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

Y. Ueda

Yoshiro Ueda

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

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

ANNEX: Instructions for users on cleaning the 'Sample Arm B' probe

Introduction:

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.

This Annex is intended to provide 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.

Affected analysers

REF Code	Name of Product
CL971029	CN-3000
CV339763	CN-6000
AX818921	CN-3500
BH584790	CN-6500

Potentially affected assays

REF code	Reagent	Assay group	MID (OUS)	MID (US)
OWWR 15 / OWWR 17	Berichrom Antithrombin III	AT BC	100308	-
OUIA	Berichrom C1-Inhibitor	C1-Inhibitor BC	100416	-
CW567587 / CG858387 / AZ550807 / CF232025	LIASAUTO P-FDP	FDP Lia	100646	-
BQ243330	Latex Test BL-2 P-FDP	FDP BL	100017	-
BF868996 / AX417778	Revohem AT	Revohem AT LRT	101296	-
OPPU05	INNOVANCE Anti-Xa	Apixaban INN Anti-Xa	6160	5670
OPPU05	INNOVANCE Anti-Xa	Edoxaban INN Anti-Xa	6180	-

OPPU05	INNOVANCE Anti-Xa	Rivaroxaban INN Anti-Xa	6140	-
221123 / 221127	BIOPHEN™ AT anti-(h)-Xa LRT	BIOPHEN AT LRT-IMI	101350	-
		BIOPHEN AT LRT-HEP	101351	-
120011	HYPHEN BioMed D-Dimer Latex LRT	Hyphen D-Dimer LRT	101357	-
120003	LIAPHEN Protein C	LIAPHEN Protein C Ag-IMI	101076	-
		LIAPHEN Protein C Ag-HEP	101303	-
120004	LIAPHEN Free Protein S	LIAPHEN Free Protein S Ag -IMI	101058	-
		LIAPHEN Free Protein S Ag -HEP	101255	-
CK585K	FIBRIPHEN LRT	FIBRIPHEN LRT -IMI	101163	-
		FIBRIPHEN LRT -HEP	101239	-
CK571K / CK572K / CK575K	FIBRIPHEN	FIBRIPHEN -IMI	101164	-
		FIBRIPHEN -HEP	101240	-

MID = Management Identification. Unique identifier assigned to an assay group.
OUS = Outside the United States of America. Indicates that the assay group is intended for use outside the United States of America.
US = United States of America. Indicates that the assay group is intended for use in the United States of America.

User-defined methods (UDMs):
Sysmex has not specifically investigated the impact of this issue on user-defined methods or laboratory-developed assays. Laboratories using such methods should assess the potential impact as part of their own validation and quality management processes.

Instructions:
Please clean the Sample Arm B probe regularly, following the instructions below.

Cleaning Procedure

1. Set the system to *Shutdown Mode*. Once the shutdown procedure is completed, switch off the analyser.
2. Open the operating cover.
3. Carefully and slowly move sample arm B towards the front of the analyser.
4. Hold sample arm B with one hand and wipe the pipette tip with a lint-free cloth moistened with purified water. (see Figure 1).
5. Carefully and slowly guide sample arm B back to the rear of the analyser.
6. Close the operating cover.



Figure 1 Cleaning Procedure for Sample Arm B probe.

Required cleaning frequency
Clean Sample Arm B probe at least once per week or after every 16,000 tests, whichever comes first. If deposit accumulation is observed, clean Sample Arm B probe immediately, regardless of the time elapsed since the last cleaning or the number of tests performed.

Documentation and reminder of the maintenance activity
Configure the cleaning of Sample Arm B probe as a user-defined maintenance item in the analyser software. Refer to the analyser Instructions for Use, chapter 15.12, “Registering user-defined maintenance parameters” on renaming a user-defined maintenance item.

For information on setting up a specific alarm configuration, refer to the analyser Instructions for use, chapter 15.13.5, “Setting alerts”. Set up a weekly alarm to ensure that the required cleaning is carried out at least once a week.

Once the cleaning has been completed, enter the maintenance activity manually:

1. Select [Maintenance] > [Manual maint.] > [Register manual maintenance].
2. Select the checkbox for the completed maintenance item, then select [OK] > [Yes].

For reference, images showing contamination on Sample Arm B probeare provided below.

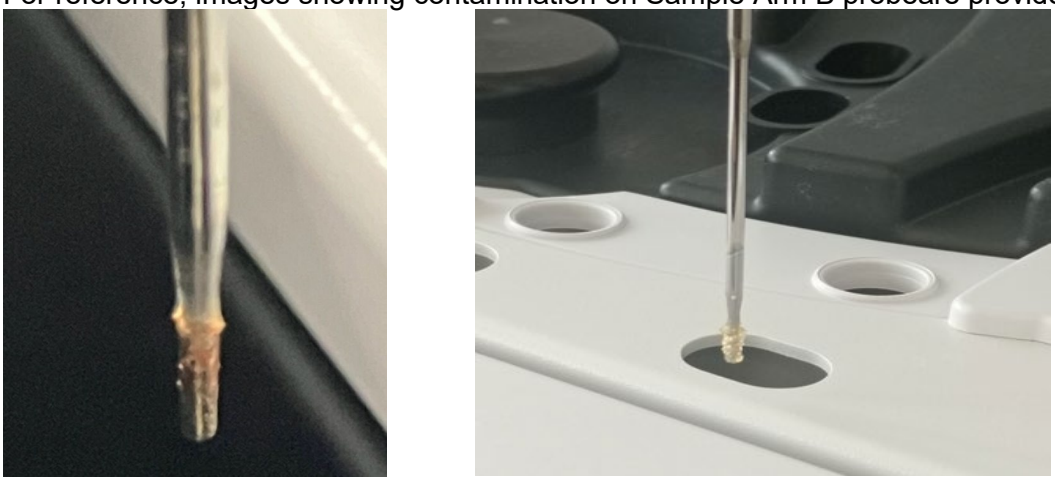


Figure 2. Example of Contamination on the Sample Arm B probe

Important!
The maintenance alert is time-based and does not monitor the number of tests carried out. The laboratory must therefore put in place a suitable procedure to ensure that sample arm B probe is cleaned before 16,000 tests have been carried out, should this threshold be reached before the next scheduled weekly cleaning. Based on the laboratory's average daily test volume, it is possible to estimate when the threshold of 16,000 tests is likely to be reached. The completion of each cleaning procedure must be documented in accordance with the laboratory's established procedures.

Further measures that Sysmex will be taking:
Sysmex intends to revise the relevant Instructions for Use and include the cleaning of sample arm B probe as a mandatory maintenance procedure. Details regarding the revision of the document will be communicated separately as soon as they become available. Although the mechanism leading to the deposit accumulation has been identified, further investigations are currently underway to determine the suitable long-term permanent corrective action.