

April 08, 2014

Molecular Imaging

## Customer Safety Advisory Notice (CAN 003-2014)

**To: Director of the Radiology Department  
Director of the Nuclear Medicine Department  
Risk Management Officer  
Users of e.cam system**

**Re: E.CAM® Patient Handling System**

Dear Valued Siemens Customer,

You are receiving this customer advisory letter because you have been identified as owning an e.cam system.

We received a report in which a patient was reportedly grasping the integrated armrest of the Patient Handling System (PHS) as the technologist pulled the PHS pallet to the home position. During this movement, when the pallet was retracted the patient's finger sustained an injury as it was caught between the moving and stationary parts of the PHS.

As described in the e.cam operator's manual, as well as the e.cam Patient Bed Safety Addendum of the operator's manual, we would like to remind you to always monitor the patient at all times while they are on the system and during initiation of any system movement. Additionally, please observe the following general good practices, which are in alignment with your operator's manual:

- Never leave the patient unattended on the system.
- When moving the patient into or out of the gantry, make sure the patient's arms, fingers, hair, and loose items such as clothing are completely positioned on the Patient Handling System.
- When moving any components of the system, all areas should be checked to ensure that there are no obstacles in the path of motion.

Please ensure that this safety advisory notice is placed in your e.cam operator's manual and disseminate this safety advisory to all operators of your e.cam system.

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



If you have any questions regarding this important safety notice, please contact your local service representative or you can contact our office at 800-888-7436 (Monday – Friday from 7:00 a.m. to 8 p.m. EST).

Sincerely,

A handwritten signature in cursive script, appearing to read "Matt Shah".

Matt Shah  
Vice President, Quality & Regulatory Affairs  
CAN 003-2014

# **e.cam Patient Bed Safety Addendum**

[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

**SIEMENS**

---

## *Legal Notice*

© 2013 by Siemens Medical Solutions USA, Inc. All rights reserved.

Siemens reserves the right to modify the design and specifications contained herein without prior notice. Please contact your local Siemens Sales Representative for the most current information.



### **Caution**

Federal law of the United States of America restricts this device to sale by or on the order of a physician.

e.cam is a registered trademark of Siemens Medical Solutions USA, Inc.

syngo is a registered trademark of Siemens AG, Healthcare.

Portions copyright (c) Chris Maunder, 1998-1999

This product includes software developed by the University of Chicago, as Operator of Argonne National Laboratory.

# Contents

Legal Notice..... ii

**e.cam Patient Bed --- Safety Issues 1**

---

Integrated Reconfigurable Arm Supports of the Patient Bed .....2

Using the Integrated Reconfigurable Arm Supports .....2



## Chapter 1

# **e.cam Patient Bed --- Safety Issues**

This e.cam addendum provides some additional safety information when using the Integrated Reconfigurable Arm Supports of the Patient Bed. Be sure to not only read and follow the instructions included in this addendum, but also those shown in the e.cam Operating Instructions manual that came with your system.

The information that follows relates to specific areas of the Patient Bed.

---

## *Integrated Reconfigurable Arm Supports of the Patient Bed*

### *Using the Integrated Reconfigurable Arm Supports*

Before using the pallet release buttons or hand control to move the patient into or out of the gantry, remind the patient to keep their hands away from beneath the patient bed's pallet and away from the sides of the system. This will help to avoid any possible contact with the system's detector(s), gantry, bed posts, frontal area of the patient bed or rear bed.

Use care when moving the patient while on the system. Watch for any potential system contact, especially with the patient's arms and fingers, legs and feet. Monitor the patient at all times (prior to, during, and after the acquisition) to prevent any part of the body from coming into contact with the system during system motion.

As a reminder, use the body wrap as necessary so the patient's hands and/or fingers do not hang over the bed or so that the patient does not grab onto the integrated arm supports or pallet.

Refer to the following warnings and figures for specific safety information and guidance when using the patient bed, specifically the integrated reconfigurable arm supports.



#### **WARNING**

Do not grab onto the integrated reconfigurable arm supports which are located on either side of the patient bed!

#### **Patient injury can result.**

- Remind patients not to grab onto the integrated arm supports that are on either side of the patient bed.





### **WARNING**

Keep patient hands and fingers away from the system's moving components! Use preventative measures to ensure nothing attached or placed around the patient can become caught, entangled, or pinched.

#### **Patient hand or finger injury may result.**

- Monitor and remind patients to keep their hands and fingers away from the system's moving components to avoid possible contact with the system's detector(s), gantry, or rear bed. If deemed necessary, use the body wrap so hands and/or fingers do not hang over the bed and possibly come in contact with the integrated reconfigurable arm supports or the pallet itself.



Figure 1. System View with Possible Contact/Pinch Points (A, B and C)



Figure 2. See A in Figure 1 for Location --- Integrated Arm Supports - Post Side (two vertical posts)



Figure 3. See B in Figure 1 for Location --- Frontal Area of the Patient Bed Integrated Arm Supports (one on each side)



Figure 4. See C in Figure 1 for Location --- Endcaps at Rear of Patient Bed





No part of this documentation may be reproduced or transmitted in any form by any means, electronic or mechanical, without written permission of Siemens Medical Solutions USA, Inc.

Trademarks and service marks used in this material are property of Siemens Medical Solutions USA, Inc. or Siemens AG. All other company, brand, product and service names may be trademarks or registered trademarks of their respective holders.

This product is provided with a CE mark in accordance with the regulations stated in Council Directive 93/42/EEC of June 14th, 1993, concerning Medical Devices.

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.

Part No. 10908884 Rev. 01

Printed in USA 08-2013

All rights reserved.

© 2013, Siemens Medical Solutions USA, Inc.

#### **EU Authorized Representative**

Siemens AG  
Medical Solutions  
Henkestrasse 127  
91052 Erlangen  
Germany

#### **Global Business Unit**

Siemens Medical Solutions USA, Inc.  
Molecular Imaging  
2501 N. Barrington Road  
Hoffman Estates, IL 60192-2061  
USA  
Phone: +1-888-826-9702  
[www.usa.siemens.com/healthcare](http://www.usa.siemens.com/healthcare)



#### **Legal Manufacturer**

Siemens Medical Solutions USA, Inc.  
Molecular Imaging  
2501N. Barrington Road  
Hoffman Estates, IL 60192-2061  
USA  
Telephone: +1-888-826-9702  
[www.usa.siemens.com/healthcare](http://www.usa.siemens.com/healthcare)

#### **Global Siemens Headquarters**

Siemens AG  
Wittelsbacherplatz 2  
80333 Muenchen  
Germany

#### **Global Siemens Healthcare Headquarters**

Siemens AG  
Healthcare Sector  
Henkestrasse 127  
91052 Erlangen  
Germany  
Phone: +49 9131 84-0  
[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

[www.usa.siemens.com/healthcare](http://www.usa.siemens.com/healthcare)



0086