



GEX DOC# 100-258

MEASURING GEX DOSIMETERS

GEX Recommended Procedure

Eff. Date: 09/21/10

Rev.: D

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1.0 PURPOSE

To describe an integrated and automated method that can be used to measure GEX WINdose and DoseStix dosimeters using the WINdose for Excel Dosimetry Software Program provided by GEX Corporation.

Advisory:

The WINdose for Excel software program was developed to assist users in the preparation of dosimetry reports by allowing the user to complete live on-screen computer data entry and fill-in appropriate Microsoft Excel worksheet cells as well as to view and print the results in the form of pre-formatted dose reports that may be reviewed and signed to formally accept and authorize the dose report records. The software utilizes built in Microsoft Excel functions with Visual Basic code and custom macros. The software was developed under life cycle design control and has been validated in accordance with generally accepted industry practices. Users must use the batch calibration specific WINdose for Excel Workbook(s) developed for their process facility and appropriate for use in their specific application.

Caution:

The software was not designed nor is it intended for use in electronic record keeping activities. The WINdose for Excel software provides data integration for the user's specific spectrophotometer (Thermo Electron Genesys 20 is standard) with a PC running Windows 2000 and Excel 2000 versions or higher. The software program also allows direct barcode reader data input into specific cells in the customized Excel spreadsheet.

2.0 SCOPE

- 2.1 This procedure discusses the techniques in the WINdose for Excel software that are common to the specific B3WINdose product worksheets in a calibration specific Microsoft Excel workbook. Certain specialty products, for example the B3110 energy measurement card or the B3106 uniformity strip, use additional requirements that are found in the WINdose for Excel Installation & Operation Manual.
- 2.2 Completed WINdose for Excel worksheets may be verified using manual techniques (see sections 4.21.1 and 4.21.2.).
- 2.3 The WINdose for Excel software program can accept data entry input from an integrated Genesys 20 spectrophotometer or by computer keyboard hand entry.

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- 2.4 The WINdose for Excel software program can also be used to print blank worksheets for use as hand data entry forms.

3.0 MATERIALS

- 3.1 WINdose Dosimetry System
- 3.2 A heat-treatment system for post irradiation heat treatment of B3 dosimeters (e.g. GEX P4800 or P4900)
- 3.4 Appropriate WINdose for Excel Calibration Specific Workbook(s).
- 3.8 Optional: Bar code reader and computer connection cables.

4.0 PROCEDURE

NOTE: B3WINdose dosimeters may exhibit a post irradiation color development and users are highly encouraged to mitigate potential post irradiation dosimeter variance by heat treatment of the B3 dosimeters before final absorbance measurement (see GEX Tech Memo 100-201, Heat Treatment of B3 Film Dosimeter Products, for detail. Alternatively, a user may establish a controlled post irradiation time period for measurement readout based on the specific batch calibration measurement data established for the calibration.

NOTE: Some users may establish separate calibration curves to accommodate application requirements at their facility. This may involve the use of multiple WINdose for Excel Calibration Specific Workbooks or the use of a calibration adjustment factor.

- 4.1 Ensure that the spectrophotometer being used for the measurements is in current calibration before use.
- 4.2 Remove the cuvette cup and close the sample compartment lid and turn on the spectrophotometer. As a precaution, be sure to restart each of the Genesys 20 instruments once every 24 hour period of use to allow the instrument to cycle through its internal performance checks (approximately 3 minutes) and then allow the instrument the full 30 minute manufacturer suggested warm up period before use.
- 4.3 Verify that the spectrophotometer is at 552 nm (or other specified wavelength appropriate to the dosimeter batch calibration being used) and is in the Absorbance mode.

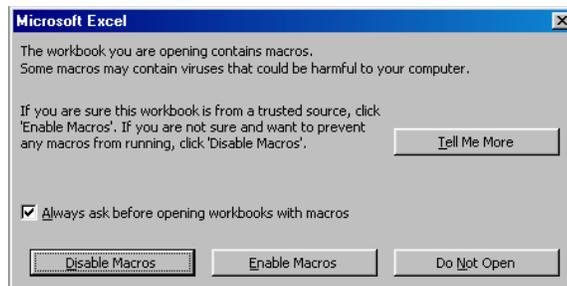


- 4.4 Place an empty dosimeter holder into the instrument. (**NOTE:** If measuring the WINdose dosimeter, the conical hole of the GEX Hinged Dosimeter Holder faces into the body of the instrument, i.e. away from the user.) Gently press it all the way down until there is no further travel. Do not force it down hard. Close the sample compartment lid and press the “0 Abs” button on the spectrophotometer to zero the holder. The instrument display should read zero. This indicates that the instrument is appropriately prepared to begin reading dosimeters.

At the beginning of each dosimetry session, when using the GEX Hinged Dosimeter Holder for B3WINdose dosimeter products the user is encouraged to practice inserting the holder several times and achieving zero readings to reacquaint the user with the holder placement technique.

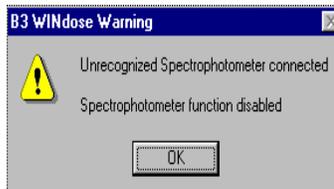
- 4.5 Gather the dosimeters for measurement. Heat treat dosimeters appropriately or document the time control needed for the dosimeters to be measured appropriately.
- 4.6 Open and start the WINdose for Excel Calibration Specific Workbook by double clicking on the file icon.
- 4.7 When Excel starts you may be asked if you wish to enable macros. Click the “Enable Macros” button to finish opening the workbook.

WARNING: Selection of “Disable Macros” will not allow the WINdose for Excel software program to operate automatically. Macro security should be set to ‘LOW’ even though the geniuses at Microsoft should know that viruses are not hidden in macros anymore.



- 4.8 The program will then search for an RS232 integrated Genesys 20 spectrophotometer for up to 30 seconds. Do not make any keyboard entries or mouse clicks during this period.

- 4.9 If the program cannot communicate with the spectrophotometer, a message window will appear on the screen.



This is a warning message, not necessarily an error message. It is still possible to use the dose calculation portion of the WINdose for Excel program in a manual mode using keyboard entry of absorbance values. There are two options:

- 4.9.1 Close the program and check the RS-232 cable connections on both the spectrophotometer and the computer. Restart the program.
- 4.9.2 Proceed without communications with the spectrophotometer. All dosimeter measurements must be made manually with the computer keyboard.

WARNING: WINdose for Excel is not intended for use in electronic record keeping or archiving functions. Stored WINdose for Excel files do not meet 21 CFR Part 11 requirements for security liability and electronic signature in electronic record keeping practices.

Printed WINdose for Excel worksheets that have been properly reviewed and signed by the user in accordance with the user's SOPs can satisfy the 21 CFR Part 11 record requirements.

- 4.11 Select the appropriate worksheet in the workbook. Click on one of the tabs (the formal term is "plys") at the bottom of the screen. There are separate worksheets for each dosimeter product or application.
- 4.12 Enter the processing information in the colored cells at the top of the screen. As information is entered, the cell turns white. Fill in any empty cells with "N/A".

NOTE: *This procedure provides a general description of use the WINdose for Excel software to record dosimeter measurements. For detailed instructions, see the appropriate sections of the WINdose for Excel Installation & Operation Manual.*

- 4.13 Enter the dosimeter number in the appropriate cell under the heading "Dosimeter ID". If using a barcode reader, pass the dosimeter package under the barcode reader. The number will be read and entered in the cell, and the next cell to the right highlighted.



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18	P8003		Dosimeter	Irradiated Absorb. Response				Adjusted
19	Max Temp	Dosimeter ID	Position	A	B	$(A_i - A_o) / t$	Dose (kGy)	Dose (kGy)
20		1234567		0.000	0.000	0.000	na	

- 4.14 Enter a dosimeter position in the appropriate cell. This can be the carrier number or a special test location or any other descriptive text, such as “reference position”.
- 4.15 Open the dosimeter package, taking care not to damage the dosimeters or touch the film area with bare fingers.
- 4.16 Remove the dosimeter holder (if needed) from the spectrophotometer and swing it open. (NOTE: Measurement of the GEX DoseStix dosimeters does not involve removal of the holder from the spectrophotometer.)
- 4.17 Place the dosimeter in the appropriate dosimeter holder and close the dosimeter holder if necessary. Select the “Irradiated Absorbance” cell of the worksheet for the dosimeter replicate being measured. Insert the loaded dosimeter holder into the spectrophotometer. Close the sample compartment lid.
- 4.18 Enter the “Irradiated Absorbance” in the appropriate cell for each dosimeter replicate in the dosimeter dose point set. The number of replicates may vary depending on the B3WINdose product worksheet being used. Simultaneously press the two keys “Ctrl & Shift” and while holding them down press the “a” letter key. The absorbance will be copied into the dose worksheet, and then the next cell to the right will be highlighted. Do not press the “Enter” key after making a measurement.

18				Irradiated Absorb		Response
19		Dosimeter ID	Position	A	B	
20	AA-	1234567	sample			#DIV/0!
21						

IMPORTANT: Verify the value in the cell against the value of the spectrophotometer display. Correct any discrepancies using the computer keyboard to overwrite the data in the computer worksheet as appropriate.

- 4.19 Remove the dosimeter from the spectrophotometer. Repeat steps 4.13 through 4.18 until all dosimeter packages for that run have been measured. Follow the specific instructions provided for the specific product worksheet in the WINdose for Excel Installation & Operation Manual.



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18				Irradiated	Absorb	Response	Calculated		Adjusted	Avg. Ref.	Avg. Ref.
19	Dosimeter ID	Position	A	B		Dose (kGy)	Formula	Dose (kGy)	Min Dose	Max Dose	
20	AA- 1234567	sample	0.396	0.334	17.568	21.3		21.3	18.1	27.6	
21	AA- 1234568	sample	0.249	0.411	15.676	18.8		18.8	15.9	24.4	
22	AA- 1234569	sample	0.424	0.232	15.568	18.6		18.6	15.8	24.2	
23	AA- 1234570	sample	0.240	0.515	18.243	22.2		22.2	18.9	28.8	
24	AA- 1234571	sample	0.512	0.395	22.351	28.0		28.0	23.8	36.3	
25	AA- 1234572	sample	0.593	0.555	28.865	38.1		38.1	32.4	49.6	

4.20 Minimum doses and maximum doses for the process run are automatically calculated and their values displayed in the appropriate cells in the top portion of the worksheet.

4.21 Print and review the dosimetry report.

4.21.1 The review can include verification of calculated values by hand calculation.

4.21.2 Doses can be verified by using the Dose Tables supplied with the specific dosimeter batch calibration report. See GEX Recommended Procedure 100-255, WINdose for Excel Verification, for detail.

NOTE: In event of operational failure of the WINdose for Excel software, dose measurement reports may be generated entirely by hand using the absorbance readouts obtained and recorded from the spectrophotometer using the information provided in sections 4.1 through 4.4 (and 4.5 if appropriate). Use a “Dose Estimate Table” to determine the dose estimate values for the recorded dosimeter absorbances.

4.22 Close the dosimetry workbook.

4.23 Reopen the master workbook to create additional reports as appropriate.

4.24 Equipment Shutdown

4.24.1 Place the empty dosimeter holder in the spectrophotometer, close the sample compartment lid and turn off the spectrophotometer.

4.24.2 After a few minutes, place the dust cover on the instrument.

4.24.3 If utilized, leave the incubator on at all times because an incubator typically requires several hours to stabilize at operating temperature when coming up from ambient room temperature.

NOTE: The Genesys 20 instrument may be left “On” continuously, requiring a simple restart each day. Like many types of equipment the instrument was designed for continuous operation. 24 hour a day operation will require that the lamp be changed approximately once every month.



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5.0 REVISION HISTORY

Date	Change Description	Revision
09/21/10	Specified 552 nm during absorbance measurement	D