

Product Notification

April, 2023

CN-COAGWASHER Remained Stability Time Error on CN Software Ver.0.23-00

Attention

Operators and Users of Sysmex CN series instrument (Software Ver.0.23-00)

Introduction

Sysmex has confirmed the inconsistency of CN-COAGWASHER remained stability time after set onboard between the outerbox label and IPU screen of the CN software Ver.0.23-00. The correct stability time after set onboard is 90 days, but the the CN IPU screen displays 60 days wrongly. This error is only affected to the CN software Ver.0.23-00 then no impact to one less than Ver.0.22-00.

Affected Products

Product Code	Product Name	Affected LOT#
AZ700649	CN-COAGWASHER	A2016 to A2070 and A3001 to A3008

Problem Description

This issue is observed if using the CN-COAGWASHER less than lot#A3008 with CN software Ver.0.23-00. The investigation revealed that the barcode label on outer box of the CN-COAGWASHER failed to be applied with the design change when Sysmex improved the CN-COAGWASHER stability time after set onboard from 60 days to 90 days.

System action to mitigate the risk

Sysmex has implemented the change of the concerned barcode label on outer box from lot#A3009.

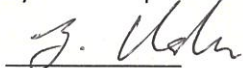
Action to be taken by the customer

1. Please distribute this notification to all appropriate persons in your organization.
2. Please continue to use the onboard CN-COAGWASHER until the "Elapsed time" on CN IPU screen below is 90 days if using the CN-COAGWASHER less than lot#A3008.

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

Quality Assurance

