**PROTOCOL APPROVAL PAGE**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| PROTOCOL # | | PRC086802 | | | | | REVISION: | | | | A | | | DATE: | | | | 10/25/18 |
| COMPLETION REPORT # | | | | | PRC086803 | | | | MVP, ECP, DP or SPCR# | | | | | | | | N/A | |
|  | | | | | | | | | | | | | | | | | | |
| TITLE: | Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service Transfer | | | | | | | | | | | | | | | | | |
| PROJECT NAME: | | | Megadyne Service Transfer | | | | | | | PROJECT LEADER: | | | | | | Jason Stivers | | |
| ProductCode: | 1000 | | | | | ProductNumber: | | N/A | | | | | BatchNumber(s): | | | | | N/A |
|  | | | | | | | | | | | | | | | | | | |
| PROTOCOL INFORMATION | | | | | | | | | | | | | | | | | | |
| ORIGINATOR: | | Jason Stivers | | | | | | | PHONE NUMBER: | | | | | | 513-337-1267 | | | |
| ORIGINATOR TITLE: | | | | Service Engineer | | | | | | | | SITE: | | Cincinnati, Ohio | | | | |
|  | | | | | | | | | | | | | | | | | | |
| PRIORITY STATUS (Specify Document Due Date): | | | | | | | | | N/A | | | | | | | | | |

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| **Protocol Document Type and Approval Governance** | | | | | | | | | | | | |
| **Type:** | | **Protocol – Service and Repair** | | | | | | | | | | |
| **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 | | |
| Service Engineer | | | | Jason Stivers | | | Jstiver1 | | | eSig in EPIcenter | | |
| Service Manager | | | | Eric Smith | | | esmith2 | | | eSig in EPIcenter | | |
| Service Quality Lead | | | | Robert Peters | | | rpeters2 | | | eSig in EPIcenter | | |
| Megadyne Service Manager/Facilitator | | | | Carly Rasband | | | crasband | | | See Non-electronic section for  external signature | | |
| Megadyne Quality Engineer | | | | Ihsan Samara | | | isamara | | | See Non-electronic section for  external signature | | |
| Megadyne Engineer | | | | Mallory Schroeder | | | Mschro11 | | | 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 purpose of this protocol is to perform the Installation Qualification (IQ) and Performance Qualification (PQ) for the service and repair bench for Megadyne Mega Power Electrosurgical Generator (product code 1000) at Ethicon Endo Surgery (EES) Service and Repair Depot, Cincinnati, Ohio.
   2. This qualification will be performed at EES Service and Repair Depot, Cincinnati, Ohio and provide evidence that all key aspects of the process adhere to the manufacturer’s approved

specification, and that the recommendations of the supplier of the equipment are suitably

considered. This includes equipment and auxiliary system installation.

* 1. This qualification will establish evidence that the process of service and repair for product code 1000, under anticipated conditions, consistently produces results that meets all predetermined requirements.
  2. The completion of these activities will validate the service and repair process for the Mega Power 1000.

1. **SCOPE**
   1. All equipment and necessary procedures involved in the service and repair process for Mega Power Electrosurgical Generator (product code 1000) will be validated through this protocol.
2. **CRITERIA FOR SUCCESS**
   1. This protocol will be considered successful when all areas outlined in the IQ and PQ have been completed per the procedures in this protocol with acceptable results and/or justifiable deviations. The creation and final approval of the protocol completion report verifies the acceptance criteria has been met.
3. **REFERENCE DOCUMENTS**

**Ethicon Documents**

* 1. CP0198, Manufacturing Process Validation Procedure
  2. CP0190, Requirements for Control of Inspection, Measuring and Test Equipment
  3. PR001566 Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions
  4. WE001143, Decontamination Procedure
  5. WE001302, Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair
  6. WE0586, Management of Change (MOC) Process
  7. FMWE0586.1, Management of Change (MOC)
  8. FM-0000809, Franchise Qualification and Training Form
  9. FRM003998, Quality Assurance Final Release Inspection Form for MegaPower 1000

**Megadyne Documents**

* 1. 3000144-01 Megadyne Mega Power Field Calibration Manual
  2. MKT-LBL-063Megadyne Mega Power Trouble Shooting Guide
  3. 3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual *~ www.e-ifu.com*
  4. 3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual *~ www.e-ifu.com*
  5. ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair
  6. ENG-WI-037 Mega Power 1000 Assembly Instructions, Service and Repair
  7. CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate

1. **EQUIPMENT AND MATERIALS**
   1. Refer to Appendix A
2. **RESPONSIBILITIES**
   1. Service Manager/Facilitator - is responsible for the review and approval of this protocol and the associated completion report.
   2. Service Engineer - is responsible for the creation, review, approval, execution, and required training prior to execution of this protocol. This includes all associated activities and the 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 execution of this protocol and assisting with creation, required training prior, and execution of this protocol. This includes the associated completion report.
   5. Service/QA/Support Technicians - are responsible for completion of required training prior to execution of this protocol and assisting with completion of all the activities to execute this protocol.
   6. Megadyne Service Manager/Facilitator - is responsible for the review and approval of this protocol and the associated completion report.
   7. Megadyne Service Engineer (or equivalent Design Engineer) - is responsible for the review and approval of this protocol and the associated completion report.
   8. Megadyne Quality Engineer - is responsible for the review and approval of this protocol and the associated completion report.
   9. Document Management - is responsible for the maintenance and archival of this protocol.
3. **STRATEGIES AND ASSUMPTIONS**
   1. To capture the relevant activities in this validation procedure, this protocol will be using the necessary guidelines outlined in CP0198 for installation, operation, and performance activities specified herein. The elements of this protocol must meet the intent of CP0198.
   2. An OQ is not required since the associated process equipment have single point operational parameters and not operational ranges. This is in accordance with CP0198.
   3. Software validations (SV) for tools and equipment used to service Mega Power 1000 are not required and additional validations are not needed.
      1. Custom software required for servicing Mega Power 1000 was validated by Megadyne. The software is not altered for use during service and repair.
      2. Other tools and equipment involved that contain software are off-the-self test equipment: ESU analyzer, electrical safety tester, and multi-meter. These contain non-customized vendor software that will not be altered for use in this service and repair.
   4. All equipment for this protocol that requires calibration will be calibrated per CP0190 and entered into EES calibration database.
   5. The IQ and PQ activities described as part of this protocol will meet their essential guidelines outlined in CP0198 for demonstrating and documenting that this process is effective and reproducible.
   6. The documented objective evidence of successful PQ activities will consist of the data created during service and repair of Mega Power 1000. This data will be recorded during protocol execution.
   7. Appendix A – IQ Information sheet will be used to perform the IQ and record necessary data at the designated service and repair area. The completion and documented data provided from this section will be evidence of successful IQ activities.
   8. A risk assessment using the Process Validation Decision tree (Appendix I of CP0198) indicates the process output is verifiable and the verification is sufficient & cost effective; thus, requiring only verification and control of the service and repair process. The validation of the service and repair process will be done through this protocol.
   9. The service and repair depot is not a clean room as discussed in CP0198, therefore, deep cleaning of the equipment will not be performed prior to installation.
   10. Measurement and analysis methods have been defined within CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate.
   11. Mega Power 1000 device for protocol execution came from Megadyne and is a Known Good Unit (KGU). A Certificate of Conformance will be provided in PRC086503.
   12. No spare parts will be needed for this protocol.
   13. The service center will be using Enterprise Complaint Management (ECM) System and Service and Repair Application, which has been validated within its systems and processes; therefore, the service database will not be re-evaluated as a part of this protocol.
   14. Each step, in the procedure section of this protocol, must pass prior to completion of the subsequent step except for “Work Order creation and device receipt” PQ procedure 10.2.1. This is done prior to execution of the PQ.
   15. One Mega Power 1000 device will be used due to limited availability of the device. An induced failure will be created on this device and the device will be serviced and repaired back to required specifications. This will be done for a total of three times with different induced failures each time per the procedures section of this protocol. This will show the ability to service and repair this device using:
       1. 3000144-01 Megadyne Mega Power Field Calibration Manual
       2. MKT-LBL-063Megadyne Mega Power Trouble Shooting Guide
       3. 3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual
       4. 3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual
       5. ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair
       6. ENG-WI-037 Mega Power 1000 Assembly Instructions, Service and Repair
       7. CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate
   16. The Management of Change (MOC) process performed by the Cincinnati EH&S department using FMWE0586.1 per WE0586 will meet the criteria outlined in CP0198. These preliminary execution assessments verify acceptable safety, environmental, and ergonomic conditions exist. The MOC will be finalized post Mega Power 1000 service and repair validation.
   17. There will be product release performed at the quality assurance area after each service and repair of the Mega Power 1000 has been completed. This activity will be documented using FRM003998, Quality Assurance Final Release Inspection Form for Mega Power 1000.
   18. If the criteria for success is not met, potential root causes and corrective actions will be documented in the completion report (if applicable) and criteria for success changes, or process changes that require revalidation maybe necessary.
4. **TRAINING**
   1. Training for service technicians and quality assurance technicians was conducted September 5, 2018 to September 7, 2018. This training covered all required activities to service and repair the Mega Power 1000.
   2. Protocol training for the required personnel shall be done prior to protocol execution and will be documented on form FM-0000809. Training is not required for protocol approvers per WE0020.
5. **PREREQUISITES**
   1. Location for service and repair will be identified prior to protocol execution.
   2. All test equipment requiring calibration will be calibrated per CP0190 and documented using Appendix A of this protocol.
   3. Megadyne will supply product specific test equipment as listed in CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate for use during this protocol.
   4. The preliminary environmental, safety, and ergonomic assessments for the Management of Change (MOC) process will be performed prior to protocol execution and included in the completion report.
   5. Installation Qualification (IQ) will be performed prior to Performance Qualification (PQ) of this protocol, except for “Work Order creation and device receipt” PQ procedure 10.2.1, which is completed prior and is a setup function.
6. **PROCEDURE**
   1. **Installation Qualification**
      1. Place all test equipment needed for service and repair at the designated service and repair bench.
      2. Utilizing Appendix A, Section 1, Equipment Utilities Requirements, perform activities:
         1. Verify all electrical receptacles needed for the designated service and repair bench are within the listed specifications and measure their output with a standard multi-meter. Record output results.
         2. Verify all associated circuit breakers for the electrical receptacles are within the specifications and properly functioning by switching the breakers on/off.
      3. Utilizing Appendix A, Section 2, Equipment List and Setup, perform activities:
         1. Verify all test equipment that required calibration are calibrated per CP0190. Record their serial number, IM&TE (Inspection, Measurement, and Test Equipment) number, calibration date and calibration due date.
         2. Verify the correct associated tools are identified and available for setup.
         3. Setup the service and repair bench with all tools and test equipment.
         4. Take a photo of the service and repair bench setup for visual record and include that photo in section 2.
         5. Verify all electrical connections (power cords and receptacles) and the associated equipment to those connections are stable and secure.
         6. Verify lighting is available and equipment bins are identified.
      4. Verify all documents and assessments in the referenced documents section of this protocol are physically or electronically identified, reviewed, and available (if applicable), at the service & repair bench and QA area.
      5. Review Appendix A for completeness and accuracy.
      6. Upon completion of this section (10.1) with acceptable results, the IQ is complete, retain documented results for the completion report.
   2. **Performance Qualification** 
      1. Create one Work Order in the Enterprise Complaint Management (ECM) System and Service and Repair Application for the Mega Power 1000 device and receive the device within the service database prior to protocol execution.
      2. A technician will perform decontamination per WE001143.
      3. A service technician will induce failure one, identified in section 10.2.12, on the Mega Power 1000.
      4. A service technician will be following steps per PR001566. Do not continue with repair, document the failure at the corresponding section of testing that fails and stop at that point. “NA” the following tests.
      5. A service technician will then troubleshoot and perform the necessary repair and testing. Document repair and testing on a new form CS-FRM-034, and in the service and repair database. Attach form to service and repair database.
      6. A service technician will perform electrical safety testing on Mega Power 1000 device following steps per PR001566, attach the electrical safety test data sheet print-out to the service and repair database.
      7. The Mega Power 1000 will be returned to required specifications through steps 10.2.4 to 10.2.7. A service technician will attach only the repair documentation, form CS-FRM-034 and electrical safety test data sheet created in steps 10.2.4 through 10.2.7 to the service and repair database, not the forms created during failure creation and identification steps 10.2.4. Retain and turnover all documentation for QA to review.
      8. A quality release technician will perform the QA Final Acceptance Testing and Release listed in PR001566 and WE001302 Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair. FRM003998, Quality Assurance Final Release Inspection Form for MegaPower 1000. Attach forms to the service and repair database.
      9. A service technician will then induce failure two in section 10.2.12 and repeat steps 10.2.4 through 10.2.7. A quality release technician will repeat step 10.2.8.
      10. A service technician will then induce failure three in section 10.2.12 and repeat steps 10.2.4 through 10.2.7. A service technician will create a box label per PR001566 after this third run and a quality release technician will repeat step 10.2.8. After final inspection, the box label will be destroyed (The Mega Power 1000 device will not actually be shipped) and a Service Summary Report printed. Retain all documentation for the completion report.
      11. Review documentation for expected results and retain them for the completion report.
      12. **Failures to induce:**
          1. **Failure one:** On the Mega Power 1000, remove the main fuse holder with both fuses at the back of the unit. Refer to 3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual.  **Result:** The device should not power on.
          2. **Failure two:** On the Mega Power 1000, unplug Front Panel Ribbon Cable from J3 connection on the Front Panel Board. Refer to ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair.
             1. **Result:** The Front Panel will not illuminate.
          3. **Failure three:** On the Mega Power 1000, unplug Power Switch P1 Cable from High Voltage Board J1 connection. Refer to ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair.
             1. **Result:** The Power Switch will illuminate, but the Front Panel will not.
7. **PRODUCT DISPOSITION**
   1. If criteria for success is met and Mega Power 1000 (product code 1000) used in this protocol passed service and repair process the device will be serviced again post-service launch and placed in the Mega Power 1000 loaner pool.
8. **INVENTORY STRATEGY**
   1. N/A
9. **COMPLETION ACTIVITIES**
   1. When the protocol has met the defined criteria for success with acceptable results and/or justifiable deviations addressed/implemented, the validation of the service and repair process for Mega Power 1000 will be complete.
   2. The completion report documenting all expected outcomes of this protocol execution will be reviewed and approved. The review and approval of the completion report proves EES Service and Repair Depot can service and repair Mega Power 1000 (product code 1000).
10. **APPENDICES**
    1. Appendix A - Installation Qualification (IQ) Information Sheet

**Appendix A**

**Installation Qualification (IQ) Information Sheet**

1. **Equipment Utilities Requirements**

Identify utility requirements and verify those utilities meet the equipment requirements. Specifications will be complete and include a max/min range or specify nominal readings with an acceptance tolerance.

|  |  |  |  |
| --- | --- | --- | --- |
| **Function** | **Specifications** | **Actual Observed** | **Acceptance**  **Yes / No** |
| **ELECTRICAL:** | | | |
| Voltage | 100-240V AC 50-60HZ |  |  |
| Phase | Single |  |  |
| Conductor Type | To meet NEC standards |  |  |
| Conductor Size | To meet NEC standards |  |  |
| Connector Type | To meet NEC standards |  |  |
| Bonded Ground | Required |  |  |
| **CIRCUIT BREAKER / DISCONNECT:** | | | |
| Location |  |  |  |
| Required Identification | Voltage **|** Current |  |  |
| Amperage Requirement | Rated amps not to exceed 20 amps on 120 VAC side |  |  |
| Rating Requirement | Minimum of type 1 |  |  |
| Insulation required | Not specified |  |  |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Specification Data Collected by: | |  |  |  | |  | |  | |
|  | | Name |  | Signature | |  | | Date | |
| Observed Data Collected by: | |  |  |  | |  | |  | |
|  | Name |  | Signature |  | | Date | |

1. **Equipment List and Setup:**

Identify equipment that has been added to the system or is being moved and setup with identified calibrated equipment requirements of equipment being installed. (NOTE: after successful completion of this protocol, equivalent calibrated instruments can be swapped to calibration schedules). Applicable Serial or LOT Number, IM&TE Number, Calibrated Date, and Calibration Due Date will be captured during execution of this protocol and included in the Completion Report.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Mega Power 1900 Software Calibration Kit | | | | | |
| Component Description: Mega Power 1900 Software Calibration Kit | | | | | |
| Manufacturer: Megadyne | | | | | |
| Serial or LOT Number: | | | | | |
| IM&TE Number: | N/A | Calibrated Date: | N/A | Calibration Due Date: | N/A |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Monopolar Footswitch (1400 or 1400J) | | | | | |
| Component Description: Monopolar Footswitch | | | | | |
| Manufacturer: Megadyne | | | | | |
| Serial or LOT Number: | | | | | |
| IM&TE Number: | N/A | Calibrated Date: | N/A | Calibration Due Date: | N/A |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Multimeter 77 | | | | | |
| Component Description: Multimeter | | | | | |
| Manufacturer: Fluke | | | | | |
| Serial or LOT Number: N/A | | | | | |
| IM&TE Number: |  | Calibrated Date: |  | Calibration Due Date: |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Bipolar Footswitch (1450 or 1450J) | | | | | |
| Component Description: Bipolar Footswitch | | | | | |
| Manufacturer: Megadyne | | | | | |
| Serial or LOT Number: | | | | | |
| IM&TE Number: | N/A | Calibrated Date: | N/A | Calibration Due Date: | N/A |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Torque wrench | | | | | |
| Component Description: wrench CAL-36/4 | | | | | |
| Manufacturer: Sturevant Richmont | | | | | |
| Serial or LOT Number: NA | | | | | |
| IM&TE Number: |  | Calibrated Date: |  | Calibration Due Date: |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Fluke 601 Pro SeriesXL International Safety Analyzer | | | | | |
| Component Description: Electrical Safety Analyzer | | | | | |
| Manufacturer: Fluke | | | | | |
| Serial or LOT Number: | | | | | |
| IM&TE Number: |  | Calibrated Date: |  | Calibration Due Date: |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component Name: Potentiometer | | | | | |
| Component Description: Potentiometer (PN: 2010127-02) | | | | | |
| Manufacturer: Megadyne | | | | | |
| Serial or LOT Number: N/A | | | | | |
| IM&TE Number: |  | Calibrated Date: | N/A | Calibration Due Date: | N/A |

**Picture of the Service Bench Setup**

|  |
| --- |
| (Place photo here) |

|  |  |  |  |
| --- | --- | --- | --- |
| **Setup & Hookup Checks** | | | |
|  | **Performed By** | **Signature** | **Date** |
| Correct Electrical Connections |  |  |  |
| Pneumatic Hookup Regulated | NA | NA | NA |
| Equipment Stable & Secure |  |  |  |
| Correct Equipment |  |  |  |
| Equipment Identification |  |  |  |
| Parts Bins Identified |  |  |  |
| Calibration requirements  complete |  |  |  |
| **Environmental Checks** | | | |
|  | **Performed By** | **Signature** | **Date** |
| Lighting |  |  |  |
| Contamination Prevention | NA | NA | NA |
| Assembly Flow Acceptable | NA | NA | NA |
|  | | | |
|  | **Performed By** | **Signature** | **Date** |
| Management of Change Process |  |  |  |

1. **Special Environmental Operating Instructions**

All service center specifications have been considered and there are no special requirements outside of normal facility operating and storage conditions that require additional evaluation, monitoring, and control.

1. **Production and Maintenance Requirements**

All applicable equipment: drawings, manuals, service and repair training, spare parts, testing forms, and training records, are to be identified, reviewed, and available as detailed in the table of this section.

|  |  |  |
| --- | --- | --- |
|  | **Type** | **Document(s)** |
| **A)** | Equipment Drawing |  |
| **B)** | Equipment/Operation/Service Manuals |  |
| **C)** | Testing forms and documentation |  |
| **D)** | Spare Parts List |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Performed by** | **Signature** | **Date:** |
| Equipment drawing issued |  |  |  |
| Equipment/Operation/Service Manuals Issued |  |  |  |
| Equipment training documented and completed |  |  |  |
| Testing forms and documentation issued |  |  |  |
| Spare Parts List reviewed |  |  |  |

1. **Operation Procedures/Manual**

All applicable procedures pertaining to the operation, maintenance, cleaning, and calibration of the equipment are to be identified, reviewed, and available as detailed in the table in this section.

|  |  |  |
| --- | --- | --- |
|  | **Type** | **Document(s)** |
| **A)** | Operation Procedures/Manuals |  |
| **B)** | Cleaning Procedures |  |
| **C)** | Calibration Procedures |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Performed by** | **Signature** | **Date:** |
| Operation Procedures/Manuals issued |  |  |  |
| Cleaning Procedures reviewed |  |  |  |
| Calibration Procedures reviewed |  |  |  |

1. **Spare Parts**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Performed by** | **Signature** | **Date:** |
| Spare Parts Issued or Ordered |  |  |  |