

Urgent Field Safety Notice

501RP+ Communication Error

Device: 501RP+
Device Code: 0023295
Software version: v2.42 and previous versions
FA Reference: FA6
Type of action: Software Update
Date: 16 September 2024

Dear valued Tosoh Customer,

This letter contains important information regarding the 501RP+ software (P/N.: 0023295) provided by Tosoh Europe to your facility.

Tosoh Europe is initiating a mandatory software update for all 501RP+ to be updated to version v2.43 or later.

Background

Through an internal investigation following a user report, Tosoh determined that in one instance, the 501RP+ experienced a temporary communication error and was unable to receive and assign results from the device. As a result, the device reported a communication timeout error, '347 HOST COMM ERR (RT)'. Upon recovery, the specimen information received before the error and a test result from another specimen received after communication was restored were linked and stored. Consequently, the device assigned the result to another specimen ID on the rack.

Risk to health

In case of communication error(s) between the analyzer(s) and the 501RP+, the software has an embedded check digit verification function, which should prevent errors from occurring and going unnoticed.

There is one reported instance for this issue globally, from the launch of the device in 2015, where this function did not work correctly due to a series of events that led to the communication error described above. We can conclude that the probability of this event is very low.

Corrective Action

Tosoh is issuing a software update to version 2.43, to be applied to all 501RP+ software installations.

This update ensures that in case 501RP+ receives abnormal data (such as for example too long data communications, or the same type of result record received in a short period of time), communication between the analyzer(s) and the 501RP+ will stop and give an error. The 501RP+ will then need to be restarted manually by the user.

Tosoh qualified service engineers will promptly implement this software update immediately upon release which is planned before the end of 2024, for all 501RP+ on the market.



TOSOH EUROPE N.V.

Until the release of software version 2.43, we have outlined a temporary corrective action. This measure is meant to mitigate the impact of this error and can be applied until software version 2.43 becomes available.

Temporary corrective action to be applied during operation

If the instrument shows error "347 HOST COMM ERR (RT)," please check if:

- The HbA1c value of the specimen tested around the time of the error is suspicious (results should be evaluated in conjunction with clinical symptoms and patient history, if available).
- Any specimen results have not been uploaded to 501RP+.

If the answer to either of these checks is "yes," the specimen should be assayed again.

Additionally, we recommend restarting the PC with 501RP+ once a week, as described in the operator manual.

We apologize for any inconvenience this may cause. We are implementing additional operational processes to prevent this from occurring again and remain committed to providing you with the highest quality products and service possible.

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 device, please forward this notice and all the related documentation to those customer(s).
- 3) Implement the temporary corrective action to be applied during operation outlined above.
- 4) Return the completed customer **Confirmation Form** on **Page 3** of this notification to vigilance.emea@tosoh.com.

A Tosoh qualified Field Service Engineer will contact you as soon as the version 2.43 is released, to take an appointment with your establishment and update the 501RP+ software

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

Ioannis Bekatoros
Director Quality Assurance and Regulatory Affairs
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**

Tosoh Reference: FA6

501RP+ - Communication Error

This form is to confirm receipt of the enclosed Tosoh Europe NV Field Safety Corrective Action dated 16 September 2024, which provides information regarding **501RP+ Communication 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.