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URGENT – Medical Device Recall - RESPONSE REQUIRED

nanoDot™ Dosimeter

August 29, 2023

Update to July 12 and July 27 Recall Notifications

Dear nanoDot Customer,

LANDAUER is voluntarily recalling all nanoDots distributed for all applications. The nanoDot is a single-use 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 +/-5.5% accuracy. LANDAUER is conducting an ongoing investigation of nanoDots and has identified a potential issue in the manufacturing process. LANDAUER has included the General Purpose (+/-10%) nanoDots in the scope of this recall out of an abundance of caution.

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 device is used off label to adjust patient dose or guide patient care, may be over- or under-exposure. LANDAUER strongly recommends that the nanoDot device not be used off-label to adjust patient dose or guide patient care decisions. We will follow up with significant updates.

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 requests that you immediately discontinue use of nanoDots. Additionally, LANDAUER requests subsequent actions from the customer summarized in the following table:

nanoDot Condition	Instruction for Customer
Unused	Return to LANDAUER with the applicable Reply Form (see below)
Used	Confirmation of Destruction via the applicable Reply Form (see below). *Please note that nanoDot devices are single use when used with patients and should be disposed after their first use.*
No nanoDots on hand	Complete the Reply Form (see below) and return to LANDAUER

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

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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 fieldaction@landauer.com within five (5) business days.
2. After receiving the Business Reply Form, LANDAUER will send you the RMA (Return Material Authorization) number and the return label to the extent you are returning unused nanoDots.
3. Use the provided RMA number and return label to package and send back the affected nanoDots to LANDAUER.

Impacted Product Information:

Model No.	Product Name	Lot/Serial Number
03033-OTO	nanoDot, screened, custom cal, One Time	All
03034-OTO	nanoDot, screened, custom cal, One Time	All
03051-OTO	nanoDot, read, One Time Only	All
03053-1MO	nanoDot, read, Mthly	All
03053-3MO	nanoDot, read, Qtrly	All
03053-OTO	nanoDot, read, One Time	All
03053-SMO	nanoDot read, Semi-Mthly	All
03055-OTO	nanoDot, screened, read, One Time Only	All
03056-000	nanoDot D2DNS screened, sealed in bag	All
03056-KIT	nanoDot D2DNS screened, sealed in bag	All
03057-OTO	nanoDot, screened, read, One Time	All
03061-1MO	nanoDot, read, Mthly	All
03061-OTO	nanoDot, read, One Time	All
03063-OTO	nanoDot, screened, read, One Time	All
03500-000	nanoDot kit (contains nanoDot A, B, C)	All
03501-000	nanoDot A - item 1 of 3 for 03500-000	All
03502-000	nanoDot B - item 2 of 3 for 03500-000	All
04217-000	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	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	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
04297-000	nanoDot, OSLN, sale	All
18100-000	nanoDot D2DNS screened, sealed in bag	All
18100-1MO	nanoDot screened, Mthly	All
18100-2MO	nanoDot screened, Bi-Mthly	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
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
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
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-KIT	Calibrate (unexposed) nanoDot D2DNS	All
18140-SET	NanoDot Calibration Set, D2DNS, unexposed	All
18150-000	Constancy (80 kVp) nanoDot D2DNN, select dose level	All
18150-KIT	Constancy (80 kVp) nanoDot D2DNN, select dose level	All
18155-000	Constancy (Cs-137) nanoDot D2DNN, select dose level	All
18155-KIT	Constancy (Cs-137) nanoDot D2DNN, select dose level	All
BC30023	QC Set For Microstar Dots	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
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

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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 LANDAUER Customer Service team at 1-708-847-0788 Monday through Friday, 8:00 a.m. to 5:00 p.m. Central Time or email fieldaction@landauer.com.

Please note that for all unused nanoDots shipped back to LANDAUER, a product replacement will be issued once the ship-hold is lifted. We apologize for any inconvenience this may cause you. Thank you for your cooperation.

Sincerely,

Harish Vishwanathan
Manager, RA/QA

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Business Reply Form – Response Required

1. Recall) information	
Recall Date*	*7/12/2023 (medical customers) 8/29/2023 (non-medical, industrial customers)*
Product/ Device name*	*All nanoDots distributed*
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.	Qty:	Date Returned (DD/MM/YY):
		Qty:	Date Returned (DD/MM/YY):
		N/A	Comments:
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Date: Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	

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☐	My organization has determined not to return the affected nanodots	Quantity on hand:
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	fieldaction@landauer.com
Postal Address	*2 Science Rd, Glenwood, IL 60425*
Deadline for returning the customer reply form*	*Within 5 business days of receipt of this letter*

Mandatory fields are marked with *