

April 23, 2014

Molecular Imaging



Customer Safety Advisory Notice (CAN 001-2014)

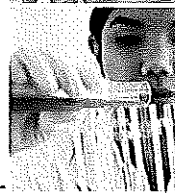
**To: Director of the Radiology Department
Director of the Nuclear Medicine Department
Risk Management Officer
Users of e.cam and Symbia E camera systems**



Re: Rear Casters of the Collimator Cart

Dear Valued Siemens Customer,

You are receiving this letter because you have been identified as owning an e.cam or Symbia E system that may be affected by a hardware problem with the collimator cart. If present, this condition could lead to a safety issue.



This letter serves as notification of an upcoming field correction. The field correction is required because we have received reports indicating the collimator cart rear casters may become loose. We have not received any reports of injury as a result of this problem. Your service engineer will inspect the cart's caster clamp and make repairs as necessary. While on site, the service engineer will also install a secondary retaining device. This new device will retain the casters in the event the clamps loosen in the future.



When does this problem occur and what is the potential risk?

This problem occurs when two conditions are present: 1. The caster has insufficient clamping force and 2. The affected caster passes over a low spot in the floor. If both conditions exist, it is possible the caster will dislodge from the bottom of the cart, allowing the cart to tip backwards toward the operator.

Since a collimator change is performed during calibration, system set up, or routine servicing of the equipment, there is no possibility of harm to the patient. However, there is potential for injury to the operator performing the collimator change.

What should you do until the repair is performed?

Based on our investigation, you can continue to use your system while waiting for the field correction to be scheduled and performed. **However, if you suspect a caster is loose, as indicated by shaking while the cart is in motion, please discontinue use of the collimator cart and notify your local Service representative.**

Otherwise, your local service engineer will contact you in approximately the next three months to schedule a retention bracket installation. The process should take approximately 30 minutes.

Please ensure that this safety advisory is placed in the System's User Manual. As always, Siemens recommends you observe the patient during studies. If you have sold this equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this equipment. Please inform us about the new owner of the equipment.

If you have any questions regarding this important safety notice, please contact your local Service 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,

A handwritten signature in black ink, appearing to read "Matt Shah". The signature is fluid and cursive, with the first name "Matt" and last name "Shah" clearly distinguishable.

Matt Shah
Vice President, RA/QA & EHS
Molecular Imaging
CAN001-2014