

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83026-01-08APR2019-VAF	SAP # TE008302601/ OESR # 193232

VALIDATION ASSESSMENT
For the Acquity CMA Test System (TE83026-01)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		11 APR 2019

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Senior Test Engineer		
Emma Pierce	Test Validation Engineer		

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signatures denote agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity CMA Test System.

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

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83026-01-08APR2019-VAF	SAP # TE008302601/ OESR # 193232

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of hardware replacement to the released Acquity CMA Test System (TE83026-01). This document shall also define the deliverable(s) required to maintain the equipment qualification based on the hardware replacement. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The TE83026-01 (Acquity CMA Test System) is located in the Venture Contractor Manufacture Site in Singapore. The station is designed to perform the final test of the Acquity Active Column Manager, P/N: 186015043, 186015038, 186015049 and 186015039. In the final test, the UUT is connected to the test station and various functional tests are performed as described in CM-A Test Procedure 735002229, Ver. 09, Rev J and Aux CM-A Test Procedure 735002236, Ver 09, Rev F. The test procedure 735002229 includes the downloading of instrument firmware. This tester has an automated test sequence and a Final Test Record is generated upon completion. The record is saved to the Sigma Data Archive and a paper copy is printed for the operator to collect.

3. DESCRIPTION OF CHANGE

The harddisk driver of PC used for the TE83026-01 test system in Venture Contractor Manufacturing Site in Singapore has been replaced and a TE83026-01 test system hard disk image was loaded on new harddisk on 08 APR 2019. Though only the hard drive was replaced/reimaged with a working OS together with test program, this change can be treated as a PC replacement. No change was made to the CMA test software.

4. RISK ASSESSMENT

4.1. High Risk Assessment

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☒	☐

4.1.2. Software/Firmware	No	Yes
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, to a different facility?	☒	☐

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83026-01-08APR2019-VAF	SAP # TE008302601/ OESR # 193232

4.2.2. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☐	☒

4.2.3. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
Is the change a test system instrument firmware update (i.e. update to a stack component)?	☒	☐

4.2.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, within the Milford site?	☒	☐

4.3. This change results in a medium Risk Assessment and the associated qualification requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

No hazards are potentially introduced to the environment, operator, assembler, service technician or end user.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

Based on the risk assessment performed above, in accordance with 730001835, Process Validation Procedure for Milford Site, complete the tables below based on the testing recommendations. Summarize the verification, qualification and validation requirements in the Comments/Justification Section of each of the tables below. If the assessment results in a recommendation of performing a partial qualification and/or bench study verification for any of the verification, qualification and/or validation activities, summarize the recommendation and explain why this is appropriate and acceptable.

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An EDV has been completed for the CM-S Program test software; the report can be found in TE0083026QX in SAP. This change does not affect the way the program controls or measures a test specification or PSC result.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification UUT firmware version, test software version, and operation of the TE83026-01 system will be verified with functional tests. Both the printed hard copy and a copy printed from the Sigma Quest Data Archive for each functional test will be included as attachments to the VAF routing form in lieu of a formal IQ report. Total 3 CMA/Aux CMA units will be tested to ensure full operation of the system. All other TE83026 systems are unaffected by this change.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This test equipment does not utilize an external measurement device and is not subject to operator induced variation. This change does not require a TMV as defined in the Process Validation Procedure 730001835.		

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83026-01-08APR2019-VAF	SAP # TE008302601/ OESR # 193232

6.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An OQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A PQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation, calibration or facilities/utilities.
- There is no impact to any other qualified, verified, or validated Process, Test Method, or Equipment.
- This qualification is a high priority as delay will impact production schedules.
- The change has been implemented by Test Engineering. The qualification activities will be executed by WPPL personnel.
- No additional training will be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.
- Should any predefined deliverable be unable to be obtained the deviation shall be addressed as an additional attachment to Objective Evidence Completion Form.

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83026-01-08APR2019-VAF	SAP # TE008302601/ OESR # 193232

**VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION**
For the Acquity CMA Test System (TE83026-01)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		11 APR 2019

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Senior Test Engineer		
Emma Pierce	Test Validation Engineer		

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signatures denote agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity CMA Test System.

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

ATTACHMENTS:

1. Executor Training Record
2. Operator Training Record
3. Photos about Harddisk Driver changing
4. Screen Captures of UUT Firmware Versions
5. Cover Sheet of Test Procedure Showing Test Software Version
6. Test Records as Printed on the Manufacturing Floor
7. Test Records as Printed from SigmaQuest Data Archive
8. Screen Captures of Test Program

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	01Mar2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	02




Employee's Signature _____ Title _____ Date 01Mar2019
 N/A self trained _____ 01Mar2019

Trainer's Signature _____ Title _____ Date

Document No.: T283026-01-08APR2019
 Iteration No.: N/A
 Attachment: 1 Page: 1 of 1
 -VAF

¹ Without preceding "90"

Appendix A: TRAINING RECORD

Document #	735002229	Document Title	CM-A Test Procedure	Version	09
				Revision	J

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

CHAN MYAE SOE (25704620)		05 Apr 2019
Printed Name	Signature	Date

☒ Read and Understood (If self-trained – If not self-trained this section can be deleted)

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

[illegible]

Print multiple copies of this Training Record Template as needed

Document No.: TE83026-01-08 APR 2019-VAF
Iteration No.: N/A
Attachment: 2 Page: 1 of 2

DOCUMENT HISTORY

Appendix A: TRAINING RECORD

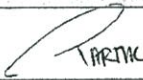
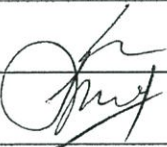
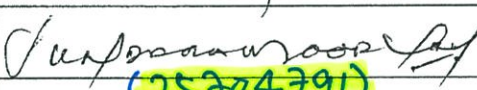
Document #	735002236	Document Title	Aux CM-A Test Procedure	Version	09
				Revision	F

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

CHAN MYAE SOE (25704620)		05 Apr 2019
Printed Name	Signature	Date

N/A Read and Understood (If self-trained – If not self-trained this section can be deleted)

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

Printed Name	Signature	Initials	Date
PARTIK (25704968)		PARTIK	05 APR 19
Lu Xing Zhou (25705156)		LV	05 APR 19
 (25704791)		Mooker	05 APR 19
End of Data			

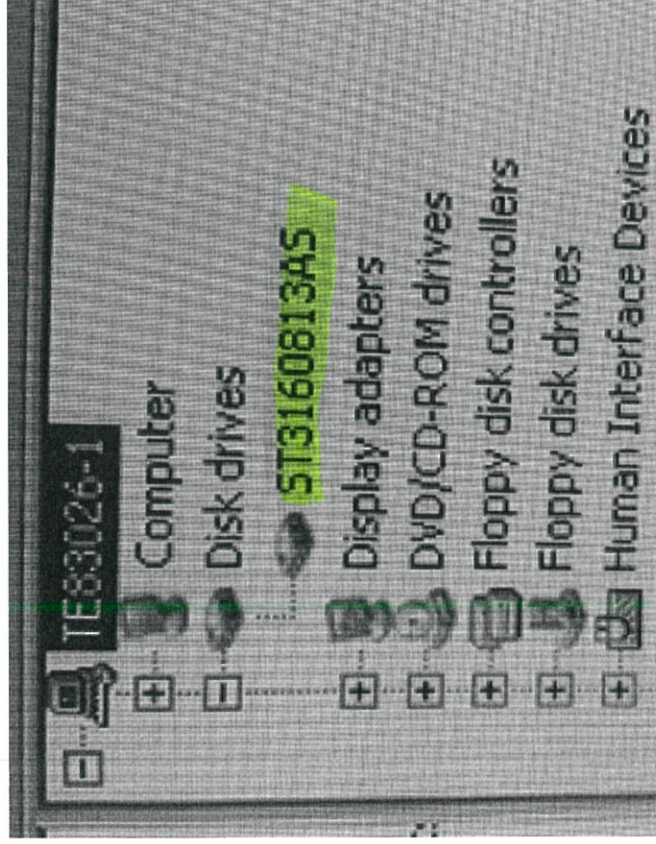
Print multiple copies of this Training Record Template as needed

Document No.: TE83026-01-08APR2019-VAF
 Iteration No.: N/A
 Attachment: 2 Page: 2 of 2

DOCUMENT HISTORY

Photos about the PC harddisk changing.

New HDD in PC



Document No.: IES3026-DI-08APR2019-VAT
Iteration No.: N/A
Attachment: 3 Page: 1 of 2

Old HDD (failing to load Windows XP)



Document No.: IES3626-01-08APR2019-JAF
Iteration No.: N/A
Attachment: 3 Page: 2 of 2

186015043 BOM

Display material BOM: General Item Overview

Material 186015043 ACQUITY UPLC CM-A

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material		Document		General						
Item	ICT	Component	Component description	Quantity	Un	A...	SIs	Valid From	Valid to	Change No.
0010	L	2790002113	ASSY, COLUMN MANAGER, ACQUITY	1	EA	☒	☐	01.06.2010	31.12.9999	9152687
0020	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	01.06.2010	31.12.9999	9152687
0030	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	01.06.2010	31.12.9999	9152687
0040	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	01.06.2010	31.12.9999	9152687
0050	L	WAT027033	CABLE TIE MINIA TURE	1	EA	☐	☐	01.06.2010	31.12.9999	9152687
0060	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	01.06.2010	31.12.9999	9152687
0070	L	2000000280	ACQUITY UPLC CM START UP KIT	1	EA	☒	☐	01.06.2010	31.12.9999	9152687
0090	L	2900000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	01.06.2010	31.12.9999	9152687
0100	L	2900000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	08.06.2011	31.12.9999	9162380
0110	L	2900001453	BOX, SHIPPING, ACTIVE COLUMN MANAGER	1	EA	☐	☐	06.03.2013	31.12.9999	9174446
0130	L	361000710	ACQUITY CM-A Firmware 1.69.154	1	EA	☐	☐	01.08.2017	31.12.9999	9215285

Document No.: IES3026-01-08APP2019-VAF
Iteration No.: N/A
Attachment: 4 Page: 1 of 4

186015038 BOM

Display material BOM: General Item Overview

Material 186015038 EQUITY Active Column Manager

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item	ICt	Component	Component description	Quantity	Un	A...	SIs	Valid From	Valid to	Change No.
0010	L	WATO06277	LABEL, CONGRATULATIONS	1	EA	☐	☐	15.02.2012	31.12.9999	9168384
0020	L	WATO24406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	15.02.2012	31.12.9999	9168384
0030	L	WATO24951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	15.02.2012	31.12.9999	9168384
0040	L	WATO27033	CABLE TIE MINIA TURE	1	EA	☐	☐	15.02.2012	31.12.9999	9168384
0050	L	WATO89526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	15.02.2012	31.12.9999	9168384
0140	L	2000000280	ACQUITY UPLC CM START UP KIT	1	EA	☒	☐	26.10.2012	31.12.9999	9173736
0150	L	279002717	ASSY, CM-A, UPC2	1	EA	☒	☐	26.10.2012	31.12.9999	9173736
0160	L	2900000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	26.10.2012	31.12.9999	9173736
0170	L	2900000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	26.10.2012	31.12.9999	9173736
0180	L	2900001453	BOX, SHIPPING, ACTIVE COLUMN MANAGER	1	EA	☐	☐	26.10.2012	31.12.9999	9173736
0190	L	3610000510	ACQUITY CM-A Firmware 1.60.136	1	EA	☐	☐	07.07.2014	31.12.9999	9189662

Document No.: T683026-01-08APR2019-VAF
Iteration No.: N/A
Attachment: 4 Page: 2 of 4

186015049 BOM

Display material BOM: General Item Overview

Material 186015049 ACQUITY UPLC H-Class CM-AUX

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item	ICT	Component	Component description	Quantity	Un	A...	SIs	Valid From	Valid to	Change No.
0010	I	200000281	Start up Kit, ACQUITY H-Class CM-AUX	1	EA	☒	☐	15.06.2010	31.12.9999	9153037
0020	I	279002135	ASSY, COLUMN MANAGER AUXILIARY, ACQUITY	1	EA	☒	☐	15.06.2010	31.12.9999	9153037
0030	I	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0040	I	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0050	I	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	15.06.2010	31.12.9999	9153037
0060	I	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	15.06.2010	31.12.9999	9153037
0070	I	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0080	I	WAT027033	CABLE TIE MINIA TURE	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0100	I	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	08.06.2011	31.12.9999	9162380
0110	I	290001454	BOX, SHIPPING, AUX COLUMN MANAGER	1	EA	☐	☐	06.03.2013	31.12.9999	9174446

Document No.: TE83026-01-08APR2019-VA F
 Iteration No.: N/A
 Attachment: 4 Page: 3 of 4

186015039 BOM

Display material BOM: General Item Overview

Material 186015039 CRDE QUITY Auxiliary Column Manager

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item	Qty	Component	Component description	Un	A...	SIs	Valid From	Valid to	Change No.
0010	L	WAT006277	LABEL, CONGRATULATIONS	EA	☐	☐	15.02.2012	31.12.9999	9168384
0020	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	EA	☐	☐	15.02.2012	31.12.9999	9168384
0030	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	EA	☒	☐	15.02.2012	31.12.9999	9168384
0040	L	WAT027033	CABLE TIE MINIATURE	EA	☐	☐	15.02.2012	31.12.9999	9168384
0050	L	WAT069526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	EA	☐	☐	15.02.2012	31.12.9999	9168384
0120	L	200000281	Start up Kit, ACQUITY H-Class CM-AUX	EA	☒	☐	26.10.2012	31.12.9999	9173736
0130	L	2790002726	ASSY, CM-AUX, UPC2	EA	☒	☐	26.10.2012	31.12.9999	9173736
0140	L	2900000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	EA	☐	☐	26.10.2012	31.12.9999	9173736
0150	L	2900001454	BOX, SHIPPING, AUX COLUMN MANAGER	EA	☐	☐	26.10.2012	31.12.9999	9173736
0160	L	2900000380	ENVELOPE, OWNER DOC. W/WINDOW	EA	☐	☐	26.10.2012	31.12.9999	9173736

Document No.: 186015039-01-08APR2019-VAF
Iteration No.: N/A
Attachment: 4 Page: 4 of 4

DOCUMENT TITLE: **ACQUITY CMA TEST PROCEDURE**

SYSTEM/ASSEMBLY NAME: **ACQUITY CMA**

PART NUMBER AFFECTED **186015043, 186015038, N2971034, 800000311, 800000434**

TEST EQUIPMENT NAME: **ACQUITY CMA TEST SYSTEM**

TEST EQUIPMENT NUMBER: **TE83026**

TEST SOFTWARE: ***1.3***

AUTHOR(S): **RAMKI TIRUR**

DATE: **July 19, 2010**

REVISED BY: **MATT BRULE**

DATE: **May 19, 2017**

Document No.: TE83026-01-08APR2019-VAF
 Revision No.: N/A
 Attachment: 5 Page: 1 of 2

WATERS CORPORATION
ENGINEERING TEST SPECIFICATION AND PROCEDURE
COMPANY CONFIDENTIAL

SYSTEM/ASSEMBLY NAME: **ACQUITY CMA AUX**

PART NUMBER AFFECTED: 279002135, 186015049, 800000314, 186015039, 279002726,
800000440

TEST EQUIPMENT NAME: **ACQUITY CMA TEST SYSTEM**

TEST EQUIPMENT NUMBER: **TE 83026**

DOCUMENT NUMBER: **735002236**

TEST SOFTWARE: *1.1*

AUTHOR(S): **MATT BRULE**

DATE: **June 02, 2011**

REVISED BY: **MATT BRULE**

DATE: **November 18, 2014**

REVISION: **F**

VALID IF CURRENT EFFECTIVE REVISION AND STAMPED IN RED BY DOCUMENT CONTROL OR WITH SAP-GENERATED TIME & DATE STAMP.

Document No.: TE83026-01-08APR2014-VAE
Iteration No.: N/A
Attachment: 5 Page: 2 of 2

THIS DOCUMENT AND ITS CONTENTS ARE EXCLUSIVE PROPERTY OF WATERS CORPORATION, MILFORD MASSACHUSETTS. THIS DOCUMENT MAY NOT BE REPRODUCED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN PERMISSION FROM WATERS CORP.

Waters Corporation

INSTRUMENT - FINAL TEST RECORD

Part Number: <u>186015043</u>	Description: <u>ACQUITY UPLC CM-A</u>
Tested By: <u>25704791</u>	Date: <u>4/8/2019</u>
Serial Number: <u>C19CMP535G</u>	TMD Number: <u>N/A</u>
Firmware Revision: <u>1.69.154</u>	Factory Order: <u>WATS1904037</u>

Electrical Safety Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Fan Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ethernet Port Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
LED Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Column LED Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Door Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 3	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 4	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 5	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 6	Pass ☒	Fail ☐	see note# _____	Pass ☐
Set Serial Number	Pass ☒	Fail ☐	see note# _____	Pass ☐
Fuses	Pass ☒	Fail ☐	see note# _____	Pass ☐
Leak Detector Interface Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH1	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH2	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH3	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH4	Pass ☒	Fail ☐	see note# _____	Pass ☐
TOP Auxillary Interface	Pass ☒	Fail ☐	see note# _____	Pass ☐
BOTTOM Auxillary Interface	Pass ☒	Fail ☐	see note# _____	Pass ☐
Heater Cooler	Pass ☒	Fail ☐	see note# _____	Pass ☐
Heater Cooler	Pass ☒	Fail ☐	see note# _____	Pass ☐
Left Valve	Pass ☒	Fail ☐	see note# _____	Pass ☐
Right Valve	Pass ☒	Fail ☐	see note# _____	Pass ☐

Instrument Result:

Pass ☒ Fail ☐

Signed: [Signature]
END OF DAY

Date: 08 APR 19

Notes:

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail; a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing; the initial form must be attached and retained.

Document No.: TE83026-01-08APR2019-VAE
 Iteration No.: N/A
 Attachment: 6 Page: 1 of 3

Waters Corporation

INSTRUMENT - FINAL TEST RECORD

Part Number: 186015038 Description: ACQUITY Active Column Manager
 Tested By: 25704791 Date: 4/10/2019
 Serial Number: D19CMP550G TMD Number: N/A
 Firmware Revision: 1.60.136 Factory Order: WATS1904063

Electrical Safety Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Fan Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ethernet Port Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
LED Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Column LED Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Door Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 3	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 4	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 5	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 6	Pass ☒	Fail ☐	see note# _____	Pass ☐
Set Serial Number	Pass ☒	Fail ☐	see note# _____	Pass ☐
Fuses	Pass ☒	Fail ☐	see note# _____	Pass ☐
Leak Detector Interface Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH1	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH2	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH3	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CM-APH4	Pass ☒	Fail ☐	see note# _____	Pass ☐
TOP Auxillary Interface	Pass ☒	Fail ☐	see note# _____	Pass ☐
BOTTOM Auxillary Interface	Pass ☒	Fail ☐	see note# _____	Pass ☐
Heater Cooler	Pass ☒	Fail ☐	see note# _____	Pass ☐
Heater Cooler	Pass ☒	Fail ☐	see note# _____	Pass ☐
Left Valve	Pass ☒	Fail ☐	see note# _____	Pass ☐
Right Valve	Pass ☒	Fail ☐	see note# _____	Pass ☐

Instrument Result:

Pass ☒

Fail ☐

Signed:

[Signature]
END OF DAY

Date:

10 APR 19

Notes:

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail; a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing; the initial form must be attached and retained.

Document No.: TE83026-01-08APR2019-VAF
 Iteration No.: N/A
 Attachment: 6 Page: 2 of 3

Waters Corporation

INSTRUMENT - FINAL TEST RECORD

Part Number: 186015049 Description: Acquity UPLC CM-AUX
 Tested By: 25704791 Date: 4/8/2019
 Serial Number: D19CMX722G TMD Number: TMD: 010641, TMD: 010643
 Firmware Revision: N/A Factory Order: WATS1904065

Electrical Safety Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
AUX ID	Pass ☒	Fail ☐	see note# _____	Pass ☐
LED Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Fan Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Column LED Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Door Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 1	Pass ☒	Fail ☐	see note# _____	Pass ☐
Ecord 2	Pass ☒	Fail ☐	see note# _____	Pass ☐
Leak Detector Interface Test	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CHC1-APH1	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CHC1-APH2	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CHC1-APH1	Pass ☒	Fail ☐	see note# _____	Pass ☐
Pre-Heater Interface TC-CHC1-APH2	Pass ☒	Fail ☐	see note# _____	Pass ☐
Heater Cooler	Pass ☒	Fail ☐	see note# _____	Pass ☐
Heater Cooler	Pass ☒	Fail ☐	see note# _____	Pass ☐

Instrument Result:

Pass ☒

Fail ☐

Signed:

[Signature]

Date:

08 APR 19

Notes:

Console test pass

END OF DATA

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail; a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing; the initial form must be attached and retained.

Document No.: TE83026-01-08APR2019
 Iteration No.: N/A
 Attachment: 6 Page: 3 of 3 JAF

Waters Corporation - Test Record

Part Number: 186015043Product: ACQUITY UPLC CM-AOperator: 25704791Start Time: 04/08/2019, 12:17:Serial Number: C19CMP535GEnd Time: 04/08/2019, 13:22:Test System: Acquity CMA Test TE83026-1

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Fan Test					PASS
Ethernet Port Test					PASS
LED Test					PASS
Column LED Test					PASS
Door Test					PASS
Ecord 3					PASS
Ecord 4					PASS
Ecord 5					PASS
Ecord 6					PASS
Set Serial Number					PASS
Fuses					PASS
Leak Detector Interface Test					PASS
Pre-Heater Interface TC-CM-APH1					PASS
Pre-Heater Interface TC-CM-APH2					PASS
Pre-Heater Interface TC-CM-APH3					PASS
Pre-Heater Interface TC-CM-APH4					PASS
TOP Auxillary Interface					PASS
BOTTOM Auxillary Interface					PASS
Heater Cooler					PASS
Heater Cooler					PASS
Left Valve					PASS
Right Valve					PASS

Acquity CMA Test Overall Result - PASS

Signed: Date: 11 Apr 2019

Printed from Sigma Quest Data Archive.

END OF DATA

 11 Apr 2019

Document No.: TE83026-01-08APR2019-VAF
 Iteration No.: N/A
 Attachment: 7 Page: 1 of 3

Waters Corporation - Test Record

Part Number: 186015038Product: ACQUITY Active Column ManagerOperator: 25704791Start Time: 04/10/2019, 18:27:Serial Number: D19CMP550GEnd Time: 04/10/2019, 19:34:Test System: Acquity CMA Test TE83026-1

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Fan Test					PASS
Ethernet Port Test					PASS
LED Test					PASS
Column LED Test					PASS
Door Test					PASS
Ecord 3					PASS
Ecord 4					PASS
Ecord 5					PASS
Ecord 6					PASS
Set Serial Number					PASS
Fuses					PASS
Leak Detector Interface Test					PASS
Pre-Heater Interface TC-CM-APH1					PASS
Pre-Heater Interface TC-CM-APH2					PASS
Pre-Heater Interface TC-CM-APH3					PASS
Pre-Heater Interface TC-CM-APH4					PASS
TOP Auxillary Interface					PASS
BOTTOM Auxillary Interface					PASS
Heater Cooler					PASS
Heater Cooler					PASS
Left Valve					PASS
Right Valve					PASS

Acquity CMA Test Overall Result - PASS

Signed: Date: 11 Apr 2019

END OF DATA

Printed from Sigma Quest Data Archive
 11 Apr 2019

Document No.: TE83026-01-08APR2019-VAF
 Iteration No.: N/A
 Attachment: 7 Page: 2 of 3

Waters Corporation - Test Record

Part Number: 186015049Product: Acquity UPLC CM-AUXOperator: 25704791Start Time: 04/08/2019, 16:26:Serial Number: D19CMX722GEnd Time: 04/08/2019, 17:18:Test System: Acquity CMA AUX Test TE 83026-1

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
AUX ID					PASS
LED Test					PASS
Fan Test					PASS
Column LED Test					PASS
Door Test					PASS
Ecord 1					PASS
Ecord 2					PASS
Leak Detector Interface Test					PASS
Pre-Heater Interface TC-CHC1-APH1					PASS
Pre-Heater Interface TC-CHC1-APH2					PASS
Pre-Heater Interface TC-CHC1-APH1					PASS
Pre-Heater Interface TC-CHC1-APH2					PASS
Heater Cooler					PASS
Heater Cooler					PASS

Acquity CM AUX Test Overall Result - PASS

Signed: Date: 11 Apr 2019

Printed from Sigma Quest Data Archive.

 11 Apr 2019

END OF DATA

Document No.: TE83026-01-08APR2019-VAF

Iteration No.: N/A

Attachment: 7 Page: 3 of 3

Acquity CMA Test Program

Automated Test

Start

Stop

When only running some tests make sure that the correct preheaters are connected if necessary.

Part Number: 186015043
 Factory Order: WATS1904064
 Operator: 25704791

Change

Serial Number: D19CMP566G

If there is an applicable TMD enter the number.

TMD:

Firmware Rev: 1.68.154

Acquity CMA Test

Skip ☐

- Electrical Safety Tests ☐
- Power Up / RS232 Port ☐
- Fan Check ☐
- Firmware Load ☐
- Ethernet Port ☐
- Front Panel LEDs ☐
- Column LEDs ☐
- Door Switch ☐
- E-Cord 3 ☐
- E-Cord 4 ☐
- E-Cord 5 ☐
- E-Cord 6 ☐
- Serial Number ☐
- Fuses ☐
- Leak Detector ☐
- Pre-Heater 1 ☐
- Pre-Heater 2 ☐
- Pre-Heater 3 ☐
- Pre-Heater 4 ☐
- Upper Aux ☐
- Lower Aux ☐
- Heater / Cooler 1 ☐
- Heater / Cooler 2 ☐
- Left Valve Actuation ☐
- Right Valve Actuation ☐

Skip All ☐

Test Status

Is the POWER LED on the front panel lit green?

Yes

No

Cancel

Print Report

Sigmaquest

Production / Debug

Quit

Waters Corp. Test Engineering M Brule 19 MAR 2015

Revision: 1.3

Acquity CMA AUX Test

Automated Test

Start

Stop

Part Number: _____

Factory Order: _____

Operator: _____

Change

Skip ☐

- Electrical Safety Tests ☐
- Power Up / RS232 Port ☐
- Read UUT ID ☐
- UUT Power ☐
- Front Panel LEDs ☐
- Fan Check ☐
- Column LEDs ☐
- Door Switch ☐
- E-Cord 1 ☐
- E-Cord 2 ☐
- Leak Detector ☐
- Pre-Heater 1 ☐
- Pre-Heater 2 ☐
- Pre-Heater 3 ☐
- Pre-Heater 4 ☐
- Heater / Cooler 1 ☐
- Heater / Cooler 2 ☐

Skip All ☐

Quit

Print Report ☐ Sigmaquest ☐

Production / Debug ☐

Serial Number: _____

This test requires A-CMA at version 1.51 to Control the AUI unit.

Waters Corp. Test Engineering M Endle

22/Feb/2012

Revision 1.1

TE 83026-1

Document No.: TE83026-01-08APR2019
 Iteration No.: N/A
 Attachment: 8 Page: 2 of 2