



The Electrosurgical Authority®

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**Archive Zip Pen BN Test Reports****Change Request**

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Lucy Richards (LRICHARDS)		02 Aug 2016, 08:30:06 AM	Approved

**Collaboration**

Name/Signature	Title	Date	Meaning/Reason
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Paul Borgmeier (PBORGMEIER)		12 Oct 2016, 10:15:15 AM	Complete
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Curt Doel (CDOEL)	Quality Manager	25 Oct 2016, 03:29:47 PM	Complete
Mark Glassett (MGLASSETT)		26 Oct 2016, 09:17:20 AM	Complete

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Lucy Richards (LRICHARDS)		26 Oct 2016, 11:53:58 AM	Complete

**RA-Approval**

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Haven McCall (HMCCALL)	VP RA/QA	26 Oct 2016, 04:29:19 PM	Approved

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Curt Doel (CDOEL)	Quality Manager	13 Dec 2016, 12:05:45 PM	Approved

**ENG-Approval**

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Paul Borgmeier (PBORGMEIER)		27 Oct 2016, 08:44:48 AM	Approved

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Lucy Richards (LRICHARDS)		13 Dec 2016, 01:04:29 PM	Approved

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Authored By: Mark Glassett

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## 1. ABSTRACT

Zip Pen REF 2525-10BN samples were ship tested per protocol ENG-PRT-325 and ASTM D4169 and passed all tests. Catalog number 2525-10BN was tested. This testing is representative of catalog 2525-10ECBN also. The only difference between the two products is the connector, 2525-10BN has the larger connector. Therefore, the testing is considered acceptable for both catalog numbers.

## 2. OBJECTIVE

The purpose of this test report is to document that the Zip Pen REF 2525-10BN and 2525-10ECBN meets the requirements for shipping test per protocol ENG-PRT-325 and ASTM D4169.

## 3. RESULTS

The Zip Pen samples for this shipping test were built at New Deantronics. The samples were REF 2525-10BN Lot# S150571 which are also representative of 2525-10ECBN. The package configuration is documented on drawings X2525-10BN Rev D and X2525-10ECBN Rev A.

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Two cartons of 2525-10BN each with 30 units inside were tested per protocol ENG-PRT-325. The test consisted of the following elements and is documented in appendix I:

<b>Treatment/Test</b>	<b>Description</b>
Megadyne IEC shipping and storage cycle	Temperatures from -40°C to 70°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 210 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 of Zip Pen, Electrode, Holster and Bag

Product inspection resulted in the following and is documented in appendix II:

The boxes had minor indentations on the corners consistent with typical drop test treatment and are acceptable per the protocol.

One of the boxes was partially punctured on one side by the concentrated impact test. The puncture did not cause any damage to the product inside of the box. Since there was no product damage the impact test is considered acceptable per the protocol.

Inspection of the product revealed the following. All samples had random wear on the bag and there were some small holes. Samples had very light white particulate. Samples had fine scratches on the nozzle that were only visible under magnification. The holsters had rub marks that were visible without magnification. There were no bent electrodes and all of the caps were in place.

#### 4. DISCUSSION

Minor indentations in the box are expected in shipping tests and are acceptable. The puncture from the concentrated impact test is not unusual. The important thing is that the product inside of the container is not damaged. This condition is acceptable.

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Wear marks and tiny holes in the bags from rubbing are not a cause for rejection on this product because it is not sterile. The purpose of the bag is to contain the tubing and cable so the healthcare worker can manage it. The bag performed its function of containing the product and therefore minor damage to it is acceptable.

Small particulate was present on the product that was seen under magnification. This is due to rubbing during the vibration portion of the test. The particulate was not visible to the naked eye and is therefore acceptable. There were also scratches on the nozzle seen under magnification, these are also acceptable.

There were rub marks on the holster visible to the naked eye. These type of marks are not uncommon and do not affect the functionality of the holster. Therefore, these marks are acceptable.

## 5. CONCLUSIONS

The Zip Pencil meets the acceptance criteria of the protocol for shipping test. The acceptance criteria were as follows:

<b>Test</b>	<b>Acceptance Criteria</b>
Shipping Carton	Each box shall remain intact and not collapse or break open
Product Damage	There shall be no product damage to the Zip Pen, electrode, holster or poly bag.

## 6. RECOMMENDATIONS

The Zip Pen bulk non-sterile product packaging is considered acceptable and shall be documented per QA-SOP-013. In addition to the drawings and ENG-DMR-012 will be revised to add catalog items 2525-10BN and 2525-10ECBN upon successful completion of all testing.

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## Appendix I Shipping Test Log sheet

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	Shipping Test – Zip Pen 2525-10BN	Revision: A
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### APPENDIX I Shipping Test Log Sheet

#### Preconditioning:

Start Date: 6-21-2016 Chamber Number: 01268  
Completion Date: 6-25-2016 Last Calibration: 5-24-2016  
Signature/Date: Paul Valprede 7-6-2016 Calibration due: 5-31-2017

#### Drop Test:

Catalog 2525-108W Weight 141bs. Drop Height: 15" (CDI)

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Top	Face 1	PV 7-6-2016
2	15 in.	Edge	Edge 5-3	PV 7-6-2016
3	15 in.	Edge	Edge 6-3	PV 7-6-2016
4	15 in.	Corner	Corner 2-3-5	PV 7-6-2016
5	15 in.	Corner	Corner 4-3-6	PV 7-6-2016
6	15 in.	Bottom	Face 3	PV 7-6-2016

#### Comments:

Signature: Paul Valprede Date: 7-6-2016

#### Compression Test:

Catalog 2525-10 Pounds Force 210lbs.

#### Comments:

Signature: Paul Valprede Date: 7-6-2016

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Appendix I  
Shipping Test Log sheet (continued)

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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: 7-6-2016

Signature: Paul Valpreda Date: 7-6-2016

Concentrated impact test

Package dimensions: Length 16" Width 16" Height 9"

# of units tested 2 Test Mass 1.5 lb. Drop Height 32"

Completion Date: 7-6-2016

Signature: Paul Valpreda Date: 7-6-2016

Second Drop Test:

Catalog 2525-10BN 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 7-6-2016
2	15 in.	Face	Face 4	PV 7-6-2016
3	15 in.	Face	Face 6	PV 7-6-2016
4	15 in.	Corner	Corner 2-1-5	PV 7-6-2016
5	15 in.	Edge	Edge 2-1	PV 7-6-2016
6	30 in.	Bottom	Face 3	PV 7-6-2016

Comments: \_\_\_\_\_

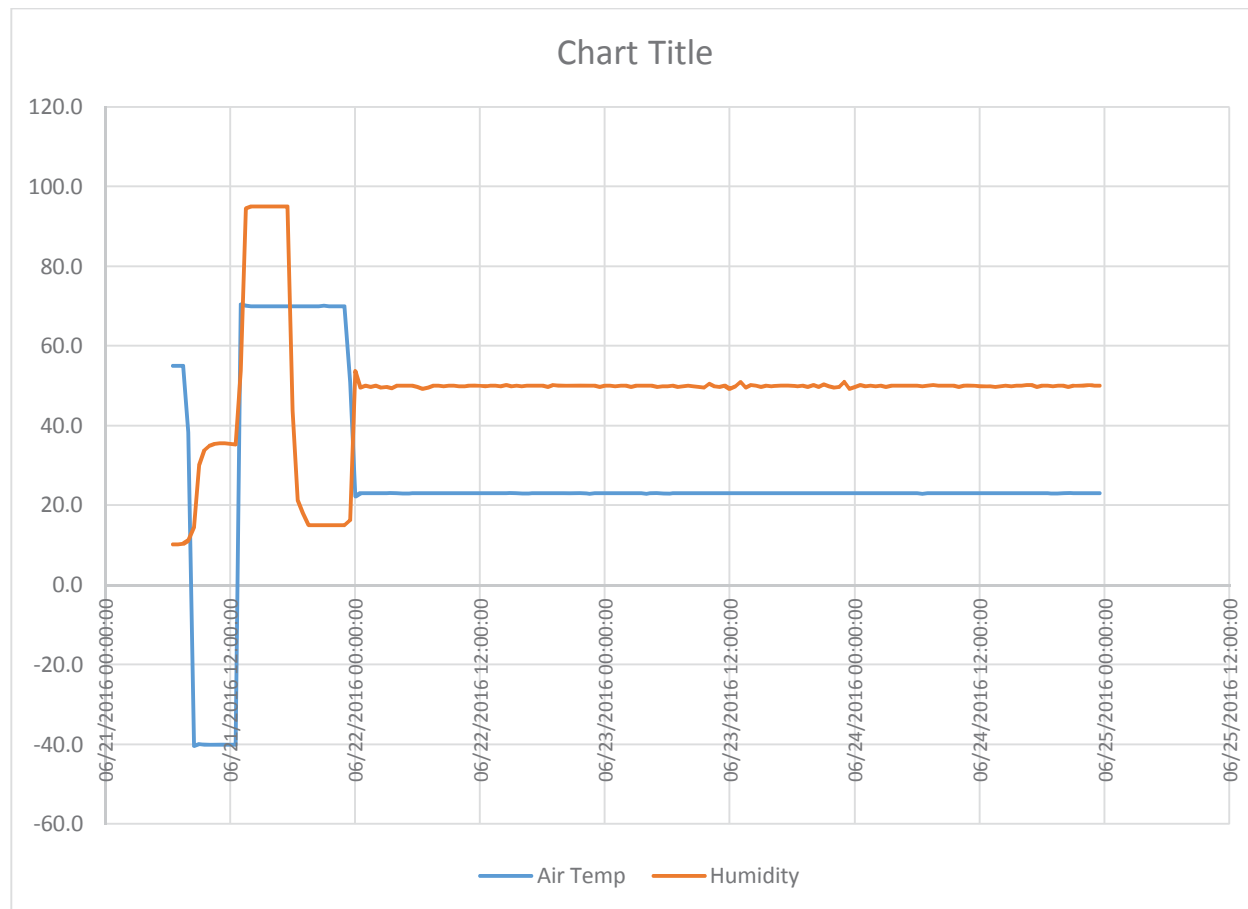
Signature: Paul Valpreda Date: 7-6-2016

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Appendix I  
Shipping Test Log sheet (continued)  
Environmental cycle and preconditioning



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Appendix II  
Product Damage Inspection Log Sheet

Zip Pencil & Package Inspection Post Ship Test 2525-10BN LOT - S150571 Data Collection Form			
Post Ship Test Inspection			Comments
Sample	Configuration	PASS/FAIL	
1	2525-10BN - LOT S150571	PASS	All samples had random bag wear and some had holes. All samples had very light white particulate randomly throughout and most samples had fine scratches on the nozzle, not visible with the naked eye. Most holsters had rub marks and wear spots.
2	2525-10BN - LOT S150571	PASS	
3	2525-10BN - LOT S150571	PASS	
4	2525-10BN - LOT S150571	PASS	Magnification Used: Vision Engineering Mantis Elite Microscope at 10X - Calibration Not Required This inspection was done in accordance with protocol number - YENG-RPT-325
5	2525-10BN - LOT S150571	PASS	
6	2525-10BN - LOT S150571	PASS	
7	2525-10BN - LOT S150571	PASS	
8	2525-10BN - LOT S150571	PASS	
9	2525-10BN - LOT S150571	PASS	
10	2525-10BN - LOT S150571	PASS	
11	2525-10BN - LOT S150571	PASS	
12	2525-10BN - LOT S150571	PASS	
13	2525-10BN - LOT S150571	PASS	
14	2525-10BN - LOT S150571	PASS	
15	2525-10BN - LOT S150571	PASS	
16	2525-10BN - LOT S150571	PASS	
17	2525-10BN - LOT S150571	PASS	
18	2525-10BN - LOT S150571	PASS	
19	2525-10BN - LOT S150571	PASS	
20	2525-10BN - LOT S150571	PASS	
21	2525-10BN - LOT S150571	PASS	
22	2525-10BN - LOT S150571	PASS	
23	2525-10BN - LOT S150571	PASS	
24	2525-10BN - LOT S150571	PASS	
25	2525-10BN - LOT S150571	PASS	
26	2525-10BN - LOT S150571	PASS	
27	2525-10BN - LOT S150571	PASS	
28	2525-10BN - LOT S150571	PASS	
29	2525-10BN - LOT S150571	PASS	
30	2525-10BN - LOT S150571	PASS	
		7/5/2016 PV	
Paul Valpreda			7/5/2016
Inspector Name			Date
Paul Valpreda			7-5-2016
Inspector Signature			Date

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Appendix III  
Product Documentation



March 30, 2016

Megadyne Medical Products Inc.  
11506 South State Street,  
Draper, Utah 84020  
U.S.A.

**Taiwan**  
大德企業股份有限公司  
New Deantronics Taiwan, Ltd.  
新北市土城區中興路4段51號12樓  
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

Attention: Mr. Mark Glassett

Dear Mark,

Enclosed please find the following items:

Item	Part No.	Description	Quantity
1	2525-10BN	Zip Pen, Electrosurgical Pencil w/ E-Z Clean, Holster & 10FT Tubing that is <b>bulk packaged</b>	120PCS

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

Please let us know if you have any further request and questions.

Best regards

**Ivon Liu**  
Product Manager  
New Deantronics Taiwan, Ltd.  
12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng City,  
Taipei County 23675,  
Taiwan R.O.C.  
TEL: 886 2 2268 1726 Ext 260  
FAX: 886 2 2268 3800  
e-mail: [ivon@newdean.com.tw](mailto:ivon@newdean.com.tw)

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New Deatronics Ltd.  
1990 North California Blvd.  
Suite 1040  
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 23675,  
Taiwan R.O.C.  
Tel: 886. 2. 2268. 1726  
Fax: 886. 2. 2268. 3800

### PACKING LIST

MD-622/16

Invoice Date: March 20, 2016  
Invoice No.: MD-622/16  
For Account & Risk of Messrs.: Megadyne Medical Products, Inc.  
11506 South State Street  
Draper, Utah 84020 U.S.A.  
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.  
Ship Via: UPS#12A109756667916300  
Sailing On: March 20, 2016  
From / To: Taipei / Salt Lake City, U.S.A.  
Payment Terms: Net 45 days / Ex-Works

Martin & Neri  
Megadyne  
PO. 26502  
Salt Lake City  
Carton No.: 001-004  
Made In Taiwan  
R. O. C.

Carton No.	Description	Quantity (Cartons)	(Pieces)	N. W. (kgs)	G. W. (kgs)	Meas. (cuft)
001-004	ZIP PEN, Bulk Non-sterile	1	30	5.46	8.20	3.24
4	P/O No.: 26502 PIN: 2525-10BN ND PIN: PB352BMI Lot No.: S150571	4	120	21.84	32.80	12.96
Total: 4 Ctns		4	120	21.84	32.80	12.96

#### Remarks:

- Megadyne Medical Products Establishment Registration: 1721194
- DEV (Device Foreign Manufacturer Registration Number): 9681191
- Country of Origin: Taiwan, R. O. C.
- Harmonized Tariff Code & FDA Information

HTS Code	PIN	S10 (K) #	ND Listing #	Megadyne Listing #	Product code
9818.90.6000	60200XX Series, 0030, 0030H, 0035, 0035H, 0030BN, 0030HBN, 0035BN, 0035HBN, 0038, 0038H, 0038BN, 0038HBN, 0039, 0039H, 0039BN, 0039HBN, 0039HBN, 0039HBN, 0039HBN, 0039HBN	K965054	D163906	D009824	GRI
9018.90.6000	6020045 & 6020046 Series	K050102	N/A	D009836	GRI
8544.42.5000	4000, 4005	K982748	D028893	N/A	GRI
8544.42.5000	3750023-01, 3750026-01	K072539	N/A	D037574	GRI
7413.21.1000	4500032-XX Series	N/A	N/A	N/A	GRI
3917.21.0000	4500033-XX Series	N/A	N/A	N/A	GRI
9008.20.8030	4100050-XX Series	N/A	N/A	N/A	GRI
8544.40.2000	0870, 0875, 0880	K982130	D028893	N/A	GRI
9018.90.6000	TC100	Exempt	D170518	N/A	MDM
9018.90.6000	PC39H	K982749	D163908	N/A	GRI
9018.90.6000	0855C	K060255	D163891	N/A	GRI
9018.90.6000	2525-10, 2540, 2540, 2525-10EC, 2525-13, 2525-10BN	K141587	D237510	D236909	GRI

New Deatronics Taiwan, LTD

Lydia Chang  
Authorized

