

INSTALLATION QUALIFICATION REPORT

For the 2489 ACQUITY TUV PRETEST DOWNLOAD STATION (TE82964-1)

PREPARED BY

Name	Role	Signature	Date
Ernest Chua	Process Validation Engineer		09 FEB 21

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

REVIEWED BY

Name	Role	Signature	Date
Mark Jussaume	Senior Test Engineer		11 FEB 21

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

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		16.Feb.2021

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

REVISION HISTORY

VERSION:	03	ORIGINATOR:	Ernest Chua	Change ID:	N/A
SUMMARY OF CHANGE: New software program developed for part number 186019007, Arc Premier TUV					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of 730004135, Installation Qualification Protocol, for the TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD STATION.

1.1 SYSTEM BACKGROUND

The TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD STATION, is designed to download instrument firmware and assign the instrument serial number for 2489 and ACQUITY TUV Detectors:

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.

used to perform functionality testing of Waters Corporation's TUV detectors. The system uses a PC with serial ports to communicate to the UUT, utilizing test routines that are embedded within the UUT firmware.

The 2489 ACQUITY TUV PRETEST DOWNLOAD STATION TE82964-1 is located at Flex, Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD STATION, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE82964-22JAN2021-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD 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, 2489 ACQUITY TUV PRETEST DOWNLOAD STATION complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD 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
TUV	Tunable UV/Vis Absorbance Detector

5.0 TRAINING

The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. The training records are provided as Attachments 7.1.

The operator of the TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD STATION was trained according to the Test Specification and Procedure 735005364 Rev A Ver 00. The training records are provided as Attachment 7.2.

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 735005364 Revision A Version 00 was confirmed to be in SAP with a status of Ready. A screen capture is provided below:

Document List After Selection 1 Hits									
Rev/Lev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To
	TSP	735005364	00	000	ARC PREMIER TUV PRETEST	READY			

6.2 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 7.4.

6.2.1 One (1) UUTs was tested using the TE82964-1, 2489 ACQUITY TUV PRETEST DOWNLOAD STATION with all tests passing.

6.2.2 The firmware version for P/N 186019007 is 1.69.2682. A screen capture is as follows:

Display material BOM: General Item Overview

Material: 186019007 Arc PREMIER TUV
Plant: CRDE Waters Single Design Plant
Alternative BOM: 1

Item	IC	Component	Component description	Quantity	Un	Ass	Sta	Valid
0010	L	200000448	S/U IQR, ACQ Arc, 2998/2489/2475	1	EA	☒	08	
0020	L	279004503	ASSY, 2489 W/FLOW CELL, PREMIER	1	EA	☒	08	
0030	L	290000695	BOX, SHIPPING, DETECTOR, 2998 LG	1	EA	☒	08	
0040	L	361000709	ACQ /Arc 2489 UV/VIS FFW v1.69.2682	1	EA	☒	08	

6.2.3 A picture of the tester showing the firmware version is as follows:



6.2.4 The test record of passing result is provided as Attachment 7.5.

6.3 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	None
IQ-06	Pass	Attachments 7.4 and 7.5	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: Test record 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
735005364 Revision A Version 00	Test Spec and Procedure, ARC PREMIER TUV PRETEST
TE82964-22JAN2021-VAF	Validation Assessment Form for 2489 ACQUITY TUV PRETEST DOWNLOAD STATION

Title: Individual Training Form

Document No: 730002657

Version No: 01

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Training Type:	Read and Understood		
Name:	Ernest Chua	Employee ID:	618144
Date of Training:	26 AUG 2020		
Comments:	N/A		

Document Number	Title	Rev #
730004135	Installation Qualification Protocol	03
	N/A <i>ding</i> 26 AUG 2020	

ding

Process Validation Engineer

26 AUG 2020

Employee's Signature

Title

Date

N/A Self-trained

ding

26 AUG 2020

Trainer's Signature

Title

Date

Document No.: TE82964-1-IQRIteration No.: 03Attachment: 7.1 Page: 01 of 01

Installation Qualification Protocol

Version # 03

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Appendix A: TRAINING RECORD

Document #	735005364	Document Title	Arc Premier TUV 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.

[illegible]

Print multiple copies of this Training Record Template as needed

Document No.: **TE82964-1-IQR**

Iteration No.: 03

Attachment: 7.2 Page: 01 of 01

Installation Qualification Protocol

Document # 730004135

Version # 03

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[illegible]

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82964-1	Equipment Name:	2489 ACQUITY TUV PRETEST DOWNLOAD 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: 186019007 Serial Number: A21PTU001A		All required CTQ Specification measurements result in a Pass	PASS	EC 09 FEB 21
		Firmware version: 1.69.2682	PASS	EC 09 FEB 21
Comments: N/A <i>Xing</i> 09 FEB 2021				
Overall Test Conclusion		Document No.: TE82964-1-IQR Iteration No.: 03 Attachment: 7.4 Page: 01 of 01		
☒ Pass ☐ Fail				

WATERS CORPORATION - TEST RECORD

Part Number:	186019007	Product:	ARC PREMIER TUV DETECTOR
Operator:	JOEL M. DEDUYO	Start Date/Time:	28 JAN 2021 1730
Serial Number:	A21PTU001A	End Date/Time:	28 JAN 2021 1830
Test System:	TUV DOWNLOAD/PRETEST STATION	Order:	N/A
Test Software:	N/A	Location:	FLEXTRONICS.SG

TMD: N/A

Firmware: 1.69.2682

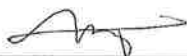
Test Name	LSL	Measurement	USL	Unit	Outcome		
Visual Inspection	—	—	—	—	PASS ☒	FAIL ☐	See Event Log ☐
Electrical Safety	—	—	—	—	PASS ☒	FAIL ☐	See Event Log ☐
Calibration	—	—	—	—	PASS ☒	FAIL ☐	See Event Log ☐
Fan	—	—	—	—	PASS ☒	FAIL ☐	See Event Log ☐
Keypad	—	—	—	—	PASS ☒	FAIL ☐	See Event Log ☐
Display	—	—	—	—	PASS ☒	FAIL ☐	See Event Log ☐

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

Instrument Overall Result -

PASS ☒

FAIL ☐

Signed:  246154	Date: 28 JAN 2021
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END OF DATA