



Tuesday, November 28, 2023

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 MiSeq™Dx 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
MiSeqDx Instrument	00816270020002	15036706/Dx-410-1001

Table 2: Feature Summary

Software Name	New Version	Features included in Release
MiSeq Operating Software (MOS)	v4.1.1	<ul style="list-style-type: none">• New Local Run Manager framework (v4.1.0)• Remediation of the LRM cybersecurity vulnerability• Remote access to the LRM Web User Interface restored
MiSeq Control Software (MCS)	v4.1.0	<ul style="list-style-type: none">• New Local Run Manager framework (v4.1.0)• Remediation of the LRM cybersecurity vulnerability• Remote access to the LRM Web User Interface restored

Additional details of the MiSeq Operating Software v4.1.1, MiSeq Control Software v4.1.0, Local Run Manager v4.1.0, and compatible Local Run Manager Module versions can be found [here](#).

Issue Summary

Illumina has released new software versions that remediates the cybersecurity vulnerability and restores remote access to the LRM Web User Interface. New versions of the MiSeq Operating

Technical Support:
techsupport@illumina.com

Customer Care:
customercare@illumina.com

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Software (MOS) v4.1.1, MiSeq Control Software (MCS) v4.1.0, which includes Local Run Manager v4.1.0, are available for installation on the MiSeqDx instruments.

Please note that this is a **required** upgrade. Illumina will no longer be distributing older versions of the software. Going forward, only the versions listed in this notification will be installed on MiSeqDx instruments.

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 MOS, MCS, 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.

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Sincerely,

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](#).

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Verification Form

Dear Customer,

Illumina sent you a follow up Quality Notice FSN2023-1452 regarding a remediation for the MiSeqDx instruments LRM cybersecurity vulnerability that is now available.

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 within 5 business days. Alternatively, you may e-mail Illumina Technical Support 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 FSN2023-1452 and that I read and understood its content.	Yes <input type="checkbox"/> No <input type="checkbox"/>
The information has been brought to the attention of all relevant users.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Distributor/Importer Responses	Not applicable <input type="checkbox"/>
I have identified customers that received or may have received the product.	Yes <input type="checkbox"/> No <input type="checkbox"/>
I have informed the identified customers of this notice.	Yes <input type="checkbox"/> No <input type="checkbox"/> Date (DD-MMM-YYYY)

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