SIEMENS

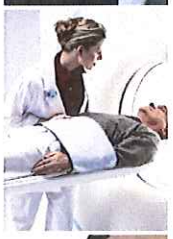
Molecular Imaging

Customer Advisory Notice

CAN 002-2016

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

Re: Update for users of e.cam and all Symbia systems with foresight detectors



Dear Valued Siemens Customer,

The purpose of this letter is to inform you of an upcoming update for your e.cam or Symbia system with foresight detectors.

We have determined that e.cam or Symbia systems with foresight detectors performing gated or dynamic acquisitions may lose some detector time-information. Our risk analysis indicates that the probability of this occurrence is remote. In the lifetime of the product, we have received three complaints, none of which led to misdiagnosis or adverse events.

The resulting risk is that the framing of the image data and the calculated ejection fraction values may be lower. Although misdiagnosis could be possible if ejection fraction values are used as a sole input to diagnosis, we have not received any reports of that nature.

A software patch (MI16-001) and corresponding operator manual addendum will be provided. Once the software patch is installed on your system, the improvements will further reduce the likelihood of the issue occurring. If the issue does occur after the patch installation, the following caution will appear on the PPM:

> "⚠ **CAUTION**
> Detector information has been lost.
> The nuclear acquisition data just completed may be compromised.
> Prior to your next acquisition, follow Perform Daily Shutdown and Start-up as described in the operator manual. If the problem persists, contact Customer Service."

We expect to begin deploying this patch by May 2016. You will be contacted either by an automatic system update notification or by your local CSE to schedule this update.

What should you do until the update is installed?

Based on the results of our risk assessment indicating that the probability of occurrence is remote, you may continue to use your system. Please ensure that this advisory is placed in the system's instructions for use.

To reduce the likelihood of this issue, perform Daily Shutdown and Start-up as described in the operator manual.

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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 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,

Matt Shah
Vice President, RA/QA & EHS
Molecular Imaging
CAN002-2016

SIEMENS

Software Patch MI16-001 Addendum

The software patch MI16-001 is provided to address an issue with e.cam/Symbia systems where detector information may be lost.

The following caution will appear if this issue occurs:

CAUTION

Detector information has been lost.

The nuclear acquisition data just completed may be compromised.

Prior to your next acquisition, follow Perform Daily Shutdown and Start-up as described in the operator manual. If the problem persists, contact Customer Service.

This device bears a CE mark in accordance with the provisions of Council Directive 93/42/EEC of June 14, 1993 concerning medical devices and the Council Directive 2011/65/EU of June 08, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The CE marking applies only to Medical Devices which have been put on the market according to the above-mentioned EC Directive.

Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

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