Urgent Field Safety Notice

FSCA2606

Oct 15th, *2026*

Title: CN Series – Risk of falsely low measurement results due to deposit accumulation on Sample Arm B probe

Product Name	CN-3000, CN-6000, CN-3500, CN-6500
Product Description	The CN-3000, CN-6000, CN-3500 and CN-6500 are fully automated blood coagulation analysers intended to measure haemostasis parameters using clotting, chromogenic, immunoassay and aggregation methods.
Device Identifier	**CN-3000** UDI-DI: 04987562499700 UPC: 636090499709 REF: CL971029 **CN-6000** UDI-DI: 04987562499687 UPC: 636090499686 REF: CV339763 **CN-3500** UDI-DI: 04987562527694 UPC: 636090527693 REF: AX818921 **CN-6500** UDI-DI: 04987562527687 UPC: 636090527686 REF: BH584790
Production Identifier (Lot No./Serial No.)	All serial numbers.
Type of Action	Sysmex issues instructions to users to prevent this issue from occurring. The instructions include the procedure for cleaning Sample Arm B probe as well as the recommended cleaning frequency. If cleaning is performed in accordance with these instructions, the risk of falsely low measurement results can be significantly reduced.

Description of Situation:
Dear Valued Customer,
Cc : Chairman of the Medical Board and relevant Heads of Department of the affected healthcare facilities

This Field Safety Notice (FSN) is intended to inform users of a potential risk of falsely low measurement results associated with deposit accumulation on Sample Arm B probe.

Sysmex has identified that deposits may accumulate on the Sample Arm B probe of the affected CN-Series analysers. The deposits may interfere with sample dispensing, so that less sample than intended is delivered to the reaction cuvette. This may result in measurement results that are incorrectly too low being reported for the assays potentially affected.

Sysmex has received seven complaints worldwide associated with this issue. Based on the information available to Sysmex as of 15 October 2026, no patient harm has been reported in connection with these complaints.
Although only a limited number of complaints have been received worldwide, Sysmex has decided to issue this FSN as a precautionary measure.

The list of affected assays is set out in the Annex.

Risk to Health:
Falsely low measurement results may lead to a delayed or missed diagnosis, inappropriate treatment decisions or unnecessary changes to therapy. Depending on the clinical context, this may result in serious harm to the patient, requiring additional medical intervention, and, in severe cases, may lead to life-threatening complications.

Actions taken by Sysmex:
- Sysmex is issuing this Field Safety Notice and providing affected users with instructions on regular cleaning of Sample Arm B probe.
- Sysmex will update the applicable Instructions for Use to include this cleaning procedure as a routine maintenance activity.
- Further corrective actions, including improvements to the automated cleaning process, are being developed and will be communicated separately where applicable.

Actions to be taken by the user:

1. Check whether any of your CN-Series analysers within your organization are affected.
2. Clean the sample arm B probe immediately, in accordance with the enclosed instructions, before further routine use. Thereafter, carry out cleaning at the specified intervals.
3. Record each completed cleaning procedure in the analyser's maintenance log.

4. Check the recent quality control data for unexplained shifts, trends or results outside the measurement range that may be related to inadequate sample delivery.
5. This problem may be indicated by abnormal quality control results, unexpected patient results, discrepancies in repeat tests or visible accumulation of deposits. The absence of any abnormalities in quality control alone does not mean that no patient results have been compromised. A retrospective review should therefore be considered if there are indications that deposits may have formed or that sampling may have been inadequate. The scope of such a review should be determined by the laboratory's responsible healthcare professional in consultation with Sysmex
6. Please forward this notice to all affected individuals within your organisation, as well as to any organisations to which the affected devices may have been passed on.
   Please keep this notice and the resulting measures under review for an appropriate period of time.
7. Complete the acknowledgement of receipt and return it to your authorised local Sysmex representative.

Sincerely yours

Sysmex Corporation

[redacted]

Safety Officer
Vice President of Quality Assurance
Regulatory Affairs & Quality Assurance