

## For the CPSM Final Test System (TE0084050-18)

### PREPARED BY

| Name        | Role                 | Signature                                                                           | Date        |
|-------------|----------------------|-------------------------------------------------------------------------------------|-------------|
| Luo HuaZhen | Senior Test Engineer |  | 04 Jun 2021 |

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

### REVIEWED BY

| Name        | Role                    | Signature                                               | Date |
|-------------|-------------------------|---------------------------------------------------------|------|
| Eric Turner | Principal Test Engineer | Email attached is served as digital signature from Eric |      |

The "Reviewed By" signature[s] 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

| Iteration:                                      | 00 | Originator: | Luo HuaZhen | Change ID: | N/A |
|-------------------------------------------------|----|-------------|-------------|------------|-----|
| Summary of Change: First document for approval. |    |             |             |            |     |

## 1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of the Installation Qualification Protocol 730004135, Ver. 03 for the CPSM Final Test System (TE0084050-18).

### 1.1 SYSTEM BACKGROUND

The CPSM Final Test System (TE0084050-18) is located in Venture Singapore. The station is used to test FTN, FL, and ARC FTN sample managers listed in the CPSM Final Test Procedure 735002984. The system performs testing to ensure the product meets the critical to quality specifications in accordance with the appropriate functional specification document (refer to § 9.0 of this report).

The CPSM Final Test System downloads firmware to the UUT, verifies electrical connection and assembly, performs various calibrations, verifies functional mechanical performance and assembly, and verifies chemistry performance. Upon completion of all testing a Final Test Record is automatically generated and saved to the SigmaSure Data Archive; a copy of the record is printed as part of the Device History Record.

## 2.0 SCOPE

This Installation Qualification Report details the qualification activities undertaken for the CPSM Final Test System (TE0084050-18), based on the requirements of the executed Installation Qualification Protocol 730004135, Ver. 03 as detailed in the Process Validation Procedure 730001835.

## 3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The CPSM Final Test System (TE0084050-18) 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 CPSM Final Test System (TE0084050-18) complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Installation Qualification Report, the CPSM Final Test System (TE0084050-18) can be considered fully qualified and fit for intended use.

## 4.0 ABBREVIATIONS

The following definitions are used in this document:

| Term  | Explanation                            |
|-------|----------------------------------------|
| FTN   | Flow through Needle                    |
| BOM   | Bill of Materials                      |
| CAL   | Calibration                            |
| cGMP  | Current Good Manufacturing Practice    |
| CPSM  | Common Platform Sample Manager         |
| CTQ   | Critical to Quality                    |
| FL    | Fixed Loop                             |
| IQ(R) | Installation Qualification (Report)    |
| N/A   | Not Applicable                         |
| NPI   | New Product Introduction               |
| OESR  | Operations Engineering Service Request |
| P/N   | Part Number                            |
| PM    | Preventative Maintenance               |
| S/N   | Serial Number                          |

| Term | Explanation                           |
|------|---------------------------------------|
| SAP  | Enterprise Resource Planning Software |
| TSP  | Test Specification and Procedure      |
| UUT  | Unit Under Test                       |

## 5.0 TRAINING

The executor of this Installation Qualification has been trained to the Installation Qualification Protocol 730004135, Ver. 03. The operator of the CPSM Final Test System (TE0084050-18) was trained according to the CPSM Final Test Procedure 735002984, Rev. T, Ver. 15. The executor and operator training records are provided as Attachment 7.1 and Attachment 7.2, respectively.

## 6.0 QUALIFICATION RESULTS

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The CPSM Final Test Procedure 735002984, Rev. T, Ver. 15 and the CPSM Final Test Maintenance Procedure 735003028, Rev. E, Ver. 04 were confirmed to be in SAP with a status of Release General. Screen captures of each document status are provided as Attachment 7.4.

6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.2.1 The ambient temperature and humidity were measured using a Temperature/ Humidity Meter and were determined to be within specification as defined by the Acquity Common Platform Sample Manager FTN and FL Functional Specification 721001299, Ver. 12. The temperature/ humidity meter certificate of calibration is provided as Attachment 7.6.

6.2.2 The electrical supply was measured using a Digital Multimeter and was determined to be within specification as defined by the Acquity Common Platform Sample Manager FTN and FL Functional Specification 721001299, Ver. 12. The digital multimeter certificate of calibration is provided as Attachment 7.7.

6.2.3 The Test Station was confirmed to have the six (6) dedicated electrical outlets and the one (1) network connection required.

6.2.4 The space and test bench of the CPSM Final Test System (TE0084050-18) 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. A 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 Procedure 730004135, Ver. 03. The completed script is provided as Attachment 7.9.

6.3.1 The CPSM Final Test System (TE0084050-18), Waters TUV, Waters Acquity Column Manager, and Waters Acquity BSM were all confirmed to be in the PM Mater List with a twelve (12) month maintenance cycle. A screen capture from the database entry for each item is provided as Attachment 7.10.

6.3.2 The CPSM Final Test Station (TE0084050-18) is newly installed and therefore does not have a recent Calibration/ PM Record. Note that the date of Cal/ PM Due listed on Test Script IQ-03: Instrumentation Calibration Verification is not a full maintenance cycle from the installation date because the system and its existing stack components are serviced together.

6.3.3 The Waters TUV, Waters Acquity Column Manager, and Waters Acquity BSM in use at this system were used with the previous CPSM Final Test System (TE83064-15) and have had preventative maintenance within the last twelve (12) months. The most recent Preventative Maintenance Record is provided as Attachment 7.11.

Note that these components receive preventative maintenance as a stack, not individually, and the date of Last Cal/ PM listed on Test Script IQ-03: Instrumentation Calibration Verification reflects the date the preventative maintenance was completed.

- 6.4 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 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 CPSM Final Test Procedure 735002984, Rev. T, Ver. 15 is Test Software 1.03 and was verified to match the version listed in the header of the Final Test Record. Refer to Attachment 7.16.
- 6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.13; refer to the picture provided as Attachment 7.8.
- 6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges.
- 6.5.2 It was confirmed that the glass bottles in use at the test station were secured.
- 6.5.3 It was confirmed that the tank in use at the test station was secured.
- 6.5.4 This system is not equipped with an emergency stop or guarding.
- 6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.14.
- 6.6.1 One FTN (P/N: 186015085) was tested using the CPSM Final Test System (TE0084050-18) with all tests passing. The passing test record as printed to the floor and as printed from the SigmaSure Data Archive are provided as Attachment 7.16.
- The firmware version listed in the BOM in SAP for P/N: 186015085 is version 1.71.395, as shown in the screen capture from SAP provided as Attachment 7.15. It was verified that the UUT was installed with firmware version 1.71.395; refer to the header information in the Final Test Record provided as Attachment 7.16.
- 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 | Pass/Fail | Objective Evidence              | Deviations |
|--------|-----------|---------------------------------|------------|
| IQ-01  | Pass      | Attachments 7.3 and 7.4         | None       |
| IQ-02  | Pass      | Attachments 7.5 through 7.8     | None       |
| IQ-03  | Pass      | Attachments 7.9, 7.10, and 7.11 | None       |
| IQ-04  | Pass      | Attachments 7.12 and 7.16       | None       |
| IQ-05  | Pass      | Attachment 7.13 and 7.8         | None       |
| IQ-06  | Pass      | Attachments 7.14, 7.15 and 7.16 | None       |

## 7.0 ATTACHMENTS

- 7.1 Completed Executor Training Record
- 7.2 Completed Operator Training Record
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Screen Capture of Each Document Status in SAP
- 7.5 Completed Test Script IQ-02: Site Verification
- 7.6 Temperature/ Humidity Meter Certificate of Calibration
- 7.7 Digital Multimeter Certificate of Calibration
- 7.8 Picture of Test Station Work Area
- 7.9 Completed Test Script IQ-03: Instrument Calibration Verification
- 7.10 Screen Captures from the PM master list
- 7.11 Stack Component Preventative Maintenance Record
- 7.12 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.13 Completed Test Script IQ-05: General Safety and Alarms
- 7.14 Completed Test Script IQ-06: Functional Verification
- 7.15 BOM in SAP
- 7.16 Final Test Record as Printed to the Floor and Printed to SigmaSure Data Archive

## 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 document:

| Document Number | Document title                                                             |
|-----------------|----------------------------------------------------------------------------|
| 735002984       | CPSM Final Test Procedure                                                  |
| 730000523       | Good Documentation Practices                                               |
| 730004135       | Installation Qualification Protocol                                        |
| 735003028       | CPSM Final Test Maintenance Procedure                                      |
| 721001299       | Acquity Common Platform Sample Manager FTN and FL Functional Specification |
| 721003992       | Veyron CPSM FTN Functional Specification Document                          |
| 721007514       | Velox FTN Functional Specification                                         |
| 721013356       | Acquity ARC Bio FTN Functional Specification Document                      |
| 730000945       | Global Training Policy                                                     |
| 730002845       | Validation Report Template                                                 |
| 730001835       | Process Validation Procedure                                               |

## Title: individual Training Form

Document No: 730002657

Version No: 00

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|                         |                     |                                |        |
|-------------------------|---------------------|--------------------------------|--------|
| <b>Training Type:</b>   | Read and Understood |                                |        |
| <b>Name:</b>            | Luo HuaZhen         | <b>Employee ID<sup>1</sup></b> | 618078 |
| <b>Date of Training</b> | 19SEP2019           |                                |        |
| <b>Comments:</b>        | N/A                 |                                |        |

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


Senior Test Engineer
19SEP2019  
 Employee's Signature Title Date

N/A self trained

19SEP2019  
 Trainer's Signature Title Date

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.1 Page: 1 of 1

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

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## Appendix A: TRAINING RECORD

|            |           |                |                 |          |    |
|------------|-----------|----------------|-----------------|----------|----|
| Document # | 735002984 | Document Title | CPSM Final Test | Version  | 15 |
|            |           |                |                 | Revision | T  |

☒ Read and Understood

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

| Printed Name | Signature                                                                         | Initials | Date        |
|--------------|-----------------------------------------------------------------------------------|----------|-------------|
| Htay Ei Lwin |  | Lwin     | 03 Jun 2021 |
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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | IQ-01                                                              | <b>IQ Test Name:</b>   | Associated Documentation Verification                                                                                          |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | TE0084050-18                                                       | <b>Equipment Name:</b> | CPSM Final Test                                                                                                                |                           |
| <b>Installation Site:</b> Venture, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | CPSM Final Test Procedure<br>735002984 Rev. T, Ver. 15             |                        | General Release                                                                                                                | HZ 04 Jun 2021            |
| CAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | CPSM Final Test Maintenance Procedure<br>735003028 Rev. E, Ver. 04 |                        | General Release                                                                                                                | HZ 04 Jun 2021            |
| <p><b>Comments:</b></p> <p style="text-align: center;">N/A HZ 04 Jun 2021</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                    |                        |                                                                                                                                |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                    |                        | <p><b>Document No.:</b> TE0084050-18-IQR</p> <p><b>Iteration No.:</b> 00</p> <p><b>Attachment:</b> 7.3 <b>Page:</b> 1 of 1</p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                    |                        |                                                                                                                                |                           |



































| RevL... | Type | Document  | Vs | Part | Description               | Status text     | Current Ve | Valid From | Valid To   | Change No. | Long name     |
|---------|------|-----------|----|------|---------------------------|-----------------|------------|------------|------------|------------|---------------|
| A       | TSP  | 735002984 | 00 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 26.06.2013 | 01.08.2013 | 9180812    | Richard Davis |
| B       | TSP  | 735002984 | 01 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 02.08.2013 | 09.09.2013 | 9181693    | Richard Davis |
| C       | TSP  | 735002984 | 02 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 10.09.2013 | 12.08.2014 | 9182048    | Richard Davis |
| D       | TSP  | 735002984 | 03 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 13.08.2014 | 01.10.2014 | 9190826    | Richard Davis |
| E       | TSP  | 735002984 | 04 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 02.10.2014 | 15.10.2014 | 9191879    | Richard Davis |
| F       | TSP  | 735002984 | 05 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 16.10.2014 | 16.03.2015 | 9192202    | Richard Davis |
| G       | TSP  | 735002984 | 06 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 17.03.2015 | 19.07.2015 | 9195127    | Richard Davis |
| H       | TSP  | 735002984 | 07 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 20.07.2015 | 10.09.2015 | 9199652    | Richard Davis |
| J       | TSP  | 735002984 | 08 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 11.09.2015 | 08.01.2017 | 9200668    | Richard Davis |
| K       | TSP  | 735002984 | 09 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 09.01.2017 | 25.09.2017 | 9209711    | Richard Davis |
| L       | TSP  | 735002984 | 10 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 26.09.2017 | 31.07.2018 | 9218193    | Richard Davis |
| M       | TSP  | 735002984 | 11 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 01.08.2018 | 05.05.2020 | 9221643    | Richard Davis |
| N       | TSP  | 735002984 | 12 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 06.05.2020 | 05.08.2020 | 9235384    | Richard Davis |
| P       | TSP  | 735002984 | 13 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 06.08.2020 | 09.02.2021 | 9236552    | Richard Davis |
| R       | TSP  | 735002984 | 14 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 10.02.2021 | 04.05.2021 | 9239274    | Richard Davis |
| T       | TSP  | 735002984 | 15 | 000  | CPSM Final Test Procedure | RELEASE GENERAL |            | 05.05.2021 | 31.12.9999 | 9241073    | Eric Turner   |













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| Rev | RevL... | Type | Document  | Vs | Part | Description                           | Status text     | Current Ve                                                                          | Valid From | Valid To   | Change No. | Long name     |
|-----|---------|------|-----------|----|------|---------------------------------------|-----------------|-------------------------------------------------------------------------------------|------------|------------|------------|---------------|
| A   |         | CAL  | 735003028 | 00 | 000  | CPSM Final Test Maintenance Procedure | RELEASE GENERAL |  | 16.08.2013 | 29.10.2013 | 9182085    | Richard Davis |
| B   |         | CAL  | 735003028 | 01 | 000  | CPSM Final Test Maintenance Procedure | RELEASE GENERAL |  | 30.10.2013 | 03.08.2014 | 9183977    | Richard Davis |
| C   |         | CAL  | 735003028 | 02 | 000  | CPSM Final Test Maintenance Procedure | RELEASE GENERAL |  | 04.08.2014 | 01.05.2017 | 9190469    | Richard Davis |
| D   |         | CAL  | 735003028 | 03 | 000  | CPSM Final Test Maintenance Procedure | RELEASE GENERAL |  | 02.05.2017 | 29.11.2020 | 9215404    | Richard Davis |
| E   |         | CAL  | 735003028 | 04 | 000  | CPSM Final Test Maintenance Procedure | RELEASE GENERAL |  | 30.11.2020 | 31.12.9999 | 9238571    | Richard Davis |

Iteration No.: 00

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# Installation Qualification Protocol

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                  |                        |                                                                                                                                       |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | IQ -02                                           | <b>IQ Test Name:</b>   | Site Verification                                                                                                                     |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | TE0084050-18                                     | <b>Equipment Name:</b> | CPSM Final Test                                                                                                                       |                           |
| <b>Installation Site:</b> Venture, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 4 – 40 °C                                        | 22.6C                  | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| Relative Humidity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 20 – 80 %<br>non condensing                      | 52%                    | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| Electrical Supply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 90 – 264 VAC<br>47 – 63 Hz                       | 223.8VAC<br>49.97Hz    | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| Electrical Outlets                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ≥ 5                                              | 6                      | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| Network Available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | ≥ 1                                              | 1                      | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| Workspace                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Adequate space for testing and service           |                        | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| Test Station Bench                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Large and strong enough to support all equipment |                        | Pass                                                                                                                                  | HZ 04 Jun 2021            |
| <p><b>Comments:</b><br/>Temperature, humidity, and electrical supply specified in 721001299.</p> <ul style="list-style-type: none"> <li>Ambient temperature/humidity measured using a Humidity/Temp Indicator, Serial Number: CC8451</li> <li>Electrical supply measured using a Multimeter, Serial Number: 23372874</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><b>Document No.:</b> TE0084050-18-IQR</p> <p><b>Iteration No.:</b> 00</p> <p><b>Attachment:</b> 7.5 <b>Page:</b> 1 <b>of</b> 1</p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                  |                        |                                                                                                                                       |                           |



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



## Certificate of Calibration

Date: March 22, 2021

**Customer:**

GES SINGAPORE PTE LTD  
28 MARSILING LANE  
SINGAPORE 739152

Cert No. 551220084172300

Work Order #: SG-111017295

|                |                                       |                     |                |
|----------------|---------------------------------------|---------------------|----------------|
| MPC Control #: | 1Q538RT4WS1P                          | Serial Number:      | 1Q538RT4WS1P   |
| Asset ID:      | N/A                                   | Department:         | N/A            |
| Gage Type:     | WIRELESS ENVIRONMENTAL MONITORING     | Performed By:       | FRANKE DAI     |
| Manufacturer:  | UBIBOT                                | Received Condition: | IN TOLERANCE   |
| Model Number:  | WS1 PRO                               | Returned Condition: | IN TOLERANCE   |
| Size:          | N/A                                   | Cal. Date:          | March 22, 2021 |
| Temp/RH:       | 21°C / 50 %                           | Cal. Interval:      | 12 MONTHS      |
| Location:      | Calibration performed at MPC facility | Cal. Due Date:      | March 22, 2022 |

**Calibration Notes:**

Performance test passed. See attached data (1 Page).

### Standards Used to Calibrate Equipment

| I.D.   | Description.                    | Model         | Serial              | Manufacturer | Cal. Due Date | Traceability #  |
|--------|---------------------------------|---------------|---------------------|--------------|---------------|-----------------|
| CC8451 | HUMIDITY/TEMP INDICATOR & PROBE | HMI41 / HMP46 | V0330143 / V0920024 | VAISALA      | Sep 14, 2021  | 551220083824675 |

### Procedures Used in this Event

| Procedure Name      | Description                                                              |
|---------------------|--------------------------------------------------------------------------|
| MPC-THD-001 Rev. 01 | Temperature, Humidity and Dew Point Devices, General, rev01, Jan-21-2020 |

Calibrating Technician:

*Frankie Dai*

FRANKE DAI

QC Approval:

*Jun Calimag*

JUN CALIMAG

**STATEMENTS OF PASS OR FAIL CONFORMANCE:** The uncertainty of measurement has been taken into account when determining compliance with specification. All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCCL Z540.3-2008 and in case without guard banded the probability of false-accept depending on test uncertainty ratio.

**THE CALIBRATION REPORT STATUS:**

**PASS-** Term used when compliance statement is given, and the measurement result is PASS.

**PASS<sup>2</sup>**- Term used when compliance statement is given, and the measurement result is conditional passed or PASS<sup>2</sup>.

**FAIL-** Term used when compliance statement is given, and the measurement result is FAIL.

**FAIL<sup>2</sup>**- Term used when compliance statement is given, and the measurement result is conditional failed or FAIL<sup>2</sup>.

**REPORT OF VALUE** - Term used when reported measurement is not requiring compliance statement in report.

**ADJUSTED-** When adjustments are made to an instrument which changes the value of measurement from what was measured as found to new value as left.

**LIMITED** - When an instrument fails calibration but is still functional in a limited manner.

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

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*25.3.21*

## Calibration Report of Ubibot WS1 Pro Wireless Environmental Monitoring

|                |              |                   |                |
|----------------|--------------|-------------------|----------------|
| MPC Control #: | 1Q538RT4WS1P | Serial Number:    | 1Q538RT4WS1P   |
| Asset ID:      | N/A          | Calibration Date: | March 22, 2021 |

### Temperature Accuracy @ 40%RH

| Range        | Nominal | Lower Limit | As Found | As Left | Error | Upper Limit | Result | Uncertainty ( $\pm$ ) |
|--------------|---------|-------------|----------|---------|-------|-------------|--------|-----------------------|
| -20 to 60 °C | 10.0 °C | 9.7 °C      | 10.1 °C  | 10.1 °C | 0.5 % | 10.3 °C     | PASS   | 0.069 °C              |
| -20 to 60 °C | 20.0 °C | 19.7 °C     | 19.8 °C  | 19.8 °C | 1.0 % | 20.3 °C     | PASS   | 0.069 °C              |
| -20 to 60 °C | 30.0 °C | 29.7 °C     | 29.8 °C  | 29.8 °C | 0.7 % | 30.3 °C     | PASS   | 0.069 °C              |

### Relative Humidity Accuracy @ 20°C

| Range        | Nominal  | Lower Limit | As Found | As Left  | Error | Upper Limit | Result | Uncertainty ( $\pm$ ) |
|--------------|----------|-------------|----------|----------|-------|-------------|--------|-----------------------|
| 10 to 90 %RH | 40.0 %RH | 37.0 %RH    | 42.0 %RH | 42.0 %RH | 5.0 % | 43.0 %RH    | PASS   | 0.57 %RH              |
| 10 to 90 %RH | 50.0 %RH | 47.0 %RH    | 51.4 %RH | 51.4 %RH | 2.8 % | 53.0 %RH    | PASS   | 0.57 %RH              |
| 10 to 90 %RH | 75.0 %RH | 72.0 %RH    | 73.0 %RH | 73.0 %RH | 2.7 % | 78.0 %RH    | PASS   | 0.57 %RH              |

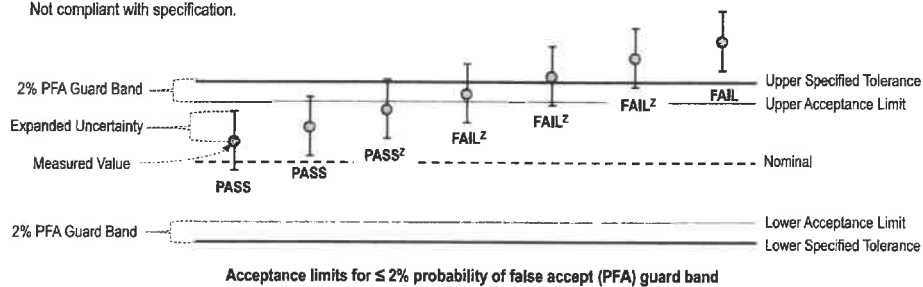
### Statements of Pass or Fail Conformance

The uncertainty of measurement has been taken into account when determining compliance with specification.

All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCCL Z540.3-2006

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

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



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

This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCCL Z540.3-2006, Method 6 — Guard Bands Based on Test Uncertainty Ratio.

- End of Calibration Report -



## MULTIMETER CALIBRATION REPORT

Equipment : Multimeter Cal Date : 31 / Dec / 2020  
Brand Name : FLUKE Next Cal Date : 31 / Dec / 2021  
Model : FLUKE 115 Environment Cond. : N.A.  
GES/Mfg Serial No. : 23372874 Equipment Used : Yokogawa Portable Calibrator  
Cal Procedure : WI-QMS-044 S/No. 2422

### Calibration Data

| Calibrator Output | Accuracy         |                  | Measured Reading<br>(before) | Measured Reading<br>(after) |
|-------------------|------------------|------------------|------------------------------|-----------------------------|
|                   | Digital          | Analog           |                              |                             |
| 300 mV            | 297.9 ~ 302.1 mV | 270.0 ~ 330.0 mV | 300.1                        | N.A.                        |
| 3 V               | 2.979 ~ 3.021 V  | 2.700 ~ 3.300 V  | 2.999                        | N.A.                        |
| 30 V              | 29.79 ~ 30.21 V  | 27.00 ~ 33.00 V  | 29.99                        | N.A.                        |
| 20 mA             | 19.86 ~ 21.14 mA | 18.00 ~ 22.00 mA | NA                           | N.A.                        |

Result : Pass / Fail

Remarks : Multimeter is tested ok within calibration range and Multimeter is not used to test current.

### Calibrated by

Name/sign : Lee Kwang Quek

Designation : Senior Technician

Date : 31 DEC-2020

### Reviewed by

Name/sign : Sheliyan Sathivelu

Designation : Senior QA Engineer

Date : 04 Jan 2021

Document No.: TE0084050-18-IQR

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# Installation Qualification Protocol

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                |                                                                                                                                |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IQ-03          | <b>IQ Test Name:</b>                                                                                                           | Instrumentation Calibration Verification |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | TE0084050-18   | <b>Equipment Name:</b>                                                                                                         | CPSM Final Test                          |
| <b>Installation Site:</b> Venture, 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>                |
| CPSM Final Test System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | W1-17GC0117    | Last Cal/PM: 16 Dec 2020<br>Cal/PM Due: 16 Dec 2021                                                                            | HZ 04 Jun 2021                           |
| Waters Acquity Column Manager                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | W1-16GC0045    | Last Cal/PM: 13 Dec 2020<br>Cal/PM Due: 13 Dec 2021                                                                            | HZ 04 Jun 2021                           |
| Waters Acquity BSM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | W1-16GC0044    | Last Cal/PM: 12 Dec 2020<br>Cal/PM Due: 12 Dec 2021                                                                            | HZ 04 Jun 2021                           |
| Waters Acquity TUV Detector                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | W1-16GC0046    | Last Cal/PM: 08 Dec 2020<br>Cal/PM Due: 08 Dec 2021                                                                            | HZ 04 Jun 2021                           |
| <p><b>Comments:</b></p> <p style="text-align: center;">N/A HZ 04 Jun 2021</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                |                                                                                                                                |                                          |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                | <p><b>Document No.:</b> TE0084050-18-IQR</p> <p><b>Iteration No.:</b> 00</p> <p><b>Attachment:</b> 7.9 <b>Page:</b> 1 of 1</p> |                                          |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                |                                                                                                                                |                                          |

| NO | LOCATION | EQUIPMENT ID | EQUIPMENT NAME                 | MANUFACTURER | MODEL     | MANUFACTURER SERIAL NO | CALIBRATION SOURCE / PM SOURCE | CALIBRATION CYCLE / PM CYCLE | LAST CALIBRATION / LAST PM | NEXT CALIBRATION / NEXT PM | REMARK              |
|----|----------|--------------|--------------------------------|--------------|-----------|------------------------|--------------------------------|------------------------------|----------------------------|----------------------------|---------------------|
| 39 | WATERS   | W1-16GC0044  | I-Class BSM                    | WATERS       | 186015000 | G09UPB976R (ID#91849)  | VENTURE                        | 12                           | 12/12/2020                 | 12/12/2021                 | Consigned equipment |
| 40 | WATERS   | W1-16GC0045  | ACQUITY UPLC CM-A              | WATERS       | 186015043 | D11CMP973N (ID#82510)  | VENTURE                        | 12                           | 13/12/2020                 | 13/12/2021                 | Consigned equipment |
| 41 | WATERS   | W1-16GC0046  | UPLC TUV Detector              | WATERS       | 186015028 | G05UPT009N (ID#91405)  | FLEXTRONICS                    | 12                           | 08/12/2020                 | 08/12/2021                 | Consigned equipment |
| 83 | WATERS   | W1-17GC0117  | Acquity CPSM Final Test System | WATERS       | LENOVO    | TE83064-15             | VENTURE                        | 12                           | 16/12/2020                 | 16/12/2021                 | Consigned equipment |

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## WATERS CORPORATION CPSM FINAL TEST SYSTEM PREVENTIVE MAINTENANCE RECORD

|                                      |                                          |                                   |
|--------------------------------------|------------------------------------------|-----------------------------------|
| Test System I.D. <u>TE83064-15</u>   | Test System Location: <u>VENTURE GES</u> |                                   |
| Due Date: <u>12 DEC 2020</u>         | Interval (Months): <u>12</u>             | Next Due Date: <u>16 DEC 2021</u> |
| Calibration/Maintenance Coordinator: |                                          |                                   |

| SECTION 1 Firmware   | Firmware Version | Performer               | Date               |
|----------------------|------------------|-------------------------|--------------------|
| BSM Firmware Version | <u>1.60.267</u>  | <u>KHACUM</u>           | <u>13 DEC 2020</u> |
| TUV Firmware         | <u>1.60.2275</u> | <u>MUHAMMAD SHAMSUL</u> | <u>08 DEC 2020</u> |
| CM Firmware          | <u>1.69.154</u>  | <u>MOORTY</u>           | <u>13 DEC 2020</u> |

| SECTION 2: SYSTEM MAINTENANCE                                     | RESULT                                                                                    | Performer     | Date               |
|-------------------------------------------------------------------|-------------------------------------------------------------------------------------------|---------------|--------------------|
| Step 2.1 Inspect Ethernet Cables                                  | REPLACED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>          | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.2 Inspect Serial Port Cables                               | REPLACED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>          | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.3 Inspect Rear Panel QSPI Cable                            | REPLACED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>          | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.4 Inspect the Event Input/Output Cable                     | REPLACED/REPAIRED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.5 Inspect the Leak Detector Cables                         | REPLACED/REPAIRED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.6 Inspect Solvent Select lines                             | REPLACED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>          | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.7 Inspect Waste Lines and Container                        | REPLACED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>          | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.8 Production Test Solution, 700004107                      | Expiration Date:<br><u>07 JAN 2023</u>                                                    | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.9 Carryover Test Solution, 700004105                       | Expiration Date:<br><u>07 MAR 2021</u>                                                    | <u>KHACUM</u> | <u>14 DEC 2020</u> |
| Step 2.10 Preventive Maintenance for PC Attach Maintenance Record | PERFORMED <input checked="" type="checkbox"/>                                             | <u>KHACUM</u> | <u>14 DEC 2020</u> |

Waters Confidential

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| SECTION 3 BSM Maintenance      |                                               |              |                    |
|--------------------------------|-----------------------------------------------|--------------|--------------------|
| Location: <u>VENTURE GES.</u>  |                                               |              |                    |
|                                | RESULT                                        | Performer    | Date               |
| Performed Maintenance Protocol | PERFORMED <input checked="" type="checkbox"/> | <u>Kumar</u> | <u>12 Dec 2020</u> |

| SECTION 4 TUV Maintenance Protocol |                                               |                         |                   |
|------------------------------------|-----------------------------------------------|-------------------------|-------------------|
| Location: <u>FUEX SINGAPORE</u>    |                                               |                         |                   |
|                                    | RESULT                                        | Performer               | Date              |
| Performed Maintenance Protocol     | PERFORMED <input checked="" type="checkbox"/> | <u>Muhammad Shamsul</u> | <u>8 Dec 2020</u> |

| SECTION 5: CM MAINTENANCE          |                                                                                  |              |                    |
|------------------------------------|----------------------------------------------------------------------------------|--------------|--------------------|
| Location: <u>VENTURE GES.</u>      |                                                                                  |              |                    |
|                                    | RESULT                                                                           | Performer    | Date               |
| Step 5.1 Replaced ACQUITY Column   | REPLACED:<br>YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | <u>Kumar</u> | <u>14 Dec 2020</u> |
| Step 5.2 Replaced XBridge Column   | REPLACED:<br>YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | <u>Kumar</u> | <u>14 Dec 2020</u> |
| Step 5.3 Inspect Active PreHeaters | REPLACED:<br>YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | <u>Kumar</u> | <u>14 Dec 2020</u> |

| SECTION 6: Characterize System Leak Rate | RESULT (nL/min)  | Performer    | Date               |
|------------------------------------------|------------------|--------------|--------------------|
| ARC System Leak Rate                     | <u>0.0000400</u> | <u>Kumar</u> | <u>14 Dec 2020</u> |
| Record H-Class System Leak Rate          | <u>0.0000507</u> | <u>Kumar</u> | <u>14 Dec 2020</u> |
| I-Class System Leak Rate                 | <u>0.0000640</u> | <u>Kumar</u> | <u>14 Dec 2020</u> |

| SECTION 7: System Verification                                      | RESULT      | Performer    | Date               |
|---------------------------------------------------------------------|-------------|--------------|--------------------|
| Execute CPSM Final Test (735002984)<br>Attach the Final Test Record | <u>PASS</u> | <u>Kumar</u> | <u>16 Dec 2020</u> |

# CPSM Final Test Station Calibration Utility

class select  
I-Class 2

## Instructions

Connect the BSM output line to the Column Manager's  
Input line using an Acquity union PN 405003460.  
Select Characterize System Leak Rate when ready.

## Characterize System Leak Rate



Iteration  
3 of 3



### Results

0.000080

0.000040

0.000072

ARC Leak Rate

0.0000400

H-Class Leak Rate

0.0000507

I-Class Leak Rate

0.0000640

EXIT

error in (no error)

| status                              | code |
|-------------------------------------|------|
| <input checked="" type="checkbox"/> | 0    |
| source                              |      |
| <div></div>                         |      |

SN 13

27.6902

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# Waters Corporation - Test Record

|                                  |                                       |
|----------------------------------|---------------------------------------|
| Part Number: <u>186015088</u>    | Product: <u>I-Class FTN Plus</u>      |
| Operator: <u>25705598</u>        | Start Time: <u>12/16/2020, 15:45:</u> |
| Serial Number: <u>M20FNP179G</u> | End Time: <u>12/16/2020, 18:39:</u>   |
| Test System: <u>TE83064-15</u>   | Order: <u>2011046</u>                 |
| Test Software: <u>1.42</u>       | Location: <u>GES/Venture,SG</u>       |

Firmware: 1.71.395 (Feb 14 2018 09:30:12)

| Name                             | LSL  | Measurement | USL   | Unit       | Outcome |
|----------------------------------|------|-------------|-------|------------|---------|
| Electrical Safety Test           |      |             |       |            | PASS    |
| Power-on Initialization          |      |             |       |            | PASS    |
| Fans                             |      |             |       |            | PASS    |
| Firmware Download                |      |             |       |            | PASS    |
| ReStart Initialization           |      |             |       |            | PASS    |
| Sample Compartment Door & Lights |      |             |       |            | PASS    |
| Jumper Configuration             | 133  | 133         |       |            | PASS    |
| Test Event Inputs                |      |             |       |            | PASS    |
| Test Event Outputs               |      |             |       |            | PASS    |
| Test SPI Interface               |      |             |       |            | PASS    |
| Test Leak Detectors              |      |             |       |            | PASS    |
| Test Ecord Interface             |      |             |       |            | PASS    |
| Theta Drive Calibration          |      |             |       |            | PASS    |
| Tray Cal Offset                  | -180 | -85.18      | 180   | Deg        | PASS    |
| R Axis Calibration               |      |             |       |            | PASS    |
| R Offset                         | -3   | 0.27        | 3     | mm         | PASS    |
| Z Axis Calibration               |      |             |       |            | PASS    |
| Z Offset                         | -3   | -1.07       | 3     | mm         | PASS    |
| Needle Seal Calibration          |      |             |       |            | PASS    |
| Needle Seal Position             | 55   | 56.48       | 58    | mm         | PASS    |
| Needle Seal Force                | 48   | 52.24       | 68    | lb/inch    | PASS    |
| Zp Offset                        | -3   | 1.21        | 3     | mm         | PASS    |
| Sample Tray Select Switch        |      |             |       |            | PASS    |
| Check Theta Drive Belt           |      |             |       |            | PASS    |
| R/Theta Positioner Test          |      |             |       |            | PASS    |
| 1st Move Error                   | -0.3 | 0.13        | 0.3   |            | PASS    |
| Zp Pierce                        | -20  | 0           | 20    | Lost Steps | PASS    |
| Z Pierce                         | -20  | -1          | 20    | Lost Steps | PASS    |
| R Lost Steps                     | -20  | -1          | 20    | Lost Steps | PASS    |
| Sample Cooler Test               |      | -0.8799     | -0.6  | Deg C/Min  | PASS    |
| Test Pressure Transducer         | 0.45 | 0.5066      | 0.55  | PSI        | PASS    |
| BOS Pump Test                    |      |             |       |            | PASS    |
| Methanol Prime                   |      |             |       |            | PASS    |
| Sample Syringe Decay             | -15  | -8.3        | 15    | PSI        | PASS    |
| Dynamic Leak Test                |      | -7          | 500   | nL/min     | PASS    |
| Needlewash Prime                 |      |             |       |            | PASS    |
| Test Preblank Injections         |      | 0           | 740.3 | area       | PASS    |
| Carryover                        |      | 0           | 0.04  | ppm        | PASS    |
| Chemistry Precision Area         | 0    | 0.4944      | 0.5   | %RSD       | PASS    |

|                            |       |          |     |      |      |
|----------------------------|-------|----------|-----|------|------|
| Chemistry Precision Height | 0     | 0.6299   | 0.9 | %RSD | PASS |
| Chemistry X-Intercept      | -0.2  | -0.0597  | 0.2 | ul   | PASS |
| Chemistry Linearity (R^2)  | 0.999 | 0.999993 | 1   |      | PASS |
| Methanol Purge             |       |          |     |      | PASS |
| Air Purge                  |       |          |     |      | PASS |
| Park Inject Valve          |       |          |     |      | PASS |
| Home Needle                |       |          |     |      | PASS |
| Save Serial Number         |       |          |     |      | PASS |

## CPSM Final Test Overall Result - PASS

Signed:

*ham*

Date:

16 DEC 2020

END OF DATA

# Installation Qualification Protocol

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                            |                        |                                                                                                                                 |                           |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------|--|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | IQ-04                      | <b>IQ Test Name:</b>   | Test Software and Instrument Firmware Version                                                                                   |                           |  |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | TE0084050-18               | <b>Equipment Name:</b> | CPSM Final Test                                                                                                                 |                           |  |
| <b>Installation Site:</b> Venture, 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> |  |
| Test Equipment Software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Version: 1.03              | Version: 1.03          | Pass                                                                                                                            | HZ 04 Jun 2021            |  |
| <p><b>Comments:</b><br/>Test equipment software version specified in 735002984.</p> <p style="text-align: center;">N/A HZ 04 Jun 2021</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                            |                        |                                                                                                                                 |                           |  |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |                        | <p><b>Document No.:</b> TE0084050-18-IQR</p> <p><b>Iteration No.:</b> 00</p> <p><b>Attachment:</b> 7.12 <b>Page:</b> 1 of 1</p> |                           |  |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                            |                        |                                                                                                                                 |                           |  |

## Installation Qualification Protocol

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | IQ-05        | <b>IQ Test Name:</b>                                                 | General Safety and Alarms                                                                                                       |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | TE0084050-18 | <b>Equipment Name:</b>                                               | CPSM Final Test                                                                                                                 |                           |
| <b>Installation Site:</b> Venture, 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 04 Jun 2021            |
| Glass Bottles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |              | Secure                                                               | Pass                                                                                                                            | HZ 04 Jun 2021            |
| Waste Tanks                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |              | Secure and located below the system                                  | Pass                                                                                                                            | HZ 04 Jun 2021            |
| Emergency Stop                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |              | System ceases operation upon<br>depressing the Emergency Stop button | Pass                                                                                                                            | HZ 04 Jun 2021            |
| Guarding                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |              | Shielding in place to prevent<br>hazard during operation             | Pass                                                                                                                            | HZ 04 Jun 2021            |
| <p><b>Comments:</b></p> <p style="text-align: center;">N/A HZ 04 Jun 2021</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |              |                                                                      |                                                                                                                                 |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |              |                                                                      | <p><b>Document No.:</b> TE0084050-18-IQR</p> <p><b>Iteration No.:</b> 00</p> <p><b>Attachment:</b> 7.13 <b>Page:</b> 1 of 1</p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |              |                                                                      |                                                                                                                                 |                           |

# Installation Qualification Protocol

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IQ-06        | <b>IQ Test Name:</b>                                         | Functional Verification                                                                                                         |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | TE0084050-18 | <b>Equipment Name:</b>                                       | CPSM Final Test                                                                                                                 |                           |
| <b>Installation Site:</b> Venture, 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: 186015085<br>Serial Number: D21FTP387G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |              | All required CTQ Specification measurements result in a Pass | Pass                                                                                                                            | HZ 04 Jun 2021            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |              | UUT Firmware Version: 1.71.395                               | Pass                                                                                                                            | HZ 04 Jun 2021            |
| <p><b>Comments:</b></p> <p style="text-align: center;">N/A HZ 04 Jun 2021</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |              |                                                              |                                                                                                                                 |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |              |                                                              | <p><b>Document No.:</b> TE0084050-18-IQR</p> <p><b>Iteration No.:</b> 00</p> <p><b>Attachment:</b> 7.14 <b>Page:</b> 1 of 1</p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |              |                                                              |                                                                                                                                 |                           |

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 Subitems
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| Alternative BOM | 1 |
|-----------------|---|

Material Document General

| Item | ICt | Component | Component description                    | Quantity | Un | Asm                                 | SIs                      | Valid From   | Valid to     | Chan |
|------|-----|-----------|------------------------------------------|----------|----|-------------------------------------|--------------------------|--------------|--------------|------|
| 0001 | L   | 200000261 | KIT, SUK, WATERS ACQUITY SM FTM          | 1        | EA | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0002 | L   | 279003866 | ASSY, SAMPLE MANAGER, FTM-H              | 1        | EA | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0003 | L   | 290000380 | ENVELOPE, OWNER DOC. W/WINDOW            | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0004 | L   | 290000872 | BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48 | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0005 | L   | 290001191 | BOX, SHIPPING, CPSM                      | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0006 | L   | 361000774 | ACQUITY UPLC SM-FTM Firmware v1.71.395   | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0007 | L   | WAT006277 | LABEL, CONGRATULATIONS                   | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0008 | L   | WAT024951 | CERTIFICATE OF FUNCTIONAL PERF           | 1        | EA | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0009 | L   | WAT027033 | CABLE TIE MINIATURE                      | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |
| 0010 | L   | WAT089526 | DESICCANT, ACTIVATED, BAGGED, 8 UNITS    | 2        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20. 04. 2018 | 31. 12. 9999 | 922% |

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Iteration No.: 00

Attachment: 7.15 Page: 1 of 1

# Waters Corporation - Test Record

Part Number: 186015085

Product: H-Class FTN Plus

Operator: 25705147

Start Time: 06/03/2021, 11:51:

Serial Number: D21FTP387G

End Time: 06/03/2021, 14:17:

Test System: TE0084050-18

Order: 2100322

Test Software: 1.03

Location: GES/Venture,SG

TMD: TMD011012

TMD: TMD011014

Firmware: 1.71.395

| Name                             | LSL  | Measurement | USL   | Unit       | Outcome |
|----------------------------------|------|-------------|-------|------------|---------|
| Electrical Safety Test           |      |             |       |            | PASS    |
| Power-on Initialization          |      |             |       |            | PASS    |
| Fans                             |      |             |       |            | PASS    |
| Firmware Download                |      |             |       |            | PASS    |
| Sample Compartment Door & Lights |      |             |       |            | PASS    |
| Jumper Configuration             |      | 129         | 129   |            | PASS    |
| Test Event Inputs                |      |             |       |            | PASS    |
| Test Event Outputs               |      |             |       |            | PASS    |
| Test SPI Interface               |      |             |       |            | PASS    |
| Test Leak Detectors              |      |             |       |            | PASS    |
| Test Ecord Interface             |      |             |       |            | PASS    |
| Theta Drive Calibration          |      |             |       |            | PASS    |
| Tray Cal Offset                  | -180 | 33.89       | 180   | Deg        | PASS    |
| R Axis Calibration               |      |             |       |            | PASS    |
| R Offset                         | -3   | -0.02       | 3     | mm         | PASS    |
| Z Axis Calibration               |      |             |       |            | PASS    |
| Z Offset                         | -3   | -1.53       | 3     | mm         | PASS    |
| Needle Seal Calibration          |      |             |       |            | PASS    |
| Needle Seal Position             | 48   | 56.46       | 68    | mm         | PASS    |
| Needle Seal Force                | 48   | 61.81       | 68    | lb/inch    | PASS    |
| Zp Offset                        | -3   | 1.29        | 3     | mm         | PASS    |
| Sample Tray Select Switch        |      |             |       |            | PASS    |
| Check Theta Drive Belt           |      |             |       |            | PASS    |
| R/Theta Positioner Test          |      |             |       |            | PASS    |
| 1st Move Error                   | -0.3 | 0.13        | 0.3   |            | PASS    |
| Zp Pierce                        | -20  | 1           | 20    | Lost Steps | PASS    |
| Z Pierce                         | -20  | 1           | 20    | Lost Steps | PASS    |
| R Lost Steps                     | -20  | 0           | 20    | Lost Steps | PASS    |
| Sample Cooler Test               |      | -0.885      | -0.6  | Deg C/Min  | PASS    |
| Test Pressure Transducer         | 0.45 | 0.511       | 0.55  | VDC        | PASS    |
| BOS Pump Test                    |      |             |       |            | PASS    |
| Methanol Prime                   |      |             |       |            | PASS    |
| Sample Syringe Decay             | -15  | 3.8         | 15    | PSI        | PASS    |
| Dynamic Leak Test                |      | 1           | 500   | nL/min     | PASS    |
| Needlewash Prime                 |      |             |       |            | PASS    |
| Check Acquity Stack              |      |             |       |            | PASS    |
| Test Preblank Injections         |      | 0           | 860.9 | area       | PASS    |

Ser. No.: D21FTP387G

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Iteration No.: 00

Attachment: 7.16 Page: 1 of 4

|                            |       |          |      |      |      |
|----------------------------|-------|----------|------|------|------|
| Carryover                  |       | 0        | 0.06 | ppm  | PASS |
| Chemistry Precision Area   | 0     | 0.1221   | 0.5  | %RSD | PASS |
| Chemistry Precision Height | 0     | 0.2771   | 0.9  | %RSD | PASS |
| Chemistry X-Intercept      | -0.2  | 0.0059   | 0.2  | ul   | PASS |
| Chemistry Linearity (R^2)  | 0.999 | 0.999979 | 1    |      | PASS |
| Methanol Purge             |       |          |      |      | PASS |
| Air Purge                  |       |          |      |      | PASS |
| Park Inject Valve          |       |          |      |      | PASS |
| Home Needle                |       |          |      |      | PASS |
| Save Serial Number         |       |          |      |      | PASS |

## CPSM Final Test Overall Result - PASS

Signed: *win*

Date: *03 Jun 2021*

END OF DATA

# Waters Corporation - Test Record

|                                  |                                       |
|----------------------------------|---------------------------------------|
| Part Number: <u>186015085</u>    | Product: <u>H-Class FTN Plus</u>      |
| Operator: <u>25705147</u>        | Start Time: <u>06/03/2021, 11:51:</u> |
| Serial Number: <u>D21FTP387G</u> | End Time: <u>06/03/2021, 14:17:</u>   |
| Test System: <u>TE0084050-18</u> | Order: <u>2100322</u>                 |
| Test Software: <u>1.03</u>       | Location: <u>GES/Venture,SG</u>       |

TMD: TMD011012

TMD: TMD011014

Firmware: 1.71.395

| Name                             | LSL    | Measurement | USL   | Unit       | Outcome |
|----------------------------------|--------|-------------|-------|------------|---------|
| Electrical Safety Test           |        |             |       |            | PASS    |
| Power-on Initialization          |        |             |       |            | PASS    |
| Fans                             |        |             |       |            | PASS    |
| Firmware Download                |        |             |       |            | PASS    |
| Sample Compartment Door & Lights |        |             |       |            | PASS    |
| Jumper Configuration             |        | 129.0       | 129.0 |            | PASS    |
| Test Event Inputs                |        |             |       |            | PASS    |
| Test Event Outputs               |        |             |       |            | PASS    |
| Test SPI Interface               |        |             |       |            | PASS    |
| Test Leak Detectors              |        |             |       |            | PASS    |
| Test Ecord Interface             |        |             |       |            | PASS    |
| Theta Drive Calibration          |        |             |       |            | PASS    |
| Tray Cal Offset                  | -180.0 | 33.89       | 180.0 | Deg        | PASS    |
| R Axis Calibration               |        |             |       |            | PASS    |
| R Offset                         | -3.0   | -0.02       | 3.0   | mm         | PASS    |
| Z Axis Calibration               |        |             |       |            | PASS    |
| Z Offset                         | -3.0   | -1.53       | 3.0   | mm         | PASS    |
| Needle Seal Calibration          |        |             |       |            | PASS    |
| Needle Seal Position             | 48.0   | 56.46       | 68.0  | mm         | PASS    |
| Needle Seal Force                | 48.0   | 61.81       | 68.0  | lb/inch    | PASS    |
| Zp Offset                        | -3.0   | 1.29        | 3.0   | mm         | PASS    |
| Sample Tray Select Switch        |        |             |       |            | PASS    |
| Check Theta Drive Belt           |        |             |       |            | PASS    |
| R/Theta Positioner Test          |        |             |       |            | PASS    |
| 1st Move Error                   | -0.3   | 0.13        | 0.3   |            | PASS    |
| Zp Pierce                        | -20.0  | 1.0         | 20.0  | Lost Steps | PASS    |
| Z Pierce                         | -20.0  | 1.0         | 20.0  | Lost Steps | PASS    |
| R Lost Steps                     | -20.0  | 0.0         | 20.0  | Lost Steps | PASS    |
| Sample Cooler Test               |        | -0.885      | -0.6  | Deg C/Min  | PASS    |
| Test Pressure Transducer         | 0.45   | 0.511       | 0.55  | VDC        | PASS    |
| BOS Pump Test                    |        |             |       |            | PASS    |
| Methanol Prime                   |        |             |       |            | PASS    |
| Sample Syringe Decay             | -15.0  | 3.8         | 15.0  | PSI        | PASS    |
| Dynamic Leak Test                |        | 1.0         | 500.0 | nL/min     | PASS    |
| Needlewash Prime                 |        |             |       |            | PASS    |
| Check Acquity Stack              |        |             |       |            | PASS    |
| Test Preblank Injections         |        | 0.0         | 860.9 | area       | PASS    |
| Carryover                        |        | 0.0         | 0.06  | ppm        | PASS    |
| Chemistry Precision Area         | 0.0    | 0.1221      | 0.5   | %RSD       | PASS    |
| Chemistry Precision Height       | 0.0    | 0.2771      | 0.9   | %RSD       | PASS    |
| Chemistry X-Intercept            | -0.2   | 0.0059      | 0.2   | ul         | PASS    |
| Chemistry Linearity (R^2)        | 0.999  | 0.999979    | 1.0   |            | PASS    |

Methanol Purge  
Air Purge  
Park Inject Valve  
Home Needle  
Save Serial Number

PASS  
PASS  
PASS  
PASS  
PASS

CPSM Final Test Overall Result - PASS

|         |                     |       |                |
|---------|---------------------|-------|----------------|
| Signed: | N/A, SigmaSure Copy | Date: | HZ 04 Jun 2021 |
|---------|---------------------|-------|----------------|

END OF DATA

Document No.: TE0084050-18-IQR  
Iteration No.: 00  
Attachment: 7.16 Page: 4 of 4

**From:** [Eric Turner](#)  
**To:** [HuaZhen Luo](#)  
**Subject:** RE: Venture CPSM upgrade TE83064-15 to TE0084050-18  
**Date:** Wednesday, 9 June, 2021 01:23:32  
**Attachments:** [image016.png](#)  
[image017.png](#)  
[image004.png](#)

---

Hi HuaZhen

This email will serve as my digital signature in accordance with TMD010801

Thank you

**Eric Turner**  
Principal Test Engineer

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**From:** HuaZhen Luo <[HuaZhen\\_Luo@waters.com](mailto:HuaZhen_Luo@waters.com)>

**Sent:** Tuesday, June 8, 2021 4:54 AM

**To:** Adam Townsend <[Adam\\_Townsend@waters.com](mailto:Adam_Townsend@waters.com)>; Eric Turner <[Eric\\_Turner@waters.com](mailto:Eric_Turner@waters.com)>; Bill Bates <[Bill\\_Bates@waters.com](mailto:Bill_Bates@waters.com)>

**Cc:** Matt Brule <[Matt\\_Brule@waters.com](mailto:Matt_Brule@waters.com)>; Edwin Koh <[Edwin\\_Koh@waters.com](mailto:Edwin_Koh@waters.com)>

**Subject:** RE: Venture CPSM upgrade TE83064-15 to TE0084050-18

Hi Adam,

We verified with latest image (including test program 1.03) today. The same observation was found on this image. It may timeout intermittently if we keep running seal calibration in diagnostic mode.

We also tested on Golden Test Box, the same observation was found.

Now we're running a full test with local build test box and latest image. The run is still in progress, we didn't see error on seal calibration for this time.

Hi Eric,

Understand you're ok with IQ report as attached. Can we have your sign off of review on this IQR? So that we can send it for QA approval.

After then, we can proceed to next tester (TE83064-17) upgrade once 1<sup>st</sup> tester (TE0084050-18) IQ is approved per schedule.

Thank you and please advise if anything required to be done in Venture/WPPL.

**Luo HuaZhen**  
Senior Test Engineer

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