



The Electrosurgical Authority®

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Zip Pen Thermal Protocol and Report

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Collaboration

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Mark Glassett (MGLASSETT)			In Process
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Balaji Sudabattula (BSUDABATTULA)			
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Balaji Sudabattula (BSUDABATTULA)		24 Oct 2014, 01:25:53 PM	Approved

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Lucy Richards (LRICHARDS)		24 Oct 2014, 02:03:59 PM	Approved

Final Release

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Balaji Sudabattula (BSUDABATTULA)			
Lucy Richards (LRICHARDS)		24 Oct 2014, 02:04:15 PM	Approved

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1. ABSTRACT

Zip Pen and Extension Nozzle samples that have been through accelerated aging to simulate 3 years, and have been exposed to shipping cycle temperature extremes, were subjected to thermal tests required for compliance to IEC 60601-1. The Zip Pen and Extension Nozzles passed the requirements of the standard.

Additional investigative testing was performed to evaluate the thermal characteristics of the Zip Pen and Extension Nozzles under simulated use conditions.

2. OBJECTIVE

The objective of this test report is to document compliance of the Zip Pen and Extension Nozzle catalog items 2525-10, 2525-15, 2540 and 2560 with IEC 60601-1 clause 11.1.2.2 requirements for temperature of a device that is not an applied part but is likely to contact the patient.

3. RESULTS

3.1. Zip Pen IEC 60601-1 Temperature Test

3.1.1. The Zip Pen and Extension Nozzle samples required by the protocol were tested at 300 Watts Cut for the duty cycle of the Mega Power generator

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which is 10 seconds on and 30 seconds off for one hour as required by IEC 60601-2-2 clause 201.11.1.1. All samples passed the test requirement, which is not to exceed a temperature of 41°C.

- 3.1.2. The Zip Pen and Extension Nozzle samples required by the protocol were tested at 120 Watts Coag for the duty cycle of the Mega Power generator which is 10 seconds on and 30 seconds off for one hour as required by IEC 60601-2-2 clause 201.11.1.1. All samples passed the test requirement which is not to exceed a temperature of 41°C.

3.2. Simulated Use Thermal Investigation

- 3.2.1. The Zip Pen and Extension Nozzle samples were tested in a simulated use condition at 50 Watts Cut for 10 seconds per the requirements of the protocol. There was no melting or other damage to the nozzle where it comes in close proximity to the electrode. Although not a specific requirement of the protocol, the nozzle temperature did not exceed 41°C.
- 3.2.2. The Zip Pen and Extension Nozzle samples were tested in a simulated use condition at 50 Watts Coag for 10 seconds per the requirements of the protocol. There was no melting or other damage to the nozzle where it comes in close proximity to the electrode. Although not a specific requirement of the protocol, the nozzle temperature did not exceed 41°C.

4. DISCUSSION

Zip Pen Catalog item 2525-15 and Extension Nozzles catalog number 2540 and 2560 were used for this testing. See Attachment 1 for lot numbers. All samples were subjected to accelerated aging and to shipping and storage extremes of -40°C to 70°C and humidity of 15% to 95% to support label claims prior to testing. Documentation of accelerated aging is shown as Attachment 3. For Zip Pen, refer to test report ENG-RPT-377 for documentation of shipping and storage extremes. For extension nozzles, refer to ENG-RPT-391 for documentation of shipping and storage extremes.

4.1. Zip Pen IEC 60601-1 Temperature Test

- 4.1.1. The Zip Pen samples were measured for temperature before and after each test as required by the protocol. The temperatures were measured using the calibrated FLIR T300 thermal imaging camera. The thermal images and

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data analysis are shown in Attachment 2. The comparisons of temperatures before and after activation are summarized as follows:

Sample and Test Description	Temperature		
	Before (°C)	After (°C)	Change (°C)
Zip Pen No extension, 300 W Cut	22.1	26.3	4.2
Zip Pen No extension, 120 W Coag	23.2	23.3	0.1
Zip Pen 2540 extension, 300 W Cut	21.9	27.3	5.4
Zip Pen 2540 extension, 120 W Coag	23.2	24.0	0.8
Zip Pen 2560 extension, 300 W Cut	20.8	24.4	3.6
Zip Pen 2560 extension, 120 W Coag	23.3	24.7	1.4

- 4.1.2. The maximum temperature for the three test configurations was with the 2540 extension at 300 W Cut. The highest temperature was 27.3°C. The requirement of the protocol and IEC 60601-1:2012 clause 11.1.2.2 is that the temperature be below 41°C. The Zip Pen and Extension Nozzles meet the requirements of the protocol and 60601-1:2012.

4.2. Simulated Use Thermal Investigation

- 4.2.1. The Zip Pen samples were measured for temperature after each test. The temperatures were measured using the calibrated FLIR T300 thermal imaging camera. The thermal images and the data analysis are shown in attachment 2. One baseline temperature measurement was made prior to activations at the beginning of the tests. The maximum temperatures not including the electrode are summarized as follows:

Test Description	Temperature (°C)
Test 7 pre, Zip Pen Baseline	22.0
Test 7 post, Zip Pen No extension, 50 W Cut	23.8
Test 8, Zip Pen No extension, 50 W Coag	24.5
Test 9, Zip Pen 2540 extension, 50 W Cut	24.4
Test 10, Zip Pen 2540 extension, 50 W Coag	25.2
Test 11, Zip Pen 2560 extension, 50 W Cut	24.8
Test 12, Zip Pen 2560 extension, 50 W Coag	25.2

- 4.2.2. The temperatures measurements do not include the electrode. This is because the electrode is specified as a component that is intended to provide heat to the patient per IEC 60601-2-2 clause 201.11.1.2.1. The

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standard states for active electrodes that “Disclosure of temperatures and clinical effects is not required”.

5. CONCLUSIONS

The Zip Pen and Extension Nozzles meet the requirements of IEC 60601-1:2012 Clause 11.1.2.2 when tested at maximum power for Cut and Coag on the rated duty cycle with the Mega Power electrosurgical generator.

The distal end of the Zip Pen and Extension Nozzles are not damaged by the heat of the electrode under simulated use conditions.

6. RECOMMENDATIONS

Since the temperature of the device does not exceed 41°C, no changes to the product or labeling are required. In order to document the acceptance to the temperature requirements, updates to the Essential Requirements RA-ER-009, Product Specification ENG-PS-007, Risk Analysis ENG-RMF-045, Device master Record ENG-DMR-012, and Test Matrix ENG-IOM-022 are required.

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Attachment 1 Product and Equipment Data Sheet

FDA Handpiece / Nozzle test									
29 & 30 Sept 2014									
Paul Valpreda & Tom Carlyle									
Device Description								Last Calib.	Next Due
FLIR T300, SN 453000505 (MMP ID# 01429)								1/30/2014	1/30/2015
MegaVac Plus, Model 350-D, SN 4211								N.A.	N.A.
Mega Power 1000, SN 134358006								N.A.	N.A.
ZIP Pencils:									
Prod. ID	Lot #	Sample#	Other Identification						
2525-10	S140045	12	X3900225-01 Rev 01 2013-08						
2525-10	S140045	14	X3900225-01 Rev 01 2013-08						
2525-10	S140045	25	X3900225-01 Rev 01 2013-08						
Nozzle Extensions:									
Prod. ID	Lot #	Sample#	Other Identification						
2540	S140119	N.A.	2.7" (68mm) Extension Nozzle						
2560	S140120	N.A.	5.2" (132mm) Extension Nozzle						
Electrodes:									
Prod. ID	Lot #	Sample#	Expires	Other Identification					
0312	140303	N.A.	2019-01	2.5" Stainless, Uncoated					
0314	142218	N.A.	2019-06	6.5" Stainless, Uncoated					
0314A	141664	N.A.	2019-04	4.0" Stainless, Uncoated					

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Attachment 2 Thermal Images and Data Sheet

Test #	Test description	IR Photo Info				Analyses Area [#]	Measured		Calculated		
		[Pre / Post]	Date	Time	File name		Min. Temperature [°C]	Max. Temperature [°C]	Delta Temperature [°C]	Max. Delta [°C]	Max. Max. [°C]
1	Pure Cut, 300W, 300Ω, No Additional Nozzle	Pre	9/29/2014	10:03:57 AM	Ir_0679.jpg	AR01	22.2	23.5			
						AR02	22.2	23.5			
						AR03	22.1	23.6			
		Post	9/29/2014	11:12:21 AM	Ir_0684.jpg	AR01	23.5	24.8	2.6	4.2	26.3
						AR02	23.3	25.1	2.9		
						AR03	23.0	26.3	4.2		
2	Spray Coag, 120W, 500Ω, No Additional Nozzle	Pre	9/29/2014	11:41:53 AM	Ir_0685.jpg	AR01	23.2	24.3			
						AR02	23.2	24.3			
						AR03	23.2	24.4			
		Post	9/29/2014	12:43:19 PM	Ir_0688.jpg	AR01	22.2	23.0	-0.2	0.1	23.3
						AR02	22.1	23.0	-0.2		
						AR03	22.1	23.3	0.1		
3	Pure Cut, 300W, 300Ω, Medium Nozzle (2.7" Extension)	Pre	9/29/2014	1:16:32 PM	Ir_0690.jpg	AR01	21.9	24.4			
						AR02	22.0	25.1			
						AR03	22.0	24.0			
		Post	9/29/2014	2:18:25 PM	Ir_0693.jpg	AR01	22.9	27.3	5.4	5.4	27.3
						AR02	22.9	25.7	3.7		
						AR03	22.6	24.4	2.4		
4	Spray Coag, 120W, 500Ω, Medium Nozzle (2.7" Extension)	Pre	9/29/2014	2:56:15 PM	Ir_0694.jpg	AR01	23.2	24.0			
						AR02	23.2	24.0			
						AR03	23.1	24.1			
		Post	9/29/2014	4:05:02 PM	Ir_0698.jpg	AR01	21.8	24.0	0.8	0.8	24.0
						AR02	21.8	23.8	0.6		
						AR03	21.7	22.8	-0.3		
5	Pure Cut, 300W, 300Ω, Long Nozzle (5.2" Extension)	Pre	9/30/2014	7:33:37 AM	Ir_0699.jpg	AR01	20.8	23.0			
						AR02	20.8	23.8			
						AR03	20.9	24.7			
		Post	9/30/2014	8:41:23 AM	Ir_0705.jpg	AR01	23.0	24.3	3.5	3.6	24.4
						AR02	22.9	24.4	3.6		
						AR03	22.8	24.0	3.1		
6	Spray Coag, 120W, 500Ω, Long Nozzle (5.2" Extension)	Pre	9/30/2014	9:04:21 AM	Ir_0708.jpg	AR01	23.3	25.0			
						AR02	23.4	25.1			
						AR03	23.3	25.0			
		Post	9/30/2014	10:08:03 AM	Ir_0712.jpg	AR01	22.8	24.7	1.4	1.4	24.7
						AR02	22.8	24.6	1.2		
						AR03	22.7	24.2	0.9		

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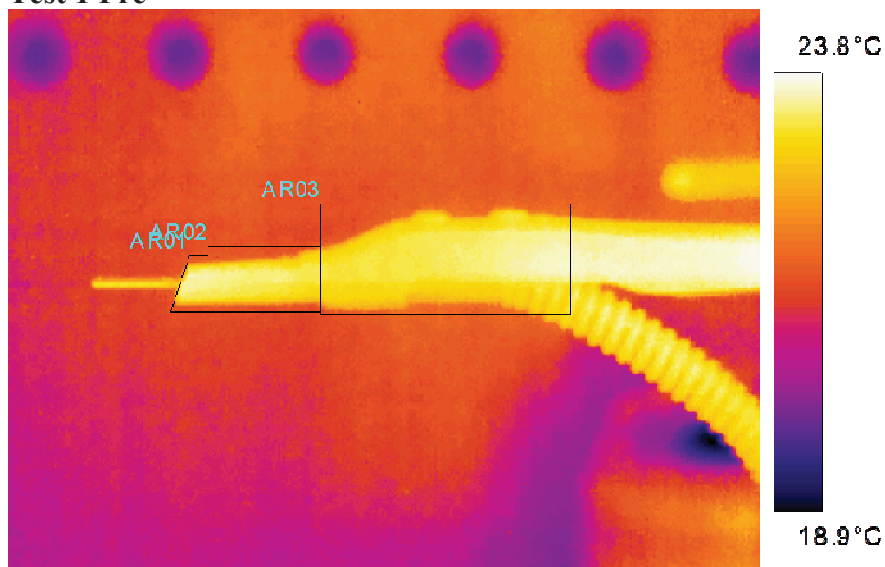
						Measured			Calculated		
		IR Photo Info				Analyses Area	Min. Temperature	Max. Temperature	Delta Temperature	Max. Delta	Max. Max
Test #	Test description	Pre / Post	Date	Time	File name	[#]	[°C]	[°C]	[°C]	[°C]	[°C]
7	Image of handpiece with long nozzle left on after 1 Hr test + Pure Cut, 50W, Long Nozzle	Pre	9/30/2014	12:54:18 PM	lr_0722.jpg	AR01	22.2	23.6			
						AR02	22.0	23.6			
						AR03	22.0	23.3			
		Post	9/30/2014	1:01:18 PM	lr_0723.jpg	AR01	22.0	23.8	1.6	1.6	23.8
						AR02	22.1	22.9	0.9		
						AR03	22.2	23.0	1.0		
8	Image of handpiece with long nozzle left on after 1 Hr test + Spray Coag, 50W, Long Nozzle	Pre	9/30/2014	12:54:18 PM	lr_0722.jpg	AR01	22.2	23.6			
						AR02	22.0	23.6			
						AR03	22.0	23.3			
		Post	9/30/2014	1:04:39 PM	lr_0724.jpg	AR01	22.6	24.3	2.1	2.5	24.5
						AR02	22.2	24.5	2.5		
						AR03	22.2	24.0	2.0		
9	Image of handpiece with long nozzle left on after 1 Hr test + Pure Cut, 50W, Medium Nozzle	Pre	9/30/2014	12:54:18 PM	lr_0722.jpg	AR01	22.2	23.6			
						AR02	22.0	23.6			
						AR03	22.0	23.3			
		Post	9/30/2014	1:14:00 PM	lr_0727.jpg	AR01	22.3	24.2	2.0	2.4	24.4
						AR02	22.3	24.4	2.4		
						AR03	22.8	24.4	2.4		
10	Image of handpiece with long nozzle left on after 1 Hr test + Spray Coag, 50W, Medium Nozzle	Pre	9/30/2014	12:54:18 PM	lr_0722.jpg	AR01	22.2	23.6			
						AR02	22.0	23.6			
						AR03	22.0	23.3			
		Post	9/30/2014	1:15:14 PM	lr_0728.jpg	AR01	22.4	24.8	2.6	3.2	25.2
						AR02	22.4	25.2	3.2		
						AR03	23.0	24.8	2.8		
11	Image of handpiece with long nozzle left on after 1 Hr test + Pure Cut, 50W, No additional nozzle	Pre	9/30/2014	12:54:18 PM	lr_0722.jpg	AR01	22.2	23.6			
						AR02	22.0	23.6			
						AR03	22.0	23.3			
		Post	9/30/2014	1:25:10 PM	lr_0733.jpg	AR01	19.7	23.8	1.6	2.8	24.8
						AR02	21.4	24.7	2.7		
						AR03	23.4	24.8	2.8		
12	Image of handpiece with long nozzle left on after 1 Hr test + Spray Cut, 50W, No additional nozzle	Pre	9/30/2014	12:54:18 PM	lr_0722.jpg	AR01	22.2	23.6			
						AR02	22.0	23.6			
						AR03	22.0	23.3			
		Post	9/30/2014	1:26:37 PM	lr_0734.jpg	AR01	20.6	24.9	2.7	3.2	25.2
						AR02	22.6	25.2	3.2		
						AR03	23.5	24.9	2.9		

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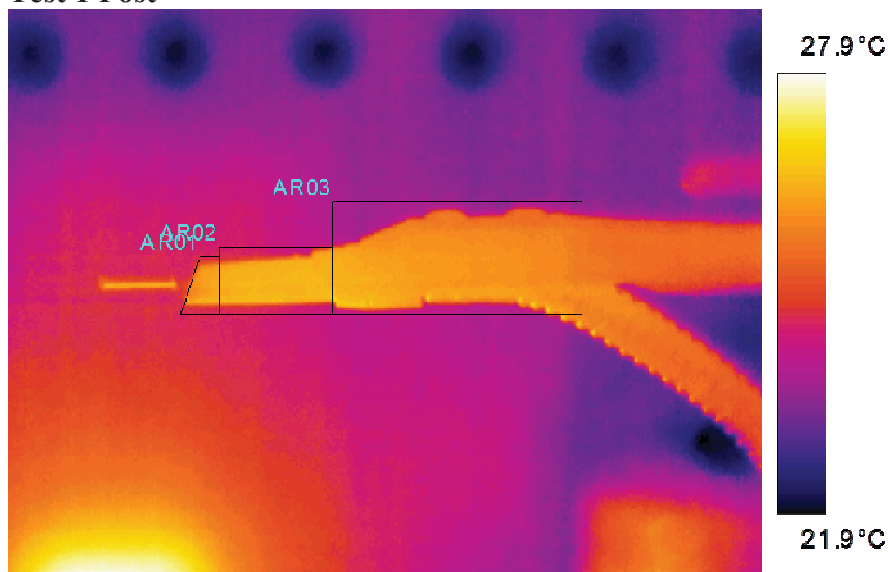
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Attachment 2 Thermal Images

Test 1 Pre



Test 1 Post

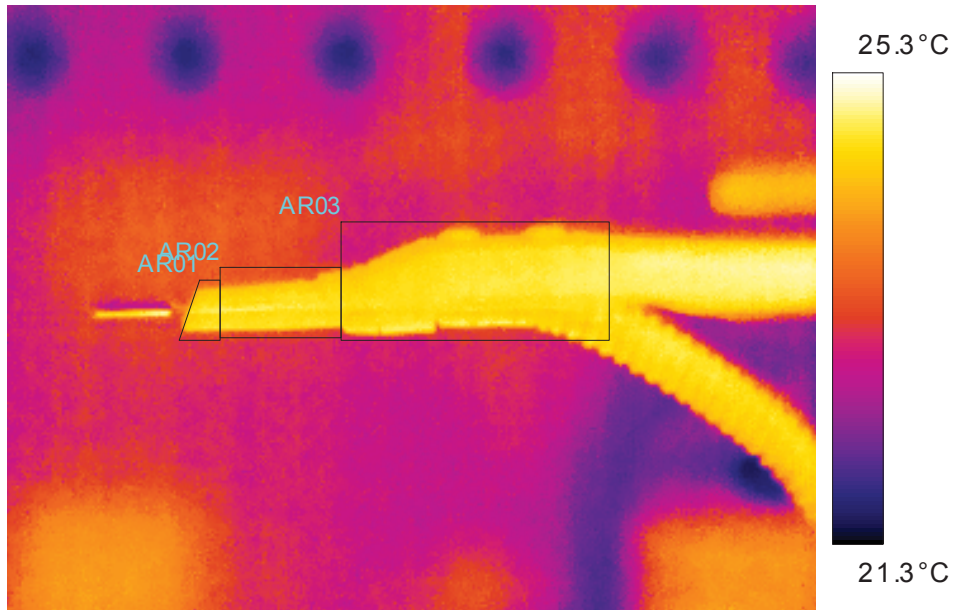


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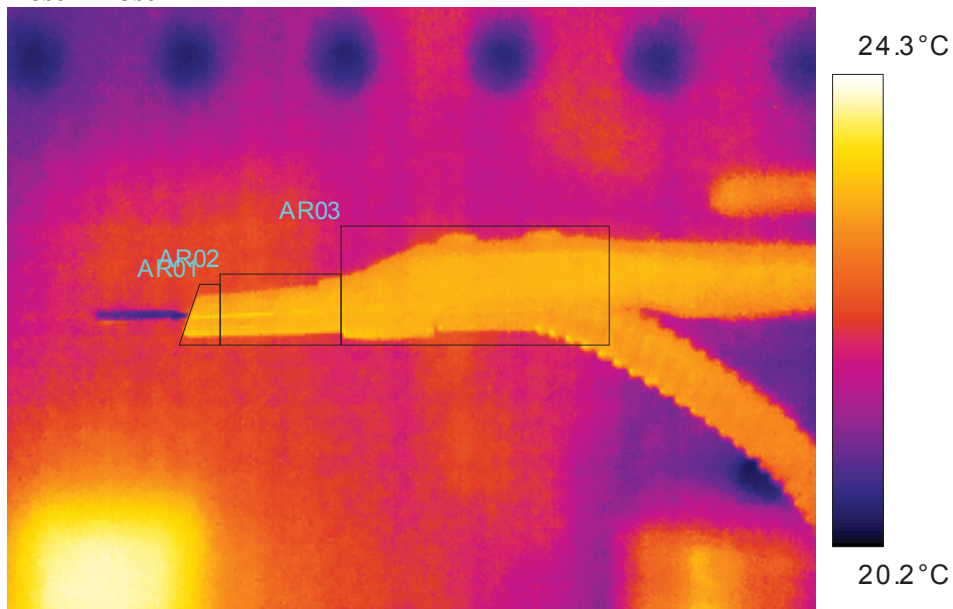
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Test 2 Pre



Test 2 Post

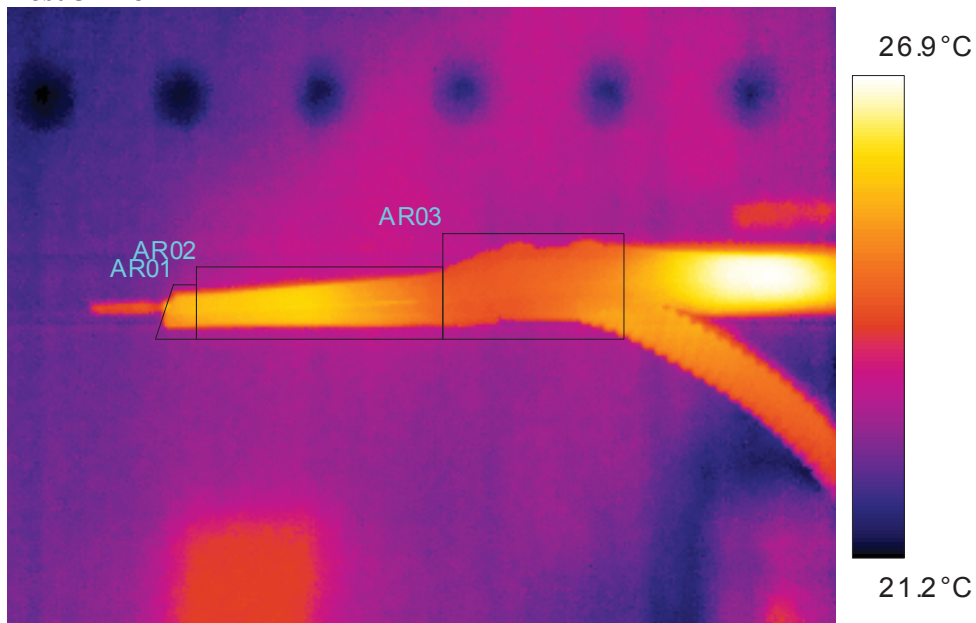


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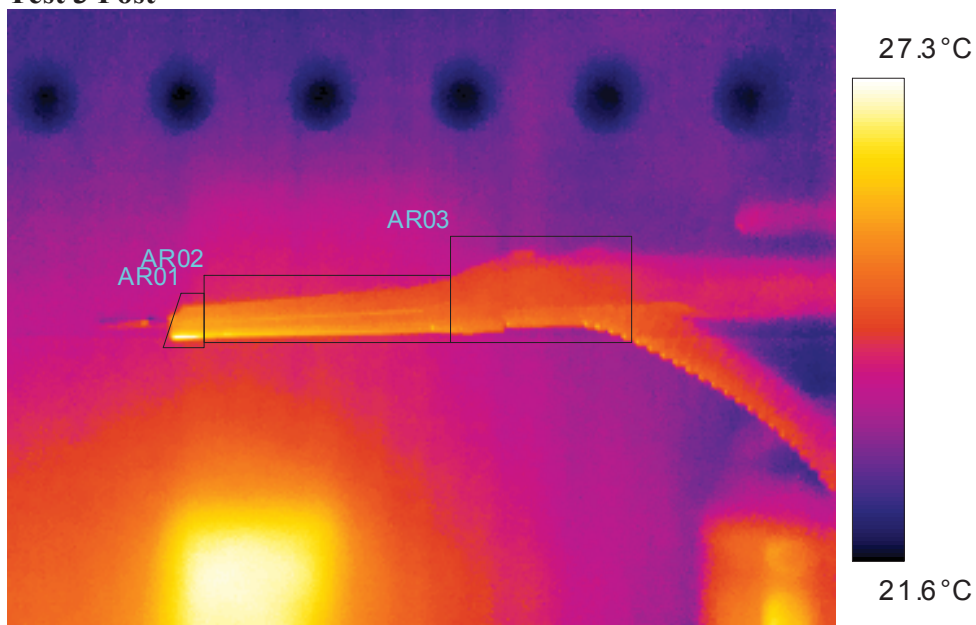
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Test 3 Pre



Test 3 Post

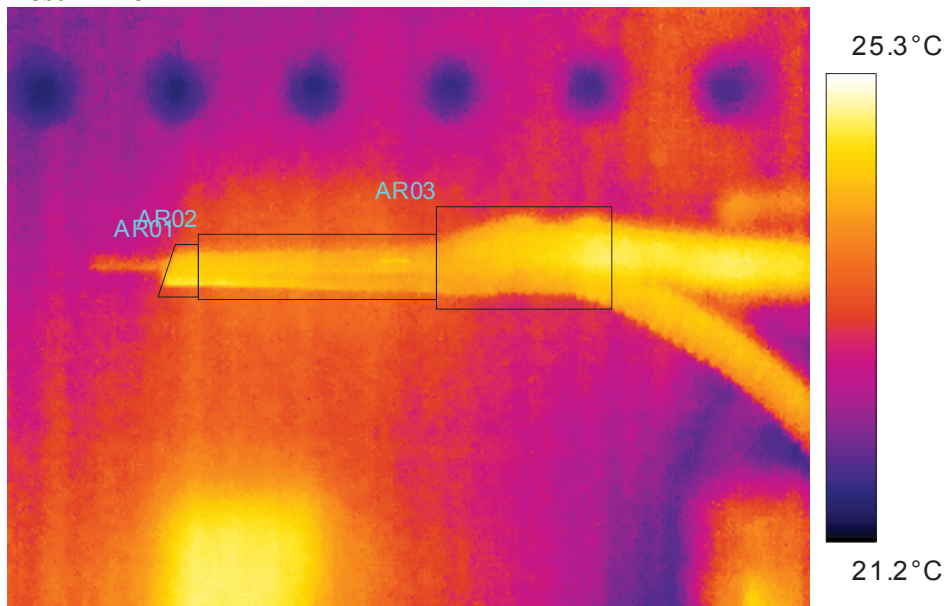


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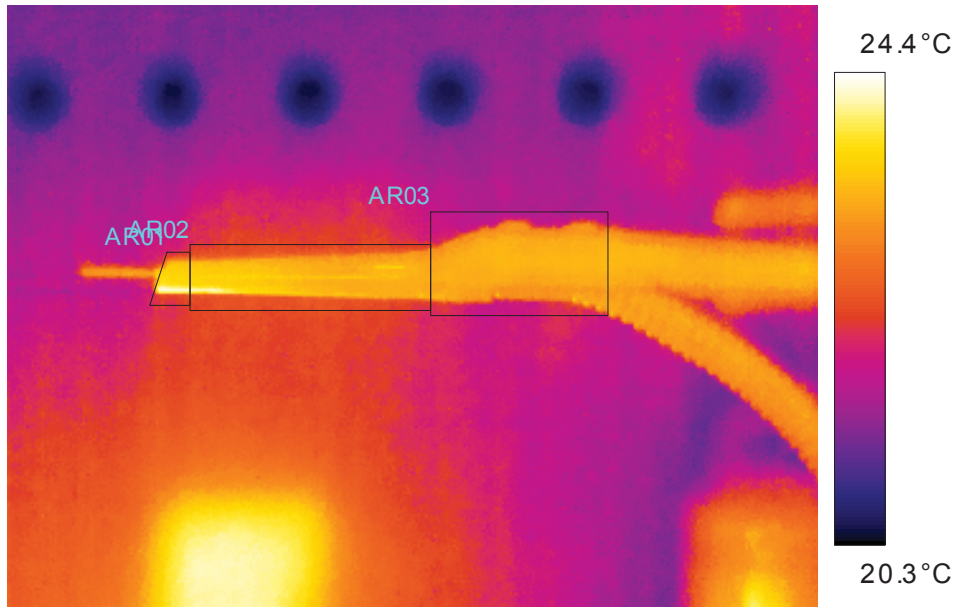
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Test 4 Pre



Test 4 Post

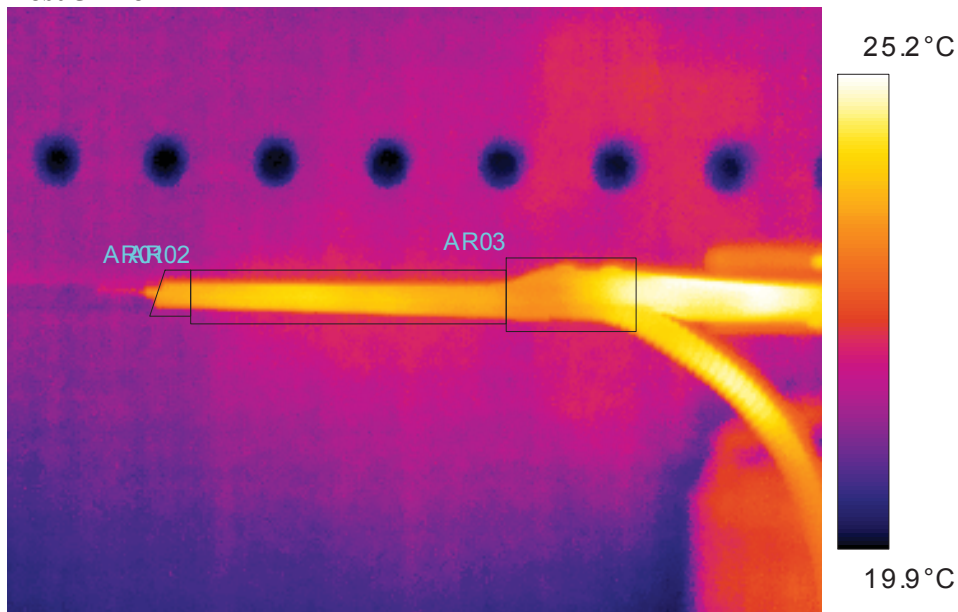


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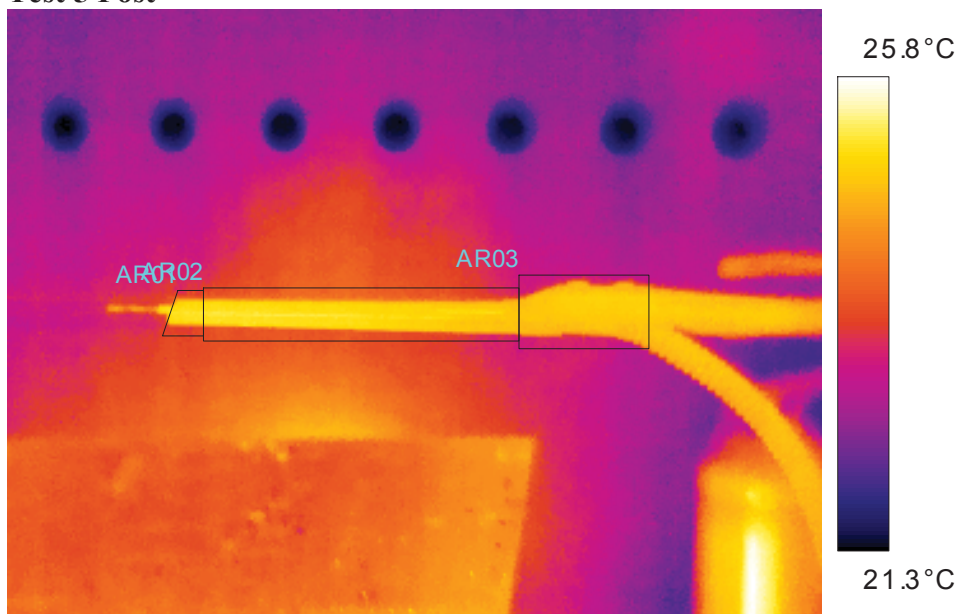
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Test 5 Pre



Test 5 Post

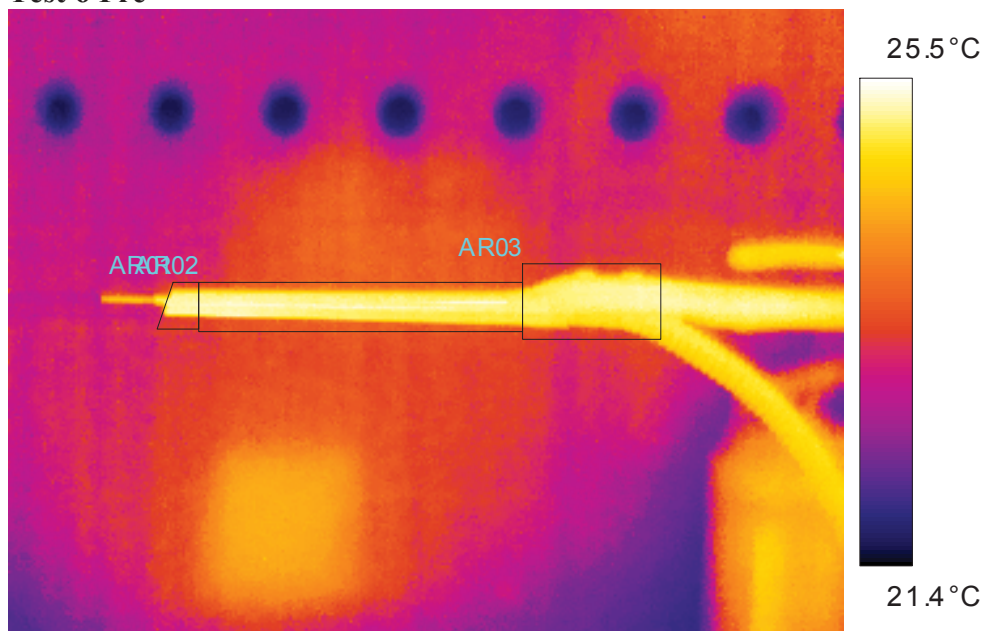


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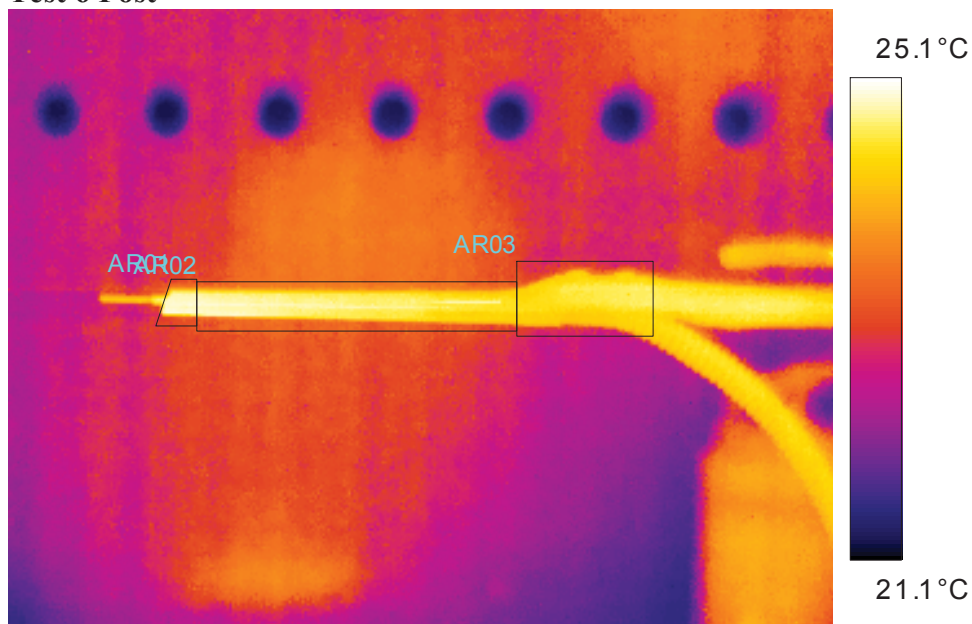
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Test 6 Pre



Test 6 Post

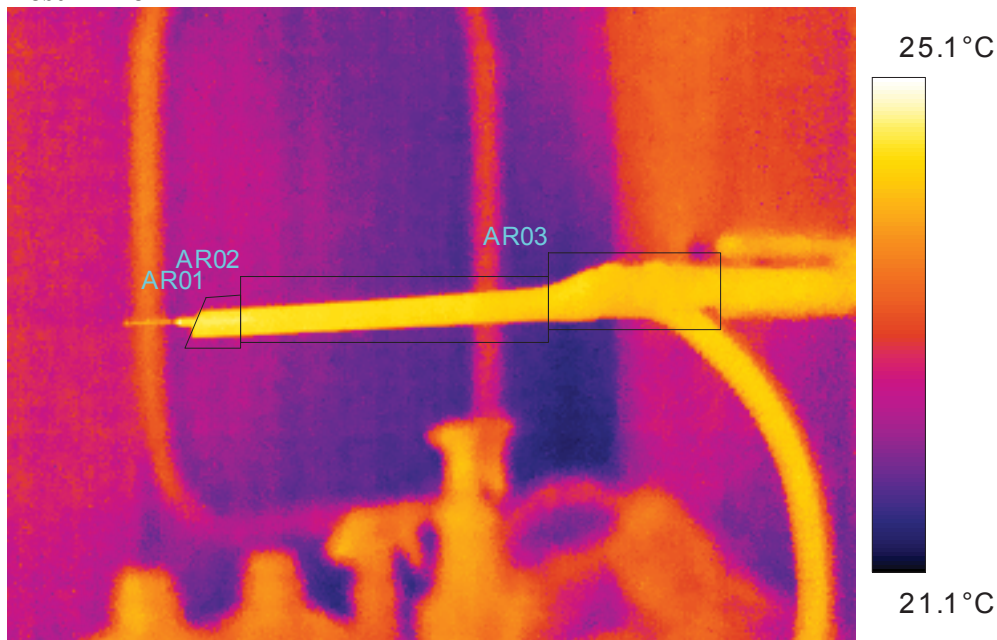


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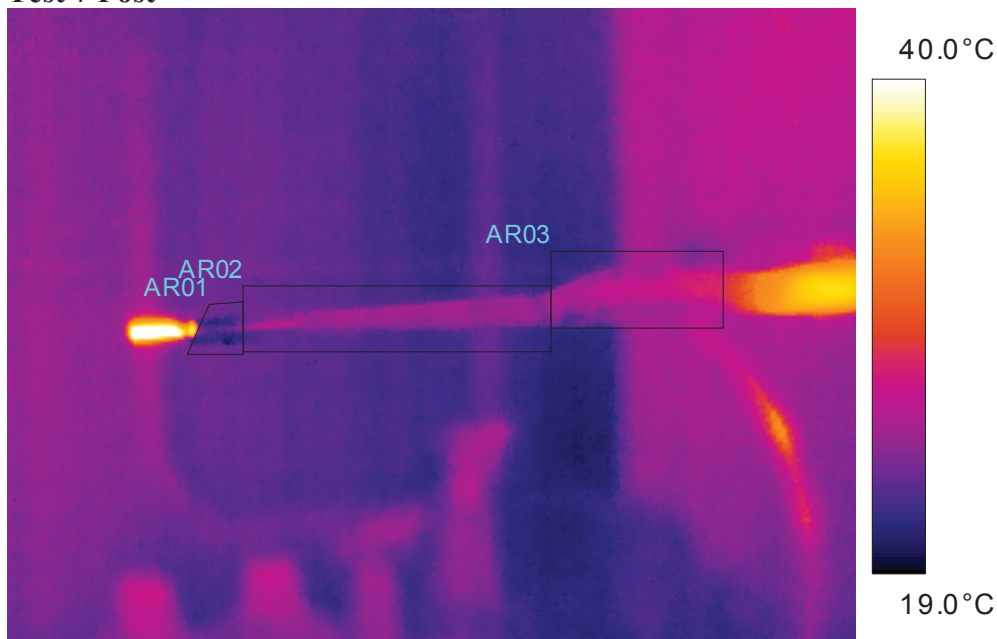
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Thermal Images Continued

Test 7 Pre



Test 7 Post

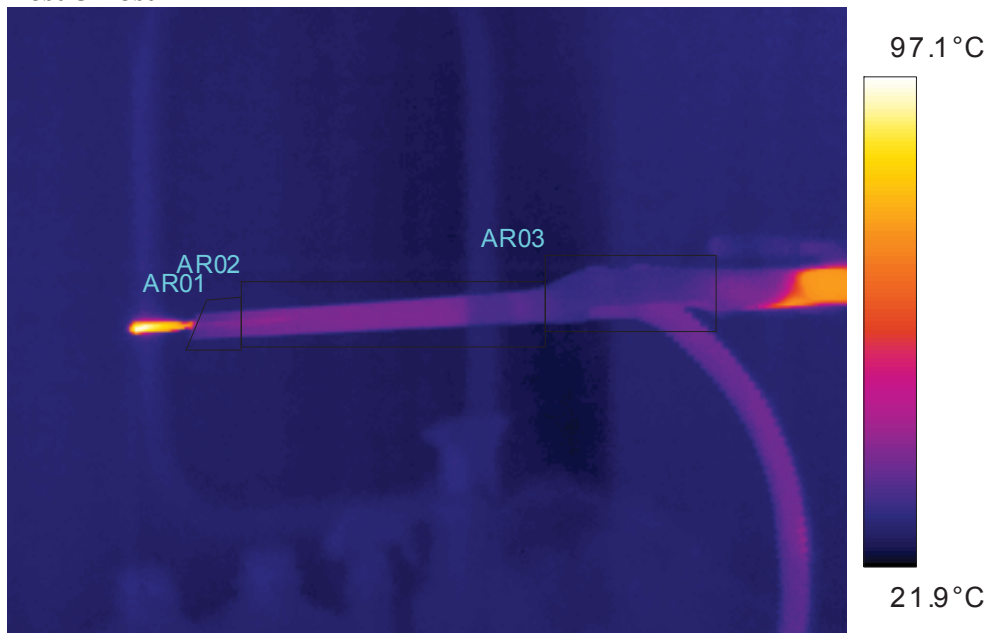


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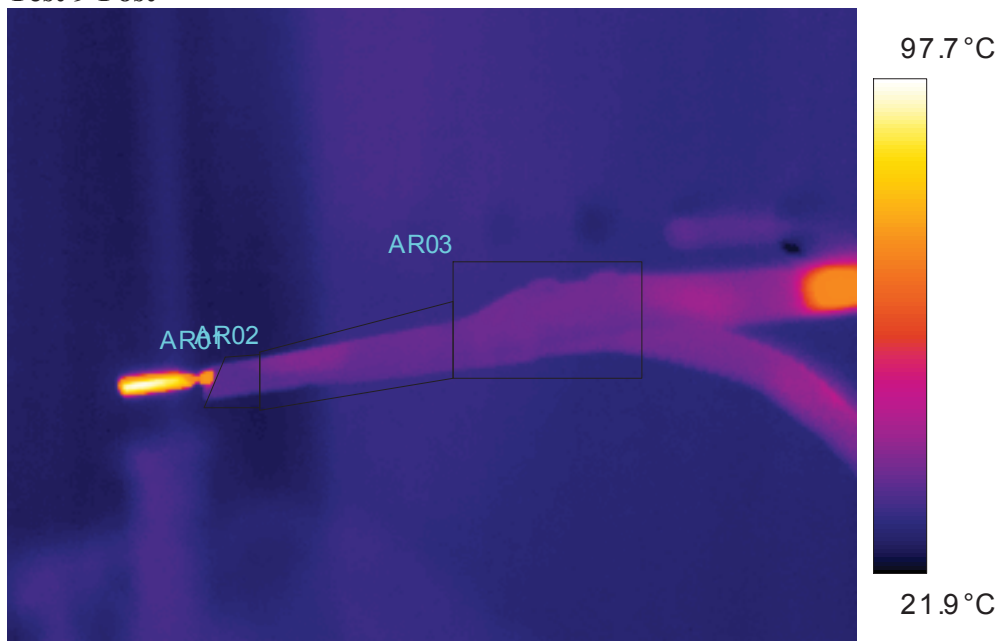
Megadyne Medical Products, Inc.	TEST REPORT	Document Number <u>ENG-RPT-395</u>
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Thermal Images Continued

Test 8 Post



Test 9 Post

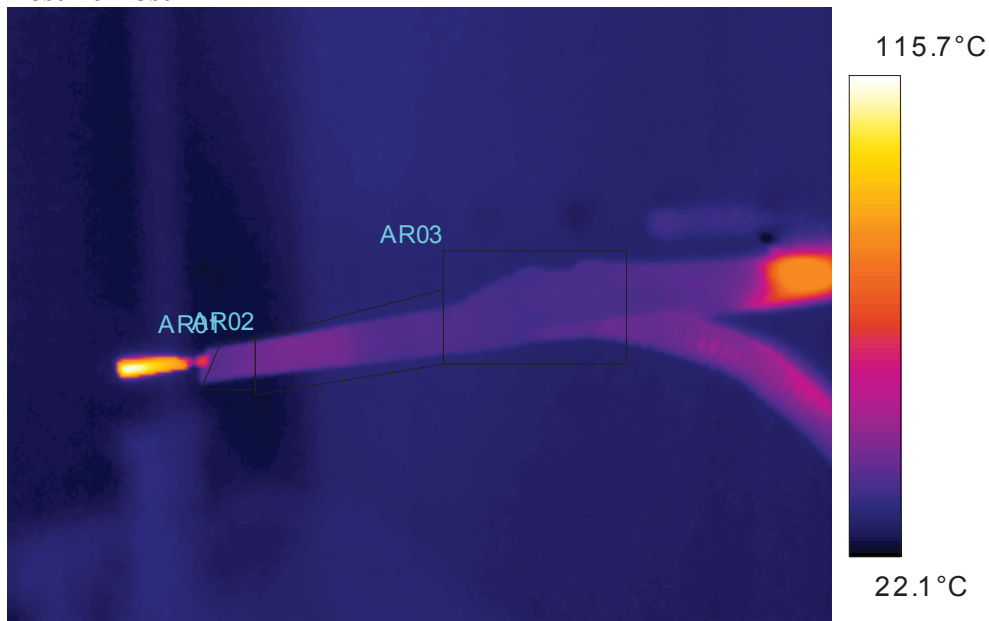


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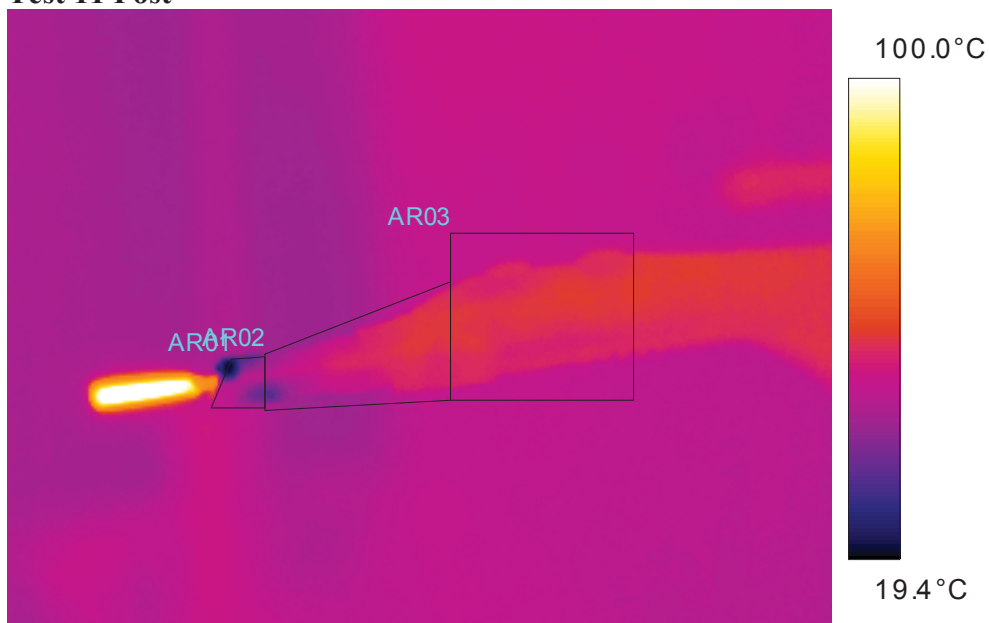
Megadyne Medical Products, Inc.	TEST REPORT		Document Number <u>ENG-RPT-395</u>
	Zip Pen and Extension Nozzles, Thermal Evaluation Test Report		Revision: 001
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Thermal Images Continued

Test 10 Post



Test 11 Post

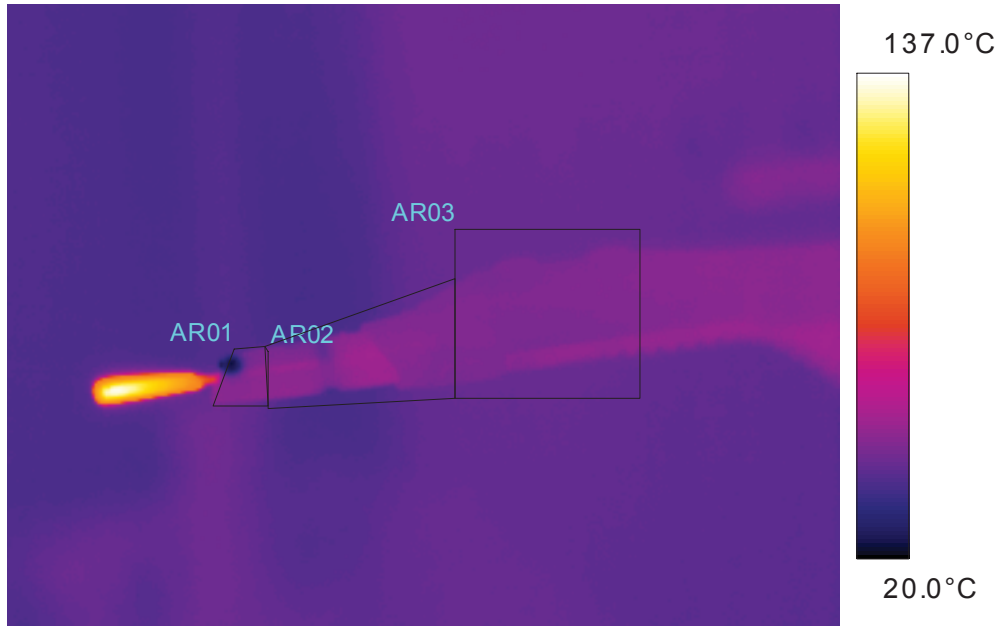


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Thermal Images Continued

Test 12 Post



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Attachment 3 Accelerated Aging

Accelerated Aging In Process

Product: 2540 and 2560 Nozzle Extensions
Lot Numbers S140119, S140120

Temperature 55°
Relative Humidity Ambient

Required Time 15 weeks 6 days
(111 days)

Thermotron ID Number 448478

Last Calibration Date 5-30-13

Calibration Due Date 5-31-14 Recalibrated 5-29-14
New Due Date 5-31-15

Start	Time	Initials	Stop	Time	Total	Initials
29 Apr 2014	18:00	WJS	18 Aug 2014	14:30	111 days	WJS

If this aging needs to be interrupted for any reason,
contact Mark Glassett at ext. 845

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**Attachment 3 Cont.
Accelerated Aging**

Accelerated Aging In Process

Product: 2525-15 E-Z Clear Pencil
Lot Numbers S140045

Temperature 55°
Relative Humidity Ambient

Required Time 15 weeks 6 days
(111 days)

Thermotron ID Number 448478

Last Calibration Date 5-30-13

Calibration Due Date 5-31-14

Start	Time	Initials	Stop	Time	Total	Initials
11 Mar 2014	14:00	MB	7:50, 4-25-14	7:50	43	PV
25 Apr 2014	8:00	MB	5-21-14	9:00	111	MB

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