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Dome Switch Supplier Change

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1. REFERENCES

Document Number	Rev.	Document name
IEC 60601-2-2:2009	N/A	Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-1: 2012	N/A	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
XENG-IOM-018	A	Telescoping pencils IOM
XENG-PS-013	F	Telescoping Pencils, Product Specification
ENG-WI-001	010	Sterilization Chart
ENG-RMF-043	006	Risk Management Plan - Smoke Evacuation Pencil and Accessories
ENG-RMF-044	002	Hazard Assessment summary - Smoke Evacuation Pencil and Accessories
ENG-RMF-045	009	Risk Analysis - Smoke Evacuation Risk Analysis
ENG-DMR-012	009	Device Master Record - Smoke Evacuation Pencil and Accessories
ENG-IOM-012	005	Input/ Output Conformance Test Matrix – Project Zip
MKT-US-002	002	Usability Requirements Specification – Smoke Evacuation Pencils
ENG-PRT-228	001	Test Protocol – Zip Pencil mechanical protocol
ENG-PRT-230	001	Test Protocol – Zip Pencil fluid ingress protocol
ENG-PRT-302	001	Test Protocol – ISOS2 EO Sterilized Product Design Verification
ENG-PRT-604	001	Pencil Dome Switch - Supplier Change - Shipping Conditioning Test Protocol
ENG-PRT-605	001	EO Sterilization of ZIP Pen ACE700 blade Dome Switch Change
4010343 or X4010343	D	MG existing dome – drawing
4010345 or X4010345	B	MG proposed dome – drawing
6020350	001	ZIP Pencil w/ ND Dome sub-assembly
X6020351	001	ACE Blade 700, w/ ND Dome sub-assembly
6020348	001	Rally Pencil w/ ND Dome sub-assembly
X6020349	001	Rally GEM Modified w ND Dome sub-assembly
X252510N	A	ZIP Pencil w/ ND Dome
XME725M1CN	A	ACE Blade 700, w/ ND Dome
X251010JN	A	Rally Pencil w/ ND Dome
XME725M1STN	A	Rally GEM Modified w ND Dome

2. PURPOSE

The purpose of this test protocol is to define the electrical and mechanical testing of the stainless-steel dome switch which is integral in the function of certain electrosurgical

pencils. The change is prompted because the existing tool for 4010343-01 reaching end of life and can no longer support production needs. This protocol defines the testing that the proposed dome design will perform to verify the standards, input documents and ensure other requirements are met.

3. BACKGROUND

The Original Equipment Manufacturer (OEM) of select Megadyne pencils (refer to Scope for the full list of product codes) has requested a supplier change for the dome switch which is within every surgical pencil product (see ENG-DCC-015). The current dome switch is part number X4010343-01 and the proposed dome switch is 4010345-01, more information on the design change can be found ENG-DCC-015. This protocol will perform an assessment of the proposed dome switch to ensure it meets all design requirements for the product codes that it is used in. The dome switch is used to translate mechanical force from a depressed plastic button (5800097-01, 5800136-01 or 5800137-01) to an electrical contact on the pencil's PCB (4010337-01 or 4010122-01).

A substantial review of each pencil's historic design verification testing as referenced in the associated pencil's Input/Output Matrix (ENG-IOM-012 and ENG-IOM-018) documents and the pencil's Design Master Records (DMR) was performed, and six tests were identified as being pertinent to the dome switch's mechanical and electrical performance. These tests, which will be evaluated under this protocol, are:

1. Activation Force Test
2. Activation Over Time Test
3. Fluid Ingress Test
4. Handpiece High Frequency Dielectric Withstand Test
5. Handpiece Mains Frequency Dielectric Withstand Test
6. Continuity Measurement Test

4. SCOPE

This protocol pertains to the electrical and mechanical functionality of the new dome switch (4010345-01) component found in the ZIP, ACE, Rally, Rally GEM and Refine products.

Prior to this protocol all samples shall be exposed to their respective sterilization cycle, EO (refer to ENG-PRT-605) for the ACE and Rally GEM products, and Gamma (refer to ENG-WI-001) sterilization for the ZIP and Rally products. The sterilization applied was

designed to be worst case scenario for each of the products and is at a minimum the maximum dosage.

All products have been conditioned through thermal cycling and shipping conditions (refer to protocol ENG-PRT-604).

This protocol is based on historical pencil design verification testing and follows historical pencil conditioning prior to mechanical and electrical functionality testing.

Testing in this protocol will test the following pre-production final assemblies:

1) X252510N (ZIP) represents the various configurations within the ZIP pen products. Each of the variations are a modification of the cord length, cord connector or the product is not sterilized. The product codes listed below all have the same dome/button interface and will all be represented with the X252510N testing:
    - 252510 – ZIP Pen, Electrosurgical Pencil w/E-Z Clean, Holster, 10 Foot Tubing
    - 252510BN – ZIP Pen, Bulk Non-Sterile
    - 252510EC – ZIP Pen with Erbe Connector
    - 252510ECBN – ZIP Pen with Erbe Connector Bulk Non-Sterile
    - 252515 – ZIP Pen, Electrosurgical Pencil w/E-Z Clean, Holster, 15 Foot Tubing
    - 252515EC – ZIP Pen, Electrosurgical Pencil w/E-Z Clean, Holster, 15 Foot Tubing with Erbe Connector

2) XME725M1CN (ACE) represents the various configurations within the ACE pen products. Each of the variations are a modification of cord connector or blade type. The product codes listed below all have the same dome/button interface and will all be represented with the XME725M1CN testing:
    - ME7251C – ACE Blade 700, 2.5”, ZIP Pen, “C” Connector, 10 Foot Tubing
    - ME7251E – ACE Blade 700, 2.5”, ZIP Pen, “EC” Connector, 10 Foot Tubing
    - ME725M1C – ACE Blade 700, 2.5”, Modified, ZIP Pen, “C” Connector, 10 Foot Tubing
    - ME725M1E – ACE Blade 700, 2.5”, Modified, ZIP Pen, “EC” Connector, 10 Foot Tubing

3) X251010JN (Rally) represents the various configurations of the Rally pen products. Each of the variations are a modification of the cord length, or not sterilized. The

product codes listed below all have the same dome/button interface and will all be represented with the X251010JN testing:

- 251010J – Megadyne Telescoping Smoke Evacuation Pencil, 10 FT
- 251010BN – Megadyne Telescoping Smoke Evacuation Pencil, 10 FT, Bulk Non-Sterile
- 252515JN – Megadyne Telescoping Smoke Evacuation Pencil, 15 FT
- 252515BN – Megadyne Telescoping Smoke Evacuation Pencil, 15 FT, Bulk Non-Sterile

4) XME725M1STN (Rally GEM/Refine) represents the various configurations of the Rally GEM or Refine pen products. Each of the variations are a modification of cord length or blade type. The product codes listed below all have the same dome/button interface and will all be represented with the XME725M1STN testing:
   - ME7251ST – Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector, 2.5” Blade, 10 FT
   - ME725M1ST – Megadyne ACE Blade 700, 2.5” Blade, Modified, Telescoping Pencil, 15 FT
   - ME7251T – Megadyne Telescoping Soft Tissue Dissector, 2.5” Blade, 10 FT
   - ME725M1T – Megadyne Telescoping Soft Tissue Dissector, 2.5” Blade, Modified, 10 FT

Button switch pencils are representative for both finished sterile and bulk non-sterile configurations.

The DMR for ZIP and ACE product codes is ENG-DMR-012. The DMR for Rally and Rally GEM/Refine product codes is XENG-DMR-017.
The ZIP Pen and Ace Blade product codes use ENG-PS-007 to document engineering requirements. ENG-IOM-012 and ENG-IOM-004 document where those requirements are verified for the Zip Pen and Ace Blade product codes respectively. The below requirements will need to be verified under this PRT due to the dome change:

- PRS 1301: The Button peak activation force is between 250 grams to 700 grams
- PRS 1409: The handheld portion of the device meets the requirements for fluid ingress per the requirements of IEC 60601-2-2 clause 201.11.6.5 b).
- PRS 1402: Device continuity for each circuit, CUT and COAG, shall have resistance no greater than 50 ohms with the button depressed.
- PRS 1403: Device resistance for each circuit, CUT and COAG, shall have resistance greater than 100,000 ohms without buttons depressed.

- PRS 1407: The hand held portion of the device meets the requirements for high frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.103. The rated voltage of the device is 5.5 kV peak.
- PRS 1408: The hand held portion of the device meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak.

The Rally, Rally GEM and Refine product codes use XENG-PS-013 to document engineering requirements. ENG-IOM-018 documents where those requirements are verified for the Rally, Rally GEM, and Refine product codes. The below requirements need to be verified under this PRT due to the dome change:

- PRS 1106: The product shall demonstrate reliability by meeting specification after a minimum of 500 activation cycles for each button - After cycling, Cut and Coag should each measure less than 50 ohms when depressed and greater than 10,000 ohms when released.
- PRS 1301: Button activation force is between 250 and 700 grams.
- PRS 1410: The hand-held portion of the device meets the requirements for fluid ingress per the requirements of IEC 60601-2-2 clause 201.11.6.5 b, which is after saline application in the Standard orientation, the button can be operated 10 times with a measured current of $\leq$ 2.5 mA, at 0.5 seconds after release
- PRS 1402: Device continuity for each circuit, CUT and COAG, shall have resistance no greater than 50 ohms with the button depressed.
- PRS 1403: Device resistance for each circuit, CUT and COAG, shall have resistance greater than 10,000 ohms without buttons depressed/after button released.
- PRS 1408: The hand-held portion and holster of the device meets the requirements for high frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.103. The rated voltage of the device is 5.5 kV peak. (6.6 kV peak is the test voltage used for 30 sec. test)
- PRS 1409: The hand-held portion and holster of the device meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak. (6.6 kV peak is the test voltage used for 30 sec. test)

Table 1 below shows what tests will be used to verify the requirements listed.

Table 1: Test to Requirement Matrix

Test Name	Rally/Rally	Ace/Zip

	GEM/Refine Requirement Number	Requirement Number
Activation Force Test	PRS 1301	PRS 1301
Activation Over Time Test	PRS 1106	N/A
Fluid Ingress Test	PRS 1410	PRS 1409
Handpiece High Frequency Dielectric Withstand Test	PRS 1408	PRS 1407
Handpiece Mains Frequency Dielectric Withstand Test	PRS 1409	PRS 1408
Continuity Measurement Test	PRS 1402 PRS 1403	PRS 1402 PRS 1403

5. ACCEPTANCE CRITERIA

5.1. Continuity Measurement Test

5.1.1. The device is considered acceptable if the button resistance is less than 50 Ω when depressed.

5.1.7. The device is considered acceptable if the button resistance is greater than 100,000 Ω when the button is not depressed.

5.2. Handpiece High Frequency Dielectric Withstand Test

5.2.7. The device is considered acceptable if the test voltage is maintained for 30 seconds, and;

5.2.8. There were no visible signs of damage such as melted insulation.

5.3. Handpiece Mains Frequency Dielectric Withstand Test

5.3.7. The device is considered acceptable and passes this test if the test voltage was reached and maintained for 30 seconds and;

5.3.8. There were no visible signs of damage such as melted insulation and;

5.3.9. The HiPot did not alarm.

5.4. Fluid Ingress Test

5.4.7. The device is considered acceptable if, after applying saline in the Standard orientation, the button can be operated 10 times with the current being less than or equal to 2.5 mA (measured as 2.5 mV on the oscilloscope) at a time period of 0.5 seconds after the button is released. (The standard requires the AC impedance of the switch to exceed 2.0 kw within 0.5 seconds after release. Using a voltage of 10 V_{p-p}, a current of 5.0 mA or less is necessary to meet this requirement).

5.4.8. The inverted orientation test of Pencil (buttons down) is performed as a worst-case situation and is not a requirement of the Standard. With that noted, any inadvertent activation of the Pencil due to fluid ingress in this orientation should be noted and Engineering notified for further investigation.

5.5. Activation Force Test

5.5.7. The Pencil button activation force shall be within the range specified by the DMR. This range is 250 to 700 grams.

5.6. Activation Over Time Test

5.6.7. Button resistance is less than 50 Ω after 500 activations. Resistance is greater than 100,000 Ω when button is not depressed after 500 activations.

6. RISK ASSESSMENT

6.1. Risk Analysis ENG-RMF-045 identifies the risks associated with the Smoke Evacuation Pencils for Ace and Zip product codes.

The following table details the risks associated with this change.

Failure Mode*	Cause	Mitigation	Verification
Buttons too hard to press	Incorrect geometry of dome switch or incorrect material type	Validate button activation force, cyclic button activation, process control at supplier	Test report ENG-RPT-685
Buttons too easy to press – no tactile response, but operable	Incorrect geometry of dome switch or incorrect material type	Validate button activation force, cyclic button activation, process control at supplier	Test report ENG-RPT-685
Buttons too easy to press – always activated	Incorrect geometry of dome switch or incorrect material type	Validate button activation force, cyclic button activation, max power test, process control at supplier	Test report ENG-RPT-685
Buttons too easy to press – Switches fail during surgery	Incorrect geometry of dome switch or incorrect material type	Validate button activation force, cyclic button activation, process control at supplier	Test report ENG-RPT-685
Self-Activation	Fluid enters housing causing short circuit to internal components	Pencil designed to prevent short circuit due to fluid ingress, material and supplier selection and product validation	Test report ENG-RPT-685

*see ENG-RMF-045 item #'s 5-d, 6-d, 7-d, 8-d and 16-d for hazard information

6.2. Risk Analysis ENG-RMF-052 identifies the risks associated with the Telescoping Pencils for Rally, Rally GEM and Refine product codes.

Row ID	Design element (part number, subsystem, and function)	General hazard and code	**Failure Mode (hazard / hazardous situation)	Design cause	**Effect of the failure on the device**	**Harm of the failure on the patient, clinical staff, property, or environment** (given the effect on the device).	Harm Sever. Level	Initial Occ. Prob. (no risk control)	Prelim. risk assess.	Recommended Minimum Control	Risk mitigation/risk control (identify specific documents) Risk verification records Notes
220	Dome Switches (M100600, Activate ESU to provide signal to electrode, Provide tactile response	ME-16 - Loss of electrical /mechanical integrity.	Self-activation	Dome too close to contact	Device cannot be used safely/Replace Device	Burn- surgical intervention is indicated to prevent further injury or permanent damage	S3	F5	Prelim. risk is Level 2	High Controls	ENG-PS-013: PRS 1301, PRS 1402, PRS 1403

	to user)										
230	Dome Switches (M100600, Activate ESU to provide signal to electrode, Provide tactile response to user)	ME-16 - Loss of electrical /mechanical integrity.	Inadvertent Activation	Dome too soft	Device cannot be used safely/Replace Device	Burn- surgical intervention is indicated to prevent further injury or permanent damage	S3	F5	Prelim. risk is Level 2	High Controls	ENG-PS-013: PRS 1301
240	Dome Switches (M100600, Activate ESU to provide signal to electrode, Provide tactile response to user)	HI-09 - Insufficient visibility, audibility, or tactile feedback.	No tactile response	Dome too soft	Device does not function as expected/Device may be replaced	Surgery- Procedure completed within expected time	S1	F5	Prelim. risk is Level 1	Normal Controls	ENG-PS-013: PRS 1301
250	Dome Switches (M100600, Activate ESU to provide signal to electrode, Provide tactile response to user)	ME-17 - Incorrect mechanical force (too high or too low)	Cannot be activated	Dome too hard to depress	Energy not delivered/Replace Device	Surgery- Procedure completed within expected time	S1	F5	Prelim. risk is Level 1	Normal Controls	ENG-PS-013: PRS 1301
260	Dome Switches (M100600, Activate ESU to provide signal to electrode, Provide tactile response to user)	ME-08 - Degradation or deterioration in function from repeated use (within surgery and over the life of reusable devices).	Fails during use (reliability)	Material selection	Device Cannot Function/Device Replaced	Surgery- Procedure completed within expected time	S1	F5	Prelim. risk is Level 1	Normal Controls	ENG-PS-013: PRS 1106 (a)

**265	Dome Switches (M100600, Activate ESU to provide signal to electrode, Provide tactile response to user)	ME-17 - Incorrect mechanical force (too high or too low)	Device remains activated after button is released	Dome Design - dome does not rebound	Device cannot be used safely/Replace Device	Burn- surgical intervention is indicated to prevent further injury or permanent damage	S3	F5	Prelim. risk is Level 2	High Controls	ENG-PS-013: PRS 1403

The occurrence level for all lines listed in this protocol will be updated with the results of this testing.

7. EXPERIMENTAL DESIGN & SAMPLE JUSTIFICATION

7.1. Certification of Conformance for all test samples can be found in **Attachment 11.1 through 11.4**.

7.2. Sterilization:

X252510CN and X251010JN have been gamma sterilized according to Sterilization chart specification found in Section 7.2.4 of ENG-WI-001. The results of sterilization can be found in **Attachment 11.1 and 11.3**.

XME725M1CN and XME725M1STN have been EO sterilized according to protocol ENG-PRT-605. The results of sterilization can be found in **Attachment 11.5 and 11.6**.

7.3. Thermal conditioning:

Product was Thermal/Humidity cycled per ENG-PRT-604. Results can be found in **Attachment 11.7 and 11.8**.

7.4. Ship test conditioning:

Product was ship tested per ENG-PRT-604. Results can be found in **Attachment 11.7 and 11.8**.

7.5. Below in **Table 2** is how the devices will be grouped and what tests each group of devices will be performing. Note that there will need to be a group for each of the four product codes being tested

Table 2: Groups of Test Devices

Test Group	Quantity	Test
Group A	30	Activation Force Test
		Continuity Measurement Test
Group B	30	Fluid Ingress Test
Group C	30	Handpiece Mains Frequency Dielectric Withstand Test
Group D	30	Handpiece High Frequency Dielectric Withstand Test

Test Description	Button Switch (252510, ME725M1C, 251010J, ME725M1ST)	Total Dome Switches
Pencil meets High Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.103; XENG-PS-010 4.1.4)	30 ea.	240 ea.
Pencil meets Mains Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.104)	30 ea.	240 ea.
Pen finger switch activation resistance of 50 ohms maximum	30 ea.	240 ea.
Pencil finger switch non-activation resistance of 100,000 ohms minimum	30 ea.	240 ea.
Fluid Ingress Test (IEC 60601-2-2 Clause 201.11.6.5 b)	30 ea.	240 ea.
Button Activation Force	30 ea.	240 ea.
Button Activation over Time	30 ea.	240 ea.

7.6. Sample Size Justification

7.6.7. Risk Justification – As per QA-SOP-012 Statics Procedure 30 parts per product code will be tested for each of the verification tests.

7.6.8. Specific to the component, if a dome switch sticks or inverts creating a constant “activated” state during operation, the risk is a Class I failure, which could potentially result in injury. For a Class I risk defect, a Confidence level of 95% and a Reliability level of 98% will be established for the sample size justification. Each verification test will be examined for this failure mode.

7.6.9. Sample Size Justification – The sample size for a Class III failure of a device which does not work properly calls for n = 30 parts. This is for each of the device verification tests.

7.6.10. Sample Size Justification – The sample size for a Class I failure of a dome switch inverting and creating a constant "activated" state calls for n= 150 to 300 parts.

7.6.11. Total Samples – The total number of products to be tested under this protocol will allow for thirty (30) samples in four (4) separate design verification functional tests and four (4) product codes for a total of 480 units. As there are 2 dome switches per product, there will be a total of 960 dome switches tested in this protocol.

8. DEFINITIONS AND ACRONYMS

TERM	ABBREVIATION
ND	New Deantronics
CUT	Cut button or rocker switch on the Pencil
COAG	Coagulation button or rocker switch on the Pencil
ESU	Electrosurgical Unit

9. EQUIPMENT

9.1. Handpiece High Frequency and Mains Frequency Dielectric Withstands Testing

9.1.1. HiPot Tester

9.1.2. Ohmmeter (or multi-meter)

9.1.3. 0.9% Saline solution

9.1.4. Modified Mega Power ESU or equivalent (having an approximately sinusoidal waveform with frequency between 300 kHz and 5 kHz with a Crest Factor = 6 +/- 10%)

9.1.5. Oscilloscope

9.1.6. 1000:1 High Voltage Probe

9.1.7. Electrosurgical generator foot switch

9.1.8. Inductive current coil with an output of 1Volt per 1 Amp

9.1.9. Workbench with insulated top (preferably wood)

9.1.10. 3:1 step-up transformer

9.1.11. Stopwatch or equivalent

9.1.12. Fluke 8920A True RMS Voltmeter, or equivalent

9.1.13. Aluminum Foil

9.1.14. Paper towel or porous cloth

9.1.15. Test leads

9.2. Button Activation Force

9.2.1. Instron 4464 Test Machine with these key parameters

9.2.1.1. Instron program test name is “Dome Switch Activation”

9.2.1.2. Instron crosshead speed is 1.0 inch per minute

9.2.1.3. Instron load cell is 10 pounds

9.2.1.4. Load level (load threshold) is 2.0 lbf

9.2.2. Activation Force Testing Accessory (AFTA)

9.2.3. Multimeter

9.2.4. Shear pin with spring clip (see Appendix VII)

9.2.5. Vise

9.2.6. Vise Fixture Base – 2010341-01 (See Appendix VII)

9.2.7. ZIP and ACE fixture – 2010516-01 (See Appendix VII)

9.2.8. Rally and Rally GEM fixture – 2010342-01 (See Appendix VII)

9.3. Activation Over Time

9.3.1. Cycle testing device – 6010210-01 with the cycle cam attachments – 601510-01 (See Appendix X)

9.3.2. ZIP and ACE fixture – 201516-01 (See Appendix X)

9.3.3. Rally and Rally GEM fixture – 2010342-01 (See Appendix X)

9.3.4. Multimeter

9.4. Fluid Ingress

9.4.1. Ohmmeter or multimeter

9.4.2. 0.9% Saline solution

9.4.3. TDS 2014 Tektronix Oscilloscope or equivalent

9.4.4. Appropriate leads for connections for the test set-up

9.4.5. Stop watch or equivalent

9.4.6. Container to support device and 1 Liter of liquid

9.4.7. Function Generator

9.4.8. Currant loop

10. PROCEDURE

10.1. Prior to each test document the manufacturer, model number, and calibration information for all equipment used throughout each test procedure.

10.2. Label each of the devices as follows:

10.2.1. The devices will have a number that is in the following format *X.Y.ZZ*

10.2.2. In the *X.Y.ZZ* format the *X* represents the product code of the device and should be replaced with the letter listed below depending on the product code.

10.2.2.1. *X* should be replaced by Z for product code X252510N.

10.2.2.2. *X* should be replaced by A for product code XME725M1CN.

10.2.2.3. *X* should be replaced by R for product code X251010JN.

10.2.2.4. *X* should be replaced by G for product code XME725M1STN.

10.2.3. In the *X.Y.ZZ* format the *Y* represents the testing group of the device and should be replaced with the letter associated with the testing group listed in **Table 2**.

10.2.4. In the *X.Y.ZZ* format the *ZZ* represents the number of the device in the testing group. The *ZZ* will go up sequentially from 1 to 30 for each test device.

10.2.5. For example, if a X252510N device were set to perform the Continuity Measurement Test from Test Group A listed in **Table 2** then the devices would be labeled *Z.A.1, Z.A.2. Z.A.3*, etc.

10.3. **Continuity Measurement Test**

10.3.1. Depress each activation button and note anomalies.

10.3.2. Using an ohmmeter, measure and record the resistance of the device. Check all possible activation points. The device under test is considered out of tolerance if the resistance is greater than 50 ohms when the button is depressed or less than 100,000 ohms when the button is released.

10.3.3. Repeat 10.3.1 thru 10.3.2 for all samples. Record results in datasheet before and after each test performed for each sample.

10.4. Handpiece High Frequency Dielectric Withstand Test

10.4.1. Document all information for this test per 10.1 of this protocol. Identify each sample device as per 10.2.1 through 10.2.5 of this protocol. Check device continuity as per 10.3.1 through 10.3.3 of this protocol.

10.4.2. **Appendix I** illustrates the equipment setup for this test. The equipment needs for this test are: modified Mega Power ESU, the 3:1 transformer, high voltage probe, and oscilloscope on the workbench.

10.4.3. Check that the high voltage probe is connected to the oscilloscope channel 1. Also check that channel 1 is set to read peak voltage.

10.4.4. Connect an appropriate test lead from the yellow output of the transformer to the common output of the ESU.

10.4.5. Connect an appropriate test lead from the brown output of the transformer to the return receptacle on the ESU.

10.4.6. Wrap the hand switching device in a cloth that is soaked in 0.9% saline. The cloth should be wet, but not dripping.

10.4.6.1. The cloth must extend a minimum of 6 inches (150 mm) onto the device's cord.

10.4.6.2. The IEC 60601-2-2 standard requires that the cloth must extend 0.2 inches (5 mm) onto an acceptable electrode that has been inserted into the hand switching device. On the Pencil the electrode is surrounded by the nozzle. Therefore, position the cloth such that it extends a minimum of 0.2 inches (5 mm) into the nozzle.

10.4.7. Wrap the center of the cloth covered hand switching device in aluminum foil. The aluminum foil should be a minimum of ½ inch wide and make good contact with the cloth.

10.4.8. Check the plug on the hand switching device for multiple connections. If the plug has multiple connections short the connections together. This will be referred to as the *test cable's plug junction.*

10.4.9. Using an appropriate test lead, plug one end of the test lead into the red output of the transformer and the other end into the plug junction.

10.4.10. Using an appropriate test lead, attach one end of the test lead to the black output of the transformer and attach the other end to the aluminum foil wrapped around the device.

5.1.2. Clip the return of the high voltage probe to the end of the aluminum foil on the wrapped device.

10.4.11. Activate the SPRAY COAG mode using the foot switch and adjust the power on the ESU to achieve a minimum of 1.2 times (120%) the published Rated Accessory Voltage for the accessory being tested.

10.4.11.1. For a Rated Accessory Voltage greater than 4,000 Vpeak the Crest Factor of the test waveform must be 6 +/- 10%.

10.4.11.2. For a Rated Accessory Voltage (Uacc) greater than 1,600 Vpeak and less than or equal to 4,000 Vpeak the Crest Factor (cf) of the test waveform must be:

$$cf = (Uacc - 400\ Vpeak) / 600\ Vpeak.$$

10.4.12. Watch for breakdown. Breakdown is indicated by sparks, visible degradation, black smoke, or a sudden drop in voltage. Blue corona is normal and is not considered a failure.

10.4.13. Maintain the potential for 30 seconds using the stopwatch unless breakdown occurs first.

10.4.14. At the conclusion of 30 seconds, release the foot switch and disconnect the test cable.

10.4.15. Record sample number and maximum peak voltage seen on the oscilloscope. Also record whether the device passed or failed and if there was any damage.

10.4.16. Repeat 10.4.6 through10.4.16 for all samples. Record results in spreadsheet.

10.5. Handpiece Mains Frequency Dielectric Withstand Testing

CAUTION: This is a high voltage test. Place a warning sign near the test apparatus as a notification that a dangerous test is in progress. Do not touch any portion of the device or the test setup while testing is in process.

10.5.1. Document all information for this test per 10.1 of this protocol. Identify each sample device as per 10.2.1 through 10.2.5 of this protocol. Check device continuity as per 10.3.1 through 10.3.3 of this protocol.

10.5.2. This test must follow the high frequency dielectric withstand testing in 10.4.

10.5.3. Place the HiPot on the workbench and remove excess equipment.

10.5.4. Appendix II shows a set-up for mains frequency dielectric withstand testing of a hand switching device. This generic figure may be used as a reference to aid in setting up the mains frequency dielectric withstand test.

10.5.5. The hand switching device should be prepared for testing using saline and aluminum foil, following steps 10.4.6 to 10.4.7.

10.5.6. Attach the active lead from the HiPot to the device's plug junction.

10.5.7. Place an appropriate test lead from the ground output on the HiPot to the end of the aluminum foil wrapped device.

10.5.8. Turn on the HiPot. Raise the voltage 500 V/s until the voltage reaches the required value for testing.

10.5.8.1. The standard states that the mains test voltage must be 1000 Vpeak more than the Rated Accessory Voltage. The test voltage is converted to Vrms and rounded up to the nearest increment on the HiPot.

10.5.9. Maintain the potential for at least 30 seconds using a stopwatch unless breakdown occurs first.

10.5.10. Watch for breakdown. Breakdown is indicated by the alarm on the HiPot.

10.5.11. At the conclusion of 30 seconds, turn the knob on the HiPot all the way down, and turn the power switch off. Disconnect the device.

10.5.12. Using an ohmmeter, measure the resistance of the depressed finger switch 10 times and verify switch is open (de-energized) when released.

10.5.13. If the device has more than one finger switch, repeat 10.5.11 above for all other hand switches.

10.5.14. Record sample number, all resistance values, and if there was dielectric breakdown.

10.5.15. Repeat all steps in sections 10.5.5- through10.5.14 for all samples. Record results in spreadsheet.

10.6. Fluid Ingress Test

10.6.1. Document all information for this test per 10.1 of this protocol. Identify each sample device as per 10.2.1 through 10.2.5 of this protocol. Check device continuity as per 10.3.1 through 10.3.3 of this protocol.

10.6.2. Appendix V shows the setup used for fluid ingress testing. Place the function generator, current loop, oscilloscope, 1liter saline solution, stop watch, and container on workbench.

10.6.3. Turn on function generator and set for 10 V_{p-p} and 1kHz.

10.6.3.1. Ensure the offset = 0

10.6.3.2. Ensure the waveform is sinusoidal.

10.6.4. Connect one end of a coax cable to the connector of the current loop. Connect the other end of the coax to channel 1 on the oscilloscope (make sure channel 1 is set to read a 1x probe). When measuring current with the loop, voltage is displayed on the oscilloscope as a 1 to 1 correlation (1 amp = 1 volt)

10.6.5. Turn the oscilloscope on and set the display to show 250 ms/division and 5 mV/division.

10.6.6. Set the cursors on the oscilloscope to be ± 2.5 mV or as close to this setting as possible.

10.6.7. Using the trigger menu, set the *Slope* to "Rising" and the *Mode* to "Normal".

10.6.8. Set the trigger point to approximately 2.5 mV using the trigger knob.

10.6.9. Connect the appropriate leads to the function generator.

10.6.10. Place the sample to be tested in the container with the cord and plug out of the container.

10.6.11. Using the test lead identified in 9.4, connect one wire to the common pin on the Pencil plug and the other wire to the cut or COAG pin on the plug (depending on which mode is being tested).

10.6.12. The wire connected to the plug's common pin must go through the current loop before connecting to the pin.

10.6.13. Center the signal on the oscilloscope around the center line, i.e. 0 Volts.

10.6.14. Verify that the signal is between the cursors or is less than or equal to ± 2.5 mV. If not, mark the sample as defective, remove it from the test and replace with a new sample.

10.6.15. Disconnect the test lead from the current activation pin (cut or COAG) and connect to the remaining activation pin on the plug (cut or COAG).

10.6.16. Verify that the signal is between the cursors or is less than or equal to ± 2.5 mV. If not, mark the sample as defective, remove it from the test and replace with a new sample.

10.6.17. With the test cable connected, hold the Pencil handle horizontally at least 2 inches above the bottom of the container with the buttons on top.

10.6.18. Pour 1 liter of 0.9% saline over the pencil housing during a 15 second interval so that it wets the entire length of the handle.

10.6.19. Allow the fluid to drain away freely.

10.6.20. Immediately press the button of the mode being tested and release. After the button release measure the voltage value at 500 ms on the oscilloscope.

10.6.20.1. The voltage should be between the cursor lines, or less than or equal to ± 2.5 mV.

10.6.20.2. When the button on the Pencil is pressed, the voltage on the screen should go up. The signal should extend past the cursors.

10.6.20.3. After the button is released, the voltage should drop to less than or equal to ± 2.5 mV. The time is measured beginning from the last high point, before it drops.

10.6.21. Record in Appendix II if the sample passed or failed (i.e. measured between the cursor lines at the 500 ms mark or not).

10.6.22. Repeat steps 10.6.20 nine more times

10.6.23. Change the test cable connection on the Pencil plug to measure the remaining mode.

10.6.24. Repeat all steps for the remaining mode.

10.6.25. Repeat all steps for each sample. Record results in spreadsheet.

10.7. **Activation Force Test**

10.7.1. Document all information for this test per 10.1 of this protocol. Identify each sample device as per 10.2.1 through 10.2.5 of this protocol. Check device continuity as per 10.3.1 through 10.3.3 of this protocol.

10.7.2. Install the 10 pound load cell in the Instron. Set the cross-head speed to 0.787 inch per minute (20mm/minute). The travel of a dome switch is .012" nominal. Devise a program in the Instron that will travel at this rate for this distance.

10.7.3. Insert a test pin suitable for button force testing in the load cell mounting socket.

10.7.4. Use an engineering supplied holding fixture in the vise. Insert the Pencil under test in the holding fixture with the Cut button directly below the test pin in the load cell.

10.7.5. Identify the sample in the Instron test software.

10.7.6. Balance the load to zero the Instron.

10.7.7. Run the test.

10.7.8. Reposition the Pencil to test the Coag button and repeat the test.

10.7.9. Repeat the above test for the remaining samples.

10.7.9.1. Record results in spreadsheet. Provide the test data to engineering for use in the Test Report.

10.8. **Activation Over Time Test**

10.8.1. Document all information for this test per 10.1 of this protocol. Identify each sample device as per 10.2.1 through 10.2.5 of this protocol. Check device continuity as per 10.3.1 through 10.3.3 of this protocol.

10.8.2. Mount the device into the product specific test holding fixture.

10.8.3. Secure the test holding fixture to the cycle testing machine.

10.8.4. Turn the power on the cycle testing machine.

10.8.5. Press the cycle start button.

10.8.6. Once the digital counter has reached 100 (the cycling cam depresses the device 5 times per rotation) turn the power off.

10.8.7. Test the continuity of the pencil. Record the resistance in the table provided.

10.8.8. Test the continuity of the pencil with button released. Record the resistance in the table provided.

5.1.3. Repeat the above test for the remaining samples.

11. ATTACHMENTS

11.1. Certificate of Compliance for X252510N_SM1910009 – ZIP Pencil – Certification of Irradiation for Gamma Sterilization included.

11.2. Certificate of Compliance for XME725M1CN_SM1910010 – ACE Pencil

11.3. Certificate of Compliance for X251010JN_SM1910018 – Rally Pencil – Certification of Irradiation for Gamma Sterilization included

11.4. Certificate of Compliance for XME725M1STN_SM1910019 – Rally GEM Pencil

11.5. EO XME725M1CN – ACE Pencil Sterilization Report

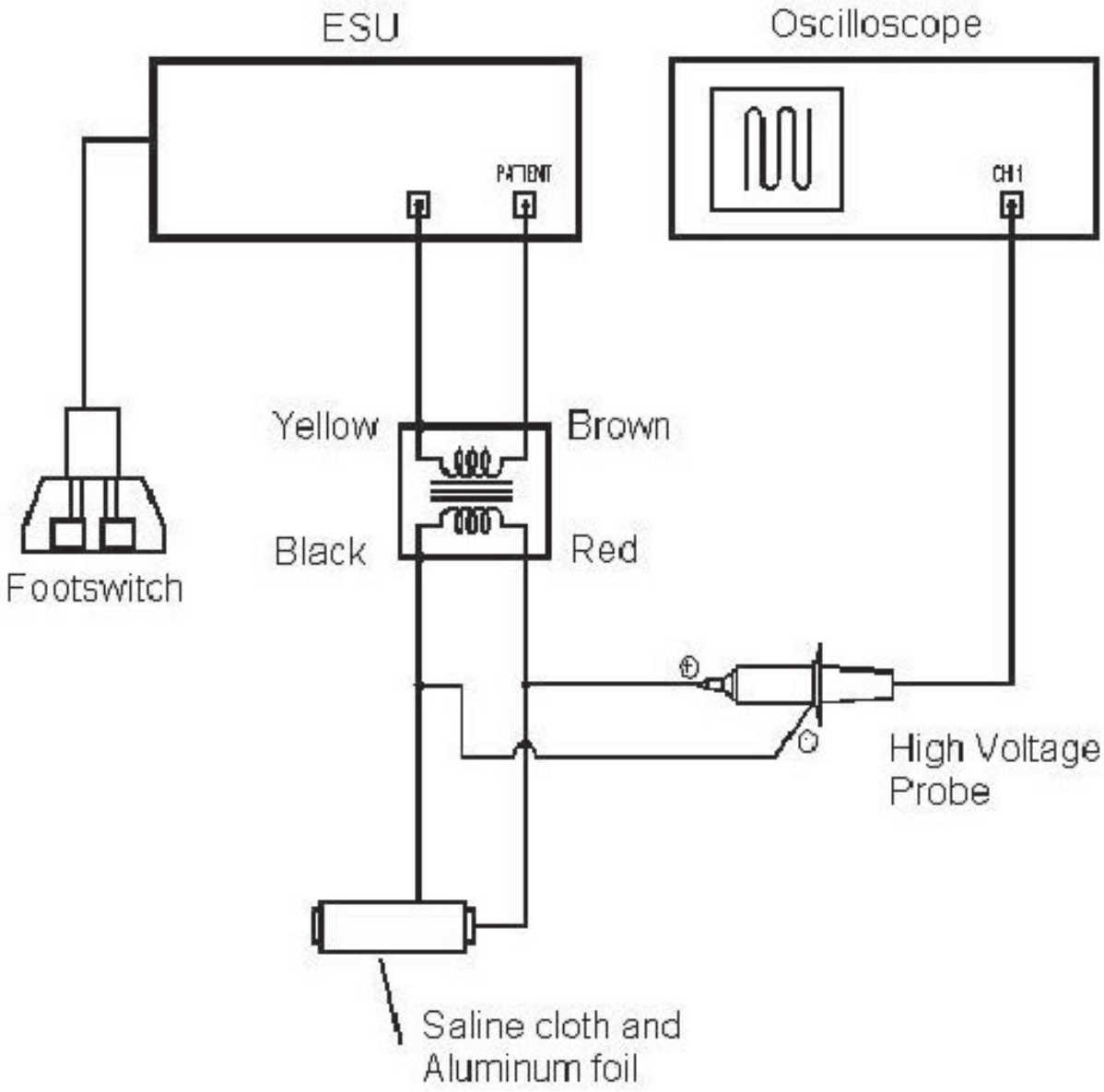
11.6. EO XME725M1STN – Rally GEM Pencil Sterilization Report

11.7. MEGA190656_ASTM ZIP – Rally – Shipping Conditioning and Thermocycling Report

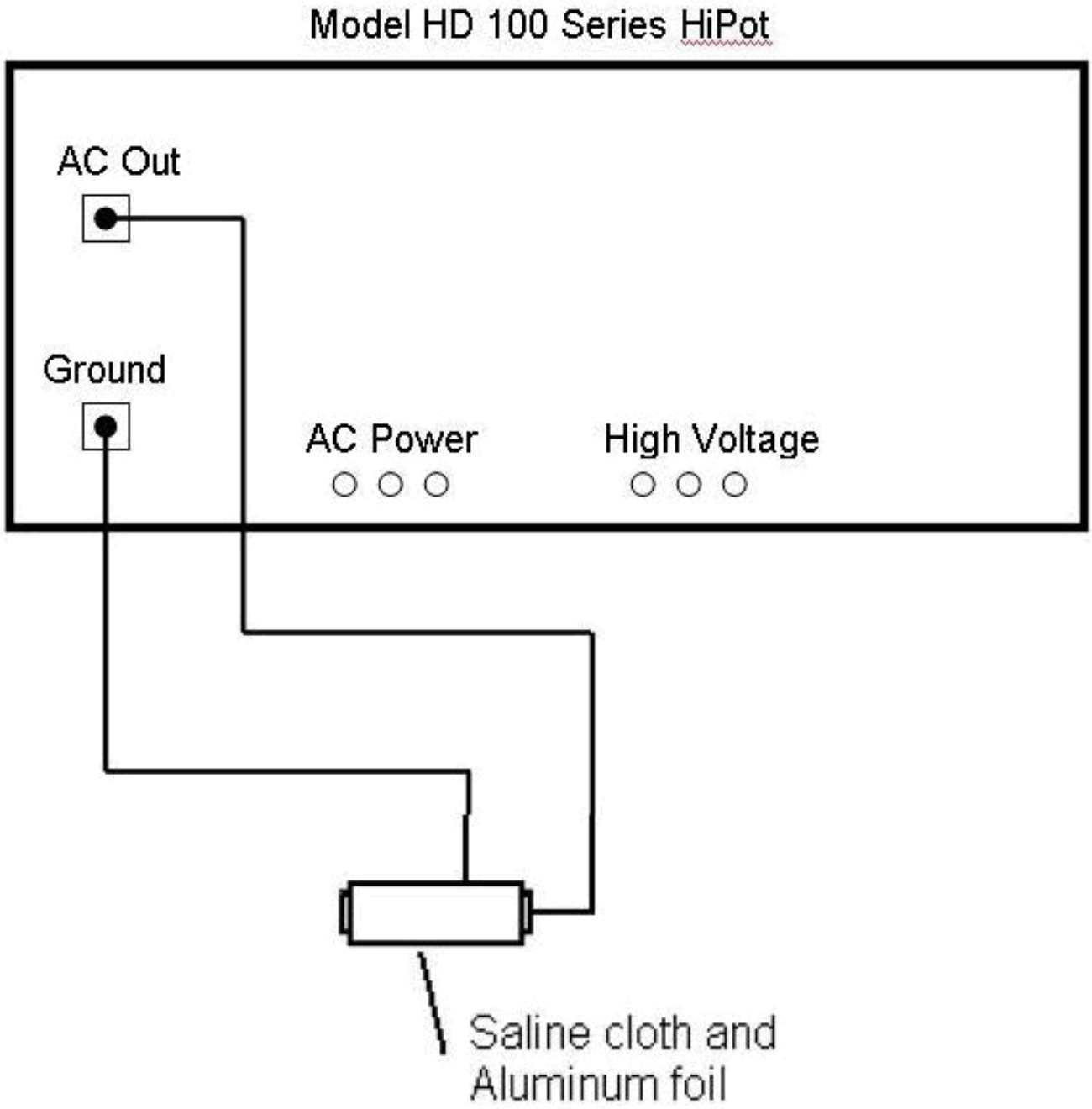
11.8. MEGA190658_ASTM ACE – GEM – Shipping Conditioning and Thermocycling Report

12. APPENDIX

Appendix I: Handpiece High Frequency Dielectric Withstand Test Setup



Appendix II: Handpiece Mains Frequency Dielectric Withstand Test Setup



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Appendix III: Datasheet for Handpiece High Frequency Dielectric Withstand and Mains Frequency Testing

Samples	Configuration X.Y.ZZ	High Frequency		Mains	Button Activation			
					CUT		COAG	
		Max V_{peak} (kV)	P/V	P/V	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
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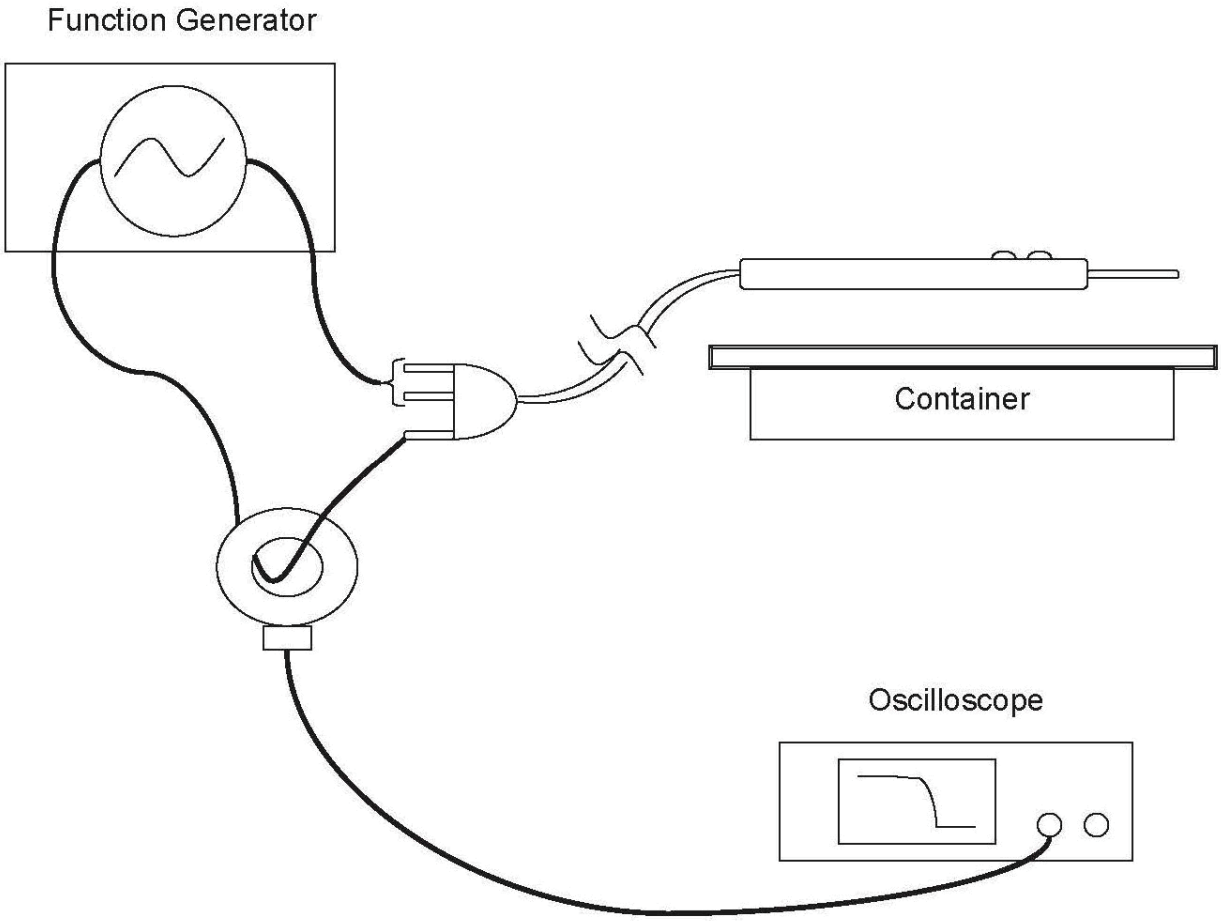
26								
27								
28								
29								
30								

Operator Name (Print)	Operator Signature	Date

Appendix IV: Handpiece High Frequency Dielectric Withstand and Mains Frequency Equipment Calibration Log

Calibration Information			
Multimeter		Generator	
Fluke 179 True RMS Multimeter		Mega Power 1000	
Serial Number		Serial Number	
Megadyne Number		Megadyne Number	
Calibration Date		Calibration Date	
Calibration Due		Calibration Due	
Oscilloscope		HiPot Test Generator	
Tektronix TDS 3012B		Hipotronics Model HD 100 Series	
Serial Number		Serial Number	
Megadyne Number		Megadyne Number	
Calibration Date		Calibration Date	
Calibration Due		Calibration Due	
High Voltage Probe		Inductive Current Coil	
Tektronix P6015A High Voltage Probe		Peerson Current Monitor, Model 2100	
Serial Number		Serial Number	
Megadyne Number		Megadyne Number	
Calibration Date		Calibration Date	
Calibration Due		Calibration Due	
RMS Voltmeter			
Fluke 8920A True RMS Voltmeter			
Serial Number			
Megadyne Number			
Calibration Date			
Calibration Due			

Appendix V: Handpiece Fluid Ingress Testing Setup



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Appendix VI: Datasheet for Handpiece Fluid Ingress Testing

Samples	Configuration X.Y.ZZ	Fluid Ingress		Button Activation			
				CUT		COAG	
		Pass	Fail	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
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25							
26							
27							
28							
29							
30							

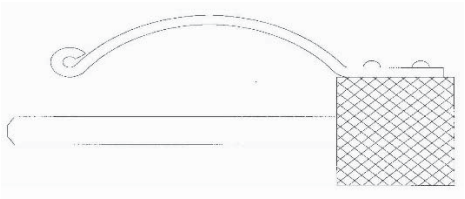
Operator Name (Print)	Operator Signature	Date

Appendix VII: Fluid Ingress Calibration Information

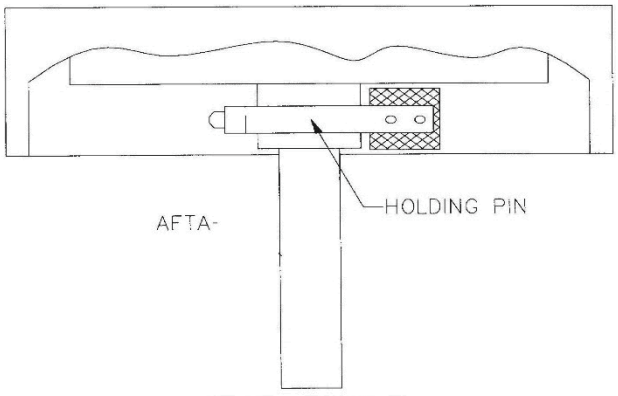
Calibration Information			
HiPot Test Generator		Multimeter	
Hipotronics Model HD 100 Series		Fluke 179 True RMS Multimeter	
Serial Number		Serial Number	
Megadyne Number		Megadyne Number	
Calibration Date		Calibration Date	
Calibration Due		Calibration Due	
Oscilloscope		Inductive Current Coil	
Tektronix TDS 3012B		Peerson Current Monitor, Model 2100	
Serial Number		Serial Number	
Megadyne Number		Megadyne Number	
Calibration Date		Calibration Date	
Calibration Due		Calibration Due	

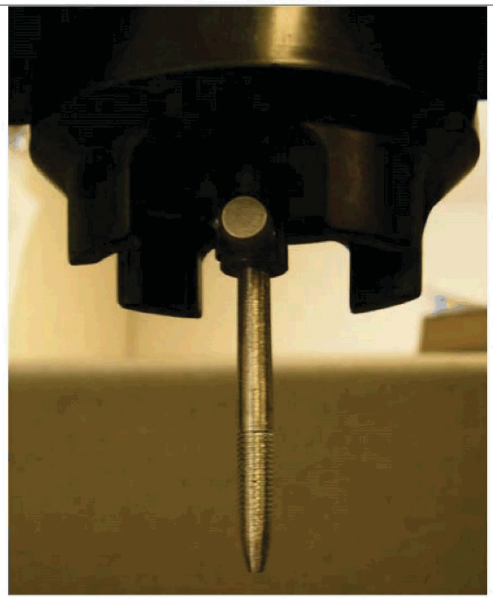
Appendix VIII: Button Activation Force Testing Fixtures and Setup

Steel Pin

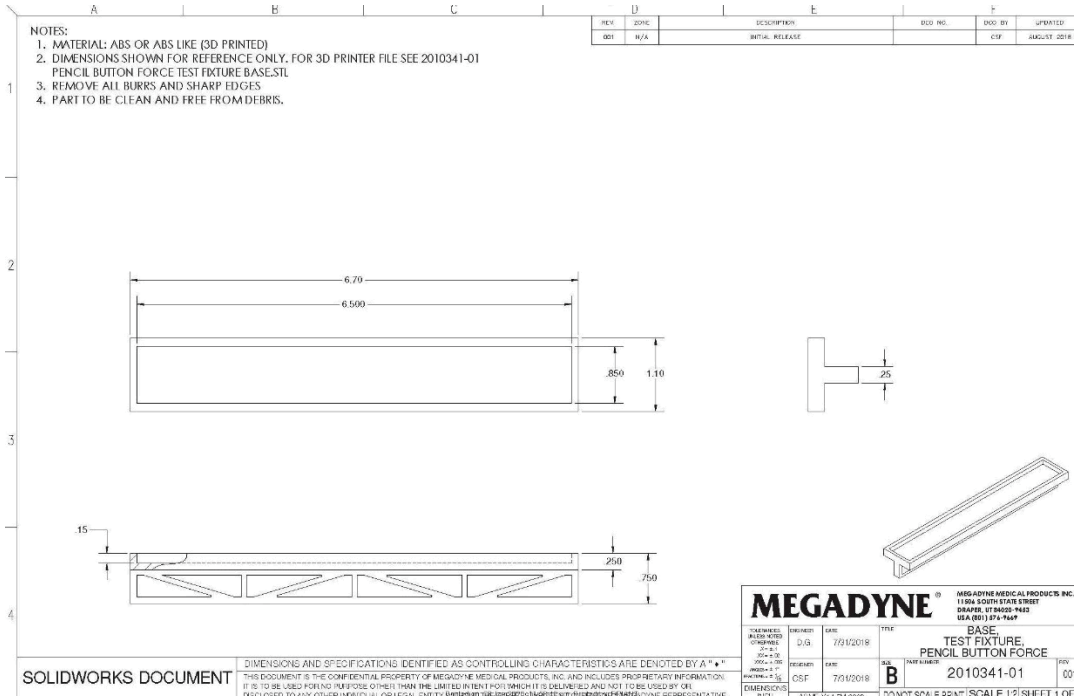


Sheer Pin with Spring Clip

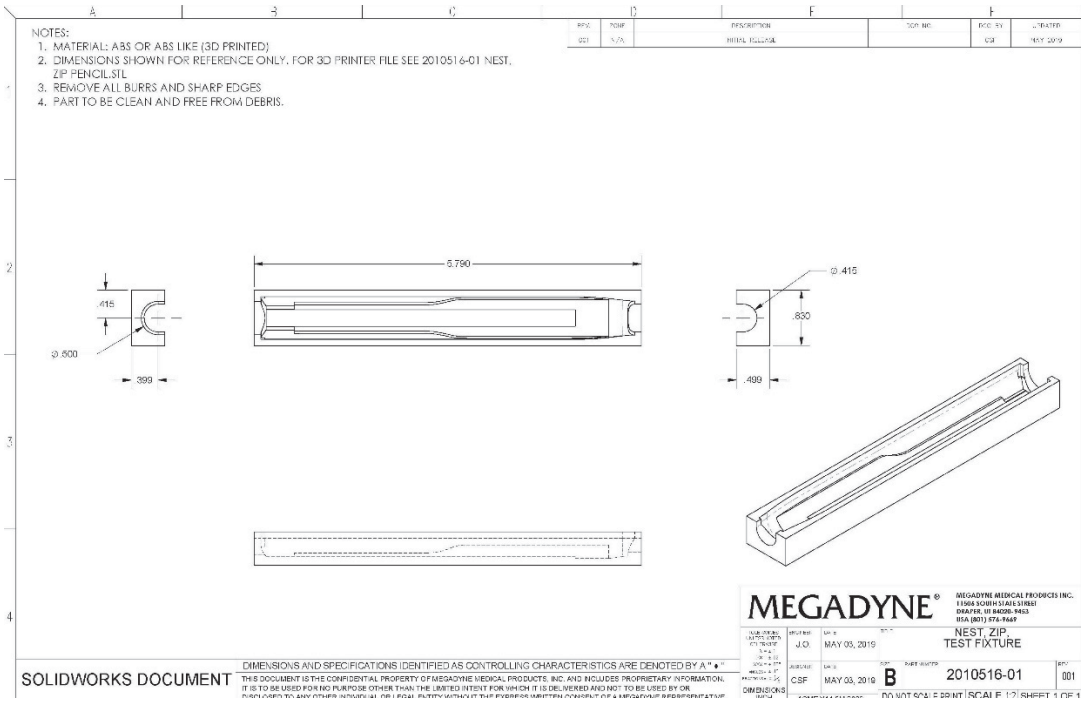




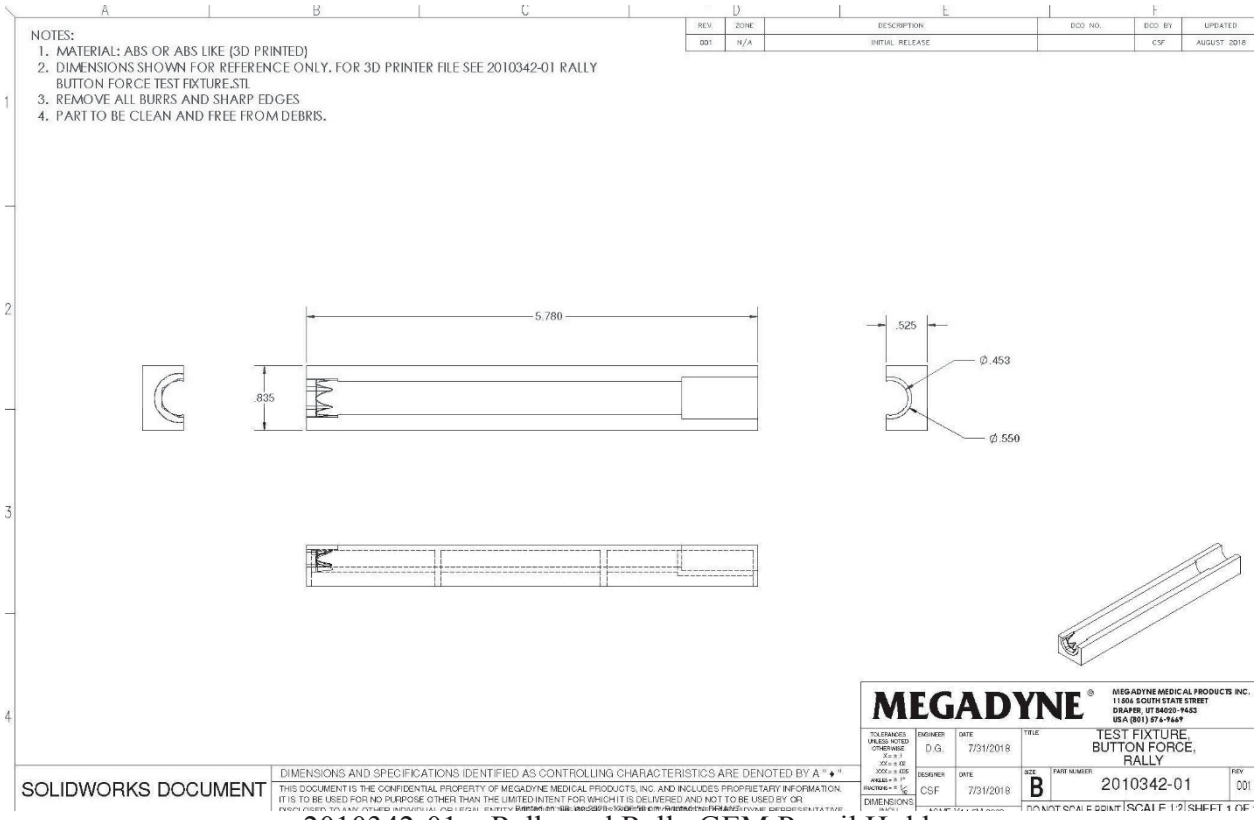
Pin Assembly in Load Cell



2010341-01 – Device Holder Base



2010516-01 – ZIP and ACE Pencil Holder



2010342-01 – Rally and Rally GEM Pencil Holder

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Appendix IX: Datasheet for Handpiece Button Force Activation Testing

Samples	Configuration X.Y.ZZ	Button Force		Button Activation			
				CUT		COAG	
		CUT	COAG	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1							
2							
3							
4							
5							
6							
7							
8							
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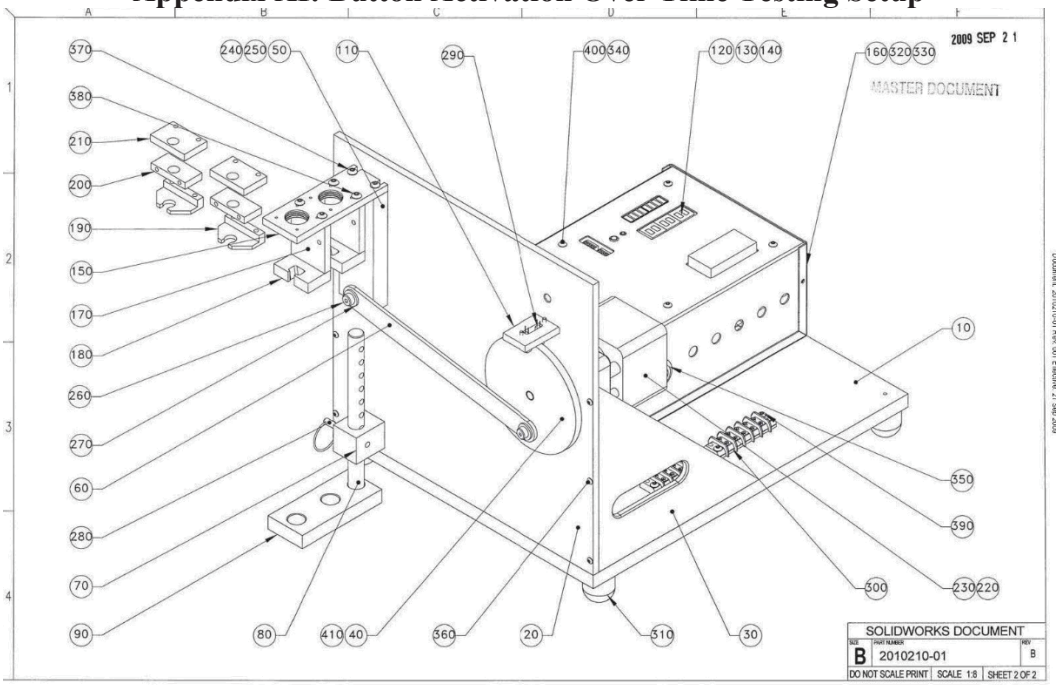
29							
30							

Operator Name (Print)	Operator Signature	Date

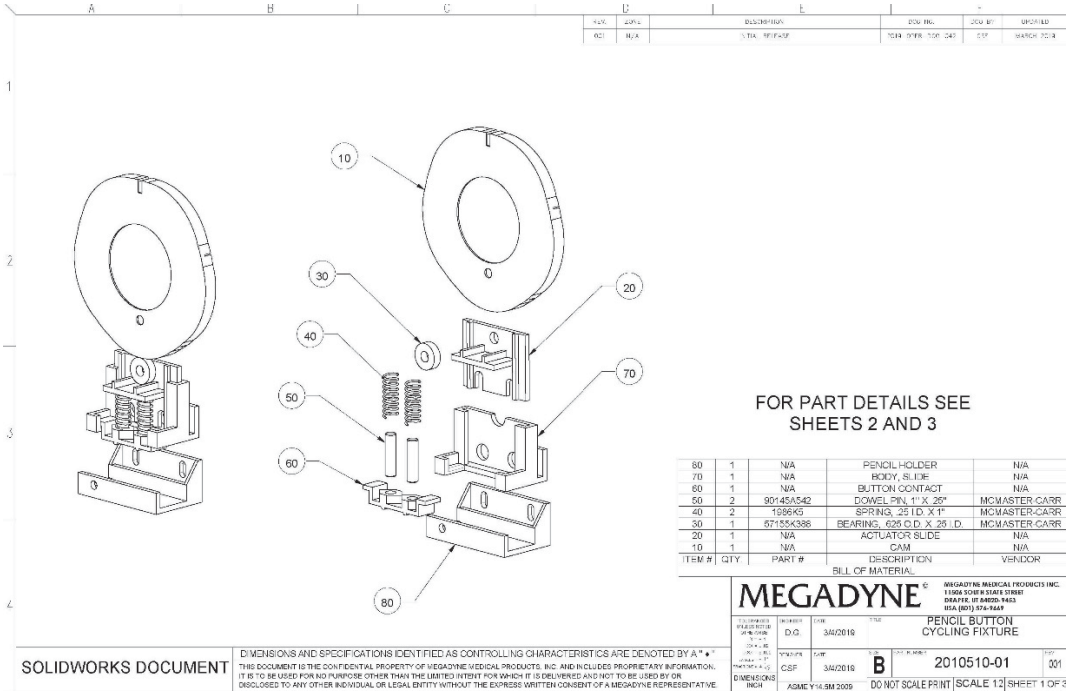
Appendix X: Button Force Activation Calibration Information

Calibration Information			
Instron		Multimeter	
Instron 4464		Fluke 179 True RMS Multimeter	
Serial Number		Serial Number	
Megadyne Number		Megadyne Number	
Calibration Date		Calibration Date	
Calibration Due		Calibration Due	

Appendix XI: Button Activation Over Time Testing Setup



Cycle Testing Machine



Cycle Testing Cam

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Appendix XII: Datasheet for Handpiece Force Over Time Testing

Samples	Configuration X.Y.ZZ	Button Activation Pre Cycle Testing				Button Activation Post Cycle			
		CUT		COAG		CUT		COAG	
		Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
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25									
26									
27									
28									
29									
30									

Operator Name (Print)	Operator Signature	Date

Appendix XIII: Button Activation Over Time Calibration Information

Calibration Information	
Multimeter	
Fluke 179 True RMS Multimeter	
Serial Number	
Megadyne Number	
Calibration Date	
Calibration Due	