DoseControl® Dosimetry System

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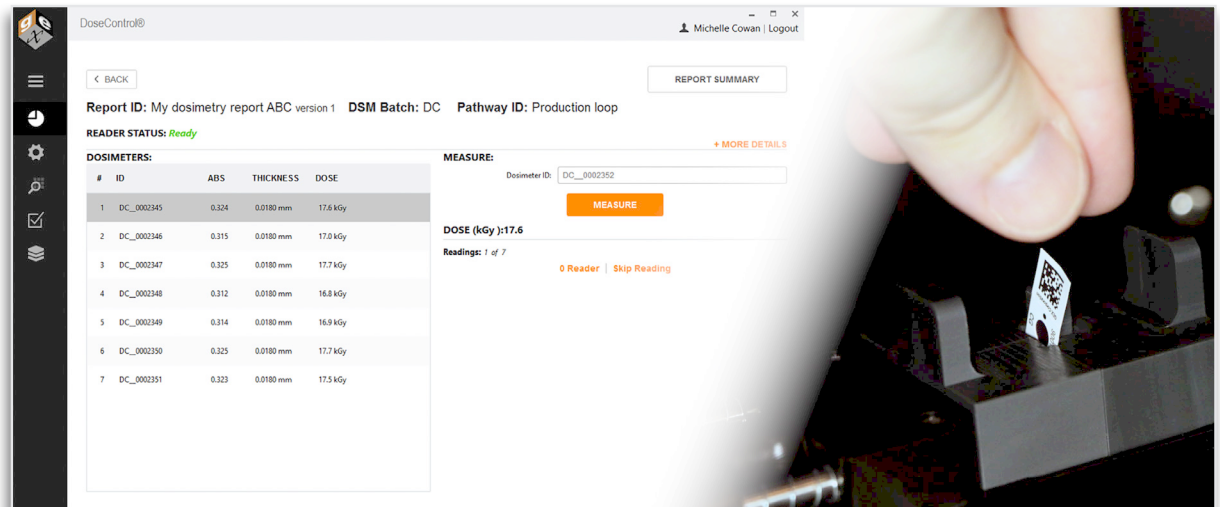
Built for the industrial radiation process industry, DoseControl® is a powerful and flexible dosimetry system for optical dosimeters.

DoseControl makes dosimetry simple.

- ☑ Capture dosimeter measurment data.
- ☑ Automatically calculate dose traceable to a national metrology institute.
- ☑ Create dosimetry reports.
- ☑ Maintain permanent dosimetry records.

DoseControl helps you easily comply with industry standards & requirements for dosimetry

Designed to fulfill ISO 11137-1 and all relevant ISO/ASTM published standards for the radiation sterilization of medical devices for an optical dosimetry system.

Meets cGMP, FDA 21 CFR Part 11 and EU Annex 11. Software-controlled workflow, complete audit trail with user and timestamp. No electronic signatures.

Designed to meet data and system security requirements per IEC 62443. Secure software development. Prevents unwanted access and restricts users permissions. Closed system.

DoseControl® System Flexible Options

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Wide Range of Applications & Modalities

DoseControl is the ideal dosimetry system for a majority of industrial radiation processes that use:

- ✔ Gamma
- ✔ X-Ray
- ✔ High Energy Electron Beam (30keV to 25MeV)
- ✔ Low Energy Electron Beam (80keV to 300 keV)

Works with Many Dosimeter Types

DoseControl has specialized dosimeter holders for the following dosimeters to provide consistent dosimeter alignment for each measurement:

- ✔ B3 radiochromic (~300Gy to 150kGy)
- ✔ FWT radiochromic (~300Gy to 150kGy)
- ✔ GAFCHROMIC HD-V2 film (10-1000 Gy)
- ✔ CTA film (10-300 kGy)
- ✔ Harwell PMMA Red Perspex (10-60 kGy) and Amber Perspex (2-25 kGy)

Spectrophotometer Options

Select the follow Thermo Fisher Scientific spectrophotometer models: Thermo Evolution One Plus or Thermo GENESYS 30.

Thermo GENESYS 30

Thermo Evolution One Plus

Basic Setup - 1 Dosimetry Workstation

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

Connected Setup - 1 or more Dosimetry Workstations

- Install DoseControl software on one or many PCs.
- Connect each PC to an on-premise MS SQL Server/application database via network.
- All Workstations share the same data (connected to the same application database).

Integrated Setup - share DoseControl data with other systems

- Install DoseControl software on one or many PCs.
- Integrate and share DoseControl data with other systems such as ERP, MES, QMS, SAP, etc.
- You can push data from another system into DoseControl to include in your dosimetry reports. You can pull dosimetry data out of DoseControl and share with another system.
- No custom integration work. Dedicated import/export tables in the DoseControl application database.

DoseControl® Features & Benefits

Benefits

- Permanent records of dosimeter measurement and ensuring the integrity of data.

- Simple software user interface reduces error

- Controlled workflow - Operators must follow the controlled workflow within the software. Software ensures every measurement follows the same process.

- Software controls the spectrophotometer and settings. Operators cannot view or change the software configuration.
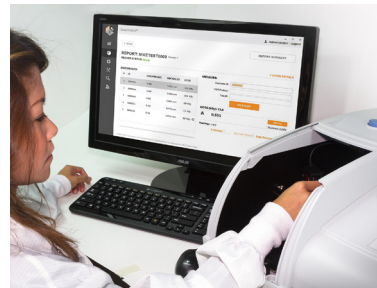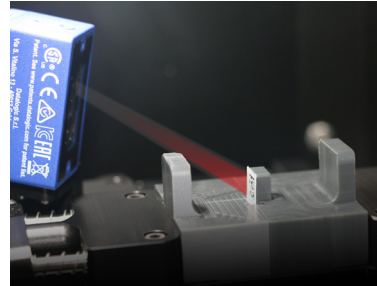
Key Benefit - Data integrity

DoseControl meets the current requirements and industry expectations for data integrity, 21 CFR Part 11, and Annex 11.

- ✓ **Process controls**
- ✓ **Device checks**
- ✓ **Change control**
- ✓ **Authorized user access & controls**
- ✓ **Audit Trail**
- ✓ **Record access and retrievability**

Designed to Meet Industry Standards & Guidelines

ISO 11137 part 1 & 3. Sterilization of health care products

ISO/ASTM 52628 Standard Practice for Dosimetry in Radiation Processing

ISO/ASTM 51261 Standard Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

ISO/ASTM 51275 Standard Practice for Use of a Radiochromic Film Dosimetry System

ISO/ASTM 51276 Standard Practice for Use of a Polymethylmethacrylate Dosimetry System

ISO/ASTM 51650 Standard Practice for Use of a Cellulose Acetate Dosimetry System

Features

Specialized hardware

- High quality Thermo spectrophotomers are the ideal option to measure optical dosimeters. Wide SBW high resolution for thin film dosimetry, consistent and reliable measurements.

- Specialized dosimeter holders keep the dosimeter in place for repeatable results. Solid and robust, the holders will withstand years of heavy use.

- Internal barcode scanner captures the dosimeter ID at time of measurement (B3).

- Internal laser micrometer captures dosimeter thickness at time of measurement (PMMA).

Use dosimetry data as you need!

- Highly flexible and configurable to meet the needs of your specific process.

- DoseControl admin users can create unique report types with customizable report header fields.

- Export dosimetry reports to Excel or secure PDF format.

- Export to Excel template is fully customizable.

- Default PDF templates available; or custom PDF report modules available (extra fee).

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SYSTEM NAME	DSM TYPE	B3 ADD-ONS	PMMA ADD-ONS	PERFORMANCE (PV) TESTING[1]	PV DAILY CHECK[2] TEST	REPORT AUTOMATION	INTEGRATION
Evolution-DoseControl system	B3 FWT PMMA CTA GAF	• Built-in **dosimeter ID scanner** • Hand-held scanner	Built-in laser micrometer	**Equipment:** • Spectronic Standards • Evolution Xenon lamp • Thermo Mercury lamp **Interface:** • Thermo Insight software • DoseControl P.V. Module	**P.V. Module:** Photometric and wavelength accuracy tests for attached reader. Built-into DoseControl software. Daily PV test of reader with results report.	**Product Specification Module:** Automatically enters process specification information for a dosimetry report.	Built-in capability to integrate data with other systems.
GENESYS 30-DoseControl system	B3 FWT GAF	• Built-in **dosimeter ID scanner** • Hand-held scanner	None.	**Equipment:** • Spectronic Standards **Interface:** • G30 touchpad	No P.V. Module.	**Product Specification Module:** Automatically enters process specification information for a dosimetry report.	Built-in capability to integrate data with other systems.

[1] See ASTM 51275 (2021) §7.3 Performance Verification of Instrumentation

[2] See ASTM 51275 (2021) §7.3.3 Implementation of a daily check program for instrument