

Implementation Guide for the DoseControl® Dosimetry System



GEX Doc# 100-267

1.0 SCOPE

The GEX DoseControl® System is intended for use as a single dosimetry system solution, specifically developed to satisfy the generic dosimetry needs of radiation sterilization application users worldwide. The GEX DoseControl® Dosimetry System is an electro-mechanical dose measurement system (see full system description below).

The compilation and execution of the *installation qualification (IQ)*, *operational qualification (OQ)*, and *performance/process qualification (PQ)* provides appropriate verification and test evidence to support the DoseControl® Dosimetry System validation prior to first use.

GEX DoseControl® Dosimetry System Description:

The DoseControl® Dosimetry System is a tool used for generating dosimetry reports for any commercial/industrial radiation processing application, and in particular for radiation sterilization applications that use routine dosimetry. The system controls the setup of the dosimetry system calibrations, irradiation pathways, dosimeter batches, spectrophotometers, dosimetry report header information, and fully integrates the spectrophotometers' to control the measurement process. The system software is designed to be 21 CFR part 11 compliant. Therefore, electronic records of dosimetry reports are maintained, and contain a complete audit trail.

Spectrophotometers are the core of the system hardware, which are provided by Thermo Scientific. The Evolution 220 Spectrophotometer (Evo22) is the primary unit that provides complete compliance with all of the stated requirements in 21 CFR part 11. The Genesys 30 (G30) and Genesys 20 (G20) Spectrophotometers are alternatives for B3 dosimetry processes only, and do not provide the internal barcode scanning feature for B3 DoseStix, as with the Evo220. The Genesys 20 also lacks the ability to return its serial number by command, and as such fails requirements related to traceability of the instrument used to perform measurements.

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

Internal and external barcode scanners are options for any spectrophotometer as an automatic way to enter dosimeter ID's into the software. The Evo220 can be fitted with an internal barcode scanner to provide absolute verification of dosimeter ID's during the measurement process.

An integrated laser micrometer is an option for the measurement of PMMA dosimeters. It automates the measurement so that it is simultaneous with the dosimeter absorbance measurement, and ensures traceability of the measurement to a given dosimeter so that one cannot accidentally mix the absorbance and thickness measurements. Custom Gauge Blocks are manufactured and certified for the calibration verification process of the laser micrometer.

The Evolution 220 performance verification accessories (called the CVC Carousel and the Mercury Lamp) are used to provide verification of instrument performance as well as calibration verification. The Spectronic Standards Set is the performance verification accessory used for the Genesys 20 and 30 Spectrophotometers.

All hardware has been assigned a unique GEX part number; they are stock items and the parts are managed and controlled by GEX QMS procedures.

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2.0 PURPOSE

This document provides GEX recommended guidance for the implementation of a site-specific DoseControl® Dosimetry System by the user. The information is intended to facilitate the implementation of DoseControl® Dosimetry Systems.

3.0 PROCEDURE

User Implementation:

DoseControl® Dosimetry Systems only use GEX catalogue components that have been validated using generally accepted “IQ/OQ/PQ” validation guidance. Users are provided with a summary statement of the *GEX DoseControl® validation* to incorporate with their independent, internal validation requirements.

GEX recommends that a DoseControl® Dosimetry System user develops their own site-specific validation plan based on the verification of their specific user requirements specification (URS) document, and using the GEX recommendations described below along with the related test cases designed to appropriately challenge and verify their site-specific URS’s.

User Implementation Plan Outline:

The IQ/OQ/PQ protocols incorporate GEX recommended instruction along with the input of a series of user site-specific test cases, provided as objective evidence that the DoseControl® System (as installed and tested at a user site) satisfies *user requirements specification* (URS) criteria. The DoseControl® User Validation Outline described below embraces generally accepted IQ/OQ/PQ validation guidance, and adopts the following definitions of these IQ, OQ and PQ acronyms:

- IQ is an acronym for “Installation Qualification”; defined as establishing confidence that process equipment and ancillary systems are compliant with GEX product specifications, and that GEX manufacturer installation and usage recommendations are suitably considered and incorporated into the user’s site-specific SOPs.
- OQ is an acronym for “Operational Qualification”; defined as establishing objective evidence that the DoseControl® hardware and software integration, when installed and used in accordance with the established SOP’s, results in a dose measurement system that demonstrates measurement system performance within predicted GEX R&R determined limits.
- PQ is an acronym for “Performance Qualification”; defined as performance or process qualification, and demonstrates that the DoseControl® hardware components, software, and complete dosimetry system functionality satisfies the user’s site-specific URS criteria.

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3.1 User Verification and Validation Outline

Below are the user verification and validation activities required to ensure correct implementation at the user's NOTE: Repeat testing as appropriate for each dosimetry workstation or for any combination of hardware/software components.

3.1.1 User Validation Plan IQ activities should involve:

Appropriate receiving inspection and acceptance documentation, assembly installation and testing records of the DoseControl® Hardware (Genesys 20's or Genesys 30's; Evolution 220's; MX2 Laser Micrometer Assembly, etc.) per the appropriate GEX provided documentation and instructions provided with the hardware and software. NOTE: Allow 4 to 6 hours to complete these activities:

- a. The facility's "System Administrator" shall refer to and follow the DoseControl® Dosimetry User Manual instructions (GEX Doc #100-266).

NOTE: Allow 4-8 hours to execute all of the following Section 1.0 activities.

- b. Install the DoseControl® software onto the appropriate computer system(s) per section 1.2 of the DC User Manual.
- c. Setup and configure the DoseControl® software settings per site-specific rules and requirements.
- d. Configure IT determined DoseControl® software database storage locations (see section 1.6 of the DC User Manual).
- e. Select and configure "User Management" control settings per section 1.7 of the DC User Manual.
- f. Setup and configure "Dosimetry" settings per section 2.0 of the DC User Manual.
- g. In section 2.0 of the DC User Manual, devote sufficient time for a thorough review of the detailed descriptions and subsections.

NOTE: Compile the appropriate details necessary to execute the *setup* and *configuration* actions before initiating these setup and configuration activities specified in section 2.0 of the DC User Manual.

For example:

- Determine the dosimetry rules and practices to be applied within the DoseControl® Software.
- Define an initial list of authorized users with their assigned access level permissions.
- Determine the header information for each dosimetry report type (e.g. "Production", "Dose Mapping", "R&R", "Test", etc.)
- Prepare dosimeter batch information with dosimeter batch specific calibration curve coefficients with authorized start and end dates.
- Determine the dosimeter re-read practice option(s) to be implemented.

3.1.2 User Validation Plan OQ activities should involve:

3.1.2.1 User SOP's that are developed to be used with DoseControl® software and incorporates information from the DoseControl® Dosimetry User Manual (GEX Doc #100-266). User to evaluate SOP effectiveness and release final SOP's.

3.1.2.2 Dosimetry system characterization R&R testing: Pull representative dosimeter samples irradiated to low, middle, and high doses. Use a single dosimeter from each of the three dose ranges and perform repeat measurements in the instrument to be validated to assess the intrinsic dosimetry system's variability over the system's usable dose range.

NOTE: The purpose of performing repeatability testing of any particular dosimeter is to assess a normally expected thickness or intrinsic variability value for a given set of components installed on a particular dosimetry workstation. Using low, middle, and high dosed dosimeters provides an assessment over the normally expected dose range. GEX hardware components and sub-assemblies are considered interchangeable and expected to produce similar

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measurement results within normally expected variability limits. Therefore, assembly and installation of different component pairings can be expected to yield normally expected variability R&R test results. Variability can be determined during IQ by testing different component pairings and repeating this variability R&R test to determine a reproducibility value for all possible component pairings.

- 3.1.2.3 If the DoseControl® Dosimetry System is a replacement for an existing dosimetry system it may be appropriate to a run side-by-side comparison test to demonstrate equivalency.

3.1.3 User Validation Plan PQ activities should involve:

- 3.1.3.1 Follow the DoseControl® User Manual, section 3.0 instructions to execute a series of test cases designed to challenge your site-specific DoseControl® Dosimetry System, and provides output evidence that the dosimetry system(s) as installed fully satisfies all URS's.
- 3.1.3.2 Perform dosimeter batch calibration verification testing if the dosimetry system characterization R&R testing performed in OQ does not show equivalency (e.g. perform a dosimeter batch calibration or calibration audit).
- 3.1.3.3 Train the initial users to the DoseControl® Dosimetry System.
- 3.1.3.4 Evaluate competency of individual users by repeating appropriate test cases and evaluating the output results.
- 3.1.3.5 Establish a DoseControl® bug reporting practice per section 4.0 of the DC User Manual. Report and log all identified bugs with appropriate screen shots that document any error messages that are not able to be overcome with a simple program exit and restart action.

3.2 Authorize and Implement DoseControl® System for routine use:

- 3.2.1 Create an implementation plan with related departments and consider the following:
- The relationship to other systems and/or known or potential interruptions in operations.
 - The need for increased quality and operational oversight (required for any new system)
 - Include any additional or required continual verification activities in the plan.

4.0 EXAMPLES

4.1 IQ Protocol

- 4.1.1 GEX DoseControl® Dosimetry Systems are comprised of custom measurement hardware components integrated with DoseControl™ software on local area-networked computers to create, manage, and store dosimetry report records in an electronic database with the potential capability of pulling and pushing data from other user enterprise database software programs.
- 4.1.2 The IQ protocol is written in support of the Evolution 220 based DoseControl® Dosimetry System Validation Plan. The scope, strategy, acceptance criteria, and protocol prerequisites for this IQ protocol are described below.
- 4.1.3 The IQ processes described below involve performing separate test cases of hardware and software IQ activities, followed by execution of integrated system IQ actions which provide evidence that the DoseControl® Dosimetry System (as installed) satisfies the purchase specifications and meets all specified URS performance requirements.

NOTE: An IQ/OQ package is available from Thermo Scientific for those who do not want to draft their own. The package is available as *GEX Part# P4380*. In addition, on-site IQ/OQ service is available from Thermo Scientific in some service areas for those who prefer that the manufacturer installs and verifies instrument performance. Contact GEX customer service for more information if this is of interest.

4.2 IQ Strategy and Acceptance Criteria

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- 4.2.1 The IQ will demonstrate that DoseControl® dosimetry software and hardware integration are appropriately challenged, and are installed and satisfactorily functioning in accordance with GEX DoseControl® requirement specifications.
- 4.2.2 The prerequisites for this IQ protocol are simply the successful receipt and acceptance of the DoseControl® hardware and software in accordance with the part numbers specified on the originating purchase order(s) along with formal authorization of this protocol.

4.3 Hardware IQ

- 4.3.1 Receiving inspection activities verify that the hardware, as supplied, conforms to the purchase and requirement specifications.
- 4.3.2 Verify installation of all hardware in accordance with manufacturer supplied instructions and guidance documentation:
 - 4.3.2.1 Install the most current version of the Thermo Scientific Insight Software on each Evolution 220 dosimetry workstation computer setup. Thermo Scientific reference documents are located at <http://www.thermoscientific.com>.
 - 4.3.2.2 If appropriate, schedule and/or complete performance IQ/OQ from Thermo Scientific for each of the basic Evolution 220 Spectrophotometers.
 - 4.3.2.3 Alternatively, verify installation of the Evolution 220 instruments by performing the GEX recommended practice provided in *GEX Doc #100-156, P4300 Evolution 220 Spectrophotometer*.
 - 4.3.2.4 Conduct performance (calibration) verification using the accessories that have been supplied; CVC Carousel (GEX P/N: P4320), Spectronic Standards (GEX P/N: P4220), or Mercury Lamp (GEX P/N: P4310).
- 4.3.3 Assemble and install all of the GEX Evolution 220 DoseControl® Dosimeter Holder System components. Verify form, fit, and functionality of each type.
 - 4.3.3.1 Install the “hot-swappable” baseplate assembly (GEX P/N: P4330) per *GEX Doc #100-159, Evolution 220 Dosimeter Holder System*.
 - 4.3.3.2 Verify that all dosimeter holders (GEX P/N’s: P4332, P4334, P4338, P4345) supplied with the DoseControl® Dosimetry Systems can be placed and removed from the “hot-swappable” baseplate (GEX P/N: P4330). Reference *GEX Doc #100-159, Evolution 220 Dosimeter Holder System*.
- 4.3.4 If applicable, refer to *GEX Doc #100-164, P4350 & P4355 MX2 Metralight Laser Micrometer and Gauge Blocks* for instructions on connecting the laser micrometers that were supplied and already mounted on the Evo220 Hot-Swappable Baseplate (GEX P/N: P4330).
 - 4.3.4.1 Follow the detailed instructions provided in the GEX Doc#100-164 to set-up, install, and complete IQ for these hardware components.
- 4.3.5 Appropriately identify individual hardware components and assemblies as appropriate in accord with user-defined practices.
- 4.3.6 Determine and implement appropriate preventive maintenance and calibration activities for each hardware component and sub-system assembly according to user defined practices.

4.4 Software IQ

- 4.4.1 Verify and document the DoseControl® software version.
- 4.4.2 Follow *GEX Doc #110-266, DoseControl® Software User Guide* to install the software and prepare the appropriate identification records of the software installation on the appropriate dosimetry workstation computers.
- 4.4.3 Follow *GEX Doc #110-266, DoseControl® Software User Guide* to install the software and prepare appropriate identification records of the software installation and its pathway location on the appropriate network server.
- 4.4.4 Complete the ‘installation and IT configuration’ actions per section 1.0 of GEX Doc #100-266. Contact GEX for technical support as appropriate.

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4.5 System PQ

- 4.5.1 Verify that the 'COM' settings for the Evolution 220 Spectrophotometer are selected in the Windows Device Manager. Setup according to *GEX Doc #110-266, DoseControl® Software User Guide*.
- 4.5.2 If applicable, verify that the 'COM' settings for the Metralight MX-2 Laser Micrometer are selected in the Windows Device Manager. Setup according to *GEX Doc #110-266, DoseControl® Software User Guide*
- 4.5.3 If applicable, verify that any barcode scanner will register scans within the 'Search Bar' on the Home page of the DoseControl® software.

4.6 Review and Approve IQ

- 4.6.1 Assemble, review, and approve the OQ documentation before commencing the PQ protocol activities; this completes the manufacturer recommended IQ actions.

4.7 Example OQ Protocol

- 4.7.1 Prerequisites
 - 4.7.1.1 IQ is complete.
 - 4.7.1.2 SOP's have been developed.
 - 4.7.1.3 Appropriate test cases used to challenge and demonstrate that the DoseControl® System satisfies the FRS (factory requirement specifications) have been developed and approved.
- 4.7.2 OQ activities consist of:
 - 4.7.2.1 Execution of the test cases.
 - 4.7.2.2 Evaluation of test case results.
- 4.7.3 Hardware OQ
 - 4.7.3.1 Refer to *GEX Doc #100-156, P4300 Evolution 220 Spectrophotometer* for a detailed OQ test case.
 - 4.7.3.2 Refer to *GEX Doc #100-164, P4350 & P4355 MX2 Metralight Laser Micrometer and Gauge Blocks* for a detailed OQ test case.
 - 4.7.3.3 Corrective actions to resolve any test case deviations which may include:
 - Changes to the system hardware or software
 - SOP modifications
 - Modification of the FRS (factory requirement specifications)
- 4.7.4 Software OQ
 - 4.7.4.1 Many of the DoseControl® software's main functions require the hardware to execute properly and as such a separate software OQ is not performed. Instead all FRS are validated in System OQ to satisfy this portion of the validation. This simply means that the System OQ is comprehensive to include all 'software-only' functions.
- 4.7.5 System OQ
 - 4.7.5.1 GEX provides a manufacturer's Certificate of Validation to satisfy the user's need for validation of a "black box" system.

Note: The user cannot validate GEX FRS because they are proprietary and must accept the vendor's System OQ validation package by accepting the provided certificate, auditing the vendor's validation package, or both.

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4.8 Review and Approve OQ

4.8.1 Assemble, review, approve and authorize the OQ documentation before commencing the PQ protocol activities.

4.8.2 This completes the manufacturer recommended OQ actions.

4.9 Example PQ Protocol

4.9.1 Prerequisites

4.9.1.1 OQ is complete.

4.9.1.2 SOPs have been revised with all changes resulting from changes to FRS and deviations in OQ.

4.9.2 Hardware PQ

4.9.2.1 The performance of the hardware is validated in the system PQ that satisfies this requirement.

4.9.3 Software PQ

4.9.3.1 The performance of the software is validated in the system PQ that satisfies this requirement.

4.9.4 Perform appropriate dosimeter batch calibrations or calibration audits of all DoseControl® systems in accord with ISO/ASTM 51261 Calibration guidance.

4.9.4.1 Establish appropriate dosimetry system batch calibration verification and re-calibration intervals.

4.9.5 System PQ

4.9.5.1 Execution of the PQ Test Cases

4.9.5.2 Evaluation of Test Case results.

4.9.5.2.1 Corrective actions to resolve test case deviations which may include:

4.9.5.2.1.1 Changes to the system hardware or software;

4.9.5.2.1.2 SOP modifications or;

4.9.5.2.1.3 Modification of the URS.

4.9.6 Train and certify DoseControl® user personnel.

4.9.7 This completes the PQ actions.

4.9.7.1 Assemble and review PQ documentation.

4.9.7.2 Authorize the DoseControl® systems for use.

References

[GEX Documents:](#)

- 100-156, Product Specifications and Usage Information for the Evolution 220 Spectrophotometer
- 100-159, Product Specifications and Usage Information for the Dosimeter Holder System Hardware
- 100-164, Product Specifications and Usage Information MX2 Metralight Laser Micrometer and Gauge Blocks
- 200-166, DoseControl® User Manual

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DATE	CHANGE DESCRIPTION	REVISION
11/15/16	Initial release.	A
03/27/17	Revised to reflect the new registered trademark status instead of TM per ECO# 70278.	B

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