Document Number: PRC097117
Revision: A
Group: Protocol
Type: Protocol Software Validation
State: Released
Latest Released: YES
Implemented Date: 08/10/2020
Stamp Date: Monday, August 10, 2020 10:50:31 AM EST

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Protocol Number: PRC097117

Revision: A **Page: 1 of 23**

EQUIPMENT SOFTWARE VALIDATION APPROVAL PAGE

PROTOCOL #	**PRC097117**	**REVISION:**	**A**	**DATE:**	**08/03/2020**
COMPLETION REPORT #	**PRC097119**	**MVP, ECP, DP or SPCR#**		**DC003495**	

TITLE:	**E20291 PTFE Refrigeration Station Software Validation**				
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:**	**Planta Independencia**

PRIORITY STATUS (Specify Document Due Date):	**N/A**

Protocol Document Type and Approval Governance			
Type:	**EQUIPMENT SOFTWARE VALIDATION**		
Organization Responsible-Governance	☐ **New Product Development** **Pre-Launch/Stabilization** **(CP0258 or CP0150 if applicable)**	☒ **Lifecycle Engineering** **Post Stabilization** **(CP0150 if applicable)**	☐ **External Manufacturing** **(CP0231/CP0150)**

APPROVAL LIST:

Function	Name	User I.D.	Signature/Date
ORIGINATOR	Osvaldo Mendez	OMendezC	eSing in EPICENTER
MEST Equipment Eng.	Javier Diaz	JDiaz24	eSing in EPICENTER
Plant Quality Eng.	Victor Cantu	vcantusi	eSing in EPICENTER
BU Manufacturing Eng.	Irvin Rivera	Iriver36	eSing in EPICENTER
Lifecycle Quality Engineer	Ihsan Samara	isamara	eSing in EPICENTER

DISTRIBUTION LIST: (create as necessary)

Revision	Date	Change Description
A	08/03/2020	Original Issue

1.0 PURPOSE

1.1 The purpose of this Software Validation is to establish by objective evidence that the software controlling E20291 PTFE Refrigeration Station Maximo ID: ES2910 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 PTFE Refrigeration Station E20291 Maximo ID: ES2910, equipment applicable for all Megadyne product codes, located at Coating Line 173 with software SRC003419 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 PTFE Refrigeration Station drawing number E20291

5.0 EQUIPMENT AND MATERIALS

5.1 Equipment and Software Identification

5.1.1 Program Number: SRC003419

5.1.2 Program Revision Level: A

5.1.3 Production Line/Location: Megadyne Coating Line 173/ Independencia Plant

5.1.4 Equipment Number: E20291

5.1.5 Juarez Control Number (if applicable): Maximo ID ES2910

5.1.6 Equipment Name: PTFE Refrigeration Station

5.1.7 Program Type: Labview Interface.

5.1.7.1 Development Software: Labview 2018 Ver 18

5.1.7.2 Controller Type: PC

6.0 RESPONSIBILITIES

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 PTFE Refrigeration Station is covered by PFMEA RMD001679

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?	
☒	YES, the RMD001679 will be updated under ECN number ECN029419
☐	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 The PTFE Refrigeration Station will be tested with maximum number of PTFE material allowed in the fridge. This will represent most extreme case.

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
0014ABN	EZ Clean Flat Blade, 4.0", BNS
0014AMBN	EZ Clean Modified Blade, 4.0", Bulk Non-Sterile
0014MBN	EZ Clean Modified Flat Blade, 6.5", Bulk Non-Sterile
0014AMD	EZ Clean Modified Blade, 4.0" with Nosecone
0014MD	EZ Clean Modified Flat Blade, 6.5" with Nosecone
0029M	EZ Clean Modified Bayonet Flat Blade, 5.75"
C117M	EZ Clean Modified Flat Blade, 4.72", Custom

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

8.0 TRAINING

8.1 Training is required for operators, mechanics, technicians, engineers, and other personnel associated with running the protocol except for the originator and approvers

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 PRC097117 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, 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 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 other 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 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 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 Product used for testing will be returned to manufacturing since it is only used as mass in the fridges during testing, handled accordingly and placed in calibrated fridges.

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 PRC097119 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 E20291

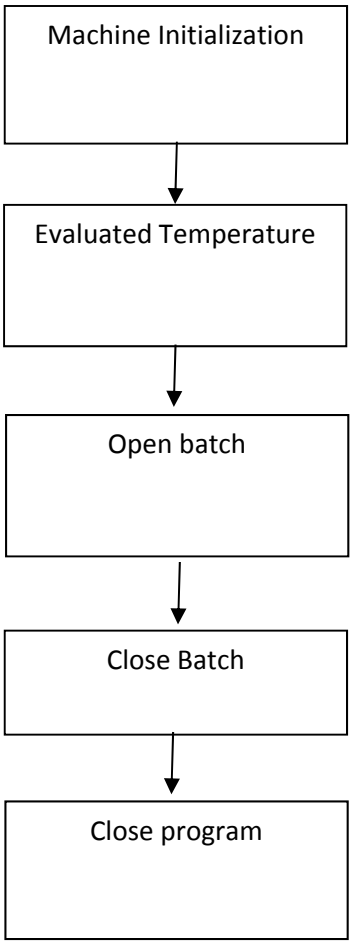
Enter high level description of the machine's operation.

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
2.0 Edit Values (Temperature)	*2.1 Equipment must allow to check temperature values at the refrigeration station PTFE.*	2
3.0 Open/Close Batches	*3.1 Equipment must allow to open and close batches*	3
4.0 Machine Alarm Messages	*4.1 Equipment must display alarm messages.*	4

Appendix 2

Equipment Software Design Description

This is an embedded software used to control the PTFE Refrigeration Station and allows the user to interact with it. An electronic copy of the software will be documented & recorded under Software SRC003419 Rev A.



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	Turn Paint refrigerator switch to ON position	Paint refrigerator switch is turned on, display its turn on and ups turn on. Repeat for all three refrigerators.		☐ Pass ☐ Fail	☐ Yes ☒ No	
2	Turn PC ON	PC turns on and LabVIEW application "_Main.vi" is displayed.		☐ Pass ☐ Fail	☒ Yes ☐ No	
3	Close LabVIEW application press file then close all and shut down computer Turn Refrigerator switch to OFF position Push button power of UPS	Computer shuts down. Refrigerator switch is turned off, display turns off. UPS is 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**
Test Conducted By			

TEST CASE 2: Edit Values (Temperature)						
STEP	**PROCEDURE**	**EXPECTED RESULT**	**ACTUAL RESULT**	**Pass / Fail**	**Printout of screen Required**	**COMMENTS**
1	Repeat steps #1 and #2 from Test Case 1. Machine is ready.	Shows in _Main.vi displays next Menu: • Number of Fridges • Abrir Lote • Cerrar Lote • Rango de Temperatura • Historial de lotes • Salir		☐ Pass ☐ Fail	☒ Yes ☐ No	
2	Check the temperature of the Fridge 1 also temperature of at _Main.vi	The temperature shows at display of Fridge 1 must be same of the information shows at _ Main.vi “Refrigerador 01” with a tolerance of +/-1°F		☐ Pass ☐ Fail	☐ Yes ☒ No	
3	Check the temperature of the Fridge 2 also temperature of at _Main.vi	The temperature shows at display of Fridge 2 must be same of the information shows at _ Main.vi “Refrigerador 02” with a tolerance of +/-1 °F		☐ Pass ☐ Fail	☐ 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			

TEST CASE 2: Edit Values (Temperature)						
4	Check the temperature of the Fridge 3 also temperature of at _Main.vi	The temperature shows at display of Fridge 3 must be same of the information shows at _ Main.vi “Refrigerador 03” with a tolerance of +/-1 °F		☐ Pass ☐ Fail	☒ Yes ☐ No	
5	Check the temperature of Fridge 1 it stays 39 °F – 49.5° F +/- 1 °F	The temperature shows at _Main.vi shows “Temperatura dentro de rango” in color blue if temperature it stays 39 °F- 49.5°F +/- 1 °F		☐ Pass ☐ Fail	☒ Yes ☐ No	
6	Check the temperature of Fridge 2 it stays 39 °F- 49.5°F +/- 1 °F	The temperature shows at _ _Main.vi shows “Temperatura dentro de rango” in color blue if temperature it stays 39 °F- 49.5°F +/- 1°F		☐ Pass ☐ Fail	☒ Yes ☐ No	
7	Check the temperature of Fridge 3 it stays 39 °F- 49.5°F +/- 1 °F	The temperature shows at _ _Main.vi shows “Temperatura dentro de rango” in color blue if temperature it stays 39 °F- 49.5°F +/- 1°F		☐ Pass ☐ Fail	☒ Yes ☐ No	
8	Place in Fridge 1 PTFE material, check the temperature of Fridge 1 it stays 39 °F- 49.5°F +/- 1 °F	The temperature shows at _Main.vi shows “Temperatura dentro de rango” in color blue if temperature it stays 39 °F- 49.5°F +/- 1°F	Number of PTFE gallons used:	☐ Pass ☐ Fail	☐ Yes ☒ No	
9	Place in Fridge 2 PTFE material, check the temperature of Fridge 1 it stays 39 °F- 49.5°F +/- 1 °F	The temperature shows at _Main.vi shows “Temperatura dentro de rango” in color blue if temperature it stays 39 °F- 49.5°F +/- 1°F	Number of PTFE gallons used:	☐ Pass ☐ Fail	☐ 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			

TEST CASE 2: Edit Values (Temperature)						
10	Place in Fridge 3 PTFE material, check the temperature of Fridge 1 it stays 39 °F- 49.5°F +/- 1 °F	The temperature shows at _Main.vi shows “Temperatura dentro de rango” in color blue if temperature it stays 39 °F- 49.5°F +/- 1 °F	Number of PTFE gallons used:	☐ Pass ☐ Fail	☐ Yes ☒ No	
11	Press “Salir” at _Main.vi	The program of LabView should close.		☐ Pass ☐ Fail	☐ Yes ☒ No	

TEST CASE 3: Open/Close Batches						
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**
Test Conducted By			

TEST CASE 3: Open/Close Batches						
1	Repeat steps #1 and #2 from Test Case 1. Machine is ready.	Shows in _Main.vi displays next Menu: • Number of Fridges • Abrir Lote • Cerrar Lote • Rango de Temperatura • Historial de lotes • Salir		☐ Pass ☐ Fail	☐ Yes ☒ No	
2	Select “Abrir Lote” at “Refrigerador 01”	Shows “Abrir lote, ingrese número de lote”, Numero de lote, Usuario, Abrir lote, Cancelar, Conexion Escaner		☐ Pass ☐ Fail	☒ Yes ☐ No	
3	Scan barcode of the batch	Shows number of the batch in “Numero de Lote”, shows instructions “Seleccione Abrir Lote o Cancelar” section in “Usuario” reminds empty.		☐ Pass ☐ Fail	☒ Yes ☐ No	
4	Write User name	Write user name in “usuario”		☐ Pass ☐ Fail	☒ 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			

TEST CASE 3: Open/Close Batches						
5	Press “Abrir lote”	_Main.VI Shows a table “Lista de Lotes Abiertos Actualmente” the number of batch in section “Numero de lote” also Date/time in section “Fecha de inicio”		☐ Pass ☐ Fail	☒ Yes ☐ No	
6	Close Batch	Click in number of batch in table “Lista de Lotes abiertos actualmente” the batch turns orange and press “Cerrar Lote” number of batch and Date/Time should be deleted in the table.		☐ Pass ☐ Fail	☐ Yes ☒ No	
7	Select “Historial de lotes” in Refrigerador 01	Shows in folder “FridgeDataLog_01” Excel files of batches was opened and closed.		☐ Pass ☐ Fail	☐ Yes ☒ No	
8	Select one Excel file	Excel file shows: • Timestamp • Temperature • Number of batch • User		☐ Pass ☐ Fail	☐ Yes ☒ No	
9	Close excel file	Excel file is closed and shows folder “FridgeDataLog_01”		☐ Pass ☐ Fail	☐ Yes ☒ No	
10	Close folder “FridgeDataLog_01”	Folder “FridgeDataLog_01” is closed and shows _Main.vi		☐ Pass ☐ Fail	☐ 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			

TEST CASE 3: Open/Close Batches						
11	Select “Abrir Lote” at “Refrigerador 01”	Shows “Abrir lote, ingrese número de lote”, Numero de lote, Usuario, Abrir lote, Cancelar, Conexion Escáner.		☐ Pass ☐ Fail	☐ Yes ☒ No	
12	Scan barcode of the batch	Shows number of the batch in “Numero de Lote”, shows instructions “Seleccione Abrir Lote o Cancelar” section in “Usuario” reminds empty.		☐ Pass ☐ Fail	☐ Yes ☒ No	
13	Select “Cancelar”	Function of open batch is canceled and shows menu selection.		☐ Pass ☐ Fail	☐ Yes ☒ No	
14	Select “Abrir Lote” at “Refrigerador 02”	Shows “Abrir lote, ingrese número de lote”, Numero de lote, Usuario, Abrir lote, Cancelar, Conexion Escaner .		☐ Pass ☐ Fail	☐ Yes ☒ No	
15	Scan barcode of the batch	Shows number of the batch in “Numero de Lote”, shows instructions “Seleccione Abrir Lote o Cancelar” section in “Usuario” reminds empty.		☐ Pass ☐ Fail	☐ 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			

TEST CASE 3: Open/Close Batches						
16	Write User name	Write user name in “usuario”		☐ Pass ☐ Fail	☐ Yes ☒ No	
17	Press “Abrir lote”	_Main.VI Shows a table “Lista de “Lotes Abiertos Actualmente” the number of batch in section “Numero de lote” also Date/time in section “Fecha de inicio”		☐ Pass ☐ Fail	☐ Yes ☒ No	
18	Close Batch	Click on number of batch in table “Lista de Lotes abiertos actualmente” the batch turns orange and press “Cerrar Lote” number of batch and Date/Time should be deleted in the table.		☐ Pass ☐ Fail	☐ Yes ☒ No	
19	Select “Historial de lotes” in Refrigerador 02	Shows in folder “FridgeDataLog_02” Excel files of batches were opened and closed.		☐ Pass ☐ Fail	☐ Yes ☒ No	
20	Select one Excel file	Excel file shows: • Timestamp • Temperature • Number of batch • User		☐ Pass ☐ Fail	☐ Yes ☒ No	
21	Close excel file	Excel file is closed and shows folder “FridgeDataLog_02”		☐ Pass ☐ Fail	☐ 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			

TEST CASE 3: Open/Close Batches						
22	Close folder “FridgeDataLog_02”	Folder “FridgeDataLog_02” is closed and shows _Main.vi		☐ Pass ☐ Fail	☐ Yes ☒ No	
23	Select “Abrir Lote” at “Refrigerador 02”	Shows “Abrir lote, ingrese numero de lote”, Numero de lote, Usuario, Abrir lote, Cancelar, Conexion Escaner .		☐ Pass ☐ Fail	☐ Yes ☒ No	
24	Scan barcode of the batch	Shows number of the batch in “Numero de Lote”, shows instructions “Seleccione Abrir Lote o Cancelar” section in “Usuario” reminds empty.		☐ Pass ☐ Fail	☐ Yes ☒ No	
25	Select “Cancelar”	Function of open batch is canceled.		☐ Pass ☐ Fail	☐ Yes ☒ No	
26	Select “Abrir Lote” at “Refrigerador 03”	Shows “Abrir lote, ingrese numero de lote”, Numero de lote, Usuario, Abrir lote, Cancelar, Conexion Escaner.		☐ Pass ☐ Fail	☐ 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			

TEST CASE 3: Open/Close Batches						
27	Scan barcode of the batch	Shows number of the batch in “Numero de Lote”, shows instructions “Seleccione Abrir Lote o Cancelar” section in “Usuario” reminds empty.		☐ Pass ☐ Fail	☐ Yes ☒ No	
28	Write User name	Write user name in “usuario”		☐ Pass ☐ Fail	☐ Yes ☒ No	
29	Press “Abrir lote”	_Main.VI Shows a table “Lista de “Lotes Abiertos Actualmente” the number of batch in section “Numero de lote” also Date/time in section “Fecha de inicio”		☐ Pass ☐ Fail	☐ Yes ☒ No	
30	Close Batch	Click in number of batch in table “Lista de Lotes abiertos actualmente” the batch turns orange and press “Cerrar Lote” number of batch and Date/Time should be deleted in the table.		☐ Pass ☐ Fail	☐ Yes ☒ No	
31	Select “Historial de lotes” in “Refrigerador 03”	Shows in folder “FridgeDataLog_03” Excel files of batches was opened and closed.		☐ Pass ☐ Fail	☐ 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			

TEST CASE 3: Open/Close Batches						
32	Select one Excel file	Excel file shows: • Timestamp • Temperature • Number of batch • User		☐ Pass ☐ Fail	☐ Yes ☒ No	
33	Close excel file	Excel file is closed and shows folder “FridgeDataLog_03”		☐ Pass ☐ Fail	☐ Yes ☒ No	
34	Close folder “FridgeDataLog_03”	Folder is closed and shows _Main.vi		☐ Pass ☐ Fail	☐ Yes ☒ No	
35	Select “Abrir Lote” at “Refrigerador 03”	Shows “Abrir lote, ingrese número de lote”, Numero de lote, Usuario, Abrir lote, Cancelar, Conexion Escáner.		☐ Pass ☐ Fail	☐ Yes ☒ No	
36	Scan barcode of the batch	Shows number of the batch in “Numero de Lote”, shows instructions “Seleccione Abrir Lote o Cancelar” section in “Usuario” reminds empty.		☐ Pass ☐ Fail	☐ Yes ☒ No	
37	Select “Cancelar”	Function of open batch is canceled.		☐ Pass ☐ Fail	☐ 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			

TEST CASE 3: Open/Close Batches						
38	Select “Salir”	_Main.vi should be close		☐ Pass ☐ Fail	☐ Yes ☒ No	

TEST CASE 4: Machine Alarm Messages

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: Machine Alarm Messages						
STEP	**PROCEDURE**	**EXPECTED RESULT**	**ACTUAL RESULT**	**Pass / Fail**	**Printout of screen Required**	**COMMENTS**
1	Switch turn off “Fridge 1”	When the temperature starts to increase above of 49.5°F, _Main.vi shows at “Refrigerador 01” “Temperatura fuera de rango” in red color.		☐ Pass ☐ Fail	☒ Yes ☐ No	
2	Switch turn off “Fridge 2”	When the temperature starts to increase above of 49.5°F, _Main.vi shows at “Refrigerador 02” “Temperatura fuera de rango” in red color.		☐ Pass ☐ Fail	☐ Yes ☒ No	
3	Switch turn off “Fridge 3”	When the temperature starts to increase above of 49.5. °F, _Main.vi shows at “Refrigerador 03” “Temperatura fuera de rango” in red color.		☐ Pass ☐ Fail	☐ Yes ☒ No	
4	Switch turn on “Fridge 1”	When the temperature starts to decrease below of 49.5. °F, _Main.vi shows at “Refrigerador 01” “Temperatura dentro de rango” in blue color and temperature in green color.		☐ Pass ☐ Fail	☒ Yes ☐ No	
5	Switch turn on “Fridge 2”	When the temperature starts to decrease below of 49.5. °F, _Main.vi shows at “Refrigerador 02” “Temperatura dentro de rango” in blue color and temperature in green color.		☐ Pass ☐ Fail	☐ 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			

TEST CASE 4: Machine Alarm Messages						
6	Switch turn on “Fridge 3”	When the temperature starts to decrease below of 49.5. °F, _Main.vi shows at “Refrigerador 03” “Temperatura dentro de rango” in blue color and temperature in green color.		☐ Pass ☐ Fail	☐ 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			

Appendix 4:

21 CFR Part 11 Compliance: Assessment Filter

Software Identification:	SRC003419 Rev A
Equipment Identification:	E20291 PTFE Refrigeration Station

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 SRC003419 Rev A is an embedded software used to control the PTFE Refrigeration Station and allows the user to interact with it.

Software ID	Software Type	Software Function
SRC003419 Rev A	LabView	Controls temperature profile and safety features in this machine.
		Controls operation and safety features in this machine.
		Controls status indicators in the machine.

This software does not store any electronic records.

1. Does the software store GXP-related information in electronic format?	☐ Yes ☒ No

If YES, then the equipment must be validated per WE0690 for compliance to 21 CFR Part 11.