

FIELD SAFETY NOTICE (FSN)

Dear Sysmex customer,

It has come to our attention that Sysmex haematology IVD analyser

XN-550

might report wrong measurement results due to improper mixing of a sample only under the combination of the following conditions

- the XN-550 is connected to a host computer and
- a host communication error occurs during a sampler run

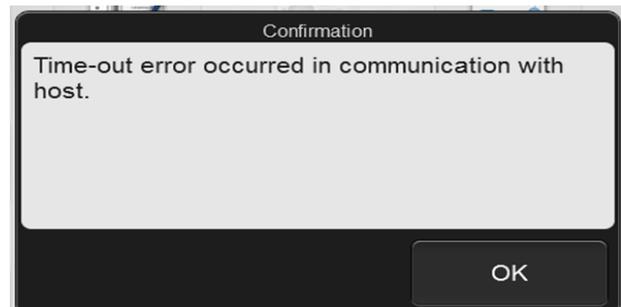
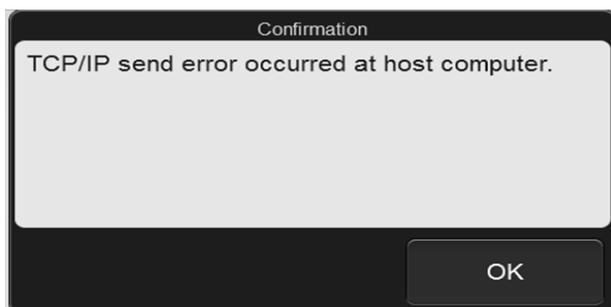
This may lead to wrong diagnostic and patient treatment decisions and serious outcome for patients. All other customers are not affected.

Herewith we request you:

- 1) Distribute this FSN to the responsible device operators in your organisation
- 2) Make sure that below described Immediate Action will be applied immediately
- 3) Please follow your internal SOPs regarding retrospective judgement of affected samples
- 4) Confirming back to us that you have received this FSN by the hereby attached AoR form

Detailed description of the problem

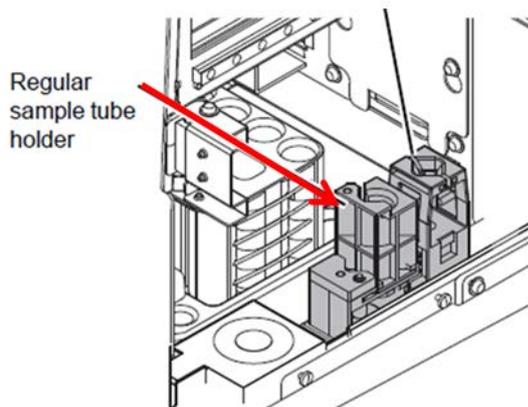
- In case a host communication error appears during XN-550 sampler analysis, it results in an error message and the sampler stops.
- If at that time a sample tube is located in the sample tube holder, it will not be processed until the error is accepted. The time between appearance and acceptance of the error can vary depending on the attendance of the analyser. During this time sedimentation of the blood sample will occur.
- After accepting the error the sample tube might be processed without additional mixing, which could lead to potentially wrong measurement results due to blood cell sedimentation.



Examples of possible error messages of the XN-550 which would indicate erroneous communication with the host.

Immediate Action to avoid the risk of false measurement results

In case an error message related to host communication and/ or TCP/IP connection appears during an XN-550 sampler run due to a host communication failure, it is MANDATORY to check the sample tube holder and remove the sample tube, if possible, BEFORE accepting the error and restarting the sampler. In case the sample tube holder is not accessible, accept the error message and do NOT use the measurement result from this particular measurement. Make sure the sample is re-analysed. Otherwise there is a risk for aspiration without prior mixing, leading to wrong measurement results.



If the described host communication error appeared during XN-550 sampler analysis, check the sample tube holder as indicated in the image and remove the sample tube, if present, before accepting the error message and restarting of the sampler.

Permanent Field Safety Corrective Action (FSCA):

Currently the identified root cause being instable host connections is under investigation with regards to Sysmex device addressing this safely in routine operation. After final countermeasure is known, we will inform permanent corrective action.

We very much apologize for any inconvenience this may cause on your side and thank you for your kind understanding and continued support of Sysmex and our products.

Yours sincerely,

Sysmex Europe GmbH

Thomas Kröger

Safety Officer



Customer's
Acknowledgment of Receipt (AoR)

We hereby confirm the receipt of Field Safety Notice (FSN) issued 6th March, 2017 concerning the Field Safety Corrective Action on the IVD medical device

XN-550

with regards to a **false results in case a host communication error occurs during a sampler run of the XN-550.**

We hereby also confirm that the described Immediate Action will be applied by us.

Institution

Address

Responsible & authorized Person,

Position

Signature

Place / Date