

Customer Safety Advisory Notice CAN 007-2016

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

Re: Update for users of e.cam and Symbia E systems

Dear Valued Siemens Customer,

We have received reports of patients' hair being caught in the e.cam and Symbia E patient bed up/down drive. The purpose of this letter is to remind users of the patient positioning instructions for your e.cam or Symbia E system and to inform you of an update that will be performed by your local Siemens service representative.

The "safety overview and important information" section of the e.cam user manual states:
"It is the operator's duty to ensure whenever moving the equipment and/or its components, that such movements are performed only when it is assured that no risk of injury to any individual(s) can occur as a result of such movement."

"Caution: Do not leave the patient unattended at any time while he/she is positioned on the patient handling system (PHS)."

"When moving any components of the system, all areas should be checked to ensure that there are no obstacles in the path of motion."

The "safety and external labeling" section of the Symbia E manual states:
"Avoid contact with pinch points and other areas of potential injury. These are areas where parts of the body (for example, fingers, feet, hair, skin, etc.) or things attached to or placed around the body (for example, sheets, IV lines, electrical leads, etc.) can become caught, entangled in, or pinched by the system's moving parts."

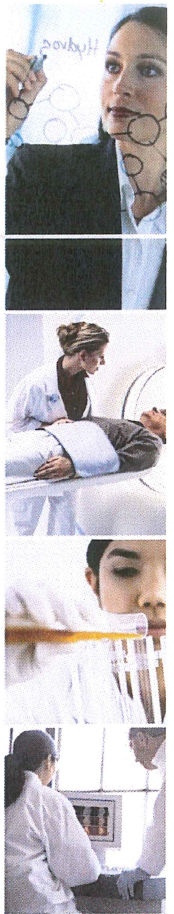
"Warning: Improper patient positioning, or subsequent patient movement after positioning, could put the patient in the path of system motion!"

*"Patient injury and system damage can result.
Always observe the patient and maintain communication to ensure that patient body parts (for example, patient limbs, clothing, hair, IVs, etc.) are clear of contact to avoid pinching or crushing."*

We have reviewed our complaint history and risk analysis and determined that e.cam or Symbia E systems pose a risk of moderate injury due to hair entanglement. Moderate injuries are defined to be those that require minor first aid. In the lifetime of the e.cam and Symbia E product, we have received customer complaints that resulted in minor injury.

What should you do?

Please review the "safety" sections of the user manual with your staff.



Based on the results of our risk assessment the likelihood of moderate injury is low, you may continue to use your system under the guidelines set forth in this letter. Please ensure this advisory is placed in the system's instructions for use.

While the current bed design meets industry standards and specifications, Siemens has designed an enhancement kit to further reduce the gap in the patient bed up/down drive. Siemens e.cam and Symbia E customers will receive this enhancement. Your local Siemens service organization will be contacting you to schedule this update. No enhancement can replace good operator practices; as stated in the user manuals, operators should properly position the patient and observe the patient at all times.

If you have sold this equipment and it is no longer in your possession, we kindly ask that you forward this notice to the new owner of this equipment. Furthermore, please inform us about the new owner of the equipment so that they may receive future notices directly.

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 important 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,

