Operational Qualification Tests

User Manual

Serstech, 2021

Introduction

The Operational Qualification ensures that the whole equipment is operating in accordance with Good Manufacturing Practices (GMP) and meets its operational specifications. This is determined by performing a series of operational tests and documenting the results of the tests to ensure all the specifications are met.

To perform Operational Qualification (OQ) for the Serstech 100 Indicator it is needed to perform a series of tests with a Serstech System Testing software (OQ Tests). The Serstech System Testing software has been designed and developed at Serstech (Sweden) and follows specific procedures based on the ASTM International "*Standard Practice for Testing the Performance of Scanning Raman Spectrometers*" (Designation: E1683-02, re-approved 2007).

The Operational Qualification test series verify and record the instruments' ability to meet specified performance criteria after installation and repetitive use. The OQ involves comprehensive testing of the complete system using established conditions and known sample characteristics for specific applications.

A goal of this OQ is to ensure the accuracy and precision of the sold instruments and to uncover potential problems before customers spend valuable time running performance checks following repairs. The Serstech System Testing software - OQ test series has been developed based on the identified critical control points and includes the following tests:

1. Dark background-hot pixels test
2. Resolution test
3. Throughput test
4. x-axis, accuracy, and stability test

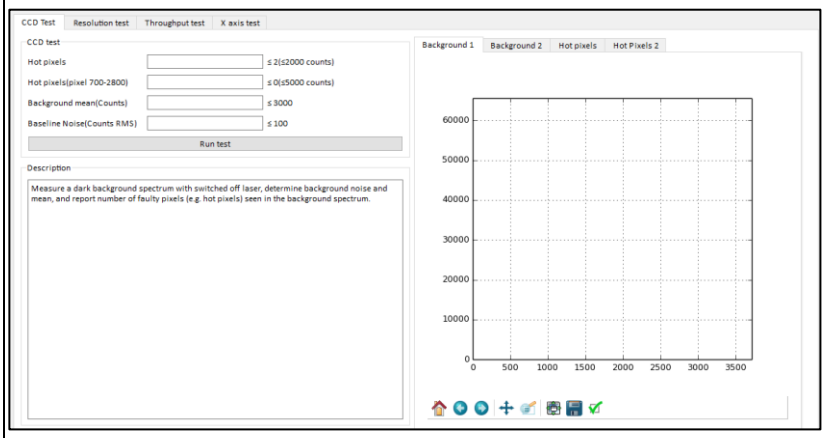
Prior to the testing process, please connect your indicator to the PC via the USB cable. To perform the OQ tests, please follow all instructions listed in sequence below.

Test setup

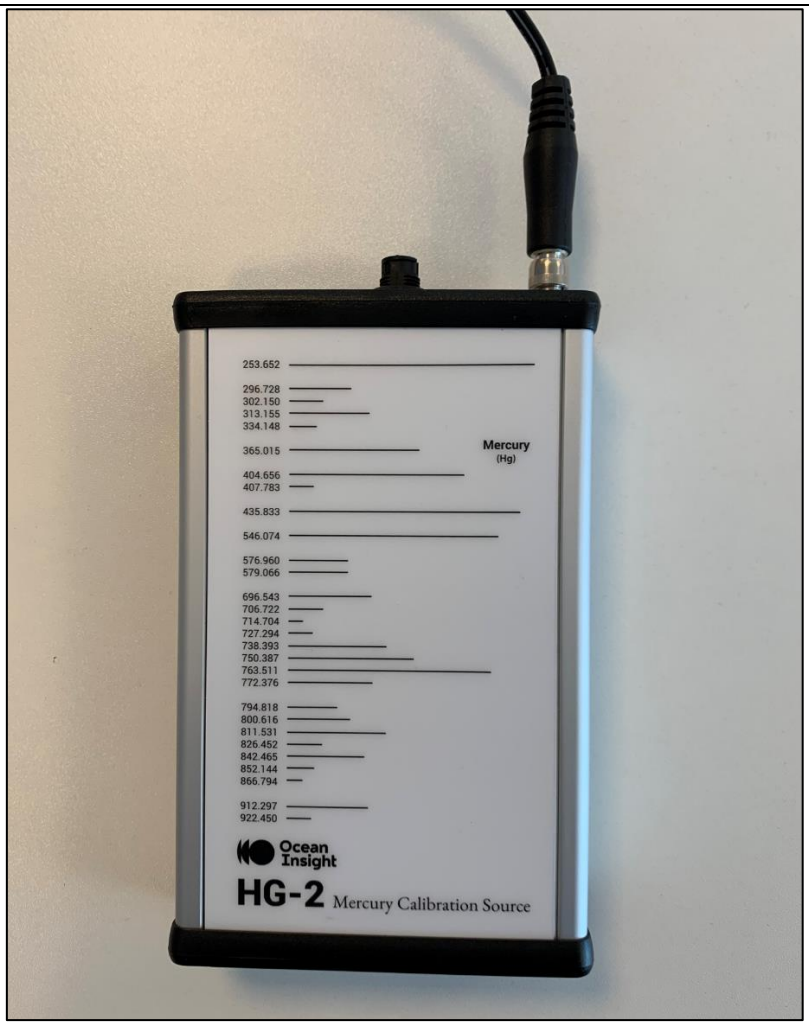
Overview of the components

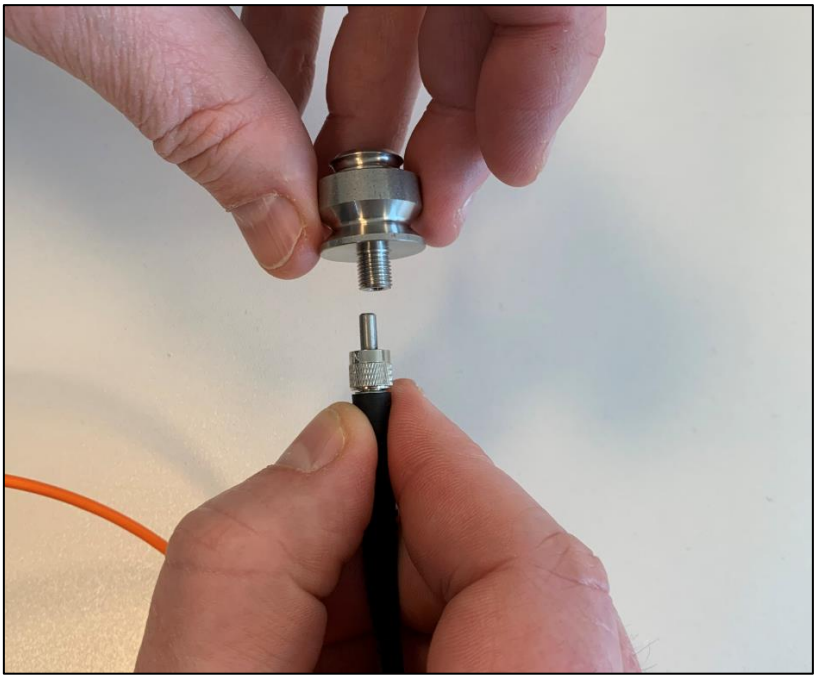
Amount	Description
1	Mercury-Argon arc lamp
1	1 optical fiber attached to optical fiber adapter
1	Sealed vial containing Cyclohexane
1	Vial holder

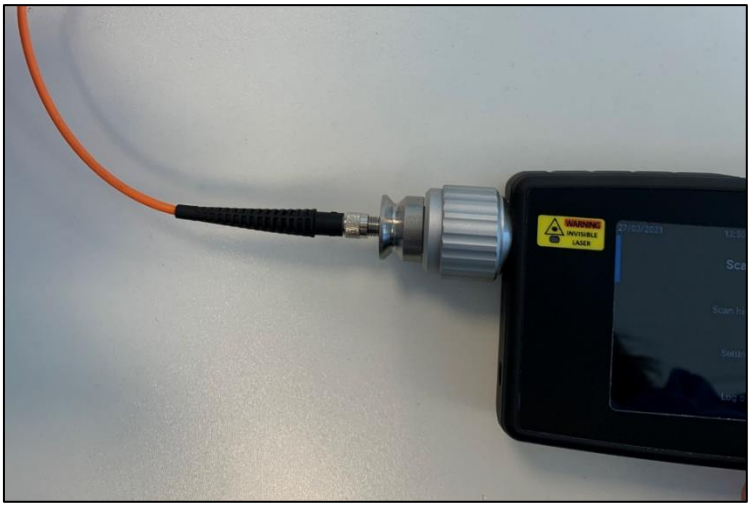
Test steps

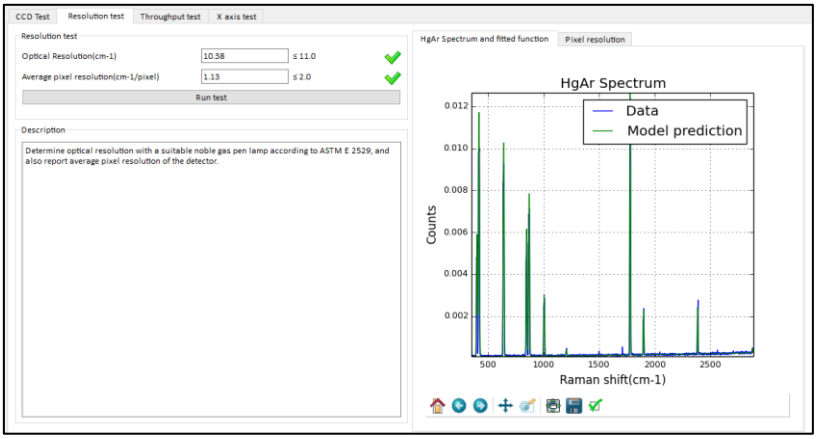
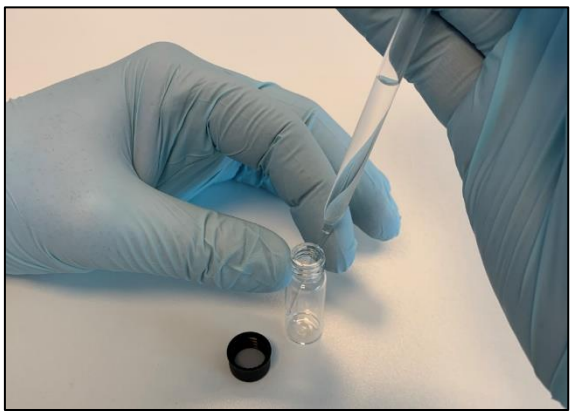
Start the software by double click on the application file and select the OQ Tests.	
Click on the first test which is the CCD Test (Dark background-hot pixels test). Prior to running this test, you will be asked to attach the polystyrene calibration control cap to the instrument's probe. Select "Run test".	

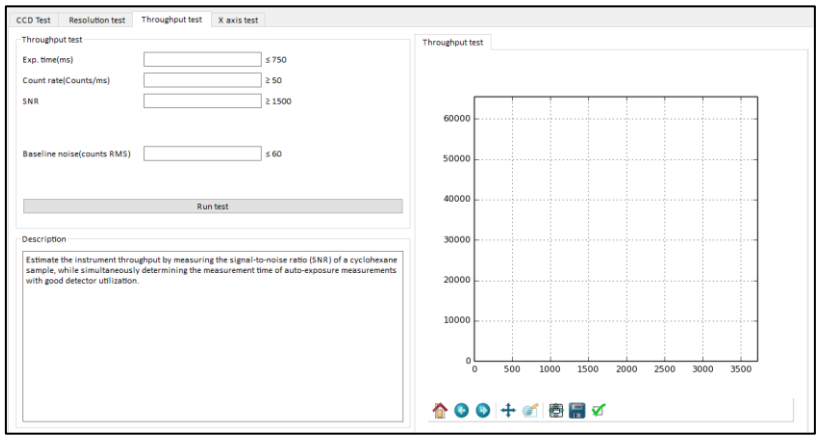
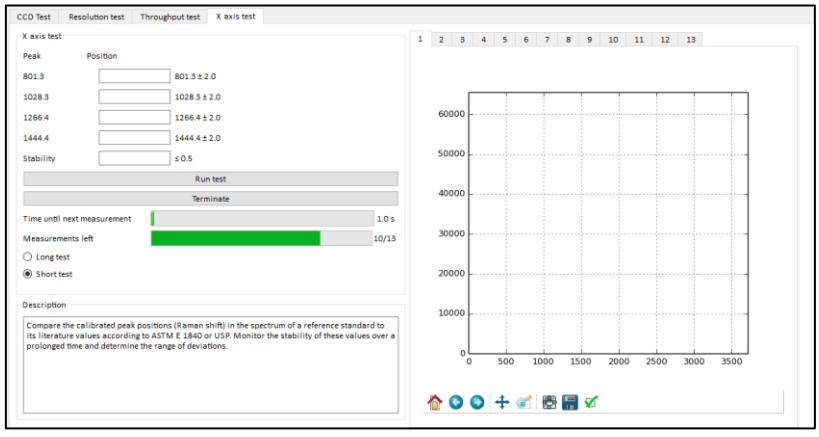
Next test is the Resolution test. Before performing this test, connect the Mercury-Argon to the power outlet.



Connect the optical fiber by attaching it to the lamp fiber output and turn it ON. (Leave it ON for about 2 minutes before running the test).	
Attach the fiber adapter to the optical fiber cable.	

Put the adapter on the indicator's probe.	 

Click on “Run Test” and then “Measure”.	
Next test is the <u>Throughput test</u>. Prepare the Cyclohexane sample by filling a clear vial. Attach the vial holder to the instrument.	 

To run the test, click on “Run test”.	
Final test is <u>the X-axis accuracy and stability test</u>. Keep the vial holder containing the cyclohexane sample attached to the indicator and select, either to perform the “Long stability tests” (60min), or the “Short stability tests” (30min).	

Once the x-axis stability tests are done, the results from all the cyclohexane measurements will be shown on the window. You can navigate to the results by selecting from 1 to 12. You can save the result files in your PC in JSON format (File -> Save result)