



Customer address:

Copy :

Eng, Hui-Min <Hui-Min.Eng@ziehm.com>

Chairman Medical Board and relevant Head of Departments

Important safety information

Field Safety Notice

February 1, 2018

<Dear Customer>,

Today we would like to provide you with Product Information regarding Field Safety Notice (FSN) #070-0063 OrthoScan Inc. has initiated. This FSN is intended to notify you that a mandatory Field Safety Corrective Action (FSCA) for OrthoScan Inc. mini C-arms in the field must be performed.

The purpose of this notice is to inform you about the corrective action we have initiated for our products. We also would like to inform you about precautionary measures (section 5) on avoiding non-conforming workflows and request that you communicate to all authorized personnel operating the affected OrthoScan Inc. mini C-arms of our recommended measures to avoid any hazardous situation.

If you have any further questions about this product information, please feel free to contact via email: Eng, Hui-Min <Hui-Min.Eng@ziehm.com>

Best regards,

OrthoScan Inc.



General Information

It is the intent of this FSN to inform you of actions that must be taken.

This Field Safety Corrective Action (FSCA) is performed to comply with international standards relevant for market approvals. The FSCA is not a result of any patient injury, hazardous malfunction or any other safety related issue of OrthoScan Inc. mini C-arms.

This condition has resulted in a self-initiated voluntary recall of products to correct this issue and comply with regulatory requirements.

Ziehm Imaging Singapore, acting on behalf of OrthoScan, has reported this FSCA and the according implementation program to the appropriate authorities.

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1. Affected Systems

The following systems are affected by the FSCA:

- OrthoScan MDI 1000-0005 Windows XP OS
- OrthoScan HD FD 1000-0004 Windows XP OS

2. Affected Operating Systems and Serial Numbers

The above listed systems are affected by the FSCA and operate with the Windows XP Operating System in conjunction with the MX200 and MX200_OSC_MDI Operating Systems. All software versions are affected. The serial numbers of all affected devices delivered to you and your domain are listed in Appendix A of this FSN.

3. Relevant Issue

OrthoScan has determined there is a potential Hazard where the user should not select the Digital Zoom feature when the Fluoroscopic X-ray beam is active. If selected when the X-ray beam is active, the Digital Zoom Feature will prevent the system from displaying the full active x-ray field on the monitor whereby a portion of the active image receptor field of view not displayed on the monitor is greater than 3% of SID in violation of DIN EN 60601-2-54 (IEC 60601-2-54)

The requirements for the C-arms are: along each of the two major axes of the IMAGE RECEPTION AREA, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the IMAGE RECEPTION AREA shall not exceed 3% of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTOR PLANE is NORMAL to the X-RAY BEAM AXES.

To achieve compliance with IEC/DIN/ EN 60601-2-54 beyond all workflows, a software update to OrthoScan Inc. MX200 and MX200_OSC_MDI Software is required.

4. Possible Hazardous Situations

If the user were to activate the Digital Zoom feature while in live acquisition the un-viewable portion of the active x-ray field displayed on the monitor would exceed 3% of SID.

Regarding IEC/DIN/EN 60601-2-54 the exposed x-ray field beyond the view displayed on the monitor may not exceed 3% of the SID.

Note: The affected devices running on the Windows XP, MX200 and MX200_OSC_MDI operating system do not control the x-ray exposure or intensity, so there is no hazard to the patient or user related to x-ray dosage control.



5. Precautionary Measures

The manufacturer OrthoScan Inc. advises customers they may continue to operate the affected device with **caution** until the correction has been carried out on-site. During this time the user should adhere to the following information.

User should avoid non-conforming workflows by taking the following measures:

- When visualizing the image with magnification, user should only select Digital Zoom as part of a post image capture operation whereby the Fluoroscopic X-ray beam is not active.
- Please alert all staff members working with the device that they should never select the Digital Zoom while the Fluoroscopic x-ray beam is active. This will avoid a potentially hazardous situation.
- Familiarize the Staff with the proper workflows to avoid the potential hazard of selecting Digital Zoom when the Fluoroscopic x-ray beam is active.

6. Corrective Actions regarding the Device

To achieve compliance with standards beyond all workflows a software update is mandatory. Ziehm Imaging Singapore, acting on behalf of OrthoScan, shall complete the software update.

7. Course of Action for implementing the Corrective Measure

This condition has resulted in a self-initiated voluntary recall of products to correct this issue and comply with regulatory requirements. To implement this recall in an efficient and user-friendly manner, the Software Developer has delivered a single USB dongle known as the "Digital Zoom Software USB Up-loader" that will automate all system models and configurations. The Digital Zoom Software Up-loader is composed of a modified DLL file that will automate system identification and deployment of a software update to correct this condition.

When the user has confirmed access to the affected system, arrangements to update the system using the USB updater will be scheduled.



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8. Field Safety Notification Acknowledgement

Upon receiving this notice, complete the "Field Safety Notice Acknowledgement Form" provided with this FSN and return it as soon as possible via fax to [+65 6396 3009](tel:+6563963009) or via email sending scanned form to [Eng, Hui-Min <Hui-Min.Eng@ziehm.com>](mailto:Hui-Min.Eng@ziehm.com)

Best regards,
Hui Min

Hui Min Eng (Ms)
Marketing

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E-mail: hui-min.eng@ziehm.com

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



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Confirmation of receipt of Field Safety Notice

Please send this form to OrthoScan Inc.

by fax:

or scanned via email:

Recipient information

Contact name

Organization

Email address

Department

Address Line 1

Address Line 2

<XXX>

City

Postcode

Country

Subject Device Information

Mobile C-arms of OrthoScan

Model:

Serial no.:

I hereby confirm receipt of the Field Safety Notice published by OrthoScan Inc.
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