

Date: JULY 19, 2023

Ref: MRAA-9074

Dear Customer,

Field Safety Notice

Affected Products:

CLAM-2030 CL

CLAM-2040 CL

Description of issue (Reason):

The specimens are placed in a specimen container and loaded into the instrument.

Specimens are managed by linking the position of the specimen container with a barcode attached to the specimen container.

By selecting a sample and analysis method from the PC, sample preparation is performed.

We found that when multiple specimen containers with identical barcode were simultaneously loaded in an analyzer, a software malfunction causes the wrong specimen container location information to be incorrectly linked to a barcode.

When the specimen container location information is incorrectly linked to the barcode, incorrect results may be reported to the physician.

How to identify the affected products:

Your authorized Shimadzu local representative can investigate whether your product(s) is affected or not. Please contact your local Shimadzu representative.

Corrective action plan by Shimadzu:

We will modify the software not to analyze specimen containers with duplicate barcode and warn the customer that the specimen containers will not be analyzed when multiple specimen containers with identical barcode are detected in the same analysis sequence.

The analysis of specimen containers other than those with duplicate barcodes will continue.

We will inform customers to check the specimen containers that were not analyzed if the warning is displayed after the analysis is completed.

Actions to be taken by customer:

Do not load multiple specimen containers with the same barcode in an analyzer at the same time until the software has been updated.



Medical Regulatory Policy Department

Post Market Surveillance Section

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You will be contacted by Shimadzu's local representative to determine whether your system requires the above corrective action. If you are not contacted by Shimadzu, please call Shimadzu local representative.