

Customer Safety Advisory Notice

CAN 009-2016

To: Director of the Radiology Department
Director of the Nuclear Medicine / PET Imaging Department
Risk Management Officer
Users of Siemens Biograph mCT and Siemens Biograph mCT Flow

Re: Biograph mCT and Biograph mCT Flow Light Marker Window

Dear Valued Siemens Customer,

We have become aware, from our supplier, of a possible hardware issue involving the light marker window on your Biograph mCT or Biograph mCT Flow system. We have not had any reports of complaints on the Biograph mCT or Biograph mCT Flow regarding this issue.

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

The light marker windows (see Figure 1) used for the positioning laser and integrated into the front cover of your Biograph mCT or Biograph mCT Flow system may loosen and potentially drop out. In this case there is a risk that a person could touch the electrical or rotating parts of the gantry in the unlikely event that they reach through the window opening. This could result in a serious injury such as, electrical shock or physical harm.

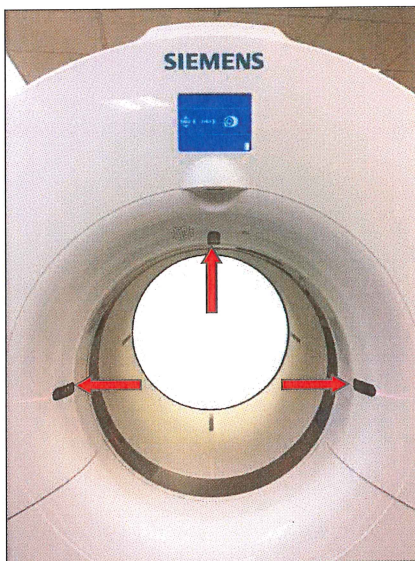


Figure 1

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

In the event that the light marker window is missing or loose, you should not use the Biograph mCT or Biograph mCT Flow and you should immediately contact your local Siemens Customer Service Engineer for correction of the problem.

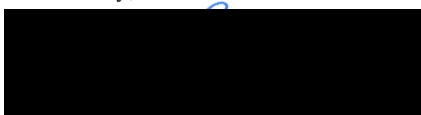
Please ensure that this customer advisory notice is placed in your Biograph Operator's Manual and disseminated to all operators of the Biograph mCT and Biograph mCT Flow systems. If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment, and please inform Siemens about the change in ownership.

Adverse events or quality problems experienced with the use of this product should be reported to Siemens through the contact information provided below and may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

If you have any questions regarding this advisory notice, please contact your local Siemens representative at the contact numbers provided below.

- America: 1-800-888-7436
- Europe, Middle East, and Africa: +49 9131 940 4000
- Asia and Australia: +86 (21) 3811 2121

Sincerely,



Matt Shah
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CAN009-2016