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To all users of the following as below:

See Table 1

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Customer Advisory Notice MR074/23/P

CUSTOMER ADVISORY NOTICE

Customer information about loosened screws on horizontal drive of patient table

Dear customer,

This letter is to inform you of a potential issue associated with the following products:

Name of the product	Siemens Model Number
Patient table motorized 025 cpl.	11291355
Patient table mobile 025 cpl.	11291356
Patient table fixed 025 cpl.	11291357
Patient Table mobile P016 1.5T cpl	11338299
Patient Table mobile P016 3T cpl	11338300
Patient Table fix P025 3T cpl	11338304
Patient Table fix P025 1.5T cpl	11338305
Patient Table mobile P025 3T cpl	11338312
Patient Table mobile P025 1.5T cpl	11338313
Patient table stationary P004 cpl.	11344445
Patient table mobile P004 cpl.	11344446
Patient table motorized P004 cpl.	11344447

Table 1

What is the problem and when does it occur?

Screws inside the patient table may become loose and potentially fall off. If the screws fall off, the tabletop position will no longer correspond to the displayed position. Especially after table movement in two different directions, the displayed table position can differ by up to 4 cm.

The wrong position of the tabletop is not easily recognized by the user nor detected by the MR system, and no error message will be displayed.

What is the impact to operation of the system and what are the possible risks?

There are two scenarios:

1. The MR-only radiotherapy planning workflow is based on MR images only. Patient marking is done using an external laser on the MR system. This external laser projects a crosshair onto the patient's skin according to coordinates derived from the reference point that the user defined in the MR images. Between image acquisition and laser point projection, the MR patient table is moved out from the magnet isocenter to the laser isocenter such that the previously marked anatomy is now under the laser crosshair. If the patient table movement is incorrect due to loosened screws, even if only in the millimeter range, the patient will be marked incorrectly. This patient marker will be used to set up the patient at the linear accelerator for beam delivery. If the reference point is displaced from the target anatomy, the beam will be displaced to the same extent with the ensuing risk of underdosing the tumor (failure of treatment) or overdosing neighboring tissue (toxicity, potential harm).
2. In an MR+CT radiotherapy planning workflow, the user will not be impacted by this issue. The MR system is used to acquire images that are subsequently fused with CT images in Siemens Healthineers or 3rd party software. The CT images will have a correct anatomy and reference position. The fused (MR+CT) images are correct irrespective of the loosened screw issue as the fusion is performed based on landmarks or manual registration and not table position.

What steps can the user take to detect whether the tabletop movement is still within specification?

1. Move the head coil to the magnet isocenter position.
2. Move the patient table to the home position (zero position).
3. The system will show that the patient table is in the home position.
4. Visually check that the tabletop is fully in the home position, see Figure 1.
5. In case of error, there could be a deviation of up to 4 cm, see Figure 2.
6. If after visual check the tabletop is not in the home position, your tabletop is affected and must not be used for marking reference points with an external laser.

Figure 1: Tabletop moved to home position - works as specified.

Figure 2: Tabletop moved to home position - Home position with deviation

How will the issue finally be resolved?

Siemens Healthineers will correct the issue by replacing the potentially affected screws at customer sites with the field update MR075/23/P. This replacement program is planned to start by June 2024. With the replacement, the root cause is eliminated.

In case of further questions, please contact your local service organization.

Dissemination of the content of this notice

Please ensure that all users of the affected products within your organization and others who may need to be informed receive the information provided with this notice and comply with the recommendations therein.

We appreciate your understanding and cooperation with this advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this advisory is retained with your product-related records appropriately. Please keep this information at least until the measures have been finalized.

As applicable: Acknowledge receipt of this Advisory Notice

Please fill out the attached Acknowledgment of Receipt and follow the instructions for returning it to Siemens Healthineers.

What if you no longer have this device/equipment?

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

The <relevant National Competent Authority> will be informed of this notice, if required.

Sincerely yours

Siemens Healthcare GmbH

Electronically signed by: Steffen Schroeter
Reason: I have reviewed this document
Date: Apr 17, 2024 09:14 GMT+2

Steffen Schröter
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