

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

Waters - Wilmslow

Equipment Qualification Protocol

Venture ACQUITY QDa Test Floor

For Internal Use Only

Document reviewed and approved electronically

Author: Paul Slater

Date: 26 Oct 2017.

Waters - S4BA 7494

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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.

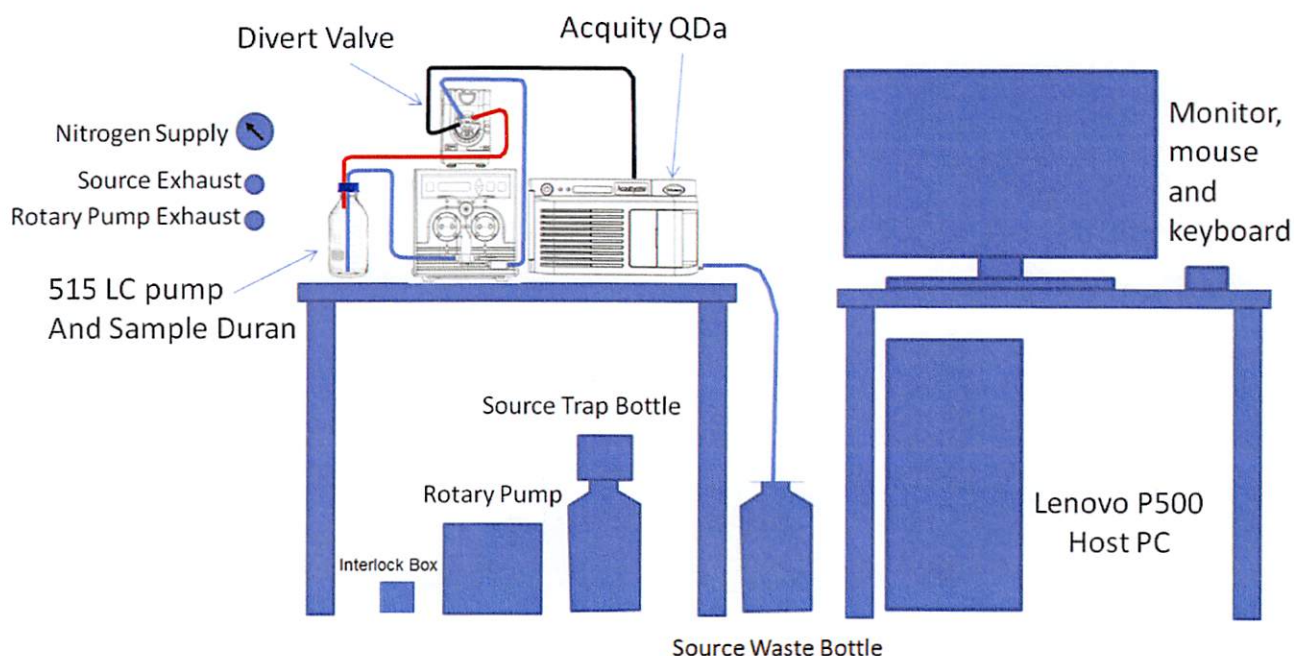


Figure 1 – Test Bay System – Venture Singapore

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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
SIDDHARTH UDAYSHANKAR	PRODUCT ASSURANCE ENGINEER		S.U
Paul Slater	Principle Product Assurance Engineer		PS
EDWINA BEANLAND	PROCESS VALIDATION ENGINEER		EB

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 IQ_Source	Installation Qualification for MassLynx
71550093001_MassLynx 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:	MKI		
Serial Number:	KAA 0270		
Asset No:	UK05 100 2274		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	GES VENTURE, 28 MARSLING LANE, SINGAPORE 739152		
Comments 			
Signed (Operator)		Date	29 NOV 2017
Reviewed (2 nd Party)		Date	14 DEC 2017

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11.1.2. Rotary Pump

Equipment Name	Vacuumbrand Rotary Pump		
Equipment Description:	Rotary Pump		
Make:	Vacuumbrand		
Model/Type:	RE 6W		
Serial Number:	42662507		
Asset No:	N/A		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	GES VENTURE, 28 MARSLING LANE, SINGAPORE 739152		
Comments			
Signed (Operator)		Date	29 NOV 2017
Reviewed (2 nd Party)		Date	14 DEC 2017

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11.1.3. Interlock Box

Equipment Name	Interlock Box		
Equipment Description:	Interlock Box		
Make:	Waters		
Model/Type:	N/A		
Serial Number:	890 23		
Asset No:	N/A		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	GES VENTURE, 28 MARSI LING LANE, SINGAPORE 739152		
Comments 			
Signed (Operator)		Date	29 NOV 2017
Reviewed (2 nd Party)		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:	86 / 031		
Asset No:	N/A		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	GES VENTURE, 28 Maxsiling Lane, Singapore 739152		
Comments			
Signed (Operator)		Date	29 Nov 2017
Reviewed (2 nd 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:	H17515980A		
Asset No:	5308 PS 13DEC2017		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	GES Venture, 28 Marsiling Lane, Singapore 739152		
Comments 			
Signed (Operator)		Date	29 Nov 2017
Reviewed (2 nd Party)		Date	14 DEC 2014

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11.1.6. Sample Divert Box

Equipment Name	Sample Divert Box		
Equipment Description:	Waters ACQUITY Divert Valve		
Make:	Waters		
Model/Type:	MXT 710 - 323		
Serial Number:	A0000 50265		
Asset No:	N/A		
Materials of construction:	N/A		
Risk Assessment	N/A		
Location:	GES venture, 28 Marsiling Lane, Singapore 739152		
Comments 			
Signed (Operator)		Date	29 Nov 2017
Reviewed (2 nd 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)	☒ Yes / No
External Training Provided on equipment (if yes give details below)	☒ Yes / No
Comments On site training by Paul Slater, principle product assurance engineer for the system	
Signed (Operator)	
Reviewed (2 nd Party)	
Date	29 Nov 2017
Date	14 DEC 2017

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11.3. EQ003- Documentation Review

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

Documentation	Details		Location
Commissioning Documentation	N/A		N/A
Declaration of Conformity (CE certificate)	N/A		N/A
Operation and Maintenance manual	45747 – SMITS user Manual 46202 – ACQUITY QDa test procedure		SAP
Materials List / Spares / Bill of Materials	N/A		N/A
Drawings	Type	Rev No.	Location
	Electrical Diagram	N/A	N/A
	Pneumatic Diagram	N/A	N/A
	Hydraulic Diagram	N/A	N/A
	Mechanical Assembly	N/A	N/A
	Layout Drawing	N/A	N/A
	P & ID	N/A	N/A
	Schematic	N/A	N/A
Comments: 			
Signed (Operator)			Date 29 NOV 2017
Reviewed (2 nd Party)			Date 14 DEC 2017

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11.4. EQ004 – Equipment Calibration

Purpose: To add current calibration state of equipment during qualification

Does equipment under test require calibration prior to EQ activities?	Yes/No No		
Recommended calibration frequency?	Annual		
Has Equipment been calibrated prior to starting this protocol? If so, provide details below			
N/A	Calibrated on		Calibration due

Comments:

Calibrated as part of testing EQ

Signed (Operator)	<i>Walt</i>	Date	29 NOV 2017
Reviewed (2 nd Party)	<i>E. Brundage</i>	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 (Yes / No)	Acceptable (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	29 Nov 2017
Reviewed (2 nd Party)		Date	16 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	- Rated Voltage - 100 to 240V - Rated Frequency - 50/60Hz - Maximum supply fuse / circuit breaker rating – 13 to 16A - Power Connection – IEC 60320 C14 receptacle - Located within 2 m of the instrument.	237V AC 50.03 Hz W1-16G,P0073-23372873	Pass
Independent Socket for Rotary Pump	- Rated Voltage - 200 to 240V - Rated Frequency - 50/60Hz - Maximum supply fuse / circuit breaker rating – 13 to 16A - Power Connection – IEC 60320 C14 receptacle - Located within 2 m of the instrument.	237 V AC 50.03 Hz	Pass
Socket for 515 pump	- Rated Voltage - 220 to 240V - Rated Frequency - 50/60Hz - Maximum supply fuse / circuit breaker rating – 3.15A - Power Connection – IEC 60320 C14 receptacle	237V AC 50.03 Hz	Pass
2 Sockets for Data System	- Rated Voltage - 200 to 240V - Rated Frequency - 50/60Hz - Maximum supply fuse / circuit breaker rating – 2.5 to 16A - Power Connection – IEC 60320 C14 receptacle	237 V AC 50.03 Hz	Pass
Socket for Diverter Valve	- Rated Voltage - 100 to 240V - Rated Frequency - 50/60Hz - Maximum supply fuse / circuit breaker rating – 13 to 16A - Power Connection – IEC 60320 C14 receptacle	237 V AC 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.	Cannot be measured	Pass

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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: 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 nd Party)		Date	14 Dec 2017

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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 100PSI Confirmed	Pass S.U 29 NOV 2017
Connection	Regulator must be fitted with an adapter to connect to a 6-mm OD FEP tube	Confirmed	Pass S.U 29 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: <u>110 PSI</u> Pressure measured on Test Bay regulator running at 1200l/hr - with no other bays using Nitrogen: <u>100 PSI</u> Pressure measured on Test Bay regulator running at 1200l/hr - with a 1200l/hr flow added from any other bay: <u>95 PSI</u>	Pass S.U 29 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. <u>90 PSI → 95 PSI → 97 PSI → 100 PSI</u> 4 Bay 3 Bay 2 Bay 1 Bay	Pass S.U 29 NOV 2017

Comments:

Signed (Operator)		Date	29 NOV 2017
Reviewed (2 nd Party)		Date	14 DEC 2017

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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 <u>vacuum</u> 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 S.U 29 Nov 2017
Rotary Exhaust – Connectivity	The rotary pump exhaust gases must be vented to the atmosphere outside the laboratory through a user-supplied fume hood or industrial vent. The exhaust may be connected to an existing laboratory vent carrying gases from other sources. The exhaust must NOT be connected to the QDa source exhaust system.	The fumehoods are separated by over 2m.	Pass S.U 29 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.	The pipe internal diameter is UPVC 100mm. The fitting enters the pipe vertically, so well away from any accumulation of condensed liquid	Pass S.U 29 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 S.U 29 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 S.U 29 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 S.U 29 Nov 2017
Rotary Pump Oil Level	Rotary pump is filled with oil to the upper level mark	confirmed	S.U Pass 29 Nov 2017
Oil trap	Oil trap is fitted	confirmed	S.U Pass 29 Nov 2017

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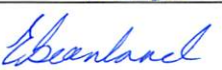
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11.9. EQ009 – Installation Checks of the Source Exhaust System - Utility

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 vacuum 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)	The draw cannot be measured directly with the gas off. But a strong draw can be felt by hand.	Pass S.U 29 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. The exhaust must NOT be connected to the rotary pump exhaust system.	Confirmed over 2m between fumehood exhausts.	Pass S.U 29 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 constraint 6.5mbar when gas is switched on. 1mbar when gas is off.	Concession S.U 29 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 S.U 29 NOV 2017
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 S.U 29 NOV 2017

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

Signed (Operator)		Date	29 NOV 2017
Reviewed (2 nd Party)		Date	14 DEC 2017

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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?		Yes/No	
If yes, enter details	Requires a host PC to drive the QDa under test.		
Comments: Record the Host PC name and Domain Name: <i>Waters - S4BA7494 /corp</i> Record the IP Address of the Host PC <i>^{S-U} 10.249.40.119</i>			
Signed (Operator)	<i>[Signature]</i>	Date	<i>29 Jan 2017</i>
Reviewed (2 nd Party)	<i>[Signature]</i>	Date	<i>14 DEC 2017</i>

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

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

Does equipment require computer software to operate successfully?			Yes/No	
If yes, enter details below:				
ACQUITY QDa AMITS	Version No.	3.1	SVAF Approved	Yes / No
PuTTY	Version No.	0.60	SVAF Approved	Yes / No
Engineers Dashboard	Version No.	1.2.659.24837	SVAF Approved	Yes / No
Chrome	Version No.	62.0.3202.94	SVAF Approved	Yes / No
MassLynx	Version No.	4.1 SCN 947 SCN 961	SVAF Approved	Yes / No
Microsoft Office	Version No.	14.0.7190.5000	SVAF Approved	Yes / No
Comments:				
Signed (Operator)			Date	29 Nov 2017
Reviewed (2 nd Party)			Date	14 DEC 2017

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – Venture ACQUITY QDa Test Floor Test Bays	
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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
	Convolutd 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

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	
	Power up the QDa. Confirm the QDa backing pump powers up, and that after 5 minutes, the instrument runs the source pressure test.	confirmed	Y
Were all acceptance criteria met – Y/N			
Deviation Number (if required)		N/A	
Comments:			
Signed (Operator)		30 Nov 2017	
		14 Dec 2017	

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12.2. EQ013 – Operational Checks of 515 pump

12.2.1. 515 Pump Pressure Decay

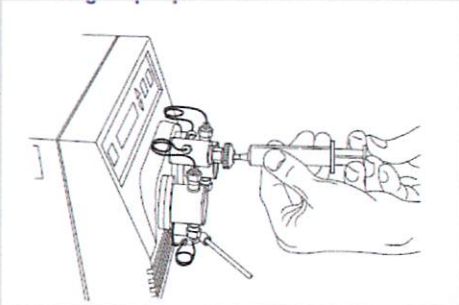
Objective/Rationale:

Confirm 515 pump operates correctly

Equipment Required

Equipment	Lot Number/Calibration Number	Expiry/Cal Due date
Plug pin high pressure 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	Turn on the pump and allow it to completed all start-up checks Replace the current solvent with a 1l bottle of LC-MS Grade methanol Set the pump flow parameter to 1.000mL/min BUT do not press Run/Stop at this point 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 Withdraw several mls of eluent with the syringe, then close the valve handle. Expel the contents of the syringe into a suitable waste container Press the Run/Stop key to start the pump Let the pump run for about a minute to allow the pump pressure to settle. Press the Run/Stop key to stop the pump	S.V 2017 28 NOV 2018 S.V

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Function	Experimental Details				Initial / Date
Pressure Decay Test	Disconnect the tubing at the pump outlet and cap the outlet with the plug pin In the pump's LCD display, set the high pressure limit (HPL) to 4000psi and the flow parameter to 0.200 mL/min. Set the pump flow parameter to 3.000mL/min Press Run/Stop to start the pump When the pump shuts off (1.2s after exceeding 4000psi), start the stop watch. Press the up or down key to clear the Hi Press Message 30s after pressure shut off, note down the pressure reading. This is P1 300s after pressure shut ff, note down the pressure reading. This is P2 Loosen a fitting to relieve the pump pressure and remove the plug.				S.U 28 NOV 2017
Results	P1	P2	Pressure Decay – (P1-P2/P1)		S.U 28 NOV 2017
			Expected Result	Actual Result	
	4192	4192	≤0.15	0	
Were all acceptance criteria met – Y/N Y/N					
Deviation Number (if required) N/A					
Comments:					
Signed (Operator)				Date	28 NOV 2017
Reviewed (2 nd Party)				Date	14 DEC 2017

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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 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 28 Nov 2017
0.500mL/min flow rate check	Set the flow rate to 0.500mL/min and start the pump When the flow and pressure stabilise, simultaneously insert the outlet tubing into the 10mL volumetric flask and start the stopwatch. Stop the stopwatch when the bottom of the meniscus reaches the volume level mark on the flask Record the elapsed time in seconds and the observed system pressure. The flow rate can then be calculated by Calculated flow rate = Volume of flask/(measured time in seconds)/60	S.U 28 Nov 2017
1.000mL/min flow rate check	Set the flow rate to 1.000mL/min and start the pump When the flow and pressure stabilise, simultaneously insert the outlet tubing into the 10mL volumetric flask and start the stopwatch. Stop the stopwatch when the bottom of the meniscus reaches the volume level mark on the flask Record the elapsed time in seconds and the observed system pressure The flow rate can then be calculated by Calculated flow rate = Volume of flask/(measured time in seconds)/60	S.U 28 Nov 2017

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5.000mL/min flow rate check	Set the flow rate to 5.000mL/min and start the pump When the flow and pressure stabilise, simultaneously insert the outlet tubing into the 25mL volumetric flask and start the stopwatch. Stop the stopwatch when the bottom of the meniscus reaches the volume level mark on the flask Record the elapsed time in seconds and the observed system pressure The flow rate can then be calculated by Calculated flow rate = Volume of flask/(measured time in seconds)/60)					
	Set Flow Rate	Observed System Pressure (psi)	Observed Elapsed Time (s)	Calculated Flow Rate (mL/min)		
				Expected Result	Actual Result	
	0.500	367	1164	0.469-0.531	0.515	S.U 28 NOV 2017
	1.000	749	619	0.968-1.032	0.969	S.U 28 NOV 2017
5.000	44	114	4.94-5.06	5.263	S.U 28 NOV 2017	
Were all acceptance criteria met – Y/N Y/N						
Deviation Number (if required)			1			
Comments: Failed 5.000mL/min flow rate check. Concession – The requirement is 0.350 mL/min.						
Signed (Operator)				Date	28 NOV 2017	
Reviewed (2 nd 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. Open Admin. Enter Admin password. The Admin Details within AMITS must be edited to match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore. Confirm the Admin Details within AMITS match those within 46215, "Aquity QDa Installation – Link to Network" for Venture Singapore.	confirmed.	Y
AMITS User List	Refresh AMITS. (f5 key) Open Admin. Click on the downward pointing arrow beside the Test Engineer drop list. Confirm the engineer list contains UKPLMPSL.	confirmed.	Y.
AMITS link to Storage Solution	Open AMITS. Open Test Run Details. From the product type list, select "simulator". Enter the following details: Serial Number: EQ-Protocol Open the Dashboard Confirm a completed test record is visible. (All the Statuses in every test section are "PASS")	confirmed	Y

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AMITS timely Data Exchange with Storage Solution.	Open AMITS. Open Test Run Details. From the product type list, select “simulator”. Enter the following details: Serial Number: Test Bay Number Sample Batch Number: N/A Sample Use By Date: N/A Test Box Number: Divert Valve serial number Test Rig Number: N/A Procedure Document Number: this document		
	Open the Dashboard Click the “Start here” button. Follow the on-screen instructions to start a simulated test run. Use your AMITS account. Follow the on-screen prompts for manual interlock lock tests by clicking the continue button. Allow the test sequence to complete. (approx 15 minutes) Confirm the test sequence completes. (All the Statuses in every test section are “PASS”)	<i>confirmed</i>	<i>Y</i>
Were all acceptance criteria met – Y/N			
Deviation Number (if required)		<i>(Y/N)</i>	
Deviation Number (if required)			
<i>N/A.</i>			
Comments:			
Signed (Operator)		<i>Paul Hatt</i>	
Reviewed (2 nd Party)		<i>E. Beards</i>	
Date		29 Nov 2017	
Date		14 DEC 2017	

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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	This test requires the gold brick ACQUITY QDa to be pumped down. Open PuTTY Select connection type "Serial" Select the Speed associated with the DCC PCB installed on the Gold Brick instrument. Either 9600 or 115200 Click Open Into the "->" type rmm Confirm ***** * * RIO Main Menu * ***** 1. Shutdown RIO 2. Set Menu Size 3. Access subsystems 4. Lock All subsystems 5. Unlock All subsystems 6. Start Memory-Mapped Page Poll 7. Stop Memory-Mapped Page Poll 8. Find Symbol 999. EXIT Is displayed.	Confirmed.	Y

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Were all acceptance criteria met – Y/N		☒ Y ☐ N	
Deviation Number (if required)		N/A	
Comments:			
Signed (Operator)	<i>Paul Mator</i>	Date	30 NOV 2017
Reviewed (2 nd Party)	<i>E. Beauland</i>	Date	14 DEC 2017

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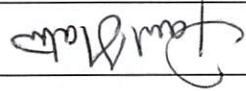
12.3.3. MassLynx

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	This test requires the gold brick ACQUITY QDa to be pumped down. Open MassLynx 4.1 Wait until MassLynx has fully booted, and says that the instrument is present. Open MS Console Wait until MS Console opens. • If the console is blank (no data from the QDa) , close MassLynx • run C:\Program Files (x86)\Waters Instruments\Bin\StopMassLynxProcesses • run C:\Program Files (x86)\Waters Instruments\Bin\StopAcquityProcesses • Open MassLynx 4.1 • Wait until MassLynx has fully booted, and says that the instrument is present. • Open MS Console • Wait until MS Console opens. Open Trouble Shoot / Service Mode Enter the password 1147 Open Trouble shoot / Show Tune page From the tune page, Select Acquires / Reinitialize. Select Lens Control Switch the machine into Operate Confirm the readbacks from the lens control are greater than zero, and the instrument API gas comes on. Place the instrument into standby.	confirmed	Y

Deviation Number (if required)		N/A	
Were all acceptance criteria met – Y/N		(Y/N)	
Comments:			
Signed (Operator)		Date	
		30 NOV 2017	
Reviewed (2 nd Party)		Date	
		14 DEC 2017	

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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	This test requires the gold brick ACQUITY QDa to be pumped down, and connected to a nitrogen supply. Open MassLynx 4.1 Wait until MassLynx has fully booted, and says that the instrument is present. Open Engineer Dashboard Wait until Start Engineer Dashboard pop-up appears. Select Connect to instrument, and click OK Select Historic Readbacks. Select Data Select PRESSURE_SENSOR_RB and add it to the items that will be recorded. Click OK Click the record button.		
	Confirm the chart plotted by Dashboard is not a flat line but varying with random values all less than 10mBar. Open the source enclosure door on the front of the QDa, and then close it. Confirm the chart plotted stays low for about 2 minutes, but then records a spike >50mBar. (confirms Dashboard functionality and Test Bay source exhaust system) Close Engineers Dashboard.	confirmed. confirmed.	Y Y

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Were all acceptance criteria met – Y/N		(Y/N)	
Deviation Number (if required)		N/A	
Comments:			
Signed (Operator)	<i>Paul Hato</i>	Date	30 NOV 2017
Reviewed (2 nd Party)	<i>E. Beaulac</i>	Date	14 DEC 2017

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12.4. EQ015 – Operational Checks of the Divert Valve

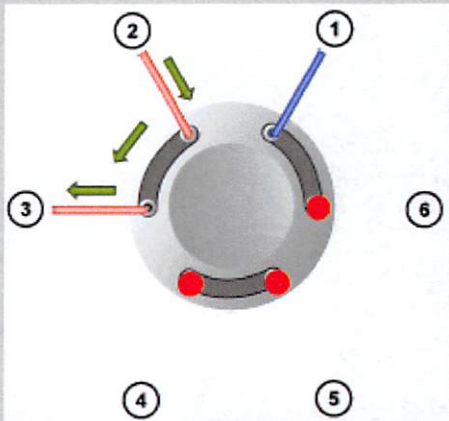
Objective/Rationale:

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	This test requires the gold brick ACQUITY QDa to be pumped down, and connected to a nitrogen supply. Power up the Divert valve, with the Divert control cable (441001851) not connected to the QDa. Confirm the Valve Position displayed is "1"	" 2 ".	Y
Installation of the Peek Tubing to the Divert Valve.	Confirm the peek tubing is connected between the 515 pump and the Divert Valve. The peek tube must be fitted to port 2. Confirm the peek tubing is connected between the Divert valve and the sample Duran bottle. The peek tube must be fitted to port 3. 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.	1 2. 6	Y

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N																		
The Divert Valve delivers sample back to the sample Duran bottle when AMITS does not require sample.	Run the 515 pump to run mode, and deliver 350ul/min methanol to the divert valve  Valve Position "1". Confirm while is position "1" the sample diverted back to the supply bottle, and no sample sent through the pipe connected to port 1.	"2" confirmed.	Y																		
Divert Valve control cable is attached to the ACQUITY QDa.	Connect the divert valve control cable to the gold brick. ACQUITY QDa Confirm that the wires from the control cable are connected to the correct ports on the ACQUITY QDa. <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> N/A N/A N/A Confirm the Divert Valve remains in position "1"	Signal	Colour	Port No.	Stop Flow +	Red	1	Stop Flow -	Black	2	Switch +	White	3	Switch -	Black	4	Analog -	Black	9	confirmed. "2"	Y
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
The divert valve can be controlled by the test bay software.	This test requires the gold brick ACQUITY QDa to be pumped down. Open PuTTY Select connection type "Serial" Select the Speed associated with the DCC PCB installed on the Gold Brick instrument. Either 9600 or 115200 Click Open Into the "->" type rmm This will display: <pre>***** * * RIO Main Menu * *****</pre> 1. Shutdown RIO 2. Set Menu Size 3. Access subsystems 4. Lock All subsystems 5. Unlock All subsystems 6. Start Memory-Mapped Page Poll 7. Stop Memory-Mapped Page Poll 8. Find Symbol 999. EXIT If the instrument is correctly connected. Type in : 3 <enter> 1<enter> 1<enter> 406<enter> Confirm the Divert Valve moves from position "1" to position "2". Confirm liquid starts to come out of the tube connected to port 1 on the Divert Valve.	"2" to "1" confirmed.	y y

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Reset the system back to recycle mode.	In PuTTY, type in 405<enter> Confirm the Divert Valve is restored to position 1, and the liquid is being recycled back into the Duran bottle. In PuTTY, type in 999<enter> 999<enter> 999<enter> To exit from rioMainMenu.	"1" to "2"	Y
Were all acceptance criteria met – Y/N (Y/N)			
Deviation Number (if required)		2	
Comments: check valve required –replaced. No help – piston seal? swapped heads over and now working fine. Error in document. refer to deviation #2.			
Signed (Operator)	<i>Paul Blato</i>	Date	30 NOV 2017
Reviewed (2 nd Party)	<i>E. Beantland</i>	Date	14 DEC 2017

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

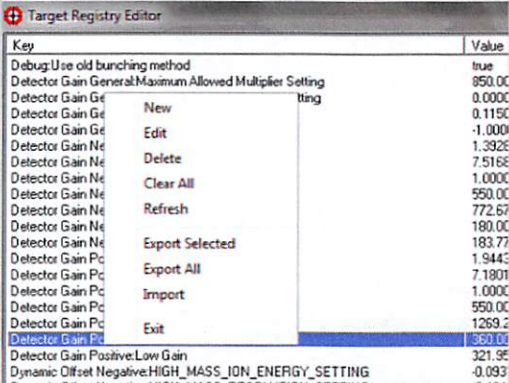
Objective/Rationale:

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

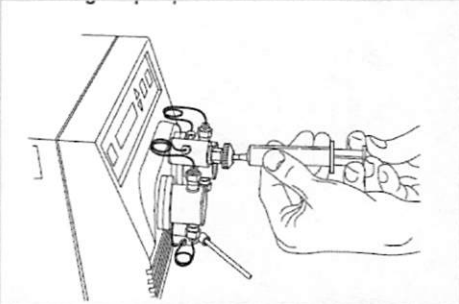
Acceptance Criteria:

Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Mass Lynx Configuration	This test requires the gold brick ACQUITY QDa to be pumped down. Open MassLynx 4.1 Wait until MassLynx has fully booted, and says that the instrument is present. Open MS Console Wait until MS Console opens. • If the console is blank (no data from the QDa) , close MassLynx • run C:\Program Files (x86)\Waters Instruments\Bin\StopMassLynxProcesses • run C:\Program Files (x86)\Waters Instruments\Bin\StopAcquityProcesses • Open MassLynx 4.1 • Wait until MassLynx has fully booted, and says that the instrument is present. • Open MS Console • Wait until MS Console opens. Open Trouble Shoot / Service Mode Enter the password 1147 Open Configure / Health Monitor Configuration -go to next row in this table-		

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Restore ACQUITY QDa Target Registry to a previously working configuration.	This test requires that the target registry associated with the Gold Brick instrument when it was last working is available. Save the Gold Brick Target Registry onto the Test Bay desktop. Open Target Registry: (C:\MassLynx\Kestrel\TargetRegistryEditor.exe) Enter the authorisation code 1147 This will display the current target registry settings for the instrument. Right mouse click the table, and select Import.  Select the target registry file that was saved on the host PC desktop. Close the target Registry. Confirm the target registry update has been completed	confirmed	Y

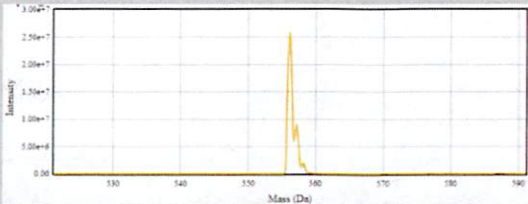
Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – Venture ACQUITY QDa Test Floor Test Bays	
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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Prepare the 515 pump with QDa Setup Solution.	Stop the 515 flow Change the Methanol 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. 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 Withdraw several mls of eluent with the syringe, then close the valve handle. Expel the contents of the syringe into a suitable waste container. Take the "recycle" peek tube from the sample Duran bottle, and leave it in a suitable waste container Press the Run/Stop key to start the pump at 350ul/min. Let the pump run for about 5 minutes to allow the pump pressure to settle, and to expel any remaining methanol from the system. Take the "recycle" peek tube from the waste container, and refit it to the sample 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. Confirm the sample is being recycled into the sample Duran Bottle.	confirmed confirmed	Y Y

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Run AMITS Peak Shape Test Sequence on ACQUITY QDa	Open AMITS. Open Test Run Details. From the product type list, select "Acquity_QDa_Setup_Solution". Enter the following details: Serial Number: Test Bay Number Sample Batch Number: YYMMDD-00** Sample Use By Date: N/A Test Box Number: Divert Valve serial number Test Rig Number: Gold Brick QDa Serial Number Procedure Document Number: this document Open the Dashboard Click the "Start here" button. Follow the on-screen instructions to start a test run. Use your AMITS account. 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) Confirm more than one test within the sequence has been run. (Confirms Network connection to storage system) Confirm whether the test sequence completed, and a pop up was displayed referring to saving the data on SigmaQuest was displayed. 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.	"2" to "1" confirmed - confirmed	y y y

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Run AMITS Peak Shape Test Sequence on ACQUITY QDa (continued)	Confirm the Positive Pump Stability Test passed. (confirms the 515 pump is suitable for purpose) If the stability test failed, log what actions were required to correct the issue. Open the LOG for the Positive Pump Stability Test. Confirm there was a 556Da peak with partially resolved isotopes, similar to the image below. 	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.	Open the target registry and refresh. Export All to the test bay PC desktop, and name the treg file as: Test_Bay_*** - where *** is the test bay number. Open a File Explorer window, and enter the following location: FTP://164.39.5.34 A pop up window will request a USERNAME. Use WAT-PAE. The pop up will also request a password. Use registry2014 Save a copy of the final beam pre health check TREG file within this FTP site.. Confirm the file was successfully saved onto the FTP site.	confirmed	Y

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Save PDF record on Storage Solution.	In AMITS, open the SUMMARY for the Peak Shape Test Sequence that was run. Use the AMITS tool to print the summary onto Chrome. Use Chrome to save the printout as a PDF file onto the host pc desktop. Use Windows Explorer to copy the PDF file onto the storage solution folder: ***\PROJECT FOLDERS\Project Folders - Instruments\QDa\17Q4 Where *** is the network name of the storage solution Confirm the file was successfully saved on the storage solution.	confirmed	Y
Were all acceptance criteria met – Y/N Y/N			
Deviation Number (if required)		2	
Comments: Reference to direct valve default position. See deviation #2			
Signed (Operator)	<i>Paul Glatow</i>	Date	30 NOV 2017
Reviewed (2 nd Party)	<i>L. Beckman</i>	Date	14 DEC 2017

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12.6. EQ017 – Shutdown of Test System

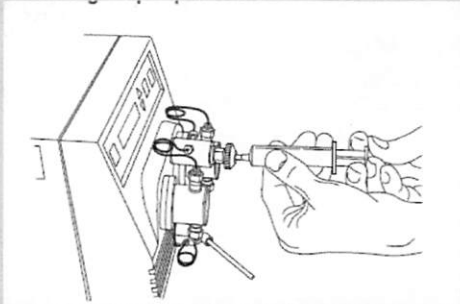
Objective/Rationale:

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 Criteria Met Y/N
Shut down the Gold Brick ACQUITY QDa	Power off the ACQUITY QDa. Confirm the action has been completed.	confirmed	Y.

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Prepare the 515 pump with Methanol	Stop the 515 flow Change the QDa Setup Solution Duran Bottle, for a bottle of Methanol. 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 Withdraw several mls of eluent with the syringe, then close the valve handle. Expel the contents of the syringe into a suitable waste container. Take the "recycle" peek tube from the Methanol Duran bottle, and leave it in a suitable waste container Press the Run/Stop key to start the pump at 350ul/min. 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. 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. Confirm the sample is being recycled into the sample Duran Bottle. Switch Off the 515 pump. Confirm the 515 pump has been powered off.	confirmed confirmed confirmed	✓ ✓ ✓

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Description	Result Expected	Result Actual	Acceptance Criteria Met Y/N
Were all acceptance criteria met – Y/N		Y/N	
Deviation Number (if required)		2 and 3	
Comments: See deviation 2 regarding documentation error. See deviation 3 regarding GES_Venture account.			
Signed (Operator)		Date	13 DEC 2017
Reviewed (2 nd Party)		Date	14 DEC 2017

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13. MAINTAINING THE VALIDATED STATE

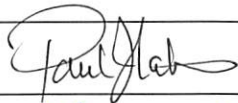
13.1. Maintenance & PPM Summary

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:

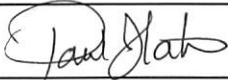
48550 QDa Sub-Contractor PM Procedure

48552 QDa Sub-Contractor PM Test Record.

Signed (Operator)		Date	13 Dec 2017
Reviewed (2 nd Party)		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.

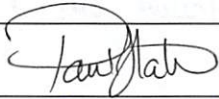
SOP Released in EDMS	(Yes / No / NA)	SOP Number:	46202
SOP Title	46202 – TSP ACQUITY QDa AMTS Test Procedure		
Signed (Operator)		Date	13 Dec 2017
Reviewed (2 nd Party)		Date	14 DEC 2017

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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
		EOD PS 13 DEC 2017.		
Comments:				
Signed (Operator)			Date	13 DEC 2017
Reviewed (2 nd Party)			Date	14 DEC 2017

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14.2. Validation Deviation Form*

Deviation No.	1	EQ Test No.	EQ-013
Deviation Details SIS pump failed 5ml/min flow test. It did pass 0.5ml/min and 1.0ml/min flow tests.			
Corrective Actions None. The flow rate used by the system test is 0.35ml/min.			
Outcome None. No change required. The failure will not affect the system.			
Deviation Closed (Yes/No)	Y	Date	13 Dec 2017
Signed (Operator)		Date	13 Dec 2017.
Approved (Quality Assurance)		Date	20 Dec 17

*duplicate as required (single sheet per deviation only)

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15. ATTACHMENTS

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

Attachment No.	EQ Test No.	Details	No. of pages	Operator Initials
1	EQ-007 EQ-008 EQ-009	Photographs of test bay and exhaust system	3	PS
2	EQ-014	screenshot of AMITS network.	1	PS
3	EQ-014	screenshot of AMITS Storage PC link to user list	1	PS
4	EQ-014	screenshot of AMITS Storage PC link to data	1	PS
5	EQ-014	screenshot of AMITS simulator run	1	PS
6	EQ-014	screenshot of Putty	1	PS
7	EQ-014	screenshot of Masslynx file page	1	PS
8	EQ-014	screenshot of Dashboard.	1	PS
9	EQ-016	screenshot from MS Console configuration	1	PS
10	EQ-016	screenshot from AMITS completing test sequence	1	PS
11	EQ-016	screenshot of pump stability peak shape	1	PS
12	EQ-016	Test data accepted automatically by SigmaSwe	1	PS
13	EQ-016	FTP site accessible using GES_Venture account.	1	PS
		EOD PS 13 DEC 2017		

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Attachment No.	EQ Test No.	Details	No. of pages	Operator Initials
		EOD PS 13 DEC 2017		

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14.2. Validation Deviation Form*

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

*duplicate as required (single sheet per deviation only)

Waters THE SCIENCE OF WHAT'S POSSIBLE.®		EQ Protocol – Venture ACQUITY QDa Test Floor Test Bays	
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14.2. Validation Deviation Form*

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

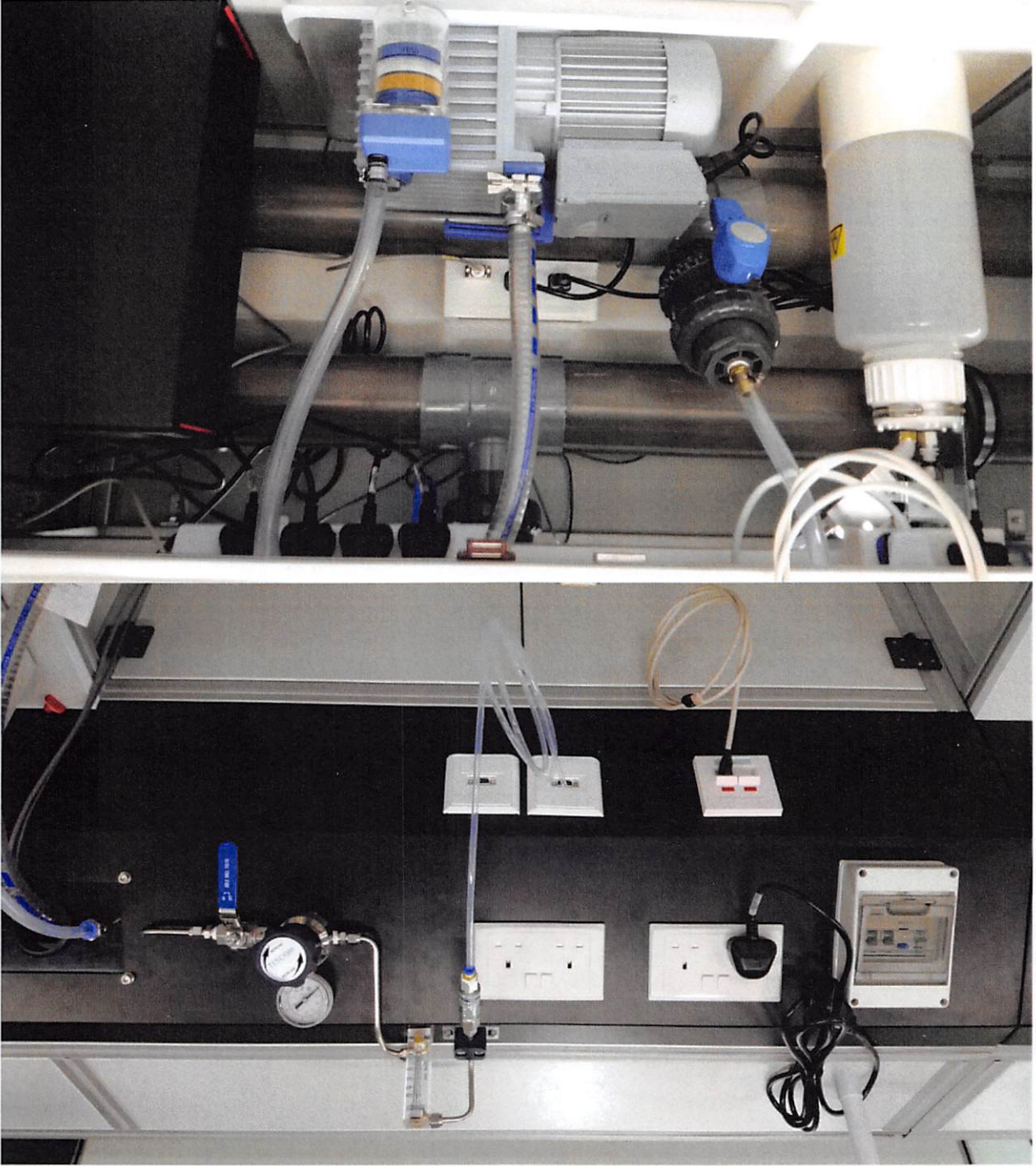
*duplicate as required (single sheet per deviation only)

VAL001104 – Waters - S4BA7494

Attachment No: 1 , EQ007, EQ008, EQ009, -Generic Photograph representing all four test bays.

Page 1 of 3 PS 13DEC 2017





Attachment No: 1 , EQ007, EQ008, EQ009, Generic Photograph representing all four test bays.

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



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Attachment No: 2 , EQ014 *PS 13 Dec 2017*

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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 tabs: "Test Run Details", "Dashboard", "Test Log", "Summary", "DHR", "Sigma Data", "History", and "Admin". The "Admin" tab is selected, leading to the "Administration" page.

The "Administration" page contains the following configuration fields:

- Tests Database: C:\Program Files (x86)\AMITS\release\AMITS\MTTestModules
- Results Database: \\10.249.40.230\test_results
- Users Database: \\10.249.40.230\MTTestUsers
- SigmaQuest Folder: \\10.249.40.230\CamstarQueue
- Temp Folder: \\10.249.40.230\test_results\temp2
- Station GUID: A981D906-C2FE-417F-A91A-626887E58D33
- Station Name: S4BA7494

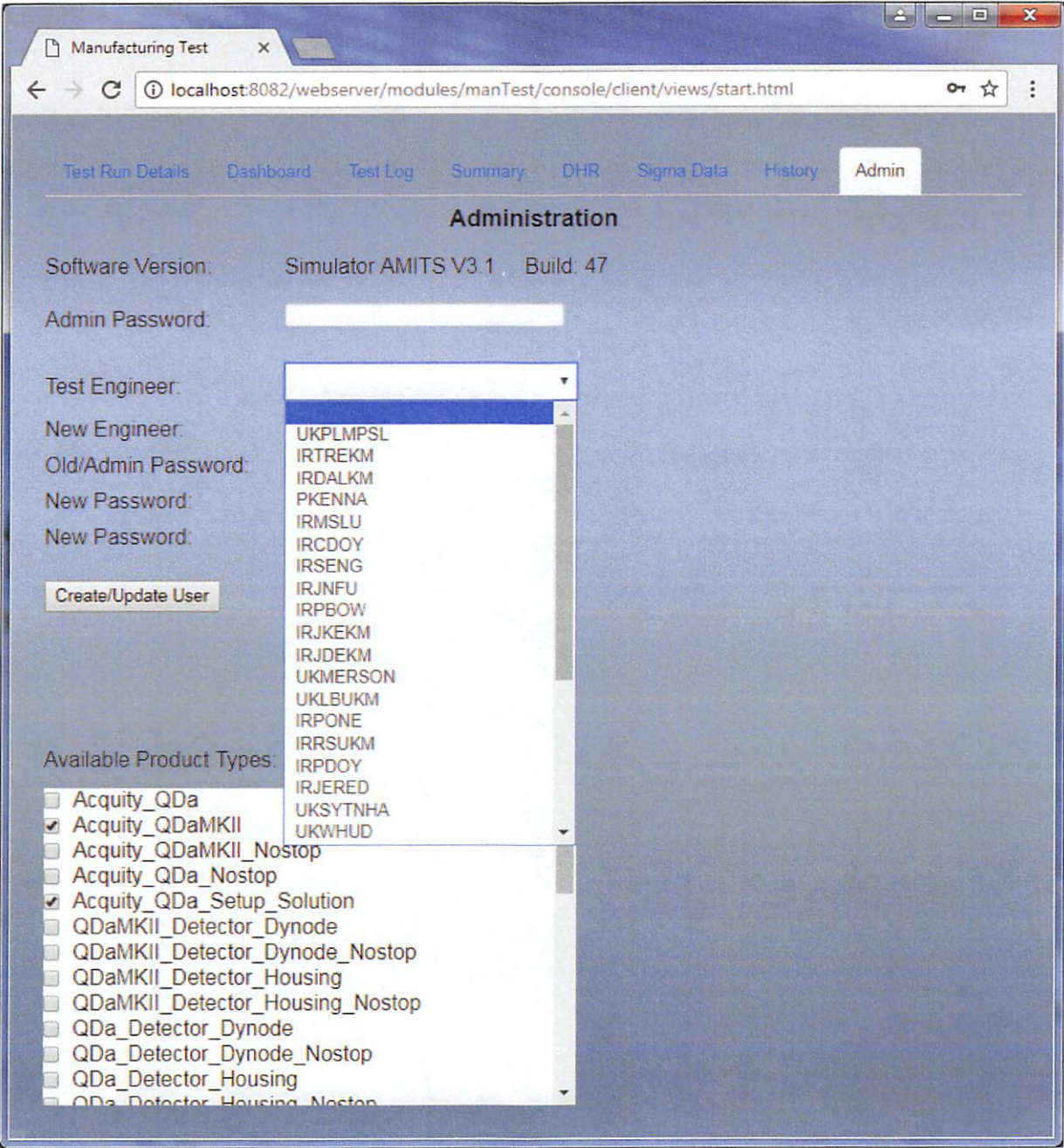
Below these fields are sections for "Location" and "Area":

- Location:** A dropdown menu showing "Venture" with a "Remove" button next to it. Below it is an "Add Location:" field with an "Add" button.
- Area:** A dropdown menu showing "Test Floor" with a "Remove" button next to it. Below it is an "Add Area:" field with an "Add" button.

The "Sigma Version:" field is a dropdown menu set to "7".

At the bottom, there is a section titled "Available Product Types:" with a list of checkboxes:

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

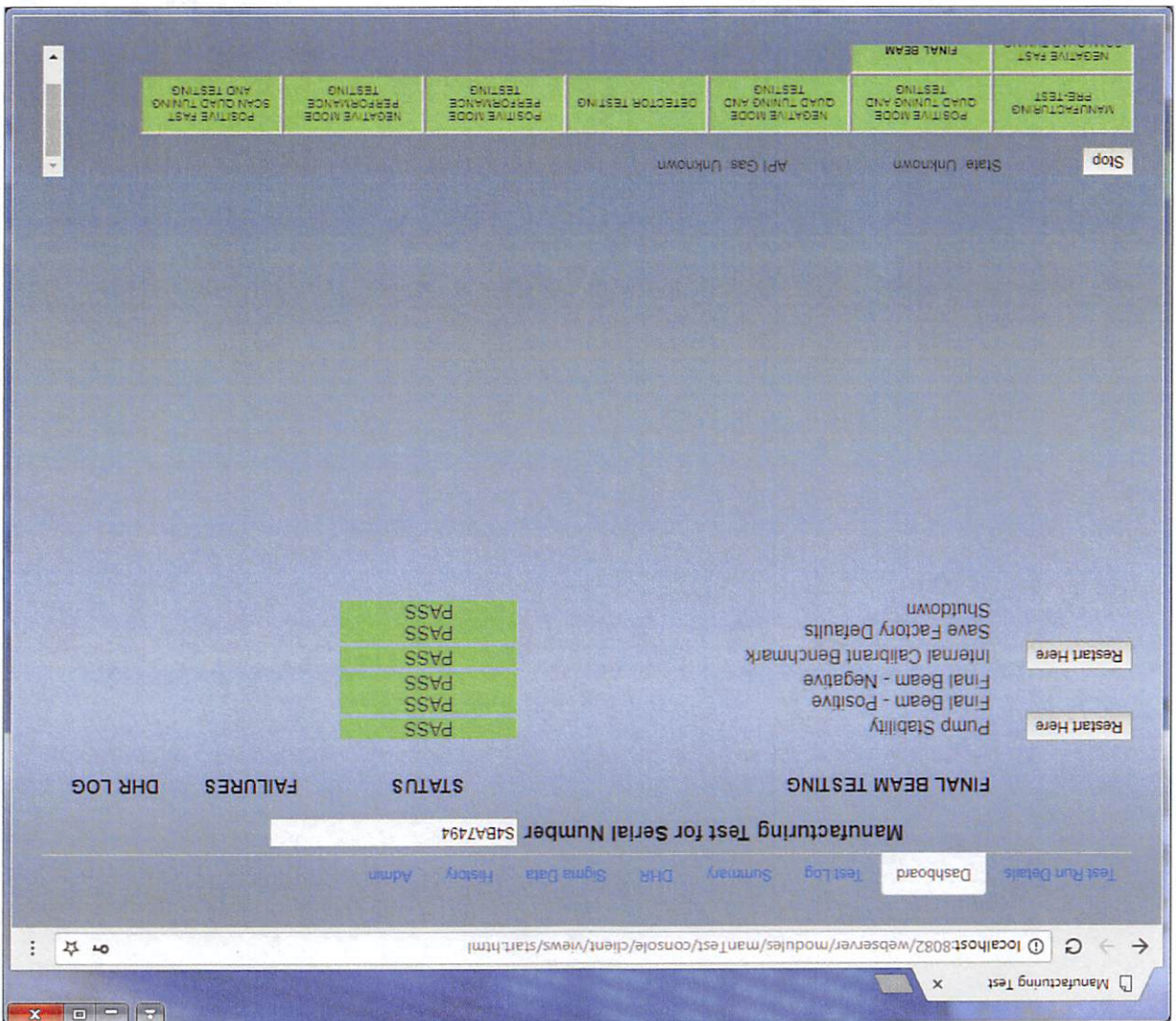


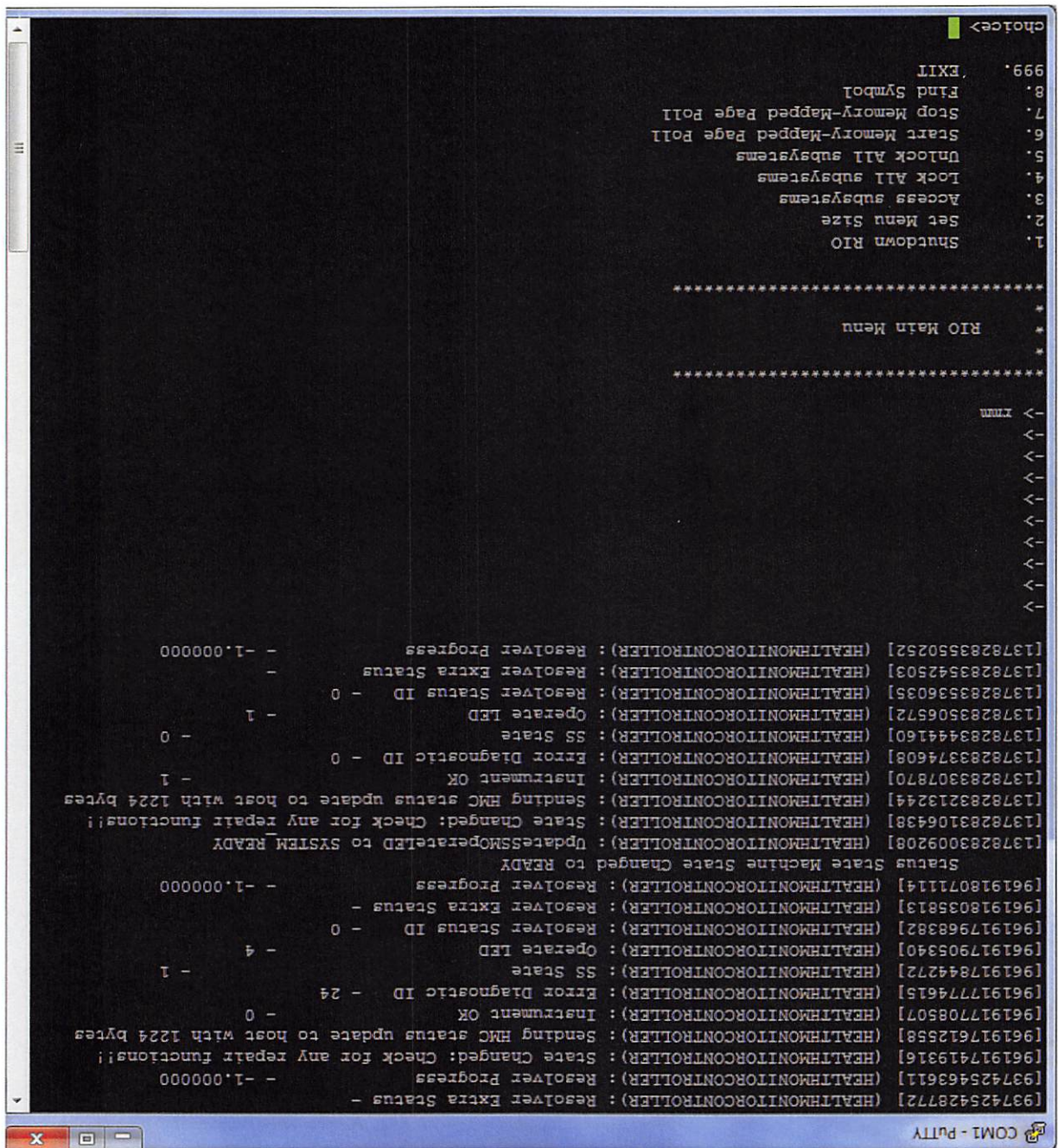
Manufacturing Test for Serial Number **EQ-Protocol**

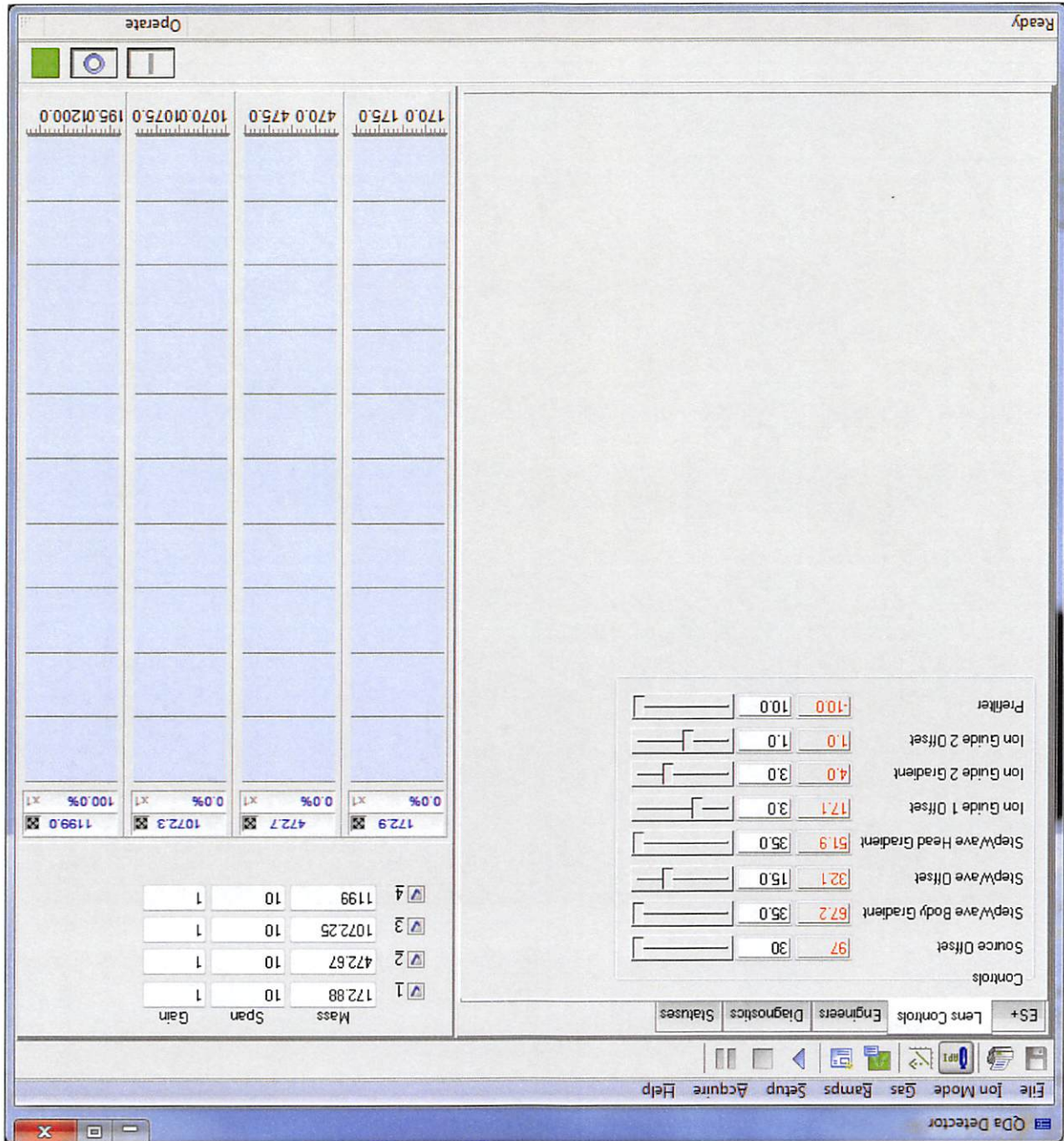
MANUFACTURING PRE-TEST	STATUS	FAILURES	DHR LOG
Start			
Simulator Configuration	PASS		
Instrument Preparation	PASS		
Manual Interlock	PASS		
Source Exhaust	PASS		
Source Leak	PASS		
Align Quad RF Generator	PASS		
Critical Voltages	PASS		
RF Breakdown	PASS		
Desolvation Heater	PASS		
Calibrant Heater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

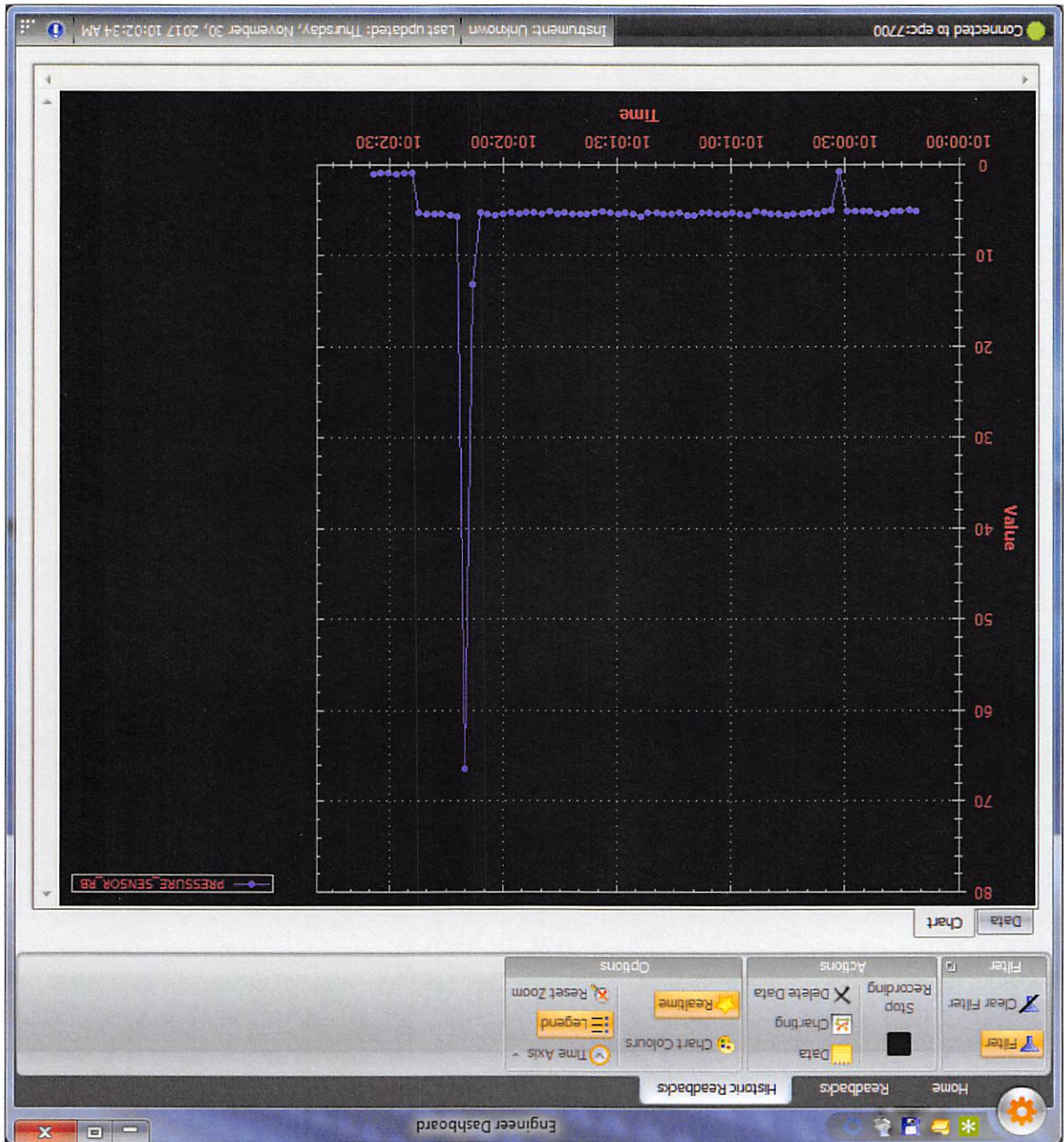
Stop State: Unknown API Gas: Unknown

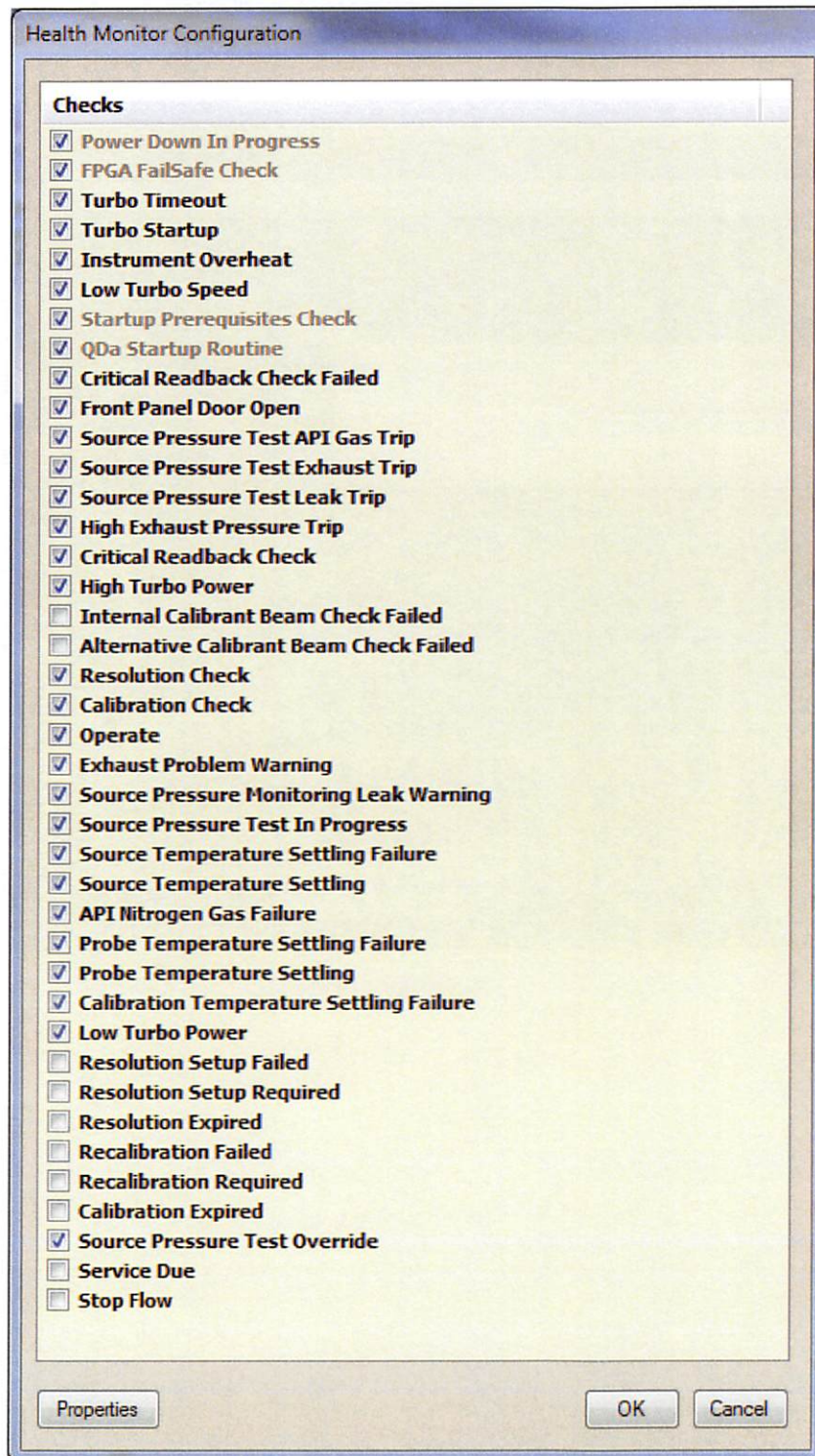
MANUFACTURING PRE-TEST	POSITIVE MODE QUAD TUNING AND TESTING	NEGATIVE MODE QUAD TUNING AND TESTING	DETECTOR TESTING	POSITIVE MODE PERFORMANCE TESTING
NEGATIVE MODE PERFORMANCE TESTING	POSITIVE FAST TUNING	NEGATIVE FAST TUNING	FINAL BEAM	











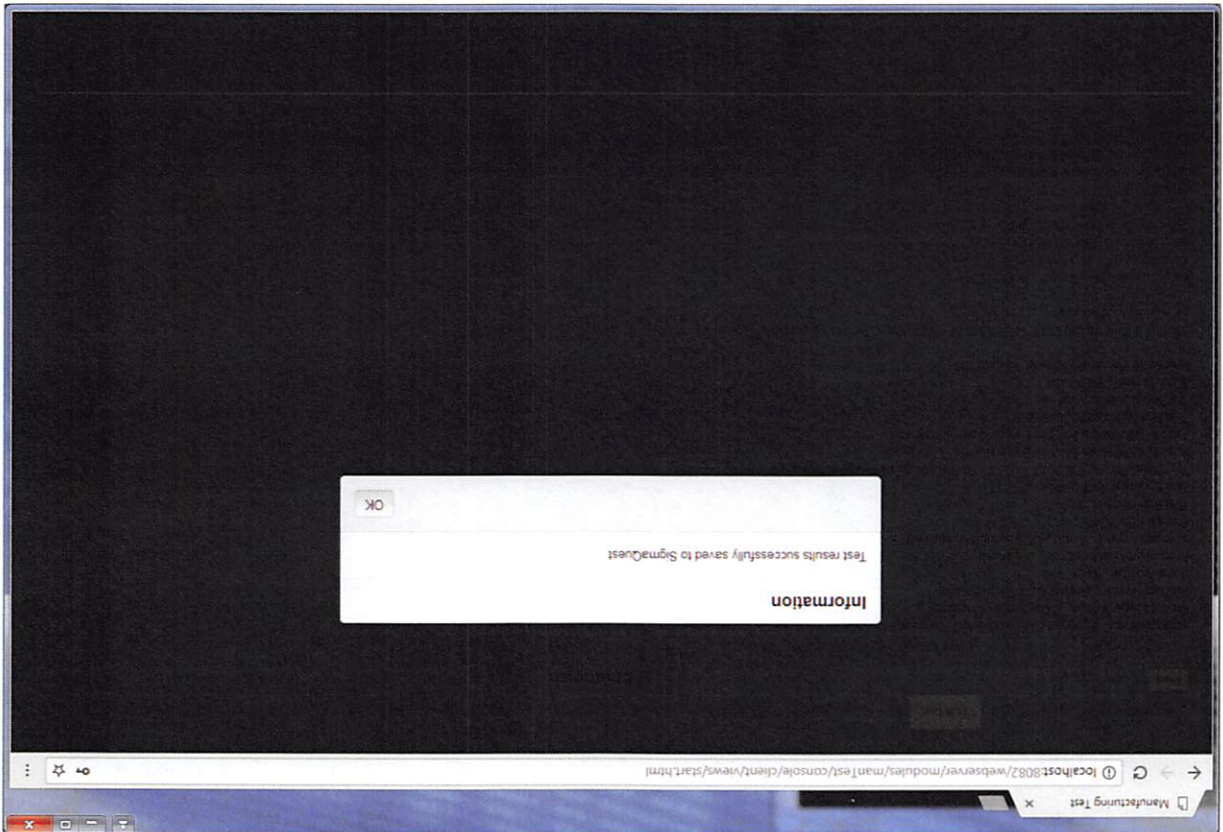
The image shows a 'Health Monitor Configuration' dialog box with a list of checks and their status. The dialog has a title bar, a list area, and buttons for 'Properties', 'OK', and 'Cancel' at the bottom.

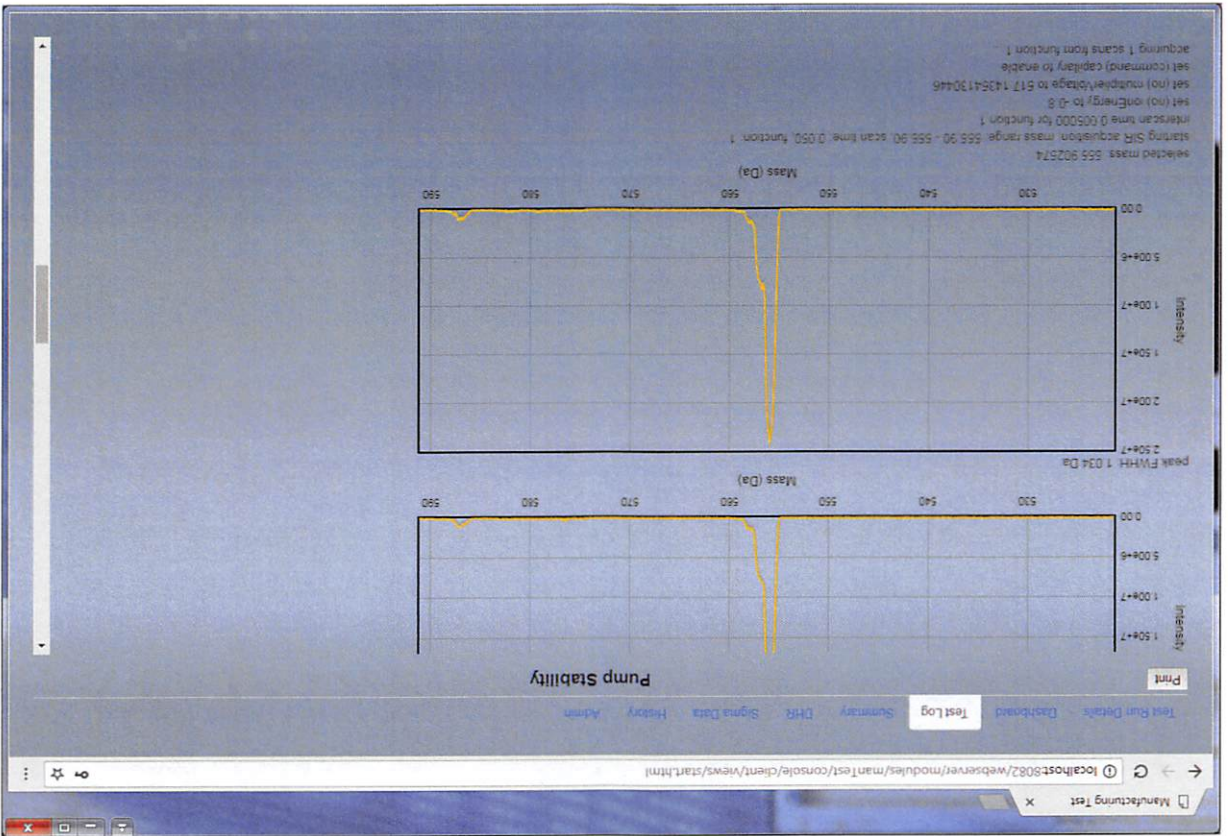
Check	Status
Power Down In Progress	Checked
FPGA FailSafe Check	Checked
Turbo Timeout	Checked
Turbo Startup	Checked
Instrument Overheat	Checked
Low Turbo Speed	Checked
Startup Prerequisites Check	Checked
QDa Startup Routine	Checked
Critical Readback Check Failed	Checked
Front Panel Door Open	Checked
Source Pressure Test API Gas Trip	Checked
Source Pressure Test Exhaust Trip	Checked
Source Pressure Test Leak Trip	Checked
High Exhaust Pressure Trip	Checked
Critical Readback Check	Checked
High Turbo Power	Checked
Internal Calibrant Beam Check Failed	Unchecked
Alternative Calibrant Beam Check Failed	Unchecked
Resolution Check	Checked
Calibration Check	Checked
Operate	Checked
Exhaust Problem Warning	Checked
Source Pressure Monitoring Leak Warning	Checked
Source Pressure Test In Progress	Checked
Source Temperature Settling Failure	Checked
Source Temperature Settling	Checked
API Nitrogen Gas Failure	Checked
Probe Temperature Settling Failure	Checked
Probe Temperature Settling	Checked
Calibration Temperature Settling Failure	Checked
Low Turbo Power	Checked
Resolution Setup Failed	Unchecked
Resolution Setup Required	Unchecked
Resolution Expired	Unchecked
Recalibration Failed	Unchecked
Recalibration Required	Unchecked
Calibration Expired	Unchecked
Source Pressure Test Override	Checked
Service Due	Unchecked
Stop Flow	Unchecked

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Attachment No: 10 , EQ016 05 13 DEC 2017

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[illegible]

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