



Operational Qualification Tests User Manual Vers.1

As it is mentioned in the Operational Qualification documentation, 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.

In order 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).

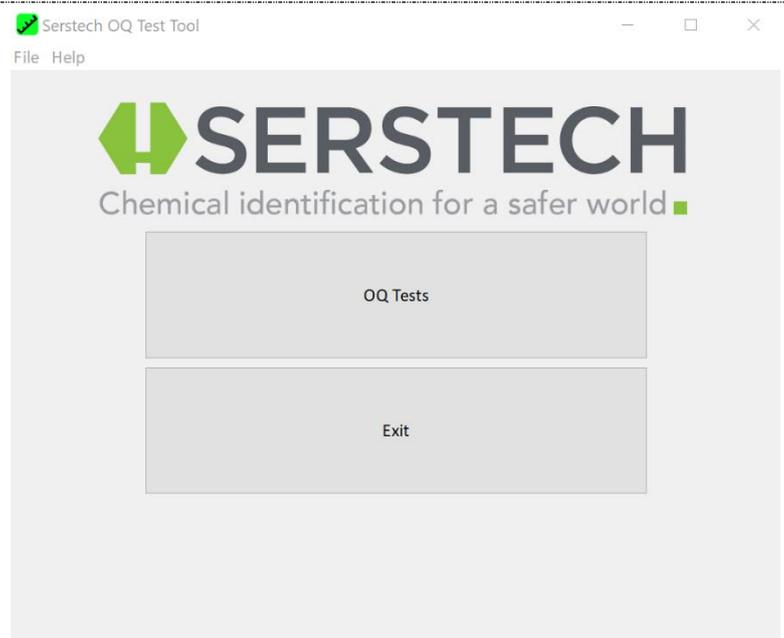
The Operational Qualification test series verify and record the instruments' ability to meet specified performance criteria after installation and repetitive use. The OQ involves comprehensive testing of the complete system using established conditions and known sample characteristics for specific applications.

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

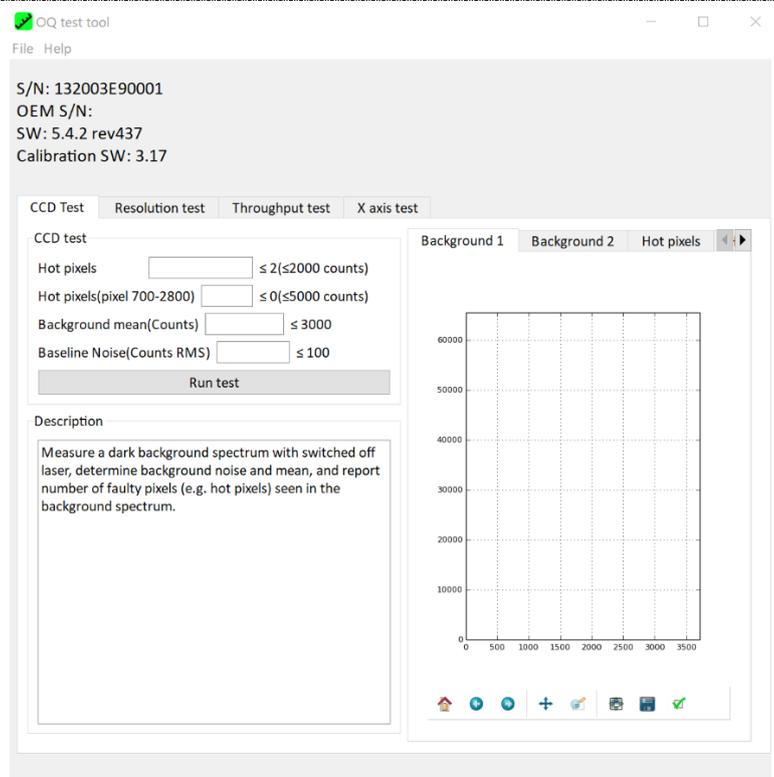
Prior to the testing process, please connect your indicator to the PC via the USB cable. To perform the OQ tests, please follow all instructions listed in sequence below.

1.Start the software and select the OQ Tests.



2.To start performing the OQ tests in the instrument, please click on the first test which is the CCD Test (Dark background-hot pixels test).

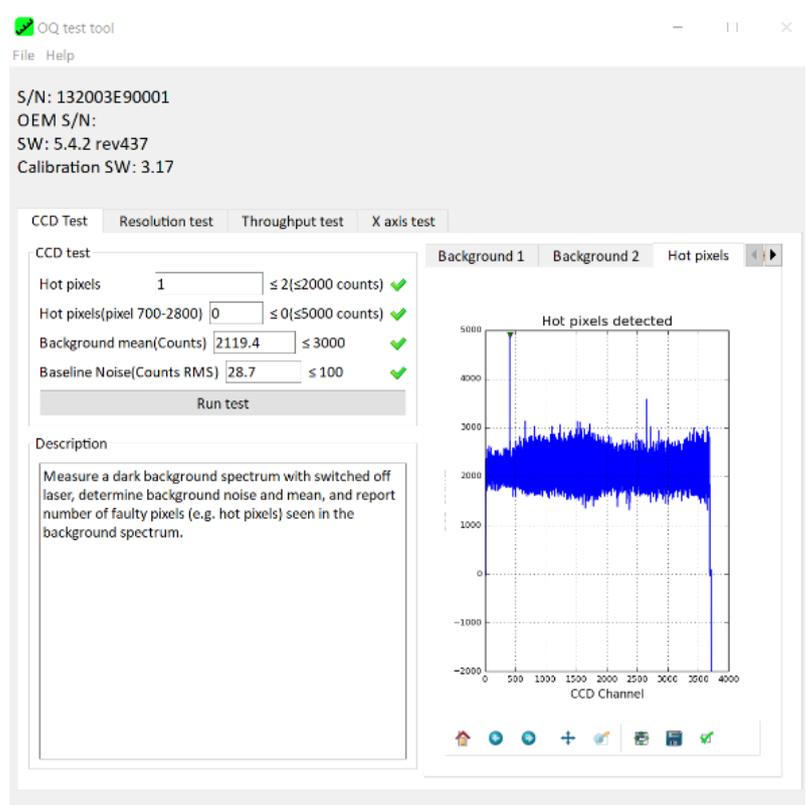
Prior to running this test, you will be asked to attach the polystyrene calibration control cap to the instrument's probe. Once you attach the calibration control cap, please select "Run test".



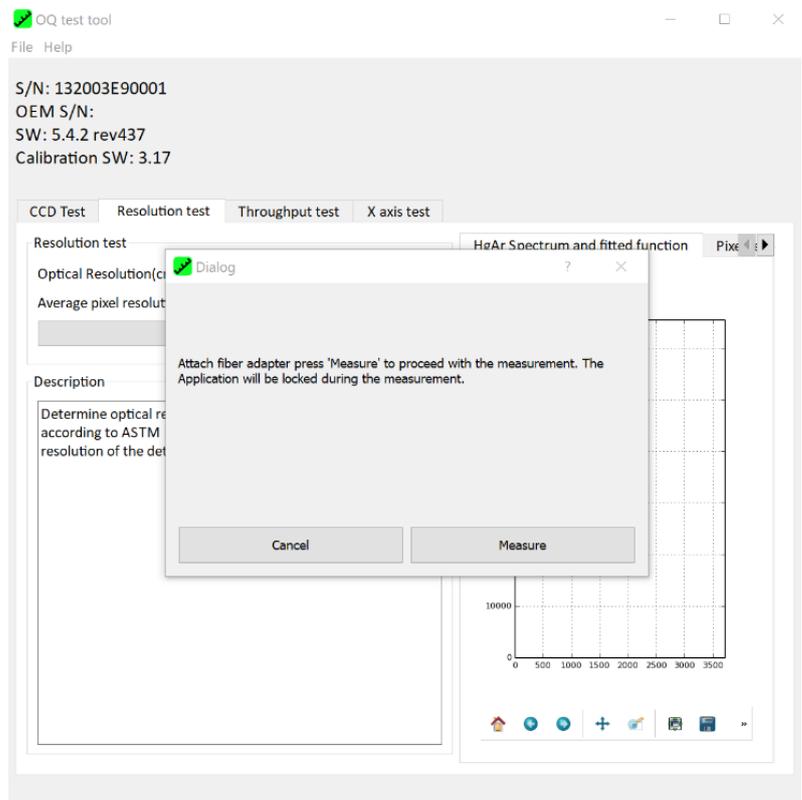
3.Once the test is performed, you will be able to view the results in the screen. You can navigate through the results by selecting Background 1, Background 2, Hot Pixels and Hot Pixels

(pixel 700-2800). The latter Hot pixel is the region used for identification.

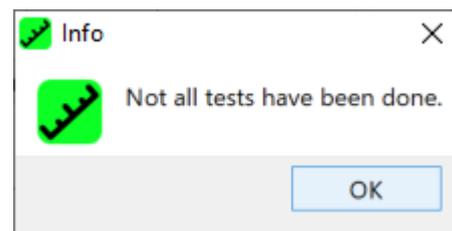
4.To save the results, you can click on “Files” on the top of the software’s window and a JSON file format will automatically be saved in a selected area in your PC.



5.Next in line test is the Resolution test. Keep in mind that before performing this test you need to turn on and leave the Mercury-Argon lamp for 10min. In order to perform this test please, connect the optical fibre that is attached to the lamb to the indicator’s probe and click on “Run Test” and then “Measure”.

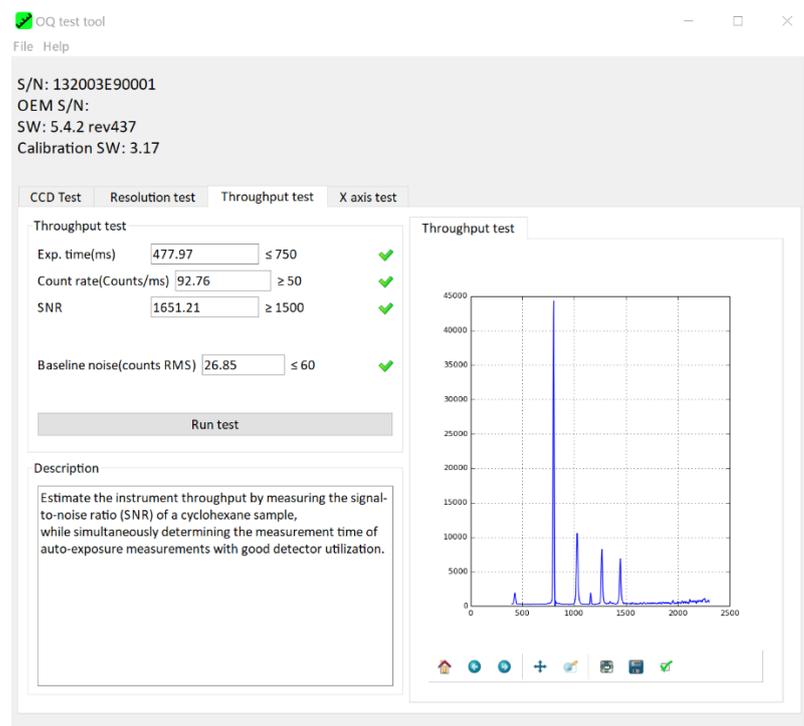


6. Once the test is done, you will be able to view the results. You can save the result files by clicking on "Files" on the top of the software and a JSON file will automatically be saved in a selected area in your PC. The "Not all test have been done." pop-up message will appear, just click OK.



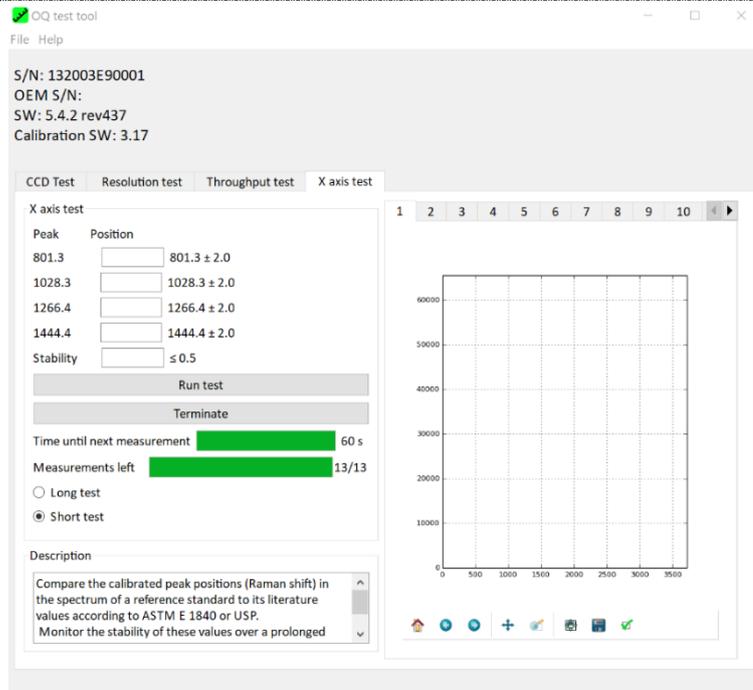
7. Next test is the Throughput test where you need to attach the vial holder containing the cyclohexane sample. To run the test, please click on "Run test".

8. Once the test is done, you will be able to view the results. You can save the result files in your PC in a JSON form.



9. Final test is the x-axis accuracy and stability test. To perform this test, please keep the vial holder containing the cyclohexane sample attached to the indicator and select, either to perform the “Long stability tests” (which takes approximately 60min.), or the “Short stability tests” (which takes approximately 30min.). To obtain the x-axis accuracy maximum and stability tests, we recommend running the long test.

10. 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.



The background features a grey, semi-transparent image of a Serstech device, possibly a handheld spectrometer or analyzer, with a control panel. The panel includes a yellow 'OK' button, a power button, a menu button, and a 'SERSTECH' logo. Overlaid on this is a complex, light-colored molecular structure with spheres and connecting lines, resembling a network or a chemical model.

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