

Test Equipment Number: TE83057-1

Location: Milford Production

1. PURPOSE

The purpose of the Legacy Equipment Qualification (LEQ) protocol is to define a method to qualify test equipment developed prior to the release of procedure 730001835. This excludes test equipment for In Vitro Diagnostics (IVD) products. Once completed, this executed LEQ protocol will serve as objective evidence that critical requirements of the test equipment adhere to Test Engineering's requirements and recommendations.

2. BACKGROUND

This qualification is a series of inspections and tests to ensure that critical requirements necessary for product quality are satisfied, and that documents and procedures necessary to properly operate and maintain the system are in place. Critical requirements are defined in the Test Specification and Procedure (TSP).

3. ACCEPTANCE CRITERIA

The LEQ will be considered successful when all appropriate sections have been completed. This includes but not limited to:

- Reviews and approvals
- Test scripts and summary report
- Objective evidence

Objective evidence (such as documents, printouts, training records, screenshots, photos, test reports, etc) will be dated, referenced to the test script # and attached to this document. Please do not leave any fields blank. If not applicable please fill in N/A.

3.1. Failure to Meet Acceptance Criteria

The pass / fail decision will be based on the number and severity of defects found during the qualification. In the event that there is failure to meet any of the acceptance criteria, the protocol signatories must decide to: Accept (with justification) or reject the qualification. In the case of a rejected qualification, Test Engineering will assess and record the risk, then make the necessary changes and re-qualify the test equipment. All comments will be captured or referenced in section 5.

4. IDENTIFY THE LEQ PERFORMERS

Responsibility	Name (Print)	Title	Signature	Initial & Date
Performer	Eric Turner	Principal Test Engineer		ET 26 JAN -2015

5. LEQ SUMMARY REPORT

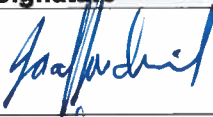
5.1. Test Equipment No.: TE83057-1

Test Equipment Name: Detector Download-Config System

Test Script No.	LEQ Test Name	Pass/Fail
LEQ-01	Associated Documentation and Software Verification	PASS
LEQ-02	Equipment Calibration and Preventative Maintenance Verification	PASS
LEQ-03	Test Verification	PASS
LEQ-04	Fault Insertion Test	PASS

Comments:

N/A

Responsibility	Name (Print)	Title	Signature	Date
Reviewer (Test Engineering)	Jaaffar Ismail	Manager, Test Engineering		06 Feb 2015 06 Feb 2015
Approver (Quality)	Laurie Ashmore	Sr. Quality Engineer		06 Feb 2015

Note: If not applicable please fill in N/A.

6. LEQ PROTOCOL SCRIPTS

LEQ Test Name: Associated Documentation and Software Verification		Test Script No.: LEQ-01	
Test Equipment No.: TE83057-1			
Test Equipment Name: Detector Download-Config System			
Purpose: To verify that supporting documentation and software is available and released.			
Test execution: Complete the table below. If documents are unavailable state why in the comments section.			
Type	Title; Doc. No.; Rev. or Ver. No.	Approved (Yes \ No \ N/A)	Initial & Date
Test Specification and Procedure (TSP)	735003015, Rev E	Pending this LEQ	ET 05-FEB-2015
Calibration/Preventative Maintenance Procedure	735003102, Rev A	In ECR Loop	ET 05-FEB-2015
Test Equipment Functional Requirement Document	N/A	N/A	N/A
Verify the Test Equipment Software version is listed in the TSP and displayed on the Test Equipment.		Yes	ET 05-FEB-2015
Ensure documentation and software listed above is captured in SAP or on the Finserv2 drive.		Yes	ET 05-FEB-2015
Comments: Functional Requirements based on specifications in TSP 			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Note: If not applicable please fill in N/A.

Title: Legacy Equipment Qualification (LEQ)

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LEQ Test Name: Equipment Calibration and Preventative Maintenance (PM) Verification				Test Script No.: LEQ-02	
Test Equipment No.: TE83057-1					
Test Equipment Name: Detector Download-Config System					
Purpose: To list all critical items associated with test equipment and to verify that they have been PM'd and/or calibrated. Test execution: - Verify that all critical instruments are calibrated and/or PM'd. This is verified by obtaining a PM/calibration due date from the calibration/PM sticker. - Verify the calibration/PM records are available and completed accurately per the Calibration/Preventative Maintenance Procedure.					
Description	Waters P/N or Asset No	Serial Number	Last Calibration Date	Calibration due date	Initial & Date
Detector Download-Config System	TE83057-1	TE83057-1	(new)	Aug 13, 2015	ET 26-JAN-2015
Audit Question(s)?			Cal/PM Procedure No.	Approved (Yes \ No \ N/A)	Initial & Date
Are calibration/PM records available and completed accurately per the Calibration/Preventative Maintenance Procedure?			735003102	In process	ET 26-JAN-2015
Comments: PM to be done on computer as there are no instruments or calibratable devices on this system.					
Overall Test Conclusion: ☒ Pass ☐ Fail					

Note: If not applicable please fill in N/A.

LEQ Test Name: Test Verification	Test Script No.: LEQ-03		
Test Equipment No.: TE83057-1			
Test Equipment Name: Detector Download-Config System			
Purpose: To verify that testing the specified Units Under Test (UUT) and achieving a PASSED result for all UUTs will demonstrate that the test system meets all requirements for functionality and safety. (Previously executed records may be submitted as objective evidence) Test execution: - Each operator will test a different UUT and will perform to the Test Specification and Procedure. Operators are to record their name, UUT serial number, test result, and initial & date below. - Attach the UUT final test record to this report. (Previously executed records may be submitted as objective evidence) - Verify operator's training record(s) are available.			
Operators	UUT Serial Number	Pass / Fail	Initial & Date
Ian Inthirathvongsy	A15URI393M	Pass	ET 26 JAN 2015
Ian Inthirathvongsy	M14URI391M	Pass	ET 26 JAN-2015
Ian Inthirathvongsy	M14URI389M	Pass	ET 26 JAN 2015
Eric Turner	A15P14999M	Pass	ET 26 JAN-2015
Comments: Only one operator uses this test system. Signed Test Records are in each instrument's DHR. One additional test record is provided to show the Altus A-30 detector part number and instrument name are in the test record when it is the type tested.			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Note: If not applicable please fill in N/A.

Title: Legacy Equipment Qualification (LEQ)

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LEQ Test Name: Fault Insertion Test			Test Script No.: LEQ-04	
Test Equipment No.: TE83057-1				
Test Equipment Name: Detector Download-Config System				
UUT Part Number: 186015070		UUT Serial Number: D13URI015R, M14URI385M, K14URI346M		
Purpose: To verify that the test equipment will fail UUTs that are not achieving requirements for functionality and safety. <u>The requirements for this script may be met with previously completed qualification record such as the "Test Equipment Functional Requirement" document.</u> Test execution: Attach the UUT(s) final test record to this report. (Previously executed records that demonstrate the equipment screening failures may be submitted as objective evidence to satisfy the requirements of this test script.)				
Critical requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
Leak Detector Functions	Leak detector not connected (M14URI385M)	FAIL	Yes	ET 26-JAN-2015
Firmware downloaded properly	Wrong build (44) (D13URI015R)	FAIL	Yes	ET 26-JAN-2015
Serial Number programmed	Serial Number not programmed (K14URI346M)	FAIL	Yes	ET 26-JAN-2015
Comments: N/A				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Note: If not applicable please fill in N/A.

DOCUMENT HISTORY

VERSION:	00	ORIGINATOR:	Jaaffar Ismail	Change ID:	N/A
SUMMARY OF CHANGE:					
Initial Release					

LEQ-01
ET
05-FEB-2015

WATERS CORPORATION

ENGINEERING TEST SPECIFICATION AND PROCEDURE

COMPANY CONFIDENTIAL

SYSTEM/ASSEMBLY NAME: **ACQUITY RI REFRACTOMETER**

PART NUMBER AFFECTED: **186015070, 800000433, 700009416, 279002791, 186020070, 289008021, 289009485**

TEST EQUIPMENT NAME: **DECAY TESTER, ACQUITY RI DOWNLOAD-CONFIG, ACQUITY RI NOISE-DRIFT TEST, ACQUITY RI RESPONSE TEST**

TEST EQUIPMENT NUMBER: **TE82713, TE83057, TE83059, TE83060, TE83078**

DOCUMENT NUMBER: **735003015**

TEST SOFTWARE:



(TE83057)



(TE83059)



(TE83060)



(TE83078)

AUTHOR(S): **CHARLES BERGERON**

DATE: **December 08, 2013**

REVISED BY: **ERIC TURNER**

DATE: **January 10, 2015**

REVISION: **E**

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LEQ-03
ET 26-JAN-2015

+
LEQ-01
ET 05-FEB-2015

Download-Configure System TE83057-1
C:\Program Files\RI Download Config

File Instrument Control Info Settings

Serial Number Entry

Scan serial number or type in number and press Enter. You may change operator name or press Cancel to abort.

Serial Number
A15P14999M

Factory Order
LEQ

TMD(s)

Operator
USPLMEC54

Change Operator

Cancel

Enter

Quit

Stal

Waters Corp.

Test System:TE83057-1 Revision: 1.2 (01/2015) Config Version: Tsw1.2_Hw0.0_Prod1.0

(C) 2015

LE&-03
ET
26-JAN-2015

Waters Corporation - Instrument Final Test Record

Part Number: 186020070

Product: Altus A-30 RI
Detector

Operator: USPLMEC54

Start Time: 01/26/2015
13:22:28

Serial Number: A15P14999M

Factory Order: LEQ

Firmware Rev. : 1.40 Build#: 45 (May 17 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Altus A-30 Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Leak Detector Checked					PASS
Electrical Safety					PASS

Notes:

Signed:

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.

COPY

LEQ-05
ET
26-JAN-2015

Waters Corporation - Instrument Final Test Record

Part Number: 186015070 Product: Acquity RI Detector

Operator: USIINKM Start Time: 01/06/2015, 07:00:07.000

Serial Number: M14URI389M Factory Order: 3951636

Firmware Rev. : 1.40 Build#: 45 (May 17 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Acquity RI Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Leak Detector Checked					PASS
Electrical Safety					PASS

Notes:

Signed: _____

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LEQ -05
ET
06-JAN-2015

Waters Corporation - Instrument Final Test Record

Part Number: 186015070 Product: Acquity RI Detector

Operator: USIINKM Start Time: 01/15/2015, 11:01:21.000

Serial Number: A15URI393M Factory Order: 3953984

Firmware Rev. : 1.40 Build#: 45 (May 17 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Acquity RI Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Leak Detector Checked					PASS
Electrical Safety					PASS

Notes:

Signed: _____

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LEQ-03
ET
26-JAN-2015

Waters Corporation - Instrument Final Test Record

Part Number: 186015070 Product: Acquity RI Detector

Operator: USIINKM Start Time: 01/06/2015, 08:18:44.000

Serial Number: M14URI391M Factory Order: 3951636

Firmware Rev. : 1.40 Build#: 45 (May 17 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Acquity RI Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Leak Detector Checked					PASS
Electrical Safety					PASS

Notes:

Signed: _____

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LEK-04
ET
26-JAN-2015

Waters Corporation - Instrument Final Test Record

Part Number: 186015070 Product: Acquity RI Detector

Operator: USIINKM Start Time: 04/07/2014, 09:19:06.000

Serial Number: D13URI015R

Firmware Rev. : 1.40 Build#: 44 (Mar 21 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Acquity RI Download-Config					FAIL
Firmware Download					FAIL
Serial Number Set					PASS
Leak Detector Checked					PASS
Electrical Safety					PASS

Notes:

Signed: _____

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LEA-04
ET
26-JAN-2015

Waters Corporation - Instrument Final Test Record

Part Number: 186015070 Product: Acquity RI Detector
Operator: USIINKM Start Time: 12/16/2014, 11:06:32.000
Serial Number: M14URI385M TMD: 07633

TMD : 09147

Factory Order : 3948240

Firmware Rev. : 1.40 Build#: 45 (May 17 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Acquity RI Download-Config					FAIL
Firmware Download					PASS
Serial Number Set					PASS
Leak Detector Checked					FAIL
Electrical Safety					PASS

Notes:

Signed: _____

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LEW-04
26-JAN-2015
ET

Waters Corporation - Instrument Final Test Record

Part Number: 186015070 Product: Acquity RI Detector

Operator: USLFAKM Start Time: 10/17/2014, 15:57:12.000

Serial Number: K14URI346M Factory Order: 3923033

Firmware Rev. : 1.40 Build#: 45 (May 17 2013)

Name	LSL	Measurement	USL	Unit	Outcome
Acquity RI Download-Config					FAIL
Firmware Download					PASS
Serial Number Set					FAIL
Leak Detector Checked					PASS
Electrical Safety					PASS

Notes:

Signed: _____

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