

Spectrophotometer Measurement Repeatability Test Procedure

GEX Doc# 100-273

1.0 PURPOSE

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

2.0 SCOPE

The procedure is specifically for the GENESYS 30 and Evolution 220 Spectrophotometers, from Thermo Fisher Scientific, used with GEX supplied off-the-shelf holders / holder systems, which are integrated into the sample compartment of the spectrophotometer, and used with film and Perspex dosimeters.

Characterization of measurement repeatability to determine a component of dosimeter measurement uncertainty is outside the scope of this procedure; this testing 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 to doses representing low, middle, and high magnitudes over the range of intended use.
 - 4.4.1.1 Collect one (1) low-range dosimeter, one (1) middle-range dosimeter, and one (1) high-range dosimeter.
 - 4.4.1.2 Example: the dose range for B3 WINdose at the user site is 5.0 to 60.0 kGy. (So that means 5.0, 30.0, and 60.0 kGy nominal dosed dosimeters are used for qualification).

5.0 PREREQUISITES

- 5.1 The equipment has been installed in accordance with GEX instructions (reference GEX Docs in Section 8.0).
- 5.2 The equipment has passed Installation Qualification (refer to *GEX Doc# 100-281 DoseControl Hardware Qualification Protocol*).
- 5.3 The user has the GEX PSU and Procedure documents (see Section 8 – Associated Documents) available that contain the operating instructions for the hardware or has drafted internal operating procedures based on the same PSU's to use during this test.

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.

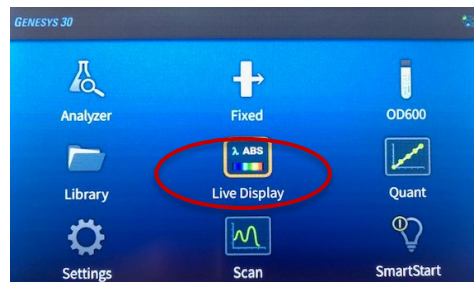
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- 6.1.1 The acceptance criteria provide the ability to discern if the equipment is operating correctly and is the maximum allowable specification. User results will often be significantly lower than the acceptance criteria if the equipment is operating correctly.
- 6.2 Complete one Form (#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 this Form two (2) times.
 - 6.2.2 Example 2: If only B3 DoseStix dosimeters will be routinely measured on the spectrophotometer, complete this Form one (1) time.

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 dose. Record the results in the respective Dose 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 220 spectrophotometer, skip to section 7.3.4.
 - 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  on the keypad.

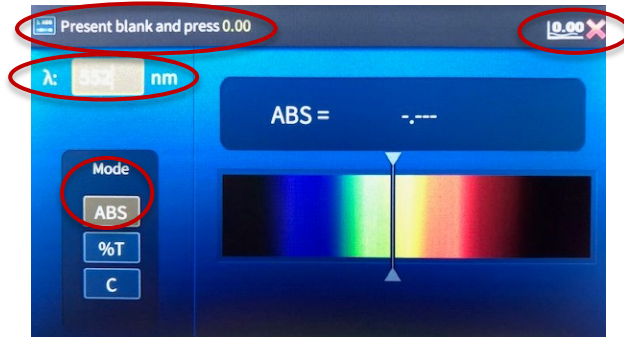


- 7.3.3.5 Input the correct wavelength setting for the dosimeter type you are measuring. Select “Done”.
- 7.3.3.6 The “Mode” defaults to “ABS” for absorbance which is the necessary setting for this test.
- 7.3.3.7 The screen provides instruction in the top-left corner for the next user action.

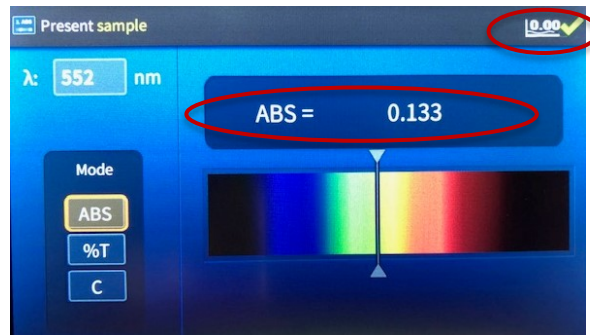
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- 7.3.3.8 Ensure the dosimeter holder is empty, then zero the instrument by pressing the yellow “0.00” button. The top-right corner indicates if the instrument has been zeroed or not.



- 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.



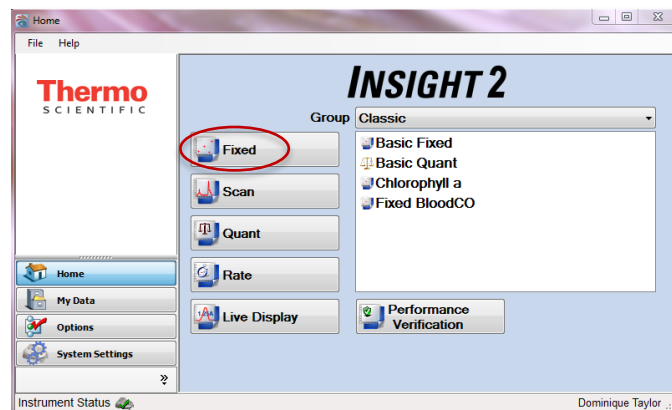
- 7.3.3.10 After recording the measurement, remove the dosimeter, and insert the same sample into the holder. Record the data for dosimeter #2.

- 7.3.3.11 Repeat steps above until all dosimeters have been measured at low, medium, and high doses.

7.3.4 ***Evolution 220 Model Spectrophotometer***

- 7.3.4.1 Turn on the Evo220 Spectrophotometer in accordance with GEX Doc #100-156.

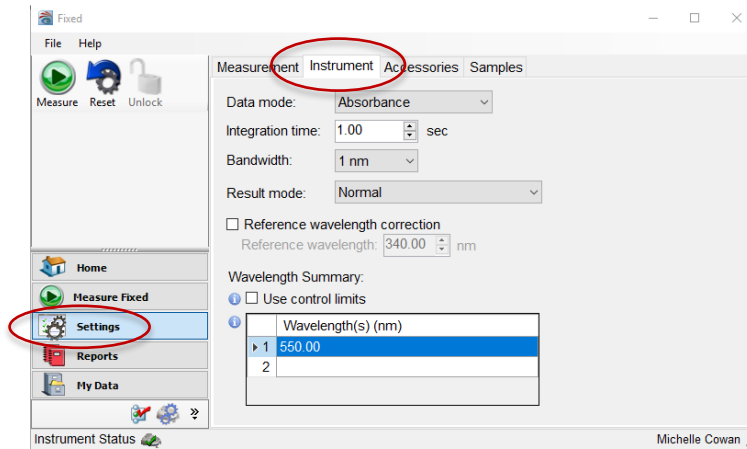
- 7.3.4.2 Open the Thermo Insight software. On the home screen, select “Fixed”.



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

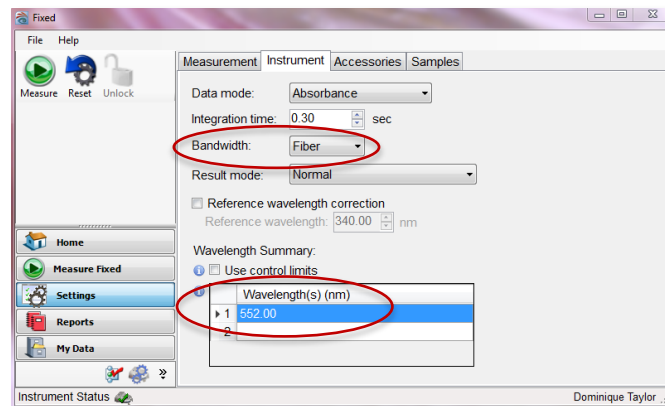
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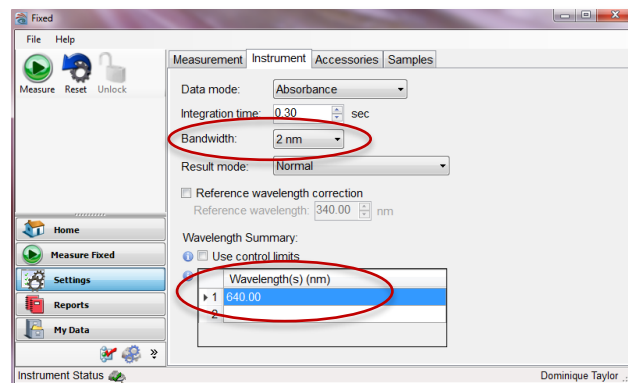


7.3.5 Dosimeter measurement: the bandwidth and wavelength settings are determined by the type of dosimeter being measured:

7.3.5.1 **Film Dosimeters**; select the “Fiber” bandwidth from the dropdown options and input the wavelength setting for the dosimeter. Example below is for B3 dosimeters.



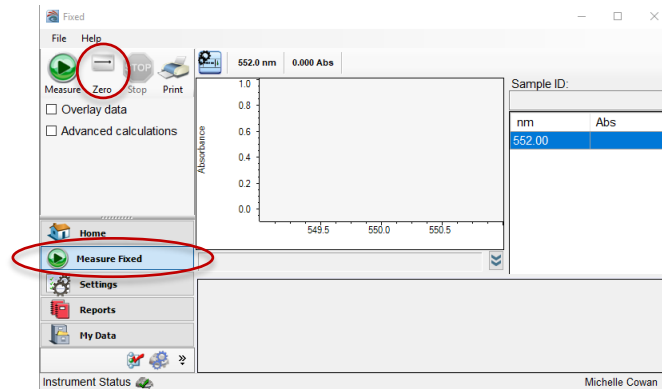
7.3.5.2 **Perspex Dosimeters**; select the “2nm” bandwidth from the dropdown options and input the wavelength setting. Example below for Red Perspex dosimeters.



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

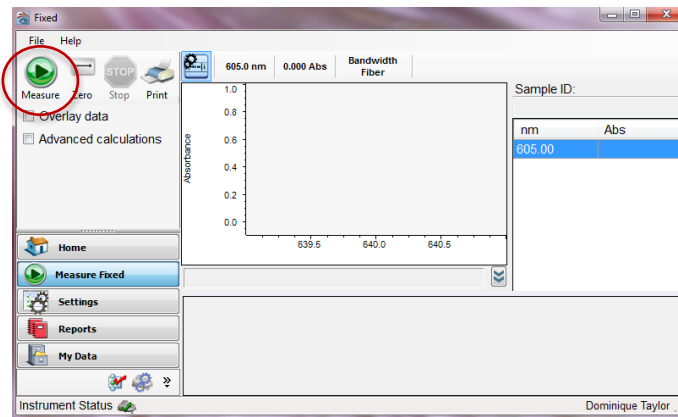
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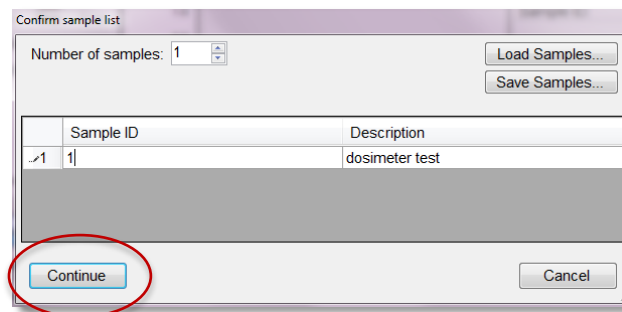


7.3.7 Ensure the dosimeter holder is empty, then select “Zero” from the upper-left of the screen.

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



7.3.9 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.



7.3.10 Click “Continue” to take the measurement.

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

7.3.12 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.

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7.3.13 Zero the spectrophotometer when changing from one dose 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 (row 41 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 Evo220 Spectrophotometer - Product Specifications and Usage (PSU)
- 100-159, Evo220 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
- 100-281, DoseControl Hardware Qualification Protocol

9.0 REVISION HISTORY

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

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