

SIEMENS

Healthcare

Safety Advisory Notice

To all users of the SIEMENS

SOMATOM Emotion 6 Slice Configuration
SOMATOM Emotion 16 Slice Configuration

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Re: SOMATOM Emotion 6 / 16 Slice Configuration with fatigued bolts holding the balance weights of the data measurement system (DMS)

Dear customer,

This letter is to inform you of a potential malfunction and hence potential hazard to patients and personnel when using the **SOMATOM Emotion 6 / 16 Slice Configuration**.

When does this malfunction occur and what are the potential risks?

We recently detected that the bolts (Fig. 1) used to fix the balance weight of the DMS may show signs of metal fatigue. Accordingly the function of these bolts may potentially degrade over time and impact stability.

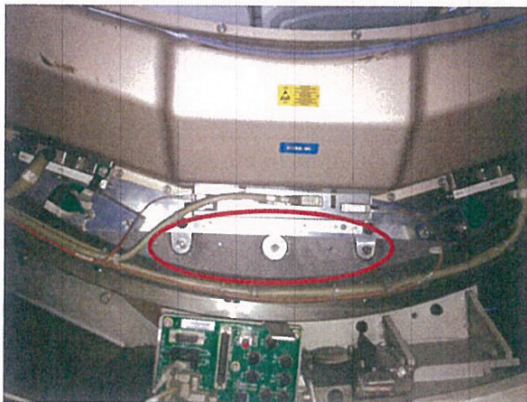


Fig. 1: Bolts used to fix the DMS balance weight

The rupture of a single bolt is not posing a hazard by itself but it cannot be fully ruled out that all the bolts break over time causing the DMS balance weight to drop into the gantry. As a consequence ongoing scans will be aborted immediately. Under unfavorable circumstances mechanical damage of the gantry cover and of the Plexiglas protection ring inside the gantry opening may occur. This situation potentially exposes the patient or operator to the risk of getting into contact with rotating parts.

How can the operator help to this issue ?

In view of the involved hardware components there is no direct workaround for the operator.

How will the issue finally be resolved ?

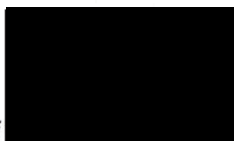
We have carefully analyzed this issue and developed a solution improving the mechanical stability of the assembly. As instructed by the Update Information UI CT007/15/P our service engineers will start in May - 2015 to replace all the bolts holding the DMS balance weight by a new model. The aging properties of the new bolts are far superior and material fatigue resistance is drastically increased.

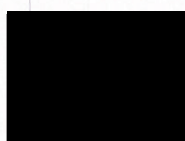
We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

The relevant National Competent Authority has been informed of this notice.

Sincerely Yours


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