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For the 2690 Pump Tray Tester (TE82526-2)

as per 73000183

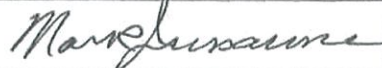
Jan. 16 Mar 20

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		25 FEB 20

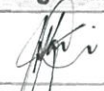
The "Prepared By" signature denotes that this document accurately describes the qualification activities.

REVIEWED BY

Name	Role	Signature	Date
Mark Jussuame	Senior Test Engineer		25 FEB 20

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		26.Feb.2020

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 TE82526-2, the 2690 Pump Tray Tester.

1.1 SYSTEM BACKGROUND

The TE82526-2, 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 additional 2690 Pump Tray Tester TE82526-2 is being deployed to the Flextronics Contract Manufacturing Site in Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82526-2, 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 TE82526-2, 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 TE82526-2, 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 TE82526-2, 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

5.0 TRAINING

The operator of the TE82526-2, 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

Thumbnail (Images)

Rev.	Type	Document	Vs. Part	Description	Status text	Current Ver	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		11.09.1998	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 Hart
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 TE82526-2, 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 TE82526-2, 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 TE82526-2, 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 TE82526-2, 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 P/N: 289000525 (S/N: 06L0H071)

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

Installation Qualification Protocol

Document # 730004135

Version # 03

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Appendix A: TRAINING RECORD

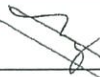
Document #	WAT210700	Document Title	TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY	Version	00
				Revision	09

Training Performed By: (If not used this section can be deleted)

SELF		10 FEB 2020
Printed Name	Signature	Date

☒ 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 MAMALATED DEDUYO	246154 	JOEL	10 FEB 2020
N/A  10 FEB 2020			

Print multiple copies of this Training Record Template as needed

Document No.: TE82526-2-1QR
Iteration No.: 00
Attachment: 7.1 Page: 1 of 1

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
N/A JG 19SEP2019		


Employee's Signature

Senior Test Engineer 19SEP2018
Title Date

Trainer's Signature

N/A self trained JG 19SEP2019
Title Date

Document No.: TE82526-2-2QR
Iteration No.: 00
Attachment: 7.2 Page: 1 of 1

¹ Without preceding "90"

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82526-2	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	Release General	H2 25FEB20	
Comments: NA H2 25FEB20				
Overall Test Conclusion ☒ Pass ☐ Fail		Document No.: <u>TE82526-2-IQR</u> Iteration No.: <u>00</u> Attachment: <u>7.3</u> Page: <u>1</u> of <u>1</u>		

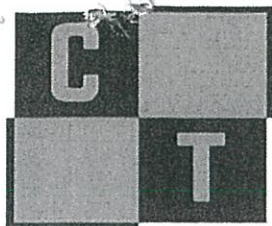
Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ -02	IQ Test Name:	Site Verification	
Equipment #	TE82526-2	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	21°C to 22°C	Pass	HZ 25FEB20
Relative Humidity	10 % to 80 %, Non-Condensing	56% to 58%	Pass	HZ 25FEB20
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%	236.2 VAC 50.01 HZ	Pass	HZ 25FEB20
Electrical Outlets	Minimum of 4 dedicated outlets	4	Pass	HZ 25FEB20
Network Available	Minimum of 1 dedicated network	1	Pass	HZ 25FEB20
Workspace	The system has sufficient room for the test station, UUT and service		Pass	HZ 25FEB20
Test Station Bench	The Test Station Bench is large and strong enough to support the station		Pass	HZ 25FEB20
Comments: - Ambient temperature/humidity measured using a Temperature/Humidity Meter, Control Number EQID 0418 - Electrical supply measured using a Multimeter, Control Number EQID 0245 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.: TE82526-2-IQR	
☒ Pass ☐ Fail			Iteration No.: 00 Attachment: 7.4 Page: 1 of 1	



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
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: EQID 0418
Yepthimich 10 JAN 20

Calibrated by :

Saathyish Vejayandran

EMP ID : 1107

Approved by :

Siva

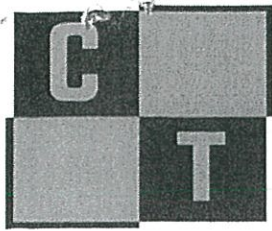
EMP ID : NA

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.



Document No.: TER2526-2-IQR
Iteration No.: 00
Attachment: 7.5 Page: 1 of 4



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.

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Document No.: TE82526-2-IQR
Iteration No.: 00
Attachment: 7.5 Page: 2 of 4

IQ-02 TEST SCRIP DATA SHEET:

AMBIENT TEMPERATURE: 21 °C to 22 °C

Verified using

THERMOHYGROGRAPH

Serial Number : 5650

EQID : 0418EQID : 0418

Calibration Due Date: 07-Jan-2021

flex
SKW-MFG4018-00
Temperature and Humidity Monitoring Record

Rev: A
Form A

Month / Year : Feb 20
Equipment Used : Thermohygrograph
EQ ID : 0418
Floor Level : 5th Floor
Serial Number : 3650
Temperature Range : 18°C to 30°C
Area : Production
Calibration due date : 07 Jan 21
Humidity Range : 25%RH to 85%RH

Date Check	Time Check	Min. Temp. (°C)	Max. Temp. (°C)	Min. Humidity (%RH)	Max. Humidity (%RH)	Spec. Check since last recording?	Temp. (°C)	Humidity (%RH)	Date Out	Time Out	Operator / Signature	NCMR
1	0913	22	23	61	62	Yes / No	NA	NA	NA	NA	Wang Zheng fu	NA
2	X	X	X	X	X	Yes / No	X	X	X	X	Wang Zheng fu	X
3	0956	22	23	59	61	Yes / No	NA	NA	NA	NA	Wang Zheng fu	NA
4	0728	22	23	57	60	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
5	0743	22	23	56	58	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
6	0723	21	23	55	59	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
7	0720	22	23	57	59	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
8	0718	22	23	56	58	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
9	X	X	X	X	X	Yes / No	X	X	X	X	Yep Him Wah	X
10	1015	21	22	55	60	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
11	0807	21	22	56	60	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
12	0734	21	22	56	58	Yes / No	NA	NA	NA	NA	Yep Him Wah	NA
13						Yes / No						
14						Yes / No						
15						Yes / No						
16						Yes / No						
17						Yes / No						
18						Yes / No						
19						Yes / No						
20						Yes / No						
21						Yes / No						
22						Yes / No						
23						Yes / No						
24						Yes / No						
25						Yes / No						
26						Yes / No						
27						Yes / No						
28						Yes / No						
29						Yes / No						
30						Yes / No						
31						Yes / No						

Note: X - No Operation (example: Saturday, Sunday, Plant Shutdown and Public Holiday)
NA - Not Applicable

Document No.: TE82526.2-IQR
Iteration No.: 00
Attachment: 7.5 Page: 3 of 4

RELATIVE HUMIDITY: 56 % to 58 %

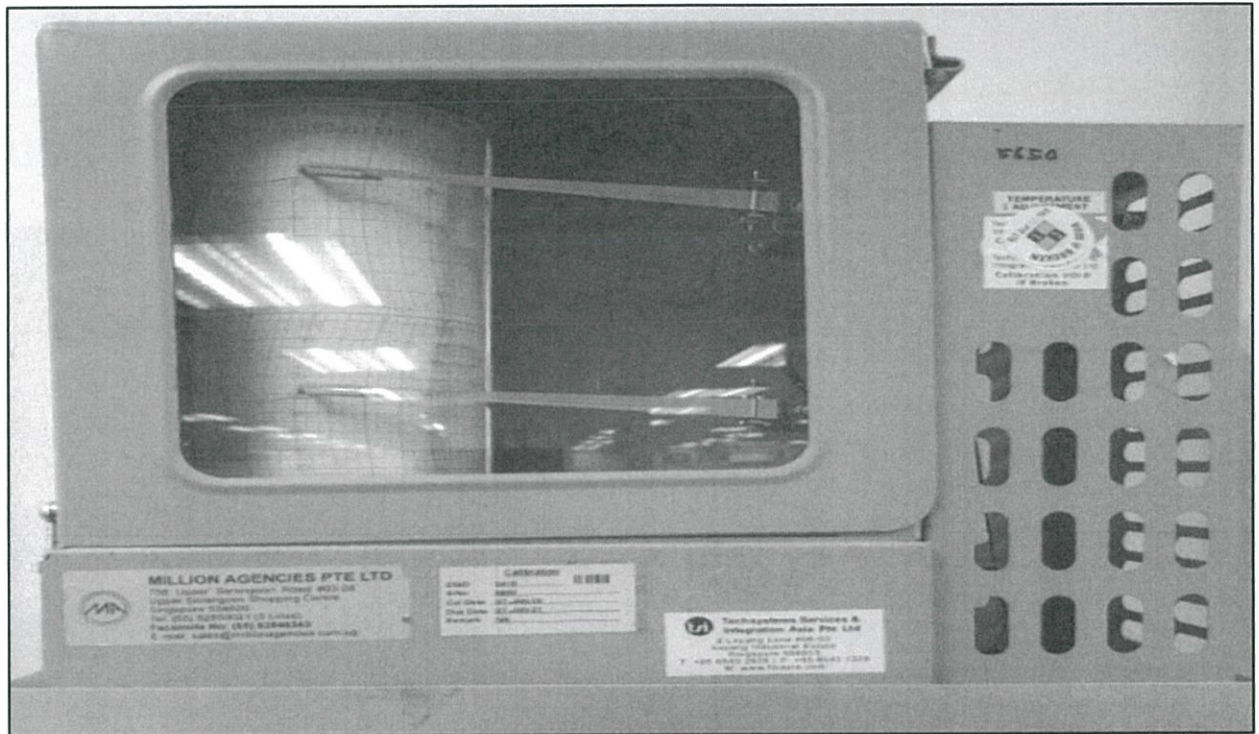
Verified using

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



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

Sandra Lim
Associate Engineer



Approved By

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

Document No.: TE82526-2-IQR
Iteration No.: 00
Attachment: 7.6 Page: 1 of 6

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

Document No.: TE82526-2-IQR

Iteration No.: 00

Attachment: 7.6 Page: 2 of 6



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

Document No.: TES2526-2-IQR

Iteration No.: 08

Attachment: 7.6 Page: 3 of 6



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[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

Document No.: TE82526-2-2QR
Iteration No.: 00
Attachment: 7.6 Page: 4 of 6


Sandra Lim



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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
	3.3 ~ 32.9999 V	45 Hz ~ 10 kHz
	33 ~ 329.999 V	45 Hz ~ 1 kHz
	330 ~ 1000 V	45 Hz ~ 1 kHz
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

Sn

Sandra Lim

Document No.: TE82526-2-IQR
Iteration No.: 00
Attachment: 7.6 Page: 5 of 6

ELECTRICAL SUPPLY : Minimum 4 dedicated outlets

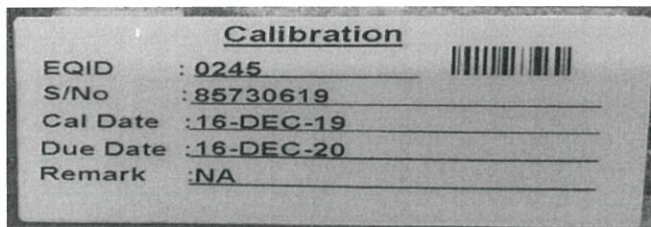
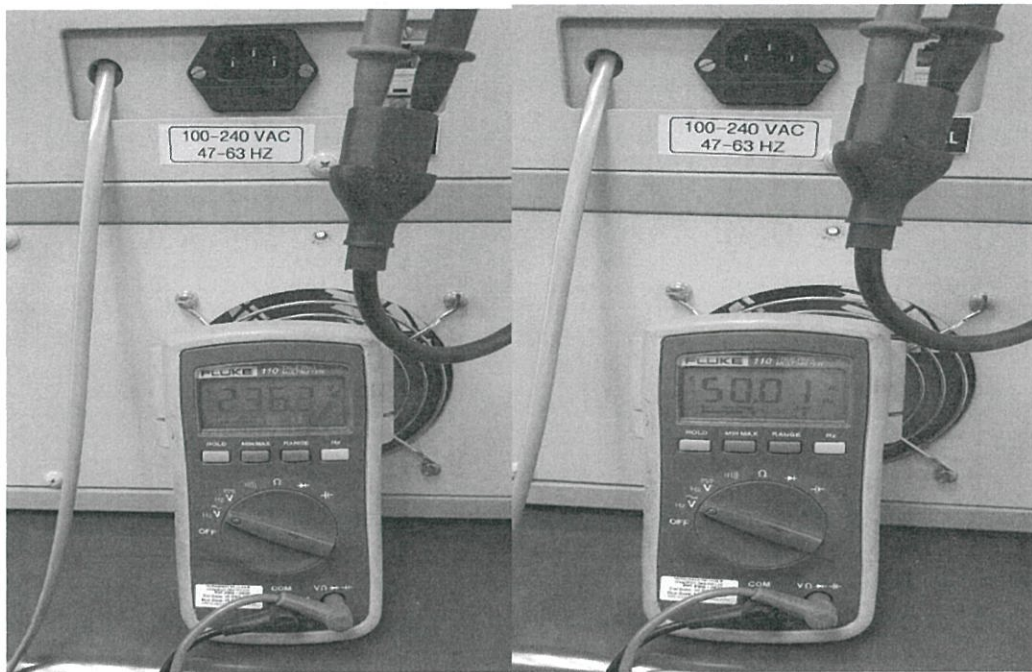
Verified using :

FLUKE 110 TRUE RMS MULTIMETER

Serial Number: 85730619

EQID: 0245

Calibration Due Date: 16-Dec-2020



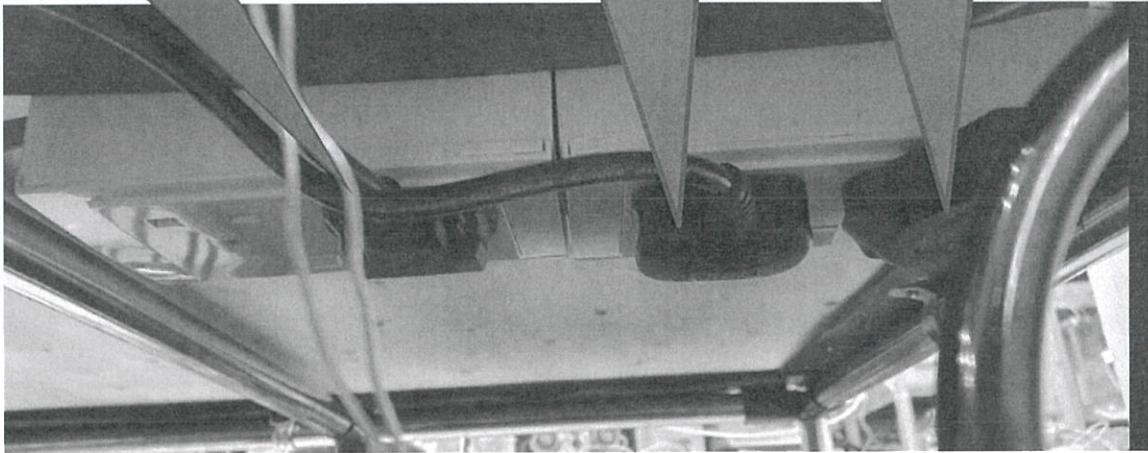
Document No.: TE82526-2-IQR
Iteration No.: 00
Attachment: 7.6 Page: 6 of 6

ELECTRICAL OUTLET

TE82526-2 Pump
Tray Tester (AC Line)

LCD Monitor (AC Line_

Computer Work
Station (AC Line CPU)



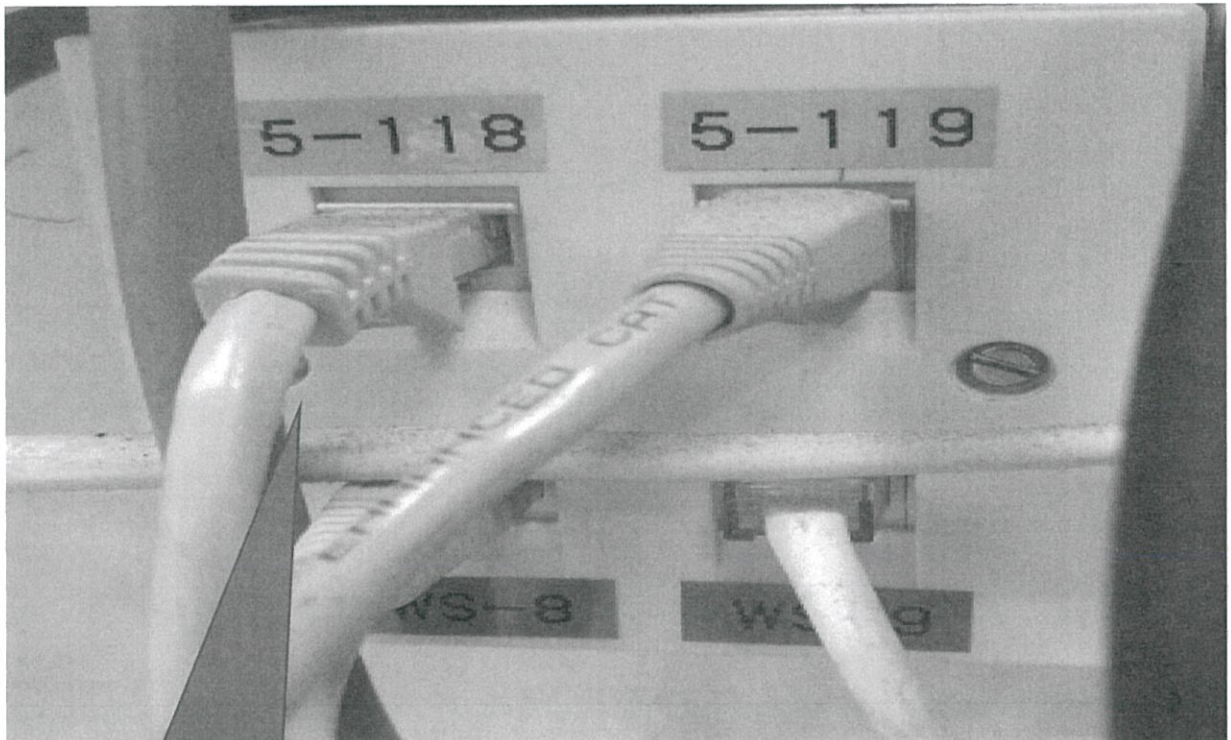
AND HR 200
Electronics Balance
(AC Line)



Document No.: TE82526-2-IQR
Iteration No.: 00
Attachment: 7-7 Page: 1 of 2

NETWORK AVAILABLE : Minimum of 1 dedicated network

Blue Sticker : WS-8 is a dedicated network



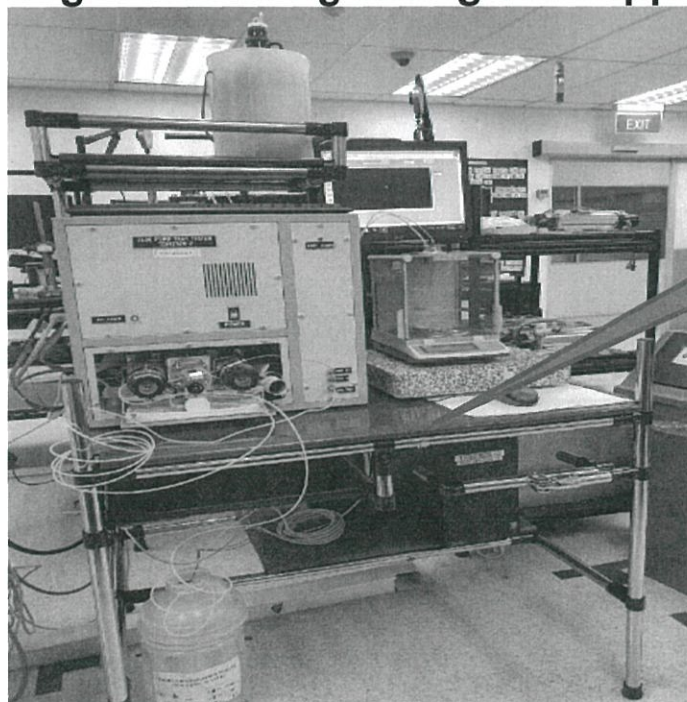
WS-8 is a dedicated network

Document No.: TE825262-IQR
Iteration No.: 00
Attachment: 7.7 Page: 2 of 2

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



Installation Qualification Protocol

Document # 730004135

Version # 03

Page 3 of 8

Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification	
Equipment #	TE82526-2	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	12303631	Last Cal/PM: 07 FEB 20 Cal/PM Due: 07 AUG 20		H2 25 FEB 20
Comments: Electronics Weigh Balance is the only equipment that require calibration				
Overall Test Conclusion		Document No.: TE82526-2-IQR Iteration No.: 00 Attachment: 7.9 Page: 1 of 1		
☒ Pass ☐ Fail				



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE 5 #07-02/03
TECHPLACE II SINGAPORE 569874
65 67484384



Certificate of Calibration

Date: February 07, 2020

Cert No. 551220083486062

Customer:

WATERS PACIFIC PTE LTD

1 SCIENCE PARK ROAD, #02-08 THE CAPRICORN
SINGAPORE SCIENCE PARK II
SINGAPORE 117528

Work Order #: SG-11013410

MPC Control #: 12303631

Serial Number: 12303631

Asset ID: 2769

Department: N/A

Gage Type: ELECTRONIC WEIGHING BALANCE

Performed By: ZHIYUAN LIM

Manufacturer: A&D

Received Condition: IN TOLERANCE

Model Number: HR200

Returned Condition: IN TOLERANCE

Size: N/A

Cal. Date: February 07, 2020

Temp/RH: 21°C / 55 %

Cal. Interval: 6 MONTHS

Location: Calibration performed at Customer's facility

Cal. Due Date: August 07, 2020

Calibration Notes:

Calibration performed at FLEXTRONICS MANUFACTURING PTE. LTD. facility

Performance test passed. See attached data (2 Pages).

Standards Used to Calibrate Equipment

I.D.	Description.	Model	Serial	Manufacturer	Cal. Due Date	Traceability #
CG7300	WEIGHT SET 29 PC	E1/E2	061	N/A	Mar 22, 2020	551220082899020

Procedures Used in this Event

Procedure Name	Description
MPC-WEI-001 Rev. 04	Weighing Instruments, General, rev04, Jan-23-2020

Calibrating Technician:

ZHIYUAN LIM

QC Approval:

JUN CALIMAG

Statements of Pass or Fail Conformance: The uncertainty of measurement has been taken into account when determining compliance with specification, as per ILAC-G8:03/2009. All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCCL Z540.3-2006.

The status of compliance with the acceptance criteria is reported as:

PASS - Compliant with specification.

FAIL - Not compliant with specification.

FAIL¹ - The measured value is not within the acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% is within the specified tolerance.

PASS² - The measured value is within acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% exceeds the specified tolerance.

The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k=2$, which for a normal distribution corresponds to a coverage probability of approximately 95%, unless otherwise stated. This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCCL Z540.3 Method 6-Guard Bands based on Test Uncertainty Ratio. Calibration cycles and resulting due dates were submitted/approved by the customer. Any number of factors may cause an instrument to drift out of tolerance before the next scheduled calibration. Recalibration cycles should be based on frequency of use, environmental conditions and customer's established systematic accuracy. All standards are traceable to SI through the National Institute of Standards and Technology (NIST) and/or recognized national or international standards laboratories. Services rendered include proper manufacturer's service instruction and are warranted for no less than thirty (30) days. The information on this report pertains only to the instrument identified, this may not be reproduced in part or in a whole without the prior written approval of the issuing MP Calibration Laboratory.

Document No.: TEB2576-2-JQR
Iteration No.: 00
Attachment: 7.10 Page: 1 of 3



Calibration Report of A&D HR200 Electronic Weigh Balance

MPC Control #: 12303631
Asset ID: 2769

Serial Number: 12303631
Calibration Date: February 07, 2020

Repeatability Test

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
210.0000 g	5.0000 g	4.9999 g	5.0000 g	5.0000 g	5.0001 g	PASS	NA
210.0000 g	75.0000 g	74.9999 g	75.0000 g	75.0000 g	75.0001 g	PASS	NA

The standard deviation was found to be: 0.0000 g

Linearity Test or Test for Errors of Indication

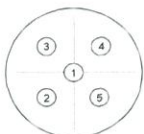
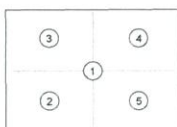
Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
210.0000 g	0.2000 g	0.1998 g	0.2000 g	0.2000 g	0.2002 g	PASS	0.000070 g
210.0000 g	0.5000 g	0.4998 g	0.5000 g	0.5000 g	0.5002 g	PASS	0.000070 g
210.0000 g	1.0000 g	0.9998 g	1.0000 g	1.0000 g	1.0002 g	PASS	0.000070 g
210.0000 g	2.0000 g	1.9998 g	2.0000 g	2.0000 g	2.0002 g	PASS	0.000070 g
210.0000 g	3.0000 g	2.9998 g	3.0000 g	3.0000 g	3.0002 g	PASS	0.000074 g
210.0000 g	4.0000 g	3.9998 g	4.0000 g	4.0000 g	4.0002 g	PASS	0.000075 g
210.0000 g	5.0000 g	4.9998 g	5.0000 g	5.0000 g	5.0002 g	PASS	0.000075 g
210.0000 g	6.0000 g	5.9998 g	6.0000 g	6.0000 g	6.0002 g	PASS	0.000082 g
210.0000 g	10.0000 g	9.9998 g	10.0000 g	10.0000 g	10.0002 g	PASS	0.000083 g
210.0000 g	50.0000 g	49.9998 g	50.0000 g	50.0000 g	50.0002 g	PASS	0.00015 g
210.0000 g	100.0000 g	99.9998 g	100.0000 g	100.0000 g	100.0002 g	PASS	0.00025 g
210.0000 g	200.0000 g	199.9998 g	200.0000 g	200.0000 g	200.0002 g	PASS	0.00047 g

Eccentricity Test

Function Tested	Nominal	Lower Limit	As Found	Deviation from Center	Upper Limit	Result	Uncertainty ($\pm$)
Center	70.0000 g	69.9998 g	70.0000 g	0.0000 g	70.0002 g	PASS	NA
Front Left	70.0000 g	69.9998 g	69.9999 g	0.0001 g	70.0002 g	PASS	NA
Back Left	70.0000 g	69.9998 g	70.0000 g	0.0000 g	70.0002 g	PASS	NA
Back Right	70.0000 g	69.9998 g	70.0000 g	0.0000 g	70.0002 g	PASS	NA
Front Right	70.0000 g	69.9998 g	69.9999 g	0.0001 g	70.0002 g	PASS	NA

Positions of Load for Test of Eccentricity

- Center
- Front Left
- Back Left
- Back Right
- Front Right



Calibration Report of A&D HR200 Electronic Weigh Balance

MPC Control #: 12303631
Asset ID: 2769

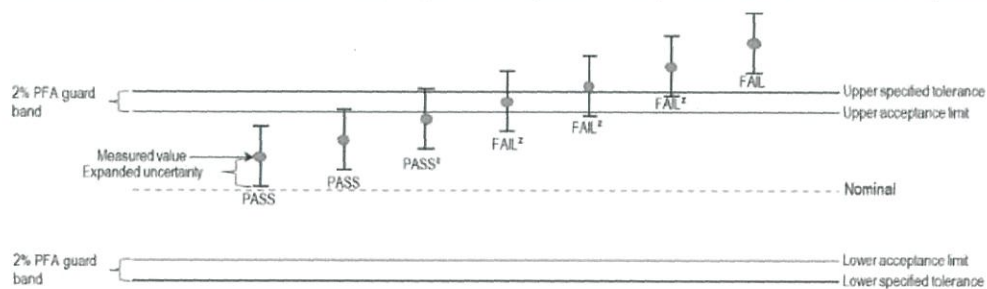
Serial Number: 12303631
Calibration Date: February 07, 2020

Statements of Pass or Fail Conformance

The uncertainty of measurement has been taken into account when determining compliance with specification, as per ILAC-G8:03/2009.
All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCCL Z540.3-2006.

The status of compliance with the acceptance criteria is reported as:

- PASS - Compliant with specification
- FAIL - Not compliant with specification.
- FAIL^z - The measured value is not within the acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% is within the specified tolerance.
- PASS^z - The measured value is within acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% exceeds the specified tolerance.



Acceptance limits for $\leq 2\%$ probability of false accept (PFA) guard band

The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k=2$, which for a normal distribution corresponds to a coverage probability of approximately 95%, unless otherwise stated.

This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCCL Z540.3 Method 6-Guard Bands based on Test Uncertainty Ratio.

- End of Calibration Report -

[1]	Product (If Any):	WATERS
[2]	Flextronics Fiscal Year:	Apr 19 To Mar 20

[illegible]

[8] Remark: New Equipment Release on Feb 20.

PM Frequency:  = Non PM,  = Others, W = Weekly, M = Monthly, Q = Quarterly, H = Half Yearly, Y = Yearly

9] Prepared By : Joel Mamalateo Deduyo

[10] **Verified By: Nallaiyandurai Phani Bhushan**

Sign _____

Sign : _____

Date : 07 Feb 2020

Date : 07 Feb 2020

End of Document

Document No.: 180506-2
Iteration No.: 00
Attachment: 7.11 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 4 of 8

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82526-2	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: 1.0	Pass	H2 25FEB20	
Comments: This test station does not download firmware.					
Overall Test Conclusion ☒ Pass ☐ Fail			Document No.: TE82526-2-IQR Iteration No.: 00 Attachment: 7-12 Page: 1 of 1		

DOCUMENT TITLE: **TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY**

SYSTEM/ASSEMBLY NAME: **ALLIANCE PUMPTRAY**

PART NUMBER AFFECTED **279000419, 279000524, 289000526, 700000713, 700001030, WAT270463, WAT271078**

TEST EQUIPMENT NAME: **ALLIANCE PUMPTRAY TESTER**

TEST EQUIPMENT NUMBER: **TE82526**

TEST SOFTWARE: ***1.0***

AUTHOR(S): **MIKE COTTER**

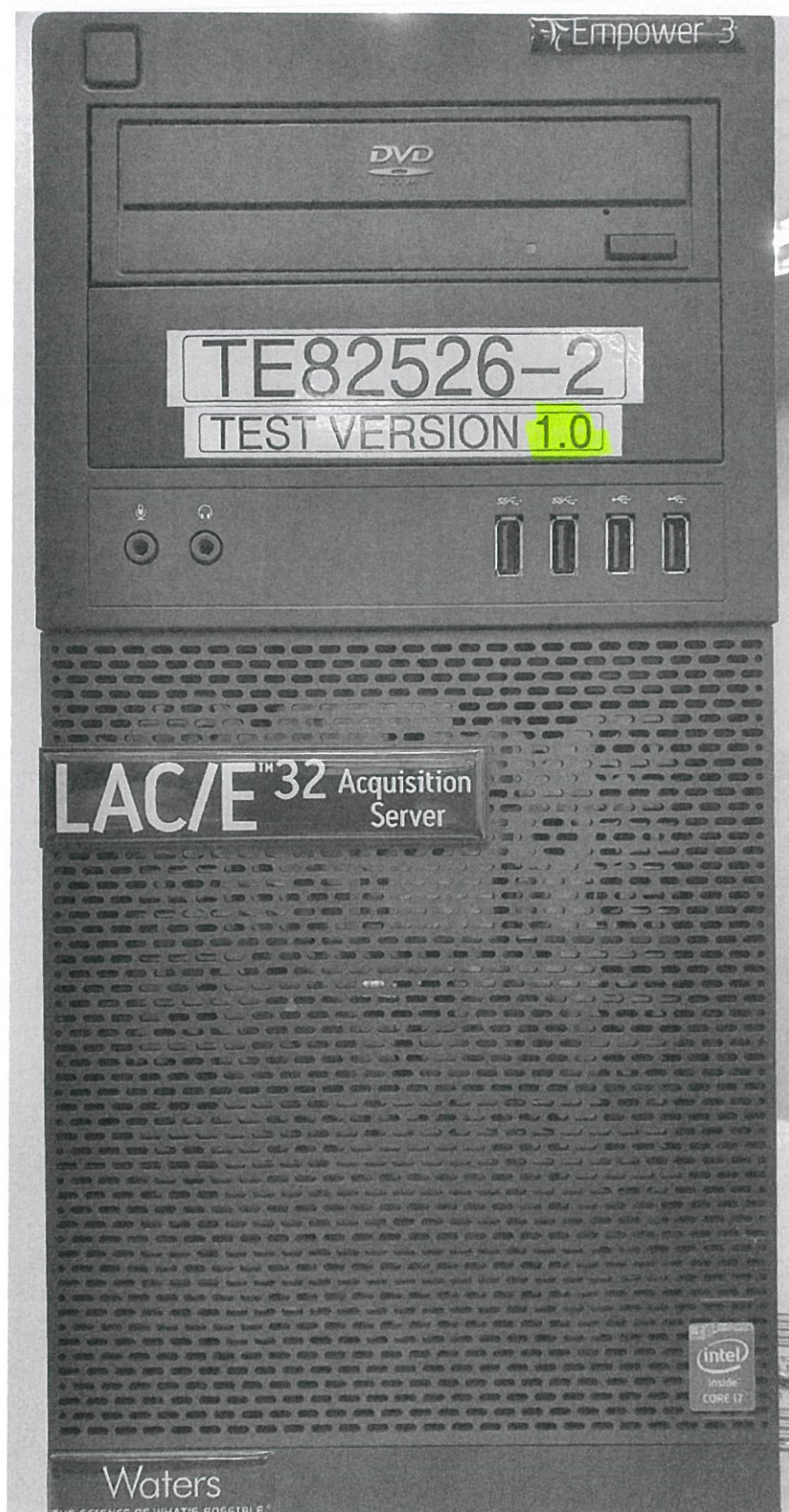
DATE: **April 30, 1998**

REVISED BY: **MIKE COTTER**

DATE: **May 05, 2016**

Document No.: TE82526 2-JQR
Iteration No.: 00
Attachment: 7.13 Page: 1 of 2

IQ-04 Software and Instrument Firmware Version



Document No.: TE82526-2-IQR
Iteration No.: 00
Attachment: 7.13 Page: 2 of 2

Installation Qualification Protocol

Document # 730004135

Version # 03

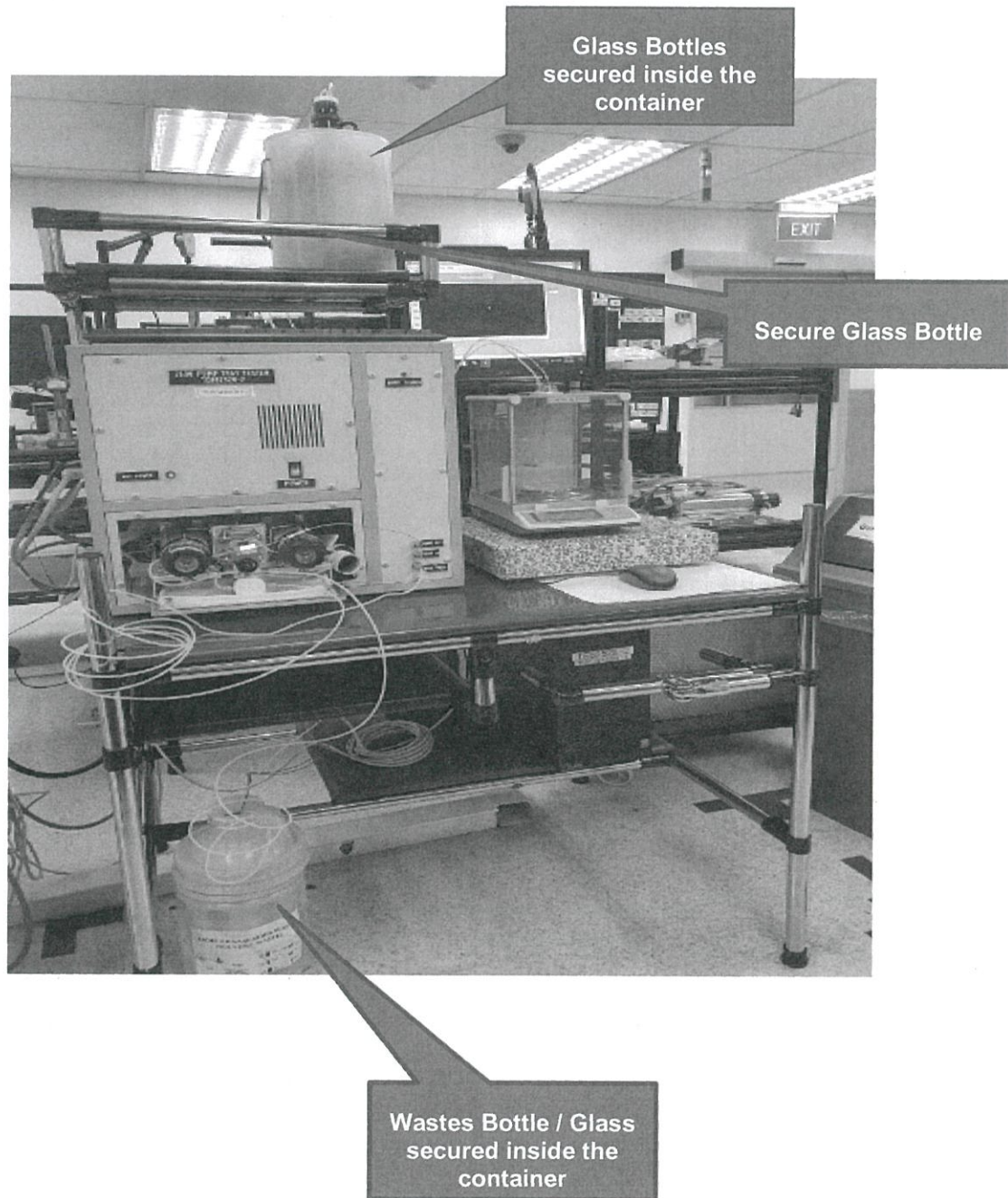
Page 5 of 8

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE82526-2	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)	Pass	HZ 25FEB20
Glass Bottles		Secure	Pass	HZ 25FEB20
Waste Tanks		Secure and located below the system	Pass	HZ 25FEB20
Emergency Stop		System ceases operation upon depressing the Emergency Stop button	N/A	HZ 25FEB20
Guarding		Shielding in place to prevent hazard during operation	Pass	HZ 25FEB20
Comments: N/A HZ 25FEB20				
Overall Test Conclusion ☒ Pass ☐ Fail			Document No.: <u>TE82526-2-IQR</u> Iteration No.: <u>00</u> Attachment: <u>7.14</u> Page: <u>1</u> of <u>1</u>	

IQ-05 Test Script Data Sheet:

Station does not have Pinch Points/ sharp edges

Glass Bottle is secured by plastic container



Document No.: TE82526 2-IQR
Iteration No.: 00
Attachment: 7.15 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 6 of 8

Test Script #	IQ-06	IQ Test Name:	Functional Verification
Equipment #	TE82526-2	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
Part Number: 289000526 Serial Number: 06L0H071	All required CTQ Specification measurements result in a Pass	Pass	H2 25FEB20
Comments: N/A H2 25FEB20			
Overall Test Conclusion ☒ Pass ☐ Fail		Document No.: TE82526-2-IQR Iteration No.: 00 Attachment: 7.16 Page: 1 of 1	

Waters Corporation

SUBASSEMBLY TEST RECORD

Part Number:	289000526	Description:	Alliance Pump Tray
Tested By:	246154	Date:	12/2/2020 3:12:53 pm
Serial Number:	06L0H071	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: 42 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
Compress Volume (≤ 20 %) - Actual: 17 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Primary Decay Test

Total decay (≤ 150 psi) - Actual: 30 PSI PASS ☒ FAIL ☐ see note # _____ PASS ☐
Compress Volume (≤ 20 %) - Actual: 10 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Flow Rate Test [Measured Flow: 0.998 ml/min]

($\leq \pm 1\%$) - Actual: -0.22 % ERROR PASS ☒ FAIL ☐ see note # _____ PASS ☐

Ripple Test

($\leq 2.5\%$) - Actual: 1.4 % PASS ☒ FAIL ☐ see note # _____ PASS ☐

Pump Tray Result: PASS ☒ FAIL ☐ Signed: 246154 JOEL Date: 12 / FEB / 2020

Notes: N/A

Pump PCB S/N: 216000425-E 110120461M Accum. Xducer S/N: 295842 Prim. Xducer S/N: 295907

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.

Document No.: TEG2526-2-DR
Iteration No.: 00
Attachment: 7.12 Page: 1 of 1