MEGADYNE® Est. 1985

The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-PRT-230

DOCUMENT TITLE: Fluid Ingress Test - Zip Pencil

DOCUMENT NOTES:

Initial release into MasterControl

Document Information

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

Date Information

Effective Date: 21 Mar 2014	Expiration Date:
Release Date: 21 Mar 2014	Next Review Date:

Control Information

Author: PBORGMEIER	Owner: ENG-APPR
Previous Number: 1150721-10	Change Number: 14-037-01

<table>
<tr><td rowspan="4">Megadyne Medical Products, Inc.</td><td>TEST PROTOCOL</td><td>Document Number
1150721-10</td></tr>
<tr><td rowspan="3">Fluid Ingress Test – Zip Pencil
MASTER DOCUMENT</td><td>Revision: A</td></tr>
<tr><td>Effective Date:
2014 MAR 21</td></tr>
<tr><td>Page 1 of 11</td></tr>
</table>

Mark Glassett 21 Mar 2014
Engineering Verification:

Lucy Richards 21 Mar 2014
D.C. Verification:

Authored By: Darcy Greep and Mark Glassett

TABLE OF CONTENTS

Page

1. REFERENCE

IEC 60601 – 2 – 2: 2009	Section 201.11.6.5 (b) Ingress of water or particulate matter into ME equipment and ME systems

2. APPENDIX

Appendix I: Hand Switching Device Fluid Ingress Test Setup
Appendix II: Test Recording Sheet

3. SCOPE

This protocol evaluates the effects of fluid ingress on the Zip Pencil.

4. PURPOSE

Fluid entering the Zip Pencil housing may result in self activation or other as-yet-unknown conditions. The purpose of this protocol is to identify the effects of device exposure to a known volume of fluid in conformance with IEC 60601-2-2:2009 to ensure proper and safe operation.

5. BACKGROUND

IEC 60601-2-2 is the industry standard that applies to medical electrical equipment. This is a required test to evaluate the design and safety of Zip Pencil in protecting the user and patient against inadvertent activation due to fluid entering the device.
The Standard requirements are as follows:

b) * The electrical parts of FINGERSWITCHES shall be protected against the effects of ingress of liquids that might cause inadvertent energization of the APPLIED PART (see also 201.8.8.3.103).

Compliance is checked by the following test.

The a.c. impedance of each of the switching terminals of the ACTIVE CONNECTOR shall be measured using a frequency of at least 1 kHz and a voltage of less than 12 V. The ACTIVE HANDLE is supported horizontally at least 50 mm above any surface with the switch activating parts uppermost. One litre of 0,9 % saline solution is poured steadily from above over the ACTIVE HANDLE over a period of 15 s so as to wet the entire length of the ACTIVE HANDLE. The *liquid is allowed to drain away freely. The a.c. impedance of the switching terminals shall remain greater than 2 000 Ω.*

Immediately after, each FINGERSWITCH is operated and released 10 times. The a.c. impedance of the switching terminals shall exceed 2 000 Ω within 0,5 s after each release.

6. DEFINITIONS AND ACRONYMS

NA

7. APPARATUS

7.1. TDS 2014 Tektronix Oscilloscope, or equivalent

7.2. 0.9% Saline

7.3. Appropriate leads for connection of the test set-up

7.4. Container to support device and hold 1 Liter of fluid

7.5. Ohmmeter (or multi-meter)

7.6. Stop watch or equivalent

7.7. Function generator

7.8. Current loop

8. RISK ASSESSMENT

Document 1300041-10 (Risk Analysis, Smoke Evacuation Accessories) identifies the risks associated with fluid ingress. The highest severity rating is 10 for patient burn attributable to incorrect mode activation or self activation. The following list shows failure mode, cause, mitigation and verification for fluid ingress.

Failure Mode	Cause	Mitigation	Verification
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	Material, design and assembly requirements are defined on drawing. Fluid Ingress Test Report 1150721-01.

9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION

A sample size of 30 pieces shall be used for this test. A smaller or larger sample size may be used with appropriate justification. The use of 30 samples has statistical significance as identified in SOP 1010035-10, Sampling and Statistical Techniques.

10. PROCEDURE

10.1. Document the manufacturer, model number, and calibration information for all equipment used throughout this procedure.

10.2. Assign each sample a unique identifier and record on sample with permanent marker or other permanent method.

10.3. Prior to testing, use an ohmmeter to measure and record the resistance of each Zip Pencil. Check both Cut and Coag switches. A device is considered out of tolerance if the resistance is greater than 50 ohms when the button is depressed or less than 10,000 ohms when the button is released. Do not use an out of tolerance pencil for testing.

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

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

10.5.1. Ensure the offset = 0

10.5.2. Ensure the waveform is sinusoidal.

10.6. 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)

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

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

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

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

10.11. Connect the appropriate lead to the function generator.

10.12. Place the Zip Pencil to be tested in the container with the cord and plug out of the container.

10.13. Using the test lead identified in 10.11, connect one wire to the common pin on the Zip Pencil plug and the other wire to the cut or coag pin on the plug (depending on which mode is being tested).

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

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

10.16. 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.

10.17. 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).

10.18. 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.

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

10.20. 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.

10.21. Allow the fluid to drain away freely.

10.22. 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.

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

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

10.22.3. 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.

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

10.24. Repeat steps 10.22 through 10.23 nine more times

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

10.26. Repeat 10.22 through 10.24 for the remaining mode.

10.27. Repeat all steps, 10.12 – 10.26 for each sample.

10.28. Perform a worst case test by repeating steps 10.12-10.27 with the Zip Pencil inverted at a 45 degree angle (buttons down) and by pouring the saline into the pencil housing between the extended tubing and the housing as shown in the following illustrations.

Illustration A – Inverted at a 45° Angle for Worst Case Fluid Ingress Testing

11. ACCEPTANCE CRITERIA

11.1. 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.

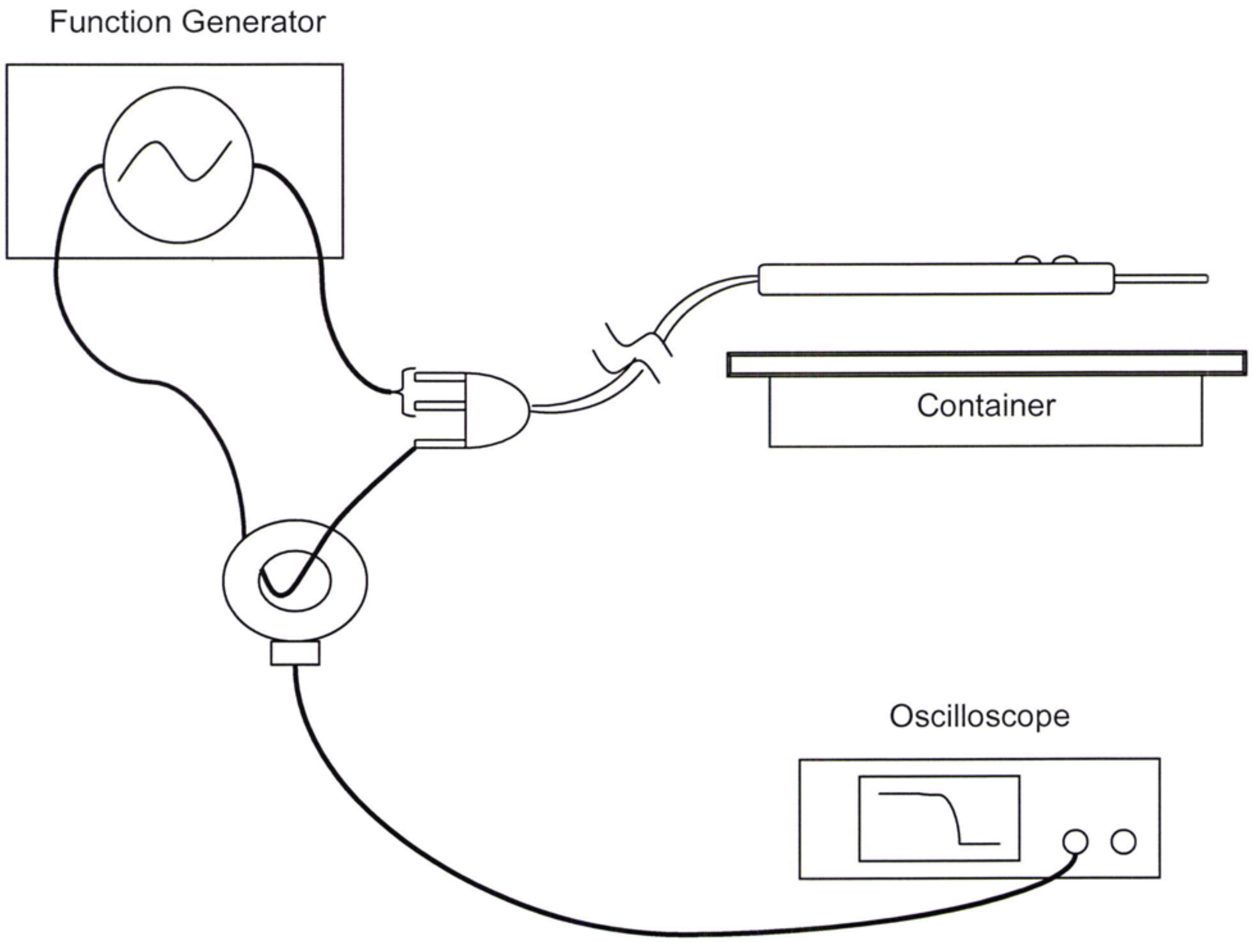
(The standard requires the AC impedance of the switch to exceed 2.0 kΩ within 0.5 seconds after release. Using a voltage of 10 $V_{p\text{-}p}$, a current of 5.0 mA or less is necessary to meet this requirement).

11.2. The inverted orientation test of Zip 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 Zip Pencil due to fluid ingress in this orientation should be noted and Engineering notified for further investigation.

12. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-037-01	Initial Release	2014 MAR 21

Appendix I: Hand Switching Device Fluid Ingress Test Setup



Appendix II: Test Recording Form

Fluid Ingress Test

Sample #	Data Collection Form		FLUID INGRESS (pass/fail)	
	CUT	COAG	CUT	COAG
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Calibration Information:

Function Generator

Megadyne #:

Calibration Date:

Calibration Due:

Multimeter

Megadyne #:

Calibration Date:

Calibration Due:

Current Loop

Megadyne #:

Calibration Date:

Calibration Due:

Oscilloscope

Megadyne #:

Calibration Date:

Calibration Due:

Operator Name Operator Signature Date completed