

Siemens AG, H CP XP MK, Allee am Rotheismpark 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

Telephone
Fax
E-Mail

Date

Safety Advisory Notice

To all users of a SIEMENS stereotactic biopsy device in combination with Mammomat Inspiration mammography system

Contact person of
the Business Unit
Department

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Date

**Re: Stereo biopsy device in combination with Mammomat Inspiration mammography system:
Potential movement of needle positioning device if safety switch is not locked properly**

Dear customer,

This letter is to inform you of a potential malfunction and hence potential risk to patients when using a stereotactic biopsy device on the Mammomat Inspiration mammography system.

When does this malfunction occur and what are the potential risks?

The stereo biopsy devices (serial numbers see attached list) for Mammomat Inspiration mammography systems might have integrated a safety switch which causes a failure of the functionality. The pin implemented in the safety switch may not put enough pressure on the safety circuit to prohibit movement. The needle positioning device may move even with the safety switch being set sideward. If this occurs with the needle being already inserted, it could lead to an unintentional patient injury.

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

To avoid injury of the patient please carefully follow the instructions in the user manual – chapter safety switch:

Siemens AG
Healthcare Sector, Management: Hermann Requardt
Clinical Products Division, Management: Britta Fuenfstueck
X-Ray Products, Management: Andre Hartung

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Siemens Aktiengesellschaft: Chairman of the Supervisory Board: Gerhard Cromme;
Managing Board: Joe Kaeser, Chairman, President and Chief Executive Officer, Roland Busch, Klaus Helmrich,
Hermann Requardt, Siegfried Russewurm, Ralf P. Thomas
Registered offices: Berlin and Munich, Germany; Commercial registries: Berlin Charlottenburg, HRB 12300, Munich, HRB 6684
WEEE-Reg.-No. DE 23691322

To ensure proper functioning, the biopsy unit safety switch must be inspected every day it is used:

- After the biopsy unit is mounted, you must check if you are able to rotate the safety switch to the left and to the right without any interference.
 - When the safety switch is in the center position (where movement is possible), you must be able to move the needle holder via the manual control (hand box) without any problems in the X, Y or Z directions.
 - When the safety switch is turned to the left or right (movement is blocked), you must not be able to move the needle holder via the manual control (hand box) in the X, Y or Z directions.
 - When the safety switch is moved to the manual override position, it should automatically return to the left or right position.
 - If one of these steps cannot be performed, please contact Customer Service.
- We recommend to inspect the safety switch before every biopsy until the problem is solved.

In case the needle holder moves unintentionally, please press the emergency stop.

How will the issue finally be resolved?

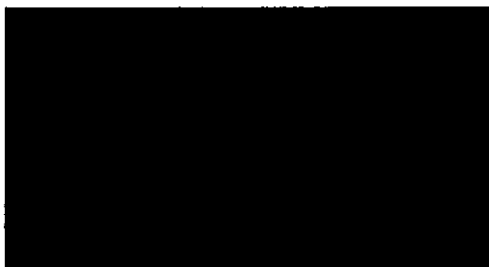
Siemens is preparing a modification of the safety switch that will resolve this potential malfunction. The field modification will be available beginning of October.

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 is implemented.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask you to 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



CEO H'CP XP



H CP XP QM

List of serial numbers of the stereo biopsy devices which are affected:

1014; 1037; 1057;

1110; 1121; 1139; 1199;

1208; 1281; 1283;

1336;

1413; 1425;

1520; 1541; 1558; 1565;

1732; 1737; 1764; 1799;

1828; 1838; 1870; 1877; 1879

2000 – 2033;

2035 – 2043;

2045

2047 – 2050;

2053 – 2068;

2070 – 2086;

2091