

1. PURPOSE

The purpose of the Test Equipment Qualification Assessment (TEQA) is to document the assessment of an engineering change to released Download Configure Station (TE83057-1). 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 RIs (2414, 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. DESCRIPTION OF CHANGE

- 3.1. A section of code will test the part number entered by the operator and, if it is Arc or PKI A-10, the system will send 'setserial xxxxxxxxxx', where xxxxxxxxxx is the serial number entered (scanned) by the operator. Otherwise 'setserialnumber xxxxxxxxxx' shall be sent.

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

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 _____ execution | | |

☐ Other _____

4. RISK ASSESSMENT

- This minor software change will not result in any impact to health and safety, documentation, calibration, or facilities/utilities.
- A partial LEQ will be performed to show that the serial numbers can be programmed into all models. As this is not a parametric test, one test of each model will sufficiently verify the change.
- This change is required to download the current firmware onto the Arc and PKI A-10 RI detector.
- No additional training will be required as this change is transparent to the operator.

EMI/Safety Assessment: No effect on EMI/Safety.

5. FUNCTIONAL ASSESSMENT

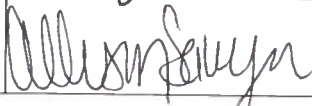
Test Equipment No.: TE83057-1

Test Equipment Name: Download Configure Station

Questions	Yes/No
Does a TEQ need to be created / revised based on the proposed change?	No
Does a TEQ need to be executed based on the proposed change?	No
Does a TEV need to be created / revised based on the proposed change?	No
Does a TEV need to be executed based on the proposed change?	No
Does an LEQ need to be revised based on the proposed change?	Yes
Does an LEQ need to be executed based on the proposed change?	Yes

Comments/Justification:

This equipment was qualified under the LEQ (legacy equipment qualification) model for existing equipment. The LEQ shall be changed to require the testing of one of each model of RI on this test station, verifying serial number programming capability and that no previous functionality is affected on any model. Existing LEQ is located in \\winserv2\TETest Equipment\TE83057 FIN Detector Download\.

Responsibility	Name (Print)	Title	Signature	Date (DD-MMM-YYYY)
Reviewer /Author	Erie Turner	Test Engineer		13-AUG-2015
Reviewer	Matt Franklin	Manufacturing Engineer		13 Aug 2015
Approver (Quality)	Allison Sawyer	Quality Engineer		14 Aug 15

Note: Once approved all items in the Assessment section designated "Yes" are action(s) 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 trained performer (ref. 730001835).