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| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                                           | Project number EQAF 0018                                  | Version No: 00 |

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# Waters - Wilmslow

## Equipment Qualification Protocol

### Venture ACQUITY QDa Test Floor

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**For Internal Use Only**

Document reviewed and approved electronically

Author: Paul Slater

Date: 26 Oct 2017.

Waters - S4gK 7626

|                                                   |                                                           |                |
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| Document No: VAL001104                            | 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 four ACQUITY QDa Test Floor, Test Bays 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 an equipment description and functionality, refer to the Validation Plan VAL001102

## 2. SCOPE

This protocol is restricted to the ACQUITY QDa Test Floor, Test Bays which are 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.

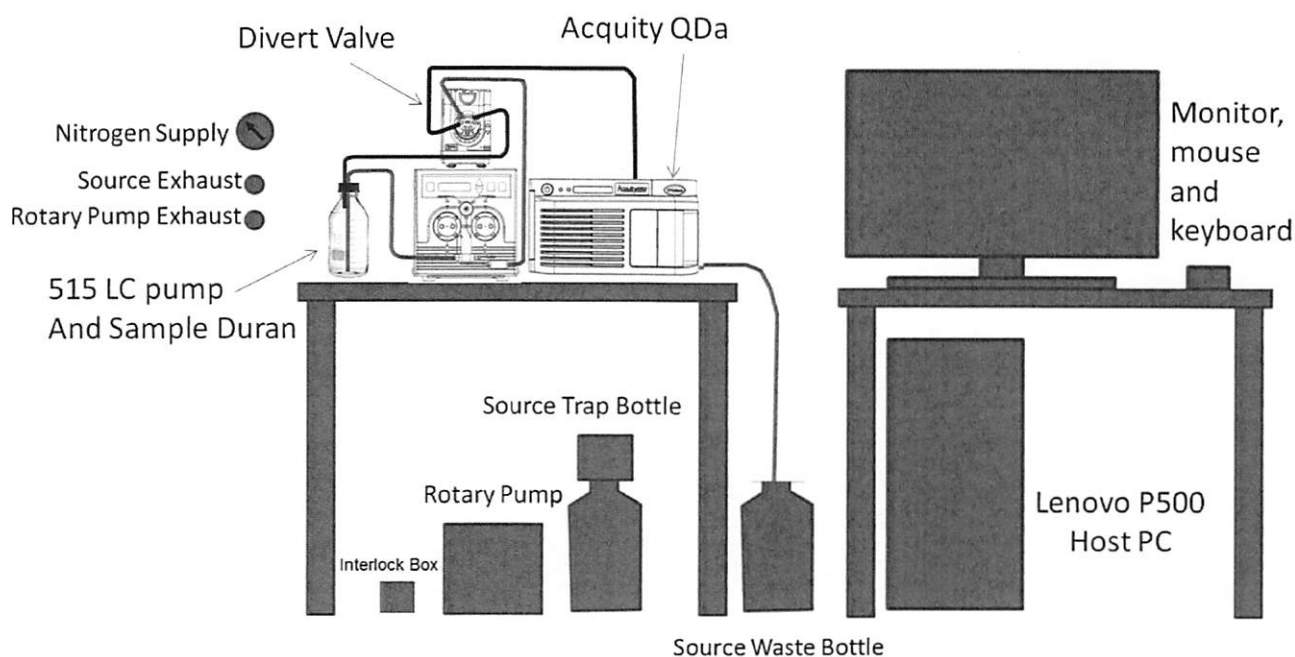


Figure 1 – Test Bay System – Venture Singapore

|                                                   |                                                           |                |
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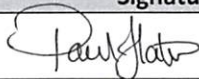
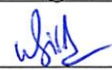
### 3. RESPONSIBILITIES & SIGNATURE PAGE

#### 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 |   | 28 NOV 2017 |
| SIDDHARTH UDAYSHANKAR | PRODUCT ASSURANCE ENGINEER           |  | 29 NOV 2017 |
| EDWINA BEANLAND       | PROCESS VALIDATION ENGINEER          |   | 14 DEC 2017 |
|                       |                                      |                                                                                     |             |
|                       |                                      |                                                                                     |             |
|                       |                                      |                                                                                     |             |

### 4. ABBREVIATIONS

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

### 5. REFERENCES

The following references are applicable to completion of this protocol.

| Document Number | Document title                                |
|-----------------|-----------------------------------------------|
| VAL001102       | Equipment Qualification Plan                  |
| VAL001105       | EQ Protocol Venture Test Bay DataStorage      |
| WAT068980       | 515 HPLC Pump Operators Guide                 |
| 46202           | QDa AMITS Test Procedure                      |
| 46215           | Acquity QDa Installation - link to Network    |
| 48550           | QDa Schivo Preventative Maintenance Procedure |
| 715002115rA_IQ  | Installation Qualification for 515 Pump       |
| 715002115rA_OQ  | Operational Qualification for 515 Pump        |
| 730003703       | Equipment Qualification Procedure             |

|                                                   |                                                                         |                |
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| Document Number                   | Document title                          |
|-----------------------------------|-----------------------------------------|
| 71550093001_MassLynx<br>IQ_Source | Installation Qualification for MassLynx |
| 71550093001_MassLynx<br>OQ_Source | Operational Qualification for MassLynx  |

## 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

## 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 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 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.

|                                                   |                                                           |                |
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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      | Health and Safety Testing                                                       | EQ005   |
| 6      | Installation Checks of 13AMP Mains Wall Sockets – Utility                       | EQ006   |
| 7      | Installation checks of Nitrogen Supply – Utility                                | EQ007   |
| 8      | Installation checks of Rotary Pump Exhaust System – Utility                     | EQ008   |
| 9      | Installation checks of source exhaust system – Utility                          | EQ009   |
| 10     | Installation checks of Test Bay Computer Hardware                               | EQ0010  |
| 11     | Installation checks of Test Bay Computer Software                               | EQ0011  |
| 12     | Installation Checks of Gold Brick ACQUITY QDa                                   | EQ0012  |
| 13     | Operational Checks of the 515 Pump                                              | EQ0013  |
| 14     | Operational Checks of Test Bay Software and Network                             | EQ0014  |
| 15     | Operational Checks of the Sample Divert Valve                                   | EQ0015  |
| 16     | Operational Checks of the Test Bay System, including the Gold Brick ACQUITY QDa | EQ0016  |
| 17     | Shutdown of test bay system                                                     | EQ0017  |

|                                                   |                                                           |                |
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## 11. EQUIPMENT INSTALLATION TESTING

### 11.1. EQ001 - Equipment Details

**Purpose:** To enter equipment details being installed.

#### 11.1.1. Gold Brick QDa UUT

|                                  |                                                  |      |             |
|----------------------------------|--------------------------------------------------|------|-------------|
| Equipment Name                   | ACQUITY QDa.                                     |      |             |
| Equipment Description:           | as above.                                        |      |             |
| Make:                            | Waters Corp                                      |      |             |
| Model/Type:                      | MKII                                             |      |             |
| Serial Number:                   | KAA 0270                                         |      |             |
| Asset No:                        | UK05 100 22 74                                   |      |             |
| Materials of construction:       | N/A.                                             |      |             |
| Risk Assessment                  | N/A                                              |      |             |
| Location:                        | GES VENTURE, 28 Marsiling lane, Singapore 739152 |      |             |
| <b>Comments</b>                  |                                                  |      |             |
| Signed (Operator)                | Paul Hato                                        | Date | 28 Nov 2017 |
| Reviewed (2 <sup>nd</sup> Party) | E. Beauland                                      | Date | 14 DEC 2017 |

|                                                   |                                                           |                |
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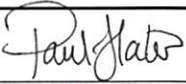
#### 11.1.2. Rotary Pump

|                                  |                                                   |      |              |
|----------------------------------|---------------------------------------------------|------|--------------|
| Equipment Name                   | Vacubrand Rotary Pump                             |      |              |
| Equipment Description:           | Rotary Pump                                       |      |              |
| Make:                            | Vacubrand.                                        |      |              |
| Model/Type:                      | R E 6W                                            |      |              |
| Serial Number:                   | 43291203                                          |      |              |
| Asset No:                        | N/A.                                              |      |              |
| Materials of construction:       | N/A                                               |      |              |
| Risk Assessment                  | N/A                                               |      |              |
| Location:                        | GES VENTURE , 28 Marsiling Lane, Singapore 739152 |      |              |
| <b>Comments</b>                  |                                                   |      |              |
| Signed (Operator)                | <i>Paul Gato</i>                                  | Date | 28 Nov 2017. |
| Reviewed (2 <sup>nd</sup> Party) | <i>Ebealand</i>                                   | Date | 14 DEC 2017  |



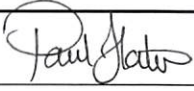
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#### 11.1.4. Source Trap Bottle

|                                  |                                                                                     |      |              |
|----------------------------------|-------------------------------------------------------------------------------------|------|--------------|
| Equipment Name                   | Source Trap Bottle.                                                                 |      |              |
| Equipment Description:           | Source Trap Bottle. 289010013                                                       |      |              |
| Make:                            | Waters.                                                                             |      |              |
| Model/Type:                      | N/A.                                                                                |      |              |
| Serial Number:                   | 971002. <sup>PS</sup> 29 NOV 2017.86 / 006                                          |      |              |
| Asset No:                        | N/A.                                                                                |      |              |
| Materials of construction:       | N/A                                                                                 |      |              |
| Risk Assessment                  | N/A                                                                                 |      |              |
| Location:                        | GES venture, 28 Marsiling Lane, Singapore 739152.                                   |      |              |
| <b>Comments</b>                  |                                                                                     |      |              |
| Signed (Operator)                |   | Date | 28 NOV 2017. |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 DEC 2017  |

|                                                                                                                                                          |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
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#### 11.1.5. 515 Pump

|                                  |                                                                                     |      |             |
|----------------------------------|-------------------------------------------------------------------------------------|------|-------------|
| Equipment Name                   | 515 Pump.                                                                           |      |             |
| Equipment Description:           | 515 Pump.                                                                           |      |             |
| Make:                            | Waters.                                                                             |      |             |
| Model/Type:                      | 515 Pump. WAT 207000                                                                |      |             |
| Serial Number:                   | H17515993A                                                                          |      |             |
| Asset No:                        | 5400                                                                                |      |             |
| Materials of construction:       | N/A.                                                                                |      |             |
| Risk Assessment                  | N/A                                                                                 |      |             |
| Location:                        | Ges venture, 28 Marsiling Lane, Singapore 739 152                                   |      |             |
| <b>Comments</b>                  |                                                                                     |      |             |
| Signed (Operator)                |   | Date | 28 Nov 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 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                                           |                   |                                                                                     |      |             |                                  |                                                                                     |      |             |
| <b>Comments</b><br>Principle product assurance engineers on product.                                                                                                                                                                                                                                                                                                                  |                                                                                     |                   |                                                                                     |      |             |                                  |                                                                                     |      |             |
| <table border="1"> <tr> <td>Signed (Operator)</td> <td></td> <td>Date</td> <td>28 NOV 2017</td> </tr> <tr> <td>Reviewed (2<sup>nd</sup> Party)</td> <td></td> <td>Date</td> <td>14 DEC 2017</td> </tr> </table> |                                                                                     | Signed (Operator) |  | Date | 28 NOV 2017 | Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 DEC 2017 |
| Signed (Operator)                                                                                                                                                                                                                                                                                                                                                                     |  | Date              | 28 NOV 2017                                                                         |      |             |                                  |                                                                                     |      |             |
| Reviewed (2 <sup>nd</sup> Party)                                                                                                                                                                                                                                                                                                                                                      |  | Date              | 14 DEC 2017                                                                         |      |             |                                  |                                                                                     |      |             |

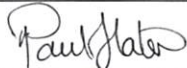
**Purpose:** To ensure the required documentation to support the equipment is available.

**Comments:**

|                                                                                                                                                          |                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
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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?                                                          |               | Annual         |                        |
| Has Equipment been calibrated prior to starting this protocol? If so, provide details below |               |                |                        |
| <b>N/A</b>                                                                                  | Calibrated on | n/a            | Calibration due<br>n/a |
| <b>Comments:</b><br>Calibrated as part of testing EQ.                                       |               |                |                        |
| Signed (Operator)                                                                           |               | Date           |                        |
|          |               | 28 Nov 2017.   |                        |
| Reviewed (2 <sup>nd</sup> Party)                                                            |               | Date           |                        |
|          |               | 14 DEC 2017    |                        |

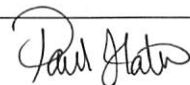
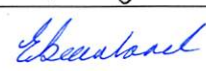
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### 11.5. EQ005 - Health and Safety Testing

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

Comments:

|                                  |                                                                                     |      |             |
|----------------------------------|-------------------------------------------------------------------------------------|------|-------------|
| Signed (Operator)                |  | Date | 13 DEC 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 DEC 2017 |

|                                                   |                                                           |                |
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#### 11.6. EQ006 – Installation Checks of 13AMP Mains Wall Sockets - Utility

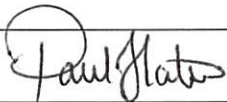
**Purpose:** To record the utility requirements and connections required for the equipment to operate

| Utility                                                | Expected Result                                                                                                                                                                                                                                                                        | Actual Result                                         | Pass / Fail              |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------|
| Independent Socket for ACQUITY QDa – Performance Model | <ul style="list-style-type: none"> <li>Rated Voltage - 100 to 240V</li> <li>Rated Frequency - 50/60Hz</li> <li>Maximum supply fuse / circuit breaker rating – 13 to 16A</li> <li>Power Connection – IEC 60320 C14 receptacle</li> <li>Located within 2 m of the instrument.</li> </ul> | 237 V AC.<br>50.03 Hz.<br><br>W1 - 16AP0073 - 2337288 | Pass<br><br>PG JAN 2018. |
| Independent Socket Socket for Rotary Pump              | <ul style="list-style-type: none"> <li>Rated Voltage - 200 to 240V</li> <li>Rated Frequency - 50/60Hz</li> <li>Maximum supply fuse / circuit breaker rating – 13 to 16A</li> <li>Power Connection – IEC 60320 C14 receptacle</li> <li>Located within 2 m of the instrument.</li> </ul> | 237 V AC<br>50.03 Hz                                  | Pass                     |
| Socket for 515 pump                                    | <ul style="list-style-type: none"> <li>Rated Voltage - 220 to 240V</li> <li>Rated Frequency - 50/60Hz</li> <li>Maximum supply fuse / circuit breaker rating – 3.15A</li> <li>Power Connection – IEC 60320 C14 receptacle</li> </ul>                                                    | 237 V AC<br>50.03 Hz                                  | Pass                     |
| 2 Sockets for Data System                              | <ul style="list-style-type: none"> <li>Rated Voltage - 200 to 240V</li> <li>Rated Frequency - 50/60Hz</li> <li>Maximum supply fuse / circuit breaker rating – 2.5 to 16A</li> <li>Power Connection – IEC 60320 C14 receptacle</li> </ul>                                               | 237 V AC<br>50.03 Hz                                  | Pass                     |
| Socket for Diverter Valve                              | <ul style="list-style-type: none"> <li>Rated Voltage - 100 to 240V</li> <li>Rated Frequency - 50/60Hz</li> <li>Maximum supply fuse / circuit breaker rating – 13 to 16A</li> <li>Power Connection – IEC 60320 C14 receptacle</li> </ul>                                                | 237 V AC<br>50.03 Hz                                  | Pass                     |
| All Sockets                                            | Voltage supply stability is critical for instrument operation, the nominal power supply voltage must fall within the ranges specified above at all times to allow for the occasional 10% surge.                                                                                        | Can Not be measured                                   | Pass.                    |

|                                                                                                                                                          |                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|  <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |                          |
| Document No: VAL001104                                                                                                                                   | Project number EQAF 0018 |
| Version No: 00                                                                                                                                           |                          |

| Utility     | Expected Result                                                                                                                                                                                                                                                                                                                                                                     | Actual Result | Pass / Fail |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------|
| All Sockets | The supplies must be wired with a protective earth and fused or fitted with circuit-breakers within the specified ratings, in accordance with local regulations.                                                                                                                                                                                                                    | Confirmed.    | Pass.       |
| All Sockets | The site must provide evidence that:<br><br>The main power supply must not have brown-outs/surges greater than $\pm 10\%$ , and must not exceed the specified maximum operating range for more than 0.3 sec. Transient voltage drops to half nominal voltage or less must have a duration of less than 20 ms. There must be less than 1.0 V RMS of ripple on the main power supply. | N/A.          | Pass.       |

Comments:

|                                  |                                                                                     |      |              |
|----------------------------------|-------------------------------------------------------------------------------------|------|--------------|
| Signed (Operator)                |  | Date | 29 Nov 2017. |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 Dec 2017  |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

### 11.7. EQ007 – Installation Checks of Nitrogen Supply - Utility

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

| Utility                              | Expected Result                                                                                                                                                                                                                                         | Actual Result                                                                                                                                                                                                                                                                                                                                               | Pass / Fail               |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Nitrogen Supply                      | The ACQUITY QDa Detector requires a supply of dry, oil-free nitrogen with a purity of at least 95%. The nitrogen must be regulated at 6.0 to 6.9 bar (87 to 100 psi) outlet pressure, using a two-stage gas regulator with an appropriate outlet range. | 6.9 bar. 100 PSI<br>confirmed.                                                                                                                                                                                                                                                                                                                              | Pass<br>28 Nov 2017       |
| Connection                           | Regulator must be fitted with an adapter to connect to a 6-mm OD FEP tube                                                                                                                                                                               | confirmed.                                                                                                                                                                                                                                                                                                                                                  | Pass<br>28 Nov 2017       |
| Supply –Cross talk between test bays | Adding or removing a 1200l/hr flow from another test bay must not alter the pressure observed on this test bay by more than 10%.                                                                                                                        | Pressure measured on Test Bay regulator with no bays using Nitrogen:<br><u>110 PSI</u> .<br><br>Pressure measured on Test Bay regulator running at 1200l/hr - with no other bays using Nitrogen:<br><u>100 PSI</u> .<br><br>Pressure measured on Test Bay regulator running at 1200l/hr - with a 1200l/hr flow added from any other bay:<br><u>95 PSI</u> . | Pass<br>PS<br>28 Nov 2017 |
| Supply – Maximum output              | The pressure must remain between 6.0 to 6.9 bar (87 to 100 psi) when all four bays are run at 1200l/hr.                                                                                                                                                 | Pressure measured on Test Bay regulator with a 1200l/hr flow on all the test bays.<br>X. <u>90 PSI</u> → <u>95 PSI</u> → <u>97 PSI</u> → <u>100 PSI</u><br>4 Bay      3 Bay      2 Bay      1 Bay.                                                                                                                                                          | Pass<br>28 Nov 2017       |
| <b>Comments:</b>                     |                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                             |                           |
| Signed (Operator)                    |                                                                                                                                                                      | Date                                                                                                                                                                                                                                                                                                                                                        | 28 Nov 2017               |
| Reviewed (2 <sup>nd</sup> Party)     |                                                                                                                                                                      | Date                                                                                                                                                                                                                                                                                                                                                        | 14 DEC 2017               |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

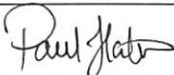
### 11.8. EQ008 – Installation Checks of Rotary Pump Exhaust System - Utility

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

| Utility                            | Expected Result                                                                                                                                                                                                                                                                                                                     | Actual Result                                                                                                                                                                                      | Pass / Fail            |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Rotary Exhaust – Active Vent       | The active exhaust vent must provide a minimum <b>vacuum</b> of 2 mbar (0.030 psi) below atmospheric pressure (negative pressure). It must be capable of supporting a maximum of four instrument exhaust gas loads of 4x 2500 L/hour (10000L/hour)                                                                                  | Not measurable – but a high level of draw can be felt on the exhaust port.                                                                                                                         | Pass<br>PS 28 Nov 2017 |
| Rotary Exhaust – Connectivity      | <p>The rotary pump exhaust gases must be vented to the atmosphere outside the laboratory through a user-supplied fume hood or industrial vent.</p> <p>The exhaust may be connected to an existing laboratory vent carrying gases from other sources.</p> <p>The exhaust must NOT be connected to the QDa source exhaust system.</p> | The fume hoods are separated by over 2m.                                                                                                                                                           | Pass<br>PS 28 Nov 2017 |
| Rotary Exhaust – Test Bay fittings | The rotary pump exhaust piping must be connected to the test bay rotary pump exhaust fitting in such a manner that no condensed oil vapour can collect and cause an air lock.                                                                                                                                                       | <sup>PS 29 Nov 2017</sup><br><del>No fittings</del> , but the pipe internal diameter is uPVC 100mm. The fittings enter the pipe vertically so well away from any accumulation of condensed liquid. | Pass<br>PS 28 Nov 2017 |
| Rotary Pump – Accessibility        | The rotary pump must be accessible for routine maintenance tasks such as checking the oil level and inspecting the oil vapour trap.                                                                                                                                                                                                 | Easy access and the oil mist filter is easy to see.                                                                                                                                                | Pass<br>PS 28 Nov 2017 |
| Rotary Exhaust – Test Floor        | It must be possible to drain condensed oil vapour from the Rotary Pump exhaust system                                                                                                                                                                                                                                               | No top, but the system is accessible for modification.                                                                                                                                             | Pass<br>PS 28 Nov 2017 |
| Rotary pump - Cleanliness          | It must be possible to fit a rotary pump drip tray (WAT088667) to the system at a future date. (30 x 51 cms)                                                                                                                                                                                                                        | Tray fitted.                                                                                                                                                                                       | Pass<br>PS 28 Nov 2017 |
| Rotary Pump Oil Level              | Rotary pump is filled with oil to the upper level mark                                                                                                                                                                                                                                                                              | confirmed.                                                                                                                                                                                         | Pass<br>PS 28 Nov 2017 |
| Oil trap                           | Oil trap is fitted                                                                                                                                                                                                                                                                                                                  | confirmed.                                                                                                                                                                                         | Pass PS 28 Nov 2017    |

|                                                                  |                                                                         |                |
|------------------------------------------------------------------|-------------------------------------------------------------------------|----------------|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |                |
| Document No: VAL001104                                           | Project number EQAF 0018                                                | Version No: 00 |

Comments:

|                                  |                                                                                   |      |             |
|----------------------------------|-----------------------------------------------------------------------------------|------|-------------|
| Signed (Operator)                |  | Date | 28 Nov 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 DEC 2017 |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

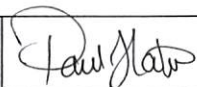
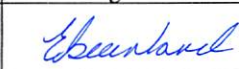
### 11.9. EQ009 – Installation Checks of the Source Exhaust System - Utility

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

| Utility                               | Expected Result                                                                                                                                                                                                                                | Actual Result                                                                                                         | Pass / Fail                      |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Source Exhaust – Active Vent          | The active exhaust vent must provide a minimum <u>vacuum</u> of 2 mbar (0.030 psi) below atmospheric pressure (negative pressure). It must be capable of supporting a maximum four instrument exhaust gas loads of 4x 1200 L/hour (4800L/hour) | Draw can not be measured directly with gas off. But a strong draw can be felt by hand.                                | Pass<br>PS 28 NOV 2017           |
| Source Exhaust – Connectivity         | The Source exhaust gases must be vented to the atmosphere outside the laboratory through a laboratory fume hood or to an active exhaust vent.<br><br>The exhaust must NOT be connected to the rotary pump exhaust system.                      | Confirmed.<br><br>over 2m between fume hood exhausts.                                                                 | Pass<br>PS 28 NOV 2017           |
| Source Exhaust Test Bay Back Pressure | When all four test bays are delivering 1200l/hr to the source exhaust system, the back pressure read on an ACQUITY QDa pressure sensor must be less than 10mBar.                                                                               | Unable to measure. Only one instrument available on test floor. A single instrument = 6.5 mBar gas on 1 mBar gas off. | concession<br><br>PS 28 NOV 2017 |
| Source Exhaust – Test Floor           | It must be possible to drain condensed sample from the Rotary Pump exhaust system                                                                                                                                                              | No tap, but pipework easily accessible for modification, and over 100mm in diameter.                                  | Pass<br>PS 28 NOV 2018           |
| Source Exhaust – Test Floor           | The source exhaust system leak rate into the test floor environment must be kept to a minimum amount. Confirm all fittings on test bay are secure.                                                                                             | confirmed. Strong suction of source exhaust system will prevent leaks reaching test floor environment.                | Pass<br>PS 28 NOV 2017           |

**Comments:**

Only had access to a single QDa, so unable to test system with 4x 1200L/hr entering the source exhaust system.

|                                  |                                                                                     |      |              |
|----------------------------------|-------------------------------------------------------------------------------------|------|--------------|
| Signed (Operator)                |  | Date | 28 NOV 2017. |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 DEC 2017  |

|                                                                                                                                                          |                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|  <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |                          |
| Document No: VAL001104                                                                                                                                   | Project number EQAF 0018 |
| Version No: 00                                                                                                                                           |                          |

### 11.10. EQ010 – Installation Checks of the Test Bay Computer Hardware - Utility

**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                                                                                                                                            |  | Requires a host PC to drive the QDa under test. |                         |
| <b>Comments:</b><br>Record the Host PC name and Domain Name: <i>Waters - S4BK7626 / corp</i><br><br>Record the IP Address of the Host PC <i>10. 249. 40. 246</i> |  |                                                 |                         |
| Signed (Operator)                                                                                                                                                |  | <i>Paul Hlatko</i>                              | Date <i>28 Nov 2017</i> |
| Reviewed (2 <sup>nd</sup> Party)                                                                                                                                 |  | <i>Ebeantand</i>                                | Date <i>14 DEC 2017</i> |

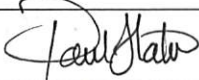
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|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------|
|  <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |                          |                |
| Document No: VAL001104                                                                                                                                   | Project number EQAF 0018 | Version No: 00 |

### 11.11. EQ011 – Installation Checks of the Test Bay Computer Software - Utility

**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. | 3.1                       | SVAF Approved  | <u>Yes</u> /No |
| PuTTY                                                             | Version No. | 0.60                      | SVAF Approved  | <u>Yes</u> /No |
| Engineers Dashboard                                               | Version No. | 1.2.659.24837             | SVAF Approved  | <u>Yes</u> /No |
| Chrome                                                            | Version No. | 62.0.3202.94              | SVAF Approved  | <u>Yes</u> /No |
| MassLynx                                                          | Version No. | 4.1<br>scn 947<br>scn 941 | SVAF Approved  | <u>Yes</u> /No |
| Microsoft Office                                                  | Version No. | 14.0.7190.5000            | SVAF Approved  | <u>Yes</u> /No |

Comments:

|                                  |                                                                                     |      |             |
|----------------------------------|-------------------------------------------------------------------------------------|------|-------------|
| Signed (Operator)                |  | Date | 25 NOV 2017 |
| Reviewed (2 <sup>nd</sup> Party) |  | Date | 14 DEC 2017 |

|                                                   |                                                           |                |
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

## 12. EQUIPMENT OPERATION TESTING

### 12.1. EQ012 – Installation Checks of the Gold Brick ACQUITY QDa

#### Objective/Rationale:

To ensure the Gold Brick QDa is installed correctly

#### Acceptance Criteria:

| Description    | Result Expected                                                                                                                        | Result Actual | Acceptance Criteria Met Y/N |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| QDa location   | QDa is in a suitable location                                                                                                          | Confirmed     | (Y)/N                       |
| Aperture disc  | 0.2mm aperture disk is fitted                                                                                                          | Confirmed     | (Y)/N                       |
| Rotary pump    | Rotary pump is filled with oil to the upper level mark                                                                                 | confirmed     | (Y)/N                       |
|                | Oil trap is fitted                                                                                                                     | confirmed     | (Y)/N                       |
|                | Rotary pump exhaust is fitted to a suitable extraction system                                                                          | confirmed     | (Y)/N                       |
|                | Rotary pump vacuum hose is connected between the pump and the instrument                                                               | confirmed     | (Y)/N                       |
|                | Pump control cable is fitted between the pump relay box and the control port on the rear of the instrument                             | confirmed     | (Y)/N                       |
|                | Pump relay box connected to the rotary pump                                                                                            | confirmed     | (Y)/N                       |
|                | Pump relay box is connected to the laboratory power supply                                                                             | confirmed     | (Y)/N                       |
| Source Exhaust | Source exhaust tube is connected to the source exhaust valve assembly and the exhaust trap bottle in a downward gradient with no loops | confirmed     | (Y)/N                       |
|                | Convoluting tubing is fitted on the source exhaust valve assembly and a waste container                                                | confirmed     | (Y)/N                       |
|                | Exhaust trap bottle valve control cable is connected to the rear panel                                                                 | confirmed     | (Y)/N                       |
|                | 4mm drain tube is fitted to the rear of the instrument                                                                                 | N/A           | (Y)/N                       |

|                                                                                                                                                          |                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|  <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |                          |
| Document No: VAL001104                                                                                                                                   | Project number EQAF 0018 |
| Version No: 00                                                                                                                                           |                          |

| Description                                                                                                                                        | Result Expected                                                                                                                      | Result Actual                                                                       | Acceptance Criteria Met Y/N |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------|
| QDa Set-up                                                                                                                                         | Probe is installed                                                                                                                   | confirmed                                                                           | Y/N                         |
|                                                                                                                                                    | Probe is connected to the divert valve                                                                                               | confirmed                                                                           | Y/N                         |
|                                                                                                                                                    | Divert Valve cable is connected to the QDa                                                                                           | confirmed                                                                           | Y/N                         |
|                                                                                                                                                    | Instrument LAN cable connected to Host PC.                                                                                           | confirmed                                                                           | Y/N                         |
|                                                                                                                                                    | Serial cable is connected between the QDa and the Host PC                                                                            | confirmed                                                                           | Y                           |
|                                                                                                                                                    | Power up the QDa.<br>Confirm the QDa backing pump powers up, and that after 5 minutes, the instrument runs the source pressure test. | confirmed                                                                           | Y.                          |
| <div> <div>Were all acceptance criteria met – Y/N</div> <div>Y</div> </div> <div> <div>Deviation Number (if required)</div> <div>N/A.</div> </div> |                                                                                                                                      |                                                                                     |                             |
| <div>Comments:</div> <div></div>                                                                                                                   |                                                                                                                                      |                                                                                     |                             |
| Signed (Operator)                                                                                                                                  |                                                                                                                                      |  | 28 NOV 2017                 |
|                                                                                                                                                    |                                                                                                                                      |  | 14 DEC 2017                 |

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|---------------------------------------------------|--------------------------|-------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

## 12.2. EQ013 – Operational Checks of 515 pump

### 12.2.1. 515 Pump Pressure Decay

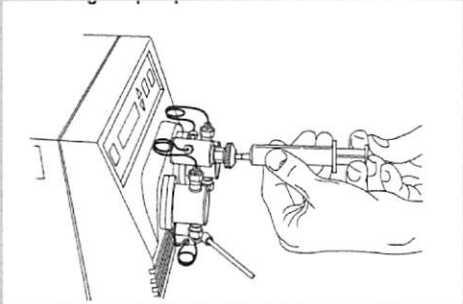
#### Objective/Rationale:

Confirm 515 pump operates correctly

#### Equipment Required

| Equipment                                         | Lot Number/Calibration Number | Expiry/Cal Due date |
|---------------------------------------------------|-------------------------------|---------------------|
| Plug pin high pressure<br>Part Number (289008451) | N/A                           | N/A                 |
| LC/MS Grade Methanol                              | N/A                           | N/A                 |
| Calibrated Stopwatch                              | 261830 / 4543                 | 08 NOV 2018         |

#### Acceptance Criteria:

| Function                                   | Experimental Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial / Date                            |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| Priming the pump with LC/MS Grade Methanol | <p>Turn on the pump and allow it to completed all start-up checks</p> <p>Replace the current solvent with a 1l bottle of LC-MS Grade methanol</p> <p>Set the pump flow parameter to 1.000mL/min BUT do not press Run/Stop at this point</p> <p>Fully depress the priming syringe plunger to remove all air from the syringe, then insert the syringe into the luer fitting at the centre of the draw-off valve handle.</p>  <p>Turn the draw-off valve handle anti-clockwise about ½ turn to open the valve</p> <p>Withdraw several mls of eluent with the syringe, then close the valve handle. Expel the contents of the syringe into a suitable waste container</p> <p>Press the Run/Stop key to start the pump</p> <p>Let the pump run for about a minute to allow the pump pressure to settle.</p> <p>Press the Run/Stop key to stop the pump</p> | <p>S. U<br/>2017<br/>29 NOV 2018 S.U.</p> |

|                                                   |                          |                                                                         |  |
|---------------------------------------------------|--------------------------|-------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

| Function                                                                      | Experimental Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                     |                             |               | Initial / Date                 |
|-------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------|---------------|--------------------------------|
| Pressure Decay Test                                                           | Disconnect the tubing at the pump outlet and cap the outlet with the plug pin<br>In the pump's LCD display, set the high pressure limit (HPL) to 4000psi and the flow parameter to 0.200 mL/min.<br>Set the pump flow parameter to 3.000mL/min<br>Press Run/Stop to start the pump<br>When the pump shuts off (1.2s after exceeding 4000psi), start the stop watch.<br>Press the up or down key to clear the Hi Press Message<br>30s after pressure shut off, note down the pressure reading. This is P1<br>300s after pressure shut ff, note down the pressure reading. This is P2<br>Loosen a fitting to relieve the pump pressure and remove the plug. |                                                                                     |                             |               | S.U<br>2017<br>29 Nov 2017 S.U |
| Results                                                                       | P1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | P2                                                                                  | Pressure Decay – (P1-P2/P1) |               | S.U<br>29 Nov 2017             |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     | Expected Result             | Actual Result |                                |
|                                                                               | 4589                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 4589                                                                                | ≤0.15                       | 0             |                                |
| Were all acceptance criteria met – Y/N <span style="float: right;">Y/N</span> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |                             |               |                                |
| Deviation Number (if required)                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |                             |               |                                |
| Comments:                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |                             |               |                                |
| Signed (Operator)                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                             | Date          | 29 Nov 2017                    |
| Reviewed (2 <sup>nd</sup> Party)                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                             | Date          | 14 DEC 2017                    |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

### 12.2.2. 515 Pump Flow Accuracy

#### Objective/Rationale:

Testing the flow rate accuracy of the pump

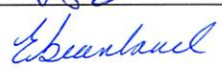
#### Equipment Required

| Equipment                                         | Lot Number/Calibration Number | Expiry/Cal Due date |
|---------------------------------------------------|-------------------------------|---------------------|
| Backpressure regulator<br>Part Number (289008451) | N/A                           | N/A                 |
| Class A 10mL Volumetric Flask                     | N/A                           | N/A                 |
| Class A 25mL Volumetric Flask                     | N/A                           | N/A                 |
| LC/MS Grade Methanol                              | N/A                           | N/A                 |
| Calibrated Stopwatch                              | 261830/4543                   | 08 NOV 2018         |

#### Acceptance Criteria:

| Function                    | Experimental Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial/Date       |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Pressure Restriction        | Fit the backpressure regulator to the pump outlet                                                                                                                                                                                                                                                                                                                                                                                                                                         | S.U<br>29 Nov 2017 |
| 0.500mL/min flow rate check | Set the flow rate to 0.500mL/min and start the pump<br>When the flow and pressure stabilise, simultaneously insert the outlet tubing into the 10mL volumetric flask and start the stopwatch.<br>Stop the stopwatch when the bottom of the meniscus reaches the volume level mark on the flask<br>Record the elapsed time in seconds and the observed system pressure.<br>The flow rate can then be calculated by<br>Calculated flow rate = Volume of flask/(measured time in seconds)/60) | S.U<br>29 Nov 2017 |
| 1.000mL/min flow rate check | Set the flow rate to 1.000mL/min and start the pump<br>When the flow and pressure stabilise, simultaneously insert the outlet tubing into the 10mL volumetric flask and start the stopwatch.<br>Stop the stopwatch when the bottom of the meniscus reaches the volume level mark on the flask<br>Record the elapsed time in seconds and the observed system pressure<br>The flow rate can then be calculated by<br>Calculated flow rate = Volume of flask/(measured time in seconds)/60)  | S.U<br>29 Nov 2017 |

|                                                   |                          |                                                                         |  |
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| 5.000mL/min<br>flow rate check                                                                 | Set the flow rate to 5.000mL/min and start the pump<br>When the flow and pressure stabilise, simultaneously insert the outlet tubing into the 25mL volumetric flask and start the stopwatch.<br>Stop the stopwatch when the bottom of the meniscus reaches the volume level mark on the flask<br>Record the elapsed time in seconds and the observed system pressure<br>The flow rate can then be calculated by<br>Calculated flow rate = Volume of flask/(measured time in seconds)/60) |                                                                                     |                           |                               | S.V<br>29 NOV 2017 |       |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------|-------------------------------|--------------------|-------|
|                                                                                                | Set Flow Rate                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Observed System Pressure (psi)                                                      | Observed Elapsed Time (s) | Calculated Flow Rate (mL/min) |                    |       |
|                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     | Expected Result           | Actual Result                 |                    |       |
|                                                                                                | 0.500                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 443                                                                                 | 1174                      | 0.469-0.531                   |                    | 0.511 |
|                                                                                                | 1.000                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 849                                                                                 | 596                       | 0.968-1.032                   |                    | 1.007 |
| 5.000                                                                                          | 81                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 118                                                                                 | 4.94-5.06                 | 5.08                          | S.V<br>29 NOV 2017 |       |
| Were all acceptance criteria met – Y/N                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |                           |                               | Y/N                |       |
| Deviation Number (if required)                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |                           |                               | 1                  |       |
| Comments: Failed 5.000mL/min flow rate check.<br>Concession - The requirement is 0.350 mL/min. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |                           |                               |                    |       |
| Signed (Operator)                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                           | Date                          | 29 NOV 2017        |       |
| Reviewed (2 <sup>nd</sup> Party)                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                           | Date                          | 14 DEC 2017        |       |

|                                                   |                                                           |                |
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### 12.3. EQ014 – Operational Checks of Test Bay Software and Network

The AMITS Storage PC or VM must have completed its installation Checks from (VAL001105) before proceeding with this test. The results from this test will be used as part of the operational checks for the storage system.

#### 12.3.1. 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 Network Configuration    | Open AMITS.<br>Open Admin.<br>Enter Admin password.<br>The Admin Details within AMITS must be edited to match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore.<br><br>Confirm the Admin Details within AMITS match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore. | confirmed.<br>Storage PC IP address used.                | Y<br>PS 28 NOV 2017         |
| AMITS User List                | Refresh AMITS. (f5 key)<br>Open Admin.<br>Click on the downward pointing arrow beside the Test Engineer drop list.<br><br>Confirm the engineer list contains UKPLMPSL.                                                                                                                                                                          | confirmed.                                               | Y<br>PS 28 NOV 2017         |
| AMITS link to Storage Solution | 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")                                                     | S4BK7626 – EQ-Protocol.<br><br>confirmed, all tests pass | Y<br>PS 28 NOV 2017         |

|                                                   |                          |                                                                         |  |
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

|                                                      |                                                                                                                                                                                                                                                                                                                                                                                                               |                               |                             |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------|
| AMITS timely Data Exchange<br>with Storage Solution. | Open AMITS.<br>Open Test Run Details.<br>From the product type list, select "simulator".<br>Enter the following details:<br><br>Serial Number: Test Bay Number<br>Sample Batch Number: N/A<br>Sample Use By Date: N/A<br>Test Box Number: Divert Valve serial number<br>Test Rig Number: N/A<br>Procedure Document Number: this document                                                                      | confirmed all<br>tests passed | Y<br><br>PS<br>28 NOV 2017. |
|                                                      | Open the Dashboard<br>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>Allow the test sequence to complete. (approx 15 minutes)<br><br>Confirm the test sequence completes. (All the Statuses in every test section are "PASS") |                               |                             |
| Were all acceptance criteria met – Y/N               |                                                                                                                                                                                                                                                                                                                                                                                                               | Y/N                           |                             |
| Deviation Number (if required)                       |                                                                                                                                                                                                                                                                                                                                                                                                               | N/A                           |                             |
| Comments:                                            |                                                                                                                                                                                                                                                                                                                                                                                                               |                               |                             |
| Signed (Operator)                                    | <i>Paul Hatcher</i>                                                                                                                                                                                                                                                                                                                                                                                           | Date                          | 28 NOV 2017                 |
| Reviewed (2 <sup>nd</sup> Party)                     | <i>Ebenezer</i>                                                                                                                                                                                                                                                                                                                                                                                               | Date                          | 14 DEC 2017                 |

|                                                   |                          |                                                                         |  |
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| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

### 12.3.2. PuTTY

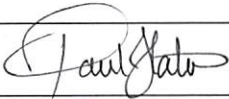
#### Objective/Rationale:

To confirm the installation of PuTTY functions correctly.

#### Acceptance Criteria:

| Description                                   | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Result Actual | Acceptance Criteria Met Y/N |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| PuTTY link via serial cable to Gold Brick QDa | <p>This test requires the gold brick ACQUITY QDa to be pumped down.</p> <p>Open PuTTY<br/>           Select connection type "Serial"<br/>           Select the Speed associated with the DCC PCB installed on the Gold Brick instrument. Either 9600 or 115200<br/>           Click Open<br/>           Into the "-&gt;" type rmm</p> <p>Confirm<br/>           *****<br/>           *<br/>           * RIO Main Menu<br/>           *<br/>           *****</p> <ol style="list-style-type: none"> <li>Shutdown RIO</li> <li>Set Menu Size</li> <li>Access subsystems</li> <li>Lock All subsystems</li> <li>Unlock All subsystems</li> <li>Start Memory-Mapped Page Poll</li> <li>Stop Memory-Mapped Page Poll</li> <li>Find Symbol</li> </ol> <p>999. EXIT</p> <p>Is displayed.</p> | confirmed     | Y                           |
|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |               | 28 NOV 2017                 |

|                                                                                                                      |                                              |                |
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|                                                                                                                      | Test Bays                                    |                |
| Document No: VAL001104                                                                                               | Project number EQAF 0018                     | Version No: 00 |

|                                        |                                                                                   |      |              |
|----------------------------------------|-----------------------------------------------------------------------------------|------|--------------|
| Were all acceptance criteria met – Y/N |                                                                                   | Y/N  |              |
| Deviation Number (if required)         |                                                                                   | N/A  |              |
| Comments:                              |                                                                                   |      |              |
|                                        |                                                                                   |      |              |
| Signed (Operator)                      |  | Date | 28 Nov 2017. |
| Reviewed (2 <sup>nd</sup> Party)       |  | Date | 14 Dec 2017  |

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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

### 12.3.3. MassLynx

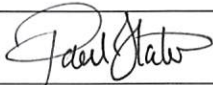
#### Objective/Rationale:

To confirm the installation of MassLynx functions correctly.

#### Acceptance Criteria:

| Description                      | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Result Actual | Acceptance Criteria Met Y/N |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| MassLynx Control Over Instrument | <p>This test requires the gold brick ACQUITY QDa to be pumped down.</p> <p>Open MassLynx 4.1</p> <p>Wait until MassLynx has fully booted, and says that the instrument is present.</p> <p>Open MS Console</p> <p>Wait until MS Console opens.</p> <ul style="list-style-type: none"> <li>• If the console is blank (no data from the QDa) , close MassLynx</li> <li>• run C:\Program Files (x86)\Waters Instruments\Bin\StopMassLynxProcesses</li> <li>• run C:\Program Files (x86)\Waters Instruments\Bin\StopAcquityProcesses</li> <li>• Open MassLynx 4.1</li> <li>• Wait until MassLynx has fully booted, and says that the instrument is present.</li> <li>• Open MS Console</li> <li>• Wait until MS Console opens.</li> </ul> <p>Open Trouble Shoot / Service Mode</p> <p>Enter the password 1147</p> <p>Open Trouble shoot / Show Tune page</p> <p>From the tune page, Select Acquires / Reinitialize.</p> <p>Select Lens Control</p> <p>Switch the machine into Operate</p> <p>Confirm the readbacks from the lens control are greater than zero, and the instrument API gas comes on.</p> <p>Place the instrument into standby.</p> | confirmed     | Y<br>PS 28 NOV 07           |

|                                                                                                                      |                          |                                                           |  |
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| <br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |  |
| Document No: VAL001104                                                                                               | Project number EQAF 0018 | Version No: 00                                            |  |

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|----------------------------------------|--|-----------------------------------------------------------------------------------|--|-------|-------------|
| Were all acceptance criteria met – Y/N |  |                                                                                   |  | (Y/N) |             |
| Deviation Number (if required)         |  |                                                                                   |  | N/A   |             |
| Comments:                              |  |                                                                                   |  |       |             |
|                                        |  |                                                                                   |  |       |             |
| Signed (Operator)                      |  |  |  | Date  | 28 Nov 2017 |
| Reviewed (2 <sup>nd</sup> Party)       |  |  |  | Date  | 14 DEC 2017 |

|                                                   |                                                           |                |
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| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

#### 12.3.4. Engineers Dashboard

##### Objective/Rationale:

To confirm the Engineers Dashboard functions correctly.

##### Acceptance Criteria:

| Description                                             | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Result Actual | Acceptance Criteria Met Y/N    |
|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------------|
| Engineer Dashboard link via LAN cable to Gold Brick QDa | <p>This test requires the gold brick ACQUITY QDa to be pumped down, and connected to a nitrogen supply.</p> <p>Open MassLynx 4.1</p> <p>Wait until MassLynx has fully booted, and says that the instrument is present.</p> <p>Open Engineer Dashboard</p> <p>Wait until Start Engineer Dashboard pop-up appears.</p> <p>Select Connect to instrument, and click OK</p> <p>Select Historic Readbacks.</p> <p>Select Data</p> <p>Select PRESSURE_SENSOR_RB and add it to the items that will be recorded.</p> <p>Click OK</p> <p>Click the record button.</p> <p>Confirm the chart plotted by Dashboard is not a flat line but varying with random values all less than 10mBar.</p> <p>Open the source enclosure door on the front of the QDa, and then close it.</p> <p>Confirm the chart plotted stays low for about 2 minutes, but then records a spike &gt;50mBar. (confirms Dashboard functionality and Test Bay source exhaust system)</p> <p>Close Engineers Dashboard.</p> | Confirmed.    | <p>Y</p> <p>BS 28 NOV 2017</p> |

|           |              |                                        |                  |
|-----------|--------------|----------------------------------------|------------------|
|           |              | Were all acceptance criteria met – Y/N |                  |
|           |              | Deviation Number (if required)         | N/A              |
| Comments: |              |                                        |                  |
|           |              | Signed (Operator)                      | <i>Paul Math</i> |
|           |              | Reviewed (2 <sup>nd</sup> Party)       | <i>Shenland</i>  |
| Date      | 28 Nov 2017. | Date                                   | 14 Dec 2017      |

|                                                    |                                                                  |                       |
|----------------------------------------------------|------------------------------------------------------------------|-----------------------|
| <p>Document No: VAL001104</p>                      | <p>Project number EQAF 0018</p>                                  | <p>Version No: 00</p> |
| <p>Waters<br/>THE SCIENCE OF WHAT'S POSSIBLE.®</p> | <p>EQ Protocol – Venture Acuity Qda Test Floor<br/>Test Bays</p> |                       |

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| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

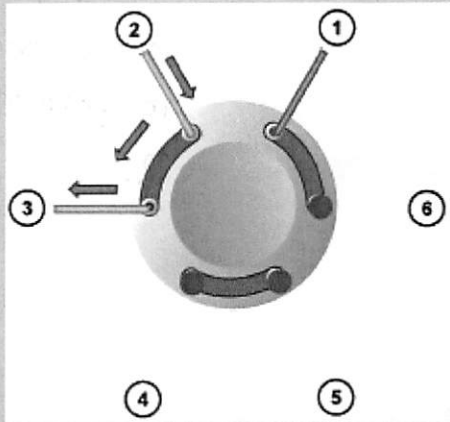
#### 12.4. EQ015 – Operational Checks of the Divert Valve

##### Objective/Rationale:

To confirm the Divert Valve is installed correctly and operates correctly.

##### Acceptance Criteria:

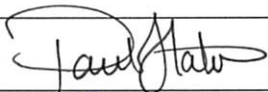
| Description                                          | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                  | Result Actual                                                                                     | Acceptance Criteria Met Y/N           |
|------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---------------------------------------|
| Default position of the Divert Valve                 | <p>This test requires the gold brick ACQUITY QDa to be pumped down, and connected to a nitrogen supply.</p> <p>Power up the Divert valve, with the Divert control cable (441001851) not connected to the QDa.</p> <p>Confirm the Valve Position displayed is "1"</p>                                                                                                                                                             | <p>Default Value = 2 not 1.</p> <p>error in document.</p>                                         | <p>Y</p> <p>PS</p> <p>28 NOV 2017</p> |
| Installation of the Peek Tubing to the Divert Valve. | <p>Confirm the peek tubing is connected between the 515 pump and the Divert Valve. The peek tube must be fitted to port 2.</p> <p>Confirm the peek tubing is connected between the Divert valve and the sample Duran bottle. The peek tube must be fitted to port 3.</p> <p>Confirm there is a peek tube connected to port 1 on the divert valve. This is the tube that will be connected to the QDa later in this protocol.</p> | <p>fitted to port 1</p> <p>fitted to port 2</p> <p>fitted to port 6</p> <p>error in document.</p> | <p>Y</p> <p>PS</p> <p>28 NOV 2017</p> |

| Description                                                                                                 | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Result Actual                                                       | Acceptance Criteria Met Y/N            |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
|-------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|----------------------------------------|----------|-------------|-----|---|-------------|-------|---|----------|-------|---|----------|-------|---|----------|-------|---|-------------------------------|---------------------------------------|
| <p>The Divert Valve delivers sample back to the sample Duran bottle when AMITS does not require sample.</p> | <p>Run the 515 pump to run mode, and deliver 350ul/min methanol to the divert valve</p>  <p>Valve Position "1".</p> <p>Confirm while is position "1" the sample diverted back to the supply bottle, and no sample sent through the pipe connected to port 1.</p>                                                                                                                                                                                                                                                                               | <p>While in position 2 sample is diverted back to supply bottle</p> | <p>Y</p> <p>PS</p> <p>28 NOV 2017.</p> |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
| <p>Divert Valve control cable is attached to the ACQUITY QDa.</p>                                           | <p>Connect the divert valve control cable to the gold brick. ACQUITY QDa</p> <p>Confirm that the wires from the control cable are connected to the correct ports on the ACQUITY QDa.</p> <table border="1"><thead><tr><th>Signal</th><th>Colour</th><th>Port No.</th></tr></thead><tbody><tr><td>Stop Flow +</td><td>Red</td><td>1</td></tr><tr><td>Stop Flow -</td><td>Black</td><td>2</td></tr><tr><td>Switch +</td><td>White</td><td>3</td></tr><tr><td>Switch -</td><td>Black</td><td>4</td></tr><tr><td>Analog -</td><td>Black</td><td>9</td></tr></tbody></table> <p>Confirm the Divert Valve remains in position "1"</p> | Signal                                                              | Colour                                 | Port No. | Stop Flow + | Red | 1 | Stop Flow - | Black | 2 | Switch + | White | 3 | Switch - | Black | 4 | Analog - | Black | 9 | <p>Remains in position 2.</p> | <p>Y</p> <p>PS</p> <p>28 NOV 2017</p> |
| Signal                                                                                                      | Colour                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Port No.                                                            |                                        |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
| Stop Flow +                                                                                                 | Red                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1                                                                   |                                        |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
| Stop Flow -                                                                                                 | Black                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2                                                                   |                                        |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
| Switch +                                                                                                    | White                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 3                                                                   |                                        |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
| Switch -                                                                                                    | Black                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 4                                                                   |                                        |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |
| Analog -                                                                                                    | Black                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 9                                                                   |                                        |          |             |     |   |             |       |   |          |       |   |          |       |   |          |       |   |                               |                                       |

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| Description                                                         | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Result Actual                                                                                                                          | Acceptance Criteria Met Y/N                   |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <p>The divert valve can be controlled by the test bay software.</p> | <p>This test requires the gold brick ACQUITY QDa to be pumped down.</p> <p>Open PuTTY<br/>           Select connection type "Serial"<br/>           Select the Speed associated with the DCC PCB installed on the Gold Brick instrument. Either 9600 or 115200<br/>           Click Open<br/>           Into the "-&gt;" type rmm</p> <p>This will display:<br/>           *****<br/>           *<br/>           * RIO Main Menu<br/>           *<br/>           *****</p> <ol style="list-style-type: none"> <li>Shutdown RIO</li> <li>Set Menu Size</li> <li>Access subsystems</li> <li>Lock All subsystems</li> <li>Unlock All subsystems</li> <li>Start Memory-Mapped Page Poll</li> <li>Stop Memory-Mapped Page Poll</li> <li>Find Symbol</li> </ol> <p>999. EXIT</p> <p>If the instrument is correctly connected.</p> <p>Type in :<br/>           3 &lt;enter&gt;<br/>           1&lt;enter&gt;<br/>           1&lt;enter&gt;<br/>           406&lt;enter&gt;</p> <p>Confirm the Divert Valve moves from position "1" to position "2".<br/>           Confirm liquid starts to come out of the tube connected to port 1 on the Divert Valve.</p> | <p>Confirm, '406'<br/>           moves divert valve<br/>           to position "1" not<br/>           2.</p> <p>error in document.</p> | <p>Y</p> <p>PS<br/>           28 NOV 2017</p> |

|                                                                                                                      |                          |                                                           |  |
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| Document No: VAL001104                                                                                               | Project number EQAF 0018 | Version No: 00                                            |  |

| Description                                                                                                                                      | Result Expected                                                                                                                                                                                                                                         | Result Actual                                                       | Acceptance Criteria Met Y/N |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------|
| Reset the system back to recycle mode.                                                                                                           | In PuTTY, type in<br>405<enter><br><br>Confirm the Divert Valve is restored to position 1, and the liquid is being recycled back into the Duran bottle.<br><br>In PuTTY, type in<br>999<enter><br>999<enter><br>999<enter><br>To exit from rioMainMenu. | confirmed.<br><br>405 returns divert valve from position "1" to "2" | Y<br><br>PS<br>28 NOV 2017  |
| Were all acceptance criteria met – Y/N <div style="text-align: right;">(Y)N</div>                                                                |                                                                                                                                                                                                                                                         |                                                                     |                             |
| Deviation Number (if required)                                                                                                                   |                                                                                                                                                                                                                                                         | 2                                                                   |                             |
| Comments: <p>Conversion required. logic reversed as divert valve is default position "2" not "1".</p> <p>This is the same for all test bays.</p> |                                                                                                                                                                                                                                                         |                                                                     |                             |
| Signed (Operator)                                                                                                                                |                                                                                                                                                                      | Date                                                                | PS 28 NOV 2017.             |
| Reviewed (2 <sup>nd</sup> Party)                                                                                                                 |                                                                                                                                                                      | Date                                                                | 14 DEC 2017                 |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

**12.5. EQ016 – Operational Checks of the Test Bay System, including the Gold Brick ACQUITY QDa**

**Objective/Rationale:**

To confirm the test bay system will test an ACQUITY QDa.

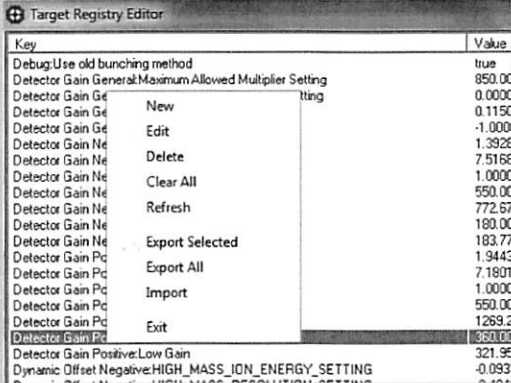
**Acceptance Criteria:**

| Description             | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Result Actual | Acceptance<br>Criteria Met<br>Y/N |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------|
| Mass Lynx Configuration | <p>This test requires the gold brick ACQUITY QDa to be pumped down.</p> <p>Open MassLynx 4.1<br/>Wait until MassLynx has fully booted, and says that the instrument is present.<br/>Open MS Console<br/>Wait until MS Console opens.</p> <ul style="list-style-type: none"> <li>• If the console is blank (no data from the QDa) , close MassLynx</li> <li>• run C:\Program Files (x86)\Waters Instruments\Bin\StopMassLynxProcesses</li> <li>• run C:\Program Files (x86)\Waters Instruments\Bin\StopAcquityProcesses</li> <li>• Open MassLynx 4.1</li> <li>• Wait until MassLynx has fully booted, and says that the instrument is present.</li> <li>• Open MS Console</li> <li>• Wait until MS Console opens.</li> </ul> <p>Open Trouble Shoot / Service Mode<br/>Enter the password 1147<br/>Open Configure / Health Monitor Configuration</p> <p>-go to next row in this table-</p> |               |                                   |

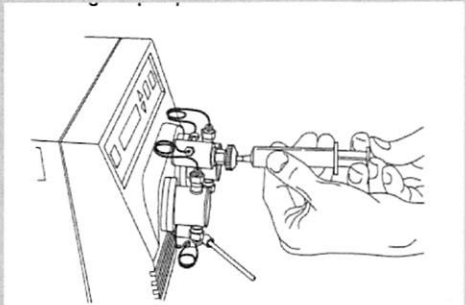
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
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| Description                            | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Result Actual | Acceptance<br>Criteria Met<br>Y/N |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------|
| Mass Lynx Configuration<br>(Continued) | Edit the configuration so only the following options are NOT checked with a tick:<br><i>Internal Calibrant Beam Check Failed.</i><br><i>Alternative Calibrant Beam Check Failed.</i><br><i>Resolution Setup Failed</i><br><i>Resolution Setup Required</i><br><i>Resolution Expired</i><br><i>Recalibration Failed</i><br><i>Recalibration Required</i><br><i>Calibration Expired</i><br><i>Service Due</i><br><i>Stop Flow</i><br><br>Confirm the configuration has been set as above. | confirmed     | Y<br><br>PS<br>28 NOV 2017        |
| Close MassLynx                         | Shut down MassLynx.<br>Shut down MS Console.<br><br>Then use<br>C:\Program Files (x86)\Waters Instruments\Bin\<br>StopMassLynxProcesses.<br><br>Confirm that MassLynx and MS Console are no longer present on the screen.                                                                                                                                                                                                                                                               | confirmed     | Y<br><br>PS<br>28 NOV 2017        |

|                                                   |                                                           |                |
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| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

| Description                                                                       | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Result Actual                                                                                                                                                                                                                                                                                                      | Acceptance Criteria Met Y/N            |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| <p>Restore ACQUITY QDa Target Registry to a previously working configuration.</p> | <p>This test requires that the target registry associated with the Gold Brick instrument when it was last working is available.</p> <p>Save the Gold Brick Target Registry onto the Test Bay desktop.</p> <p>Open Target Registry:<br/>(C:\MassLynx\Kestrel\TargetRegistryEditor.exe)</p> <p>Enter the authorisation code 1147</p> <p>This will display the current target registry settings for the instrument.</p> <p>Right mouse click the table, and select Import.</p>  <p>Select the target registry file that was saved on the host PC desktop.</p> <p>Close the target Registry.</p> <p>Confirm the target registry update has been completed</p> | <p><u>POS MODE</u></p> <p>HM POS -1.268</p> <p>HM Setup -8.39 327</p> <p>Linearity 109.52</p> <p>LM POS 0.796</p> <p>LM Setup 0.325508</p> <p>LM ION IE -0.80</p> <p>HM ION IC 0.11</p> <p><u>NEG. MODE</u></p> <p>USER LM RES 0.06</p> <p>USER HM RES. 0.00</p> <p>LM ION ENERGY -0.39</p> <p>LM ION ENERGY 0</p> | <p>Y</p> <p>PS</p> <p>28 Nov 2017.</p> |

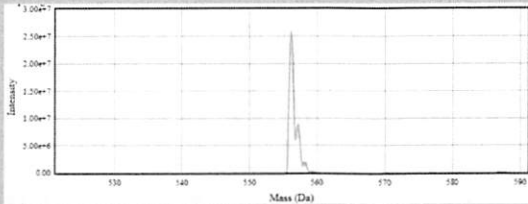
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

| Description                                          | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Result Actual                       | Acceptance Criteria Met Y/N  |
|------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------|
| <p>Prepare the 515 pump with QDa Setup Solution.</p> | <p>Stop the 515 flow</p> <p>Change the Methanol Duran Bottle, for a bottle of QDa Setup Solution. The solution does NOT need to be validated, or in date to prove the test bay system functions correctly.</p> <p>Fully depress the priming syringe plunger to remove all air from the syringe, then insert the syringe into the luer fitting at the centre of the draw-off valve handle.</p>  <p>Turn the draw-off valve handle anti-clockwise about ½ turn to open the valve</p> <p>Withdraw several mls of eluent with the syringe, then close the valve handle. Expel the contents of the syringe into a suitable waste container.</p> <p>Take the “recycle” peek tube from the sample Duran bottle, and leave it in a suitable waste container</p> <p>Press the Run/Stop key to start the pump at 350ul/min.</p> <p>Let the pump run for about 5 minutes to allow the pump pressure to settle, and to expel any remaining methanol from the system.</p> <p>Take the “recycle” peek tube from the waste container, and refit it to the sample Duran bottle.</p> <p>Confirm the sample is running at 350ul/min, and the pressure read back on the 515 pump is the same +/- 10% over 1 minute.</p> <p>Confirm the sample is being recycled into the sample Duran Bottle.</p> | <p>confirmed.</p> <p>confirmed.</p> | <p>PS</p> <p>28 Nov 2017</p> |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

| Description                                       | Result Expected                                                                                                                                                                                                                                                                                                                                                                                        | Result Actual | Acceptance<br>Criteria Met<br>Y/N |
|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------|
| Run AMITS Peak Shape Test Sequence on ACQUITY QDa | Open AMITS.<br><br>Open Test Run Details.<br><br>From the product type list, select "Acquity_QDa_Setup_Solution".<br><br>Enter the following details:<br><br>Serial Number: Test Bay Number<br>Sample Batch Number: YYMMDD-00**<br>Sample Use By Date: N/A<br>Test Box Number: Divert Valve serial number<br>Test Rig Number: Gold Brick QDa Serial Number<br>Procedure Document Number: this document |               |                                   |
|                                                   | Open the Dashboard<br><br>Click the "Start here" button.<br><br>Follow the on-screen instructions to start a test run. Use your AMITS account.<br><br>Follow the on-screen prompts and allow the test sequence to complete.                                                                                                                                                                            |               |                                   |
|                                                   | Confirm the Divert valve position changed from "1" to "2" during the test sequence, and back to "1" once the test sequence had stopped. (Confirms the systems automated control over the Divert Valve)                                                                                                                                                                                                 | "2" to "1"    | Y                                 |
|                                                   | Confirm more than one test within the sequence has been run. (Confirms Network connection to storage system)                                                                                                                                                                                                                                                                                           | confirmed.    | Y                                 |
|                                                   | Confirm whether the test sequence completed, and a pop up was displayed referring to saving the data on SigmaQuest was displayed.<br><br>If the test sequence stopped due to a failure, restart the test sequence from the first test, and confirm a pop up was displayed referring to saving the data on SigmaQuest was displayed.                                                                    | confirmed.    | Y                                 |

|                                                   |                                                           |                |
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

| Description                                                                        | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Result Actual | Acceptance Criteria Met Y/N |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| Run AMITS Peak Shape Test Sequence on ACQUITY QDa (continued)                      | <p>Confirm the Positive Pump Stability Test passed. (confirms the 515 pump is suitable for purpose)</p> <p>If the stability test failed, log what actions were required to correct the issue.</p> <p>Open the LOG for the Positive Pump Stability Test.</p> <p>Confirm there was a 556Da peak with partially resolved isotopes, similar to the image below.</p>                                                                                                                   | confirmed.    | Y.                          |
| Run a Sigmaprobe download from the Storage Solution, as described within VAL001105 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |               |                             |
| Run AMITS Peak Shape Test Sequence on ACQUITY QDa (continued)                      | Using a PC with access to SigmaSure, confirm the Sigma Data from this test bay has been accepted within the SigmaSure database, and correctly associated with the PC name entered into the Admin page, as instructed in section 12.3.1                                                                                                                                                                                                                                                                                                                              | confirmed     | Y                           |
| Save Target Registry on FTP site.                                                  | <p>Open the target registry and refresh. Export All to the test bay PC desktop, and name the treg file as:</p> <p>Test_Bay_*** - where *** is the test bay number.</p> <p>Open a File Explorer window, and enter the following location:</p> <p><u>FTP://164.39.5.34</u></p> <p>A pop up window will request a USERNAME. Use WAT-PAE.</p> <p>The pop up will also request a password. Use registry2014</p> <p>Save a copy of the final beam pre health check TREG file within this FTP site..</p> <p>Confirm the file was successfully saved onto the FTP site.</p> | confirmed     | Y                           |

|                                                                                                                      |                          |                                                           |  |
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| <br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |  |
| Document No: VAL001104                                                                                               | Project number EQAF 0018 | Version No: 00                                            |  |

| Description                                                                   | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Result Actual | Acceptance Criteria Met Y/N |
|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------|
| Save PDF record on Storage Solution.                                          | <p>In AMITS, open the SUMMARY for the Peak Shape Test Sequence that was run.</p> <p>Use the AMITS tool to print the summary onto Chrome.</p> <p>Use Chrome to save the printout as a PDF file onto the host pc desktop.</p> <p>Use Windows Explorer to copy the PDF file onto the storage solution folder:<br/>           \\***\PROJECT FOLDERS\Project Folders - Instruments\QDa\17Q4</p> <p>Where *** is the network name of the storage solution</p> <p>Confirm the file was successfully saved on the storage solution.</p> | confirmed,    | y                           |
| Were all acceptance criteria met – Y/N <span style="float: right;">Y/N</span> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |               |                             |
| Deviation Number (if required)                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 2,            |                             |
| Comments: Reference to direct valve default position. See Deviation # 2.      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |               |                             |
| Signed (Operator)                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                              | Date          | 29 Nov 2017                 |
| Reviewed (2 <sup>nd</sup> Party)                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Date          |                             |

|                                                                  |                                                                   |                |
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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/>Test Bays</b> |                |
| Document No: VAL001104                                           | Project number EQAF 0018                                          | Version No: 00 |

## 12.6. EQ017 – Shutdown of Test System

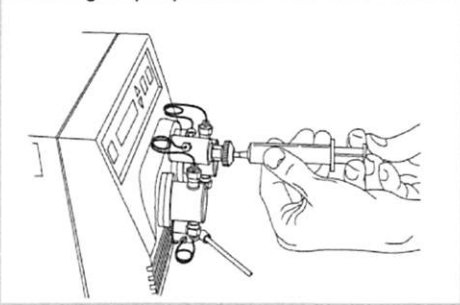
### Objective/Rationale:

To shut down the test bay system, so the Gold Brick QDa can be moved onto the next test bay.

### Acceptance Criteria:

| Description                             | Result Expected                                                          | Result Actual | Acceptance<br>Criteria Met<br>Y/N |
|-----------------------------------------|--------------------------------------------------------------------------|---------------|-----------------------------------|
| Shut down the Gold Brick<br>ACQUITY QDa | Power off the ACQUITY QDa.<br><br>Confirm the action has been completed. | confirmed     | Y.                                |

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

| Description                           | Result Expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Result Actual                        | Acceptance<br>Criteria Met<br>Y/N |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----------------------------------|
| Prepare the 515 pump with<br>Methanol | Stop the 515 flow<br>Change the QDa Setup Solution Duran Bottle, for a bottle of Methanol.<br>Fully depress the priming syringe plunger to remove all air from the syringe, then insert the syringe into the luer fitting at the centre of the draw-off valve handle.                                                                                                                                                                                                                                                                                                                                                                                   |                                      |                                   |
|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      |                                   |
|                                       | Turn the draw-off valve handle anti-clockwise about ½ turn to open the valve<br>Withdraw several mls of eluent with the syringe, then close the valve handle. Expel the contents of the syringe into a suitable waste container.<br>Take the “recycle” peek tube from the Methanol Duran bottle, and leave it in a suitable waste container<br>Press the Run/Stop key to start the pump at 350ul/min.<br>Let the pump run for about 5 minutes to allow the pump pressure to settle, and to expel any remaining QDa Setup Solution from the system.<br>Take the “recycle” peek tube from the waste container, and refit it to the Methanol Duran bottle. |                                      |                                   |
|                                       | Confirm the sample is running at 350ul/min, and the pressure read back on the 515 pump is the same +/- 10% over 1 minute.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | confirmed.                           | Y                                 |
|                                       | Confirm the sample is being recycled into the sample Duran Bottle.<br>Switch Off the 515 pump.<br>Confirm the 515 pump has been powered off.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | confirmed<br>confirmed<br>confirmed. | Y<br>Y<br>Y                       |

|                                                                  |                          |                                                                         |  |
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| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.®</small> |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                                           | Project number EQAF 0018 | Version No: 00                                                          |  |

| Description                                                                                                              | Result Expected                                                                    | Result Actual | Acceptance Criteria Met Y/N |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------|-----------------------------|
| Were all acceptance criteria met – Y/N                                                                                   |                                                                                    | <u>Y</u> /N   |                             |
| Deviation Number (if required)                                                                                           |                                                                                    | 2 and 3.      |                             |
| Comments: See Deviation 2 regarding documentation error<br>See Deviation 3 regarding GES_Venture user account amendment. |                                                                                    |               |                             |
| Signed (Operator)                                                                                                        |   | Date          | 29 Nov 2017                 |
| Reviewed (2 <sup>nd</sup> Party)                                                                                         |  | Date          | 14 DEC 2017                 |

|                                                   |                                                           |                |
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® | EQ Protocol – Venture ACQUITY QDa Test Floor<br>Test Bays |                |
| Document No: VAL001104                            | 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 test bay will be maintained using:

48550 – QDa Sub-contractor PM Procedure

48552 – QDa Sub-contractor PM Test Record.

|                                  |                   |      |             |
|----------------------------------|-------------------|------|-------------|
| Signed (Operator)                | <i>Paul Mator</i> | Date | 13 DEC 2017 |
| Reviewed (2 <sup>nd</sup> Party) | <i>Heenan</i>     | Date | 14 DEC 2017 |

#### 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: | 46202       |
| SOP Title                        | 46202 – TSP ACQUITY QDa AMITS TEST PROCEDURE. |             |             |
| Signed (Operator)                | <i>Paul Mator</i>                             | Date        | 13 DEC 2017 |
| Reviewed (2 <sup>nd</sup> Party) | <i>Heenan</i>                                 | Date        | 14 DEC 2017 |

|                                                   |                          |                                                                         |  |
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

#### 14. DEVIATIONS

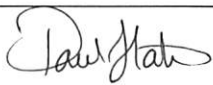
This section details any deviations raised during execution of this protocol. For deviation guidance, refer to the Equipment Qualification procedure – 730003703.

##### 14.1. Deviation Summary

| Deviation No.                                                                                                                                                                                                                                                                                                                                                                                                                                       | EQ Test No. | Details                                     | Closed (Yes/No) | Operator Initial & Date |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------------------------------------|-----------------|-------------------------|
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                   | EQ-013      | 515 pump failed 5ml/min test.               | Yes.            | PS 13 DEC 2017          |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                   | EQ-015      | Documentation error regarding divert valve. | Yes             | PS 13 DEC 2017          |
| 3                                                                                                                                                                                                                                                                                                                                                                                                                                                   | EQ-016      | GES_Venture user account required amending. | Yes             | PS 13 DEC 2017          |
| <div style="position: relative; height: 100px;"> <div style="position: absolute; top: 0; left: 0; width: 100%; height: 100%; border: 1px solid black; transform: rotate(-45deg); transform-origin: top left;"></div> <div style="position: absolute; top: 0; left: 0; width: 100%; height: 100%; pointer-events: none;"> <div style="position: absolute; top: 0; left: 0; width: 100%; height: 100%; border: 1px solid black;"></div> </div> </div> |             |                                             |                 |                         |
| Comments:                                                                                                                                                                                                                                                                                                                                                                                                                                           |             |                                             |                 |                         |
| Signed (Operator)                                                                                                                                                                                                                                                                                                                                                                                                                                   |             | <i>Paul Hato</i>                            | Date            | 13 DEC 2017             |
| Reviewed (2 <sup>nd</sup> Party)                                                                                                                                                                                                                                                                                                                                                                                                                    |             | <i>Heunlan</i>                              | Date            | 14 DEC 2017             |

|                                                   |                          |                                                                         |  |
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| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

#### 14.2. Validation Deviation Form\*

|                                                                                                                             |                                                                                     |                    |                |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------|----------------|
| <b>Deviation No.</b>                                                                                                        | 1                                                                                   | <b>EQ Test No.</b> | EQ 013, 12.2.2 |
| <b>Deviation Details</b><br>515 pump failed 5.00ml/min flow test.<br>It passed 0.5ml/min flow test and 1.0ml/min flow test. |                                                                                     |                    |                |
| <b>Corrective Actions</b><br>None. The desired flowrate is 0.35ml/min.                                                      |                                                                                     |                    |                |
| <b>Outcome</b><br>No change required. The failure will not affect the system.                                               |                                                                                     |                    |                |
| <b>Deviation Closed (Yes/No)</b>                                                                                            | Yes                                                                                 | <b>Date</b>        | 13 Dec 2017    |
| <b>Signed (Operator)</b>                                                                                                    |  | <b>Date</b>        | 13 Dec 2017    |
| <b>Approved (Quality Assurance)</b>                                                                                         |  | <b>Date</b>        | 20 Dec 17      |

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

|                                                   |                                                           |                |
|---------------------------------------------------|-----------------------------------------------------------|----------------|
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| Document No: VAL001104                            | Project number EQAF 0018                                  | Version No: 00 |

## 15. ATTACHMENTS

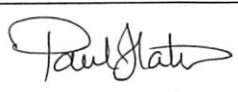
List all appended attachments to this protocol in the table below.

| Attachment No. | EQ Test No.                | Details                                                                                                    | No. of pages | Operator Initials |
|----------------|----------------------------|------------------------------------------------------------------------------------------------------------|--------------|-------------------|
| 1              | EQ-007<br>EQ-006<br>EQ-009 | Photographs of test bay and exhaust system                                                                 | 3            | PS                |
| 2              | EQ-014                     | screenshot link to AMITS network.                                                                          | 1            | PS                |
| 3              | EQ-014                     | screenshot from AMITS link to storage PC – user list                                                       | 1            | PS                |
| 4              | EQ-014                     | screenshot from AMITS link to storage PC-data                                                              | 1            | PS                |
| 5              | EQ-014                     | screenshot from AMITS simulator run                                                                        | 1            | PS                |
| 6              | EQ-014                     | screenshot from Putty                                                                                      | 1            | PS                |
| 7              | EQ-014                     | screenshot from Masslynx tune page                                                                         | 1            | PS                |
| 8              | EQ-014                     | screenshot from Dash Board                                                                                 | 1            | PS                |
| 9              | EQ-016                     | screenshot of AMITS failure caused by User Account setting                                                 | 1            | PS                |
| 10             | DEVIATION<br>3             | screenshots of User Account setting correction required to allow GES_Venture account to function correctly | 1            | PS                |
| 11             | EQ-016                     | screenshots of pump stability peak shape                                                                   | 1            | PS                |
| 12             | EQ-016                     | Test data automatically accepted by signature                                                              | 1            | PS                |
| 13             | EQ-016                     | FTP site accessible using GES_Venture account                                                              | 1            | PS                |
|                | EOD PS 13 Dec 2017         |                                                                                                            |              |                   |
|                |                            |                                                                                                            |              |                   |
|                |                            |                                                                                                            |              |                   |



|                                                   |                          |                                                                         |  |
|---------------------------------------------------|--------------------------|-------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

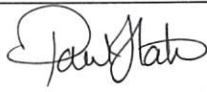
**14.2. Validation Deviation Form\***

|                                     |                                                                                                                                                                                                        |                    |             |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------|
| <b>Deviation No.</b>                | 2                                                                                                                                                                                                      | <b>EQ Test No.</b> | EQ 015      |
| <b>Deviation Details</b>            | <p>Default position of divert valve was "2" not "1".</p> <p>This meant there were a lot of errors in the documentation, and the divert valve had to be plumbed differently to perform as expected.</p> |                    |             |
| <b>Corrective Actions</b>           | <p>Peek tube between S15 pump and divert valve = port 1</p> <p>Peek tube between Divert valve and sample duran = port 2</p> <p>Peek tube between divert valve and QDa = port 6</p>                     |                    |             |
| <b>Outcome</b>                      | <p>By performing the above change, the divert valve performed correctly.</p>                                                                                                                           |                    |             |
| <b>Deviation Closed (Yes/No)</b>    | Yes                                                                                                                                                                                                    | <b>Date</b>        | 13 Dec 2017 |
| <b>Signed (Operator)</b>            |                                                                                                                     | <b>Date</b>        | 13 DEC 2017 |
| <b>Approved (Quality Assurance)</b> |                                                                                                                     | <b>Date</b>        | 20 Dec 17   |

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

|                                                   |                          |                                                                         |  |
|---------------------------------------------------|--------------------------|-------------------------------------------------------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.® |                          | <b>EQ Protocol – Venture ACQUITY QDa Test Floor</b><br><b>Test Bays</b> |  |
| Document No: VAL001104                            | Project number EQAF 0018 | Version No: 00                                                          |  |

**14.2. Validation Deviation Form\***

|                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                     |                    |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------|--------------|
| <b>Deviation No.</b>                                                                                                                                                                                                                                                                                                                                                                                                                           | 3                                                                                   | <b>EQ Test No.</b> | EQ 016       |
| <b>Deviation Details</b><br><p>GES-Venture account created for the host pc system did not have the correct rights to allow AMTS to function fully.</p> <p>The failure was caused by the User Account Control notification setting. When changed to "Never Notify", the software worked correctly.</p> <p>The AMTS software before this point used accounts with full administrative rights, which allowed users to see the Waters network.</p> |                                                                                     |                    |              |
| <b>Corrective Actions</b><br><p>UAC reset to "Never Notify"</p>                                                                                                                                                                                                                                                                                                                                                                                |                                                                                     |                    |              |
| <b>Outcome</b><br><p>AMTS functioned correctly.</p>                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                     |                    |              |
| <b>Deviation Closed (Yes/No)</b>                                                                                                                                                                                                                                                                                                                                                                                                               | Yes                                                                                 | <b>Date</b>        | 13 DEC 2017  |
| <b>Signed (Operator)</b>                                                                                                                                                                                                                                                                                                                                                                                                                       |  | <b>Date</b>        | 13 DEC 2017. |
| <b>Approved (Quality Assurance)</b>                                                                                                                                                                                                                                                                                                                                                                                                            |  | <b>Date</b>        | 20 Dec 17    |

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

VAL001104 - Waters-S4BK7626

Attachment No: 1 , EQ007, EQ008, EQ009, 25 13 Dec 2017

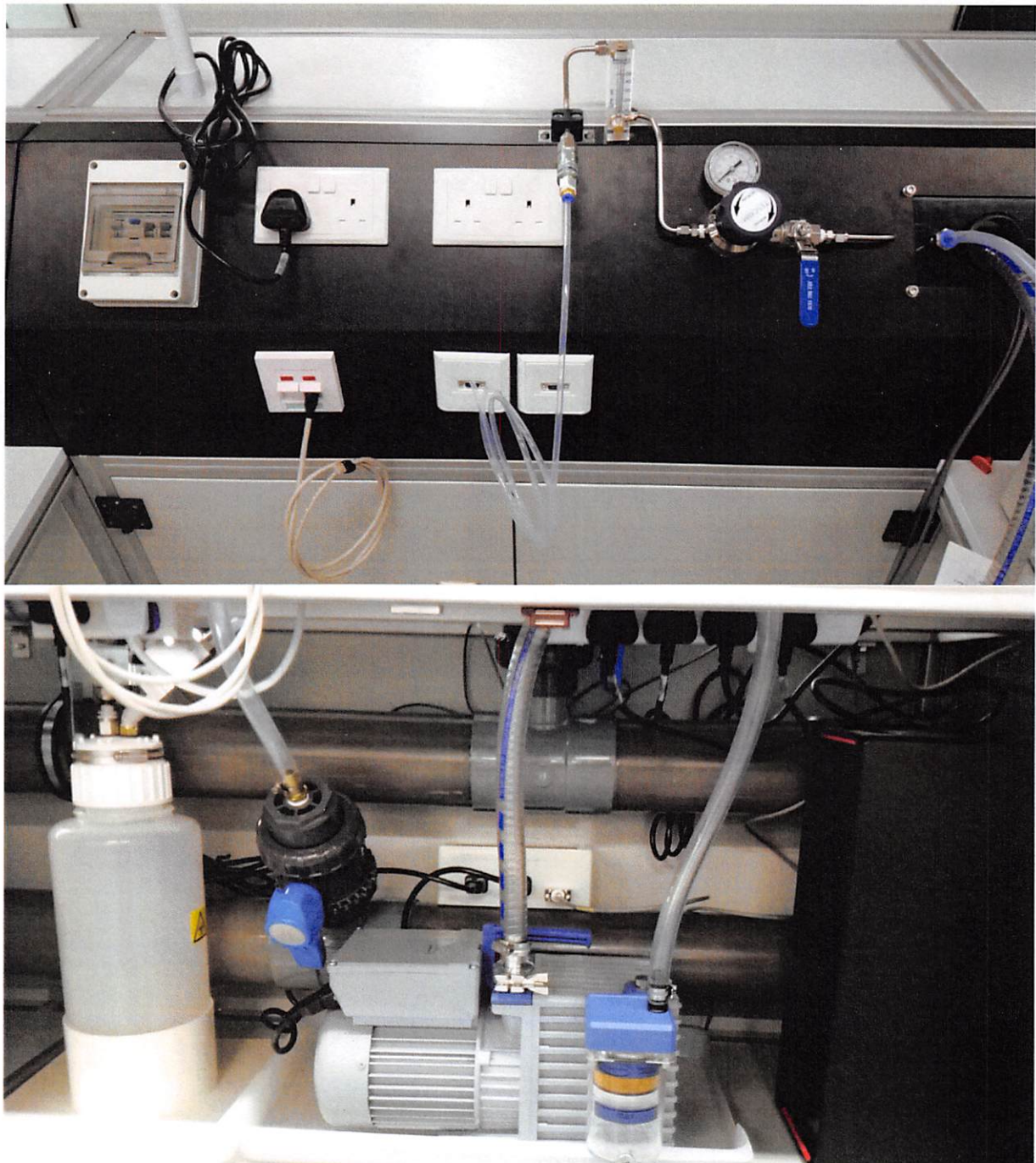
Page 1 of 3



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Attachment No: 1 , EQ007, EQ008, EQ009, PS 13 DEC 2017

Page 2 of 3



Attachment No: 1 , EQ007, EQ008, EQ009, 25 13 DEC 20 17

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Drainage taps  
have been fitted,  
but after this  
photo was  
taken.



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Attachment No: 2 , EQ014 ES 13 Dec 2017

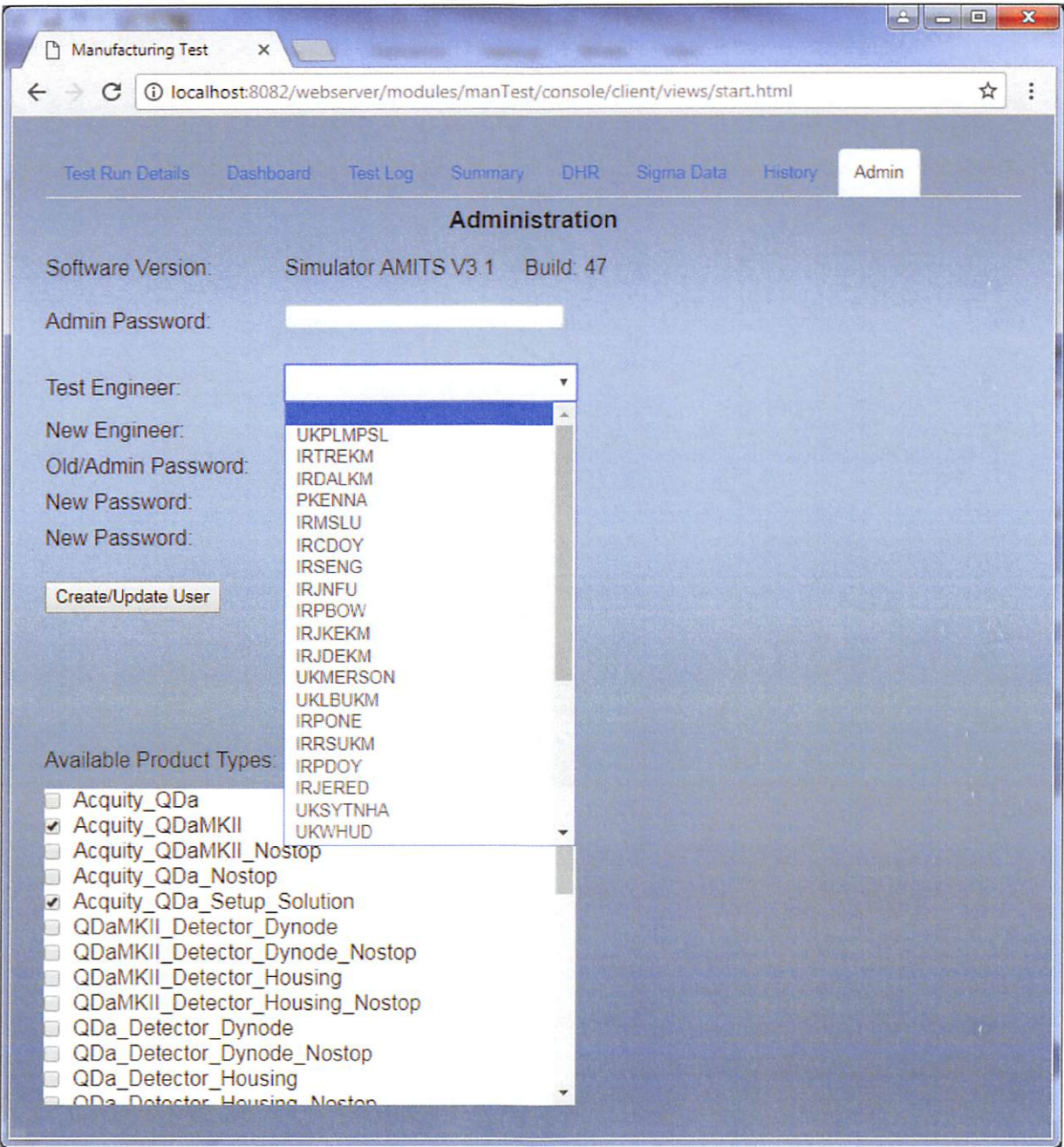
Page 1 of 1

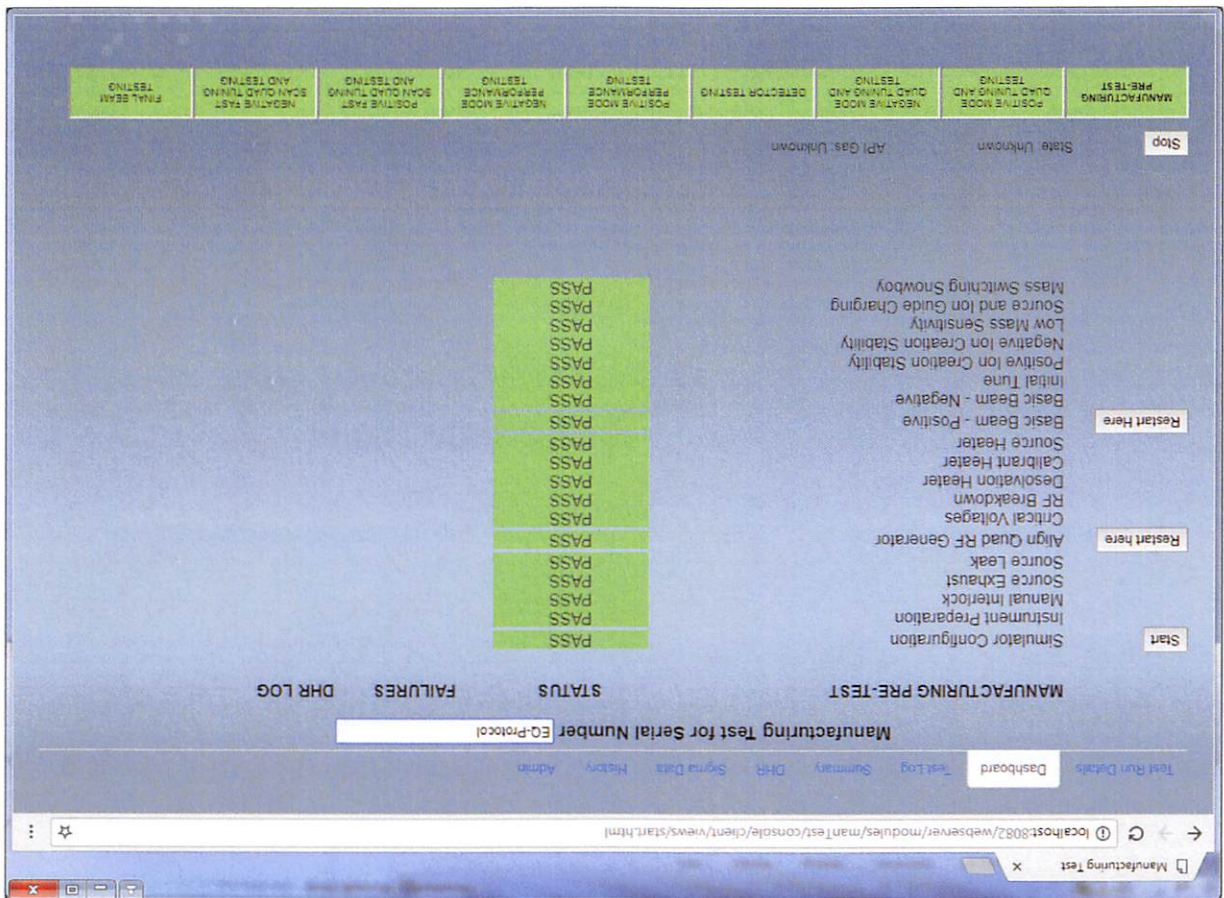
The screenshot shows a web browser window titled "Manufacturing Test" with the address bar displaying "localhost:8082/webserver/modules/manTest/console/client/views/start.html". The interface has a navigation bar with links: "Test Run Details", "Dashboard", "Test Log", "Summary", "DHR", "Sigma Data", "History", and "Admin" (which is highlighted). Below the navigation bar is a section titled "Administration".

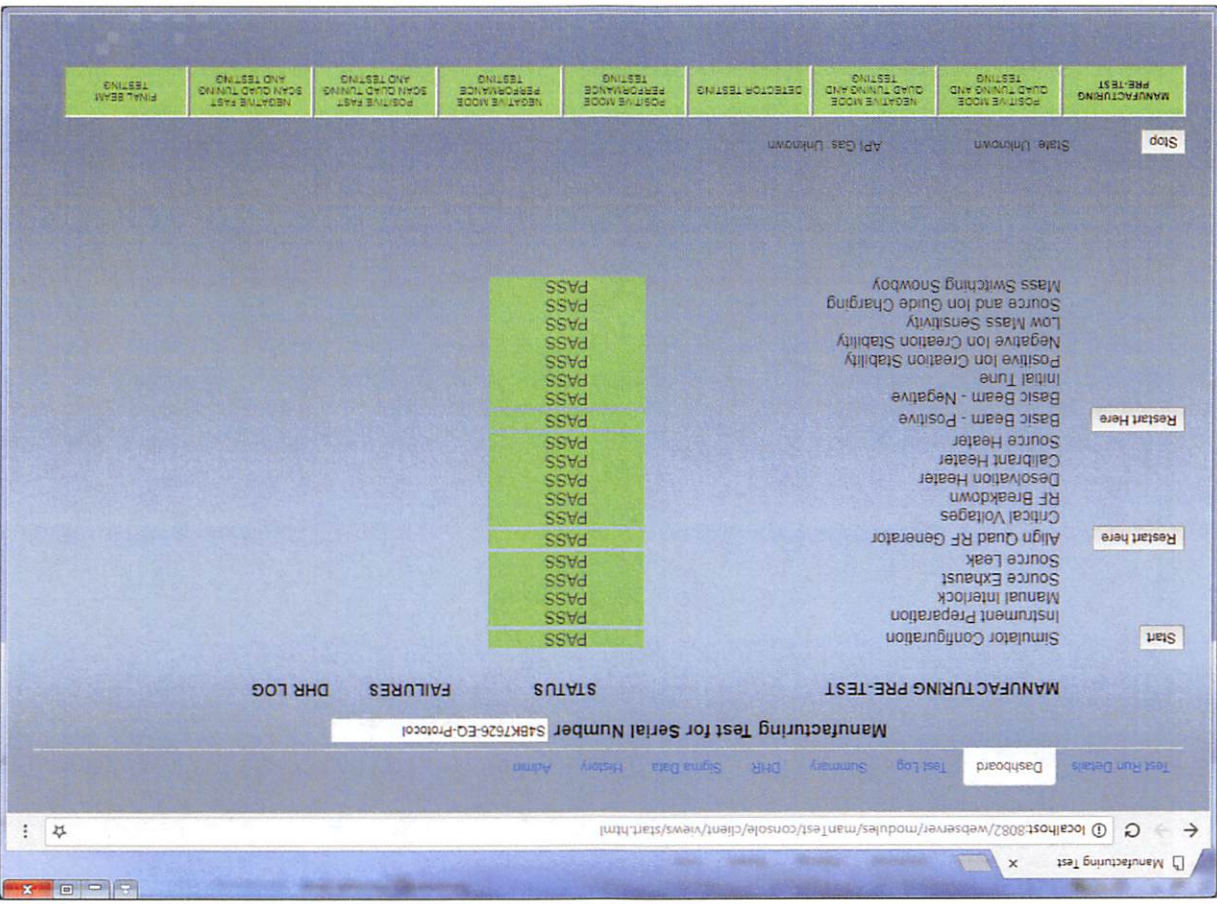
The "Administration" section contains the following fields and controls:

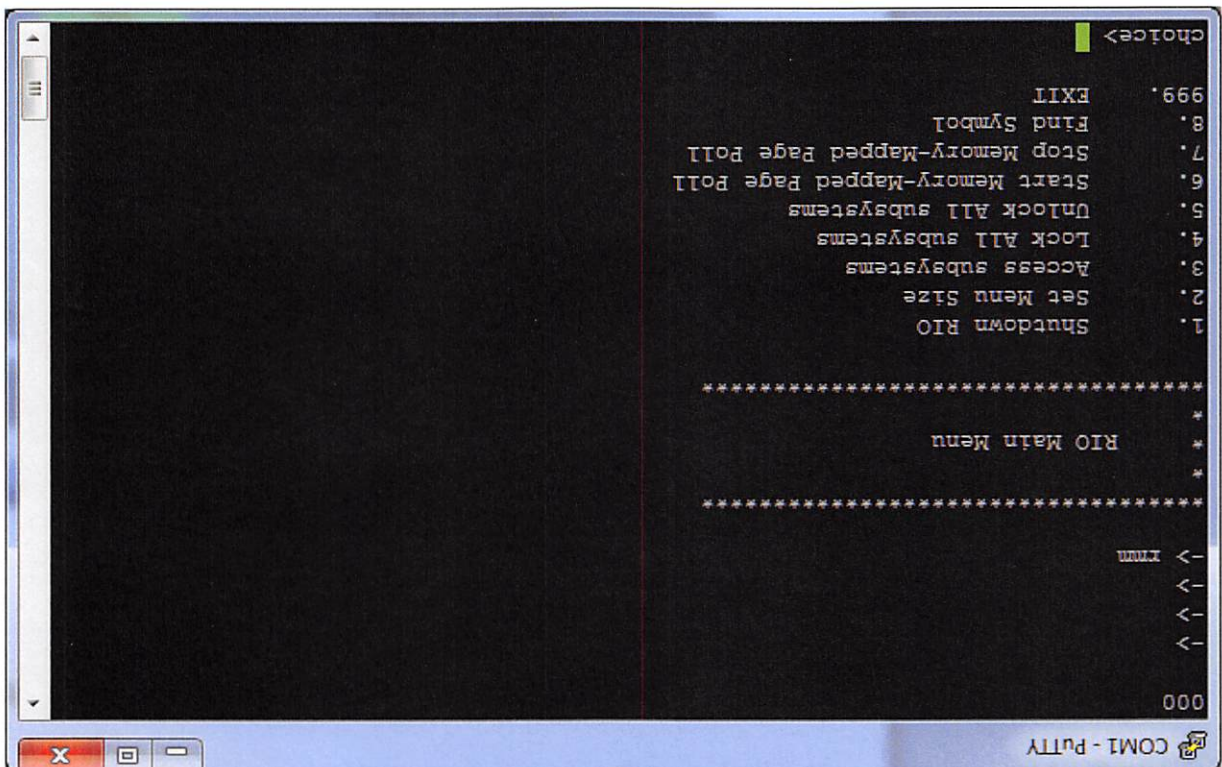
- Tests Database: C:\Program Files (x86)\AMITS\release\AMITS\IMTestModules
- Results Database: \\10.249.40.230\test\_results
- Users Database: \\10.249.40.230\IMTestUsers
- SigmaQuest Folder: \\10.249.40.230\CamstarQueue
- Temp Folder: \\10.249.40.230\test\_results\temp2
- Station GUID: A981D906-C2FE-417F-A91A-626887E58D33
- Station Name: S4BK7626
- Location: Venture (dropdown menu) with a "Remove" button.
- Add Location: (text input) with an "Add" button.
- Area: Test Floor (dropdown menu) with a "Remove" button.
- Add Area: (text input) with an "Add" button.
- Sigma Version: 7 (dropdown menu).
- Available Product Types: A list of checkboxes for various product types, including "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", and "QDa\_Detector\_Housing\_Nostop". The "Acquity\_QDaMKII" and "Acquity\_QDa\_Setup\_Solution" checkboxes are checked.

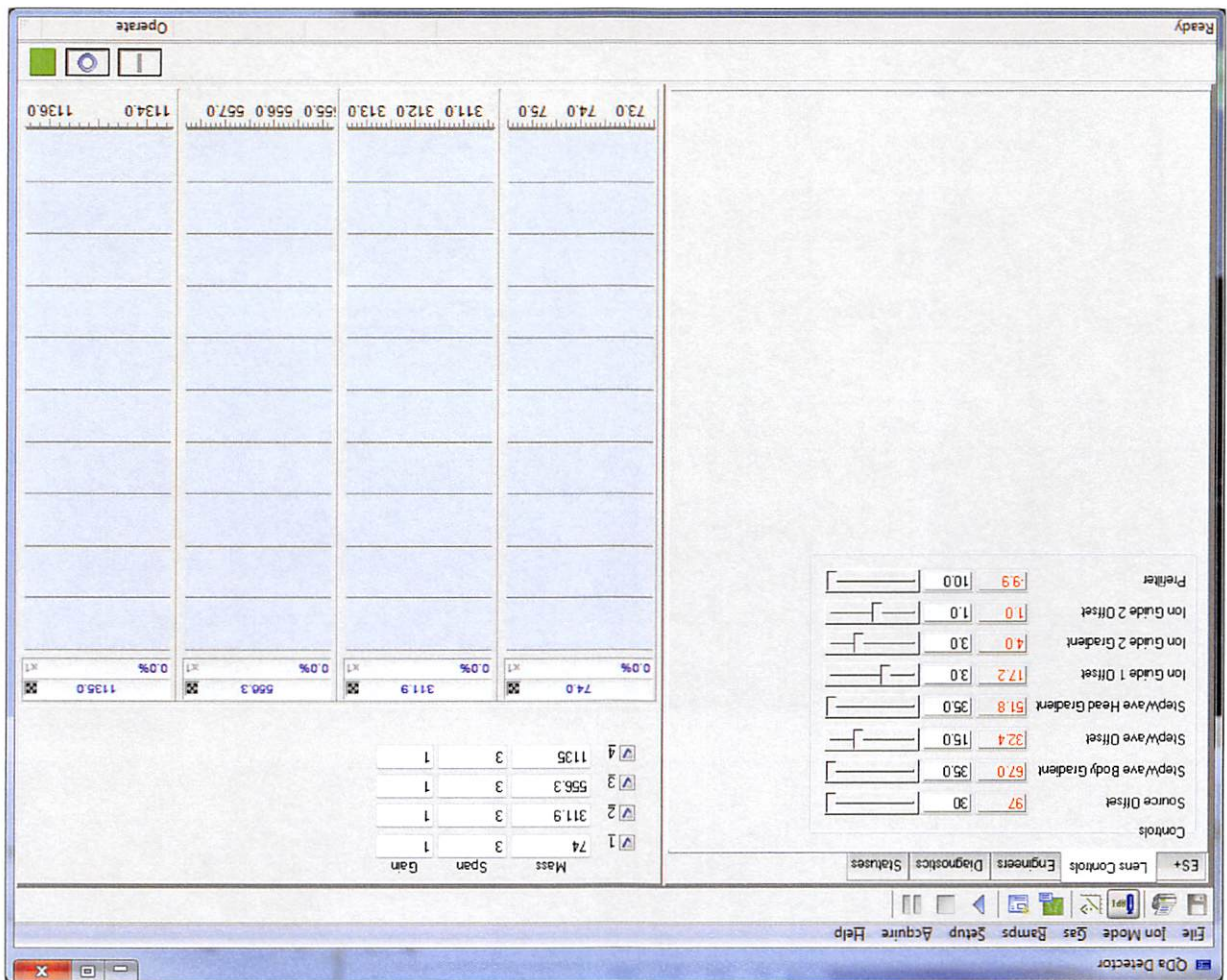
Attachment No: 3 , EQ014 PS 13 Dec 2017

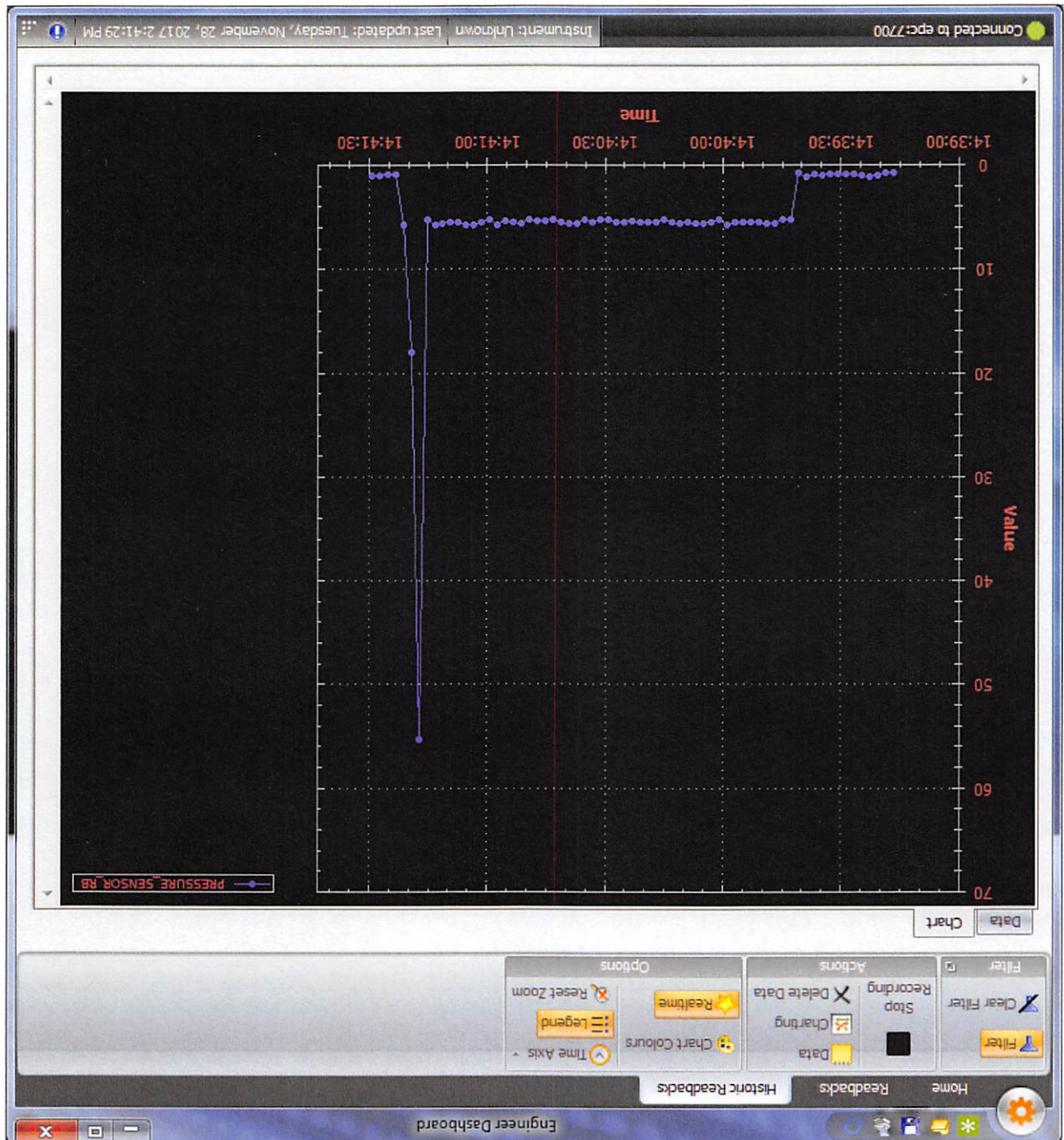


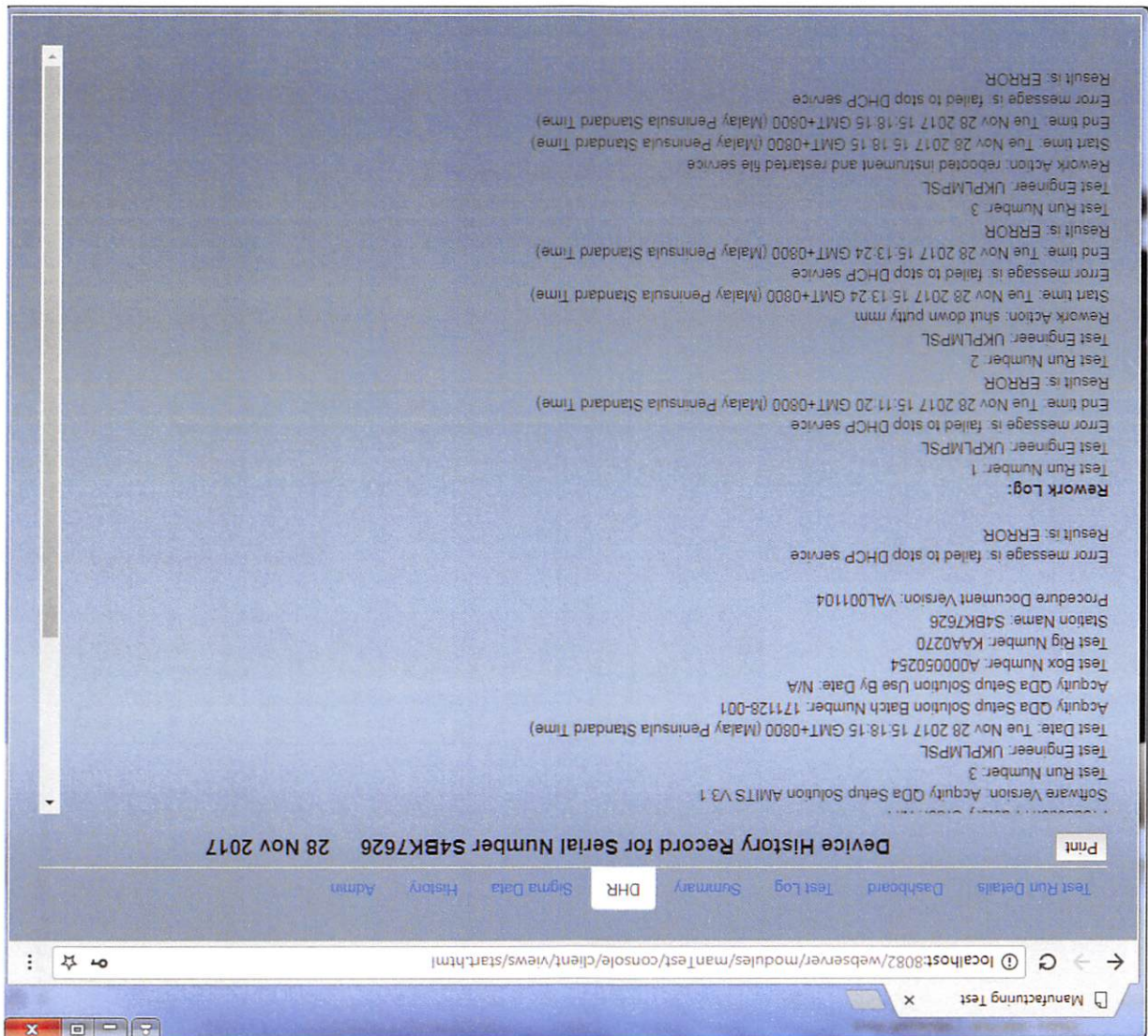


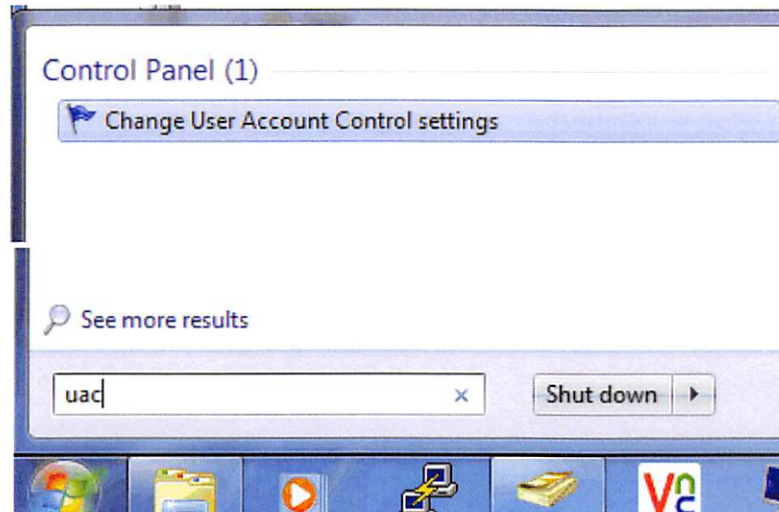




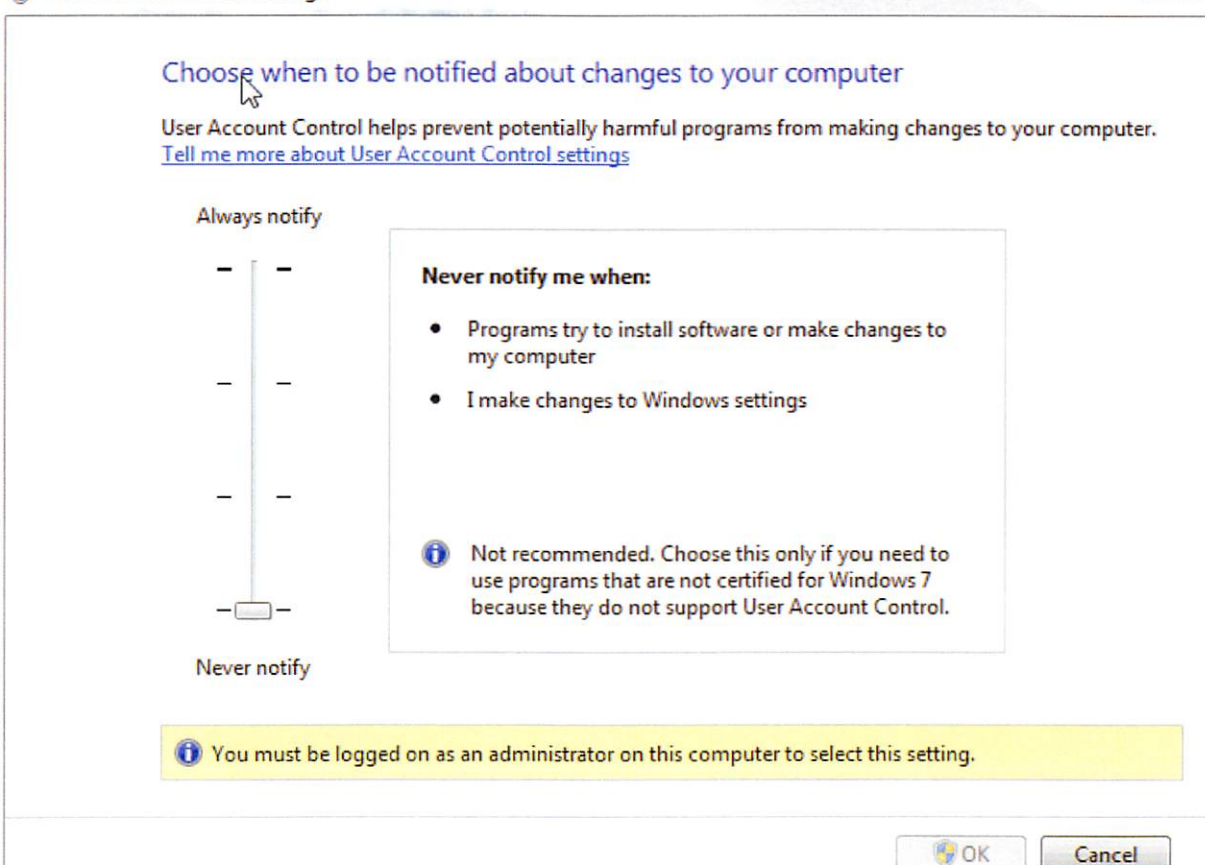


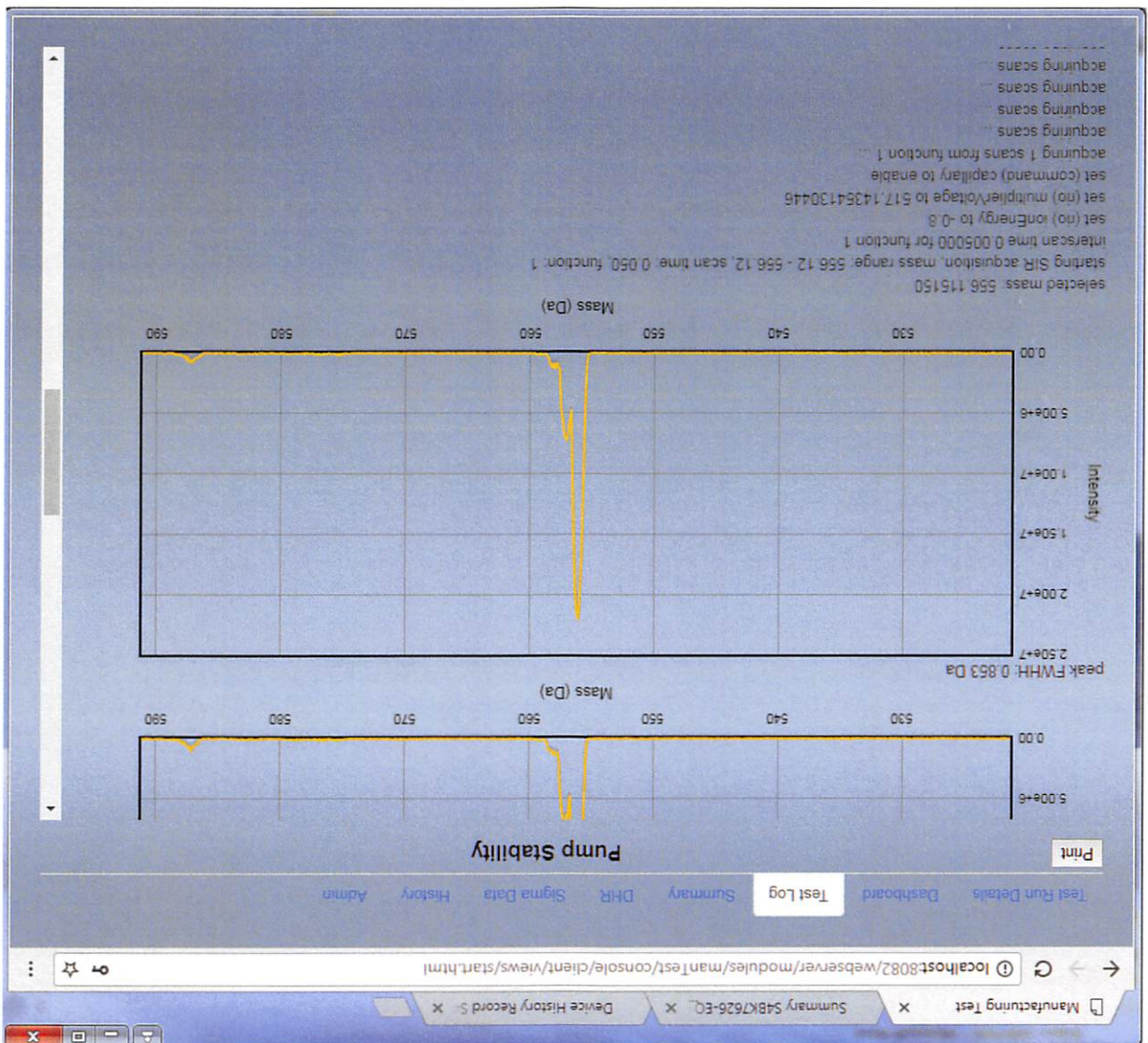






User Account Control Settings





[illegible]

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Attachment No: 13 , EQ016 PS 13 DEC 2017

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