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DOCUMENT TITLE: Test Matrix, Input/Output Conformance, Project Alpha - Ace Blade

DOCUMENT NOTES:

Updates for release of ACE Blade 700 products.

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**ZIPACE ACE Blade IOM****Change Request**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		12 Feb 2018, 08:20:22 AM	Approved

**Collaboration**

Name/Signature	Title	Date	Meaning/Reason
Mallory Schroeder (MSCHROEDER)	Engineer	21 Feb 2018, 01:36:11 PM	Complete
Paul Borgmeier (PBORGMEIER)		22 Feb 2018, 08:57:19 AM	Complete
Darlene Hull (DHULL)	Regulatory	22 Feb 2018, 09:20:47 AM	Complete
Mike Ehninger (MEHNINGER)		22 Feb 2018, 09:26:33 AM	Complete
Dave Shimkus (DSHIMKUS)		22 Feb 2018, 09:55:46 AM	Complete
Mike Hintze (MHINTZE)		22 Feb 2018, 10:17:27 AM	Complete
Curt Doel (CDOEL)	Quality Manager	22 Feb 2018, 12:45:34 PM	Complete
Tyler Skinner (TSKINNER)	Project Engineer	22 Feb 2018, 01:13:13 PM	Complete

**Document Review**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		22 Feb 2018, 01:59:13 PM	Complete

**RA-Approval**

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	22 Feb 2018, 02:06:08 PM	Approved

**QA-Approval**

Name/Signature	Title	Date	Meaning/Reason
Curt Doel (CDOEL)	Quality Manager	22 Feb 2018, 02:11:16 PM	Approved

**ENG-Approval**

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		22 Feb 2018, 02:16:25 PM	Approved

**Training Review**

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		

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Lucy Richards (LRICHARDS)

22 Feb 2018, 02:17:25 PM

Approved

**Final Release**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		22 Feb 2018, 02:17:37 PM	Approved

Megadyne Medical Products, Inc.	<b>INPUT/OUTPUT CONFORMANCE TEST MATRIX</b>	Document Number <b>ENG-IOM-004</b>
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PROJECT NAME: ACE BLADE 700

PROJECT - SPECIFIC  
CHECKLIST REVISION: 002

#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
<b>1.0 DEVICE REQUIREMENTS</b>							
1.1	INTENDED USE						
1.1.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 1.0)	The ACE Blade will be a benefit to clinicians. Surgeons will be able to use one electrode from "open to close". The ACE Blade will be used to make the initial skin incision in ACE Mode and then used to perform electrosurgery throughout the case using the coagulation mode of choice without needing to remove the ACE Blade. In addition the clinician will have a safer environment in which to work as the scalpels will be removed from the procedure.	510K Design Validation Clinical Marketing ENG-PRT-121 ENG-PRT-122	Report memo's from Animal lab trials Pig Study White Paper Pre-clinical study comparing ACE blade with Standard electrosurgical cut and scalpel located with Memo dated Oct 17, 2008 in section 3.5 of the Project Alpha Phase 3 Book Report 1150426-01 Skin Tensile Pull Report ENG-RPT-196 (1150433-01) Marketing Evaluation Results	Closed	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
1.1.2	MKT-CMR-023	3.0 The new ACE Blade needs to have a geometry that is fine tuned to function with the ACE Mode of the MEGADYNE MEGA Power electrosurgical generator to provide a "scalpel like" effect on tissue. A "scalpel like" effect means the ACE Blade needs to perform like a scalpel, but also perform the functions of a standard non-stick electrosurgical blade:	ENG-PRT-121 ENG-PRT-122	ENG-RPT-196	PASS	TS 2/21/2018	ME 2/21/2018
1.2	CONFIGURATIONS						

**Megadyne Medical Products, Inc.**

**INPUT/OUTPUT CONFORMANCE TEST MATRIX**

**PROJECT ALPHA – ACE BLADE**

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PROJECT ALPHA – ACE BLADE				Revision: 002		
#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature
1.2.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.9 & 3.2.12)	The ACE Blade will come in standard configurations.	Design Specification Drawing(s) Verification Testing	Drawing # 3500078-XX 1 <sup>st</sup> article inspection	Closed	SH 12/15/2009 ACE Blade 700 TS 2/21/2018
		ACE12A E-Z Clean 2.75" ACE Blade ACE14A E-Z Clean 4" ACE Blade ACE14 E-Z Clean 6.5" ACE Blade ACE30H Rocker Switch Pencil with ACE Blade and Holster ACE35H Button Switch Pencil with ACE Blade and Holster ACE36H Rocker Switch Pencil with Modified ACE Blade and Holster ACE37H Button Switch Pencil with Modified ACE Blade and Holster ACE12BNS ACE Blade, I/C, Bulk, Non-Sterile 2.5" (QTY 500)	ACE12A ACE14A ACE14 ACE30H ACE35H ACE36H ACE37H ACE12BNS			ACE Blade 700 ME 2/21/2018
1.2.2	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.12.1)	The ACE Blade will come in modified configurations (insulation extends to the distal 2.5mm +0.5 mm/-0.25 of the blade & is crescent cut).	Design Specification Drawing(s) Verification Testing	Requirement addressed in Project ACE Modified: Drawings ACE12AM, ACE14AM, ACE14M, ACE12MBNS, 6020164-XX, Crescent is made by 2010263-XXX using cutting dies 2010263-002 and 2010263-007 per procedure OPER-WI-054.	CLOSED	S. Horner 12/13/2010 ACE Blade 700 TS 2/21/2018
		ACE 12AM (2.75 INCH) ACE 14M (6.5 INCH) ACE 14AM (4 INCH) ACE12MBNS ACE Blade I/C, Modified, Bulk, Non-Sterile 2.5" (QTY 500)	Design crescent into cutting die tools			
1.2.3	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.13)	The ACE Blade will need to also be packaged with electrosurgical pencils both button and rocker configurations	Design Specification -Drawing(s) Design Verification ACE Ship Testing Protocol # 1150523-01	Drawing: ACE30H, & ACE35H Ship Test Report 1150523-01	CLOSED	Modified PTFE CLOSED Drawing: ACE36H, & ACE37H Ship Test Report 1150542-01
		ACE 30H (2.75 INCH, w/ Rocker pencil and holster) ACE 35H (27.5 INCH, w/ Button pencil and holster) ACE 36H (2.75 INCH Modified, w/ Rocker pencil and holster) ACE 37H (2.75 INCH Modified, w/ Button pencil and holster)	ACE Modified Pencil Ship Testing Protocol # 1150542-01			Modified Signature below SH 12/6/2010 TS 2/21/2018 ME 2/21/2018
1.3	PRODUCT DESCRIPTION					

<b>INPUT/OUTPUT CONFORMANCE TEST MATRIX</b> <b>PROJECT ALPHA – ACE BLADE</b>	
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Origin of Input (Standards – Internal/External)				Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.2) Modified (CMR Rev C Section 3.2.12.2)				The color of the insulation that covers the electrode needs to be purple (ACE blades) or gray (ACE 700), and may include black on “Modified” electrodes	Design Specification Drawing(s)/Incoming inspection Verification Testing Sterilization testing ENG-PRT-106	Drawing: 4100048-XX (-03 B2 material & -04 A4 material) Report 1150404-01 Insulation Bond Strength – B2 Material Report 1150404-02 Insulation Bond Strength – A4 Material after 5yr/Acc age Report 1150129-02 Printed Electrode Adhesion – A4 Material after 5yr/Acc age Report 1150404-03 Insulation Bond Strength – A4 Material 80 kGy exposure Report 1150129-03 Printed Electrode Adhesion – A4 Material 80 kGy exposure ACE Modified: Drawing 4100052-XX (-03 is Black)	CLOSED	SH 12/15/2009	ME 12/15/2009
MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.3)				The insulation of the ACE Blade will be pad printed with “ACE BLADE” on one side and “MEGADYNE” on the other.	Design Specification Drawing(s) In process 100% Quality inspection	Cliché Drawing # 3900191-02 Artwork acceptance DCO 08-267-01	Closed	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.5)				Individual pouches will be labeled with an “ACE Blade” logo.	Design Specification Drawing(s)	Artwork Drawing(s): 3900179-01 3900181-01 3900183-01 3900185-01	Closed	SH 12/15/2009	ME 12/15/2009
Megadyne Medical Products R&D requirement. ISO 11137:1994				• The device meets all essential design inputs after 1X sterilization by Gamma (40kGy).	Design Validation: Design verification testing following sterilization	Report 1150397-01 Coating Adhesion Report 1150395-01 Rust Evaluation Report 1150401-01 Blade Bend Fatigue Report 1150402-01 Electrode Insertion Report 1150403-01 Simulated Use Strength Report 1150404-01 Insulation Bond	Closed	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018

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**PROJECT ALPHA – ACE BLADE**

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
1.3.5	Megadyne Medical Products R&D Requirement. ISO 11137:1994	<ul style="list-style-type: none"> <li>It is desirable that the device meet all essential design inputs after 2X sterilization (80kGy). This 2X sterilization (80kGy) does not include the holster</li> </ul>	Design Validation: Design verification testing following sterilization	Report 1150404-03 Insulation Bond Strength – A4 Material 80 kGy exposure Report 1150129-03 Printed Electrode Adhesion – A4 Material 80 kGy exposure Report 11500383-07 High Frequency Mains and Leakage – A4 Material 80 kGy exposure	Closed	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
1.3.6	Megadyne Medical Products R&D Requirement. ISO 11137:1994	<ul style="list-style-type: none"> <li>It is desirable that the ACE Modified device meet all essential design inputs after 2X EtO.</li> </ul>	ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150527-01 Ship testing Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150542-01 ACE Modified Pencil Ship Test Report 1150527-04 T=5 year Testing	ACE Modified Closed	SH 12/6/2010 SH 1/14/2011 TS 2/21/2018	Modified Signature below ME 12/6/2010 M. Ehninger 1/14/2011 ME 2/21/2018
1.4	<b>PERFORMANCE REQUIREMENTS</b>		Verification/Validation Test Protocol# 1150403-10 Clinical Testing Protocol # 1150433-10	Report 1150403-01 Simulated Use Report 1150403-02 Simulated Use Report 1150433-01 Marketing Evaluation Results	Closed	SH 12/15/2009 SH 12/6/2010 TS 2/21/2018	ME 12/15/2009 ME 12/6/2010 ME 2/21/2018
1.4.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.1.1)	The ACE Blade will need to have a durable outer insulation that will maintain integrity throughout a case.	ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	1.15027-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150522-01 Report 1150404-01 See Rationale #2 in Appendix I	ACE Modified Closed	Modified Signature below SH 12/6/2010 TS 2/21/2018	Modified Signature below ME 12/6/2010 ME 2/21/2018
1.4.1.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.10 & 3.2.11)	Blade design to incorporate a Hex lock feature to prevent the tip from rotating in the hand piece	N/A	THIS REQUIREMENT WILL NOT BE ADDRESSED WITHIN THE FRAMEWORK OF PROJECT ALPHA AS DEFINED BY THE PROJECT TEAM AND MANAGEMENT	N/A	N/A	N/A

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INPUT/OUTPUT CONFORMANCE TEST MATRIX				Document Number ENG-IOM-004 Revision: 002 Page 5 of 29			
#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
1.4.2	Megadyne Medical Products R&D requirement. Standard in CEI 60601-2-2 (59.103) Essentials Matrix (9.1, 11.1, 12.6.1)	The insulated hand-held portion of the device will withstand a low mains frequency voltage of 1,500 Vrms	Verification test Protocol# 1150383-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report # 1150382-03 Dielectric testing Report # 1150382-05 Dielectric testing Report 11500383-07 High Frequency, Mains and Leakage – A4 Material 80 kGy exposure ACE Modified Verification Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing	CLOSED	SH 12/15/2009 ACE Modified Closed	Modified Signature below ME 12/6/2010 M. Ehninger 1/14/2011
1.4.3	Megadyne Medical Products R&D requirement. Standard in CEI 60601-2-2 (59.103) Essentials Matrix (9.1, 11.1, 12.6.1)	The insulated hand-held portion of the device will withstand a voltage of 1.5 times the maximum specified high frequency voltage rating at the specified frequency.	Verification test Protocol# 1150383-10	Report # 1150382-03 Dielectric testing Report # 1150382-05 Dielectric testing Report 11500383-07 High Frequency, Mains and Leakage – A4 Material 80 kGy exposure ACE Modified Verification Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing	CLOSED	SH 12/15/2009 ACE Modified Closed	Modified Signature below ME 12/6/2010 M. Ehninger 1/14/2011
1.4.4	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.5)	Must work in all monopolar modes.	Verification test Protocol# 1150403-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150403-01 Simulated Use Report 1150403-02 Simulated Use Report 1150403-03 Simulated Use T=0 Report 1150403-04 Simulated Use T=2 Report 1150403-05 Simulated Use T=5 Report 1150403-07 Simulated Use for 305 ACE Modified Verification Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing See Rationale #5 in Appendix I	CLOSED	SH 12/15/2009 ACE Modified Closed	Modified Signature below ME 12/6/2010 M. Ehninger 1/14/2011

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
1.4.5	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.7 & 7.0)	Must be Compatible with standard electrosurgical pencils.	Design Specification Drawing(s)	Substrate Drawing 3500078-XX (Shaft Diameter is .093" – standard for electrodes) Report 1150402-01 Electrode Insertion ACE700 (ACE12BN5 and ACE12MBN5) shaft diameter (3500078-XX) (which is the mating feature to electrosurgical pencils) is same dimension as standard EZ clean shaft diameter (3500086-XX)	PASS	TS 2/21/2018	ME 2/21/2018
1.4.6	MKT-CMR-023) (250024-10) ACE CMR Requirement (Section 7.0)	The ACE blade needs to be durable enough to be used for skin incisions as well as soft tissue dissection where electrosurgical instruments are used.	Clinical Testing Protocol # 1150433-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Verification test Report 1150403-01 Simulated Use Report 1150433-02 Simulated Use Report 1150433-01 Marketing Evaluation Results ACE Modified Verification Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing	CLOSED	SH 12/15/2009	ME 12/15/2009
1.4.7	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 7.0)	The ACE Blade must meet all electrosurgical standards where applicable	ASTM coating adhesion tape test results on stainless steel plates must achieve a score of 4B or 5B.	See Rationale #2 in Appendix I. Refer to all sections within this document as needed	ACE Blade 700	ACE Blade 700 TS 2/21/2018	ACE Blade 700 ME 2/21/2018
1.4.8	ASTM Standards adhesion test #D-3359, Method B			Report 1150397-03 Coating Adhesion for ACE Dry Blast Process	CLOSED	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
1.4.9	Megadyne Medical Products R&D requirement.	ACE Blades must show no evidence of corrosion (rust) on any surface of the electrode following accelerated aging and subsequent visual inspection.	Verification/Validation Test Protocol# 1150398-10	Report 1150398-01 Rust Evaluation Report 1150398-03 Rust Evaluation following various tumble times at Hobson Report 1150398-04 Rust Evaluation for 305 SS	CLOSED	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
1.4.10	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.4)	ACE Blades must demonstrate improved or equivalent coating finish quality to current Megadyne PTFE coated electrodes	Verification/Validation Test Protocol# 1150403-10	Report 1150403-01 Simulated Use Report 1150403-02 Simulated Use Report 1150403-03 Simulated Use T=0 Report 1150403-04 Simulated Use T=2 Report 1150403-05 Simulated Use T=5 Report 1150403-07 Simulated Use for 305	CLOSED	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018

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1.4.11	Megadyne Medical Products R&D requirement. MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.2)	ACE Blades must survive a minimum of 3 consecutive bends consisting of 90°, 180° without breaking. Note the bend force values from each test to determine equivalency with existing product	Verification/Validation Test Protocol# 1150401-10	Report 1150401-01 Blade Bend Fatigue Report 1150401-02 Blade Bend Fatigue Report 1150401-03 Blade Bend Fatigue for 305	PASS	TS 2/21/2018	ME 2/21/2018
1.4.12	Megadyne Medical Products R&D requirement.	3.1.1.2 Must be able to be bent to approximately 60 degrees (comparable to 0012)	Verification/Validation Test Protocol# 1150402-10	Report 1150402-01 Electrode Insertion	CLOSED	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
1.4.13	Megadyne Medical Products R&D requirement.	The device under test passes if the insertion/extraction force is comparable to existing Megadyne electrode force values. Insertion force and extraction force should measure between 3 and 6 lbf.	Verification/Validation Test Protocol# 1150403-10	Report 1150403-01 Simulated Use Report 1150403-02 Simulated Use Report 1150403-03 Simulated Use T=0 Report 1150403-04 Simulated Use T=2 Report 1150403-05 Simulated Use T=5 Report 1150403-07 Simulated Use for 305	CLOSED	SH 12/15/2009	ME 12/15/2009
1.4.14	Megadyne Medical Products R&D requirement.	Simulated use test blades must demonstrate equivalent or improved coating performance, adhesion, and degradation attributes for a given power setting when compared to predicate Megadyne PTFE coated electrodes.	Verification/Validation Test Protocol# 1150403-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing	ACE Modified Closed	Modified Signature below SH 12/6/2010 SH 1/14/11	Modified Signature below ME 12/6/2010 M. Ellinger 1/14/2011
		Activation of blades must demonstrate typical electrosurgical effect under low/medium/high power settings without any adverse conditions.	Verification/Validation Test Protocol# 1150403-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150403-01 Simulated Use Report 1150403-02 Simulated Use Report 1150403-03 Simulated Use T=0 Report 1150403-04 Simulated Use T=2 Report 1150403-05 Simulated Use T=5 Report 1150403-07 Simulated Use for 305	CLOSED	SH 12/15/2009 TS 2/21/2018	ME 12/15/2009 ME 2/21/2018
				Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing	ACE Modified Closed	Modified Signature below SH 12/6/2010 SH 1/14/11	Modified Signature below ME 12/6/2010 M. Ellinger 1/14/2011
						TS 2/21/2018	ME 2/21/2018

**Megadyne Medical Products, Inc.**

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**PROJECT ALPHA – ACE BLADE**

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method
1.4.15	Megadyne Medical Products R&D requirement.	Modified blades must demonstrate continued resistance to insulation splitting during activation. Thermal degradation at the distal end of the insulation at high power settings is common and expected. Modified electrodes exhibiting a propagating type split (i.e. nylon stocking) is considered unacceptable.	Verification/Validation Test Protocol# 1150403-10 A ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.
1.4.16	Megadyne Medical Products R&D requirement.	The blades insulated with Sumitomo B2 heat shrink insulation, must produce a minimum bond strength value of 10 lbs. The insulation jacket must not break loose and slip over non-coated portions of the electrode during testing. Accordion style compression of the insulation, without breaking loose and sliding, is considered acceptable.	Verification/Validation Test Protocol# 1150404-10 ENG-PRT-421
1.4.17	Megadyne Medical Products R&D requirement.	The blades insulated with Sumitomo A4 heat shrink insulation, must produce a minimum bond strength value of 10 lbs. The insulation jacket must not break loose and slip over non-coated portions of the electrode during testing. Accordion style compression of the insulation, without breaking loose and sliding, is considered acceptable.	Verification/Validation Test Protocol# 1150404-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.
1.4.18	Megadyne Medical Products R&D requirement.	The blades insulated with Sumitomo B2 heat shrink insulation, must display required ink adhesion capabilities	ENG-PRT-421 Verification/Validation Test Protocol# 1150129-10

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1.4.19	Megadyne Medical Products R&D requirement.	The blades insulated with Sumitomo A4 heat shrink insulation, must display required ink adhesion capabilities	Verification/Validation Test Protocol# 1150129-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150129-02 Printed Electrode Adhesion – A4 Material Report 1150129-03 Printed Electrode Adhesion – A4 Material after 80 kGy exposure ACE Modified Verification Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing	CLOSED ACE Modified Closed	Modified Signature below ME 12/6/2010 M. Ehninger 1/14/2011
1.4.20	Megadyne Medical Products R&D requirement.	The blades must not be damaged during shipment	Verification Testing Ship Test Protocol #1150345-10 ACE Pencil Ship Test Protocol #1150523-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10. ACE Pencil Ship Test Protocol #1150542-10	Report 1150345-07 Ship Testing Report 1150345-09 Ship Testing Report 1150345-12 Ship Testing Report 1150523-01 ACE Pencil Ship Test ACE Modified Verification Report 1150527-01 Ship Test Report 1150542-01 ACE Modified Pencil Ship Test	CLOSED ACE Modified CLOSED	Modified Signature below ME 12/6/2010
1.4.21	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.3)	Must provide a safety advantage for sharps injuries.	Verification Testing Memo to DHF	See Rationale #1 in Appendix I Verification reports dated 11/16/09 from Darcy Greep 3500078-XX	PASS	TS 2/21/2018 ME 2/21/2018
1.5	CLINICAL REQUIREMENTS					
1.5.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.1)	Must be able to perform skin incision with minimal to no blanching of tissue.	Verification Test Pig Trial Protocol & Memo dated Oct. 17, 2008 .located in Phase 3 section 3.5 Clinical Testing Protocol # 1150433-10	Pig Trial white paper located with Protocol/Memo dated Oct 17, 2008 in Phase3 section 3.5 Report 1150433-01 Marketing Evaluation Results	CLOSED TS 2/21/2018	SH 12/15/2009 ME 2/21/2018

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature
1.5.2	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.1)	Perform skin incisions with wound healing/scar formation equivalent to a scalpel.	Verification Test Pig Trial Protocol # located in DHF section 3.5 Verification reports Skin Tensile Pull Test Protocol # 1150426-10 Clinical Testing Protocol # 1150433-10	Pig Trial Report located in DHF section 3.5 Verification reports Report 1150426-01 Skin Tensile Pull Report 1150433-01 Marketing Evaluation Results Lee BJ, et al. Advanced Cutting Effect System versus Cold Steel Scalpel: Comparative Wound Healing and Scar Formation in Targeted Surgical Applications. Plast Reconstr surgery Glob open. 2014;2(10). (075570-70630)	PASS	TS 2/21/2018 ME 2/21/2018
1.5.3	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.1.6)	Durable enough to last an entire case from “open to close”	Verification Test Clinical Testing Protocol # 1150433-10	Report 1150433-01 Marketing Evaluation Results See Rationale #2 in Appendix I.	CLOSED	SH 12/15/2009 TS 2/21/2018 ME 12/15/2009 ME 2/21/2018
1.5.4	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 7.0)	The ACE blade needs to be durable enough to be used for skin incisions as well as soft tissue dissection where electrosurgical instruments are used.	Verification Test Clinical Testing Protocol # 1150433-10	Report 1150433-01 Marketing Evaluation Results See Rationale #2 in Appendix I.	PASS	TS 2/21/2018 ME 2/21/2018
1.5.5	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.12.1, 7.0)	The insulation of the electrode must be durable and able to withstand the heat of electrosurgery as well as some of the mechanical forces associated with surgery.	Verification Test Insulation Bond Strength Protocol # 1150404-01 Printed Electrode Adhesion Protocol # 1150429-10 Dielectric Testing Protocol # 1150383-10 Clinical Testing Protocol # 1150433-10	Report 1150404-03 insulation Bond Strength Report 1150129-01, 1150129-02, Report 1150129-03 Printed Electrode Adhesion Report # 1150383-03, 1150383-05, 1150383-07 Dielectric testing Report 1150433-01 Marketing Evaluation Results See Rationale #3 and #4 in Appendix I	PASS	TS 2/21/2018 ME 2/21/2018
2.0	BIOCOMPATIBILITY		OPER-FRM-051 ENG-RPT-452 Appendix V	ACE Modified Verification testing Report 1150527-02 T=0 Testing Report 1150527-03 T=2 Testing Report 1150527-04 T=5 year Testing See Rationale #3 and #4 in Appendix I		

<b>INPUT/OUTPUT CONFORMANCE TEST MATRIX</b> <b>PROJECT ALPHA – ACE BLADE</b>	
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Origin of Input (Standards – Internal/External)				Design Input		Conformance Method		Output of Conformance		Requirement Status		Project Engineer Signature		Reviewer Signature				
2.1 ISO 10993-1:2003 Biological evaluation of medical devices -- Part 1: Evaluation and testing Essentials Matrix (7.1, 7.2, 7.5)				The Device shall yield acceptable results when tested for cytotoxicity.				Nelson Laboratories test # 2955510 for Sumitomo B2 Insulation Nelson Laboratories test # 460663 for Sumitomo A4 Insulation ACE Modified post EtO Exposure Nelson Laboratories test # 541497 for Black PTFE Insulation				CLOSED	SH 12/15/2009	ME 12/15/2009				
2.2 ISO 10993-1:2003 Biological evaluation of medical devices -- Part 1: Evaluation and testing Essentials Matrix (7.1, 7.2, 7.5)				The Device shall yield acceptable results when tested for sensitization.				Nelson Laboratories test # 297443 for Sumitomo B2 Insulation Nelson Laboratories test # 460665 for Sumitomo A4 Insulation ACE Modified post EtO Exposure Nelson Laboratories test # 541496 for Black PTFE Insulation				CLOSED	SH 12/15/2009	ME 12/15/2009				
2.3 ISO 10993-1:2003 Biological evaluation of medical devices -- Part 1: Evaluation and testing Essentials Matrix (7.1, 7.2, 7.5)				The Device shall yield acceptable results when tested for irritation.				Nelson Laboratories test # 297444 for Sumitomo B2 Insulation Nelson Laboratories test # 460664 for Sumitomo A4 Insulation ACE Modified post EtO Exposure Nelson Laboratories test # 541499 for Black PTFE Insulation				CLOSED	SH 12/15/2009	ME 12/15/2009				

<b>INPUT/OUTPUT CONFORMANCE TEST MATRIX</b> <b>PROJECT ALPHA – ACE BLADE</b>	
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Origin of Input (Standards – Internal/External)				Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
2.4 ISO 10993-1:2003 Biological evaluation of medical devices -- Part 1: Evaluation and testing Essentials Matrix (7.1, 7.2, 7.5)				The Device shall yield acceptable Bio burden levels.  NOTE: Bio burden yield was not performed on the BN product codes. Bulk non-sterile product may be exposed to additional bio burden as part of additional manufacturing processes.	Biocompatibility testing Protocol # STP0036 (External Vendor Protocol)	Nelson Laboratories test # 449076 ACE B2 clinical device Bio burden Nelson Laboratories test # 460376 ACE A4 device Bio burden Nelson Laboratories test # 503035 ACE adjusted process Bio burden ACE Modified Nelson Laboratories test # 546082 ACE Modified Bio burden	CLOSED	SH 12/15/2009	ME 12/15/2009
<b>3.0 PACKAGING AND LABELING</b>				The insulation of the ACE Blade will be pad printed with “ACE BLADE” on one side and “MEGADYNE” on the other.	Design Specification Drawing(s) In process 100% Quality inspection	Cliché Drawing # 3900191-02 Artwork acceptance DCO 08-267-01	CLOSED	SH 12/15/2009	ME 12/15/2009
3.1 MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.3)				The color of the ink used will be white (what is currently used in production)	Design Specification Drawing(s)	ACE Subassembly Drawing: 6030081-XX ACE Modified Subassembly Drawing: 6030082-XX	CLOSED	TS 2/21/2018	ME 2/21/2018
3.2 MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.3)				Individual pouches will be labeled with an “ACE Blade” logo.	Design Specification Drawing(s)	Artwork Drawing(s): 3900179-01 3900181-01 3900183-01 3900185-01 ACE Modified: 3900182-01 3900184-01 3900186-01	CLOSED	SH 12/15/2009	ME 12/15/2009
3.3 MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.5)				Blade packaging will be defined for kit packers and provided bulk non-sterile	Design Specification -Drawing(s) Design Verification Ship Testing Protocol # 1150345-10	THIS REQUIREMENT WILL NOT BE ADDRESSED WITHIN THE FRAMEWORK OF PROJECT ALPHA AS DEFINED BY THE PROJECT TEAM AND MANAGEMENT	N/A	TS 2/21/2018	ME 2/21/2018
3.4 MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 7.0)									

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
3.5	ACE Regulatory Requirement Marketing ACE Clinical Evaluation Protocol	Individual pouches for marketing evaluation will be labeled with "Marketing Evaluation Only".	Design Specification -Drawing(s) Design Verification Clinical Testing Protocol # 1150433-10	Report 1150433-01 Marketing Evaluation Results Clinical Test Report # 1150433-01	CLOSED	SH 12/15/2009	ME 12/15/2009
3.5	UNIT LABEL	<p>ISO 11607:2003 Packaging for terminally sterilized medical devices; FDA EN 1041, 1998 Terminology, symbols and information supplied by manufacturer</p> <p>Essentials Matrix (13.1, 13.2, 13.3 – as applicable)</p> <p>ISO 11607-2:2006 Packaging for terminally sterilized medical devices.</p>	<p>The pouch label shall minimally include a textual description or symbolic indication of the following:</p> <ul style="list-style-type: none"> <li>• The product name</li> <li>• Reference (reorder SKU) number</li> <li>• The Device configuration</li> <li>• The lot designation prefixed by the word "LOT"</li> <li>• The year and month of expiration</li> <li>• The manufacturer's and/or suppliers name and contact information</li> <li>• Patent Information – when applicable</li> <li>• CE mark and notified body number</li> </ul>	<p>Artwork Drawing(s): 3900179-01 3900181-01 3900183-01 3900185-01</p> <p>ACE Modified: 3900182-01 3900184-01 3900186-01</p> <p>ACE12A 3150898-01 3150634-01 3900181-01 ACE12AM 3150899-01 3150635-01 3900182-01 ACE14 3150900-01 3150638-01 3900183-01 ACE14AM 3150902-01 3150637-01 3900184-01 ACE14M 3150903-01 3150639-01 3900186-01</p>	PASSCLOSED	SH 12/15/2009	ME 12/15/2009

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Origin of Input (Standards – Internal/External)				Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
3.5.9	ISTA Method 2A Shipping test Essentials Matrix (4,5,8,1,8,3)	Labeling remains clear and legible under normal shipping, handling and storage.	Design Verification Ship testing Protocol #1150345-10 ACE Pencil Ship testing Protocol #1150523-10	Report 1150345-07 Ship Testing Report 1150345-09 Ship Testing Report 1150345-12 Ship Testing Report 1150345-17 Ship Testing Ship Test Report 1150523-01	ACE Modified Verification Report 1150527-01 ACE modified Pencil Ship Test Report 1150542-01	ACE Modified CLOSED	CLOSED	SH 12/15/2009	ME 12/15/2009
3.6	UNIT BOX	The ACE Blade will be packaged sterile 12 per box or 500 in BN configuration. Requirement (Section 3.2.4)	Design Specification Drawing(s)	Drawing(s); ACE12A, ACE14 ACE14A ACE12AM, ACE14AM, ACE14M	BN CONFIGURATIONS: ACE12BNS ACE12MBNS	ACE Modified CLOSED	CLOSED	SH 12/15/2009	ME 12/15/2009
3.6.2	Megadyne Medical Products requirement. Essentials Matrix (13.6 – as applicable)	One IFU shall be contained with a single box of product	Design Specification Drawing(s)	Drawing(s); ACE12A, ACE14 ACE14A 1 <sup>st</sup> Article Inspection ACE Modified: Drawing 4100052-XX (-03 is Black) IFU 3000318	ACE Modified CLOSED	ACE Modified CLOSED	CLOSED	SH 12/15/2009	ME 12/15/2009
						ACE Blade 700	ACE Blade 700	ACE Blade 700	ACE Blade 700
						TS 2/21/2018	TS 2/21/2018	ME 2/21/2018	ME 2/21/2018

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
3.6.3	ISTA Method 2A Essentials Matrix (4.5,8.1,8.3)	The case shall protect the Device from damage during normal shipping, handling and storage	Design Verification Ship testing Protocol #1150345-10 ACE Pencil Ship Test Protocol #1150523-10  ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10. ACE Pencil Ship Test Protocol #1150542-10	Report 1150345-07 Ship Testing Report 1150345-09 Ship Testing Report 1150345-12 Ship Testing Report 1150345-17 Ship Testing Report 1150523-01 ACE Pencil Ship Testing  ACE Modified Verification Report 1150527-01 ACE modified Pencil Ship Test Report 1150542-01	CLOSED	SH 12/15/2009	ME 12/15/2009
3.6.4	ISTA Method 2A Shipping test Essentials Matrix (4.5,8.1,8.3)	The labeling shall remain clear and legible under normal shipping, handling and storage.	Design Verification Ship testing Protocol #1150345-10 ACE Pencil Ship Test Protocol #1150523-10  ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10. ACE Pencil Ship Test Protocol #1150542-10	Report 1150345-07 Ship Testing Report 1150345-09 Ship Testing Report 1150345-12 Ship Testing Report 1150345-17 Ship Testing Report 1150523-01 ACE Pencil Ship Testing  ACE Modified Verification Report 1150527-01 ACE modified Pencil Ship Test Report 1150542-01	CLOSED	SH 12/15/2009	ME 12/15/2009

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Origin of Input				Design Input		Conformance Method		Output of Conformance		Requirement Status		Project Engineer Signature		Reviewer Signature		
#	(Standards – Internal/External)															
3.6.5	ISO 11607:2003 Packaging for terminally sterilized medical devices; FDA EN 1041,1998 Terminology, symbols and information supplied by manufacturer Essentials Matrix (13.1, 13.2, 13.3 – as applicable)	The Unit Box or box label shall minimally include a textual description or symbolic indication of the following:		Design Specification Label Artwork #		Artwork Drawing(s): 3150632-01 3150634-01 3150636-01 3150638-01		PASSCLOSED		SH 12/15/2009		ME 12/15/2009				
3.6.15	ISO 11607-2:2006 Packaging for terminally sterilized medical devices.	• The product name • Reference (reorder SKU) number • The Device configuration • The number of Devices • The lot designation prefixed by the word 'LOT' • The year and month of expiration • The manufacturer's and/or suppliers name and contact information • Patent information – when applicable • CE mark and notified body number • A bar code or bar codes shall be on the unit box label.		ACE Modified Artwork Drawing(s): 3150635-01 3150637-01 3150639-01		ACE Modified CLOSED								Modified Signature below SH 12/6/2010	Modified Signature below ME 12/6/2010	
				ACE12A		ACE Blade 700								ACE Blade 700	ACE Blade 700	
				3150898-01		TS 2/21/2018								ME 2/21/2018		
				3150634-01												
				3900181-01												
				ACE12AM												
				3150899-01												
				3150635-01												
				3900182-01												
				ACE14												
				3150900-01												
				3150638-01												
				3900185-01												
				ACE14A												
				3150901-01												
				3150636-01												
				3900183-01												
				ACE14AM												
				3150902-01												
				3150637-01												
				3900184-01												
				ACE14M												
				3150903-01												
				3150639-01												
				3900186-01												
3.6.16	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.7)	New Artwork for Unit Boxes for all 2.75" ACE blades		Unit Box Artwork # 3200040-01		Artwork acceptance DCO 09-097-01 1 <sup>st</sup> Article inspection		CLOSED		SH 12/15/2009		ME 12/15/2009		ME 2/21/2018		
3.6.17	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.7)	New Artwork for Unit Boxes all 4" and 6.5" ACE blades		Unit Box Artwork # 3200041-01		Artwork acceptance DCO 09-097-01 1 <sup>st</sup> Article inspection will occur as part of full scale launch		CLOSED		SH 12/15/2009		ME 12/15/2009		ME 2/21/2018		
3.7	SHIPPER BOX															

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Origin of Input (Standards – Internal/External)				Design Input		Conformance Method		Output of Conformance		Requirement Status		Project Engineer Signature		Reviewer Signature							
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3.7.1	Megadyne Medical Products requirement.			22 Unit boxes will be contained within a shipper box for all 2.75" ACE blades				Design Specification Drawing(s)				CLOSED ACE Modified CLOSED									
3.7.2	Megadyne Medical Products requirement.			11 Unit boxes will be contained within a shipper box for all 4" and 6.5" ACE blades				Design Specification Drawing(s)				CLOSED ACE Modified CLOSED									
3.8	SHIP TESTING			Packaging needs to be robust enough to protect the tip from receiving any damage from shipping				Verification Testing Ship Test Protocol #1150345-10 ACE Pencil Ship Test Protocol #1150523-10				CLOSED SH 12/15/2009									
3.8.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.6) ISTA Method 2A Essentials Matrix (4.5.8.1.8.3) ISO 11607-1			The device will not be damaged or bent during normal shipping and handling				ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.				ACE Modified CLOSED									
3.8.2	Megadyne Medical Products requirement. ISTA Method 2A Essentials Matrix (4.5.8.1.8.3)			Device must meet essential test requirements following exposure to standard shipping temperatures				Verification Testing Ship Test Protocol #1150345-10 ACE Pencil Ship Test Protocol #1150523-10				CLOSED SH 12/15/2009									
								ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.				ACE Modified CLOSED									
								ACE Pencil Ship Test Protocol #1150542-10				CLOSED SH 12/15/2009									
								Report 1150345-07 Ship Testing Report 1150345-09 Ship Testing Report 1150345-12 Ship Testing Report 1150345-17 Ship Testing Report 1150523-01 ACE Pencil Ship Testing				Modified Signature below ME 12/6/2010									
								ACE Modified Verification Report 1150527-01 ACE modified Pencil Ship Test Report 1150542-01				Modified Signature below SH 12/6/2010									
												TS 2/21/2018 ME 2/21/2018									
												Modified Signature below SH 12/6/2010									
												TS 2/21/2018 ME 2/21/2018									

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
3.8.3	MKT-CMR-023 (1250024-10) ACE CMR Requirement ((Section 3.2.6) ISTA Method 2A Essentials Matrix (4.5.8.1.8.3))	Packaging needs to be robust enough to protect the tip from receiving any damage from shipping  The sterile barrier will not be compromised during normal shipping	Verification Testing Ship Test Protocol #1150345-10 ACE Pencil Ship Test Protocol #1150523-10  ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10, ACE Pencil Ship Test Protocol #1150542-10	Report 1150345-07 Ship Testing Report 1150345-09 Ship Testing Report 1150345-12 Ship Testing Report 1150345-17 Ship Testing Report 1150523-01 ACE Pencil Ship Testing  ACE Modified Verification Report 1150527-01 ACE modified Pencil Ship Test Report 1150542-01	CLOSED	SH 12/15/2009	ME 12/15/2009
3.8.4	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.6) Essentials Matrix (4.5.8.1.8.3) ISO 11607-1	Packaging needs to be robust enough to protect the tip from receiving any damage from shipping  ACE12BN5 and ACE12MBN5 only	ENG-PRT-278	ENG-RPT-530	PASS	TS 2/21/2018 SH 12/6/2010 ME 2/21/2018	ME 2/21/2018
<b>4.0</b>	<b>SHELF LIFE TESTING</b>						
4.1	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.6) ISO 11607-1	The ACE Blade shall meet all essential design input requirements 2 years accelerated aged from date of manufacture.	Design verification testing following aging Protocol #1150399-10  ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150398-01, 1150398-02 Rust Evaluation Report 1150401-01 Blade Bend Fatigue Report 1150403-01, 1150403-02, -03 & -04 Simulated Use Report 1150404-02 Insulation Bond Strength  ACE Modified Verification Report 1150527-03 T=2 Year testing Report 1150527-04 T=5 year Testing	CLOSED	SH 12/15/2009	ME 12/15/2009
4.2	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.6) ISO 11607-1	The Device shall meet all essential design input requirements 2 years from date of manufacture.	Real time aging Work Instruction #1100149-10	Reports pending completion of 5 year shelf life testing Test Report and Product submitted for aging. See Phase 3 book section 3.5 1100149-10 form	CLOSED	TS 2/21/2018 SH 12/6/2010 ME 12/6/2010 SH 1/14/11 ME 1/14/11 TS 2/21/2018 ME 2/21/2018	ME 2/21/2018

**Megadyne Medical Products, Inc.**

**INPUT/OUTPUT CONFORMANCE TEST MATRIX**

**PROJECT ALPHA – ACE BLADE**

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
4.3	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.6) ISO 11607-1	The ACE Blade shall meet all essential design input requirements 5 years from date of manufacture.	Design verification testing following aging Protocol #1150399-10 ACE Modified verification testing following 2X EtO sterilization and testing using Protocol 1150527-10.	Report 1150398-01, 1150398-02 Rust Evaluation Report 1150401-01 Blade Bend Fatigue Report 1150403-01, 1150403-02, -03 & -04 Simulated Use Report 1150404-02 Insulation Bond Strength	CLOSED	SH 12/15/2009	ME 12/15/2009
4.4	MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 3.2.6) ISO 11607-1	The Device shall meet all essential design input requirements 5 years from date of manufacture.	Real time aging Work Instruction #1100149-10	Reports pending completion of 5 year shelf life testing Test Report and Product submitted for aging. See Phase 3 book section 3.5 1100149-10 form	CLOSED	SH 12/15/2009	ME 2/21/2018
5.0	<b>REGULATORY</b>	A 510(k) application shall be submitted to the FDA.	Receipt of 510(k) clearance from the FDA	FDA Clearance letter Dated: 10/21/08	Closed	SH 12/15/2009	ME 12/15/2009
5.1	FDA Requirement; FDA: Supplementary Guidance on Pre-Market Notification for Medical Devices Guidance for Industry and FDA MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 7.0)	ACE Blade 700	By inspection of ENG-DMR-001	ACE Blade 700 K081791	ACE Blade 700 TS 2/21/2018	ACE Blade 700 TS 2/21/2018	ACE Blade 700 ME 2/21/2018
5.2	FDA Requirement; FDA: Supplementary Guidance on Pre-Market Notification for Medical Devices Guidance for Industry and FDA MKT-CMR-023 (1250024-10) ACE CMR Requirement (Section 7.0)	A CE Mark application shall be submitted to the appropriate organization	Receipt of CE Certificate from NSAI	CE Mark received on 5/22/2009	Closed	SH 12/15/2009	ME 12/15/2009
6.0	<b>Usability Specification</b>	The Rx only symbol is required to be on the package label and the description of the symbol in the IFU.	Design	See Zip ACE DHF section 2.1 for regulatory strategy	ACE Blade 700 ACE Blade 700 TS 2/21/2018	ACE Blade 700 TS 2/21/2018	ACE Blade 700 ME 2/21/2018
6.1	MKT-US-004			3151071-01 3151072-01	PASS	TS 2/21/2018	ME 2/21/2018

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#	Origin of Input (Standards – Internal/External)	Design Input	Conformance Method	Output of Conformance	Requirement Status	Project Engineer Signature	Reviewer Signature
6.2	MKT-US-004	A statement and/or symbol that the device is packaged sterile is required on the package label and in the IFU.	Design	3900311, 3900313, 3900312, 3900314	PASS	TS 2/21/2018	ME 2/21/2018
6.3	MKT-US-004	Instructions for avoiding procedures where RF current could cause patient injury are required in the IFU.	IFU	If FU directs user to review generator IFU prior to use of the product for risks involving RF signals.	PASS	TS 2/21/2018	ME 2/21/2018
6.4	MKT-US-004	Failure to protect the junction of the pencil and E-Z Clean electrode from ingress of fluid could result in alternate current path burns.	ENG-PRT-439	Test Report ENG-RPT-555	PASS	TS 2/21/2018	ME 2/21/2018

#### REVISION HISTORY

Revision	Document Change Order Number	Description of Change	Effective Date
A	09-339-01	Initial Release through Phase 3 Development	2009-12-15
B	10-270-01	Update Conformance Test Matrix for all testing done to date and added ACE modified conformance aspects, removed ACE12 from listing	2010-12-15
C	11-020-01	Update Conformance Test Matrix to close out accelerate 5 year age testing per report 1150527-04	2011-01-24
001A		Several Changes throughout. Added Section 6. Project Engineer and Reviewer columns were cleared as needed. Lines where only the document number were updated do not need review and signature. Lines with new information or other changes need signature. Added Appendix L.	
		See Master Control for description of later revisions	

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### **Appendix I: Rationales**

The ACE700 group of products (ME7251C, ME7251E, ME725M1C, ME725M1E) is a subset of the ACE Blade product (ACE12A, ACE14, ACE14A, etc.) and shares the same requirements as other ACE blade products. ACE products are part of the EZ Clean family of electrodes. The tip design of the ACE700 is currently on the market as ACE Blade products (ACE12A, ACE14, ACE14A, etc.). Therefore, the Evaluation of a User Interface of Unknown provenance (UOUP) process (described in IEC 62366-1:2015 Annex C) was used to show equivalence of design. Complaints were analyzed and risk levels were assessed as indicated in the following sections utilizing Complaints Data and Risk Management Files.

No further output of conformance verification is necessary for the ACE700 family based on equivalence of design and acceptable risk levels of the current ACE blade tip family. A detailed explanation for each requirement for which this process was used is shown below.

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#1

**Requirements:** Must provide safety advantage for sharps injuries.

**Rationale:** The ACE product line was launched in June of 2009. ACE Blades (Substrate 3500078-XX) are designed with a flat cutting surface width of .001 to .004 inches. During manufacturing, any sharp edges are intentionally removed by mechanical means before coating with PTFE; a material with one of the lowest known coefficients of friction.

Complaint Records for the entire life of the product (July 2009 through November 2017) were searched for classifications of “Injury”, and “Performance Failure: Unknown”. Other Complaint classifications were not applicable. As part of Megadyne’s complaint tracking process, product codes are added to the complaint database when the first complaint on a given product code is received. Product codes that have no received complaints are not included in the complaint database. Only product codes ACE12, ACE12A, ACE12AM, ACE14, ACE14A, ACE14M, ACE30H, and ACE35H are included in the database, so search results are limited to those product codes.

Of the approximately 460,000 cases, ACE products that have been produced and sold, there is not a single confirmed sharps injury due to the ACE blade during manufacturing or use.

Product Code	Total ACE products distributed (samples and sales) July 2009 through Nov. 2017
ACE12	2
ACE12A	141,388
ACE12AEPP	19
ACE12AM	43,456
ACE14	13,038
ACE14A	15,341
ACE14AM	4,783
ACE14M	4,119
ACE30H	187,040
ACE35H	45,727
ACE36H	167
ACE37H	6,966
Grand Total	462,046

Lifetime ACE Distribution

NOTE: There is one unconfirmed complaint (2013007808) of a penetration injury potentially

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associated with an ACE Blade. The complaint was not confirmed. Because the product LOT number was not reported the complaint cannot conclusively be attributed to the ACE product line.

Even if this complaint were confirmed to be a result of a sharp electrode, this failure type has a rate of .00022% which is below the action level of .0012 (per RA-WI-002 Rev. 002) for the “Injury” complaint classification. No action would be taken.

**Conclusion:** The ACE product provides a safety advantage for sharps injuries.

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#2

**Requirements:** The ACE Blade will need to have a durable outer insulation that will maintain integrity throughout a case

**Rationale:** ACE products have been used in as many as 460,000 cases (See the “Lifetime ACE Distribution” table in Rationale #1) based on the number of units sold and distributed as samples since launch in 2009.

Complaint records for the entire life of the product (July 2009 through November 2017) were searched for classifications of “Arcing/Sparking”, “Injury”, and “Performance Failure: Unknown”. Other complaint classifications were not applicable. As part of Megadyne’s complaint tracking process, product codes are added to the complaint database when the first complaint on a given product code is received. Product codes that have not received complaints are not included in the complaint database. Only product codes ACE12, ACE12A, ACE12AM, ACE14, ACE14A, ACE14M, ACE30H, and ACE35H are included in the database, so search results are limited to those product codes.

Only one complaint (2015009745) due to the insulation has been reported during the life of the product. This single complaint also shows evidence that the electrode may have been exposed to high mechanical forces, (i.e. grasped by hemostats) and cannot be solely attributed to the insulation.

Even if this complaint was confirmed to be a result of an insulation failure, this failure type has a value of .00022% which is below the action level of .0005% for the “Damage: Insulation” failure code (per RA-WI-002 Rev. 002). No action would be taken.

**Conclusion:** The ACE product has a durable outer insulation that will maintain integrity throughout the case.

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### #3

**Requirements:** The modified insulation will need to be durable enough to withstand the high temperatures and mechanical forces that accompany electrosurgery.

**Rationale:** Temperatures experienced during electro-surgery are addressed in Rationale #4.

Standard modified electrodes and ACE modified products (codes with the letter “M” in the product code”) are manufactured with different colors of the same PTFE insulation (4100052-01 for Standard and 4100052-03 for ACE). The PTFE version of modified insulation replaced an older design in June of 2009. Based on sales and distribution figures from 2011 to 2017, modified products have been used in as many as 9.6 million cases. Distribution totals from 2009 and 2010 were excluded to ensure that only the current modified insulation design was reviewed and not the previous design.

Complaint records over the 2011 to 2017 time period was sorted for failure codes related to insulation damage and splitting. Complaint Records were searched for classifications of “Insulation”, “zMechanical Integrity: Insulation, melt”, and “zMechanical Integrity: Insulation, split”. Other Complaint classifications were not applicable. As part of Megadyne’s complaint tracking process, product codes are added to the complaint database when the first complaint on a given product code is received. Product codes that have not received a complaint are not included in the complaint database. Only modified product codes 0012AM, 0012AMB, 0012AMD, 0012M, 0012MBN, 0014AM, 0014AMB, 0014M, 0014MBN, 0036, 0036H, 0036HBN, 0037, 0037BN, 0037H, 0037HBN, ACE12AM, and ACE14M are included in the database, so search results are limited to these product codes.

Product Code	All products distributed (ea.) Jan. 2011 through Nov. 2017	Number of Complaints	Complaints reviewed	
0012AM	1,297,094	2	2013007812	2016010936
0012AMB	604,850	9	2011005561 2011005990 2011006067 2011006084 2011006255	2012006390 2012006461 2016011766 2016011767
0012AMD	26,670.00	-		-
0012M	3,628,094	4	2011005876 2012006696	2015009851 2016010761
0012MD	57,112	-		-

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Product Code	All products distributed (ea.) Jan. 2011 through Nov. 2017	Number of Complaints	Complaints reviewed	
0012MBN	606,603	9	2011005569 2011006064 2011006252 2014008703 2014008710	2014009589 2015010316 2016011100 2016011365
0014AM	748,467	-	-	-
0014AMD	4,849	-	-	-
0014AMBN	277,291	-	-	-
0014M	1,035,396	2	2014009013	2016011298
0014MD	2,159	-	-	-
0014MBN	148,355	-	-	-
0036	6,219	-	-	-
0036BN	13,766	-	-	-
0036H	52,837	3	2013008299 2016010804	2017012018
0036HBN	54,545	2	2015010205	2016011352
0037	13,060	-	-	-
0037BN	154,511	-	-	-
0037H	40,457	-	-	-
0037HBN	836,483	5	2012006583 2013007475 2016011820	2016011824 2017012154
ACE36H	91	-	-	-
ACE37H	1,955	-	-	-
ACE12AM	50,440	-	-	-
ACE14AM	5,396	-	-	-
ACE14M	4,514	-	-	-
<b>Grand Total</b>	<b>9,671,214</b>	<b>36</b>		
<b>Failure Rate</b>			<b>.00037%</b>	
<b>Action Level</b>			<b>.0005</b>	

A search for split insulation complaints returned 0 results for the time period in question.

Sales and distribution of modified products

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Complaints that were the result of failed insulation of any kind, including use related issues, are included in the results above. Even if all of these complaints were confirmed to be a result of failed modified insulation due to manufacture at Megadyne, the total failure rate has a value of .00037% which is less than the action level of .0005% (per RA-WI-002 Rev. 002). No action would be taken.

**Conclusion:** The ACE product has a durable outer insulation that will maintain integrity throughout the case.

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#### #4

**Requirement:** The insulation of the electrode must be durable and able to withstand the heat of electrosurgery as well as some of the mechanical forces associated with surgery.

**Rationale:** Adequate mechanical integrity of the insulation is established in Rationale #3.

Data collected in ENG-RPT-452 (See Appendix V) shows that no part of the pencil or electrode is heated to a temperature of greater than 27.2 °C for the Mega Power generator's maximum stated duty cycle.

All electrodes are exposed to 174 °C (345 °F, See OPER-FRM-051) for insulation recovery (insulation shrinkage) during the manufacturing process. All design verification and validation testing was performed on product that had been exposed to this temperature.

Complaint Records for the entire life of the product were searched for classifications of “Arcing/Sparking”, and “Damage”, “Flame/Flash/Fire”, “Injury”, and “Performance Failure: Unknown”. Other Complaint classifications were not applicable. As part of Megadyne’s complaint tracking process, product codes are added to the complaint database when the first complaint on a given product code is received. Product codes that have not received a complaint are not included in the complaint database. Only product codes ACE12, ACE12A, ACE12AM, ACE14, ACE14A, ACE14M, ACE30H, and ACE35H have complaints associated with them, so search results are limited to those product codes. The review of complaints shows that one complaint (2015009745) due to the insulation has been reported during the life of the product (approximately 462,046 cases, see “Lifetime ACE Distribution” table above). This single complaint also shows evidence that the electrode may have been exposed to high mechanical forces, (i.e. grasped by hemostats, etc.) and cannot be solely attributed to a design failure of the insulation.

Even if this complaint were confirmed to be a result of an insulation design failure, this failure type has a rate of .00022% which is below the action level of .0005 (per RA-WI-002 Rev. 002) for the “EZC – Damage: Insulation” complaint classification. No action would be taken.

The insulation is durable to at least 174 °C (345 °F), well above the 27.2 °C temperature experienced during the Mega Power generator's maximum stated duty cycle.

**Conclusion:** The insulation of the electrode is durable and able to withstand the heat of electrosurgery as well as some of the mechanical forces associated with surgery.

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## #5

**Requirement:** Must work in all monopolar modes..

**Rationale:** The ACE blade was verified to be compatible with all standard monopolar electrosurgery modes by testing at the “worst case” boundary conditions. Pure CUT and Spray COAG are considered “worst case” scenarios for simulated use testing of PTFE coated electrodes.

The Pure CUT waveform produces conditions which cause the electrode substrate to heat more readily, more so than other cut modes. Pure CUT historically has shown the greatest potential for coating delamination or ‘flaking’ and is a good indicator for acceptable/unacceptable coating adhesion under simulated use testing.

The Spray COAG waveform has a more aggressive output and is designed to deliver energy through multiple locations on the electrode. Spray COAG is typically used for procedures requiring fulguration which can produce more elevated temperatures in the electrode compared to other COAG modes. Although not as ‘hot’ as a Pure CUT activation, this mode can produce substantial heating of the electrode in order to assess coating integrity under simulated use.

As such, these modes were employed to assess adhesion, integrity, and performance of the PTFE coating and substrate integrity on ACE blade electrodes. Although all modes were not tested as part of the protocol, the critical, more aggressive ESU modes were evaluated as a means of qualifying the ACE Blade for use with all ESU modes.

**Conclusion:** The insulation of the electrode is durable and able to withstand the heat of electrosurgery as well as some of the mechanical forces associated with surgery.