

Number: ENG-RPT-329

Version: C.2

Released: 02-Jun-2020

Name: Test Protocol - Zip Pencil, Mechanical

Windchill Signature History Report			
Signature	Role	Event Date	Vote
Kuykendall, Steve [ETHUS Non-J&J] (SKuykend)	Quality Engineering	02-Jun-2020 15:20:27 EDT	Approve
Brooks, Gracie [ETHUS] (gbrooks9)	Research and Development	02-Jun-2020 15:03:31 EDT	Approve

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Authored By: Mark Glassett and Revised By: Mallory Schroeder (M.S.)

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1. ABSTRACT

E-Z Clear™ Pencil samples that have been exposed to three year accelerated aging and shipping cycle temperature extremes were subjected to mechanical tests required by protocol 1150719-10 and IEC 60601-2-2: 2009. The E-Z Clear™ Pencil passed the requirements of the standard for these tests. The specific clauses of the IEC 60601-2-2 standard for each test are listed below.

Required Test	IEC 60601-2-2 Clause
E-Z Clear Plug Connector Strain Relief	201.8.10.4.2
E-Z Clear Handle Strain Relief	201.8.10.4.2
E-Z Clear Electrode Retention	201.15.4.1.102

Additional tests were performed to demonstrate the E-Z Clear™ pencil meets the requirements of DMR 1020024-10. Note the E-Z Clear™ pencil is the same as the ZIP-PEN®. The product was never released as E-Z Clear™, it was rebranded as ZIP-PEN ® prior to release to market.

2. OBJECTIVE

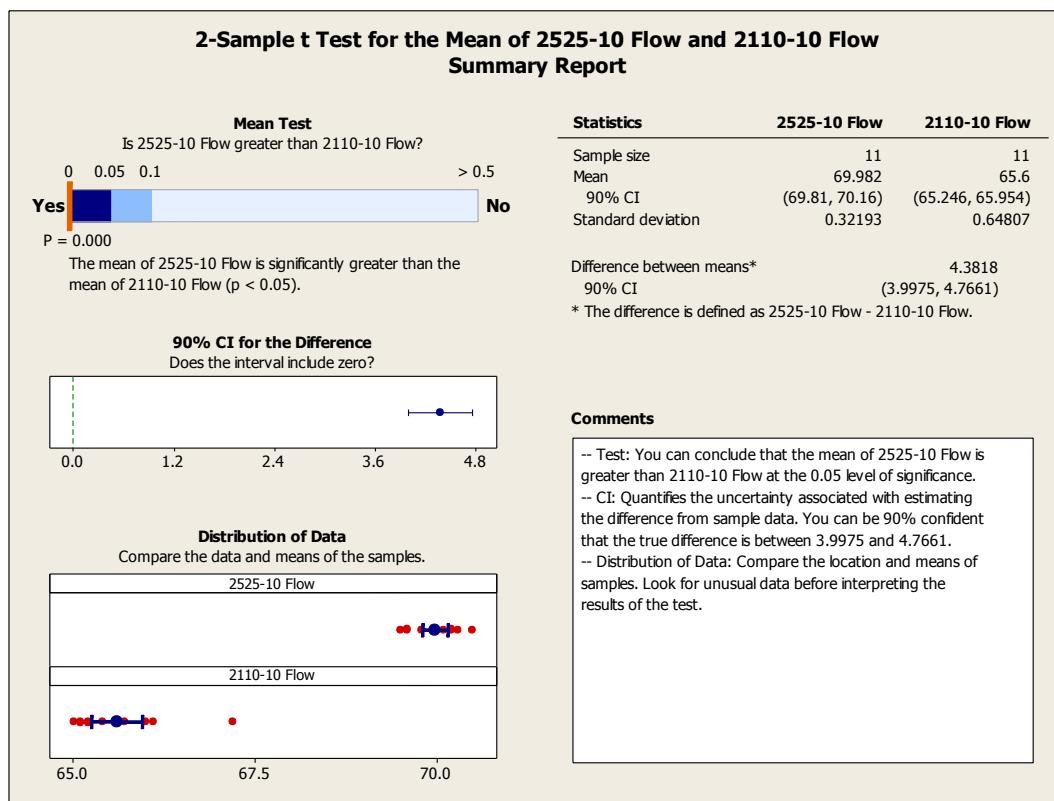
The objective of this test report is to document compliance of the E-Z Clear™ Pencil catalog items 2525-10 and 2525-15 with DMR 1020024-10 and IEC60601-2-2: 2009 mechanical characteristics after shipping extremes and accelerated aging to simulate three years expiration life.

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3. RESULTS

3.1. E-Z Clear Pencil Flow Rate

Eleven samples of the E-Z Clear™ 2525-10 Pencil were tested for flow rate in comparison to the UltraVac 2110-10. The requirement for the protocol is that the E-Z Clear™ pencil have a flow rate equal to or greater than the UltraVac 2110-10 when tested at maximum flow on the Mega Vac. The data shall be evaluated with a 't test'. The results of the 't test' show that the E-Z Clear™ pencil has a higher flow rate than the UltraVac as shown below. This meets the acceptance criteria of the protocol.

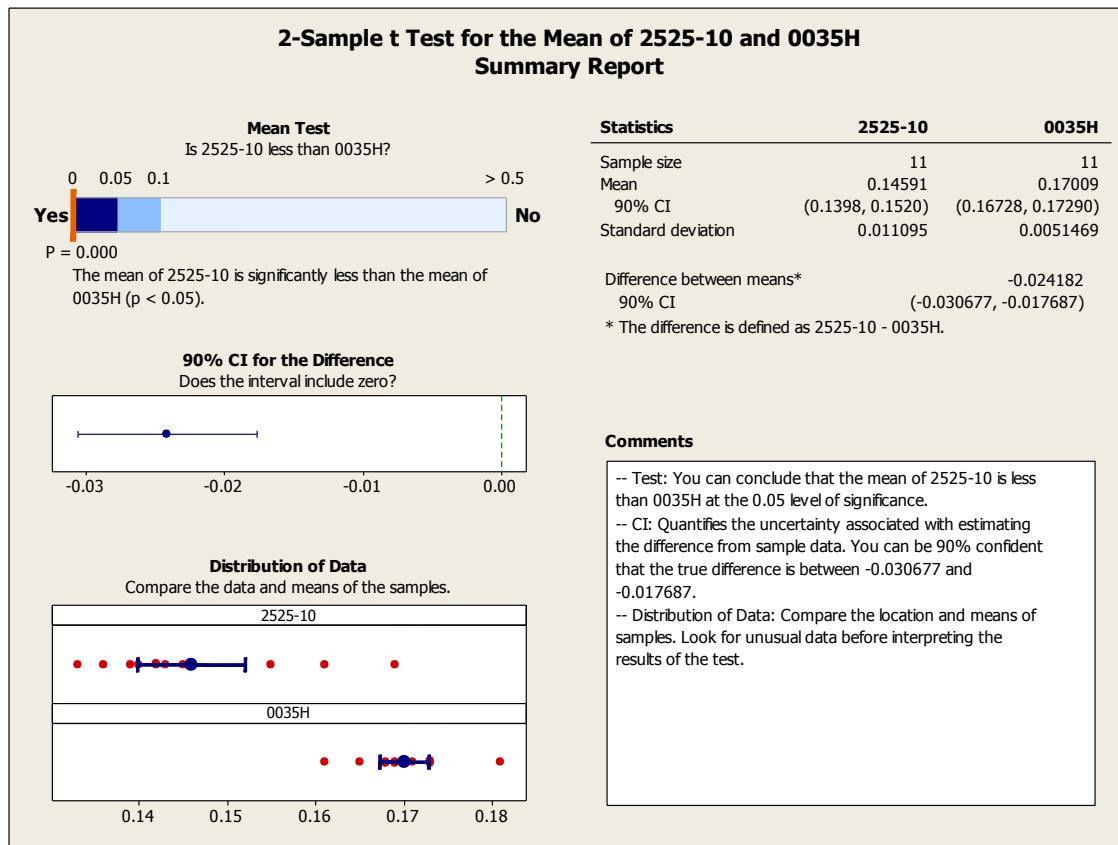


3.2. E-Z Clear™ Pencil Electrode Wobble

Eleven samples of the E-Z Clear™ 2525-10 Pencil were tested for electrode wobble in comparison to the Megadyne disposable pencil. For this test, disposable pencil Cat# 0035H Lot #1211176 pencils were used. The electrode wobble for the E-Z Clear™ 2525-

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10 pencil is less than the disposable pencil as shown in the data below. The raw data is shown in Appendix II. This meets the acceptance criteria of the protocol.

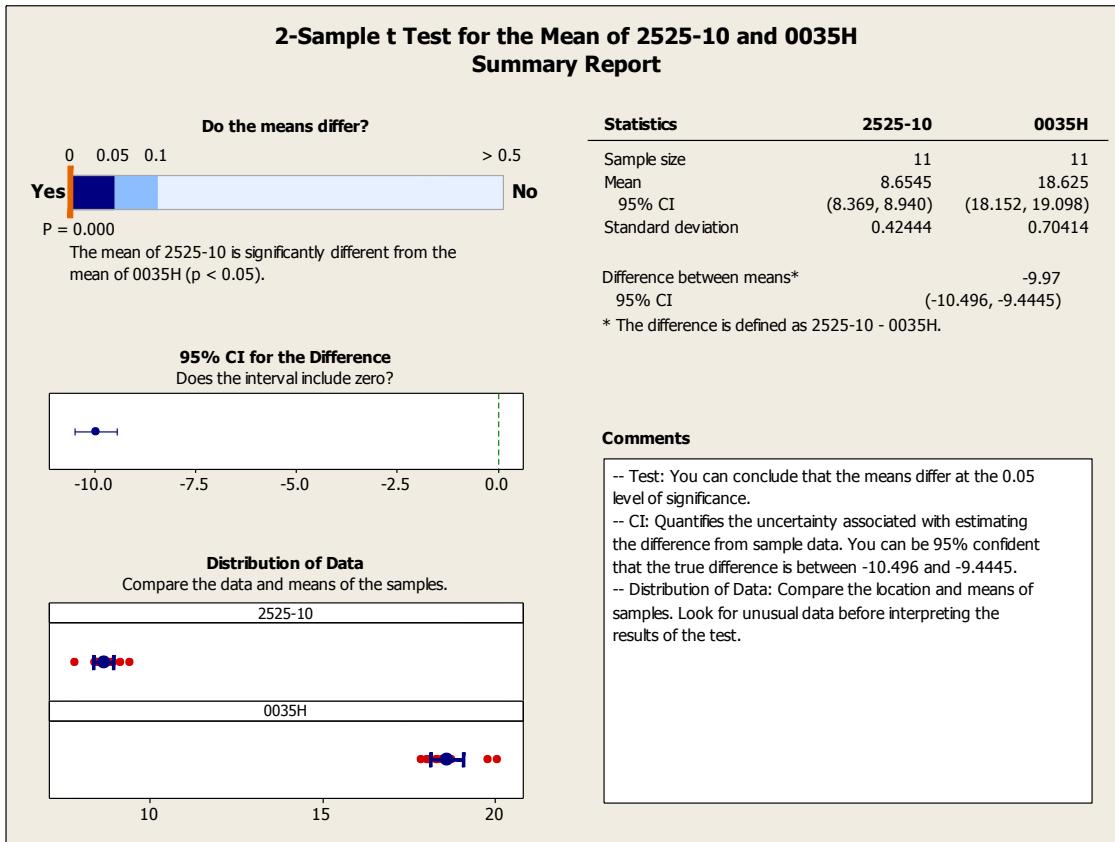


3.3. Plug Insertion Extraction Force

Eleven cable samples from the E-Z Clear™ 2525-10 Pencil were tested for plug insertion force. The technician was unable to run the extraction force test. He was not able to zero out the Instron machine with the plug in the connector and get reasonable data.

Engineering allowed the protocol to be completed without the extraction data. The rational for this is that insertion and extraction force typically mirror each other in this type of test. The E-Z Clear™ Pencil plug has significantly lower insertion force than the disposable pencil as shown in the graph below. The plug insertion data is shown in appendix III.

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The lower insertion force does not meet the acceptance criteria written in the protocol which was to be equivalent to the disposable pencil as determined by the t-test. Since the protocol was not met for this parameter, Marketing was consulted on the resulting insertion force. Criteria established in MKT-CMR-029 in the Condition of Use section and established as a product specification in ENG-PS-007 section 4.4.1.10 PRS 1310 requires that the insertion and extraction force be a minimum of 2lbs. The Marketing Product Manager evaluated the plug's insertion force data and judged the insertion force manually on a standard Mega power ESU and agreed the insertion and extraction force of the plug met the minimum 2lbs of force which was considered acceptable. The plug's insertion and extraction force were also compared on competitive ESU's and were judged to meet the minimum 2lbs of force and considered acceptable. Therefore, even though the criteria written in the protocol was not met, Marketing has accepted the plug insertion force. No further modifications to product specifications or customer criteria need be updated.

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3.4. Tubing Strength

Thirty Tubing samples from the E-Z Clear™ 2525-10 Pencil were tested for tubing strength at the Mid Tube Connector. The results are summarized as follows:

2525-10 GLOBAL MED Tubing Lot S130230		
Statistic	Force (lbf)	Results
Mean	6.0	
Maximum	8.23	
Minimum	5.08	<ul style="list-style-type: none">• 12 of 15 samples, the tube came off of the connector• 2 of 15 samples, the sample did not break or disconnect, the tubing stretched• 1 of 15 samples, the tubing broke

2525-10 SMOOTH BOR Tubing Lot S130227		
Statistic	Force (lbf)	Results
Mean	8.29	
Maximum	8.54	
Minimum	8.02	<ul style="list-style-type: none">• 15 of 15 samples, the sample did not break or disconnect, the tubing stretched

There is no current specification for the strength of this connection. The protocol acceptance criterion was that the tubing connection shall be stronger than the tubing. The results did not show this to be the case for the Global Med tubing. For the Smooth Bor tubing the result was that the tubing stretched and neither broke nor became disconnected.

Because of the mixed results, 11 samples of Ultra Vac were subjected to the same test to determine if these two tubing materials are at least equivalent to the existing product. The results of the Ultra Vac testing are as follows:

2110-10 Ultra Vac Tubing Lot 5199		
Statistic	Force (lbf)	Results
Mean	8.29	
Maximum	8.79	
Minimum	7.04	<ul style="list-style-type: none">• 9 of 11 samples, the sample did not break or disconnect, the tubing stretched• 2 of 11 samples, the tubing broke

Based on the comparison of the three tubing samples from different suppliers, it is clear that the Global Med tubing has different characteristics.

When comparing the connection force data of the Global Med tubing to that of the Ultra Vac, Global Med tubing's connection force is greater than that of Ultra Vac's 4.16 pounds. In determining if this connection force meets customer's specification, a review of customer complaints for 2012 to 2013 shows there are no complaints for the tubing disconnecting with a 4.16 pound retention force. This would argue that the greater

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connection force of 6.0 pounds for the Global Med tubing will meet customer expectations. Refer to appendix IV for tubing strength data including the customer complaint information.

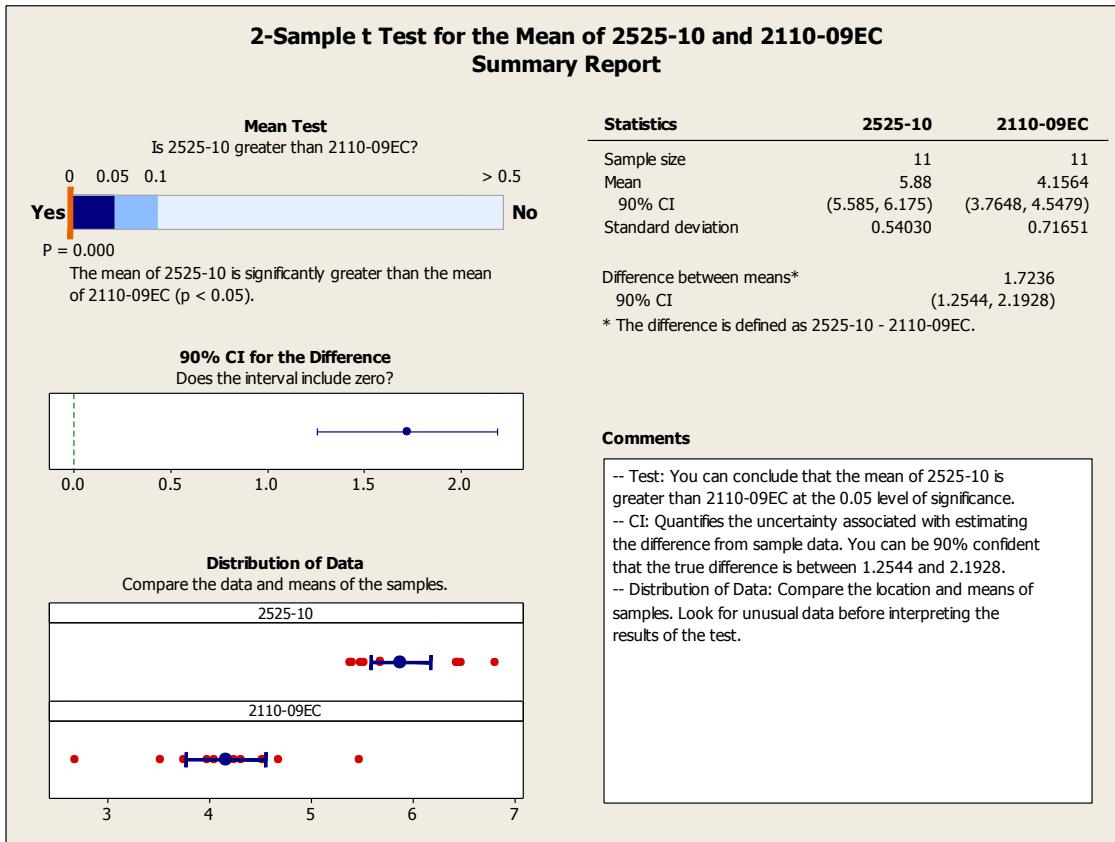
3.5. Proximal Connector Removal Force

Eleven samples of the E-Z Clear™ 2525-10 Pencil were tested for proximal connector removal force in comparison to the Ultra Vac 2110-09EC. The proximal connector removal force for the E-Z Clear™ pencil is greater than the Ultra Vac 2110-09EC as shown in the data summary below. The 't test' analysis is also shown. Note that removal mechanism for the two sample groups was different. On the E-Z Clear™ Pencil the connector came off of the filter. On the Ultra Vac the tubing disconnected from the connector. The raw data is shown in Appendix V. This meets the acceptance criteria of the protocol.

Proximal Connector Removal force, E-Z Clear 2525-10 Lot S130410		
Statistic	Force (lbf)	Results
Mean	5.9	• 11 of 11 samples, the connector came off of the filter
Maximum	6.8	
Minimum	5.4	

Proximal Connector Removal force, Ultra Vac 2110-09EC Lots 5138, 4168		
Statistic	Force (lbf)	Results
Mean	4.2	• 11 of 11 samples, the tubing disconnected from the connector
Maximum	5.5	
Minimum	2.7	

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3.6. Electrode Extraction Force and Retention

Thirty E-Z Clear™ 2525-10 Pencil samples were tested for electrode extraction force and retention. The results are summarized as follows:

Statistic	Load (lbf)
Mean	2.74
Minimum	1.27
Maximum	4.19
Standard Deviation	0.65
Electrode Retention Test	All 30 samples passed

The requirement from the protocol is that all extraction forces shall be within the range of 1.5 to 4.5 pounds. There was one sample outside of this range at 1.27 pounds. The specified range is a process parameter designed to make sure that the pencils meet the electrode retention test and is a requirement in the DMR. All 30 samples passed the

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retention test required in IEC 60601-2-2: 2009 clause 201.15.4.1.102. Refer to the data in appendix VI.

The supplier was notified that one sample was outside specification for the extraction force test. Process adjustments were made and additional samples provided for a retest. The test method was also reviewed prior to testing of 30 additional samples. The second samples were from lot S140075. See section 4, Discussion, for sample information and conditioning rationale. The data summary for the second set of samples is as follows:

Statistic	Load (lbf)
Mean	2.85
Minimum	2.13
Maximum	3.86
Standard Deviation	0.453

These samples meet the acceptance criteria of the protocol. The raw data is shown in Appendix VI.

3.7. Button Force

Thirty E-Z Clear 2525-10 Pencil samples were tested for button activation force. The acceptance range for the protocol is 300 to 700 grams. The results are summarized as follows:

Statistic	Cut Force (grams)	Coag Force (grams)
Mean	532	527
Minimum	470	419
Maximum	588	622
Standard Deviation	36	46

All of the button activation forces meet the acceptance criteria of the protocol. The button activation force requirement in ENG-PS-007 PRS 1301 is specified as 250 to 700 g, also met by this testing. Refer to the data in appendix VII.

3.8. Plug Strain Relief

Thirty samples of the E-Z Clear™ 2525-10 Pencil plug were tested for plug strain relief per the protocol and IEC 60601-2-2 clause 201.8.10.4.2. All of the samples met the requirements of the protocol and the standard. The data is shown in Appendix VIII.

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3.9. Handle Strain Relief

Thirty samples of the E-Z Clear™ 2525-10 Pencil handle were tested for handle strain relief per the protocol and IEC 60601-2-2 clause 201.8.10.4.2. All of the samples met the requirements of the protocol and the standard. The data is shown in Appendix IX.

3.10. Nozzle Pry Force

Thirty samples of the E-Z Clear™ 2525-10 Pencil were tested per the protocol. The protocol requirement was to hold the pencil horizontal and apply up to 20 pounds force to the end of the nozzle. The acceptance criterion was that the nozzle shall not break or become disassembled below 10 pounds. None of the pencils broke or became disassembled with the application of 20 pounds. The nozzle flexed but there was no damage. The E-Z Clear™ Pencil meets the requirements of the protocol. Refer to the data in appendix X.

4. DISCUSSION

The samples used for the testing were catalog 2525-10 E-Z Clear™ Pencils Lot S130230, S130227, S130410 and S140075 and catalog 2525-15 Lot S130231. The 2525-10 and 2525-15 catalog numbers are the same product with the exception of tube and cord length. The samples used for controls were catalog 2110-10 Lot 5199 and 2110-09EC Lots 5138 and 4168.

Prior to testing, samples that required aging were subjected to accelerated aging at 55°C for a time period meant to simulate three years of real time storage. All samples were 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. A summary of the sample conditioning is as follows:

Sample Description	Conditioning
2525-10 Lots S130227 and 130230	Aging at 55°C, Shipping Extremes
2525-15 Lots S130228 and 130231	Aging at 55°C, Shipping Extremes
2525-10 Lot S130410	Shipping Extremes
2525-10 Lot S140075	None
2110-09EC Lots 4168 and 5138	Warehouse Samples
2110-10 Lot 5199	Warehouse Samples
0035H Lot 1211176	Warehouse Samples

4.1. E-Z Clear Pencil Flow Rate

Eleven samples of the E-Z Clear™ Pencil were tested for flow rate in comparison to the 2110-10 Ultra Vac. The E-Z Clear™ Pencils used for this testing were conditioned with

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accelerated aging and shipping temperature extremes. The E-Z Clear™ Pencil meets the acceptance criteria of the protocol.

2525-15 data collected here is superseded by ENG-RPT-403.

	Average Flow Rate		
Smoke Evacuator	E-Z Clear 2525-10 Lot S130230	Ultra Vac 2110-10 Lot 5199	E-Z Clear 2525-15 Lot S130231
Megadyne MegaVac Plus	70.0	65.6	69.5

4.2. E-Z Clear™ Pencil Electrode Wobble

Eleven samples of the E-Z Clear™ Pencil 2525-10 Lot S130230 were tested for electrode wobble in comparison to the Megadyne disposable pencil. The E-Z Clear™ Pencils used for this testing was conditioned with accelerated aging and shipping temperature extremes. The E-Z Clear™ Pencil meets the acceptance criteria of the protocol. The raw data is shown in Appendix II.

4.3. Plug Insertion Force

Eleven cable samples with attached plug ends from the E-Z Clear™ Pencil Lot S130410 were tested for plug insertion force. The E-Z Clear™ Pencils used for this testing were conditioned with shipping temperature extremes only. This is determined to be acceptable because the Plug insertion force is a test of metal to metal contact. Due to the nature of the materials used in the plug pins, aging at 55°C is not considered to have a significant effect on the properties of the metal components. The E-Z Clear™ Pencil failed to meet the acceptance criteria set forth in the protocol. While Megadyne does not have a written specification for plug insertion force, an average plug extraction force for the E-Z Clear™ pencil is demonstrated to be 8.65 lbs. Marketing was consulted on the demonstrated insertion/extraction force of the E-Z Clear™ pencil. The Marketing Product Manager accessed the plug's insertion/extraction force data and in both the Mega power ESU and competitive ESU's and determined the forces comfortable and reasonable for consumer use. After determining the performance acceptable, a full review of the data was conducted and accepted as sufficient for consumer use.

4.4. Tubing Strength

Thirty Tubing samples from the E-Z Clear™ Pencil were tested for tubing strength at the Mid Tube Connector, and as they were compared to the Ultra Vac tubing. While there is no current specification for the strength of the Mid Tube Connector and tubing, this test was included in the protocol to ensure that the Mid Tube connection remains intact during use. The results were mixed with some samples coming disconnected, some experiencing tube stretching and other tubes breaking. The key take away from this test was that the connections for the E-Z Clear™ Pencil with either type of tubing were

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stronger than the weakest connection of the existing Ultra Vac 2110-09EC. This fact, of the connections being stronger, was made clear during the data review with the Marketing Product Manager and she concluded that the connection strength is acceptable for customer use and approved the use of the tube/connection combination.

4.5. Proximal Connector Removal Force

Eleven samples of the E-Z Clear™ Pencil were tested for proximal connector removal force in comparison to the Ultra Vac 2110-09EC. The proximal connector removal force for the E-Z Clear™ pencil is greater than the Ultra Vac 2110-09EC and meets the acceptance criteria of the protocol.

4.6. Electrode Extraction Force and Retention

Thirty E-Z Clear™ samples were tested for electrode extraction force and retention. Note that the test samples were not aged samples. This is determined to be acceptable because the electrode extraction force is a test of metal to metal contact components. Aging at 55°C is not considered to have a significant effect on the properties of the metal components.

The requirement from the protocol is that all extraction forces shall be within the range listed in the DMR of 1.5 to 4.5 pounds. On the first set of samples, there was one sample outside of this range at 1.27 pounds. The supplier was notified that one sample was outside specification for the extraction force test. They reviewed their processes and created another sample set. The Megadyne test method was also reviewed and refined. After process review and test method refinement, the second set of samples passed the requirements. See appendix VI for extraction data and a description of the test method.

All 30 samples of the first test set passed the retention test required in IEC 60601-2-2:-2009 clause 201.15.4.1.102.

4.7. Button Force

Thirty samples of the E-Z Clear™ Pencil were tested for button force. The button force meets the acceptance criteria of the protocol

4.8. Plug Strain Relief

Thirty samples of the E-Z Clear™ Pencil plug were tested for plug strain relief per the protocol and IEC 60601-2-2 clause 201.8.10.4.2. All of the samples met the requirements of the protocol and the standard.

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4.9. Handle Strain Relief

Thirty samples of the E-Z Clear™ Pencil handle were tested for handle strain relief per the protocol and IEC 60601-2-2 clause 201.8.10.4.2. All of the samples met the requirements of the protocol and the standard.

4.10. Nozzle Pry Force

Thirty samples of the E-Z Clear™ Pencil were tested per the protocol. The protocol requirement was to hold the pencil horizontal and apply up to 20 pounds force to the end of the nozzle. The acceptance criterion was that the nozzle shall not break or become disassembled below 10 pounds. None of the pencils broke or became disassembled with the application of 20 pounds. The nozzle flexed but there was no damage. The E-Z Clear™ Pencil meets the requirements of the protocol.

5. CONCLUSIONS

This testing demonstrates that the E-Z Clear™ Pencil catalog numbers 2525-10 and 2525-15 comply with the required standards referenced in section 1 after three year accelerated aging and shipping and storage condition exposure.

In addition to standards requirements, the results of this report show compliance with the DMR 1020024-10. There were two tests where the acceptance criteria of the protocol were not met. They are summarized as follows:

- 1) Plug insertion force; the plug insertion forces for the E-Z Clear™ pencil are lower than the Megadyne disposable pencils. The lower forces are adequate to keep the plug in the generator receptacle under normal use and were determined to be acceptable and approved by Marketing.
- 2) Tubing to connector strength; the Global Med tubing had lower connection strength than the Ultra Vac at the mid tube connector. However, the connection strength was greater than the Ultra Vac connection at the proximal connector. Since the E-Z Clear™ connection is greater than the weaker connection of the Ultra Vac proximal connector, and there are no customer complaints for tubing coming disconnected on the Ultra Vac, the lower connection strength of the E-Z Clear™ is considered acceptable.

6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the E-Z Clear™ Pencil to IEC 60601-2-2: 2009 and protocol 1150719-10 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 will be put aside for testing per Megadyne Protocol 1150309-10.

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The testing also demonstrated compliance to IEC 6060 1-2-2: 2009 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”.

The testing for electrode extraction initially did not meet the requirements of the protocol. Testing was repeated with modification to the manufacturing process and the test method and results readily met the requirements of the protocol.

7. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-052-01	Initial Release	2014-03-28
001	See Master Control	Transfer to Master Control – No Change	2014-06-25
002	See Master Control	Update appendices with calibration information of brass weights and Instron, add reference to ENG-PS-007 button force requirement, removal of competitive smoke evacuator testing as they are not required for verification	See Master Control
B	See Windchill	Reworded and clarified summaries	See Windchill
C	See Windchill	Reworded and clarified summaries	See Windchill

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APPENDIX I E-Z Clear Handpiece Flow Test Data

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	MASTER DOCUMENT	Revision: 01
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Appendix I:
FLOW RATE *MUP 2210 lot 5364 Filter*

Flow Meter ID# 01272
Flow Meter Last Calibration Date April 2013
Flow Meter Calibration Due Date April 2014
Smoke Evacuator Make and Model MUP 350-D
Smoke Evacuator Serial Number J4211

*Note: Blk/
in pencils*

Zip Pen Catalog 2525-10		Lot #	UltraVac Catalog 2110-10		Lot#
Sample #	Flow Rate	<i>T₁</i> <i>Filter</i>	1	<i>T₁</i> <i>Filter</i>	<i>5199</i>
1	A1-5	55.4 <i>57.2</i>	70.3	57.2 <i>67.2</i>	
2	A1-6	57.2	70.5	58.9 <i>65.1</i>	
3	A1-7	56.3	70.2	62 <i>65.2</i>	
4	A1-8	55.9	70.2	63 <i>65.2</i>	
5	A1-11	55.6	70.0	61.7 <i>66.0</i>	-65.1
6	A1-17	57.3	70.1	61.8 <i>66.1</i>	
7	A1-18	56.5	69.5	61.2 <i>65.1</i>	
8	A1-14	54.1	69.6	60.0 <i>65.0</i>	
9	A1-19	54.8	70.0	60.3 <i>65.0</i>	
10	A1-20	55.7	69.6	61.6 <i>65.4</i>	
11	A1-10	57.6	69.5	57.4 <i>65.6</i>	

Test Performed by: S. M. Date: 2/10/14

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Appendix I:
FLOW RATE

Flow Meter ID# 01272
Flow Meter Last Calibration Date April 2013
Flow Meter Calibration Due Date April 2014
Smoke Evacuator Make and Model MID 350-D
Smoke Evacuator Serial Number 14211

Zip Pen Catalog 2525-10		Lot # <u>S130231</u>	UltraVac Catalog 2110-10	Lot#
Sample #	Flow Rate	Sample #	Flow Rate	
1	<u>C1-19</u>	1	<u>69.8</u>	
2	<u>C1-17</u>	2	<u>69.7</u>	
3	<u>C1-13</u>	3	<u>69.5</u>	
4	<u>C1-5</u>	4	<u>69.7</u>	
5	<u>C1-4</u>	5	<u>69.6</u>	
6	<u>C1-9</u>	6	<u>69.7</u>	
7	<u>C1-11</u>	7	<u>69.9</u>	
8	<u>C1-18</u>	8	<u>70.1</u>	
9	<u>C1-16</u>	9	<u>69.1</u>	
10	<u>C1-15</u>	10	<u>69.2</u>	
11	<u>C1-18</u>	11	<u>69.0</u>	

Test Performed by: M. Tk Date: 2/12/19

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APPENDIX II
E-Z Clear Handpiece Electrode Wobble Data

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Appendix H ELECTRODE WOBBLE			
Zip Pen Catalog 2525-10	Lot # S130230	Single-Use Pencil Catalog 0035H	Lot # 1211176
Sample #	Wobble	Sample #	Wobble
1	0.136	1	0.165
2	0.142	2	0.173
3	0.161	3	0.161
4	0.169	4	0.168
5	0.133	5	0.171
6	0.142	6	0.169
7	0.139	7	0.168
8	0.143	8	0.173
9	0.145	9	0.169
10	0.155	10	0.173
11	0.140	11	0.181

Thomas L N Carlyle 2/15/2014
Operator Name Date


2014-2-26
Operator Signature Date

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APPENDIX III

E-Z Clear Handpiece Plug Insertion

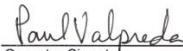
MASTER DOCUMENT

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Appendix III PLUG INSERTION FORCE			
Zip Pen Catalog 2525-10	Lot # S130410	Single-Use Pencil Catalog 0035H	Lot # 1211176
Sample #	Insertion force	Sample #	Insertion force
1	8.460	1	18.340
2	8.480	2	18.520
3	7.810	3	18.320
4	8.410	4	18.090
5	8.620	5	18.600
6	8.430	6	20.080
7	9.400	7	18.470
8	9.130	8	19.810
9	8.930	9	18.740
10	8.650	10	17.860
11	8.880	11	18.040

Paul Valpreda
Operator Name

2-12-2014
Date


Operator Signature

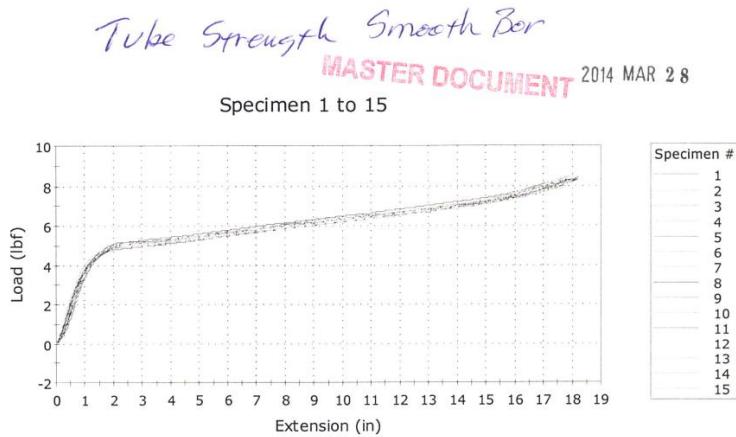
2-12-2014
Date

Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously
omitted calibration information. See
Appendix XII for calibration record
applicable to this test date. Only
one Instron was in use at
Megadyne, Asset # 01028

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-329
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APPENDIX IV
E-Z Clear Handpiece Tubing Strength data and Complaint Summary



	Maximum Load (lbf)	Specimen label	Notes
1	8.02	Smooth Bor B2 - 1	Tubing did not break or disconnect
2	8.38	Smooth Bor B2 - 2	Tubing did not break or disconnect
3	8.42	Smooth Bor B2 - 3	Tubing did not break or disconnect
4	8.19	Smooth Bor B2 - 4	Tubing did not break or disconnect
5	8.30	Smooth Bor B2 - 5	Tubing did not break or disconnect
6	8.28	Smooth Bor B2 - 6	Tubing did not break or disconnect
7	8.15	Smooth Bor B2 - 7	Tubing did not break or disconnect
8	8.31	Smooth Bor B2 - 8	Tubing did not break or disconnect
9	8.17	Smooth Bor B2 - 9	Tubing did not break or disconnect
10	8.54	Smooth Bor B2 - 10	Tubing did not break or disconnect
11	8.25	Smooth Bor B2 - 11	Tubing did not break or disconnect
12	8.32	Smooth Bor B2 - 12	Tubing did not break or disconnect
13	8.25	Smooth Bor B2 - 13	Tubing did not break or disconnect
14	8.48	Smooth Bor B2 - 14	Tubing did not break or disconnect
15	8.26	Smooth Bor B2 - 15	Tubing did not break or disconnect
Maximum	8.54		
Mean	8.29		
Minimum	8.02		
Standard Deviation	0.13397		

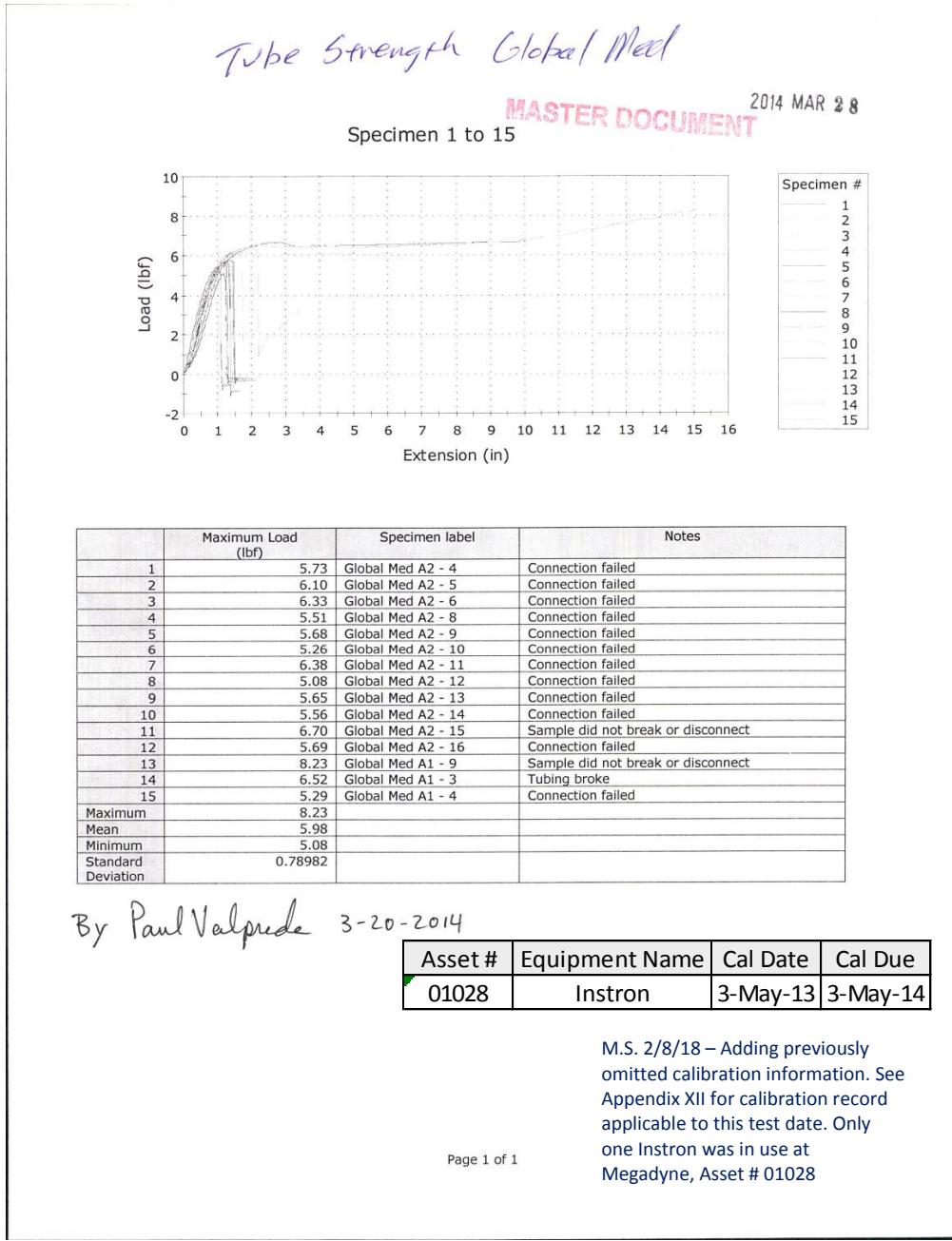
By Paul Valpredo

3-20-2014

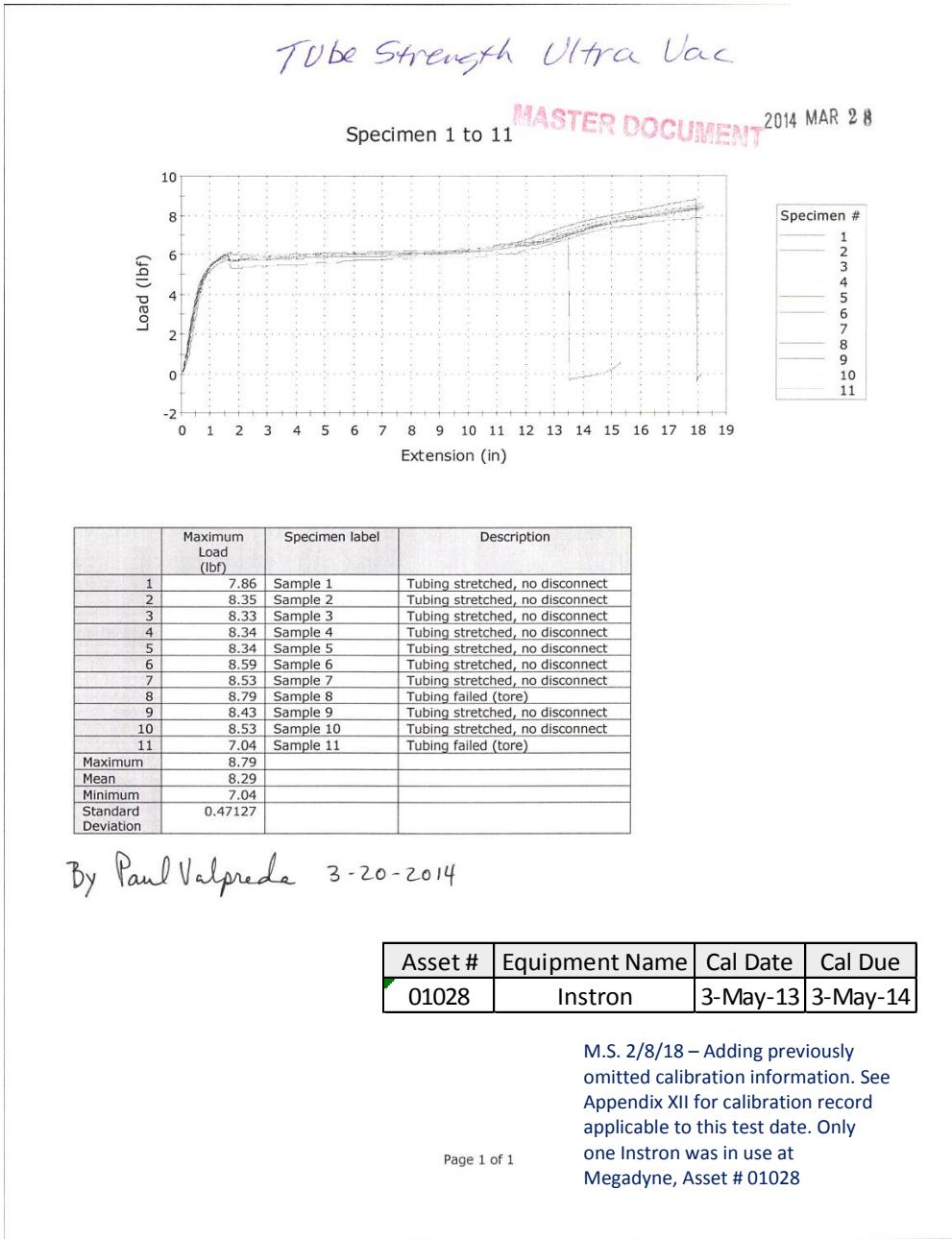
Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously omitted calibration information. See Appendix XII for calibration record applicable to this test date. Only one Instron was in use at Megadyne, Asset # 01028

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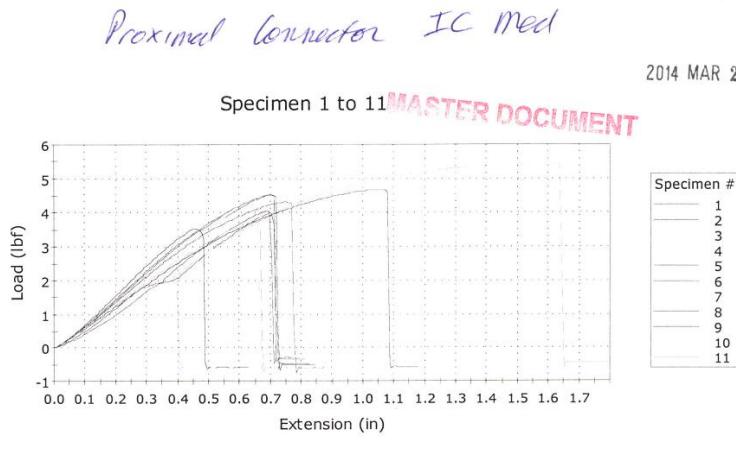


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MASTER DOCUMENT				2014 MAR 28
ComplaintID	Part#	Lot Number	Descriptions / Steps to Dup.	Comments
2012006600	2110-09	4562	Something inside pencil broke	
2012006907	2110-09	4594	acorn locking nut has broken	
2012006908	2110-09	4781	Acorn locking nut "disintegrated" (split and fell apart) during a procedure...	
2012006995	2110-09	Unk	The screw has come apart (cracked) during the procedure. This has resulted in...	
2012007001	2110-09	4254	The nut on the Ultra Vac is breaking off and falling into the patient.	
2012007216	2110-09	4425	Activation failure	
2012007233	2110-09	UNK	The smoke evac pencil chuck (locking nut) on the handle broke off.	
2013007747	2110-09	4425	0012 spins during procedure. Procedure is total knee, left leg. Dr. W....	
2013007863	2110-09	5043	Two each ultra vac pencils stopped working in mid surgical procedure.	
2013008102	2110-09	4516	Surgeon tried to release the 'knob' to retract back the shaft to the ori...	
2013008253	2110-09	4580	Less than an hour into the surgery, the locking nut cracked into pieces.	
2013008491	2110-09	4894	Melted pencil/wire.	
2013008349	2110-10	5121	Issues with the buttons not activating	
2013008392	2110-10	unk	When the nurse took this item (2110-10) out of the package, the cord was stuck together	
2013008468	2110-10	5121	Inadvertently activating with no buttons or pedals pushed.	
2013008512	2110-10	5159	This is the new style and he thought that the cut button didn't work and...	
2013008565	2110-10	Unk	Having trouble with shorting out.	
2013008575	2110-10	5199	Patient has two burns from the suction bovie. Additional information received...	
2014008606	2110-10	5290	Teflon tip stuck to patient tissue and plaster around the tip of suction...	
2014008630	2110-10	unk	After 10 minutes in use, the activation button quit working. 2nd issue in...	
2014008722	2110-10	5342	We have another suction bovie went out.	
2013007773	2110-09EC	4780	19 pieces of broken Ultra Vac handpieces. They broke in the adjustment area. He has 19 Ultra Vacs units that have manifested the break on the nut allows the unit to telescope out.	
2013008489	2110-09EC	5173	The hospital had several damaged tips. The tip was bent before use..	
2013008490	2110-09EC	5198	No current coming through the pencil.	

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APPENDIX V
E-Z Clear Handpiece Proximal Connector Strength



	Maximum Load (lbf)	Specimen label	Notes
1	4.04	2110-09EC Pencil 1	Tubing connection failed
2	3.98	2110-09EC Pencil 2	Tubing connection failed
3	5.47	2110-09EC Pencil 3	Tubing connection failed
4	3.75	2110-09EC Pencil 4	Tubing connection failed
5	4.68	2110-09EC Pencil 5	Tubing connection failed
6	4.54	2110-09EC Pencil 6	Tubing connection failed
7	4.24	2110-09EC Pencil 7	Tubing connection failed
8	3.52	2110-09EC Pencil 8	Tubing connection failed
9	4.52	2110-09EC Pencil 9	Tubing connection failed
10	2.67	2110-09EC Pencil 10	Tubing connection failed
11	4.31	2110-09EC Pencil 11	Tubing connection failed
Maximum	5.47		
Mean	4.16		
Minimum	2.67		
Standard Deviation	0.71524		

By Paul Valpreda 3-20-2014

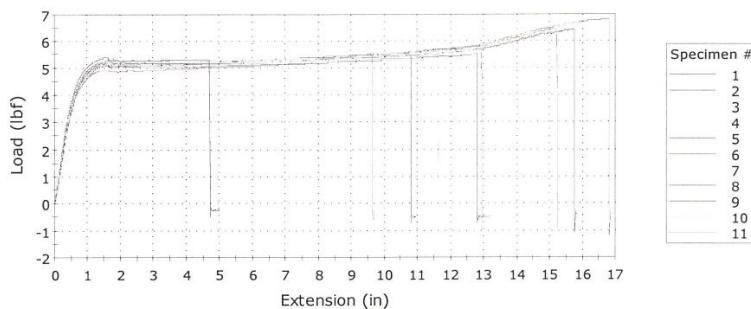
Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously omitted calibration information. See Appendix XII for calibration record applicable to this test date. Only one Instron was in use at Megadyne, Asset # 01028

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Proximal Connector Zip

Specimen 1 to 11 **MASTER DOCUMENT** 2014 MAR 28



	Maximum Load (lbf)	Specimen label	Notes
1	5.38	2525-10, T=0 Pencil 3	Connector broke free
2	6.81	2525-10, T=0 Pencil 4	Connector broke free
3	5.40	2525-10, T=0 Pencil 5	Connector broke free
4	6.43	2525-10, T=0 Pencil 6	Connector broke free
5	6.44	2525-10, T=0 Pencil 7	Connector broke free
6	5.68	2525-10, T=0 Pencil 8	Connector broke free
7	5.48	2525-10, T=0 Pencil 9	Connector broke free
8	5.39	2525-10, T=0 Pencil 10	Connector broke free
9	5.52	2525-10, T=0 Pencil 11	Connector broke free
10	5.68	2525-10, T=0 Pencil 12	Connector broke free
11	6.47	2525-10, T=0 Pencil 13	Connector broke free
Maximum	6.81		
Mean	5.88		
Minimum	5.38		
Standard Deviation	0.54067		

By Paul Valpreda 3-20-2014

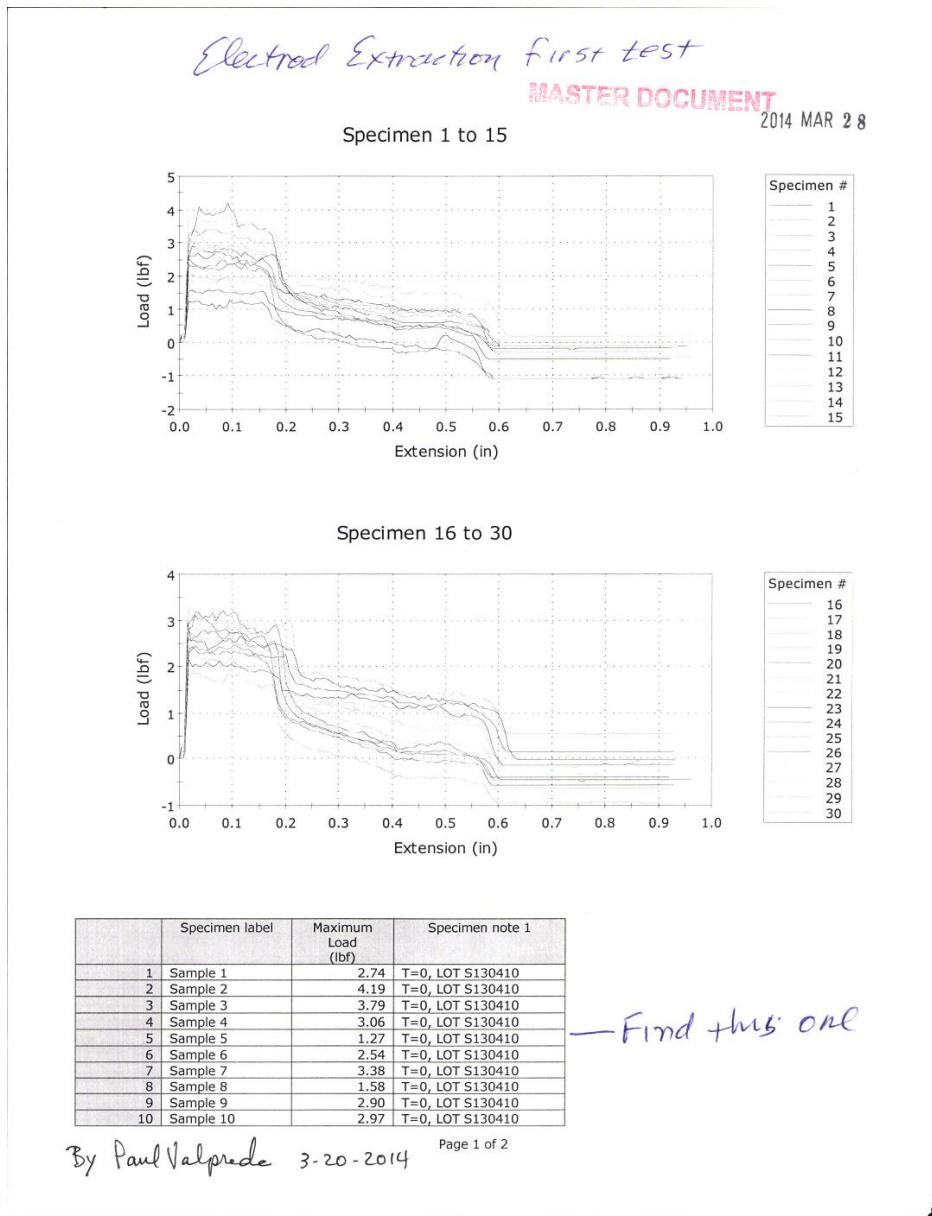
Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously omitted calibration information. See Appendix XII for calibration record applicable to this test date. Only one Instron was in use at Megadyne, Asset # 01028

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APPENDIX VI
E-Z Clear Handpiece Electrode Extraction Force



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-329
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	Specimen label	Maximum Load (lbf)	Specimen note 1
11	Sample 11	2.57	T=0, LOT S130410
12	Sample 12	3.26	T=0, LOT S130410
13	Sample 13	3.41	T=0, LOT S130410
14	Sample 14	1.96	T=0, LOT S130410
15	Sample 15	2.06	T=0, LOT S130410
16	Sample 16	3.12	T=0, LOT S130410
17	Sample 17	3.22	T=0, LOT S130410
18	Sample 18	2.35	T=0, LOT S130410
19	Sample 19	2.35	T=0, LOT S130410
20	Sample 20	2.16	T=0, LOT S130410
21	Sample 21	2.80	T=0, LOT S130409
22	Sample 22	2.21	T=0, LOT S130409
23	Sample 23	2.99	T=0, LOT S130409
24	Sample 24	2.43	T=0, LOT S130409
25	Sample 25	3.33	T=0, LOT S130409
26	Sample 26	2.47	T=0, LOT S130409
27	Sample 27	3.10	T=0, LOT S130409
28	Sample 28	2.78	T=0, LOT S130409
29	Sample 29	3.21	T=0, LOT S130409
30	Sample 30	1.87	T=0, LOT S130409
Maximum		4.19	
Mean		2.74	
Minimum		1.27	
Standard Deviation		0.64712	

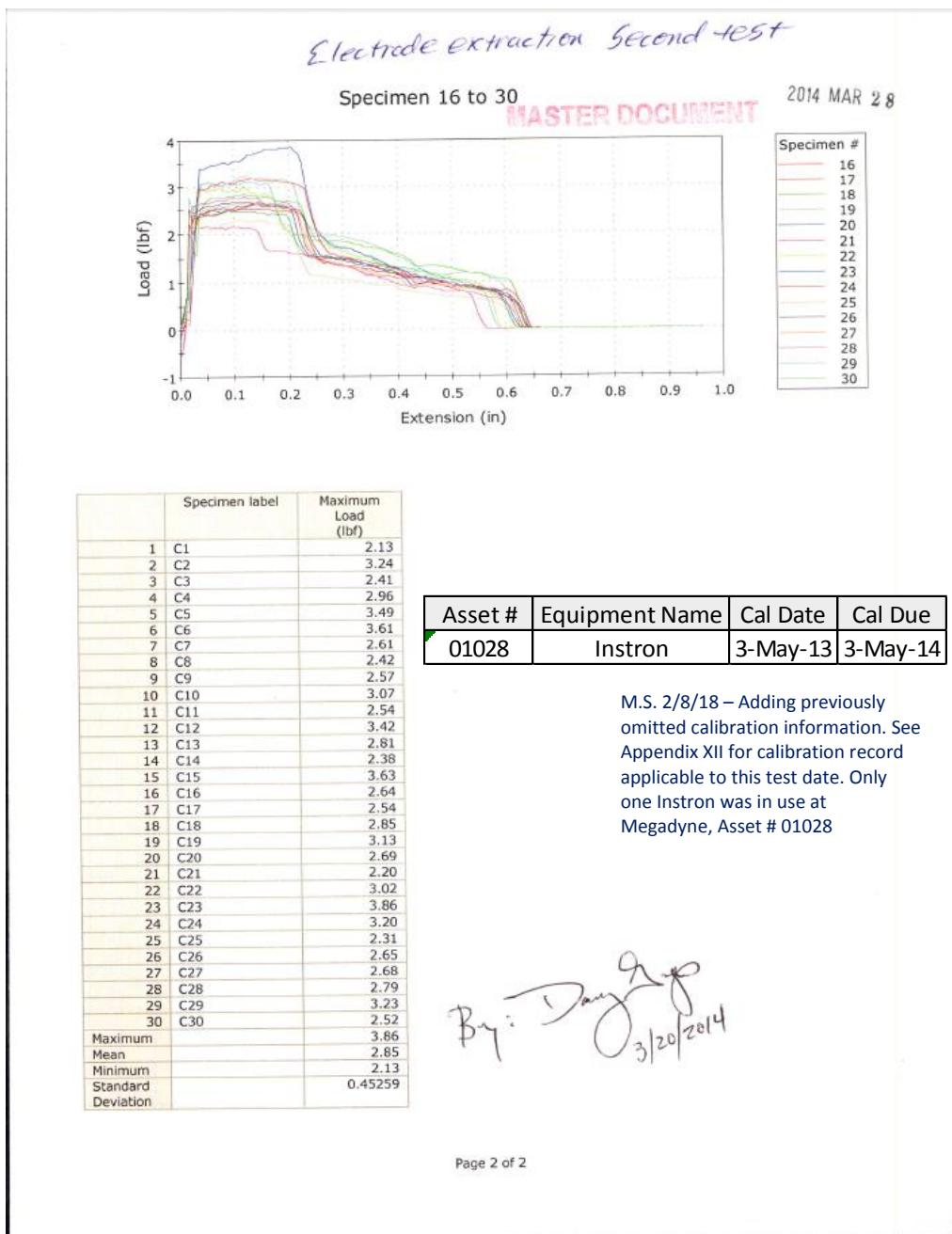
MASTER DOCUMENT

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Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously omitted calibration information. See Appendix XII for calibration record applicable to this test date. Only one Instron was in use at Megadyne, Asset # 01028

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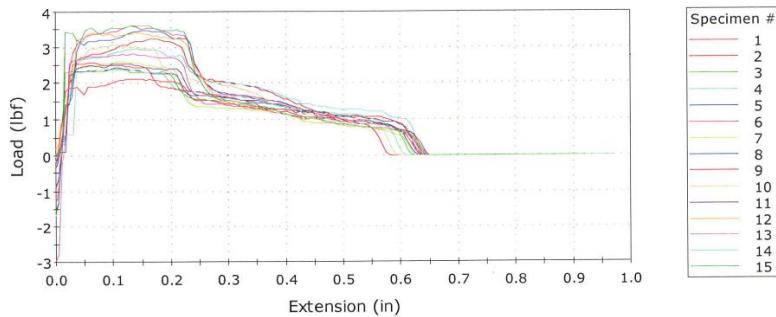
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MASTER DOCUMENT

- Use 50 N Transducer with "swivel" connector for clamp (giving more freedom of movement)
- Zero the load with pin installed in upper clamp
- Push pencil collet onto pin
- Reset position of crosshead while holding pencil body out of the way of the fixture (which is clamped into the bottom clamp)
- Upon reaching the home position, push the pencil body into the fixture
- Run the test
- This provides an accurate zero position for the Instron to measure from when pulling out of the collet, even though the starting force for each pencil will be different due to location in the fixture, etc.
- The results should be more accurate than inserting the pin into the collet and then zeroing the transducer because of forces applied upon insertion that are not zeroed out because the pencil is not allowed any freedom of movement after the insertion.

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Specimen 1 to 15



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Zip Pencil Electrode Retention Evaluation		
Sample Number	Config.	Held Electrode PASS/FAIL
1	2525-10 LOT S130410	PASS
2	2525-10 LOT S130410	PASS
3	2525-10 LOT S130410	PASS
4	2525-10 LOT S130410	PASS
5	2525-10 LOT S130410	PASS
6	2525-10 LOT S130410	PASS
7	2525-10 LOT S130410	PASS
8	2525-10 LOT S130410	PASS
9	2525-10 LOT S130410	PASS
10	2525-10 LOT S130410	PASS
11	2525-10 LOT S130410	PASS
12	2525-10 LOT S130410	PASS
13	2525-10 LOT S130410	PASS
14	2525-10 LOT S130410	PASS
15	2525-10 LOT S130410	PASS
16	2525-10 LOT S130410	PASS
17	2525-10 LOT S130410	PASS
18	2525-10 LOT S130410	PASS
19	2525-10 LOT S130410	PASS
20	2525-10 LOT S130410	PASS
21	2525-10 LOT S130409	PASS
22	2525-10 LOT S130409	PASS
23	2525-10 LOT S130409	PASS
24	2525-10 LOT S130409	PASS
25	2525-10 LOT S130409	PASS
26	2525-10 LOT S130409	PASS
27	2525-10 LOT S130409	PASS
28	2525-10 LOT S130409	PASS
29	2525-10 LOT S130409	PASS
30	2525-10 LOT S130409	PASS

2/15/2014
PV

Paul Valpreda
Operator Name

Paul Valpreda
Operator Signature

2/15/2014
Date

MASTER DOCUMENT

2014 MAR 28

Calibration Information:

Brass Weights	
N/A	
Serial Number	56206
Megadyne Number	01085
Calibration Date	1/30/2012
Calibration Due	1/31/2022

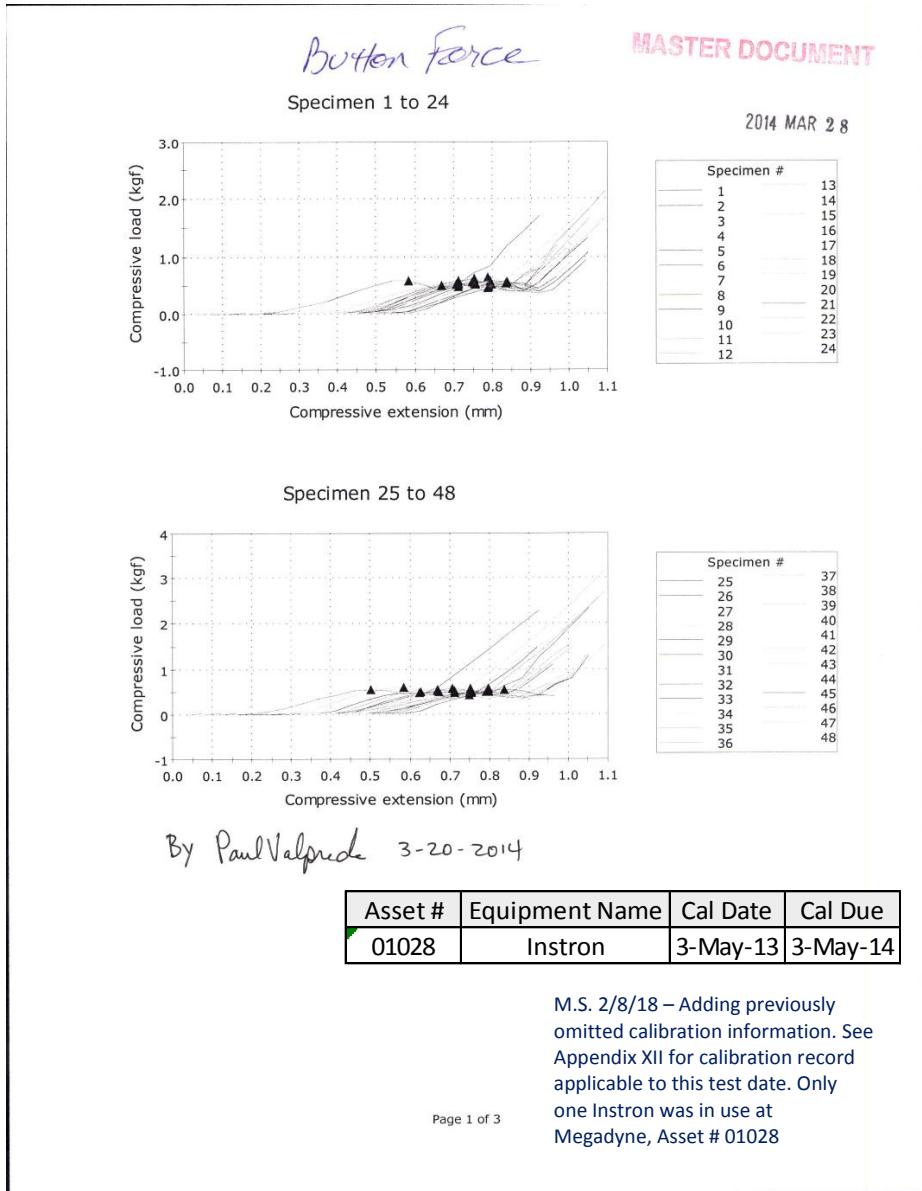
Weight (grams): 60.07

Scale

CEN-TECH Digital Scale (Paint Room)	
Serial Number	N/A
Megadyne No.	01248
Calibration Date	08/2013
Calibration Due	8/31/2014

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APPENDIX VII
E-Z Clear Button Force

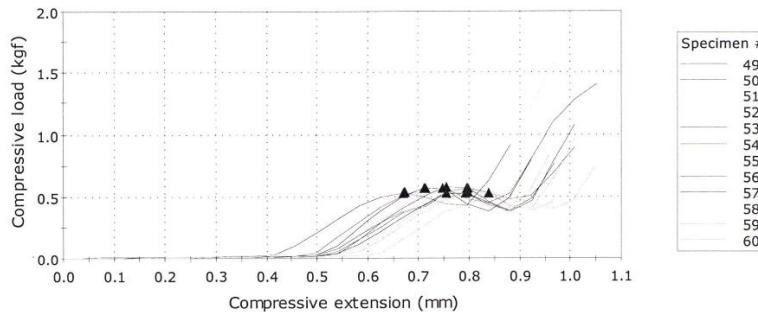


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Specimen 49 to 60

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Specimen #
49
50
51
52
53
54
55
56
57
58
59
60

	Compressive load at Preset Point (Cursor) (kgf)	Specimen label	Notes
1	0.47442	A3 Sample 1 CUT	
2	0.54285	A3 Sample 1 COAG	
3	0.51533	A3 Sample 2 CUT	
4	0.48514	A3 Sample 2 COAG	
5	0.53287	A3 Sample 3 CUT	
6	0.57232	A3 Sample 3 COAG	
7	0.57281	A3 Sample 4 CUT	
8	0.52605	A3 Sample 4 COAG	
9	0.55722	A3 Sample 5 CUT	
10	0.50486	A3 Sample 5 COAG	
11	0.58279	A3 Sample 6 CUT	
12	0.56209	A3 Sample 6 COAG	
13	0.51192	A3 Sample 7 CUT	
14	0.47880	A3 Sample 7 COAG	
15	0.54041	A3 Sample 8 CUT	
16	0.54870	A3 Sample 8 COAG	
17	0.52726	A3 Sample 9 CUT	
18	0.60763	A3 Sample 9 COAG	
19	0.56623	A3 Sample 10 CUT	
20	0.54017	A3 Sample 10 COAG	
21	0.58084	A3 Sample 11 CUT	
22	0.62225	A3 Sample 11 COAG	
23	0.50973	A3 Sample 12 CUT	
24	0.44763	A3 Sample 12 COAG	
25	0.56185	A3 Sample 13 CUT	
26	0.53944	A3 Sample 13 COAG	
27	0.58840	A3 Sample 14 CUT	
28	0.49560	A3 Sample 14 COAG	
29	0.47880	A2 Sample 7 CUT	
30	0.46784	A2 Sample 7 COAG	
31	0.51606	B2 Sample 2 CUT	
32	0.46930	B2 Sample 2 COAG	
33	0.49146	B2 Sample 7 CUT	
34	0.48514	B2 Sample 7 COAG	
35	0.50437	B2 Sample 8 CUT	
36	0.41926	B2 Sample 8 COAG	
37	0.52312	B2 Sample 10 CUT	

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MASTER DOCUMENT			
	Compressive load at Preset Point (Cursor) (kgf)	Specimen label	Notes
38	0.51899	B2 Sample 10 COAG	
39	0.47320	B2 Sample 14 CUT	
40	0.49439	B2 Sample 14 COAG	
41	0.48927	B3 Sample 11 CUT	
42	0.52970	B3 Sample 11 COAG	
43	0.55332	B3 Sample 12 CUT	
44	0.56136	B3 Sample 12 COAG	
45	0.54431	B3 Sample 13 CUT	
46	0.52849	B3 Sample 13 COAG	
47	0.47028	B3 Sample 14 CUT	
48	0.55478	B3 Sample 14 COAG	
49	0.57841	B3 Sample 15 CUT	
50	0.52361	B3 Sample 15 COAG	
51	0.52483	B3 Sample 16 CUT	
52	0.56867	B3 Sample 16 COAG	
53	0.56769	B3 Sample 17 CUT	
54	0.56258	B3 Sample 17 COAG	
55	0.53262	B3 Sample 18 CUT	
56	0.53092	B3 Sample 18 COAG	
57	0.52970	B3 Sample 19 CUT	
58	0.57110	B3 Sample 19 COAG	
59	0.56988	B3 Sample 20 CUT	
60	0.53701	B3 Sample 20 COAG	
Maximum	0.62225		
Minimum	0.41926		
Mean	0.52943		
Standard Deviation	0.04		

Testing was performed on 2/18/2014 by Paul Valpreda

Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously omitted calibration information. See Appendix XII for calibration record applicable to this test date. Only one Instron was in use at Megadyne, Asset # 01028

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APPENDIX VIII

E-Z Clear Handpiece Plug Strain Relief

MASTER DOCUMENT

2014 MAR 28

Zip Pencil Testing, P/N 2525-10 : LOT #s S130230 (A2) & S130227 (B2) - Plug End Rotation Data

PLUG			
ROTATION ON PLUG - 100 CYCLES			
Sample Number	Rotation P/F	Sample Number	Rotation P/F
A2-1	PASS		
A2-2	PASS		
A2-3	PASS		
A2-4	PASS		
A2-5	PASS		
A2-6	PASS		
A2-7	PASS		
A2-8	PASS		
A2-9	PASS		
A2-10	PASS		
A2-11	PASS		
A2-12	PASS		
A2-13	PASS		
A2-14	PASS		
A2-15	PASS		
B2-1	PASS		
B2-2	PASS		
B2-3	PASS		
B2-4	PASS		
B2-5	PASS		
B2-6	PASS		
B2-7	PASS		
B2-8	PASS		
B2-9	PASS		
B2-10	PASS		
B2-11	PASS		
B2-12	PASS		
B2-13	PASS		
B2-14	PASS		
B2-15	PASS		
Mass: 18.41 g		Date: 2/8/2014	
Resistance Pass Value (Ω): <50			

CALIBRATION INFORMATION	
Metric Scale	
CEN-TECH Digital Scale (Paint Room)	
Serial Number	N/A
Megadyne No.	01248
Calibration Date	08/2013
Calibration Due	8/31/2014

Brass Weights	
N/A	
Serial Number	56206
Megadyne Number	1085
Calibration Date	1/30/2012
Calibration Due	1/30/2022

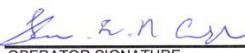
M.S. 1/9/18 – Fixing typo, see attached calibration record in Appendix XI and recorded dates in Appendix VI for further evidence of calibration date of this equipment

Thomas Carlyle 2/8/2014
OPERATOR NAME DATE


2014-2-26
OPERATOR SIGNATURE DATE

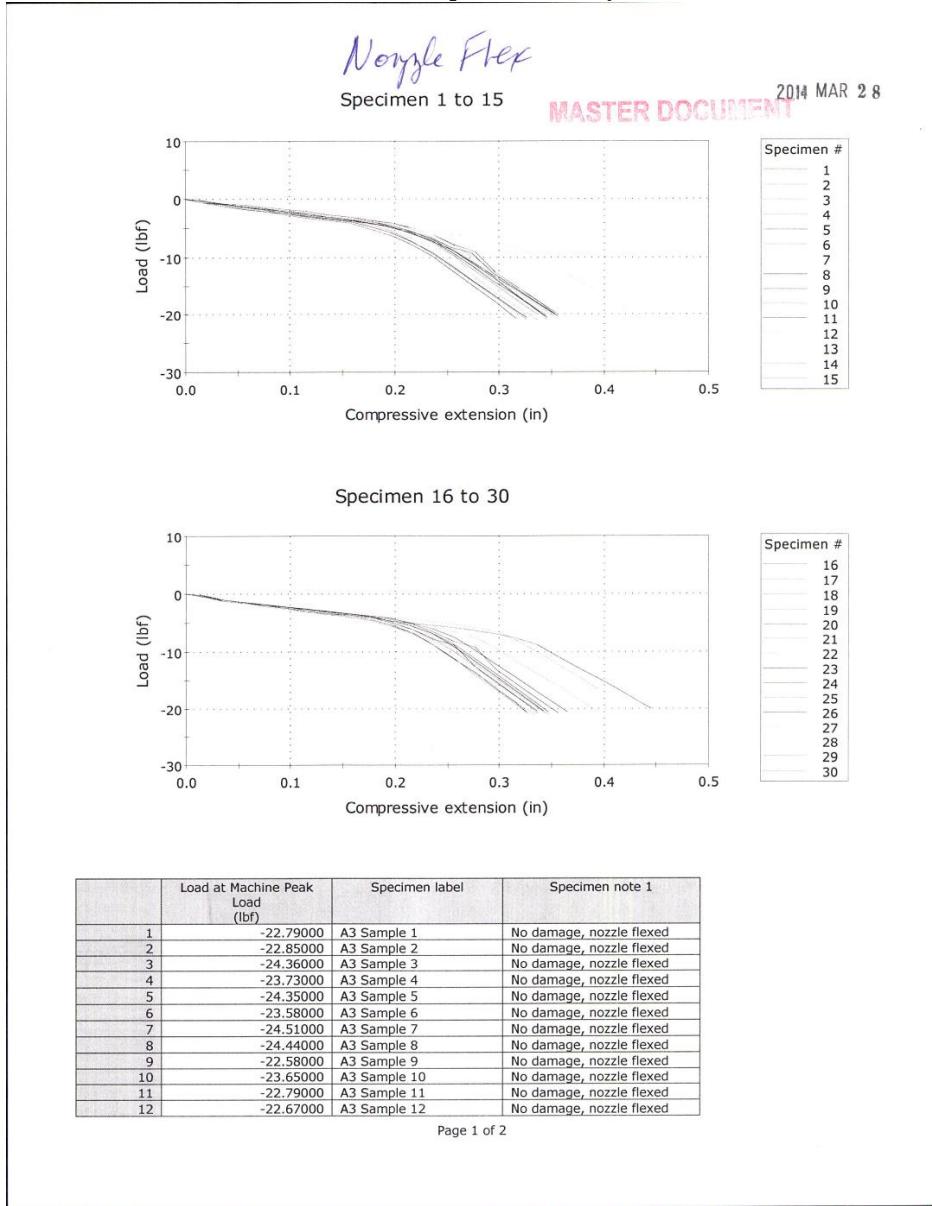
Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-329
	Zip Pencil Mechanical	Revision: C
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APPENDIX IX
E-Z Clear Handpiece Pencil Strain Relief

PENCIL : 2525-10 - LOT S130230 (A2) & LOT S130227 (B2)			
ROTATION ON PENCIL - 200 CYCLES			
Sample Number	Rotation P/F	Sample Number	Rotation P/F
A2-1	P		
A2-2	P		
A2-3	P		
A2-4	P		
A2-5	P		
A2-6	P		
A2-8	P		
A2-9	P		
A2-10	P		
A2-11	P		
A2-12	P		
A2-13	P		
A2-14	P		
A2-15	P		
A2-16	P		
B2-1	P		
B2-2	P		
B2-3	P		
B2-4	P		
B2-5	P		
B2-6	P		
B2-7	P		
B2-8	P		
B2-9	P		
B2-10	P		
B2-11	P		
B2-12	P		
B2-13	P		
B2-14	P		
B2-15	P		
Mass: 80 g	Date: 2/15/2014		
Resistance Pass Value (Ω): <50			
NOTE: Sample A2-7 tubing torn where it connects to the handpiece. Therefore it was dropped. A2-16 used instead.			
Thomas L N Carlyle		2/15/2014	
OPERATOR NAME		DATE	
		2014-2-26	
OPERATOR SIGNATURE		DATE	

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-329
	Zip Pencil Mechanical	Revision: C
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APPENDIX X
E-Z Clear Handpiece Nozzle Pry Force



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-329
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	Load at Machine Peak Load (lbf)	Specimen label	Specimen note 1
13	-23.88000	A3 Sample 13	No damage, nozzle flexed
14	-25.38000	A3 Sample 14	No damage, nozzle flexed
15	-24.79000	B3 Sample 11	No damage, nozzle flexed
16	-22.95000	B3 Sample 12	No damage, nozzle flexed
17	-23.07000	B3 Sample 13	No damage, nozzle flexed
18	-23.40000	B3 Sample 14	No damage, nozzle flexed
19	-22.78000	B3 Sample 15	No damage, nozzle flexed
20	-23.30000	B3 Sample 16	No damage, nozzle flexed
21	-22.15000	B3 Sample 17	No damage, nozzle flexed
22	-23.83000	B3 Sample 18	No damage, nozzle flexed
23	-23.17000	B3 Sample 19	No damage, nozzle flexed
24	-23.23000	B3 Sample 20	No damage, nozzle flexed
25	-23.56000	A2 Sample 7	No damage, nozzle flexed
26	-23.36000	B2 Sample 11	No damage, nozzle flexed
27	-23.54000	B2 Sample 12	No damage, nozzle flexed
28	-24.76000	B2 Sample 13	No damage, nozzle flexed
29	-24.27000	B2 Sample 14	No damage, nozzle flexed
30	-23.41000	B2 Sample 15	No damage, nozzle flexed
Maximum	-22.15000		
Minimum	-25.38000		
Mean	-23.57100		
Standard Deviation	0.77		

2014 MAR 28

Testing was performed on 2/24/2014 by Paul Valpreda

Paul Valpreda 3-20-2014

Asset #	Equipment Name	Cal Date	Cal Due
01028	Instron	3-May-13	3-May-14

M.S. 2/8/18 – Adding previously omitted calibration information. See Appendix XII for calibration record applicable to this test date. Only one Instron was in use at Megadyne, Asset # 01028

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APPENDIX XI 01085 Brass Weights Calibration Information

105 West 2950 South
Salt Lake City, Utah 84115
Phone: 801-464-7700
Fax: 801-464-5107
westerncal.com



WSC Report Number: 400596
Asset Number: 01085

SUBCONTRACTOR CALIBRATION

Western States Calibration subcontracted the calibration of this item using an approved vendors list. This document serves as a cover sheet for the subcontractor's calibration certificate. The results reported on this attached certificate apply only to the item calibrated.

Attention: Alan Holt
Megadyne Medical Products
11506 South State Street
Draper, UT 84020

Received: 01/20/2012
Date Done: 01/30/2012
Date Due: 01/31/2022
Calibration Interval: 120 Months
Calibrated at Customer's Site: False

Asset Number: 01085
Manufacturer S/N: UNKNOWN
Instrument: Set, Weight,
Manufacturer: Unknown
Model Number: 20 G TO 1 KG

As Found: In Tolerance
As Returned: In Tolerance
Physical Damage: False
Returned Not Calibrated: False

Vendor: Quality Control Services
2340 SE 11th Avenue
Portland, OR 97214

Vendor Contact: Main Line
Vendor Phone: 503-236-2712

Comments (i.e. adjustments, repairs, modifications, limitations and/or deviations from procedure):

Tested by Quality Control Services, Inc. Refer to 2 page attachment. Traceable Number: 20120212.

WSC Authorized Signatory: Janice 2/3/12

et
02/01/12

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QUALITY CONTROL SERVICES

LABORATORY EQUIPMENT • SALES • SERVICE • CALIBRATION • REPAIRS
2340 SE 11TH Ave. Portland, Oregon 97214 • Box 14831 Portland, Oregon 97293
(503) 236-2712 • FAX (503) 236-2885 • www.qc-services.com



Report of Calibration

Firm: Western States Calibration
Address: 105 West 2950 South
City/State/Zip: Salt Lake City, UT 84115

Test Completed: 01/30/12
Purchase Order: 400616
Traceable Number: 20120212

Test Item: 1kg to 20g Weight Set
Asset No.: 01085

Manufacturer: Troemner

Material: Brass Assumed Density: 8.39 g/cm³

Range: 1kg to 20g Tolerance Class: ASTM Class 6

Method and Traceability

The procedure used for this calibration is NIST IR 6969 Stage 4 Double Substitution Weighing Design. Standards used for comparison are traceable to the National Institute of Standards and Technology (reports on file) and are part of a comprehensive measurement assurance program for ensuring continued accuracy and traceability within the level of uncertainty reported. The Traceable Number listed above is Traceable to National Standards through an unbroken chain of comparison each having stated uncertainty.

Standards Used:

20kg to 200g Working Standards Were Calibrated: 11/23/11 Due: 12/31/12 Standards ID: 7764
100g to 1mg Working Standards Were Calibrated: 04/14/12 Due: 04/14/12 Standards ID: 723318
Mass Comparators Used: MET-04, 05 Test Facility: Ross

Conventional Mass: "The conventional value of the result of weighing a body in air is equal to the mass of a standard, of conventionally chosen density, at a conventionally chosen temperature, which balances this body at this reference temperature in air of conventionally chosen density. International Recommendation 83 (OIML IR 33 1973, 1979). "Conventional Value of the Result of Weighing in Air" (Previously known as "Apparent Mass") is 8.0g/cm³.

Uncertainty: The uncertainty is calculated according to NIST Technical Note 1297. The reported uncertainty of the standard is combined with the uncertainty of the measurement process in a root sum square formula using a K factor of 2 to give an approximate 95% level of confidence.

Conventional Mass Values are listed on page 2 of this report.

page 1 of 2

Date: 01/30/12

Signature James E. Ross

Quality Control Services, Inc.
Metrology Laboratory Manager
E-mail jross@qc-services.com

This document shall not be reproduced, except in full, without the express approval of Quality Control Services Mass Laboratory.
Form number WT00 Customer number WPS03 Revision Date: 11/12/09

Member: National Conference of Standards Laboratories and Weights & Measures

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Established 1974

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2340 SE 11th Ave. Portland, Oregon 97214-14831 Portland, Oregon 97293
(503) 236-2712 • FAX (503) 236-2335 • www.qc-services.com



Calibration Services
Certificate Number: 1550.01
Laboratory code: 115953

Report of Calibration

Firm: Western States Calibration
Address: 105 West 2950 South
City/State/Zip: Salt Lake City, UT 84115

Test Completed: 01/30/12
Purchase Order: 400616
Traceable Number: 20120212

Test Item: 1kg to 20g Weight Set
Asset No.: 01085

Manufacturer: Troemner

Laboratory Environment at time of test

Temperature °C	Pressure mmHg	Humidity %RH
21.664	762.963	46.4

Conventional Mass Value

Nominal Value	As Found grams	As Found Correction (mg)	Uncertainty (mg)	Tolerance (mg)
1kg	999.99673000	-3.2700	0.1487	100
500g	500.00268800	2.6880	0.1182	50
200g	200.00527101	5.2710	0.1036	20
200g 1 dot	200.01285052	12.8505	0.1036	20
100g	99.99917949	-0.8205	0.1016	10
50g	50.00411527	4.1153	0.1006	7
20g	19.99934443	-0.6556	0.1003	3

Comments: These weights were received in good condition and were within ASTM Class 6 tolerances As Found.
As Found values should be considered to be As Left values.

Accredited by the American Association for Laboratory Accreditation (A2LA) under Calibration Laboratory Code 115953 and Certificate Number 1550.01. This laboratory meets the requirements of ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. This laboratory also meets the requirements of ANSI/ASL Z540-1-1994 and any additional program requirements in the field of calibration.

Quality Control Services, Inc.
Metrology Laboratory Manager

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Date: 01/30/12

Signature James E. Ross

Member: National Conference of Standards Laboratories and Weights & Measures

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APPENDIX XII 01028 Instron Calibration Information

Device ID 01028

CERTIFICATE OF CALIBRATION

ISSUED BY: INSTRON CALIBRATION LABORATORY

DATE OF ISSUE: 03-May-13 CERTIFICATE NUMBER: 228050313100530

INSTRON®

Instron
825 University Avenue
Norwood, MA 02062-2643
Telephone: (800) 473-7838
Fax: (781) 575-6750
Email: service_requests@instron.com

Type of Calibration: Force
Relevant Standard: ASTM E4-10
Date of Calibration: 03-May-13

Perry Kunz
Customer Requested Due Date: 03-May-14

Digitally signed by Perry Kunz
DN: cn=Perry Kunz, ou=US, i=Norwood,
st=MA, ou=LER
Date: 2013.05.03 16:58:58 -04'00'
I attest to the accuracy and
integrity of this document
Date: 2013.05.03 16:58:58 -04'00'

Customer

Name: Megadyne Medical Prod
Address: 11506 S State Street
Draper, UT 84020
AHOLT@MEGADYNE.COM
P.O./Contract No.: FP05054_2
Contact: Alan Holt

Machine

Manufacturer: 4464 Manufacturer: Instron
Serial Number: 4464C2820 Transducer ID: 2525-816/0306
System ID: 4464C6638 Capacity: 100 lbf
Range Type: Auto Type: Tension/Compression

BS/11/13

Classification

1. GPIB - PASSED

Certification Statement

This certifies that the forces verified with machine indicator(s) (listed above) that passed are WITHIN $\pm 1\%$ accuracy, 1% repeatability, and zero return tolerance.
All machine indicators were verified on-site at customer location by Instron in accordance with ASTM E4.
The certification is based on runs 1 and 2 only. A third run is taken to satisfy uncertainty requirements according to ISO 17025 specifications.
The verification and equipment used conform to a controlled Quality Assurance program which meets the specifications outlined in ANSI/NCSL Z540-1, ISO 10012, ISO 9001:2008 and ISO/IEC 17025:2005.

Method

The testing machine was verified in the 'as found' condition with no adjustments carried out.

The load cell indicated on this certificate was removed from the force measuring system and verified per ASTM E4, Annex A1.3.

Instron CalproCR Version 3.24

The results indicated on this certificate and the following report relate only to the items verified. If there are methods or data included that are not covered by the NVLAP accreditation it will be identified in the comments. Any limitations of use as a result of this verification will be indicated in the comments. This report must not be used to claim product endorsement by NVLAP or the United States government. This report shall not be reproduced, except in full, without the approval of the issuing laboratory.

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CERTIFICATE OF CALIBRATION

NVLAP ACCREDITED CALIBRATION LABORATORY No. 200301-0

CERTIFICATE NUMBER:
228050313100530

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Summary of Results

Temperature at start of verification: 72.80 °F.

Indicator 1. - GPIB (lbf)

Range (%)	Full Scale (lbf)	Tested Force Range (lbf)	Mode	ASTM E4 Max Error (%)	ASTM E4 Max Repeat Error (%)	Zero Return	Resolution (lbf)	ASTM E4 Lower Limit (lbf)
100	1.10149 to 100.3165	T		0.98	0.07	Pass	0.0027	0.54
100	-1.10149 to -100.4883	C		0.64	0.09	Pass	0.0027	0.54

Temperature at end of verification: 73.00 °F.

Data Point Summary - Indicator 1. - GPIB (lbf)

TENSION

% of Range	Run 1 Error (%)	Run 2 Error (%)	Run 3 Error (%)	ASTM E4 Repeat Error (%)	Relative Uncertainty* (%)	Uncertainty of Measurement* (± lbf)
100% Range (Full Scale: 100.3165 lbf)						
1	0.68	0.68	0.68	0.00	0.19	0.002
2	0.55	0.55	0.55	0.00	0.14	0.003
4	0.59	0.52	0.52	0.07	0.14	0.006
7	0.81	0.88	0.83	0.07	0.14	0.010
10	0.88	0.89	0.86	0.01	0.13	0.015
20	0.87	0.86	0.78	0.01	0.15	0.030
40	0.88	0.84	0.85	0.04	0.13	0.053
70	0.89	0.88	0.90	0.01	0.13	0.094
100	0.98	0.97	0.98	0.01	0.13	0.129

Data Point Summary - Indicator 1. - GPIB (lbf)

COMPRESSION

% of Range	Run 1 Error (%)	Run 2 Error (%)	Run 3 Error (%)	ASTM E4 Repeat Error (%)	Relative Uncertainty* (%)	Uncertainty of Measurement* (± lbf)
100% Range (Full Scale: -100.4883 lbf)						
1	0.14	0.14	0.14	0.00	0.19	0.002
.2	0.64	0.55	0.27	0.09	0.27	0.006
4	0.41	0.34	0.30	0.07	0.15	0.006
7	0.53	0.58	0.55	0.05	0.13	0.010
10	0.42	0.41	0.42	0.01	0.13	0.013
20	0.46	0.46	0.47	0.00	0.13	0.028
40	0.39	0.39	0.38	0.00	0.13	0.052
70	0.25	0.26	0.26	0.01	0.13	0.093
100	0.11	0.07	0.09	0.04	0.13	0.132

* The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, providing a level of confidence of approximately 95%.

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NVLAP ACCREDITED CALIBRATION LABORATORY No. 200301-0

CERTIFICATE NUMBER:
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Data - Indicator 1 - GPIB (lbf)

TENSION

% of Range	Run 1		Run 2		Run 3	
	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)
100% Range (Full Scale: 100.3165 lbf)						
0 Return	0.00536		0.00805		0	
1	1.109	1.10149	1.109	1.10149	1.109	1.10149
2	2.215	2.20297	2.215	2.20297	2.215	2.20297
4	4.432	4.40594	4.429	4.40594	4.429	4.40594
7	6.948	6.89248	8.268	8.19616	7.152	7.09312
10	12.34	12.23264	11.11	11.01184	11.74	11.63936
20	22.12	21.9296	20.98	20.80192	20.25	20.0928
40	38.75	38.4128	42.82	42.46336	40.15	39.81152
70	70.79	70.16448	74.44	73.7888	70.9	70.27104
100	101.3	100.31648	100.7	99.73248	100.7	99.7264

Data - Indicator 1 - GPIB (lbf)

COMPRESSION

% of Range	Run 1		Run 2		Run 3	
	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)
100% Range (Full Scale: -100.4883 lbf)						
0 Return	-0.00537		0.00536		-0.00806	
1	-1.103	-1.10149	-1.103	-1.10149	-1.103	-1.10149
2	-2.217	-2.20297	-2.215	-2.20297	-2.209	-2.20297
4	-4.424	-4.40594	-4.421	-4.40594	-4.419	-4.40594
7	-6.816	-6.77984	-7.506	-7.46304	-7.705	-7.66304
10	-10.45	-10.40672	-9.584	-9.54464	-9.697	-9.65664
20	-21.22	-21.12224	-20.59	-20.496	-21.07	-20.97088
40	-39.8	-39.64352	-40.8	-40.6432	-40.2	-40.04768
70	-70.71	-70.536	-72.64	-72.45024	-71.27	-71.08704
100	-100.6	-100.48832	-100.5	-100.42784	-101	-100.91328

The Return to Zero tolerance is \pm the indicator resolution, 0.1 % of the maximum force verified in the range, or 1% of the lowest force verified in the range, whichever is greater.

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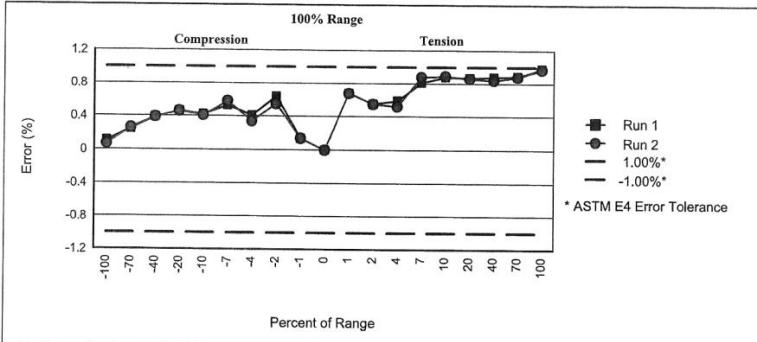
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NVLAP ACCREDITED CALIBRATION LABORATORY No. 200301-0

CERTIFICATE NUMBER:
228050313100530

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Graphical Data - Indicator 1 - GPIB (lbf)



Verification Equipment

Make/Model	Serial Number	Description	Calibration Agency	Capacity	Cal Date	Cal Due
Extech 445580	1025210	temp. indicator	Tektronix	NA	26-Jul-12	26-Jul-14
Interface 9840	67001	force indicator	Interface	NA	03-Oct-11	03-Oct-13
Interface 617108	617108	load cell	Instron	110 lbf	01-Nov-12	01-Nov-13
Troemner Dead Weights - Metric	136 (Metric)	dead weight set	Instron	NA	20-Apr-12	20-Apr-17

The value of acceleration due to gravity used to calculate the force exerted by the mass was 9.80081 m/s².

Verification Equipment Usage

Range	Full Scale (%)	Standard Serial Number	Mode	Percent(s) of Range	Lower Limit for Standard Class A / A1 (lbf)
100	617108	T	7/10/20/40/70/100	3 / 3	
100	136 (Metric)	T	1/2/4	NA	
100	617108	C	7/10/20/40/70/100	3 / 3	
100	136 (Metric)	C	1/2/4	NA	

Instron standards are traceable to NIST.

The standard Class A lower limit is used for systems with an accuracy of +/- 1.0% and the standard Class A1 lower limit is used for systems with an accuracy of +/- 0.5%.

Standard forces have been temperature compensated as necessary.

Comments

3 verification runs were performed.

Instron CalproCR Version 3.24

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+/- 1% of reading tolerance for each run as well as the repeatability between runs was observed.
Dead weights were rotated 240° between verification runs.

Verified by: Perry Kunz
Field Service Engineer

NOTE: Clause 20 of ASTM E4 states; It is recommended that testing machines be verified annually or more frequently if required. In no case shall the time interval between verifications exceed 18 months (except for machines in which long term test runs beyond the 18 month period). Testing machines shall be verified immediately after repairs that may in any way affect the operation of the weighing system or values displayed. Verification is required immediately after a testing machine is relocated and where there is a reason to doubt the accuracy of the force indicating system, regardless of the time interval since the last verification.

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Device 10 01028

CERTIFICATE OF CALIBRATION

ISSUED BY: INSTRON CALIBRATION LABORATORY

DATE OF ISSUE: 03-May-13 CERTIFICATE NUMBER: 228050313113505

Instron
825 University Avenue
Norwood, MA 02062-2643
Telephone: (800) 473-7838
Fax: (781) 575-5750
Email: service_requests@instron.com

NVLAP
Lab code: 200301-0

Page 1 of 5 pages

Perry Kunz
Duly signed by Perry Kunz
DN: ckerrykunz, cr:US, H:Norwood,
st:MA, ct:VER
Reason: I attest to the accuracy and
integrity of this document
Date: 2013.05.03 15:55:09 -06'00'

APPROVED SIGNATORY

Type of Calibration: Force
Relevant Standard: ASTM E4-10
Date of Calibration: 03-May-13
Customer Requested Due Date: 03-May-14

Customer
Name: Megadyne Medical Prod
Address: 11506 S State Street
Draper, UT 84020
AHOLT@MEGADYNE.COM
P.O./Contract No.: FP05054_2
Contact: Alan Holt

Machine
Manufacturer: 4464
Serial Number: 4464C2820
System ID: 4464C6638
Range Type: Auto

Transducer
Manufacturer: Instron
Transducer ID: 2525-817/0135
Capacity: 10 lbf
Type: Tension/Compression

Classification
1. GPIB - PASSED

Certification Statement
This certifies that the forces verified with machine indicator(s) (listed above) that passed are WITHIN $\pm 1\%$ accuracy, 1 % repeatability, and zero return tolerance.
All machine indicators were verified on-site at customer location by Instron in accordance with ASTM E4.
The certification is based on runs 1 and 2 only. A third run is taken to satisfy uncertainty requirements according to ISO 17025 specifications.
The verification and equipment used conform to a controlled Quality Assurance program which meets the specifications outlined in ANSI/NCSL Z340-1, ISO 10012, ISO 9001:2008 and ISO/IEC 17025:2005.

Method
The testing machine was verified in the 'as found' condition with no adjustments carried out.

The load cell indicated on this certificate was removed from the force measuring system and verified per ASTM E4, Annex A1.3.

Instron CalproCR Version 3.24

The results indicated on this certificate and the following report relate only to the items verified. If there are methods or data included that are not covered by the NVLAP accreditation it will be identified in the comments. Any limitations of use as a result of this verification will be indicated in the comments. This report must not be used to claim product endorsement by NVLAP or the United States government. This report shall not be reproduced, except in full, without the approval of the issuing laboratory.

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CERTIFICATE OF CALIBRATION

NVLAP ACCREDITED CALIBRATION LABORATORY No. 200301-0

CERTIFICATE NUMBER:
228050313113505

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Summary of Results

Temperature at start of verification: 72.60 °F.

Indicator 1. - GPIB (lbf)

Range (%)	Full Scale (lbf)	Tested Force Range (lbf)	Mode	ASTM E4 Max Error (%)	ASTM E4 Max Repeat Error (%)	Zero Return	Resolution (lbf)	ASTM E4 Lower Limit (lbf)
100	0.110149	to 9.91337	T	-0.59	0.05	Pass	0.00027	0.054
100	-0.110149	to -9.91337	C	-0.68	0.09	Pass	0.00027	0.054

Temperature at end of verification: 73.40 °F.

Data Point Summary - Indicator 1. - GPIB (lbf)

TENSION

% of Range	Run 1 Error (%)	Run 2 Error (%)	Run 3 Error (%)	ASTM E4 Repeat Error (%)	Relative Uncertainty* (%)	Uncertainty of Measurement* (± lbf)
100% Range (Full Scale: 9.91337 lbf)						
1	-0.59	-0.59	-0.32	0.00	0.26	0.000
2	-0.45	-0.45	-0.32	0.00	0.17	0.000
4	-0.43	-0.43	-0.37	0.00	0.16	0.001
7	-0.53	-0.53	-0.56	0.00	0.13	0.001
10	-0.50	-0.50	-0.59	0.00	0.14	0.002
20	-0.45	-0.50	-0.36	0.05	0.16	0.003
40	-0.52	-0.48	-0.41	0.04	0.14	0.006
70	-0.44	-0.48	-0.44	0.04	0.13	0.009
100	-0.51	-0.48	-0.48	0.03	0.13	0.013

Data Point Summary - Indicator 1. - GPIB (lbf)

COMPRESSION

% of Range	Run 1 Error (%)	Run 2 Error (%)	Run 3 Error (%)	ASTM E4 Repeat Error (%)	Relative Uncertainty* (%)	Uncertainty of Measurement* (± lbf)
100% Range (Full Scale: -9.91337 lbf)						
1	0.14	0.14	-0.04	0.00	0.22	0.000
.2	-0.45	-0.45	-0.54	0.00	0.16	0.000
4	-0.32	-0.38	-0.38	0.06	0.14	0.001
7	-0.32	-0.39	-0.32	0.07	0.14	0.001
10	-0.68	-0.59	-0.41	0.09	0.20	0.002
20	-0.59	-0.50	-0.54	0.09	0.14	0.003
40	-0.54	-0.52	-0.52	0.02	0.13	0.005
70	-0.61	-0.56	-0.48	0.05	0.15	0.009
100	-0.48	-0.40	-0.48	0.08	0.14	0.012

* The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, providing a level of confidence of approximately 95%.

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NVLAP ACCREDITED CALIBRATION LABORATORY No. 200301-0	CERTIFICATE NUMBER: 228050313113505
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Data - Indicator 1. - GPIB (lbf)

TENSION

% of Range	Run 1		Run 2		Run 3	
	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)
100% Range (Full Scale: 9.91337 lbf)						
0 Return	0.00644		0		-0.00081	
1	0.1095	0.110149	0.1095	0.110149	0.1098	0.110149
2	0.2193	0.220297	0.2193	0.220297	0.2196	0.220297
4	0.4387	0.440594	0.4387	0.440594	0.4381	0.440594
7	0.6574	0.660891	0.6574	0.660891	0.6572	0.660891
10	1.096	1.10149	1.096	1.10149	1.095	1.10149
20	2.193	2.20297	2.192	2.20297	2.195	2.20297
40	4.383	4.40594	4.385	4.40594	4.388	4.40594
70	6.58	6.60891	6.577	6.60891	6.58	6.60891
100	9.863	9.91337	9.866	9.91337	9.866	9.91337

Data - Indicator 1. - GPIB (lbf)

COMPRESSION

% of Range	Run 1		Run 2		Run 3	
	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)
100% Range (Full Scale: -9.91337 lbf)						
0 Return	0.00241		-0.00054		0.00026	
1	-0.1103	-0.110149	-0.1103	-0.110149	-0.1101	-0.110149
2	-0.2193	-0.220297	-0.2193	-0.220297	-0.2191	-0.220297
4	-0.4392	-0.440594	-0.4389	-0.440594	-0.4389	-0.440594
7	-0.6588	-0.660891	-0.6583	-0.660891	-0.6588	-0.660891
10	-1.094	-1.10149	-1.095	-1.10149	-1.097	-1.10149
20	-1.095	-1.10149	-2.192	-2.20297	-2.191	-2.20297
40	-2.191	-2.20297	-4.383	-4.40594	-4.383	-4.40594
70	-4.379	-4.40594	-6.572	-6.60891	-6.577	-6.60891
100	-6.577	-6.60891	-9.874	-9.91337	-9.866	-9.91337

The Return to Zero tolerance is \pm the indicator resolution, 0.1 % of the maximum force verified in the range, or 1% of the lowest force verified in the range, whichever is greater.

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Data - Indicator 1. - GPIB (lbf)

TENSION

% of Range	Run 1		Run 2		Run 3	
	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)
100% Range (Full Scale: 9.91337 lbf)						
0 Return	0.00644		0		-0.00081	
1	0.1095	0.110149	0.1095	0.110149	0.1098	0.110149
2	0.2193	0.220297	0.2193	0.220297	0.2196	0.220297
4	0.4387	0.440594	0.4387	0.440594	0.4381	0.440594
7	0.6574	0.660891	0.6574	0.660891	0.6572	0.660891
10	1.096	1.10149	1.096	1.10149	1.095	1.10149
20	2.193	2.20297	2.192	2.20297	2.195	2.20297
40	4.383	4.40594	4.385	4.40594	4.388	4.40594
70	6.58	6.60891	6.577	6.60891	6.58	6.60891
100	9.863	9.91337	9.866	9.91337	9.866	9.91337

Data - Indicator 1. - GPIB (lbf)

COMPRESSION

% of Range	Run 1		Run 2		Run 3	
	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)	Indicated (lbf)	Applied (lbf)
100% Range (Full Scale: -9.91337 lbf)						
0 Return	0.00241		-0.00054		0.00026	
1	-0.1103	-0.110149	-0.1103	-0.110149	-0.1101	-0.110149
2	-0.2193	-0.220297	-0.2193	-0.220297	-0.2191	-0.220297
4	-0.4392	-0.440594	-0.4389	-0.440594	-0.4389	-0.440594
7	-0.6588	-0.660891	-0.6583	-0.660891	-0.6588	-0.660891
10	-1.094	-1.10149	-1.095	-1.10149	-1.097	-1.10149
20	-1.095	-1.10149	-2.192	-2.20297	-2.191	-2.20297
40	-2.191	-2.20297	-4.383	-4.40594	-4.383	-4.40594
70	-4.379	-4.40594	-6.572	-6.60891	-6.577	-6.60891
100	-6.577	-6.60891	-9.874	-9.91337	-9.866	-9.91337

The Return to Zero tolerance is \pm the indicator resolution, 0.1 % of the maximum force verified in the range, or 1% of the lowest force verified in the range, whichever is greater.

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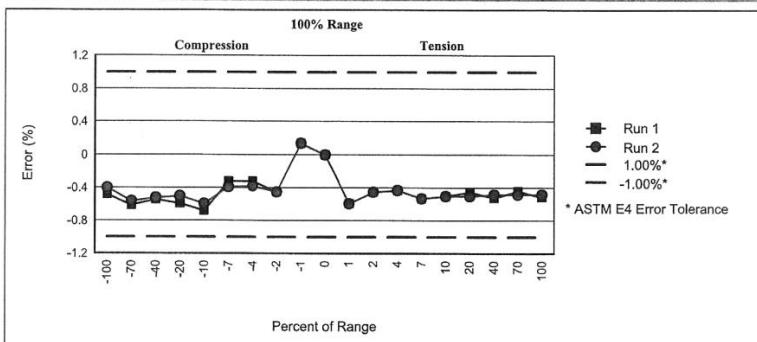
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Graphical Data - Indicator 1. - GPIB (lbf)



Verification Equipment

Make/Model	Serial Number	Description	Calibration Agency	Capacity	Cal Date	Cal Due
Extech 445580	1025210	temp. indicator	Tektronix	NA	26-Jul-12	26-Jul-14
Troemner Dead Weights - Metric	136 (Metric)	dead weight set	Instron	NA	20-Apr-12	20-Apr-17

The value of acceleration due to gravity used to calculate the force exerted by the mass was 9.80081 m/s^2 .

Verification Equipment Usage

Range	Full Scale (%)	Standard Serial Number	Mode	Percent(s) of Range	Lower Limit for Standard Class A / A1 (lbf)
100	136 (Metric)		T	1/2/4/7/10/20/40/70/100	NA
100	136 (Metric)		C	1/2/4/7/10/20/40/70/100	NA

Instron standards are traceable to NIST.

Standard forces have been temperature compensated as necessary.

Comments

3 verification runs were performed.
+/- 1% of reading tolerance for each run as well as the repeatability between runs was observed.
Dead weights were rotated 240° between verification runs.

Instron CalproCR Version 3.24

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Verified by: Perry Kunz
Field Service Engineer

NOTE: Clause 20 of ASTM E4 states; It is recommended that testing machines be verified annually or more frequently if required. In no case shall the time interval between verifications exceed 18 months (except for machines in which long term test runs beyond the 18 month period). Testing machines shall be verified immediately after repairs that may in any way affect the operation of the weighing system or values displayed. Verification is required immediately after a testing machine is relocated and where there is a reason to doubt the accuracy of the force indicating system, regardless of the time interval since the last verification.