

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 1 of 8

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification		
Equipment #	TE82988-12	Equipment Name:	Global Test System		
Installation Site: Venture: WPPL, 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	210001115 KESTREL DCC (Kanye) Programming and Test Instructions 50593, Rev. 03, Rev. 03				
CAL	Waters GTS Preventative Maintenance and Calibration Procedure 735004006, Rev. A, Ver. 00				
Comments:					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: _____ of _____		
☐ Pass ☐ Fail					

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 2 of 8

Test Script #	IQ -02	IQ Test Name:	Site Verification		
Equipment #	TE82988-12	Equipment Name:	Global Test System		
Installation Site: Venture: WPPL, Singapore					
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	59-86° F (15-30° C)				
Relative Humidity	20%-80%, Non-Condensing				
Workspace	Adequate space for testing and service				
Test Station Bench	Large and strong enough to support all equipment				
Electrical Supply	50-60 HZ, 85-132 or 180-350 VAC				
Electrical Outlets	>= 1				
Network Available	>= 1				
Vacuum	40 cfm (1.13 cubic meters/min) minimum vacuum flow and a minimum vacuum pressure of 23 inches Hg (78 kPa).				
Comments: All acceptance Criteria listed in table above specified in GTS Site Preparation Guide_Rev 5.					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail					
Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification		

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 3 of 8

Equipment #	TE82988-12	Equipment Name:	Global Test System
Installation Site: Venture: WPPL, 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
		Last Cal/PM: Cal/PM Due:	
		Last Cal/PM: Cal/PM Due:	
		Last Cal/PM: Cal/PM Due:	
		Last Cal/PM: Cal/PM Due:	
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Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 4 of 8

		Last Cal/PM: Cal/PM Due:	
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		Last Cal/PM: Cal/PM Due:	

Comments:

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

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 5 of 8

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version																					
Equipment #	TE82988-12	Equipment Name:	Global Test System																					
Installation Site: Venture: WPPL, 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 <table border="1"> <thead> <tr> <th>Description</th><th>Acceptance Criteria</th><th>As Found</th><th>Pass/Fail</th><th>Initial & Date</th></tr> </thead> <tbody> <tr> <td>Test Sequence 210001115HVC</td><td>Version: C</td><td>Version:</td><td></td><td></td></tr> <tr> <td>Test Sequence 210001115</td><td>Version: C</td><td>Version:</td><td></td><td></td></tr> <tr> <td>NI TestStand</td><td>Version: 4.2.1</td><td>Version:</td><td></td><td></td></tr> </tbody> </table> Comments:					Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	Test Sequence 210001115HVC	Version: C	Version:			Test Sequence 210001115	Version: C	Version:			NI TestStand	Version: 4.2.1	Version:		
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date																				
Test Sequence 210001115HVC	Version: C	Version:																						
Test Sequence 210001115	Version: C	Version:																						
NI TestStand	Version: 4.2.1	Version:																						
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____																						
☐ Pass ☐ Fail																								

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 6 of 8

Test Script # IQ-05		IQ Test Name: General Safety and Alarms	
Equipment # TE82988-12		Equipment Name: Global Test System	
Installation Site: Venture: WPPL, 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)		
Safety Labels	Clearly highlight hazards or requirement of equipment		
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			

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 7 of 8

Test Script # IQ-06	IQ Test Name: Functional Verification		
Equipment # TE82988-12	Equipment Name: Global Test System		
Installation Site: Venture: WPPL, 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	Initial & Date
Part Number: TE83004 Serial Number:	All required CTQ Specification measurements result in a Pass		
Part Number: 210001115 Serial Number:	All required CTQ Specification measurements result in a Pass		
Comments: GTS SelfTest Fixture TE83004 will be connected and tested according to Waters GTS Preventative Maintenance and Calibration Procedure 735004006, Rev. A, Ver. 00; This test is to check GTS overall functionality. A selftest report will be printed out as Objective Evidence for this test. UUT 210001115 will be loaded on test fixture 279002953 to run functional test. A test report will generated as object evidence for this test.			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

Page 8 of 8

Appendix A: TRAINING RECORD

Document #	50593	Document Title	210001115 KESTREL DCC (Kanye) Programming and Test Instructions	Version	03
				Revision	03

☐ Read and Understood

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

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