Customer Safety Advisory Notice
CAN 002-2022

To: Director of the Radiology Department
Director of the Nuclear Medicine / SPECT Imaging Department
Risk Management Officer
Users of Siemens Healthineers' Symbia Intevo 6 and Intevo Bold systems

Re: Symbia Intevo 6 and Intevo Bold CT balancing weights

Dear valued Siemens Healthineers customer,

This letter is to inform you of the possibility that your Symbia Intevo 6 or Intevo Bold system(s) may have a materials issue with the threaded fasteners used to mount the vibration-balancing weights of the CT subsystem.

When does this malfunction occur and what are the potential risks?
Symbia Intevo 6 and Intevo Bold systems with the following serial numbers may be affected by this issue:

Model #	Description	Serial #'s
10764803	Intevo 6 Series	2352, 2353, 2354
11007962	Intevo Bold Series	1499, 1501, 1505, 1510

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

One or more of the threaded fasteners securing the balancing weights may fail and the balancing weights may come loose. The issue is most likely to occur when the CT subsystem is rotating.

The potential risks of this issue could include significant system vibrations, loud noises and the ejection of loose parts from the system. System damage and injury to nearby individuals is possible.

There have been no reports of this issue occurring in the field. A detailed analysis of this issue determined that the probability of ejected parts occurring is remote but not impossible.

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.

If any changes in system vibrations or noises are detected, then activate the Emergency Stop (E-Stop), discontinue use of the system immediately and contact your service engineer.

What is being done by the manufacturer to address this issue?
Siemens Healthineers is addressing the issue through a scheduled service visit to replace the relevant parts on the affected scanners. Your local service organization will begin contacting customers in the first quarter of calendar year 2022 to schedule this work.

Please ensure that this notice is placed in the Symbia Intevo 6 or Intevo Bold Operator Manual and disseminated to all operators of the scanner.

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

Siemens Healthineers
2501 N. Barrington Road
Hoffman Estates, IL 60192 USA

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