

Customer Advisory Notice

CAN 001-2016

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

Re: User manual addendum for Symbia E and e.cam collimator change

Dear Valued Siemens Customer,

The purpose of this letter is to inform you that we are providing an addendum to the Symbia E and e.cam user manual with specific enhancements to the instructions for collimator change.

We have received complaints regarding incidents where collimator change activities have resulted in operator injury. Our investigation found that these incidents may have been avoided by operators properly following specified instructions. The system was designed to safely store and exchange collimators, however if the instructions are not followed serious injuries, such as broken bones and lacerations, may occur. We have determined that although the existing user manual is correct, additional supplemental instructions, with the inclusion of visual aids, may further clarify and emphasize the proper collimator change process.

What should you do?

Inform your staff of the enhancements that have been made to the user manual and continue to use your system. Please ensure that this advisory notice and addendum instructions are placed with the system's instructions for use. All system use information should be available to all operators of the system.

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. Please inform us about the new owner of the equipment.

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,

[Redacted Signature]

Matt Shah
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Molecular Imaging
CAN001-2016

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