

Siemens Healthcare GmbH, HC DI XP MK, Siemensstr. 3, Healthcare Building 1,
91301 Forchheim

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

Contact person of
the Regional Unit
Department

Telephone
Fax
E-mail

Date

Field Safety Notice

To all users of systems
MAMMOMAT Revelation VC10 with Biopsy Option

Contact person of
the Business Unit
Department

Telephone
E-Mail
Date

[REDACTED]

[REDACTED]
[REDACTED]
July 1, 2019

Re: Software issues on your MAMMOMAT Revelation with software version VC10 and Biopsy Option

Dear Customer,

Patient and user safety are our utmost priority at Siemens Healthineers.

It has come to our attention that, in rare instances, some customers have experienced an issue during biopsy procedures. This occurred with the software version which is currently on your MAMMOMAT Revelation with Biopsy Option.

With this letter, we are providing background information about this issue, how to prevent it, and how to handle the issue if it occurs.

1. What is the issue and when does it occur?

Siemens Healthineers has become aware of an error that can occur when performing a biopsy using the InSpec function. The acquisition workstation can become unresponsive to normal user interaction. The issue can only occur in rare cases if all interactions described below happen:

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Jochen Schmitz, Michael Reitermann

Siemensstr. 3
Healthcare Building 1
91301 Forchheim
Germany

[siemens.com/healthcare](https://www.siemens.com/healthcare)

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

- the workflow changes during biopsy by switching to the InSpect mode (the user double clicks the InSpect projection view icon)

and, at the same time

- the user performs a right-mouse click at the acquisition workstation while the InSpect projection view is becoming active (changes color to white)

If the described system interaction happens in combination, a pop-up context window confirming the workflow step cannot be confirmed and no further interaction with the system seems possible.

2. What harm is associated with this issue?

- If the acquisition workstation becomes unresponsive during InSpect it may become difficult to release the patient from the system following standard workflow steps. In this case the manual removal of the biopsy needle may cause minor to moderate injury to the breast tissue. Siemens Healthineers has not received any reports of such injuries.

3. How can the issue be prevented?

The operator should refrain from performing mouse-clicks at the acquisition workstation during activation of the InSpect projection view (wait until the box is completely white).

4. How can the issue be handled if it occurs?

If the operator encounters the situation described above and the InSpect pop-up dialog window "Please insert the specimen cup at the right/left side according to lumination" cannot be confirmed or the system is unresponsive to mouse interaction, the operator can easily proceed with the biopsy workflow in seconds by performing the following steps:

- Press the keyboard buttons CTRL + ALT + S simultaneously.
- A "savelog" window will appear.
- Click the "savelog" prompted dialog and the syngo UI will become active.
- The user-interface is responsive again and the InSpect pop-up dialog window "Please insert the specimen cup at the right/left side according to lumination" can be confirmed.

How will the issue finally be resolved?

Siemens Healthineers will provide a field software update that will eliminate the issue described above. This will be provided free of charge. The software patch will be available by August 2019. Your local Siemens Healthineers Service organization will contact you as soon as the software update is available for your system.

Applications training includes information about how to release the patient from the system should the system become unresponsive. Completion of the applications training is mandatory before system hand-over.

We appreciate your understanding and cooperation with the field safety notice and ask you to immediately instruct your personnel accordingly.

Please ensure that this field safety notice is placed in the system instructions. Your personnel must remain aware of this issue until the software update has been installed.

What if you no longer have this device/equipment?

If this device/equipment is no longer in your possession, please forward this safety notice to the new owner of this device/equipment. If applicable, please inform us about the new owner of the device/equipment.

In case you have further questions regarding this issue, please call the Uptime Service Center.

Sincerely yours

— July 2019

