

Customer Safety Advisory Notice

CAN 001-2023

To: Director of the Radiology Department
Director of the Nuclear Medicine / SPECT Imaging Department
Risk Management Officer
Users of Siemens Healthineers' Symbia Pro.specta systems

Re: Symbia Pro.specta SLD look-ahead sensors

Dear valued Siemens Healthineers customer,

This letter is to inform you of the possibility that during a whole-body planar scan with auto-contour, the short-linear drive (SLD) look-ahead sensors may trigger earlier than expected and may result in detector 1 positioning further from the patient than needed. This may lead to a reduction in image resolution.

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

The issue may occur in any Symbia Pro.specta system when performing a whole-body planar scan with auto-contour turned on and the patient positioned with high knees, for example with a high knee rest. During the move to the start position, the SLD sensor may detect the knees resulting in detector 1 not moving as close to the patient as possible. White sheets on the patient may cause the sensors to trigger earlier than without sheets. Additionally detector 1 may stay distanced from the patient for longer than needed.

The potential risk of this issue is lower image resolution due to increased distance between the patient and detector 1. No report of misdiagnosis has been reported. A detailed analysis of this issue determined that the probability is remote but not impossible.

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

To avoid this issue, it is recommended to:

1. Leave auto-contour on and:
 - a. Position patient's knees as low as reasonable using a pillow or shorter knee rest. Avoid tall knee rests.
 - b. Position patient's knees apart, not pressed together.
 - c. If possible, avoid placing a white sheet on top of the patient's knees.
 - d. With shorter patients, position their head closer to the center of the SPECT field of view (FoV), leaving some space between the top of the head and the outermost edge of the SPECT FoV.
 - e. Observe system contouring distance through the whole-body planar scan. If detector 1 positioning is too high, consider repositioning the patient or performing additional scans such as statics or whole-body planar with auto-contour turned off.
2. Or, turn auto-contour off and follow proper patient positioning and detector height configuration for a non-auto-contour scan.

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

Siemens Healthineers is working to address this issue through a scheduled service visit. Your local service organization will begin contacting customers in the fourth quarter of calendar year 2023 to schedule this work.

Please ensure that this notice is placed in the Symbia Pro.specta 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.

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,

Vice President, RA/QA & EHS
Siemens Healthineers
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