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Revision History for (PRC090336)

SUMMARY OF CHANGES	
Revision No.	Description of Change
A	New Revision

PERFORMANCE QUALIFICATION REPORT

Document Title:	Megadyne Mega Soft Service Performance Qualification Completion Report
Document Number / Revision:	PRC090336, A
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:	Power supply with current limit: GW Instek GPS-4303 Fluke 87 V True RMS Multimeter Mega Soft Test Cable, 6000101-01
PQ Protocol Reference:	PRC090335

1. DOCUMENT APPROVALS

Function	Name	Signature	Date
Originator	Jason Stivers, Service Engineer	eSig in EPICENTER	eSig in EPICENTER
Service Manager	Eric Smith, Service Manager	eSig in EPICENTER	eSig in EPICENTER
Service Quality Representative	Robert Peters, Customer Quality Team Lead	eSig in EPICENTER	eSig in EPICENTER
Service Engineer	Ibrahim Bitar, Service Engineer	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. EXECUTIVE SUMMARY

Performance Qualification (PQ) has been completed for the Megadyne Mega Soft Pad Service process located in Ethicon Endo Surgery Service and Repair Depot, Cincinnati, Ohio, following the strategy laid out in the Validation Plan (PRC090329 Rev. A) and the PQ Protocol (PRC090335 Rev. A). There were three deviations in total. Deviation one and three have been resolved and are closed. Deviation two is open and is waiting for a form release to be closed.

The PQ acceptance criteria defined in PRC090335 Rev. A were satisfactorily met, as documented in Attachment 2. The testing conducted establishes that the Megadyne Mega Soft Pad Service process, under anticipated conditions, consistently produces a product which meets predetermined requirements.

3. PURPOSE

The report summarizes the Performance Qualification [PQ] for the Megadyne Mega Soft Pads Service process located in Ethicon Endo Surgery Service and Repair Depot, Cincinnati, Ohio.

The purpose of this Performance Qualification Report is to document the objective evidence that the process control limits and action levels for the Megadyne Mega Soft Pads Service process results in product that meets all predetermined specifications within PR001567 Megadyne Mega Soft Patient Return Electrode Service Instructions.

4. SCOPE & BACKGROUND

The scope of this Performance Qualification study is to validate the Service process for the Megadyne Mega Soft Patient Return Electrode, using the equipment listed in table 2 within the Megadyne Mega Soft Service Performance Qualification (PRC090335), and within the Megadyne Mega Soft Installation Qualification Protocol (PRC090332).

5. PREREQUISITES

The pre-requisites that must be fulfilled prior to PQ execution are shown below.

Table 1 – Pre-Requisites

Pre-Requisite	Document Title	Reference Doc. # or Attachment
IQ Protocol Completion	Megadyne Mega Soft Installation Qualification Protocol	PRC090332 Rev. A
IQ Protocol Completion Report	Megadyne Mega Soft Service Installation Qualification Completion Report	PRC090334 Rev. A
Service and Repair Instructions	Mega Soft Patient Return Electrode Service and Repair Instructions	ENG-WI-053 Rev. 4
Process Specification Release	Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	PR001567 Rev. A
Trainings on PQ Protocol and Servicing of Megadyne Mega Soft	Megadyne Mega Soft Service Performance Qualification	Detailed in Section 11 of this Protocol

Pre-Requisite	Document Title	Reference Doc. # or Attachment
Process Risk Assessment Completion	Mega Soft Pad Family Risk Analysis	ENG-RMF-021 Rev. 010
Service Form	Megadyne Mega Soft Patient Return Electrode Service Form	FRM004077 Rev. A
Quality Assurance Form	Quality Assurance Final Release Form for Megadyne™ Mega Soft™ Reusable Patient Return Electrodes	FRM003999 Rev. A

6. RESULTS AND DISCUSSION

All requirements were met to successfully complete the protocol, PRC090335A. The results for this validation are documented in Attachments (1-14) of this completion report and are evidence that the criteria for success of PRC090335A was met.

During our first protocol execution, six Mega Soft Pads were used during the execution of the Performance Qualification (PRC090335A). Three induced failures were created on three of the pads; deeming them “bad” pads. The remaining three pads had no induced failures and were deemed “good” pads. The devices were serviced to required specifications. The testing showed the ability to service the device. Six work orders (WO-401893, WO-401896, WO-401897, WO-401898, WO-401900, WO-401901) were created to document the PQ prior to execution.

Prior to the first execution of PRC090335, we discovered that our three “good” pads did not meet the expiration date attribute of Section 9.1 Inspection Parameters. We completed a deviation report (Deviation 1) and documented the resolutions within the deviations. During the execution of the protocol, we discovered FRM003999 Rev A Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes needed to be revised to fit the requirements of the process specification PR001567 Megadyne Mega Soft Patient Return Electrode Service Instructions. We completed another deviation report (Deviation 2) and documented the resolutions within the deviations.

When we were completing the Performance Qualification Report when we discovered that the devices were not evaluated for all failure criteria as per Megadyne Mega Soft Patient Return Electrode Service Form (FRM004077 Rev A). We proceeded to write a third deviation report (Deviation 3) and documented the resolution within the deviation. Due to the corrective action within the third deviation, the PQ Procedure Steps were re-run an additional time with the Corrective Action in place. Note: Deviation 1 was utilized to print out a new expiration date label for the pad that represented the color/staining failure before re-executing the protocol. Six new work orders were created (WO-405261, WO-405262, WO-405266, WO-405268, WO-405271, WO-405272) to document the 2nd execution of the PQ.

The six assets are listed below with the three failures that were induced:

6.1 Asset #172144002: On this Megadyne Mega Soft Patient Return Electrode the Service Engineer received the pad prior to execution with a bad expiration date. This resulted in the pad failing the inspection parameter during the service process.

6.2 Asset #185239002: On this Megadyne Mega Soft Patient Return Electrode the Service Engineer induced a cut to the pad. This resulted in the pad failing the inspection parameters during the service process.

6.3 Asset #174495014: On this Megadyne Mega Soft Patient Return Electrode the Service Engineer received the pad prior to execution with non-uniform discoloring. This resulted in the pad failing the inspection parameter during the service process.

6.4 Asset #180036019: On this Megadyne Mega Soft Patient Return Electrode the Service Engineer did not induce any failures. This resulted in the pad passing all test criteria during the service process.

6.5 Asset #180538016: On this Megadyne Mega Soft Patient Return Electrode the Service Engineer did not induce any failures. This resulted in the pad passing all test criteria during the service process.

6.6 Asset #181111021: On this Megadyne Mega Soft Patient Return Electrode the Service Engineer did not induce any failures. This resulted in the pad passing all test criteria during the service process.

All data collected used for evidence to determine criteria for success and successful PQ execution, are found in the attachments. Testing data was recorded on the documents listed for all six pads: FRM004077, Megadyne Mega Soft Patient Return Electrode Service Form and FRM003999, Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes. These forms are included for both passing and failing pads. Additionally, the passing pads include the corresponding printed box labels required by PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions.

Table 2 – Assets with Associated Work Orders

Execution	Asset	Work Order	Processing Status
1	172144002	WO-401893	Completed
1	185239002	WO-401896	Completed
1	174495014	WO-401897	Completed
1	180036019	WO-401898	Completed
1	180538016	WO-401900	Completed
1	181111021	WO-401901	Completed
2	172144002	WO-405261	Completed
2	185239002	WO-405262	Completed
2	174495014	WO-405266	Completed
2	180036019	WO-405268	Completed
2	180538016	WO-405271	Completed
2	181111021	WO-405272	Completed

7. OPERATING PROCEDURES

Six Megadyne Mega Soft Pads were used to execute the PQ protocol. The service process specified for Megadyne Mega Soft Pads was performed on the devices twice by two different technicians for a total of four times to show the ability to service and repair this device using the following:

7.1 PR001567 Rev. A, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions

7.2 ENG-WI-053 Rev. 4, Mega Soft Patient Return Electrode Service and Repair Instructions

7.3 FRM004077 Rev. A, Megadyne Mega Soft Patient Return Electrode Service Form

7.4 FRM003999 Rev. A, Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes

8. DEVIATIONS

During the execution of the Performance Qualification test cases, the testing resulted in three deviations, summarized as follows:

Table 3 – Summary of Deviations

Reference	Section	Protocol Requirements	Type [Error, Deviation, Failure] Deviation Description	Resolution	Status [Closed, Open]
Deviation #1 Attachment #4	Section 9.1	Expiration Date Inspection Parameter	Prior to the execution of the Performance Qualification (PRC090335), it was discovered that the three "good" pads did not meet the expiration date attribute of Section 9.1 Inspection Parameters. These inspection parameters can be found within PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions, for EES Service Center.	To complete the execution, labels were printed out with passing expiration dates, and placed over the original expiration date locations on the "good" pads. A label font style and size was utilized that was similar to the original laser etching to insure that this did not influence the protocol outcome, Labels were also printed and applied to the three "bad" Pads to ensure that no undue test bias was induced based on an expiration date appearance difference between the two device groups. After the execution of PRC090335, as per Section 15, all the pads will be scrapped per WE000866.	Closed
Deviation #2 Attachment #5	Section 14.6	FRM003999	During the execution of the Performance Qualification (PRC090335), it was discovered that FRM003999 Rev A Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes needed to be	Both requirements identified within this Deviation were marked as being "Not Applicable" (N/A) on FRM003999 during execution of the protocol PRC090335. FRM003999 will be revised (post testing) to remove these two requirements: "Verify there are no stains	Open (Form changes have been approved and are awaiting release.)

Reference	Section	Protocol Requirements	Type [Error, Deviation, Failure] Deviation Description	Resolution	Status [Closed, Open]
			revised to fit the actual requirements of the process specification: PR001567 Megadyne Mega Soft Patient Return Electrode Service Instructions. FRM003999 includes a step for Quality to "Verify there are no stains greater than 3 inches in diameter," and a ruler is listed as a test device. Neither of these attributes are included in the latest revision of PR001567 which is based upon ENG-WI-053 Rev 004.	greater than 3 inches in diameter" and "use a ruler as a test device". Once this revision is complete, it will meet the requirements of PR001567 Rev A and ENG-WI-053 Rev 004. While testing the pad that had the discoloration induced failure (Asset # 174495014), we documented at the bottom of FRM003999 the following: Checking – "Verify the stain/discoloration is documented" Result – "The stain/discoloration was documented." This was used to document/identify the induced failure in the corrected form.	
Deviation #3 Attachment #6	Section 12.2	Test Strategy	The induced failures on the Megadyne Mega Soft Patient Return Electrodes did not adhere to the Test Strategy found in Section 12.2 of PRC090335 Rev A ("…and the device will be evaluated for all pass/fail criteria"). After initial execution of the PRC090335A Procedure steps, it was uncovered during data review that the devices were not evaluated for all failure criteria per Megadyne Mega Soft Patient Return Electrode Service Form (FRM004077 Rev A). The pads were evaluated for failures in a sequential fashion, starting with Expiration Date, then Cuts and	The first failed execution of the Protocol Procedure steps will be documented within the Megadyne Mega Soft Service Performance Qualification Completion Report. Deviation 1 will be utilized to print out a new expiration date label for the pad that has the color/staining failure. With this new expiration date label, it is ensured that the corresponding failure for this pad, asset #174495014, should be the color/staining failure therefore meeting the requirement that the devices will be evaluated for all failure criteria as per the original test strategy found in Section 12.2 of PRC090335A.	Closed

Reference	Section	Protocol Requirements	Type [Error, Deviation, Failure] Deviation Description	Resolution	Status [Closed, Open]
			Tears, and lastly discoloration. This evaluation was halted whenever the first failure mode was uncovered, rather than evaluating for all three failures. Due to the fact that "bad" pad representing the discoloration failure also had an expiration date failure, no data was documented for that pad around its appearance.		

Deviations in this validation have been investigated and resolved and there are no further actions.

9. PROCESS MONITORING AND CONTROL

This process is monitored and controlled through continual equipment calibration, preventative maintenance, environmental monitoring, and final product verification.

9.1 Process Parameters (KPIVs)

N/A

9.2 Product Requirements (KPOVs)

N/A

10. PRODUCT DISPOSITION

The pads associated with this protocol will be placed in Long Term Hold where they will eventually be scrapped per WE000866.

11. CONCLUSION

The Criteria for success associated with PRC09335A was met. All (3) "bad" Pads with failures were properly identified by each Operator during each of their trials, and the (3) "good" Pads (Containing no induced or pre-existing failures) were properly identified as passing by each Operator during each of their trials. This demonstrates with a 99% Reliability at 95% confidence that this Service Process can properly evaluate and identify "Passing" and "Failing" Mega Soft Pads. The service process for Megadyne Mega Soft Patient Return Electrodes can be considered to be validated, and as a result, Ethicon Endo-Surgery Service and Repair Depot can be considered to be approved to perform service for this product.

The Mega Soft Pads that were used during PRC090335A execution will be processed into long term hold for future scrapping per WE000866.

12. ATTACHMENTS

Attachment 1 Executed Protocol

Attachment 2 Second Executed Protocol

Attachment 3 Signature and Protocol Training Log

Attachment 4 Deviation 1

Attachment 5 Deviation 2

Attachment 6 Deviation 3

Attachment 7 First Executed Protocol Test 1, Technician 1 Service Forms & Quality Release Forms

Attachment 8 First Executed Protocol Test 1, Technician 2 Service Forms & Quality Release Forms

Attachment 9 First Executed Protocol Test 2, Technician 1 Service Forms & Quality Release Forms

Attachment 10 First Executed Protocol Test 2, Technician 2 Service Forms & Quality Release Forms

Attachment 11 Second Executed Protocol Test 1, Technician 1 Service Forms & Quality Release Forms

Attachment 12 Second Executed Protocol Test 1, Technician 2 Service Forms & Quality Release Forms

Attachment 13 Second Executed Protocol Test 2, Technician 1 Service Forms & Quality Release Forms

Attachment 14 Second Executed Protocol Test 2, Technician 2 Service Forms & Quality Release Forms