

Urgent Safety Notice



February 2011

Unintentional radiation exposure when using double foot switch KF21
Ziehm Material number 20125

Affected Ziehm Imaging C-arm devices

Models: Ziehm 8000, Ziehm Compact, Ziehm Solo, Ziehm Vision, Ziehm Vision FD, Ziehm Vision FD Vario 3D, Ziehm Vision RFD, Ziehm Vision R, Ziehm Vision Vario 3D, Ziehm Vista plus

Problem description

Ziehm Imaging has been notified by its supplier that some type KF21 double foot switches may fail to switch off radiation after starting the exposure.

In Ziehm C arm devices, a yellow radiation warning light indicates that exposure has been started. In addition to this warning indicator for the device operator, a safety time interval forces radiation to be switched off. This helps to ensure maximum operator and patient safety.

Action taken

Ziehm Imaging has decided to initiate a voluntary remedial action and will exchange the double foot switch.

We ask for your assistance in carrying out the exchange:

Please identify the affected device on the serial number in the enclosed delivery note. Please replace the foot switch with the enclosed foot switch. The procedure is described in detail in the instructions included with this notice.

Remove the connector from the old foot switch and dispose of the foot switch in accordance with regulations. Of course, you may also return it to us.

Please complete the enclosed confirmation form as proof of disposal and return it to us by fax at +49 (0) 911.2172.589.

We regret any inconvenience this may cause and thank you for your cooperation.

If you have any further questions concerning this matter, please contact our technical hotline at +49 (0) 911.2172.500.

Yours sincerely,

Gerhard Niederhoff
Director Service