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DOCUMENT TITLE: Zip Pen Product Specification Verification Test Report

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Title: Zip Pen Product Specification Verification Test Report

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ENG-RPT-418 Zip Product Verif Rpt

Change Request

Name/Signature	Title	Date	Meaning/Reason
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Collaboration

Name/Signature	Title	Date	Meaning/Reason
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Joni Stegeman (JSTEGEMAN)	Ethicon Quality	14 Feb 2018, 04:45:02 PM	Complete
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RA-Approval

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Joni Stegeman (JSTEGEMAN)	Ethicon Quality	21 Feb 2018, 08:47:02 AM	Approved

ENG-Approval

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Paul Borgmeier (PBORGMEIER)		20 Feb 2018, 11:08:18 AM	Approved

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Quick Approval

Approve Now

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Lucy Richards (LRICHARDS)		21 Feb 2018, 10:46:05 AM	Approved

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

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1. ABSTRACT

Zip Project Catalog Numbers 2525-10, 2525-15, 2540, 2560, 2211 and 2220 were evaluated for conformance to requirements of the product specification ENG-PS-007 that were not verified under other protocols. The evaluation was done per of ENG-PRT-290. The Zip Pen and other accessories for the Zip Project met the requirements of the protocol for 19 design attributes required by the Product Specification.

2. OBJECTIVE

The objective of this test report is to document conformance to requirements of the product specification ENG-PS-007 for attributes that are not verified in other protocols.

3. RESULTS

3.1. BUTTON SIZE

3.1.1. Zip Pen button size measures 0.0699 square inches. The disposable pencil button size is 0.0697 square inches. The surface area of the two buttons is approximately the same (within .0002 inches square) and meets the requirements of the protocol. See calculations in Appendix I.

3.2. BRANDING

3.2.1. The Zip Pen Handle is gray pantone 427 with green inly that is pantone 356. The Megadyne name is molded into the handle and colored green

pantone 356. This design meets the requirements of the protocol. See verification in Appendix II.

3.3. TIP EXPOSURE

3.3.1. The average tip exposure of the Zip Pen is 0.87". The average tip exposure of the UltraVac is 0.93". This comparison shows that the Zip Pen has a .06" shorter exposure than the Ultra Vac on average. Note that a shorter exposure is more desirable than a longer exposure. The comparison data is as follows:

Product	Average Tip Exposure, inches	Standard Deviation	Range
Zip Pen 2525-10	0.87	.007	.864 - .887
Ultra Vac 2110-10	0.93	.086	.820 – 1.012

The requirement in the product specification is that the Zip Paen tip exposure be comparable to the Ultra Vac. Note that the Zip Pen standard deviation is very small indicating that the tip exposure is very consistent from one pencil to the next. The Ultra Vac has a much larger standard deviation (over ten times larger) indicating that it is less consistent from one pencil to the other. The standard deviation of the Ultra Vac is larger than the difference between the two averages. Statistically, the averages are not equal for a confidence interval of 90%. However, the range of values for the Zip Pen is within the range of values for the Ultra Vac. Given this fact, it can be concluded that the tip exposure for the two devices is comparable and meets the protocol. In order to make the requirement clearer for the Zip pen Product Specification, the Product Specification will be revised to be more specific. See data in Appendix III.

3.4. NOZZLE CLARITY

3.4.1. The nozzle design is clear in the area of the electrode and meets the requirements of the protocol. See verification in Appendix IV

3.5. CORD CONTAINMENT

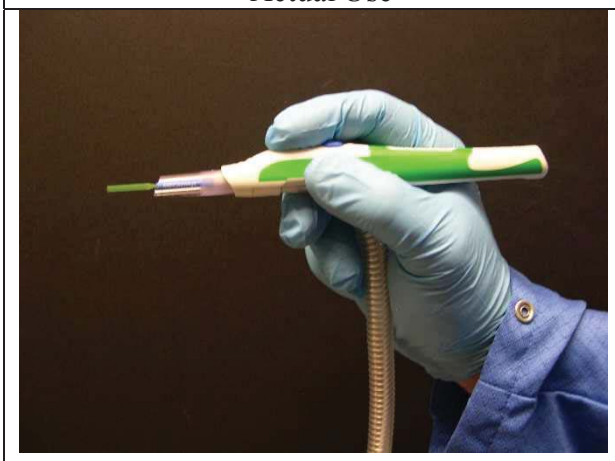
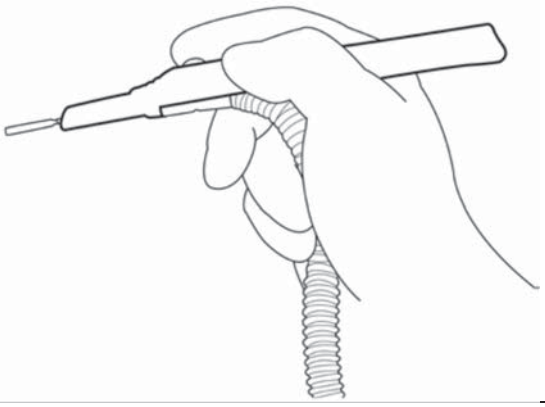
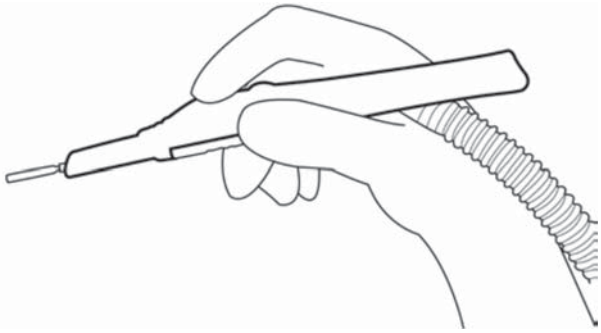
3.5.1. The cord is contained within the tubing for the first 64 inches and meets the requirements of the protocol. See verification in Appendix V.

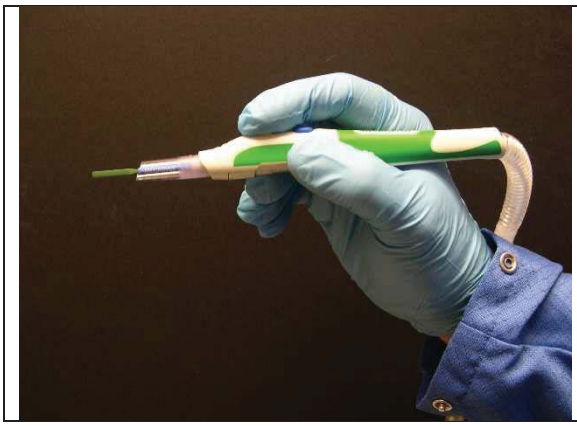
3.6. TUBING SWIVEL

3.6.1. The tubing has a swivel that is 8 inches from the connection to the Zip Pen and meets the requirements of the protocol. See verification in Appendix VI.

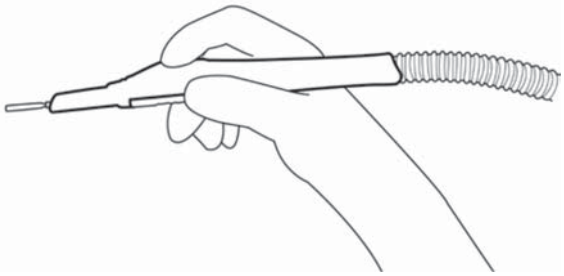
3.7. TUBING ERGONOMICS

3.7.1. The photo's below show that the tubing can be positioned in the manner that is shown in the IFU and meets the requirements of the protocol. See photos below and verification in Appendix VII.

Actual Use	IFU
	Trigger Method 
	Tube Over Hand Method 



Traditional Tube Position



3.8. BUTTON LOCATION

3.8.1. The yellow button is located nearest to the electrode end of the Zip Pen and the blue button is located farthest from the electrode end of the Zip Pen. This meets the requirements of the protocol. See verification in Appendix VIII.

3.9. ULPA FILTER EFFICIENCY

3.9.1. A review of the specification sheet and drawing for the ULPA filter media shows that the filter efficiency exceeds the required efficiency of 99.999% for 0.1 to 0.2 micron particles and meets the requirements of the protocol. See verification in Appendix IX. Note that there was a typographical error on the particle size for the efficiency in the protocol. The efficiency should be 99.999% at 0.1 – 0.2 micron particle size. The protocol listed 0.01 – 0.02 and will be corrected at DCO.

3.10. ULPA FILTER FLUID TRAP

3.10.1. A review of the drawing and of an actual product shows that the ULPA filter has a fluid trap and meets the requirements of the protocol. See verification in Appendix X.

3.11. ULPA FILTER CONNECTOR

3.11.1. A review of the drawing and of an actual product shows that the ULPA filter has a threaded connector that mates with the Zip Pen and meets the requirements of the protocol. See verification in Appendix XI.

3.12. CARBON FILTER CHARCOAL

3.12.1. A review of the Carbon filter data sheet and the actual product shows that it contains Charcoal and meets the requirements of the protocol. See verification in Appendix XII.

3.13. ZIP ELECTRODE INSERTION

3.13.1. Installation trials of 11 electrodes into 11 Zip Pens demonstrated that the electrode cannot be installed incorrectly. The installed electrodes met the maximum resistance requirement of less than 50 ohms. The Zip Pen meets he requirements of the protocol. See verification in Appendix XIII.

3.14. ZIP PEN PACKAGING

3.14.1. The Zip Pen shipping box is an RSC design. The drawing shows that the shipping box will contain one IFU per box and have 20 units in each box. The Zip Pen packaging meets the requirements of the protocol. See verification in Appendix XIV.

3.15. ZIP EXTENSION NOZZLE PACKAGING

3.15.1. The Extension Nozzle shipping box is an RSC design. The drawing shows that the shipping box will contain one IFU per box and have 10 units in each box. The Extension Nozzle packaging meets the requirements of the protocol. See verification in Appendix XV

3.16. ZIP PEN AND EXTENSION NOZZLE UNIT LABELING

3.16.1. The Zip Pen and Extension Nozzle unit labels contain the information required by the protocol. The Zip Pen and Extension Nozzle unit labels meet the requirements of the protocol. See verification in Appendix XVI.

3.17. ZIP PEN AND EXTENSION NOZZLE SHIPPER LABELING

3.17.1. The Zip Pen and Extension Nozzle shipping labels contain the information required by the protocol. The Zip Pen and Extension Nozzle shipping labels meet the requirements of the protocol. See verification in Appendix XVII.

3.18. ULPA AND CARBON FILTER UNIT LABELING

3.18.1. The ULPA and Carbon Filter unit labels contain the information required by the protocol. The ULPA and Carbon Filter unit labels meet the requirements of the protocol. See verification in Appendix XVIII.

3.19. ULPA AND CARBON FILTER SHIPPER LABELING

3.19.1. The ULPA and Carbon Filter shipping labels contain the information required by the protocol with one exception. The ULPA Filter shipping label does not have the product trade name on the label. The label has been approved through the DCO process by management and is what Marketing requested. The product specification and protocol will be revised at DCO. The labels meet the requirements of the protocol with exception of one item that will be revised. See verification in Appendix XIX.

4. CONCLUSIONS

The products in the Zip Project were verified to meet the requirements of the protocol which shows that the products meet the Product Specification with one minor exception. For that one minor exception the Product Specification will be revised.

5. RECOMMENDATIONS

The following documentation for the Zip Project will be updated as a result of this test report: The Input/output conformance test matrix ENG-IOM-012 will be updated to show verification per this test report. The Product Specification ENG-PS-007 will be updated to clarify and correct the requirements identified in this report. The Smoke Evacuation Accessories Risk Analysis ENG-RMF-045 will be updated to show this test report in the appropriate verification areas.

Appendix I
Button Size

Appendix I:
BUTTON SIZE

Zip Pen Button Size Calculation from ENG-DWG-588

Width .226 PV 2-6-2015

Length .358 PV 2-6-2015

Calculation $\pi\frac{(.226)^2}{4} + [(.358 - .226) \times .226] = .0699$ MB 2-6-15

Two Dimensional Area: .0699 in^2

Disposable Pencil Button Size Calculation

Catalog Number: 0039 Lot Number: 10664

Button Diameter: .298 PV 2-6-2015

Calculation: $\pi\frac{(.298)^2}{4} = .0697\ in^2$ MB 2-6-15

Appendix II
Branding

Appendix II
BRANDING

Reference ENG-DWG-650

Verify that the Pen Body has the following:

Body Color is Gray Pantone 427: (YES)/NO Initials/Date PV 1-26-2015

TPR inlay is Green Pantone 356: (YES)/NO Initials/Date PV 1-26-2015

Megadyne Name: (YES)/NO Initials/Date PV 1-26-2015

Appendix III
Tip Exposure

Appendix III

TIP EXPOSURE

Zip Pen Catalog Number: 2525-10 Lot Number: 5140303

Ultra Vac Catalog Number: 2110-10 Lot Number: 5408

Zip Pen Sample Number	Measurement		Ultra Vac Sample Number	Measurement
Z1	.867		U1	.996
Z2	.877		U2	.977
Z3	.871		U3	.978
Z4	.868		U4	1.012
Z5	.878		U5	.986
Z6	.864		U6	.992
Z7	.887		U7	.976
Z8	.870		U8	.821
Z9	.869		U9	.821
Z10	.875		U10	.820
Z11	.883		U11	.825

Appendix IV: Nozzle Clarity
Appendix V: Cord Containment

Appendix IV

NOZZLE CLARITY

Reference Drawing ENG-DWG-594

Verify that the Nozzle meets the following:

Material is clear and not opaque: (YES)/NO Initials/Date PV 1-26-2015

Comments: _____

_____

Appendix V

CORD CONTAINMENT

Reference Drawing ENG-DWG-716

Verify that the Assembly meets the following:

Cord is assembled inside the tube for at least the first 64 inches:

(YES)/NO Initials/Date PV 1-26-2015

Comments: _____

_____

Appendix VI
Tubing Swivel

Appendix VI

TUBING SWIVEL

Reference Drawing ENG-DWG-716

Verify that the Assembly meets the following:

The assembly has a swivel component approximately 8 inches from the handle connection:

(YES)/NO Initials/Date PV 1-26-2015

Comments: _____

_____

Appendix VII: Tubing Ergonomics
Appendix VIII: Button Location

Appendix VII

TUBING ERGONOMICS

Reference IFU MKT-LBL-531

Verify that the Assembly meets the following:

The Tube/Cord can be configured as shown for the three methods in the IFU. Photograph the three configurations for the test report:

(YES)/NO Initials/Date PV 2-4-2015

Comments: _____

_____

Appendix VIII

BUTTON LOCATION

Reference Drawing ENG-DWG-716

Verify that the Assembly meets the following:

The Yellow CUT Button is nearest to the electrode and the Blue COAG Button is farthest from the electrode:

(YES)/NO Initials/Date PV 1-27-2015

Comments: _____

_____

Appendix IX: Filter Efficiency
Appendix X: ULPA Filter Fluid Trap

Appendix IX

ULPA FILTER EFFICIENCY

Reference Assembly Drawing ENG-DWG-1017and
Component Drawing ENG-DWG-1015

Verify that the Assembly meets the following:

The assembly has a minimum filtration efficiency of 99.999% for ~~.01 - .02~~ 0.1 0.2 micron particles:

(YES)/NO Initials/Date PV 1-29-2015

Comments: _____

_____

Appendix X

ULPA FILTER FLUID TRAP

Reference Assembly Drawing ENG-DWG-1017

Verify that the Assembly meets the following:

The assembly has a Fluid Trap:

(YES)/NO Initials/Date PV 1-28-2015

Comments: _____

_____

Appendix XI: ULPA Filter Connector
Appendix XII: Charcoal Carbon Filter

Appendix XI

ULPA FILTER CONNECTOR

Reference Component Drawing ENG-DWG-1017

Verify that the Assembly meets the following:

The assembly has a threaded connector that is compatible with the Zip Pen Proximal Adapter ENG-DWG-1160:

(YES)/NO Initials/Date PV 1-28-2015

Comments: _____

_____

Appendix XII

CHARCOAL CARBON FILTER

Obtain a sample of Carbon Filter 2220

Verify that the Filter meets the following:

The Filter connects to the Mega Vac and/or Mega Vac Plus

The filter contains charcoal

(YES)/NO Initials/Date PV 1-29-2015

Comments: _____

_____

Appendix XIII
Zip Electrode Insertion

Appendix XIII

ZIP ELECTRODE INSERTION

Zip Pen Catalog Number: 2525-10 Lot Number: S140303

Electrode Catalog Number: 0014A Lot Number: 150088

Zip Pen Sample Number	Insertion Correct Yes/No	Continuity (Ohms)	Pass/Fail
C1	yes	0.8	PASS
C2	yes	0.8	PASS
C3	yes	0.7	PASS
C4	yes	1.7	PASS
C5	yes	1.2	PASS
C6	yes	0.7	PASS
C7	yes	1.0	PASS
C8	yes	0.7	PASS
C9	yes	9.2	PASS
C10	yes	0.9	PASS
C11	yes	0.7	PASS

Equipment Information	
Equipment	Fluke Multimeter, True RMS
Cert Number	497572
Asset Number	01372
Cal Date	9/12/2014
Cal Due	9/30/2015

M.S. 1/10/18 – Adding missing equipment & calibration information. Calibration record attached in Appendix XIII

WESTERN STATES CALIBRATION
the [illegible] exposure in all things

Certificate Number: 497572
Asset Number: 01372

CERTIFICATE of CALIBRATION

Western States Calibration certifies this instrument has been cleaned, calibrated and inspected in accordance with said Instrument Calibration Procedure. This calibration was performed in accordance with requirements of ISO/IEC 17025, ISO 9001:2008, and ANSI/NCSL Z540-1 with measuring standards traceable to the National Institute of Standards and Technology. Units of measurement are stated according to the International System of Units (SI). The results reported on this certificate apply only to the items calibrated. All data is reported as raw data and uncorrected for uncertainty or environmental effects. It is the end users responsibility to determine fitness for use. Measurement uncertainty is not taken into account when determining In/Out of tolerance conditions. This certificate shall not be reproduced except in full, without the written approval of Western States Calibration. Measurement Uncertainty (EMU) is reported per measurement, where available, @ k = 2.

Attention: Alan Holt
Megadyne Medical Products
11506 South State Street

Draper, UT 84020

PO Number: 23845

Asset Number: 01372
Manufacturer S/N: 93480388
Instrument: Multimeter, True RMS,
Manufacturer: Fluke Corp
Model Number: 179
Asset Location: N/A

Received: 09/11/2014
Date Done: 09/12/2014
Date Due: 09/30/2015
Calibration Interval: 12 Months
Calibrated at Customer's Site: No

As Found: In Tolerance
As Returned: In Tolerance
Physical Damage: No

Characteristic Tested	Nominal Value	Tolerance	As Found	% Error	As Returned	% Error	TAR	EMU
AC Volts								
600.0 mV Range	300.0 mV~@ 45 Hz	296.7 to 303 mV	299.7	-9 %	Same	-9 %	24:1	170.8 µV
6.000 V Range	5.000 V~@ 500 Hz	4.947 to 5.053 V	4.990	-19 %	Same	-19 %	14:1	4.6 mV
|	5.000 V~@ 1 kHz	4.897 to 5.103 V	4.951	-48 %	Same	-48 %	26:1	4.6 mV
60.00 V Range	50.00 V~@ 45 Hz	49.47 to 50.53 V	49.90	-19 %	Same	-19 %	20:1	30.9 mV
|	50.00 V~@ 1 kHz	48.97 to 51.03 V	50.02	2 %	Same	2 %	39:1	30.9 mV
600.0 V Range	300.0 V~@ 45 Hz	296.7 to 303 V	299.7	-9 %	Same	-9 %	20:1	203.7 mV
|	500.0 V~@500 Hz	494.7 to 505 V	500.1	2 %	Same	2 %	17:1	366.0 mV
|	500.0 V~@ 1 kHz	489.7 to 510 V	500.1	1 %	Same	1 %	33:1	366.0 mV
1000 V Range	1000 V~@ 45 Hz	987 to 1010 V	995	-38 %	Same	-38 %	21:1	925.2 mV
DC Volts								
6.000 V Range	5.000 V	4.992 to 5.008 V	4.999	-13 %	Same	-13 %	10:1	1.0 mV
600.0 V Range	300.0 V	299.5 to 300.5 V	299.9	-20 %	Same	-20 %	20:1	64.0 mV
1000 V Range	1000 V	996 to 1004 V	1000	0 %	Same	0 %	44:1	584.7 mV
1000 V Range	-1000 V	-1002 to -998 V	-1000	0 %	Same	0 %	31:1	584.7 mV
AC Volts Frequency								
99.99 Hz Range	45.00 Hz~@1 V	44.94 to 45.06 Hz	45.00	0 %	Same	0 %	49:1	5.9 mHz
99.99 kHz Range	50.00 kHz~@ 5 V	49.94 to 50.06 kHz	50.00	0 %	Same	0 %	48:1	6.0 Hz
DC Volts Frequency								
99.99 Hz Range	45.00 Hz~@ 3 V	44.94 to 45.06 Hz	45.00	0 %	Same	0 %	49:1	5.9 mHz
99.99 kHz Range	50.00 kHz~@ 30 V	49.94 to 50.06 kHz	50.00	0 %	Same	0 %	48:1	6.0 Hz
DC Millivolts								
600.0 mV Range	30.0 mV	29.8 to 30.2 mV	30.0	0 %	Same	0 %	38:1	58.1 µV
|	-300.0 mV	-300.5 to -299.5 mV	-299.8	40 %	Same	40 %	21:1	63.2 µV
600.0 mV Range	600.0 mV	599.3 to 600.7 mV	599.6	-57 %	Same	-57 %	9.5:1	106.6 µV
Resistance								
600.0 Ohm Range	500.0 Ohm	495.3 to 504.7 Ohm	500.1	2 %	Same	2 %	30:1	188.1 mOhm
50.00 MOhm Range	19.00 MOhm	18.68 to 19.32 MOhm	18.99	-3 %	Same	-3 %	10:1	35.7 kOhm
Continuity								
Beeper On 25 Ohm	Pass/Fail	Pass/Fail	PASS		Same			
Beeper Off 250 Ohm	Pass/Fail	Pass/Fail	PASS		Same			

westerncal.com phone 801.466.1700 fax 801.484.5104 105 west 2950 south salt lake city, utah 84115.3433

Certificate Number: 497572

Characteristic Tested	Nominal Value	Tolerance	As Found	% Error	As Returned	% Error	TAR	EMU
Diode								
2.400 V Range	2.000 V	1.978 to 2.0[illegible] V	2.002	9 %	Same	9 %	>100:1	606.8 µV
Temperature								
|	0.0 °C	-1.0 to 1.0 °C	0.0	0 %	Same	0 %	5.3:1	0.23 °C
|	-40.0 °C	-41.4 to -38.[illegible] °C	-40.0	0 %	Same	0 %	7.4:1	0.23 °C
|	400.0 °C	395.0 to 405.[illegible] °C	399.8	-4 %	Same	-4 %	22:1	0.27 °C
Capacitance								
1000 nF Range	900 nF	886 to 914 nF	900	0 %	Same	0 %	15:1	1.2 nF
AC Current								
6.000 A Range	4.000 A~@ 45 Hz	3.937 to 4.063 A	3.999	-2 %	Same	-2 %	5.7:1	12.7 mA
10.00 A Range	9.00 A~@ 1 kHz	8.84 to 9.1[illegible] A	8.99	-6 %	Same	-6 %	7.9:1	24.9 mA
60.00 mA Range	3.00 mA~@ 45 Hz	2.92 to 3.08 mA	3.02	25 %	Same	25 %	31:1	6.4 µA
|	50.00 mA~@ 1 kHz	49.22 to 50.[illegible] mA	49.94	-8 %	Same	-8 %	11:1	83.3 µA
400.0 mA Range	400.0 mA~@ 1 kHz	393.7 to 406.[illegible] mA	399.0	-16 %	Same	-16 %	7.2:1	1.0 mA
DC Current								
60.00 mA Range	3.00 mA	2.94 to 3.06 mA	3.01	17 %	Same	17 %	>100:1	5.8 µA
|	50.00 mA	49.47 to 50.[illegible] mA	49.99	-2 %	Same	-2 %	30:1	21.1 µA
400.0 mA Range	-400.0 mA	-404.3 to -395.[illegible] mV	-399.9	2 %	Same	2 %	12:1	417.4 µA
6.000 A Range	4.000 A	3.957 to 4.0[illegible] A	4.001	2 %	Same	2 %	14:1	3.7 mA
10.00 A Range	-9.00 A	-9.12 to -8.[illegible] A	-9.00	0 %	Same	0 %	20:1	8.9 mA

(- "Out of Tolerance" condition) (0 % Error of Limit - May represent a condition with an Asymmetrical Tolerance that can not be calculated.)*
(Unit of Measure for both As Found and As Returned are the same as the Nominal Value.)

Standards Utilized (Make, Model & Description)	Trace Number	Asset Number	Date Due
Wavetek Corp 9100 Calibrator, Multifunction,	474841	WSC601	03/06/2015
ARCO ELECTRONICS SS-32 Capacitor, Standard,	413166	WSC657	06/14/2015

Description of Material or Parts Used	Quantity	Material or Parts ID
Fuse	1	DMM44/100
Battery	1	9 V

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

Battery and blown fuse were replaced.

Calibration Procedure: 10224 R1

Quality Manager: Lon Miles

Degrees Fahrenheit: 73.0
Percent Humidity: 32.0

Calibration Technician: Kirk Scriber 09/12/2014

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westerncal.com phone 801.466.1700 fax 801.484.5107 105 west 2950 south salt lake city, utah 84115.3433

Appendix XIV
Zip Pen Packaging

Appendix XIV

ZIP PEN PACKAGING

Reference Assembly Drawings 2525-10 and 2525-15

Verify that the Assembly meets the following:

The assembly box is an RSC style box:

(YES)/NO Initials/Date PV 1-29-2015

The assembly requires an IFU in each box:

(YES)/NO Initials/Date PV 1-29-2015

The assembly requires 20 units per box:

(YES)/NO Initials/Date PV 1-29-2015

Comments: _____

_____

Appendix XV
Zip Pen Extension Nozzle Packaging

Appendix XV

ZIP EXTENSION NOZZLE PACKAGING

Reference Assembly Drawing 2540 and 2560

Verify that the Assembly meets the following:

The assembly box is an RSC style box:

(YES)/NO Initials/Date PV 1-29-2015

The assembly requires an IFU in each box:

(YES)/NO Initials/Date PV 1-29-2015

The assembly requires 10 units per box:

(YES)/NO Initials/Date PV 1-29-2015

Comments: _____

_____

Appendix XVI
Zip Pen and Extension Nozzle Unit Labeling

Appendix XVI

ZIP PEN AND EXTENSION NOZZLE UNIT LABELING

Reference Unit Label Drawings ENG-DWG-272, ENG-DWG-277, MKT-LBL-514 and MKT-LBL-517. Verify that the Labels meet the following:

Requirement	2525-10	2525-15	2540	2560
Label Part Number	X	X	X	X
Label Revision and Date	X	X	X	X
Bar code	X	X	X	X
Catalog Number and Symbol	X	X	X	X
Product Trade Name	X	X	X	X
Manufacturer symbol and name/info	X	X	X	X
Graphic of the product	X	X	X	X
E-Z Clean Logo	X	X	N/A	N/A
Lot Number and Symbol	X	X	X	X
Expiration Date and Symbol	X	X	X	X
CE Mark	X	X	X	X
EC Rep and symbol	X	X	X	X
Sterilization Symbol	X	X	X	X
Do Not Reuse Symbol	X	X	X	X
Consult Instructions Symbol	X	X	X	X
Rx Only Symbol	X	X	X	X
Do Not Use if Package is Damaged Symbol	X	X	X	X
The words "OPEN HERE"	X	X	N/A	N/A
Refer to Instructions for Use for Patent Information	X	X	N/A	N/A
Temperature and Humidity Symbol	X	X	X	X
Rated Voltage Symbol	X	X	N/A	N/A

Acceptance (YES)/NO Initials/Date PV 1-29-2015

Comments: _____

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Appendix XVII
Zip Pen and Extension Nozzle Shipping Labels

Appendix XVII

ZIP PEN AND EXTENSION NOZZLE SHIPPING LABELS

Reference Shipper Label Drawings MKT-LBL-499, MKT-LBL-510, MKT-LBL-515 and MKT-LBL-516. Verify that the Labels meet the following:

Requirement	2525-10	2525-15	2540	2560
Label Part Number	X	X	X	X
Label Revision and Date	X	X	X	X
Bar code	X	X	X	X
Catalog Number and Symbol	X	X	X	X
Manufacturer symbol and name/info	X	X	X	X
Product Trade Name	X	X	X	X
Graphic of the product	X	X	X	X
E-Z Clean Logo	X	X	N/A	N/A
CE Mark	X	X	X	X
EC Rep and symbol	X	X	X	X
Lot Number and Symbol	X	X	X	X
Expiration Date and Symbol	X	X	X	X
Sterilization Symbol	X	X	X	X
Do Not Reuse Symbol	X	X	X	X
Consult Instructions Symbol	X	X	X	X
Rx Only Symbol	X	X	X	X
Do Not Use if Package is Damaged Symbol	X	X	X	X
Temperature and Humidity Symbol	X	X	X	X
Quantity per box symbol	X	X	X	X

Acceptance (YES)/NO Initials/Date PV 1-29-2015

Comments: _____

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Appendix XVIII
ULPA and Carbon Filter Unit Labeling

Appendix XVIII

ULPA AND CARBON FILTER UNIT LABELING

Reference Unit Label Drawings MKT-LBL-518 and MKT-LBL-522. Verify that the Labels meet the following:

Requirement	~~2221~~ 2211	2220
Label Part Number	X	X
Label Revision and Date	X	X
Bar code	X	X
Catalog Number and Symbol	X	X
Product Trade Name	X	N/A
Manufacturer symbol and name/info	X	X
Graphic of the product	X	X
Lot Number and Symbol	X	X
CE Mark	X	X
EC Rep and symbol	X	X
Consult Instructions Symbol	X	X
Rx Only Symbol	X	X
Temperature and Humidity Symbol	X	X

Acceptance (YES) NO Initials/Date PV 1-29-2015

Comments: _____

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Appendix XIX
ULPA and Carbon Filter Shipper Labels

Appendix XIX

ULPA AND CARBON FILTER SHIPPING LABELS

Reference Shipping Label Drawings MKT-LBL-519 and MKT-LBL-523. Verify that the Labels meet the following:

Requirement	~~2221~~ 2211	2220
Label Part Number	X	X
Label Revision and Date	X	X
Bar code	X	X
Catalog Number and Symbol	X	X
Manufacturer symbol and name/info	X	X
Product Trade Name		N/A
Graphic of the product	X	X
CE Mark	X	X
EC Rep and symbol	X	X
Lot Number and Symbol	X	X
Consult Instructions Symbol	X	X
Rx Only Symbol	X	X
Temperature and Humidity Symbol	X	X
Quantity per box symbol	X	X

Acceptance (YES)/NO Initials/Date PV 1-10-2018

Comments: PV - Original conductor of test corrected missing initials.