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Revision History for (PRC090329)

SUMMARY OF CHANGES	
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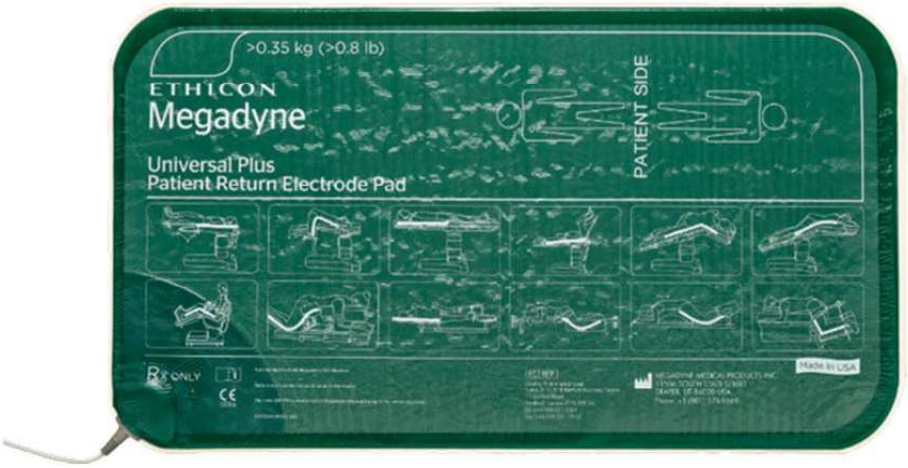
VALIDATION PLAN

Document Title:	Megadyne Mega Soft Service Validation Plan
Document Number / Revision:	PRC090329A
Site / Location:	Ethicon Endo Surgery Service and Repair Depot, Cincinnati, Ohio
Project / Area:	Service and Repair
Product/Process:	Service process for the Megadyne Mega Soft Patient Return Electrode, Product Codes: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S
Equipment:	All equipment used in the process will be identified in the qualification documents listed below.
Validation Assessment Reference:	DOC026078



1.0 DOCUMENT APPROVALS

Function	Name	Signature	Date
Originator	Jason Stivers, Staff Service Engineer	eSig in EPICENTER	eSig in EPICENTER
Service Manager	Eric Smith, Service Manager	eSig in EPICENTER	eSig in EPICENTER
Service Engineer	Ibrahim Bitar, Service Engineer	eSig in EPICENTER	eSig in EPICENTER
Service Quality Representative	Robert Peters, Customer Quality Team Lead	eSig in EPICENTER	eSig in EPICENTER
Megadyne Service Manager / Designee	Paul Borgmeier, Director of R&D (and Service)	See NON- eSig Files Tab in EPICENTER	See NON- eSig Files Tab in EPICENTER
Megadyne Service Engineer / Technical Product Owner	John Minuth, Senior Design Engineer	See NON- eSig Files Tab in EPICENTER	See NON- eSig Files Tab in EPICENTER
Megadyne Quality Representative / Designee	Steve Kuykendall, Life Cycle Quality Engineer	See NON- eSig Files Tab in EPICENTER	See NON- eSig Files Tab in EPICENTER

2.0 PURPOSE

The purpose of this Validation Plan is to present a logical and structured approach to the validation of the Service Process for the Megadyne Mega Soft Patient Return Electrode (Product Codes: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S) at Ethicon Endo Surgery (EES) Service and Repair Depot, Cincinnati, Ohio. Validation will follow a risk-based approach. The deliverables outlined in this validation plan have been selected to ensure risks associated with the process will be considered and mitigated appropriately through the validation.

3.0 SCOPE & BACKGROUND

The service process for the Megadyne Mega Soft Patient Return Electrode will be implemented at Ethicon Endo-Surgery (EES) Service and Repair Depot for the service process. The scope of this validation covers the equipment and components intended for use at EES. A Validation Assessment (reference DOC026078) was conducted, and decisions are documented in this validation plan. This validation effort will include testing to demonstrate that the Process/ Product/ Equipment will operate properly and consistently in GxP areas and will meet its intended use.

3.1 Pre-Requisites

Document Name	Document Reference Number	Approval / Release date
Mega Soft Patient Return Electrode Service and Repair Instructions	ENG-WI-053	11/13/2018
Operation of RMI Laser Marking System	OPER-WI-053	3/22/2019
Mega Soft Pad Family Risk Analysis	ENG-RMF-021	10/31/2018

4.0 DEFINITIONS, TERMS AND ABBREVIATIONS

Refer to the 100632965 Franchise Glossary for Validation (Shared) for terminology and abbreviations used in the validation program.

Table 1 – Definitions

Term/ Abbreviation	Definition
Master Control	Megadyne's document control system.
EES	Ethicon Endo-Surgery
Mega Soft Pad	Common term for the Mega Soft Patient Return Electrode

5.0 DESCRIPTION

This validation plan outlines the information and processes that will be used to perform validation of service for the Megadyne Mega Soft Patient Return Electrode. The planned protocols will be summarized along with all assumptions, exceptions and/or limitations. This validation plan will also document the equipment that will be used during these validation efforts.

5.1 Product

5.1.1. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units or generators.

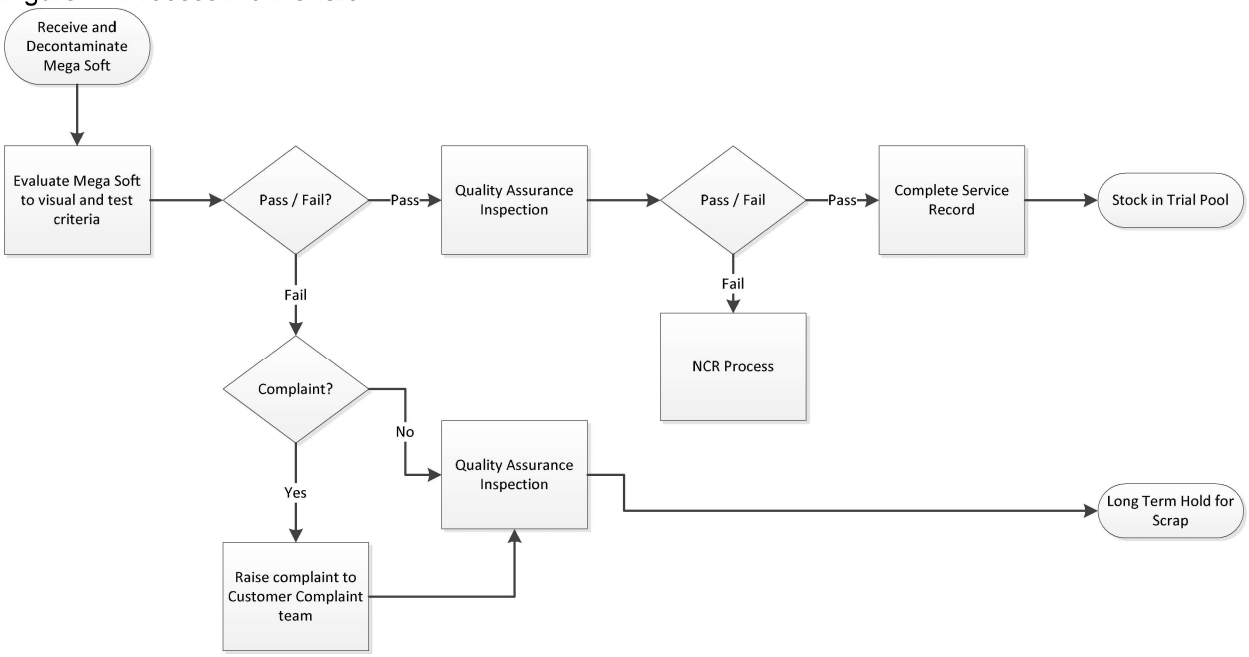
5.2 Process

5.2.1. The service of the Megadyne Mega Soft Patient Return Electrode includes the following:

- 5.2.1.1. Receipt and Decontamination of the product
- 5.2.1.2. Visual and Testing evaluation
- 5.2.1.3. Quality Assurance inspection
- 5.2.1.4. Service Record completion
- 5.2.1.5. Move to Trial Pool for customer evaluations or Long Term Hold for scrap.

5.2.2. The process flow chart of the service of the Mega Soft is depicted in
5.2.3. Figure 1 below.

Figure 1. Process Flow Chart



5.3 Equipment

The equipment that will be utilized within the Megadyne Mega Soft Pad Service Process is listed within Section 5.3.1 below.

5.3.1. Components (Equipment List)

5.3.1.1. Mega Soft Test Cable, 6000101-01
5.3.1.1.1. Custom test cable made by Megadyne to connect the Mega Soft Pad to the test setup
5.3.1.2. Power supply with current limit: GW Instek GPS-4303
5.3.1.2.1. Power supply used to apply current to the Mega Soft Pad in order to measure voltage across the electrodes.
5.3.1.3. Fluke 87 V True RMS Multimeter
5.3.1.3.1. Digital multimeter used to measure voltage across the Mega Soft Pad electrodes.

5.4 Supporting Systems

5.4.1. Power supply used to apply current to the Mega Soft Pad utilizes a standard electrical outlet (120V @ 60Hz.).

6.0 ROLES & RESPONSIBILITIES

6.1. Responsibilities for the review and approval of this validation plan are outlined in CP0160.

6.1.1. Service Manager/Facilitator – is responsible for the review and approval of this validation plan and the associated validation summary report.

6.1.2. Service Engineer – is responsible for the validation plan and associated validation summary report.

6.1.3. Service Quality Lead – is responsible for the review and approval of this validation plan and the associated validation summary report.

6.1.4. Megadyne Service Manager/Facilitator – is responsible for the review and approval of this validation plan and the associated validation summary report.

6.1.5. Megadyne Service Engineer (or equivalent Design Engineer) – is responsible for the review and approval of this validation plan and the associated validation summary report.

6.1.6. Megadyne Quality Engineer – is responsible for the review and approval of this validation plan and the associated validation summary report.

6.1.7. Document Management – is responsible for the maintenance and archival of this validation plan and associated validation summary report.

7.0 RISK ASSESSMENT

A Failure Modes and Effect Analysis (FMEA) and Risk Assessment / Process & Product Characterization has been conducted and can be referenced in Mega Soft Pad Family Risk Analysis ENG-RMF-021, retained in Master Control. A review of the manufacturer's FMEA worksheet determined that the process used to service the Mega Soft successfully mitigates risks identified in the FMEA. The work instruction, in-process checks, and final release inspection mimic manufacturing mitigations for undesirable risks.

7.1 Assumptions, Exclusions, or Limitations

7.1.1. To capture the relevant activities in the validation procedure, the Validation Plan, Installation Qualification Protocol, and Performance Qualification Protocol will be following the guidelines outlined within CP0198. The elements of these protocols will adhere to the intent of CP0198.

7.1.2. An Operation Qualification (OQ) is not required since the associated process equipment have single point operational parameters and not operational ranges. This is in accordance with CP0198.

7.1.3. The location for service will be identified prior to the IQ and PQ protocol execution.

7.1.4. Software validations (SV) for tools and equipment used to service Mega Soft Pads are not required and additional validations are not needed.

7.1.4.1. The multimeter involved in this service process is off-the-shelf, and its associated software has not been altered. (It contains non-customized vendor software that will not be altered for use in this service and repair process.)

7.1.4.2. The power supply involved in this service process is off-the shelf, and its associated software has not been altered. (It contains non-customized vendor software that will not be altered for use in this service and repair process.)

7.1.5. Megadyne will supply product specific test equipment as listed in the Work Instructions (and documented within Section 5.3.1) for use within this service process.

7.1.6. The IQ and PQ activities will adhere to the guidelines outlined within PR-0000089 and CP0198 for demonstrating and documenting that this process is effective and reproducible.

7.1.7. 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 installation qualification report.

7.1.8. IQ protocol will be performed prior to PQ protocol, except for work order creation and device receipt, which is completed prior and is a setup function.

7.1.9. The service and repair depot is not a clean room facility as discussed in CP0198, therefore, deep cleaning of the equipment will not be performed prior to installation.

7.1.10. Measurement and analysis methods have been defined within Megadyne's ENG-WI-053 Mega Soft Patient Return Electrode Service and Repair Instructions and OPER-WI-053 Operation of RMI Laser Marking System, as well as EES's PR001567 Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions.

7.1.11. Mega Soft pads used for protocol execution came from Megadyne. The units will be both a "known-good unit" and units in a variety of non-functional and/or visually non-acceptable states. The non-functional/non-acceptable units will be used to test the fail condition of the process and will be captured in the validation plan report. Note that pads are available in a variety of sizes. Testing and service is equivalent regardless of model/size.

7.1.12. The service center will be using Enterprise Complaint Management (ECM) System and the Service and Repair Application, which have both been validated; therefore, these applications will not be re-evaluated as part of this protocol.

7.1.13. 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 Megadyne Mega Soft service validation.

7.1.14. Electrical safety testing is not required, as the device contains only a passive electrode circuit. Additionally, the intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units, or generators.

7.1.15. If the criteria for success of either the IQ or PQ Protocol is not met, potential root causes and corrective actions will be documented in the respective completion report. If criteria for success, or process changes are required, revalidation may be necessary.

7.1.16. Training of Service and Quality Assurance Technicians was conducted September 5, 2018 to September 7, 2018. This training covered all required activities to evaluate the Mega Soft pads.

7.1.17. 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 PR-0000089.

8.0 VALIDATION STRATEGY

Evaluation steps within the service process for the Mega Soft Pads will be validated by objective evidence that the process consistently produces a result meeting its predetermined specifications.

The documented objective evidence of successful PQ activities will consist of the data created during the evaluation of the Mega Soft. This data will be recorded during protocol execution.

Multiple Mega Soft pads will be used to evaluate multiple failure modes of the pads. A failure will be induced or will pre-exist within a device (blind to the technician performing the qualification) and the device will be evaluated for pass/fail criteria. This will be done for a total of three times with a different failure for each pad per the Performance Protocol procedure section. A known-good pad will also be evaluated for pass/fail criteria.

Evidence will be included in the PQ report for the Box Label steps within the process of evaluation of the Mega Soft pads so that the specified requirement will have been fulfilled.

The service and repair bench setup will be verified through completion of the IQ protocol report.

The IQ information sheet will be used to perform the IQ and record necessary data at the designated service and repair area. The data documented on this information sheet will provide evidence of successful IQ activities. The successful completion of the IQ activities will serve as the Verification of the service and repair bench setup.

There will be product release activities performed by a Quality Assurance Technician after each evaluation of the Mega Soft pad has been completed. This activity will be documented using FRM003999, Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes.

These documented QA verification activities will be used as objective evidence of the successful evaluation of each device.
Validation will be documented using the following documents:

1. PRC090330, Megadyne Mega Soft Service Validation Summary Report
2. PRC090332, Megadyne Mega Soft Service Installation Qualification
3. PRC090334, Megadyne Mega Soft Service Installation Qualification Completion Report
4. PRC090335, Megadyne Mega Soft Service Performance Qualification
5. PRC090336, Megadyne Mega Soft Service Performance Qualification Completion Report

8.1 Installation Qualification

An IQ protocol will be developed to verify that the critical equipment installations were performed successfully, the recommendations of the manufacturer have been suitably considered, test equipment is properly calibrated, and that the necessary documentation is in place. Instrument and equipment calibrations will be handled according to CP0190.

The IQ Protocol must be approved prior to the commencement of execution. An IQ report shall be generated summarizing the results. Any observed deficiencies and the corrective actions are to be addressed in the IQ Report. The approved IQ Protocol and IQ Report will be included in the validation documentation.

8.2 Test Method Validation

N/A

8.3 Operational Qualification

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.

8.4 Performance Qualification

During the PQ protocol, evaluation of the Mega Soft pad will be completed. Multiple Mega Soft pads will be used to evaluate multiple failure modes of the pads. A failure will be induced or will pre-exist within a device (blind to the technician performing the qualification) and the device will be evaluated for all pass/fail criteria. This will be done for a total of three times with a different failure for each pad per the Performance Protocol procedure section. A known-good pad will also be evaluated for all pass/fail criteria. This will show the ability to evaluate this device using:

1. PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions
2. ENG-WI-053 Mega Soft Patient Return Electrode Service and Repair Instructions
3. OPER-WI-053 Operation of RMI Laser Marking System
4. FRM003999, Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes
5. FRM004077, Megadyne Mega Soft Patient Return Electrode Service Form

The PQ Protocol must be approved prior to the commencement of the execution. A PQ report shall be generated summarizing the results. Any observed deficiencies and the corrective actions would be addressed in the completion report. The approved PQ Protocol and PQ Report will be included in the validation documentation.

8.5 Process Verification

Box Label steps within the process of Service for the Mega Soft Patient Return Electrode will be verified by objective evidence that the process consistently produces a result meeting its predetermined specifications.

The service bench setup will be verified by examination and provision of objective evidence that specifies requirements that have been fulfilled.

Final QA verification will be used as evidence of the service and repair validation by examination and provision of objective evidence that the requirements for a specific intended use can be consistently fulfilled.

8.6 Deviation Handling

Deviations arising during testing shall be recorded and be traceable throughout correction, retest, and final closure in accordance with PRC090332, Megadyne Mega Soft Service Installation Qualification and PRC090335, Megadyne Mega Soft Service Performance Qualification.

9.0 ACCEPTANCE CRITERIA

The process will be considered validated and acceptable for use once all Protocol Criteria for success have been satisfied, and the associated Protocol Completion Reports have been released. Acceptance Criteria will be outlined in each Protocol for individual Protocol acceptance.

10.0 PRODUCT DISPOSITION AND CONTROL

Product evaluated during this process validation will be evaluated again, post-service launch, per service process specification PR001567. Unit(s) passing evaluation will be placed in the Trial Pool. Unit(s) failing evaluation will be scrapped.

11.0 REFERENCE DOCUMENTS

The following documents support this Validation Plan:

Document Title	Reference
Franchise Glossary for Validation (Shared)	100632965
Management of Change (MOC)	FMWE0586.1
Change Control/Approval Matrix	CP0160
Requirements for Control of Inspection, Measuring and Test Equipment	CP0190
Manufacturing Process Validation Procedure	CP0198
Megadyne Mega Soft Service Validation Assessment	DOC026078
Mega Soft Pad Family Risk Analysis	ENG-RMF-021
Mega Soft Patient Return Electrode Service and Repair Instructions	ENG-WI-053
Franchise Qualification and Training Form	FM-0000809
Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes	FRM003999
Megadyne Mega Soft Patient Return Electrode Service Form	FRM004077
Operation of RMI Laser Marking System	OPER-WI-053
Franchise Procedure for Validation	PR-0000089
Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	PR001567
Megadyne Mega Soft Service Validation Summary Report	PRC090330
Megadyne Mega Soft Service Installation Qualification	PRC090332
Megadyne Mega Soft Service Installation Qualification Completion Report	PRC090334
Megadyne Mega Soft Service Performance Qualification	PRC090335
Megadyne Mega Soft Service Performance Qualification Completion Report	PRC090336
Management of Change (MOC) Process	WE0586