

Product Notification

June, 2022

CN series unexpected false liquid detection error on the reagent probe

Attention

Operators and Users of Sysmex CN series instrument

Introduction

Sysmex has confirmed that there is a potential risk of unexpected "Operational error of reagent arm B (code: 32102)" errors due to falsely liquid detected at tip of the reagent probe B.

Affected Products

Name of Product	Affected SN Range
CN-3000	A1243 and before
CN-6000	A2021 and before
CN-3500	A1017 and before
CN-6500	A1036 and before

Problem Description

Sysmex found that the liquid level may be erroneously detected with the measurement error during the probe descending to aspirate the reagent if a cleaning liquid adheres to the reagent probe tip. Re-testing is required for measuring samples with the measurement error. There are the following 2 hazardous situations that the cleaning liquid adheres to the reagent probe tip.

- Wash solution remaining at the tip of cleaning nozzle is contacted and adhered to the reagent probe tip.
- Wash solution remaining at the drain line has backflow up and adhered to the reagent probe tip.

Sysmex action to mitigate the risk

Sysmex has changed the design of the concerned cleaning nozzle and drain line.
Our local Field Service Engineer will implement this correction at the concerned instrument.

Actions to be taken by the customer

1. Please distribute this customer letter to all appropriate persons in your organization.
2. For mandatory correction, please co-operate with local service representatives to prevent this potential issue. The FCA would be taken for 1.5 hours.

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

Sincerely yours

Sysmex Corporation



Yoshiro Ueda

Vice President at Sysmex Corporation
Post-marketing Quality Assurance