FSN Ref: FSN-C-25-07
FSCA Ref: C-25-07

Date: 18 JUL 2025

Urgent Field Safety Notice (FSN)
XtremeCT

For Attention of: Healthcare professionals utilizing XtremeCT

Contact details of manufacturer
SCANCO Medical AG Fabrikweg 2 8306 Brüttisellen Switzerland www.scanco.ch Tel: +41-(0)44-805 9800 Fax: +41-(0)44-805 9801 Email: info@scanco.ch

1. Information on Affected Devices

1. 1. Device Type

CT-system (HR-pQCT)

1. 2. Commercial name

XtremeCT

1. 3. Primary clinical purpose of device

This computed tomography system is designed to measure the bone density and quantify the three-dimensional micro architecture of the bone at the human extremities. The equipment will be used in the diagnosis and treatment monitoring of osteoporosis.

1. 4. Affected serial or lot number range

ScannerID	Serial Nr		ScannerID	Serial Nr
SC3300	04043001		SC3326	07110900

SC3303	04071501		SC3329	08030700	
SC3304	04082600		SC3330	08111100	
SC3311	05080500		SC3331	09020300	
SC3312	05080501		SC3332	09030400	
SC3313	05112300		SC3333	09030401	
SC3316	06041900		SC3334	09060400	
SC3317	06050800		SC3336	10070600	
SC3318	06051200		SC3338	10090601	
SC3319	06051201		SC3340	10121300	
SC3321	07041100		SC3341	10122100	
SC3322	06121100		SC3343	12100800	
SC3323	07012300		SC3345	13091000	
SC3324	07012301		SC3346	13092701	
SC3325	07012302				

2. Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the product problem

A vertically mounted metal plate inside the bore may fall down due to component degeneration.

2. 2. Hazard giving rise to the FSCA

Patient harm is possible: The plate may fall down when a patient extremity is in the bore, potentially injuring the patient. No harm to users or third parties is possible.
If the actions outlined in the FSN are followed, there is no residual risk.

2. 3. Probability of problem arising

There is a reasonable probability that the problem will arise.

2. 4. Predicted risk to patient

Potential harm: If the part falls during a patient measurement, injury to the arm or leg is possible. According to intended use, no other body parts are in the scanner. The scanner is used only for extremities. Possible injury: laceration, skin abrasion, broken bone, haematoma

2. 5. Background on Issue

SCANCO Medical AG was notified about a XtremeCT system malfunction. The metal plate had fallen down, but no harm to patient, user or third party occurred.

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User

- ☒ Identify Device
- ☒ Quarantine Device
- ☐ Return Device
- ☐ Destroy Device
- ☐ On-site device modification / inspection
- ☐ Follow patient management recommendation
- ☒ Take note of amendment / reinforcement of Instructions For Use (IFU)
- ☐ Other
- ☐ None

The device must not be used until the corrective action has been performed by the manufacturer.

3.	2. By when should the action from the customer be completed?	Immediately (identify device and quarantine device)
3.	3. Is customer Reply Required? (Please, use form attached)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None The manufacturer SCANCO Medical AG will improve the mounting system of the metal plate. The IFU has been amended to include an updated maintenance plan. After 5 years the mounting system of the metal plate must be serviced.	
3.	5. By when should the action from the manufacturer be completed?	SCANCO Medical AG will contact you immediately after receipt of the customer reply form to determine a service appointment.

4. General Information		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN?	Not planned yet
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	4. List of attachments/appendices:	Form for customer reply
4.	5. Name/Signature	[redacted] Head of QM/RA SCANCO Medical AG [redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

SCANCO MEDICAL

Field Safety Notice (FSN)
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-C-25-07
FSN Date	18 JUL 2025
Product/ Device name	XtremeCT
Serial Number	

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	I performed all actions requested by the FSN.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
☐	I do not have any affected devices.

Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	info@scanco.ch
Postal Address	SCANCO Medical AG Fabrikweg 2 8306 Brüttisellen Switzerland www.scanco.ch
Customer Helpline	+41 44-805 9800
Fax	+41 44-805 9801
Deadline for returning the customer reply form	15 AUG 2025

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.