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| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> | <b>EQ Protocol – Venture ACQUITY QDa Test Floor<br/>AMITS Storage System</b> |                |
| Document No: VAL001105                                           | Project number EQAF 0018                                                     | Version No: 00 |

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# Waters - Wilmslow

## Equipment Qualification Protocol

### Venture ACQUITY QDa Test Floor

### AMITS Storage System

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**For Internal Use Only**

Document reviewed and approved electronically

Author: Paul Slater

Date: 27 Oct 2017.

MM7521

|                                                                  |                          |                                                                                    |  |
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| Document No: VAL001105                                           | Project number EQAF 0018 | Version No: 00                                                                     |  |

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## 1. PURPOSE

The purpose of this protocol is to describe the procedures for conducting Equipment Qualification of the AMITS Storage System installed and operated at GES Venture, as detailed in the Equipment Qualification Plan VAL001102 which has been assessed and deemed that qualification is required as detailed in EQ Assessment form EQAF 0018.

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 design qualification work has been performed and documented, to confirm that the equipment specifications meet the User Requirement Specification, Functional Designs and Acceptance Testing.
- The equipment conforms to the relevant manufacturer's technical description and installation requirements.
- The principal features of the equipment and components are installed correctly.
- There is sufficient information available to enable the equipment to be operated and maintained safely, effectively and consistently.
- All equipment calibration requirements have been identified prior to operational testing and performance qualification.
- The equipment operates within its required process parameters.

For equipment description and functionality, refer to the Validation Plan VAL001102.

## 2. SCOPE

This protocol is restricted to the AMITS Storage System which is located in GES Venture, 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 testing will be performed as detailed in the Validation Plan and associated Validation Assessment.

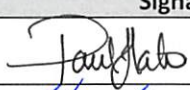
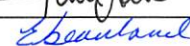
## 3. RESPONSIBILITIES & SIGNATURE PAGE

### 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 7300003703 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 Eng. |  | PS       |
| EDWINA BEANLAND<br>EOD PS 28 NOV 2017. | PROCESS VALIDATION ENGINEER      |  | EB       |
|                                        |                                  |                                                                                      |          |
|                                        |                                  |                                                                                      |          |
|                                        |                                  |                                                                                      |          |
|                                        |                                  |                                                                                      |          |

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#### 4. ABBREVIATIONS

| Abbreviation | Explanation                           | Abbreviation | Explanation                  |
|--------------|---------------------------------------|--------------|------------------------------|
| EDMS         | Electronic Document Management System | VP           | Validation Plan              |
| GMP          | Good Manufacturing Practise           | VR           | Validation Report            |
| GDP          | Good Documentation Practise           | VM           | Virtual Machine on server    |
| DQ           | Design Qualification                  | QA           | Quality Assurance            |
| GMP          | Good Manufacturing Practices          | GDP          | Good Documentation Practices |
| QDa          | Mass spectrometer                     | DHR          | Device History Record        |
| EQ           | Equipment Qualification               | -            | -                            |

#### 5. REFERENCES

The following references are applicable to completion of this protocol.

| Document Number                | Document title                                         |
|--------------------------------|--------------------------------------------------------|
| VAL001102                      | Equipment Qualification Plan                           |
| VAL001104                      | EQ Protocol – Venture ACQUITY QDa Test Floor Test Bays |
| 71550093001_MassLynx IQ_Source | Installation Qualification for MassLynx                |
| 71550093001_MassLynx OQ_Source | Operational Qualification for MassLynx                 |
| 46202                          | QDa AMITS Test Procedure                               |
| 46215                          | Acquity QDa Installation - link to Network             |
| 730003703                      | Equipment Qualification Procedure                      |

#### 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 and using the Validation Deviation in 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:

EQ 0018 - 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 Storage System

|                                                   |                                                                              |                |
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## 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 filed with the EQ following 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 the AMITS Storage System. 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 Specification or associated equipment risk assessments detailed within the Validation Plan VAL001102. 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

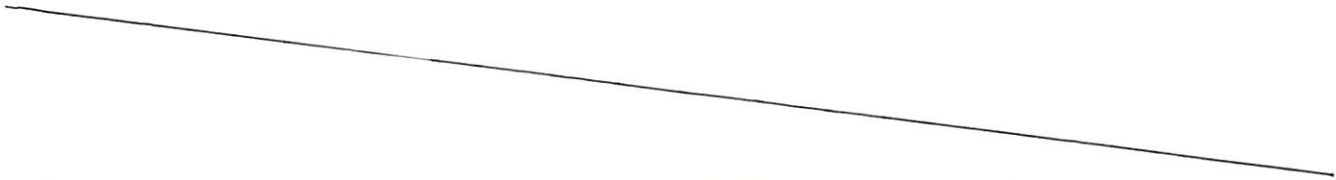
| TM No. | Description of Requirements or Tests                              | Section |
|--------|-------------------------------------------------------------------|---------|
| 1      | Equipment Details                                                 | EQ001   |
| 2      | Training Requirements                                             | EQ002   |
| 3      | Documentation Review                                              | EQ003   |
| 4      | Calibration Check                                                 | EQ004   |
| 5      | Installation– Utility                                             | EQ005   |
| 6      | Health and Safety Testing                                         | EQ006   |
| 7      | Installation checks of Storage System Hardware (VM or Storage PC) | EQ007   |
| 8      | Installation checks of Storage Software (VM or Storage PC)        | EQ008   |
| 9      | Operational Checks of Storage 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                                                                                         | THINKSTATION P510.                                                                  |      |             |
| Equipment Description:                                                                                 | STORAGE PC                                                                          |      |             |
| Make:                                                                                                  | LENOVO                                                                              |      |             |
| Model/Type:                                                                                            | P510 THINKSTATION                                                                   |      |             |
| Serial Number:                                                                                         | S4C M0575                                                                           |      |             |
| Asset No:                                                                                              | 007521                                                                              |      |             |
| Materials of construction:                                                                             | N/A                                                                                 |      |             |
| Risk Assessment                                                                                        | N/A                                                                                 |      |             |
| Location:                                                                                              | GES VENTURE, 28 MARSILING LANE, SINGAPORE 739152.                                   |      |             |
| <b>Comments</b><br> |                                                                                     |      |             |
| Signed (Operator)                                                                                      |  | Date | 28 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party)                                                                       |  | Date | 13 DEC 2017 |

|                                                                  |                          |                                                                                    |  |
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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) | <input checked="" type="radio"/> Yes / No |
| External Training Provided on equipment (if yes give details below) | <input checked="" type="radio"/> Yes / No |

#### Comments

Principle Product Assurance Engineer on system.

|                                  |                   |      |               |
|----------------------------------|-------------------|------|---------------|
| Signed (Operator)                | <i>Paul Hater</i> | Date | 28 NOV 2017 . |
| Reviewed (2 <sup>nd</sup> Party) | <i>E. Bannock</i> | Date | 13 DEC 2017   |

|                                                   |                                                                      |                |
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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                                                             | N/A                 |         | N/A         |
| 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         |
| <b>Comments:</b><br><div style="border: 1px solid black; height: 100px; width: 100%;"></div> |                     |         |             |
| Signed (Operator)                                                                            |                     | Date    | 28 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party)                                                             |                     | Date    | 13 DEC 2017 |

|                                                                  |                          |                                                                                    |  |
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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/ <b>No</b>                         |  |                 |
| Recommended calibration frequency?                                                          | Daily/Monthly/Yearly etc... <b>N/A</b> |  |                 |
| Has Equipment been calibrated prior to starting this protocol? If so, provide details below |                                        |  |                 |
| <b>N/A</b>                                                                                  | Calibrated on                          |  | Calibration due |

**Comments:**

Required fixed IP address. 10.249.40.230.

|                                  |                   |      |             |
|----------------------------------|-------------------|------|-------------|
| Signed (Operator)                | <i>Paul Hater</i> | Date | 28 Nov 2017 |
| Reviewed (2 <sup>nd</sup> Party) | <i>Ebeauland</i>  | Date | 13 DEC 2017 |

|                                                                  |                          |                                                                                    |  |
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### 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     | Phasing , Voltage, Frequency etc. connected     | N/A           | N/A         |
| Compressed Air Supply | Min Supply Pressure, Line Size and connected    | N/A           | N/A         |
| Process Gas           | Min Supply Pressure, Line Size and connected    | N/A           | N/A         |
| Exhaust / Vacuum      | Min flow rate, Line Size and connected          | N/A           | N/A         |
| Water grade           | Min flow rate/pressure, Line Size and connected | N/A.          | N/A.        |

**Comments:**

|                                  |                                                                                     |      |             |
|----------------------------------|-------------------------------------------------------------------------------------|------|-------------|
| Signed (Operator)                |  | Date | 28 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 13 DEC 2017 |

|                                                   |                          |                                                                                    |  |
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### 11.6. EQ006 - Health and Safety Testing

Purpose: To record all Health and Safety details of the equipment and ensure the equipment is safe to use.

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

Comments:

|                                  |                                                                                     |      |             |
|----------------------------------|-------------------------------------------------------------------------------------|------|-------------|
| Signed (Operator)                |  | Date | 28 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 13 DEC 2017 |

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### 11.7. EQ007 – Computer Hardware

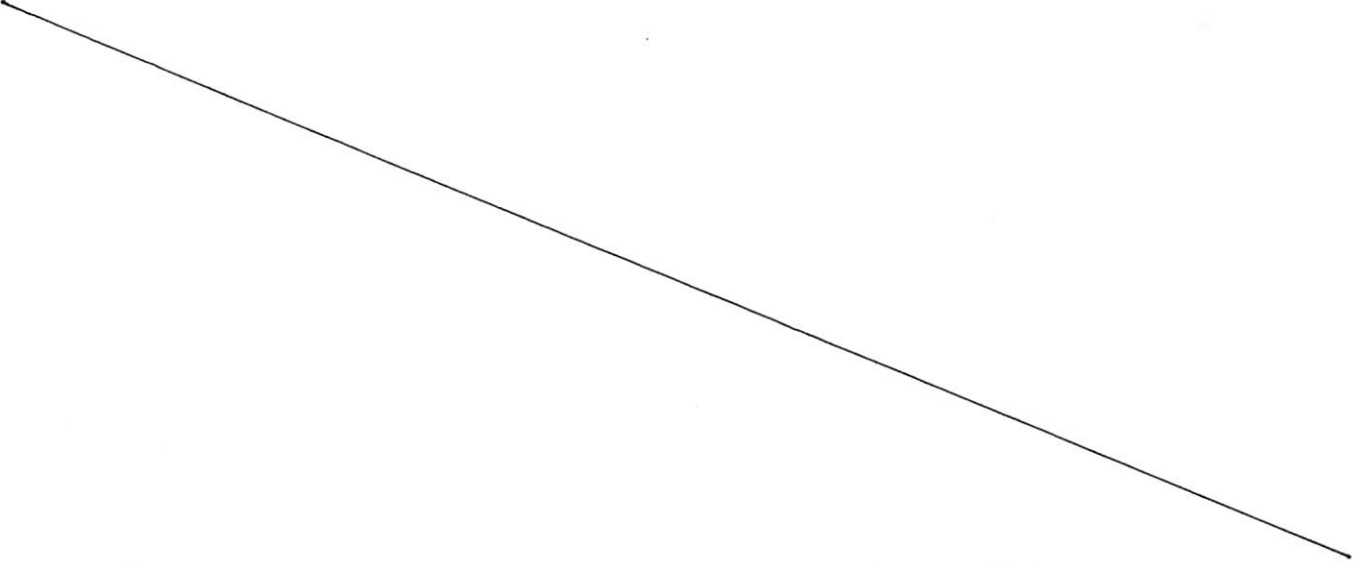
**Purpose:** Record any computer hardware required for the equipment which has not been supplied by the manufacturer.

|                                                                                                                                  |                          |                |                |
|----------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------|----------------|
| Does equipment require computer hardware to operate successfully?                                                                |                          | <u>Yes</u> /No |                |
| If yes, enter details                                                                                                            | Equipment is storage PC. |                |                |
| <b>Comments:</b><br>Record the Host PC name and Domain Name: MM 7512, CORP<br>Record the IP Address of the Host PC 10.249.40.230 |                          |                |                |
| Signed (Operator)                                                                                                                | <i>Paul Slater</i>       | Date           | PS 28NOV 2017. |
| Reviewed (2 <sup>nd</sup> Party)                                                                                                 | <i>Ebeauland</i>         | Date           | 13DEC2017      |

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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?                                       |                                                                                     |                         |               | <u>Yes</u> /No |
| If yes, enter details below:                                                                            |                                                                                     |                         |               |                |
| ACQUITY QDa AMITS                                                                                       | Version No.                                                                         | V 3.1                   | SVAF Approved | <u>Yes</u> /No |
| Chrome                                                                                                  | Version No.                                                                         | 62.0.3202.94            | SVAF Approved | <u>Yes</u> /No |
| MassLynx                                                                                                | Version No.                                                                         | v4.1 SCN 947<br>SCN 961 | SVAF Approved | <u>Yes</u> /No |
| Microsoft Office                                                                                        | Version No.                                                                         | 14.0.7190.5000          | SVAF Approved | <u>Yes</u> /No |
| SigmaProbe                                                                                              | Version No.                                                                         | 7.1.2.                  | SVAF Approved | <u>Yes</u> /No |
| TeamViewer                                                                                              | Version No.                                                                         | 12.0.88438              | SVAF Approved | <u>Yes</u> /No |
| <b>Comments:</b><br> |                                                                                     |                         |               |                |
| Signed (Operator)                                                                                       |  |                         | Date          | 28 NOV 2017    |
| Reviewed (2 <sup>nd</sup> Party)                                                                        |  |                         | Date          | 13 DEC 2017    |

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## 12. EQUIPMENT OPERATION TESTING

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

Objective/Rationale:

The AMITS Storage PC or VM operational testing requires data from the test bays to confirm functionality. A break in the test sequence is highlighted to say when VAL001104 (EQ Protocol – Venture ACQUITY QDa Test Floor Test Bay) must be performed on at least one test bay.

#### 12.1.1. Network Visibility

Objective/Rationale:

To confirm all the Test Bay PCs are visible to the AMITS Storage PC or VM, using the domain and user accounts supplied by Wilmslow IT group.

Acceptance Criteria:

| Description            | Result Expected                                                                                                                      | Result Actual                                                                                                                              | Acceptance Criteria Met Y/N |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Test Bay PC Visibility | This test requires all the Test Bay System host PCs to be powered up, and physically linked to the Test Floor network via LAN cable. |                                                                                                                                            |                             |
|                        | Open Windows Remote Access.                                                                                                          | waters-<br>54BK9317                                                                                                                        | Y                           |
|                        | Enter the PC name of the first Test Bay System host PC.                                                                              | 10.249.40.135                                                                                                                              | PS 28 NOV 2017              |
|                        | Log into the PC, using the domain supplied by Wilmslow IT group                                                                      | waters-<br>54BA7494                                                                                                                        | Y                           |
|                        | Confirm the Login Name used.                                                                                                         | 10.249.40.119                                                                                                                              | PS 28 NOV 2017              |
|                        | Confirm the domain name used.                                                                                                        | waters-<br>54BK7626                                                                                                                        | Y                           |
|                        | Repeat until all the test bays have been accessed.                                                                                   | 10.249.40.246                                                                                                                              | PS 28 NOV 2017              |
|                        | Confirm the desktop of each machine can be accessed from the Storage PC / VM.                                                        | waters-<br>54BK7529<br>10.249.40.69,<br><br>GES_venture<br>.CORP.<br><br>Confirmed each desktop<br>can be accessed from<br>the storage PC. | Y<br>PS 28 NOV 2017         |



|                                                   |                                                                      |                |
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### 12.1.2. ACQUITY QDa AMITS

#### 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 Storage Folders       | <p>The storage folder structure and sharing rights on the Storage PC or VM must be as defined within 46215 "Aquity QDa Installation – Link to Network" for Venture Singapore.</p> <p>Confirm the necessary shared folders are present by using windows explorer and using the following address:</p> <p>\\***IP address of the storage PC or VM\</p>               | <p>Folders confirmed present.</p> <p>\\10.249.40.230\.</p> | <p>Y</p> <p>PS 28 Nov 2017.</p> |
| AMITS Network Configuration | <p>Open AMITS.</p> <p>Open Admin.</p> <p>Enter Admin password.</p> <p>The Admin Details within AMITS must be edited to match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore.</p> <p>Confirm the Admin Details within AMITS match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore.</p> | <p>Confirmed.</p>                                          | <p>Y</p> <p>PS 28 Nov 2017.</p> |

|                                                   |                          |                                                                                    |  |
|---------------------------------------------------|--------------------------|------------------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>AMITS Storage System</b> |  |
| Document No: VAL001105                            | Project number EQAF 0018 | Version No: 00                                                                     |  |

|                                                 |                                                                                                                                                                                                                                                                                             |                                  |                      |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| AMITS link to Storage Solution – Simulated Data | Open AMITS.<br>Open Test Run Details.<br>From the product type list, select “simulator”.<br>Enter the following details:<br><br>Serial Number: EQ-Protocol<br><br>Open the Dashboard<br><br>Confirm a completed test record is visible. (All the Statuses in every test section are “PASS”) | Confirmed all tests are present. | Y<br>PS 28 NOV 2017. |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|

**The Storage Solution is at this point confirmed ready to accept data from the test bay systems**  
**Perform VAL001104 on at least 1 test bay to create data.**  
**Once created, the data needs to be processed further using VAL001105 before VAL001104 can be completed.**

|                                            |                                                                                                                                                                                                                                                                                            |                       |                     |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------------|
| AMITS link to Storage Solution – Live Data | Open AMITS.<br>Open Test Run Details.<br>From the product type list, select “Acquity_QDa_Setup_Solution”.<br>Enter the following details:<br><br>Serial Number: A Test Bay Number used for VAL001104<br><br>Open the Dashboard<br>Confirm a completed or partially test record is visible. | 548K 7626-EQ-Protocol | Y<br>PS 28 NOV 2017 |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------------|

|                                        |       |
|----------------------------------------|-------|
| Were all acceptance criteria met – Y/N | (Y/N) |
| Deviation Number (if required)         | N/A   |

Comments:

|                                  |                     |      |             |
|----------------------------------|---------------------|------|-------------|
| Signed (Operator)                | <i>Paul Glat</i>    | Date | 28 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party) | <i>E. Beardsall</i> | Date | 13 DEC 2017 |

|                                                   |                                                                      |                |
|---------------------------------------------------|----------------------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |                |
| Document No: VAL001105                            | Project number EQAF 0018                                             | Version No: 00 |

### 12.1.3. SigmaProbe / Data transfer to SigmaSure Database

#### Objective/Rationale:

To confirm the installation of SigmaProbe will correctly transfer data from the Store PC / VM to SigmaSure database in Milford, when using a VPN connection. This test sequence assumes that there is not a permanent secure link between the Storage PC/VM and the Waters network.

#### Acceptance Criteria:

| Description                                 | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Result Actual | Acceptance Criteria Met Y/N |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| SigmaProbe Installation on Storage PC or VM | Open:<br>C:\Camstar\Probe\Service\SigmaProbe-config.xml<br><br>Confirm the SigmaQueue settings are:<br><br><pre> &lt;SigmaQueue queue-name="SigmaQueue" queue-directory="C:\Camstar\Probe\CamstarQueue\" hostname="sigmaprod.corp.waters.com" service-url="/sigma/services/UnitReport" ssl-enabled="false" interval="10" max-file-size="2048000" save-reports="true" save-reports- directory="C:\Camstar\Probe\CamstarQueueBackup\" validateFiles="true" guid="A981D906-C2FE-417F-A91A-626887E58D33" xml-file-compressed="false" monitor-connect="true" max-files-in-buffer="100" number-of-threads="3" transmission-delay="0" delete-duplicate-files="true" /&gt; </pre> | Confirmed.    | Y<br>PS 28 Nov 2017.        |

|                                                   |                                                                      |                |
|---------------------------------------------------|----------------------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |                |
| Document No: VAL001105                            | Project number EQAF 0018                                             | Version No: 00 |

|                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                        |   |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|---|
| Confirm a test xml is ready for export | <p>Open:</p> <p>C:\Camstar\Probe\CamstarQueue</p> <p>Confirm at least one xml file is present.</p> <p>If the folder is empty, check that VAL001104 section 12.5 – EQ16 – Operational Checks of the Test Bay System, including Gold Brick ACQUITY QDa has been run to create the xml.</p> <p>If it has been run, check that the record has not been already imported into SigmaSure. If it has, this test section has passed, and all the following checks can be stated as met the acceptance criteria.</p>                                                                                                                                                                            | <p>Record was moved to SigmaSure immediately. So no file was left in Camstar Queue</p> | y |
| Start SigmaProbe Batch File            | <p>Open:</p> <p>C:\Camstar\Probe\Service</p> <p>Run SigmaProbe.bat</p> <p>Confirm the xml file in C:\Camstar\Probe\CamstarQueue is still present</p> <p>If the file is missing, check that the record has not been already imported into SigmaSure. If it has, this test section has passed, and all the following checks can be stated as met the acceptance criteria.</p>                                                                                                                                                                                                                                                                                                            | <p>SigmaProbe ran automatically</p>                                                    | y |
| Start Remote Waters SSL VPN            | <p>In Internet Explorer (not Chrome), enter the following address:</p> <p><a href="https://remote.waters.com/">https://remote.waters.com/</a></p> <p>Sign in using a Waters Username and Password. Follow any instructions given on the screen. The process can take several minutes to complete.</p> <p>Once the SSL VPN connection is complete, START a Pulse Secure connection. Follow any instructions given on the screen. The process can take several minutes to complete.</p> <p>Once the Pulse Secure connection is complete, confirm the C:\Camstar\Probe\CamstarQueue folder is now empty, as SigmaProbe would have picked up the file and transferred it to SigmaSure.</p> | <p>SigmaProbe ran automatically. No need for SSL VPN.</p>                              | y |

|                                                                  |                          |                                                                                    |  |
|------------------------------------------------------------------|--------------------------|------------------------------------------------------------------------------------|--|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>AMITS Storage System</b> |  |
| Document No: VAL001105                                           | Project number EQAF 0018 | Version No: 00                                                                     |  |

|                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                  |             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------------|
| Open SigmaProbe                                                                                                                                                  | <p>While in an active SSL VPN session, it is possible to see SigmaSure using a viable account.</p> <p>In Chrome, (not Internet Explorer), enter the following address:<br/> <a href="http://sigmaprod.corp.waters.com/sigma/SigmaSure.do">http://sigmaprod.corp.waters.com/sigma/SigmaSure.do</a></p> <p>Sign in with a valid SigmaSure username and password.</p> <p>Confirm, updating using the latest date range, that the record/s created by VAL001104 have been imported successfully within SigmaSure.</p> | confirmed.                       | y           |
| Sign out of Remote Waters SSL VPN                                                                                                                                | <p>Sign out of Remote Waters SSL VPN.</p> <p>Confirm the Waters SSL VPN session has ended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                    | Update occurred without SSL VPN. | y           |
| <p>Were all acceptance criteria met – Y/N</p> <p style="text-align: right;">(Y/N)</p>                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                  |             |
| <p>Deviation Number (if required)</p>                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>N/A</p>                       |             |
| <p>Comments:</p> <p>Delay in obtaining results due to Host PC account not allowing AMITS to reset DHCP service. Fault in GES_Venture account has been fixed.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                  |             |
| Signed (Operator)                                                                                                                                                | Paul Hlatw                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Date                             | 28 Nov 2017 |
| Reviewed (2 <sup>nd</sup> Party)                                                                                                                                 | E. Bantard                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Date                             | 13 DEC 2017 |

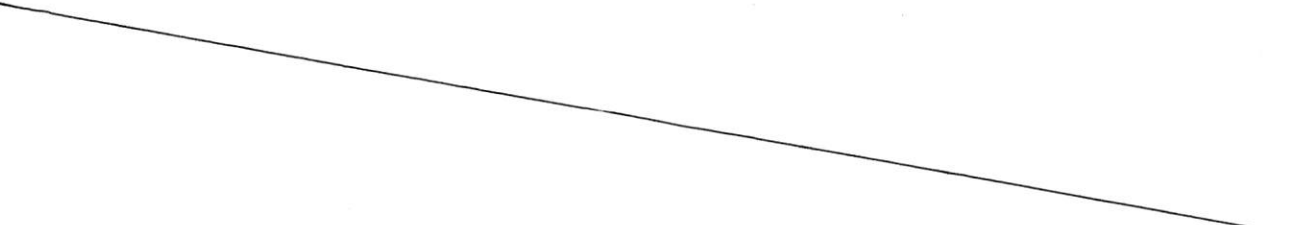
|                                                   |                                                                      |                |
|---------------------------------------------------|----------------------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |                |
| Document No: VAL001105                            | Project number EQAF 0018                                             | Version No: 00 |

#### 12.1.4. TeamViewer

##### Objective/Rationale:

To confirm the installation of TeamViewer will allow remote access to the Storage PC / VM at any time. This test sequence assumes that there is not a permanent secure link between the Storage PC/VM and the Waters network.

##### Acceptance Criteria:

| Description                                                                                       | Result Expected                                                                                                                                                                                           | Result Actual | Acceptance Criteria Met Y/N |
|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| Open TeamViewer session                                                                           | From a Waters PC outside of Venture, open Teamviewer.<br><br>Use Partner ID and password as supplied by Waters Wilmslow IT Group.<br><br>Confirm it is possible to access the Storage PC / VM in Venture. | confirmed     | Y.                          |
| Were all acceptance criteria met – Y/N                                                            |                                                                                                                                                                                                           |               |                             |
| Deviation Number (if required)                                                                    |                                                                                                                                                                                                           | N/A           |                             |
| Comments:<br> |                                                                                                                                                                                                           |               |                             |
| Signed (Operator)                                                                                 |                                                                                                                        | Date          | 29 NOV 2017                 |
| Reviewed (2 <sup>nd</sup> Party)                                                                  |                                                                                                                        | Date          | 13 DEC 2017                 |

|                                                   |                                                                      |                |
|---------------------------------------------------|----------------------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |                |
| Document No: VAL001105                            | Project number EQAF 0018                                             | Version No: 00 |

## 12.2. EQ009 – Operational Check of Network Load

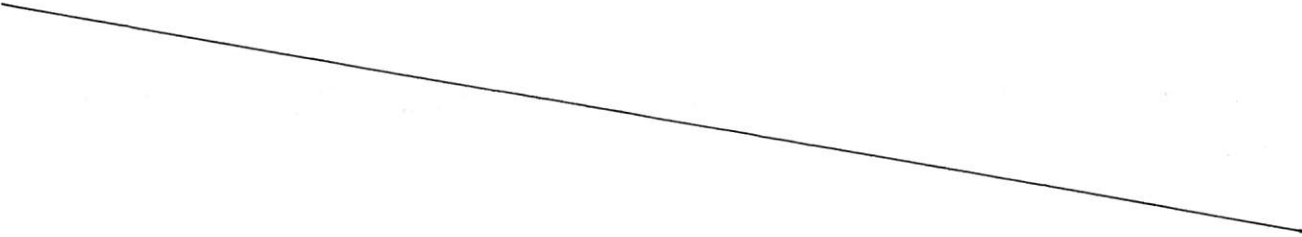
Objective/Rationale:

The Network System must be able to function when all available test bays are running AMITS.

Acceptance Criteria:

| Description           | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Result Actual | Acceptance Criteria Met Y/N |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| Maximise Network Load | <p>On all four test bays:</p> <p>Open AMITS.<br/>Open Test Run Details.<br/>From the product type list, select “simulator”.<br/>Enter the following details:</p> <p>Serial Number: Test Bay Number_Load_Test<br/>Sample Batch Number: N/A<br/>Sample Use By Date: N/A<br/>Test Box Number: N/A<br/>Test Rig Number: N/A<br/>Procedure Document Number: VAL001105</p> <p>Open the Dashboard on all test Bays</p> <p>All four test bays must be running this test simultaneously. The test only lasts 13 minutes, so the time taken for all four systems to start the “Align Quad RF Generator” test must be less than 10 minutes to stress test the system with at least 3 minutes of simultaneous data transfer.</p> <p>Click the “Start here” button.<br/>Follow the on-screen instructions to start a simulated test run. Use your AMITS account.<br/>Follow the on-screen prompts for manual interlock lock tests by clicking the continue button.<br/>Immediately start the next test bay test, and repeat until all four bays are running the tests at the same time.</p> <p>Allow the test sequence to complete.</p> <p>Confirm the test sequence completes on all the test bays. (All the Statuses in every test section are “PASS”)</p> | confirmed.    | y                           |

|                                                   |                          |                                                                      |  |
|---------------------------------------------------|--------------------------|----------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |  |
| Document No: VAL001105                            | Project number EQAF 0018 | Version No: 00                                                       |  |

|                                                                                                 |                     |      |             |
|-------------------------------------------------------------------------------------------------|---------------------|------|-------------|
|                                                                                                 |                     |      |             |
| Were all acceptance criteria met – Y/N                                                          |                     | Y/N  |             |
| Deviation Number (if required)                                                                  |                     | N/A  |             |
| Comments:<br> |                     |      |             |
| Signed (Operator)                                                                               | <i>Paul Hatcher</i> | Date | 28 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party)                                                                | <i>E. Beauland</i>  | Date | 13 DEC 2017 |

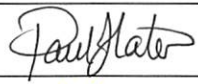
|                                                                  |                                                                      |                |
|------------------------------------------------------------------|----------------------------------------------------------------------|----------------|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |                |
| Document No: VAL001105                                           | Project number EQAF 0018                                             | Version No: 00 |

### 13. MAINTAINING THE VALIDATED STATE

#### 13.1. Maintenance & PPM 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.

The storage PC will be PM'ed annually using 48550 QDa Sub-contractor PM Procedure, and recorded using 48552 QDa Sub-contractor PM Tool Record.

|                                  |                                                                                     |      |             |
|----------------------------------|-------------------------------------------------------------------------------------|------|-------------|
| Signed (Operator)                |  | Date | 12 DEC 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 13 DEC 2017 |

|                                                   |                          |                                                                                    |  |
|---------------------------------------------------|--------------------------|------------------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>AMITS Storage System</b> |  |
| Document No: VAL001105                            | Project number EQAF 0018 | Version No: 00                                                                     |  |

### 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 / <u>NA</u> | SOP Number: |             |
|----------------------------------|----------------------|-------------|-------------|
| SOP Title                        |                      |             |             |
|                                  |                      |             |             |
| Signed (Operator)                |                      | Date        | 12 DEC 2017 |
| Reviewed (2 <sup>nd</sup> Party) |                      | Date        | 13 DEC 2017 |

|                                                                  |                          |                                                                                    |  |
|------------------------------------------------------------------|--------------------------|------------------------------------------------------------------------------------|--|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>AMITS Storage System</b> |  |
| Document No: VAL001105                                           | Project number EQAF 0018 | 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                              | PS12DEC2017. |         |                 |                         |
|                                  |              |         |                 |                         |
|                                  |              |         |                 |                         |
|                                  |              |         |                 |                         |
|                                  |              |         |                 |                         |
|                                  |              |         |                 |                         |
|                                  |              |         |                 |                         |
|                                  |              |         |                 |                         |
| Comments:                        |              |         |                 |                         |
| Signed (Operator)                |              |         | Date            |                         |
| Reviewed (2 <sup>nd</sup> Party) |              |         | Date            |                         |

|                                                   |                          |                                                                                    |  |
|---------------------------------------------------|--------------------------|------------------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>AMITS Storage System</b> |  |
| Document No: VAL001105                            | Project number EQAF 0018 | Version No: 00                                                                     |  |

14.2. Validation Deviation Form\*

| Deviation No.                                     | EQ Test No. |      |
|---------------------------------------------------|-------------|------|
| Deviation Details<br><div>N/A PS 12DEC 2017</div> |             |      |
| Corrective Actions                                |             |      |
| Outcome                                           |             |      |
| Deviation Closed<br>(Yes/No)                      |             | Date |
| Signed<br>(Operator)                              |             | Date |
| Approved<br>(Quality Assurance)                   |             | Date |

\*duplicate as required (single sheet per deviation only)

|                                                   |                                                                      |                |
|---------------------------------------------------|----------------------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>AMITS Storage System |                |
| Document No: VAL001105                            | Project number EQAF 0018                                             | Version No: 00 |

## 15. ATTACHMENTS

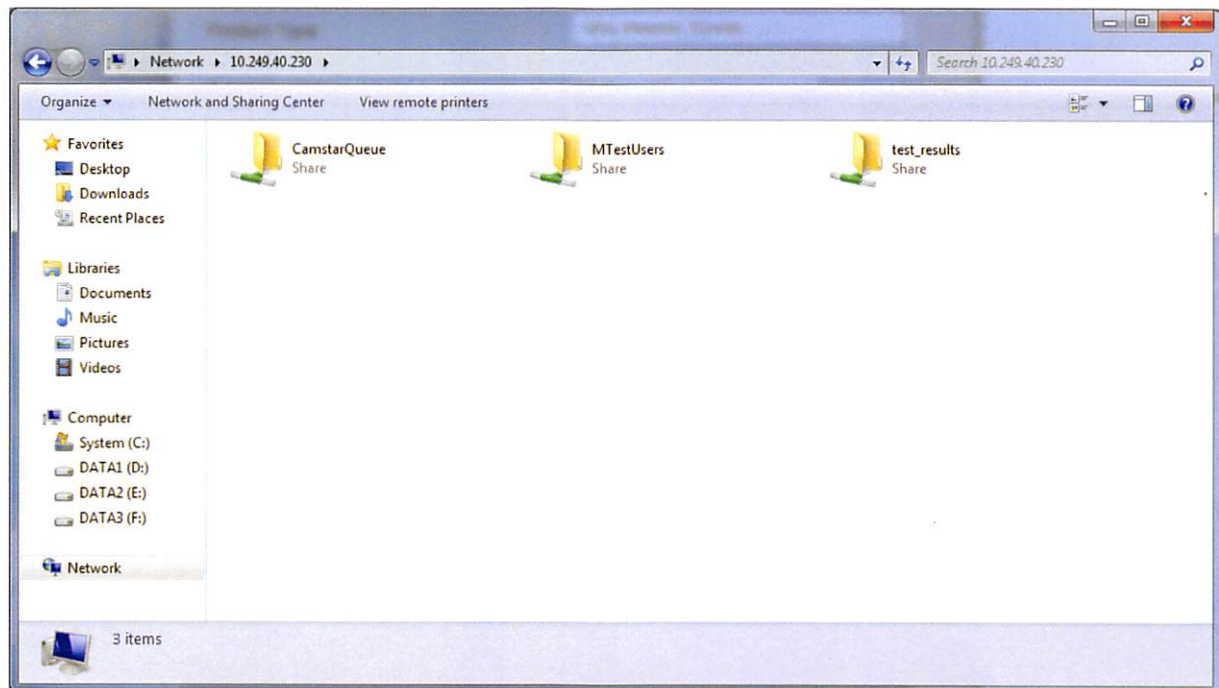
List all appended attachments to this protocol in the table below.

| Attachment No. | EQ Test No. | Details                                                                      | No. of pages | Operator Initials |
|----------------|-------------|------------------------------------------------------------------------------|--------------|-------------------|
| 1              | 12.1.2      | screen shot of file manager showing storage folders                          | 1            | PS                |
| 2              | 12.1.2      | screenshot of AMITS network configuration                                    | 1            | PS                |
| 3              | 12.1.2      | screenshot of AMITS simulation completed.                                    | 1            | PS                |
| 4              | 12.1.2      | screenshot of AMITS real data 54 BK 7626 -EQ-Protocol                        | 1            | PS                |
| 5              | 12.1.3      | screenshot of Sigma Probe configuration.                                     | 1            | PS                |
| 6              | 12.1.3      | screenshot of Sigma Sure Records showing result from 54 BK 7626 -EQ-Protocol | 1            | PS                |
| 7              | 12.1.4      | screenshot from Teamviewer access to the storage PC                          | 1            | PS                |
| 8              | 12.2        | Photograph of all four test bays running AMITS simulator at the same time.   | 1            | PS                |
|                |             |                                                                              |              |                   |
|                |             |                                                                              |              |                   |
|                |             | EOD PS 12 DEC 2017                                                           |              |                   |
|                |             |                                                                              |              |                   |
|                |             |                                                                              |              |                   |
|                |             |                                                                              |              |                   |
|                |             |                                                                              |              |                   |
|                |             |                                                                              |              |                   |



12.1.2 – ACQUITY QDa AMITS – storage folders

Attachment 1, PS 12 Dec 2017.



VAL001105 – Evidence – MM7521

### 12.1.2 – ACQUITY QDa AMITS – network configuration . Attachment 2 . PS 12 DEC 2017

Manufacturing Test x

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: MM7521

Location: Venture Remove

Add Location: Add

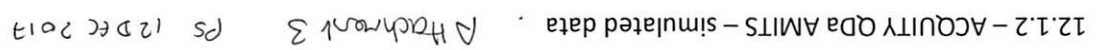
Area: Test Floor Remove

Add Area: Add

Sigma Version: 7

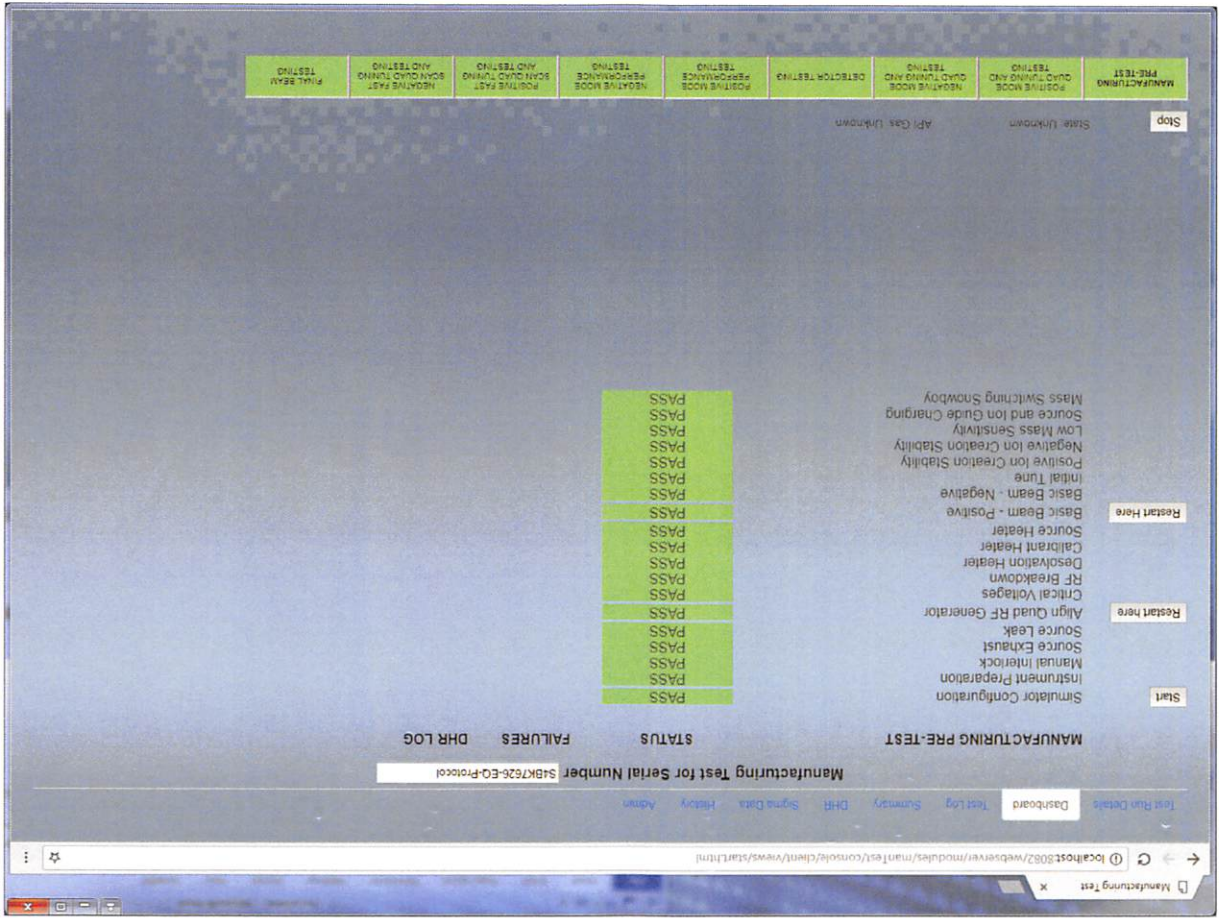
Available Product Types:

- ☒ 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
- ☒ QDa\_Quad\_Rail
- ☒ QDa\_Quad\_Rail\_Nostop
- ☒ QDa\_RCA\_Charging
- ☒ QDa\_RCA\_Detector
- ☒ QDa\_RCA\_Fast\_Tuning
- ☒ QDa\_RCA\_Heater
- ☒ QDa\_RCA\_Internal\_Cal
- ☒ QDa\_RCA\_Low\_Mass\_Sensitivity
- ☒ QDa\_RCA\_Peak\_Shape

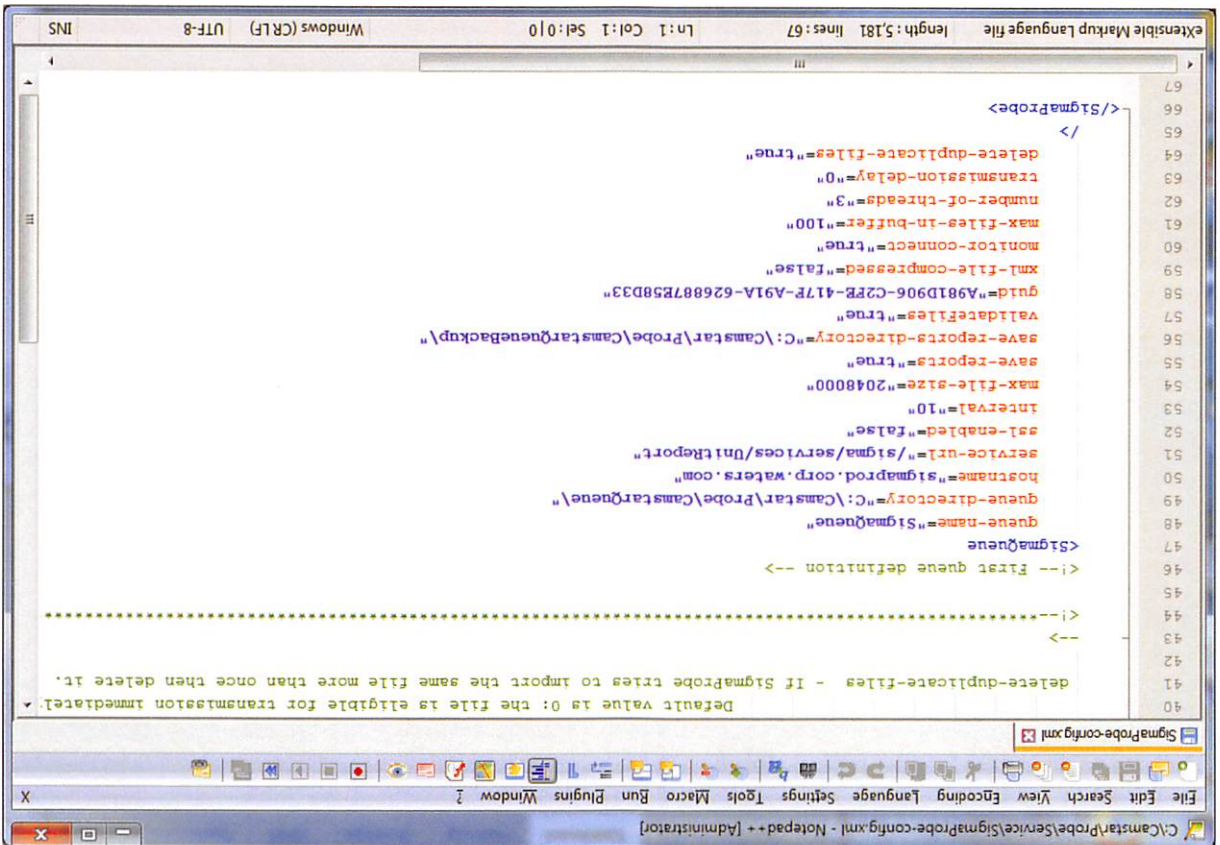


VAL001105 – Evidence – MM7521

12.1.2 – ACQUITY QDa AMITS – live data . A Hadment 4 - ps 12 Dec 2017

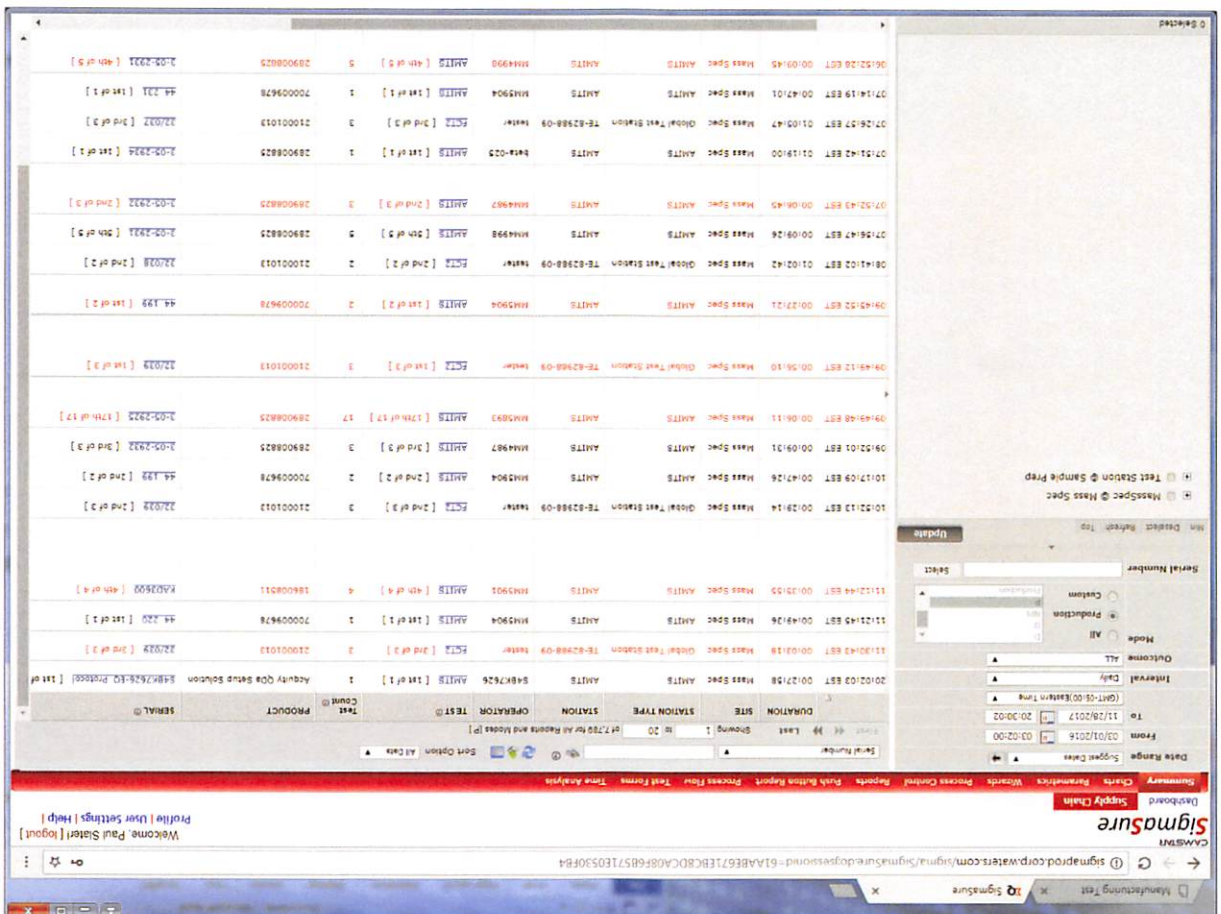


## 12.1.3 – Sigma probe configuration - Attachment 5 PS 12 DEC 2017



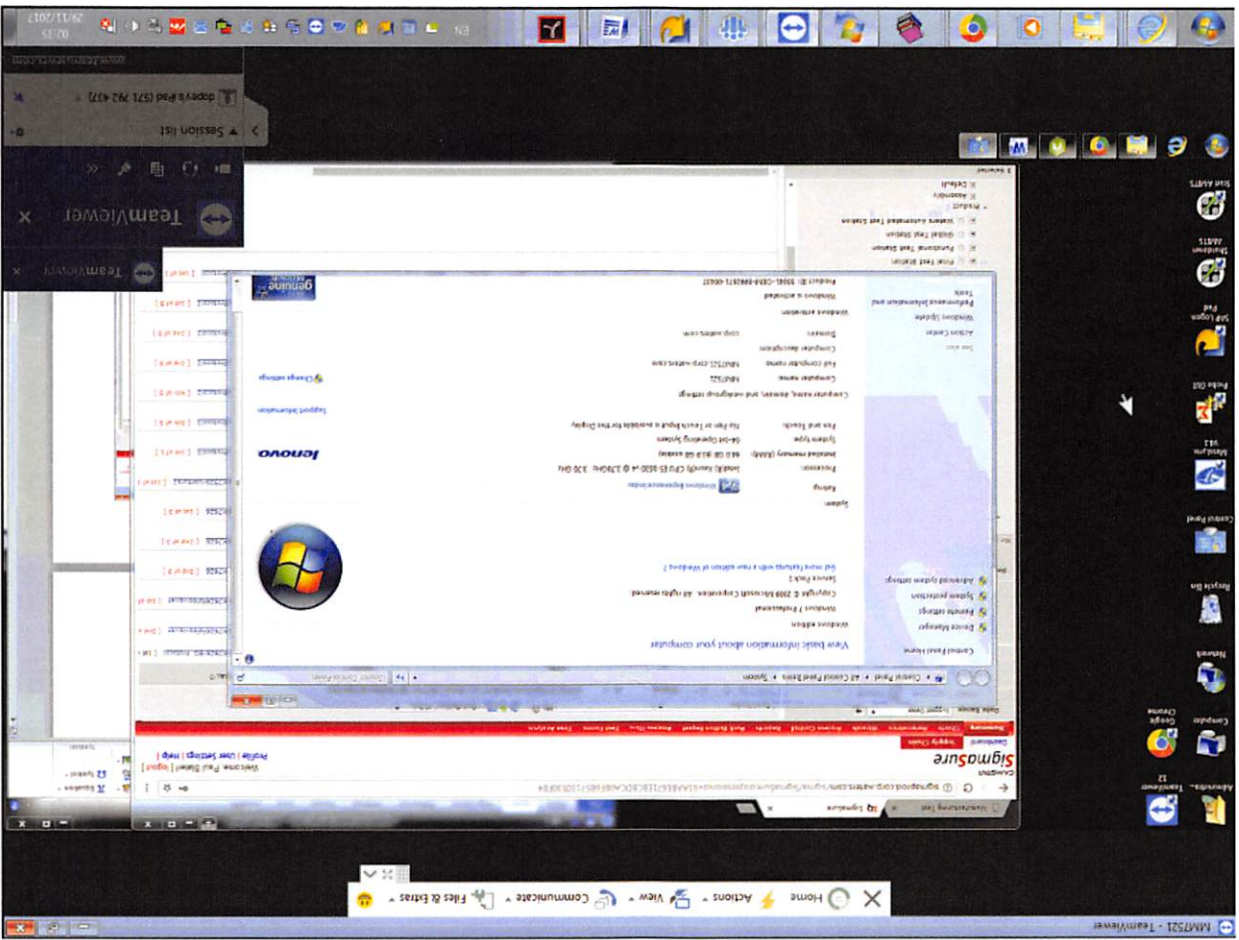
VAL001105 – Evidence – MM7521

12.1.3 – Sigma data import



VAL001105 – Evidence – MM7521

12.1.4 – Team viewer access      Attachment 7      ps 12 Dec 2017



VAL001105 – Evidence – MM7521

12.2 Test Load Attachment 8 - PS 12 DEC 2017



All instruments running AMITS live.