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2525-15 Product Documentation**Change Request**

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Lucy Richards (LRICHARDS)		01 Sep 2016, 02:46:00 PM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Rob Farnsworth (RFARNSWORTH)		12 Oct 2016, 04:40:13 PM	Complete
Katie Chamberlain (KCHAMBERLAIN)	Regulatory Manager	13 Oct 2016, 12:12:30 PM	Complete
Jill Skoczen (JSKOCZEN)		19 Oct 2016, 09:09:34 AM	Complete
Paul Borgmeier (PBORGMEIER)		25 Oct 2016, 02:43:05 PM	Complete
Curt Doel (CDOEL)	Quality Manager	26 Oct 2016, 02:04:31 PM	Complete
Dave Shimkus (DSHIMKUS)		31 Oct 2016, 09:26:18 AM	Complete
Julie Barber (JBARBER)		31 Oct 2016, 04:16:35 PM	Complete
Tara Rogers (TROGERS)		07 Nov 2016, 01:42:12 PM	Complete
Mark Glassett (MGLASSETT)		07 Nov 2016, 02:16:31 PM	Complete

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Name/Signature	Title	Date	Meaning/Reason
Chad Frampton (CFRAMPTON)			In Process
Mark Glassett (MGLASSETT)		05 Dec 2016, 04:48:27 PM	Complete
Steve Andrews (SANDREWS)		06 Dec 2016, 07:30:17 AM	Complete
Lucy Richards (LRICHARDS)		06 Dec 2016, 11:05:55 AM	Complete

RA-Approval

Name/Signature	Title	Date	Meaning/Reason
Katie Chamberlain (KCHAMBERLAIN)	Regulatory Manager	07 Dec 2016, 10:29:35 AM	Approved

QA-Approval

Name/Signature	Title	Date	Meaning/Reason
Curt Doel (CDOEL)	Quality Manager	13 Dec 2016, 11:56:29 AM	Approved

ENG-Approval

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		12 Dec 2016, 02:25:00 PM	Approved

Training Review

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Lucy Richards (LRICHARDS)		21 Dec 2016, 11:39:37 AM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		21 Dec 2016, 11:40:23 AM	Approved

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Authored By: Mark Glassett

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1. ABSTRACT

Zip Pen samples REF 2525-15 were artificially aged for equivalent of 3 years and ship tested per protocol ENG-PRT-327 to show compliance to ISO 11607-1:2009. The samples passed shipping tests after aging. Catalog number 2525-15 was tested. This testing is also representative of catalog 2525-15EC. The only difference between the two products is the connector, 2525-15 has the larger connector. Therefore, the testing is considered acceptable for both catalog numbers.

2. OBJECTIVE

The objective of this test report is to document ship testing that was done on the Zip Pen catalog item 2525-15 after accelerated aging to simulate three years expiration life, exposure to transport and storage conditions and package performance testing per protocol ENG-PRT-327 and ASTM D4169-5.

3. RESULTS

The Zip Pen samples for this shipping test were built at New Deantronics. The samples were REF 2525-15 Lot# S160050 which are also representative of 2525-15EC. The package configuration is documented on drawings X2525-15 Rev E. Product 2525-15EC uses the same package configuration.

Two cartons of 2525-15 each with 20 units inside were tested per protocol ENG-PRT-327. The test consisted of the following elements.

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Treatment/Test	Description
Artificial aging to simulate 3 years	Aging temperature of 55°C for 111 days
Megadyne IEC shipping and storage cycle	Temperatures from -40°C to 55°C Humidity from 15% to 95%
Preconditioning	ASTM D4169 preconditioning at 23°C and 50% humidity for 72 hours
Handling Test #1	Drop the product 6 times on faces, corners and edges per the protocol
Compression test	Application of compressive force of 217.5 lbs. per the protocol
Vehicle vibration	High frequency vibration for 10 minutes
Loose load vibration	Low frequency vibration for 40 minutes
Concentrated impact	Impact per ASTM D6344
Handling Test #2	Drop the product 6 times on faces, corners and edges per the protocol
Product inspection	Visual inspection for lot number and label clear and legible
Package evaluation	Dye test, bubble test, burst test, seal width inspection and product damage inspection

3.1. Accelerated Aging

The Zip Pen samples were subjected to accelerated aging at 55°C to simulate 3 years of shelf life. Documentation of the aging is shown in appendix I.

3.2. Transport and Storage Cycle and Pre-Conditioning.

The Zip Pen samples were subjected to the transport and storage cycle required by the protocol. This cycle includes temperatures from -40°C to 55°C and humidity's from 15% to 95%. This treatment is shown in Appendix I. Following the transport and storage cycle, the samples were pre-conditioned per protocol ENG-PRT-327 Rev A and ASTM D4169-05. The pre-conditioning parameters were to 23°C and 50% RH for a minimum of 72 hours. The cycling and preconditioning were performed by the Lab Technician. The technician sign off for this treatment is shown in Appendix I.

3.3. Shipping Test

The shipping test was performed by the Lab Technician. The shipping test followed protocol XENG-PRT-327 Rev A. None of the boxes broke open during the test. There were minor indentations on the corners and edges of the boxes which is typical and acceptable per the protocol. This testing is documented on the log sheet in Appendix I.

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3.4. Print and Lot Number Clear and Legible

Forty samples (two boxes) of 2525-15 were inspected per protocol XENG-PRT-327 Rev A. The package print was clear and legible and passed the protocol acceptance criteria. The Lot numbers were also clear and legible and passed the protocol acceptance criteria. This testing is documented on the log sheet in Appendix II.

3.5. Dye Penetration Test

The dye penetration test was performed per protocol XENG-PRT-327 rev A. The procedure follows ASTM F1929. Forty Zip Pen packages were dye tested and all 40 passed the protocol. See data in appendix III.

3.6. Bubble Leak Test

The Bubble Leak Test was performed on 40 samples of 2525-15. The Bubble Leak test followed protocol XENG-PRT-327 Rev A. The 2525-15 samples passed the bubble leak test criteria of the protocol. The data is shown in appendix IV.

3.7. Burst Test

The package Burst Test was performed on 40 samples of 2525-15. The package burst test followed protocol XENG-PRT-327 Rev A. The minimum burst for the protocol is 19 in. H₂O. The 40 samples passed the burst test with an average burst value of 27.51 in. H₂O and a minimum value of 23.7 in. H₂O. See data and analysis in appendix V.

3.8. Minimum Seal Width

The seal width of all 40 packages was measured by the lab technician. The technician was instructed to visually locate the area with the narrowest seal. The technician measured this area and noted on the data form which side it is located on. The minimum seal width measured for this testing was 0.20". The average minimum seal width is 0.32". The Zip Pen packages for this protocol meet the drawing requirements. Seal width data is shown in Appendix VI.

3.9. Product Damage Inspection

The product damage inspection was performed on 40 samples of 2525-15. The damage inspection looked for damage to the inner bag, holster, electrode and Zip Pen. No damage was found in the inspection. The damage inspection result is documented in Appendix VII.

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4. DISCUSSION

4.1. Shipping Test

The shipping test followed protocol XENG-PRT-327 Rev A. The compression test was calculated to require 217.5 lbs. The technician used 220 pounds for the test since that was what weights were available. Since a greater weight was used than required it was determined to be acceptable by the engineer.

4.2. Dye Penetration Test

The dye penetration test was performed per protocol XENG-PRT-327 rev A. The procedure follows ASTM F1929. The main purpose of the dye test is to highlight the seal area for seal width measurement and make it easier to identify open seals. There were no open seals and the seal width results are documented in the seal width section.

4.3. Burst Test

The package Burst Test was performed on 40 samples of 2525-15. The package burst test followed protocol XENG-PRT-327 Rev A. The minimum burst for the protocol is 19 in. H₂O. The minimum is the same one used on the Zip Pen 2525-10 pouch which is a smaller pouch. It is typical that the larger pouch will have a lower burst value. In this case we were able to use the same minimum value as the 2525-10 and still pass the test with a good margin of safety.

4.4. Minimum Seal Width

The seal width of all 40 packages was measured by the lab technician. The technician was instructed to visually locate the area with the narrowest seal. The technician measured this area and noted on the data form which side it is located on. The specification minimum is 0.20” There were two packages with seals at the minimum value. The minimum specification provides a safety factor of greater than 50% of the designed seal width. Therefore having values at the lower limit still provides high confidence that the seal will be complete and maintain a sterile barrier.

5. CONCLUSIONS

The testing demonstrates that the Zip Pen 2525-15 (15 foot) complies with the requirements of the protocol XENG-PRT-327 Rev 001 and ISO 11607-1:2006. This testing included three year accelerated aging, Temperature Storage extremes, and package performance testing.

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6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the Zip Pen packaging to ISO 11607-1:2009 after three year accelerated aging to support the three year expiration life. The package met requirements for Package Performance. It is recommended that real time age samples be put aside for testing per Megadyne Protocol ENG-PRT-057. The product can be released to market upon completion of regulatory approvals and completion of design control.

The testing also establishes shipping and storage conditions for labeling per IEC 60601-1:2012 clause 7.2.17. 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 excursions to limits allowed”.

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Appendix I
Aging, Preconditioning and Shipping Test Log sheet

Accelerated Aging In Process

Product: 2525-15 Zip Pen
Lot Number S160050
15 Foot Zip Pen
Temperature 55°
Relative Humidity Ambient

Required Time 15 weeks 6 days
(111 days)

Thermotron ID Number 1095 Relat

Last Calibration Date 5/19/15 5/23/16

Calibration Due Date 5/31/16 5/31/17

Start	Time	Initials	Stop	Time	Total	Initials
22 April 2016	11:00	<i>MS</i>	8-11-16	15:00	111	<i>MS</i>

**If this aging needs to be interrupted for any reason,
Contact Mark Glassett at ext. 845**

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Appendix I
Aging, Preconditioning and Shipping Test Log sheet (continued)

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APPENDIX I

Shipping Test Log Sheet

Preconditioning:

Start Date: 8-11-2016 Chamber Number: 01095
Completion Date: 8-15-2016 Last Calibration: 5-23-2016
Signature/Date: Paul Valpreda 8-15-2016 Calibration due: 5-31-2017

Drop Test:

Catalog 2525-15 Lot # S160050 Weight 14.5 lbs.

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Top	Face 1	PV 8-15-2016
2	15 in.	Edge	Edge 5-3	PV 8-15-2016
3	15 in.	Edge	Edge 6-3	PV 8-15-2016
4	15 in.	Corner	Corner 2-3-5	PV 8-15-2016
5	15 in.	Corner	Corner 4-3-6	PV 8-15-2016
6	15 in.	Bottom	Face 3	PV 8-15-2016

Comments:

Signature: Paul Valpreda Date: 8-15-2016

Compression Test:

Catalog 2525-15 Pounds Force 220 lbs.

Comments:

Signature: Paul Valpreda Date: 8-15-2016

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Appendix I Continued
Shipping Test Log Sheet

Vibration:

High Frequency, 10 minutes, Initials PV Low frequency 40 minutes, Initials PV

Completion Date: 8-15-2016

Signature: Paul Valpreda Date: 8-15-2016

Concentrated Impact Test 1.5 lb mass dropped from 32 inches

Face 1 Initials PV Face 2 Initials PV Face 3 Initials PV

Completion Date: 8-15-2016

Second Drop Test:

Catalog 2525-15 Weight 14 lbs. Drop Height: 15" ± 30"

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Edge	Edge 4-6	PV 8-15-2016
2	15 in.	Face	Face 4	PV 8-15-2016
3	15 in.	Face	Face 6	PV 8-15-2016
4	15 in.	Corner	Corner 2-1-5	PV 8-15-2016
5	15 in.	Edge	Edge 2-1	PV 8-15-2016
6	30 in.	Bottom	Face 3	PV 8-15-2016

Comments: _____

Signature: Paul Valpreda Date: 8-15-2016

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Appendix I
Aging, Preconditioning and Shipping Test Log sheet (continued)



New Deatronics Ltd.
1990 North California Blvd.
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Walnut Creek, CA 94596
Tel: 925.280.8388
Fax: 925.280.1788

New Deatronics Taiwan, Ltd.
12F., No.51, Sec. 4,
Chong Yang Rd., Ta Chung Dist.,
New Taipei City 25073,
Taiwan R.O.C.
Tel: 886.2.2268.1736
Fax: 886.2.2268.3800

PACKING LIST

MD-624/16

Invoice Date	April 13, 2016	Marks & Nos.
Invoice No.	MD-624/16	Megadyne
For Account & Risk of Messrs.	Megadyne Medical Products, Inc., 11506 South State Street Draper, Utah 84020 U.S.A.	PO: 26124 Salt Lake City
Shipped By	New Deatronics Taiwan, Ltd. 12F., No.51, Sec 4, Chong Yang Rd., Ta Chung Dist., New Taipei City 23675, Taiwan R.O.C	Carton No.: 001-003 Made in Taiwan R. O. C.
Ship Via	UPS# A10975MVNDC	
Sailing On	April 13, 2016	
From / To	Taipei / Salt Lake City, U.S.A.	
Payment Terms	Net 45 days / Etc-Works	

Carton No.	Description	Quantity (Cartons)	(Pieces)	N.W. (kgm)	G.W. (kgm)	Meas. (cuft)
001-003	ZIP PEN, 15 FOOT	1	40	10.04	13.74	4.31
3	P/O No.: 26124 PIN: 2525-15 ND PIN: PB7525SMI Lot No.: S160950	3	120	30.12	41.22	12.93
Total: 3 Ctns		3	120	30.12	41.22	12.93

Remark:

- Megadyne Medical Products Establishment Registration: 1721194
- DEV (Device Foreign Manufacturer Registration Number): 5681191
- Country of Origin: Taiwan, R. O. C.
- Harmonized Tariff Code & FDA Information

HTS Code	PIN	SD (IC) #	ND Listing #	Megadyne Listing #	Product code
9018.90.6000	902000XX Series, 9020, 9035H, 9035, 9035H	K365014	D163506	D002924	GEI
9018.90.6000	9020043 & 9020046 Series	90250102	N/A	D006936	GEI
8544.42.5000	409, 405	K382748	D82883	N/A	GEI
8544.42.5000	373025-01, 3750025-01	K072559	N/A	D037574	GEI
7603.21.1000	4000022-XX Series	N/A	N/A	N/A	GEI
3917.21.0000	4000022-XX Series	N/A	N/A	N/A	GEI
7608.20.0000	4100016-XX Series	N/A	N/A	N/A	GEI
8544.60.2000	0873, 0875, 0880	K382150	D020893	N/A	GEI
9008.50.0000	TC300	Everest	D173518	N/A	MDM
9018.90.6000	PC300	K082349	D163908	N/A	GEI
9018.90.6000	0855C	K080255	D163801	N/A	GEI
9018.90.6000	2525-10, 2540, 2540, 2525-10EC, 2525-15	K341587	D227510	D226949	GEI

New Deatronics Taiwan, LTD

Lynia Chang
Authorized

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Appendix II Print and Lot Number Inspection Log Sheet

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Appendix II Print Legibility Log Sheet

Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog # 2525-15	Pass	Fail
Pouch Print	40	
Lot Number Print	40	

Comments: _____

Paul Valprede
Inspected by:

8-15-2016
Date completed

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Appendix III Dye Test Documentation

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Appendix IV Dye Penetration Test Log Sheet

Catalog # 2525-15

Lot # 5160050

Sample	Pass	Fail	Comment
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	✓		
8	X		
9	✓		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		

Sample	Pass	Fail	Comment
21	X		
22	X		
23	X		
24	X		
25	X		
26	X		
27	X		
28	X		
29	X		
30	X		
31	X		
32	X		
33	X		
34	X		
35	X		
36	X		
37	X		
38	X		
39	X		
40	X		

Signature: Paul Valpreda Date: 8-17-2016

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Appendix IV
Bubble Leak Test Data

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Appendix III
Bubble Leak Test Log Sheet

Catalog # 2525-15

Lot # 5160050

Sample	Pass	Fail	Comment
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		

Sample	Pass	Fail	Comment
21	X		
22	X		
23	X		
24	X		
25	X		
26	X		
27	X		
28	X		
29	X		
30	X		
31	X		
32	X		
33	X		
34	X		
35	X		
36	X		
37	X		
38	X		
39	X		
40	X		

Signature: Paul Valprede Date: 8-17-2016

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Appendix V
Burst Test Data and Analysis

Burst Test Data Zip Pen 2525-10 Lot S140074					
Sample Number	Burst Value	Burst Loc	Sample Number	Burst Value	Burst Loc
22	27.6	R	20	27.2	R
15	25.5	R	24	26.5	R
17	47.7	R	9	25.1	R
10	26.3	R	21	24.6	R
6	43.7	L	38	25.4	R
1	24.5	R	29	27.0	R
5	25.1	R	26	25.1	R
4	27.2	R	7	26.9	R
18	30.5	R	2	27.3	R
12	26.4	R	8	27.0	R
23	24.6	R	34	41.6	R
31	26.1	R	36	23.7	R
27	24.7	R	35	29.0	R
16	26.1	R	13	27.7	R
14	25.5	R	40	27.3	R
11	27.2	R	32	25.2	R
39	26.8	R	33	26.4	R
28	26.8	R	3	26.2	R
19	24.8	R	37	25.0	R
25	24.2	R	30	24.8	R
				27.51	Average Minimum
				23.7	

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Appendix V Burst Test Data and Analysis

Lucy Richards 2012 OCT 30
D.C. Verification:

Tim Kessinger 2012 OCT 25
Second Verification:

Lot Number	Catalog Number	Description	Date Tested	Quantity Tested
5160050	2525-15	ZIP Pen 15 Foot	8-22-16	40

Equipment Serial #: 563481
Calibration Due Date: 4-30-17
Equipment Identification #: 01076
Unless otherwise specified, the sampling plan is C-0.
Burst / Creep Inspection method is specified by 1100016-10.

Specification, in. H ₂ O	Burst	Date:	Time	Initials	Burst Data, Pass/Fail – List Lane #'s for Multivac Only					
					Sample Lane #	pouch 1	Lane #	pouch 2	Lane #	pouch 3
19	27.6		16:25		22	R				
	25.5				15	R				
	47.7				17	R				
	26.3				10	R				
	43.7				6	R				
	24.5				1	R				
	25.1				5	R				
	27.2				4	R				
	30.5				18	R				
	26.4				12	R				
	24.6				23	R				
	26.1				31	R				
	24.7				27	R				
	24.1				16	R				
	25.6				14	R				
	27.2				11	R				
	26.8				39	R				

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Appendix V

Burst Test Data and Analysis

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Appendix V Burst Test Data and Analysis

Lucy Richards 2012 OCT 30
D.C. Verification:

Lot Number	Catalog Number	Description	Date Tested	Quantity Tested
3160050	2525-15	ZIP Pen 15'	8-22-16	40

Equipment Serial #: 563481

Calibration Due Date: 4-30-17

Equipment Identification #: 61076

Unless otherwise specified, the sampling plan is C=0.

Burst / Creep Inspection method is specified by 1100016-10.

Specification, In. H=0	Burst	Date:	Time	Initials	Burst Data, Pass/Fail – List Lane #'s for Multivac Only					
					Lane #	pouch 1	Lane #	pouch 2	Lane #	pouch 3
19 in the	27.2		16:35	MB	20	R				
	26.5				24	R				
	25.1				9	R				
	24.6				21	R				
	25.4				38	R				
	27.0				29	R				
	25.1				26	R				
	26.9				27	R				
	27.3				2	R				
	27.0				8	R				
	41.6				34	R				
	23.7				36	R				
	29.0				35	R				
	27.7				13	R				
	27.3				40	R				
	25.2				32	R				
	26.4				33	R				

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Appendix V

Burst Test Data and Analysis

Lot disposition:	Accept	Reject (NCMR # _____)	QA/Mfg initials, date: _____
Comments: _____			

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Appendix VI Seal Width Data

Package Seal Width Evaluation Data Collection Form

Zip-Pen 2525-15 LOT S160050						
Sample	Part/Lot	Cavity	Front	Back	Right	Left
1	2525-15 LOT S160050	1				0.38
2	2525-15 LOT S160050	1		0.36		
3	2525-15 LOT S160050	2			0.31	
4	2525-15 LOT S160050	1				0.36
5	2525-15 LOT S160050	1				0.36
6	2525-15 LOT S160050	1				0.21
7	2525-15 LOT S160050	1		0.39		
8	2525-15 LOT S160050	1				0.28
9	2525-15 LOT S160050	2				0.32
10	2525-15 LOT S160050	1				0.33
11	2525-15 LOT S160050	1			0.32	
12	2525-15 LOT S160050	2				0.34
13	2525-15 LOT S160050	1				0.33
14	2525-15 LOT S160050	1			0.20	
15	2525-15 LOT S160050	2			0.30	
16	2525-15 LOT S160050	1			0.34	
17	2525-15 LOT S160050	2				0.30
18	2525-15 LOT S160050	2				0.31
19	2525-15 LOT S160050	2				0.31
20	2525-15 LOT S160050	1				0.32
21	2525-15 LOT S160050	2				0.31
22	2525-15 LOT S160050	2			0.36	
23	2525-15 LOT S160050	2				0.36
24	2525-15 LOT S160050	2	0.25			
25	2525-15 LOT S160050	2			0.31	
26	2525-15 LOT S160050	2				0.34
27	2525-15 LOT S160050	2			0.31	
28	2525-15 LOT S160050	1			0.38	
29	2525-15 LOT S160050	1			0.31	
30	2525-15 LOT S160050	2			0.28	
31	2525-15 LOT S160050	2			0.32	
32	2525-15 LOT S160050	2				0.30
33	2525-15 LOT S160050	2			0.27	
34	2525-15 LOT S160050	1			0.39	
35	2525-15 LOT S160050	1			0.30	
36	2525-15 LOT S160050	2				0.22
37	2525-15 LOT S160050	2			0.30	
38	2525-15 LOT S160050	2			0.34	
39	2525-15 LOT S160050	2				0.34
40	2525-15 LOT S160050	1			0.32	

CALIBRATION INFORMATION	
Calipers	
Starrett MAP-1000	
Serial Number: 723	
Megadyne Number: 01039	
Calibration Date: 5/29/2014	
Calibration Due: 5/31/2016	

Paul Valpreda
Operator Name

8/24/2016
Date

Paul Valpreda
Operator Signature

8-24-2016
Date

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Appendix VII Damage Inspection

Megadyne Medical Products, Inc.	TEST PROTOCOL	<u>Document Number</u> XENG-PRT-327
	Shipping Test – Zip Pen 2525-15	Revision: A
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Appendix VI Product Damage Inspection Log Sheet

Inspect the product for damage per the protocol and enter the number of units that pass or fail in the box below. Inspect the Zip Pen, Electrode, Holster and Bag for damage. Damage includes cracks, rub marks, bent electrodes and holes in the unit bag. Also inspect for particulate in the bag and on the product.

Catalog # 2525-15	Pass	Fail
Damage	40	

Comments: No damage was observed.

Paul Valprede
Inspected by:

8-15-2016
Date completed

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