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To all users of the SIEMENS MAMMOMAT
Inspiration – Biopsy Unit

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Subject: Customer Information - MAMMOMAT Inspiration Biopsy Unit

Dear customer,

This letter is to inform you about the modification of the software operating the procedure of stereotactic biopsy. The system will be updated to system version VB10E.

What is the issue?

When a stereotactic biopsy is executed with a compression force less than 15 N the legal required accuracy of 1mm in x, y, z direction can not be assured. To ensure 1mm accuracy the breast needs to be compressed with a force above the minimum compression force. With the current product version a minimum compression force of 15N was required during the complete examination. If the compression force decreased below 15N it was only possible to acquire a scout view as next view.

Furthermore the needle holder was sent to "home position" following the automatic workflow if the next activated view was a scout view or if an error occurred during biopsy examination.

Further investigations showed that some of the delivered needle holders may, after cleaning with water and soap, show traces of corrosion between the safety switch and the surrounding housing.

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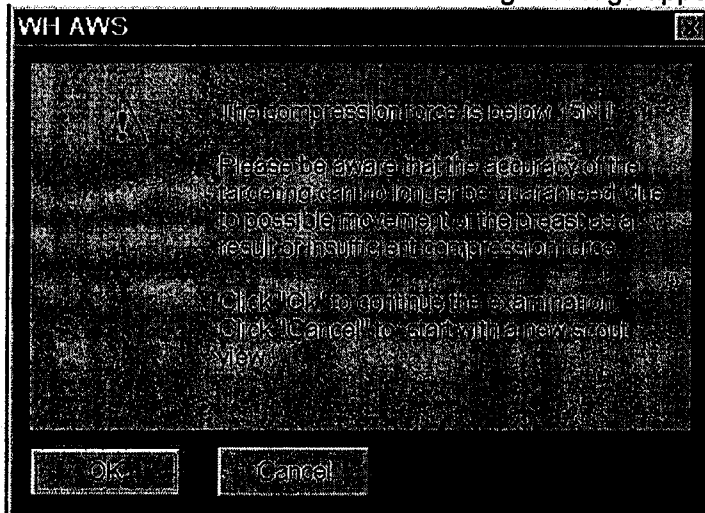
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Sitz der Gesellschaft: Berlin und München, Deutschland; Registergericht: Berlin Charlottenburg, HRB 12300, München, HRB 6684
WEEE-Reg.-Nr. DE 23691322

What measures will be taken?

As a measure the software operating the procedure of stereotactic biopsy is modified. If the compression force decreases below 15N the following message appears on AWS:



It is up to the user to accept possible inaccuracy of targeting and continue the biopsy examination with clicking "Ok" or not accepting possible inaccuracy and start with a new scout view with clicking "Cancel".

Furthermore the needle holder remains at the target position even if the next activated view is a scout view or an error occurs.

To ensure the correct functionality the safety switch of the biopsy unit shall be checked every working day:

- After the biopsy unit is mounted the safety switch shall be turned to left and right without any obstacles.
- The safety switch is in middle position (movement is possible). The needle holder shall be moved with the hand box in x, y, z direction without any problems.
- The safety switch is turned to left or right (movement is blocked). It shall not be possible to move the needle holder with the hand box in x, y, z direction.
- When the safety switch is moved to the manual over ride position shall the switch automatically move back to the left/right position.

If one of these steps cannot be performed please inform your local service.

The needle holder will be replaced with a holder where permanent bushings have been inserted to ensure that the two metal parts "safety switch" and "housing" do not get into contact with each other.

Please inform your staff regarding these modifications and insert this note into your Operator's manual.

We appreciate your understanding and cooperation in dealing with this matter.

Sincerely Yours

[Redacted Signature]

Head of Quality Management Women's Health

[Redacted Signature]

Dr. [Redacted Name]
Head of Marketing Women's Health