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1. ABSTRACT

A modification was made on a pilot run of All In One hand piece (AIO) samples to protect the PCB with PTFE tape instead of heat shrink tubing. This method of protecting the PCB has been used successfully on other products and is easier to produce in manufacturing. This test was performed in order to support a change to the product to use PTFE tape in place of the heat shrink. The pilot run samples were exposed to five year accelerated aging and subjected to the hand piece tests required for IEC 60601-2-2: 2006 4th edition to show acceptance of the change.

The AIO was tested for high frequency dielectric withstand, mains frequency dielectric withstand, and fluid ingress per the requirements of the protocol to show compliance to IEC 60601-2-2: 2006. The handpiece met the requirements of the standard for all of these tests.

2. OBJECTIVE

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3. RESULTS

3.1. Hand Piece High Frequency Dielectric

Thirty samples of the AIO hand piece were tested for high frequency dielectric withstand. The test method used for HF dielectric withstand testing was per protocol 1150383-10 paragraph 10.5. All of the AIO hand pieces passed the test at or above the required voltage of 10.8 kV for 30 seconds.

3.2. Hand Piece Mains Frequency Dielectric

The same thirty samples of the AIO hand piece that were used for HF dielectric testing were tested for mains frequency dielectric withstand. The test method used was per protocol 1150383-10 paragraph 10.6. All of the AIO hand pieces passed the test at the required voltage of 2.0 kV for 30 seconds.

3.3. Fluid Ingress

Thirty samples of the AIO hand piece were tested for fluid ingress per protocol 1150422-10. The method written in this protocol is taken from IEC 60601-2-2. All 30 of the samples passed.

4. DISCUSSION

The samples used for all of the testing were catalog 0055 AIO Handpieces Lot # 91387. These samples were exposed to accelerated aging to simulate five years prior to testing. The aging was performed at 55°C for over 185 days. See appendix II for aging data.

4.1. High Frequency Dielectric

Thirty samples of the AIO hand piece were tested for HF dielectric withstand. The test method used was per protocol 1150383-10 paragraph 10.5. All of the AIO hand pieces passed the test above the required voltage of 10.8 kV for 30 seconds. The maximum voltage achieved during the test was 11.3 kV and the minimum was 10.98 kV. The raw data is presented in a spreadsheet attached as Appendix I.

4.2. Mains Frequency Dielectric

The same thirty samples of the AIO hand piece used for HF dielectric testing were tested for mains frequency dielectric withstand. The test method used was per protocol

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1150383-10 paragraph 10.6. All of the AIO hand pieces passed the test at the required voltage of 2.0 kV for 30 seconds. The raw data is presented in a spreadsheet attached as Appendix I.

4.3. Fluid Ingress

Thirty samples of the AIO hand piece were tested for fluid ingress per protocol 1150422-10. The method written in this protocol is taken from IEC 60601-2-2 section 44.6 bb). This test requires the handpiece to be held horizontally while 1 liter of saline solution is poured over the unit in 15 seconds with the switch activating parts uppermost. A voltage is applied to the switching circuit during the saline application. After the saline is applied, each switching circuit is activated 10 times. The a.c. impedance of the open switching circuits shall remain greater than 2,000 ohms during the test. All 30 of the samples passed. The raw data is presented in a spreadsheet attached as Appendix I.

5. CONCLUSIONS

This testing demonstrates that the revised All In One Handpiece complies with the required standards that are referenced in the protocol after five year accelerated aging.

6. RECOMMENDATIONS

This testing was performed to demonstrate compliance to IEC 60601-2-2: 2006 for the revised All In One Hand piece after five year accelerated aging. The AIO subassembly drawing 6020021-01 will be revised to use the PTFE tape for protection of the PCB in place of the heat shrink tubing. Additional testing will be done real time age product when it is available.

7. REVISION HISTORY

| REVISION | DOCUMENT CHANGE ORDER NUMBER | DESCRIPTION OF CHANGE | EFFECTIVE DATE |
|----------|---------------------------------------|-----------------------|-------------------|
| A | 10-072-01 | Initial Release | 2010 APR 07 |
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APPENDIX I

All In One Dielectric Withstand & Ingress of Fluids Testing

| Sample | HIGH FREQ | | MAINS | SPLASH |
|--------|-----------------|-------|-------|--------|
| | Max Vpp (kV) | P / F | P / F | P/F |
| 1 | 11.2 | PASS | PASS | PASS |
| 2 | 11.0 | PASS | PASS | PASS |
| 3 | 11.0 | PASS | PASS | PASS |
| 4 | 11.1 | PASS | PASS | PASS |
| 5 | 11.2 | PASS | PASS | PASS |
| 6 | 11.3 | PASS | PASS | PASS |
| 7 | 11.0 | PASS | PASS | PASS |
| 8 | 11.1 | PASS | PASS | PASS |
| 9 | 11.1 | PASS | PASS | PASS |
| 10 | 11.3 | PASS | PASS | PASS |
| 11 | 11.0 | PASS | PASS | PASS |
| 12 | 11.1 | PASS | PASS | PASS |
| 13 | 11.3 | PASS | PASS | PASS |
| 14 | 11.0 | PASS | PASS | PASS |
| 15 | 11.1 | PASS | PASS | PASS |
| 16 | 11.1 | PASS | PASS | PASS |
| 17 | 11.0 | PASS | PASS | PASS |
| 18 | 10.9 | PASS | PASS | PASS |
| 19 | 11.3 | PASS | PASS | PASS |
| 20 | 11.3 | PASS | PASS | PASS |
| 21 | 11.3 | PASS | PASS | PASS |
| 22 | 11.3 | PASS | PASS | PASS |
| 23 | 11.2 | PASS | PASS | PASS |
| 24 | 11.3 | PASS | PASS | PASS |
| 25 | 11.2 | PASS | PASS | PASS |
| 26 | 11.2 | PASS | PASS | PASS |
| 27 | 11.1 | PASS | PASS | PASS |
| 28 | 11.0 | PASS | PASS | PASS |
| 29 | 11.3 | PASS | PASS | PASS |
| 30 | 11.2 | PASS | PASS | PASS |

Calibration Info:

HiPot

Megadyne Number: #01037
Calibration Date: 8/4/2009
Calibration Due: 8/31/2010

Generator

Megadyne Number: #01173
Calibration Date: N/A
Calibration Due: N/A

Oscilloscope

Megadyne Number: #01142
Calibration Date: 10/29/2009
Calibration Due: 10/31/2010

High Voltage Probe

Megadyne Number: #01138
Calibration Date: 6/9/2009
Calibration Due: 6/30/2010

Inductive Current Coil

Megadyne Number: #01288
Calibration Date: 12/21/2009
Calibration Due: 12/21/2010

Function Generator

Megadyne Number: #01195
Calibration Date: 12/16/2009
Calibration Due: 12/16/2010

Multimeter

Megadyne Number: #01372
Calibration Date: 4/28/2009
Calibration Due: 4/30/2010

Paul Valpreda

Paul Valpreda

3/23/2010

Operator Name

Operator Signature

Date

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APPENDIX II
Aging Process Sheet

Accelerated Aging In Process

Product: 0055 All In One Handpiece
Prototype with Teflon Tape on PCB
Lot Number 91387

Temperature 55°
Relative Humidity Ambient

Required Time 26 weeks 3 days
(185 days)

| Start | Time | Stop | Time | Total | ECD |
|------------|----------|------------|----------|----------|-----|
| 06/19/2009 | 3:00 PM | 09/04/2009 | 4:00 PM | 45 days | |
| 09/08/2009 | 8:45 AM | 09/18/2009 | 8:30 AM | 55 days | |
| 09/21/2009 | 3:15 PM | 09/25/2009 | 8:30 AM | 59 days | |
| 10/23/2009 | 10:00 AM | 01/12/2010 | 4:15 PM | 140 days | |
| 1/19/2010 | 8:45 AM | 1/21/2010 | 1:00 PM | 142 days | |
| 1/25/2010 | 8:30AM | 2/2/2010 | 4:00 PM | 150 days | |
| 2/8/2010 | 1:30 PM | 2/15/2010 | 11:00 AM | 157 days | |
| 2/19/2010 | 7:00 AM | 3/19/2010 | 8:15 AM | 185 days | |

Contact Mark Glassett Extension 845

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