

Product Notification

CS-1600/1300 EMC (Electromagnetic Compatibility) compliance issue

Attention

Operators and Users of Sysmex CS-1600 and CS-1300 instruments

Introduction

Sysmex Corporation observed this issue on the following products.

Affected Products

Product Code	Name of Product	Affected SN Range
BQ203979	CS-1600	12291 and before
CG705347	CS-1300	12990 and before

Issue

An electromagnetic noise (45.8dB) exceeding that of international specification(40.0dB) was observed around 145MHz when the sample probe detects the liquid surface. The noise source is identified as the oscillation output from the operational amplifier mounted on the sample probe liquid detection board PCB No.20026

Health risk

There may be two health risks associated with this issue. However, the result of Sysmex risk assessment indicates that the health risk is negligible because the measured noise level 0.13V/m is very low compared to the malfunction risk levels of 30V/m¹ and 3V/m² respectively.

¹ Pacemakers and other ICDs malfunctions risk for users.

² Other IVD instrument malfunction risk that could delay testing for patients.

Sysmex action to mitigate the risk

For compliance to EMC international specification, the design of the operations amplifier on PCB No. 20026 is changed. Replacement of the affected PCB No. 20026 shall be performed as a field corrective action.

Action to be taken by the customer

1. Please distribute this customer letter to all appropriate persons in your organization.
2. For the corrective action on the instrument, please co-operate with local service

representative when they contact you. The estimated time taken to complete this corrective action is 0.5 hour.

Reference of EMC

Electrical products when used may generate electromagnetic waves (EMI: emissions) that can cause malfunction of other electrical products or these products may receive electromagnetic waves from other electrical product (EMS: Immunity) that may cause it functional damage.

In order to meet international certification requirements for the commercialization of electrical products, we must undergo emission (EMI) measurements to ensure that there is no adverse effect from the generation of electromagnetic waves, and an immunity (EMS) test to ensure that the product is not affected by electromagnetic waves.

The compliance issue observed on our affected products is due to a deviation from international specifications of emission (EMI) measurement. This deviation could not be confirmed during the product development and testing after mass production because the noise generated was only for a very short time while the sample probe is in contact with the liquid surface.

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

Sincerely,



Janice Ho
Senior Regulatory Affairs Specialist
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