Revision History for (PRC086803)

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| **SUMMARY OF CHANGES** | |
| Revision No. | Description of Change |
| A | Original Release |
| B | Administrative Change – correct numbering in section 2. |

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# DOCUMENT APPROVALS

## Originator

| Name/Department | Signature | Date | |
| --- | --- | --- | --- |
| Jason Stivers, Ethicon Service Engineer | Electronic Signature in EpiCenter | Electronic Date in EpiCenter |

## Approvals

| Name/Department | Signature | Date | |
| --- | --- | --- | --- |
| Eric Smith, Ethicon Service Manager | Electronic Signature in EpiCenter | Electronic Date in EpiCenter |
| Robert Peters, Ethicon Service Quality | Electronic Signature in EpiCenter | Electronic Date in EpiCenter |
| Ibrahim Bitar, Ethicon Service Engineer | Electronic Signature in EpiCenter | Electronic Date in EpiCenter |
| Carly Rasband, Megadyne Service Manager/Facilitator | See Non-electronic section for  external signature | See Non-electronic section for  external signature |
| Ihsan Samara, Megadyne Quality Engineer | See Non-electronic section for  external signature | See Non-electronic section for  external signature |
| Mallory Schroeder, Megadyne Engineer | Electronic Signature in EpiCenter | Electronic Date in EpiCenter |

# Purpose

* 1. This is the Completion Report for protocol PRC086802A MegadyneTM Mega PowerTM 1000 Electrosurgical Generator Service Transfer.
  2. The purpose of this protocol was 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.
  3. This qualification was performed at EES Service and Repair Depot, Cincinnati, Ohio and provides 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 establishes 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 validates the service and repair process for the Mega Power 1000.

# Executive Summary

## An Installation Qualification (IQ) and Performance Qualification (PQ) were performed to validate the service and repair process for Megadyne Mega Power (product code 1000) at Ethicon Endo Surgery (EES) Service and Repair Depot, Cincinnati, Ohio. The IQ and PQ were successfully executed under PRC086802A and all criteria for success were met with minor deviations that did not affect the service and repair process validation. Deviations are discussed in Section 6 of this report.

## One Mega Power 1000 device was used. The service and repair process specified for Mega Power 1000 was performed on the device three times to show the ability to service and repair this device using:

### 3000144-01 Megadyne Mega Power Field Calibration Manual

### MKT-LBL-063Megadyne Mega Power Trouble Shooting Guide

### 3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual

### 3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual

### ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair

### ENG-WI-037 Mega Power 1000 Assembly Instructions, Service and Repair

### CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate

## The device passed all final testing.

# Prerequisites

## Location for service and repair will be identified prior to protocol execution.

### Service and Repair Bench was identified and allocated for the Megadyne Mega Power 1000 product at the Service Center. See Attachment 4for photograph.

## All test equipment requiring calibration will be calibrated per CP0190 and documented using Appendix A of PRC086802A.

### Test equipment requiring calibration was successfully calibrated. See Attachment 4 for documentation.

## 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.

### Prior to execution, Megadyne supplied product specific test equipment as listed in the form above. See Attachment 4 for documentation.

## 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.

### MOC was successfully completed prior to execution and closed out during execution. See Attachment 1.

## 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.

### A work order (WO-228298) was created to document the PQ prior to execution.

# Criteria for Success

## The Criteria for Success is being re-stated from PRC086802A.

### Required: 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.

#### Result: Pass - IQ and PQ execution produced acceptable results that satisfied the criteria for success with justifiable deviations. Product code 1000 was serviced and repaired and met specified requirements.

# Results / Discussion

## All requirements were met to successfully complete PRC086802A and validate the service and repair process for product code 1000. The results for this validation are documented in the attachments of this completion report and are evidence that the criteria for success of PRC086802A were met.

## All personnel involved in execution of PRC06802A were adequately trained and that training was documented in Attachment 2 and Attachment 3. Courtney Spires and Eric Peyton were the service technicians, and James Terry was the QA technician that executed protocol. Oversite was provided by Jason Stivers, the service engineer responsible for this protocol.

## PRC086802 Installation Qualification was successfully completed and documented in Attachment 1 and Attachment 4. All equipment requiring calibration were calibrated per CP0190. All equipment utilities were readily available and met the required standards within the designated service and repair bench. All equipment needed for service and repair were properly setup. Tool and equipment bins were identified. All documents needed for evaluation were readily available. The Management of Change (MOC) for safety, environmental, and ergonomics assessments were completed prior to execution, and closed-out during execution.

## PRC086802A Performance Qualification was performed from December 11, 2018 to December 19, 2018. Product code 1000 with serial number 134212001 was the device received from Megadyne with a certificate of conformance (product release certificate) and electrical safety test results, see Attachment 5. All data collected used for evidence to determine criteria for success and a successful PQ execution, are found in Attachments 6-11. Testing data was recorded on the documents listed for product code 1000: CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate, FRM003998, Quality Assurance Final Release Inspection Form for MegaPower 1000, and Service Summary Reports. These are included for the “fail” run and the “pass” run of each of the three induced failures. Additionally, the “pass” run of the third and final failure inducement includes the printed box label required by PR001566, Megadyne ™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions.

## Minor deviations were needed during the execution of PRC086802A to meet the criteria for success. These deviations in no way negatively affected the validation. See Deviations section below.

# Deviations

## Technicians were trained to PR001566, Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions. Normal ComplianceWire training had not been released to the technicians prior to the execution of the protocol. Training to the PR was documented in Attachment 2. No additional corrective actions are required, and there was no impact to the protocol as Technicians were trained to the appropriate documents and procedures prior to execution.

## In section 7.11 of protocol PRC086802, the completion report (PRC086803) is incorrectly referred to as PRC086503. This was a typographical error, and no corrective actions are required.

## In section 10.2.12.2.1 of protocol PRC086802, the result was “The Front Panel will not illuminate”. During testing, it was discovered that the device would not power on. This was an error in documenting the expected result. Resulting troubleshooting and repair of the induced failure were still correct and successful. No corrective actions are required, and there was no impact to the protocol.

# Recommendations / Conclusions

## It is recommended that the results from PRC086802A execution be accepted as meeting the criteria for success, and that the service and repair process for Megadyne Mega Power (product code 1000) be considered validated, and as a result, Ethicon Endo-Surgery Service and Repair Depot be approved to perform service and repair for this product. The Mega Power that was used during PRC086802A execution will be serviced after the line is fully approved for production and placed into the Mega Power loaner pool.

# Product Disposition

## Criteria for success was 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.

# Attachments

| Attachment Number | Attachment Title |
| --- | --- |
| 1 | Management of Change Process (MOC) FMWE0586.1 |
| 2 | PR001566A Training FM-0000809 |
| 3 | PRC086802A Training FM-0000809 |
| 4 | Installation Qualification (IQ) Information Sheet |
| 5 | Megadyne Product Release Certificate and Electrical Safety Test Result |
| 6 | Performance Qualification (PQ) Induced Failure One – Fail |
| 7 | Performance Qualification (PQ) Induced Failure One – Pass |
| 8 | Performance Qualification (PQ) Induced Failure Two – Fail |
| 9 | Performance Qualification (PQ) Induced Failure Two – Pass |
| 10 | Performance Qualification (PQ) Induced Failure Three – Fail |
| 11 | Performance Qualification (PQ) Induced Failure Three – Pass |