

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: Multiple_WPPL_TE-02OCT17-IQR_(01 of 03)		Iteration No: 00	SAP No: TE008XXXXQX (depending on the TE number)

INSTALLATION QUALIFICATION REPORT

For Various Waters LC Test Systems

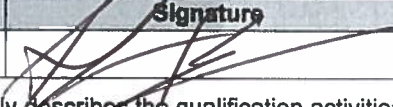
PREPARED BY

Name	Role	Signature	Date
Yeap Siew Yee	Test Validation Engineer		06 Oct 2017

REVIEWED BY

Name	Role	Signature	Date
TERRANA MORSE	Sr. Process Validation Engineer	T. Morse	10 OCT 2017

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		10 Oct 2017

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

The "Reviewed By" signature[s] denotes agreement with the description of the qualification activities.

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

REVISION HISTORY

Version	Author	Summary of change
00	Yeap Siew Yee	First document for approval

Waters THE SCIENCE OF WHAT'S POSSIBLE™		Installation Qualification Report	
Report No: Multiple_WPPL_TE-02OCT17-IQR_01 of 02		Iteration No: 00	SAP No: TE008XXXXQX (depending on the TE number)

1.0 Purpose

The purpose of the Installation Qualification Report (IQR) is to document the assessment of an engineering change to the following released test equipment:

	Description	Equipment	Part Number Tested in Venture	Location in Venture
1	PCM II Tester	TE82817-2	186002449	Waters Production Floor
2	TCM II Tester	TE82818-2	186002441	
3	PCBA board Tester	TE82824	WAT069520	
4	2475, ALTUS A-10 FLR, ACQUITY UHPLC OPTICS ALIGN	TE83031-1	279003225, 279000400, 279003302	Clean Room
5	FLR OPTICS BENCH	TE83032-1	279001335, 279003000	

This document shall include the deliverable(s) required to qualify the change to legacy test equipment used in production environment for number of years.

Qualification of the equipment shall ensure that it functions within its specifications post change.

2.0 Scope of Report

This Installation Qualification Report details the re-qualification activities undertaken for various automated TE located in Venture, Singapore based on the requirements of the executed protocol, 730004135 Installation Qualification Procedure and the approved Validation Assessment Form Multiple_WPPL_TE-02AUG2017_VAF_Approved. The equipments as per stated in section 1.0 are included in this requalification report. This report captures only the re-qualification activities to update the systems in Venture GES Singapore for use with new location adjustment.

3.0 Summary of Results - Statement of Fitness for Intended Use

Testers that are involved in this shift in Venture GES Singapore were tested in accordance with 730004135 Installation Qualification Procedure, version 00. All test scripts required per Multiple_WPPL_TE-02AUG2017_VAF_Approved were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the impacted testers comply with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Installation Qualification Report, the respective testers can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
TSP	Test Specification and Procedure
CAL/PM	Calibration/Preventive Maintenance
VAF	Validation Assessment Form
IQR	Installation Qualification Report
CPSM	Common Platform Sample Manager
FTN	Flow Thru Needle

 THE SCIENCE OF WHAT'S POSSIBLE™		Installation Qualification Report	
Report No: Multiple_WPPL_TE-02OCT17-IQR_(01 of 02)		Iteration No: 00	SAP No: TE008XXXXQX (depending on the TE number)

Term	Explanation
FL	Fixed Loop
IVD	In Vitro Diagnostic
UUT	Unit Under Test
CTQ	Critical to Quality
P/N	Part Number

5.0 Training

The executor of the Process Validation Procedure for Milford (730001835 Version 05) was trained. The operators performing functional testing in script IQ-06 were also trained to the respective TSP and are qualified to perform testing. There were no changes that required re-training of the operators, as the changes were purely testers location adjustments. Refer to Attachment 01 for copies of the training records.

6.0 Qualification Results

The following table summarizes the scripts performed for the requalification of the relocated testers (per stated in section 1.0) in Venture GES, Singapore. The objective evidence and test scripts for each individual test systems are provided as the attachments below.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-06	Pass	Attachments 02,03,04 and 05	None

Per TE83064-02AUG2017-VAF_Aproved, only test scripts IQ-06 were required to be executed. This is because the changes being verified as part of this re-qualification did not affect the results of the previously executed qualifications found in the referenced Installation Qualification Reports in Section 9.0.

Script IQ-01 Associated Documentation Verification:

This test script was not required to be performed as part of this re-qualification as there is no change in released documentation.

Script IQ-02 Site Verification:

This test script was not required to be performed as part of this re-qualification as the site has not changed.

Script IQ-03 Instrumentation Calibration Verification:

This test script was not required to be performed as part of this re-qualification as the calibration and preventative maintenance of these systems has not changed.

Script IQ-04 Test Software and Instrument Firmware Version:

This test script was not required to be performed as part of this re-qualification as the instrument firmware versions have not changed.

Script IQ-05 General Safety and Alarms:

This test script was not required to be performed as part of this re-qualification as the test station setup has not changed.

Script IQ-06 Functional Verification:

This test script was only required to be executed as the change only includes physical testers shifting and no change was made to the functionality of the respective testers (outlined in the approved VAF).

 Installation Qualification Report	
Report No: Multiple_WPPL_TE-02OCT17-IQR_(01 of 02)	Iteration No: 00
SAP No: TE008XXXXQX (depending on the TE number)	

The UUT part numbers used for functional testing were as per table below. These part numbers are functionally equivalent to all other part numbers mentioned under section 1.0.

	Description	Equipment ID	Part Number used for IQ-06
1	PCM II Tester	TE82817-2	186002449
2	TCM II Tester	TE82818-2	186002441
3	PCBA board Tester	TE82824	WAT223-02
4	2475, ALTUS A-10 FLR, ACQUITY UHPLC OPTICS ALIGN	TE83031-1	279003225
5	FLR OPTICS BENCH ALIGNMENT	TE83032-1	279001335

7.0 Attachments

- Attachment 01: Training Record to 730004135 Installation Qualification Procedure and respective TSPs
- Attachment 02: Completed Test Script Data Sheet IQ-06 Performance Verification - (Column Managers Testers)
- Attachment 03: Objective Evidence IQ-06: UUT Test Records – (Column Managers Testers)
- Attachment 04: Completed Test Script Data Sheet IQ-06 Performance Verification - (Optic Bench Testers)
- Attachment 05: Objective Evidence IQ-06: UUT Test Records – (Optic Bench Testers)

8.0 Deviation from Test Equipment Verification, Qualification, or Validation

There were no deviations generated during the execution of 730004135 Installation Qualification Procedure, Version 00.

9.0 References

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

Document Number	Document title
Multiple_WPPL_TE-02AUG2017-VAF Approved	Validation Assessment Form
735000887	PCM II Final Test Procedure
735000888	TCM II Final Test Procedure
735000629	2475 FLUORESCENCE DETECTOR
735002011	Acquity Fir Optics Bench Alignment

Waters THE SCIENCE OF WHAT'S POSSIBLE™		Installation Qualification Report	
Report No: Multiple_WPPL_TE-02OCT17-IQR (01 of 02)		Iteration No: 00	SAP No: TE008XXXXQX (depending on the TE number)

The UUT part numbers used for functional testing were as per table below. These part numbers are functionally equivalent to all other part numbers mentioned under section 1.0.

	Description	Equipment ID	Part Number used for IQ-06
1	PCM II Tester	TE82817-2	186002449
2	TCM II Tester	TE82818-2	186002441
3	PCBA board Tester	TE82824	WAT223-02
4	2475, ALTUS A-10 FLR, ACQUITY UHPLC OPTICS ALIGN	TE83031-1	279003225
5	FLR OPTICS BENCH ALIGNMENT	TE83032-1	279001335

7.0 Attachments

Attachment 01: Training Record to 730004135 Installation Qualification Procedure and respective TSPs
 Attachment 02: Completed Test Script Data Sheet IQ-06 Performance Verification - (Column Managers Testers)
 Attachment 03: Objective Evidence IQ-06: UUT Test Records – (Column Managers Testers)
 Attachment 04: Completed Test Script Data Sheet IQ-06 Performance Verification - (Optic Bench Testers)
 Attachment 05: Objective Evidence IQ-06: UUT Test Records – (Optic Bench Testers)

8.0 Deviation from Test Equipment Verification, Qualification, or Validation

There were no deviations generated during the execution of 730004135 Installation Qualification Procedure, Version 00.

9.0 References

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

Document Number	Document title
Multiple_WPPL_TE-02AUG2017-VAF_Approved	Validation Assessment Form
735000887	PCM II Final Test Procedure
735000888	TCM II Final Test Procedure
735000829	2475 FLUORESCENCE DETECTOR
735002011	Acquity Flr Optics Bench Alignment

Doc No: Multiple - WPPL - TE-0200717-1QR - (01 of 03)

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

Title: Group Training Form

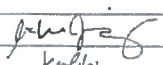
FORM

Document No: 730002656

Version No: 00

Page 1 of 1

Document Number:	730001835
Title:	Process Validation Procedure for Milford Site
Revision Number:	05
Training Type:	Web Based Training
Comments:	This training was conducted online, internationally, between Milford, MA & Singapore on 13-Sep-2017 from 09:00 - 10:00 (Timezone: ZE8). Training covered the workflow and use of the Process Validation Procedure.

Attendees			
Employee ID ¹	Name	Signature	Date
617970	Loh Wan Jing		14 Sep 2017
617978	Jen Chen		14 Sep 2017
618038	Yean Giew Yee		14 Sep 2017
617884	Reemoud Ann		14 Sep 2017
617959	Eugene Tan		14 Sep 2017
N/A AK 15 Sep 2017			

Note: 14 Sep 2017
14 Sep 2017

TERIANA MORSE

Instructor Signature

SR. PROCESS Validation
Engineer

Title

15-Sep-2017

Date



Sr. ops. Quality Engineer 15-Sep-2017

¹ Without preceding "90"

Ysy 06.05.2017

Attachment 01 page 03 of 05
Doc No: ~~74~~ Multiple_WPPL-TE-020CT17-1&R (01 of 03)
Entry
error
TSY 06.02.17



Form No. : HRM-008/00(SQP-HRM-001)

Training Attendance Record

TEST SPEC FOR 2449 PUMP CONTROLLER MODULE II
(MI-WAT-TEST-013) REV:03

Training Subject :

Training Venue :

Waters Production Line

Date : June 23, 2017

Trainer Name & Signature :

Chua Chong Keong

#	Name	Employee No	Department/Station	Signature
1	GOH SIEW TIN	25704823	Waters	
2	YAP POH LENG	25705400	Waters	
3	END OF DATA			
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				

Attachment 01
Page 04 of 05
Page 03 of 03 Entry error yet 06 OCT 17
Doc No: Multiple_WPPL-TE-02OCT17-1QR - (01 of 03)



Form No.: HRM-008/00(SQP-HRM-001)

Training Attendance Record

TEST SPEC FOR 2441 TEMPERATURE CONTROL MODULE II
(MI-WAT-TEST-012) REV:03

Training Subject :

Training Venue :

Waters Production Line

Date : June 23, 2017

Trainer Name & Signature :

Chua Chong Keong

#	Name	Employee No	Department/Station	Signature
1	GOH SIEW TIN	25704823	Waters	
2	YAP POH LENG	25705400	Waters	
3	END OF DATA			
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				

① 735000629 Rev E 2475 Fluorescence Detector
735002011 Rev C Arquty FLR Optiz Bench Alignment

Waters

WORK INSTRUCTION / OPERATING PROCEDURE

THE SCIENCE OF WHAT'S POSSIBLE.™

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 9 of 11

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: 7882817-2	Equipment Name: PCHA II Tester		
Installation Site: Venture / GES, SINGAPORE			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: 186002449 UUT Serial Number: K17PC2439G	All required CTQ Specification measurements result in a Pass.	Pass	YSY 06 OCT 2017
Comments: Refer to Attachment 03, page 01 of 08 for passing test record of UUT prior to relocation. Refer to Attachment 03, page 05 of 08 for passing test record of UUT after relocation. YSY 06 OCT 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Waters

WORK INSTRUCTION / OPERATING PROCEDURE

THE SCIENCE OF WHAT'S POSSIBLE.™

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 9 of 11

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82818-2	Equipment Name: TCM 11 Tester		
Installation Site: Venture / GES, Singapore			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: 186002441 UUT Serial Number: K17TC2387G	All required CTQ Specification measurements result in a Pass.	Pass	YSY 060CT2017
Comments: Refer to Attachment 03, page 03 of 08 for passing test record of UUT prior to relocation. Refer to Attachment 03, page 06 of 08 for passing test record of UUT after relocation. YSY 060CT2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 9 of 11

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TEP2824	Equipment Name: PCBA Board Tester (W600)		
Installation Site: Venture / GES, Singapore			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: WAT 223-02 UUT Serial Number: 3008131066	All required CTQ Specification measurements result in a Pass.	Pass	XY 06 OCT 2017
Comments: Refer to Attachment 03 page 03 of 08 and page 04 of 08 for passing test record of UUT prior relocation. Refer to Attachment 03 page 07 of 08 and page 08 of 08 for passing test record of UUT post relocation. XY 06 OCT 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Waters Corporation

INSTRUMENT FINAL TEST RECORD

Part Number:	186002449	Description:	Pump Control Module II
Tested By:	SIEW TIN	Date:	10/4/2017 9:51:28 AM
Serial Number:	K17PC2439G	Control Number:	N/A
Software Revision:	4.00 Build#: 12 (Oct 15 2008)	Factory Order:	WATS1710054

- 1) Hi - Pot / Ground Continuity Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 2) Rear Panel I/O Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 3) Pumps A, B, & C Status Test
(-12 VDC & +12 VDC) PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 4) Pumps A, B, & C Pressure Test
(-10 VDC - 0 VDC) PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 5) Pumps A, B, & C Control Test
(0 - 2133 HZ TTL) PASS ☒ FAIL ☐ see note # _____ PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed: SIEW TIN Date: 0CT 04 / 2017

Notes:

Time started: 9.48am
Time end: 9.54am
Temperature: 20.4°C
Humidity: 59.6%

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:	186002441	Description:	Temperature Control Module II
Tested By:	SIEW TIN	Date:	10/4/2017 12:22:06 PM
Serial Number:	K17TC2387G	Control Number:	N/A
Software Revision:	3.02	Factory Order:	WATS1710053

- | | | |
|--|--|--|
| 1) Hi - Pot / Ground Continuity | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 2) Keypad | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 3) LCD display | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 4) Temperature Accuracy(101°C - 103°C)
Actual °C Chm 1: 102.1 Chm 2: 102.1 Chm 3: 101.5 | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 5) Temperature Variation(≤.5°C)
Actual °C Lowest: 101.5 Highest: 102.0 Variation: 0.50 | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 6) Heater Verification | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 7) Over Temperature Alarm | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 8) Under Temperature Alarm | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 9) IEEE 488 | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 10) Set System Defaults | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |

Instrument Result: PASS ☒ FAIL ☐ Signed: Siew Tin Date: Oct/ 04/ 2017

Notes:

Time started: 12.18pm
 Time End: 12.28pm
 Temperature: 21.0°C
 Humidity: 52.8%

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.

B

WATERS CORPORATION
INSTRUMENT - FINAL TEST RECORD

Part Number: <u>WAT 223- 02</u>	Description: <u>W600 Controller</u>
Tested By: <u>Sib Tim</u>	Date: <u>OCT 1 04 2017</u>
Serial Number: <u>3008131066</u>	Control Number: <u>NA</u>
Software Revision: <u>4.2</u>	Factory Order: <u>NA</u>

- | | |
|--|---|
| (1) Electrical Safety Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (4) Fan Operation | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (5) IEEE 488 Communications | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (6) Keypad Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (7) Display Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (8) Stop Flow Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (9) External Inject Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (10) Switch One Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (11) Switch Two Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (12) Switch Three Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (13) Switch Four Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (14) Hold Output Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (15) Chart Output Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (16) Pressure Output Actual <u>-5.0</u> mV
w/o Silk (-4.5 mV to -5.5 mV)
w/Silk (-12mv +/- 1 mV) | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (17) 12 VDC External. - Actual: <u>11.94VDC</u>
(11.38 VDC and 12.62 VDC) | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (18) Sparge Valves | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (19) Pump Motor | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (19) Gradient Valves | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |

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: WAT069520, WAT069521 Serial Number: 3008131066

- (20) Serial Port Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- (21) Twelve Volt Failure Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- (22) Counter Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- (23) Temperature Reading - Actual: 35°C PASS ☒ FAIL ☐ see note # _____ PASS ☐
(31C and 37C)
- (24) Pressure Output 2994 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
PSI
(3000 PSI +/- 350 PSI) WAT069520,
(6000 PSI +/- 350 PSI) WAT069521
- (25) Heater (30 VDC +/- 3 VDC)- Actual: 30.9 VDC PASS ☒ FAIL ☐ see note # _____ PASS ☐
- (26) Transducer Excite - Actual: 5.033 VDC PASS ☒ FAIL ☐ see note # _____ PASS ☐
(5 VDC +/- .25 VDC)
- (27) Internal Switch Tests PASS ☒ FAIL ☐ see note # _____ PASS ☐
- (28) Internal Inject Test PASS ☒ FAIL ☐ see note # _____ PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed SWTn Date: OCT / 04 / 2017

Notes: NA

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:	186002449	Description:	Pump Control Module II
Tested By:	SIEW TIN	Date:	10/4/2017 4:05:53 PM
Serial Number:	K17PC2439G	Control Number:	N/A
Software Revision:	4.00 Build#: 12 (Oct 15 2008)	Factory Order:	WATS1710054

- 1) Hi - Pot / Ground Continuity Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 2) Rear Panel I/O Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 3) Pumps A, B, & C Status Test
(-12 VDC & +12 VDC) PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 4) Pumps A, B, & C Pressure Test
(-10 VDC - 0 VDC) PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 5) Pumps A, B, & C Control Test
(0 - 2133 HZ TTL) PASS ☒ FAIL ☐ see note # _____ PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed: Siew Tin Date: 0CT/04/ 2017

Notes:

Time Started : 4.02 pm
Time End : 4.08 pm
Temperature : 20.0°C
Humidity : 51.6%

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:	186002441	Description:	Temperature Control Module II
Tested By:	SIEW TIN	Date:	10/4/2017 3:46:34 PM
Serial Number:	K17TC2389G	Control Number:	N/A
Software Revision:	3.02	Factory Order:	WATS1710053

- | | | |
|---|--|--|
| 1) Hi - Pot / Ground Continuity | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 2) Keypad | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 3) LCD display | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 4) Temperature Accuracy (101°C - 103°C)
Actual °C Chm 1: 102.1 Chm 2: 102.1 Chm 3: 101.9 | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 5) Temperature Variation (≤ 5°C)
Actual °C Lowest: 102.0 Highest: 102.1 Variation: 0.15 | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 6) Heater Verification | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 7) Over Temperature Alarm | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 8) Under Temperature Alarm | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 9) IEEE 488 | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |
| 10) Set System Defaults | PASS ☒ FAIL ☐ | see note # _____ PASS ☐ |

Instrument Result: PASS ☒ FAIL ☐ Signed: Siew Tin Date: 04/04/2017

Notes:

Time started: 3:42pm
 Time End: 3:52pm
 Temperature: 20.0°C
 Humidity: 50.6%

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.

A

WATERS CORPORATION
INSTRUMENT - FINAL TEST RECORD

Part Number: <u>WAT 223-02</u>	Description: <u>W600 controller</u>
Tested By: <u>SLW T.1</u>	Date: <u>OCT 104 1 2017</u>
Serial Number: <u>3008131066</u>	Control Number: <u>NA</u>
Software Revision: <u>4.2</u>	Factory Order: <u>NA</u>

- | | |
|--|---|
| (1) Electrical Safety Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (4) Fan Operation | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (5) IEEE 488 Communications | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (6) Keypad Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (7) Display Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (8) Stop Flow Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (9) External Inject Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (10) Switch One Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (11) Switch Two Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (12) Switch Three Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (13) Switch Four Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (14) Hold Output Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (15) Chart Output Test | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (16) Pressure Output Actual <u>-5.0</u> mV
<u>w/o Silk</u> (-4.5 mV to -5.5 mV)
<u>w/Silk</u> (-12mv +/- 1 mV) | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (17) 12 VDC External. - Actual: <u>11.96 VDC</u>
(11.38 VDC and 12.62 VDC) | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (18) Sparge Valves | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (19) Pump Motor | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |
| (19) Gradient Valves | PASS ☒ FAIL ☐ see note # _____ PASS ☐ |

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: <u>WAT069520, WAT069521</u>	Serial Number: <u>3008131067</u>
--	----------------------------------

- (20) Serial Port Test PASS ☒ FAIL ☐ see note # PASS ☐
- (21) Twelve Volt Failure Test PASS ☒ FAIL ☐ see note # PASS ☐
- (22) Counter Test PASS ☒ FAIL ☐ see note # PASS ☐
- (23) Temperature Reading - Actual: 35°C PASS ☒ FAIL ☐ see note # PASS ☐
(31C and 37C)
- (24) Pressure Output 2994 PSI PASS ☒ FAIL ☐ see note # PASS ☐
PSI
(3000 PSI +/- 350 PSI) WAT069520,
(6000 PSI +/- 350 PSI) WAT069521
- (25) Heater (30 VDC +/- 3 VDC) - Actual: 30.91 VDC PASS ☒ FAIL ☐ see note # PASS ☐
lwin 09 Oct 17
- (26) Transducer Excite - Actual: 5.034 VDC PASS ☒ FAIL ☐ see note # PASS ☐
(5 VDC +/- .25 VDC)
- (27) Internal Switch Tests PASS ☒ FAIL ☐ see note # PASS ☐
- (28) Internal Inject Test PASS ☒ FAIL ☐ see note # PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed SWT Date: Oct 10 4 2017

Notes: It is verified that the actual value of item (25) is to be
30.91 VDC.
lwin 09 Oct 17

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

THE SCIENCE OF WHAT'S POSSIBLE.™

WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 9 of 11

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE83031 -1		Equipment Name: Acquity UHPLC FLR Optic Bench	
Installation Site: VENTURE / GES, SINGAPORE			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: 279003225 UUT Serial Number: 1710045-06	All required CTQ Specification measurements result in a Pass.	Pass	Ysy 06 OCT 2017
Comments: Refer to Attachment 05, page 01 of 04 for passing test record of UUT prior relocation. Refer to Attachment 05, page 03 of 04 for passing test record of UUT post relocation. Ysy 06 OCT 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 9 of 11

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE83032 -1		Equipment Name: PLR Optic Bench Alignment	
Installation Site: VENTURE / GES, SINGAPORE			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: 079001335 UUT Serial Number: 1710042-14	All required CTQ Specification measurements result in a Pass.	PASS	YSY 06 OCT 2017
Comments: Refer to Attachment 05, page 02 of 04 for passing test record of UUT prior relocation. Refer to Attachment 05, page 04 of 04 for passing test record of UUT post relocation. YSY 06 OCT 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Doc No: Multiple-WPPL-TE-0202T17-1&R-(01 of 03)

Waters Corporation - Instrument Final Test Record

Part Number: 279003225Product: Acquity UHPLC
FLR Optics BenchOperator: GaoLongStart Time: 10/04/2017
15:45:34Serial Number: 1710045-06

Name	LSL	Measurement	USL	Unit	Outcome
Acquity UHPLC FLR Optics Bench Alignment					PASS
Mirror Adjust					PASS
Restart					PASS
Normalize	396	396.6	398	nM	PASS
Sample energy		43.2		EU	PASS
Ram-Ray Ratio		1.04		%	PASS
Val-Ram Ratio		44.87		%	PASS
Reference Energy		1727.9		EU	PASS
Photodiode Out (V)		4.181		Volts	PASS

Notes:

N/A xy 0902T17

Signed:

GaoLongDate: 10/04/2017

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: <u>279001335</u>	Product: <u>FLR Optics Bench</u>
Operator: <u>GaoLong</u>	Start Time: <u>10/04/2017</u> <u>11:18:04</u>
Serial Number: <u>1710042-14</u>	

Name	LSL	Measurement	USL	Unit	Outcome
FLR Optics Bench Alignment					PASS
Mirror Adjust					PASS
Restart					PASS
Normalize	415	415.4	417	nM	PASS
Sample energy		35.4		EU	PASS
Ram-Ray Ratio		0.35		%	PASS
Val-Ram Ratio		27.39		%	PASS
Reference Energy		762.6		EU	PASS
Gain		0.5		Level	PASS
Photodiode Out(V)		3.567		Volts	PASS

Notes:

N/A

10/09/2017

Signed: <u>Long</u>	Date: <u>OCT 04, 2017</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: 279003225

Operator: GaoLong

Serial Number: 1710045-06

Product: Acquity UHPLC
FLR Optics Bench

Start Time: 10/06/2017
14:22:48

Name	LSL	Measurement	USL	Unit	Outcome
Acquity UHPLC FLR Optics Bench Alignment					PASS
Mirror Adjust					PASS
Restart					PASS
Normalize	396	396.6	398	nM	PASS
Sample energy		47.2		EU	PASS
Ram-Ray Ratio		1.07		%	PASS
Val-Ram Ratio		44.58		%	PASS
Reference Energy		1706.6		EU	PASS
Photodiode Out (V)		4.216		Volts	PASS

Notes:

N/A xy 09062017

Signed: Long

Date: 10/06/2017

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.

Doc No: Multiple_WPPL_TE-0200T17-1QR-(01 of 03)

Waters Corporation - Instrument Final Test Record

Part Number: 279001335Product: FLR Optics BenchOperator: GaoLongStart Time: 10/06/2017,
14:36:23Serial Number: 1710042-14

Name	LSL	Measurement	USL	Unit	Outcome
FLR Optics Bench Alignment					PASS
Mirror Adjust					PASS
Restart					PASS
Normalize	415	415	417	nM	PASS
Normalize	415	415.8	417	nM	PASS
Sample energy		34.4		EU	PASS
Ram-Ray Ratio		0.34		%	PASS
Val-Ram Ratio		26.67		%	PASS
Reference Energy		765.1		EU	PASS
Gain		0.5		Level	PASS
Photodiode Out(V)		3.807		Volts	PASS

Notes:

N/A xy 09 OCT 2017

Signed:

Date: 06T 06, 2017

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.