



**Document Number: PRC097508**

**Revision: A**

**Group: Protocol**

**Type: Protocol Software Validation**

**State: Released**

**Latest Released: YES**

**Implemented Date: 08/25/2020**

**Stamp Date: Tuesday, August 25, 2020 6:41:49 PM EST**

## EQUIPMENT SOFTWARE VALIDATION APPROVAL PAGE

PROTOCOL #	PRC097508	REVISION:	A	DATE:	08/21/2020
COMPLETION REPORT #	PRC097509	MVP, ECP, DP or SPCR#	DC003495		

TITLE:	Pre-Heat Oven E19578 MaxID:ES4357 Software Validation Protocol				
PROJECT NAME:	Mimas	PROJECT LEADER:	Rafael Palma		
Product Code:	See Table 1	Product Number:	See Table 1	Batch Number(s):	N/A

PROTOCOL INFORMATION					
ORIGINATOR:	Osvaldo Mendez		PHONE NUMBER:	3102	
ORIGINATOR TITLE:	Engineer II		SITE:	Independencia Plant	

PRIORITY STATUS (Specify Document Due Date):	N/A
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Protocol Document Type and Approval Governance			
Type:	EQUIPMENT SOFTWARE VALIDATION		
Organization Responsible-Governance	<input type="checkbox"/> <u>New Product Development</u> Pre-Launch/Stabilization (CP0258 or CP0150 if applicable)	<input checked="" type="checkbox"/> <u>Lifecycle Engineering</u> Post Stabilization (CP0150 if applicable)	<input type="checkbox"/> <u>External Manufacturing</u> (CP0231/CP0150)

APPROVAL LIST:			
Function	Name	User I.D.	Signature/Date
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MEST Equipment Eng.	Javier Diaz	JDiaz24	eSing in EPICENTER
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Lifecycle Quality Engineer	Ihsan Samara	isamara	eSing in EPICENTER

## DISTRIBUTION LIST: (create as necessary)

Revision	Date	Change Description
A	08/21/2020	Original Issue

## 1.0 PURPOSE

- 1.1 The purpose is to validate the software installed in the E19578 Pre-Heat Oven, MAXIMO ID ES4357 located at Megadyne Coating L173. This validation will be used to ensure that the machine function as intended to perform the pre-heating process to the blades.

## 2.0 SCOPE

The software validation protocol applies only to the software controlling the Pre-Heat Oven E19578 Maximo ID: ES4357, equipment applicable for all Megadyne product codes, located at Coating Line 173 with software SRC003427 Rev A.

## 3.0 CRITERIA FOR SUCCESS

- 3.1 The "Actual Results" must meet the "Expected Results" for each test case, if the test case fails to meet the criteria for success, perform root cause analysis, corrective action and verify the corrective action completion and effectiveness. Document the corrective action and results in the Completion Report.

## 4.0 REFERENCE DOCUMENTS

- 4.1 The following reference the documents used to develop, to support, or are referenced within this Software Validation protocol.

Pre-Heat Oven drawing number E19578

## 5.0 EQUIPMENT AND MATERIALS

- 5.1 Equipment and Software Identification

5.1.1 Program Number: **SRC003427**

Program Revision Level: A

Production Line/Location: Line 173 / Independencia Plant, CME-5

Equipment Number: E19578

MAXIMO ID Number: ES4357

Equipment Name: Pre-Heat Oven

5.1.1.1 Controller Type: PLC Allen Bradley CompactLogix L24ER QB1B

Program Type: Ladder Program / Ver 1.0.0

Development Software: Studio 5000 Logix Designer Ver. 30.01.00

5.1.1.2 Controller Type: HMI Allen Bradley PanelView Plus

Program Type: Touch HMI

Development Software: FactoryTalk View Studio Ver. 9.0

- 5.1.1.3 Controller Type: Safety Controller Omron G9SP  
 Program Type: Function Blocks (Safety Controller)  
 Development Software: G9SP Configurator 2.10
- 5.1.1.4 Controller Type: DELL Computer OptiPlex 7070  
 Program Type: LabVIEW Application - Main\_Oven Application Ver. 18  
 Development Software: LabVIEW 2018 Ver. 18.0.1f4

## 5.2 Materials

N/A

## 6.0 RESPONSIBILITIES

- 6.1 Overall conduct of Protocol and Completion Report: Equipment Engineer / Manufacturing Engineer / Trained Designee.
- 6.2 Equipment / Materials / Product Disposition: Equipment Engineer / Manufacturing Engineer / Trained Designee.

## 7.0 STRATEGIES AND ASSUMPTIONS

- 7.1 Risk Analysis.  
 This Software Validation for Pre-Heat Oven is covered by PFMEA RMD001679 Rev A (Draft).

Will this software (or software modification) modify the safety of the process to the end user in any manner not addressed by the current PFMEA?	
<input checked="" type="checkbox"/>	YES, the PFMEA RMD001679 will be updated under ECN number ECN029419
<input type="checkbox"/>	NO, current PFMEA addresses the safety of the process to the end user.

- 7.2 Each test case will provide assurance that the software requirements are met.
- 7.3 Software is not intended to create or store any quality record, Part 11.
- 7.4 Objective evidence of some test cases will be documented (screen captures) through Completion Report PRC097509 Rev A, per WE0020 Rev CH.

**Table 1- Product codes**

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"

Code	Description
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
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

Code	Description
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

## 8.0 TRAINING

- 8.1 Since the protocol will be conducted and execute by an engineer that has knowledge on the equipment, no training and translations of the protocol are required.
- 8.2 If applicable, training will be recorded under form FM-0000809 Rev 15 and included in the Completion Report PRC097509 Rev A.

## 9.0 PREREQUISITES

- 9.1 Approved Software Validation Protocol PRC097508 Rev A prior to execution of this protocol.
- 9.2 PFMEA RMD001679 Rev A shall be in "Working" status in EPICenter.

## 10.0 PROCEDURE

- 10.1 The Test Cases in Appendix 3 shall be followed in order throughout the execution of the test.
- 10.2 For each Test Case, execute the defined step(s) and observe, and check mark the results in the proper check box on the Test Case sheet.
- 10.3 Any discrepancy in the expected versus the actual result shall be documented in the comments column of the Test Case sheet.
- 10.4 Upon completion of each Test Case, the designee performing the test shall sign and date the Test Case sheet.
- 10.5 Upon completion of the Test Cases, the Test Case sheets will be returned to Equipment Engineer or designee.
- 10.6 All test results will be evaluated for Pass/Fail and the results recorded in the Test Case Pass/Fail column by Equipment Engineer or designee.
- 10.7 Any discrepancy or remarks will be analyzed, and corrective action determined by Equipment Engineer or designee.
- 10.8 Any discrepancies or unusual machine operations requiring correction will be corrected and the test procedure repeated. Discrepancies or unusual machine operation not requiring corrective action shall be documented in the completion report.
- 10.9 Objective evidence will be included in the test cases for keys steps and documented in the Completion Report.

10.9.1 Key Steps are marked with YES for "Printout of Screen Required" column of appendix 3.  
10.10 Maximo WO will be created and documented in the completion report for this protocol.

**11.0 PRODUCT DISPOSITION**

11.1 N/A

**12.0 COMPLETION ACTIVITIES**

- 12.1 Upon satisfactory completion of software validation by meeting defined Criteria for Success, and the Completion Report has been approved, an ECN will be issued for the release of the software controlling this machine, in preparation for production use.
- 12.2 Completion Report will be documented in PRC097509 Rev A.

**13.0 APPENDICES**

- 13.1 Appendix 1: Equipment Software Requirements Specification and Verification and Validation Matrix
- 13.2 Appendix 2: Equipment Software Design Description
- 13.3 Appendix 3: Equipment Software Test Cases
- 13.4 Appendix 4: 21CFR Part 11 Compliance

# Appendix 1

## Equipment Software Requirements Specification

### And

## Verification and Validation Matrix for equipment E19578

Enter high level description of the machine's operation.

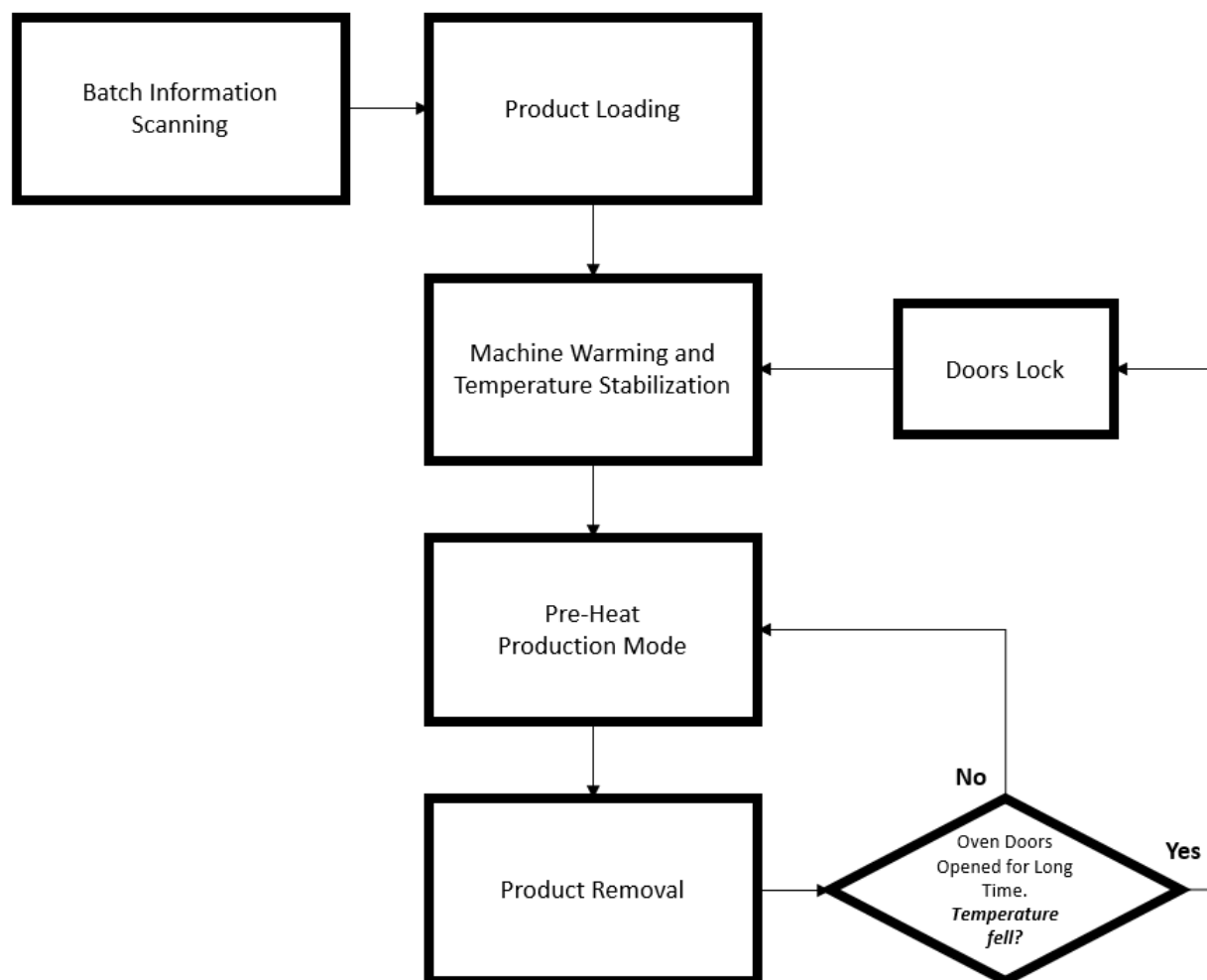
Requirement	Description of requirement	Verified with Test Case(s)
1. Power-Up and Shut Down	1.1 Equipment must demonstrate that is safe to turn on and turn off.	1
2. Users	2.1 Equipment must allow profiles creation and modification.	2
3. Recipes	3.1 Equipment must allow creation and modification of recipes.	3
4. Production Mode	4.1 Equipment must allow cycle start or terminate recipe.	4
5. Manual Mode	5.1 Equipment must allow manual operation.	5
6. Calibration	6.1 Equipment must allow to operate the machine for calibration test.	6
7. Alarm Messages and Emergency Devices	7.1 Equipment must be safe for operation and display alarm messages.	7



## Appendix 2

### Equipment Software Design Description

This is an embedded software used to control the Pre-Heat Oven. The following is a Flow Diagram of the Software.



### Appendix 3 – Equipment Software Test Cases

#### TEST CASE 1: Power Up and Shut Down

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of Screen Required	COMMENTS
1	<p>Ensure all the equipment is turned OFF and the E-Stops are released.</p> <p>Turn the Power knob of the Main Panel below the computer to ON position</p>	<p>HMI turned ON, after a minute, the Initialization screen is displayed and shows following messages:</p> <p>STEP: Start of Initialization Routine STATUS: Ethernet Device Not Available – Check for Ethernet Modules (blinking)</p> <p>Badge Information box is empty.</p> <p>Comm Modules: -Badge ID (ON) -Protocol 3 (ON) -LabView (OFF) -Scanner (ON)</p> <p>Oven doors interlocks LEDs turn ON green. Oven status LED blinks yellow.</p> <p>STEP: Start of Initialization Routine STATUS: Press the Enable Button to Activate the Machine (Blue Button).</p>		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	Turn ON the computer CPU.	<p>Computer is turned ON.</p> <p>“Pre-Heat Oven” monitoring application is opened after a few seconds.</p> <p>Comm Module “LabView” indicator turns ON.</p>		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

### Appendix 3 – Equipment Software Test Cases

#### TEST CASE 1: Power Up and Shut Down

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of Screen Required	COMMENTS
3	Turn the Power Knob of the Oven to ON position and push the Oven POWER switch to ON position.	The Oven High Temperature Controller turned ON.  Oven Status LED turns UP yellow.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
4	Press Blue HABILITAR button for 1 second.	Main Menu screen is displayed.  Following buttons are displayed: -PRODUCT SELECTION (disabled) -EDIT USER (disabled) -MODEL EDITION (disabled) -MANUAL (disabled) -CALIBRATION (disabled) -MACHINE INFORMATION (enabled)  Badge Information box is empty.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
5	In the following sequence:  -Push the Oven Power switch to OFF position -Turn the Oven Power knob to OFF position -Turn OFF the computer by pressing CPU Power button. -Turn the Main Panel Power knob to OFF position	All the equipment turned OFF.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 2: Users						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
6	Turn ON and initialize the machine by performing steps 1 to 6 from Test Case 1.	Machine is initialized, HMI displays Main Menu screen.  Following buttons are displayed: -PRODUCT SELECTION (disabled) -EDIT USER (disabled) -MODEL EDITION (disabled) -MANUAL (disabled) -CALIBRATION (disabled) -MACHINE INFORMATION (enabled) -Log Out  Badge Information box is empty.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
7	Scan an ENGINEERING or SUPER USER level ID in the Badge Scanner.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.  The logged user's name is showed in the USER textbox of the "Oven Grande" application in the Computer Monitor.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
8	Press EDIT USER button.	The EDIT USER Menu is displayed.  Logged user information is displayed.  Registered users list is displayed, the logged user is selected in the list. User selection buttons are displayed.  Following buttons are showed: -EDIT -DELETE -SEARCH -NEW USER -RETURN		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 2: Users						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
9	Scan a not registered ID.	A not used slot is selected in the list.  The logged user information is cleared.  NAME, LAST NAME, BADGE and LEVEL enables for edition.  SAVE and CANCEL buttons appear.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
10	Press NAME button.	Alphanumeric keyboard is showed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11	Type "Test" and press Enter button.	The NAME box shows "Test".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
12	Press LAST NAME button.	Alphanumeric keyboard is showed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
13	Type "User" and press Enter button.	The LAST NAME box shows "User".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
14	Using the UP and DOWN buttons of the LEVEL box, select OPERATOR level, then press ENTER button.	OPERATOR level is highlighted in the LEVEL box.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
15	Press SAVE button.	Pop-up message "PLEASE CONFIRM THE CHANGES" is displayed with CONFIRM and CANCEL buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 2: Users						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
16	Press CONFIRM button.	Test User has been created with OPERATOR user level.  SAVE and CANCEL buttons disappear.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
17	Press RETURN button.	Main Menu screen is displayed with all the buttons enables and logged user information.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
18	Press Log Out button.	Logged information is cleared.  The logged user's name is showed in the USER textbox of the "Oven Grande" application in the Computer Monitor.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
19	Scan Test User ID.	Test User information is displayed.  Following buttons are displayed: -PRODUCT SELECTION (disabled) -EDIT USER (disabled) -MODEL EDITION (disabled) -MANUAL (disabled) -CALIBRATION (disabled) -MACHINE INFORMATION (enabled) -Log Out  The logged user's name is showed in the USER textbox of the "Oven Grande" application in the Computer Monitor.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
20	Press Log Out button.	Logged information is cleared.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 2: Users						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
21	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
22	Press EDIT USER button.	EDIT USER Menu is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
23	Scan the Test User ID.	Test User information is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
24	Press EDIT button.	NAME, LAST NAME and LEVEL boxes are enabled for edition.  SAVE and CANCEL button appear.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
25	In the LEVEL box, select MAINTENANCE, then press Enter button.	The MAINTENANCE level is highlighted.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
26	Press SAVE button.	Pop-up message "PLEASE CONFIRM THE CHANGES" is displayed with CONFIRM and CANCEL buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
27	Press CONFIRM button.	Test User shows MAINTENANCE level now.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 2: Users						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
28	Press RETURN button.	Main Menu screen is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
29	Press Log Out button.	Logged user information is cleared, only MACHINE INFORMATION button is enabled.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
30	Scan Test User ID.	The Test User information is displayed with the new MAINTENANCE level.  Following buttons are enabled: -PRODUCT SELECTION -MANUAL -MACHINE INFORMATION		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
31	Press Log Out button.	Logged user information is cleared, only MACHINE INFORMATION button is enabled.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
32	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
33	Press EDIT USER button.	EDIT USER Menu is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
34	Select Test User in the registered users list, then press Enter button.	Test User information is displayed in the boxes.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			



TEST CASE 2: Users						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
35	Press DELETE button.	Pop-up message "PLEASE CONFIRM THE CHANGES" is displayed with CONFIRM and CANCEL buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
36	Press CONFIRM button.	The Test User is cleared from the registered users list and its information is cleared from the boxes.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
37	Press RETURN button.	Main Menu screen is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
38	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
39	Press MODEL EDITION button.	Model Edition screen is displayed.  Following boxes are enabled for edition: -Product Code -Sampling Time -Number Of Segments -General Time Out  Following buttons are displayed: -SAVE -NEXT -MENU		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
40	Press the Down selection button to find an empty slot. Once an empty slot is selected, press Enter button.	The empty slot is selected. The showed values are cleared and set to default values.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
41	Press Product Code box.	Alphanumeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
42	Type "Test123", then press Enter button.	Product Code box and Current Selection box show "Test123".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
43	Press Sampling Time box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
44	Type "20", then press Enter button.	Sampling Time box shows "20 s".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
45	Press Number Of Segments box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
46	Type "5", then press Enter button.	Number Of Segments box shows "5".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
47	Press General Time Out box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
48	Type "50", then press Enter button.	General Time Out shows "50 m".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
49	Press SAVE button.	Pop-up message "DO YOU REALLY WANT TO ACCEPT THE CHANGES?" is displayed with YES and NO buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
50	Press YES button.	"Test123" recipe is showed now in the recipes list.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
51	Press General Time Out box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
52	Type "15", then press Enter button.	General Time Out shows "15 m".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
53	Press Number Of Segments box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
54	Type "2", then press Enter button.	Number Of Segments box shows "2".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
55	Press SAVE button.	Pop-up message "DO YOU REALLY WANT TO ACCEPT THE CHANGES?" is displayed with YES and NO buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
56	Press YES button.	The new Test123 recipe parameters are displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
57	Press NEXT button.	Model Edition – Temperature is displayed.  Product Code box shows “Test123”.  Segment 1 and Segment 2 Temperature, Time, Temperature Min, Temperature Max and Time Out of Range boxes show default values.  Following buttons are displayed: -PREVIOUS -MENU		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
58	Press Segment 1 Temperature box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
59	Press 150”, then press Enter button.	Segment 1 Temperature box shows “150.00 °F”.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
60	Press Segment 1 Time box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
61	Press “5”, then press Enter button.	Segment 1 Time box shows “5 m”.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
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TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
62	Press Segment 1 Temperature Min box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
63	Press "120", then press Enter button.	Segment 1 Temperature Min box shows "120.00 °F".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
64	Press Segment 1 Temperature Max box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
65	Press "250", then press Enter button.	Segment 1 Temperature Max box shows "250.00 °F".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
66	Press Segment 1 Time Out Of Range box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
67	Press "2", then press Enter button.	Segment 1 Time Out Of Range box shows "2.0 m".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
68	Press Segment 2 Temperature box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
69	Press "150", then press Enter button.	Segment 2 Temperature box shows "150.00 °F".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
70	Press Segment 2 Time box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
71	Press "5", then press Enter button.	Segment 2 Time box shows "5 m".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
72	Press Segment 2 Temperature Min box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
73	Press "120", then press Enter button.	Segment 2 Temperature Min box shows "120.00 °F".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
74	Press Segment 2 Temperature Max box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
75	Press "250", then press Enter button.	Segment 2 Temperature Max box shows "250.00 °F".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
76	Press Segment 2 Time Out Of Range box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
77	Press "2", then press Enter button.	Segment 2 Time Out Of Range box shows "2.0 m".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 3: Recipes						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
78	Press PREVIOUS button.	Model Edition screen is displayed, Test123 recipe information still displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
79	Press SAVE button.	Pop-up message "DO YOU REALLY WANT TO ACCEPT THE CHANGES?" is displayed with YES and NO buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
80	Press YES button.	The recipe changes has been saved.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
81	Press NEXT button.	The Temperature, Time, Temperature Min, Temperature Max and Time Out Of Range values are displayed for all the segments.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
82	Press MENU button.	Main Menu screen is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			



### TEST CASE 4: Production Mode

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
83	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.  Press Blue HABILITAR button.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.  Blue button turns ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
84	Push the Oven INTERIOR LIGHT switch to ON position.	The Oven interior light is ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
85	Press PRODUCT SELECTION button.	Product Selection screen is displayed.  STEP: Scan Product Code STATUS: ...  PRODUCT CODE and LOT NUMBER boxes are displayed empty.  Comm Modules indicators are ON.  MAIN MENU button is showed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
86	Create a type-128 barcode for "0012" text and scan it with the barcode scanner.	Following message changed:  STEP: Scan Lot Number...  PRODUCT CODE box shows "0012".		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

**TEST CASE 4: Production Mode**

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
87	Create a type-128 barcode for "123456" text and scan it with the barcode scanner.	STEP: Press Accept to Continue or Cancel to Start Over STATUS: ...  LOT NUMBER box shows "123456"  ACCEPT and CANCEL buttons appear.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
88	Press ACCEPT button.	Production screen is displayed.  STEP: Open Guards And Insert Product in Oven STATUS: Do Not Interrupt the Machine...  The 0012 recipe information is displayed in the screen textboxes.  MAIN MENU button is showed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
89	Open the right oven door, then the left door.	STEP: Waiting For Condition To Start Cycle STATUS: Close Guards		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

**TEST CASE 4: Production Mode**

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
90	Close the left oven door, then the right door.	STEP: Waiting For Temperature In Range To Run The Segment Number 1 STATUS: Do Not Interrupt The Machine...  STEP message changes to: "Running The Segment Number 1" once the machine reaches the set temperature.  Machine starts 0012 recipe cycle.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
91	Wait for the Recipe Segment 1 finish.	Once the cycle ends, following messages are displayed:  STEP: Temp Reached STATUS: Open Guards To Take Product... Or Finish Lot  END LOT button appears.  Oven doors unlock.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
92	Open the oven doors.	Current Temperature starts decreasing for a few seconds, then it starts increasing to reach set temperature again.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
93	Close the oven doors.	No changes.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
94	Press END LOT button.	Pop-up message "DO YOU REALLY WANT TO EXIT FROM AUTO MODE?" is displayed with YES and CANCEL buttons.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

**TEST CASE 4: Production Mode**

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
95	Press YES button.	Main Menu screen is displayed. Logged user information is cleared. Only MACHINE INFORMATION button is enabled.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
96	Turn ON the printer.	Printer is turned ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
97	In the computer Pre-Heat Oven application, select the LOG'S tab.	The history of the completed cycles is displayed in the Data_Logs list. READ FILE OR UPDATE and PRINT REPORT buttons are displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
98	In the Folders Log list, select "30_05_2020", then press READ FILE OR UPDATE button.	Data_Logs list displays the completed cycles from the 30_05_2020 file.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
99	Select the application's PLOT tab.	Machine Operation Trend graphic is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
100	Press PRINT PLOT button.	Photos application is opened, graphic is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

**TEST CASE 4: Production Mode**

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
101	Press the Printer icon button.	Page configuration window is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
102	Ensure "Xerox VersaLink B400" printer and "Landscape" orientation are selected.  Press Print button.	Graphic is printed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 5: Manual Mode						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
103	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.  Press Blue HABILITAR button for 1 second.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.  Blue button turns ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
104	Press MANUAL button.	Manual Mode screen is displayed.  Comm Modules indicators are ON.  Following buttons are displayed: -I/O Status -Read -ESPANOL -ADVANCED CONFIG -NEXT -MAIN MENU		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
105	Press NEXT button.	Manual Mode – Controller screen is displayed.  Comm Modules indicators are ON. Current Temperature is displayed.  Following buttons are displayed: -Start Heat -Temperature -Power On Cooling System -Unlock Guards -ADVANCED CONFIG -PREVIOUS -I/O Status -ESPANOL -MAIN MENU		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 5: Manual Mode						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
106	Press the Temperature box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
107	Type "120", then press Enter button.	"120 °F" is displayed in the Temperature box.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
108	Press Start Heat button.	Temperature is increasing to reach the 120 °F set point.  Gray Start Heat button turns Blue Stop Heat button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
109	Once the set point temperature is reached, press Stop Heat button.	Temperature is decreasing.  Blue Stop Heat button turns Gray Start Heat button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
110	Press Power On Cooling System button.	Cooling system start working, temperature keeps decreasing.  Gray Power On Cooling System button turns Blue Power Off Cooling System button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
111	Press Power Off Cooling System button.	Cooling system stop working.  Blue Power Off Cooling System button turns Gray Power On Cooling System button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

### TEST CASE 5: Manual Mode

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
112	Press Unlock Guards button.	Oven doors unlock.  Blue HABILITAR button turns OFF.  MACHINE NOT ENABLED alarm message appears blinking.  Blue Unlock Guards button turns Gray Lock Guards button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
113	Open Oven Doors.	No changes.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
114	Close Oven Doors.	No changes.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
115	Press Lock Guards button.	Oven doors lock.  Gray Lock Guards button turns Blue Unlock Guards button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
116	Press Blue HABILITAR button for 1 second.	Blue HABILITAR button turns ON.  MACHINE NOT ENABLED message is cleared.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
117	Press MAIN MENU button.	Main Menu screen is displayed.  Only MACHINE INFORMATION button is enabled.  Logged user information is cleared.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			



TEST CASE 6: Calibration						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
118	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.  Press Blue HABILITAR button for 1 second.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.  Blue button turns ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
119	Press Calibration button.	Calibration screen is displayed.  Comm Modules indicators are ON. Current Temperature is displayed.  Following buttons are displayed: -Start Heat -Send Data -Power On Cooling System -Unlock Guards -MAIN MENU  Following boxes are displayed: -Temperature -High Offset -Current High Offset -Low Offset -Current Low Offset		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
120	Press the Temperature box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 6: Calibration						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
121	Type "120", then press Enter button.	"130 °F" is displayed in the Temperature box.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
122	Press the High Offset box.	Numeric keyboard is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
123	Type "0", then press Enter button.	"0 °F" is displayed in the High Offset box.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
124	Press Start Heat button.	Temperature is increasing to reach the 130 °F set point.  Gray Start Heat button turns Blue Stop Heat button. Send Data button turns blue for a few seconds.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
125	Once the set point temperature is reached, press Stop Heat button.	Temperature is decreasing.  Blue Stop Heat button turns Gray Start Heat button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

TEST CASE 6: Calibration						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
126	Press Power On Cooling System button.	Cooling system start working, temperature keeps decreasing.  Gray Power On Cooling System button turns Blue Power Off Cooling System button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
127	Press Power Off Cooling System button.	Cooling system stop working.  Blue Power Off Cooling System button turns Gray Power On Cooling System button.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
128	Press MAIN MENU button.	Main Menu screen is displayed.  Only MACHINE INFORMATION button is enabled.  Logged user information is cleared.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

**TEST CASE 7: Alarm Messages and Emergency Devices**

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
129	Scan the ENGINEERING or SUPER USER level ID in the Badge Scanner.  Press Blue HABILITAR button for 1 second.	Scanned ID information is showed in the Name, Last Name, ID and Level textboxes.  All the buttons are enabled.  Blue button turns ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
130	Press the HMI E-Stop.	Oven Status LED starts blinking yellow.  Blue HABILITAR button turns OFF.  Following messages are displayed: STEP: Start Of Initialization Routine STATUS: Pull-Up the E-Stop.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
131	Pull the HMI E-Stop.	STEP: Start Of Initialization Routine STATUS: Press the Enable Button to Activate the Machine (Blue Button)		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
132	Turn the Oven Power knob to OFF position.	STEP: Start Of Initialization Routine STATUS: Ethernet Device Not Available – Check for Ethernet Modules  Comm Modules, Protocol 3 indicator turns OFF.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
Test Conducted By			

**TEST CASE 7: Alarm Messages and Emergency Devices**

STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS
133	Turn the Oven Power knob to ON position.	STEP: Start Of Initialization Routine STATUS: Press the Enable Button to Activate the Machine (Blue Button)  Comm Modules, Protocol 3 indicator turns ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
134	Close the LabVIEW application in the computer monitor.	STEP: Start Of Initialization Routine STATUS: Ethernet Device Not Available – Check for Ethernet Modules  Comm Modules, LabView and Protocol 3 indicators turn OFF.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
135	Press the Windows key in the computer keyboard, then type "Oven_DAQ" and press Enter.	Pre-Heat Oven LabVIEW application opens.  STEP: Start Of Initialization Routine STATUS: Press the Enable Button to Activate the Machine (Blue Button)  Comm Modules, Protocol 3 and LabView indicators turn ON.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
136	Press Blue HABILITAR button for 1 second.	Main Menu is displayed.		<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
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## Appendix 4:

### 21 CFR Part 11 Compliance: Assessment Filter

Software Identification:	SRC003427 Rev. A																		
Equipment Identification:	Pre-Heat Oven E19578, MAXIMO ID ES4357																		
<p>Describe the software and explain the intended use, including any data/records produced, and any applicable procedures governing use of the software and/or records:</p> <p>The software listed in Section 5 of this document is used to control the Pre-Heat Oven E19578 with MAXIMO ID ES4357. The software functions are:</p> <table border="1"> <thead> <tr> <th>Source Code</th> <th>Controller</th> <th>Function</th> </tr> </thead> <tbody> <tr> <td rowspan="9">SRC003427 Rev. A</td> <td rowspan="3">PLC Allen Bradley CompactLogix L24ER QB1B</td> <td>Machine Status Display</td> </tr> <tr> <td>Machine Manual Operation</td> </tr> <tr> <td>Machine Automatic Operation</td> </tr> <tr> <td rowspan="3">HMI Allen Bradley PanelView Plus</td> <td>Control Interface with the Machine</td> </tr> <tr> <td>Alarms Visualization</td> </tr> <tr> <td>Machine Status Display</td> </tr> <tr> <td>Safety Controller Omron G9SP</td> <td>Safety Features Control</td> </tr> <tr> <td rowspan="2">DELL Computer OptiPlex 7070</td> <td>Machine Cycle Real Time Monitoring</td> </tr> <tr> <td>Machine Cycle Graphic Print</td> </tr> </tbody> </table>			Source Code	Controller	Function	SRC003427 Rev. A	PLC Allen Bradley CompactLogix L24ER QB1B	Machine Status Display	Machine Manual Operation	Machine Automatic Operation	HMI Allen Bradley PanelView Plus	Control Interface with the Machine	Alarms Visualization	Machine Status Display	Safety Controller Omron G9SP	Safety Features Control	DELL Computer OptiPlex 7070	Machine Cycle Real Time Monitoring	Machine Cycle Graphic Print
Source Code	Controller	Function																	
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If YES, then the equipment must be validated per WE0690 for compliance to 21 CFR Part 11.																			