

Customer / User
First Name Last Name
Company/Position
Street
Place
Country

Important safety information

11/01/2019

Dear Sir or Madam,

Ziehm Imaging GmbH is specialized in the development, production and international marketing of mobile X-ray-based imaging solutions. The safety of patients and operators during the daily use of our products is our primary concern.

We are writing to inform you about a corrective measure which we have initiated for our products.

Concerns:

Mobile X-ray devices / C-arms of Ziehm Imaging GmbH Model:
Ziehm Solo FD, Ziehm Vision RFD, Ziehm Vision RFD 3D

with circuit board U713e combined with firmware version K341
and with manufacturer date November 2018

Issue:

Recently, a new version of the circuit board U713e was released for production of all Ziehm Solo FD, Ziehm Vision RFD and Ziehm Vision RFD 3D devices. This new circuit board with firmware version K341 causes a malfunction during the export of images in combination with the activated feature Autocrop.

With Autocrop activated, a stored image where collimation was applied will contain a software-based, darkened Autocrop overlay covering the collimated parts of the image. When exporting such a collimated image (via USB, CD or PACS), the Autocrop overlay will wrongly cover the entire actual image content instead of the collimated parts. The image can therefore not be used for documentation purposes. This malfunction applies for all kinds of image export formats, including the most commonly used DICOM and TIF formats.

The physical collimation of the radiation beam is not affected and works as intended.

Precautionary measures:

As an immediate measure, the Autocrop feature shall be deactivated and cannot be used until further notice. This can be done in the 'Config' – 'Operation settings' menu by removing the check mark for 'Display autocrop' and confirming with 'Apply' afterwards. Please also refer to chapter 19.2.8 in the operating instructions for Solo FD and RFD Hybrid Edition, chapter 18.2.8 for the RFD and chapter 20.2.8 for the RFD 3D.

If the Autocrop feature is already deactivated, please do not activate this feature.

With Autocrop deactivated consequently, both the images and the collimation will be displayed correctly and in original condition.

If you have any images in your PACS affected by the abovementioned issue, please deactivate the Autocrop feature as described above, and resend the images to the PACS.

Please ensure that all staff authorized to operate or who operate the device are familiar with these possibilities for avoiding non-conforming workflow situations.

Corrective measures on the device:

We are working on an efficient solution to resolve the issue and we will contact you as soon as it is available.

The competent authorities have been informed of this procedure.

If you have any further queries regarding this product information, please contact our Safety Officer, Ralf Vogt – preferably in writing – at:

FSCA@ziehm.com; Tel.: +49 (0) 911 2172 218; Fax: +49 (0)911 2172 39 143

Please confirm receipt of this important information by returning the attached acknowledgment of receipt.

Sincerely

Ralf Vogt
Ziehm Imaging GmbH
Safety Officer

Stefan Fiedler
Ziehm Imaging GmbH
Director QM / RA

Confirmation of receipt of Field Safety Notice

Please send this form to Ziehm Imaging GmbH

by fax: +49 (0)911 2172-390

scanned via email: FSCA@ziehm.com

Recipient information

Contact name	<XXX>
Organization	<XXX>
Email address	<XXX>
Department	<XXX>
Address Line 1	<XXX>
Address Line 2	<XXX>
City	<XXX>
Postcode	<XXX>
Country	<XXX>

Subject Device Information

Mobile C-arms of Ziehm Imaging GmbH

Model: <XXX>

Serial no.: <XXX>

I hereby confirm receipt of the Field Safety Notice published by Ziehm Imaging GmbH on 11. January 2019

I have taken note of the safety information regarding the devices concerned and the recommended precautionary measures stated in the Field Safety Notice.

Name (block letters)

Date

Position

Signature

Contact information (other than the above stated address)

Contact name	
Institution	
Email address	
Organization unit	
Address	
Address	
City	
Postcode	
Country	