



**Factory Acceptance Test Protocol  
Model 5000P Heat Sealer**

FAT 5000PUEC  
Revision: Original

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## TABLE OF CONTENTS

<b>1. OBJECTIVE</b>	<b>3</b>
<b>2. SCOPE</b>	<b>3</b>
<b>3. EQUIPMENT/SYSTEM DESCRIPTION</b>	<b>3</b>
<b>4. STRATEGY/RATIONALE</b>	<b>3</b>
<b>5. RESPONSIBILITES</b>	<b>4</b>
<b>6. PARTIES</b>	<b>5</b>
<b>7. QUALIFICATION METHODS</b>	<b>6</b>
7.1 QUALIFICATION	6
7.2 EVALUATION OF TEST RESULTS	6
7.3 TEST EQUIPMENT AND MATERIALS	6
7.4 PERSONNEL	6
7.5 DATA ASSEMBLY	6
7.6 FINAL APPROVAL	6
<b>8. ACCEPTANCE CRITERIA</b>	<b>7</b>
<b>9. ACCEPTANCE DISPOSITION</b>	<b>7</b>
9.1 APPROVE THE ACCEPTANCE	7
9.2 REJECT THE ACCEPTANCE	7
<b>10. FACTORY ACCEPTANCE TEST DISPOSITION</b>	<b>8</b>
<b>11. ATTACHMENTS</b>	<b>9</b>
11.1 VALIDATION SIGNATURE IDENTIFICATION SHEET (UECFORM-2)	10
11.2 MANUALS/DOCUMENTS WORKSHEET (UECFORM-7)	11
11.3 MAJOR COMPONENTS WORKSHEET (UECFORM-9)	12
11.4 INSTRUMENT INSTALLATION WORKSHEET (UECFORM-10)	13
11.5 PRODUCT CONTACT VERIFICATION WORKSHEET (UECFORM-11)	14
11.6 UTILITY VERIFICATION WORKSHEET (UECFORM-12)	15
11.7 SPARE PARTS WORKSHEET (UECFORM-13)	16
11.8 LUBRICANTS WORKSHEET (UECFORM-14)	17
11.9 EHS+S VERIFICATION WORKSHEET (UECFORM-17)	18
11.10 OPERATIONAL TESTING WORKSHEET (UECFORM-26)	19-20
11.11 BACK UP AND RESTORE VERIFICATION WORKSHEET (UECFORM-28)	21
11.12 POWER FAILURE VERIFICATION WORKSHEET (UECFORM-29)	22
11.13 SCREEN VERIFICATION WORKSHEET (UECFORM-30)	23
11.14 PERFORMANCE TESTING WORKSHEET (UECFORM-34)	24-25

## **1. OBJECTIVE**

The purpose of this testing is to verify that the Urania model 5000P Validatable Rotary Band Sealer consistently and reliably performs sealing of end user's pouches as defined by all preceding agreed upon documents including RFQ, quotation, and purchase order.

## **2. SCOPE**

The scope of this test protocol is limited to the end user's pouch as defined and initialed under "Parties" in this document. Any additional pouches configurations and varieties must have their own document assigned and initialed.

## **3. EQUIPMENT/SYSTEM DESCRIPTION**

The Urania Model 5000P system uses an Allen Bradley CompactLogix® control structure in our industry leading rotary band heat sealer. A large, full color touchscreen HMI monitors and informs the user of all phases of operation. The Model 5000P is fully validatable with respect to speed, temperature, and force. Urania utilizes a real-time monitoring system for all three of these crucial sealing parameters.

An alarm and error history with time/date stamp is standard. The alarm/error information may be downloaded to a customer supplied printer, compact flash, or through an Ethernet connection. Alarms for belt speed errors, force limits, and temperature variations ensure proper operation and immediate notification in the event of a problem. An administrator level keyswitch is used to securely limit access to parameters and settings reserved for qualified technicians.

Various options are available and can be integrated based on a customer's needs.

## **4. STRATEGY/RATIONALE**

The strategy for this Factory Acceptance Testing involves document reviews and short trial runs to verify that the machine operates and performs the required functions as outlined in the original purchase order.

The Factory Acceptance Testing will include various worksheets which are marked with an "X" to the left of the UECFORM Number/ Worksheet Name. All identified worksheets will be attached to the FAT and are listed under the Table of Contents.

## 5. RESPONSIBILITIES

### END USER

#### FUNCTIONAL AREA

#### RESPONSIBILITIES

VALIDATION

COORDINATES FAT ACTIVITIES, EVENTS, AND MILESTONES

CREATES FINAL FAT DOCUMENT

MANUFACTURING / OPERATIONS

VISITS URANIA'S FACILITY FOR (OR HOSTS) FAT TRIALS

ENSURES FAT REQUIREMENTS ARE MET AND PROPERLY RECORDED IN THIS DOCUMENT

REVIEWS AND CREATES FINAL REPORT BASED ON FAT

SITE QUALITY ASSURANCE

ENSURES ALL FAT PROCEDURES ARE IN COMPLIANCE WITH COMPANY POLICIES

REVIEWS THE FAT REPORT FROM MANUFACTURING

ENGINEERING

REVIEWS AND GIVES FINAL APPROVAL TO THE FAT REPORT

### URANIA

#### FUNCTIONAL AREA

#### RESPONSIBILITIES

VALIDATION

SUPPORT FAT ACTIVITIES ON SITE

REVIEWS AND MAKES SUGGESTIONS FAT DOCUMENT PRIOR TO TRIALS

ENGINEERING

ENSURES FAT REQUIREMENTS ARE MET PRIOR TO TRIALS AND APPROVES FINAL FAT DOCUMENT

CORRECTS ANY ANNOMOLIES FROM FAT TRIALS BEFORE SHIPMENT OF THE MACHINE

**6. PARTIES**

**END USER**

**FUNCTIONAL AREA**

**RESPONSIBLE PARTIES**

VALIDATION

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MANUFACTURING / OPERATIONS

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SITE QUALITY ASSURANCE

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ENGINEERING

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**URANIA**

**FUNCTIONAL AREA**

**RESPONSIBLE PARTIES**

VALIDATION

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ENGINEERING

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## 7. QUALIFICATION METHODS

### 7.1 Qualification

Specific test procedures and the acceptance criteria are defined on each individual worksheet. All test results will be documented and initialized on the corresponding worksheet.

All worksheets will be reviewed, including signature and date of reviewer.

If additional sheets are required to document results or note observations, additional pages of the worksheet may be printed. The General Data Sheet UECNFORM-1 may also be used for this purpose.

### 7.2 Evaluation of Test Results

All test results obtained during the execution of this protocol will be evaluated against the acceptance criteria defined on the individual qualification worksheets.

### 7.3 Test Equipment and Materials

As applicable, test equipment will be in current calibration and calibration will be traceable to the National Institute of Standards and Technology (NIST) or applicable Urania standards.

### 7.4 Personnel

A list will be provided of the names, title, & signatures of all personnel who perform or review any section of, or attachments within this document. This excludes named approvers on the approval page. Refer to UECFORM-2 for "Signature Identification on Sheet".

### 7.5 Data Assembly

The completed protocol will be assembled in an orderly manner, including all raw data and supporting documentation. If data is not attached to the final report, it will be referenced within the final report detailing where the data is stored. A final report will be used to summarize the test results, describe any discrepancies and their resolutions and recommend the equipment/system for acceptance.

### 7.6 Final Approval

Final approval of the executed protocol, including all results, conclusions, discrepancies and corrective actions presented in the summary, is indicated by signature on the Approval Page of the Final Report. Upon completion of the final approval page, the equipment/system shall be considered accepted. The executed FAT, including all associated supporting documents, will be stored as detailed within.

## **8. ACCEPTANCE CRITERIA**

All acceptance criteria are set in the individual worksheets and should be summarized by their respective section within the final report.

## **9. ACCEPTANCE DISPOSITION**

If there is a failure to meet any of the acceptance criteria, the protocol signatories decide to:

9.1 Approve the Acceptance, OR Approve the acceptance with rationale and appropriate corrective action plan.

9.2 Reject the Acceptance

In order to reject the acceptance, or a portion thereof, an investigation will be conducted and documented to identify the root cause(s) of the failure to meet the acceptance criteria. A correct action plan shall be developed. The investigation and corrective action plan shall be approved by the original qualification protocol signatories

**10. FACTORY ACCEPTANCE TEST DISPOSITION**

The following items were verified upon completion of FAT execution corresponding to the Model 5000P heat sealer:

<u>ITEM</u>	<u>YES/NO</u>	<u>DATE</u>
All FAT tests completed?	_____	_____
Acceptance criteria met?	_____	_____
Any test still open?	_____	_____

If any test is still open, document the reason with course of action in the comments section.

Comments:

Verified by: \_\_\_\_\_ DATE \_\_\_\_\_  
\_\_\_\_\_ DATE \_\_\_\_\_



## 11. ATTACHMENTS

The following documents are attached to this protocol

Attachment Number	Attachment Name
1 UECFORM-2	Signature Identification Sheet
2 UECFORM-7	Manuals/Documents
3 UECFORM-9	Major Components
4 UECFORM-10	Instrument Installation Verification
5 UECFORM-11	Product Contact Verification
6 UECFORM-12	Utility Verification
7 UECFORM-13	Spare Parts
8 UECFORM-14	Lubricants
9 UECFORM 17	EHS+S Safety Verification
10 UECFORM-26	Operational Testing
11 UECFORM-28	Backup and Restore
12 UECFORM-29	Power Failure
13 UECFORM-30	Screen Verification / Security Access/Edit Configuration
14 UECFORM-34	Performance Testing

**1 UECFORM-2                      Signature Identification Sheet**

<b>NAME (Print)</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>

FAT 5000PUEC MODEL 5000P HEAT SEALER

**2 UECFORM-7 Manuals/Documents**

Manuals / Documents
<b>OBJECTIVE:</b> This test is to verify the presence of vendor and/or company documents for the equipment/system (e.g. Manuals, Cleaning/Passivation Cert., ASME cert., and welding cert.) and their location.
<b>ACCEPTANCE CRITERIA:</b> Manuals and system documents are available and properly documented as to their title, document number and storage location.
<b>TEST PROCEDURE:</b> Review the system documentation and list any manuals, vendor documents, specifications, etc. including hardware and software. Record document title, document number and storage location for each document.
<b>TOOLS:</b> No tools are required for this section.

REQUIREMENT	DOCUMENT DESCRIPTION	RESULT
2.000 2.001 2.002 2.003 2.004 2.005	OPERATION MANUAL PREVENTATIVE MAINTENANCE ERROR EXPLANATION AND TROUBLESHOOTING GENERAL FUNCTIONS SCHEDULED MAINTENANCE	PRESENT _____ NOT PRESENT _____ NOTES
2.100 2.101 2.102 2.103	ASSEMBLY DRAWINGS / BOM WIRING SCHEMATICS PNEUMATIC DRAWINGS (IF REQ) SPARE PARTS LIST	PRESENT _____ NOT PRESENT _____ NOTES
2.200 2.201 2.202	ELECTRONIC COPY OF SOFTWARE (IF REQ) CE TEST REPORT AND TAG (IF REQ) UL TEST REPORT AND TAG (IF REQ)	PRESENT _____ NOT PRESENT _____ NOTES

COMMENTS:	
Performed By:	Date:
Reviewed By:	Date:

FAT 5000PUEC MODEL 5000P HEAT SEALER

**3 UECFORM-9 Major Components**

**Major Components of Equipment/System**

**OBJECTIVE:** To identify and verify that major components, including hardware, of the equipment/system are installed as specified.

**ACCEPTANCE CRITERIA:** All major components of this equipment/system are identified and installed as specified.

**TEST PROCEDURE:** Record and verify that all major equipment is installed and properly identified (i.e. Pumps, motors, mixers/impellers, etc.) Inspect each major component for the information requested in the table below and document the actual information in the "As Installed" column. For those components that cannot be verified from a physical inspection, reference the manufacturer's manuals and documentation for installation specifications. Reference ancillary documentation associated with the item under inspection (i.e. commissioning documents, specifications, etc.)

**TOOLS:** No tools are required for this section.

REQUIREMENT	COMPONENT DESCRIPTION	AS SPECIFIED / INSTALLED
3.000 3.001 3.002 3.003 3.004 3.005	ALLEN BRADLEY PLC & COMPONENTS COLOR TOUCHSCREEN HMI DUAL THERMOCOUPLES _____ WATT HEATERS PROPER FILTERS / RELAYS E-STOP(S) & CONTROL SWITCHES	INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____
3.100 3.101 3.102 3.103	DRIVE MOTOR SEAL BELTS COVERS & SAFETY LABELS ADJUSTABLE STAND	INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____
3.200 3.201 3.202	OPTION #1 OPTION #2 OPTION #3	INSTALLED _____ NOT _____ INSTALLED _____ NOT _____ INSTALLED _____ NOT _____

COMMENTS:

Performed By:	Date:
Reviewed By:	Date:

FAT 5000PUEC MODEL 5000P HEAT SEALER

**4 UECFORM-10 Instrument Installation Verification**

Instrument Installation Verification	
<b>OBJECTIVE:</b> To verify that all instruments installed on the equipment are identified.	
<b>ACCEPTANCE CRITERIA:</b> All instrumentation are installed, identified and documented. The "As Installed" column matches the "As Specified" column.	
<b>TEST PROCEDURE:</b> Record and verify that the instruments of the equipment/system listed below are installed and properly identified. Indicate if instruments are: "Critical", Non-Critical" or "For Reference Only". If instrument calibration is required for qualification, check box and attach copy of calibration report or reference location.	
<b>TOOLS:</b> No tools are required for this section.	
<b>REFERENCES:</b> None.	

REQUIREMENT	INSTRUMENT MODEL & SERIAL #	CALIBRATION DATE
4.000 SEALER SPEED VERIFICATION	MANUFACTURER  MODEL NUMBER  SERIAL NUMBER	DATE
4.100 TEMPERATURE VERIFICATION	MANUFACTURER  MODEL NUMBER  SERIAL NUMBER	DATE
4.200 FORCE VERIFICATION	MANUFACTURER  MODEL NUMBER  SERIAL NUMBER	DATE

COMMENTS:

Performed By:	Date:
Reviewed By:	Date:

**5 UECFORM-11 Product Contact Verification**

Product Contact Surfaces	
<b>OBJECTIVE:</b> To ensure contact surfaces are identified for this equipment/system.	
<b>ACCEPTANCE CRITERIA:</b> All product contact surfaces are identified.	
<b>TEST PROCEDURE:</b> Identify equipment surfaces including materials of construction and finishes, as applicable, which are in direct contact with product.	
<b>TOOLS:</b> No tools are required for this section	
<b>REFERENCES:</b> None	

REQUIREMENT	CONTACT SURFACE	MATERIAL / PLATING
5.000  METAL COMPONENTS	SEALING BARS (POUCH) COOLING BARS (POUCH) TOP STOP (POUCH) SEALER COVER STAND VARIOUS INTERNALS VARIOUS INTERNALS	C360 BRASS / POLYON COATING C360 BRASS / POLYON COATING 316 STAINLESS 316 STAINLESS 316 STAINLESS 6061 ALUMINUM / CLEAR ANODIZE 6061 ALUMINUM / CLEAR HARD CT
5.100  POLYMER COMPONENTS	TOP STOP (OPTIONAL / POUCH) DRIVE HUBS	DELTRIN, UHMW, OR TEFLON HIGH FRICTION POLYURETHANE
5.200  OTHER COMPONENTS	SEALING BELTS (POUCH) DRIVE BELTS (POUCH) SEAL ROLLERS (POUCH)	TEFLON COATED POLYESTER NEOPRENE OR POLYURETHANE HIGH TEMP RED SILICONE

COMMENTS:

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Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

**6 UECFORM-12**

**Utility Verification**

Utility Verification
<b>OBJECTIVE:</b> To verify that the required utilities for this equipment/system have been supplied and are connected.
<b>ACCEPTANCE CRITERIA:</b> All utilities have been installed and verified to meet specifications.
<b>TEST PROCEDURE:</b> Verify actual utility supplied (measured or stated value) against requirements for the equipment/system. Measurement equipment used must be calibrated and information recorded in the tools section.
<b>REFERENCE:</b>

REQUIREMENT	SPECIFIED VALUE	OBSERVED VALUE / CHECK
6.000 ELECTRICAL REQUIREMENTS	115VAC  60Hz  15A	
6.100 AIR REQUIREMENTS	1.5CFM @ 80PSI (OPTIONAL)	
6.200 OTHER REQUIREMENTS		

COMMENTS:	
Performed By:	Date:
Reviewed By:	Date:

**7 UECFORM-13 Spare Parts**

Spare Parts List
<b>OBJECTIVE:</b> To verify a spare parts list exists for the equipment/system.
<b>ACCEPTANCE CRITERIA:</b> Spare parts list(s) (manufacturer and/or company) for the equipment/system exist and are available.
<b>TEST PROCEDURE:</b> Record the title, document number and location of the spare parts lists in the table below (a copy of list may be attached if desired).
<b>TOOLS:</b> No tools are required for this section.
<b>REFERENCES:</b> None.

REQUIREMENT	DOCUMENT CONTENTS	INCLUDED
7.000 MANUFACTURED COMPONENTS	LIST OF ALL URANIA MANUFACTURED COMPONENTS RECOMMENDED TO BE KEPT (ON PREMESIS) BY END USER FOR REPLACEMENT. TO INCLUDE URANIA PART #	YES _____ NO _____
7.100 COMMERCIAL COMPONENTS	LIST OF ALL COMMERCIALLY PURCHASED COMPONENTS RECOMMENDED TO BE KEPT (ON PREMESIS) BY END USER FOR REPLACEMENT. TO INCLUDE URANIA PART #	YES _____ NO _____
7.200 OTHER COMPONENTS		YES _____ NO _____

COMMENTS:	
Performed By:	Date:
Reviewed By:	Date:



FAT 5000PUEC MODEL 5000P HEAT SEALER

**8 UECFORM-14 Lubricants**

Lubricants
<b>OBJECTIVE:</b> To ensure all approved lubricants are identified and listed which support this equipment/system.
<b>ACCEPTANCE CRITERIA:</b> A list of acceptable lubricants is identified.
<b>TEST PROCEDURE:</b> Reference the title, document number, and location of acceptable lubricant list or include information below.
<b>TOOLS:</b> No tools are required for this section.
<b>REFERENCES:</b> None.

REQUIREMENT	LUBRICANT SPEC / FREQUENCY	POUCH CONTACT Y/N APPROVED Y/N
8.000 SCHEDULED MAINTENANCE		YES _____ NO _____ YES _____ NO _____
8.100 PREVENTATIVE MAINTENANCE		YES _____ NO _____ YES _____ NO _____
8.200 OTHER LUBRICANTS		YES _____ NO _____ YES _____ NO _____

COMMENTS:	
Performed By:	Date:
Reviewed By:	Date:

**9 UECFORM 17 EHS+S Safety Verification**

EHS+S Verification
<b>OBJECTIVE:</b> To verify that the equipment/system meets EHS+S (Environment, Health, Safety & Sustainability) requirements.
<b>ACCEPTANCE CRITERIA:</b> Perform any required EHS+S verifications listed. The equipment/system will be inspected for any potential EHS+S issues. The equipment will be found acceptable as built or any deficiencies found will be corrected prior to acceptance.
<b>TEST PROCEDURE:</b> Verify that an EHS+S review was performed in order to ensure the satisfactory installation of the unit. Attach a copy of all reports or completed check lists where applicable.
• <b>REFERENCES:</b> None.

REQ	DESCRIPTION	COMPLIANT
9.000 9.001 9.002	COMPONENTS ARE CERTIFIED CE/ UL AS REQUIRED WIRES & CABLES ARE PROPERLY LABELED & ROUTED POWER & AIR CONNECTIONS ARE CLEARLY LABELED	YES _____ NO _____ YES _____ NO _____ YES _____ NO _____
9.100 9.101 9.102 9.103 9.104	MOVING PARTS / PINCH PTS ARE PROPERLY GUARDED SAFETY LABELS ARE INSTALLED WHERE REQUIRED EASILY REMOVABLE GUARDS ARE INTERLOCKED AN OPEN INTERLOCK STOPS THE SEALER IMMEDIATELY AN OPEN INTERLOCK REQUIRES A MANUAL RESET	YES _____ NO _____ YES _____ NO _____ YES _____ NO _____ YES _____ NO _____ YES _____ NO _____
9.200 9.201 9.202 9.203	NOISE IS 80db MAX 3 FT FROM MACHINE AT MAX LOAD HOT EXTERNAL SURFACES DO NOT EXCEED 55 DEG C HOT EXTERNAL SURFACE ARE PROPERLY LABELED STAND PROVIDES A STABLE BASE FOR THE SEALER	YES _____ NO _____ YES _____ NO _____ YES _____ NO _____ YES _____ NO _____

COMMENTS:	
Performed By:	Date:
Reviewed By:	Date:

FAT 5000PUEC MODEL 5000P HEAT SEALER

**10 UECFORM-26 Operational Testing**

**Operational Testing**

**OBJECTIVE:** To verify that the systems' operational functions, controls, alarms and interlocks (not tested in the EHSS verification worksheet (UECFORM-17), and indicators operate per design.

**ACCEPTANCE CRITERIA:** Where applicable, the "Observed Results" must match the criteria defined in "Expected Test Results".

**TEST PROCEDURE:** Perform each test according to the procedure listed, with the unit operating in accordance with the applicable current SOP governing the use of the equipment/system. Begin with the equipment in operation.

**TOOLS:** Enter text here

	TOOLS	ID	CALIBRATION DUE DATE
	Shimpo DT-105 digital Tachometer or equivalent		
	Omega Model CL24 Digital thermometer or equivalent		
	Mark-10 Digital Force Gauge or equivalent		

**REFERENCES:** None.

Function/Procedure/Step	Test	Expected Result	Observed Result	Compliant Yes/No
10.000 - Set belt speed to desired value and let speed stabilize. When machine has stabilized at set speed, measure belt speed using digital tachometer.	Belt Speed (dwell)	Measured speed on digital tachometer is within +/- 3% of set point speed on control panel.		
10.001 - Set sealer band temperature to desired value and let sealer complete warm-up cycle. When machine has stabilized at operating temperature, measure temperature,	Sealing Temperature	Measured temperature on digital thermometer is within +/- 5 deg. C of set point temperature on control panel.		
10.002 - Allow sealer to warm-up and stabilize for 15 minutes. Following procedure in Urania 5000P Operating Manual and force validation/calibration fixture, compare force shown on calibration fixture to "Current Force" display on control panel.	Force (Sealing Pressure)	Force shown and calibration fixture is within +/- 0.1 lb. of "Current Force" shown on control panel.		
10.003 - Access user selectable HMI screens and verify that all screens have option to select English or Spanish language and that language translations are correct.	Language (optional)	All user selectable HMI screens have the option to select English or French Language and translations are correct		

FAT 5000PUEC MODEL 5000P HEAT SEALER

<p>10.004 - Create and save recipe of desired set-up parameters. Change set-up parameters to different values and allow machine to stabilize at new values. Set machine to previously saved recipe and verify set-up parameters. Set to programmed values once machine stabilizes.</p>	<p>Recipe set-up/ recall</p>	<p>Selected recipe correctly sets parameters to the values defined when the recipe was created.</p>		
<p><b>If Acceptance Criteria was not met: DR# _____</b></p>				
<p>COMMENTS:</p>				
<p>Performed By:</p>			<p>Date:</p>	
<p>Reviewed By:</p>			<p>Date:</p>	

**11 UECFORM-28**

**Backup and Restore**

**Back Up and Restore**

**OBJECTIVE:** To verify and document through testing that the system software back-up and recovery can be executed in accordance with the system specifications.

**ACCEPTANCE CRITERIA:** System software backup and recovery meets acceptance criteria as stated below.

**TEST PROCEDURE:** Obtain the backup/recovery instructions or documentation (SOPs, guidelines, etc.) for the system configuration and include the procedure as part of this document. Verify that the document contain specific instructions rebuilding or reloading the system configuration from archived copies. If instructions or documentation are not available, record in comment section. If necessary, use a portable PC to perform a file backup using any recovery by loading the backup version. Record the results.

**TOOLS:** None

**REFERENCES:**

Component Software	Program Name	Version Date	Backup Complete (Yes/No)	System Restore Complete (Yes/No)	Properly Labeled (Yes/No)	Installed Version Same as Backup (Yes/No)	Criteria Met Yes/No
11.000 PLC Software							
11.001 HMI Software							

If Acceptance Criteria was not met, DR# \_\_\_\_\_

**Comments:**

Performed By

Date:

Reviewed By

Date:

FAT 5000PUEC MODEL 5000P HEAT SEALER

**12 UECFORM-29 Power Failure**

<b>Power Failure</b>				
<b>OBJECTIVE:</b> To verify the proper response of the equipment/system to a power failure and power restoration (if the UPS is assigned to this system fail)				
<b>ACCEPTANCE CRITERIA:</b> Observed result meets specified result.				
<b>TEST PROCEDURE:</b> Follow the procedure specified in the "Test Procedure" column. Document observed result below.				
<b>TOOLS:</b> None				
<b>REFERENCES:</b>				
Req. #	Test Procedure	Specified Result	Observed Result	Compliance Yes/No
12.000	Cut power to system to simulate power failure. Observe results.	System shuts down to "Safe State" with all motion stopped and no damage to system. Manual reset required to restart		
12.001	Restore power to system and restart. Observe results.	System restarts, retains PLC program and recovers. Production data (such as pouch count) has not been lost as a result of the power failure.		
<b>If Acceptance Criteria was not met DR#</b> ___ ___				
Comments:				
Performed By			Date:	
Reviewed By			Date:	

FAT 5000PUEC MODEL 5000P HEAT SEALER

**13 UECFORM-30 Screen Verification / Security Access/Edit Configuration**

<b>Screen Verification / Security Access and Edit Configuration</b>				
<b>OBJECTIVE:</b> To verify the Screens Touch Screen interface functions comply with the information required and that the equipment/systems physical security protection is installed and no changes to the PLC configuration or calibration parameters can be made without proper access				
<b>ACCEPTANCE CRITERIA:</b> Observed result meets specified result.				
<b>TEST PROCEDURE:</b> Follow the procedure specified in the "Test Procedure" column. Document observed result below.				
<b>TOOLS:</b> None				
<b>REFERENCES:</b>				
Req	Test Procedure	Specified Result	Observed Result	Compliant Yes/No
13.000	Log in as "Operator": attempt to access functions necessary to run the machine (view counters, select pre-programmed recipes, etc.)	Operator screens and functions can be accessed		
13.001	While logged in as "Operator", attempt to access "administrator level functions (reset counters, modify set-up parameters, modify recipes, etc.)	Administrator screens and functions cannot accessed		
13.002	Log in as "Administrator": Attempt to access functions necessary to run the machine, view counters, select p e-programmed recipes. Attempt to access "administrator level functions (reset counters, modify set-up parameters, modify recipes)	All Operator and Administrator screens and function can be accessed. Set-up parameters and recipes can be modified. Counters can be reset.		
13.003	Log into system as Operator or Administrator. Leave the system idle. Observe results.	The screen notifies the operator that the maximum period of inactivity is being approached and that they will be logged off. If no action is taken in the specified time, the system logs the person off.		
<b>If Acceptance Criteria was not met, DR# _____</b>				
Comments:				
Performed By			Date:	
Reviewed By			Date:	

FAT 5000PUEC MODEL 5000P HEAT SEALER

**14 UECFORM-34 Performance Testing**

<b>Performance Testing</b>				
<b>OBJECTIVE:</b> To verify (detail specific objective that applies to this test).				
<b>ACCEPTANCE CRITERIA:</b> The observed result matches the expected result, as detailed in each instruction.				
<b>TEST PROCEDURE:</b> Perform each test according to the test method listed, with the unit operating in accordance with the applicable current SOP governing the use of the equipment/system. Begin with the equipment ready for operation.				
<b>TOOLS</b>	<b>TOOLS</b>			
	<b>ID</b>	<b>CALIBRATION DUE DATE</b>		
<b>REFERENCES:</b>				
Req.	Instruction/ Expected Result	Observed Result	Compliant Yes/No	
14.000	Determine and document appropriate set points for each pouch variety. Set-up sealer to run current pouch, allow to stabilize at settings and run 100 pouches through the sealer. Visually inspect seals and peel seal to verify complete sealing, correct seal width and seal position. Ten (10) pouches drawn at random from the "good" output will be subjected to any additional testing.			
14.001	During run, introduce 10 pouches with known folds and creases in the seal area to the sealer and observe if sealer detects and rejects those pouches. Expected result - Folded and creased pouches are detected and rejected. Audible alarm sounds, light tower displays "red" and error condition is displayed on HMI			
14.002	Force "out of tolerance" conditions for set-up parameters and observe response. Expected result - Pouches in the sealer when set-up parameters are out of tolerance are rejected. Audible alarm sounds, light tower displays "red" and error condition is displayed on HMI			



FAT 5000PUEC MODEL 5000P HEAT SEALER

14.003	During run identified above, operate sealer at 350 to 400 inches per minute (for manual in-feed). Expected result - Sealer properly seals at desired run rates for each pouch and maintains set-up parameters within tolerance limits for each set point.		
14.004	Pre-count all pouches to be run through the sealer. Run pre-counted pouches through sealer on acceptance trials above. Verify count as displayed on control panel pouch count display matches the actual number of pouches.		
<b>If Acceptance Criteria was not met, DR# _____</b>			
<b>Comments</b>			
Performed By		Date:	
Reviewed By		Date:	