Application note

ThermoFisher SCIENTIFIC

Performance Verification Tests: How to Set Limits

For Thermo Scientific™ Evolution™ UV-Visible Spectrophotometers, special performance verification (PV) test methods are available within the Thermo Scientific™ Insight™ Pro software. These tests are designed to check a variety of different instrument performance specifications against either given specifications or those outlined by commonly referenced regulating bodies. Specifically, for the Evolution One and Evolution One Plus, tests are available to make sure the instrument specifications fall within the specifications outlined by the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP). Performance tests specific to USP and EP requirements are also available for the Evolution Pro, however this instrument can be tested against Japanese Pharmacopoeia (JP) specifications as well.

Tips for Setting Performance Limits

While the PV tests specific to the pharmacopoeia requirements are built in to the instrument software and require no further modifications, labs which would like to check for alternative acceptance limits can also perform customized tests within the Insight Pro software. These alternative verifications can be common when following standard methods or protocols which outline specific instrument requirements outside of the pharmacopoeia. Because these limits can be adjusted, it is important that any source of variation be considered when setting these limits.

The first source of uncertainty is the inherent variation introduced by the instrument itself. This is outlined as the uncertainty in the given specification (e.g., photometric accuracy, stray light, etc.) of the instrument as per the guaranteed specification.

For many PV tests, this measurement is conducted using a calibrated standard material, such as a potassium chloride solution to test for stray light or a holmium oxide filter for wavelength accuracy. In these cases, it is necessary to consider not only the uncertainty of the instrument but also the uncertainty associated with the standard.

For certified standards, the uncertainty will be reported in addition to the accepted standard value (e.g., wavelength, absorbance, etc.) by the standard manufacturer. When choosing a standard to use, it is best to use “traceable” standards, a classification indicating the standard was measured using an instrument calibrated according to national reference methods (e.g., NIST traceable standards).

When establishing alternative acceptance limits, the sum of the instrument uncertainty and the uncertainty in the standard is the tightest limit that can be applied to the measurement. This is outlined in equation 1, where S_{instru} is the established uncertainty in the instrument and S_{std} is the uncertainty in the standard.

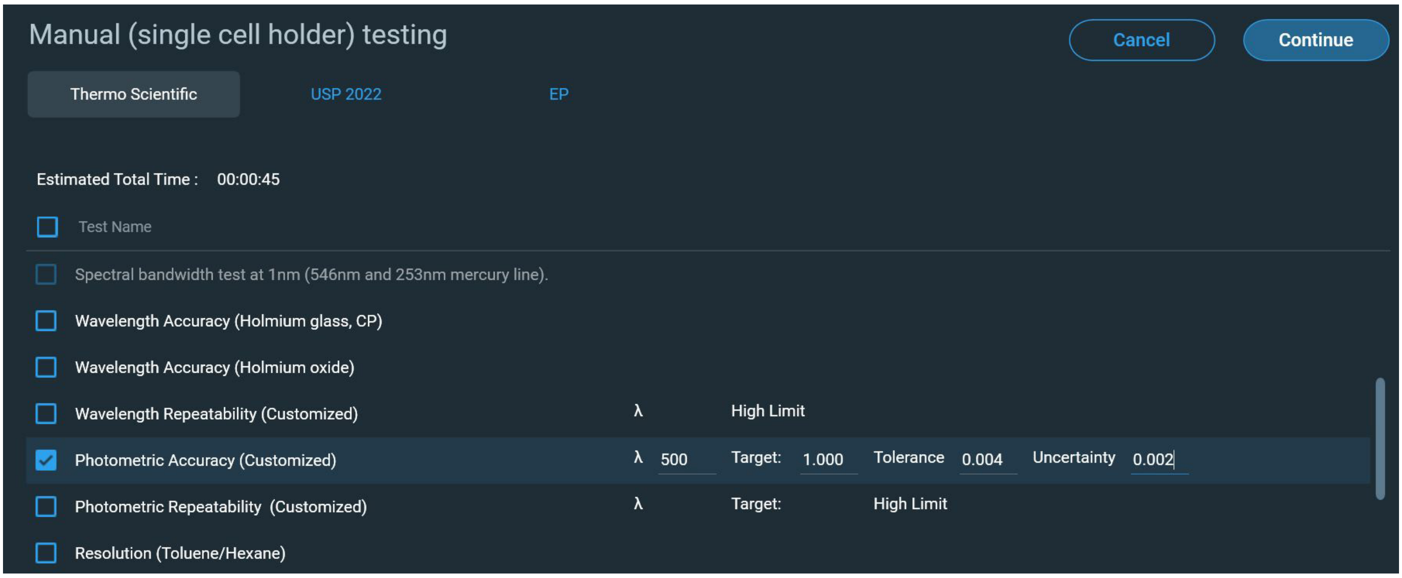
Equation 1.

$$limit = \pm\ (|S_{instru}|+|s_{std}|)$$

For example, if photometric accuracy were to be tested using an instrument with an uncertainty of +/- 0.004 A and the documentation for the standard outlines and uncertainty of +/- 0.002 A, the tightest limit that could be used would be +/- 0.006 A. Note, the calculation in equation 1 will not be needed for PV tests which do not require a standard.

Instead, the minimum acceptance limit will be the instrument uncertainty. Additionally, if a protocol is chosen in which the PV test limit is smaller than the limit calculated in equation 1, then the instrument may not be appropriate or a standard with a smaller uncertainty may be needed.

Regardless of whether stricter regulations are required, it is important to ensure an instrument is consistently meeting the manufacturer’s specifications. Key performance metrics can be assessed, either through pre-defined methods or customized PV tests, to ensure the data collected can be trusted. By accounting for both the instrument and standard uncertainty, errors in these verification methods can be more easily avoided.



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