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WORK INSTRUCTION

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	APPROVED	JA 12-MAR-2019
CAL	Waters GTS Preventative Maintenance and Calibration Procedure 735004006, Rev. A, Ver. 00	COMPLETED	JA 12-MAR-2019

Comments:

THE GTS PREVENTIVE MAINTENANCE WAS RELEASED UNDER
INTERNAL DOCUMENT NUMBER X1-ENG-048.

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

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.
HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

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)	24.3 °C	PASS	JA 12-MAR-2019	
Relative Humidity	20%-80%, Non-Condensing	48.0 %	PASS	JA 12-MAR-2019	
Workspace	Adequate space for testing and service	2.5M X 2.5M	PASS	JA 12-MAR-2019	
Test Station Bench	Large and strong enough to support all equipment	2.5M X 2.5M	PASS	JA 12-MAR-2019	
Electrical Supply	50-60 HZ, 85-132 or 180-350 VAC	50.03 HZ 120.8 VAC, 3 PHASE	PASS	JA 12-MAR-2019	
Electrical Outlets	>= 1	1	PASS	JA 12-MAR-2019	
Network Available	>= 1	1	PASS	JA 12-MAR-2019	
Vacuum	40 cfm (1.13 cubic meters/min) minimum vacuum flow and a minimum vacuum pressure of 23 inches Hg (78 kPa).	28.5 in Hg	PASS	JA 12-MAR-2019	
Comments: All acceptance Criteria listed in table above specified in GTS Site Preparation Guide_Rev 5.					
Overall Test Conclusion ☒ Pass ☐ Fail			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
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
MULTIFUNCTION IO MODULE NI: PXI-6229	97021	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
MULTIFUNCTION IO MODULE NI: PXI-6229	97022	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
SOURCE MEASUREMENT UNIT NI: PXI-4130	97023	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
DC ELECTRONIC LOAD CHROMA: 63103A	1) 97010 2) 97011 3) 97012 4) 97013	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
DC POWER SUPPLY TDK LAMBDA: GEN# 60-12.5	1) 97015 2) 97016 3) 97017 4) 97018	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
DC POWER SUPPLY TDK LAMBDA: GEN# 30-25	1) 97019 2) 97020	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
FOUR CHANNEL DIGITIZING OSCILLOSCOPE TEKTRONIX: TDS 3054C	97024	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
FUNCTION/ARBITRARY WAVEFORM GENERATOR AGILENT: 33220A	97026	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019
DIGITAL MULTIMETER AGILENT: 34411A	97025	Last Cal/PM: 21-FEB-2019 Cal/PM Due: 21-FEB-2020	JA 12-MAR-2019

Title: Installation Qualification Protocol

Document # 730004135

Version # 02

Page 4 of 8

PROGRAM RESISTANCE CARD GEOTEEST: GX1164-01	97014	Last Cal/PM: 05-MAR-2019 Cal/PM Due: 05-MAR-2021	JA 12-MAR-2019
TRUE RMS MULTIMETER FLUKE: 87111	7764 Q543	Last Cal/PM: 17-JAN-2019 Cal/PM Due: 17-JAN-2020	JA 12-MAR-2019
ALARM HYGROMETER DRUMMOND: HT-5B	EA11065248	Last Cal/PM: 18-APR-2018 Cal/PM Due: 18-APR-2019	JA 12-MAR-2019
		Last Cal/PM: Cal/PM Due:	
		Last Cal/PM: Cal/PM Due:	
		Last Cal/PM: Cal/PM Due:	
		Last Cal/PM: Cal/PM Due:	

Comments:

PLEASE REFER TO THE ATTACHED CAL REPORT OF
THE INSTRUMENT THAT WERE USED.

Overall Test Conclusion

☒ Pass

☐ Fail

Document No.: _____

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					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Test Sequence 210001115HVC	Version: C	Version: C	PASS	JA 12-MAR-2019	
Test Sequence 210001115	Version: C	Version: C	PASS	JA 12-MAR-2019	
NI TestStand	Version: 4.2.1	Version: 4.2.1	PASS	JA 12-MAR-2019	
Comments: PLEASE REFER TO THE ATTACHED PHOTOS					
Overall Test Conclusion			Document No.: _____		
☒ Pass ☐ Fail			Iteration No.: _____		
			Attachment: _____ Page: ____ of ____		

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)	PASS	JA 12-MAR-2019
Safety Labels	Clearly highlight hazards or requirement of equipment	PASS	JA 12-MAR-2019
Emergency Stop	System ceases operation upon depressing the Emergency Stop button	PASS	JA 12-MAR-2019
Guarding	Shielding in place to prevent hazard during operation	PASS	JA 12-MAR-2019
Comments: PLEASE REFER TO THE ATTACHED PHOTOS			
Overall Test Conclusion ☒ Pass ☐ Fail		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	

Title: Installation Qualification Protocol

Document # 730004135

Version # 02

Page 7 of 8

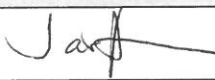
Test Script # IQ-06	IQ Test Name: Functional Verification		
Equipment # TE82988-12	Equipment Name: Global Test System		
Installation Site: Venture: WPPL, Singapore			
Purpose: To verify that the system operates as expected. Test Execution: - Select the UUT(s) or tests to be performed as defined within 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: QUAL-12MAR19	All required CTQ Specification measurements result in a Pass	PASS	JA 12-MAR-2019
Part Number: 210001115 Serial Number: 21/0600	All required CTQ Specification measurements result in a Pass	PASS	JA 12-MAR-2019
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. PLEASE REFER TO THE ATTACHED TEST LOGFILES			
Overall Test Conclusion		Document No.: _____	
☒ Pass ☐ Fail		Iteration No.: _____	
		Attachment: _____ Page: ____ of ____	

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
JASON KGBK/ANI		JA	12-MAR-2019

Document No.: _____

Iteration No.: _____

Attachment: _____ Page: ____ of ____