

Customer Safety Advisory Notice
CAN 011-2017

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: Update - Biograph mCT and Biograph mCT Flow Light Marker Window

Dear Valued Siemens Customer,

Last year we informed you about a potential problem with the light marker windows on your Biograph mCT or Biograph mCT Flow system via Safety Advisory Notice MI516/16/S, CAN 009-2016. The purpose of this letter is to you inform you that we will be releasing a field action update, MI503/17/S to address this problem.

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

We informed you that 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.

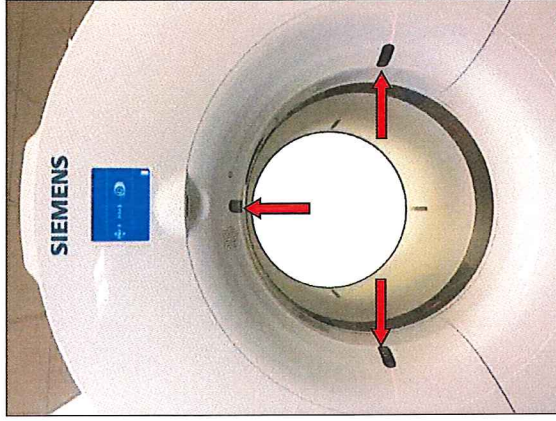


Figure 1

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

In the event that the light marker window is missing or lose, 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.

What has been done by the manufacturer to address this issue?

Through the upcoming field action update, MI513/17/S we will remove and replace the mounting hardware of the light marker windows on your system(s). The glued windows will be replaced with new light marker windows that contain a clip design solution that is more reliable and cannot drop out, unless excessive external force is applied.

You can expect to be contacted to schedule this service in January 2018.

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
Vice President, RA/QA & EHS
Molecular Imaging
CAN011-2017