

INSTALLATION QUALIFICATION REPORT

For the TUV FINAL TEST STATION (TE82903-9)

PREPARED BY

Name	Role	Signature	Date
Ernest Chua	Process Validation Engineer		27 JAN 21

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

REVIEWED BY

Name	Role	Signature	Date
Luo Huazhen	Senior Test Engineer		27 JAN 2021

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		

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

REVISION HISTORY

VERSION:	02	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 TE82903-9, TUV FINAL TEST STATION.

1.1 SYSTEM BACKGROUND

The TE82903-9, TUV FINAL TEST STATION, is 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 996 Wavelength Accuracy Kit, WAT042885, and Absorbance Detector 10mm Cell Linearity, WAT042881, are used during testing.

Performance tests include Linearity, Wavelength Accuracy, Noise, Dual Noise and Drift. The ACQUITY TUV test does not perform Linearity or Wavelength Accuracy tests.

The system has four (4) stations and can run up to four (4) UUTs at the same time. Each station program is functionally identical, with the exception of the Station number in the program display header.

All data collected is sent to the SigmaSure server.

The TUV FINAL TEST STATION TE82903-9 is located at Flex, Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82903-9, TUV FINAL TEST STATION, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE82903-12JAN2021-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82903-9, TUV FINAL TEST 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 TE82903-9, TUV FINAL TEST STATION complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82903-9, TUV FINAL TEST 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 TE82903-9, TUV FINAL TEST STATION was trained according to the Test Specification and Procedures 735005365 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 735005365 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										
RevLev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.
	TSP	735005365	00	000	ARC PREMIER TUV FINAL TEST	READY				Mark Jussaume

6.2 Test Script IQ-04: Software and Instrument Firmware Version 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 The firmware version listed for P/N 186019007 is Version 1.69.2682. A screen capture from the SAP is as follows:

Item	ICt	Component	Component description	Quantity	Un	Asm	Sl	V
0010	L	200000448	S/U Kit, ACQ Arc, 2998/2489/2475	1	EA	☒	0	▲
0020	L	279004503	ASSY, 2489 W/FLOW CELL, PREMIER	1	EA	☒	0	▼
0030	L	290000695	BOX, SHIPPING, DETECTOR, 2998 LG	1	EA	☐	0	□
0040	L	361000709	ACQ /Arc 2489 UV/Vis F/W v1.69.2682	1	EA	☐	0	□
0050	L	716004595	Info. Set, ACQ Arc & 2489 UV Detector	1	EA	☒	0	□
0060	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	0	□
0070	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	0	□
0080	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	0	□
0090	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	1	EA	☐	0	□
0100	L	WAT089533	BAG, POLY 2ML	1	EA	☐	0	▲

6.3 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.

6.3.1 One (1) UUT (P/N: 186019007) was tested using the TE82903-9, TUV FINAL TEST STATION with all tests passing. The screenshot of passing result is provided as Attachment 7.6.

6.4 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-04	Pass	Attachment 7.4	None
IQ-06	Pass	Attachments 7.5 and 7.6	None

7.0 ATTACHMENTS

- 7.1 Completed Executor Training Record 730004135, Ver. 03
- 7.2 Completed Operator Training Record 735005365 Rev A Ver 00
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Completed Test Script IQ-06: Functional Verification
- 7.6 Objective Evidence IQ-06: Test record of passing UUT (P/N: 186019007)

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
735005365, Rev A, Ver 00	Test Spec and Procedure, Arc PREMIER TUV Final Test
TE82903-12JAN2021-VAF	Validation Assessment Form (VAF) for TUV FINAL TEST STATION

Title: Individual Training Form

Document No: 730002657

Version No: 01

Page 1 of 1

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.: TE82903-9-IQRIteration No.: 02Attachment: 7.1 Page: 01 of 01

Installation Qualification Protocol

Document # 730004135

Version # 03

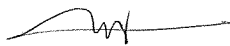
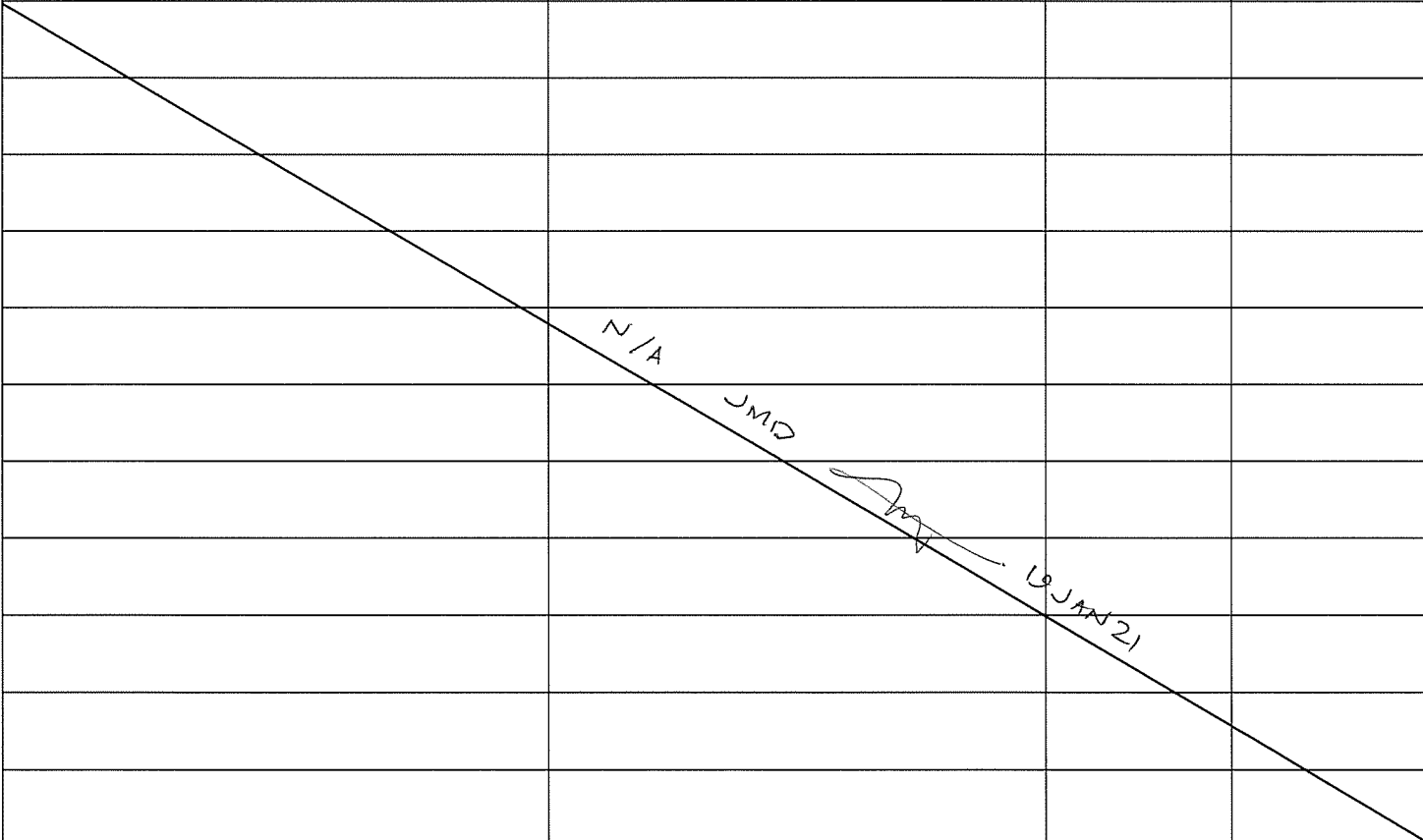
Page 11 of 12

Appendix A: TRAINING RECORD

Document #	735005365	Document Title	Arc Premier TUV Final Test	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	19 JAN 21
			

Print multiple copies of this Training Record Template as needed

Document No.: TE82903-9-IQRIteration No.: 02Attachment: 7.2 Page: 01 of 01

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 5 of 8

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82903-9	Equipment Name:	TUV Final Test 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 FINAL TEST TEST PROCEDURE, 735005365 REVISION A, VERSION 00	READY	EC 27 JAN 21	
Comments: N/A <i>Xing</i> 27 JAN 2021				
Overall Test Conclusion		Document No.: <u>TE82903-9-IQR</u>		
☒ Pass ☐ Fail		Iteration No.: <u>02</u>		
		Attachment: <u>7.3</u> Page: <u>01</u> of <u>01</u>		

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 6 of 8

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82903-9	Equipment Name:	TUV Final Test Station		
Installation Site: Flex, Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).					
Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.					
Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
ACQUITY SDS Final Test Station System Software	Revision: 1.69.2682	Revision: 1.69.2682	PASS	EC 27 JAN 21	
Comments: N/A <i>Ling</i> 27 JAN 2021					
Overall Test Conclusion		Document No.: TE82903-9-IQR			
☒ Pass ☐ Fail		Iteration No.: 02			
		Attachment: 7.4 Page: 01 of 01			

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 7 of 8

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82903-9	Equipment Name:	TUV Final Test 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 27 JAN 21
Comments: N/A <i>Xing</i> 27 JAN 2021				
Overall Test Conclusion			Document No.: <u>TE82903-9-IQR</u> Iteration No.: <u>02</u> Attachment: <u>7.5</u> Page: <u>01</u> of <u>01</u>	
☒ Pass ☐ Fail				

Waters Corporation

INSTRUMENT FINAL TEST RECORD

Part Number:	186019007	Description:	Arc Premier TUV Detector
Tested By:	JOEL M. DEDUYO	Date:	1/25/2021 2:07 PM
Serial Number:	A21PTU001A	Control Number:	N/A
Software Revision:	1.69.2682	Factory Order:	N/A

Drift @ 230 nm

(<= 100 μ AU) - Actual: 39u AU PASS ☒ FAIL ☐

Noise @ 230 nm

(<= 5 μ AU) - Actual: 2.2u AU PASS ☒ FAIL ☐

Dual Noise @ 230/280 nm

(<= 35 μ AU) - Actual: 5.9u AU PASS ☒ FAIL ☐

Erbium cuvette scan 200 - 600 nm

(255.00 +/- 1 nm) - Actual: 255.30 nm PASS ☒ FAIL ☐

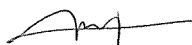
(378.80 +/- 1 nm) - Actual: 378.80 nm PASS ☒ FAIL ☐

(522.40 +/- 1 nm) - Actual: 522.90 nm PASS ☒ FAIL ☐

Linearity

(<= 5.0% @ 2.5 AU) - Actual: 2.79 %RSD PASS ☒ FAIL ☐

Instrument Result: PASS ☒ FAIL ☐

Signed:  246154 Date: 25 JAN / 2021

Notes: TE82903-9

Drift Count: 2

Noise Count: 1

Dual Noise Count: 1

230 nm Energy [nA]: Sample Energy: 159.653015 Reference Energy: 213.310471

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