

Urgent Field Safety Notice

DIRECTVIEW software versions 5.6b and v5.7 (current releases) with DR LLI Auto Stitch option on DRX Evolution Systems w/Premium and Full Featured Wall stands.

Carestream Health FSCA MA-2015-007 Device modification

Date: 3rd August 2015

Attention: Software defect may cause incorrect auto stitching on some Long Length Imaging (LLI) images.

Details on affected devices:

DIRECTVIEW software versions 5.6b and greater and v5.7 (current releases) with DR LLI Auto Stitch option on DRX Evolution Systems w/Premium and Full Featured Wall stands.

Description of the problem:

Carestream has identified a software defect that impacts image alignment when using the automatic stitching option for long length images. If there is no use of external fiducial markers or measurement tools (i.e. radio opaque ruler) when building a composite image and the technologist relies solely on the auto stitching software, there could be a risk of undetected stitching error that would otherwise get noticed and corrected with the use of manual stitching.

Advice to users:

Carestream recommends that the auto stitching feature is turned off and the Manual Stitch Editor is used to create all composite images until the software correction is completed.

Please complete and fax back the attached confirmation form within 5 working days.

Action taken by the manufacturer:

Carestream staff will update the software on your device to correct this issue over the next five months.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions or in the event of any concern, please call your local Service support number.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.



Kevin Wright
Director, International Regulatory Affairs