MEGADYNE

Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions

1. SCOPE

This Process Specification (PR) applies to the following product codes(s), assembly numbers(s) & work center(s).
Product Code: Megadyne™ Mega Power™ 1000
Assembly Number: 1000
Work Center: N/A

2. DEFINITIONS

N/A

3. REFERENCE DOCUMENTS

3.1 100499476, Procedure for Handling Capital Equipment Complaint Analysis
3.2 CP0190, Requirements for Control of Inspection, Measuring and Test Equipment
3.3 CP000407, Servicing Procedure
3.4 FRM002813, Non-eSig Form for Enterprise Change Notices (ECNs)
3.5 FRM001409, Service Traveler Report Form
3.6 FRM001442, Service Center Label Reconciliation/ Verification Form
3.7 FRM003998, Quality Assurance Final Release Inspection Form for Megadyne™ Mega Power™ 1000 Electrosurgical Generator System
3.8 PR-0000256, Franchise Procedure for Control of Nonconforming Product and Nonconforming Processing
3.9 WE001302, Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair
3.10 WE001147, Handling, Storage, Packing and Shipping Product for the Service Center
3.11 **

MEGADYNE REFERENCE DOCUMENTS

3.1 3000144-01, Megadyne Mega Power Field Calibration Manual
3.2 MKT-LBL-063, Megadyne Mega Power Trouble Shooting Guide
3.3 3000158-01, Megadyne Mega Power Electrosurgical Generator Operators Manual ~ *www.e-ifu.com*
3.4 3000159-01, Megadyne Mega Power Electrosurgical Generator Service Manual ~ *www.e-ifu.com*
3.5 ENG-WI-035, Mega Power 1000 Packaging Instructions, Service and Repair
3.6 ENG-WI-036, Mega Power 1000 Disassembly Instructions, Service and Repair
3.7 ENG-WI-037, Mega Power 1000 Assembly Instructions, Service and Repair
3.8 CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate

4. OPERATIONS LISTING

N/A

5. EQUIPMENT/MATERIALS

5.1 Custom

5.1.1 Mega Power 1900 Software Calibration Kit
5.1.1.1 **Active Electrode for Electrosurgical Pencil (PN: 500447707)
5.1.1.2 **CQM Fixture (Potentiometer) (PN: 2010127-02)
5.1.1.3 **Low Frequency Leakage Cable (PN: 500432111)
5.1.1.4 **Monopolar Return Test Cable (PN: 3750030-01)
5.1.1.5 **Patch Cord Banana Plug Black (PN: 3750031-02)
5.1.1.6 **Patch Cord Banana Plug Red (PN: 3750031-01)
5.1.1.7 **(Qty 2) Serial Cable (PN: 3750033-02) with Ferrites
5.1.1.8 **Calibration Software (PN: 6020101-01)

5.1.2 **Service Computer with serial ports and calibration software installed

5.1.3 Monopolar Footswitch (1400 or 1400J)

5.1.4 Bipolar Footswitch (1450 or 1450J)

5.1.5 **

5.2 Standard

5.2.1 Fluke QA-ESII Electrosurgery Analyzer

5.2.2 Fluke 77 V Multimeter

5.2.3 Fluke 601 Pro SeriesXL International Safety Analyzer

5.2.4 **Chroma Programable AC Source Model 61604

5.2.5 **

5.2.6 **

5.2.7 **

5.2.8 Quad Tech Meridian HV1 Wire and Harness Analyzer

5.2.9 Associated Research Inc. Line Leakage Tester 620L

5.2.10 Associated Research Inc. Matrix Scanner SC6540

5.2.11 Associated Research Inc. Omnia II Series

5.2.12 Associated Research power technologies 6000 series AC source

5.2.13 Sturtevant Richmont CAL-36/4 Roto Torq Driver

6. GENERAL INFORMATION

6.1. Responsibilities (Reference CP000407)

6.1.0. The Service Center Manager or Facilitator is responsible to ensure this procedure is followed. Employees are responsible to ensure that all products are serviced in compliance with this procedure.

6.1.1. Megadyne referenced documents are controlled in Megadyne's document control system. They are made available on the EES Service Center SharePoint/Office 365 web site in the Service Communications > Megadyne > Service Documents folder.

6.1.2. For external approvals (non-e signatures) to this document see FRM002813 "Non-eSig Form for Enterprise Change Notices (ECNs)".

6.1.3. Employees are responsible to ensure that calibrated test equipment are within the (CP0190) calibration date and chemical(s) are within the expiration period.

6.1.4. Employees will document service activities in the service database. When the service database is not available revert to paper-based system, using Service Traveler Form (FRM001409), Quality Assurance Final Release Inspection Form for Megadyne™ Mega Power™ 1000 Electrosurgical Generator System (FRM003998), and any other service data listed in this process specification to track and record the service and quality processes. When the Database becomes available each individual needs to enter or attach the product service information that they performed from the forms into the service database.

6.1.5. A work order must be created in the service database to capture the service and repair actions.

6.1.6. Data collection sheets for inspection and tests will be signed and dated by the associate performing the data collection. The record will be scanned and attached to the service database.

6.1.7. Alternatively, Instruction Templates in the service database may be used in lieu of data collection sheets. When used, Instruction Templates must be completed with data and results captured as tests are performed. Note data collection sheets must be used when the service database is not available.

7. PROCESS SPECIFICATIONS/INSTRUCTIONS

Note: When calibrated equipment is used during the testing of the device, the identity of the test equipment and next calibration date used to perform measurement activities shall be recorded in the service record

7.1 Initial Evaluation

7.1.1 Inspect serial number on the unit being serviced and verify that it matches the serial number in the Complaint Tracking System per 100499476, Procedure for Handling Capital Equipment Complaint Analysis. Review service history records for the unit under test. If using CS-FRM-034 to document the service, capture Mega Power Information and complete Part A: Equipment Calibration.

7.1.1.1 Note: RGA (Return Goods Authorization) will be substituted by Work Order number in the Mega Power Information section.

7.1.1.2 If using instruction templates, document the calibrated equipment information on the WOA (Work Order Activity).

7.1.1.3 **If unit being serviced is an old faceplate configuration of the Mega Power 1000, the unit cannot be serviced due to the discontinuation of service of the configuration by Megadyne. See Appendix A for diagrams to determine "old" versus "new" faceplate.

7.1.1.3.1 Document the following in the Service Database Work Order:

7.1.1.3.1.1 **The unit received is an Original (Old) Faceplate Mega Power. Ethicon Service Center is not authorized to analyze or service old faceplate configurations of the Mega Power 1000.

7.1.1.3.2 **

7.1.1.3.2.1 **

7.1.1.3.3 **

7.1.1.3.4 Forward to QA for review.

7.1.2 Review service history records for the unit under test. Record the results in the service database.

7.1.3 Verify whether unit being serviced is a loaner/exchange or customer unit.

7.1.4 Confirm that the software version of the unit under test matches the software version listed on the asset in the service database.

7.1.4.1 If software version is missing on the asset in the database, add it to the asset record.

7.1.5 Confirm that the RoHS status of the unit is listed on the asset in the service database.

7.1.5.1 If the RoHS status is missing from the asset in the database, add it to the asset record.

7.1.6 Complete Section 1 of the Mega Power Repair Form (CS-FRM-034).

7.1.6.1 If using CS-FRM-034 to document the service, record the results in Table B1 and Table B2.

7.1.6.2 If using instruction templates in the service database, record the results in the following:

7.1.6.2.1 EES SC Mega Power New Faceplate Test Form V1

7.1.6.3 Attach the error logs to the service database.

7.1.7 If unit is returned with a complaint, verify reason for return and attempt to duplicate problem reported by customer. If after normal analysis/unit evaluation, the reason for return cannot be confirmed or the unit is found to be a “Conforming Device”, document all activities performed and pursue additional failure investigational activities as outlined.

7.1.7.1 Use the Service Manual (3000159-01), Operator’s Manual (3000158-01), and Troubleshooting Guide (MKT-LBL-063) for reference.

7.1.7.2 An activity will be used to document any additional failure investigation performed by the technician, engineer, and/or follow-up with the customer and/or sales representative for additional information.

7.1.7.3 **

7.1.8 Record analysis findings in service database as identified during the evaluation and diagnostic process.

7.1.8.1 If using CS-FRM-034 to document the service, complete Section 2: Investigation.

7.1.8.1.1 If service database is not available, document results in Section 2.

7.1.8.1.2 If service database is being used, add the following in Section 2:

7.1.8.1.2.1 N/A See service database

7.1.9 If fault/s is found, proceed to Repair section.

7.1.10 If no fault/s is found, proceed to Testing section.

7.2 Repair

7.2.1 Perform all repairs using the Mega Power Disassembly Instructions (ENG-WI-036) and Mega Power Assembly (ENG-WI-037) as reference.

7.2.1.1 **Note:** Defective Motherboards may be replaced by Motherboards denoted by an “R” in the part number of the part.

7.2.1.1.1 RoHS (non-leaded) Motherboards (6020088-03 or 6020088-R3) can be used in RoHS or non-RoHS units.

7.2.1.1.1.1 Note: RoHS Motherboards (6020088-03 or 6020033-R3 that have been used in non-RoHS units must be labeled as non-RoHS in the Motherboard return process below.

7.2.1.1.2 Non-RoHS (leaded) Motherboards (6020088-02 or 6020088-R2) can only be used on non-RoHS units.

7.2.1.2 ****Note:** ENG-WI-037 (Revision 001) lists torque specifications specific to the torque driver used by Megadyne Service and Repair. Refer to the following chart for conversion to N-m:

Value in ENG-WI-037	Torque specification in N-m
1	0.3
2	0.4
3	0.6
4	0.7
5	0.8
6	1.0
7	1.1
8	1.2
9	1.4
10	1.5
11	1.6
12	1.8
13	1.9
14	2.0
15	2.2
16	2.3
17	2.4
18	2.5
19	2.7
20	2.8
21	2.9

7.2.2 Record repair results in service database.

7.2.2.1 If using CS-FRM-034 to document the service, complete Section 3: Repair Actions.

7.2.2.1.1 If service database is not available, document results in Section 3.

7.2.2.1.2 If service database is being used, add the following in Section 3, tables B4, B5, and B6:

7.2.2.1.2.1 N/A See Service Database

7.2.3 Perform all service bulletins that are required and document in the service database.

7.2.4 **Note:** If fault(s) is identified during any part of the process after repair has been performed, return the unit back to repair for resolution.

7.2.5 Any repair or replacement of a part that is not identified by a service bulletin or the service manual during the service event will be converted into a complaint and documented within the service database. Exceptions to this are parts that are replaced due to disassembly/reassembly or service bulletin or service manual directed parts and improvements to the product that are for customer experience or are cosmetic in nature and do not affect the functionality of the device. An additional exception is when

the customer has indicated that the device was damaged due to their actions (i.e. dropped). Exceptions will not be classified as complaints. The steps to be taken to convert into a complaint are listed below.

7.2.5.1 The repair technician who identifies a complaint on the device will initiate the Complaint Review Request in the service database.

7.3 **

7.3.1 **

7.3.1.1 **

7.3.1.1.1 **

7.3.1.1.2 **

7.3.1.1.3 **

7.3.1.1.4 **

7.3.1.1.5 **

7.4 Calibration

7.4.1 When replacing a Motherboard, the calibration procedure must be performed. Refer to 3000144-01 for instructions.

7.4.1.1 Document the activity in the service database.

7.5 Testing

7.5.1 Once the Mega Power has been reassembled, test per Mega Power Repair Form (CS-FRM-034) Part C through Part F.

7.5.1.1 If using CS-FRM-034 to document the service, record the results in Table C1, C2, D1, D2, D3, D4, E1, E2, F1, F2, and F3.

7.5.1.2 If using instruction templates in the service database, record the results in the following:

7.5.1.2.1 EES SC Mega Power New Faceplate Test Form V1

7.6 Electrical Safety Tests

Safety Notes: Ensure that the chains or other barriers are in place while operating the Electrical Safety Tester to prevent associates from entering the testing area. Ensure that the Safety Rescue Hook is available.

7.6.1 Select the model number of Device Under Test (DUT) in the drop down DUT # field of the electrical safety equipment.

7.6.2 Scan or type the serial number of the DUT in the serial number field.

7.6.3 Verify the Test Name Field populates.

7.6.3.1 If the Test Name field does not populate contact Facilitator/Manager.

7.6.4 Click the Test button.

7.6.4.1 Remove external fuse and check value. Ensure that the fuse is in accordance with the fuse rating label on the unit.

7.6.4.2 During testing, the test will pause and give direction for attaching and/or removing test cables.

7.6.4.3 If DUT is accompanied with a power cord, use during tests.

Warning: Testing may produce up to 5000V AC or DC. Use caution, do not remove or attach cables or touch DUT until prompt appears and lightning bolt extinguishes on front of test equipment.

7.6.5 **When testing is complete, print test results.

7.6.6 If unit fails, send unit back to repair

7.6.7 The responsible technician will attach the electrical safety test results to the service record in the service database.

7.6.8 If using CS-FRM-034 to document the service, record the following:

7.6.8.1 RGA (Work Order Number) and serial number in the Mega Power Information above Part G on the test form.

7.6.8.2 For Tables G1 through G6 the technician performing electrical safety test box, will record the following:

7.6.8.2.1.1 N/A – Results attached to service database.

7.6.9 Alternately, the Fluke 601 Pro Series XL International Safety Analyzer may be used to conduct electrical safety testing.

7.6.9.1 Refer to CS-FRM-034 for test steps and pass/fail ranges for each step.

7.6.9.2 If using CS-FRM-034 to document the service, disregard the “N/A – Results attached to service database” step above, and record the values on the form.

7.6.9.3 If using Instruction Templates to document the service, document the results in the digital test form in the service database.

7.7 Test Form Completion

7.7.1 If using CS-FRM-034 to document the service, complete the following:

7.7.1.1 A certified repair technician who did not perform the testing will review the document.

7.7.1.2 Technician Performing Tests box to be completed by repair technician who performed the testing.

7.7.1.3 Megadyne Review box to be completed by the repair technician who reviewed the document.

7.7.1.4 Attach the completed form (CS-FRM-034) to the service database.

7.8 Box Label

7.8.1 Create and print box label

7.8.1.1 See Appendix B for box label template minimum required fields.

7.8.2 Save an electronic version of the box label and attach to the service database.

7.9 QA Final Test

7.9.1 Refer to WE001302, Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair for documentation of Inspection within the service database. Note: Test sheets/test forms referenced by the instructions below may be substituted by instruction templates (digital test forms) in the service data base. Refer to active service bulletins for details. The use of service database instruction test requires test data and results to be captured as the test is performed. If the device is designated as un-repairable it will be documented on form CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate or identified in the digital test form, if applicable.

7.9.2 Visual Inspection

7.9.2.1 Document the following inspection criteria on FRM003998, Quality Assurance Final Release Inspection Form for Megadyne™ Mega Power™ 1000 Electrosurgical Generator System.

7.9.2.1.1 Verify the serial number on the unit matches the serial number on the information sheet.

7.9.2.1.2 Verify the serial number and manufacture label is secure, clear and legible on the top of the unit.

7.9.2.1.3 For “old” faceplate devices, the device is unrepairable at the service center and is required to be returned to Megadyne for repair. See Appendix A for diagrams to determine “old” versus “new” faceplate. **Note: No further inspection will be required on unrepairable devices at this point.**
7.9.2.1.4 Verify the paintwork/finish is commensurate with the age of the device and would not lead anyone to question the safety or efficiency of the device. This includes that it’s not damaged and is free of major scratches, dents or blemishes that could affect the function of the assembly.
7.9.2.1.5 *Verify the ESU Output Connection Instruction label is applied to the front of the bezel.
7.9.2.1.6 Verify that four rubber feet are secure on the unit.
7.9.2.1.7 Verify that all foot switch connections are secure on the back of the unit.
7.9.2.1.8 Verify the printer connection cover and volume button are present and secured.
7.9.2.1.9 Verify the front display is secure and green Off/On button is present.
7.9.2.1.10 Verify the patient return prongs and hand piece ports are present and secure.
7.9.2.1.11 Verify screws are fitted and secure on the unit.
7.9.2.1.12 Turn unit upside down and shake by hand (If possible) to check for loose debris.
7.9.2.1.13 Verify sticker “Not for Human Use” is applied (If applicable).

7.9.3 Functional Inspection

7.9.3.1 Functional testing is not required by QA for product release.

7.9.4 Final Release

7.9.4.1 Refer to WE001302 for final release instructions.
7.9.4.2 If release activity indicates nonconformity, refer to nonconformance process PR-0000256, Franchise Procedure for Control of Nonconforming Product and Nonconforming Processing.
7.9.4.3 Move all completed QA approved devices to the appropriate designated shipping/loaner pool area.

7.10 Shipping

7.10.1 Perform shipping actions as per WE001147. For specific packaging instructions and materials, refer to ENG-WI-035, Section 9. Procedure.
7.10.1.1 Step 5 is not applicable, as manuals are available at e-ifu.com.
7.10.1.2 Steps 8 and 9 are not applicable, as box labels are created and applied per WE001147.

8. APPENDICES

8.1. Appendix A - Faceplate diagrams
8.2. Appendix B – Box label

Appendix A - Faceplate diagrams

Figure 1 – New Faceplate

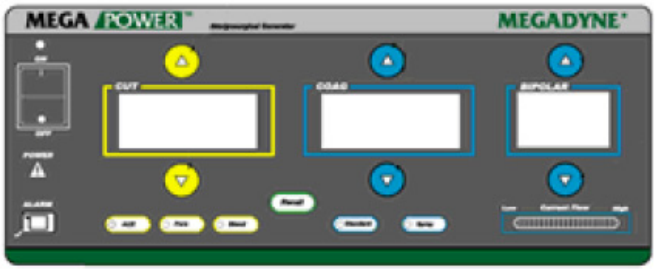

Figure 2 – Old Faceplate

Appendix B – Box label

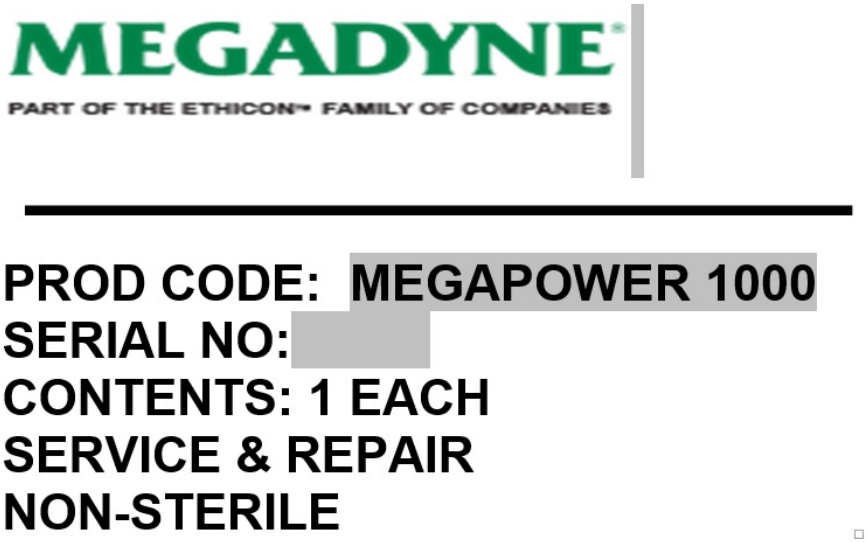

Figure 3 – Mega Power 1000 box label

REVISION SUMMARY

REV	C	SUMMARY
ECN#	ECN0031203	Removed references to obsolete procedure WE0647. Clarified 1900 Kit in Custom Equipment section. Clarified electrical safety test equipment in Standard Equipment section. Updated Initial Evaluation section to reflect the discontinuation of Old Faceplate Mega Power service. Removed Motherboard Return section. Minor clarification in Electrical Safety Test section.
REV	B	**SUMMARY**
ECN#	ECN027268	Removed “Conclusion statement from section 7.1.1.3.1 Removed Contact Worldwide Technical Customer Support to from section 7.1.1.3.2 Added Confirm that the RoHS status of the unit is listed on the asset in the service database to section 7.1.5. If the RoHS status is missing from the asset in the database, add it to the asset record.to section7.1.5.1 Updated part number, Work Order number, and IRL number (after created) section7.3.1.1.2 Added spaces for reference document section for Good documentation practices. Added Verify the ESU Output Connection Instruction label is applied to the front of the bezel to section 7.9.2.15. Removed “WTCS” Though out document
REV	A	**SUMMARY**
ECN#	ECN022833	New Issue