) requirements that are not tested under other protocols. This pertains to the Zip Pen products identified in MKT-CMR-029, including cat numbers 2525-10 (252510), 2525-10EC (252510EC), 2525-10BN

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(252510BN), 2525-10ECBN (252510ECBN), 2525-15EC (252515EC), and 2525-15 (252515), ME7251C, ME7251E, ME725M1C, ME725M1E. These Zip products share the same design, differing only in cord / tubing length, active electrode type, and/or packaging. This protocol also pertains to the Extension Nozzle cat numbers 2540 (2540J) and 2560 (2560J), connector filter/tubing 2140 (2140J), and ULPA Filter 2211 (2211J). The catalog numbers in parentheses are new catalog numbers referring to the same product, due to transition of product information from Megadyne Medical Products to Ethicon Endo Surgery. The old and new catalog numbers are interchangeable as it relates to referencing a product.

3. OBJECTIVE

The purpose of this test protocol is to document conformance to requirements of customer and marketing (MKT-CMR-029), usability (MKT-US-002) and product specification (ENG-PS-007) that are not verified under other protocols.

4. PROTOCOL DEVIATIONS

Two deviations were made from the protocol. Plug extraction force testing was not completed here, as an equivalent test has already been conducted in R150215 Section 5.7 and R150216 section 5.8 per P-140308-E-3 and P140311-E-2 respectively. These are New Deantronics documents and housed in their quality system. See ENG-IOM-014 for the results. While a different product the plug is the same. The requirement for plug extraction is a minimum of 2lb per ENG-PS-010. The Zip product spec ENG-PS-007 is being updated from a minimum of 6lb to a minimum of 2lb to remain consistent across Megadyne product lines.

An additional ESU, Covidien FT10, was tested for physical plug compatibility. As mentioned in ENG-PRT-451, there is no specification of exact ESUs which must be compatible, but MKT-CMR-029 states that the Zip Pen will have a standard three-prong plug and be compatible with most standard ESUs in the market. As an additional ESU was available, it was included in this testing to further fulfill this requirement.

5. RESULTS

Testing was conducted on February 13, 2018 by Mallory Schroeder and Paul Valpreda at Megadyne Medical Products (11506 State St, Draper, UT 84020). Zip Pen samples were tested, with samples noted in ENG-PRT-451 under 'Experiment Design / Sample Size Justification.' Training was conducted, with the record found in Appendix XIV. All data is found in Appendix I - XIII.

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5.1. Cable & Tube Length, Connector Dimension, Swivel Distance

Three (3) samples of each Zip Pen (252510EC and 252515) were measured to find the Cable Length, Tube Length, and Swivel Distance using a measuring tape. The ID of the 22mm Connector found on three (3) samples of 252510EC was measured using calipers. See results in the following table:

| Catalog Number | Cable Length | | Tube Length | | ID of Connector | | Swivel Distance | |
|----------------|--------------|-----------------|-------------|-----------------|-----------------|----------------|-----------------|-------------------|
| | Criteria | Measured (in.) | Criteria | Measured (in.) | Criteria | Measured (in.) | Criteria | Measured (in.) |
| 252510EC | 120+/-6in | 114.3/114.5/115 | 120+/-2.6in | 119/120.2/119.8 | .875+/-0.005in | .874/.878/.877 | 8+/-1in | 8.125/8.125/8.125 |
| 252515 | 180+/-6in | 174/174.3/174.1 | 176+/-3.6in | 176/177/178 | .875+/-0.005in | See 252510EC | 8+/-1in | 8.25/8.1/7.9 |

See Appendix I for raw data.

5.2. E-Z Clean Coating

Electrode from Catalog #2525-10EC Lot #1511014 was coated with E-Z Clean coating.

Electrode from Catalog #2525-15 Lot #S170066 was coated with E-Z Clean coating.

See Appendix II for raw data.

5.3. Holster, Plug, Cord Color

The Holster from Catalog #2525-15 Lot #S160050 is Pantone 427.

The Plug from Catalog #2525-15 Lot #S160050 is Pantone 427.

The Cord from Catalog #2525-15 Lot #S160050 is Pantone 427.

Parts from Catalog #2525-15 Lot #S160050 match drawing 6020312 Rev 007.

See Appendix III for raw data.

5.4. Plug Branding

The plug clam shell from Catalog #2525-10EC Lot #1511014 has 'MEGADYNE' branding and matches drawing 6020312 Rev 007.

See Appendix IV for raw data.

5.5. Angled Nozzle, Clarity

The Nozzle from Catalog #2525-15 Lot #S160050 was angled, clear (not opaque), and matched drawing 5800104-01 Rev 003.

The Nozzle from Catalog #2540 Lot #1507123 was angled, clear (not opaque), and matched drawing 5800309 Rev 002.

The Nozzle from Catalog #2560 Lot #1507124 was angled, clear (not opaque), and matched drawing 5800308 Rev 002. See Appendix V for raw data.

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5.6. Cord Exit, Tube Containment Length

Three (3) samples of each Zip Pen (252510EC and 252515) were measured to find the Cord Length Exiting Tube and Tube Containment length using a measuring tape. See results in the following table:

| Catalog Number | Lot Number | Cord Length Exiting Tube | | Tube Containment Length | |
|----------------|------------|--------------------------|-------------------|-------------------------|----------------|
| | | Criteria | Measured (in.) | Criteria | Measured (in.) |
| 252510EC | 1511014 | greater than 48 in. | 49.8/50/50.2 | greater than 64 in. | 64.4/65/64.6 |
| 252515 | S170066 | greater than 48 in. | 108.3/108.9/109.1 | greater than 64 in. | 65.2/65.3/65.1 |

See Appendix VI for raw data.

5.7. Cord Containment

Paper was wrapped around the cable in 11 of 11 samples of Catalog #2525-15 Lot #S160050 and matched drawing 6020191-01 Rev 005.

The cord was wrapped and contained within the holster in 11 of 11 samples of Catalog #2525-15 Lot #S160050 and matched drawing 6020191-01 Rev 005.

See Appendix VII for raw data.

5.8. ESU Plug Compatibility

A plug from Catalog #2525-15 Lot# S160050 was successfully inserted into eight (8) different Electrosurgical Units (ESU). See Appendix VIII for a list of ESUs and data.

5.9. Plug Extraction Force

Not tested – See Protocol Deviations.

5.10. Extension Nozzle Length

Three (3) samples of each extension nozzles (2540 and 2560) were measured using calipers. See results in the following table:

| Catalog Number | Lot Number | Criteria | Measured (in.) |
|----------------|------------|---------------|-------------------|
| 2540 | 1507123 | 2.79+/- .02in | 2.779/2.775/2.776 |

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|------|---------|---------------|-------------------|
| 2560 | 1507124 | 5.29+/- .02in | 5.272/5.273/5.275 |
|------|---------|---------------|-------------------|

See Appendix IX for raw data.

5.11. 2211 ULPA Filter Attachment

The threaded connector of Catalog # 2140 Lot #172763 was successfully threaded with Catalog #2211 Lot #15169 and found to be compatible.

See Appendix X for raw data.

5.12. EC Connector Instron Pull Test

The EC Connector was removed from the 7/8" port of a smoke filter using an Instron. The Maximum force measured was 7.16 lbf, the minimum force measured was 4.86 lbf, and the mean force measured was 6.18 lbf with a standard deviation of 0.668 lbf. Of the eleven (11) samples tested, seven (7) failed by the tubing coming off of the connector, while four (4) did not disconnect, the tubing merely stretched. All samples passed the 4 lbf requirement.

See Appendix XI for raw data.

5.13. Cable, Plug Cytotoxicity

Both the Cable (ND Part # C302600) and Plug (New Deantronics Part # F507100, F507200 or F505100, F505200) of the Zip Pen have demonstrated acceptable biocompatibility.

The cable jacket material of New Deantronics Part # C302600 is the same material as New Deantronics Part # C103700—Light Gray PVC CTi color code XEU003---PMS427C, SHORE A, 75 +/- 3 with Plasticizer PN-1030. This jacket material was tested in New Deantronics Report R130811-E. See Appendix XII for cable specifications and test report.

The plug material of New Deantronics Part # F507100, F507200 or F505100, F505200 is the same material as the Zip Pen body (New Deantronics Part #F105400, Megadyne part # 6010135-01-- ABS, Gray Pantone Color 427. This material is tested in ENG-RPT-337 per ENG-PRT-235 and meets biocompatibility requirements. Therefore, the plug also meets biocompatibility requirements.

5.14. 2211 ULPA Filter Efficiency

2211 demonstrates 99.999% efficiency for particles 0.1 to 0.2 micron as specified in 6000019-01 rev 005. See Appendix XIII for Certificate of Compliance from Custom Filter LLC. Test methods used to determine efficiency also attached in Appendix XIII.

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6. DISCUSSION

6.1. Cable & Tube Length, Connector Dimension, Swivel Distance

Three 2525-10EC samples and three 2525-15 samples were examined per the protocol. The requirements of the protocol were met.

6.2. E-Z Clean Coating

One 2525-10EC sample and one 2525-15 sample were examined per the protocol. The requirement of the protocol was met.

6.3. Holster, Plug, Cord Color

One 2525-15 accelerated aged sample was examined per the protocol. The requirement of the protocol was met.

6.4. Plug Branding

One 2525-10EC sample was examined per the protocol. The requirement of the protocol was met.

6.5. Angled Nozzle, Clarity

One accelerated aged 2525-15 sample, one 2540, and one 2560 were examined per the protocol. All samples met the requirements of the protocol.

6.6. Cord Exit, Tube Containment Length

Three samples of both 2525-10EC and 2525-15 were measured per the protocol. All samples met the requirements of the protocol.

6.7. Cord Containment

Eleven accelerated aged and ship tested 2525-15 samples were examined per the protocol. All samples met the requirements of the protocol.

6.8. ESU Plug Compatibility

One accelerated aged and ship tested 2525-15 sample was tested with eight competitive ESUs with standard three-prong plugs per the protocol. The requirement per the protocol was met.

6.9. Plug Extraction Force

Not tested— See Protocol Deviations.

6.10. Extension Nozzle Length

| | | |
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Three samples of both 2540 and 2560 were tested per the protocol. All samples met the requirement of the protocol.

6.11. 2211 ULPA Filter Attachment

One sample of 2211 and 2140 were tested per the protocol. The requirement per the protocol was met.

6.12. EC Connector Instron Pull Test

Eleven samples of 2525-10EC were tested per the protocol. All samples met the requirement of the protocol.

6.13. Cable, Plug Cytotoxicity

Documentation is provided, meeting the requirement of the protocol.

6.14. 2211 ULPA Filter Efficiency

Documentation is provided, meeting the requirement of the protocol.

7. CONCLUSIONS

This testing demonstrates that the Zip Pen meets requirements per ENG-PRT-451.

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APPENDIX I. Cable & Tube Length, Connector Dimension, Swivel Distance Acceptance Sheet

| | | |
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Appendix I: Cable & Tube Length, Connector Dimension, Swivel Distance

252510EC

Catalog Number: 2525 10EC Lot Number: 1511014

| Sample Number | 22mm Connector Diameter | Tube Length | Cord Length | Swivel Distance from Handle |
|---------------|-------------------------------|-------------|-------------|-----------------------------------|
| 1 | 0.874 in | 119 in | 119.3 in | 8.125 in |
| 2 | 0.878 in | 120.2 in | 119.5 in | 8.175 in |
| 3 | 0.877 in | 119.8 in | 115 in | 8.125 in |

Matches Drawing 5800099-01 Rev 005, 6020312 Rev 007: YES/NO YES

252515

Catalog Number: 2525 15 Lot Number: 5170066

| Sample Number | Tube Length | Cord Length | Swivel Distance from Handle |
|---------------|-------------|-------------|-----------------------------|
| 1 | 176 in | 174 in | 8.25 in |
| 2 | 177 in | 179.3 in | 8.1 in |
| 3 | 178 in | 174.1 in | 7.9 in |

Matches Drawing 6020191-01 Rev 005: YES/NO YES

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

Equipment Name, Number, Cal Date, Cal Due Date: (for 22 mm) Calipers, #01531,
Cal Date 1/16/17, Cal Due 1/31/19, (Else) Measuring Tape, #01577, Cal Date 1/23/17
Cal Due 1/31/19

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APPENDIX II. E-Z Clean Coating Acceptance Sheet

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Appendix II
E-Z Clean Coating

252510EC

Catalog Number: 2525-10EC Lot Number: 1511014

Electrode is Coated with E-Z Clean: YES/NO

252515

Catalog Number: 2525-15 Lot Number: S170066

Electrode is Coated with E-Z Clean: YES/NO

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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APPENDIX III. Holster, Plug, Cord Color Acceptance Sheet

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2-13-18 M.S. Aged sample used

2525-15 (accelerated aged)

252510EC-

Catalog Number: 2525-15

Appendix III Holster, Plug, Cord Color

Lot Number: S160050

Holster Color is Pantone 427: YES/NO

Plug Color is Pantone 427: YES/NO

Cord Color is Pantone 427: YES/NO

Matches Drawing 6020312 Rev 007: YES/NO

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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APPENDIX IV. Plug Branding Acceptance Sheet

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Appendix IV Plug Branding

252510EC

Catalog Number: 252510EC Lot Number: 1511014

Plug has 'MEGADYNE' Branding: YES/NO
Matches Drawing 6020312 Rev 007: YES/NO

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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APPENDIX V. Angled, Clarity Nozzle Acceptance Sheet

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211318 M.S. Type: Angled nozzle used
252510EC 252515 (aged / ship tested)

Appendix V
Angled Nozzle, Clarity

Catalog Number: 252515 Lot Number: 5160050

Nozzle is Angled: YES/NO
Nozzle is Clear and Not Opaque: YES/NO
Material Name from 5800104-01 Rev 003: Polycarbonate, clear Dow Calibre 2081-15
purple tint

2540J

Catalog Number: 2540 Lot Number: 1507123

Nozzle is Angled: YES/NO
Material Name from 5800309 Rev 002: Polycarbonate, clear Dow Calibre 2081-15
purple tint

2560J

Catalog Number: 2560 Lot Number: 1507124

Nozzle is Angled: YES/NO
Material Name from 5800308 Rev 002: Polycarbonate, clear Dow Calibre 2081-15
purple tint

Test Conducted By (Name): Mallory Schroeder Date: 2113/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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APPENDIX VI. Cord Exit Length Acceptance Sheet

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Appendix VI Cord Exit, Tube Containment Length

252510EC

Catalog Number: 2525-10EC Lot Number: 1511014

| Sample Number | Cord Exit Length | Cord Length Within Tubing |
|---------------|------------------|---------------------------|
| 1 | 49.8 in | 69.4 in |
| 2 | 50 in | 65 in |
| 3 | 50.2 in | 69.6 in |

252515

Catalog Number: 2525-15 Lot Number: 5170066

| Sample Number | Cord Exit Length | Cord Length Within Tubing |
|---------------|------------------|---------------------------|
| 1 | 108.3 in | 65.2 in |
| 2 | 108.9 in | 65.3 in |
| 3 | 109.1 in | 65.1 in |

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

Equipment Name, Number, Cal Date, Cal Due Date: Measuring Tape, #01577
Cal Date 1/23/18, Cal Due 1/31/19

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APPENDIX VII. Cord Containment Acceptance Sheet

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Appendix VII Cord Containment

252515 – Accelerated Aged and Ship Tested

Catalog Number: 252515 Lot Number: 5160050

| Sample # | Paper Wrapped: Pass/Fail | Cord Wrapped and in Holster: Pass/Fail |
|----------|--------------------------|--|
| 1 | P | P |
| 2 | P | P |
| 3 | P | P |
| 4 | P | P |
| 5 | P | P |
| 6 | P | P |
| 7 | P | P |
| 8 | P | P |
| 9 | P | P |
| 10 | P | P |
| 11 | P | P |

Matches Drawing 6020191-01 Rev 005: YES/NO

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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| | II, Zip Pen | Page 15 of 52 |

APPENDIX VIII. ESU Physical Plug Compatibility Acceptance Sheet

| | | |
|--|--|---------------------------------------|
| Megadyne Medical Products, Inc. | TEST PROTOCOL | Document Number ENG-PRT-451 |
| | Zip Pen | Revision: 001 |
| | Requirement Verification Protocol | Page 24 of 26 |

2-13-18 *Type:*
M.S. *Used aged 15'*
sample
←252510EC 252515 (aged, ship tested)
Catalog Number: 2525-15 Lot Number: S160050

| ESU Name | Serial # | Pass/Fail | Comments |
|------------------------|--------------|-----------|----------|
| Valley Lab Force 2 | F8H35778T | P | NA |
| Force Triad | T7H3707E | P | NA |
| Erbe V10 300D | 11286376 | P | NA |
| Erbe ICC 350 | B-1092 | P | NA |
| Conmed Sabre 2700 | 916KGS027 | P | NA |
| Conmed System 500 | 04MGPS8 | P | NA |
| Covidien ValleyLabFT10 | 75J013170X | P | NA |
| Force FX | - CF2A2062ZA | P | NA |
| NA | NA | NA | NA |
| NA | NA | NA | NA |
| NA | NA | NA | NA |

Test Conducted By (Name): Mallory Schroeder Date: 2/15/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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| | | |
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| | Product Specification Verification Test Report II, Zip Pen | Page 16 of 52 |
| | | |

APPENDIX IX. Extension Nozzle Length Acceptance Sheet

| | | |
|--|--|---|
| Megadyne Medical Products, Inc. | TEST PROTOCOL | Document Number ENG-PRT-451 Revision: 001 |
| | Zip Pen Requirement Verification Protocol | Page 25 of 26 |
| | | |

Appendix IX Extension Nozzle Length

2540J

Catalog Number: 2540 Lot Number: 1507123

| Sample Number | Extension Nozzle Length |
|---------------|-------------------------|
| 1 | 2.779 in |
| 2 | 2.775 in |
| 3 | 2.776 in |

Matches Drawing 5800309 Rev 002: YES/NO

2560J

Catalog Number: 2560 Lot Number: 2560 1507124

| Sample Number | Extension Nozzle Length |
|---------------|-------------------------|
| 1 | 5.272 in |
| 2 | 5.273 in |
| 3 | 5.275 in |

Matches Drawing 5800308 Rev 002: YES/NO

Test Conducted By (Name): Mallory Schroeder Date: 2/13/18

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

Equipment Name, Number, Cal Date, Cal Due Date: Starrett Calipers
#01531, Cal Date 1/16/17, Cal Due 1/31/19

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APPENDIX X. 2211 ULPA Filter Attachment Acceptance Sheet

| | | |
|--|--|--|
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| | Zip Pen Requirement Verification Protocol | Page 26 of 26 |
| | | |

Appendix X
2211 ULPA Filter Attachment

2211

Catalog Number: 2211 Lot Number: 15169

2140

Catalog Number: 2140 Lot Number: 172763

Connector is Compatible: YES/NO

Test Conducted By (Name): Mallory Schroeder Date: 2/13/16

Test Conducted By (Signature): Mallory Schroeder

Comments: NA

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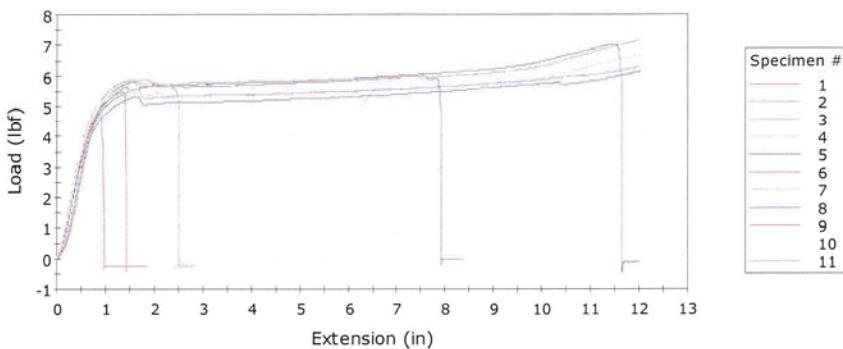
| | | |
|--|---|--|
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APPENDIX XI. EC Connector Instron Pull Test

Tuesday, February 13, 2018

EC Connector Instron Pull Test.is_tens

Specimen 1 to 11



| | Maximum Load (lbf) | Specimen label |
|--------------------|-----------------------|----------------|
| 1 | > 5.48 | LOT S150489 |
| 2 | > 5.91 | LOT S150489 |
| 3 | > 7.16 | LOT S150489 |
| 4 | > 6.68 | LOT S150489 |
| 5 | > 7.02 | LOT 1511014 |
| 6 | > 6.01 | LOT 1511014 |
| 7 | > 5.91 | LOT 1511014 |
| 8 | > 6.15 | LOT 1511014 |
| 9 | > 4.86 | LOT 1511014 |
| 10 | > 6.50 | LOT 1511014 |
| 11 | > 6.31 | LOT 1511014 |
| Maximum | 7.16 | |
| Minimum | 4.86 | |
| Mean | 6.18 | |
| Standard Deviation | 0.668 | |

Completed by
Paul Valpreda on 2-13-2018
Instron # 01028
Calibrated Date:
1/24/18
Calibrated Due:
1/24/19

| | Specimen note 1 |
|----|-----------------------------------|
| 1 | Tubing came off connector |
| 2 | Tubing came off connector |
| 3 | Tubing stretched, no other damage |
| 4 | Tubing stretched, no other damage |
| 5 | Tubing came off connector |
| 6 | Tubing came off connector |
| 7 | Tubing came off connector |
| 8 | Tubing stretched, no other damage |
| 9 | Tubing came off connector |
| 10 | Tubing came off connector |
| 11 | Tubing stretched, no other damage |

Page 1 of 1

| | | |
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APPENDIX XII. Cable Cytotoxicity


CHING TAI ELECTRIC WIRE & CABLE CO. LTD.
新泰工业股份有限公司

SPECIFICATION FOR APPROVAL

CUSTOMER : NEW DEANTRONICS
CUSTOMER P/N : C302600
DESCRIPTION : 3C CABLE
VENDOR P/N : SF1AC048
REV. NO : 2013.03.25
DATE : 2013.03.25
PART NO : GKA021



審核 (Check): Cecil You 工程部 (Engineer) : Chris Lee

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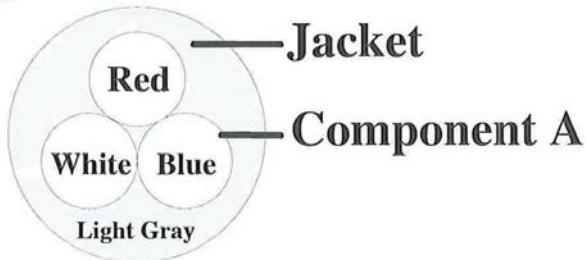
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CTi CHING TAI ELECTRIC WIRE & CABLE CO., LTD.
5, Hwa Cheng Road, Hsin Chuang City 24211, Taiwan, R.O.C.
Tel: 886-2-29940447 Fax: 886-2-29940446

THE SPECIFICATION
OF
3C CABLE

1. Construction
1.1 Configuration



1.2 Component

1.2.1 Component A

- | | |
|----------------------|---|
| a. Size of conductor | : AWG 26 (7 x 0.16mm) Anneal copper wire |
| b. Insulation | |
| b1. Material | : PPE (CTi color code XEB018— PP_ST861+PE_3366, mix rated = 1 : 1) |
| b2. Overall diameter | : 0.97 ± 0.03mm |
| b3. Wall thickness | : min. 0.20mm |
| b4. Color code | : Blue (CTi color code XEB018+XCB010) Red (CTi color code XEB018+XCB003) White (CTi color code XEB018+XCB012) (SHORE A 97 ± 3) |

1.3 Jacket

1.3.1 Outer Jacket

- | | |
|---------------------|--|
| a. Material | : PVC |
| b. Overall diameter | : 2.92 ± 0.05mm |
| c. Wall thickness | : min. 0.354mm |
| d. Color code | : Light Gray (CTi color code XEU003) (XEU003—PMS427C, SHORE A 75 ± 3) |
| e. Plasticizer | : PN-1030 |



VENDOR P/N : SFIAC048
REV. NO : 2013.03.25

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| |
|--|
|  CHING TAI ELECTRIC WIRE & CABLE CO. LTD. 新泰工业股份有限公司 |
| <u>SPECIFICATION FOR APPROVAL</u> |
| CUSTOMER : NEW DEANTRONICS |
| CUSTOMER P/N : C103700 |
| DESCRIPTION : 1C CABLE |
| VENDOR P/N : SF8AC030 |
| REV. NO : 2012.07.16 |
| DATE : 2012.07.16 |
| PART NO : GKB019 |
|  |
| 審核 (Check): <u>Jacky Huang</u> 工程部 (Engineer) : <u>Jayme Lee</u> |
| ***** |

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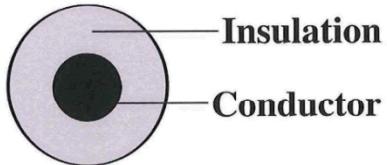
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CHING TAI ELECTRIC WIRE & CABLE CO., LTD.
5, Hwa Cheng Road, Hsin Chuang City 24211, Taiwan, R.O.C.
Tel: 886-2-29940447 Fax: 886-2-29940446

**THE SPECIFICATION
OF
1C CABLE**

1. Construction
1.1 Configuration



1.2 Component

- | | |
|----------------------|---|
| a. Size of conductor | : AWG 24 (19 x 0.12mm) Anneal copper wire |
| b. Insulation | |
| b1. Material | : PVC |
| b2. Overall diameter | : $3.0 \pm 0.1\text{mm}$ |
| b3. Wall thickness | : min. 1.02mm |
| b4. Color code | : Gray (CTi color code XEU003) (XEU003—PANTON427C, SHORE A 75±3) |
| b5. Plasticizer | : PN-1030 |

2. Marking : N/A



VENDOR P/N : SF8AC030
REV. NO : 2012.07.16

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| | | | |
|---------------------------------|---|----------|------------|
| NEW DEANTRONICS Ltd. | Biocompatibility Test Report | DCC # | R130811-E |
| | PVC Cable Jacket (Part Number C103700) Biocompatibility Report | Revision | 08/13/2013 |

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| APPROVALS | | | |
|-------------|--------------------|-------------------------------|---------------|
| R&D | Jerry C | James Huang | Date 9/4/2013 |
| QA/QC | Sylvia 9/6/2013 | Emilia Brillien Larry Wong | Date 9/4/2013 |
| Lab Mgr. | glyn L. Jaen | | Date 9/4/2013 |
| Product Mgr | Lawrence Hsu | | Date 9/4/2013 |

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| | | | |
|---|---|----------|------------|
| NEW DEANTRONICS Ltd. | Biocompatibility Test Report | DCC # | R130811-E |
| PVC Cable Jacket (Part Number C103700) Biocompatibility Report | | Revision | 08/13/2013 |

1. Purpose

This study will be performed to determine the biological reactivity of a mammalian cell culture (L929) (Cytotoxicity) in response to PVC Cable jacket (Cable P/N: C103700).

2. Scope/History Background

2.1 The PVC Cable jacket (P/N: C103700) is supplied by Ching Tai Electric Wire & Cable Co., Ltd. The color (Gray, PMS# 427C, Plasticizer: PN-1030) of PVC cable is specified by customer and the cable did not contact with human body. Therefore, only Cytotoxicity test is selected for biocompatibility test.

2.2 Surface area of the cable jacket sending to Toxikon for biocompatibility test is calculated manually and surface area of each sample is about 200 cm² (10 cm x 10cm x 0.05 cm).

2.3 Part Number:C103700

2.4 Lot:1010726

2.5 Photo of package are show below.



2.6 Testing material sterilization

The PVC Cable jacket which sending to Toxikon for biocompatibility test must undergo Gamma irradiation sterilization process.

3. Test Result Summary: PASS

3.1 Biological reactivity (Grade 2) was observed in the L929 mammalian cells at 48 hours post exposure to the test article extract.

3.2 The C103700 Cable Outer Jacket is considered non-cytotoxicity and meets the requirements of the ISO 10993-5.

3.3 L929 MEM Elution Test Report: Refer to Toxikon Final GLP Report:13-02756-G1

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|  NEW DEANTRONICS Ltd. | Biocompatibility Test Report | DCC # | R130811-E |
| | PVC Cable Jacket (Part Number C103700) Biocompatibility Report | Revision | 08/13/2013 |

4. Responsibility

- 4.1 Sample Preparation: New Deantronics Taiwan, Ltd.
- 4.2 Product biocompatibility Test: Toxikon Corporation
- 4.3 Gamma Irradiation sterilization: China Biotech Corporation

5. Equipment and Materials

- 5.1 The cable jacket is irradiated at 115.3-115.8 kGy by China Biotech Corporation. (Irradiation Run# NEW13362-K).

6. Process Methodology

Follow the following protocols

- 6.1 Toxikon L929 MEM Elution Test protocol number: P13-0097-00A.

7. Reference Document

- 7.1 ISO 10993-5, 2009, Biological evaluation of medical devices —Part 5: Tests for *In Vitro* Cytotoxicity.
- 7.2 ISO 10993-12, 2012, Biological evaluation of medical devices —Part 12: Sample Preparation and Reference Materials.
- 7.3 ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.
- 7.4 Toxikon L929 MEM elution test protocol number: P13-0097-00A.
- 7.5 Toxikon Final GLP Report: 13-02756-G1.
- 7.6 New Deantronics Protocol: P130728-E.
- 7.7 Drawing of Cable: C103700.

8. Data Treatment

All raw data pertaining to this study and a copy of the final report are to be retained in designated New Deantronics Document Control Center archive files.

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Certificate of Compliance

Customer Name: New Deantronics Taiwan Ltd.
Manufactured by: Ching Tai Electric Wire & Cable Co.,Ltd.
P.O. Number: N/A
Customer P/N: N/A
Cti P/N: XEU003
Cti Lot Number: 1010726A3
Quantity: 10*10cm 3pcs

Signed:
Printed Name: Winson Chen
Title: Sales

Date: Aug 30,2013

Materials

Resin Cti P/N: XEU003
PVC(with PN-1030 plasticizer)
Cti Pigment P/N:
XDB001 White
XDB002 Blackte
XDB032 Yellow

Mat'l Lot#

1010726A3

| |

| |



QR-002-2

1/1

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F. 001



中國生化科技股份有限公司

CHINA BIOTECH CORPORATION

誠信正直·誠實忠勤·社會公眾

TEL:886-4-23597515 FAX:886-4-23597080

台中市工業區33路10號

10, 33rd Road, Taichung Industrial Park,

Taichung, Taiwan R.O.C 407

DATE : 2013/7/2

照射證明書

CERTIFICATE OF IRRADIATION

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大瓏企業(股)公司
NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE : 2013/06/15

照射批號 IRRADIATION RUN NUMBER : NEW13362-K

客戶產品已照射 MATERIALS PROCESSED :

| 箱 數 CASE | 內 容 DESCRIPTION | 客戶產品批號 LOT NO |
|-------------|-------------------------------|----------------------------------|
| 1 (4PCS) | Cable outer jacket C103700 | 1010726 Biocompatibility Test |

總數 1 箱 CASE

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：
China Biotech Corporation certifies that the material listed above (has described by its manufacturer).
received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 115.3 kGy ; 最 高 劑 量 115.8 kGy
MINIMUM DOSAGE 115.3 kGy ; MAXIMUM DOSAGE 115.8 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量MIN 100.0 kGy ; 最高劑量MAX 120.0 kGy

確 認 者
CERTIFIED BY
品保部主管
QUALITY ASSURANCE

確保人類健康 · 珍惜自然環境

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TOXIKON
ADVANCING YOUR INNOVATION

GLP
TEST REQUISITION FORM

Sample Shipment to:
Toxikon Corporation
Attn: Sample Login
15 Wiggins Avenue, Bedford, MA 01730
Ph: (781) 275-3330 FAX: (781) 271-1138

| | |
|---|---|
| 1: REPORT ADDRESSED AND MAILED TO | 2: BILLING INFORMATION |
| Company Name: New Deantronics Taiwan | Purchase Order No.: 19072013-01 |
| Company Contact: Jya-Li Tsau | Quotation No.: 13-01-16-0005 |
| Address: 12F, No. 51, Sec. 4, Chong Yang Rd. | Billing Address (If different): One Ygnacio Center 990 N. California Blvd. Suite 1040 |
| City: Tu Cheng Dist., New Taipei City | City: Walnut Creek |
| State: | State: California |
| ZIP Code: 23675 | ZIP Code: 94596 |
| Country: Taiwan | Country: USA |
| Phone No.: 886 (0) 2 22681726 | Billing Comments: |
| Fax No.: | |
| Email: jya_ll@newdean.com.tw | |
| 3: TEST ARTICLE IDENTIFICATION | 4: CONTROL ARTICLE IDENTIFICATION |
| Test Article Name (Exact wording will be in the final report): PVC cable jacket (P/N: C103700) | Control Article Name (If Sponsor-Supplied): |
| LOT/BATCH No.: 1010726 | LOT/BATCH No.: _____ |
| CAS Code (if applicable): _____ | CAS Code (if applicable): _____ |
| Amount Submitted: 4 Units | Amount Submitted: _____ |
| Sample Submitted Is: <input checked="" type="radio"/> Sterile <input type="radio"/> Not Sterilized | Sample Submitted Is: <input type="radio"/> Sterile <input checked="" type="radio"/> Not Sterilized |
| Storage Condition: <input checked="" type="radio"/> Room Temp. <input type="radio"/> 4°C±2°C <input type="radio"/> -20°C±4°C <input type="radio"/> -80°C±10°C <input type="radio"/> Other Temp: _____ | Storage Condition: <input type="radio"/> Room Temp. <input checked="" type="radio"/> 4°C±2°C <input type="radio"/> -20°C±4°C <input type="radio"/> -80°C±10°C <input type="radio"/> Other Temp: _____ |
| 5: DISPOSITION OF TEST/CONTROL ARTICLE | If samples to be returned, please provide shipping account information: <input type="radio"/> UPS <input checked="" type="radio"/> FedEx <input type="radio"/> Other: _____ Account Number: _____ |
| <input checked="" type="radio"/> Discard <input type="radio"/> Return unused <input type="radio"/> Return used & unused | |

* Note: Sponsor is responsible for supplying all test and control material characterization data as specified by GLP regulations (Sec. 105 and 113). Unless specified on the test request form, 1) all samples will be stored at room temperature, 2) all samples will be disposed of without prior notice to Sponsor, and 3) If Sponsor does not provide shipping account number, then Sponsor will incur a minimum of \$125 per shipment of returned test article.

TOXIKON USE ONLY

| | |
|---------------------------------|-----------------------|
| STUDY DIRECTOR SIGNATURE: _____ | DATE: _____ |
| TOXIKON PROJECT NUMBER: _____ | LOGIN INITIALS: _____ |
| | LOGIN DATE: _____ |

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Protocol and Report Deviation Amendment

This protocol and report deviation amendment is to explain the test results of Toxikon Report 13-02756-G1 is not impacted, although the test article lot number shown on the Toxikon test request form is test article's supplier lot number, instead of New Deantronics's internal lot number.

A. Related Protocol and Report Information

(1). Protocol Number and Title:

P130728-E; PVC Cable Jacket (Part Number C103700) Biocompatibility Protocol

(2). Corresponding Report Number and Title:

R130811- E, PVC Cable Jacket (Part Number C103700) Biocompatibility Report

(3). Test Material and Lot

PVC Cable Jacket (P/N: C103700); Lot: 1010726A3

B. Reason of Deviation:

(1) Original Test Article Identification:

New Deantronics Internal Protocol (P130728-E) and Report (R130811-E)

Section 2.3 and 2.4

Test Article Part Number: C103700

Lot: 1010726

Toxikon Test Request Form (submitted in July 23, 2013) and Test Report

G13-02756-G1

Test Article Part Number: C103700

Lot number: 1010726

(2) Change of Test Article Identification:

Section 2.3 and 2.4

Test Article Part Number: C103700

Lot: 1010726A3

(3) Justification of Test Article Identification Change:

The lot number 1010726A3 shown on the test article label is placed by the supplier, Ching Tai Electric Wire & Cable Co., Ltd. However, the end letter A3 is misinterpreted as non-essential when Gamma irradiation service and Toxikon test request form are prepared. Thus, the lot information on the supplier certificate is not consistent with the irradiation certificate and test protocol & report.

Refer to the Certificate issued by Ching Tai Electric Wire & Cable Co., the formulation of the test article (lot 1010726A3) submitted to Toxikon for

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cytotoxicity test is the same as the formulation of New Deantronics Part Number C103700 for mass production.

Materials

Mat'l Lot#

| | | |
|-------|---|-----------|
| Resin | Cti P/N: XEU003 PVC(with PN-1030 plasticizer) Cti Pigment P/N: XDB001 White XDB002 Blackte XDB032 Yellow | 1010726A3 |
| | | |

(4) Impact of Change:

No impact on test results. The formulation of the test article is the same formulation to be used in mass production, i.e., the part number of the test article is the same. Although the New Deantronics' internal lot number of the test article is not available, the manufacturing process of the test article is equivalent to the process to be used in mass production. Therefore, it is concluded the test results are not impacted.

Created by:

Name: Jya-li Tsau

9/3/2013

Position: Regulatory Affairs Manager and Microbiology Laboratory Director

Date: Sep. 3, 2013

Approved by:

Name: Da-Yu Chen

9/6/2013

Position: Quality Assurance Manager

Date: Sep. 3, 2013

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FINAL GLP REPORT: 13-02756-G1

L929 MEM ELUTION TEST – ISO

Test Article
PVC cable jacket (P/N: C103700)

*21 CFR Part 58 Compliance
GLP for Nonclinical Laboratory Studies*

Report Date
August 12, 2013

Study Director
Ryan Ross, B.S.

Sponsor
New Deantronics Taiwan
12F, No.51, Sec. 4, Chong Yang Road
Tu Cheng Dist., New Taipei City 23675
Taiwan

Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

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L929 MEM Elution Test – ISO
Project# 13-02756-G1
PVC cable jacket (P/N: C103700)

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*L929 MEM Elution Test – ISO
Project# 13-02756-G1
PVC cable jacket (P/N: C103700)*

STUDY SUMMARY

The potential biological reactivity of a mammalian cell culture (mouse fibroblast L929) in response to exposure to the extract of the test article, PVC cable jacket (P/N: C103700), was determined. The test article was extracted in Minimum Essential Medium (MEM) with 10% Fetal Bovine Serum (referred to as complete MEM) for 24 ± 2 hours at 37 ± 1 °C. Negative and positive controls were prepared similarly. The maintenance medium of L929 cells grown in 6-well plates was replaced with the neat (100%) extracts in 3 replicates, and the cells were incubated for 48 ± 2 hours at 37 ± 1 °C. The biological reactivity of the cells following the exposure to the extracts was visually observed with a microscope, and graded on a scale of 0 to 4.

There was mild biological reactivity (Grade 2) of the cells exposed to the test article extract. The response obtained from the positive and negative control article extracts confirmed the suitability of the test system.

Based on the criteria of the protocol and the ISO 10993–5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.

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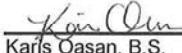
TOXIKON

*L929 MEM Elution Test – ISO
Project# 13-02756-G1
PVC cable jacket (P/N: C103700)*

QUALITY ASSURANCE STATEMENT

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

| Phase | Inspection Date | Date Reported to Study Director | Date Reported to Management |
|---------------------|-----------------|---------------------------------|-----------------------------|
| DOSE ADMINISTRATION | 07/26/13 | 07/26/13 | 07/26/13 |
| DATA | 08/05/13 | 08/05/13 | 08/05/13 |
| FINAL REPORT | 08/12/13 | 08/12/13 | 08/12/13 |



Karl Oasan, B.S.
Quality Assurance

Date
8/12/13

| | | |
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*L929 MEM Elution Test – ISO
Project# 13-02756-G1
PVC cable jacket (P/N: C103700)*

GLP COMPLIANCE STATEMENT

This study meets the technical requirements of the protocol.

This study was conducted in compliance with the current U.S. Food and Drug Administration 21 CFR, Part 58 Good Laboratory Practices for Nonclinical Laboratory Studies.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article, 21 CFR, Part 58.105, and its mixture with carriers, 21 CFR, Part 58.113.

SIGNATURES

| Signature Information | |
|-----------------------|---------------------|
| Protocol Number | P13-0097-00A |
| Study Director | Ryan Ross, B.S. |
| Study Supervisor | Abhik Basu |
| Company | Toxikon Corporation |

VERIFICATION DATES

The study initiation day is the date the protocol is signed by the Study Director.

| Verification Dates | |
|----------------------|----------|
| Test Article Receipt | 07/18/13 |
| Project Log | 07/19/13 |
| Study Initiation | 07/22/13 |
| Study Completion | 08/12/13 |


Ryan Ross, B.S.
Study Director

Date

8/12/13

| | | |
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L929 MEM Elution Test – ISO
Project# 13-02756-G1
PVC cable jacket (P/N: C103700)

1.0 PURPOSE

The purpose of the study was to determine the potential biological reactivity of a mammalian cell culture (L929) in response to the test article extract.

2.0 REFERENCES

The study was based upon the following references:

- 2.1 ISO 10993–5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity.
- 2.2 ISO 10993–12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.
- 2.3 ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

3.0 COMPLIANCE

The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The Sponsor supplied the following information on a GLP Test Requisition Form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

4.1 Test Article:

| | |
|------------------|---|
| Name | PVC cable jacket (P/N: C103700) |
| CAS/Code Number | Not Supplied by Sponsor (N/S) |
| Lot/Batch Number | 1010726 |
| Sponsor Note | Samples were sterilized by Gamma Radiation at 115.3-115.8 kGy |

4.2 Negative Control Article (Toxikon Supplied):

| | |
|-------------------|---|
| Name | Negative Control High Density Polyethylene Equivalent to Negative Control USP High Density Polyethylene Reference Standard (Negative Control Plastic) |
| Toxikon QC Number | CSC-04-05-009-CC |

4.3 Positive Control Article (Toxikon Supplied):

| | |
|-------------------|------------------|
| Name | Natural Rubber |
| Toxikon QC Number | CSC-12-03-004-CC |

| | | |
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*L929 MEM Elution Test – ISO
Project# 13-02756-G1
PVC cable jacket (P/N: C103700)*

4.4 Untreated Control – Extraction Medium (Toxikon Supplied):

| | |
|-------------------|---|
| Name | Serum-Supplemented (complete) Minimum Essential Medium (MEM) |
| Additive | 10% of fetal bovine serum, 100 U/mL Penicillin, 0.1 mg/mL Streptomycin, 2 mM L-Glutamine (final concentrations in medium) |
| Toxikon QC Number | LPR-13-07-0446 |

5.0 IDENTIFICATION OF TEST SYSTEM

The test system was mouse fibroblast CCL-1 (NCTC clone 929) cells, also known as L929 cells. The cell line was obtained from the American Type Culture Collection (ATCC), Manassas, Virginia.

6.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

6.1 Justification of Test System:

Historically, mouse fibroblast L929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles.

6.2 Route of Administration:

The test article was extracted and administered *in vitro* to mouse fibroblast L929 cells through a medium compatible with the test system, as indicated on the GLP Test Requisition Form.

7.0 EXPERIMENTAL DESIGN AND DOSAGE

7.1 Preparation of Test and Control Articles:

7.1.1 The test article was prepared according to the ISO 10993–12 guidelines and Sponsor specifications, as itemized in the table below.

| Sample | Amount | Vehicle | Volume | Ratio | Temperature | Time |
|----------------------|--------------------|-----------------|--------|-----------------------|-------------|--------------|
| Test Article | 30 cm ² | complete MEM | 10 mL | 3 cm ² /mL | 37 ± 1 °C | 24 ± 2 hours |
| Positive Control | 30 cm ² | complete MEM | 10 mL | 3 cm ² /mL | 37 ± 1 °C | 24 ± 2 hours |
| Negative Control | 30 cm ² | complete MEM | 10 mL | 3 cm ² /mL | 37 ± 1 °C | 24 ± 2 hours |
| Untreated Control | N/A | complete MEM | 10 mL | N/A | 37 ± 1 °C | 24 ± 2 hours |

N/A: Not Applicable

7.1.2 Extracts prepared with complete MEM were tested at 100% (neat) concentration.

7.1.3 The test article was placed in an extraction vessel and the appropriate medium was added. The medium completely covered the test article.

| | | |
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7.1.4 The positive (Natural Rubber, 0.23 cm thick) and negative (Negative Control Plastic, 0.06 cm thick) control articles were prepared following ISO 10993-12 ratios and extracted with the same medium at the same temperature and for the same duration as the test article, as itemized in the table above.

7.1.5 An untreated control (blank) was prepared for parallel treatment and comparison. The untreated control is the extraction medium that is subjected to the same temperature and for the same duration as the test article, as itemized in the table above.

7.1.6 Each extract was agitated vigorously prior to administration.

7.1.7 After the completion of the extraction, the extracts were kept at room temperature and were used the same day the extraction was completed. The test article appeared unchanged by the extraction procedure and the extract was clear and free from particulates. No storage of the extracts occurred.

7.2 Pre-Dose Procedure:

7.2.1 Cell Culture Preparation:

Cell cultures were removed from culture flasks by enzymatic digestion (trypsin/EDTA) and the cell suspension was centrifuged. The cells were then re-suspended in culture medium and seeded at 2×10^5 cells per well in 2 mL of complete MEM in a 6-well plate. The cultures were incubated for not less than 16 hours ($5 \pm 1\%$ carbon dioxide (CO_2), $37 \pm 1^\circ\text{C}$, $> 90\%$ humidity) so that cells formed a sub-confluent monolayer.

7.2.2 pH Measurement:

The color of the test article extract did not indicate an obvious change of pH (yellow or purple) so the pH of the extract was not adjusted.

7.2.3 Sterility:

The test article extract was not filter sterilized prior to being applied to the cell monolayer.

7.3 Dose Administration:

A 2 mL volume of extract of the test article and control articles, as well as the untreated control, were used to replace the maintenance medium of the cell culture. All dosing was done in triplicate.

7.4 Post-Dose Procedure:

7.4.1 Incubation:

All cultures were incubated for 48 ± 2 hours at $37 \pm 1^\circ\text{C}$, in a humidified atmosphere containing $5 \pm 1\%$ CO_2 .

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7.4.2 Grading:

The reactivity of the cells was evaluated at time 24 and 48 hours. The response of the cell monolayer was evaluated under a microscope at a 10 x 10 magnification. A cytochemical stain (Trypan Blue) was used in the evaluation. The biological reactivity (cellular degeneration and malformation) was rated on a scale of 0 to 4 based on the following table.

| Grade | Reactivity | Description of Reactivity Zone |
|-------|------------|--|
| 0 | None | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| 1 | Slight | Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable. |
| 2 | Mild | Not more than 50% of the cells are round, devoid of intracytoplasmic granules, no extensive cell lysis; not more than 50% growth inhibition observable. |
| 3 | Moderate | Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable. |
| 4 | Severe | Nearly complete or complete destruction of the cell layers. |

8.0 EVALUATION CRITERIA

8.1 Test System Suitability:

The test system is considered suitable if the following conditions are met:

- The negative control article and untreated control show no signs of cellular reactivity (Grade 0).
- The positive control article shows greater than a Mild reactivity (Grade 2).

If the test system is not considered suitable, the test is repeated.

8.2 Determination of Cytotoxic Effect:

The test article meets the requirements of the test if none of the cultures treated with the test article show greater than a Mild reactivity (Grade 2).

8.3 Control of Bias Statement:

The study and its design employed methodology to minimize uncertainty of measurement and control of bias for data collection and analysis, which included but was not limited to: concurrent control data, system suitability assessment, blanks, and replicates.

9.0 RESULTS

The Reactivity grades are summarized in the following table:

| Time | Date | Test Article | | | Controls | | | | | | | | | |
|----------|----------|--------------|---|---|----------|---|---|----------|---|---|---|---|---|--|
| | | Untreated | | | Negative | | | Positive | | | | | | |
| A | B | C | A | B | C | A | B | C | A | B | C | | | |
| 24 Hours | 07/27/13 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 4 | 4 | |
| 48 Hours | 07/28/13 | 2 | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 4 | 4 | |

| | | |
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10.0 CONCLUSION

Based on the criteria of the protocol and the ISO 10993–5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.

11.0 RECORDS

- 11.1 Original raw data will be archived at Toxikon Corporation.
- 11.2 A copy of the final report and any report amendments will be archived at Toxikon Corporation.
- 11.3 The original final report and a copy of any protocol amendments or deviations will be forwarded to the Sponsor.
- 11.4 All used and unused test article shall be disposed of by Toxikon, per Sponsor's request.

12.0 CONFIDENTIALITY AGREEMENT

Per corporate policy, confidentiality shall be maintained in general, and in specific accordance with any relevant agreement specifically executed between Toxikon and the Sponsor.

13.0 UNFORESEEN CIRCUMSTANCES

Any unforeseen circumstances were documented in the raw data. However, no unforeseen circumstances that affected the integrity of the study were noted.

14.0 PROTOCOL AMENDMENTS/DEVIATIONS

There were no protocol amendments or deviations. No changes to the protocol were required.

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APPENDIX I
Software Systems

| Software | Use | Publisher/Vendor | Location |
|---|---|----------------------------|----------------|
| Adobe Acrobat 8 Professional | Document preparation | Adobe Systems, Inc. | San José, CA |
| DocuKnowledge 3.0 | Lotus Domino-based document management system used for SOPs | Prelude Computer Solutions | Parsippany, NJ |
| Lotus Domino Rel. 5 | Client-server application for Sponsor, sample, test codes, and quotation management application databases | IBM Corporation | Armonk, NY |
| Matrix Gemini 5.3.5 | Laboratory Information Management System | Autoscribe Limited | Reading, UK |
| MS Office 2007 and/or 2010 Small Business Suite | Business software (suite includes Word, Excel, PowerPoint, Outlook, Publisher, Office tools) | Microsoft Corporation | Redmond, WA |
| Rees CentronSQL System 2.0 | Environmental monitoring and metrology system | Rees Scientific | Trenton, NJ |

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APPENDIX XIII. 2211 ULPA Filter Efficiency



Custom Filter LLC represents and warrants that the goods listed below were manufactured by Custom Filter LLC to the standards that generally apply to the manufacture of filters or goods, and conform to the samples, designs and specifications furnished and/or approved by the Purchaser authorizing the manufacture of goods. See Custom Filter LLC's Terms and Conditions of Sale.

| | | |
|--|--|----------|
| CF Part Number: | 20753 | |
| Megadyne Part Number | 2211 | |
| Product Description: | ULPA Filter | |
| IFU Part Number and Rev: | MKT-LBL-548, Rev002 | |
| Seal Tested per CF Router # | 14.13.4 – CF PN 20753, 100% | |
| Leak Tested, @ 1.5 PSI, max leak rate of 10ml/min. | C=0, AQL=1.0 | |
| Purchase Order Number: | 26154 | |
| Lot Number(s): | 15336 Qty. 15338 460 540 | |
| Ship Date: | 01/07/2016 | |
| Bill Moreland <i>B.M.</i> | Quality Manager | 02/12/16 |
| Signature of Certifying Official | Title | Date |

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TECHNICAL DATA SHEET

Nitto

Document No. EMEH 14-440100

Date: Jan.13.2014

To: Custom Filter LLC

Nitto Denko Corporation

Technical Support Center - YL-S Division
Fumizawa Area, Fumizawa Bldg.
Higashisumi-cho,
Saitama 300-0021, JAPAN

TEMISH Test report

Test sample: NTF9598-U*8

Table 1. Test report.

| Product Name | NTF9598-U* | Size | 604Wx320m | |
|--------------------------------------|------------|----------|-----------|-------------------|
| LotNo. | SD0712-Q1 | #1 | #2 | #3 #4 |
| Pressure drop | [Pa] | 267 | 232 | 290 258 |
| | | 280 | 271 | 236 274 |
| Collection efficiency (0.1~0.2μm) | [%] | 99.99999 | 99.99999 | 99.99999 99.99992 |
| | | 99.99999 | 99.99999 | 99.99999 99.99995 |
| Thickness | [μm] | 0.02 | - | - - |

Note: The calculation method is according to JIS C 9306-1996, and the test condition is at 23°C and 50% relative humidity. However, this data do not guarantee the performance for the application, so we can not be responsible. Please note, the document that may include this information is subject to revision. In such case, the latest version of document should be the valid document.

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Inspection Report

NITTO DENKO CORPORATION
Kanto Quality Administration Section
Quality Management Dept.
Functional Base Products Sector

T. Fujita

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TO: Custom Filter LLC

Supply Product Quality Specification

Product name: TEMISH

Product number: NTF9329-U16

Reception Confirmation Signature

Date 6/12/14

Person in charge DW COA

Responsible person S.B

Submitted date _____

NITTO DENKO CORPORATION
FUNCTIONAL BASE PRODUCTS SECTOR
QUALITY MANAGEMENT DEPT.
KANTO QUALITY ADMINISTRATION SECTION

CHECKED BY J. Ariyoshi

PREPARED BY M. Aragama

Distributed to: Your company×2, Copy for return×1
After signing your name in reception confirmation signature, please return 1 copy to us.

| | | |
|-------------------------------|-------------|------------------|
| Issued and revised History | Issued date | 30 January, 2014 |
| | Revised | |
| | Revised | |

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3. Quality

3.1 Appearance

The product shall be free from remarkable breakage of PTFE porous membrane, except splices, and contamination to be detectable by the visual inspection.

The defect of appearance that is dirt with 5mm or more length, or 10mm² or more area of piece except splices, foreign materials or joint of non woven sheet material is marked with red marker. Also all of the defects, which are remarkable scratches on the PTFE porous membrane to be detectable by the visual inspection are marked with red marker.

3.2 Size

The size of product is shown on Table-1.

Table-1 Size of product

| Item | Unit | Standard value |
|------------|--------|-------------------------|
| Thickness | mm | (0.32) [Reference data] |
| Width | mm | 604 +/- 1 |
| Length *1) | m/roll | (300~500) |

*1) Random length shall be allowable.

The joint distance of the product is more than 30m.

The total number of splices shall be 2 places/roll or less.

The joint method is shown on Figure-2. The joint parts with red marker are clearly indicated so that they are recognized from the direction of width of sheet.

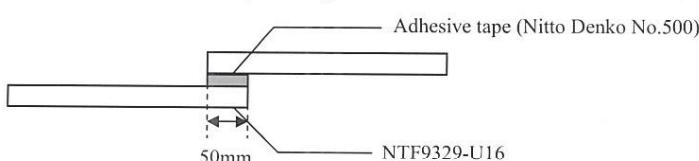


Figure-2 Jointing method

3.3 Properties

The properties are shown on Table-2.

Table-2 Properties of product

| Item | Unit | Standard values |
|-----------------------|------------|-----------------|
| Pressure drop | Average | Pa |
| Collection efficiency | Each value | % |

4. Test

4.1 Test condition

After holding the sample for more than an hour under conditions of temperature 25+/-5 (°C) and humidity 65+/-20 (%RH), the test shall be performed.

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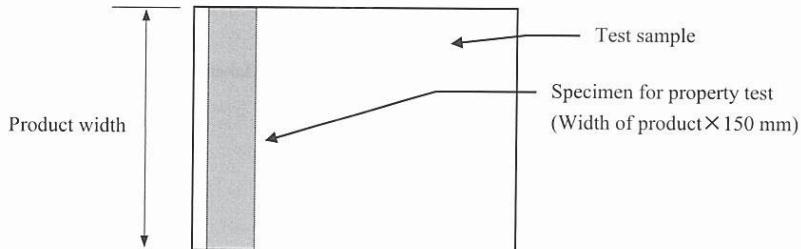


Figure-5 Location of measurement of properties (Width of product X 150 mm)

(1) Pressure drop

The effective measuring area is 100 cm², and the face velocity is 5.3 cm/sec. The pressure drop is measured with a manostat gauge (minimum scale: 1Pa) or the electrical pressure transmitter (minimum scale: 1Pa) or the electrical pressure gauge (minimum scale: 1Pa or less).

The average value of sample is picked from start and end of each winding roll and it shall be satisfy the standard value.

(2) Collection efficiency

Collection efficiency is measured with No.2 and No.4 collection efficiency tester by the measurement condition shown on Table-3. The measurement value of sample is picked from start and end of each winding roll and it shall be satisfy the standard value.

Table-3 Collection efficiency measurement conditions

| Item | Conditions |
|--|---|
| Aerosol source material | cold DOP (Diethyl phthalate) or PAO (poly-a-olefin) |
| Upstream particle concentration (0.1 to 0.2μm) | 1 × 10 ⁹ particles/L or more |
| Measurement area | 100cm ² |
| Face velocity | 5.3 cm/sec |
| Measurement time | 1 min |

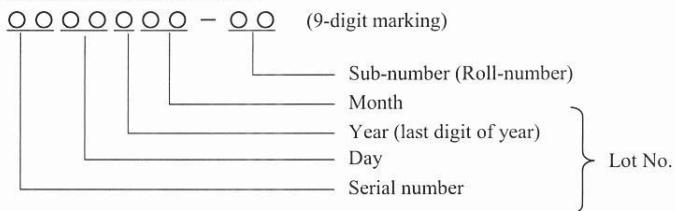
The collection efficiency object particle diameter range is 0.1 to 0.2 m. Count the upstream particle concentration and the downstream particle concentration with the laser particle counter, and the collection efficiency is calculated by using the following formula.

$$\text{Collection efficiency (\%)} = \left(1 - \frac{\text{Downstream particle concentration (piece/L)}}{\text{Upstream particle concentration (piece/L)}} \right) \times 100$$

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*1) Lot number is indicated as follows.



8. Warranty period

The warranty period shall be 12 months after delivery. We guarantee only the original form of the product and not the processed product. The product quality stated in the section in the 3 is guaranteed provided that the product is stored under the conditions specified section in the 9 above as properly packaged before shipping and handling under the conditions specified in the section 10.

9. Cautions for storing the product

9.1 Outer box storing (Before opening the outer box)

- 9.1.1 Please do not apply load on the outer box to avoid deformation and please avoid direct sunlight and high temperature for storing the product.

- 9.1.2 Please keep the product away from oils and soaps.

9.2 Inner bag storing (After opening the outer box)

- 9.2.1 Please do not apply load on the inner bag directly to avoid deformation and please avoid direct sunlight and high temperature for storing the product.

10. Caution for handling the product

- (1) The air permeability of the product might decrease (the pressure drop might rise) if the liquids of the low surface tension such as detergent, solvent, oil and etc and substances such as the muddy water, dusts, microbial reproduction touch the product. For that there is no influence in the installation side, the position and the membrane property of the PTFE porous membrane, please design the defense structure of the product carefully.
- (2) Please be carefully design the pleating and forming way of the product for preventing a leak and a tear on pleating and forming the product.
- (3) The product can be damaged being charged by static electricity, so when processing the product, please earth and remove the electricity by an ion blow etc. and take the earth in the production machine.
- (4) The pleating block shall not be piled after pleating. If it is necessary to pile the pleating, please note electrification and the electrical discharge of each pleating blocks.
- (5) When you shall discharge the electrified product touching by hand, the penetration hole of about 20~70µm might be opened in the product and collection efficiency might decrease.
So please be careful handling.
- (6) The product needs to be careful handling for fragile and soft membrane.
- (7) Please store wrapping the product to avoid the electrostatic dusts.
- (8) Please do not handle the product with sharp jigs.

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-END-

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APPENDIX XIV. Training Record

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FRM003512 Rev. B

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