

Information for Field Corrective Action (i-FCA)

Title: CN series – Sample arm B pipette damage issue		
FCA Number	FCA 2510	Issue Date: 2-Dec-2025

Legal Manufacturers	<input checked="" type="checkbox"/> S-Corp, <input type="checkbox"/> Hyphen, <input type="checkbox"/> SPG <input type="checkbox"/> other()
Product Name and Model	CN-series
Product Code	CN-3000 CL971029 CN-6500 BH584790 PCB No.30024 CB628766
Lot(s) Affected / Estimated Qty	Refer to the attachment regarding CN series PCB No.30024 CB628766: 25A1 – 25G3
Distribution Center Affected	<input checked="" type="checkbox"/> SEU, <input checked="" type="checkbox"/> SAI, <input checked="" type="checkbox"/> SCH, <input checked="" type="checkbox"/> SAP, <input checked="" type="checkbox"/> STW, <input checked="" type="checkbox"/> SKR <input type="checkbox"/> Other ()
Initial Source of Information	<input checked="" type="checkbox"/> Quality Complaint (136588, 137297, 137900) <input type="checkbox"/> Other ()

Event or Problem Description:
 Sysmex was reported that sample arm B pipette is damaged because of the reverse rotation of the motor for z-axis. This issue may be caused by design change No.323D206 (PCB No.30024 is changed)

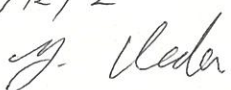
FCA type at S-Corp	<input type="checkbox"/> FSCA <input checked="" type="checkbox"/> Non-FSCA
Risk Estimation	Risk Index: <input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High <input type="checkbox"/> Very High
	Severity: 2 Probability: 1
	Rationale: Severity: 3 Treatment may not be able to start, which may lead to continued shock and pain. Probability: 1 In most cases, the doctor makes decisions even without coagulation test results.

Content of FCA Implementation:

- Please replace the PCB No.30024 by using FCA kits according to ECR W3CI00222.
- Please dispose of the PM parts in the warehouse and stock FCA kits as a replacement.
- FCA kits will be delivered by February 2026.
- This FCA needs monitoring.

Implementation period	March 31, 2027
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2025/12/2
 Original signature is on file
 Yoshiro Ueda
 Vice President of Regulatory Affairs and Quality Assurance Div.

2025/12/2


Attachments:
[Monitoring list, FCA2510 Explanatory document](#)