**EQUIPMENT SOFTWARE VALIDATION APPROVAL PAGE**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| PROTOCOL # | | PRC097512 | | | | | REVISION: | | | | A | | | DATE: | | | | 08/27/2020 |
| COMPLETION REPORT # | | | | | PRC097513 | | | | MVP, ECP, DP or SPCR# | | | | | | | | DC003495 | |
|  | | | | | | | | | | | | | | | | | | |
| TITLE: | Software Validation Protocol for Megadyne L174 E20172 Automated Label Applier | | | | | | | | | | | | | | | | | |
| PROJECT NAME: | | | MIMAS | | | | | | | PROJECT LEADER: | | | | | | Rafael Palma | | |
| ProductCode: | 0012, 0012A, 0012AM, 0014, 0014A, 0014AM, 0014M, 0012M, 0013, 0013M, 0118, 0118A | | | | | ProductNumber: | | 0012, 0012A, 0012AM, 0014, 0014A, 0014AM, 0014M, 0012M, 0013, 0013M, 0118, 0118A | | | | | BatchNumber(s): | | | | | N/A |
|  | | | | | | | | | | | | | | | | | | |
| PROTOCOL INFORMATION | | | | | | | | | | | | | | | | | | |
| ORIGINATOR: | | Ricardo Miranda | | | | | | | PHONE NUMBER: | | | | | | 915-791-3296 | | | |
| ORIGINATOR TITLE: | | | | Process Engineer | | | | | | | | SITE: | | 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** | | | | | Ricardo Miranda | | | rmiran | eSig in EPIcenter | | |
| MEST Equipment Engineer | | | | | Javier Diaz | | | jdiaz24 | eSig in EPIcenter | | |
| Plant Quality Engineer | | | | | Victor Cantu | | | Vcantusi | eSig in EPIcenter | | |
| BU Manufacturing Engineer | | | | | Alan Arrieta | | | aarriet1 | eSig in EPIcenter | | |
| Lifecycle Quality Engineer | | | | | Ihsan Samara | | | Isamara | eSig in EPIcenter | | |
| **DISTRIBUTION LIST: (create as necessary)** | | | | | | | | | | | |
| **Revision** | **Date** | | | **Change Description** | | | | | | | |
| A | 08/27/2020 | | | Original Issue | | | | | | | |

1. **PURPOSE**
   1. The purpose is to validate the software installed in Automated Label Applier E20172, Maximo ID ES4457 located at Megadyne L174. This validation will be used to ensure that the machine function as intended to print and apply the pressure sensitive label to the product SU boxes.
2. **SCOPE**
   1. The software validation protocol applies only to the software controlling the equipment listed in Table 1.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Equipment Description | Machine Number | Maximo ID Number | Serial # | Software |
| Automated Label Applier | E20172 | ES4457 | PROD-20145A | SRC003430 |

Table 1 – List of Equipment

1. **CRITERIA FOR SUCCESS**
   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.
2. **REFERENCE DOCUMENTS**
   1. The following table lists the documents used to develop, to support, or are referenced within this Software Validation protocol.

| Document Number | Document Title |
| --- | --- |
| ECR0001689 Rev A | Enterprise Change Request. |
| E20172 Rev A | Automated Label Applier |
| FB003341 Rev A | Validation Master Plan for MIMAS Project. |

Table 2 – Referenced Documents

1. **EQUIPMENT AND MATERIALS**
   1. **Equipment and Software Identification**
      1. Program Number: **SRC003430**

Program Revision Level: A

Production Line/Location: Line 174 / Independencia Plant, CME-4

Equipment Number: E20172

MAXIMO ID Number: ES4457

Equipment Name: Automated Label Applier

* + - 1. Controller Type: PLC Allen Bradley MicroLogix 1400 1766-L32BXB

Program Type: Ladder Program / Ver 1.0.0

Development Software: RS Logix 500 Ver. 11.0

* + - 1. Controller Type: Maple System Display HMI5043LB

Program Type: Operator Interface

Development Software: EZwarePlus Ver. 5.07

* + - 1. Controller Type: Omron G9SP Safety Controller

Program Type: Safety Controller (Function blocks)

Development Software: G9SP Configurator 2.10

* 1. Materials
     1. The following Table shows the required material:

|  |  |
| --- | --- |
| **Component Part Number:** | **Component Description:** |
| **3200212-01 (Mode code 02) and 3200201-01 (Mode code 03)** | **Sales Unit Box for:** 0012, 0012A, 0012AM, 0012M, 0013, 0013M, 0118, 0118A |
| **3200213-01 (Mode code 02) and 3200203-01 (Mode code 03)** | **Sales Unit Box for:** 0014, 0014A, 0014AM, 0014M |

1. **RESPONSIBILITIES**
   1. Overall conduct of Protocol and Completion Report: Equipment Engineer / Manufacturing Engineer / Trained Designee.
   2. Equipment / Materials / Product Disposition: Equipment Engineer / Manufacturing Engineer / Trained Designee
2. **STRATEGIES AND ASSUMPTIONS**
   1. Risk Analysis:  
      This Software Validation for Automated Label Applier 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? | |
|  | YES, the PFMEA RMD001679will be updated under ECN number ECN029419 |
|  | NO, current PFMEA addresses the safety of the process to the end user. |

* 1. Each test case will provide assurance that the software requirements are met.
  2. Software is not intended to create or store any quality record, Part 11.
  3. \*\*Objective evidence for this Software Validation will be collected by Test Cases requiring screen print will be documented through (screen captures) in the Completion Report PRC097513 Rev A, per WE0020 Rev CH.

1. **TRAINING**
   1. Since the protocol will be conducted and executed by an engineer that has knowledge of the equipment, training and translation of the protocol will not be required.
   2. If applicable, training will be recorded under form FM-0000809 Rev 15 and included in the Completion Report PRC097513 Rev A.
2. **PREREQUISITES**
   1. Approved Software Validation Protocol PRC097512 Rev A prior to execution of this protocol.
   2. PFMEA RMD001679 Rev A shall be in “Working” status in Epicenter.
3. **PROCEDURE**
   1. The Test Cases in Appendix 3 shall be followed in order throughout the execution of the test.
   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.
   3. Any discrepancy in the expected versus the actual result shall be documented in the comments column of the Test Case sheet.
   4. Upon completion of each Test Case, the designee performing the test shall sign and date the Test Case sheet.
   5. Upon completion of the Test Cases, the Test Case sheets will be returned to Equipment Engineer or designee.
   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.
   7. Any discrepancy or remarks will be analyzed, and corrective action determined by Equipment Engineer or designee.
   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.
   9. Objective evidence will be included in the test cases for key steps and documented in the Completion Report.
      1. Key Steps are marked with YES for “Printout of Screen Required” column of appendix 3.
   10. Maximo WO will be created and documented in the Completion Report for this protocol.
4. **PRODUCT DISPOSITION**
   1. Parts shall be disposed by designee to be scrapped.
5. **COMPLETION ACTIVITIES**
   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.
   2. Completion Report will be documented in PRC097513 Rev A.
6. **APPENDICES**
   1. Appendix 1: Equipment Software Requirements Specification and Verification and Validation Matrix
   2. Appendix 2: Equipment Software Design Description
   3. Appendix 3: Equipment Software Test Cases
   4. Appendix 4: 21CFR Part 11 Compliance

**Appendix 1**

**Equipment Software Requirements Specification**

**And**

**Verification and Validation Matrix for equipment E20172**

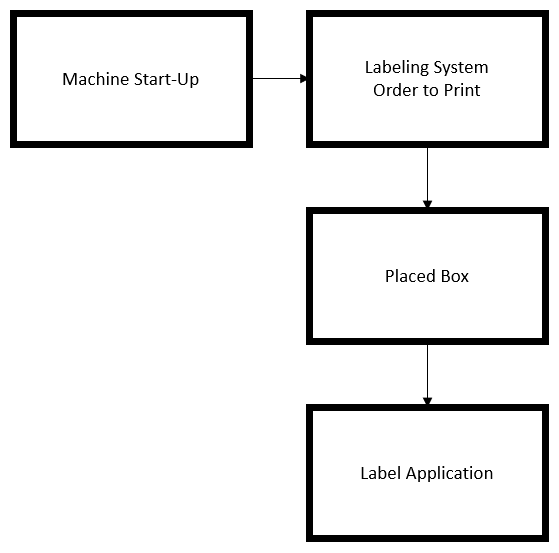
# Enter high level description of the machine’s operation.

|  |  |  |
| --- | --- | --- |
| **Requirement** | **Description of requirement** | **Verified with Test Case(s)** |
| 1. Machine Power-Up and Shut Down | * 1. Equipment must demonstrate that is safe to turn on and turn off. | 1 |
| 1. Production Mode | * 1. Equipment must allow cycle start or terminate recipe at the Label Applier. | 2 |
| 1. Safety and Emergency Devices | * 1. Equipment must be safe for operation and display alarm messages. | 3 |

**Appendix 2**

**Equipment Software Design Description**

This is an embedded software used to control the Automated Label Applier. The following is a Flow Diagram of the Software.



| **Appendix 3 - Equipment Software Test Cases** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| TEST CASE 1: Machine Power Up and Shut Down | | | | | | |
| **STEP** | **PROCEDURE** | **EXPECTED RESULT** | **ACTUAL RESULT** | **Pass / Fail** | **Printout of Screen Required** | **COMMENTS** |
|  | Turn the POWER knob to ON position. | The Machine Status LED turns ON red.  The HMI displays following messages:  -PASO: Maquina en Falla  -ESTATUS: Presione Boton Habilitar  Following button is displayed:  -MANUAL  Printer turns ON, display shows message “PRINTER READY”. |  | Pass  Fail | Yes  No |  |
|  | Press Blue “HABILITAR” button for 2 seconds. | Air flow activates.  Blue “HABILITAR” button turns ON.  HMI message change to:  -PASO: Maquina en Falla  -ESTATUS: Cargar Etiqueta a Impresora |  | Pass  Fail | Yes  No |  |
|  | Press E-Stop button. | Air flow cuts off.  Blue “HABILITAR” button turns OFF.  HMI message change to:  -PASO: Maquina en Falla  -ESTATUS: Jale E Stop |  | Pass  Fail | Yes  No |  |
|  | Pull E-Stop button. | HMI messages change to:  -PASO: Maquina en Falla  -ESTATUS: Presione Boton Habilitar |  | Pass  Fail | Yes  No |  |
|  | Press Blue “HABILITAR” button for 2 seconds. | Air flow activates.  Blue “HABILITAR” button turns ON.  HMI message change to:  -PASO: Maquina en Falla  -ESTATUS: Cargar Etiqueta a Impresora |  | Pass  Fail | Yes  No |  |
|  | Turn the POWER knob to OFF position. | HMI, Printer and Machine Status LED turn OFF. Air flow cuts off.  Machine turns OFF. |  | Pass  Fail | Yes  No |  |

| TEST CASE 2: Production Mode | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **STEP** | **PROCEDURE** | **EXPECTED RESULT** | **ACTUAL RESULT** | **Pass / Fail** | **Printout of screen Required** | **COMMENTS** | |
|  | Turn the POWER knob to ON position. | The Machine Status LED turns ON red.  The HMI displays following messages:  -PASO: Maquina en Falla  -ESTATUS: Presione Boton Habilitar  Following button is displayed:  -MANUAL  Printer turns ON, display shows message “PRINTER READY”. |  | Pass  Fail | Yes  No |  | |
|  | Press Blue “HABILITAR” button for 2 seconds. | Air flow activates, digital pressure gauge turns ON.  Blue “HABILITAR” button turns ON.  HMI message change to:  -PASO: Maquina en Falla  -ESTATUS: Cargar Etiqueta a Impresora |  | Pass  Fail | Yes  No |  | |
|  | Using Labeling Printing System connected to the Label Applier, send an order to print labels. | Yellow RESET button starts blinking.  Printer display shows “Printing 1 of 5”  PASO: Maquina en Falla  ESTATUS: Presione de Reset |  | Pass  Fail | Yes  No |  | |
|  | Press Yellow RESET button. | The pneumatic cylinder goes to home position.  Machine Status LED start blinking yellow. Yellow FALLA buton turns OFF.  PASO: Inicio Ciclo  ESTATUS: Coloque Caja |  | Pass  Fail | Yes  No |  | |
|  | Place a 3200024-02 (REGULAR) sales unit box in the label applying fixture. | PASO: Inicio Ciclo  ESTATUS: Presione Opto |  | Pass  Fail | Yes  No |  | |
|  | Activate the OTB sensor. | A label is feed and placed in the applier pneumatic cylinder, but not applied. |  | Pass  Fail | Yes  No |  | |
|  | Activate the OTB sensor. | The label is applied to the box.  PASO: Pieza Terminada  ESTATUS: Retire Caja |  | Pass  Fail | Yes  No |  | |
|  | Remove the regular box from the label applying fixture. | PASO: Inicio Ciclo  ESTATUS: Coloque Caja |  | Pass  Fail | Yes  No |  | |
|  | Place a 3200023-02 (SMALL) sales unit box in the label applying fixture. | PASO: Inicio Ciclo  ESTATUS: Presione Opto |  | Pass  Fail | Yes  No |  | |
|  | Activate the OTB sensor. | A label is feed and placed in the applier pneumatic cylinder, but not applied. |  | Pass  Fail | Yes  No |  | |
|  | Activate the OTB sensor. | The label is applied to the box.  PASO: Pieza Terminada  ESTATUS: Retire Caja |  | Pass  Fail | Yes  No |  | |
|  | Remove the small box from the label applying fixture. | PASO: Inicio Ciclo  ESTATUS: Coloque Caja |  | Pass  Fail | Yes  No |  | |

| TEST CASE 3: Safety and Emergency Devices | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **STEP** | **PROCEDURE** | **EXPECTED RESULT** | **ACTUAL RESULT** | **Pass / Fail** | **Printout of screen Required** | **COMMENTS** | |
|  | Press the E-Stop button. | Air flow cuts, digital pressure gauge turns OFF.  Machine Status LED turns red.  Blue HABILITAR button turns OFF.  PASO: Maquina en Falla  ESTATUS: Jale E-Stop |  | Pass  Fail | Yes  No |  | |
|  | Pull the E-Stop button. | PASO: Maquina en Falla  ESTATUS: Presione Boton Habilitar |  | Pass  Fail | Yes  No |  | |
|  | Press Blue HABILITAR button for 2 seconds. | Blue HABILITAR button turns ON.  Yellow FALLA button starts blinking.  Digital pressure gauge turns ON and air flow is restored.  PASO: Maquina en Falla  ESTATUS: Presione de Reset |  | Pass  Fail | Yes  No |  | |
|  | Press Yellow RESET button. | Yellow RESET button turns OFF.  Machine Status LED starts blinking yellow.  The pneumatic cylinder goes to home position.  PASO: Inicio Ciclo  ESTATUS: Coloque Caja |  | Pass  Fail | Yes  No |  | |
|  | Place a box in the label applying fixture. | PASO: Inicio Ciclo  ESTATUS: Presione Opto |  | Pass  Fail | Yes  No |  | |
|  | Place one hand through the light curtains. | PASO: Inicio Ciclo  ESTATUS: Libere Cortinas |  | Pass  Fail | Yes  No |  | |
|  | Without removing the hand, activate the OTB sensor. | No changes. |  | Pass  Fail | Yes  No |  | |
|  | Remove the hand from the light curtain, then activate the OTB sensor. | Label is applied to the box. |  | Pass  Fail | Yes  No |  | |

**Appendix 4:**

**21 CFR Part 11 Compliance: Assessment Filter**

|  |  |  |
| --- | --- | --- |
| Software Identification: | SRC003430 Rev. A | |
| Equipment Identification: | Automated Label Applier E20172, MAXIMO ID ES4457 | |
| 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 listed in Section 5 of this document is used to control the Automated Label Applier E20172 with MAXIMO ID ES4457. The software functions are:   |  |  |  | | --- | --- | --- | | **Source Code** | **Controller** | **Function** | | SRC003430 Rev. A | PLC Allen Bradley MicroLogix 1400 1766-L32BXB | Machine Operation | | Omron G9SP Safety Controller | Machine Safety Features | | Maple System Display HMI5043LB | Machine Status Display |   This software does not store any quality record. | | |
| 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. | | |