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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.

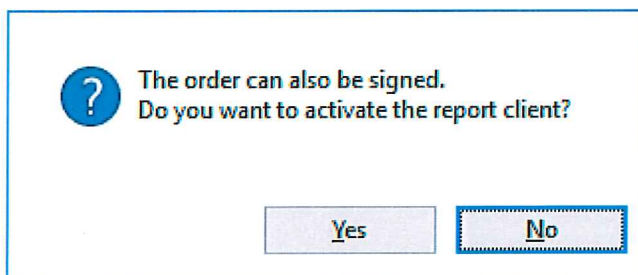
**Advice on action to be taken by the user:**



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