



URGENT Field Safety Notice

AIA®-CL300 Immunoassay Analyzer - False lower temperature limit error

Product: AIA-CL300
Product Code: 0024450
Software version: V1.04
FA Reference: FA4
Type of action: Mandatory software update
Date: 16 August 2023

Dear Valued Tosoh Customer,

This letter contains important information regarding the AIA-CL300 Immunoassay Analyzer (P/N.: 0024450) provided by Tosoh Europe to your facility. Tosoh Europe is initiating a mandatory software update for all AIA-CL300 instruments having version 1.04 to be upgraded to software version 1.05.

Background

The instrument monitors the temperature of the incubator unit at regular intervals. Temperature information is obtained at the beginning of each cycle of temperature monitoring and when assay or Daily Check is executed. The timing of when an assay or Daily Check is scheduled to start, determines the point at which the instrument accesses temperature data after resetting. When this occurs immediately after resetting, the instrument might erroneously record a temperature of 0°C for the incubator.

Temperature sensor errors, indicating that the temperature of one or more sensors is below the lower limit, might occur when the assay or the Daily Check begins, even if the overall temperature control of the instrument is working properly.

The following errors have been observed in rare cases:

- “[3060] The temperature of the substrate heat rack has fallen below the lower limit”.
- “[3061] The temperature of the dispense lane has fallen below the lower limit”.
- “[3062] The temperature of the incubator sensor 1 has fallen below the lower limit”.
- “[3063] The temperature of the incubator sensor 2 has fallen below the lower limit”.
- “[3064] The temperature of the washer/diluent has fallen below the lower limit”.



Risk to health

In case of error “[3062] The temperature of the incubator sensor 1 has fallen below the lower limit”, a recovery can be done by resetting the instrument by the main power switch.

Patient results are not affected, nevertheless reporting of results is delayed due to the restart of the instrument.

Temperature errors other than 3062 (such as 3060/3061/3063/3064) can be ignored as daily check and/or assay will be processed without interruptions. As the instrument will automatically recover immediately after the error occurs, patient results are not affected and are not flagged by the instrument.

Corrective Action

Tosoh is issuing a software update to clear the temperature errors with version 1.05. This update ensures that temperature information will no longer be initialized at the start of an assay or Daily Check, thereby preventing the occurrence of temperature limit errors. Tosoh qualified service engineers will promptly implement this software update for all instruments in the market immediately upon release.

In the interim, until the release of software version 1.05, we have outlined a temporary solution in Technical Bulletin AIA-CL300-T013. This measure will effectively mitigate the impact of Error 3062 and can be applied to all instruments until software version 1.05 becomes available.

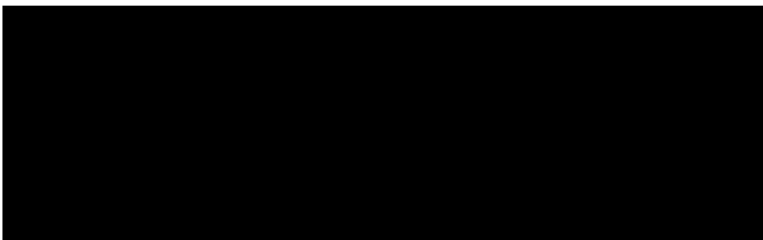
Actions to be taken by the Customer

- 1) Ensure that all the contents of this Field Safety Notice are read and understood by those within your organization who need to be aware.
- 2) If you have further distributed the impacted product, please forward this notice and all the related documentation to those customer(s).
- 3) Return the completed customer **Confirmation Form on Page 3** of this notification to vigilance.emea@tosoh.com

Once software version 1.05 becomes available, Tosoh qualified service engineers will promptly contact your facility to schedule an appointment for updating the instrument.

Should you have any questions or require assistance relating to this notification, please contact your local Tosoh representative or the QA/RA department at vigilance.emea@tosoh.com.

On behalf of the manufacturer



Senior Quality Assurance and Regulatory Affairs Manager EMEA
Tosoh Europe NV



CONFIRMATION FORM

**PLEASE COMPLETE AND FAX BACK TO QA/RA department: +32 (0)13 66 47 49
or email to: Vigilance.EMEA@tosoh.com**

Our Reference: FA4

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This form is to confirm receipt of the enclosed Tosoh Europe NV Field Safety Corrective Action dated 16 August 2023, which provides information regarding **AIA-CL300 Immunoassay Analyzer – False lower temperature limit error**. Please complete the below form.

- 1) Name of Facility:

- 2) Tosoh Customer Code (if known) :

- 3) Name of contact person:

- 4) Telephone number of contact person:

- 5) Email address of contact person:

(1): I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Customer Name

Date: (DD/MM/YY):

Customer Signature:

Thank you for your kind cooperation.