PRC090332 A

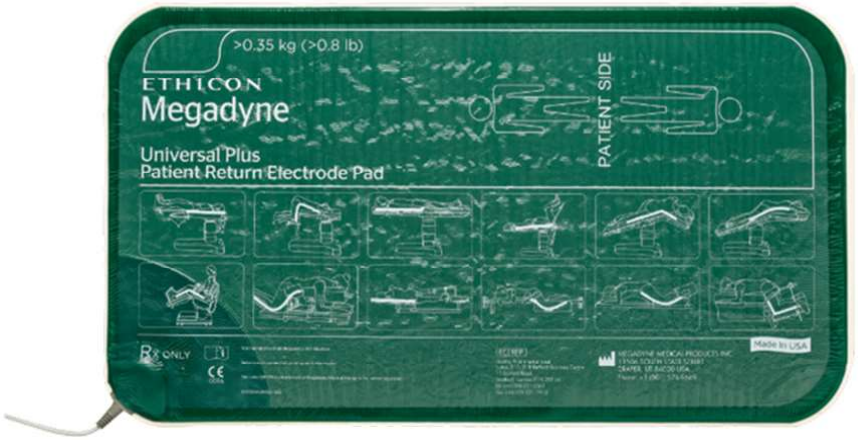
Document Number: PRC090332
Revision: A
Group: Protocol
Type: Protocol Equipment Install Qual
State: Released
Latest Released: YES
Implemented Date: 10/01/2019
Stamp Date: Tuesday, October 1, 2019 4:49:49 PM EST

Revision History for PRC090332

SUMMARY OF CHANGES	
Revision No.	Description of Change
A	Original Release

INSTALLATION QUALIFICATION PROTOCOL

Document Title:	Megadyne Mega Soft Service Installation Qualification
Document Number / Revision:	PRC090332A
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:	INSTEK AMERICA CORP, 5198 Brooks Street, Montclair, CA. 91763 Fluke Corporation, 6920 Seaway Blvd, Everett, WA 98203 Megadyne Medical Products, 11506 State St, Draper, UT 84020
Validation Assessment Reference:	DOC026078 Megadyne Mega Soft Service Validation Assessment
Completion Report Reference:	PRC090334 Megadyne Mega Soft Service Installation Qualification Completion Report



Mega Soft Patient Return Electrode

Picture of Bench Setup:

To be included within the Completion Report

1. DOCUMENT APPROVALS

The following document approvals are required per CP0160 Change Control/Approval Matrix, maintained in Epicenter, Ethicon Endo Surgery's document control system.

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

This protocol outlines the Installation Qualification for the service bench for the Megadyne Mega Soft Patient Return Electrode located in Cincinnati, Ohio. PR-0000089 Franchise Procedure for Validation (Shared) defines the requirements & approach for Installation Qualification at Ethicon Endo Surgery (EES) Service and Repair Depot, Cincinnati, Ohio.

The Initial and full qualification will be performed at EES Service and Repair Depot, Cincinnati, Ohio and provide evidence that all key aspects of the process adhere to the manufacturer's approved specification, and that the recommendations of the supplier of the equipment are suitably considered. This includes equipment and auxiliary system installation.

The purpose of this Installation Qualification (IQ) is to establish by objective evidence that the Service bench for the Mega Dyne Mega Soft's functional capabilities 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.

3.1 Equipment information

The equipment that will be utilized within the Mega Soft Service process is listed within section 12.

3.2 Process information

A picture of the service and repair bench will be included in the Megadyne Mega Soft Installation Qualification Completion Report.

The blank spaces within this protocol are intentionally left blank as they will be completed during execution of the protocol and included in the Installation Qualification Report.

This installation qualification protocol identifies the different installation qualification scripts (section 12) along with functional verification scripts (section 13) for the service and repair bench.

The service and repair bench installation will utilize the installed equipment to service the Mega Soft. The equipment listed in section 12 will be used to evaluate the Mega Soft per PR001567 Megadyne™ Mega Soft™ Reusable Patient Return Electrodes Service Instructions.

3.3 Product information

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 (ESU), or generators.

3.4 Out of Scope

Electrical safety testing is not required, as Mega Soft pads are not considered active elements as there are no motors or power source.

No spare parts are required for the service of Mega Soft Pads, as no repairs will be authorized for the process.

4. DEFINITIONS, TERMS AND ABBREVIATIONS

Refer to the 100632965 Franchise Process Validation Glossary of Terms (shared) for terminology and abbreviations used in the validation program.

5. ROLES & RESPONSIBILITIES

Responsibilities for the review and approval of this Installation Qualification are outlined in CP0160.

Service Manager/Facilitator – is responsible for the review and approval of this protocol and the associated completion report.

Service Engineer – is responsible for the creation, review, approval, execution, and required training prior to execution of this protocol. This includes all associated activities and the completion report.

Service Quality Team Lead – is responsible for the review and approval of this protocol and the associated completion report.

Service Repair Technician – is responsible for the execution of this protocol and assisting with creation, required training prior, and execution of this protocol. This includes the associated completion report. A second technician is responsible for the review of the scripts.

Service/Quality Assurance Technicians – are responsible for completion of required training prior to execution of this protocol and assisting with completion of all the activities to execute this protocol.

Megadyne Service Manager/Facilitator – is responsible for the review and approval of this protocol and the associated completion report

Megadyne Service Engineer (or equivalent Product Owner or Engineer) – is responsible for the review and approval of this protocol and the associated completion report.

Megadyne Quality Engineer – is responsible for the review and approval of this protocol and the associated completion report

Document Management – is responsible for the maintenance and archival of this protocol.

6. ACCEPTANCE CRITERIA

Installation Qualification (IQ) means establishing by objective evidence that all key aspects of the Service Bench equipment installation adhere to the Ethicon Endo Surgery approved specification and that the recommendations of Megadyne are suitably considered.

The following approved specifications were utilized as the source for the creation of the acceptance criteria within this IQ.

- ENG-WI-053 Mega Soft Patient Return Service and Repair Instructions
- CP0190, Requirements for Control of Inspection, Measuring and Test Equipment

All deviations from this protocol will be documented per instructions in PR-0000089 Franchise

Procedure for Validation (Shared).

The acceptance criteria for this IQ will be that the installation qualification test scripts along with the functional / operational verification test scripts as documented within section 12 and 13 have been completed / passed.

Final approval of the IQ Report verifies the acceptance criteria has been met.

7. PRE-REQUISITES

Location for service and repair will be identified prior to protocol execution.

All test equipment requiring calibration will be calibrated per CP0190 and documented using Section 11 of this protocol.

All equipment, tools, accessories, and documents for the setup of the Service bench have been identified within this installation qualification and are present.

Megadyne will supply product specific test equipment as listed in ENG-WI-053 Mega Soft Patient Return Service and Repair Instructions for use during this protocol.

8. DEVIATION HANDLING

If deviations occur during the execution of this Installation Qualification, they will be documented per instructions in PR-0000089 Franchise Procedure for Validation (Shared). All deviations shall be documented in the Installation Qualification Report.

9. REFERENCE DOCUMENTS

Table 1 – References

Document Number	Document Title
CP0160	Change Control/Approval Matrix
CP0190	Requirements for Control of Inspection, Measuring and Test Equipment
ENG-WI-053	Mega Soft Patient Return Service and Repair Instructions
FM-0000809	Franchise Qualification and Training Record Form (Shared)
PR001567	Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions
PR-0000089	Franchise Procedure for Validation (Shared)
PRC090329	Megadyne Mega Soft Service Validation Plan
PRC090335	Megadyne Mega Soft Service Performance Qualification
FRM004077	Megadyne Mega Soft Patient Return Electrode Service Form
WE001302	Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair

Document Number	Document Title
FRM003999	Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes
100632965	Franchise Process Validation Glossary of Terms (Shared)

10. SIGNATURE LOG & PROTOCOL TRAINING LOG

Training for service technicians and quality assurance technicians was conducted on September 5-7, 2018. This training covered all required activities to service the Mega Soft Pad. Refresher training for the topics covered in the training as well as training for PR001567 will be conducted prior to the execution of this protocol and documented on Form FM-0000809, Franchise Qualification and Training Record Form (Shared).

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.

11. LIST OF CALIBRATED INSTRUMENTS USED IN THE EXECUTION OF THE PROTOCOL

Objective: To summarize the calibrated instruments used in the execution of the protocol.

Procedure: For each instrument used in the execution of the protocol, complete the table below. The calibration requirements are outlined in CP0190.

Instrument / Equipment Unique Identifier	Manufacturer / Description	Calibration Due Date
	Power supply with current limit: GW Instek GPS-4303	
	Fluke 87 V True RMS Multimeter	

Comments			
Performed By:	Print Name:	Signature:	**Date:**
Reviewed by:	Print Name:	Signature:	**Date:**

12. INSTALLATION QUALIFICATION TEST SCRIPTS

12.1 Verification of Pre-IQ Activity Completion

Objective: To confirm the completion of planned pre-IQ activity.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.1.1	*PRC090329 Megadyne Mega Soft Service Validation Plan* Test: Verify that the plan is available in the Product Lifecycle Management (PLM) system, Epicenter. Test Procedure: Log into Epicenter PLM system and search for PRC090329. Verify that it is available and released. Document the revision level.	Acceptance Criteria: The document is available, released, and has an associated revision level.			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.1.2	*PRC090332 Megadyne Mega Soft Service Installation Qualification* Test: Verify that the protocol is available in the Product Lifecycle Management (PLM) system, Epicenter. Test Procedure: Log into Epicenter PLM system and search for PRC090332. Verify that it is available and released. Document the revision level.	Acceptance Criteria: The document is available, released, and has an associated revision level.			

Comments:				
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

12.2 Verification of Engineering Documentation

Objective: To verify that all planned Engineering documentation with the equipment under scope has been received by the site.

Procedure: Review Engineering documentation to confirm that all has been received.

Acceptance Criteria: Engineering documentation has been received.

Pre-Requisites: n/a

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.2.1	*PR001567 Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions* Test: Verify that the procedure is available in the Product Lifecycle Management (PLM) system, Epicenter. Test Procedure: Log into Epicenter PLM system and search for PR001567. Verify that it is available and released. Document the revision level.	Acceptance Criteria: The procedure is available, released, and has an associated revision level.			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.2.2	*ENG-WI-053 Mega Soft Patient Return Service and Repair Instructions* Test: Verify that the procedure is available on the EES Service & Repair Sharepoint. Test Procedure: Verify that the procedure is available on the EES Service & Repair Sharepoint.	Acceptance Criteria: The procedure is available, released, and has an associated revision level.			
12.2.3	*FRM004077 Megadyne Mega Soft Return Electrode Service Form* Test: Verify that the form is available in the PLM system, Epicenter. Test Procedure: Log into Epicenter PLM system and search for FRM004077. Verify that it is available and released. Document the revision level.	Acceptance Criteria: The form is available, released, and has an associated revision level.			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.2.4	*WE001302 Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair* Test: Verify that the procedure is available in the PLM system, Epicenter. Test Procedure: Log into Epicenter PLM system and search for WE001302. Verify that it is available and released. Document the revision level.	Acceptance Criteria: The procedure is available, released, and has an associated revision level.			
12.2.5	FRM003999 Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes Test: Verify that the form is available in the PLM system, Epicenter. Test Procedure: Log into Epicenter PLM system and search for FRM003999. Verify that it is available and released. Document the revision level.	Acceptance Criteria: The form is available, released, and has an associated revision level.			
Comments:					

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
Performed By:	Print Name:		Signature:	**Date:**	
Reviewed by:	Print Name:		Signature:	**Date:**	

12.3 Verification of Equipment and Ancillary System Installation

Objective: To verify that the Equipment has been received as expected and that installation is in accordance with Mega Soft Patient Return Service and Repair Instructions.

Procedure: Follow the test script and verify that equipment is received and installed as expected.

Acceptance Criteria: Equipment is received and installed as expected.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.3.1	*Power supply with current limit: GW Instek GPS-4303* Test: Verify that the equipment is present and properly located and secured within the workstation. Record and verify equipment product code, description and serial/lot number if applicable Test Procedure: Visually verify that the equipment is in the Service and Repair Center, labelled, and properly located and secured within the work station. Record the equipment product code, description, serial/lot number if applicable.	Acceptance Criteria: The equipment is present, labelled, and properly positioned within the workstation (Secure, no ergonomic issues, etc.). Correct equipment information is recorded Acceptance Criteria Source: Mega Soft Patient Return Service and Repair Instructions, MOC and Service Bench Picture included in Installation Qualification Protocol			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.3.2	*Fluke 87 V True RMS Multimeter* Test: Verify that the equipment is present and properly located and secured within the workstation. Record and verify equipment product code, description and serial/lot number if applicable Test Procedure: Visually verify that the equipment is in the Service and Repair Center, labelled, and properly located and secured within the work station. Record the equipment product code, description, serial/lot number if applicable.	Acceptance Criteria: The equipment is present, labelled, properly positioned within the workstation (Secure, no ergonomic issues, etc.). Correct equipment information is recorded Acceptance Criteria Source: Mega Soft Patient Return Service and Repair Instructions, MOC and Service Bench Picture included in Installation Qualification Protocol			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.3.3	*Mega Soft Test Cable, 6000101-01* Test: Verify that the equipment is present and properly located and secured within the workstation. Record and verify equipment product code, description and serial/lot number if applicable Test Procedure: Visually verify that the equipment is in the Service and Repair Center, labelled, and properly located and secured within the work station. Record the equipment product code, description, serial/lot number if applicable.	Acceptance Criteria: The equipment is present, labelled, and properly positioned within the workstation (Secure, no ergonomic issues, etc.). Correct equipment information is recorded Acceptance Criteria Source: Mega Soft Patient Return Service and Repair Instructions, MOC and Service Bench Picture included in Installation Qualification Protocol			

Comments:				
Performed By:	Print name:	Signature:	**Date:**	
Reviewed by:	Print name:	Signature:	**Date:**	

12.4 Verification of Equipment User Requirements Specifications

Objective: To verify that the equipment met the acceptance criteria.

Procedure: Execute as per test script procedure. The acceptance criteria source should be agreed / approved in advance.

Acceptance Criteria: As per test script and acceptance criteria source.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.4.1	*Power supply with current limit: GW Instek GPS-4303, Mega Soft Test Cable, 6000101-01* Test: Verify that the Mega Soft Test Cable plugs into the Power Supply's Channel 2 receptacle and the unit is switchable to the Channel 2 outputs. Test Procedure: Plug the Mega Soft Test Cable into the Power Supply's Channel 2 receptacle and verify that the unit is either in or switchable to Channel 2.	Acceptance Criteria: Mega Soft Test Cable plugs into Channel 2 of Power Supply and Power Supply is switched to Channel 2.			

Comments:				
Performed By:	Print Name: N/A	Signature: N/A	**Date:**	N/A
Reviewed by:	Print Name: N/A	Signature: N/A	**Date:**	N/A

12.5 Verification of Connection to Utilities and Utility Supply

Objective: To verify and record that the utilities and services supplied to the asset are suitable.

Procedure: Using calibrated instruments and equipment have the personnel executing the protocol verify and record that the utilities and services supplied to the asset are suitable.

Acceptance Criteria: As per test script and acceptance criteria source. Specifications will be complete and include a max/min range or specify nominal readings with an acceptable tolerance.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.5.1	Voltage Test: Verify the voltage at all Mega Soft Service Workbench outlets Test Procedure: Using a Volt Meter, measure and record the Voltage at each outlet	100-240 V AC 50-60 HZ is observed			
12.5.2	Phase Test: Verify the number of electrical phases associated with the power going to the Mega Soft Service Workbench outlets Test Procedure: Open the electrical panel serving the Mega Soft Service Workbench. Visually verify that the wiring reflects single phase.	Single Phase is observed			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.5.3	Bonded Ground Test: Verify the grounding of the conductors used to bring electricity to the Mega Soft Service Workbench Test Procedure: Open the electrical panel serving the Mega Soft Service Workbench. Visually inspect the grounding of the conductors bringing power to the workbench. Document whether there is a bonded ground	Bonded Ground is Present			
12.5.4	Circuit Breaker / Disconnect Location Test: Verify that the location of the electrical panel serving the Mega Soft Service Workbench is properly labelled and accessible. Test Procedure: Locate the electrical panel serving the Mega Soft Service Workbench. Visually inspect the surrounding area to confirm accessibility. Open the electrical panel and verify that the breakers are properly labelled.	The electrical panel is clearly labelled and accessible			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.5.5	Circuit Breaker / Disconnect Required Identification Test: Verify that the Voltage and Current are properly identified on the Circuit Breakers or Disconnect for the Mega Soft Service Workbench Test Procedure: Open the electrical panel serving the Mega Soft Service Workbench. Visually verify that the Voltage/Current is clearly identified.	Voltage | Current is clearly identified within the electrical service panel			
12.5.6	Circuit Breaker / Disconnect Amperage Requirement Test: Document the Circuit Breaker/Disconnect Amperage for the Mega Soft Service Workbench Test Procedure: Open the electrical panel serving the Mega Soft Service Workbench. Visually inspect the size of the Circuit Breaker(s) or disconnect serving the Mega Soft Service Workbench and document the associated Amperage.	Rated amps not to exceed 20 amps on 120 VAC side			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.5.7	Circuit Breaker / Disconnect Rating Requirement Test: Document the Circuit Breaker/Disconnect Rating for the Mega Soft Service Workbench Test Procedure: Open the electrical panel serving the Mega Soft Service Workbench. Visually verify and document the Rating of the Circuit Breaker(s) or disconnect serving the Mega Soft Service Workbench	Circuit breakers or disconnect have are minimum of Type 1			
12.5.8	Correct Electrical Connections Test: Verify the proper electrical connections of the Mega Soft Service Workbench equipment Test Procedure: Visually inspect the electrical connections of all the applicable equipment on the Mega Soft Service Workbench. (Connected to the correct Voltage, Power cords are in good condition, routing of wires is safe, etc.)	All workbench equipment is connected to the correct voltage, power cords are in good condition, and wire routing is safe.			

Comments:				
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

12.6 Verification of Equipment Procedures / Work Instructions

Objective: To verify that any procedures and/or work instructions which are required for the equipment operation are approved and released. All applicable procedures pertaining to the operation, maintenance, cleaning, and calibration of the equipment are to be identified, reviewed, and available as detailed in the table in this section.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.6.1	Calibration Procedures Test: Verify that calibration procedures exist for the following equipment: Power supply with current limit: GW Instek GPS-4303, Fluke 87 True RMS Multimeter Test Procedure: Document the Calibration Procedure Number for the following equipment: GW Instek GPS-4303, Fluke 87 True RMS Multimeter	Procedures exist and are available.			
12.6.2	Operation Procedures/Manuals Test: Verify that the Service and Repair Instructions are released and available. Test Procedure: Document the Service Instructions Number and Revision and verify that it is released in Epicenter.	Procedures exist and are available.			

Comments:				
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

12.7 Verification of Equipment Maintenance and Spare Parts

Objective: To verify all applicable equipment: drawings, manuals, service and repair training, spare parts, testing forms, and training records are to be identified, reviewed, and available as details in the table of this section. We are also verifying that spare parts have been issued or ordered along with reviewing the Spare Parts List.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.7.1	Service Equipment Manuals Test: Verify that all required Service Process Equipment Manuals are available. Procedure: Verify that Manuals are available for all applicable Service Process Equipment.	Manuals are available for all applicable Service Process Equipment			
12.7.2	Service Process Equipment Maintenance Training Test: Verify that personnel have been trained around the maintenance of all applicable Service Process Equipment. Procedure: Review evidence of equipment maintenance Training	Training has been documented around the maintenance of all applicable Service Process Equipment			

Comments:	Equipment required for this Installation has no spare parts available to the end-user.			
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

12.8 Verification of Equipment Instrument Calibration

Objective: To verify that all equipment instrumentation installed on the Mega Soft Service Workbench is calibrated, as appropriate, in accordance with calibration procedure.

Procedure: For each instrument embedded in the equipment verify that it is calibrated, as appropriate, in accordance with local site calibration procedure CP0160. Calibration records shall be available as part of review and approval of the executed protocol.

Acceptance Criteria: Instruments shall show evidence of up to date calibration to meet requirements as outlined in CP0160.

Instrument / Equipment Unique Identifier	Manufacturer / Description	Calibration Date
	Power supply with current limit: GW Instek GPS-4303	
	Fluke 87 V True RMS Multimeter	

Comments:				
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

12.9 Verification of Equipment Environmental Requirements

Objective: To verify specific environmental requirements for the equipment.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.9.1	N/A	N/A	N/A	N/A	N/A

Comments:	No equipment environmental requirements.			
Performed By:	Print Name: N/A	Signature: N/A	**Date:**	N/A
Reviewed by:	Print Name: N/A	Signature: N/A	**Date:**	N/A

12.10 Verification of Environment, Health and Safety & Sustainability Requirements

Objective: The Mega Soft Service Workbench and associated servicing process have been reviewed, and there are no special requirements outside of normal facility operating and storage conditions that require evaluation, monitoring, and control.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.10.1	Health/Safety Requirements The Mega Soft Service Workbench and associated servicing process meets Health, Safety, Ergonomic, and Sustainability requirements Procedure: Review the Service Process and Procedures with the EH&S Organization as part of MOC Process	No Health, Safety, Ergonomic, or Sustainability concerns are documented on within the MOC Document Or There is documented evidence within the MOC Document that any concerns have been addressed.			
12.10.2	Lighting The Mega Soft Service Workbench has sufficient Lighting Procedure: Review the Service Process and Procedures with the EH&S Organization as part of MOC Process	No Lighting concerns are documented on within the MOC Document Or There is documented evidence within the MOC Document that any concerns have been addressed.			

Comments:				
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

12.11 Verification of Materials of Construction / Product Contacting Materials

Objective: To verify that the Materials of Construction / Product Contacting Materials are as specified and that there are no detrimental effects on the process / product.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.11.1	N/A	N/A	N/A	N/A	N/A

Comments:	Verification of material of construction / product contacting materials is not required for the Service Bench for the Mega Soft because the materials that are utilized during the service and repair process are the same as those used in original equipment manufacturing.			
Performed By:	Print Name: N/A	Signature: N/A	**Date:**	N/A
Reviewed by:	Print Name: N/A	Signature: N/A	**Date:**	N/A

12.12 Verification of Computer Hardware Installation

Objective: To verify that Computer Hardware has been properly supplied and installed as specified.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.12.1	N/A	N/A	N/A	N/A	N/A

Comments:	No Computer Hardware is required for the installation.			
Performed By:	Print Name: N/A	Signature: N/A	**Date:**	N/A
Reviewed by:	Print Name: N/A	Signature: N/A	**Date:**	N/A

13. FUNCTIONAL / OPERATIONAL VERIFICATION TEST SCRIPTS

13.1 Functional Verification Testing

Objective: To verify the functionality of the Service Bench of the Mega Soft.

Pre-Requisites: All the installation test scripts have been positively completed and reviewed prior to execution of functional verifications

- The purpose of this test is to check that the equipment used in the service and repair process is functioning according to its acceptance criteria.
- The MOC for the Service and Repair bench has been completed and will be attached to the Installation Qualification Report.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
13.1.1	*Fluke 87 True RMS Multimeter* Test: Verify that the equipment is functional Test Procedure: Power on Fluke Multimeter in the DC voltage mode and verify that the unit is on and ready (zeros appear on the screen).	Acceptance Criteria: Multimeter powers on in DC voltage mode. Acceptance Criteria Source: Fluke Multimeter User Manual			
13.1.2	*Power supply with current limit: GW Instek GPS-4303* Test: Verify that the equipment is functional Test Procedure: Power on Power supply with current limit (GW Instek GPS-4303) and verify that the unit is on and ready	Acceptance Criteria: Power supply turns on. Acceptance Criteria Source: Power supply with current limit: GW Instek GPS-4303 User Manual.			

Comments:				
Performed By:	Print Name:	Signature:	**Date:**	
Reviewed by:	Print Name:	Signature:	**Date:**	

13.2 Operational Verification Testing

Objective: To verify the Equipment Operational requirements are met.

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
13.2.1	N/A	N/A	N/A	N/A	N/A
Comments:	Equipment operational checks (setup of Power Supply, Test Cable, and Multimeter) are performed in-process and will be tested during Performance Qualification (PRC090335 Megadyne Mega Soft Service Performance Qualification). Electrical safety testing is not required, as Mega Soft pads are not considered active elements as there are no motors or power source.				
Performed By:	Print Name:	Signature: N/A		**Date:**	N/A
Reviewed by:	Print Name:	Signature: N/A		**Date:**	N/A