



FT/IR-4000/6000 Series 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 FT/IR-4000/6000 instruments are provided with a 'Validation' software package as part of the Spectra Manager II software package. This Validation software provides various performance tests that can be used to evaluate the continued performance of an FT-IR instrument.

When utilizing an FT-IR spectrometer, it is often desired to obtain a confirmation of the instrument performance by conducting instrument qualification tests. The FT/IR-4000/6000 Instrument Validation software 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 FT/IR-4000/6000 series, based on the performance specifications for each instrument. This software utilizes a majority of tests that compare current performance vs. historical data as well as 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 majority of these tests compare the current instrument performance against data collected shortly after installation. Other tests utilize the Polystyrene film that is included with the instrument. In addition, a NIST traceable polystyrene film can be used for some of the performance tests. 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 such as a glass standard (P/N 6713-F429A) which can be obtained from Jasco. The 'Linearity' test requires user-established linearity standards, such as a solution or other quantitative standards. Specific tests required to conform to standards established by US Pharmacopeia (USP), the European Pharmacopeia (EP), the Japanese Pharmacopeia (JP) or Japan 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 collection of the original historical data soon after instrument installation (Figure 2). 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 tests. At the end of the qualification tests, a detailed report can be saved in an electronic format and also printed out for inclusion in the 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.

Conclusion

The Spectra Manager II software includes an instrument Validation package that can be used to evaluate the performance of a FT/IR-4000/6000 UV-Vis instrument. These performance tests can be selected and performed as needed by a user to ensure optimum performance of the FT/IR-4000/6000 instrument.

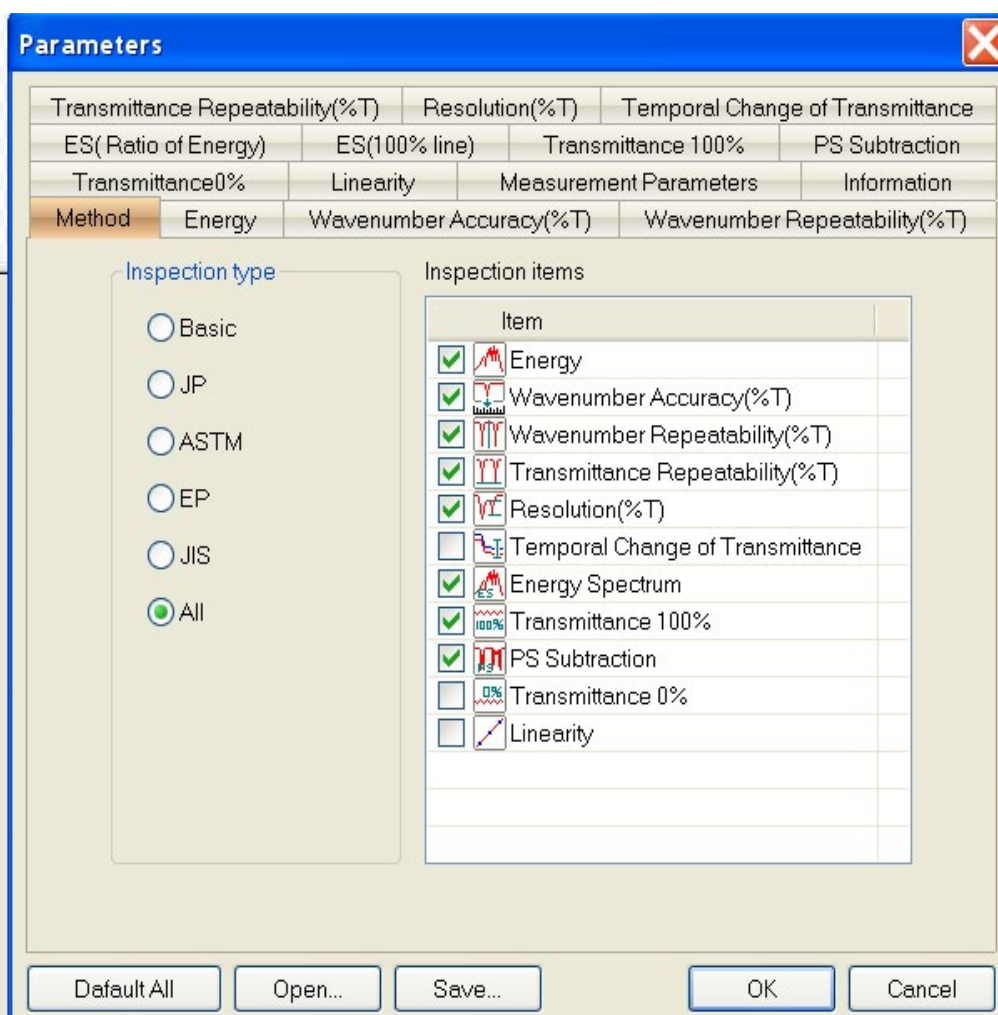


Figure 1: Available performance evaluation tests in the Validation software. Unchecked items require external standards that are not included with the standard instrument.

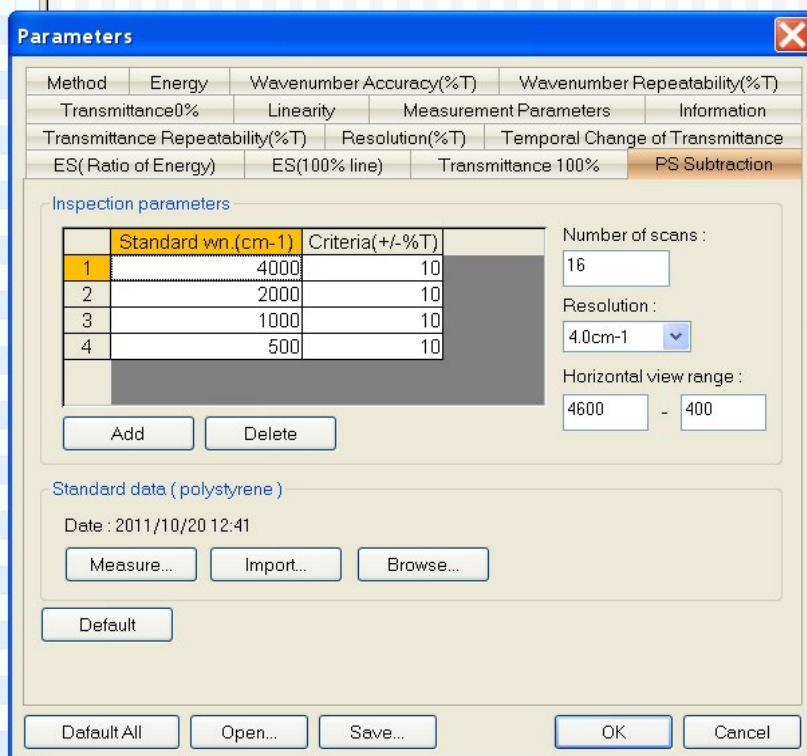


Figure 2: The Polystyrene Subtraction test. The 'Standard data (polystyrene)' can be measured after the instrument installation, or, imported from a collection of a standard polystyrene spectrum.

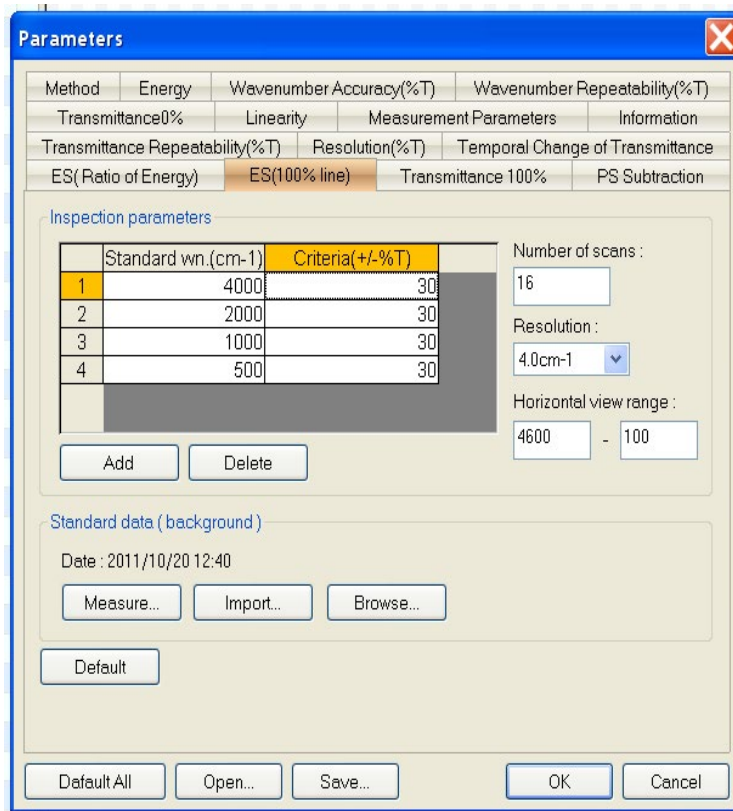


Figure 3: The Energy Subtraction (ES) performance dialog using a previously collected Energy (Background) spectrum. In this dialog, the historical data is also collected or imported by the user.

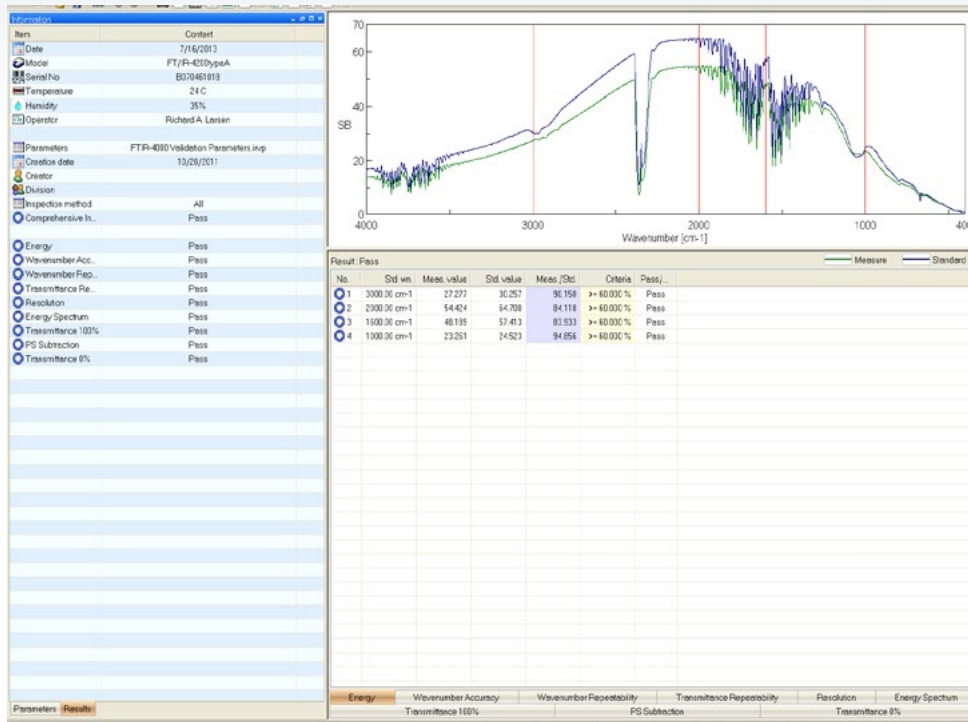


Figure 4: Instrument Validation results for specified tests that do not require the external standards. All tests have 'Passed' and the results can be saved electronically and/or printed to an attached printer.