

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

Waters - Wilmslow

Equipment Qualification Protocol

ACQUITY QDa Test Floor – update to AMITS v4.1

Control of Change – 23

For Internal Use Only

Document reviewed and approved electronically

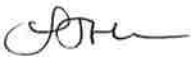
Host PC — Waters - S4BK 7529 PS 19MAR2018
GES Venture

Author: Paul Slater

Date: 05-MAR-2018

Post Review / Approval

Completion of the following signature blocks indicates your review and approval of the completion of the EQ.

Approved by	Signature	Job Title	Date
Paul Merson		Director Product Assurance Engineering	22 MAR 2018
Edwina Beanland		Process Validation Engineer	21 MAR 2018
Steven Hill		Quality Engineer, CSV	22 MAR 2018

Upon completion of the signature box, the equipment has met all requirements outlined within this document, unless otherwise stated, and is deemed fit for purpose.

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

TABLE OF CONTENTS

1. Purpose	3
2. Scope	3
3. Responsibilities & Signature Page	4
3.1. Responsibilities	4
3.2. Operator Signature Details	4
4. Abbreviations	4
5. References	5
6. Acceptance Criteria	5
7. Documentation	5
8. Ancilliary Equipment	5
9. Materials	5
10. Qualification Test Matrix	5
11. Equipment Installation Testing	7
11.1. EQ001 – Equipment Details	7
11.2. EQ002 – Training Requirements	8
11.3. EQ003 – Documentation Review	9
11.4. EQ004 – Equipment Calibration	10
11.5. EQ005 – Utility Installation	11
11.6. EQ006 – Health and Safety Testing of Equipment	12
11.7. EQ007 – Computer Hardware	13
11.8. EQ008 – Computer Software	14
12. Equipment Operation and Performance Testing	15
12.1. EQ009 – Operational Checks of Test Bay Software and Network	15
13. Maintaining the Validated State	18
13.1. Planned Preventative Maintenance/Calibration Summary	18
13.2. Standard Operating Procedure	18
14. Deviations	19
14.1. Deviation Summary	19
14.2. Validation Deviation Form*	20
15. Attachments	21

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

1. PURPOSE

The purpose of this protocol is to describe the procedures for conducting Equipment Qualification of the AMITS v4.1 updated ACQUITY QDa Test Bays installed and operated at GES Venture, as detailed in the Equipment Qualification Plan EQ Plan – AMITS v4.1 update at Venture (VAL001194) which has been assessed and deemed that qualification is required as detailed in EQ Assessment form EQAF-AMITS V4.1 Update to AMITS v4.1 – Venture (VAL001191).

This protocol can also be used to describe the procedures for conducting Equipment Qualification of the AMITS v4.1 updated ACQUITY QDa Test Bays installed and operated at WPPL, as detailed in the Equipment Qualification Plan EQ Plan – AMITS v4.1 update at WPPL (VAL001195) which has been assessed and deemed that qualification is required as detailed in EQ Assessment form EQAF-AMITS V4.1 Update to AMITS v4.1 – WPPL (VAL001192).

Execution and approval of this protocol will ensure that the equipment is installed and operating to relevant manufacturers specifications, and ensures that the equipment is suitable for its intended use.

The objective of this protocol is to provide documented evidence that:

- The equipment conforms to the relevant manufacturer's installation requirements.
- The principal features of the equipment and components are installed correctly.
- The equipment operates, as expected, within its required process parameters.

For equipment description and functionality, refer to the EQ Plan – AMITS v4.1 update at Venture (VAL001194), and EQ Plan – AMITS v4.1 update at WPPL (VAL001195).

2. SCOPE

This protocol is restricted to the ACQUITY QDa Test Bays which are located in GES Venture, and WPPL Singapore.

The list of equipment installation tests are pre-defined within this protocol, however may be omitted if deemed not applicable during execution, by marking as 'N/A' – Not Applicable. Equipment operation/performance testing will be performed as detailed in the EQ Plan and associated EQAF Assessment.

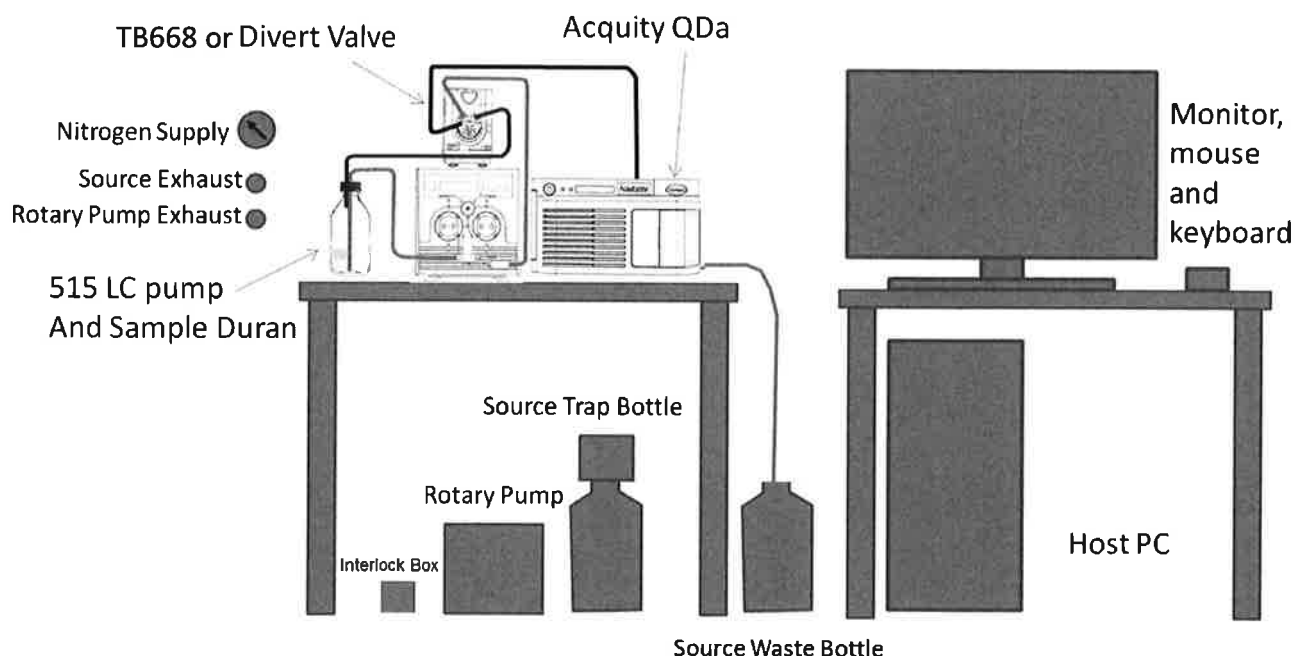


Figure 1 – Test Bay System – Venture and WPPL Singapore

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

3. RESPONSIBILITIES & SIGNATURE PAGE

3.1. Responsibilities

Prior to start of qualification activities, this document must be pre-approved by completion of the required signature box on the main title page. Refer to the Equipment Qualification procedure 730003703 for details on responsibilities. A Quality Assurance signature is always required, prior to commencement.

3.2. Operator Signature Details

All individuals that require making entries into this protocol after pre-approval are required to fill their details in the table below. This also includes anyone who is tasked with reviewing the document.

Name	Job Title	Signature	Initials
Paul Slater	Principle Product Assurance Engineer		19 MAR 2018
EDWINA BEANLAND	Process Validation Engineer		21 MAR 2018

4. ABBREVIATIONS

Abbreviation	Explanation	Abbreviation	Explanation
EDMS	Electronic Document Management System	EQ	Equipment Qualification
P & ID	Piping and Instrumentation Diagram	VR	Validation Report
DQ	Design Qualification	QA	Quality Assurance
GMP	Good Manufacturing Practices	GDP	Good Documentation Practices
URS	User Requirements Specification	FAT	Factory Acceptance Test
AMITS	Automated Manufacturing Instrument Test Software.		

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

5. REFERENCES

The following references are applicable to completion of this protocol.

Document Number	Document title
VAL001194	Equipment Qualification Plan – EQ Plan – AMITS v4.1 - Venture
VAL001191	EQAF – Update to AMITS v4.1 - Venture
VAL001195	Equipment Qualification Plan – EQ Plan – AMITS v4.1 - WPPL
VAL001192	EQAF – Update to AMITS v4.1 - WPPL
46215	Acquity QDa Installation - link to Network
45747	Automated Manufacturing Instrument Test Software Reference Manual

6. ACCEPTANCE CRITERIA

Overall acceptance criterion of the equipment is that all the tests are completed and documented satisfactorily with positives outcomes. The equipment must be shown to be fit for its intended purpose.

Each individual acceptance criterion is detailed within the appropriate EQ test sections.

If, during testing and an acceptance criterion is not met, a deviation should be raised as a deviation (section 14) of this protocol. For deviation and concession guidance, refer to the Equipment Qualification Procedure 730003703.

7. DOCUMENTATION

All paper documentation generated as part of the EQ testing should be attached to this protocol by using the attachments section 15. Each attached document should be appropriately labelled with the project number, EQ test number, the protocol number and page number, for example:

EQAF 18 - Test EQ### page # of #

Each page should also be initialled and dated by the operator to comply with GMP/GDP procedures.

Where data is attached to an electronic location, it must be in **.pdf format only** and contain header and footer information with the above EQ reference, if possible. Pages **are not** required to be signed and dated. A copy of the electronic document must be added to the Validation Project Folder:

P:\MS Quality Group\Validation Documentation\System Validation\EQAF\EQAF0018 - Singapore Venture – Test Bays

8. ANCILLIARY EQUIPMENT

Any test equipment used within this EQ protocol as part of testing should be subject to calibration and a planned preventative maintenance program, unless a justification can be provided for use.

All testing equipment should be recorded within each of the EQ test sections and include the asset number, calibration date and frequency of calibration. A copy of each calibration certificate should be attached in section 15 - Attachments, following the reference detailed in Section 7 – Documentation. See the Equipment Qualification Procedure for further information on test and calibration equipment.

9. MATERIALS

Any materials/chemicals used in this qualification should be recorded in each of the test sections for traceability and include relevant information such as; certificate of Analysis (C of A) lot number, manufactured date, expiry date and number used etc, and be traceable.

10. QUALIFICATION TEST MATRIX

The following installation and operational tests will be performed on each of the four Venture ACQUITY QDa Test Floor Test Bays. Installation tests are pre-defined and if not appropriate should be entered as N/A during execution of the protocol. Operation testing will test the critical factors outlined in the manufacturers specifications, User Requirement

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

Specification or associated equipment risk assessments detailed within the Validation Plan VAL001194. Each critical factor should be added to the EQ test matrix (table 1). See the Equipment Qualification Procedure for further information on qualification test matrices and setting up qualification testing.

Table 1 - EQ Test Matrix

Description of Requirements or Tests	Section
Equipment Details	EQ001
Training Requirements	EQ002
Documentation Review	EQ003
Calibration Check	EQ004
Utility Installation	EQ005
Health and Safety Testing of Equipment	EQ006
Computer Hardware	EQ007
Computer Software	EQ008
Operational Checks of Test Bay Software and Network	EQ009

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

11. EQUIPMENT INSTALLATION TESTING

11.1. EQ001 – Equipment Details

Purpose: To enter equipment details being installed.

Equipment Name	N/A		
Equipment Description:	N/A		
Make:	N/A		
Model/Type:	N/A		
Serial Number:	N/A		
Asset No:	N/A		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	N/A		
Comments	Software update. Software installation covered in section 12		
Signed (Operator)		Date	19 MAR 2018
Reviewed (2 nd Party)		Date	21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

11.2. EQ002 – Training Requirements

Purpose: To ensure training has been given to relevant personnel, prior to starting qualification work

Internal Training Provided on equipment (if yes give details below)	(Yes) / No
External Training Provided on equipment (if yes give details below)	(Yes) / No
Comments Product Assurance Administrator to perform tasks associated with 46215. No initial training received/required.	
Signed (Operator)	 Date19MAR 2018
Reviewed (2 nd Party)	 Date21MAR2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®		EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00	

11.3. EQ003 – Documentation Review

Purpose: To ensure the required documentation to support the equipment is available.

Documentation	Details		Location
Commissioning Documentation	N/A		N/A
Declaration of Conformity (CE certificate)	N/A		N/A
Operation and Maintenance manual	45747 – Automated Manufacturing Instrument Test Software Reference Manual		SAP
Materials List / Spares / Bill of Materials	N/A		N/A
Drawings	Type	Rev No.	Location
	Electrical Diagram	N/A	N/A
	Pneumatic Diagram	N/A	N/A
	Hydraulic Diagram	N/A	N/A
	Mechanical Assembly	N/A	N/A
	Layout Drawing	N/A	N/A
	P & ID	N/A	N/A
	Schematic	N/A	N/A
Comments: 			
Signed (Operator)		<i>Paul Glatz</i>	Date 19 MAR 2018
Reviewed (2 nd Party)		<i>Eberhard</i>	Date 21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

11.4. EQ004 – Equipment Calibration

Purpose: To add current calibration state of equipment during qualification

Does equipment under test require calibration prior to EQ activities?		Yes/ <u>No</u>	
Recommended calibration frequency?		Yearly	
Has Equipment been calibrated prior to starting this protocol? If so, provide details below			
515 Pump	Calibrated on	28 NOV 2017	Calibration due 28 NOV 2018
Comments: 			
Signed (Operator)			Date 19 MAR 2018
Reviewed (2 nd Party)			Date 21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

11.5. EQ005 – Utility Installation

Purpose: To record the utility requirements and connections required for the equipment to operate

Utility	Expected Result	Actual Result	Pass / Fail
Electrical Supply	N/A	N/A	N/A
Compressed Air Supply	N/A	N/A	N/A
Process Gas (type)	N/A	N/A	N/A
Exhaust / Vacuum	N/A	N/A	N/A
Water grade	N/A	N/A	N/A
Other	N/A	N/A	N/A
Comments: 			
Signed (Operator)		Date	19MAR 2018
Reviewed (2nd Party)		Date	21MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

11.6. EQ006 – Health and Safety Testing of Equipment

Purpose: To record all Health and Safety details of the equipment and ensure the equipment is safe to use. PPE should be added to the specific test.

Requirement		Result (Yes / No)	Acceptable (Yes / No)
Pressure	Pressure ratings of piping components / pressure vessels are compatible with operating conditions?	N/A	
	Pressure relief devices provided where applicable?	N/A	
	Internal lines, regulators and pressure gauges are labelled?	N/A	
Guarding	Are all mechanical hazards adequately guarded?	N/A	
	Are all mechanical hazards adequately labelled & identified?	N/A	
	Are all thermal hazards adequately guarded?	N/A	
	Are all thermal hazards adequately labelled & identified?	N/A	
	Are all guards fixed or interlocked?	N/A	
Exhaust	Equipment exhausted where required?	N/A	
Pumps	Are facilities services, inputs & outputs, labelled with direction of flow?	N/A	
	Have facilities lines been adequately secured?	N/A	
	Do the pumps and motors have over temperature & over pressure protection?	N/A	
Power Down Test	Does the system returns to a safe state following a power cycle?	N/A	
PAT Test	Does the equipment require P.A.T. testing prior to use	N/A	
Flash Test	Does the equipment require Flash testing prior to use	N/A	

Comments:

Signed (Operator)		Date	19 MAR 2018
Reviewed (2nd Party)		Date	21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

11.8. EQ008 – Computer Software

Purpose: Record software required for the equipment including operating systems, version numbers, MS Excel spreadsheets any other related software.

Does equipment require computer software to operate successfully?			Yes/No	
If yes, enter details below:				
ACQUITY QDa AMITS	Version No.	4.1	SVAF Approved	☒ Yes / No
PuTTY	Version No.	6.60	SVAF Approved	☒ Yes / No
Engineers Dashboard	Version No.	1.2.659.24837 FS 19 MAR 18 1.2.60.24837	SVAF Approved	☒ Yes / No
Chrome	Version No.	65.0.3325.146	SVAF Approved	☒ Yes / No
MassLynx	Version No.	4.1 SN947 SN 961	SVAF Approved	☒ Yes / No
Microsoft Office	Version No.	14.0.7190.5000	SVAF Approved	☒ Yes / No
Comments:				
Signed (Operator)			Date	19 MAR 2018
Reviewed (2 nd Party)			Date	21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

12. EQUIPMENT OPERATION AND PERFORMANCE TESTING

12.1. EQ009 – Operational Checks of Test Bay Software and Network

Objective/Rationale:

To confirm the installation of ACQUITY QDa AMITS functions correctly.

Acceptance Criteria:

Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
AMITS Network Configuration	Open AMITS. Open Admin. Enter Admin password. The Admin Details within AMITS must be edited to match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore. Confirm the Admin Details within AMITS match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore.	Confirmed. Attachment 1.	Y PS 15 MAR 2018
AMITS User List	Refresh AMITS. (f5 key) Open Admin. Click on the downward pointing arrow beside the Test Engineer drop list. Confirm the engineer list contains UKPLMPSL.	Confirmed Attachment 2	Y PS 18 MAR 2018
AMITS link to Storage Solution	Open AMITS. Open Test Run Details. From the product type list, select "simulator". Enter the following details: Serial Number: EQ-Protocol Open the Dashboard Confirm a completed test record is visible. (All the Statuses in every test section are "PASS")	Confirmed. Attachment 3	Y PS 18 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

AMITS timely Data Exchange with Storage Solution.	Open AMITS. Open Test Run Details. From the product type list, select "simulator". Enter the following details: Serial Number: Test Bay Number-DD-MMM-YY Sample Batch Number: N/A Sample Use By Date: N/A Test Box Number: Divert Valve serial number Test Rig Number: N/A Procedure Document Number: this document Open the Dashboard Click the "Start here" button. Follow the on-screen instructions to start a simulated test run. Use your AMITS account. Follow the on-screen prompts for manual interlock lock tests by clicking the continue button. Allow the test sequence to complete. (approx 15 minutes) Confirm the test sequence completes. (All the Statuses in every test section are "PASS")	5 mins 35 seconds. Confirmed. Attachment 4	RS 18 MAR 2018
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 THE SCIENCE OF WHAT'S POSSIBLE.®		EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00	

AMITS PDF data accepted by Nu-Genesis	Final iterations of the AMITS DHR, DHR Summary, and History Record sheets must be stored / printed at this point. Store / Print the records as directed below :																		
	Complete DHR – Print to PDF and save in – \\tu-server-paeag\AMITS The file should be saved as - Device History Record ***xxxx_Post Health Check.																		
	DHR Summary - Print to PDF and save in – \\tu-server-paeag\AMITS. The file should be saved as - Summary ***xxxx_Post Health Check.																		
	History Record - Print to PDF and save in – \\tu-server-paeag\AMITS. The file should be saved as - History ***xxxx_Post Health Check.																		
	For the above file naming conventions - *** = the host pc name, and xxxx = the date. Confirm all three records are successfully transferred to Nu-Genesis.	Confirmed Attachment 5	PS 18 MAR 2018																
<table border="1"> <tr> <td>Were all acceptance criteria met – Y/N</td> <td colspan="3" style="text-align: center;">(Y) N</td> </tr> <tr> <td>Deviation Number (if required)</td> <td colspan="3"></td> </tr> <tr> <td colspan="4">Comments:</td> </tr> <tr> <td colspan="4" style="height: 100px;"></td> </tr> </table>				Were all acceptance criteria met – Y/N	(Y) N			Deviation Number (if required)				Comments:							
Were all acceptance criteria met – Y/N	(Y) N																		
Deviation Number (if required)																			
Comments:																			
Signed (Operator)		Date	18 MAR 2018																
Reviewed (2 nd Party)		Date	21 MAR 2018																

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00

13. MAINTAINING THE VALIDATED STATE

13.1. Planned Preventative Maintenance/Calibration Summary

Purpose: To record the calibration or planned preventative maintenance schedules have been set up as required in the calibration database and provide objective evidence.

N/A software update			
Signed (Operator)		Date	19 MAR 2018
Reviewed (2 nd Party)		Date	21 MAR 2018

13.2. Standard Operating Procedure

Purpose: to record the SOP details that must be written for operators to use the equipment.

SOP Released in EDMS	(Yes) / No / NA	SOP Number:	45747
SOP Title	Automated Manufacturing Instrument Test Software – Reference Manual .		
Signed (Operator)		Date	19 MAR 2018
Reviewed (2 nd Party)		Date	21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®		EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00	

14. DEVIATIONS

This section details any deviations raised during execution of this protocol. For deviation guidance, refer to the Equipment Qualification procedure – 730003703.

14.1. Deviation Summary

Deviation No.	EQ Test No.	Details	Closed (Yes/No)	Operator Initial & Date
N/A.				
Comments:				
Signed (Operator)		<i>Paul Gato</i>	Date	19 MAR 2018
Reviewed (2nd Party)		<i>Shenlon</i>	Date	21 MAR 2018

Waters THE SCIENCE OF WHAT'S POSSIBLE.®		EQ Protocol – AMITSv4.1 Update Singapore	
Document No: VAL001197	Project number: EQAF-0018 / 0017h	Version No: 00	

14.2. Validation Deviation Form*

Deviation No.	N/A	EQ Test No.	N/A
Deviation Details N/A			
Corrective Actions N/A			
Outcome N/A			
Deviation Closed (Yes/No)	N/A	Date	N/A
Signed (Operator)	<i>Paul Hlatky</i>	Date	19 MAR 2018
Approved (Quality Assurance)	<i>John</i>	Date	22 MAR 2018

*duplicate as required (single sheet per deviation only)

VAL001197 – EQ Protocol – AMITSv4.1 update Singapore

Attachment Number: 1

~~EQ009~~ EQ009 PS 18MAR2018

Page 1 of 1

AMITS Network Configuration

Manufacturing Test

localhost:8082/webserver/modules/manTest/console/client/views/start.html

Test Run Details Dashboard Test Log Summary QHR Sigma Data History Admin

Administration

Tests Database: C:\Program Files (x86)\AMITS\release\AMITSMTestModules

Results Database: \\10.249.40.230\test_results

Users Database: \\10.249.40.230\AMTestUsers

SigmaQuest Folder: \\10.249.40.230\CamstarQueue

Temp Folder: \\10.249.40.230\test_results\temp2

Station GUID: A981D906-C2FE-417F-A91A-626887E58D33

Station Name: S4BK7529

Location: Venture Remove

Add Location: Add

Area: Test Floor Remove

Add Area: Add

Sigma Version: 7

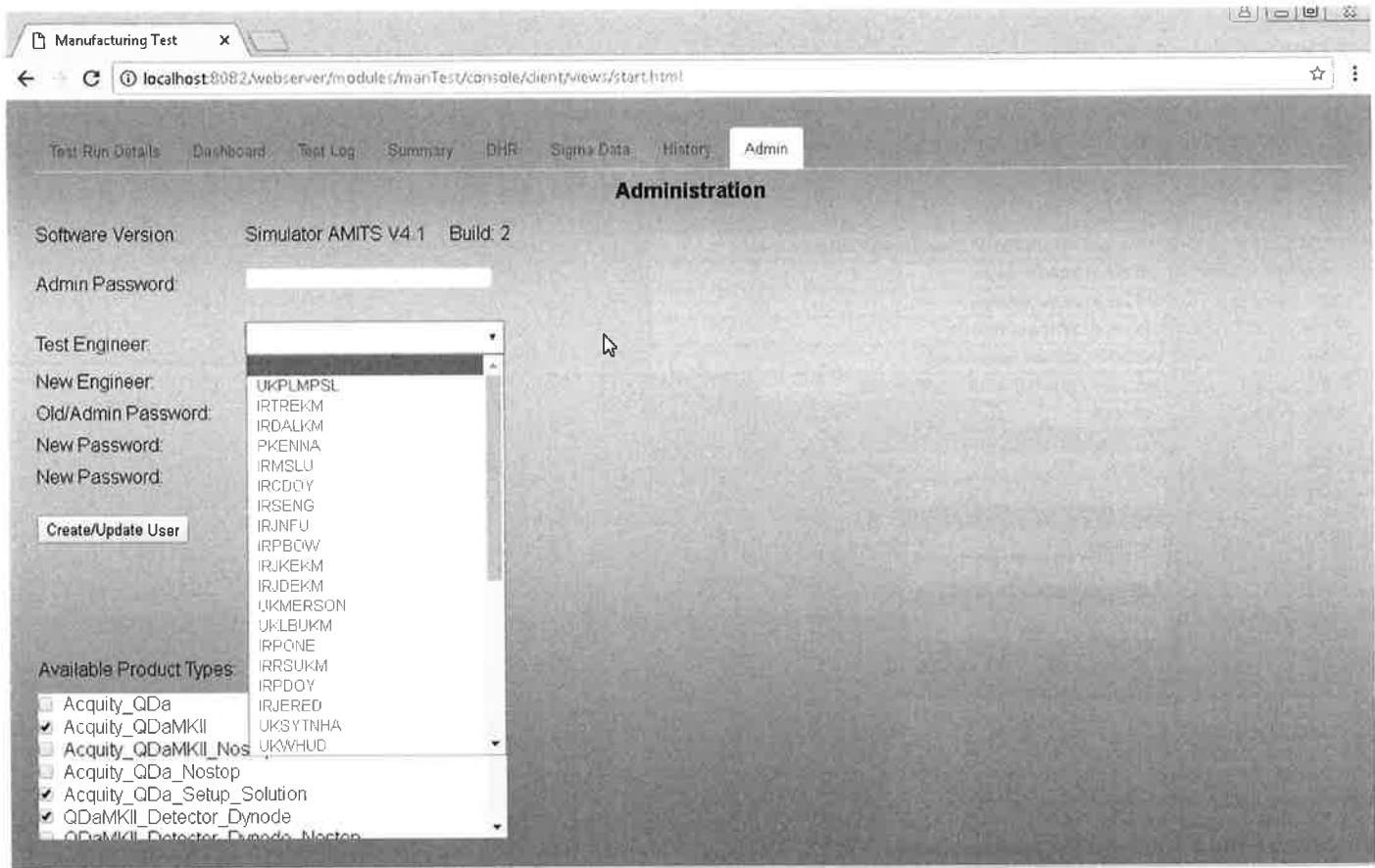
Available Product Types

- ☐ Acquity_QDa
- ☒ Acquity_QDaMKII
- ☐ Acquity_QDaMKII_Nostop
- ☐ Acquity_QDa_Nostop
- ☒ Acquity_QDa_Setup_Solution
- ☒ QDaMKII_Detector_Dynode
- ☐ QDaMKII_Detector_Dynode_Nostop

PS 18MAR2018

VAL001197 – EQ Protocol – AMITSv4.1 update Singapore
Attachment Number: 2
EQ009
Page 1 of 1

AMITS User List



PS 18 MAR 2018

VAL001197 – EQ Protocol – AMITSv4.1 update Singapore

Attachment Number: 3

EQ009

Page 1 of 1

AMITS link to Storage Solution

The screenshot shows the AMITS Manufacturing Test interface. The browser address bar displays `localhost:8082/webserver/modules/manTest/console/client/views/start.html`. The interface has a navigation bar with tabs: Test Run Details, Dashboard, Test Log, Summary, DHR, Signal Data, History, and Admin. The main section is titled "Manufacturing Test for Serial Number EQ-Protocol". Below this, there is a table with columns: MANUFACTURING PRE-TEST, STATUS, FAILURES, and DHR LOG. The table lists various test steps and their results, all of which are "PASS".

	MANUFACTURING PRE-TEST	STATUS	FAILURES	DHR LOG
Start	Simulator Configuration	PASS		
	Instrument Preparation	PASS		
	Manual Interlock	PASS		
	Source Exhaust	PASS		
	Source Leak	PASS		
Restart Here	Align Quad RF Generator	PASS		
	Critical Voltages	PASS		
	RF Breakdown	PASS		
	Desolvation Heater	PASS		
	Calibrant Heater	PASS		
	Source Heater	PASS		
	Basic Beam - Positive	PASS		
	Basic Beam - Negative	PASS		
Restart Here	Initial Tune	PASS		
	Positive Ion Creation Stability	PASS		
	Negative Ion Creation Stability	PASS		
	Low Mass Sensitivity	PASS		
	Source and Ion Guide Charging	PASS		
	Stop	State: Unknown	API Gas: Unknown	

At the bottom of the interface, there is a row of buttons for different test modes: MANUFACTURING PRE-TEST, POSITIVE MODE QUAD TUNING AND TESTING, NEGATIVE MODE QUAD TUNING AND TESTING, DETECTOR TESTING, POSITIVE MODE PERFORMANCE TESTING, NEGATIVE MODE PERFORMANCE TESTING, POSITIVE FAST SCAN QUAD TUNING AND TESTING, NEGATIVE FAST SCAN QUAD TUNING AND TESTING, and FINAL BEAM TESTING.

PS 18 MAR 2018

VAL001197 – EQ Protocol – AMITSv4.1 update Singapore
Attachment Number: 4
EQ009
Page 1 of 1

AMITS timely Data Exchange with Storage Solution.

The screenshot shows a web browser window with multiple tabs. The active tab is titled 'History waters-S4BK7529-07-MAR-2018'. The address bar shows the URL 'localhost:8082/webserver/modules/manTest/console/client/views/start.html'. The application interface has a top navigation bar with links: 'Test Run Details', 'Dashboard', 'Test Log', 'Summary', 'DHR', 'Sigma Data', 'History', and 'Admin'. Below this, there is a 'Print' button and a title 'Rework History for Serial Number waters-S4BK7529-07-MAR-2018 7 Mar 2018'. The main content area displays the following information:

Test Run Number: 1
Start Details:
Start Section: MANUFACTURING PRE-TEST
Start Test: Simulator Configuration
Test Engineer: UKPLMPSL
Start time: Wed Mar 07 2018 21:04:16 GMT+0800 (Malay Peninsula Standard Time)

Stop Details:
Stop Section: FINAL BEAM TESTING
Stop Test: Shutdown
End time: Wed Mar 07 2018 21:09:51 GMT+0800 (Malay Peninsula Standard Time)
Result is: COMPLETE

PS 18 MAR 2018

VAL001197 – EQ Protocol – AMITSv4.1 update Singapore

Attachment Number: 5

EQ009

Page 1 of 1

Link to Nu-Genesis

Browse Search
Log off ?

Projects
File ▾ Annotate ▾ Tools ▾

Links
 ▾ Recently viewed
 ▾ SCMS-PAE-DEV
 ▾ AMITS_QDA
 ▾ AMITS_QDa
 ▾ TU-SERVER-PAEDB
 ▾ AMITS
 ▾ AMITS
 ▾ AMITS_QDa
 ▾ AMITS_Raven
 ▾ DefaultView
 ▾ All Available
 ▾ SCMS-PAE-DEV
 ▾ TU-SERVER-PAEDB
 ▾ AMITS
 ▾ AMITS_QDa
 ▾ AMITS_Raven
 ▾ DefaultView
 ▾ Fusion1
 ▾ Fusion2

Project: AMITS View: AMITS_QDa
 Select All None

	Report Name	Product Type	Product Number	Serial Number ▾	Produ
1	History KAD3630.pdf				
2	History KAD3629.pdf				
3	History KAD3631.pdf				
4	036b4d62-e475-4193-b7e1-90d729332830.pdf				
5	History KAA0270-180212_004.pdf				
6	History waters-S4BK7529-07-MAR-2018.pdf				
7	History waters-S4BK7529-07-MAR-2018.pdf				
8	Summary waters-S4BK7529-07-MAR-2018.pdf			waters-S4EK7529-07-MAR-2018	N/A
9	Device -History Record waters-S4BK7529-07-MAR-2018.pdf	simulator	95999	waters-S4EK7529-07-MAR-2018	N/A
10	Device -History Record waters-S4BK7529-07-MAR-2018.pdf	simulator	95999	waters-S4EK7529-07-MAR-2018	N/A
11	Summary waters-S4BK7529-07-MAR-2018.pdf			waters-S4EK7529-07-MAR-2018	N/A
12	Device -History Record KAD3631.pdf	Acquity_QDaMKII	186008511	<AD3631	4331
13	Summary KAD3631.pdf			<AD3631	4331
14	Device -History Record KAD3630.pdf	Acquity_QDaMKII	186008511	<AD3630	4331
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16	Summary KAD3629.pdf			<AD3629	4331
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More...

<http://tu-server-paedb/ser/let/WsbVisionSer/let/3c3c12%3a/TU-SERVER-PAEDB/05/index.html?gclid=602...>

PS 18 MAR 2018

