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Revision History for PRC096666 Rev A

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

INSTALLATION QUALIFICATION PROTOCOL

Document Title:	IQ Protocol for Preheat Oven E19578 and Coating Modifier Scale E20258
Document Number / Revision:	PRC096666 Rev A
Site / Location:	Independecia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juarez, Chihuahua, 32575, Mexico.
Project / Area:	Megadyne Line 173
Equipment:	Preheat Oven, Blades Coating Process Fixtures and Coating Modifier Scale
Equipment Supplier:	Despatch, Fisher Precision and Turtle and Hughes
Validation Assessment Reference:	DC003495 Rev A

1. DOCUMENT APPROVALS

Document Type as per Approval Matrix CP0160: Protocol – Installation Qualification.

Governance: Lifecycle Engineering - Post- Stabilization.

Function	Name	Signature	Date
Originator	Osvaldo Mendez	Electronic Signature in PLM System	Electronic Date in PLM System
MEST Equipment Engineer	Omar Tovar	Electronic Signature in PLM System	Electronic Date in PLM System
Plant Quality Engineer	Victor Cantu	Electronic Signature in PLM System	Electronic Date in PLM System
Business Unit Manufacturing Engineer	Alan Arrieta	Electronic Signature in PLM System	Electronic Date in PLM System
Preventive Maintenance Engineer	Cesar Montoya	Electronic Signature in PLM System	Electronic Date in PLM System
Lifecycle Quality Engineer	Ihsan Samara	Electronic Signature in PLM System	Electronic Date in PLM System

2. PURPOSE

The purpose of this installation qualification is to perform an initial & full validation and demonstrate & document that the, E19578 Preheat Oven MaxID: ES4357 , Coating modifier scale E20258 and T02737 Blades coating process equipment and fixtures are safe, properly installed and operate as intended for the Megadyne line 173 at Independencia.

3. SCOPE & BACKGROUND

The scope of this installation qualification is limited to the new equipment E19578 Preheat Oven MaxID: ES4357and T02737, Coating modifier scale E20258 and Blades coating process fixtures installed for production coating line 173.

The requirement for this IQ is due to the transfer of the Megadyne product line from Draper Utah to Ethicon Endo Surgery Independencia located in Ciudad Juarez Chihuahua.

All activities of this protocol are limited to the product codes listed in Table 1.

Code	Description
0012	EZ Clean 2.5" Blade
0012A	EZ Clean 2.75" Blade
0012AM	EZ Clean 2.75" Modified Blade
0012MBN	EZ Clean Modified Flat Blade, BNS, 2.5"
0014	EZ Clean 6.5" Blade
0014A	EZ Clean Blade, 4.0"
0014AM	EZ Clean Modified Blade, 4.0"
0014M	EZ Clean Modified Flat Blade, 6.5"
0012BN5	EZ Clean Flat Blade, BNS, 2.5" (Quantity 500)
0012ABN	EZ Clean, Bulk NS, 2.75" (Quantity 100)
0012M	EZ Clean 2.5" Modified Blade
0014BN	EZ Clean Blade, 6.0", BNS
0012AMBN	EZ Clean, Modified Blade, Bulk NS, 2.75"
0013	EZ Clean 2.75" Needle
0013M	EZ Clean Modified Needle, 2.75"
0118	EZ Clean Sharp Needle, 2.0"
0118A	EZ Clean Sharp Needle, 2.5"
C012ABN	EZ Clean, 2.75", Custom Exposure, Bulk Non-Sterile (QTY 100)
0012AMD	EZ Clean 2.75" Modified Blade with Nosecone
0012MD	EZ Clean 2.5" Modified Blade with Nosecone
0014ABN	EZ Clean Flat Blade, 4.0", BNS
0014AMBN	EZ Clean Modified Blade, 4.0", Bulk Non-Sterile
0014MBN	EZ Clean Modified Flat Blade, 6.5", Bulk Non-Sterile
0014AMD	EZ Clean Modified Blade, 4.0" with Nosecone
0014MD	EZ Clean Modified Flat Blade, 6.5" with Nosecone
0029M	EZ Clean Modified Bayonet Flat Blade, 5.75"
C117M	EZ Clean Modified Flat Blade, 4.72", Custom

Code	Description
C117MBN	EZ Clean Modified Flat Blade, 6.5", Bulk Non-Sterile
0012AP	EZ Clean Precision Blade 2.75
0066	EZ Clean AIO 2.5" Flat Blade
0017	EZ Clean Flat 13.5"
0113	EZ Clean Blunt Needle, 2.75"
0113A	EZ Clean Modified Blunt Needle
0113M	EZ Clean Modified Blunt Needle, 2.75"
0013MD	EZ Clean Modified Needle, 2.75" with Nosecone
0013MBN	EZ Clean Modified Needle, BNS, 2.75"
0013BN	EZ Clean Needle, 2.75, BNS
0016	EZ Clean Needle, 6.0"
0016A	EZ Clean Needle, 4.0"
0016AM	EZ Clean Modified Needle, 4.0"
0016M	EZ Clean Modified Needle, 6.0"
0119	EZ Clean Angled Sharp Needle, 45 Degree
0119A	EZ Clean Sharp Needle, Angle 45 Degree (4mm)
0120	EZ Clean Angled Sharp Needle, 90 Degree
0121	EZ Clean Sharp Needle, 6.5"
0028	EZ Clean Bayonet Needle, 5.75"
0028M	EZ Clean Modified Bayonet Needle, 5.75"
0022	EZ Clean Lap Needle, 13.5"
0022S	EZ Clean Lap Needle, 13.5", SS
0690	Indicator Shaft, 32 cm
0695	Indicator Shaft, 38 cm
0690S	Indicator Shaft, 32 cm, Split Stem
0695S	Indicator Shaft, 38 cm, Split Stem
0029	EZ Clean Bayonet Flat Blade, 5.75"
C117	EZ Clean Flat Blade, 4.75", Custom
0012MP	EZ Clean Precision Modified Blade 2.5
0014MP	EZ Clean, Precision Modified Blade 6.5
0012AMP	EZ Clean Precision Blade, Modified 2.75
0014AP	EZ Clean Precision Blade 4.0
0014AMP	EZ Clean Precision Blade, Modified 4.0
0064	EZ Clean AIO Lap Flat Blade, 31cm

Table 1: Product codes.

3.1 Equipment information

Equipment Description	Machine Number	Maximo ID Number	Serial #	Supplier

Preheat Oven	E19578	ES4357	194863	Despatch
Blades coating process fixtures	T02737	n/a	n/a	Fisher Precision
Coating Modifier Scale	E20258	n/a	6A4456124	Turtle and Hughes

Table 2: Equipment information (Curing area)

3.2 Process information

Fixture T02737 Blades coating process fixtures is used to hold blades in vertical position to be coated. E19578 Pre-heat Oven is used to heat up blades, for better adherence, before PTFE coating is applied to the blades, Coating Modifier Scale is used to weigh the mix-up of PTFE coating before its applied to the blades.

3.3 Product information

Product applicable for this Installation Qualification protocol is listed in Table 1.

3.4 Out of Scope

All equipment and product not listed/mentioned in this installation qualification protocol.

4. DEFINITIONS, TERMS AND ABBREVIATIONS

Refer to 100632965 Franchise Glossary for Validation (Shared) for terminology and abbreviations used in the Ethicon, Ethicon Endo Surgery, and Cardiovascular and Specialty Solutions (CSS) validation program.

5. ROLES & RESPONSIBILITIES

Equipment Set up	Originator or Equipment Engineer
Training	Originator or Designee
Perform machine operation	Originator or Designee
Documentation of Test Results	Originator or Quality Engineer
Summarization of Results	Originator or Quality Engineer
Overall conduct protocol	Originator or Designee
Review of executed IQ Protocol	Quality Engineer
Safety Requirements	EES Safety Engineer
Supervise Installation activities	Facilities Engineer
Energy Management System	Facilities Engineer
Testing Equipment	Contractor
Calibration Current	Contractor
PM Current	Contractor

6. ACCEPTANCE CRITERIA

All equipment and fixtures listed in Table 2 must successfully pass the requirements of sections 12 and 13 of this PRC096666 Rev A protocol.

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

7. PRE-REQUISITES

100632324 Rev 3 Appendix 03- Installation Qualification Protocol Template (Shared)

7.1 The purpose of this section is to ensure that the validation deliverables preceding this stage of the validation cycle have been completed and approved.

7.2 Any associate responsible for execution of this protocol shall be trained prior to execution. Associates may be exempted from training if they reviewed/approved this protocol in Epicenter. All training documents shall be attached to the completion report of this protocol.

7.3 Equipment must be installed and properly connected to AC, DC, water source and / or compressed air as needed.

7.4 Applicable Preventive Maintenance should be completed prior the execution of this protocol for all the equipment listed in Table 2.

7.5 Equipment required calibration should be calibrated prior the execution of this protocol.

7.6 Complete EHS assessment prior to the execution of this protocol.

Document Name	Document Reference Number	Reference/ Approval Date
Criticality Assessment	PRC091842 Rev D	Ensure that the engineering study has been reviewed, approved, signed off and dated by all individuals required on the approval list prior to beginning the IQ protocol.
Installation Qualification Protocol	PRC096666 Rev A	Ensure that the protocol has been reviewed, approved, signed off and dated by all individuals required on the approval list prior to beginning the IQ protocol.
MOCCME	PRC094670 Rev A	Ensure that the protocol has been reviewed, approved, signed off and dated by all individuals required on the approval list prior to beginning the IQ protocol.

Table 3: Pre-requisites documentation

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

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

Document Number	Document Title
PRC091842 Rev D	Criticality Assessment
DC003495 Rev A	Enterprise Change Request
WE0020 Rev CH	Protocols and Engineering Studies
FRM002746 Rev B	EHS Assessment Form

Document Number	Document Title
PR-0000372 Rev 22	Franchise Procedure for Ethicon Training Process
PRC094670 Rev A	MOCCME

10. SIGNATURE LOG & PROTOCOL TRAINING LOG

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

Personnel involved in this IQ to execute the process, not familiar with the equipment, will be trained and documented on FM-0000809 which will be added in the Completion Report of this Installation Qualification Protocol.

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: Complete the table below for each instrument used in the execution of the protocol. The calibration requirements are outlined in WE0166 Rev AX.

Instrument / Equipment Unique Identifier	Manufacturer / Description	Calibration Due Date

Comments		
Performed By:	Signature:	**Date:**
Reviewed by:	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.

Procedure: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Planned pre-IQ activity has been documented and completed [approved].

Pre-Requisites: n/a

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.1.1	**Test:** IQ Protocol Approved. PRC096666 Rev A	IQ Protocol must be released in EpiCenter prior to execution.			
12.1.2	**Test:** Criticality Assessment Approved. PRC091842 Rev D	Criticality Assessment must be approved in EpiCenter prior to IQ.			
12.1.3	**Test:** MOCCME PRC094670 Rev A	MOCCME PRC094670 Rev A must be approved in EpiCenter prior to IQ execution.			
Comments:					
Performed By:	Signature:			**Date:**	
Reviewed by:	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: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Actual result must satisfy the Acceptance criteria for each test case.

Pre-Requisites: n/a

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.2.1	**Test:** Equipment Drawing listed in Table 2 Rev A **Test Procedure:** Review release status of equipment listed in Table 2 in Epicenter.	Equipment drawing listed in Table 2 Rev A is in working status in Epicenter. A preliminary drawings file must be attached in the Completion Report.			
Comments:					
Performed By:	Signature:			**Date:**	
Reviewed by:	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 expectations.

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

Acceptance Criteria: Equipment is received and installed as expected.

Pre-Requisites: n/a

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.3.1	**Test:** Verify electrical connections**.** **Test Procedure:** Visually verify the electrical connections for equipment listed in Table 2 are in good conditions.	Electrical connections are in good conditions.			
12.3.2	**Test:** Verify electrical drops. **Test Procedure:** Using Multimeter test Voltage supply.	Electrical drop has a voltage Preheat Oven: 240 +/-10%. Coating Modifier Scale: 120 +/-10%.	Actual drop voltage for: Preheat Oven: _____ Coating Modifier Scale: _____		
12.3.3	**Test:** E19578 Preheat Oven control panel access. **Test procedure:** Visually verify control panel access has no visible obstacles.	E19578 Preheat Oven control panel access with no restrictions.			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.3.4	**Test:** E19578 Preheat Oven front door clearance. **Test procedure:** Measure clearance for front door swing >21”	Clearance for door swing >21”	Actual clearance: _____		
12.3.5	**Test:** Verify E20258 Coating modifier scale placed on bench top **Test Procedure:** Visually verify the Coating modifier scale is placed on a flat bench top	Installation location bench top surface is visually flat accordingly.			

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

12.4 Verification of Equipment User Requirements Specifications

Objective: To verify the attainment of User Requirements is as documented

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

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

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.4.1	**Test:** E19578 Preheat Oven Control Cabinet integration. **Test Procedure:** Visual verification of the Control Cabinet presence and integration.	E19578 Preheat Oven Control cabinet is integrated.			
12.4.2	**Test:** E19578 Preheat Oven (HMI) Panel View **Test Procedure:** Visual verification of the Panel View (HMI) presence.	E19578 Preheat Oven Panel View (HMI) installed on the equipment			
12.4.3	**Test:** E19578 Preheat Oven Emergency Stop button (E-Stop) **Test Procedure:** Visual verification of the Emergency Stop button (E-Stop) presence, readily accessible and its correct identification.	E19578 Preheat Oven the Emergency Stop button (E-Stop) is properly installed, readily accessible and identified.			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.4.4	**Test:** T02737 Blades coating process fixtures material holding. **Test Procedure:** Visually verify fixture holds 108 blades vertically on place accordingly.	T02737 Blades coating process fixtures hold 108 blades vertically satisfactory.	Blades in fixture: _____		
12.4.5	**Test:** E20258 Coating Modifier Scale numeric display **Test Procedure:** Visually verify numeric display is present.	Numeric display for E20258 Coating modifier scale is present and visible.			
12.4.5	**Test:** E20258 Coating Modifier Scale weighing pan **Test Procedure:** Visually verify weighing pan is present.	Weighing pan for E20258 Coating modifier scale is present and visible.			
12.4.5	**Test:** E20258 Coating Modifier Scale weighing pan **Test Procedure:** Visually verify weighing pan is accordingly flat and without obstructions.	Weighing pan for E20258 Coating modifier scale is accordingly flat and without obstructions.			

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

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 qualified personnel verify and record that the utilities and services supplied to the asset are suitable.

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

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.5.1	**Test:** E19578 Preheat Oven power voltage connection. **Test procedure:** Connect the Preheat Oven main power cable to a corresponding VAC outlet and turn it on.	E19578 Preheat Oven MaxID: ES4357 must be connected to an electrical drop voltage of 240V +/-10%. Equipment must turn on.			
12.5.2	**Test:** E20258 Coating Modifier Scale power voltage connection. **Test procedure:** Connect the Coating Modifier Scale main power cable to a corresponding VAC outlet and turn it on.	E20258 Coating Modifier Scale must be connected to an electrical drop voltage of 120 +/-10%. Equipment must turn on.			
Comments:					
Performed By:	Signature:			**Date:**	
Reviewed by:	Signature:			**Date:**	

12.6 Verification of Equipment Procedures / Work Instructions

N/A, equipment procedure will be documented in a PQ protocol.

12.7 Verification of Equipment Maintenance and Spare Parts

Objective: To verify that Equipment complies with the local maintenance procedures.

Procedure: Verify using the test scripts below that Equipment Maintenance for the equipment has been adequately considered and has been set-up on the local maintenance system; and that Spare Parts have been listed ordered and received.

Acceptance Criteria: As per test scripts.

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.7.1	**Test:** Equipment Registry is completed. **Test Procedure:** Equipment registry in Maximo using form FMWE0366.3.	**Acceptance Criteria:** Equipment is registered as an asset in Maximo. Form FMWE0366.3 is filled. Note: Spare parts list will be attached in Completion Report.			
Comments:					
Performed By:	Signature:			**Date:**	
Reviewed by:	Signature:			**Date:**	

12.8 Verification of Equipment Instrument Calibration

Objective: To verify that all equipment instrumentation is suitable for its intended used and calibrated, as appropriate, in accordance with calibration procedure.

Procedure: For each instrument embedded in the equipment verify that it is suitable for its intended use and calibrated, as appropriate, in accordance with local site calibration procedure CP0190. Calibration records shall be available as part of review and approval of the executed protocol.

Acceptance Criteria: Instruments shall be suitable for their intended use and calibrated to meet requirements as outlined in CP0190.

Pre-Requisites: N/A

Instrument / Equipment Unique Identifier	Manufacturer / Description	Calibration Date

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

12.9 Verification of Equipment Environmental Requirements

N/A. No environmental requirements are needed for this equipment.

12.10 Verification of Environment, Health and Safety & Sustainability Requirements

Objective: To verify Environment, Health and Safety & Sustainability Requirements have been achieved for the equipment under scope.

Procedure: Follow the test script and document the actual results.

Acceptance Criteria: Actual result must satisfy the Acceptance criteria for each test case.

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.10.1	**Test:** EHS Assessment Form FRM002746 Rev B for equipment listed in table 1. **Test Procedure:** EHS engineer must audit the safety and ergonomic conditions of this equipment using the form FRM002746 Rev B	EHS Assessment Form FRM002746 Rev B is filled and approved by an EHS designee.			
Comments:					
Performed By:		Signature:		**Date:**	
Reviewed by:		Signature:		**Date:**	

12.11 Verification of Materials of Construction / Product Contacting Materials

Objective: To verify Product Contacting Materials requirements have been achieved for the equipment under scope.

Procedure: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Actual result must satisfy the Acceptance criteria for each test case.

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.11.1	**Test:** T02737 Blades coating process fixtures electrode contact. **Test Procedure:** Visual verification of electrode loading into coating process fixtures.	Electrodes show no damage when loaded and been held by T02737 Blades coating process fixtures.			
12.11.2	**Test:** E20258 Coating Modifier Scale weighs PTFE paint **Test Procedure:** Place the beaker glass containing PTFE paint in weighing pan of E20258 Coating Modifier Scale and set scale display for units of grams to show weight of PTFE paint	E20258 Coating Modifier must display the correct weight of the beaker glass with PTFE paint.			
Comments:					
Performed By:		Signature:		**Date:**	
Reviewed by:		Signature:		**Date:**	

12.12 Verification of Computer Hardware Installation

Objective: To verify of Computer Hardware Installation requirements have been achieved for the equipment under scope.

Procedure: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Actual result must satisfy the Acceptance criteria for each test case.

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.12.1	**Test:** E19578 Preheat Oven display (panel view plus). **Test Procedure:** Visual verification of the display (panel view plus) presence.	E19578 Preheat Oven display (panel view plus) installed to equipment.			
12.12.2	**Test:** E19578 Preheat Oven PLC system. **Test Procedure:** Visual verification of the PLC system presence.	E19578 Preheat Oven PLC system installed.			
12.12.3	**Test:** E19578 Preheat Oven computer. **Test Procedure:** Visual verification of the computer presence.	E19578 Preheat Oven computer installed.			
Comments:					

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

12.13 Verification of Computer Software Installation

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

Procedure: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Actual result must satisfy the acceptance criteria

Pre-Requisites: N/A

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
12.13.1	**Test:** E19578 Preheat Oven software installation verification. **Test Procedure:** Verify the software installed is working properly.	E19578 Preheat Oven software controls and maintains temperature, as well as manual inputs.			
Comments:					
Performed By:	Signature:			**Date:**	
Reviewed by:	Signature:			**Date:**	

13. FUNCTIONAL / OPERATIONAL VERIFICATION TEST SCRIPTS

13.1 Functional Verification Testing

Objective: To verify the functionality of the supplied and installed equipment as specified.

Procedure: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Actual result must satisfy the Acceptance criteria for each test case.

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

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
13.1.1	**Test:** E19578 Preheat Oven energization. **Test Procedure:** The machine must turn on when the main POWER switch is rotated to the ON position. The machine must turn off when the main POWER switch is rotated to the OFF position.	E19578 Preheat Oven turns on properly, by rotating the main POWER switch to the ON position. The machine turns off when the main POWER switch is set to the OFF position.			
13.1.2	**Test:** E19578 Preheat Oven Power Outage. **Test Procedure:** Once the machine is turned on, turn off the utility supply (electrical power) and verify that equipment reacts as specified.	When the power interruption happens, process must stop. Verify that the equipment can be restored to an operational state after such event.			

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
13.1.3	**Test:** E20258 Coating Modifier Scale energization. **Test Procedure:** The equipment must turn on when push button ON/OFF The equipment must turn off when the when push for second time button ON/OFF	E20258 Coating Modifier Scale turns properly, by pushing button ON/OFF The equipment turns off when push for second time button ON/OFF.			
13.1.4	**Test:** E20258 Coating Modifier Scale Power Outage. **Test Procedure:** Once the equipment is turned on, turn off the utility supply (electrical power) and verify that equipment reacts as specified.	When the power interruption happens, process must stop. Verify that the equipment can be restored to an operational state after such event.			
Comments:					
Performed By:	Signature:			**Date:**	
Reviewed by:	Signature:			**Date:**	

13.2 Operational Verification Testing

Objective: To verify that the equipment operates the cycle as intended

Procedure: Follow the test script and document the actual results. This table is left blank in the protocol and will be filled and attached to the completion report.

Acceptance Criteria: Actual result must satisfy the Acceptance criteria for each test case. Correct Software performance will be documented in Software Validation and will be provided in completion report.

Pre-Requisites: N/A

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

Reference #	Test / Test Procedure	Acceptance Criteria	Actual Result	PASS / FAIL	Initials / Date:
13.2.1	**Test:** E19578 Preheat Oven set point run. **Test Procedure:** Select and run, in panel view display, defined set point.	Equipment will run and maintain defined temperature.			
13.2.2	**Test:** E19578 Preheat Oven temperature monitoring. **Test procedure:** Verify Preheat Oven controls monitor temperature out of range.	E19578 Preheat Oven alarms when temperature is out of spec.			
13.2.3					
Comments:					
Performed By:		Signature:		**Date:**	
Reviewed by:		Signature:		**Date:**	