

GENESYS 30 Performance Verification GEX Doc# 100-270

1.0 PURPOSE

To provide a method for performance verification testing of the GENESYS 30 Spectrophotometer, using the Spectronic Standards Set 2.

<u>NOTE:</u> Users typically employ the term 'calibration', but the appropriate terminology for the process of testing that a spectrophotometer is performing within manufacturer specifications is called, 'Performance Verification' (P.V.).

2.0 DEFINITIONS

- 2.1 <u>Complete Performance Verification (Complete P.V.)</u>: the process of testing the spectrophotometer using a full battery of tests, including wavelength and photometric accuracy testing, at three (3) or more points to verify the instrument is performing within the tolerances of the published specifications for that instrument.
- 2.2 <u>Short Performance Verification (Short P.V.)</u>: the process of testing the wavelength and/or photometric accuracy at one point as an interim method performed between Complete P.V. of the instrument.
 - 2.2.1 NOTE: A Short P.V. test performed at a frequency of 24 hours (this is synonymous with terms such as "daily verification" or "daily check"), and reduces the risk that measurement instruments give erroneous results between the typically longer cycle of Complete P.V. tests.

3.0 FREQUENCY

- 3.1 Complete P.V.
 - 3.1.1 Thirty (30) days ±15 days
 - 3.1.1.1 Ninety (90) days ±15 days is the suggested frequency if performing daily verification (e.g. every 24 hours or less) using a Short P.V. method in addition to the Complete P.V.
 - 3.1.2 After any of the following events:
 - Installation;
 - Location change;
 - After instrument servicing from Thermo;
 - Instrument is jarred or dropped;
 - Before and after lamp replacement.
- 3.2 Short P.V.
 - 3.2.1 Frequency is dictated by user policy (e.g. "every 24 hours at minimum"), and must be justified by the user based on risk assessment. A frequency not to exceed every 24 hours is recommended.
 - 3.2.2 Users that employ a Short P.V. method on a short-term frequency may justify a longer period between the execution of Complete P.V. of the instrument (see 3.1.1.1).
 - 3.2.3 Currently no Short P.V. method is integrated with the DoseControl software for the GENESYS 30 spectrophotometer. User's must implement their own, manual method if they wish to have this or switch to the Evolution 220 spectrophotometer.

NOTE: GEX does plan to develop a Short P.V. method for the GENESYS 30 spectrophotometer, integrated into the DoseControl software. We hope this will be available by Jan 1, 2021.

3.3 External cleaning, replacing a PC, replacing the power cable, or replacing the USB cable that connects the spectrophotometer to a PC *are not* events that require any type of P.V. testing.

4.0 MATERIALS

4.1 GEX Part# P4220 – Spectronic Standards Set 2 and accompanying Calibration Certificate.



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<u>Note</u>: This procedure may be modified to use the original Spectronic Standards Set of the same GEX part number or an equivalent set from another manufacturer.

- 4.2 GEX Part# P4400 GENESYS 30 Spectrophotometer
- 4.3 GEX Part# P4405 GENESYS 30 dosimetry holder system baseplate with beam tubes
- 4.4 GEX Part# P4420 WINdose dosimeter holder (receiver only)
- 4.5 GEX Doc# 100-269 Spectrophotometer Performance Verification Forms

5.0 SETUP & DESCRIPTION OF TESTS

<u>NOTE:</u> Some users may find that the Performance Verification test method supplied onboard the GENESYS 30 is sufficient instead of this protocol. See the Thermo Scientific GENESYS 30 User Guide for details.

- 5.1 The objective of this testing is to determine if the measured photometric and wavelength results on the user's GENESYS 30 lie within an acceptable range.
- 5.2 The acceptable range is derived by adding/subtracting (±) the summation of the instrument specification and the reference standard's uncertainty to the certified value for a given reference standard.
- 5.3 First, the user needs to enter pertinent information from the calibration certificate for the Spectronic Standards into *GEX Doc# 100-269(a)*, GENESYS 30 *Performance Verification Form*.
 - 5.3.1 The form calculates the upper and lower limits for each test by calculating the allowable variability from the sum of the uncertainty of each standard plus the instrument specification for each test. The specifications and summation method are given in the Thermo Scientific Spectronic Standards Set 2 User Guide
 - 5.3.2 <u>NOTE:</u> If preferred this information can be entered in advance by a senior person and the form protected so that a technician can simply enter measurement results later. The acceptance criteria is the same for any GENESYS 30, so only one form is required to be pre-filled for each Spectronic Standards Set 2 on site. The form should be reviewed and updated each time the standards set is recertified.
 - 5.3.3 <u>NOTE:</u> GEX does not recommend that there is a need to perform the Stray Light testing that is available with the Spectronic Standards Set 2 if using B3 or FWT dosimeters due to their peak absorbance being above the range where Stray Light test standards are tested and above where the impact of Stray Light is of concern to the user.
- 5.4 First, complete all of the information in cells D2 through D8.
- 5.5 Next, configure the spreadsheet with information from the Calibration Certificate for Photometric Accuracy.
 - 5.5.1 There are nominal 50%T, 30%T, 10%T, and 3%T Standards for Photometric Accuracy testing. Each standard is labeled with a serial number ID that is referenced on the Calibration Certificate.
 - 5.5.2 Each standard is certified at multiple wavelengths. This procedures tests at 465nm (at the bottom) and 590nm (at the top) to bracket the B3 wavelength of measurement of 552nm. If measuring other dosimeters, adjust this procedure as necessary using the values at other certified wavelengths.

Relevant					
Performance Specifica-	Spectrophotometer	Photometric Accuracy	Photometric Repeatability	Wavelength Accuracy	Stray Light
tions for	SPECTRONIC 200E	±0.01 A at 0.3 A ±0.05 A at 1.0 A	±0.3%T at 50%T	±2 nm	<0.2%T (SRE 400)†
Scientific	GENESYS 20	±0.003A from 0.0 to 0.3A 1.0% from 0.301A to 2.5A	Not Stated	±2.0 nm	<0.1%T (SRE 400)
Spectropho- tometers	GENESYS 30	±0.002A (0 - 0.3A) 0.5% of ABS reading (0.301A - 2.5A)	± 0.002 A	± 2 nm	<0.1%T at 340nm and 400nm



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To establish pass/fail criteria for testing spectrophotometers, add the uncertainty printed on the calibration report for the standard to the specification for the instrument shown in the table above.

FIGURE 1: Excerpts taken from the Thermo Scientific Spectronic Standards Set 2 User Guide

5.5.3 Enter the ID, Certified Value, and Uncertainty of each of these standards at 465nm (from the standard's Calibration Certificate) into the specified spreadsheet cells according to the table below:

Standard Type	Standard ID	Certified Value	Uncertainty
50%T	F4	G4	H4
30%T	F5	G5	H5
10%T	F6	G6	Н6
3%T	F7	G7	H7

5.5.4 When complete it should look like this example below:

	Photometric Performance at 465nm (values are in absorbance units)							
1	Standard ID	Certified Value	Uncertainty	G30 Spec	Lower Limit	Upper Limit	Value As Found	Pass/Fail
	SA0799-1	0.2889	0.0026	0.0020	0.2843	0.2935		FAIL
	SA0799-2	0.4765	0.0026	0.0024	0.4715	0.4815		FAIL
	SA0799-3	1.0334	0.0031	0.0052	1.0251	1.0417		FAIL
U	SA0799-4	1.5356	0.0070	0.0077	1.5209	1.5503		FAIL

5.5.5 Enter the ID, Certified Value and Uncertainty of each of these standards at 590nm (from the standard's Calibration Certificate) into the specified spreadsheet cells according to the table below:

Standard Type	Standard ID	Certified Value	Uncertainty
50%T	F10	G10	H10
30%T	F11	G11	H11
10%T	F12	G12	H12
3%T	F13	G13	H13

5.5.6 When complete it should look like this example below:

	Photometric Performance at 590nm (values are in absorbance units)							
1	Standard ID	Certified Value	Uncertainty	G30 Spec	Lower Limit	Upper Limit	Value As Found	Pass/Fail
	SA0799-1	0.3004	0.0026	0.0020	0.2958	0.3050		FAIL
	SA0799-2	0.5017	0.0026	0.0025	0.4966	0.5068		FAIL
	SA0799-3	1.0968	0.0031	0.0055	1.0882	1.1054		FAIL
V	SA0799-4	1.6306	0.0070	0.0082	1.6154	1.6458		FAIL

- 5.5.7 The preparation of the form is complete for photometric accuracy testing.
- 5.6 Next, configure the spreadsheet with information from the Calibration Certificate for Wavelength Accuracy, using the 4 nm SBW.
 - 5.6.1 One standard is used for Wavelength Accuracy testing; it is labeled with a serial number ID that is referenced on the Calibration Certificate.
 - 5.6.2 The standard is certified at (3) three wavelengths. This procedures tests at a nominal 525nm (at the bottom) and 782nm (at the top) to bracket the B3 wavelength of measurement at 552nm. If measuring other dosimeters, then adjust this procedure as necessary.
 - 5.6.3 Enter the ID, Certified Value and Uncertainty of the wavelength standard at the nominal 525nm wavelength (from the standard's Calibration Certificate) into the cells F20:F22.
 - 5.6.4 Enter the ID, Certified Value and Uncertainty of the wavelength standard at the nominal 782nm wavelength (from the standard's Calibration Certificate) into the cells K20:K22.
 - 5.6.5 Adjust the wavelength values in H17:H31 and M17:M31 to evenly space the test wavelengths around the certified value if the default values are not already spaced evenly.



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Wavelength Accurac	y Test at 525nm (nominal)	Wavelength Acc	Wavelength Accuracy Test at 782nm (nominal)		
	Measured Data (A) (nm)		Measured Data (A)	(mm)	
	515			770	
	516			771	
	517			772	
Standard ID: SA0799	-5 518	Standard ID:	SA0799-5	773	
Certified Value (nm): 521.8	519	Certified Value (nm):	777.2	774	
Uncertainty (nm): 1.0	520	Uncertainty (nm):	1.0	775	
G30 Spec (nm) 2.0	521	G30 Spec (nm)	2.0	776	
Lower Limit (nm): 519.0	522	Lower Limit (nm):	774.0	777	
Upper Limit (nm): 525.0	523	Upper Limit (nm):	780.0	778	
	524			779	
Peak As Found (nm): #N/A	525	Peak As Found (nm):	#N/A	780	
Pass/Fail: #N/A	526	Pass/Fail:	#N/A	781	
	527	_		782	
	528			783	
	529			784	

- 5.7 Signatures
 - 5.7.1 Enter the names and titles of persons that will perform and review the test underneath the signature lines.

6.0 PROCEDURE

- 6.1 Before beginning testing ensure the following:
 - 6.1.1 The GENESYS 30 powered on with no dosimeter holder in the sample compartment;
 - 6.1.2 The sample compartment lid was closed during the warm up period;
 - 6.1.3 The instrument has been left powered on for a minimum of 30 minutes.
- 6.2 <u>NOTE:</u> The sample compartment lid must be closed before taking each reading during this procedure because the acceptance criteria is derived from specifications established by Thermo with the lid closed.
- 6.3 Insert the GEX Part# P4420 WINdose dosimeter holder <u>receiver</u> into the baseplate and ensure that it is fully and correctly seated.



6.3.1 The glass filters are designed to fit into the holder in only one direction; with the glass facing to the right.





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- 6.4 This procedure is executed using form *GEX Doc# 100-269(a), GENESYS 30 Performance Verification Form.* The form will provide Pass or Fail results for each test.
- 6.5 Open the form and complete all of the information in cells D2 through D8.

6.6 Photometric Accuracy Testing

- 6.6.1 Testing at 465nm
 - 6.6.1.1 Select the Live icon on the GENESYS 30 display.
 - 6.6.1.2 Set the wavelength to 465nm in the ABS mode.



- 6.6.1.3 Clear any sample and close the sample compartment lid.
- 6.6.1.4 Press the yellow '0.00' soft key to zero the instrument.



- 6.6.1.5 Carefully remove the Standard ID XXXXX-1 labeled 50% from the Spectronic Standards case and insert it into the GENESYS 30.
 - 6.6.1.5.1 Close the lid of the sample compartment.
 - 6.6.1.5.2 Wait for the value to stabilize.
 - 6.6.1.5.3 Record the result in cell L4.
 - 6.6.1.5.4 Remove the standard
- 6.6.1.6 Repeat 6.6.1.4 through 6.6.1.5.4 for the standards XXXXXX-2 (30%T), XXXXXX (10%T), and XXXXXX-4 (3%T) and record the values in cells L5:L7.
- 6.6.2 Testing at 590nm
 - 6.6.2.1 Change the wavelength setting to 590nm
 - 6.6.2.2 Repeat the steps in 6.6.1 at this new wavelength setting and record the results in L10:L13.

6.7 Wavelength Accuracy Testing

- 6.7.1 Testing at 525nm (nominal value)
 - 6.7.1.1 Select the Scan icon on the GENESYS 30 display.





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- 6.7.1.2 Set the testing to use the absorbance mode.
- 6.7.1.3 Use the arrow soft-keys to navigate to the lower limit and enter 500 nm and then to the upper limit and enter 600 nm.



- 6.7.1.4 Then move the cursor to the graphing icon using the down arrow key.
- 6.7.1.5 Clear any sample and then close the sample compartment lid.
- 6.7.1.6 Press the yellow '0.00' soft key to zero the instrument.
- 6.7.1.7 Open the lid and insert the Wavelength Accuracy test standard XXXXXX-5 with the lambda (λ) symbol label on the top of the filter.
- 6.7.1.8 Press the green 'Play' symbol button to execute the scanning measurements.
- 6.7.1.9 When the scan has completed and with the cursor on the graphing icon use the left and right arrow keys to move the cursor to the lowest wavelength (cell H17).



- 6.7.1.10 Record the value in cell G17.
- 6.7.1.11 Move the cursor the right one nm using the right arrow soft key.



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- 6.7.1.12 Record the next value in cell G18
- 6.7.1.13 Continue this process until all data is recorded in cells G19:G31 for all necessary wavelengths on the form.
- 6.7.2 Testing at 782 nm (nominal value)
 - 6.7.2.1 Use the arrow soft-keys to navigate to the lower limit and enter 700 nm and then to the upper limit and enter 800 nm.
 - 6.7.2.2 Repeat the method described in section 6.7.1 and enter the measured data into cells L17:L31.
- 6.8 Review all entries for formatting and ensure the form is complete.
- 6.9 If any of the values fall outside the limits, the form will report "FAIL". Otherwise, all tests will display "PASS".
 - 6.9.1 Procedure for handling a failure of any test in the performance verification testing for the GENESYS 30.
 - 6.9.1.1 Reboot the instrument. Leave it turned on for at least 2 hours before repeating the entire procedure to determine if the failure is repeatable.
 - 6.9.1.2 If the test passes the second time, then repeat the testing a 3rd time to confirm that test #1 was in error.
 - 6.9.1.3 If the second test confirms the failing result, the instrument will require service.
 - 6.9.1.3.1 The user may install a new lamp and then repeat the testing. See *GEX Doc# 100-167, GENESYS 30 Spectrophotometer Product Specifications and Usage (PSU)* for details.
 - 6.9.1.3.2 Otherwise, contact GEX Customer Service at <u>cs@gexcorp.com</u> for assistance or contact Thermo Scientific directly to arrange service for the instrument.
- 6.10 Print and sign the form and obtain the reviewer's signature.
- 6.11 Retain the form as an official record.



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7.0 ASSOCIATED DOCUMENTS

- GEX Doc #100-113, Spectronic Standards Set 2 Product Specifications and Usage (PSU)
- 100-167, GENESYS 30 Spectrophotometer Product Specifications and Usage (PSU)
- 100-169, GENESYS 30 Replacement Lamp Product Specifications and Usage (PSU)
- 100-269, Spectrophotometer Performance Verification Forms
- Thermo Scientific Spectronic Standards Set 2 User Guide

8.0 **REVISION HISTORY**

DATE	CHANGE DESCRIPTION	REVISION
10/29/18	Initial release.	А
05/24/19	Sections 3 & 4 edited for content clarity. Picture added after 5.2.14. Section 7 doc reference to 100-269 – title change. Other minor language edits. ECO 70446.	В
07/14/19	Revised Section 3.2 to clarify that no integrated method exists for this in DoseControl at this time. ECO 70463.	С

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