

Megadyne Medical Products, Inc.	TEST REPORT	<u>Document Number</u> 1150721-01
	Fluid Ingress - Zip Pencil	Revision: A
	MASTER DOCUMENT	Effective Date: 2014 MAR 21
		Page 1 of 5

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Engineering Verification:

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1. ABSTRACT

Zip Pencil samples that have been exposed to three year accelerated aging and shipping cycle temperature extremes were subjected to the fluid ingress test required for compliance to IEC 60601-2-2: 2009 clause 201.11.6.5.b). The Zip Pencil passed the requirements of the standard for this test.

An additional test was performed where the Zip Pencil was tested for fluid ingress with the pencil inverted and the tubing zipped out of the housing. This Zip Pencil also passed this variation of the ingress test.

2. OBJECTIVE

The objective of this test report is to document compliance of the Zip Pencil catalog items 2525-10 and 2525-15 with IEC60601-2-2: 2009 clause 201.11.6.5.b) requirements for fluid ingress after shipping extremes and accelerated aging to simulate three years expiration life.

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3. RESULTS

3.1. Continuity

Thirty samples of the Zip Pencil were tested for continuity prior to the fluid ingress test per protocol 1150721-10. The requirement is that a sample is considered out of tolerance if the resistance is greater than 50 ohms when the button is depressed or less than 10,000 ohms when the button is released. All 30 of the samples passed.

3.2. Fluid Ingress

Thirty samples of the Zip Pencil were tested for fluid ingress per protocol 1150721-10. The method written in this protocol is taken from IEC 60601-2-2:2009 clause 201.11.6.5.b). All 30 of the samples passed.

The same 30 samples were tested a second time with the pencil inverted per the protocol. All 30 of the samples passed.

4. DISCUSSION

The samples used for the testing were 15 each of catalog 2525-10 Zip Pencils Lot #S130231 and 15 each of catalog 2525-15 Lot #S130228. The 2525-10 and 2525-15 catalog numbers are the same product with the exception of tube and cord length. Samples from each of these catalog numbers were used to show compliance across different lots of product.

Prior to testing, these samples were subjected to accelerated aging at 55°C to simulate three years shelf life. They were also exposed to temperature and humidity extremes to simulate possible exposure during the shipping and storage of the device. For documentation of this aging and conditioning refer to test report 1150720-01. The sample size required for this testing was 30 units.

4.1. Continuity

The thirty samples referenced above were selected for the fluid ingress test. The samples were tested for continuity prior to the ingress testing to insure that they were functioning correctly. The 30 samples all met the requirements for continuity of less than 50 ohms when the button is depressed and greater than 10,000 ohms when no button is depressed. Documentation of this test is shown in Appendix I.

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4.2. Fluid Ingress

The thirty samples referenced above were tested for fluid ingress per protocol 1150721-10. The method written in the protocol is taken from IEC 60601-2-2 clause 201.11.6.5.b). This test requires the Zip Pencil to be held horizontally while 1 liter of saline solution is poured over the unit in 15 seconds with the switch activating parts uppermost. A voltage is applied to the switching circuit during the saline application. After the saline is applied, each switching circuit is activated 10 times. The a.c. impedance of the open switching circuits shall remain greater than 2,000 ohms during the test. All 30 of the samples passed. Documentation of this test is shown in Appendix I.

The same 30 samples were tested in an inverted position per the protocol. The same electrical parameters were applied only with the pencil inverted per the protocol and the saline poured into the switch area. All 30 of the samples passed. Documentation of this test is shown in Appendix I.

5. CONCLUSIONS

This testing demonstrates that the Zip Pencil complies with IEC 60601-2-2:2009 after three year accelerated aging and shipping and storage conditions.

6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the Zip Pencil to IEC 60601-2-2: 2009 clause 201.11.6.5.b) after three year accelerated aging to support the three year expiration life. This accelerated age test will support the three year expiration life of the product for market introduction. Real time age samples from the first production lot will be put aside for testing per Megadyne Protocol 1150309-10.

The testing also demonstrated compliance to IEC 60601-2-2: 2009 clause 201.11.6.5.b) after exposure to extreme shipping and storage conditions. The shipping box labels of the products will show the international symbols for shipping and storage with temperatures of 5°C to 50°C and relative humidity of 15% to 95%. The IFU will include the note "Normal storage conditions are assumed. Brief excursion to temperature/humidity extremes is permitted".

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7. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-037-01	Initial Release	

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APPENDIX I
See attached data

MASTER DOCUMENT

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Ingress of Fluids Data Collection Form

2014 MAR 21

All Samples 3 Year Accelerated Aged

Sample	Configuration	INITIAL CONTINUITY		FLUID INGRESS		INVERTED TEST
		CUT (Ω)	COAG (Ω)	CUT	COAG	
3	2525-10 LOT S130231	1.9	1.4	PASS	PASS	PASS
4	2525-10 LOT S130231	2.1	1.4	PASS	PASS	PASS
5	2525-10 LOT S130231	1.5	1.8	PASS	PASS	PASS
6	2525-10 LOT S130231	1.3	2.9	PASS	PASS	PASS
7	2525-10 LOT S130231	1.3	1.5	PASS	PASS	PASS
8	2525-10 LOT S130231	2.4	1.5	PASS	PASS	PASS
9	2525-10 LOT S130231	2.0	1.1	PASS	PASS	PASS
11	2525-10 LOT S130231	1.1	1.3	PASS	PASS	PASS
12	2525-10 LOT S130231	1.9	1.5	PASS	PASS	PASS
13	2525-10 LOT S130231	3.3	1.7	PASS	PASS	PASS
14	2525-10 LOT S130231	2.5	1.6	PASS	PASS	PASS
15	2525-10 LOT S130231	1.4	1.4	PASS	PASS	PASS
17	2525-10 LOT S130231	1.9	2.7	PASS	PASS	PASS
19	2525-10 LOT S130231	2.1	1.2	PASS	PASS	PASS
1	2525-10 LOT S130228	2.3	1.1	PASS	PASS	PASS
2	2525-10 LOT S130228	1.5	1.1	PASS	PASS	PASS
3	2525-10 LOT S130228	1.2	1.6	PASS	PASS	PASS
4	2525-10 LOT S130228	1.2	1.8	PASS	PASS	PASS
5	2525-10 LOT S130228	1.6	1.5	PASS	PASS	PASS
6	2525-10 LOT S130228	3.0	1.4	PASS	PASS	PASS
7	2525-10 LOT S130228	1.4	1.8	PASS	PASS	PASS
11	2525-10 LOT S130228	1.8	1.7	PASS	PASS	PASS
12	2525-10 LOT S130228	1.2	1.4	PASS	PASS	PASS
14	2525-10 LOT S130228	1.5	1.3	PASS	PASS	PASS
15	2525-10 LOT S130228	1.6	2.9	PASS	PASS	PASS
16	2525-10 LOT S130228	1.7	1.7	PASS	PASS	PASS
17	2525-10 LOT S130228	1.3	1.9	PASS	PASS	PASS
18	2525-10 LOT S130228	1.2	1.9	PASS	PASS	PASS
19	2525-10 LOT S130228	1.1	1.7	PASS	PASS	PASS
20	2525-10 LOT S130228	2.5	3.2	PASS	PASS	PASS

Paul Valpreda

2/8/2014

Operator Name(s)

Date Completed

Paul Valpreda

Operator Signature

2-8-2014

Date

Primary Equipment List (Station 1, Paul's):

CALIBRATION INFORMATION	
Multimeter	
<i>Fluke 179 True-RMS Multimeter</i>	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2012
Calibration Due:	9/30/2014
Generator	
<i>Mega Power 1000</i>	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
<i>Tektronix TDS 3012B</i>	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/19/2013
Calibration Due:	10/31/2014
Hitpot Tester	
<i>Hipotronics Model HD 100 Series</i>	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe	
<i>Tektronix P6015A High Voltage Probe</i>	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	7/23/2013
Calibration Due:	7/31/2014
Inductive Current Coil	
<i>Pearson Current Monitor, Model 2100</i>	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/25/2013
Calibration Due:	1/25/2014
RMS Voltmeter	
<i>Fluke 8920A True RMS Voltmeter</i>	
Serial Number:	4540017
Megadyne Number:	01255
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014
Waveform Generator	
<i>BK Precision 4084AWG</i>	
Serial Number:	40849136407060000
Megadyne Number:	01458
Calibration Date:	9/17/2013
Calibration Due:	9/30/2014