Customer Safety Advisory Notice
CAN 001-2023

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

Symbia Pro.Specta

Update Instructions – Safety Update - MI010/23/S
SLD Look Ahead Sensor CAN

SIEMENS Healthineers

Update Instructions

Symbia Pro.Specta

Safety Update - MI010/23/S

SLD Look Ahead Sensor CAN

Update within deadline	1 month			
Security Vulnerability Patch (200/800)	☐ Yes	☑ No		
Affected	☑Warranty	☑Contract	☑Others	
Update by	☐ Customer	☐ RSC	☐ Apps	☑CSE
Remote Update	☐ SRS RUH	☐ ASU	☑No	
Intranet download available	☐ Yes	☑No		
Update material required	☐ Yes	☑No		
Material free of charge	☑ Yes	☐ No	☐ No, credit if returned	
Return of parts	☐ Yes	☑No		
Constancy Check	☐ Yes	☑No		
Application training needed	☐ Yes	☑No	☐ Recommended	
Application training time	0 h			
Estimated completion time	.25 h			
Number of CSEs	1			

Remarks

N.A.

Scope

Material number	See systems/Products affected
Software Version	N.A.
Related to Update Instructions	MI010/23/S

Change reference no.	769552
Name	miproductsupporthes.team@siemens-healthineers.com
Department	SHS CS MI O HES&KNV

Document Version

Siemens Healthcare GmbH reserves the right to change its products and services at any time.

In addition, manuals are subject to change without notice. The hard copy documents correspond to the version at the time of system delivery and/or printout. Versions to hard copy documentation are not automatically distributed.

Please contact your local Siemens Healthineers office to order a current version or refer to our website http://www.siemens-healthineers.com.

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1 Preparation

1.1 General Information

1.1.1 Systems/Products Affected

All Symbia Pro.Specta Q3, X3, and X7 models that were manufactured with a SLD Look Ahead Optical Sensor assembly.

Obtain the material and serial numbers from your local Update Management or Dispatch.

1.1.2 Reason for the Update

The reason for this update is to inform the customer 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.

1.1.3 Additional Information

n.a.

1.1.4 Prerequisites

You must ensure that you use the latest version of the document. Always refer to the Services Knowledge Base (SKB) to obtain the latest version.

1.1.5 Special Tools

n.a.

1.2 Material Information

1.2.1 Ordering Information

n.a.

1.2.2 Return of Parts

n.a.

2 Update

2.1 Work Steps

1 Navigate to: https://skb.siemens-healthineers.com

2 Enter **SKB0137230** into the search bar.

3 Click on the **Search** button.

4 Double click the only result that appears titled **MI010/23/S SLD Look Ahead Sensor CAN** to open the SKB.

5 Open the desired language .PDF attachment at the bottom of the page.

6 Print or save a copy of the letter.

7 The letter may be delivered to the customer in three ways:

- Hand deliver a printed hardcopy of the letter to the customer.
- Email an electronic copy to the customer and the customer must acknowledge receiving the letter.
- Mail a hardcopy of the letter to the customer via certified mail.

8 Report the update once proof of delivery has been received.

2.2 Final Work Steps

1 Make a copy of the filled-out Completion Protocol.

2 The update has to be reported by authorized employees, either via:

- Automated data transfer (only in countries connected to SAP via an Update Handling Interface)
- The "Update Handling" on the Siemens Healthcare Intranet/Extranet -> Customer Services application (for countries NOT connected to SAP via the Update Handling Interface)
- The Completion Protocol (for countries that do not have one of the connections indicated above)

The update is not considered to have been performed until the IVK structure in the Installed Base is updated.

2.3 Customer Information

◆ Inform the customer of:

- A solution to this Customer Advisory Notice will be ready in the fourth quarter of calendar year 2023.

2.4 Changes to Previous Version

n.a.

3 Completion Protocol

Symbia Pro.Specta
Safety Update - MI010/23/S
SLD Look Ahead Sensor CAN

3.1 Reason for the Update

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3.2 Protocol

This update has been completed successfully. The customer was informed of the "Customer (Safety) Advisory Notice": **MI010/23/S**

Customer	.....		
Customer No.	.....	**Func. Location**	.....
Material No. of the system	.....	**Serial number of the system**	.....
Notification	.....		
Remark	.....		
Remark	.....		
Country	.....	**Site**	.....
Performed by	.....	**Telephone**	.....
Date	.....	**Signature**	.....

File the protocol in the corresponding binder.

siemens-healthineers.com

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
[redacted]

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