LIFE TECHNOLOGIES HOLDINGS PTE LTD.
33 MARSILING INDUSTRIAL ESTATE ROAD #07-06
SINGAPORE (739256)

URGENT FIELD SAFETY NOTICE: ION TORRENT™ GENEXUS™ DX SOFTWARE 6.8.4.0 AND EARLIER

FSCA REF: PR 961455

Product Name	Device Identifier (DI)	Catalog Number
Ion Torrent™ Genexus™ Dx Software v6.8.4.0 and earlier	10190302018883	A40006911

Date: X November 2026

Institution:
Address:
Country:

Dear Customer,

We are writing to inform you of a Field Safety Corrective Action related to security vulnerabilities identified in the Ion Torrent™ Genexus™ Dx Software version 6.8.4.0 and earlier.

Device Intended Use:

The Ion Torrent™ Genexus™ Dx Integrated Sequencer is an in vitro diagnostic (IVD) medical device intended to be used by trained personnel in a professional laboratory environment for automated, qualitative targeted sequencing of human DNA or RNA extracted from formalin-fixed, paraffin-embedded (FFPE) tumor tissue samples or plasma samples.

Reason for the Field Safety Corrective Action:

Thermo Fisher Scientific has identified security vulnerabilities in the Ion Torrent™ Genexus™ Dx Software version 6.8.4.0 and earlier through a routine internal security review.
The vulnerabilities, if exploited could allow an unauthorized user to make changes to certain instrument settings, software or data.

Hazard giving rise to the FSCA

If successfully exploited, the identified cybersecurity vulnerabilities could potentially result in unavailable, incomplete or altered test results, including false-negative or false-positive results. No confirmed cybersecurity exploitation, related customer complaints, adverse events or patient harm associated with these vulnerabilities has been identified.

Probability of occurrence

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The probability of adverse health consequences is considered remote. Successful patient-impacting exploitation requires multiple technical preconditions and advanced knowledge of the Genexus Dx software, associated workflows, result data and clinical relevance

Action being taken by Thermo Fisher Scientific

Thermo Fisher Scientific has developed Genexus™ Dx Software version 6.8.4.1 to address the identified vulnerabilities.
A Thermo Fisher Scientific field service representative will contact affected customers to coordinate the upgrade.

Actions To Be Taken by the User

Pending implementation of the software update, please:

- Restrict access to authorized personnel only. Exploiting these vulnerabilities requires access to the local network. Limiting access helps reduce the risk of unauthorized activity.
- Confirm the Genexus™ Integrated Sequencer and any associated systems are not directly accessible from the public Internet and are protected by appropriate network security controls, such as firewalls or network segmentation.
- Continue monitoring connected systems for unexpected connections or other unusual network activity so that any potential issues can be identified and investigated promptly.

In addition, please:

- Back up system data prior to the software upgrade.
- Ensure all relevant personnel within your organization are informed of this Field Safety Corrective Action.
- Complete and return the Customer Response/Acknowledgement Form provided with this Field Safety Notice.

We apologize for any inconvenience caused and appreciate your cooperation.

The Competent Authority of your country has been informed of this Field Safety Corrective Action.

Sincerely,



Scott E Gray
Director, Quality Assurance
Thermo Fisher Scientific

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FIELD SAFETY CORRECTIVE ACTION CUSTOMER RESPONSE SHEET
Acknowledgement and Receipt Form
(Customer response is required)
FSCA Ref: PR 961455

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Customer Name and Address:
_____
_____

Customer Country:
_____

I have read and understand the instructions provided in the Field Safety Notice dated Click to enter date
☐YES ☐ NO

Customer Signature of Receipt: _____ Date: _____

Please email a copy of this response sheet to Thermo Fisher Scientific at genexusdx.notifications@thermofisher.com.

For any technical questions or concerns please contact our Technical Support at genexusdx.notifications@thermofisher.com.

Thermo Fisher Scientific Reference Number: PR 961455