**PROTOCOL APPROVAL PAGE**

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| PROTOCOL # | | PRC088247 | | | | | REVISION: | | | | A | | | DATE: | | | | 02/26/2019 |
| COMPLETION REPORT # | | | | | PRC088248 | | | | MVP, ECP, DP or SPCR# | | | | | | | | N/A | |
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| TITLE: | Mega Power 1000 Instruction Template Qualification Protocol | | | | | | | | | | | | | | | | | |
| PROJECT NAME: | | | Service and Repair Digital Test Forms | | | | | | | PROJECT LEADER: | | | | | | Jason Stivers | | |
| ProductCode: | 1000 | | | | | ProductNumber: | | N/A | | | | | BatchNumber(s): | | | | | N/A |
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| PROTOCOL 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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| **Protocol Document Type and Approval Governance** | | | | | | | | | | | | |
| **Type:** | | **Service Protocol - Other** | | | | | | | | | | |
| **Organization Responsible-**  **Governance** | |  | **New Product Development**  **Pre-Launch/Stabilization**  **(CP0258 or CP0150 if applicable)** | |  | **Lifecycle Engineering**  **Post Stabilization (CP0150 if applicable)** | |  | **External**  **Manufacturing**  **(CP0231/CP0150)** | |  | **Other** |
|  | | | | | | | | | | | | |
| **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 | | |
| **DISTRIBUTION LIST: (create as necessary)**  **NOTE: (Juarez Only):** Planners must sign for notification only. | | | | | | | | | | | | |
| **Revision** | **Change Description** | | | | | | | | | | | |
| A | Original Document | | | | | | | | | | | |

1. **PURPOSE**
   1. The service and repair data base (S&R Application) utilized to document service and repair of the Mega Power 1000 Electrosurgical Generator contains functionality called Instruction Templates. This functionality enables device testing results during the service process to be captured digitally, removing the need for scanning and/or retaining paper forms. This protocol will verify that the Instruction Templates created for Mega Power 1000 testing capture the exact information – both wording and test ranges – of the test form for Mega Power Service.
2. **SCOPE**
   1. The scope of this protocol covers the following Instruction Templates in the service data base:
      1. EES SC Mega Power New Faceplate Test Form V1
         1. Corresponds to CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate
      2. EES SC QA Megadyne Mega Power 1000 Inspection and Test Results V1
         1. Corresponds to FRM003998, Quality Assurance Final Release Inspection Form for Megadyne™ Mega Power™ 1000 Electrosurgical Generator System
3. **CRITERIA FOR SUCCESS**
   1. The criteria for success of this protocol are as follows:
      1. Exact word-for-word replication of all the verbiage of the test steps on the physical test forms to the Instruction Templates.
      2. Exact upper and lower limit replication of all test ranges listed on the physical test forms to the Instruction Templates.
4. **REFERENCE DOCUMENTS**
   1. 100549929 Franchise WI for Service and Repair Administrative Support and Data Setup (Shared)
   2. FM-0000809 Franchise Qualification and Training Record Form (Shared)
   3. CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate
   4. FRM003998, Quality Assurance Final Release Inspection Form for Megadyne™ Mega Power™ 1000 Electrosurgical Generator System
   5. PR001566 Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions
5. **EQUIPMENT AND MATERIALS**

Service & Repair Application OneMD Service and Repair

Instruction Test Templates: EES SC Mega Power New Faceplate Test Form V1, EES SC QA Megadyne Mega Power 1000 Inspection and Test Results V1

1. **RESPONSIBILITIES**
   1. Service Engineer/Site Representative will create the protocol and the associated completion report.
   2. Business owner is responsible for the review and approval of this protocol and the associated completion report.
   3. Service Quality Lead is responsible for the review and approval of this protocol and the associated completion report.
   4. Service Repair Technician is responsible for completion of required training prior to completion of this protocol and will execute the protocol.
   5. Document Management is responsible for the maintenance and archival of this protocol.
2. **STRATEGIES AND ASSUMPTIONS**
   1. The template FMWE0020.2 was chosen to document this testing as the protocol does not include Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), combination OQ and PQ, Test Method Validation (TMV), or Process Confirmation.
   2. Instruction templates listed in the Scope section above were created in advance of execution of this protocol by a service data base user with administrative access per 100549929.
   3. Verbiage in each test step will be compared word-for-word requiring an exact match to obtain a pass value. Objective evidence will be captured via screen shot.
   4. Upper and lower limits will be verified for each test range, requiring an exact match to obtain a pass value. Objective evidence will be captured via screen shot.
   5. This protocol will be executed with the service data base user (Technician) logged into the data base with administrative permission to view the test range numerical values. Non-administrative view of the Instruction Template only allows the user to enter a value, and the system will deliver a pass/fail result based on the pre-determined values (taken from the Mega Power Test Form) programmed into the Instruction Template.
   6. Instruction Sections in the data base and corresponding titles may not align exactly with sections in the CS-FRM-034. They were created as such in the Instruction Template for clarity and ease of use in the system. Wording of individual steps will be tested in this protocol rather than the Instruction Section Names.
3. **TRAINING**
   1. The Technician executing the protocol must first be trained to the protocol by reading and understanding content. This will be documented using FM-0000809.
4. **PREREQUISITES**
   1. Not applicable.
5. **PROCEDURE**
   1. Log into the service data base and navigate to the following Instruction Template:
      1. EES SC Mega Power New Faceplate Test Form V1
         1. Per Appendix 1, for each “Compare wording” step of the test in the Instruction Template, verify that the wording in the test step corresponds exactly to the wording in CS-FRM-034.
            1. Take a screen shot (or screen shots) of the Instruction Template test step(s) showing the correct wording to retain for objective evidence.
            2. Record the result on Appendix 1 - Data Capture Sheet.
         2. Per Appendix 1, for each “Compare upper and lower limits” step, press “Edit” and verify that the upper and lower limits correspond exactly to the values on CS-FRM-034.
            1. Take a screen shot of the Edit screen showing the correct values to retain for objective evidence.
            2. Record the result on Appendix 1 - Data Capture Sheet.
      2. EES SC QA Megadyne Mega Power 1000 Inspection and Test Results V1
         1. Per Appendix 1, for each “Compare wording” step of the test in the Instruction Template, verify that the wording in the test step corresponds exactly to the wording in FRM003998.
            1. Take a screen shot (or screen shots) of the Instruction Template test step(s) showing the correct wording to retain for objective evidence.
            2. Record the result on Appendix 1 - Data Capture Sheet.
      3. Print name, sign, and date the Data Capture Sheet and retain for the completion report.
         1. Compile the screen shots for objective evidence into a single document, making sure to clearly label the images, noting the corresponding steps on the Data Capture Sheet. Retain for the completion report.
6. **PRODUCT DISPOSITION**
   1. Not applicable – no product being tested.
7. **INVENTORY STRATEGY**
   1. Not applicable – no product being tested.
8. **COMPLETION ACTIVITIES**
   1. When the success criteria have been met, the Instruction Templates listed in the Scope section will be qualified for use per PR001566.
9. **ATTACHMENTS**
   1. PRC088247 Attachment 1 – Data Collection Form