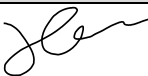


For the 2690 Pump Tray Tester (TE82526-4)

**PREPARED BY**

| Name        | Role                 | Signature                                                                           | Date        |
|-------------|----------------------|-------------------------------------------------------------------------------------|-------------|
| Luo HuaZhen | Senior Test Engineer |  | 28 Mar 2020 |

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 |
|-------------------------------------------------------|----|-------------|-------------|------------|-----|
| <b>SUMMARY OF CHANGE:</b> 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 ID <sup>1</sup> | 618078 |
| Date of Training | 19SEP2019           |                          |        |
| Comments:        | N/A                 |                          |        |

| Document Number | Title                               | Rev. # |
|-----------------|-------------------------------------|--------|
| 730004135       | Installation Qualification Protocol | 03     |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |
|                 |                                     |        |

 Senior Test Engineer 19SEP2018  
Employee's Signature Title Date

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

Document No.: TE82526-4-IQR  
Iteration No.: 00  
Attachment: 7.2 Page: 1 of 1

<sup>1</sup> Without preceding "90"

# Installation Qualification Protocol

Document # 730004135

Version # 03

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                             |                        |                                                                                                                                    |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | IQ-01                                                       | <b>IQ Test Name:</b>   | Associated Documentation Verification                                                                                              |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | TE82526-4                                                   | <b>Equipment Name:</b> | Pump Tray Tester                                                                                                                   |                           |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                             |                        |                                                                                                                                    |                           |
| <p><b>Purpose:</b><br/>To verify that supporting documentation is available prior to the completion of qualification.</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-01 Test Script Data Sheet</li> <li>SAP screenshots of below available document(s)</li> </ul> |                                                             |                        |                                                                                                                                    |                           |
| <b>Document Type</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Title, Doc. #, Version/Revision #</b>                    |                        | <b>Status in SAP</b>                                                                                                               | <b>Initial &amp; Date</b> |
| TSP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY, Rev 09 |                        | Release General                                                                                                                    | HZ 27Mar20                |
| <p><b>Comments: N/A</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                             |                        |                                                                                                                                    |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                             |                        | <p>Document No.: <u>TE82526-4-IQR</u></p> <p>Iteration No.: <u>00</u></p> <p>Attachment: <u>7.3</u> Page: <u>1</u> of <u>1</u></p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                             |                        |                                                                                                                                    |                           |

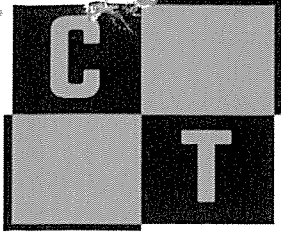
# Installation Qualification Protocol

Document # 730004135

Version # 03

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                          |                        |                                                                                                                                    |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | IQ -02                                                                   | <b>IQ Test Name:</b>   | Site Verification                                                                                                                  |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | TE82526-4                                                                | <b>Equipment Name:</b> | Pump Tray Tester                                                                                                                   |                           |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                          |                        |                                                                                                                                    |                           |
| <p><b>Purpose:</b><br/>To verify the location in which the test equipment is to be installed is suitable for use.</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>List additional applicable parameters in the Parameters column. Rows may be added as needed.</li> <li>Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column.</li> <li>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.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-02 Test Script Data Sheet</li> <li>Photo(s) of the work area, as applicable</li> <li>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.</li> <li>Copies of calibration certificates for measurement tools, if applicable</li> </ul> |                                                                          |                        |                                                                                                                                    |                           |
| <b>Parameters</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Acceptance Criteria</b>                                               | <b>As Found</b>        | <b>Pass/Fail</b>                                                                                                                   | <b>Initial &amp; Date</b> |
| Ambient Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 18 °C to 28 °C                                                           | 21 °C - 22 °C          | Pass                                                                                                                               | HZ 27Mar2020              |
| Relative Humidity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 10 % to 80 %, Non-Condensing                                             | 54 % to 55%            | Pass                                                                                                                               | HZ 27Mar2020              |
| Electrical Supply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 100 VAC to 240 VAC, 50 Hz/60 Hz ±5%                                      | 239.7 VAC<br>50 HZ     | Pass                                                                                                                               | HZ 27Mar2020              |
| Electrical Outlets                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Minimum of 4 dedicated outlets                                           | 4                      | Pass                                                                                                                               | HZ 27Mar2020              |
| Network Available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Minimum of 1 dedicated network                                           | 1                      | Pass                                                                                                                               | HZ 27Mar2020              |
| Workspace                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | The system has sufficient room for the test station, UUT and service     |                        | Pass                                                                                                                               | HZ 27Mar2020              |
| Test Station Bench                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | The Test Station Bench is large and strong enough to support the station |                        | Pass                                                                                                                               | HZ 27Mar2020              |
| <p><b>Comments:</b></p> <ul style="list-style-type: none"> <li>Ambient temperature/humidity measured using a Temperature/Humidity Meter, Control Number EQID: 0418</li> <li>Electrical supply measured using a Multimeter, Control Number EQID: 0245</li> </ul> <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                          |                        |                                                                                                                                    |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                          |                        | <p>Document No.: <u>TE82526-4-IQR</u></p> <p>Iteration No.: <u>00</u></p> <p>Attachment: <u>7.4</u> Page: <u>1</u> of <u>1</u></p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> 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

|                                             |                                |
|---------------------------------------------|--------------------------------|
| <b>CERTIFICATE NUMBER :</b> CTS-111-1014-20 | <b>JOB NUMBER :</b> CTJ19-8721 |
| <b>RECEIVED DATE :</b> 30-Dec-19            | <b>ISSUE DATE :</b> 08-Jan-20  |

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

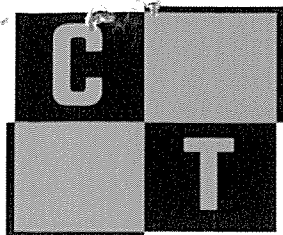
This certificate may not be reproduced other than in full, except with the prior written approval of the issuing Laboratory.  
The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council.



Document No.: TE82526-4-IQR

Iteration No.: 00

Attachment: 7.5 Page: 1 of 4



# CALTEK PTE. LTD.

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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.



Document No.: TE82526-4-IQR

Iteration No.: 00

Attachment: 7.5 Page: 2 of 4



**RELATIVE HUMIDITY: 54 % to 55 %**

Verified using

**THERMOHYGROGRAPH**

Serial Number : 5650

EQID : 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

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[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

|                                                                   |
|-------------------------------------------------------------------|
| <b>REVIEWED &amp; ACCEPTED</b>                                    |
| <b>SIGN:</b> <u>CHANG MEI LAN</u>                                 |
| <b>DATE:</b> <u>20 DEC 19</u>                                     |
| <b>REMARKS:</b> <u>EQID 0245</u><br><u>Mov'd Shangw 20 Dec 19</u> |

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 ± 3) °C  
Humidity : (35 ~ 65) %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

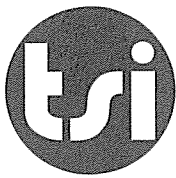


Approved By

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

zby

Document No.: TE82526-4-IQR  
Iteration No.: 00  
Attachment: 7.6 Page: 1 of 6



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[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.

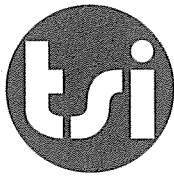
Test Performed By

Sandra Lim

Document No.: TE82526-4-IQR

Iteration No.: 00

Attachment: 7.6 Page: 2 of 6



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## 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       |          |

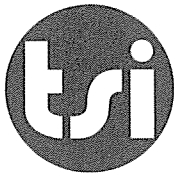
Test Performed By

Sandra Lim

Document No.: TE82526-4-IQR

Iteration No.: 00

Attachment: 7.6 Page: 3 of 6



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## 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 |          |

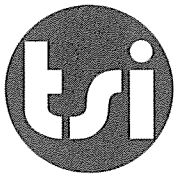
Test Performed By

Document No.: TE82526-4-IQR

Iteration No.: 00

Attachment: 7.6 Page: 4 of 6

Sandra Lim



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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 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 $\mu$ V  |
|                        | 3.3 ~ 32.9999 V                     | 45 Hz ~ 10 kHz | 0.05 % + 693 $\mu$ 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 $\mu$ V  |
|                        | 30 ~ 329.9999 V                     |                | 0.0064 % + 500 $\mu$ V |
|                        | 100 ~ 1000 V                        |                | 0.0064 % + 1.5 mV      |
| Resistance Generation  | 330 ohm ~ 1.09999 k $\Omega$        |                | 0.17 % + 0.07 $\Omega$ |
|                        | 3.3 ~ 10.9999 k $\Omega$            |                | 0.010 % + 0.7 $\Omega$ |
|                        | 33 ~ 109.999 k $\Omega$             |                | 0.013 % + 7 $\Omega$   |
|                        | 330 k $\Omega$ ~ 1.09999 M $\Omega$ |                | 0.017 % + 63 $\Omega$  |
|                        | 3.3 ~ 10.9999 M $\Omega$            |                | 0.07 % + 635 $\Omega$  |
|                        | 11 ~ 32.9999 M $\Omega$             |                | 0.12 % + 635 $\Omega$  |
| Capacitance Generation | 0.33 ~ 1.0999 $\mu$ F               |                | 0.29 % + 1.2 nF        |

Document No.: TE82526-4-IQR  
Iteration No.: 00  
Attachment: 7.6 Page: 5 of 6

*Sr*

Sandra Lim

## **ELECTRICAL SUPPLY : Minimum 4 dedicated outlets**

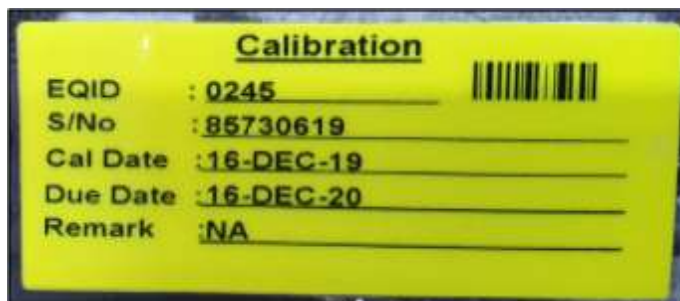
Verified using :

FLUKE 110 TRUE RMS MULTIMETER

Serial Number: 85730619

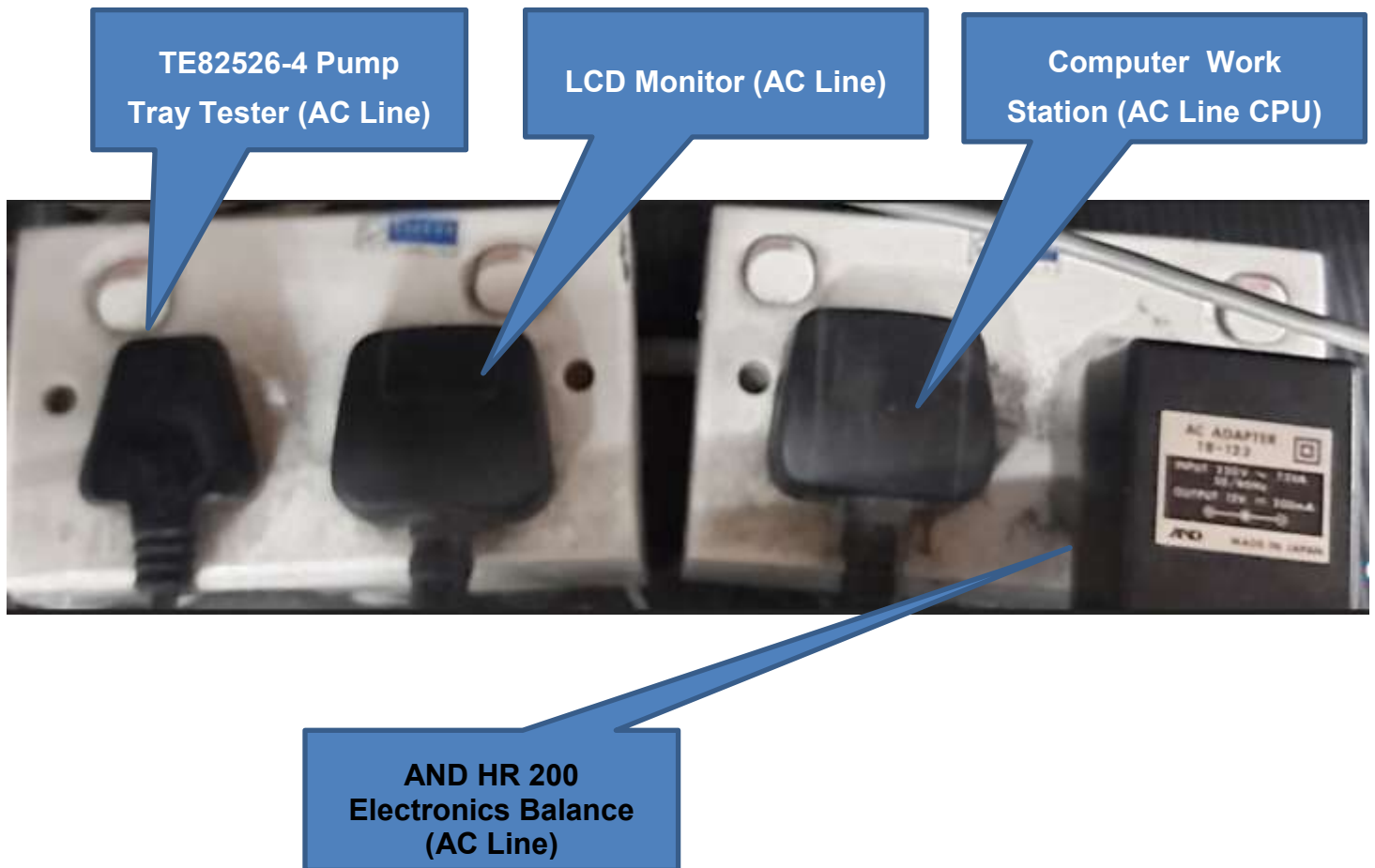
EQID: 0245

Calibration Due Date: 16-Dec-2020



## Minimum 4 dedicated outlets

### ELECTRICAL OUTLET



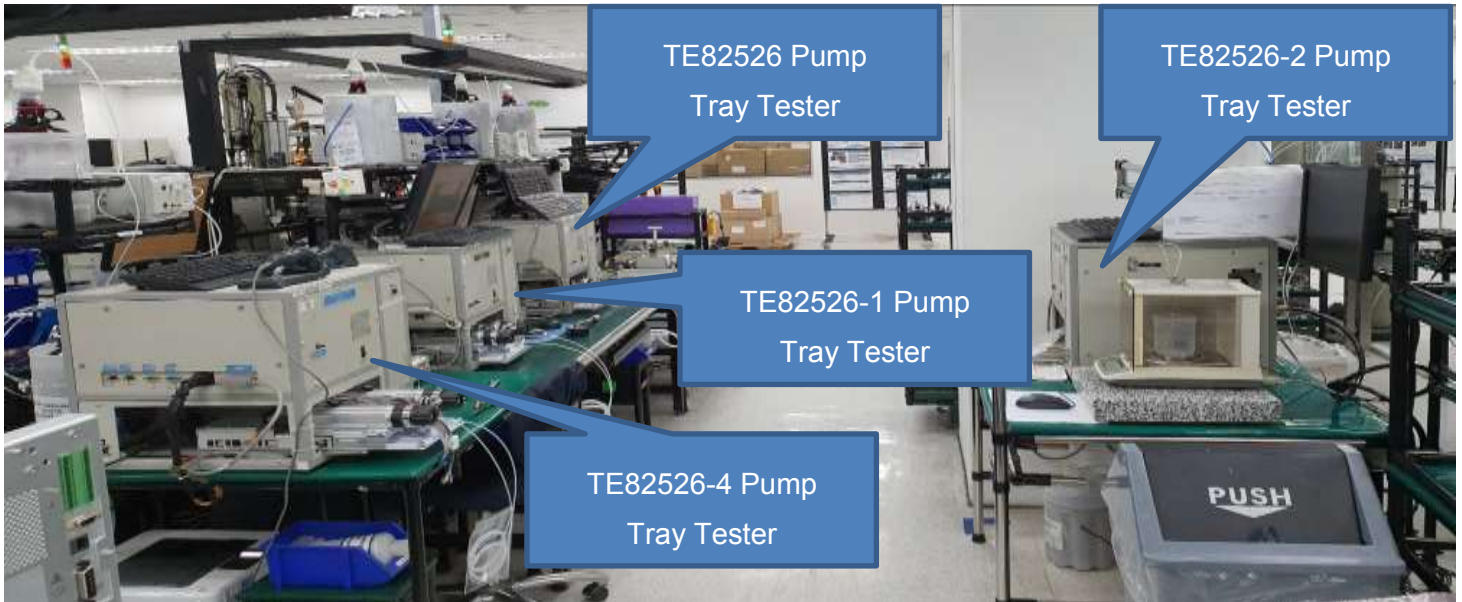
**NETWORK AVAILABLE : Minimum of 1 dedicated network**  
Blue Sticker : Dedicated network for Pump Tray Area



Document No.: TE82526-4-IQR  
Iteration No.: 00  
Attachment: 7.7 Page: 2 of 2

WS-9 is a dedicated network

**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 6

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                |                                                                                                                                |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IQ-03          | <b>IQ Test Name:</b>                                                                                                           | Instrumentation Calibration Verification |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | TE82526-4      | <b>Equipment Name:</b>                                                                                                         | Pump Tray Tester                         |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |                                                                                                                                |                                          |
| <p><b>Purpose:</b><br/>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.</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-03 Test Script Data Sheet</li> <li>Copies of calibration and/or maintenance certificates</li> <li>Screen captures from the associated Calibration database</li> </ul> |                |                                                                                                                                |                                          |
| <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Asset #</b> | <b>Cal/PM Dates</b>                                                                                                            | <b>Initial &amp; Date</b>                |
| Electronics Weigh Balance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12200404       | Last Cal/PM: 13-Jan-2020<br>Cal/PM Due: 13-Jul-2020                                                                            | HZ 27 Mar 2020                           |
| <p><b>Comments:</b></p> <ul style="list-style-type: none"> <li>Electronics Weigh Balance is the only equipment that require calibration</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |                                                                                                                                |                                          |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                | <p>Document No.: <u>TE82526-4-IQR</u><br/> Iteration No.: <u>00</u><br/> Attachment: <u>7.9</u> Page: <u>1</u> of <u>1</u></p> |                                          |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                |                                                                                                                                |                                          |



# MING DENG METROLOGY SERVICES PTE LTD

Company Registration No.: 199701342C  
Blk 20, #04-12, Woodlands Link, Singapore 738733  
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Email: singapore@mdmetrology.com.sg  
Website: www.mdmetrology.com.sg



## CALIBRATION REPORT MDF200015-2

**Issue to** : **Flextronics Manufacturing (Singapore) Pte Ltd**  
No. 1, Kallang Place  
Singapore 339211

**Description** : **WEIGHING SCALE**  
**Manufacturer** : AND (HR-200)  
**Serial Number** : 12200404 (0216)  
**Capacity** : 0 - 210g  
**Graduation** : 0.0001g  
**Date of Calibration** : 13 Jan 2020  
**Date of Issue** : 16 Jan 2020  
**Date Due** : 13 Jul 2020  
**Ambient Temperature** : 22.2 °C  
**Relative Humidity** : 62.5 % relative humidity  
**Location** : Production

**REVIEWED & ACCEPTED**  
**SIGN:** CHANG MEI LAN   
**DATE:** 31 JAN 2020  
**REMARKS:** FAID 0216  
JOEL 31 JAN 2020

### Calibration Method

As generally given in In-house Procedure MDCP-20 : 2005.

### Repeatability

The repeatability was expressed as a standard deviation together with the relative size of the maximum difference between two successive readings. The repeatability was determined at near zero, half maximum and maximum load of the weighing scale. The largest standard deviation was selected as the repeatability of the weighing scale.

### Linearity

The linearity of the weighing scale was determined by placing known masses on the pan in increasing steps up to its maximum capacity of 200g. The difference between the applied mass and the corresponding actual readings were calculated as the errors of the scale readings.

### Off-centre

The off-centre loading result was determined by placing a mass of 100g for the 0 to 200g range and moving the mass to various positions on the pan. The maximum difference between the readings was then obtained.

### Hysteresis

The hysteresis of the weighing scale was determined using a mass of 75g for the 0 to 200g range, applied at an increasing and decreasing directions on the pan up to the maximum load. The difference between the indicated values and that of the applied mass was determined.

### Reference Standard Used

Standard Weights, S/No: M105, traceable to SI units through NMC(Singapore) & NIM(Thailand) via Report No: MDL190571-1 & MTL190924; due date: 01 Mar 2020.

### Calibration Result

The expanded uncertainty is  $\pm 0.0001g$ , at approximately 95% confidence level with coverage factor,  $k = 2$ . No adjustment was done unless After Adjustment readings are reported.

The requirements stated in this report are taken from Manufacturer's Specification,  $\pm 0.0002g$ .

The user should decide on the usability and recalibration interval of this item based on its requirements and intended use.

This calibration report only applies to the calibration of this item.

Calibrated by :

Treerayut Soodtumrong  
Calibration Officer

Reviewed by :

Koo Chih Wei  
Approving Officer



# M I N G D E N G

## METROLOGY SERVICES PTE LTD

Company Registration No.: 199701342C  
Blk 20, #04-12, Woodlands Link, Singapore 738733  
Tel: (65) 6759 1189 (3 lines) Fax: (65) 6759 7656  
Email: singapore@mdmetrology.com.sg  
Website: www.mdmetrology.com.sg

Report Number : MDF200015-2  
Serial Number : 12200404 (0216)  
Date of Calibration : 13 Jan 2020

### Calibration Results

#### Repeatability of Reading

| Applied Mass<br>(g) | Standard Deviation<br>of Reading<br>(g) | Maximum Difference Between<br>Successive Readings<br>(g) |
|---------------------|-----------------------------------------|----------------------------------------------------------|
| 5.0000              | 0.00003                                 | 0.0000                                                   |
| 75.0000             | 0.00003                                 | 0.0000                                                   |

#### Linearity and Errors of the Weighing Scale

| Applied Mass<br>(g) | Actual Reading<br>(g) | Error<br>(g) |
|---------------------|-----------------------|--------------|
| 0.0000              | 0.0000                | 0.0000       |
| 0.2000              | 0.2000                | 0.0000       |
| 0.5000              | 0.5001                | + 0.0001     |
| 1.0000              | 0.9999                | - 0.0001     |
| 2.0000              | 1.9999                | - 0.0001     |
| 3.0000              | 2.9999                | - 0.0001     |
| 4.0000              | 3.9999                | - 0.0001     |
| 5.0000              | 5.0000                | 0.0000       |
| 6.0000              | 6.0000                | 0.0000       |
| 10.0000             | 9.9999                | - 0.0001     |
| 50.0000             | 49.9999               | - 0.0001     |
| 100.0000            | 99.9998               | - 0.0002     |
| 200.0000            | 200.0000              | 0.0000       |

#### Off-Centre Loading

| Position<br>on the pan | Centre   | Front   | Back     | Left    | Right   | Maximum<br>Difference |
|------------------------|----------|---------|----------|---------|---------|-----------------------|
| Reading (g)            | 100.0000 | 99.9998 | 100.0002 | 99.9998 | 99.9998 | 0.0004                |

#### Hysteresis

| Load (g) | Hysteresis (g) |
|----------|----------------|
| 75.0000  | < 0.0001       |

Note: The user is recommended to re-verify the performance of the weighing scale on site prior to use.

Calibrated by :   
Treerayut Soodtumrong  
Calibration Officer

Document No.: \_\_\_\_\_  
Iteration No.: \_\_\_\_\_  
Attachment : \_\_\_\_\_ Page \_\_\_\_ of \_\_\_\_

SKW-EQM4006-00  
Preventive Maintenance Master Schedule

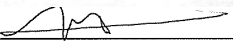
Rev: A

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

| [3] Month/Year | Apr 19                    | May 19 | Jun 19 | Jul 19 | Aug 19 | Sep 19 | Oct 19 | Nov 19 | Dec 19 | Jan 20 | Feb 20 | Mar 20 | NA | NA | NA | NA | NA | NA | NA |
|----------------|---------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----|----|----|----|----|----|----|
| [4] Workweek   | NA                        | NA     | NA     | NA     | NA     | NA     | NA     | NA     | NA     | NA     | NA     | NA     | NA | NA | NA | NA | NA | NA | NA |
| [5] Date       | NA                        | 09     | NA     | NA     | NA     | NA     | NA     | 08     | NA     | NA     | NA     | NA     | NA | NA | NA | NA | NA | NA | NA |
| [6] PM ID      | [7] Equipment Description |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
| PM 00401       | 2690 Pump Tray Tester     |        | H      |        |        |        |        |        | H      |        |        |        |    | NA | NA | NA | NA | NA | NA |
| End Of Data    |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |
|                |                           |        |        |        |        |        |        |        |        |        |        |        |    |    |    |    |    |    |    |

[8] Remark: N/A

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

9] Prepared By : Mohammad Shamsul[10] Verified By : Joel Mamalateo DeduyoSign : Sign : Date : 29 Mar 19Date : 01 Apr 2019

\*End of Document\*

Document No.: TE82526-4-IQR  
Iteration No.: 00  
Attachment: 7.11 Page: 1 of 1

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## Installation Qualification Protocol

Document # 730004135

Version # 03

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                            |                        |                                                                                                                                 |                           |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------|--|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | IQ-04                      | <b>IQ Test Name:</b>   | Test Software and Instrument Firmware Version                                                                                   |                           |  |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | TE82526-4                  | <b>Equipment Name:</b> | Pump Tray Tester                                                                                                                |                           |  |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |                        |                                                                                                                                 |                           |  |
| <p><b>Purpose:</b><br/>To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-04 Test Script Data Sheet</li> <li>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.</li> <li>Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable</li> </ul> |                            |                        |                                                                                                                                 |                           |  |
| <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Acceptance Criteria</b> | <b>As Found</b>        | <b>Pass/Fail</b>                                                                                                                | <b>Initial &amp; Date</b> |  |
| TE82526 Test Software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Version: 1.0               | Version: 1.0           | Pass                                                                                                                            | HZ 27 Mar 2020            |  |
| <p><b>Comments:</b></p> <ul style="list-style-type: none"> <li>This test station does not download firmware.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                        |                                                                                                                                 |                           |  |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |                        | <p>Document No.: <u>TE82526-4-IQR</u><br/> Iteration No.: <u>00</u><br/> Attachment: <u>7.12</u> Page: <u>1</u> of <u>1</u></p> |                           |  |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                            |                        |                                                                                                                                 |                           |  |

# IQ-04 Test Software and Instrument Firmware Version

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

Document Number: WAT210700

Test Specification and Procedure

Revision: 09

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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:



AUTHOR(S): MIKE COTTER

DATE: April 30, 1998

REVISED BY: MIKE COTTER

DATE: May 05, 2016

## **IQ-04 Test Software and Instrument Firmware Version**



Document No.: TE82526-4-IQR  
Iteration No.: 00  
Attachment: 7.13 Page: 2 of 2

## Installation Qualification Protocol

Document # 730004135

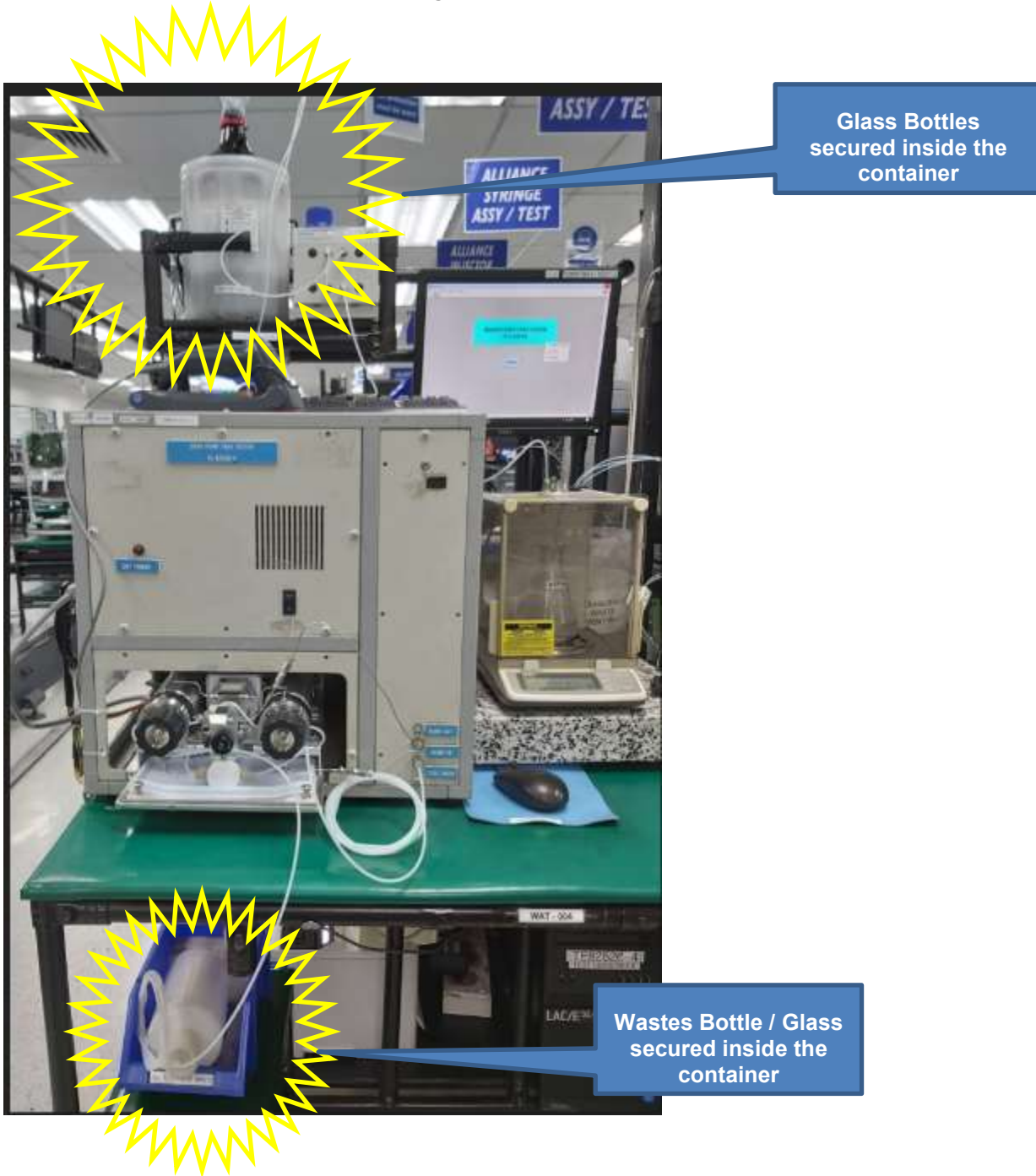
Version # 03

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |           |                                                                      |                                                                                                                                     |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | IQ-05     | <b>IQ Test Name:</b>                                                 | General Safety and Alarms                                                                                                           |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | TE82526-4 | <b>Equipment Name:</b>                                               | Pump Tray Tester                                                                                                                    |                           |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |                                                                      |                                                                                                                                     |                           |
| <p><b>Purpose:</b><br/>To verify that the equipment can operate in a safe manner, within its designated location.</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>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&amp;S shall be consulted as necessary.</li> <li>List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column.</li> <li>Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-05 Test Script Data Sheet</li> <li>Photo(s) of the secured glass bottles, tanks, etc., if applicable</li> <li>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.</li> </ul> |           |                                                                      |                                                                                                                                     |                           |
| <b>Safety Inspection</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |           | <b>Acceptance Criteria</b>                                           | <b>Pass/Fail</b>                                                                                                                    | <b>Initial &amp; Date</b> |
| Mechanical Safety/<br>Pinch Points/Sharp Edges                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           | None Found (or mitigated appropriately)                              | Pass                                                                                                                                | HZ 27 Mar 20              |
| Glass Bottles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |           | Secure                                                               | Pass                                                                                                                                | HZ 27 Mar 20              |
| Waste Tanks                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |           | Secure and located below the system                                  | Pass                                                                                                                                | HZ 27 Mar 20              |
| Emergency Stop                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           | System ceases operation upon<br>depressing the Emergency Stop button | N/A                                                                                                                                 | HZ 27 Mar 20              |
| Guarding                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |           | Shielding in place to prevent<br>hazard during operation             | Pass                                                                                                                                | HZ 27 Mar 20              |
| <p><b>Comments:</b> N/A</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |           |                                                                      |                                                                                                                                     |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |                                                                      | <p>Document No.: <u>TE82526-4-IQR</u></p> <p>Iteration No.: <u>00</u></p> <p>Attachment: <u>7.14</u> Page: <u>1</u> of <u>1</u></p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |           |                                                                      |                                                                                                                                     |                           |

## IQ-05 Test Script Data Sheet:

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



## Installation Qualification Protocol

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |           |                                                              |                                                                                                                      |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IQ-06     | <b>IQ Test Name:</b>                                         | Functional Verification                                                                                              |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | TE82526-4 | <b>Equipment Name:</b>                                       | Pump Tray Tester                                                                                                     |                           |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                                                              |                                                                                                                      |                           |
| <p><b>Purpose:</b><br/>To verify that the system operates as expected.</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835.</li> <li>List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column.</li> <li>Define the appropriate Acceptance Criteria within the Acceptance Criteria column.</li> <li>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.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-06 Test Script Data Sheet</li> <li>Copy of the Test Record(s) for the UUT(s), as applicable</li> <li>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.</li> <li>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.</li> <li>For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.</li> </ul> |           |                                                              |                                                                                                                      |                           |
| <b>UUT Part Number/Serial Number</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           | <b>Acceptance Criteria</b>                                   | <b>Pass/Fail</b>                                                                                                     | <b>Initial &amp; Date</b> |
| Part Number: 289000526<br>Serial Number: 13LOHO42                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |           | All required CTQ Specification measurements result in a Pass | Pass                                                                                                                 | HZ 27 Mar 2020            |
| <b>Comments:</b> N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |           |                                                              |                                                                                                                      |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                                                              | Document No.: <u>TE82526-4-IQR</u><br>Iteration No.: <u>00</u><br>Attachment: <u>7.16</u> Page: <u>1</u> of <u>1</u> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |           |                                                              |                                                                                                                      |                           |

# 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 ( $\leq 150$  psi) - Actual: 20 PSI PASS ☒ FAIL ☐ see note # \_\_\_\_\_ PASS ☐  
Compress Volume ( $\leq 20$  %) - Actual: 15 % PASS ☒ FAIL ☐ see note # \_\_\_\_\_ PASS ☐

### Primary Decay Test

Total decay ( $\leq 150$  psi) - Actual: 102 PSI PASS ☒ FAIL ☐ see note # \_\_\_\_\_ PASS ☐  
Compress Volume ( $\leq 20$  %) - Actual: 10 % PASS ☒ FAIL ☐ see note # \_\_\_\_\_ PASS ☐

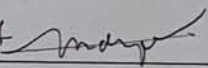
### Flow Rate Test

[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  Date: 26/MAR/2020

Notes: N/A

Pump PCB S/N: 210000425-E  
250220159 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.