
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:

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

Signature



Ann-Christin Johansson
QA & Regulatory Specialist