

**Customer Notification
(Urgent Field Safety Notice)**

CN-2017-09
06-Jul-2017

**Important Information on issue pertaining DI-60
on possible risk of mix-up of results**

Dear Distributors & Business Partners;
Cc : Chairman Medical Board and relevant Head of Department

Sysmex Asia Pacific has just received an Urgent Field Safety Notice from Cellavision via S-Corp pertaining to possible risk of mix-up of results in DI-60. Attached within is the Field Safety Notice issued by Cellavision for your reference.

The affected product are listed as follows:-

Product Code	Product name
CC286297	DI-60

For the detailed information on the problem description, please kindly refer to the attached Field Safety Notice issued by Cellavision.

Please take note of the two actions to be taken as stated in the Cellavision Field Safety Notice.

For your information, the updated software will be released in Mid July (Tentatively) through ECR.

Contact Reference

If you have question concerning this information, please contact Sysmex Asia Pacific Customer Care team via AP GCD system. We would be glad to assist you further.

We deeply apologize for any inconvenience caused, and we thank you for your kind patience and continued support.

Yours sincerely,



Shingo Maeda
VP Business Admin and Planning
Sysmex Asia Pacific

Field Safety Notice

DI-60

FSCA-identifier : FSCA-CV-2017-001

Type of action: Device Modification

Date: 2017-06-16

To all DI-60 customers

Details on affected devices:

Product name: DI-60

Part No: CC286297

Description of the problem:

Possible risk of mix-up of results!

Sequence of events:

- DI-60 encounters a barcode problem when processing a slide, Slide 1
- A picture of the barcode of Slide 1 is taken and a temporary Order-ID, i.e. ERRYYYYMMDDhhmmss, is given to Slide 1.
- The image of the barcode will be stored in the database and displayed in the Order data dialog so that the user can identify the slide and reassigning the correct Order-ID to the slide.
- The next slide, Slide 2, from slide maker/stainer SP-10 has a barcode error, and an ERR barcode with a sequential number is assigned to Slide 2.
- When Slide 2 is presented to the DI-60, it reads the sequential barcode starting with ERR.
- The DI-60 then incorrectly attaches the picture taken from Slide 1 to the ERR barcode from Slide 2. This will give the false impression that the DI-60 barcode reader could not read the barcode of Slide 2.

If the user is not careful, there is a risk that the user assigns an incorrect Order-ID (the Order-ID belonging to Slide 1) to Slide 2.

Advise on action to be taken by the user:

1. Refrain from using slides with barcodes starting with ERR according to the CellaVision instructions for use for DI-60 (PM-10832-01).
2. Pay attention to barcodes starting with ERR in Order data dialog in order to reassign the correct Order-ID only to ERR-codes in the format ERRYYYYMMDDhhmmss.

Field Safety Corrective action (FSCA)

1. CellaVision has released new versions of the software, CDMS 5.0.2 and CDMS 6.0.2.
2. Sysmex service technician will book a time for upgrading the installed software to CDMS version 5.0.2 or 6.0.2 on all DI-60.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation and to any organisation where a DI-60 has been installed.

This notice needs also to be passed on to all service technicians for DI-60 within your organisation.

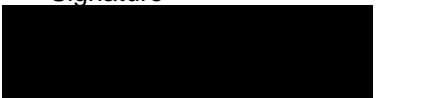
For any technical questions or requests in regards to this FSCA, please get in contact with CellaVision (service@cellavision.se).

Contact reference person:

Ann-Christin Johansson
CellaVison AB
Mobilvägen 12
SE-223 62 Lund
Phone: +46 46 460 1607
Cell: +46 763 499 529
E-mail: ann-christin.johansson@cellavision.se

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature



Ann-Christin Johansson
QA & Regulatory Specialist