

Important Safety Notice

April 15, 2016

Dear Sir or Madam,

The Ziehm Imaging GmbH specializes in the development, production and global marketing of mobile X-ray based imaging solutions. The safety of patients and operators during daily use of our devices is our top priority.

The purpose of this notice is to inform you about a corrective action which we have initiated for our products.

Concerns:	Mobile X-ray devices / C-arms of the company Ziehm Imaging GmbH of the models: Ziehm Vision; Ziehm Vision FD; Ziehm Vision R; Ziehm Vision RFD; Ziehm Vision RFD 3D; Ziehm Solo
Issue:	From on our information, the device installed at your site does not fully meet the requirements of DIN EN 60601-2-54 with respect to specified workflows regarding <ul style="list-style-type: none">• acoustic warning signals after accumulated loading of the X-ray tube for more than (5) minutes and• the separation of setting or resetting mechanisms and radiation switches
Relevant standards:	Section 203.6.2.1 of DIN EN 60601-2-54 (and/or IEC 60601-2-54) stipulate(s) that X-ray tube loading may be accumulated for a maximum duration of 5 min without a warning signal sounding, (paragraph 1), and that the setting and resetting mechanisms be separated from the radiation switches (paragraph 3).

Possible hazardous situation:

- A** Under ongoing accumulated X-ray tube loading (fluoroscopy) for the first patient, the warning message „*Exposure is terminated in 35 seconds. Press OK to stop the alarm.*“ is displayed after a radiation time of 4:55 min, accompanied by an acoustic warning signal after a further 5 seconds. The warning message contains a countdown running down from 35 s to 0 s. After the warning message has been acknowledged by pressing the OK button incorporated in the message box, the warning sound stops or does not occur, and the radioscopy can be continued without any restrictions. This process repeats itself every 4:55 min. If –without a prior shut-down of the device- another patient is created or retrieved from the archive and such patient undergoes a continuous radioscopy (fluoroscopy), the timer function is disrupted. The warning messages regarding radiation time are no longer displayed and the acoustic warning signal no longer occurs in the required 4:55 min time interval.
- B** In the Ziehm Vision RFD 3D X-ray systems, the warning message „*Scan exceeds radiation time of 5 minutes. Reset time?*“ can be acknowledged by pressing the radiation switch.

Precautionary measures:

You can continue to use your device/s until the corrective action has been implemented in the device on site.

If one of the situations outlined above should occur, you can avoid non-conforming workflows by taking the following measures:

- A** If you want to examine several patients in a row and submit each patient to a radioscopy exam, re-start the system prior to each individual patient. This means that after each completed examination the device must be completely shut down and the new patient created and the examination commenced only after a system re-start.
- B** Always use the „OK“ button incorporated in the message box for switching off the warning message.

Please ensure that all the staff authorized to operate / operating the device are familiar with these ways to avoid non-conforming workflow situations.

Corrective actions to the device:

In order restore conformity to standards across all workflows, a software update, of which we will inform you in a separate notice, will be provided.

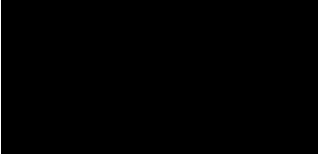
The competent authorities have been informed about this action.

In case you have any further queries regarding this field safety notice, please contact – preferably in writing – our Safety Officer Ralf Vogt at:

FSCA@ziehm-eu.com; Phone: +49 (0) 911.2172.218; Fax: +49 (0)911.2172.39.143

We kindly ask you to confirm receipt of this important information by returning the attached acknowledgment of receipt.

Sincerely yours,



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