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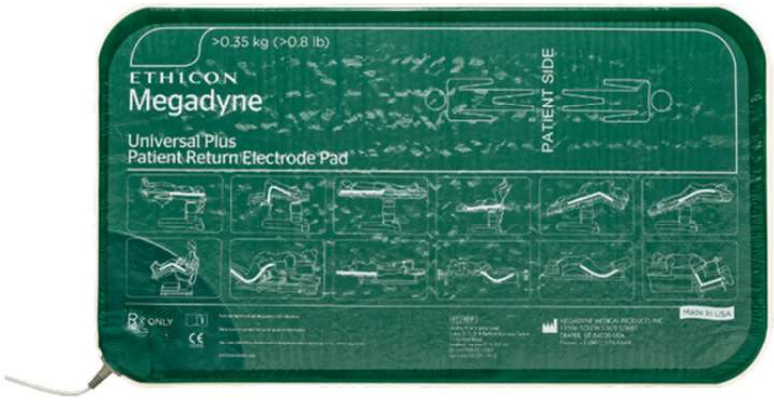
Revision History for (PRC090335)

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

PERFORMANCE QUALIFICATION PROTOCOL

Document Title:	Megadyne Mega Soft Service Performance Qualification
Document Number / Revision:	PRC090335A
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 Megadyne Mega Soft Service Installation Qualification Protocol (PRC090332)
Validation Assessment Reference:	DOC026078 Megadyne Mega Soft Service Validation Assessment
Completion Report Reference:	PRC090336



Megadyne Mega Soft Pad

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

The protocol outlines the Performance Qualification for service evaluation of the Megadyne Mega Soft Patient Return Electrode (Mega Soft Pad) located at Ethicon Endo Surgery (EES) Service and Repair Depot, Cincinnati, Ohio. PR-0000089 Franchise Procedure for Validation (Shared) defines the requirements & approach for Performance Qualification. This validation is a prospective performance qualification and is the initial performance qualification for the Service Process for the Megadyne Mega Soft Patient Return Electrode.

The purpose of this Performance Qualification is to establish by objective evidence that:

- The Megadyne Mega Soft Patient Return Electrode service process can identify useful life within expiration dates, cosmetic, and functional failures and confirm product quality.

3. SCOPE AND 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 below, and within the Megadyne Mega Soft Installation Qualification Protocol (PRC090332).

The blank spaces within this protocol are intentionally left blank as they will be completed during the Megadyne Mega Soft Service Performance Qualification Completion Report (PRC090336).

Table 1 - Products Applicable to this Performance Qualification.

Product Code or Product Family Identifier	Description
0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S	The Megadyne Mega Soft Patient Return Electrode is designed to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units, or generators.

Table 2 - Equipment Applicable to this Performance Qualification.

All test equipment requiring calibration will be calibrated per CP0190.

Equipment ID#/ Product Code	Equipment Description
6000101-01	Mega Soft Test Cable
ES4187	Power supply with current limit: GW Instek GPS-4303
019665	Fluke 87 V True RMS Multimeter

4. DEFINITIONS, TERMS AND ABBREVIATIONS

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

The following abbreviations / acronyms are used in this document:

Table 3 - Definitions

Term/ Abbreviation	Definition
EES	Ethicon Endo Surgery
Mega Soft Pad	Common term for the Mega Soft Patient Return Electrode

5. ROLES & RESPONSIBILITIES

Responsibilities for the review and approval of this Performance Qualification Protocol are listed below (and conform to 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 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 protocol.

Service/QA/Support 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 Design 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. PRE-REQUISITES

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

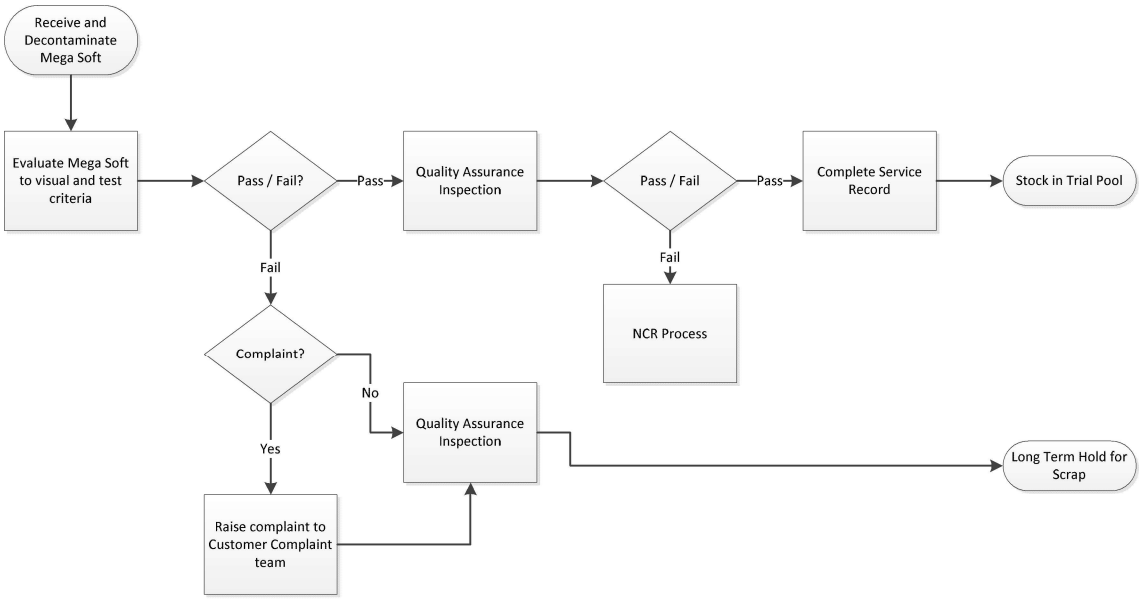
Table 3 – Pre-Requisites

Pre-Requisite	Document Title	Reference Doc. # or Attachment
IQ Protocol Completion	Megadyne Mega Soft Installation Qualification Protocol	PRC090332 Rev. A

Pre-Requisite	Document Title	Reference Doc. # or Attachment
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
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

The above items that are pending completion will be verified for completion prior to PQ execution in the completion report.

7. SERVICE PROCESS FLOW



8. REQUIREMENTS AND ACCEPTANCE CRITERIA / CTQ LIST

Table 4 - CTQ List

Attribute	Test Method	Specification	Acceptance Criteria

Attribute	Test Method	Specification	Acceptance Criteria
Expiration Date Inspection	Expiration Date Inspection Steps 7.1.6.2.2.1 to 7.1.6.2.2.1.1 in PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	Specifications for the Expiration Date Inspection Steps can be found in Section 7.1.6.2.2.1 of the PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	Demonstrated ability to distinguish between devices with acceptable Expiration Dates and those that have expired.
Tear/Cut Inspection	Tear/Cut Inspection Steps 7.1.6.2.2.2 to 7.1.6.2.2.2.1 in PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	Specifications for the Tear/Cut Inspection Steps can be found in Section 7.1.6.2.2.2 of the PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	Demonstrated ability to properly identify devices with Tears and Cuts.
Visual/Discoloration Inspection	Visual/Discoloration Inspection Steps 7.1.6.2.2.4.1 to 7.1.6.2.2.4.2.2 in PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	Specifications for the Visual/Discoloration Inspection Steps can be found in Section 7.1.6.2.2.4 of the PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions	Demonstrated ability to properly identify devices with unacceptable Discoloration.
Final Test	Testing Procedure Steps 8.4.1 to 8.4.3 in ENG-WI-053, Mega Soft Patient Return Electrode Service and Repair Instructions	Specifications for the Final Test Steps can be found in Section 8.4 of the ENG-WI-053, Mega Soft Patient Return Electrode Service and Repair Instructions	Demonstrated ability to properly identify devices that pass the Final Test.

9. PROCESS PARAMETERS

Process inputs were established by Megadyne and documented within ENG-WI-053, Mega Soft Patient Return Electrode Service and Repair Instructions. Process inputs were further parameterized in PR001567, Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions, for EES Service Center.

9.1 – Inspection Parameters

Attribute	Acceptance
Expiration Date	**At least 130 days of remaining life per PR001567**
Tears or Cuts	**No cuts or Tears per PR001567**
Staining or Discoloration	**No dark brown staining or discoloration,** **No non-uniform brown staining or discoloration,** **No stains that appear black or like blood per PR001567**

9.2 – Final Test Parameters

Current	Time	Acceptance (Output Voltage)
1.0 Amp	**60 Seconds**	**0-2 Volts**

10. OPERATING PROCEDURES

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

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

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

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

11. TRAINING REQUIREMENTS

Training of Service and Quality Assurance Technicians was conducted September 05, 2018 to September

07, 2018. The training covered all required activities to service the Megadyne Mega Soft Patient Return Electrode. Refresher training for the topics covered in the training was conducted during the execution of PRC090332 Megadyne Mega Soft Installation Qualification. 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.

12. TEST STRATEGY

12.1 The test plan is to perform process PR001567, encompassing initial evaluation which includes the evaluation of the device performance using the service and operation manuals as guides, box label creation, quality final testing, and final release.

12.2 The process will involve the creation of induced failure modes used to evaluate the Mega Soft 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 six times; three Mega Soft Pads will have induced failures, and three Mega Soft Pads will have no induced failures.

12.3 The six qualification tests will be identified in the performance qualification report.

13. SAMPLING PLAN AND RATIONALE

13.1 Multiple Megadyne Mega Soft Pads will be used. A failure will be induced within a device (blind to the technician performing the qualification) and the device will be serviced back to specifications. This will be done a total of six times, with a different induced failure for three of the Mega Soft Pads, and no induced failures for the remaining three. This will demonstrate the ability to evaluate this device.

13.2 Rationale for the number of pads used is based on a Mann-Whitney Test. This test is used to determine the effectiveness of the test plan. In this case, we will use the combination rule where n = 6 and r = 3. The goal is to identify 3 good pads (no induced failures) from a group of 6. When performing the test, the order of the identification of the pads is irrelevant. The probability of identifying all 3 good pads as “pass” and all 3 bad pads (induced failures) as “fail” is 1 in 20, or 0.05. If this test is successfully repeated 4 times (Two Technicians/Two Tests) the probability of identifying all good pads as “pass” and all bad pads as “fail”, by chance, is 0.054. Thus, the test is 1-0.054, or 99.9994% effective and demonstrates the ability of a technician to observe a failure and appropriately ‘fail” or “reject” the pad.

$$ {}_n\mathrm{C}_r = \frac{n!}{(n-r)!}r! $$

$$ {}_6\mathrm{C}_3 = \frac{6!}{(6-3)!}3! = 20 $$

14. TEST PLAN

14.1 Create six individual Work Orders in the Service Application for Megadyne Mega Soft Patient Return Electrode device and receive the devices within the service database prior to protocol execution. Objective evidence of this is captured in the creation of the service summary report.

14.2 A support technician will perform decontamination per WE001143 and record within the service database. Objective evidence of this is captured in the creation of the service summary report.

14.3 A service engineer will induce failures (blind to the service technician) on three of the Mega Soft Pads. The remaining three pads will have no induced failures on them. The failures induced by the service engineer will be recorded within the completion report.

14.4 A service technician will select one of the six Mega Soft Pads at random and follow steps per PR001567, Megadyne Mega Soft Reusable Patient Return Electrode Service Instructions. If failure occurs, cease testing, document the failure at the corresponding section of FRM004077, Megadyne Mega Soft

Patient Return Electrode Service Form, N/A the remaining blocks, and initial/date. The device will be forwarded on to a quality release technician.

14.5 A service technician will create a box label per PR001567. Not Applicable for units to be scrapped. Objective evidence of this is captured in the service database.

14.6 A quality release technician will perform the QA Final Testing and Release listed in PR001567 and WE001302, and document utilizing FRM003999, Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes. Attach the completed forms to the service database. Return the product into the protocol process until step 14.9 is completed.

14.7 After this final inspection step performed by the quality release technician, if a box label was created, then the box label will be destroyed (the Megadyne Mega Soft Pad will not actually be shipped) and a service summary report will be printed. Retain all documentation for the completion report.

14.8 A service technician will repeat steps 14.4 through 14.5 until all six Mega Soft Pads have been serviced.

14.9 A quality release technician will repeat step 14.6 through 14.7 until all six Mega Soft Pads have been final tested.

14.10 Review documentation for expected results, complete the data collection table found in section 20 and retain them for the completion reports.

14.11 Repeat test for a total of 4 times in order to satisfy the Mann-Whitney calculation and verify the rationale.

15. MATERIAL DISPOSITION

If criteria for success of this protocol is met, the Megadyne Mega Soft Patient Return Electrodes used in this protocol will be serviced again (Post-Service Launch) and either placed in the Megadyne Mega Soft Patient Return Electrode trial pool, or failed devices will be scrapped per WE000866.

16. DEVIATION HANDLING

If deviations occur during the execution of this Performance Qualification, they will be documented using the Validation Deviation Form 100646188. All deviations and corrective actions shall be documented in the Performance Qualification Report. Any associated criteria for success changes, or process modifications will be assessed, and revalidated if deemed necessary.

17. REFERENCE DOCUMENTS

The following documents are used to develop, to support, or are referenced within this Performance Qualification Protocol.

Table 6 - Reference Documents

Document Number	Document Title
CP0160 Rev. GV	Change Control/Approval Matrix
CP0190 Rev. BJ	Requirements for Control of Inspection, Measuring and Test Equipment
ENG-WI-053 Rev. 4	Mega Soft Patient Return Electrode Service and Repair

Document Number	Document Title
FM-0000809 Rev. 15	Franchise Qualification and Training Record Form (Shared)
FRM003999 Rev. A	Quality Assurance Final Release Inspection Form for Megadyne Mega Soft Reusable Patient Return Electrodes
FRM004077 Rev. A	Megadyne Mega Soft Patient Return Electrode Service Form
PR-0000089 Rev. 13	Franchise Procedure for Validation
PR001567 Rev. A	Megadyne Mega Soft Reusable Patient Return Electrodes Service Instructions
PRC090332 Rev. A	Megadyne Mega Soft Installation Qualification Protocol
PRC090334 Rev. A	Megadyne Mega Soft Service Installation Qualification Completion Report
PRC090336 Rev. A	Megadyne Mega Soft Service Performance Qualification Completion Report
WE000866 Rev. G	Equipment Service Work Instruction for the Disposal of Capital Equipment
WE001143 Rev. S	Decontamination Procedure
WE001302 Rev. AV	Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair
100632965 Rev. 3	Franchise Glossary for Validation (Shared)
100646188 Rev. 3	Validation Deviation Form

18. APPENDICES

The following are appendices to this document.

Table 7 – Appendix

Appendix Number	Attachment Name
1	Signature and Protocol Training Log
2	Data Collection Forms

19. APPENDIX 1 – SIGNATURE AND PROTOCOL TRAINING LOG

Signature Log Objective: to identify the personnel participating in the qualification activities.

Table 8 – Signature Log

Name	Job Title	Signature / Initials / Date
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____

Training Log objective: to provide documented evidence of training to the protocol.

Training records are located within FM-0000809 and will be attached report.

20. APPENDIX 2 - DATA COLLECTION FORMS

20.1 PQ Test 1, Technician 1

Title: Megadyne Mega Soft Patient Return Electrode Service PQ Test

Table 9 – Performance Qualification Test Records

20.1.1 PQ Test 1 Records					
Pad SN Ref. 14.4-14.5	**Tech. Pass/Fail** Ref. 14.4-14.5	**QA Pass/Fail** Ref. 14.6-14.7	**Acceptance Criteria** Ref. 14.10	**Results** Ref. 14.10	**Reviewer Pass/Fail** Ref. 14.10
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
Comments or Deviations:					

Performed by (Technician):	Print Name:	Signature:	Date:
Performed by (QA):	Print Name:	Signature:	Date:
Reviewed by:	Print name:	Signature:	Date:

20.2 PQ Test 1, Technician 2

Title: Megadyne Mega Soft Patient Return Electrode Service PQ Test

Table 10 – Performance Qualification Test Records

20.2.1 PQ Test 1 Records					
Pad SN Ref. 14.4-14.5	**Tech. Pass/Fail** Ref. 14.4-14.5	**QA Pass/Fail** Ref. 14.6-14.7	**Acceptance Criteria** Ref. 14.10	**Results** Ref. 14.10	**Reviewer Pass/Fail** Ref. 14.10
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
Comments or Deviations:					

Performed by (Technician):	Print Name:	Signature:	Date:
Performed by (QA):	Print Name:	Signature:	Date:
Reviewed by:	Print name:	Signature:	Date:

20.3 PQ Test 2, Technician 1

Title: Megadyne Mega Soft Patient Return Electrode Service PQ Test

Table 11 – Performance Qualification Test Records

20.3.1 PQ Test 2 Records					
Pad SN Ref. 14.4-14.5	**Tech. Pass/Fail** Ref. 14.4-14.5	**QA Pass/Fail** Ref. 14.6-14.7	**Acceptance Criteria** Ref. 14.10	**Results** Ref. 14.10	**Reviewer Pass/Fail** Ref. 14.10
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
Comments or Deviations:					

Performed by (Technician):	Print Name:	Signature:	Date:
Performed by (QA):	Print Name:	Signature:	Date:
Reviewed by:	Print name:	Signature:	Date:

20.4 PQ Test 2, Technician 2

Title: Megadyne Mega Soft Patient Return Electrode Service PQ Test

Table 12 – Performance Qualification Test Records

20.4.1 PQ Test 2 Records					
Pad SN Ref. 14.4-14.5	**Tech. Pass/Fail** Ref. 14.4-14.5	**QA Pass/Fail** Ref. 14.6-14.7	**Acceptance Criteria** Ref. 14.10	**Results** Ref. 14.10	**Reviewer Pass/Fail** Ref. 14.10
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
			Both Technician and Quality successfully identified pass or fail		
Comments or Deviations:					

Performed by (Technician):	Print Name:	Signature:	Date:
Performed by (QA):	Print Name:	Signature:	Date:
Reviewed by:	Print name:	Signature:	Date: