

## URGENT – Medical Device Recall - RESPONSE REQUIRED

### microStar® Reader for Medical Uses

February 7, 2024

Dear Valued microStar Reader Customer,

**Landauer is recalling the original microStar readers for medical uses.**

**Product Description:** The microStar reader is a portable reader that has been used with Landauer InLight® and nanoDot® dosimeters. When used with InLight dosimeters, the system is intended for non-medical, occupational applications. When used with the nanoDot dosimeter, the system is intended for both medical and non-medical applications.

**Reason for the Action:** Landauer recalled the nanoDot dosimeter in July 2023 and the microSTARii medical dosimetry system in November 2023. Landauer also announced that it was permanently discontinuing the microSTARii medical dosimetry system, including the nanoDot dosimeter, in November 2023. Landauer has initiated this action to remove all reference to use of the microStar readers with the nanoDot or any other dosimeter for medical applications from the product’s user manual and software and to remove microStar readers from customers who use them only for medical applications.

These actions follow Landauer’s divestiture of its therapy physics businesses and decision to focus its strategy on being the leader in occupational dosimetry products and related services. This action does not relate to any deficiency in the performance of the microStar reader for non-medical, occupational purposes.

**Potential Risk:** The nanoDot dosimeter was recalled due to the potential that some nanoDots may be outside the specified accuracy range. The current action is intended to eliminate potential medical use of the microStar reader with nanoDots. Landauer has not identified performance issues with the microStar reader when used with the InLight dosimeter for occupational safety uses.

**Impacted Product Information:**

Model No.	Product Name	Lot/Serial Number
10015-000/100.00/100.01/100.02/102.01/102.02/110.00/110.01/110.02/201.00/201.01/201.02	microStar Reader	All
10016-000/ 101.00/101.01/101.02		All
10036-000		All
10044-000		All
10055-000		All
BC30058		All
BC30059		All

*Note: all other accessories (e.g., laptop, barcode scanner) associated with the microStar reader are not part of this recall.*

## Actions to be Taken by the Customer/User:

### If using the product for medical applications only:

1. Immediately discontinue use of microStar reader
2. Fill out Business Reply Form
3. Return affected product to Sedgwick, a third-party recall firm that is assisting Landauer with this action), in accordance with the instructions below.

### If using the product for non-medical applications only:

1. Fill out Business Reply Form
2. Update Software by logging into <https://ftp.landauer.com/>, using following credentials and follow the instructions to install the new software.  
**Username: microstar6**  
**Password: Hsdtduw3w7284\*@**
3. Review the revised User Manual available at <https://www.landauer.com/user-manuals>. Please refer to the User Manual provided by this link before using the product; all older versions are obsolete.

### If using the product for medical and non-medical applications:

1. Immediately discontinue use of microStar reader for medical applications
2. Fill out Business Reply Form
3. Update Software by logging into <https://ftp.landauer.com/>, using following credentials and follow the instructions to install the new software.  
**Username: microstar6**  
**Password: Hsdtduw3w7284\*@**
4. Review the revised User Manual available at <https://www.landauer.com/user-manuals>. Please refer to the User Manual provided by this link before using the product; all older versions are obsolete.

To ensure compliance with FDA recall-related obligations, please immediately execute the following actions:

1. Fill out the attached 'Business Reply Form' and send the signed form to [Landauer\\_microStar@sedgwick.com](mailto:Landauer_microStar@sedgwick.com) within five (5) business days. **The form should be returned even if you do not have a microStar reader.**
2. After receiving the Business Reply Form, if you are using the microStar for medical applications only, Sedgwick will send you a return label for the return of your microStar reader(s). Please return affected product using the return label provided. If you have any questions about the return process, contact Sedgwick at [Landauer\\_microStar@sedgwick.com](mailto:Landauer_microStar@sedgwick.com).
3. If using the product for medical applications only, uninstall the microStar software from the laptop and discard the software CD. Please confirm these actions in the Business Reply Form and be sure to export any data for preservation prior to uninstallation of the software.

We apologize for any inconvenience and thank you for your business and loyalty.

Sincerely,




Brian Malone  
Sr. Director, RA/QA

## Business Reply Form – Response Required

<b>1. Recall) information</b>	
Recall Date*	02/07/2024
Product/ Device name*	microStar Reader
Product Model No's & Quantity	ALL

<b>2. Customer Details</b>	
Account Number	
Healthcare (or other) Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

<b>3. * Customer action undertaken on behalf of Healthcare Organization</b>		
<input type="checkbox"/>	I confirm receipt of the Recall Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	Usage of microStar readers in your organization	<input type="checkbox"/> medical application (e.g. Patient therapy, diagnostic imaging, etc.) <input type="checkbox"/> non-medical application (e.g. Occupational dosimetry, workstation studies, area monitoring, etc.) <input type="checkbox"/> Both
<input type="checkbox"/>	I performed all actions requested by the Recall Notice.	Customer to complete or enter N/A
<input type="checkbox"/>	The information has been brought to the attention of all relevant users.	Customer to complete or enter N/A

<input type="checkbox"/>	<p>I have returned affected devices used exclusively for medical applications - enter number of devices returned and date complete. The serial number must be provided for each device returned. (The serial number, as indicated in the picture below with a green box, can be found at the rear of the microStar reader)</p> 	<p>Qty: Serial No./s:</p>
<input type="checkbox"/>	<p>I have updated the software</p>	<p>Customer to complete or enter N/A</p>
<input type="checkbox"/>	<p>I do not have any affected devices.</p>	<p>Customer to complete or enter N/A</p>
<input type="checkbox"/>	<p>I have previously returned my nanoDot recall business reply form</p>	
<p>Data transfer and privacy practices will adhere to the policy outlined on <a href="https://www.landauer.eu/legal-notice/privacy-notice/">https://www.landauer.eu/legal-notice/privacy-notice/</a></p>		
<p>Print Name*</p>		
<p>Signature*</p>		
<p>Date*</p>		
<p><b>5. Return acknowledgement to sender</b></p>		
<p>Email</p>		<p>Landauer_microStar@sedgwick.com</p>
<p>Deadline for returning the customer reply form*</p>		<p><i>Within 5 business days of receipt of this letter</i></p>

**Mandatory fields are marked with \***