



Urgent FIELD SAFETY NOTICE

Waters Xevo TQ-S Micro IVD (PN: 186007833IVD)

FSCA Ref.: 1218959-09/27/2023-001-C

Device Modification

02OCT2023

Attention: Customer

Details on affected devices:

Xevo TQ-S Micro IVD (P/N: 186007833IVD) ; Serial Number: QEF1441

The Waters Xevo TQ-S Micro IVD is a tandem quadrupole, atmospheric pressure ionization (API) mass spectrometer. It is designed for routine UPLC-MS/MS analyses in quantitative applications and can operate at fast acquisition speeds compatible with Ultra Performance LC.

Description of the problem:

After investigation, a design vulnerability relating to firmware of Xevo TQ-S Micro IVD has been identified that, under specific circumstances, data from the previous scan of sample is still present and counted in the current scan. This can lead to the output being artificially high and introduces a risk of a false positive result.

In the current configuration the problem is extremely unlikely to occur. However, if components are changed at a future date this may increase the risk.

Advise on action to be taken by the user:

The instrument can continue to be operated whilst awaiting modification. A Waters field service engineer will contact you to schedule correction of your affected instrument.

Please complete the attached Reply Verification Tracking Form and return it to Waters per the instructions within the form by the **13 October 2023**. Completion of this form will expedite the field correction activity and provides evidence that Waters has notified you about this correction.

Waters Corporation will also provide a copy of this FSN (Field Safety Notice) to Danish Medicines Agency along with Field Safety Corrective Action.

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

Sincerely,

Wendy Baker
Director, Clinical Quality Assurance
Email: Wendy_Baker@waters.com
Phone: +44(0) 161 946 2718

DocuSigned by:
Wendy Baker
Signer Name: Wendy Baker
Signing Reason: I approve this document
Signing Time: 02-Oct-2023 | 3:21:00 PM BST
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REPLY VERIFICATION TRACKING FORM

Medical Device Recall – Correction – Waters Xevo TQ-S Micro IVD (PN: 1860078331VD)

<i>Organization Name</i>	
<i>Address</i>	
<i>Contact Name</i>	
<i>Contact Phone Number</i>	
<i>Contact E-mail Address</i>	

<i>Name of Product Affected</i>	<i>Serial Number</i>
<i>Waters Xevo TQ-S Micro IVD System</i>	<i>QEF1441</i>

INSTRUCTIONS FOR COMPLETING THIS REPLY VERIFICATION TRACKING FORM:

Return completed form by **13 October 2023**, the 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) / Serial Number(s) noted above.
- I DO NOT have the affected product(s) / Serial Number(s) noted above.

Name (Print): _____

Signature: _____ Date: _____

(DD/MMM/YYYY)

Please return the completed form via email to:
(Email) waters_qualityaction@waters.com

