**COMPLETION REPORT APPROVAL PAGE**

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| COMPLETION REPORT # | | | | | | PRC088248 | | REVISION: | | | | A | | DATE: | | | | 3/26/19 | |
| PROTOCOL # | | | PRC088247 | | | | | MVP, ECP, DP or SPCR# | | | | | | | | N/A | | | |
|  | | | | | | | | | | | | | | | | | | | |
| TITLE: | Mega Power 1000 Instruction Template Qualification Completion Report | | | | | | | | | | | | | | | | | | |
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| **STATUS** | |  | | **SALEABLE** | | |  | | **NON-SALEABLE** | | | | | | | |  | | **N/A** |
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| COMPLETION REPORT INFORMATION | | | | | | | | | | | | | | | | | | | |
| ORIGINATOR: | | | Jason Stivers | | | | | | | PHONE NUMBER: | | | | | 513.337.1267 | | | | |
| ORIGINATOR TITLE: | | | | | Service Engineer | | | | | | SITE: | | Cincinnati | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| PRIORITY STATUS (Specify Document Due Date): | | | | | | | | | | N/A | | | | | | | | | |

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| **Refer to Protocol Document for Type and Approval Governance Information** | | | | | | |
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| **APPROVAL LIST:** | | | | | | |
| **Function** | | | **Name** | **User I.D.** | | **Signature/Date** |
| **ORIGINATOR** | | | Jason Stivers | Jstiver1 | | eSig in EPIcenter |
| BUSINESS OWNER | | | Eric Smith | esmith2 | | eSig in EPIcenter |
| SERVICE ENGINEER | | | Jason Stivers | jstiver1 | | eSig in EPIcenter |
| SERVICE QUALITY LEAD | | | Robert Peters | rpeters2 | | eSig in EPIcenter |
|  | |  | |  | |  |
| **Additional Completion Approvals (N/A If Not Applicable)** | | | | |  | |
| **Function** | | | **Name** | **User I.D.** | | **Signature/Date** |
| **Test Conducted By** | | | Varlie Waggaman | vwggaman | | eSig in EPIcenter |
| **Data Authentication** | | | N/A | N/A | | N/A |
| **Product Destroyed By** | | | N/A | N/A | | N/A |
| **DISTRIBUTION LIST: (create as necessary)** | | | | | | |
| **Revision** | **Change Description** | | | | | |
| A | Original Issue | | | | | |

1. **SUMMARY**
   1. The Mega Power 1000 Instruction Template Qualification testing was successfully completed on March 20, 2019. Verbiage and testing range values were successfully compared between the physical forms and the digital forms in the service data base.
2. **CRITERIA FOR SUCCESS**
   1. The criteria for success of this protocol are as follows:
      1. **Required:** Exact word-for-word replication of all the verbiage of the test steps on the physical test forms to the Instruction Templates.
         1. **Result:** Exact word-for-word replication of all the verbiage of the test steps on the physical test forms to the Instruction Templates was found and documented.
      2. **Required:** Exact upper and lower limit replication of all test ranges listed on the physical test forms to the Instruction Templates.
         1. **Result:** Exact upper and lower limit replication of all test ranges listed on the physical test forms to the Instruction Templates was found and documented.
3. **TEST SUMMARY**
   1. GEN11 Instruction Template Qualification
      1. The test was conducted on March 20, 2019.
      2. The test was conducted at the Ethicon Endo-Surgery Service Center, one of the buildings of the Ethicon Endo-Surgery, Inc. 4545 Creek Road, Cincinnati, OH, 45242 campus.
      3. The testcompared verbiage and test ranges in the digital forms in the service data base with the physical test forms for exact replication.
      4. Varlie Waggaman, Service Repair Technician, conducted the test.
      5. The following data sets are captured as objective evidence of successful completion and are attached in Epicenter:
         1. Screen Captures
         2. Data Collection Sheet
   2. No gages or calibrated equipment was used for the test
   3. \*\*Testing Location:

Cincinnati Campus (all buildings): Ethicon Endo-Surgery, Inc. 4545 Creek Road, Cincinnati, OH, 45242

Albuquerque: Ethicon Endo-Surgery, 3801 University Blvd, S.E., Albuquerque, NM, 87106

Torres: Ethicon Endo-Surgery, S.A. de C.V., Avenida De Las Torres No 7125, Colonia Savarcar 118, Ciudad Juarez, Chihuahua, 32580, Mexico

Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juarez, Chihuahua, 32575, Mexico

Other (please specify):

1. **OVERVIEW OF FACTS/RESULTS**
   1. The test technician was trained to the protocol PRC088247A. This was documented in PRC088248A – Attachment 1 – FM-0000809 Franchise Qualification and Training Record Form (Shared).
   2. The test technician compared all test step verbiage and test limit values between the Instruction Template and the physical test forms per the instructions in the protocol.
   3. The objective evidence and the successful results are captured in the following appendices:
      1. PRC088248A Attachment 2 – Screen Shots
      2. PRC088248A Attachment 3 – Data Collection Form
   4. The physical test forms that were compared to the Instruction Templates in the data base are captured in the following appendices:
      1. PRC088248A Attachment 4 – CS-FRM-034 revision 4
      2. PRC088248A Attachment 5 – FRM003998 revision A
   5. All protocol steps passed, and the success criteria were met.
2. **RECOMMENDATIONS**
   1. This qualification met the success criteria. It is recommended that the Megadyne Mega Power 1000 Instruction Templates be released for use in Mega Power 1000 Service and Repair. PR001566 Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions has been updated to reflect the option to use the qualified digital test forms.
3. **APPENDICES**
   1. PRC088248A – Attachment 1 – FM-0000809 Franchise Qualification and Training Record Form (Shared)
   2. PRC088248A Attachment 2 – Screen Shots
   3. PRC088248A Attachment 3 – Data Collection Form
   4. PRC088248A Attachment 4 – CS-FRM-034 revision 4
   5. PRC088248A Attachment 5 – FRM003998 revision A
4. **Maximo Work Order Reference:**
   1. N/A – Maximo not used for this qualification activity.
5. **SUMMARY OF COMPLETION ACTIVITIES**
   1. Steps outlined in PR001566 detailing use of the Mega Power 1000 digital test forms will be used as an option for documenting service and repair testing for the Mega Power 1000.