Selecting a Performance Verification Method for the Evolution 220 Spectrophotometer

GEX Doc# 100-221

1.0 PURPOSE

Many options are available for Performance Verification (P.V.) testing of the Evolution 220 Spectrophotometer. Users may find it difficult to determine what P.V. method to use, which are 'required', which are 'recommended' by GEX or Thermo Fisher Scientific, and most importantly what is best for the user's application. GEX document 100-221 discusses the available options, and provides a method to assist users in making a decision to fit their needs.

2.0 BACKGROUND

GEX outlined two distinct types of Performance Verification (P.V.) testing related to the monitoring of the Evolution 220 Spectrophotometer, used as part of the DoseControl dosimetry system. The terms "Short P.V" and "Complete P.V." are defined in *GEX Doc# 100-271, Evolution220 Performance Verification Procedure*.

3.0 SELECTION OF P.V. TYPES AND FREQUENCIES

The absolute lowest risk position for any business is to execute a complete verification of performance using all available tests for each spectrophotometer before each use of the instrument. However, such a practice is not practical for any users, given the value of time and internal resources for the business. The second lowest risk position is to perform some type of daily check of the spectrophotometer (or maybe multiple times per day), in addition to performing regularly scheduled complete performance verification. The highest risk position is to check the performance every thirty (30) days or more.

Therefore, the user needs to make a risk assessment based on the importance of the measurements to the overall quality of the product/process to which the measurements pertain, and balance the operational needs of the business in accordance with the level of risk. Only then can a determination of the frequency of both 'Short' and 'Complete' P.V. test methods be completed.

GEX recommends that all dosimetry users in medical device, pharmaceutical, food, or any other regulated applications should perform Short P.V. testing every 24 hours at a minimum. Such a practice will ensure at least daily that the instrument is performing within specification at a single, commonly used absorbance value at a single wavelength near to that normally used to measure dosimeters. If that policy is enacted, the user still needs to perform Complete P.V., and the recommended interval is every three (3) months or ninety (90) days, which is the longest period that can be recommended for a Complete P.V. In general, such a policy will limit the risk period to no more than 24 hours.

The following issues may warrant a loosening of the requirements stated above:

- Dosimetry is not being used in a regulatory application.
- Metrology staff or equivalent within the user's company has defined standardized criteria based on risk that is not as stringent as that recommended by GEX.

In the cases above, loosening the Short P.V. (daily check) process to a couple times per week (2 times per week), or not at all, is one option. The other is performing Complete P.V. only once or twice per year.

In summary, the decision lies with the user, and GEX makes clear recommendations about the process the user should engage in when making a determination. Users are encouraged contact GEX Customer Service to discuss P.V. frequencies and types for their business or any related technical details.

4.0 OVERVIEW OF METHODS FOR COMPLETE P.V.

4.1 Onboard Testing using Thermo Insight Software

The instrument can perform the following five (5) tests without any optical filters, and using the Performance Verification feature of the Thermo Insight software:

- *Wavelength Accuracy* - using internal Xenon lamp at approximately 542nm.
- *Wavelength Repeatability* - using the internal Xenon lamp at approximately 542nm.
- *Photometric Noise (0 A)* - the detector captures noise in the input signal at 260nm output from the Xenon lamp.

- *Baseline Flatness* – an automated standard test of the flatness of a baseline (0 A) by scanning from 200-800nm with smoothing of the results.
- *Photometric Drift/Drift* – Automated capture of absorbance value drift over a one-hour period.

4.2 Calibration Verification Carousel

The following tests are available with the NIST version of the CVC. Refer to applicable Thermo documentation for details of tests available with other versions.

- Wavelength Accuracy with traceable Holmium Oxide filter at each of the following nominal wavelengths: 287nm, 361nm, 536nm.
- Wavelength Repeatability with traceable Holmium Oxide filter using standard deviation of multiple measurements of the 361nm peak.
- Stray light at 220nm and 340nm using Thermo filters (non-traceable).
- Absorbance Accuracy with traceable Potassium Dichromate filter at 235nm, 257nm, 313nm 350nm, and 546.1nm.
- Photometric (absorbance) Repeatability with traceable Potassium Dichromate using standard deviation of multiple measurements of the 546nm peak.

4.3 Mercury Lamp Accessory

Wavelength Accuracy testing at each of the following wavelengths: 254nm, 365nm, 436nm, 546nm, 872 nm.

4.4 Spectronic Standards Set 2

The following tests are available with the Spectronic Standards Set 2. Refer to applicable Thermo documentation for details.

- Photometric Accuracy testing at any of the following nominal absorbance values: 0.3 A, 0.5 A, 1.0 A, 1.5 A.
- Photometric Accuracy testing at any of the following nominal wavelength values: 400nm, 525nm, 782nm.
- Stray Light testing that is available with the Spectronic Standards Set 2 is not mandatory because any influence of stray light would be detected by the two tests listed above when the spectrophotometer is used at the wavelengths and absorbance ranges associated with the measuring optical dosimeters.

5.0 SELECTION OF METHOD FOR COMPLETE P.V.

5.1 General Considerations

Four (4) different methods exist for performance verification that are outlined in the procedure above. Users may consider using one method, all methods, or any combination of the available methods. Selecting what is best can be a bit overwhelming. The key considerations are:

- Most important: are you planning to take advantage of the Performance Verification Module of the DoseControl software to execute 'daily' checks? If the answer is *yes*, then the frequency of complete P.V. testing can be reduced (e.g. every 90 days). If the answer is *no*, then P.V. should be performed more frequently (e.g. every 30 days).
- Next, knowing the answer to the question above, consider who is going to perform the P.V. at the facility. Are they a dedicated metrology resource or is it something that routine operator will be expected to perform in their spare time? This input helps determine how much of a factor the time and complexity of the execution factor into the decision. You may not want the routine operator to have to manage disassembling the dosimeter holder system, for example.
- In addition, there should be some consideration of value for time spent. If you can have more confidence with very little extra effort because of implementing an additional method, then the value is high. If risk that the instrument is out of specification is not reduced by performing the testing, then is it valuable and why perform it?
- Finally, and most importantly, the consideration of what testing is required to adequately test the instrument. GEX believes that for the application of measuring dosimeters in the visible light spectrum the execution of wavelength and photometric accuracy are the only mandatory elements. GEX also believes that when the manufacturer offers additional testing that is simple to execute then the user should take advantage of that opportunity.

5.2 Specific Considerations

Be sure the read the description of each method described in Section 6 above and then read the evaluation of each below.

A. Onboard Testing using Thermo Insight Software

A.1 This testing would be complete except it lacks two key characteristics:

A.1.1 There is no photometric testing which is mandatory for complete performance verification.

A.1.2 The wavelength tests are not traceable to a national standard.

A.2 The value of these tests is that they can be performed with the GEX Dosimeter Holder System installed.

A.3 These tests are considered non-mandatory, but with the exception of the Drift test, they offer a very fast and effortless way to perform additional P.V. checks of the instrument including wavelength verification.

A.4 Given the Wavelength Accuracy specification of ±0.8nm of the Evolution 220, the Xenon lamp testing available here is an exceptional tool despite the fact that Xenon emission lines are not classified as a primary standard.

B. Calibration Verification Carousel (CVC) Testing

B.1 The calibration carousel is a near perfect tool for complete performance verification, but it also lacks two key characteristics:

B.1.1 The wavelength accuracy testing maximum value is approximately 536nm which is below the measurement wavelength of B3, FWT and Harwell Perspex dosimeters that the DoseControl system is used to measure.

B.1.2 The device can only be used by removing the GEX Dosimeter Holder System.

B.2 GEX does not recommend using this device more frequently than every 90 days due to the inconvenience of removing the holder system.

B.3 GEX recommends that the user must also perform additional wavelength accuracy testing using the Mercury Lamp or using the Spectronic Standards wavelength filter or equivalent to verify a value above the measurement wavelength for the dosimeters.

C. Mercury Lamp Accessory Testing

C.1 The mercury lamp is a great tool for comprehensive verification of wavelength accuracy and is convenient because it can be executed with the dosimeter holder system installed.

C.2 It has no re-calibration costs because it is a primary standard and no re-certification is ever required to continue using it.

D. Testing using Spectronic Standards Set 2 (or equivalent)

D.1 This method generates a complete performance verification of the instrument of the two key parameters of Photometric and Wavelength Accuracy (and stray light if desired).

D.2 All testing is completed with the GEX dosimeter holder system installed in the Evolution 220. No removal required.

D.3 The process is labor intensive (20-30 minutes maximum).

D.4 Utilizes a revision protected MS Excel spreadsheet for reporting results.

6.0 RECOMMENDATIONS SUMMARY

6.1 GEX recommends that daily performance checks are implemented via the module in the DoseControl software, which will check a single point of Photometric and Wavelength accuracy at a frequency no greater than every 24 hours.

6.2 GEX recommends a complete performance verification using either:

6.2.1 A CVC in combination with the Mercury Lamp to run all available tests with those accessories every ninety (90) days.

6.2.2 A Spectronic Standards Set to perform the testing every ninety (90) days.

6.3 We recommend that all onboard testing is not required unless there is cause.

6.3.1 If problems are experienced with the instrument, or if it is removed from service for major maintenance such as Xenon lamp replacement, test all five (5) onboard parameters before executing the complete P.V.

7.0 RELATED DOCUMENTS

- GEX Doc #100-113, Spectronic Standards Set 2 - Product Specifications and Usage (PSU)
- GEX Doc #100-156, Evolution 220 Spectrophotometer – Product Specifications and Usage (PSU)
- GEX Doc #100-157, P4310 Mercury Lamp Accessory – Product Specification and Usage (PSU)
- GEX Doc #100-158, P4320 Calibration Validation Carousel (CVC) – Product Specification and Usage (PSU)
- GEX Doc# 100-271, Evolution220 Performance Verification Procedure

8.0 REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
05/24/19	Initial release.	A