

microSTAR[®]ii

medical dosimetry system

USER MANUAL



LANDAUER[®]

v1.4 | 5/18/2020

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CHAPTER 1 INTRODUCTION & BACKGROUND

The microSTARⁱⁱ Medical Dosimetry System is used as an independent secondary dose verification system that performs comprehensive measurement readings of the nanoDot[™] Optically-Stimulated Luminescence (OSL) dosimeter. The system reads the dosimeter, performs analyses using calibration parameters and customer-specific configurations, and provides in-depth reporting for review. The system stores the data for reference and cumulative dosage records. It uses a compact Optical Engine with a high-powered Light-Emitting Diode (LED) and Pulsed Optically-Stimulated Luminescence (POSL) to provide a precise radiation dose measurement.

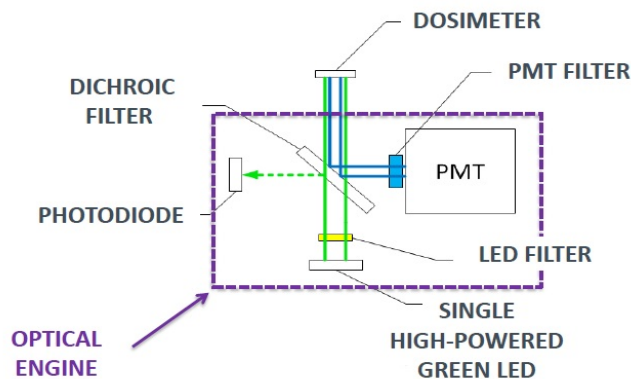


Figure 1-1: Optical Engine Components

This user manual contains detailed information for the microSTARⁱⁱ Medical Dosimetry System, including operation of both the reader and application software after installation and configuration is complete. It includes useful information pertaining to quality assurance and compliance checks, system configuration updates, measurement procedures, reporting, system administration, and troubleshooting for the system.

Related documentation can be found at <http://landauer.com/microstariii>. This includes:

- **microSTARⁱⁱ Installation & Configuration Guide** for detailed instructions on how to setup, configure, and test your system at installation.

- **Frequently Asked Questions** for information about the system design, operations, and term definitions.
- **microSTARⁱⁱ™ – A new system for medical dosimetry:** a white paper that details the design and performance of the system.

1.1 Limitations of Product Scope

The microSTARⁱⁱ Medical Dosimetry System has been designed as a secondary dose verification system. The system should only be employed as one of a number of tools in a program of quality assurance for the primary dose verification systems being used. As such, the results obtained with the microSTARⁱⁱ should not be used to guide patient care decisions. Instead, it may be used as a secondary method to validate the prediction or assessment of radiation dose to patients resulting from therapeutic or diagnostic procedures.

The nanoDot[™] dosimeter used in the microSTARⁱⁱ Medical Dosimetry System is manufactured as a single-use device (②) only for use with patients. When used for calibration and quality control (QC), the nanoDot dosimeter may be used in accordance with the recommended replacement schedule detailed in Table 2 of Section 2.1.3. Due to the potential for changes in dosimeter performance with accumulating life-time dose, LANDAUER[®] and its affiliates do not support reuse of the nanoDot dosimeter for use with patients.

R Only. Caution: Federal law restricts this device to sale by or on the order of a qualified medical provider.

The user assumes full responsibility for implementing site-specific procedures to ensure correct patient identification, HIPAA-compliant management of patient Personally Identifiable Information (PII), dosimeter verification, and proper usage including: transport, handling, placement, and timely readout. It is strongly recommended site-specific written Standard Operating Procedures be implemented prior to the launch of a medical dosimetry program.

Customers who intentionally disregard these stated limitations of product scope assume full responsibility for any negative consequences resulting from any such use.

1.1.1 Indications For Use

The LANDAUER[®] microSTAR^{®ii} Medical Dosimetry System provides an accurate, reliable, and easy-to-use dosimeter and reader intended for use in measuring dose on-phantom or on-patient in medical dosimetry applications, such as radiotherapy and diagnostic radiology. When used to measure patient dose, the system is used to provide a secondary verification of radiation dose as a means of Quality Control for the primary dose calculation method. The output of the microSTARⁱⁱ system is not used to adjust the dose to the patient.

1.1.2 Manufacturer

LANDAUER at 2 Science Road in Glenwood, IL 60425.

1.2 Best Practices

To achieve the best results using the microSTAR^{®ii} Medical Dosimetry System, comply with the best practice operating principles listed below. The contents of this manual provide the instructions and guidance to support these standards.

- ✓ Implement the microSTARⁱⁱ QA program and monitor reader performance trends. Do not perform readings if the Daily QA test has failed.
- ✓ Allow the reader to warm up for 60 minutes after it has been powered on prior to use. This will allow the system to stabilize for improved performance.
- ✓ Do not open the reader drawer during nanoDot analysis.
- ✓ Do not remove the drawer from the reader during normal operations.
- ✓ Set the nanoDot flat in the tray with the barcode facing up and in the upper-left corner of the dosimeter. If the nanoDot is incorrectly positioned in the reader drawer the reader may be significantly damaged. (See Figure 3-2 for correct nanoDot positioning.)
- ✓ Verify the correct sensitivity is displayed when scanning nanoDot serial numbers prior to reading. (See section 2.1.3 for more information.)
- ✓ When reading nanoDots, note the form of the dose calculation formula on the *Reading* tab and ensure that the values used in the calculation are correct.
- ✓ Prior to analyzing a nanoDot, verify that the correct calibration name(s) appears in the Current Calibration fields on the *Reading* tab.
- ✓ Always use the average of 3-4 readings to calculate an average estimate of dose for medical dosimetry applications to improve accuracy.

- ✓ To minimize outside interference, which can affect measurement precision, do not place reader near high Electromagnetic Field (EMF) generating equipment, such as CT machines.
- ✓ Complete a system calibration annually as part of routine system maintenance.
- ✓ Clean the reader and the drawer regularly to get rid of any debris generated after 1,000 open/close cycles of regular use (See Chapter 11 more for information).

1.3 Conventions and Standards

The following symbol is used within this documentation to mark risks, warnings, and other information.



Caution

This symbol denotes information that could affect the equipment operation or cause issues with overall dosimetry operations.



Single Patient Use Only

This symbol indicates a device or product is intended for single patient use only.



Prevention of Personal Injury

To prevent eye damage and personal injury, please adhere to the following:

- Do not attempt to remove portions of the enclosure or otherwise disassemble the reader. The Reader contains a high-power LED, which under specific conditions could cause damage to the eye. Please refer service to an approved technician.
- Do not alter the Reader and use only as specified or the protection provided by the Reader can be compromised.
- Use only a LANDAUER-approved power supply to power the Reader.
- Use the Reader indoors only.
- Do not use the Reader if it has been altered or is damaged.

CHAPTER 2 SYSTEM OVERVIEW



Figure 2-1: Full microSTARⁱⁱ System

The microSTARⁱⁱ Medical Dosimetry System includes both hardware and software components. The hardware is used to scan and read the nanoDot[™] dosimeter. The software provides the tools necessary to manage the reader, view stored measurement data, generate reports, manage patient assignment, and manage inventory. This section provides an overview of the hardware components and software interface.

Note: For detailed hardware and software setup instructions and configuration, see the *microSTARⁱⁱ Installation & Configuration Guide*.

2.1 Hardware

The microSTARⁱⁱ Medical Dosimetry System consists of the microSTARⁱⁱ reader, a laptop or all-in-one computer with installed software, and associated peripherals (including a mouse, keyboard, and barcode scanner).

2.1.1 Reader

The microSTARⁱⁱ reader includes a drawer and two LED indicators. The indicators show if the reader is powered on and it is performing a readout.

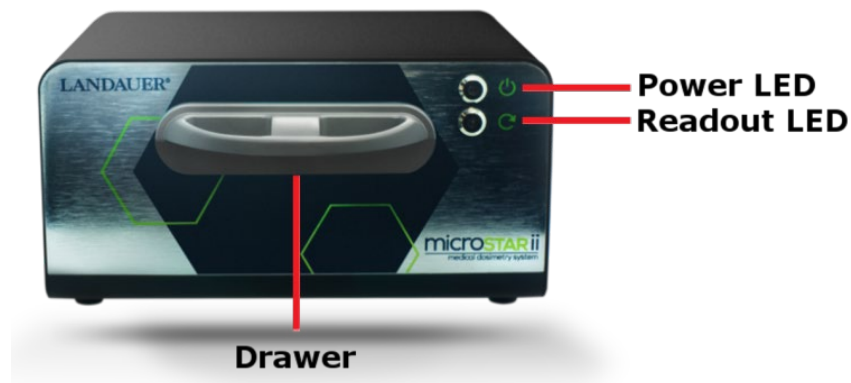


Figure 2-2: Reader Front

The microSTARⁱⁱ reader drawer is used to hold the nanoDot dosimeter and correctly position its active OSL element for readout. To ensure that the reader drawer operates correctly, the nanoDot dosimeter must be properly positioned within the recessed well. (See section 3.3 for more information on positioning a nanoDot.)



Figure 2-3: Reader Drawer



CAUTION: Under normal operating conditions, the reader drawer should not be removed from the reader. Under special conditions (e.g., maintenance or troubleshooting), the drawer can be removed. The drawer can only be removed while the power is turned OFF to avoid potential damage to the optical engine. The reader drawer must be fully inserted before connecting the reader to a power source and turning the reader ON.

The back of the reader includes a power connector socket, a power button, a USB port, and an identification label with the reader serial number and other hardware information.



Figure 2-4: Reader Back

2.1.2 Computer

LANDAUER will supply the computer hardware (all-in-one or laptop) required for use with this system. The computer provided should be used in conjunction with the microSTARii reader. It will run a Windows Operating System and will be loaded with the microSTARii application and supporting programs.

2.1.3 nanoDot™

The microSTARii Medical Dosimetry System is used to read nanoDot OSL dosimeters. The dosimeters come in sealed, labelled plastic packages that protect against contamination. It is recommended unused dosimeters remain stored in shipment packaging.

When it is time to perform a readout (for pre-verification or dose) the dosimeter is removed from the pouch and set in the recessed well in the reader drawer. The active element is highlighted in the crosshair circle in Figure 2-5 below.



Figure 2-5: nanoDot Dosimeter



CAUTION: If the nanoDot is incorrectly positioned in the reader drawer (e.g., not set in completely or put in with barcode facing down) the reader may be significantly damaged. (See Figure 3-2 for correct nanoDot positioning.)

The nanoDot label includes the following information:

- **Barcode** used to scan the dosimeter information into the system. (Left in Figure 2-5.)
- **Serial number** used to track and manually enter dosimeter information into the system. (Right in Figure 2-5.)
- **Relative sensitivity** is included as part of the serial number. Sensitivity can be determined by taking the first three digits in the serial number and dividing it by 100. In example in Figure 2-5, the serial number is DN091042837, thus making the sensitivity 0.91.

Two types of nanoDot dosimeters are available for purchase:

- **Unscreened (General)** nanoDots use a general sensitivity based on the average readings for the OSL material. These devices have an accuracy of $\pm 10\%$ in sensitivity determination. These dosimeters are also referred to as General nanoDots.
- **Screened (Patient)** nanoDots are individually tested to ensure a high accuracy in sensitivity determination ($\pm 5.5\%$). These are recommended for therapy and other applications that require more precise measurements. These dosimeters are also referred to as patient nanoDots.

Screened nanoDots can also be used to set performance baselines and validate operational performance, including the following:

- **Calibration dosimeters (calsets)** are used to create the calibration factor(s) used for dose calculation (Section 9.1).

- **Quality Control (QC) dosimeters** are read to verify the accuracy of the calibration and resulting computed dose. (Used in Chapter 5 best practices and general calibration troubleshooting in Chapter 12.) These dosimeters can be used for the Daily QC Check (see Section 5.1), in addition to other QC methodologies.

Note: The nanoDot is intended to be used in combination with an existing system performance monitoring methodology. The nanoDot is not intended for independent use as an occupational or standalone dosimeter.

The nominal dose levels for the 80 kVp and Cs-137 (662 keV) NIST-traceable LANDAUER Calibration, QC, and Consistency Sets are summarized in the following table. The actual dose level is listed on the LANDAUER Calibration Certificate issued with the set.

NOTE: Calibration and QC sets for other energies are available as non-standard sets.

THERAPY: 662 keV (GAMMA)			DIAGNOSTIC: 80 kVp (X-RAY)		
Application: QA only (Therapy Users will perform on-site clinical calibrations using their own LINAC and clinical geometry).			Application: QA + uses where the exposure conditions emulate the application exposure conditions.		
Calibration Set	QC Set	Consistency	Calibration Set	QC Set	Consistency
Low Dose in cGy (Linear Range)			Low Dose in cGy (Linear Range)		
Unexposed	Unexposed	-	Unexposed	Unexposed	-
1.0	-	-	0.5	0.5	-
5.0	5.0	-	3.0	3.0	-
10.0	10.0	-	-	-	-
High Dose in cGy (Linear Range)			High Dose in cGy (Linear Range)		
50.0	50.0	-	50.0	50.0	-
100.0	100.0	100.0	100.0	100.0	100.0
200.0	200.0	-	-	-	-

Table 1: Calibration and QC Dosimeter Set Energies

All dosimeters for use with patients are single use only (②). However, dosimeters used for QC and Calibration purposes may be read multiple times in accordance with the replacement frequency listed in the table above, based on depletion per use.

	DEPLETION RATE	REPLACEMENT FREQUENCY
Weak Beam	0.2%	Every six months or after 10 uses (whichever comes first)
Strong Beam	2.0%	Every three months or after five uses (whichever comes first)

Table 2: Replacement Recommendations for QC and Calibration Dosimeters ONLY

2.2 Software

The microSTARii Medical Dosimetry System includes:

1. Embedded software within the reader (firmware)
2. Reader device driver that controls the reader (sending commands or data to and from the reader firmware)
3. Software application used to operate the reader, manage data, and report dosimetry results
4. SQL database to store reader data

2.2.1 Main Functions

The software supports the following main functions:

- **Quality Assurance**
The system supports both quality assurance of the system and the dosimeters used.
- **Dosimeter Tracking (Patient Assignment)**
Dosimeters can be assigned to a patient to record information including: track dose, usage cycle, and location used.
- **Intrinsic and Dosimetry Measurements**
Measurements are initiated through the software. The system is calibrated and reads are configured based on usage and application.
- **Reporting**
A robust reporting set supports analysis, trending, and compliance reporting.

2.2.2 User Interface Overview

The user interface includes view buttons at the top of the window and session status information at the bottom of the window. Figure 2-6 outlines key areas on the user interface.

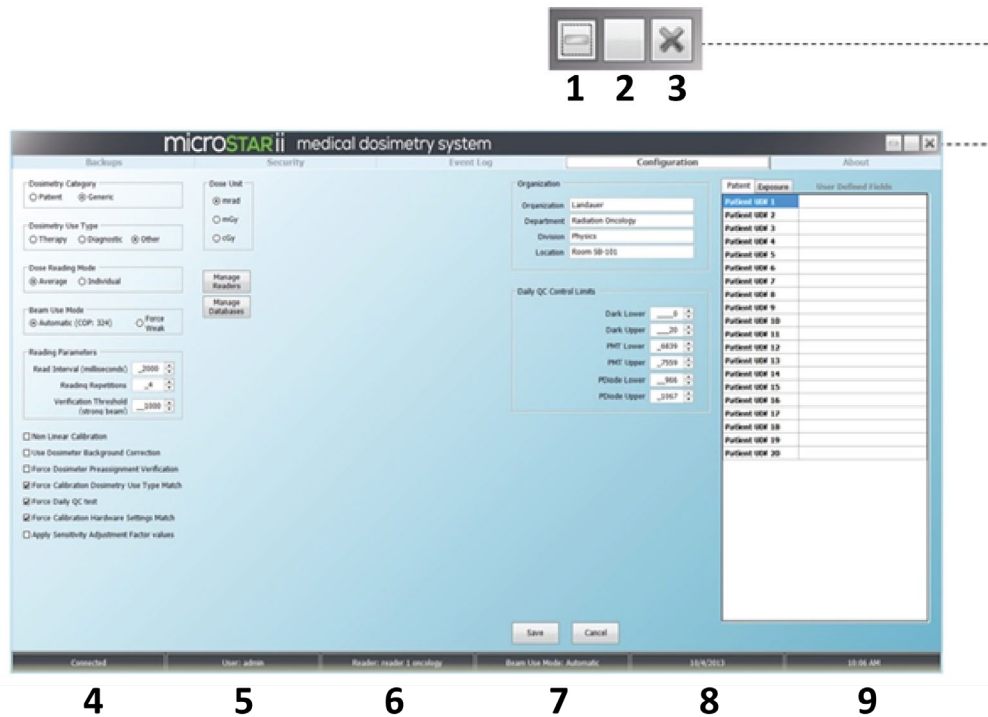


Figure 2-6: User Interface Overview

LABEL	DESCRIPTION
1	Button to minimize the application window to Microsoft taskbar
2	Button to maximize window to full computer screen or restore the window to its previous size
3	Button to exit the software application
4	Reader Connection Status (Connected or Disconnected)
5	Username of the Logged In User
6	Name of the Connected Reader (the reader name assigned at installation)
7	Current Beam Use Mode (Automatic vs. Forced Weak)
8	Current Date
9	Current Time

The user interface has eleven main user screens. The screens are visible based on permissions level and profile assigned. (For a full listing of profile permission and permissions for default profiles, see *Appendix A: Profile Permissions Listing*.)

SCREEN	SHORT DESCRIPTION
About	microSTAR ⁱⁱ system information: user software version, the SQL database version, the reader device driver version, the connected reader's firmware version, the computer name, and Unique Identifier for the software installed at each facility.
Backups	Database management for creating backups, restoring backup files, and database resets.
Calibration	Reader calibration factor(s) used in the dose calculation formula shown on the <i>Reading</i> tab. The calibration dosimeters are read on this screen as part of the system calibration.
Configuration	Basic operating parameters for the reader and customizable software configuration. This tab includes operations configuration, such as Dosimetry Category, Dosimetry Use Type, Dose Reading Mode, Beam Use Mode, and Dose Unit. It also includes advanced configuration, such as compliance settings, field options, and QC limits.
Data	Full reporting of all measurement data collected through reads.
Dosimeter Assignment	Listing of patient information and associated dosimeter(s). New assignments and assignment updates can be made on this tab.
Event Log	A log of software activities used to troubleshoot issues or log usage patterns.
QA	Quality Control tests used to evaluate the reader's stability, verify the reader is operating correctly prior to clinical use, and determine the background measurements prior to patient assignment and clinical use.
Reading	Main interface used to initiate a reading for both Patient and Generic dosimetry. It includes fields needed to associate additional data with the readout and check on the Daily QC status.

SCREEN	SHORT DESCRIPTION
Security	User account management and profile configuration.
Sensitivity Assessment	The toolset used to assess a population of nanoDots, validate the accuracy of labeled sensitivity, complete on-screen and structured sensitivity assessment reporting, and input a sensitivity correction using a Sensitivity Adjustment Factor (SAF).

CHAPTER 3 SYSTEM OPERATIONS

3.1 Startup

The microSTARⁱⁱ Medical Dosimetry System startup sequence is outlined in the following flowchart.



Figure 3-1: Startup Sequence

STEP 1: Verify Connections

Check the physical connections from the reader to the computer. Ensure they match the setup instructions in the installation guide.

STEP 2: Turn on the Reader

Press the power button on the back of the device (Figure 2-4) to turn the reader on. When the reader is fully powered, the LED indicator on the front will be illuminated (Figure 2-2).

NOTE: The reader should be turned on at least 60 minutes prior to use.

STEP 3: Turn on the Computer

Turn on the computer according to the manufacturer's instructions for the model of computer that came with your reader.

STEP 4: Log on to the Computer

Log on to the computer operating system. This information will be unique to your facility, because the default computer logon credentials should have been changed by your System Administrator at installation. If you do not know the computer logon information, contact your System Administrator for assistance.

Default Credentials	Logon	USERNAME: admin
		PASSWORD: system

Note: This information should have been changed as part of the installation procedure. If it has not been changed, complete the steps in the installation guide to change the logon credentials.

STEP 5: Launch Software



To launch the microSTARⁱⁱ application software, double-click on the application icon shortcut located on the computer desktop.

STEP 6: Log on to User Account

Enter your username and password on the application start screen.

NOTE: If you do not have an assigned username and password, contact your System Administrator to request a user account. HIPAA regulations require that each user of the system has a separate and unique logon. You should not operate the software from another user's account.

Default Admin Credentials	microSTAR ⁱⁱ Logon	USERNAME: admin
		PASSWORD: starii

Note: This information should have been changed as part of the installation procedure. If it has not been changed, complete the steps in the installation guide to change the logon credentials. This admin account only provides permissions for administrative functions. It cannot be used to perform dosimetry measurements.

3.2 Shutdown

The system can be partially or fully shut down. A partial shutdown involves shutting down the software and computer only. A full shutdown is a shutdown of the whole system: software, computer, and reader.

3.2.1 Partial Shutdown

A partial shutdown should be performed at the end of each user session to prevent unauthorized access to the system. Use the following steps to complete a partial shutdown:

- STEP 1:** Exit the microSTARⁱⁱ software application.
- STEP 2:** Log out of the computer.

3.2.2 Full Shutdown

A full shutdown should be performed if the system is being moved or decommissioned. It can also be performed at the end of each day, depending on the protocol established by your facility. Use the following steps to complete a full shutdown:

- STEP 1:** Exit the microSTARⁱⁱ software application.
- STEP 2:** Log out of the computer, and shut it down.
- STEP 3:** Turn off the microSTARⁱⁱ reader using the power button on the back of the reader (Figure 2-4).

3.3 Positioning the nanoDot

If the nanoDot is incorrectly positioned in the reader drawer (e.g., not set in completely or put in with barcode facing down) the reader may be significantly damaged.

For the nanoDot to be properly read and the drawer to close:

- ✓ the nanoDot must be put in the tray well with the barcode facing up and at the upper-left corner
- ✓ the nanoDot must be sitting flat in the tray



Figure 3-2: Correct nanoDot Orientation

If the drawer does not easily close, do not try to force it to close. If the drawer will not close, see section *12.4 Hardware Issues* for troubleshooting guidance.

3.4 Ejecting the nanoDot

To eject the nanoDot, pull the blue ejector toward the nanoDot. If the nanoDot does not properly eject, see section *12.4 Hardware Issues* for troubleshooting guidance.

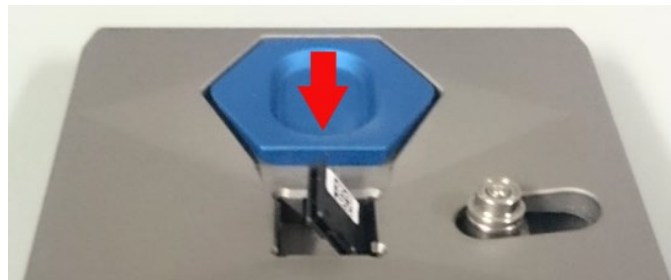


Figure 3-3: Ejected nanoDot

CHAPTER 4 CONFIGURATION

General and advanced configuration options are available on the *Configuration* tab. Permissions to change configuration options are based on the profile associated with your account. (See *Appendix A: Profile Permissions Listing* for default access information.)

The following subsections define configuration options for both general operations and advanced configuration of the microSTARⁱⁱ Medical Dosimetry System.

NOTE: To apply any changes made on the *Configuration* tab, click the Save button.

The screenshot displays the Configuration Tab interface with the following sections:

- Dosimetry Category:** Radio buttons for Patient and Generic (Generic is selected).
- Dosimetry Use Type:** Radio buttons for Therapy, Diagnostic, and Other (Therapy is selected).
- Dose Reading Mode:** Radio buttons for Average and Individual (Average is selected).
- Beam Use Mode:** Radio buttons for Automatic and Force Weak (Force Weak is selected).
- Reading Parameters:** Spinners for Read Interval (2000), Reading Repetitions (4), and Verification Threshold (500).
- Dose Unit:** Radio buttons for mrad, mGy, and cGy (cGy is selected).
- Organization:** Text fields for Organization (Medical Facility), Department (Radiology), Division, and Location (Washington).
- Daily QC Control Limits:** Spinners for Dark Lower (0), Dark Upper (20), PMT Lower (844), PMT Upper (933), PDiode Lower (845), and PDiode Upper (934).
- Checkboxes:**
 - Non Linear Calibration
 - Use Dosimeter Background Correction
 - Force Dosimeter Preassignment Verification
 - Force Calibration Dosimetry Use Type Match
 - Force Daily QC test
 - Force Calibration Hardware Settings Match
 - Apply Sensitivity Adjustment Factor values
- Buttons:** Manage Readers, Manage Databases, Save, and Cancel.
- Table:** A table with columns Patient, Exposure, and User Defined Fields. It lists Patient UDF 1 through Patient UDF 20.

Figure 4-1: Configuration Tab

4.1 General Configuration

The following subsections provide a basic overview of the general configuration properties on the *Configuration* tab (Figure 4-1). These areas are updated as part of the standard operations process. For information on Advanced configuration done as part of administration or reconfiguration, see section *4.2 Advanced Configuration*.

4.1.1 Dosimetry Category

microSTARⁱⁱ can be used to read both screened and unscreened dosimeters. Configuration and read options are updated based on the dosimetry category selected on the *Configuration* tab.

- **Generic:** Typically used for QA or phantom dosimetry applications. It does not require assignment to a specific patient with a detailed patient record.
- **Patient:** Typically used for medical dosimetry applications. This category includes enhanced database and reporting features (e.g., patient assignment, exposure information tracking, individualized dosimeter reports). This category can only be used with the *Average* dose reading mode.

For information on performing a read using the two categories, see *Chapter 7 Dosimetry Reads*.

4.1.2 Dosimetry Use Type

The system provides configurations for three use types:

1. **Diagnostic** is used for basic patient medical dosimetry that does not require detailed patient association and tracking.
2. **Therapy** is used for complex patient medical dosimetry requiring tracking patient and exposure information.
3. **Other** is used for other applications (e.g., research or industrial) that do not require patient-specific reporting.

4.1.3 Dose Reading Mode

To calculate the dose, a sequence of readings is completed on the dosimeter (based on the *Reading Repetitions* value on the *Configuration* tab). The system has two dose reading modes:

1. Average

In Average reading mode, the Dose AVG, STDEV & CV will be calculated across all acquired readings and written to the database. The operator has the option of selecting the readings to include in the calculation. This is the only option for the *Patient* dosimetry category.

2. Individual

In Individual reading mode, a dose is computed for each individual reading independently and no dose average is reported. This option is only available for the *Generic* dosimetry category.

4.1.4 Beam Use Mode

The reader is designed to operate at two different LED levels depending on the range of doses being measured:

- **Weak Beam** LED level is used to measure high doses and extends the standard operating range of the reader.
- **Strong Beam** LED level is used in the low dose range to extend the reader dynamic range and improve accuracy by accounting for varied counting statistics.

The system can be set up in one of two configurations:

1. Automatic

The reader automatically switches between the strong and weak LED levels when reading dosimeters, based on the pretest counts obtained prior to initiating a normal photomultiplier tube (PMT) count reading. This ensures that the LED stimulation level is always optimized for the selected dose level.

2. Force Weak

The reader only uses the weak LED level regardless of dose level.

NOTE: Non-Linear calibrations must be performed in this mode.

The following table provides configuration recommendations for each beam use mode based on the calibration mode (Linear or Non-Linear).

	LINEAR		NON-LINEAR	
	Use Type	Dose Range	Use Type	Dose Range
Automatic	Diagnostic and Other (Low Dose)	0-COP* COP-300 cGy	N/A	
Force Weak	Therapy	15-300 cGy	Therapy	300-1500 cGy

**Cross-Over-Point (COP): The reader-specific Cross-Over-Point that defines the boundary between Low and High Doses, which is established during manufacturing to be approximately equivalent to 15 cGy at 662 keV.*

4.1.5 Dose Unit

The Dose Unit is set prior to performing a read. This is based on the exposure of the dosimeter being read. The system supports three units of measurement: mrad, mGy, and cGy.

The calibration factors used for a measurement are based on the Dose Unit configuration setting at the time you pull the information, regardless of what unit was used during the calibration. The measurement data will be converted to the configured measurement automatically.

4.2 Advanced Configuration

The following subsections provide an overview of advanced configuration properties on the *Configuration* tab (Figure 4-1). These areas are updated after a major system or process change. For information on general configuration done as part routine operations, see section *4.1 General Configuration*.

4.2.1 Configuring Organization Information

The following organization information is used in the dosimetry reading database records and Structured Dose Reports generated for patient dosimetry:

- Organization
- Department
- Division
- Location

To change the organization information, complete the following steps:

- STEP 1:** Log on to the microSTARⁱⁱ application under an Administrator account.
- STEP 2:** Navigate to the *Configuration* tab.
- STEP 3:** Update the *Organization* fields.
- STEP 4:** Click the Save button at the bottom of the *Configuration* tab.

Organization	
Organization	Northwest Medical Center
Department	Radiation Oncology
Division	Physics
Location	Bld 2 Rm 194

Figure 4-2: Configuration - Organization Field

4.2.2 Configuring User Defined Fields

User Defined Fields (UDF) are used to include additional information in the measurement database records. (See *Appendix C: Standard Database Values* for the database value definitions for recording and reporting.) UDF data values are entered on the *Dosimeter Assignment* and *Reading Screens*, either at the time of assignment or before executing a reading, as shown in the figures below.

NOTE: Consult with your HIPAA compliance officer to ensure full compliance with regulations for patient information handling.

To add a UDF, complete the steps below:

- STEP 1:** Log on under an Administrator account.
- STEP 2:** Navigate to the *Configuration* tab.
- STEP 3:** Double-click in the field next to the UDF, and enter in the name. (Figure 4-3)

NOTE: The default tab is *Patient*. To add an *Exposure* UDF, click the *Exposure* tab to bring up the Exposure UDF table.

- STEP 4:** Click the Save button at the bottom of the *Configuration* tab.

Some examples of Patient UDF include:

- Height
- BMI
- Anterior-Posterior Chest Thickness

- Primary Physician
- Emergency Contact Phone Number
- Blood Type
- Allergies

Patient	Exposure	User Defined Fields
Patient UDF 1		Telephone: Home #
Patient UDF 2		Telephone: Cell #
Patient UDF 3		Address: Street Number
Patient UDF 4		Address: Street
Patient UDF 5		Address: Apt/Unit #
Patient UDF 6		Address: City or Town
Patient UDF 7		Address: State or Province
Patient UDF 8		Address: Country
Patient UDF 9		Address: Zip or Postal Code
Patient UDF 10		Email Address
Patient UDF 11		Telephone: Work #
Patient UDF 12		
Patient UDF 13		
Patient UDF 14		
Patient UDF 15		
Patient UDF 16		
Patient UDF 17		
Patient UDF 18		
Patient UDF 19		
Patient UDF 20		

Patient	Exposure	User Defined Fields
	Exposure UDF 1	Phantom Type:
	Exposure UDF 2	Phantom Thickness:
	Exposure UDF 3	Phantom Material:
	Exposure UDF 4	Dosimeter Depth in Phantom:
	Exposure UDF 5	
	Exposure UDF 6	
	Exposure UDF 7	
	Exposure UDF 8	
	Exposure UDF 9	
	Exposure UDF 10	
	Exposure UDF 11	
	Exposure UDF 12	
	Exposure UDF 13	
	Exposure UDF 14	
	Exposure UDF 15	
	Exposure UDF 16	
	Exposure UDF 17	
	Exposure UDF 18	
	Exposure UDF 19	
	Exposure UDF 20	

Figure 4-3: UDF Examples

NOTE: Once established, only new UDFs should be added. Editing a previously established UDF at a later date can lead to database anomalies, because the new definition label may not correlate with previously collected database entries.

4.2.3 Setting the Reading Parameters

The *Reading Parameters* should be set at the time of installation. The system has three reading parameters:

1. **Read Interval**

The time (in milliseconds) between successive readings. During installation it is set to the minimum interval necessary for accurate and efficient readings.

2. **Reading Repetitions**

The number of times that a single dosimeter will be read in a single measurement cycle. The range available is based on the *Dose Reading Mode* value:

- **Average** reading mode range is 2-5.

NOTE: Two times is the minimum reproducible read, and five times is the highest number of reads that can be performed without reading depletion effects impacting accuracy. (This is important for low-dose readings performed with the Strong Beam.)

- **Individual** reading mode range is 1-99.

3. Verification Threshold

The threshold set for background dose readings. If the background dose is higher than this value, then the pre-assignment test will fail. The default and recommended value is 500 counts. The value can be lowered for very low dose applications to reduce the acceptable limit.

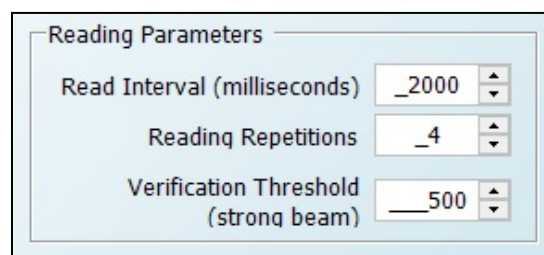


Figure 4-4: Configuration - Reading Parameters

4.2.4 Changing Daily QC Limits

The *Daily QC Control Limits* values are established as part of installation. These values should not be changed unless a significant and expected change in the reader status has occurred (e.g., service or preventative maintenance).

The Daily QC limits are changed through the *Reader QC Tests* on the *QA* tab. When the test is run and accepted, the values on the *Configuration* tab will automatically update. (For more information on updating the QC Control Limits, see section 5.2.) In the event that the QC limits were changed in error, the limits can be reset manually on the *Configuration* tab by an Administrator.

To reset the Daily QC Control Limits complete the following steps:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Administrator account.
- STEP 2:** Navigate to the *Configuration* tab.
- STEP 3:** Update the *Daily QC Control Limits* fields.
- STEP 4:** Click the Save button at the bottom of the *Configuration* tab.

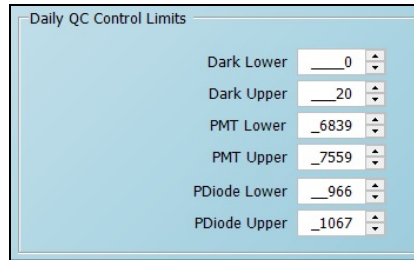


Figure 4-5: Daily QC Control Limits

4.2.5 System Compliance Checks

The microSTARⁱⁱ application has a set of built-in compliance checks designed to ensure quality tests are completed, the dosimetry selections and validations are completed, and the settings are correct. If compliance criteria are not met, the operator will see a warning message. These compliance checks are selected by default. They can be turned off/on in the *Configuration* tab.

NOTE: If the settings are turned on, you will not be able to proceed with operations until you have met the compliance requirements. If the settings are turned off, you will still receive a warning message that the compliance requirements have not been met, but you will be able to proceed with operations.

COMPLIANCE SETTING	DESCRIPTION
Force Dosimeter Preassignment Verification	<p>A dosimeter must be verified as unexposed prior to readout or assignment.</p> <p>This setting is used with the <i>Use Dosimeter Background Correction</i> setting. If background correction is enabled, <i>Force Dosimeter Preassignment Verification</i> is enabled and cannot be disabled.</p> <p>This setting is recommended for medical dosimetry applications to comply with professional standards and best practices.</p>
Force Calibration Dosimetry Use Type Match	<p>Calibration Type and Dosimeter Use Type must match for the dosimeter to be read.</p> <p>This setting is recommended for medical dosimetry applications and optional for other applications.</p>

COMPLIANCE SETTING			DESCRIPTION
Force Daily QC Test			<p>Daily QA test must be passed in order to perform a dosimeter read.</p> <p>This setting is recommended for medical dosimetry applications and optional for other applications.</p>
Force	Calibration	Hardware	<p>Settings Match</p> <p>Current hardware settings must match the hardware settings for the selected calibration in order to perform a dosimeter read.</p> <p>This setting is recommended for all dosimetry applications. It should only be turned off if directed by LANDAUER personnel during troubleshooting.</p>

CHAPTER 5 READER QUALITY ASSURANCE

The microSTARⁱⁱ Quality Assurance (QA) program is designed to ensure optimal reader performance for the medical dosimetry application. In addition to manufacturing QA tests of reader and screened nanoDots and verification of reader performance at installation, routine Quality Control and Preventive Maintenance tests should be completed on an on-going basis.

All routine QC tests are run on the *QA* tab.

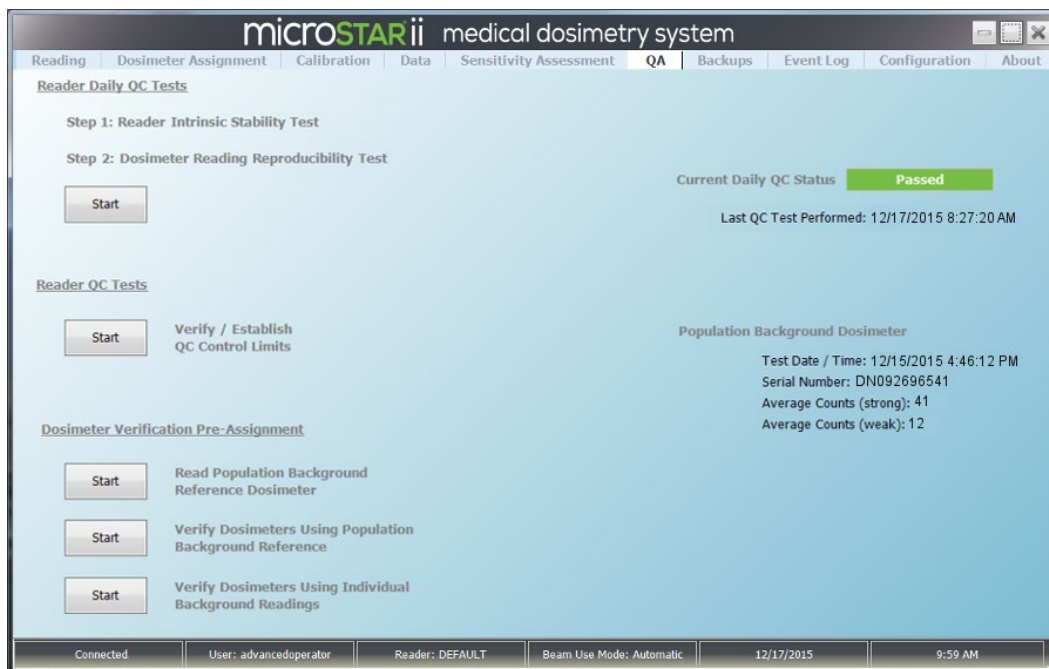


Figure 5-1: QA Tab

Routine QA tests support the two main types of microSTARⁱⁱ readings:

1. Intrinsic

Readings generated in Self-Test mode without a dosimeter. These readings are used to characterize the reader performance and monitor stability. They assess the stability of the PMT and LED output using a sentinel Photodiode (P-Diode). These tests are focused on the following values:

- Dark Count is an indicator of PMT and electronics' dark current and can be influenced by electronic noise or stray light leakage into the reader.
- PMT assesses the stability of the PMT and LED operating together (similar to routine dosimetry measurements).
- P-Diode assesses the stability of the LED light output, independent of the LED, using the photodiode.

The minimum (MIN), maximum (MAX), average (AVG), standard deviation (STDEV), and coefficient of variation (CV) are computed across all measurement cycles.

2. Dosimetry

Readings of nanoDot dosimeters used to measure the dose of radiation the dosimeters have been exposed to.

The Reader QA tests are grouped into two main tests:

1. Reader Daily QC Tests

These tests should be completed every day the reader is being used to ensure the reader is stable and the dosimeters can be consistently read. Both types of readings (intrinsic and dosimetry) are completed as part of Daily QC Tests.

2. Reader QC Tests

These tests should be done as part of installation and periodically during operations as part of general maintenance. This test first establishes QC Control Limits (at installation) and verifies/allows you to update QC Control Limits after a major change.

For information on the Dosimeter Verification Pre-Assignment section of the QA tab, see Chapter 5.

5.1 Reader Daily QC Tests

The Reader Daily QC Tests are required prior to completing dosimetry reads (unless the compliance check is turned off, see section 4.2.5 for details).

The *Current Daily QC Status* on the QA can be one of three statuses:



CAUTION: Do not perform medical dosimetry measurements if the Daily QC Status is *Failed*.

The Daily QC Tests are completed in two steps:

1. Reader Intrinsic Stability Test

Runs five cycles of intrinsic measurement data and compares the data with upper and lower control limit thresholds (CTRL-LL and CTRL-UL, respectively) for Dark, PMT, and P-Diode.

In order to pass the test, the following criteria must be met:

- **PMT & P-Diode AVG:** Fall between the upper and lower Control Limits
- **Dark:** None are greater than 20.

2. Dosimeter Reading Reproducibility Test

Reads a high-dose (100 cGy) consistency nanoDot ten times in sequence. This cycle verifies the reader is operating reliably and consistently for medical dosimetry measurements. To pass the test, the coefficient of variation (CV) across all readings should be < 1.0%.

NOTE: Two high-dose consistency nanoDots were included with the microSTARⁱⁱ shipment. If you need replacement nanoDots contact LANDAUER Technical Support. (See Section 12.1 for contact details.)

To run the Reader Daily QC Tests, complete the following steps:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *QA* tab.
- STEP 3:** Under *Reader Daily QC Tests*, click the Start button (Figure 5-1). The Reader Intrinsic Measurement Test will start. When it is complete, click OK on the Reader Daily QC Test results prompt. The report will be updated with a

colored bar reflecting the test results (green for a passed test, red for a failure). The test will move on to the next step if the test is passed.

- STEP 4:** In the *Daily QC Test: Step 2* prompt, enter the serial number or scan the barcode for a high-dose consistency nanoDot.
- STEP 5:** Place the consistency nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
- STEP 6:** Click OK to start the Reading Reproducibility Test. When it is complete, click OK on the Reader Daily QC Test results prompt. The report will be updated with a colored bar reflecting the test results (Figure 5-2).
- STEP 7:** Click the Complete button to complete and exit the test.
- STEP 8:** **If either test was failed**, resolve the error and rerun the test. (See section 12.6.1 *Reader Daily QC Tests Failure* for troubleshooting information.)

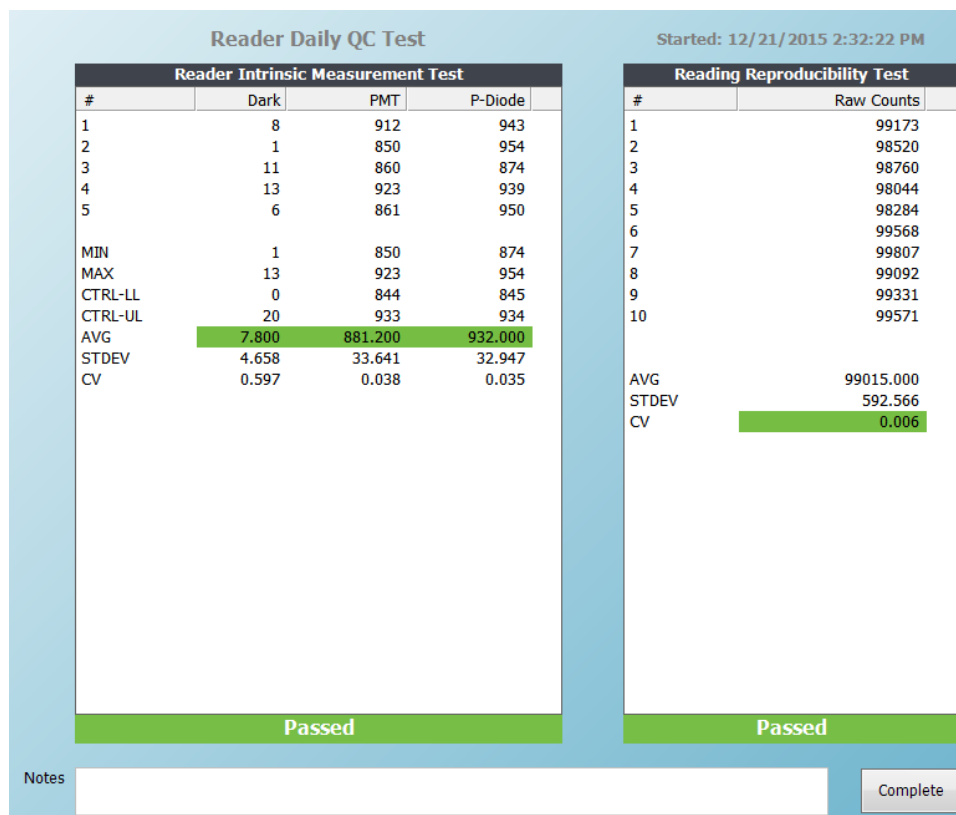


Figure 5-2: Daily QC Tests – Passed

When the *Daily QC Test* is passed, the status on the *QA* and *Reading* tabs will be updated to Passed.

A copy of the report is saved on the computer (C:\Program Files\LandauerInc\microSTARii Reader\Reports) and can be accessed through the Reader Reports shortcut on the desktop. (For more information see section *8.1.4 microSTARii Daily QC Test Report*.)

5.2 Reader QC Tests

The reader QC test is an intrinsic test that is completed during installation to set a baseline for reader performance. This test should be run post-installation to define new control limits in the following cases:

- ✓ The reader has undergone preventive maintenance.
- ✓ The reader has undergone repair.
- ✓ You have been instructed by LANDAUER Technical Support to re-establish your limits.

In order to pass the Reader QC tests, the following criteria must be met:

1. **Dark Count MAX:** ≤ 20
2. **PMT Count CV:** ≤ 0.05 (5%)
3. **P-Diode Count CV:** ≤ 0.05 (5%)

To verify QC Control Limits meet the criteria, complete the following steps:

- STEP 1:** Log on to the microSTARii application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *Configuration* tab. Note the values in the *Daily QC Control Limits* section.
- STEP 3:** Navigate to the *QA* tab.
- STEP 4:** Under *Reader QC Test*, click the *Verify/Establish QC Control Limits Start* button. (See Figure 5-1.)
- STEP 5:** A *High precision intrinsic measurement test* prompt will appear. Confirm there is no dosimeter in the reader and that the door is closed.
- STEP 6:** After 20 cycles of measurements have been completed, the report will be updated with a colored bar reflecting the test result (green for a passed test, red for a failure). Click OK on the test results dialog box.

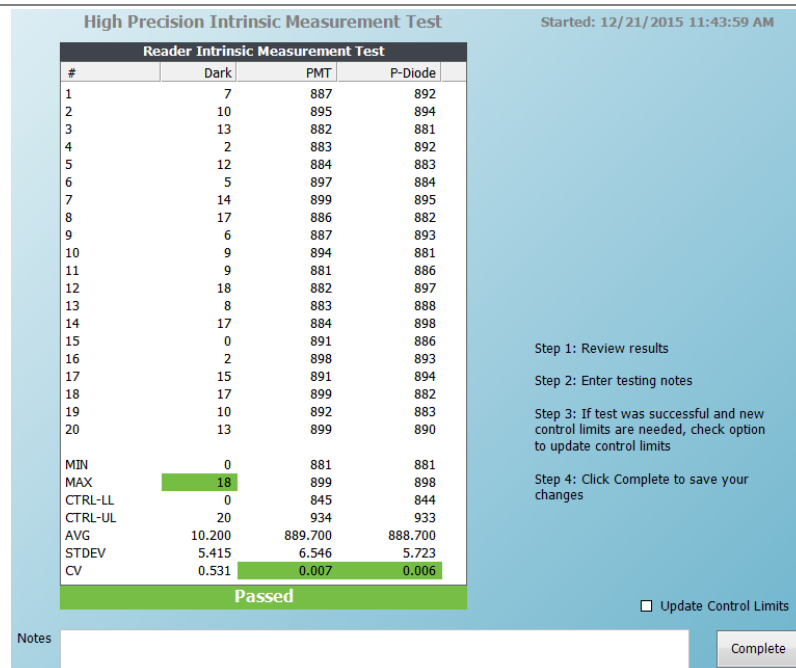


Figure 5-3: Reader QC Tests – Passed

- STEP 7:** If the test passed, click the Complete button to complete and exit the test.
- To maintain the system control limits, ensure the *Update Control Limits* check box is unchecked (Figure 5-4) prior to clicking the Complete button.
 - To update the control limits, check the *Update Control Limits* check box (Figure 5-4) prior to clicking the Complete button. Click OK on the confirmation message. Navigate to the *Configuration* tab, and confirm the values have updated from the previous entries (noted in Step 2).

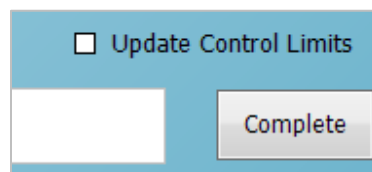


Figure 5-4: Update Control Limits Option

If the test failed, click the Complete button to complete and exit the test. Do not select the *Update Control Limits* check box. Resolve the error and rerun the test. (See section 12.6.2 *Reader QC Tests Failure* for troubleshooting information.)

A copy of the report is saved on the computer (C:\Program Files\LandauerInc\microSTARii Reader\Reports) and can be accessed through the Reader Reports shortcut on the desktop. (For more information see section 8.1.3 *microSTARii Control Limit Test Report*.)

CHAPTER 6 DOSIMETER VERIFICATION & PRE- ASSIGNMENT

Dosimeter dose verification measurements are used to record the amount of background dose (if any) present on a dosimeter prior to usage. This dose information is recorded and can be factored into the measurement calculations.

This verification can be used for the following:

- ✓ Background correction for low-dose applications
- ✓ To ensure a dosimeter is unused and that it has not accumulated an unexpected dosage during handling or storage prior to usage in high-dose applications

Dosimeter Verification Pre-Assignment measurements are run from the *QA* tab (Figure 5-1).

NOTE: The *Use Dosimeter Background Correction* setting must be enabled on the *Configuration* tab for the results to be used for background correction. If the setting is not enabled, the formula will use a background count value of zero. (See *Background Correction* in section 7.2.5 for more information.)

Dosimeter verification includes three processes that can be grouped into two main sets:

1. General Background Using Reference Dosimeter

This set of verification measurements allows the operator to use a single dosimeter in the lot to determine the background dose and apply it to the rest of the lot. By only reading one dosimeter, the rest of the lot can remain in their packaging.

a. Read Population Background Reference Dosimeter

This test is used to assess the exposure of a defined population of dosimeters. A single nanoDot from the lot (*reference dosimeter*) is removed from its packaging and read. That data is used to estimate background radiation exposure of the whole lot. This should only be used when the group of nanoDots are from the same lot and are stored in the same conditions.

b. **Verify Dosimeters Using Population Background Reference**

Once the lot has a representative background radiation dose established from the previous reading, this verification is run to apply the background dose information to each nanoDot in the lot based serial number. This verification can only be run if the Population Background Reference has been determined for the lot. The population background reference information is applied to the nanoDot without having to remove it from the packaging.

2. **Individual Verification of Each Dosimeter**

This verification readout is used to test each dosimeter for background dose. It requires that each dosimeter be removed from its packaging to be read.

a. **Verify Dosimeters Using Individual Background Readings**

This verification is run on a nanoDot to determine the actual dose for the dosimeter tested. Each nanoDot must be removed from the packaging and read individually. The background counts are stored and can be used to correct for cumulative exposure to the dosimeter prior to use. (This can improve accuracy in low-dose applications.)

NOTE: For background reads, three measurements are obtained using the weak beam followed by three readings using the strong beam. The background must be assessed in both modes, because it is not known in advance whether the dosimeter will receive a high or low dose. To pass the test, the strong beam counts must be lower than the Verification Threshold shown on the *Configuration* tab. The default Verification Threshold is set to 500 counts, but can be adjusted by the System Administrator. (For more information on Verification Threshold, see section *4.2.3 Setting the Reading Parameters*.)

Both sets of verification are run from the *QA* tab (Figure 5-1). All of the readout information can be accessed from the *Data* tab.

6.1 General Background Using Reference Dosimeter

To record a reference for the lot and apply the reference information to the lot, you must run both the *Read Population Background Reference Dosimeter* and the *Verify Dosimeters Using Population Background Reference* verifications.

Complete the following steps to run the *Read Population Background Reference Dosimeter* process:

-
- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *QA* tab.
- STEP 3:** Click the Start button next to *Read Population Background Reference Dosimeter*.
- STEP 4:** Follow the steps on the screen.
- a. Select dosimeter type: screened or unscreened. (Yes or No in the Screened field.)
 - b. Click to put the cursor in the Dosimeter # field. Scan or enter dosimeter serial number.
 - c. Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
 - d. Click Read.
 - e. Review result and verify that the status is Passed. If not, repeat the test, check the verify threshold on the *Configuration* tab, or use a different dosimeter.
 - f. Enter notes (if applicable).
 - g. Click Complete to save.

The Population Background Reference Dosimeter counts are written to the database and updated in the *Population Background Dosimeter* section on the *QA* tab. The remaining dosimeters in the defined population can now be assigned this background value using the Population Background Reference Dosimeter assignment.

Figure 6-1: Population Background Reference Dosimeter Screen

Complete the following steps to run the *Verify Dosimeters Using Population Background Reference* process:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *QA* tab.
- STEP 3:** Verify the *Population Background Dosimeter* section on the *QA* tab has valid reference information.

Figure 6-2: Population Background Dosimeter Section

- STEP 4:** Click the Start button next to *Verify Dosimeters Using Population Background Reference*.
- STEP 5:** Follow the steps on the screen.
 - a. Select the number of dosimeters to verify.
 - b. Select dosimeter type: screened or unscreened. (Yes or No in the Screened field.)

- c. Click to put the cursor in the Dosimeter # field. Scan or enter dosimeter serial number for each dosimeter to be verified.
- d. Review result, and verify that the status for each dosimeter is Population Passed.
- e. Enter notes (if applicable).
- f. Click Complete to save.

The counts are written to the database. If the data will be used for background corrections, a correction will be made to the background counts to account for the relative sensitivity between the Population Background Reference Dosimeter and the dosimeter being verified.

Population Background Reference Started: 11/17/2013 4:49:52 PM

Step 1: Select number of dosimeters to verify
 Step 2: Select dosimeter type: screened or unscreened
 Step 3: Scan or enter the serial number for each dosimeter to be verified
 Step 4: Review results
 Step 5: Enter testing notes
 Step 6: Click complete to save

Number of Dosimeters to Verify:

Number of Dosimeters Verified:

Screened:

Dosimeter #:

Dosimeter Background Test			
Serial Number	Avg Counts (weak)	Avg Counts (strong)	Status
DN08430871X	44	257	Population Passed
DN083531228	44	257	Population Passed
DN080141781	44	257	Population Passed
DN080203094	44	257	Population Passed
DN080127624	44	257	Population Passed

Verification Threshold (strong beam): 300

Notes:

Figure 6-3: Verify Dosimeters Using Population Background Reference

6.2 Verify Dosimeters Using Individual Background Readings

Complete the following steps to run the *Verify Dosimeters Using Individual Background Readings* process:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *QA* tab.
- STEP 3:** Click the Start button next to *Verify Dosimeters Using Individual Background Readings*.
- STEP 4:** Follow the steps on the screen.
 - a. Select the number of dosimeters to verify.
 - b. Select dosimeter type: screened or unscreened. (Yes or No in the Screened field.)
 - c. Click to put the cursor in the Dosimeter # field. Scan or enter dosimeter serial number to be verified.
 - d. Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
 - e. Click Read.
 - f. Review result and verify that the status for each dosimeter is Passed. If not, discard the dosimeter and select a replacement and run the verification again.
 - g. Enter notes (if applicable).
 - h. Click Complete to save.

The counts are written to the database. If the data will be used for a background correction, the individual background measurement counts will be used in the dose calculation.

Individual Background Readings Started: 2/8/2016 10:39:53 AM

Step 1: Select number of dosimeters to verify
 Step 2: Select dosimeter type: screened or unscreened
 Step 3: Scan or enter the serial number for dosimeter to be verified
 Step 4: Click Read
 Step 5: Review result and verify that the status is Passed. If not, discard dosimeter and select a replacement.
 Step 6: Repeat process for each dosimeter
 Step 7: Enter testing notes
 Step 8: Click complete to save

Number of Dosimeters to Verify:

Number of Dosimeters Verified:

Screened: Yes No

Dosimeter #:

Dosimeter Background Test			
Serial Number	Avg Counts (weak)	Avg Counts (strong)	Status
DB08600406V	7	84	Passed
DB085025210	9	62	Passed
DB091065260	16	142	Passed
DB087020108	10	104	Passed
DB08902508K	13	118	Passed

Readings	
Counts	Beam
13	Week
11	Week
15	Week
129	Strong
177	Strong
48	Strong

Verification Threshold (strong beam): 500

Notes:

Number of dosimeters to verify

Desired number of verifications has been reached.

Figure 6-4: Verify Dosimeters Using Individual Background Readings

CHAPTER 7 DOSIMETRY READS

microSTARⁱⁱ is used to measure the dose for two main categories: Generic (unscreened nanoDots) and Patient (screened nanoDots). Each category includes different reading criteria.

- **Generic:** Typically used for QA or phantom dosimetry applications.
- **Patient:** Typically used for medical dosimetry applications. This category includes enhanced database and reporting features.



CAUTION: If the nanoDot is incorrectly positioned in the reader drawer (e.g., not set in completely or put in with barcode facing down) the reader may be significantly damaged. (See section 3.3 for correct nanoDot positioning.)

The following subsections provide the procedures for performing dosimeter measurements using Generic and Patient categories on a fully-calibrated reader. The instructions provide basic configuration information and values needed for the read procedure. For detailed information about general and advanced configuration, see *Chapter 4 Configuration*.

NOTE: Accurate dosimetry measurements require that a reader calibration has been established using radiation exposure conditions similar to the measurement application radiation energy level, dose level, and geometry, including the presence of overlying material that may attenuate the radiation entering the dosimeter or surrounding material that may cause increased detection of scattered radiation. Calibration is performed as part of the system installation and configuration. For detailed information about reader calibration, see section *9.2 Measurement Calibration*.

7.1 Generic Dosimetry

Generic Dosimetry follows the basic process flow outlined in Figure 7-1 and is not associated with use with patients (refer instead to Section 7.2 Patient Dosimetry).

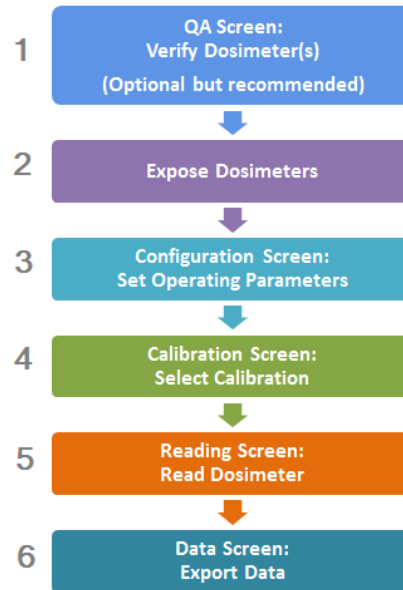


Figure 7-1: Generic Dosimetry Process

STEP 1: Verify Dosimeter

- a. Navigate to the *QA* tab.
- b. Run the Dosimeter Verification Pre-Assignment (if necessary). See *Chapter 5* for details.
- c. Perform Reader Daily QC tests (if necessary). See *section 5.1* for more information.

STEP 2: Expose the Dosimeter(s)

Expose the dosimeter(s) according to the application of interest.

STEP 3: Set Operation Parameters

- a. Navigate to the *Configuration* tab.
- b. Update the following fields:

CONFIGURATION SETTING	CONFIGURATION VALUE
Dosimetry Category	Generic
Dosimetry Use Type	Therapy, Diagnostic or Other (as applicable)
Dose Reading Mode	Average or Individual (as applicable)
Beam Use Mode	Automatic or Force Weak
Reading Repetitions	Four (4) minimum recommended for Average; Operator preference for Individual.

- c. Click the Save button to update the parameters.

STEP 4: Select Calibration

- a. Navigate to the *Calibration* tab.
- b. Click the check box in the *Select* column for the calibration that matches the measurement condition.
- c. Click the Save button to update the calibration used.

STEP 5: Read Dosimeter

- a. Navigate to the *Reading* tab.
- b. Verify the following fields:
 - **Patient Dosimetry Category** value is *Generic*
 - **Current Calibration** selection matches your entry in Step 4
 - **Calibration Use Type** selection matches your entry in Step 4
 - **Daily QC Status** is *Passed* (if necessary)
- c. Enter a Process ID value.
- d. Click to put the cursor in the Dosimeter # field. Scan the dosimeter or enter the serial number.
- e. Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
- f. On the New Dosimeter dialog box, if the nanoDot is a screened nanoDot click Yes to confirm, otherwise click No.
- g. Click the Read button to initiate the readings. A number of sequential readings will be completed (based on your *Reading Repetitions* configuration).

- h. Unselect the Used check box for Outlier Reads, as necessary (see section 7.2.5 for more information).
- i. Click Complete to complete the reading.
- j. Repeat steps d-h for each dosimeter.

STEP 6: Export Data

- a. Navigate to the *Data* tab.
- b. Filter results by the Process ID column to pull your data set.
- c. Click Export button.

NOTE: The data export is available in XLS, PDF, and XML formats. For more information on filtering the report, see section 8.2.

Figure 7-2 shows the *Reading* tab when the system is configured for a Generic read.

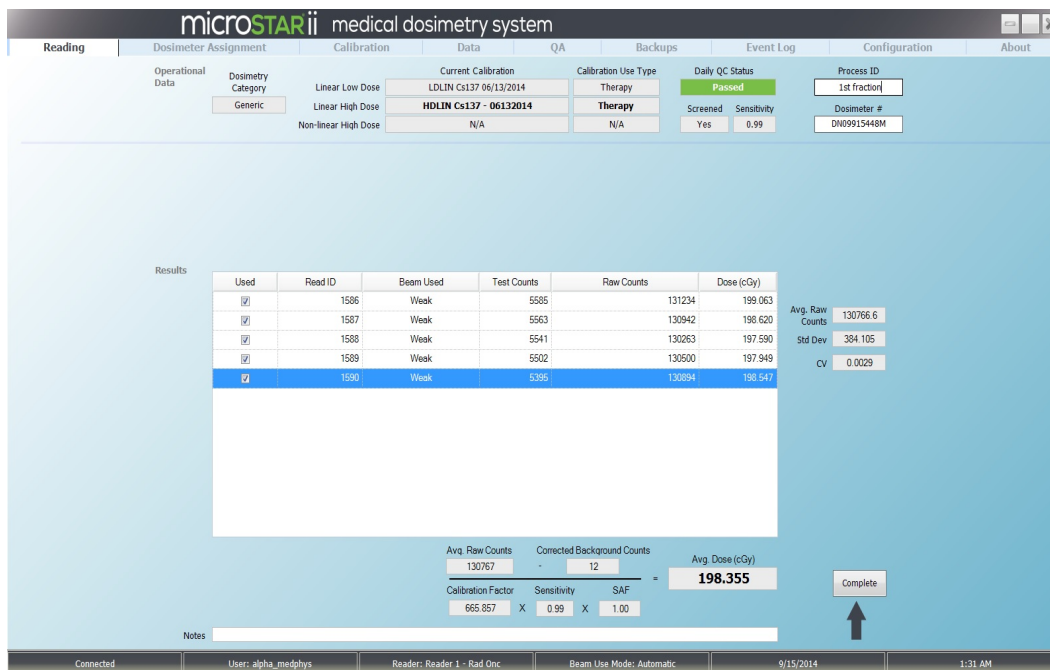


Figure 7-2: Reading Tab (Generic)

7.2 Patient Dosimetry

Patient dosimetry can be broken into two main methods:

1. Radiation Therapy
2. Diagnostic Imaging

Each method has the same process steps, but they differ in the sequence of the process. Figure 7-4 shows the full process flow for both patient dosimetry methods. The *Assign Dosimeter* step occurs at different points based on the method used. For applications when the patient is known in advance, the Radiation Therapy method should be used. If the dosimeter assignment is not known in advance (e.g., dosimeters being sent to a central processing facility) use the Diagnostic Imaging method to assign the dosimeter to a Patient ID after the exposure.

NOTE: If the dosimeter is not assigned to the patient prior to it being entered in for a reading or if you attempt to read a calibration dosimeter, you will receive a message asking you to assign the device. The read options on the screen will be disabled until the dosimeter is assigned.

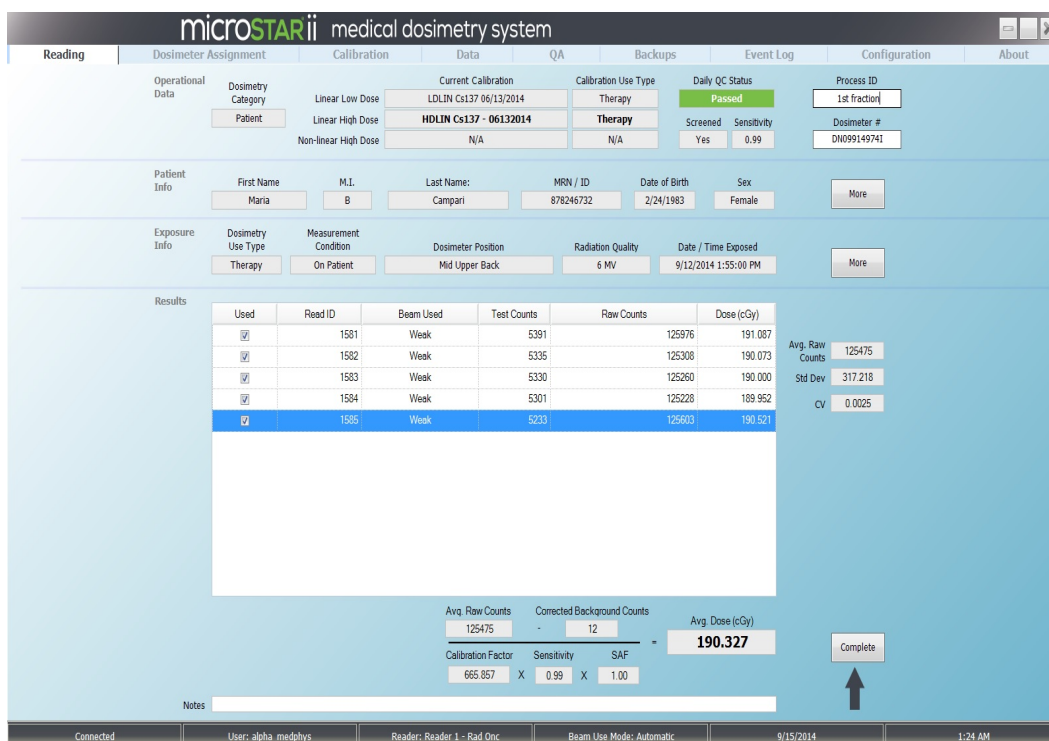


Figure 7-3: Reading Tab (Patient)

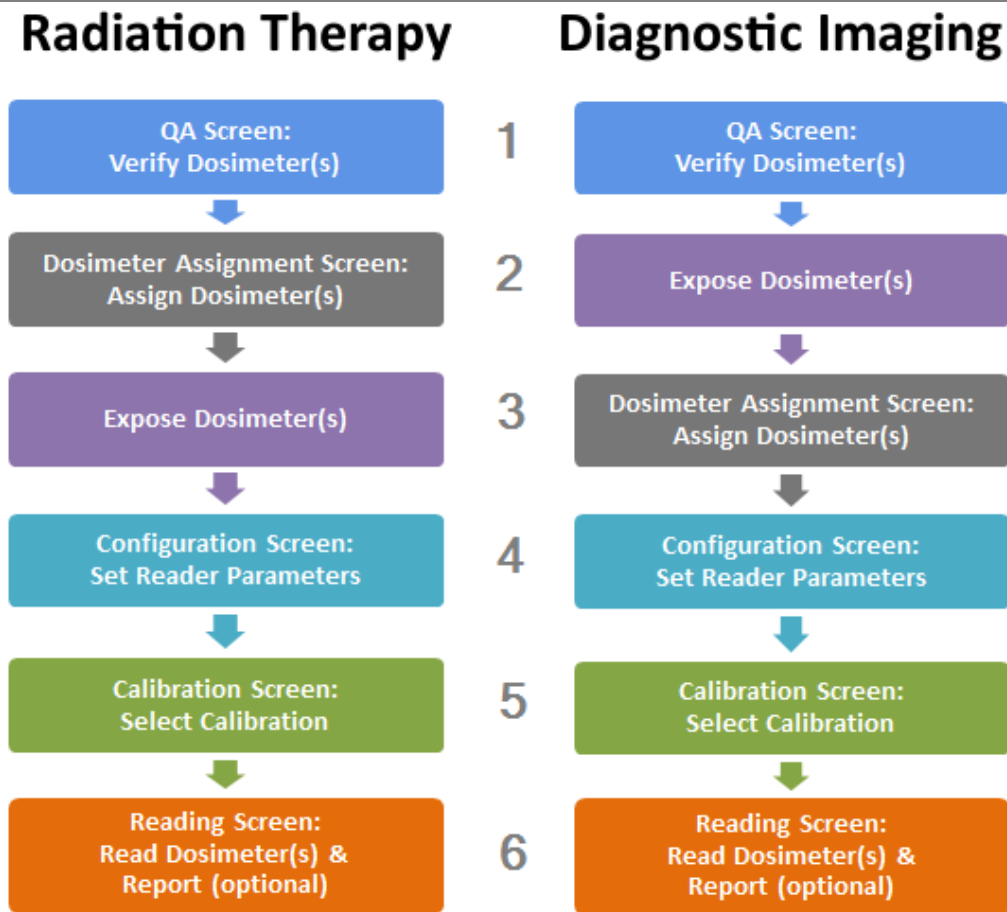


Figure 7-4: Patient Dosimetry

7.2.1 Radiation Therapy

STEP 1: Verify Dosimeter

- Navigate to the *QA* tab.
- Run the Dosimeter Verification Pre-Assignment (if necessary). See *Chapter 5* for details.
- Perform Reader Daily QC tests (if necessary). See section 5.1 for more information.

STEP 2: Assign Dosimeter(s)

Complete the steps in the *Assigning a Dosimeter to a Patient* section.

STEP 3: Expose the Dosimeter(s)

The dosimeter(s) is placed on the patient during a clinical procedure or treatment involving radiation to measure the dose associated with the procedure or treatment.

STEP 4: Set Operation Parameters

- a. Navigate to the *Configuration* tab.
- b. Update the following fields:

CONFIGURATION SETTING	CONFIGURATION VALUE
Dosimetry Category	Patient
Dosimetry Use Type	Therapy or Other (as applicable)
Dose Reading Mode	Average
Beam Use Mode	Automatic or Force Weak
Reading Repetitions	Four (4) minimum recommended
Other	Fill in all other options as required for the dosimetry application and dose range studied (i.e., Non Linear Calibration)

- c. Click the Save button to update the parameters.

STEP 5: Select Calibration

- a. Navigate to the *Calibration* tab.
- b. Click the check box in the *Select* column for the calibration that matches the current clinical measurement condition.
- c. Click the Save button to update the calibration used.

STEP 6: Read Dosimeter

- a. Navigate to the *Reading* tab.
- b. Verify the following fields:
 - **Dosimetry Category** value is *Patient*
 - **Current Calibration** selection matches your entry in Step 5
 - **Calibration Use Type** selection matches your entry in Step 5
 - **Daily QC Status** is *Passed*
- c. Enter a Process ID value.
- d. Click to put the cursor in the Dosimeter # field. Scan the dosimeter or enter the serial number.
- e. Review the *Patient* and *Exposure* Info fields. If there is data missing, click the field to add the information, or click the More button to bring up the Edit screen. Update the information, and click OK to save the changes.

-
- f. Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
 - g. On the New Dosimeter dialog box, if the nanoDot is a screened nanoDot click Yes to confirm, otherwise click No.
 - h. Click the Read button to initiate the reading. A number of sequential readings will be completed (based on your *Reading Repetitions* configuration).
 - i. Unselect the Used check box for Outlier Reads, as necessary (see section 7.2.5 for more information).
 - j. Verify that the CV value is below 0.05 and that the average dose displayed is within the expected range for the type of nanoDot (General Purpose or Screened) and Dose Unit selection.
 - k. Click Complete to complete the reading.
 - l. On the Complete dialog box, select the Complete or Complete and Report option:
 - **Complete** writes the data to the database.
 - **Complete and Report** writes the data to a database and generates a Structured Dose Report. The XML and PDF reports are written to the microSTARⁱⁱ Reports directory, accessed via the *microSTARⁱⁱ Reports* desktop shortcut or at C:\Landauer_Inc\microSTARⁱⁱ Reader\Reports.
 - m. Repeat steps d-l for each dosimeter.
 - n. To see the measurement data in the application, navigate to the *Data* tab. For more information on filtering the report, see section 8.2.

7.2.2 Diagnostic Imaging

STEP 1: Verify Dosimeter

- a. Navigate to the *QA* tab.
- b. Run the Dosimeter Verification Pre-Assignment (if necessary). See *Chapter 5* for details.
- c. Perform Reader Daily QC tests (if necessary). See section 5.1 for more information.

STEP 2: Expose the Dosimeter(s)

The dosimeter(s) is placed on the patient during a clinical procedure or treatment involving radiation to measure the dose associated with the procedure or treatment.

STEP 3: Assign Dosimeter(s)

Complete the steps in the *Assigning a Dosimeter to a Patient* section.

STEP 4: Set Operation Parameters

- a. Navigate to the *Configuration* tab.
- b. Update the following fields:

CONFIGURATION SETTING	CONFIGURATION VALUE
Dosimetry Category	Patient
Dosimetry Use Type	Diagnostic or Other (as applicable)
Dose Reading Mode	Average
Beam Use Mode	Automatic or Force Weak
Reading Repetitions	Four (4) minimum recommended
Other	Fill in all other options as required for the dosimetry application and dose range studied (i.e., Non Linear Calibration)

- c. Click the Save button to update the parameters.

STEP 5: Select Calibration

- a. Navigate to the *Calibration* tab.
- b. Click the check box in the *Select* column for the calibration that matches the current clinical measurement condition.
- c. Click the Save button to update the calibration used.

STEP 6: Read Dosimeter

- a. Navigate to the *Reading* tab.
- b. Verify the following fields:
 - **Dosimetry Category** value is *Patient*
 - **Current Calibration** selection matches your entry in Step 5
 - **Calibration Use Type** selection matches your entry in Step 5
 - **Daily QC Status** is *Passed*
- c. Enter a Process ID value.
- d. Click to put the cursor in the Dosimeter # field. Scan the dosimeter or enter the serial number.

-
- e. Review the *Patient* and *Exposure* Info fields. If there is data missing, click the field to add the information, or click the More button to bring up the Edit screen. Update the information, and click OK to save the changes.
 - f. Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
 - g. On the New Dosimeter dialog box, if the nanoDot is a screened nanoDot click Yes to confirm, otherwise click No.
 - h. Click the Read button to initiate the reading. A number of sequential readings will be completed (based on your *Reading Repetitions* configuration).
 - i. Unselect the Used check box for Outlier Reads, as necessary (see section 7.2.5 for more information).
 - j. Verify that the CV value is below 0.05 and that the average dose displayed is within the expected range for the type of nanoDot (General Purpose or Screened) and Dose Unit selection.
 - k. Click Complete to complete the reading.
 - l. On the Complete dialog box, select the Complete or Complete and Report option:
 - **Complete** writes the data to the database.
 - **Complete and Report** writes the data to a database and generates a Structured Dose Reports. The XML and PDF reports are written to the microSTARⁱⁱ Reports directory, accessed via the *microSTARⁱⁱ Reports* desktop shortcut or at C:\Landauer_Inc\microSTARⁱⁱ Reader\Reports.
 - m. Repeat steps d-l for each dosimeter.
 - n. To see the measurement data in the application, navigate to the Data tab. For more information on filtering the report, see section 8.2.

7.2.3 Patient Account Management

NOTE: Consult with your HIPAA compliance officer to ensure full compliance with regulations for PII handling.

TIP: If you do not see the patient in the listing, use the search function to find the patient record. (Searching by Last Name or MRN/ID is a quick way to pull the patient record.)

Adding a New Patient

Complete the following steps to add a new patient record:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *Dosimeter Assignment* tab.
- STEP 3:** Click the Add Patient button.
- STEP 4:** Enter the patient information in the Patient Info dialog box (Figure 7-5):
- MRN/ID
 - First Name
 - Middle Initial
 - Last Name
 - Date of Birth
 - Age (auto-populates based on Date of Birth)
 - Sex
 - Notes
 - User Defined Fields

User Defined Fields	
Allergies	
Blood Type	
Height	
BMI	

Figure 7-5: Patient Info Dialog Box

- STEP 5:** Click OK to save the patient record.

Editing Patient Information

Patient data can be changed at any time for future reporting. Complete the following steps to edit an existing patient record:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *Dosimeter Assignment* tab.
- STEP 3:** Double-click on the row for the patient record.
- OR**
- Click the row to select, then click the Edit Patient button.
- STEP 4:** Edit the fields in the Patient Info dialog box (Figure 7-5).
- STEP 5:** Click OK to save the changes.

Deleting Patient Information



CAUTION: Patient demographic database entries should only be deleted when the patient did not have a dosimetry measurement or if the data has been exported or transferred to a separate database. Deleting patient records after a dosimeter readout will permanently remove the associated dosimetry record from the database. In order to restore the information, you would have to restore the backup from that point in time.

Complete the following steps to delete existing patient record:

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *Dosimeter Assignment* tab.
- STEP 3:** Click the row of the patient record to select, and click the Delete Patient button.
- STEP 4:** Click OK on the confirmation prompt.

7.2.4 Dosimeter Assignment

Dosimeter patient assignments are managed on the *Dosimeter Assignment* tab.

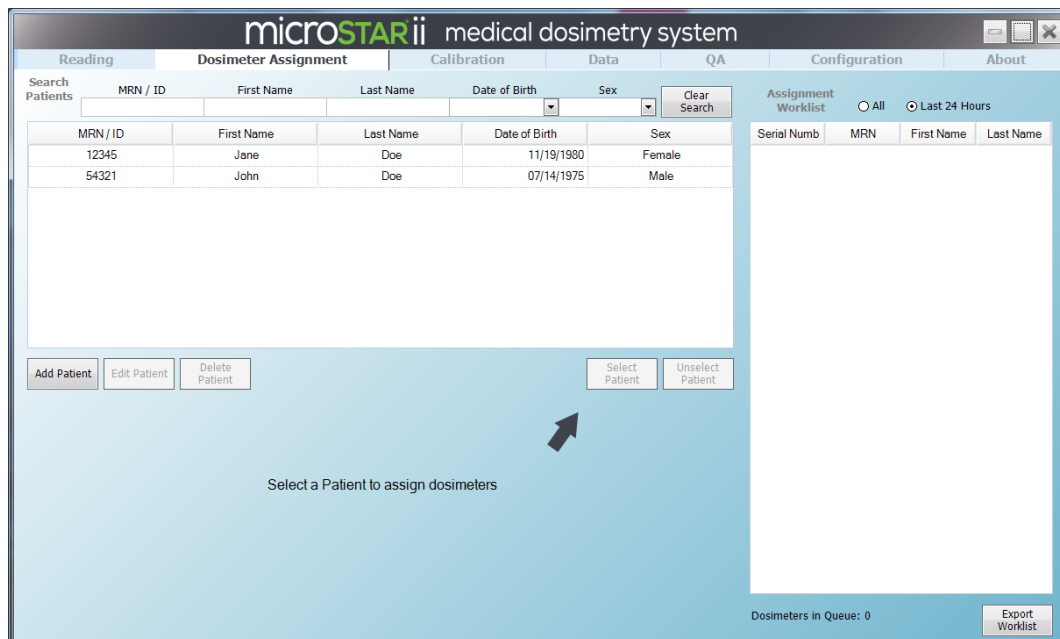


Figure 7-6: Dosimeter Assignment

Assigning a Dosimeter to a Patient

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *Dosimeter Assignment* tab.

- STEP 3:** Click to highlight the patient row. (If the patient is not in the database, follow the instructions in the *TIP: If you* do not see the patient in the listing, use the search function to find the patient record. (Searching by Last Name or MRN/ID is a quick way to pull the patient record.)
- STEP 4:** Adding a New Patient section.)
- STEP 5:** Click the Select Patient button. The *Dosimeter ID* section will be displayed.

Serial Number	Status	Position on Patient
DN074260076	Assignment Pending	
DN07413224B	Assignment Pending	
DN074070186	Assignment Pending	

Figure 7-7: Dosimeter Assignment - Dosimeter ID Section

- STEP 6:** Enter in the Required Dosimeter Count (number of dosimeters that will be assigned to this patient).
- STEP 7:** Click to put the cursor in the Enter Dosimeter Serial Number field. Enter in the serial number or scan in each dosimeter. The dosimeters will be listed as Assignment Pending.
- STEP 8:** Double-click on the row for each dosimeter line item.
- OR**
- Click to select, and click the Edit Assignment button.
- STEP 9:** In the Exposure Info dialog box:
- Dosimetry Category:** Verify that the value is Patient.
 - Dosimeter Use Type:** Select the application type (Diagnostic, Therapy, or Other).
 - Other Fields:** Optional
- STEP 10:** Click OK to save changes.
- STEP 11:** Complete Steps 7-9 for all Assignment Pending dosimeters.
- STEP 12:** Click the Update Assignment button.
- STEP 13:** Click OK on the confirmation prompt to update the assignments and include them on the Assignment Worklist.

NOTE: Patient Information and Exposure Information for assigned dosimeters (even those in the worklist) can be edited or added at any time on the Reading Screen prior to initiating the dosimeter reading.

All assigned dosimeters appear on the Assignment Worklist. This worklist tracks all dosimeters that have not been read. This report can be used to confirm the accuracy of the Patient or Exposure Information against other information systems prior to dosimeter readout. (For more information, see section *8.1.1 Assignment Worklist*.)

Editing Assigned Dosimeters

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
 - STEP 2:** Navigate to the *Dosimeter Assignment* tab.
 - STEP 3:** Click to highlight the row for the patient.
 - STEP 4:** Click the Select Patient button. The *Dosimeter ID* section will be displayed (Figure 7-7).
 - STEP 5:** Double-click on the row for each dosimeter line item.
- OR**
- Click to select, and click the Edit Assignment button.
 - STEP 6:** Edit the Exposure Info in the dialog box.
 - STEP 7:** Click OK to save changes.

Deleting Assigned Dosimeters

- STEP 1:** Log on to the microSTARⁱⁱ application with an Operator or Advanced Operator account.
- STEP 2:** Navigate to the *Dosimeter Assignment* tab.
- STEP 3:** Click to highlight the row for the patient.
- STEP 4:** Click the Select Patient button. The *Dosimeter ID* section will be displayed (Figure 7-7).
- STEP 5:** Click to highlight the dosimeter, and click the Remove Assignment button.
- STEP 6:** Click OK on the confirmation prompt.

7.2.5 Modifying Results

Omitting Outlier Readings

In the *Average* dose reading mode (in the *Set Operation Parameters* step of both Generic and Patient Dosimetry), you can omit outlier, or irregular, measurements, while a reading session is in progress.

All acquired readings have their Used check box selected by default. To omit an Outlier Reading, clear the check box next to that individual reading. The reported dose, which dynamically updates as readings are acquired, is automatically recomputed whenever any individual reading's Used status changes.

Background Correction

Dosimeters may be exposed to a background dose from natural background radiation during transportation or storage or exposure to radiation from other sources in the medical environment. The dose calculation formula on the *Reading* tab corrects for this additional dose. The dose is determined using the Dosimeter Verification Pre-Assignment function. To set the value, use the instructions in Chapter 5.

To turn on this feature, complete the following steps:

- STEP 1:** Log on to the microSTARⁱⁱ application (all three default profiles have the necessary permissions).
- STEP 2:** Navigate to the *Configuration* tab.
- STEP 3:** Select the check box next to *Use Dosimeter Background Correction*.
- STEP 4:** Click the Save button to commit the changes.

NOTE: Enabling this setting automatically enables the Force Dosimeter Preassignment Verification compliance check. (See section *4.2.5 System Compliance Checks* for more information.)

CHAPTER 8 REPORTING

8.1 Available Reports

REPORT	DESCRIPTION
Assignment Worklist	Listing of all unread assigned dosimeters (PDF, XLS, and XML)
Calibration Data	Spreadsheet containing an export of the calibration information from the <i>Calibration</i> tab
microSTAR ⁱⁱ Control Limit Test Report	Output from the Reader QC Test – Verify/Establish QC Control Limits (PDF, XLS, and XML)
microSTAR ⁱⁱ Daily QC Test Report	Output from the Reader Daily QC Tests (PDF, XLS, and XML)
Sensitivity Assessment	Results of the Sensitivity Assessment test (XLS)
Structured Dose Report	An individual report for a patient dosimeter measurement (XML and PDF)

8.1.1 Assignment Worklist

The Assignment Worklist is shown on the *Dosimeter Assignment* tab (Figure 7-6). Assigned dosimeters shown in the worklist are those which have not completed their use cycle, (i.e., have not yet been read).

Use the *All* and *Last 24 Hours* radio buttons to filter the worklist. The default setting is Last 24 Hours. If you need to see information beyond that range, select the *All* radio button.

As dosimeters are read on the *Reading* tab they will be removed from list, which makes the Assignment Worklist a useful tool to manage dosimeter workflow and tracking electronically. This report can be exported for manual tracking and to confirm the accuracy of the Patient or Exposure information against other information systems prior to dosimeter readout.

To export the worklist, complete the instructions below:

-
- STEP 1:** Log on to the microSTARⁱⁱ application as an Operator or Advanced Operator.
 - STEP 2:** Navigate to the *Dosimeter Assignment* tab.
 - STEP 3:** Click the Export Worklist button. The export is saved to C:\Program Files\LandauerInc\microSTARⁱⁱ Reader\Reports

8.1.2 Calibration Data Export

The calibration data from the *Calibration* tab can be exported into a spreadsheet to support calibration documentation and provide verification.

To export the calibration data, complete the instructions below:

- STEP 1:** Log on to the microSTARⁱⁱ application as an Operator or Advanced Operator.
- STEP 2:** Navigate to the *Calibration* tab (Figure 9-2).
- STEP 3:** Click the Export button.
- STEP 4:** Enter a filename and location for the XLS file.
- STEP 5:** Click Save to save the export.

8.1.3 microSTARⁱⁱ Control Limit Test Report

After a *Verify/Establish QC Control Limits* test is run, the microSTARⁱⁱ Control Limit Test Report (PDF, XLS, and XML versions) is saved to C:\Program Files\LandauerInc\microSTARⁱⁱ Reader\Reports. It includes the results for all 20 reads, the final values, the test results (pass/fail), and if the Control Limits were updated based on the results.

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MicroSTARⁱⁱ Control Limit Test Report

Date / Time of Test: 09/23/2013 06:00:54 PM
Reader: DEFAULT
Test Performed by: alpha_medphys

High Precision Intrinsic Measurement Test Control Limits Updated: Yes

Reading	Dark Counts	PMT Counts	P-Diode Counts
1	12	17501	1105
2	11	17334	1113
3	9	17475	1100
4	9	17321	1121
5	10	17224	1111
6	9	17350	1098
7	12	17236	1094
8	13	17308	1084
9	10	17216	1107
10	8	17483	1093
11	13	17172	1083
12	10	17098	1079
13	13	17073	1102
14	8	17386	1093
15	11	17278	1102
16	9	17112	1094
17	9	17222	1083
18	14	17220	1085
19	13	17267	1099
20	10	17084	1085
Min	8	17088	1079
Max	14	17501	1121
CTRL-LL	0	16403	1042
CTRL-UL	20	18130	1151
AVG	10.650	17266.500	1096.550
STDEV	1.872	131.459	11.413
CV	0.176	0.008	0.010
Test Result	PASSED	PASSED	PASSED

Comments:

Signature of Reviewer: _____ Date Reviewed: _____

IMPORTANT NOTE: Reader Control Limits should only be changed when justified, i.e. after reader repair or preventative maintenance consistent with QA "Best Practices".
Contact Landauer Customer Service at 1-800-561-2708 if reader Daily QC results exceed Control Limits.

Figure 8-1: Example Control Limit Test Report (PDF)

8.1.4 microSTARⁱⁱ Daily QC Test Report

After both steps for the Reader Daily QC Tests are run, the microSTARⁱⁱ Daily QC Test Report (PDF, XML and XLS versions) is saved to C:\Program Files\LandauerInc\microSTARⁱⁱ Reader\Reports. It includes the results for all cycles/reads, the final values, and the test results (pass/fail).

MicroSTARⁱⁱ Daily QC Test Report

Date / Time of Test: 06/22/2014 12:08:03 PM
Reader: Reader 1 - Rad Onc
Test Performed by: alpha_medphys

STEP 1: Daily Intrinsic Measurement Test

Reading	Dark Counts	PMT Counts	P-Diode Counts
1	3	8220	1030
2	3	8071	1025
3	2	8237	1005
4	4	8185	1028
5	1	8128	1042
Min	1	8071	1005
Max	4	8237	1042
CTRL-LL	0	7548	956
CTRL-UL	20	8343	1057
AVG	2.600	8168.200	1026.000
STDEV	1.140	68.489	13.398
CV	0.439	0.008	0.013
Test Result	PASSED	PASSED	PASSED

STEP 2: Reading Reproducibility Test

Reading	Element Counts
1	65402
2	65341
3	64998
4	65054
5	64780
6	64972
7	64994
8	64849
9	64489
10	64709
AVG	64958.801
STDEV	275.208
CV	0.004
Test Result	PASSED

Comments:
Signature of Reviewer: _____ Date Reviewed: _____

IMPORTANT NOTE: Reader Control Limits should only be changed when justified, i.e. after reader repair or preventative maintenance consistent with QA "Best Practices".
Contact Landauer Customer Service at 1-800-563-2709 if reader Daily QC results exceed Control Limits.

Figure 8-2: Example Daily QC Test Report (PDF)

8.1.5 Sensitivity Assessment

After the Sensitivity Assessment is completed (section 9.4.3), a report will be produced showing the following information:

nanoDot Population Statistics

- Labeled Sensitivity Range
- % Difference in Labeled vs Adjusted Sensitivity (Min, Max, Avg)

nanoDot Population Statistics	Labeled Sensitivity Range	% Difference in Labeled vs Adjusted Sensitivity		
	0.79 to 0.96	Min	Max	Avg
		-2.62 %	4.39 %	1.62 %

Figure 8-3: nanoDot Population Statistics

Selected nanoDot Data

- Serial Number
- Labeled Sensitivity
- Adjusted Sensitivity
- % Difference
- New SAF*
- SAF* Lookup (current SAF if custom value saved)

Selected nanoDot Data	Serial Number	Labeled Sensitivity	Adjusted Sensitivity	% Difference	New SAF*	SAF* Lookup
	DB082070614	0.82	0.836	1.95 %	1.020	None

Figure 8-4: Selected nanoDot Data

Additional nanoDot Information

- Case Serial Number
- Reader Name
- Read By
- Read Date Time
- Used
- E1_Counts
- E1_Counts_Corrected
- Calibration ID
- Deep Dose
- Avg Dose
- Stdev
- CV

CaseSerialNumber	ReaderName	ReadBy	ReadDateTime	Used	E1_Counts	E1_Counts_Corrected	CalibrationID	DeepDose
DB082070614	1604	Tester	08/10/2014 08:14 PM	<input checked="" type="checkbox"/>	108428	132229.269	17	203.430
DB082070614	1604	Tester	08/10/2014 08:14 PM	<input checked="" type="checkbox"/>	108894	132797.562	17	204.304
DB082070614	1604	Tester	08/10/2014 08:14 PM	<input checked="" type="checkbox"/>	108634	132480.489	17	203.816
DB082070614	1604	Tester	08/10/2014 08:14 PM	<input checked="" type="checkbox"/>	108766	132641.465	17	204.064

Figure 8-5: Readings Information

Avg Dose	203.903	Stdev	0.373	CV	0.002
----------	---------	-------	-------	----	-------

Figure 8-6: Summary Information

The exported XLS includes four worksheets:

1. **Info** contains the overall population information including the minimum, maximum, and average % difference between labeled and adjusted sensitivity.
2. **Summary Report** lists the sensitivity assessment results for each dosimeter including the percent difference between labeled and Corrected or Adjusted Sensitivity.
3. **Data** contains all the reading data for the nanoDot population.
4. **Calibration** identifies the calibration data and calibration factor used in the calculation of dose for dosimeters in the test population.

8.1.6 Structured Dose Report

A Structured Dose Report (SDR) contains information about a patient dosimetry Read. It includes:

- Organization Information
- Date/Time of Report
- Patient Information
- Dosimeter Information
- Exposure Conditions
- Results
- Comments
- Signature Field

This report is generated during the Patient Dosimetry reading. When the read is complete, click the Complete and Report button on the Complete confirmation prompt to generate the report. (For more information, see section *7.2 Patient Dosimetry*.)

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MicroSTARⁱⁱ Patient Dosimetry Quality Assurance Report	
Date / Time of Report: 08/20/2015 01:57:52 PM	
<u>Patient</u>	
Last Name: Doe	
First Name: Jane	
Middle Name: A	
MRN: 9999999999	
Sex: Female	
Date of Birth: 10/26/1941	
<u>Dosimeter</u>	
Serial #: DN074260076	
Screened: True	
<u>Exposure Conditions</u>	
Position on Patient: Lt. Lower Back	
Depth (cm): N/A	
Buildup Used: N/A	
Buildup Thickness (cm): N/A	
Buildup Material: N/A	
Field Size (cm): 10 x 10	
SSD (cm): 105.0	
Date / Time of Exposure: 08/19/2015 11:00:00 AM	
Radiation Quality: 6MV	
<u>Results</u>	
Date / Time of Reading: 08/20/2015 11:00:02 AM	
Measured Dose (cGy): 204.595	
Prescribed Dose (cGy): 100.0	
Percentage Dose Delivered: 204.59%	
Comments:	
Name of Medical Physicist Reviewer (Print Clearly) _____	
Signature of Medical Physicist Reviewer _____	
Date Reviewed _____	
IMPORTANT DISCLAIMER: This dose report is provided to assist with verification of results obtained via primary dosimetry systems, consistent with medical dosimetry QA and "best practices". As such, patient care decisions must not be driven by the results reported herein.	

Figure 8-7: Example SDR



This report can be used to support third-party reimbursement for dosimetry services. It can also be used as a mechanism to record the dosimetry data into the patient's Electronic Medical Record for documentation purposes.

8.2 Report Filtering

8.2.1 General Information

Table data on each tab can be sorted in ascending and descending order by clicking on the column header. Columns can be arranged by clicking and dragging the column to the desired location.

8.2.2 Icons

ICON	DESCRIPTION
	The Column Picker allows you to customize the columns visible in the table.
	The Clear Filters button clears the filters set for all columns (button at the beginning of the row) or the specific column (button in each column filter field).

8.2.3 Advanced Filters

The data sets on the following tabs can be filtered based on complete/partial text:

- Dosimeter Assignment**
 The dosimeter assignment patient information table can be filtered. (The search fields do not include UDF.)
- Data**
 All data columns can be filtered based on text or predefined filters based on existing content. All report data can be filtered by Report Type, Reader, and Date Range.

NOTE: In order to use the date range filter, select the Custom radio button.

- Event Log**
 All event columns can be filtered based on text or predefined filters based on existing content.

The Data and Event Log filters support the following search criteria:

1. Selective inclusion/exclusion of logical condition data by True or False status
2. Selective inclusion/exclusion of any data value for a specific attribute from search result
3. Text-based filters (includes: = , ≠ , contains, begins with, ends with)
4. Number-based filters (includes: = , ≠ , > , ≥ , < , ≤)
5. Advanced text- and number-based filters that can combine basic text or number filter criteria in an AND/OR logical framework

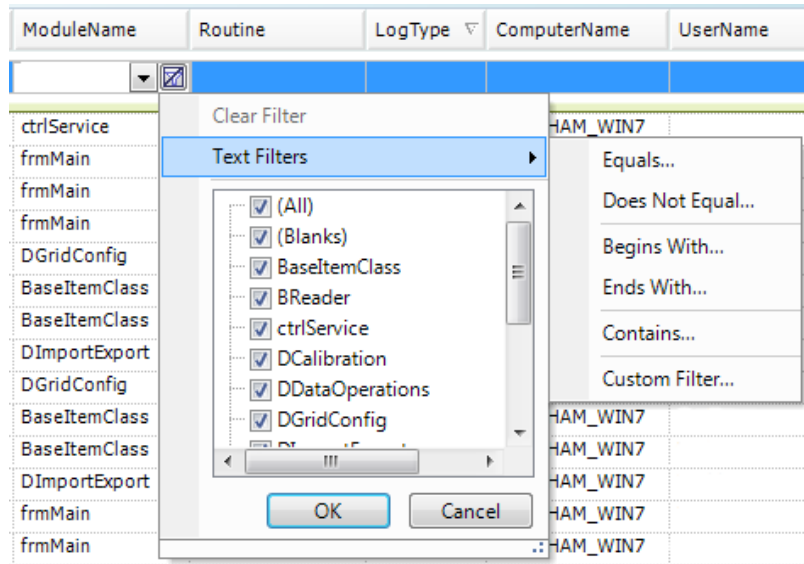


Figure 8-8: Text Filter Menu

8.2.4 Data Template

On the *Data* tab, you can save a report template for custom column order/visibility, filters, and other settings.

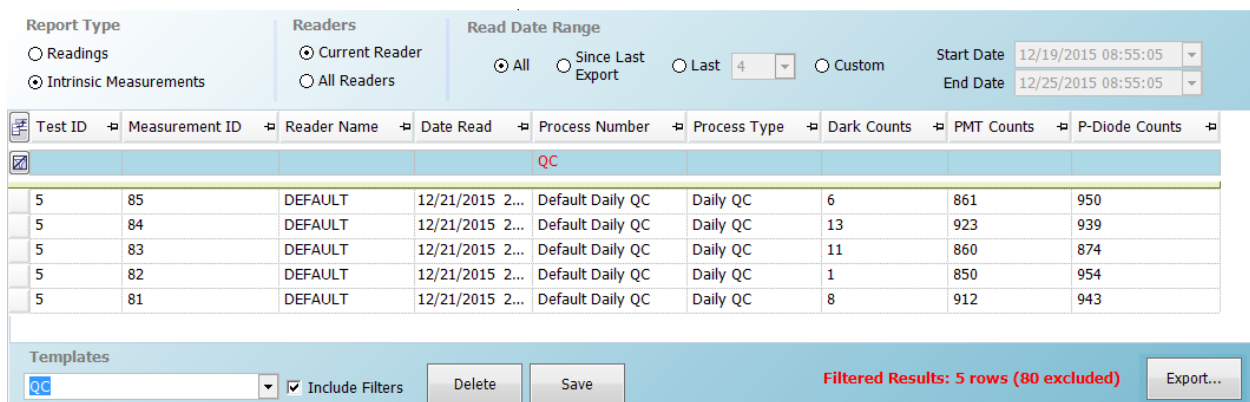


Figure 8-9: Data Report Template

To create a template, complete the following steps:

-
- STEP 1:** Log on to the microSTARⁱⁱ application as an Operator or Advanced Operator.
- STEP 2:** Navigate to the *Data* tab.
- STEP 3:** Customize the report using filters and search criteria.
- STEP 4:** Enter a template name in the *Templates* field at the bottom of the screen (Figure 8-9).
- STEP 5:** If you want to save the formatting and do not want column filters included, unselect the check box next to *Include Filters*.
If you want to save the formatting and all column filters, select the check box next to *Include Filters*.
- STEP 6:** Click the Save button.

To delete a template, complete the following steps:

- STEP 1:** Log on to the microSTARⁱⁱ application as an Operator or Advanced Operator.
- STEP 2:** Navigate to the *Data* tab.
- STEP 3:** Select the template in the *Templates* dropdown menu.
- STEP 4:** Click the Delete button and confirm deletion.

CHAPTER 9 ADVANCED OPERATIONS

The following subsections provide information on advanced operations of microSTARⁱⁱ. This includes information about Linear/Non-Linear ranges, general calibration, creating simulated calibrations, and calculating and applying Sensitivity Adjustment factors. These procedures should only be completed by advanced users. The associated permissions must be assigned in order to complete these operational tasks.

9.1 Changing Read Type (Linear and Non-Linear)

While the site read type (i.e., Linear or Non-Linear) is generally static and configured upon installation, in more complex operations or after a change in operations, you may find it necessary to change your read type calibration from Non-Linear to Linear or vice versa.

Linear read ranges are the standard use range. Linear reads apply to most applications.

Non-Linear read ranges are used for high reads to compensate for OSL super-linearity above 300cGy and PMT saturation above 50Gy. It is common in 6 MV therapy applications. For therapy applications where the dose is expected to be greater than 300 cGy, a Non-Linear calibration is required.

To change the read calibration type, navigate to the *Configuration* tab and select/unselect the *Non Linear Calibration* check box.

When you change the read range, the *Calibration* tab will change to reflect the options available for that type:

Linear Calibration

- ✓ Will **only** show calibrations configured for Linear read conditions. (Non-Linear calibrations will not show up in the listing.)
- ✓ Will show a single Calibration Factor value (CalibFactor column).

Non-Linear Calibration

- ✓ Will only show all calibrations configured for Non-Linear read conditions. (Linear calibrations will not show up in the listing.)
- ✓ Will include three Calibration Factor columns: CalibFactor A, CalibFactor B, and CalibFactor C.

9.2 Measurement Calibration

The microSTARⁱⁱ Medical Dosimetry System employs a relative dose calculation method. This calculation is based on reader response characterization using reference dosimeters that have been irradiated at known exposed dose levels, spaced evenly across the required dose range. The dosimeters are exposed under controlled conditions using a radiation spectrum and exposure geometry close to that of the intended application and in which the delivered dose is known to a high degree of accuracy.

The reader calibration factors are calculated by reading the calibration dosimeters on the *Calibration* tab of the microSTARⁱⁱ software. These factor(s) are applied to convert raw PMT counts to dose when reading test dosimeters.

NOTE: microSTARⁱⁱ has four default calibrations included (two Linear and two Non-Linear), *Factory Default Calib*. These are **not for clinical use**. They are database placeholders.

Calibrations are performed in the following cases:

- ✓ As part of installation and configuration of the system
- ✓ After major system maintenance/changes
- ✓ During troubleshooting or system diagnostics
- ✓ Annually as part of routine maintenance

Calibrations are performed using one of the two types of calibration dosimeters (calsets):

1. LANDAUER-Manufactured

LANDAUER ships a calset with the microSTARⁱⁱ that includes common dose ranges (80 kVp or 662 keV, or other non-standard energies depending on customer application). This set is primarily used for system performance monitoring.

2. Custom (Manufactured by the Customer)

Dosimeters irradiated by the customer to meet specific known doses for therapy and other clinical applications. These sets mirror the conditions of the operational environment.

NOTE: All LANDAUER-manufactured calsets provide a baseline for 80 kVp, 662 keV, or other exposure conditions. A custom calset will mirror the conditions in your facility. To create a custom calset, irradiate screened nanoDots using the exposure conditions in your environment.

The following table provides a guideline for custom calsets exposure levels.

RECOMMENDED CUSTOM CALSET EXPOSURE	
<i>Doses in cGy</i>	
Linear Calibration (Beam Use Mode: Automatic)	
Low Dose Linear Range (<15 cGy)	unexposed, 5 cGy, 10cGy
High Dose Linear Range (>15 cGy)	50, 100, 200 cGy
Linear Calibration (Beam Use Mode: Force Weak)	
High Dose Linear Range (>1cGy)	10, 50, 100, 200 cGy
Non-Linear Calibration	
High Dose Non-Linear Range (300-1500 cGy)	50, 100, 300, 500, 800, 1000, 1500 cGy
<i>Note: The benefits of the Linear Calibration using force weak mode are that you only have to perform a single calibration and the reader will be operated using the weak beam, which is associated with lower depletion rates.</i>	

When performing calibrations, use the following best practices:

- ✓ The Beam Use Mode setting on the *Configuration* tab must be *Automatic*.
- ✓ At least three dosimeters must be exposed at each dose level to ensure an accurate characterization of reader response that is not biased by individual dosimeter sensitivity labeling and reader linearity.
- ✓ At least four measurements should be taken on each calibration dosimeter.
- ✓ The reader must be re-calibrated after repair or preventive maintenance and new Control Limits for the Intrinsic Measurement metrics should be established. (See section 5.2 *Reader QC Tests* for information on setting new control limits.)

- ✓ After a calibration is performed it must be verified by acquiring measurements using dosimeters that have been exposed to known dose levels. Perform a measurement on the *Reading* tab with the QC set dosimeters. A comparison of the known dose to measured dose is performed. If they match (within $\pm 5.5\%$), the calibration is deemed acceptable for use. (See section *Chapter 7 Dosimetry Reads* for more information on performing a read.)

9.2.1 Calibration Considerations

The energy dependence of aluminum oxide at the radiation energy level of interest will define or limit the range over which a calibration of the reader performed at a specific radiation energy will be useful. Figure 9-1 shows the relative response of the nanoDot through a wide energy range.

For example, the small energy dependence in the Megavoltage (MV) range permits a calibration at a reference condition (typically 6 MV), which can then be used across a broad range (6-20 MV) of Megavoltage photon or electron energies while still maintaining a high degree of accuracy. In the diagnostic range by comparison, a calibration at 80 kVp is valid for a narrower range of applications due to the strong energy dependence in this region. However, the requirements for accuracy in diagnostic imaging are typically not as high as in radiation therapy applications, so the choice of calibration reference condition and the range over which this condition would be appropriate is based on organization accuracy requirements. The following are known to be limiting factors in the diagnostic energy range and should be considered when determining calibrations: OSL energy dependence, angular dependence, exposure geometry, and attenuation and scatter effects.

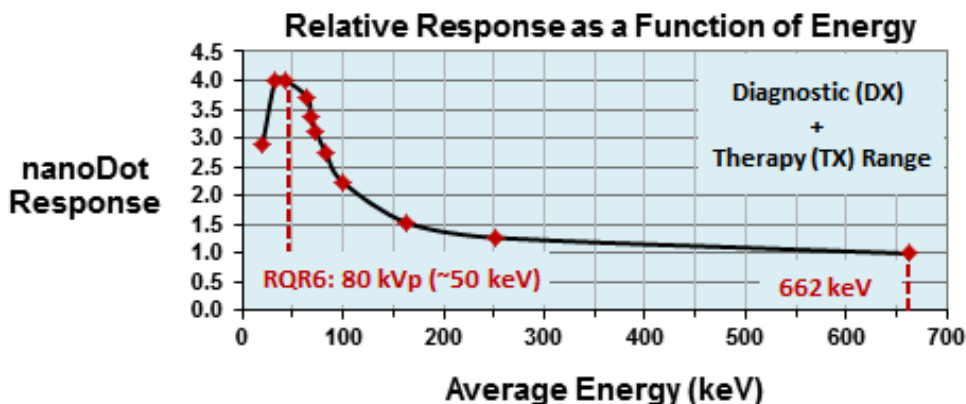


Figure 9-1: Energy Response (Diagnostic & Therapy Range)

9.2.2 Performing a System Calibration

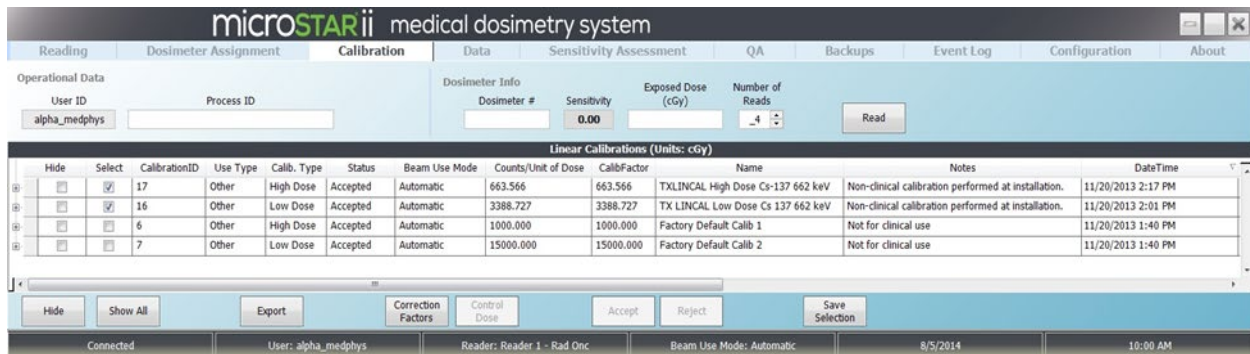


Figure 9-2: Calibration Tab

To perform a new calibration, use the following procedure. The general procedure is the same for all calibrations (LANDAUER-manufactured calsets, custom calsets, Linear, and Non-Linear). The configuration settings defined in Step 2 determine the type of calibration being performed (e.g., Dose Units and Linear vs. Non-Linear).

- STEP 1:** Log on to the microSTARii application as an Operator or Advanced Operator.
- STEP 2:** Navigate to the *Configuration* tab, and verify the following values for the settings listed:

CONFIGURATION SETTING	CONFIGURATION VALUE
Dose Units (Radio Button)	LANDAUER-Manufactured: mrad
	Custom Calset: Typically cGy for radiation therapy applications
Non-Linear Calibration (Check Box)	Linear Calibration: Unselected Check Box
	Non-Linear Calibration: Selected Check Box
Beam Use Mode (Radio Button)	Automatic
Force Calibration Hardware Settings Match (Check Box)	Selected

- STEP 3:** Click Save button to commit changes, if any.
- STEP 4:** Navigate to the *Calibration* tab.
- STEP 5:** Sort the calibration dosimeters in dose order.
- STEP 6:** Enter a unique name in the Process ID field.

-
- STEP 7:** Complete the following steps for each dosimeter:
- a. Click in the Dosimeter # field. Scan an unread dosimeter from the set or enter the serial number into the Dosimeter # field. The Sensitivity field will automatically update. (It should match the number printed on the top of the nanoDot, *DN###*.) *See section 2.1.3 for label information.*
 - b. Fill in Exposed Dose Field (if not automatically populated).
 - **LANDAUER-Manufactured:** Enter the dose value from the LANDAUER Calibration Certificate into the Exposed Dose field.

NOTE: Do not enter the nominal dose value reflected on the dosimeter clear plastic bag label; use the Shallow Dose Equivalent (SDE) for each dosimeter shown on the Calibration Certificate. For unexposed dosimeters enter 0.0.

 - **Customer-Manufactured:** Enter in the known dose from customer exposure.
 - c. Enter the Number of Reads value. (2-5 reads can be completed, 4 are recommended.)
 - d. Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (See Figure 3-2 for correct nanoDot positioning.)
 - e. Click the Read button to run a series measurements.
 - f. Repeat steps a-e for each dosimeter.

- STEP 8:** After all dosimeters have been read, review all of the calibration data to ensure the displayed dose levels are correct and reflected in the correct dose units. If necessary, omit any inconsistent or outlier readings by unselecting the Used check box for that result.

Verify the following for the results:

- a. The CV across all sensitivity-corrected counts for each dose level are within acceptable limits (≤ 0.05 is recommended).
- b. For a specific dose range, only doses corresponding to that dose range are included in the calibration data group.

- STEP 9:** For each new calibration,
- a. **To accept the calibration**, select the Pending calibration, and click the Accept button.
 - b. **To reject the calibration**, select the Pending calibration, and click the Reject button.

NOTE: The calibration should be rejected if the STDEV is greater than the acceptable limit (e.g., 0.05) or if you are using the same beam and geometry as the current configuration, but the calibration factor is significantly different than the previous calibrations (e. g. greater than 5%). Reject the calibration, resolve the issue, and run the calibration again.

- STEP 10:** Fill in the values on the Calibration dialog box, and click OK to confirm.
- a. Cs-137 Calibration Use Type: Other
 - b. 80 kVp Calibration Use Type: Diagnostic
 - c. Custom Calibration Use Type: Therapy

9.3 Simulated Calibrations

Simulated calibrations are pairs of strong and weak beam calibrations created based on existing calibrations that were created using the LANDAUER-provided NIST-traceable sets or customer-manufactured sets. Simulated calibrations can be created if you do not have a full calibration set with the desired exposure properties. If you do not have a controlled way to deliver an exposure at the desired energy setting in your facility or cannot create a full calibration set, simulated calibrations can be used. Simulated calibrations are not recommended for use in therapy applications.

NOTES:

You cannot make a simulated calibration from another simulated calibration. Simulations can only be created from measured calibrations using dosimetry measurements.

Both a strong and weak beam version must be created for each simulated calibration.

Complete the following steps to create simulated calibrations:

- STEP 1:** Log on to the microSTARⁱⁱ application as an Operator or Advanced Operator.
- STEP 2:** Navigate to the *Calibrations* tab.
- STEP 3:** Click the gray box to the left of the High Dose Calibration to be simulated to select the entire row.
- STEP 4:** Click the Correction Factors button to create a simulated calibration for the reader. Fill in the values on the *Create New Calibration* dialog box.

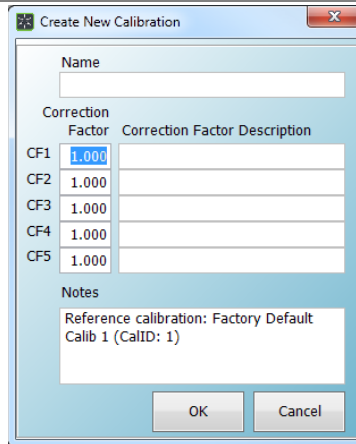


Figure 9-3: Create New Calibration Dialog Box

STEP 5: Click OK to save the simulated calibration. The new calibration will automatically be selected and the calibration factors will be highlighted in yellow when approved.

STEP 6: Select the Low Dose Calibration to be simulated. Repeat Steps 4 & 5.

9.4 Sensitivity Adjustment Factor Values



CAUTION: The implementation of the SAF is a custom feature and is not recommended for routine medical dosimetry applications. LANDAUER precisely determines the sensitivity value in controlled conditions. If the SAF is implemented, the LANDAUER-determined sensitivity assignment is voided.

NOTES:

The SAF correction factor is only supported in **Linear** dose calculations.

If you are experiencing an issue with the sensitivity of your nanoDots, contact LANDAUER for assistance (See section 12.1 for contact information).

The *Sensitivity Assessment* tab features are used to assess the sensitivity for each nanoDot in a test population that has been exposed to a precisely known dose. The re-computed sensitivity is referred to as the Measured Sensitivity (S_m) or Adjusted Sensitivity (S_{corr}) and is given by $S_m = S_{adj} = S_{lab} * SAF$, where SAF is the Sensitivity Adjustment Factor (SAF).

The SAF is the conversion factor, which when multiplied with the labeled sensitivity value results in a corrected sensitivity. From the assessment, a new SAF can be saved.

By default the microSTARⁱⁱ system operates with a SAF value of 1.0 for each dosimeter using a Linear dose calculation formula that shows a default SAF value of 1.0. The SAF for each dosimeter in a population can be evaluated computationally, and a report can be generated without modifying the existing SAF value stored in the database.

9.4.1 Test Conditions

For a valid sensitivity assessment, the test must be run in the following conditions:

- Prior to running the assessment, the reader performance stability must be established. The reader must be recently calibrated using calibrates that have been exposed under the same conditions as those in the test population of nanoDots.
- The exposure or dose level should be known to a very high degree of accuracy, ideally within 1%. The population of test nanoDots can include one or more dosimeters, but for best results at least ten dosimeters.
- If dosimeters are exposed in separate groups, it is recommended that an ionization detector is used to confirm consistent exposure levels between groupings.
- Each dosimeter should be read at least four times on the reading screen under the same conditions (using the same calibration selection, beam mode, etc.).
- A new Process ID for the population should be entered for all dosimeter readings obtained in order to identify the population.
- The exposure should exceed 100 rad to ensure good counting statistics.

9.4.2 Sensitivity Assessment Test Calculations

The Sensitivity Assessment Test averages a set of dose measurements and compares that information to the known dose level to determine how closely they match. The accuracy rate increases as the number of dosimeters in the set increases. If 4-5 readings of each dosimeter in the set were averaged to obtain the dose of the nanoDot, and the readings were very reproducible (low CV), the reading and known dose should closely match.

If there is a significant difference in values and the interval of time between the calibration used to read the dosimeter, the test was very short, and the reader performance was stable, the difference may be a result of uncertainty in labeled sensitivity of the nanoDot.

If the difference between these measurements is assessed for the whole population of nanoDots, symmetry in the distribution would be expected. There would not be an appreciable positive or negative bias.

Linear Dose Calculation Formula

$$Dose (cGy) = \frac{Raw\ Counts}{S \times CF}$$

The Corrected Sensitivity (S_{corr}) can be thought of as the level of sensitivity that would have been required to yield the known exposed dose level for the same counts and reader condition (i.e., using the same calibration factor). Using substitution, the Corrected Sensitivity can be determined from the following expression:

$$S_{corr} = S_{lab} \times \frac{Measured\ Dose}{Known\ Exposed\ Dose}$$

where S_{lab} is the labeled sensitivity of each individual dosimeter and S_{corr} is the sensitivity that would have yielded the known exposed dose.

The Corrected Sensitivity (S_{corr}) can also be expressed in the context of the SAF required to convert the labeled sensitivity to the corrected sensitivity as shown below:

$$S_{corr} = S_{lab} \times SAF$$

from which the SAF for an individual dosimeter can be estimated directly from the ratio of the Measured Dose to Known Exposed Dose:

$$SAF = \frac{Measured\ Dose}{Known\ Exposed\ Dose}$$

The uncertainty in sensitivity assessment at the time of manufacture of the screened nanoDot is known to be $\pm 3\%$ under highly controlled test conditions, but because these estimates in the field are based on actual readings for which the accuracy is specified to be within $\pm 5.5\%$, the SAF computed under these conditions can be as high as $\pm 5.5\%$.

The more useful indicator of a systematic issue with sensitivity assessment is the comparison of the minimum, maximum, and average percent difference (% Diff) between the labeled and corrected sensitivity and whether there is a consistent and appreciable bias in the distribution of these results across the population of dosimeters.

$$\% Diff = \frac{S_{lab} - S_{corr}}{S_{lab}}$$

9.4.3 Running a Sensitivity Assessment

Running a Sensitivity Assessment provides statistics of a pre-read population of nanoDots for both the full population of dosimeters (*nanoDot Population Statistics*) and each individual dosimeter (*Selected nanoDot data*).

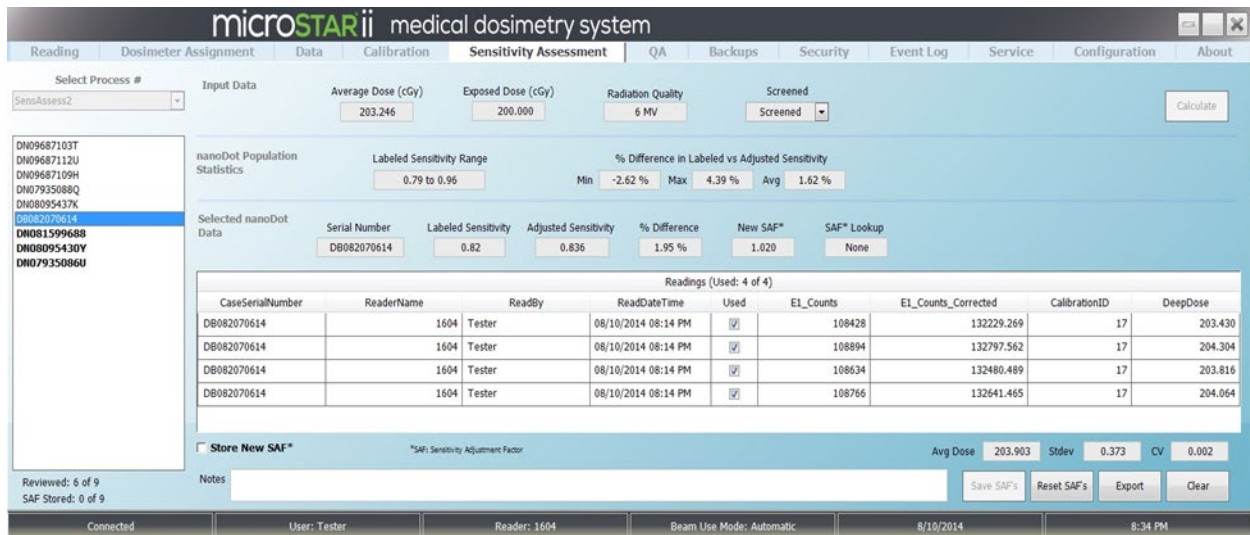


Figure 9-4: Completed Sensitivity Assessment

Complete the following steps to run a Sensitivity Assessment:

- STEP 1:** Log on to the microSTARii application as an Advanced Operator.
- STEP 2:** Navigate to the *Reading* tab, and run a full set of reads on your population of nanoDots using a unique Process ID. (For information on performing a read, see *7.1 Generic Dosimetry*.)
- STEP 3:** Navigate to the *Sensitivity Assessment* tab.
- STEP 4:** Select Process # for the population read in Step 2 from the drop-down menu.
- STEP 5:** Fill in the Input Data:
 - a. Average Dose
 - b. Exposed Dose (known dose amount)
 - c. Radiation Quality (e.g., 18 MV, 10 MV, 6 MV, 120 kVp, and 80 kVp)
 - d. Screened (Yes/No)
- STEP 6:** Press the Calculate button to run the assessment and compare the measurement information to the known dose.
- STEP 7:** Review the result for each dosimeter by selecting the dosimeter serial number in the listing on the left-hand menu (under the Process ID). If necessary, omit any inconsistent or outlier readings by unselecting the Used check box for that result.
- STEP 8:** Click the Export button to export the report as a XLS file.

9.4.4 Saving a New SAF Value

In limited cases (e.g., specific investigational studies or special conditions/requirements) new SAF values can be configured based on the assessment results.

After running a Sensitivity Assessment (section 9.4.3), complete the following steps to save a new SAF.

- STEP 1:** Select the dosimeter with the new SAF.
- STEP 2:** Select the *Store New SAF** check box.
- STEP 3:** Repeat for all dosimeters that you want updated.
- STEP 4:** Click the Save SAF's button to store the SAF values for each dosimeter.

NOTE: An SAF result cannot be saved for a dosimeter until its results are reviewed. However, a Sensitivity Assessment Report can be exported at any time regardless of whether the SAF has been updated or saved.

- STEP 5:** Navigate to the *Configuration* tab and select the check box for *Apply Sensitivity Adjustment Factor (SAF) Values*.

NOTE: The *Apply Sensitivity Adjustment Factor (SAF) Values* option on the *Configuration* tab must be enabled for the custom SAF value to be used in the dose calculation formula. If this configuration is not enabled, the SAF value in the dose calculation formula for a read will use the default of 1.0.

9.4.5 Resetting SAF Value

To reset the SAF value from the saved value to the default value of 1.0, complete the steps below:

- STEP 1:** Log on to the microSTARⁱⁱ application as an Advanced Operator.
- STEP 2:** Navigate to the *Sensitivity Assessment* tab.
- STEP 3:** Select the Process ID for the population of dosimeters you have a SAF set for.
- STEP 4:** Click the Reset SAF's button. Click OK on the confirmation prompt.

CHAPTER 10 SYSTEM ADMINISTRATION

10.1 Profile Management (Security)

NOTE: We highly recommend that you install and maintain anti-virus software, firewalls, and other security tools onto the microSTARⁱⁱ laptop per the policies, guidelines, and recommendations provided by the IT and/or Information Security teams within your business.

All profile administration is completed on the *Security* tab of the microSTARⁱⁱ software application. This tab is only visible to Administrators. Profiles control the features, functions, and screens that users have access to. The default profiles are Administrator, Advanced Operator, and Operator. You can define other profile types based on the features available. (For a full listing of profile permission and permissions for default profiles, see *Appendix A: Profile Permissions Listing*.)

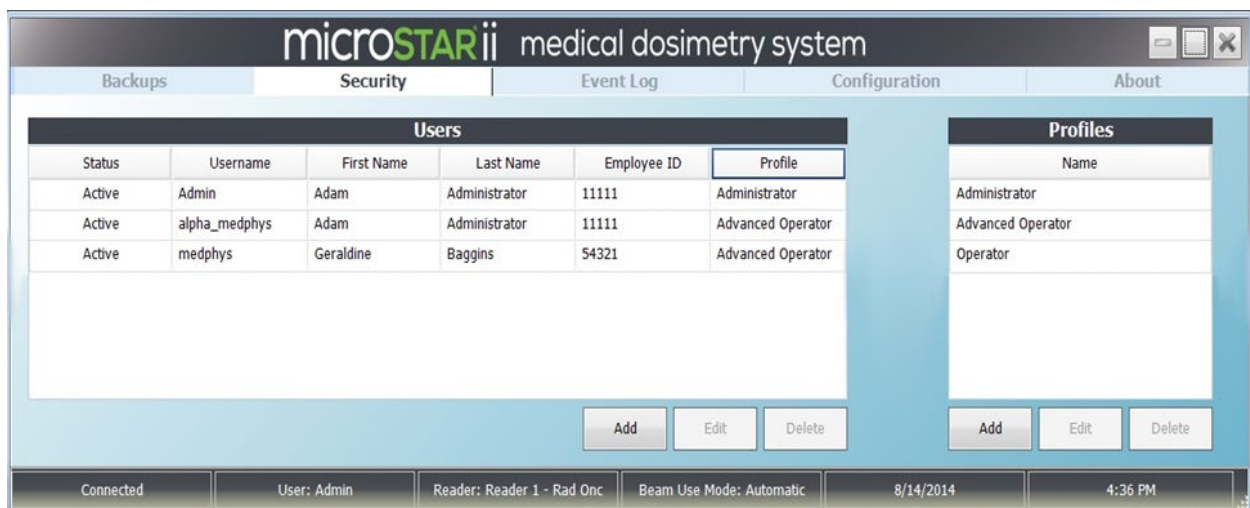


Figure 10-1: Security Tab

10.1.1 Reviewing Profiles

The Profiles table lists all of the active profiles in your system. Double-click on the Name in the Profile table to view the permissions for the profile.

10.1.2 Adding New Profiles

To add a profile, complete the following steps:

- STEP 1:** Click the Add button under the Profiles table.
- STEP 2:** Fill in the Name field and select the boxes next to the desired permissions for each category.
- STEP 3:** Click OK to add the profile.

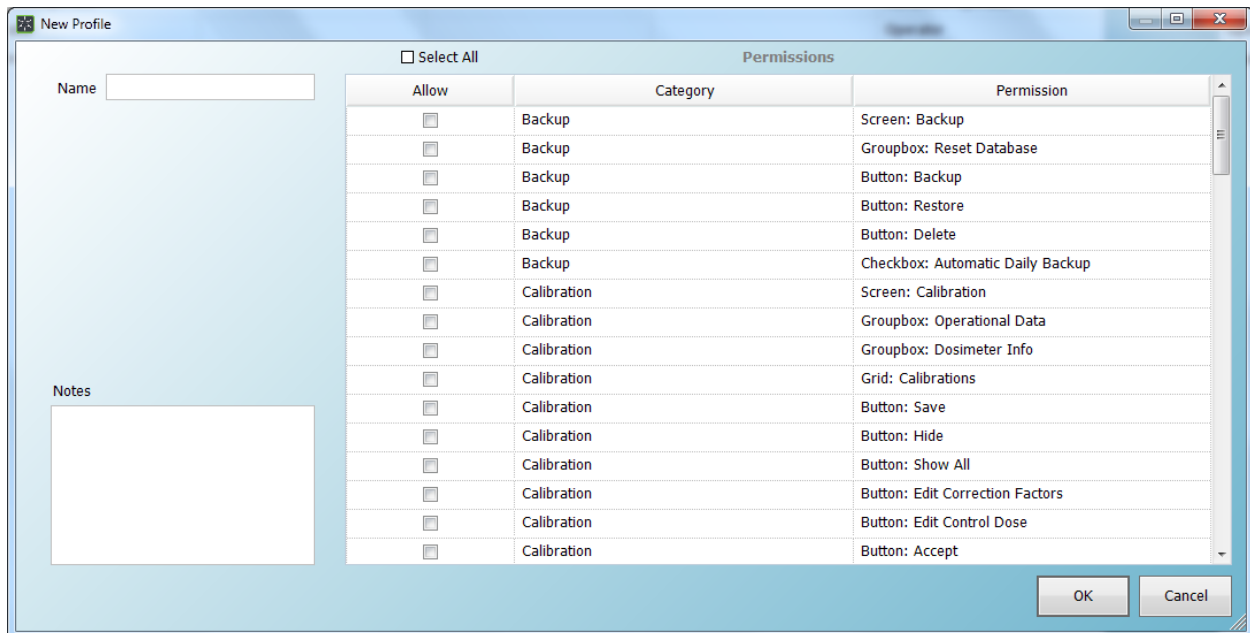


Figure 10-2: New Profile

10.1.3 Editing an Existing Profile

To edit an existing profile, complete the following steps:

- STEP 1:** Double-click on the profile name in the Profiles table.
OR
Select the desired profile and click the Edit button below the Profiles table.
- STEP 2:** In the Edit Profile dialog box, update the profile information.
- STEP 3:** Click the OK button to save the changes.

10.2 User Access Management (Security)

All user account administration is completed on the *Security* tab of the microSTARⁱⁱ software application (Figure 10-1). This tab is only visible to Administrators.

10.2.1 Reviewing User Account

The Users table provides user account information. From this table, you can see the following user account configurations:

- Status: Active or Suspended
- Username
- First Name
- Last Name
- Employee ID
- Profile: Administrator, Advanced Operator, Operator, or Other Custom Profile

10.2.2 Adding User Account

Note: User fields are limited to 32 characters. Password information is encrypted.

To add a user account, complete the following steps:

- STEP 1:** Click the Add button under the Users table.
- STEP 2:** Fill in the fields in the dialog box (Figure 10-3).
- a. Username
 - b. Password (must be greater than four characters, with no spaces)
 - c. Confirm Password
 - d. Profile (must be selected to add a new user)
 - e. Employee ID
 - f. First Name
 - g. Last Name
 - h. Active (Y/N Check Box)
 - i. Notes (optional)
- Note: Fields a-d are required.*
- STEP 3:** Click OK to add the user.

Figure 10-3: New User Form

10.2.3 Editing Existing User Account

User accounts can be edited in two ways:

1. **In the Users Table**
 - a. Double-click on the user account row in the Users table.
 - b. Edit information in the Edit User dialog box.
2. **In the Edit User Window**
 - a. Click the user account row in the Users table to highlight it.
 - b. Click the Edit button below the Users table.
 - c. Edit information in the Edit User dialog box.

Figure 10-4: Edit User Form

10.2.4 Deleting a User Account

Complete the following steps to delete a user account:

- STEP 1:** In the Users table, click to highlight the row for the user account you want to delete.
- STEP 2:** Click the Delete button under the Users table.
- STEP 3:** Click Yes on the confirmation prompt.

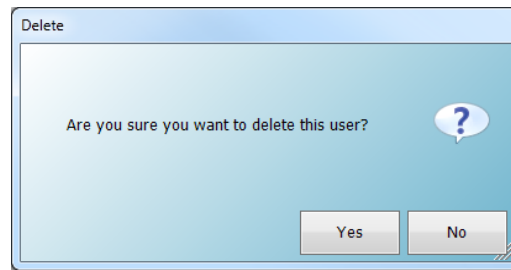


Figure 10-5: Account Deletion Confirmation Prompt

10.3 Adding a Reader

Each reader has unique hardware settings loaded in firmware that will impact performance and calibration factors if not taken into account. A Unique Identification (UID) number is used to ensure the correct calibration settings and configurations are associated with the correct reader when it is connected. If you want to run multiple microSTARⁱⁱ readers using the same computer, you must add the reader through the software to assign the reader a UID.

Complete the following steps to add a new reader:

- STEP 1:** Log on to the microSTARⁱⁱ application as an Administrator or Advanced Operator.
 - STEP 2:** Navigate to the *Configuration* tab.
 - STEP 3:** Click the Manage Readers button.
 - STEP 4:** Click the Add New Reader button on the Reader Management dialog box.
 - STEP 5:** Enter in a unique name for the new reader, and click OK to add the reader.
-
- NOTE:** All other fields are generated by the microSTARⁱⁱ system.
-
- STEP 6:** Select the Used check box for the added reader and click OK to save the changes.

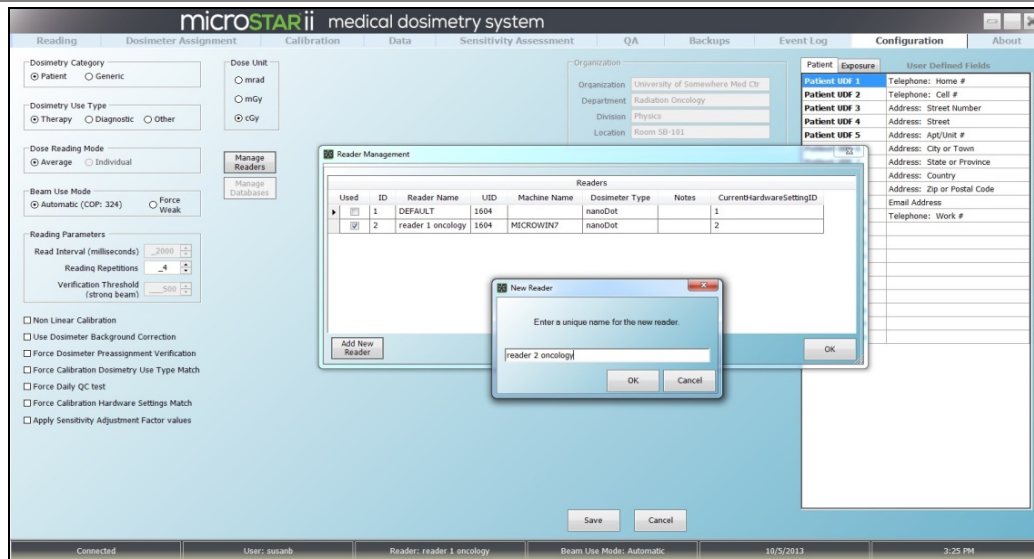


Figure 10-6: Configuration - Adding New Reader

10.4 System Backup

On the *Backup* tab, Advanced and Administrator default profiles can access the system back up information to complete the following tasks:

- Review of backup files and frequency
- Perform a manual backup as needed
- Access backup data file folder contents
- Restore an existing backup file
- Reset the database

Backup files can be sorted by clicking on the column name.

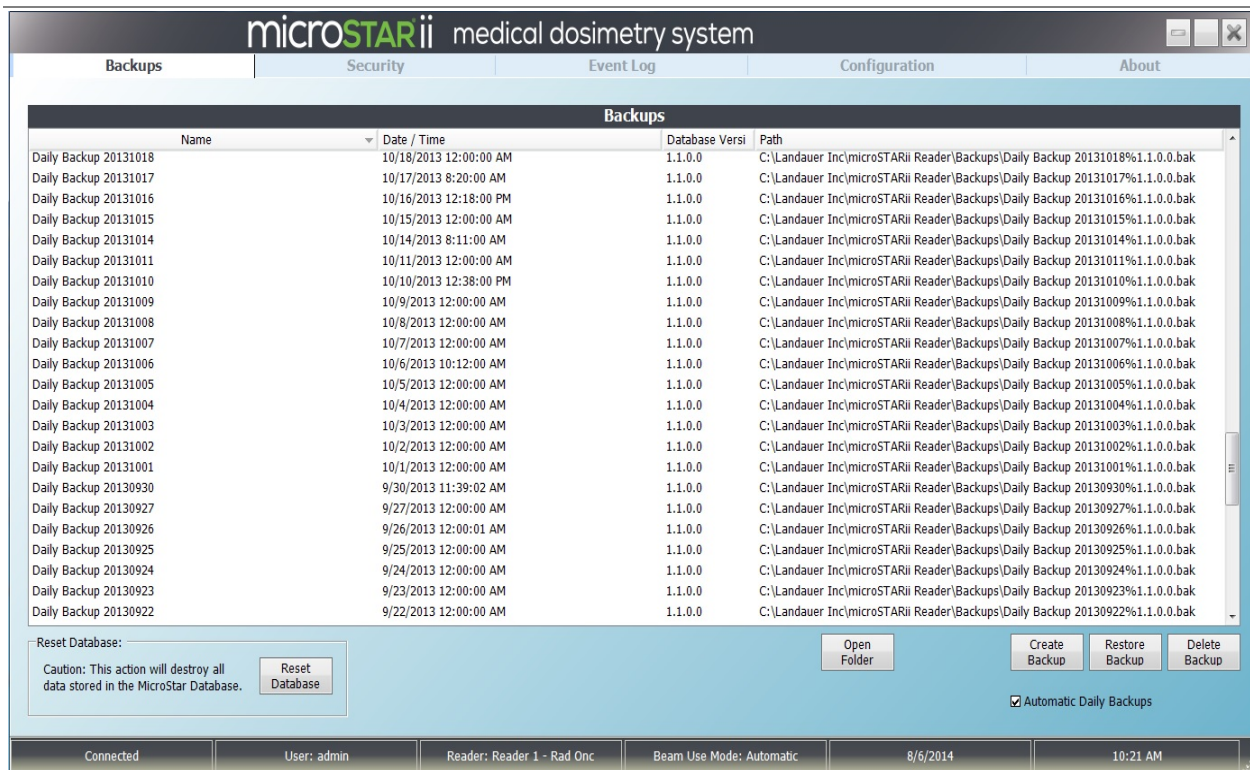


Figure 10-7: Backup Tab

In addition, Administrators can perform more advanced backup management from the *Backup* tab:

1. Configure Automatic Daily Backups

Select the *Automatic Daily Backups* check box to enable this feature. Unselect to turn it off.

NOTE: When enabled, the database will be backed up at just past midnight each day unless the software is not running at that time. If the software is not running, the backup will be performed automatically the next time the software is launched. Automatic backup files are listed in the grid with the following format: *Daily Backup YYYYMMDD*.

2. Create Backup

- a. Click the Create Backup button under the backup file listing to generate a new backup file.
- b. Enter a name for the new file in the Create Backup dialog box.
- c. Click OK to generate a backup file.

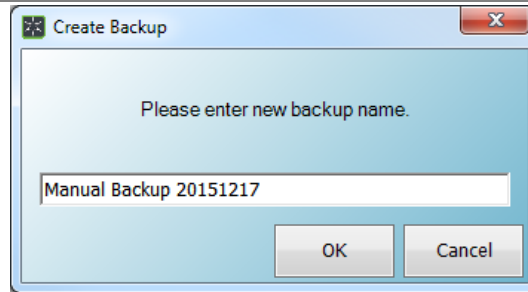


Figure 10-8: Create Backup Filename

3. Restore Backup

NOTE: You will lose all data recorded after the point of the backup file selected. This includes measurement data, user account information, configuration, and calibration information.

- a. Click the row to select the backup file to restore.
- b. Click the Restore Backup button.
- c. Click Yes on the warning prompt (Warning Message: *DATA MAY BE LOST! Are you sure you want to restore backup...*).
- d. Click OK on the Restore Complete dialog box to restart the application.

4. Delete Backup

- a. Click the row to select the backup file to delete. To select a range, use standard multi-select functions (hold SHIFT for a range; CTRL for individual files).
- b. Click Yes on the confirmation prompt to delete the backup files.

5. Reset Database

CAUTION: All microSTARⁱⁱ data will be deleted, which includes but is not limited to, measurement data, user account and profile information, configuration, and calibration information.

- a. Click the Reset Database button.
- b. Click Yes on the Data Operations confirmation prompt to delete all stored data.

NOTE: A backup operation is automatically performed whenever the database is reset; the software performs a backup prior to the reset to allow the database to be restored, as necessary.



10.5 Database Management

The database connectivity information is set up on installation. In the case of a change of database location or credential changes, use the following instructions to update the database connection parameters:

- STEP 1:** Log on to the microSTARⁱⁱ application as an Administrator.
- STEP 2:** Navigate to the *Configuration* tab (Figure 4-1).
- STEP 3:** Click the Manage Database button.
- STEP 4:** In the Database Management dialog box, update the information as necessary:
 - a. DB Server
 - b. Database
 - c. Integrated Authentication
 - d. DB User
 - e. Password
- STEP 5:** Click the Test button to validate the connection using the new values.
- STEP 6:** Click OK to update the configuration.

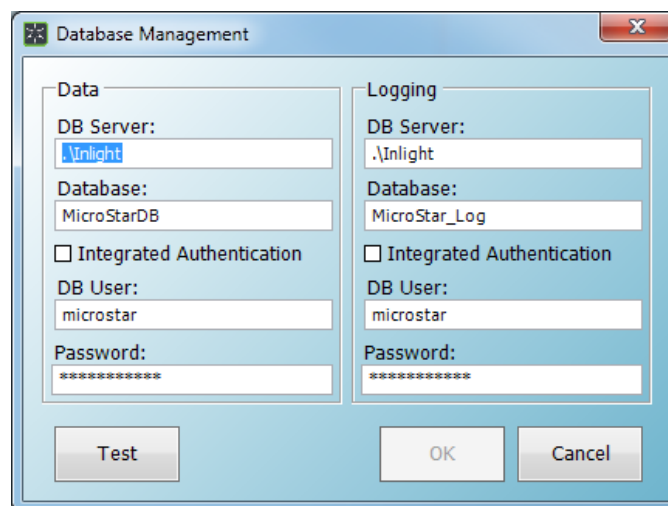


Figure 10-9: Database Management

CHAPTER 11 CLEANING PROCEDURES

The new microSTARⁱⁱ drawer is designed to assure tight positioning inside the reader sleeves. Traces of dust/debris can develop over extended use through the normal operation of pushing and pulling the drawer in and out of the reader. The drawer can also develop sharp edges over time due to normal wear and tear. We recommend inspecting the bottom of your drawer for sharp edges before each cleaning. If sharp edges are found, please contact LANDAUER InLight[®] Customer Service to order a replacement drawer (Telephone: 800-561-2708, email: inlightcustserv@landauer.com).

The following cleaning procedure is recommended at a minimum of once per 1000 open/close cycles of daily operation, or more frequently if dust or debris is observed:

PRECAUTION: *Always use personal protective equipment to protect skin and eyes when handling chemicals and using pressurized cleaning products.*

11.1 Preparation:

1. Power off the reader.
2. Remove the reader drawer.
3. Inspect the bottom of the drawer for sharp edges on the sliding grooves.

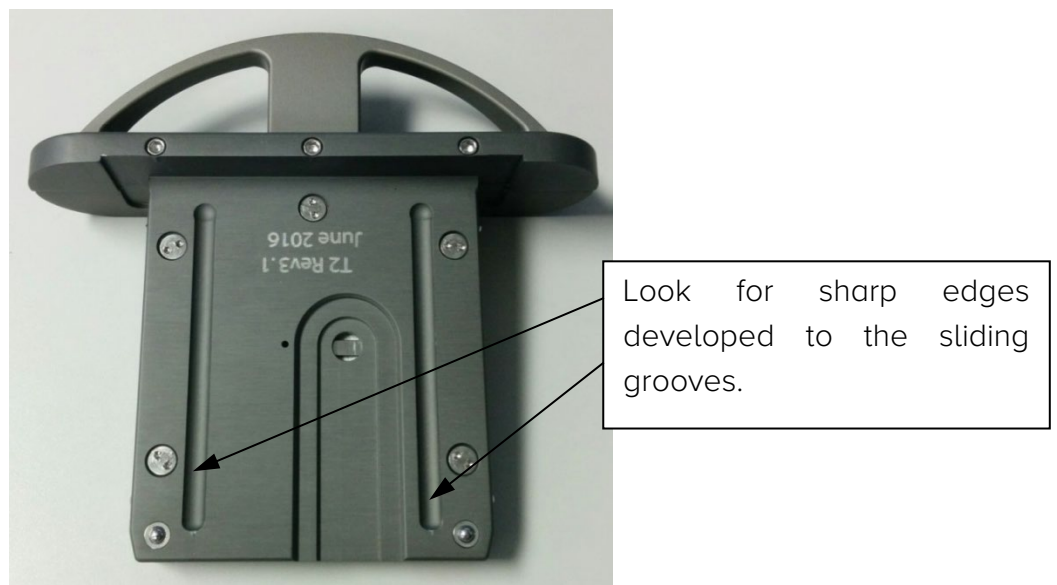


Figure 11-1: Drawer Bottom

11.2 Cleaning the Drawer

4. Use a compressed gas duster to clean the drawer with pressurized air. Direct the duster:
 - to the center of the nanodot holder while pushing the sled bushing away to expose and clean the sled and inside of the drawer.
 - to the upper side of the hexagon ejector while pushing the ejector to expose the ejector sitting area and clean inside of the drawer
 - to the metal deflector inside the drawer while pushing the sled bushing sideways
 - to all sides of the drawer to blow off any dust and debris attached to the drawer

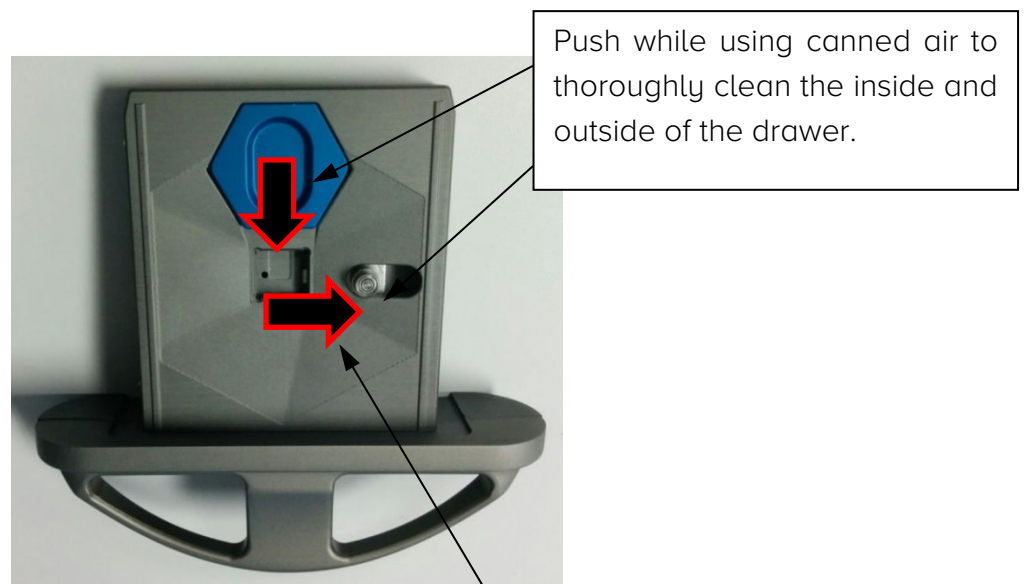


Figure 11-2: Cleaning the Drawer



Figure 11-3: Cleaning the Drawer Deflector

11.3 Cleaning the Reader

5. Clean the inside of the reader sleeves
 - Use a mini desktop vacuum cleaner to remove the dust and debris from inside the reader sleeves
 - Use the gas duster on both of the ball plungers while pressing the ball down. Wear safety goggles when doing the cleaning task.
 - Use the gas duster on the inside of the reader sleeves. Be thorough to remove all dust and debris. Wear safety goggles when doing the cleaning task.
 - Use cotton swab with 97% and above isopropyl alcohol or optical grade cleanser to clean the lens area of the optical engine.

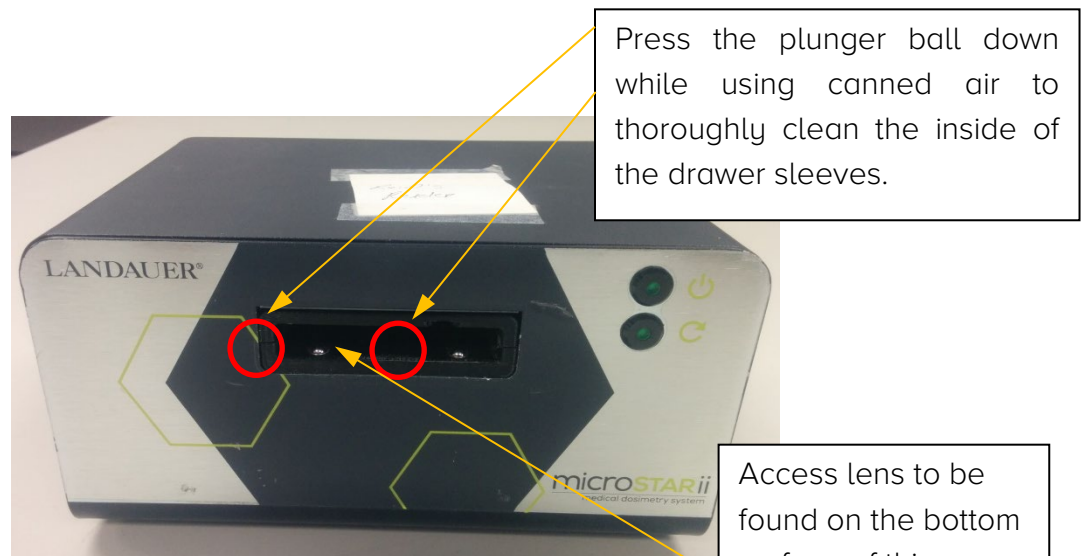


Figure 11-4: Cleaning Drawer Sleeves

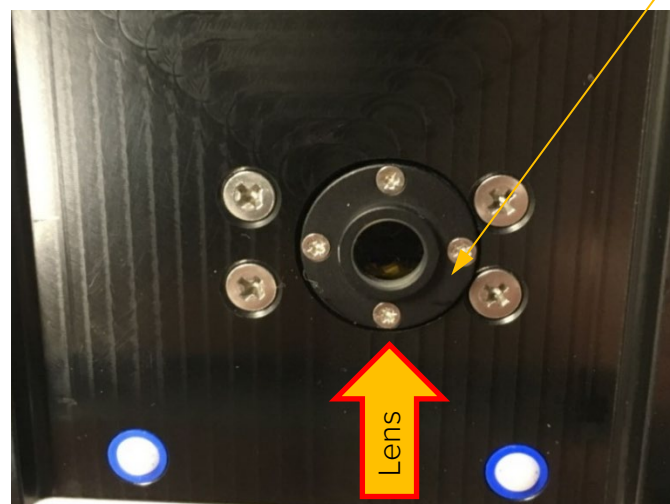


Figure 11-5: Cleaning the Lens

6. Replace the reader drawer.
7. Power on the reader. Note: make sure the reader has been powered for at least 60 minutes before performing the next reading session.
8. Perform reader QC test (“Intrinsic Measurement Test,” following Chapter 7.1.1 of Installation & Configuration Guide) to verify the reader consistency in Dark, PMT, and P-diode counts before and after cleaning.

CHAPTER 12 TROUBLESHOOTING

This section provides information needed to troubleshoot system and operations issues. If you need further assistance, contact LANDAUER Technical Support.

12.1 Technical Support

Address	LANDAUER Customer Service 2 Science Rd. Glenwood, IL 60425
Telephone	800-561-2708
Email	inlightcustserv@landauerinc.com
Operating Hours	Monday–Friday: 8:00 am to 4:30 pm Central Time

When calling LANDAUER, please provide the representative with the following information:

- Your contact information (Name, Phone #, Email Address, and Organization/Facility)
- Type of Call (Informational or System Failure)
- Severity of Issue
- Device Status (Operational or System Down)
- Type of Issue (Hardware/Software)
- Reader Serial # (see back of reader)
- Software Version (see the *About* tab)
- Approximate Age of System

Please provide specific details of your hardware or software failure (if available):

- Operator User Name & Permissions Level (Administrator, Advanced Operator or Operator)
- System Warnings or Symptoms Encountered Prior to the Issue
- Screenshot of Software Issue/Message
- Picture of Hardware Issue/Failure
- Event Logs

12.2 Event Logs

The event log provides a detailed listing of all user actions and software events on the microSTARⁱⁱ software with the following record information:

- LogID
- Date/Time
- Application Name
- Module Name
- Routine
- Log Type
- Computer Name
- User Name
- App User Name
- Message
- Tag
- Stack Trace

LogId	DateTime	ApplicationName	ModuleName	Routine	LogType	ComputerName	Username	AppUserName	Message	Tag	StackTrace
117419	08/14/2014 4:39:04 PM	MicroStar	frmMain	uxEditProfile	3	MICROWIN7	Admin	Admin	"Edit" clicked.		
117418	08/14/2014 4:39:04 PM	MicroStar	frmProfileEdit	uxCancel	3	MICROWIN7	Admin	Admin	"Cancel" clicked.		
117417	08/14/2014 4:39:01 PM	MicroSTARii	BaseItemClass	DataExecuteData...	3	MICROWIN7	Admin	Admin	MSSP_GetProfile...		@RETURN_VALU...
117416	08/14/2014 4:38:59 PM	MicroStar	frmMain	uxEditUser	3	MICROWIN7	Admin	Admin	"Edit" clicked.		
117415	08/14/2014 4:38:59 PM	MicroStar	frmUserEdit	uxCancel	3	MICROWIN7	Admin	Admin	"Cancel" clicked.		
117414	08/14/2014 4:38:48 PM	MicroSTARii	BaseItemClass	DataExecuteData...	3	MICROWIN7	Admin	Admin	MSSP_GetAllProfi...		@RETURN_VALU...
117413	08/14/2014 4:38:48 PM	MicroSTARii	BaseItemClass	DataExecuteData...	3	MICROWIN7	Admin	Admin	MSSP_GetProfile...		@RETURN_VALU...
117412	08/14/2014 4:34:35 PM	MicroStar	frmMain	uxMaximize	3	MICROWIN7	Admin	Admin	"uxMaximize" clic...		
117411	08/14/2014 4:34:18 PM	MicroStar	frmMain	uxDeleteProfile	3	MICROWIN7	Admin	Admin	"Delete" clicked.		
117410	08/14/2014 4:34:18 PM	MicroSTARii	BaseItemClass	DataExecuteData...	3	MICROWIN7	Admin	Admin	MSSP_GetAllProfi...		@RETURN_VALU...
117409	08/14/2014 4:34:18 PM	MicroSTARii	BProfile	Delete	3	MICROWIN7	Admin	Admin	MSSP_DeleteProf...		@RETURN_VALU...
117408	08/14/2014 4:34:18 PM	MicroSTARii	ctrlUsers	uxDeleteProfile...	3	MICROWIN7	Admin	Admin	Dialog: Are you s...	Yes	
117407	08/14/2014 4:34:14 PM	MicroStar	frmMain	uxDeleteProfile	3	MICROWIN7	Admin	Admin	"Delete" clicked.		
117406	08/14/2014 4:34:14 PM	MicroSTARii	BaseItemClass	DataExecuteData...	3	MICROWIN7	Admin	Admin	MSSP_GetAllProfi...		@RETURN_VALU...
117405	08/14/2014 4:34:14 PM	MicroSTARii	BProfile	Delete	3	MICROWIN7	Admin	Admin	MSSP_DeleteProf...		@RETURN_VALU...

Figure 12-1: Event Log

12.2.1 Usage Information

- Events are reported in a descending time sequence from most to least recent.
- The range of events displayed can be adjusted by specifying a start and end date for reporting and clicking the Update button.
- Events can be sorted by clicking on the column name.
- Use the search field at the top of each column to filter for specific events. (For information on advanced filtering, see section 8.2.)

12.2.2 Exporting the Event Log

The Event Log can be exported to an XML report for further troubleshooting or to gain point-in-time information:

STEP 1: Log on to the microSTARii application as an Administrator or Advanced User.

STEP 2: Navigate to the *Event Log* tab, and click the Update button to ensure you have the most current data set.

NOTE: Enter in a date range if you want to narrow the export to a specific event set.

STEP 3: Click the Export button.

NOTE: All data for the date range set will be exported, regardless of search/filter criteria.

STEP 4: Select the location for the export, enter a file name, and click Save.

12.3 System Version Information

When contacting LANDAUER Technical Support or during other troubleshooting scenarios, you may need to provide the version number for microSTARⁱⁱ system components. Log on under any user account and navigate to the *About* tab. This tab contains the version numbers for system, database, reader communication, and firmware. It also contains the computer name and unique identifier information.

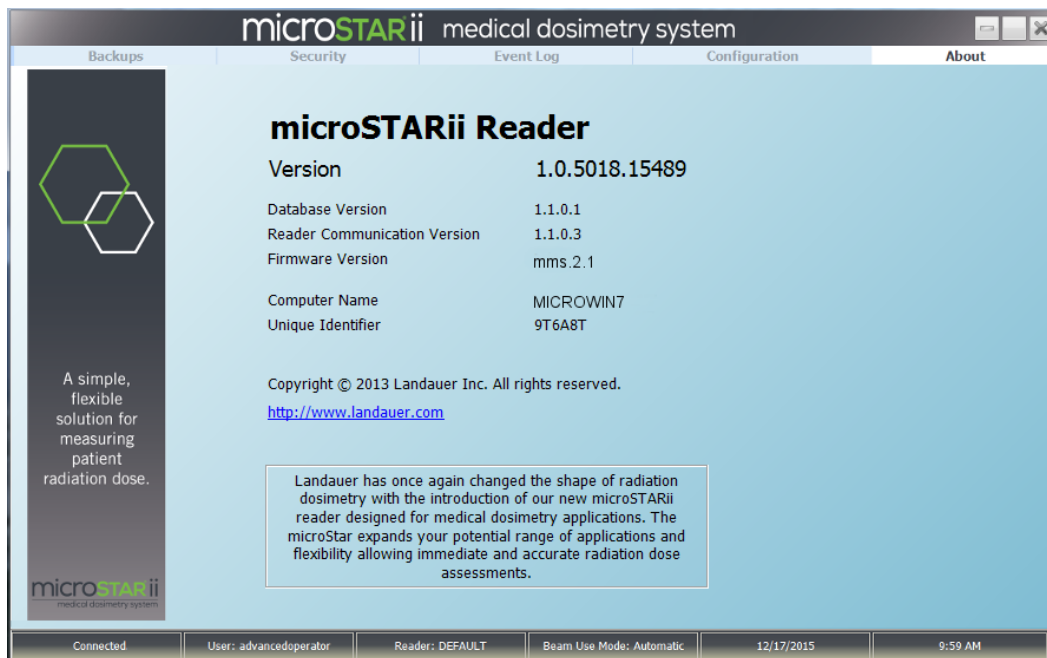


Figure 12-2: About Tab Example

12.4 Hardware Issues

Hardware issues can result in inconsistent readouts, inability to perform readouts, and stability issues.

The following table contains potential hardware issues. If you have a hardware failure, contact LANDAUER Technical Support (see section 12.1 for contact information).

ISSUE	INDICATIONS	POTENTIAL CAUSE(S)	CORRECTIVE ACTION
Cannot Close Reader Drawer	The drawer will not slide all the way in. It gets stuck before completely closing.	<ul style="list-style-type: none"> - The nanoDot is inserted incorrectly. Do not try to force drawer to close, because it may result in opening pin damage. - The pin in tray that opens the nanoDot is bent from incorrect nanoDot placement. The bent pin prevents the closing mechanism from functioning properly. 	<p>Check the position of the nanoDot and condition of the drawer.</p> <p>If there is hardware damage, contact LANDAUER Technical Support.</p>
Sensitivity Readings Vary for Same nanoDot	The sensitivity readings are different for the same nanoDot. When scanned with the barcode scanner, the serial numbers are showing up differently for the same nanoDot.	Barcode Scanner is failing.	Contact LANDAUER Technical Support for replacement hardware.

ISSUE	INDICATIONS	POTENTIAL CAUSE(S)	CORRECTIVE ACTION
PMT Light Strike Causing Drift	The PMT Counts are consistently high.	Removing the drawer to remove/replace nanoDot. The removal of the drawer allows light into the reader causing PMT drift over time (1-2 years).	Run QC checks and validate the system calibration. Contact LANDAUER Technical Support for assistance.
Reader Does Not Turn On	Power light does not illuminate when power button is pressed.	<ul style="list-style-type: none"> - DC adaptor is not plugged into outlet. - DC adaptor is not plugged into reader. - DC adaptor hardware failure. 	Check connections. If there is hardware damage, contact LANDAUER Technical Support.
Software Will Not Connect To Reader	Reader Connection Error: Not Connected Please click the Connect button to try again.	<ul style="list-style-type: none"> - Reader is not powered on. - USB cable is loose or not connected. - Hardware failure. 	Ensure the reader is turned on and check connections. If there is hardware damage, contact LANDAUER Technical Support.

ISSUE	INDICATIONS	POTENTIAL CAUSE(S)	CORRECTIVE ACTION
nanoDot Barcode Will Not Scan	The nanoDot barcode cannot be read by the barcode scanner.	<ul style="list-style-type: none"> - Barcode Scanner is failing. - Excessive wear on the nanoDot label has rendered it unreadable. 	<p>If this happens with a large number of nanoDots, contact LANDAUER Technical Support for replacement hardware.</p> <p>If the nanoDot label is worn, manually enter the serial number.</p>
Reader Door is Open Error When Drawer is Closed	After closing the drawer and ensuring it is seated correctly, the microSTARii application displays a Reader Door is Open error.	Door closed magnetic sensor has failed.	Contact LANDAUER Technical Support for replacement hardware.
Cannot remove nanoDot from Drawer	When sliding the ejector, the nanoDot stays in the drawer and cannot be removed.	<ul style="list-style-type: none"> - Ejector Failure - Damaged nanoDot 	In version 2.5 drawers and higher, insert a paperclip in the small opening on the backside of the tray and push out the nanoDot.

12.5 Error Messages

The microSTARii application was designed to provide detailed error messages with instructions on clearing the error (e.g., Reader Door is Open - Please close the door before continuing). If you encounter one of these instructional messages, perform the resolution noted, and continue to receive the error(s), contact LANDAUER Technical Support for

further troubleshooting. (See section *12.1 Technical Support* for contact information). Some of the corrective actions may require assistance from your local IT support.

The following table contains common error and warning messages with resolution instructions.

TAB	MESSAGE	POTENTIAL CAUSE(S)	CORRECTIVE ACTION
Backups	Data restore failed [backup file name].	<ul style="list-style-type: none"> - Issues with the .bak file. - System permission issues. 	Check Administrative security permissions for the system account and SQLServer Disc Administrator account.
Backups	Backup failed: [system error]	<ul style="list-style-type: none"> - Issues with the .bak file. Failure writing to the file. - System permission issues. Issues accessing database. 	Check Administrative security permissions for the system account and SQLServer Disc Administrator account.
Reading and Calibration	Reader communication connection failed. Try again.	Connectivity issues.	<ul style="list-style-type: none"> - Turn reader on. - Check USB connection.
All Tabs	No reader found in configuration. Choose a reader.	The reader connected is not configured to be used.	<ol style="list-style-type: none"> 1. Go to the <i>Configuration</i> tab and click the Manage Readers button. 2. Confirm the reader is selected (the Used box is checked).

TAB	MESSAGE	POTENTIAL CAUSE(S)	CORRECTIVE ACTION
All Tabs	<p>Database Server Connection Fail. The microStar database connection is not available anymore. Please check if the server is turned on and if the SQL Server service is running as well. The application will be closed now.</p>	<p>Connectivity issues.</p>	<ul style="list-style-type: none"> - Confirm that the system is fully up and running. - Check Database Connectivity (ensure the username and password are valid).
Data	<p>XML Report could not be translated Errors (e.g., XML Calibrations Report could not be translated: Calibrations Report Error)</p>	<ul style="list-style-type: none"> - Changes to the SQL table column names. - Resource File value changes (removed or renamed). 	<p>Contact LANDAUER Technical Support. (See section 12.1 Technical Support for contact information).</p>

12.6 Failed QC Tests

12.6.1 Reader Daily QC Tests Failure

Use the information in the following table to diagnose failures in the *Reader Daily QC Tests*. After the corrective action is taken, rerun the test. If the test continues to fail after corrective action, contact LANDAUER Technical Support for further troubleshooting. (See section 12.1 *Technical Support* for contact information).

STEP 1: READER INTRINSIC STABILITY TEST			
FAILURE	INDICATIONS	POTENTIAL CAUSE	CORRECTIVE ACTION
Failed Dark Count Test	<ul style="list-style-type: none"> - Dark Counts that exceed the upper threshold - Reader Door is Open error message - PMT Counts Higher than Max Limit 	Reader Door Open	Close the reader drawer. If it is already closed, confirm that it is tightly closed. If failures persist, run in a dark room to test for light leakage.
		Outside Electrical Interference	Move reader to another location (away from potential interference)
		PMT Failure	Contact Technical Support
Failed PMT Counts	<ul style="list-style-type: none"> - PMT Count & P-Diode Count Average is outside the range 	Failing PMT	Contact Technical Support

STEP 2: READING REPRODUCIBILITY TEST

FAILURE	INDICATIONS	CORRECTIVE ACTION
Reader Door Open Error Message	The reader door is open.	Close the reader drawer. If it is already closed, confirm that it is tightly closed. If failures persist, run in a dark room to test for light leakage.
Low Raw Counts	There is no nanoDot in the drawer.	Place the nanoDot in the drawer.
CV Failure and Erratic Measurements	Outside Interference (EMF)	Move the reader to another location (away from potential interference).

12.6.2 Reader QC Tests Failure

Use the information in the *STEP 1: READER INTRINSIC STABILITY TEST* table in section 12.6.1 to diagnose failures in the *Verify/Establish QC Control Limits* test. After the corrective action is taken, rerun the test. If the test continues to fail after corrective action, contact LANDAUER Technical Support for further troubleshooting. (See section *12.1 Technical Support* for contact information).

12.7 Operations Issues

The following table contains issues that may be encountered during operations. If the corrective actions listed do not resolve the issue, contact LANDAUER Technical Support for further troubleshooting. (See section *12.1 Technical Support* for contact information).

ISSUE	INDICATIONS	CORRECTIVE ACTION
Reader Not Ready	Erratic Measurements	Wait 60 minutes after start for the reader to warm up.
Incorrect Calibration	Results do not match expected dose measurement.	<ol style="list-style-type: none"> 1. Confirm the reader has properly warmed up (60 minutes after restart). 2. Ensure the correct calibration is selected on the <i>Calibration</i> tab (High/Low Dose).

ISSUE	INDICATIONS	CORRECTIVE ACTION
		<ol style="list-style-type: none"> 3. Run Daily QC on <i>QA</i> tab. (If system is not configured to automatically run it.) 4. Check environmental factors (extreme temperature shift and potential EMF interference). 5. Run new calibration using LANDAUER calset and compare Calibration Factors (Section 9.2.2). <ol style="list-style-type: none"> a. If the calibration factor(s) match, continue with system configuration (read QC dosimeters and run QC Control Limit test). b. If the calibration factor(s) do not match, contact LANDAUER Technical Support. <p>NOTE: These corrective action steps verify the reader is operating correctly. If you are using the LANDAUER-manufactured calset and the results are not matching expectations, you should create a custom calset for your environment.</p>
<p>Cannot remove nanoDot from Drawer</p>	<p>When sliding the ejector, the nanoDot stays in the drawer and cannot be removed.</p>	<p>This could be caused by one of the following:</p> <ul style="list-style-type: none"> - Ejector Failure - Damaged nanoDot <p>In version 2.5 drawers and higher, insert a paperclip in the small opening on the backside of the tray, and push out the nanoDot.</p>

Appendix A: Profile Permissions Listing

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
Backup	Screen: Backup		✓	✓
Backup	Groupbox: Database	Reset		✓
Backup	Button: Backup		✓	✓
Backup	Button: Restore			✓
Backup	Button: Delete			✓
Backup	Checkbox: Automatic Daily Backup			✓
Calibration	Screen: Calibration	✓	✓	
Calibration	Groupbox: Operational Data	✓	✓	
Calibration	Groupbox: Dosimeter Info	✓	✓	
Calibration	Grid: Calibrations	✓	✓	
Calibration	Button: Save	✓	✓	
Calibration	Button: Hide	✓	✓	
Calibration	Button: Show All	✓	✓	
Calibration	Button: Edit Correction Factors	✓	✓	
Calibration	Button: Edit Control Dose	✓	✓	
Calibration	Button: Accept	✓	✓	

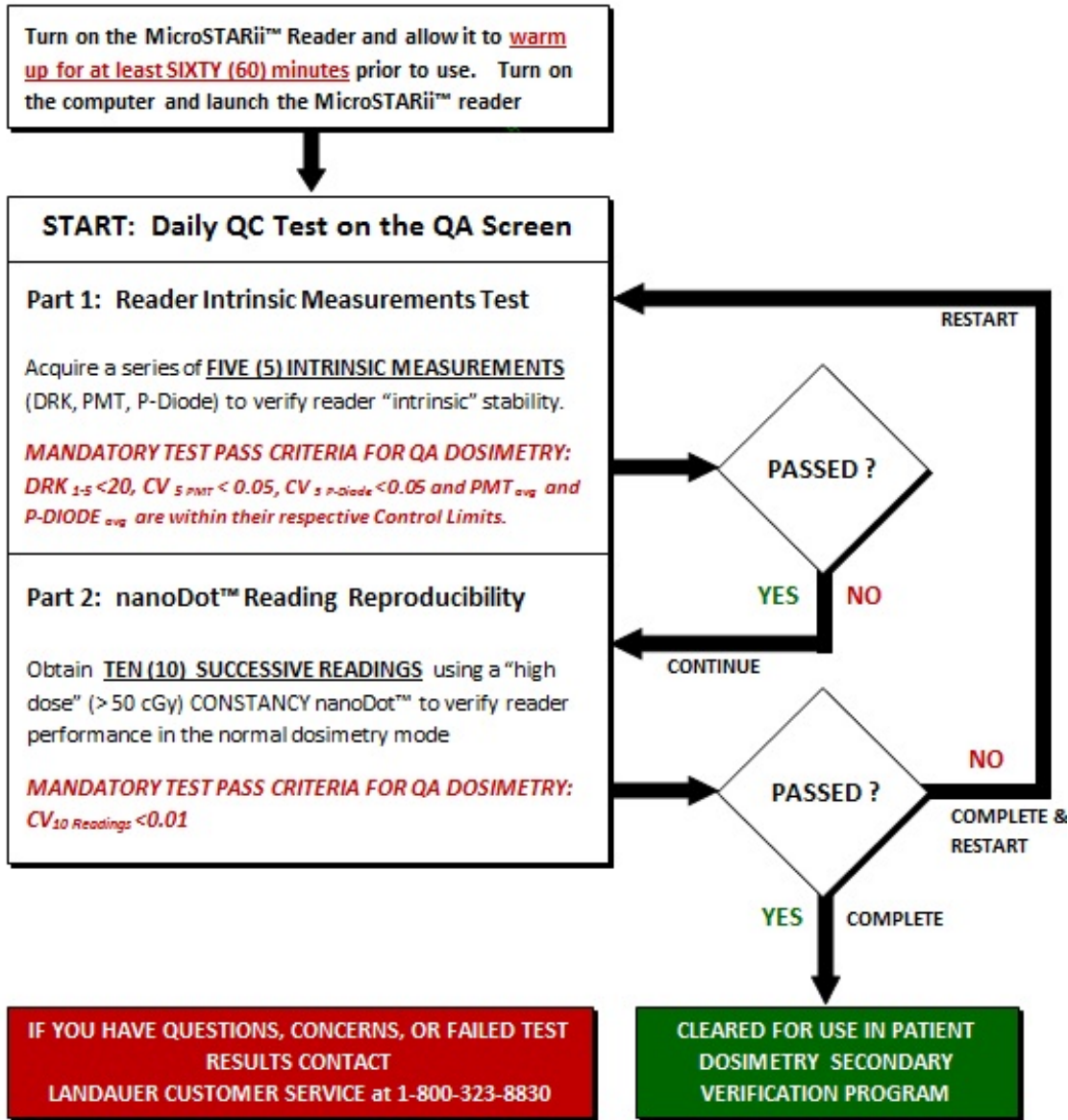
CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
Calibration	Button: Reject	✓	✓	
Configuration	Screen: Configuration	✓	✓	✓
Configuration	Checkbox: Apply Sensitivity Adjustment Factor Value		✓	✓
Configuration	Checkbox: User Dosimeter Background Correction	✓	✓	✓
Configuration	Checkbox: Non Linear Calibration	✓	✓	✓
Configuration	Groupbox: Display Unit	✓	✓	✓
Configuration	Groupbox: Beam Use Mode		✓	✓
Configuration	Button: Reader Management		✓	✓
Configuration	Button: Database Management			✓
Configuration	Button: Add New Reader		✓	✓
Configuration	Groupbox: Daily QC Control Limits			✓
Configuration	Groupbox: Organization			✓
Configuration	Checkbox: Force Calibration Dosimetry Use Type Match		✓	✓

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
Configuration	Checkbox: Force Dosimeter Preassignment Verification		✓	✓
Configuration	Checkbox: Force Daily QC		✓	✓
Configuration	Groupbox: User Defined Fields			✓
Configuration	Textbox: Read Interval			✓
Configuration	Groupbox: Dosimetry Category	✓	✓	✓
Configuration	Groupbox: Dosimetry Use Type	✓	✓	✓
Configuration	Groupbox: Dose Reading Mode	✓	✓	✓
Configuration	Textbox: Reading Repetitions		✓	✓
Configuration	Textbox: Verification Threshold			✓
Configuration	Checkbox: Force Calibration Hardware Settings Match		✓	✓
Configuration	Textbox: Reader Serial Number			✓
Configuration	Textbox: Reader Notes			✓
Data	Screen: Data	✓	✓	
Data	Groupbox: Templates	✓	✓	
Data	Button: Export	✓	✓	

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
Dosimeter Assignment	Screen: Dosimeter Assignment	✓	✓	
Dosimeter Assignment	Button: Export Worklist	✓	✓	
Dosimeter Assignment	Button: Add Patient	✓	✓	
Dosimeter Assignment	Button: Edit Patient	✓	✓	
Dosimeter Assignment	Button: Delete Patient	✓	✓	
Dosimeter Assignment	Button: Edit Assignment	✓	✓	
Dosimeter Assignment	Button: Remove Assignment	✓	✓	
Dosimeter Assignment	Textbox: Serial Number	✓	✓	
Event Log	Screen: Event Log		✓	✓
QA	Screen: QA	✓	✓	
Reading	Screen: Reading	✓	✓	
Reading	Button: Patient Details	✓	✓	
Reading	Button: Assignment Details	✓	✓	
Security:	Screen: Security			✓
Sensitivity Assessment	Screen: Sensitivity Assessment		✓	
Sensitivity Assessment	Sensitivity Adjustment Factors ->Edit SAF		✓	

Appendix B: Reader Daily Quality Control

microSTARⁱⁱ Reader Daily Quality Control



LANDAUER®

microSTARⁱⁱ
medical dosimetry system

LDR-PROCESS-2015-100

Appendix C: Standard Database Values

Dosimetry Category
Dosimetry Use Type

Patient ID
Medical Record Number (MRN)
First Name
Middle Name
Last Name
Sex
Date of Birth
Patient Notes

Assignment ID
Assignment Date
Assignment Notes

Reader ID
Reader Name
Reader UID
Reader Notes
Hardware Setting ID
Hardware Setting Name
Hardware Setting Notes
Cross-Over-Point (COP)

New Cal ID
Exposed Dose
Daily QC Status

Organization
Division
Location
Department

Process ID
Process Number
Process Type

Dosimeter ID
Dosimeter Position
Date Exposed
Radiation Quality
Radiation Field Size
SSD
Dosimeter Depth
Buildup Used
Buildup Thickness
Buildup Material

Field ID
FieldNumber
Field Name
Plan UID

User ID
Read User Name
Read ID
Date Read
Serial Number
Screened Flag
Sensitivity
Beam Used
Beam Use Mode
Raw Counts
Used Flag
Counts STDEV
Counts CV
Average Counts
Verification Mode
Verification Dosimeter Serial Number
Background Counts
Background Corrected Counts
Test Counts
Background Correction Used Flag
Sensitivity Adjustment Factor
Sensitivity Adjustment Factor Used Flag
Dose Reading Mode
Dose
Average Dose
Predicted Dose
Units
Result ID
Result Notes
Date Exported

Appendix D: Glossary

aluminum oxide (Al_2O_3 or $\text{Al}_2\text{O}_3\text{:C}$):

Aluminum Oxide is a ceramic metal manufactured from bauxite. Al_2O_3 represents the pure form whereas $\text{Al}_2\text{O}_3\text{:C}$ represents carbon-doped aluminum oxide, which is the form used in LANDAUER dosimeters.

annealing (optical):

The physical process in which dosimeters are exposed to visible light source with UV filtered out designed to liberate electrons from dosimetric traps. Landauer does not recommend annealing dosimeters for reuse because high dose exposures can shift the dosimeter's sensitivity.

assignment (dosimeter):

The act of associating a single dosimeter with a specific patient ID. Within the microSTARⁱⁱ software, this association or assignment occurs on the *Dosimeter Assignment* tab. There, the serial numbers of one or more patient dosimeters are linked to that patient's demographic information, before or after exposure, but prior to performing a readout operation.

background radiation:

Minor dose accumulated on a dosimeter from unintended sources, such as transportation, storage, or exposure to radiation from other sources in the medical environment.

calibration (reader):

The act of establishing reader conversion factor(s) that will be used in the formula used to convert reader raw PMT counts to dose. This involves reading dosimeters with known radiation dose levels and characterizing the relationship between measured PMT raw counts and exposed dose level.

Calibration of the reader must be performed using dosimeters that have been exposed under conditions that emulate the clinical application; the same radiation energy or spectrum, exposure geometry and scattering conditions should be used.

Two calibration options are used in the microSTARⁱⁱ Medical Dosimetry System: Linear and Non-Linear. The decision about which to use is primarily dependent on the magnitude of doses expected to be measured.

See also: *calibration factor(s)*

calibration factor(s):

The conversion factors used to convert reader raw counts to units of absorbed dose.

When dose calculation is based upon a Linear calibration, there is a single calibration factor (CF) due to the Linear relationship between reader raw counts corrected for sensitivity (X; where $X = \text{Raw PMT counts} / S$; where $S = \text{Sensitivity of the nanoDot}$) and dose. The Linear dose calculation formula is the following:

$$Dose = \frac{X}{CF}$$

When the dose calculation is based upon a Non-Linear calibration where the dose calculation takes the form of a quadratic formula, the calibration factors are the coefficients A, B, and C in the dose calculation formula of the form:

$$Dose = Ax^2 + Bx + C$$

Calibration factors of either type are displayed in the data grid on the *Calibration* tab, dependent on the current selection on the *Configuration* tab (i.e., Non-Linear Calibration has been selected or unselected).

For medical dosimetry applications in the Megavoltage range, the Linear calibration option is usually used to measure doses below 300 cGy, whereas the Non-Linear calibration is used to measure doses > 300 cGy.

coefficient of variation (CV):

Reported within the microSTARⁱⁱ software as an indication of the variance in readings obtained using one or more dosimeters or by performing multiple reads on the same dosimeter. The coefficient of variation or CV is computed from the ratio of the Standard Deviation across all readings divided by the Average.

control limits:

Maximum and minimum values used to ensure the microSTARⁱⁱ reader is operating within expected performance levels.

Cross-Over-Point (COP):

A parameter established uniquely for each reader during manufacturing and is used by the reader to determine the LED intensity (weak or strong beam usage) during readout whenever the reader is operated with the Automatic Beam Mode selected on the *Configuration* tab. The COP can vary based on the range being read. The COP is established for each reader using a Cs-137 (662 keV) spectrum and corresponds to a dose

level of approximately 15 cGy at 662 keV. In the diagnostic imaging range where the dosimeter energy-dependent response is increased by threefold or higher, the COP count threshold will be reached at significantly lower doses. For this reason, the maximum dose level for the low dose range for the 80 kVp calset, is 3.0 cGy. This ensures all calibration nanoDots within the Low Dose range are read using the strong beam. This over-response at 80 kVp also explains why the maximum dose in the High Dose range is 100 cGy for this set; higher doses would correspond to the Non-Linear High Dose region.

dark counts:

An intrinsic measurement quantity obtained automatically in the microSTARⁱⁱ self-test mode that refers to the reader photomultiplier tube counts obtained in the absence of LED stimulation. A high dark count result can be an indicator of excessive photomultiplier electronic noise or more commonly light leakage that can occur if the reader drawer is opened during reading or is not properly closed before initiating a reading.

See also *PMT Counts* and *LED Counts*

depletion (reading):

When reading the dosimeter, a very small fraction of dosimetric traps are released after the application of optical stimulation. This decrease reduces the total dose information stored within the dosimeter. Depletion due to reading explains why the reader raw PMT counts will show a decreasing trend if a large number of readings are performed in sequence. The amount of depletion per reading is strongly dependent on the intensity of the stimulating LED used during the readout process.

See also *Strong / Weak Beam*

dose (absorbed):

The absorbed dose is the amount of energy deposited in tissue or other media by ionizing radiation and is expressed in units (J/Kg) or Gray.

dosimeter (passive):

A passive radiation measuring device used to measure dose. LANDAUER dosimeters are used in a variety of applications including: occupational, environmental and medical. The dosimeter used in the microSTARⁱⁱ Medical Dosimetry System is the nanoDot.

general purpose nanoDot:

Dosimeters that are generated using standard process and protocols. These use a general sensitivity based on the average readings for the OSL material. They have an accuracy of $\pm 10\%$. (Also referred to as general population nanoDot.)

Light Emitting Diode (LED):

The microSTARⁱⁱ reader component used to stimulate the OSL detector element in the nanoDot dosimeter, which results in the emission of luminescence photons.

linear (calibration):

A mode of reader calibration associated with calibration of the reader in its known LINEAR operating range. In this range, the reader signal is proportional to dosimeter dose. This range may correspond to the Low Dose (below COP) or High Dose (higher than COP) ranges.

luminescence (optical):

The phenomenon when light photons are produced by atoms of a material at normal or low temperatures. This occurs when ground state electrons are excited in some manner to a higher energy state. As they return to the ground state, their excess energy is emitted in the form of light with an energy and wavelength dictated by the difference in energy level between the excited state and the ground state. In OSL Dosimetry, the electron excited state is created when radiation interacts in the OSLD material. The excited electron, which would otherwise return to the ground state and emit luminescence light promptly, is captured in an electron trap, allowing the OSLD material to store absorbed energy. This absorbed energy or dose is released at the time of readout when optical stimulation is used to release the trapped electron, which subsequently returns to a lower energy level when it interacts at luminescence centers within the OSDL material.

microSTARⁱⁱ:

An OSLD reader distributed by LANDAUER. The original microSTAR reader employed Optically-Stimulated Luminescence (CW-OSL) technology. The microSTARⁱⁱ reader employs Pulsed Optically-Stimulated Luminescence (POSL) technology.

nanoDot:

Discrete dosimeter used in medical dosimetry. It is comprised of a thin disk of powdered aluminum oxide, doped with carbon, suspended in an epoxy matrix, and encapsulated in a light tight case. The OSL element has a 4 mm active diameter and an active thickness of 0.2 mm. The nanoDot case dimensions are: 1.0 cm x 1.0 cm x 0.2 cm.

non-Linear (calibration):

A dose calculation using a second order polynomial whose coefficients are calibration factors, employed to characterize the reader response, particularly in the super-linear region beyond 300 cGy (at Megavoltage energies).

Photomultiplier Tube (PMT):

A vacuum tube that converts luminescence photons to a useful electronic signal that is processed and counted to yield reader PMT counts.

Photodiode (P-Diode):

A semiconductor device that converts light into current. The current is generated when photons are absorbed in the semiconductor layer, producing charge carriers.

PMT Counts:

PMT Counts are counts acquired by an internal photodiode within the optical engine and are used to assess the stability of the LED light output. This count is obtained during the self-test mode operations.

Pulsed Optically Stimulated Luminescence (POSL):

A mode of Optically-Stimulated Luminescence in which the optical stimulation and measurement of luminescence emission are separated in time. Optical stimulation is applied by cycling or pulsing the LED on and off and the emitted luminescence light is collected in the intervals between stimulation, i.e., when the LED pulse is turned off.

Quality Control (QC) Dosimeters:

Dosimeters irradiated with known doses that are NIST-traceable. They are used to verify the accuracy of calibration by establishing whether the reader can reproduce a dose reading within $\pm 5.5\%$ of the known dose.

readout:

The process of acquiring an absorbed dose reading using the microSTARⁱⁱ Medical Dosimetry System. This occurs when the dosimeter is positioned in the reader drawer and read to perform a dose measurement.

screened nanoDots:

Dosimeters that are individually tested to determine their sensitivity, labeled and then retested to confirm the accuracy of labeling. As a result, they have an accuracy of $\pm 5.5\%$ in comparison with General Purpose nanoDots whose accuracy is only $\pm 10\%$.

secondary dose verification:

An independent approach to verifying dose in medical imaging. This involves using a measurement system and device that are designed for QA of a primary dosimetry system. The primary dosimetry system, such as a Treatment Planning System, is directly involved in patient care. The secondary dose verification system is not; it is used as an additional quality check of the primary system. If a discrepancy is identified, further investigation and

a root cause analysis must be performed, which would include a check of the primary dosimetry system and possibly verification of the radiation emitting device output levels and calibration. Results obtained using a secondary dose verification system should never be used to direct patient care decisions.

sensitivity (labeled):

A value that defines the unique response normalization factor for a dosimeter. This is used to correct for the response differences between different nanoDot dosimeters due to variations in their OSL active element composition resulting from differences in density, thickness, homogeneity, etc. The accuracy of the nanoDot labeled sensitivity is defined by the manufacturing method. This value is assigned to a dosimeter at the time of manufacture. This value is encoded in the dosimeter serial number label.

See also: *General Purpose nanoDot* and *Screened nanoDot*

Standard deviation (STDEV):

A measure of dispersion in a frequency distribution, equal to the square root of the mean of the squares of the deviations from the arithmetic mean of the distribution.

strong beam:

A mode of LED illumination employed in the microSTARⁱⁱ reader wherein the LED is operated with a longer pulse duration to achieve better stimulation efficiency for low dose applications requiring higher statistical accuracy.

weak beam:

A mode of LED illumination employed in the microSTARⁱⁱ reader wherein the LED is operated with a shorter pulse duration in dose applications to ensure the reader photomultiplier does not saturate.