



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

**CN-2017-17  
06-Dec-2017**

**Important Information on issue pertaining CellaVision DM Software, CellaVision Remote Review Software, DI Remote Review Software, CellaVision DM Systems, DI-60**

Dear Customers, Healthcare Professional;

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 software bug has been discovered in versions 6.0.1 and 6.0.2 of CellaVision DM Software. Attached within is the Field Safety Notice issued by Cellavision for your reference.

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

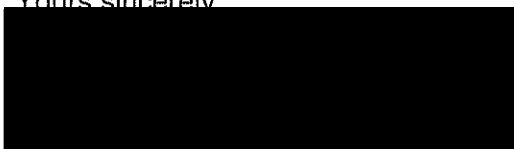
Please take note of the actions to be taken as stated in the Cellavision Field Safety Notice.

**Contact Reference**

If you have question concerning this information, please contact Sysmex Asia Pacific Customer Care team. 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

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## **Field Safety Notice**

**CellaVision DM Software, CellaVision Remote Review Software, DI Remote Review Software, CellaVision DM Systems, DI-60**

**FSCA-identifier : FSCA-CV-2017-002**

**Type of action: Device Modification**

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Date: 7 November 2017

### **Details on affected devices:**

#### **Software**

<b>Product Name</b>	<b>Article number</b>
CellaVision® DM Software, upgrade from version 4.0 or higher to version 6.x.x.	AW736222
CellaVision® DM Software, upgrade from version 6.0.1 or higher to version 6.x.x.	BS914899
DI Remote Review Software, version 6.x.x, Non expiring license, Hardware license key.	AD742566
CellaVision® DM Software for DM96, upgrade from version 3.2.x or below to version 6.0.x	CDMS-966032
CellaVision DM Software for DM96, upgrade from version 4.0.x or higher to version 6.0.x	CDMS-966040
CellaVision DM Software for DM96, upgrade from version 6.0 or higher to version 6.0.x	CDMS-9660UP
CellaVision® DM Software for DM1200, upgrade from version 3.2.x or below to version 6.0.x	CDMS-126032
CellaVision DM Software for DM1200, upgrade from version 4.0.x or higher to version 6.0.x	CDMS-126040
CellaVision DM Software for DM1200, upgrade from version 6.0 or higher to version 6.0.x	CDMS-1260UP
CellaVision DM Software for DM9600, upgrade from version 5.0.x or higher to version 6.0.x	CDMS-976050
CellaVision DM Software for DM9600, upgrade from version 6.0 or higher to version 6.0.x	CDMS-9760UP
CellaVision® Remote Review Software, version 6.0.x, Annual license, Hardware license key	CRRS-006001
CellaVision® Remote Review Software, version 6.0.x, Non expiring license, Hardware license key	CRRS-006099
CellaVision® Remote Review Software, Team Edition, version 6.0.x, Non expiring license.	CRRS-TE6099
CellaVision® Remote Review Software, Group Edition, version 6.0.x, Non expiring license.	CRRS-GR6099
CellaVision® Remote Review Software, Enterprise Edition, version 6.0.x, Non expiring license.	CRRS-EN6099

**Instruments**

DI-60	CC286297
CellaVision DM96	XU-10020-01
CellaVision DM1200	XU-10127-01
CellaVision DM9600	XU-10288-01

**Description of the problem:**

A bug has been discovered in versions 6.0.1 and 6.0.2 of CellaVision DM Software where comments are not sent to LIS.

**How do I know if I am an affected user?**

This problem can only occur if ALL three below conditions are met:

1. the instrument/remote review station is installed with *versions 6.0.1 or 6.0.2* of CellaVision DM Software, CDMS;  
AND
2. a workflow with *multiple slides* per blood sample is used;  
AND
3. WBC, RBC or PLT comments are added to the last slide *after* it has already been signed.

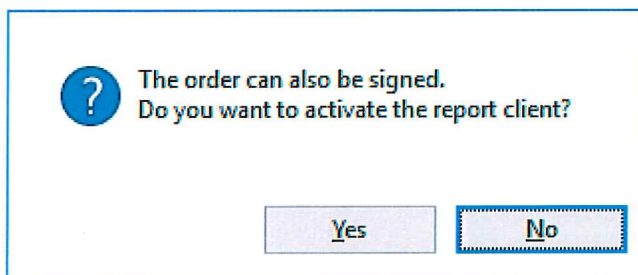
**Advice on action to be taken by the user:**



Users that *do not* have a workflow involving ALL three conditions above, will not have this problem and do not need to take any action.

Users that do have a workflow involving ALL three conditions above shall follow the actions below.

**Immediate Action for Affected Users – Workaround**

1. When the last slide has been signed in a multiple slide order, the user is prompted to activate the report client to sign the order → click **No**.



2. Reopen the Order/Slide, which will activate the *Report View*.
3. Add any comments. 
4. Close the Order/Slide 
5. Reopen the Order/Slide.
6. Verify that the comments are visible in the *Report View*, and sign the order.

**Corrective Action**

CellaVision is releasing a software patch correcting the bug.

CellaVision recommend any affected users to contact their local vendor and book a service appointment for installation of the patch.

**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 CellaVision DM system or DI-60 has been installed.

This notice needs also to be passed on to all service technicians for CellaVision DM systems or 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](mailto: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  
Acting VP Quality