

Siemens Healthcare GmbH, HC DI CT QT, Siemensstr. 1, 91301 Forchheim

Safety Advisory Notice

To users of the SIEMENS

SOMATOM Definition AS,
SOMATOM Definition Flash

Name
Department

Dr. Markus Nagel
HC DI CT QT

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Safety Advisory Notice CT031/16/S

Re: SOMATOM Definition AS manufactured from May 2008 until December 2013 and SOMATOM Definition Flash manufactured from September 2009 until July 2012

Dear customer,

We would like to inform you about a hardware issue of your SOMATOM CT and the related corrective action.

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

We became aware, that in rare cases the small light marker window (see Fig. 1a and 1b) used for the positioning laser and integrated in the front cover of your CT could loosen and potentially drop out. In this case there is a risk that a person touches rotating or electrical parts of the gantry when reaching through the window opening. There is a risk for serious injury e.g. by electrical shock or physical harm to fingers.

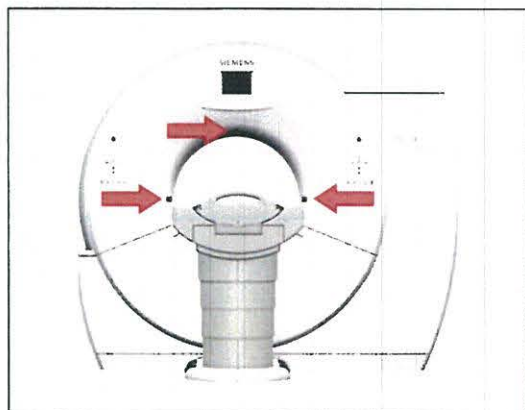


Fig. 1a: SOMATOM Definition Flash

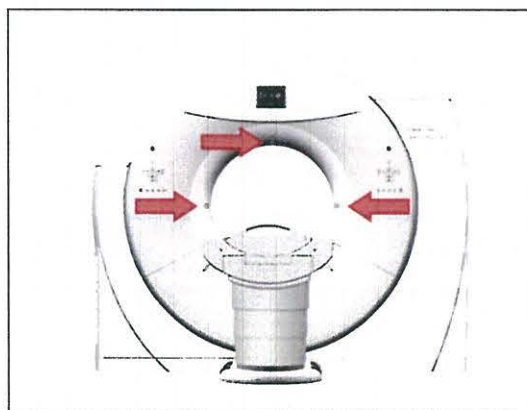


Fig. 1b: SOMATOM Definition AS

How can the operator help to avoid the potential risk of this issue?

As operator you should not use the CT system in case a light marker window is missing or loose. Please inform immediately the Siemens Service for correction.

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Thomas Rathmann, Michael Reitermann

Siemensstr. 1
91301 Forchheim
Germany

Tel.: +49 (9191) 180
siemens.com/healthcare

Chairman of the Supervisory Board: Siegfried Russwurm
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

How will the issue finally be resolved?

Our experts will develop a solution for the correction of the problem as quickly as possible. As soon as we released the correction, we will inform you about the start of the measure and we will inform you when this correction has been successfully implemented.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the medical device's instructions for use. Your personnel should maintain awareness until a solution is implemented.

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

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

— Sincerely Yours,



Head of CT
Computed Tomography
Siemens Healthcare GmbH
Forchheim
Germany



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Head of CT QT
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SOMATOM Definition Flash

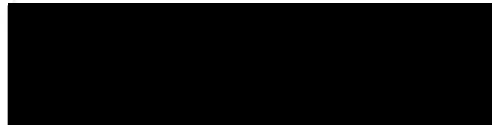
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Safety Advisory Notice CT030/16/S



Re: SOMATOM Definition AS and SOMATOM Definition Flash with previous service activity on light marker window

Dear Customer,

We would like to inform you about a hardware issue of your SOMATOM CT and the related corrective action.

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

We have been informed that the small light marker window (see Fig. 1a and 1b) used for the positioning laser and integrated in the front cover of your CT had loosened in the past. The problem has subsequently been fixed by your local service specialist. We now became aware that the repaired light marker window could loosen again and potentially drop out. In this case there is a risk that a person touches rotating or electrical parts of the gantry when reaching through the window opening. There is a risk for serious injury e.g. by electrical shock or physical harm to fingers.

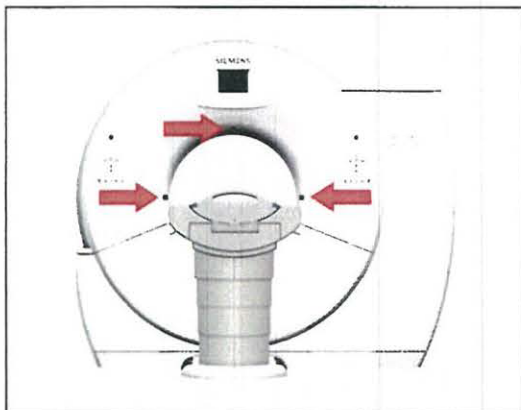


Fig. 1a: SOMATOM Definition Flash

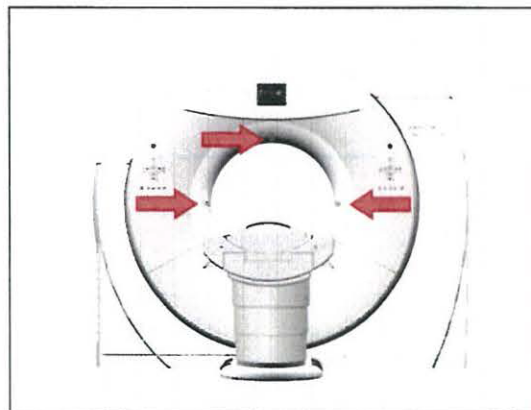


Fig. 1b: SOMATOM Definition AS

How can the operator help to avoid the potential risk of this issue?

As operator you should not use the CT system in case a light marker window is missing or loose. Please inform immediately the Siemens Service for correction.

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Management: Bernhard Montag, Chairman;
Thomas Rathmann, Michael Reitermann

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How will the issue finally be resolved?

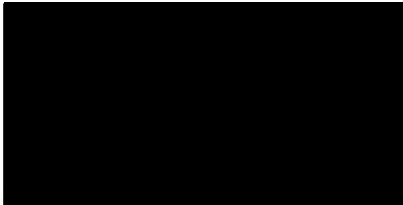
Our experts will develop a solution for the correction of the problem as quickly as possible. As soon as we released the correction, we will inform you about the start of the measure and we will inform you when this correction has been successfully implemented.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the medical device's instructions for use. Your personnel should maintain awareness until a solution is implemented.

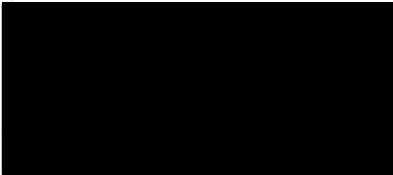
If you have sold this medical device and it is no longer in your possession, we kindly ask you to forward this safety advisory notice to the new owner of this device. Please inform us about the new owner of the device.

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