Document Number: PRC090334
Revision: A
Group: Completion Report
Type: None
State: Released
Latest Released: YES
Implemented Date: 11/13/2019
Stamp Date: Wednesday, November 13, 2019 2:01:13 PM ES

Revision History for (PRC090334)

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

INSTALLATION QUALIFICATION REPORT

Document Title:	Megadyne Mega Soft Service Installation Qualification Completion Report
Document Number / Revision:	PRC090334, A
Site / Location:	Ethicon Endo Surgery Service and Repair Depot, Cincinnati, Ohio
Project / Area:	Service and Repair
Equipment:	Power supply with current limit: GW Instek GPS-4303 Fluke 87 V True RMS Multimeter Mega Soft Test Cable, 6000101-01
Equipment Supplier:	All equipment used in the process will be identified in the Reference IQ Protocol.
Reference IQ Protocol:	PRC090332, A

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. PURPOSE

The report summarizes the Installation Qualification [IQ] for the Megadyne Mega Soft Pad Service Bench, supplied by Megadyne located in Ethicon Endo Surgery Service and Repair Depot, Cincinnati, Ohio.

The purpose of this Installation Qualification Report is to document the objective evidence that:

- The Installation Qualification has established by objective evidence that all key aspects of the Megadyne Mega Soft Pad Service Bench installation adhere to the approved specification and that the recommendations of Megadyne are suitably considered.
- The functional capabilities of the Megadyne Mega Soft Pad Service Bench have been verified.

3. SCOPE & BACKGROUND

This IQ protocol will be used as the validation for the Service bench for the Mega Soft.

The requirement for this IQ is due to the introduction of the new Service bench for the Mega Soft to the service depot in Cincinnati, Ohio.

The Megadyne Mega Soft Service bench is used to evaluate the Mega Soft Patient Return Electrode.

The equipment in scope within this IQ consists of a Service bench that includes equipment which will be used during the Service process detailed in Megadyne™ Mega Soft™ Reusable Patient Return Electrodes Service Instructions.

4. EXECUTIVE SUMMARY

Installation Qualification (IQ) has been completed for the Megadyne Mega Soft Pad Service Bench, supplied by Megadyne 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 IQ Protocol (PRC090332 Rev. A). During the IQ Protocol execution, there were no deviations. All tests met protocol requirements. Minor clerical errors were found in sections 12.4 and 12.8. These errors were corrected on the attached protocol per GDP [one line cross out, initial, & date] and had no impact on the validation or expected outcome.

The IQ acceptance criteria defined in PRC090332 Rev. A were satisfactorily met, as summarized in Attachment 1. The testing conducted establishes that all key aspects of the Megadyne Mega Soft Pad Service Bench installation adheres to the approved specifications, the recommendations of Megadyne are suitably considered, and the functional capabilities have been verified.

5. DEVIATIONS

No validation deviations were generated during the execution of the protocol. All tests met the requirements of the protocol.

6. CONCLUSION

The Installation Qualification has established by objective evidence that all key aspects of the Megadyne Mega Soft Pad Service Bench installation adhere to the Megadyne approved specification and that the recommendations of Megadyne have been suitably considered.

The Installation Qualification has met the acceptance criteria in the protocol based on the requirements outlined in PR-0000089 Franchise Procedure for Validation (Shared).

7. ATTACHMENTS

Attachment No.	Title

Attachment 1	Executed Installation Qualification Protocol
Attachment 2	Management of Change
Attachment 3	Training FM-0000809