GEX CORPORATION
THE DOSIMETRY COMPANY

DOSECONTROL® DOSIMETRY SOFTWARE
USER GUIDE

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NLog, NLog.Config, NLog.Schema	BSD 3-clause	https://raw.githubusercontent.com/NLog/NLog/master/LICENSE.txt
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Prism.Core, Prism.Mef, Prism.Unity, Prism.Wpf	MIT	https://github.com/PrismLibrary/Prism/blob/master/LICENSE
Rx-Core, Rx-Interface, Rx-Linq, Rx-Main, Rx-PlatformServices	Apache 2.0	https://github.com/Reactive-Extensions/Rx.NET/blob/develop/LICENSE
System.ValueTuple	MIT	https://github.com/dotnet/corefx/blob/master/LICENSE.TXT
Unity	Apache 2.0	https://github.com/unitycontainer/unity/blob/master/LICENSE
WindowsAPICodePack	Microsoft	https://github.com/aybe/Windows-API-Code-Pack-1.1/blob/master/LICENCE

DESCRIPTION

This manual provides instructions in usage and troubleshooting of GEX Corporation's DoseControl software for versions 1.1.2018. 1.6598 or higher. This software provides an interface for measuring dosimeters in the UV/VIS range using Evolution 220, GENESYS 30 and GENESYS 20 Spectrophotometers to generate dosimetry reports. DoseControl regulates the measurement process which provides a repeatable test method while allowing the user flexibility in the configuration of the workflow. Electronic data storage in SQL allows for a variety of reporting options to get results from the system into a format that meets the user's requirements.

DoseControl was developed to provide a modern platform with broad. The software is designed for expansion with the addition of new functionality and features to be added in the future.

Platform Requirements

Below are the optimal and minimum requirements:

Optimal Requirements for PC Workstations

- Windows 10 x64
- .NET Framework 4.6.2
- At least 8 GB RAM
- 3.0 GHz Quad Core processor
- At least 100 GB hard drive space
- 1900 x 1200 screen resolution or higher capable widescreen monitor
- Adobe Reader
- Microsoft Excel 2014 or higher

Minimum Requirements for PC Workstations

- Windows 7 x32 or higher
- .NET Framework 4.6.2
- 2 GB RAM or higher
- 2.0 Ghz processor or higher
- 20GB hard disk space
- Adobe Reader
- Microsoft Excel 2007 or higher

Optimal Requirements for Application Database Servers

- Microsoft Windows server 2012 or higher
- At least 100 GB hard drive space
- At least 16 GB RAM
- Microsoft SQL Server 2012 or higher

Minimum Requirements for Application Database Servers:

- SQL Server 2008 R2 – using Microsoft's minimal requirements

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Validation and Compliance
GEX has concluded a complete validation of the system and instructions for installation and operation. The documentation is maintained and available for audit at our offices in Denver, CO U.S.A.

An assessment has been made, and it has been found that this software and the lifecycle design comply with all applicable sections of both 21 CFR part 11 and EU Annex 11. The end-user must fulfill user responsibilities and comply with all sections of these two regulations that are related to system security and documentation in the installation, maintenance, and operation of this product to be fully compliant.

TABLE OF CONTENTS

1 Installation and System Configuration

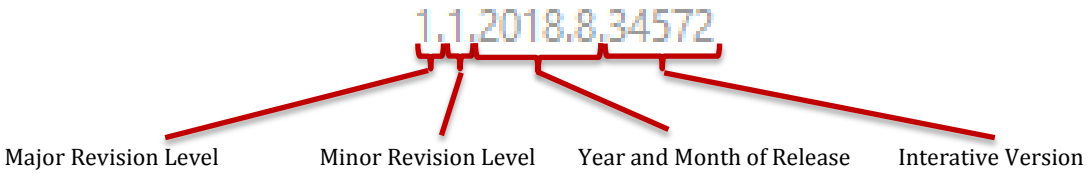
The entirety of this section is designed to provide instruction to the *System* Administrator for the software installation and subsequent configuration of the operational aspects of the software (IT-related configuration).

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. For more information about the program please visit www.gexcorp.com.

This software was developed for use on laptop and desktop PCs running Microsoft Windows using the .NET platform. The primary coding language is C#.

The development has been version controlled and each new software build is automatically assigned a unique ID number. The version number is shown in the lower right-hand corner of the DoseControl screen at all times. The current formatting of the version number is explained below.



- *Iterative Version* – an unique number that identifies a specific software build. This increasing number is automatically generated by the software that manages the DoseControl application code. ***Note:*** This number was 4 digits and with this release it has expanded to 5 digits.
- *Year/Month of Release* – determined by the date in which the build is assembled by the software development team.
- *Minor Version* – manually issued by GEX when there is a significant addition, reduction or change in functionality.
- *Major Version* – manually issued by GEX. Goes up by one digit when the is a significant change in the overall architecture, user interface, or scope of the software

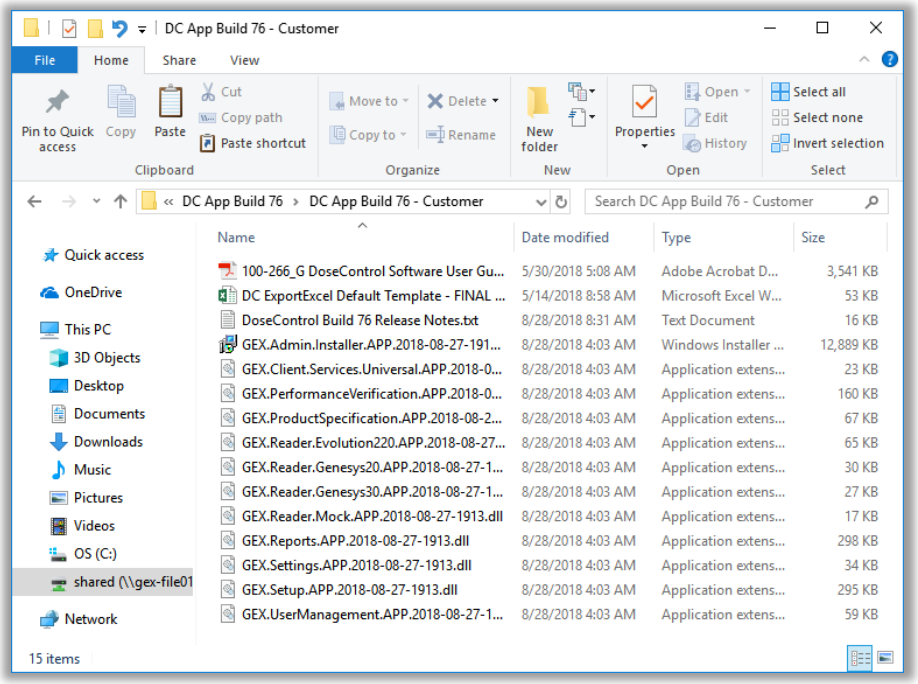
1.2 First Time Installation

NOTE: For complete instructions on installing an upgrade to an existing installation, please see Section 10 of this User Guide.

NOTE: A Microsoft SQL database instance must first be installed prior to installing the application. The SQL instance should be installed and managed per your company's data governance policy. For Basic User licenses, this should be Microsft SQL Express installed on a PC or laptop. For Premier or Enterprise licenses of DoseControl, a full version of Microsoft SQL must be installed on a database server that meets the requirements stated in this manual. See Section 9 for more information on Microsoft SQL and SQL Express.

Receive a Software Build from GEX

The application installation package consists of an .msi file for installation, .dll files that the user must load manually after running installation, and software related documentation such as Software Release Notes and User Guide. There are multiple module.dll files that are deployed with the .msi file. It will look similar to the image below, but some users will receive more .dll files for functionality they have purchased than other users will receive.

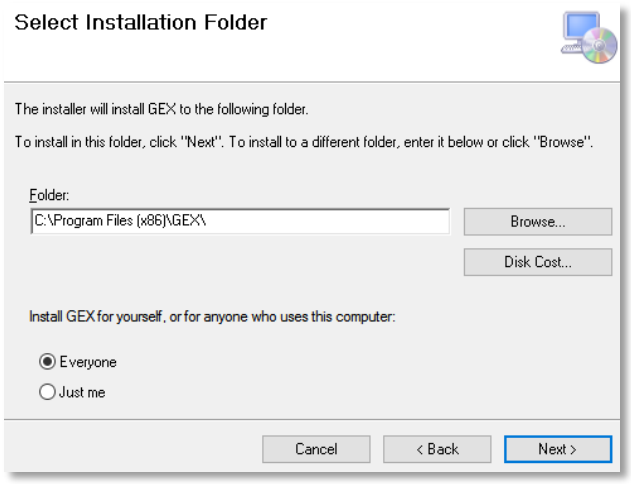


Installation Instructions

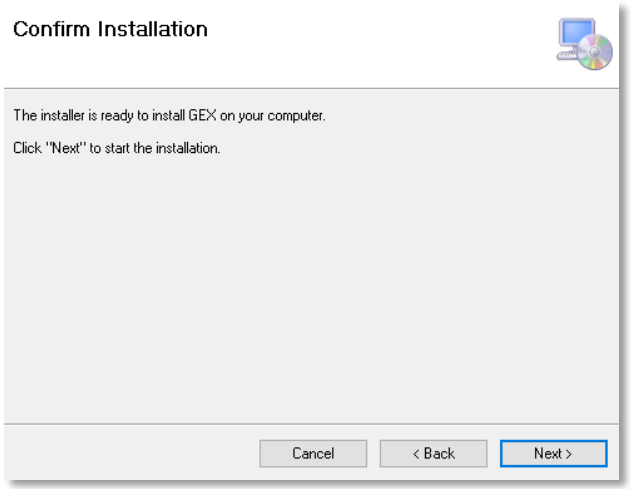
1. Place the .msi installer on the desktop of the computer for installation.

2. Double-click .msi. Follow prompts to complete the install of the application.

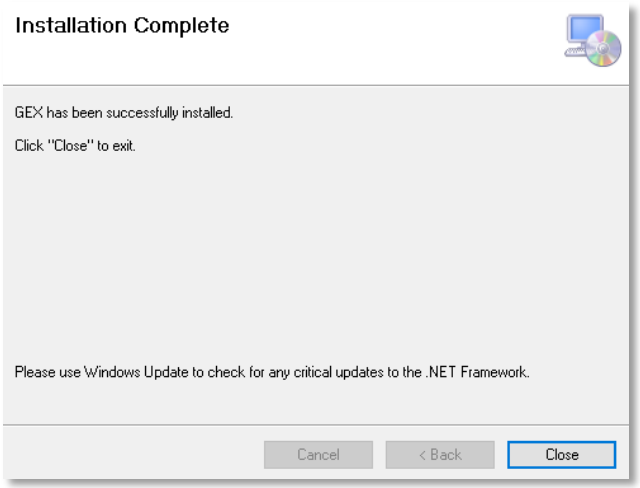
3. Select the folder to install the application to on the computer.



4. Confirm the installation.

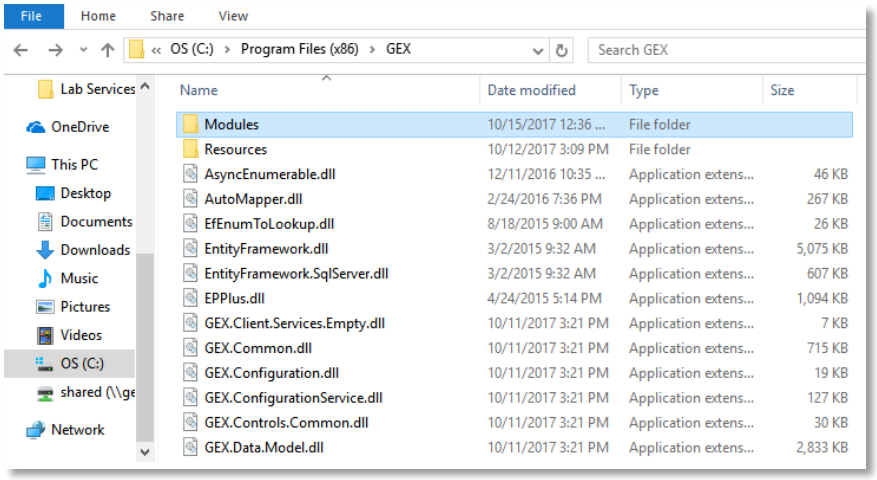


5. Verify that the installation completes – you should see this message below:



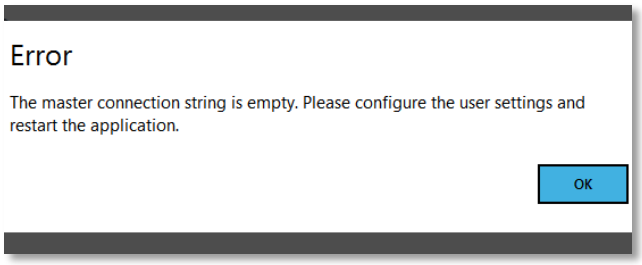
6. For some users but not all, this may be a necessary step. Right-click on each .dll provided with the .msi file. Select 'Properties' and check 'Unblock' under security for each of the Modules (if asked). Confirm any messages regarding authorization. In addition, some companies may have software that controls sensitive files like .dll's and you may have to use other features. Ask your IT experts for more information.

7. Move all .dll files into the Modules folder located in *C:\Program Files (x86)\GEX\Modules* or the location where you have installed the application. Close the folder and go to the desktop.



8. Double-click on the application shortcut icon "GEX" with the GEX logo that was installed on the desktop. See image below. If the icon does not appear on the desktop, find the .exe file named 'GEX' located in the Program Files folder.

9. The software will show an error indicating that the master connection string is empty (see below). This string must be entered before you can proceed to finish the installation. Click 'OK'.



1.3 Connection and Storage Configuration

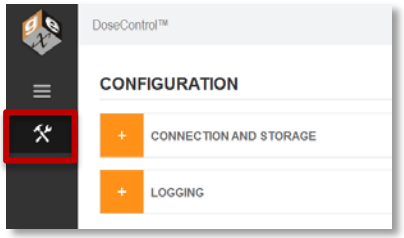
DoseControl uses a configuration file with the file extention *.json* to store the data required to connect to the SQL database, and this is shared between all of the users of a particluar PC; this is called the "Master Connection String". The application does not work unless it can connect to the SQL database that contains all the configuration data used to operate the application. Therefore, the user will always see the screen above if the .json file is missing or incomplete.

In addition, the .json file stores the global administrator password for DoseControl. Upon first running of the application, the .json file must be created, and the exact same steps are required if the .json file is deleted.

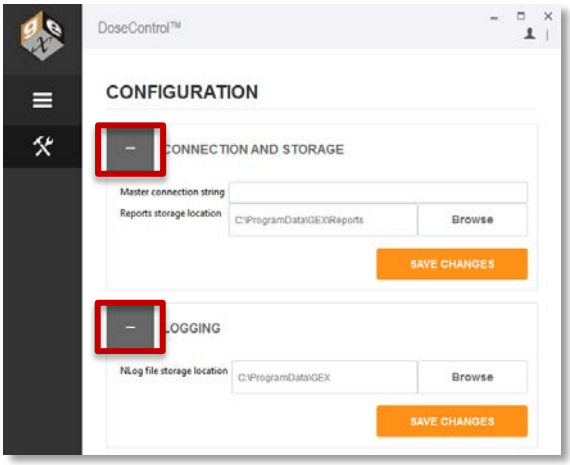
NOTE: See section 9.4 for detailed information for contructing a connection string.

Continuing the steps from the previous section (1.2) of the User Guide above:

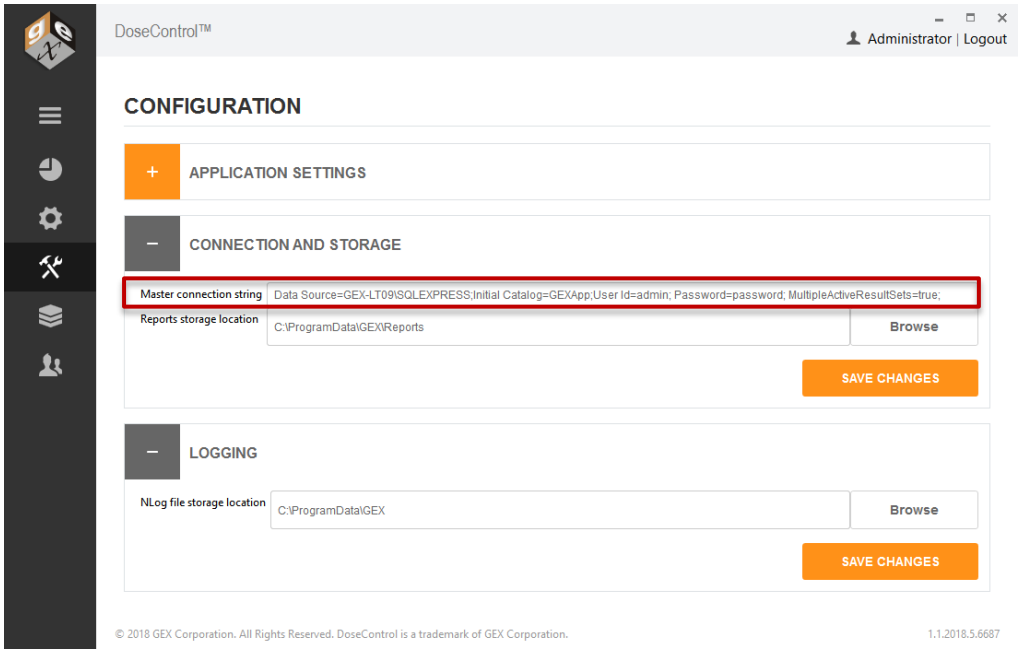
10. Click "OK" on the error message. The message clears and the user is now on the Settings screen of the application, indicated by the "hammer and wrench" icon in the menu bar.



11. Expand the 'Connection and Storage' and 'Logging' fields by clicking the orange box with the plus symbol (+).



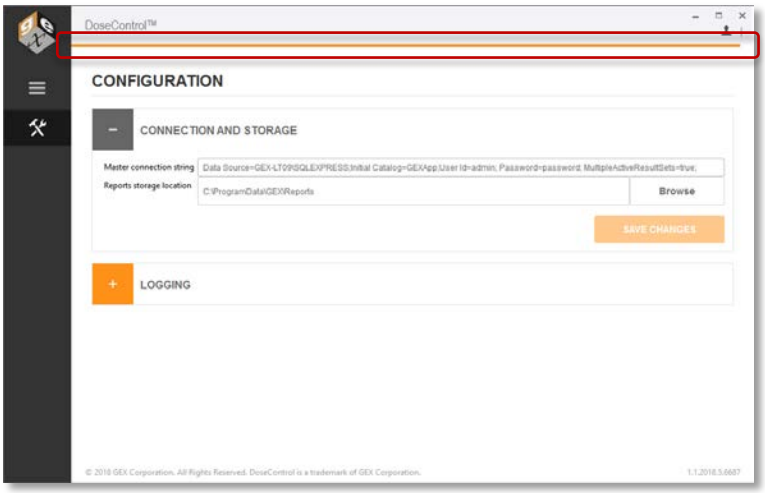
12. You must enter the master connection string. At this time, you can also change the Reports and NLog storage locations, if desired:



- *Report Storage Location* - directory where all the reports generated by the system are created (the user can save them elsewhere but a copy is always created and stored in this specified location).
- *NLog File Storage Location* - directory where the NLog and archived versions of the NLog are stored. The NLog records all errors in the system along with some general expected processes. This log may be used by GEX in the event of a need for troubleshooting.

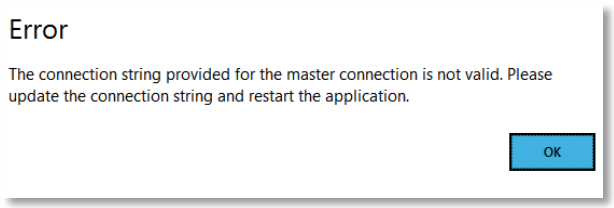
13. Select the 'Save Changes' button on each field one time; this will initiate the configuration of the database if the connection string is correct.

    The progress is shown using the length of the orange bar near the top of the screen.

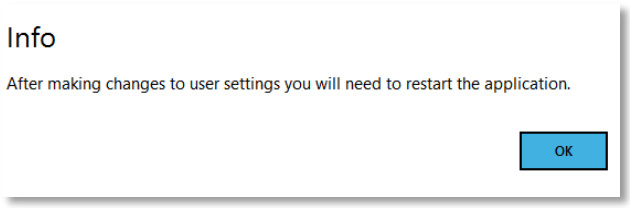


The bar will get longer as the status progresses. If DoseControl is having problems connecting to the database, the orange bar may go back and forth and may take some time before the screen changes.

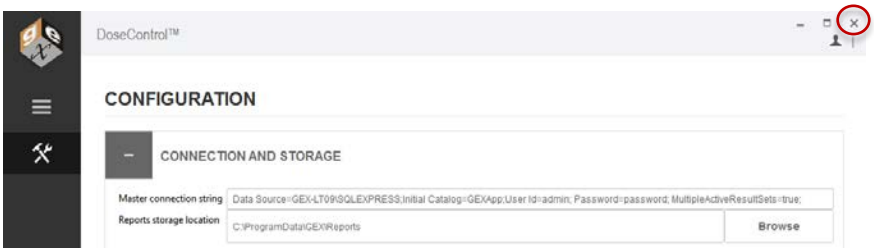
If the connection string is not correct, an error message will appear to alert the Administrator. If this message appears, you must augment the string because something is not correct.



Select 'OK'. Review the string and make any necessary changes. Select 'Save Changes' again. When the string is entered correctly you will be prompted by an info message to restart the application. Select 'OK'.



14. Once the string is correct, and the filepaths for Reports and Nlog have are satisfactory, close the application using the 'X' at the top-right corner of the screen.

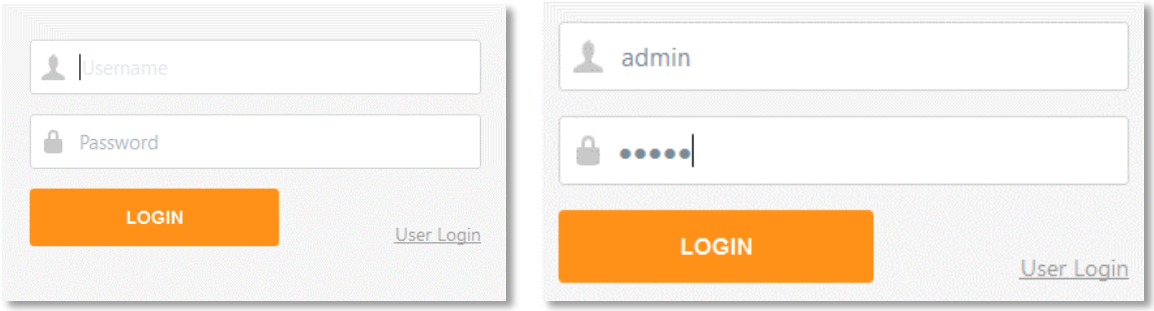


15. Restart the application by double-clicking the GEX application icon on the desktop.

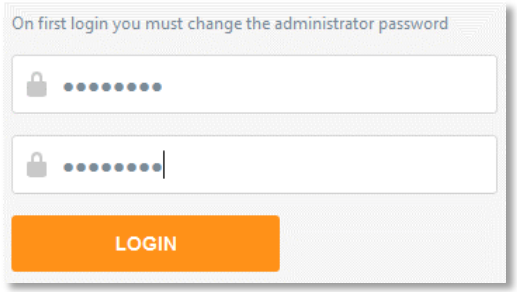
1.4 Establish Global Administrator Login

Continuing the steps from the previous section (1.3) of the User Guide above:

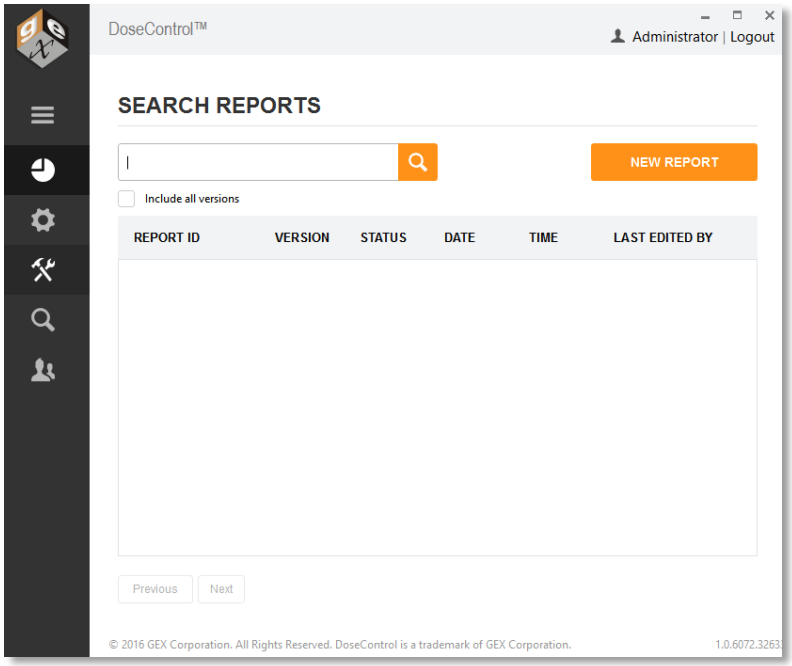
16. Upon re-opening the application after successful entry of the connection string you will be prompted to setup the Administrator login. This is the only login that is managed by the application outside of the database. It can be reset if needed, but please write down your selected password.
17. Select the small text to the right of the orange 'LOGIN' button that says 'Admin Login'.
18. Enter username "admin" and password "admin" and select 'LOGIN'.



19. You will then be prompted to change the Administrator password. There are no requirements for password length or characters. This will be the System Administrator password. Write down your password for the username 'admin'.
20. Press 'Login'.



21. You will be taken to the Home Screen. Installation is complete.

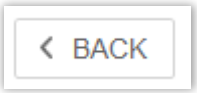


Installation is complete. Proceed to the next section for important information and then begin configuration following the ongoing instructions below.

1.5 General Overview

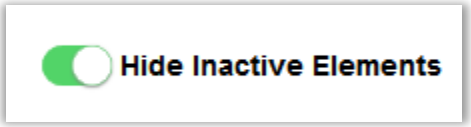
Helpful hints for using DoseControl

- *Do not assume* the use of the Enter key is synonomous with pressing a button on a screen. In some cases the enter key will work and in others it does not.
- 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 on the screen.
- Use the "Back" button on the top-left of any screen to return to the previous screen.



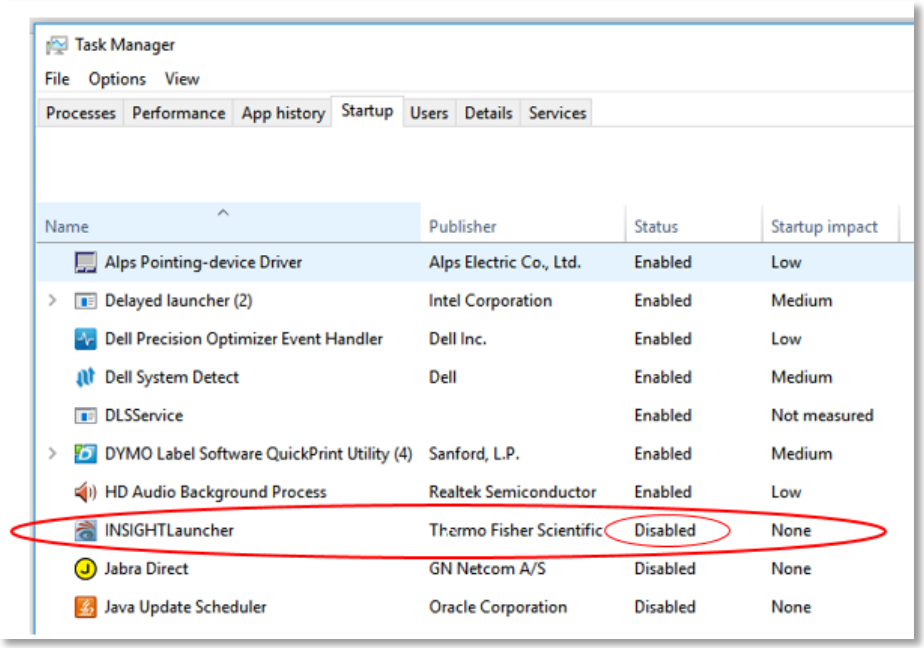
- Use the Trash Can icon to delete items in the configuration section. Once a configuration item is used, it can no longer be deleted.

- Inactive configuration items can be removed from the view at the user's discretion. Use the "Hide Inactive Elements" switch on the applicable screens if you only want to view only active items.



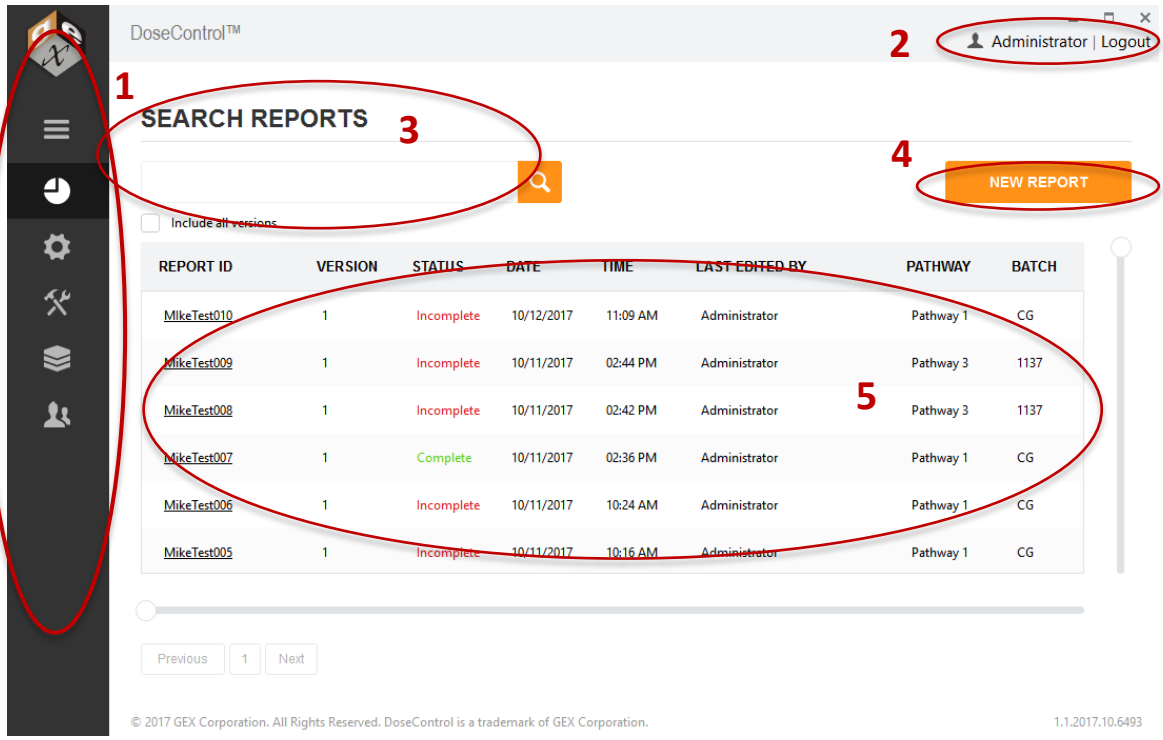
- You must always use the available "Save Changes" feature to save any additions or changes on these screens. There is no auto-saving of configuration entries. However, measurements are auto-saved and there is never a time when you can forget to save a measurement.

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



Overview of Home Screen Features

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.

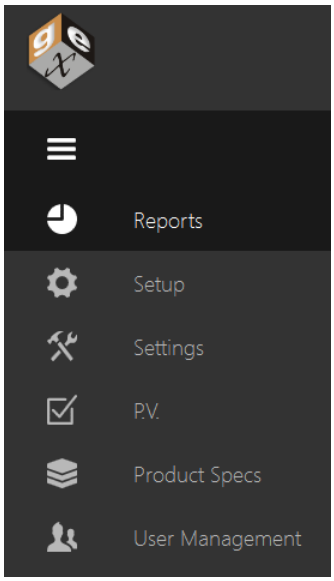


HOME SCREEN OVERVIEW

The home screen has five main features:

1) ***Menu bar*** – provides links to the different sections of the application
2) ***User 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 creating a new measurement session (report).
5) ***Reports List*** – displays a list of all reports that exist in the system (when the search bar is blank) or displays the results of a specific search. Also provides summary information about the report: Report ID number, version, status (pending/complete), latest date and time the report was created/processed, the user associated with the report, and the pathway and batch used in each report.

Overview of the Menu Bar



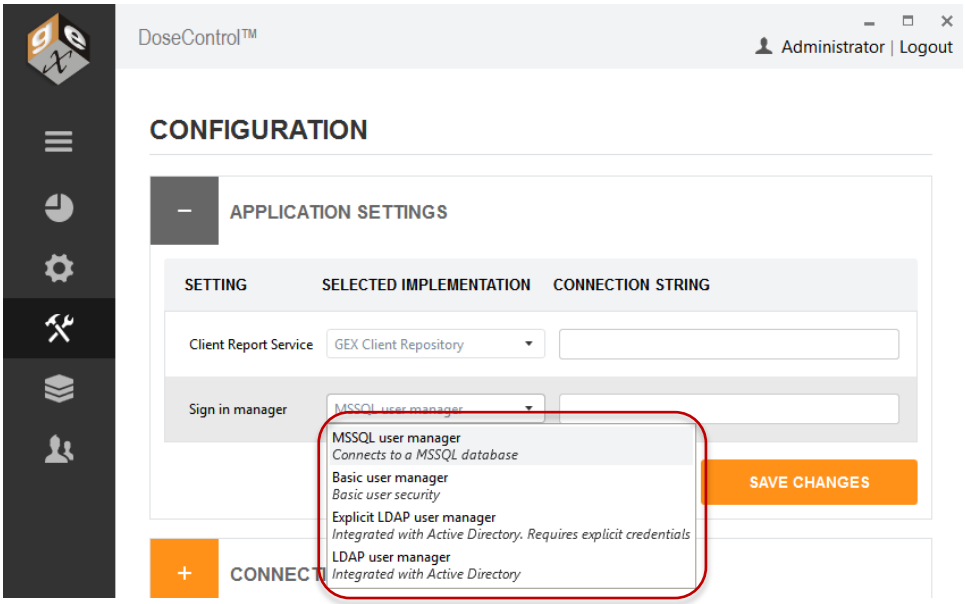
The menu bar is always visible on the top-left of all screens in the application. The function of the 'three bars' icon is to expand and contract the menu bar from using icons to displaying icons and text.

- *Reports* – This is the 'home' screen
- *Setup* – for configuration of dosimetry related items
- *Settings* – for configuration of IT and general items
- P.V. – Performance Verification module (*Evo220 only*)
- Product Specs – Product Specifications module (*added cost*)
- *Audit Search* – For viewing of the audit log
- *User Management* – managing users and permissions

1.6 User Management

User Management is controlled via the Sign In Manager feature and includes two key facets of operational control of the software: control of user access into the software (Access Control) and the permissions to allow users access to distinct features within the software (User Roles).

There are 4 options for user management that the System Administrator must choose from which enable a range of user management methodologies. Simply choose 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. Details are given below about each user management method.



The user management method can be changed by the System Administrator at any time.
All user information is maintained for the life of the software unless the database is archived by the end-user.

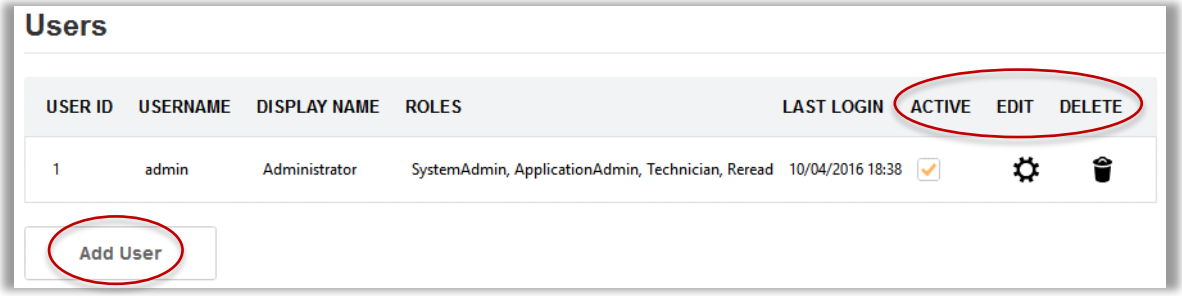
Selecting a Sign In Manager

The user chooses the option that best fits their needs:

1) **Basic User Manager**
   This option is designed for users that do not have any requirements for access control and seeking very simple access. Enabling this feature will require the user to push the "Login" button to login rather than having to manage usernames and passwords. Only the date and time of all logins and logouts is retained since there is only one user.

   This feature is designed for single PC installations with a Basic software license using SQL Express. 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:** Basic User Manager is not 21 CFR part 11 compliant.

2) **MSSQL User Manager**
   With this user manager 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, if desired you can uncheck 'Active' to make a user inactive as a temporary way to enable and disable users.



NOTE: Once a user has performed any action in the system including configuration or measuring dosimeters, the account cannot be deleted; it can only be made inactive.

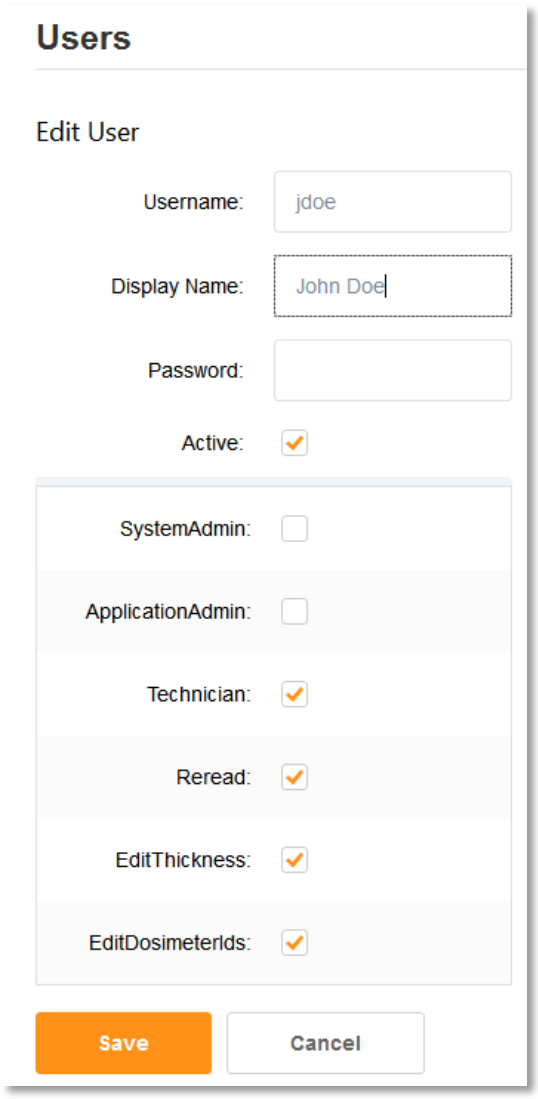
On the "Edit User" screen (see image on next page) you can enter or edit the username, display name, and/or password for the user, as well as select the user roles. Users may be assigned multiple roles by selecting multiple checkboxes. Select the orange 'Save' button to save the information.

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* – allows access to the "Settings" screen for managing dosimetry calibrations, etc. on that screen.
- *Technician* – allows users to create reports and perform dosimetry measurements.

- *Reread* – must be checked if using the reread role as part of reread policy (see section 3.5).
- *Edit Thickness* – allows users to make edits to the thickness of dosimeter reading. The feature is designed to be reserved for select and trained users. See section 3.9 for more detail.
- E*dit Dosimeter ID's* – allows the user to have the ability to edit or delete dosimeters from a report. The feature is designed to be reserved to select and trained users. See section 3.10 for more detail.

EDIT USER SCREEN



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 reread permission.
5. Select "Save".

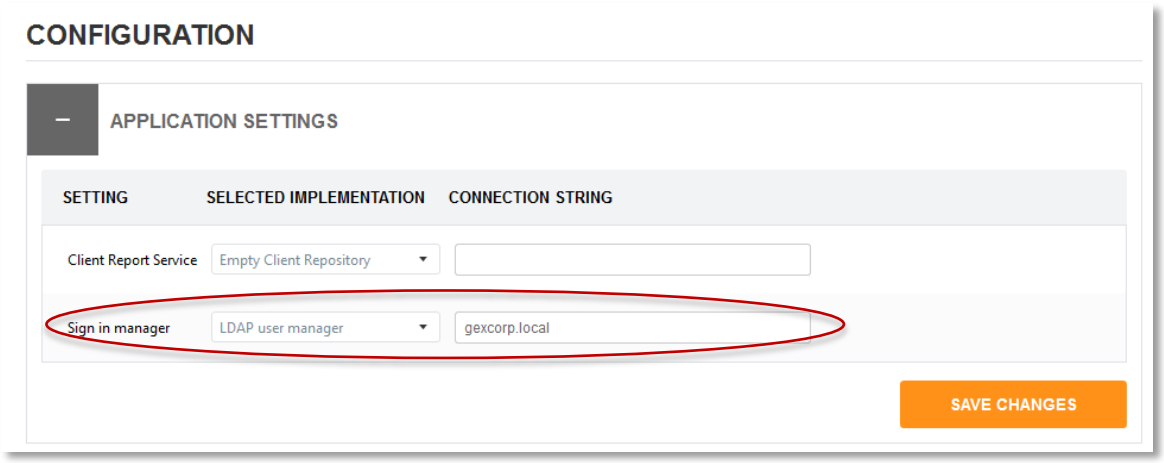
3) LDAP User Manager

This user management method allows control of the login using the username that is logged into Microsoft Windows. It should only be used if you are controlling access to the computer via Windows user lock out features.

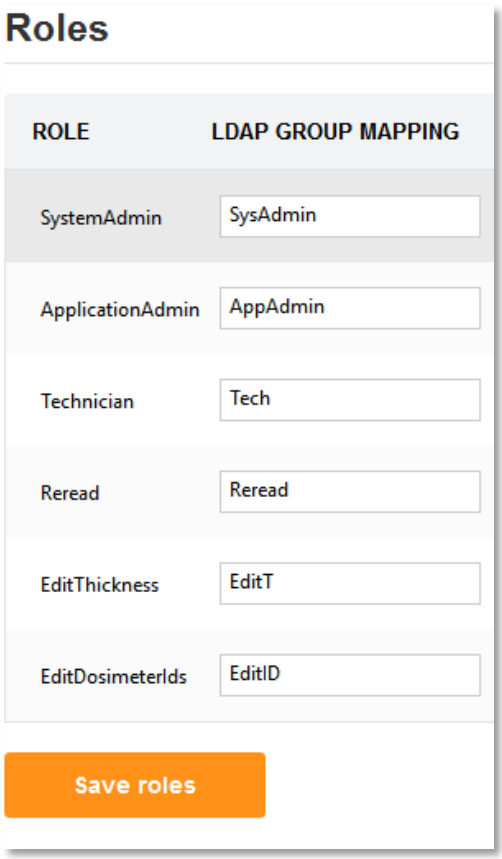
This method for user management utilizes an existing Lightweight Directory Access Protocol (LDAP) within a company network so that users of DoseControl can be managed by IT personnel using enterprise level Active Directory technology. Most likely, your company's IT department will need to assist with the setup of LDAP user manager. This involves setting up a Microsoft active directory Universal Security Group for DoseControl and sub-groups within that user group to match the four roles that DoseControl offers.

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

Paste the active directory address into the LDAP Group Mapping box in the DoseControl Setup menu 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.



NOTE: The format of connection strings vary based on the company's network configuration. The Connection String in the image above is only an example. This may also be a network IP address rather than a network location name.



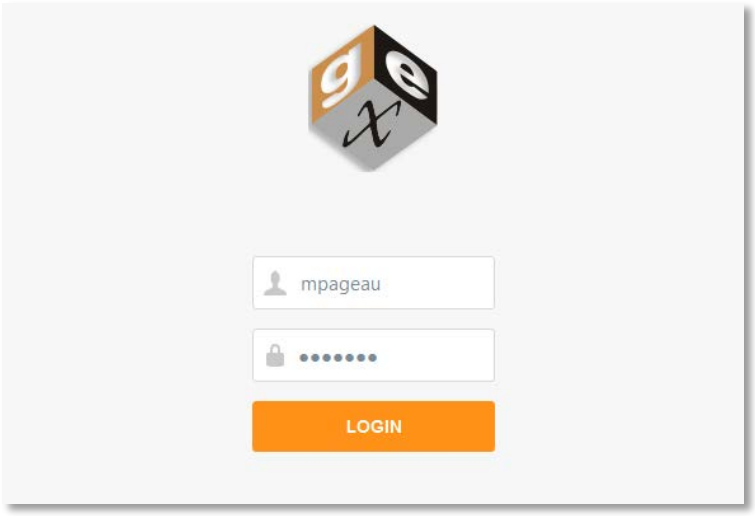
- In the box for the LDAP group mapping names, enter the names of the Active Directory user groups that are created by IT for the DoseControl user roles.
- The same 6 roles that are described in the beginning of this section are available.
- Group names used in the boxes in the image left are examples only.

4) Explicit LDAP User Manager

This user manager function is very similar to the standard LDAP user manager but the application actually controls the user directly with the Active Directory rather than using the already authenticated user whom is logged into the computer. This is most appropriate when the company uses 'workstation PC's' where the login to the computer is generic – the actual user doesn't log into the PC. In this case, we must prevent unauthorized access to the DoseControl software in order to comply with 21 CFR part 11 and similar requirements.

With this user manager, the user will be required to login with his company network login and password in order to open DoseControl. This user manager, in combination with using the 'User Lock Out' feature (explained in Section 2), allows complete control over login to the software while still using the Active Directory. This reduces the amount of user management by the Admin, and can be left to an IT department to manage according to company IT policy.

The configuration is performed exactly that same as described in the LDAP User Manager instructions. The user will see the fields for Username and Password (see image below) anytime login is required.


mpageau
LOGIN

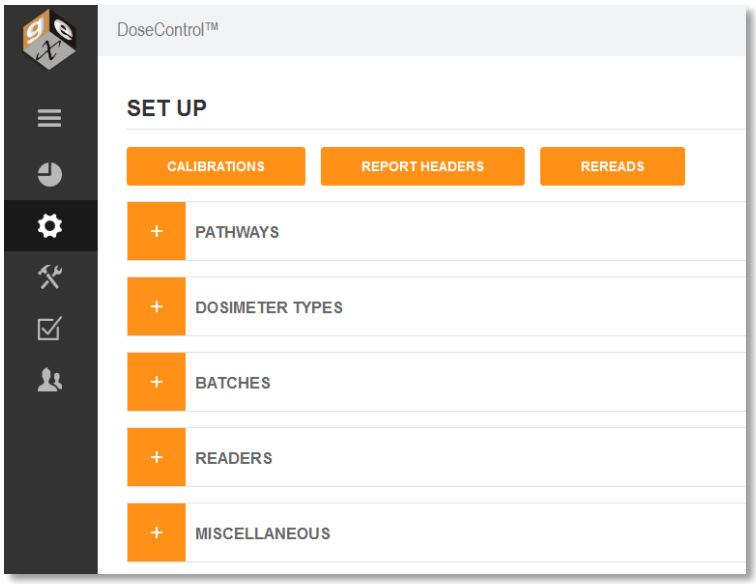
2 Setup – Dosimetry Configuration

The entirety of this section is designed to provide instruction to the *Application* Administrator for the configuration the functional aspects of the software related to dosimetry.

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, rereads, and miscellaneous 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.



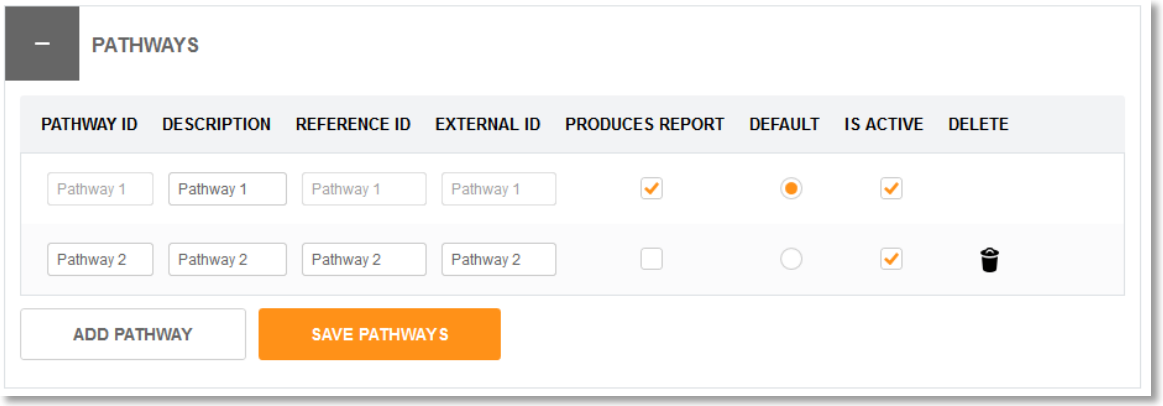
SETUP SCREEN

It is a requirement that a calibration is active in the system otherwise the system won't allow dosimeter measurement. 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, and external ID to setup a pathway (name all four the same unless you have special needs with integration, in which case you will have to name the external ID as needed). For example, the user may have a Production pathway and Research pathway. Do not check the box "Produces Report"; leave unchecked unless you are specifically instructed by GEX.

You can activate the most commonly used pathway as 'default'. This will allow it to show up first in the list of options when creating a new report.

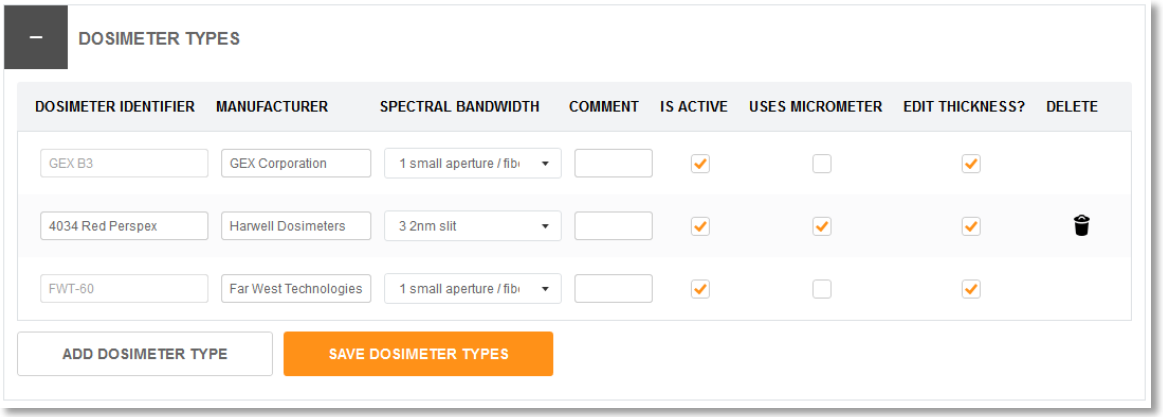


PATHWAY SETUP

*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 and configuration of what types of dosimeters are available for use *before* multiple batches can be added for a given dosimeter type.



1) Enter a Dosimeter Identifier (name) and 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.
4) Use the checkbox to make a dosimeter type active or inactive.

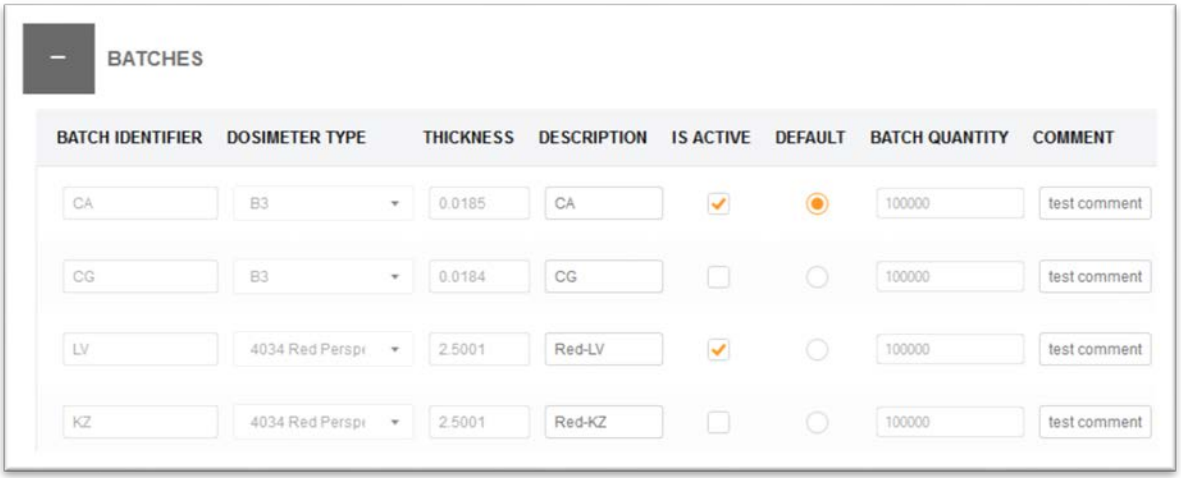
5) Select the “Uses Micrometer” checkbox only for configurations of Perspex dosimeters using the integrated laser micrometer (see section 2.5 for more detail). This box can be activated or deactivated at any time.

6) Select the “Edit Thickness?” checkbox if you need to allow the user to manually edit a thickness value using the keyboard (the user must be assigned this role – this feature can be controlled by individual user permission):

   - For example, in the case of dealing with an FWT-60 film where the actual measured thickness is different than the stated average.
   - If the laser micrometer system is not functioning correctly, and when using Perspex dosimeters, this box can abe enabled. This box can be activated or deactivated anytime.

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 Identifier (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 and any comment to go with the information.



BATCH SETUP

The Batch ID and Description must reference the two-alpha GEX B3 dosimeter batch ID exactly and nothing more for the barcode reading feature to work, and for most Enterprise integrations to operate without error. DoseControl verifies the two-alpha batch ID using the barcode reader and when importing dosimeter ID’s that are input via integration with enterprise or process systems. See the batch setup example above for reference on how B3 should be configured.

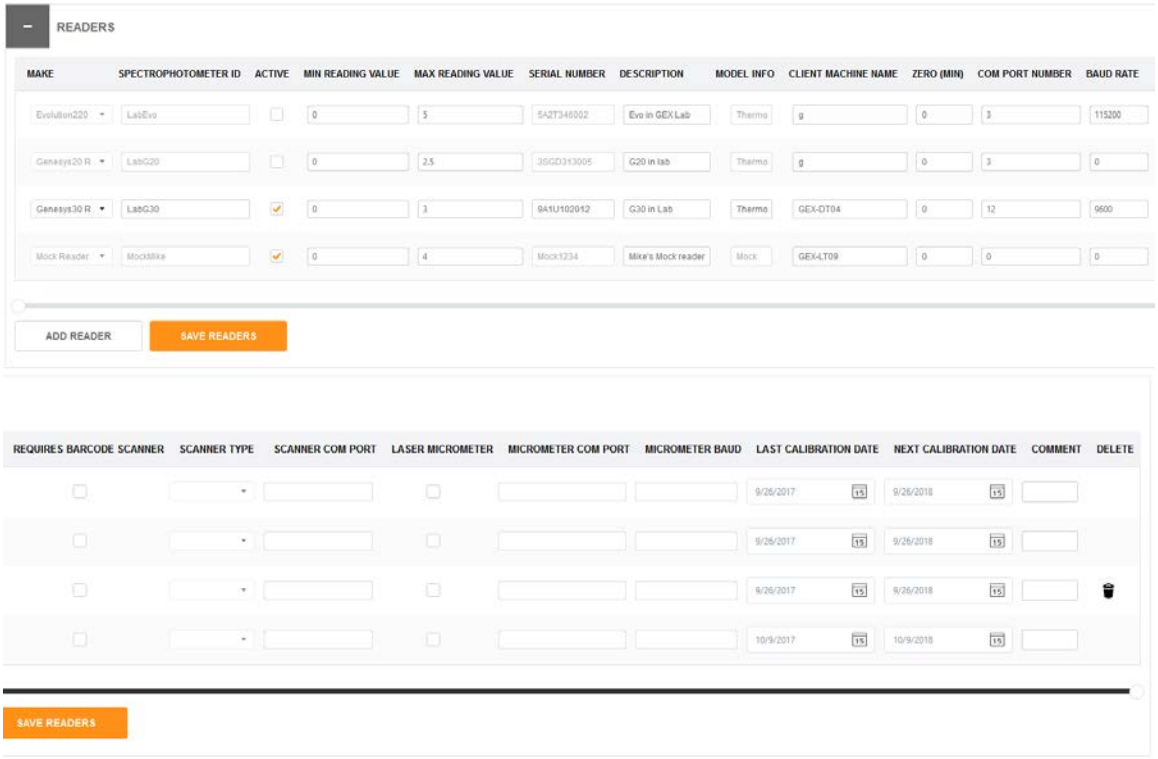
Please note that once a batch has been associated with any report in the system by creating a report, the batch cannot be deleted from the system.

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

Thermo Scientific application software used does not run "in the background" to control the Thermo spectrophotometers. DoseControl uses direct integration for instrument control. The user must configure each spectrophotometer for use with the system.

This is the most complex of the system configurations and 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 instructions for using the field:

- **Make**: Select Evolution 220, GENESYS 30, or GENESYS 20.
- **Spectrophotometer ID**: The name the user wants to be displayed on-screen and on their reports. Assign a name that users will recognize as the Spectrophotometer ID number.
- **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 even if they connect it to a DoseControl PC.
- **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 "reread", and the value is archived. 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 2.5 A, GENESYS 30 is 3 A and the Evolution 220 is 4 A). Using this logic, a measurement of -0.125 A is recognized by the system as not possible and is simply archived, and the user may try again. An error message will appear on the screen when any invalid measurement occurs.

- **Serial Number:**

  - *GENESYS 30 & Evolution 220 models*: enter the 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. If the configuration does not match the setup, the instrument will not operate.

  - *GENESYS 20*: the serial number of a GENESYS 20 cannot be verified by any communication technique. Therefore, enter the serial number for record keeping purposes.

- **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.

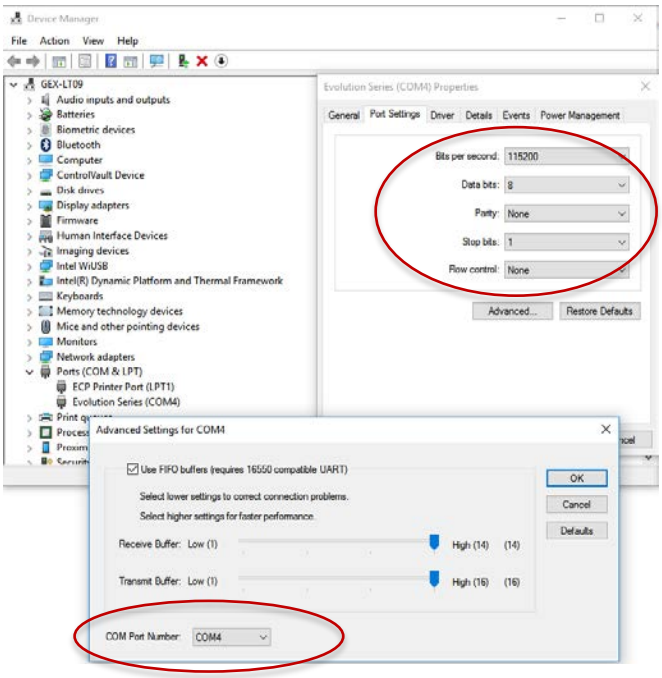
- **Model Info**: Enter the manufacturer name, if desired (the drop-down for Model, which is the first field, uses the name "Make" when really it is the model – these two field names will be fixed in a future update).

- **Client Machine Name**: Enter the exact Microsoft Windows PC name. The software will verify that it is connected to a specific PC upon attempting instrument initialization, and will fail and prevent use of the measuring functions unless configured correctly.

  An instrument can be attached to a different PC but the administrator must change this setting and enter the new PC name prior to use. The electronic record, therefore, has joint traceability back to both the PC ID and the Instrument serial number for every action in the software.

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

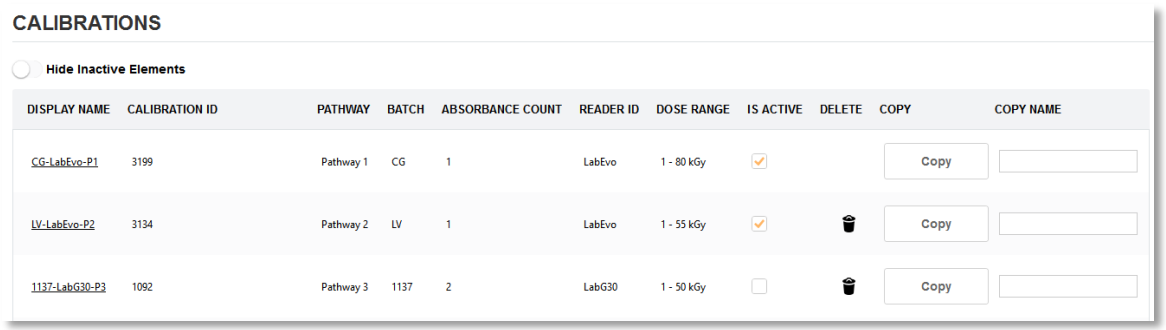
- **COM Port Number**: The COM port number of the connected spectrophotometer and the COM port number on the software must match. On the user's computer, go to "Device Manager" and "Ports (COM and LTP)". Find the instrument located in the list. Right-click and select 'properties' and 'advanced'. You 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. GEX suggests using the default baud rate, which is 9600 for the GENESYS 20 or GENESYS 30 . For the Evolution 220 the baud rate is 115200. Enter the baud rate into this field and ensure the matching baud rate is used for the device in MS Windows' Device Manger. See the picture above for reference.
- **Requires Barcode Scanner:** select this option only if you will use the instrument to measure B3 DoseStix dosimeters and are using the integrated barcode reader (GEX P/N: P4360) for scanning ID's inside the Evolution 220 sample compartment. Uncheck this box to disable the barcode scanner at any time.
- **Scanner Type:** Select from the available MS-2 or MS-3 models.
- **Scanner COM Port:** For the MS-3 only, a COM Port number is required to be configured.
- **Laser Micrometer:** select this box only if you have an integrated Metralight Laser Micrometer (GEX P/N: P4350) and are actively using it. Uncheck this box for all other configurations.
- **Micrometer COM Port:** enter the COM port number that the laser micrometer is connected to on the PC. Leave blank if not applicable.
- **Micrometer Baud:** enter the Baud Rate of 115200, and verify that the COM port that the laser micrometer is connected to has the matching rate. Leave blank if not applicable.
- **Last Calibration Date**: enter the Date the spectrophotometer was last calibrated or the date of the last complete performance verification. The system will prevent use of the instrument unless this date is earlier than today's date.
- **Next Calibration Date:** enter the Date the spectrophotometer must be calibrated next or the date that a complete performance verification is due. The system will prevent use of the instrument beyond this date. The administrator may change this date anytime as needed.
- **Comment**: Enter a comment regarding the spectrophotometer, if desired.

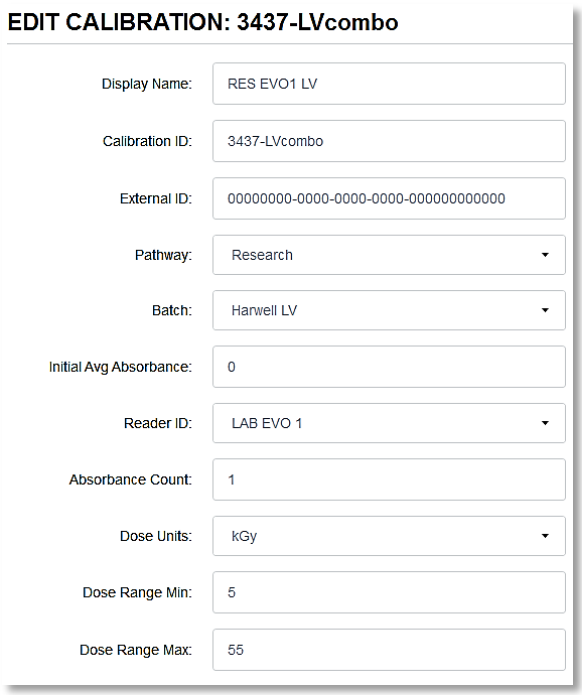
2.6 Calibrations (Dosimeter Batch Calibration): Configuration

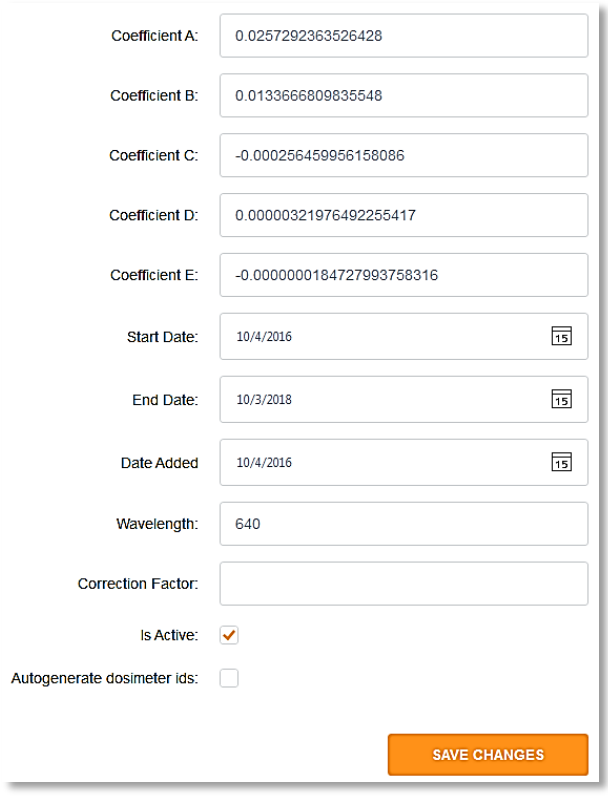
The user must manually enter the details of a calibration into the system to use it. A list of calibrations is built over time as the user adds them. Below is an image of a calibration list:



NOTE: Before entering a new calibration, please be sure that the pathway, batch, and reader for the calibration you wish to add are active in the configuration. You may have to deactivate others before you can activate the items you need to configure the new calibration.

The two screenshots below 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").





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. This may be equivalent to the calibration ID or may be some other identifier that is easy to use. Name must be unique within the system.
- **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. Name must be unique within the system.
- **External ID**: leave field blank unless otherwise instructed by GEX.
- **Pathway:** select the Pathway associated with the calibration from the drop-down list of active pathways. If you deactivate a Pathway in the pathway configuration, it will deactivate all calibrations associated with it. Therefore, the Pathway must be active before you can create a new calibration using that Pathway.
- **Batch:** select the dosimeter batch ID associated with the calibration from the drop-down list of active batches. If you deactivate a Batch in the batch configuration, it will deactivate all calibrations associated with it. Therefore, the Batch must be active before you can create a new calibration using that batch.
- **Initial Avg. Absorbance:** enter the initial average absorbance for the dosimeter, if any. Enter '0' or leave the field empty for no value.
- **Reader ID:** select the spectrophotometer ID associated with the calibration from the drop-down list of active instruments (readers). If you deactivate a Reader in the reader configuration, it will deactivate all calibrations associated with it. Therefore, the Reader must be active before you can create a new calibration using that reader.
- **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 up to a maximum of 4.

  NOTE: the statistical rereads feature of DoseControl will currently only work if the absorbance count is 1. For more information, see "Rereads" below in this section.
- **Dose Units:** select kGy or Gy. In either case, the resolution of dose is fixed at one significant digit in the software (e.g. 12.5 kGy or 1250.0 Gy). This resolution applies to all dose fields in the software.
- **Dose Range Min**: enter the minimum dose from the calibration so that the software will warn users when the measured dose is below this range.
- **Dose Range Max:** enter the maximum dose from the calibration so that the software will warn users when the measured 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 '0'.
- **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. Otherwise use today's date.
- **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.

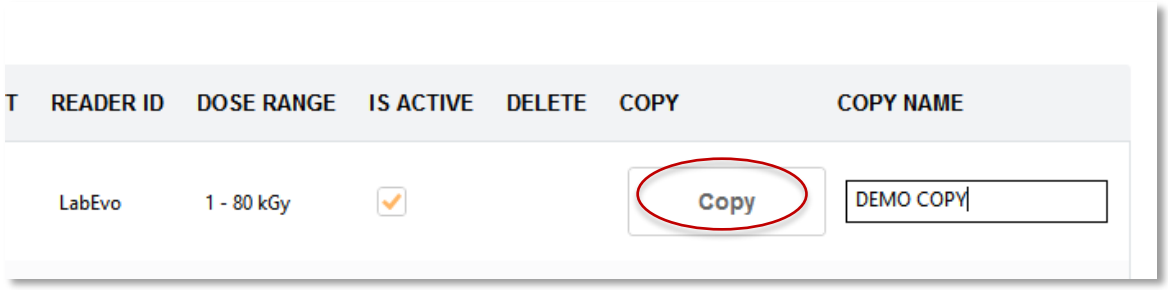
- **Date Added**: verify the Date that the calibration information was entered into DoseControl. This is autogenerated.
- **Wavelength**: enter the wavelength of measurement in nanometers (nm) that is to be used for the calibration. Enter without any units (e.g. '552').
- **Correction Factor**: allows the Application Administrator to introduce a linear correction factor on the measured dose. The user should enter "1.0" if there is no correction factor to be used. This is designed to be used when a known bias in the calibration is determined.
- **Is Active**: the calibration must be checked as 'active' 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 manually. For example, if the user wants to simply read dosimeters in sequence and not add the extra time of recording ID's.

  Currently, this feature cannot be edited after using a calibration. It must be determined by the user in advance of using the calibration if the user wants to use it or not.

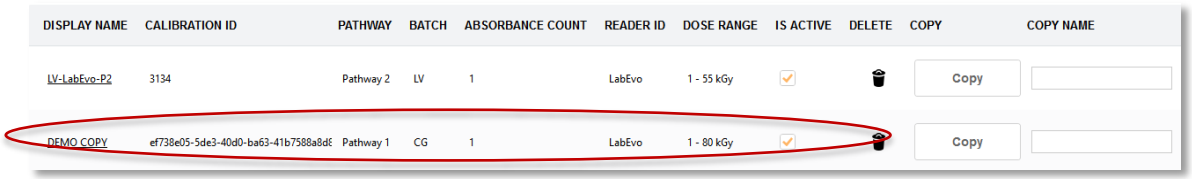
**Make sure to press the "Save Changes" button after making any changes before leaving the screen.

Copying a Calibration

A duplicate calibration can be created by the touch of a button to ease configuration for some users. Enter the new Display Name that you want to use for the new calibration in the field on the far right, in the row of the calibration you wish to copy.



Next, select the 'copy' button and the new calibration will appear at the bottom of the list, see below.



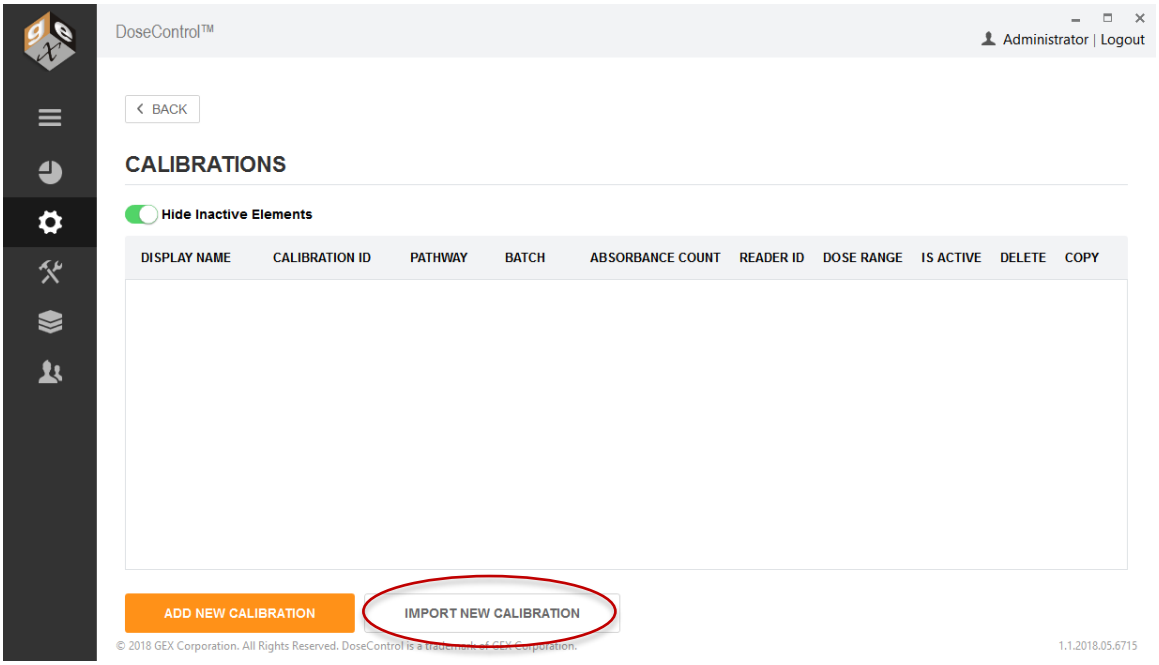
The current calibration that you create the copy from will be deactivated. The user will then have to open the new calibration created, make any necessary modifications to it, activate it, and save the changes.

Unlike other screens, calibrations cannot be activated/deactivated with the box on the list screen. The user must open and scroll to the bottom, activate/deactivate, and then select “Save Changes”.

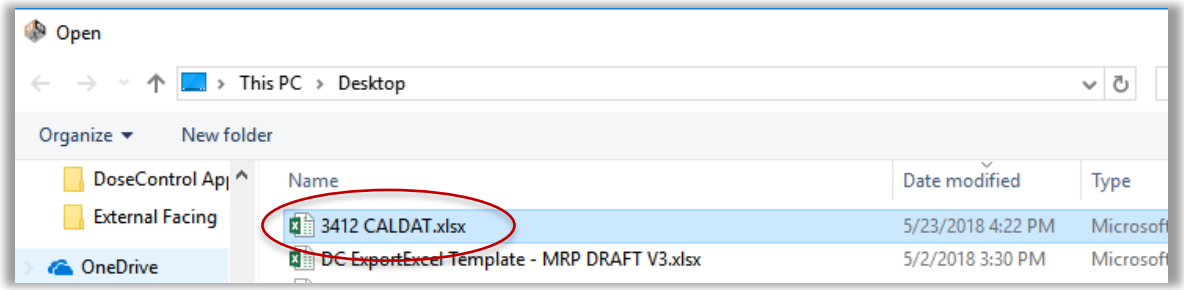
Importing a Calibration

Users can now import a calibration into the software from a GEX “CALDAT.xlsx” file. These files are issued by GEX Calibration Services. The file cannot have the old .xls extention. To use an old file with this extention, open the file and resave it as a newer file with the .xlsx extension.

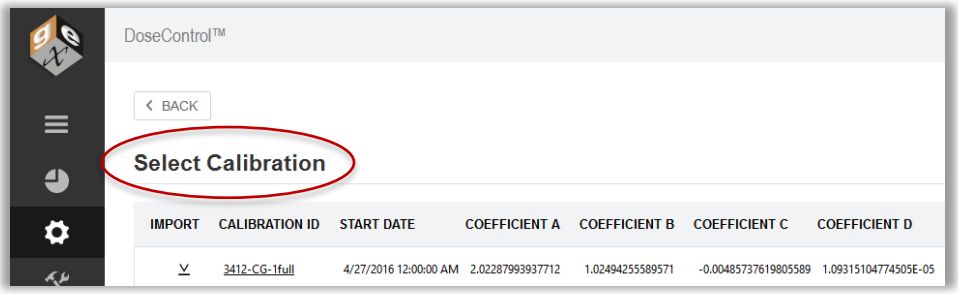
To import a calibration select the ‘Import Calibration’ button at the bottom of the screen.



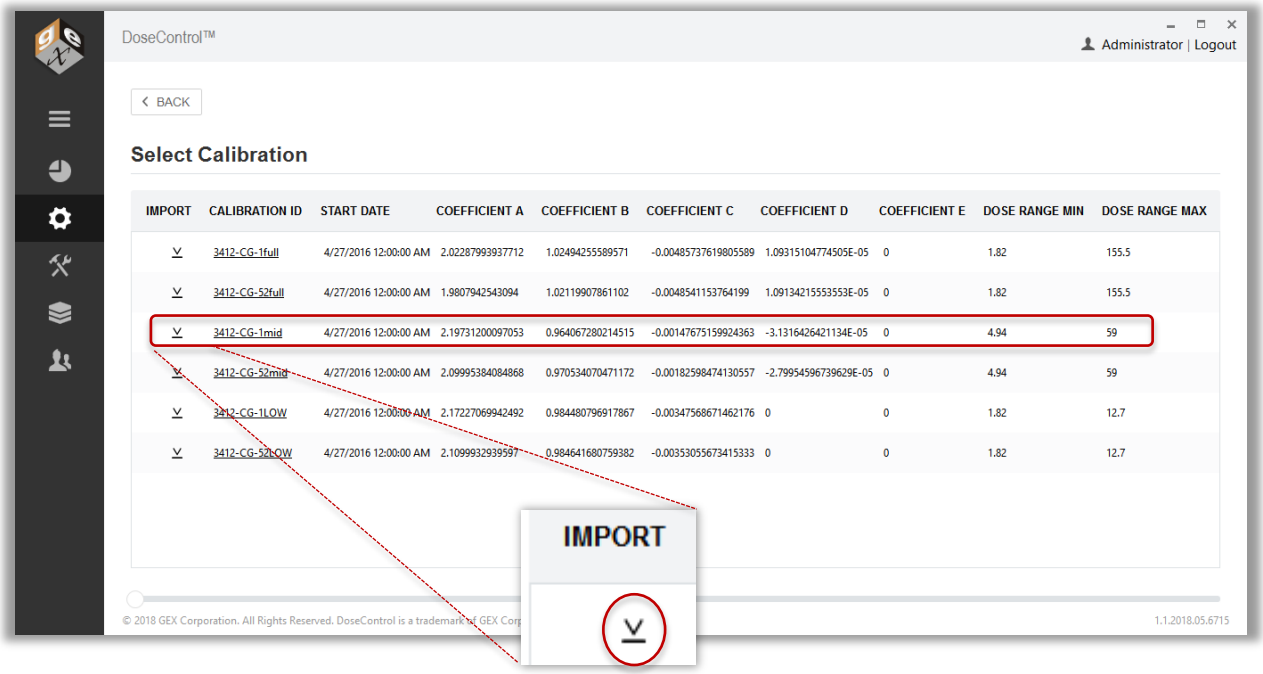
Navigate to the CALDAT.xlsx file that you wish to use and press ‘OK’.



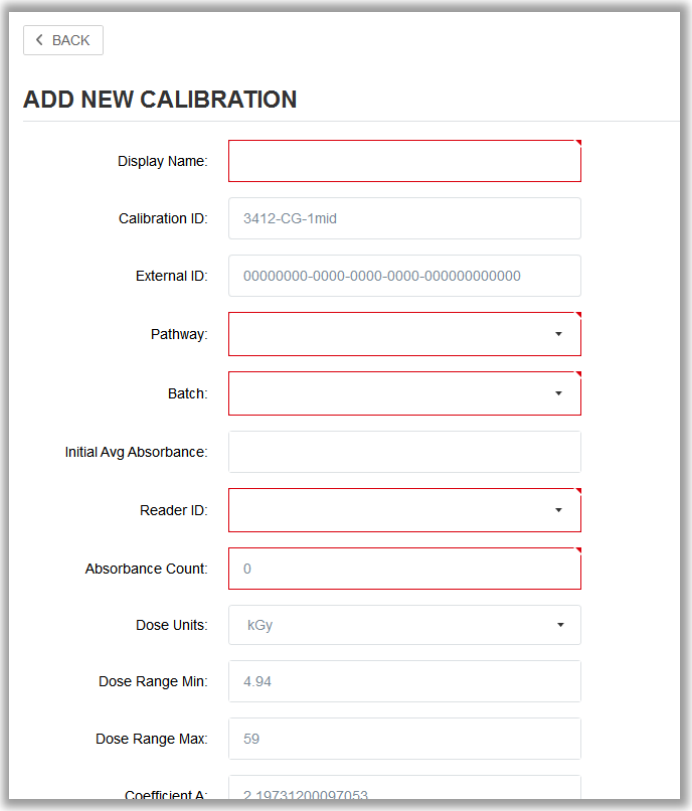
A list of available calibrations will display on the screen. Select from the available options. The data from this calibration will pre-fill a new calibration configuration screen. Give the calibration a Calibration Name and select the Pathway, Batch and Reader ID for the new calibration from the dropdown menus, as appropriate.



Select the down-arrow icon to import the calibration information into DoseControl. The calibration



configuration screen will then appear with data partially complete. The Application Admin must complete the remaining information and selections.



2.7 Report Headers: Standard Configuration

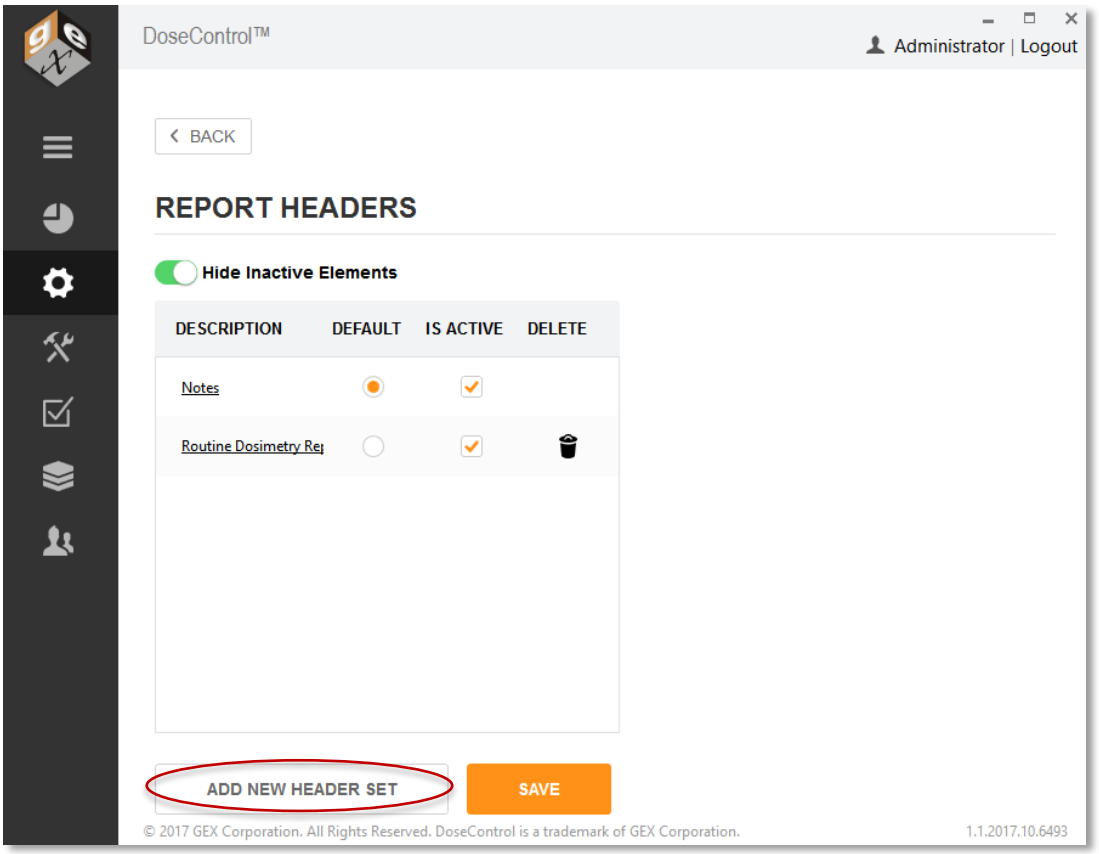
The Report Headers configuration can have a significant impact on the workflow that the technician will routinely follow for a specific measurement activity. We typically segregate dosimetry into two groups, routine dosimetry and research dosimetry with the latter including all testing and validation of the irradiation process and establishment of product dose specifications.

Many companies want to record specific information regarding regular or routine production runs of product through the irradiator, such as product information or dose specification to which the dosimetry measurements are associated. Sometimes several different sets of information may need to be recorded with the dosimetry for the various production, testing, or research activities that occur within a given facility. Each type of activity can be considered a different type of report (called a header set) containing fields that the user will complete with the required information. Integration with other systems to auto-fill this type of information is also possible with DoseControl.

The Report Header feature of DoseContol is the most dynamic configuration item within the application and requires the most amount of forethought, planning, and care to get the best results from the software. The data that the operators enter into a 'report header' will be stored as part of the electronic record for a given report. In addition, custom PDF layouts can be developed to output this information onto a printed report. Finally, all report header information entered by the user when working on a specific dosimetry report is available to the user in the Export to Excel output feature in the software.

DoseControl allows the user to configure special fields for operational needs such as a *Minimum* and *Maximum Dose specification* for a product, as well as dose correlation ratios such as *Dref:Dmin* and

Dref:Dmax (from dose mapping) so that this special information can be used by the system to calculate the min and max dose for a process load. The software is flexible in this configuration option to allow for an almost infinite number of different pieces of information that the user may want to record along with the subsequent measurements.

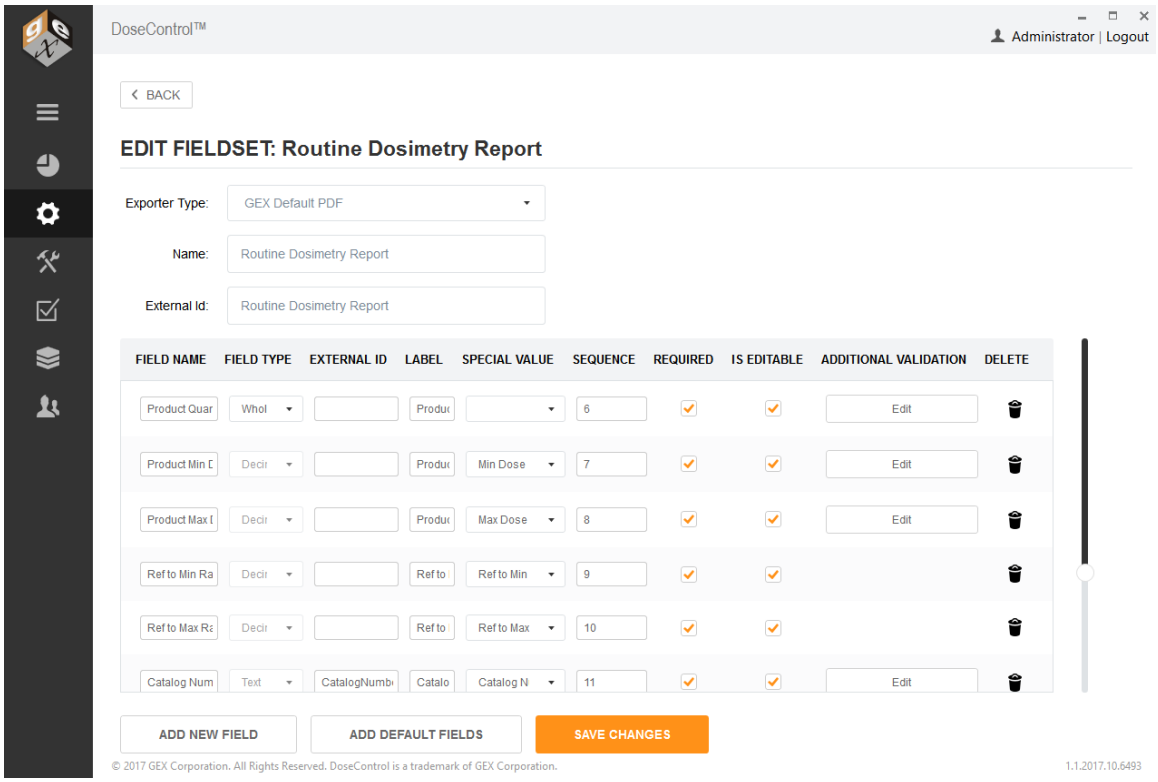


LIST OF REPORT HEADERS (empty on first use)

Creating a Report Header

Press the “Add New Header Set” button on the Report Headers screen to create a new set of fields for a specific use. Begin by selecting the Exporter Type from the drop down list of available PDF report layouts. There is a default layout that does not export any header information but exports measurement data and related information. GEX also supplies generic alternative layouts but these require specific Report Header configurations that are not flexible for the user. For more information about these, contact GEX Customer Service. Also, custom PDF report layouts can be created for customers and added to the application at any time by pasting a new, custom .dll file for that new PDF layout. Contact GEX customer service with questions.

Next, enter a Name of your choosing for the Report Header and copy/paste that name into the External Identifier field (these should match when you name them), and save the header by selecting the orange “Add Field Set” button which adds the report to the list. Select the orange “Save” button. The user can then select the underlined name of the report header in the list and add fields by selecting the white “Add New Field” button for the report that will be displayed when selected.

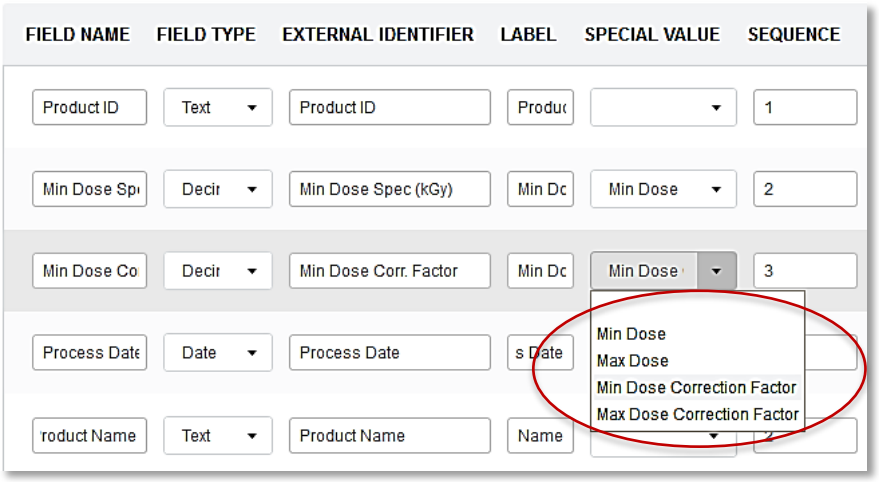


ADDING A NEW REPORT HEADER

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 what the field is intended to capture 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 is only used in import circumstances for Enterprise license users. For more information see *GEX Doc# 100-268, User Guide for Integration with DoseControl Software* for more information on using this field for imported reports.
- **Label**: enter the name of the field as you want to see it displayed on-screen (the software will automatically add a colon ":" at the end of the name provided when displayed to the operator).
- **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 fields:

1. *Min Dose* – allows the user to be able to enter a Minimum Dose Specification for dosimetry reports to facilitate comparison of D_{min} doses against the Min Dose Specification when creating dosimetry reports.
2. *Max Dose* – allows the user to be able to enter a Maximum Dose Specification for dosimetry reports to facilitate comparison of D_{max} doses against the Max Dose Specification when creating dosimetry reports.
3. *Ref to Min Ratio* – allows 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. *Ref to Max Ratio* – allows the user to be able to enter a Correlation Factor $D_{Ref}/D_{max.}$. The software will calculate all measured doses against the ratio.
5. *TS531 Issue* – do not use.
6. *Catalog Number* – see section 4 for more details on using this Special Value feature exclusively with the optional Product Specification Module.
7. *Specification ID* – see section 4 for more details on using this Special Value feature exclusively with the optional Product Specification Module.



- **Sequence**: this is a numeric value. This field allows the Admin to change the sequence number for the field (the sequence for how it will appear on the screen for the operator during dosimetry report creation) from the sequence in which the Admin entered them into the header configuration.
- **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. If you make a field 'Required' you must make it 'Editable' or else you will create a major problem for the software. This is true unless you have an Enterprise License and are importing data into the field automatically. In that instance, you may choose to not allow the operator to edit the imported value, in which case you would uncheck this option.

- **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.

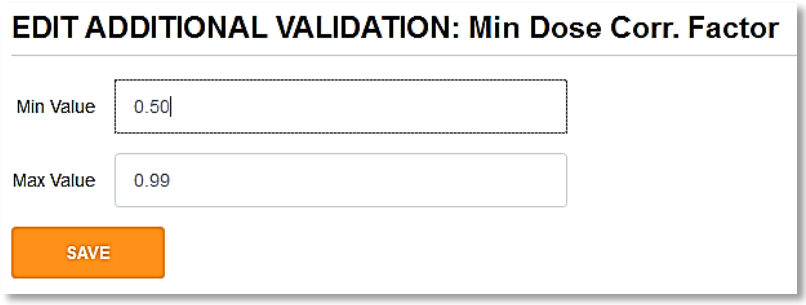
  Below are descriptions of the validation types that are available for the five different Field Types that were described above**:**

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

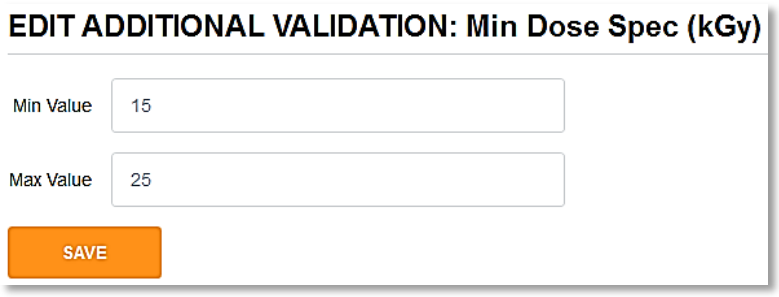
  2. ***Date Field Validation*** – The user can select the minimum and maximum date that will be available to the user. By default, the calendars will default to today's date.

  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.

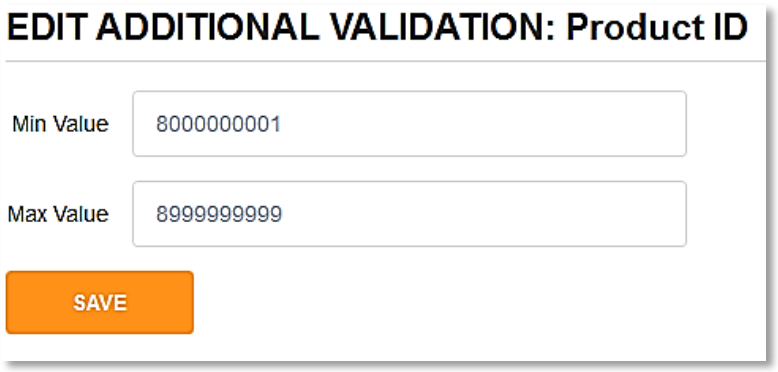


     Example 2
     I create a "Min Dose Specification" field. The lowest min dose I have is 15 kGy and the highest is 25 kGy. I can prevent user entry errors outside that range. The operator will be notified and operator notification usually increases task awareness. While this cannot prevent all user entry errors, it is a valuable tool to utilize.

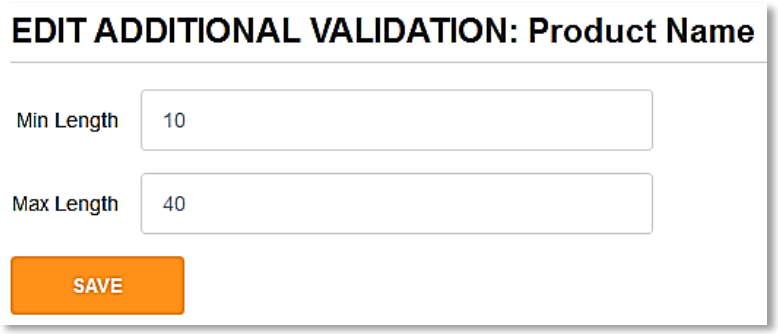


  4. ***Whole Number Field Validation*** – The user can enter a minimum and maximum numeric value.

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



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.



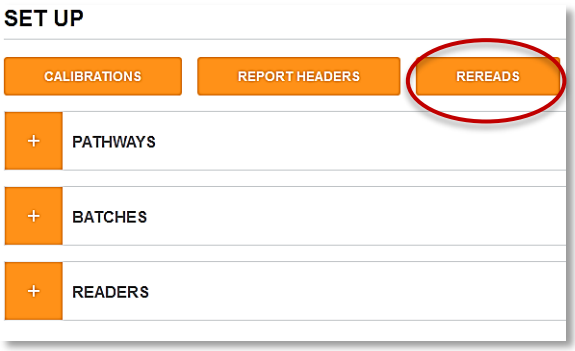
2.8 Report Headers: Integrated Configurations

For information on configuring Report Headers to work with the Product Specification module and/or with Import tables, please refer to *GEX Doc# 100-268, User Guide for Integration with DoseControl Software*.

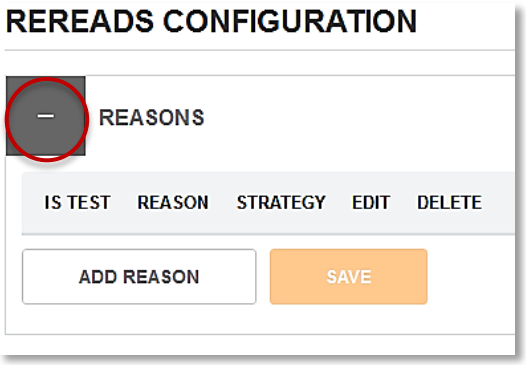
2.9 Rereads: Configuration

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

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



SETUP SCREEN



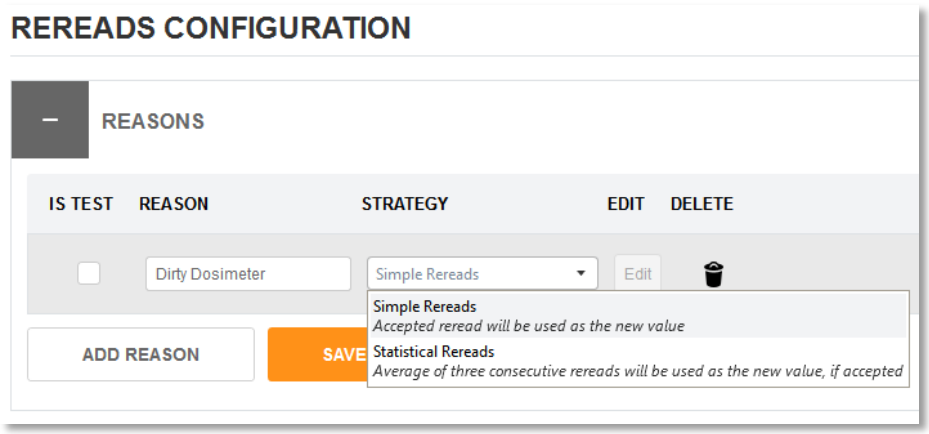
REASONS SCREEN

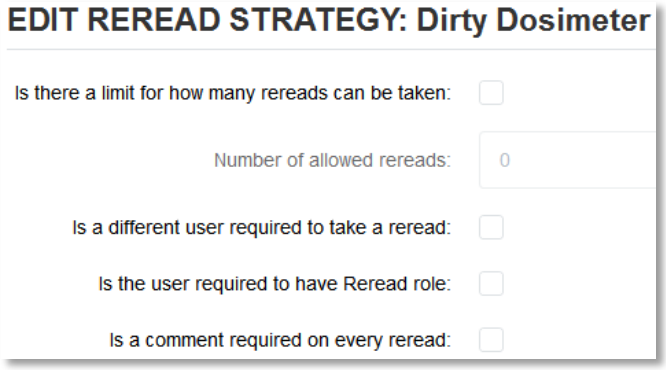
1. To begin, select "REREADS" on the setup screen. Expand the 'Reasons' field by clicking on the orange box with the 'plus' sign next to "REASONS".
2. Add as many reasons as needed using the "ADD REASON" button. At least one reason must be added to allow any configuration of rereads. For each reason a reread 'strategy' and configuration for that strategy will be required. There are two different strategies to use:
    - *Simple Rereads* - this strategy uses the default workflow of single measurement where the user will take a measurement which will replace the original measurement on the screen.
    - *Statistical Rereads* - this strategy will require the technician to make three measurements of the dosimeter in question and, if desired, allows a statistical evaluation of the results to determine if the reread data supports accepting the original measurement or supports changing the original measurement. You can also choose to include the original measurement in the statistical evaluation.

Remember that the system is 21 CFR part 11 compliant and the original reading is never discarded. Each of the two reread strategies is configurable with a variety of variables and each type is explained in more detail below. Let's use two example reread reasons; one to account for a situation where a dosimeter is found to be dirty after the original measurement, and the second for a situation where you want confirmation of the original dose measurement.

Example 1 – 'Simple' Rereads

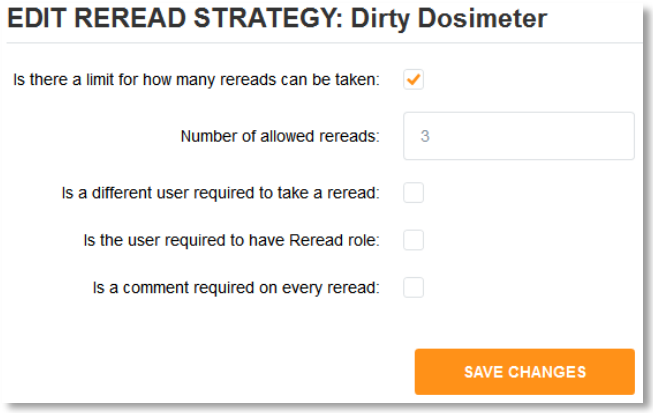
For the first example, we enter the name 'Dirty Dosimeter' and then select the "Simple Rereads" strategy from the drop-down menu. Select the orange "Save" button. This selection of a strategy activates the 'edit' button to the right of the strategy. Select 'edit' to access where you can configure the reread strategy. A few configuration options are available to you and they are described below. After making your choices when editing the reread strategy, 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 rereads. In the field below 'Number of allowed rereads' enter the number or quantity. Using this feature means that after the number of allowed rereads is met that no user (even the Administrator) will ever be able to reread that same dosimeter ID for any reason.



- ***Is a different user required to take the reread?***

  Check this box to force an entirely different user to login and reread the dosimeter in question before the user can proceed with the dosimetry report. Currently this process is manual; the

application does not log the user out and bring them back to the measurement. The user must logout, another user must login, open the same report and begin the reread process anew.

- ***Is the user required to have reread role?***

  Check this box to allow the restriction of who is allowed to reread dosimeters based on role. In order to reread a dosimeter, the user must be assigned the "Reread" role, which is configured in the User Management module explained in section 1.6 of this guide.

- ***Is a comment required on every reread?***

  Check this box if you would like to require a comment every time the user selects 'reread'. This allows details to be captured beyond just the reason that the user selects ("Dirty Dosimeter"). The comment will be required with every reread if more than 1 is allowed by configuration.

Example 2 – 'Statistical Rereads'

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 we are certain that the measurement procedure was followed correctly. For this let's configure rereads for verification that the original measurement is statistically reproducible. We will select the "Statistical Reread" strategy for this reason and configure it.

CAUTION: At this time, the statistical reread 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 in addition to those in the simple reread configuration:

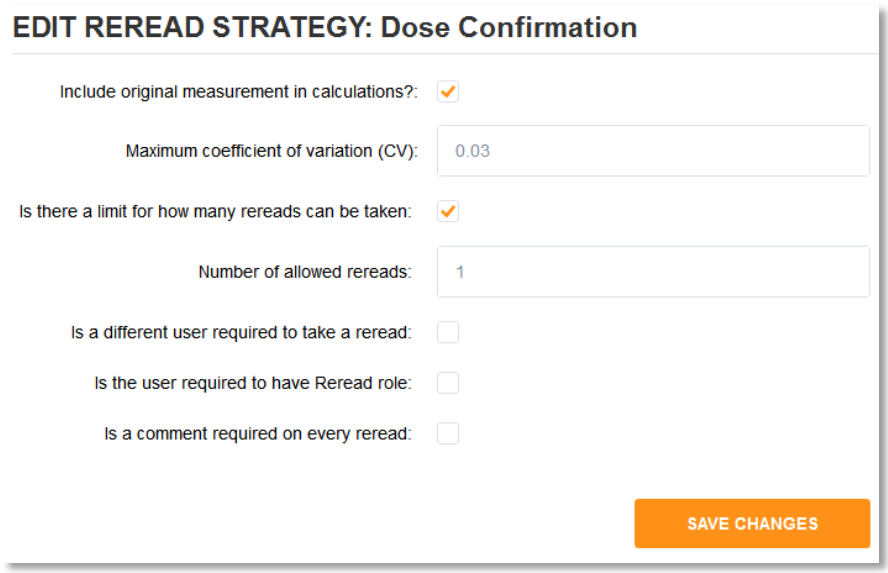
1. ***Include original measurement in calculations?***

   By selecting this box, the system will include the original measurement in the evaluation of the average dose of 3 additional rereads taken in succession. Leaving it unselected configures the system to average only the 3 rereads together.

2. ***Maximum coefficient of variation (C.V.)***

   The coefficient of variation entered here will be used as 'pass/fail' criteria for the reread session. The doses of each of the measurements will be averaged and a coefficient of variation for those doses will be calculated and compared against the value we enter here. Enter a CV value here not a CV% value – see example below for 3%.

   If the calculated CV of the rereads is lower than the maximum allowed that we have configured, the reread session passes and the average dose becomes the new dose for that dosimeter ID in the dosimeter report. If it fails the CV test, the reread session fails and the original dose is retained as the measured value for the dosimeter ID, and the reread measurements are rejected.

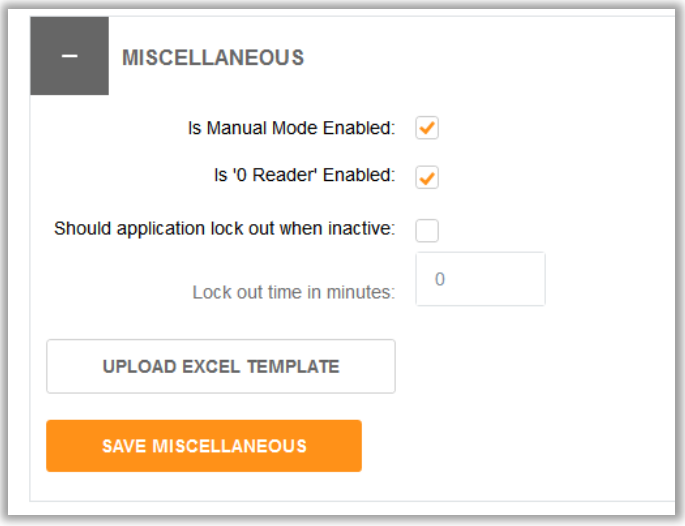


In the configuration above, we have configured it to include the original measurement in the evaluation, and we have limited the number of reread sessions to 1. This means that no user will be allowed to ever take any more rereads for that dosimeter, and there is no way for anyone (including the Administrator) to override this.

To summarize rereads, a wide number of configurations are possible for each strategy (the 2 options for strategy are 'simple' and 'statistical') that is chosen for any reread reason. The Administrator may setup one or many reasons depending on the needs and/or desires for collecting information and controlling the reread process.

2.10 Miscellaneous Configuration

You guessed it. We couldn't find a better place to put these options. Below are the miscellaneous configuration options in detail:



Manual Mode

Manual Mode is a feature that allows the entry of absorbance values on the Measure screen. Any entry done in this fashion is flagged as 'manual' in the database to distinguish it from actual measurements. This feature can be very helpful when validating the dose output of the software after configuring a calibration for a dosimeter batch.

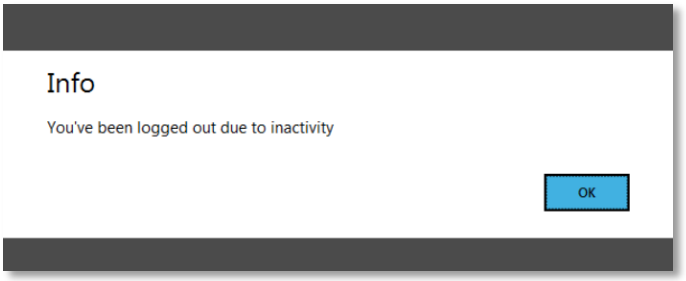
There is no section in this User Manual that explains the use of the Manual Mode features. Those interested may contact GEX for assistance.

Enable '0 Reader'

This feature literally removes or restores the button on the measure screen and allows the technician who is reading dosimeters to decide when to zero the instrument. Some users have expressed an interest in not allowing this feature, and forcing the technician to follow a more strict workflow using the zero that was performed at the opening of the report only.

User Lock-Out

This feature allows the Admin to configure the system to lock the user out of the software after a period of inactivity (in minutes). Any use of the keyboard or mouse will reset the timer. When a user is locked out, a message will display to the user as shown below.

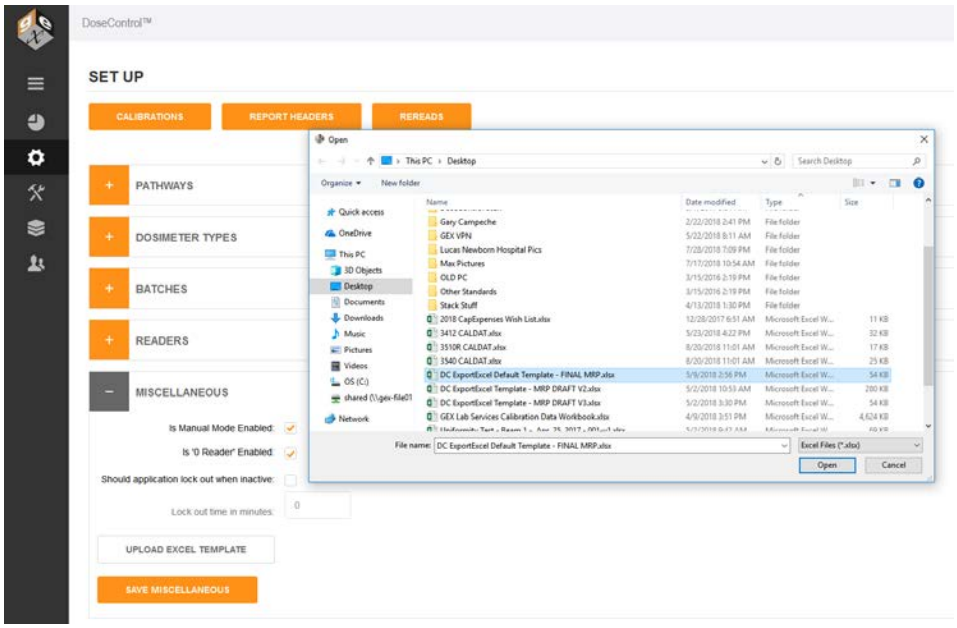


Upload Excel Tempate

Use this feature to upload a GEX provided MS Excel file. The software will output data to this Excel file if provided, otherwise here is a default loaded with the application upon installation. To use something other than the system default use this button. This is highly recommended. If no file was provided with your installation contact GEX to request a customized MS Excel Export File.

To load a customized file, press the Upload Excel Tempate button and then search for the file to upload. Press the 'Open' button and the file will upload. The file uploaded is saved automatically so there is no need to press the "Save Miscellaneous" button.

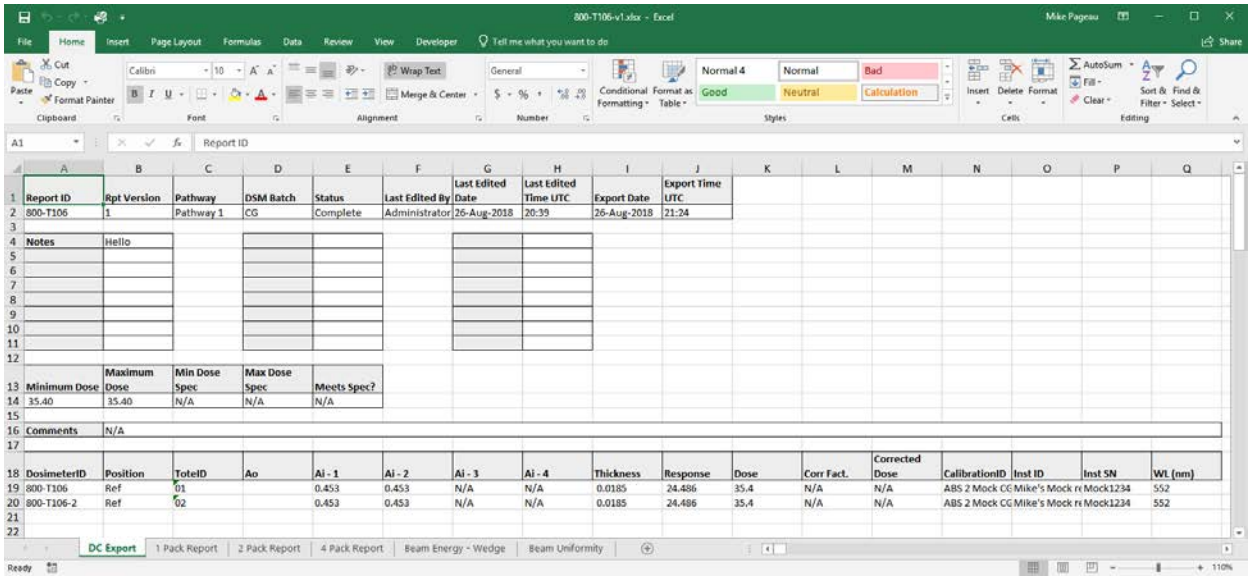
Now when you use the Export to Excel function on the Summary Screen, the data will export to the specific file you have uploaded. Please note that exporting to custom files will likely increase the time it takes to export the MS Excel file from a fraction of a second to 3 or more seconds.



Once GEX has provided the custom file, it is then maintained by the user. Any future customizations can be made by the user may contact GEX Customer Service for assistance. Anything that is possible in MS Excel is possible in the Export Template. Linking worksheets to display the output data and then performing data analysis using the functions of MS Excel is the planned design of DoseControl. Files can be protected and controlled by the Appllication Administrator since the template can only be update using this one, controlled feature.

For more detailed information or for a demonstration contact GEX Customer Service.

Below is the layout of the data in the first tab of Excel that the user may link to in other worksheets. To review in detail, export one using a report or contact GEX Customer Service.



Report ID	Rpt Version	Pathway	DSM Batch	Status	Last Edited By	Last Edited Date	Last Edited Time UTC	Export Date	Export Time UTC
800-T106	1	Pathway 1	CG	Complete	Administrator	26-Aug-2018	20:39	26-Aug-2018	21:24

Notes	Hello

Minimum Dose	Maximum Dose	Min Dose Spec	Max Dose Spec	Meets Spec?
35.40	35.40	N/A	N/A	N/A

Comments	N/A

DosimeterID	Position	ToteID	Ao	Ai - 1	Ai - 2	Ai - 3	Ai - 4	Thickness	Response	Dose	Corr Fact.	Corrected Dose	CalibrationID	Inst ID	Inst SN	WL (nm)
800-T106	Ref	01		0.453	0.453	N/A	N/A	0.0185	24.486	35.4	N/A	N/A	ABS 2 Mock CG	Mike's Mock r	Mock1234	552
800-T106-2	Ref	02		0.453	0.453	N/A	N/A	0.0185	24.486	35.4	N/A	N/A	ABS 2 Mock CG	Mike's Mock r	Mock1234	552

The layout does not change except that the system adds a row for each dosimeter ID in the report. All other information has a static position. By linking other tabs (see other tabs shows in this example) the data can be transformed into virtually any layout that the user wishes.

3 Creating Reports & Measuring Dosimeters

3.1 Create/Measure Overview

The fundamental purpose of the application is to create dosimetry reports using dosimeter measurements, 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 reread dosimeters, print reports, and export data. We also introduce some other features that are very helpful when needed such as skipping dosimeters (handling missing or damaged dosimeters).

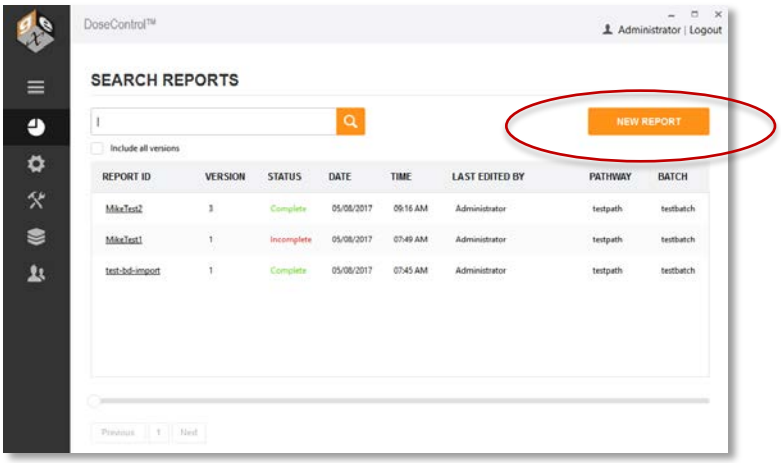
Helpful hints:

- The search button with the magnifying glass icon on the home screen is linked to the 'enter' key. You can simply enter a Report ID or dosimeter ID and press enter to search.
- Dosimeters must be given a "Dosimeter ID" by the user or automatically (see Section 2.6 – Calibration Configuration for automatic ID option) before a measurement is allowed. The software requires a unique identifier for every dosimeter – there can be no duplicate ID's in the system.

3.2 Creating New Reports

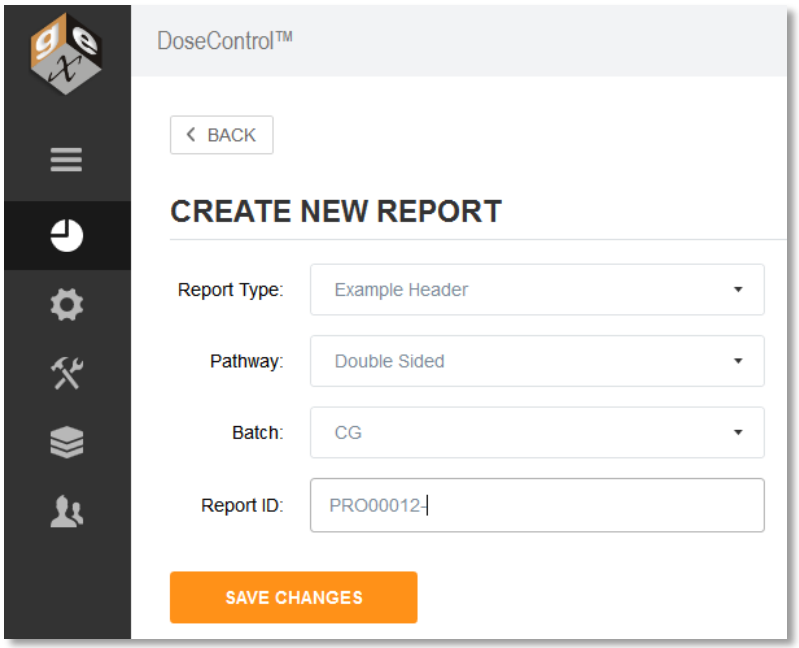
By selecting the orange 'New Report' button on the home screen, the user is asked to make three selections that setup the type of report, and allows the software to choose the calibration for the batch/pathway/instrument combination being used.

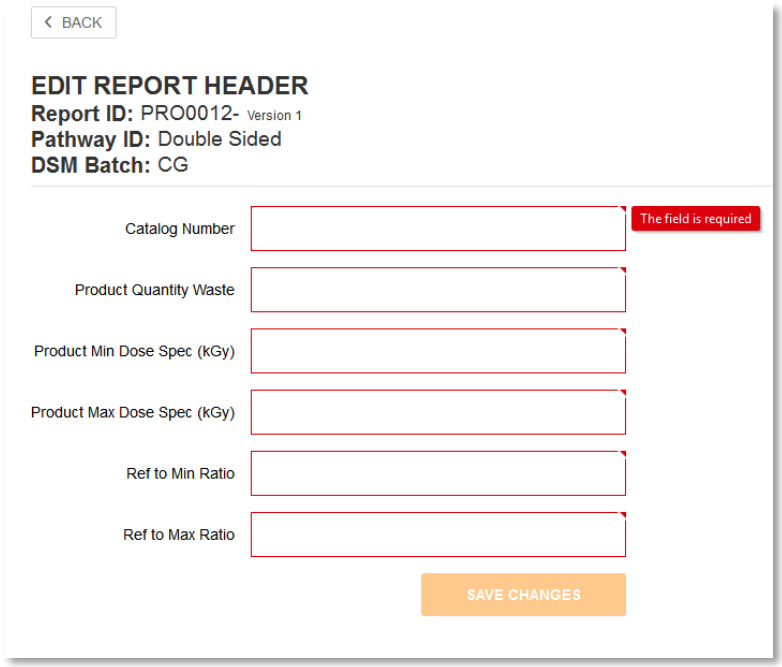
The user does not select a calibration from a list to begin the measurement and report session but rather, the appropriate calibration is chosen by the application based on the pathway, measurement instrument, and dosimeter batch based on inputs to the software by connection to the spectrophotometer and as selected by the user. This approach uses a workflow-based decision rather than a user-knowledge based decision to guide the user for creation of a report for their intended use.



To create a new report from the home screen:

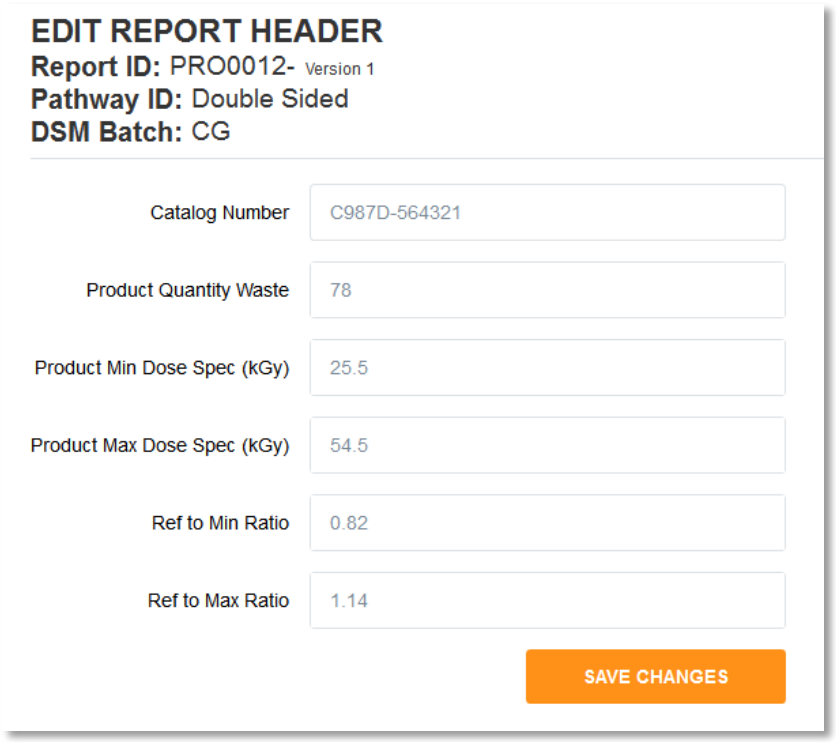
1. Press the orange ‘New Report’ button on the home screen (shown above)
2. Use the default selection or choose a ‘Report Type’ (configured section 2.7).
3. Use the default selection or choose a ‘Pathway’ (configured section 2.2).
4. Use the default selection or choose a ‘Batch’ (configured section 2.4).
5. Enter a unique report identifier (Report ID) for the session and select ‘Save Changes’.





Next, you are presented with the 'Edit Report Header' screen (above) where information can be entered in the Report Header fields which were configured in Section 2.7. Remember that any restrictions established in the configuration will be enforced on this screen. In the example above, we selected that the fields are 'required'. Therefore, they appear in red outline and the operator cannot go to the next step until they are completed. Below is an example of completed header.

In the example, note that we have used all four of the 'Special Value' fields (see Section 2.7) in this header. These numeric fields will be used in the application and their use is explained in Section 3.4. By completing the fields and selecting 'Save Changes', you have completed report creation and will be taken to the Measure screen.



3.3 Measuring Dosimeters

3.3.1 Measure Screen Overview

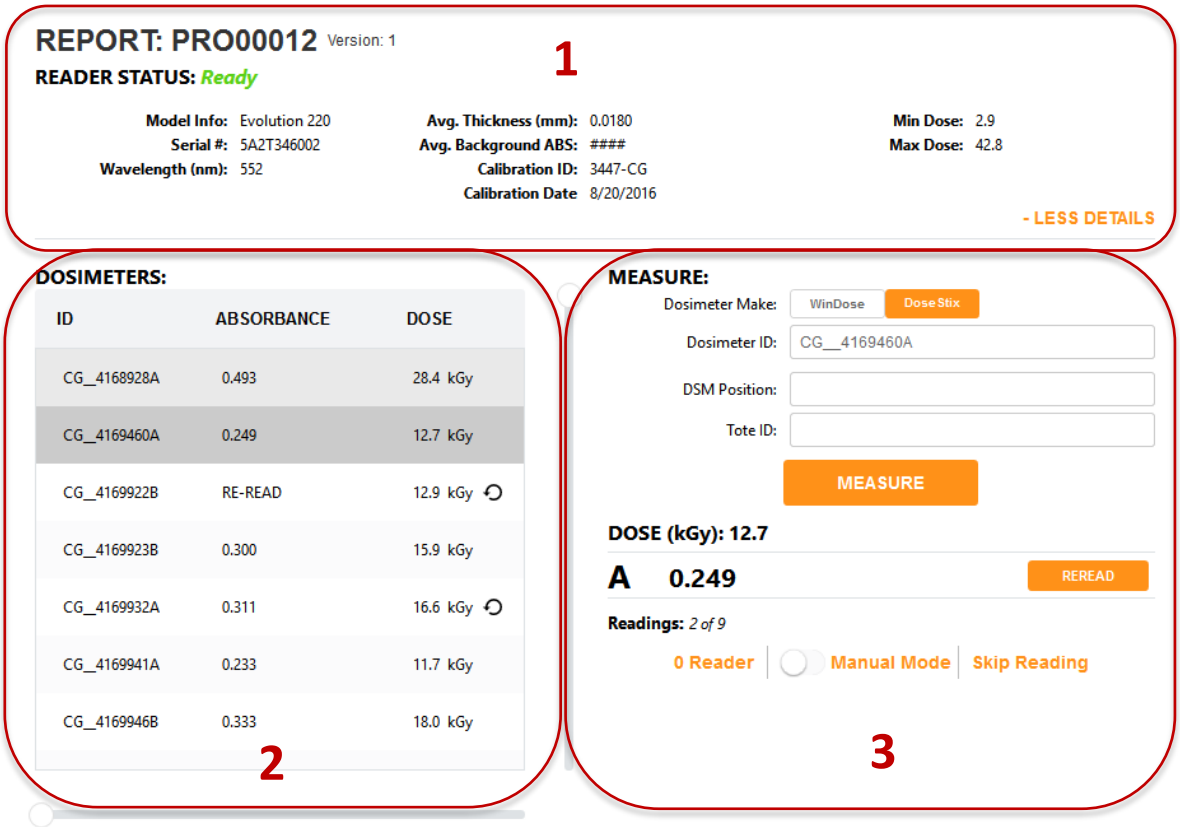
The measure screen is where users will spend the majority of their time in the software. The measure screen is where dosimeter ID's and absorbance measurements are collected along with additional dosimeter related information.

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' or 'More Details' on the upper-right side of the screen.

2) ***Dosimeter List*** located on the left side and builds as measurements are taken. The currently active dosimeter that is displayed 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 optionally enter the tote ID (i.e. carrier number). This field may also be used in other ways for continuous conveyor type E-beam systems to describe succession of dosimeters (e.g. 1, 2, 3) for your records.



'MEASURE' SCREEN POST-MEASUREMENTS

Section 1 - Calibration Information

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.

The spectrophotometer's status is always indicated in the top-left of the screen:

- 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.
- NOT INITIALIZED means that an instrument is not detected (see troubleshooting for more details).

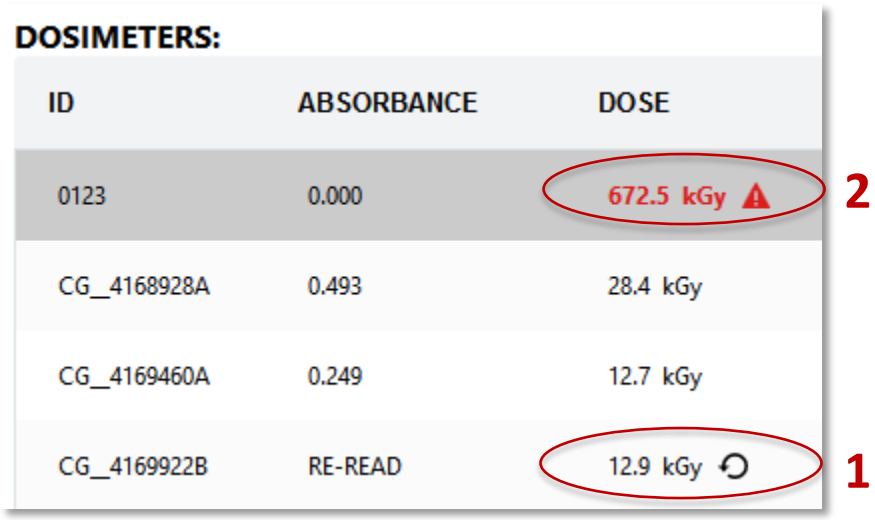
NOTE: The user interface is locked when the instrument is initializing or busy.

The initialization process for the spectrophotometer prepares the instrument for measurement and 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

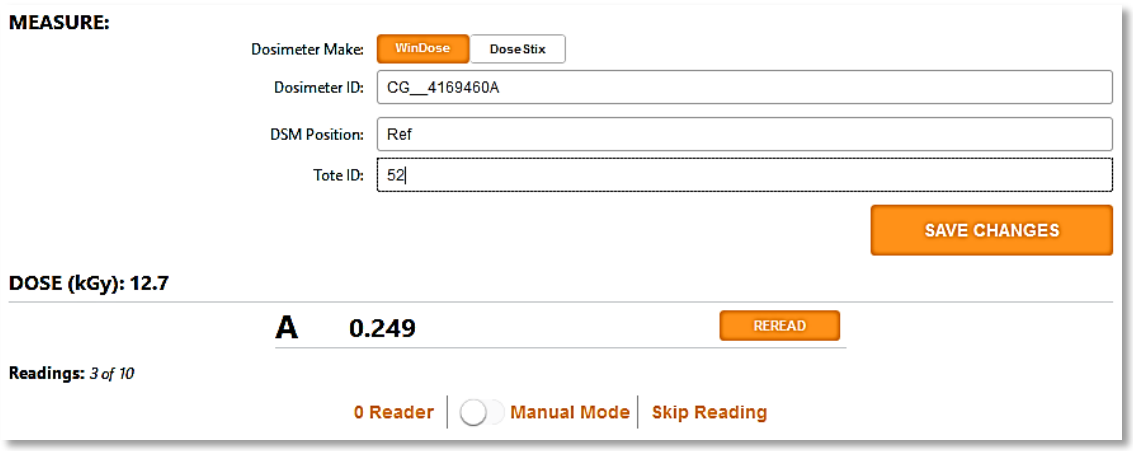
The dosimeter list is the expanding list of measurements. The list contains the Dosimeter ID, Absorbance, Thickness, and Dose for each measurement. The row that is highlighted in grey in the list indicates which dosimeter's information is being displayed in section 3, Measure.

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.

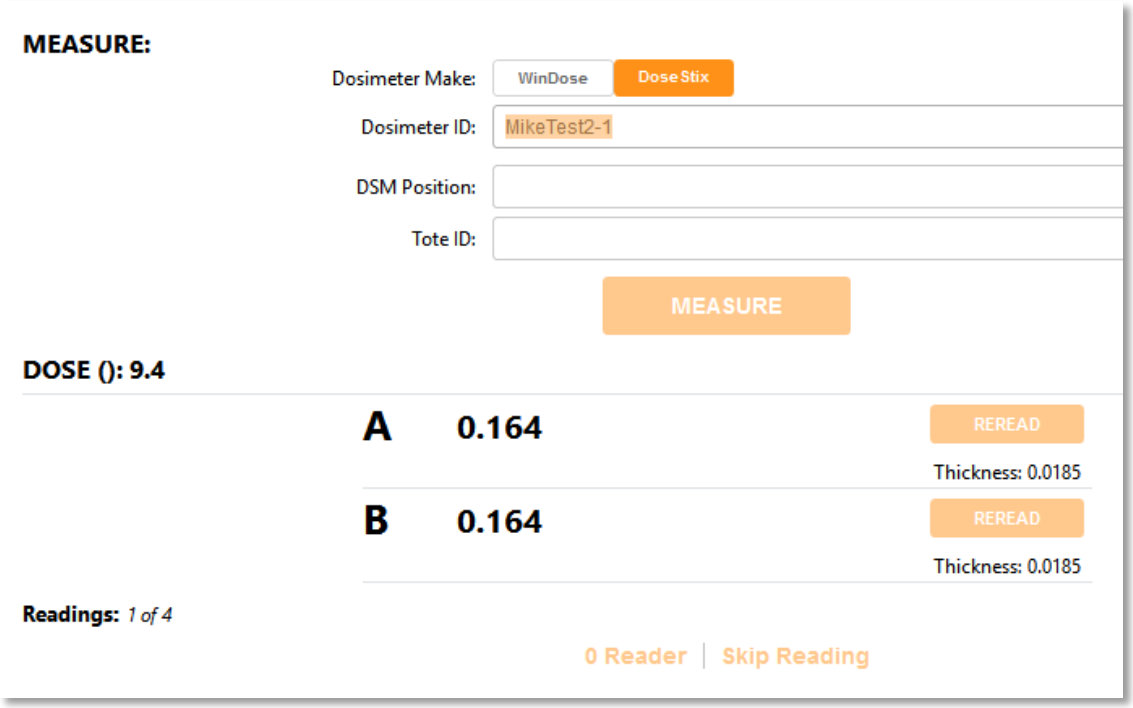


Section 3 – Measure

This section displays the information for the active dosimeter, and provides options for certain configurations. 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 configured for two dosimeters, then you will see two rows, one for A and one for B, as shown below. Also displayed at the bottom of the screen is the 'position' in the list, in this case 'Reading 1 of 4'.

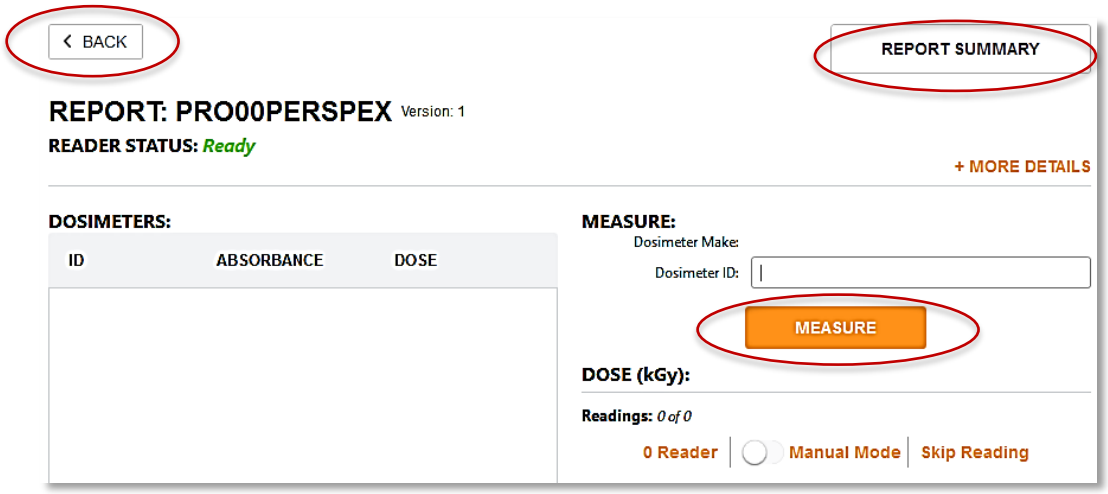


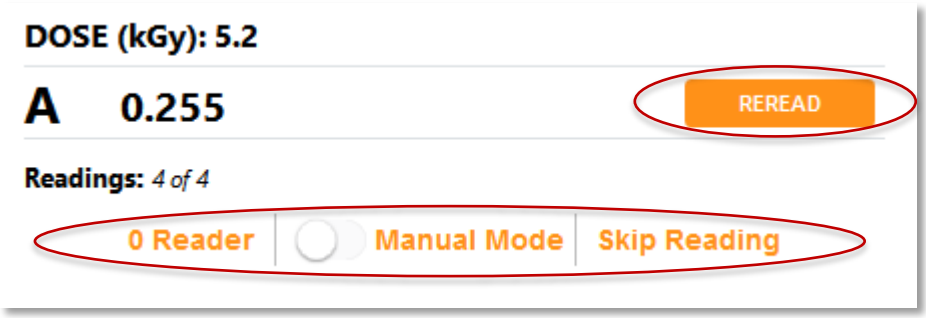
Measure Screen Buttons

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. 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).

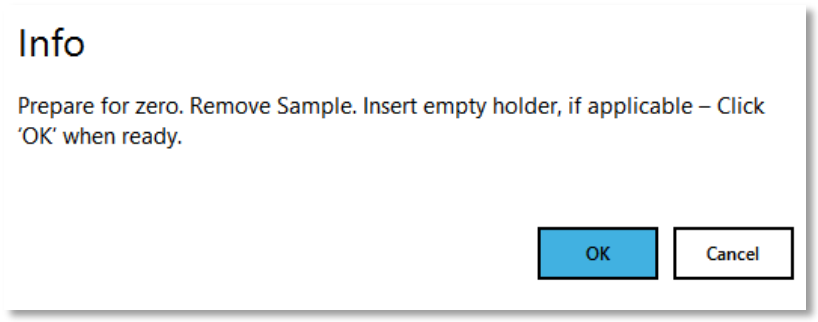
  NOTE: When using spectrophotometers that have a zeroing button on the instrument body, it is recommended that operators are trained not to use that feature, but to use the zeroing button within the software instead. If the user presses the zero button on the instrument, the zeroing event is not recorded in the software audit trail. It is better to have a complete audit trail, and there is no method currently available for disabling the button on the instruments.

- **Manual Mode:** used in the event that the spectrophotometer will not connect (see section 3.7 for usage instructions and Section 2.9 for disabling).

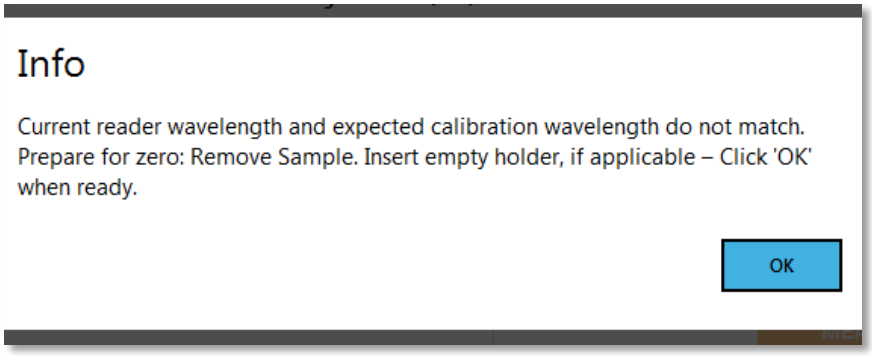
- **Skip Reading:** allows the user to create a record when a reading must be skipped (e.g. lost dosimeter), and the user is required to enter a reason that becomes part of the report comments (see section 3.6 for more details).

3.3.2 Procedure for Dosimeter 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).



NOTE: The software verified the wavelength setting of the spectrophotometer before every measurement. If it is not correct, it will inform the user and then set the instrument to the new wavelength and force the user to zero before making a measurement.

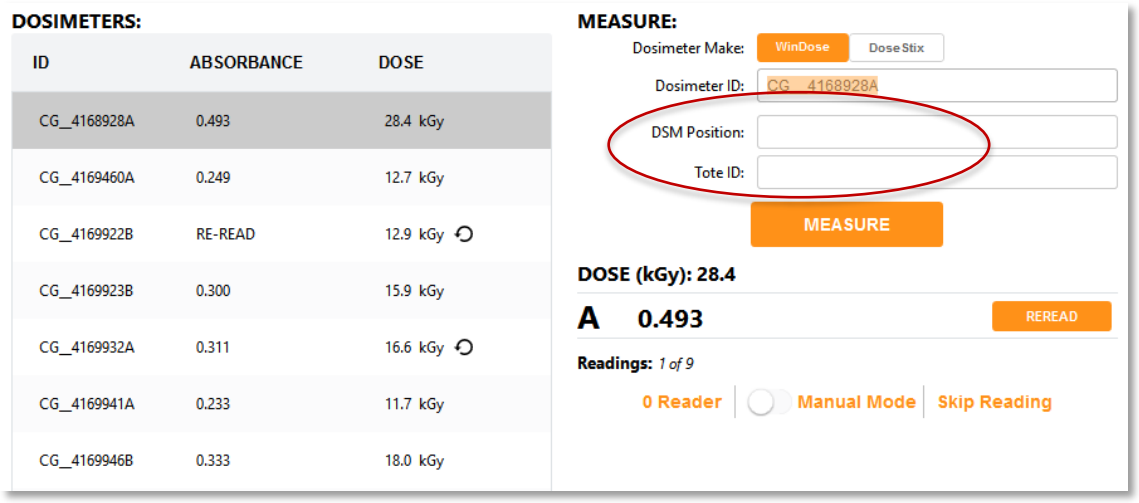


2) The cursor defaults to the Dosimeter ID field (see image below) and is ready to accept a manually typed or scanned value. You must provide a Dosimeter ID for each measurement or use the 'Auto-generate ID' feature checkbox in the Calibration Setup.

3) To measure the dosimeter's absorbance value, select the 'Measure' button.

4) The absorbance measurement and thickness (measured value for Perspex dosimeters or average thickness value from the calibration for film dosimeters) will appear for the dosimeter. The absorbance and dose values will calculate. If the absorbance count is 2 or more (e.g. A and B dosimeter) the absorbance and thickness are the average of both replicates.

5) Enter a 'DSM Position' and 'Tote ID' if you desire.



MEASURE SCREEN: MEASURING DOSIMETER ID

6) Repeat the measurement process for all required dosimeters. The measurement list will update with each action, as appropriate.

7) To reread a dosimeter, select the reread button. Follow the configured workflow. Review section 3.5, Rereading Dosimeters for complete details.

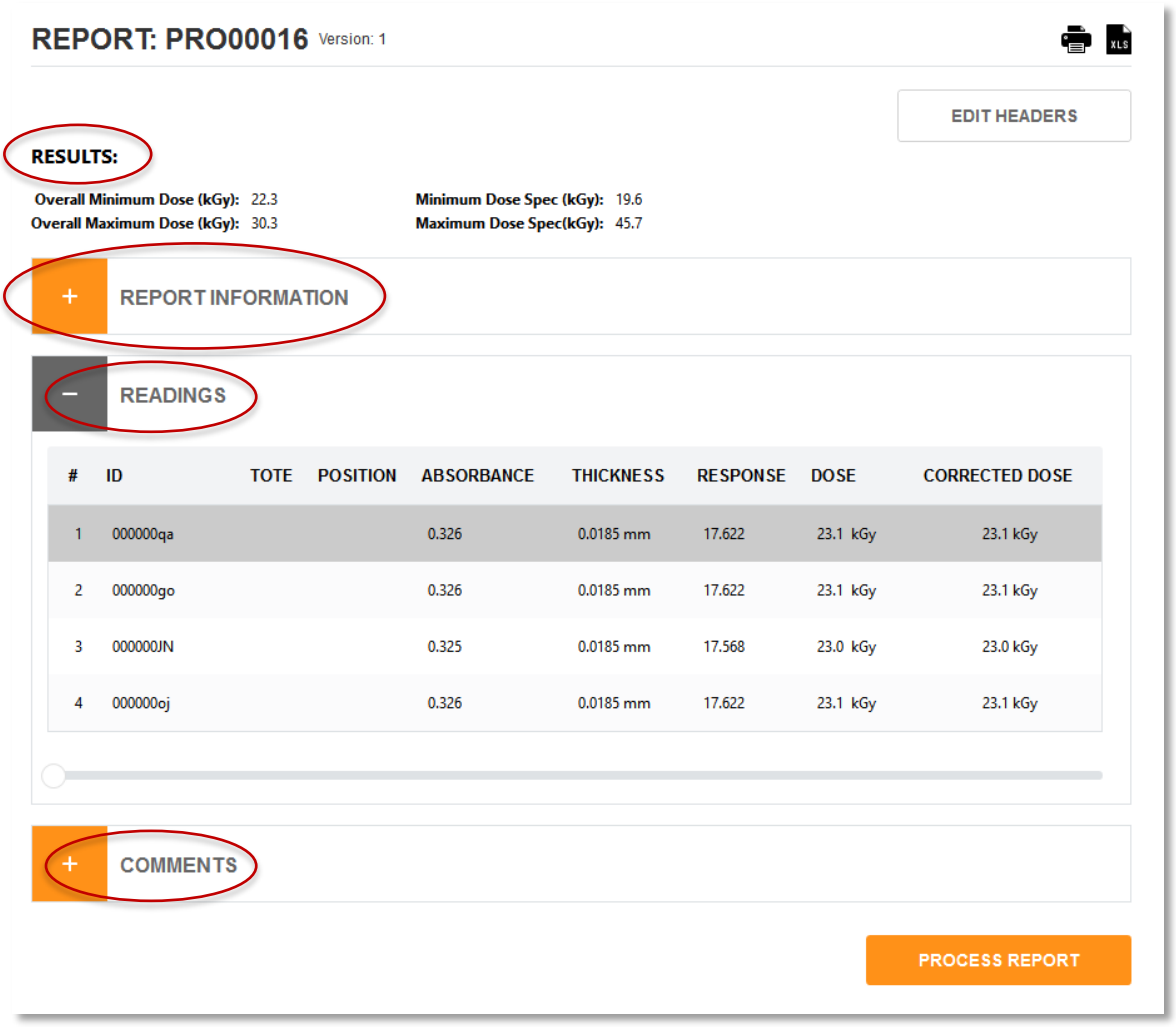
During measurements or upon completion, the user can select the 'Report Summary' button at the top-right of the screen. A new screen appears that provides a summary of the information collected in the report. The data can be reviewed by the technician before taking any further action.

3.4 Report Summary

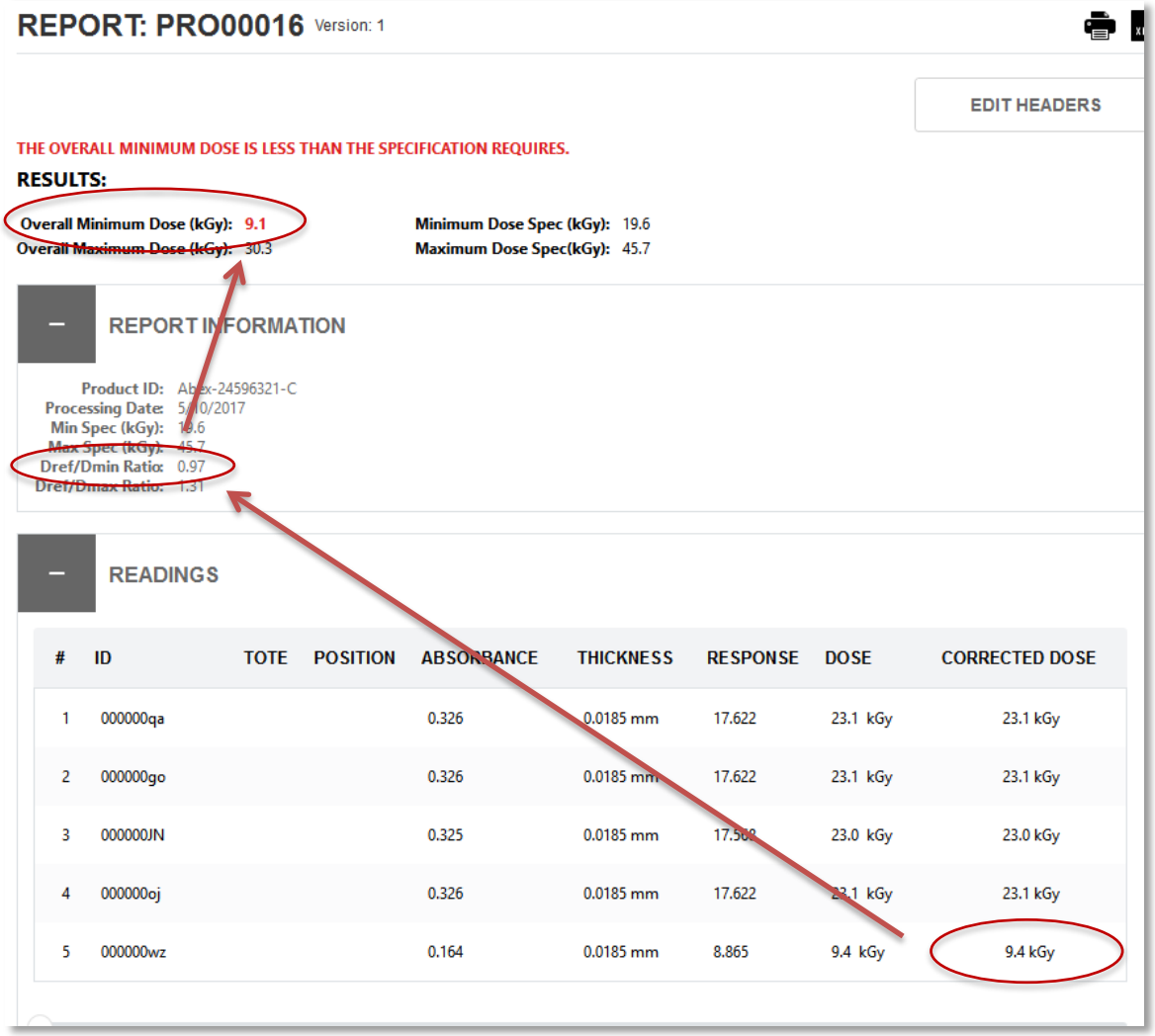
The Report Summary provides a view of the overall report information including some key features that are not available on the 'Measure' screen.

There are four sections:

1. *Results* – Lists the overall minimum and maximum measured doses as well as the minimum and maximum dose specifications, if configured (see 'Results' below for details)
2. *Report Information* – A listing of the Report Header information for the report. Use the 'Edit Headers' button at the top-right of the summary screen to edit the data in these fields at any time.
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.



EXAMPLE OF REPORT WITH PASSING SPECIFICATION



EXAMPLE OF REPORT WITH FAILING SPECIFICATION AND OVERALL MINIMUM CALCULATION

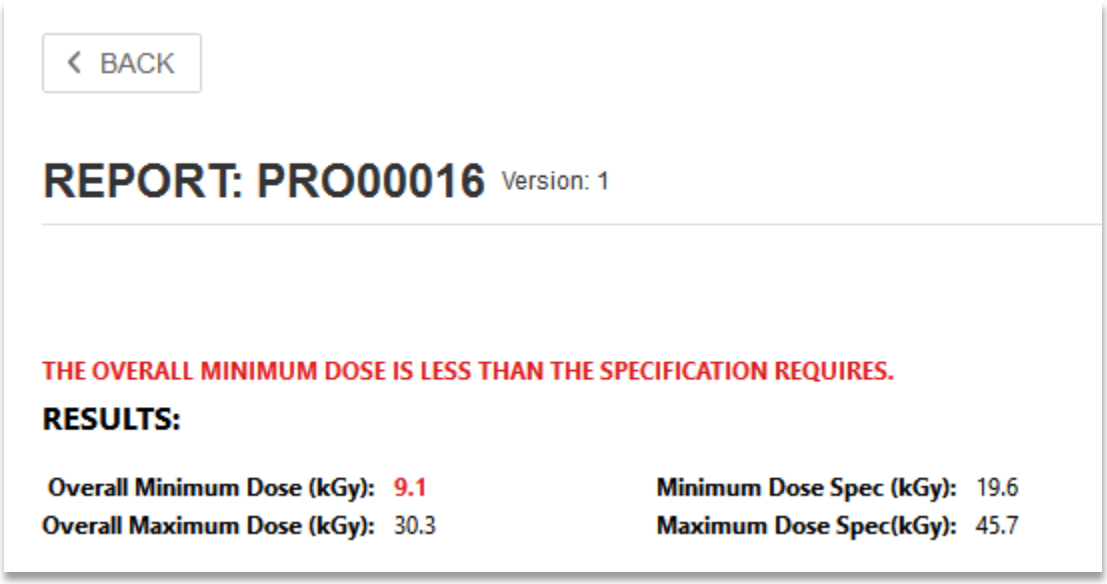
Results

The results section provides the following information:

1) *Overall Minimum Dose:*
   - The lowest measured dose in the entire report is displayed.
   - When the 'special value' field "Min Dose Correlation Factor" is configured (dose map correlation factor Dref/Dmin) in the Report Header the lowest measured dose multiplied by the factor entered in the header is displayed.
   - Example – in the image above the lowest measured dose in the report is 9.4 kGy. When you multiply that by the ratio of 0.97 the resulting Overall Minimum Dose to the product is 9.1 kGy.
2) *Overall Maximum Dose:*
   - The highest measured dose in the entire report is displayed.

- When the 'special value' field "Max Dose Correlation Factor" is configured (dose map correlation factor Dref/Dmax) in the Report Header the highest measured dose multiplied by the factor entered in the header is displayed.
- Example – The highest measured dose in the report is 23.1 kGy. When you multiply that by the ratio of 1.31 the resulting Overall Maximum Dose to the product is 30.3 kGy.

3) *Minimum Dose Spec* – the value is only displayed if the 'special value' field "Min Dose" is configured in Report Headers. Otherwise, this field does not appear.
4) *Maximum Dose Spec* – the value is only displayed if the 'special value' field "Max Dose" is configured in Report Headers. Otherwise, this field does not appear.
5) *Dose Specification Compliance Messaging* (see example of failing specification below):
   - A message will display if the 'Overall Minimum Dose' is less than the 'Minimum Dose Spec' and the dose will be identified in red bold font.
   - A message will display if the 'Overall Maximum Dose' is less than the 'Maximum Dose Spec' and the dose will be identified in red bold font.



Readings

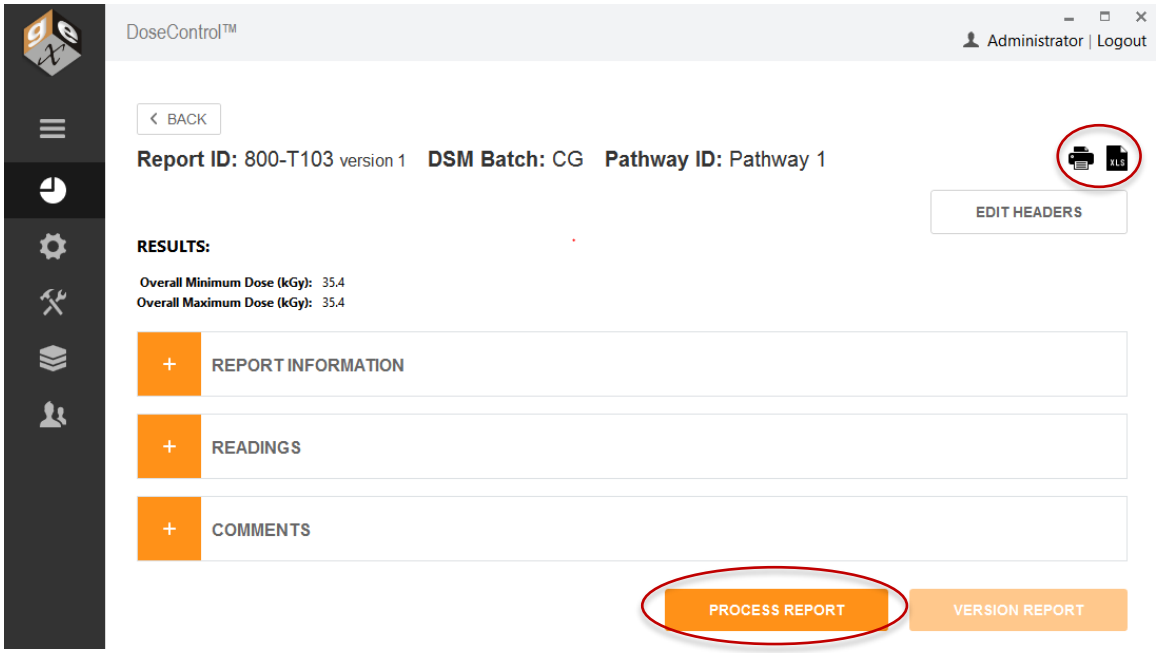
The Readings section is a summary of all information on the Measure screen for each dosimeter but also includes 'Corrected Dose'. The corrected dose is the measured dose multiplied by the Correction Factor in the Calibration configuration for the Calibration ID used in the report.

3.5 Process / Version Reports

Process Report

Once all measurements are finished, the report is not complete until 'Process Report' has been selected by the user (see image 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 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.

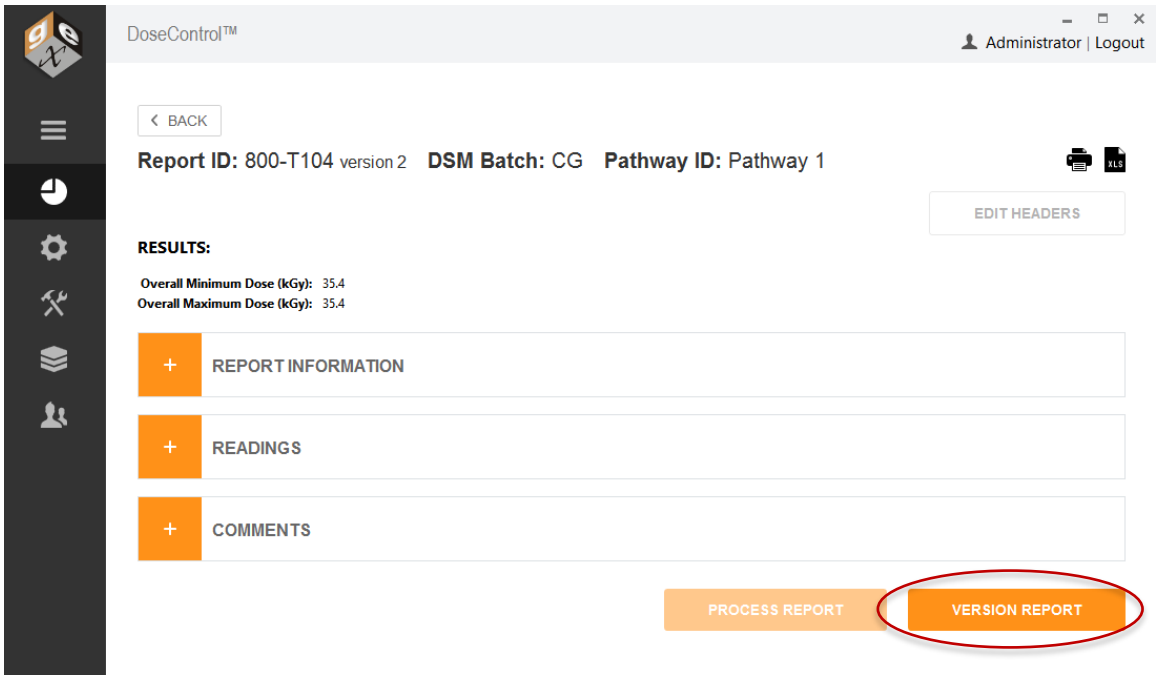


Version Report

Any report with a *Complete* status (the report has been processed) can be versioned at any time by any user using the 'Version Report' button. This creates a new report with a new version number but will then allow for editing. The user can edit the header information if there were errors. Also, any dosimeter can be measured if the reread 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 at a later time using the search function to do the same.



3.6 Report Outputs – PDF or MS Excel

The report may be output to a PDF file or to Microsoft® Excel® at any time regardless of the status of a report being *Complete* or *Incomplete*. Both output types will note if a report is incomplete by denoting so in the field for the Report Date/Time or in a field specifically for the designation of Complete/Incomplete status.

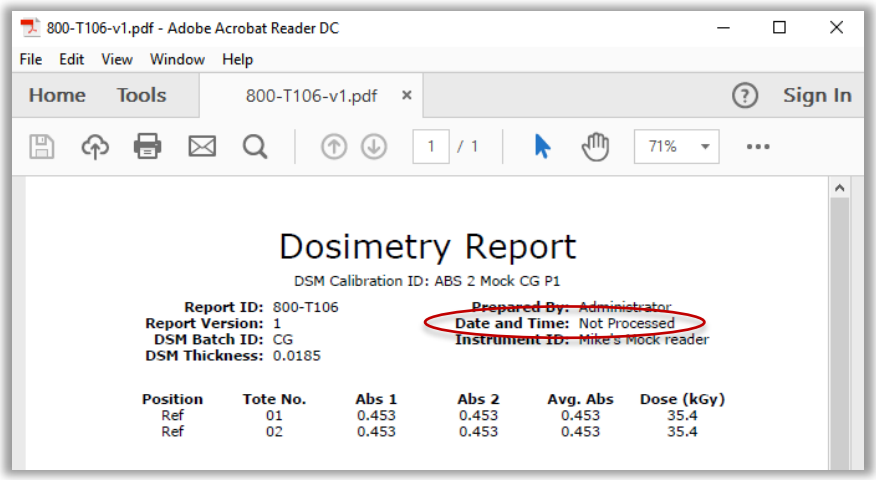
Export to PDF

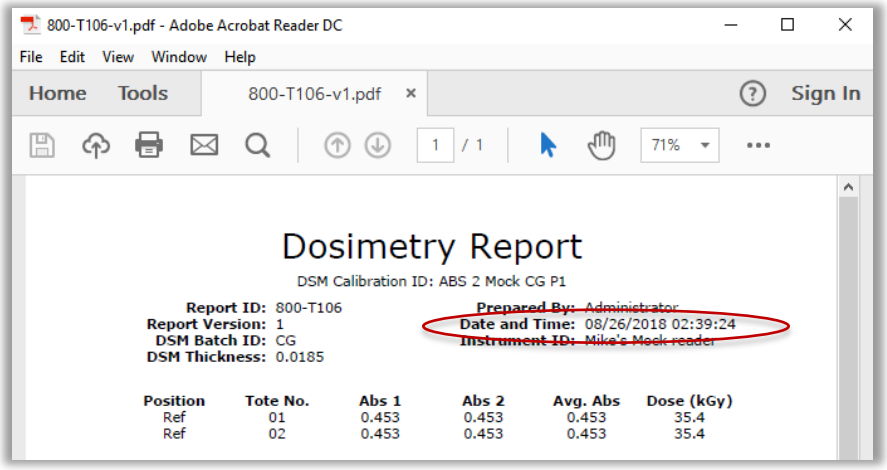
The PDF Exporter Type allows the selection of specific .dll files when the user sets up the Report Header (see Section 2.7 for details). Select the printer icon to open the .PDF file from the exporter that was chosen in setup. The PDF can be printed and/or saved using Adobe Acrobat Reader or equivalent. Use the features of the the PDF application for saving and printing.

Default PDF Exporter – The default PDF layout is very simple and will display up to two absorbance readings per dosimeter ID. Any fields not used are left blank which is not ideal for users in regulated applications.

Other PDF Exporters – GEX is in process of offering more PDF exporters with the basic application at no extra cost. More information on these may be obtained from GEX Customer Service. These include common layouts for single and double pouched dosimeters and for reference dosimetry where there are ratios used to calculate dose using a reference position.

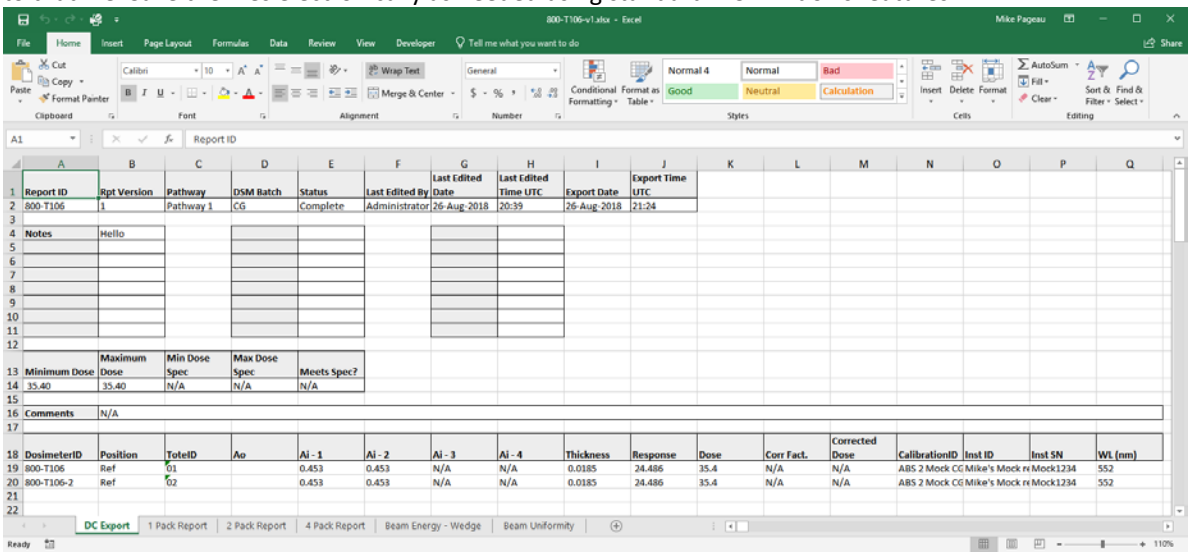
Custom PDF Exporters – From the simple addition of customer logos and information to one of our other PDF exporters to a completely custom look, feel, and layout, GEX builds these custom files for our customers for an hourly development rate.





Export to Excel

Select the 'XLS' icon to export data into a MS Excel file. If a custom file is used the data will be exported to that file. Save the files electronically as needed using standard MS Windows features.

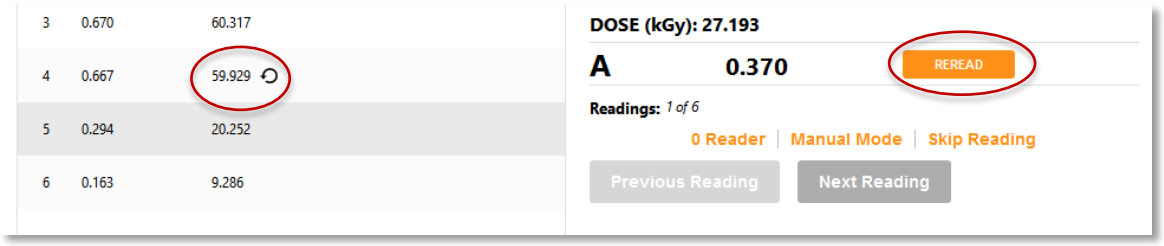


3.7 Rereading Dosimeters

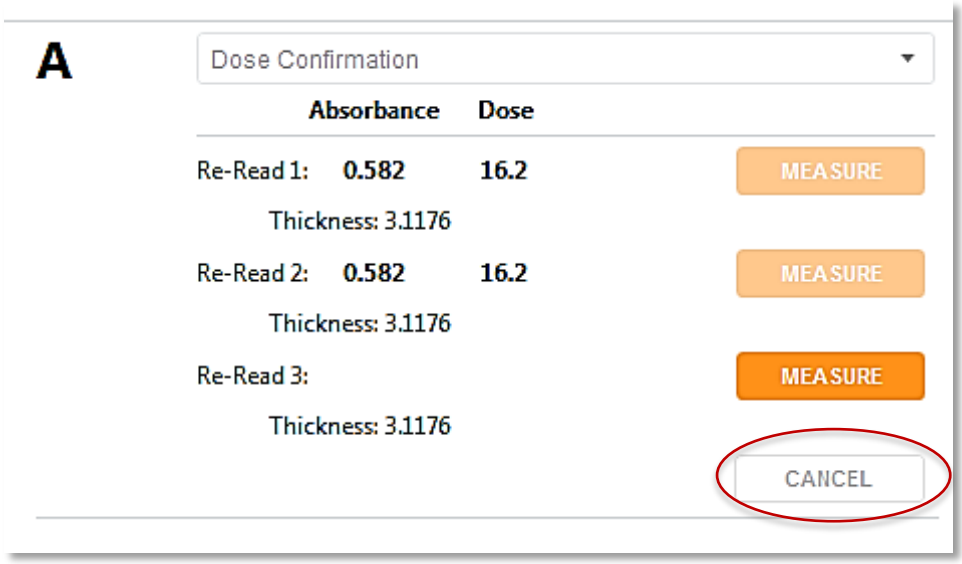
Sometimes a dosimeter needs to be re-measured/ reread. The 'reread' button appears in place of the 'measure' button after reading any dosimeter one time (see image below). The user may re-measure or reread during the measurement session on an at-will basis by default. Additional control of reread performance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

Reread 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 but all measurements are stored electronically and there is no instance in which an electronic record of a measurement is not retained for the life of the application data set. However, an icon on the screen indicates which dosimeters were re-measured. All events are logged and measurement data is retained in the Audit Trail for auditing purposes.

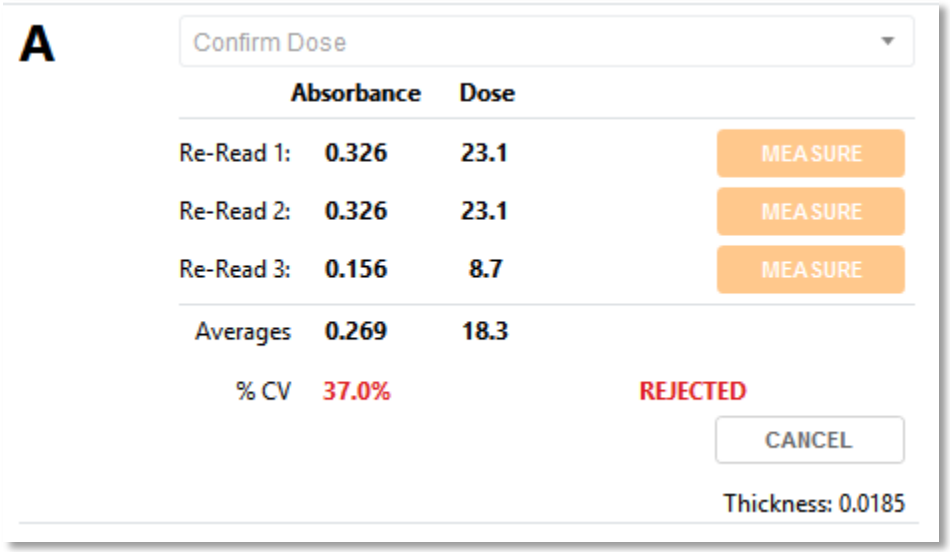


If the administrator has configured any reasons for rereads, then the screen will ask the user to select the reason. Additionally, if statistical rereads were configured for a given reason, the application will require that the user make three measurements of the same dosimeter before it will allow the report to continue. A 'cancel' button can be found and used before the first reread is taken, but once the measurement is taken the reread 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 reread 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 rereads is to verify repeatability of the three measurements (or four if including the original measurement). See image below:



STATISTICAL REREAD FAILURE

In the case of statistical rereads, if the reread average value is accepted, the absorbance and thickness will now reflect *'Reread'* 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 *'Reread'* is noted in their place.

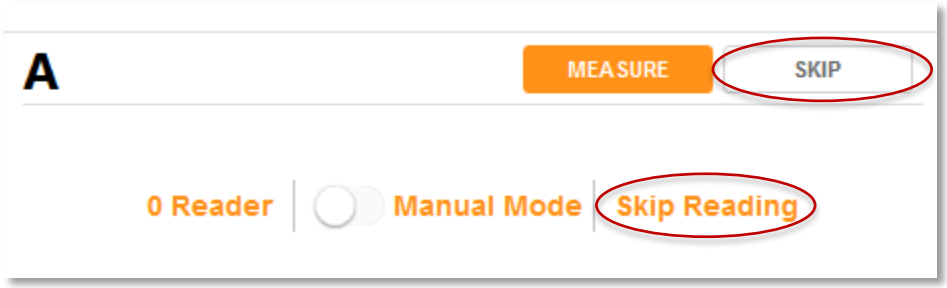
3.8 Skipping Dosimeters

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.

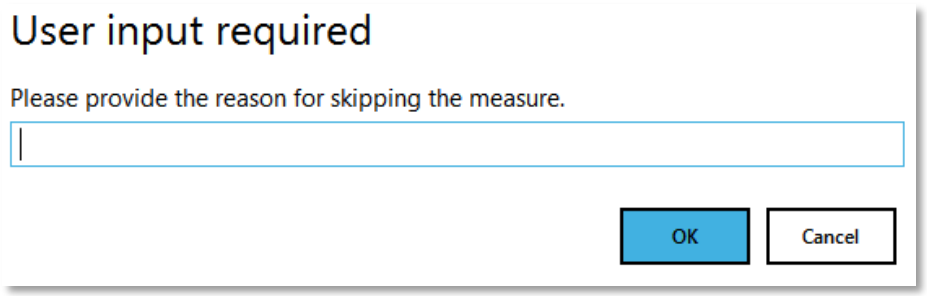
Example 2
In the case where all dosimeters from a particular packet, the packet itself is missing, or the dosimeter ID is missing.

The software manages both issues. 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 Reading' at the bottom of the 'measure' screen (see image below).



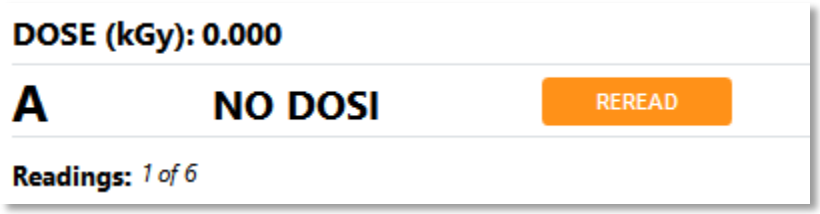
MEASURE SCREEN

In either instance, a 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 which version the comment was applied.

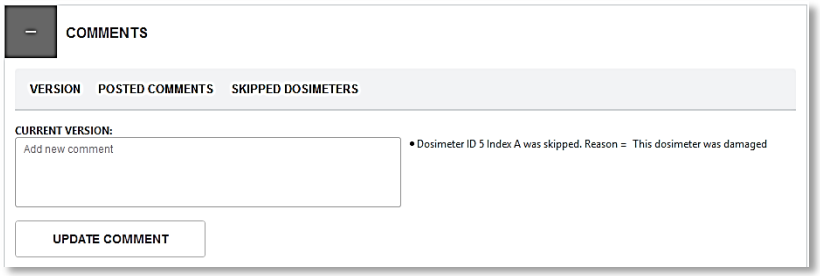


MESSAGE BOX: SKIPPING A DOSIMETER

The screen will display "NO DOSI" in the fields for the skipped 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 image 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.

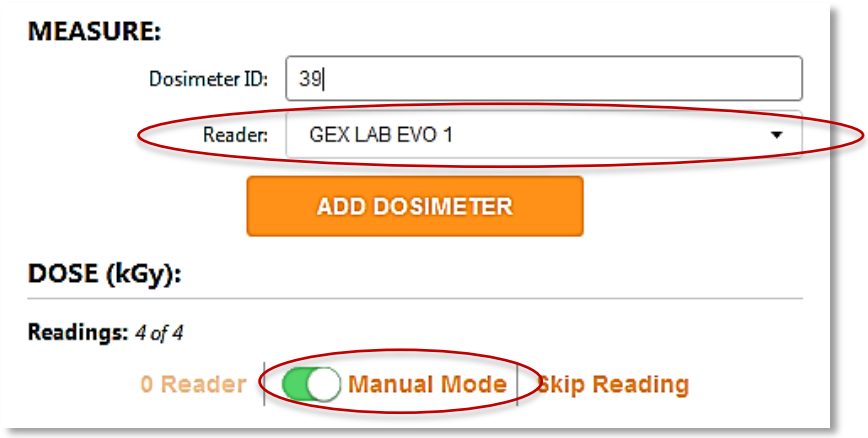


NOTE: Once a measurement has been acquired for a dosimeter, there is no ability to skip the measurement for that dosimeter ID. The user will have to reconcile that with their Quality Assurance department if they need to disqualify a dosimeter measurement.

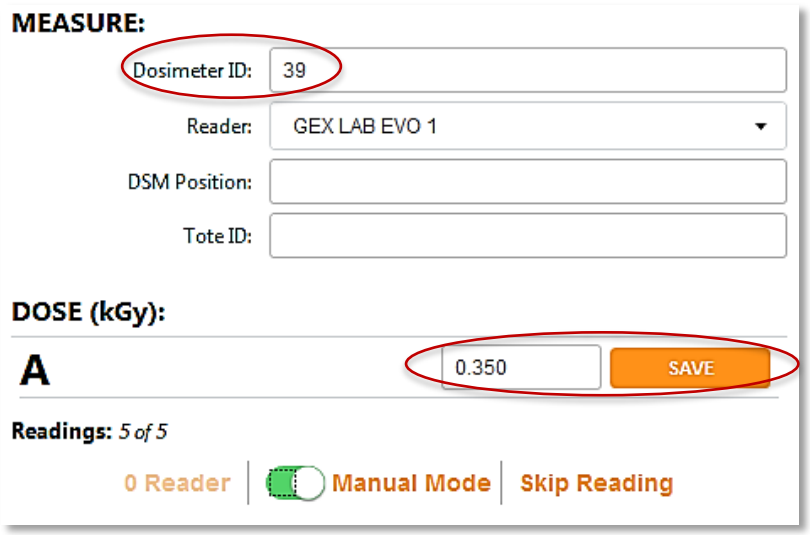
3.9 Using Manual Mode for Absorbance Measurements

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.

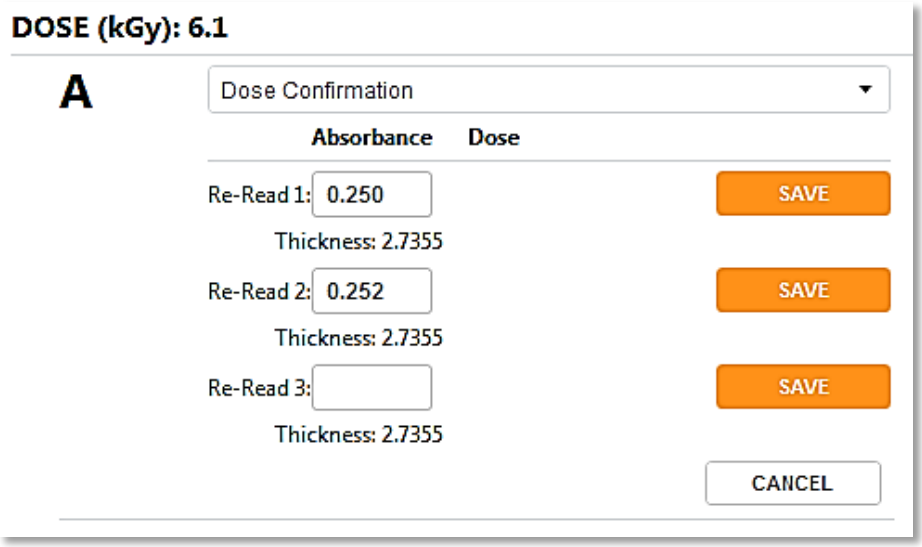
1. Select the Manual Mode switch to turn on. A new drop-down menu titled "Reader" allows the user to select the instrument, where the manual measurement records will be applied. Enter a dosimeter ID and select 'Add Dosimeter'. See below.



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



NOTE: Manual operation also works for making rereads. The process is the same but for statistical rereads, the user must enter and 'Save' each of the three values manually.

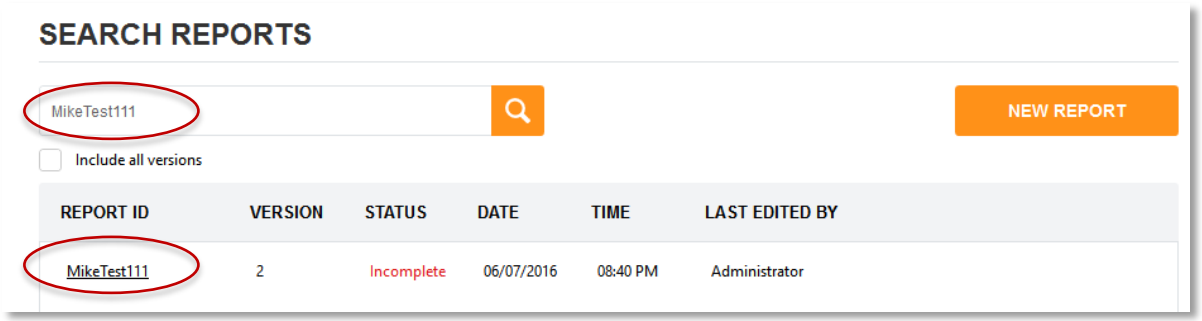


CAUTION: Manual rereads feature has not been fully tested for all workflow scenarios. This feature handles a very fringe case and will be improved upon in later versions. Also, at this time there is no manual entry for thickness values. Therefore, the system is not fully operational for such a situation.

3.10Reports List and Searching for Reports

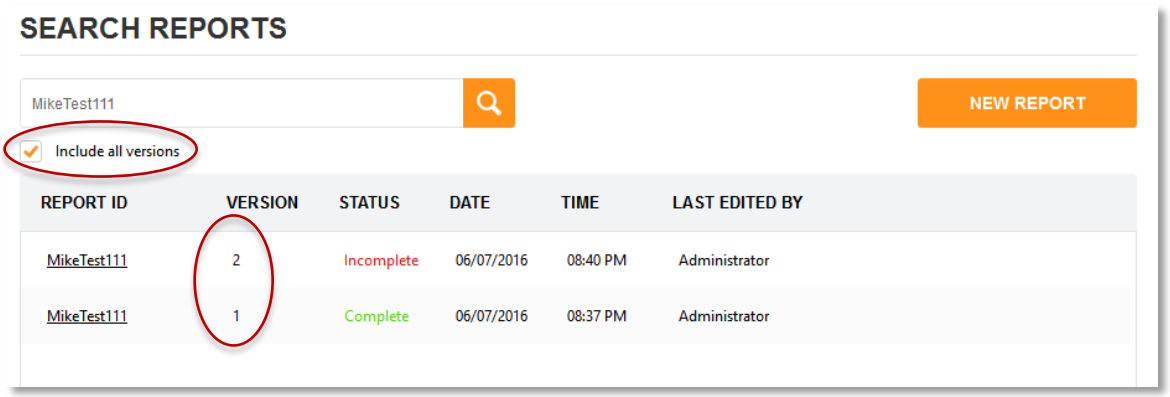
Searching for an existing report

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.



SEARCHING FOR EXISTING REPORT

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.



SEARCH FOR ALL VERSIONS OF EXISTING REPORT

Status of a Report

A report is either complete or incomplete.

- **Complete:** The user has completed the report and selected 'Process Report'. (Completed reports are read-only).
- **Incomplete:** User has not completed the required header information or all of the necessary dosimeter measurements.

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.

Actions Available for Completed Reports

There are three available actions the user can perform when viewing a 'completed' report.

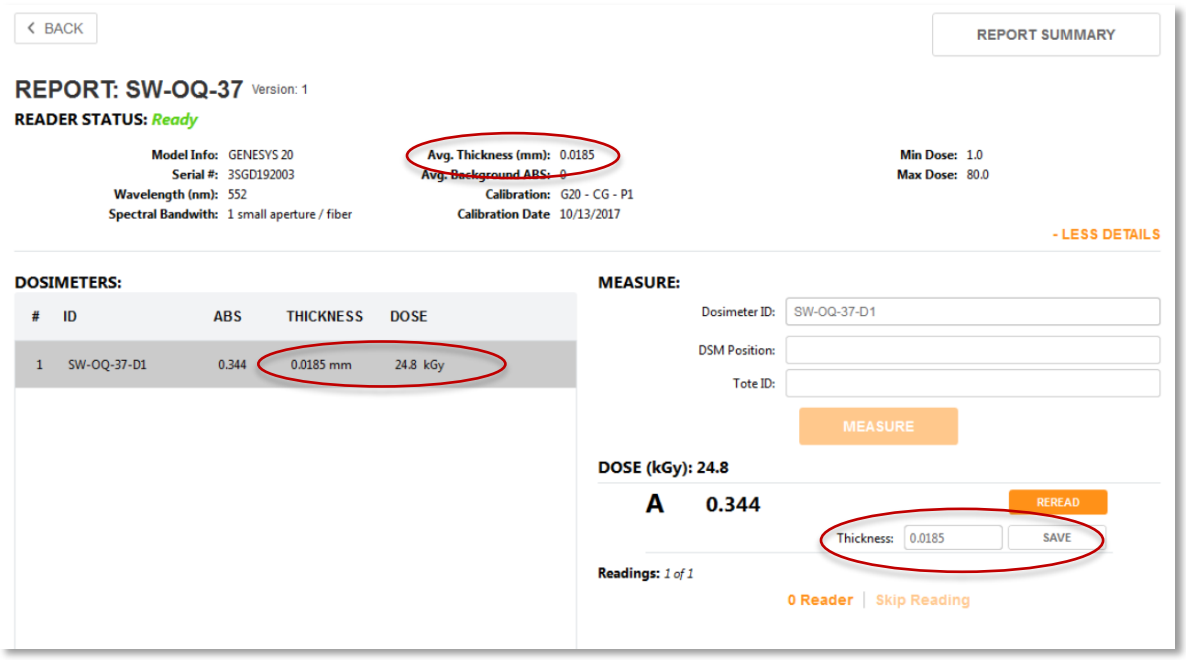
1. **New Version** – Creates a new revision level of the same Report ID allowing the user to edit report header information, re-measure dosimeters, fix typos, etc.
2. **Print** – Generates a .PDF file the user can then print with standard conventions.
3. **Export to Excel** – Inserts the data from all four tabs from the onscreen report into four tabs in an MS Excel file and asks the user to save the file.

3.11Editing Dosimeter Thickness

Situations arise where the thickness of a dosimeter needs to be adjusted in a dosimetry equation. For example, if the routine practice is to use an average film dosimeter thickness but there is a strange measurement, and the investigation finds the actual thickness is significantly different than the average. The need for this feature also arises if there is a problem with the Laser Micrometer when measuring PMMA dosimeters because you must have a measured thickness value. A backup, digital hand micrometer can be used and the user can type in the thickness value.

The Application Administrator must disable the "Uses Laser Mic" option in the Reader Configuration for this feature to function. Otherwise, the system will not find a laser micrometer and will take readings using the average thickness that the user can go back to later and enter the thickness. So there can be two workflows for using this. One is to enter the thickness after taking each absorbance measurement, and the other is to enter all thicknesses after entering all absorbances. The user has the choice of what option works best for their situation.

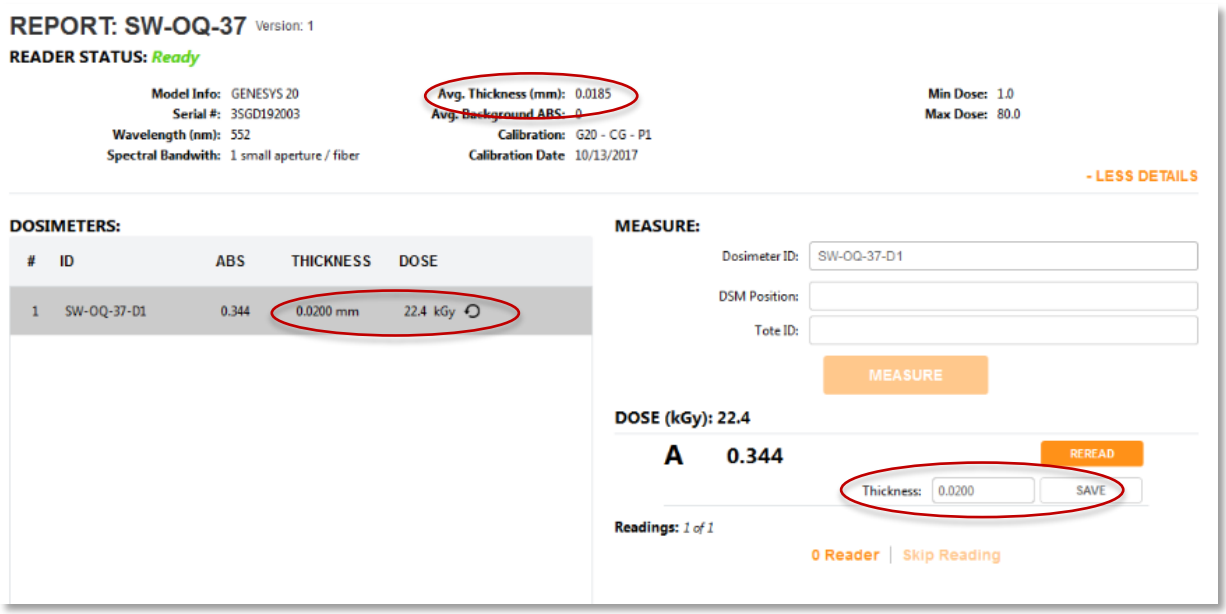
The process for editing thickness requires the 'Edit Thickness' user role to be set for any specific operator to have the ability to make edits; see section 1.6 for more details. In addition, the 'Edit Thickness' feature must be enabled for the dosimeter type; see section 2.3. Both of these items must be configured before the 'Edit Thickness' process is possible in the system.



MEASURE SCREEN: EDIT THICKNESS ACTIVATED

The user will see a slightly different Measure Screen view when Edit Thickness is configured. There is a box for the thickness value, and a save button to the right of it (see image below). In this mode, the system will always use the average thickness for a dosimeter that is stored with the calibration, unless the user enters a different value. In the example below, the value initially matches the average.

Enter a new thickness value and select the save button next to the entry. The new value saves in the dosimeter list on the left, and the dose re-calculates.



NOTE: The inherent data integrity of thickness measurements that are entered with the keyboard is not the same as the integrity of using an average thickness or a value measured with an integrated thickness gauge. Therefore, it is recommended that this feature be used only as needed and restricted to a select few qualified operators. Also, please note that the system tracks manual edits to thickness as an event, and can differentiate records that are manually altered. This is to preserve the data integrity and comply with 21 CFR part 11, while also creating a record of manual edits that is easily traceable.

3.12 Editing and Deleting Dosimeter ID's

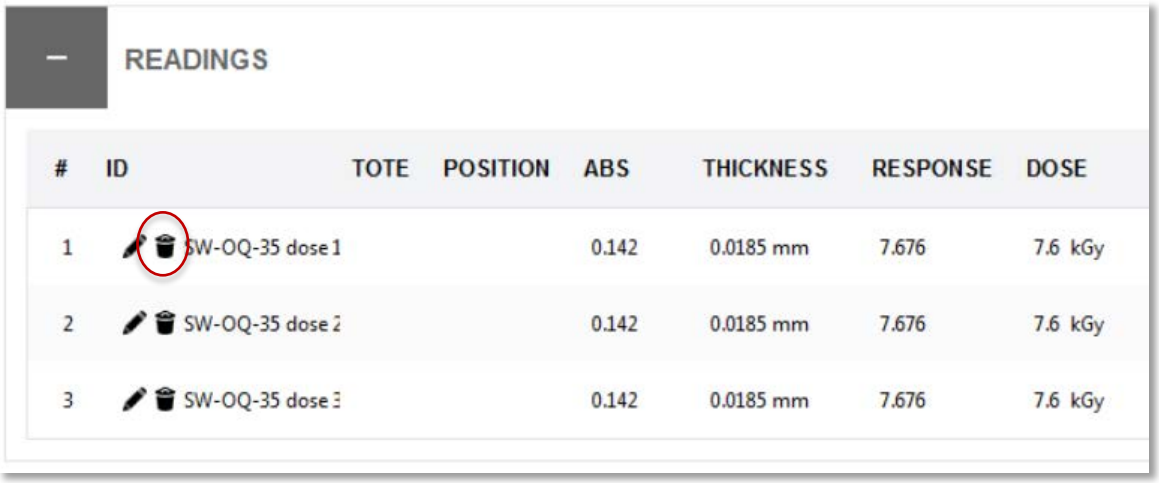
Sometimes there is a need to edit a dosimeter ID or to remove one from a report entirely. The system allows for this but there are rules governing these actions. The first rule is that these actions are only allowed to be perfomed by users that have the permission. Permission is applied per user as described in Section 1.6. Please note that editing functionality complies with the system rules that are compliant with 21 CFR part 11, and a full audit trail is captured for any deleting or edits of the dosimeter ID.

Both editing and deleting actions are accomplished from the Summary Screen in a report.

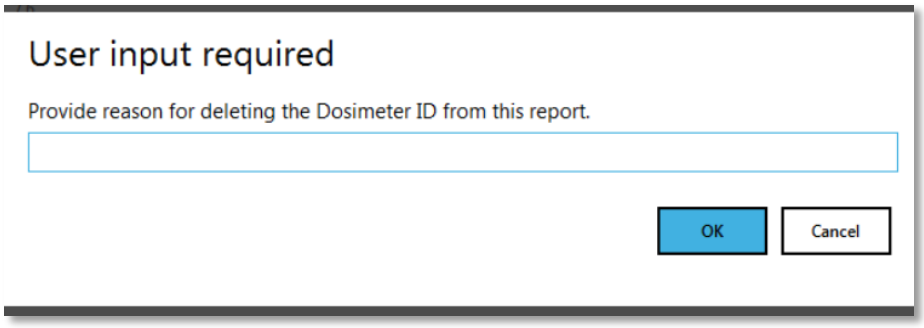
Deleting a Dosimeter ID

If a dosimeter is measured on the wrong report, then it can be deleted from that report. At this time, there is no feature to move it to a different report. The user has to delete from one report and then go and measure it in the other report. The process for deleting is very simple. Locate the dosimeter ID that needs to change, and select the Trash Can icon at the far-left of the row.

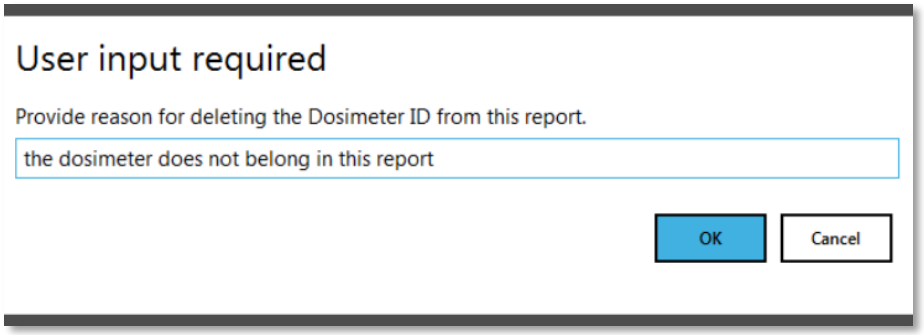
In the example below, we will delete the reading # 1 from the report:



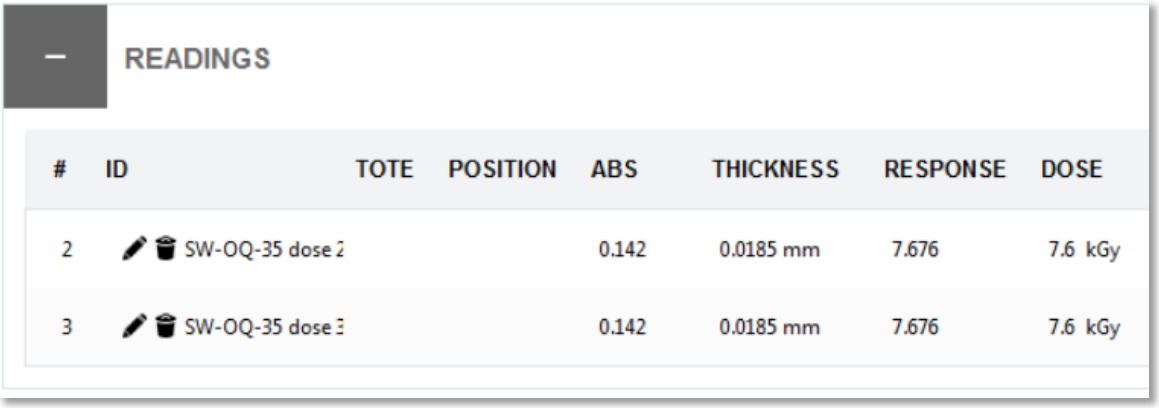
The software will require the user to enter a reason why the dosimeter is being deleted.



Enter a reason of 3 characters or more.

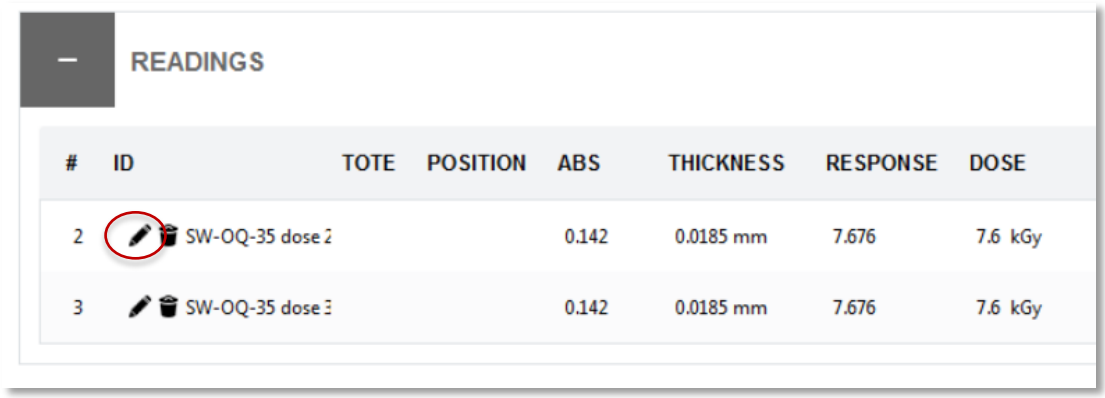


The dosimeter ID selected is now deleted from the report; see below:

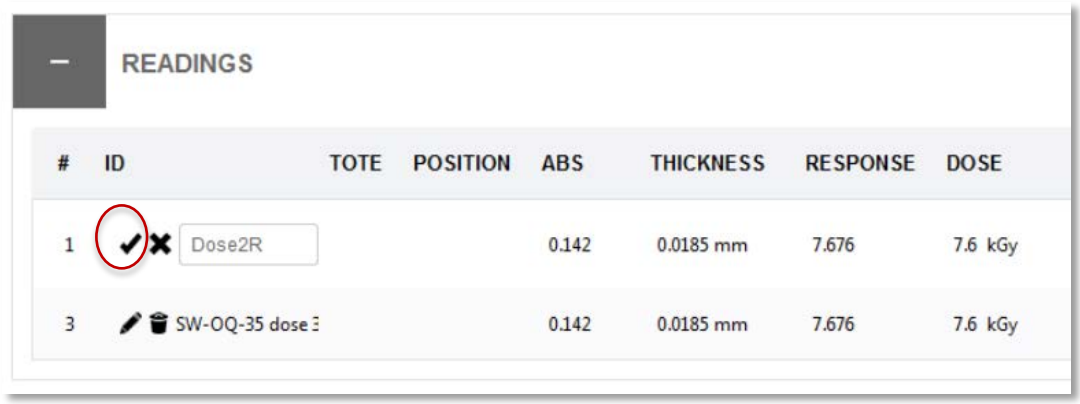


Editing a Dosimeter ID

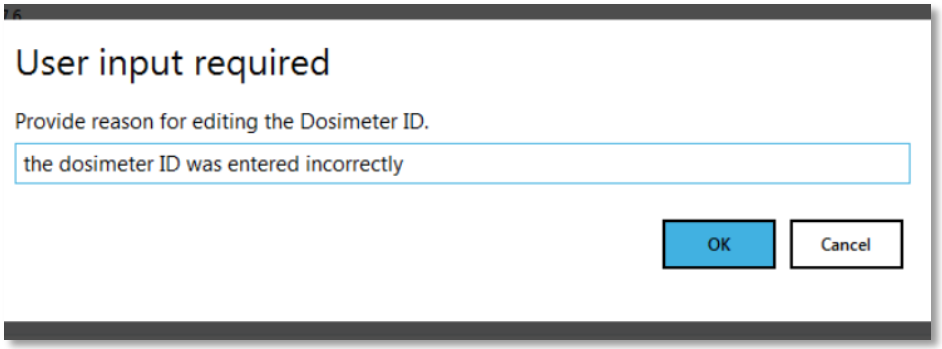
If there is an error in the ID, then the user may edit and change the ID. If there is a duplicate dosimeter ID that is trying to be used, or if a dosimeter ID was entered manually and incorrectly, then there will be a need to edit the ID. Locate the dosimeter ID that needs to change and select the Pencil icon at the far-left of the row.



Make the edit, and then select the checkmark icon to save the change. If you did not intend to change anything, then select the 'X' icon.



After selecting the checkmark icon, a message will appear asking the user to enter a reason why the dosimeter ID needs to be edited. Enter a reason of 3 characters or more:



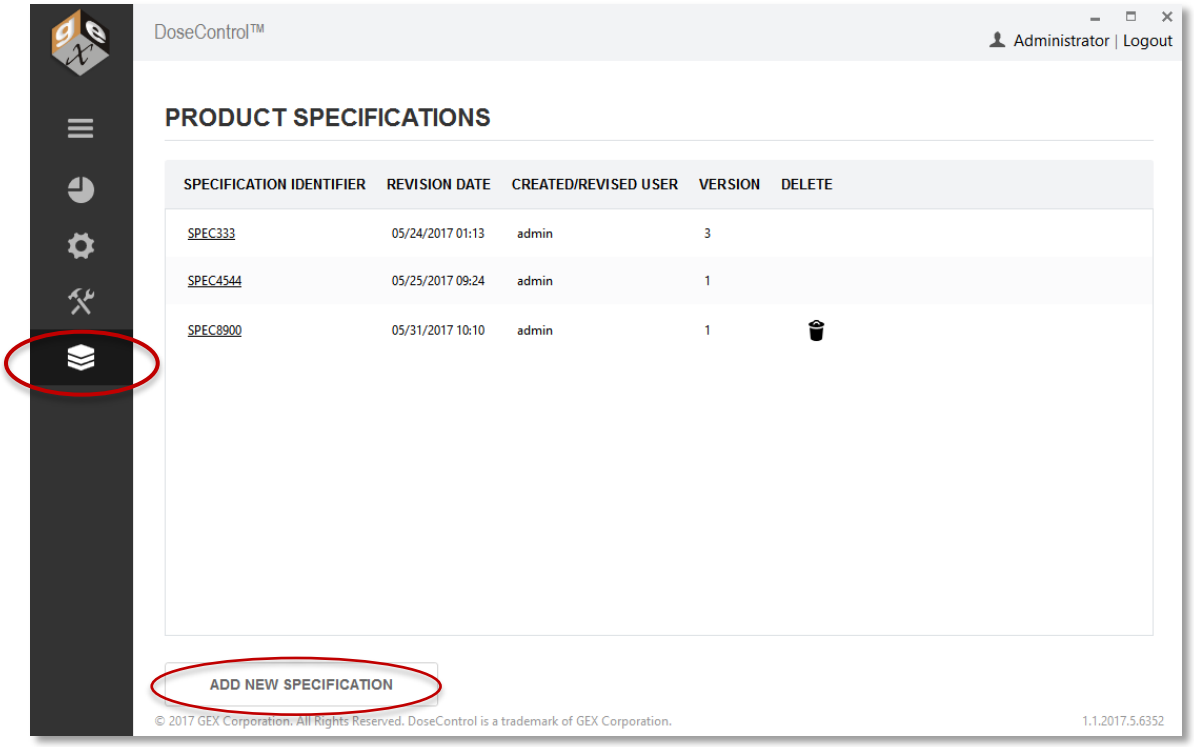
Select the "OK" button, and the change will be saved.

NOTE: readings will automatically be re-numbered (column 1) when items are deleted.

4 Product Specifications

The product specifications module can be purchased to allow you to store product specifications so that you can use DoseControl to compare the results of dosimetry against the required specifications. You can also add min and max dose correlation factors so that DoseControl can calculate dose to the minimum and maximum positions in the irradiation load if you are measuring at a reference position.

The process interacts with the Report Headers feature, and it is that feature that must be configured correctly in order to pull the product specifications from this module into Dosimetry Reports. Let's begin by looking at the features and functions of the Product Specifications Module. The image below shows the home screen for Product Specifications. By selecting the 'stack' icon in the left menu bar you will be taken to this screen.

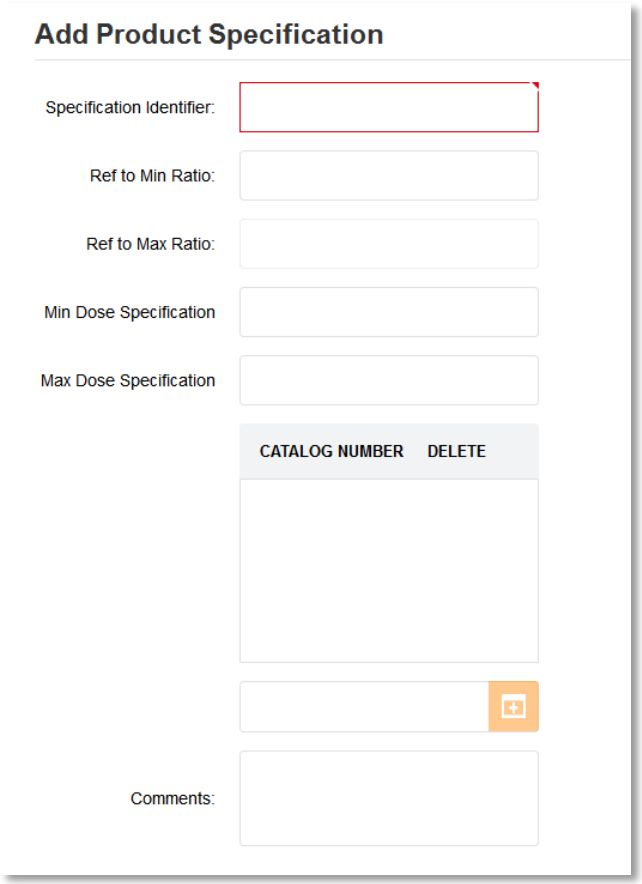


PRODUCT SPECIFICATIONS: HOME SCREEN

The home screen lists the specification, their revision date, the username of the person that created or edited it, and a version number. From here, you can either open an existing specification by clicking on the ID or you can add a new specification.

Adding or Editing a Specification

When selecting the "Add New Specification" button, a new screen will appear as shown below. The purpose of each field is described below.



Specification ID – Each specification requires a unique ID to identify the information that it contains otherwise the specification cannot be saved.

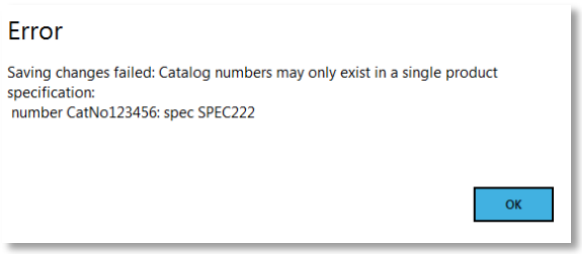
Ref to Min Ratio – Ratio of dose at the position the dosimeter is placed to the minimum dose location in the process load (product). Must be less than the 'Ref to Max Ratio'.

Ref to Max Ratio – Ratio of dose at the position the dosimeter is placed to the maximum dose location in the process load (product). Must be greater than the 'Ref to Min Ratio'.

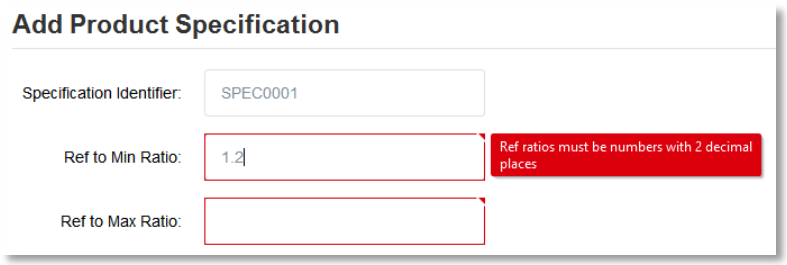
Min Dose Specification – Value (in kGy) that the product requires. Must be less than the 'Max Dose Specification'.

Max Dose Specification – Value (in kGy) that cannot be exceeded. Must be more than the 'Min Dose Specification'.

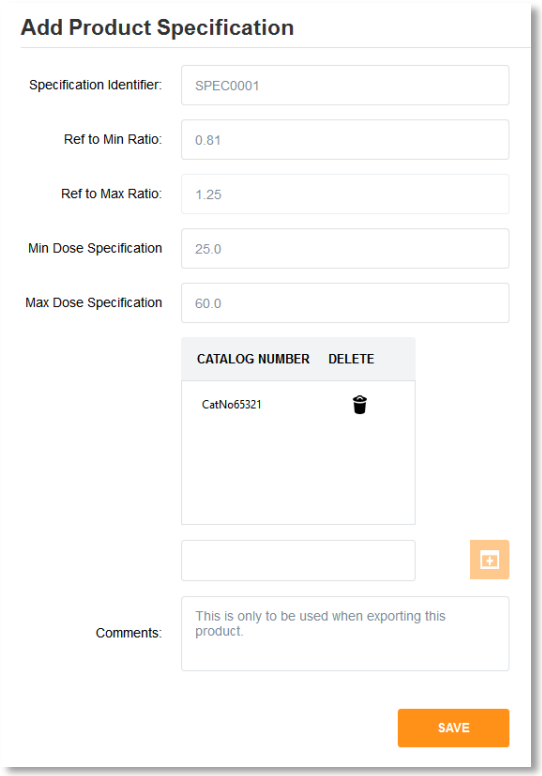
Catalog Number – A unique identifier for a specific product. Multiple catalog numbers can be added to a single specification as there are often products with the same ratios and specifications. However, a given catalog number may only exist within one specification. If the user tries to enter it into more than one specification, an error message will appear:



The numerical values in the fields must contain the required number of significant digits in order to save the specification. The software notifies the user if the value entered does not match the required digits:



The completed specification can be saved once all entries are completed and conform to the requirements. There is also an optional comment field. See image below:



All edits made to a saved product specification are recorded in the audit trail. The specifications list on the home screen for this module will automatically update by revisioning upward, changing the date, and changing the username of the last person to edit the record.

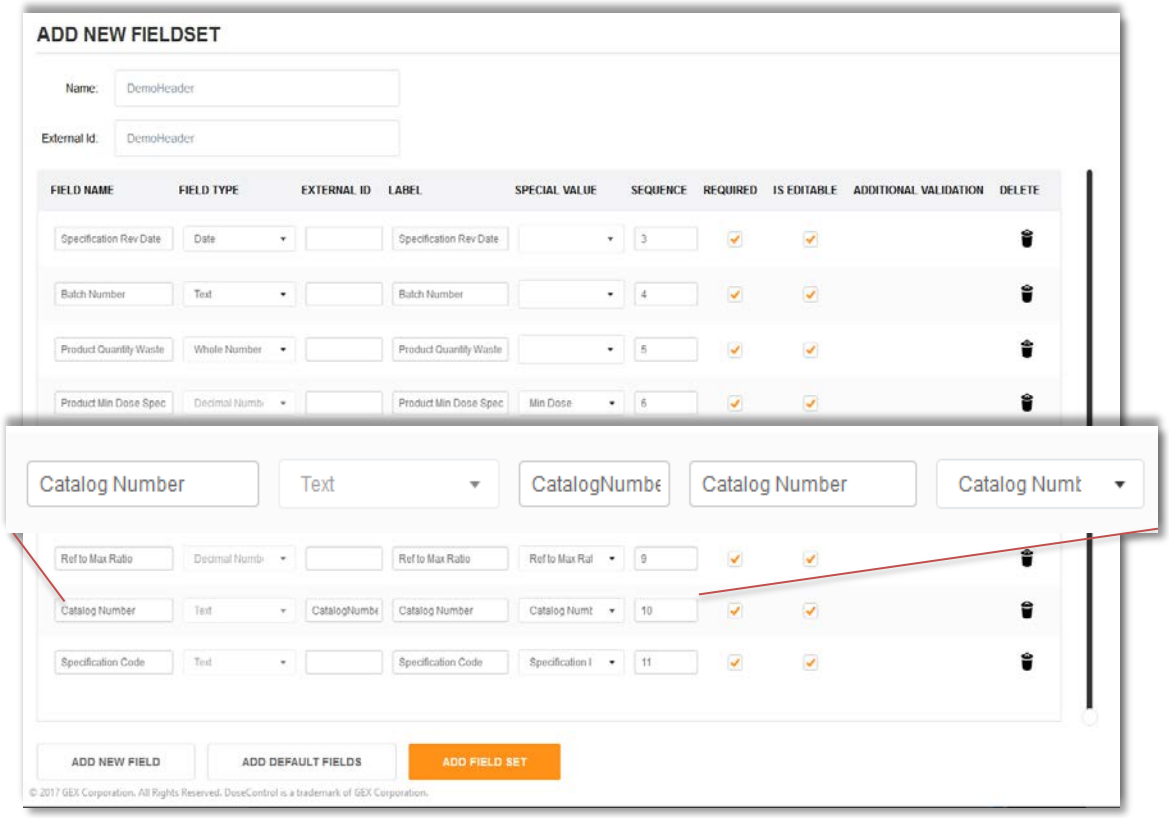
Using Product Specification data from the module in a Dosimetry Report

NOTE: Currently, the product specification module is not fully functional unless the Catalog Number is input into DoseControl via the 'Import' feature described in Section 5.

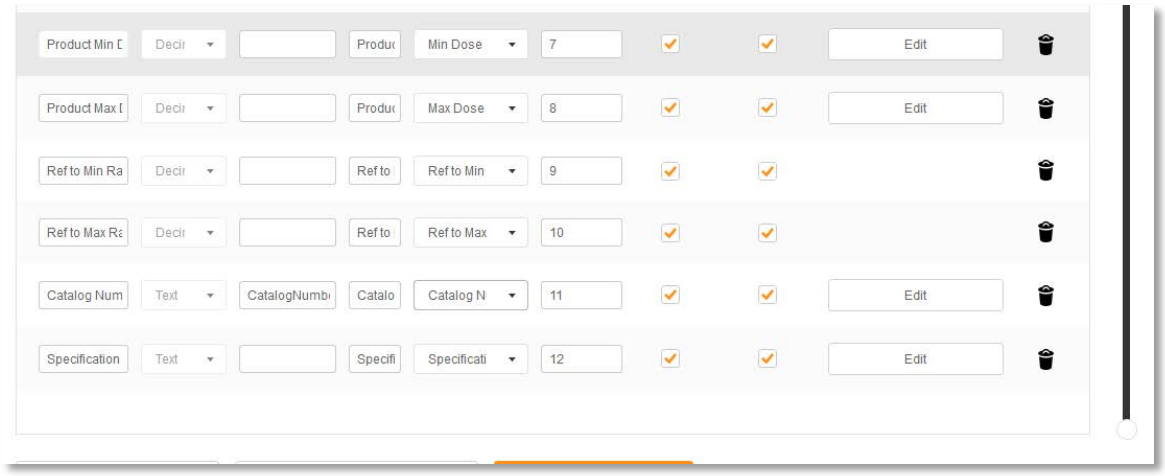
To successfully use the product specification in a dosimetry report, you must configure a report header that can import the information contained in the product specification. This requires that the Catalog Number is created as a field in the header, and it must have this precise configuration shown in the images below (except that the 'Label' field can be any name that you wish to assign to the Catalog Number. For example, you could rename it to be "Catalog #").

The other five pieces of information from each product specification can be sent to a report header for that header set, if the special value field in the report header configuration is used. Most users will want the min and max spec values, as well as the min and max ratio values. Often the Specification ID is desired to be contained in individual dosimetry reports.

Once the header is configured in this way, a dosimetry report can be created, and the user can enter the Catalog Number from the system into the report header. The system will import the specifications into the report.



Below is the default configuration for the 6 fields that you can setup for use in a Report Header:



NOTE: The information in the section above is only relevant for use with the Product Specification module add-on feature of DoseControl.

5 Import/Export Electronic Data

DoseControl has 'Import Tables' and 'Export Tables' which are separate from the database tables that are required to run the application. The end-user can put information into these tables and integrate with DoseControl to pass and receive dosimetry related information. This can be done if the user has purchased an Enterprise License for DoseControl.

The first purpose of this feature is to allow the user to import min and max dose specifications and ratios as described in the previous section, if they already stored electronically rather than using the Product Specifications Module. Moreover, the user can pass any information for display to the routine operator of the software when creating reports. Oftentimes, the user would like certain information at hand within the dosimetry system including items such as; Catalog Number, Product Description, etc. This is quite simple and can be performed by any database professional.

The second purpose of this feature is to allow the user to utilize electronic dosimetry records. Therein lies a tremendous amount of information that can be utilized for activites such as product release processes, process control, process data analysis, and the analysis of dosimetry related metrics.

A separate document provides the details of inserting data into DoseControl import tables and retrieving data from DoseControl export tables (*GEX Doc# 100-268, User Guide for Integration with DoseControl Software*). The structure of the tables, as well as data rules governing the integration are provided in detail here. Contact Mike Pageau at mpageau@gexcorp.com or +1 720 810-2225 to obtain a copy of the document.

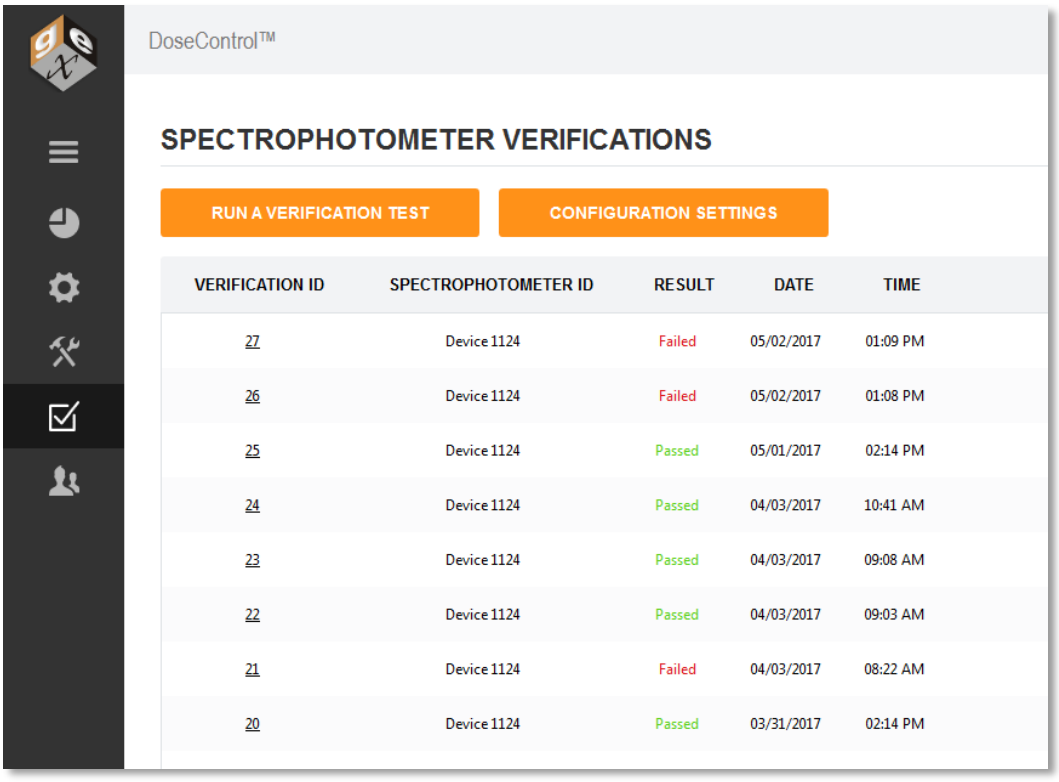
6 Performance Verification (PV)

A module for the users of the Thermo Evolution 220 Spectrophotometer can be configured to require performance verification (PV) testing of *photometric accuracy* and *wavelength accuracy* of the Evolution 220 at a frequency defined by the user. PV was designed to be a 'daily check' type of verification so it is relatively fast and it is not comprehensive. However, it does test the two most important aspects of the instrument as it relates to the accuracy of absorbance measurements that allows the user to limit risk of measurement inaccuracy to be the time period since the last PV test.

First, a brief definition and discussion of each test:

Photometric Accuracy – the closeness of the measured intensity values to the actual intensity values. DoseControl allows the user to use any reference that has a value certified in absorbance units in the operational wavelength range of the Evolution 220 over the operational range of intensity (absorbance value).

Wavelength Accuracy – the closeness of the wavelength value reported by the instrument to the actual value. DoseControl locates the peak near 542 nm of the internal xenon lamp, and displays the measured and allowed range of wavelengths. A xenon lamp has strong, fundamental lines throughout the UV-visible range, and are an intrinsic property of the lamp that serve as a fundamental wavelength standard and does not require calibration. The wavelength and tolerance values cannot be changed. Use an empty cell holder. The hardcoded values assigned for acceptance criteria are provided by the instrument manufacturer.



PERFORMANCE VERIFICATION HOME SCREEN

The home screen shown above features a list of all the tests run for all Evolution 220 spectrophotometers in the system.

- *Verification ID* – unique test ID auto-assigned by the software to each PV test
- *Spectrophotometer ID* – the ID from the Reader Configuration in Setup
- *Result* – Passed or Failed (incomplete PV tests automatically fail)
- *Date* – Date of completion of the PV test
- *Time* – Time of completion of the PV test

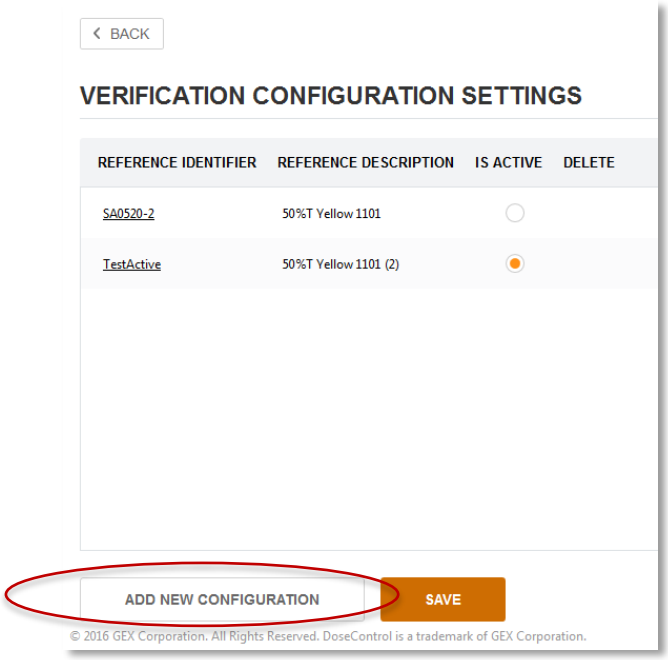
The orange 'Run A Verification Test' button will be greyed out unless a reference is active and an Evolution 220 is attached to the PC that you are using.

Upon initial configuration of PV, the software will require PV to be completed on all Evolution 220s before any measurements can be taken in the Reports module with a respective instrument. The PV test can then be performed 'at will' and/or can be triggered by the software after the timer expires at the frequency configured by the administrator. The timer begins after successful completion of PV. The elapse of the timer will not interrupt a measurement session that is in-progress.

Currently, the software is hardcoded to require that a different user complete the PV if the user that initially attempts PV fails the test. The software provides on-screen instructions for login/logoff in such instances. In such a case, the second user must pass and then the original user must then also pass the test for the instrument status to become active again for measurements.

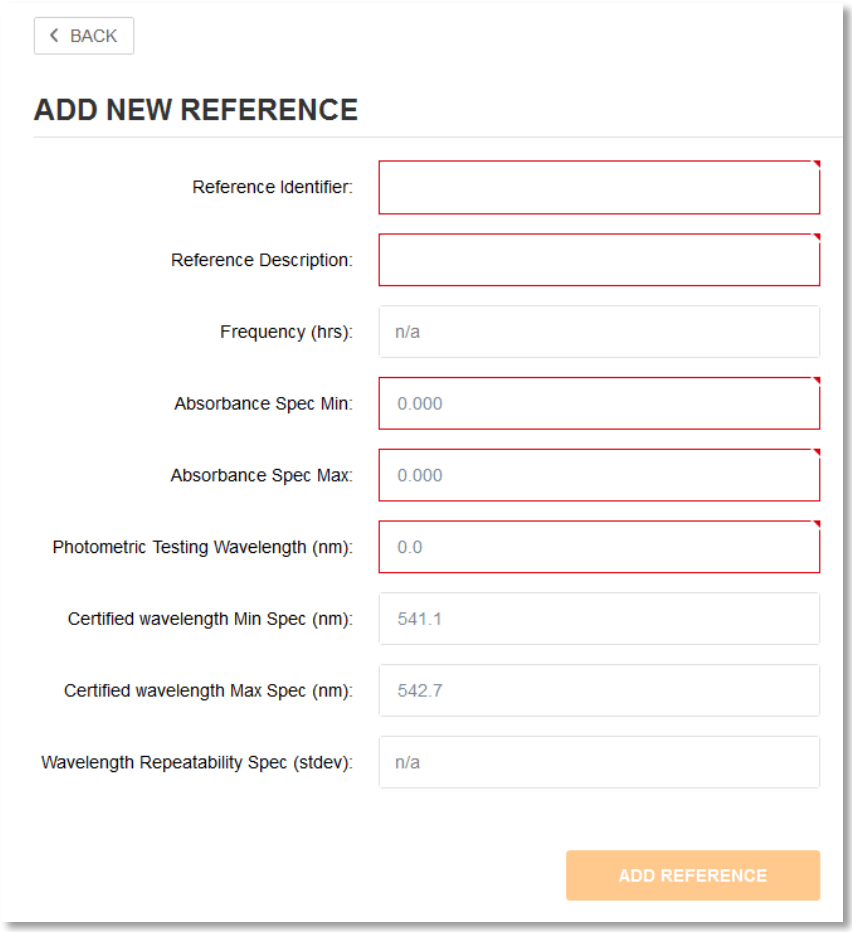
6.1 Configuring PV

From the PV home screen, select the orange "Configuration Settings" button. Then select the white "Add New Configuration" button.



CONFIGURATION SETTINGS SCREEN

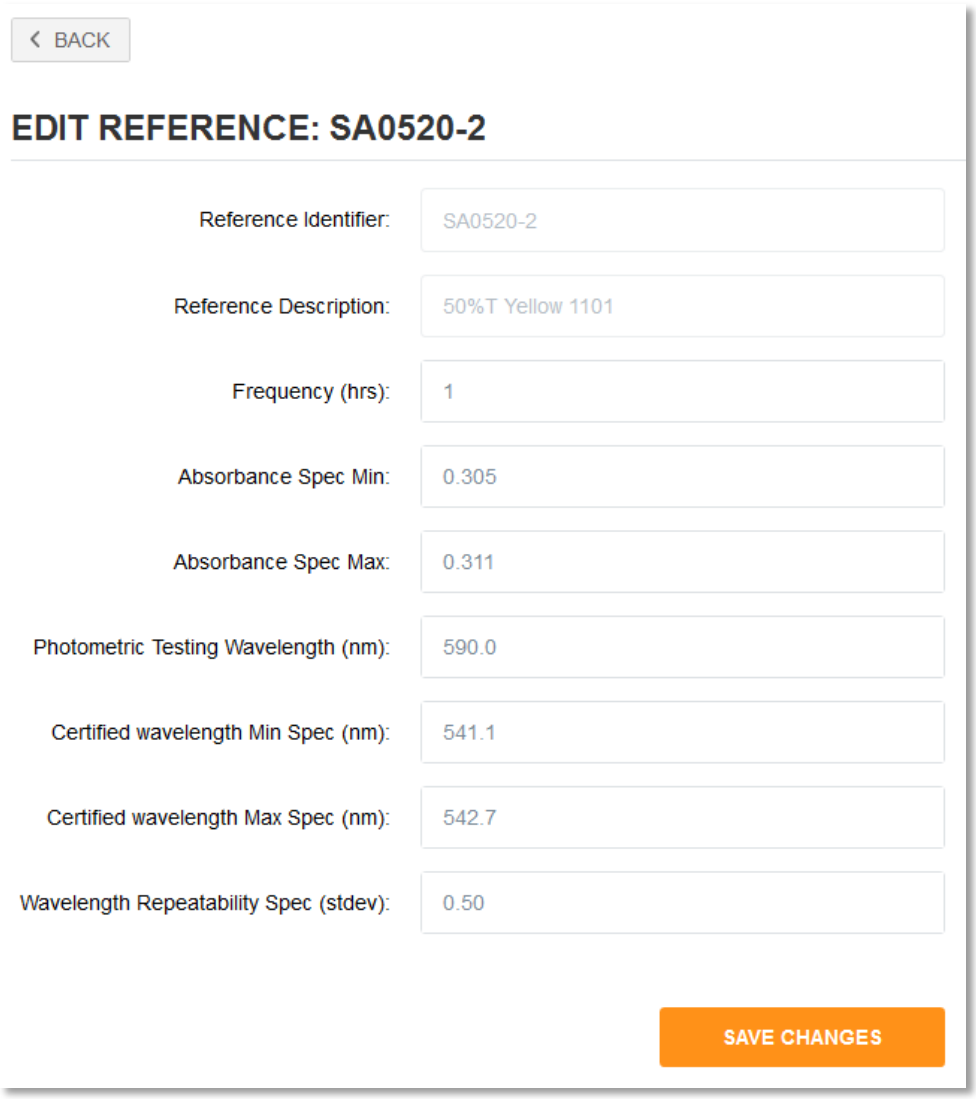
The settings screen above lists all the references in the system by ID number and description, and allows the Admin to activate or deactivate one of them. Only one reference may be active at any given time but the system allows more than one reference to be added/configured which allows for updating a specific reference's details by giving it a new name or configuring multiple references that may be swapped in and out of use. Next, complete all required fields (see below). When complete, select the orange "Add Reference" button to save the new reference. References may also be edited.



- *Reference Identifier* – Enter an ID for the photometric reference. Thermo filters have an assigned ID labeled on the filter that is used on the Certificate of Calibration.
- *Reference Description* – Enter a text description of the ID as additional detail to the ID.
- *Frequency (hrs)* – Enter the frequency for PV testing (e.g. 24 hours). Leave this field 'n/a' or enter '0' if you want to configure PV for 'as needed' to let operators choose when to perform PV.
- *Absorbance Spec Min* – The certified minimum value of the photometric reference in absorbance units. For Spectronic Standards, round the uncertainty up to the nearest thousandth (e.g. ±0.003 A at k=3) and subtract from the certified value (e.g. 0.308 A certified value minus 0.003 A = 0.305 A).
- *Absorbance Spec Max* – The certified maximum value of the photometric reference in absorbance units. For Spectronic Standards, round the uncertainty up to the nearest

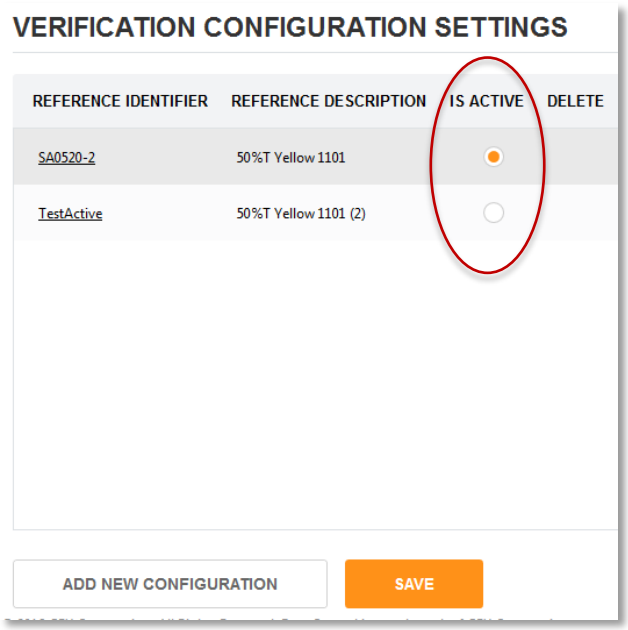
thousandth (e.g. ±0.003 A at k=3) and add to the certified value (e.g. 0.308 A certified value plus 0.003 A = 0.311 A)

- *Photometric Testing Wavelength (nm)* – The wavelength at which the photometric standard is certified, in tenths of nanometers (e.g. 590.0 nm).
- *Certified wavelength Min Spec (nm)* – Wavelength accuracy min specification hardcoded at 541.1 nm.
- *Certified wavelength Max Spec (nm)* – Wavelength accuracy min specification hardcoded at 542.7 nm.
- *Wavelength Repeatability Spec (stdev)* – the allowable standard deviation for the 3 wavelength accuracy tests. Thermo's specification is 0.50.



EDIT REFERENCE SCREEN

The radio button 'Is Active' may be selected to make any reference in the list active. Press 'Save' when complete (see below).



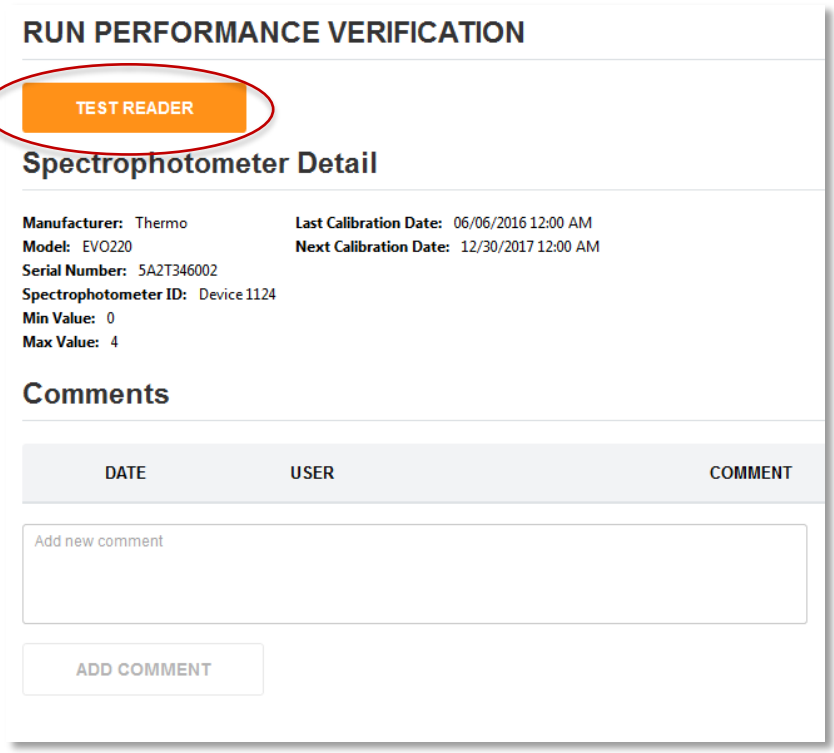
6.2 Performing PV

Users must be assigned to the Technician role in User Manager to run Performance Verification (PV) tests. Anyone can view previously executed test results. PV can be accessed and performed from the PV home screen by simply pressing the orange 'Run A Verification Test' button, which brings up the *Run Performance Verification* test screen. The PV test screen lists the details of the attached spectrophotometer, and also features a 'Comments' section. Comments can be added before or after running a PV test.

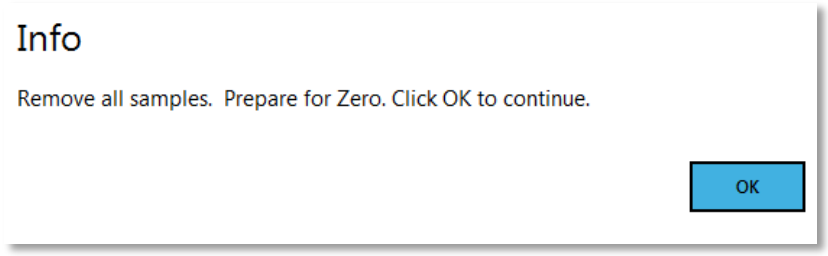
NOTE: Before proceeding, swap the receiving piece of the film dosimeter holder system (GEX Part# P4334) into the GEX holder system baseplate before beginning PV. This holder is designed to hold 1cm^2 reference filters in addition to the GEX film dosimeter holder.

Unlike during the measurement of dosimeters, the front panel and lid for the sample compartment of the Evolution 220 Spectrophotometer should be closed during the entirety of PV testing except when inserting/removing the reference. The criteria for the PV test results was determined using the sample compartment closed and it should always be executed in that same manner.

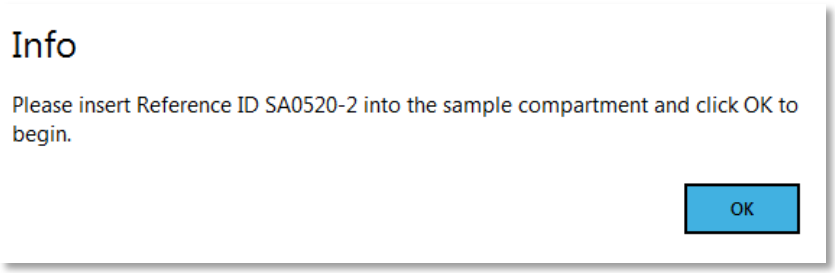
Once the user has started PV, canceling the process it not an option. If interrupted by power outage or other reason, the PV test will be incomplete and all incomplete tests automatically fail. The instrument remains unavailable for use until the passing criteria is achieved.



Press the orange 'Test Reader' button to begin (see above). The PV test will initialize and an info message will appear as shown below, asking the user to prepare to zero the instrument.



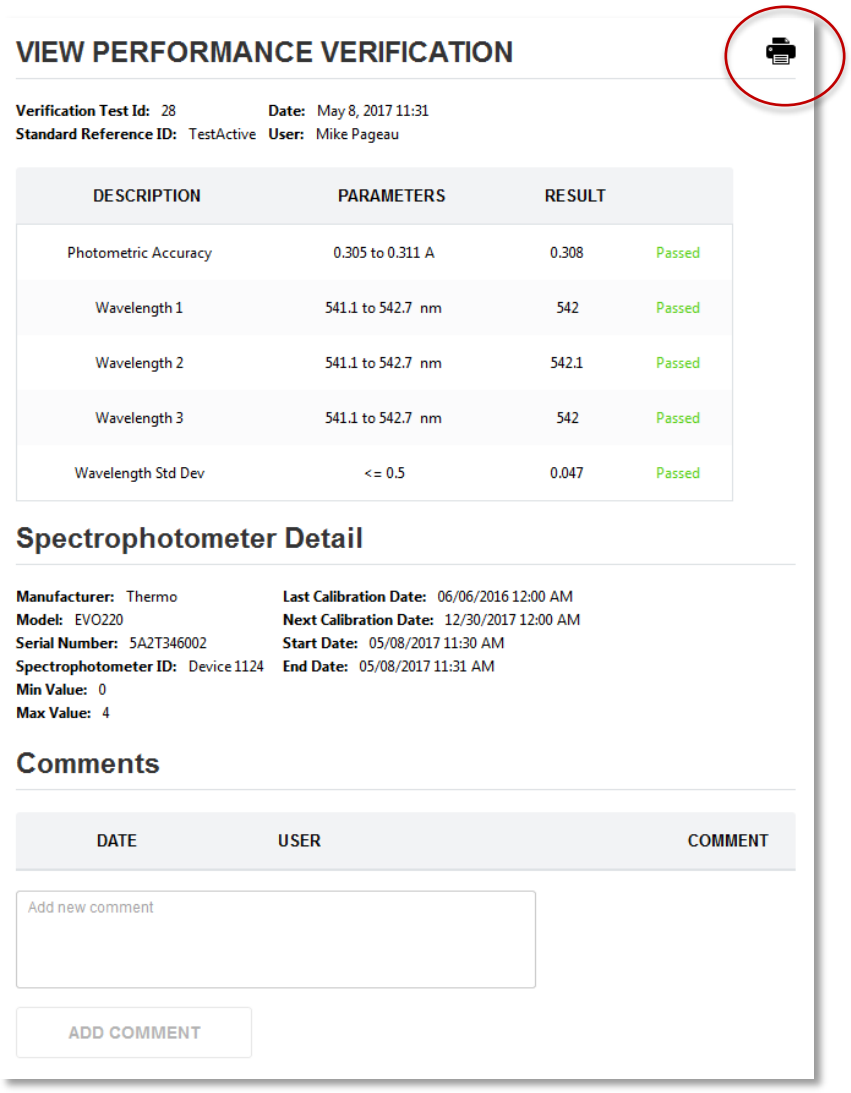
After this mandatory zeroing, press OK. The software will ask the user to insert a specific reference ID, see below.

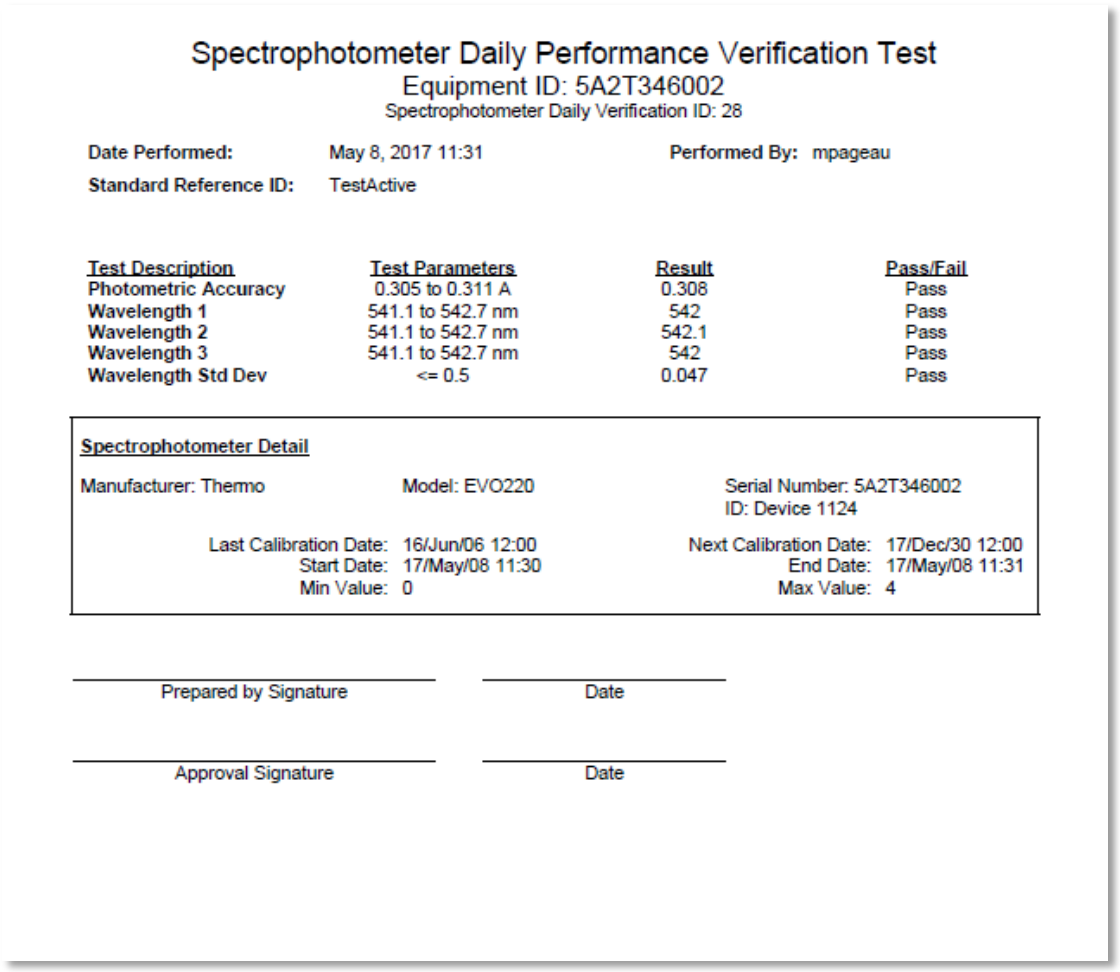


Insert the Reference ID that is requested, close the sample compartment lid, and press 'OK'. The Photometric Accuracy Test will complete, and a similar message to the one above will appear asking you

to remove the sample. Remove the sample, close the sample compartment lid, and press 'OK'. The PV testing will then proceed to completion. While PV is ongoing, the DoseControl menu bar is greyed out to prevent the user from navigating away from the test that is in-process.

While the test is in-process, a progress bar along the top indicates that testing is in-progress. Each test shows the result of the test as they complete, displays the test acceptance criteria, and the software automatically determines pass or fail. Even if one or more of the individual tests fail, PV will perform all required tests in sequence in order to generate the complete results. The results are then displayed to the user. The user has the option to add comments to the PV results (type the comment and click the 'Add Comment' button). Using the printer icon in the top-right, the user also has the option to print the PV test report or it may be printed at a later time by accessing any particular PV Test ID from the PV home screen.





Spectrophotometer Daily Performance Verification Test
Equipment ID: 5A2T346002
Spectrophotometer Daily Verification ID: 28

Date Performed: May 8, 2017 11:31 **Performed By:** mpageau
Standard Reference ID: TestActive

Test Description	Test Parameters	Result	Pass/Fail
Photometric Accuracy	0.305 to 0.311 A	0.308	Pass
Wavelength 1	541.1 to 542.7 nm	542	Pass
Wavelength 2	541.1 to 542.7 nm	542.1	Pass
Wavelength 3	541.1 to 542.7 nm	542	Pass
Wavelength Std Dev	<= 0.5	0.047	Pass

Spectrophotometer Detail

Manufacturer: Thermo Model: EVO220 Serial Number: 5A2T346002
ID: Device 1124

Last Calibration Date: 16/Jun/06 12:00 Next Calibration Date: 17/Dec/30 12:00
Start Date: 17/May/08 11:30 End Date: 17/May/08 11:31
Min Value: 0 Max Value: 4

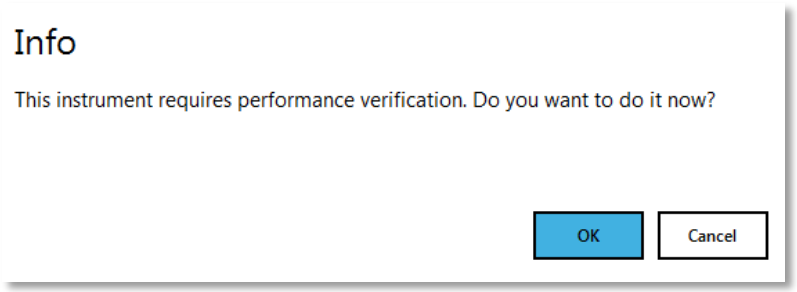
Prepared by Signature Date

Approval Signature Date

PV TEST RESULTS PDF

6.3 Required PV

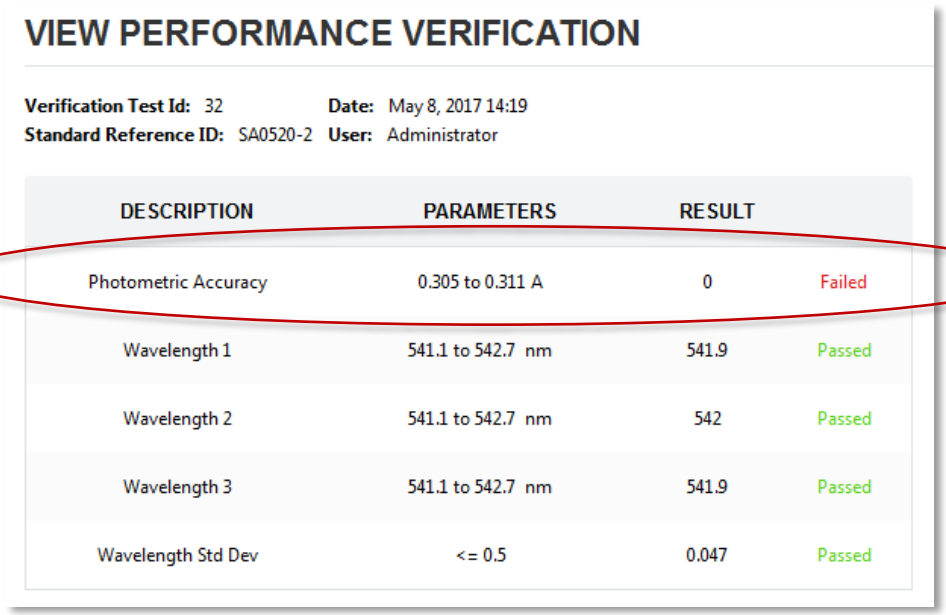
Upon first use of the software with an Evolution 220 Spectrophotometer configured in 'Readers' the user will see the info message below. Also, if the PV timer expires (if configured) the user will be directed to PV from the Measure Screen if trying to create a report. Press 'OK' to proceed. Pressing 'Cancel' will allow administrative use of the software but no measurements will be allowed with the instrument.



6.4 PV Pass/Fail

If the PV test passes, the user can proceed immediately to any area of the software after completion.

If the PV test fails, then the instrument is not allowed to be used to make measurements until two (2) successive PV tests are passed, first by a different user from the one that failed and then again by the user that last failed PV in succession.

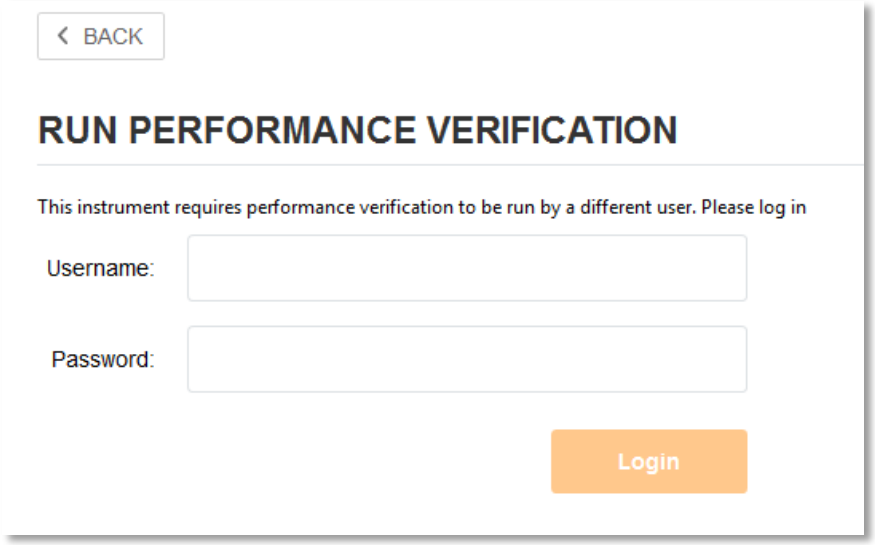


VIEW PERFORMANCE VERIFICATION

Verification Test Id: 32 **Date:** May 8, 2017 14:19
Standard Reference ID: SA0520-2 **User:** Administrator

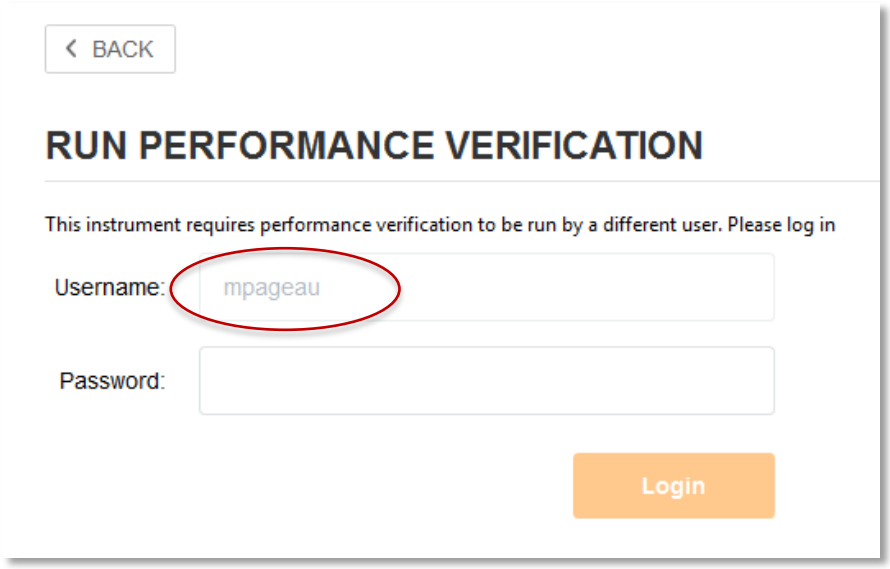
DESCRIPTION	PARAMETERS	RESULT	
Photometric Accuracy	0.305 to 0.311 A	0	Failed
Wavelength 1	541.1 to 542.7 nm	541.9	Passed
Wavelength 2	541.1 to 542.7 nm	542	Passed
Wavelength 3	541.1 to 542.7 nm	541.9	Passed
Wavelength Std Dev	<= 0.5	0.047	Passed

When the user returns to the PV home screen after PV failure or if the user attempts to open a report and measure a dosimeter after PV failure, the software will notify the user with an Info message stating, “This instrument requires performance verification. Do you want to do it now?”. It will proceed to the screen below and require a new user to login.



Any user with the Technician role may login and proceed. The process will repeat until a PV test is passed. If the instrument will not pass PV, it is likely in need of service. Contact GEX Customer Support or Thermo Customer Support for assistance.

After a different user has passed PV, the software will require the last user that failed PV to log back in.



The user specified must login and complete a successful PV for the software to unlock use of the spectrophotometer for dosimeter measurements.

7 Audit Trail

DoseControl features an audit trail table in the SQL database to capture a separate and confined audit trail in addition to the trail in the various database tables that contain the application data. All add/edit/delete actions within DoseControl along with a variety of other actions are logged. The Audit Trail table is used to record the date/time, username, related report ID, and dosimeter reading ID (if applicable) prior to and after a change (as applicable) and the reason (as applicable – currently the only action in DoseControl that requires a reason is skipping dosimeters).

The software itself does not currently have a user interface to query and sort data from this Audit Trail table. It must be queried by an IT specialist directly from the backend. A future update will add the user interface into DoseControl so that users can query the table from within the application.

The table below shows an example of the data in the table:

Id	TimeStamp	UserId	Message	ReportId	ReadingId	PreviousValue	NewValue	Type
1	2017-05-04 17:05:50...	1	User logged i...	NULL	NULL	NULL	NULL	21
2	2017-05-04 17:05:54...	1	Updated admi...	NULL	NULL	NULL	NULL	1
3	2017-05-04 17:06:04...	1	NULL	NULL	NULL	[{"Interface":"GEX.Services.Common.IClientReportServi...	[{"Interface":"GEX.Services.Common.IClientReportServi...	33
4	2017-05-04 17:06:22...	1	NULL	NULL	NULL	NULL	NULL	21
5	2017-05-04 17:07:47...	1	NULL	NULL	NULL	{"Id":1,"CalibrationIdentifier":"testcal","GeneratesDosim...	{"Id":1,"CalibrationIdentifier":"testcal","GeneratesDosim...	4
6	2017-05-04 17:07:47...	1	NULL	NULL	NULL	{"ReaderType":{"Id":3,"Type":"GEX.Reader.Mock.Mo...	{"ReaderType":{"Id":3,"Type":"GEX.Reader.Mock.Mo...	7
7	2017-05-04 17:07:47...	1	NULL	NULL	NULL	NULL	{"Id":0,"SpectrophotometerId":"LabEvo","SerialNumber...	6
8	2017-05-04 17:07:49...	1	NULL	NULL	NULL	NULL	{"Id":1,"IsManualModeEnabled":false}	55
9	2017-05-04 17:08:26...	1	NULL	NULL	NULL	{"Id":1,"CalibrationIdentifier":"testcal","GeneratesDosim...	NULL	5
10	2017-05-04 17:10:42...	1	NULL	NULL	NULL	NULL	{"Id":2,"CalibrationIdentifier":"LabEvo testbatch Testpat...	3
11	2017-05-04 17:12:10...	1	NULL	NULL	NULL	{"HeaderFields":[{"Id":1,"SetId":1,"ExternalIdentifier":"...	{"HeaderFields":[{"Id":2,"SetId":1,"ExternalIdentifier":"...	19
12	2017-05-04 17:12:34...	1	NULL	NULL	NULL	{"HeaderFields":[{"Id":2,"SetId":1,"ExternalIdentifier":"...	{"HeaderFields":[{"Id":2,"SetId":1,"ExternalIdentifier":"...	19
13	2017-05-04 17:15:38...	1	NULL	NULL	NULL	[{"Interface":"GEX.Services.Common.IClientReportServi...	[{"Interface":"GEX.Services.Common.IClientReportServi...	33
14	2017-05-04 17:15:58...	1	NULL	NULL	NULL	NULL	NULL	21
15	2017-05-04 17:17:07...	1	NULL	NULL	NULL	NULL	{"Id":1,"SpecificationIdentifier":"MikesSpec001","Versi...	56
16	2017-05-04 17:17:10...	1	NULL	1	NULL	NULL	{"Id":1,"ReportIdentifier":"test-bd-import","ReportVersio...	24
17	2017-05-04 17:17:27...	1	NULL	1	NULL	{"ReportHeaderFieldValues":[{"ReportHeaderField":{"Id...	{"ReportHeaderFieldValues":[{"ReportHeaderField":{"Id...	25
18	2017-05-04 17:17:28...	1	NULL	1	1	{"Absorbances":[],"Id":1,"ReportId":1,"CalibrationId":nu...	{"Absorbances":[{"Id":1,"ReportId":1,"ReadingId":4,"A...	28
19	2017-05-04 17:17:28...	1	NULL	1	NULL	{"Id":1,"ReportIdentifier":"test-bd-import","ReportVersio...	{"Id":1,"ReportIdentifier":"test-bd-import","ReportVersio...	25

SQL TABLE – dbo.AuditEntries

One of the keys to understanding the data in the AuditEntries table is the last column “type”. Type is used as a classification system which is defined in a separate table called “dbo.Enum_AuditEntryType”.

Id	Name
0	Add User
1	Update User
2	Delete User
3	Add Calibration
4	Update Calibration
5	Delete Calibration
6	Add Reader
7	Update Reader
8	Delete Reader
9	Add Batch
10	Update Batch
11	Delete Batch
12	Add Dosimeter Type
13	Update Dosimeter Type
14	Delete Dosimeter Type
15	Add Pathway
16	Update Pathway
17	Delete Pathway
18	Add Report Header Set
19	Update Report Header Set
20	Delete Report Header Set
21	Login
22	Logout
23	Login Failed
24	Add Report
25	Update Report
26	Delete Report
27	Add Reading
28	Update Reading
29	Delete Reading
30	Abandon Report

Id	Name
31	Version Report
32	Process Report
33	Update Configurations
34	Add Reread Strategy
35	Update Reread Strategy
36	Delete Reread Strategy
37	Update Role Mapping
38	Generate Output
39	Add Reread
40	Reread Session Completed
41	Reread Session Failed
42	Absorbance Archived
43	Add Performance Verification Reference
44	Update Performance Verification Reference
45	Delete Performance Verification Reference
46	Zero Reader
47	Add Performance Verification
48	Update Performance Verification
49	Delete Performance Verification
50	Add Comment
51	New Default Pv Reference
52	Pv Started
53	Pv Completed
54	Pv Incomple Marked As Failed
55	Miscellaneous Changed
56	Add Product Specification
57	Update Product Specification
58	Delete Product Specification

SQL TABLE – dbo.Enum_AuditEntryType

Each entry type has a number that is noted in the dbo.AuditEntries for each audit entry. Please note, audit entry type 30 is not in use. For information on specific entry types that are not clear, please contact GEX customer service. GEX also maintains some SQL scripts for running queries on the audit trail table that are provided to users upon request.

8 Errors and Troubleshooting

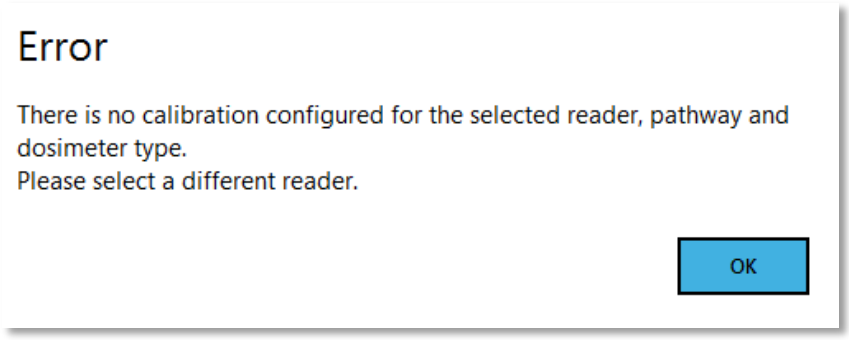
Errors can happen from time to time. Often an error message appears and contains some informative text that may help GEX personnel to determine the source of the problem. Always capture a screenshot image of any error message for GEX to review.

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.

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

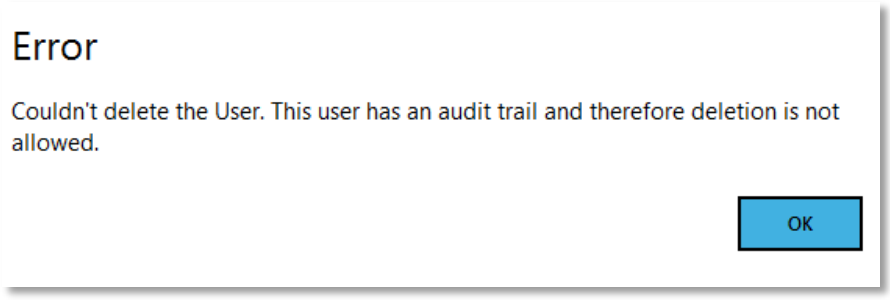
8.1 Common Errors

Calibration Not Configured



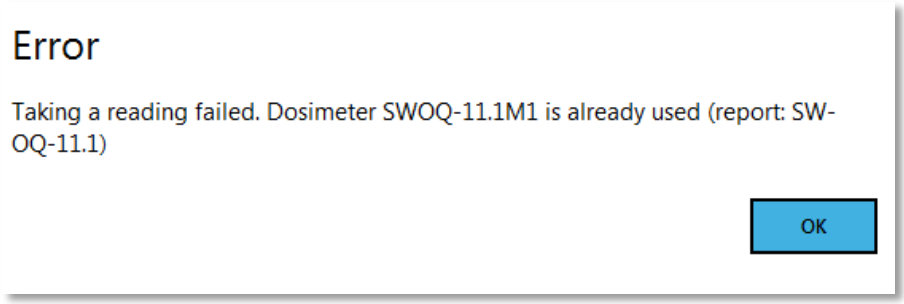
The error message above is the most common error when using DoseControl, and occurs when the user tries to create new reports or open existing reports. If there is not a calibration configured for the Pathway, Batch, and Reader that is being attempted, this message will appear. If you have continual trouble, then review the calibrations, pathways, batches, and readers for configuration errors. Commonly, the issue is the End Date of the Batch Calibration or the Calibration End Date for the Reader is to blame. GEX will try to improve this messaging in a future release to be more informative of the precise problem.

Delete User Error



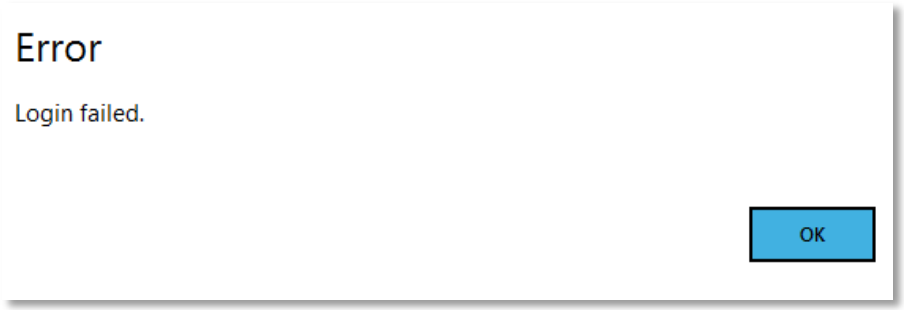
If the System Administrator tries to delete a User from the MSSQL User Management module (and that user already has performed an action in the system), then that user cannot be deleted.

Duplicate Dosimeter



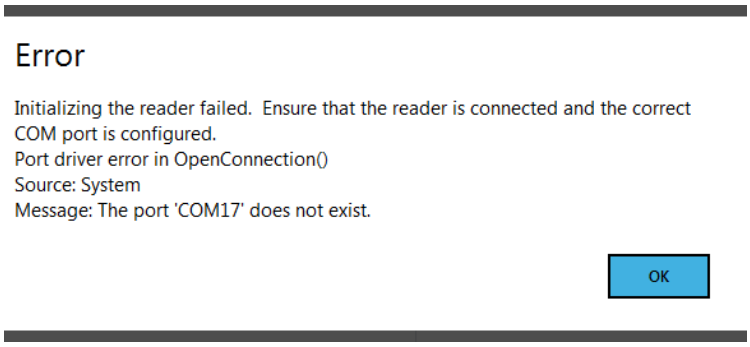
The system pops an error if the user tries to enter a duplicate dosimeter ID into the system and informs the user of the Report ID in which that number exists.

Login Failure



The login failure occurs typically when the user enters the incorrect username or password.

Port Driver Error



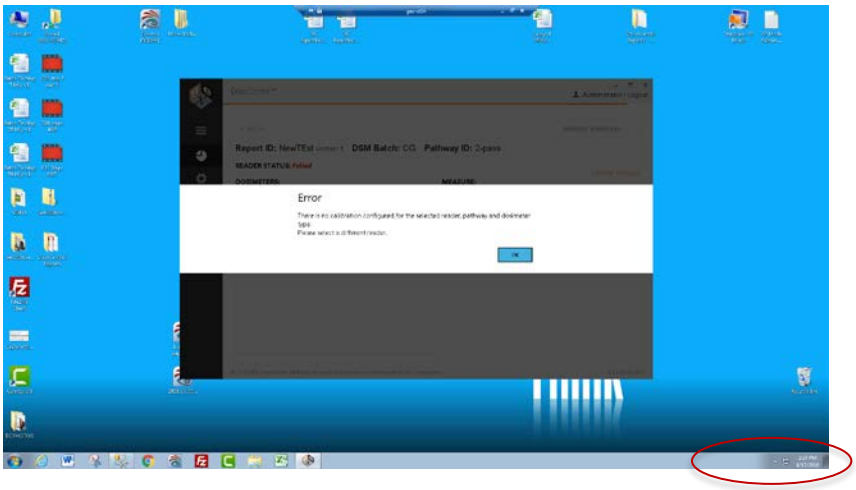
The error message above occurs when the software cannot find an instrument that is supposed to be connected to the PC. If 'OK' is selected, the software can be used but cannot make measurements. If the instrument is connected but is not being recognized, then check the COM Port Number and Baud Rate in Reader configuration.

8.2 Reporting Problems to GEX

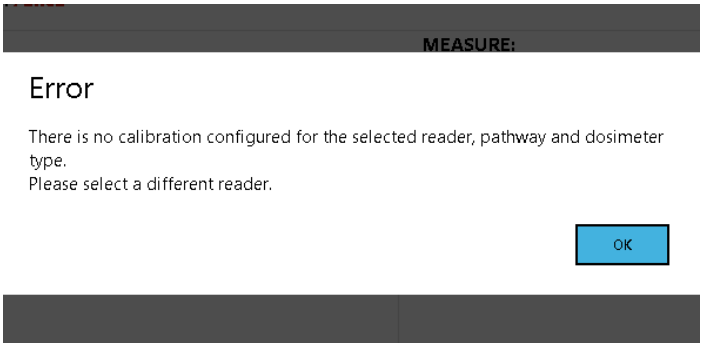
When a problem is discovered in the software, as much information as possible must be gathered and reported to GEX. It might be a bug, it might be user error, it might be that the system design never planned for what you are doing. No matter the circumstance, the issue should be reported to GEX. The protocol for documenting the problem and contacting GEX is described below:

1) Document the following:
   a. A general description of the error.
      Example: *Problem = No calibration configured for report*
   b. What is the user trying to do when the error occurs?
      Example: *I was opening an existing dosimetry report*
   c. What version number of the application are they running (located in the lower-right hand corner)?
      Example: *Version 1.1.2018.4.6325*
   d. Is it something performed all of the time or is the function seldomly used?
      Example: *This is performed a few times each day*

2) Next, take a full screen shot that includes the date/time in the system tray of the PC.
3)

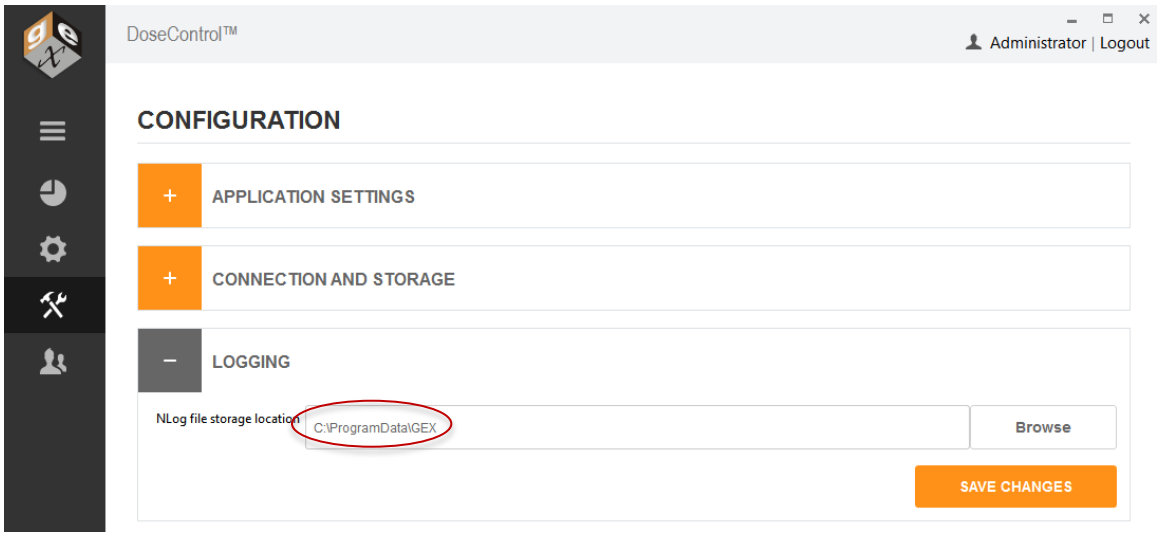


Then, if needed, take a closer shot of the actual message on the screen (with large monitor sizes the actual text may be hard to read on a full screenshot so this helps ensure the error message is clear).

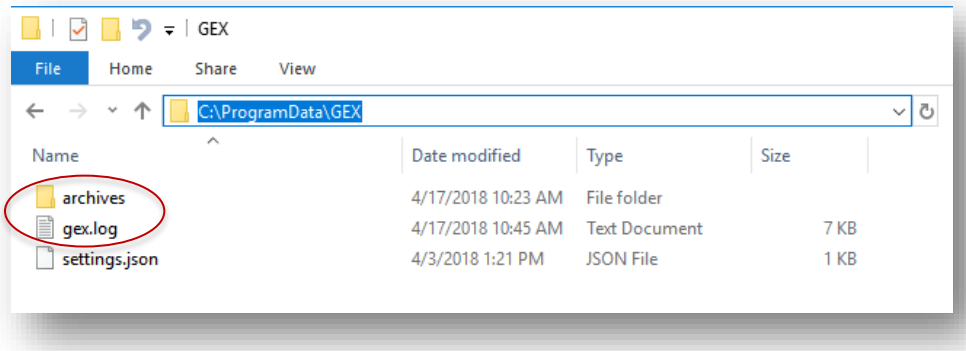


4) Document the timeline related to the initial discovery of this error and any details that may be useful.
Example: *I opened the application for the first time today and this was the first task I attempted.*

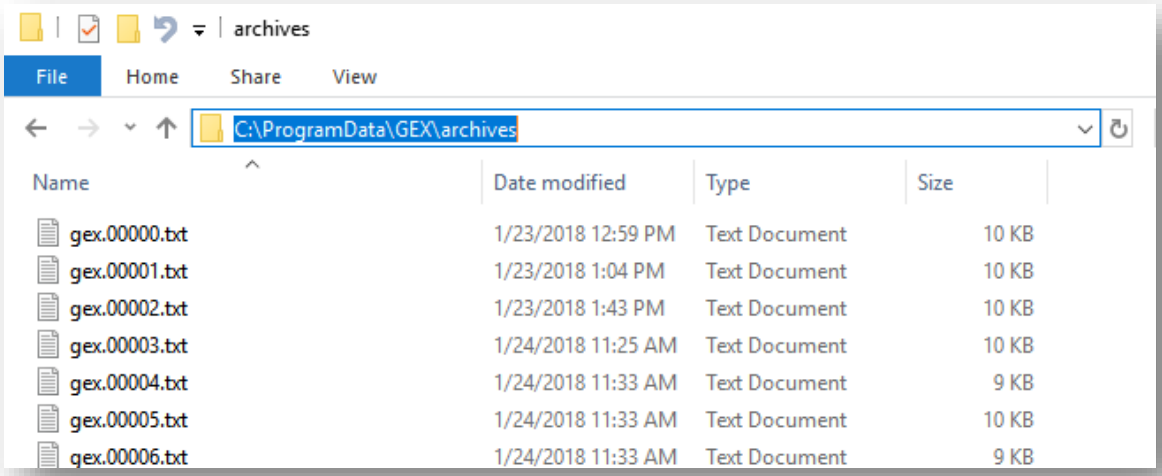
5) Find the Nlog file in the Program Data folder C:\ProgramData\GEX or whatever filepath you have assigned in the Logging Configuration. See example below



You can paste this address directly into a Windows Explorer address bar and it should open the folder. Copy the log file and include in the submission to GEX.

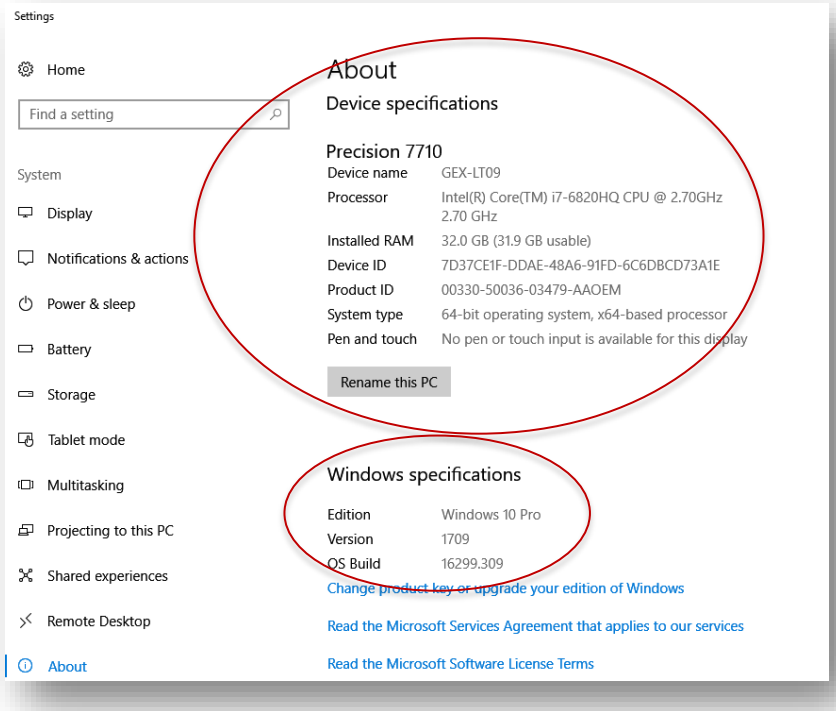


The 'gex.log' file is the log for the current user logged in for the current session in DoseControl. If you want to retrieve a log from a previous session or user, open the "archives" folder and find the appropriate log file for the session in which the error happened. The system maintains an archive of all log files using a sequential numbering system



The log files can be sorted by Date Modified as well. When you have an error, capture the date and time that the error occurred by taking a screenshot. Then find the log file whose date modified corresponds to a date/time that is the closest date/time after the incident.

6) Document your PC specifications. Operating System version? Processor? Memory/RAM? The easiest way to do this is to view the computer name and take a screenshot (steps to open this information vary by the version of MS Windows).



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

8) Contact GEX Customer Service to report the error and provide this information. Send an e-mail to cs@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.

8.3 Suggesting Improvements

We are constantly seeking user feedback. If you would like to see general or specific improvements to the software user interface, functionality, or performance, please contact GEX. Improvement suggestions should be reported by e-mail to the same contact details listed in Section 6.2 with a message 'IMPROVE' added to text 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 day after day. GEX will review and contact you to if there are any questions about your suggestion.

Changes can take time to deploy if they are approved. If you are adamant about a specific change or timeline for a change, contact GEX Customer Service at cs@gexcorp.com to discuss options.

9 Installing and Configuring Microsoft SQL

Introduction to Microsoft SQL
DoseControl uses Microsoft SQL for storing almost all application data and it is necessary to use SQL or SQL Express version 2008 R2 or higher. Microsoft offers many different versions of SQL but there is one major division into what is called SQL Express and regular SQL.

SQL Express is a type of SQL that is available for free from Microsoft with any licensed Windows installation. That means you can install it on any PC or laptop at no cost. The method for installing SQL Express involves downloading the installation package from Microsoft and executing that your PC. If you have purchased the Basic License for DoseControl then you will use SQL Express installed on a single PC. An SQL Express database cannot be shared between PC's; it will only be useful for the PC on which it is installed.

SQL is a database that resides on a centralized server and is accessed by multiple PC's. SQL is licensed to companies in many different ways and you will be responsible for determining and managing your licensing if you choose to use SQL with DoseControl. GEX does not sell or license SQL nor are we versed in the myriad of licensing options offered by Microsoft.

9.1 Microsoft .NET Framework

Microsoft .NET Framework 4.6.2 or higher is required for DoseControl to operate on any PC.

1. Download Microsoft .NET 4.6 framework here.
2. Run the installer to completion on each PC or laptop that will use DoseControl.
3. No other actions are required and no configuration necessary for .NET framework to function as needed.

9.2 SQL Express

If you purchased a Basic License for DoseControl, follow these steps to download and install SQL Express before you attempt to use DoseControl.

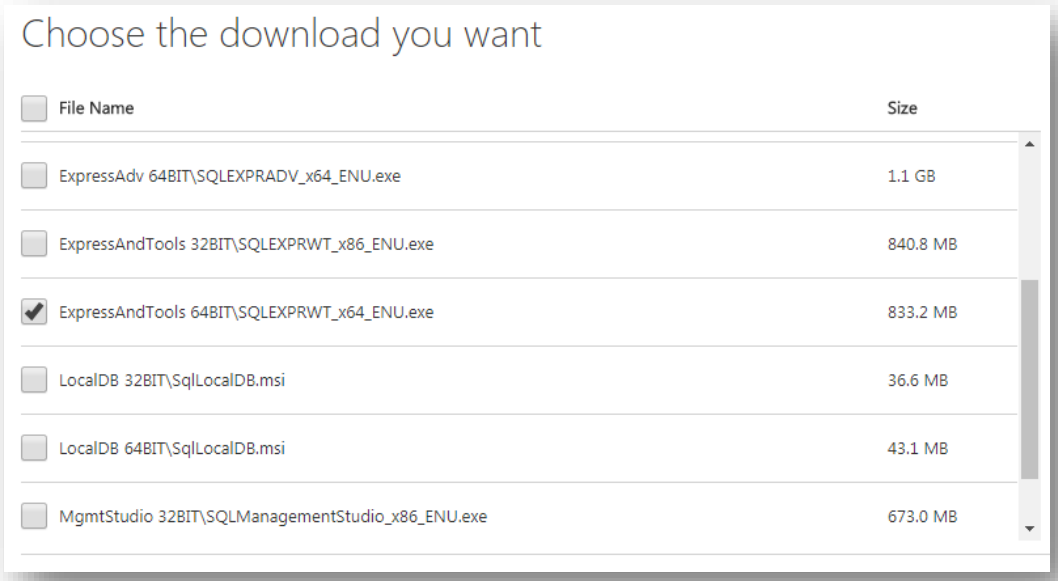
***Note**: This guide was written while installing SQL Server Express 2014 on a computer running Windows 7 Pro x64. Some details and screens may vary depending on the version of Windows and SQL being used.*

***Note**: DoseControl will work with any SQL or SQL Express version 2008 R2 or higher. We recommend the 2014 version or higher. The SQL Server Express 2016 version is not supported on Windows 7.*

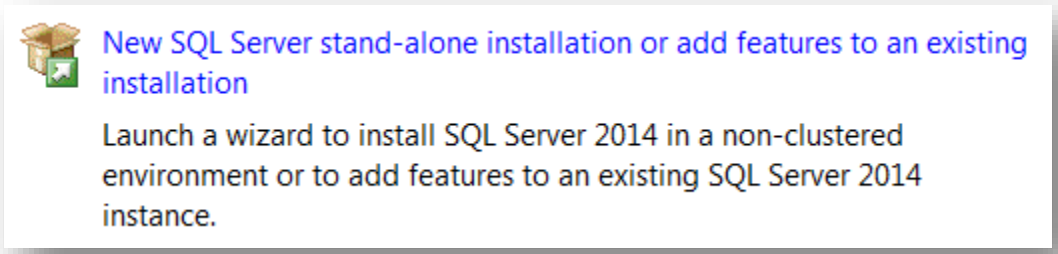
1. First, you need to download SQL Express from Microsoft
   - Download SQL Server 2014 Express here.

2. If using Windows 64 bit, then select the **ExpressAndTools 64BIT\SQLEXPRWT_x64_ENU.exe**. If you are using the 32-bit version of windows, select **ExpressAndTools 32BIT\SQLEXPRWT_x86_ENU.exe**.

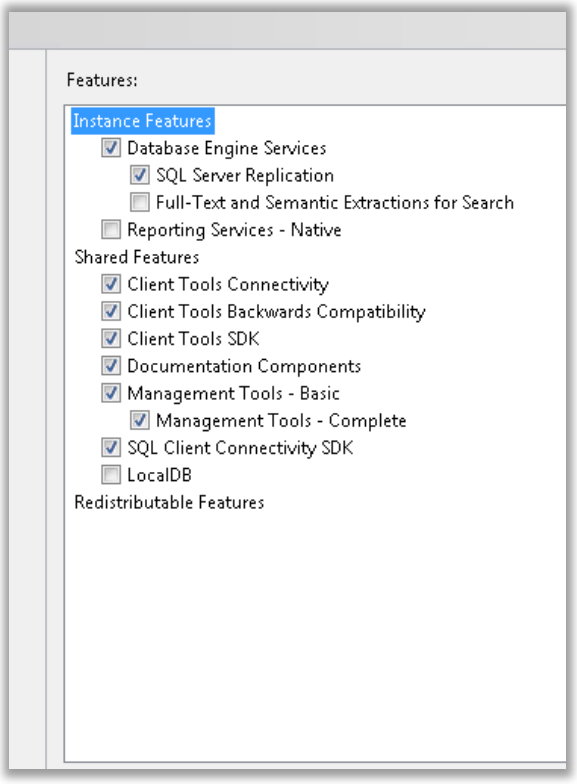
3. Click the Next button. The file will begin to download to your computer. Let the download fully complete.



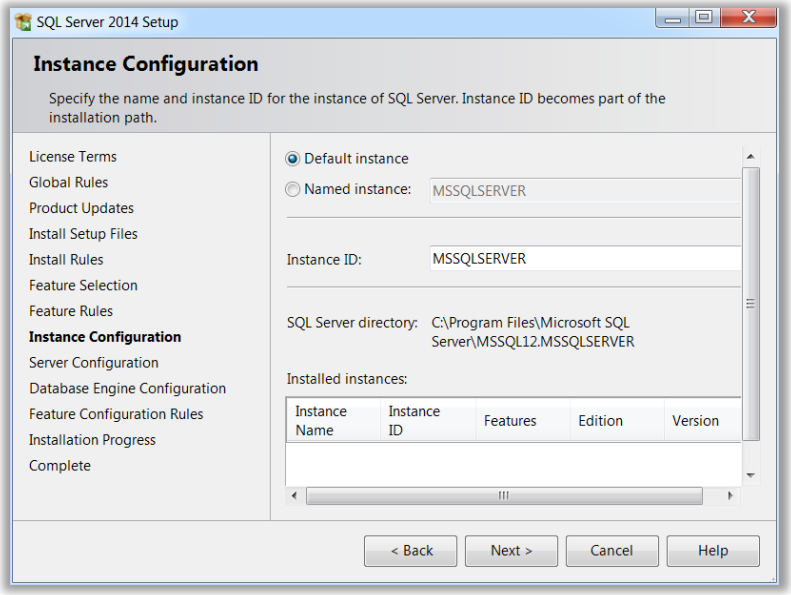
4. Find and double-click the downloaded installer.
5. Click **Run** if prompted, then click **OK** in the **Choose Directory for Extracted Files** dialog box.
6. Once the installer starts, click **New SQL Server stand-alone installation . . .**



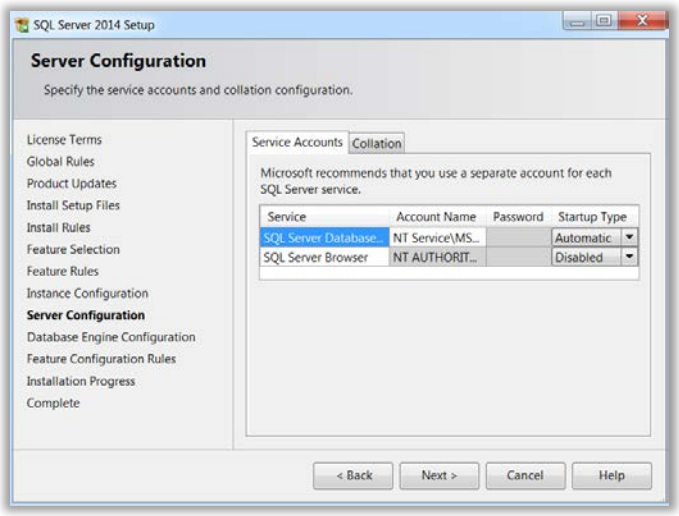
7. Accept the license terms and click **Next**.
8. Select the following features and click **Next**:



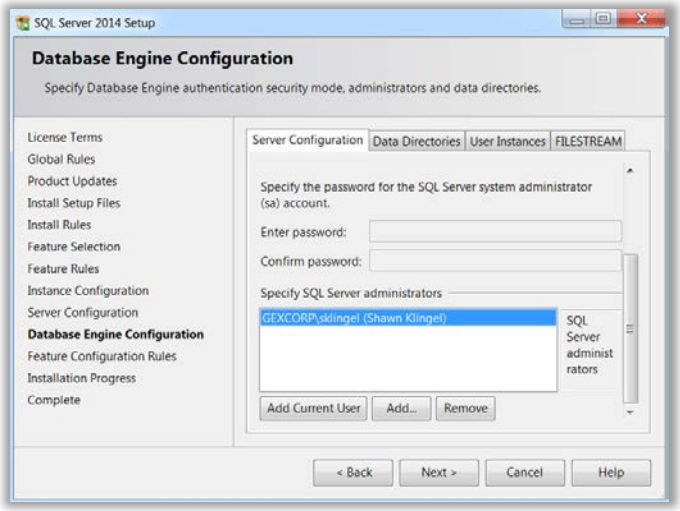
9. Accept the defaults on the **Instance Configuration** screen and click **Next**.



10. Accept the defaults on the **Server Configuration** screen and click **Next**.



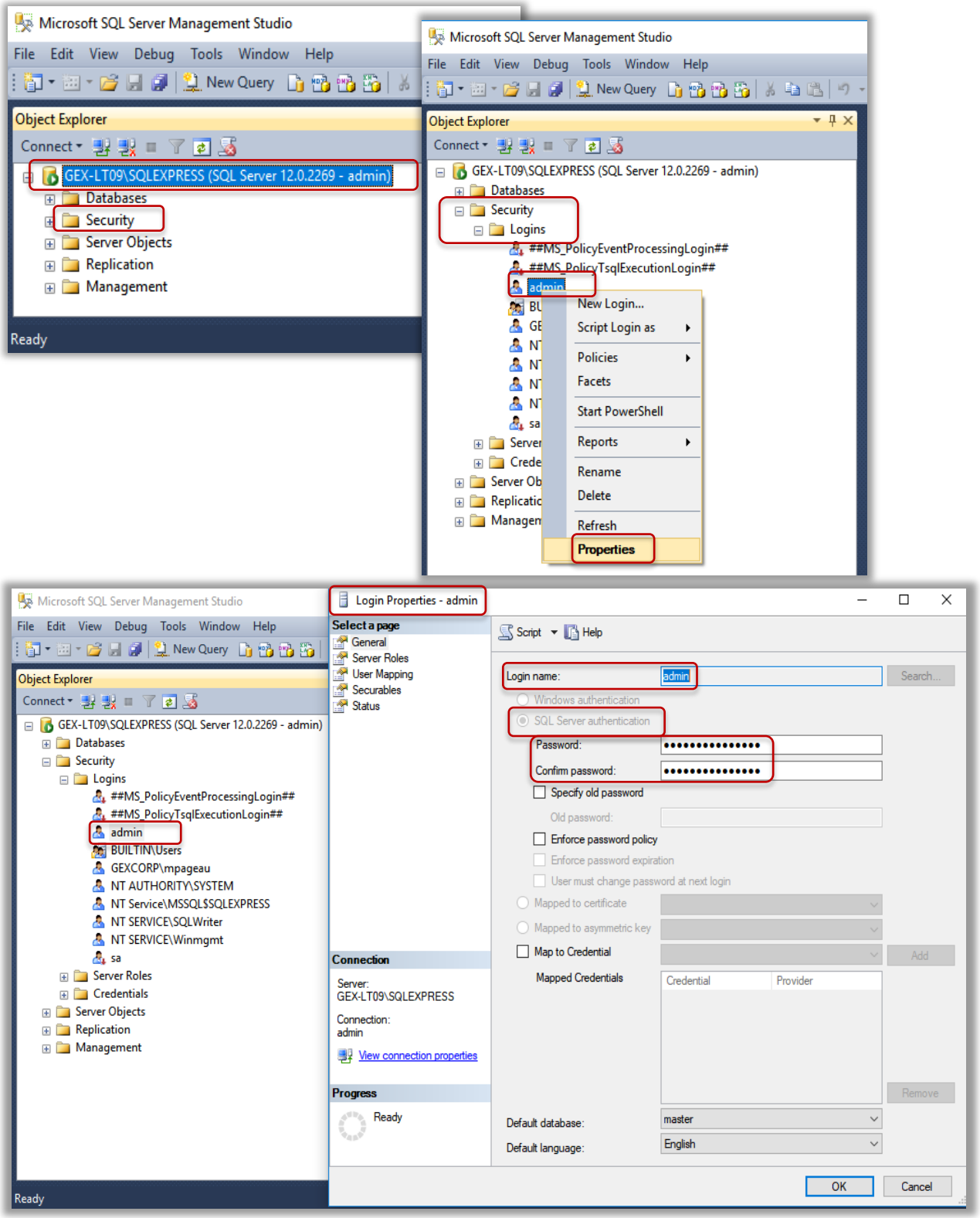
11. On the **Database Engine Configuration** screen, accept the defaults. Confirm that the current user is added under **Specify SQL Server administrators**. If it is not, click the **Add Current User** button. Click **Next**.



12. On the **Installation Complete** screen, click **Close**.
13. Perform a Windows Update to install the latest patches and updates for SQL Server Express 2014.
14. In the start menu, find the shortcut for **SQL Server 2014 Management Studio** and pin it to the task bar.

9.3 Configuring SQL Authentication

The SQL Server Admin must create a login of the SQL Authentication type for use in the connection string within DoseControl. This can be setup using SSMS. Login to SMSS and expand the 'Security Folder' for the SQL server on which your DoseControl database will reside. Create a login (User ID) or modify the properties of an existing login and ensure that SQL Server Authentication is being used. Set the passwords desired. To enforce any password policy, use the additional features available in SQL.


Microsoft SQL Server Management Studio
File Edit View Debug Tools Window Help
New Query
Object Explorer
Connect
GEX-LT09\SQLEXPRESS (SQL Server 12.0.2269 - admin)
Databases
Security
Server Objects
Replication
Management
Ready
Logins
##MS_PolicyEventProcessingLogin##
##MS_PolicyTsqlExecutionLogin##
admin
New Login...
Script Login as
Policies
Facets
Start PowerShell
Reports
Rename
Delete
Refresh
Properties
Login Properties - admin
Select a page
General
Server Roles
User Mapping
Securables
Status
Script
Help
Login name:
Search...
Windows authentication
SQL Server authentication
Password:
Confirm password:
Specify old password
Old password:
Enforce password policy
Enforce password expiration
User must change password at next login
Mapped to certificate
Mapped to asymmetric key
Map to Credential
Add
Mapped Credentials
Credential
Provider
Remove
Default database:
master
Default language:
English
Connection
Server:
GEX-LT09\SQLEXPRESS
Connection:
admin
View connection properties
Progress
Ready
OK
Cancel

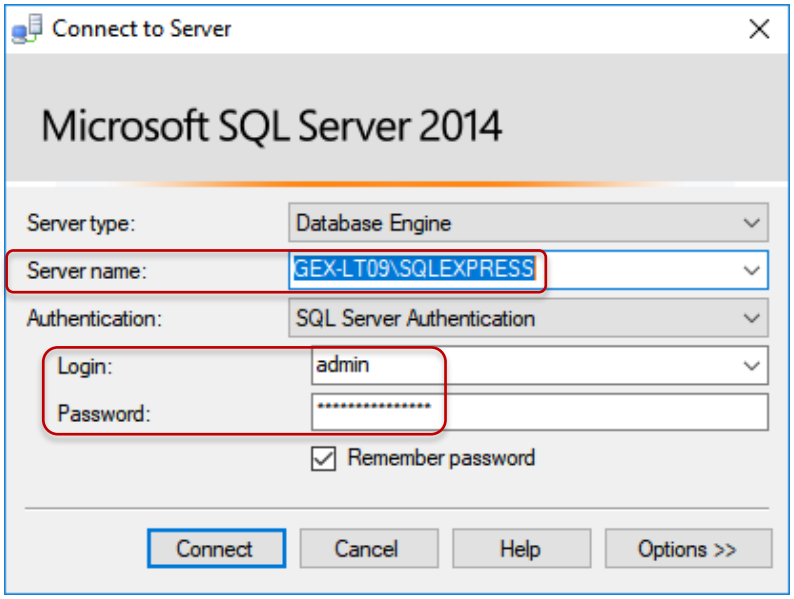
9.4 Design a Connection String

Below is an example of a connection string in which you may insert your information and try to use:

Data Source=GEX-DT04\SQLEXPRESS;Initial Catalog=GEXApp;User Id=gexcorp; Password=password; MultipleActiveResultSets=true;

- *Data Source:* The explicit SQL Server Name.
- *Initial Catalog:* The explicit name of the instance on the SQL database. This is assigned by the user when you contstruct the string. So you can choose a name at this time. If you wish to setup a test database before setting up then use the name 'DCQA', otherwise use 'DCLive'. Other suggestions include 'GEXApp' and 'DoseControl'.
- *User ID:* A SQL authentication type username
- *Password:* The SQL Password for the User ID specified

All of the items above can be determined within Microsoft's SQL Server Management Studio (SSMS) except the 'Intial Catalog' (name of the database instance) which you assign as explained above. The login page to the application may have some clues (see below). For more complex, corporate installations of SQL Servers, you will need a database engineer to help you configure SQL (see previous sections) and construct the Connection String.

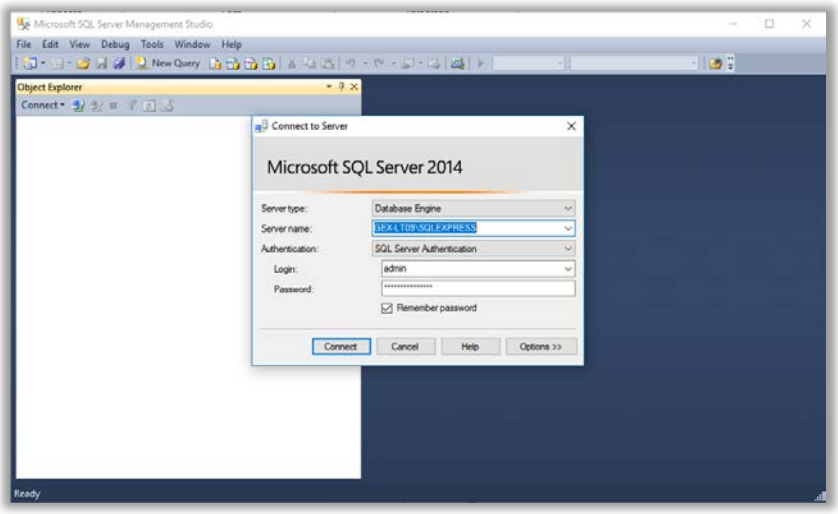


9.5 Creating a Backup of your SQL Database

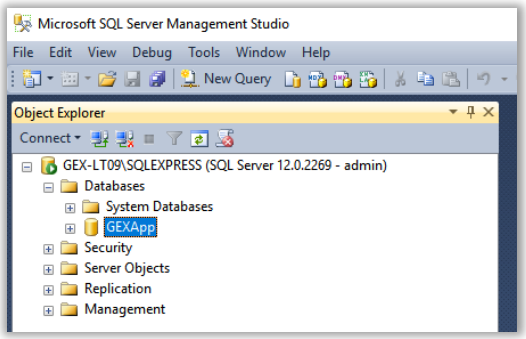
It is important to backup the database from time to time. Scheduled backups are recommended. For large-scale users, this means setting up automated backups on servers, which will not be discussed here. Herein is a manual method for backing up a SQL Express database using Microsoft's SQL Server Management Studio (SSMS).

Step by Step Instructions for Creating a SQL database Backup:

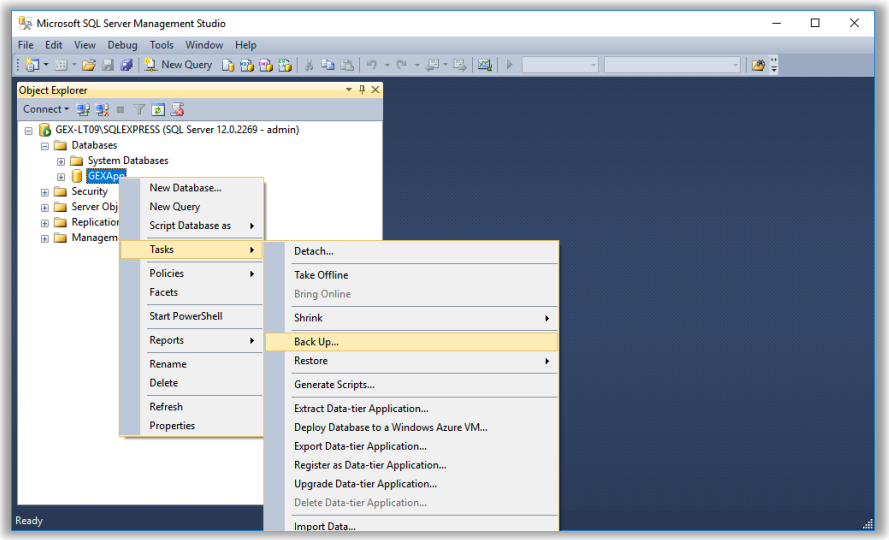
1) First, login to SSMS using the same login and password that is used in the connection string within DoseControl (or if you have another user/password that has the appropriate permissions).



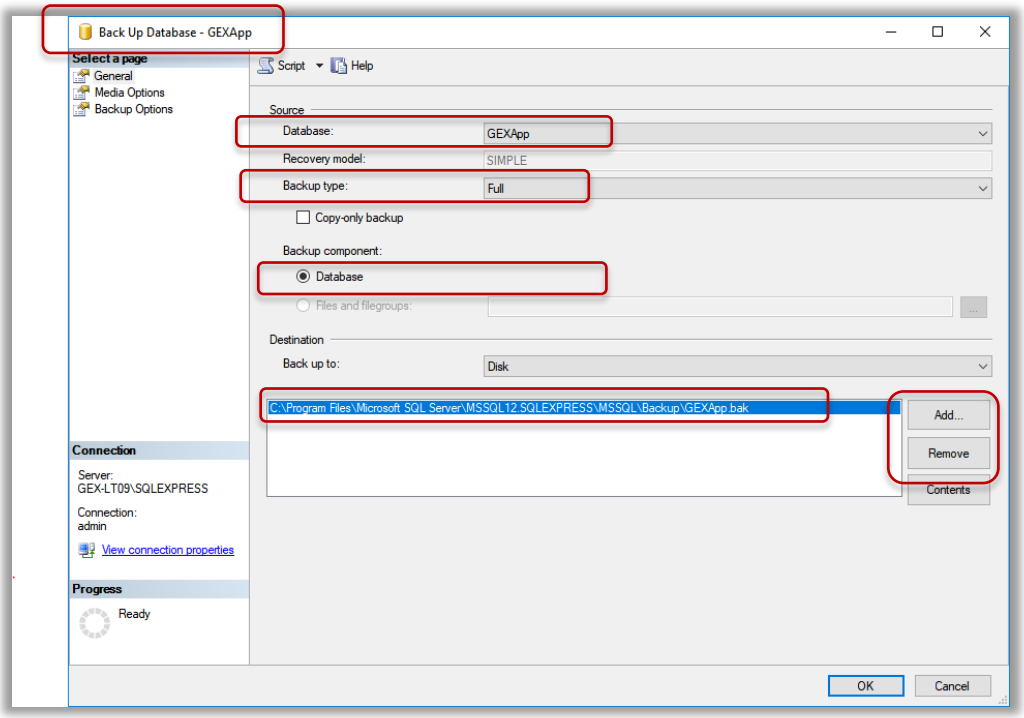
2) Expand the “Databases” folder to locate the database instance that you wish to backup. In this example it is called “GEXApp”.



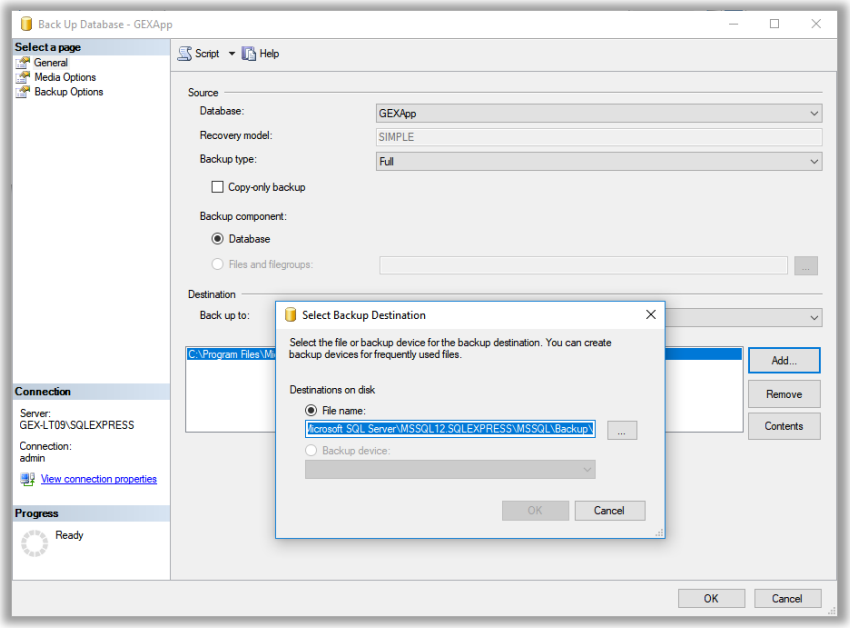
1) Right-click on the instance name and select “Tasks -> Back Up”.



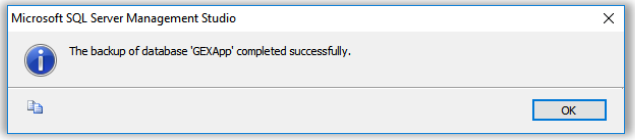
2) The Back Up Database menu will open. The settings should default as shown, but check your setting against this example.



3) The file pathway for the backup is listed. The default is into the Program Files folder on the C: drive and it is suggested you do not change it because the Restore function you use if you need to restore from backup will default to this location too. If you must, use the 'Add' and 'Remove' buttons to change the pathway to any location on the C: drive except the desktop. Do not backup to the desktop. Press the 'Add' button and a dialog box will allow you to navigate to a location of your choosing. Press 'OK' on the bottom of the screen to start the backup.



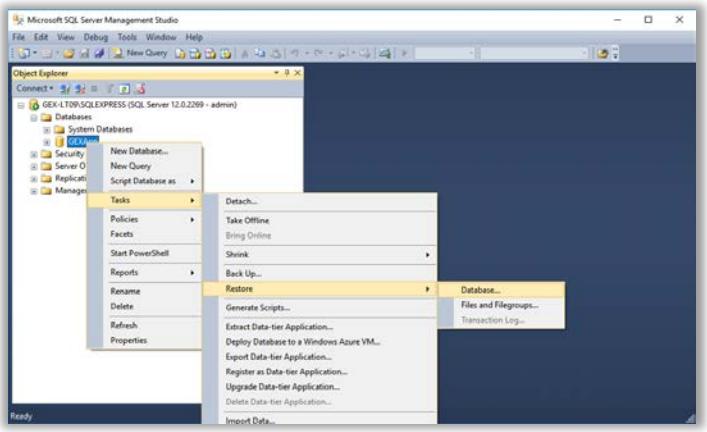
4) SSMS provides a confirmation pop up window about successful completion of the backup, otherwise it will note errors or issues. The backup is complete. The resulting file is located in the specified location and has a *.bak file extension.



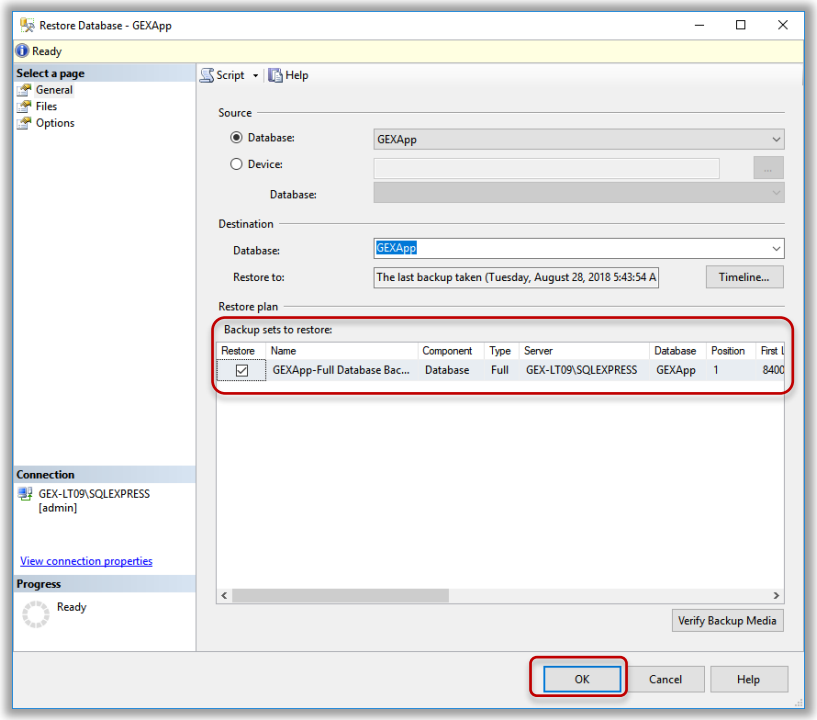
Step by Step Instructions for Restoring a SQL database from a Backup:

1) To restore a database from a *.bak file, login and navigate to the database instance in SSMS.

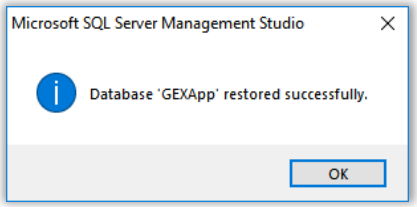
2) Right-click on the instance name and select “Tasks -> Restore -> Database…”.



3) The Restore Database menu opens.



4) There will be a list and you can select an older backup if desired. Then press the 'OK' button at the bottom of the screen.



5) The restore process is now complete. SSMS will report success or errors upon restore.

10 Version Upgrades

When it comes time to update the version of the software, there are some important topics to understand. This section discusses various issues related to upgrading the software from an older version to a newer version.

10.1 Understanding Database Software Upgrading

The key point in understanding the process of upgrading software that runs from a database is that upgrading the software means upgrading the database. There may or may not be changes to the database, but any workstations that connect to the database must all be upgraded. The usual process of upgrading involves shutting down all workstations using the software and then installing the new version on a single administrative PC. When it connects for the first time, a process called 'database migration' occurs where the database is updated with any changes to its structure (called 'schema'). At that point, if there were schema changes, they cannot be undone.

Therefore, the primary task when upgrading versions with DoseControl is to first backup the database prior to upgrading. Then, if there is a problem with the upgrade, you have the database in the correct format that you can downgrade to the previous version. Failure to backup your database prior to upgrade may cost you valuable time and create very difficult operational choices that are limited by the failure to backup your data.

10.2 Testing Environment

Many users don't want to simply update the software in a live production environment. As discussed above, there are a variety of risks in doing so that most people want to avoid. The simplest way to ensure a successful upgrade is to create a test environment that mimics the live environment and to verify the upgrade of that test installation using the upgrade installation package. If the installation is a success, then you can verify any aspect of the application data that you are upgrading and validate or qualify the installation. Then you can point the software at the live database when you are ready, and finish the qualification work with the actual data.

The test environment is as simple as having another instance of SQL in the database that is a mirror of the live environment. The simple difference will be the connection string that is used. Each instance of a database has a unique connection string. So you can fully test a new version using a test database that you point to simply by changing the connection string.

For assistance in planning and executing version upgrades, please don't hesitate to contact GEX Customer Server at cs@gexcorp.com.

11 Licensing

11.1 Maintaining License Validity

DoseControl is licensed per user site / factory site and requires that the user have paid for a license term in 1 year increments in advance. GEX should contact you when your license term has 90 days remaining but you may always contact sales@gexcorp.com with licensing questions.

11.2 Upgrading Licensing

Should you desire to upgrade your license to grow your dosimetry system or organizational structure or simply the manner in which you access and store your dosimetry data, please contact sales@gexcorp.com. Unlock the power of dosimetry anywhere with a Premier license. Here is a brief overview of the three licensing levels available for DoseControl.

BASIC

- Utilizes a SQL Express database on a stand-alone PC

PREMIER

- Multiple PC workstations (measurement/administrative/QA/management
- Provides any user with or without instrument insight into the dosimetry
- Requires user provided SQL Server maintained by user

ENTERPRISE

- Same features as for Premier but also including standardized integration features for importing/exporting data electronically

In addition, there is currently an optional module that can be purchased with any level of licensing:

- *Product Specification Module* – stores irradiation specification information for a list of customer products by Catalog (part) Number. That can then be called into reports upon entry of the product Catalog Number in a Report Header of a dosimetry report.

Appendix 1- 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 BEFORE UPGRADING

Older versions of the software must be uninstalled prior to installing a new version. Contact GEX for advice before uninstalling the software when upgrading to a new version. Data migration is built into the latest software releases.

☐ ***1. Uninstall DoseControl Program***

- On the PC go to Control panel, programs, and uninstall any GEX versions.

☐ **2. 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 sections the DoseControl User Guide.

☐ ***1.) Installation of the Program***

- Move the DoseControl Installation folder to the desktop of the PC for installation. 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. 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. If a previous version was installed, simply login and continue use with the new version.

b. Otherwise, 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'. Select 'Save Changes'.

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***

- Go to the 'Settings' menu. Configure the User Manager setting following the instructions in the DoseControl User Guide.

☐ ***6) Dosimetry Setup***

- Go to the 'Setup' menu to configure readers, batches, pathways, report headers, calibrations and rereads in accordance with the User Guide.

Installation and setup is complete!

REVISION HISTORY

Date	Change Description	Revision
12/30/16	Initial Release.	A
01/26/17	Revised to include Appendix 1 and 2 for additional instruction per ECO# 70270.	B
03/28/17	Revised to reflect new registered trademark status for DoseControl.	C
05/09/17	General revision to entire document for full update: - Minor language changes throughout - Section 1.6 User Management reorganization and polishing. - Section 2.4 added information on B3 Film dosimeter configuration. - Section 2.6 revised images and added information to many of the list items. - Section 2.7 revised descriptions of special value fields and sequence - Section 2.8 organization and correction of CV configuration - Added new Section 2.9 on Misc configuration - Section 3 overall improvement with major content added in 3.4 - Added new Section 4 on P.V. - Added new Section 5 on Audit Trail - Added new section 6.1 to list a couple of common errors	D
05/31/17	- Section 1.6 – added Explicit User Manager information - Section 2.8 – new section for configuration of report headers with integrated data - Section 2.10 – redone section to add new available features for User Lock Out and 0 Reader. - Added new Section 4 new on Product Specification module - Added new section 5 on Import/Export of Electronic Data - Appendix 2 – edited instructions for uninstall/install in the checklist	E
10/10/17	- Section 1.3 – Added icons and their funtions (trash can and hide inactive elements) - Section 1.4.1 – elaborated on reports list description, updated home screen overview image - Section 1.4.2 – updated image to reflect P.V. and product specs - Section 1.6 – Users section updated. Elaborated on user roles and how to make selections, updated configuration image, updated roles image to reflect reread and thickness edit options - Section 2.2 – Elaborated on configuration of pathways, updated image - Section 2.3 – Updated image to show the column for 'micrometer required' option - Section 2.5 – updated reader setup image, added reference to G30, referenced 'active' config option, config. field options updated - Section 2.6 – updated image, auto-generate dosimeter Id's clarified, added instructions for copying a calibration - Section 2.7 – edited description and images, clarified and added field options - Section 2.10 – user lock out clarification - Section 3.3.1 – Zero reader elaborated, - Added 3.7, using manual mode for ABS measurements - Added 3.8, Reports list in addition to searching for reports - Added 3.9, Editing dosimeter thickness - Added 3.10, Editing and deleting dosimeter ID's - Section 4.0 – catalogue number clarified, using product spec data paragraph added, - Expanded Section 8	F
05/23/2018	- Expansion of detail in section 1 with more explicit instructions - Expansion of Section 8 - New Section 9 on SQL and removal of Appendix 1 that was SQL - Appendix 2 is now Appendix 1 ECO 70377	G
06/04/18	- Pages 2-4 revised content/language - Sections 1.1 and 1.2 revised to improve the information to the user - Section 2.6 – added information about calibration import feature and revised - Section 2.7 – revised first few paragraphs to describe newer options for PDFs and to - Section 2.10 – added export to excel template upload - Section 3.5 and 3.6 new using existing material and new material from end of section 3.4 - Section 9.5 – new section - Section 10 – new section - Section 11 – new section ECO 70394	H