

Ziehm Imaging GmbH | Donaustrasse 31 | 90451 Nuremberg
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Urgent Field Safety Notice

29.04.2013

Dear Customer,

Ziehm Imaging has specialized on the development, manufacturing and global distribution of mobile X-ray devices. The safety of our devices for patients and operators in everyday use of our devices is our primary concern.

This field safety notice is issued to inform about corrective actions we have initiated for our devices

Subject: Mobile X-ray C-arms manufactured by Ziehm Imaging GmbH
Model: **XXXXXX** Serial-No: **XXXX**

Issue: According to our manufacturing documentation, the referenced device installed at your facility was not equipped with an emergency stopping device.

To fully comply with applicable standards the referenced device must be retrofitted with an emergency stopping device.

Normative Background: The international Standard IEC 60601-1 and applicable collateral Standards request, that all energy-powered movements, that may result in patient injuries, have to be equipped with an emergency stopping device

The purpose of the emergency stopping device is to immediately terminate or eliminate a hazardous situation.

Potential Hazardous Situation:

When moving the C-arm up and down, the energy-powered vertical movement might lead to a potential hazardous situation (device collides with the patient or operator)

Precautions:

All affected devices can be further operated until the correction has been carried out on-site.

In case of an hazardous situation the user can resolve the hazardous situation either by:

- operating the power-of the switch either on the front panel or on the monitor cart
- removing the power cable
- activate the push-buttons for reverse vertical movement and keeping the push-button pressed until no person is any longer in the risk zone or the device stops operating.

Please make all staff members working with the affected device alert, and familiarize them with all possibilities to resolve the hazardous situation

Corrective Actions:

Your device will be retrofitted with an emergency stopping device, to restore compliance with applicable standards.

We are going to send you necessary components and information which are suitable to implement the measure efficiently in a timely manner.

Your Competent Authority has been informed about our action.

In case you have any concerns regarding this field safety notice, please apply to our Safety Officer Ralf Vogt:

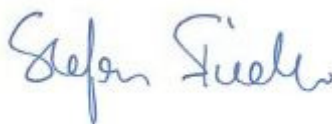
FSCA@ziehm-eu.com; Fon: +49 (0) 911.2172. 218; Fax: +49 (0)911.2172.39.143

Please acknowledge the receipt of this field safety notice by returning the attached *Field Safety Notice Acknowledgement Form*.

Kind regards



Ralf Vogt
Ziehm Imaging GmbH
Safety Officer



Stefan Fiedler
Ziehm Imaging GmbH
Director Quality Management/Regulatory Affairs

* XXXXX *

Field Safety Notice Acknowledgement Form

Please return this form to Ziehm Imaging GmbH either
 via Fax: +49.(0)911.2172-390
 scanned via E-Mail: SiBa@ziehm-eu.com

Recipient Information

Contact Name
Facility
E-mail Address
Centre/Department
Adress Line 1
Adress Line 2
City
Zip/Postal Code
Country

Subject Device Information

Mobile C-Arms Ziehm Imaging GmbH

Model:

Serial-No.:

I hereby confirm the acknowledgement of the Field Safety Notice, issued by Ziehm Imaging GmbH on the 29th of April 2013

- I'm the user of the a.m. device. I have read the remarks of the Field Safety Notice concerning the safety of the subject devices as well as proposed precautions.
- I'm not the user of the a.m. device. I brought the remarks of the Field Safety Notice concerning the safety of the subject devices as well as proposed precautions to the attention of the user of the device.

Name (blockletters)

Date

Position

Signature

Contact Information (if different as above)

Contact Name	
Facility	
E-mail Address	
Centre/Department	
Adress Line 1	
Adress Line 2	
City	
Zip/Postal Code	
Country	

