Customer Safety Advisory Notice
CAN 001-2020

To: Director of the Radiology Department
Director of the Nuclear Medicine / SPECT Imaging Department
Risk Management Officer
Users of Siemens Healthineers' Symbia S and Symbia T systems

Re: Symbia S and Symbia T system unintended detector motion

Dear valued Siemens Healthineers customer,

This letter is to inform you of the possibility that your Symbia S or Symbia T system(s) may have unintended slow motion of the detectors in specific situations which could pose a potential risk.

When does this malfunction occur and what are the potential risks?

Symbia S and Symbia T cameras with the following serial numbers may be affected by this issue:

Model #	Description	Serial # Range	Manufacturing date
8717741	Symbia S-Series	1001-1252	Oct 2005 - March 2008
8717733	Symbia T-Series	1001-1209	June 2005 - March 2008
10275007	Symbia T	1001-1032	Sept 2007 - March 2008
10275008	Symbia T2	1001-1039	Oct 2007 - March 2008
10275009	Symbia T6	1001-1029	Aug 2007 - March 2008
10275010	Symbia T16	1001	March 2008

The system model and serial number can be found on the front, lower-right corner of the gantry.

The issue may occur when a detector is moving downwards from roughly the 0 degree position radially towards the center of the camera bore, and an Emergency Stop press, touchpad engagement or power loss (ie: system shut down or power failure) occurs.

In this situation, the detector may continue to drift very slowly downward towards the center of the camera bore. If a patient is left beneath the detector, the detector may eventually contact the patient and potentially cause the patient compression related injuries. A detailed analysis determined that the likelihood of this issue occurring is improbable/highly unlikely, but not impossible.

There have been no reports of injury as a result of this issue.

How can you help to avoid the potential risk of this issue?

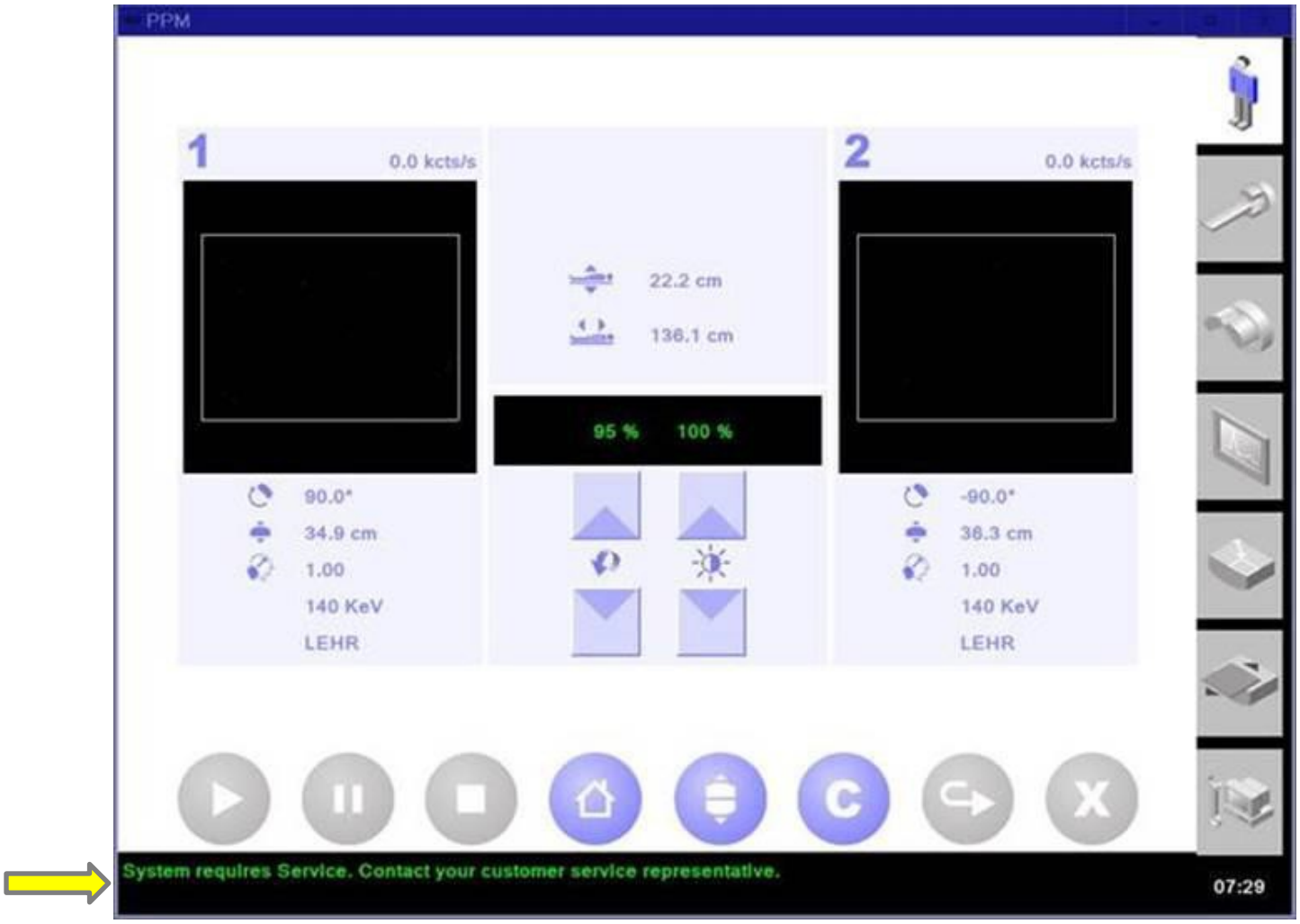
You may continue to use your system ensuring to follow all instructions in the Operator Manual. Do not leave the patient unattended at any time while the patient is positioned on the patient bed.

Siemens Medical Solutions USA, Inc.
2501 N. Barrington Road
Hoffman Estates, IL 60192 USA

In the event of an Emergency-Stop, shutdown or power loss the patient should be manually retracted from the gantry using the patient bed pallet handle and release button.

In the event of touchpad engagement, confirm there are no system errors reported on the PPM and refer to the instructions in the Operator Manual to address proper patient positioning before continuing.

If unintended detector motion is observed, downward pressure from the detector is reported by the patient at any time or the PPM presents a system error (as shown in the picture below), then manually retract the patient from the gantry using the patient bed handle and release button, stop use of the system and contact your customer service representative.



Errors or problems that result in patient re-scan or re-dose should be reported to your local Siemens Healthineers representative.

What is being done by the manufacturer to address this issue?

Siemens Healthineers' service organization is addressing the issue through an extra scheduled service visit to check the detector motion system on possibly affected Symbia S or Symbia T scanners. Your local service organization will begin contacting customers beginning in the fourth quarter of calendar year 2020. If the inspection on your system fails, the related parts will be replaced restoring it to original factory performance. Afterwards, the detector motion system on all Symbia cameras will be routinely inspected during scheduled preventive maintenance visits to assure continued proper function.

Please ensure that this customer advisory notice is placed in the Symbia S or Symbia T Operator Manual and disseminated to all operators of Symbia S or Symbia T.

If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment, and please inform Siemens Healthineers about the change in ownership.

Adverse events or quality problems experienced with the use of this product should be reported to Siemens Healthineers 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 advisory notice, please contact your local Siemens Healthineers 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,

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