

For the 2690 Pump Tray Tester (TE82526-4)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		

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

REVIEWED BY

Name	Role	Signature	Date
Mark Jussuame	Senior Test Engineer		

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:	00	ORIGINATOR:	Luo HuaZhen	Change ID:	N/A
SUMMARY OF CHANGE: First document for approval					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of Test Specification and Procedure, Alliance Pumptray WAT210700, Rev 09 for the TE82526-4, the 2690 Pump Tray Tester.

1.1 SYSTEM BACKGROUND

The TE82526-4, the 2690 Pump Tray Tester, facilitates the functional test of the following part numbers: 279000419, 279000524, 289000526, WAT270463, WAT271078, and the equivalent spare part numbers. Upon completion of all testing, a record is automatically generated and printed for the operator to collect.

This 2690 Pump Tray Tester TE82526 at the Flextronics Contract Manufacturing Site in Singapore is being retrofitted with new valves in the test box and new computer; This computer will run on Windows 10. The replacement valves are not identical but are functionally equivalent. This is a hardware change that does not change the way the system controls or measures a test specification or PSC result. The custom test software is being installed on the new PC; the change in operating system does not required any changes to the test software. This system will be delivered and installed with the new valve and PC running Windows 10.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82526-4, the 2690 Pump Tray Tester, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE82526-29JAN2020-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82526-4, the 2690 Pump Tray Tester 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 TE82526-4, the 2690 Pump Tray Tester complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82526-4, the 2690 Pump Tray Tester 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
CAL/PM	Calibration/Preventive Maintenance
S/N	Serial Number
P/N	Part Number
VAF	Validation Assessment Form
Hz	Hertz
N/A	Not Applicable
SAP	Enterprise Resource Planning Software
UUT	Unit Under Test
VAC	Volts Alternating Current
EQID	Equipment Qualification Identification
ANSI	American National Standards Institute

Term	Explanation
PSC	Production Support Checks

5.0 TRAINING

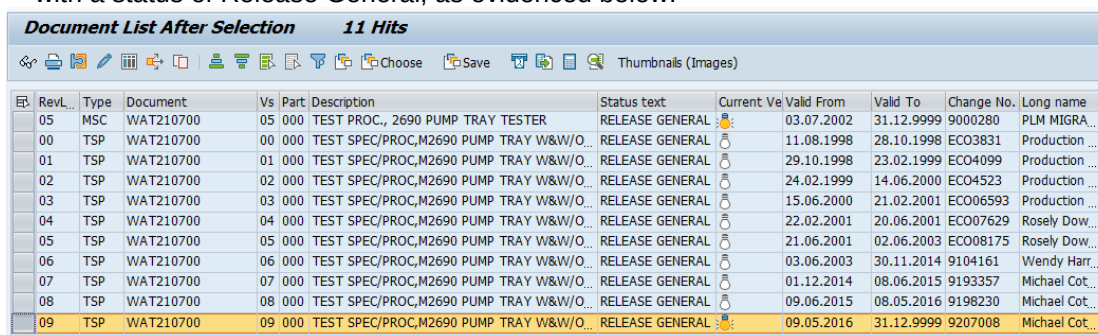
The operator of the TE82526-4, the 2690 Pump Tray Tester was trained according to the Test Specification and Procedure, Alliance Pumptray WAT210700, Rev 09. The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. Both Training records are provided 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, Alliance Pumptray WAT210700, Rev 09 was confirmed to be in SAP with a status of Release General, as evidenced below:

Document List After Selection 11 Hits



Rev.	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
05	MSC	WAT210700	05	000	TEST PROC., 2690 PUMP TRAY TESTER	RELEASE GENERAL		03.07.2002	31.12.9999	9000280	PLM MIGRA...
00	TSP	WAT210700	00	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		11.08.1998	28.10.1998	ECO3831	Production ...
01	TSP	WAT210700	01	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		29.10.1998	23.02.1999	ECO4099	Production ...
02	TSP	WAT210700	02	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		24.02.1999	14.06.2000	ECO4523	Production ...
03	TSP	WAT210700	03	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		15.06.2000	21.02.2001	ECO06593	Production ...
04	TSP	WAT210700	04	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		22.02.2001	20.06.2001	ECO07629	Rosely Dow...
05	TSP	WAT210700	05	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		21.06.2001	02.06.2003	ECO08175	Rosely Dow...
06	TSP	WAT210700	06	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		03.06.2003	30.11.2014	9104161	Wendy Harr...
07	TSP	WAT210700	07	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		01.12.2014	08.06.2015	9193357	Michael Cot...
08	TSP	WAT210700	08	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		09.06.2015	08.05.2016	9198230	Michael Cot...
09	TSP	WAT210700	09	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		09.05.2016	31.12.9999	9207008	Michael Cot...

6.2 Test Script IQ-02: Site 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 The ambient temperature and humidity were measured using Temperature/Humidity Meter and were determined to be within specification as defined by the Performance Specification, Pump Mechanics Assembly, WAT270698. The calibration record is provided as Attachment 7.5.

6.2.2 The electrical supply was measured using a Multimeter and was determined to be within specification as defined by the Performance Specification, Pump Mechanics Assembly, WAT270698. The calibration record is provided as Attachment 7.6.

6.2.3 The Test Station was confirmed to have more than the four (4) dedicated electrical outlets and minimum of 1 dedicated network required. Picture of dedicated electrical outlets and network port is provided as Attachment 7.7.

6.2.4 The space and test bench of the TE82526-4, the 2690 Pump Tray Tester were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. Picture of the Test Station work area is provided as Attachment 7.8.

6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed script is provided as Attachment 7.9.

6.3.1 The Electronics Weigh Balance of the TE82526-4, the 2690 Pump Tray Tester was confirmed to have had calibration within this time frame. The most recent calibration certificate is provided as Attachment 7.10.

6.3.2 The TE82526-4, the 2690 Pump Tray Tester was confirmed to be in the Preventive Maintenance Master Schedule with a six (6) month maintenance cycle. A screen capture from the database is provided as Attachment 7.11.

6.4 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 7.12.

6.4.1 The Test Equipment Software version listed in the TSP is Test Software 1.0 and was verified to match the version listed on the test equipment display. The objective evidence was provided as Attachment 7.13.

6.4.2 This test station does not download firmware.

6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.14.

6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges. Picture of tester station safety check is provided as Attachment 7.15

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 7.16.

6.6.1 One (1) UUTs was tested using the TE82526-4, the 2690 Pump Tray Tester with all tests passing. The test record is provided as Attachment 7.17.

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	None
IQ-02	Pass	Attachments 7.4, 7.5, 7.6, 7.7, and 7.8	None
IQ-03	Pass	Attachments 7.9, 7.10, and 7.11	None
IQ-04	Pass	Attachments 7.12 and 7.13	None
IQ-05	Pass	Attachments 7.14 and 7.15	None
IQ-06	Pass	Attachment 7.16, and 7.17	None

7.0 ATTACHMENTS

7.1 Completed Operator Training Record WAT210700, Rev 09

7.2 Completed Executor Training Record 730004135, Ver. 03

7.3 Completed Test Script IQ-01: Associated Document Verification

7.4 Completed Test Script IQ-02: Site Verification

7.5 Objective Evidence IQ-02: Temperature/Humidity Meter Calibration Record and Measurement Record

7.6 Objective Evidence IQ-02: Multimeter Calibration Record and Measurement Record

7.7 Objective Evidence IQ-02: Picture of dedicated electrical outlets and network port

7.8 Objective Evidence IQ-02: Picture of Test Station Work Area

7.9 Completed Test Script IQ-03: Instrument Calibration Verification

7.10 Objective Evidence IQ-03: Electronics Weigh Balance Calibration Record

7.11 Objective Evidence IQ-03: Screen Capture of Preventive Maintenance Master Schedule

7.12 Completed Test Script IQ-04: Test Software and Instrument Firmware Version

7.13 Objective Evidence IQ-04: Test Software version on Cover Page of TSP WAT210700 and on Test Equipment

7.14 Completed Test Script IQ-05: General Safety and Alarms

7.15 Objective Evidence IQ-05: Picture of tester station safety check

7.16 Completed Test Script IQ-06: Functional Verification

7.17 Objective Evidence IQ-06: Test Records for 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
WAT210700, Rev 09	TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY
WAT270698, Rev A	PERFORMANCE SPECIFICATION, Pump Mechanics Assembly
WAT046538, Ver. 12	Generic Electrical Safety Test Procedure
ANSI C84.1	Voltage Tolerance Standard
TE82526-29JAN2020-VAF	Validation Assessment Form for the 2690 Pump Tray Tester

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03





Employee's Signature Title Date





Trainer's Signature Title Date

Document No.: _____
 Iteration No.: _____
 Attachment: _____ Page: _____ of _____

¹ Without preceding "90"

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 1 of 6

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester	
Installation Site: Flextronics Contract Manufacturing Site in 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	TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY, Rev 09			
Comments:				
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail				

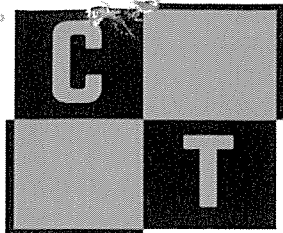
Installation Qualification Protocol

Document # 730004135

Version # 03

Page 2 of 6

Test Script #	IQ -02	IQ Test Name:	Site Verification		
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester		
Installation Site: Flextronics Contract Manufacturing Site in Singapore					
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable parameters in the Parameters column. Rows may be added as needed. - Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column. - Verify and/or measure the applicable parameters and complete the Table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report. Objective Evidence: - Completed IQ-02 Test Script Data Sheet - Photo(s) of the work area, as applicable - The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR. - Copies of calibration certificates for measurement tools, if applicable					
Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Ambient Temperature	18 °C to 28 °C				
Relative Humidity	10 % to 80 %, Non-Condensing				
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%				
Electrical Outlets	Minimum of 4 dedicated outlets				
Network Available	Minimum of 1 dedicated network				
Workspace	The system has sufficient room for the test station, UUT and service				
Test Station Bench	The Test Station Bench is large and strong enough to support the station				
Comments: - Ambient temperature/humidity measured using a Temperature/Humidity Meter, Control Number - Electrical supply measured using a Multimeter, Control Number Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail					



CALTEK PTE. LTD.

23 Tagore Lane, #04-08/09/10/11 Tagore 23 Warehouse, Singapore 787601
Tel: (65) 64520300 Fax: (65) 64520500
Email: info@caltexgroup.com Website: www.caltexgroup.com

CALIBRATION CERTIFICATE

CERTIFICATE NUMBER :	CTS-111-1014-20	JOB NUMBER :	CTJ19-8721
RECEIVED DATE :	30-Dec-19	ISSUE DATE :	08-Jan-20

INSTRUMENT :	THERMOHYGROGRAPH	Ambient Temperature :	(23 ± 5) °C
MANUFACTURER :	HISAMATSU MFG. CO.	Relative Humidity :	(55 ±10) % r.h.
MODEL NO :	TN-2500	Date of Calibration :	07-Jan-20
PART NO :	-	Recommended Due Date :	07-Jan-21
SERIAL NO :	5650	Instrument Code :	CT3260
CUSTOMER :	FLEXTRONICS MANUFACTURING (SINGAPORE) PTE LTD.	Range :	-
		Asset/Tag/Id/Code :	0418
		Page No :	1 of 2
		Status :	As Found
		JR No :	JR-17388

The described instrument has been calibrated at Caltex laboratory under the ambient conditions stated above.

This certificate provides traceability of measurement to the International System of Units (SI) and/or to units of measurement realised at the National Metrology Centre (NMC), Singapore or other recognized national metrology institutes.

The calibration method was carried out according to In-house Technical Calibration Procedure CTTM-T10-2007, as guide.

S.No.	REFERENCE INSTRUMENT(S)	SERIAL NO	DUE DATE
1.	Std.Hygrometer c/w probe	60813824/20055608	02-May-20

RESULTS OF CALIBRATION :

- The expanded uncertainty of measurement associated with the calibration is estimated at a level of confidence of approximately 95 % with a coverage factor of $k=2.00$.
- The results of calibration are given on the attached calibration data sheet(s).
- The user should determine the suitability of the instrument for its intended use.
- No Adjustments done.

REVIEWED & ACCEPTED

SIGN: CHANG MEL LAN

DATE: 09 JAN 2020

REMARKS: FID 0418

Yepthimich 10 JAN 20

Calibrated by :

Saathyish Vejayandran

EMP ID : 1107

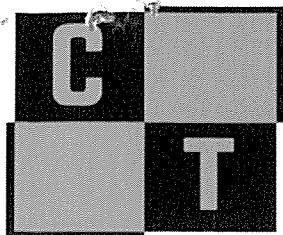
Approved by :

Siva

EMP ID : NA

This certificate may not be reproduced other than in full, except with the prior written approval of the issuing Laboratory.
The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council.





CALTEK PTE. LTD.

23 Tagore Lane, #04-08/09/10/11 Tagore 23 Warehouse, Singapore 787601
Tel: (65) 64520300 Fax: (65) 64520500
Email: info@caltekgroup.com Website: www.caltekgroup.com

CALIBRATION CERTIFICATE

CERTIFICATE NUMBER : CTS-111-1014-20

JOB NUMBER : CTJ19-8721

ISSUE DATE : 08-Jan-20

PAGE NUMBER : 2 of 2

Calibration Results: RELATIVE HUMIDITY MEASUREMENT @ FIXED TEMPERATURE OF 23°C

Mean Reference Reading	Mean Instrument Reading - Before Adjustment	Error	Expanded Uncertainty
%rh	%rh	%rh	%rh
24.7	25.5	0.8	2.5
49.8	50.0	0.2	2.5
84.3	85.5	1.2	3.0

Calibration Results: TEMPERATURE MEASUREMENT @ NOMINAL RELATIVE HUMIDITY OF 50%r.h.

Mean Reference Reading	Mean Instrument Reading - Before Adjustment	Error	Expanded Uncertainty
°C	°C	°C	°C
17.8	18.2	0.4	0.6
23.9	24.2	0.3	0.6
29.8	30.4	0.6	0.6

Calibrated by :

Saathyish Vejayandran

EMP ID : 1107

Approved by :

Siva

EMP ID : NA

This certificate may not be reproduced other than in full, except with the prior written approval of the issuing Laboratory.
The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council.



AMBIENT TEMPERATURE: 21 °C to 22 °C

THERMOHYGROGRAPH

Serial Number : 5650

EQID : 0418EQID : 0418

Calibration Due Date: 07-Jan-2021

Document No.: _____
Iteration No.: _____
Attachment : _____ Page _____ of _____

RELATIVE HUMIDITY: 54 % to 55 %

Verified using

THERMOHYGROGRAPH

Serial Number : 5650

EQID : 0418EQID : 0418

Calibration Due Date: 07-Jan-2021



Calibration	
EQID	: 0418
S/No	: 5650
Cal Date	: 07-JAN-20
Due Date	: 07-JAN-21
Remark	: NA

Document No.: _____
 Iteration No.: _____
 Attachment : _____ Page ____ of ____



Techsystems Services & Integration Asia Pte Ltd

2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913

T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com

[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

CALIBRATION CERTIFICATE

Ref. No. : FMS / 2629

Page : 1 of 5

Customer : Flextronics Manufacturing (Singapore) Pte Ltd
Address : 1 Kallang Place
Singapore 339211

REVIEWED & ACCEPTED
SIGN: CHANG MEI LAN
DATE: 20 DEC 19
REMARKS: EQID 0245
Mord Shamsul 20 Dec 19

Equipment ID : 0245
Description : Multimeter
Model : 110
Manufacturer : Fluke
Serial No. : 85730619

Co-ordinator : Neo Hui Hui
Telephone : 6543 2855
Ext : 207

Date Calibrated : 16 Dec 2019
Next Due Date : 16 Dec 2020
Location : Electrical Laboratory

Temperature : $(23 \pm 3) ^\circ\text{C}$
Humidity : $(35 \sim 65) \% \text{rh}$

The above instrument has been tested in general accordance with its manufacturer's published specifications and Performance Test Procedure in Calibration Information PN1608592.

The measurement report attached to this certificate indicates all the test results obtained at the time of testing.
The intended use of the instrument shall be ascertained based on the end user's requirement.
Recalibration interval was determined based on end user's requirements.

As Found : ☒ In / ☐ Out Tolerance
As Left : In Tolerance

Adjustment Done : ☐ Yes / ☒ No

The measurement standards are traceable to SI Units through National Metrology Centre (NMC), Singapore; National Institute of Standards and Technology (NIST), USA; National Physical Laboratory (NPL), UK or other recognised National Standard Laboratories.

The Laboratory's Quality System is in accordance with the Quality Standard ISO 9001:2015.

Conformance terms of "In Tolerance" and "Out of Tolerance" used in this certificate are determined by comparison of measured values against warranted specifications and do not take measurement uncertainties into account.

Test Performed By

Sj

Sandra Lim
Associate Engineer

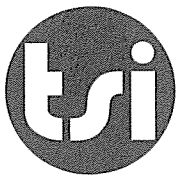


Approved By

lcu

Gee Chen Loong
Manager, Technical Services
16-Dec-2019

zby



Techsystems Services & Integration Asia Pte Ltd

2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913

T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com

[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Page : 2 of 5

Date : 16 Dec 2019

Reference : FMS / 2629

Description : Multimeter

Model : 110

Manufacturer : Fluke

Serial Number : 85730619

Measuring Instruments used in this performance test :-

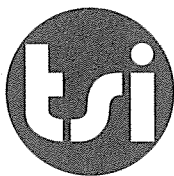
Instrument	Serial No. (Cal Report No.)	Eqpt ID	Due Date	Remarks
MULTI-PRODUCT CALIBRATOR	6775016 (EL007672)	S0269	24 Apr 2020	

Legend and Explanations for Measurement Report:

- [*] - if shown next to the result recorded, it means the reading is out of the specified limits
- [Deviation] - if shown, is computed as [Deviation] = [UUT Reading] - [True Value] {Reference: Int Volcab in Metrology JCGM 200:2008}
- [Correction] - if shown, is computed as [Correction] = [True Value] - [UUT Reading].
Correction is used to apply to the UUT reading (add) to give a true reading.

Test Performed By

Sandra Lim



Techsystems Services & Integration Asia Pte Ltd

2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913

T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com

[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 16 Dec 2019

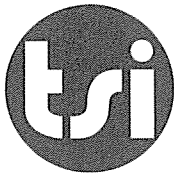
Ref. No. : FMS / 2629

Page : 3 of 5

Test			Specified Limits		Results	Comments
AC Voltage Test						
Range (V)	Freq (Hz)	Input (V)	Min (V)	Max (V)	Reading (V)	
6	50	300 m	0.294	0.306	0.301	
6	500	300 m	0.294	0.306	0.301	
6	50	5	4.947	5.053	5.000	
6	500	5	4.947	5.053	5.002	
60	500	50	49.47	50.53	50.25	
600	500	600	593.7	606.3	602.4	
Frequency Test						
Voltage : 5 V						
Range (kHz)		Input (kHz)	Min (kHz)	Max (kHz)	Reading (kHz)	
50		50	49.93	50.07	49.97	
DC Voltage Test						
Range (V)		Input (V)	Min (V)	Max (V)	Reading (V)	
6		0	-0.002	0.002	0.000	
6		5	4.963	5.037	5.001	
60		-50	-50.37	-49.63	-50.05	
600		600	595.6	604.4	600.4	
Continuity Test						
Beeper On @ 20 Ω			Pass / Fail		Pass	
Beeper Off @ 250 Ω			Pass / Fail		Pass	
Resistance Test						
Range (Ω)		Input (Ω)	Min (Ω)	Max (Ω)	Reading (Ω)	
600		0	-0.2	0.2	0.2	
600		500	495.3	504.7	500.2	
6 k		5 k	4.954 k	5.046 k	4.999 k	
60 k		50 k	49.54 k	50.46 k	49.97 k	
600 k		500 k	495.4 k	504.6 k	500.0 k	
6 M		5 M	4.954 M	5.046 M	4.984 M	
40 M		30 M	29.52 M	30.48 M	29.58 M	

Test Performed By

Sandra Lim



Techsystems Services & Integration Asia Pte Ltd

2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913

T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com

[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 16 Dec 2019

Ref. No. : FMS / 2629

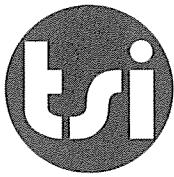
Page : 4 of 5

Test		Specified Limits		Results	Comments
Diode Test					
Range (V)	Input (V)	Min (V)	Max (V)	Reading (V)	
2.2	2	1.980	2.020	2.001	
Capacitance Test					
Range (nF)	Input (nF)	Min (nF)	Max (nF)	Reading (nF)	
1000	800	783	817	799	

				Test Completed	

Test Performed By

Sandra Lim



Techsystems Services & Integration Asia Pte Ltd

2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913

T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com

[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 16 Dec 2019

Ref. No. : FMS / 2629

Page 5 of 5

The Expanded Uncertainties of measurement (excluding the uncertainties of the Unit Under Test) for the results given in this report, with a confidence level of approximately 95% at Coverage Factor $k = 2$, are as follows:

Parameters	Range		Uncertainty
AC Voltage Generation	33 ~ 329.999 mV	45 Hz ~ 10 kHz	0.0058 % + 23 μ V
	3.3 ~ 32.9999 V	45 Hz ~ 10 kHz	0.05 % + 693 μ V
	33 ~ 329.999 V	45 Hz ~ 1 kHz	0.06 % + 8 mV
	330 ~ 1000 V	45 Hz ~ 1 kHz	0.06 % + 92 mV
Frequency Generation	1.2 ~ 11.999 kHz		29 ppm + 1 mHz
DC Voltage Generation	0 ~ 32.99999 V		0.0058 % + 50 μ V
	30 ~ 329.9999 V		0.0064 % + 500 μ V
	100 ~ 1000 V		0.0064 % + 1.5 mV
Resistance Generation	330 ohm ~ 1.09999 k Ω		0.17 % + 0.07 Ω
	3.3 ~ 10.9999 k Ω		0.010 % + 0.7 Ω
	33 ~ 109.999 k Ω		0.013 % + 7 Ω
	330 k Ω ~ 1.09999 M Ω		0.017 % + 63 Ω
	3.3 ~ 10.9999 M Ω		0.07 % + 635 Ω
	11 ~ 32.9999 M Ω		0.12 % + 635 Ω
Capacitance Generation	0.33 ~ 1.0999 μ F		0.29 % + 1.2 nF

Sandra Lim

ELECTRICAL SUPPLY : Minimum 4 dedicated outlets

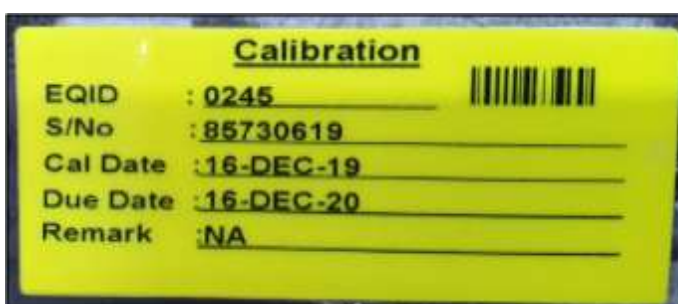
Verified using :

FLUKE 110 TRUE RMS MULTIMETER

Serial Number: 85730619

EQID: 0245

Calibration Due Date: 16-Dec-2020



Document No.: _____

Iteration No.: _____

Attachment : _____ Page ____ of ____

ELECTRICAL OUTLET

TE82526-4 Pump
Tray Tester (AC Line)

LCD Monitor (AC Line)

Computer Work
Station (AC Line CPU)



AND HR 200
Electronics Balance
(AC Line)

Document No.: _____
Iteration No.: _____
Attachment : _____ Page ____ of ____

NETWORK AVAILABLE : Minimum of 1 dedicated network

Blue Sticker : Dedicated network for Pump Tray Area



WS-9 is a dedicated network

Document No.: _____
Iteration No.: _____
Attachment : _____ Page ____ of ____

WORK SPACE: The system has sufficient room for the test station, UUT and service



TEST STATION BENCH : The test station bench is large and strong enough to support the station



Document No.: _____
Iteration No.: _____
Attachment : _____ Page ____ of ____

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 3 of 6

Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification	
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester	
Installation Site: Flextronics Contract Manufacturing Site in Singapore				
Purpose: To verify that all critical instruments are in the calibration database and that a calibration and/or a preventive maintenance has been performed, as appropriate. Test Execution: - List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed. - Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below. Objective Evidence: - Completed IQ-03 Test Script Data Sheet - Copies of calibration and/or maintenance certificates - Screen captures from the associated Calibration database				
Description	Asset #	Cal/PM Dates		Initial & Date
Electronics Weigh Balance		Last Cal/PM: Cal/PM Due:		
Comments: Electronics Weigh Balance is the only equipment that require calibration				
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail				

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 4 of 6

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester		
Installation Site: Flextronics Contract Manufacturing Site in 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	
TE82526 Test Software	Version: 1.0	Version:			
Comments: This test station does not download firmware.					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail					

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 5 of 6

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester	
Installation Site: Flextronics Contract Manufacturing Site in Singapore				
Purpose: To verify that the equipment can operate in a safe manner, within its designated location.				
Test Execution: - List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary. - List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column. - Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below.				
Objective Evidence: - Completed IQ-05 Test Script Data Sheet - Photo(s) of the secured glass bottles, tanks, etc., if applicable - The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.				
Safety Inspection		Acceptance Criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges		None Found (or mitigated appropriately)		
Glass Bottles		Secure		
Waste Tanks		Secure and located below the system		
Emergency Stop		System ceases operation upon depressing the Emergency Stop button		
Guarding		Shielding in place to prevent hazard during operation		
Comments:				
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail				

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 6 of 6

Test Script #	IQ-06	IQ Test Name:	Functional Verification
Equipment #	TE82526-4	Equipment Name:	Pump Tray Tester
Installation Site: Flextronics Contract Manufacturing Site in 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: Serial Number:	All required CTQ Specification measurements result in a Pass		
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

IQ-05 Test Script Data Sheet:

Station does not have Pinch Points/ sharp edges
Glass Bottle is secured by plastic container



Document No.: _____
 Iteration No.: _____
 Attachment : _____ Page ____ of ____

Waters Corporation

SUBASSEMBLY TEST RECORD

Part Number:	289000526	Description:	Alliance Pump Tray
Tested By:	246154	Date:	26/3/2020 4:44:07 pm
Serial Number:	13L0H042	Control Number:	N/A
Software Revision:	N/A	Factory Order:	N/A

Seal Wash Functional Test PASS ☒ FAIL ☐ see note # _____ PASS ☐

Accumulator Decay Test

Total decay (≤ 150 psi) - Actual: 20 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
Compress Volume (≤ 20 %) - Actual: 15 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Primary Decay Test

Total decay (≤ 150 psi) - Actual: 102 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
Compress Volume (≤ 20 %) - Actual: 10 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Flow Rate Test [Measured Flow: 0.999 ml/min]
($\leq \pm 1\%$) - Actual: -0.15 % ERROR PASS ☒ FAIL ☐ see note # _____ PASS ☐

Ripple Test
($\leq 2.5\%$) - Actual: 1.2 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Pump Tray Result: PASS ☒ FAIL ☐ Signed: 246154 JOEL Date: 26/MAR/2020

Notes: N/A

Pump PCB S/N: 210000425 - E
250220159M Accum. Xducer S/N: 299361 Prim. Xducer S/N: 299414

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.