
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

Date: 7 November 2017

Details on affected devices:

Software

Product Name	Article number
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.

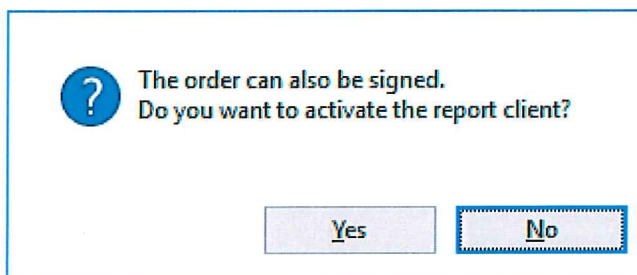
Advice on action to be taken by the user:



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).

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
Acting VP Quality