UHDD™ Tablet De-Duster IQ/OQ

We don’t just sell machines—
we provide service.

Version 1.3 provided by Callie Scott

LFA Signature Identification

Prepared by	Name	Title	Date
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Approved by	**Name**	**Title**	**Date**
Manufacturing			
Engineering			
Quality			

Comments:

Reviewed By: Date:

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Comments:

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Qualification Protocol

Purpose and Background

The purpose of this Installation Qualification (IQ)/Operational Qualification (OQ) Protocol is to establish documented evidence that the UHDD™ and its ancillary systems have been installed according to the system specifications, have been configured per applicable manufacturer's recommendations, design specifications, and process requirements, and performs the intended functions as specified in the protocol.

Scope

Equipment

This IQ/OQ Protocol applies to the following equipment:

Items	System Information
URS Reference	N/A
Factory Acceptance Testing (FAT) Reference	
Project Master Validation Plan Number	N/A
Site Master Validation Plan Number	N/A
Equipment Name/Description	UHDD/Tablet de-duster
Manufacturer	LFA Machines
Model Number	1
Serial Number	
Equipment ID Number or Asset Number	
Previous Qualification/Validation Number(s) (if applicable)	N/A
Is system new, modified, moved, periodic review, or revalidation?	
If revalidation, attach necessary change control document(s) and record attachment number. Provide reason for revalidation.	

Comments: .....

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System Requirements

This IQ/OQ Protocol applies to the following system requirements:

System Requirement	Target
Output Speed Target	1,000,000 tablets per hour
Availability	90% (10% of potential availability taken up by cleaning, maintenance, etc.)
Quality Rate	+/-5% accuracy
Overall Equipment Effectiveness (OEE)	90-95%
Crew Target	1 person

Comments: .....

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Responsibilities

The table below displays information regarding the individuals involved in developing this qualification protocol.

Department/Individual	Responsibilities
Validation Author	• Develops the process validation plan, protocol, and report. • Confirms accuracy and completeness of the validation and qualification deliverables.
Validation Project Leader	• Defines validation and qualification deliverables (i.e., process validation plan, protocol, and report, project monitoring, protocol execution). • Acquires inputs from any needed technical experts to determine the activities appropriate to the validation. • Identifies the resources required to conduct the validation.
Technical Representative	• Provides knowledge with regard to the equipment/process/product undergoing validation and qualification. • Provides assistance to the Validation Project Leader with respect to the technical aspects of the equipment/process/product. • Provides help with study designs, acceptance criteria, and statistical analysis, as necessary.
Quality Assurance/Quality Management	• Reviews and approves validation and qualification documentation. • Ensures that each document is complete, accurate, and compliant with applicable validation requirements. • Reviews and approves deficiencies that occur during validation.

Comments: .....

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General Requirements

Completion of Installation Qualification (IQ) and Operational Qualification (OQ) shall be governed by the following general guidelines:

- Prior to starting any test case, the individual(s) involved in the test execution shall be trained on both the protocol and applicable procedure(s) required to execute the test cases.
- Except for the protocol approvers, each person who performs or reviews any section of tests within this document must complete the Signature Identification sheet.
- All tests that require the person executing the protocol to make a comparison, calculation or a judgment of satisfactory completion, will include a “Pass” or “Fail” column. This section will require the person executing the protocol to enter the disposition of each test or test step as appropriate.
- Any discrepancy encountered during execution will be documented as a deviation and will require analysis to determine the root cause, assessment of deviation risk, and corrective action recommendation, including repeat testing as appropriate. The deviation must be reviewed and approved prior to completing the associated test case. Each deviation shall be sequentially numbered and listed in a supported report log. The corresponding test case should reference the related deviation number.
- All test instruments used in the execution of this protocol must have a current calibration certification, traceable to NIST or applicable international standards. When the certificates for these instruments are held in the quality system (i.e., site calibration program), a verification of certification is sufficient. For all other instruments, current calibration must be demonstrated through calibration certificates.
- Any comments regarding the test case(s) will be recorded on the data sheets under the “Comments” section.
- The “Reviewed By” signature line will be signed by an independent reviewer who has read the respective test case and agrees with execution and conclusions.
- All supporting documentation and attachments must be identified or labeled with the minimum of the identification number, pagination (page of page), protocol number, and applicable test case(s).

General Acceptance Criteria

- The test case is successful and passes when all test steps meet the acceptance criteria.
- Successful completion of the protocol is achieved when all test cases have been successfully completed and all deviations resolved.

Comments: .....

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Codes and Abbreviations

Code	Meaning
amps	Amperes
CE	Certification mark that indicates conformity with health, safety, and environmental protection standards sold within the European Economic Area
°C	Degree centigrade
Dev No.	Deviancy number
IQ	Installation Qualification
kg	Kilogram
m	Meter
mm	Millimeter
MPa	Megapascal
NIST	National Institute of Standards and Technology
OQ	Operational Qualification
Pa	Pascal
PPE	Personal protective equipment
RH	Relative humidity

Comments: .....

Reviewed By: ..... Date: .....

Equipment and Process Description

UHDD™ Process

The basic mechanism of the UHDD™ Tablet De-Duster involves using an agitation system to loosen dust from tablets' surface as they pass through the machine.

Charging the Electromagnet

Once the electromagnet loses its charge, the vibratory spring will move back to its original position. As the armature moves back and forth, it creates a vibratory motion that results in the tablets moving up through the machine.

Removal of Dust by Vibration

While the tablets are being moved upward through the machine, the vibratory power removes the excess dust and produces smooth and clean tablets which are expelled through the discharge chute.

Comments: .....

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Test Equipment

Equipment	Serial Number	Calibration Certificate Number	Calibration Date	Initial and Date
Graduated steel ruler				
Indoor thermometer				
Hygrometer				
Multimeter				
Compact force gauge				
Scale (kg or lbs)				

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

UHDD™ - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. UHDD01	PACKING LIST		
Purpose of Test			
To confirm the presence of the packing list with the appropriate information.			
Method			
1	Locate packing list with the shipping container.		
2	Confirm the package list includes description of products, quantity, net weight, and gross weight.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Description of products is present.		
2	Quantity of products is present.		
3	Net weight of shipment is present.		
4	Gross weight of shipment is present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

UHDD™ - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. UHDD02	QUALIFICATION CERTIFICATE		
Purpose of Test			
To confirm the presence of CE qualification certificate.			
Method			
1	Inspect the CE certification.		
2	Confirm signature of authorized LFA personnel.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	CE qualification certificate is complete.		
2	Signature of authorized LFA personnel is present.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

UHDD™ - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. UHDD03	FACTORY ACCEPTANCE TEST REPORT AND QUALITY CONTROL CHECKLIST		
Purpose of Test			
To confirm the presence of factory acceptance test (FAT) report.			
Method			
1	Inspect the FAT report.		
2	Confirm quality control checklist from LFA Taiwan location is included.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	FAT report is complete.		
2	Quality control checklist from LFA Taiwan location is complete.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

UHDD™ - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. UHDD04	MATERIAL CERTIFICATE
Purpose of Test	
To confirm the presence of materials certificate.	
Method	
1	Point of contact materials are certified by third party.
2	Confirm materials are accurate to LFA standard.

Results

Test	Acceptance Criteria	Pass/Fail
1	Feeder material is confirmed to be SUS316.	
2	Discharge Chute material is confirmed to be SUS316.	
3	Sifter material is confirmed to be SUS316.	

Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

UHDD™ - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. UHDD05	PRODUCT MANUAL		
Purpose of Test			
To confirm the presence of product manual.			
Method			
1	Find the UHDD™ product manual at https://www.lfatabletpresses.com/product-data in Product Manuals section.		
2	Confirm product manual link is accessible.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Product manual PDF is accessible and can be downloaded.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Document Qualification

UHDD™ - Serial Number

The objective of Document Qualification is to confirm the presence and validity of the appropriate documents.

TEST No. UHDD06	ELECTRICAL WIRING DIAGRAM		
Purpose of Test			
To confirm the presence of electrical wiring diagram.			
Method			
1	Find the appropriate product manual at https://www.lfatabletpresses.com/product-data in Product Manuals section.		
2	Inspect the electrical wiring diagram in the product manual's appendix.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Electrical wiring diagram is accessible within the manual.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Installation Position and Space Qualification

UHDD™ - Serial Number

The objective of Installation Position and Space Qualification is to confirm the space and environmental conditions required for installation and operation.

TEST No. UHDDIS01	WORKSPACE SURFACE		
Purpose of Test			
To confirm the workspace surface accounts for the machine's weight and force exerted by machine and user.			
Method			
1	Ensure workspace surface supports machine's weight of 70 kg (around 154 lbs).		
2	Ensure the workspace surface supports an additional 18 kg (around 40 lbs).		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace surface is sturdy enough to support 88 kg (around 194 lbs).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Installation Position and Space Qualification

UHDD™ - Serial Number

The objective of Installation Position and Space Qualification is to confirm the space and environmental conditions required for installation and operation.

TEST No. UHDDIS02	WORKSPACE TEMPERATURE		
Purpose of Test			
To confirm the workspace's temperature levels are acceptable for machine operation.			
Method			
1	Measure the workspace's temperature with an indoor thermometer.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace temperature measures within 18-24 °C (64-75 °F).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Installation Position and Space Qualification

UHDD™ - Serial Number

The objective of Installation Position and Space Qualification is to confirm the space and environmental conditions required for installation and operation.

TEST No. UHDDIS03	HUMIDITY		
Purpose of Test			
To confirm the workspace's relative humidity levels are acceptable for machine operation.			
Method			
1	Measure the workspace's humidity with a hygrometer.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace relative humidity measures within 45-65% RH.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

UHDD™ - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. UHDDSM01	LIFTING EQUIPMENT		
Purpose of Test			
To confirm that the proper lifting equipment is available for mounting the machine.			
Method			
1	Ensure engine hoist and lifting strap are available.		
2	Ensure lifting strap supports the machine and does not induce any swinging or tilting of the machine.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Engine hoist and lifting strap are in position.		
2	Lifting strap is secure and support the machine's weight in a balanced way.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

Installation Qualification Protocol

Safety Measures Qualification

UHDD™ - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. UHDDSM02	PERSONAL PROTECTIVE EQUIPMENT		
Purpose of Test			
To confirm user has access to the following items of personal protective equipment (PPE) for use during machine operation.			
Method			
1	Ensure protective equipment is on hand before using the machine.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Steel toe boots are in possession.		
2	Heavy duty grip gloves are in possession.		
3	Back support belt is in possession.		
4	Safety goggles are in possession.		
5	Disposable latex/rubber gloves are in possession.		
6	Hairnet and/or beard net are in possession (if applicable).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

UHDD™ - Serial Number

The objective of Safety Measures Qualification is to confirm that machine installation meets requirements of safe production.

TEST No. UHDDSM05	CORRECT LOCAL VOLTAGE		
Purpose of Test			
To confirm that the workspace has the correct local voltage for the machine.			
Method			
1	Ensure the workspace has the correct voltage.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Workspace electrics support single phase 110 V (USA) or 220 V (UK).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

UHDD™ - Serial Number

The objective of Equipment Appearance Qualification is to confirm no damage to the machine's appearance during installation.

TEST No. UHDDEA01	NAMEPLATE	
Purpose of Test		
To confirm that the nameplate is securely fixed onto the machine and its information is clear.		
Method		
1	Ensure that the nameplate is securely fitted to the machine.	
2	Ensure that the nameplate contains details that are pertinent to the operation of the machine.	
Results		
Test	Acceptance Criteria	Pass/Fail
1	Nameplate is present.	
2	Nameplate displays machine name.	
3	Nameplate displays version number.	
4	Nameplate displays serial number.	
5	Nameplate displays voltage and power requirements.	
6	Nameplate displays motor type.	
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Installation Qualification Protocol

Equipment Appearance Qualification

UHDD™ - Serial Number

The objective of Equipment Appearance Qualification is to confirm no damage to the machine's appearance during installation.

TEST No. UHDDEA02	MACHINE BODY AND WIRING
Purpose of Test	
To confirm that the machine has no obvious damage to body and/or wiring.	
Method	
1	Inspect the machine body for obvious indentations, spots, scratches, cracks, or any other damages.
2	Inspect the wiring, cables, and electrical box for damage.

Results

Test	Acceptance Criteria	Pass/Fail
1	Machine body has no obvious damage.	
2	Machine's wiring, cables, and electrical box have no damage.	

Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments: .....

Reviewed By: ..... Date: .....

UHDD™ - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. UHDDOQ01	ELECTRICAL OUTPUT LEVELS		
Purpose of Test			
To confirm that the machine's hertz, voltage, and kilowatt levels are correct.			
Method			
1	Use a multimeter to measure the machine for each unit.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum hertz is 60 (USA) and 50 (UK).		
2	Maximum volts is 110 V (USA) and 220 V (UK).		
3	Maximum kilowatts is 0.15.		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

UHDD™ - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. UHDDOQ02	VACUUM PRESSURE		
Purpose of Test			
To confirm that the vacuum's pressure is at 2.7 m^3 per hour (-1 MPa).			
Method			
1	Measure the vacuum's pressure with a compact force gauge.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Vacuum's pressure is 2.7 m^3 per hour (-1 MPa) (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

UHDD™ - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. UHDDOQ03	AIR COMPRESSOR PRESSURE		
Purpose of Test			
To confirm that the air compressor's pressure is 0.1 m^3 per hour (0.05 MPa).			
Method			
1	Measure the vacuum's pressure with a compact force gauge.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Air compressor's pressure is 0.1 m^3 per hour (0.05 MPa) (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

UHDD™ - Serial Number

The objective of Production and Output Qualification is to confirm the maximum production and output values of the machine.

TEST No. UHDDOQ04	MAXIMUM TABLET OUTPUT		
Purpose of Test			
To confirm that the machine's maximum tablet output is 1,000,000 per hour.			
Method			
1	Automatically operate the machine for one minute with tablets.		
2	Record the amount of tablets de-dusted in one minute.		
3	Multiply the amount of tablets de-dusted in one minute by 60.		
Results			
Test	Acceptance Criteria		Pass/Fail
1	Maximum tablet output is 1,000,000 per hour (+/-5%).		
Result	Dev No.	Completed by (Initial/Date)	Verified by (Initial/Date)

Comments:

Reviewed By: Date:

Protocol Deviation Log

UHDD™ - Serial Number

Record each of the deviations raised during the completion of the protocol and the date the deviation is resolved.

Deviation No.	Deviation Description	Date Resolved	Initial and Date

Comments:

Reviewed By: Date:

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