

Date: 06 March 2024

Urgent Field Safety Notice
Torrent Suite™ Dx Software versions 5.14 and earlier
used in connection with Ion PGM™ DX Systems

Contact details of local representative (name, e-mail, telephone, address etc.)*

This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Dear Valued Customer:

This communication is to inform you that Thermo Fisher Scientific has recently completed penetration testing on the Torrent Suite™ Dx software which runs on the PGM Dx system™. During the testing, some vulnerabilities were identified. At this time, Thermo Fisher Scientific has not received any reports indicating that these vulnerabilities have been exploited; however, exploitation of the vulnerability by a threat actor may allow them to alter settings, configurations, software, or data on the instrument. Possible outcomes include: no results being available for patient samples tested and possible alteration of results.

Product Name	Installer SKU	Updater SKU
Torrent Suite™ Dx Software 5.12.5	A46166	A46167
Torrent Suite™ Dx Software 5.8	A36601	A36602
Torrent Suite™ Dx Software 5.6.4	A33178	A33178

Torrent Suite™ Dx software runs on the Ion PGM™ Dx Instrument System. The Ion PGM Dx Instrument System is composed of Ion OneTouch Dx Instrument, Ion OneTouch ES Dx Instrument, Ion PGM Dx Chip Minifuge, Ion PGM Dx Sequencer, Ion Torrent Server, and Torrent Suite™ Dx System Software. The Ion PGM™ Dx Instrument System is intended for targeted sequencing of human genomic DNA (gDNA) from peripheral whole-blood samples and DNA and RNA extracted from formalin-fixed, paraffin-embedded (FFPE) samples.

The population at greatest risk includes the intended use population that could benefit from use of identified targeted therapies. Individuals in the population of greatest risk are more likely clinically to be susceptible to a negative outcome if results are altered.

Thermo Fisher Scientific advises customers using impacted versions of Torrent Suite™ Dx to disconnect the Ion PGM™ Dx sequencer, Ion OneTouch™ instrument and the Ion PGM™ Torrent Server from the customer's network to mitigate the vulnerabilities.

To access the data results generated on the instrument, Thermo Fisher Scientific recommends connecting the Ion OneTouch instrument and the Ion PGM Dx Sequencer directly into the Ion PGM Torrent Server.

Customers can access the Ion PGM Torrent Server by connecting their laptops (with WiFi disabled) directly into the server. Please, have your IT department contact your local Thermo Fisher Scientific field support team for mitigation guidance.

Thermo Fisher Scientific also advises the user facility to have proper network firewalls and controlled access to laboratory equipment and laboratory systems.

We will keep you informed if new or additional information becomes available.

Contacting your support representative

If you have questions, please have your IT department contact your local Thermo Fisher Scientific field support team for EMEA region:

ngs-eusupport@thermofisher.com

Thermo Fisher Scientific confirms that this notice has also been sent to the appropriate Regulatory Competent Agencies.

Sincerely,

[Redacted signature]

[Redacted title]

[Redacted address]

Thermo Fisher Scientific

CUSTOMER RESPONSE SHEET
Acknowledgement and Receipt Form
(Customer response is required)

Product Name	Installer SKU	Updater SKU
Torrent Suite™ Dx Software 5.12.5	A46166	A46167
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Customer Name and Address:

Customer Name
Device Name
Street Address
City, State, Zip Code

I have read and understood the instructions provided in this letter dated XX MM YYYY.

YES NO

I have shipped this product to another facility:	<input type="checkbox"/> YES	<input type="checkbox"/> NO
If "YES," I have notified that facility of this issue:	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Number of customers/facilities notified:		
Date notified:		

Customer Signature: _____ **Date:** _____

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

For any questions or comments please contact Technical Support at pgmdx.notifications@thermofisher.com.

Thermo Fisher Scientific Reference Number: PR# 756842