

Customer Safety Advisory Notice CAN001-2015

**To: Director of the Radiology Department
Director of the Nuclear Medicine Department
Risk Management Officer
Users of e.cam systems installed prior to December 31st, 2004**

Re: Safety Update for e.cam regarding unintended mechanical motion

Dear Valued Siemens Customer,

The purpose of this letter is to inform you of an upcoming safety update for your e.cam system. We have received a singular report of unintended detector motion. The root cause of this motion was determined to be the simultaneous failure of two components, the radial brake circuit and touch pad. This unique combination of failures caused the axis brake to be ineffective, which ultimately led to the detector motion.

Because this unintended motion requires a simultaneous failure, it is believed that this condition is extremely rare. Siemens has designed and will install an improved brake control circuit which will correct this condition. There have been no reports of injury as a result of this behavior; however, it is remotely possible that a compression injury to the patient could occur.

In order for an injury to occur, the following series of events must be present;

1. The detector configuration angle must be 180 degrees.
2. The detector with the failed brake circuit must be above the patient.
3. The detector with the faulty brake circuit must be under power (in motion).
4. System power must cycle within a very short time period, preventing the brake circuit from charging.

The most likely condition that could lead to a rapid power cycling is a touch pad failure. Your system was designed with a daily touch test. This test and/or its failure should not be ignored.

Additionally, activating the emergency stop (e-stop) or a system power failure, between 0.05 and 0.1 seconds after initiating motion could lead to this failure. Siemens has determined that the likelihood that these events would occur over such a small time window is very low. Due to this very low likelihood, the e-stop should still be used confidently.

Based on our investigation you can continue to use your system with confidence while waiting for the repair to be scheduled and performed.

Your local service engineer will be contacting you to schedule a repair by December 2015. The process should take approximately one hour.

What should you do until the repair is performed?

Continue to use your system. Please ensure that this safety advisory is placed in the system's instructions for use. As always, Siemens reminds you to observe the patient during studies.

If you experience difficulty or a failure while performing the daily touch pad test, discontinue use and contact your local service representative.

If you observe unintended detector motion, remove the patient, discontinue use of the system, and contact your local service representative.

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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
CAN001-2015