

1.0 PURPOSE

To provide explicit instructions for testing measurement repeatability using a spectrophotometer and dosimeter holder system at 3 (three) absorbance (A) values over the range of use.

2.0 SCOPE

This procedure is for the GENESYS 30 and Evolution (Evolution One Plus and Evolution 220 models) spectrophotometers from Thermo Fisher Scientific, used with GEX dosimeter holders' systems which are integrated into the sample compartment of the spectrophotometer, and used to measure film and Perspex dosimeters.

Characterization of measurement repeatability to determine a component of dosimeter measurement uncertainty is outside the scope of this procedure; this procedure is not a gage repeatability and reproducibility study (Gage R&R) nor is it a Measurement Systems Analysis (MSA).

3.0 FREQUENCY

- 3.1 As needed for Operational Qualification (OQ) of the spectrophotometer and dosimeter holder system.
- 3.2 As needed for re-qualification of the spectrophotometer and dosimeter holder system.

4.0 MATERIALS

- 4.1 Spectrophotometer.
- 4.2 All dosimeter holder accessories/parts required for the measurement of the specific dosimeter type used in the test.
- 4.3 Any dosimeter handling tools used in the routine measurement of the specific dosimeter type used in the test.
- 4.4 Dosimeter samples.
 - 4.4.1 Collect samples of the dosimeters that have been irradiated or exposed to U.V. light to absorbances representing low, middle, and high magnitudes over the absorbance (A) range of intended use.
 - 4.4.1.1 Collect one low-range dosimeter, one middle-range dosimeter, and one high-range dosimeter.
Example: B3 dosimeter samples approximate absorbance values of 0.09-0.3A (low), 0.3-0.6A (medium), and 0.6-1.5A (high).

5.0 PREREQUISITES

- 5.1 The spectrophotometer and GEX dosimeter holder system have been installed in accordance with GEX instructions (reference GEX Docs in Section 8.0).
- 5.2 The equipment in 5.1 has passed Installation Qualification (refer to *GEX Doc# 100-280 DoseControl Hardware Qualification Protocol*).
- 5.3 GEX PSU and Procedure documents (see *Section 8 – Associated Documents*) available. These documents contain the operating instructions for the hardware. The user may draft internal operating procedures based on the GEX PSU and Procedure documents to use during this procedure.

6.0 OVERVIEW



- 6.1 Enter results into *GEX Doc# 100-272 Spectrophotometer Measurement Repeatability Form*. The form is validated by GEX and will automatically determine Pass or Fail using the displayed acceptance criteria.
 - 6.1.1 The acceptance criteria provide the ability to discern if the equipment is operating correctly and is the maximum allowable specification. User results will often be significantly lower than the acceptance criteria if the equipment is operating correctly.
- 6.2 Complete one Form (*GEX Doc #100-272*) for each spectrophotometer and for each dosimeter type being qualified on that equipment.

- 6.2.1 Example 1: If two B3 dosimeter types (B3 WINdose and B3 DoseStix) will be routinely measured on one spectrophotometer, complete one Form for the B3 WINdose and one Form for the B3 DoseStix.
- 6.2.2 Example 2: If only B3 DoseStix dosimeters will be routinely measured on the spectrophotometer, complete one Form for the B3 DoseStix dosimeter.

7.0 PROCEDURE

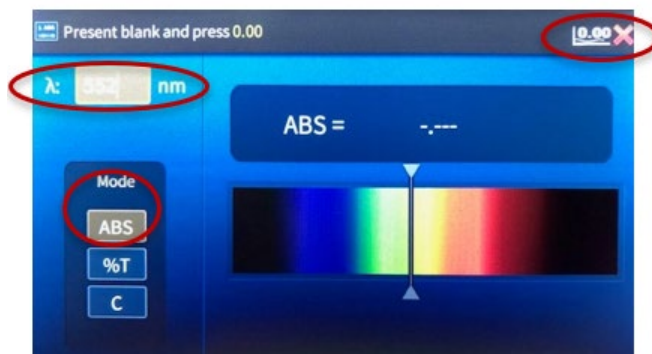
- 7.1 Open *GEX Doc# 100-272 Spectrophotometer Measurement Repeatability Form* in MS Excel or equivalent.
- 7.2 Complete the gray cells in Column B to document the general information for each test.
- 7.3 Measure each dosimeter sample thirty (30) consecutive times for each absorbance value. Do not zero the spectrophotometer between measurements. Record the results in the respective Absorbance (Abs.) column on the Form (#100-272). Use the process below based on your model of spectrophotometer.
 - 7.3.1 For dosimeter types that are inserted into a holder that is fixed inside the sample compartment (e.g. DoseStix or Perspex), remove the dosimeter and re-insert it into the holder for each measurement.
 - 7.3.1.1 Insert the dosimeter into the holder with the same orientation each time. Do not flip or change the orientation of the dosimeter in the holder between successive measurements.
 - 7.3.2 For dosimeter types that are inserted into a holder, that are then inserted into a fixed receiver or cuvette (e.g. WINdose / 1cm² film dosimeters), do not remove the dosimeter from the holder during the testing, but re-insert the holder into the receiver/cuvette.

7.3.3 GENESYS 30 Model Spectrophotometer

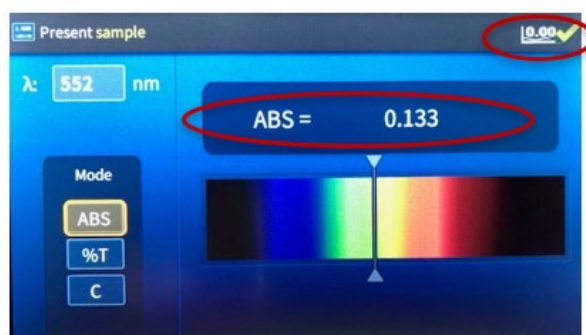
- 7.3.3.1 If using the Evolution One Plus model spectrophotometer, skip to section 7.3.4. If using the Evolution 220 model spectrophotometer, skip to section 7.3.5.
- 7.3.3.2 Start-up the instrument in accordance with the instructions in *GEX Doc# 100-167 GENESYS 30 Spectrophotometer – Product Specifications and Usage (PSU)*.
- 7.3.3.3 Insert the appropriate dosimeter holder according to *GEX Doc #100-168, GENESYS 30 Dosimeter Holder System - Product Specifications and Usage (PSU)*.
- 7.3.3.4 From the instrument home screen, select “Live Display” and press the Play button  or  keypad.



- 7.3.3.5 Input the correct wavelength setting for the dosimeter type you are measuring. Select “Done”.
- 7.3.3.6 The “Mode” defaults to “ABS” for absorbance which is the necessary setting for this test.
- 7.3.3.7 The screen provides instruction in the top-left corner for the next user action.
- 7.3.3.8 Ensure the dosimeter holder is empty, then zero the instrument by pressing the yellow “0.00” button. The top-right corner indicates if the instrument has been zeroed or not.



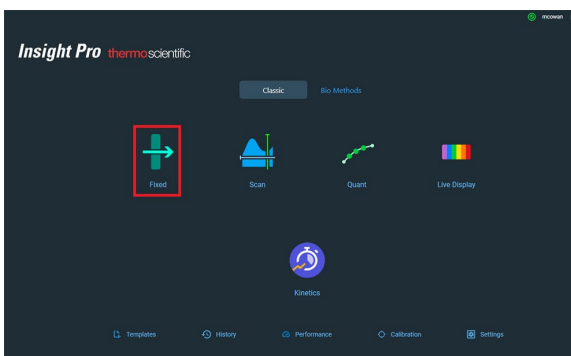
- 7.3.3.9 After the instrument is zeroed, insert a dosimeter to be measured, and type the absorbance value into the form for dosimeter #1.



- 7.3.3.10 After recording the measurement, remove the dosimeter, and insert the same sample into the holder. Record the data for dosimeter #2.
- 7.3.3.11 Repeat steps above until all dosimeters have been measured at low, medium, and high Absorbance (A) values.

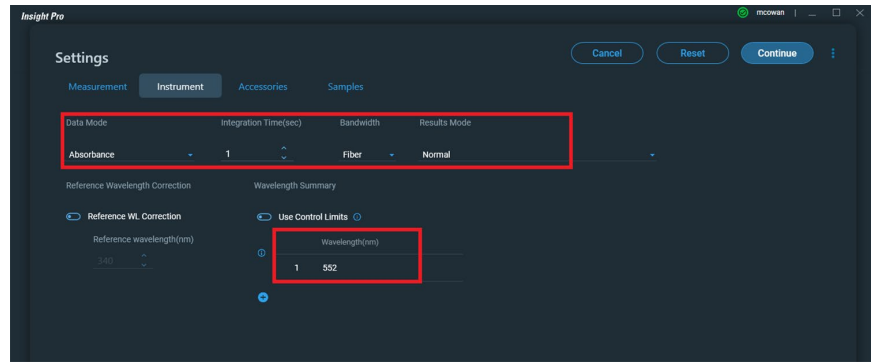
7.3.4 Evolution One Plus or 220 model Spectrophotometer with Thermo Insight Pro software

- 7.3.4.1 Turn on the Evolution spectrophotometer in accordance with GEX Doc #100-156.
- 7.3.4.2 Open the Thermo Insight Pro software. On the main screen, select “Fixed”.

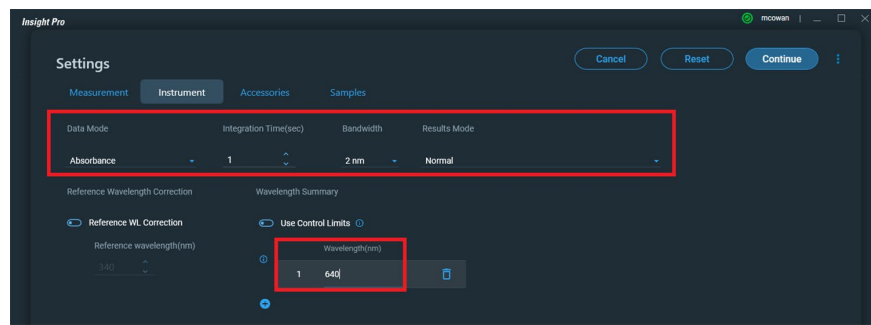


- 7.3.4.3 Select the “Instrument” settings tab. Configure the instrument settings based on the type of dosimeter to be measured:

7.3.4.3.1 **Film dosimeters:** Data mode – “Absorbance”, Bandwidth – “Fiber”, Wavelength – enter the measurement wavelength (nm) for the dosimeter type (Example: B3 is “552”).




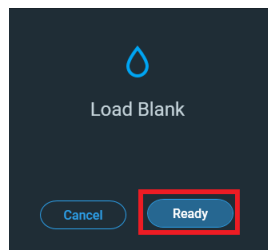
7.3.4.3.2 Perspex dosimeters: Data mode – “Absorbance”, Bandwidth – “2nm”, Wavelength – enter the measurement wavelength (nm) for the dosimeter type (Example: Red Perspex is “640”).




7.3.4.4 After the Instrument settings are configured, click “Continue” to move to the measurement screen.

7.3.4.5 Place the appropriate dosimeter holder into the baseplate. (Windose holder for B3 and FWT 1cmx1cm films, DoseStix holder for DoseStix films, Perspex holder for Perspex dosimeters.)

7.3.4.6 Zero the instrument by clicking the “Blank” icon.  Click the “Confirm” button to confirm the name of the test. The “Load Blank” prompt appears. Click “Ready” after confirming the dosimeter receiver is empty. The Evolution will zero.



7.3.4.7 Place the low Absorbance sample into the dosimeter holder. Click the “Play” button to begin a measurement. 

7.3.4.8 Type a sample ID when prompted (example: low Absorbance B3 Windose).

7.3.4.9 Click “Ready” to measure the dosimeter. The measured Absorbance value will appear in a list on the screen. Record the value in the results Form *GEX Doc# 100-272*.

7.3.4.10 Remove the dosimeter and carefully replace the dosimeter into the dosimeter holder. If measuring Windose or FWT, do not remove the sample from the hinged holder; remove the hinged holder and then carefully replace the holder into the receiver.

7.3.4.11 Do not zero between measurements. Click the “Play” button to measure the sample again, enter a sample ID when prompted, and click “Ready” to measure.

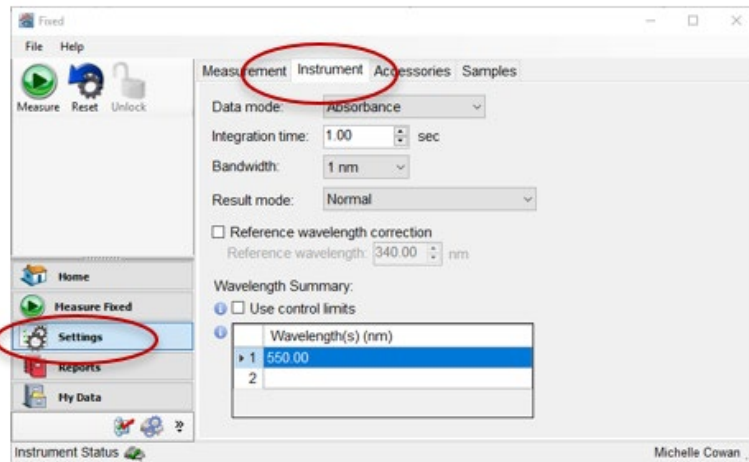
- 7.3.4.12 Repeat this sample measurement process for a total of 30 times for the sample. Enter the measured absorbance value in the Form *GEX Doc# 100-272*.
- 7.3.4.13 For the medium and high Absorbance samples, repeat the steps 7.3.4.6 to 7.3.4.12.
- 7.3.4.14 When the testing is complete and all measured values are recorded in Form *GEX Doc# 100-272*, sign/date the completed Form, and have a reviewer sign/date the Form.

7.3.5 ***Evolution 220 Model Spectrophotometer with Thermo INSIGHT 2 software***

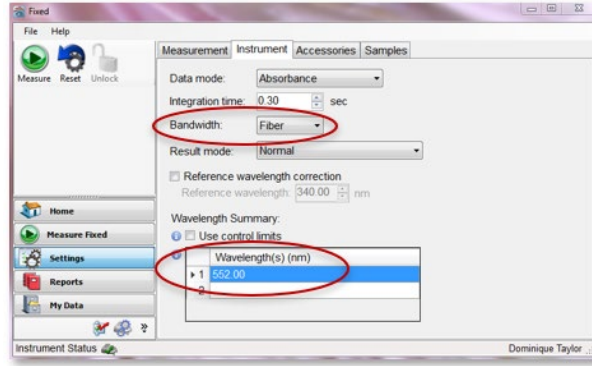
- 7.3.5.1 If using the Thermo Insight Pro version of software with the Evolution 220, follow the instructions given in section 7.3.4 (above).
- 7.3.5.2 Turn on the Evo220 Spectrophotometer in accordance with GEX Doc #100-156.
- 7.3.5.3 Open the Thermo INSIGHT software. On the home screen, select “Fixed”.



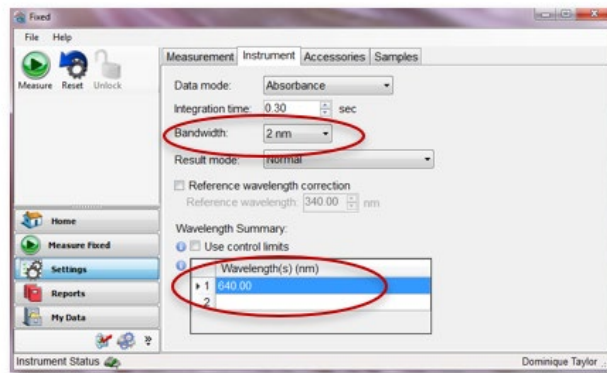
- 7.3.5.4 Select the “Settings” button and the “Instrument” tab. The other tabs may be left alone.



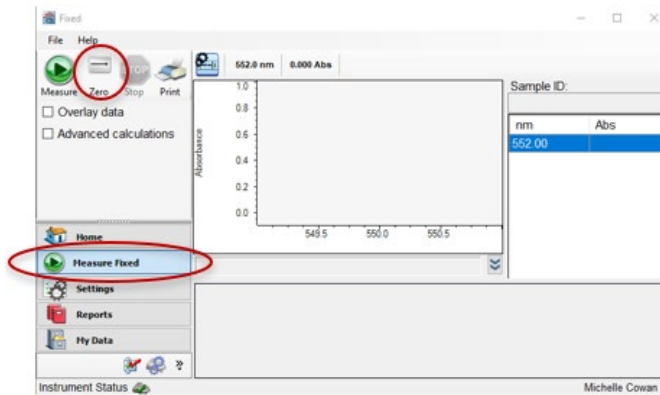
- 7.3.6 Dosimeter measurement: the bandwidth and wavelength settings are determined by the type of dosimeter being measured:
 - 7.3.6.1 **Film Dosimeters:** select the “Fiber” bandwidth from the dropdown options and input the wavelength setting for the dosimeter. Example below is for B3 dosimeters.



7.3.6.2 **Perspex Dosimeters:** select the “2nm” bandwidth from the dropdown options and input the wavelength setting. Example below for Red Perspex dosimeters.

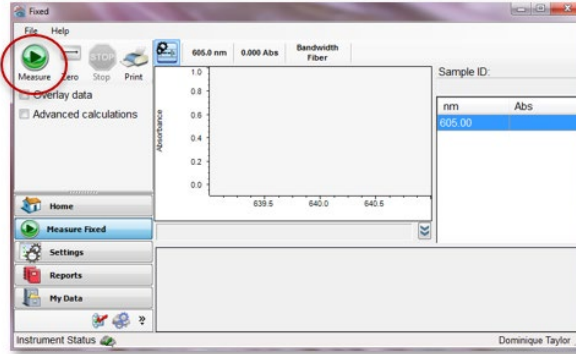


7.3.7 Once the correct settings are entered, select “Measure Fixed” from the left menu to proceed.

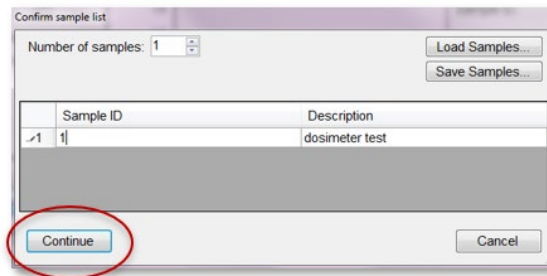


7.3.8 Ensure the dosimeter holder is empty, then select “Zero” from the upper left of the screen.

7.3.9 After the instrument is zeroed, insert a dosimeter to be measured.



7.3.10 Press the green “Measure” button (or F6 on your keyboard). You will be prompted to input an ID and description for the sample. Click in the cells and name the dosimeter or use the default name. The Sample ID will automatically iterate by one number each time a measurement is taken.



7.3.11 Click “Continue” to take the measurement.

7.3.12 After the measurement is recorded, repeat the steps above until all repeated measurements are complete.

7.3.13 Transfer the measurement data directly from the screen into the appropriate cells on the form, using copy and paste features of MS Windows, and double-check your work. Alternatively, save your work and transfer the data to the form afterwards.

7.3.14 Zero the spectrophotometer when changing from one Absorbance sample to another (i.e. after each set of 30 samples are measured)

7.4 Enter your Name and Title, and the same information for the reviewer under the signature lines located at the bottom of the form.

7.5 Sign and date the form. Also have responsible personnel review, then sign and date the form.

8.0 ASSOCIATED DOCUMENTS

- [100-156](#), P4300 Thermo Evolution Spectrophotometer - Product Specifications and Usage (PSU)
- [100-159](#), Evolution Dosimeter Holder System - Product Specifications and Usage (PSU)
- [100-167](#), P4400 Genesys 30 Spectrophotometer – Product Specifications and Usage (PSU)
- [100-168](#), GENESYS 30 Dosimeter Holder System – Product Specifications and Usage (PSU)
- [100-272](#), Spectrophotometer Measurement Repeatability Form
- [100-280](#), DoseControl IQOQ Protocol for DoseControl Dosimetry System

9.0 REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
05/24/2019	Initial release.	A
12/12/2021	<ul style="list-style-type: none"> - 4.4.1: clarified sub step and added 4.4.1.2. - 7.3: added instruction do not zero in between measurements of the same dose sample to clarify the procedure (based on customer feedback for improving procedure). - 7.3.3.1: added reference of section 7.3.4 for Evo OnePlus users and 7.3.5 for Evo220 users. - 7.3.4: added reference of Evo OnePlus and added instructions for Thermo Insight Pro software. - Corrected document number for DoseControl IQOQ Protocol to 100-280. ECO 70595. 	B
05/09/2024	<ul style="list-style-type: none"> - Section 4.0, updated to allow dosimeter samples to use Absorbance (A) values. The spectrophotometer is measuring the dosimeter’s absorbance (A) value. - Removed all mentions of “Dose” with regards to using dosimeter samples and replaced with “Absorbance”. - Section 7.4, updated to include “Name and Title” for the “Performed by” and “Reviewed by”. ECO 70675	C

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APPROVED
 By Dominique Taylor at 2:47 pm, May 09, 2024