

Title: *Installation Qualification Protocol*

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1. PURPOSE

The purpose of this Installation Qualification (IQ) protocol is to provide a series of Test Scripts to be used to qualify the installation of any Milford site process equipment and ancillary system to ensure compliance to manufacturer's guidelines and/or Waters requirements.

Once completed, the applicable executed IQ protocol Test Script Data Sheets will be included within an Installation Qualification Report (IQR), which will serve as objective evidence that all key aspects of the equipment and ancillary system are correctly installed.

2. SCOPE

This Installation Qualification protocol shall be used for all equipment within a method or process that makes a decision which can affect product, or that the improper installation and/or configuration would impact the assessment or production of product, as defined in 730001835, Process Validation Procedure for Milford Site.

3. ΔABBREVIATIONS

Term	Definition / Abbreviation
%	Percent
#	Number
°C	Degrees Celsius
Cal	Calibration
CTQ	Critical to Quality
Doc.	Document
EH&S	Environmental Health and Safety
GDP	Good Documentation Practices
Hz	Hertz
ID	Identification
IQ	Installation Qualification
IQR	Installation Qualification Report
LED	Light Emitting Diode
N/A	Not Applicable
PM	Preventive Maintenance
SAP	Enterprise Resource Planning (ERP) software
TSP	Test and Specification Procedure
UUT	Unit Under Test
VAC	Voltage Alternating Current
VAF	Validation Assessment Form
WI	Work Instruction

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4. ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Engineering Managers	- Ensure implementation of this protocol and affiliated operating procedures. - Review and/or approve all necessary documentation deliverables, as required. - Assign resources as required to support validation activities.
Originator	- Coordinate the execution of the applicable IQ activities. - Author the IQ Report summarizing results, upon completion of IQ activities.
Executor	- Execute applicable IQ activities per instructions from Originator using the applicable Test Scripts. - Responsible for providing the Originator with objective evidence needed to meet the requirements outlined in the applicable Test Scripts. - Follow all GDP requirements per Waters' Good Documentation Practices 730000523.
Reviewer	Review the finalized IQ Report.
Approver	Review and approve the finalized IQ Report.

5. RELATED DOCUMENTS

Doc #	Document Title
730000837	Waters Global Validation Policy
730001833	Test Engineering Management Policy
730001835	Process Validation Procedure for Milford Site
730001799	Operating Procedure, Calibration and Preventive Maintenance
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy
730000523	Waters' Good Documentation Practices
730000483	Global WI/Operating Procedure Template
730002232	Process Validation Master Plan - Milford

6. FORMS/TEMPLATES

Doc #	Document Title
730002845	Validation Report Template

6.1. ΔRecords

The executed Test Script Data Sheets shall be used as objective evidence within the associated IQ Report. The IQ Report shall be stored in SAP in accordance with 730001835, Process Validation Procedure for Milford Site.

7. ΔHEALTH & SAFETY

All personnel performing any part of this IQ shall be trained to this protocol, and/or the operating procedure(s) when applicable, prior to the start of any testing. A Training Record shall be filled out and attached to the associated IQR when training has been performed. A blank Training Record is provided as Appendix A and may be used. If used, the Originator and/or Executor shall digitally edit/enter the Document Number, Document Title, and the Version/Revision/Iteration in the light gray cells.

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8. ΔPROCEDURE

The applicable Test Script Data Sheets provided after this Section shall be executed as follows:

- 8.1. The Originator and/or Executor shall digitally edit/enter any descriptive information and acceptance criteria, as applicable, in the light gray cells of the Test Script prior to execution. Rows may be added as needed.
- 8.2. Black text requirements are not to be edited or removed and shall be verified when applicable.
- 8.3. N/A may be entered for any blank parameter or cell that is not used or not applicable.
- 8.4. Blue text examples are provided and should be changed to font color black and/or edited/removed as applicable prior to execution.
- 8.5. Blank and/or unused (blue text) rows may be removed.
- 8.6. The Executor shall perform the applicable Test Scripts, hand writing in all results in the white cells following proper GDP, as defined in 730000523, Good Documentation Practices.
- 8.7. Each page of the applicable Test Script Data Sheets shall have the Report Document Number, Report Iteration, Attachment Number, and be paginated, as defined in 730002845, Report Template.

An example of an IQR Attachment stamp/markings is shown below:

Document No.: TE83064-1-IQR
 Iteration No.: 00
 Attachment: 8.1 Page: 1 of 1

The stamp shown above is available for use from the Validation Team for unmarked attachments.

8.8. Acceptance Criteria

The IQ will be considered successful when all applicable sections have been completed and an IQR has been written in accordance with 730002845, Validation Report Template, and has been approved. Only the Test Scripts that apply to the Equipment being qualified shall be performed.

Objective evidence will be included in, or attached to, the associated IQR. Examples of objective evidence include, but are not limited to:

- All completed protocol Test Script Data Sheets
- Screenshots
- Calibration/PM Certificates and/or Records
- Photos
- Test reports

8.8.1. Failure to Meet Acceptance Criteria

If the standard IQ execution is not able to be performed follow the following steps:

- If a discrepancy is found which can be resolved, make the change and then continue with the execution. Discrepancies and their resolutions shall be summarized in the Deviation section of the IQR.
- In the event that a discrepancy is not able to be resolved the Originator must decide to either submit the IQR to the appropriate signatories with a recommendation to accept, with justification, or reject the qualification. In the case of a rejected qualification the applicable engineering personnel shall assess the issue and determine if changes can be made in order to move forward with the IQ.

8.9. Installation Qualification Report

8.9.1. An Installation Qualification Report shall be written in accordance with 730002845, Validation Report Template, upon completion of all applicable IQ Test Script requirements. The IQR shall summarize the results of the testing performed and any deviations that occurred.

8.9.2. ΔThe following Test Scripts shall be used, as applicable, for the execution of the Installation Qualification:

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Test Script # IQ-01	IQ Test Name: Associated Documentation Verification		
Equipment # TE or Val #	Equipment Name: Enter the equipment name & serial number/ID, if applicable		
Installation Site: Enter the equipment installation site, i.e. Milford Production Clean Room			
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
Enter the Document Type from SAP, i.e. TSP	Enter the Title Document number, Version/Revision numbers		
Enter the Document Type from SAP, i.e. Cal	Enter the Title Document number, Version/Revision numbers		
Comments:			
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 # TE or Val #	Equipment Name: Enter the equipment name & serial number/ID, if applicable			
Installation Site: Enter the equipment installation site, i.e. Milford Production Clean Room				
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable environmental/input 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, as appropriate. - 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			
Workspace	Sufficient room for the test station, UUT and service			
Test Station Bench	Large and strong enough to support the station			
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			
Comments: - Ambient temperature/humidity measured using an ExTech Model 445703 Thermohygrometer, Control Number 95648. - Electrical supply measured using a Fluke 189 Multimeter, Control Number 98209.				
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 # TE or Val #	Equipment Name: Enter the equipment name & serial number/ID, if applicable		
Installation Site: Enter the equipment installation site, i.e. Milford Production Clean Room			
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
Enter the equipment or tooling nomenclature		Last Cal/PM: Cal/PM Due:	
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 # TE or Val #	Equipment Name: Enter the equipment name & serial number/ID, if applicable			
Installation Site: Enter the equipment installation site, i.e. Milford Production Clean Room				
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
Equipment Software	Version: 1.0	Version:		
Instrument Firmware P/N: 186017013	Version: 1.65.6205	Version:		
Comments:				
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail				

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Test Script # IQ-05		IQ Test Name: General Safety and Alarms	
Equipment # TE or Val #		Equipment Name: Enter the equipment name & serial number/ID, if applicable	
Installation Site: Enter the equipment installation site, i.e. Milford Production Clean Room			
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
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			

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Test Script # IQ-06	IQ Test Name: Functional Verification		
Equipment # TE or Val #	Equipment Name: Enter the equipment name & serial number/ID, if applicable		
Installation Site: Enter the equipment installation site, i.e. Milford Production Clean Room			
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	Initial & Date
Part Number: 186015070 Serial Number: F18URI994M	Enter "All required CTQ Specification measurements result in a Pass" or the appropriate acceptance criteria		
	UUT Firmware Version: 1.40.45		
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

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Appendix A: TRAINING RECORD

Document #	Enter the Doc. #	Document Title	Enter the Document Title	Version	00
				Revision	A

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

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DOCUMENT HISTORY

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.					