Recall

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Quality Notification
Urgent Medical Device Recall

Dear Customer,

In May 2022, Illumina contacted customers regarding a Local Run Manager (LRM) cybersecurity vulnerability which included the NextSeq™ 550Dx instruments. Illumina is following up regarding the Local Run Manager (LRM) cybersecurity vulnerability. This notice outlines the issue summary, Illumina's actions, and required customer actions.

Table 1: Affected Product(s)

Product Affected	Unique Device Identifier – Device Identifier Number	Catalog Number
NextSeq 550Dx Instrument	00816270020125	20005715

Table 2: Feature Summary

Software Name	New Version	Features Included in Release
NextSeq Operating Software (NOS)	v1.7.0	• New Local Run Manager (v4.1.0) framework for use in the Dx mode • Remediation of the LRM cybersecurity vulnerability • Remote access to the LRM Web User Interface restored
NextSeq Control Software (NCS)	v4.2.0	• New Local Run Manager (v4.0.0) framework for use in the RUO mode • Remediation of the LRM cybersecurity vulnerability • Remote access to the LRM Web User Interface restored

Additional details of the NextSeq Operating Software v1.7.0, NextSeq Control Software v4.2.0, Local Run Manager v4.1.0 and v4.0.0, and compatible Local Run Manager Module versions can be found here.

Issue Summary

Illumina has released a new software version that remediates the cybersecurity vulnerability and restores remote access to the LRM Web User Interface. New versions of the NextSeq Operating Software (NOS) v1.7.0 and NextSeq Control Software (NCS) v4.2.0, which both include Local Run

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Manager (v4.1.0 and v4.0.0, respectively), are available for installation on the NextSeq 550Dx instruments.

Please note that this is a **required** upgrade. Illumina will no longer be distributing older versions of the software. All new software installations will be of the updated versions listed in this notice.

Note: The affected instruments have a dual boot mode, and it is required to install the appropriate software upgrade in each mode (Dx mode and RUO mode) of each instrument.

New instruments are now shipping with the updated NOS, NCS, and LRM software.

Illumina Actions

An Illumina Field Representative will contact you to schedule an on-site visit to install the new software.

The pertinent local and international regulatory bodies, including the Competent Authorities, have been notified.

Required Customer Actions

Please complete the Verification Form to acknowledge that you have received this notice. We kindly ask that you email the completed form to Illumina Technical Support techsupport@illumina.com within 5 business days.

Alternatively, you may e-mail Illumina Technical Support techsupport@illumina.com to provide the information requested in the form.

We Are Here to Help

NOTE: If you suspect your instrument may have been compromised by an unauthorized user, please immediately unplug the network cable and contact Illumina Technical Support techsupport@illumina.com.

If you experience an adverse event due to this vulnerability with the use of the affected products, please report it to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. You can complete and submit the report online at www.fda.gov/medwatch/report.htm. In regions outside the USA, please contact your local regulatory authority.

Illumina takes security issues very seriously. We are committed to supporting you in addressing this vulnerability. We recognize the impact this change may have on your operation. We are committed to providing you with the highest quality service and support during this change process.

For questions or concerns, please contact Illumina Technical Support techsupport@illumina.com.

Technical Support:
techsupport@illumina.com

Customer Care:
customercare@illumina.com

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Sincerely,

Electronically signed by:
Gary Workman
Reason: Approver
Date: Oct 9, 2023 18:26 PDT

Electronically signed by:
Karen Gutekunst
Reason: Approver
Date: Oct 11, 2023 09:03 PDT

Gary Workman
VP, Global Quality

Karen Gutekunst
VP, Regulatory Affairs

Why You're Receiving This Notification

You are receiving this notification because our records indicate that you are the appropriate contact for your organization for product changes, product obsolescence, and quality issues.

Please be aware that these notifications contain essential information about our products and are not marketing communications. As such, you may receive these notifications despite having opted-out of receiving marketing communications from Illumina. If you are not the appropriate individual in your organization to receive these notifications, you may unsubscribe from these notifications by submitting this form. For more information, please see our Privacy Policy.

Technical Support:
techsupport@illumina.com

Customer Care:
customercare@illumina.com

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Verification Form

Dear Customer,

Illumina sent you a follow up Quality Notification FSN2023-1450 regarding the remediation for the NextSeq 550Dx instruments LRM cybersecurity vulnerability.

Please complete the Verification Form to acknowledge that you have received this notice. We ask that you kindly email the completed form to Illumina Technical Support techsupport@illumina.com per any of the following methods:

- Print, complete, and e-mail the form to Illumina Technical Support techsupport@illumina.com
- Navigate to an electronically editable form here and e-mail the completed form to Illumina Technical Support techsupport@illumina.com
- E-mail Illumina Technical Support techsupport@illumina.com to provide the information requested in the form.

Verification Form	
Company Name	
Information of Person Completing Form	
Print Name:	
Print Title:	
Date (DD-MMM-YYYY):	
Customer Responses	
I confirm receipt of FSN2023-1450 and that I read and understood its content.	Yes ☐ No ☐
The information has been brought to the attention of all relevant users.	Yes ☐ No ☐
Distributor/Importer Responses	**Not applicable ☐**
I have identified customers that received or may have received the product.	Yes ☐ No ☐
I have informed the identified customers of this notice.	Yes ☐ No ☐ Date (DD-MMM-YYYY):

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