

FIELD SAFETY NOTICE (FSN)

SAL/TSM for CS-5100

Mandatory Parameter Change

Important Information on a GLP combination product (SAL/TSM) for connection to
Sysmex Automated Blood Coagulation Analyzer CS-5100

Dear Valued Sysmex Customers,

It has come to our attention that a (potential) risk can occur, if the CS-5100 is shutting down longer than 30 minutes in a combination with SAL/TSM system of GLP systems. This can lead to wrong assignment of sample results, because of non-synchronized working lists on the GLP systems Track and Sysmex instrument due to an interface communication issue. The track will cancel samples after a non-activity period of the instrument. Not all samples can be cancelled via the interface. The instrument will continue to process previous samples data but aspiration may be performed on a new sample not matching the previously advised sample. This may result in wrong result assignment and possible wrong patient treatment.

1. Facilities concerned

Facilities which use Automated Blood Coagulation Analyzer CS-5100 connected to GLP systems Track.

2. Phenomenon and root cause

Analyser downtime is causing non-synchronized working lists of the GLP systems Track and the Automated Blood Coagulation Analyzer CS-5100. GLP systems is cancelling the Track internal working list and advising the analyser. Samples already in processing currently cannot be cancelled via the interface. Physically presented and expected sample do not match which is not detected during sampling operation. Wrongly assigned measurement values from an analysed sample to a next upcoming sample due to interface communication issue is likely.

3. Workaround (Immediate Action)

Information about the potential risk by this FSN.

Please increase the "Instruction Time Out" in TSM

(TSM: Admin -> Parameter -> Service 'Maximal age of instructions')

from actual 30 minutes to 240 minutes (4h) or 360 min (6h).

4. Countermeasure (Permanent Field Safety Corrective Action (FSCA))

GLP systems are redeveloping the interface and communication protocol.

The interface development and improvement is expected in beginning 2017.

5. Look back statement:

Sysmex does not recommend a look back of previously generated results since the coagulation status changes over the time, and does recommend that this communication is reviewed with the laboratory medical director.

If you have any question, please feel free to contact to your local Sysmex representative.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use this product.

Please send back the attached AoR duly signed in pdf format to vigilance@sysmex-europe.com or by post **latest until 9th of December 2016**. Thank you.

We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours

Sysmex Europe GmbH

Thomas Kröger
Safety Officer

Norderstedt, 2nd December, 2016

Customer's

Acknowledgment of Receipt (AoR)

We hereby confirm the receipt of Field Safety Notice (FSN) issued 2nd December, 2016 concerning the Field Safety Corrective Action (FSCA) on the non-IVD

GLP systems TRACK (combined with IVD CS-5100)

with regards to an "Increase of Instruction Time Out" in Track Sample Manager (TSM) of GLP systems Track.

Please send back this confirmation to vigilance@sysmex-europe.com latest until December 9th, 2016

Institution

Address

Responsible & authorized Person

Position

Place / Date

Signature