

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

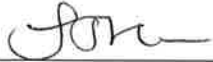
Host PC - Waters S4BK7626
GES Venture.

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.

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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.

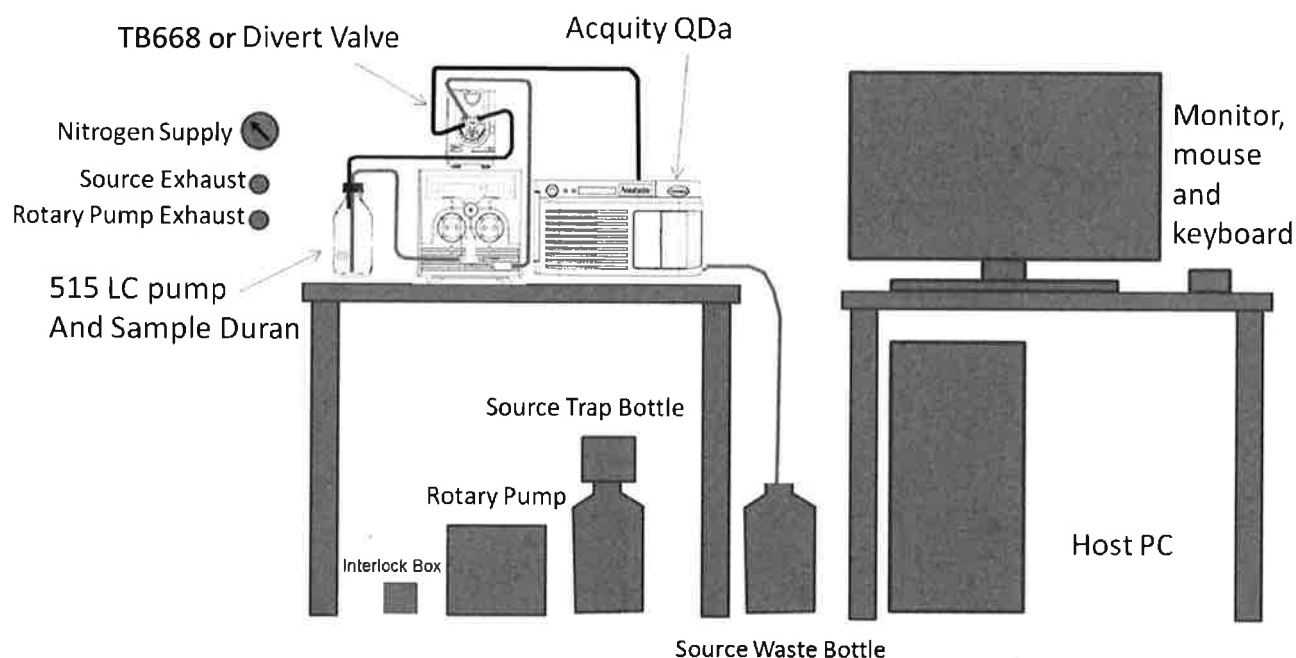


Figure 1 – Test Bay System – Venture and WPPL Singapore

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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		PS
EDWINA BEANLAND	PROCESS VALUATION ENGINEER		EB

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.		

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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

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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

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

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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)	 Date 21 MAR 2018
Reviewed (2nd Party)	 Date 21 MAR 2018

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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)			Date 21 MAR 2018
Reviewed (2nd Party)			Date 21 MAR 2018

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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	29 Nov 2017	Calibration due 29 Nov 2018
Comments:			
Signed (Operator)			Date 21 MAR 2018
Reviewed (2 nd Party)			Date 21 MAR 2018

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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	21 MAR 2018
Reviewed (2 nd Party)		Date	21 MAR 2018

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11.7. EQ007 – Computer Hardware

Purpose: Record any computer hardware required for the equipment which has not been supplied by the manufacturer.

Does equipment require computer hardware to operate successfully?		<u>Yes</u> /No	
If yes, enter details	P510 Host PC		
Comments: Record the Host PC name and Domain Name: Waters S4 BK 7626 CORP\ GES Venture Record the IP Address of the Host PC 10.249.40.246			
Signed (Operator)		Date	21 MAR 2018
Reviewed (2 nd Party)		Date	21 MAR 2018

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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.	0.60	SVAF Approved	☒ Yes / No
Engineers Dashboard	Version No.	1.2.659.24837	SVAF Approved	☒ Yes / No
Chrome	Version No.	65.0.3325.146	SVAF Approved	☒ Yes / No
MassLynx	Version No.	4.1 SCN 947 SCN 961	SVAF Approved	☒ Yes / No
Microsoft Office	Version No.	14.0.7190.5000	SVAF Approved	☒ Yes / No
Comments:				
Signed (Operator)			Date	21 MAR 2018
Reviewed (2 nd Party)			Date	21 MAR 2018

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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.

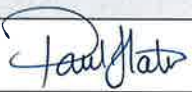
Acceptance Criteria:

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 21MAR 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 21MAR 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 21MAR 2018

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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")	5mins 26 secs - confirmed Attachment 4	Y PS 21MAR2018
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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	Y PS 21MAR2018
Were all acceptance criteria met – Y/N			
Deviation Number (if required)			
Comments:			
Signed (Operator)		Date	
		21 MAR 2018	
Reviewed (2 nd Party)		Date	
		21 MAR 2018	

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13. MAINTAINING THE VALIDATED STATE

13.1. Planned Preventative Maintenance/Calibration Summary

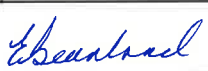
Purpose: To record the calibration or planned preventative maintenance schedules have been set up as required in the calibration database and provide objective evidence.

N/A software update

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

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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)		Date	21 MAR 2018
Approved (Quality Assurance)		Date	22 MAR 2018

*duplicate as required (single sheet per deviation only)

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15. ATTACHMENTS

List all appended attachments to this protocol in the table below.

Attachment No.	EQ Test No.	Details	No. of pages	Operator Initials
1	12.1	Admin details match 76215	1	PS
2	12.1	Admin user list	1	PS
3	12.1	AMITS link to storage solution	1	PS
4	12.1	AMITS timely data exchange with storage solution	1	PS
5	12.1	AMITS PDF data accepted by NuGenesis.	1	PS
EOD PS 21 MAR 2018				

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AMITS Network Configuration

Manufacturing Test

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

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

Administration

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

Results Database: \\10.249.40.230\test_results

Users Database: \\10.249.40.230\MTTestUsers

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: S4BK7626

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
- ☒ QDaMKII_Detector_Housing
- ☒ QDaMKII_Detector_Housing_Nostop
- ☒ QDa_Detector_Dynode
- ☒ QDa_Detector_Dynode_Nostop
- ☒ QDa_Detector_Housing
- ☒ QDa_Detector_Housing_Nostop

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Attachment Number: 2

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AMITS User List

The screenshot shows the 'Administration' section of the AMITS software interface. The browser address bar indicates the URL is `localhost:8082/webserver/modules/manTest/console/client/views/start.html`. The navigation menu includes 'Test Run Details', 'Dashboard', 'Test Log', 'Summary', 'DHR', 'Sigma Data', 'History', and 'Admin'. The 'Admin' tab is active, displaying the 'Administration' page.

Software Version: Acquity QDa MKII AMITS V4.1 Build: 2

Admin Password:

Test Engineer:

New Engineer:

Old/Admin Password:

New Password:

New Password:

Available Product Types:

- ☒ Acquity_QDa
- ☒ Acquity_QDaMKII
- ☒ Acquity_QDaMKII_Nos
- ☒ Acquity_QDa_Nostop
- ☒ Acquity_QDa_Setup_Solution
- ☒ QDaMKII_Detector_Dynode
- ☒ QDaMKII_Detector_Dynode_Nostop
- ☒ QDaMKII_Detector_Housing
- ☒ QDaMKII_Detector_Housing_Nostop
- ☒ QDa_Detector_Dynode
- ☒ QDa_Detector_Dynode_Nostop
- ☒ QDa_Detector_Housing
- ☒ QDa_Detector_Housing_Nostop

A dropdown menu is open for the 'Test Engineer' field, showing a list of user IDs: UKPLMPSL, IRTREKM, IRDALKM, PKENNA, IRMSLU, IRCCOY, IRSENG, IRJNFU, IRFBOW, IRJKEKM, IRJDEKM, UKMERSON, UKLBUKM, IRPONE, IRRSUKM, IRPDOY, IRJERED, UKSYTNHA, and UKWHUD.

PS 21MAR2018

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AMITS link to Storage Solution

Manufacturing Test for Serial Number

	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		
Restart Here	Source Heater	PASS		
	Basic Beam - Positive	PASS		
	Basic Beam - Negative	PASS		
	Initial Tune	PASS		
	Positive Ion Creation Stability	PASS		
	Negative Ion Creation Stability	PASS		
	Low Mass Sensitivity	PASS		
	Source and Ion Guide Charging	PASS		
	Mass Switching Snowboy	PASS		

Stop State: Unknown API Gas: Unknown

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	FINAL BEAM TESTING
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PS 21 MAR 2018

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Attachment Number: 4

EQ009

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AMITS timely Data Exchange with Storage Solution.

The screenshot shows a web browser window with the address bar displaying 'localhost:8082/webserver/modules/manTest/console/client/views/start.html'. The browser tab is labeled 'Manufacturing Test'. The web application has a blue header with navigation links: 'Test Run Details', 'Dashboard', 'Test Log', 'Summary', 'DHR', 'Sigma Data', 'History', and 'Admin'. Below the header, there is a 'Print' button and a title 'Rework History for Serial Number waters-S4BK7626-07-MAR-2018 7 Mar 2018'. The main content area displays test details for 'Test Run Number: 1'. The 'Start Details' section includes: 'Start Section: MANUFACTURING PRE-TEST', 'Start Test: Simulator Configuration', 'Test Engineer: UKPLMPSL', and 'Start time: Wed Mar 07 2018 22:31:13 GMT+0800 (Malay Peninsula Standard Time)'. The 'Stop Details' section includes: 'Stop Section: FINAL BEAM TESTING', 'Stop Test: Shutdown', 'End time: Wed Mar 07 2018 22:36:39 GMT+0800 (Malay Peninsula Standard Time)', and 'Result is: COMPLETE'.

Test Run Number: 1

Start Details:

Start Section: MANUFACTURING PRE-TEST

Start Test: Simulator Configuration

Test Engineer: UKPLMPSL

Start time: Wed Mar 07 2018 22:31:13 GMT+0800 (Malay Peninsula Standard Time)

Stop Details:

Stop Section: FINAL BEAM TESTING

Stop Test: Shutdown

End time: Wed Mar 07 2018 22:36:39 GMT+0800 (Malay Peninsula Standard Time)

Result is: COMPLETE

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Attachment Number: 5

EQ009

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Link to Nu-Genesis

The screenshot displays the AMITSv4.1 web application interface. The browser address bar shows the URL: <http://tu-server-paewb/serlet/WebVisionServlet/%3cV2%3e/TU-SERVER-PAEDB>. The application has a menu bar with File, Edit, View, Favorites, Tools, and Help. Below the menu bar is a search bar and a "Log off" button. The left sidebar contains a "Projects" section with a "Links" tree view. Under "Recently viewed", there are links to SDMS-PAE-DEV, AMITS_QDA, and TU-SERVER-PAEDB. Under "All Available", there are links to SDMS-PAE-DEV and TU-SERVER-PAEDB. The main content area shows the "Project: AMITS" and "View: AMITS_QDa". Below this is a table with columns: Report Name, Product Type, Product Number, Serial Number, and Productic. The table contains three rows of reports, all filtered by the search term "*s4bk7626*".

	Report Name	Product Type	Product Number	Serial Number	Productic
s4bk7626					
1	Summary waters-S4BK7626-07-MAR-2018.pdf			waters-S4BK7626-07-MAR-2018	N/A
2	Device History Record waters-S4BK7626-07-MAR-2018.pdf	simulator	99999	waters-S4BK7626-07-MAR-2018	N/A
3	History waters-S4BK7626-07-MAR-2018.pdf				

End of Reports

ukplmpsl on TU-SERVER-PAEDB

PS 21 MAR 2018

