



Carl Zeiss Meditec AG 81379 Munich

To whom it may concern

Division/Dept.: MED- QM
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Date: 2025-01-31

FIELD CORRECTIVE ACTION

FCA-MUC-2024-001 FORUM 4.4 DICOM Metadata not updated

Dear Colleagues and Sales Partners,

As part of Carl Zeiss Munich continuous focus on reliability and safety, we continuously monitor the performance of our products. This letter is to inform you about a Field Corrective Action (FCA) for FORUM 4.4.0 with the aim to correct inconsistent Meta Data information.

Problem Description.

The issue occurs when patient information is edited, patients are merged, or documents are reassigned using FORUM versions 4.2.3, 4.2.4, 4.2.5, and 4.2.6, AND exported, retrieved, or forwarded in DICOM format using FORUM 4.4.0. This could result in incorrect patient information in external DICOM systems, such as DICOM modalities. Due to differences in demographic data in the retrieved DICOM files, the DICOM modality software may crash or display incorrect information.

Address of Record:
Goeschwitzer Strasse 51 - 52
07745 Jena, Germany

Address for Delivery:
Carl Zeiss Meditec AG
Kistlerhofstrasse 75
81379 München

Banks:
Deutsche Bank Jena
Account: 624536900 (BLZ 820 700 00)
IBAN: DE90 8207 0000 0624 5369 00
BIC/ SWIFT: DEUT DE 8EXXX

Commerzbank Jena
Account: 258072800 (BLZ 820 400 00)
IBAN: DE31 8204 0000 0258 0728 00
BIC/ SWIFT: COBADEFFXXX

Commercial Register:
Local Court Jena HRB 205623

VAT-ID No.: DE 811 922 737
WEEE-Reg.-No.: DE55298748

Chairman of the Supervisory Board:
Dr. Karl Lamprecht

Board of Management:
Dr. Markus Weber (CEO)
Justus Felix Wehmer

Hazard involved:

There is no potential hazard due to the incorrect Meta Data information in FORUM, however there are potential issues with devices which retrieve data from FORUM.

Under the mentioned conditions the workplaces will keep retrieving the patient's initial, unmodified data, resulting in:

- If a DICOM file used to generate a report has been reassigned from Patient A to Patient B, any report generated thereafter will include Patient B's information but will still be stored in Patient A's original record. Also, the analysis data will use the Patient's A demographics.

- If the original and updated birthdates are in different age groups within the reference database, Retina and Glaucoma Workplaces will compare them incorrectly. The user is not able to identify that the wrong age range is used for comparison with the reference data

Affected product:

FORUM customers who upgraded from 4.2.3, 4.2.4, 4.2.5 or 4.2.6 to 4.4.0 **AND** edited patient information, merged patients, or reassigned documents before the FORUM upgrade to 4.4.0.

Customers who have a fresh installation of 4.4.0 without any previous upgrades are not affected.

Actions to be taken:

In an effort to conduct this FCA, it is required that you perform the following steps:

- Identify the affected customers (who upgraded from FORUM 4.2.x to FORUM 4.4.0) in your territory.
- Immediately send out the FIELD NOTICE along with the Acknowledgement and Receipt form to the affected customers. If needed, please translate the Field notice and Acknowledgement Form into local language.
- Run the Meta Data Fix Tool at all Identified Customer sites where an upgrade to 4.4.0 from 4.2.x has occurred.

For more technical details, please refer to the service bulletins FORUM_SB_025_V01_2024-06-24 and FORUM_SB_025_V02_2024-08-07

The FCA is considered completed when all customers have been contacted and all customer sites with upgrades to 4.4.0 from 4.2.x have applied the Meta Data Fix tool 1.0 or 1.0.1.

Please send copies of completed service report to:

SafetyOfficerMuc.med.de@zeiss.com

We expect the completion latest by 30th of June 2025

We thank you very much for your careful attention, your consequent feedback, and your continuous support. We apologize for any inconvenience this situation might cause. If you have any questions, please contact us

Best regards

Carl Zeiss Meditec AG

ppa. Rebecca Berghorn

Head of Digital Health Center of Excellence

i.V. Babette Blessing

Head of Quality – Site Munich

Annex

Service Report



Report after installation of software

Confirmation of Corrective Action MUC-2024-001

(To be filled in completely by service engineer)

Meta data fix tool connected to FORUM Archive & Viewer 4.4:

Customer information or system's site of installation:

Name:	
Address:	

Details of service assignment:

Service Engineer (name & company)	
Tool execution successful?	<input type="checkbox"/> YES <input type="checkbox"/> FAILED (→ comments)
Comments:	

I hereby confirm that I have executed the update:

(Date, service engineer's signature)

Please return completed report by EMAIL to:

SafetyOfficerMuc.med.de@zeiss.com

Quality Management
Carl Zeiss Meditec AG Kistlerhofstr. 75
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