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Johnson & Johnson Medical KK Sugakawa, Japan

Service of the Megadyne Mega Soft Reusable Patient Return Electrode (Product Codes – 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S)

Factbook # FB003349

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Factbook Approval

We have reviewed and do approve Factbook #FB003349, Addendum to Factbook F-261 (EpiCenter document Number FB001103), for the service of the Mega Soft Patient Return Electrode at Johnson & Johnson Medical KK Sugakawa, Japan. We find that the documentation contained in this factbook meets the requirements as defined by WE001534, Rev F, 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 product(s).

E-Sig in EpiCenter

Shannon Gillespie
Manager, Service Center

E-Sig in EpiCenter

Date

E-Sig in EpiCenter

Robert Peters
Team Leader, Customer Quality
Worldwide Service and Repair

E-Sig in EpiCenter

Date

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FACTBOOK CHECKLIST

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

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 EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

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FACTBOOK STRATEGY

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

The support data establishing Johnson & Johnson Medical KK Sugakawa, Japan as an Ethicon Endo-Surgery authorized service center for the Megadyne Mega Soft equipment contained in this Factbook.

The process follows WE001534 Rev F, 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 information is an Addendum to the original Factbook F-261 that qualified Johnson & Johnson Medical KK Sugakawa, Japan as an authorized service center for the GEN04, SCM12, SCM23, and STHC1. The original product codes SCM12, SCM23, and STHC1 were sold to another company and are not part of this factbook process. Johnson & Johnson Medical KK also services the RF60 generator approved in factbook number FB002269, GEN11 approved in factbook number FB002911, and Megadyne Mega Power 1000 approved in factbook number FB003289. Those factbooks and associated service of products are not affected by this factbook. This Factbook documents their training and qualification to evaluate the product codes, 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, and 0848S.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff 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 F, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers.

1.0 SERVICE SYSTEM QUALITY ASSESSMENT

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SERVICE SYSTEM QUALITY ASSESSMENT

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

Refer to section 1.0 of Factbook F-261 (EPI Center document number FB001103) for the support documentation that a servicing quality system assessment was conducted according to established procedures. Ongoing quality assessments of this facility will be maintained on file in EtQ per schedule.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

2.0 TECHNICAL TRAINING RESULTS

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TECHNICAL TRAINING RESULTS

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

On February 26-28, 2019, one service repair technician (Service Manager) from the J&J K.K. Medical Company Ltd. Japan Service and Repair Depot was provided training at Megadyne Medical Products, Draper, Utah for the following products:

- Evaluation of the Megadyne Mega Soft Reusable Patient Return Electrodes (Product Codes: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S).

The training was conducted by Megadyne Service and Repair Product Engineer Trainers John Minuth and Tyler Skinner with assistance from Megadyne Repair Technician, Bruce Hevelone. 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 and work instructions required to be covered during the training for product codes. Additionally, procedures/manuals that included testing, quality inspection, and product release were covered in the training. Troubleshooting information was also covered, which included identifying common causes of failure and service testing. Afterward, standard service center processes, such as bench tests and product release tests were demonstrated. To demonstrate the ability to evaluate the products, the technician trainees were 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 the J&J KK Medical.

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 service of the Megadyne products listed above, and as a qualified and authorized trainer for the product.

1. Kohei Seki, Service Manager

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. Kohei Seki, Service Manager

Attached evidence of completion of these activities is:

- Franchise Qualification and Training Record Form (Shared)
- Training Agenda
- The Science of Electrosurgery – training presentation
- Mega Soft Patient Return Electrode, Service and Repair Form – objective evidence of completed device testing
- Mega Soft Training Exam Results

- Certificate of Training

Note: Training Agenda and Training Record Form include references to the Megadyne Mega Power Electrosurgical Generator and the Mega Vac and Mega Vac Plus smoke evacuators. These references are not applicable for this factbook. The smoke evacuator products are not sold or serviced in the Japan market but were included in Megadyne training session. The Mega Power product was included in a prior factbook.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Staff Service Engineer

3.0 DOCUMENTATION SYSTEM

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DOCUMENTATION SYSTEM

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

Procedures, work instructions, and items that are non-product specific to Mega Soft Reusable Patient Return Electrode already reside in the J&J Medical KK documentation system as they were previously qualified as a service center. Refer to section 3.0 of Factbook F-261 (EpiCenter document Number FB001103). Procedures, work instructions, and items that are product specific to the Mega Soft Reusable Patient Return Electrode have been created and implemented into the J&J Medical KK service process and are listed below.

Megadyne Reference Documents

- ENG-WI-053 Mega Soft Patient Return Electrode Service and Repair Instructions
- OPER-WI-053 Operation of RMI Laser Marking System
- ENG-FRM-013 Mega Soft Patient Return Electrode, Service and Repair Form

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Jason Stivers
Service Engineer, EES – Service Staff Engineer

4.0 EQUIPMENT INSTALLATION QUALIFICATION RESULTS

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EIQ RESULTS

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

All equipment necessary to perform service and repair activities on the Megadyne Mega Soft Reusable Patient Electrode have been installed at the J&J K.K. Medical Products Service and Repair Depot, Sukagawa, Japan location. The validation process including Installation Qualification and Performance Qualification is documented in the attached Validation Summary, SKG-2020-02-01 Revision 1.

As described in the service procedures, the product specific test equipment used for the testing of the Megadyne Mega Soft are as follows:

Custom
Mega Soft Test Cable, 6000101-01

Standard
Yokogawa Digital Multimeter TY530 (Reference F-216)
Instek DC Power Supply (Reference F-221)

The J&J K.K. Medical Products Service and Repair Depot 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 J&J K.K. Medical Products 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 local J&J K.K. 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 and calibration certificates for Standard Equipment listed above are attached to this Factbook.

The installed equipment used at J&J K.K. meets all applicable standards.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

5.0 PHYSICAL REQUIREMENTS

ETHICON
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PHYSICAL REQUIREMENTS

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

Refer to Attachment for the support documentation that the J&J K.K. Medical Products Service and Repair Depot, Sukagawa, Japan has the necessary physical requirements to provide adequate space for the service of the Mega Soft Reusable Patient Return Electrode.

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

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

6.0 OPERATING AGREEMENT

ETHICON
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OPERATING AGREEMENT

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

EES and Johnson & Johnson Medical KK, Japan have entered into an operating agreement. The Operating Agreement is located in International Contract database and can be located under e-ICD # 1340355. An amendment to the original agreement is attached to this factbook.

Additionally, Johnson and Johnson K.K. Medical Products, has entered into a quality agreement with Ethicon Endo-Surgery, LLC. The most recent version of that agreement is in Adaptive under #100592785.

E-Sig in EpiCenter

Jason Stiver
Service Engineer, EES – Service Staff Engineer

7.0 START-UP ACTIVITIES

ETHICON
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START-UP ACTIVITIES

Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

In accordance with WE001534 Rev F, the following start-up activities have taken place to prepare the Johnson & Johnson Medical KK Sugakawa, Japan service center to begin service on the Megadyne Mega Soft Reusable Patient Electrode.

- Spare parts are not needed, as no repairs are conducted on this product.
- Johnson & Johnson Medical KK has been added to the authorized supplier list. (EES CASL)
- Loaner/trial pool processes have been established per business needs.
- 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 Mega Soft reporting as well.
- Equipment required to perform testing has been purchased and properly installed.
- Accessories needed to include with shipments of Mega Soft have been received from Megadyne
- Evaluation tracking and expediting through the service center will be performed using existing processes and identification sheets identified within those processes.
- 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.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

8.0 SUPPLIER APPROVAL

ETHICON
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Supplier Approval
Date: April 21, 2020

From: Jason Stivers

Attention: Factbook # FB003349

Re: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S

Reference section 8.0 of Factbook F-261 (EpiCenter document Number FB001103) for the support documentation that established the J&J K.K. Medical Products Service and Repair Depot, Sukagawa, Japan as an authorized supplier. The service center will be maintained on the approved supplier list according to WE0652, Monitoring/Communication with Service Centers and Parts Depots. An image of the current Approved Supplier List as of April 17, 2020, is attached as evidence.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer