

Siemens Healthcare GmbH, SHS DI XP WH PRM, Siemensstr. 3, Healthcare Building 1,
91301 Forchheim

Contact person of
the Regional Unit
Department

<To the person in charge of the unit where the SIEMENS
product is operated, and the administrative head of
organization>

Telephone
Fax
E-mail

Date

Safety Advisory Notice

To all users of the SIEMENS MAMMOMAT Revelation

Contact person of
the Business Unit
Department

Telephone
Fax
E-Mail

Re: MAMMOMAT Revelation system versions VC10B, VC10C or VC10D using Tomo Biopsy Unit – Error regarding vacuum biopsy system removal during InSpect view

Dear customer,

This letter is to inform you that the previous safety advisory notice announced with update instruction XP011/20/S did not provide a complete set of instructions on how to remove the vacuum needle out of the needle holder. Therefore, this letter intends to provide this missing instruction (please see the italic highlighted sections below). This letter supersedes the letter provided with update instruction XP011/20/S.

We excuse for any inconvenience this might have come along with.

What is the underlying issue requiring corrective action and when does the issue occur?

If an examination is interrupted due to any system error *or by user action* while

- the InSpect Projection View (PV) is active, and
- a vacuum biopsy system is used,

the tube arm can only be moved to a $\pm 6^\circ$ position by using the rotation buttons instead of the $\pm 15^\circ$ position that is possible with other Projection Views. The $\pm 15^\circ$ manual movement range allows easy removal of the vacuum biopsy system to release the patient from the unit. The limitation to $\pm 6^\circ$ manual movement range may lead to difficulties in removing the vacuum biopsy system.

Siemens Healthcare GmbH
Management: Bernhard Montag, President and Chief Executive Officer;
Jochen Schmitz, Christoph Zindel

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Chairman of the Supervisory Board: Ralf P. Thomas
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

What is the impact on system operation and what are the potential risks?

Due to limitation to $\pm 6^\circ$ manual movement range, it may be difficult to remove the vacuum biopsy system. This may cause minor to moderate injury to the breast tissue.

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

If the operator encounters the situation described above, then

1. the InSpect PV functionality must be deactivated by selecting the option "PV" with the right mouse button and then choosing the function "Disable exposure".
2. *After that, a stereo measurement needs to be added and activated by right-clicking on the previously deactivated "PV", selecting "Add" and selecting another biopsy "PV" (e.g. Stereo-Pair, Stereo-Scout, Tomo-Scout).*
3. *The selected new "PV" then needs to be activated by a double-click.*

Following these actions, the normal biopsy mode becomes active, and the tube head can be moved to the $\pm 15^\circ$ position, providing enough space to easily remove the vacuum needle out of the needle holder.

What influence does this issue have on already examined patients?

The error has no influence on previously examined patients.

How will the issue finally be resolved, and the corrective action be implemented?

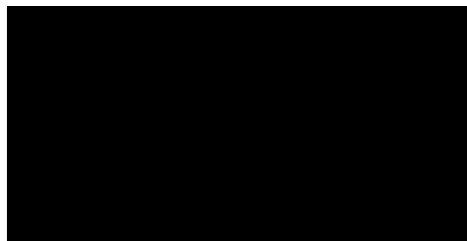
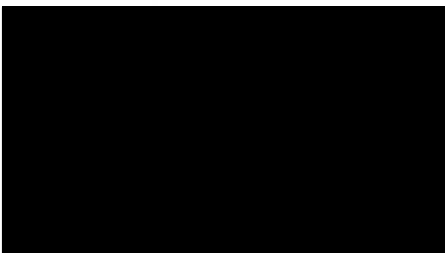
Siemens Healthineers will provide a field software update VC10E for MAMMOMAT Revelation with VC10B, VC10C and VC10D versions that will resolve the issue described. This field modification will be available in the third quarter of calendar year 2020. This update will be provided to you free of charge.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the system's instructions for use. Your personnel should maintain awareness until the modification has been implemented.

If you have any additional questions on the steps described above, please contact your local service representative.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely yours,



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Re: MAMMOMAT Revelation system versions VC10B, VC10C or VC10D using Tomo Biopsy Unit – Error regarding vacuum biopsy system removal during InSpect view

Dear customer,

This letter is to inform you of a potential issue and a corrective action that will be performed on your MAMMOMAT Revelation system with software versions VC10B, VC10C or VC10D with Tomo Biopsy Unit option and the InSpect functionality, to prevent a possible hazard to patients.

What is the underlying issue requiring corrective action and when does the issue occur?

If an examination is interrupted due to any system error while

- the InSpect Projection View (PV) is active and
- a vacuum biopsy system is used

the tube arm can only be moved to a $\pm 6^\circ$ position by using the rotation buttons instead of the $\pm 15^\circ$ position that is possible with other Projection Views.

The $\pm 15^\circ$ manual movement range allows easy removal of the vacuum biopsy system to release the patient from the unit.

The limitation to $\pm 6^\circ$ manual movement range may lead to difficulties in removing the vacuum biopsy system.

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Due to limitation to $\pm 6^\circ$ manual movement range, it may be difficult to remove the vacuum biopsy system. This may cause minor to moderate injury to the breast tissue.

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

If the operator encounters the situation described above, the InSpect PV functionality should be deactivated by using a right mouse click, selecting "PV" option and choosing "deactivate" function. Following this action, the normal biopsy mode remains active, and the tube head can be moved to the $\pm 15^\circ$ position, providing enough space to easily remove the vacuum needle out of the needle holder.

What influence does this issue have on already examined patients?

The error has no influence on previously examined patients.

How will the issue finally be resolved, and the corrective action be implemented?

Siemens Healthineers will provide a field software update VC10E for MAMMOMAT Revelation with VC10B, VC10C and VC10D versions that will resolve the issue described. This field modification will be available in the third quarter of calendar year 2020. This update will be provided to you free of charge.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the system's instructions for use. Your personnel should maintain awareness until the modification has been implemented.

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Sincerely yours,

