

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

TE83026-08APR2019-VAF

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.

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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 Contract Manufacturing 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 03, Rev 1 and Aux CM-A Test Procedure 735002236, Ver 03, Rev 1. 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 hard drive of the hddisk driver of PC used for the TE83026-01 test system in Venture Contract Manufacturing Site in Singapore has been replaced and a TE83026-01 test system hard disk image was loaded on new hddisk 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?	☒	☐

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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 <i>see email</i> An EDV has been completed for the CMA-3 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. <i>Note that CMA-Aux units do not have firmware.</i> 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.		

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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.

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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		

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ATTACHMENTS:

- ~~1. Editor Training Record~~ not needed - didn't execute I/O
2. Operator Training Record
- ~~3. Photos about Harddisk Drive changing~~ not needed
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~~ not needed - CMA firmware version is printed on manufacturing test records

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

Trainer's Signature

Title

Date

This attachment not needed

Document No.: 7300026-01-08APR2019
 Iteration No.: N/A
 Attachment: 1 Page: 1 of 1

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)	<i>[Signature]</i>	05 Apr 2019
Printed Name	Signature	Date

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

- This line 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)	<i>[Signature]</i>	PARTIK	05 APR 19
Lu Xing Zhou (25705156)	<i>[Signature]</i>	LV	05 APR 19
<i>[Signature]</i> (25704741)	<i>[Signature]</i>	Mooshy	05 Apr 19
End of Data			

operators should write their own ID#

Print multiple copies of this Training Record Template as needed

Document No.: **TE83026-01-08APR2019-VAE**
 Iteration No.: **N/A**
 Attachment: **2** Page: **1** of **2**

DOCUMENT HISTORY

This should not be on this page

Appendix A: TRAINING RECORD

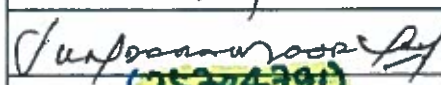
Document #	735002236	Document Title	Aux CM-A Test Procedure	Version	09
				Revision	F

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

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

☒ 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
PARAK (25704968)		PARAK	05 APR 19
Lu Ling Zhou (25705156)		LV	05 APR 19
 (25704791)		Mookerjee	05 APR 19
End of Data			
	See comments on attachment 2 pg. 1		

Print multiple copies of this Training Record Template as needed

Document No.: TE23026-01-08APR2019-IAF
 Iteration No.: N/A
 Attachment: 2 Page: 2 of 2

DOCUMENT HISTORY

Photos about the PC harddisk changing.

New HDD in PC



This attachment
not needed

Document No.: TEF3026-D1-08APR2019-VAT
Iteration No.: 1/2
Attachment: 3 Page: 1 of 2

Old HDD (failing to load Windows XP)



not needed

Document No.: TER3676-01-08APR2019-JAF
Iteration No.: N/A
Attachment: 3 Page: 2 of 2

186015043 BOM

Display material BOM: General Item Overview

Material 186015043 ACQUITY UPLC C4-A

Plant CDDZ Waters Single Design Plant

Alternative BOM 1

Material Document General

Item ID	Component	Component description	Quantity	Un	A...	Sts	Valid From	Valid to	Change No.
0010 L	279002113	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	WAT024931	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒		01.06.2010	31.12.9999	9152687
0050 L	WAT027033	CABLE TIE MINIATURE	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	200000280	ACQUITY UPLC C4 START UP KIT	1	EA	☒		01.06.2010	31.12.9999	9152687
0080 L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐		01.06.2010	31.12.9999	9152687
0100 L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐		08.06.2011	31.12.9999	9162380
0110 L	290001453	BOX, SHIPPING, ACTIVE COLUMN MANAGER	1	EA	☐		06.03.2013	31.12.9999	9174466
0130 L	361000710	ACQUITY C4-A Firmware 1.65.154	1	EA	☐		01.08.2017	31.12.9999	9215285

Document No.: TFS3026-01-08APR2019-VAF
Iteration No.: N/A
Attachment: A Page: 1 of 4

186015038 BOM

Display material BOM: General Item Overview

Material 186015038 Plant CRDE Waters Single Design Plant Alternative BOM 1

2

Material Document General

Item	IC	Component	Component description	Quantity	Un	A...	Sta	Valid From	Valid to	Change No.
0010	1	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	15.02.2012	31.12.9999	9168384
0020	1	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	15.02.2012	31.12.9999	9168384
0030	1	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	15.02.2012	31.12.9999	9168384
0040	1	WAT027033	CABLE TIE MINIA TURE	1	EA	☐	☐	15.02.2012	31.12.9999	9168384
0050	1	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	15.02.2012	31.12.9999	9168384
0140	1	206000280	ACQUITY UPLC CN START UP KIT	1	EA	☒	☐	26.10.2012	31.12.9999	9173736
0150	1	279002717	ASSY, CH-A, UPC2	1	EA	☒	☐	26.10.2012	31.12.9999	9173736
0160	1	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	26.10.2012	31.12.9999	9173736
0170	1	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	26.10.2012	31.12.9999	9173736
0180	1	290001453	BOX, SHIPPING, ACTIVE COLUMN MANAGER	1	EA	☐	☐	26.10.2012	31.12.9999	9173736
0190	1	361000510	ACQUITY CH-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

no firmware- this screen capture
not needed

186015049 BOM

Display material BOM: General Item Overview

Material 186015049 ACQUITY UPLC H-CLASS CH-AUX

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item ID	Component	Component description	Quantity	Un	A...	Slr	Valid From	Valid to	Change No.
0010 L	200000281	Start up KE, ACQUITY H-CLASS CH-AUX	1	EA	☒	☐	15.06.2010	31.12.9999	9153037
0020 L	279002135	ASSY, COLUMN MANAGER AUXILIARY, ACQUITY	1	EA	☒	☐	15.06.2010	31.12.9999	9153037
0030 L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0040 L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0050 L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	15.06.2010	31.12.9999	9153037
0060 L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	15.06.2010	31.12.9999	9153037
0070 L	290000822	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0080 L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	15.06.2010	31.12.9999	9153037
0100 L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	08.06.2011	31.12.9999	9162380
0110 L	290001454	BOX, SHIPPING, AUX COLUMN MANAGER	1	EA	☐	☐	06.03.2013	31.12.9999	9174446

Document No.: 1863026-01-68APR2019-0AF
Iteration No.: N/A
Attachment: 4 Page: 3 of 4

no firmware- this screen capture
not needed

186015039 BOM

Display material BOM: General Item Overview

Material 186015039 CRDE Waters Single Design Plant

C

Material Plant Alternative BOM 1

Material Document General

Item ID	Component	Component description	Quantity	Un	Alt	Valid From	Valid to	Change No.
0010 L	MAI006277	LABEL, CONGRATULATIONS	1	EA	☐	15.02.2012	31.12.9999	9168364
0020 L	MAI024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	15.02.2012	31.12.9999	9168364
0030 L	MAI024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	15.02.2012	31.12.9999	9168364
0040 L	MAI027033	CABLE TIE MINIATURE	1	EA	☐	15.02.2012	31.12.9999	9168364
0050 L	MAI089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	15.02.2012	31.12.9999	9168364
0120 L	200000261	Start up KE, ACQUITY H-Class CH-AUX	1	EA	☒	26.10.2012	31.12.9999	9173736
0130 L	279002726	ASSY, CH-AUX, UPC2	1	EA	☒	26.10.2012	31.12.9999	9173736
0140 L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	26.10.2012	31.12.9999	9173736
0150 L	290001454	BOX, SHIPPING, AUX COLUMN MANAGER	1	EA	☐	26.10.2012	31.12.9999	9173736
0160 L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	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-VAF
Iteration No.: N/A
Attachment: 5 Page: 2 of 2

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Waters Corporation

INSTRUMENT - FINAL TEST RECORD

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

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: *Remy Brown* Date: 08 APR 19
 Notes: END OF DAY

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.: TE53026-01-08APR2019-VAF
 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: *Ameyam...* Date: 10 APR 19
 Notes: END OF DAY

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.

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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: Two: 010641, Two: 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 ☐

No need to highlight

Instrument Result: Pass ☒ Fail ☐ Signed: [Signature] Date: 08 APR 19

Notes:

Console test pass
END OF DAY

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.

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 Attachment: 6 Page: 3 of 3 JAF

Waters Corporation - Test Record

Part Number: <u>186015043</u>	Product: <u>ACQUITY UPLC CM-A</u>
Operator: <u>25704791</u>	Start Time: <u>04/08/2019, 12:17:</u>
Serial Number: <u>C19CMP535G</u>	End Time: <u>04/08/2019, 13:22:</u>
Test System: <u>Acquity CMA Test TE83026-1</u>	

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: <u>11 Apr 2019</u>
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END OF DATA

 11 Apr 2019

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Waters Corporation - Test Record

Part Number: <u>186015038</u>	Product: <u>ACQUITY Active Column Manager</u>
Operator: <u>25704791</u>	Start Time: <u>04/10/2019, 18:27:</u>
Serial Number: <u>D19CMP550G</u>	End Time: <u>04/10/2019, 19:34:</u>
Test System: <u>Acquity CMA Test TE83026-1</u>	

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: <u>11 Apr 2019</u>
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END OF DATA

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 11 Apr 2019

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

Waters Corporation - Test Record

Part Number: <u>186015049</u>	Product: <u>Acquity UPLC CM-AUX</u>
Operator: <u>25704791</u>	Start Time: <u>04/08/2019, 16:26:</u>
Serial Number: <u>D19CMX722G</u>	End Time: <u>04/08/2019, 17:18:</u>
Test System: <u>Acquity CMA AUX Test TE 83026-1</u>	

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: <u>11 Apr 2019</u>
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END OF DATA

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

Iteration No.: N/A

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Acquity CMA Test Program

Automated Test

Start

Stop

When only running speed tests make sure that the correct probe wires are connected if necessary.

Part Number: 186015043

Factory Order: WATS1904064

Operator: 25704791

Change

Serial Number: D19CMP5065

Twid:

Timings File: 1.69.154

Makeup Corp. Test Engineering 10/18/2015

Electrical Safety Tests

Power Up / FS222 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

Feedback: 1.3

Acquity CMA Test

TE83026-1

Test Status

Is the POWER LED on the front panel lit green?

Yes

No

Cancel

Quit

Print Report

Print Results

Production / Testing

Firmware on test record - this
screen capture not needed

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Attachment: 8 Page: 1 of 2

Acquity CMA AUX Test Program

Acquity CMA AUX Test

TE 33026-1

Automated Test

Start

Stop

Part Number

Factory Order

Operator

Change

Serial Number

This test requires a CMA-A of version 1.5.1 or later. Contact the AUI unit.

Electrical Safety Tests

Power Up / RS232 Port

Read IULT ID

UUT Power

Front Panel LEDs

Fan Check

Column LEDs

Door Switch

Ex-Cord 1

Ex-Cord 2

Leak Detector

Pre-Heater 1

Pre-Heater 2

Pre-Heater 3

Pre-Heater 4

Heater / Cooler 1

Heater / Cooler 2

Skip

Print Report

Print Summary / Debug

Quit

Firmware on test record- this
screen capture not needed

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