

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

PREPARED BY

Name	Role	Signature	Date
Neil Kinsella	Manufacturing Engineer		19 April 2013

REVIEWED BY

Name	Role	Signature	Date
Barry Duggan	Manufacturing Manager		24 Apr 13
Derry O'Donovan	Engineering Manager		22-Apr-2013
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 Operational Qualification activities.

The "Reviewed By" signature[s] denotes agreement with the description of the Operational 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 Full Final Test Station No.1, henceforth referred to as “Test Station” located at Venture in Singapore.

This qualification protocol is designed to document the Operational Qualification (OQ) for the Final Test Station No.1. The equipment will be exercised to demonstrate operation as per operational requirements. When all test requirements are completed (including all relevant attachments) and release approval given, this section of the protocol forms the record of Operational Qualification for the Final Test Station No.1.

OQ will concentrate on the functionality of the Final Test Station No.1 and will build on the level of assurance already provided by the execution of the latest approved revision of the Final Test Station No.1 Installation Qualification Protocol reference number 0274-IQ.

Prior to implementation of this OQ, Installation Qualification documentation will have been completed. This will have demonstrated that all aspects of the Final Test Station No.1 adhere to the approved design intentions and that manufacturers’ recommendations have been considered.

1.1 General

The validation effort will comply with the Waters Validation Global 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 Operational Qualification of Final Test Station No.1. The report will outline the results of the Operational Qualification for Final Test Station No.1 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)
TMH HANU CHENIA	26 APR 2013	<i>[Signature]</i> 29 MAY 2013	

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

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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 730000523 “Good Documentation Practices (GDP) procedure”. [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 Final Test Station No.1

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 LabView 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 LabView 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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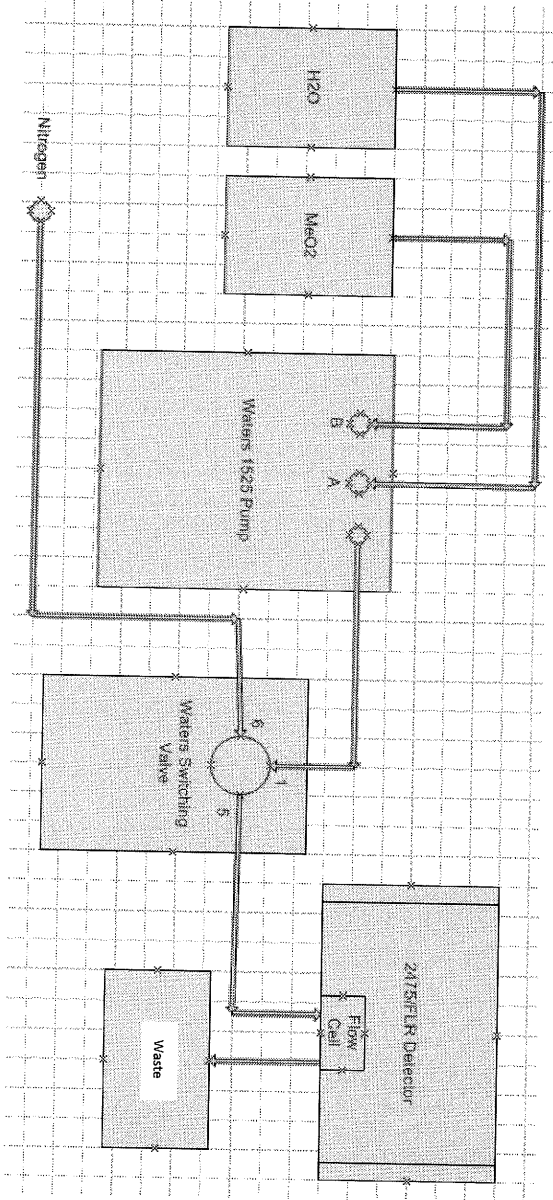
5.2 Sequence of Events

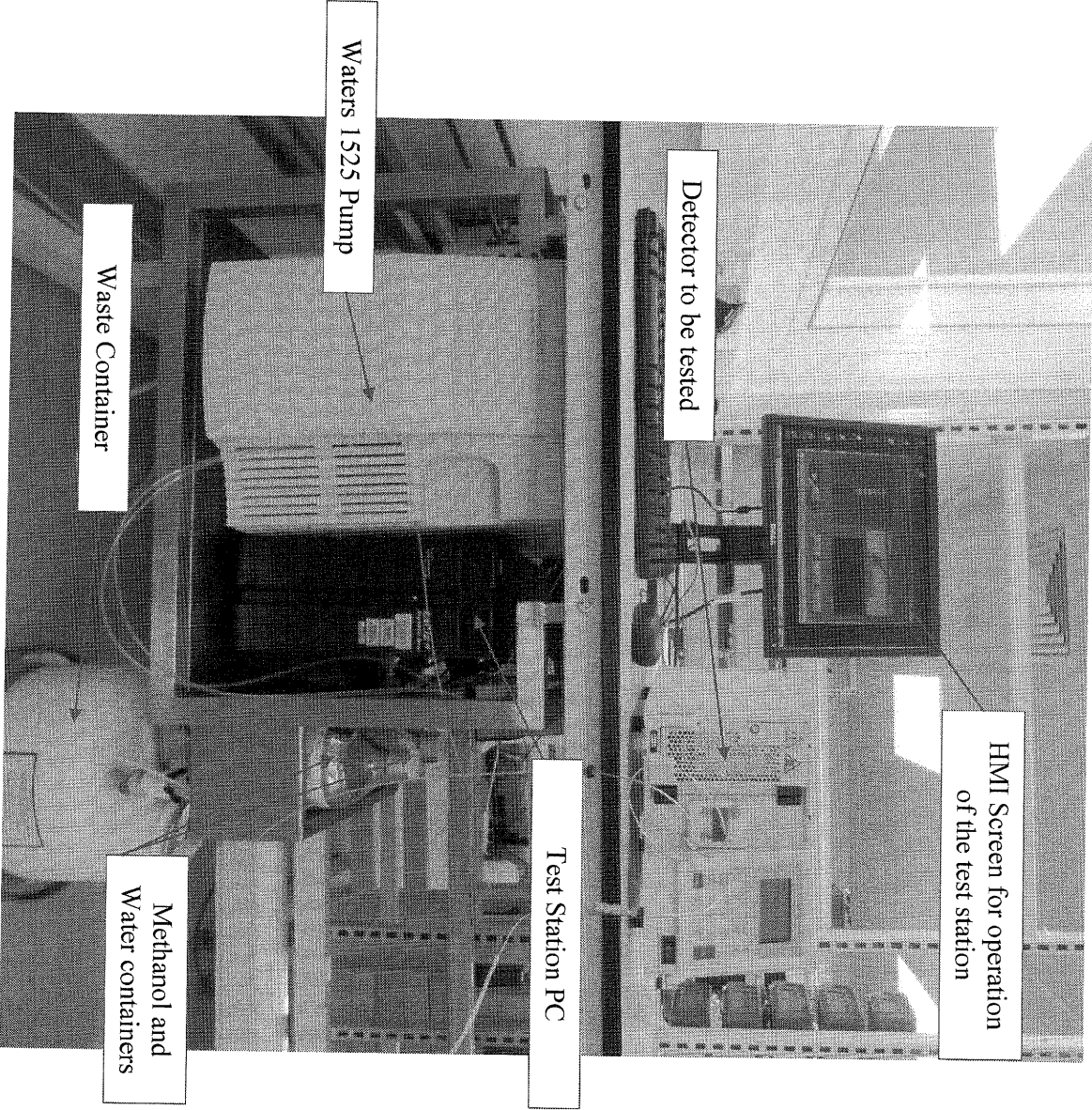
The Asset number for the Test station is WX2145

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.

2 x FLR detectors and 2 x 2475 detectors will be used for this validation. All 4 detectors will be tested using the test station 5 times. This protocol is a benchmarking exercise.

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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 Operational Qualification (OQ)

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 OQ studies:

- OQ-01 Training Confirmation
- OQ-02 Components / Ancillary Equipment

The following tests, along with any others the author deems necessary, may be included as part of this protocol:

- OQ-01 Training Confirmation
- OQ-02 Components / Ancillary Equipment
- OQ-03 Security Verification
- OQ-04 Loss of Power
- OQ-06 Operator Interface / HMI Testing
- OQ-07 Critical Quality Attribute Testing

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	OO-Q01	To ensure the executor of the protocol is suitably trained to do so
Components / Ancillary Equipment	OO-Q02	To record any product components / ancillary equipment that will be necessary for operational testing
Security Verification	OO-Q03	To verify that the system is protected against unwanted users
Loss of Power	OO-Q04	To verify that the test station can recover from a power out situation
Operator Interface / HMI Testing	OO-Q06	To verify and document the operation of the HMI s/w
Critical Quality Attribute Testing	OO-Q07	To insure that the test station performs as expected

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

6.3 OO Test Scripts

Test name: Training Confirmation			Test no.: OO-Q01
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 and 735000615	Yes	Pass	Tan H.C. 29-May-2013
Training Record(s) Attached	Yes	Pass	Tan H.C. 29-May-2013
Comments: N/A			
Overall Test Conclusion:		Pass ☒	Fail ☐
Performed By:	Initial	Signature	Date
Tan Hui Chen	Tan H.C.	<i>[Signature]</i>	29-May-2013

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Reviewed By	Role	Signature	Date

Test name: Components / Ancillary Equipment Required for Qualification	Test no.: OQ-02
---	------------------------

Purpose:
To record any product components and / or any ancillary equipment that will be necessary for operational testing.

Test execution:
Verify that required components to be used in the operational qualification are available.
Document all relevant identification of any materials to be used. Attach supporting documentation to the protocol.

Component / Equipment	As Found (Serial no.)	Initial & Date
186002475	B11475994M	TKM H.C. 29-MAY-2013
186002475	B11475983M	TKM H.C. 29-MAY-2013
186015029	MO9UPF765R	TKM H.C. 29-MAY-2013
186015029	K08UPF480R	TKM H.C. 29-MAY-2013

Comments:

N/A

Performed By:	Initial	Signature	Date
TKM HONN CHEN	TKM H.C.		29-MAY-2013
Reviewed By	Role	Signature	Date

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Test name: Security Verification		Test no.: OQ-03	
Purpose: To verify that system security is adequate for intended use and in accordance with specifications			
Test execution: Refer to the data table for instruction. Document actual results of each test in the table. Ensure that all parameter settings are returned to initial state after execution. Refrain from recording passwords in this document. If this is unavoidable, ensure that passwords are changed following qualification.			
Test Procedure	Expected Result	Actual result	Pass / Fail
Attempt User access with incorrect password	Access denied	Access denied	Pass
Attempt User access with correct password	Access given	Access given	Pass
Initial & Date 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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Test name: Loss of Power			Test no.: OQ-04	
Purpose: To verify and document the response and recovery of Equipment Description to a simulated power failure during routine production.				
Test execution: Refer to the data table for instruction. Document actual results of each test in the table. Ensure that all parameter settings are returned to initial state after execution or if system returns to a default setting, this must be communicated up front and the results confirmed. Use the final tester to test an instrument and attach the results to this protocol. Then test the instrument again and during the test power down the instrument by unplugging the test station. Restore power by plugging back in the test station. Then use the test station to test the instrument again and verify that the results are within +/-10% of the original results.				
Parameter	Settings		Pass / Fail	Initial & Date
	Pre-Power Failure	Post-Power Failure		
Initialisation test	Pass	Pass	Pass	Tan H.C. 29 May 2013
Calibration test	Pass	Pass	Pass	Tan H.C. 29 May 2013
PMT calibration test	Pass	Pass	Pass	Tan H.C. 29 May 2013
Normalize test	Pass	Pass	Pass	Tan H.C. 29 May 2013
Re-start test	Pass	Pass	Pass	Tan H.C. 29 May 2013
Rayleigh test	365.2	365.3	Pass	Tan H.C. 29 May 2013
Raman test	416.6	416.7	Pass	Tan H.C. 29 May 2013
R-R valley test	Pass	Pass	Pass	Tan H.C. 29 May 2013
W1 resolution test	Pass	Pass	Pass	Tan H.C. 29 May 2013
Stray Ratio test	Pass	Pass	Pass	Tan H.C. 29 May 2013
Signal to noise test	Pass	Pass	Pass	Tan H.C. 29 May 2013

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Comments:

N/A

Overall Test Conclusion:		Pass ☒	Fail ☐
Performed By:	Initial	Signature	Date
TKM HONK CHENKA	Ta HC		29-MAY-2013
Reviewed By	Role	Signature	Date

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Test name: Alarms / Interlocks / Emergency Stops					Test no.: OQ-05
Purpose: To verify that all alarms / interlocks / emergency stops function as intended					
Test execution: Prepare and run Equipment Description under routine conditions. Simulate fault conditions as described in the data table so as to trigger alarms/interlock/emergency stops. Perform all tests specified. (Clear each fault condition prior to performing the next).					
Alarm/Interlock/ E-Stop Description	Test Method	Expected Result	Actual Result	Pass / Fail	Initial & Date
Comments:					
Overall Test Conclusion: Pass ☐ Fail ☐					
Performed By:	Initial	Signature		Date	
Reviewed By	Role	Signature		Date	

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Test name: Operator Interface / HMI Testing			Test No.: OQ-06
Purpose: To verify the sequence of operations for the Equipment Description.			
Test execution: Verify that the Equipment Description operates as expected. Document the results of the test in the data table below. Connect a detector to the test station and proceed with the test procedure as per 735000615, Fluorescence Detector Final Test System. Attach screen shots of all for each of the tests completed.			
Function	Expected Result	Actual result	Pass / Fail
1 Click on operator name	Operator name list appears	as expected	Pass
2 Select operator name	Operator name appears in name field	as expected	Pass
3 Press start button	Serial number screen appears	as expected	Pass
4 Scan serial number and press ok	Testing starts	as expected	Pass
5 Click on abort test	Testing stops	as expected	Pass
6 Click print previous	Prints results from previous test	as expected	Pass
7 Click in diagnostic button	Diagnostic screen appears	as expected	Pass
8 Click instrument power on	Instrument powers up	as expected	Pass
9 Click instrument power off	Instrument powers down	as expected	Pass
10 Click pump control tab	Pump control screen appears	as expected	Pass
11 Click path arrow until "nitrogen" is selected	Nitrogen flows through flow cell	as expected	Pass
12 Press start again	Nitrogen stops flowing	as expected	Pass
13 Click path arrow until "water" is selected	Water flows through flow cell	as expected	Pass
14 Press start again	Water stops flowing	as expected	Pass
15 Click on Signal/Noise test tab	Signal/Noise screen appears	as expected	Pass
16 Click start scan	Instrument scans for	as expected	Pass

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	Rayleigh and Raman peaks	as expected	Pass	THMC 29-MAY-13
Click return to main	Diagnostic screen closes and main screen is visible	as expected	Pass	THMC 29-MAY-13
Click on exit	Application shuts down	as expected	Pass	THMC 29-MAY-13

N/A

Overall Test Conclusion:	Pass ☒	Fail ☐	
Performed By:	Initial	Signature	Date
THOMAS CHEN	Tau H-C.	[Signature]	29-MAY-13
Reviewed By	Role	Signature	Date

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Test name: Critical Quality Attribute Testing	Test No.: OQ-07
Purpose: Test to ensure that critical operating requirements are demonstrated to be achievable within defined acceptance criteria.	
Test execution: See individual Test Sheets and any additional worksheets as required Overall test passes if all critical requirements meet their respective acceptance criteria. Use the test station to test 4 detectors, 2 x 2475 and 2 x FLR. Test each detector 5 times. Record the results below. All detectors must pass all tests. Attach results sheets to this protocol.	

Critical requirement	Actual Result	Actual Result	Actual Result	Actual Result	Actual Result	Pass / Fail	Initial & Date
	Test No.1	Test No.2	Test No.3	Test No.4	Test No.5		
2475 No.1 Initialisation test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 PMT calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Normalize test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Re-start test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Rayleigh test (350 +/- 2.5nm)	351.4	351.5	351.5	351.4	351.4	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Raman test (397 +/- 2.5nm)	396.4	396.5	396.5	395.7	396.4	Pass	Tan H.C. 29 MAY 2013
2475 No.1 R-R valley test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 W1 resolution test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Stray Ratio test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013
2475 No.1 Signal to noise test (1000<S/N<4000)	2331.01	2464.2	2555.81	2499.69	2642.01	Pass	Tan H.C. 29 MAY 2013
2475 No.2 Initialisation test	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C. 29 MAY 2013

(P/F)							
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
Calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13 29 MAY 13
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
PMT calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
Normalize test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
Re-start test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
2475 No.2	350.7	350.7	350.8	350.9	350.9	Pass	Tan H.C 29 MAY 13
Rayleigh test (350 +/- 2.5nm)							
2475 No.2	396.5	395.8	396.7	396.7	395.9	Pass	Tan H.C 29 MAY 13
Raman test (397 +/- 2.5nm)							
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
R-R valley test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
WI resolution test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
2475 No.2	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
Stray Ratio test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
2475 No.2	2014.98	2049.18	2009.08	2100.52	1980.7	Pass	Tan H.C 29 MAY 13
Signal to noise test (1000<S/N<4000)							
FLR No.1 Initialisation test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
FLR No.1	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
Calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
FLR No.1	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
PMT calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
FLR No.1	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
Normalize test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
FLR No.1	Pass	Pass	Pass	Pass	Pass	Pass	Tan H.C 29 MAY 13
Re-start test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	29 MAY 13
FLR No.1	365.3	365.2	365.2	365.2	364.5	Pass	Tan H.C 29 MAY 13
Rayleigh test (365 +/- 2.5nm)							
FLR No.1	416.7	416.7	416.6	416.7	416.7	Pass	Tan H.C 29 MAY 13
Raman test (416 +/-							

2.5nm)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.1							
R-R valley test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.1							
WI resolution test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.1							
Stray Ratio test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.1							
Signal to noise test (1000<S/N<4000)	2750.51	2801.88	2893.31	3182.63	2555.08	Pass	THW HC 29 MAY 13
FLR No.2 Initialisation test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
Calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
PMT calibration test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
Normalize test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
Re-start test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
Rayleigh test (365 +/- 2.5nm)	365.3	364.8	364.8	364.8	364.8	Pass	THW HC 29 MAY 13
FLR No.2							
Raman test (416 +/- 2.5nm)	416.7	416.1	416.9	416.8	416.8	Pass	THW HC 29 MAY 13
FLR No.2							
R-R valley test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
WI resolution test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
Stray Ratio test (P/F)	Pass	Pass	Pass	Pass	Pass	Pass	THW HC 29 MAY 13
FLR No.2							
Signal to noise test (1000<S/N<4000)	3180.87	3377.29	3207.22	2841.43	3296.17	Pass	THW HC 29 MAY 13

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Comments:

N/A

Overall Test Conclusion:

Pass



Fail



Performed By:

initial

Signature

Date

TAN HOU CHEN

TAN H C



29 MAY 13

Reviewed By

Role

Signature

Date

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Test name: Critical Process Parameter Testing			Test No.: OQ-08	
Purpose: Test to ensure that critical operating requirements are demonstrated to be achievable within defined acceptance criteria.				
Test execution: Set Final Test Station No.1 up to required values and operate as per instructions. Record actual parameter values. Make Pass/Fail decision.				
Critical requirement	Required Settings	Actual Value	Pass / Fail	Initial & Date
Comments:				
Overall Test Conclusion: Pass ☐ Fail ☐				
Performed By:	Initial	Signature	Date	
Reviewed By	Role	Signature	Date	

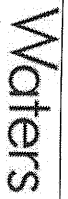
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	OO for 2475 / FLR Final Test Station No.1
for completion in Venture	
Document No: 0274-OQ	Version No: 00

Test name: Functional Testing		Test No.: OO-09		
Purpose: Test to ensure that operational requirements are demonstrated to be achievable within defined acceptance criteria.				
Test execution: Set Final Test Station No.1 up to required values and operate as per instructions. Record actual parameter values. Make Pass/Fail decision.				
Critical requirement	Required Settings	Actual Value	Pass / Fail	Initial & Date
Comments:				
Overall Test Conclusion: Pass ☐ Fail ☐				
Performed By:	Initial	Signature	Date	
Reviewed By	Role	Signature	Date	

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

7.0 Verification of Completion of Operational Qualification Testing

Qualification Test	Executed [Yes / No]	Complies [Pass / Fail / N/A]	Deviation No. (if applicable)	Initial / Date
Training Confirmation	Yes	Pass	N/A	TAMHC 29-MAY-13
Components / Ancillary Equipment	Yes	Pass	N/A	TAMHC 29-MAY-13
Security Verification	Yes	Pass	N/A	TAMHC 29-MAY-13
Loss of Power	Yes	Pass	N/A	TAMHC 29-MAY-13
Operator Interface / HMI Testing	Yes	Pass	N/A	TAMHC 29-MAY-13
Critical Quality Attribute Testing	Yes	Pass	N/A	TAMHC 29-MAY-13
Comments: N/A				
Performed By	Initial	Signature	Date	
TAMONC/CHEN	TAMHC.		29-MAY-13	
Approved By	Role	Signature	Date	

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

8.0 Release of Operational Qualification

Review and complete the following:

	Yes / No / N/A	Performed by, Date
OO 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).	<i>NO</i>	<i>TAM H. C. 29-MAY-2013</i>
If No , proceed to next point		
All operational qualification test sheets are complete and comply with respective requirements (See Section 7.0)		
If No , proceed to Section 8.1	<i>YES</i>	<i>TAM H. C. 29-MAY-2013</i>
If Yes , enter N/A in section 8.1 and proceed to Section 8.2		

8.1 Operational Qualification Release Provisional Approval

If it is proposed to continue to Production execution prior to completing Operational Qualification, this section must be completed. The justification for proceeding under these conditions is that the issues, detailed below, are not considered likely to have an adverse impact on the Production. The Protocol Executor must prepare this rationale, which must be approved. Operational Qualification issues are as follows (attach supporting documentation as required):

Prepared By:	Role	Signature	Date
Reviewed By	Role	Signature	Date

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

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 Final Test Station No.1 is now released for Production. Full approval will only be given when these outstanding issues are deemed fully closed.

Operational Qualification (OO) has been performed, has been reviewed by Waters Technical Personnel, and has outstanding items that are deemed not critical to product quality. Final Test Station No.1 is provisionally released for Production.

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

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

8.2 Operational Qualification Release Full Approval

By signing this section, those people below agree that the requirements of Operational 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.

Operational Qualification (OO) has been successfully performed, has been reviewed by Waters Technical Personnel, and is acceptable. Final Test Station No.1 is now released for Production.

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

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

9.0 Attachments

Attach. No.	Documents/Contents	Section Ref.	Document Ref.	No. of Pages
1	Deviation List	N/A		
2	Deviation Report	N/A	N/A	
3	Training Records	OQ-01	N/A	2
4	Test Records	OQ-04	N/A	2
5	Print Screen	OQ-06	N/A	
6	Test Records	OQ-07	N/A	20
7				
8				
9				
10				

Attachment 1 - Deviation List

Record references to any and all (make multiple copies as required) deviations raised during the execution of this Operational 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.

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 Beam Alignment 2475		✓			Nalpsalla	Tan H.C.	26 APR 13
0271-IR	0	Optics Beam Alignment 2475		✓			Nalpsalla	Tan H.C.	26 APR 13

Attachment 3 + 1

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

Waters Corporation - Instrument Final Test Record

Part Number: <u>186015029</u>	Product: <u>Acquity FLR</u>
Operator: <u>KLoo</u>	Start Time: <u>05/28/2013, 08:43:07</u>
Serial Number: <u>K08UPF480R</u>	Firmware Revision: <u>1.40</u>

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.3	367.5	nM	PASS
Rayleigh Energy		15222939		EU	PASS
Gain		0.3			PASS
Raman Wavelength	413.5	416.7	418.5	nM	PASS
Raman Energy	100	54306	100000	EU	PASS
Ram-Ray Valley Energy		7948		EU	PASS
Optical Resolution		14.64			PASS
Stray Light Ratio		0.36			PASS
Signal/Noise Ratio	1000	3032.96	4000		PASS

Notes:

Pre - Power Failure.

Signed: <u>TAH N.C.</u>	Date: <u>28/MAY/13</u>
-------------------------	------------------------

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.

Waters Corporation - Instrument Final Test Record

Part Number: 186015029
Operator: KL Loo
Serial Number: K08UPF480R

Product: Acquity FLR
Start Time: 05/28/2013,
07:57:20
Firmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.2	367.5	nM	PASS
Rayleigh Energy		16633103		EU	PASS
Gain		0.35			PASS
Raman Wavelength	413.5	416.6	418.5	nM	PASS
Raman Energy	100	59089	100000	EU	PASS
Ram-Ray Valley Energy		8248		EU	PASS
Optical Resolution		13.96			PASS
Stray Light Ratio		0.36			PASS
Signal/Noise Ratio	1000	2792.02	4000		PASS

Notes:

*Post-Power Failure*Signed: *JAN H.C.*Date: *28/May/13*

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.



2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result
Initialize	☐
Calibrate	☐
PMT Cal	☐
Normalize	☐
Re-Start	☐
Rayleigh	☐
Raman	☐
R-R Valley	☐
WL Resolution	☐
Stray Ratio	☐
S/N Ratio	☐
Purge	☐

KLLoo
 ✓ HCTan
 MIMI
 Khalip

Firmware Rev.
 Serial Number

F, connect serial cable to instrument, connect tubing(click ram), enter serial number, select operator from list, turn on instrument power switch and press Start Test. Note: Pump will start, so make sure pump is in remote mode and armed, and fluid containers have fluids (see tubing page for details)

Start Test

Abort Test

FLR?(T) ☐

Print Previous

Diagnostics

EXIT

Waters Corporation
 Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0
 (C) 2011

Attachment 5-1

WATERS

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SigmaQueue

Empower

2475 Final Test

SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console

2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result
Initialize	☐
Calibrate	☐
PMT Cal	☐
Normalize	☐
Re-Start	☐
Rayleigh	☐
Raman	☐
R-R Valley	☐
Wl Resolution	☐
Stray Ratio	☐
S/N Ratio	☐
Purge	☐

Operator
HCTan

Firmware Rev.

Serial Number

With instrument OFF, connect serial cable to instrument, connect tubing(click tubing details for diagram), enter serial number, select operator from list, turn on instrument power switch and press Start Test. Note: Pump will start, so make sure pump is in remote mode and armed, and fluid containers have fluids (see tubing page for details)

Start Test

Abort Test

FLR?(T)

Print Previous

Diagnostics

EXIT

Waters Corporation
Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0
(C) 2011

Attachment 5-2

WATERS

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Recycle Bin Calculator New Text Document

SigmaQueue
Empower
2475 Final Test
SigmaProbe GUI
Sigmaserver
9600 BPS Terminal
38400 BPS Terminal
ACQUITY Console

2475/FLR Final Test System, TE802760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result	Operator	Firmware Rev.	Serial Number
Initialize		HCTan		
Calibrate		With instrument OFF, connect serial cable to instrument, connect tubing(click tubing details for diagram), enter serial number, select operator from list, turn on instrument power switch and press Start Test. Note: Pump will start, so make sure fluid containers have fluids (see tubing details)		
PMT Cal				
Normalize				
Re-Start				
Rayleigh				
Raman				
R-R Valley				
WL Resolution				
Stray Ratio				
S/N Ratio				
Purge				

Enter SN

Enter or Scan Serial Number

Serial Number

TMD(s), separate with commas

OK

Start Test

Abort Test

FLR?(T)

Print Previous

Diagnostics

EXIT

Waters Corporation

Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0

(C) 2011

WATERS

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Attachment 5-4

Recycle Bin Calculator

New Text Document

SigmaQueue

Empower

2475 Final Test

SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console

2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result
Initialize	Initializing..
Calibrate	
PMT Cal	
Normalize	
Re-Start	
Rayleigh	
Raman	
R-R Valley	
WI Resolution	
Stray Ratio	
S/N Ratio	
Purge	

Operator: HCTan Firmware Rev.: Serial Number: B11475983M

Waiting for instrument to complete initialization, this can take up to six minutes....monitor below and instrument display for progress

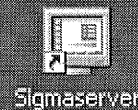
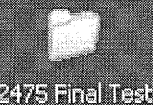
Start Test Abort Test FLR?(T)

Print Previous Diagnostics EXIT

Waters Corporation Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0 (C) 2011

Waters

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2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result
Initialize	Aborted..
Calibrate	
PMT Cal	
Normalize	
Re-Start	
Rayleigh	
Raman	
R-R Valley	
WI Resolution	
Stray Ratio	
S/N Ratio	
Purge	

Operator
HCTan

Firmware Rev.

Serial Number
B11475983M

Powering Down Unit..

Continue

Start Test

Abort Test

FLR?(T)

Print Previous

Diagnostics

EXIT

Waters Corporation

Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0

(C) 2011

Attadmet 43-12

WATERS

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FLR 2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result
Initialize	Aborted..
Calibrate	
PMT Cal	
Normalize	
Re-Start	
Rayleigh	
Raman	
R-R Valley	
WI Resolution	
Stray Ratio	
S/N Ratio	
Purge	

Operator
HCTan

Firmware Rev.

Serial Number
B11475983M

Powering Down Unit..

Continue

Start Test

Abort Test

FLR?(T)

Print

Diagnostics

EXIT

Waters Corporation

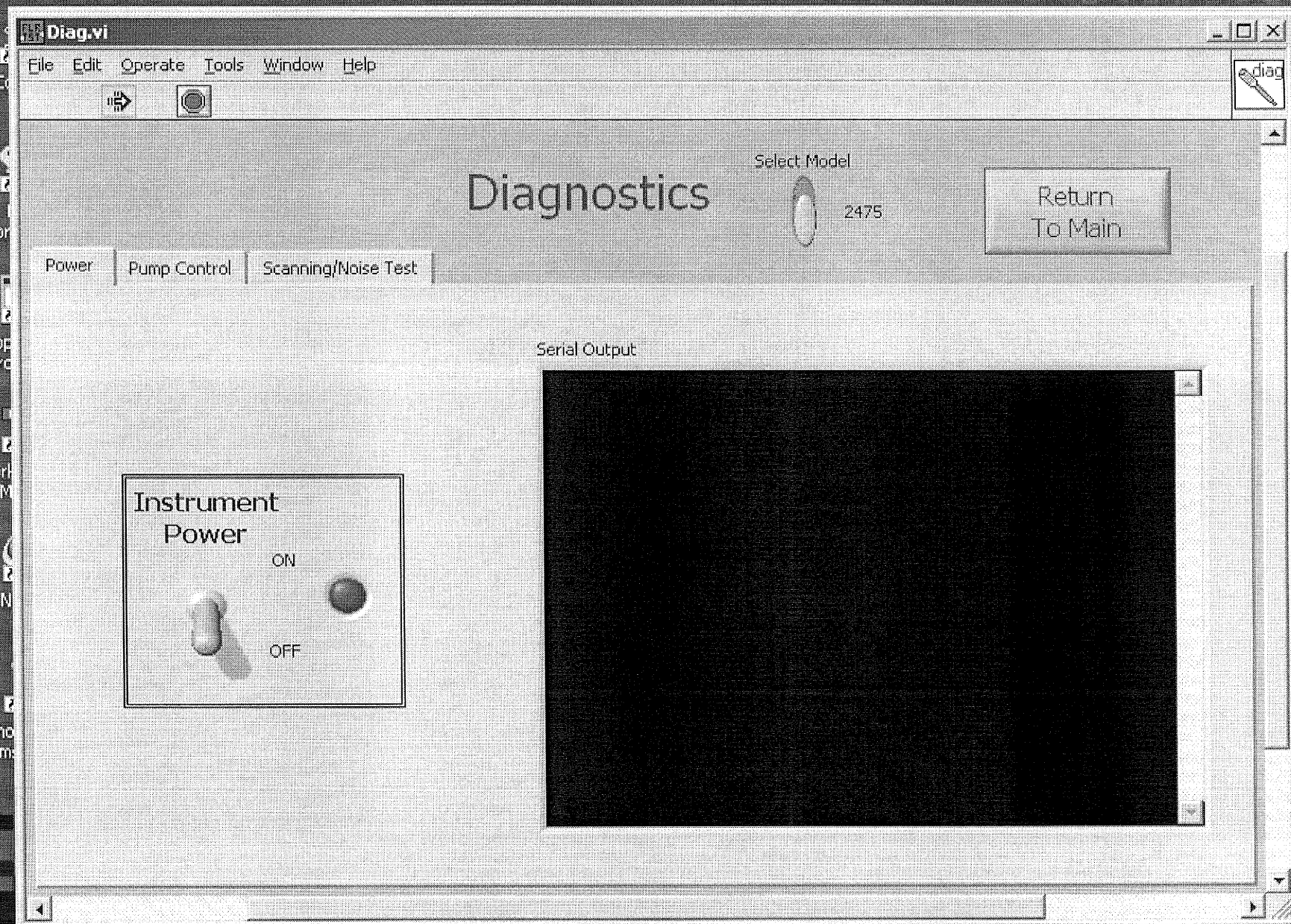
Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0

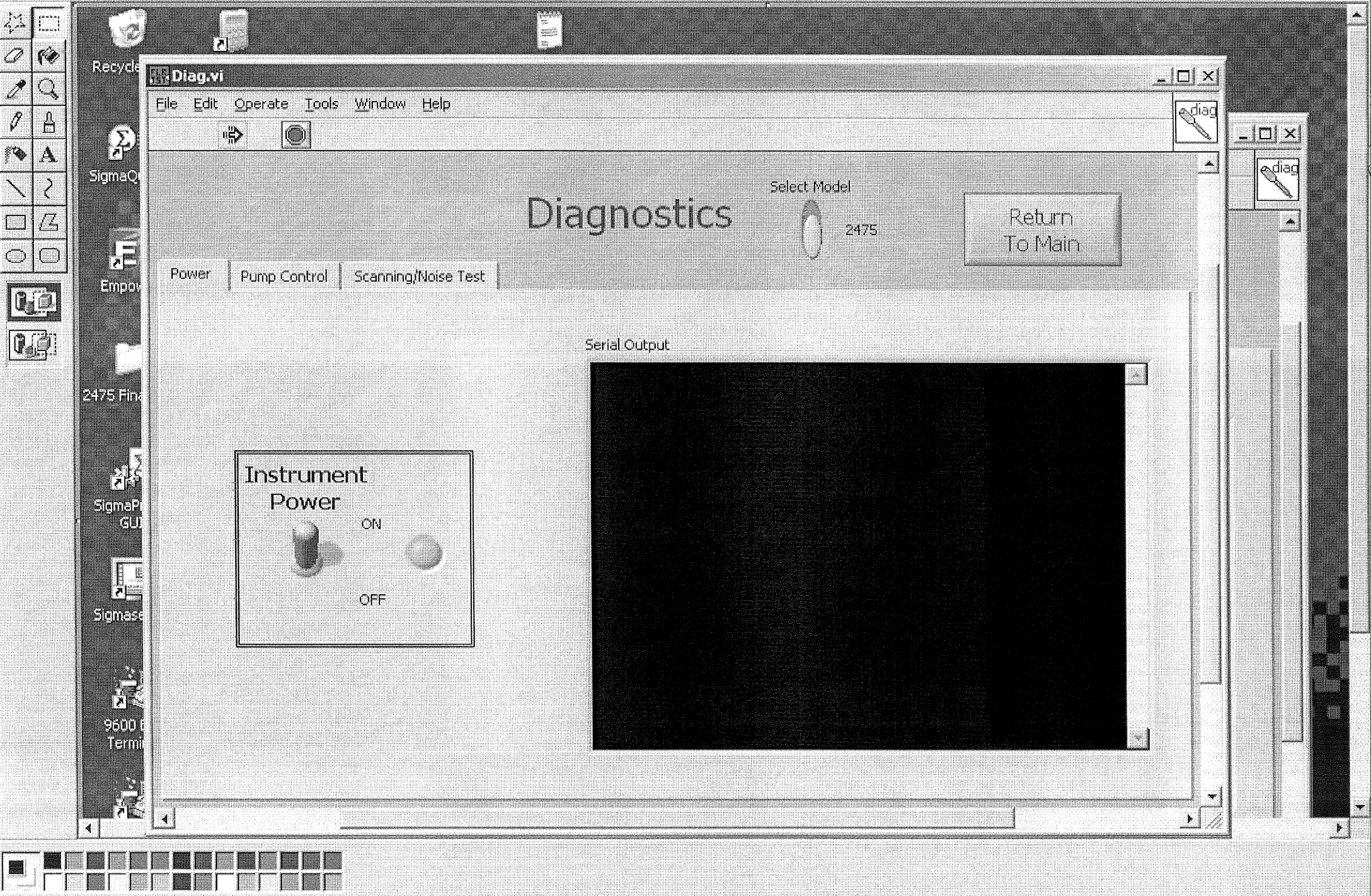
(C) 2011

Attachment 5 - 6

WATERS

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Attached 5-8

SigmaQueue

Empower

2475 Final Test

SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console

Diag.vi

File Edit Operate Tools Window Help

diag

Diagnos

Select Model

2475

Return To Main

Power

Pump Control

Scanning/Noise Test

Instrument Power

ON

OFF

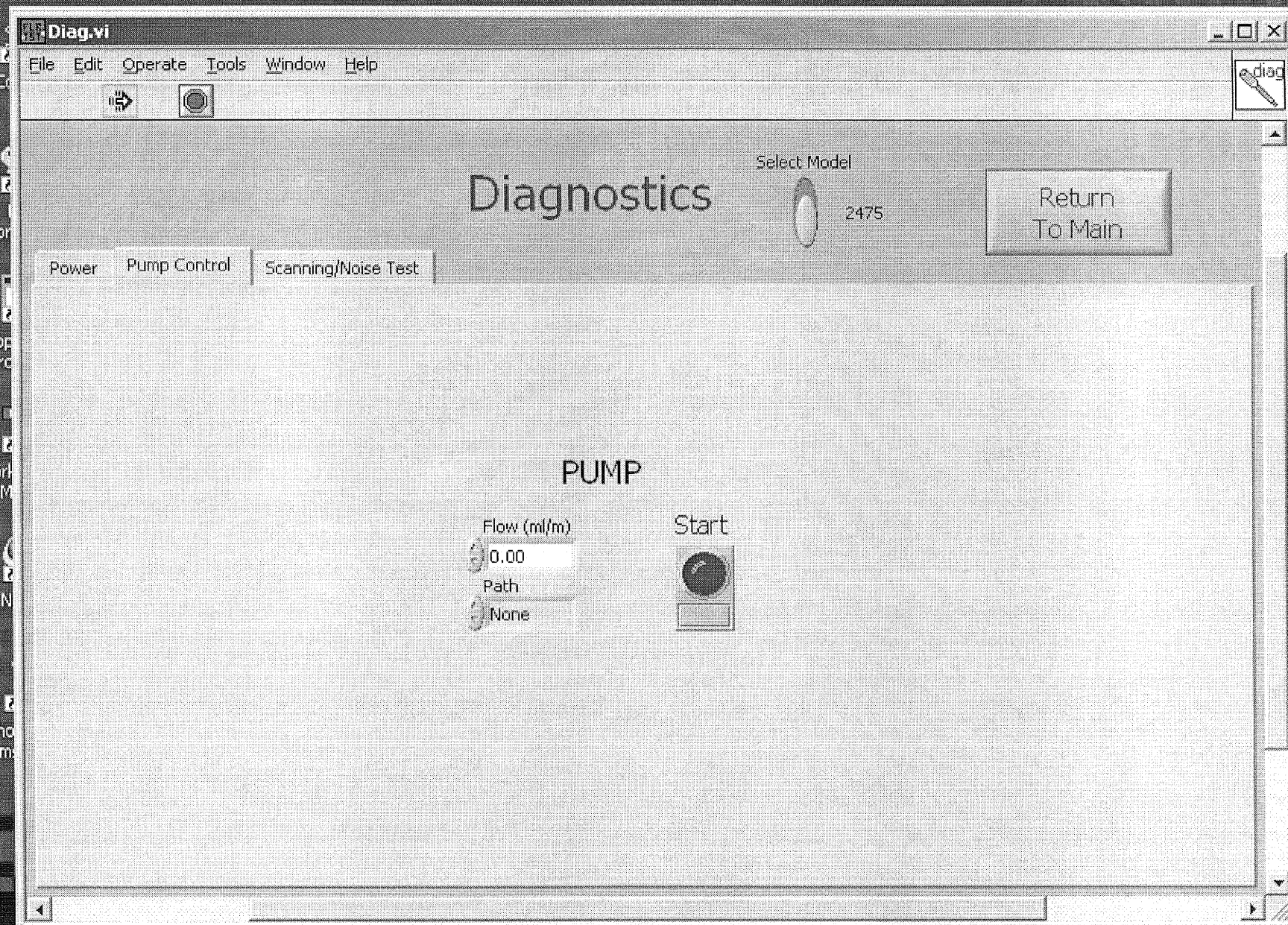
Serial Output

CONSOLE:> 21.97: Acqman is now initialized

Attached 5-9

VVUETS

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Recycle Bin

Calculator

New Text Document

SigmaQueue

Empower

2475 Final Test

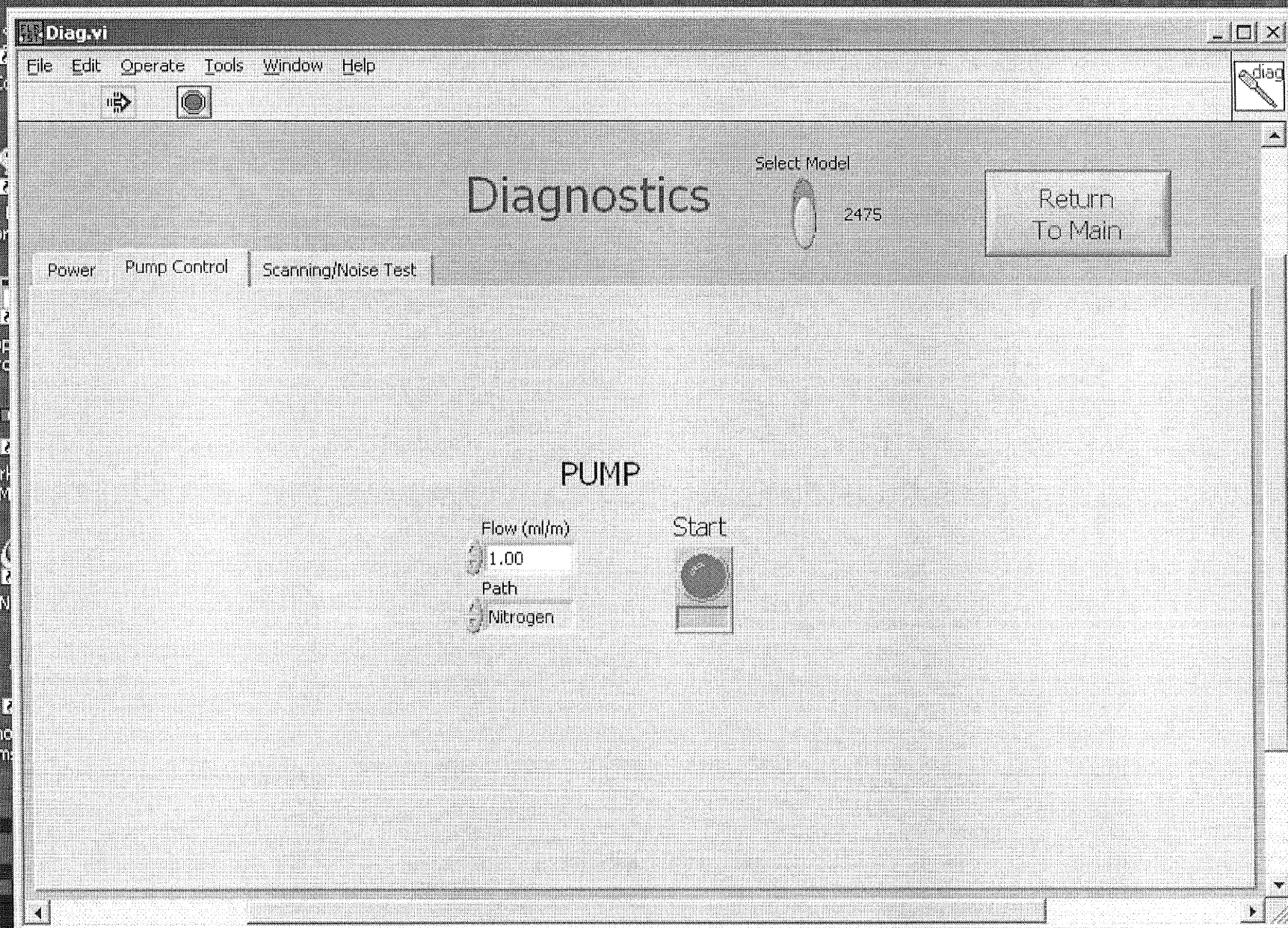
SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console



Attachment 5-11

VVCIERS

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SigmaQueue

Empower

2475 Final Test

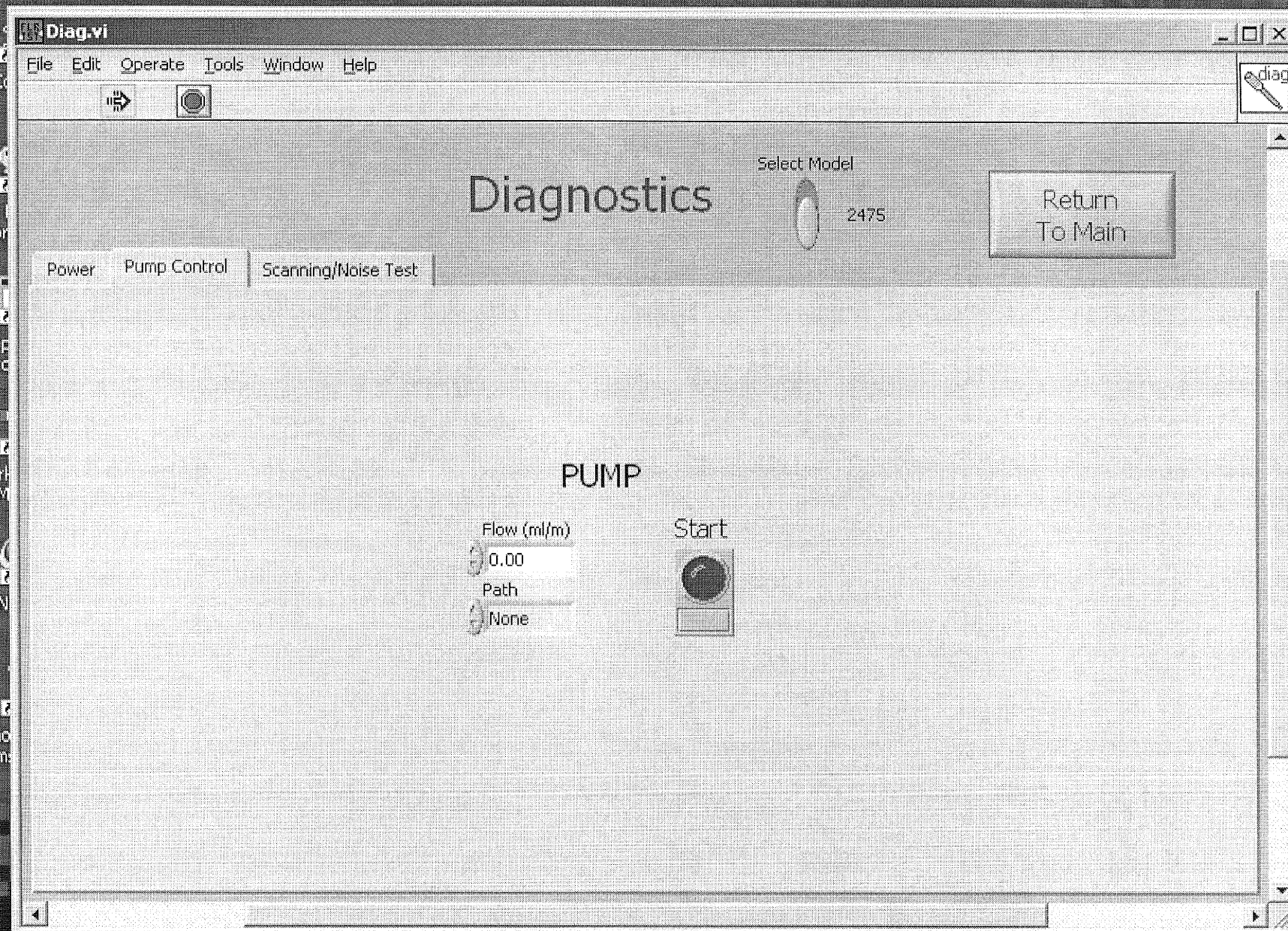
SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console



Attachment 5-12

VYVATERS

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- SigmaQueue
- Empower
- 2475 Final Test
- SigmaProbe GUI
- Sigmaserver
- 9600 BPS Terminal
- 38400 BPS Terminal
- ACQUITY Console

Diag.vi

File Edit Operate Tools Window Help



diag

2475

Return To Main

Power

Pump Control

Scanning/Noise Test

PUMP

Flow (ml/m)
1.00

Path
Water

Start

Attachment 5-13

WATERS

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SigmaQueue

Empower

2475 Final Test

SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console

Diag.vi

File Edit Operate Tools Window Help



diag



2475

Select Model

Return To Main

Power

Pump Control

Scanning/Noise Test

PUMP

Flow (ml/m)
0.00

Path
None

Start

Attached 5-14

VVATEIS

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SigmaQueue

Empower

2475 Final Test Stop Pro

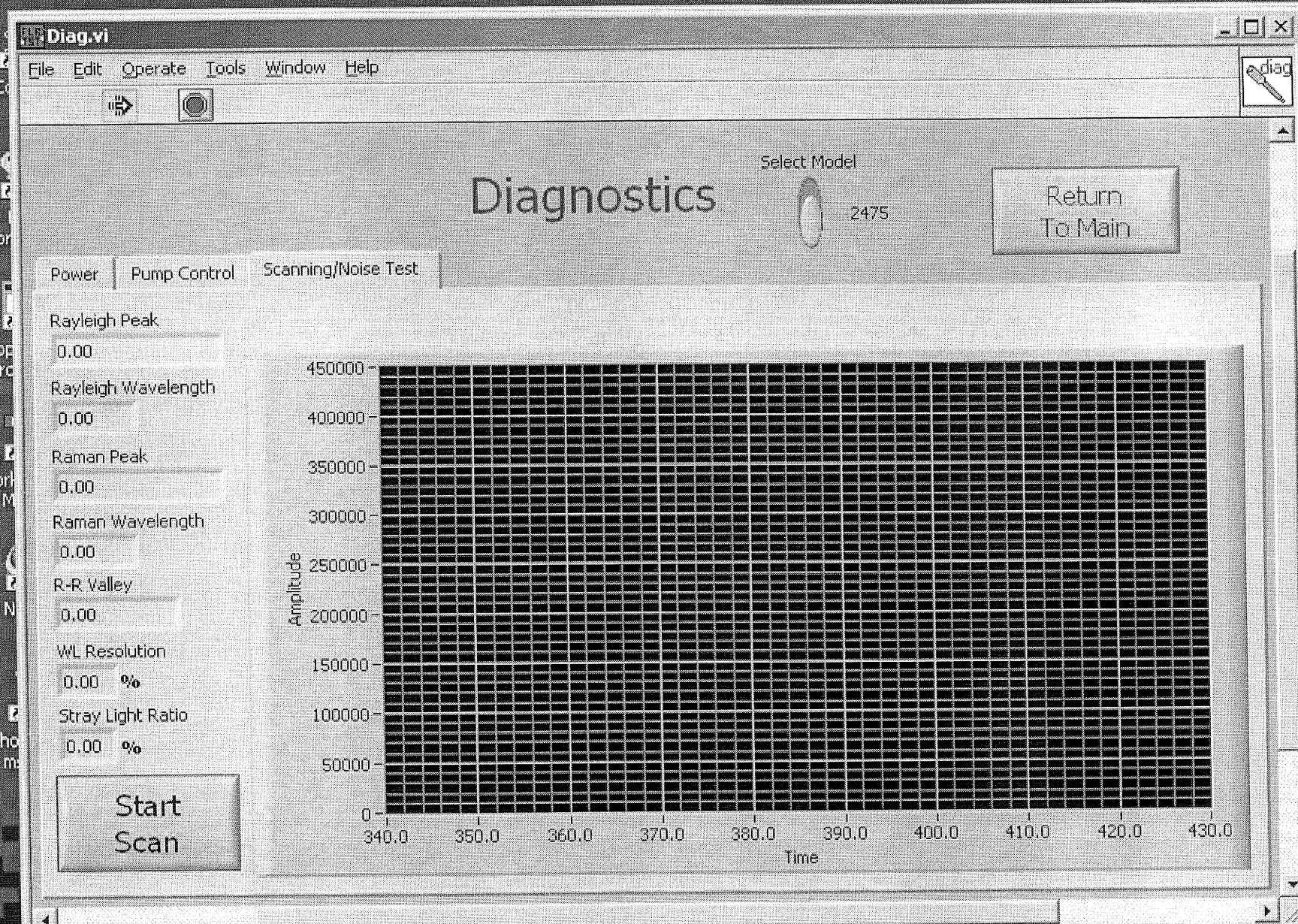
SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console



Attachment 5-15

Waters

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SigmaQueue

Empower

2475 Final Test Stop Pro

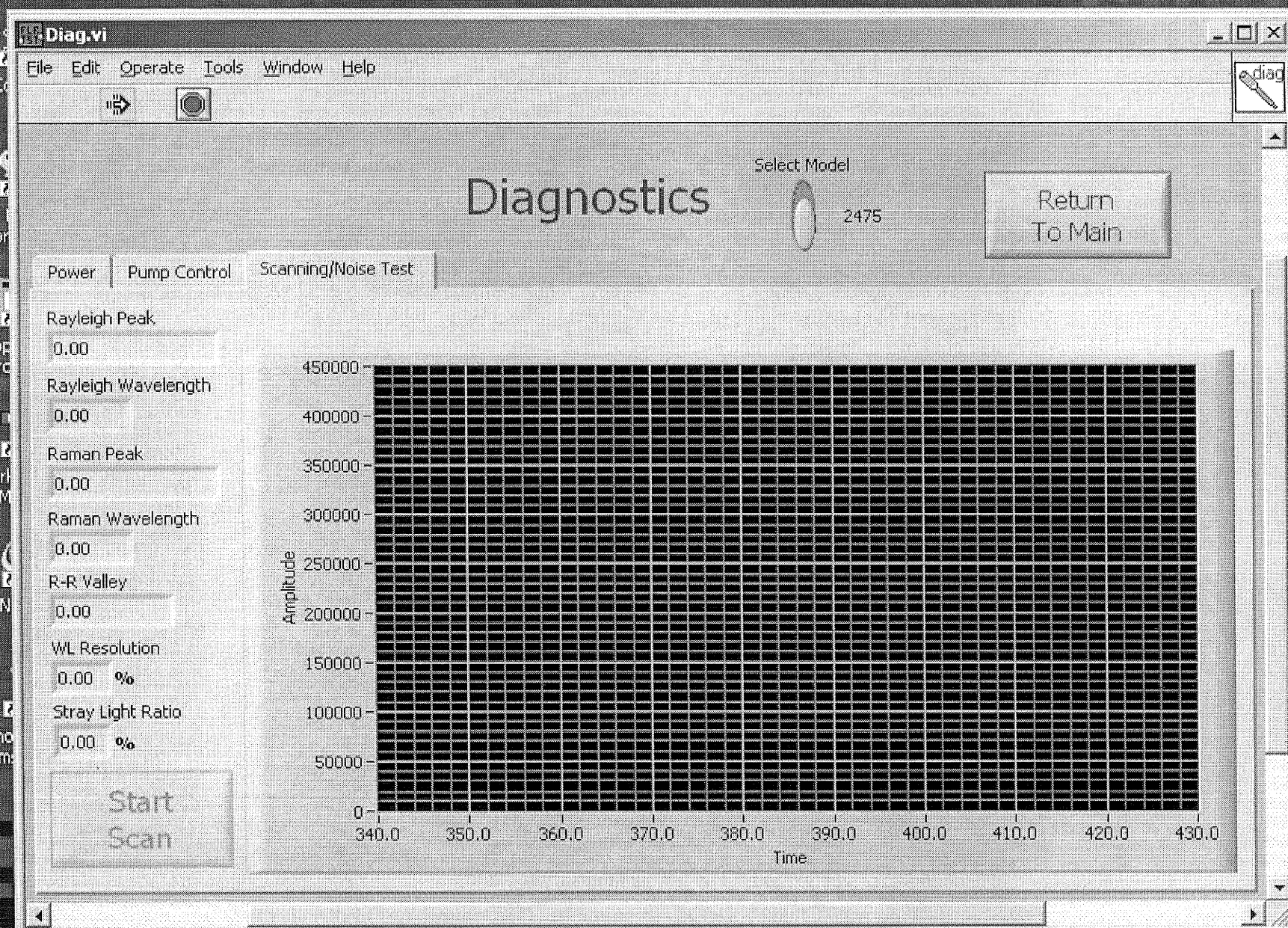
SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console



Attached S-16

VVOTERS
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2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Operator

HCTan

Firmware Rev.

Serial Number

Step

Result

Initialize

Calibrate

PMT Cal

Normalize

Re-Start

Rayleigh

Raman

R-R Valley

WI Resolution

Stray Ratio

S/N Ratio

Purge

Start Test

Abort Test

FLR?(T)

Print Previous

Diagnostics

EXIT

Waters Corporation

Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0

(C) 2011

With instrument OFF, connect serial cable to instrument, connect tubing(click tubing details for diagram), enter serial number, select operator from list, turn on instrument power switch and press Start Test. Note: Pump will start, so make sure pump is in remote mode and armed, and fluid containers have fluids (see tubing page for details)

Attache 5-17

WATERS

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SigmaQueue

Empower

2475 Final Test

SigmaProbe GUI

Sigmaserver

9600 BPS Terminal

38400 BPS Terminal

ACQUITY Console

2475/FLR Final Test System, TE#82760

2475-Acq FLR Fluorescence Detector Final Test

Step	Result
Initialize	
Calibrate	
PMT Cal	
Normalize	
Re-Start	
Rayleigh	
Raman	
R-R Valley	
WI Resolution	
Stray Ratio	
S/N Ratio	
Purge	

Start Test

Abort Test

FLR?(T)

Print Previous

Diagnostics

EXIT

Waters Corporation

Test System:TE82760-5 Revision:2.0 (5/2011) Config Version:Tsw2.0_Hw0.0_Prod0.0

(C) 2011

Operator

HCTan

Firmware Rev.

Serial Number

With instrument OFF, connect serial cable to instrument, connect tubing(click tubing details for diagram), enter serial number, select operator from list, turn on instrument power switch and press Start Test. Note: Pump will start, so make sure pump is in remote mode and armed, and fluid containers have fluids (see tubing page for details)

Attachment 5-18

WATERS

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Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: HCTanStart Time: 05/22/2013,
02:32:18Serial Number: B11475983MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	351.4	352.5	nM	PASS
Rayleigh Energy		6816647		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.4	399.5	nM	PASS
Raman Energy	100	93471	100000	EU	PASS
Ram-Ray Valley Energy		43432		EU	PASS
Optical Resolution		46.47			PASS
Stray Light Ratio		1.37			PASS
Signal/Noise Ratio	1000	2331.01	4000		PASS

Notes:

Signed: THN HCDate: 22/MAY/13

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.

Affidavit 6-2

Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: HCTanStart Time: 05/22/2013,
03:06:58Serial Number: B11475983MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	351.5	352.5	nM	PASS
Rayleigh Energy		6658683		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.5	399.5	nM	PASS
Raman Energy	100	90932	100000	EU	PASS
Ram-Ray Valley Energy		42220		EU	PASS
Optical Resolution		46.43			PASS
Stray Light Ratio		1.37			PASS
Signal/Noise Ratio	1000	2464.2	4000		PASS

Notes:

Signed: *TAHAN*Date: *22/MAY/13*

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Attachment 6-3

Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: HCTanStart Time: 05/22/2013,
04:58:44Serial Number: B11475983MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					
Calibrate					PASS
PMT Cal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	351.5	352.5	nM	PASS
Rayleigh Energy		6059777		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.5	399.5	nM	PASS
Raman Energy	100	81767	100000	EU	PASS
Ram-Ray Valley Energy		37967		EU	PASS
Optical Resolution		46.43			PASS
Stray Light Ratio		1.35			PASS
Signal/Noise Ratio	1000	2555.81	4000		PASS

Notes:

Signed: TAN MCDate: 22/MAY/13

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Attachment 6-4

Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: HCTanStart Time: 05/22/2013,
06:15:44Serial Number: B11475983MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	351.4	352.5	nM	PASS
Rayleigh Energy		6488093		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	395.7	399.5	nM	PASS
Raman Energy	100	87084	100000	EU	PASS
Ram-Ray Valley Energy		41243		EU	PASS
Optical Resolution		47.36			PASS
Stray Light Ratio		1.34			PASS
Signal/Noise Ratio	1000	2499.69	4000		PASS

Notes:

Signed: TAN HCDate: 22/MAY/13

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Attachment 6-5

Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: HCTanStart Time: 05/22/2013,
06:49:37Serial Number: B11475983MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	351.4	352.5	nM	PASS
Rayleigh Energy		6457537		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.4	399.5	nM	PASS
Raman Energy	100	86896	100000	EU	PASS
Ram-Ray Valley Energy		41012		EU	PASS
Optical Resolution		47.2			PASS
Stray Light Ratio		1.35			PASS
Signal/Noise Ratio	1000	2642.01	4000		PASS

Notes:

Signed: TAU HC.Date: 22/MAY/13

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Attachment 6-6

Waters Corporation - Instrument Final Test Record

Part Number: <u>186002475</u>	Product: <u>2475 Detector</u>
Operator: <u>KLloo</u>	Start Time: <u>05/23/2013, 02:31:07</u>
Serial Number: <u>B11475994M</u>	Firmware Revision: <u>2.02</u>

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	350.7	352.5	nM	PASS
Rayleigh Energy		5694561		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.5	399.5	nM	PASS
Raman Energy	100	74688	100000	EU	PASS
Ram-Ray Valley Energy		30921		EU	PASS
Optical Resolution		41.4			PASS
Stray Light Ratio		1.31			PASS
Signal/Noise Ratio	1000	2014.98	4000		PASS

Notes:

Signed: TKM HC

Date: 2014/05/13

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.

Attachment 6-7

Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: KLLooStart Time: 05/23/2013,
03:52:27Serial Number: B11475994MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	350.7	352.5	nM	PASS
Rayleigh Energy		5364018		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	395.8	399.5	nM	PASS
Raman Energy	100	71503	100000	EU	PASS
Ram-Ray Valley Energy		29401		EU	PASS
Optical Resolution		41.12			PASS
Stray Light Ratio		1.33			PASS
Signal/Noise Ratio	1000	2049.18	4000		PASS

Notes:

Signed: JAN M.C.Date: 23/MAY/13

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Attachment 6-8

Waters Corporation - Instrument Final Test Record

Part Number: <u>186002475</u>	Product: <u>2475 Detector</u>
Operator: <u>KLloo</u>	Start Time: <u>05/23/2013, 04:28:24</u>
Serial Number: <u>B11475994M</u>	Firmware Revision: <u>2.02</u>

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	350.8	352.5	nM	PASS
Rayleigh Energy		5369929		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.7	399.5	nM	PASS
Raman Energy	100	71264	100000	EU	PASS
Ram-Ray Valley Energy		29169		EU	PASS
Optical Resolution		40.93			PASS
Stray Light Ratio		1.33			PASS
Signal/Noise Ratio	1000	2009.08	4000		PASS

Notes:

Signed: TMW H.C.Date: 23 MAY 13

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Affidavit 6-9

Waters Corporation - Instrument Final Test Record

Part Number: 186002475Product: 2475 DetectorOperator: KLlooStart Time: 05/23/2013,
05:08:36Serial Number: B11475994MFirmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	350.9	352.5	nM	PASS
Rayleigh Energy		5527830		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	396.7	399.5	nM	PASS
Raman Energy	100	73773	100000	EU	PASS
Ram-Ray Valley Energy		29976		EU	PASS
Optical Resolution		40.63			PASS
Stray Light Ratio		1.33			PASS
Signal/Noise Ratio	1000	2100.52	4000		PASS

Notes:

Signed: JAN H.C.Date: 23/MAY/13

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Attachment 6-10

Waters Corporation - Instrument Final Test Record

Part Number: 186002475
 Operator: KLloo
 Serial Number: B11475994M

Product: 2475 Detector
 Start Time: 05/23/2013,
08:40:32
 Firmware Revision: 2.02

Name	LSL	Measurement	USL	Unit	Outcome
2475 Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	347.5	350.9	352.5	nM	PASS
Rayleigh Energy		5426252		EU	PASS
Gain		1			PASS
Raman Wavelength	394.5	395.9	399.5	nM	PASS
Raman Energy	100	72647	100000	EU	PASS
Ram-Ray Valley Energy		29585		EU	PASS
Optical Resolution		40.72			PASS
Stray Light Ratio		1.34			PASS
Signal/Noise Ratio	1000	1980.7	4000		PASS

Notes:

Signed: TAN H.C.Date: 23/MAY/13

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Attachment 6-11

Waters Corporation - Instrument Final Test Record

Part Number: 186015029Product: Acquity FLROperator: HCTanStart Time: 05/22/2013,
02:33:33Serial Number: K08UPF480RFirmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMT Cal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.3	367.5	nM	PASS
Rayleigh Energy		15411059		EU	PASS
Gain		0.3			PASS
Raman Wavelength	413.5	416.7	418.5	nM	PASS
Raman Energy	100	55257	100000	EU	PASS
Ram-Ray Valley Energy		7968		EU	PASS
Optical Resolution		14.42			PASS
Stray Light Ratio		0.36			PASS
Signal/Noise Ratio	1000	2750.51	4000		PASS

Notes:

Signed: JAN H.C.Date: 22/MAY/13

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Attachment 6-12

Waters Corporation - Instrument Final Test Record

Part Number: <u>186015029</u>	Product: <u>Acquity FLR</u>
Operator: <u>KLloo</u>	Start Time: <u>05/22/2013, 03:09:39</u>
Serial Number: <u>K08UPF480R</u>	Firmware Revision: <u>1.40</u>

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.2	367.5	nM	PASS
Rayleigh Energy		15118021		EU	PASS
Gain		0.3			PASS
Raman Wavelength	413.5	416.7	418.5	nM	PASS
Raman Energy	100	54008	100000	EU	PASS
Ram-Ray Valley Energy		7661		EU	PASS
Optical Resolution		14.18			PASS
Stray Light Ratio		0.36			PASS
Signal/Noise Ratio	1000	2801.88	4000		PASS

Notes:

Signed: TKNAC.

Date: 22/MAY/13

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Waters Corporation - Instrument Final Test Record

Part Number: <u>186015029</u>	Product: <u>Acquity FLR</u>
Operator: <u>KLloo</u>	Start Time: <u>05/22/2013, 03:52:02</u>
Serial Number: <u>K08UPF480R</u>	Firmware Revision: <u>1.40</u>

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					
Calibrate					PASS
PMT Cal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.2	367.5	nM	PASS
Rayleigh Energy		15262710		EU	PASS
Gain		0.3			PASS
Raman Wavelength	413.5	416.6	418.5	nM	PASS
Raman Energy	100	54179	100000	EU	PASS
Ram-Ray Valley Energy		7847		EU	PASS
Optical Resolution		14.48			PASS
Stray Light Ratio		0.35			PASS
Signal/Noise Ratio	1000	2893.31	4000		PASS

Notes:

Signed: TKW H.C.

Date: 22/MAY/13

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Attachment 6-14

Waters Corporation - Instrument Final Test Record

Part Number: <u>186015029</u>	Product: <u>Acquity FLR</u>
Operator: <u>KLoo</u>	Start Time: <u>05/22/2013, 04:26:48</u>
Serial Number: <u>K08UPF480R</u>	Firmware Revision: <u>1.40</u>

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.2	367.5	nM	PASS
Rayleigh Energy		15154920		EU	PASS
Gain		0.3			PASS
Raman Wavelength	413.5	416.7	418.5	nM	PASS
Raman Energy	100	53731	100000	EU	PASS
Ram-Ray Valley Energy		7672		EU	PASS
Optical Resolution		14.28			PASS
Stray Light Ratio		0.35			PASS
Signal/Noise Ratio	1000	3182.63	4000		PASS

Notes:

Signed: TAM H.C.Date: 22/MAY/13

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Attached 6-15

Waters Corporation - Instrument Final Test Record

Part Number: <u>186015029</u>	Product: <u>Acquity FLR</u>
Operator: <u>KLLOO</u>	Start Time: <u>05/22/2013</u> <u>05:36:54</u>
Serial Number: <u>K08UPF480R</u>	Firmware Revision: <u>1.40</u>

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	364.5	367.5	nM	PASS
Rayleigh Energy		16586073		EU	PASS
Gain		0.35			PASS
Raman Wavelength	413.5	416.7	418.5	nM	PASS
Raman Energy	100	58064	100000	EU	PASS
Ram-Ray Valley Energy		8395		EU	PASS
Optical Resolution		14.46			PASS
Stray Light Ratio		0.35			PASS
Signal/Noise Ratio	1000	2555.08	4000		PASS

Notes:

Signed: TAU H.C.

Date: 22 MAY 113

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Attachment 6-16

Waters Corporation - Instrument Final Test Record

Part Number: 186015029Product: Acquity FLROperator: HCTanStart Time: 05/22/2013,
06:41:23Serial Number: M09UPF765RFirmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	365.3	367.5	nM	PASS
Rayleigh Energy		11019426		EU	PASS
Gain		0.1			PASS
Raman Wavelength	413.5	416.7	418.5	nM	PASS
Raman Energy	100	34558	100000	EU	PASS
Ram-Ray Valley Energy		5795		EU	PASS
Optical Resolution		16.77			PASS
Stray Light Ratio		0.31			PASS
Signal/Noise Ratio	1000	3180.87	4000		PASS

Notes:

TAMM.C. 22/MAY/13

Signed: ~~TAMM.C.~~

TAMM.C.

Date: 22/MAY/13

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Attachment 6-17

Waters Corporation - Instrument Final Test Record

Part Number: 186015029
 Operator: HCTan
 Serial Number: M09UPF765R

Product: Acquity FLR
 Start Time: 05/22/2013,
07:38:44
 Firmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	364.8	367.5	nM	PASS
Rayleigh Energy		16077127		EU	PASS
Gain		0.15			PASS
Raman Wavelength	413.5	416.1	418.5	nM	PASS
Raman Energy	100	49504	100000	EU	PASS
Ram-Ray Valley Energy		8222		EU	PASS
Optical Resolution		16.61			PASS
Stray Light Ratio		0.31			PASS
Signal/Noise Ratio	1000	3377.29	4000		PASS

Notes:

Signed: TAN H.C.Date: 22/MAY/13

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Attached 6-18

Waters Corporation - Instrument Final Test Record

Part Number: 186015029
 Operator: HCTan
 Serial Number: M09UPF765R

Product: Acquity FLR
 Start Time: 05/22/2013,
08:14:31
 Firmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	364.8	367.5	nM	PASS
Rayleigh Energy		10352808		EU	PASS
Gain		0.1			PASS
Raman Wavelength	413.5	416.9	418.5	nM	PASS
Raman Energy	100	32380	100000	EU	PASS
Ram-Ray Valley Energy		5459		EU	PASS
Optical Resolution		16.86			PASS
Stray Light Ratio		0.31			PASS
Signal/Noise Ratio	1000	3207.22	4000		PASS

Notes:

Signed: TAU H.C.Date: 22/MAY/13

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Attachment 6.19

Waters Corporation - Instrument Final Test Record

Part Number: 186015029
 Operator: KLloo
 Serial Number: M09UPF765R

Product: Acquity FLR
 Start Time: 05/22/2013,
09:05:34
 Firmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					
Calibrate					PASS
PMTCal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	364.8	367.5	nM	PASS
Rayleigh Energy		16326528		EU	PASS
Gain		0.15			PASS
Raman Wavelength	413.5	416.8	418.5	nM	PASS
Raman Energy	100	50291	100000	EU	PASS
Ram-Ray Valley Energy		8135		EU	PASS
Optical Resolution		16.18			PASS
Stray Light Ratio		0.31			PASS
Signal/Noise Ratio	1000	2841.43	4000		PASS

Notes:

Signed: TMV Y.C.Date: 22 May 13

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Attachment 6-20

Waters Corporation - Instrument Final Test Record

Part Number: 186015029Product: Acquity FLROperator: KLlooStart Time: 05/22/2013,
09:39:34Serial Number: M09UPF765RFirmware Revision: 1.40

Name	LSL	Measurement	USL	Unit	Outcome
Acquity FLR Final Test					PASS
Calibrate					PASS
PMTcal					PASS
Normalize					PASS
Restart					PASS
Rayleigh Wavelength	362.5	364.8	367.5	nM	PASS
Rayleigh Energy		15627460		EU	PASS
Gain		0.15			PASS
Raman Wavelength	413.5	416.8	418.5	nM	PASS
Raman Energy	100	48537	100000	EU	PASS
Ram-Ray Valley Energy		7881		EU	PASS
Optical Resolution		16.24			PASS
Stray Light Ratio		0.31			PASS
Signal/Noise Ratio	1000	3296.17	4000		PASS

Notes:

Signed: TKM H.C.Date: 22 MAY/13

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