# **DoseControl Software User Guide**

Software versions: 1.5.2020.11.17000 and 1.6.2022.1.17000

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### 1 Introduction

DoseControl Dosimetry System is an automatic, software-controlled dosimeter measurement system used for radiochromic film and PMMA dosimetry. The system has specialized holders for B3 dosimeters (B3 WINdose and B3 DoseStix), FWT-60 dosimeters, CTA dosimeters, and Harwell PMMA dosimeters.

The DoseControl System is used in industrial routine dosimetry applications such as medical device sterilization, pharmaceutical manufacturing, and the curing of inks and coatings. DoseControl software is 21 CFR part 11 compliant and meets the requirements of published guidance for the irradiation processing industry, specifically the medical device sterilization industry.

The DoseControl Dosimetry System is a complete, off-the-shelf dosimetry system. The DoseControl software is connected to one of the following spectrophotometers:

- Thermo GENESYS 20 spectrophotometer
- Thermo GENESYS 30 spectrophotometer
- Thermo Evolution spectrophotometer

#### **General Features**

- All dosimeter measurement information and related metadata is captured and permanently recorded by the DoseControl software.
- The software ensures a valid calibration is used for the calculation of dose from dosimeter response.
- The application Administrator can control the dosimetry workflow for each user within the DoseControl software:
  - User access, roles, and permissions
  - Dosimeter measurement workflow, including re-measurements
  - Spectrophotometer actions and performance verification

#### **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 → ReportName version 2).

#### 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.

#### **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 (Evolution spectrophotometer only)

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

#### 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. See Integration with Other Systems.

#### Data storage

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.

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

Basic License		Premier License	Enterprise License		
Windo	etry software installed on ws PC. Data stored on PC, MS SQL Server Express ase.	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 - plus integration capabilities with other systems.		

#### Integration with Other Systems (Enterprise License only)

DoseControl software has a built-in structure to simplify and minimize costs to integrate with other systems (such as SPC, QMS).



### **DoseControl**

- Import process and product data into DoseControl software.
- Export process, product, and dosimeter measurement data from the DoseControl software.

Use a database professional within your own organization to integrate with the DoseControl software's import or export tables. Push data into the SQL import tables; and pull data from the SQL export tables. No custom software development is needed.

#### Some examples:

- Import information about the irradiation process and dosimetry for that process to make it easy for the
  operator to simply click and open the imported dosimetry report and begin measurements. Reduces input
  errors.
  - o Dosimeter ID's that were included in the irradiation process run.
  - Min and max dose specifications and correlation ratios
  - o Process-specific information such as: Catalog Number, Product Description, etc.
- Export dosimetry information for product release processes, process control, process data analysis, and the analysis of dosimetry related metrics.

Talk to GEX Customer Service or refer to *GEX Doc # 100-268, User Guide for Integration with DoseControl* for complete details about integrating DoseControl with other systems, and a description of DoseControl software's import and export table fields.

## 2 Platform Requirements

#### 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 <u>Appendix 1: Installation & Setup of Microsoft SQL Server Express (for Basic License).</u>
- For more information about SQL Server editions, please see the Microsoft website <a href="https://docs.microsoft.com/en-us/sql/sql-server/editions-and-components-of-sql-server-2016?view=sql-server-ver15SQL">https://docs.microsoft.com/en-us/sql/sql-server/editions-and-components-of-sql-server-2016?view=sql-server-ver15SQL</a>

#### PC Workstation Requirements:

#### **Optimal Requirements for PC Workstations:**

- Windows 10 x64
- .NET Framework 4.6.2
- 16 GB RAM
- 8th Gen Intel i7 Quad Core processor equivalent or higher
- At least 100 GB hard drive space
- 1900 x 1200 screen resolution or higher capable widescreen monitor
- Adobe Reader
- Microsoft Excel 365 desktop version

#### Minimum Requirements for PC Workstations:

- Windows 10 x64 or higher
- .NET Framework 4.6.2
- 4 GB RAM or higher
- 6th Gen Intel i5 Quad Core processor equivalent or higher
- 20 GB hard disk space
- Adobe Reader
- Microsoft Excel 2014 or higher desktop version

#### **Database Server Requirements:**

## Optimal Requirements for Application Database Servers:

- Microsoft Windows server 2016 or higher
- At least 100 GB hard drive space
- At least 16 GB RAM
- Microsoft SQL Server 2017 or higher

## Minimum Requirements for Application Database Servers:

- Microsoft SQL Server 2014 SP3\* or higher
- Microsoft Windows server 2012 R2 or higher

\* 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 <u>https://docs.microsoft.com/en-</u>

us/lifecycle/announcements/sql-server-2012-windowsserver-2012-end-of-support for more information.

#### **Pre-Installation**

Please complete the following items before installing DoseControl:

#### **Log on with an Administrator Account**

You will need to log on to the computer where DoseControl is being installed with an account that has administrative privileges.

#### **Install and/or Configure SQL Server**

DoseControl software uses Microsoft SQL Server. The GEX application connects to a SQL database to save and edit all system configuration parameters and dosimetry measurement information. Microsoft offers several licenses for its SQL Server technology and DoseControl can connect to a either a lightweight version installed directly on a laptop or PC, or to a larger scale SQL Server setup on a network or in the cloud. DoseControl software requires a SQL Server database setup prior to the software installation.

- Premier/Enterprise License Contact your IT or technical support to set up the SQL Server (see Platform Requirements above).
- Basic License: The basic setup requires MS SQL Server Express installed on the same PC workstation on which you will install DoseControl. Installing MS SQL Server Express takes only a few minutes. You must successfully complete all the steps in <u>APPENDIX 1: Installation & Setup of Microsoft SQL Server</u> <u>Express</u>. This will provide you the connection string required in the next task.

#### **<u>Create a connection string</u>**

**Premier/Enterprise license installations**: For more complex, corporate installations of SQL Server, you will need assistance from your IT/Technical Support to help you configure SQL and provide the information necessary to construct the Master Connection String for the DoseControl installation.

Basic license installations with MS SQL Server Express: You will have created your Master Connection String by completing the steps in <u>APPENDIX 1</u>.

#### First Time Installation of Software

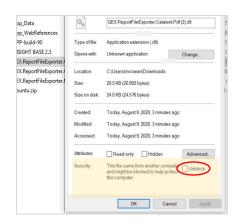
GEX will send you a DoseControl Software installation package, which is a folder that contains everything you will need. There is the main application, plus a list of modules (\*.dll files). The modules are specific to your application install. You can add new modules to DoseControl if needed in the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

#### IMPORTANT

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.

#### IMPORTANT

Some companies may have network security in place to control externally-sourced and sensitive files like \*.msi and \*.dll's, files types that are necessary for the installation of GEX software. Ask your IT personnel for more information. Also, sometimes Microsoft Windows operating systems will 'block' \*.dll files as security protection. 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.



## Files included in your GEX DoseControl install folder:

- \*.msi file: Installer
- \*.dll files: Modules
- MS Excel file: Default
   dosimetry report
- Release notes, User Guide

📕 > This PC > Desktop > APP-build-90 - GEX Master						
Name	Date modified	Туре	Size			
100-266_J DoseControl Software User Guide.pdf	4/7/2020 3:49 PM	Adobe Acrobat D	5,996 KB			
DC Export to Excel Template - RevC FINAL.xlsx	7/6/2020 5:17 PM	Microsoft Excel W	850 KB			
DoseControl Build 90 Release Notes.txt	7/6/2020 3:19 PM	Text Document	20 KB			
📌 GEX.Admin.Installer.msi	7/10/2020 9:34 AM	Windows Installer	13,195 KB			
GEX.AuditSearch.dll	7/10/2020 9:34 AM	Application extens	93 KB			
GEX.Client.Services.3M.dll	7/10/2020 9:34 AM	Application extens	29 KB			
GEX.Client.Services.Universal.dll	7/10/2020 9:34 AM	Application extens	23 KB			
GEX.PerformanceVerification.dll	7/10/2020 9:34 AM	Application extens	160 KB			
GEX.ProductSpecification.dll	7/10/2020 9:34 AM	Application extens	71 KB			
GEX.Reader.Evolution220.dll	7/10/2020 9:34 AM	Application extens	64 KB			
GEX.Reader.Genesys20.dll	7/10/2020 9:34 AM	Application extens	30 KB			
GEX.Reader.Genesys30.dll	7/10/2020 9:34 AM	Application extens	27 KB			
GEX.Reader.Mock.dll	7/10/2020 9:34 AM	Application extens	17 KB			
GEX.ReportFileExporter.Greenville.Pdf.dll	7/10/2020 9:34 AM	Application extens	22 KB			
GEX.ReportFileExporter.RefDose1Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	20 KB			
GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	21 KB			
GEX.ReportFileExporter.Services.dll	7/10/2020 9:34 AM	Application extens	8 KB			
GEX.ReportFileExporter.Standard1Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	17 KB			
GEX.ReportFileExporter.TwoPackEBeam.Pdf.dll	7/10/2020 9:34 AM	Application extens	24 KB			
GEX.ReportFileExporter.TwoPackGamma.Pdf.dll	7/10/2020 9:34 AM	Application extens	22 KB			
GEX.Reports.dll	7/10/2020 9:34 AM	Application extens	312 KB			
GEX.Settings.dll	7/10/2020 9:34 AM	Application extens	34 KB			
GEX.Setup.dll	7/10/2020 9:34 AM	Application extens	315 KB			
GEX.UserManagement.dll	7/10/2020 9:34 AM	Application extens	59 KB			

Screenshot of GEX installation files

#### Installation Instructions

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



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

Welco	me to the	e GEX S	etup Wiz	ard			5
The install	ler will guide y	ou through the	steps require	d to install G	EX on your con	npuner.	
Unauthoria	ed duplication	n or distribution	of this progra	m, or any p	v and internation ortion of it, may i ant possible uni	result in se	vere civi
			< Bo		Next >		ancel

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

	der		4
e installer will install GEX to the fo	allowing folder.		
install in this folder, click "Next".	To install to a different folder, enter it be	aw ar cli	ck "Browse".
older:			
C:\Program Files (x86)\GEX\			Browse
			Disk Cost
nstall GEX for yourself, or for any			
nstall GEX for yourself, or for any	one who uses this computer:		
nstall GEX for yourself, or for any	one who uses this computer:		

4 Confirm the installation. Click "Next":

GEX .			-		
Confirm Installation					4
The installer is ready to install GEX on ;	your computer.				
Click "Next" to start the installation.					
	< Back	Next	_	0	ncel

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

🕼 GEX	-		×
Installation Complete			5
GEX has been successfully installed.			
Click "Close" to exit.			
Please use Windows Update to check for any critical updates to the NET	T Framewo	ork.	
< Back Close	99	Ca	ncel

- 6 Remove any security blocks on the module files (\*.dll files). Sometimes Microsoft Windows operating systems will block \*.dll files as security protection. 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.
- 7 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.

^				A			
lame	Date modified	Туре	Size	Name	Date modified	Туре	Size
100-266_J DoseControl Software User Guide.pdf	4/7/2020 3:49 PM	Adobe Acrobat D	5,996 KB	Modules	8/9/2020 1:47 PM	File folder	
DC Export to Excel Template - RevC FINAL.xlsx	7/6/2020 5:17 PM	Microsoft Excel W	850 KB	Resources	8/9/2020 1:31 PM	File folder	
DoseControl Build 90 Release Notes.txt	7/6/2020 3:19 PM	Text Document	20 KB	📕 🗟 AsyncEnumerable.dll	12/11/2016 10:35 AM	Application extension	46 KB
BEX.Admin.installer.msi	7/10/2020 9:54 AM	Windows Installer	15,195 KB	AutoMapper.dll	8/12/2019 12:42 PM	Application extension	283 KB
GEX.AuditSearch.dll	7/10/2020 9:34 AM	Application extens	93 KB	EfEnumToLookup.dll	8/18/2015 9:00 AM	Application extension	26 KB
GEX.Client.Services.3M.dll	7/10/2020 9:34 AM	Application extens	29 KB	EntityFramework.dll	3/2/2015 9:32 AM	Application extension	5,075 KB
GEX.Client.Services.Universal.dll	7/10/2020 9:34 AM	Application extens	23 KB	EntityFramework.SqlServer.dll	3/2/2015 9:32 AM	Application extension	607 KB
GEX.PerformanceVerification.dll	7/10/2020 9:34 AM	Application extens	160 KB	EPPlus.dll	4/24/2015 5:14 PM	Application extension	1,094 KB
GEX.ProductSpecification.dll	7/10/2020 9:34 AM	Application extens	71 KB	excel.template.xlsx	7/10/2020 9:01 AM	Microsoft Excel Work	850 KB
GEX.Reader.Evolution220.dll	7/10/2020 9:34 AM	Application extens	64 KB	GEX.Client.Services.Empty.dll	7/10/2020 9:04 AM	Application extension	7 KB
GEX.Reader.Genesys20.dll	7/10/2020 9:34 AM	Application extens	30 KB	GEX.Common.dll	7/10/2020 9:03 AM	Application extension	728 KB
GEX.Reader.Genesys30.dll	7/10/2020 9:34 AM	Application extens	27 KB	GEX.Configuration.dll	7/10/2020 9:04 AM	Application extension	19 KB
GEX.Reader.Mock.dll	7/10/2020 9:34 AM	Application extens	17 KB	GEX.ConfigurationService.dll	7/10/2020 9:04 AM	Application extension	136 KB
GEX.ReportFileExporter.RefDose1Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	20 KB	GEX.Controls.Common.dll	7/10/2020 9:04 AM	Application extension	41 KB
GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	21 KB	GEX.Data.Model.dll	7/10/2020 9:04 AM	Application extension	3,250 KB
GEX.ReportFileExporter.Services.dll	7/10/2020 9:34 AM	Application extens	8 KB	GEX.Empty.dll	7/10/2020 9:04 AM	Application extension	8 KB
GEX.ReportFileExporter.Standard1Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	17 KB	GEX.ExcelExporter.dll	7/10/2020 9:03 AM	Application extension	8 KB
GEX.ReportFileExporter.TwoPackEBeam.Pdf.dll	7/10/2020 9:34 AM	Application extens	24 KB	GEX.exe	7/10/2020 9:04 AM	Application	3,741 KB
GEX.ReportFileExporter.TwoPackGamma.Pdf.dll	7/10/2020 9:34 AM	Application extens	22 KB	<ul> <li>GEX.exe.config</li> </ul>	7/10/2020 9:04 AM	Configuration Sourc	8 KB
GEX.Reports.dll	7/10/2020 9:34 AM	Application extens	312 KB	🖹 gex.ico	2/17/2020 12:18 PM	ICO File	32 KB
GEX.Settings.dll	7/10/2020 9:34 AM	Application extens	34 KB	GEX.Login.dll	7/10/2020 9:04 AM	Application extension	41 KB
GEX.Setup.dll	7/10/2020 9:34 AM	Application extens	315 KB	GEX.Math.dll	7/10/2020 9:03 AM	Application extension	26 KB
GEX.UserManagement.dll	7/10/2020 9:34 AM	Application extens	59 KB	GEX.Menu.dll	7/10/2020 9:03 AM	Application extension	12 KB
				GEX.MockCalculator.dll	7/10/2020 9:03 AM	Application extension	7 KB

8 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.)



9 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 (see below). This connection string must be entered before you can proceed to finish the installation. **Click 'OK'**.

Error	
The master connection string is empty. Please configure the user settings an restart the application.	nd
	ОК

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

	DoseControl®	_ C × Administrator   Logout
≡	CONFIGURATION	
4	+ APPLICATION SETTINGS	
¢ %	+ CONNECTION AND STORAGE	
قر	+ LOGGING	
\$ ₽		
T		
	© 2020 GEX Corporation. All Rights Reserved. DoseControl is a registered trademark of GEX Corporation.	1.4.2020.7.17000

11 Expand "Connection and Storage" menu item.

CONFIGURATION  APPLICATION SETTINGS  CONNECTION AND STORAGE  Mather connections ating	
- CONNECTION AND STORAGE	
Master connection string	
Reports storage location C:\ProgramData\GEX\Reports	Browse
	SAVE CHANGES
+ LOGGING	

12 Enter your connection string into the Master Connection String field. Refer to section <u>Pre-Installation</u> for instructions on how to write the connection string (connects DoseControl software to the SQL Server database).

	DoseControl®		_ □ × ▲ Administrator   Logout
=	CONFIGURAT	ON	
4	+ APPLICATI	DN SETTINGS	
¢ %	- CONNECT	ON AND STORAGE	
42.5 G.	Master connection string	Data Source=GEX-LT22/SQLEXIPRESS Initial Catalog=GEXsampleDA 3 User Id=admin Password=Passwo	rd,MultipleActiveResultSets=true;
ï۵	Reports storage location	C.\ProgramData/GEX\Reports	Browse
\$			SAVE CHANGES
Ţî,	+ LOGGING		
	© 2020 GEX Corporation. All R	ahts Reserved. DoseControl is a registered trademark of GEX Corporation.	1.4.2020.7.17000

13 Click "Save Changes" button one time. If the connection string is correct, the software will initiate the connection 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.

	DoseControl®	_ □ > L Administrator   Logou	
≡	CONFIGURATION		
4	+ APPLICATION SETTINGS		
<b>\$</b>	- CONNECTION AND STORAGE		
<b>*</b> ق	Master connection string         Data Bource-GEX.1723/604.DDPRERS.Jnitid Catalog-GEXeexplicIA.3,User M-advin,Passware           Reports storage location         C:\Program.Data/GEX.NPepols	d-Password MultipleActiveResultSets=true,	
۲		SAVE CHANCES	
Ťî.	+ LOGGING		
	-		

14 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	
	on string provided for the master connection is not valid. Please onnection string and restart the application.
	ок

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

20	DoseControl®	L Administrator   Logout
=	CONFIGURATION	
•	+ APPLICATION SETTINGS	
•		
	Info	
	After making changes to user settings you will need to restart the application.	
	x	
T	+ LOGGING	
	© 2020 GEX Corporation. All Rights Reserved. DoseControl is a registered trademark of GEX Corporation.	1.4.2020.7.17000

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

#### Next Step: Create Global Administrator Login

**17** After first-time installation, 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**'



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

E.	
1 admin	
•••••	
LOGIN	<u>User Login</u>

**19** 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.

	0
	X
	st login you must change the administrator password
1	Password
4	Confirm Password

20 Type new password and confirm new password. Press 'Login'.

	e Q
	X
On fir	st login you must change the administrator password
ŵ	******
	••••••

#### IMPORTANT

Please write down the DoseControl Global Administrator username and password when you create this account. It can be reset if needed, but it is best not to forget or lose it.

NOTE

The Global Administrator Login is for the DoseControl software and is not the SQL Server admin login or 'sa' account.

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

e de	E A
LOGIN	🔔 admin
Admin Login	LOGIN

22 You will be taken to the Home Screen. The software installation is complete. The version number is located in the lower right corner.

	DoseControl®						Ŧ	– 🗆 – Administrator   Logou
=	SEARCH REF	PORTS						
٩	1		Q					NEW REPORT
<b>#</b>	Include all versions REPORT ID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH
* ق								
\$ \$								
<b>1</b> 1								
	Previous Next							
	© 2020 GEX Corporation. All	Rights Reserved. D	oseControl is a r	egistered trade	mark of GEX Corp	poration.		1.4.2020.7.17000

23 Next Step: Configure the software. See <u>Software Feature Descriptions</u> and <u>Configure Dosimetry Process</u> <u>Parameters</u> sections.

## 4 Upgrade to a New Version of DoseControl Software

Upgrading to a new version of DoseControl software is not difficult and the process takes 10-15 minutes. All your configuration information from the previous version and your dosimetry reports and records will transfer to the new version when you upgrade.

#### 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.

#### Upgrade preparation instructions:

1 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.

Lab Services ^	Name	Date modified	Туре	Size		
OneDrive	Modules	10/15/2017 12:36	File folde-	s (C:) > Program Files (x86) > GEX > Modules		✓ ♂ Search M.
This PC	Resources AsyncEnumerable.dll	10/12/2017 3:09 PM 12/11/2016 10:35	File folde	Name	Date modified	Туре
Desktop	AutoMapper.dll EfEnumToLookup.dll	2/24/2016 7:36 PM 8/18/2015 9:00 AM	Applicati	GEX.AuditSearch.dll	2/14/2020 1:39 PM	Application extens
Downloads	EntityFramework.dll	3/2/2015 9:32 AM	Applicati Applicati	GEX.Client.Services.Universal.dll GEX.Reader.Evolution220.dll	2/14/2020 1:38 PM 2/14/2020 1:38 PM	Application extens Application extens
h Music	EntityFramework.SqlServer.dll	3/2/2015 9:32 AM	Applicati	GEX.Reader.Evolution220.dll	2/14/2020 1:38 PM 2/14/2020 1:38 PM	Application extens
E Pictures	EPPlus.dll GEX.Client.Services.Empty.dll	4/24/2015 5:14 PM 10/11/2017 3:21 PM	Applicati Applicati	GEX.Reader.Genesys30.dll	2/14/2020 1:38 PM	Application extens
Videos	GEX.Common.dll	10/11/2017 3:21 PM	Applicati	GEX.Reader.Mock.dll	2/14/2020 1:38 PM 2/14/2020 1:38 PM	Application extens
Shared (\\ge	GEX.Configuration.dll	10/11/2017 3:21 PM	Applicati	GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	2/14/2020 1:38 PM	Application extens
Network	GEX.ConfigurationService.dll GEX.Controls.Common.dll	10/11/2017 3:21 PM 10/11/2017 3:21 PM	Applicati Applicati	GEX.ReportFileExporter.Services.dll GEX.ReportFileExporter.Standard1Pack.Pdf.dll	2/14/2020 1:38 PM 2/14/2020 1:38 PM	Application extens Application extens
~	GEX.Data.Model.dll	10/11/2017 3:21 PM	Applicat	GEX.ReportFileExporter.TwoPackEBeam.Pdf.dll	2/14/2020 1:38 PM	Application extens
				GEX.ReportFileExporter.TwoPackGamma.Pdf.dll GEX.Reports.dll	2/14/2020 1:38 PM 2/14/2020 1:38 PM	Application extens Application extens
				GEX.Settings.dll	2/14/2020 1:38 PM	Application extens
				GEX.Setup.dll	2/14/2020 1:38 PM	Application extens

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.

		1 Administrator   Log
CONFIGURA	TION	
+ APPLICA	TION SETTINGS	
- CONNEC	TION AND STORAGE	
Master connection strin	g Data Source=GEX-LT22/SQLEXPRESS Initial Catalog=GEXsampleDA 3 User 1	Id=admin;Password=Password;MultipleActiveResultSets=Irue;
Reports storage location	n C:/ProgramDataiGEX/Reports	Browse
Reports storage location	<sup>6</sup> C iProgramÜstaliGEX/Reports	Browse SAVE CHANGES
Reports storage location	U Programouerice Antipols	
	U Programouerice Antipols	
	U Programouerice Antipols	
	U Programouerice Antipols	

Return to TOC

- 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 instructions in <u>APPENDIX 1: Installation & Setup of Microsoft SQL</u> Server Express (for Basic License).)

Si Microsoft SQL Server Management Studio		- 0 X
File Edit View Debug Tools Window Help		
		- 👩 🗄
Object Explorer	<del>~</del> # X	
Connect - 🛃 🕵 🗉 🍸 🗾 🍒		
GEX-LT09\SQLEXPRESS (SQL Server 12.0.2269	admin)	
🖂 🛅 Databases		
GEXAND		
New Database		
🗉 🧰 Server Obj 🔋 New Query		
Replication     Script Database as		
🕀 🞑 Managen Tasks 🕨	Detach	
Policies +	Take Offline	
Facets	Bring Online	
Start PowerShell	Shrink	
Reports +	Back Up	
Rename	Restore	
Delete	Generate Scripts	
Refresh	Extract Data-tier Application	
Properties	Deploy Database to a Windows Azure VM	
	Export Data-tier Application	
	Register as Data-tier Application	
	Upgrade Data-tier Application	
	Delete Data-tier Application	
Ready	Import Date	ai.

**Premier/Enterprise License Instructions:** Contact your IT/Technical Support to backup your SQL Server database instance of DoseControl application.

#### Instructions to Upgrade GEX/DoseControl Software

- 5 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.
- 6 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).
- 7 Install new version of GEX/DoseControl application
  - 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.



8 Place the modules for the new version of GEX/DoseControl into Modules folder.

#### NOTE

Ensure the Modules \*.dll files are 'unblocked'. Go to the modules folder for the GEX application. Right-click on the first \*.dll file and select properties. Click Unblock. Repeat for all \*.dll files.

→ This PC → Desktop → APP-build-90 - GEX Master		~	Search AP., J	> This PC > Windows (Ci) > Program Files	(x80) → GEX		
Name	Date modified	Type	See	Name	Date modified	Type	See
100-266_J DoseControl Software User Guide.pdf	4/7/2020 5:40 PM	Adobe Acrobat D.,	5,996 KB	Medules	8/9/2020 1:47 PM	File folder	
DC Export to Excel Template - RevC FINALadax	7/6/2020 5(17 PM	Microsoft Excel W	850 KB	Resources	\$/9/2020 1/31 PM	Filefolder	
DoseControl Build 90 Release Notes bat	7/6/2020 5:19 PM	Test Document	20 KB	S AsyncEnumerable.dl	12/11/2016 10:35 AM	Application extension	45 KB
🚰 GEX Admin Installer und	7/10/2020 6-24 434	Windows Installer	13,195 KB	AutoMapper.dll	8/12/2019 12:42 PM	Application extension	283 KB
GEX.AuditSearch.dll	7/10/2020 9:34 AM	Application extens	90 N	EtEnumToLookup.dll	M/10/2015 9:00 AM	Application extension	25 103
GEX.Client.Services 3M.dll	7/10/2020 9:34 AM	Application extern	29 KB	EntityFramework.dll	3/2/2015 9:32 AM	Application extension	5,075 KB
GEX.Client.Services.Universal.dll	7/10/2020 9:34 AM	Application extens	23 KB	EntityFramework Sq/Server.dll	3/2/2015 9:32 AM	Application extension	607 KB
CEX.Performance/enfication.dl	7/10/2020 9:34 AM	Application extens	160.03	S EPPlus.dl	4/24/2015 5:14 PM	Application extension	1,094 KB
GEX.ProductSpecification.dll	7/10/2020 9:34 AM	Application extens	71 KB	accel templatester	7/10/2020 9:01 AM	Microsoft Excel Work	850 KB
GEX.Reader.Evolution228.dll	7/10/2020 9:34 AM	Application extens	64 K3	GEX.Client.Services.Empty.dll	7/10/2020 9:04 AM	Application extension	7.03
GEX.Reader.Generys20.dl	7/10/2020 9:34 AM	Application extens	BO KB	GEX.Common.dl	7/10/2020 9:03 AM	Application extension	728 KB
GEX Reader. Genesys30.dll	7/10/2020 9/34 AM	Application extens	27 KB	GEX.Configuration.dll	7/10/2020 9:04 AM	Application extension	19 KB
CEXBeader.Moricell	7/10/2020 9:14 AM	Application extens	17.03	GCConfigurationService.dll	7/10/2020 9/04 AM	Application extension	135 KB
GEX.ReportFileExporter.RefDose1Pack.Pdf.dll	7/10/2020 9:34 AM	Application extens	20 KB	GEX.Controls.Common.dll	7/10/2020 9:04 AM	Application extension	41 KB
GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	7/10/2020 9/34 AM	Application extens	21.08	GEV.Data.Model.dl	7/10/2020 9/04 AM	Application extension	3,250 K8
GEX.ReportFileExporter.Services.dl	7/10/2020 9:34 AM	Application extens	8 KB	GEX.Empty.dll	7/10/2020 9:04 AM	Application extension	8 68
GEX.ReportFileExporter Standard IPack Pdf.dll	7/10/2020 9:34 AM	Application extens	17 KB	GEX.ExcelExportend1	7/10/2020 9/03 AM	Application extension	8 KB
CLX.Reporti i/el.sporter.lwoPackLBeam.Pdt.dll	7/10/2020 9:04 AM	Application extens	24.03	GEX.exe	7/10/2020 9/04 AM	Application	3,741.03
GEX.ReportFileEsporter.TwoPeckGemme.Pdf.dll	7/10/2020 9:34 AM	Application extern	22 KB	@ GEX.exe.config	7/10/2020 9:04 AM	Configuration Sourc	8 KB
GEX.Reports.dl	7/10/2020 9/34 AM	Application extens	312 KB	gexico	2/17/2020 12:18 PM	ICO File	32 KB
S GEX.Settings.dl	7/10/2020 9:34 AM	Application extens	341.63	GEXLegin.dll	7/10/2020 9:04 AM	Application extension	41 KB
GEX Setup: dll	7/10/2020 9:34 AM	Application extens	815 KB	GEX.Madv.dll	7/10/2020 9:03 AM	Application extension	26 KB
GEX.UserManagement.dll	7/10/2020 9:34 AM	Application extens	22.0	GDCMenu.dl	7/10/2020 9:03 AM	Application extension	12 08
				R. GEX MarchCalculator ellipsic	7/10/2020 9/03 AM	Application extension	7 88

• 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.

(C:) → Program Files (x86) → GEX → Modules			
Name	Date modified	Туре	Size
GEX.AuditSearch.dll	2/14/2020 1:39 PM	Application extension	g
GEX.Client.Services.3M.dll	2/14/2020 1:39 PM	Application extension	2
GEX.Client.Services.Universal.dll	2/14/2020 1:38 PM	Application extension	1
GEX.PerformanceVerification.dll	2/14/2020 1:38 PM	Application extension	10
GEX.ProductSpecification.dll	2/14/2020 1:38 PM	Application extension	1
GEX.Reader.Evolution220.dll	2/14/2020 1:38 PM	Application extension	
GEX.Reader.Genesys20.dll	2/14/2020 1:38 PM	Application extension	
GEX.Reader.Genesys30.dll	2/14/2020 1:38 PM	Application extension	
GEX.Reader.Mock.dll	2/14/2020 1:38 PM	Application extension	
GEX.ReportFileExporter.RefDose1Pack.Pdf.dll	2/14/2020 1:38 PM	Application extension	
GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	2/14/2020 1:38 PM	Application extension	
GEX.ReportFileExporter.Services.dll	2/14/2020 1:38 PM	Application extension	
GEX.ReportFileExporter.Standard1Pack.Pdf.dll	2/14/2020 1:38 PM	Application extension	
GEX.ReportFileExporter.TwoPackEBeam.Pdf.dll	2/14/2020 1:38 PM	Application extension	
GEX.ReportFileExporter.TwoPackGamma.Pdf.dll	2/14/2020 1:38 PM	Application extension	
GEX.Reports.dll	2/14/2020 1:38 PM	Application extension	31
GEX.Settings.dll	2/14/2020 1:38 PM	Application extension	
GEX.Setup.dll	2/14/2020 1:38 PM	Application extension	3

#### 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. See the <u>Troubleshooting</u> section below to resolve any errors.

9 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.



**11** The upgrade process is complete. You should see the Reports home screen of the GEX/DoseControl software with the new version ID (see screenshot below with highlighted version ID). The home screen should list your existing dosimetry reports.

SEARCH REI	PORTS							
1		Q					-	NEW REPO
Include all versions								
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH	
Sample2	1	Incomplete	8/7/2020	232 PM	Administrator	ebeam1	DA	
Sample	1	Incomplete	8/7/2020	229 PM	Administrator	ebeam1	DA	
518	1	Incomplete	8/5/2020	1144 AM	Administrator	cbcam1	DA	
CI test 7	1	lacomplete	8/5/2020	7:13 AM	Administrator	cbcam1	DA	
CTS min-max	1	Incomplete	8/5/2020	7.07 AM	Administrator	ebeamt	DA	
CT5 dr1	1	Incomplete	8/5/2020	7.05 AM	Administrator	ebeam1	DA	
512	1	Incomplete	8/5/2020	6:55 AM	Administrator	ebeam1	DA	
513	1	Incomplete	8/5/2020	653 AM	Administrator	ebeam2iow	DA	
Catalent Test 3	1	Incomplete	8/5/2020	652 AM	Administrator	ebeam2iow	DA	

Your configuration settings should be intact. Under the sprocket icon check that your set up is correct.

	READERS	CALIBRATIONS	REPORT HEADERS	REREADS
				Hide Inactive Element
)	+ PATHWAYS			
	+ DOSIMETER	TYPES		
	+ BATCHES			
	+ MISCELLAN	EOUS		

#### Troubleshooting - How to Resolve a Common Error During an Upgrade

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 this error message:

<b>.</b>	×	
There are missing reader module DLL files for this installation: GEX.Reader.Genesys20.Genesys20Reader, GEX.Reader.Genesys20, Version=1.0.0.0, Culture=neutral, PublicKeyToken=null		
ОК		

Why would a module file be missing? There are several possible reasons:

- ✓ 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 cs@gexcorp.com or call +1 303400-9640.
- ✓ 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.
- The module file was accidently not copied into C:\Program Files (x86)\GEX\Modules.  $\checkmark$

#### To resolve this error:

Step 1: Determine which module file is missing.

Name	Date modified	Туре	Size
GEX.AuditSearch.dll	10/12/2020 3:02 PM	Application extension	93 KE
GEX.Client.Services.3M.dll	10/12/2020 3:02 PM	Application extension	29 KE
GEX.Client.Services.Universal.dll	10/12/2020 3:02 PM	Application extension	23 KE
GEX.PerformanceVerification.dll	10/12/2020 3:02 PM	Application extension	160 KE
GEX.ProductSpecification.dll	10/12/2020 3:02 PM	Application extension	72 KE
GEX.Reader.Evolution220.dll	10/12/2020 3:02 PM	Application extension	66 KE
GEX.Reader.Genesys30.dll	10/12/2020 3:02 PM	Application extension	27 KE
GEX.Reader.Mock.dll	10/12/2020 3:02 PM	Application extension	17 KE
GEX.ReportFileExporter.RefDose1Pack.Pdf.dll	10/12/2020 3:02 PM	Application extension	20 KE
GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	10/12/2020 3:02 PM	Application extension	20 KE
GEX.ReportFileExporter.Services.dll	10/12/2020 3:02 PM	Application extension	8 KE
GEX.ReportFileExporter.Standard1Pack.Pdf.dll	10/12/2020 3:02 PM	Application extension	16 KE
GEX.ReportFileExporter.TwoPackEBeam.Pdf.dll	10/12/2020 3:02 PM	Application extension	24 KE
GEX.ReportFileExporter.TwoPackGamma.Pdf.dll	10/12/2020 3:02 PM	Application extension	22 KE
GEX.Reports.dll	10/12/2020 3:02 PM	Application extension	312 KE
GEX.Settings.dll	10/12/2020 3:02 PM	Application extension	34 KE
GEX.Setup.dll	10/12/2020 3:02 PM	Application extension	316 KE
GEX.UserManagement.dll	10/12/2020 3:02 PM	Application extension	59 KB

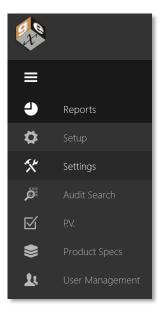
GEX.Reader

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

> This PC > Windows (C:) > Program Files (x86) > GEX	Modules		~ 0	Search M.
Name	Date modified	Туре	Size	
GEX.AuditSearch.dll	10/12/2020 3:02 PM	Application extension		93 KB
GEX.Client.Services.3M.dll	10/12/2020 3:02 PM	Application extension		29 KB
GEX.Client.Services.Universal.dll	10/12/2020 3:02 PM	Application extension		23 KB
GEX.PerformanceVerification.dll	10/12/2020 3:02 PM	Application extension		160 KB
GEX.ProductSpecification.dll	10/12/2020 3:02 PM	Application extension		72 KB
GEX.Reader.Evolution220.dll	10/12/2020 3:02 PM	Application extension		66 KB
SEX.Reader.Genesys20.dll	10/12/2020 3:02 PM	Application extension		30 KB
GEX.Reader.Genesys30.dll	10/12/2020 3:02 PM	Application extension		27 KB
GEX.Reader.Mock.dll	10/12/2020 3:02 PM	Application extension		17 KB
GEX.ReportFileExporter.RefDose1Pack.Pdf.dll	10/12/2020 3:02 PM	Application extension		20 KB
GEX.ReportFileExporter.RefDose2Pack.Pdf.dll	10/12/2020 3:02 PM	Application extension		20 KB
GEX.ReportFileExporter.Services.dll	10/12/2020 3:02 PM	Application extension		8 KB
GEX.ReportFileExporter.Standard1Pack.Pdf.dll	10/12/2020 3:02 PM	Application extension		16 KB
GEX.ReportFileExporter.TwoPackEBeam.Pdf.dll	10/12/2020 3:02 PM	Application extension		24 KB
GEX.ReportFileExporter.TwoPackGamma.Pdf.dll	10/12/2020 3:02 PM	Application extension		22 KB
GEX.Reports.dll	10/12/2020 3:02 PM	Application extension		312 KB
GEX.Settings.dll	10/12/2020 3:02 PM	Application extension		34 KB
GEX.Setup.dll	10/12/2020 3:02 PM	Application extension		316 KB
GEX.UserManagement.dll	10/12/2020 3:02 PM	Application extension		59 KB

## 5 Software Feature Descriptions

#### 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.

**Settings:** The system and IT related configuration fields, such as the connection to the SQL database, network file storage configurations, user access setup.

**Audit Search:** View the complete history of all activity recorded by DoseControl, with filters, search and audit report creating capabilities.

**P.V. (Performance Verification)\*:** The P.V. module is currently 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'.

**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.

**User Management:** Configure user roles and permissions when using the MSSQL or LDAP user management modes.

\*Optional modules not available to all users

#### Reports (Home) screen description

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

DoseControl®						1	– Administrato
SEARCH F	REPORTS						2
	3	٩			Ŧ	N	EW REPOR
REPORT ID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH
CT test 7	2	Incomplete	8/9/2020	3:51 PM	Administrator	ebeam1	DA
CTF	1	Complete	8/9/2020	3:51 PM	Administrator	ebeam1	DA
Sample2	1	Complete	8/9/2020	3:51 PM	Administrator	ebeam1	DA
Sample	1	Incomplete	8/7/2020	2:29 PM	Administrator	ebeam1	DA
CT5 min-max	1	Incomplete	8/5/2020	7:07 AM	Administrator	ebeam1	DA
CT6 dr1	1	Incomplete	8/5/2020	7:05 AM	Administrator	ebeam1	DA

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 must be 'incomplete' or 'complete'. A 'complete' report is a processed report that cannot be altered. Incomplete reports need to be completed.

**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

#### **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. Type a partial or full Report ID or dosimeter ID.

#### Measurement screen description

	BACK								REPORT SUMM
	oort ID: Rej der status:		334 version 1	DSM Batch:	:DA Pathway ID: eb	eam1			
		Model Info:	9A1U102012 552	fiber	Avg. Thickness (mm): 0.0174 Avg. Background ABS: 0.000 Calibration: DA cal Calibration Date: 5/4/203			Min Dose: 2.1 Max Dose: 60.0	
DOS	IMETERS:					MEASURE:			- LES
#	ID	ABS	THICKNESS	DOSE			Dosimeter ID:	DA_1023340	
1	DA_10233344	0.135	0.0174 mm	5.9 kGy		4		MEASURE	
2	DA_1023335	0.144	0.0174 mm	6.5 kGy		DOSE (kGy ):5.1			
3	DA_1023336	0.342	0.0174 mm	19.4 kGy	3	Readings: 6 of 6		0 Reader   Skip Reading	
4	DA_1023337	0.170	0.0174 mm	8.1 kGy	-				
5	DA_1023338	0.100	0.0174 mm	3.8 kGy					
6	DA_1023339	0.122	0.0174 mm	5.1 kGy		(			

The numbers in the picture above correlate to the numbered descriptions below

- **1 Header Info** The header 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/Name and the report version
  - Dosimeter batch ID, batch version, batch thickness
  - Pathway ID
  - Measurement instrument status
  - Spectrophotometer name, serial number, measurement wavelength, spectral bandwidth
  - Calibration dosimetry system calibration information (Cal ID, Cal date, Cal min/max dose).
- 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 for more details).

- 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.
  - The <sup>•</sup> icon indicates that a dosimeter has been re-measured.
  - The A icon indicates that the dose exceeds the calibrated range. Dose measurements that are outside of the calibrated range are also highlighted in **bold red font**. Doses that are outside of the range are not valid, and the notification should alert the operator to review the measurement.

3	DA_7642987A	0.490	0.0174 mm	29.9 kGy
4	DA_7642988A	0.588	0.0174 mm	37.3 kGy 🖸
5	DA_7642989A	0.061	0.0174 mm	1.4 kGy 🔺
6	DA_7642990A	0.471	0.0174 mm	28.5 kGy
7	DA_7642991A	0.906	0.0174 mm	65.5 kGy 🛕 🗘
8	DA_7642992A	0.496	0.0174 mm	30.3 kGy
	Dosim	eter list v	with icon a	lerts

Measure – The Measure section displays the information for the active dosimeter. 4

MEASURE:				
A	Dosimeter ID:	DA_1023339		
В	DSM Position:	ref		
	C Tote ID:	67		
			SAVE CHANGE	s
DOSE (kGy ):5.1		MEASURE		
G A	0.122	E	REREAD	
		Thickness: 0.01	174 SAVE	
Readings: 6 of 6		0 Reader   Skip Rea	ading	
		o Reader   Skip Ke	ading	

- A. 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.
- B. DSM Position (optional): The user can enter the dosimeter position in 'DSM Position' (optional). This would be the location of the dosimeter in the process load. For a dosimeter placed at the 'Reference Position' the technician may enter "Ref".
- C. 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.
- D. Dose (kGy): Displays the dose calculation for the active dosimeter.
- E. Absorbance: Displays the measured absorbance of the active dosimeter.
- F. Thickness: Displays the thickness of the dosimeter, as configured by the Admin in Batches setup. (The ability to edit the thickness is a user permission, as configured by the Admin. In this screenshot, the logged in user has permission to edit and save a dosimeter thickness value.)
- G. Replicate(s): Displays the dosimeter replicate for the current dosimeter measurement. Example:

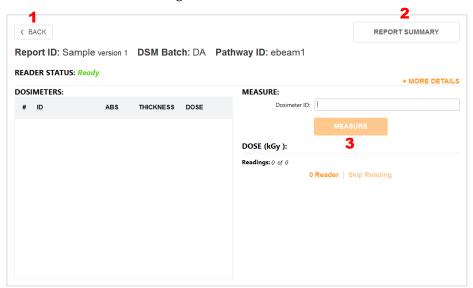
Dosimeter ID:	DA_10233344	
DSM Position:	ref	
Tote ID:	21	
	MEASURE	
DOSE (kGy ):5.9		
A 0.135		REREAD
	Thickness: 0.0174	SAVE
Readings: 1 of 9		
-	Reader Skip Reading	
•	Reader   Skip Reading	

MEAS	OKE:				
	Dosimeter ID:	DA_1249999			
	DSM Position:	ref 1			
	Tote ID:	33			
		MEASURE			
DOSE	(kGy ):31.2				
Α	0.507				REREAD
		Thickness:	0.0174		SAVE
в	0.507				REREAD
		Thickness:	0.0174		SAVE
Readin	gs: 1 of 3				
	0	Reader   Skip	Readir	g	

Measurement with 2 replicates

#### **Measure Screen Buttons**

The measurement screen has the following action buttons:



- 1 Back Return to the Home Screen
- 2 Report Summary view the Report Summary screen (see Report Summary section for details).
- 3 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.
- 4 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.

DOSE	(kGy ):17.3			
Α	0.311		4	REREAD
		Thickness: 0.0174		SAVE
Readin	gs: 1 of 2	5 6		
		0 Reader   Skip Readi	ng	

**5 0 Reader** – Initiates the on-screen messages and workflow to zero the spectrophotometer (the zeroing workflow is forced for all users each time a new measurement session is opened or re-opened).

#### NOTE

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.

**6** 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.

## 6 Configure Dosimetry Process Parameters

This section provides instruction to the Application Administrator (AppAdmin) for the configuration of the functional aspects of the software related to dosimetry. This must be done prior to using the software for dosimetry measurements and reporting.

#### **Overview of Setup Menu**

Select the "Setup" icon on the left menu bar.



From the software Setup menu, the Application Admin can configure the following:

- Pathways (Radiation pathways): The software can be configured to handle dosimetry for multiple facilities, irradiators, or pathways in each irradiator. Go to Configure Pathways.
- Dosimeter types: Configure the types of dosimeters to be used. Go to Configure Dosimeter Types.
- Dosimeter batches: Configure the dosimeter batch ID that is specific to a calibration. Go to Configure Dosimeter Batches.
- Readers (Measurement instruments): Spectrophotometer information. Go to Configure Readers.
- **Calibrations:** Information for each dosimeter batch 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 Configure Calibrations.
- **Report Headers:** Setup the information to be included in a dosimetry report by configuring report headers. For complete information about dosimetry reports and how to configure report headers, please see the Dosimetry Reports section.
- Miscellaneous Dosimetry Workflow Configurations:
  - **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 Configure Re-reads.
  - Other: Manual Mode option, Enable '0' Reader option, User Lock Out option, Filter Report List option. Go to Configure Miscellaneous.

#### NOTE

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.

#### NOTE

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

NOTE

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

#### Pathways: Configuration

≡ 4	SET UP	CALIBRATIONS	REPORT HEADERS	REREADS	
<b>\$</b>				O	Hide Inactive Elements
*	+ PATHWAYS	)			
ة¢.	+ DOSIMETER TY	PES			
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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 must define at least one pathway for the system to function.

- 1 Enter a pathway ID, description, reference ID, and external ID to setup a pathway (hint: name all four the same unless you have special needs with integration, in which case you will have to name the external ID as needed). For example, the user may have a Production pathway and Research pathway.
- 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 the most used pathway as 'default'. This will allow it to show up first in the list of options when creating a new report.

DESCRIPTION	REFERENCE ID	EXTERNAL ID	PRODUCES REPORT	DSM LOCKED 0	DEFAULT	IS ACTIVE	DELETE
Production Loop	Production Loop	Production Loop			۲	<ul> <li>Image: A start of the start of</li></ul>	
Research Loop - Low	Research Loop - Low	Research Loop - Low				<ul> <li>Image: A start of the start of</li></ul>	
Research Loop - High	Research Loop - High	Research Loop - High				$\checkmark$	
Pathway 3	Pathway 3	Pathway 3				$\checkmark$	
SAVE PATH	WAYS						
	Production Loop Research Loop - Low Research Loop - High Pathway 3	Production Loop Production Loop Research Loop - Low Research Loop - Low Research Loop - High	Production Loop     Production Loop       Research Loop - Low     Research Loop - Low       Research Loop - High     Research Loop - High       Research Loop - High     Research Loop - High       Pathway 3     Pathway 3	Production Loop       Production Loop         Research Loop - Low       Research Loop - Low         Research Loop - High       Research Loop - High         Pathway 3       Pathway 3	Production Loop       Production Loop         Research Loop - Low       Research Loop - Low         Research Loop - High       Research Loop - High         Pathway 3       Pathway 3	Production Loop       Production Loop       @         Research Loop - Low       Research Loop - Low	Production Loop       Production Loop         Research Loop - Low       Research Loop - Low         Research Loop - High       Research Loop - High         Research Loop - High       Research Loop - High         Pathway 3       Pathway 3

Example Pathways Setup

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.

#### NOTE

Pathways cannot be deleted from the system after any dosimeter measurement or dosimetry report has been created using that pathway.

#### **Dosimeter Types: Configuration**

Dos	sControl®	_ 🗆 🗙 Administrator   Logout
≡ <sup>s</sup>	ET UP	
e	READERS CALIBRATIONS REPORT HEADERS REREAD	s
•		Hide Inactive Elements
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م چ	+ DOSIMETER TYPES	
Ŀ	+ BATCHES	
	+ MISCELLANEOUS	
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The system requires input and configuration of what types of dosimeters (B3, FWT-60, CTA, or PMMA/Perspex) will be used. (Setup Dosimeter Types before you configure Batches).

- 1 Enter a Dosimeter Identifier (name) and the manufacturer.
- 2 Select a measurement Spectral Bandwidth.
  - Use option "1 small aperture / fiber" for radiochromic film (B3, FWT) dosimeters.
  - Use option "3 2nm Slit" for Perspex or CTA dosimeters.
- 3 Enter a comment, if desired.
- 4 Use the checkbox to make a dosimeter type active or inactive.
- 5 PMMA dosimeters only Select the "Uses Micrometer" checkbox if you are using the GEX supplied Laser Micrometer (GEX Product #P4350) hardware with your Evolution spectrophotometer.
- 6 Select the "Edit Thickness?" checkbox if you need to allow the user to manually edit a thickness value using the keyboard (the user must be assigned this role in the User Management administration this feature can be controlled by individual user permission See <u>User Access, User Roles and Permissions</u>):
  - For example, in the case of dealing with an FWT film where the actual measured thickness is different than the stated average.

OSIMETER IDENTIFIER	MANUFACTURER	SPECTRAL BANDWIDTH	COMMENT	IS ACTIVE	USES MICROMETER	EDIT THICKNESS?	DELETE
GEX B3	GEX Corporation	1 small aperture / fib. •		]			
4034 Red Perspex	Harwell Dosimeters	3 2nm slit 🔹		]			Ŷ
FWT-60	Far West Technologies	1 small aperture / fib: •		]			

Example: Dosimeter types setup

#### 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.

	DoseControl®			±,	_ □ × Administrator   Logout
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<u>لا</u>	+ BATCHES	>			
	+ MISCELLANE	OUS			
	© 2020 GEX Corporation. All Rights	Reserved. DoseControl is a registere	d trademark of GEX Corporation.		1.4.2020.7.17000

On the Batches configuration screen, follow the steps below to setup a batch:

- **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.

BATCH IDENTIFIER	VERSION	EXTERNAL ID	DOSIMETER TYPE	THICKNESS	DESCRIPTION	IS ACTIVE	DEFAULT	BATCH QUANTITY	COMMENT	DELE
DA	1	DA	B3 •	0.0179	DA 0179		۲	0		1
ZZ	1	ZZ	4034 Red Pe 🔻	3.0000	ZZ			0		1

Example: Batches Setup

#### **Batch Revision Level**

On rare occasions, it may be necessary to have a Batch ID with two different thicknesses configured in the software. This happens when you are using a batch of dosimeters, for example batch 'CG' with a thickness of 0.0179mm, and then receive a new shipment of dosimeters of batch 'CG' with a thickness of 0.0182mm. In this event, you will need to create a new version of the Batch ID 'CG'.

- Version 1: Batch ID 'CG', thickness 0.0179
- Version 2: Batch ID 'CG', thickness 0.0182

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. **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".

BATCHIDENTIFIER	VERSION	EXTERNAL ID	DOSIMETER TYPE	THICKNESS	DESCRIPTION	IS ACTIVE	DEFAULT	BATCH QUANTITY	COMMENT	DELET
DA	1	DA	- 00	0.0178	DA 0179	]	۲	0		
77	1	77	4034 Hod Pottpr *	3.0000	77			0		2

**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.

- BATCHES										
BATCH IDENTIFIER	VERSION	EXTERNAL ID	DOSIMETER TYPE	THICKNESS	DESCRIPTION	IS ACTIVE	DEFAULT	BATCH QUANTITY	COMMENT	DELETE
DA	1	DA	B3 •	0.0179	DA 0179		۲	0		
DA	2	DA	B3 •	0.0182	DA 0182		0	0		Ŷ

4 Click "Save Batches" button.

#### Readers: Configuration

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 <u>GEX Doc# 100-156</u>

If you are using the integrated barcode scanner (scanner is integrated with the dosimeter holder system inside the spectrophotometer), setup the barcode scanner <u>before</u> using DoseControl. Refer to the product specification and usage documentation for the scanner.

Matrix120 Barcode Scanner Product Specification and Usage Document – <u>GEX Doc# 100-132</u>

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

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	+ MISCELLANEOUS	

To setup a new spectrophotometer in DoseControl software, follow the steps below:

- 1 Click the "Readers" button from the 🚺 Setup Menu.
- 2 Next, click the "Add New Reader" button.
- **3 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".

- 4 Model Info: Select the spectrophotometer model type from the dropdown.
- 5 Is Active: The instrument status. Check "Is Active" if the instrument will be used in the dosimetry process. 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".
  - Thermo GENESYS 30 specification for min reading value is "0".
  - Thermo Evolution specification for min reading value is "0".
- 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.

8 Serial Number: Enter the serial number of the GENESYS 30 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.

NOTE

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.

#### 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.

- **9 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".
- 10 Make (Optional): Enter the reader's manufacturer name, if desired, "Thermo Scientific".
- 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. Go to your PC settings, device specifications.
- **12** Zero (Optional): Enter a maximum idle time (in minutes) for the spectrophotometer before the system alerts the user to zero "0" the reader.
- **13 COM Port Number:** Ensure the spectrophotometer has been installed and connected as per the instructions given in the reader's <u>product document</u>. 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.

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Keyboards     Memory te     Mice and o     Monitors     Monitors     Ports (COM     ECP Print	levices It Device prers arface Devices vices ammic Platform and Thermal Framework chnology devices ther pointing devices lapters	General Port Settings		one	> > > > > > >
> Process A	Vanced Settings for COM4	problems.	<ul> <li>High (14) (1-</li> <li>High (16) (11</li> </ul>		ncel

- 14 Baud Rate (bits per second): Use a baud rate of 115200 for the GENESYS 30 and Evolution. For the GENESYS 20 use 9600. Enter the baud rate into this field. 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 (<u>internal barcode scanners only</u>): Tick this box if the reader has an internal barcode reader, installed with the GEX holder system inside the reader. (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.
  - The Scanner S/N (serial number) and Scanner COM Port will automatically populate if the scanner is setup and connected to the PC.

File Options Device Help		- 	, 🍪	DoseControl®			1 Administr
Device Selection				Zero (min):	0		
	Selected Device Details	s Matrix	<u> </u>				
	Name Model	M120 210-000 WVGA SER+USB STD		COM Port Number:	13		
M120 169.254.4.190; Matrix SN: G19L25728	Layout Type	Alone		COM Port Number.	15		
	Internal Network Role	Stave					
$\square$	Status	GEXDC18 Running	~	Baud rate:	115200		
	Startup Info	OK	•				
	IP Address	169,254.4.190					
	Application SW Version	1533	*	Requires Barcode Scanner:	✓		
	Loader Version	4.2.0.28					
	Control Foreign	1.2.0.20	2 22	Scanner S/N:	G19L25728		
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	Mon	nitor Device					
				Next Calibration Date:	10/28/2021	15	
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	55 Web	Monitor			ce and other pointing devices		
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					twork adapters		
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					Communications Port (COM1)		
					Evolution Series (COM4)		
					Genesys30 (COM13)		
					Matrix120 (COM14)		
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NOTE

For 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 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 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.
- **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.

NOTE

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.

Error

The selected reader is overdue for calibration. Unable to proceed.

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

ОК

## **Dosimeter Batch Calibrations: Configuration**



Before entering a new Calibration, make sure the Pathway, Batch, and Reader are "active" for the calibration you wish to add.

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	+ MISCELLANEOUS	
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Calibration functions define the mathematical relationship between the dosimeter response and dose for each spectrophotometer in the DoseControl dosimetry system. Using the calibration coefficients setup in the software by the Application Admin, the software calculates the absorbed dose of the dosimeter in terms of specific net absorbance ( $\Delta k$ ) where the net optical absorbance at a selected wavelength ( $\Delta A_\lambda$ ) is divided by the thickness of the dosimeter, otherwise known as optical pathlength (d) in millimeters, as follows:  $\Delta k = \Delta A_\lambda / d$ 

## NOTE

Reference the methods described in ISO/ASTM 51275, Standard Practice for Use of a Radiochromic Film Dosimetry System or related standards for PMMA or CTA dosimeters.

To ensure dosimetry data integrity, the software verifies and ensures a specific batch of dosimeters is linked to the correct calibration and the correct spectrophotometer and irradiation process pathway, eliminating the need for dose look-up tables or manual processes. Only one calibration can be "active" at a time for each combination of dosimeter batch, reader, and irradiation pathway. See below: Calibration ID "DA cal G30" is active for batch "DA", reader ID "GEX Lab G30" and pathway "ebeam 1":

Hide Inactive Eleme	ents										
ISPLAY NAME	CALIBRATION ID	PATHWAY	BATCH	ABSORBANCE COUNT	READER ID	DOSE RANGE	IS ACTIVE	DELETE	COPY		COPY NAME
DA cal G30	DA cal G30	ebeam1	DA	1	GEX Lab G30	2.07 - 60 kGy		)		Сору	
Riso cert 20C-19 CC	Riso cert 20C-19 CC	ebeam1	сс	1	GEX Lab G30	7.05 - 112.99 kGy				Сору	
Riso 2019	Riso 2019	ebeam1	cc	1	GEX Lab G30	15 - 75 kGy		9		Сору	

*Example:* Active calibration for a specific pathway, dosimeter batch, and reader.

#### NOTE

On the main Calibration screen (shown above), a list of calibrations is built over time as the user adds them. Unused Calibrations can be deleted using the trashcan icon<sup>2</sup>. Please note that once a Calibration has been used and is associated with any dosimetry report in the system, the Calibration cannot be deleted.

## New Calibration Setup: Configure manually or import a CALDAT.xlsx file

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

- Enter the configuration data manually (See <u>Manual Setup for a New Calibration</u>)
- Click and import a CALDAT.xlsx file directly into DoseControl. See <u>Import a New Calibration</u>. CALDAT files
  are issued by GEX as one of the process outputs when a user contracts GEX Calibration Services to perform
  their curve fitting.

ADD NEW CALIBRATION	IMPORT NEW CALIBRATION

### Manual Setup for a New Calibration

		Coefficient D:	0	
Display Name:	DA cal G30			
		Coefficient E:	0	
Calibration ID:	DA cal G30	Start Date:		1.5
Pathway:	ebeam1	Start Date.		
Batch:	DA	End Date:		15
Initial Avg Absorbance:	0.000	Date Added		15
Reader ID:	GEX Lab G30	Wavelength:	552	
Absorbance Count:	1	Correction Factor:	1	
Dose Units:	kGy	Is Active:	×	
Dose Range Min:	2.07	Autogenerate dosimeter ids:		
Dose Range Max:	60			SAVE CHANGES
Coefficient A:	2.14805583922283			
Coefficient B:	0.961153630810102			
Coefficient C:	-0.003043147383782			

Example of new calibration configuration

To setup a new calibration in DoseControl software, follow the steps below:

- 1 On the 🚺 Set Up screen, click the "Calibrations" button.
- 2 On the main Calibration screen, click the "Add New Calibration" Button.
- 3 **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.

- 5 External ID: Leave this field blank (unless otherwise instructed by GEX).
- 6 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.
- 7 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.
- 8 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.
- 9 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.
- 10 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.

#### NOTE

If you are using the <u>statistical rereads method</u> for re-reading dosimeters, this feature will only work if the absorbance count is "1". For more information, see <u>Dosimeter Re-reads: Configuration</u> section.

- **11 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.
- 12 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.
- **13 Dose Range Max:** Enter <u>the maximum dose from the calibration</u> 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.
- **14** 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<sup>2</sup> + dx<sup>3</sup> + ex<sup>4</sup>. If there is no coefficient value, enter a '0'.

Example of cubic curve fit coefficients, from the CALDAT.xlsx file:

F	G	H		J	K
CURVETY	COEF0	COEF1	COEF2	COEF3	COEF4
Cubic	2.24965141421786	0.659910896976561	-0.00173287135155131	0.00000244487572661155	0

#### Calibration configuration setup in DoseControl:

Coefficient A:	2.24965141421786
Coefficient B:	0.659910896976561
Coefficient C:	-0.00173287135155131
Coefficient D:	0.00000244487572661155
Coefficient E:	0

- **15 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.
- **16** 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.

### NOTE:

The End Date is not editable after the Calibration is used in the software. To change the End Date of a Calibration, you must make a copy of the Calibration and edit the End Date field in the new Calibration.

- 17 Date Added: Autogenerated date when the calibration is added to the software.
- 18 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 without any units (e.g. '552').
- 19 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.
- **20** 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.
- **21** 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.

#### 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.

- 22 Check the "Is Active" box to activate the new calibration for use.
- 23 To finish, click "Add Calibration" button.

#### Import a New Calibration

#### NOTE

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. See <u>Manual Setup for a</u> New Calibration directions.

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

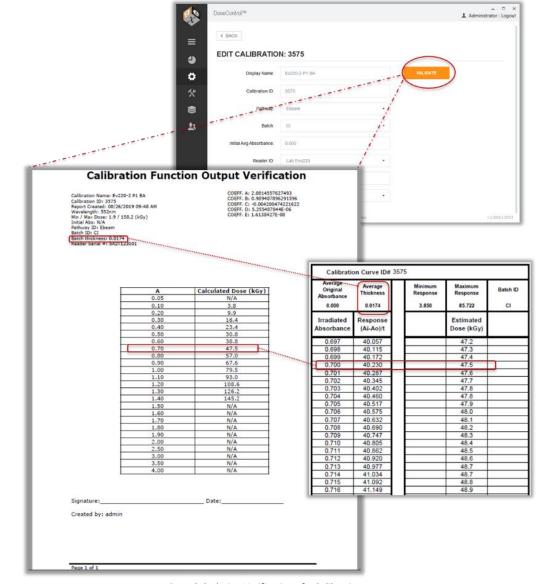


- 5 Most of the calibration information is directly uploaded into the new calibration setup. To complete the new calibration setup, complete the missing fields (see field descriptions above).
- 6 Check the "Is Active" box to activate the new calibration for use.
- 7 To finish, click "Add Calibration" button.

## How to Verify Dose Calculation of a Calibration

The Edit Calibration screen features a push-button verification test report using the "Validate" button. With the output the Application Admin can verify the dose calculation is correct before activating a calibration in the software. The output is a PDF file that can be saved or printed. Compare any field on the PDF to the Dose Table from the calibration or any other information from the calibration such as the coefficients and document the results on paper.

See screenshot below:



Dose Calculation Verification of a Calibration Return to TOC

## 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.

		T READER ID	DOSE RA	NGE	IS ACTIVE DE	LETE COPY		COPY N/	AME			
		LabEvo	1 - 80 kGy	/	✓		Сору	DEMO (	сору			
DISPLAY NAME	CALIBRAT	ION ID	PATHWAY	BATCH	ABSORBANCE COU	NT READER ID	DOSE RANGE	IS ACTIVE	DELETE	СОРУ	COPY NAME	
LV-LabEvo-P2	3134		Pathway 2	LV	1	LabEvo	1 - 55 kGy	<b>~</b>	Ŷ	Сору		
DEMO COPY	ef738e05-5	de3-40d0-ba63-41b7588a8d8	Pathway 1	CG	1	LabEvo	1 - 80 kGy	<ul> <li>Image: A start of the start of</li></ul>	ŷ	Сору		

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".

# - - × DoseControl® 2 Administrator | Logout SET UP ≡ 4 Hide Inactive Elen ø PATHWAYS \* ø DOSIMETER TYPES BATCHES 11 MISCELLANEOUS

## Dosimeter Re-reads (re-measurement): Configuration

### About Re-reading (re-measuring) Dosimeters

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 for the Application Admin to define how a user can re-read a dosimeter in the dosimetry process. 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.

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.

#### NOTE

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 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.

The Application Admin 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 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 re-read.
- Define if and how a re-read measurement replaces the original measurement: The software allows for two re-read strategy or methods:

- Simple Re-reads: The user will take a measurement which will replace the original measurement on the screen.
- Statistical Re-reads: will require the technician to make three measurements of the dosimeter in question and, if desired, allows a statistical evaluation of the results to determine if the reread data supports accepting the original measurement or supports changing the original measurement. You can also choose to include the original measurement in the statistical evaluation.
- Define how many re-reads can be performed for a dosimeter: The Admin can limit the number of times a user can re-read a dosimeter.
- Define if a comment is required by the user performing the re-read.

### 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.

#### 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.

#### **Configure Re-read parameters**

To setup a re-read process follow the steps below:

- 1 Define reasons that the technician measuring dosimeters will be forced to select from when initiating the reread workflow.
  - On the Setup Screen, select the "REREADS" button. Expand the 'Reasons' field by clicking on the orange box with the 'plus' sign next to "REASONS".



- 2 Add as many reasons as needed using the "ADD REASON" button. If you want to use the re-read feature of the software, you must have at least one reason configured.
- 3 Define a re-read strategy (simple or statistical) for each reason. Select either "Simple Rereads" or "Statistical Rereads" from the Strategy drop-down menu.

REREADS CONFIGU	RATION	
- REASONS		
IS TEST REASON	STRATEGY	EDIT DELETE
Dirty Dosimeter	Simple Rereads	Edit
ADD REASON	Accepted reread will be SAVE Statistical Rereads Average of three consecu	used as the new value utive rereads will be used as the new value, if accepted

4 Click the orange "Save" button to save the "reason" and the "strategy" associated with this reason.

5 Next, click the "View" button to edit the re-read controls for this reason.

REASON	STRATEGY	EDIT DELETE
dirty dosimeter	Simple Rereads	• View

• Checkbox "yes/no" to limit the number of re-reads allowed by the system.

#### Caution:

When using this 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.

- If checkbox is ticked, next enter the number of allowed re-reads.
- Checkbox "yes/no" if a different user is required to perform a re-read. The software will require the
  user to logout and then a different user must login to the software and perform the re-read.
- Checkbox "yes/no" if the user logged in to the software must have a "Reread role", as defined by the software user management roles and permissions setup. (See Configuration of User Access and User Roles section.)
- Checkbox "yes/no" to require the user to enter a comment on every re-read measurement performed. This allows the user to provide details about the re-read to be recorded, in addition to the "reason" selected.
- 6 Click "Save Changes" to save the settings.

#### Example of "Simple Reread" setup

For the first example, we have chosen to allow for a user to re-read a dosimeter and the new dose measurement will replace the original measurement. The Admin has setup two reasons for a re-read:

**Dirt on dosimeter** – This reason is available in the event a dosimeter was accidently placed on a dusty countertop or touched by fingers. The "dirt on dosimeter" reason allows the technician to re-read the dosimeter up to 3 times. No other user is required to login and perform the re-read. The technician does not need to be assigned a "Reread Role" as a user, and there is no requirement for a comment.

**Dose verification** – This reason is vaguer than a dirty dosimeter and is available whenever the user is uncertain about a measurement. Perhaps the technician did not place the dosimeter into the spectrophotometer correctly, or there was a question about the "0" zeroing of the reader, or any other concern. In this reason, the user can re-read the dosimeter up to 3 times and is required to enter a comment detailing the event.

- REASONS		
REASON	STRATEGY	EDIT DELETE
dirty dosimeter	Simple Rereads	View
dose verification	Simple Rereads	▪ Edit
ADD REASON	SAVE	

EDIT REREAD STRATEGY: dirt	on dosimeter	EDIT REREAD STRATEGY: dos	e verification
Is there a limit for how many rereads can be taken:		Is there a limit for how many rereads can be taken:	<b>v</b>
Number of allowed rereads:	3	Number of allowed rereads:	3
Is a different user required to take a reread:		Is a different user required to take a reread:	
Is the user required to have Reread role:		Is the user required to have Reread role:	
Is a comment required on every reread:		Is a comment required on every reread:	<b>~</b>
	SAVE CHANGES		SAVE CHANGES

## Example of a "Statistical Reread" setup

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".

	DoseControl®	
≡	< BACK	
Ð	EDIT REREAD STRATEGY: Dos	e Confirmation
•	Include original measurement in calculations?:	
A JU	Maximum coefficient of variation (CV) (default value is 0.03):	0.03
^ ق	is there a limit for how many rereads can be taken:	<ul><li>✓</li></ul>
·	Number of allowed rereads:	6
\$	Is a different user required to take a reread:	
<u>.</u>	Is the user required to have Reread role:	
	Is a comment required on every reread:	
		SAVE CHANGES

When we select "Statistical Reread" strategy, on the Edit screen the Admin will see same the options available for the simple re-read configuration along with two additional configuration options specific to statistical rereads. For a statistical re-read, the Admin will need to consider the following:

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

2 Maximum coefficient of variation (C.V.): The coefficient of variation entered here will be used as 'pass/fail' criteria for the reread session. The doses of each of the measurements will be averaged and a coefficient of variation for those doses will be calculated and compared against the value we enter here. Enter a CV value here not a CV% value – 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.

3 Number of allowed rereads when using the statistical strategy: Your value must allow for 3 rereads in a single session. A value of less than 3 will still allow three. So, 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.

#### NOTE

In the configuration screenshot (above), we have configured it to include the original measurement in the evaluation, and we have limited the number of reread sessions to 2 (6 total rereads). This means that no user will be allowed to ever take any more rereads for that dosimeter, and there is no way for anyone (including the Administrator) to override this.

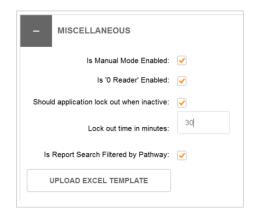
# **Dosimetry Reports and Report Headers: Configuration**

See *Dosimetry Reports* section.

# **Minor Configuration Features**

To setup the features list below, follow these steps:

1 On the 🖸 Setup screen, click to expand the "Miscellaneous" menu.



2 Select the checkbox "yes/no" to activate a feature. See description of the features below:

### **Manual Mode**

When Manual Mode is enabled, 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. 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.

#### Enable "0" Reader"

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.

DUSCO	Control®							1	Administrator   Log
< 1	BACK							REPO	RT SUMMARY
Rep	ort ID: Samp	le2 version	2 DSM Ba	tch: DA	Pathway ID	: ebeam1			
	DER STATUS: Re	ady							+ MORE DETAIL
	IMETERS:				MEASU	RE: Dosimeter ID:	D3_122m		
	ID	ABS	THICKNESS	DOSE		DSM Position	Long Lands		
1	DA_123er	0.311	0.0174 mm	17.3 kOy		Tote ID:			
2	DA_123e3	0.311	0.0174 mm	17.3 kGy			MEASU	RE	
					DOSE (	:Gy ):17.3			
					Α	0.311			REREAD
							Thickness	0.0174	SAVE
_					Readings	1 of 2	Reader Sk	ip Reading	

#### **User Lock-Out**

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:

Info	
You've been logged out due to inactivity	
	ОК

#### Filter the Report List 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.

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.

Include all version		٩	UNAL NAL	1			NEW REPOR
REPORT ID	VERSION	STATUS			LAST EDITED BY	PATHWAY	BATCH
<u>x12345</u>	1	Complete	9/18/2019	08:34 PM	Administrator	21	DA
T091819-06	1	Complete	09/18/2019	08:34 PM	Administrator	C.R. 1	DA
T091819-01	1	Complete	09/18/2019	08:32 PM	Administrator	VAL 1	DA
T091819-02	1	Complete	09/18/2019	08:32 PM	Administrator	VAL 1	DA
T091819-03	1	Complete	09/18/2019	08/32 PM	Administrator	VAL 1	DA
T091819-05	2	Incomplete	09/18/2019	06:35 PM	Administrator	VAL 1	DA

Drop-down menu to filter by irradiation pathway

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:

	DoseControl®						1	_ Administrator	× Logout
≡	SEARCH RE	PORTS		_			<b>_</b>		
4	I		Q	C.R. 1		•		NEW REPORT	
\$	Include all versions REPORT ID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH	
*	<u>×12345</u>	1	Complete	09/18/2019	08:34 PM	Administrator	C.R. 1	DA	
ö	1091819-06	1	Complete	09/18/2019	08:34 PM	Administrator	C.R. 1	DA	
۲							$\square$		
1.									
	Previous 1	Vent							
	© 2019 GEX Corporation. Al	ll Rights Reserved. D	oseControl is a re	gistered trademar	k of GEX Corpor	ation.		1.3.2019	.9.21843

Filtered Report list displays one irradiation pathway

## Upload Excel Template

The UPLOAD EXCEL TEMPLATE button is used to upload a GEX provided MS Excel file. (See <u>Dosimetry Reports</u> section for details and instructions on how to setup and use dosimetry report templates.)

# 7 Configure User Access, User Roles and Permissions

User access, roles and permissions are controlled by the DoseControl System Administrator. DoseControl software provides a flexible and secure way to control how users can login to the software, and what screens each user can see, and what activities each user can do within the software.

## Overview

### **User Access options:**

Setup the method for user logins to the 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.

**MS SQL username/password:** 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.

**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 to maintain 21 CFR part 11 compliant security (see <u>Configuration</u> section).

## NOTE

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).

### IMPORTANT

Basic User Manager is not 21 CFR part 11 compliant.

### **User Role options:**

Assign an access level, or role, for each user; determine what screens can a user see and access.

**System Admin** – can access/manage software connections, data storage connections, user management (who can be added to DoseControl and how they use it). System Admin has access to the DoseControl software Settings icon and screen, which allows configuration of all IT-related information, connection to the database, reports storage location, etc.

**Application Admin** – can configure/set parameters for dosimetry related settings within the software, including user roles and permissions (what functions users can perform within DoseControl). Application Admin has access to the DoseControl software Setup icon and screen, which allows the configuration of all dosimetry process parameters, report setup, etc.

• Product Specification Module - The Application Admin can add, edit, and delete product specifications.

 P.V. (performance verification) Module for the Evolution reader – The Application Admin can configure the specifications for the performance verification testing.

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

#### User Permissions available:

Allow or disallow which actions are permitted for each user. (See <u>Software Feature Descriptions</u> section for information about the dosimeter measurement process.)

**Re-read** – allows user to perform dosimeter re-reads, under the parameters set by the Application Admin. See <u>Software Feature Description</u> section for information about re-reads and the dosimeter measurement process.

Edit Dosimeter IDs - allows user to edit or remove dosimeters from a report.

Edit Thickness - allows user to edit the thickness of a dosimeter for a dosimeter measurement.

### How to setup User Access for DoseControl software

- 1 Login using the DoseControl software Global Admin username and password, or as the System Admin.
- 2 Click the Settings Configuration icon on the toolbar.
- **3** Expand the "Applications Settings" menu item.

APPLICATI	ON SETTINGS	
SETTING	SELECTED IMPLEMENTATION CONNECTION STRING	
Client Report Service	Empty Client Repository	
Sign in manager	MSSQL user manager	
	MSSQL user manager Connects to a MSSQL database	
	Basic user manager Basic user security	SAVE CHANGES
	Explicit LDAP user manager Integrated with Active Directory. Requires explicit credentials	
CONNECT	LDAP user manager Integrated with Active Directory	

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

## How to setup user roles and permissions using SQL user manager

#### Follow the steps below:

- 1 Login using the DoseControl software Global Admin username and password, or as the user with System Admin role. Click the **TR** Users Configuration icon on the 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.

USER ID	USERNAME	DISPLAY NAME	ROLES	LASTLOGIN	ACTIVE	EDIT	DELET
1	admin	Administrator	SystemAdmin, ApplicationAdmin, Techniclan, Reread, EditThickness, EditDosimeterlds	8/9/2020 4:41 PM		¢	9
2	AppAdmin	Application Admin	ApplicationAdmin, Technician, Reread, EditThickness, EditDosimeterlds	5/20/2020 12:34 PM	✓	¢	9
3	SysAdmin	System Admin	SystemAdmin, Technician, Reread, EditThickness, EditDosimeterIds	5/20/2020 12:35 PM	<ul> <li>Image: A start of the start of</li></ul>	¢	9
4	Tech	Technician	Technician, Reread, EditThickness, EditDosimeterlds	5/20/2020 12:38 PM	<b>~</b>	¢	4
5	SystemAdmin	System Admin no read	SystemAdmin	5/20/2020 12:20 PM		¢	4
6	ApplicationAdmin	ApplicationAdmin no read	ApplicationAdmin	5/20/2020 12:22 PM		¢	9
7	Operator	Operator	Technician	8/9/2020 4:31 PM		¢	9
8	Manager	Manager	ApplicationAdmin, Technician	8/9/2020 4:28 PM	<b>~</b>	¢	9

3 To add a user, select the 'Add User' button. Enter the Usename, Display Name, Password. Tick "active" to make the user active in the system. Select user roles and permissions for this new user (see descriptions of User Role options and Permission above). Example:

Edit User	
Username:	John Doe
Display Name:	John Doe
Password:	
Active:	✓
SystemAdmin:	
ApplicationAdmin:	
Technician:	~
Reread:	
EditThickness:	
EditDosimeterlds:	
Save	Cancel

- 4 To edit an existing user, select the 🌣 sprocket icon.
- 5 To delete a user, click the 👕 trash can icon. You can only delete users that have not used the software to create a report.
- 6 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.
- 7 Always click "Save" button to save user settings.

## How to set up user roles and permissions using LDAP/Explicit LDAP

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. 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.

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.

## Follow these steps:

- 1 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).
- 3 Login to DoseControl as the System Admin. Click on the Configuration Settings icon and expand the "Application Settings" menu.
- 4 Select either LDAP User Manager or Explicit LDAP User Manager in the drop down menu.
- 5 Paste the Active Directory address into the "Connection String" field in the Application Settings menu.

- APPLICATION SETTINGS					
SETTING	SELECTED IMPLEMENTATION	CONNECTION STRING			
Client Report Service	Empty Client Repository				
Sign in manager	Explicit LDAP user manager	ongex.local			
			SAVE CHANGES		

## NOTE

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

Roles	
ROLE	LDAP GROUP MAPPING
SystemAdmin	SysAdmin
ApplicationAdmin	AppAdmin
Technician	Tech
Reread	Reread
EditThickness	EditT
EditDosimeterlds	EditlD
Save roles	

# 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.

# 8 Configure Storage Locations

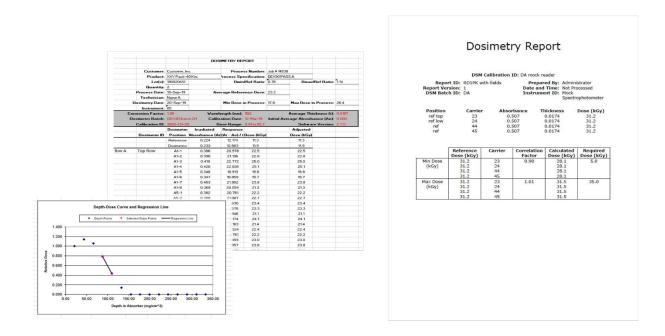
The System Administration user role can make changes to the software settings, connections, and storage locations. Use the default file paths or change the storage locations at the time of first installation or at any time in the future.

	DoseControl®		_
≡	CONFIGURAT	ION	
÷	+ APPLICATIO	ON SETTINGS	
✿ ☆	- CONNECTI	ON AND STORAGE	
	Master connection string	Data Source=GEX-LT22\SQLEXPRESS;Initial Catalog=GEXsampleDA.3;User Id=admin;Password=Password;Multipl	eActiveResultSets=true;
ø	Reports storage location	C:\ProgramData\GEX\Reports	Browse
♥		SA	VE CHANGES
<u>1</u> .			
	NLog file storage location	C:\ProgramData\GEX	Browse
		SA	VE CHANGES
	© 2020 GEX Corporation. All Ri	ights Reserved. DoseControl is a registered trademark of GEX Corporation.	1.4.2020.7.17000

**Reports storage location:** file pathway for where the DoseControl dosimetry reports are stored. Default is C:\ProgramData\GEX\Reports. DoseControl can use mapped network drives as storage locations (example: \\Shared\Reports). Your IT department will need to configure these network shares to allow your users' access.

**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.

# 9 Dosimetry Reports



# **Overview: Dosimetry Reports in DoseControl**

Dosimetry report data is output in both MS Excel (\*.xlsx) and secure PDF file types. The user can save or print a dosimetry report in Excel or PDF format. The layout and content of a dosimetry report is flexible and configurable, and the DoseControl Admin can setup one or more report types to meet the unique needs of the user's dosimetry process, such as a report for routine process dosimetry, E-beam testing, dose mapping, and dosimeter batch calibrations.

The Admin needs to set up and configure report types before using the system. When a user is ready to begin a new report and measure dosimeters, the user selects one of the configured report types displayed in a dropdown menu. The software will then prompt the user to enter any information required for the report, and then the user can begin dosimeter measurements. All the dosimeter measurements and related information are recorded and output in the pre-configured report format, to be saved or printed as Excel and/or PDF files.

# Managing dosimetry reports

The 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 report, in either MS Excel or secure PDF. 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.

GEX provides several report types templates; or you can create custom report templates to upload into DoseControl:

MS Excel templates (ready to use from GEX)	PDF templates (ready to use from GEX)
<ul> <li>Dosimeter Measurement – report for measuring dosimeter absorbance and dose for routine dosimetry.</li> <li>Beam Energy – ebeam testing, 10MeV Riso wedge</li> <li>Beam Scan Uniformity - ebeam testing</li> <li>DoseMap (30) – dose map report for 30 dosimeters</li> <li>DoseMap (85) – dose map report for 85 dosimeters</li> <li>DoseMap (135) – dose map report for 135 dosimeters</li> <li>Ebeam – Dosimeter Batch Calibration</li> <li>Gamma – Dosimeter Batch Calibration</li> </ul>	<ul> <li>Standard 1 Pack PDF: report for measuring dosimeter absorbance and dose for routine dosimetry, 1 dosimeter/pouch.</li> <li>GEX Default PDF (Standard 2 Pack PDF): report for measuring dosimeter absorbance and dose for routine dosimetry, 2 dosimeter/pouch</li> <li>Ref Dose 1 Pack PDF: for routine monitoring dosimetry, includes reference dose, correlation factor, required dose. 1 dosimeter/pack</li> <li>Ref Dose 2 Pack PDF: for routine monitoring dosimetry, includes reference dose, correlation factor, required dose. 2 dosimeter/pack</li> </ul>

# Custom MS Excel templates

You can customize Excel templates as needed, using the original template provided by GEX (Excel skills required).

GEX can customize Excel template for you (additional fee).

- 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

# **Custom PDF templates**

GEX can customize PDF template for you (additional fee).

- 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

# How to use Excel report format in DoseControl

## IMPORTANT

Before you can measure dosimeters and export measurement information into an Excel document, the Admin must setup and configure the dosimetry report headers and fields as described in <u>Dosimetry Reports: Configuring report types and</u> data fields in <u>DoseControl software</u>.

NOTE

See <u>APPENDIX 4: Excel Report Data Fields</u> for complete details and examples of the pre-formatted Excel reports provided by GEX.

The 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 (\*.xlsx file).

# How to upload the Excel template:

- 1 Click on the sprocket icon to open the Set Up screen.
- **2** Open the Miscellaneous section and click the "Upload Excel Template" button.

≡	SET UP			
4	READERS	CALIBRATIONS	REPORT HEADERS	REREADS
\$				
*	+ PATHWAYS			
ة <b>ير</b>	+ DOSIMETER	TYPES		
	+ BATCHES			
	- MISCELLAN	EOUS		
		nual Mode Enabled: 🧹		
		'0 Reader' Enabled: 🧹		
	Should application loci	out time in minutes:		
	Is Report Search F	iltered by Pathway: 🧹		
	UPLOAD EXCEI	TEMPLATE		
	SAVE MISCELL	ANEOUS		

3 Navigate to the Excel template you want to upload and click "Open". The template will automatically upload into DoseControl.

-> 👻 🕇 🔲 > This PC >	Desktop v O	Search Desktop	۶
rganize • New folder			
Pictures	↑ Name	Date modified	Туре
This PC	APP Build 87 - GEX Master	3/30/2020 7:07 PM	File folde
3D Objects	APP-build-79	1/10/2020 12:41 PM	File fold
Apple iPhone	APP-build-89 - GEX Master	5/5/2020 9:28 AM	File folde
Desktop	docs	6/3/2020 4:49 PM	File folde
Documents	Expenses	1/29/2020 11:09 A	
Downloads	GENESYS30 Driver	5/5/2020 11:55 AM	File folde
Music	Modules for GEX DC	6/1/2020 4:04 PM	File folde
Pictures	Reports	6/3/2020 3:25 PM	File folde
Videos	Templates	5/5/2020 11:57 AM	File folde
Windows (C:)	DC Export to Excel Template - RevB FINALXLSX	5/27/2020 7:05 AM 6/1/2020 4:09 PM	Microsof
	e of export to exter reinplate - nevo minatives	0/1/2020 4:09 PM	MICIOSOI
shared (S:)	v (		
File name: DC	Export to Excel Template - Rev8 FINALXLSX	Excel Files (*.xlsx)	

- 4 Template upload is complete. (There is no alert that says successful upload). This template will now be the template used when exporting dosimetry reports to Excel from the software.
- **5** Click the "Save Miscellaneous".

#### IMPORTANT

Windows security on your PC will sometimes cause issues when using external documents, such as the \*.xlsx template provided by GEX. To avoid this, save the \*.xlsx template from the GEX installation folder to your PC and rename the file. In addition, you may also need to remove security blocks. To do this, right-click on the \*.xlsx file, go to Properties, then under the General tab Attributes click "Unblock", and then save the file.

## How to use PDF reports in DoseControl

PDF report templates are included in the DoseControl software installation package that you received from GEX. Your IT personnel will place the PDF exporter modules (both the standard and custom PDF report templates) in the modules folder within the GEX program files upon installation of the software.

NOTE

See <u>APPENDIX 3: PDF Report Data Fields</u> for complete description of data fields and examples of the standard PDF report templates.

Unlike Excel report templates, the Admin does not need to upload any PDF report templates. DoseControl will automatically recognize the PDF exporter modules and will display the available PDF templates in a drop-down menu.

### Description of PDF report exporter types:

- Standard 1 Pack PDF for routine process monitoring with 1 dosimeter per pouch.
- Standard 2 Pack PDF for routine process monitoring with 2 dosimeter per pouch.
- Ref Dose 1 Pack PDF for routine process monitoring with 1 dosimeter per pouch, includes reference dose fields which calculate min and max dose to product using dose measured at a reference monitoring locatio.
- Ref Dose 2 Pack PDF for routine process monitoring with 2 dosimeter per pouch, includes reference dose fields which calculate min and max dose to product using dose measured at a reference monitoring location.
- Custom Report PDF can contain any measurement and process information, per customer requirements.

### Next steps:

Before you can measure dosimeters and export measurement information into a PDF document, the Admin must setup and configure the dosimetry report headers and fields as described in <u>Dosimetry Reports: Configuring Report Types and</u> <u>Data Fields</u> below.

# **Dosimetry Reports: Configuring Report Types and Data Fields**

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

### To create a new report type:

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

	DoseControl®	_
≡	SET UP	
¢	READERS CALIBRATIONS REPORT HEADERS REREA	
<b>#</b> %	+ PATHWAYS	Hide Inactive Elements
م قر	+ DOSIMETER TYPES	
۲		
Ť.		
	+ MISCELLANEOUS	
	© 2020 GEX Corporation. All Rights Reserved. DoseControl is a registered trademark of GEX Corporation.	1.4.2020.7.17000

The Report Headers main screen displays a list of report types that have been created by the Admin. Example:

Hide Inactive Elements         DEFAULT         IS ACTIVE         COPY         COPY NAME         DELETE         ALLOW MANUAL PRODUCT SPECS           Report Sample RDINK         ✓         Copy         □
Roport Sample 8011K
Samula Recoil Default O Opy
Ebeam lett Report Copy
Report RDIRK.reg Copy
Window text count Copy
SUBSCIPCS Copy

- 3 On the Report Headers screen, click "Add New Header Set" button.
- 4 Select "Exporter Type" from the dropdown menu.
  - For details about Exporter Types see <u>How to use PDF reports in DoseControl</u>.
  - For Excel reports, simply select "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

DoseControl Dosimetry Software User Guide

	SET: Ebeam Test Report	
Exporter Type:	Standard 1 Pack PDF 🔹	
Name:	Ebeam Test Report	
External ld:	Ebeam Test Report	

## How to add report header fields to the new report configuration:

DoseControl captures most necessary dosimeter measurement information (batch, calibration, reader information), but you may want additional content on your reports. Example of this 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.

#### When to use report header fields:

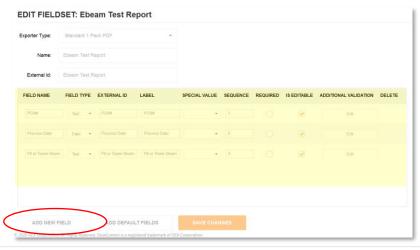
Excel Reports	<ul> <li>Report header fields not required.</li> <li>Add additional report headers, as needed. See <u>How to Customize Excel</u> <u>report templates</u> for information about changing and adding fields to Excel report templates.</li> </ul>
PDF Reports	<ul> <li>Using GEX Default, Standard 1 pack PDF report layouts – No additional report header fields required.</li> </ul>
	<ul> <li>Using GEX Ref Dose 1 pack, Ref Dose 2 pack PDF report layouts – Set up report headers as defined in <u>APPENDIX 3: PDF Report Data Fields</u></li> </ul>
	<ul> <li>Using a Custom PDF report layout provided by GEX – Set up report header as defined by GEX staff.</li> </ul>

### How to add report header fields:

6 After you have created a Report type from the steps 1-3 above, 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.

ADD FIELD SET

7 After you have created a Report type from the steps 1-3 above, you can add report header fields by clicking "Add New Field" button. (To quickly add a standard set of default fields, click "Add Default Fields".)





- 8 Enter each field's data information. Description for each data field:
  - **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 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:

	The	FieldType field is required.	•	7	<b>~</b>	Û
Confir	mation					
Date						
Decim	nal Number					
Whole	e Number					
Text						

- 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. (Only used for Ref Dose report types – <u>APPENDIX 3: PDF Report Data Fields</u>). Special Value calculations in the software for the following:
  - 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.

ef:Max Ratios	Decin	Ref:Max Ratio	s Ratios	• 7			•		Ŷ
				Min Dose Max Dose Ref to Min Ratio Ref to Max Ratio TS531 Issue					
FIELD NAME	FIELD TYPE	EXTERNAL ID	LABEL	SPECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDATION	DELETE
Min spec	Decin 🔻	Min spec	Min Dose	Min Dose 🔻	1		<ul><li>✓</li></ul>	Edit	

- 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) Tick both the "Required" and "Is Editable" boxes to enable the required field. Return to TOC

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

## Examples of Report Header fields setup:

Hide Inactiv	ve Element	s								
DESCRIPTION	DEF	AULT IS	ACTIVE	COPY	c	COPYNAME	DEL	ETE		
Routine Process Re	eport	۲	<b>~</b>		Сору			Ŷ		
Ref Dose - Routine	e Proces		<b>~</b>		Сору			Ŷ		
Riso Wedge Test R	Report		✓		Сору			Ŷ		
Dose Map			<b>~</b>		Сору			Ŷ		
		ET 1 Pack PC	DF		•					
porter Type: Name:	Standard Routine D	1 Pack PC	Report		•					
porter Type: Name: External Id:	Standard Routine D Routine D	1 Pack PC	Report Report	LABEL	* SPECIAL VALUE	E SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDATION	DELETE
porter Type: Name: External Id:	Standard Routine D Routine D	1 Pack PE osimetry R	Report Report	LABEL PCN#	SPECIAL VALUE	E SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDATION	DELETE
porter Type: Name: External Id:	Standard Routine D Routine D	1 Pack PE osimetry R EXTERN	Report Report		SPECIAL VALUE				ADDITIONAL VALIDATION	
Porter Type: Name: External Id: FIELD NAME FI	Standard Routine D Routine D IELD TYPE Text	1 Pack PC osimetry R extern.	Report Report	PCN#	SPECIAL VALUE	• 1		✓	ADDITIONAL VALIDATION	Ŷ
External Id: FIELD NAME FI PCN# Process desc	Standard Routine D Routine D HELD TYPE Text • Text •	1 Pack PE osimetry R EXTERN PCN# ess desc	Report Report IAL ID cription s Date	PCN#	SPECIAL VALUE	• 1		<b>y</b>	ADDITIONAL VALIDATION	Ŷ

xporter Type:	Standard	1 Pack PDF		•					
Name:	Riso Wed	ge Test Report							
External Id:	Riso Wed	ge Test Report							
FIELD NAME	FIELD TYPE	EXTERNAL ID	LABEL	SPECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDATION	DELET
PCN#	Text •	PCN#	PCN#	•	1			Edit	Ŷ
Process desc	Text •	Process descrij	Proces	•	2			Edit	9
Process Date	Date •	Process Date	Proces	•	3			Edit	9
Pit or Tower B	Text •	Pit or Tower Bea	Pit or Te	•	4		✓	Edit	Î
Line speed	Text •	Line speed	Line sp	•	5		<b>~</b>	Edit	Ŷ

## How to 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).

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

IMPORTANT

Do not delete the **DC Export** worksheet! DoseControl puts the dosimetry report information into DC Export.

All the other tabs are basic report templates that you can customize. The data in the DC Export cells are linked to the other reports.

e Home	Insert I	Page Layout	Formulas	Data Rev	iew View	Help Acrobat									iể Share	Cor
e nome	insen	rage cayour	Formulas	Data Nev	iew view	Help Acrobat									E Share	ç çon
Ψ.	: × 🗸	fx														
А	В	с	D	E	F	G	н	1	L L	к	L	м	N	0	Р	Q
Report ID	Rpt Version	Pathway	DSM Batch	Status	Last Edited By	Last Edited Date	Last Edited Time UTC	Export Date	Export Time UTC							
Report Name 12	32	ebeam1	DA	Incomplete	Administrator	03-Jun-2020	21:10	03-Jun-2020	21:24							
	-									_						
PCN#	1234AB	1			1											
Process Date	6/3/2020															
it or Tower Bea	Pit															
it or Tower Bea	im															
ine Speed																
Omin/Ref Ratio																
max/Ref Ratio																
		1														
	Maximum		Max Dose													
Minimum Dose	Dose	Min Dose Spec	Spec	Meets Spec?												
31.20	31.20	N/A	N/A	N/A												
Comments	(ver.1) = Powe	r failure at facil	ity for 48 hours	s, including prod	ess date/time in	npacts A/C of facility a	and lab areas. Noted ten	perature 26C	60RH in lab ar	ea						
												Corrected				
DosimeterID	Position	ToteID	Ao	Ai - 1	Ai - 2	Ai - 3	Ai - 4	Thickness	Response	Dose	Corr Fact.	Dose	CalibrationID	Inst ID	Inst SN	WL (nm)
DA_123458	ref upper	23	0	0.507	N/A	N/A	N/A	0.0174	29.138	31.2	1	31.2	DA mock read	e Mock Spectro	09765	552
A_123457	ref lower	24	0	0.507	N/A	N/A	N/A	0.0174	29.138	31.2	1	31.2	DA mock read	e Mock Spectrop	09765	552

4	\utoS	Save 💽 🕅	日 ら~			Rep	ort Name 123	4-v2.xlsx +			♀ Search	
Fi	le	Home	Insert	Page Layou	it Form	ulas Da	ata Revie	ew Vie	w Help	Acrob	at	
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		В	c	D	E	F	G	н	1.1		к	
1	Α	В	U	U	E	F	G	н		J	ĸ	
2												
3												
1						RY REPOR						
5			1234AB		-		Report Name	1234				
6		Process Spec:	-			in Process:						
7 8		Process Date: Technician:		_		in Process: in/Ref Ratio:						
8 9		osimetry Date:		-		in/Ref Ratio: ax/Ref Ratio:	-					
0		nstrument S/N:				viewed by:	U					
1		nstrument om.	03705		No	wieweu by.						
12	Do	simeter Batch:	DA		Average Th	nickness (t):	0.0174	Wavele	ength (nm): 5	52		
13		Calibration ID:	DA mock re	adeltial Ave								
14												
15			Dosimeter	Irradiated	Response							
6		Dosimeter ID	Position	Abs.	(Ai - Ao) / t	Dose (kGy)						
.7		DA_123458	ref upper	0.507	29.138	31.2						
8		DA123457	reflower	0.507	29.138	31.2						
9		0000000	0	0.000	0.000	0.0						
20		0000000	0	0.000	0.000	0.0						
21		0000000	0	0.000	0.000	0.0						
2		0000000	0	0.000	0.000	0.0						
23		0000000	0	0.000	0.000	0.0						
24		0000000	0	0.000	0.000	0.0						
25		0000000	0	0.000	0.000	0.0						
26		0000000	0	0.000	0.000	0.0						
27		0000000	0	0.000	0.000	0.0						
		0000000	0	0.000	0.000	0.0						
28		0000000	0	0.000	0.000	0.0						

See <u>APPENDIX 4: Excel Report Data Fields</u> for complete information, such as the details about each Excel data field, and definition of each field.

## How to set up Excel template with additional report header fields

- 1 First, the Admin must setup the additional Report Headers in DoseControl. (See: <u>How to create a new report</u> <u>type and How to add report header fields to the new report configuration</u>.)
  - The report headers will automatically appear on the exported Excel DC Export worksheet.
  - These additional report fields will appear in the sequence configured in the DoseControl Report Headers setup.

The additional report headers automatically populate the dynamic section of DC Export tab.

L Report ID	Rpt Version	EDIT FIEL	DSET: RDP	ATPON						
2 Report Name 12	2									
3		Exporter Type:	Ref Dose 1 Par	ck PDF	•					
PCN#	1234AB									
5 Process Date	6/3/2020	Name:	RDPK1 PCN							
5 Line Speed		reame.	NOTICITION							
7 Dmin/Ref Ratio			ſ			1				
Dmax/Ref Ratio		External Id:	RDPK1 PCN							
)			L			1				
0		FIELD NAME	FIELD TYPE	EXTERNAL ID	LABEL	SPECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDA
1		FIELD IVAILE	HEED THE	EXTERNALID	LADEL	SPECIAL VALUE	SEQUENCE	REQUIRED	13 EDITABLE	ADDITIONAL VALIDA
2		[Detter Dec		(D.U. D.I.						
	Maximum	Ref:Min Ratio	Decimal Numb	Ref:Min Ratio	Dmin/Ref Ratio	Ref to Min Rat •	4		<ul> <li>Image: A start of the start of</li></ul>	
3 Minimum Dose	Dose									
4 31.20	31.20	Ref:Max Ratio	Decimal Numb	<ul> <li>Ref:Max Ratio</li> </ul>	Dmax/Ref Ratio	Ref to Max Ra 🔹	5			
5										
6 Comments	(ver.1) = Power	DONN		PCN#	PCN#		1			
.7		PCN#	Text	· FCIN#	FCN#	•	1		$\checkmark$	
8 DosimeterID	Position	Process Date	Date	Process Date	Process Date		2		Image: A start and a start	
9 DA_123458	ref upper									
0 DA_123457	ref lower									
1		Line Speed	Text	Line Speed	Line Speed	•	6			
2										
3										
4										
5				A dditio	a ranart had	dara configu	radia			
6						aders configu				
.7				DoseCo	ontrol. The	sequence nu	mber of			
8	C Frances 1					ermines the o				
	C Export 1									
leady 💽					> Reported	to DC Expor	ι.			

- 2 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.)
- 3 When the cell linking is complete, save the Excel worksheet as your new Excel dosimetry report template. Upload the new template into DoseControl. For instructions about how to upload the template, see <u>How to</u> <u>upload the Excel template</u> in the section above.
- 4 Every time you create a report using this Report Type template, the data from DoseControl will automatically populate the fields of the Excel report.

Aı	itoSave 💽 🗍	9 ° °				Wedge Test 1	demo-v2.xlsx 👻			♀ Search	ı			
ile	Home	insert Page	e Layout Forr	nulas	Data	Review Vie	ew Help	Acrobat						
_	1 🔏 Cut	Calibri	~ 10	✓ A <sup>^</sup> A <sup>^</sup>	.   =	= - 18/-	ab Wrap Text			~	A A	Ŧ.		
_[	Copy ~										- 4	74		
۱S ۷	Server at Pain	ter B I	└ ~   ⊞ ~   ≦	<u>h ~ A</u> ~	·   =	= = = =	🖽 Merge & 🤇	Center ~ 🛛 \$ 👻	% 🤊 📅	i .00 Conditi i →20 Formatt	ional Forn ing ~ Tak			
	Clipboard	5	Font		5	Alian	nment	F3	Number	- Fall	ing in		ity	
	cipboard	(a)	Tone		121	Aligi	ment	131	Number	121			, cy	
	▼ 1	$\times \checkmark$	f <sub>x</sub>											
	А	В	с	D		E	F	G	н	1		J		
1				1				Last Edited	Last Edited		Expo	ort Time		
1	Report ID	Rpt Version	Pathway	DSM Bat	tch	Status	Last Edited By	Date	Time UTC	Export Dat	е <u></u> UTC			
1	Nedge Test 1 de	1	pathway1	DA		Incomplete	Administrator	15-Oct-2020	20:14	15-Oct-202	0 20:1	4		
	Test Description				Aut	toSave 💽 🖉 🗜	1 9 ° ° '		DC Expor	t to Excel Templa	te - RevC F	INAL_WEDGE	TEST.xlsx -	
Ľ	Process Date	10/15/2020			File	Home In	isert Page	Layout Formu	as Data	Review	View	Help A	robat	
H	Process Number				, ne		, age	cayour ronnu				noip A		
-	Process Specifica				· (^	🔏 Cut	Arial	~ 8 ~	A^ Aĭ =	= =   %	~ ab_∖	Vrap Text		
H	Power	15	-		Paste	Copy ~	D 7							0/ 8
	Ave Beam Currer	5			~ ~	🛛 ダ Format Painte	er B I L		<u> </u>		→=   ↔		er 🖌 🖇	- % 🤊
-	ine Speed	5	_			Clipboard	5	Font	5	4	lignment		F3	Number
ŀ														
ŀ		Maximum	Min Dose	Max Do	C7	• E	×	='DC Export'	!B4					
l,	Minimum Dose	Dose	Spec	Spec		АВ	С	D	E	F	G	н		J
μ	15.70	15.70	N/A	N/A	1									
ŀ	20170	20110			2									
				<b>4</b>	3									
	Example	of linking	colle in a	, i	4									
		-			5			Beam Ener	gy Test	using Ri	sø We	edge		
		y report te	mplate to											
	DC Expo	rt data.			7	Test Description			1		Number:			
	<ul> <li>In this</li> </ul>	example Be	eam Energy		8	Process Dat				Process Spe				
		n Excel, for			9 10	Technicia Dosimetry Dat	-			Avg. Beam Cu	ower, kW:			
					11	Instrumer					ne Speed:			
		cell, link to			12						ie opeen	·		
	corresp	conding fiel	d output in		13	Correction Facto			elength (nm):			Average Th	nickness (t):	0.0000
	DC Ex	oort.			14	Dosimeter Batc			alibration ID:	0			Wedge S/N:	
			mplate and		15 16	Dosimeter	Depth in Al	Irradiated	Response	Dose (kGy)		Adjusted		
					16	0000000		Absorbance (Ai) 0.000	(Ai - AoJ/t 0.000	0.0		Dose (kGy) 0.0		
	upload	into DoseC	Jontrol.		17	0000000		0.000	0.000	0.0		0.0		
					19	0000000		0.000	0.000	0.0		0.0		
					20	0000000		0.000	0.000	0.0		0.0		
					20	0000000	0.402	0.000	0.000	0.0		0.0		
					20 21 22	0000000		0.000	0.000	0.0		0.0		

<u>Final result:</u> All data for this report will automatically populate the Excel Beam Energy report, including the additional report headers configured by the Admin Setup>Report Headers.

	В	eam Energ	y Test	using F	Risø We	edge		
				-		-		
Test Description	Wedge test de	escription		Proce	ss Number:	1234A		
Process Date:	10/15/2020			Process Specification:		ABC-123		
Technician:	Administrator				Power, kW:	15		
Dosimetry Date:	15-Oct-2020			Avg. Beam Current, µA:		5		
Instrument:	mock				Line Speed:	5		
Correction Factor:	1.00	Wave	length (nm):	0		Average TI	nickness (t):	0.0000
Dosimeter Batch:	0	C	alibration ID:	0			Wedge S/N:	
	Depth in Al	Irradiated	Response			Adjusted		
Dosimeter ID	(cm)	Absorbance (Ai)	(Ai - Ao)/t	Dose (kGy)		Dose (kGy)		
DA_1234567	0.138	0.311	16.455	15.7		15.7		
DA_1234568	0.226	0.311	16.455	15.7		15.7		
DA1234569	0.314	0.311	16.455	15.7		15.7		
DA1234570	0.402	0.311	16.455	15.7		15.7		
DA 1234571	0.490	0.311	16.455	15.7		15.7		

# 10 General Use of DoseControl Dosimetry System

# **Overview: Measuring Dosimeters in DoseControl**

To measure dosimeters in the software, you must have configured all dosimetry process parameters, dosimeter report types and report headers prior to beginning any measurements. See <u>Configure</u> <u>Dosimetry Process Parameters</u> section and the <u>Dosimetry Reports</u> section for more information.

## Quick links:

- Process for Creating a New Dosimetry Report
- Process for Using Existing Dosimetry Reports
- How to search for a report or dosimeter ID
- Procedure for Dosimeter Measurement
  - o How to re-measure (re-read) a Dosimeter
- About the Report Summary Screen
  - o Process a Complete Report
  - How to Create a New Version of a Report
  - o How to export a report to PDF or Excel format
- How to Use the Audit Trail

## About Barcode Scanning of Dosimeter IDs

## **Process for Creating a New Dosimetry Report**

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:

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

SEARCH REI	PORTS							
		Q			chear	1	-	NEW REP
Include all versions								
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH	
Demo Report	2	Incomplete	7/5/2020	11:27 AM	Administrator	ebeam1	DA	
nedoe1	1	incomplete	6/16/2020	9:48 AM	Administrator	ebeam1	DA	
123 Default	1	incomplete	6/16/2020	9:46 AM	Administrator	ebeam1	DA	
123eb	1	Incomplete	6/15/2020	11:21 AM	Administrator	ebeam1	DA	
del2	1	Incomplete	6/8/2020	3:13 PM	Administrator	ebeam1	DA	
20k rd	1	incomplete	6/7/2020	11:18 AM	Administrator	ebeam1	DA	
2pk.eb	9E	Incomplete	6/7/2020	11:17 AM	Administrator	ebeam1	DA	
2pk default	1	Incomplete	6/7/2020	11:16 AM	Administrator	ebeam1	DA	
ND1PK with helds	1.1	Incomplete	6/5/2020	2:08 PM	Administrator	ebeam1	DA.	

- 2 The next screen will prompt the user to select the appropriate information for this new report:
  - Select one of the pre-configured 'Report Type' options from the dropdown menu. In this example, the user selects "Ebeam Test Report" to choose the report for measuring dosimeters for an e-beam test.

Report Type:	Std 1 pack	•
	Ebeam Test Report	
Pathway:	Std 1 pack	
Batch:	DA	•
Report ID:		

- Select a 'Pathway' (Irradiation pathway).
- Select a 'Batch' (dosimeter batch).
- Enter a new, unique Report ID to name the new dosimetry report.
- Click "Save Changes" button.

CREATE	NEW REPORT
Report Type:	Ebeam Test Report
Pathway:	ebeam1 ·
Batch:	DA
Report ID:	Report 1234
SAVE CH	ANGES

3 The next screen will prompt the user to enter the appropriate dosimetry process information into the report headers (as configured by the Admin). In this example, the Admin has configured three report header fields – PCN#, Process Date, and Pit/Tower Beam. The user types in the PCN#, selects a process date from the popup calendar, and types 'Pit Beam'.

Report ID: Rep	oort 1234 version 1	DSM Batch: DA Pathway ID: ebeam1
PCN#	123AWR-1	
Process Date	8/13/2020	15
Pit or Tower Beam	Su Mo Tu We Th Fr S 26 27 28 29 30 31	
	2 3 4 5 6 7 9 10 11 12 13 14 1	5 2 SAVE CHANGES
	23 24 25 26 27 28 2 30 31 1 2 3 4	9

4 Click "Save Changes" and the new report is created, and the user will be able to begin dosimeter measurements.



Fields are outlined in red if the Admin configured these fields as "required".

Report ID:	Wedge test 02J	une2020 version 1	DSM Batch: DA	Pathway ID: ebeam1
PCN#				
Process Date	Select a date		15	
		SAVE CHANGE	s	

Report header fields outlined in red are required.

**5** Once the report is created, DoseControl will open the dosimeter measurement screen and prompt the user to prepare to zero '0' the spectrophotometer and begin measurements.

		_ 🗢 🛪 L Administrator   Logout
=	K BACK      Report ID: Report 1234 version 1 DSM Batch: DA Pathway ID: ebeam1      READER STATUS: Ready	REPORT SUMMARY
0	DOSIMETERS: MEASURE:	
	Info Prepare for zero. Remove Sample. Insert empty holder, if applicable – Click: 'OK' when ready.	

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

# **Process for Using Existing Dosimetry Reports**

## **Open an Existing Report**

- 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.

SEARCH REPORTS									
1		Q	ebeam	1	Ţ		NEW REPORT		
Include all versions									
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH		
Wedge test 02June2020	1	Incomplete	6/3/2020	3:02 PM	Administrator	ebeam1	DA		
Report Name 1234	2	Incomplete	6/3/2020	3:01 PM	Administrator	ebeam1	DA		

- 3 To quickly find an existing report, use the Search bar to find an existing report by Report ID, Dosimeter ID. See <u>Search Reports</u> section for details.
- 4 The software will prompt the user to zero '0' the spectrophotometer. Click 'OK" to zero the reader. You can begin measuring dosimeters.

## Create a New Version of a Report

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. To create a new version, follow the instructions given in <u>Create a New Version of a</u> <u>Report</u> in the Report Summary Screen section.

# **Process for Dosimeter Measurement**

#### **Measuring Dosimeters**

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

Info	
Prepare for zero. Remove Sam when ready.	ple. Insert empty holder, if applicable – Click 'OK'
	ОК

#### NOTE

The software verifies the measurement wavelength setting of the spectrophotometer before every measurement, and ensure it matches the calibration. If it is not correct, the software will inform the user and then set the instrument to the correct wavelength and force the user to zero the spectrophotometer before making a measurement.

Info	
Current reader wavelength and expected calibration wavelength do not match. Prepare for zero: Remove Sample. Insert empty holder, if applicable – Click 'OK when ready.	
ОК	
Furnarda matification	

Example notification

2 The cursor defaults to the Dosimeter ID field and is ready to accept a manually typed or barcode scanned value.

	DoseControl®			_ 5 × ▲ Administrator   Logout
=	< BACK			REPORT SUMMARY
4	Report ID: Report 1234 version 1 DSM Batch: DA Pathway ID: ebeam1 READER STATUS: Ready			
•	DOSIMETERS:	MEASURE:		+ MORE DETAILS
*	# ID ABS THICKNESS DOSE		Dosimeter ID:	
ö			MEASURE	
\$		DOSE (kGy ): Readings: 0 of 0		
L.			0 Reader   Skip Reading	
<u>~</u> `				

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

MEASURE:	
Dosimeter ID:	DA123459
	MEASURE

4 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 (pre-configured in 'Batches' by the Admin), and the calculated dose.

Report ID: Repo	rt Name 1	234 version 1	DSM Batch: DA	Pathway ID: ebeam1					
READER STATUS: Re	ady								
		Model Info: M Serial #: 05 relength (nm): 55 ral Bandwidth: 1	9765	Avg. Thickness (mm): 0.0174 Avg. Background ABS: 0.000 Calibration: DA mock res Calibration Date: 5/22/2020 8:				Min Dese: 2.1 Max Dese: 60.0	- LESS DETAIL
DOSIMETERS:					MEASURE:				
# ID	ABS	THICKNESS	DOSE			Dosimeter	r ID:	JA123456	
1 DA_123456	0.507	0.0174 mm	31.2 kGy			DSM Positi	ion		
1 DA_123456	0.507	0.0174 mm	31.2 KUY			Tote	D:		
								MEASURE	
					DOSE (kGy ):31.2				
						Α	0.50	07 REREAD Thickness: 0.0174 SAVE	
					Readings: 1 of 1			0 Reader   Skip Reading	

## NOTE

The 'thickness' value is the average thickness value of the dosimeter batch from the calibration configuration. 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. See Measurement Screen section for details.

Rep	ort ID: Report	Name 12	34 version	1 DSM Batc	h: DA Pathway ID:	ebeam1						
REA	DER STATUS: Ready											
			Model Info: Serial #: elength (nm): al Bandwidth:	09765		Avg. Thickness (mm): 0.4 Avg. Background ABS: 0.4 Calibration: DJ Calibration Date: 5/	000 A mock reader				Min Dose: 2.1 Max Dose: 60.0	- LESS DETAILS
DOS	IMETERS:							MEASURE:				
	ID .	ABS	THICKNESS	DOSE					Dosimeter ID:	DA_123456		
1	DA_123456	0.507	0.0174 mm	31.2 kGy					DSM Position: Tote ID:			
								DOSE (kGy ):31.2			MEASURE	
									<b>A</b> 0.	.507	REREAD Thickness: 0.0174 SAVE	
								Readings: 1 of 1		0 R	Reader   Skip Reading	

5 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.

R	еро	rt ID: Report N	ame 12	34 version 1	DSM Batch: DA	Pathway ID: ebeam1						
R	ADE	R STATUS: Ready										
				Model Info: N Serial #: 0 elength (nm): 5 al Bandwidth: 1	9765	Avg. Thickness (mm): 0.01 Avg. Background ABS: 0.00 Calibration: DA Calibration Date: 5/22	00 mock reader	и			Min Dose: 2.1 Max Dose: 60.0	- LESS DETAILS
D	DSIM	NETERS:						MEASURE:				
		D	ABS	THICKNESS	DOSE				Dosimeter ID:	DA_123	456	
	1	DA_123456	0.507	0.0174 mm	31.2 kGy				DSM Position: Tote ID:			
												SAVE CHANGES
											MEASURE	
L								DOSE (kGy ):31.2				
									A 0.	.507	REREAD Thickness: 0.0174 SAVE	
								Readings: 1 of 1			0 Reader   Skip Reading	

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

								REPORT SUMMARY
eport I	D: 1234 Sample Rep	port version '	DSM Batc	h: DA Pathway ID: ebe	eam1			
ADER S	TATUS: None							
	Model Info: Serial #: Wavelength (nm): Spectral Bandwidth:	9A1U102012 552	/ tiber	Avg. Thickness (mm): 0.0174 Avg. Background ABS: 0.000 Calibration: DA cal G: Calibration Date: 5/4/2020			Min Dose: 2.1 Max Dose: 60.0	
		Taman operate,	- Hou	calibration bace. 3/92020				- LESS DETAIL
SIMETI					MEASURE:			
# ID	ABS	THICKNESS	DOSE			Dosinteter ID:		
1 001	0.500	0.0174 mm	30.6 kGy				MEASURE	
2 002	0.252	0.0174 mm	13.4 kGv		DOSE (kGy ):			
2 002	0.252	0.0174 mm	13.9 KBy		Readings: 7 of 5			
3 003	0.510	0.0174 mm	31.4 kGy				0 Reader   Skip Reading	
4 004	0.494	0.0174 mm	30.2 kGy O					
5 005	0.485	0.0174 mm	29.5 kGy					

## How to re-measure (re-read) a Dosimeter

7 To re-read a dosimeter, select the "REREAD" button.

Re	port ID: Rep	ort Name 12	234 version 1	DSM Batch: [	A Pathway ID: ebeam1			
RE	ADER STATUS:	Ready						
			Model Info: 1 Serial #: 0 relength (nm): 1 ral Bandwidth: 1	29765	Avg. Thickness (mm): 0.0174 Avg. Background ABS: 0.000 Calibration: DA modx reac Calibration Date: 5/22/2020 0.1			Min Dove: 2.1 Mar Dove: 0.03
DO	SIMETERS:					MEASURE:		- LESS DE IAILS
	ID	ABS	THICKNESS	DOSE			Dosimeter ID:	Dt_DA_123466
	1 DA_123456	0.507	0.0174 mm	31.2 KGy			DSM Position: Tote ID:	on [nf] ID: [2]
								SAVE CHANGES
								MEASURE
						DOSE (kGy ):31.2		
							<b>A</b> 0.	0.507 RESELD Thickness: 0.0174 SAVE
						Readings: 1 of 1		0 Reader   Skip Reading

8 Next, choose a reason for the re-read from the dropdown menu. The Admin has pre-configured how re-reads are performed (simple measurement replacement of the original or statistical re-read process – see <u>Reread</u> <u>Configuration</u> for details). The Admin also configured a list of allowed reasons to perform a re-read, and if a comment is required.

Α	
	dirty dosimeter
	dose verification
	dirt on dosimeter
	not heat treated
Readings: 1 of 3	
	0 Reader Skip Reading

9 Click "Measure" to re-read the dosimeter:

DOSE (kGy ):31.2			
Α	dirt on dosimeter		•
			MEASURE
			CANCEL
	Thickness:	0.0174	SAVE
Readings: 1 of 3			
	0 Reader Skip	o Reading	

**10** In this example of a simple reread, the new measurement replaces the old value and is seen in the dosimeter's information. A re-read symbol indicates the dosimeter has been re-measured:

R	epo	rt ID: Report N	Name 12	234 version 1	DSM Batch: D	A Pathway ID: ebeam1				
R	AD	R STATUS: Ready								
				Model Info: M Serial #: 05 relength (nm): 55 ral Bandwidth: 1	9765	Avg. Thickness (mm): 0.0174 Avg. Background ABS: 0.000 Calibration: DA mock read Calibration Date: 5/22/2020 8:19			Min Dose: 2.1 Max Dose: 60.0	- LESS DETAILS
D	DSIN	IETERS:					MEASURE:			
		D	ABS	THICKNESS	DOSE			Dosimeter ID:	DA_123456	
L.		DA_123456	0.507	0.0174 mm	31.2 kGy <b>O</b>			DSM Position:	ref	
P	1	un_illinit	0.007	0.01741111	512 koj -0			Tote ID:	23	
									MEASURE	
							DOSE (kGy ):31.2			
								A 0.	507 REREAD Thickness: 0.0174 SAVE	
							Readings: 1 of 1		0 Reader Skip Reading	

## How to Skip a Dosimeter Measurement

11 To skip a dosimeter reading, scan or enter the Dosimeter ID and then click the "Skip Reading" button. Enter a reason when prompted and click "OK". The skipped dosimeter ID will be recorded, and the absorbance will note "NO DOSI" with a dose of "N/A". See screenshots below.

< BACK									
1 Bridit								REPOI	RT SUMMARY
teport ID: Re	eport Name 12	34 version 2	DSM Batch: D	A Pathway II	D: ebeam1				
EADER STATU	S: Ready								
	Model Info: Serial #:			Avg. Thickness (mm):			Min Dose Max Dose		
	Wavelength (nm):	552			DA mock reader		Max Dose	60.0	
	Spectral Bandwidth:	1 small aperture.	fiber	Calibration Date:	: 5/22/2020 8:19 AM				- LESS DETAILS
OSIMETERS:					MEASURE:	Dosimeter ID: DA	mad		
ø ID	ABS	THICKNESS	DOSE			Dosimeter ID: DA	123458		
1 DA_123458	0.507	0.0174 mm	31.2 kGy 🖸				MEASURE		
2 DA_123457	0.507	0.0174 mm	31.2 kGy		DOSE (kGy )	:31.2			
					Readings: 2 of				
						0	Reader   Skip Reading		
Please pro			<b>)</b> ipping the me	asure.					
	ovide the rea			asure.			ОК	ancel	
Please pro	vide the reas	son for sk	ipping the me		1Way ID: ebeam1		OK	ancel	
Please pro	neter	son for sk	ipping the me		<b>1way ID:</b> ebeam1	[	ОК	ancel	
Please pro	Report Name	son for sk	ipping the me		-	ASURE:	ОК	ancel	+ 8
Please pro	Report Name	son for sk	on 2 DSM Bat		-		OK C	ancel	-1
Please pro Lost dosin Report ID: READER STAT DOSIMETERS # ID	Report Name	thickni	on 2 DSM Bat		-		ter ID: DA 123459	ancel	-
Please pro Lost dosin Report ID: READER STAT	Report Name	thickni	on 2 DSM Bat		-	Dosime DSM Pc	ter ID: DA 123459	ancel	+1
Please pro Lost dosin Report ID: READER STAT DOSIMETERS # ID	Report Name rUS: Ready : : ABS 458 0.507	tion for sk 1234 versi тніскля ао174 m	on 2 DSM Bate		-	Dosime DSM Pc	ter ID: DA_122459 sttion: cee ID:	ancel	+1

## **Report Summary Screen**

## **Report Summary Screen Overview**

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:

A NO DOSI

0 Reader | Skip Reading

Readings: 3 of 3

#### Return to TOC

TAILS

< BAI		lame 12	234 version 1	DSM Batch: DA Pathway ID: ebeam1				REPORT SUMMARY	
READE	R STATUS: Ready							+ MORE DE	ETAILS
DOSIM	IETERS:				MEASURE:				
	D	ABS	THICKNESS	DOSE		Dosimeter	r ID: DA	A_123457	
						DSM Positi	tion:		
1	DA_123456	0.507	0.0174 mm	31.2 kGy <b>O</b>		Tote	e ID:		
2	DA_123457	0.507	0.0174 mm	31.2 kGy				MEASURE	
					DOSE (kGy ):31.2				
						Α	0.50	7 REREAD	
								Thickness: 0.0174 SAVE	
					Readings: 2 of 2			0 Reader   Skip Reading	

## **Report Summary sections:**

- A. Results Lists the overall minimum and maximum measured doses as well as the minimum and maximum dose specifications, if configured (see 'Results' below for details)
- **B.** 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.
- C. Readings Same as the dosimeter list from the 'Measure' screen.
- D. Report Summary Statistics Lists the statistics for the report
  - Average measured dose
  - o Measured dose standard deviation
  - Measured dose C.V.%
  - o Minimum measured
  - Maximum measured
- E. 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.

	DoseControl®	🛓 Administrator   I
≡	Report ID: Report Name 1234 version 2 DSM Batch: DA Pathway ID: ebeam1	÷.
٤	A results:	EDIT HEADERS
\$	Overall Minimum Deer (kdy): 112 Overall Maximum Deer (kdy): 312	
*	B - REPORT INFORMATION	
قر	RONE 123488 Process Date: 6/2200	
	Pit or Tower Beam: Pit	
	C – readings	
<u>1</u> :	ID TOTE POSITION ABS THICKNESS RESPONSE DOSE	
	1 ✔ 🗑 DA_123468 23 refupper 0.507 0.0174 mm 29138 31.2 kGy O	
	2 ✔ T DA_123457 24 reflower 0.507 0.0174 mm 25138 31.2 kGy	
	D - Dose summary statistics	
	Average Measured Dose: 312.4Gy Measured Dose: Col: 60% Measured Dose: Col: 60% Measured Dose: Col: 60% Measured: 0.5Gy Measured: 312.4Gy	
	COMMENTS	
	PROCESS REPORT	VERSION REPORT
	© 2021 GEX Corporation. All Rights Reserved. DeseControl is a registered trademark of GEX Corporation.	1.5.2020.11

Report Summary screen

## **Edit Report Information and Report Headers**

Edit Headers: Click the "Edit Headers" button to edit the Report Information for the report. Add or change the values in the report header fields, then click "Save Changes":

				< BACK		
DSM Batch: DA Pa	athway ID: ebeam1	🖶 🖬 📄		Report ID: De	mo Report version 2 DSM Batch: DA	Pathway ID: ebeam1
		EDIT HEADERS		Min Dose	6	
				May Dava	74	1
				Max Dose	10	
maximum Dose spec(koy): 73	3.0			Ref to Min Ratio	0.89	
				Ref to Max Ratio	1.08	
					SAVE CHANGES	
	Minimum Dose Spec (kGy): 6	DSM Batch: DA Pathway ID: ebeam1 Minimum Dese Spec (KGy: 60 Maximum Dese Spec (KGy: 75.0	EDIT HEADERS	EDIT HEADERS	DSM Batch: DA Pathway ID: ebeam1  EDIT HEADERS Min Does Spec (Kigy: 60 Maximum Does Spec (Kigy: 730 Ref to Min Ratio	DSM Batch: DA Pathway ID: ebeam1  EDIT HEADERS  Minimum Does Spec (Migy: 60 Maximum Dees Spec (Migy: 730  Maximum Dees Spec (M

Edit Report header information

#### Delete and Edit a dosimeter reading

Delete a dosimeter reading: Click the click the trash can icon next to a dosimeter ID PA\_123456 and enter a comment when prompted.

User input required	
Provide reason for deleting the Dosimeter ID from this report.	
Dosimeter DA_123456 was damaged	
ОК Сал	icel

Edit a dosimeter reading: Click the click the pencil icon next to a dosimeter ID **TA\_123456** and change the dosimeter ID information. Click the checkmark icon to save the edit. Enter a comment when prompted.

User input required			
Provide reason for editing the Dosimeter ID	).		
DA_123456 should be DA_123458. ID# mist	typed.		
	1	✓ X DA_123458	OK Cancel
		Edit a dosimeter reading	

#### NOTE

The Admin can control the deleting and editing of dosimeter ID's through User Permissions. Only users with the "edit dosimeter IDs" role can perform this action. See <u>Configure User Roles and Permissions</u>.

#### Add a Comment to a Report

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

- COMMENTS	
VERSION POSTED COMMENTS SKIPPED DOSIMETERS	
CURRENT VERSION:	
Power failure at facility for 48 hours, including process date/time impacts A/C of facility and lab areas. Noted temperature 26C, 60RH in lab area	
UPDATE COMMENT	

Add a comment

## **Process a Complete Report**

**Process a Complete 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.

	DoseControl®	_ & ×
** = •	C BACK Report ID: CG 2pk auto mock 1 version 1 DSM Batch: CG Pathway ID: pathway1	
•	RESULTS:	EDIT READERS
*	Overall Minimum Dove (Kdy): 26.1 Overall Minimum Dove (Kdy): 26.1	
اتم	+ REPORT INFORMATION	
⊠ \$	+ READINGS	
<u>1</u> 1	+ DOSE SUMMARY STATISTICS	
	+ COMMENTS	
	PROCESS REPORT	VERSION REPORT
	© 2021 GEX Corporation. All Rights Reserved. DoseControl is a registered trademark of GEX Corporation.	1.5.2020.11.17000

Process Report button

		Q	ebeam	1	•	N	IEW REPORT
Include all versions							
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH
Report Name 1234	1	Complete	6/3/2020	2:58 PM	Administrator	ebeam1	DA
Wedge test 02June2020	1	Incomplete	6/3/2020	10:06 AM	Administrator	ebeam1	DA
Wedge test ABC	1	Incomplete	6/3/2020	10:05 AM	Administrator	ebeam1	DA
87rev2	1	Incomplete	6/1/2020	4:11 PM	Administrator	ebeam1	DA
demo	1	Incomplete	5/29/2020	2:38 PM	Administrator	ebeam1	DA
786	1	Incomplete	5/29/2020	2:26 PM	Administrator	ebeam1	DA

Processed report shows a status of 'Complete' in the Report list screen

## Create a New Version of a Report

Version 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.

Repor	t ID: Report 1234 version	1 DSM Batch: DA	Pathway ID: ebeam	1			÷ 5	
							EDIT HEADERS	
RESULT	SI							
	nimum Dose (kGy): 17.3 almum Dose (kGy): 17.3							
+	REPORT INFORMATION							
+	READINGS							
+	COMMENTS							
						PROCESS REPORT	VERSION REPORT	
		Report ID: Rep	port 1234 version 2	DSM Batch: DA	Pathway	ID: ebeam1		
		PCN#	123AWR-1					
		Process Date	8/13/2020	1	5			
		Pit or Tower Beam	pit					
			(	SAVE CHANGES				

Make any needed changes to the new version of a report.

Rep	ort ID: Repor		234 version 2	DSM Batc	h: DA Pathway ID		EPORT SUMMARY
DOS	METERS:				MEASURE:		+ MORE DETAIL
#	ID	ABS	THICKNESS	DOSE	Dosimeter ID:	DA123458	
					DSM Position:	ref	
1	DA_123458	0.507	0.0174 mm	31.2 kGy 🖸	Tote ID:	23	
2	DA_123457	0.507	0.0174 mm	31.2 kGy			
					DOSE (kGy ):31.2		
					A 0.507		REREAD
						Thickness: 0.017	4 SAVE
					Readings: 1 of 2	Reader   Skip Rea	ding

Make dosimeter measurements or re-reads as necessary in Version 2 of a report.

SEARCH REP	SEARCH REPORTS									
report 1234		Q					•		NEW F	REPORT
<ul> <li>Include all versions</li> </ul>										
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH			
Report 1234	2	Incomplete	8/13/2020	1:19 PM	Operator	ebeam1	DA			
Report 1234	1	Complete	8/13/2020	1:14 PM	Operator	ebeam1	DA			

Version 2 and Version 1 visible on the main reports screen.

## Export a Dosimetry Report to MS Excel or Print to PDF

**PDF Reports:** To export or print a secure PDF of the dosimetry report, click the printer icon in the upper right of the Report Summary screen. This will create a PDF of the report with the content, data, and design format configured by the Admin. The PDF is secure and cannot be altered. You can save, download or print the PDF. For Admin configuration instructions, see How to Set up a new Report Type and configure the report content section for details.

GEX Doc#100-266\_L Release Date: 08Aug2023

K BACK  Report ID: Report Name 1234 version 2 DSM Batch: DA Pathway ID: ebeam1	
Report ID. Report Name 1234 Version 2 DSW Batch. DA Pathway ID. ebeam	TEP ILS
	EDIT HEADERS
RESULTS:	
Overall Minimum Dose (KGy): 31.2 Overall Maximum Dose (KGy): 31.2	
+ REPORT INFORMATION	
+ READINGS	

Print to PDF and Export to Microsoft Excel icons

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. For Admin configuration instructions, see How to use PDF reports in DoseControl section for details.

Report ID:	Report Name	Prepared By:	Administrator
Report Version: DSM Batch ID:		Date and Time: Instrument ID:	
DSM Thickness:	0.0174		opeenoprocometer
<ul> <li>omments:</li> <li>Version 1 - Po</li> </ul>	wer failure at facility fo	r 48 hours, includina	process date/time
Version 1 - Po	ower failure at facility fo ility and lab areas. Not		

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.

Save As				×
$\leftarrow \rightarrow \lor \uparrow$ ] > This PC > Desktop > Reports		~ Ü	Search Reports	م
Organize • New folder			1	•• 0
<ul> <li>OneDrive - Personal</li> </ul>	^ Name ^	Date modified	Туре	Size ^
Attachments	1 renameonsave.zip	5/29/2020 11:43 A	zip Archive	836 KI
> Documents	1-v1.xlsx	5/29/2020 11:40 A	Microsoft Excel W	840 KI
lab	76-v1.xlsx	5/28/2020 10:31 PM	Microsoft Excel W	906 KI
OneNote Uploads	76-v2.xlsx	5/28/2020 10:34 PM	Microsoft Excel W	908 KI
Pictures	💾 76-v3.zip	5/28/2020 10:50 PM	zip Archive	900 KI
Pictures .	79 default-v1.xlsx	5/29/2020 9:59 AM	Microsoft Excel W	840 KI
V	v < 1			>
File name: Report Name 1234-v2.xisx				~
Save as type: All files (*.*)				~
A Hide Folders			Save	Cancel

Export to MS Excel file

			DOSIMETR	Y REPOR	T			
PCN#:	1234AB		Dosimet	ry Report ID:	Report Name	1234		
Process Spec:			Min Dose	in Process:	31.2			
Process Date:	Pit		Max Dose	in Process:	31.2			
Technician:	Administrator		Dm	in/Ref Ratio:	0			
Dosimetry Date:	03-Jun-2020		Dm	ax/Ref Ratio:	0			
Instrument S/N:	09765		Re	eviewed by:				
osimeter Batch:	DA		Average Th	hickness (t):	0.0174	Wave	elength (nm):	552
Calibration ID:	DA mock rea	adefinitial Av	erage Abso	rbance (Ao):	0.000			
	Dosimeter	Irradiated	Response					
Dosimeter ID	Position	Abs.	(Ai - Ao) / t	Dose (kGy)				
DA_123458	ref upper	0.507	29.138	31.2				
DA_123457	ref lower	0.507	29.138	31.2				
0000000	0	0.000	0.000	0.0				
0000000	0	0.000	0.000	0.0				

Sample MS Excel report

## Searching dosimetry reports

Use the Search bar on the main reports screen to quickly find information. Search by report ID, dosimeter ID and other keywords. Filter by pathway and versions. Default list shows current versions of reports. Tick the "Include all versions" to display all versions.

EARCH REP	ORTS						
DA_78958		٩					ebeam1 •
Include all versions							
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH
Wedge test ABC	1	incomplete	6/3/2020	6:28 PM	Administrator	ebeam1	DA
Report Name 1234	z	incomplete	6/3/2020	3:10 PM	Administrator	ebeam1	DA
87rex2	1	Complete	6/3/2020	3:04 PM	Administrator	ebeam1	DA
Wedge test 02June2020	1	Incomplete	6/3/2020	3:02 PM	Administrator	ebeam1	DA
demo	1	incomplete	5/29/2020	2:38 PM	Administrator	ebeam1	DA
206	1	incomplete	5/29/2020	2:26 PM	Administrator	ebeam1	DA
noUniformity upload	2	Complete	5/29/2020	2:03 PM	Administrator	ebeam1	DA
fixUniformGraph	1	incomplete	5/29/2020	1:15 PM	Administrator	ebeam1	DA
uniformRename	1	Incomplete	5/29/2020	1:07 PM	Administrator	ebeam1	DA
noUniformity	1	Incomplete	5/29/2020	1:05 PM	Administrator	ebeam1	DA

EARCH REP	ORTS							
DA_78958		٩					ebeam1	•
Include all versions								
REPORTID	VERSION	STATUS	DATE	TIME	LAST EDITED BY	PATHWAY	BATCH	
Wedge test ABC	1	Incomplete	6/3/2020	6:28 PM	Administrator	ebeam1	DA	

Search reports

# Alerts for Measurements Outside the Min/Max Range

**Outside the product specification min/max dose range:** 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 A next to the result, and report an alert statement. These alerts are present on both the measurement screen and the report summary screen.

	Minimum Dose (kGy): 1 Maximum Dose (kGy): 3						ose Spec (kGy): 10. ose Spec(kGy): 45.		
-	REPORT INFO		4						
	Min Dose:         10           Max Dose:         45           Min Ratio:         0.87           Max Ratio:         1.01								
-	READINGS								
#	ID	TOTE	POSITION	ABS	THICKNESS	RESPONSE	DOSE	CALC. MIN DOSE (kGy)	CALC. MAX DOSE (kGy)
1	1001	55	13	0.500	0.0174 mm	28.736	30.6 kGy	26.6	30.9
2	1002	65	2	0.252	0.0174 mm	14.483	13.4 kGy	11.7	13.5
3	1 🖉 003	23	1	0.510	0.0174 mm	29.310	31.4 kGy	27.3	31.7
4	1004	55	2	0.494	0.0174 mm	28.391	30.2 kGy 🖸	26.3	30.5
5	1 🖉 🖉 005	45	5	0.485	0.0174 mm	27.874	29.5 kGy	25.7	29.8
6	1006	47	2	0.073	0.0174 mm	4.195	2.1 kGy 🖸	1.8 🔺	2.1 🛕
7	1007	11	4	0.328	0.0174 mm	18.851	18.5 kGy	16.1	18.7
	_								

Dosimeter measurement that is below the minimum dose of the product specification, as shown on the Report Summary screen.

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

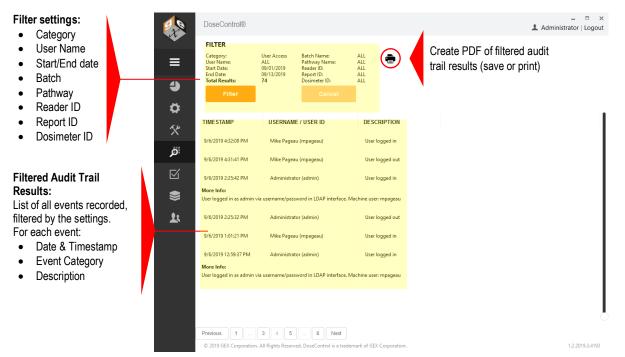
< BACK									REPORT SUMMARY
Report	ID: 567 Rep	ort Sam	ple DEF ver	rsion 3 DSM Batch: DA	Pathway ID: ebeam1				
READER S	STATUS: None								
			Model Info: G Serial #: 9/ relength (nm): 5: ral Bandwidth: 1	A1U102012	Avg. Thickness (mm):         0.0174           Avg. Background ABS:         0.000           Calibration:         DA cal G30           Calibration Date:         5/4/2020 12:00	AM		Min Dose: 2.1 Max Dose: 60.0	
DOSIMET	FRS					MEASURE:			- LESS DETAILS
# ID		ABS	THICKNESS	DOSE			Dosimeter ID:		
1 DA,	_7642985A	0.374	0.0174 mm	21.6 kGy				MEASURE	
2 DA,	_7642986A	0.364	0.0174 mm	20.9 kGy		DOSE (kGy ):			
3 DA,	_7642987A	0.490	0.0174 mm	29.9 kGy		Readings: 1 of 12		0 Reader   Skip Reading	
4 DA,	_7642988A	0.588	0.0174 mm	37.3 kGy <b>O</b>					
5 DA.	_7642989A	0.061	0.0174 mm	1.4 kGy 🛕					
6 DA,	_7642990A	0.471	0.0174 mm	28.5 kGy					
7 DA,	_7642991A	0.906	0.0174 mm	65.5 kGy 🛕 🔿					
8 DA_	_7642992A	0.496	0.0174 mm	30.3 kGy					
9 DA,	_7642993A	0.599	0.0174 mm	38.2 kGy					
10 DA	_7642994A	0.453	0.0174 mm	27.2 kGy					
11 DA	_7642995A	0.487	0.0174 mm	29.7 kGy					
12 DA	_7642996A	0.049	0.0174 mm	0.7 kGy 🛕 🖸					

Dosimeter measurements that are outside the range of the batch calibration Min Dose/Max Dose, as shown on the Measurement screen.

## Using the Audit Trail and Audit Reports Feature

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. For complete description, see *Audit Trail and Audit Reports* in the DoseControl System Description section.

Overview of the Audit Trail Search screen:



## How to Search and Filter the Audit Trail

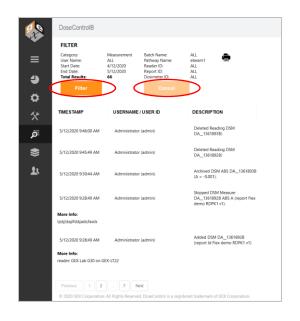
To search and filter the audit trail:

1 Select the magnifying glass icon on the tool bar to view the Audit Trail Search screen.

(	<b>\</b>						1 Administra	= 0 tor   Log	out
	≡	orts 2/2020 2/2020	Katch Name: Pathway Name: Reader ID: Report ID:	ALI ALI ALI	-				
	4	92020	Cancel	AU					
	<b>¢</b>								
	*	JSERNAM	IE / USER ID		DESCRIPTION				Ĭ
	jö:	Administrat	tor (admin)		Flex demo RDPK1 (v2): Generated Report output.				
	\$								
	1	Administrat	tor (admin)		Her demo RUPE1 (v2): Generated Report output.				
		Administrat	tor (ødmin)		Processed Report ID Flex demo RDPK1 (v2)				
		Astroinistees	ter (solaria)		Edited Report ID Recidento RDPK1	1			Ч
Γ		4	Next						
		lights Reserv	red. DoseControl is a reg	istere	d trademark of GDX Corporation.			2020.7.170	.00

2 The Audit Trail Search screen will load with the results of the last search performed on the system; the results are not displayed real-time. The user will need to perform a new query by pressing the "Filter" button.

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# IMPORTANT

Press the 'Cancel' button to cancel a search, if needed, during the search function to stop the search. If the filter is too broad and includes an excessively large data quantity, it can cause an extended search time as DoseControl compiles all the results from the database (or may lockup the application). Simply click 'Cancel' to stop the search and set the filter to include a narrower search.

3 The Filter screen will open. Select the filtering criteria and then press the "Save" button. To return to the Audit Search Results screen, press the "Cancel" button.

AUDIT SEAF	RCH FILTER
Category:	Measurement •
User Name:	ALL ~
Batch:	DA •
Pathway:	ebeam1 ·
Reader:	ALL -
Report Id:	ALL
Dosimeter Id:	ALL
Start Date:	4/12/2020 15 End Date: 5/12/2020 15
SAVE	CANCEL

Filter Screen for Audit Trail

#### Searches of the audit trail can be filtered by the following:

- Date range
- Event Type:
  - User Access events (e.g. Login, logout, failed login)
  - o Configuration events (e.g. add, edit, or delete dosimeter batch calibrations)
  - o Reports (e.g. create, process, version)

- Measurement (e.g. measure, remeasure)
- o Instrument zeroing
- Performance Verification (start, end, pass/fail)
- Irradiation Pathway ID
- Dosimeter Batch ID
- Measurement Instrument ID
- Dosimeter ID
- Report ID

## Save/Print PDF Audit Trail Report

Audit trail results can be generated into a PDF Report by pressing the PDF button on the screen. The PDF Report contains all same information that is displayed in the audit trail filter results on the screen.



#### Example Audit Trail Report PDF file:

GEX DoseCo	ntrol Sc	attware Audit Trail		
		JILWALE AUULT ITAL	Rep	ort
Audit Categories:	UserAccess		Start	End
User Name(s):		Date Range: 09/0	1/2019	09/13/2019
			:00 AM	6:00:00 AM
Dosimeter Batch(s):	All			
Irradiation Pathway(s):		Report ID(s) All		
Reader(s):		Dosimeter ID(s) All		
Total records:		bosinicici 10(3) An		
i otali i ecolusi				
Date/Time	User Name	Event Description		22
12-Sep-2019 11:57:58	Administrator	User logged in; More Info: User logged in as ad		10.
12-Sep-2019 10:40:25	(admin)	usemame/password in LDAP interface. Machine	user: mpage	au
12-Sep-2019 10:40:25	Administrator (admin)	User logged in; More Info: User logged in as ad username/password in LDAP interface. Machine		201
12-Sep-2019 10:06:20	Administrator	User logged in; More Info: User logged in as ad		
	(admin)	username/password in LDAP interface. Machine	user: mpage	au
12-Sep-2019 9:58:00	Administrator	User logged in; More Info: User logged in as ad		
12-Sep-2019 8:50:59	(admin) Administrator	username/password in LDAP interface. Machine User logged in; More Info: User logged in as ad		au
12-Sep-2019 8:50:59	(admin)	username/password in LDAP interface. Machine	min via	20
12-Sep-2019 8:43:52	Administrator	User logged in; More Info: User logged in as ad		
	(admin)	usemame/password in LDAP interface. Machine	user: mpage	au
	Administrator	User logged out		
12-Sep-2019 6:28:51				
12-Sep-2019 6:28:51 12-Sep-2019 6:26:46	(admin) Administrator	User logged in; More Info: User logged in as ad		

#### IMPORTANT

The results of the audit trail search (filter) are rendered to PDF by the application. For a large data set this can take an extensive number of minutes to complete. The application allows a maximum of 10,000 records to be printed to PDF in a single request. Therefore, if your "Total Results" is greater than 10,000 you will need to refine the search until that number is less than 10,000 for the PDF to render. DoseControl will alert the user if the record number exceeds this capacity.

# Using DoseControl Software in 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.

How to use Manual Mode:

1

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.

Rep	oort ID: Fx	demo defau	t rpt version 1	DSM Bat	tch: DA Pathway ID:	ebeam1			
REA	DER STATUS	Model In Serial Wavelength (nr	fo: Gen30 #: 9A1U102012 n): 552 th: 1 small aperture	e / fiber	Avg. Thickness (mm): 0 Avg. Background ABS: 0 Calibration: c Calibration Date: 5	000 xpy DA		Min Dose: 2.1 Max Dose: 600	- LESS DETAILS
	IMETERS:					MEASURE:		Da anad	
#	ID	ABS	THICKNESS	DOSE			Dosimeter ID:	DA_00004	
1	DA_00002	0.456	0.0174 mm	27.4 kGy				ADD DOSIMETER	
2	DA_00003	0.456	0.0174 mm	27.4 kGy		DOSE (kGy ):27.4	1		
						Readings: 2 of 2	0 Read	Manual Mode Sp Reading	

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:

F	Rep	ort ID: Fx	demo default	rpt version 1	DSM Batch: D	DA Pathway ID: el	beam1		
F	EAD	ER STATUS	Failed						
			Model Info:			Avg. Thickness (mm): 0.01			Min Dose: 2.1
			Serial #: Wavelength (nm):	9A1U102012 552		Avg. Background ABS: 0.00 Calibration: copy			Max Dose: 60.0
			Spectral Bandwidth:		/ fiber	Calibration Date: 5/19			
	osu	METERS:					MEASURE:		- LESS DETAIL
1	#		ABS	THICKNESS	DOSE		MEASORE.	Dosimeter ID:	DA 00004
	-	10	AB3	THICKNESS	DOSE				
	1	DA_00002	0.456	0.0174 mm	27.4 kGy				ADD DOSIMETER
							DOSE (kGy ):27.4		
	2	DA_00003	0.456	0.0174 mm	27.4 kGy		Readings: 2 of 2		
								0 Read	der Manual Mode Skip Reading
									der manual mode Skip Reading

**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.

R	ер	ort ID: Fx	demo default i	pt version 1	DSM Batch: D/	A Pathway ID	: ebeam1						
R	AD	ER STATUS	Failed										
			Model Info: Serial #:	Gen30 9A1U102012		Avg. Thickness (mm): Avg. Background ABS:					Min Dose: Max Dose:		
			Wavelength (nm): Spectral Bandwidth:		/ fiber	Calibration: Calibration Date:	copy DA 5/19/2020 2:21 AM						
D	osu	METERS:					MEASU	RF-					- LESS DETAILS
	#	ID	ABS	THICKNESS	DOSE				Dosimeter ID:	DA_00004			
	1	DA 00002	0.456	0.0174 mm	27.4 kGy				DSM Position:				
	2	D.4. 00000	0.456	0.0174 mm					Tote ID:				
	2	DA_00003	0.456	0.01/4 mm	27.4 kGy		DOSE (	kGy ): N/A		[			
	3	DA_00004	N/A	mm	N/A			Α			0.445	SAVE	
							Peading	1 2 of 2		Thickness		SAVE	
							neutrig.		0 Read	jer 🚺 Manual	Mode Skip	Reading	
							Reading	#3 of 3	0 Read	Thickness:		Reading	

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.

READ	ER STATUS	Failed				ay ID: ebe										
		Model Info:	9A1U102012 552	/ fiber	vg. Backgrou Calil	s (mm): 0.0174 nd ABS: 0.000 bration: copy D on Date: 5/19/20							ose: 2.1			
0051	METERS:		- sman operate			5,1572	MEASURE:								- L	ESS DETAI
	ID	ABS	THICKNESS	DOSE			Incrisone.		Dosimeter ID:	DA_0000	4					
1	DA_00002	0.456	0.0174 mm	27.4 kGy					DSM Position: Tote ID:							
2	DA_00003	0.456	0.0174 mm	27.4 kGy			DOSE (kGy ):26	<b>5.6</b>	lote ID:							
3	DA_00004	0.445	0.0174 mm	26.6 kGy				A	0.445							
							Readings: 3 of 3		0.Peed		Thicknes	s: 0.0174	Chie De	SAVE		

# NOTE

The Admin must enable the Manual Mode to allow use of this feature. See Manual Mode in the <u>Minor Features</u> <u>Configuration</u> section.

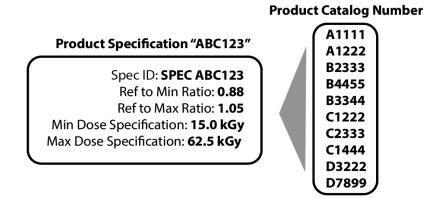
#### NOTE

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

# **Product Specification Module Overview**

The Product Specifications Module can be purchased separately for a one-time fee. 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 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.



The 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.

# Setup and Configure a New Product Specification

## **Product Specification Home Screen**

Click the 'stack' icon in the Menu Bar you can view the Product Specifications screen.

	DoseControl®					1 Adr	=
=	PRODUCT SPECIF	ICATIONS					
4	SPECIFICATION IDENTIFIER	REVISION DATE	CREATED/REVISED USER	VERSION	DELETE		
•	SPEC -X	8/13/2020 1:44 PM	admin	1	Ŷ		
*	SPEC123	8/13/2020 1:43 PM	admin	1	Ŷ		
تۇر	SPEC4444	8/13/2020 1:43 PM	admin	1	Ŷ		
2 1							
	ADD NEW SPECIFICAT		registered trademark of GEX Corp	poration.			1.4.2020.7.17000



The Product Specifications home screen lists all the specifications, revision date, the username of the person that created or edited it, and a version number. From this screen, the Admin can either open an existing specification by clicking on the Spec ID or add a new specification by clicking the "Add New Specification" button.

## **Add New Product Specification**

- 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:

Add Product Specification				
Specification Identifier:	SPEC - XYZ			
Ref to Min Ratio:	0.88			
Ref to Max Ratio:	1.02			
Min Dose Specification	12.4			
Max Dose Specification	46.0			
	CATALOG NUMBER	DELETE		

**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.

**3** Next, add a **Catalog Number** to 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):

CATALOG NUMBER	DELETE	
A111-22	Ŷ	
B222-4	Ŷ	
C33-44	Ŷ	
A6-syringe	Ŷ	
82905 - glass	Ŷ	
V445-78		

- 4 Add a comment to the comment field, if desired.
- 5 Click "Save" to save the new Product Specification. The Product Specification will appear on the home screen list of specifications.



The dose and correlation fields must have the correct number of significant digits (2 decimal places).

Specification Identifier:	SPEC0001	
Ref to Min Ratio:	1.2	Ref ratios must be numbers with 2 dec places
Ref to Max Ratio:		

## NOTE

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:

Error	
Saving changes failed: Catalog numbers may only exist in a singl specification: number Product ABC: spec SPEC123	le product
	ОК

## Create a Dosimetry Report Configuration for Use with the Product Specification Module

The Admin must setup up a report type to be specifically used with the Product Specifications Module.

#### NOTE

For information about report header field configuration, see *Dosimetry Reports: Configuring Report Types and Data Fields* in the Dosimetry Reports section of this manual.

The Admin must create a report type with all the Product Specification "special value" fields configured:

- 1 Create a new report type. (See directions in <u>Dosimetry Reports: Configuring Report Types and Data Fields</u> in the <u>Dosimetry Reports</u> section of this manual.)
- 2 For the new report type, add data fields for all the Product Specification requirements:
- 3 For each of these data fields, select the corresponding "Special Value" from the drop down menu. The Special Value fields in the Report Header <u>must</u> be selected for the items in the Product Specification. (If the Correlation Factors Dref:Dmin and Dref:Dmax are not used in the spec or set to "1" they don't have to be configured in the header.)

FIELD NAME	FIELD TYPE	EXTERNAL ID	LABEL	SPECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDATION	DELETE
Ref:Min Ratio	Decir 💌	Ref:Min Ratio	Ref to Min Ratio	Ref to Min 🔹	3		<ul><li>✓</li></ul>		Ŷ
Ref:Max Ratio	Decir 🔻	Ref:Max Ratio	Ref to Max Ratio	Ref to Max 🔹	4				4
Specification ID	Text 💌		Specification ID	•	5		<ul><li>✓</li></ul>		Ŷ
				Min Dose Max Dose Ref to Min Ratio Ref to Max Ratio TS531 Issue Catalog Number Specification Id					

## IMPORTANT

FIELD NAME	FIELD TYPE	LABEL	SPECIAL VALUE
Specification ID	Text	Specification ID	Specification Id
Min Spec	Decimal number	Min Spec	Min Dose
Max Spec	Decimal number	Max Spec	Max Dose
Ref:Min Ratio	Decimal number	Ref to Min Ratio	Ref to Min Ratio
Ref:Max Ratio	Decimal number	Ref to Max Ratio	Ref to Max Ratio
Catalog Number	Text	Product ID	Catalog Number

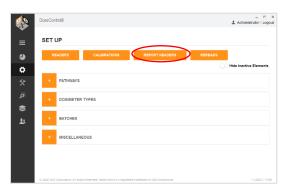
## Field Names, Field Type and Special Value must be entered exactly as shown in table below:

# Activating the Product Specifications Module

The Admin can activate the Product Specification module for use with specific dosimetry reports from the "Report Headers" configuration screen.

Ø

- **1** Select the "Setup" icon on the left menu bar.
- 2 Select the "Report Headers" button



3 In the Report Headers list, select "Allow Manual Product Specs" for the report type. This will activate the automatic Product Specification module for use with this report type.

Hide Inactive E	ements						
DESCRIPTION	DEFAULT	IS ACTIVE	COPY	COPY NAME	DELETE	ALLOW MANUAL PRODUCT SPECS	
Ebeam Test Report			Сору				
Report RD1PK req	۲		Сору			$\bigcirc$	
Wedge test report		✓	Сору				
RDPK1 PCN		<b>~</b>	Сору		Ŷ		

4 Select "Required" to make the fields required (the user must enter data in these fields when creating a dosimetry report). Select "Is Editable" to allow user to make changes to the report information. See <u>Dosimetry</u> <u>Reports: Report Types and Data Fields</u> section for details.

FIELD NAME	FIELD TYPE	EXTERNAL ID	LABEL	SPECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VALIDATION	DELETE
Min spec	Decin 💌	Min spec	Min Dose	Min Dose 🔹	1			Edit	
Max spec	Decin 💌	Max spec	Max Dose	Max Dose 🔹	2			Edit	

5 Click "Save Changes" to save the report type setup.

## Using the Product Specification module

When a Technician creates a new dosimetry report to measure dosimeters, the Technician will see a drop-down menu to "Find Catalog Number". The Technician can either select the appropriate Catalog Number from the list and the associated product specifications for this Catalog Number will automatically be imported into the report's header. The Catalog Number drop-down also has type-ahead search capabilities, so the Technician can type the first number or letter and the list will filter.

The correct process specification for that Catalog Number will automatically populate the report header fields. See screenshots:

	DoseControl™	_ □ × ▲ Administrator   Logout
≡	C BACK Report ID: Test083119-01 version 1 DSM Batch: CH Pathway ID: S11	
4	Find Catalog Number: N/A v	
<b>\$</b>	Specification ID N/A	
** ق	Min Dose (KGy)	
\$	Max Dose (KGy)	
<u>.</u>	Dref Dmin	
	Dref.Dmax	
	SAVE CHANGES	
	© 2019 GEX Corporation. All Rights Reserved. DoseControl is a trademark of GEX Corporation.	1.2.2019.3.15110

Select a Catalog Number from the drop-down menu

< BACK		
Report ID: 37231	version 2 DSM Batch: 1137	Pathway ID: Pathway 3
Find Catalog Number:	4082	~
OrderNumber	408205 408206 408208	
RunNumber	408210 🕞 408213 408214	
CatalogNumber	303366	
Description	Syringe 60ml LL Tip 1ml	

Drop-down menu includes quick-type filter that displays a list of options based on what is typed

	DoseControl™	💄 Admin	_ □ × istrator   Logout
<b>▼</b> ≡	K BACK	est083119-01 version 1 DSM Batch: CH Pathway ID: S11	
÷	Find Catalog Numb	ver: X65432 v	
<b>\$</b>	Specification ID	X999999	
*⁄ هر	Min Dose (kGy)	15	
تو الا	Max Dose (kGy)	60	
ž.	Dref:Dmin	0.85	
_	Dref:Dmax	1.26	
		SAVE CHANGES	
	© 2019 GEX Corporation	. All Rights Reserved. DoseControl is a trademark of GEX Corporation.	1.2.2019.3.15110

Product Specifications automatically populate new dosimetry report setup.

The purpose of the P.V. module is to provide a short-term verification or 'daily check' of the reader's absorbance measurement accuracy. The P.V. module is intended to be used as an additional check to the user's complete performance verification protocols for the reader. It is <u>not</u> a replacement for a complete performance verification of the reader.

# **Requirements for the P.V. Module:**

- The P.V. module is for use with the Thermo Evolution spectrophotometer.
- The P.V. module is designed to use a photometric standard from the Thermo Spectronic Standards kit (or other NIST-traceable standards set, certified in absorbance units, for the performance verification of the Thermo Evolution UV-Visible spectrophotometer). The standard should fit into the GEX dosimeter holder for Windose dosimeters (GEX product #P4334).
- The P.V. module requires two users to be setup in the User Manager with username/password.

# Overview of the P.V. Module

- The P.V. module provides performance verification (PV) testing of a single point of photometric accuracy, wavelength accuracy, and wavelength repeatability of the Evolution.
- 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 then 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.
- The P.V. test results can be saved or printed as a secure PDF. All P.V. tests are recorded in the audit trail.
- If any test parameter fails, DoseControl will not allow dosimeter measurements using the failed reader. The
  module enforces a process that guides a second user to log in, repeat the P.V. test. If the second test passes,
  the software prompts the first user to log in and repeat the P.V. test to confirm the passing 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.
- The P.V. test is executed by any user with a Technician role, as defined in the software's user manager.
- The P.V. test parameters and frequency are configured by the Application Admin. The Admin can set P.V. frequency for any timeframe, at which point the technician will be automatically prompted to perform a P.V. test at the designated time. Or, the Admin can set to P.V. to operate on-demand, so that the technician can click the module button and perform a P.V. test at will.

DoseControl uses a single photometric standard from the user's kit to test photometric accuracy, and the internal xenon lamp of the Evolution to test wavelength accuracy and repeatability. The Evo's xenon lamp is an excellent standard to use as a reference for wavelength accuracy. The element xenon has strong, fundamental lines throughout the UV-visible range; therefore, the Evo's xenon lamp provides a fundamental wavelength standard that never requires calibration.

#### NOTE

The wavelength accuracy test criteria were developed by Thermo Scientific and are used for wavelength accuracy and repeatability testing in the Thermo Insight software for the Evolution. These acceptance criteria values cannot be changed and are hard coded into the DoseControl software.

### NOTE

While the xenon emission lines are a manufacturer (Thermo) standard, xenon is not recognized by all organizations as a traceable reference. However, the only requirement for wavelength accuracy is that the instrument is continually verified to be accurate against some type of fixed reference, for which xenon is a perfect solution.

## Description of the P.V. module tests:

**Photometric Accuracy** – The Photometric Accuracy test determines the spectrophotometer's measured signal intensity values compared to the actual signal intensity values. DoseControl uses a single photometric standard. The user must place the

**Wavelength Accuracy & Repeatability** – The Wavelength Accuracy & Repeatability test determines the wavelength value reported by the spectrophotomer compared to the actual value. DoseControl locates the peak wavelength near 541.9 nm of the Evolution's internal xenon lamp and repeats the test three (3) times.

The P.V. home screen shown below features a list of all the tests run for all Evolution spectrophotometers in the system.

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

	DoseControl™				
≡	SPECTROPHO		CATIONS		
4	RUN A VERIFICATI	ON TEST CONF	IGURATION SETTIN	NGS	
\$	VERIFICATION ID	SPECTROPHOTOMETER ID	RESULT	DATE	TIME
*	27	Device 1124	Failed	05/02/2017	01:09 PM
$\boxtimes$	<u>26</u>	Device 1124	Failed	05/02/2017	01:08 PM
	25	Device 1124	Passed	05/01/2017	02:14 PM
<u>1</u> 1	<u>24</u>	Device 1124	Passed	04/03/2017	10:41 AM
	23	Device 1124	Passed	04/03/2017	09:08 AM
	22	Device 1124	Passed	04/03/2017	09:03 AM
	21	Device 1124	Failed	04/03/2017	08:22 AM
	20	Device 1124	Passed	03/31/2017	02:14 PM

P.V. module home screen

# Configure the Performance Verification P.V. Module

To set up the parameters for a performance verification (P.V.) test within the module:

- 1 Select the P.V. module icon from the menu bar to open the P.V. home screen.
- **2** Click the "Configuration Settings" button.

	DoseControl®	_ = × Administrator   Logout
=	SPECTROPHOTOMETER VERIFICATIONS	
4	RUN & VERIFICATION TEET CONFIGURATION SETTINGS	
۵	No ventrations found for the current reader	
*		
تقر		
Ø		
۲		
11		
	Previus Net	
	© 2020 GEX Corporation. All Rights Reserved. DeseControl is a registered trademark of GEX Corporation.	1.4.2525.7.17000

- 3 On the Verification Configurations Settings screen, click the "Add New Configuration" button:
- 4 Choose one (1) standard from the Thermo Spectronic Standards Kit (or similar standards kit). Use the calibration certificate from the Standards Kit to determine the certified absorbance value for the standard. Use the wavelength closest to the wavelength that will be used to measure the dosimeter. Use 546.1nm for B3 dosimeters because B3 is measured at 552nm. Example:

hermo Fish				P
225 Verona Rd., Bid Aadison, WI 53711 U			NVLAP LAB	CODE 200955-0
Technical Support: 1 8 International Support + www.lhermo.com	1 608 273 5017 Cert	ficate of Ca		APF
	SPECTRO	ONIC Standards 2	2 Kit 840-253100	( M)
Submitted to: GEX CORP 7330 S ALTON WAY CENTENNIAL, CO 8 JSA CHRISTINE WOLFE	10112	Certific Date of Perform	Number: SA0799 ate Number: CC0114: Calibration: 18 Jun 21 ned by: RONALD CHR athod: 397-018500 Re Used: EV300 999002 v e Temperature: 23 ± 1	020 RISTIANSON V A
	insmittance Values and			
Standard ID	SA0799 -1	SA0799 -2	SA0799 -3	SA0799 -
Nominal %T	50 %T	30 %T	10 %T	3 %T
Uncertainty	± 0.30 %T	± 0.18 %T	± .071 %T	± 0.048 %
440,0 nm	45.12 %T	27.10 %丁	7.40 %T	2.08 %T
			9.28 %T	2.92 %7
465.0 nm	51. <b>46</b> %⊤	33.51 %T	9.20 701	
465.0 nm 546.1 nm	51.46 %⊤ 52.14 %T	33.51 %T 34.40 %T	8.99 %T	2.78 %T
				2.78 %T
546.1 nm	52.14 %T	34.40 %T	8.99 %T	
546.1 nm 590.0 nm 635.0 nm	52.14 %T	34.40 %T <u>\$1,56 %T</u> 31.09 %T	8.99 %T	2.34 %J 3.05 %T
546.1 nm 590.0 nm 635.0 nm Certified Absorbance	52.14 %T 50.08 %T 50.27 %T Values and Uncertain	34.40 %T 31.55 %T 31.09 %T	8.99 %T 8.02 %T 9.55 %T	2.34 %J 3.05 %T
546.1 nm 590.0 nm 635.0 nm Certified Absorbance Standard ID	52.14 %T 50.00 %T 50.27 %T Values and Uncertaint SA0799 -1	34.40 %T 31.56 %T 31.09 %T	8.99 %T 8.02 %T 9.55 %T SA0799 -3	2.34 %J 3.05 %T SA0799 - 1.5 A
546.1 nm 590.0 nm 635.0 nm Certified Absorbance Standard ID Nominal Abs	52.14 %T 50.09 %T 50.27 %T Velues and Uncertaint SA0799 -1 0.3 A	34.40 %T 31.55 %T 31.09 %T Kies SA0799 -2 0.5 A	8.99 %T 8.02 %T 9.55 %T SA0799 -3 1.0 A	2.34 %J 3.05 %T SA0799 -
546.1 nm 590.0 nm 635.0 nm Certified Absorbance Standard ID Nominal Abs Uncertainty	52.14 %T 50.09 %T 50.27 %T Values and Uncertaint SA0799 -1 0.3 A ± 0.0026 A	34.40 %T 31.55 %T 31.09 %T % \$A0759 -2 0.5 A ± 0.0026 A	8.99 %T 8.02 %T 9.55 %T SA0799 -3 1.0 A ± 0.0031 A	2.34 %J 3.05 %T SA0799 - 1.5 A ± 0.0070
546.1 nm 590.0 nm 635.0 nm Certified Absorbance Standard ID Nominal Abs Uncertainty 440.0 nm	52.14 %T 50.09 %T 50.27 %T Values and Uncertaint SA0799 -1 0.3 A ± 0.0026 A 0.3456 A	34.40 %T 31.56 %T 31.09 %T \$	8.99 %T 8.02 %T 9.55 %T SA0799 -3 1.0 A ± 0.0031 A 1.1306 A	2.34 %] 3.05 %] 5A0799 - 1.5 A ± 0.0070 1.6822 A 1.5352 A
Certified Absorbance Standard ID Nominal Abs Uncertainty 440.0 nm	52.14 %T 50.00 %T 50.27 %T Values and Uncertaint SA0799 -1 0.3 A ± 0.0026 A 0.3455 A 0.2865 A	34.40 %T 31.56 %T 31.09 %T SA0799 -2 0.5 A ± 0.0026 A 0.5671 A 0.4748 A	8.99 %T 8.02 %T 9.55 %T SA0799 -3 1.0 A ± 0.0031 A 1.1306 A 1.0325 A	2.34 %J 3.05 %T SA0799 - 1.5 A ± 0.0070 1.6822 A

- 5 Complete all the required fields on the Add New Reference screen. Click "Add Reference" button when complete. See example in screenshot below.
  - Reference Identifier Enter an ID for the photometric reference. Reference filters typically have an assigned ID number labeled on the filter that is used to link the physical filter to the Certificate with the values pertaining to that filter.
    - IMPORTANT: The Reference Identifier will be the name that is displayed to the user when performing a P.V. test in the software. Make sure you use a reference ID that clearly identifies the correct standard. Example: SA0799-2 30%T provides the exact ID printed on the standard's label.
  - o Reference Description Enter a text description of the ID as additional detail to the ID.
  - **Frequency (hrs)** Enter the frequency for PV testing (e.g. 24 hours). Leave this field 'n/a' or enter '0' if you want to configure PV for 'as needed' to let operators choose when to perform PV.
  - Absorbance Spec Min The minimum acceptance limit of the Photometric Reference in absorbance units to the thousandths (to 3 decimal places, .000).

**IMPORTANT:** Thermo's published absorbance accuracy for the **Evolution One Plus is ±0.004A** and for the **Evolution 220 is ±0.006A.** It is the customer's responsibility to always reference the Thermo product specification documentation for the Evolution spectrophotometer.

 Absorbance Spec Min is calculated by: <u>Return to TOC</u> **Absorbance Spec Min** = Certified value of Reference – (Reference Uncertainty + Evolution Specification for ABS accuracy)

Example calculation (using calibration certificate above):

0.4548 = 0.4634 - (0.0026 + 0.004)

ABS Spec Min is 0.455 (rounded to 3 decimal places).

 Absorbance Spec Max – The maximum acceptance limit of the photometric reference in absorbance units to the thousandths (to 3 decimal places, .000).

> Absorbance Spec Max = Certified Value of Reference + (Reference Uncertainty + Evolution Specification for ABS accuracy)

Example calculation (using calibration certificate above):

0.472 = 0.4634 + (0.0026 + 0.004)

ABS Spec Max is 0.472 (rounded to 3 decimal places).

- Photometric Testing Wavelength (nm) The wavelength at which the photometric standard is certified, in tenths of nanometers (e.g. 546.1 nm).
- Certified wavelength Min Spec (nm) Wavelength accuracy min specification is hardcoded at 541.1 nm.
- Certified wavelength Max Spec (nm) Wavelength accuracy min specification is hardcoded at 542.7 nm.
- Wavelength Repeatability Spec (stdev) the allowable standard deviation for the 3 wavelength accuracy tests.

**IMPORTANT:** Thermo's published wavelength accuracy for the **Evolution One Plus is 0.05nm** and for the **Evolution 220 is 0.50 nm**, so enter the appropriate specification into the Wavelength Repeatability Spec field. It is the customer's responsibility to always reference the Thermo product specification documentation for the Evolution spectrophotometer.

ADD NEW REFERENCE	
Reference Identifier:	SA0799-2 30%T standard
Reference Description:	SA0799-2 0.5A 30%T standard
Frequency (hrs):	n/a
Absorbance Spec Min:	0.455
Absorbance Spec Max:	0.472
Photometric Testing Wavelength (nm):	546.1
Certified wavelength Min Spec (nm):	541.1
Certified wavelength Max Spec (nm):	542.7
Wavelength Repeatability Spec (stdev):	0.50
Example of new ref	ADD REFERENCE

6 Click "Is Active" switch to activate the Reference. When a user conducts a P.V. test, the active reference will be used. Only one reference can be active at a time.

	REFERENCE DESCRIPTION	IS ACTIVE	DELETE	
SA0799	30%T from SA0799	۲	Ŷ	

7 Click "Save" button to save the configuration settings.

# Performing a Performance Verification (P.V.) of the Evolution Reader

## 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.

#### IMPORTANT

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

There are two ways to perform a P.V. test in DoseControl. Users can perform a P.V. test on-demand at any time directly from the P.V. main screen. If the Admin configured the module so that a P.V. test must occur at a specific frequency (e.g. every 24 hours) the software will automatically prompt the user to perform a P.V. test at that time. The user will not be able to proceed to measuring dosimeters until the P.V. is complete and the reader passes the test. The software will show a message asking if the user to perform the P.V. test:

Info
This instrument requires performance verification. Do you want to do it now?
OK Cancel
Example of prompt for user to perform a P.V.

Example of prompt for user to perform a P.V.

Follow the instructions below to perform a P.V. test. Carefully follow the on-screen prompts:

- 1 Ensure the correct holder is inserted in the Evolution. The Windose dosimeter holder is also used to hold reference standards.
- 2 Click the P.V. icon to open the P.V. main screen.
- 3 Click the "Run a Verification Test" button.

	DoseControl®					L Technician   Logo	× tut
=			ATIONS				
<b>●</b> ☑	VERIFICATION ID	SPECTROPHOTOWETER ID	RESULT	DATE	TINE		
	1	Tab Lvo 5421 HNI02	Parcent	1/15/2020	413 PM		
	Previous 1 Next						
	© 2020 GEX Corporation. A1 R)	ghts Reserved. DoseControl is a registered	trademark of GEX	Corporation.		1.4.2020.7.1700	10

Return to TOC

**4** Next, click the "Test Reader" button:

TEST READER	<u> </u>		
ectrophoto	meter Detail		
disclarer: Thermo et: EV0220 INember: SA2134600 Imphotometer ID: Lat datue: 4 Watue: 4	Next Calibration Dat	# #175,000 13.03 AM #E #175,2233 12.05 AM	
mments			
DATE	USER	CONVENT	
nov comma f			
new contract			

5 Next, the software will show a message telling the user to remove all samples from the dosimeter holder in the Evolution reader. Remove any samples from the dosimeter holder and close the lid of the Evo to prepare it for zeroing. Click "Ok" after confirming there is no standard or dosimeter in the holder.

Info	
Remove all samples. Prepare for Zero. Click OK to continue.	
	ОК

- 6 The Evolution reader will proceed to zero. The reader will make an audible sound as its zeroing.
- 7 Next, the software will show a message instructing the user to insert the reference. Insert the reference with the correct reference ID into the dosimeter holder. Click "Ok" after inserting the reference and closing the lid of the Evo.

Info	
Please insert Reference ID SA0799 into the sample compartment and click OK to begin.	
	ОК

8 Next, the software will show a message instructing the user to remove the reference from the holder. Remove the reference and close the lid of the Evo. Click "Ok" to continue.

Info	
Please remove Reference ID SA0799 from the sample compartment and click OK to continue.	
C	к

**9** The P.V. test will take approximately 2 minutes to complete. The Evo reader will make audible sounds as it proceeds through the test. When the test is complete, the software will display the results:

VIEW PERFORMA	NCE VERIFICATIO	N	
fication Test Id: 1 Da Indard Reference ID: SA0799 U	te: Aug 15, 2020 16:13 er: Administrator		
DESCRIPTION	PARAMETERS	RESULT	
Photometric Accuracy	0.455 to 0.472 A	0.463	Passed
Wavelength 1	541.1 to 542.7 nm	541.6	Passed
Wavelength 2	541.1 to 542.7 nm	541.5	Passed
Wavelength 3	541.1 to 542.7 nm	541.5	Passed
Wavelength Std Dev	<= 0.5	0.047	Passed
pectrophotomete	er Detail		
Value: 0 Value: 4	Last Calibration Date: Next Calibration Date: Start Date: 8/15/2020 4: End Date: 8/15/2020 4:	8/15/2023 12:00 AI	
Comments			
DATE	USER		COMM
Add new comment			
020 GEX Corporation. All Rights Res	erved. DoseControl is a registered tra	demark of GEX Cor	poration.

**10** To create a secure PDF document of the P.V. test results click the printer icon in the upper right corner of the screen (see screenshot above). The software will create a PDF document that can be saved or printed.

Date Performed:	15 Aug 2020 16:13	Performed By: admin	
Standard Reference ID:	SA0799		
<u>Test Description</u> Photometric Accuracy Wavelength 1 Wavelength 2 Wavelength 3 Wavelength Std Dev	Test Parameters 0.455 to 0.472 A 541.1 to 542.7 nm 541.1 to 542.7 nm 541.1 to 542.7 nm <= 0.5	Result           0.463           541.6           541.5           541.5           0.047	<u>Pass/Fail</u> Pass Pass Pass Pass Pass
Spectrophotometer Detail			
Manufacturer: Thermo	Model: EVO220	Serial Number: 5A ID: Lab Evo 5A2T	
s	tion Date: 8/15/2020 12:00 AM tart Date: 8/15/2020 4:07 PM lin Value: 0	Next Calibration Date: End Date: Max Value:	AM 8/15/2020 4:13 PM
Prepared by Signa	ature	Date	

# Performance Verification (P.V.) Pass/Fail

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

Wavelength 2         541.1 to 542.7 rm         541.3         Named           Wavelength 3         541.3 to 542.7 rm         541.5         Named           Wavelength 3:dd Dav         <         0.01.7         Named           exectors/photometre Detail          Named         Named           winners: Thrms:         Las Collemation Date:         #171/0202 12020 MM           winners: W		SA2T346002 End Date: 8/15/2020 4:			
Wavelength 3         541.1 to 5427 rm         541.5         Passed           Wavelength 3 to Day         <         <         8.0         0.047         Passed	afacturer: Thermo	Last Calibration Date: 8 Next Calibration Date:	8/15/2023 12:00 AM		
			0.047	Passed	
Wavelength 2 541.1 to 542.7 nm 541.5 Passed	Wavelength 3	541.1 to 542.7 nm	541.5	Passed	
	Wavelength 2	541.1 to 542.7 nm	541.5	Passed	
Wavelength 1 541.1 to 542.7 nm 541.6 Passed		541.1 to 542.7 nm	541.6	Passed	
DESCRIPTION PARAMETERS RESULT Photometric Accuracy 0.455 to 0.472 A 0.463 Pessed				Passard	

If the P.V. test fails, the Evolution reader is not allowed to be used to make measurements 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.

VIEW PERFORMANCE VERIFICATION					
Verification Test Id: 32 Standard Reference ID: SA0520-2	Date: May 8, 2017 14:19 User: Administrator				
DESCRIPTION	PARAMETERS	RESULT			
Photometric Accuracy	0.305 to 0.311 A	0	Failed		
Wavelength 1	541.1 to 542.7 nm	541.9	Passed		
Wavelength 2	541.1 to 542.7 nm	542	Passed		
Wavelength 3	541.1 to 542.7 nm	541.9	Passed		
Wavelength Std Dev	<= 0.5	0.047	Passed		

#### Instructions for P.V. test failure

- Return to the P.V. main screen by clicking the checkmark icon 1
- 2 The software will notify the user with an message stating, "This instrument requires performance verification. Do you want to do it now?" Click "Ok".
- 3 The software will require a different user to login. Any user with a Technician or Admin role can login.

RUN PERFORMA	NCE VERIFICATION
his instrument requires performance	e verification to be run by a different user. Please log in
Jsername:	
Password:	

- 4 Proceed with the P.V. test.
- 5 If this P.V. test is a pass, the software will ask for the original user to login again and perform the P.V. test a second time.
- 6 If the original user completes a passing P.V. test the reader is then available to all Technicans for measurement.

## IMPORTANT

The original user specified <u>must</u> login and complete a successful PV for the software to unlock use of the spectrophotometer for dosimeter measurements. The software will not open or allow measurements until both P.V. tests are complete and successful.

7 If the subsequent P.V. tests continue to fail, the Evolution reader is likely in need of service. Contact GEX Customer Support or Thermo Customer Support.

NOTE

A demonstration video is available on our website - http://www.gexcorp.com/videolibrary.html

# 13 APPENDIX 1: Installation & Setup of Microsoft SQL Server Express (for Basic License)

# **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 <u>official Microsoft site "Editions and</u> <u>supported features of SQL Server 2019"</u>.

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

## 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.

## Installing SQL Server Express 2019

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.

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

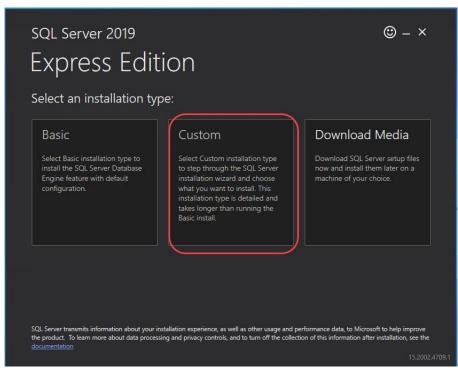
- 1 Log in as an administrator
- 2 Download SQL Server Express installer

Go to the <u>Microsoft SQL Server 2019 Express download page</u>, select the English language version, and then click the "Download" button to download the installer. **Note:** 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.

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

#### 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.

<sup>SQL Server 2019</sup> Express Edition		⊕ – ×
Specify SQL Server media downloa	ad target location	
MEDIA LOCATION CASQL2019	Browse	MINIMUM FREE SPACE 6578 MB DOWNLOAD SIZE 266 MB
	Close < P	revious Install

## 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".

髕 SQL Server 2019 Setup				-		×
Install Rules Setup rules identify potential pr can continue.	oblems that	might occur while running Setup. Failures must be corrected befo	ore Setup			
Install Rules Feature Selection Feature Rules Instance Configuration Java Install Location Server Configuration	Operation Hide deta				Re-n	un
Database Engine Configuration Consent to install Microsoft R Consent to install Python Feature Configuration Rules Installation Progress Complete	Result ③ ▲ ③	Rule Consistency validation for SQL Server registry keys Computer domain controller Windows Firewall SQL 2019 minimum CTP for Upgrade and Side by Side Support	Status Passed Warning Passed			
		< Back	Next >		Cancel	

#### 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:

Fea	tures:
Ins	stance Features
Т	✓ Database Engine Services
15	SQL Server Replication
	Machine Learning Services and Language Extensions
	🗌 R
	Python
	Java
	Full-Text and Semantic Extractions for Search
	PolyBase Query Service for External Data
	Java connector for HDFS data sources
Sh	ared Features
١Г	Client Tools Connectivity
	Client Tools Backwards Compatibility
	Client Tools SDK
	SQL Client Connectivity SDK
	LocalDB
Re	distributable Features

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:

🏗 SQL Server 2019 Setup					-		×
Instance Configuration	ı						
Specify the name and instance	ID for the instance of S	QL Server. Instance ID	becomes part of	the installation path.			
Install Rules Feature Selection	O Default instance						
Feature Rules	Named instance:	SQLEXPRESS					
Instance Configuration Server Configuration Database Engine Configuration Feature Configuration Rules Installation Progress	Instance ID:	SQLEXPRESS					
	SQL Server directory:	C:\Program Files\Mie	crosoft SQL Serve	r\MSSQL15.SQLEXPRESS			
Complete	Installed instances:						
	Instance Name	Instance ID	Features	Edition	Ver	rsion	-
				< Back Next >		Cance	4

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.

🐮 SQL Server 2019 Setup						-		×
Database Engine Config	juration							
Specify Database Engine authen parallelism, Memory limits, and F		administrators, data	a directori	ies, TempD	B, Max degree o	of		
Install Rules	Server Configuration	Data Directories	TempDB	Memory	User Instances	FILESTREAM		
Feature Selection Feature Rules	Specify the authent	ication mode and a	dministra	tors for the	e Database Engir	ne.		
Instance Configuration	Authentication Mod	de						
Server Configuration	O Windows authen	tication mode						
Database Engine Configuration	Mixed Mode (SQ	L Server authentica	tion and \	Nindows a	uthentication)			
Feature Configuration Rules	Specify the password for the SQL Server system administrator (sa) account.							
Complete 🥑	2 Enter password:							
	Confirm password:	•••••						
	Specify SQL Server a	administrators						
						er administrators have ted access to the Database		
					Engine.	eu access to the	Database	
•	7							
	Add Current User	Add Re	move					
					< Back	Next >	Cance	el

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.

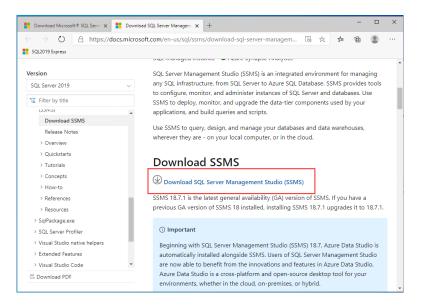
Feature Selection	Information about the Setup operation or po	ssible next steps:	
eature Selection	Feature	Status	
istance Configuration	🥝 Database Engine Services	Succeeded	
-	SQL Browser	Succeeded	
erver Configuration	SQL Writer	Succeeded	
atabase Engine Configuration	Client Tools Connectivity	Succeeded	
eature Configuration Rules	SQL Client Connectivity SDK	Succeeded	
stallation Progress	SQL Client Connectivity	Succeeded	
omplete			
	Details:		
	Details: Install successful.		 
		ving location:	
	Install successful.	-	

#### 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.

15 Download SSMS

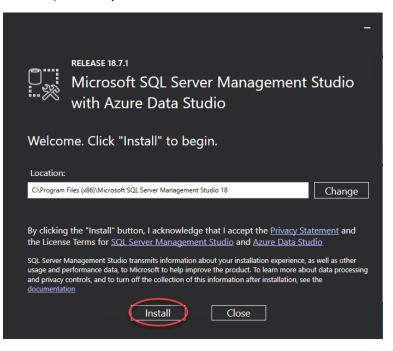
<u>IMPORTANT</u>: You should still be logged in to the computer as an administrator for the following steps. The SQL Server Installation Center window should still be open (if it is not, then you can launch it from the start menu). Click the Install SQL Server Management Tools link. A download page will open in your web browser; click the Download SQL Server Management Studio (SSMS) link:



#### 16 Open the installer

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

17 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.



#### 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.

18 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".

- C	er Management Studio		Quick Launch (Ctrl+Q)	_ م		×
File Edit View Pro	Geet Tools Window I 모르 Connect to Server		×	-   <b>5</b> -   -⊡ ⊡-   *0	÷	
Object Explorer		SQL Server				
Connect 👻 🍟 🗮 🗋	Server type:	Database Engine	~			
	Server name:	WINDEV2010EVAL\SQLEXF	YRESS ~			
	Authentication:	Windows Authentication	~			
	User name:	WINDEV2010EVAL\User	~			
	Password:					
		Remember password				
		Connect Cancel	Help Options >>			
🗇 Ready						

#### 19 Configure SQL Authentication logins

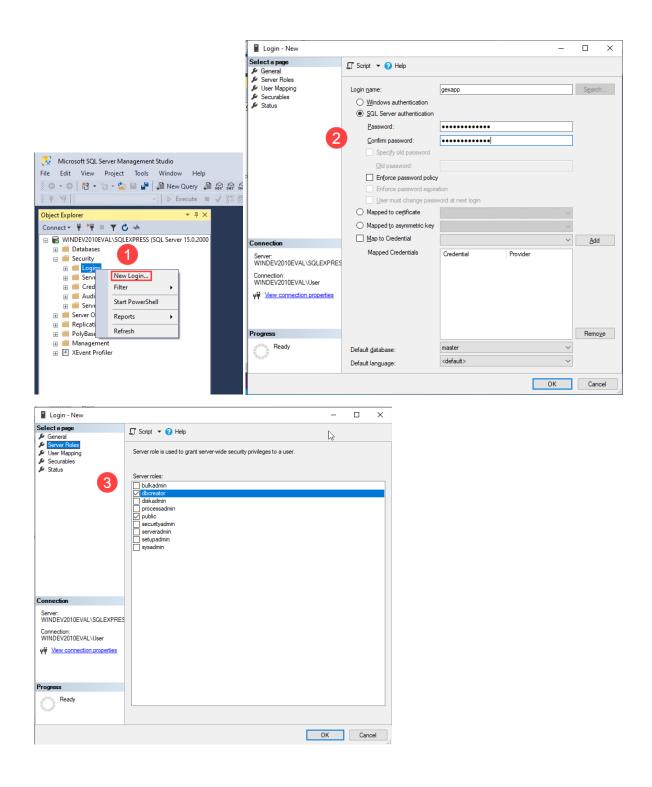
**Step 1:** Expand the "Security" folder for the SQL server on which your DoseControl database will reside. Right-click on "Logins" and select "New Login...".

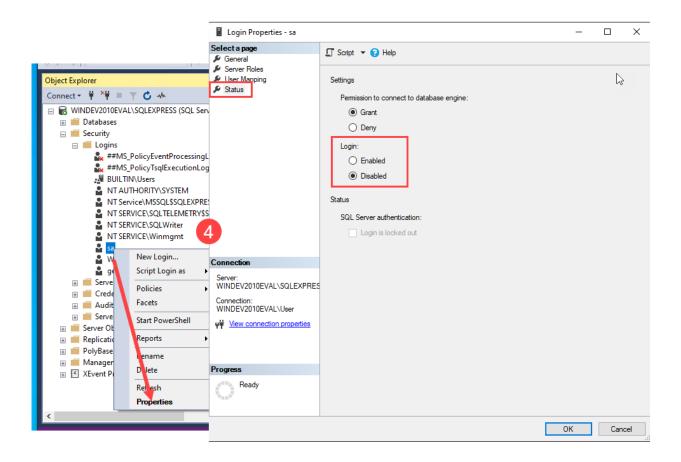
**Step 2:** In the "General" section, enter the Login name **gexapp** (all lower case, no spaces). Select "SQL Server Authentication". Enter a Password and Confirm password. Unless your IT department or database administrator require you to enable a password enforcement policy, uncheck "Enforce password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

**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:





#### Create a Connection String for DoseControl

<u>NOTE</u>: The following steps are written explicitly for Basic License users creating a connection string in SQL Server Express. Premier or Enterprise License users, please consult your IT or technical support team.

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;

- 20 If SSMS is still open, close it and reopen it. If not, you can launch SSMS from the start menu.
- 21 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:

	SQL Server				
Server type:	Database Engine	~			
Server name:	WINDEV2010EVAL\SQLEXPRESS				
Authentication:	Windows Authentication	~			
User name:	WINDEV2010EVAL\User	~			
Password:					
	Remember password				
	Connect Cancel Help	Options >>			

- 22 The Initial Catalog value is the name of the database where the DoseControl data will reside. It will be named GEXApp.
- 23 The connection string's User ID value is the Login <u>gexapp</u> that you created in the preceding step Configure SQL Authentication logins.
- 24 The connection string's **Password** value was also set in the **Configure SQL Authentication logins s**tep. You **must** use the password that you saved in that step.
- 25 The DoseControl connection string uses Multiple Active Results Sets. (For information about SQL Server data operations, please see the Microsoft documentation <u>here</u>.)
- 26 You may copy this and use the following connection string when installing DoseControl, <u>but you must</u> <u>change the Data Source and Password values to your specific values</u>:

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

27 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 Step 11 below under <u>First Time Installation of Software - Installation Instructions</u>).

# 14 APPENDIX 2: Backup & Restore Database Instructions for Microsoft SQL Server Express (Basic License)

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

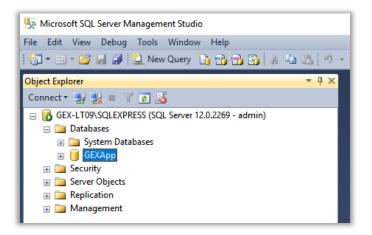
You must perform the following steps using an account that has <u>administrative privileges</u> for the computer that is hosting SQL Server.

#### 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).

😼 Microsoft SQL Server Management Studio				_	
File Edit View Debug Tools Window Help					
🗄 🛅 = 🗁 = 💕 🗐 🥔 🔔 New Query 🎲 📸 🕯	n 🖞 🕺 🕹 🕹 👘 🖓	· (* - 💭 - 🖳 🔤   🔌   🕨 [		- 🛛 🖉 🏺	
Object Explorer	<b>-</b> 4 ×				
Connect 🕶 🛃 🖳 🔲 🍸 💽 😹					
	Connect to Server		×		
	Microsoft SQ	L Server 2014			
	Server type:	Database Engine	~		
	Server name:	GEX-LT09\SQLEXPRESS	~		
	Authentication:	SQL Server Authentication	~		
	Login:	admin	~		
	Password:	•••••			
		Remember password			
	Connect	Cancel Help	Options >>		
Ready					

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".

5 Microsoft SQL Serve	r Management Studio		- 0 ×				
File Edit View Debug Tools Window Help							
: 🛐 • 🗃 • 💕 🚽 🥥 🔔 New Query 🔓 📸 📸 🚳 🖄 👘 • 🔍 • 💭 • 🖓 • 🖓 🖓 🖕							
Object Explorer							
Connect • 🛃 🛃 =							
	XPRESS (SQL Server 12.0.2269 -	in)					
Databases	NFRE35 (50): 56/76/ 12/0/2205 -						
🗉 🚞 System [	Databases						
🗉 间 GEXApo	New Database						
🗉 🚞 Security 🗉 🚞 Server Obj	New Query						
E      Replication	Script Database as						
🗉 🚞 Managem	· · ·						
	Tasks 🕨	Detach					
	Policies +	Take Offline					
	Facets	Bring Online					
	Start PowerShell	Shrink					
	Reports +	Back Up					
	Rename	Restore					
	Delete	Generate Scripts					
	Refresh	Extract Data-tier Application					
	Properties	Deploy Database to a Windows Azure VM					
		Export Data-tier Application					
		Register as Data-tier Application					
		Upgrade Data-tier Application					
		Delete Data-tier Application					
Ready		Import Data					

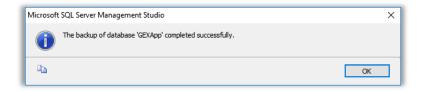
4 The Back Up Database menu will open. The settings should default as shown but check your setting against this example.

Select a page	Script - Ch Help		
Carl General	Script V La Help		
Media Options	Source		
Backup Options	Database:		
		GEXApp	
	Recovery model:	SIMPLE	
	Backup type:	Full	
	Copy-only backup		
	Backup component:		
	Database		
	Files and filegroups:		
	Destination		
	Back up to:	Disk	
	C:\Program Files\Microsoft SQL Ser	ver\MSSQL12.SQLEXPRESS\MSSQL\Backup\GEXApp.bak	Add
Connection			Remov
Server:			
GEX-LT09\SQLEXPRESS			Conten
Connection: admin			
View connection properties			
Progress			
Ready			
West of Contract o			

- 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.

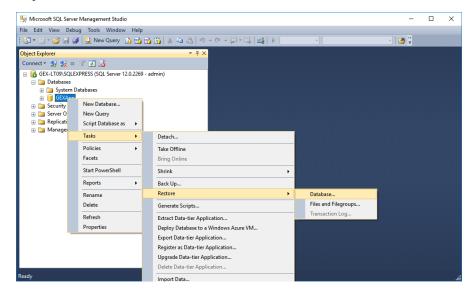
🔋 Back Up Database - GEXAp	р				-		$\times$
Select a page	🔄 Script 🔻 🛐 He	lp					
Media Options Backup Options	Source						
	Database:		GEXApp				$\sim$
	Recovery model:		SIMPLE				
	Backup type:		Full				$\sim$
	Copy-only	backup					
	Backup compone	ent:					
	Database						
	<ul> <li>Files and f</li> </ul>	ilegroups:					
	Destination						
	Back up to:	Select Backup	Destination	×		_	
		Select the file or ba	ackup device for the backup destination. You can create		- (		
	C:\Program Files\M	backup devices for	r frequently used files.			Add	~
Connection		Destinations on dis	*			Remov	
Server:		File name:	(				_
GEX-LT09\SQLEXPRESS			Server\MSSQL12.SQLEXPRESS\MSSQL\Backup\			Conten	ls
admin		O Backup de	vice:				
View connection properties							
Progress			OK Cancel				
Ready							
To a star				-			
				5		ノ	-
					OK	Canc	я .

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.



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

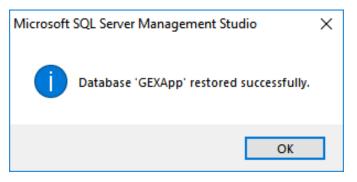
- 1 To restore a database from a \*.bak file, login and navigate to the database instance in SSMS.
- 2 Right-click on the instance name and select "Tasks -> Restore -> Database...".



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.

Ready								
- <i>,</i>								
Select a page General Files	Script 👻 🚺 Help							
Poptions	Source Database: Device:	GEXApp	)					~
	Database: Destination							~
	Database:	GEXApp						~
	Restore to:	The last	backup taker	n (Tuesd	ay, August 28, 2018 5:43:54	4 A	Timeli	ne
	Restore plan Backup sets to restore:							
	Restore Name	atabase Bac	Component Database	Type Full	Server GEX-LT09\SQLEXPRESS	Database GEXApp	Position 1	First L 8400
Connection								
GEX-LT09\SQLEXPRESS [admin] View connection properties								
Progress			_					
Ready	<					Verif	y Backup N	> Nedia

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



# 15 APPENDIX 3: PDF Report Data Fields

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. If you require different data fields, layout, logos, etc. contact GEX. GEX can create a custom PDF template for you using any dosimeter measurement data and user input fields that you wish and designed in a layout that meets your needs.

### Exporter Type: GEX Default PDF

**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 Ve	rt ID: 2pk defa rsion: 1 ch ID: DA	ult test	Date and	ed By: Admini Time: Not Pro ent ID: Mock Spectro	
DSM Thick Position	(ness: 0.0174) Tote No.	Abs 1	Abs 2	Avg. Abs	Dose (kGy)
ref 1 ref 1	33 35	0.507 0.507 0.507	0.507 0.507 0.507	0.507 0.507 0.507	31.2 31.2 31.2 31.2

Example of Default PDF report

# Exporter Type: Standard 1 Pack PDF

**Description:** 1 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)	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)		

		ry Report	
Report ID: 0 eport Version: 1 DSM Batch ID: E SM Thickness: 0	123Std1pk 33 Film - DA	Prepared By: M Date and Time: N Instrument ID: La	ot Processed
Position 10 11 12 13	<b>Tote No.</b> 44 44 44 44	<b>Abs 1</b> 0.473 0.478 0.641 0.640	Dose (kGy) 26.0 26.3 38.1 38.1

# Exporter Type: Ref Dose 1 Pack PDF

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

**<u>Report header setup</u>**: Required. Go to **Setup > Report Headers** and set up the four Fields list in **bold**. Must enter these fields exactly, case sensitive.

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

Report Ver	rt ID: 1234 Re rsion: 1 th ID: B3 Film		Prepa Date and	30 red By: Admin   Time: Not Pr ent ID: Lab G3	ocessed	
Position	Carrie			hickness 0.0185	Dose (kGy	
1 2	1		363 590	0.0185	18.8	
3	1		174	0.0185	26.1 27.4	
4	1		193	0.0185		
5	1		540	0.0185	38.1	
6	1	0.4	179	0.0185 26.4	26.4 O	
	Reference Dose (kGy)	Carrier	Correlation Factor	Calculated Dose (kGy)	Require Dose (kG	
Min Dose (kGy)	18.8	1	0.02	0.4	10.0	
Max Dose (kGy)	38.1	1	0.02	0.8	70.0	

Example of Reference Dose 1 Pack PDF Report

# Exporter Type: Ref Dose 2 Pack PDF

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

<u>Report header setup</u>: Required. Go to Setup > Report Headers and set up the four Fields list in **bold**. Must enter these fields exactly, case sensitive.

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

Dosimetry ReportDSM Calibration ID: P1B3-G30-2Report ID: Report Version: 1 DSM Batch ID: B3 Film - DA Catalog Number: 543Prepared By: Date and Time: Not Processed Instrument ID: Lab G30PositionCarrierABS 1ABS 2Avg. 0.591Thickness 0.518Dose (kGy) 34.212440.5910.5910.5910.018534.4
Report ID:RD2PPrepared By:AdministratorReport Version:1Date and Time:Not ProcessedDSM Batch ID:B3 Film - DAInstrument ID:Lab G30Catalog Number:5435431000000000000000000000000000000000000
Report Version:1Date and Time:Not ProcessedDSM Batch ID:B3 Film - DAInstrument ID:Lab G30Catalog Number:543Position Carrier ABS 1ABS 2Avg.ThicknessDose (kGy)12440.5910.5910.5910.018534.40.5890.5880.5890.018534.2
(kGy) 12 44 0.591 0.591 0.591 0.0185 34.4 0.589 0.588 0.589 0.0185 34.2
12 44 0.591 0.591 0.591 0.0185 34.4 0.589 0.588 0.589 0.0185 34.2
Reference         Carrier         Correlation         Calculated         Required           Dose (kGy)         Factor         Dose (kGy)         Dose (kGy)
Min Dose 34.2 1.00 34.2 10.0 (kGy)
Max Dose 34.4 44 1.50 51.6 50.0 (kGy)

# 16 APPENDIX 4: Excel Report Data Fields

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

A	В	С	D	E	F	G	н	1.1	J.	К	L	м	N	0	P	Q
							Last Edited		Export Time							
Report ID	Rpt Version	Pathway	DSM Batch	Status	Last Edited By	Date	Time UTC	Export Date	UTC							
		1			1											
		1														
					1											
	Maximum	Min Dose	Max Dose		1											
Minimum Dose	Dose	Spec	Spec	Meets Spec?												
Comments																
												Corrected				
DosimeterID	Position	ToteID	Ao	Ai - 1	Ai - 2	Ai - 3	Ai - 4	Thickness	Response	Dose	Corr Fact.	Dose	CalibrationID	Inst ID	Inst SN	WL (nm)
	Export Bea	m Energy I	Beam Scan Unifo	ormity r Uni	formity Dos	eMan(30)	loseMan(85)	DoseMap(135	) Et (+							
DC	<u>.</u>					completes)   a	a second (sec)	e erennah/.ee	,							

Data always exported from DoseControl.

Report Header fields. These fields depend on the Admin setup of report headers fields in DoseControl.

### Data exported from DoseControl software

This table describes the data exported from DoseControl software:

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
Minimum Dose	Minimum dose of the dosimeter batch calibration (from Calibration configuration)
Maximum Dose	Maximum dose of the dosimeter batch calibration (from Calibration configuration)
Min Dose Spec	Minimum dose for the process
Max Dose Spec	Maximum dose for the process
Meets Spec?	Does the measured dose of the dosimeters in report meet the spec? Y/N
Comments	Report comments
Dosimeter ID	Dosimeter ID number, serial number
Position:	Dosimeter position (reference, description)
ToteID:	Tote ID/Carrier number
<b>A</b> 0	Background absorbance measurement (usually 0)
Ai-1	Absorbance measurement of dosimeter 1
Ai-2	Absorbance measurement of dosimeter 2
Ai-3	Absorbance measurement of dosimeter 3
Ai-4	Absorbance measurement of dosimeter 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. Cdose=correction factor x measured dose
Calibration ID:	Calibration ID (from Calibration configuration, laboratory provided cal ID)
Instrument ID:	Spectrophotometer name
Inst SN	Spectrophotometer serial number (from Calibration configuration)
Wavelength:	Spectrophotometer set wavelength for measurement (from Calibration configuration)

#### **Additional Report Header Data Fields**

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

А	В	С	D			G Last Edited	Last Edited		J Export Time	K					
Report ID	Rpt Version	Pathway	DSM Batch	Status	Last Edited By		Time UTC	Export Date	UTC	•					
RD1PK with fie		ebeam1	DA	Incomplete	Administrator		20:08	05-Jun-2020	20:09						
		coconia	DA .	incomplete	, and the second second	00 5011 2020	20100	00 7411 2020	20105	-					
Batch Number	r G-000034														
Product Quant															
Product Min D															
Product Max D															
Ref to Min Rat		_		_											
Ref to Max Rat	tid 1.01	_		-											
				-			-								
	Maximum	Min Dose	Max Dose												
Minimum Dos		Spec	Spec	Meets Spec?											
31.20	31.20	5.00	35.00	True											
Comments	N/A														
										_				_	
Devise to the	De altria	7-1-10						Thistophysics				Corrected	Colline March		
DosimeterID cc44	Position ref top	ToteID 23	0 Ao	Ai - 1 0.507	Ai - 2 N/A	Ai - 3 N/A	Ai - 4 N/A	Thickness 0.0174	Response 29.138	Dose 31.2	Corr Fact.	Dose 31.2	Calibration		Inst SN Dectrop 09765
cc45	reflow	23	0	0.507	N/A N/A	N/A N/A	N/A	0.0174	29.138	31.2	1	31.2			pectrop 09765
cc46	ref	44	0	507	N/A	N/A	N/A	0.0174	29.138	31.2	1	31.2			pectrop 09765
		45	0	0. 7	N/A	N/A	N/A	0.0174	29.138	31.2	1	31.2			pectrop 09765
cc47	ref	EDIT F	IELDSET ype: Ref	Cose 1 Pack PDI	lefault fi										
cc47	ref	EDIT F	IELDSET ype: Ref mme: RD11		lefault fi										
cc47	reţ	EDIT F Exporter T Na	IELDSET ype: Ref me: RD11 aild: RD11	Dose 1 Pack PDI PK default fields	lefault fie		SP	PECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VA	LIDATION	DELETE	
cc47	reţ	EDIT F Exporter T Na Externa	IELDSET ype: Ref mme: RD11 ai ld: RD11 ME	Dose 1 Pack PDI PK default fields PK default fields	lefault fie	elds -		ECIAL VALUE	SEQUENCE	REQUIRED	IS EDITABLE	ADDITIONAL VA		DELETE	
cc47		EDIT F Exporter T Na Externa FIELD N/ Batch N	IELDSET ype: Ref mme: RD11 ai ld: RD11 ME	Dose 1 Pack PDI PK default fields PK default fields FIELD TYPE E	lefault fie	elds -								DELETE	
cc47	ref	EDIT F Exporter T Na Externa FIELD NA Batch N	IELDSET ype: Ref RD11 ume: RD11 ME umber	Dose 1 Pack PDI PK defauit fields PK defauit fields FIELD TYPE E	lefault fie	elds	ity Waste		4		<b>~</b>			DELETE	
cc47		EDIT F Exporter T Na Externa FIELD NJ Batch N Product	IELDSET ype: Ref ime: RD11 iME umber Quantity Waste	Dose 1 Pack PDI PK default fields PK default fields FIELD TYPE E Text • Whol •	lefault fie	elds LABEL Batch Number Product Quant	ity Waste	× ×	5	<ul><li>✓</li></ul>	<b>V</b>			DELETE	
cc47		EDIT F Exporter T Na Externa FIELD NJ Batch N Product	IELDSET ype: Ref RD11 al ld: RD11 al ld: R	Dose 1 Pack PDD PK default fields PK default fields FIELD TYPE E Text + Whol + Dedr +	lefault fie	elds LABEL Batch Number Product Quant Product Min Du	ity Waste	▼ ▼ Min Dose ▼	5	V V V	V V			DELETE	

# 17 APPENDIX 5: Validation & Compliance, Software History & Versions

DoseControl software was developed for use on laptop and desktop PCs running Microsoft Windows using the .NET platform. The primary coding language is C#. This software is copyright protected under the laws of the United States of America. DoseControl<sup>®</sup> is a registered trademark of GEX Corporation.

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



Iterative Version – a unique number that identifies a specific software build. This increasing number is automatically generated by the software that manages the DoseControl application code. Note: This number was 4 digits and with this release it has expanded to 5 digits.

Year/Month of Release - determined by the date in which the build is assembled by the software development team.

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

Major Version – manually issued by GEX. Goes up by one digit when the is a significant change in the overall architecture, user interface, or scope of the software

#### Validation and Compliance

GEX has validated the DoseControl system and the associated instructions for installation and operation. The documentation is available for audit at our offices in Palm City, FL U.S.A. or electronic copies may be purchased.

- Compliant with ISO 11137, ISO/ASTM 51275, 51261, 51649, 52628 consensus standards.
- Compliant with electronic records requirements of US FDA 21 CFR, Part 11 with the exclusion of electronic signatures.
- 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.

#### NOTE

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.

# 18 APPENDIX 6: Licensing

This 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.

#### **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
LingKit	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
moreling	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

# 19 APPENDIX 7: Troubleshooting

There is no calibration configured for the selected reader, pathway and dosimeter type. Please select a different reader. No Active or Valid Calibration Error Error There is no active or valid calibration on this workstation for the Reader, Batch and Pathway and Pathway, and Pathway and Path	Resolution: Add a configuration or activate a calibration. Cause: The dosimeter batch calibration is overdue. Resolution: Re-calibrate the dosimeter batch and activate a valid calibration.
Unable to Proceed.	Cause: The spectrophotometer is overdue for a complete performance verification
The selected reader is overdue for calibration. Unable to proceed.	Resolution: Perform the complete performance verification, and go to Setup>Readers>change the 'Next Calibration Date' to a future date for the next performance verification due date.
Delete User Error Error Couldn't delete the User. This user has an audit trail and therefore deletion is not allowed.	Cause: If the System Administrator tries to delete a User from the MSSQL User Management module (and that user already has performed an action in the system), then that user cannot be deleted.
Duplicate Dosimeter Error	Cause: If a user tries to scan or enter a Dosimeter ID that already exists in the system.
Taking a reading failed. Dosimeter SWOQ-11.1M1 is already used (report: SW-OQ-11.1)	Resolution: Enter a unique Dosimeter ID. System does not allow duplicate IDs.
Login Failure Error Login failed.	Cause: Incorrect username and/or password.

	Course Indiantes a physical disconnect
Open Connection( ) or Port Driver Error Error Initializing the reader failed. Ensure that the reader is connected and the correct COM port is configured. Port driver error in OpenConnection() Source: System Message: The port 'COM17' does not exist. OK	<ul> <li>Cause: Indicates a physical disconnect between the reader and the software.</li> <li>Check that the spectrophotometer is connected to the PC (G30 home screen &gt; Settings &gt; Connect to PC</li> <li>Check to see if the correct COM port and baud rate are configured in Reader setup.</li> <li>Check to see if the reader USB cable is disconnected or plugged into an incorrect port.</li> </ul>
Decksorterer	Course Indiantes a disconnect between
Reader not responding Error	Cause: Indicates a disconnect between the reader and the software. • Ensure the spectrophotometer USB cable is connected to the PC.
Reader is not responding: The operation has timed out.	<ul> <li>Check that the spectrophotometer is connected to the PC (G30 home screen &gt; Settings &gt; Connect to PC)</li> <li>For G30 and Evo users: Ensure the Reader baud rate is set to 115200 and the Device Manager properties for the instrument is also 115200.</li> <li>For G20 users: Ensure the Reader baud rate is set to 9600 and the Device Manager properties is also 9600.</li> </ul>
Error for MS Excel report	Cause: An error message like this
Microsoft Excel X We found a problem with some content in 169 def-v1.atsc. Do you want us to try to recover as much as we can? If you trust the source of this workbook, click Yes. Ves No	screenshot indicates a problem with the Excel template that is uploaded to DoseControl. Resolution: Open the Excel template file and check each tab for errors in formulas.
Error message: 'You don't have permission to save in this location'	Cause: Windows permission issue.
	Resolution: Contact your IT administrator to obtain permission. This issue particularly occurs when you try to save Office 2010 or Office 2007 documents in Windows 10, Windows 8 or Windows 7. https://youtu.be/HeARH0JrWNc
Error printing report file	Cause: The report file has been moved
Error printing report file Error Printing failed. The system cannot find the file specified	from the configured storage location or is blocked due to a change to the user's network.
ок	Resolution: Contact your IT administrator.
Evolution Slit Wheel Error Error message: 'IReader Method: SetSpectralBandwidth_SLIT1 N/A Message: Motor not homed, position undefined (reader command: SLIT1, error type: MotorUnhomed)	Error message can be for SLIT1 or SLIT2. Cause: The Evolution reader needs to be repaired.
Code:2>SLIT-1 -6'	Resolution: Contact GEX Customer Support, or Thermo if you have purchased the reader directly from Thermo.

# 20 APPENDIX 8: Customer Support

#### IMPORTANT

To help GEX Support provide the best service, please make a copy (screen capture) of any error messages and be able describe the details of your issue.

#### GEX Customer Support by Web (fastest response)

General Support information https://www.gexcorp.com/support.html

Request assistance & submit a support ticket for DoseControl software https://gexcorp.atlassian.net/servicedesk/customer/portal/2

GEX document library https://library.gexcorp.com/

#### **GEX Customer Support by Phone**

Office hours: Monday - Friday, 8am to 5pm GMT-7 November through March, GMT-8 April through October.

Email: cs@gexcorp.com

Phone: +1 303-400-9640

#### GEX Customer Support by Email

Email: cs@gexcorp.com

#### Formal correspondence

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