Waters

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Urgent Field Safety Notice – Second Communication

Waters Instruments: **The issue is present in the software accessory and is independent of the instrumentation used to acquire the data.** The issue is not limited to instruments listed, but applies to any instrument running the affected software accessory.

Xevo TQ-S, IVD (PN: 186005453IVD)
Xevo TQD IVD (PN: 186005833IVD)
Xevo TQ-S Micro IVD (PN: 186007833IVD)
Xevo TQ-XS, IVD (PN: 186008453IVD)

using Accessories:
Kit, NeoLynx v4.2, IVD (PN: 667005682IVD)
Kit, NeoLynx v4.1 IVD (PN: 667002653)
Kit, IonLynx v4.2 IVD (PN: 667005757IVD)

FSCA: 1218959-10/08/2021-001-C
Device Modification

12Jan2022 – First Communication
31Mar2022 – Second Communication

Attention: Customer

Details on affected devices:
Waters Corporation has initiated a Product Alert regarding our NeoLynx and IonLynx software applications. The issue is independent of the instrumentation used to acquire the data.

Description of the problem:

After investigation a vulnerability has been found within the NeoLynx or IonLynx processing browser, where the final sample of a batch may have tests not displayed when viewed within the NeoLynx or IonLynx processing browser and in reports generated from the browser.

The issue only presents when the last occurrence of the Auto Refresh feature begins before all the data has processed. This is a race condition, as the system is attempting multiple tasks that occasionally result in the refresh occurring before the processing has completed. The data saved in the NeoLynx or IonLynx results file (.nrf) is complete. However, automatically generated reports may contain only the data displayed in the browser. **A manual refresh or reopening of the results file (.nrf) ensures the complete data set is displayed within the Browser.**

Advise on action to be taken by the user:
Our records indicate that you have purchased NeoLynx and/or IonLynx software. To ensure continued reliability of our products, Waters has issued this product alert to make you aware of the issue referenced above and provide the following recommendations:

- Waters recommends the use of manual refresh at the end of an analysis or prior to generating any reports from the browser
- Waters also reminds customers to use QCs at the end of an analysis as directed by the Waters IVD instructions for use and Clinical Laboratory Standards Institute (CLSI) guidance.

Please complete the attached Reply Verification Tracking Form and return it to Waters per the instructions within the form. Completion of this form will expedite the field correction activity and provides evidence that Waters has notified you about this correction.

Feel free to contact me if you have any questions or concerns regarding this issue.

Sincerely,
Randy Koester
Sr. Director, Global Quality Assurance
Email: Randy_Koester@waters.com
Phone: +1 508 482 2323

DocuSigned by:
Randy Koester
Signer Name: Randy Koester
Signing Reason: I approve this document
Signing Time: 12-Apr-2022 | 1:50:51 PM EDT
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REPLY VERIFICATION TRACKING FORM

Medical Device Recall – Correction – Waters Instruments

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Company Name:

Region:

Contact Person:

Email:

Name of Software Accessory Affected

INSTRUCTIONS FOR COMPLETING THIS REPLY VERIFICATION TRACKING FORM:
This completed form is required for tracking purposes. Please check the applicable boxes below. Your signature and date are required.

☐ I acknowledge receipt of this letter

☐ I have the affected product(s)

☐ I DO NOT have the affected product(s)

Name (Print): _____

Signature: _____ Date: _____

(DD/MM/YYYY)

Please return the completed form via email or fax to:
(email) waters_quality@waters.com
(fax) US: 508 482 2339 / Outside US: +1 508 482 2339