



## V-600 Instrument Validation Software

### Introduction

When utilizing analytical instruments in a controlled or regulated laboratory, it is usually required to perform some manner of performance evaluation of the instrument to ensure that it is operating to stated specifications. The V-600 UV-Vis/NIR instruments are provided with a 'Validation' software package as part of the Spectra Manager II software package. This Validation software provides many performance tests that can be used to evaluate the continued performance of a UV-Vis instrument.

When utilizing a UV-Vis spectrophotometer, it is often desired to obtain a confirmation of the instrument performance by conducting instrument qualification tests. The V-600 Instrument Validation software package contained within the Spectra Manager II software provides a set of packaged analysis functions to verify that the instrument is performing to design specifications. The 'Pass/Fail' criteria are established for each instrument in the V-600 series, based on the performance specifications for each instrument. This software can utilize 'internal' or 'intrinsic' standards and can also include external standards, with performance specifications which are traceable to NIST or some other recognized authority.

Figure 1 outlines the various performance tests that can be selected within the software. The qualification tests that do not require external standards have been checked within the displayed software dialog. The unchecked qualification tests require other external standards and these can be obtained through Jasco by specifying the external standards kit. Specific tests required to conform to standards established by US Pharmacopeia (USP), the European Pharmacopeia (EP) Japanese Pharmacopeia (JP) or the Japanese Industrial Standards (JIS) can be selected, or, individual tests can be selected from the list by the user performing the validation tests.

The tests are easily performed and the only required user input is the listing of the Photometric Accuracy values (Figure 2) and the Photometric Repeatability values from the selected external standards. All other performance tests have specified values applied according to the instrument type and the required instrument parameters are specified dependent upon the individual test procedure (Figure 3). When the tests are initiated, the software performs each test, telling the user when to insert the specific standards for the performance

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tests. At the end of the qualification tests, a detailed report, including pass/fail results, data and instrument conditions can be saved in an electronic format and also printed out for inclusion in an instrument notebook (Figure 4). Although it depends upon internal protocol procedures established by the laboratory, Jasco generally recommends performing these tests on at least a quarterly or semi-yearly basis.

## Conclusions:

The Spectra Manager II software includes an instrument Validation package that can be used to evaluate the performance of a V-600 UV-Vis instrument. These performance tests can be selected and performed as needed by a user to confirm optimum performance of the V-600 instrument.

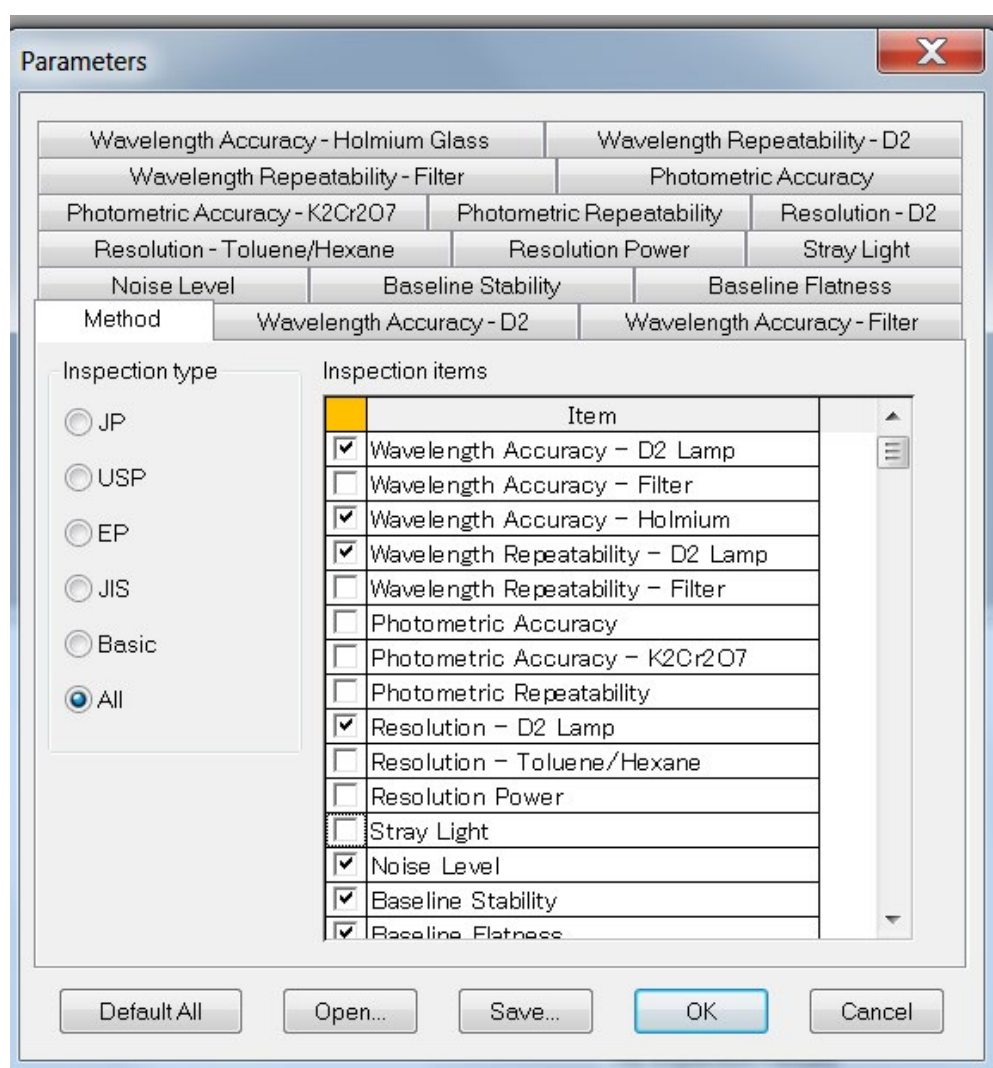


Figure 1: Available performance evaluation tests in the Validation software. Unchecked items require external standards that are not included with the standard instrument.

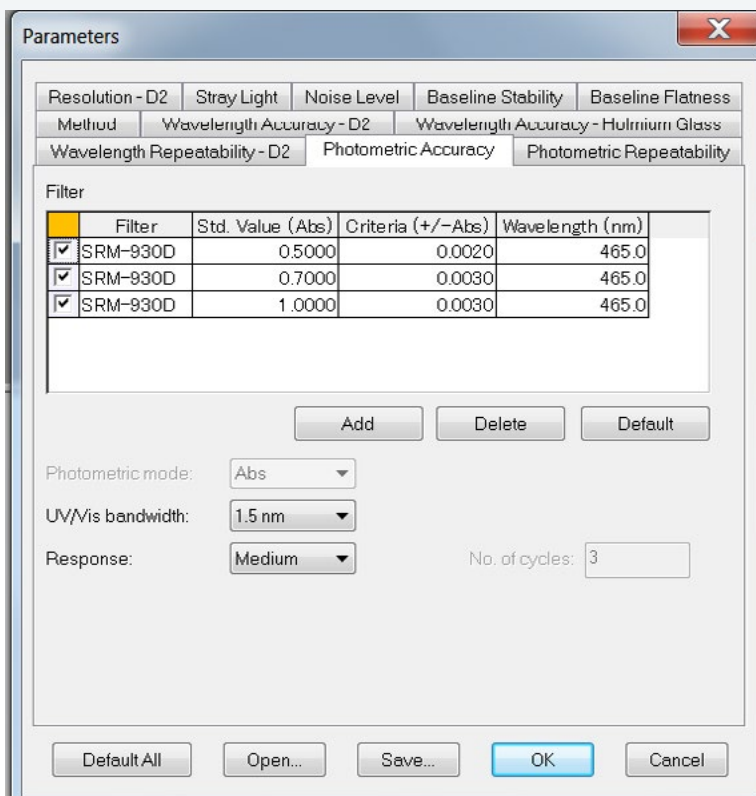


Figure 2: Photometric Accuracy tests. The 'Std. Value (Abs)' and 'Criteria (+/- Abs)' values for each standard are input by the user based on the tested performance values for the standards.

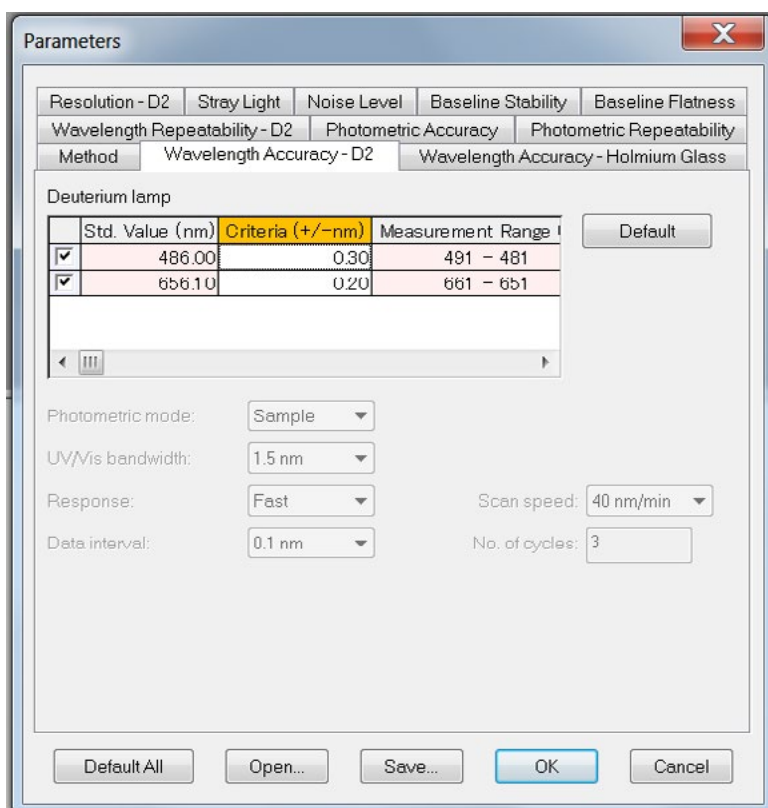


Figure 3: The Wavelength Accuracy performance dialog using the D2 lamp. In this dialog, no inputs from the user are required.

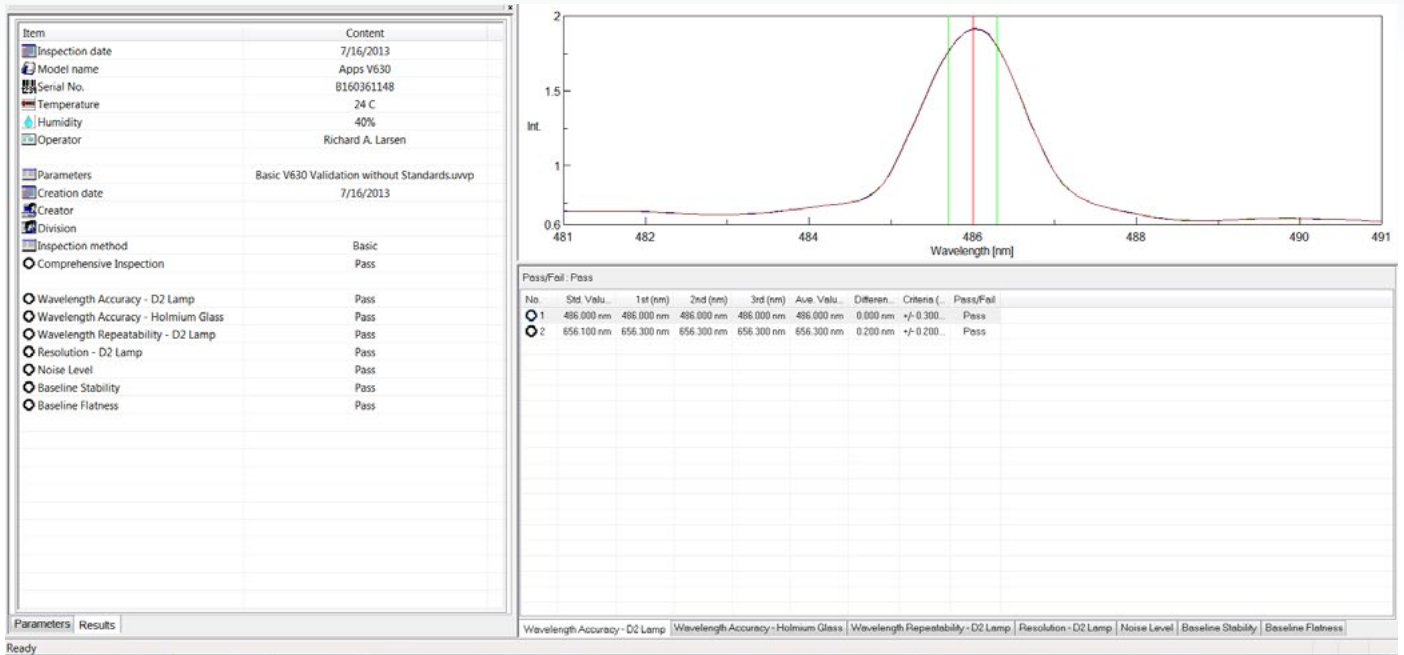


Figure 4: Instrument Validation results for specified 'Basic' tests. All tests have 'Passed' and the results can be saved electronically and/or printed to an attached printer.