

Siemens Healthcare GmbH, HC DI XP MK IN , Allee am Röthelheimpark 2,  
91052 Erlangen

<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 ADD MY INFORMATION

Telephone  
Fax  
E-Mail

Date

### Customer Safety Advisory Notice

To all users of the Siemens Mammomat Inspiration  
with Biopsy functionality

Contact person of the Business Unit  
Department Susanne Niemann  
HC DI XP MK IN WH  
Telephone 09191 18 4091  
Fax  
E-Mail susanne.niemann@siemens.com  
Date

### **Re: Software Issues on your Mammomat Inspiration system with software version VB30 and Biopsy functionality**

**Dear Customer,**

This letter is to inform you about a potential issue with your the Siemens Mammomat Inspiration running on the software version VB30 and with a Biopsy option.

#### **When do these issues occur and what are the potential risks?**

Siemens has become aware of potential errors that may occur while performing a biopsy. The system may freeze and the biopsy functionality may become not available in the following situations:

1. Drop of the compression force, e.g. this may occur due to a patient sudden movement during the active targeting phase.
2. Or use of the inversion tool while the scout image is active during the targeting phase

As a result of a system freeze, the biopsy may have to be repeated.

**Siemens Healthcare GmbH**  
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WEEE-Reg.-No. DE 64872105

### **What steps can the user take to avoid the potential risk of this issue?**

- 1.) When the error message is displayed, the user is advised not to close this window but to cancel the active target first and then close the error message window. After these steps are completed the user can start all over.
- 2.) It is advised not to use the inversion tool while the scout image is active.

In case of system freeze the acquisition workplace must be rebooted.

### **How will the issue finally be resolved?**

Siemens will release a field modification to resolve this issue as soon as possible. The new software will be provided to the affected customers free of charge. A Siemens service engineer will contact affected customers to schedule implementation of the modification for your system.

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

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.

We thank you for your cooperation.

Sincerely yours,

*Francois Nolte  
Head of HC DI XP*

*Jürgen Buckow  
HC DI XP QT*

### Acknowledgement of receipt

Customer address:

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I hereby confirm as the owner / responsible operator of the Mammomat Inspiration with the Serial number \_\_\_\_\_(optional) that I received the following document:

### **Customer Safety Advisory Notice**

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Place, Date \_\_\_\_\_

Name \_\_\_\_\_

Signature \_\_\_\_\_