This manual provides instructions in usage and troubleshooting of GEX DoseControl® software.
GEX DOSECONTROL® DOSIMETRY SOFTWARE USER MANUAL

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DESCRIPTION

GEX Corporation’s DoseControl® Software provides an interface for measuring dosimeters using Evolution 220 and Genesys 20 Spectrophotometers to generate dosimetry reports. DoseControl® regulates the measurement process thereby providing a repeatable method while allowing the user configuration flexibility. Electronic data storage provides a significant improvement opportunity and value to the users of dosimetry data.

DoseControl® was developed to provide a modern platform with broad capabilities to allow a user to generate dosimetry reports meeting their requirements. Designed for electronic data storage and for integration with other systems, the software allows for expansion with the addition of new functionality and features in the future.

Platform Requirements
Below are the optimal and minimum requirements:

**Optimal Requirements for Client Workstations**
- Windows 8.1 x64 or higher
- .NET Framework 4.6.1
- At least 4 GB RAM
- 2.0 GHz processor or higher
- At least 10 GB hard drive space
- 1900 x 1200 screen resolution
- Latest COM to USB drivers for attached spectrophotometer
- Adobe Reader
- Windows Excel 2007 or later

**Optimal Requirements for Application Database Servers**
- Windows server 2012 or higher
- At least 100 GB hard drive space
- At least 16GB RAM
- Microsoft SQL Server 2012 or higher
- Following these guidelines

**Minimum Requirements for Clients Workstations**
- Windows 7 x32 or higher
- .NET Framework 4.5.2
- 1 GB RAM or higher
- x32 processor
- 16GB hard disk space
- Adobe Reader
- Windows Excel 2007 or later

**Minimum Requirements for Application Database Servers:**
- SQL Server 2008 R2
  - 2008 R2 Standard 32 bit system requirements
  - 2008 R2 Standard 64 bit system requirements
- SQL Server 2012
- MySQL - Coming soon
  - See Supported Platforms and Versions
- Oracle 11g Express or higher - Coming soon
If you have trouble, first please see section 2.2 and 2.3 of this manual. If problems persist, please contact GEX Customer Support by email or phone.

Office hours: Monday – Friday 8am to 5pm Mountain Standard Time or Mountain Daylight Time (or as defined in a contract with GEX).

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1 Installation and IT Configuration

1.1 General Information

DoseControl® Software creates and manages dosimetry reports for routine dosimetry performed for radiation processing or general research activities. The software has two main functions: creating a new dosimetry report or editing an existing dosimetry report. The software is integrated with a spectrophotometer, and the data from dosimeter readings is directly input to the dosimetry report database.

DoseControl® allows you to do the following:

**Integration with spectrophotometer**
- Zero spectrophotometer
- Indicates if spectrophotometer is ready or busy
- Data from dosimeter measurement directly input into report database

**Create/maintain traceable records**
- Dosimeter ID
- Dosimeter position
- Tote ID
- Product Information
- All dosimeter measurement data – avg. absorbance, adjusted dose, min/max dose
- Any comments and/or changes to reports recorded
- Version controlled

**Produce complete dosimetry reports**
- Print
- Export to Excel
- Edit reports, create new versions, and re-measurement of dosimeters

1.2 Installing the Application

The application installation package is delivered as an .msi file for installation. In addition, there are multiple module.dll files that are deployed with the .msi file. The application may be installed on as many PC’s as the user desires in the user’s facility, referencing any contractual clauses that may exist.

NOTE: An SQL database instance must first be installed by IT personnel prior to installing the application. The SQL instance should be installed per your company’s data governance policy.

1. Place the .msi installer on the desktop of the computer for installation.

2. Double click .msi. Follow prompts to complete the install of the application.
3. Select the folder to install the application to on the computer.

Select Installation Folder

The installer will install GEX to the following folder.
To install in this folder, click "Next". To install to a different folder, enter it below or click "Browse".

Folder:
\Program Files (x86)\GEX

Browse...

Install GEX for yourself, or for anyone who uses this computer:
- Everyone
- Just me

4. Confirm the installation.

Confirm Installation

The installer is ready to install GEX on your computer.
Click "Next" to start the installation.
5. Verify that the installation completes – you should see this message below:

   Installation Complete

   GEX has been successfully installed.
   Click “Close” to exit.

   Please use Windows Update to check for any critical updates to the .NET Framework.

   Cancel  < Back  Close

6. Right-click on each .dll provided with the .msi file. Select ‘Properties’ and check ‘Unblock’ under security for each of the Modules.

7. Move all .dll files into the Modules folder in C:\Program Files (x86)\GEX\Modules or where you have installed the application.

8. Double-click on the application shortcut icon “GEX” with the GEX logo that was installed on the desktop. See image below:
9. The software will show an error indicating that the master connection string is empty. This string must be entered before you can proceed to finish the installation. Click ‘OK’.

![Error](image)

**NOTE:** The master connection string is the information that the application needs to connect with the SQL database that will be the repository for all electronic data for DoseControl. This string will look something like the example shown below. If using SQL Express on a single PC it will look very similar. If you are connecting to a SQL server that your company has setup, the IT engineers that set it up should be able to provide you with the connection string.

10. Expand the ‘Connection and Storage’ and ‘Logging’ fields by clicking the orange box with the plus symbol (+). Enter a connection string for both **Connection** and **Storage** as well as **Logging**.

![Connection and Storage](image)

![Logging](image)

11. Select ‘Save Changes’ button on each field one time; this will initiate the configuration of the database. The progress is shown using the length of the orange bar near the top of the screen. It will get longer as the status progresses. When complete you will be prompted to restart the application. Select ‘OK’ (this process will happen twice – one time for each click of the individual ‘Save Changes’ buttons).
12. Close the application using the ‘X’ at the top-right corner of the screen.

13. Restart the application by double-clicking the GEX application icon.

14. You will now be prompted to setup the Administrator login. Select the small text to the right of the orange ‘LOGIN’ button.

15. Enter username “admin” and password “admin” and select ‘LOGIN’.

16. You will then be prompted to change the Administrator password. There are no requirements for password length or characters.
17. You will be taken to the Home Screen. Installation is complete.

1.3 Before You Begin

Helpful hints for using DoseControl®

- Only the Application Administrator may perform the actions described in this section.
- Use a mouse to select fields.
- Do not use the Enter key except for on the search screen (the search icon is linked to the Enter button because it is otherwise not active).
- If you are typing and nothing is happening on-screen make sure you have selected the field for entry. The application does not always default to a particular field.
- Use the “Back” button on the top-left of any screen it is available to return to the previous screen.

ATTENTION: Users of the Evolution 220 spectrophotometer must disable a startup menu item called “INSIGHT Launcher” that is installed with the Thermo Scientific Insight 2 software. The startup menu in Microsoft Windows is usually accessed by the “task manager” and contains the processes that are
initiated on your PC when Windows starts. You must disable this Thermo startup menu item otherwise it will block the COM port to communicate with the DoseControl® software.

1.4 Home Screen and Main Menu Overview

On the home screen, a list of the latest reports is displayed along with a button to start a new report. The user can start a new report, select an existing report, or search for a report. The user can select a report from the list by clicking on the report ID. The search uses either the Report ID, if known, or can search by Dosimeter ID to retrieve the report associated with the Dosimeter ID.

1.4.1 Overview of Home Screen Features
HOME SCREEN OVERVIEW

The home screen has five main features:

1) Menu bar (see details below).

2) User and Login bar: details who is logged in and provides the logout feature.

3) Search bar: allows the user to search the system using either Report ID’s or Dosimeter ID’s that have been previously used.

4) New Report button: used to begin a measurement session.

5) Reports list: provides a listing of reports by most recent or displays the results of a search. The list of existing reports provides summary information about the report: Report ID number, version, status (pending/complete), latest date and time the report was created/processed, and the user associated with the report.

1.4.2 Overview of the Menu Bar

The menu bar is always visible on the top left of all screens in the application. The function of the three bars icon is to simply expand and contracts the bar from using icons to displaying icons and text.

- Reports – This is the ‘home’ screen
- Setup - for configuration of dosimetry related items
- Settings – for configuration of IT and general items
- Audit Search – For viewing of the audit log
- User Management – managing users and permissions
1.5 Starting and Stopping the Application

The GEX .lnk file is used to start the program and is installed on the user’s desktop. The GEX logo is displayed as the file icon. Double-click on the GEX icon to open the application.

Use the ‘X’ button located in the upper-right corner of every DoseControl® window to close the application. All data will be automatically saved before exiting. Microsoft Windows conventions will also close the program.

1.6 Reconfiguring Log and Report Storage Locations

The application required the user to designate default storage locations for the Connection and Storage as well as Logging upon initial installation. The location of the database can be changed and the Connection Strings updated as needed. This should be performed by qualified personnel only.

1.7 User Management

User Management includes both the control of access into the software (Access Control) as well as assigning user roles and permissions. Each user will have a username and password to login to DoseControl™. Login and password information can be managed from within the application using the onboard MSSQL (Microsoft SQL) User Management option or controlled at the domain level using Microsoft Windows LDAP. Enabling the LDAP method allows you to utilize corporate level logins and passwords so that the user doesn’t have to maintain a separate set of login credentials just for this application.
Selecting a User Management Method
The user chooses one of the available three user management options that best fits their needs. Simply select the type of “Sign In Manager” by selecting it from the drop-down menu. Select “Save Changes” when complete with your selection. The application will require a restart anytime the user management method is changed.

The user management method can be changed at a later date at the Administrators discretion. All user information is maintained for the life of the software unless the database is archived.

1) MSSQL User Manager
With this user type the access control and user roles and permissions are managed by the System Administrator within the DoseControl® application (onboard). The Admin can setup users and passwords as well as assign roles. From the “Users” screen you can add, edit, delete, and make users active or inactive. To add a user, select the ‘Add User’ button. To edit an existing user, select the ‘sprocket’ icon in the row that the user appears in the User List. You can only delete users that have not used the software to create a report. Finally, you can uncheck ‘Active’ to make a user inactive if you desire as a temporary way to enable and disable users.

On the “Edit User” screen you can enter or edit the username, display name, and/or password for the user as well as selecting the user roles. Users are assigned multiple roles by selecting multiple checkboxes. Select the orange ‘Save’ button to save the information. Below is a list of the roles that can be assigned:
SystemAdmin – allows access to the “Setup” screen for managing connections and storage locations as well as user management.

ApplicationAdmin – gives the user access to the “Settings” screen for managing dosimetry calibrations, etc. on that screen.

Technician – this option must be checked to allow users to create reports and perform dosimetry measurements.

Reread - this box must be checked in order for a Technician to be able to re-read dosimeters.

Procedure:
1. Enter the Username, Display Name, and Password for a given user.
2. Select the checkboxes for the user to make them active or inactive.
3. Select all the checkboxes that apply for a particular user.
4. Select if the user will have re-read permission.
5. Select “Save”.

2) **Basic User Manager**
   This option is designed for scenarios where the software does not fall under any requirements for access control. Enabling this feature will simply require the user to push the “Login” button to login rather than having to manage usernames and passwords. This feature is designed for single PC installations for an individual or local workstation setups where access control is not required. This method will record the domain and username from Microsoft Windows as the user for the audit trail in the application. In this setup, there is no username and password requirement at login.
   
   **NOTE:** This User Manager is not 21 CFR part 11 compliant.

3) **LDAP User Manager**
   This user management method allows the software to utilize an existing Lightweight Directory Access Protocol (LDAP) user directory within an existing company network so that users of DoseControl® can be managed by IT personnel using company level technology. Your company’s IT department will need to assist with the setup of LDAP user manager. This involves setting up a Microsoft active directory user group for DoseControl® and filters within that user group to match the four roles that DoseControl offers.

   Employees must be placed in one or more of the four active directory user groups based on the desired privileges for that employee. For example, a single person needs to be in the Application Admin user group in order to administer the dosimetry aspects, and also in the Technician user group in order to measure dosimeters. This is a direct corollary to checking multiple user roles for a single user.

   Paste connection string with filter into the LDAP Group Mapping box after selecting LDAP User Manager from the drop-down menu on the Setup screen. Select “Save Changes”. Close and restart the application. Login as the System Admin and paste the addresses into the respective role boxes.

   ![Roles](image)

   **NOTE:** Once a user has performed any action in the system for configuration or measuring dosimeters the account cannot be deleted; it can only be made inactive.
2 Setup – Dosimetry Configuration

2.1 Overview of Setup Menu

The setup of the application for dosimetry measurements and reporting requires the Application Administrator to first configure the measurement instruments, dosimeter types, irradiation pathways, dosimeter batches, calibrations, report headers, and rereads for the system. Select the “Setup” icon on the menu bar.

Setup must be completed during initial configuration and maintained as necessary to adapt to changes to any of these seven setup items.

DoseControl® is unique because the routine user does not select a calibration from a list to begin the measurement and report session but rather, the appropriate calibration is chosen by the application based on the pathway, measurement instrument, and dosimeter batch based on inputs from the user. This approach uses a workflow-based decision rather than a user-knowledge based decision.

It is a requirement that a calibration is active in the system in order to measure dosimeters. For initial qualification of DoseControl® dosimetry systems a generic calibration can be used. Only one calibration is allowed to be active for any combination of pathway, instrument (reader), and batch at any given time.

2.2 Pathways (Radiation Pathways): Configuration

The system can be configured to handle dosimetry for multiple facilities, irradiators, or pathways in a given irradiator using the “Pathway” setup feature. Enter the ID, description, reference ID (name all three the same) to setup a pathway. For example, the user may have a Production pathway and
Research pathway. If a paper report will be generated select the checkbox and make the pathway “active” as well.

*Pathways cannot be deleted from the system after any report has been created using that pathway.

### 2.3 Dosimeter Types: Configuration

The system requires input of what types of dosimeters are available for use and configured before multiple batches can be added for a given dosimeter type.

1. Enter a Dosimeter Identifier (name) such as “B3”. Type in the manufacturer.
2. Select a measurement Spectral Bandwidth.
   - Use option 1 “small aperture / fiber” for film dosimeters.
   - Use option 3 “2nm Slit” for Perspex dosimeters.
3. Provide a comment, if desired.

Use the checkbox to make a dosimeter type active or inactive. Select the “Edit Thickness?” checkbox if you need to allow the user to manually enter a thickness value using the keyboard. This user option is available when thickness is independently determined by the user to be different from the average used in the calibration. For example, in the case of dealing with an FWT-60 thickness outlier, or when using Perspex dosimeters if the laser micrometer system is not functioning correctly.
CAUTION: The ‘Edit Thickness’ feature is designed for single replicate dosimeter packages. However, a thickness change to a single dosimeter replicate in multiple dosimeter replicate packages requires the user to hand calculate and enter an overall average thickness of all replicates, in order for the software to calculate the correct dose. Contact GEX Customer Service for more information regarding the issue of changing individual thickness when using this practice with multiple replicate dosimeter packaging.

*The user may delete a dosimeter type only if it has never been used in a report.

### 2.4 Batches (Dosimeter Batch): Configuration

Dosimeter batches must be added so that the software will recognize calibrations with a specific batch. Enter a Batch Name that will appear on screen for users. Select the ‘Dosimeter Type’ and enter an additional description, if needed. Enter the ‘Average Thickness’ for film dosimeters for the batch (for Perspex dosimeters leave this field blank). Check the “Is Active” box when you are ready to make the batch and any associated calibrations available to technicians using the software. You may enter a Quantity, Manufacturer Name, and any comment to go with the information.

*Batches cannot be deleted from the system after any report has been created using that batch.

By selecting the ‘Default’ radio button, the batch selected will appear in the drop-down menu on the “Create Report” screen. If one dosimeter batch is used most frequently, making it the default increases efficiency by eliminating the task of the operator selecting it each time a new report is created.

### 2.5 Readers (Spectrophotometer): Configuration

The system detects and controls the measurement instruments. The manufacturer application software is not used and does not run “in the background”; we use direct instrument control.

NOTE: This is the most complex of the three configurations because it has the most fields to complete.
READER SETUP

*Readers cannot be deleted from the system after any report has been created using that reader.

Below is a detailed description of the purpose of each field and/or instructions for using the field:

- **Make**: Select Evo 220, Genesys 30 or Genesys 20.
  
  NOTE: during software development a “Mock” reader is available. Setting up a calibration using the mock reader allows the user to test the software measurement session features without having an instrument attached. The “mock” reader simply generates random numbers from .040 to 0.999 A.
• **Spectrophotometer ID**: The name the user wants to be displayed on-screen and on their reports. NOTE: assign a name that users will recognize as the equipment ID number.

• **Min Reading Value**: The minimum absorbance that should be considered a valid measurement.

• **Max Reading Value**: The minimum absorbance that should be considered a valid measurement. NOTE: the software will isolate measurements outside this range as being invalid measurements. The data is retained but the value is not counted as a “measurement” or a “re-read”. Typically, the minimum value would be 0.000, and the maximum would be the maximum absorbance value the instrument is capable of measuring (Genesys 20 maximum spec. is 2.500A and the Evolution 220 is 5.000A).

• **Is Active**: The instrument status. An instrument should be unchecked as active if it is removed from service, and then the software will prevent any user from making measurements with that instrument.

• **Serial Number**: Enter the Evolution 220’s Serial Number as it appears on the equipment tag. The software verifies the instrument’s serial number upon initialization, before every zero, and every measurement to provide measurement data traceability.

  NOTE: For the Genesys 20 this field is not active. You may enter the Genesys 20’s Serial Number as a comment or in the description, but the Genesys 20 doesn’t support instrument serial number verification.

• **Description**: Input field for descriptive information such as “located in the lab” that helps the Application Administrator in large organizations to know which instrument is located where.

• **Model Info**: Enter the manufacturer name, if desired.

• **Client Machine Name**: Enter the Microsoft Windows PC name.

  NOTE: After creating records using a reader attached to a specific PC name, the record is locked and this field cannot be changed. To replace a PC in the system, the user must deactivate the older reader record associated with the old PC and create a new record noting the new Client Machine Name. This also means that the user must deactivate any calibrations associated with the old reader record that references the old PC name.

• **Zero (min)**: Enter a maximum idle time for the spectrophotometer before the system requires it to be zeroed. Designed so that users can implement control over operators if needed.

• **COM Port Number**: The com port number of the connected spectrophotometer and this com port number on the software must match. On the user’s computer, go to “Device Manager” and “Ports (COM and LTP)”. Find the instrument located in the list. Right-click and select ‘properties’ and ‘advanced’. You can change the COM Port using the drop-down list circled below:
• **Baud Rate (bits per second):** the baud rate in the COM Port properties must match that setup in the instrument (see the Spectrophotometer Manual for details on adjusting the baud rate). GEX suggests using the default baud rate, which is 9600 for the Genesys 20 and 115200 for the Evolution 220. Enter the baud rate into this field and ensure the port and instrument properties match. See the COM PORT NUMBER picture above for reference.

• **Default for PC?:** Multiple instruments can be configured on one PC. Select this field to make the most commonly used instrument the default selection when creating reports.

• **Requires Barcode Scanner:** select only if you will use the instrument to measure B3 dosimeters and are using the integrated barcode reader (GEX P/N: P4360) for scanning ID’s. Uncheck this box to disable the barcode scanner.

• **Laser Micrometer:** select this box only if you will have an integrated Metralight Laser Micrometer (GEX P/N: P4350) and are actively using it. Uncheck this box as needed when switching between dosimeter types.

• **Micrometer COM Port:** enter the COM port number that the laser micrometer is connected to.

• **Micrometer Baud:** enter the Baud Rate for the COM port that the laser micrometer is connected to (typically = 115200).

• **Last Calibration Date:** enter the Date the spectrophotometer was last calibrated.

• **Next Calibration Date:** enter the Date the spectrophotometer must be calibrated next. The system will prevent use of the instrument beyond this date. The administrator may change this date anytime as needed.
• **Comment**: Enter a comment, if desired.

### 2.6 Calibrations (Dosimeter Batch Calibration): Configuration

The user must manually enter the details of a calibration into the system in order to use it in the system. A list of calibrations is built over time as the user adds them. Below is an image of a calibration list:

#### CALIBRATIONS

<table>
<thead>
<tr>
<th>DISPLAY NAME</th>
<th>CALIBRATION ID</th>
<th>PATHWAY</th>
<th>BATCH</th>
<th>THICKNESS</th>
<th>ABSORBANCE COUNT</th>
<th>READER ID</th>
<th>DOSE RANGE</th>
<th>IS ACTIVE</th>
<th>DELETE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mock Reader CA DualBeam</td>
<td>3199-C combo</td>
<td>DualBeam CA</td>
<td>0.018</td>
<td>1</td>
<td></td>
<td>Mock Reader</td>
<td>1.36 - 75.0 kGy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3100-B</td>
<td>3100-B</td>
<td>Gamma-IP CA</td>
<td>0.018</td>
<td>1</td>
<td></td>
<td>Mock Reader</td>
<td>1.36 - 75.0 kGy</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

#### CALIBRATION LIST EXAMPLE

### EDIT CALIBRATION: 3437-LV combo

- **Display Name**: RES EVO1 LV
- **Calibration ID**: 3437-LV combo
- **External ID**: 00000000-0000-0000-0000-000000000000
- **Pathway**: Research
- **Batch**: 3437-LV combo
- **Initial Avg Absorbance**: 0
- **Reader ID**: LAB EVO 1
- **Absorbance Count**: 1
- **Dose Units**: kGy
- **Dose Range Min**: 0
- **Dose Range Max**: 55
- **Coefficient A**: 0.025729259324628
- **Coefficient B**: 0.0133666698635548
- **Coefficient C**: -0.000256498856150086
- **Coefficient D**: 0.000003219796492255417
- **Coefficient E**: -0.000000018472703758316
- **Start Date**: 10/4/2016
- **End Date**: 10/3/2016
- **Date Added**: 10/4/2016
- **Wavelength**: 640
- **Correction Factor**:
- **Is Active**: ✓
- **Autogenerate dosimeter ids**:

#### ADD NEW/EDIT CALIBRATION

The two screenshots above show the add/edit calibration screen that the user must complete for each batch/pathway/instrument combination for each dosimeter batch calibration (proper terminology is “dosimetry system calibration”).

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Software Version: 1.0.6134.20732  
Release Date: 03/28/17
Below is a detailed description of the purpose of each field when adding a calibration and/or instructions for using the field:

- **Display Name**: the name of the calibration the user wants displayed onscreen and in reports.

- **Calibration ID**: the official calibration ID number generated at the time of curve fitting. This field provides reference to some type of calibration report that provides the history for the calibration as well as associating it with certificates and traceability to a specific standards laboratory.

- **External ID**: Field not used.

- **Pathway**: select the pathway associated with the calibration from the drop-down list of active pathways.

- **Batch**: select the dosimeter batch ID associated with the calibration from the drop-down list of active batches.

- **Initial Avg. Absorbance**: enter the initial average absorbance for the dosimeter, if any. Enter ‘zero’ for no value.

- **Reader ID**: select the instrument ID associated with the calibration from the drop-down list of active instruments (readers).

- **Absorbance Count**: the number of dosimeter replicates in the dosimeter package. If a pouch has 1 dosimeter, replicate A, or so forth, enter 1. If there are 2 dosimeters in a package enter 2. The software will associate that there must be ‘X’ number of dosimeters for each dosimeter ID.

  NOTE: the statistical rereads feature will only work if the absorbance count is 1. For more information, see “Rereads” below in this section.

- **Dose Units**: select kGy or Gy.

- **Dose Range Min**: the minimum dose from the calibration is entered so that in routine use the software will warn users when the dose is below this range.

- **Dose Range Max**: the maximum dose from the calibration is entered so that in routine use the software will warn users when the dose is above this range.

- **Coefficient A through E (0 – 4)**: enter each of the calibration coefficients in this order. If there is no value, enter a ‘zero’.

- **Start Date**: select the Date on which the calibration will become active. This allows the Application Administrator to set a date in the future when the calibration will become active.

- **End Date**: select the Date on which the calibration should become inactive. This allows the Application Administrator to control how long a calibration may be used.

- **Date Added**: select the Date that this information was completed.

- **Wavelength**: enter the wavelength of measurement without any units (e.g. ‘552’).
• **Correction Factor**: allows the Application Administrator to introduce a linear correction factor. The user should enter “1.0” if there is no correction factor to be used.

• **Is Active**: the calibration should be checked as ‘active’ in order to utilize it in the software. The system will inactivate calibrations automatically if pathways, readers, or batches used herein are inactivated.

• **Auto generate Dosimeter ID's**: check this box to have the system generate Dosimeter ID’s for cases where the user will not enter them. For example, if the user wants to simply read dosimeters in sequence and not add the time of recording ID’s.

*Make sure to press the “Save Changes” button after making any changes before leaving the screen.*

### 2.7 Report Headers: Configuration

This configuration option allows the user setup one or more reports and to have specific on-screen information related to each of their reports, and allows users to associate certain pieces of information about the product being irradiated or about the irradiation process itself with the measurements. The information may vary depending on the type of report the user desires to generate such as a production, test, research, etc. where the user desires to record different header information at the report level.

DoseControl® allows the user to configure these fields for on-screen use and to setup special fields such as min and max dose correction factors from dose maps so that the user can enter the ratios and the system can calculate the min and max dose for a process load.

First the user creates a title for the Report Type such as “Production Report” by selecting the orange “Add Field Set” button and entering the name and external identifier (these should match when you name them) and adds that report to the list by pressing the orange “Save” button. The user can then click on the underlined name of the report header in the list and add fields by pressing the white “Add New Field” button for the report that will be displayed when it is selected.
ADD/EDIT FIELDS TO INCLUDE IN THE REPORT HEADER

Below is a detailed description of the purpose of each field and/or instructions for using the field:

- **Field Name**: this name is only displayed on this screen to identify what piece of information the field is intended to convey when in use. For example, if you need a field in your report to enter the Minimum Dose Specification you might assign a field name of “Min Dose Spec (kGy)”.

- **Field Type**: select the type of field from the five options available in the drop-down menu:
  1. Confirmation: creates a “yes or no” field where the user can confirm something or not. Example “Were dosimeters heat treated?”
  2. Date: creates a date field where the user will select a date from the calendar that will default to the date of when the user is completing the field.
  3. Decimal Number: creates a numeric field that allows decimal numbers.
  4. Whole Number: creates a numeric field that allows whole numbers.
  5. Text: creates a field for alphanumeric entries.

- **External Identifier**: the external identifier should be the same as the “Field Name” from above.

- **Label**: enter the name of the field as you want it displayed on-screen.

- **Special Value**: the selection allows the software to utilize the user entries to make calculations in the software; only required if you wish to create one of the following four fields:
  
  1. *Min Dose* – select to allow the user to be able to enter a Minimum Dose Specification (kGy or Gy). The user’s entry will be used for comparison of measured doses (corrected using correlation as described below, if applicable) against specification when measuring dosimeters.
  2. *Max Dose* - select to allow the user to be able to enter a Minimum Dose Specification (kGy or Gy). The user’s entry will be used for comparison of measured doses (corrected using correlation as described below, if applicable) against specification when measuring dosimeters.
3. *Min Dose Correction Factor* – select to allow the user to be able to enter a Correlation Factor $D_{ref}/D_{min}$. The software will calculate all measured doses against the ratio.

4. *Max Dose Correction Factor* - select to allow the user to be able to enter a Correlation Factor $D_{ref}/D_{max}$. The software will calculate all measured doses against the ratio.

### THE FOUR SPECIAL VALUE OPTIONS

- **Sequence**: the sequence number for the field on the screen during dosimetry report creation. Fields will appear in sequence from top to bottom.

- **Required**: check this box if you want to make the completion of this field a requirement. Otherwise the user will have the option to leave it blank.

- **Is Editable**: check this box if you want to allow the field to be editable.

  CAUTION: This feature should only be used to allow editing of information that is transferred to DoseControl® from another system through system integration!

- **Additional Validation**: selecting the ‘edit’ button under each field name allows the user to create field validation requirements. This should be used to make the fields conform to data structure requirements, if applicable. For example, if a field is called “Product ID Number” and that number is always ten digits, we can enforce that the user supplies a value that is exactly ten digits long. A variety of things can be implemented by completing the validation requirements in various ways.

Below are descriptions of the validation types that are available for the five different Field Types that were described above:

1. **Confirmation Field Validation** – No validation available.

2. **Date Field Validation** – The user can select the minimum and maximum date that will be available to the user. By default, the calendars will default to today’s date.

3. **Decimal Field Validation** - The user can enter a minimum and maximum numeric decimal value.

---

**Example 1**
I create a “Min Dose Correction Factor” field. I know the value should be between 0.50 and 0.99.

**EDIT ADDITIONAL VALIDATION: Min Dose Corr. Factor**

<table>
<thead>
<tr>
<th>Min Value</th>
<th>0.50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Value</td>
<td>0.99</td>
</tr>
</tbody>
</table>

**Example 2**

I create a “Min Dose Specification” field. The lowest min dose I have is 15 kGy and the highest is 25 kGy. I can prevent user entry errors outside that range. The operator will be notified and operator notification usually increases task awareness. While this cannot prevent all user entry errors, it is a valuable tool to utilize.

**EDIT ADDITIONAL VALIDATION: Min Dose Spec (kGy)**

<table>
<thead>
<tr>
<th>Min Value</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Value</td>
<td>25</td>
</tr>
</tbody>
</table>

4. **Whole Number Field Validation** – The user can enter a minimum and maximum numeric value.

**Example**

I have a “Product ID” field that must always be 10 characters long and always begins with the number ‘8’.

**EDIT ADDITIONAL VALIDATION: Product ID**

<table>
<thead>
<tr>
<th>Min Value</th>
<th>8000000001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Value</td>
<td>8999999999</td>
</tr>
</tbody>
</table>

5. **Text Field Validation**

**Example**

I have a field to type into the ‘Product Description’ but I am exporting my dosimetry reports electronically via systems integration to a corporate database that will not accept entries longer than 40 characters.
2.8 Re-Reads: Configuration

By default, the system workflow for re-measurement of samples is the same as the workflow for making first-time measurements. This means that re-reads can be performed at the user’s discretion without any limitations. However, if needed, there is a setup feature to configure different requirements or limitations depending on an individual’s user requirements.

To configure re-reads, the user must begin first by assigning reasons that the technician measuring dosimeters will be forced to select from when initiating the re-read workflow.

1. To begin, select “REREADS” on the setup screen. Expand the ‘Reasons’ field by clicking on the orange box with the ‘plus’ sign next to “REASONS”.

2. Add as many reasons as needed. At least one reason must be added to allow any configuration of re-reads. For each reason a re-read ‘strategy’ and configuration will be required.

**Example 1**
Assume that you want to setup two reasons; one to account for a situation where a dosimeter is found to be dirty after the original measurement, and the second for confirmation of the original dose measurement.

For the first reason, select the “Simple Rereads” strategy from the drop-down menu and select the orange “Save” button. The “Simple Rereads” strategy uses the default workflow of a single measurement where the user will take a measurement which will replace the original measurement. The underlying rationale for this strategy is that the dosimetry system produces a normally expected probability distribution with all measurements assumed to be from the same population. Note that the
system is 21 CFR part 11 compliant and the original reading is not discarded. Each reading will be viewable as a chain of events in the Audit Log.

3. Selection of a strategy activates the ‘edit’ button to the right of the strategy. Select ‘edit’ to move the screen to where you can select the re-read strategy.

4. A few re-read options are available to choose from and are described below. After making your choice, select the orange ‘Save Changes’ button.

- **Is there a limit on how many rereads can be taken?**
  Check this box to limit the number of re-reads. In the field below ‘Number of allowed rereads’ enter the number or quantity. Using this feature means that after the number of allowed re-reads is met that no user (even the Administrator) will ever be able to re-read that same dosimeter ID for any reason.
• **Is a different user required to take the re-read?**
  Check this box to force an entirely different user to login and re-read the dosimeter in question before the user can proceed with the dosimetry report.

• **Is the user required to have re-read role?**
  Check this box to allow the restriction of who is allowed to re-read dosimeters based on any quality or business needs. In order to re-read a dosimeter, the user must be assigned “Reread Permission”, which must be activated in the User Management configuration explained in section 1.6.

• **Is a comment required on every re-read?**
  Check this box if you would like to require a comment every time the user selects ‘re-read’. Allows details to be captured beyond just the reason that the user selects (“Dirty Dosimeter”).

**Example 2**
For the second example we’ll create another reason and select the other strategy. Our reason will be “Dose Confirmation” to handle a situation where the original dosimeter reading does not conform to an expectation but we can find no visible dosimeter defect can be found and are certain that the measurement procedure was followed correctly. However, in this case, one desires verification that the original measurement is statistically reproducible. We will select the “Statistical Reread” strategy for this reason and configure it.

The “Statistical Reread” strategy will force the technician to make three measurements of the dosimeter in question and allow the statistical evaluation of the results to determine if the re-read data supports accepting the original measurement or supports changing the original measurement. We can also choose to include the original measurement in the statistical evaluation.

CAUTION: at this time, the statistical re-read strategy is only available when the “Absorbance Count” for a given calibration is set to “1”. This is because a method for handling one dosimeter out of a package of two total dosimeters using this strategy has not been determined.

When we select “Statistical Reread” strategy on the ‘Rereads Configuration’ screen, we have the two new configuration options that appear when we edit the strategy:

1. **Include original measurement in calculations?**
   By selecting this box, the system will include the original measurement in the evaluation.
2. **Maximum coefficient of variation (C.V.)**

The coefficient of variation (percentage) entered here will be used as ‘pass/fail’ criteria for the reread session. The doses of each of the measurements (three forced re-reads, including the original measurement if selected above) will be averaged and a coefficient of variation for the doses will be calculated and compared against the value we enter here.

If the calculated C.V. is lower than the maximum allowed that we choose, the re-read session passes and the average dose becomes the new dose for that dosimeter ID in the dosimeter report. If it fails, the re-read session fails and the original measurement is retained as the value for the dosimeter ID, and the re-read measurements are rejected.

**EDIT REREAD STRATEGY: Dirty Dosimeter**

Include original measurement in calculations?  

Maximum coefficient of variation (C.V.):

2

Is there a limit for how many rereads can be taken?

Number of allowed rereads:

1

Is a different user required to take a reread:

Is the user required to have Reread role:

Is a comment required on every reread:

In the configuration above, we have chosen to include the original measurement in the evaluation and we have limited the number of re-read sessions to 1. This means that no user will be allowed to ever take any more re-reads for that dosimeter, and there is no way for anyone including the Administrator to override this.

In review, a wide number of configurations are possible for each re-read reason. The Administrator may setup one or many reasons depending on the needs and/or desires for collecting information and controlling the re-read process.
3 Creating Reports & Measuring Dosimeters

3.1 Create/Measure Overview

The fundamental purpose of the application is to create dosimetry reports (including dosimetry measurement), to generate outputs (printed report, electronically exported data) and to save that information as an electronic record so that it can be managed over time and used in a variety of ways.

This section reviews how to create reports, search for reports, measure and re-read dosimeters, print reports, and export data. We also introduce some other features that may not be commonly used but are very helpful when needed such as skipping dosimeters (handling missing or damaged dosimeters), and Manual Mode Operation (using the software to calculate doses if the connection to the spectrophotometer fails).

Helpful hints:
- The search button with the magnifying glass icon on the home screen is linked to the ‘enter’ key. You can simply enter a report or dosimeter ID and press enter to search if you wish.
- Dosimeters must be given a “Dosimeter ID” before a measurement is allowed. The software requires a unique identifier for every dosimeter. The application can automatically assign one if the user does not wish to enter one themselves. It creates an ID using an algorithm and ensures that it is unique.

3.2 Creating New Reports

By selecting the orange ‘New Report’ button on the home screen, the user is asked to make three selections that setup the type of report, and allows the software to choose the calibration for the batch/pathway/instrument combination being used.

1. Select a ‘Report Type’ that you have configured in the setup.
2. Choose the ‘Pathway’ and ‘Dosimeter Type’.
3. Enter a unique report identifier (Report ID) for the session and select ‘save changes’. (The default selections that appear when you enter this screen are configured in setup. Set the defaults to the most common selections and so the only item to enter here is the Report ID.)

CREATE NEW REPORT

| Report Type: 2 Production Report |
| Pathway: Production |
| Dosimeter Type: B0 |
| Report ID: Test999871 |

SAVE CHANGES
3.3 Measuring Dosimeters

3.3.1 Measure Screen Overview

The measure screen is where users will spend the majority of their time in the software. Everything described thus far is related to setup of the system to record measurements (with report information included). This section describes dosimeter measurements.

The measure screen is where dosimeter ID’s and absorbance measurements are collected along with additional dosimeter related information.

The screen is split into three major sections (see image below):

1) **Header Info** featuring the report ID, version and measurement instrument status, as well as spectrophotometer, dosimeter, and dosimetry system calibration information that is collapsible and expandable by selecting the orange text “Less Details/More Details”.

2) **Dosimeter List** located on the left side builds as measurements are taken. The currently active dosimeter that is in section three is highlighted in section two. You can select any dosimeter in the list and it will pull the measurement information into the ‘Measure’ section on the right.

3) **Measure** section located on the right side is where user actions are focused. There are a variety of features:
a. The user can select the **WINdose or DoseStix** Toggle Button if using B3 dosimeters. Otherwise this toggle button will not appear for other dosimeters.

b. The user can enter the dosimeter position in ‘DSM Position’ (optional). This would be the location of the dosimeter in the process load. For a dosimeter placed at the ‘Reference Position’ the technician may enter “Ref”.

c. The user can enter the tote or carrier number (optional), and is applicable for tote/carrier based systems. This field may also be used in other ways for continuous conveyor type E-beam systems.

---

**Section 1 - Calibration Information**

Based upon the spectrophotometer ID, the irradiation pathway, and the batch ID of the dosimeters, the software automatically chooses the appropriate calibration curve for the necessary task. The Calibration ID is displayed along with pertinent information from the calibration that may or may not be of interest to all users. Therefore, the section is expandable by using the ‘+ More Details’ expander. The Report ID is listed on the top-left along with the version of that report for easy reference.

In addition, the spectrophotometer status is always visible on top-left of the screen. The spectrophotometer’s status is indicated in the top-left and explained below:

- **READY** indicates that the system is ready to make a measurement.
- **INITIALIZING** indicates that the instrument is initializing.
- **BUSY** indicates the instrument is performing some function such as a measurement or zero. The software is locked when the instrument is initializing or busy so no functions can interfere.
- **NOT INITIALIZED** means that an instrument is not detected (see troubleshooting for more details).
The initialization process for the spectrophotometer includes preparing the instrument for measurement which involves; testing the connection, verifying instrument’s serial number, and ensuring that the spectral bandwidth (SBW) and wavelength settings match those required in the dosimeter calibration. If there is a discrepancy, the software will reconfigure the instrument settings to be correct and follow the zeroing workflow before allowing the user to make measurements.

**Section 2 – Dosimeter List**
The dosimeter list is the running list of measurements. The list tells us the Dosimeter ID, Absorbance, Thickness, and Dose for each measurement. There are also some features that are cues to the technician. The row that is highlighted in grey in the list indicates what dosimeter’s information is being displayed in section 3, Measure.

There are two icons that are used as visual cues. One icon indicates that a particular dosimeter has been re-measured (1), and the other icon indicates that the dose exceeds the calibrated range (2). Dose measurements that are outside of the calibrated range are also highlighted in bold red font. Doses that are outside of the range are not valid, and the notification should alert the operator to review the measurement.

![Dosimeters Table](image)

**Section 3 – Measure**
This section displays the information for the active dosimeter, and provides options for certain configurations. Also see details in section 3.3.1 above.

![Measure Section](image)
It also displays the Dose value and the Absorbance value next to the letter ‘A’. The ‘A’ identifies the first dosimeter replicate for a particular ID. If you had configured for two dosimeters, then you would see two rows, one for A and one for B. Also listed is the ‘position’ in the list. In this case, reading 3 of 10.

**Measure Screen Buttons**
The measurement screen has the following action buttons:

- **Back**: return to the Home Screen
- **Report Summary**: view the Report Summary screen (see section on Report Summary below for more details).
- **Measure**: this button inserts the dosimeter ID into the database, verifies the instrument wavelength setting, and then measures the dosimeter absorbance if the setting is correct. If it is not correct, the instrument will correct it or will inform the technician that it is unable to proceed.
- **Reread**: initiates the workflow for re-measurement of a sample, based on the user configuration described earlier and using methods as described in section 3.5 below. This button only appears after the initial measurement of a dosimeter has been made.

  - **0 Reader**: initiates the on-screen messages and workflow to zero the spectrophotometer (the zeroing workflow is forced for all users each time a new measurement session is opened or re-opened).
  - **Manual Mode**: used in the event that the spectrophotometer will not connect (see section 3.7 below for more information).
  - **Skip Reading**: allows the user to create a record that a reading must be skipped, and the user is required to enter a reason that becomes part of the report comments (see section 3.6 below for more details).
**NOTE:** some setups for certain users may not include the zero button, manual mode, or skip reading features by design. Therefore, one or more of these functions is not available to the user.

### 3.3.2 Procedure for Dosimeter Measurement

The user should follow a strict measurement procedure dictated by the procedure used for measurement of calibration samples coupled with any allowable variance in procedure that has been characterized. The software cannot control the time of measurement for the user. However, it does record the time and date of each measurement.

1) Upon entry to the measure screen, follow the on-screen prompts to remove dosimeter samples from the sample compartment and prepare for zero (see image below).

![Info]

2) See image below. The cursor defaults to the Dosimeter ID field and is ready to accept a typed or scanned value. You must provide a Dosimeter ID for each measurement or use the auto-generate feature checkbox in the Calibration Setup.

3) Enter a ‘DSM Position’ and ‘Tote ID’ if you desire.

4) To measure the dosimeter’s absorbance value, select the ‘Measure’ button.

5) The absorbance measurement and thickness (measured or average value in the calibration) will appear for the dosimeter. The average absorbance and dose values will calculate. The measurement list will also update.
6) Repeat the measurement process for all required dosimeters for the report. All dosimeters must have a measurement or be noted as 'skipped' before the report can be processed (or moved to completed status).

7) To re-read a dosimeter, select the re-read button. Follow the configured workflow. Review section 3.5, Re-reading Dosimeters section below for complete details.

The dosimeter measurement process may be repeated as many times as needed. During measurements or upon completion, the user can select the ‘Report Summary’ button at the top-right of the screen. This will take you to a new screen that provides a summary of the information collected in the measurement session. The data can be reviewed by the technician before taking any further action.

3.4 Report Summary

The Report Summary provides a view of the overall report information including some key features that are not available on the ‘Measure’ screen.

There are four sections:

1. *Results* – Lists the overall minimum and maximum measured doses as well as the minimum and maximum dose specifications (if fully configured).


3. *Readings* – Same as the dosimeter list from the ‘Measure’ screen.

4. *Comments* – All comments are collected here. Skipped readings will be noted here and are not editable here. General report comments can be entered and saved here.
Process Report

Once all measurements are finished, the report is not yet complete until ‘Process Report’ has been selected by the user (see below). The user should thoroughly review the report for any errors by reviewing the ‘summary’ screen before taking this action.

After all dosimeter measurements and all required header information have been completed for a report, the ‘Process Report’ button becomes available on the bottom-right of the ‘summary’ screen. Select ‘Process Report’ to complete and electronically save the report.

Print or Export Report

Once a report is processed, the user may still ‘Print’, or ‘Export to Excel’. They may also perform these tasks while the report is incomplete. Select the printer icon to open a .PDF file that can be printed and/or saved. Select the ‘XLS’ icon to export data into a MS Excel file. Save the files electronically as needed using standard MS Windows conventions.
Create a New Version of a Report

The user may create a new version of a report after it has been processed by selecting the ‘Report’ button. This creates a new report with a new version number but will still allow for editing. The user can edit the header information if there were errors. Also, any dosimeter can be measured if the re-read policy allows. For example, you may prefer the technician to complete the report they are working on even if certain dosimeters require verification. A QA representative could open the report, version it, and re-measure any dosimeters while working under their username (helps the end-user ensure compliance with 21 CFR part 11). The user can print or export data at any time from the summary screen or can return later using the search function to do the same.
3.5 Re-reading Dosimeters

Sometimes a dosimeter needs to be re-measured or re-read. The ‘reread’ button appears in place of the ‘measure’ button after reading any dosimeter (see image below). The user may re-measure or re-read during the measurement session on an at-will basis by default. Additional control of re-read performance is available for configuration by the Application Administrator as explained in section 2.8.

Re-read measurements may occur by the technician at the time of measurement, or the user may process a report and then return later to re-measure dosimeters either in an incomplete or previously completed report (assuming normal procedure for measurement time after irradiation is followed).

If a dosimeter is re-measured, the new value will be displayed and the average absorbance and dose (kGy) will be updated appropriately. The original reading is removed from on-screen display. However, an icon indicates which dosimeters were re-measured and a future feature (still in development) will allow an auditor to view the measurement history for any individual dosimeter in the report. All events are logged and measurement data is retained for auditing purposes.

If the administrator has configured any reasons for re-reads, then the screen will ask the user to select the reason. Additionally, if statistical re-reads were configured for a given reason, the application will require that the user make three measurements of the same dosimeter before it will allow the report to continue. A ‘cancel’ button can be found and used before the first re-read is taken, but once the measurement is taken the re-read process cannot be reversed.
Select ‘measure’ for each independent reading. If the readings C.V. % passes the statistical criteria, the system will simply proceed and will accept the result without any extra notification to the user. If the re-read C.V. % does not pass the specification, the results will be displayed to the user and the user can exit back to the normal measurement mode by selecting the “Cancel” button.

NOTE: the purpose of statistical re-reads is to verify repeatability of the three measurements (or four if including the original measurement). See image below:

In the case of statistical re-reads, if the re-read average value is accepted, the absorbance and thickness will now reflect ‘Re-Read’ because the average dose of the three measurements is what was accepted. The absorbance and thickness of that dose are no longer available as a single value and ‘Re-read’ is noted in their place.

3.6 Skipping Dosimeters

Long term, there may be times when a dosimeter package or a dosimeter from a package is notably damaged or missing and the user needs to strike it and remove it from the report. These two cases need to be addressed, and the software handles both.

Example 1
In the case where one missing dosimeter replicate from a dosimeter package of more than one (e.g. 1 of 2 dosimeters is damaged or missing); we would want to use the other dosimeter measurement only.

Example 2
In the case where all dosimeters from a particular packet, the packet itself is missing, or the dosimeter ID is missing.

The software manages both issues simply. For the first example, if a single dosimeter is damaged and the other is acceptable, then the user can select ‘Skip’ on the ‘measure’ screen. If all dosimeters are damaged or missing and the entire dosimeter needs to be skipped, select ‘Skip Measure’ at the bottom of the ‘measure’ screen (see image below).
In either instance, a pop-up message box will appear that provides the user with the means to enter a brief rationale that documents why the measurement is being skipped (see image below). The user is required to enter a brief comment which is saved to the record when the user selects ‘OK’ to record the comment. Comments are added to the version summary. The software manages comments for each version separately so the user can distinguish to which version the comment was applied.

**SKIPPING A DOSIMETER**

The screen will display “NO DOSI” in the fields for the readings, as appropriate. If only one dosimeter replicate is missing, than the other value is used to calculate dose. If both dosimeters are missing, “No DSM” appears on the measurement list and the summary screen. See below.

The comment that the user entered is displayed to the right of the general report comments on the ‘Report Summary’ screen, as shown below.
3.7 Using Manual Mode for Measurements

If the spectrophotometer will not connect to the software and a report needs to be completed by the user, the user can manually enter absorbance values. This is designed to be a temporary solution for a working spectrophotometer that has connection problems with DoseControl® software. The user can use the onboard spectrophotometer display or use manufacturer software to obtain absorbance values that are entered into DoseControl. The user is able to toggle back and forth from Manual Mode to Automatic Mode by using the ‘Manual Mode’ button at the bottom of the screen, but only if a spectrophotometer is not detected. The application will remain in Manual Mode until the user toggles back to Automatic Mode or exits the application. All manual readings are flagged in the system because they inherently have a lower level of measurement integrity that some users may wish to be able to track.

1. Select the Manual Mode switch to turn on. A new drop-down menu titled “Reader” allows the user to select the instrument, where the manual measurement records will be applied. Enter a dosimeter ID and select ‘Add Dosimeter’. See below.

2. Next, the user is required to enter the absorbance value into the open cell. Select ‘Save’.

---

**MEASURE:**

- **Dosimeter ID:** 39
- **Reader:** GEX LAB EVO 1

**DOSE (kGy):**

- **Readings:** 4 of 4
- **0 Reader**

**Manual Mode**

**Skip Reading**

---

**MEASURE:**

- **Dosimeter ID:** 39
- **Reader:** GEX LAB EVO 1

**DOSE (kGy):**

- **0.350**

**Readings:** 5 of 5

**Manual Mode**

**Skip Reading**
NOTE: Manual operation also works for making rereads. The process is the same but for statistical re-reads, the user must enter and ‘Save’ each of the three values manually.

**DOSE (kGy): 6.1**

<table>
<thead>
<tr>
<th>Absorbance</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-Read 1:</td>
<td>0.250</td>
</tr>
<tr>
<td>Thickness:</td>
<td>2.7355</td>
</tr>
<tr>
<td>Re-Read 2:</td>
<td>0.252</td>
</tr>
<tr>
<td>Thickness:</td>
<td>2.7355</td>
</tr>
<tr>
<td>Re-Read 3:</td>
<td></td>
</tr>
<tr>
<td>Thickness:</td>
<td>2.7355</td>
</tr>
</tbody>
</table>

CAUTION: Manual re-reads feature has not been fully tested for all workflow scenarios. This feature handles a very fringe case and will be improved upon in later versions. Also, at this time there is no manual entry for thickness values. Therefore, the system is not fully operational for such a situation.

### 3.8 Searching for Reports

#### 3.8.1 Searching for an existing report:

The search function will find all reports with that report number or the report that includes the dosimeter ID entered in the search bar. The search will return the latest version of the report(s) found.

**SEARCH REPORTS**

- MikeTest111
- MikeTest111

The user can also select ‘include all versions’, and select ‘search’. The search will find and list all versions of the report(s) found. See image below.
3.8.2 Status of a Report:

A report is either completed or incomplete.

- **Incomplete**: User has not completed the required header information or all of the necessary dosimeter measurements.

- **Complete**: The user has completed the report and selected ‘Process Report’. (Completed reports are read-only).

3.8.3 Actions Available for Incomplete Reports

With an incomplete report, there are six available options the user can perform using the available buttons on the ‘Measure’ or ‘Summary’ screens:

- **Edit Report**
  Navigates to the ‘Report Header’ information screen. This is the screen where general information related to the report exists or is entered that was configured in Section 2.7, Report Headers.

- **Measure**
  Navigates to the ‘Dosimeter Measurement’ screen.

- **Process Report**
  This action sends electronic data to connected databases and finalizes the status of a report from ‘incomplete’ to ‘complete’. NOTE: In some cases, a report cannot be completed until the required information is entered or the required measurements are made. The button is not active unless everything is completed.

- **Print**
  Generates a .PDF file that the user can print with standard conventions.

- **Export to Excel**
  Inserts the data from all four tabs from the onscreen report into four tabs in an MS Excel file and asks the user to save the file.
3.8.4 Actions Available for Completed Reports:

There are three available actions the user can perform when viewing a ‘completed’ report (also see Exhibit 10).

1. **New Version**
   Creates a new revision level of the same Report ID allowing the user to edit report header information, re-measure dosimeters, fix typos, etc.

2. **Print**
   Generates a .PDF file the user can then print with standard conventions.

3. **Export to Excel**
   Inserts the data from all four tabs from the onscreen report into four tabs in an MS Excel file and asks the user to save the file.
4 Errors and Troubleshooting

Errors can happen from time to time. Often an error message appears and contains some informative text that may help GEX personnel to determine the source of the problem. Always capture a screenshot image or ‘snip’ image of any error message for GEX to review.

Sometimes an error may occur and the software may malfunction or ‘crash’ as a result. Do not be alarmed. The software and database are designed to recover from such errors. Simply restart the software and the software will operate normally upon restart. Please document the process for reproducing the error with as many pictures as possible because this is more challenging for conducting an investigation than when an error message is displayed.

NOTE: Please document and report all errors to GEX Customer Service (see below).

4.1.1 Reporting Bugs to GEX

When a problem is discovered in the software, as much information as possible must be gathered and reported to GEX. The protocol for documenting the problem and contacting GEX is described below:

1) Provide a general description of the error. Be as detailed as possible:
   a. What is the user trying to do when the error occurs?
   b. What version number of the application are they running (located in the lower-right hand corner)?
   c. Is it something that they do all the time or is it functionality that they seldom use?

2) What is the timeline related to the initial discovery and reporting of this error?

3) Find the log file in the Application Data folder (search for %appdata% to easily find this folder). Copy the log file and include in the submission to GEX.

4) Are you able to readily reproduce the issue? What are the numbered steps to reproduce? The steps to reproduce the issue consistently should be provided in numbered order.


6) Is there a temporary workaround the user can follow while we work to fix the issue? Describe in detail the procedures to restart or recover from errors that occur, if possible, and use that procedure as a workaround until the issue can be addressed. This is to ensure continuity of operations.

7) Contact GEX Customer Service to report the error and provide this information. Send an e-mail to mpageau@gexcorp.com with “BUG” in the subject line, the information to report from above, and your complete contact details. For urgent matters call Mike Pageau directly at +1 720-810-2225 after sending the e-mail.

4.1.2 Requesting Improvements to DoseControl®

If you could like to see areas of improvement to the software user interface, functionality or performance, please contact GEX. Improvement suggestions should be reported by e-mail to the same contact details but instead should be assigned ‘IMPROVE’ in the subject line. Include a detailed...
description of the suggested change/improvement(s) with pictures. A compiled list of suggestions is preferred rather than multiple requests from the same user at the same time. GEX will review and contact you to discuss each suggestion.
5 Appendix 1 – Installing and Configuring Microsoft SQL Express

Note: This guide was written while installing SQL Server Express 2014 on a computer running Windows 7 Pro x64 with 4 GB RAM. Please make necessary adjustments for the specific type of SQL installation.

Note: The SQL Server Express 2016 version is not supported on Windows 7.

1. Download and install Microsoft .NET 4.6 framework here.

2. DoseControl will work with any SQL or SQL Express version 2008 R2 or higher. We recommend the 2014 version - Download SQL Server 2014 Express here.

3. Select the ExpressAndTools 64BIT\SQLEXPRWT_x64_ENU.exe option and click Next (select the x86 version if the client computer is the 32-bit version of windows):

![Choose the download you want](image)

4. Double-click the downloaded installer. Click Run if prompted, then click OK in the Choose Directory for Extracted Files dialog box.

5. Once the installer starts, click New SQL Server stand-alone installation . . .

![New SQL Server stand-alone installation or add features to an existing installation](image)

Launch a wizard to install SQL Server 2014 in a non-clustered environment or to add features to an existing SQL Server 2014 instance.

6. Accept the license terms and click Next.
7. Select the following features and click **Next**:

   - **Instance Features**
     - Database Engine Service
     - SQL Server Replication
     - Full-Text and Semantic Extractions for Search
     - Reporting Services - Native

   - **Shared Features**
     - Client Tools: Connectivity
     - Client Tools: Backwards Compatibility
     - Client Tools: SDK
     - Documentation Components
     - Management Tools - Basic
       - Management Tools - Complete
     - SQL Client Connectivity SDK
     - LocalDB

   - **Redistributable Features**

8. Accept the defaults on the **Instance Configuration** screen and click **Next**.
9. Accept the defaults on the Server Configuration screen and click Next.

![Server Configuration Screen](image)

10. On the Database Engine Configuration screen, accept the defaults. Confirm that the current user is added under Specify SQL Server administrators. If it is not, click the Add Current User button. Click Next.

![Database Engine Configuration Screen](image)


12. Perform a Windows Update to install the latest patches and updates for SQL Server Express 2014.

13. In the start menu, find the shortcut for SQL Server 2014 Management Studio and pin it to the task bar.
6 Appendix 2 – DoseControl Software Installation Checklist

PURPOSE
To provide users with explicit step-by-step instructions for uninstalling existing versions and installing a new version of the software.

PREREQUISITES

☐ 1. Microsoft .NET Verification
   - All user PC’s should be running Microsoft .NET version 4.6.1 or higher. Here is the link to download it: https://www.microsoft.com/en-us/download/details.aspx?id=49981.

☐ 2. SQL Database Instance Creation
   - A Microsoft SQL instance must be created on the Server or PC before installation.

☐ 3. Receipt of DoseControl® installation files
   - A method for distributing the installation package from GEX to the user must be agreed upon and executed in advance. The files cannot be emailed. The easiest method is using a Dropbox method. GEX can also upload via FTP or as a last resort can ship the installation files on a USB Thumb Drive.

☐ 4. SQL Server User and Password Verification
   - Verify that the user in the master connection string has DB Create privileges.
   - Verify the current password that will be used on the installation day for the SQL Server is correct.

☐ 5. DoseControl® User Manual
   - The user should have the latest revision of the GEX User Manual – GEX Doc#100-266 for reference. It can be downloaded here http://www.gexcorp.com/pdf/100-266_A%20DoseControl%20Software%20User%20Guide%20V.4.3.pdf

UNINSTALLING EXISTING VERSIONS OF THE SOFTWARE FROM A PC
All current versions of the software must be uninstalled prior to installing a new version.

☐ 1. Delete the SQL Database “GEXApp” on the Server
   - Caution: This action will delete all existing application data. Create a backup of the database prior to deleting it from this server. You can also rename the older database and leave it on the existing server.
     - On the server Launch SQL Management Server Studio (SMSS), find the GEXApp database, right-click and choose ‘Delete’ (check both checkboxes at bottom of dialog box that appears) and click ‘OK’.

☐ 2. Delete AppData on the PC
   - On the PC in windows explorer, type %appdata% , and then delete the ‘GEX’ folder that appears in that the app data folder.

☐ 3. Uninstall DoseControl® Program
   - On the PC go to Control panel, programs, and uninstall any GEX versions.
4. Manually Delete GEX Program Folder
- On the PC go to C:\Program Files (x86) and delete the “GEX” folder.

INSTALLATION OF THE SOFTWARE ON A PC

The following installation steps should be executed and verified while following section 1.2 and 1.7 of the DoseControl User Manual.

1.) Installation of the Program
- Move the DoseControl installation folder to the desktop of the PC for installation and double click the GEX.Admin.Installer.msi installer file and follow the on-screen prompts.

2) Manually Load .dll Files
a. Right Click on each Module in the installation folder and select Properties and check ‘Unblock’ under ‘Security’ for each of the Modules, if necessary. If “Unblock” does not appear, ignore this step.
b. Copy and paste all module.dll files into the folder C:\Program Files (x86)\GEX\Modules

3) Master Connection String
a. Launch the application
b. Expand ‘Connection and Storage’ and enter the master database connection string. Press the ‘Save Changes’ button.
   Note: The connection string has the following format: Server=SQLSERVERNAMEorADDRESS;Initial Catalog=GEXApp;Integrated Security=false;User ID=SQLUSERID;Password=SQLPASSWORD
c. Expand ‘Logging’ and enter the exact same connection string used in ‘Connection and Storage’. Press the ‘Save Changes’ button.
d. Close and reopen the application.

4) Change Admin Password
- Select ‘Admin Login’ and enter the user ID “admin” and the password “admin”
- When prompted, change the Admin password to something of your choosing and write down your new password.
- Close and reopen the application.

5) Setup User Management
Choose one of the following:
- Go to the ‘Settings’ menu. Expand ‘Application Settings’. Change Sign in manager drop-down menu to ‘Basic user manager’. Save changes. Close and reopen the application
- Go to the ‘Settings’ menu. Expand ‘Application Settings’. Change Sign in manager drop-down menu to ‘MSSQL user manager’. Save changes. Close and reopen the application
- For LDAP / Active Directory Configuration:
  - Go to the ‘Settings’ menu. Expand ‘Application Settings’. ‘LDAP user manager’ is already selected. Paste the active directory IP or address in the connection string box. Press ‘Save Changes’.
  - Go to the ‘User Management’ menu. Enter the Active Directory address information for each of the 4 user roles, as appropriate.

6) Dosimetry Setup
- For manual dosimetry setup, go to the ‘Setup’ menu to configure readers, batches, pathways, report headers, calibrations and re-reads in accordance with the user manual. Installation is complete.

- For pre-configured dosimetry setup, close DoseControl and execute the provided SQL script in SQL Management Server Studio (SMSS). Proceed to step 7.

7) Setup Integration Connection

**Note:** Complete this step only if you have custom integration to DoseControl with an enterprise system

a. Open the settings menu from the menu bar and expand ‘Application Settings’. In the Client Report Service selection box, select the appropriate custom data Service, then paste the connection string for the enterprise database into the box. Press ‘Save Changes’.

**Note:** The format for this connection string may vary depending on the database type but in general the string will look like this: `Data Source = INTEGRATIONSERVERNAMEorADDRESS;Persist Security Info=True;User Id=DBUSERID; Password=DBPASSWORD`

b. Close and reopen the application.

c. Installation is complete.

### REVISION HISTORY

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<th>Date</th>
<th>Change Description</th>
<th>Revision</th>
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<td>10/18/16</td>
<td>Initial Release.</td>
<td>A</td>
</tr>
<tr>
<td>01/26/17</td>
<td>Revised to include Appendix 1 and 2 for additional instruction per ECO# 70270.</td>
<td>B</td>
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<tr>
<td>03/27/17</td>
<td>Revised to reflect the new registered trademark status instead of TM per ECO# 70278.</td>
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