

 Waters THE SCIENCE OF WHAT'S POSSIBLE.®	Equipment Qualification Assessment Form
Document No: EQAF0018	Version No: 00

EQAF Number	EQAF0018
Equipment Name	Venture ACQUITY QDa Test Bay and Network system
Model Number	Venture ACQUITY QDa Test Bays 1 - 4

Description:

The Venture ACQUITY QDa Network system currently consists of 4 test bays. There are two models for the Network based on whether the Waters network is permanently available or not through Venture.

Proposal 1 - Subcontractor model without permanent access to Waters Network.

Figure 1 shows the network model based on a system installed in a sub-contractor without any permanent link to Waters servers. This relies on the test bay PCs being linked to a storage PC via a switch. The data stored on the storage PC would need to be manually backed up to a server in Waters.

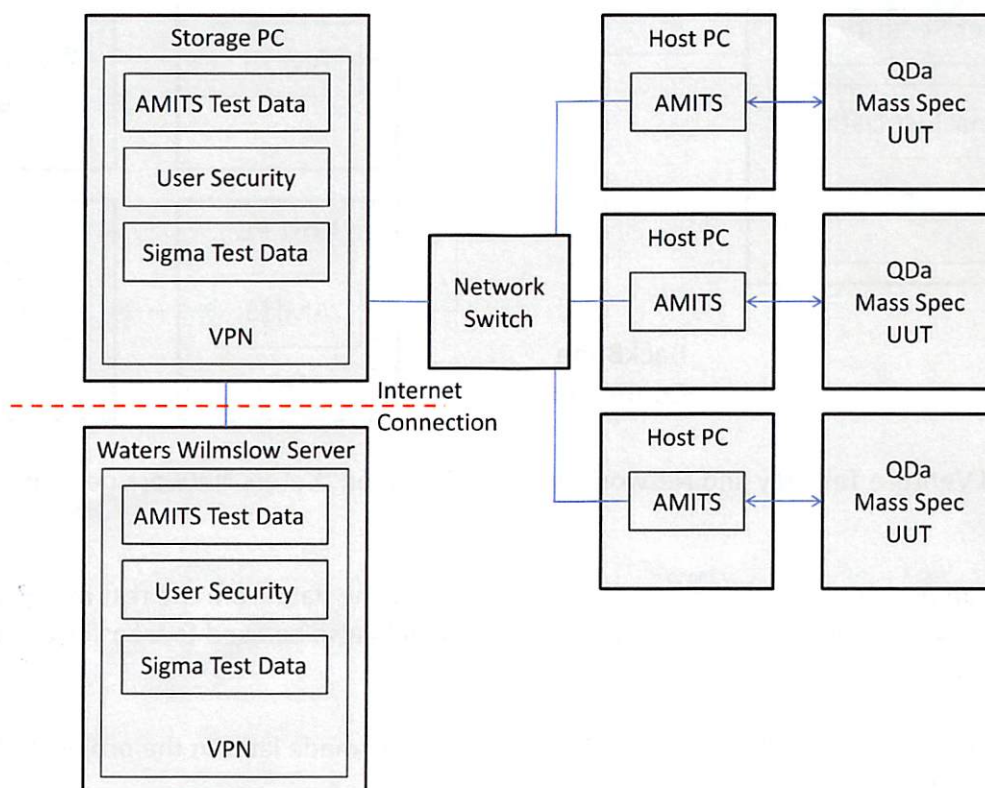


Figure 1 - Proposed Venture Test Bay and Network System – Based on a subcontractor model without permanent access to Waters Network.

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Qualification Assessment Form
Document No: EQAF0018	Version No: 00

The proposed data back up procedure uses a manually activated VPN link to copy the data on the storage PC to a server in Waters Wilmslow. The same manually activated VPN link would also be used to transfer trend analysis data to SigmaSure.

Proposal 2 - Permanent Access to Waters Network Model.

Figure 2 shows the network model based on a system installed in a sub-contractor with a permanent link to Waters servers. This relies on the test bay PCs being linked to a server in Waters.

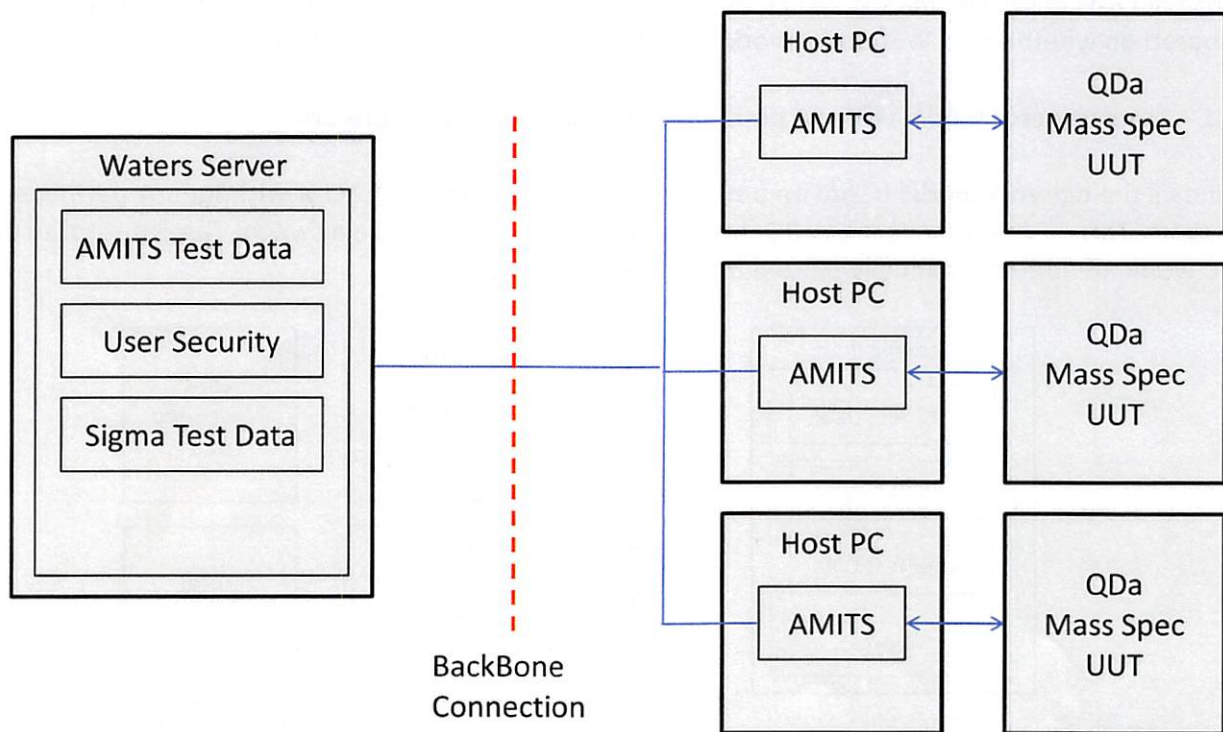


Figure 2 - Proposed Venture Test Bay and Network System – Based on Waters Network being permanently available.

The proposed back up procedure uses a link to automatically copy the data from the test bay PCs to a server in Waters Wilmslow or Wexford in real-time. The same process would also be used to transfer trend analysis data to SigmaSure in real-time.

Confirmation of the system choice (Proposal 1 or Proposal 2) will be made later in the project before the EQ protocols are produced.

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Qualification Assessment Form
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Test Bay System

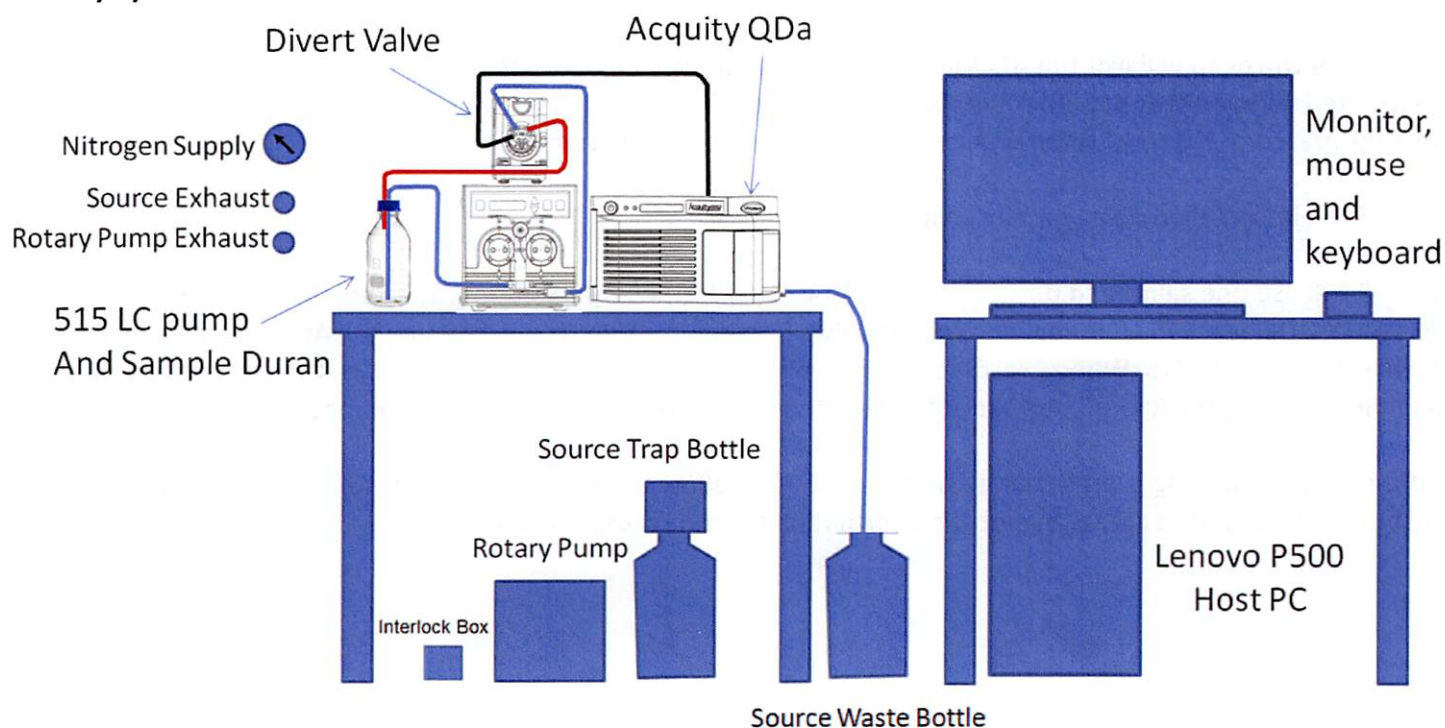


Figure 3 - Proposed Venture Test Bay System

Each test bay system (figure 3) is designed to receive an ACQUITY QDa, and allow it to be pumped under vacuum once it is powered up. The ACQUITY QDa vacuum system consists of a turbo molecular pump that is supported by the test bay rotary pump. The rotary pump is a "wet" pump that uses oil to achieve its pumping action.

The rotary pump exhaust is contaminated with oil vapour. It will exit the rotary pump via an oil condensing filter attached to the rotary pump. The exhaust gas is then connected to a dedicated Rotary Pump Exhaust port associated with the test bay. There is a site requirement for the Rotary Pump Exhaust system that prevents any build up of back pressure, or cross contamination to any other exhaust systems.

The rotary pump is placed on a tray to capture any oil that condenses on the unit and escapes the Rotary Pump Exhaust system.

Once the ACQUITY QDa achieves an acceptable level of vacuum, it will perform a number of firmware driven tests.

Once the firmware tests have completed, the ACQUITY QDa will be ready for testing by a validated version of Automated Manufacturing Instrument Test Software (AMITS) designed to test the ACQUITY QDa.

The firmware driven tests, and AMITS will require that the instrument is supplied with Nitrogen within a specified

 THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Qualification Assessment Form
Document No: EQAF0018	Version No: 00

pressure range.

The waste Nitrogen will exit the ACQUITY QDa via the source trap bottle to a dedicated Source Exhaust port associated with the test bay. There is a site requirement for the source exhaust system that prevents any build up of back pressure, or cross contamination from any other exhaust systems.

AMITS will be installed on a test bay host PC.

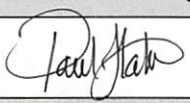
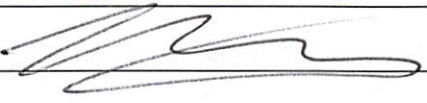
AMITS will use one sample to perform the tests, ACQUITY QDa Setup Solution. The sample is delivered to the ACQUITY QDa by a 515 LC pump, via a divert valve. The divert valve is controlled by the ACQUITY QDa, which in turn is driven by AMITS. When AMITS requires sample, the divert valve sends sample to the instrument. When sample is no longer required, the sample is diverted back to the sample supply Duran bottle.

Other software packages are required on the host PC to allow the Venture engineer to read the ACQUITY QDa test procedure, and to gather diagnostic information for root cause analysis.

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Qualification Assessment Form
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Operator		Paul Slater	
Department		Product Assurance Engineer	
Sections	Questions	Enter X in box below	
A	Is the Equipment used in manufacturing, testing, packaging, filling, labelling, environmental control or storage of product?	YES X	NO
If "Yes" then continue to section B. If "No" then the equipment is EXEMPT – go to section F.			
B	Does the equipment have moving parts or electrical control systems, such as an HMI?	YES X	NO
If "Yes" then continue to section D. If "No" then continue to section C.			
C	Is the equipment required for production, test or control of any critical to quality attributes?	YES X	NO
If "Yes" then equipment requires VERIFICATION – go to section G If "No" then the equipment is exempt from qualification and can be put into general use.			
D	Does the equipment make a decision which can affect product	YES X	NO
If "Yes" then equipment requires QUALIFICATION – go to section H If "No" then continue to section E			
E	Would the improper set-up (installation and or configuration) of the equipment impact the assessment or production of product?	YES X	NO
If "Yes" then equipment requires QUALIFICATION – go to section H If "No" then equipment requires VERIFICATION – go to section G			
Outcome (Enter X in box below)			
Exempt		Verification	☒ <i>er</i> 24 OCT 2017
		Qualification	X
F	Exempt		
N/A			
G	Verification		
N/A			

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Qualification Assessment Form
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H	Qualification		
Qualification is deemed required. An equipment Qualification Plan should now be produced. For all equipment requiring qualification, the EQAF number now becomes the project number.			
I	Attachments		
Attachment No.	Details	No. of pages	Operator Initials
J	Approvals		
Completed by	Signature	Job Title	Date
Paul Slater		Principle Product Assurance Engineer	19 OCT 2017
Approved by	Signature	Job Title	Date
Edwina Beanland		Process Validation Engineer	23 OCT 2017
Paul Merson		Product Assurance Director	19 OCT 2017
David Bentley		Quality Validation Engineer	24 OCT 17