

Title: Test Equipment Qualification Assessment

Protocol No: TE83057-TEQA

Revision: A

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1. PURPOSE

The purpose of the Test Equipment Qualification Assessment (TEQA) is to document the assessment of an engineering change to TE83057, Detector Download-Configure System. This document will also define the deliverable(s) required to maintain the Test Equipment qualification, which will be based on the engineering change. Qualification of the test equipment will ensure that it functions within its specifications to verify product performance.

2. BACKGROUND

The Detector Download-Configure System is currently being used in production to qualify that Acquity RIs are downloaded with the proper firmware, the serial number written to its RAM and the leak detector tested. The change made to the test software allows for the testing of another model, the Altus A-30, which is functionally identical to the Acquity RI.

3. DESCRIPTION OF CHANGE

3.1. Add code to the test software that asks the operator to scan the part number of the unit to be tested. Store the part number and instrument name in the test record.

3.2. Is the equipment used for the testing of IVD final instruments? ☐ Yes ☒ No

3.3. Please check the appropriate box(es) below that will be revised as a result of this change:

☐ Hardware

☐ Waters Instruments	☐ Mechanical Component(s)	☐ Computer
☐ Electrical Component(s)	☐ Fluidic Components	☐ PCBA
☐ Pneumatic Component(s)	☐ Other _____	

☒ Software

☐ Computer

☐ Setting	☐ Operating System	☐ Image
☐ Antivirus software	☐ Hardware Driver(s)	
☐ Other _____		

☒ Test equipment Software

☐ Specification	☒ Data Collection	☐ Firmware
☐ Method (Empower)	☒ Source Code	
☐ Other _____		

☐ Other _____

4. TECHNICAL IMPACT OF CHANGE

- The additional product to be tested (Altus A-30 RI detector) on this equipment are functionally identical to what is currently tested (Acquity RI detector)
- The execution path for product testing is in no way affected by the software change
- Based on the part number entered by the operator, the test report will show the proper model name and part number - this will be evidenced in the LEQ

5. QUALIFICATION ASSESSMENT

5.1. Test Equipment No.: TE83057-2 Test Equipment Name: Detector Download-Configure System

Document No.	Questions	Yes/No
n/a	Does the IQ need to be created / revised based on the proposed change?	n/a
	Does the IQ need to be executed based on the proposed change?	n/a
n/a	Does the OQ need to be created / revised based on the proposed change?	n/a
	Does the OQ need to be executed based on the proposed change?	n/a
n/a	Does the TEV need to be created / revised based on the proposed change?	n/a
	Does the TEV need to be executed based on the proposed change?	n/a
n/a	Does the software validation need to be created / revised based on the proposed change?	n/a
	Does the software validation need to be executed based on the proposed change?	n/a
n/a	Does the PQ need to be created / revised based on the proposed change?	n/a
	Does the PQ need to be executed based on the proposed change?	n/a

Comments/Justification:

This is considered legacy equipment as its development occurred before departmental procedures changed so an LEQ will be performed. The system will not be released into production until the LEQ is executed and approved. This TEQA and the LEQ will be supporting documents in the ECR (9193748) that will allow for the system release.

Responsibility	Name (Print)	Title	Signature	Date (DD-MMM-YYYY)
Reviewer /Author	ERIC TURNER	Test Engineer		21-JAN-2015
Reviewer	Matthew Franklin	Manufacturing Engineer		21-Jan-2015
Approver (Quality)	Wayne Aaron Snyder	Quality Manager		21 Jan 2015

Note: Once approve all items in the Assessment section designated "Yes" are action to be assigned and executed. These completed items will be captured and archived by the Test Engineering. The item(s) may be executed by a performer (ref. 730001835).

DOCUMENT HISTORY

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