



## **GEX DOC# 100-255**

### **WINDOSE FOR EXCEL VERIFICATION**

GEX Recommended Procedure

Eff. Date: 07/27/07

Rev.: C

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## **1.0 PURPOSE**


To describe the GEX WINDose for Excel dosimetry software and performance verification of Calibration Specific WINDose for Excel Workbooks.

## **2.0 FREQUENCY**

- 2.1 As part of the initial acceptance and performance verification testing of the dosimetry system and the WINDose for Excel software.
- 2.2 Whenever a change is made to the software such as is provided by GEX with each B3 dosimeter batch calibration or in the case of a change to the dosimeter average thickness used in the software for a given batch of dosimeters.

## **3.0 INFORMATION & PROCEDURE**

- 3.1 The WINDose for Excel software developed by GEX uses calculation functions internal to the Microsoft Excel for Windows software program. The Microsoft Excel program is a commercially available spreadsheet program that has undergone separate industrial validation. No changes are made to its code.
- 3.2 The Genesys 20 spectrophotometer contains its own operating system. The software used in the Genesys 20 EPROM (firmware) is the manufacturer's warm-up and self-diagnostic functions. These are pass/fail codes which cannot be altered by the user; should there be an error, the instrument will cease to operate. The Genesys 20 software program has undergone separate validation, and the operation codes were developed and are maintained by Thermo Spectronic Instruments.
- 3.3 The communications protocols are standard for Microsoft products. The WINDose for Excel workbooks have been set to recognize Genesys 20 spectrophotometers with 2.0 or 2.1 operating systems. Verification of data transfer is accomplished by operator comparison of the absorbance value of the spectrophotometer display against the transferred absorbance value recorded in the WINDose for Excel dosimetry worksheet.
- 3.4 The bar code reader contains its own operating system functions. The user cannot alter this system. Verification of accurate communications is accomplished by


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operator visual verification of the value on the bar code label against the value recorded in the WINdose for Excel dosimetry worksheet.

- 3.5 Curve fitting of the batch specific dosimeter response in a calibration is described in **Validation Calculations** section of the Terastat, Inc. **Calibrate!** software manual maintained at GEX. The coefficients of the user's batch specific "best fit" calibration curve are entered by GEX and embedded in a hidden and password protected worksheet in the WINdose for Excel workbook. The **Calibrate!** calibration software program was developed by TeraStat, Inc. and validated separately. A statement of validation is maintained at GEX.
- 3.6 Dose measurement is described in the supplied WINdose for Excel Installation and Operations Manual. The document describes handling methods and discusses the spreadsheets that calculate the doses. Formulas use standard Excel functions. Several options are available to the user depending on the layout format of the desired report shown on the computer screen and the computer printable output.
- 3.7 Dosimetry Report layouts may be specifically customized for a company or a facility division within a company. The user is responsible for requesting custom altering of the appearance of the forms from GEX Corporation. However the pre-validated WINdose for Excel calculational fields can not be modified or moved.
  - 3.7.1 Verification of the dosimeter response is accomplished by the calculation:  

$$R = (A_i - A_o) / t$$
, where  
 $A_i$  = Absorbance<sub>irradiated</sub> of the individual dosimeter  
 $A_o$  = Absorbance<sub>original</sub>, average for the batch  
 $t$  = thickness, average for the batch  
NOTE: "Ao" may be set to zero to minimize instrument noise on measurements and "t" may be set to one or may also be changed to account for changes in thickness of dosimeter stocks coming from the same dosimeter batch that was initially calibrated.
  - 3.7.2 Verification of any dose estimated by the WINdose for Excel program is accomplished by using the "Dose Estimate Table" provided with the GEX Calibration Report. Verify that the dose estimate value displayed in the WINdose for Excel spreadsheet agrees within 0.1 kGy of the corresponding dose values found in the "Dose Estimate Table" for any specific dosimeter absorbance or response value.

NOTE: All Dose Reports generated using the GEX WINdose for Excel software program are intended to be reviewed and evaluated by the user for accuracy and formally authorized by the user in order for the Dose Reports

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to be used as formal records. The GEX WINDose for Excel software program was not designed for compliance with 21 CFR Part 11.

- 3.8 Protection is applied to the spreadsheets in two ways:
- 3.8.1 The spreadsheet cells and the macros that calculate doses and communicate with a spectrophotometer are password protected and can only be accessed by GEX operations personnel. The GEX Corporation Quality Assurance Department maintains the password.
  - 3.8.2 The calibration identification and curve coefficients are contained in a hidden password protected worksheet. The GEX Corporation Quality Assurance Department maintains the password.
- 3.9 As supplied, the dosimetry worksheets may be altered by the user as described in the manual, and the user is responsible for maintaining the integrity of the worksheet format.
- 3.10 During software development and validation, the communications and the data entry forms were subjected to forced error entry and general data entry abuse. Failure points were documented and reported to the programmer for analysis, corrective action and implementation. The software code is version and change controlled.

## 5.0 REVISION HISTORY

Date	Revision	Change Description
07/27/07	C	Editorial language changes and addition of notes