# DoseControl Software User Guide 100-266

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Product user guide for DoseControl software version 2.0

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# 1 DoseControl® Dosimetry System Overview

## 1.1 About the DoseControl Dosimetry System

The DoseControl® is an off-the-shelf dosimetry system used for generating dosimetry reports for any commercial/industrial radiation processing application, with a dose range of approximately 100 Gy to 300 kGy (depending on dosimeter type).

The DoseControl® dosimetry system integrates a powerful FDA 21CFR Part 11/EU Annex 11 conforming dosimetry software with a Thermo Scientific spectrophotometer, controlling the measurement process and making it simple to create and maintain dosimetry records. This system is a versatile solution for industrial routine dosimetry applications, and complies with all industry standards for the radiation sterilization industry.

## 1.1.1 DoseControl is designed for many types of dosimeters

DoseControl has specialized dosimeter holders for B3 radiochromic, FWT radiochromic, GAFCHROMIC HD-V2 film, CTA film, and Harwell PMMA (Red and Amber Perspex) dosimeters.

- B3 dosimeter IDs can be scanned using an internal barcode scanner, designed to integrate with DoseControl
- Harwell PMMA dosimeter thickness can be measured using an internal laser micrometer, designed to integrate with DoseControl.

#### 1.1.2 DoseControl integrates with hardware components to control the dosimeter measurement process

#### **Spectrophotometers**

DoseControl software connects to and controls one of the following spectrophotometers:

- Thermo Scientific Genesys 20 spectrophotometer\*
- Thermo Scientific GENESYS 30 spectrophotometer
- Thermo Scientific Evolution spectrophotometer

The Thermo Evolution Spectrophotometer (Evo) and the Thermo GENESYS 30 (G30) are the instruments that provides complete compliance (see page 6) with all of the stated requirements in FDA 21CFR part 11/EU Annex 11. A barcode scanner can be mounted inside the sample compartment to capture the B3 dosimeter ID serial number for each measurement (see *Barcode Scanners* below).

The Genesys 20 (G20) spectrophotometer does <u>not</u> provide the internal barcode scanning feature for B3 dosimeters. The Genesys 20 also lacks the ability to return its serial number by command, and <u>is not compliant with FDA 21CFR part 11 traceability requirements</u>.



**IMPORTANT** - GEX DoseControl software can integrate with the Genesys 20. **Thermo Genesys 20 instrument retirement date is June 30, 2023.** Thermo is not supporting the Genesys 20 spectrophotometer after the retirement date.

#### **GEX dosimeter holders**

GEX dosimeter holders allow the user to insert a dosimeter into a spectrophotometer in a reproducible manner so that the optical dosimeter is perpendicular to the light source of the spectrophotometer to ensure accurate measurement.

GEX manufactures specialized baseplates and holders that fit inside the sample compartment of the the Thermo Evolution, the Thermo GENESYS 30, and Thermo G20 spectrophotometers.

#### **Barcode scanners**

Internal and external barcode scanners are options for any spectrophotometer as an automatic way to enter dosimeter IDs into the software.

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The Evolution and GENESYS30 spectrophotometer can be fitted with an internal barcode scanner to capture the B3 dosimeter ID serial number for each measurement, permanently linking each dosimeter ID to its dose measurement.

#### **Laser Micrometer**

An integrated laser micrometer is an option for the measurement of PMMA dosimeters. The laser micrometer is mounted inside the Evolution spectrophotometer sample compartment and captures the dosimeter thickness value at the same time as the absorbance measurement, ensuring traceability of the measurement to a given dosimeter so that one cannot accidently mix the absorbance and thickness measurements. Custom Gage Blocks are manufactured and certified for the calibration verification process of the laser micrometer.

#### Thermo Scientific Performance Verification Accessories

- The Thermo Mercury Lamp is used for instrument re-calibration and performance verification testing.
- The Thermo Spectronic Standards Set is the performance verification accessory used for the Genesys 20, GENESYS 30 and Evolution spectrophotometers

#### 1.2 DoseControl Software - Overview

DoseControl is a FDA 21 CFR Part 11/EU Annex 11 compliant electronic recordkeeping system that controls the dosimeter measurement workflow. The primary purpose of the system is to collect dosimeter measurement data and produce dosimetry reports.

#### 1.2.1 Dosimetry Report Management

Dosimetry measurement information is contained in Dosimetry Reports; reports are managed through a versioning system.

- Create New Report: Select "New Report" and choose from a drop-down menu of pre-configured report types.
- Report Summary screen: Review overall report information, measurement results, any process results (min/max, measurements outside the range), comments, and more. Review before processing a report.
- *Process Report*: Final report is complete; the user selects "Process Report" to save this version of the report (example: ReportName version 1). Process reports are shown in green in the Report List main screen.
- Version Report: User can create versions of an existing report that has been processed (example: ReportName version 1 and ReportName version 2).

Details: How to create, use and export reports (see page 153) and How to search for a Report or Dosimeter ID (see page 150)

#### 1.2.2 Dosimeter Measurement Workflow

DoseControl provides step-by-step management of the dosimetry workflow. The Technician users can measure dosimeters (see page 176) in the software, and the Application Administrator pre-configures all dosimetry process parameters (see page 67), dosimeter report types and report headers.

- DoseControl software controls spectrophotometer.
- Specialized holders ensure consistent dosimeter placement.
- Every measurement follows the same process.
- Eliminates user error.

Details: How to measure dosimeters. (see page 176)

#### 1.2.3 Dosimeter Rereads (re-measurements)

DoseControl provides a controlled process for handling dosimeter rereads (re-measurements). Each measurement is captured and recorded by the audit trail, so the measurement history is not lost (21 CFR part 11 requirement). This means the original

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measurement and all subsequent re-read measurements are permanently recorded by the software. A re-read measurement value is displayed in the dosimetry report; all measurements are recorded in the audit trail.

Details: How to Reread (re-measure) dosimeters (see page 179) and About Rereads (see page 133)

#### 1.2.4 Audit Trail

The audit trail is separate from the dosimeter measurement and reporting areas of DoseControl. The Application Admin can access the audit trail.

**Details:** How to Use the Audit Trail (see page 191).

#### 1.2.5 Performance Verification of the Evolution spectrophotometer

Optional module available for DoseControl-Evolution dosimetry systems. The purpose of the Performance Verification (P.V.) Module is to provide a short-term verification or 'daily check' of the reader's absorbance measurement accuracy.

**Details:** About the Performance Verification Module (see page 204)

#### 1.2.6 Product Specification Module (optional)

Optional module available for all dosimetry systems. The Product Specification Module automates report creation and eliminates user input errors. User can simply select a product from a drop-down menu and the software will automatically fill in the dosimetry process specification information related to that product.

**Details:** About the Product Specification Module (see page 195)

#### 1.2.7 DoseControl Software Outputs

#### **Dosimetry Reports**

DoseControl outputs secure PDF reports and Microsoft Excel reports. Customize these reports with customer and process information, or use a standard template for routine dosimetry, reference dose dosimetry, E-beam testing, dose mapping, and dosimeter batch calibrations. *Details:* Setup - Dosimetry Reports (see page 91).

#### **Audit Trail Reports**

DoseControl software permanently records all events and creates an audit trail that is available to save or print as a secure PDF report. Within the software, the user can filter the audit trail as needed and create a report with the relevant historical events. The user can save and print audit reports. (See Audit Trail and Audit Reports section).

#### Performance Verification Reports (DoseControl-Evolution systems only)

Save and print performance verification summary reports for wavelength and photometric accuracy of the Evolution spectrophotometer.

#### **Calibration Verification Reports**

Save and print Calibration Function Output Verification reports for the dosimeter batch calibration verification functionality in DoseControl. *Details:* Setup Calibrations (Dosimeter Batch Calibration) (see page 80)

## Export data to integrated system (Enterprise license)

Export any data from DoseControl, including any information recorded related to the dosimeter measurement, process parameters, product specific information, and more.

#### 1.3 Absorbed Dose Calculation

## 1.3.1 How dose the DoseControl dosimetry system calculate dose?

A radiochromic dosimeter is a device that, when irradiated, exhibits a quantifiable change in Response that can be related to absorbed dose in a the dosimeter. Following ASTM 51261:2013 guidance, DoseControl software calculates the "absorbed dose" of a dosimeter based on the dosimeter's Response (R) value, where **R = f(Dose)**.

Response (R) = 
$$a + bx + cx^2 + dx^3 + ex^4$$
  
where R = (Ai-Ao)/T

Ao is the initial background Absorbance of the dosimeter prior to exposure to ionizing radiation.

**Ai** is the measured Absorbance of the dosimeter after exposure to ionizing radiation. The Absorbance is measured by the spectrophotometer.

**T** is the dosimeter batch thickness value.

**R** is the calculated Response value.

## 1.3.2 Calibrate your dosimetry system to achieve doses traceable to a certified standard

To establish a relationship between the dosimeter batch Response and Dose, you must calibrate your dosimetry system (also called 'dosimeter batch calibration'). Dosimetry batch calibration is the process where the response of a dosimetry system is characterized through comparison with a traceable reference or standard. The calibration method for the dosimetry system is designed to ensure the integrity of the measurements made with the user's dosimetry system. Routine dosimetry systems should be calibrated in accordance with the requirements of ISO/ASTM 51261.

The Calibration Laboratory will provide you with calibration curve coefficients, and you will enter this in the software in Setup - Calibrations (see page 80).



DoseControl uses the calibration coefficients (provided by the Calibration Laboratory) to calculate dose using the equation R = f(Dose), as per **ASTM 51261:2013**. The calibration curve is derived in mathematical form, y = f(x), where dosimeter response is the dependent variable (y) and absorbed dose is the independent variable (x), such that y = a + bx + cx2 + dx3 + ex4.

## 1.4 Understanding Valid vs Invalid Dose values

DoseControl uses the dosimeter batch Calibration coefficients as part of the dose calculation. The dosimeter batch calibration has a minimum and maximum dose range. Each dose point on the calibration curve that is within the calibration's dose range is a valid dose.

Definition of valid vs invalid dose

- A "valid" dose is one that is greater than or equal to the minimum dose of the Calibration and less than or equal to the maximum dose of the Calibration.
- An "invalid" dose is one that is outside the Calibration range. This applies equally to "measured" and "adjusted" doses (adjusted dose is a measured dose multiplied by a linear correction factor stored in the calibration configuration record).

#### 1.4.1 How dose the DoseControl dosimetry system calculate dose?

DoseControl follows these rules for handling dose values:

- When a dosimeter's dose is VALID, the software displays/outputs the numerical value of dose (in the user interface and in outputs (i.e., Excel, PDF, Export Tables). A "valid" dose is one that is greater than or equal to the minimum dose of the Calibration and less than or equal to the maximum dose of the Calibration.
- When a dosimeter's dose is INVALID, the software screen will display a graphical indication. An "invalid" dose is one that is outside the Calibration range. This applies equally to "measured" and "adjusted" doses (adjusted dose is a measured dose multiplied by a linear correction factor stored in the calibration configuration record).

See more details: Measurement Screen alerts (see page 182)

## 1.5 Product Development & Software Versions

DoseControl® is a registered trademark of GEX Corporation and is copyright protected under the laws of the United States of America.

## 1.5.1 Product Development

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

#### GEX maintains a ISO 9001:2015 certified Quality Management System.

- All DoseControl® system hardware has been assigned a unique GEX part number; they are stock items, and the parts are managed and controlled by GEX QMS procedures.
- DoseControl® software product lifecycle management and validation procedures are controlled by GEX QMS.

GEX Quality Policy: https://www.gexcorp.com/quality.html

#### 1.5.2 Software Versions

DoseControl software is version controlled. 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.

## 2.0.0 (Major.Minor.Build)

**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

Minor Version - manually issued by GEX when there is a significant addition, reduction or change in functionality.

Iterative Build - a unique number that identifies a specific software build.

### 1.6 Validation & Compliance

GEX has validated the DoseControl system and the associated instructions for installation and operation in accordance with GEX QMS policies. See Product Development and ISO 9001:2015 compliance (see page 6).

- Validation documentation is available for audit at GEX offices in Palm City, FL U.S.A. or electronic copies may be purchased.
- Current product specification and usage documents are available in the document library, and maintained in accordance with GEX QMS policies.

## 1.6.1 Compliance with Industry Guidelines and Standards

- Compliant with ISO 11137, ISO/ASTM 51275, 51261, 51649, 52628 consensus standards.
- Compliant with electronic records requirements of US FDA 21 CFR, Part 11. DoseControl does not have electronic signature functionality.

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· An internal GEX assessment has determined that this software and the lifecycle design comply with all applicable sections of EU Annex 11 with regard to electronic records.



#### User responsibilities

The end-user must follow and abide by the system security and product documentation for the installation, maintenance, and operation of this product in order to be fully compliant with the above listed guidelines.

## 1.7 DoseControl Software - License options

DoseControl software is for use by licensed operators only. Licensing is provided to each customer in the GEX Software License Terms and Conditions document provided to each customer with purchase.

## 1.7.1 DoseControl Software License Type Options

Basic License - Install the software on one PC. The MS SQL Server/application database installed on the same PC.

Premier License - Install the software on many PCs. Connect the PCs to an on-premise MS SQL server/application database.

Enterprise License - Install the software on many PCs. Connect the PCs to an on-premise MS SQL server/application database. Integrate DoseControl software data with other systems (ERP, MES, QMS, SAP, Netsuite, PeopleSoft, etc.).

#### 1.7.2 About the DoseControl Application Database

DoseControl uses Microsoft SQL Server as the database for storing application data. SQL Server is licensed to companies in many 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 is it versed in the myriad of licensing options offered by Microsoft.



### **Details:**

- DoseControl platform requirements (see page 10)
- Technical guidelines (see page 13)

Depending on the DoseControl license type, the DoseControl dosimetry system can store data in the following structures:

Basic License	Premier License	Enterprise License	
Dosimetry software installed on Windows PC. Data stored on PC, using MS SQL Server Express database.	Dosimetry software installed on one or more PC's and connected to a single SQL Server. Data stored in SQL Server database.	Same as Premier - includes integration capabilities with other systems.	

## 1.7.3 Open Source and Third-Party Software Licenses

GEX's DoseControl software incorporates certain open source and third-party software components. By ordering, using or installing the DoseControl Software, and pursuant to GEX's Software License Terms and Conditions, you agree to be bound by the terms of the following licenses:

Name	Source	License Link
AsyncEnumerator	MIT	https://opensource.org/licenses/MIT
AutoMapper	MIT	https://github.com/AutoMapper/AutoMapper/blob/master/ LICENSE.txt
CommonServiceLocator	MS-PL	https://opensource.org/licenses/MS-PL
ef-enum-to-lookup	MIT	https://opensource.org/licenses/MIT
EntityFramework	Microsoft	https://www.microsoft.com/web/webpi/eula/ net_library_eula_enu.htm
EPPlus	LGPL-3.0	https://opensource.org/licenses/LGPL-3.0
Extended.Wpf.Toolkit	MS-PL	https://github.com/xceedsoftware/wpftoolkit/blob/master/license.md
Hashids.net	MIT	https://github.com/ullmark/hashids.net/blob/master/ LICENSE.txt
LinqKit	MIT	https://raw.githubusercontent.com/scottksmith95/LINQKit/master/license.txt
MahApps.Metro	MIT	https://github.com/MahApps/MahApps.Metro/blob/master/ LICENSE
MahApps.Metro.Resources	MIT	https://github.com/MahApps/MahApps.Metro.Resources/blob/master/LICENSE
Microsoft.VisualStudio.SlowCheetah	MIT	https://raw.githubusercontent.com/Microsoft/slow-cheetah/master/LICENSE
morelinq	Apache	http://www.apache.org/licenses/LICENSE-2.0
Newtonsoft.Json	MIT	https://raw.githubusercontent.com/JamesNK/ Newtonsoft.Json/master/LICENSE.md
NLog, NLog.Config, NLog.Schema	BSD 3-clause	https://raw.githubusercontent.com/NLog/NLog/master/ LICENSE.txt

NSubstitute	BSD 3-clause	https://raw.githubusercontent.com/nsubstitute/NSubstitute/master/LICENSE.txt
Oracle.ManagedDataAccess	Oracle	http://www.oracle.com/technetwork/licenses/distribution-license-152002.html
PDFSharp	MIT	http://www.pdfsharp.net/PDFsharp_License.ashx
PDFSharp.MigraDoc	MIT	http://www.pdfsharp.net/MigraDoc_License.ashx
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

## 2 DoseControl Software Administration

## 2.1 DoseControl Software Platform Requirements

## 2.1.1 Microsoft SQL application database

DoseControl uses Microsoft SQL for storing almost all application data.

- For many DoseControl users with a Basic License, an ideal option is to use Microsoft SQL Express, which is a lightweight version of MS SQL with a 10GB limit on database size. You can setup MS SQL Express easily by following the instructions in Installation and Setup of Microsoft SQL Server Express (see page 41)
- For more information about SQL Server editions, please see the Microsoft website https://learn.microsoft.com/en-us/sql/ sql-server/editions-and-components-of-sql-server-2017?view=sql-server-ver16

#### 2.1.2 PC Workstation Requirements

Optimal Requirements for PC Workstations	Minimum Requirements for PC Workstations
<ul> <li>Windows 10* x64</li> <li>.NET Framework 4.8.1</li> <li>16 GB RAM</li> <li>8th Gen Intel i7 Quad Core processor equivalent or higher</li> <li>At least 100 GB hard drive space</li> <li>Adobe Reader</li> <li>Microsoft Excel 365 desktop version</li> </ul>	<ul> <li>Windows 10* x64 or higher</li> <li>.NET Framework 4.8.1</li> <li>4 GB RAM or higher</li> <li>6th Gen Intel i5 Quad Core processor equivalent or higher</li> <li>20 GB hard disk space</li> <li>Adobe Reader</li> <li>Microsoft Excel 2014 or higher desktop version</li> </ul>



DoseControl v2.0 utilizes .NET framework 4.8.1 to extend the lifespan and maintainablity of the DoseControl software product, allowing the software to function on future operating systems released by Microsoft.



## CAUTION

.NET Framework is not available for older Windows 10 OS versions. Customers should upgrade the Windows 10 Enterprise LTSC (long-term servicing channel) 2019 (Version 1809) to the Windows 10 Enterprise LTSC 2021 (version 21H2). Customers may attempt to run DoseControl v2.0 on .NET Framework 4.8 machines, but this is unsupported by GEX. More information (see page 11).

## 2.1.3 Database Server Environment Options

#### On the PC

## **MS SQL Server Express**

· Microsoft SQL Server Express 2017 or higher\*



i Use optimal PC requirements (see above).

#### On a LAN

### MS SQL Server (Licenced)

- Microsoft SQL Server 2017 Standard or higher\*
- Microsoft Windows server 2019
- (i) Consult your IT department to setup this environment.

#### On the cloud

#### MS SQL Server on Windows Server 2019 Virtual Machine

- (i) Consult your IT department to setup this environment. GEX does not host data.
- ⚠ DoseControl software requires a constant connection to the database.
  - \*GEX supports Microsoft Windows Server and SQL Server versions that have not expired per Microsoft's documented end of support dates. This does not include products with Extended Security Updates (ESUs). See https://docs.microsoft.com/en-us/lifecycle/announcements/sql-server-2012-windows-server-2012-end-of-support for more information.

#### 2.1.4 Guidance for .NET Framework 4.8.1

#### 2.1.4.1 Microsoft Windows OS release compatibility with .NET Framework 4.8.1

Operating system	Preinstalled with the OS	Installable separately	DC v2.0.0 compatible	DC v1.x compatible
Windows 11, 2022 Update (version 22H2)	.NET Framework 4.8.1		Yes	Yes
Windows 11	.NET Framework 4.8	.NET Framework 4.8.1	Yes	Yes
Windows 10 2022 Update (version 22H2)	.NET Framework 4.8	.NET Framework 4.8.1	Yes	Yes
Windows 10 November 2021 Update (version 21H2)	.NET Framework 4.8	.NET Framework 4.8.1	Yes	Yes
Windows 10 May 2021 Update (version 21H1)	.NET Framework 4.8	.NET Framework 4.8.1	Yes	Yes

Windows 10 October 2020 Update (version 20H2)	.NET Framework 4.8	.NET Framework 4.8.1	Yes	Yes
Windows 10 (version 1809)	.NET Framework 4.7.2	.NET Framework 4.8	No	Yes
Windows 10 (version 1709)	.NET Framework 4.7.1	.NET Framework 4.8	No	Yes

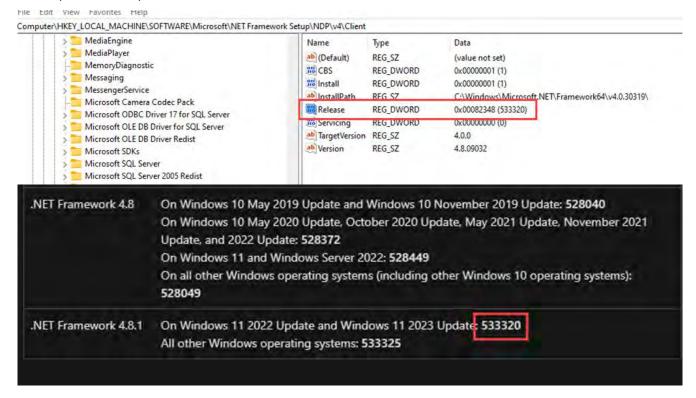
#### 2.1.4.2 How to install .NET framework on a Windows 10 PC

See Microsoft guidance: https://devblogs.microsoft.com/dotnet/announcing-dotnet-framework-481/

#### 2.1.4.3 Use this detection method to use to see what .NET framework is installed on a PC:

https://learn.microsoft.com/en-us/dotnet/framework/migration-guide/how-to-determine-which-versions-are-installed#detect-net-framework-45-and-later-versions

Use this guidance to determine what .NET framework is currently installed on your PC. Look for **533325** (on a Windows 10 OS) or a **533320** (Windows 11 OS).



#### 2.2 DoseControl Software Technical Guidelines

The purpose of this section is to provide recommendations for the application database, PC workstation and network aspects of DoseControl Software.

#### 2.2.1 Windows PC Workstation

• DoseControl application users need Write permissions for the ProgramData directory (C:\ProgramData\GEX) and any configured network report storage locations. See Report Storage (see page 40) configuration options.

#### 2.2.2 MS SQL Server and application database connection

- DoseControl requires a constant connection with the MS SQL server and application database.
- DoseControl is validated and supported on Microsoft SQL Server instances see Platform Requirements (see page 10).



If the connection to the application database is lost or broken, DoseControl will not work. Users cannot login to DoseControl and cannot use DoseControl.

#### 2.2.3 Application database

- DoseControl will create the application database when the application connects to the database for the first time. You do not need to create the database in advance.
- DoseControl requires the DBCREATOR user role in SQL Server to create the application database when DoseControl software is first connecting to the database Server.
- DoseControl data is only stored in the application database<sup>1</sup>.

## 2.2.4 Software Interruption Management

- No data is cached locally<sup>1</sup>.
- · Reader disconnection problem: In the event that the attached, active spectrophotometer (Reader) is disconnected from the PC (USB connection is lost or broken), DoseControl has a "Manual Mode" workflow to handle this situation. Manual Mode allows the user to manually enter dosimeter measurement information into the report, in the event of reader
- · Reader failure problem: All dosimeter measurements in a report are measured using a specific Calibration for the Reader-PC workstation. In the event that the attached, active spectrophotometer (Reader) fails during dosimeter measurements such that the Report is incomplete, there is a reader failure workflow (see page 186) to allow the user to switch to a new Reader (and new Calibration) to complete the report.

#### 2.2.5 Data Integrity

- DoseControl software (version 2.0.0 and higher) is built using a secure code signing process that meets the recommendations of CA Security Council. When the user installs DC 2.0 software, GEX is the identified and verified software publisher, confirmed by a publicly trusted certification authority. GEX follows the CA published guidelines.
- · DoseControl does not have an API or software intermediary that might allow another application to access it.

<sup>&</sup>lt;sup>1</sup>Several items are encrypted and stored in the C:\ProgramData\GEX in the settings.json file (a connection string to the database, for example).

<sup>&</sup>lt;sup>1</sup>DoseControl requires a <u>constant connection</u> with the MS SQL server and application database. If the connection to the application database is lost or broken, DoseControl will not work. Users cannot login to DoseControl and cannot use DoseControl.

- In general, the application database is not encrypted (see Data Encryption section below) and relies on the customer's data integrity policies for their server, PC and network.
- GEX software engineering process protects all components of the DoseControl software from tampering and unauthorized access, controlled by the GEX QMS (ISO 9001:2015 certified Quality Management System).
- GEX provides a complete SBOM for DoseControl that follows the NIST published guidelines Secure Software Development
  Framework (SSDF) Version 1.1 9(2022) that describes recommendations for mitigating the risk of software vulnerabilities.
  SBOM stands for Software Bill Of Materials: a nested description of software artifact components and metadata. This
  information can also include licensing information, persistent references, and other auxiliary information.
  - SBOM available upon request.
- GEX monitors potential and identifies any residual vulnerabilities in the DoseControl software releases. GEX will send an email communication to DoseControl customer in the event of a suspected risk or software vulnerability related to any of the open source or third-party software packages used in DoseControl. If you have a specific email or contact that you want to include on these communications, contact support@gexcorp.com.

## 2.2.6 Data encryption

DoseControl has AES-256 bit encryption. This includes:

- Values in the settings.json file (C:\ProgramData\GEX)
- the dbo.Users table password values (if you select the DoseControl user access, the user access information is stored in dbo.Users)
- the Global Administrator 'admin' password (also stored in dbo.Users)

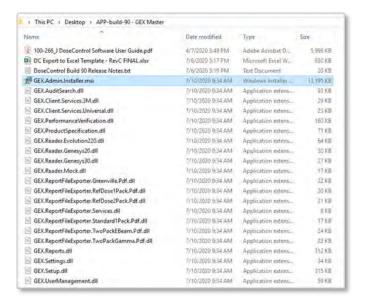
## 2.3 Files included in your DoseControl Software Installation folder

#### 2.3.1 DoseControl Installation files

GEX will send you a DoseControl Software installation package, which is a folder that contains everything you will need. There is the main application, plus a list of modules (\*.dll files). The modules are specific to your application install. You can add new modules to DoseControl if needed in the future (example: if you purchase a new Product Specifications module).

#### Files included in your GEX DoseControl install folder:

- \*.msi file: Installer
- \*.dll files: Modules
- MS Excel file: Default dosimetry report called DC Export to Excel Template.xlsx
- · G30 Driver (if included in your DoseControl System)
- · Software release notes, DoseControl Software User Guide PDF, DoseControl License and license agreeement



#### 2.4 Pre-Installation Checklist

i Please complete the following items before installing DoseControl software

## 2.4.1 Log on with an Administrator Account for the PC computer

You will need to log on to the computer where DoseControl is being installed with an account that has administrative privileges. You will need admin privileges to install DoseControl, copy modules to the Program folder, as well as install the necessary drivers and software for any hardware associated with the DoseControl Dosimetry System. Be prepared in advance.

#### 2.4.2 Decide on the Global Administrator password for the DoseControl software.

DoseControl requires you to set up a Global Admin account for the software. Upon first installation, DoseControl software will prompt you to create this Global Admin account - so be ready to enter a password. You cannot change the Global Admin's password at a later date.



Write down the password for the Global Administrator account. Keep the Global Admin username/password in a safe place. You cannot change this password at a later date.

# 2.4.3 Install Microscoft SQL Server - DoseControl software requires a SQL Server setup prior to the software installation.

DoseControl software uses a Microsoft SQL Server for its application database. The GEX application connects to a SQL database to save and edit all system configuration parameters and dosimetry measurement information. Installing MS SQL Server Express takes only a few minutes.

**(i)** 

**Recommendation for DoseControl Basic License:** Use MS SQL Server Express installed on the same PC workstation on which you will install DoseControl.

• Installing SQL Server Express 2019 instructions (see page 42)

#### 2.4.4 Install Microsoft SQL Server Management Studio (SSMS)

SSMS is a tool that allows you to manage your MS SQL Server Express server and the application database for DoseControl.

• Installing SQL Server Express 2019 instructions (see page 48)

### 2.4.5 Create a master connection string

You will use a connnection string to connect the DoseControl software with the MS SQL Server (application database).

- Write down your connection string. This makes it easy to copy & paste it into the DoseControl master connection string field.
  - Instructions to create your Master Connection String based on your MS SQL Server Express server (see page 16)

## 2.5 Create a Connection String for DoseControl

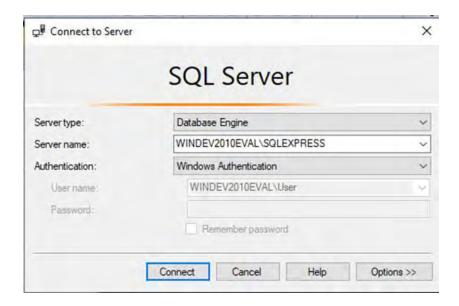
- Prerequisite Have you completed the following steps?
  - 1. installed MS SQL Server Express (see page 42) or MS SQL Server?
  - 2. installed SSMS (SQL Server Management Studio (see page 48))
  - 3. configure SQL Server Express for use with DoseControl (see page 50)

## 2.5.1 Create a Connection String for DoseControl

The connection string that DoseControl will use to connect to the database will take the following form, and you will replace the highlighted portions with your system's values:

Data Source=<servername\datasource>; Initial Catalog=GEXApp; User ID=gexapp; Password=<your gexapp login password>; MultipleActiveResultSets=true;

- If SSMS is still open, close it and reopen it. If not, you can launch SSMS from the start menu.
- To get the Data Source value for your connection string, make note of the Server name (Data Source) that appears in the Connect to Server window. Based on the preceding steps it should appear as <YOURCOMPUTERNAME>\SQLEXPRESS (including the backslash). For example, the GEX test environment appears as WINDEV2010EVAL\SQLEXPRESS:



- 3 The Initial Catalog value is the name of the database where the DoseControl data will reside. It will be named **GEXApp**. (You can name the database whatever you want!)
- 4 The connection string's **User ID** value is the Login **gexapp** that you created in the preceding step **Configure SQL Authentication logins**.
- **5** The connection string's **Password** value was also set in the **Configure SQL Authentication logins** step. You **must** use the password that you saved in that step.
- Instructions for installing MS SQL Server Express (see page 41). Includes how to setup a SQL user access.

  Instructions for setting up a SQL Username/Password (see page 50) in SSMS for your connection string.
- **6** The DoseControl connection string uses Multiple Active Results Sets. (For information about SQL Server data operations, please see the Microsoft documentation here.)
- 7 You may copy this and use the following connection string when installing DoseControl, **but you must change the Data Source and Password values to your specific values**:

Data Source= WINDEV2010EVAL\SQLEXPRESS; Initial Catalog=GEXApp; User Id=gexapp; Password=password1234; MultipleActiveResultSets=true;

**8** Keep a copy of this connection string available. You will enter the connection string in DoseControl after installing the software as part of the setup process. (See *First Time Installation of DoseControl Software - Installation Instructions*) (see page 18).

## 2.6 DoseControl Software Installation - First time installation

GEX will send you a DoseControl Software installation package, which is a folder that contains everything you will need. There is the main application, plus a list of modules (\*.dll files). The modules are specific to your application install. You can add new modules to DoseControl if needed in the future (example: if you purchase a new Product Specifications module).



You will need administrator privileges for your PC on your network to install GEX DoseControl software, or you will need your IT personnel with admin privileges to install the software for you.

## 2.6.1 Before you start

Pre-installation tasks complete? (see page 15)

#### 2.6.2 Installation Instructions

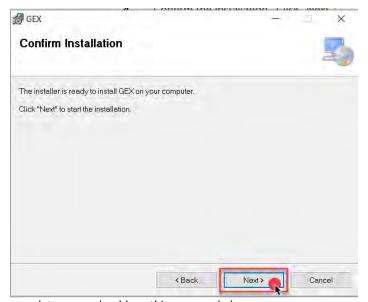
- Place the .msi installer on the desktop of the computer for installation.
- 2 Double-click .msi. Follow prompts to complete the install of the application.



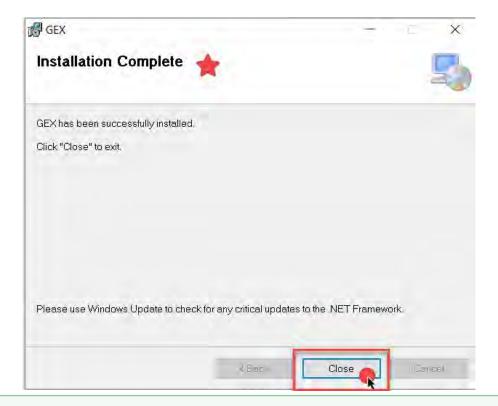
3 Select the folder to install the application to on the computer.



4 Confirm the installation. Click "Next":

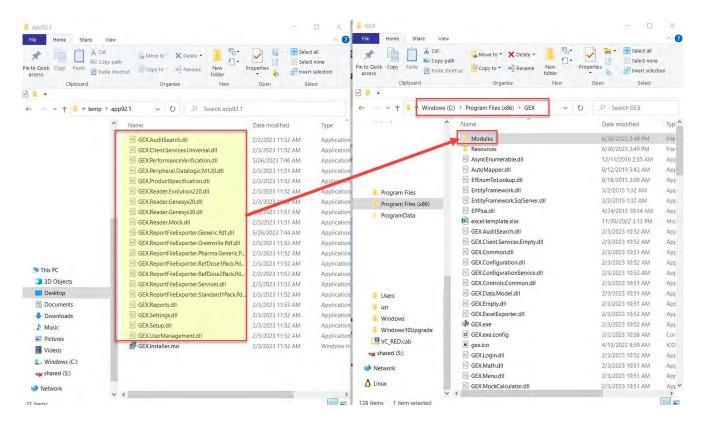


5 Verify that the installation completes – you should see this message below:



.NET Framework 4.8.1 (or higher) must be installed on the PC. If not, the GEX installer will stop and will prompt you to install 4.8.1 and will provide a link to update the .NET framework.

Move all .dll files from the Installation folder 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.

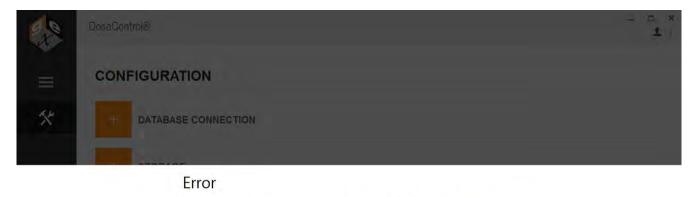


7 **Double-click on the application shortcut icon "GEX" with the GEX logo that was installed on the desktop.** (If the icon does not appear on the desktop, find the .exe file named 'GEX' located in the Program Files(x86) folder.)



8 Next, enter your Master Connection String to connect the software to your SQL Server.

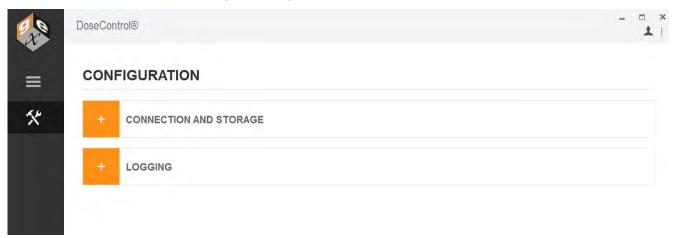
The software will show an error indicating that the master connection string is empty. This connection string must be entered before you can proceed to finish the installation. **Click 'OK'**. Go to steps 9 and 10.



The master connection string is empty. Please configure the user settings and restart the application.



**9** After you click 'OK' on the error message, the Configuration screen will appear.



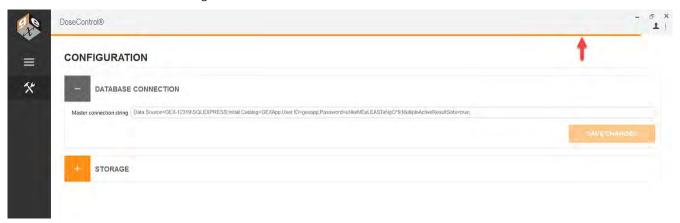
10 Enter your connection string into the Master Connection String field. Expand *Database Connection* and enter a master connection string to connect DoseControl to the application database.





Instructions for writing a Master Connection String. (see page 16)

11 Click "Save Changes" button one time. The software will connect to the database. The progress is shown by orange bar near the top of the screen. 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.



13 If the connection string is not correct, an error message will appear to alert the Administrator. If this message appears, you must fix any errors or misinformation in the connection string because something is not correct.

## Error

The connection string provided for the master connection is not valid. Please update the connection string and restart the application.

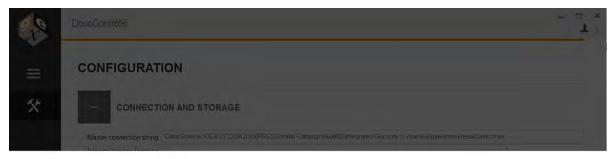


Select 'OK'. Review the string and make any necessary changes. Select 'Save Changes' again.



Problems connecting DoseControl to the database?

- Connection string not connecting (see page 260)
- Microsoft SQL Server configuration and troubleshooting guide (see page 252)
- 14 When the string is entered correctly you will be prompted by an info message to restart the application. Select 'OK'.



#### Info

After making changes to user settings you will need to restart the application.





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

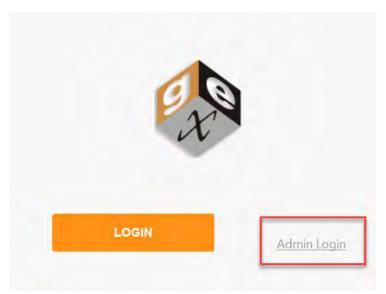


## 2.7 Create Global Administrator Login

## 2.7.1 What is the Global Administrator user?

The Global Administrator user name is 'admin'. The 'admin' user is built into the DoseControl software, and has full user access and priviledges for DoseControl. You create the password for the 'admin' user one time, upon the first installation of the software.

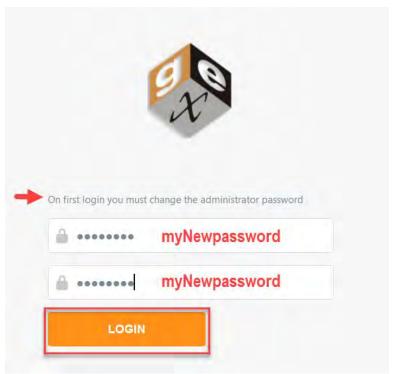
- 4
- Please write down the DoseControl Global Administrator username and password when you create this account. You cannot reset the password at a later date! It is best not to forget or lose it.
- (i) The Global Administrator Login is for the DoseControl software and is <u>not</u> the SQL Server admin login or 'sa' account. This global admin user has full access and priviledges for DoseControl, so keep the login information safe.
- 1 After first-time installation (see page 18), you will be prompted to setup the **Global Administrator Login** for DoseControl. Select the small text to the right of the orange LOGIN button that says '**Admin Login**'



2 Enter username "admin" and password "admin" and select 'LOGIN'.

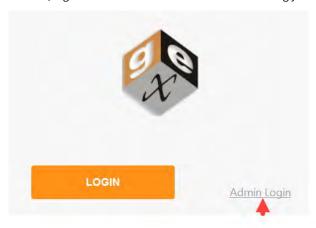


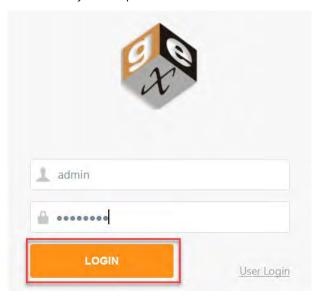
**3** You will then be prompted to change the Administrator password. There are no requirements for password length or characters. This will be the DoseControl Global Administrator password.



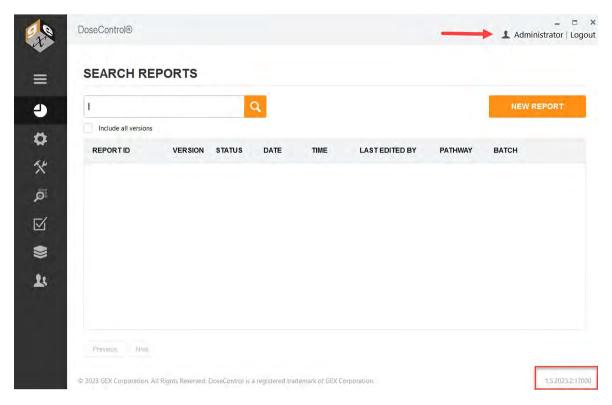
Type new Global Admin password and confirm new password. Press 'Login'.

4 Next, login to the software as the Global Admin using your username "admin" and your new password.





5 You will be taken to the Home Screen. The software installation is complete. The version number is located in the lower right corner. You can see the Global Admin user is logged in (upper right).



## 2.8 DoseControl Software - User Access, Roles and Permissions



Only the System Administrator (see page 27) or Global Admin (see page 24) users can setup User Access and User Roles in DoseControl. The Application Admin (see page 27) can setup permissions (see page 35) as part of the dosimetry setup.

### 2.8.1 DoseControl Software - User Access

User access means how a user can access (login) to the DoseControl software.

#### 2.8.1.1 User Access options

The System Admin or global administrator must setup the method for user to login to the DoseControl software.

**Basic (no username/password):** In Basic setup, there is no username and password requirement at login. Enabling this option will require the user to simply push the "Login" button to open DoseControl and is designed for single PC installations with a Basic software license using SQL Server Express. This user access method will record the domain and username from Microsoft Windows as the user for the audit trail in the application, and only the date and time of all logins and logouts is retained since there is only one user.



Basic User Manager is not 21 CFR part 11 compliant.

**DoseControl User Manager:** In the MS SQL user access setup, user roles and permissions are managed by the DoseControl application System Administrator (onboard). The DoseControl System Admin can setup users and passwords, assign roles, make users active/inactive. DoseControl has AES-256 bit encryption

**LDAP:** In the LDAP user management option, DoseControl allows access to users with their corporate network username. This means a user can simply login to Windows (using their corporate username/password) and the DoseControl software will open for this user. This method uses an existing Lightweight Directory Access Protocol (LDAP) within a company network (typically Active Directory) and DoseControl users are managed by IT personnel. Control access to the computer via the Windows user lock-out feature to maintain 21 CFR part 11 compliant security.

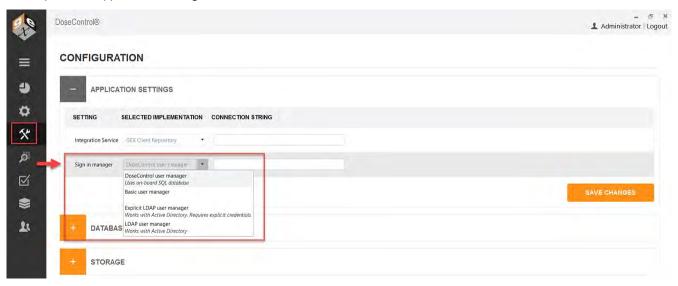
**Explicit LDAP** – In the Explicit LDAP method, the user will login to DoseControl software with their LDAP username/password. DoseControl will prompt the user to enter this username/password. This method uses an existing Lightweight Directory Access Protocol/Active Directory technology within a company network and users are managed by IT personnel using Active Directory technology. Use DoseControl's user lock-out feature (see page 128) to maintain 21 CFR part 11 compliant security.

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 three DoseControl user roles (System Admin, Application Admin, Technician).

## 2.8.1.2 How to setup User Access

- 1 Login using the DoseControl software Global Admin username and password, or as the System Admin.
- 2 Click the System (hammer/wrench) icon on the left toolbar.
- 3 Expand the "Applications Settings" menu item.



**4** Select a Sign In Manager option from the pulldown menu. Select one of the options: Basic user manager, DoseControl user manager, LDAP user manager, Explicit LDAP user manager.

#### 5 Re-start DoseControl as prompted.

#### 2.8.2 DoseControl Software - User Roles

'User roles' means what a user can do in DoseControl software. This includes what screens and information the user can see and use within the software.

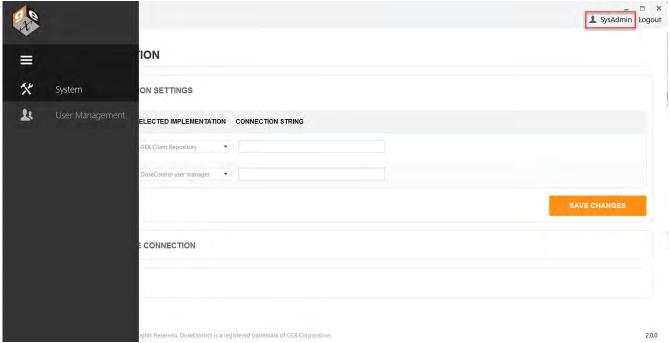
#### 2.8.2.1 User Role options

The System Admin or global administrator can assign an a user role for each user. You can give each user one or multiple roles to control what each user can see and do in the software.

#### **System Admin**

The System Admin has access to the DoseControl software System icon and screen (hammer/wrench icon), which allows configuration of all IT-related information such as user access setup, connection to the database, reports storage location.

- System Admin <u>cannot</u> see or access the DoseControl software Setup icon and screens (sprocket icon).
- System Admin <u>cannot</u> see or access the dosimetry reports or measurement screens.
- System Admin cannot see or access the Audit Trail.



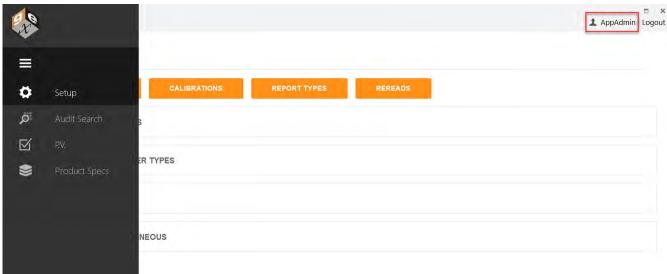
System Admininstrator user role can see the System (hammer/wrench) screen, and the User Management (people) screen.

### **Application Admin**

The Application Admin has access to the DoseControl software Setup icon and screens (sprocket icon), and can configure all dosimetry process parameters, dosimeter batches, calibrations, spectrophotometers, report setup, etc. This includes allowing specific user permissions (see page 35) related to the dosimetry process.

- Application Admin <u>cannot</u> see the System configuration.
- Application Admin <u>cannot</u> see or access the dosimetry reports or measurement screens.
- Product Specification Module The Application Admin can configure product specifications.

• P.V. (performance verification) Module for the Evolution reader – The Application Admin <u>can configure the specifications</u> for the performance verification testing, and can perform a P.V. Test.

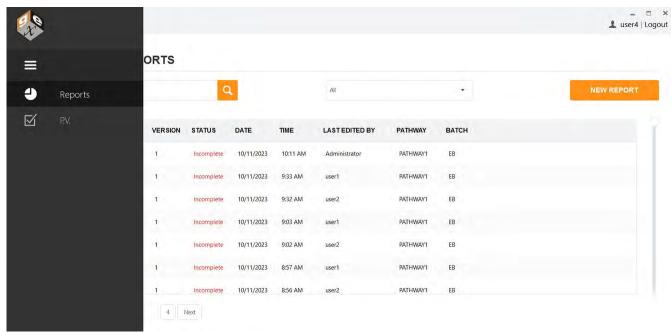


Application Admin user role can see the Setup (sprocket icon) screen, the Audit Trail screen, the PV configuration and execution screens (performance verfication module for Evolution), and the Product Specification Module configuration screen.

#### **Technician**

The Technician can perform dosimetry measurements and create dosimetry reports. The Technician role can only see the main Reports icon and measurement screens, and perform dosimeter measurements in accordance with the configuration settings created by the Application Admin.

- Product Specification Module The Technician <u>can select a product specification when starting a new dosimetry report</u> <u>but cannot add a Product Specification or alter any settings.</u>
- P.V. (performance verification) Module for the Evolution reader The Technician <u>can perform a P.V. test but cannot configure or alter the P.V. settings.</u>



Technician user role can see the Reports screen and can measure dosimeters, and can see the PV Module execution screen.

## Reminder

The global administrator user (see page 24) has full access and permissions in DoseControl. This global user is setup during first installation of the software.

## 2.8.2.2 SQL user manager - How to Setup roles & permissions

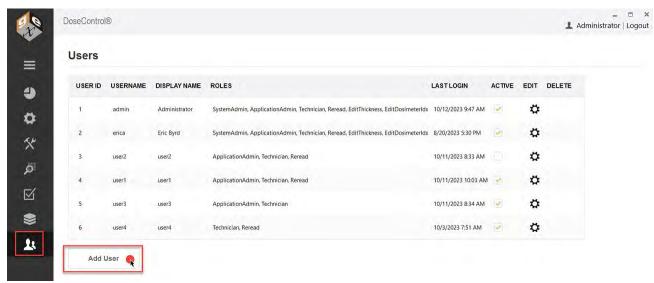
If you have selected 'DoseControl user manager' in Application Settings, follow these instrustions to setup user roles and permissions.



1 Login as Global Admin, or as the user with System Admin role. Click the Users Configuration icon on the left toolbar.

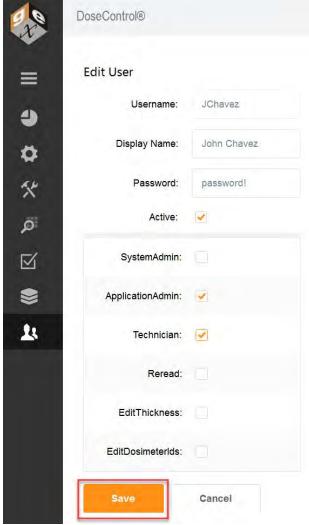


**2** From User configuration screen, you can set up new users and passwords and assign roles for each user. From the "Users" screen you can add, edit, delete, and make users active or inactive.



Users management screen

**To add a user, click the 'Add User' button.** Enter the Usename, Display Name, Password. Tick "active" to make the user active in the system. Select user roles (see page 29) and permissions (see page 35) for this new user. Example:



Example new user configuration

- 4 To edit an existing user, select the sprocket icon.
- 5 To delete a user, click the trash can icon.
- **To make a user "active" or "inactive", use the checkbox in the Active column.** You can uncheck 'Active' to make a user inactive as a temporary way to enable and disable users.



Options to activate/inactivate, edit or delete a user

- You cannot delete a user if that user has created a report or measured dosimeters in the software.
- Always click "Save" button to save changes to the user settings.

#### 2.8.2.3 LDAP/Explicit LDAP - How to Setup roles & permissions

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 Group for DoseControl and sub-groups within that user group to match the four roles that DoseControl offers.

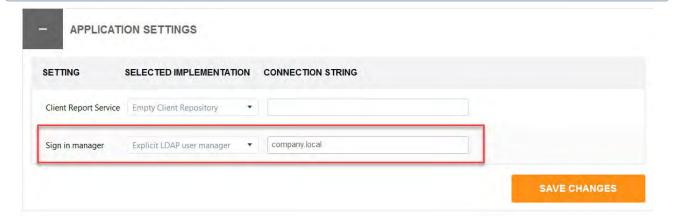
This method for user management utilizes an existing Lightweight Directory Access Protocol (LDAP) within a company network so that users of DoseControl can be managed by IT personnel using Active Directory technology.

Users must be placed in one (or more) of the sub-groups based on the desired privileges for that employee. This means a single user can have multiple roles. 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.

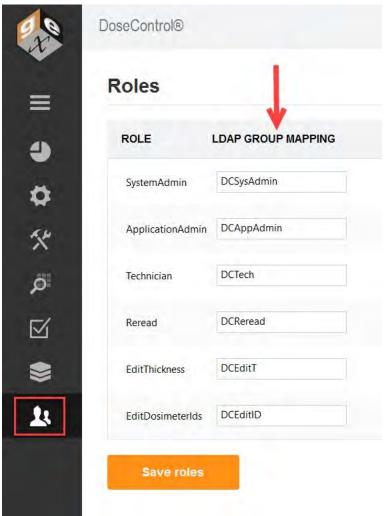
- Within Active Directory, have your IT personnel create user groups based on the DoseControl user roles and user permissions of "System Admin", "Application Admin", "Technician", "Reread", "Edit Thickness", "Edit Dosimeter ID".
- 2 Based on the desired privileges for that employee, place users in one or more of the AD user groups. Again, a user can be placed in multiple user groups (example: User1 can be Application Admin and Technician and Reread).
- Login to DoseControl as the System Admin. Click on the System (hammer/wrench) icon and expand the "Application Settings" menu.



- 4 Select either LDAP User Manager or Explicit LDAP User Manager in the drop down menu.
- Paste the Active Directory address into the "Connection String" field in the Application Settings menu. 5
  - (i) The format of LDAP connection strings varies based on the company's network configuration. The connection string address may also be a network IP address rather than a network location name. (The example address in the image above is only an example.)



- 6 Select "Save Changes". Close and restart the application.
- Login as the System Admin and paste the Active Directory user group names (LDAP User Mapping addresses) into the respective 7 role boxes. Click "Save Roles".



Example user group names



# **⚠** IMPORTANT

If a user is logged into a PC when changes are made to their membership in Microsoft AD groups by IT as they relate to the DoseControl LDAP user management, the user must log out of Windows and log back in before the changes are realized.

#### 2.8.3 DoseControl Software - User Permissions

i The Application Admin (see page 35) user can configure user permissions.

#### 2.8.3.1 What are User Permissions?

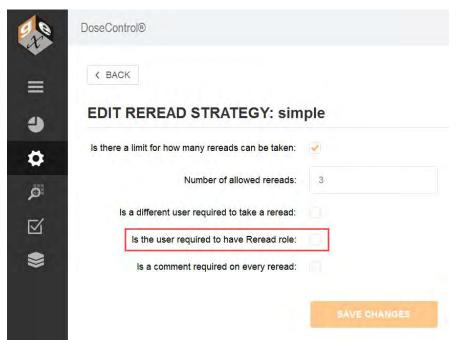
User Permissions allow you to control the specific actions permitted for each user. <u>User Permissions are optional!</u> If you do not want to control the specific actions listed below, do not activate the permission.

### 2.8.3.2 Description of User Permissions

#### 1 Re-read

The Re-read permission enables a *specific user to perform dosimeter re-reads* (see page 133), as per the Reread setup (see page 136) parameters configured by the Application Admin. The specified user must have this 'ReRead' permission active in the user manager (see User Manager instructions (see page 0) below).

To enable this permission for a Reread configuration (see page 136), check the box "Is the user required to have a Reread role" in the Reread setup.

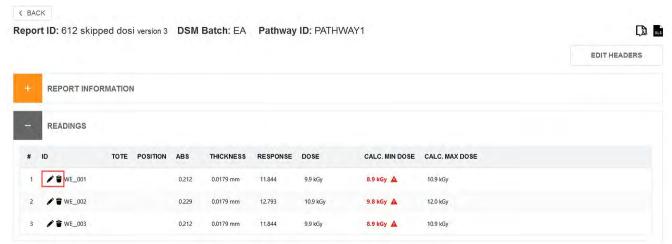


Screenshot of the Reread permission checkbox in the Reread configuration.

#### 2 Edit Dosimeter IDs

Edit Dosimeter IDs permission allows <u>any Application Admin user</u> to edit or remove dosimeters from a report. The purpose of this permission is to allow the Application Admin user the ability to maintain a clean and accurate dosimetry report. A user may want to correct any dosimeter ID errors or remove a dosimeter from a report.

If Edit Dosimeter IDs permission is active for a user, the user will be able to see the edit icon (pencil) and the delete icon (trash can) next to the dosimeter ID on the report summary screen.



Report Summary Screen: Pencil icon - Edit the dosimeter ID. Trash can icon - delete dosimeter ID from report.

**②** 

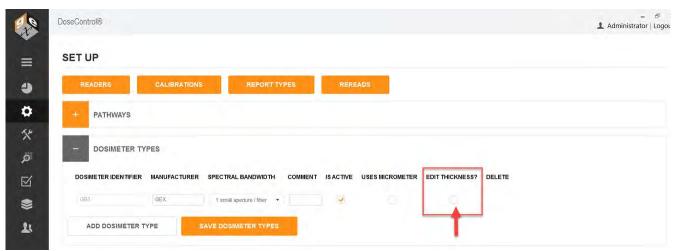
#### **GMP** compliant

When the Application Admin edits a dosimeter ID or deletes a dosimeter ID from a report, the user must enter a comment for this event, and the comment is recorded with the event in the Audit Trail.

#### 3 Edit Thickness

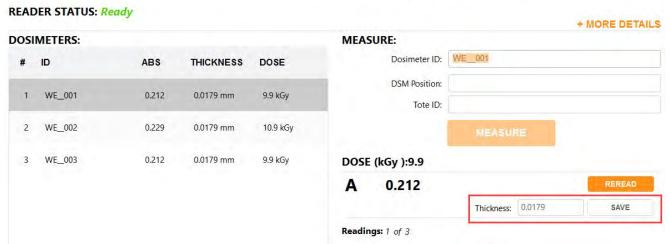
Edit Thickness permission allows a specified user to edit the thickness of a dosimeter for a dosimeter measurement. The specified user must have this EditThickness permission active in the user manager (see User Manager instructions (see page 0) below).

- The Edit Thickess permission is activated in Dosimeter Types (see page 70). (screenshot A)
- If active, the software will have a Thickness field on the measurement screen, and this user can change and save the value. (screenshot B)



A: 'Edit Thickness' permission activated in the Dosimeter Types configuration.





B: 'Edit Thickness' allows the logged in user with permission to edit the dosimeter thickness on the measurement screen.

Certain types of dosimeters use the Edit Thickness permission feature, such as Harwell Perspex (PMMA) and FWT dosimeters. Edit Thickness is not used for B3 dosimeters.

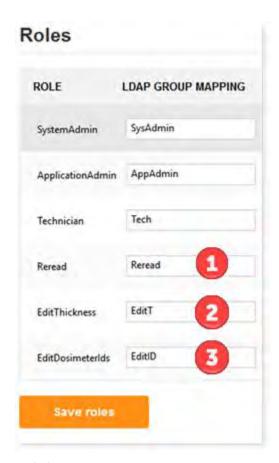
# 2.8.3.3 LDAP User Manager - Setup Permissions

# **LDAP User Manager**

Place each individual user into the desired LDAP Group to enable the permission. Add user the appropriate group: 1 for Reread, 2 for Edit Thickness, 3 for EditDosimeterIds.

**②** 

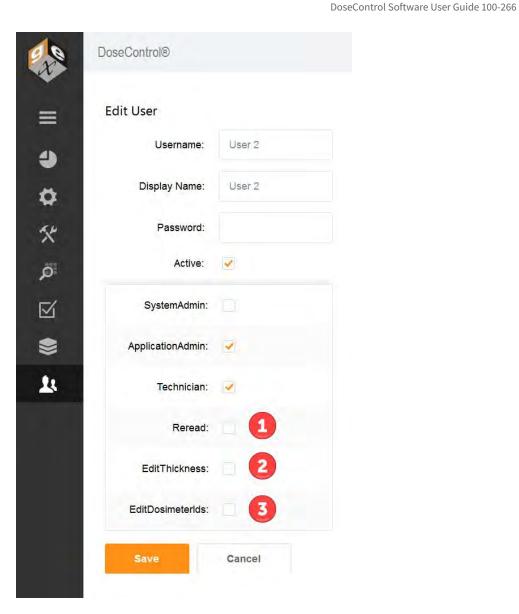
**Example:** to enable the "reread" permission for user John Chavez (jchavez@company.com), place this user into the Reread group (number 1 below).



# 2.8.3.4 SQL User Manager - Setup Permissions

# **SQL User Manager**

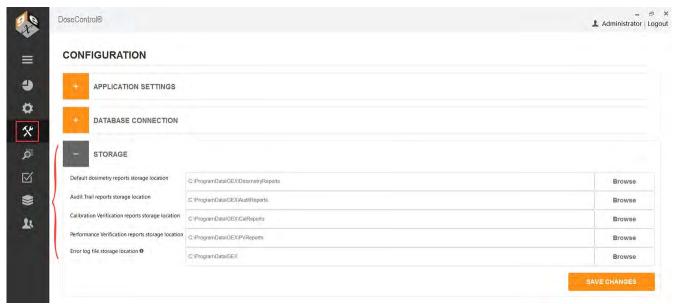
Activate or inactive the permission for each individual user. Check the appropriate permission box and click "Save". Check 1 for Reread. Check 2 for Edit Thickness. Check 3 for EditDosimeterIds.



# 2.9 Reports Storage configuration

The System Administration user (or global admin user) can make changes to the report file storage locations.

- 1. Go to Systems (hammer/wrench icon) → Storage.
- 2. Use the default file paths or change the storage locations at the time of first installation or at any time in the future. DoseControl can use mapped network drives\* as storage locations (example: \\Shared\Reports).
- \*NOTE: Your IT department will need to configure these network shares to allow your users' access.



**Default Dosimetry Reports storage location:** file pathway for where the DoseControl dosimetry reports are stored. Default is C: \ProgramData\GEX\DosimetryReports. When the user clicks the PDF report icon in the dosimetry report screen, this will output the report to this location.

**Audit Trail Reports storage location:** file pathway for where the audit trail reports are stored. Default is C: \ProgramData\GEX\AuditReports. When the user clicks the PDF report icon in the audit log screen, this will output the report to this location.

**Calibration Verification Reports storage location:** file pathway for where the Calibration Verification reports are stored. Default is C:\ProgramData\GEX\CalReports. When the user clicks the PDF report icon in the Calibration configuration screen, this will output the report to this location.

**Performance Verification Reports storage location:** file pathway for where the Performance Verification reports are stored. Default is C:\ProgramData\GEX\PVReports. If you have the P.V. Module for the Evolution installed, when the user clicks the PDF report icon in the PV Test report screen, this will output the report to this location.

**Nlog files storage location:** file pathway for where DoseControl stores error log files. GEX uses these log files to help troubleshoot any problems or errors. Keep this as the default C:\ProgramData\GEX, unless determined otherwise by your IT/Technical organization.

=

NOTE: When a user makes a change to the report storage location, this event is not recorded in the audit trail.

# 2.10 Setup - Microscoft SQL Server Express



This Setup - Microsoft SQL Server Express section is for Basic License (see page 7) users that want to install and manage a MS SQL Server Express installation on the PC that has DoseControl software.

#### 2.10.1 Install Microsoft SQL Server Express

(i) Before you install MS SQL Server Express, make sure your PC meets the DoseControl Software Platform Requirements. (see page 10)

Instructions are intended for DoseControl Basic License users to download and install MS SQL Server Express on a single PC.

#### 2.10.1.1 SQL Server Overview

DoseControl software requires a SQL database. SQL is a database that resides on a centralized server and is accessed by multiple PCs. SQL is licensed to companies in many ways and you will be responsible for determining and managing your licensing. GEX does not sell or license SQL. For in-depth information about the various SQL Server types and options, please visit the official Microsoft site "Editions and supported features of SQL Server 2019".

Many Basic License users of DoseControl use Microsoft SQL Server Express, a free edition of SQL Server, for the database.

Download Microsoft SQL Server Express from the Microsoft website.

MS SQL Server Express 2019 - Link to Microsoft download page.

MS SQL Server Express 2022 - Link to Microsoft download page. Go to "SQL Server Express" download section.

#### 2.10.1.2 Introduction to Microsoft SQL Express (A Lightweight Version of MS SQL Server)

Microsoft SQL Express is available from Microsoft with any licensed Windows installation. A SQL Express database cannot be larger than 10 GB size; this size is sufficient for many users. You can migrate to SQL standard from SQL Express at any time by paying the license fee.

The method for installing SQL Express involves downloading the installation package from Microsoft and installing it on your PC. If you have purchased the Basic License for DoseControl then you will use the SQL Express database installed on a single PC. A SQL Express database cannot be shared between PC's.



#### IMPORTANT

You must perform all the following installation and configuration steps using an account that has administrative privileges for the computer that will host SQL Server. For Basic License users, this is typically the same computer on which DoseControl is being installed.

#### 2.10.1.3 Download and Install Microsoft SQL Server Express 2019

#### Log in as an administrator

# **Download SQL Server Express installer**

Go to the Microsoft SQL Server Express download page and download SQL Server Express. Click the "Download" button to download the installer.

Next, you will execute the installer and follow the on-screen prompts to install SQL Server.

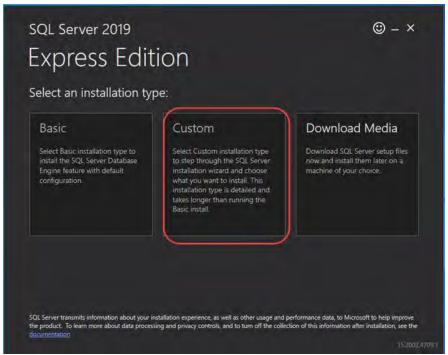
Publish date: Nov 15, 2023

4

**Note:** Select the English language version of MS SQL Server. DoseControl may run on SQL in other languages but has not been formally tested (customers have sometimes been successful) and GEX is unable to support users running other languages.

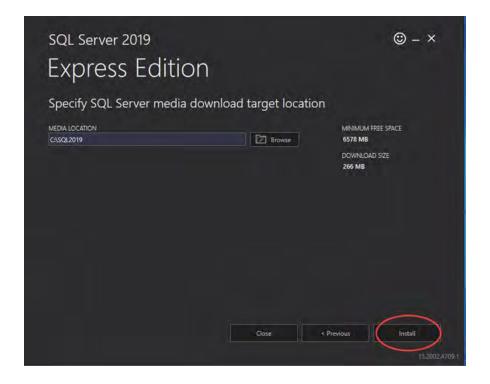
### 3 Select Installation Type

When you execute the downloaded file, you will be prompted for an administrator account. The installer will open a window. The window offers three possible ways to install SQL Server Express Edition which are Basic, Custom and Download Media. Select "Custom".



### 4 Select a location for installing.

Keep the default Media Location and click the "Install" button. The installation process will begin, and you will see a progress window.



# 5 The SQL Server Installation Center opens

In the installation center window, click the "New SQL stand-alone installation..." link. The SQL Server 2019 Setup window opens.

#### 6 License Terms

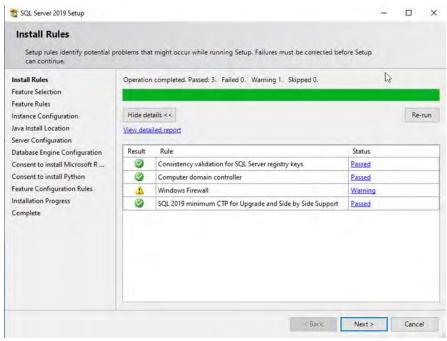
Accept the license terms and click "Next". The Global Rules page will open and display a progress bar, and then the Microsoft Update page will open.

## 7 Microsoft Update

Select the option to "Use Microsoft Update to check for updates (recommended)" and click "Next". The Install Setup Files window will open and display a progress bar, and then the Install Rules page will open

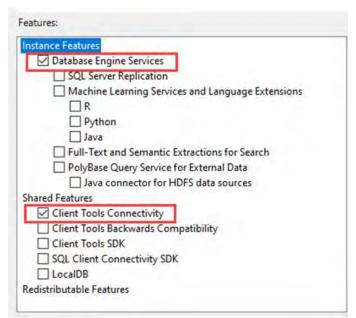
## 8 Install Rules

On the Install Rules page, each Rule should have a Status of "Passed", but you may see a warning for Windows Firewall. Disregard this warning and click "Next".



#### 9 Feature Selection

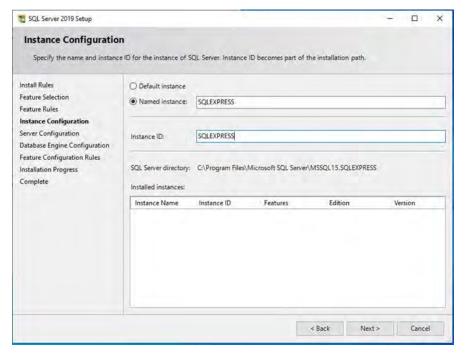
On the Feature Selection page, click the "Unselect All" button. In the Features list, only select the following Instance Features: Database Engine Services and Client Tools Connectivity:



Keep all other default values and click "Next". The Feature Rules page will open very briefly, and then the Instance Configuration page will open.

### 10 Instance Configuration

If not already selected, choose "Named Instance" and enter "SQLEXPRESS" for both the Named Instance and the Instance ID:



Click "Next".

### 11 Server Configuration

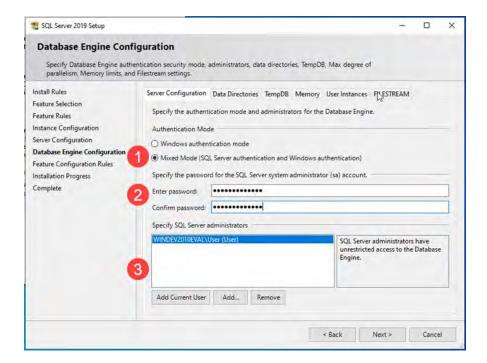
Change no values and click "Next".

# 12 Database Engine Configuration

On the Server Configuration tab, **1**) select "Mixed Mode", **2**) specify the password for the SQL Server system administrator (sa) account, and **3**) if the current user installing SQL is not displayed in the "Specify SQL Server administrators" list, click the "Add Current User" button.



**IMPORTANT:** Ensure that you make a copy of the sa password and keep it in a secure location.



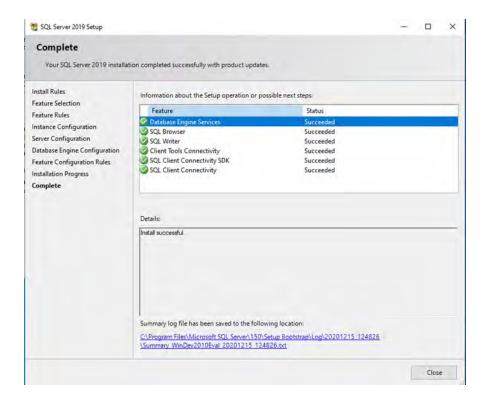
Do not change any of the values on any other tab in the Database Engine Configuration page. Click "Next". The Feature Configuration Rules page will open very briefly, and then the Installation Process page will open.

# 13 Installation Process

SQL Server Express is now being installed and progress bar will appear. When the process completes the Complete page will open.

#### 14 Complete

The Status for each Feature in the list should be "Succeeded". Click the "Close" button.



F Next Step: Install SSMS (SQL Server Management Studio) (see page 48)

# 2.10.2 Install SSMS (SQL Server Management Studio)



Prerequisite - Have you installed MS SQL Server Express (see page 42)?

#### 2.10.2.1 Install SQL Server Management Studio (SSMS)

You may be curious as to why you need to install something else other than SQL Server itself. SQL Server, like other modern relational databases, uses a client-server architecture. The database itself is the server and contains all the data and the capability to add, modify, delete, and access the data. A client is needed to connect to the database and perform specific commands. The most popular client by far for SQL Server is Microsoft's SQL Server Management Studio (SSMS), which you will install in this section.

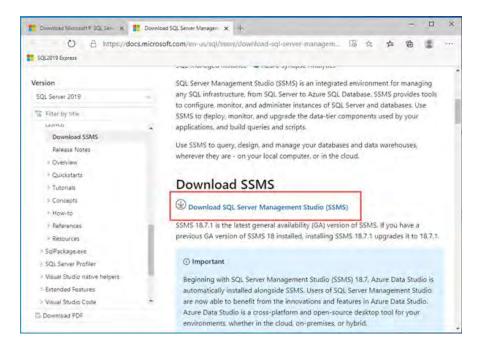
#### **Download SSMS**



(i) <u>IMPORTANT</u>: We are assuming that you just installed MS SQL Server Express (see page 42). You should still be logged in to the computer as an administrator for the following steps. The SQL Server Installation Center window should still be open (if it is not, then you can launch it from the start menu).

Or download from the Microsoft SQL Server Management Studio site.

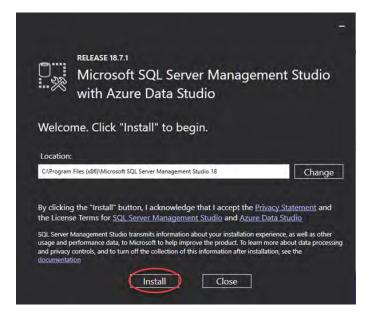
Click the Install SQL Server Management Tools link. A download page will open in your web browser; click the Download SQL Server Management Studio (SSMS) link:



#### Open the installer

Once downloaded, open the installer file (you will need to provide admin permission).

Click the "Install" button to begin. A progress screen will app Let it progress through until completion, then you will see a screen indicating successful setup - click close. SQL Server Management Studio (SSMS) is now installed. You can pin SSMS to your taskbar or Start menu.





Publish date: Nov 15, 2023

- 1. Configure SQL Server Express for use with DoseControl (see page 50)
- 2. Create a Connection String for DoseControl (see page 16)

# 2.10.3 Configure SQL Server Express for Use with DoseControl



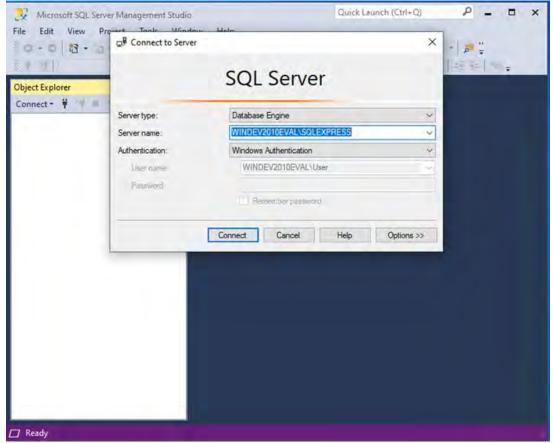
Prerequisite - Have you installed MS SQL Server Express (see page 42) and installed SSMS (SQL Server Management Studio (see page 48)?

#### 2.10.3.1 Configure SQL Server Express for Use with DoseControl

Still logged in as an administrator, follow the remaining steps to configure SQL Server Express so that DoseControl will work on your system.

#### **Connect to your Database Server**

If not already, open SQL Server Management Studio (SSMS) (you can locate SSMS in the Window Start menu). In the Connect to Server window, the Server name field should automatically display your SQLEXPRESS server. Authentication should be set to Windows Authentication. Click "Connect".



#### **Configure SQL Authentication logins**

Step 1: Expand the "Security" folder for the SQL server on which your DoseControl database will reside. Right-click on "Logins" and select "New Login...".

Step 2: In the "General" section, enter the Login name gexapp (all lower case, no spaces). Select "SQL Server Authentication". Enter a Password and Confirm password. Unless your IT department or database administrator require you to enable a password enforcement policy, uncheck "Enforce password policy".

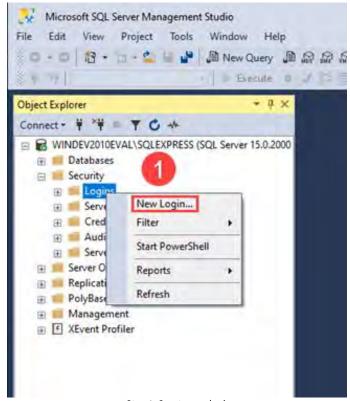
**IMPORTANT:** Ensure that you make a copy of the password and keep it in a secure location.

Step 3: Next, select the "Server Roles" section and ensure "dbcreator" and "public" are selected. Click OK.

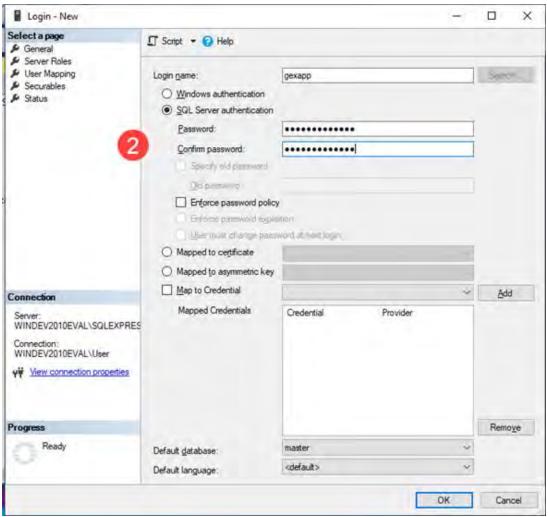
The user must have the 'dbcreator' and 'public' server roles. When DoseControl software first connects to MS SQL Server it will create the application database. If the user does not have these roles assigned, DoseControl will not connect properly.

Step 4: As a security precaution, expand the Logins folder, right click the "sa" login, and select Properties. Open the Status section, and under Login, select Disabled and then click "OK".

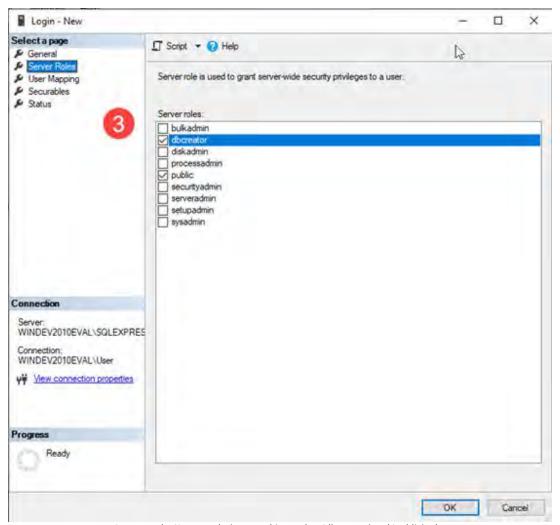
## See the following screenshots for clarification:



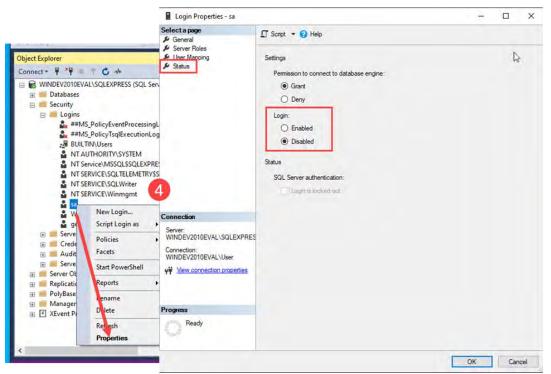
Step 1: Create new login



Step 2: Create a new user with SQL Server authentication specifically for DoseControl.



 $Step \ 3: Under \ `Server Roles' \ ensure \ this \ user \ has \ `dbcreator' \ and \ `public' \ roles.$ 



Step 4: You can disable the 'sa' user.

Next Step: Create a Connection String for DoseControl (see page 16)

# 2.11 Managing your database

**②** 

This *Managing your Database* section is for Basic License (see page 7) users that want to install and manage a MS SQL Server Express installation on the PC that has DoseControl software.

# 2.11.1 Backup Database

(i) Instructions for Microsoft SQL Server Express. Instructions are intended for DoseControl Basic License users to backup and restore a MS SQL Server database.

It is important to back-up 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 Server Express database using Microsoft's SQL Server Management Studio (SSMS).

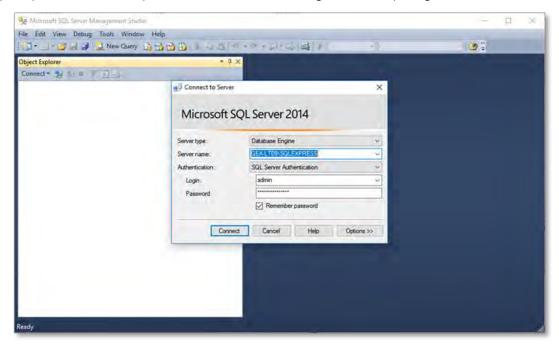


#### IMPORTANT

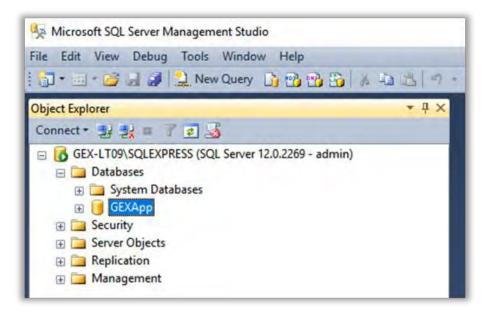
You must perform the following steps using an account that has <u>administrative privileges</u> for the computer that is hosting SQL Server.

# 2.11.1.1 Step-by-Step Instructions for Creating a SQL database Backup:

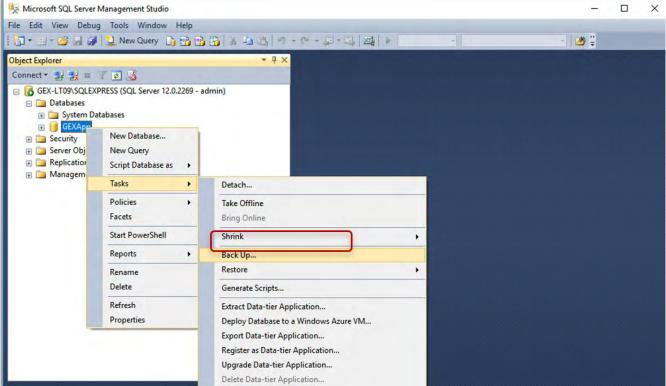
1 First, login to SSMS using either a) your SQL Windows Authentication administrator login or b) another user/password that has the appropriate permissions (for example, a SQL Server Authentication login with admin privileges).



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

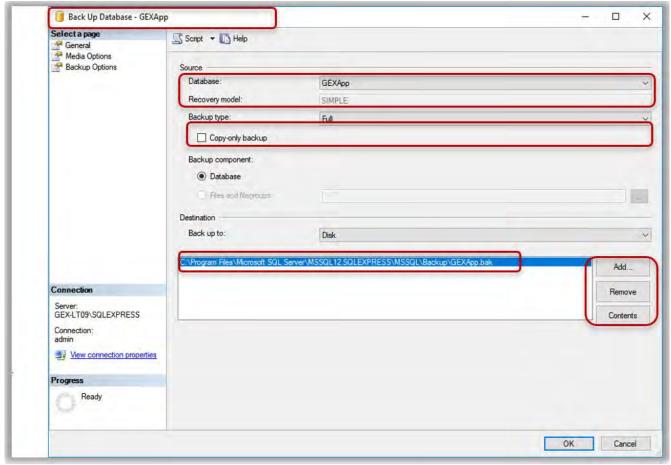


**3** Right-click on the instance name and select "Tasks -> Back Up".

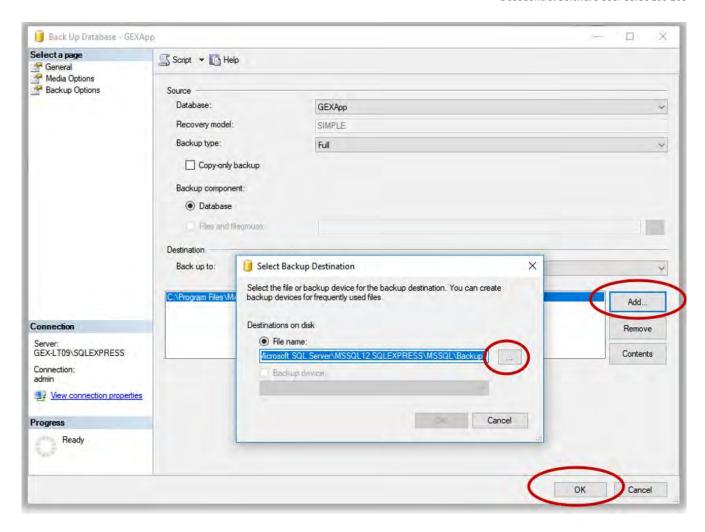


Select "Back Up"

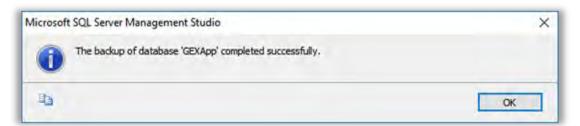
4 The Back Up Database menu will open. The settings should default as shown but check your setting against this example.



- 5 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. 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.
- **6** Press the 'Add' button and a dialog box will allow you to navigate to a location of your choosing. Name the backup file with the \*.bak file extension. Press 'OK' on the bottom of the screen to start the backup.



7 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.



# 2.11.2 Restore a Database from a backup

This Restore Database from a backup section is intended for DoseControl Basic License (see page 7) users to backup and restore a MS SQL Server Express database.

It is important to back-up 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 restoring up a SQL Server Express database from a backup using Microsoft's SQL Server Management Studio (SSMS).

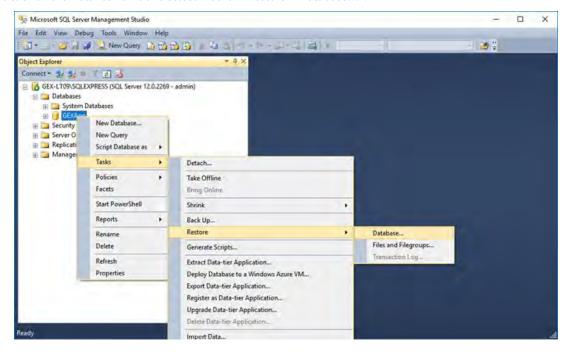


#### IMPORTANT

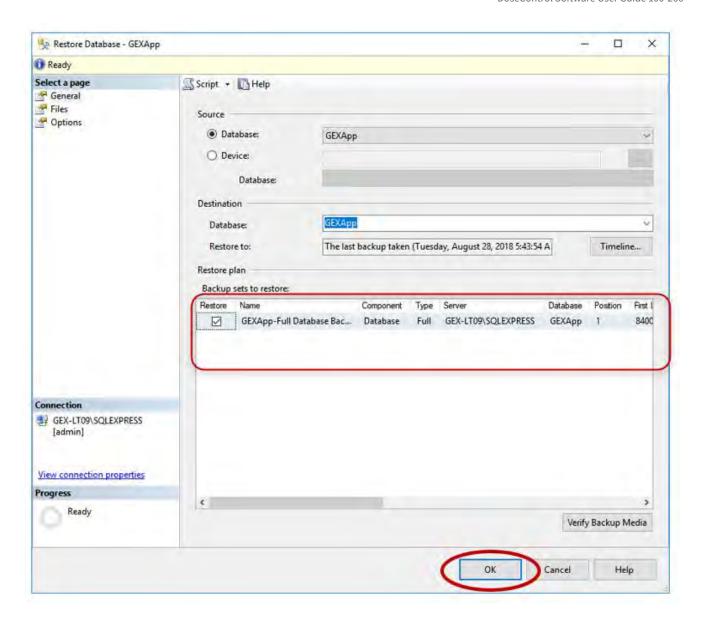
You must perform the following steps using an account that has <u>administrative privileges</u> for the computer that is hosting SQL Server.

## 2.11.2.1 Step-by-Step Instructions for Restoring a SQL database from a Backup:

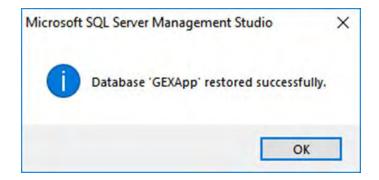
- 1 To restore a database from a \*.bak file, login and navigate to the database instance in SSMS.
- 2 Right-click on the instance name and select "Tasks -> Restore -> Database...".



3 The Restore Database menu opens. 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.



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



# 2.12 Upgrade to a New Version of DoseControl Software

# COMMON QUESTION

"Will I have to reconfigure DoseControl when I upgrade to a new version?" No! All your configuration information from the previous version and your dosimetry reports and records will transfer to the new version when you upgrade. Upgrading to a new version of DoseControl software is not difficult and the process takes 10-15 minutes.

#### (i) IMPORTANT

Backup your database prior to any attempted upgrade in the event something happens during the upgrade process. Also, make a copy of configuration information (take screenshots of your current configuration or keep a record of your configuration settings). See Upgrade Preparation instructions below.

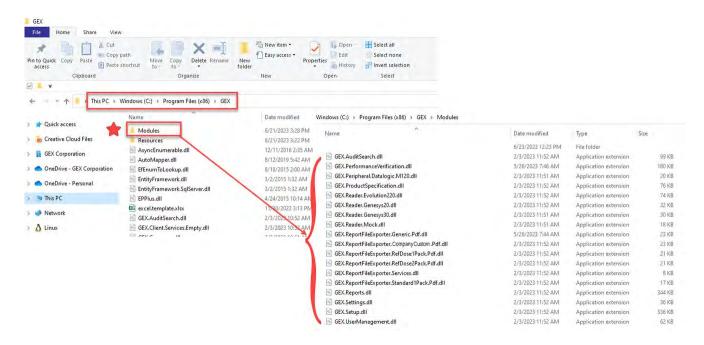


### ▲ WARNING!

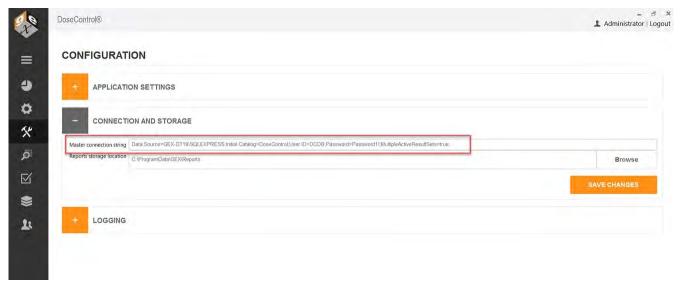
If you have a Premier or Enterprise license and have multiple PCs connected to a shared database - DO NOT INSTALL THE UPGRADE VERSION ON ANY OF THE PCs until you have fully uninstalled the DoseControl software (follow instructions below), and you must also delete or rename the settings.json file located in C:\ProgramData\GEX on each PC. When the upgrade is complete on all PC's you will need to re-enter the connection string in Connections and Storage.

## 2.12.1 Upgrade preparation

Take a screenshot of the list of module files for your current installation. Save screenshot image to desktop. Go to C: \Program Files (x86)\GEX\Modules. Your modules are the \*.dll files located in Modules folder.



**2 Open GEX DoseControl software. Take a screenshot of your connection string and save image to desktop.** Copy the text of your connection string and save as a .txt file or Word file.



- **3** If you wish, take screenshots of any configuration settings (Readers, Calibrations, etc.). Or, keep a record of your DoseControl configuration information.
- 4 Make a backup of your database. Always keep a current backup of your database in the event of a problem during upgrading the software.

- Basic License (Local SQL Server installation on PC) Instructions: Open SSMS (SQL Server Management Studio) and login. In the Object Explorer, open Databases. Right click on your database instance, go to Tasks > Backup. Create a \*.bak file of your existing database. For complete details see Backup MS SQL Server Express database (see page 54) instructions.
- Premier/Enterprise License Instructions: Contact your IT/Technical Support to backup your SQL Server database instance of DoseControl application.

#### 2.12.2 Upgrade Instructions:



#### IMPORTANT

Remember the modules in Program Files(x86)\GEX\Modules must include all the modules from the previous installation at a minimum. Compare the screenshot of your previous install Modules folder to the new Modules folder. Your new installation must have all the same module files as your old version, plus any new modules included with the version - you cannot have any missing module files, or the upgrade will not complete.

#### Download new version of DoseControl software.

- Download the new version install folder sent from GEX. This link was given to you by GEX.
- Save/place install folder onto your desktop.

#### Uninstall old version of GEX/DoseControl application.

- Uninstall GEX/DoseControl application from each PC workstation you wish to upgrade (use the "Add/Remove programs" via Windows system settings).
- Delete the GEX Program folder (found in C:\Program Files (x86)\GEX).



# ▲ WARNING!

If you have multiple PCs connected to a shared database - DO NOT INSTALL THE UPGRADE VERSION ON ANY OF THE PCs until you have fully uninstalled the DoseControl and you must also delete or rename the settings ison file located in C: \ProgramData\GEX on each PC.

#### Install new version of GEX/DoseControl application 7

· Double click the .msi installer in the new version folder. Follow prompts to install the new version of DoseControl on your PC. Install will take less than 1 minute.

#### Place the modules for the new version of GEX/DoseControl into Program Files(x86)\GEX\Modules.

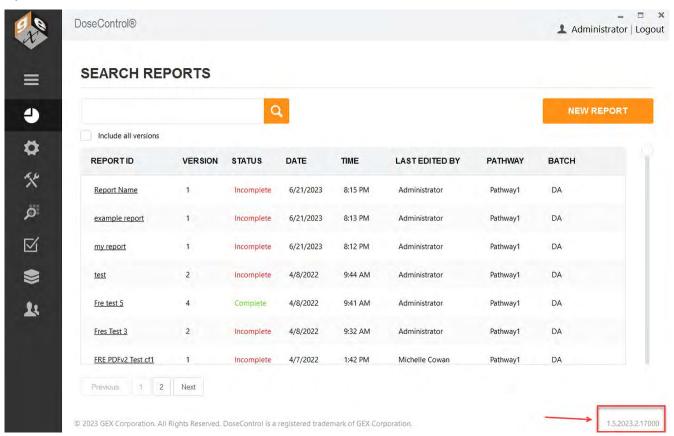
- · Copy all the \*.dll files (module files) that are included in the install folder. These modules are specific to your software installation – there may be new, additional modules added for your upgrade.
- Go to Program Files(x86)\GEX\Modules and paste the copied Modules into the Modules folder.
- On your desktop you will see the GEX/DoseControl application icon. Double click to open.
- 10 Enter your Global Admin username and password when prompted. Or, enter the Connection String when prompted.

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11 The upgrade process is complete. You should see the Reports home screen of the GEX/DoseControl software with the new version ID (version number is in the lower righthand corner of the screen). The home screen should list your existing dosimetry reports.



Your original DoseControl configuration settings should be intact. Go to the Setup icon (sprocket icon) and check that your original configuration set up is correct.

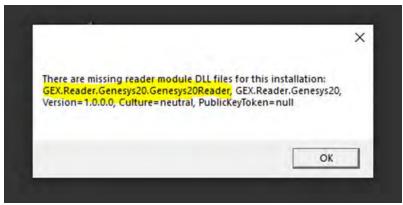
# 2.12.3 Watch a Demo

https://youtu.be/fZRZsZ-Ln5A

# 2.12.4 Common error for a software upgrade

#### 2.12.4.1 Problem

Error message about a missing module file. All the module files (\*.dll files) in the upgrade must match the original installation. If a module is missing, you will see an error message indicating which module files are missing.



Example of missing module error message

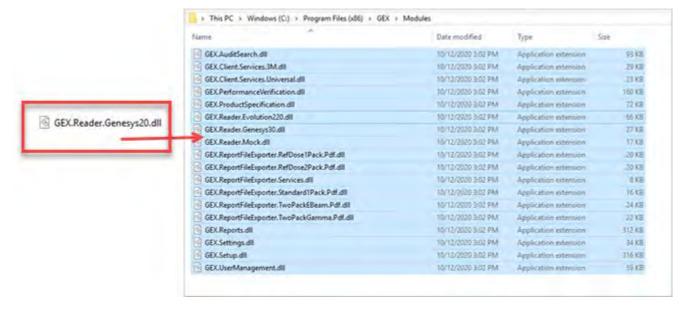
# 2.12.4.2 Solution

#### Possible reasons for this error:

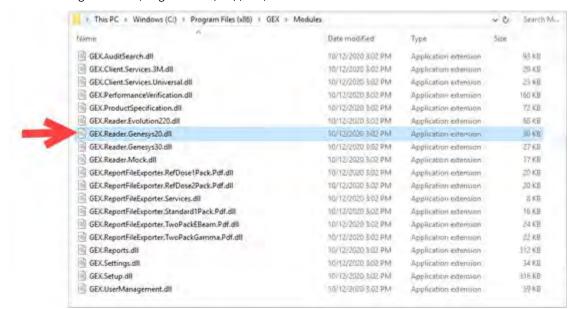
- 1. The module file is missing from the installation package sent from GEX. Contact GEX if one of your module files is not included in the installation package sent to you. Email support@gexcorp.com or call +1 303-400-9640
- 2. The module file was accidently not copied into C:\Program Files (x86)\GEX\Modules.
- 3. **The module file is blocked by your security settings.** To 'unblock' the \*.dll files included with the GEX software installation files, right click on each \*.dll file and select 'Properties'. If the file is blocked, click the 'unblock' checkbox to remove the security block.

#### To resolve this error:

Step 1: Determine which module file is missing.



**Step 2:** Place the missing file into C:\Program Files (x86)\GEX\Modules.

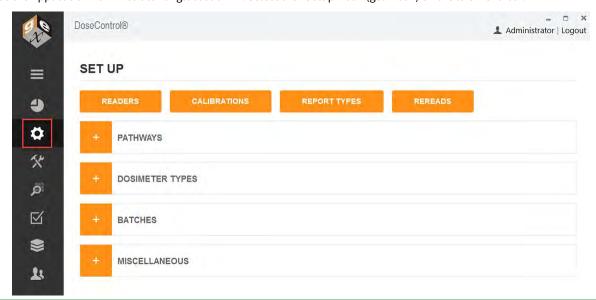


# 3 DoseControl Software Setup for Dosimetry

Browse all articles in this section

# 3.1 Overview of Setup Menu

Login as the Application Administrator or global admin. Select the "Setup" icon (gear icon) on the left menu bar.



Application Admin must complete the software setup configuration prior to qualification and usage; the software configuration must be maintained as necessary when changes to the user's dosimetry process occur such as new calibrations, new measurement instruments are added, instrument calibration dates have changed, etc.

### 3.1.1 From the software Setup menu, the Application Admin (or global admin) user can configure the following:

# 3.1.1.1

Pathways (Radiation pathways):

The software can be configured to handle dosimetry for multiple facilities, irradiators, or pathways in each irradiator. Go to Setup -Pathways (see page 68).

#### 3.1.1.2 Dosimeter Types:

Configure the types of dosimeters to be used. Go to Setup - Dosimeter Types (see page 70).

# 3.1.1.3 Dosimeter Batches:

Configure the dosimeter batch ID that is specific to a calibration. Go to Setup - Batches (see page 72).

### 3.1.1.4 Readers (Spectrophotometers):

Spectrophotometer information. Go to Setup - Readers (see page 75).

#### 3.1.1.5 Calibrations:

Setup the information for each dosimeter batch calibration (also known as dosimetry system calibration). Calibration functions define the mathematical relationship between the dosimeter response and dose for each instrument. Each combination of pathway, batch, and reader may have one active calibration at any given time. Go to Setup - Calibrations (see page 80).



For IQOQ qualification and testing of the dosimetry system any calibration (e.g. a generic calibration) may be used.



It is a requirement that a calibration be active in the system otherwise the software will not allow dosimeter measurement. Only one calibration can be active for any combination of pathway, measurement instrument (reader), and dosimeter batch at any given time.

#### 3.1.1.6 Report Types:

Setup the information to be included in a dosimetry report by configuring report types and report header fields.

- · About Dosimetry Reports in DoseControl
- Setup Report Types (see page 91)

### 3.1.1.7 Re-reads (re-measurement of a dosimeter):

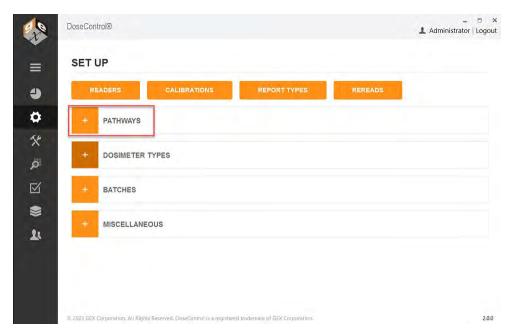
Configure dosimeter re-read process, reasons, number of re-reads allowed, how the user can do a re-read, etc. Go to Setup - Rereads (see page 133).

#### 3.1.1.8 Miscellaneous Dosimetry Workflow Configurations:

· Manual Mode option, Enable '0' Reader option, User Lock Out option, Filter Report List option. Go to Setup -Miscellaneous (see page 126).

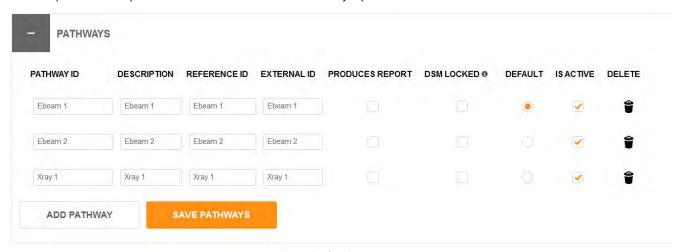
# 3.2 Setup - Pathways

The system can be configured to handle dosimetry for multiple facilities, irradiators, or pathways within each irradiator using the "Pathway" setup feature. The App Admin (see page 29) must define at least one pathway for the system to function.

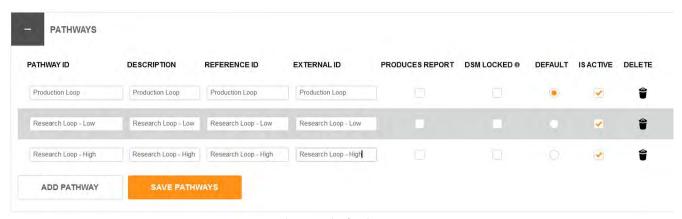


### 3.2.1 Setup a new Pathway

- 1 Enter a pathway ID, description, reference ID, and external ID to setup a pathway For example, the user may have a Production pathway and Research pathway.
  - (i) Enter the same name for all four fields of a Pathway. (If you are integrating with another system, you can name the external ID as needed.)
- 2 <u>Do not</u> check the box "Produces Report"; leave unchecked unless you are specifically instructed by GEX.
- 3 <u>Do not</u> check the box 'DSM Locked'; leave unchecked unless you are specifically instructed by GEX.
- 4 Activate a 'default' Pathway. The default Pathway is the one most commonly used. This Pathway will display as the first option in the dropdown list of options when a user creates a new dosimetry report.



Example of Pathways setup



Another example of Pathways setup

#### 3.2.2 Recommendations

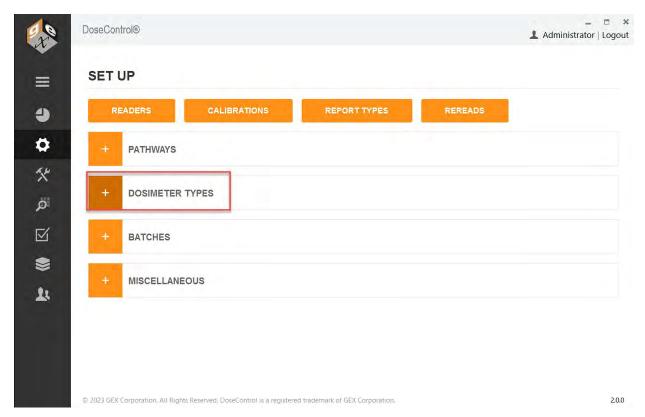
It can be useful to create multiple pathways based on the range of dose or application. For example, if an irradiator has a single pathway that is used for both routine processing and dose qualification in which the two applications may have different dosimeter calibrations.

(i) **NOTE!** A Pathway cannot be deleted from the system after the Pathway is used in a dosimetry report.

## 3.3 Setup - Dosimeter Types

(i) NOTE: Setup Dosimeter Types before you configure Batches.

DoseControl software requires you to setup the type(s) of dosimeters (B3, FWT-60, CTA, or PMMA/Perspex) will be used in the system.



## 3.3.1 Setup a new Dosimeter Type

- Enter a Dosimeter Identifier (name) and the manufacturer.
- Select a measurement Spectral Bandwidth (SBW).
  - Use option "1 small aperture / fiber" SBW for radiochromic film (B3, FWT) dosimeters.
  - Use option "3 2nm Slit" SBW for Perspex or CTA dosimeters.
  - Use option "4 1nm slit" for GAFCHROMIC dosimeters
- Enter a comment, if desired. 3
- 4 Use the checkbox to make a dosimeter type active or inactive.
- "Uses Micrometer": Select the "Uses Micrometer" checkbox if you are using the GEX supplied Laser Micrometer (GEX Product #P4350) hardware with your Evolution spectrophotometer. (PMMA dosimeters only.)
- "Edit Thickness": This permission allows the user to manually edit a thickness value on the measurement screen. The user must be assigned the 'Edit Thickness' permission by the Application Admin - this feature can be controlled by individual user permission - See DoseControl Software - User Access, Roles and Permissions (see page 27)).

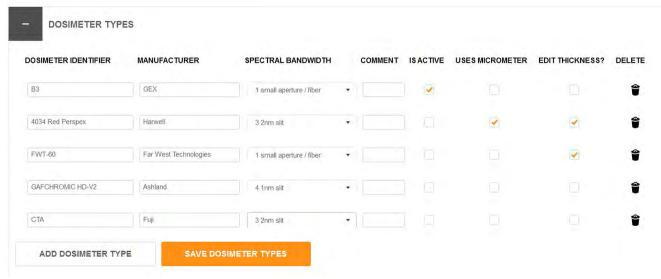


Do not select the "Edit Thickness" checkbox if you are using B3 dosimeters.



#### **USE CASE:**

'Edit Thickness' feature is useful when dealing with FWT film dosimeters where the actual measured thickness is different than the stated average.



Example of Dosimeter Types

## 3.4 Setup - Batches (Dosimeter Batch)

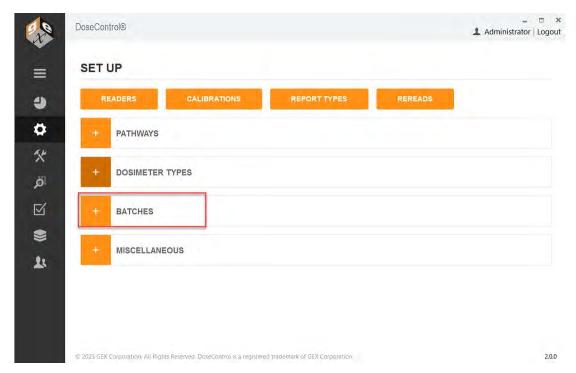
## 3.4.1 Setup a New Batch

## 3.4.1.1 Batches (Dosimeter Batch): Configuration

Dosimeters are manufactured and sorted into batches. B3 dosimeters have a 2-digit alpha code to indicate the Batch ID. Each dosimeter batch is associated with a nominal average thickness value, which is printed on the dosimeter product's Certificate of Compliance and on the product box.

## Example: Batch "DA", thickness 0.0179mm

Dosimeter thickness is used in the dose calculation, so it is important to manage different batches of dosimeters. The software links a specific dosimeter batch ID and its associated thickness value.



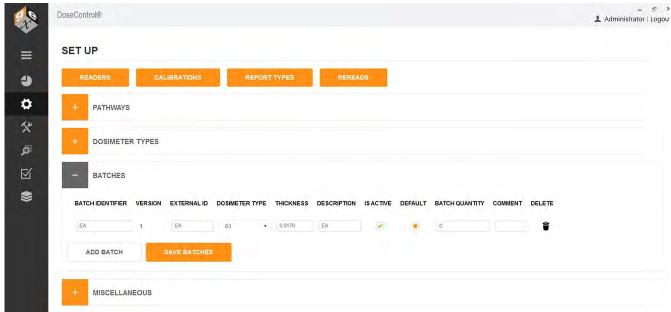
## 3.4.1.2 Instructions to setup a new Batch

Go to the Batches configuration screen.

- 1 Select the 'Dosimeter Type' from the drop-down menu.
- 2 Enter the Batch Identifier (Batch ID), and External ID. If you are using B3 dosimeters with a barcode dosimeter ID, this Batch ID must reference the two-alpha B3 dosimeter batch ID exactly and nothing more.

**Example:** CC or DA or AB. This is necessary for the barcode-reading feature to work, and for most Enterprise data 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 below for reference on how B3 should be configured.

- 3 Enter the 'Average Thickness' for the dosimeter batch. Enter numbers only (do not include millimeters 'mm').
  - **B3 dosimeters** the thickness is printed on the Certificate of Compliance received with your shipment of dosimeters and is also printed on each box of dosimeters.
- **4** Check the "Is Active" box when you are ready to make the batch and any associated calibrations available to technicians using the software.
- 5 You may enter a Quantity and any comment to go with the information (optional).
- **6** By selecting the 'Default' radio button, the batch selected will appear as the default option in the drop-down menu on the "Create New Report" screen. If a certain batch is used frequently, setting this as the default will make it easier for a technician to setup a new dosimetry report.



Example Batch setup

#### 3.4.2 Batch versions

## 3.4.2.1 About Batch Revision Level

On rare occasions, it may be necessary to have a Batch ID with two different thicknesses configured in the software. This may happen when you are using a batch of dosimeters, for example batch 'DA' with a thickness of 0.0198 mm, and then receive a new shipment of dosimeters of batch 'DA' with a thickness of 0.0188 mm. In this event, you will need to create a new version of the Batch ID 'DA'.

## Version 1: Batch ID 'DA', thickness 0.0198

## Version 2: Batch ID 'DA', thickness 0.0188

To use the version of the Batch ID, click the "Is Active" box. You will be able to measure dosimeters by selecting either of the active Batch ID's from the dropdown menu when creating a new dosimetry report.

**(i)** 

**NOTE:** You will not be able to mix multiple batch versions in a single dosimetry report because each Batch ID is linked to a specific calibration; you must select one Batch ID version to use in a report.

#### Follow these steps to create a new version of a Batch ID with a new thickness:

- 1 Go to Setup > Batches configuration screen
- 2 Find the Batch ID and type a new thickness value in the Thickness field. Click "Save".



Batch DA v1

3 Version 2 of the Batch ID will appear below version 1. Click the "Is Active" box to activate the new batch version for use.



Batch DA v2

4 Click "Save Batches" button.

## 3.5 Setup - Readers (Spectrophotometer)

 $\odot$ 

## **IMPORTANT - BEFORE READER SETUP**

<u>Before</u> using DoseControl software, setup and connect the spectrophotometer to the PC workstation.

Refer to the product specification and usage documentation for the spectrophotometer to ensure the correct setup and connection to the DoseControl software.

- Thermo GENESYS 30 Product Specification and Usage Document GEX Doc# 100-167
- Thermo Evolution Product Specification and Usage Document GEX Doc# 100-156



#### Matrix Scanner?

If you are using the integrated barcode scanner (the Matrix barcode scanner is installed with the dosimeter holder system inside the spectrophotometer):

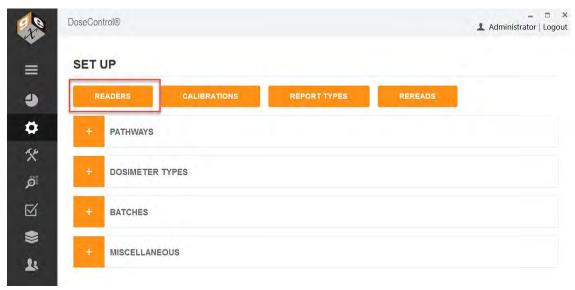
- 1. Setup the barcode scanner before using DoseControl. Refer to the product specification and usage documentation for the scanner. Matrix120 Barcode Scanner Product Specification and Usage Document - GEX Doc# 100-132
- 2. The Matrix scanner can be used for 1 dosimeter/pouch ONLY (absorbance count = 1 in Calibration (see page 80)). If you use 2 dosimeter/pouch (absorbance count = 2 in Calibration), you must use a different solution (hand-held scanner or type dosimeter ID).

## 3.5.1 About Readers (Spectrophotometers)

DoseControl controls the spectrophotometer reader, and ensures the correct reader is connected to the system to ensure data integrity. Each spectrophotometer must be configured within the software and properly connected to work with the software and PC.

## Information you will need:

- Spectrophotometer instrument serial number
- PC name (the machine name of your PC workstation to be used with the dosimetry system)
- Connection information
  - COM port number for the GENESYS 30 or Evolution
  - · Baud rate settings
- Spectrophotometer instrument calibration dates



## 3.5.2 Setup a new Reader (spectrophotometer)

- Click the "Readers" button from the Setup Menu.
- 2 Next, click the "Add New Reader" button.

- Reader ID: Enter name for the spectrophotometer that will be the on-screen and report name for this reader. Examples "Lab 1 G30 reader" "Dosimetry Lab G30".
- **Model Info:** Select the spectrophotometer model type from the dropdown.
- Is Active: The instrument status. Check "Is Active" if the instrument will be used in the dosimetry process. 5
  - (i) Uncheck the "Is Active" tick box when you want to remove the reader from service, and the software will prevent any user from making measurements with that instrument even if they connect it to a DoseControl PC.
- 6 Min Reading Value: The minimum absorbance that should be considered a valid measurement.
- Thermo GENESYS 20 specification for min reading value is "0.001".
- Thermo GENESYS 30 specification for min reading value is "0.001".
- Thermo Evolution specification for min reading value is "0.001".
- 7 Max Reading Value: The minimum absorbance that should be considered a valid measurement.
- Thermo GENESYS 30 specification for max reading value is "2.5".
- Thermo GENESYS 30 specification for max reading value is "3".
- Thermo Evolution specification for max reading value is "4".
- NOTE: The software will flag measurements outside the reader's Min/Max range as invalid measurements. The data is retained but the value is not counted as a "measurement" or a "reread"; the value is flagged as archived in the database.
- Serial Number: Enter the serial number of the Evolution or GENESYS 30 spectrophotometer as it appears on the equipment tag. The software verifies the instrument's serial number upon initialization (when the software is first opened), before every zero "0" of the GENESYS 30, and every dosimeter measurement; this S/N verification provides measurement data traceability.

⚠ CAUTION: If the reader's serial number configured in the software does not match the actual serial number of the reader connected to the system, the instrument will not operate.

- (i) NOTE: For the older models of Thermo spectrophotometers, the serial number of a GENESYS 20 cannot be electronically verified by the software (GENESYS 20 readers cannot be used as part of an FDA 21 CFR part 11 compliant system). However, you may enter the serial number of the GENESYS 20 in the "Serial Number" field for record keeping purposes.
- **Description:** Enter descriptive information about the spectrophotometer. The purpose is to help to the Application Administrator in large organizations identify one reader from another. Example: "located in the lab" or "G30 ABC123 located in Lab 1".
- Make (Optional): Enter the reader's manufacturer name, if desired, "Thermo Scientific". 10
- 11 Client Machine Name: Enter the exact Microsoft Windows PC name. The software will verify that it is connected to this specific PC each time the software is opened; and the software will give an error message and prevent use of the measuring functions if this PC name is configured incorrectly. The Client Machine Name verification provides measurement data traceability.

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Go to your PC settings, device specifications (Windows search 'View your PC Name')

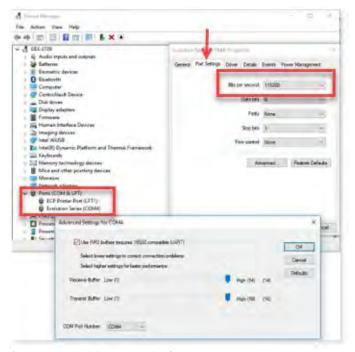


A CAUTION: If the PC Name configured in the software does not match the actual PC name of the PC connected to the system, the instrument will not operate.

- 12 Zero (Optional): Enter a maximum idle time (in minutes) for the spectrophotometer before the system alerts the user to zero "0" the reader.
  - (i) When the configured time expires, the software will alert the user to zero "0" the instrument. This can happen at inconvenient times. We recommend that you do not use the Zero option. Instead, make the "zero reader" button on visibile on the measurement screen to allow users to zero at will - see Setup - Miscellaneous (see page 126).
- 13 COM Port Number: Ensure the spectrophotometer has been installed and connected as per the instructions given in the reader's product document (see page 0).

Enter the COM port number of the connected spectrophotometer.

- To find the COM port number, on the PC go to "Device Manager" and "Ports (COM and LTP)". Find the instrument located in the list under "Ports".
- Right-click and select 'properties' and 'advanced' to display and/or change the port settings.



- **14** Baud Rate (bits per second): Enter the baud rate into this field.
  - Use a baud rate of 115200 for the GENESYS 30 and Evolution.
  - · For the GENESYS 20 use 9600.



MPORTANT Ensure the same baud rate entered in this field is the same displayed in the MS Windows' Device Manger; they must match. Follow the directions above for how to find the port/baud settings on the PC.

#### 15 Requires Barcode Scanner (internal barcode scanners only):



Do not tick this box if you have an external barcode reader. You can use an external barcode reader to scan dosimeter IDs, but you do not need to set up external readers in the Reader configuration.

Tick this box if the reader has an internal barcode reader (Matrix 120 barcode scanner), installed with the GEX holder system inside the reader.

• The Scanner S/N (serial number) and Scanner COM Port will automatically populate if the scanner is setup and connected to the PC.



## (i) IMPORTANT

For DoseControl software version 1.5.x and higher the previous barcode scanners sold with the system, the Microscan MS-2 and MS-3, are no longer supported in the DoseControl software. Users must upgrade to the Datalogic Matrix 120 barcode scanner to retain barcode scanning functionality.

- 16 Laser Micrometer (PMMA dosimeters only): Tick this box if reader has an internal laser micrometer installed on the GEX holder system inside the Evolution reader.
  - Locate the port number for the laser micrometer in the PC's Device Manager.
  - Baud rate will be **115200**.
- 17 Last Calibration Date: Enter the Date the spectrophotometer was last calibrated or the date of the last complete performance verification. You do not need to enter a Last Calibration Date if you do not want to use this feature!
- 18 Next Calibration Date: Enter the Date the spectrophotometer must be calibrated next or the date that a complete performance verification is required. The Application Admin may change this date anytime as needed. You do not need to enter a Next Calibration Date if you do not want to use this feature!



## WARNING

The system will prevent measurement activities if the spectrophotometer is not within the specified calibration date timeframe. If the "Next Calibration Date" has expired, the software will show an error message (see example below). You must perform the performance verification for the spectrophotometer and the DoseControl App Admin must change the Reader's "Next Calibration Date" to a new date in the future.

**19 Comment (Optional):** Enter a comment regarding the spectrophotometer.

## 3.6 Setup - Calibrations (Dosimeter Batch Calibration)

#### 3.6.1 About Calibrations in DoseControl

#### 3.6.1.1 What is a 'Calibration'?

A Calibration is a short word for a 'Dosimeter Batch Calibration' (also called a Dosimetry System Calibration).

The end-user typically performs a Dosimeter Batch Calibration for each dosimeter 'batch', the irradiation pathway, and a specific reader (spectrophotometer). The Calibration is a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by (dose) standards. Routine dosimetry systems should be calibrated in accordance with the requirements of ISO/ASTM 51261.

As a result of the Dosimeter Batch Calibration activities, the certified calibration laboratory will provide the end-user with a calibration curve. The calibration curve is a mathematical expression of the relation between dosimeter response and corresponding value of dose certified traceable to a national or international standard dose.

Read More: How DoseControl calculates dose (see page 5)

## 3.6.1.2 Calibration format used by DoseControl

You calibration laboratory must be fit the calibration curve as Response = f(Dose), where dosimeter response is the dependent variable y, and dose is the independent variable x.

Response (R) =  $a + bx + cx^2 + dx^3 + ex^4$ where R = (Ai-Ao)/T

## 3.6.1.3 How do Calibrations work in DoseControl?

The end-user will input the calibration curve coefficients provided by the lab into the Calibration setup screen (see page 80) in the DoseControl software. DoseControl software will use the calibration curve coefficients to calculate dose.

- A Calibration is specific to an active dosimeter Batch (see page 72), active Reader (see page 75), and active irradiation Pathway (see page 68) in the software. If any of these items are "inactive", the Calibration will automatically inactivate.
- You must have an active Calibration to measure dosimeters in the software.

The Next Step: Setup a new Calibration in DoseControl (see page 80)

## 3.6.2 Setup a New Calibration



#### Prequisite

Before entering a new Calibration, make sure the Calibration's associated Pathway (see page 68), Batch (see page 72), and Reader (see page 75) are setup and "active" in the software.

Only the Application Administrator (see page 29) or global admin user can setup a Calibration.

## **New Calibration Setup options**

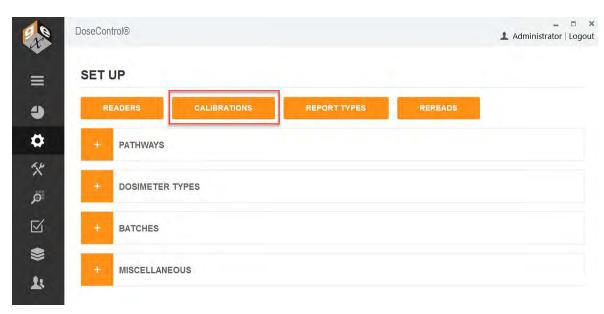
There are two ways to set up a new calibration in DoseControl:

- 1. Enter the configuration data manually
- 2. Import a Calibration (see page 85) directly into DoseControl.

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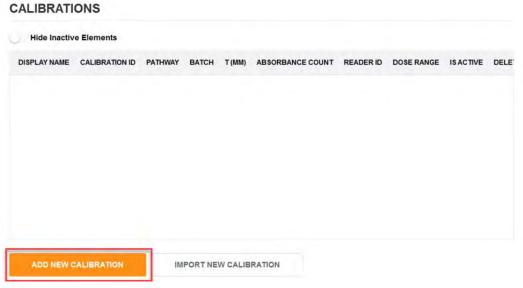
DoseControl Software User Guide 100-266 - - DoseControl Software Setup for Dosimetry

Publish date: Nov 15, 2023



## 3.6.2.1 Manual Setup

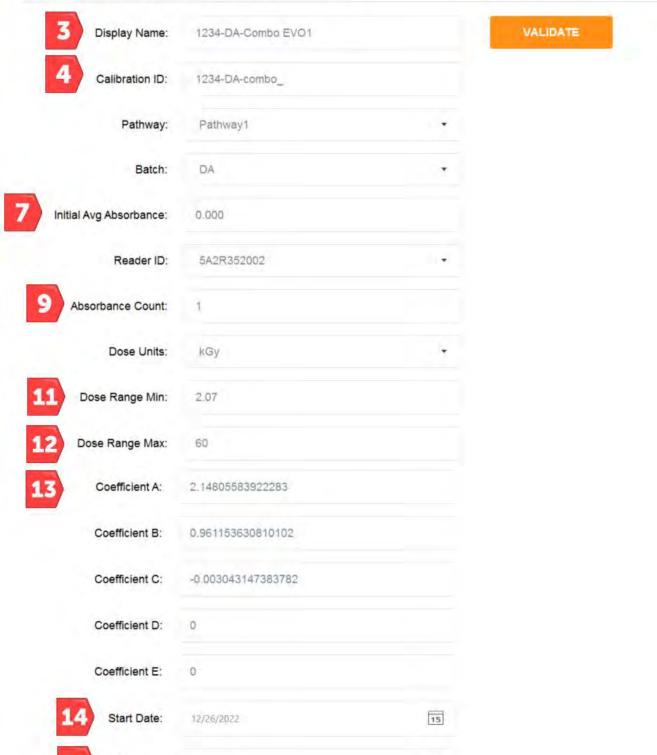
- 1 On the Set Up screen, click the "Calibrations" button.
- 2 On the main Calibration screen, click the "Add New Calibration" Button.

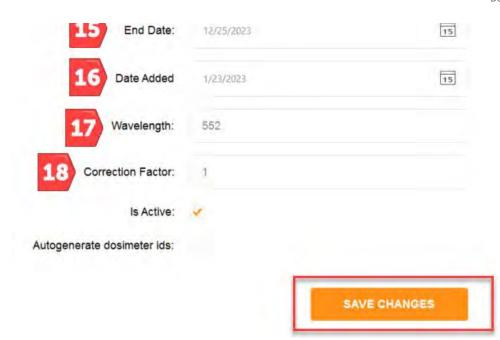


## 3.6.2.2 Enter Calibration information



# EDIT CALIBRATION: 1234-DA-combo\_





- **Display Name**: Enter the name of the calibration to be displayed onscreen and in reports. This may be equivalent to the calibration ID or may be some other identifier that is easy to use. This calibration Display Name must be unique within the system.
- **4 Calibration ID**: Enter a calibration ID number that is generated at the time of curve fitting that uniquely identifies the specific curve being used. This field provides reference to an external calibration report and associates it with certificates and traceability to a specific laboratory. Calibration ID must be unique within the system.
- **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.
- **6 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.
- 7 **Initial Avg. Absorbance:** Enter the initial average absorbance for the dosimeter, if any, to be used in the calculation of net absorbance  $\Delta A_{\lambda}$ . Enter '0' or leave the field empty for no value.
- **8 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.
- **9 Absorbance Count**: Enter the number of dosimeter replicates in the dosimeter package or pouch this number will be specific for your dosimetry process. If a pouch has 1 dosimeter, replicate A, or so forth, enter "1". If there are 2 dosimeters in a pouch enter "2". The software will associate that there must be 'X' number of dosimeters for each dosimeter ID up to a maximum of 4.



#### **CAUTION**

If you are using the <u>statistical rereads method</u> (see page 136) for re-reading dosimeters, the statistical rereads feature will only work if the absorbance count is "1". For more information, see <u>Setup Rereads</u> - <u>Configuration</u> (see page 136).

- **10 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.
- **11 Dose Range Min**: Enter the <u>minimum dose from the calibration</u> so that the software will warn users when the measured dose is below this range. You can find the minimum dose from the calibration certificate provided by the certified calibration laboratory.
- **12 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. You can find the maximum dose from the calibration certificate provided by the certified calibration laboratory.
- **Coefficient A through E (0 4)**: Enter each of the calibration coefficients using the full number of significant digits, in the order of a + bx +  $cx^2 + dx^3 + ex^4$ . If there is no coefficient value, enter a '0'.

## Example calibration curve fit coefficients from the lab:

wõ.	A	В	C	D	E	F	G	H	T.	J	K
1	CALID	CALDATE	SETTING	MACHINE	COMM	CURVETYPE	COEF0	COEF1	COEF2	COEF3	COEF4
2	1234-DA-combo	12/27/2018	552nm	Combo		Quadratic	2.14805583922283	0.961153630810102	-0.00304314738378152	0.0000	0.0000
3									_	-	
4							Α	В	C	D	E

## Calibration configuration setup in DoseControl:

2.14805583922283
0.961153630810102
-0.00304314738378215
0
0

- **14 Start Date**: Select the Date on which the calibration will become active. The Application Administrator can set a date in the future when the calibration will become active, if needed. Otherwise, use today's date.
- **15 End Date**: Select the Date on which the calibration should become inactive. The Application Administrator can set how long a calibration may be used. This date is editable after the fact so that the administrator can extend the use of a calibration, if desired. Changing the End Date is an audited event.
- **16 Date Added**: Autogenerated date when the calibration is added to the software.
- **17 Wavelength**: Enter the wavelength of measurement in nanometers (nm) that is used for the calibration. For B3 dosimeters, this wavelength is 552 (unless otherwise indicated on your calibration certificate provided by the certified calibration laboratory). Enter <u>without</u> any units (e.g. '552').
- **18** Correction Factor: Enter a linear correction factor to be applied to the measured dose.



**Enter a value of "1.0" if there is no correction factor used in your calibration (most typical).** A correction factor can be used for a variety of reasons but is not common.

- 19 Is Active: The calibration must be checked as 'Active' to be used in the software. The system will automatically inactivate a calibration if pathways, readers, or batches associated with the calibration are inactivated.
- 20 Auto generate Dosimeter ID's: Check this box to have the system automatically generate random Dosimeter ID's. Use this feature only if you DO NOT want the user to manually enter Dosimeter IDs or if you are not using a barcode scanner to enter Dosimeter IDs. For example, if the user wants to simply read dosimeters in sequence and not add the extra time of manually typing dosimeter ID's.



#### (i) IMPORTANT

Currently, the Auto-generate Dosimeter ID feature cannot be changed or 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.

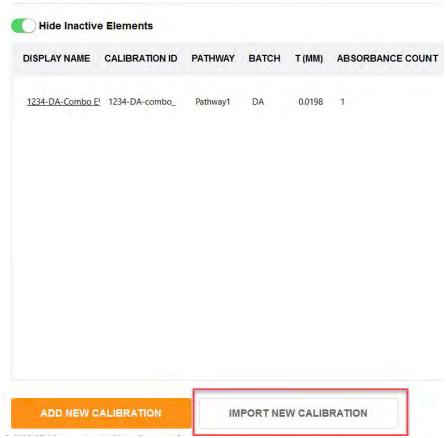
- 21 Check the "Is Active" box to activate the new calibration for use.
- **22** To finish, click "Add Calibration" button.
  - 3.6.2.3 Import a Calibration



Import feature is only available for GEX calibration files CALDAT.xlsx. For calibrations provided by other calibration laboratories, please manually configure the calibration information directly into the software.

On the Calibration Set Up screen, click the "Import New Calibration" button.

## **CALIBRATIONS**



- **2** Browse for the CALDAT.xlsx file.
- 3 Click the carrot icon to import.

## **Select Calibration**



- 4 Most of the calibration information is directly import into the new calibration setup. To complete the new calibration setup, complete the missing fields (see field descriptions above).
  - (i) **NOTE** The software will round the calibration coefficients to 15 decimal places.
- 5 Check the "Is Active" box to activate the new calibration for use.

(i) NOTE

You cannot delete a Calibration or edit any fields in the Calibration after it has been used in the software. 21CFR Part 11 compliance.

(i) NOTE

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

## 3.6.3 Change an Existing Calibration

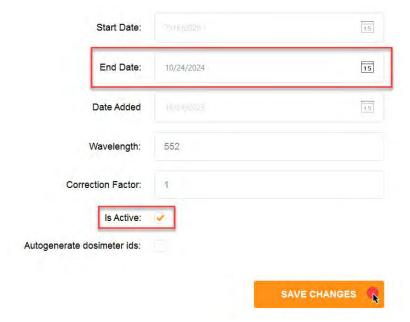
(i) Only the Application Administrator (see page 29) or global admin user can setup a Calibration.

(i) Once a Calibration is used in the software, only the "End Date" field can be edited (only in DoseControl v2.0.0 and higher). All other fields are not changeable. You can copy an existing Calibration to make a new Calibration, and change any necessary fields.

#### 3.6.3.1 Edit the Calibration End Date

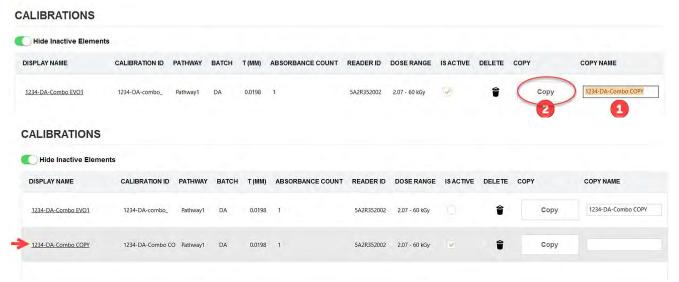
Once the Calibration End Date is expired, the software will not allow dosimeter measurements using this Calibration. You need to perform a dosimeter batch calibration.

To change the End Date, open the Calibration and change to a date in the future. Click "Save". (This action is recorded in the audit log as a configuration change event.)



## 3.6.3.2 How to Copy an Existing 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.



The newly created copy calibration will be activated, and the original calibration will be deactivated. Open the new calibration that you 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".

## 3.6.4 Verify the Dose Calculation Accuracy of a Calibration



#### Verify the Calibration before using!

Read ASTM 51621:2013 for guidance about how to verify your calibration. The calibration "validate" feature in DoseControl is designed as a helpful tool but does not replace the ASTM 51621 guidance.

## 3.6.4.1 Easy Calibration Function Verification

The Calibration setup screen features a push-button verification test report using the "Validate" button. This feature helps the Application Admin to verify the dose calculation is correct before activating a calibration in the software.



- 1 Click "Validate" button to create the Calibration Function Output Verification.
- **2** Compare the Absorbance (A) and Calculated Dose (kGy) fields on the Calibration Function Output Verification report to the Dose Table from the calibration (the dose table is provided by the calibration laboratory).
- 3 Confirm the Calibration's information is correct, such as the coefficients and dose range, and document the results on paper.

## **Calibration Function Output Verification**

Calibration Name: 1234-DA-Combo EVO1 Calibration ID: 1234-DA-combo\_ Report Created: 24 Jun 2023 09:09:48 Wavelength: 552nm Min / Max Dose: 2.1 / 60.0 (kGy) Initial Abs: 0.000 Pathway ID: Pathway1 Batch ID: DA Batch thickness: 0.0198 Reader Serial #: 5A2R352002 COEFF. A: 2.14805583922283 COEFF. B: 0.961153630810102 COEFF. C: -0.003043147383782 COEFF. D: 0 COEFF. E: 0

Α	Calculated Dose (kGy)			
0.050	N/A			
0.100	3.0			
0.200	8.5			
0.300	14.2			
0.400	20.1			
0.500	26.2			
0.600	32.7			
0.700	39.5			
0.800	46.7			
0.900	54.4			
1.000	N/A			
1.100	N/A			
1,200	N/A			
1.300	N/A			
1.400	N/A			
1.500	N/A			
1.600	N/A			
1.700	N/A			
1.800	N/A			
1.900	N/A			
2.000	N/A			
2.500	N/A			
3.000	N/A			
3.500	N/A			
4.000	N/A			

Signature:	Date:	
0.5-0.20	1000	

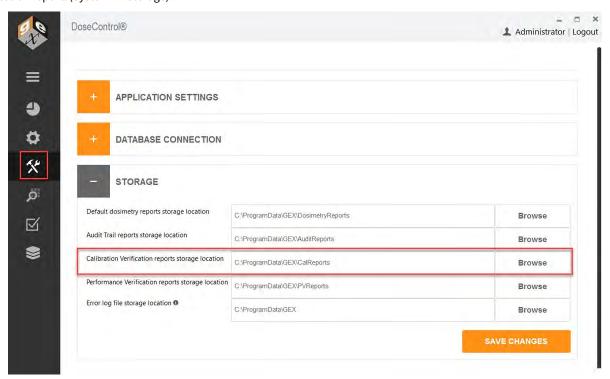
Example Calibration Function Verification report PDF

Publish date: Nov 15, 2023

Created by: admin

**4** The Calibration Function Output Verification report is a secure PDF file that can be saved or printed. The report is automatically saved to the configured report storage location.

The System Administrator or global administrator (see page 27) can change the storage location of the Calibration Function Output Verification report. (System  $\rightarrow$  Storage).



## 3.7 Setup - Dosimetry Reports

## 3.7.1 Overview: Dosimetry Report Setup

## 3.7.1.1 What are Dosimetry Reports?

DoseControl uses reports to organize dosimeter measurements and contextual information related the those measurements. The DoseControl reporting feature of the software is highly flexible. You can create different report types, add custom header fields to each report type, and control when the report is viewed, saved, or printed. Reports can be output to Excel or secure PDF format.

When a technician begins the dosimeter measurement process in the software, all the active Report Types are displayed in a dropdown menu to the user. The technician must choose one of the available Report Type options, and then the software will prompt the user to enter any report header information required for the report. After entering information into the report header fields, the user can begin dosimeter measurements.

When the the report is completed, the user can view, save or print the report in **Excel** or **secure PDF** format (based on the allowed output options).

👉 Read More: Learn about the Report management and dosimeter measurement workflow (see page 153).

#### 3.7.1.2 Report Output Formats

Any of the process and measurement data recorded by DoseControl can be output into a report, in either MS Excel or secure PDF file formats.

- MS Excel Reports DoseControl exports report data into Excel, and the data can be used in a variety of ways. You can build your dosimetry report template however you want, and then upload the template file into DoseControl to use for your dosimetry reports. For details - go to About Excel Dosimetry Report (see page 106)s.
- PDF Reports DoseControl exports report data into a PDF format. The PDF reports are secure and not editable. For details - go to About PDF Dosimetry Reports (see page 115).

## 3.7.1.3 Report Types

The Report Types 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. It can have a significant impacton the workflow that the technician will routinely follow for a specific measurement activity. It can also be integral to capturing information to which the dosimetry pertains.

You can create Report Types specific to a dosimetry activity. Flow to setup Report Types (see page 96).

Example Report Types:

- · Routine Dosimetry Report
- · Production Dosimetry Report
- Research Loop Dosimetry Report
- Test Dosimetry

- · E-Beam Energy Report
- · E-Beam Uniformity Report
- Dose Mapping
- · Dosimeter batch calibration

#### 3.7.1.4 Report Header Fields

Each Report Type can be configured with report header fields that are unique to your process and your company. For basic dosimetry reports, you do not need any report header fields!



Do not confuse the customizable Report Header fields with the information automatically captured by the software. The software records all the dosimetry information associated with each dosimeter measurement, such as the reader (spectrophotometer) ID of the instrument used to make a measurement, the dosimeter batch calibration ID, the irradiation pathway ID, etc.

Examples of report header fields that users input into dosimetry reports:

- · Description of the product or process to which the dosimetry pertains Run ID, Process Control Number (PCN), Product ID, Product Name, Product Desciption, Batch Number.
- Irradiation specfications such as Minimum Required Dose (min dose) and Maximum Acceptable Dose (max dose).
- Correlation Factors used to calculate dose in one location to another (e.g. Dref:Dmax Ratio)
- E-beam information, power, current, conveyor speed, etc.
- Date of irradiation
- Confirmation of dosimeter heat treatment (Y/N?)

The data that the operators enter into a report's "header" will be stored as part of the electronic record for a given report. 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.

👉 How to set up Report Header fields (see page 99).

Publish date: Nov 15, 2023

## 3.7.1.5 Auto-fill report header field information

There are ways to make the software automatically fill the report header fields.

- Product Specification Module (see page 195)
- Integrate DoseControl with other systems. Report header field values can be imported into DoseControl from another system.

## 3.7.1.6 Report Output Controls

You can setup how the reports can be viewed, output, and in what format (PDF or Excel). See Control Report Output Options (see page 103).



The Application Admin (see page 91) user can configure dosimetry report types, header fields and output controls.

## 3.7.1.7 About Reference Dose Reports

Routine process monitoring may use a reference dosimeter placed in a set location during the irradiation process. The reference dosimeter verifies the product's dose specification conformance.

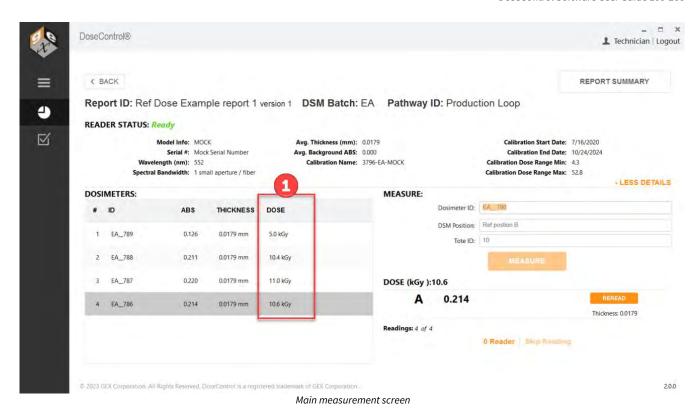
Product dose mapping establishes the minimum dose specification (Min Dose Spec) and maximum dose specification (Max Dose Spec), and defines the ratio to the reference dosimeter location (Ref to Min Ratio and Ref to Max Ratio).

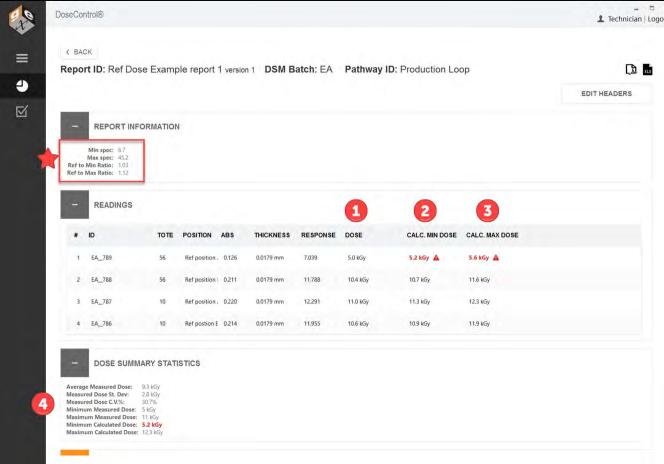
#### How does a "Reference Dosimetry" report type function in DoseControl?

A Ref Dose report functions different from a standard report. The main measurement screen will look the same, but the Report Summary screen will show the calculated minimum and maximum dose for each dosimeter based on the process specification. The Report Summary screen will display the Dose, the Calculated Minimum Dose (Dose \* Ref:Min ratio), and the Calculated Maximum Dose (Dose \* Ref:Max ratio).

process specification report header fields values display the Min Dose Spec, Max Dose Spec and the Ref:Min Ratio, Ref:Max Ratio.

- 1 Dose value
- 2 Calculated Min Dose (Dose \* Ref:Min ratio = Calc. Min Dose).
- 3 Calculated Max Dose (Dose \* Ref:Max ratio = Calc. Max Dose)
- 4 Dose Summary Statisitics this section displays a summary of results in the report.





Report Summary screen with calculated doses based on the reference dosimetry values

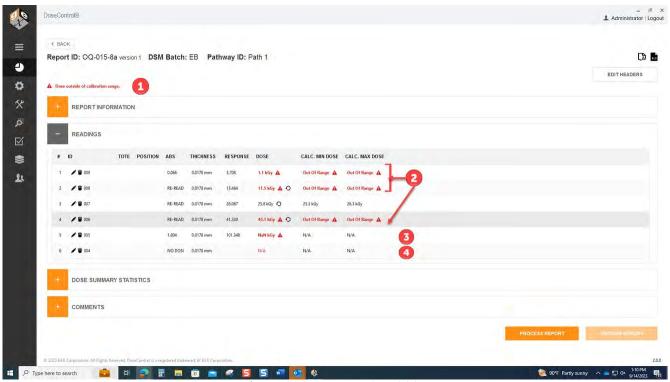


If the calculated min or max dose value is outside the Min/Max Dose Specification, the value will appear in **bold red font** with an alert icon.

### How does the Ref Dose report type handle invalid dose values?

The dosimeter batch calibration has a dose range. If a dose is outside this range, the dose is not valid. A Ref Dose report will display invalid doses as follows:

- 1 Alert message at the top of the Report Summary screen "Dose outside of the calibration range"
- 2 Dose numerical value in red font with alert icon. Calculated Min/Max Doses display "Out of Range" with alert icon.
- **3** If a dosimeter measurement is so far outside the calibration range that a **Dose** value cannot be calculated as a number, the software displays "NaN" in red font with alert icon. **Calculated Min/Max Doses** display N/A.
- **4** If a dosimeter measurement is skipped (no measurement), the software displays "NODOSI" for the **Dose** and **Calculated Min/Max Doses** display N/A.



Reference dosimetry report with invalid doses

- 👉 Learn more about how DoseControl handles valid and invalid doses (see page 5).
- FNext steps: How to Setup Dosimetry Reports (see page 91)

## 3.7.2 Setup - Report Types

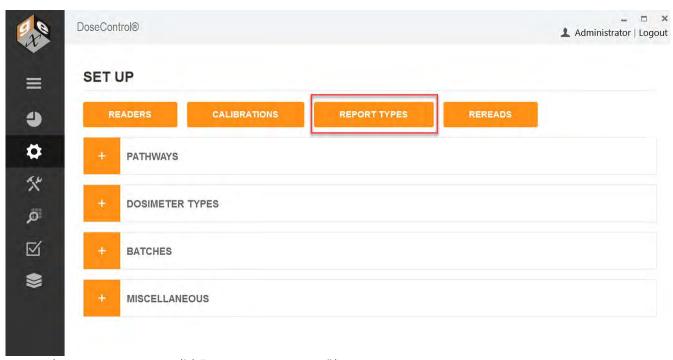
The Application Admin must set up dosimetry report types and report headers prior to using the software to make dosimeter measurements or creating reports.

## 3.7.2.1 Who can configure Report types?

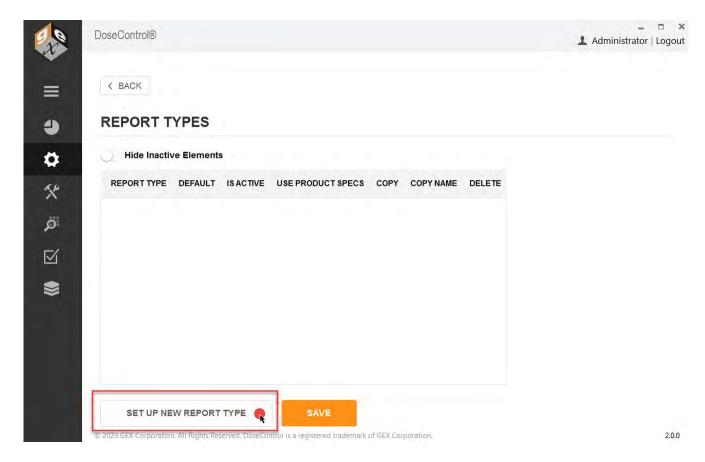
The Application Admin user (see page 29)can create new dosimetry report types and configure report headers. Each report type can have different data fields and layouts, depending on specific reporting needs and requirements.

## 3.7.2.2 How to Setup New Report Types

- 1 Open Set Up by clicking the sprocket icon.
- 2 Click on the "Report Types" button.

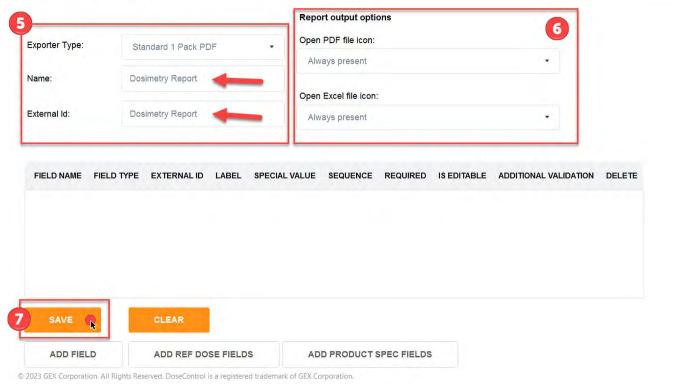


**3** On the Report Types screen, click "Set Up New Report Type" button.



- 4 Select "Exporter Type" from the dropdown menu.
  - (i) You must select an 'Exporter Type' for your report, regardless if you plan to output reports in Excel or PDF format.
    - For a PDF report select the appropriate PDF template for Exporter Type
    - For an Excel report select the "Standard 1 Pack PDF" for your exporter type.
- 5 Type a **report name** into the "Name" field; copy the report name into the "External ID" field.
- 6 Select the **Report Output Options.** You can control the report file output (Excel/PDF icons) options. **More details** see Control Report Outputs and Visibility (see page 103).
- 7 Click 'Save' to save the new report setup.

## SET UP NEW REPORT TYPE



New Report Type set up screen

FNext step: Add report header fields to a report type setup (see page 99) (if needed).

## 3.7.2.3 Setup Report Header Fields

## What is a "Report Header Field"?

DoseControl captures most necessary dosimeter measurement information (batch, calibration, reader information, logged-in user, etc.), but you may want additional content on your reports.

A "report header field" is a field that you create in the Report Type setup.

An example of a "report header" would be your process number, product number, process or product descriptions, or anything else relevant to your specific products and process. If you want the operator/technician to enter a Process number for each report, you will need to configure this field in the report header setup.

Another example: If you use a reference dosimeter you will want the Min Dose Spec, Max Dose Spec, Ref:Min Ratio and Ref:Max Ratio report header fields.

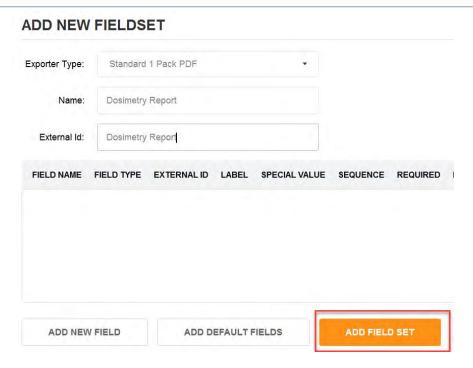
## Before you start

Setup a Report type (see page 96). You must have a new Report type setup in the software before you can add the header fields to the report.

## Add Report Headers fields in a Report Type configuration

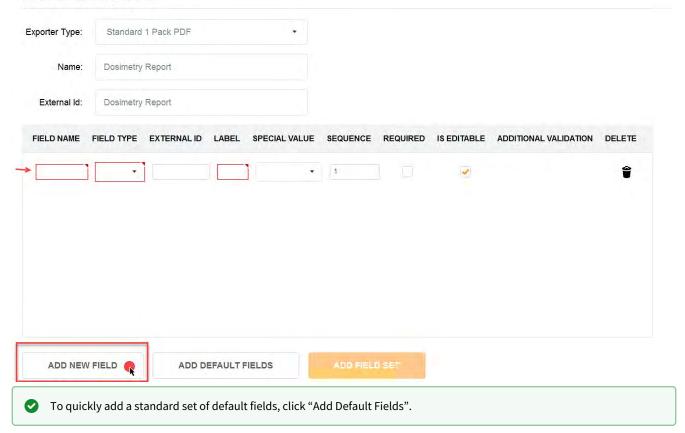
1 After you have created a Report type (see page 96), if no additional report header fields are needed, click "Add Field Set" button on the bottom of the screen to save the new report type.

(i) You may not want any extra report header fields on your report. You will still need the Report type setup in the software.



2 Next, you can add report header fields by clicking "Add New Field" button.

## ADD NEW FIELDSET



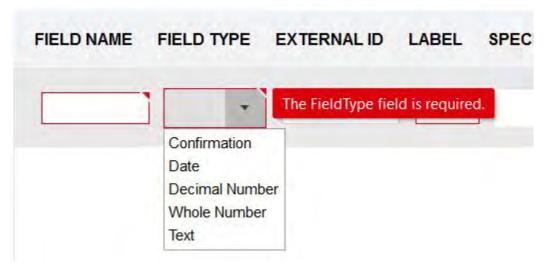
3 Enter each field's data information.

**Field Name:** this is the name given for the field. For example, if you need the user to enter the Minimum Dose Specification you might assign a field name of "Min Dose Spec (kGy)".

**External Identifier:** copy the Field Name. The external identifier is only used in import circumstances for Enterprise license users.

**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 user).

**Field Type:** select the data type of field from the five options available in the drop-down menu:



*Confirmation:* creates a "yes or no" field where the user can confirm something or not. Example "Were dosimeters heat-treated?"

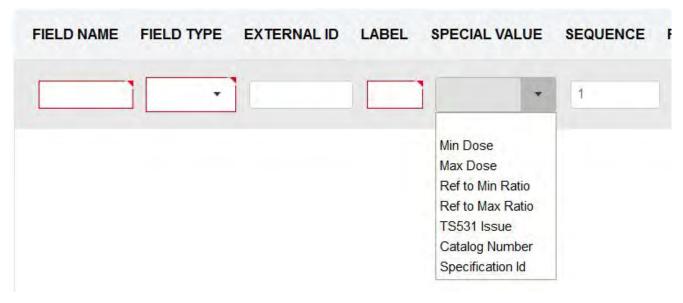
*Date:* creates a date field where the user will select a date from the calendar that will default to the date of when the user is completing the field.

Decimal Number: creates a numeric field that allows decimal numbers.

Whole Number: creates a numeric field that allows whole numbers.

Text: creates a field for alphanumeric entries.

**Special Value:** this field is usually left blank; select the Special Value from the dropdown if required. Special Value calculations in the software for the following reference dosimetry information:



**Min Dose** – allows the user to be able to enter a Minimum Dose Specification for dosimetry reports to facilitate comparison of Dmin doses against the Min Dose Specification when creating dosimetry reports.

**Max Dose** – allows the user to be able to enter a Maximum Dose Specification for dosimetry reports to facilitate comparison of Dmax doses against the Max Dose Specification when creating dosimetry reports.

**Ref to Min Ratio** – allows the user to be able to enter a Correlation Factor DRef/Dmin. The software will calculate all measured doses against the ratio.

**Ref to Max Ratio** – allows the user to be able to enter a Correlation Factor DRef/Dmax.. The software will calculate all measured doses against the ratio.

TS531 Issue - Disabled. Do not use.

Catalog Number - for Product Specification Module (see page 195) only.

Specification ID - for Product Specification Module (see page 195) only.

To setup a reference dosimetry report type, see Ref Dose 1 Pack PDF Report Setup (see page 120) and Ref Dose 2 Pack PDF Report Setup (see page 123) instructions.

**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?:** This will set the field as "required" (the user must fill in the field for each report) – <u>Tick both the "Required" and "Is Editable" boxes to enable the required field.</u>

**Is Editable:** Always keep the "Is Editable" box checked. "Is Editable" feature allows users to make changes to entered information in a report header field, in the event of this information is not completed or mis-typed in a dosimetry report. The "Is Editable" feature is disabled only for integrated systems with information imported from other systems (Enterprise License only.)

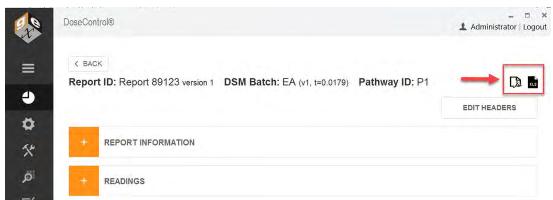
**Additional Validation** – add field validation requirements (if needed). Click "Edit" button to enter requirements. This adds parameters for the user and will alert the user if the field entry is outside these parameters. Examples of additional validation requirements for field: min/max limits for the number of characters allowed in the field (example: limit to a 10-digit entry), min/max range limits for dose minimum and dose maximum.

4 When finished, **click "Save Changes"** button on the bottom of the screen to save the new report type.

### 3.7.2.4 Control Report Outputs

The Application Admin (see page 27) user can control report outputs.

The default setting is to allow both Excel and PDF print icons on the report screen at all times.



Default functionality: PDF icon and Excel icon are active and visible on the Report's Summary screen at all times.

You can change the setting to allow a variety of report output options, for example:

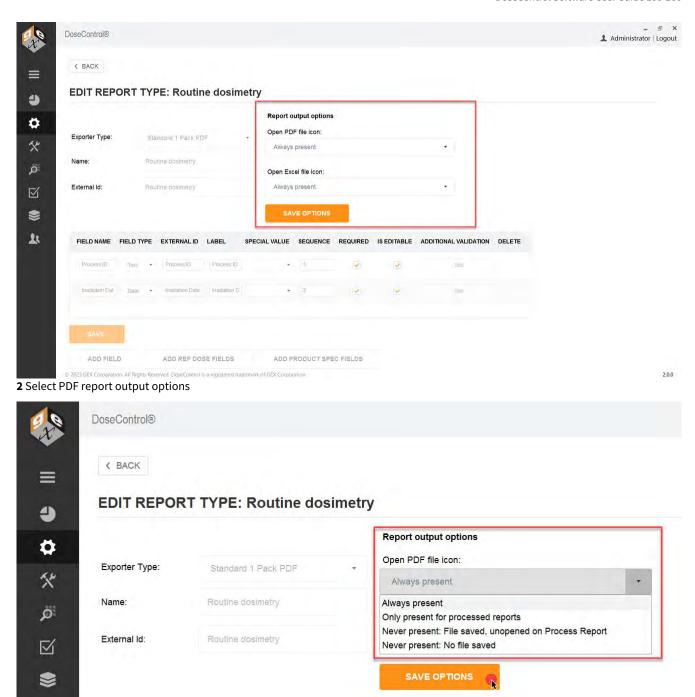
- Only allow PDF format
- Only allow Excel format
- Only allow users to see and print a "processed" report
- Automatically save a report (PDF or Excel format) to the report storage location when the "Process Report" button is clicked and never allow the user to see or physically print a report.

## Before you start

Setup a Report type (see page 96). You must have a new Report type setup in the software before you can add the header fields to the report.

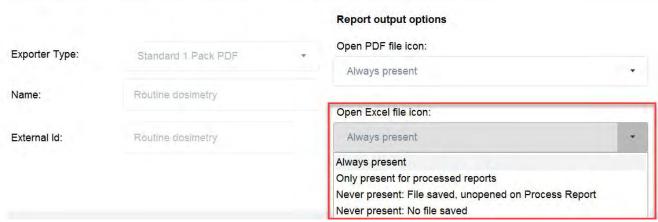
## **Instructions to Control Report Export/Printing**

1 After you have created a Report type (see page 96), change the Report Output Options as desired.



3 Select Excel report output options

# **EDIT REPORT TYPE: Routine dosimetry**

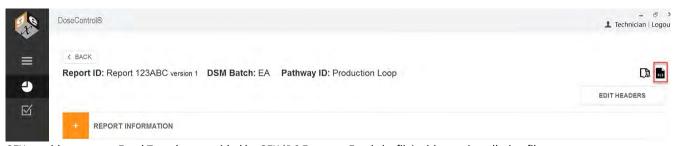


4 Click "Save Options" button

## 3.7.3 About Excel Dosimetry Reports

## 3.7.3.1 About the DC Export to Excel Template

When the user clicks the Excel icon on the report summary screen, DoseControl exports the report data to the DC Export tab of the Excel.xlsx file.

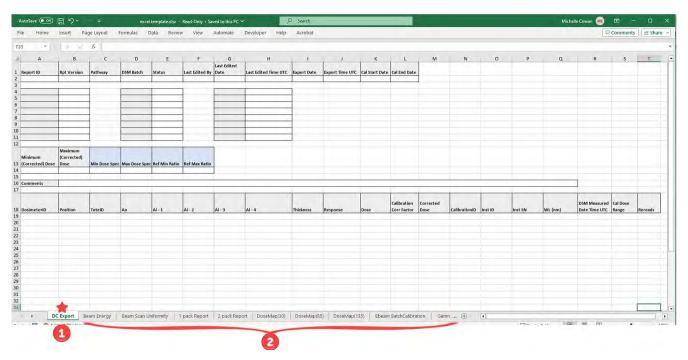


GEX provides a starter Excel Template provided by GEX (DC Export to Excel.xlsx file) with your installation files.

- 1. **DC Export tab** this tab cannot be deleted! Data is exported to this tab.
- 2. **Your Report tabs** Various Report Types (different reports that you have setup under "Report Types" have cells that link to the cells in the DC Export tab. GEX provide standard Excel report templates (see section below), but you can alter or delete these report tabs as needed.

Δ

Do not delete the DC Export tab in the Excel template file. DoseControl exports report data into this tab.



## 3.7.3.2 Customize your Excel Report Template

DoseControl exports report data into Microsoft Excel format, and the data can be used in a variety of ways.

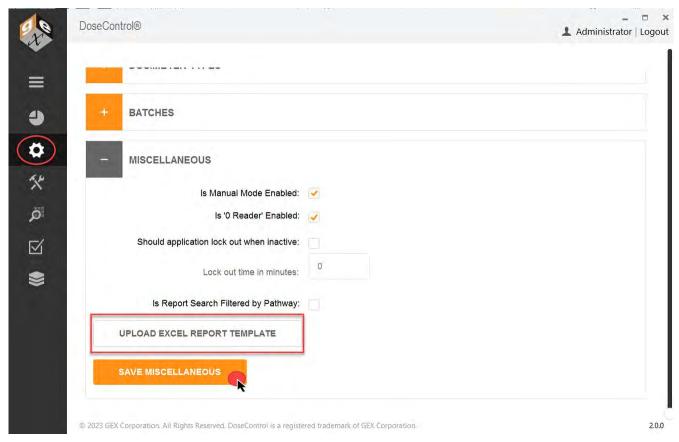
Step 1: Use the starter Excel Template provided by GEX (DC Export to Excel.xlsx file with your installation files)

**Step 2:** Setup a Report Type (see page 96) (Setup → Report Types). Use the "Standard 1 Pack PDF" exporter type (or any PDF exporter type), enter a report name, and setup the report header fields (see page 99).

**Step 3:** Edit the Excel Template (*DC Export to Excel.xlsx*), and rename it. Use **linked cells in Excel** to build your dosimetry report template's layout and data, and it is completely customizable. You will link the relevant exported data in the Excel report's **DC Export tab** to your report's tab.

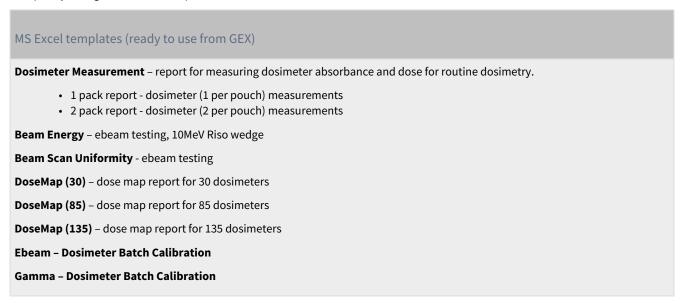
- How to customize Excel report templates (see page 111).
- Learn more about the DC Export fields (see page 109)

**Step 4:** When you finish customizing your Excel template .xlsx, save it. Next, upload the DC Export to Excel Template (see page 129) into DoseControl to use for your dosimetry reports. For detailed instructions, go to How to use Excel report format in DoseControl.



#### 3.7.3.3 Standard Excel Report Header Templates

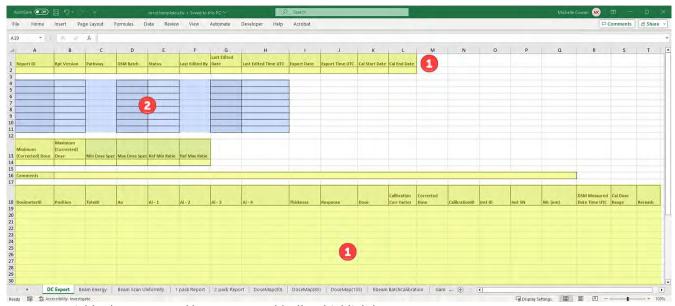
GEX provides generic reports in Excel format (*DC Export to Excel.xlsx* file with your installation files). The Application Admin (see page 27) can quickly configure a standard report header in DoseControl.



## 3.7.3.4 Excel Report Data Fields

## **DC Export to Excel**

The DC Export worksheet contains a dosimeter report's exported data from DoseControl. (Excel template is provided by GEX in the installation folder (see page 14).). DoseControl exports data to the DC Export tab in the Excel template.



- 1. Fields alway exported by DoseControl (yellow highlight)
- 2. Custom report header fields (if any) export by DoseControl (blue highlight). Report headers are exported in sequential order.

## Data always exported

DoseControl exports data to the DC Export tab in the Excel template. This table describes the data always exported for a report:

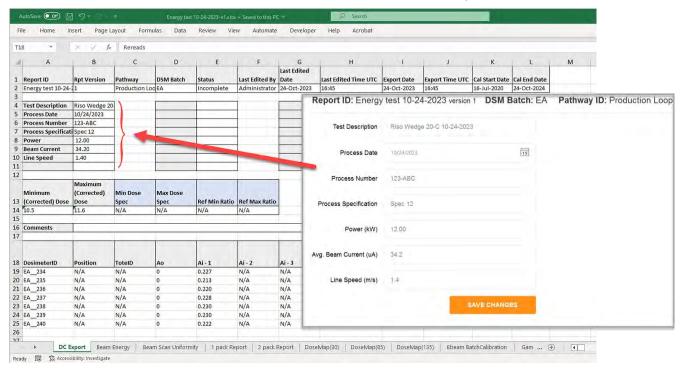
FIELD NAME:	DESCRIPTION:
Report ID:	Unique name/identifier of the report, entered at new report creation
Rpt Version:	Version number of the report
Pathway:	Irradiation pathway for report, selected from configured Pathways
DSM Batch:	Dosimeter batch ID (from Calibration configuration)
Status:	Status of report, processed or incomplete
Last Edited by:	Username that is logged in at the time of most recent report activity
Last Edited date:	Date of most recent report activity
Last Edited time UTC:	Time of most recent report activity, in UTC
Export Date:	Date of report export activity

Export Time UTC:	Time of report export activity, in UTC
Cal Start Date	Start date of the dosimeter batch calibration for the report
Cal End Date	End date of the dosimeter batch calibration for the report
Minimum (Corrected) Dose	Minimum dose of all measured dosimeters in the report. Corrected dose = Dose * Correction Factor of the Calibration (if any).
Maximum (Corrected) Dose	Maximum dose of all measured dosimeters in the report. Corrected dose = Dose * Correction Factor of the Calibration (if any).
Min Dose Spec	Minimum dose specification for the process. (This is a special value field only used in Reference Dosimetry reports. It will be empty if the field is not used in the report.)
Max Dose Spec	Maximum dose specification for the process. (This is a special value field only used in Reference Dosimetry reports. It will be empty if the field is not used in the report.)
Ref Min Ratio	Ref:Min Ratio for the process. (This is a special value field only used in Reference Dosimetry reports. It will be empty if the field is not used in the report.)
Ref Max Ratio	Ref:Max Ratio for the process. (This is a special value field only used in Reference Dosimetry reports. It will be empty if the field is not used in the report.)
Comments	Report comments
Dosimeter ID	Dosimeter ID number, serial number
Position:	Dosimeter position (reference, description)
ToteID:	Tote ID/Carrier number
A <sub>0</sub>	Background absorbance measurement (usually 0)
Ai-1	Absorbance measurement of dosimeter replicate 1. (If you are using 1 dosimeter per pouch, you have 1 dosimeter "replicate". The dosimeter's measured absorbance is Ai-1.)
Ai-2	Absorbance measurement of dosimeter replicate 2. (If you are using 2 dosimeters per pouch, you have 2 dosimeter "replicates". The dosimeter's measured absorbance is Ai-1 and Ai-2.)
Ai-3	Absorbance measurement of dosimeter replicate 3. (If you are using 4 dosimeters per pouch, you have 4 dosimeter "replicates". The dosimeter's measured absorbance is Ai-1, Ai-2, Ai-3, Ai-4.)
Ai-4	Absorbance measurement of dosimeter replicate 4. (If you are using 4 dosimeters per pouch, you have 4 dosimeter "replicates". The dosimeter's measured absorbance is Ai-1, Ai-2, Ai-3, Ai-4.)
Thickness	Dosimeter thickness (from Batches configuration)
Response	Calculated response value R=(Ai-A0)/t (Ai is the average of all the dosimeter replicates)
Dose	Measured dose (dose measured by the spectrophotometer)
Correction factor	Correction factor (from Calibration configuration)
Corrected dose:	Dosimeter reading's corrected dose. Corrected Dose = Dose * Correction Factor (from the calibration, if any).

Calibration ID:	Calibration ID (from Calibration configuration, laboratory provided cal ID)
Inst ID:	Spectrophotometer (Reader) name
Inst SN	Spectrophotometer (Reader) serial number
WL (nm)	Spectrophotometer set wavelength for measurement (from Calibration configuration)
DSM Measured Date Time UTC	The datetime stamp for the dosimeter measurement
Cal Dose Range	The min/max dose range for the dosimeter batch Calibration
Rereads	Number of rereads for this dosimeter ID. Original meaurement is "1". Reread measurement is "2". Next reread measurement is a "3".

Report header data exported

The additional report header data fields section of DC Export is called the Report Headers (as configured by the Admin in Report Headers setup). Upon export to Excel, these fields will populate in the same sequence configured in the Report Header setup.



## 3.7.3.5 Example - Customize Excel report templates

You can customize the \*.xlsx template provided by GEX to create your own report setups, add logos, add content fields, change the layout, etc. Once you are finished with your customizations, upload the new file into DoseControl (see steps above in About Excel report templates in DoseControl section).



See Details - Excel Report Data Fields (see page 111) for details about each Excel data field, and definition of each field.

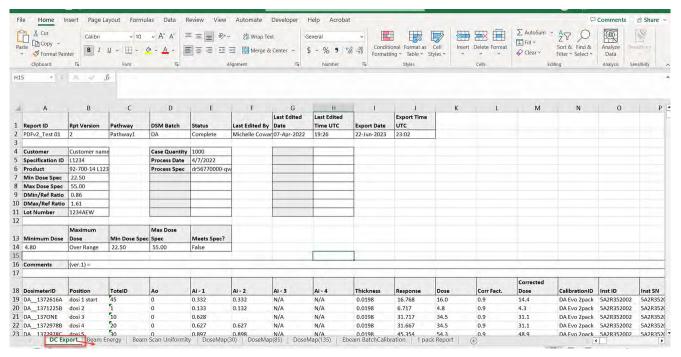
#### How Excel Report templates work in DoseControl

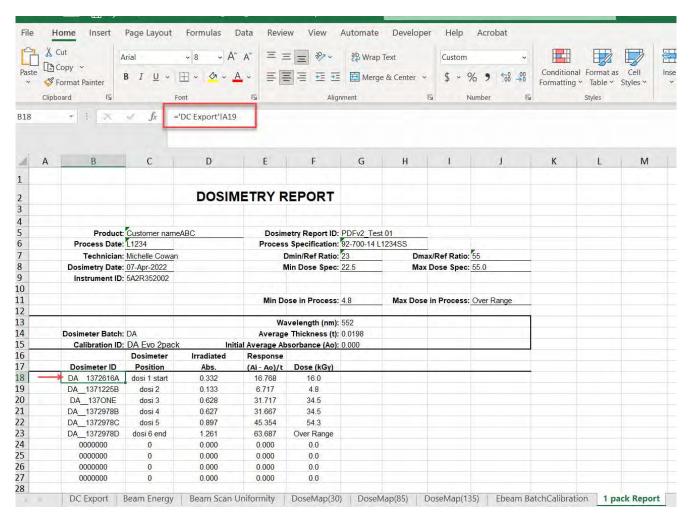
1 The GEX \*.xlsx template is setup to receive data from the software into the first worksheet "DC Export".

4

<u>Do not delete the **DC Export** worksheet in the DC Export to Excel.xlsx!</u> DoseControl puts the dosimetry report information into DC Export.

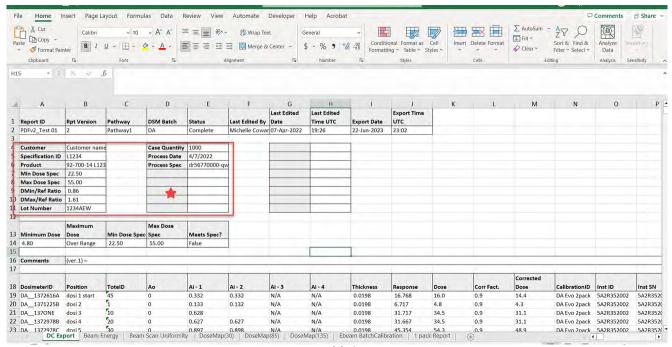
2 You can customize the DC Export to Excel.xlsx any way that works for you. The data in the DC Export cells are linked to the other reports. All the other tabs are basic report templates that you can customize using the Excel 'linked cells' feature to copy the data into other reports in the workbook.





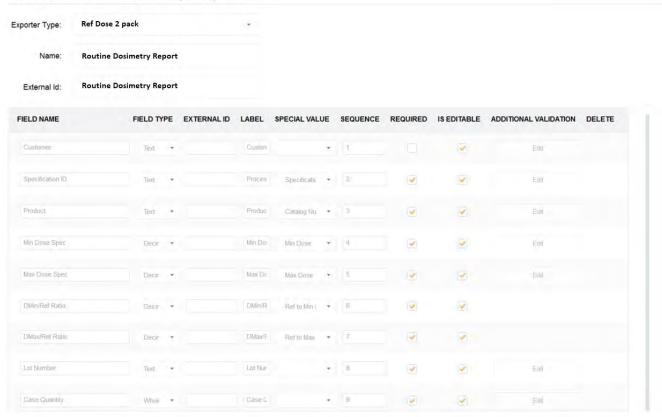
## **Instructions to Customize your Excel Report**

- 1 First, the Admin must setup the additional Report Headers in a Report type setup in DoseControl.
- 2 Each time the user clicks the Excel button on the Report Summary screen, the report is exported to Excel. The report headers will automatically appear on the exported Excel DC Export worksheet. See area in red box in the screenshot below these are the Report Fields setup for this report type. The report fields will appear in the sequence configured in the DoseControl Report Headers setup.



Export to Excel dosimetry report

# **EDIT FIELDSET: Dosimetry Report**



Report header fields setup (example)

- 3 Next, using the link feature in Excel, you will need to link the additional fields in DC Export to the correct cell of your Excel report. Repeat this process for each of the additional report header fields. (See example screenshots below.)
- **4** When the cell linking is complete, save the Excel worksheet as your new Excel dosimetry report template. Upload the new template into DoseControl (see page 129).
- 5 Upload the new DC Export to Excel template (see page 129) into DoseControl (Go to Misc → Upload Template). The next time you export a dosimetry report to Excel in DoseControl, the software will output it to your template.

## 3.7.4 About PDF Dosimetry Reports

#### 3.7.4.1 Standard PDF Report Header Templates

GEX provides generic reports layouts in PDF formats. The Application Admin (see page 27) can quickly configure a standard report header in DoseControl.

## See the setup instructions for each of the standard PDF reports:

- Standard 1 Pack PDF Report (see page 118) Basic dosimetry report for dosimetry (1 dosimeter per pouch)
- Standard 2 Pack PDF Report (GEX Default) (see page 116) Basic dosimetry report for dosimetry (2 dosimeter per pouch)
- Ref Dose 1 Pack PDF Report (see page 120) 1 dosimeter/pouch, routine process monitoring dosimetry with reference position information.

• Ref Dose 2 Pack PDF Report (see page 123) - 2 dosimeters/pouch, routine process monitoring dosimetry with reference position information.

Standard PDF Report Types are not customizable.

## 3.7.4.2 Custom PDF Report Modules

GEX can develop a PDF report module for you (additional fee). You load the custom PDF report module in the DoseControl module folder.

- · Choose what fields appear for each report's header (what information you want included on a report)
- Create new fields, specific to your application (i.e., your product number, your process)
- Alter templates for specific use (i.e. 5MeV wedge, unique dose map)
- Change layout
- · Add your logo



if you ever upgrade to a newer version of DoseControl software, your custom PDF report module(s) will be upgraded to the new version at no additional cost.

## 3.7.4.3 GEX Default (Standard 2 pack) PDF Report Setup

This section describes the default PDF report types and data fields. Most data fields are automatically output from DoseControl; the **bolded** data fields need to be configured under Report Headers by the Admin.

## **GEX Default (Standard 2 Pack) PDF Report - Setup Instructions**

Description: 2 dosimeters/pouch, routine process monitoring dosimetry. All fields in the table below are included in this report. Report header setup: None.

FIELD NAME:	DESCRIPTION:	FIELD NAME:	DESCRIPTION:
Report Version:	Version number of the report	Tote No:	Tote number (tote or carrier)
DSM Batch ID:	Dosimeter batch ID (from Calibration configuration)	Abs 1:	Absorbance measurement of dosimeter 1
DSM Thickness:	Dosimeter thickness (from Calibration configuration)	Abs 2:	Absorbance measurement of dosimeter 2
Prepared by:	Username that is logged in at the time of report processing	Avg. Abs	Average absorbance of Abs 1 and Abs 2
Date and Time:	Date/time report was processed; will say "not processed" for unprocessed report	Dose (kGy)	Calculated dose in kGy (uses calibration coefficients in Calibration)
Instrument ID:	Spectrophotometer serial number (from Calibration configuration)		

# Dosimetry Report

DSM Calibration ID: DA mock reader copy

Report ID: 2pk default test

Report Version: 1

DSM Batch ID: DA

Prepared By: Administrator Date and Time: Not Processed

Instrument ID: Mock

Spectrophotometer

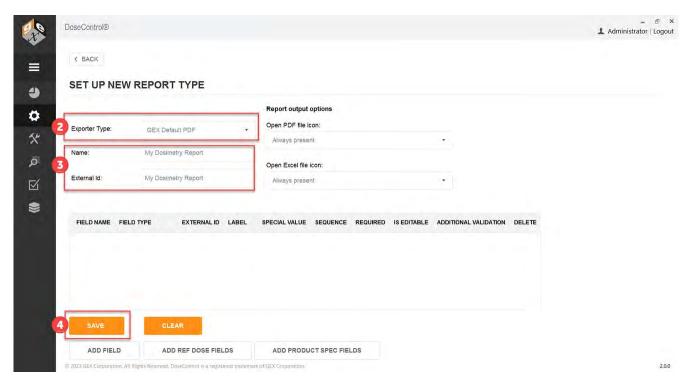
DSM Thickness: 0.0174

Position	Tote No.	Abs 1	Abs 2	Avg. Abs	Dose (kGy)
ref 1	33	0.507	0.507	0.507	31.2
ref 1	35	0.507	0.507	0.507	31.2
		0.507	0.507	0.507	31.2

Example of GEX Default PDF report

#### Report header setup

- **1** Go to Setup > Report Types
- **2** Select GEX Default PDF from the Exporter Type selector.
- **3** Enter a Name. Copy the report Name into External Id.
- 4 Click Save



## 3.7.4.4 Standard 1 Pack PDF Report Setup

This section describes the default PDF report types and data fields. Most data fields are automatically output from DoseControl; the **bolded** data fields need to be configured under Report Headers by the Admin.

## **Standard 1 Pack PDF Report - Setup Instructions**

<u>Description</u>: 1 dosimeters/pouch, routine process monitoring dosimetry. All fields in the table below are included in this report. <u>Report header setup</u>: None.

FIELD NAME:	DESCRIPTION	FIELD NAME:	DESCRIPTION:
Report Version:	Version number of the report	Tote No:	Tote number (tote or carrier)
DSM Batch ID:	Dosimeter batch ID (from Calibration configuration)	Abs 1:	Absorbance measurement of dosimeter 1
DSM Thickness:	Dosimeter thickness (from Calibration configuration)	Dose (kGy)	Calculated dose in kGy (uses calibration coefficients in Calibration)
Prepared by:	Username that is logged in at the time of report processing		
Date and Time:	Date/time report was processed; will say "not processed" for unprocessed report		
Instrument ID:	Spectrophotometer serial number (from Calibration configuration)		

# Dosimetry Report

DSM Calibration ID: P1B3-G30

Report ID: c123Std1pk

Report Version: 1

DSM Batch ID: B3 Film - DA

DSM Thickness: 0.0185

Prepared By: Michelle Cowan Date and Time: Not Processed

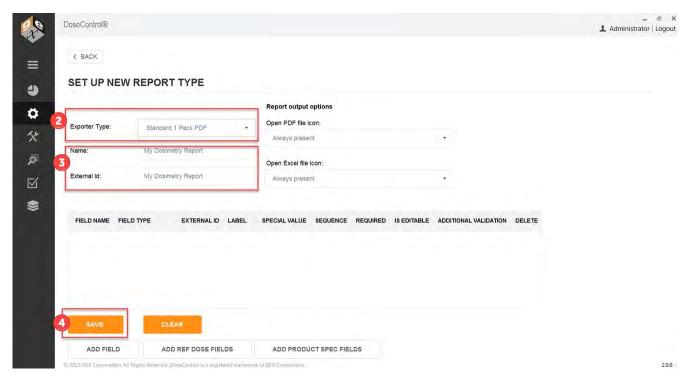
Instrument ID: Lab G30

Position	Tote No.	Abs 1	Dose (kGy)
10	44	0.473	26.0
11	44	0.478	26.3
12	44	0.641	38.1
13	44	0.640	38.1

Example of Standard 1 Pack PDF Report

## Report header setup

- **1** Go to Setup > Report Types
- **2** Select Ref Dose 1 Pack PDF from the Exporter Type selector.
- **3** Enter a Name. Copy the report Name into External Id.
- 4 Click the "Add Ref Dose Fields" button.
- 5 Click Save



## 3.7.4.5 Ref Dose 1 Pack PDF Report Setup

This article describes the default PDF report types and data fields. Most data fields are automatically output from DoseControl; the **bolded** data fields need to be configured under Report Type by the Application Administrator user.

## Ref Dose (Reference Dosimetry) 1 Pack PDF - Setup instructions

**<u>Description</u>**: 1 dosimeters/pouch, routine process monitoring dosimetry with reference position information. All fields in the table below are included in this report.

**Report Header fields:** Yes. See instructions below.

FIELD NAME:	DESCRIPTION:	FIELD TYPE:	SPECIAL VALUE FIELD:
Report ID:	Unique name/identifier of the report	Text	
Report Version:	Version number of the report	Whole number	
DSM Batch ID:	Dosimeter batch ID (from Calibration configuration)	Text	
Catalog Number:	Identifying information item being processed	Text	
Prepared by:	Username that is logged in at the time of report processing	Text	
Date and Time:	Date/time report was processed; will say "not processed" for unprocessed report	Text	
Instrument ID:	Spectrophotometer serial number (from Calibration configuration)	Text	

Position:	Dosimeter position (reference, description)	Text	
Carrier:	Carrier number/ID	Text	
Absorbance:	Absorbance measurement of dosimeter 1	Decimal number	
Thickness:	Dosimeter thickness	Decimal number	
Calculated Dose (kGy)	Calculated dose in kGy (uses calibration coefficients in Calibration and Dmin or Dmax ratio)	Decimal number	
Required Dose (kGy)	Required dose according to process specifications	Decimal number	
Min spec	Minimum dose for the process	Decimal number	Min Dose
Max spec	Maximum dose for the process	Decimal number	Max Dose
Ref:Min Ratio	Ratio of min dose to the dosimeter reference position	Decimal number	Ref to Min Ratio
Ref:Max Ratio	Ratio of max dose to the dosimeter reference position	Decimal number	Ref to Max Ratio

# Dosimetry Report

## DSM Calibration ID: P183-G30

Report ID: 1234 RefD1pk

Report Version: 1

DSM Batch ID: B3 Film - DA Catalog Number: A567

Prepared By: Administrator Date and Time: Not Processed Instrument ID: Lab G30

Position	Carrier	Absorbance	Thickness	Dose (kGy)
1	1	0.363	0.0185	18.8
2	1	0.590	0.0185	34.3
3	1	0.474	0.0185	26.1
4	1	0.493	0.0185	27.4
5	1	0.640	0.0185	38.1
6	1	0.479	0.0185	26.4

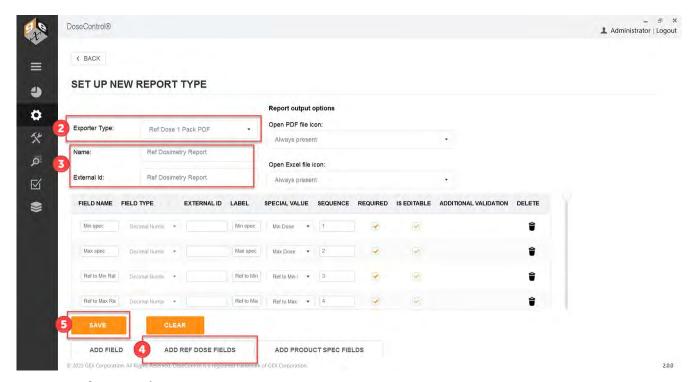
	Reference Dose (kGy)	Carrier	Correlation Factor	Calculated Dose (kGy)	Required Dose (kGy)
Min Dose (kGy)	18.8	1	0.02	0.4	10.0
Max Dose (kGy)	38.1	1	0.02	0.8	70.0

WARNING! The required minimum dose has not been met.

Example of Reference Dose 1 Pack PDF Report

## Report header setup

- 1 Go to Setup > Report Types
- **2** Select Ref Dose 1 Pack PDF from the Exporter Type selector.
- **3** Enter a Name. Copy the report Name into External Id.
- 4 Click the "Add Ref Dose Fields" button.
- 5 Click Save



## 3.7.4.6 Ref Dose 2 Pack PDF Report Setup

This article describes the default PDF report types and data fields. Most data fields are automatically output from DoseControl; the **bolded** data fields need to be configured under Report Type by the Application Administrator user.

## **Ref Dose 2 Pack PDF - Setup instructions**

**<u>Description</u>**: 2 dosimeters/pouch, routine process monitoring dosimetry with reference position information. All fields in the table below are included in this report.

## **Report Header Fields:** Yes. See instructions below.

FIELD NAME:	DESCRIPTION:	FIELD TYPE:	SPECIAL VALUE FIELD:
Report ID:	Unique name/identifier of the report	Text	
Report Version:	Version number of the report	Whole number	
DSM Batch ID:	Dosimeter batch ID (from Calibration configuration)	Text	
Catalog Number:	Identifying information item being processed	Text	
Prepared by:	Username that is logged in at the time of report processing	Text	
Date and Time:	Date/time report was processed; will say "not processed" for unprocessed report	Text	
Instrument ID:	Spectrophotometer serial number (from Calibration configuration)	Text	

Position:	Dosimeter position (reference, description)	Text	
Carrier:	Carrier number/ID	Text	
Absorbance:	Absorbance measurement of dosimeter 1	Decimal number	
Thickness:	Dosimeter thickness	Decimal number	
Calculated Dose (kGy)	Calculated dose in kGy (uses calibration coefficients in Calibration and Dmin or Dmax ratio)	Decimal number	
Required Dose (kGy)	Required dose according to process specifications	Decimal number	
Min spec	Minimum dose for the process	Decimal number	Min Dose
Max spec	Maximum dose for the process	Decimal number	Max Dose
Ref:Min Ratio	Ratio of min dose to the dosimeter reference position	Decimal number	Ref to Min Ratio
Ref:Max Ratio	Ratio of max dose to the dosimeter reference position	Decimal number	Ref to Max Ratio

# Dosimetry Report

DSM Calibration ID: P1B3-G30-2

Report ID: RD2P

Report Version: 1 DSM Batch ID: B3 Film - DA

Catalog Number: 543

Prepared By: Administrator Date and Time: Not Processed

Instrument ID: Lab G30

Position	Carrier	ABS 1	ABS 2	Avg.	Thickness	Dose (kGy)
12	44	0.591	0.591	0.591	0.0185	34.4
		0.589	0.588	0.589	0.0185	34.2

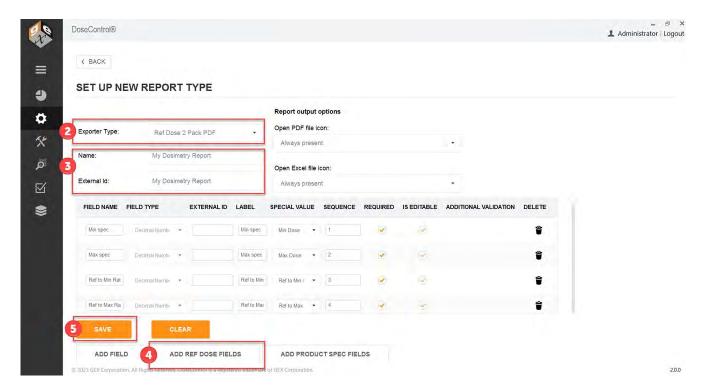
	Reference Dose (kGy)	Carrier	Correlation Factor	Calculated Dose (kGy)	Required Dose (kGy)
Min Dose (kGy)	34.2		1.00	34.2	10.0
Max Dose (kGy)	34.4	44	1.50	51.6	50.0

WARNING! The required maximum dose has been exceeded.

Example of Reference Dose 2 Pack PDF Report

## Report header setup

- 1 Go to Setup > Report Types
- **2** Select Ref Dose 2 Pack PDF from the Exporter Type selector.
- **3** Enter a Name. Copy the report Name into External Id.
- 4 Click the "Add Ref Dose Fields" button.
- 5 Click Save

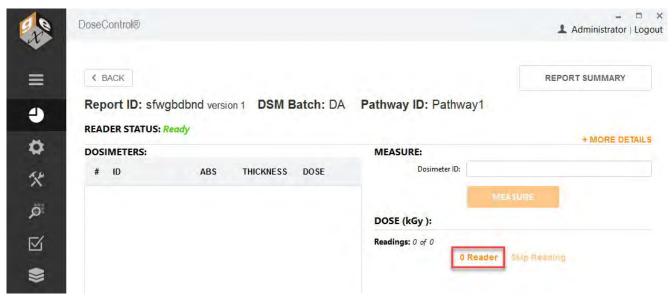


## 3.8 Setup - Miscellaneous

## 3.8.1 Setup - Enable "0" Reader"

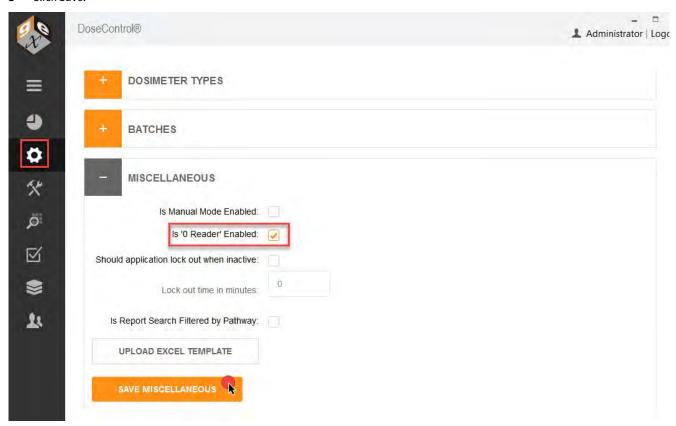
#### 3.8.1.1 About "0" Reader" feature

This feature removes or restores the '0 Reader' button on the measure screen. The "0 Reader" button allows the technician who is reading dosimeters to decide when to zero the spectrophotometer and can do so directly from the main measurement screen.



## 3.8.1.2 How to make the "0" Reader" button on measurement screen visible to users

- **1** Go to the Setup screen (sprocket icon) → Miscellaneaous.
- 2 Enable 'Manual Mode'
- 3 Click Save.



#### 3.8.2 Setup - Manual Mode

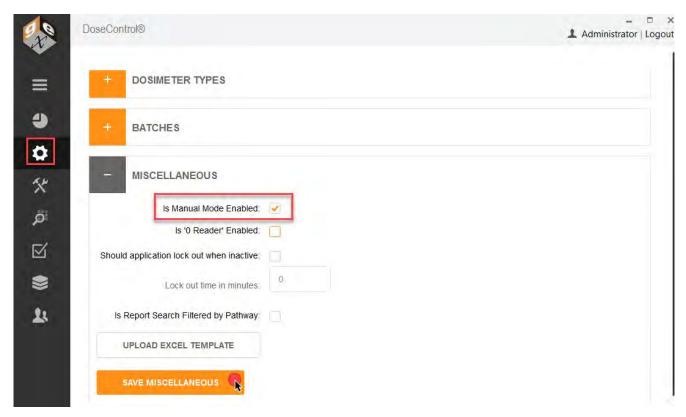
#### 3.8.2.1 About 'Manual Mode'

When Manual Mode is enabled, if the active reader for the workstation is not connected to the PC or is powered off, then the 'Manual Mode' button will appear on the measurement screen.

- Manual Mode allows the user to type in dosimeter absorbance values on the measurement screen.
- · Any entry done in manual mode is flagged as 'manual' in the database to distinguish it from automatic measurements.
- This feature can be very helpful when validating the dose output of the software after configuring a calibration for a dosimeter batch.

## 3.8.2.2 How to enable the 'Manual Mode' functionality

- **1** Go to the Setup screen (sprocket icon) → Miscellaneaous.
- 2 Enable 'Manual Mode'
- 3 Click Save.



## 3.8.3 Setup - User Lock-Out

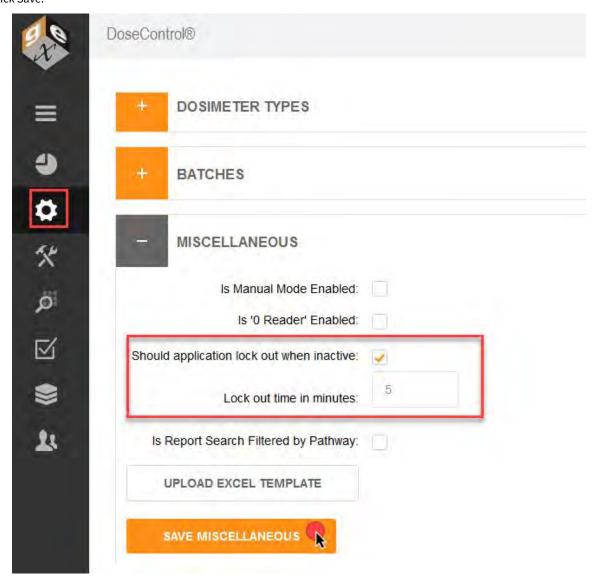
## 3.8.3.1 About 'User Lock-out' functionality

This feature allows 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 lock-out timer. When a user is locked out, a message will display to the user "You have been logged out due to inactivity." The user will need to log into DoseControl again.



## 3.8.3.2 How to enable the 'User Lock Out' functionality

- **1** Go to the Setup screen (sprocket icon) → Miscellaneaous.
- 2 Enable 'Should application lock out when inactive'
- 3 Enter a number of minutes for the lock-out timer.
- 4 Click Save.



# 3.8.4 Setup - Upload an Export to Excel Report Template

## 3.8.4.1 About Excel reports in DoseControl

The Excel reporting feature of the software is highly flexible and allows you to control exactly what information is contained on a report and how the report looks. Any of the process and measurement data recorded by DoseControl can be output into a MS Excel

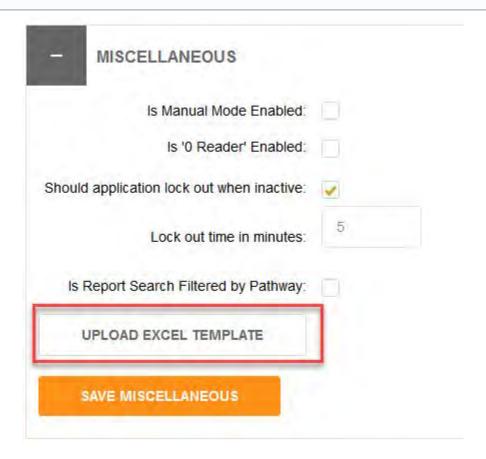
format report. The Admin can create new dosimetry report types, and each report type can have different data fields and layouts, depending on specific reporting needs and requirements.

The Application Admin must upload the MS Excel template into DoseControl. GEX provides a MS Excel dosimetry report template file, which is included in the software installation folder (see page 14) (\*.xlsx file).

Read more: About Excel Reports (see page 106)

## 3.8.4.2 How to upload a new DC Export to Excel report template

- **1** Go to the Setup screen (sprocket icon) → Miscellaneaous.
- 2 The button is used to upload MS Excel file DC Export to Excel (report template)
- 3 Click Save.
  - (i) **NOTE:** The software will not display a confirmation message that the DC Export to Excel template was uploaded. Click Save and then test an Excel report output to confirm.



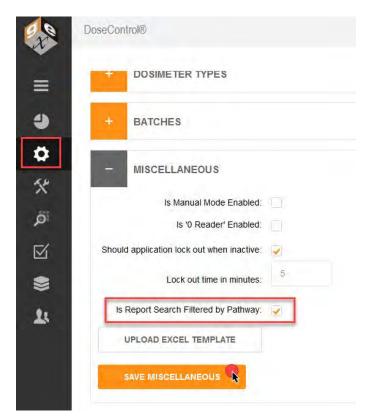
#### 3.8.5 Setup - Report search 'Filter by Pathway'

#### 3.8.5.1 About filtering reports by Pathway

Activating this feature will allow the user to modify the view on the home screen (Reports List) for the PC on which the setting is activated. It is designed to segregate reports at different irradiators within one site or between irradiation sites while allowing the user to maintain a single SQL database containing all dosimetry records.

## 3.8.5.2 To activate Pathway filter

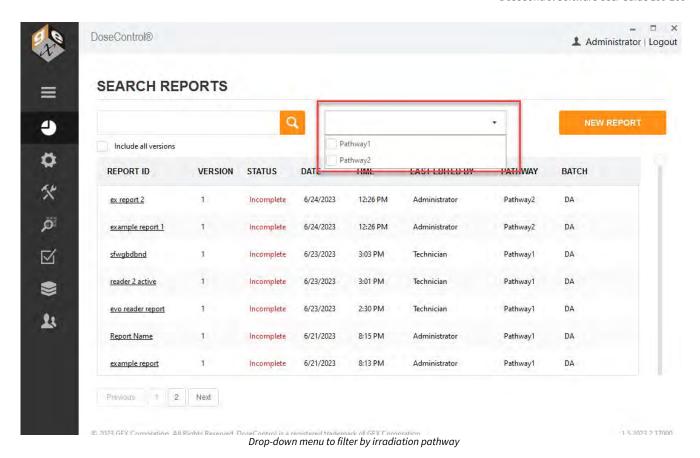
- **1** Go to the Setup screen (sprocket icon) → Miscellaneaous.
- 2 Enable 'Is Report Searchable by Pathway'
- 3 Click Save.



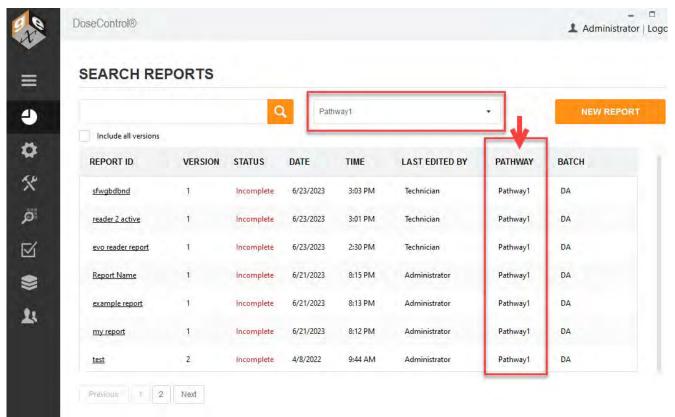
## 3.8.5.3 How to use filter by Pathway on the home screen

When activated the user has new filtering options on the Reports List screen to filter by one or more pathways. This is used when there are multiple dosimetry workstations or laboratories to only view the reports that are relevant to the work on that PC. The preference of these settings is maintained for all users of the PC and is modifiable by all users of the PC.

To use the feature, simply select the arrow of the new drop-down menu and check one or more Pathways you wish to view in the list. The others will not be shown.



Once your selection is made, select the Search button to run the initial filter. Afterwards and continuously thereafter, the application will only display reports from the selected pathway:



Reports filtered by Pathway 1

## 3.9 Setup - Rereads

## 3.9.1 About Rereads

## 3.9.1.1 What is a "Reread"?

In the event a dosimeter is mishandled, placed in the holder incorrectly, is dirty, is damaged, or if a measurement value is different than expected, it is important to have a controlled process that allows the user to "reread" (i.e., re-measure) the dosimeter.

For example, if the technician reads a dirty dosimeter the resulting dose measurement will not be accurate. The technician can carefully wipe or flick dust off the dosimeter and then re-read the dosimeter, and the new (correct) dose measurement will be seen on the final dosimetry report.

#### 3.9.1.2 What happens to the dosimeter's measurement during a reread?

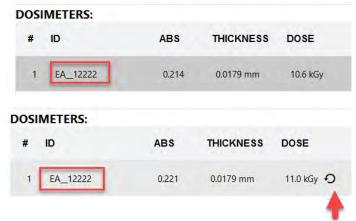


## IMPORTANT!

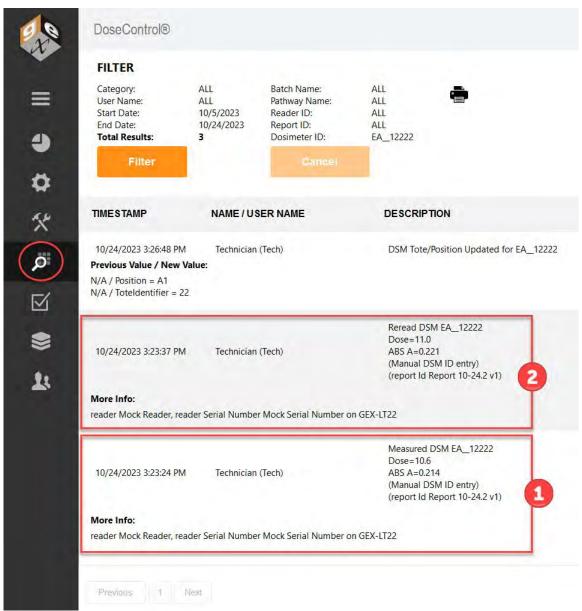
A dosimeter's original measurement and all subsequent re-read measurements are permanently recorded by the software, and measurement events are logged in the audit trail (FDA 21 CFR part 11 compliant). The dosimeter's original measurement information is not lost or overwritten.

The re-read measurement value replaces the original measurement in the dosimetry report, on the measurement screen, in the exported reports (Excel and PDF), and in the export tables (for integrated systems.) On the measurement screen, a reread symbol appears next to the dosimeter's dose value.

All measurements (original and rereads) are logged in the audit trail (screenshot below, 1 is the original measurement, 2 is the reread measurement).



Dosimeter EA\_12222 original measurement and reread measurement with icon.



Audit trail for dosimeter EA\_12222 measurements

## 3.9.1.3 Who can setup the Reread parameters?

The Application Admin (see page 27) can setup Rereads in DoseControl to control how users can re-read a dosimeter.

By default, DoseControl software allows unlimited re-reads (re-measurements) of a dosimeter, and each re-read absorbance measurement replaces the previous measurement in the dosimetry report.

## 3.9.1.4 Reread Methods - "Simple" and "Statistical"

## **Simple Reread**

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The user will take a measurement which will replace the original measurement on the screen.

#### **Statistical Rereads**

A statistical reread session requires the technician to make three measurements of the dosimeter 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 choose to include or exclude the original measurement in the statistical evaluation.

If the results of the statistical reread session pass the statistical evaluation, the new dose result replaces the original dose measurement on the screen, in reports, and in exported data.

#### 3.9.1.5 Control Reread parameters

The Application Admin (see page 29) can setup different requirements and restrictions for the dosimeter re-read process, if desired. An overview of what the Admin can configure for re-reads:

- **User permissions:** Restrict re-read activity to specific users given a re-read role.
- Define if multiple users are required to do a re-read: Require a different user to login and perform the re-read.
- Define reasons for re-reads: Admin define "reasons" allowed for the user to perform a re-read of a dosimeter. These reasons will be available to the technician in a drop-down menu. A reason is selected, and the user can then perform a reread.
- Define if and how a re-read measurement replaces the original measurement: The software allows for two re-read methods, "Simple rereads" and "Statistical rereads"
- Define how many re-reads can be performed for a dosimeter: The Admin can limit the number of times a user can reread a dosimeter.
- Define if a comment is required by the user performing the re-read.



#### CAUTION

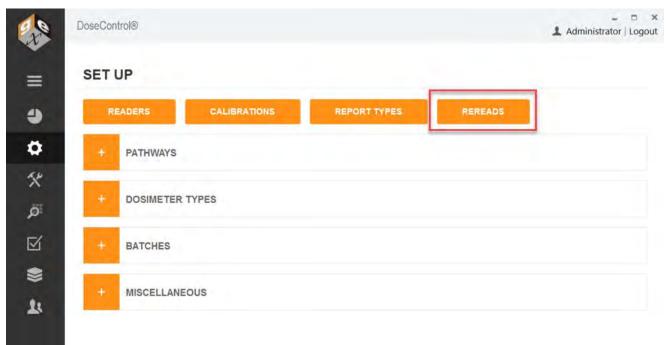
Once a re-read reason is used for a dosimeter, the user cannot ever select a different reason. If the reread is interrupted, the software retains the position of any reread sequence so that it can enforce the number of allowed rereads. Therefore, users need to be properly trained to make their selection of the reason for rereading because failure to do so may limit the available workflows to reread that dosimeter again.

#### 3.9.2 Setup Rereads

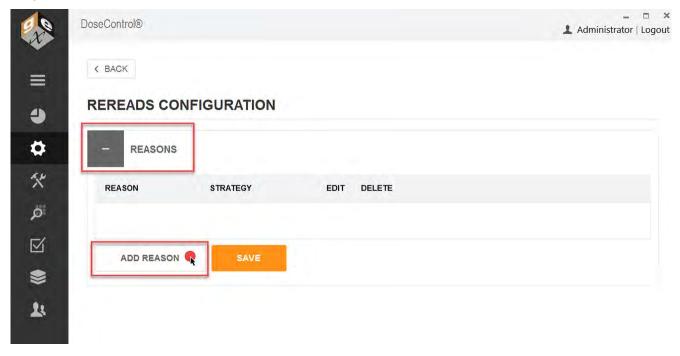


1 The Application Admin (see page 29) can setup Reread parameters in DoseControl. The default functionality allows unlimited rereads.

## 3.9.2.1 Setup Reread parameters



- 1 On the Setup screen, select the "REREADS" button.
- 2 Expand the 'Reasons' field. Click "Add Reason" to define a reason for a reread measurement. (Add as many reasons as needed using the "ADD REASON" button.)



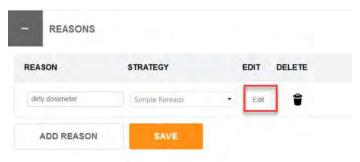
This "reason" will appear on a dropdown on the measurements screen, and a technician doing a reread will select from this dropdown of "reason" to initiate the reread workflow.

⚠ IMPORTANT! Once a Reread reason has been used in DoseControl it cannot be deleted or edited. In addition, there is no way to inactivate the Reread reason, so the Reread reason will always appear as a option in the dropdown menu.

Define a Reread strategy ("simple" or "statistical"). Select either "Simple Rereads" or "Statistical Rereads" from the Strategy drop-down menu.



- Click the orange "Save" button to save the Reread reason. 3
- Next, click the "Edit" button to edit the re-read controls for this reason.



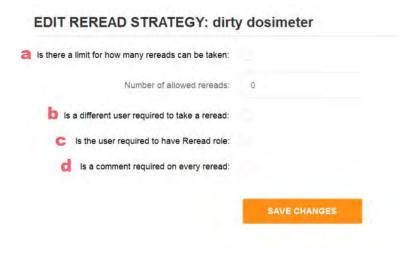
Edit the Reread strategy to control the reread process.



Caution. When using the "limit number of rereads" feature, be aware that once the number of allowed re-reads has been reached, the system will not allow any additional measurements by any user, including the Application Admin.

- a) Is there a limit for how many rereads can be taken? If checkbox is ticked, enter the number of allowed rereads.
- b) Is a a different user is required to perform a re-read? If this box is checked, the software will force a user to logout and then a different user must login to the software to perform the re-read.

- c) Is the user logged in to the software must have a "Reread role"? If this box is checked, the user performing the reread must have a Reread user permission. (A "Reread role" is defined by the software user management roles and permissions setup See User Roles and Permissions. (see page 35))
- **d)** Is a comment required on every reread? If this box is checked, the software will prompt the user to enter a comment when a reread is performed. The user can provide details about the re-read to be recorded, in addition to the "reason" description selected.



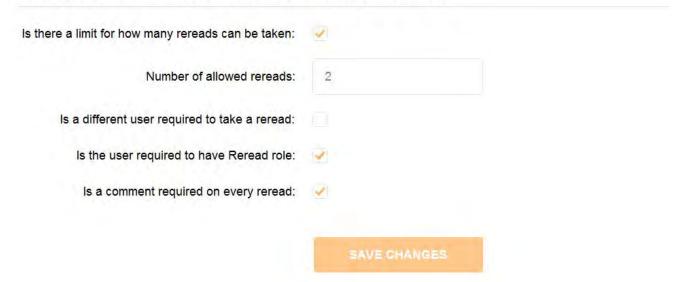
- 5 Click "Save Changes" to save the settings.
  - 3.9.2.2 Setup a "Simple" Reread strategy

The user will take a reread (a re-measurement) of the dosimeter, and the reread results will replace the original measurement on the screen.

Follow the instructions above to setup a 'simple' reread strategy.

Example 'simple' reread setup:

# **EDIT REREAD STRATEGY: Operator read error**



Example setup for a "Simple" reread - limits number of rereads to 2, the user must have a reread role permission, and the user must enter a comment for each reread. (Example only)

## 3.9.2.3 Setup a "Statistical" Reread strategy

Requires the user to make three measurements (in succession) of the dosimeter. The App Admin can allow a statistical evaluation of the results to determine if the reread data supports accepting the original measurement or supports changing the original measurement. Or, the App Admin can also choose to include the original measurement in the statistical evaluation.

# =

## **IMPORTANT CONFIGURATION**

A statistical reread consists of <u>3 rereads per session</u> and the final result is an average of the 3 rereads. If you limit the *Number of Allowed rereads*, do this in increments of 3, such as 3, 6, 9 12, etc.

- 👉 Follow the instructions above to setup a 'statistical' reread strategy.
- Fread More: Important Details about Statistical Rereads (see page 141)

Example 'statistical' reread setup:

## **EDIT REREAD STRATEGY: Dosimeter reread**

Include original measurement in calculations?:			
Maximum coefficient of variation (CV) (default value is 0.03):	0.03		
there a limit for how many rereads can be taken:	~		
Number of allowed rereads:	6		
Is a different user required to take a reread:			
Is the user required to have Reread role:			
Is a comment required on every reread:			
		SAVE CHANGES	

Statistical reread: There is a statistical evaluation of the results to determine if the reread data (C.V. of 0.03), and this does not include the original measurement. Allows 2 statistical rereads sessions (3 reading per session). (Example only)



#### **A** CAUTION

The statistical reread strategy is only available when the "Absorbance Count" for a given calibration is set to "1" (1 dosimeter per pouch). This is because a method for handling one dosimeter out of a package of two total dosimeters using this strategy has not been determined.

## 3.9.2.4 Details about Statistical Rereads



#### **A** CAUTION

The statistical reread strategy is only available when the "Absorbance Count" for a given calibration is set to "1" (1 dosimeter per pouch). This is because a method for handling one dosimeter out of a package of two total dosimeters using this strategy has not been determined.

A statistical re-read strategy is typically used to handle a situation where the original dosimeter reading does not conform to an expectation but there is no visible dosimeter defect and we are certain that the measurement procedure was followed correctly.

The Admin wants to configure re-reads for verification that the original measurement is statistically reproducible. This strategy will require the technician to make three (3) 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.

In this example, we use the statistical reread strategy reason and name it "Dose Confirmation".

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# EDIT REREAD STRATEGY: dose confirmation

0.03		
6		
	6	

For a statistical re-read, the Admin will need to consider the following:

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.



Be careful about including the original measurement. If the original measurement was extremely bad (user zero'd with the dosimeter in the holder prior to measurement, the dosimeter was very dirty, etc.), and this original measurement is included in the statistical evaluation "pass/fail" C.V. for the reread session, the session may fall outside the accepted C.V. because of the original measurement even if the reread measurements were good.

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 – the system defaults to 0.03 (3%) and it is recommended that the value should lie between 0.003 and 0.03 (0.3% to 3.0%) depending on how aggressive the user wants to be and for what reason.

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.

-

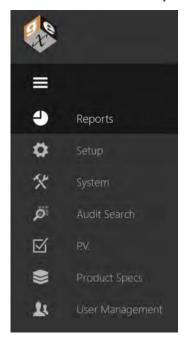
DoseControl Software User Guide 100-266

3 Number of allowed rereads when using the statistical strategy: Your value must allow for <u>3 rereads in a single session</u>. The "Number of allowed rereads" must be a factor of 3 for a statistical reread. For example, if you want to allow two statistical reread sessions then set the number of allowed rereads to six (6), or in multiples of 3 for any total number of sessions.

# 4 How to Use the DoseControl Dosimetry System

#### 4.1 DoseControl Software Screens

### 4.1.1 Left menu bar description



Reports: The main/home screen of the application you will see when DoseControl opens. It displays and allows search of a list of existing dosimetry reports, and where creating new dosimetry reports is initiated.

Setup: Configuration your dosimetry, such as batches, readers (spectrophotometers), and calibrations. The Application Admin (see page 27) user can see and access Setup.

System: The system and IT related configuration fields, such as the connection to the SQL database, network file storage configurations, user access setup. The System Administrator (see page 27) user can see and access System.

Audit Search: View the complete history of all activity recorded by DoseControl, with filters, search and audit report creating capabilities. The Application Admin (see page 27) user can see and access the Audit Trail.

P.V. (Performance Verification)\*: The P.V. module is only available for the Evolution spectrophotometer. It provides a minimal performance verification testing routine at one point of photometric accuracy and wavelength accuracy designed as a 'daily verification'. The Application Admin user and Technician user (see page 27) can see and access the P.V. Module to execute PV tests. The Application Admin has full access to setup PV Test Methods.

**Product Specifications\*:** The optional Product Specs module has the areas to configure dosimetry parameters such as Min and Max Dose specifications and dose mapping correlation ratios for specific products. The user can select a product name from a dropdown menu, and the process specifications will automatically populate the headers of the new dosimetry report. The Application Admin (see page 27) can setup Product Specifications in the module.

User Management: Configure user roles and permissions when using the MSSQL or LDAP user management modes. The System Administrator (see page 27) user can see and access User Management.

(i) \*Optional modules not available to all users. If the Module is not installed, you will not see the icon in the left menu bar.

#### 4.1.2 Reports (Home) screen description

The Reports screen (home screen) displays a list of existing reports and allows you to create reports and search for reports.

Report ID: The unique name of the dosimetry report

Version: Report version number. Check the 'Include all versions' box to see all versions of reports; uncheck to see only the most current versions.

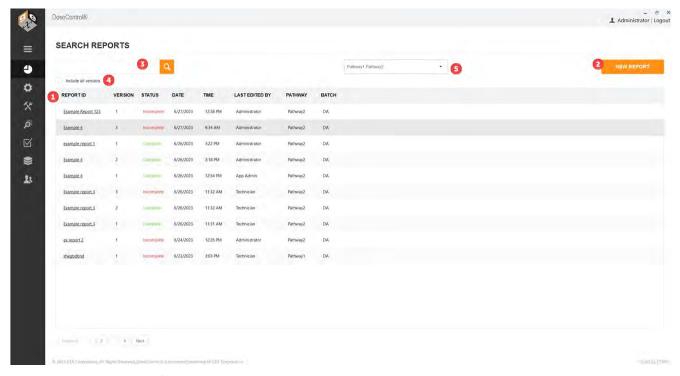
Status: A report status can be 'Incomplete' or 'Complete'. A 'complete' report is a processed report that cannot be altered. Incomplete reports can be edited and you can add dosimeter measurements.

Date and Time: The date and time of the last view/edit to the report

Last edited by: The name of the user to last edit the report

Pathway: The radiation pathway for the report

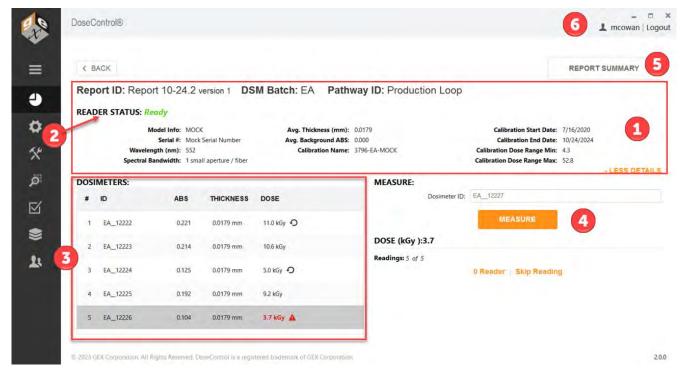
Batch: The dosimeter batch ID for the report



### 4.1.2.1 Report Screen actions:

- 1 Click on a Report ID to open a dosimetry report and go to the active measurement screen.
- 2 Click 'New Report' to begin a new report, fill in the relevant dosimetry process information for that report, and go to the active measurement screen.
- 3 Search existing reports (see page 150). Type a partial or full Report ID or dosimeter ID.
- 4 Click to include all report versions (see page 162) in the list
- 5 If 'Report Search Filtered by Pathway' (see page 131) is active, the dropdown is here.

### 4.1.3 Measurement screen description



1 Report Information – The report's header section is collapsible and expandable by selecting the orange text 'Less Details' or 'More Details' on the upper-right side of the screen. The header section will display the following information:

**Report ID:** Report Name and the report version

**DSM Batch:** Dosimeter batch ID, batch version, average batch thickness, background absorbance value

Pathway ID (irradiation pathway)

**Spectrophotometer (Reader):** model information, serial number, measurement wavelength, spectral bandwidth

**Calibration information:** dosimetry system calibration information (Calibration ID, Cal start/end dates, Calibration min/max dose range).

2 Reader (Spectrophotometer) status – the 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.

FAILED means that an instrument is not detected (see troubleshooting (see page 252) for more reader connection errors).

3 **Dosimeter List** – List builds as dosimeter measurements are taken. Each row contains the **Dosimeter ID**, **Thickness**, **Absorbance**, and **Dose** for each measurement. The row that is highlighted in grey in the list indicates which dosimeter's information is being displayed in the active "Measure" area of the screen.

Reread icon indicates that a dosimeter has been re-measured.



**Alert icon and bold red font** indicates that the dose is outside the calibrated range. Doses that are outside of the range are not valid, and the notification should alert the operator to review the measurement. **See Alerts for Dosimeters that are Outside Range** (see page 182)



4 Measure – The Measure section displays the information for the active dosimeter. Scan or type a Dosimeter ID and click the Measure button to measure the dosimeter.

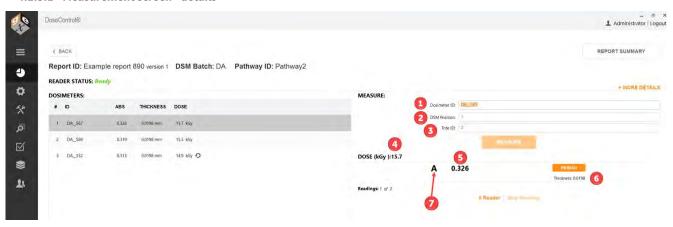
See Details about the Measurement section (see page 147) for details

**Report Summary** – When the user is finished measuring dosimeters, click Report Summary to see the final information and export reports.

See Report Summary screen (see page 159) details.

**6** Logged in user - You can see the logged in user in the upper right corner of the screen.





- **1 Dosimeter ID:** Unique identification for the dosimeter. For B3 dosimeters, the Dosimeter ID includes the batch ID and Dosimeter number. Click in this field and scan the dosimeter barcode into this field, or type a Dosimeter ID.
- **2 DSM Position (optional):** Dosimeter position. 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".

- **Tote ID (optional):** 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.
- **4 Dose (kGy):** Displays the dose calculation for the active dosimeter.
- **Absorbance:** Displays the measured absorbance of the active dosimeter.
- **Thickness:** Displays the thickness of the dosimeter, as configured by the Admin in Batches setup. (See also 'Edit Thickness' permission (see page 35) for users.)
- 7 Replicate(s): Displays the dosimeter replicate for the current dosimeter measurement.

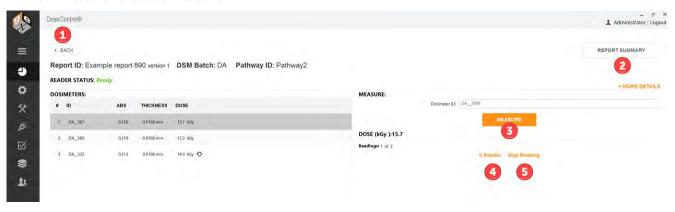
A is one dosimeter per pouch



### A and B is two dosimeters per pouch



#### 4.1.3.2 Measurement screen - buttons



- Back Return to the Home Screen
- Report Summary view the Report Summary screen (see Report Summary section (see page 159) for details).
- Measure Measure 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.
- 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).

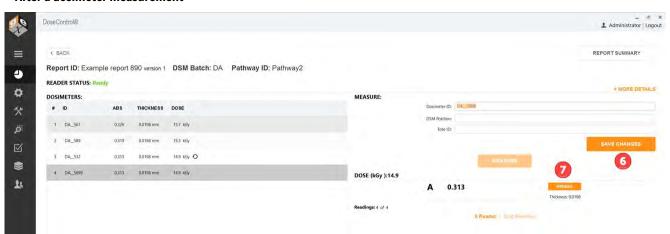


### (i) NOTE

For G20 users: If the user presses the zero button on the G20 instrument, the zeroing event is not recorded in the software audit trail. There is no method currently available for disabling the zero button on the G20 instrument. Train operators to only zero the G20 instrument through the software and not to use the buttons on the instrument so that the event is recorded in the audit trail.

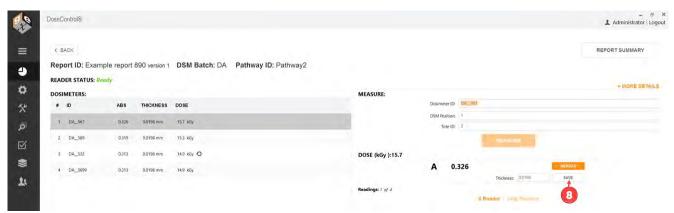
Skip Reading – allows the user to create a record when a reading must be skipped (e.g. lost dosimeter), and the user is required to enter a reason that becomes part of the report comments.

#### After a dosimeter measurement



- Save Changes User can enter a DSM (dosimeter) position and Tote ID, then click Save Changes to associate this information with the Dosimeter.
- 7 Reread - Initiates the workflow for re-measurement of a sample, based on the user configuration described earlier and using methods as described in Rereads section. This button only appears after the initial measurement of a dosimeter has been made.

### If 'Edit Thickness' Permission is active



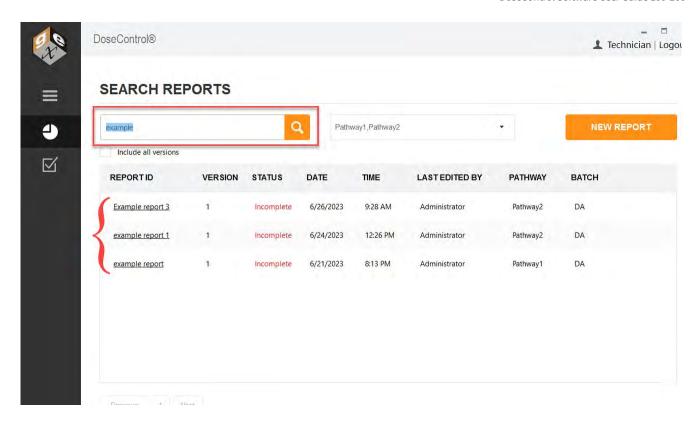
**Save** – User can enter a thickness value for the dosimeter and click Save. Only available if the 'Edit Thickness' permission (see page 70) is active.

# 4.2 How to search for a Report or Dosimeter ID

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report, search for reports on the home screen, and measure dosimeters.

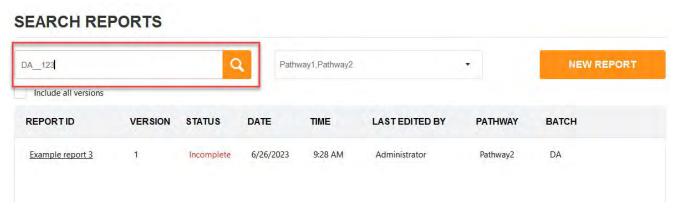
# 4.2.1 Search by report ID or report Name

Use the Search bar on the main reports screen to quickly find information. The list will show all reports with the search term in the Report ID.



### 4.2.2 Search for Dosimetry ID

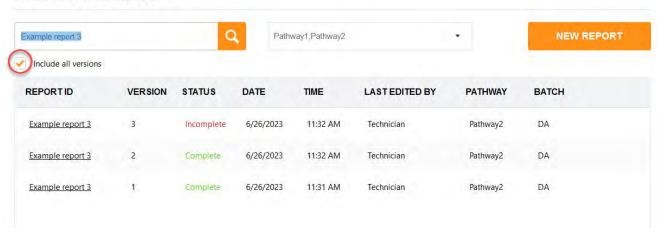
Use the Search bar on the main reports screen to quickly find the report containing the Dosimeter ID. The list will display the report with the dosimeter ID



### 4.2.3 Filter by report version.

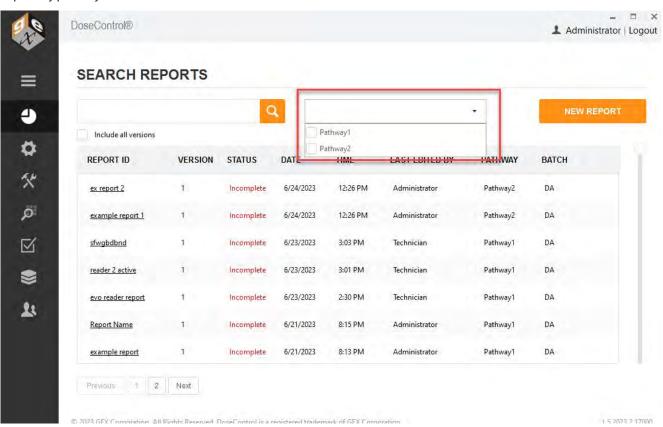
Default list shows current versions of reports. Tick the "Include all versions" to display all versions.

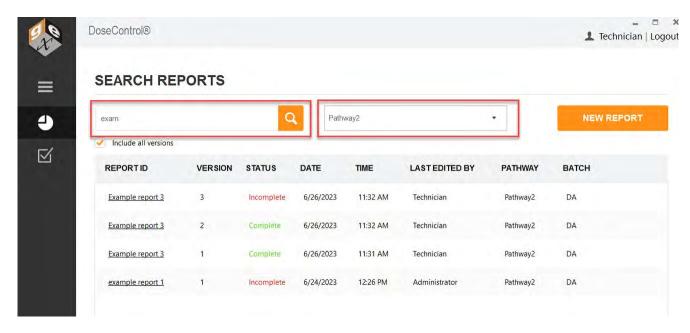
# SEARCH REPORTS



# 4.2.4 Filter by Pathway

If you have enabled 'Is Report Searchable by Pathway' (see page 131) (Setup screen (sprocket icon) → Miscellaneaous), you can filter the Reports by pathway.





# 4.3 How to create, use and export Reports

### 4.3.1 Report and Measurement Workflow

Here is the report management and dosimeter measurement workflow:

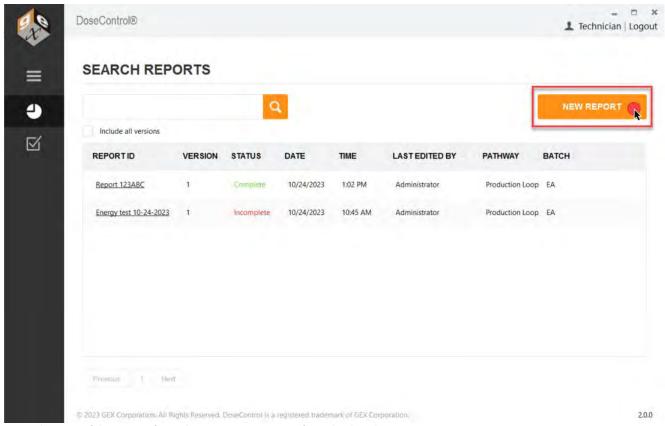
- 1 Create a Report. To start a measurement session, you create a new Report ID, enter any report header fields (if required).
- **2 Software controls the measurement process.** The software controls the reader (spectrophotometer) and will guide you to the measurement screen, asking you to zero "0" the instrument prior to measuring a dosimeter.
- **3 Measure dosimeters.** Next, you can measure all the dosimeters into the report. Until you complete the report, the report status is *Incomplete*.
- **4 Review the Report.** When you are finished the dosimeter measurements, you go to the "Report Summary" screen to review the information. You can edit report headers, review the dosimeter measurements, and enter a comment.
- **5 Complete/Process the Report.** When the report is completed, you click the PROCESS REPORT button. This locks the information in the report so that it cannot be edited. The status is *Complete*.
- **6 Output the report.** You can save or print the report in Excel or PDF format.

# 4.3.2 How to Create a New Report

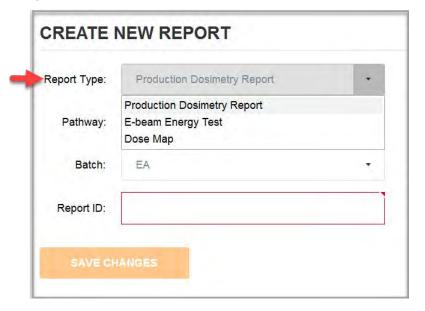
Any user (with a Technician role (see page 27)) can create a report and measure dosimeters.

#### 4.3.2.1 Create a Dosimetry Report Instructions

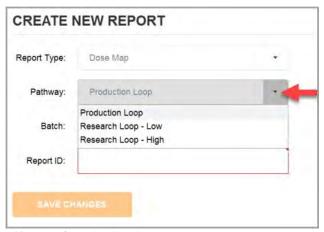
1 On DoseControl's main screen, click the "New Report" button to create a new dosimetry report and begin dosimeter measurements.



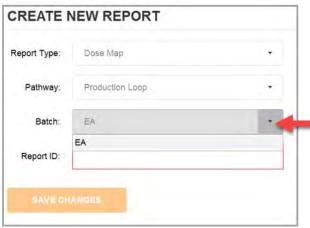
2 Select one of the pre-configured 'Report Type' options from the dropdown menu.



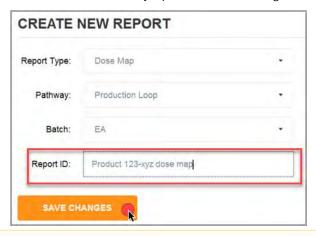
3 Select a 'Pathway' (Irradiation pathway) option from the dropdown menu.



Select a 'Batch' (dosimeter batch) option from the dropdown menu.

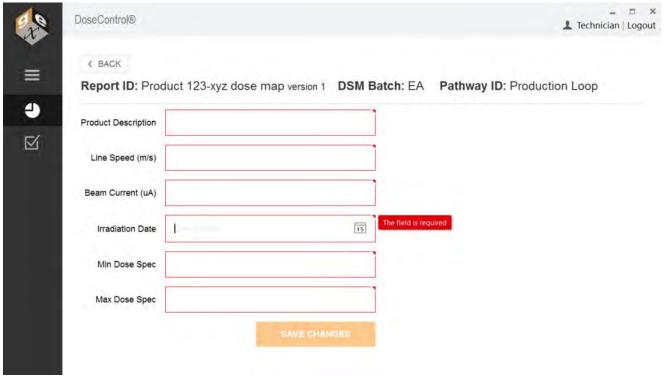


**Enter a new, unique Report ID** to name the new dosimetry report. Click "Save Changes" button.



▲ Do not use any forbidden printable ASCII characters (illegal filename characters) in the Report ID! <>: " / \ | ? \*

**6** Enter values into the report's header fields (if prompted). Click "Save Changes" when complete.



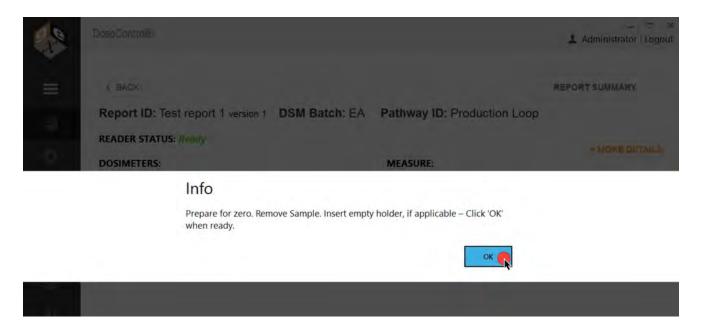
Example of new report with header fields

If there are no report headers setup for the Report Type selected, simply click the "Save Changes" button to go to the measurement screen.

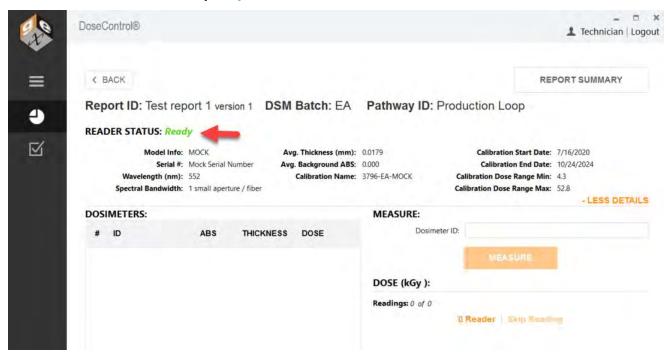


Example of new report with no header fields

- (i) **Reminder** The Application Admin can setup report header fields (see page 99) for each Report Type (see page 96). The report header fields are unique to your process.
- 7 Next, DoseControl will open the dosimeter measurement screen and prompt the user to **prepare to zero '0' the spectrophotometer (Reader)** and begin measurements.



**8** After zeroing the Reader, the dosimeter measurement screen will then open and is now ready for the user to perform measurements. Reader Status should say *Ready*.

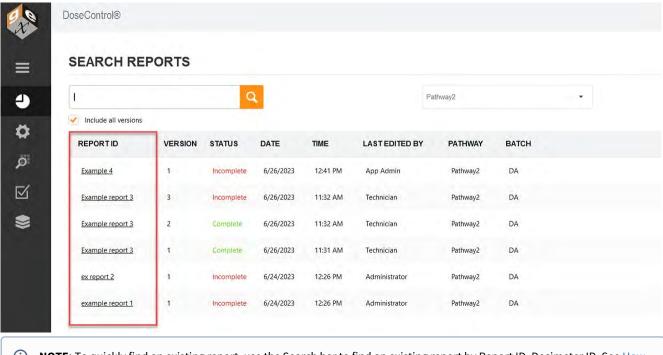


### 4.3.3 How to Open a Existing Report

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A dosimetry report will contain all the dosimeter measurement information and all the associated calibration and process information. To measure dosimeters after irradiation, the user must create a new dosimetry report.

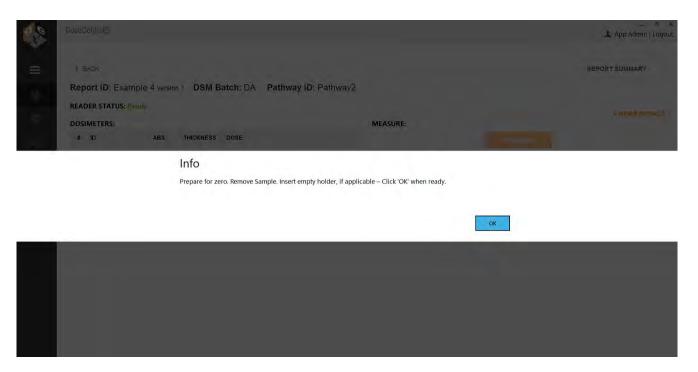
### 4.3.3.1 Instructions

- **1** Go to the DoseControl home screen by clicking the icon on the toolbar.
- 2 Click a Report ID to open an existing dosimetry report.



**NOTE:** To quickly find an existing report, use the Search bar to find an existing report by Report ID, Dosimeter ID. See How to search for a Report or Dosimeter ID (see page 150) section for details.

**3** DoseControl will open the dosimeter measurement screen and prompt the user to prepare to zero '0' the spectrophotometer. Follow the on-screen instructions.



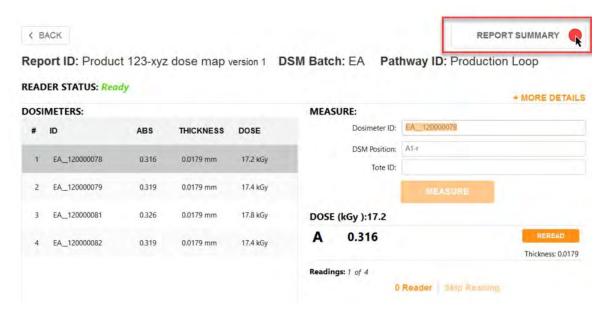
**4** The dosimeter measurement screen will then open and is now ready for the user to perform measurements. Reader Status should say *Ready*.



### 4.3.4 Report Summary Screen

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A dosimetry report will contain all the dosimeter measurement information and all the associated calibration and process information.

The Report Summary provides a view of the overall report information including some key features that are not available on the 'Measure' screen. View a summary of the dosimetry report at any time by clicking the "Report Summary" button in the upper right of the screen:

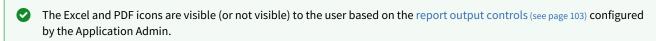


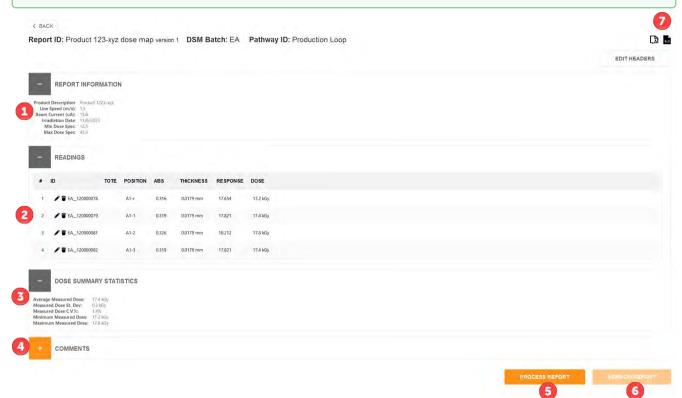
### 4.3.4.1 Report Summary sections

- 1. **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.
- 2. **Readings** Dosimeter ID list from the 'Measure' screen, Tote, Position, Absorbance, (dosimeter) thickness, Dose. If the report uses the special value fields\*, Calculated Min Dose, Calculated Max Dose.
- \*Reference dosimetry reports have special value fields for Min Dose Spec, Max Dose Spec, Ref:Min Ratio, Ref:Max Ratio
- **②**

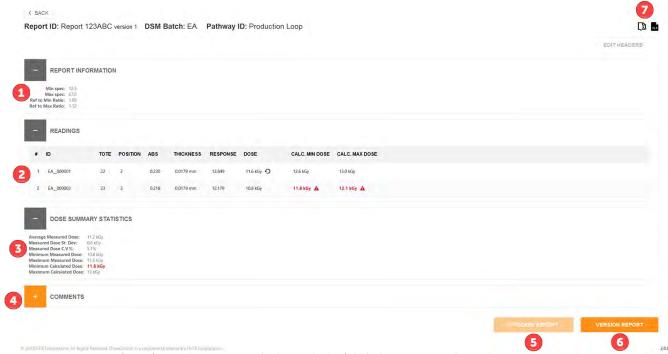
The Application Administrator user role can edit the Dosimeter ID or (soft) delete a dosimeter from a report by clicking on the pencil and trash can icons. The Technician user <u>cannot</u> see the icons or edit Dosimeter ID information in the Readings section.

- For details see How to edit/delete items in a Report (see page 167)
- About User Roles (see page 29).
- 3. **Report Summary Statistics** Lists the statistics for the report
- 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.
- 5. **Process a Report** When you finish a report, you need to "process" or complete the report. Click the "Process Report" button at the bottom of the Report Summary screen. After a report is processed, the button will be greyed out and you cannot make any changes or added dosimeter measurements to the report. See About Completing a Report (see page 164).
- 6. **Version a Report -** To create a new version of a report, click the "Version Report" button. See About Versioning Reports (see page 162).
- 7. Output/Print a Report You can output the report in Excel and PDF formats.





Report Summary screen. An Application Admin is logged in and can see the edit Dosimeter ID icons in the Readings section. The report is not completed so the "Process Report" button is active.



Report Summary screen for a reference dosimetry report (with special value fields). The report is complete so the "Process Report" button is greyed out and the "Version" button is active.

### 4.3.5 How to 'Version' a Report

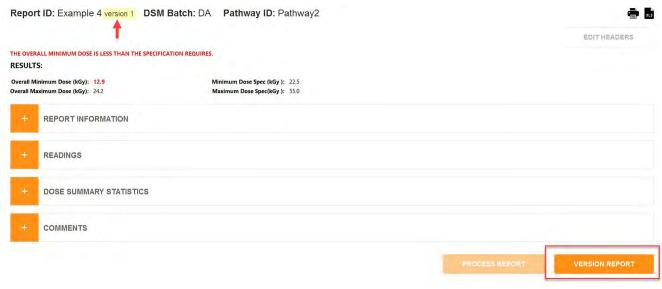
**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A dosimetry report will contain all the dosimeter measurement information and all the associated calibration and process information.



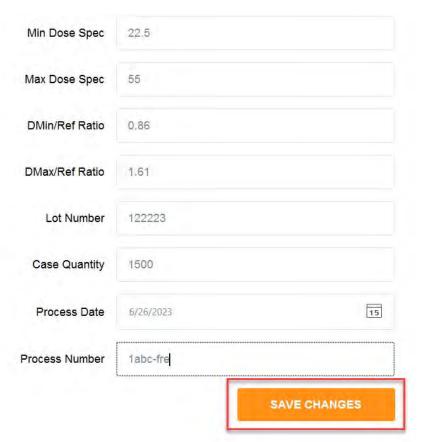
After a report is processed and complete, you must create a version of the report to add additional measurements or make any changes to the report.

#### 4.3.5.1 Create a new version of a report

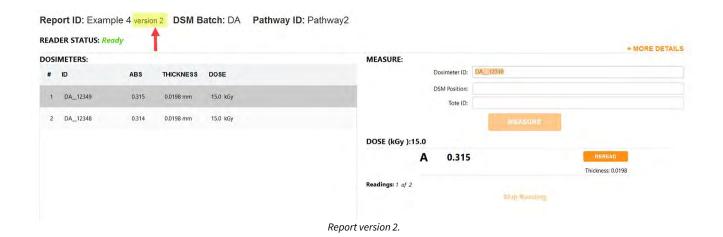
Click the "Version Report" button on lower right of the Report Summary screen. This will create the next iterative version number for the report. Make changes to the report's header information, if necessary. Click "Save Changes". The software will then open the active measurement screen, with the new version of the report open.

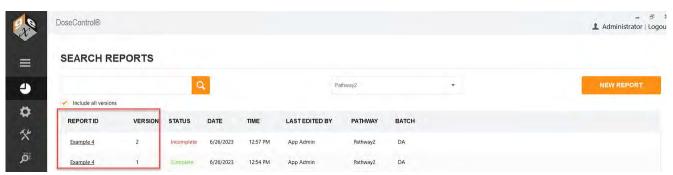


Click Version Report



Change any report headers (if needed), the click "Save Changes".





Version 2 and Version 1 visible on the main reports screen (check "Include all versions")

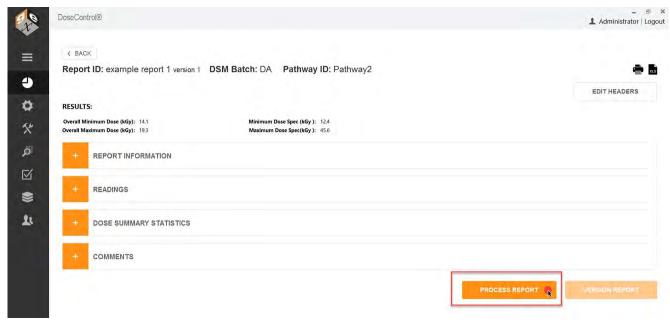
# 4.3.6 How to Complete a Report

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A dosimetry report will contain all the dosimeter measurement information and all the associated calibration and process information.

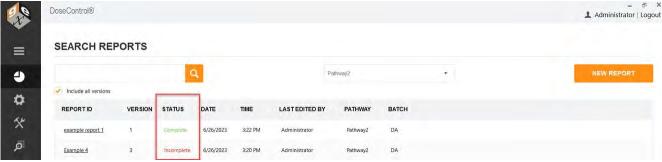
i You cannot edit, add dosimeters or perform measurements in a Completed or processed report. The report is locked.

# 4.3.6.1 How to Complete a Report (called "processing" a report)

When you finish a report, you need to "process" or complete the report. To process a completed report, click the "Process Report" button at the bottom of the Report Summary screen. This saves a final version of the report and changes the report status from *Incomplete* to *Complete*.



Process Report

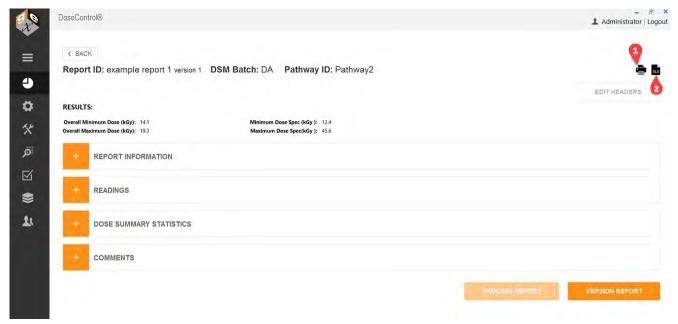


Report status is now "Complete"

### 4.3.7 How to Export a Report to Excel

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A dosimetry report will contain all the dosimeter measurement information and all the associated calibration and process information.

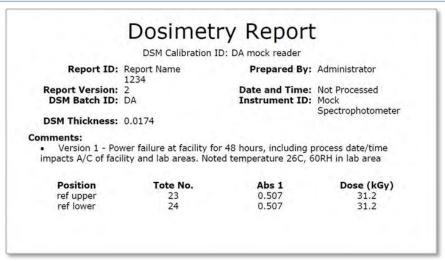
### 4.3.7.1 Report Summary Screen print/export buttons



### 4.3.7.2 1 Export to PDF report format

To export the dosimetry report to PDF format (secure PDF), click the printer icon in the upper right of the Report Summary screen. This will create a PDF document with the content, data and design format configured by the Admin. You can print the PDF or save to any location.

(i) For report header setup instructions for the App Admin user, see Setup Report Headers in DoseControl (see page 91) and About PDF Report fields (see page 118).

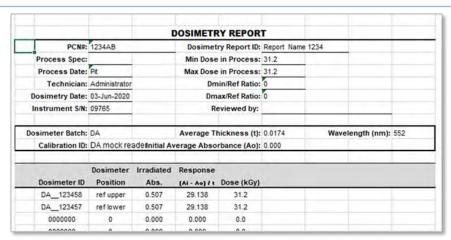


Example PDF report

### 4.3.7.3 2 Export to Excel report format

To export the dosimetry report to MS Excel (\*.xlsx), click the XLS document icon in the upper right of the Report Summary screen. This will create an Excel document of the report with the content, data, and design format configured by the Admin. You can save the report to any location, or print.

For report header setup instructions for the App Admin user, see Setup Report Headers in DoseControl (see page 91) and About Excel Data Fields (see page 109).



Example Excel report

### 4.3.8 How to edit/delete items in a Report

Quick summary - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A user with App Admin (see page 29) user role + "Edit Dosimeters" permissions (see page 35) can edit and/or delete dosimeters in a report. A user with App Admin (see page 29) user role + "Edit Thickness" permissions (see page 70) can edit a dosimeter's thickness in a report.



### Most items in a dosimetry report cannot be edited or deleted.

- Report ID not editable
- · Dosimeter measurement results not editable
- The Report's (and dosimeter measurements in the report) Calibration information, Reader information, Batch information, Pathway - not editable
- Event date/time (i.e. all events) not editable

#### 4.3.8.1 How to edit a Report Header

You may want to correct a report header that was entered incorrectly.

- 1 Login to DoseControl with Technician user role.
- 2 Open the report → Report Summary screen

**3** Click the "Edit Headers" button to edit the Report Information for the report.



4 Add or change the values in the report header fields, then click "Save Changes".



**5** The changes are made to the Report headers

Customer

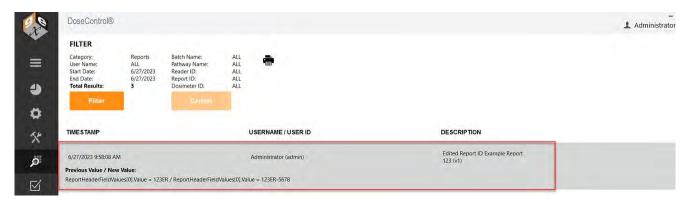


SAVE CHANGES

6 The changes to the Report header are recorded in the audit trail (filter Reports)

< BACK

**Customer Name** 



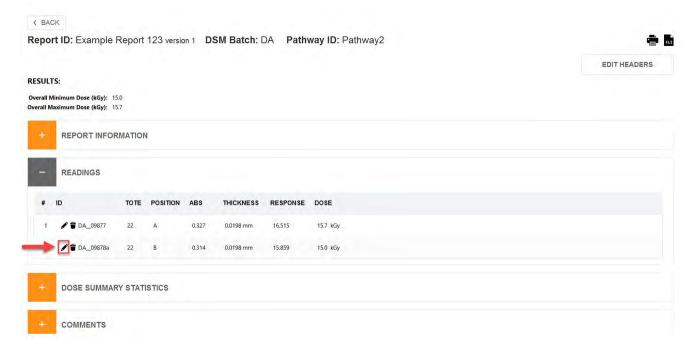
### 4.3.8.2 How to Edit a Dosimeter ID in a Report

You may want to correct a dosimeter ID that was mis-typed or scanned incorrectly. Or you may want to change the dosimeter ID for any reason. DoseControl allows you to do this, with certain restrictions.

- You must an App Admin (see page 29) user role + "Edit Dosimeters" permission (see page 35) to edit dosimeter IDs in a report.
   Read more about the Edit Dosimeters permission (see page 167).
- · You must enter a comment that is recorded with the edit dosimeter ID event in the audit trail.

#### Instructions

- 1 Login to DoseControl (with App Admin user with EditDosimeterIDs permissions).
- **2** Open the report → Report Summary screen
- 3 Click on the edit icon (pencil icon) next to the dosimeter ID you want to edit.



**4** Edit the dosimeter ID. Click the checkmark  $\checkmark$  to save the change.



**5** Enter a reason for the edit when prompted.



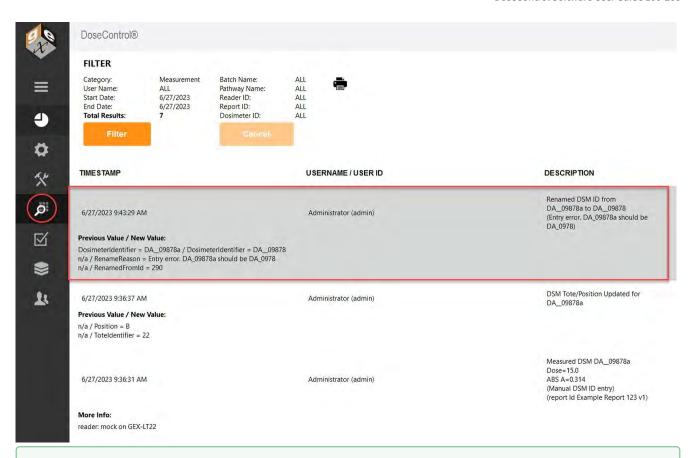


**6** The dosimeter ID is changed in the report.



#	ID	TOTE	POSITION	ABS	THICKNESS	RESPONSE	DOSE
1		22	Α	0.327	0.0198 mm	16.515	15.7 kGy
2	<b>▶ 1</b> DA_09878	22	В	0.314	0.0198 mm	15.859	15.0 kGy

7 The event is recorded in the audit trail (measurement filter)



# $\bigcirc$

### FDA 21 CFR Part 11 compliant

When the Application Admin deletes a dosimeter ID from a report, the dosimeter ID and associated measurement data remains permanently recorded in the database. The dosimeter is removed from the report but is not deleted from the software. Also, the edit or delete event is recorded in the Audit Trail, along with the original data and the edited data, the date/time stamp of the event, and the logged in user associated with the event.



### **GMP compliant**

When the Application Admin edits a dosimeter ID or deletes a dosimeter ID from a report, the user must enter a comment for this event, and the comment is recorded with the event in the Audit Trail.

#### 4.3.8.3 How to Delete a Dosimeter ID in a Report

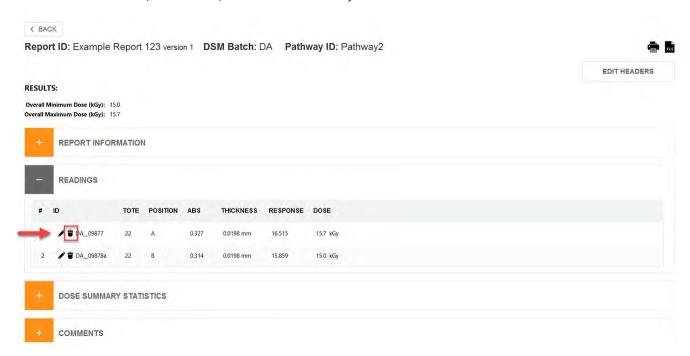
The purpose of deleting a dosimeter is to maintain a clean, easy-to-read report. You many want to delete a dosimeter from a report for a variety of reasons - damaged dosimeter, a user error, etc.

DoseControl allows you to do this, with certain restrictions.

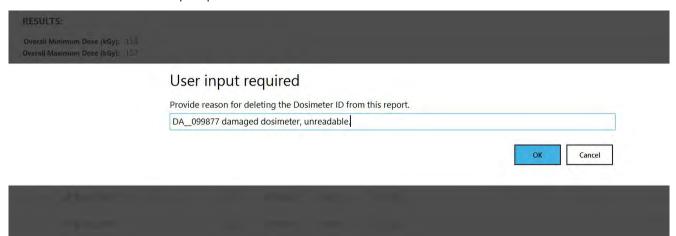
- You must an App Admin (see page 29) user role + "Edit Dosimeters" permission (see page 35) to edit/delete dosimeter IDs in a report. Read more about the Edit Dosimeters permission (see page 167).
- You must enter a comment that is recorded with the edit dosimeter ID event in the audit trail.

### Instructions

- 1 Login to DoseControl (with App Admin user with EditDosimeterIDs permissions).
- **2** Open the report → Report Summary screen
- 3 Click on the delete icon (trash can icon) next to the dosimeter ID you want to edit.



4 Enter a reason for the edit when prompted.



**5** The dosimeter ID is removed from the report.

# Report ID: Example Report 123 version 1 DSM Batch: DA Pathway ID: Pathway 2

### **RESULTS:**

Overall Minimum Dose (kGy): 15.0 Overall Maximum Dose (kGy): 15.7



# REPORT INFORMATION



ID	TOTE	POSITION	ABS	THICKNESS	RESPONSE	DOSE
<b>∕ 1</b> DA_09878	22	В	0.314	0.0198 mm	15.859	15.0 kGy

6 The event is recorded in the audit trail.



# GMP compliant

When the Application Admin edits a dosimeter ID or deletes a dosimeter ID from a report, the user must enter a comment for this event, and the comment is recorded with the event in the Audit Trail.

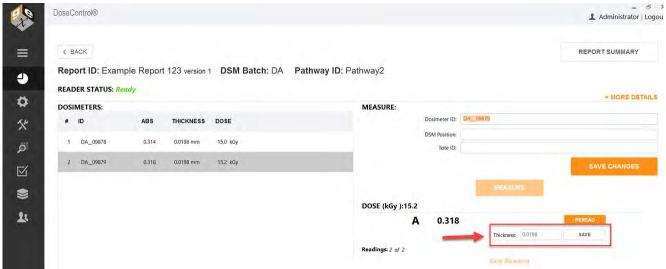


### FDA 21 CFR Part 11 compliant

When the Application Admin deletes a dosimeter ID from a report, the dosimeter ID and associated measurement data remains permanently recorded in the database. The dosimeter is removed from the report but is not deleted from the software. Also, the edit or delete event is recorded in the Audit Trail, along with the original data and the edited data, the date/time stamp of the event, and the logged in user associated with the event.

### 4.3.8.4 How to Edit Dosimeter Thickness in a Report

You may want the user to be able to input a thickness value for each dosimeter directly on the measurement screen.



Edit thickness field for a dosimeter on the measurement screen

DoseControl allows you to do this, with certain restrictions.

- You must an Technician (see page 29)user role + "Edit Thickness" permission (see page 35) to edit/delete dosimeter IDs in a report. Read more about the Edit Dosimeter Thickness on the measurement screen. (see page 0)
- · Edit dosimeter thickness event is recorded in the audit trail.



#### **USE CASE:**

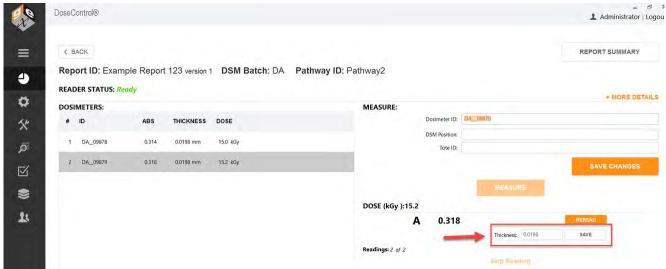
'Edit Thickness' feature is useful when dealing with aFWT film where the actual measured thickness is different than the stated average.

#### Instructions

1 Login to DoseControl as a Technician user. Dosimeter Thickness permission must to active in Dosimeter Types setup.

**Dosimeter Thickness** - If active, Edit Dosimeter IDs permission allows any user with both Application Admin and Technician user roles to edit the thickness of a dosimeter for a dosimeter measurement. Setup - Dosimeter Types (see page 70).

 ${\bf 2}$  Edit the dosimeter thickness as needed. Click Save to update the value.



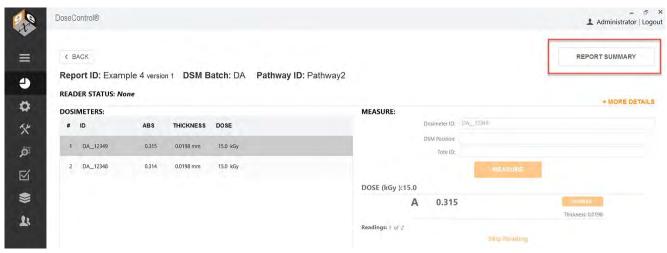
Edit thickness field for a dosimeter on the measurement screen

### 4.3.9 How to add a comment to a Report

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and measure dosimeters. A dosimetry report will contain all the dosimeter measurement information and all the associated calibration and process information. To measure dosimeters after irradiation, the user must create a new dosimetry report

#### 4.3.9.1 Instructions

1 Go to the Report Summary screen.



2 To add a comment to a report, expand the Comments area and type a comment. Click Update Comment to save:

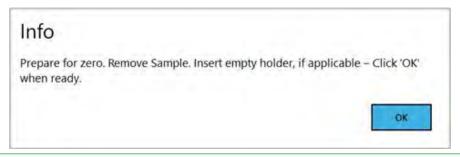


#### 4.4 How-to measure dosimeters

# 4.4.1 How to Measure Dosimeters

**Quick summary** - Any user (with a Technician role (see page 27)) can measure dosimeters on the report's measurement screen. When the reader is active and connected to the DoseControl system, the user simply places the dosimeter into the holder, enters a dosimeter ID on the screen, and then clicks the "measure" button. The measured absorbance and dose will appear next to the dosimeter's ID on the screen.

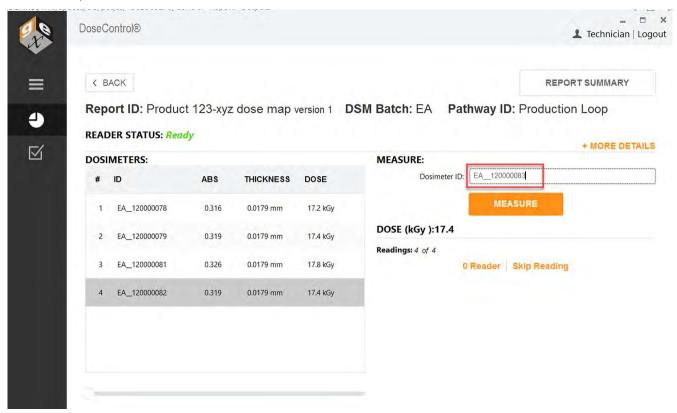
- 1 From the DoseControl home screen, create a new report or open an existing report.
- 2 The software will open the measurement screen. You will always "zero" the reader at the start of every measurement session. Follow the on-screen prompts.
  - · Remove dosimeter samples from the sample compartment.
  - Click OK to zero the reader.





The software verifies the measurement wavelength setting of the spectrophotometer before every measurement and ensure it matches the calibration settings. The measurement wavelength is set in the Calibration configuration, and the software will automatically control the measurement wavelength of the spectrophotometer.

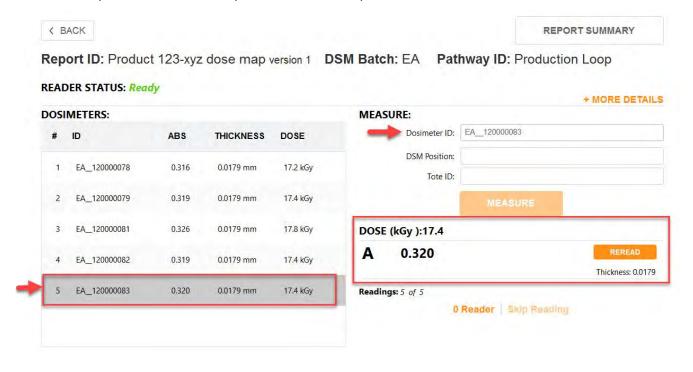
- 3 The cursor defaults to the Dosimeter ID field. Capture the Dosimeter ID in one of the following ways:
  - a) Type a dosimeter ID into the Dosimeter ID field.
  - b) Scan the dosimeter ID using a hand-held scanner
  - **c)** If you have an internal barcode scanner installed, just click the "Measure" button and the dosimeter ID is automatically captured.



- (i) If you have the internal Matrix 120 scanner installed in the sample compartment you DO NOT need to enter a dosimeter ID. The ID will be automatically scanned when you click "Measure". See How to use the Matrix scanner
- 4 Click the 'Measure' button to measure the dosimeter's absorbance value.



5 The dosimeter is measured and the measurement information is shown in the Dosimeters list section of the screen, displaying the dosimeter ID, the measured absorbance, the dosimeter thickness, and the calculated dose.



NOTE

The 'thickness' value is the average thickness value of the dosimeter batch (the Batch (see page 72)is setup by the App Admin) associated with the active calibration (see page 80) (dosimeter batch calibration). The ABS 'absorbance' value is the value measured by the spectrophotometer. If the absorbance count is 2 or more (e.g. A and B dosimeter) the absorbance and thickness are the average of both replicates.

NOTE

The 'dose' is calculated by the software using the active calibration (see page 80) information.

5 For each Dosimeter ID, you can enter a 'DSM Position' (dosimeter position, such as reference) and 'Tote ID' (the tote, carrier number) if you desire. Click the "Save Changes" button. This information will be saved with the Dosimeter ID measurement information.

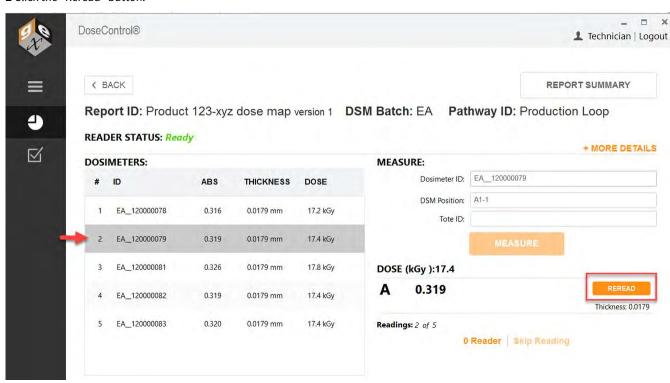


6 Repeat the measurement process for all required dosimeters. The measurement list will update with each action.

#### 4.4.2 How to Reread (re-measure) Dosimeters

Quick summary - Any user (with a Technician role (see page 27)) can measure and reread dosimeters on the report's measurement screen.

- 4.4.2.1 How to reread (re-measure) a dosimeter
- **1** For any dosimeter in a report, click to highlight the dosimeter you want to reread.
- 2 Click the "Reread" button.



**3** Select a reread reason from the dropdown options.

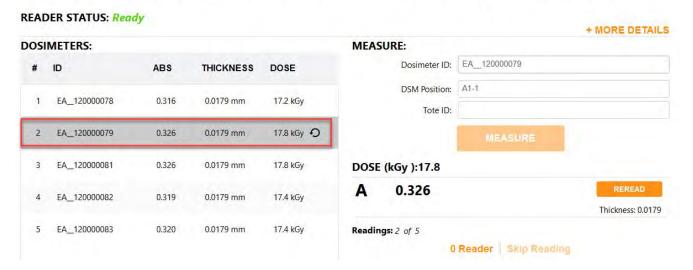


**4** Follow the software prompts to complete the reread.



**5** The completed reread measurement appears in the dosimeter list on the screen and in reports. A reread icon appears next to the dosimeter.

Report ID: Product 123-xyz dose map version 1 DSM Batch: EA Pathway ID: Production Loop



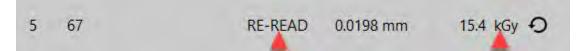
#### 4.4.2.2 "Simple" reread example

(i) A reread that uses the "simple" method will replace the original absorbance (ABS) and dose values with the new values. A reread icon will appear next to the dose to indicate the dosimeter has been reread. See Statistical Reread rejected result (see page 181).



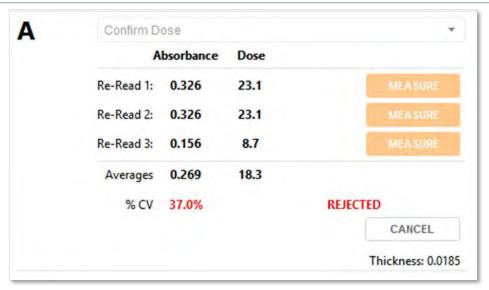
#### 4.4.2.3 "Statistical" reread example

(i) If a reread using the "statistical" method passes the statistical test, the absorbance (ABS) will say **RE-REREAD**, and the dose value will be the new value. A reread icon will appear next to the dose to indicate the dosimeter has been reread.



#### 4.4.2.4 Statistical Reread "Rejected" Result

i) **NOTE:** the purpose of statistical rereads is to verify repeatability of the three measurements (or four if including the original measurement).



Question: What happens if a statistical reread results C.V. % fails the statistical specification?

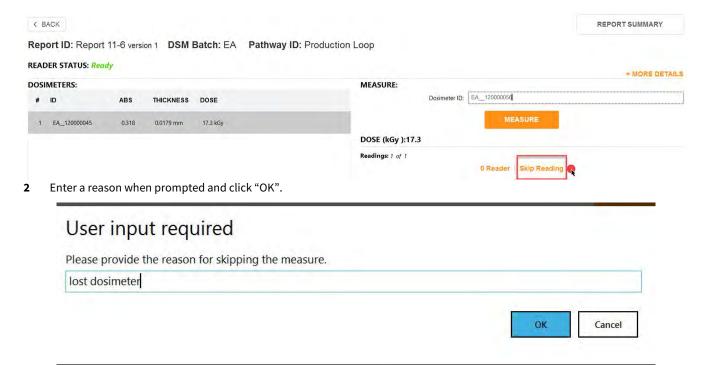
**Answer:** The C.V. % will be in bold red and **REJECTED**. The original Dose value remains on the measurement screen. The user can exit back to the normal measurement mode by selecting the "Cancel" button.

## 4.4.3 How to 'skip' a dosimeter measurement

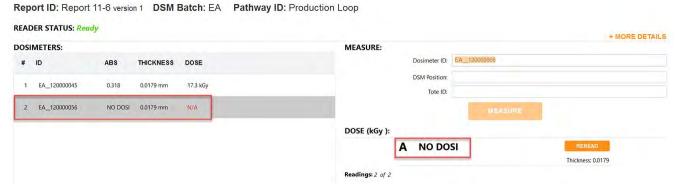
Quick summary - Any user (with a Technician role (see page 27)) can measure and reread dosimeters on the report's measurement screen.

## 4.4.3.1 To skip a dosimeter measurement

1 To skip a dosimeter reading, scan or enter the Dosimeter ID and then click the "Skip Reading" button.



The skipped dosimeter ID will be recorded, and the absorbance will note "NO DOSI" with a dose of "N/A".



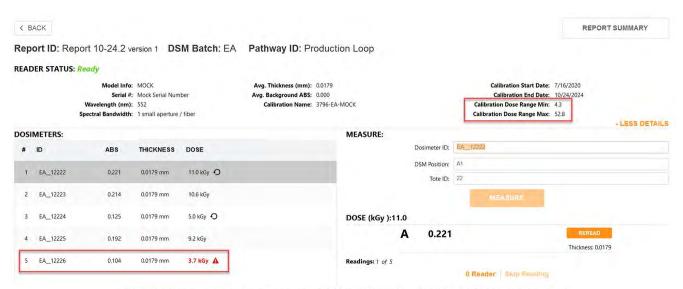
#### 4.4.4 Alerts for dosimeter measurements outside dose range

Quick summary - Any user (with a Technician role (see page 27)) can measure and reread dosimeters on the report's measurement screen.

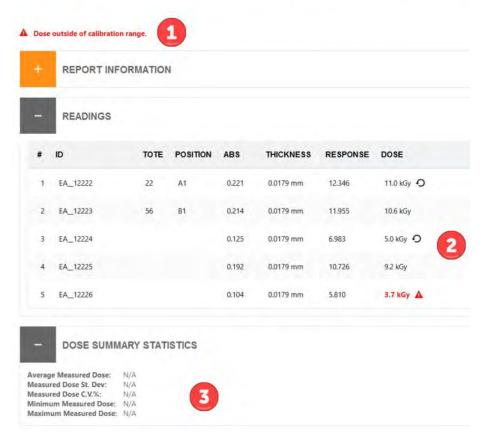
### 4.4.4.1 Alerts for Measurements Outside the Calibration Min/Max Dose Range

### Doses that are outside of the Calibration min and max range are not valid.

If a dosimeter measurement is outside the dose range of the batch calibration's minimum and maximum, DoseControl will highlight the out of range dose in **red font** and place an alert icon next to the result. These alerts are present on both the measurement screen and the report summary screen.



Report ID: Report 10-24.2 version 1 DSM Batch: EA Pathway ID: Production Loop



Report Summary screen will display 1) an alert "Dose outside of calibration range", 2) the dose in bold red font, 3) will not calculate dose summary statistics.

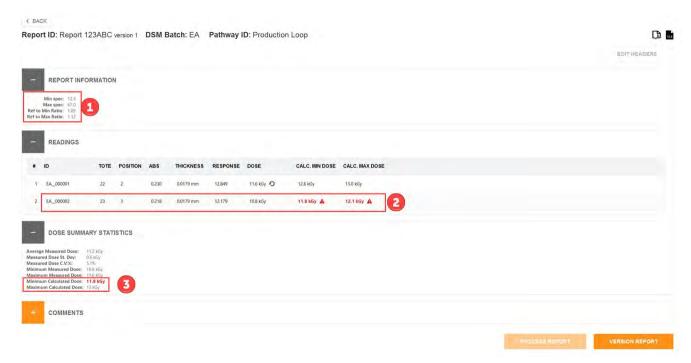
DoseControl Software User Guide 100-266

#### 4.4.4.2 Alerts for Measurements Outside the Process Specifications Min/Max Dose Range

#### This feature applies only to reports with report headers Min Dose Spec, Ref:Min Ratio, Max Dose Spec, Ref:Max Ratio.

If a dosimeter measurement is outside the range of the product specification's overall minimum or maximum dose, DoseControl will highlight the out of range dose in **red** color, place an alert icon next to the result, and report an alert statement. These alerts are present on both the measurement screen and the report summary screen.

- 1. Process specification fields
- 2. Calculated Min Dose and Calculated Max Dose fields in bold red font with alert that the dose is outside the process Min/Max Dose Specification
- 3. Dose Summary Statistics displays dose in bold red font if the dose is outside the process Min/Max Dose Specification



## 4.4.5 How to use DoseControl in 'manual mode'

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and use the software's reporting and dosimeter measurement features.



The Application Admin must enable Manual Mode (see page 127) to allow use of this feature. See Setup - Manual Mode. (see page 127)

#### 4.4.5.1 What is Manual Mode?

Manual Mode allows the user to record dosimeter measurements in the DoseControl software when the configured reader (spectrophotometer) is disconnected from the system. The user measures the dosimeter in the reader and then types the absorbance value in the DoseControl measurement screen; the absorbance value is recorded in the dosimetry report just as an

automatic measurement would be. This feature can be very helpful when validating the dose output of the software after configuring a calibration for a dosimeter batch, or if some event occurs that prevents the spectrophotometer from connecting to the software.

#### 4.4.5.2 How to Use Manual Mode

1 If the configured reader for the workstation is not connected or is powered off, then the Manual Mode button will appear on the measurement screen. The Reader Status will display *Failed* because the reader is disconnected. Toggle Manual Mode to the "on" position. The toggle switch will have a green color to indicate Manual Mode is operating.



2 Type the dosimeter ID into the Dosimeter ID field on the measurement screen. Click "Add Dosimeter" button. You will see the dosimeter's ID added to the Dosimeters list without an absorbance value, thickness or calculated dose:



3 Using the reader, measure the dosimeter's absorbance value and note the value displayed on the reader's screen (GENESYS 20 or 30) or in the Thermo Insight software (Evolution). Ensure the measurement wavelength is correct for the type of dosimeter being measured. Use 552nm for B3 dosimeters.



**4** Type the measured absorbance value into the DoseControl. Click the "Save" button.



5 The thickness value automatically populates (this is the thickness from the calibration) and the software calculates the dose. You will see the dosimeter's absorbance value, thickness value, and dose displayed in the dosimeter list.



(i) Any entry done in Manual Mode is flagged as 'manual' in the database to distinguish it from automatic measurements.

#### 4.4.6 Reader failure workaround

**Quick summary** - Any user (with a Technician role (see page 27)) can create a report and use the software's reporting and dosimeter measurement features.

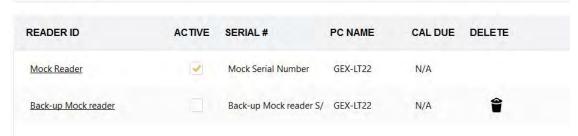
The Application Admin must enable Manual Mode (see page 127) to allow use of this feature.

DoseControl has a special workflow in place for when a spectrophotometer breaks or fails in the middle of dosimetry report before you can complete all the measurements. You can deactivate the failed reader and activate a back-up reader, then create a new version of the Report and repeat the dosimeter measurements in the new version of the report using the back-up reader.

#### 4.4.6.1 Prerequisites to use the back-up spectrophotometer

Make sure that you have a primary Reader (active) and the associated Calibration (active) and the back-up Reader/Calibration (inactive) setup in the software:

## READERS



Primary reader and back-up reader setup in "Readers".

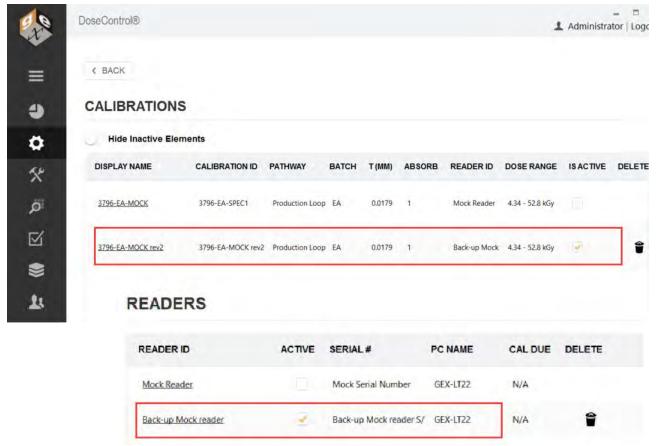
#### **CALIBRATIONS**



Primary reader's calibration is active; back-up reader's calibration is setup in "Calibrations"

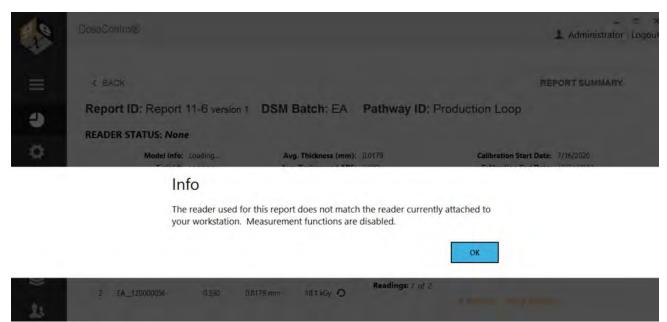
### 4.4.6.2 Workflow description

- **1** If the active Reader breaks or does not pass a performance verification test, go to Setup → Readers and inactivate the reader. Click "Save Changes" to save the inactive status. The reader's associated calibration will automatically inactivate.
- 2 Activate the back-up reader and associated calibration. Go to Setup → Reader and click "active", and "Save Changes".
- 3 Activate the Calibration associated with the back-up reader. Go to Setup → Calibration and click "active", and "Save Changes".

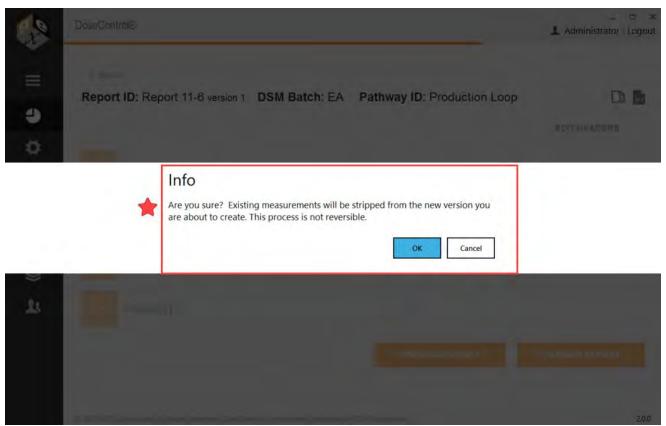


Backup Reader and associated Calibration activated.

4 Open the incomplete report. The software will not allow dosimeter measurements because the back-up Reader ID does not match the report's reader/calibration. Click OK on the warning message.



- **5** Go to Report Summary and click "Process Report" to complete the report. This will lock the Report version.
- 6 On Report Summary and click "Version" to create a new version of the report. The software will warn the user and ask "Are you sure? Existing measurements will be stripped from the new version you are about to create. This process is not reversible." Click OK to proceed. The software will remove the dosimeter absorbance and dose measurements in Report version 2. (Report version 1 has the dosimeter measurements made by the original Reader.)



- 7 Click OK. The report (v2) opens.
  - 1. Notice Report version 2 is using the newly active back-up Reader and associated Calibration.
  - 2. Notice the software has removed the dosimeter absorbance and dose values.

This will allow you to measure the dosimeters and complete the Report.



**8 Measure the dosimeters and complete the report.** The absorbance and dose for each dosimeter appears on the measurement screen, the Report Summary screen and all report outputs. Notice the reread symbol next to the dose - the software treats the measurement as a reread because any original measurement (in Report v1) is not overwritten.



## 4.5 How to use the Audit Trail

i The Application Administrator (see page 29) or global admin user can see and use the Audit Trail in DoseControl.

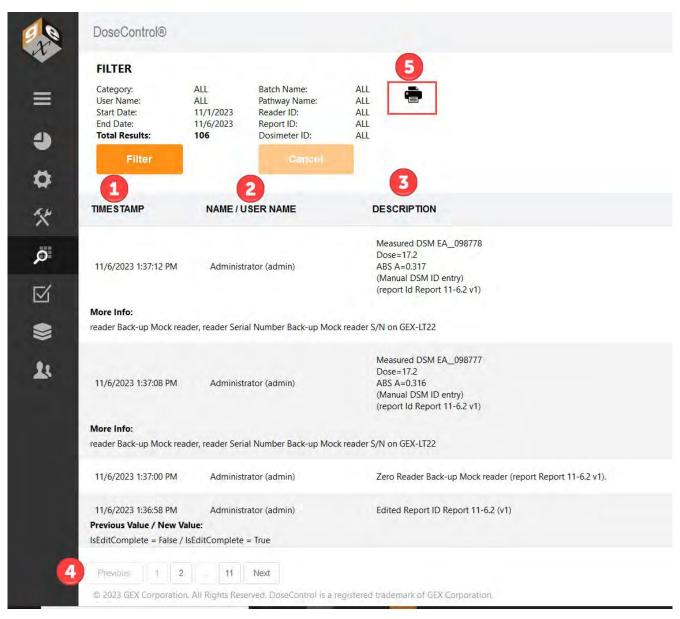
The Audit Trail feature in DoseControl allows the users to search, filter and view the historical record of events from the database. The user can also compile an audit report, and save and print the report. The audit trail is separate from the report screen and measurement functionality, and is accessible only by the Application Admin user role.

#### 4.5.1 Filtered Audit Trail Results

List of all events recorded, filtered by the settings. For each event:

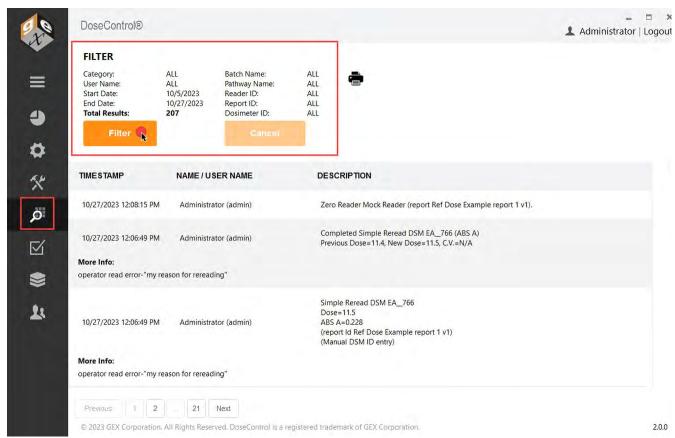
- 1. **Date & Timestamp** the date and time of the event (matches the PC clock and regional settings)
- 2. **UserName / User ID** the user logged into the software at the time of the event.
- 3. **Description** details about the event category and details about the event
  - a. **More info** Some audit log events contain a "more info" detail that lists the event's Previous value / New Value or item details
- 4. Pages of results
- 5. **Print PDF** of audit log filtered results.

3 Set the Audit Report storage location, as needed. See Report Storage Location configuration (see page 40).

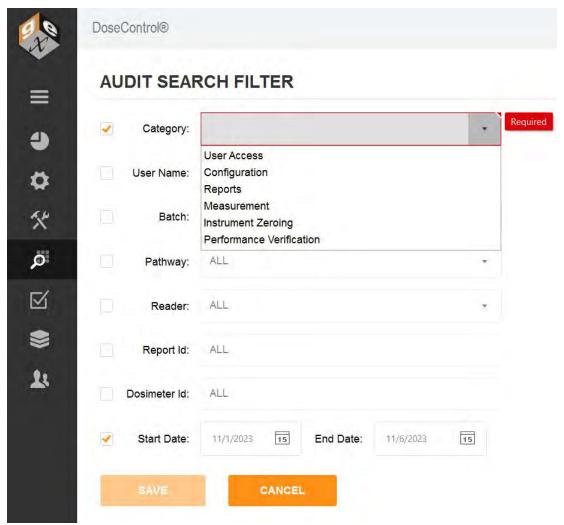


### 4.5.2 Filter settings

Use the "Filter" button to filter audit trail events.



Audit trail main screen



Example: filtered by Category type and Date Range

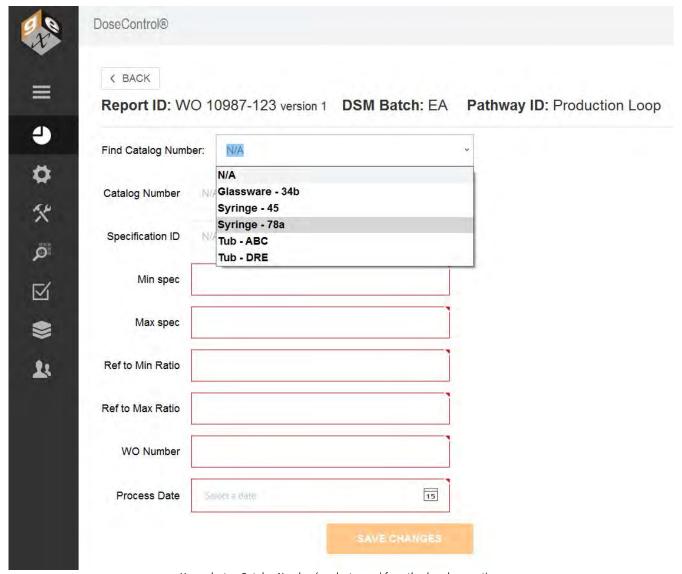
- Category select a Category of event types to narrow down the search. Filter events:
  - User Access
  - Configuration
  - Reports
  - Measurement
  - · Instrument Zeroing
  - Performance Verification
- Start/End date select a date range.
- User Name select a specific user name.
- Batch select a specific batch ID
- Pathway select a specific irradiation pathway ID
- · Reader ID select a specific reader ID
- Report ID enter a Report ID
- Dosimeter ID enter a Dosimeter ID

## **5 Product Specification Module (optional)**

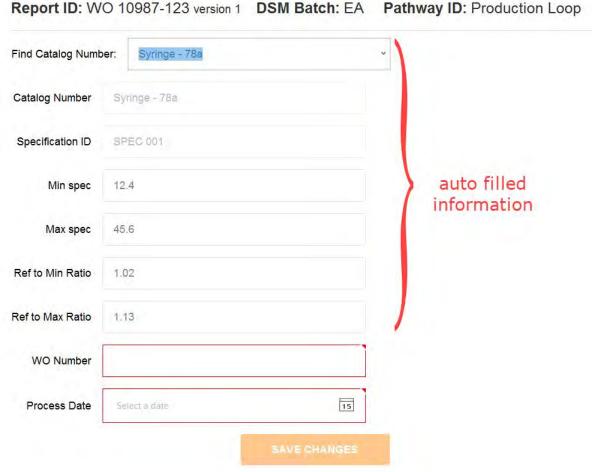
## **5.1 Product Specification Module - Overview**

#### 5.1.1 Overview

The Product Specifications Module can be purchased separately for a one-time fee. The Module automates report creation and eliminates user input errors. User can simply select a product from a drop-down menu and the software will automatically fill in the dosimetry process specification information related to that product.



 ${\it User selects a Catalog \, Number \, (product \, name) \, from \, the \, drop down \, options.}$ 



Report header fields auto-populate with the correct product and process specification information, based on the Catalog Number selected by the user.

## 5.1.2 How Does the Product Specification Module Work?

(i) The Application Admin (see page 29) can create product specifications in the Product Spec Module. The Technician user role (see page 29) cannot see or access the Product Spec module configurations.

This module allows you to store dosimetry specifications (such as min/max required dose, Dref:Dmin, Dref: Dmax) for multiple products, so that a Technician does not have to manually enter the product information and specifications for a new dosimetry report. This reduces the risk of error due to the constant user data entry.

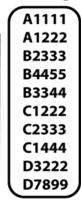
The Application Admin can assign any number of products to a single dosimetry specification. In DoseControl, the Technician clicks a product's Catalog Number from a dropdown menu and the associated specification will automatically populate the correct fields.

## **Product Catalog Number**

## Product Specification "ABC123"

Spec ID: **SPEC ABC123**Ref to Min Ratio: **0.88**Ref to Max Ratio: **1.05** 

Min Dose Specification: **15.0 kGy** Max Dose Specification: **62.5 kGy** 



The Application Admin must setup up a report type to be specifically used with the Product Specifications Module. The Module can be activated for one type of dosimetry report and not activated for another, depending on your needs. For example, a dosimetry report used for routine processing can utilize the product specification functionality and a dosimetry report used for e-beam testing may not.

## 5.2 Setup Product Specifications

(i)

Only users with Application Admin role (see page 29) can setup the Product Specification module.

#### 5.2.1 Add New Product Specification

Click the 'stack' icon in the Menu Bar you can view the Product Specifications home screen.

- 1 Click the "Add New Specification" button on the Product Specification home screen.
- 2 On the pop-up screen, enter the new specification information into each field:



**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'.

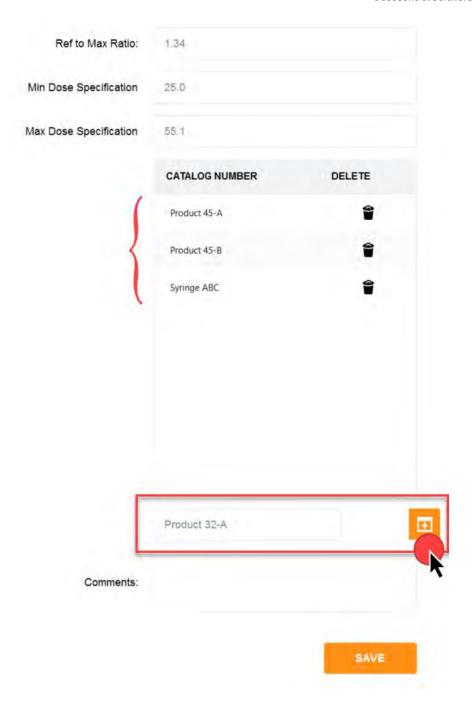
**Catalog Number** – A unique identifier for a specific product. Multiple catalog numbers can be added to a single specification as there are often products with the same ratios and specifications. A Catalog Number can only be associated with one Product Specification.



## (i) IMPORTANT

The dose and correlation fields (ratio fields) must have the correct number of significant digits (2 decimal places).

Next, add a Catalog Number. The Catalog Number is a product identifier. You can add multiple Catalog Numbers as the list of products to be associated with the Product Specification. Type the catalog number into the field below the list and click the + button to add (see screenshot below):



A product Catalog Number can only be associated with <u>one</u> Product Specification. If the Admin attempts to enter the same Catalog Number to another Product Specification, the software will show an error message.

- Add a comment to the comment field, if desired.
- Click "Save" to save the new Product Specification. The Product Specification will appear on the home screen list of specifications.

## 5.3 Setup Report Headers for Use with the Product Specification Module

Need help setting up Report Headers? See instructions for how to setup Dosimetry Report Headers and Data Fields (see page 91).

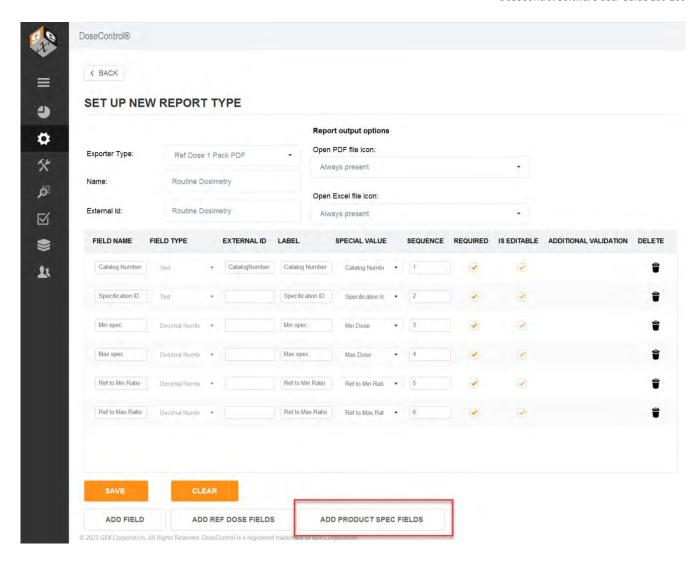


(i) IMPORTANT:

The Application Admin (see page 200) must setup up a report type to be specifically used with the Product Specifications Module.

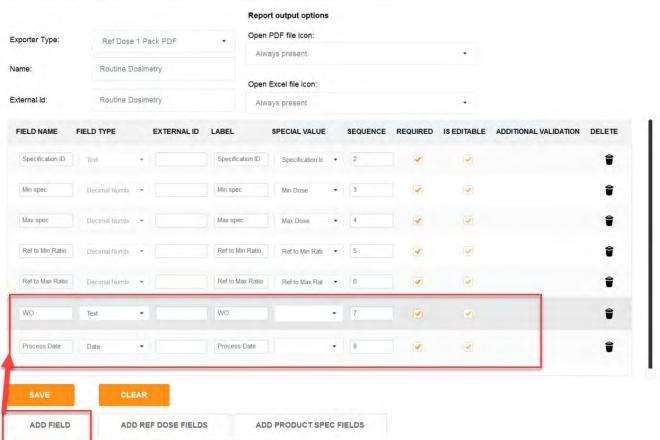
## 5.3.1 Report Type Setup Instructions for a Product Spec report

- Go to Setup → Report Type. Create a new report type.
- Click "Add Product Spec Fields" to add the required report headers fields

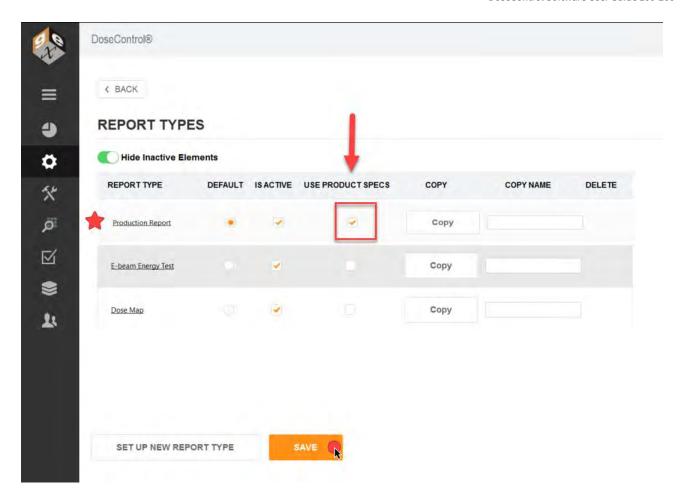


- 3 If desired, add more report header fields specific to your process. In the example below, a Work Order number field is added, and a Process Date field is added.
- 4 Click "Save" to save the report type setup.

# SET UP NEW REPORT TYPE



For the report type you just created, on the main Report Types screen click the "Use Product Specs" box. Make the report type "active" in the software. Click "Save" to save the update.



# 6 Performance Verification Module (optional)

#### 6.1 What is Performance Verification?

#### 6.1.1 What is 'Performance Verification'?

For the Thermo Evolution spectrophotometer, a performance verification test confirms that absorbance measurements at a given wavelength are traceable to an international standard and that the instrument is performing within specified limits.

(i) Users sometime employ the term 'calibration', but the appropriate terminology for the process of testing that a spectrophotometer is performing within manufacturer specifications is called 'performance verification' (P.V.).

#### 6.1.2 Definitions

#### 6.1.2.1 Complete Performance Verification (Complete P.V.)

The process of testing the spectrophotometer using a full range of tests including wavelength and photometric accuracy testing at three or more points to verify the instrument is performing within the tolerances of the published specifications for that instrument.

#### 6.1.2.2 Short Performance Verification (Short P.V.) or 'Daily Check'

The process of testing the wavelength and/or photometric accuracy at one point as an interim verification performed between Complete P.V. of the instrument. Short P.V. test (this is synonymous with terms such as "daily verification" or "daily check") performed at a frequency of 24 hours reduces the risk of measurement instruments giving erroneous results between the typically longer cycle of Complete P.V. tests. The P.V. Module (see page 204) is designed to provide a "daily verification" test of the Evolution.

Guidance document ISO/ASTM 51275:2013(E) Standard Practice for Use of a Radiochromic Film Dosimetry System Performance Verification of Instrumentation (spectrophotometer):

7.3.2 Implementation of a daily check program intended to verify instrument performance before and after measurement sessions is also recommended.

Further reading - GEX Technical Report 100-221 Selecting P.V. Method for the Evolution spectrophotometer Many options are available for Performance Verification (P.V.) testing of the Evolution Spectrophotometer. Users may find it difficult to determine what P.V. method to use, which are 'required', which are 'recommended' by GEX or Thermo Fisher Scientific, and most importantly what is best for the user's application. This technical report discusses the available options, and provides a method to assist users in making a decision to fit their needs.

## 6.2 About the Performance Verification (P.V.) Module

## 6.2.1 P.V. Module: A 'Daily Check' of reader performance

The purpose of the Performance Verification (P.V.) Module is to provide a short-term verification or 'daily check' of the reader's absorbance measurement accuracy. The P.V. Module follows the guidance in ISO/ASTM 51275:2013(E) Standard Practice for Use of a Radiochromic Film Dosimetry System, section 7.3.2 Implementation of a daily check program intended to verify instrument performance before and after measurement sessions is also recommended.

(i) The P.V. Module is intended to be used as an additional check of instrument perfomance, as part of the user's complete performance verification protocols for the reader. It is not a replacement for a complete performance verification of the reader.

#### 6.2.2 About P.V. Test Methods

A performance verification test method (P.V. Method) verifies the wavelength accuracy and the photometric accuracy of the attached, active reader.

- Photometric Accuracy: The photometric accuracy test will use a certified photometric accuracy reference standard measured at 1 or 2 fixed wavelengths. You can use any reference standard that has a value certified in Absorbance units (A). The photometric accuracy test parameters are defined by the reference standard's certifed value.
  - Test the photometric accuracy at 1 fixed wavelength
  - Test the photometric accuracy at 2 fixed wavelength, which allows you to bracket the wavelength of use (e.g. 552nm for B3 dosimeters).
- · Wavelength Accuracy: The wavelength accuracy test the closeness of the wavelength value reported by the reader to the actual value. The software locates the peak near 541.9nm of the internal xenon lamp, and repeats the test three (3) times. The wavelength accuracy test parameters are defined by the published Thermo Evolution spectrophotometer specification for wavelength accuracy.

#### 6.2.3 How does the P.V. Module work?

- The P.V. Module is designed to use the Thermo Spectronic reference standards (GEX product P4220) and the Windose dosimeter holder (GEX product P4334). **See P.V. Module Requirements** (see page 205).
- The user will follow the on-screen instructions to perform a P.V. test. The P.V. test takes about 2-3 minutes to complete. **See P.V. Module Workflow** (see page 206).

#### 6.3 P.V. Module Requirements

- The P.V. module performs a 'daily check' PV test of the Thermo Evolution spectrophotometer.
- The P.V. module is designed to use a photometric standard from the Thermo Spectronic Standards Kit 2 (or similiar). You can also use another NIST-traceable standards set, certified in absorbance units. See Figure 1 below.
- The reference standard must fit into the GEX dosimeter holder for Windose dosimeters (GEX product #P4334). See
- The P.V. module requires two (2) users to be setup with access to DoseControl. The users must have a Tech and/or Application Admin user role. In the event of a PV test failure, the software requires a second user to verify the results of the repeated PV tests.



Figure 1: Thermo Spectronic Standards Kit 2 (GEX Product P4220)

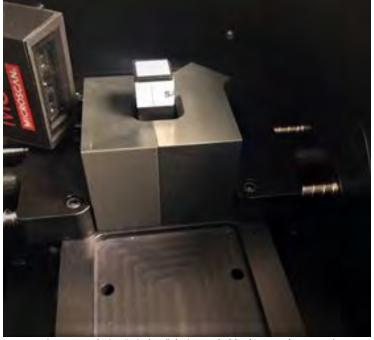


Figure 2: Evolution "Windose" dosimeter holder (GEX Product P4334)

## 6.4 P.V. Module Workflow

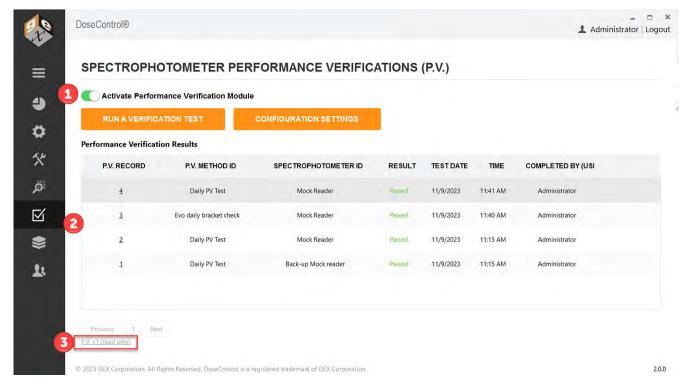
The DoseControl Performance Verification (P.V.) Module enables you to do a 'daily check' of the Evolution reader's performance directly in the software. All you need is a photometric standard from a certified Standards Kit (such as the Thermo Spectronic Standards Kit). DoseControl will walk the user through the P.V. test.

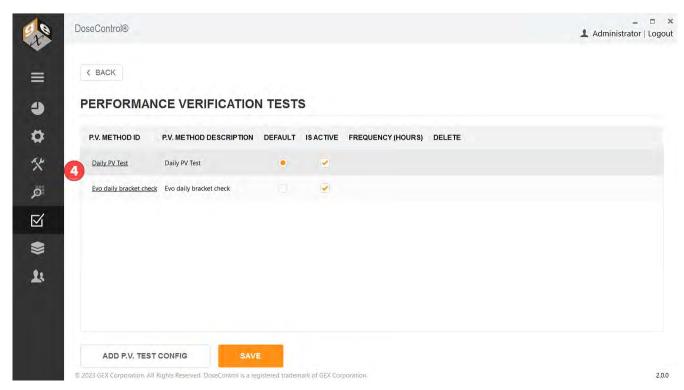
#### 6.4.1 Summary: P.V. Module operation

1. **The P.V. Module can be turned off/on in DoseControl.** This global activation switch allows the Application Admin user role to make the P.V. Module active in the software. The software will prompt you to enter a comment when you activate or inactivate the module, and the event and comment is logged in the Audit trail history.

## 2. P.V. Test results and records

- The P.V. test results can be saved or printed as a final PV Report (secure PDF format).
- All P.V. test activities and results are recorded in the audit trail (Audit Trail -> filter by Performance Verification).
- All P.V. test records are displayed on the P.V. Module main screen, with the most current P.V. test at the top of the list.
- 3. **P.V. Test records from (read only)** If you have upgraded from an older version of DoseControl, all P.V. test records executed in the older version of the software are available as PDF records.
- 4. Each P.V. Method can be made active/inactive in DoseControl.
  - A "P.V. Method" is the type of test. A specific Standards Kit is required for the P.V. Method. See P.V. Methods (see page 220).
  - Multiple P.V. Methods can be active in the software at one time. (Each P.V. Method has reference standards kit information, so this means you can have multiple standards kits available for use at the same time.)
  - The Application Admin can setup one or more P.V. Methods, and activate/inactivate as needed.





#### 6.4.2 P.V. Module Workflow

#### · P.V testing workflow description

- To perform a P.V. test, the user clicks the 'Run a Verification Test' button on the P.V. Module home screen. See How to Execute a P.V. Method (see page 234) for screenshots and details.
- The user must select from a drop-down menu of active P.V. Methods. The user can see which Standard Kit and Standard ID is expected for the P.V. Method.
- The software will guide the user through the P.V. test workflow using pop-up messages instructing the user when to zero the reader, when to insert the testing standard, and which testing standard to use.
- The P.V. test will run automatically, taking about 2 minutes to analyze the results and display a "pass" or "fail" for each of the photometric and wavelength accuracy parameters.
- If any test parameter fails, DoseControl will not allow dosimeter measurements using the failed reader.
- The module enforces a process that guides the user to repeat the P.V. test for the failed reader.
- If the second test passes, the software prompts a second user to log in and repeat the P.V. test to confirm the passing results. (Any second user must log in to confirm testing results.)
- Only if the P.V. test is passed by both the first and second reader will the software allow the reader to be used to
  make dosimeter measurements. See P.V. Test Results Pass/Fail Rules (see page 212)

## 6.5 P.V. Module User Access/Roles

Different users can do diffferent things in the P.V. Module. The Application Admin (see page 27) can activate and configure the P.V. Module, and execute a P.V. test, and the Techician (see page 27) can only execute P.V. tests.

#### 6.5.1 Application Admin user role

Screens visible to the Application Admin user role (see Figures 1 and 2 below):

- 1. Can turn off/on the P.V. Module (globally). Comment required to document reason for on or off event.
- 2. Can setup new P.V. Methods; can activate/inactivate P.V. Methods.
- 3. Can execute a P.V. test
- 4. Can view historical archive of P.V. test records (from older versions of DoseControl)

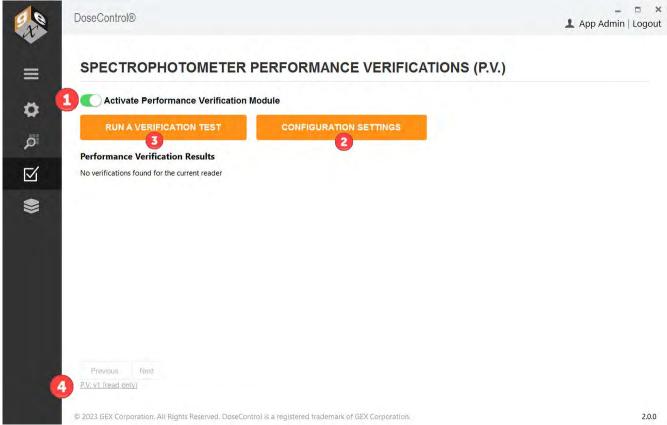
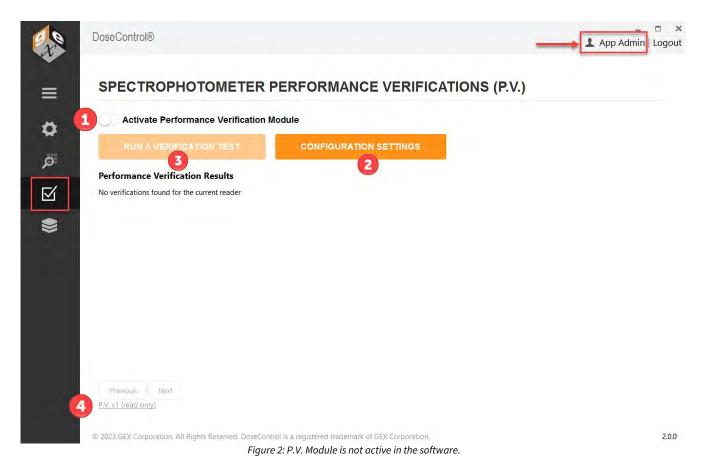


Figure 1: P.V. Module active in the software.



### 6.5.2 Technician user role

Screens visible to the Technician user role (see Figures 3 and 4 below):

- 1. Can execute a P.V. test
- 2. Can view historical archive of P.V. test records (from older versions of DoseControl)
- (i) Technician user <u>cannot</u> turn off/on the PV Module or configure the P.V. Methods.

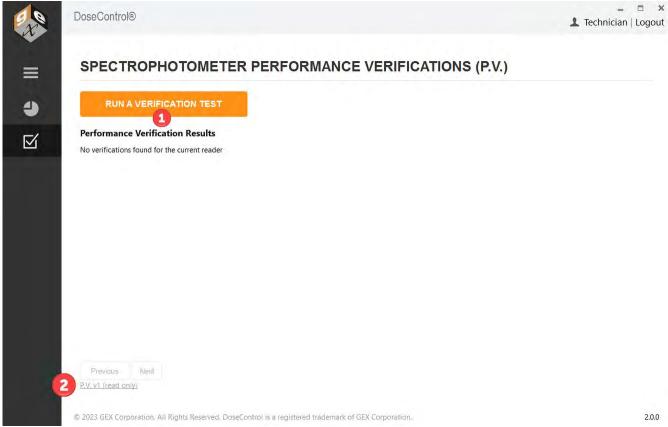


Figure 3: P.V. Module is active in the software.

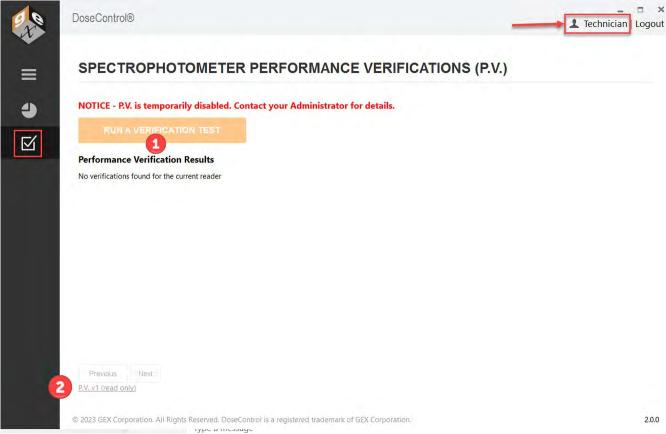


Figure 4: P.V. Module is not active in the software.

## 6.6 P.V. Test Results Pass/Fail Rules

The Technician (see page 29) or Application Admin (see page 29) user can execute a Performance Verification (P.V.)

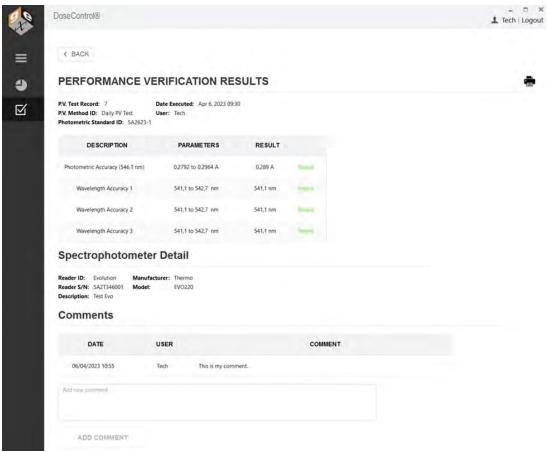
## 6.6.1 Results of the P.V. test are important!

he PASS - If the P.V. test passes, the user can proceed immediately to any area of the software after completion.

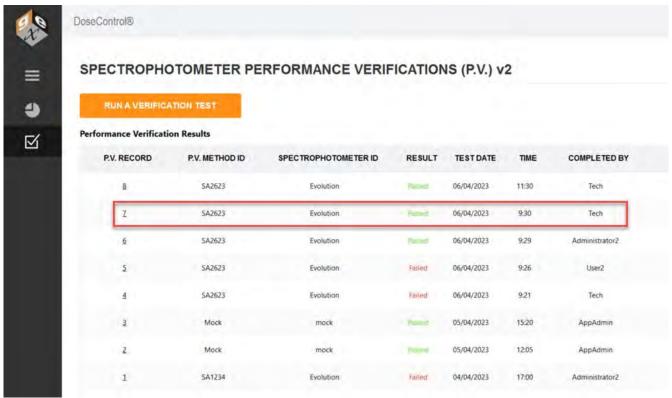
FAIL - If the P.V. test fails, the <u>Evolution reader is not allowed to be used to make measurements</u> until two (2) successive P.V. tests are passed to confirm the reader is operating within specifications. After a failed P.V. test, the software requires a different user to login and perform a P.V. test with passing results. Next, software requires the original user to login and perform a second P.V. test with passing results. If both users get passing P.V. test results, the software then allows access to all areas of DoseControl and allows the Evolution reader to be used to measure dosimeters.

#### 6.6.2 Pass/Fail Rules

RULE 1: All photometric and wavelength accuracy tests must PASS for the P.V. test to PASS.



All P.V. tests pass - result is PASS



P.V. Record result is PASS

**RULE 2:** When the P.V. test status is PASS, the user can proceed immediately to any area of the software after completion. DoseControl will allow dosimeter measurements using the attached active reader.

**RULE 3:** If one or more photometric and wavelength accuracy tests FAIL, the P.V. Test is a *FAIL*.

## PERFORMANCE VERIFICATION RESULTS

P.V. Test Record: 5 Date Executed: Apr 6, 2023 09:26

P.V. Method ID: Daily PV Test User: User2

Photometric Standard ID: SA2623-1

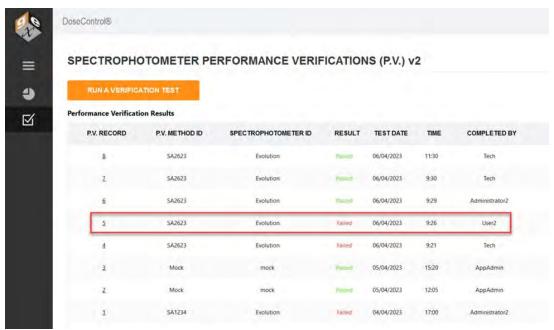
DESCRIPTION	PARAMETERS	RESULT	
Photometric Accuracy (546,1 nm)	0,2792 to 0,2964 A	0,3 A	Failed
Wavelength Accuracy 1	541,1 to 542,7 nm	541,1 nm	Passed
Wavelength Accuracy 2	541,1 to 542,7 nm	541,1 nm	Passed
Wavelength Accuracy 3	541,1 to 542,7 nm	541,1 nm	Passed

# Spectrophotometer Detail

Reader ID: Evolution Manufacturer: Thermo
Reader S/N: 5A2T346001 Model: EVO220

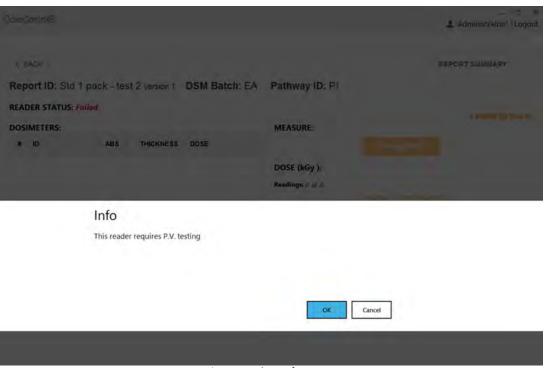
Description: Test Evo

One of the P.V. tests is failed, so the P.V. result is FAIL



P.V. Record result is FAIL

**RULE 4:** When the P.V. test FAILS, <u>DoseControl will not allow dosimeter measurements using the attached active reader.</u> (The user will be prompted to perform a PV Test again.)

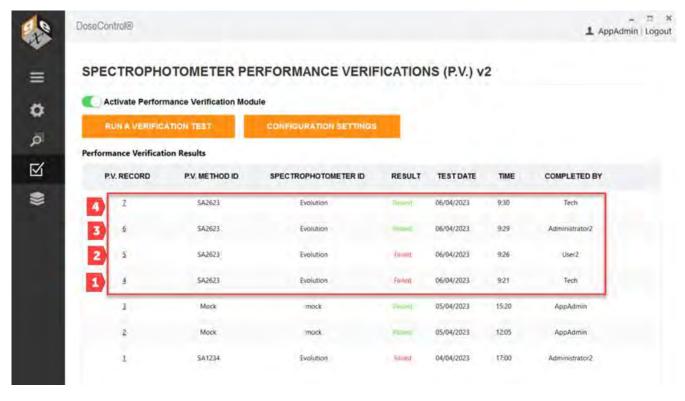


User is prompted to perform a P.V. test

**RULE 5:** When the current P.V. status is FAIL, two (2) different users must PASS two (2) consecutive P.V. Tests on the active, attached reader to achieve a PASS status. The attached reader must have a PASS status before DoseControl will allow the attached reader to be used for dosimeter measurements.

#### Example (see figure below):

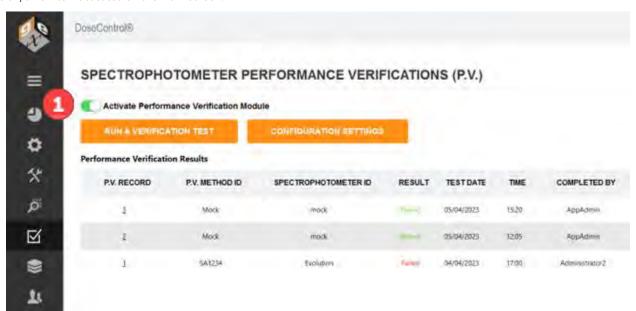
- 1. Tech user fails PV test.
- 2. User 2 fails PV test.
- 3. Adminstrator2 passes PV test.
- 4. Tech user passes PV test.
- 5. DoseControl will allow dosimeter measurements for the attached reader





## 6.7 P.V. Module on/off switch (global)

The Application Admin (see page 27)can turn the P.V. Module on or off in the system. (See User Access for the PV Module (see page 208).) The on/off switch is located on the main screen:

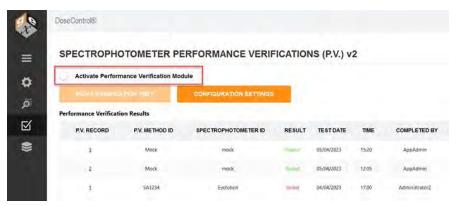


### 6.7.1 Turn on/off the P.V. Module

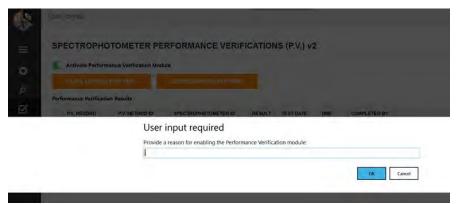
- 1 Login as the Application Administrator
- **2** Go to the P.V. icon on the sidebar menu.



3 Switch the Activate Performance Verification Module. Move the switch to the 'on' position (green) to activate; move to 'off' position (grey) to deactivate.



4 Enter a comment when prompted. A comment is required when you activate or inactivate (turn on/off) the P.V. Module.



(i) Your comment is saved in the audit trail with the P.V. Module activation event occurrence.

## 6.8 P.V. Method types

DoseControl has two different test methods for performance verification. The P.V. Method defines how your P.V. test will function. Each P.V. Method is configured with the reference standard information.

You choose which test method type works best for you.

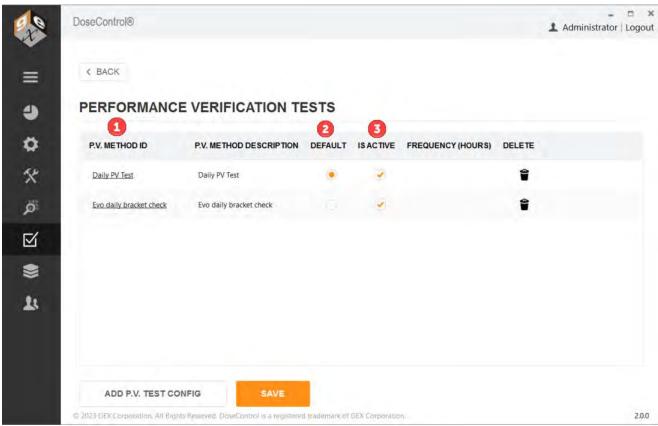
- **P.V. Method:** P.V. Method has one (1) testing wavelength for a photometric accuracy. Choose this test method to test a single wavelength near the wavelength of use. Example if your target wavelength of use if 552nm for B3 film, you should use 546.1nm as the test wavelength.
  - See how to Setup a basic P.V. Method (see page 222).
  - See how to Execute a P.V. test (basic method). (see page 234)
- **P.V. Method Bracket Wavelength of Use:** Method with two (2) testing wavelengths for photometric accuracy. Choose this test method to bracket a measurement wavelength of use. Example if your target wavelength of use is 552nm for B3 film, you should bracket this with 465nm and 590nm as the test wavelengths.
  - See how to Setup a P.V. Method (Bracket Wavelength of Use).
  - See how to Execute a P.V. test (bracket wavelength of use method) (see page 242).

#### 6.8.1 View and Control P.V. Methods

The Performance Verification Tests screen displays the list of P.V. Methods setup in the software.

- 1 P.V. Method ID and Description
- 2 Default: Select one of the P.V. test methods as the default. The default option will appear at the top of the test options available to the user.
- 3 Is Active: Activate one or more P.V. test methods. The active P.V. test methods option will appear in the options available to the user.

Publish date: Nov 15, 2023



Performance Verification Tests screen displays the P.V. Methods configured in the software.

#### **RUN A PERFORMANCE VERIFICATION TEST**

## Select P.V. Method



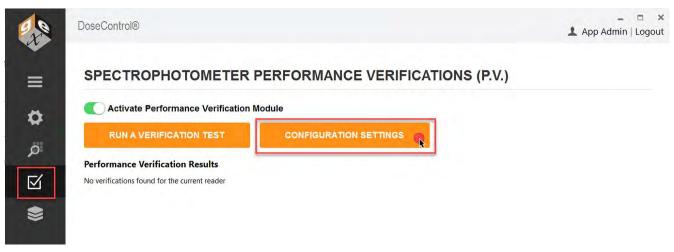
The dropdown options that the user sees at the start of a new P.V. test.

## 6.9 Setup a P.V. Test Method (Basic)

This article describes how to configure a basic Performance Verification (P.V.) test method. The P.V. Method has one (1) testing wavelength for photometric accuracy. *Example - if your target wavelength of use if 552nm for B3 film, you should a test wavelength close to 552nm (such as 546.1nm).* 

#### 6.9.1 Instructions

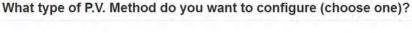
- 1 Login as the Application Administrator and click on the **P.V. Module icon on the left menu bar** to open the P.V. Module home screen.
- 2 Click the "Configuration Settings" button to go to the configuration screen.



3 Click the "Add P.V. Test Config" button at the bottom of the screen.



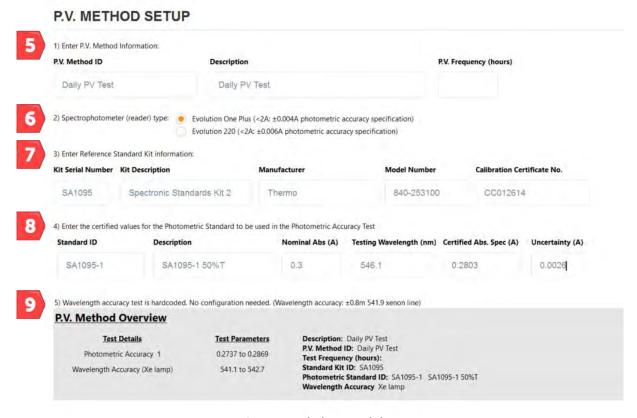
4 Choose a P.V. Method test type. Select "P.V. Method" and click OK.





P.V. Method options

Publish date: Nov 15, 2023



Setup P.V. Method, steps 5-9 below.

#### 5 Enter the P.V. Method test information:

P.V. Method ID - Unique name or identifier for the P.V. test method. Example: Daily PV Test.

**Description** – Description for the P.V. Method. Example: Daily instrument performance check.

**P.V. Frequency (hours)** – When the number of hours expires, a message will pop-up "Reader requires P.V. testing. Do you want to do it now?" The software will not allow dosimeter measurements until a P.V. test is executed and gets a PASS result. Enter the number of hours for the test frequency timer, e.g. 24, 36, 48. Leave blank for ondemand P.V. testing.



#### IMPORTANT!

Before you setup frequency, read about P.V. Frequency setup and usage in the software: About P.V. test frequency (see page 231).

#### 6 Choose Spectrophotometer (reader) type: Select one option.

**Evolution One Plus** model spectrophotometer – DoseControl will use the photometric accuracy specification:  $<2A: \pm 0.004A$ 

**Evolution 220** model spectrophotometer - DoseControl will use the photometric accuracy specification:  $<2A: \pm 0.006A$ 

#### 7 Enter Reference Standard Kit information:

**Kit Serial Number** – Enter the photometric reference standards' kit serial number. Example; SA1095. <u>See item a below.</u>

**Kit Description** – Description for the photometric reference standards' kit. This should be easily identifiable by the user. Example: Spectronic Standards Kit 2, Device ID 006.

Manufacturer - Standards' kit manufacturer. Example: Thermo.

Model Number - Standards' kit model number. Example: 840-253100. See item b below.

Calibration Certificate No.: Standards' kit calibration certificate number. Example: CC012614. See item c below.



5225 Verona Rd., Bldg. 1 Madison, WI 53711 USA



Technical Support: 1 800 532 4752 International Support +1 608 273 5017 www.thermo.com

## Certificate of Calibration SPECTRONIC Standards 2 Kit 840-253100

Submitted to: GEX CORPORATION 7330 S ALTON WAY STE 12-I CENTENNIAL CO 80112 USA Serial Number: SA1095

Certificate Number: CC012614

Date of Calibration: 09 Apr 2021

Performed by: SUSAN GANSHERT
Test Method: 397-018500 Rev A
Bench Used: CLEV300 999001

Sample Temperature: 23 ± 1 °C

Certified Percent Transmittance Values and Uncertainties

Standard ID	SA1095 -1	SA1095 -2	SA1095 -3	SA1095 -4
Nominal %T	50 %T	30 %T	10 %T	3 %T
Uncertainty	± 0.30 %T	± 0.18 %T	± .071 %T	± 0.048 %T
440.0 nm	45.46 %T	27.25 %T	7.58 %T	2.07 %T
465.0 nm	51.81 %T	33,66 %T	9.48 %T	2.91 %T
546.1 nm	52.44 %T	34.54 %T	9.21 %T	2.78 %T
590.0 nm	50.40 %T	31.69 %T	8.23 %T	2.34 %T
635.0 nm	50.59 %T	31.21 %T	9.78 %T	3.04 %T

Publish date: Nov 15, 2023

Standard ID	SA1095 -1	SA1095 -2	SA1095 -3	SA1095 -4
Nominal Abs 0.3 A 0	0.5 A	1.0 A	1.5 A	
Uncertainty	± 0.0026 A	± 0.0026 A	± 0.0031 A	± 0.0070 A
440.0 nm	0.3423 A	0.5646 A	1.1205 A	1.6837 A
465.0 nm	0.2856 A	0,4729 A	1.0231 A	1.5358 A
546.1 nm	0.2803 A	0.4616 A	1.0357 A	1.5559 A
590.0 nm	0,2976 A	0.4991 A	1.0845 A	1.6309 A
635.0 nm	0.2959 A	0.5057 A	1,0096 A	1.5166 A

#### 8 Enter the certified values for the Photometric Standard to be used in the Photometric Accuracy Test:

**Standard ID** – Enter the Standard ID for the photometric standard to be used in the P.V. test. Example: SA1095-1. See item d above

**Description** – Description for the photometric standard to be used in the test. Example: SA1095-1 50%T Standard.

Nominal Absorbance - Enter the Nominal Abs. for the photometric Standard ID. Example: 0.3A. See item e above

Testing Wavelength (nm) - Enter the wavelength to be used in the P.V. test. Example: 546.1. See item f above

**Certified Abs. Spec. (A)** – Enter the certified absorbance specification for the photometric Standard ID from the calibration certificate. Example: 0.2803 <u>See item q above</u>

#### 9 Confirm your setup - View the P.V. Method Overview.

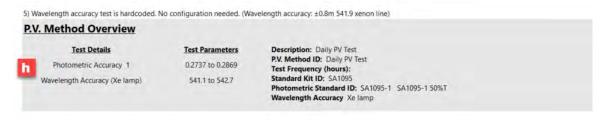
<u>Photometric Accuracy test parameters</u> – DoseControl automatically calculates the test parameters for the Test Wavelength. <u>See item h below.</u>

**Absorbance Spec Min** = Certified value of Reference – (Reference Uncertainty + Evolution Specification for ABS accuracy)

**Absorbance Spec Max** = Certified Value of Reference + (Reference Uncertainty + Evolution Specification for ABS accuracy)

<u>Wavelength Accuracy test parameters</u> – Hardcoded in DoseControl. No configuration.

**541.1 to 542.7 nm** = wavelength accuracy test parameters. The software locates the peak near 541.9nm of the internal xenon lamp, and repeats the test three (3) times. The wavelength accuracy test parameters are defined by the published Thermo Evolution spectrophotometer specification for wavelength accuracy.



P.V. Method Overview section displays the test parameters.

- 10 Click Save to complete PV Method setup.
- 11 Make the PV Method "active" and "default" in the software, as needed.

#### PERFORMANCE VERIFICATION TESTS

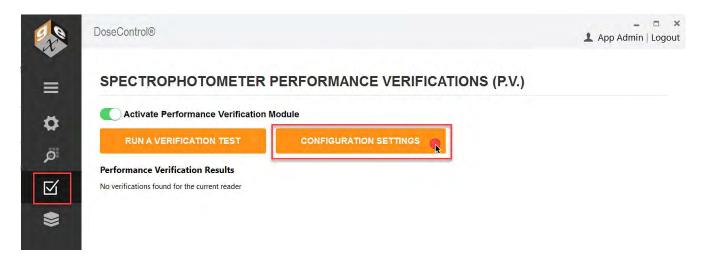


## 6.10 Setup a P.V. Test Method (Bracket Wavelength of Use)

This article describes how to configure a basic Performance Verification (P.V.) test method. The P.V. Method has one (1) testing wavelength for photometric accuracy. *Example - if your target wavelength of use if 552nm for B3 film, you should choose test wavelengths that bracket 552nm (such as 465nm and 590nm).* 

#### 6.10.1 Instructions

- 1 Login as the Application Administrator and click on the **P.V. Module icon on the left menu bar** to open the P.V. Module home screen.
- 2 Click the "Configuration Settings" button to go to the configuration screen.



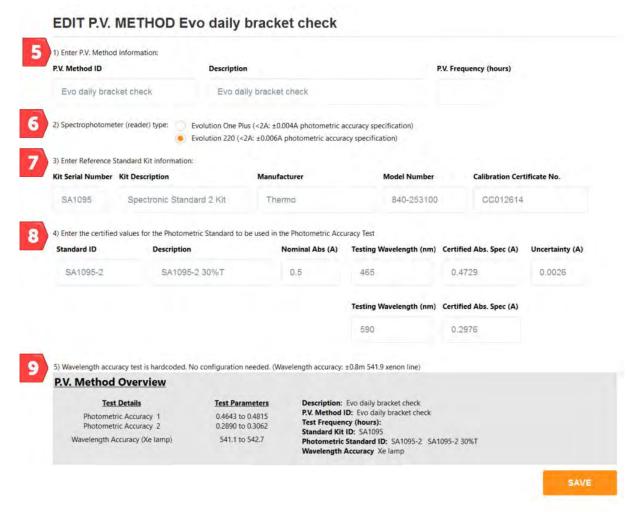
3 Click the "Add P.V. Test Config" button at the bottom of the screen.



4 Choose a P.V. Method test type. Select "P.V. Method" and click OK.



P.V. Method options - choose Bracket Wavelength of Use



P.V method information - Steps 5-9 below

#### 5 Enter the P.V. Method test information:

P.V. Method ID - Unique name or identifier for the P.V. test method. Example: Daily PV Test.

**Description** – Description for the P.V. Method. Example: Daily instrument performance check.

**P.V. Frequency (hours)** – When the number of hours expires, a message will pop-up "Reader requires P.V. testing. Do you want to do it now?" The software will not allow dosimeter measurements until a P.V. test is executed and gets a PASS result. Enter the number of hours for the test frequency timer, e.g. 24, 36, 48. Leave blank for ondemand P.V. testing.



#### IMPORTANT!

Before you setup frequency, read about P.V. Frequency setup and usage in the software: About P.V. test frequency (see page 231).

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#### 6 Choose Spectrophotometer (reader) type: Select one option.

**Evolution One Plus** model spectrophotometer – DoseControl will use the photometric accuracy specification: <2A: ±0.004A

**Evolution 220** model spectrophotometer - DoseControl will use the photometric accuracy specification: <2A: ±0.006A

#### 7 Enter Reference Standard Kit information:

**Kit Serial Number** – Enter the photometric reference standards' kit serial number. Example; SA1095. <u>See item a below.</u>

**Kit Description** – Description for the photometric reference standards' kit. Example: Spectronic Standards Kit 2, Device ID 006.

Manufacturer - Standards' kit manufacturer. Example: Thermo.

Model Number - Standards' kit model number. Example: 840-253100. See item b below.

Calibration Certificate No.: Standards' kit calibration certificate number. Example: CC012614. See item c below.



5225 Verona Rd., Bldg. 1 Madison, WI 53711 USA

Technical Support: 1 800 532 4752 International Support +1 608 273 5017 www.thermo.com



Submitted to: GEX CORPORATION 7330 S ALTON WAY STE 12-I CENTENNIAL CO 80112 USA Serial Number: SA1095
Certificate Number: CC012614
Date of Calibration: 09 Apr 2021
Performed by: SUSAN GANSHERT
Test Method: 397-018500 Rev A
Bench Used: CLEV300 999001
Sample Temperature: 23 ± 1 °C

Certified Percent Transmittane	e Values and Uncertainties
--------------------------------	----------------------------

Standard ID	SA1095 -1	SA1095 -2	SA1095 -3	SA1095 -4
Nominal %T	50 %T	30 %T	10 %T	3 %T
Uncertainty	± 0.30 %T	± 0.18 %T	± .071 %T	± 0.048 %T
440.0 nm	45,46 %T	27.25 %T	7.58 %T	2.07 %T
LOS No.	E4 D4 N/T	22 SS W.T	9.48 %T	2.91 %T

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465.0 nm	51.81 761	-33,00 701	2.40 (0)	
546.1 nm	52.44 %T	34.54 %T	9.21 %T	2.78 %T
590.0 nm	50.40 %T	31.69 %T	8.23 %T	2.34 %T
635.0 nm	50,59 %T	31.21 %T	9.78 %T	3.04 %T

Standar	d ID	SA1095 -1	SA1095 -2	SA1095-3	SA1095 -4
Nominal	Nominal Abs 0.3 A 0.5 A	1.0 A	1.5 A ± 0.0070 A		
Uncertainty	± 0.0026 A ± 0.0026 A	± 0.0031 A			
440.0	nm	0.3423 A	0.5646 A	1.1205 A	1,6837 A
465.0	nm	0.2856 A	0.4729 A	1.0231 A	1.5358 A
546.1	nm	0.2803 A	0.4616 A	1.0357 A	1.5559 A
590.0	nm	0.2976 A	0.4991 A	1.0845 A	1.6309 A
635.0	nm	0.2959 A	0.5057 A	1.0096 A	1.5166 A

Example of reference standard calibration certificate

#### 8 Enter the certified values for the Photometric Standard to be used in the Photometric Accuracy Test:

**Standard ID** – Enter the Standard ID for the photometric standard to be used in the P.V. test. Example: SA1095-2. See item d above

**Description** – Description for the photometric standard to be used in the test. This should be easily identifiable by the user. Example: SA1095-2 30%T Standard.

Nominal Absorbance – Enter the Nominal Abs. for the photometric Standard ID. Example: 0.3A. See item e above

Testing Wavelength 1 (nm) - Enter the wavelength to be used in the P.V. test. Example: 465. See item f above

**Certified Abs. Spec. 1 (A)** – Enter the certified absorbance specification for the photometric Standard ID from the calibration certificate. Example: 0.4729 <u>See item g above</u>

Testing Wavelength 2 (nm) – Enter the wavelength to be used in the P.V. test. Example: 590 <u>See item f above</u>

**Certified Abs. Spec. 2 (A)** – Enter the certified absorbance specification for the photometric Standard ID from the calibration certificate. Example: 0.4991 <u>See item g above</u>

#### 9 Confirm your setup - View the P.V. Method Overview.

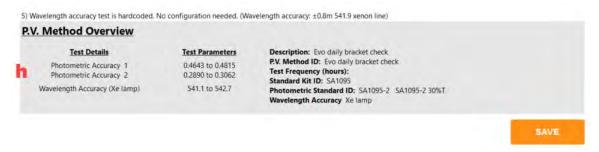
<u>Photometric Accuracy test parameters</u> – DoseControl automatically calculates the test parameters for each Testing Wavelength. <u>See item h below.</u>

**Absorbance Spec Min** = Certified value of Reference – (Reference Uncertainty + Evolution Specification for ABS accuracy)

**Absorbance Spec Max** = Certified Value of Reference + (Reference Uncertainty + Evolution Specification for ABS accuracy)

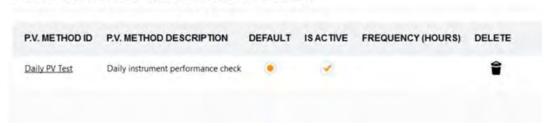
<u>Wavelength Accuracy test parameters</u> – Hardcoded in DoseControl. No configuration.

**541.1 to 542.7 nm** = wavelength accuracy test parameters. The software locates the peak near 541.9nm of the internal xenon lamp, and repeats the test three (3) times. The wavelength accuracy test parameters are defined by the published Thermo Evolution spectrophotometer specification for wavelength accuracy.



- 10 Click Save to complete PV Method setup.
- 11 Make the PV Method "active" and "default" in the software, as needed.

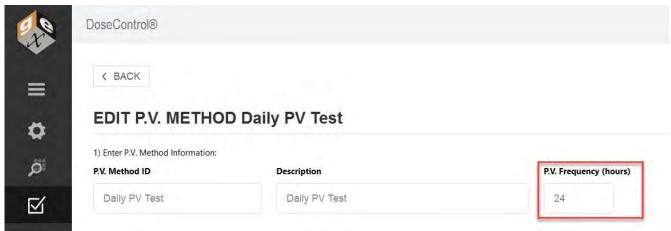
#### PERFORMANCE VERIFICATION TESTS



#### **6.11 About P.V. test frequency**

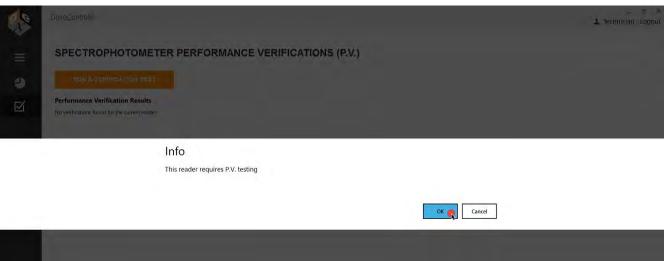
#### 6.11.1 Overview

You can set a P.V. test frequency in the P.V. Method configuration screen. The test frequency is set in number of hours. Enter the number of hours for the test frequency timer, e.g. 24, 36, 48. Leave the frequency field blank if you do not want to use this feature.



A P.V. Method setup screen with the test frequency set for every 24 hours.

When the frequency time expires, the software will prompt the user to execute a P.V. test. and will not allow dosimeter measurements until the user passes a P.V. test.



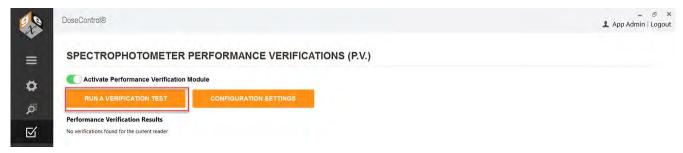
The frequency timer has expired. The software prompts the user to perform a P.V. test.

#### 6.11.2 How to start the P.V. test frequency timer

The frequency timer begins at the time you run the first P.V. test in the software. The App Admin should perform the first P.V. test at the time of day you want the timer to start.

Example - If you want P.V. test frequency to occur every 24 hours, and the prompt to appear at the start of each day, execute the first P.V. test at 8.00am. The software will prompt the users to execute a P.V. test at 8.00am each day.

- 1 Login as Application Administrator user. Go to the P.V. Module main screen. Ensure the P.V. Module is active in the software.
- **2** At the time of day you want to start the P.V. test frequency, click "Run a Verification Test" button to perform the first P.V. test in the software.

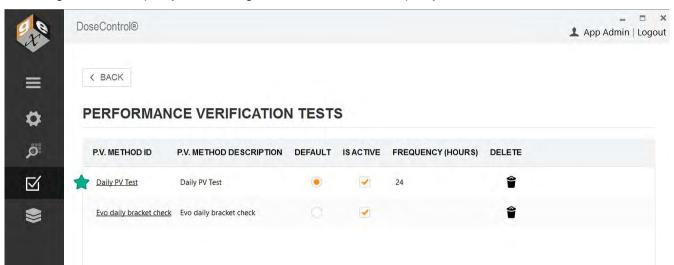


#### 6.11.3 Cautions



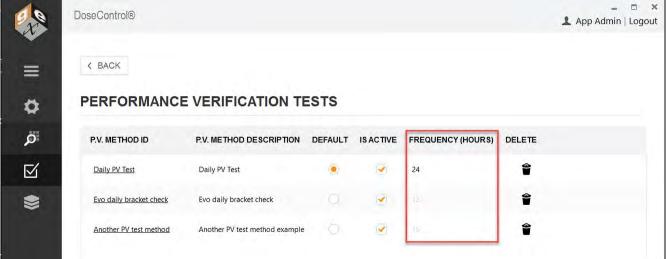
⚠ If you have multiple active P.V. methods, do not have a Frequency set for each method. Choose one (1) P.V. Method to have a frequency timer.

When using the P.V. test frequency feature, configure one P.V. Method with a frequency value.



Multiple active P.V. Methods available in the software, and one has a frequency of 24 hours. The software will prompt the user to perform a P.V. test every 24 hours.

Do not have multiple active P.V. Methods with various frequencies. The software will use the frequency configured in the "default" P.V. Method.



Do not use "frequency" feature in multiple active P.V. Methods.

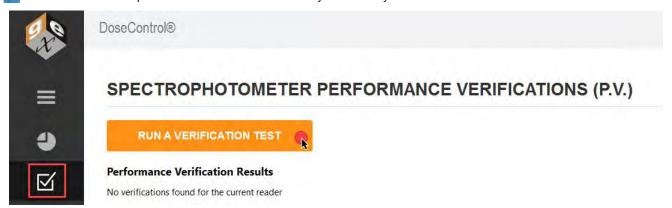
#### 6.12 How to execute a P.V. test

The Technician (see page 29) or Application Admin (see page 29) user can execute a Performance Verification (P.V.)

#### 6.12.1 When to perform a P.V. test

There are two ways to perform a P.V. test in DoseControl:

On Demand Users can perform a P.V. test on-demand at any time directly from the P.V. Module main screen.



**2 Timer Prompt** The App Admin can set the "frequency" timer in the P.V. Method configuration so that a P.V. test must occur at a specific frequency (e.g. every 24 hours). When the timer expires, the software will automatically prompt the user to execute a P.V. test. The user will not be able to proceed to measuring dosimeters until the P.V. is complete and the reader passes the test. See About P.V. test frequency (see page 231)

## Info

This reader requires P.V. testing



## 6.12.2 How to perform a Performance Verification (P.V.) test



#### REMINDER!

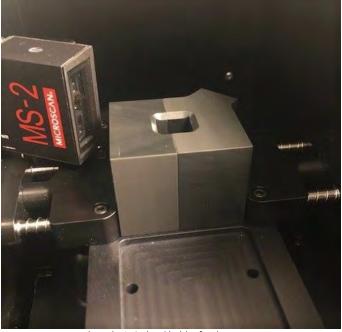
The software will walk you through the steps of a P.V. test. <u>Carefully follow the on-screen prompts in DoseControl</u>.



#### **⚠** IMPORTANT

The sample compartment of the Evolution reader must be closed during the P.V. testing. Place the front panel into position on the reader and slide the lid closed.

Ensure the correct holder is inserted in the Evolution. The 'Windose' dosimeter holder is used to hold reference standards.



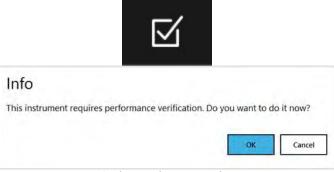
Place the 'Windose' holder for the P.V. test

Ensure you have the correct reference Standards Kit for use with the P.V. Method. Ensure the Standards Kit is calibrated before its next calibration due date. Ensure the Standard is free from fingerprints, dust and is good condition.

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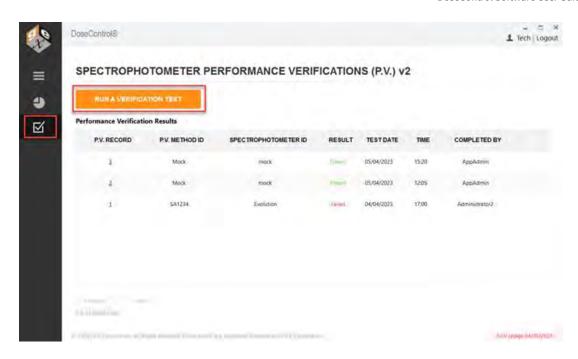


3 Click the P.V. icon to open the P.V. main screen (or click "OK" on the prompt pop-up message)

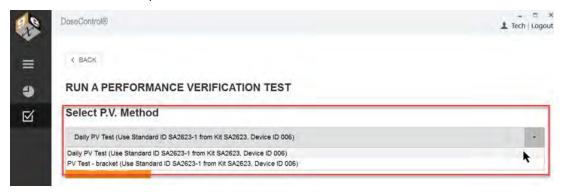


Example of prompt for user to perform a P.V.

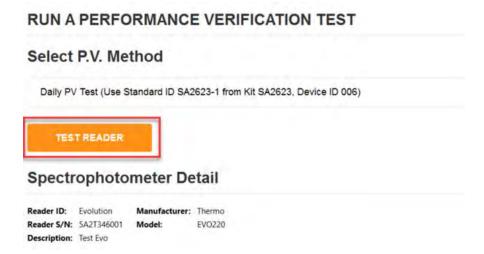
4 Click the "Run a Verification Test" button.



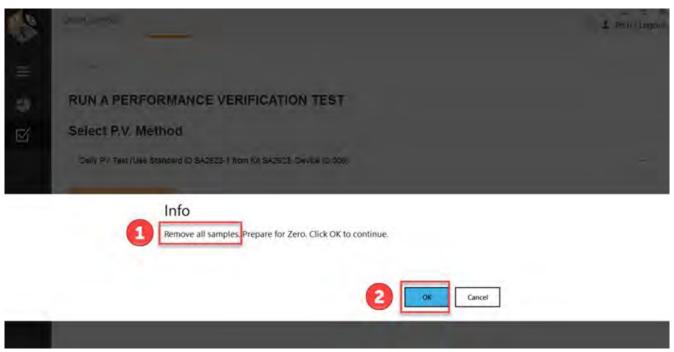
**5** Choose a P.V. Method from the drop-down menu.



6 Click the "Test Reader" button to start the P.V. test.



**7** Remove all samples from the dosimeter holder in the Evolution reader. Close the lid of the Evolution. Click "Ok". DoseControl will zero the reader before the P.V. test. Click "Cancel" to escape the P.V. test.





Ensure the 'Windose' holder is installed and empty.

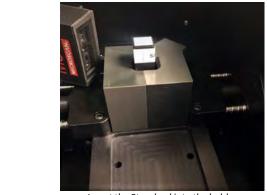




**NOTICE!** Once you click OK and the PV test has started, canceling the process it not an option.

- 8 The Evolution reader will proceed to zero. The reader will make an audible sound as its zeroing.
- 9 Insert the reference Standard ID into the dosimeter holder. Follow the on-screen prompt for the correct Standard ID information. Close the lid of the Evolution. Click "Ok".





Insert the Standard into the holder.

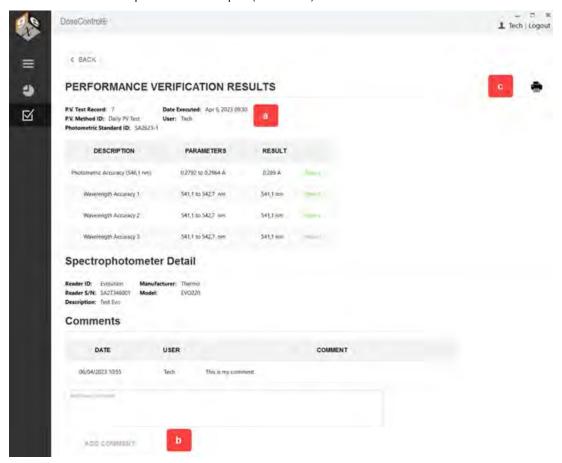


- **10** DoseControl will measure the Standard ID. The reader will make an audible sound during the measurement activity. Photometric Accuracy Test will complete.
- 11 Remove the reference Standard ID from the holder. Close the lid of the Evolution. Click "Ok" to continue.

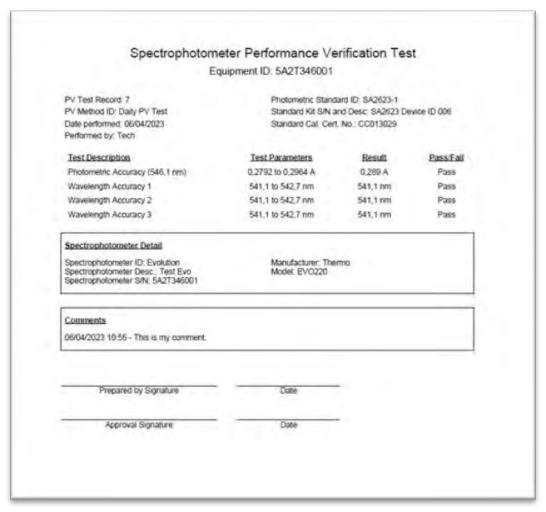


- 12 The full P.V. test will take approximately 2 minutes to complete. You will hear the reader make audible sounds during the wavelength accuracy tests.
- 13 The Evo reader will make audible sounds as it proceeds through the test. When the test is complete, the software will display the results.

- a. View P.V. test results
- b. Add a comment to the test.
- c. Click "Print" icon to print a P.V. Test Report (secure PDF)



14 Click the "Print" icon to view the PV report in PDF (see image below). A copy of the report is automatically saved to the report storage location (Connections & Storage – Storage).



Example PDF document of P.V. test results.

## (i) IMPORTANT

If interrupted by power outage or other reason, the PV test will be incomplete, and all incomplete tests automatically are assigned a "FAILED" status. The instrument remains unavailable for use until the passing criteria is achieved.

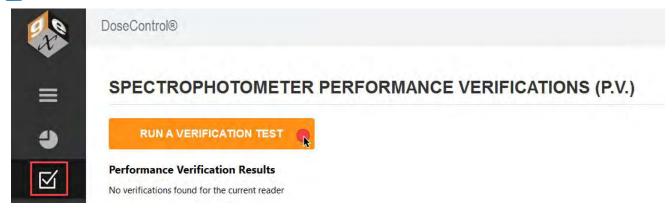
## 6.13 How to execute a P.V. test - Bracket wavelength of use

The Technician (see page 29) or Application Admin (see page 29) user can execute a Performance Verification (P.V.)

#### 6.13.1 When to perform a P.V. test

#### There are two ways to perform a P.V. test in DoseControl:

**On Demand** Users can perform a P.V. test on-demand at any time directly from the P.V. Module main screen.



2 Timer Prompt The App Admin can set the "frequency" timer in the P.V. Method configuration so that a P.V. test must occur at a specific frequency (e.g. every 24 hours). When the timer expires, the software will automatically prompt the user to execute a P.V. test. The user will not be able to proceed to measuring dosimeters until the P.V. is complete and the reader passes the test. See About P.V. test frequency (see page 231)

## Info

This reader requires P.V. testing



### 6.13.2 How to perform a Performance Verification (P.V.) test (Bracket wavelength)



#### REMINDER!

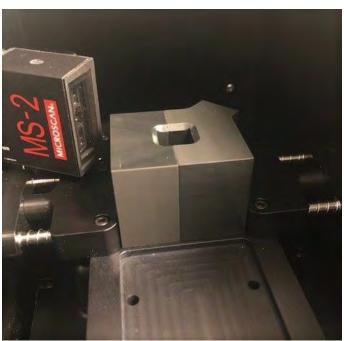
The software will walk you through the steps of a P.V. test. <u>Carefully follow the on-screen prompts in DoseControl</u>.



#### IMPORTANT

The sample compartment of the Evolution reader must be closed during the P.V. testing. Place the front panel into position on the reader and slide the lid closed.

Ensure the correct holder is inserted in the Evolution. The 'Windose' dosimeter holder is used to hold reference standards.

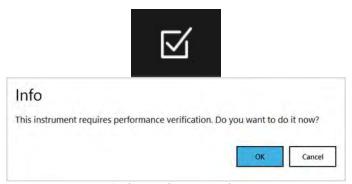


Place the 'Windose' holder for the P.V. test

2 Ensure you have the correct reference Standards Kit for use with the P.V. Method. Ensure the Standards Kit is calibrated before its next calibration due date. Ensure the Standard is free from fingerprints, dust and is good condition.



3 Click the P.V. icon to open the P.V. main screen (or click "OK" on the prompt pop-up message)

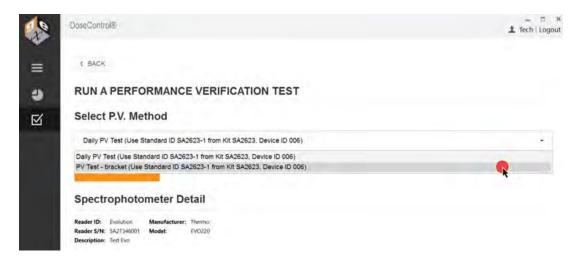


Example of prompt for user to perform a P.V.

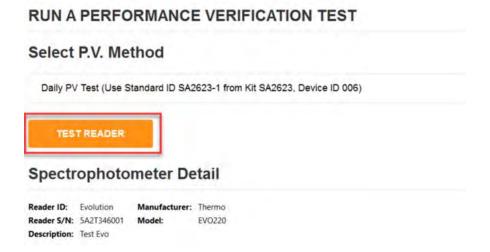
4 On the P.V. Module main screen, click the "Run a Verification Test" button.



**5** Choose a P.V. Method "bracket wavelength of use" test from the drop-down menu.

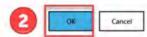


6 Click the "Test Reader" button to start the P.V. test.



**7** Remove all samples from the dosimeter holder in the Evolution reader. Close the lid of the Evolution. Click "Ok". DoseControl will zero the reader before the P.V. test. Click "Cancel" to escape the P.V. test.



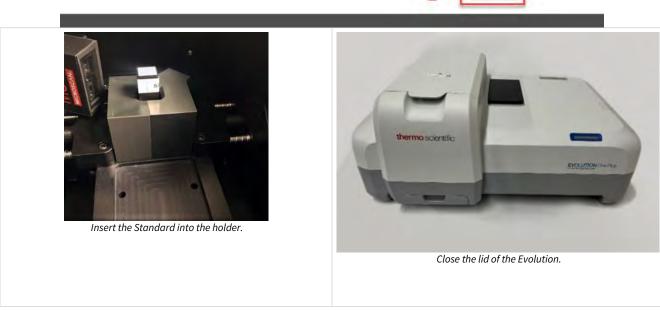




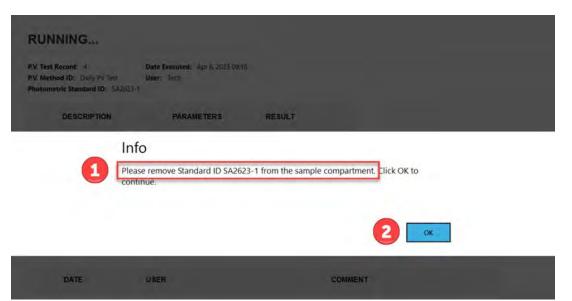
- **NOTICE!** Once you click OK and the PV test has started, canceling the process it not an option.
- 8 The Evolution reader will proceed to zero. The reader will make an audible sound as its zeroing.
- 9 Insert the reference Standard ID into the dosimeter holder. Follow the on-screen prompt for the correct Standard ID information. Close the lid of the Evolution. Click "Ok".



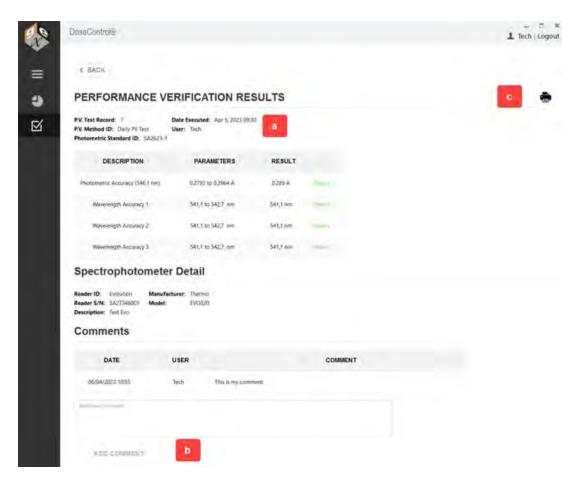




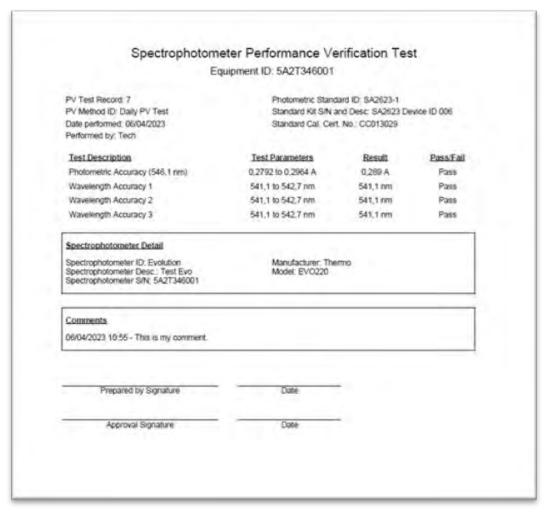
- **10** DoseControl will measure the Standard ID. The reader will make an audible sound during the measurement activity. Photometric Accuracy Test will complete.
- 11 Remove the reference Standard ID from the holder. Close the lid of the Evolution. Click "Ok" to continue.



- 12 The full P.V. test will take approximately 2 minutes to complete. You will hear the reader make audible sounds during the wavelength accuracy tests.
- 13 The Evo reader will make audible sounds as it proceeds through the test. When the test is complete, the software will display the results.
  - a. View P.V. test results
  - b. Add a comment to the test.
  - c. Click "Print" icon to print a P.V. Test Report (secure PDF)



14 Click the "Print" icon to view the PV report in PDF (see image below). A copy of the report is automatically saved to the report storage location (Connections & Storage – Storage).



Example PDF document of P.V. test results.

### (i) IMPORTANT

If interrupted by power outage or other reason, the PV test will be incomplete, and all incomplete tests automatically are assigned a "FAILED" status. The instrument remains unavailable for use until the passing criteria is achieved.

# 7 Troubleshooting

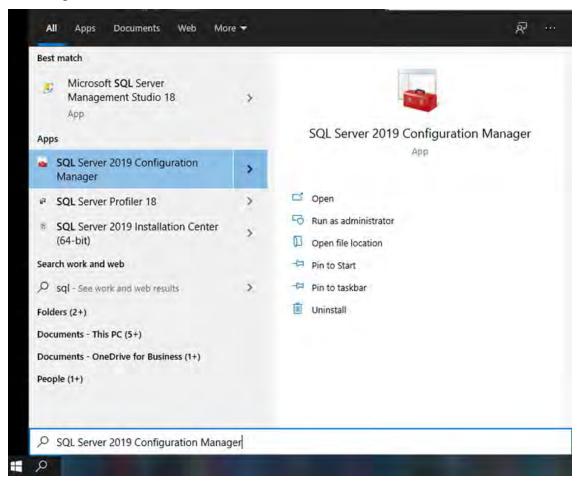
## 7.1 Microsoft SQL Server Configuration and Troubleshooting Guide

Detailed guide to setup MS SQL Server for the DoseControl application database, or if you are having issues connecting the database to DoseControl

Use the following steps to troubleshoot MS SQL Server connection issues:

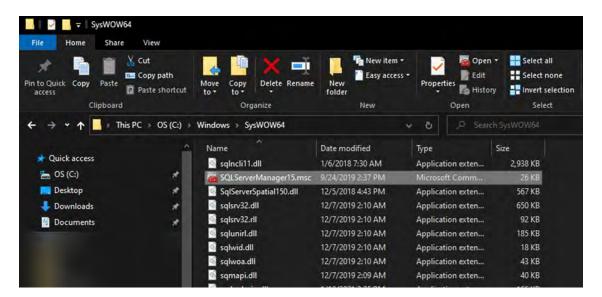
#### 7.1.1 Step 1: Enable TCP/IP for the SQL Server

a. In the start menu on the SQL Database Server (not the client machine with DoseControl installed), launch SQL Server 2019 **Configuration Manager:** 

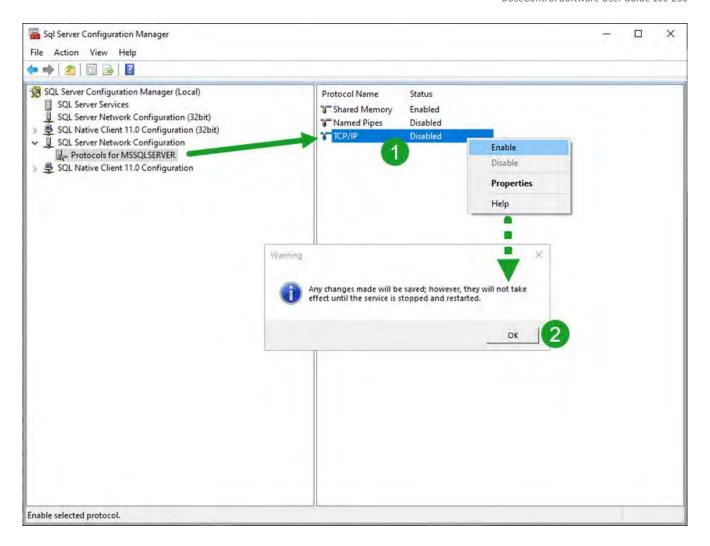


NOTE: if you don't see this in the start menu/search results, you can find it on the server in the folder %windir% \SysWOW64

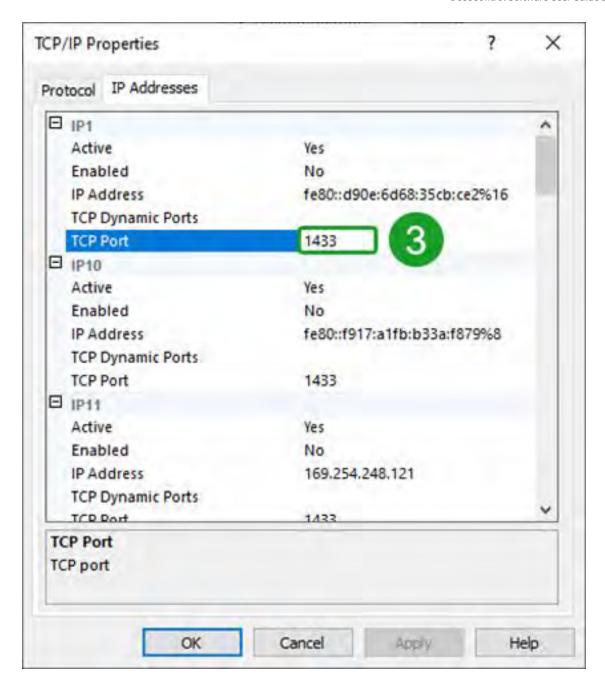
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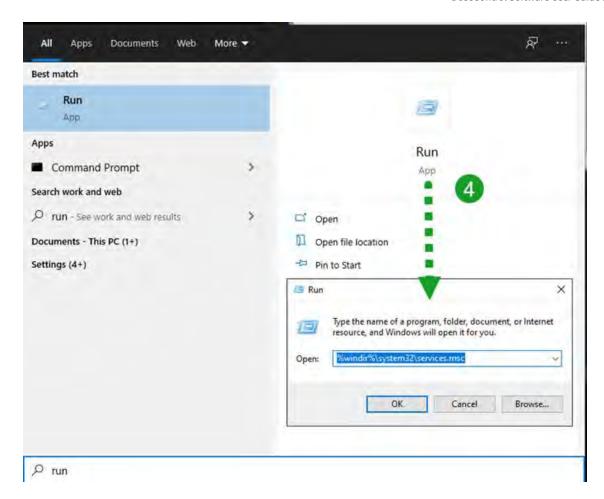
- b. In the SQL Server Configuration Manager under SQL Server Network Configuration, click Protocols for <YOURSQLSERVERNAME>, and confirm that TCP/IP is Enabled. If it is not:
  - 1. Right click TCP/IP and select Enable.
  - 2. Click **OK** in the resulting warning message.
  - Right click TCP/IP and select Properties. On the IP Addresses tab, confirm that your TCP ports are all set to 1433. If for some reason you have these ports set to different values, you will need to contact your IT administrator and discuss the reasons for this. Non-standard SQL port values are outside the scope of this document.
  - 4. Open the Windows start menu, type "run", launch the
  - 5. Run box, and enter %windir%\system32\services.msc
  - 6. In the Services list, locate
  - 7. **SQL Server (<YOURSQLSERVERNAME>)**, right click and select **Restart**. Wait for the service to restart.



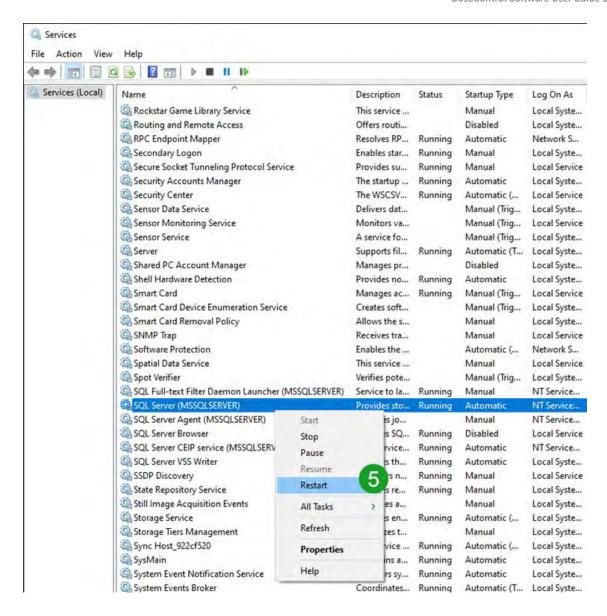
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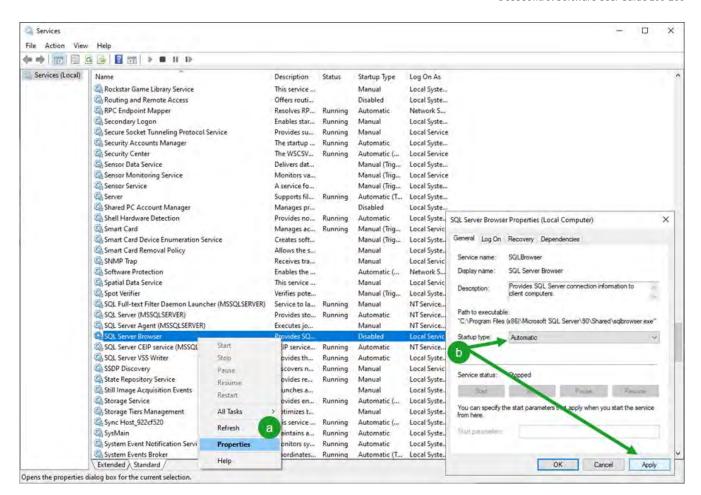


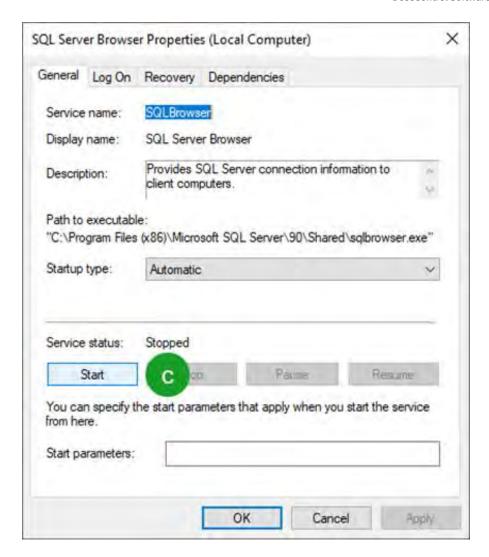
#### 7.1.2 Step 2: Start the SQL Server Browser Service.

In the Services list, locate **SQL Server Browser**. This service's **Status** should be **Running**, and its **Startup Type** should <u>not</u> be **Disabled**. To fix this:

- a. Right click the **SQL Server Browser** service and select **Properties.**
- b. Change the **Startup Type** to **Automatic** and click **Apply**.
- c. Click the **Start** button.

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After you have completed/confirmed these steps (Steps 1 and 2 above), attempt to connect DoseControl to the database again. If you are still encountering the error, here are some IT admin level troubleshooting steps (Step 3):

### 7.1.3 Step 3: Test SQL Server port 1433

a. This test requires knowledge and installation of PowerShell. Open an administrator elevated PowerShell session and enter:

### Test-NetConnection < YOURSQLSERVERNAME > - port 1433

b. You should get the following information:

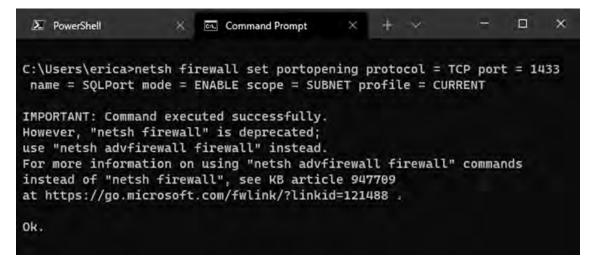


#### 7.1.4 Step 4: Confirm port 1433 is open in windows firewall and on your corporate network

a. For windows firewall, you can enter the following command in an administrator elevated command prompt:

#### netsh firewall set portopening protocol = TCP port = 1433 name = SQLPort mode = ENABLE scope = SUBNET profile = CURRENT

b. The result of that command should look like this:



c. If your corporate firewall is blocking port 1433 for SQL Server, or if a port other than 1433 is being used for communication with SQL Server then the above screenshots will not be the same as what you see on your server. You will need to address this with your IT / networking administrative team.

### 7.2 Connection String not connecting

## 7.2.1 Microsoft SQL Server Express installations

Most connection issues for MS SQL Server Express installation are caused by a spelling error or a problem with the SQL user's setup.

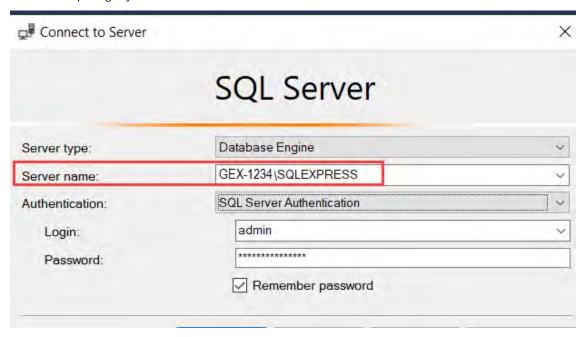
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#### 7.2.1.1 Problem with the Data Source

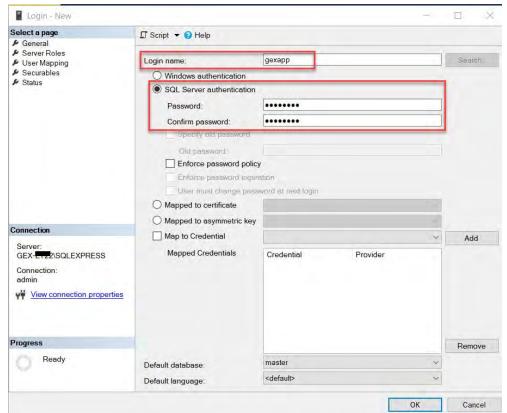
1 Check that the Data Source is correct. The Data Source is the name of your server. Open SSMS (SQL Server Management Studio) and double-check the spelling of your server name.



## 7.2.1.2 Problem with the SQL user access (User Id and Password)

- 1 Your connection string must use the username and password created in **Configure SQL Authentication logins** (see page 50). Confirm that you followed these instructions to create the SQL user and password to be used in your connection string.
- 2 Check that the user name and the password are spelled correctly in your connection string. They must match the user created in SSMS.

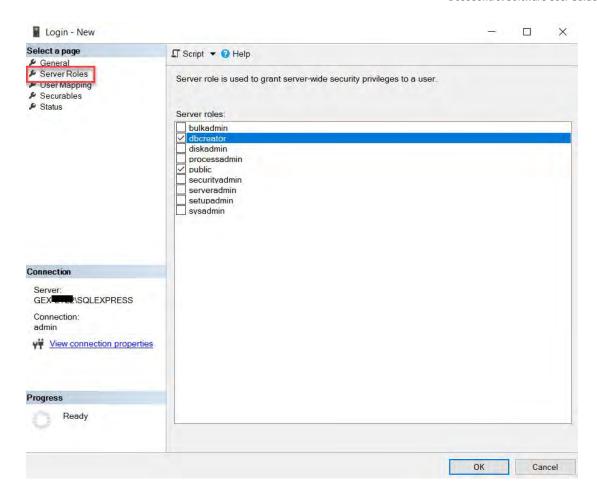
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User login for SQL Server

**3** Check that this user's 'Server Roles' and ensure this user has 'dbcreator' and 'public' roles. The user must have 'dbcreator' to allow DoseControl to create the application database.

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## 7.2.2 Microsoft SQL Server Configuration and Connection Issues

• Go to the Microsoft SQL Server Configuration and Connection Troubleshooting Guide (see page 252)

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## 7.3 Common error messages

# 7.3.1 ? Errors related to Calibration

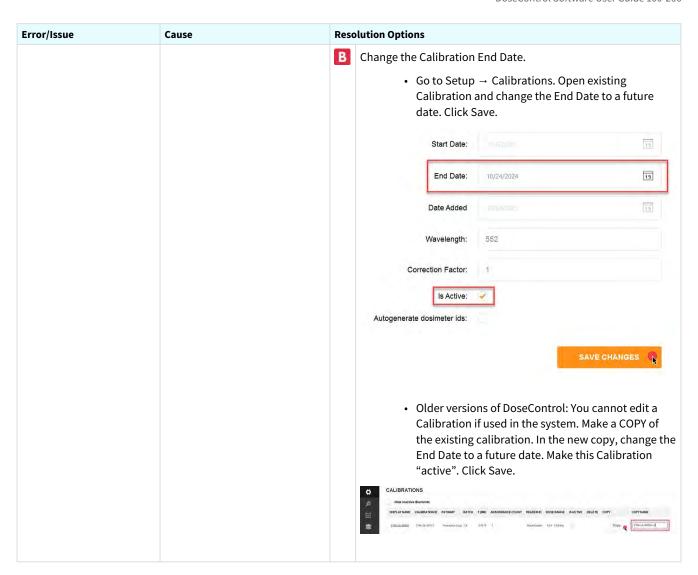
Error/Issue	Cause	Resolution Options
Calibration not configured.  Error: "There is no calibration configured for the selected reader, pathway and dosimeter type. Please select a different reader."  You have an active Pathway, Batch and Reader in the software, but you do not have an active Calibration associated with those items.  • Activate an existing calibration, or • Create a new calibration.	Activate an existing Calibration that is associated with the active Pathway, Batch and Reader. Go to Setup → Calibrations, open the calibration and check "is active" box. Save.	
	B Create a new Calibration that is associated with the active Pathway, Batch and Reader. Go to Setup → Calibrations, setup a new Calibration and check "is active" box. Save.	
No Active or Valid Calibration Error: There is no active or valid calibration on this workstation. Unable to proceed.	<ul> <li>The Calibration for the workstation is not active.</li> <li>The Calibration for the workstation is not valid (Calibration's End Date has expired)</li> </ul>	Activate an existing Calibration that is associated with the active Pathway, Batch and Reader. Go to Setup → Calibrations, open the calibration and check "is active" box. Save.

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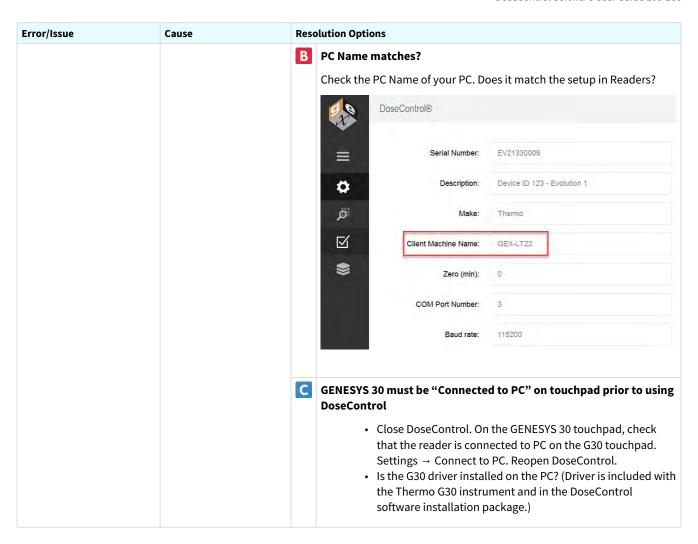
## 

Error/Issue	Cause	Res	olution Options
Open Connection() or Port Driver Error  Error: "Initializing the reader failed. Ensure the reader is connected and the correct COM port is configured.  Port driver error in OpenConnection()  Message: The port 'COM5 does not exist."	Software cannot find the attached Reader. Usually a physical disconnection.  • Is the Reader plugged into the PC and turned on?  • Port number matches?  • PC Name matches?  • GENESYS 30:  • Con nect to PC  • Driv er insta lled on PC?  • Evolution:  • Ther mo Insig ht	A	Port number matches?  Check the PC port number on the PC. Does it match the setup in Readers?  • Find Device Manager on the PC. Look for "Ports". You should see the port number for the spectrophotometer's USB connection. (GENESYS30: COM4, Evolution: COM5, etc.)  • Make sure the COM port number matches the Setup → Readers field  DoseControl®  Serial Number: EV21330009  Device ID 123 - Evolution 1  Make: Thermo  Client Machine Name: GEX-LT22  Zero (min): 0  COM Port Number: 3  Baud rate: 115200
	(with drive r) insta lled on PC?		

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Error/Issue	Cause	Reso	solution Options	
Reader not responding  Error: "Reader is not responding. The operation has timed out."	Software cannot find the attached Reader.  • May be caused by a physical disconnect (see resolution for OpenConnection() error above)  • There is an issue with the COM port's baud rate  • Problem with the USB cable.	В	<ul> <li>Is the Reader plugged into the PC and turned on?         <ul> <li>GENESYS 30 must be "Connected to PC" on touchpad prior to using DoseControl.</li> <li>Close DoseControl. Connect the reader to the PC. Reopen DoseControl.</li> </ul> </li> <li>Is the port's baud rate (bits per second) set correctly?         <ul> <li>Find Device Manager on the PC. Look for "Ports". Right-click on the spectrophotometer's port and go to "Properties → Port Settings". Set the "bits per second" to 115200. Click OK to save. (NOTE: you may need your IT department to change the PC's port settings to 115200 baud rate.)</li> <li>In DoseControl, go to Setup → Readers. Ensure the reader's COM port number is correct and the baud rate is 115200.</li> </ul> </li> <li>USB cable         <ul> <li>Are you using the USB cable provided by Thermo (included in the instrument shipping box). Do not use USB cables from other sources (i.e. Amazon). Is the USB cable in good condition?</li> <li>Is the USB port blocked? Did you IT group update the PC's security and block the USB port connectivity?</li> </ul> </li> </ul>	
Reader Overdue for Calibration  Error: "The selected reader is overdue for calibration. Unable to proceed."	Software will not allow usage of a reader if the Calibration End Date is expired.		Complete performance verification of the spectrophotometer (Reader) is required.  Application Admin user must change the Reader's "Next Calibration Date" field to a new date in the future.  Last Calibration Date: 9/21/2023 15  Next Calibration Date: 10/21/2023 15	

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## 7.3.3 Ferrors related to dosimeter measurements

Error/Issue	Cause	Resolution Options
Duplicate dosimeter ID  Error: "Taking a reading failed. Dosimeter  EA1234567 is already used (report: WO-ABC123)."	Software does not allow duplicate dosimeter IDs. If a user tries to scan or enter a Dosimeter ID that already exists in the system, this error message will appear.	Enter a unique Dosimeter ID.
Adjusting absorbances failed error  Error: "Adjusting absorbances failed. An error occurred while update the entries. See the inner exception for details."	Older versions of DoseControl have a known bug. When a dosimeter is measured, the Measure button remains active after the measurement. A user may accidently click the "Measure" button when trying to save the position or tote information.  The software does not allow a second measurement, but will display this error message.	<ul> <li>Workaround:</li> <li>Use the "Reread" button to execute a reread measurement.</li> <li>Use the "Save Changes" button to save the position and tote information</li> <li>Upgrade to a newer version of DoseControl.</li> </ul> Affects versions 1.4.2020.7.17000 and earlier.

# 7.3.4 Errors related to report export/printing

Error/Issue	Cause	Resc	olution Options
Printing permissions error  Error: 'You don't have permission to save in this location'  Error: "Printing failed. The system cannot find the file specified."	Windows permission issue for the logged in user is preventing file saving to the report storage location.	В	Contract your IT administrator to obtain permission for all DoseControls users on the PC.  • https://youtu.be/HeARH0JrWNc? si=3j1bR_cbxgaV380I  Change the report storage location to an allowed directory.  Login as System Administrator. Go to System → Storage. Change the reports storage location as desired. As long as users have permission save files to this location, DoseControl will output the reports as expected. See Report Storage configuration. (see page 40)  • Older versions: Login as System Administrator. Go to Settings → Connections → Report Storage location.

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Error/Issue	Cause	Resolution Options
Report print processing failed Error: "Processing failed: Object reference not set to instance of an object."	<ul> <li>Clicking the "Process" report button before the Report Summary screen has fully loaded</li> <li>Printing a PDF report with no dosimeter measurements</li> </ul>	Make sure you allow the screen to load all dosimeter measurements prior to clicking "Process" report. DoseControl is making a number of calls to the database and needs time.  B You cannot print a PDF report with no dosimeter measurements (affects all versions older that version 2.0.0)
Export/Print Excel report error  Message when opening the Excel file: "We found a problem with some of the content in 'your file name.xlsx'. Do you want us to try and recover as much as we can?	Click "Yes" to trust the source of the workbook.  Not a DoseControl software issue. The Excel template is corrupted or has a visible or hidden sheet with a bad calculation.	Fix the Excel template. Upload a fixed Excel template, Misc. → Upload Excel Template. Click Save.