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**Ethicon Endo-Surgery**

**Service Center (USA),**

**Cincinnati, Ohio**

**Service and Repair for the Megadyne™ Mega Power™ 1000 Electrosurgical Generator**

**(Product Code – 1000)**

**Factbook FB003300**

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## Factbook Approval

We have reviewed and do approve Factbook FB003300, for the service and repair of the Megadyne™ Mega Power™ 1000 Electrosurgical Generator - Product Code – 1000, at the Ethicon Endo-Surgery Service Center (USA), Cincinnati, Ohio.

We find that the documentation contained in this Factbook meets the requirements as defined by WE001534, Revision E, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers. The signoff of this Factbook represents the certification process and indicates the service center is to be considered authorized/qualified to perform service on the identified products.

E-Sig in Epi Center   E-Sig in Epi Center

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Eric Smith Date

Manager, Service Center

E-Sig in Epi Center   E-Sig in Epi Center

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Robert Peters Date

Team Leader, Customer Quality

Worldwide Service and Repair

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# FACTBOOK CHECKLIST

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re: 1000

|  |  |  |
| --- | --- | --- |
| **Activity** | **Complete** | **Not Applicable** |
| **Service System Quality Assessment** | **√** |  |
| **Technical Training Program** | **√** |  |
| **Documentation System** | **√** |  |
| **Equipment Installation Qualification (EIQ)** | **√** |  |
| **Physical Requirements** | **√** |  |
| **Operating Agreement** | **√** |  |
| **Start-Up Activities** | **√** |  |
| **Supplier Approval** | **√** |  |

Indicate Activity status with a single **“ √ “** mark.

E-Sig in Epi Center

Jason Stivers

Service Engineer, EES – Staff Service Engineer

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# FACTBOOK STRATEGY

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re: 1000

The support data establishing the EES Service Center in Cincinnati, Ohio authorized service center for the Megadyne™ Mega Power™ 1000 Electrosurgical Generator capital equipment is contained in this Factbook.

The process used follows WE001534 Rev E, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers. A Service and Repair Facility Qualification Record has been created which serves as the index for this Factbook. Approval signatures will appear on each memorandum page as outlined by the Service and Repair Facility Qualification Record.

This Factbook documents the training and qualification to repair the Megadyne product code Mega Power 1000 Electrosurgical Generator.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

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**Service & Repair Facility Qualification Record**

The table of contents of this Factbook is listed below. The documentation contained meets the intent of WE001534 Rev E, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers.

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**1.0 SERVICE SYSTEM QUALITY ASSESSMENT**

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# SERVICE SYSTEM QUALITY ASSESSMENT

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

An EES Staff Compliance Systems Engineer conducted the original service system quality compliance audit on September 27, 2006. The audit data can be found in the EES EpiCenter SCN025597. The EpiCenter SCN will pull up CatsWeb audit number 1847. Ongoing quality assessments of this facility will be maintained on file in EtQ per schedule. The most recent audit maintained in ETQ is IA-005567.

E-Sig in Epi Center

Jason Stivers

Service Engineer, EES – Staff Service Engineer

**2.0 TECHNICAL TRAINING RESULTS**

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# TECHNICAL TRAINING RESULTS

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

On September 5-7, 2018, five service repair technicians from the EES Service and Repair Depot were provided training at the EES Service and Repair Depot in Cincinnati, Ohio, for the following products:

* 1000, Mega Power Electrosurgical Generator

The training was conducted by Megadyne Service and Repair Trainers John Minuth and Tyler Skinner. Five Service Technicians and two Product Release Technicians were trained. Training began with a basic introduction to the product application and use, theory of operation of the system and a general product description and functional description. The attached training log contains the list of Megadyne forms, work instructions, software, and service bulletins required to be covered during the training for product codes. Additionally, procedures/manuals that included disassembly, reassembly, repair, testing, quality inspection, and product release were covered in the training. Troubleshooting information was also covered, which included identifying common causes of failure, hardware troubleshooting, and service testing. Afterward, standard service center processes, such as bench tests, electrical safely tests, and product release tests were demonstrated. To demonstrate the ability to repair the products the trainee was provided and passed a written test post training.

Finally, complaint awareness training is conducted on an annual basis and thus was not a needed deliverable for this specific training. Training records for complaint awareness are maintained within the training management system at EES.

With this successful completion of the activities referenced above, the following individual(s) should now be considered trained as an authorized EES representative capable of the analysis, service, and repair of the Megadyne products listed above, and as a qualified and authorized trainer for the product.

1. Courtney Spires, Service Center Repair Technician II
2. Christopher Kelly, Service Center Repair Technician III
3. Varlie Waggaman, Service Center Repair Technician II
4. Michael Nguyen, Service Center Repair Technician II
5. Tony Urwin, Service Center Repair Technician II

Additionally, with this successful completion of the activities referenced above, the following individual(s) should now be considered trained as an authorized EES representative capable of the final release of product to inventory and authorized to train the quality release person(s) within their center.

1. James Mike Terry, Product Release Technician IV
2. Dave Twitty, Product Release Technician IV

Attached evidence of completion of these activities is:

* Franchise Qualification and Training Record Form (Shared)
* Training Agenda
* The Science of Electrosurgery – training presentation
* Megadyne Mega Power Service Center Repair Form, New Faceplate – objective evidence of completed device testing
* Megadyne Training Test Results
* Certificate of Training

Note: Where required during training, two repair technicians partnered to work on one device, and both technicians signed the service and repair forms accordingly.

Note: Training Agenda, Training Record Form, and Certificates include references to the Megadyne Mega Soft Pad. These references are not applicable for FB003300 but were included in Megadyne training session. The Mega Soft Pad will be included in a future Fact Book.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

**3.0 DOCUMENTATION SYSTEM**

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# DOCUMENTATION SYSTEM

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re: 1000

The following documents include the corporate procedures, work instructions, process specifications, test forms, and manuals needed to repair the Megadyne™ Mega Power™ 1000 Electrosurgical Generator. The procedures can be found within the Ethicon or Megadyne documentation systems as follows:

**Ethicon Reference Documents**

Corporate Procedures:

* 100499476 Revision 3, Procedure for Handling Capital Equipment Complaint Analysis
* CP0190 Revision BH, Requirements for control of Inspection, Measuring, and Test Equipment
* CP000407 Revision U, Servicing Procedure
* PR-0000256 Revision 33, Franchise Procedure for Control of Nonconforming Product and Nonconforming Processing

Work Instructions and Forms:

* FRM001442 Revision B, Service Center Label Reconciliation/ Verification Form
* FRM002813 Revision A, Non-eSig Form for Enterprise Change Notices (ECNs)
* FRM003998 Revision A, Quality Assurance Final Release Inspection Form for Megadyne™ Mega Power™ 1000 Electrosurgical Generator System
* PR001566 Revision A, Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions
* WE001302 Revision AT, Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair
* WE001369 Revision X, Incoming Component Part Inspection Procedure for the EES Part Depot
* WE001147 Revision N, Handling, Storage, Packing and Shipping Product for the Service Center
* WE0647 Revision AA, Work Instruction for Submitting Product Complaints, Returning Complaint Devices, and Handling Customer Contacts Relating to Product Complaints

Megadyne Reference Documents

* 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 *~ www.e-ifu.com*
* 3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual *~ www.e-ifu.com*
* ENG-WI-035 Mega Power 1000 Packaging Instructions, Service and Repair
* 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

Procedures, work instructions, and items that are not product-specific already reside in the Ethicon documentation system, as they were previously qualified as a service center. Procedures, work instructions that are product-specific to the Megadyne™ Mega Power™ 1000 Electrosurgical Generator have been created and implemented into the EES Service and Repair Depot, Cincinnati, Ohio service process.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

**4.0 EQUIPMENT INSTALLATION QUALIFICATION (EIQ) RESULTS**

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### EIQ RESULTS

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

All equipment necessary to perform service and repair activities on the Megadyne™ Mega Power™ 1000 Electrosurgical Generator have been installed at the EES Service and Repair Depot, Cincinnati, Ohio location using local qualification procedure WE0020 revision CE. Equipment Installation was conducted per PRC086802A and recorded in completion report number PRC086803A (see attached).

As described in the service procedures, the product specific test equipment used for the repair and testing of the Megadyne™ Mega Power™ 1000 Electrosurgical Generator are as follows:

**Custom**

* + - Mega Power 1900 Software Calibration Kit
    - Monopolar Footswitch (1400 or 1400J)
    - Bipolar Footswitch (1450 or 1450J)
    - Potentiometer (PN: 2010127-02)

**Standard**

* + - Fluke QA-ESII Electrosurgery Analyzer
    - Fluke 77 V Multimeter
    - Fluke 601 Pro SeriesXL International Safety Analyzer
    - Sturtevant Richmont CAL-36/4 Roto Torq Driver

The EES Service and Repair Depot, Cincinnati, Ohio personnel were trained and qualified to use the above-mentioned equipment as referenced in the training section of this Factbook.

The equipment can be found within the EES Service and Repair Depot calibration system where appropriate and custom tooling or equipment identified has been documented as installed for use. Installation Qualification (IQ) and Performance Qualification (PQ) of equipment was performed. The IQ/PQ stored in Epicenter document control system represents the successful execution of test procedures which qualifies the test equipment being used as properly installed and in good working order.

Specification Sheets for Standard Equipment listed above are attached to this Factbook.

Part of product testing includes performing electrical safety testing according to appropriate standards as outlined in the service documentation. The equipment used at EES, meets all applicable standards.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

**5.0 PHYSICAL REQUIREMENTS**

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### PHYSICAL REQUIREMENTS

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

Refer to attached EES Service Center Floor Plan for the support documentation that EES Service Center in Cincinnati, Ohio has the necessary physical requirements to provide adequate space for the service and repair of the 1000.

The service center meets the electrical power requirements and has separate work spaces for product receiving/shipping, decontamination, service area, and electrical safety.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

**6.0 OPERATING AGREEMENT**

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### OPERATING AGREEMENT

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

Ethicon Endo-Surgery Service Center and Megadyne Medical Products have entered into an operating agreement. The Operating Agreement is in the International Contract database (e-ICD # 1194656) and attached to this factbook.

Additionally, Ethicon Endo-Surgery and Megadyne Medical Products have entered into a Quality Agreement with a Quality Plan. The most recent version of that agreement is in Adaptive under document number 100571196. The Quality Plan is in Epicenter under document number SCN059868.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

**7.0 START-UP ACTIVITIES**

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### START-UP ACTIVITIES

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

In accordance with WE001534 Rev E, the following start-up activities have taken place to prepare the EES Service and Repair Depot, Cincinnati, Ohio to begin service and repair on the Megadyne™ Mega Power™ 1000 Electrosurgical Generator.

* Spare parts needed to perform repairs have been received from Megadyne manufacturing and have been stocked in the EES part depot.
* Megadyne has been added to the authorized supplier list. (EES CASL)
* Loaner pool processes have been established per business needs.
* Evaluation/analysis tracking and expediting through the service center will be performed using existing processes and identification sheets identified within those processes.
* Deviations within the protocol completion report (PRC086803A) have been addressed.
* The linkage to the Complaint Management/Service System has been established. The service center has been using the process for the routing of all service data to the Complaint Management/Service System and will include 1000 reporting as well.
* Equipment required to perform repairs and testing has been purchased and properly installed.
* The service center has been made aware of the requirements for repair tracking and expediting through the repair center, and monthly reporting requirements.
* Products have been added to the monthly reporting process.
* Product-related service documentation has been delivered and implemented.
* Established access to the Megadyne SharePoint site has been completed.

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Jason Stivers

Service Engineer, EES – Staff Service Engineer

**8.0 SUPPLIER APPROVAL**

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### Supplier Approval

Date: February 13, 2019

From: Jason Stivers

Attention: Factbook FB003300 Re:1000

The EES Service Center is owned by the Ethicon Endo-Surgery organization. Adding the Service Center to the EES Approved Supplier List is not required.

Reference DOC023040 revision A in Epi Center for supporting documentation that established Megadyne Medical Products Inc. as an authorized supplier for Depot Service Parts. A screenshot of the Corporate Approved Supplier List is attached showing Megadyne Medical Products Inc. as currently being approved as of January 29, 2019.

E-Sig in Epi Center

Jason Stivers

Service Engineer, EES – Staff Service Engineer