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The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-RPT-413

DOCUMENT TITLE: Zip Pen Shipping Test Report

DOCUMENT NOTES:

Document Information

Revision: 001	Vault: MEG-Rel
Status: Release	Document Type: ENG-RPT

Date Information

Effective Date: 16 Jan 2015 3:00 PM	Expiration Date:
Release Date: 16 Jan 2015 3:00 PM	Next Review Date:

Control Information

Author: MGLASSETT	Owner: MGLASSETT
Previous Number:	Change Number: 2015-ENG-DCO-006

Signature Manifest

Document Number: ENG-RPT-413 **Revision:** 001
Title: Zip Pen Shipping Test Report

All dates and times are in Mountain Standard Time.

Zip Pen Ship Test Validation

Change Request

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		14 Jan 2015, 08:58:43 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
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Paul Borgmeier (PBORGMEIER)			
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Ronda Magneson (RMAGNESON)	RA DIrector	16 Jan 2015, 01:25:13 PM	Complete
Mark Glassett (MGLASSETT)		16 Jan 2015, 01:28:01 PM	Complete

Document Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		16 Jan 2015, 02:08:42 PM	Complete

RA-Approval

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ENG-Approval

Name/Signature	Title	Date	Meaning/Reason

Mark Glassett (MGLASSETT) Paul Borgmeier (PBORGMEIER)	16 Jan 2015, 02:58:59 PM	Approved

Training Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		16 Jan 2015, 03:00:05 PM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		16 Jan 2015, 03:00:17 PM	Approved

Authored By: Mark Glassett

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1. ABSTRACT

Zip Pen Catalog #2525-10 samples were tested per protocol XENG-PRT-229 Rev A to show compliance to ISO 11607-1:2009. The samples passed the requirements of the protocol after one revision for seal width. These products were exposed to three year accelerated aging, shipping temperature extremes and the ASTM D4169-5 performance test. The Zip Pen Catalog #2525-10 passed the testing.

2. OBJECTIVE

The objective of this test report is to document the ship testing that was done on the Zip Pen catalog item 2525-10 after accelerated aging to simulate three years expiration life, exposure to transport and storage conditions and package performance testing per ASTM D4169-5.

3. RESULTS

3.1. Accelerated Aging

The Zip Pen samples for testing were subjected to accelerated aging at 55°C to simulate 3 years of shelf life. The samples that were exposed to this aging are as follows:

Catalog Number	Lot Number	Quantity
2525-10	S140303	40

Documentation for aging is shown in Appendix IA. Note that this is a repeat of the shipping test for this product. Supporting documentation for package material compliance to ISO 11607-1 is located in ENG-RPT-330. The certificate of conformance and the sterilization certificate for the test product are also shown in appendix IA.

3.2. Transport and Storage Cycle and Pre-Conditioning.

The Zip Pen samples for testing 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-229 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-229 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.

3.4. Print and Lot Number Clear and Legible

Forty samples (two boxes) of 2525-10 were inspected per protocol XENG-PRT-229 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. Bubble Leak Test

The Bubble Leak Test was performed on 40 samples (two boxes) of 2525-10. The Bubble Leak test followed protocol XENG-PRT-229 Rev A. The 2525-10 samples passed the bubble leak test criteria of the protocol. The data is shown in appendix III.

3.6. Dye Penetration Test

The dye penetration test was performed per protocol XENG-PRT-229 rev A. The procedure follows ASTM F1929. Forty Zip Pen packages were dye tested and all 40 passed the protocol. See data in appendix IV.

3.7. Burst Test

The package Burst Test was performed on 40 samples of 2525-10. The package burst test followed protocol XENG-PRT-229 Rev A. The minimum burst for the protocol is 19 in. H_2O. The 40 samples passed the burst test with an average burst value of 27.9 in. H_2O

and a minimum value of 24.8 in. H_2O. See data in appendix V and summary statistics in Appendix VI.

3.8. Minimum Seal Width

Numerous tests of the Zip Pen package have resulted in passing all requirements except the seal width. The original seal width specification was set at 0.30" as a starting point without any data. The aged samples for this and previous protocols did not meet this minimum. As a result of all testing that has taken place on the Zip Pen package, the seal width specification has been re-evaluated. All of the data and the new seal width specification is summarized in Test report ENG-RPT-414. The new seal width specification is 0.20" minimum. The minimum seal width measured for this testing was 0.22". The average minimum seal width is 0.30" (average of the lowest measurement of each package). The Zip Pen packages for this protocol meet this new requirement. Seal width data is shown in Appendix VI.

3.9. Electrode Cap and Electrode Damage

Electrode cap and electrode damage was inspected and documented in a previous report, see test report ENG-RPT-330.

4. DISCUSSION

The samples used for the ship testing are shown in the table below:

Catalog Number	Lot Number	Quantity
2525-10	S140303	40

The Zip Pen samples were sterilized with a gamma irradiation dose equal to or greater than the minimum 50 kGy required by drawing X2525-10 rev 03. Sterilization certificate and C of C are shown in appendix IA.

4.1. Shipping Test

Two cases of 2525-10 were subjected to the shipping test. The testing followed protocol XENG-PRT-229 Rev A. This testing consisted of temperature extremes, pre-conditioning, drop test, compression test, vibration and a second drop test. The shipping test was completed with both boxes meeting the acceptance criteria.

4.2. Print and Lot Number Clear and Legible

The print and lot number inspections were performed by the Engineering Technician. Two cases of each 2525-10 were inspected per the protocol. The package print was clear and legible and passed the protocol acceptance criteria. The Lot numbers were clear and

legible and passed the protocol acceptance criteria. This inspection is documented on the log sheet in Appendix II.

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4.3. Bubble Leak Test

The bubble leak test was performed per the requirements of the protocol and ASTM F2096 on two boxes of 2525-10. There are 20 pouches in each box for a total of 40 tests. All of the 2525-10 samples passed the bubble leak test criteria of the protocol. The data is shown in appendix III.

4.4. Dye Penetration Test

In an effort to better understand the seal width failures from previous tests, the dye penetration test was added to the protocol. The dye penetration test was conducted per ASTM F1929. The test creates a visible line where the seal exists. It allows for visual confirmation of a seal and an approximation of seal width before the burst test. The requirement of the protocol is that none of the seals are breached as evident from the dye test. The test samples passed this test. The data is shown in appendix IV.

4.5. Package Burst Test

The package burst test was performed on 40 each of 2525-10 per the protocol. All 40 samples passed the minimum requirement of 19 in. H_2O. The average burst value was 27.9 in. H_2O and the minimum value was 24.8 in. H_2O. See raw data in appendix V and a summary in appendix VI. Note that previous protocols have tested a smaller sample size for burst test. In this revision of the protocol the number of burst test samples was increased. This was done to show that a lower seal width specification does not correspond to lower burst values, see test report ENG-RPT-414.

4.6. Minimum Seal Width

The nominal seal width is designed to be .37” wide and the original minimum specification on drawing X2525-10 Rev A was 0.30”. This minimum specification was chosen prior to any data collection. After testing many samples, both aged and non-aged, a justification has been written to lower the minimum seal width requirement to 0.20”. Refer to test report ENG-RPT-414. A summary for the minimum seal widths of the packages in this protocol is as follows:

Minimum measured seal width	0.22”
Average measured Minimum	0.30”
Standard Deviation of minimum measurements	0.032

The seal width for the product passes this revised specification. See data in appendix VI.

5. CONCLUSIONS

This testing demonstrates that the Zip Pencil 2525-10 (10 foot) complies with the requirements of the revised protocol ENG-PRT-229 Rev 002 and ISO 11607-2:2006. This testing included three year accelerated aging, Temperature Storage extremes, and package performance testing.

6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the Zip Pen packaging to ISO 11607-1:2009 and ISO 11607-2:2006 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 60601-1:2005 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”.

APPENDIX IA
Aging, C of C and Sterilization Certificate

Accelerated Aging In Process

Product: 2525-10 E-Z Clear Pencil
Lot Numbers S140303
4 Boxes
Temperature 55°
Relative Humidity Ambient

Required Time 15 weeks 6 days
(111 days)

Thermotron ID Number 01268

Last Calibration Date 5-8-14

Calibration Due Date 5-31-15

Start	Time	Initials	Stop	Time	Total	Initials
4 Sep 2014	14:00	MG	9-13-2014	6:30	9;	Power on
9-16-2014	13:45	MG	9-21-2014	16:00	14	Power out
9-22-2014	8:40	MG	1-2-2015	8:00		PV

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

APPENDIX IA
Aging, C of C and Sterilization Certificate

NEW DEANTRONICS
New Deantronics Group

NEW DEANTRONICS TAIWAN, LTD. WITH QUALITY SYSTEM CERTIFIED BY DNV =ISO 13485:2003=

Certificate of Compliance

Taiwan
大欣企業股份有限公司
New Deantronics Taiwan, Ltd.
12F., No.51, Sec. 4,
Chong Yang Rd., Tu Cheng Dist.,
New Taipei City 23675,
Taiwan R.O.C.
Tel: +886 2 2268-1726
Fax: +886 2 2268-3800

USA
New Deantronics Ltd.
1990 North California Blvd.
Suite 1040
Walnut Creek, CA. 94596
Tel: +1 (925) 280-6388
Fax: +1 (925) 280-1788

Customer Name: MEGADYNE MEDICAL PRODUCTS, INC.
Invoice Number : MD-493/14
P. O. Number: 24443
Customer P/N: 6020190-01 (2525-10) (With New Electrodes)
Drawing Number: X2525-10 Rev.04 Redline
New Deantronics P/N: PB352SM1 (With New Electrodes)
Lot Number: S140303
Expiration Date: 2017-07
Quantity: 80 Pieces (4 Boxes)
Carton Number: #1 ~#2 (2 Cartons)
Signed: D. Y Chen **Date:** 08-22-2014
Printed Name: Da-Yu Chen
Title: Q.A. Director

Materials		ND Mat'l Lot#	Megadyne Lot#
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, one red, one blue & one white Outer jacket: PVC, Gray	140311Z	
Plug material	F506100, TOP, ABS PA707 F506200, Bottom, ABS PA707	140408-140423 140408-140423	
Terminal	T101702 , Nickel plated brass	140310	
Overmold material	R900801, TPR	130801	
Swivel, male	F916600, HDPE	S140064	
Swivel, Female	F917000, HDPE	S130276-S140064	
Connector	F916800, HDPE	S140067	
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	140408-140414	
Button	F302500, NYLON 66	140219-140317	
Tape	A100401, PTFE	140303-140521	
PCB	H201602, PCB FR-4	140311	

QR-002-2

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APPENDIX IA
Aging, C of C and Sterilization Certificate

NEW DEANTRONICS
New Deantronics Group

NEW DEANTRONICS TAIWAN, LTD. WITH QUALITY SYSTEM CERTIFIED BY DNV ISO 13485:2003

Taiwan
大昱企業股份有限公司
New Deantronics Taiwan, Ltd.
12F., No.51, Sec. 4,
Chong Yang Rd., Tu Cheng Dist.,
New Taipei City 23675,
Taiwan R.O.C.
Tel: +886 2 2268-1726
Fax: +886 2 2268-3800

USA
New Deantronics Ltd.
1990 North California Blvd.
Suite 1040
Walnut Creek, CA. 94596
Tel: +1 (925) 280-8388
Fax: +1 (925) 280-1788

Dome	M100600, 6mm ROUND W/DIMPLE & FEET	130820	
Pen Body	F105400 ABS+TPR	140219-140321	
Nozzle	F916300, PC	140310-140326	
Collet Holder	F918100, PC	140326-140407	
Carriage	F916500, ABS	140326	
Snap Swivel, Male	F916400, HDPE	S140065	
Snap Swivel, Female	F918300, HDPE	S140065	
Tubing, Connector	F916700, HDPE	S130318-S140066	
Tubing, Convoluted	P305600, EVA	140303-140326	
Tubing, Convoluted	P305700, EVA	140303-140326	
Holster	F916900, HDPE	140318-140407	
Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	140610B (80pcs)	142008
Paper Band	A900300	140207	
Tyvek	A000400	140425	
Nylon Film	A000500 Nylon	140211	
Glue	S400900, Loctite 4061	140210	
Ink	S102000, Green, PMS356C	121127	
IFU	I010100,P/N:3000185-01 Rev.A	140512	

QR-002-2

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APPENDIX IA
Aging, C of C and Sterilization Certificate

中國生化科技股份有限公司
CHINA BIOTECH CORPORATION
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：2014/12/16

照射證明書
CERTIFICATE OF IRRADIATION REVISED

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：2014/06/23

照射批號 IRRADIATION RUN NUMBER：NEW14372-Q1

客戶產品已照射 MATERIALS PROCESSED：

箱數 BOXES		內容 DESCRIPTION	客戶產品批號 LOT NO
4	(80PCS)	2525-10 (PB352SM1)	S140303

總數 TOTAL 4 箱數 BOXES

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 MINIMUM DOSAGE 66.9 kGy；最高劑量 MAXIMUM DOSAGE 78.7 kGy

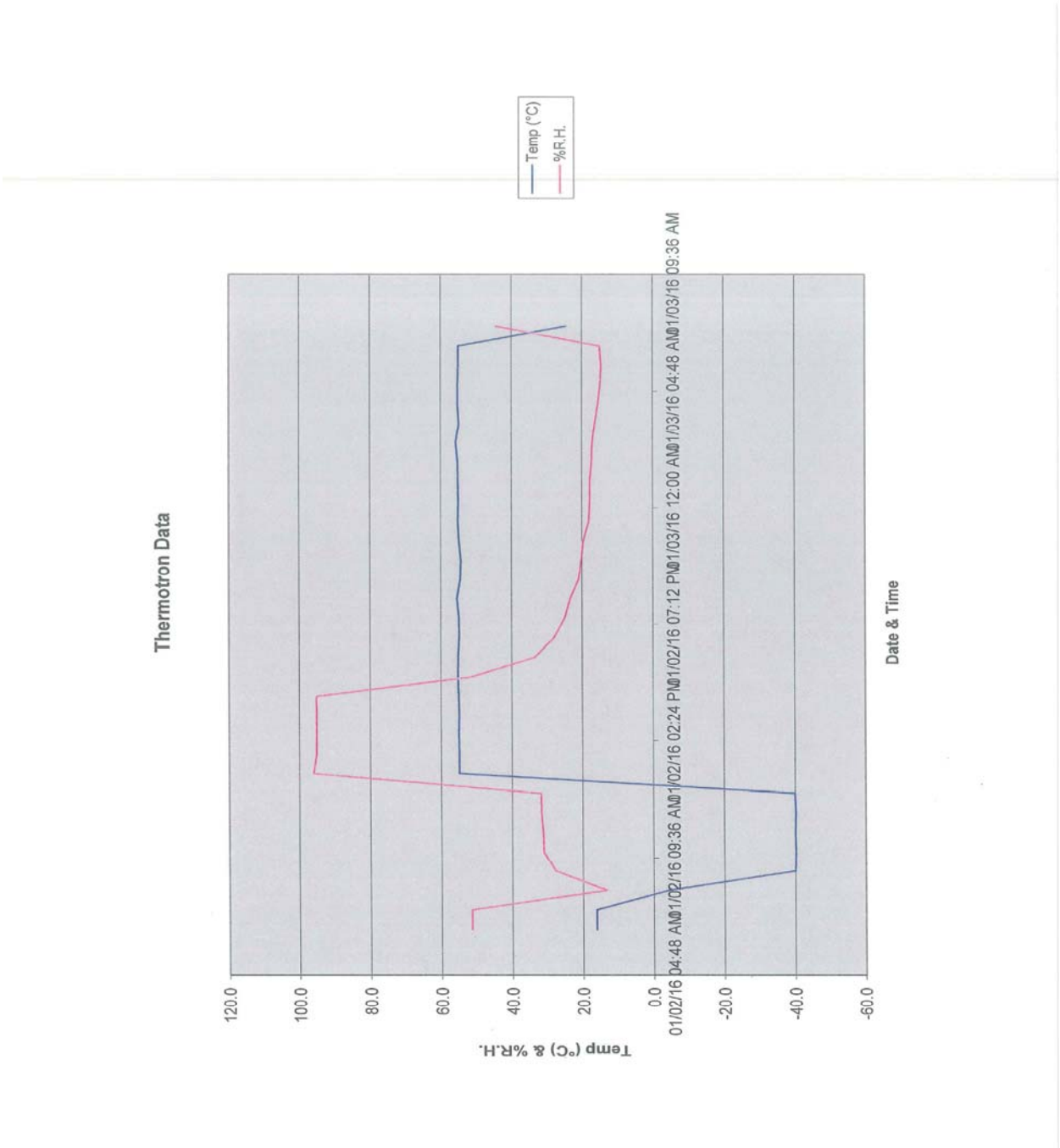
使用放射性同位素 ISOTOPE UTILIZED：鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT：最低劑量MIN 64.0 kGy；最高劑量MAX 80.0 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

APPENDIX I
Transport and Storage Cycle, Preconditioning and Ship Testing



APPENDIX I
Transport and Storage Cycle, Preconditioning and Ship Testing

APPENDIX I

Shipping Test Log Sheet

Preconditioning:

Start Date: 1-5-2015 Chamber Number: 01095

Completion Date: 1-8-2015 Last Calibration: 5-29-14

Signature/Date: Paul Valpreda 1-8-2015 Calibration due: 5-31-15

Drop Test:

Catalog 2525-10 Weight 13 Drop Height: 15

Lot 5140303

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV 1-8-2015
2	Edge	Edge 5-3	PV 1-8-2015
3	Edge	Edge 6-3	PV 1-8-2015
4	Corner	Corner 2-3-5	PV 1-8-2015
5	Corner	Corner 4-3-6	PV 1-8-2015
6	Bottom	Face 3	PV 1-8-2015

Comments: Pass

Signature: Paul Valpreda Date: 1-8-2015

Compression Test:

Catalog 2525-10 Pounds Force 275 lbs

Comments: Pass

Signature: Paul Valpreda Date: 1-8-2015

APPENDIX I
Transport and Storage Cycle, Preconditioning and Ship Testing

Appendix I Continued
Shipping Test Log Sheet

Vibration:

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

Completion Date: 1-8-2015

Signature: Paul Valprede Date: 1-8-2015

Second Drop Test:

Catalog 2525-10 Weight 13 Drop Height: 15/30
Lot 5140303

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 1-8-2015
2	Face	Face 4	PV 1-8-2015
3	Face	Face 6	PV 1-8-2015
4	Corner	Corner 2-1-5	PV 1-8-2015
5	Edge	Edge 2-1	PV 1-8-2015
6	Bottom	Face 3, Increase height to 30 inches.	PV 1-8-2015

Comments: Pass

Signature: Paul Valprede Date: 1-8-2015

APPENDIX I
Transport and Storage Cycle, Preconditioning and Ship Testing

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150720-10
	Shipping Test – Zip Pencil MASTER DOCUMENT	Revision: A
		Effective Date: 2014 MAR 27
		Page 15 of 19

Appendix I Continued
Shipping Test Log Sheet

Vibration:

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

Completion Date: 11-7-2014

Signature: Paul Valpreda Date: 11-10-2014

Second Drop Test:
Catalog 2525-10 Weight 13 lbs. Drop Height: 15" and 30"

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 11-7-2014
2	Face	Face 4	PV 11-7-2014
3	Face	Face 6	PV 11-7-2014
4	Corner	Corner 2-1-5	PV 11-7-2014
5	Edge	Edge 2-1	PV 11-7-2014
6	Bottom	Face 3, Increase height to 30 inches.	PV 11-7-2014

Comments: _____

Signature: Paul Valpreda Date: 11-10-2014

APPENDIX II
Print Legibility Log Sheet

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 # 2525-10 Lot 5140303	Pass	Fail
Pouch Print	✓	
Lot Number Print	✓	

Comments: Pass

Paul Valpreda — Inspected by:

1-8-2015 — Date completed

APPENDIX III
Bubble Leak Test Log Sheet

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* XENG-PRT-229
	Shipping Test – Zip Pen 2525-10	Revision: A
		Page 20 of 23

Appendix III
Bubble Leak Test Log Sheet

Catalog # 2525-10
Lot 5140303

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		

Catalog # 2525-10
Lot 5140303

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: [signature] Date: 1-9-2015

APPENDIX IV
Dye Penetration Test Log Sheet

Appendix IV
Dye Penetration Test Log Sheet

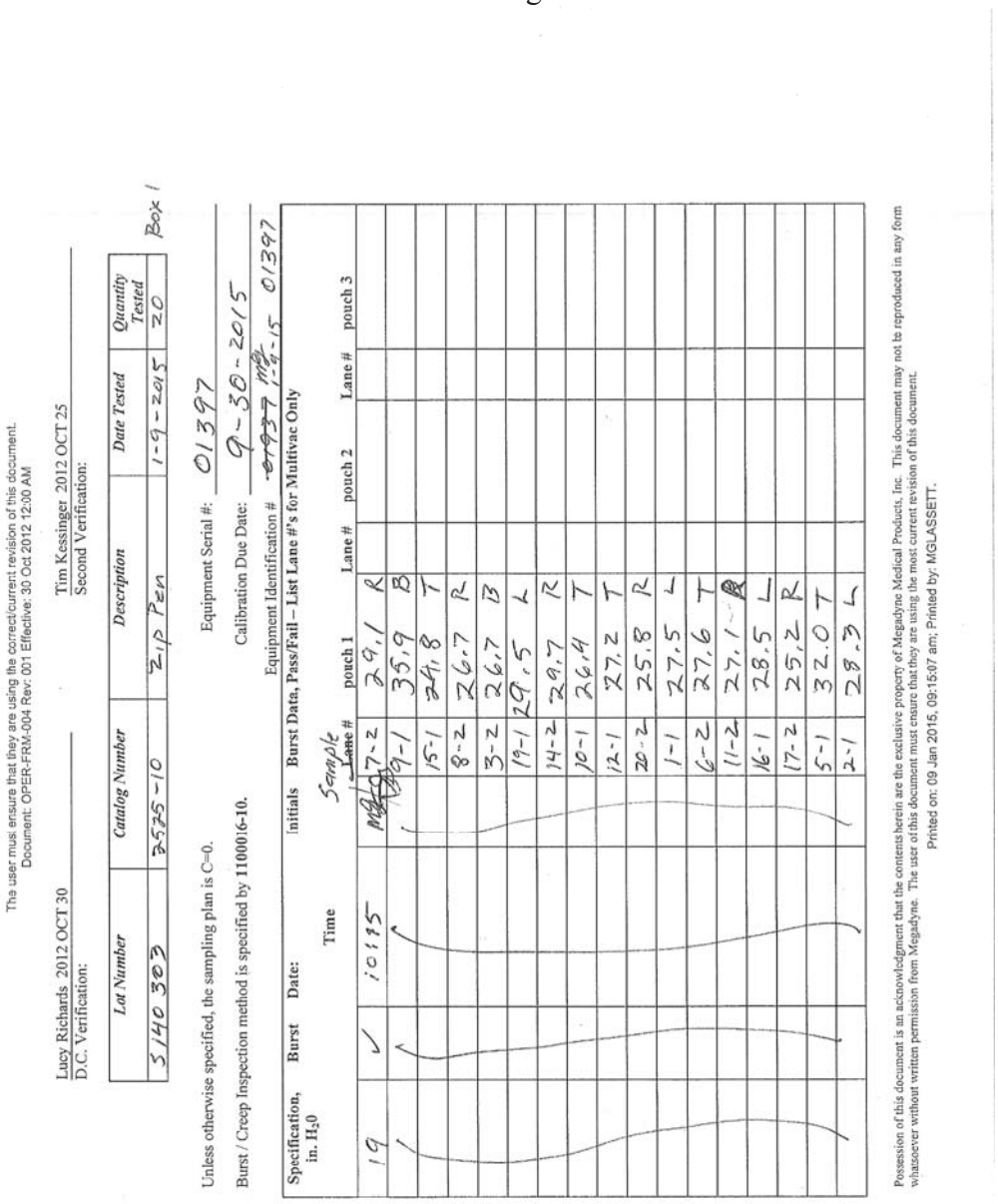
Catalog # 2525-10 Lot # 5140303

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

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

Signature: Madelyn Barrett Date: 1-12-15
1-12-15

APPENDIX V
Burst Test Log Sheet



The user must ensure that they are using the correct/current revision of this document.
Document: OPER-FRM-004 Rev: 001 Effective: 30 Oct 2012 12:00 AM

Lucy Richards 2012 OCT 30 — Tim Kessinger 2012 OCT 25
D.C. Verification: — Second Verification:

Lot Number	Catalog Number	Description	Date Tested	Quantity Tested
5140303	2525-10	Zip Pen	1-9-2015	20

Box 1

Unless otherwise specified, the sampling plan is C=0. Equipment Serial #: 01397

Burst / Creep Inspection method is specified by 1100016-10. Calibration Due Date: 9-30-2015

Equipment Identification # ~~01937~~ 1-4-15 01397

Specification, in. H_2O	Burst	Date:	Time	Initials	Burst Data, Pass/Fail – List Lane #'s for Multivac Only								
					Lane #	pouch 1	Lane #	pouch 2	Lane #	pouch 3			
19	✓	1-9-15		Sample	7-2	29.1	R						
					9-1	35.9	B						
					15-1	24.8	T						
					8-2	26.7	R						
					3-2	26.7	B						
					19-1	29.5	L						
					14-2	29.7	R						
					10-1	26.4	T						
					12-1	27.2	T						
					20-2	25.8	R						
					1-1	27.5	L						
					6-2	27.6	T						
					11-2	27.1	R						
					16-1	28.5	L						
					17-2	25.2	R						
					5-1	32.0	T						
					2-1	28.3	L						

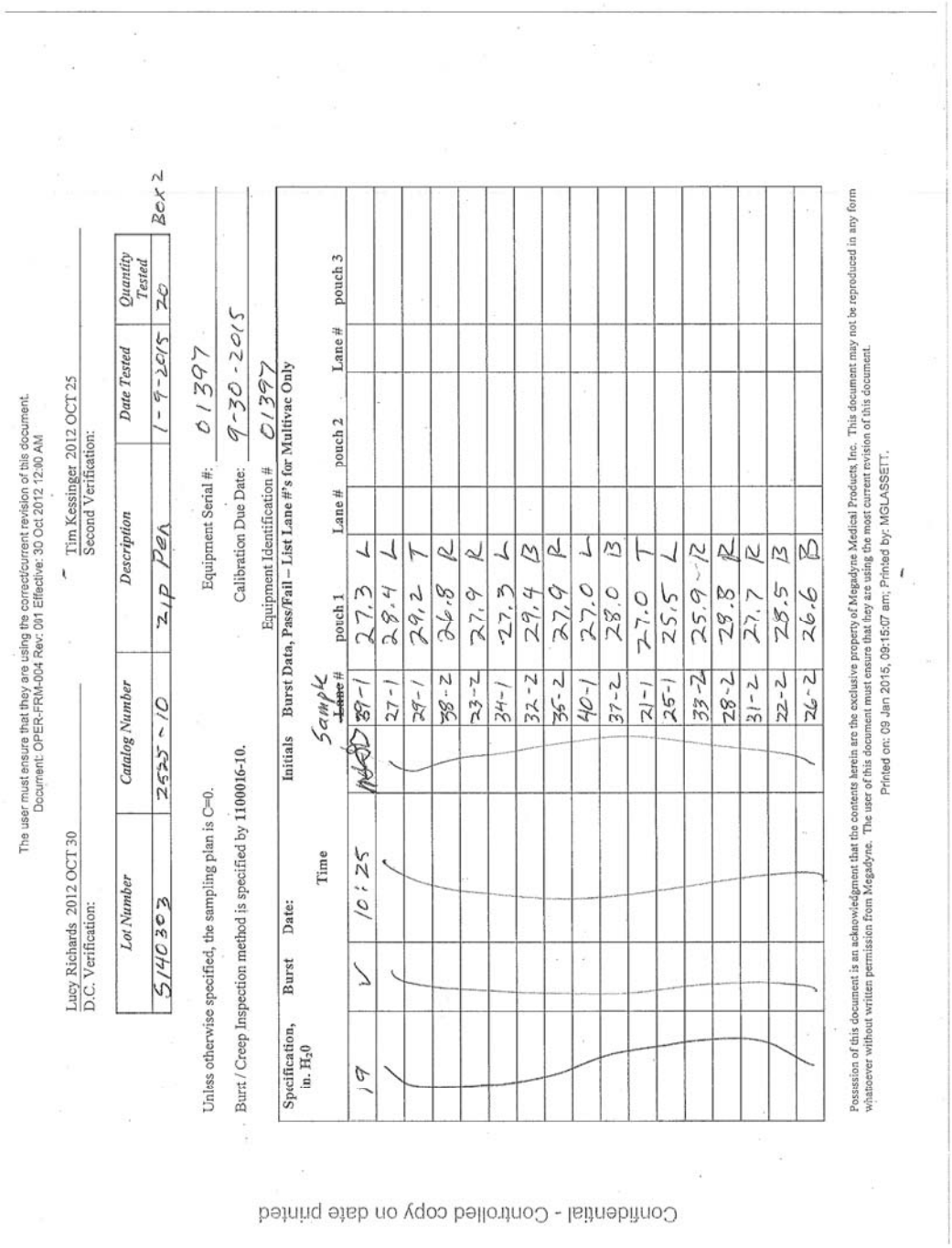
APPENDIX V
Burst Test Log Sheet

Specification, in. H_2O	Burst	Date: Time	Initials	Burst Data, Pass/Fail – List Lane #'s for Multivac Only							
				Lane #	pouch 1	Lane #	pouch 2	Lane #	pouch 3
19	✓	10:25	MG	18-1	28.6	T			
〃	〃	〃	〃	13-1	28.1	L			
〃	〃	〃	〃	4-1	28.3	L			

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

Comments: _____

APPENDIX V
Burst Test Log Sheet



The user must ensure that they are using the correct/current revision of this document.
Document: OPER-FRM-004 Rev: 001 Effective: 30 Oct 2012 12:00 AM

Lucy Richards 2012 OCT 30
D.C. Verification:

Tim Kessinger 2012 OCT 25
Second Verification:

Lot Number	Catalog Number	Description	Date Tested	Quantity Tested
5140303	2525-10	Zip Pen	1-9-2015	20

Box 2

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

Equipment Serial #: 01397

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

Calibration Due Date: 9-30-2015

Equipment Identification # 01397

Specification, in. H_2O	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	V	10:25	[illegible]	39-1	27.3	L						
				27-1	28.4	L						
				29-1	29.2	T						
				38-2	26.8	R						
				23-2	27.9	R						
				34-1	27.3	L						
				32-2	29.4	B						
				36-2	27.9	R						
				40-1	27.0	L						
				37-2	28.0	B						
				21-1	27.0	T						
				25-1	25.5	L						
				33-2	25.9	R						
				28-2	29.8	R						
				31-2	27.7	R						
				22-2	28.5	B						
				26-2	26.6	B						

APPENDIX V
Burst Test Log Sheet

Specification, in. H_2O	Burst	Date:	Time	Initials	Burst Data, Pass/Fail – List Lane #'s for Multivac Only								
					Lane #	pouch 1	Lane #	pouch 2	Lane #	pouch 3			
19	✓		10:35	MGL	30-2	28.9	R						
					24-1	29.3	L						
					36-2	27.1	B						

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

Comments: _____

APPENDIX VI
Package Seal Width Log Sheet

Appendix V
Seal Width Log Sheet

Paul Valprede 1-12-2015

Catalog # 2525-10 Lot #: S140303

Sample	Cavity	Front	Back	Right	Left
1	1	.36	.28	.33	.34
2	1	.35	.27	.32	.33
3	2	.35	.31	.33	.36
4	1	.34	.27	.34	.32
5	1	.34	.29	.33	.33
6	2	.36	.34	.35	.37
7	2	.30	.33	.31	.36
8	2	.31	.28	.33	.33
9	1	.29	.35	.29	.33
10	1	.34	.30	.34	.33
11	2	.33	.31	.29	.35
12	1	.37	.31	.24	.32
13	1	.32	.32	.34	.32
14	2	.37	.29	.34	.33
15	1	.35	.22	.30	.32
16	1	.36	.34	.35	.31
17	2	.35	.32	.32	.32
18	1	.32	.35	.32	.31
19	1	.33	.32	.34	.34
20	2	.34	.27	.33	.37
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					

Appendix VI

Started vib at 1:15 PM on 1-9-2015

APPENDIX VI
Package Seal Width Log Sheet

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* XENG-PRT-229
	Shipping Test – Zip Pen 2525-10	Revision: A
		Page 22 of 23

T. Carlyle 1/9/2015

Appendix V
Seal Width Log Sheet

Mitutoyo O.D. 8" (Inner ID #) Cert 4390-82 CAL 01473

Catalog # 2525-10 Lot #: 5140823 Cal. 4 mar 15 / pvc 31 mar 15

Sample	Cavity	Front	Back	Right	Left
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21	1	0.30	0.29	0.24	0.35
22	2	0.34	0.34	0.36	0.37
23	2	0.36	0.32	0.38	0.33
24	1	0.35	0.30	0.33	0.38
25	1	0.35	0.33	0.34	0.33
26	2	0.345	0.36	0.35	0.38
27	1	0.37	0.29	0.33	0.29
28	2	0.33	0.34	0.34	0.37
29	1	0.35	0.34	0.34	0.34
30	2	0.34	0.34	0.34	0.34
31	2	0.34	0.34	0.34	0.37
32	2	0.35	0.33	0.36	0.37
33	2	0.37	0.34	0.36	0.38
34	1	0.38	0.37	0.32	0.31
35	2	0.31	0.35	0.33	0.33
36	2	0.30	0.29	0.33	0.38
37	2	0.35	0.35	0.32	0.36
38	2	0.37	0.36	0.33	0.35
39	1	0.36	0.34	0.34	0.34
40	1	0.37	0.34	0.35	0.35

Appendix VI

APPENDIX VI
Package Seal Width Summary

Burst Test Data
Zip Pen 2525-10
Lot S140303, Box 1 and 2
Minimum Burst Specification is 19 in. H2O

Sample-Lane/Box 1	Burst Value	Burst Loc	Minimum Seal/Loc	Sample-Lane/Box 2	Burst Value	Burst Loc	Minimum Seal/ Loc
1-1	27.5	L	.28/B	21-1	27.0	T	.24/R
2-1	28.3	L	.27/B	22-2	28.5	B	.34/F,B
3-2	26.7	B	.31/B	23-2	27.9	R	.32/B
4-1	28.3	L	.27/B	24-1	29.3	L	.30/B
5-1	32.0	T	.29/B	25-1	25.5	L	.33/B,L
6-2	27.6	T	.34/B	26-2	26.6	B	.34/F,B
7-2	29.1	R	.30/F	27-1	28.4	L	.28/L
8-2	26.7	R	.28/B	28-2	28.8	R	.33/F
9-1	35.9	B	.29/F,R	29-1	29.2	T	.34/B,R,L
10-1	26.4	T	.30/B	30-2	28.9	R	.34/ALL
11-2	27.1	R	.29/R	31-2	27.7	R	.34/F,B,R
12-1	27.2	T	.24/R	32-2	29.4	B	.33/B,L
13-1	28.1	L	.32/F,B,L	33-2	25.9	R	.34/B,R,L
14-2	29.7	R	.29/B	34-1	27.3	L	.31/L
15-1	24.8	T	.22/B	35-2	27.9	R	.31/F
16-1	28.5	L	.31/L	36-2	27.1	B	.29/B
17-2	25.2	R	.32/B,R,L	37-2	28.0	B	.25/B
18-1	28.6	T	.31/L	38-2	26.8	R	.33/R
19-1	29.5	L	.32/B,R,L	39-1	27.3	L	.34/B,R,L
20-2	25.8	R	.27/B	40-1	27.0	L	.34/B
					27.9	**Average**	**0.30**
					24.8	**Minimum**	**0.22**
						Std Dev	**0.032**
						Avg-3sigma	**0.21**