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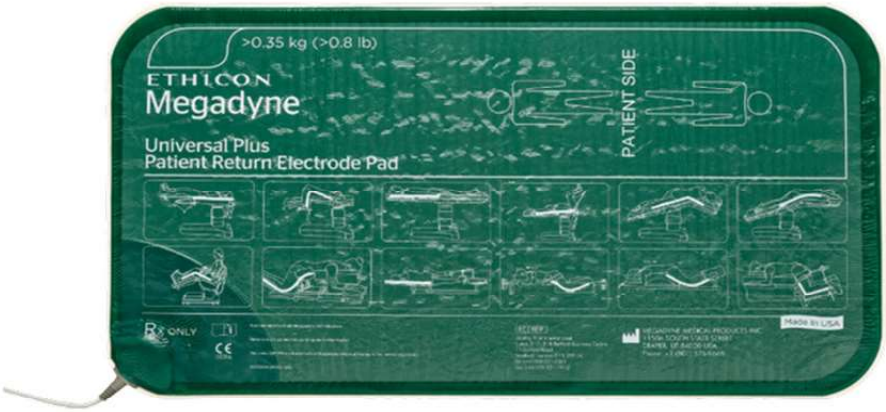
Revision History for (PRC090330)

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

VALIDATION SUMMARY REPORT

Document Title:	Megadyne Mega Soft Pad Service Validation Summary Report
Document Number / Revision:	PRC090330, 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
Validation Plan Reference:	PRC090329



1.0 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

2.0 PURPOSE

This Validation Summary Report summarizes the results of the planned validation activity for the Service process for the Megadyne Mega Soft Pad Service Validation as outlined in the Validation plan PRC090329 Rev A at Cincinnati, OH.

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.

4.0 RESULTS AND DISCUSSION

The Validation Plan for the system listed acceptance criteria and deliverables to be achieved in order to meet the requirements for validation. These are shown in the following table with the status of the requirement.

The system will be deemed acceptable when it satisfies the following criteria:

ID/Rev	Qualification	Result (pass/fail)
PRC090332	**Installation Qualification**	Pass
PRC090335	**Performance Qualification**	Pass

5.0 CONCLUSION

The successful completion of the Validation Activities documented within Validation Plan PRC090329 Rev A has established by objective evidence that all key aspects of the Service process for the Megadyne Mega Soft Patient Return Electrode to the Megadyne approved specifications.
The Service process for the Megadyne Mega Soft Patient Return Electrode is therefore considered to be validated based on the requirements outlined in PR-0000089 Franchise Procedure for Validation (Shared).

6.0 ATTACHMENTS

N/A