

Waters		IQ for 2475 / FLR Final Test Station No.1 for	
THE SCIENCE OF WHAT'S POSSIBLE.™		execution in Venture	
Document No:0274-IQ		Version No:00	

INSTALLATION QUALIFICATION PROTOCOL

For the 2475 / FLR Final Test Station No.1

PREPARED BY

Name	Role	Signature	Date
Neil Kinsella	Manufacturing Engineer		19 April 2013

REVIEWED BY

Name	Role	Signature	Date
Derry O'Donovan	Engineering Manager		22 Apr - 2013
Barry Duggan	Manufacturing Manager		24 Apr 13
Eleanor Berney	Planning Manager		25 APR 13.

APPROVED BY

Name	Role	Signature	Date
Tadhg Cassidy	Quality Manager		26 Apr 13

The "Prepared By" signature denotes that this document accurately describes the Installation Qualification activities.

The "Reviewed By" signature[s] denotes agreement with the description of the Installation Qualification activities to be undertaken

The "Approved By" signature denote that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

Version	Author	Date	Summary of change
00	Neil Kinsella	19-April-2013	First document for approval

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1.0 Purpose

The purpose of this protocol is to define the qualification procedure for the 2475 / FLR Final Test Station No.1, henceforth referred to as “Test Station” located at Venture in Singapore.

This qualification protocol is designed to document the Installation Qualification (IQ) for the Test Station. This shall be accomplished by assuring that the equipment is installed according to the manufacturer’s recommendations and Waters’ requirements. When all test requirements are completed (including all relevant attachments) and release approval given, this section of the protocol forms the record of Installation Qualification for the Test Station

1.1 General

The validation effort will comply with the Waters Process Validation Policy [1].

The operations at Waters which impact on product safety and effectiveness including all validation related activities are therefore, carried out in accordance with this policy, regulations and guidelines.

A Report (Test Report (TR) or Validation Report (VR)) will be written that captures the results of the Installation Qualification of Test Station. The report will outline the results of the Installation Qualification for Test Station as outlined in this protocol. All deviations as well as any notable findings will be discussed and the resolution of all issues will be presented.

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2.0 Responsibilities

It is the responsibility of the qualification team to develop the requirements for conducting the qualification. The end user department/equipment owner will supervise the team activities and co-ordinate the qualification effort.

Task	Responsible Group(s)
Design Equipment	Milford Engineering
Install Equipment	Milford Engineering
Commission Equipment	Milford Engineering
Prepare Protocol	Engineering, Quality
Review Protocol	Engineering, Quality
Calibrate Instruments	Engineering
Create Procedures	End User Dept.
Train Personnel	End User Dept.
Approve Protocol	Engineering, End User Dept., Quality
Execute Protocol	Venture
Prepare Summary Report	Engineering
Approve Summary Report	Engineering, End User Dept., Quality

3.0 Training

Persons other than the protocol pre-approvers, involved in this validation study, will be trained concerning the content of this protocol. This section must only be filled out if persons, other than the protocol pre-approvers, are involved in testing.

Name (Block Letters)	Date of training	Signature / Date (Trainee)	Signature / Date (Trainer)
TAM HONIA CHENA	26- APRIL- 2013	Tam H.C. 29-MAY-2013	

Note: Attach training records and document in attachment 3 of this protocol.

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4.0 General Procedure

Completion of Installation Qualifications is governed by 730000897 “Process V: Qualification Procedure” [2]. General abbreviations that may be used throughout the protocol include, but are not limited to, the following:

Abbreviation	Explanation	Abbreviation	Explanation
Amps	Amperes	Comm.	Commissioning
CPP	Critical Process Parameter	CQA	Critical Quality Attribute
°C	Degrees Celsius	°F	Degrees Fahrenheit
FAT	Factory Acceptance Testing	FDS	Functional Design Specification
Hz	Hertz	HMI	Human Machine Interface
ID	Identification	IQ	Installation Qualification
IQ/OQ	Installation Qualification & Operational Qualification	kg	Kilogram
LHS	Left Hand Side	Max.	Maximum
Min.	Minimum	N/A	Not Applicable
#	Number	OQ	Operational Qualification
PQ	Performance Qualification	P & ID	Piping & Instrumentation Diagram
POU	Point of Use	psig	Pounds per Square Inch Gauge
PLC	Programmable Logic Controller	QSR	Qualification Summary Report
rpm	Revolutions Per Minute	RHS	Right Hand Side
s	seconds	S/N	Serial Number
SAT	Site Acceptance Testing	SS	Stainless Steel
SOP	Standard Operating Procedure	TEMP	Temperature
URS	User Requirements Specification	WI	Work Instruction

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Prior to the execution of the protocol, Section 3.0 of the protocol should be completed to identify the authorised personnel responsible for carrying out the checks.

Unless specifically described, it is not a requirement that the individual test sheets contained in this protocol be executed in order.

Each checkbox is to be completed by the authorised personnel only.

All entries to be completed in accordance with Procedure: 730000523 "Good Documentation Practices (GDP)" [3].

All supporting documentation utilised for the completion of the protocol checks must be signed and dated ready to be scanned into the Waters Corporation document control system.

Each page of the supporting documentation used to verify the checks must be signed and dated with the associated Protocol Reference Number recorded.

All protocol checkboxes must be completed, blank spaces are not permitted. Where the checkbox is not applicable, the checkbox must be inserted with the letters "N/A"

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5.0 Test Station

5.1 Background

2475 and FLR detectors are tested on the test station. The test station consists of:

- PC
- Bottle of Water
- Bottle of Methanol
- Waste container
- Waters 1525 Pump
- Waters EV700 Valve

The PC on the test station runs a custom piece of LadView s/w which is used to control the 1525 pump, the EV700 valve and run a series of tests on the instrument that is connected to it. The operator connects a detector to the test station via an Ethernet cable. The LadView s/w then runs a series of tests on the detector which will verify that the instrument is operating correctly.

The 1525 pump is used to pump water through the flow cell during the testing, and pumping methanol through the flow cell for flushing it out. The EV700 valve is used to supply nitrogen to the flow cell to flush out the methanol after test.

The following tests are performed on the detector during test.

- Initialisation test
- Calibration test
- PMT calibration test
- Normalize test
- Re-start test
- Rayleigh test
- Raman test
- R-R valley test
- Wl resolution test
- Stray Ratio test
- Signal to noise test

This equipment has been used in the Wexford LC department successfully for 2 years. The equipment will be validated in Wexford before it is sent to Venture in Singapore for use there. This validation will then be done in Singapore to verify that the equipment operates as expected and that nothing has changed in transport.

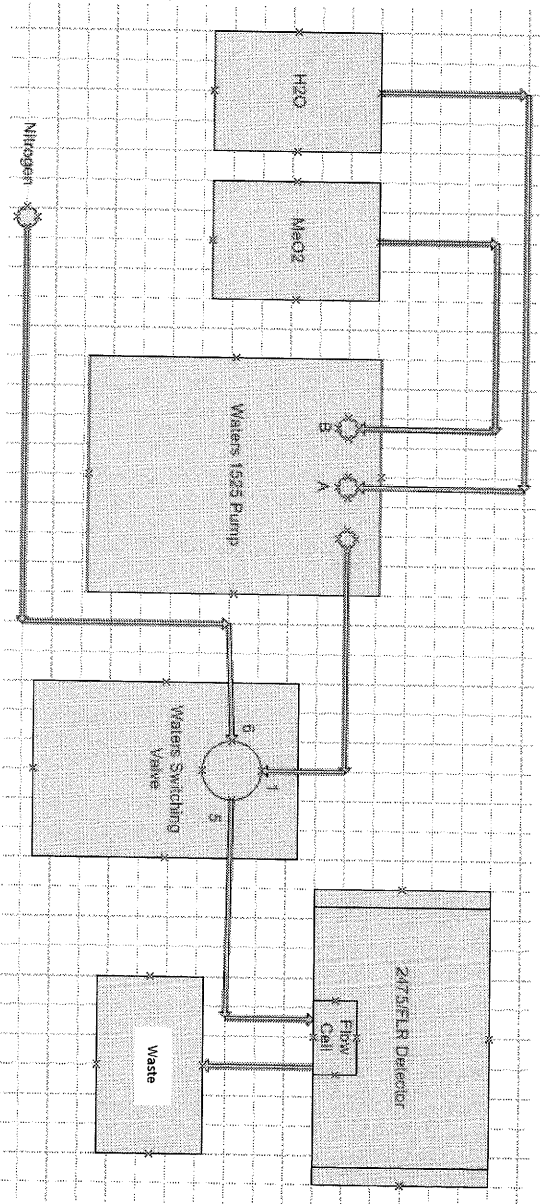
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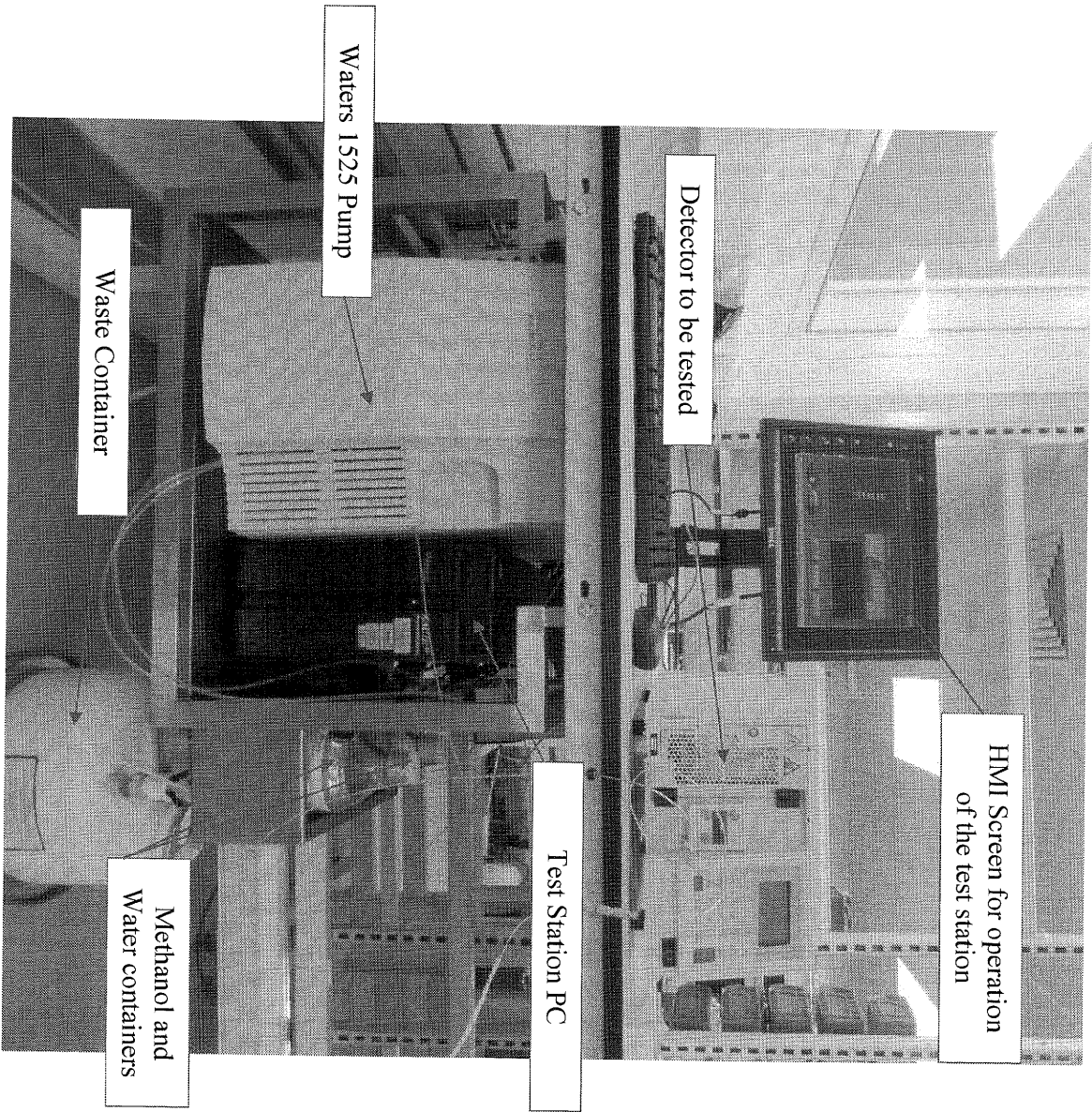
5.2 Sequence of Events

The Asset number for the Test station is WX2145
The system is set up as shown below.

- The operator connects the instrument to the test station by plugging in the ethernet cable and connecting the flow cell to the line from the switching valve.
- The operator then starts the test by scanning the instrument serial number and inputting their name into the test s/w.
- The test station performs all tests automatically without any input from the operator.
- If a test is passed, the light beside the description of that test turns green. If a test is failed, the light turns red and testing is aborted.
- When the test is complete and all tests have passed, the flow cell is flushed out first with methanol and then with nitrogen.

A more detailed description of this procedure can be found in 735000615, TEST SPEC AND PROC, 2475 FINAL TEST.





5.3 Study Rationale

This document will be used to record the state of the Test Station after it has been transferred to Venture in Singapore for use over there. A similar validation protocol will have been done in Wexford to benchmark the state of the equipment before the transfer. The validation report mentioned in section 1.1 above will compare the results of the two validations and show that the equipment operates, in Venture, as it did in the Wexford plant.

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5.4 References

The current approved versions of the following documents are referenced within this document:

Reference	Document Number	Document title
[1]	730000837	Process V.: Process Validation Policy
[2]	730000897	Process V.: Qualification procedure
[3]	730000523	Good Documentation Practices (GDP) Procedure
[4]	735000615	TEST SPEC AND PROC, 2475 FINAL TEST

6.0 Installation Qualification (IQ)

6.1 Scope & Rationale

The extent and scope of the qualification activities to be performed in this study have been determined in accordance with the current site change control procedure. [4]

The scope of this study is the qualification of the Final Test Station No.1 in Venture in Singapore.

The following tests are mandatory for all IQ studies:

- IQ-01 Training Confirmation
- IQ-02 Documentation Verification
- IQ-03 General Safety Check
- IQ-04 Drawings Verification
- IQ-05 Utility Connection Verification
- IQ-06 Equipment Component Verification
- IQ-08 Software Version

Additional tests should be added to the Traceability Matrix, Section 6.2, and the appropriate test scripts added.

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6.2 Traceability Matrix

The following test scripts will be executed to provide documented evidence that the test parameters have met with defined acceptance criteria.

Test Script	Section No	Qualification Rationale
Training Confirmation	IQ-01	To ensure the executor of the qualification protocol is suitably trained to do so
Associated Documentation Verification	IQ-02	To verify that supporting documentation is available prior to the completion of qualification
General Safety Check	IQ-03	To verify that the equipment can operate in a safe manner, within it's designated location
Drawing Verification	IQ-04	To verify that the electrical drawings are supplied with the equipment.
Utility Connection Verification	IQ-05	To verify that the correct utilities are connected to the test station.
Equipment Component Verification	IQ-06	To verify that all necessary is present and correct
Software Version	IQ-08	To record the version of the software that the test station is currently using

Any deviations during the execution of this Installation Qualification protocol must be reported and investigated.

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6.3 IQ Test Scripts

Test name: Training Confirmation			Test no.: IQ-01	
Purpose: To ensure the executor of the qualification protocol is suitably trained to do so, the following test script must be executed to provide documented evidence testing.				
Requirement	Yes / No / N/A	Pass / Fail	Initial & Date	
Executor is trained in this protocol	Yes	Pass	TKU H.C. 29-MAY-2013	
Executor is trained in procedure 735000615	Yes	Pass	TKU H.C. 29-MAY-2013	
Training Record(s) Attached	Yes	Pass	TKU H.C. 29-MAY-2013	
Comments: N/A				
Overall Test Conclusion: Pass ☒ Fail ☐				
Performed By:	Initial	Signature	Date	
TKU HONK ONENA	Tom H.C.	[Signature]	29-May-2013	
Reviewed By	Role	Signature	Date	

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Test name: Associated Documentation Verification		Test no.: IQ-02
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Purpose:

To verify that supporting documentation for the Alignment Station are available prior to the completion of qualification.

Test execution:

Complete the table below and attach supporting documentation as available.

Type	Title; Doc. No.; Rev. No.	Approved (Yes \ No \ N/A)	Initial & Date
SOP	TEST SPEC AND PROC, 2475 Final Test, 735000615, Rev:14	Yes	Tom H-C 29-MAY-2013

Comments:

N/A

Performed By:	Initial	Signature	Date
TAM KOUNA CHEN	Tom H-C.		29-MAY-2013
Reviewed By	Role	Signature	Date

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Test name: General Safety Check			Test no.: IQ-03
Purpose: To verify that the Alignment Station can operate in a safe manner, within it's designated location			
Test execution: Perform an inspection of the equipment to assess its safety related condition. Note: If any of the below requirements are not met then the overall test conclusion is deemed "Fail"			
Requirement		Actual (Y / N)	Initial & Date
General	Is the equipment CE (or other required H&S certification) marked?	Y	Tan H.C. 29-MAY-2013
Pressure	Pressure ratings of piping components / pressure vessels are compatible with operating conditions?	Y	Tan H.C. 29-MAY-2013
Pumps	Have facilities lines been adequately secured?	Y	Tan H.C. 29-MAY-2013
	Do the pumps and motors have over temperature & over pressure protection?	Y	Tan H.C. 29-MAY-2013
Power Down Test	Does the system returns to a safe state following a power cycle?	Y	Tan H.C. 29-MAY-2013

Comments: N/A

Overall Test Conclusion:		Pass ☒	Fail ☐
Performed By:	Initial	Signature	Date
Tan HONG CHUAN	Tan H.C.		29-MAY-2013
Reviewed By	Role	Signature	Date
Approved By [End User]	Role	Signature	Date
Leo Kok Leong	Section Manager		30-May-13

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Test name: Drawings Verification		Test no.: IQ-04
Purpose: To verify that drawings exist and are current.		
Test execution: Record reference of drawings in the table below.		
Type	Title, Drawing No.; Rev. No.	Initial & Date
Electrical Diagram	Final Test Station No 1 0261-1A-04, Rev 0	TAKH.C. 29-MAY-2013
Comments: N/A		
Performed By:	Initial	Signature
TAKHAK CHENGA	TAKH.C	[Signature]
Reviewed By	Role	Signature
		Date
		29-MAY-2013

Test name: Utility Connection Verification

Test no.: IQ-05

Purpose:

To check the correct connections of utilities.

Test execution:

Check that the correct utilities are connected to the equipment

Utility	Expected Result	As found	Instrument Used	Pass / Fail	Initial & Date
Electrical Supply	230Vac, 50Hz, Single Phase	219.9Vac	3070081457	Pass	Tan H.C. 29-MAY-13
Water	See attachment no.4	as expected	N/A	Pass	Tan H.C. 29-MAY-13
Waste	Waste container under station	as expected	N/A	Pass	Tan H.C. 29-MAY-13
Nitrogen	500psi < X < 1000psi	900psi	N/A	Pass	Tan H.C. 29-MAY-13
Methanol	Bottled Methanol under station	as expected	N/A	Pass	Tan H.C. 29-MAY-13

Comments:

N/A

Overall Test Conclusion:

Pass



Fail



Performed By:	Initial	Signature	Date
Tan HONK HEEAN	Tan H.C.		29-MAY-13
Reviewed By	Role	Signature	Date

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Test name: Equipment Component Verification			Test no.: IQ-06	
Purpose: To confirm equipment component details of all the critical system components for Equipment Description as defined in the system description of this protocol.				
Test execution: For each component listed, record the as-found conditions for in the data table below. Record whether or not the component should be included in a Spare Parts List				
Component Verification		As found	Required Spare Part (Yes/No)	Initial & Date
1525 Pump	Manufacturer	WATERS	No	Tan H. C. 29-MAY-2013
	Model / Type	1525/Binary HPLC Pump		
	Component identification	G0925P662R		
EV700 Valve	Manufacturer	WATERS	No	Tan H. C. 29-MAY-2013
	Model / Type	EV700-100-WA		
	Component identification	78552		
PC	Manufacturer	WATERS	No	Tan H. C. 29-MAY-2013
	Model / Type	LAC / E 32		
	Component identification	M09L32135W		
Monitor	Manufacturer	DELL	No	Tan H. C. 29-MAY-2013
	Model / Type	P1705		
	Component identification	13S-046S		
Comments: N/A				
Overall Test Conclusion:				
Performed By:		Pass ☒	Fail ☐	
THO HONG CHEN		Initial	Signature	Date
THO HONG CHEN		Tan H. C.		29-MAY-2013
Reviewed By		Role	Signature	Date

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Test name: Instrumentation Verification				Test no.: IQ-07	
Purpose: To list all critical instruments associated with Alignment Station and to verify that all critical instruments are in the calibration system and calibrated. (Note: this does not include test instruments used for the qualification – these will be recorded in Attachment 2)					
Test execution: Verify that all critical instruments are calibrated and have been included in the Calibration schedule. This is verified by obtaining a calibration due date from the calibration system. Attach calibration certificates.					
Description / Asset No	Instrument Usage range	Calibrated range	Calibration frequency	Calibration due date	Initial & Date
Temperature Controller (#)	0 to 200°C				
Timer (#)	0 to 10 sec				
Pressure Gauge (#)	0 to 10 bar				
Comments:					
Overall Test Conclusion: Pass ☐ Fail ☐					
Performed By:	Initial	Signature			Date
Reviewed By	Role	Signature			Date

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Test name: Software Version		Test no.: IQ-08	
Purpose: To verify that the installed firmware/software details have been recorded.			
Test execution: Verify the PLC/software program Where applicable a backup copy of the PLC / software must be created.			
List	As found	Pass / Fail	Initial & Date
Software manufacturer	WATERS MALFORD TEST EQUI	Pass	Tan H.C. 29-May-2013
Software version / revision	2.0	Pass	Tan H.C. 29-May-2013
Backup copy	\\\Venture\IT Test Engineering\VTES2460-5	Pass	Tan H.C. 29-May-2013
Comments: N/A			
Overall Test Conclusion:			
Pass ☒		Fail ☐	
Performed By:	Initial	Signature	Date
Tan HONG CHEN	Tan H.C.		29-May-2013
Reviewed By	Role	Signature	Date

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7.0 Verification of Completion of Installation Qualification Testing

Qualification Test	Executed [Yes / No]	Complies [Pass / Fail / N/A]	Deviation No. (if applicable)	Initial / Date
Training Confirmation	Yes	Pass	N/A	Tan H. C. 29 MAY 2013
Associated Documentation Verification	Yes	Pass	N/A	Tan H. C. 29 MAY 2013
General Safety Check	Yes	Pass	N/A	Tan H. C. 29 MAY 2013
Drawing Verification	Yes	Pass	N/A	Tan H. C. 29 MAY 2013
Utility Connection Verification	Yes	Pass	N/A	Tan H. C. 29 MAY 2013
Equipment Component Verification	Yes	Pass	N/A	Tan H. C. 29 MAY 2013
Software Version	Yes	Pass	N/A	Tan H. C. 29 MAY 2013

Comments:

N/A

Performed By	Initial	Signature	Date
Tan H. C.	Tan H. C.		29 MAY 2013
Approved By	Role	Signature	Date

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8.0 Release of Installation Qualification

Review and complete the following:

	Yes / No / N/A	Performed by, Date
IQ testing resulted in Deviations.		
If Yes, Deviations must be raised and addressed as per SOP 730000897, and referenced on test sheet and deviation list (Attachment 1).	No	Tan H. C. 29 MAY 2013
If No, proceed to next point		
All installation qualification test sheets are complete and comply with respective requirements (See Section 7.0)		
If No, proceed to Section 8.1	Yes	Tan H. C. 29 MAY 2013
If Yes, enter N/A in section 8.1 and proceed to Section 8.2		

8.1 Installation Qualification Release Provisional Approval

If it is proposed to continue to Operational Qualification execution prior to completing Installation Qualification, this section must be completed. The justification for commencing Operational Qualification under these conditions is that the issues, detailed below, are not considered likely to have an adverse impact on the Operational Qualification. The Protocol Executor must prepare this rationale, which must be approved.

Installation Qualification issues are as follows (attach supporting documentation as required):

Prepared By:	Role	Signature	Date
TAN HONG CHENG	MANUFACTURING EXECUTIVE		29-MAY-2013
Reviewed By	Role	Signature	Date

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By signing this section, those people below agree that outstanding items included in section 8.0 have been reviewed but are not fully closed. These outstanding items are deemed not to have a critical impact on the product quality, system operability, safety or compliance and therefore the Test Station is now released for Operational Qualification (OQ). Full approval will only be given when these outstanding issues are deemed fully closed.

Installation Qualification (IQ) has been performed, has been reviewed by Waters Technical Personnel, and has outstanding items that are deemed not critical to product quality. Test Station is provisionally released for Operational Qualification (OQ)

Approved By	Role	Signature	Date
Derry O'Donovan	Engineering Manager		
Approved By	Role	Signature	Date
Barry Duggan	Manufacturer Manager		
Approved By	Role	Signature	Date
Tadhg Cassidy	Quality		

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8.2 Installation Qualification Release Full Approval

By signing this section, those people below agree that the requirements of Installation Qualification have been reviewed and are deemed acceptable. Additionally, any outstanding issues, as detailed in Section 8.0, have been reviewed and are now closed out.

Installation Qualification (IQ) has been successfully performed, has been reviewed by Waters Technical Personnel, and is acceptable. Test Station is now released for Operational Qualification (OQ)

Performed By:	Role	Signature	Date
<i>THAO HONG CHEN</i>	<i>MANUFACTURING ENGINEER</i>	<i>[Signature]</i>	<i>24-MAY-2013</i>
Approved By	Role	Signature	Date
Derry O'Donovan	Engineering Manager		
Approved By	Role	Signature	Date
Barry Duggan	Manufacturer Manager		
Approved By	Role	Signature	Date
Tadhg Cassidy	Quality		

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9.0 Attachments

Attach. No.	Documents/Contents	Section Ref.	Document Ref.	No. of Pages
1	Deviation List	N/A	N/A	
2	Deviation Report	N/A	A	
3	Training Records	IQ-01	N/A	2
4	Water Specification	IQ-05	N/A	1
5	Milli-Q Calibration report	IQ-05	N/A	4
6	(TOC) Analyzer	IQ-05	N/A	2
7	Electrical Drawing	IQ-04	N/A	1
8	Venture set up	5.2	N/A	1
9		N/A		
10		N/A		

Attachment 1 - Deviation List

Record references to any and all (make multiple copies as required) deviations raised during the execution of this Installation Qualification protocol in this attachment.

Attachment 2 – Deviation Report

Fill in all information required. Complete all sections of the deviation report as required. If no deviations occur during protocol execution, a diagonal line will be drawn across the deviation form, with date and initials.

Attachment 3 – Training records

Record references to any training that is required for the execution of this study.

Attachment 1 - Deviation List

Deviation Report No.	Test Section No.	Date Raised	Date Closed	Verified By	Date
</					

ATTACHMENT 2 - Deviation Report Form

The purpose of this form is to record the details of each deviation found while executing or performing tests listed in this protocol.

1. Record the details of each deviation found while executing or performing tests listed in this protocol.
2. Record details of any proposed corrective actions that may be required in order to allow the IQ to move to the next step.

3. Record details of the deviation resolution that allows the IQ to move to final approval stage.
4. If no deviations are found mark the page as N/A. Where more than one deviation is found make additional copies of this page.

[illegible]

Attachment 3 – Training Records

[illegible]

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Attachment 4 – Water Specification

Milli-Q® water (sourced from a Q-POD unit)	
Parameter	Value
Resistivity, MΩ•cm @ 25 °C	18.2
TOC, ppb (µg/l)	< 5
Bacteria, cfu/ml	< 0.1 *
Particulates > 0.22 µm, Particulates/ml	< 1 *
Pyrogens (endotoxins), EU/ml	< 0.001 **
RNases, ng/ml	< 0.01 **
DNases, pg/µl	< 4 **
(*) With Millipak Express 0.22 µm or Biopak end filter	
(**) With Biopak end filter	
Resistivity, TOC and bacteria levels match the requirements of Type II water as described in ISO® 3696, ASTM D1193 (Type II resistivity, TOC, HBC Table 1 specification), and Purified Water as described in USP, EP.	

EMPLOYEE TRAINING RECORD

Training Delivery Method Description: Verbal, Verbal & Practical, Read & Understand or Walkthrough

Start Date: <u>26 April 2013</u>		Employee Name: <u>TAN HONG CHENG</u>				Employee Number: <u>N/A</u>			
		Employee Position: <u>MANUFACTURING ENGINEER</u>							
Procedure	Revision	Description	Delivery Method				Trainer	Trainee	Date
			V	V&P	R&U	W			
0273-IR	0	Firmware Download		✓			Nalpsalla	Tan H.C.	26 APR 13
0273-OR	0	Firmware Download		✓			Nalpsalla	Tan H.C.	26 APR 13
0276-IR	0	Hi-pot Tester		✓			Nalpsalla	Tan H.C.	26 APR 13
0274-IR	0	Final Test Station 131		✓			Nalpsalla	Tan H.C.	26 APR 13
0274-OR	0	Final Test Station 131		✓			Nalpsalla	Tan H.C.	26 APR 13
0275-IR	0	Final Test Station 132		✓			Nalpsalla	Tan H.C.	26 APR 13
0275-OR	0	Final Test Station 132		✓			Nalpsalla	Tan H.C.	26 APR 13
0270-IR	0	Lamp Alignment Station		✓			Nalpsalla	Tan H.C.	26 APR 13
0270-OR	0	Lamp Alignment Station		✓			Nalpsalla	Tan H.C.	26 APR 13
0272-OR	0	Optics Bench Alignment 2475		✓			Nalpsalla	Tan H.C.	26 APR 13
0271-IR	0	Optics Bench Alignment 2475		✓			Nalpsalla	Tan H.C.	26 APR 13

EMPLOYEE TRAINING RECORD

Training Delivery Method Description: Verbal, Verbal & Practical, Read & Understand or Walkthrough

Start Date: 18.Feb.2013		Employee Name: <u>Tan Hong Cheng</u>					Employee Number: N/A		
		Employee Position: <u>Venture Contractor</u>							
Procedure	Revision	Description	Delivery Method				Trainer	Trainee	Date
			V	V&P	R&U	W			
279001339	C	Assy,XE Lamp and Holder		✓			Paul Chy	Tan H.C. &	22.Mar.13
279002476	M	Assy,Intergrated Detector 2475		✓			Paul Chy	& Tan H.C.	10.Apr.13
289000475	C	Assy,Window Holder		✓			Paul Chy	Tan H.C. &	22.Mar.13
289000465	F	Assy,Cam and Pulley Long		✓			Paul Chy	Tan H.C. &	22.Mar.13
289000466	E	Assy Cam and Pulley,Excitation		✓			Paul Chy	Tan H.C. &	22.Mar.13
289000469	D	Assy Grating/ Bush Emission		✓			Paul Chy	Tan H.C. &	22.Mar.13
289000470	D	Assy Grating/Bushing Excitation		✓			Paul Chy	Tan H.C. &	22.Mar.13
700001624	B	ASSY, CABLE PHOTODIODE		✓			Paul Chy	Tan H.C. &	22.Mar.13
700004124	B	ASSY PSU XENON/MERCURY LAMP 150W		✓			Paul Chy	& Tan H.C.	11.Apr.13
735000589	D	TEST PROC, 2475 REAR PANEL		✓			Paul Chy	& Tan H.C.	12.Apr.13
735000615	H	TEST SPEC AND PROC, 2475 FINAL TEST		✓			Paul Chy	& Tan H.C.	12.Apr.13

Attachment 3-2

Attachment 5-1

MERCK MILLIPORE



Certificate of Calibration

Serial No.: MCC20091

Merck Millipore Corporation, an ISO9001 Certified company, hereby certifies that the instrument below meets or exceeds all published specifications and all quality and performance criteria at the time of calibration. A Traceability of measurement equipment is performed according to Merck Millipore Calibration system. The calibration will be done by using an in line test method.

EQUIPMENT TO BE CALIBRATED:

Manufacturer : Millipore SAS
System Name : Milli-Q Advantage A10
System Catalogue No. : Z000QV070
System Serial No : F0PA04507D
Location of System : GFS Singapore Pte Ltd
28 Marsiling Lane, Singapore 739152
Calibration Date : 11 Jan. 2013
Next calibration Date : 11 Jan. 2014

APPROVED METER USED TO PERFORM THE CALIBRATION:

Manufacturer : Mettler Toledo Thornton
Model No. : Meter M300 / Sensor 240-201
Serial No. : Meter 1232018832 / Sensor 11010786

	Temperature(°C)	Conductivity(µS/cm)/Resistivity(MΩ.cm)
System Display Reading	22.6 °C	18.2 MΩ.cm
Approved Meter Reading	22.63 °C	18.18 MΩ.cm
Error Limits	+/-1(°C)	+/- 0.01 µS/cm or +/-1 MΩ.cm

Calibration Result: ☒ PASS ☐ FAIL

Comment: NA

NA

Performed by : Louis Lee Signature:  Date: 11 Jan. 13

Reviewed by : Low Kok Leang Signature:  Date: 11 Jan 13

Attachment 52

Calibration Certificate No. PT1301008

Calibration Certificate

Company >	Merck Pte Ltd		
Address >	3 International Business Park, #02-01 Nordic European Centre Singapore (609927)		
Contact Person >	Ronnie Quah	Contact No >	8126 0021
Manufacturer >	THORNTON	Tag No/ID No >	Portable Unit
Instrument Type >	M300	Calibration Date >	04 Jan 2013
Serial No >	1232018832	Next Calibration Date >	04 Jan 2014

Channel - A		Sensor Model > 240-201		Serial No > 11010786			
Conductivity As Found ($\mu\text{S/cm}$)	Reference ($\mu\text{S/cm}$)	① Deviation As Found ($\mu\text{S/cm}$)	Conductivity As Left ($\mu\text{S/cm}$)	Reference ($\mu\text{S/cm}$)	① Deviation As Left ($\mu\text{S/cm}$)	Cell Constant As Found	Cell Constant As Left
17.53	18.28	-0.75	18.27	18.29	-0.02	M = 0.10387 A = 0.0000	M = 0.10288 A = 0.0000
Temperature As Found ($^{\circ}\text{C}$)	Reference ($^{\circ}\text{C}$)	② Deviation As Found ($^{\circ}\text{C}$)	Temperature As Left ($^{\circ}\text{C}$)	Reference ($^{\circ}\text{C}$)	② Deviation As Left ($^{\circ}\text{C}$)	Temperature Constant As Found	Temperature Constant As Left
25.86	25.96	-0.1	25.86	25.96	-0.1	M = 1.0000 A = 0.0000	M = 1.0000 A = 0.0000
① Admissible deviation = $\pm 2\%$ of Measured Value. ② Admissible deviation = $\pm 0.25^{\circ}\text{C}$							

Channel - B		Sensor Model > N/A		Serial No > N/A			
Conductivity As Found ($\mu\text{S/cm}$)	Reference ($\mu\text{S/cm}$)	① Deviation As Found ($\mu\text{S/cm}$)	Conductivity As Left ($\mu\text{S/cm}$)	Reference ($\mu\text{S/cm}$)	② Deviation As Left ($\mu\text{S/cm}$)	Cell Constant As Found	Cell Constant As Left
N/A	N/A	N/A	N/A	N/A	N/A	M = N/A A = N/A	M = N/A A = N/A
Temperature As Found ($^{\circ}\text{C}$)	Reference ($^{\circ}\text{C}$)	② Deviation As Found ($^{\circ}\text{C}$)	Temperature As Left ($^{\circ}\text{C}$)	Reference ($^{\circ}\text{C}$)	② Deviation As Left ($^{\circ}\text{C}$)	Temperature Constant As Found	Temperature Constant As Left
N/A	N/A	N/A	N/A	N/A	N/A	M = N/A A = N/A	M = N/A A = N/A
① Admissible deviation = $\pm 2\%$ of Measured Value. ② Admissible deviation = $\pm 0.25^{\circ}\text{C}$							

Remark : Temperature compensation type = Standard

④ This equipment is metrologically tested and the test results corresponded with the required tolerances. >

YES

Signature > 
Performed By > Easley Heng



11 Jan. 13

Attachment 5-3

Calibration Certificate No. PT1301008

Channel A (Meter) Before Calibration				
Test value	Input	Measured value	Deviation.	Limit
10M Ω	9.980M Ω	7.347	-2.633	$\pm 0.5\%$ ($\pm 0.05M\Omega$)
1M Ω	0.9999M Ω	0.9678	-0.0321	$\pm 0.5\%$ ($\pm 0.005M\Omega$)
100k Ω	100.0k Ω	99.69	-0.31	$\pm 0.5\%$ ($\pm 0.5k\Omega$)
10k Ω	10.01k Ω	10.00	-0.01	$\pm 0.5\%$ ($\pm 0.05k\Omega$)
1k Ω	1.000k Ω	0.9999	-0.0001	$\pm 0.5\%$ ($0.005k\Omega$)
100 Ω	100.1 Ω	100.1	0.0	$\pm 0.5\%$ ($\pm 0.5\Omega$)
66k Ω (Temperature)	66.00k Ω	66.07	0.07	$\pm 0.5\%$ ($\pm 0.33k$)
3k Ω (Temperature)	3.001k Ω	3.000	-0.001	$\pm 0.5\%$ ($\pm 0.015k$)
1k Ω (Temperature)	0.9994k Ω	0.9991	-0.0003	$\pm 0.5\%$ ($\pm 0.005k$)
Channel A (Meter) After Calibration				
Test value	Input	Measured value	Deviation.	Limit
10M Ω	9.980M Ω	10.14	0.16	$\pm 0.5\%$ ($\pm 0.05M\Omega$)
1M Ω	0.9999M Ω	1.003	0.0031	$\pm 0.5\%$ ($\pm 0.005M\Omega$)
100k Ω	100.0k Ω	100.2	0.2	$\pm 0.5\%$ ($\pm 0.5k\Omega$)
10k Ω	10.01k Ω	10.01	0.00	$\pm 0.5\%$ ($\pm 0.05k\Omega$)
1k Ω	1.000k Ω	1.000	0.000	$\pm 0.5\%$ ($0.005k\Omega$)
100 Ω	100.1 Ω	100.1	0.0	$\pm 0.5\%$ ($\pm 0.5\Omega$)
66k Ω (Temperature)	66.00k Ω	66.08	0.8	$\pm 0.5\%$ ($\pm 0.33k$)
3k Ω (Temperature)	3.001k Ω	3.000	-0.001	$\pm 0.5\%$ ($\pm 0.015k$)
1k Ω (Temperature)	0.9994k Ω	0.9992	-0.0002	$\pm 0.5\%$ ($\pm 0.005k$)
Channel B (Meter) Before Calibration				
Test value	Input	Measured value	Deviation.	Limit
10M Ω	9.980M Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.05M\Omega$)
1M Ω	0.9999M Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.005M\Omega$)
100k Ω	100.0k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.5k\Omega$)
10k Ω	10.01k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.05k\Omega$)
1k Ω	1.000k Ω	N/A	N/A	$\pm 0.5\%$ ($0.005k\Omega$)
100 Ω	100.1 Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.5\Omega$)
66k Ω (Temperature)	66.00k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.33k$)
3k Ω (Temperature)	3.001k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.015k$)
1k Ω (Temperature)	0.9994k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.005k$)
Channel B (Meter) After Calibration				
Test value	Input	Measured value	Deviation.	Limit
10M Ω	9.980M Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.05M\Omega$)
1M Ω	0.9999M Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.005M\Omega$)
100k Ω	100.0k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.5k\Omega$)
10k Ω	10.01k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.05k\Omega$)
1k Ω	1.000k Ω	N/A	N/A	$\pm 0.5\%$ ($0.005k\Omega$)
100 Ω	100.1 Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.5\Omega$)
66k Ω (Temperature)	66.00k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.33k$)
3k Ω (Temperature)	3.001k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.015k$)
1k Ω (Temperature)	0.9994k Ω	N/A	N/A	$\pm 0.5\%$ ($\pm 0.005k$)

11 Jan. 13

Attachment 5-4

Calibration Certificate No. PT1301008

Equipments Used in Calibration			
Instrument	Serial Number	Valid Till	
Meter 770Max	707040096	19-Oct-2013	
Sensor 230-211	724489	25-May-2013	
M300 Calibrator	698811	25-May-2013	
Remark : N/A			

for
11 Jan. 13

Attachment 6-1



CERTIFICATE OF CALIBRATION

Millipore S.A.S Quality Assurance System is approved by an accredited organization (AFAQ) in conformity with the ISO 9001
Quality Standard:
ISO 9001 Quality Certificate No. QUAL / 1991 / 3401

Total Oxidizable Carbon (TOC) Analyzer

Millipore SAS certifies that this product was successfully calibrated in accordance with Millipore's Quality Assurance System standard procedures and specifications and meets or exceeds all published specifications and all quality and performance criteria at the time of shipment. Traceability of measurement equipment is performed according to Millipore SAS Calibration system.

EQUIPMENT

Calibrated unit (TOC CAL)		TOC Reference Unit (TOC REF)	
Catalog Number:	A11RCALM1	Model: A643	
Lot number:	F2NA09520	Serial Number: 2523	
Serial Number:	55273		
Calibration Number:	1499		
Calibration Date (DD/MM/YYYY):	10/Oct/2012		

MEASUREMENT SUMMARY

Temperature – Verification.
Resistivity (compensated at 25°C) – Calibrated by comparison with a reference.
TOC – Calibrated by comparison with a reference.
The calibration was made by Millipore SAS at Millipore's plant in Molesheim (France).
The manufacturer of the calibrated equipment is MILLIPORE SAS.

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This document includes 2 pages.

Quality Assurance Manager
Laboratory Water Systems

Déborah WILD
October 12, 2012

11 Jan. 13

Rev 10 : 01 march 2012
Lot number: F2NA09520
Serial number: 55273

Site Social et Site Industriel : Millipore S.A.S. - BP 116 - 67121 Molesheim Cedex
Tél : (03) 94 94 47 00 - Téléfax : (03) 94 94 91 93
Internet : <http://www.millipore.com>

CERTIFICATE OF CALIBRATION

Resistivity and TOC measurement

INTERNAL PROCEDURES : 011 255 TS - 00084613SO

MEASUREMENT METHOD:

TOC Monitor Reference (TOC REF) Calibration:

The reference TOC monitor (TOC REF) was calibrated against standards for TOC using Benzoquinine and sucrose according suitability test as described in method <643> of USP 32 (internal procedure 00084613SO).

TOC Monitor (TOC CAL) Calibration:

The TOC REF and the TOC CAL are placed in-line (water at 25°C) on a test bench.

The calibration of the TOC CAL is performed according to the following steps:

1-Resistivity measurements

By comparison of the resistivity values measured with the Resistivity Reference and the TOC CAL at 2 points (First point below 1.8 MOhms.cm @25°C and second point greater than 17 MOhms.cm @25°C) and by linear regression, parameters are entered into the TOC CAL.

During TOC measurements cycles, temperature deviation between the Temperature Reference and the TOC CAL is measured, and admissible temperature deviation between the Temperature Reference and the TOC CAL is 2.5°C.

2-TOC Verification

Verification is performed by comparing the TOC and resistivity values measured by the TOC REF and the TOC CAL for different TOC values (between 1 and 200 ppb).

Initial TOC value is obtained by methanol injection into the ultrapure water. Decreasing TOC values are obtained by photo-oxidation of methanol by UV irradiation.

TOC admissible deviation on TOC CAL is $\pm 15\%$ or ± 1 ppb, whichever is greater.

Resistivity admissible deviation is ± 2 MOhms.cm @25°C at each test range.

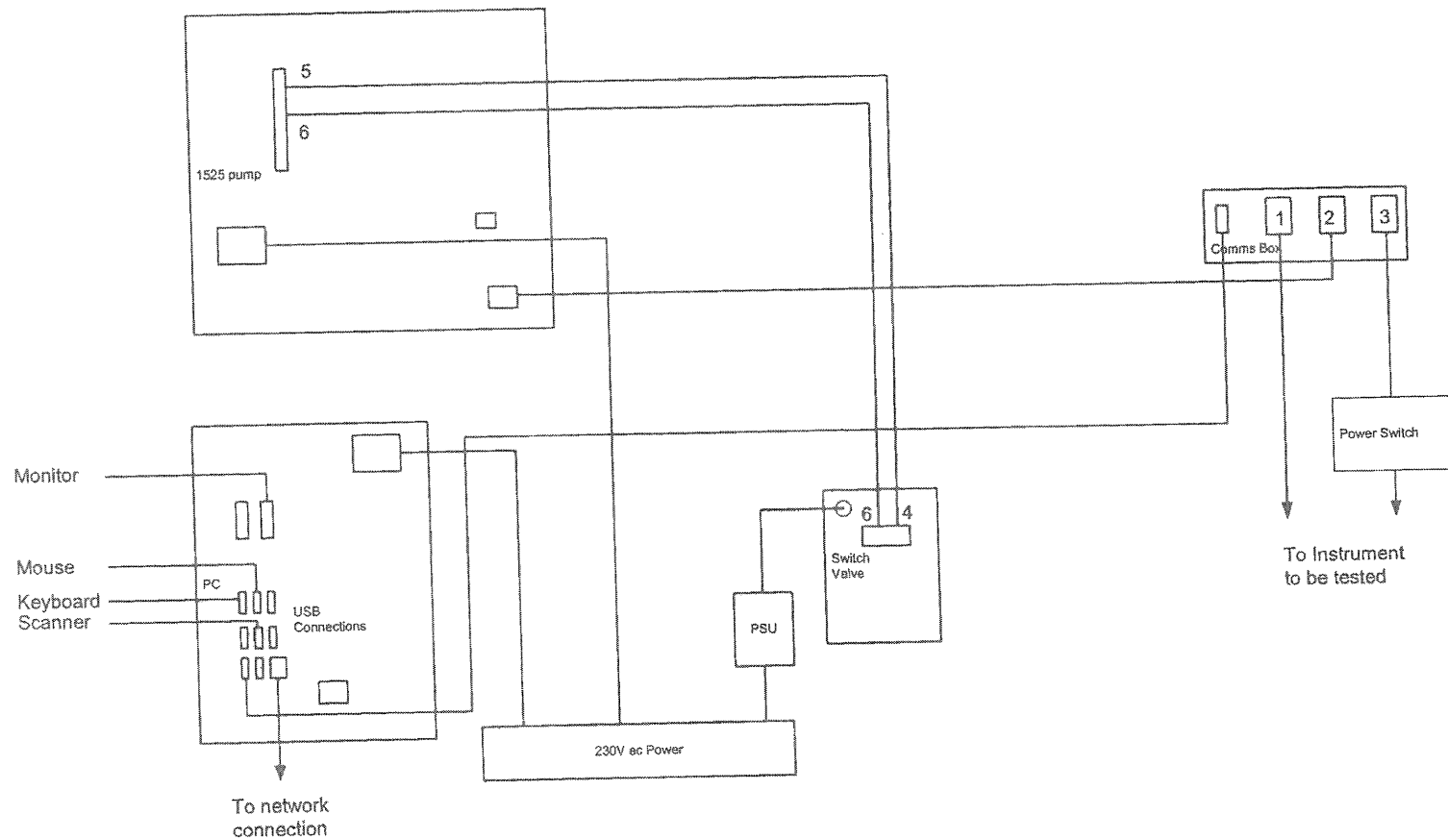
MEASUREMENT RESULTS:

TOC - ppb (TOC REF)	TOC - ppb (TOC CAL)	TOC Deviation	% TOC Deviation	Resistivity MOhms.cm@ 25°C (TOC REF)	Resistivity MOhms.cm@ 25°C (TOC CAL)	Resistivity Deviation
5.89	5.52	-0.36	-6.14	17.40	17.48	0.08
12.02	11.76	-0.26	-2.16	17.50	17.24	-0.26
25.68	25.57	-0.11	-0.41	17.40	17.77	0.37
86.29	89.82	3.53	4.09	17.40	17.28	-0.12
106.80	106.33	-0.47	-0.44	17.40	17.37	-0.03
169.30	177.98	8.68	5.12	17.40	17.58	0.18

11 Jan. 13

Rev 10 : 01 march 2012
Lot number: F2NA09520
Serial number: 55273

Siege Social et Site Industriel : Millipore S.A.S. B.P. 116 67124 Molshelm Celles
Tél : (03)4649000 Téléc : (03)4649190
Internet : <http://www.millipore.com>



Owner				Engineering		 THE SCIENCE OF WHAT'S POSSIBLE™	
Title				Final Test Station No.1			
Author		Neil Kinsella		Sign		Date	
Approved by		Dery O'Donovan		Sign		Date	
Rev		0		Layout		A4	
Scale		None		Issue Date		26-April-13	
Drawing No		0261-IQ-04		DCR No			

Attachment 167

Attachment 8

