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URGENT – Medical Device Recall - RESPONSE REQUIRED

microSTARii® Reader

November 15, 2023

Dear Valued microSTARii Reader Customer,

Landauer is voluntarily recalling all microSTARii readers utilized for all applications. The microSTARii reader is used with the nanoDot™, a single-use radiation monitoring dosimeter, and is 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 intended to provide a secondary verification of radiation dose as a means of quality control for the primary dose calculation method. The output of the system is not indicated for use to adjust the dose to the patient or to guide patient care.

Reason for the Voluntary Recall: Landauer previously recalled the nanoDot dosimeters due to reports indicating that some nanoDots may potentially provide readings outside of the specified range of +/-5.5% accuracy.

Landauer has now determined that microSTARii readers may be contributing to the nanodot dosimeter measurement inaccuracy in two possible ways. The first is related to the interaction of the reader's LED beam profile with the nanoDot dosimeter. The second is debris formation due to drawer actuation, resulting in a change of reader response that may not be detectable unless known dose QCs are being run regularly.

Potential Risk: In the radiation therapy context, if the microSTARii medical dosimetry system is used as indicated in the User Manual, the potential risk to health is very low. There may be a delay in treatment while the discrepant dose reading provided by the system is investigated. If instructions are not followed and the device is used off label to adjust patient dose or guide patient care, the potential risk may be over- or under-exposure.

Select Mitigating Factors: The output of the microSTARii medical dosimetry system is not intended to be used to adjust the dose to the patient. Instead, if a discrepancy is identified, further investigation and a root cause analysis should 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 such as the microSTARii should never be used to direct patient care decisions.

Impacted Product Information:

Model No.	Product Name	Lot/Serial Number
18000-000/18001-000/18007-000	microSTARii Reader	All

Note: all other accessories (e.g., laptop, 2D barcode scanner) associated with the microSTARii reader are not part of this recall.

Actions to be taken by the Customer/User: Immediately discontinue use of microSTARii reader. Landauer is working with Sedgwick, a 3rd-party recall consulting firm, to conduct the recall.

You MUST respond to Sedgwick with the Business Reply Form (below).

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To provide acknowledgement and assist Landauer in facilitating an effective medical device recall, please follow the process below:

1. Fill out the attached 'Business Reply Form' and send the signed form to landauer3848@sedgwick.com within five (5) business days. **The form must be returned even if you do not have a microSTARii reader**.
2. After receiving the Business Reply Form, Sedgwick will send you a return label to the extent you are returning one or more microSTARii readers.
3. Return affected product using the return label provided by Sedgwick. Contact Sedgwick at 866-204-6110 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product.
4. Uninstall the microSTARii medical dosimetry software from the laptop and discard the software CD. Please confirm in the Business Reply Form and be sure to export any data for preservation prior to uninstallation of the software.
5. If you have not done so already, please provide the nanoDot recall Business Reply Form to Sedgwick at the above email address.

Please note that Landauer is formally announcing the decision to discontinue the microSTARii medical dosimetry system, including the microSTARii reader and the nanoDot. As a result, replacement product or service will not be available moving forward.

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

Sincerely,

Brian Malone
Sr. Director, RA/QA

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Business Reply Form – Response Required

1. Recall) information	
Recall Date*	*11/15/2023*
Product/ Device name*	*microSTARii Reader*
Product Model No's & Quantity	**ALL**

2. Customer Details	
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*	

3. Customer action undertaken on behalf of Healthcare Organization		
☐	I confirm receipt of the Recall Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the Recall Notice.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	I have returned affected devices - 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 microSTARii reader) 	Qty: Serial No./s:
☐	I have uninstalled the microSTARii medical dosimetry system software from the laptop.	Customer to complete or enter N/A
☐	I do not have any affected devices.	Customer to complete or enter N/A

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☐	My organization has decided not to return the recalled microSTARii reader(s)	Quantity on hand:
☐	I have previously returned my nanoDot recall business reply form	
Print Name*		
Signature*		
Date*		
4. Return acknowledgement to sender		
Email		landauer3848@sedgwick.com
Deadline for returning the customer reply form*		*Within 5 business days of receipt of this letter*

Mandatory fields are marked with *