

INSTALLATION QUALIFICATION REPORT
For the TUV DOWNLOAD / PRETEST STATION (TE82964-1)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		21 Aug 2020

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

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer	SEE ATTACHED E-MAIL	

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

APPROVED BY

Name	Role	Signature	Date
Kah Chin TAN	Senior Quality Assurance Manager		

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

REVISION HISTORY

VERSION:	02	ORIGINATOR:	Luo HuaZhen	Change ID:	ECR9236194
SUMMARY OF CHANGE: ADD NEW ACQUITY PREMIER TUV DETECTOR PART NUMBER 186018006, 800000534					

HuaZhen Luo

From: Eric Turner
Sent: Monday, 24 August, 2020 23:23
To: HuaZhen Luo
Cc: Edwin Koh; Desmond Ann
Subject: RE: Acquity Premier TUV detector download station IQR for review

Hello,

This email will serve as my digital signature in accordance with TMD010801

Eric Turner
Principal Test Engineer

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Waters Corporation
34 Maple Street
Milford
MA 01757
USA

From: HuaZhen Luo <HuaZhen_Luo@waters.com>
Sent: Friday, August 21, 2020 4:59 AM
To: Eric Turner <Eric_Turner@waters.com>
Cc: Edwin Koh <Edwin_Koh@waters.com>; Desmond Ann <Desmond_Ann@waters.com>
Subject: Acquity Premier TUV detector download station IQR for review

Hi Eric,

Please kindly review and approve the attached IQR for TUV download station in Flex.

Thank you

Luo HuaZhen
Senior Test Engineer

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1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of Test Specification and Procedure, ACQUITY PREMIER TUV DETECTOR 735005108, Rev A for the TE82964-1, the TUV DOWNLOAD / PRETEST STATION.

1.1 SYSTEM BACKGROUND

The TE82964-1, the TUV DOWNLOAD / PRETEST STATION, is designed to download instrument firmware and assign the instrument serial number for 4289, ACQUITY TUV Detectors and ACQUITY PREMIER TUV Detectors. As per Test Specification and Procedure, ACQUITY PREMIER TUV DETECTOR 735005108, the station can support for the following part numbers: 186018006 and 800000534.

The TE82964-1, the TUV DOWNLOAD / PRETEST STATION is located at the Flex Contract Manufacturing Site in Singapore. The UUT is connected to a custom test box that simulates a leak and uses HyperTerminal to download a Serial Number to the UUT. The system does not have custom software, nor does it print a Test Record.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82964-1, the TUV DOWNLOAD / PRETEST STATION, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE82964-05AUG20-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82964-1, the TUV DOWNLOAD / PRETEST STATION was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. All Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the TE82964-1, the TUV DOWNLOAD / PRETEST STATION complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82964-1, the TUV DOWNLOAD / PRETEST STATION can be considered fully qualified and fit for intended use.

4.0 DEFINITIONS / ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
TSP	Test Specification and Procedure
S/N	Serial Number
P/N	Part Number
VAF	Validation Assessment Form
N/A	Not Applicable
SAP	Enterprise Resource Planning Software
UUT	Unit Under Test
PSC	Production Support Checks
TUV	Tunable UV/Vis Absorbance Detector
ECR	Engineering Change Request
UPLC	Ultra Performance Liquid Chromatography

5.0 TRAINING

The operator of the TE82964-1, the TUV DOWNLOAD / PRETEST STATION was trained according to the Test Specification and Procedure, ACQUITY PREMIER TUV DETECTOR 735005108, Rev A. The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. Both Training records are provided as Attachments 7.1 and 7.2, respectively.

6.0 QUALIFICATION Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Test Specification and Procedure, ACQUITY PREMIER TUV DETECTOR 735005108, Rev A was confirmed to be in SAP with a status of Ready. A screen capture from SAP is provided as Attachment 7.4.

6.2 Test Script IQ-02: Site Verification was not required to be performed as part of this test equipment qualification according to TE82964-05AUG20-VAF.

6.3 Test Script IQ-03: Site Verification was not required to be performed as part of this test equipment qualification according to TE82964-05AUG20-VAF.

6.4 Test Script IQ-04: Site Verification was not required to be performed as part of this test equipment qualification according to TE82964-05AUG20-VAF.

6.5 Test Script IQ-05: Site Verification was not required to be performed as part of this test equipment qualification according to TE82964-05AUG20-VAF.

6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.6.1 One (1) UUTs was tested using the TE82964-1, the TUV DOWNLOAD / PRETEST STATION with all tests passing. The screenshot of passing result is provided as Attachment 7.6.

6.7 This table provides a summary of each test script as performed according to 730004135, Ver. 03 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3 and 7.4	None
IQ-06	Pass	Attachments 7.5 and 7.6	None

7.0 ATTACHMENTS

7.1 Completed Operator Training Record 735005108, Rev A

7.2 Completed Executor Training Record 730004135, Ver. 03

7.3 Completed Test Script IQ-01: Associated Document Verification

7.4 Objective Evidence IQ-01: Screenshot of SAP

7.5 Completed Test Script IQ-06: Functional Verification

7.6 Objective Evidence IQ-06: Screenshot of passing result on UUT

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the Installation Qualification Protocol 730004135, Ver. 03.

9.0 References

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

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
735005108, Rev A	Test Spec and Procedure, ACQUITY PREMIER TUV DETECTOR
ECR9236194	Engineering Change Request for Project ACQUITY PREMIER TUV DETECTOR
TE82964-05AUG20-VAF	Validation Assessment Form for the TUV DOWNLOAD / PRETEST STATION

Installation Qualification Protocol

Document # 730004135

Version # 03

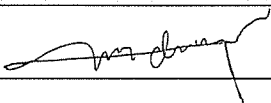
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Appendix A: TRAINING RECORD

Document #	735005107	Document Title	Acquity Premier TUV Detector Test Procedure	Version	00
				Revision	A
Document #	735005108	Document Title	Acquity Premier TUV Firmware Download/Pretest	Version	00
				Revision	A

☒ Read and Understood (If self-trained – If not self-trained this section can be deleted)

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
JOEL MAMALATEO DEDUYO		JMD	17 Aug 2020
CHAI CHUAN WEI		CCW	17 Aug 2020
HO TECK LIK		HTL	17 Aug 2020
NA JMD 17 Aug 2020			

Print multiple copies of this Training Record Template as needed

Document No.: TE82964-1-JDR
 Iteration No.: 02
 Attachment: 7.1 Page: 1 of 1

DOCUMENT HISTORY

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID ¹	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03


Senior Test Engineer
19SEP2019
 Employee's Signature Title Date

N/A self trained
JG 19SEP2019
 Trainer's Signature Title Date

¹ Without preceding "90"

Document No.: TE82964-1-IQR
 Iteration No.: 02
 Attachment: 7.2 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 1 of 2

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82964-1	Equipment Name:	TUV DOWNLOAD / PRETEST STATION	
Installation Site: Flex, Singapore				
Purpose: To verify that supporting documentation is available prior to the completion of qualification.				
Test Execution: - List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.				
Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #		Status in SAP	Initial & Date
TSP	ACQUITY PREMIER TUV PRETEST, 735005108, Version 00 Rev A		Ready	H2 21 Aug 2020
Comments: N/A H2 21 Aug 2020				
Overall Test Conclusion			Document No.: <u>TE82964-1-IQR</u> Iteration No.: <u>02</u> Attachment: <u>7.3</u> Page: <u>1</u> of <u>1</u>	
☒ Pass ☐ Fail				

Document No.: T882964-1-10P
Iteration No.: 02
Attachment: 7.4 Page: 1 of 1

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82964-1	Equipment Name:	TUV DOWNLOAD / PRETEST STATION	
Installation Site: Flex, Singapore				
Purpose: To verify that the system operates as expected. Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy. Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.				
UUT Part Number/Serial Number		Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 186018006 Serial Number: H20PTV001A		All required CTQ Specification measurements result in a Pass	Pass	HZ 21Aug2020
Comments: N/A HZ 21Aug 2020				
Overall Test Conclusion			Document No.: TE82964-1-16R Iteration No.: 02 Attachment: 7.5 Page: 1 of 1	
☒ Pass ☐ Fail				

WATERS CORPORATION - TEST RECORD

Part Number:	186018006	Product:	ACQUITY Premier TUV DETECTOR
Operator:	HO TECK LIK	Start Date/Time:	18 AUG 2020 1013
Serial Number:	H20PTV001A	End Date/Time:	18 AUG 2020 1559
Test System:	TUV Download / Pretest Station	Order:	NA
Test Software:	NA	Location:	flextronics -sg'

TMD: NA

Firmware: 1.70.2698

Test Name	LSL	Measurement	USL	Unit	Outcome		
Visual Inspection	---	---	---	---	PASS ☒	FAIL ☐	See Event Log ☐
Electrical Safety	---	---	---	---	PASS ☒	FAIL ☐	See Event Log ☐
Calibration	---	---	---	---	PASS ☒	FAIL ☐	See Event Log ☐
Fans	---	---	---	---	PASS ☒	FAIL ☐	See Event Log ☐
Lamp ID	---	---	---	---	PASS ☒	FAIL ☐	See Event Log ☐
Flowcell ID	---	---	---	---	PASS ☒	FAIL ☐	See Event Log ☐

Note: Fill in 'N/A' if not applicable.

Instrument Overall Result -

PASS ☒

FAIL ☐

Signed: C. 1093658	Date: 18 AUG 2020
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END OF DATA

Document No.: TE82964-1- IQR
 Iteration No.: 02
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