
Urgent Field Safety Notice

Waters 3777C Sample Manager IVD (PN: 725000662IVD)

FSCA: 1218959-11/17/2021-003-C

Device Modification

08Dec2021

Attention: Customer

Details on affected devices:

Waters 3777C Sample Manager IVD, 725000662IVD

Advise on action to be taken by the user:

Our records indicate that you own or lease one or more Waters 3777C Sample Manager IVD. To ensure continued safety and reliability of our products, Waters has issued this product alert to make you aware of the issue referenced above and provide the following instruction:

- **Priority samples must not be used in conjunction with single sample overlap acquisitions.**
- **The pause function, followed by sample list deletion, must not be used in conjunction with single sample overlap acquisitions.**

Any data that has been acquired using the workflows detailed below should be reviewed.

Description of the problem:

After investigation, a defect has been found that can result in a single sample being injected and recorded against the incorrect sample list location. This defect will only occur in two scenarios:

1. If the sample list is paused when adding priority samples and the single sample overlap function is also being utilized.

Our investigation has concluded that under these conditions, the single sample overlap function draws the next scheduled sample while the previous injection completes its run as expected. If the sample list is then paused to insert priority samples, the previously drawn sample continues to be injected once the sample list resumes. However, due to the defect, the data generated will be recorded against the incorrect sample list location. The sample list will then continue as expected.

The outcome of this defect is that:

- The first of the priority samples is not run at all

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- The file labelled as the first priority sample contains the data for the sample preloaded in the needle when the sample list was paused
- After the Priority samples complete, the original batch resumes, the originally preloaded sample is run a second time and the data stored in the correct data file location
- Ultimately a single data file is incorrect – it was injected from the incorrect location
- The sample vial that has been drawn from twice may be at risk if it contains limited sample volume

2. If the sample list is paused, aborted by deletion, then a new sample list started, and the single sample overlap function is also being utilized.

Our investigation has concluded that under these conditions, the single sample overlap function draws the next scheduled sample while the previous injection completes its run as expected. If the sample list is then paused and the sample queue deleted, the previously drawn sample continues to be injected when a new sample list is started.

The outcome of this defect is that:

- The first sample in the new sample list is not run at all.
- The file labelled as the first sample in the new sample list contains the data for the sample preloaded in the needle when the sample list was paused
- Ultimately a single data file is incorrect – it was injected from the incorrect location.

The corrective action for this defect is currently under investigation. A Waters field service engineer will contact you to schedule the update of your affected instrument(s) once a solution is available.

Please complete the attached Reply Verification Tracking Form and return it to Waters, by December 17, 2021, per the instructions within the form. Completion of this form 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,

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REPLY VERIFICATION TRACKING FORM

Medical Device Recall – Correction – Waters 3777C Sample Manager IVD (PN: 725000662IVD)

Company Name:

Region:

Contact Person:

Email:

<i>Name of Product Affected</i>	<i>Serial Number</i>

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) / Serial Number(s) noted above
- I DO NOT have the affected product(s) / Serial Number(s) noted above

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