

URGENT Field Safety Notice

AIA-360 Analyzer Display Screen Software Issue

Product affected: **Automated Enzyme Immunoassay Analyzer AIA-360/ Serial numbers 8461-8764, Manufactured 2019-02-07 and after**

FSCA Reference: *NC 18 FSCA*

Type of action: *Device modification*

Date Issued: *20th January 2020*

Dear Valued Tosoh Customer,

Tosoh Europe NV has become aware of a display screen software issue that causes the display to freeze when the display screen is touched at the same time as a command from the instrument firmware. The analyzer cannot process both actions at the same time, so the display screen locks up and the instrument stops. As a result, the run is aborted, and results are not retrievable. Tosoh has taken the required actions to correct this issue and will upgrade or replace the display screen to fix the problem.

The following AIA-360 analyzers with the serial number listed are at risk for this error occurring and need correction:

28479502	28479602	28479702	28479802	28479902	28489002
28489103	28489203	28489303	28489403	28489503	28489603
28489703	28489803	28489903	28499003	28549104	28549204
28549304	28549404	28549504	28549604	28549704	28549804
28549904	28559004	28559104	28559204	28559304	28559404
28559504	28559604	28599705	28599805	28599905	28609005
28609105	28609205	28609305	28609405	28659906	28669006
28669106	28669206	28669306	28669406	28669506	28669606
28669706	28669806	28669906	28679006	28679106	28679206
28679306	28679406	28679506	28679607	28679707	28679807
28679907	28689007	28689107	28689207	28739608	28739708
28739808	28739908	28749008	28749108	28749208	28749308
28749508	28749608	28749708	28749808	28749908	28759008
28759108	28759208				

Risk to Health

When there are competing signals, the display screen will stop functioning and the run will stop. The patient samples may be rerun which will cause a minor delay in reporting patient results. There is no expected adverse health consequence.

Immediate Actions to be taken by the Customer/User

- Thoroughly review the content of this letter.
- Complete the attached CONFIRMATION FORM and return it within 15-days of receiving this notification.
- Refrain from touching the display panel while the analyzer is running. If your analyzer stops and/or the display freezes, please contact your local Tosoh representative within your country.
- Identify if the serial number of your AIA-360 analyzer is listed in above table. If so, you will be contacted by a Tosoh Qualified Field Service Engineer to schedule a visit to replace the display screen which will correct the potential issue.

- File this notice with your laboratory records and forward this information to other supervisors or managers in your laboratory to ensure that they are aware of the potential issue.

Corrective Action

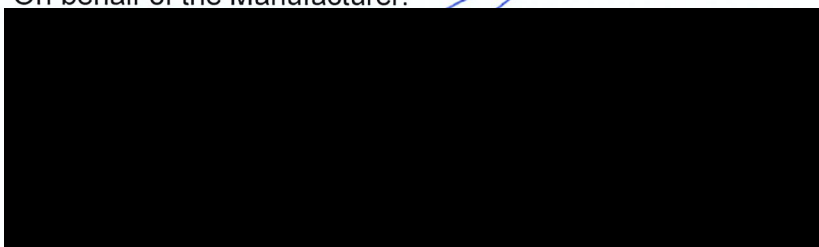
Tosoh will contact you with affected product and schedule maintenance to Upgrade the TDU2 software or to replace the display (TDU2) withing next 12 months.

If you have further questions, please contact your local Tosoh representative.

We apologize for the inconvenience this situation may cause. Should you have any questions, please contact your regional support team or send email to Info.Raqa@tosoh.com.

Sincerely,

On behalf of the Manufacturer:



Tosoh Europe NV

CONFIRMATION FORM

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

Our Reference: **NC18 FSCA**

URGENT Field Safety Notice for AIA-360 Analyzer Display Screen Software Issue

This response form is to confirm receipt of the enclosed Tosoh Europe NV Field Safety Notice dated 20th January 2020, which provides information on the AIA-360 software issue and its effect on AIA-360 analyzer operation. Please complete below form.

1) Name of Laboratory:

2) Tosoh Customer Code:

3) Name of contact person:

4) Telephone number of contact person:

5) Email address of contact person:

I confirm to have received the **NC18 FSCA**

☐ (1) I have read and understood the instructions provided in this letter, and all appropriate personnel including Lab Director and Medical Director have been notified.

☐ (2) I do not have any of the Tosoh products identified in this notification.

Customer Name :

Date: (DD/MM/YY):/...../.....

Customer Signature:

Thank you for your kind cooperation.