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URGENT – Product Recall – *Response Required*
nanoDot™ Dosimeter

November 15, 2023
Update to August 17, 2023 Recall Notice

Dear nanoDot Customers,

Landauer is voluntarily recalling all nanoDots distributed for all applications. The nanoDot is a radiation monitoring dosimeter used with the microSTAR readers. The microSTAR readers are 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 nanoDot is not indicated for use to adjust the dose to the patient or to guide patient care. Certain customers also use nanoDots for non-medical or industrial applications.

Reason for the Voluntary Recall: Landauer received reports indicating that some nanoDots may potentially be outside the specified range of accuracy. Landauer is conducting an ongoing investigation of nanoDots and has identified a potential issue in the manufacturing process.

Potential Risk: In the radiation therapy context, if the nanoDots are used as indicated, the potential risk is a delay in treatment while the discrepant reading provided by the nanoDot is investigated. The potential risk if instructions are not followed and the product is used to adjust patient dose or guide patient care may be over- or under-exposure. Landauer strongly recommends that the nanoDot product not be used to adjust patient dose or guide patient care decisions.

Select Mitigating Factors: The output of the microSTAR 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 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.

Actions to be taken by the Customer/User: Landauer is working with Sedgwick, a 3rd-party recall consulting firm, to conduct the recall. Landauer requests that you immediately discontinue use of nanoDots. Additionally, Landauer requests subsequent actions from the customer summarized in the following table:

nanoDot Condition	Instruction to be followed by the Customer
Unused	Return to Sedgwick with the applicable Reply Form (see below)
Used	Destroy/discard and acknowledge via the Business Reply Form
No nanoDots on hand	Complete the Reply Form (see below) and return to Sedgwick

You MUST respond to Sedgwick with the Business Reply Form (below) as an acknowledgement that you have received this notice.

To provide acknowledgement and assist Sedgwick in facilitating an effective product recall, please follow the process below:

1. Fill out the attached 'Business Reply Form' and email the signed form to Landauer_nanoDOT@sedgwick.com within five (5) business days.
2. After receiving the Business Reply Form, Sedgwick will email you a return label to the extent you are returning unused nanoDots.
3. Use the return label to package and send back the affected nanoDots to Sedgwick.

Impacted Product Information:

Model No.	Product Name	Lot/Serial Number
03051-OTO	nanoDot, read, One Time Only	All
03053-3MO	nanoDot, read, Qtrly	All
03053-OTO	nanoDot, read, One Time	All
03056-000/VINLNAN002(EMEA)	nanoDot D2DNS screened, sealed in bag	All
03056-KIT	nanoDot D2DNS screened, sealed in bag	All
03057-OTO	nanoDot, screened, read, One Time	All
03061-OTO	nanoDot, read, One Time	All
03063-OTO	nanoDot, screened, read, One Time	All
04217-000/VINLNAN003(EMEA)	Calibrate (80 kVp) nanoDot D2DNS, select dose	All
04217-KIT	Calibrate (80 kVp) nanoDot D2DNS, select dose	All
04217-SET	NanoDot Calibration Set D2DNS, 80 kVp	All
04218-000/VINLNAN004(EMEA)	QC (80 kVp) nanoDot D2DNS, select dose level	All
04218-KIT	QC (80 kVp) nanoDot D2DNS, select dose level	All
04218-SET	NanoDot QC Set D2DNS, 80 kVp	All
04224-000/VINLNAN006(EMEA)	Calibrate (Cs-137) nanoDot D2DNS, select dose	All
04224-KIT	Calibrate (Cs-137) nanoDot D2DNS, select dose	All
04224-SET	NanoDot Calibration Set D2DNS, Cs-137	All
04225-000	QC (Cs-137) nanoDot D2DNS, select dose level	All
04225-KIT	QC (Cs-137) nanoDot D2DNS, select dose level	All
04225-SET	NanoDot QC Set D2DNS, Cs-137	All
04293-000	nanoDot D2DNN sealed in bag	All
04293-KIT	nanoDot D2DNN sealed in bag	All
18100-000	nanoDot D2DNS screened, sealed in bag	All
18100-KIT	nanoDot D2DNS screened, sealed in bag	All
18105-000	nanoDot D2DNN sealed in bag	All
18105-KIT	nanoDot D2DNN sealed in bag	All

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18120-000	Calibrate (80 kVp) nanoDot D2DNS, select dose	All
18120-KIT	Calibrate (80 kVp) nanoDot D2DNS, select dose	All
18120-SET	NanoDot Calibration Set D2DNS, 80 kVp	All
18121-000	Calibrate (80 kVp) nanoDot D2DNS, select dose, Apple	All
18121-KIT	Calibrate (80 kVp) nanoDot D2DNS, select dose, Apple	All
18121-SET	NanoDot Calibration Set D2DNS, 80 kVp, Apple	All
18125-000	Calibrate (Cs-137) nanoDot D2DNS, select dose	All
18125-KIT	Calibrate (Cs-137) nanoDot D2DNS, select dose	All
18125-SET	NanoDot Calibration Set D2DNS, Cs-137	All
18130-000	QC (80 kVp) nanoDot D2DNS, select dose level	All
18130-KIT	QC (80 kVp) nanoDot D2DNS, select dose level	All
18130-SET	NanoDot QC Set D2DNS, 80 kVp	All
18131-000	QC (80 kVp) nanoDot D2DNS, select dose level, Apple	All
18131-KIT	QC (80 kVp) nanoDot D2DNS, select dose level, Apple	All
18131-SET	NanoDot QC Set D2DNS, 80 kVp, Apple	All
18135-000	QC (Cs-137) nanoDot D2DNS, select dose level	All
18135-KIT	QC (Cs-137) nanoDot D2DNS, select dose level	All
18135-SET	NanoDot QC Set D2DNS, Cs-137	All
18140-000	Calibrate (unexposed) nanoDot D2DNS	All
18140-SET	NanoDot Calibration Set, D2DNS, unexposed	All
18150-000/VKITCON002(EMEA)	Constancy (80 kVp) nanoDot D2DNN, select dose level	All
18150-KIT	Constancy (80 kVp) nanoDot D2DNN, select dose level	All
18155-000/VKITCON001(EMEA)	Constancy (Cs-137) nanoDot D2DNN, select dose level	All
18155-KIT	Constancy (Cs-137) nanoDot D2DNN, select dose level	All
BC30083	nanoDot QC Set - 80kVp - Sale	All
BC30084	nanoDot QC Set - 80kVp - No Charge	All
BC30088	nanoDot Calibration Set - 80kVp - No Charge	All
BC30095	Dot, D1DNN, in carrier sealed in bag	All
BC30110	Calibration set, nanoDot	All
BC30141	nanoDot QC Set - Cs137 - Sale	All
BC30142	nanoDot Calibration set - Cs137 - Sale	All

If you have additional questions, please contact the Sedgwick Customer Service team at
Landauer_nanoDOT@sedgwick.com.

We apologize for any inconvenience this may cause you. Thank you for your cooperation.

Sincerely,

Brian Malone
Sr. Director, RA/QA

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Business Reply Form – Response Required

1. Recall) information	
Recall Date*	*7/28/2023 medical applications; 8/29/2023 non-medical*
Product Name*	*nanoDot*
Product Model No's & Quantity	**ALL**

2. Customer Details	
Account Number	
Healthcare 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 confirm that all used nanoDots have been discarded/destroyed.	Customer to complete or enter N/A	
☐	I have returned affected product(s) - enter number of devices returned and date complete.	Qty:	Date Returned (DD/MM/YY):
		Qty:	Date Returned (DD/MM/YY):
		N/A	Comments:
☐	No affected product(s) are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		

☐	I do not have any affected product(s)	Customer to complete or enter N/A
☐	My organization has determined not to return the affected nanoDots	Quantity on hand:
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	Landauer_nanoDOT@sedgwick.com
Deadline for returning the customer reply form*	*Within 5 business days of receipt of this letter*

Mandatory fields are marked with *