

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester	
Installation Site: Flextronics Contract Manufacturing Site in Singapore				
Purpose: To verify that supporting documentation is available prior to the completion of qualification.				
Test Execution: - List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.				
Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #		Status in SAP	Initial & Date
TSP	TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY, Rev 09		RELEASE GENERAL	
Comments: TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY – WAT210700 Rev 09				
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail				

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Test Script #	IQ -02	IQ Test Name:	Site Verification		
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester		
Installation Site: Flextronics Contract Manufacturing Site in Singapore					
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable parameters in the Parameters column. Rows may be added as needed. - Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column. - Verify and/or measure the applicable parameters and complete the Table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report. Objective Evidence: - Completed IQ-02 Test Script Data Sheet - Photo(s) of the work area, as applicable - The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR. - Copies of calibration certificates for measurement tools, if applicable					
Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Ambient Temperature	18 °C to 28 °C				
Relative Humidity	10 % to 80 %, Non-Condensing				
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%				
Electrical Outlets	Minimum of 4 dedicated outlets				
Network Available	Minimum of 1 dedicated network				
Workspace	The system has sufficient room for the test station, UUT and service				
Test Station Bench	The Test Station Bench is large and strong enough to support the station				
Comments: - Ambient temperature/humidity measured using a Temperature/Humidity Meter, Control Number - Electrical supply measured using a Multimeter, Control Number Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail					

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Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester
Installation Site: Flextronics Contract Manufacturing Site in Singapore			
Purpose: To verify that all critical instruments are in the calibration database and that a calibration and/or a preventive maintenance has been performed, as appropriate. Test Execution: - List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed. - Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below. Objective Evidence: - Completed IQ-03 Test Script Data Sheet - Copies of calibration and/or maintenance certificates - Screen captures from the associated Calibration database			
Description	Asset #	Cal/PM Dates	Initial & Date
Electronics Weigh Balance	12200404	Last Cal/PM: 13-Jan-2020 Cal/PM Due: 13-Jul-2020	
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester
Installation Site: Flextronics Contract Manufacturing Site in Singapore			

Purpose:

To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).

Test Execution:

- List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed.
- List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column.
- Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.

Objective Evidence:

- Completed IQ-04 Test Script Data Sheet
- Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report.
- Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable

Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date
TE82526	Version: 1.0	Version:		

Comments:



Overall Test Conclusion		Document No.: _____
☐ Pass	☐ Fail	Iteration No.: _____
		Attachment: _____ Page: ____ of ____

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms
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Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester
Installation Site:	Flextronics Contract Manufacturing Site in Singapore		
Purpose: To verify that the equipment can operate in a safe manner, within its designated location.			
Test Execution: - List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary. - List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column. - Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below.			
Objective Evidence: - Completed IQ-05 Test Script Data Sheet - Photo(s) of the secured glass bottles, tanks, etc., if applicable - The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.			
Safety Inspection	Acceptance Criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found (or mitigated appropriately)		
Glass Bottles	Secure		
Waste Tanks	Secure and located below the system		
Emergency Stop	System ceases operation upon depressing the Emergency Stop button		
Guarding	Shielding in place to prevent hazard during operation		
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

Test Script #	IQ-06	IQ Test Name:	Functional Verification
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Equipment # TE82526-4		Equipment Name: Pump Tray Tester	
Installation Site: Flextronics Contract Manufacturing Site in Singapore			
Purpose: To verify that the system operates as expected.			
Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy.			
Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than “All required CTQ Specification measurements result in a Pass” then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.			
UUT Part Number/Serial Number		Acceptance Criteria	Pass/Fail
Part Number: Serial Number:		All required CTQ Specification measurements result in a Pass	
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

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Appendix A: TRAINING RECORD

Document #	WAT210700	Document Title	TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY	Version	00
				Revision	09

Training Performed By: (If not used this section can be deleted)

Printed Name	Signature	Date

☐ Read and Understood (If self-trained – If not self-trained this section can be deleted)

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date

Print multiple copies of this Training Record Template as needed

Document No.: _____
Iteration No.: _____
Attachment: _____ Page: ____ of ____

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DOCUMENT HISTORY

(Note: Complete Document History may be obtained via the Document Management System.)

VERSION:	03	ORIGINATOR:	James Stors	Change ID:	N/A
SUMMARY OF CHANGE: Changed the 730001835 document name to be current. Modified the Workspace and the Test Station Bench checks of IQ-02 Test Script Data Sheet to Pass/Fail. Added the ANSI C84.1 electrical supply tolerance specification to the Comments Section of the IQ-02 Test Script Data Sheet. Updated the Related Documents Section to be current. Updated to the current Template format.					

VERSION:	02	ORIGINATOR:	James Stors	Change ID:	N/A
SUMMARY OF CHANGE: Edited for overall grammar and terminology. Updated the Abbreviation section. Changed Performer to Executor. Updated the Records section to reference 730001835. Added Health & Safety Section. Section 8 updated to guide the Originator to type in descriptive/acceptance criteria in the Test Script Data Sheets and Training Form. Test Script Data Sheets updated to utilize gray cells for guidance and to provide a specified location for the Attachment Stamp/Marking. Removed blank rows from the Test Script Data Sheets. Removed the Electrical Safety Hi Pot/Ground Continuity test from IQ-05 Test Script Data Sheet. Added additional safety considerations to the Test Execution of IQ-05 Test Script Data Sheet. Added the Document Control Section marking to the Test Script Data Sheets and the Training Record appendix.					

VERSION:	01	ORIGINATOR:	N/A	Change ID:	N/A
SUMMARY OF CHANGE: ABANDONED					

VERSION:	00	ORIGINATOR:	James Stors	Change ID:	N/A
SUMMARY OF CHANGE: INITIAL RELEASE OF THE INSTALLATION QUALIFICATION PROTOCOL.					

Document No.: _____
Iteration No.: _____
Attachment : _____ Page ____ of ____

Calibration Due Date: 07-Jan-2021

Document No.: _____
Iteration No.: _____
Attachment : _____ Page _____ of _____

RELATIVE HUMIDITY: 54 % to 55 %

Verified using

THERMOHYGROGRAPH

Serial Number : 5650

EQID : 0418EQID : 0418

Calibration Due Date: 07-Jan-2021



Calibration	
EQID	: 0418
S/No	: 5650
Cal Date	: 07-JAN-20
Due Date	: 07-JAN-21
Remark	: NA

Document No.: _____
 Iteration No.: _____
 Attachment : _____ Page ____ of ____

ELECTRICAL SUPPLY : Minimum 4 dedicated outlets

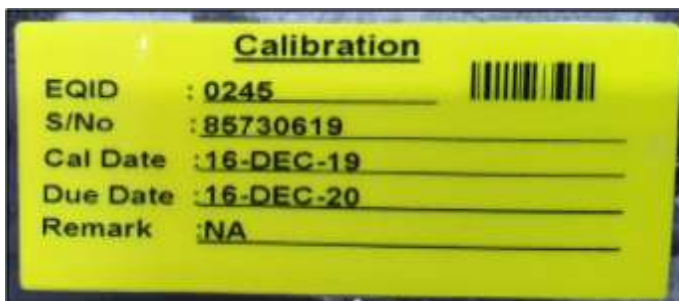
Verified using :

FLUKE 110 TRUE RMS MULTIMETER

Serial Number: 85730619

EQID: 0245

Calibration Due Date: 16-Dec-2020



Document No.: _____

Iteration No.: _____

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ELECTRICAL OUTLET

TE82526-4 Pump
Tray Tester (AC Line)

LCD Monitor (AC Line)

Computer Work
Station (AC Line CPU)



AND HR 200
Electronics Balance
(AC Line)

Document No.: _____
Iteration No.: _____
Attachment : _____ Page ____ of ____

NETWORK AVAILABLE : Minimum of 1 dedicated network

Blue Sticker : Dedicated network for Pump Tray Area



WS-9 is a dedicated network

Document No.: _____
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WORK SPACE: The system has sufficient room for the test station, UUT and service



TEST STATION BENCH : The test station bench is large and strong enough to support the station



Document No.: _____
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IQ-05 Test Script Data Sheet:

Station does not have Pinch Points/ sharp edges
Glass Bottle is secured by plastic container



Document No.: _____
 Iteration No.: _____
 Attachment : _____ Page ____ of ____

Waters Corporation

SUBASSEMBLY TEST RECORD

Part Number:	289000526	Description:	Alliance Pump Tray
Tested By:	246154	Date:	26/3/2020 4:44:07 pm
Serial Number:	13L0H042	Control Number:	N/A
Software Revision:	N/A	Factory Order:	N/A

Seal Wash Functional Test PASS ☒ FAIL ☐ see note # _____ PASS ☐

Accumulator Decay Test

Total decay (≤ 150 psi) - Actual: 20 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
Compress Volume (≤ 20 %) - Actual: 15 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Primary Decay Test

Total decay (≤ 150 psi) - Actual: 102 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
Compress Volume (≤ 20 %) - Actual: 10 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Flow Rate Test [Measured Flow: 0.999 ml/min]
($\leq \pm 1\%$) - Actual: -0.15 % ERROR PASS ☒ FAIL ☐ see note # _____ PASS ☐

Ripple Test
($\leq 2.5\%$) - Actual: 1.2 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Pump Tray Result: PASS ☒ FAIL ☐ Signed: 246154 JOEL Date: 26/MAR/2020

Notes: N/A

Pump PCB S/N: 210000425 - E
250220159M Accum. Xducer S/N: 299361 Prim. Xducer S/N: 299414

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing; the initial form must be attached and retained.

Title: individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03





Employee's Signature Title Date





Trainer's Signature Title Date

Document No.: _____
 Iteration No.: _____
 Attachment: _____ Page: _____ of _____

¹ Without preceding "90"

