

# microSTAR<sup>®</sup>ii

medical dosimetry system

## INSTALLATION & CONFIGURATION



**LANDAUER<sup>®</sup>**

v2.1 | 07/22/2019

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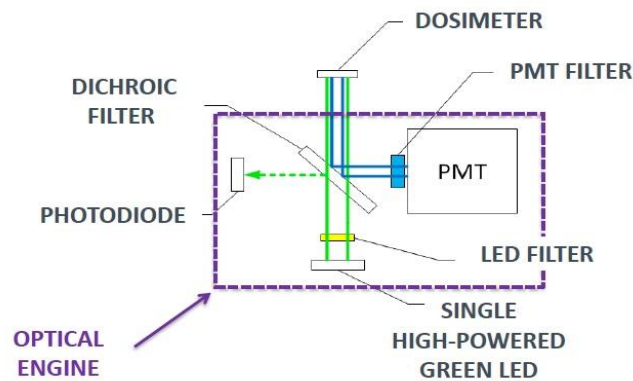
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# CHAPTER 1 INTRODUCTION

The microSTAR®ii 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 analysis 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**

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 guide contains detailed instructions on how to install and configure the microSTARii Medical Dosimetry System, including but not limited to:

- Reader Specifications & Design
- Reader and Computer Physical Setup
- Software Configuration
- Reader Verification
- Reader Calibration

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This guide is for use with the standard system configuration (reader and LANDAUER-provided computer). For assistance with custom configurations, contact LANDAUER Technical Support (*8.1 Technical Support*).

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

- **microSTARii User Manual** for detailed instructions on operations, advanced configuration, maintenance, and troubleshooting.
- **Frequently Asked Questions** for information about the system design, operations, and term definitions.
- **microSTARii™ – A new system for medical dosimetry: Part I: Technology & Initial Performance** a white paper that provides information on the design and performance.

## 1.1 Limitations of Product Scope

The microSTARii Medical Dosimetry System has been designed as a secondary dose verification system. The system should therefore only be employed as one of a number of tools in a program of quality assurance for the primary dose verification systems being used.

The results obtained with the microSTARii should not be used to guide direct patient care decisions. However, under certain specific conditions results obtained using the microSTARii Medical Dosimetry System can be cited and reported as a secondary verification of the primary systems in place used to predict or assess the radiation dose to patients resulting from diagnostic or therapeutic procedures.

The nanoDot dosimeter used in the microSTARii Medical Dosimetry System is manufactured as a single-use device. 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.

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

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 that site-specific written Standard Operating Procedures be implemented prior to launching a Medical Dosimetry Program.

## 1.2 Conventions and Standards

The following symbols are used within this documentation to mark risks, warnings, and other information.



ISO 3864, No. B.3.6  
Caution – Risk of Electrical Shock



ISO 3864, No. B.3.1  
Caution – This symbol denotes information that could affect the equipment operation.



IEC 417, NO. 5019  
Protective Conductor Terminal



IEC 417, NO. 5007 On (Supply)



IEC 417, No. 5008 Off (Supply)

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### ***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 HARDWARE SHIPMENT

## 2.1 Parts List

The following items are included in the microSTARii shipment.

### PARTS & MATERIALS

#### microSTARii Reader

#### microSTARii Reader Accessories

- Drawer
- Power Supply
- USB Cable

#### Standalone Computer (All-in-One or Laptop) with microSTARii Software Pre-Installed

#### Computer Accessories

- Power Cord
- Keyboard (if All-in-One)
- Mouse (if All-in-One)

#### Barcode Scanner

#### nanoDot Dosimeters

- 1 NIST-Traceable 80 kVp, Cs137, or Non-Standard Calibration Set (Calset) with Certificate
- 1 NIST-Traceable 80 kVp, Cs137, or Non-Standard Quality Control (QC) Set with Certificate
- 2 Consistency nanoDots
- Additional unexposed nanoDot dosimeters (Screened or General Purpose), if ordered

#### Related Documentation

- Factory Test Results Sheet
- Installation & Configuration Guide
- User Guide
- Related Field Service Bulletins
- Computer Support Documentation



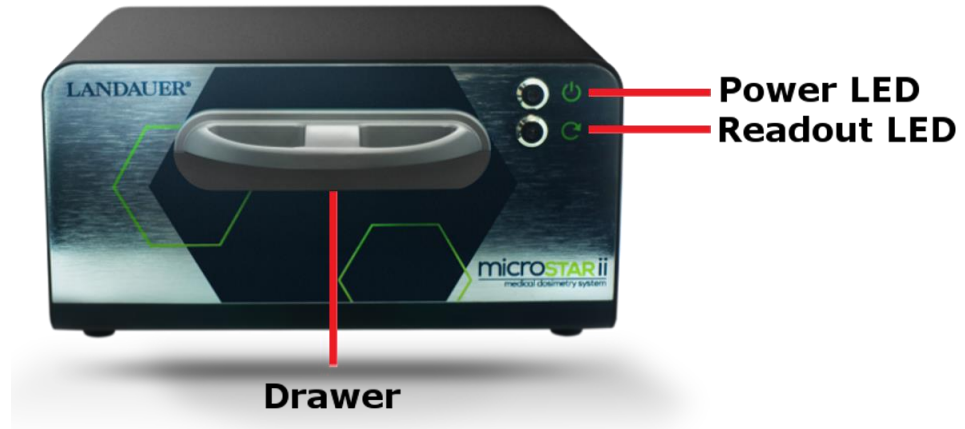


Figure 2-1: microSTARii Reader – Front



Figure 2-2: microSTARii Reader – Back


LANDAUER®																																																	
MicroSTARii Reader - Manufacturing QA Test Results																																																	
READER SERIAL #: <input style="width: 90%;" type="text"/>	TEST PERFORMED BY: <input style="width: 90%;" type="text"/>																																																
TEST DATE: <input style="width: 90%;" type="text"/>	SIGNATURE: <input style="width: 90%;" type="text"/>																																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">READER SETTINGS</th> </tr> </thead> <tbody> <tr> <td style="text-align: right;">Firmware Version:</td> <td>mms 2.1</td> </tr> <tr> <td style="text-align: right;">Crossover Point:</td> <td>299</td> </tr> <tr> <th colspan="2" style="text-align: center;">CALIBRATION FACTOR Cs-137 (662 keV)</th> </tr> <tr> <td style="text-align: right;">Low Dose (counts/mrad):</td> <td>3.873</td> </tr> <tr> <td style="text-align: right;">High Dose (counts/mrad):</td> <td>0.645</td> </tr> <tr> <th colspan="2" style="text-align: center;">LOWER LIMIT OF DETECTION (mrad)</th> </tr> <tr> <td style="text-align: right;">Low Dose:</td> <td>1.06</td> </tr> <tr> <td style="text-align: right;">High Dose:</td> <td>3.08</td> </tr> <tr> <th colspan="2" style="text-align: center;">NANODOT READING REPEATABILITY @≥ 50cGy</th> </tr> <tr> <td style="text-align: right;">Stationary Repeatability %CV:</td> <td>0.55%</td> </tr> <tr> <td style="text-align: right;">Moving Repeatability %CV:</td> <td>0.64%</td> </tr> <tr> <th colspan="2" style="text-align: center;">INTRINSIC MEASUREMENTS</th> </tr> <tr> <td style="text-align: right;">Maximum Dark Counts:</td> <td>3</td> </tr> <tr> <td style="text-align: right;">Average PMT Counts:</td> <td>4865</td> </tr> <tr> <td style="text-align: right;">PMT %CV:</td> <td>1.103%</td> </tr> <tr> <td style="text-align: right;">Average Photodiode Counts:</td> <td>1477</td> </tr> <tr> <td style="text-align: right;">Photodiode %CV:</td> <td>0.871%</td> </tr> <tr> <th colspan="2" style="text-align: center;">LIGHT LEAKAGE</th> </tr> <tr> <td style="text-align: right;">Maximum Dark Counts:</td> <td>2</td> </tr> <tr> <th colspan="2" style="text-align: center;">LINEARITY</th> </tr> <tr> <td style="text-align: right;">Slope:</td> <td>0.997</td> </tr> <tr> <td style="text-align: right;">R-Squared:</td> <td>0.9996</td> </tr> <tr> <td style="text-align: right;">Average Bias:</td> <td>-2.04%</td> </tr> </tbody> </table>		READER SETTINGS		Firmware Version:	mms 2.1	Crossover Point:	299	CALIBRATION FACTOR Cs-137 (662 keV)		Low Dose (counts/mrad):	3.873	High Dose (counts/mrad):	0.645	LOWER LIMIT OF DETECTION (mrad)		Low Dose:	1.06	High Dose:	3.08	NANODOT READING REPEATABILITY @≥ 50cGy		Stationary Repeatability %CV:	0.55%	Moving Repeatability %CV:	0.64%	INTRINSIC MEASUREMENTS		Maximum Dark Counts:	3	Average PMT Counts:	4865	PMT %CV:	1.103%	Average Photodiode Counts:	1477	Photodiode %CV:	0.871%	LIGHT LEAKAGE		Maximum Dark Counts:	2	LINEARITY		Slope:	0.997	R-Squared:	0.9996	Average Bias:	-2.04%
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Figure 2-3: Sample microSTARii Reader Manufacturing QA Test Report

**NOTE:** If your reader is operating correctly and has not been damaged during shipment, its performance at installation should be comparable to that measured during manufacturing QA Testing. Note in particular the Low and High Dose calibration factors and the PMT and P-Diode average baseline values from your test sheet and compare with the results obtained during installation testing.

## 2.2 Unpacking & Handling

The parts should be unpacked in the lab or office where the microSTARii system will be operated. Unpack the system carefully as small parts, cables and nanoDot dosimeters are included with the shipment. Inspect the box for loose parts before beginning installation.

**NOTE:** It is strongly recommended that you save the packing material and boxes in the event that a reader needs to be returned for preventive maintenance or service at a later date.

microSTARii is carefully packed at the factory to minimize the possibility of damage during shipping. However, to ensure there has not been damage in transit, inspect the exterior and contents of the box for signs of damage or mishandling. If there is visible damage to the reader, computer, or accessories upon receipt, inform the shipping company and LANDAUER, Inc. immediately.

# CHAPTER 3 READER HARDWARE SPECIFICATIONS & DESIGN

The following subsections contain specification information for the microSTARii reader hardware.

PHYSICAL SPECIFICATIONS	
<b>Dimensions</b>	<ul style="list-style-type: none"> <li>- <b>Depth:</b> 6.01 in (152.7mm)</li> <li>- <b>Width:</b> 8.13 in (206.7mm)</li> <li>- <b>Height:</b> 4.06 in (103.3mm)</li> </ul>
<b>Weight</b>	5.14 lbs. (2.33 kg)
<b>Enclosure Material</b>	Metal case, powder coated
<b>Connections</b>	USB
<b>Power</b>	6V DC, 1.0A, 100-240V +/- 10% 50-60Hz. Note: Use only the power supply provided by LANDAUER for use with microSTARii with this system.
<b>Operating Environment</b>	5°C to 40°C; < 70% Relative Humidity non-condensing; in stable conditions. <b>NOTE:</b> Extreme temperature fluctuations may impact performance. Shifts in altitude greater than 2000 meters may also impact performance.
<b>Storage Environment</b>	-20°C to 60°C; < 90% Relative Humidity non-condensing
<b>Use Location</b>	Indoor use only

PERFORMANCE SPECIFICATIONS		
METRIC	SPECIFICATION	NOTES
<b>Accuracy</b>	± 5.5%	Using screened nanoDots (k=2)
<b>Repeatability</b>	≤ 1.0%	Coefficient of Variation; n=10, dose >50+ cGy
<b>Lower Limit of Detection (LLD)</b>		
Strong Beam (Low Dose)	≤ 3 mrad	Lower limits with freshly annealed blanks
Weak Beam (High Dose)	≤ 20 mrad	Lower limits with freshly annealed blanks

## PERFORMANCE SPECIFICATIONS

METRIC	SPECIFICATION	NOTES
<b>Depletion</b>		
Strong Beam (Low Dose)	$\leq 0.60\%$	Percent depletion per read
Weak Beam (High Dose)	$\leq 0.07\%$	Percent depletion per read
<b>Intrinsic Stability</b>		
Dark	$\leq 20$	Counts/Second
LED with Photodiode	$\leq 3.0\%$	Coefficient of variation computed across 10 consecutive measurement cycles
LED with Photomultiplier Tube	$\leq 3.0\%$	
<b>Light Leakage</b>	$\leq 20$	Counts/Second

## STATEMENT OF COMPLIANCE

### Safety... IEC 61010-1; Pollution Degree 2

*Electromagnetic Compliance... International ... IEC 61326-1: Basic Electromagnetic Environment; CISPR 11: Group 1, Class A*

Group 1: Equipment has intentionally generated and/or use conductively coupled radio frequency energy which is necessary for the internal functioning of the equipment itself.

Class A: Equipment is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted and radiated disturbances.

Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. USA (FCC) ... 47 CFR 15 subpart B. This product is considered an exempt device per clause 15.103.

# CHAPTER 4 HARDWARE INSTALLATION

Use the information and instructions in the subsections to set up the computer and install the microSTARii reader and peripherals.

- ✓ Set up Computer & Connect Peripherals (4.2)
- ✓ Plug In Reader (4.3.1)
- ✓ Connect Reader (4.3.3)
- ✓ Verify Connectivity (4.3.4)

## 4.1 Installation Requirements

### 4.1.1 Environmental

microSTARii may be operated in most clinical environments that have a stable ambient temperature. For best results, it is recommended that the system be installed in a dedicated location on a stable surface away from direct sunlight.

---

**NOTE:** It is recommended that the nanoDot dosimeters be stored away from direct sunlight and fluorescent light when not in use.

---

### 4.1.2 Electrical



Before attempting to install the system, verify the wall socket that will be used is properly polarized and properly grounded. If possible, connect both the reader and the computer into a surge protection power strip and connect the power strip to the wall outlet.

## 4.2 Physical Setup: Computer

### Equipment Needed

- Computer
- Accessories (if all-in-one): Mouse and Keyboard
- Barcode Scanner

Refer to the manufacturer's User manual for PC setup and Operation.

- STEP 1:** After setting up the PC according to the instructions provided by the manufacturer, turn on the PC.
- STEP 2:** Connect accessories to the PC (i.e., mouse and keyboard)
- STEP 3:** Connect the barcode scanner USB connector to any available USB port on the computer.
- STEP 4:** Log on to the computer using the default logon credentials.

<b>Default Credentials</b>	<b>Logon</b>	<b>USERNAME:</b> admin
		<b>PASSWORD:</b> system

**Note:** The Windows password should be changed after initial log on. Ensure the updated credentials comply with organizational security policies.

## 4.3 Physical Setup: Reader

### Equipment Needed

- Drawer
- Reader
- Power Supply
- USB Cord

### 4.3.1 Install the Drawer

To install the reader drawer follow the steps below:



**Figure 4-1: Correct Drawer Orientation**

**STEP 1:** Position the drawer with the nanoDot and ejector facing up (Figure 4-1).

**STEP 2:** Slide the drawer into the reader.

**WARNING:** Improper insertion of the drawer can cause serious damage to the reader. Always insert the drawer using the orientation shown. Never force the drawer into the reader. To avoid damage to the optical engine, the drawer must be fully inserted before connecting the reader to a power source and turning the reader ON.

### 4.3.2 Connecting to Power Source



- STEP 1:** Plug the reader power supply cord into the reader and screw down the connector.
- STEP 2:** Plug the other end of the power supply cord into the power outlet. (The outlet must meet electrical requirements in 4.1.2.)

Figure 4-2: Connecting Reader Power

### 4.3.3 Connecting the Reader to the Computer

**NOTE:** The USB cable has two connectors: square (USB Type B) and rectangular (USB Type A).



- STEP 1:** Connect the USB Type B connector to the reader USB port.
- STEP 2:** Connect the USB Type A connector to any available USB port on the computer.

Figure 4-3: Reader USB Connection

### 4.3.4 Verifying Connectivity



- STEP 1:** Turn on the computer.
- STEP 2:** Turn on the reader using the Power Button.

The Power LED should illuminate.

Figure 4-4: Reader On Button

### 4.3.5 Connections Example

The connections for the all-in-one computer will similar to Figure 4-5 below.

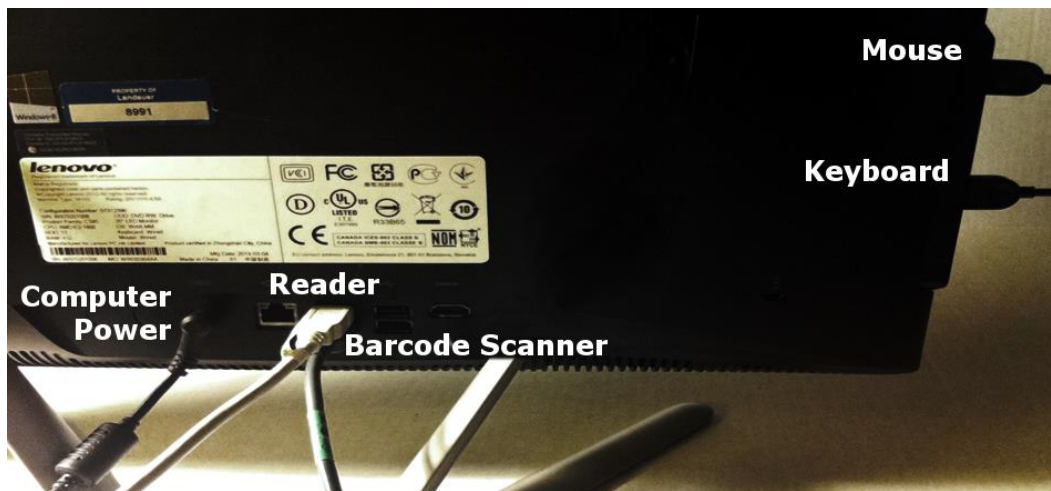


Figure 4-5: All-in-One Fully Connected



# CHAPTER 5 SOFTWARE CONFIGURATION

Use the information and instructions in the subsections to configure the software to prepare for system configuration and update system access.

- ✓ Logging Into the System (5.1)
- ✓ Changing the Default Account Password (5.2)
- ✓ Connecting the Reader (5.3)
- ✓ Setting Up Unique User Accounts (5.4)

## Information Needed

- User Account Information (user names, passwords and profile information for Advanced Operator and other system users)

**Note:** At a minimum an Advanced Operator account must be created to complete system configuration. Other accounts can be created post-installation.

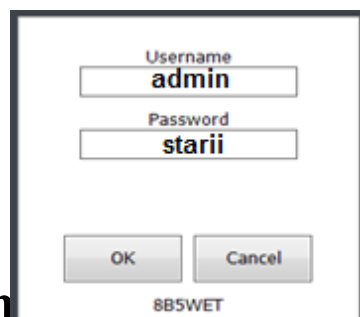
## 5.1 Logging In

Complete the following steps to log on to the microSTARii system for the first time:

**STEP 1:** From the desktop double-click the microSTARii reader application icon to launch the microSTARii Medical Dosimetry System software.



**STEP 2:** Log on to the system using the default Administrator logon credentials.



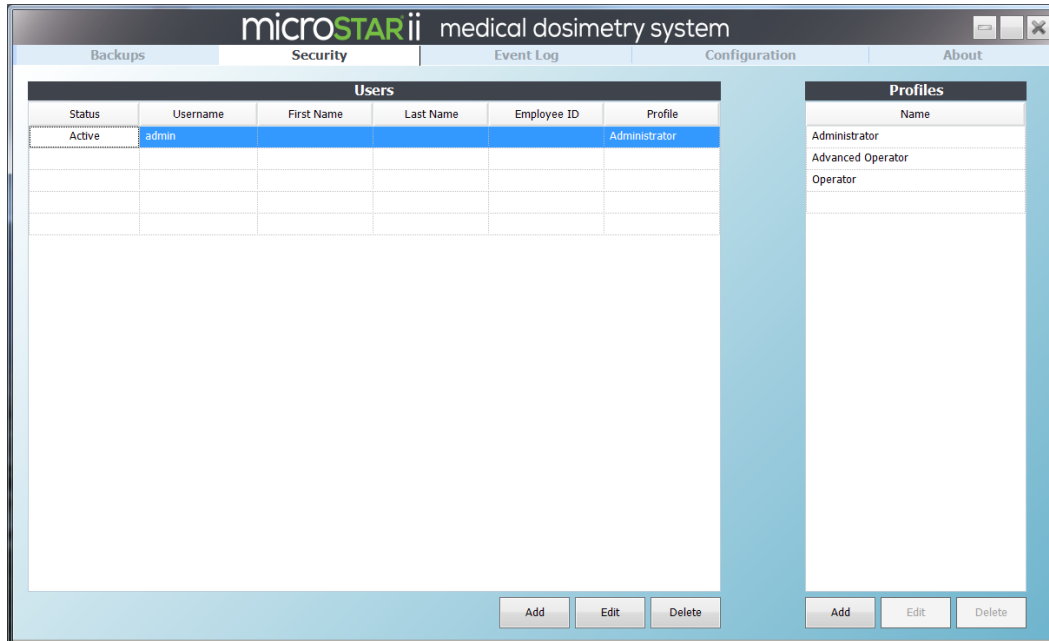
<b>Default microSTARii Logon Credentials</b>	<b>USERNAME:</b> admin
	<b>PASSWORD:</b> starii

## 5.2 Changing the Default Account Password

Figure 5-1: Log On Window

To protect system data, the default password must be changed after you have logged in for the first time. To change the default password, complete the steps below:

**STEP 1:** Navigate to the *Security* tab.



**Figure 5-2: Security Tab**

**STEP 2:** In the Users table, double-click on the admin account row to launch the Edit User window.

**OR**

Click the row to select it, and click the Edit button to launch the Edit User window.

**STEP 3:** Type in a new password, and type it again in the Confirm Password field.

**STEP 4:** Click OK to save the new password.

**STEP 5:** Log out of the microSTARii application. (Click the [X] on the upper-right of the screen.)  
Log back on to confirm the password change was successful.

## 5.3 Connecting Reader

After you have logged into the system and changed the default account, complete the following steps to confirm your reader settings and assign a reader name:

**STEP 1:** Navigate to the *Configuration* tab.

**STEP 2:** Click the Manage Readers button. (Outlined in Figure 5-3 below.)

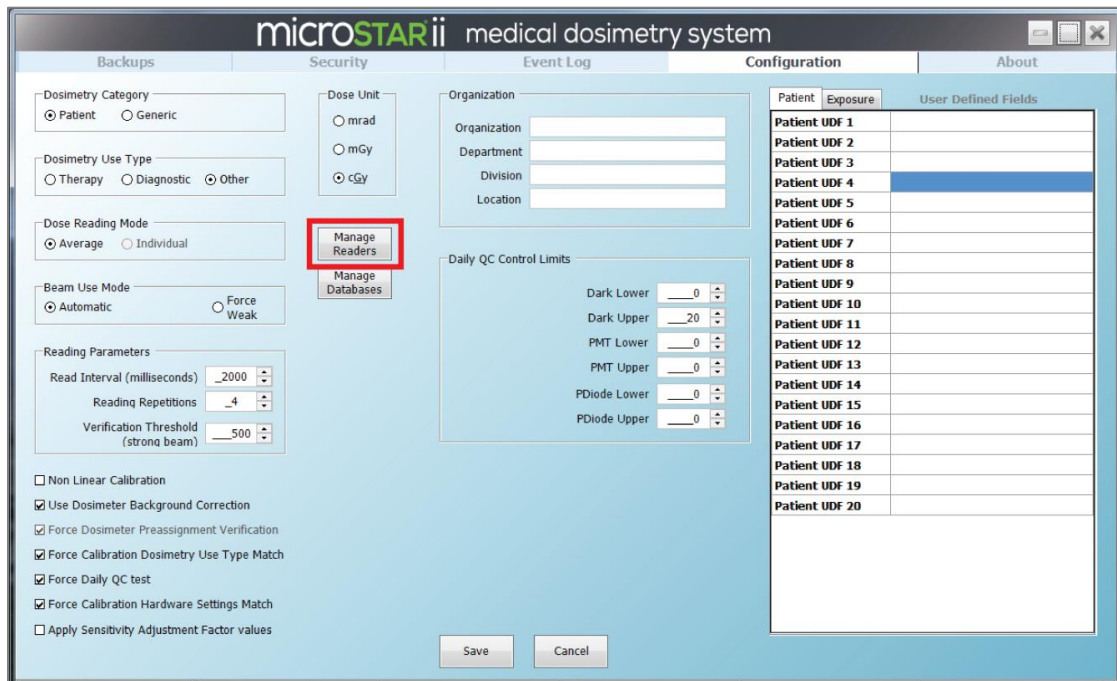


Figure 5-3: Configuration Tab – Manage Readers

**STEP 3:** In the Reader Management dialog box, validate that the reader successfully connected by verifying that the DEFAULT reader has the following two values:

- ✓ A **Reader UID** value that corresponds to the last four digits of the serial number on the back of the reader.
- ✓ The **CurrentHardwareSettingID** value is 1.

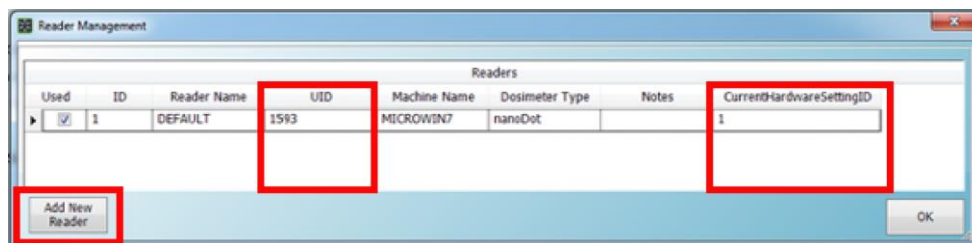


Figure 5-4: Reader Management Dialog Box

- STEP 4:** Assign a unique reader name to the reader:
- a. Click the Add New Reader button.
  - b. New Reader dialog box, enter in a unique name for the new reader.



**Figure 5-5: New Reader Dialog Box**

- c. Click OK and the new reader will be listed on the Reader Management window.
- STEP 5:** Verify the Used check box is selected next to the new reader entry. Click OK to exit the Reader Management window.

## 5.4 Creating User Accounts

To support compliance with HIPPA guidelines, microSTARii provides the capability to configure unique user accounts. Creating individual user accounts supports security audits and provides traceability.

In addition to individual accounts, microSTARii uses profiles to control user permissions. The system includes three default profiles for common permissions: Administrator, Advanced Operator, and Operator. The following table lists the default profiles and security limitations. For a full listing of permissions see *Appendix A: Profile Permissions Listing*.

PROFILE	USER TYPE	RESTRICTIONS
Administrator	Administration	<ul style="list-style-type: none"> <li>- Cannot operate reader</li> <li>- Cannot modify reader factory hardware settings</li> </ul>
Advanced Operator	Expert Level	<ul style="list-style-type: none"> <li>- Cannot create user accounts</li> <li>- Cannot access advanced configuration settings</li> <li>- Cannot modify reader factory hardware settings</li> </ul>
Operator	Routine Dosimetry	<ul style="list-style-type: none"> <li>- Cannot access most configuration settings</li> <li>- Cannot access certain advanced features such as Sensitivity Assessment</li> <li>- Cannot modify reader factory hardware settings</li> </ul>

Accounts and profiles are managed on the *Security* tab (Figure 5-2).

---

**NOTE:** The admin account cannot be used to operate the reader for dosimetry measurements. At a minimum, you must set up an account using the Advanced Operator profile to complete the configuration in *Chapter 7 Testing & Calibration.*

---

It is recommended that a system administrator account is created using the Advanced Operator profile to allow the administrator to verify reader configuration and performance during operations.

---

Complete the following steps to add a new *Advanced Operator* user account.

**STEP 1:** On the *Security* tab (Figure 5-2), click the Add button under the Users table.

**STEP 2:** Fill in the fields in the dialog box (Figure 5-6).

- a. Username
- b. Password (must be greater than four characters, with no spaces)
- c. Confirm Password
- d. Profile (select Advanced Operator)
- 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.

The image shows a 'New User' dialog box with the following fields and values:

- Username: ajones
- Password: \*\*\*\*\*
- Confirm Password: \*\*\*\*\*
- Profile: Advanced Operator
- Employee ID: 38472
- First Name: Adam
- Last Name: Jones
- Notes:  Active

Buttons: OK, Cancel

**Figure 5-6: New User Form**

**STEP 4:** Repeat steps to set up additional user accounts. (Change value in Step 2.d. for other profiles.)

The screenshot shows the microSTARii medical dosimetry system interface. At the top, there is a navigation bar with the following tabs: Backups, Security (selected), Event Log, Configuration, and About. Below the navigation bar, there are two main sections: 'Users' and 'Profiles'.

Users					
Status	Username	First Name	Last Name	Employee ID	Profile
Active	admin				Administrator
Active	ajones	Adam	Jones	38472	Advanced Operator

Profiles
Name
Administrator
Advanced Operator
Operator

**Figure 5-7: Updated User Account Listing**

# CHAPTER 6 SYSTEM CONFIGURATION

Use the information in this chapter to configure the system for reporting and dosimetry measurements.

- ✓ Organization Information
- ✓ Beam Use Mode
- ✓ Verification Threshold

## Information Needed

- Factory Test Result Sheet

## NOTES:

The system configuration outlined in this section should be completed using the **admin** account.

All configuration outlined in this chapter is completed on the **Configuration** tab.

To apply changes, click the **Save** button at the bottom of the screen.

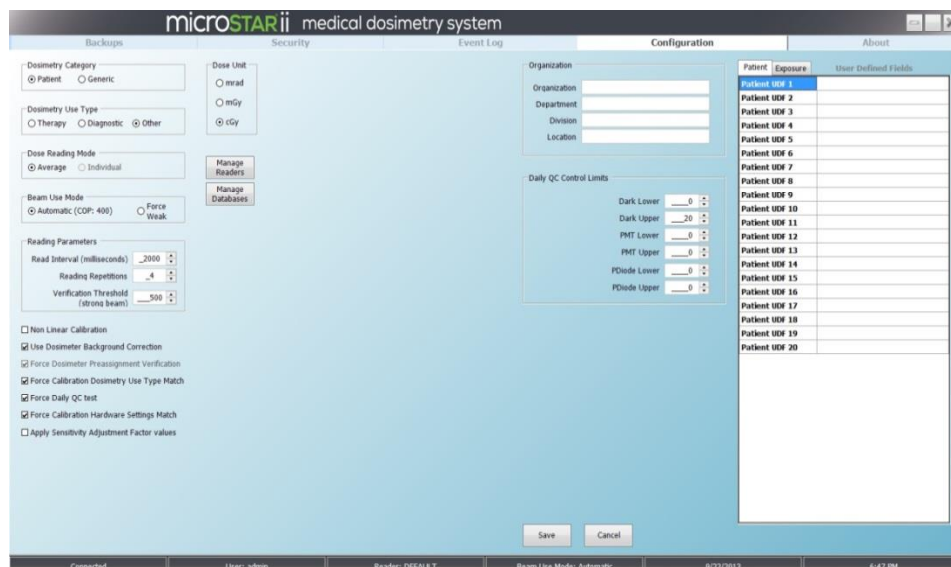
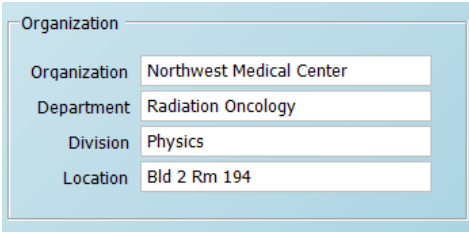
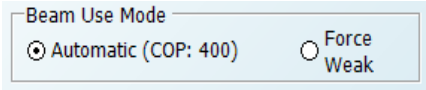
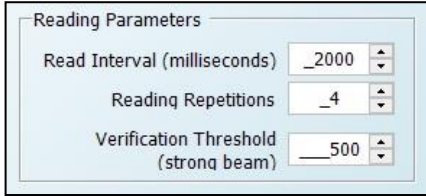


Figure 6-1: Configuration Tab

Use the information in the following table to configure the system.

**NOTE:** The Daily QC Control Limits fields are updated based on the results of the configuration tests run in section 7.1.1. Other values on the configuration screen can be modified based on usage and operational needs.

FIELD	DESCRIPTION	CONFIGURATION
<p><b>Organization</b></p>	<p>This information is used in dosimetry reports (i.e., the Patient Dose Report) and associated database records.</p> 	<p>Fill in the following fields:</p> <ul style="list-style-type: none"> <li>- Organization Name</li> <li>- Department</li> <li>- Division</li> <li>- Location</li> </ul>
<p><b>Beam Use Mode</b></p>	<p>This setting determines whether the reader switches between strong and weak LED levels (Automatic) or uses only the LED level regardless of dose level (Force Weak). In most applications, automatic mode is used. Force Weak is used in non-linear calibrations for high doses.</p> 	<ol style="list-style-type: none"> <li>1. Verify the Automatic option is selected.</li> <li>2. Validate that the COP value matches the Factory Test Results sheet.</li> </ol>
<p><b>Reading Parameters (Verification Threshold)</b></p>	<p>This setting is the limit for the dosimeter pre-assignment test.</p> 	<p>The default and recommended value for nanoDots read using the strong beam mode is 500 raw counts. The value can be lowered for very low dose applications to reduce the acceptable limit.</p> <p><b>NOTE:</b> Unexposed dosimeters that have been manufactured within the last six months prior to verification, typically yield strong beam raw count values below 200.</p>



# CHAPTER 7 TESTING & CALIBRATION

Performance testing and reader calibration must be completed in order to prepare the system for use. Use the information in this chapter to prepare the system for reporting and dosimetry measurements.

## Performance Testing

The built-in performance testing assesses the stability of the reader electronics, photomultiplier tube (PMT), and LED.

- ✓ Establish Intrinsic Test Control Limits (Reader QC Test) (7.1.1)
- ✓ Perform Intrinsic Test (Reader Daily QC Test) (7.1.2)
- ✓ Perform nanoDot Reading Reproducibility Test (7.1.2)

## Reader Calibration

Reader calibration uses the LANDAUER-provided calset and QC set of dosimeters to create the calculations needed to verify the reader performance and set a baseline for 80 kVp, Cs137, or Non-Standard exposure conditions.

- ✓ Perform Reader Calibration (7.2.1)
- ✓ Perform Post-Calibration Quality Control Check (7.2.2)

### Equipment Needed

- NIST-Traceable 80 kVp, Cs137, or Non-Standard Calset
- NIST-Traceable 80 kVp, Cs137, or Non-Standard Post-Calibration QC Set
- 1 Consistency nanoDot

As part of this step of configuration, you will need to handle the nanoDot. While the nanoDot can fit in the tray in various positions, 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. If the drawer does not easily close, do not try to force it to close.



**Figure 7-1: Correct nanoDot Orientation**



**WARNING:** 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 and nanoDot may be significantly damaged.

To eject the nanoDot, pull the blue ejector toward the nanoDot.



**Figure 2: Ejected nanoDot**

---

**NOTES:**

The system configuration and testing outlined in this section should be completed using an **Advanced Operator** account.

The reader should be turned on for at least **60 minutes** with a **connected** device status. (Status is the first value listed on the bottom bar of the microSTARii application window.)

---

## 7.1 Performance Testing

The performance testing is conducted on the *QA* tab.

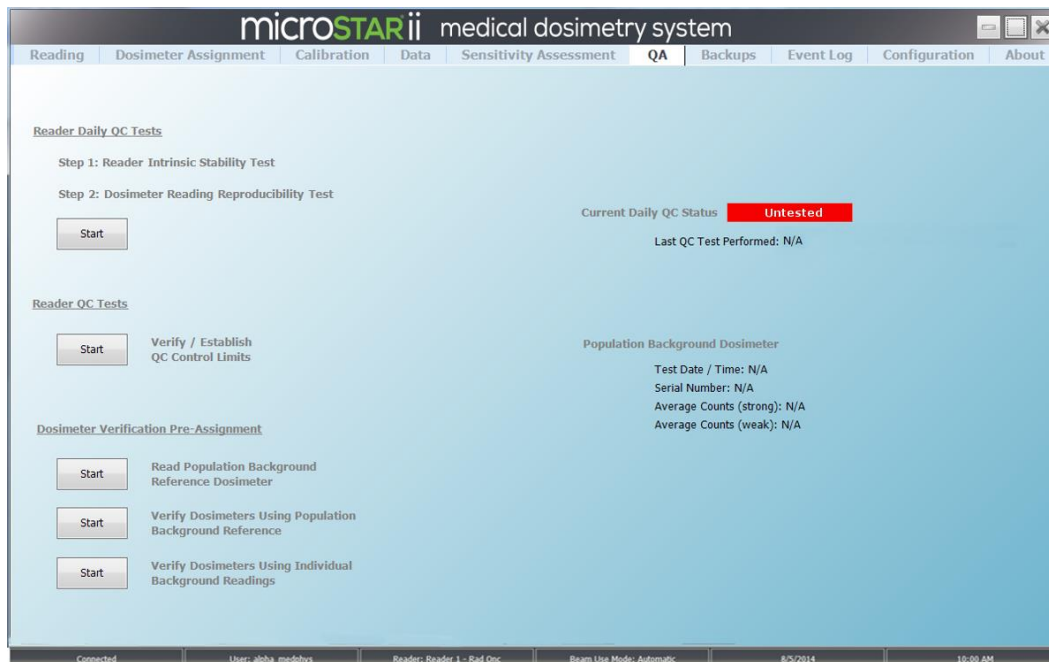


Figure 7-3: QA Screen – Untested

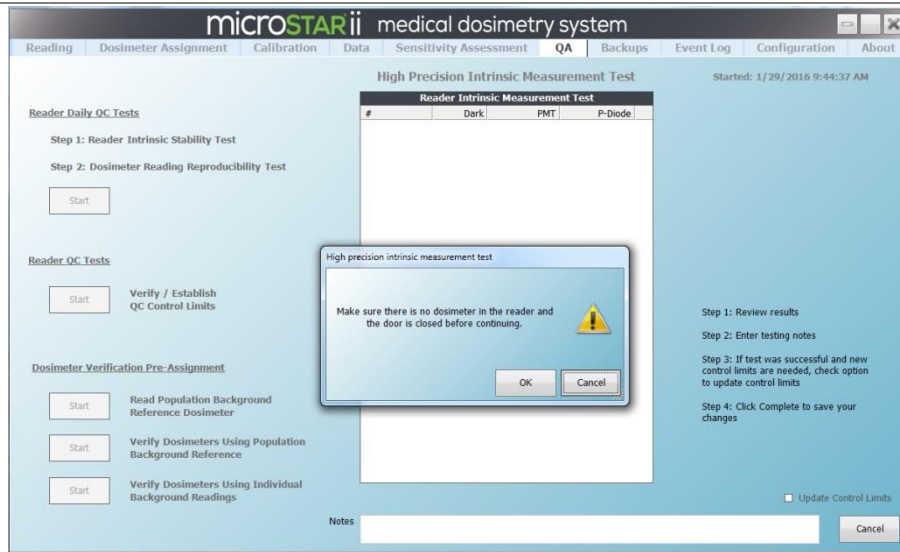
**NOTE:** The results for all tests run in this chapter can be found in the microSTARii system directory: C:\ProgramFiles\LandauerInc\microSTARiiReader\Reports. The reports are generated in PDF, XLS, and XML formats. See *Appendix B: QC Report Examples* for example reports.

It is recommended that you maintain all QC record data in either electronic or hardcopy format, for the life of the reader.

### 7.1.1 Intrinsic Test: Reader QC Test

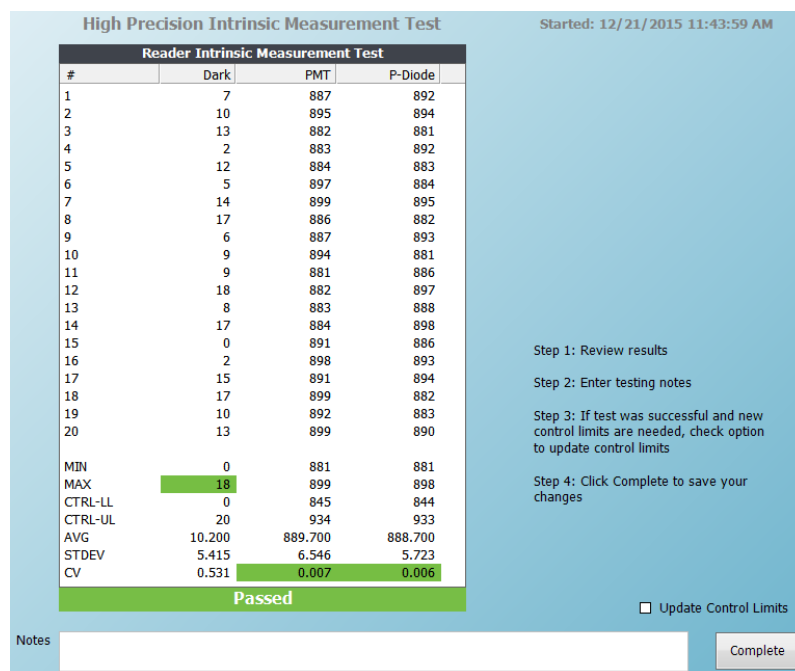
Complete the following steps to establish QC Control Limits for the system:

- STEP 1:** On the *QA* tab, click *Verify/Establish QC Control Limits* Start button.
- STEP 2:** A *High precision intrinsic measurement test* prompt will appear. Confirm there is no dosimeter in the reader and that the door is closed.



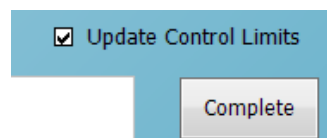
**Figure 7-4: Verify/Establish QC Control Limits**

**STEP 3:** 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 7-5: Reader QC Tests – Passed**

**STEP 4:** Select the Update Control Limits check box.



**Figure 7-6: Update Control Limits Option**

- STEP 5:** Click the Complete button to save and exit the test.  
**STEP 6:** Navigate to the *Configuration* tab, and confirm the values have updated.

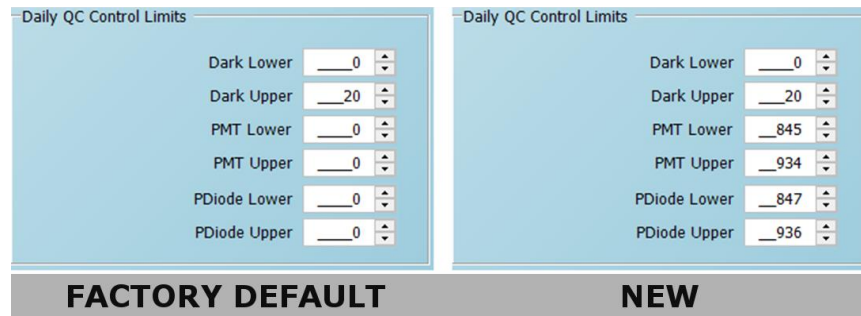


Figure 7-7: Daily QC Control Limits Update Example

## 7.1.2 Reader Daily QC Test

### Equipment Needed

- 1 High-Dose Consistency nanoDot

After the Verify/Establish Control Limits process has been completed, complete the following steps to run the Reader Daily QC Tests. This test is divided into two parts: Intrinsic Measurement and Reading Reproducibility. They are automatically run in sequence after the Start button is pressed.

- STEP 1:** On the *QA* tab, click the Start button under *Reader Daily QC Tests*. The Reader Intrinsic Measurement Test will start.
- STEP 2:** A *Daily QC Test Step 1* prompt will appear. Confirm there is no dosimeter in the reader and that the door is closed.

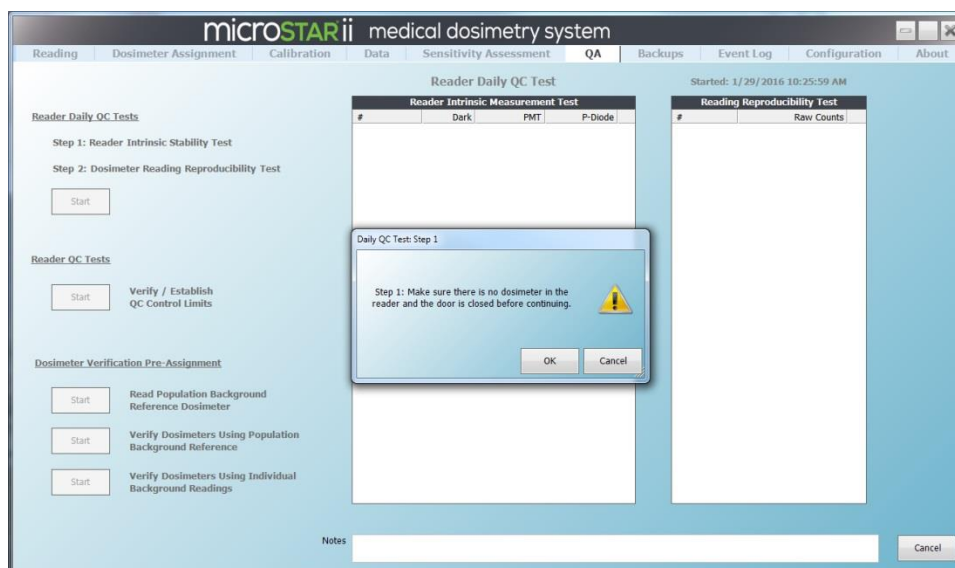
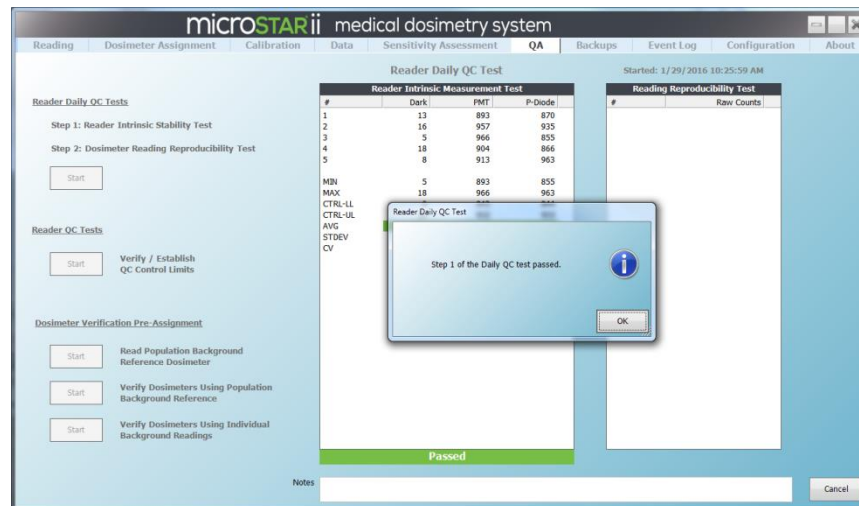


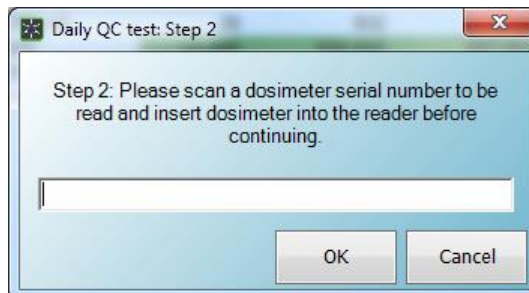
Figure 7-8: Reader Daily QC Test – Start

- STEP 3:** When the first test 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. The test will move on to the next step if the test is passed.



**Figure 7-9: Reader Daily QC Test – Step 1 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.



**Figure 7-10: Reader Daily QC Test – Consistency nanoDot Entry**

- 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. (Figure 7-1)
- STEP 6:** Click OK to start the Reading Reproducibility Test. Ten readings will be completed and the coefficient variation (CV) will be computed.
- STEP 7:** When the test 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. If the CV is  $\leq 1.0\%$  the test will pass.
- STEP 8:** Click OK on the Test Passed notification, and click the Complete button to save and exit the test.
- STEP 9:** The Current Daily QC Status on the *QA* tab should now be listed with a status of Passed.

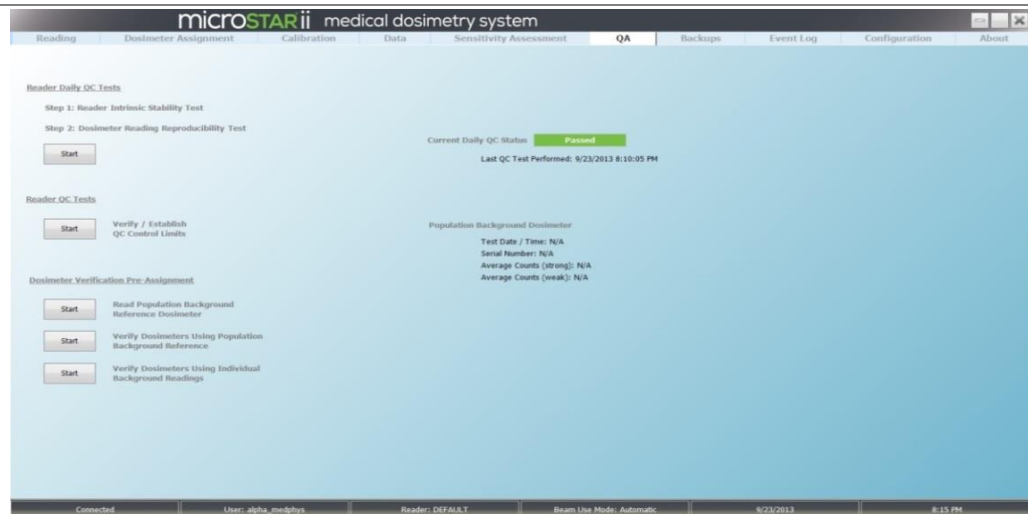


Figure 7-11: QA Tab — Daily QC Passed

## 7.2 Reader Calibration

After the performance tests are completed, the system can be calibrated using dosimeters with known doses to determine the calibration factors used to convert the raw PMT count to dose.

**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.

### 7.2.1 Initial Calibration

#### Equipment Needed

- NIST-Traceable 80 kVp, Cs137, or Non-Standard Calset (Therapy)

Complete the following steps to calibrate the reader using the LANDAUER-provided calset:

**STEP 1:** On the *Configuration* tab, confirm the following settings:

- **Beam Use Mode:** Automatic
- **Dose Unit:** mrad

**STEP 2:** From the *Calibration* tab, enter a Process ID.

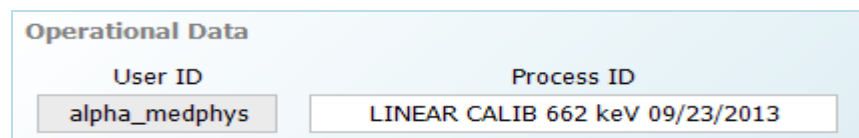


Figure 7-12: Calibration Screen Operational Data Example

**STEP 3:** Sort the calset in dose order.

**STEP 4:** Complete the following steps for each dosimeter:

- 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###.)
- Fill in Exposed Dose Field using the SDE value on the LANDAUER Calibration Certificate. For unexposed dosimeters enter 0.0.
- Enter 4 for the Number of Reads value.
- Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (Figure 7-1)
- Click the Read button to run a series readings.
- Repeat steps a-e for each dosimeter in the calset.

Figure 7-13: Dosimeter Info Field

**STEP 5:** 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 that the coefficient of variation (CV) across all sensitivity-corrected counts for each dose level within acceptable limits ( $\leq 0.05$ ), and that for a specific dose range, that only doses corresponding to that dose range are included in the calibration data group.

Linear Calibrations (Units: mrad)											
Hide	Select	CalibrationID	Use Type	Calib. Type	Status	Beam Use Mode	Counts/Unit of Dose	CalibFactor	Name	Notes	DateTime
		6		Low Dose	Pending	Automatic	5,300	5,300			9/24/2013 7:13
Expanded		ExposedDose	CountsUnit	STD	CV						
		0	85.131	9.301	0.109						
		987	5315.791	94.452	0.018						
Expanded		Used	Dosimeter #	E1 Counts	E1 Corrected						
	<input checked="" type="checkbox"/>	DN08942578G	4773	5363							
	<input checked="" type="checkbox"/>	DN08942578G	4733	5318							
	<input checked="" type="checkbox"/>	DN08942578G	4744	5330							
	<input checked="" type="checkbox"/>	DN08942578G	4715	5298							
	<input checked="" type="checkbox"/>	DN09270197P	5040	5478							
	<input checked="" type="checkbox"/>	DN09270197P	4992	5426							
	<input checked="" type="checkbox"/>	DN09270197P	4929	5358							
	<input checked="" type="checkbox"/>	DN09270197P	4899	5325							
	<input checked="" type="checkbox"/>	DN093579967	4970	5344							
	<input checked="" type="checkbox"/>	DN093579967	4792	5153							
	<input checked="" type="checkbox"/>	DN093579967	4836	5200							
	<input checked="" type="checkbox"/>	DN093579967	4833	5197							

Figure 7-14: Calibration Detail (Showing Acceptable CV)

**STEP 6:** For each new calibration, select the Pending calibration, and click the Accept button.

**STEP 7:** Fill in the values on the Calibration dialog box, and click OK to confirm.

- Cs-137 Calibration Use Type:** Other
- 80 kVp Calibration Use Type:** Diagnostic



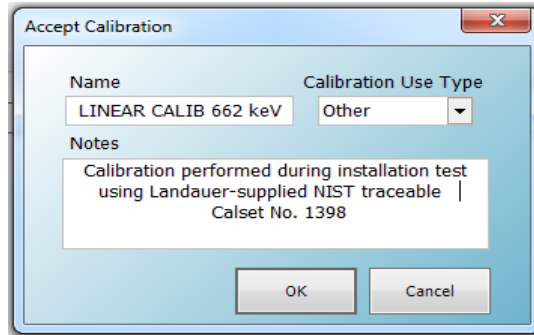


Figure 7-15: Accept Calibration Dialog Box

**STEP 8:** After completing a calibration for both the low and high dose ranges, ensure both are listed on the *Calibration* tab and are selected. Click Save the Selection at the bottom of the screen.

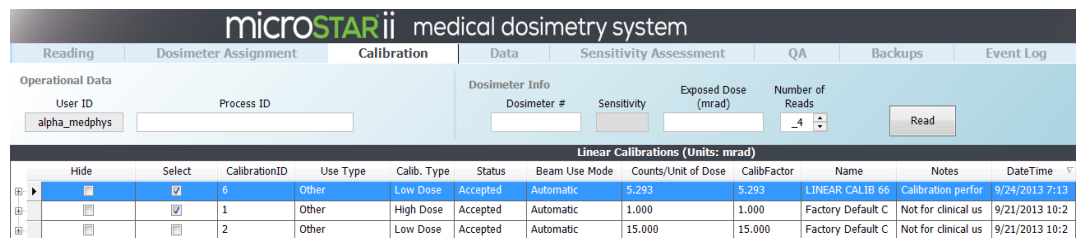


Figure 7-16: Completed Low Dose Calibration

## 7.2.2 Post-Calibration Quality Control Check

### Equipment Needed

- NIST-Traceable 80 kVp, Cs137, or Non-Standard Post-Calibration QC Set

After the system has been calibrated using the LANDAUER calset, complete the following steps to validate the calibration:

**STEP 1:** On the *Configuration* tab, confirm the following settings are configured.

CONFIGURATION SETTING	CONFIGURATION VALUE
Dosimetry Category	Generic
Dosimetry Use Type	Other
Dose Reading Mode	Average
Beam Use Mode	Automatic
Dose Unit	mrads
Reading Repetitions	4

CONFIGURATION SETTING		CONFIGURATION VALUE
<b>Force Calibration Hardware Settings Match</b>		Selected
<b>Other Checkboxes</b>		Unselected

**Dosimetry Category**

Patient  Generic

---

**Dosimetry Use Type**

Therapy  Diagnostic  Other

---

**Dose Reading Mode**

Average  Individual

---

**Beam Use Mode**

Automatic (COP: 400)  Force Weak

**Dose Unit**

mrad  
 mGy  
 cGy

**Reading Parameters**

Read Interval (milliseconds)

Reading Repetitions

Verification Threshold (strong beam)

Non Linear Calibration

Use Dosimeter Background Correction

Force Dosimeter Preassignment Verification

Force Calibration Dosimetry Use Type Match

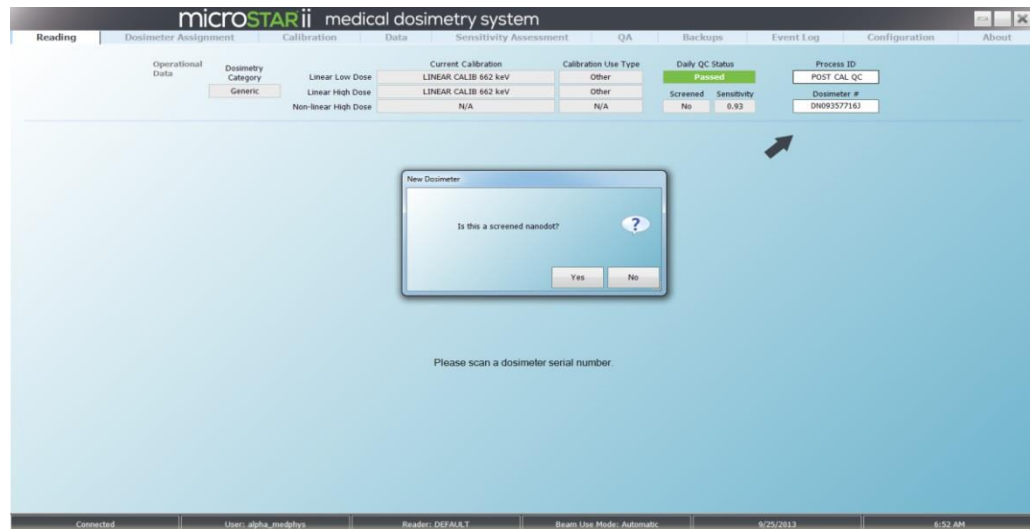
Force Daily QC test

Force Calibration Hardware Settings Match

Apply Sensitivity Adjustment Factor values

**Figure 7-17: Configuration Settings**

- STEP 2:** On the *Reading* tab, enter a unique Process ID (e.g., Post Cal QC).
- STEP 3:** Click to put the cursor in the Dosimeter # field. Scan the dosimeter or enter the serial number.
- STEP 4:** On the New Dosimeter dialog box (*Is this a screened nanoDot?*), click Yes to confirm.
- STEP 5:** On the *Process ID does not exist* prompt, click Yes to confirm the new Process ID.



**Figure 7-18: Reading Tab with QC nanoDot Settings**

- STEP 6:** Place the nanoDot in the reader drawer with the barcode facing up. Ensure the nanoDot is sitting flat. Close the drawer completely. (Figure 7-1)
- STEP 7:** Click Read. The nanoDot will be read four times and the computed dosimetry results will display on the screen.

- STEP 8:** Verify the computed dose is within  $\pm 5.5\%$  of the known exposed dose listed on the LANDAUER certificate.
- STEP 9:** Repeat Steps 3-8 for all dosimeters in the QC Set.

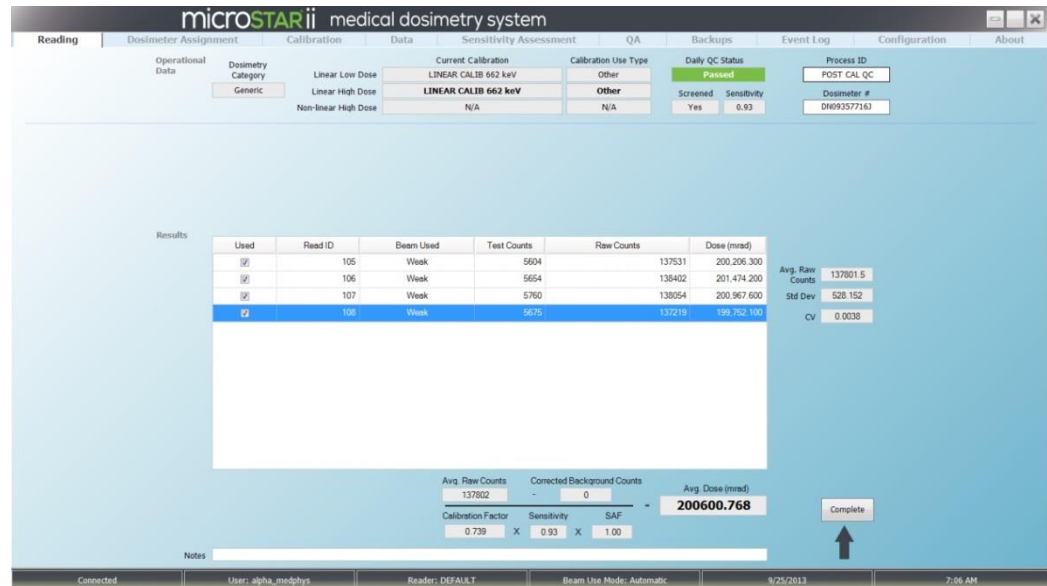


Figure 7-19: QC Set Reading Results

### 7.2.3 Custom Calibration

LANDAUER-manufactured calsets provide a baseline for 80 kVp, Cs137, or Non-Standard exposure conditions. These calsets are used to validate system performance.

After the initial calibration is completed, create a custom calset to mirror the conditions in your facility. To create a custom calset, irradiate screened nanoDots using the exposure conditions in your environment. Perform the calibration procedure outlined in section Chapter 7 using the custom calset. (Note: The Dose Unit configuration value may change based on exposure conditions.)

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

RECOMMENDED CUSTOM CALSET EXPOSURE	
Doses in cGy	
<b>Linear Calibration (Beam Use Mode: Automatic)</b>	
<b>Low Dose Linear Range (&lt;15 cGy)</b>	unexposed, 5 cGy, 10cGy
<b>High Dose Linear Range (&gt;15 cGy)</b>	50, 100, 200 cGy
<b>Linear Calibration (Beam Use Mode: Force Weak)</b>	
<b>High Dose Linear Range (&gt;1cGy)</b>	10, 50, 100, 200 cGy
<b>Non-Linear Calibration</b>	
<b>High Dose Non-Linear Range (300-1300 cGy)</b>	50, 100, 300, 500, 800, 1000, 1300 cGy

*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.*

# CHAPTER 8 TROUBLESHOOTING

If you receive error messages or need further assistance, contact LANDAUER Technical Support.

## 8.1 Technical Support

<b>Address</b>	LANDAUER Customer Service 2 Science Rd. Glenwood, IL 60425
<b>Telephone</b>	800-561-2708
<b>Email</b>	inlightcustserv@landauerinc.com
<b>Operating Hours</b>	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 additional 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 Issue
- Screenshot of Software Issue/Message
- Picture of Hardware Issue/Failure
- Event Logs

## Appendix A: Profile Permissions Listing

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
Backup	Screen: Backup		✓	✓
Backup	Groupbox: Reset Database			✓
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	✓	✓	
Calibration	Button: Reject	✓	✓	

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
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		✓	✓
Configuration	Checkbox: Force Dosimeter Preassignment Verification		✓	✓
Configuration	Checkbox: Force Daily QC		✓	✓
Configuration	Groupbox: User Defined Fields			✓
Configuration	Textbox: Read Interval			✓

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
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	✓	✓	
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	✓	✓	

CATEGORY	PERMISSION	OPERATOR	ADVANCED OPERATOR	ADMINISTRATOR
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: QC Report Examples

## Reader QC Test Example Report

University of Somewhere Med Ctr

Radiation Oncology

### MicroSTAR<sup>ii</sup> 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	17088	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
<b>Min</b>	8	17068	1079
<b>Max</b>	14	17501	1121
<b>CTRL-LL</b>	0	16403	1042
<b>CTRL-UL</b>	20	18130	1151
<b>AVG</b>	10.650	17266.500	1096.550
<b>STDEV</b>	1.872	131.459	11.413
<b>CV</b>	0.176	0.008	0.010
<b>Test Result</b>	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.

# Reader Daily QC Test Example Report

University of Somewhere Med Ctr

Radiation Oncology

## MicroSTARii Daily QC Test Report

Date / Time of Test: 09/23/2013 08:10:05 PM

Reader: DEFAULT

Test Performed by: alpha\_medphys

### STEP 1: Daily Intrinsic Measurement Test

Reading	Dark Counts	PMT Counts	P-Diode Counts
1	7	17522	1139
2	8	17459	1091
3	11	17373	1111
4	11	17419	1138
5	7	17390	1104
<b>Min</b>	7	17373	1091
<b>Max</b>	11	17522	1139
<b>CTRL-LL</b>	0	16403	1042
<b>CTRL-UL</b>	20	18130	1151
<b>AVG</b>	8.800	17432.800	1116.600
<b>STDEV</b>	2.049	59.668	21.244
<b>CV</b>	0.233	0.003	0.019
<b>Test Result</b>	PASSED	PASSED	PASSED

### STEP 2: Reading Reproducibility Test

Reading	Element Counts
1	125253
2	124846
3	124877
4	124785
5	125119
6	125164
7	124975
8	124915
9	125124
10	125028
<b>AVG</b>	125008.802
<b>STDEV</b>	153.986
<b>CV</b>	0.001
<b>Test Result</b>	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.

# Stakeholder Approval

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This document meets LANDAUER standards for quality and use.

## Signatures of Approval

*Mark Akselrod*

Mark Akselrod (Jul 26, 2019)

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Research & Development

*Fred Rice*

Fred Rice (Jul 30, 2019)

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Software/IT

*Matt Ennis*

Matt Ennis (Jul 26, 2019)

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Regulatory Assurance

*Shirin Khanna*

Shirin Khanna (Jul 30, 2019)

---

Product Manager

*Dan Chendra*

Dan Chendra (Jul 26, 2019)

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Project Manager