

Field Safety Notice

Re.: Field Safety Notice- Applicable to your COHERENCE Oncologist 2.0.49, 2.0.50, 2.0.51

Attention: Radiation Oncology Department

Dear Customer,

This letter is intended to inform you about a potential safety risk related to patient treatment when using COHERENCE Oncologist 2.0.49, 2.0.50, or 2.0.51.

Please note: COHERENCE Oncologist 1.x and 2.0.52 are not affected by the issue described below.

What is the issue and when does it occur?

Siemens Healthineers has identified a potential safety issue with the display of portal images.

This issue is related to portal images used for position correction (offset calculation) following filtering operations, when the images arrive unfiltered on the COHERENCE Oncologist.

The identified problem occurs only in case an offset calculation is followed by a filter operation.

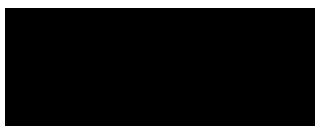
When the portal image is displayed alongside the reference image, the user normally activates the **interactive shift** or **landmark registration** functions to align the reference and the portal images. Once the alignment is accepted, the user activates the offset calculation. This shows the relative offset and/or absolute table positions in the Beam Visualization (lower right) segment.

At this point, the portal image display and offset calculations are correct. However, when a subsequent filtering action is performed, the portal image display will shift in two segments: the upper right and the lower left (blended). Only the visual display of the portal image is changed – the offset values remain correct.

Users are strongly cautioned that they must not further correct the image alignment at this time.

What are the possible risks to health?

Correcting the image alignment after the shift of the display as described above has occurred will result in incorrect offset values which could lead to incorrect repositioning of the patient. This may lead to dose to wrong location.



What steps can the user take to avoid the possible risks associated with this issue ?

To avoid the possibility of an incorrect alignment of the patient, the user must ensure that filtered images arrive on the COHERENCE Oncologist, or apply any additional filters to the image *before* using the **interactive shift** or **landmark registration** tools.

How will the issue finally be resolved?

A solution for this issue is available and a software update will be rolled out soon.

Based on our investigation you can continue to use your device.

Dissemination of the content of this notice

Please ensure that all users of COHERENCE Oncologist 2.0.49, 2.0.50, or 2.0.51 within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly.

Please include this Field Safety Notice in your COHERENCE Oncologist System Owner Manual, where it should remain until the software update has been installed.

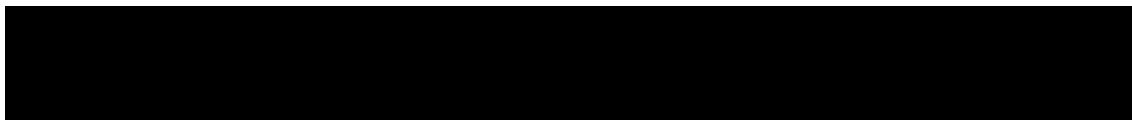
What If you no longer have this device/equipment?

If this COHERENCE Oncologist is no longer in your possession, please forward this Safety Advisory Notice to the new owner of the COHERENCE Oncologist. If applicable, please inform us about the new owner of the device.

The relevant National Competent Authority will be informed of this Field Safety Notice.

We regret any inconvenience that this may cause, and we thank you in advance for your understanding.

Sincerely,



This document is valid without original signature.

