

Title: Legacy Equipment Qualification (LEQ)

Revision: 3

Page 1 of 5

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 re-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. As this is a re-qualification of an existing LEQ, some original scripts are unnecessary and will not be performed.

2. BACKGROUND

This qualification is a series of tests to ensure that a test software change performs as described and also that existing, working code is not compromised by the change.

The Detector Download-Configure System is currently being used in production to qualify that RIs (2414, 2414 refresh, Acquity RI, PKI and Arc models) are downloaded with the proper firmware, the serial number written to its RAM and the leak detector tested, if applicable. A firmware change was implemented after this system was qualified that changed the command needed to set the instrument serial number. As a result, the test software has to be updated to send the proper command to the PKI-A10 and Arc versions.

3. ACCEPTANCE CRITERIA

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

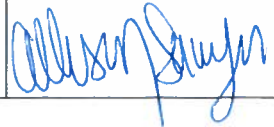
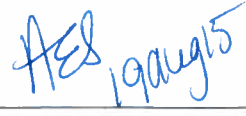
- Reviews and approvals
- Test scripts and summary report
- Objective evidence

Objective evidence (test reports) will be dated, referenced to the test script # and attached to this document.

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.

Quality Pre-approval

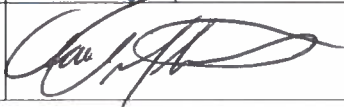
Responsibility	Name (Print)	Title	Signature	Initial & Date
PRE-APPROVAL (Quality)	Allison Sawyer	Sr. Operations Quality Engineer		

Title: Legacy Equipment Qualification (LEQ)

Revision: 3

Page 2 of 5

4. IDENTIFY THE LEQ PERFORMERS

Responsibility	Name (Print)	Title	Signature	Initial & Date
Performer	Eric Turner	Principal Test Engineer		19-AUG-2015
Production Test	Ian Inthirathvongsy	Production Specialist		19 Aug 2015

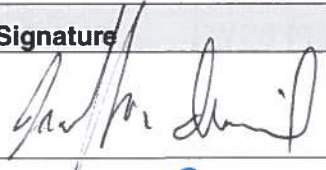
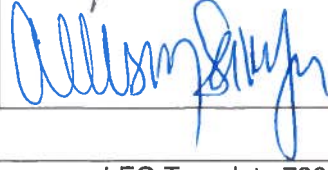
5. LEQ SUMMARY REPORT

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	Test Verification	PASS

Comments: See original LEQ for proof of documentation, preventative maintenance, and fault insertion. As this software has been qualified in the original LEQ, only a PQ type of script will be run. Objective evidence from that script will verify that the serial number can be programmed on all instrument types tested on this system and functionality of the test system has not been compromised by the change. This revision(3) differs from the last revision in that an incorrect part number referenced in section LEQ-02 has been corrected to 186241401 (2414 refresh blue). Also, a Quality pre approval section is added to the form. This is a requalification as first attempt failed. See attached, original LEQ and comments section for justification and mitigation.

Responsibility	Name (Print)	Title	Signature	Date
Reviewer (Test Engineering)	Jaaffar Ismail	Manager, Test Engineering		20-Aug-2015
Approver (Quality)	Allison Sawyer	Sr. Operations Quality Engineer		21 Aug 15

Title: Legacy Equipment Qualification (LEQ)

Revision: 3

Page 3 of 5

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)	735000558, TEST SPEC AND PROCEDURE, 2414, Rev. X and 735003015, Acquity RI Module Final Test Procedure, Rev. H	Pending this LEQ	ET 19-AUG-2015
Calibration/Preventative Maintenance Procedure	735003102, Acquity RI Configuration System Cal Proc, Rev A	Yes	ET 19-AUG-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 19-AUG-2015
Ensure documentation and software listed above is captured in SAP or on the Finserv2 drive.		Yes	ET 19-AUG-2015
Comments: Functional Requirements based on specifications in TSP. There are two test procedures listed as there are two basic types of refractive index detectors and six models - see LEQ-02 for complete description as to which procedure to use with any given model. The test system is called out in both procedures.			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Title: Legacy Equipment Qualification (LEQ)

Revision: 3

Page 4 of 5

LEQ Test Name: Test Verification			Test Script No.: LEQ-02	
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 can test all models required. Test execution: - The models are 2414, 2414 refresh (blue), Acquity Arc RI, Acquity RI, PKI A-10 and PKI A-30. - An operator will test the the Acquity RI and PKI A-30 and perform to the Test Specification and Procedure 735003015, section 3, Firmware Load. For the 2414, 2414 refresh (blue), the PKI A-10, and the Acquity Arc, the operator will perform to Test Specification and Procedure 735000558, section 3, Firmware Load. The operator is to record his or her name, UUT serial number, test result, and initial & date below. - Attach a signed, dated copy of each UUT download-config test record to this report. - Operator is trained on this equipment as supported in original LEQ. The test software change in no way affects operator interaction or procedure.				
Operators	UUT Model, PN	UUT Serial Number	Pass / Fail	Initial & Date
Ian Inthirathvongsy	2414, 186241400	H15214LEQ1	Pass	II 20 Aug 2015
Ian Inthirathvongsy	2414 refresh (blue), 186241401	H15214LEQ2	Pass	II 20 Aug 2015
Ian Inthirathvongsy	Acquity Arc RI, 186017004	H15VRILEQM	Pass	II 20 Aug 2015
Ian Inthirathvongsy	Acquity RI, 186015070	H15URILEQM	Pass	II 20 Aug 2015
Ian Inthirathvongsy	PKI A-10, N2971012	H15P06LEQM	Pass	II 20 Aug 2015
Ian Inthirathvongsy	PKI A-30, N2971039	H15P14LEQM	Pass	II 20 Aug 2015
Comments: Only one operator uses this test system.				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Title: Legacy Equipment Qualification (LEQ)

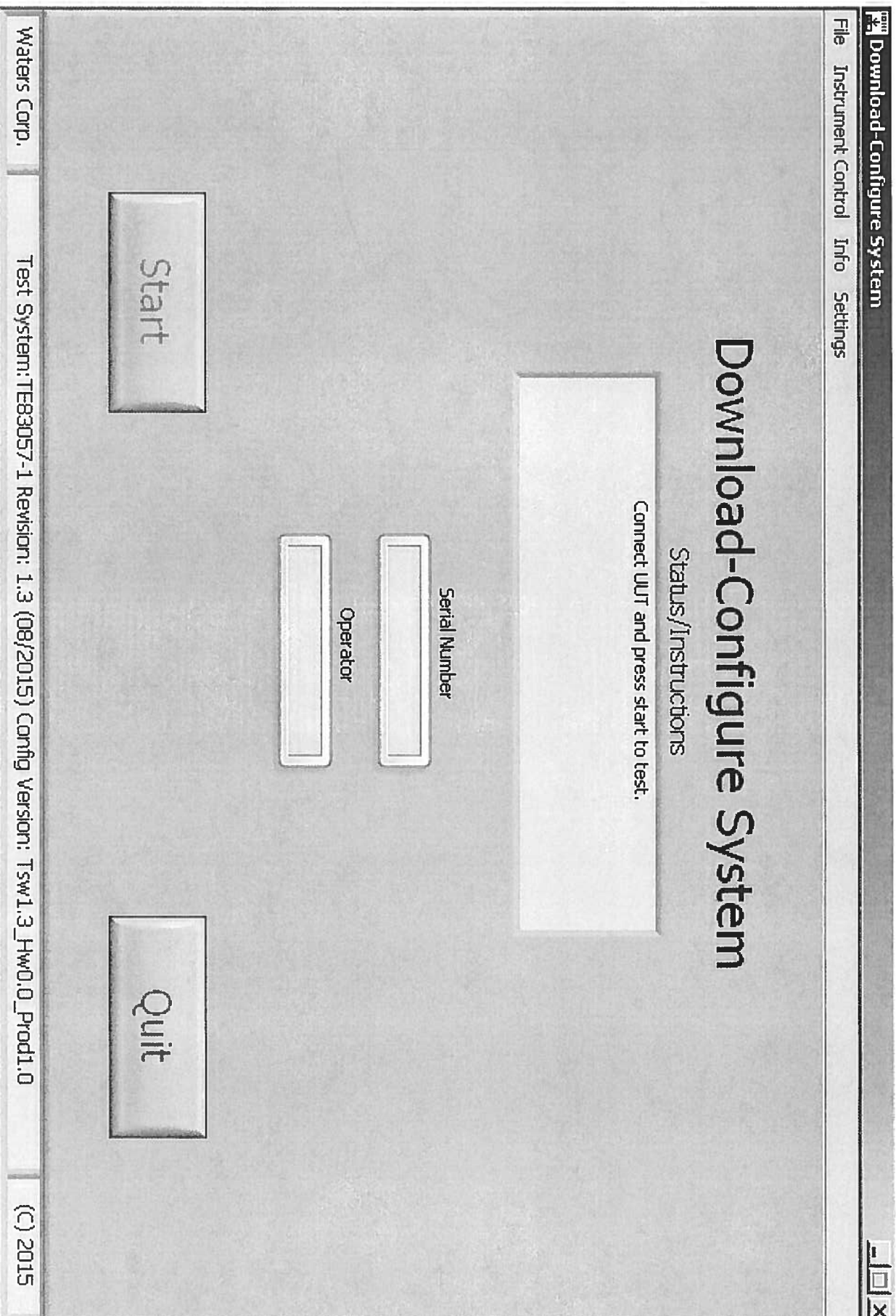
Revision: 3

Page 5 of 5

DOCUMENT HISTORY

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

LEQ-01
ET 19-MUG-2015



Waters Corporation - Instrument Final Test Record

Part Number: 186241400Product: 2414 RI DetectorOperator: USIINKMStart Time: 08/20/2015
07:00:01Serial Number: H15214LEQ1Factory Order: LEQ

Firmware Rev. : 2.04

Name	LSL	Measurement	USL	Unit	Outcome
2414 RI Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Electrical Safety					PASS

Notes:

n/A

ET 21-AUG-2015

Signed: 

20 Aug 2015

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.

LEQ-02

Waters Corporation - Instrument Final Test Record

Part Number: <u>186241401</u>	Product: <u>Refresh 2414 RI Detector</u>
Operator: <u>USIINKM</u>	Start Time: <u>08/20/2015, 07:06:06</u>
Serial Number: <u>H15214LEQ2</u>	Factory Order: <u>LEQ</u>

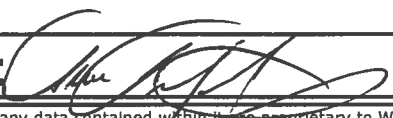
Firmware Rev. : 2.04

Name	LSL	Measurement	USL	Unit	Outcome
2414 RI Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Electrical Safety					PASS

Notes:

N/A

GT 21-AUG-2015

Signed:  20 Aug 2015

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LEQ-02

Waters Corporation - Instrument Final Test Record

Part Number: 186017004Product: Acquity Arc RI
DetectorOperator: USIINKMStart Time: 08/20/2015,
07:13:38Serial Number: H15VRILEQMFactory Order: LEQ

Firmware Rev. : 2.10 Build#: 48 (Mar 26 2015)

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

Notes:

N/A

ET 21-106-2015

Signed:  20 Aug 2015

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LEQ-02

Waters Corporation - Instrument Final Test Record

Part Number: <u>N2971012</u>	Product: <u>Altus A-10 RI</u> <u>Detector</u>
Operator: <u>USIINKM</u>	Start Time: <u>08/20/2015</u> <u>07:20:25</u>
Serial Number: <u>H15P06LEQM</u>	Factory Order: <u>LEQ</u>

Firmware Rev. : 1.0 Build#: 49 (Mar 30 2015)

Name	LSL	Measurement	USL	Unit	Outcome
Altus A-10 RI Download-Config					PASS
Firmware Download					PASS
Serial Number Set					PASS
Electrical Safety					PASS

Notes:

N/A ET 21-AUG-2015

Signed:  20 Aug 2015

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LEQ-02

Waters Corporation - Instrument Final Test Record

Part Number: N2971039Product: Altus A-30 RI
DetectorOperator: USIINKMStart Time: 08/20/2015
14:26:07Serial Number: H15P14LEQMFactory Order: LEQ

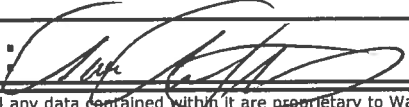
Firmware Rev. : 1.0 Build#: 51 (Mar 11 2015)

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

Notes:

N/A

ET 21-AUG-2015

Signed:  20 Aug 2015

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LEQ-02

Waters Corporation - Instrument Final Test Record

Part Number: 186015070Product: Acquity RI
DetectorOperator: USIINKMStart Time: 08/20/2015
14:30:57Serial Number: H15URILEQMFactory Order: LEQ

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:

N/A

ET 21-AUG-2015

Signed:

 20 Aug 2015

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LEQ-02

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 re-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. As this is a re-qualification of an existing LEQ, some original scripts are unnecessary and will not be performed.

2. BACKGROUND

This qualification is a series of tests to ensure that a test software change performs as described and also that existing, working code is not compromised by the change.

The Detector Download-Configure System is currently being used in production to qualify that RIs (2414, 2414 refresh, Acquity RI, PKI and Arc models) are downloaded with the proper firmware, the serial number written to its RAM and the leak detector tested, if applicable. A firmware change was implemented after this system was qualified that changed the command needed to set the instrument serial number. As a result, the test software has to be updated to send the proper command to the PKI-A10 and Arc versions.

3. ACCEPTANCE CRITERIA

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

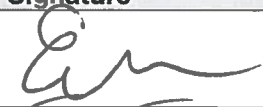
- Reviews and approvals
- Test scripts and summary report
- Objective evidence

Objective evidence (test reports) will be dated, referenced to the test script # and attached to this document.

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		18-MUG-2015
Production Test	Ian Inthirathvongsy	Production Specialist		18 Aug 2015

Quality Approver Allison Sawyer Sr. Operations Quality Engineer Allison Sawyer AES 14 Aug 15

5. LEQ SUMMARY REPORT

5.1. Test Equipment No.: TE83057-1

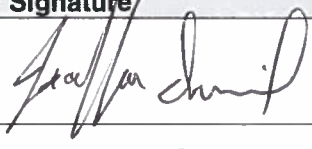
Test Equipment Name: Detector Download-Config System

Test Script No.	LEQ Test Name	Pass/Fail
LEQ-01	Associated Documentation and Software Verification	PASS
LEQ-02	Test Verification	FAIL

Comments: See original LEQ for proof of documentation, preventative maintenance, and fault insertion. As this software has been qualified in the original LEQ, only a PQ type of script will be run. Objective evidence from that script will verify that the serial number can be programmed on all instrument types tested on this system and functionality of the test system has not been compromised by the change.

LEQ-02 FAILED. The system was UNABLE to program the serial number on the first instrument tested (186241400). The operator aborted the test. TE verified the failure and, upon code inspection, it was determined the serial number programming command was not being sent correctly. A space was being stripped from the command read in resulting in setserialnumberH15214LEQM sent to the instrument, which requires a space between the command and the argument. The code was modified to add that space and tested. No production instruments were tested with this code. The LEQ will be re-run with the modified code.

The passes written on the LEQ-02 were written in error as the operator mistakenly ran the released software instead of the new software. Incorrect part number on LEQ-02 186002414 will read 186241401 on requalification.

Responsibility	Name (Print)	Title	Signature	Date
Reviewer (Test Engineering)	Jaaffar Ismail	Manager, Test Engineering		19 Aug 2015
Approver (Quality)	Allison Sawyer	Sr. operations Quality Engineer	Allison Sawyer	19 Aug 15

Title: Legacy Equipment Qualification (LEQ)

Revision: 2

Page 3 of 5

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)	735000558, TEST SPEC AND PROCEDURE, 2414, Rev. X and 735003015, Acquity RI Module Final Test Procedure, Rev. H	Pending this LEQ	ET 17-AUG-2015
Calibration/Preventative Maintenance Procedure	735003102, Acquity RI Configuration System Cal Proc, Rev A	Yes	ET 17-AUG-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 17-AUG-2015
Ensure documentation and software listed above is captured in SAP or on the Finserv2 drive.		Yes	ET 17-AUG-2015
Comments: Functional Requirements based on specifications in TSP. There are two test procedures listed as there are two basic types of refractive index detectors and six models - see LEQ-02 for complete description as to which procedure to use with any given model. The test system is called out in both procedures.			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Title: Legacy Equipment Qualification (LEQ)

Revision: 2

Page 4 of 5

LEQ Test Name: Test Verification			Test Script No.: LEQ-02	
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 can test all models required. Test execution: - The models are 2414, 2414 refresh (blue), Acquity Arc RI, Acquity RI, PKI A-10 and PKI A-30. - An operator will test the the Acquity RI and PKI A-30 and perform to the Test Specification and Procedure 735003015, section 3, Firmware Load. For the 2414, 2414 refresh (blue), the PKI A-10, and the Acquity Arc, the operator will perform to Test Specification and Procedure 735000558, section 3, Firmware Load. The operator is to record his or her name, UUT serial number, test result, and initial & date below. - Attach a signed, dated copy of each UUT download-config test record to this report. - Operator is trained on this equipment as supported in original LEQ. The test software change in no way affects operator interaction or procedure.				
Operators	UUT Model, PN	UUT Serial Number	Pass / Fail	Initial & Date
Ian Inthirathvongsy	2414, 186241400	H15214LEQ1	Pass	II 17 Aug 2015
Ian Inthirathvongsy	2414 refresh (blue), 186002414	H15214LEQ2	Pass	II 18 Aug 2015
Ian Inthirathvongsy	Acquity Arc RI, 186017004	H15VR1LEQM	N/A	ET 18-Aug-2015
Ian Inthirathvongsy	Acquity RI, 186015070	H15UR1LEQM	N/A	ET 18-Aug-2015
Ian Inthirathvongsy	PKI A-10, N2971012	H15P06LEQM	N/A	ET 18-Aug-2015
Ian Inthirathvongsy	PKI A-30, N2971039	H15PI4LEQM	N/A	ET 18-Aug-2015
Comments: Only one operator uses this test system.				
Overall Test Conclusion: ☐ Pass ☒ Fail				

DOCUMENT HISTORY

Title: Legacy Equipment Qualification (LEQ)

Revision: 2

Page 5 of 5

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

