



**Document Number: PRC097519** 

**Revision: A** 

**Group: Protocol** 

**Type: Protocol Software Validation** 

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## **EQUIPMENT SOFTWARE VALIDATION APPROVAL PAGE**

PROTOCOL	# F	PRC097	7519	REVISION	:	Α	DATE		08/27/2020
COMPLETION REPORT # PRC097520			<b>'520</b>	MVP, E	CP, DP	or SPCR#	<u>:</u> [	C003495	
TITLE:	Cu	ring O	/en w/Truck	E19582 M	axID: ES	S2904 Sc	oftware Va	lidation P	rotocol
PROJECT NAME:MIMASPROJECT LEADER:Rafael Palma					el Palma				
Product Code:	See Tabl	e 1	Product Number:	S	ee Table 1		Batch Number(s	):	N/A
PROTOCOL	INFORMA	ATION							
ORIGINATO	R:	Osv	aldo Mende	Z	PHONI	NUMB	ER:	3	102
ORIGINATO	R TITLE:		Engiı	neer II		SITE:	Р	lanta Inde <sub>l</sub>	pendencia
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PRIORITY S	TATUS (S	pecify Do	cument Due I	Date):				N/A	
Protocol Doci	ument Typ	e and A	pproval Gov	ernance					
Type:	EQUIPM	ENT SO	FTWARE VA	LIDATION					
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#### 1.0 PURPOSE

1.1 The purpose of this Software Validation is to establish by objective that the software controlling Curing Oven E19582, Maximo ID ES2904 is validated. The validation will be used to ensure that the machine functions as intended.

#### 2.0 SCOPE

2.1 The software validation protocol applies only to the software controlling the Curing oven E19582, Maximo ID ES2904 located at Megadyne Coating Line 173 with software SRC003429 Rev A.

#### 3.0 CRITERIA FOR SUCCESS

3.1 The "Actual Results" shall be the same as the "Expected Results" for each test case. For each discrepancy in each test case, a root cause analysis shall be performed, the solution implemented, and test case repeated to verify that the solution is correct and effective. Document the corrective action and results in the Completion Report.

#### 4.0 REFERENCE DOCUMENTS

4.1 Curing Oven machine drawing number E19582

#### 5.0 EQUIPMENT AND MATERIALS

- 5.1 Equipment and Software Identification
  - 5.1.1 Program Number: SRC003429
  - 5.1.2 Program Revision Level: A
  - 5.1.3 Production Line/Location: Megadyne Coating Line 173/ Independencia Plant
  - 5.1.4 Equipment Number: E19582
  - 5.1.5 Juarez Control Number (if applicable): Maximo ID ES2904
  - 5.1.6 Equipment Name: Curing oven
  - 5.1.7 Program Type: PLC (ladder logic)
  - 5.1.8 Development Software: Logix Designer Ver. 30.01
  - 5.1.9 Controller Type: Compact logix L24ER
  - 5.1.10 Program Type: Labview application
  - 5.1.11 Development Software: Labview 2018 Ver 18
  - 5.1.12 Controller Type: PC
  - 5.1.13 Program Type: Safety (function block)
  - 5.1.14 Development Software: Omrom G9SP Configurator
  - 5.1.15 Controller Type: G9SP safety controlled

#### 6.0 RESPONSIBILITIES

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

#### 7.0 STRATEGIES AND ASSUMPTIONS

7.1 Risk Analysis

This Curing Oven is covered by PFMEA RMD001679

	Will this software (or software modification) modify the safety of the process to						
the e	the end user in any manner not addressed by the current PFMEA?						
$\boxtimes$	YES, the RMD001679 will be updated under ECN number ECN029419						
$\Box$	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 for the equipment.
- 7.3 Since the oven can be tested without material no material is needed to perform test cases.
- 7.4 Software is not intended to create or store any quality records, reference Appendix 4 Part 11 Assessment Filter.

#### **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"
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

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Code	Description
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
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

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Code	Description
0064	EZ Clean AIO Lap Flat Blade, 31cm

#### 8.0 TRAINING

- 8.1 Engineers and Technicians that have been involved with the development of the of equipment are not required to be trained on its operation.
- 8.2 Training is required for others assisting in conducting the test procedure if they do not meet the requirement of 8.1. for evidence of training, FM-0000809 will be completed and included in Completion Report's Supporting Files section. Training will cover the following topics:
  - 8.2.1 System Start-Up.
  - 8.2.2 Equipment Operation and Safety Features.
  - 8.2.3 The software validation test procedure.

#### 9.0 PREREQUISITES

9.1 Protocol PRC097519 Rev A. must be released prior to execution.

#### 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. Check mark the results in the proper check box in 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 associate 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 designated associate.
- 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 designated associate.
- 10.7 Any discrepancy or remarks will be analyzed, and corrective action determined by Equipment Engineer or another associate.
- 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 key 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 A Maximo work Order NUPROD will be generated to document new Software source code and will be documented in Completion Report.

#### 11.0 PRODUCT DISPOSITION

11.1 Since the oven can be tested without material no material is needed to perform test cases.

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#### 12.0 COMPLETION ACTIVITIES

- 12.1 When the Software validation protocol has met the 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 PRC097520 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

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# Appendix 1 Equipment Software Requirements Specification And

# **Verification and Validation Matrix for Equipment E19582**

Enter high level description of the machine's operation.

Requirement	Description of requirement	Verified with Test Case(s)
1.0 Machine Power Up, Shut Down	1.1 Equipment must demonstrate that is safe to turn on and turn off	1
	2.1 Equipment must allow to log in as a different user level	2
2.0 Users Edit	2.2 Equipment must allow to access different menu	2
3.0 Create/ Edit Recipe	3.1 Equipment must allow to create a recipe	3
4.0 Auto Mode Cycle	4.1 Equipment must allow cycle start or terminate recipe at the Oven	4
5.0 Manual Mode	5.1 Equipment must allow to access manual mode	5
6.0 Calibration Mode	6.1 Equipment must allow to access calibration mode	6
7.0 Machine Alarm Messages	7.1 Equipment must display alarm messages	7
8.0 Emergency Devices	8.1 Equipment must be safe for operation	8
9.0 Setup	9.1 Equipment must allow to be programmed	9

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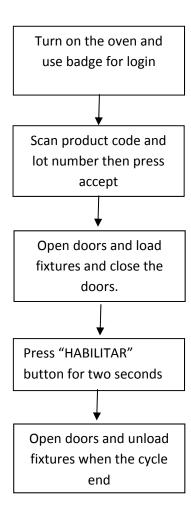
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## Appendix 2

## **Equipment Software Design Description**

This is an embedded software used to control the Curing Oven and allows the user to interact with it. An electronic copy of the software will be documented & recorded under Software SRC003429 Rev A.



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# Appendix 3

# **Equipment Software Test Cases**

	TEST CASE 1: Machine Power Up, Shut Down							
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS		
1	Ensure the emergency stop is released, turn it  Move up main switch to the ON position  Turn secondary switch to the ON position  Turn humidifier switch to the ON position  Turn power and heat switch to the ON position	Oven switch is turned on, Display turn on.  Power, heat and humidifier switch are turned on, oven extraction and recirculation fan are on.		☐ Pass ☐ Fail	☐ Yes ⊠ No			
2	Turn PC ON	PC turns on and LabVIEW application "Main_Oven.vi" is displayed.		☐ Pass ☐ Fail	☐ Yes ⊠ 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 1: Machine Power Up, Shut Down						
3	Press "HABILITAR" button for 2 seconds  Push ON/OFF button on the humidifier control	Display shows main menu screen Humidifier display shows "System ON" Oven is ready for to login		☐ Pass ☐ Fail	☐ Yes ⊠ No		
4	Push ON/OFF button on the humidifier control  Close LabVIEW application: Press file then close all and shut down computer  Turn power and heat switch to OFF position  Turn humidifier switch to OFF position  Turn secondary switch to OFF position  Move down main switch to OFF position	Computer shuts down.  Oven switch is turned off Display.  Power, heat and humidifier switch are turned off oven extraction and recirculation fan are turned off.		☐ Pass ☐ Fail	☐ Yes ⊠ 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 2: Users Edit						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS	
1	Ones the oven is ready for to login:  Using badge reader scanner scan an engineer level validated badge	Display shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass	☐ Yes ☑ No		

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	TEST CASE 2: Users Edit							
2	Press "Edicion de button	Usuarios"	Edit user screen displays information and the follow options:  • Editar usuario  • Eliminar usuario  • Guardar Usuario  • Buscar Usuario  • Nuevo Usuario  • Usuarios disponibles  • Menu Principal  • Cancelar  • Log Out Button			☐ Pass	⊠ Yes □ No	
3	Scan non validate Add a new User	d badge to	Nombre de usua Apellido de usua He De Badge Buscando usua Usuario no exisi moviendo a esp disponible Buscar Usario Nuevo usario Menu Principal Log out Button Save and Cancel Button enabled	ario rio, rente- acio		☐ Pass	⊠ Yes □ No	
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		TEST	CASE 2: Users Edit			
4	Press "Nuevo usuario" button	Shows Next options:  Nombre de usuario Apellido de usuario List "Nivel de usuario"  # De Badge		☐ Pass	⊠ Yes □ No	
5	Type Information of user in "Nombre de usuario", "Apellido de usuario" and nivel of user in List "Nivel de usuario", Press "Guardar Usuario" button	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	☐ Yes ☑ No	
6	Press "Aceptar"	User Added, entered user is displayed in users list		☐ Pass	☐ Yes	
7	Press "Menu Principal" button	Main Menu screen is displayed  Logged user information is displayed		☐ Pass	☐ Yes ☑ No	

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

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	TEST CASE 2: Users Edit							
8	Press Log Out button	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass	□ Yes ⊠ No			
9	Scan user badge previously Added	Display shows main menu screen the following options enabled:  • Seleccion de producto  • Informacion de Maquina  • User information and logout button  Main Oven.vi application shows User and level.		☐ Pass	☐ Yes ⊠ No			
10	Click "Seleccion de producto" button	Display "Seleccion de producto" screen  "Escanee Product Code" is enabled  Machine is disabled  Doors are unlocked, interlock is flashing.  Main Menu button is enabled		☐ Pass ☐ Fail	☐ Yes ⊠ No			

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	TEST CASE 2: Users Edit							
11	Press "Menu Principal" button, and press HABILITAR button for 2 seconds	Display shows Main Menu screen.  System logout logged user.  Machine information button is enabled.  Oven is enabled and ready for to login  Doors are locked		☐ Pass ☐ Fail	□ Yes ⊠ No			
12	Scan Engineer level validated badge	Display shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass	□ Yes ⊠ No			

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	TEST CASE 2: Users Edit							
13	Press "Edicion de Usuarios" button	Edit user screen displays user information and the following options:  Editar usuario Eliminar usuario Guardar Usuario Buscar Usuario Nuevo Usuario Usuarios disponibles Menu Principal Cancelar Log Out Button		☐ Pass ☐ Fail	□ Yes ⊠ No			
14	Select user to edit using arrow up or down, then press enter or scan badge	Selected user is highlighted on the users list.  User information to modify is displayed.		☐ Pass	□ Yes ⊠ No			
15	Press "Editar Usuario"	Name, Last Name and User levels lines are enabled to modify		☐ Pass	☐ Yes			

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	TEST CASE 2: Users Edit							
16	Select new user access level "Calibracion" using arrow up or down arrows then press enter button Press "Guardar usuario" button	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	☐ Yes ☑ No			
17	Press "Aceptar" button	Changes Saved User edit screen shows the new level of user		☐ Pass	☐ Yes			
18	Press "Menu Principal" button	Main Menu screen is displayed  Logged user information is displayed		☐ Pass	☐ Yes			
19	Press Log Out button	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass	☐ Yes ☑ No			

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TEST CASE 2: Users Edit						
20 Scan user badge prev	Display shows main ment the following options enal  Seleccion de pro Calibracion Informacion de N User information logout button  Main Oven.vi application User and level.	oled: oducto Maquina and	☐ Pass ☐ Fail	⊠ Yes □ No		
21 Press "Calibracion" bu	Display shows "Calibracion screen the following option enabled:  Inton  Iniciar Calentador  Encender Enfriamient  Bloquear Puertas  Enviar parametros  Menu principal	ns	☐ Pass ☐ Fail	☐ Yes ☑ No		
22 Press "Menu Principal	" button System logout logged use Buttons show in gray colo machine information button enabled  Oven is ready for to login	or and on is	☐ Pass ☐ Fail	☐ Yes ⊠ No		
Function clude on Completion Report Approval Section) Test Conducted By	Name (type or print)	Date Test Cases Complete (type or print)		Sig	nature/Date	

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	TEST CASE 2: Users Edit					
23	Scan engineer level validated badge	Display shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass ☐ Fail	☐ Yes ⊠ No	
24	Press "Edicion de usuarios" button	Edit user screen displays user information and the following options:  • Editar usuario  • Eliminar usuario  • Guardar Usuario  • Buscar Usuario  • Nuevo Usuario  • Usuarios disponibles  • Menu Principal  • Cancelar  • Log Out Button		☐ Pass	□ Yes ⊠ No	

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	TEST CASE 2: Users Edit						
25	Select user to edit using arrow up or down, then press enter or scan badge	Selected user is highlighted on the users list.  User information to modify is displayed.		☐ Pass	☐ Yes		
26	Press "Editar Usuario" Button	Name, Last Name and User levels lines are enabled to modify		☐ Pass	☐ Yes		
27	Select new user access level "Mantenimiento" using arrow up or down arrows then press enter button Press "Guardar usuario" button	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	☐ Yes ☑ No		
28	Press "Aceptar" button	Changes Saved  User edit screen shows the new level of user		☐ Pass	☐ Yes ☑ No		

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	TEST CASE 2: Users Edit						
29	Press "Menu Principal" button	Main Menu screen is displayed  Logged user information is displayed		☐ Pass	☐ Yes		
30	Press Log Out button	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass	☐ Yes ☑ No		
31	Scan user badge previously edited	Display shows main menu screen the following options enabled:		☐ Pass	☐ Yes ☑ 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 2: Users Edit						
32	Press "Control Manual" button	Display shows "Control Manual" screen the following options enabled:  • Iniciar calentador • Encender Enfriamiento • Monitor de Entradas/Salidas • Bloquear Puertas • Menu Principal		☐ Pass ☐ Fail	□ Yes ⊠ No		
33	Press "Menu Principal"	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass ☐ Fail	☐ Yes ⊠ No		

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	TEST CASE 2: Users Edit					
34	Scan engineer level validated badge	Display Shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass ☐ Fail	☐ Yes ⊠ No	
35	Press "Edicion de usuarios" button	Edit user screen displays user information and the following options:  • Editar usuario  • Eliminar usuario  • Guardar Usuario  • Buscar Usuario  • Nuevo Usuario  • Usuarios disponibles  • Menu Principal  • Cancelar  • Log Out Button		☐ Pass	□ Yes ⊠ No	

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		TEST	CASE 2: Users Edit			
36	Select user to delete using arrow up or down, then press enter or scan	Selected user is highlighted on the users list.  User information to delete is displayed.		☐ Pass	☐ Yes	
37	Press "Eliminar Usuario" button	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	☐ Yes	
38	Press" Aceptar" button	User is deleted from the users list.		☐ Pass	☐ Yes ⊠ No	
39	Press "Menu principal" button	Main Menu screen is displayed  Logged user information is displayed		☐ Pass	□ Yes	
40	Press Log Out button	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass	□ Yes ⊠ No	

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	TEST CASE 3: Create/ edit Recipe							
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS		
1	Ones the oven is ready for to login:  Using badge reader scanner scan an engineer level validated badge.	Display shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass	☐ Yes ⊠ No			
2	To create a new recipe, press "Edicion de modelo" button	Display Shows Edicion de Modelo screen the following options enabled:  • Lista de parametros  • Productos disponibles (list)  • Guardar Modelo  • Menu principal		☐ Pass	☐ Yes ⊠ No			

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	TEST CASE 3: Create/ edit Recipe						
3	Select a free row using arrow up or down, then press.	Product code boxes unlock to add new model information, an empty row is selected in the available products list.		☐ Pass	⊠ Yes		
4	Enter the new information to create:	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	⊠ Yes		
5	Press "Aceptar" button	New Product Code is saved, it is in Available Products list		☐ Pass	⊠ Yes		

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	TEST CASE 3: Create/edit Recipe						
6	Select the model previously created	Model edition screen shows in  "Lista de parametros" next options:  • Temperatura  • Tiempo de Seg(minutos)  • Temperatura minima  • Temperatura maxima  • Tiempo fuera de limite(Min)		☐ Pass ☐ Fail	☐ Yes ☑ No		
7	Type the information of the segments, select box you want to enter the information.  Press "Guardar modelo" Button	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	☐ Yes ⊠ No		
8	Press "Aceptar" button	Display Shows the new model with information previously typed		☐ Pass	☐ Yes ☑ No		

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	TEST CASE 3: Create/ edit Recipe						
9	Press "Menu principal" button	Display shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button		☐ Pass	□ Yes ⊠ No		
10	Press logout button	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass	☐ Yes ⊠ No		

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	TEST CASE 3: Create/ edit Recipe						
11	To edit a recipe, login as an Engineer	Display shows Main Menu options enabled:  Seleccion de producto Edicion de usuarios Edicion de Modelo Control Manual Calibracion Informacion de maquina User information and logout button Main Oven.vi application shows User and level		☐ Pass	☐ Yes ⊠ No		
12	Press "Edicion de modelo" button	Display Shows "Edicion de Modelo" screen the following options enabled:  • Lista de parametros  • Productos disponibles (list)  • Guardar Modelo  • Menu principal		☐ Pass	☐ Yes ⊠ No		
13	Select a Product Code to edit using arrow up or down, then press.	"Edicion de modelo" screen shows information of selected Product Code.		☐ Pass	☐ Yes		

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	TEST CASE 3: Create/ edit Recipe							
14	Enter the new information to edit:	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	□ Yes ⊠ No			
15	Press "Aceptar" button	New Product Code is saved, it is in Available Products list		☐ Pass	☐ Yes ⊠ No			
16	Select the model previously edited	Model edition screen shows in  "Lista de parametros" next options:  Temperatura Tiempo de Seg(minutos) Temperatura minima Temperatura maxima Tiempo fuera de limite(Min)		☐ Pass ☐ Fail	□ Yes ⊠ No			
17	Type the information of the segments, select box you want to enter the information.  Press "Guardar modelo" Button	Display shows message "Realmente desea Aceptar Cambios" with button options "aceptar" "cancelar"		☐ Pass	☐ Yes			

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Latest Released: YES State: Released

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Group: Protocol Type: Protocol Software Validation

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	TEST CASE 3: Create/ edit Recipe						
18	Press "Aceptar" button	Display Shows the new model with information previously typed		☐ Pass	☐ Yes ☑ No		
19	Press "Menu principal" button	Display shows Main Menu options enabled:  • Seleccion de producto  • Edicion de usuarios  • Edicion de Modelo  • Control Manual  • Calibracion  • Informacion de maquina  • User information and logout button		☐ Pass ☐ Fail	☐ Yes ☑ No		
20	Press logout button	System logout logged user. Buttons show in gray color and machine information button is enabled  Oven is ready for to login		☐ Pass	☐ Yes ☑ No		

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Group: Protocol Type: Protocol Software Validation

	TEST CASE 4: Auto mode Cycle						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS	
1	Ones the oven is ready for to login:  Using badge reader scanner scan an operator level validated badge.	Display Shows main menu screen the following options enabled:  Seleccion de producto Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass	□ Yes ⊠ No		
2	Click "Seleccion de producto" button	Display Shows "Seleccion de producto" screen.  "Escanee Product Code" is enabled  Machine is disabled  Doors are unlocked, interlock is flashing.  "Menu principal" is enabled		☐ Pass	□ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle					
3	Scan a barcode for valid product code	Shows product selection screen.  Shows in "Paso" line "Capture numero de lote"  Machine is disabled		☐ Pass	⊠ Yes □ No	
4	Scan the barcode for Lot Number	The information scanned is showed.  Press "Aceptar" to Continue or "Cancelar" to Start Oven massages appear.  Enabled "Aceptar" and "Cancelar" buttons.		☐ Pass ☐ Fail	⊠ Yes □ No	
5	Press "aceptar" button	Shows production screen.  Maquina no habilitida Shows information of product code, lot number and information of model recipe. Displayed the profile of badge and log out button. Displayed message in "Paso" line "Abra puertas e introduzca el producto" and "No interrumpa la maquina" in "Estado" line		☐ Pass ☐ Fail	⊠ Yes □ No	

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	TEST CASE 4: Auto mode Cycle						
6	Open doors and load fixtures	Maquina no habilitada.  Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "Cierre guardas" in "Estado" line.		☐ Pass ☐ Fail	☐ Yes ⊠ No		
7	Close doors	Maquina no habilitada Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "maquina no habilitada- presione habilitar (Boton Azul)" in "Estado" line.		☐ Pass ☐ Fail	☐ Yes ⊠ No		
8	Press "HABILITAR" button for 2 seconds	The oven Cycle Start the recipe selected.  Humidifier start cycle and damper is open  Door is locked		☐ Pass ☐ Fail	☐ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle						
9	Press emergency stop button	Displayed initialization screen shows and the line status shows "Jale paro de emergencia posterior"  Humidifier stop cycle and damper closes.  System logout logged user.		☐ Pass ☐ Fail	□ Yes ⊠ No		
10	Turn emergency stop button	Display shows initialization screen shows and the line status shows "Presione boton de habilitar para activar maquina (boton azul)		☐ Pass	☐ Yes ⊠ No		
11	Press "HABILITAR" button for 2 seconds	Display shows main menu screen and machine is ready for log in		☐ Pass ☐ Fail	□ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle					
12	Perform Login with badge of Operator	Displays shows main menu screen the following options enabled:  Seleccion de producto Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass ☐ Fail	□ Yes ⊠ No	
13	Press "Seleccion de producto" button	Display Shows "Selection de producto" screen.  Escanee Product Code is enabled  Machine is disabled  Doors are unlocked, interlock is flashing.  Main Menu button is enabled		☐ Pass ☐ Fail	□ Yes ⊠ No	
14	Scan a barcode for valid product code	Shows product selection screen.  Shows in step line "Capture numero de lote"  Machine is disabled		☐ Pass	☐ Yes ⊠ No	

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	TEST CASE 4: Auto mode Cycle					
15	Scan the barcode for lot number	The information scanned is showed.  Press "Aceptar" to Continue or "Cancelar" to Start Oven massages appear.  Enabled "Aceptar" and "Cancelar" buttons.		☐ Pass ☐ Fail	□ Yes ⊠ No	
16	Press "Aceptar" button	Shows production screen.  Maquina no habilitida Shows information of product code, lot number and information of model recipe. Displayed the profile of badge and log out button. Displayed message in "Paso" line "Abra puertas e introduzca el producto" and "No interrumpa la maquina" in "Estado" line		☐ Pass ☐ Fail	☐ Yes ⊠ No	
17	Open doors and load fixtures	Maquina no habilitada.  Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "Cierre guardas" in "Estado" line.		☐ Pass ☐ Fail	☐ Yes ⊠ No	

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	TEST CASE 4: Auto mode Cycle						
18	Close doors	Maquina no habilitada Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "maquina no habilitada- presione habilitar (Boton Azul)" in "Estado" line.		☐ Pass	☐ Yes ⊠ No		
19	Press "HABILITAR" button for 2 seconds	The oven Cycle Start the recipe selected.  Humidifier start cycle and damper opens  Door is locked		☐ Pass ☐ Fail	□ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle						
20	Close LabVIEW application of computer press file then close	Display shows production display, "Paso" line shows" Comunicacion de modulos no detectada en sistemas" and "Estado" line "Presione Boton de Reset para continuar", the Lamp shows red color and FALLA button shows flashing yellow color  Humidifier stop cycle and damper closed		☐ Pass ☐ Fail	□ Yes ⊠ No		
21	Open LabVIEW application trough "Application" shortcut in the desktop	The application "Main_Oven.vi" opens in the computer		☐ Pass	☐ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle						
22	Press "FALLA" button	Displays shows production display, "Paso" line shows" Numero de lote malo" and "Estado" line" Abra guardas para retirar producto" Machine not enabled		☐ Pass ☐ Fail	□ Yes ⊠ No		
23	Open guards Close guards	Shows product selection screen. Shows information of product code and main menu button. Machine is disabled		☐ Pass	☐ Yes ⊠ No		
24	Scan a barcode for valid product code	Shows product selection screen. Shows in "Paso" line "Escanee Product code". Main menu button. Machine is disabled		☐ Pass	□ Yes ⊠ No		
25	Scan the barcode for lot number	The information scanned is showed. Enabled "Aceptar" and "Cancelar" buttons.		☐ Pass	☐ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle						
26	Press "Aceptar" button	Shows production screen.  Maquina no habilitida Shows information of product code, lot number and information of model recipe. Displayed the profile of badge and log out button. Displayed message in "Paso" line "Abra puertas e introduzca el producto" and "No interrumpa la maquina" in "Estado" line		☐ Pass ☐ Fail	☐ Yes ⊠ No		
27	Open doors and load fixtures	Maquina no habilitada.  Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "Cierre guardas" in "Estado" line.		☐ Pass	☐ Yes ⊠ No		
28	Close doors	Maquina no habilitada Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "maquina no habilitada- presione habilitar (Boton Azul)" in "Estado" line.		☐ Pass	☐ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle						
29	Press "HABILITAR" button for 2 seconds	The oven Cycle Start the recipe selected.  Humidifier start cycle and damper opens  Door is locked		☐ Pass ☐ Fail	☐ Yes ⊠ No		
30	Wait for the cycle to end	Shows in "Paso" line "Ciclo completo, Remueva producto" and "Abra guardas para retirar producto" in "Estado" line. Machine disabled Cooling cycle start		☐ Pass ☐ Fail	☐ Yes ⊠ No		
31	Open doors	Shows product selection screen. information of product code and main menu button. Machine is disabled		☐ Pass ☐ Fail	□ Yes ⊠ No		

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	TEST CASE 4: Auto mode Cycle						
32	Press "Menu Principal" Button	System logout logged user. Buttons show in gray color and machine information button is enabled.  Oven is ready for to login.		☐ Pass	☐ Yes ⊠ No		

	TEST CASE 5: Manual mode							
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS		
1	Ones the oven is ready for to login:  Using badge reader scanner scan a Maintenance level validated badge.	Displays Shows main menu screen the following options enabled:  Seleccion de producto Control Manual User information and logout button  Main Oven.vi application shows User and level		☐ Pass	□ Yes ⊠ No			
2	Press "Control Manual" button	Shows "Control manual" screen and displayed next options:  Iniciar calentador  Encender enfriamiento  Bloquear Puertas  Menu Principal  Monitor de Entradas/Salidas		☐ Pass	□ Yes ⊠ No			

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Latest Released: YES State: Released

**Group: Protocol** 

Type: Protocol Software Validation

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	TEST CASE 5: Manual mode					
3	Type in line "Control de temperatura" the desired temperature and press "Iniciar Calentador" Button.	The oven starts to heat until temperature desired, the oven stops to heat when desired temperature is reached.  Heater Switch starts blinks with a color white.		☐ Pass	□ Yes ⊠ No	
4	Press "Encender Enfriamiento" Button	The oven starts cooling, Pressed button changes light gray color. Inlet and exhaust dumper cooling system moves to 90 position.		☐ Pass	☐ Yes	
5	Press again "Encender Enfriamiento" Button	The oven stops cooling and the pressed button changes dark gray color. Inlet and exhaust dumper cooling system moves to 0 position.		☐ Pass	☐ Yes ☑ No	
6	Press "Bloquear puertas" button	Passed button changes light gray color. Doors are unlocked. Machine is disabled.		☐ Pass	☐ Yes ⊠ No	

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	TEST CASE 5: Manual mode							
7	Press again "Bloquear puertas" button	Passed button changes dark gray color. Doors are locked		☐ Pass	□ Yes ⊠ No			
8	Press "HABILITAR" button for 2 seconds	Machine is enabled		☐ Pass ☐ Fail	☐ Yes ⊠ No			
9	Press "Monitor de Entradas/Salidas" Button	Input/Output screen is displayed and "Pantalla anterior" button		☐ Pass	⊠ Yes □ No			

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	TEST CASE 5: Manual mode							
10	Press "pantalla anterior" button	Shows "Control manual" screen and displayed next options:  Iniciar calentador  Encender enfriamiento  Bloquear Puertas  Menu Principal  Monitor de Entradas/Salidas		☐ Pass ☐ Fail	□ Yes ⊠ No			
11	Press "Menu Principal" button	System logout logged user. Buttons show in gray color and machine information button is enabled.  Oven is ready for to login.		☐ Pass	☐ Yes ⊠ No			

TEST CASE 6: Calibration mode						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS

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		TI	EST CASE	6: Calibration mode				
1	Ones the oven is ready login:  Using badge reader so scan a Calibration leve validated badge.	Calibracion     Informacion de maquina     Informacion de maquina	out button		☐ Pass ☐ Fail	□ Yes ⊠ No		
2	Press "Calibracion" but	Shows screen "Calibracion" displayed next options:  Iniciar calentador  Encender Enfriamiento  Bloquear puertas  Parametro alto  Parametro bajo  Enviar parametros  Control de temperatura  Menu principal	and		☐ Pass	☐ Yes ⊠ No		
3	Type in line "Control de temperatura" the desire temperature and press Calentador" Button.	ed desired, the oven stops to h	eat when ned.		☐ Pass	☐ Yes ⊠ No		
Function clude on Completion Report Approval Section)		Name (type or print)	Dat	te Test Cases Complete (type or print)		Signat	ure/Date	
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	TEST CASE 6: Calibration mode						
4	Press "Encender Enfriamiento" Button	The oven starts cooling, Pressed button changes light blue color. Inlet and exhaust dumper cooling system moves to 90 position.		☐ Pass	☐ Yes ☑ No		
5	Press again "Encender Enfriamiento" Button	The oven stops cooling and the pressed button changes blue color. Inlet and exhaust dumper cooling system moves to 0 position.		☐ Pass	☐ Yes ☑ No		
6	Press "Bloquear puertas" button	Passed button changes light blue color. Doors are unlocked. Machine is disabled.		☐ Pass	☐ Yes ☑ No		
7	Press again "Bloquear puertas" button	Passed button changes blue color. Doors are locked		☐ Pass	☐ Yes ☑ 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 6: Calibration mode							
8	Press "HABILITAR" button for 2 seconds	Machine is enabled		☐ Pas				
9	Type information in "Compesacion alta" line and Press "Enviar parametros" button	Information shows in "Parametro alta" line		☐ Pas				
10	Type information in "Compesacion baja" line and Press "Enviar parametros" button	Information shows in "Parametro baja" line		☐ Pas				
11	Press "Menu Principal" button	System logout logged user. Buttons show in gray color and machin information button is enabled.  Oven is ready for to login.	е	☐ Pas				
	TEST CASE 7: Machine Alarm Messages							
STEP	PROCEDURE		ACTUAL RESULT	Pass /	Printout of screen	COMMENTS		

	TEST CASE 7: Machine Alarm Messages						
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS	

Function (Include on Completion Report Approval Section)	Name (type or print)	Date Test Cases Complete (type or print)	Signature/Date
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Latest Released: YES State: Released



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		TEST CASE	7: Machine Alarm Messages			
1	Ones the oven is ready for to login:  Using badge reader scanner scan an operator level validated badge.	Display shows main menu screen the following options enabled:  Seleccion de producto Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass ☐ Fail	□ Yes ⊠ No	
2	Press "Seleccion de producto" button	Display Shows "Seleccion de producto" screen.  Escanee Product Code is enabled  Machine is disabled  Doors are unlocked, interlock is flashing.  Main Menu button is enabled		☐ Pass	☐ Yes ⊠ No	

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	TEST CASE 7: Machine Alarm Messages						
3	Scan a barcode valid product code	Shows product selection screen. Shows in "Paso" line "Escanee Product code". Main menu button. Machine is disabled		☐ Pass	□ Yes ⊠ No		
4	Scan the barcode for lot number	The information scanned is showed.  "Press "Aceptar" to Continue or "Cancelar" to Start Oven massages appear.  Enabled "Aceptar" and "Cancelar" buttons.		☐ Pass ☐ Fail	□ Yes ⊠ No		
5	Press "Aceptar" button	Shows production screen.  Maquina no habilitida Shows information of product code, lot number and information of model recipe. Displayed the profile of badge and log out button. Displayed message in "Paso" line "Abra puertas e introduzca el producto" and "No interrumpa la maquina" in "Estado" line		☐ Pass ☐ Fail	□ Yes ⊠ No		

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	TEST CASE 7: Machine Alarm Messages							
6	Open doors and load fixtures	Maquina no habilitada.  Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "Cierre guardas" in "Estado" line.		☐ Pass	□ Yes ⊠ No			
7	Close doors	Maquina no habilitada Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "maquina no habilitada- presione habilitar (Boton Azul)" in "Estado" line.		☐ Pass	□ Yes ⊠ No			
8	Press "HABILITAR" button for 2 seconds	The oven Cycle Start the recipe selected.  Humidifier start cycle and damper opens  Door is locked		☐ Pass	☐ Yes ☑ 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 7: Machine Alarm Messages							
9	Close LabVIEW application of computer press file then close	Display shows production display, "Paso" line shows "Comunicacion de modulos no detectada en sistemas" and "Estado" line "Presione Boton de Reset para continuar", the Lamp shows red color and FALLA button shows flashing yellow color  Humidifier stop cycle and damper closed		□ Pass □ Fail	□ Yes ⊠ No			
10	Open LabVIEW application trough "Application" shortcut in the desktop	The application "Main_Oven.vi" opens in the computer		☐ Pass ☐ Fail	□ Yes ⊠ 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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State: Released

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	TEST CASE 7: Machine Alarm Messages						
11	Press "FALLA" button	Displays shows production display, "Paso" line shows "Numero de lote malo" and "Estado" line "Abra guardas para retirar producto" Machine not enabled		☐ Pass ☐ Fai	☐ Yes ⊠ No		
12	Open doors Close doors	"Seleccion de producto" screen is displayed		☐ Pass	☐ Yes ⊠ No		
13	Press "Menu Principal" button	System logout logged user. Buttons show in gray color and machine information button is enabled.  Oven is ready for to login.		☐ Pass ☐ Fail	□ Yes ⊠ No		

	TEST CASE 8: Emergency Devices									
	STEP	PROCED	URE	EXPECTED RESU	JLT	ACTUAL RESULT	Pass / Fail	Printout of screen Required	COMMENTS	
(In	clude on C	Inction Completion Report val Section)	(	Name type or print)		Date Test Cases Complete (type or print)		Si	gnature/Date	
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	TEST CASE 8: Emergency Devices						
1	Ones the oven is ready for to login:  Using badge reader scanner scan an operator level validated badge.	Display shows main menu screen the following options enabled:  Seleccion de producto Informacion de maquina User information and logout button  Main Oven.vi application shows User and level		☐ Pass ☐ Fail	☐ Yes ⊠ No		
2	Perform run a recipe steps for auto mode cycle	The oven Cycle Start the recipe selected. Door is locked		☐ Pass	☐ Yes ⊠ No		
3	Wait that the temperature to be above 130 F Push the Emergency Stop button	Display displayed initialization screen shows and the line "Estado" shows "Jale paro de emergencia posterior" and line "Paso" shows "Iniciando rutina de encendido" Humidifier stop cycle and damper closes.  System logout logged user.  Door is locked		☐ Pass	☐ Yes ⊠ No		

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	TEST CASE 8: Emergency Devices							
4	Turn emergency stop button	Displayed initialization screen shows and the line "Estado" shows "Presione boton de habilitar para activar maquina (boton azul)"		☐ Pass ☐ Fail	□ Yes ⊠ No			
5	Press "HABILITAR" button for 2 seconds	The oven stars cooling until the temperature is below 130°F. Display shows main menu screen and machine is ready for log in		☐ Pass ☐ Fail	☐ Yes ☑ No			

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	TEST CASE 8: Emergency Devices						
6	Perform Login with badge of operator	Display shows main menu screen the following options enabled:  • Seleccion de producto  • Informacion de maquina  • User information and logout button  Main Oven.vi application shows User and level		☐ Pass	☐ Yes ⊠ No		
7	Press "Seleccion de producto" button	Display Shows "Seleccion de producto" screen.  Escanee Product Code is enabled  Machine is disabled  Doors are unlocked, interlock is flashing.  Main Menu button is enabled		☐ Pass	☐ Yes ⊠ 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 8: Emergency Devices						
8	Scan a barcode valid product code	Shows product selection screen. Shows in "Paso" line "Escanee Product code". Main menu button. Machine is disabled		☐ Pass	☐ Yes ⊠ No		
9	Scan the barcode for lot number	The information scanned is showed.  "Press "Aceptar" to Continue or "Cancelar" to Start Oven massages appear.  Enabled "Aceptar" and "Cancelar" buttons.		☐ Pass ☐ Fail	□ Yes ⊠ No		
10	Press "Aceptar" button	Shows production screen.  Maquina no habilitida Shows information of product code, lot number and information of model recipe. Displayed the profile of badge and log out button. Displayed message in "Paso" line "Abra puertas e introduzca el producto" and "No interrumpa la maquina" in "Estado" line		☐ Pass ☐ Fail	□ Yes ⊠ 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 8: Emergency Devices					
11	Open doors  Close only the door of the interlock	Machine is disabled The HABILITAR button is disabled don't permitted enabled		☐ Pass	☐ Yes ☑ No	
12	Open door Close both doors Press HABILITAR button	Machine is enabled		☐ Pass	☐ Yes ☑ No	
13	Press emergency stop button	Display displayed initialization screen shows and the line "Estado" shows "Jale paro de emergencia posterior" and line "Paso" shows "Iniciando rutina de encendido" Humidifier stop cycle and damper closes.  System logout logged user.  Door is locked		☐ Pass ☐ Fail	☐ Yes ☑ 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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	IEST CASE 8. Emergency Devices						
14	Turn emergency stop button	Displayed initialization screen shows and the line "Estado" shows "Presione boton de habilitar para activar maquina (boton azul)"		☐ Pass ☐ Fail	□ Yes ⊠ No		
15	Press "HABILITAR" button for 2 seconds	Oven is ready for to login.		☐ Pass	☐ Yes		
TEST CASE 9: Setup							
STEP	PROCEDURE	EXPECTED RESULT	ACTUAL RESULT	Pass Fail	of s	tout creen	COMMENTS

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

State: Released



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	TEST CASE 9: Setup					
1	Perform Login with badge of operator	Display shows main menu screen the following options enabled:  • Seleccion de producto  • Informacion de maquina  • User information and logout button  Main Oven.vi application shows User and level		☐ Pass ☐ Fail	⊠ Yes □ No	
2	Press "Seleccion de producto" button	Display Shows "Seleccion de producto" screen.  Escanee Product Code is enabled  Machine is disabled  Doors are unlocked, interlock is flashing.  Main Menu button is enabled		☐ Pass	⊠ Yes □ 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 9: Setup					
3	Scan a barcode valid product code	Shows product selection screen. Shows in "Paso" line "Escanee Product code". Main menu button. Machine is disabled		☐ Pass	⊠ Yes □ No	
4	Scan the barcode for lot number	The information scanned is showed.  "Press "Aceptar" to Continue or "Cancelar" to Start Oven massages appear.  Enabled "Aceptar" and "Cancelar" buttons.		☐ Pass ☐ Fail	⊠ Yes □ No	
5	Press "Aceptar" button	Shows production screen.  Maquina no habilitida Shows information of product code, lot number and information of model recipe. Displayed the profile of badge and log out button. Displayed message in "Paso" line "Abra puertas e introduzca el producto" and "No interrumpa la maquina" in "Estado" line		☐ Pass ☐ Fail	☐ Yes ☑ 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 9: Setup					
6	Open doors and load fixtures	Maquina no habilitada.  Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "Cierre guardas" in "Estado" line.		☐ Pass	□ Yes ⊠ No	
7	Close doors	Maquina no habilitada Displayed message in "Paso" line "Espere por condiciones para iniciar ciclo" and "maquina no habilitada- presione habilitar (Boton Azul)" in "Estado" line.		☐ Pass	□ Yes ⊠ No	
8	Press "HABILITAR" button for 2 seconds	The oven Cycle Start the recipe selected.  Humidifier start cycle and damper opens  Door is locked		☐ Pass	☐ Yes ⊠ 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: SRC003429 Rev A						
Equipment Identification: Curing oven ID ES2904						
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:						
The software SRC003429 Rev A is an embedded software used to control the Curing Over and allows the user to interact with it.						
Software ID	Software Type	Software Function				
	Safety Software	Controls temperature profile and safety features in this machine.				
SRC003429 Rev A	PLC Software	Controls operation and safety features in this machine.				
PC Software Controls status indicators in this machine.						
This software does not store any electronic records.						
<ol> <li>Does the software store GXP-related information in electronic format?</li> <li>Yes</li> <li>No</li> </ol>						
If YES, then the equipment must be validated per WE0690 for compliance to 21 CFR Part 11.						

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