

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Spine & Trauma 3D: Potentially Incorrect Automatic Image Registration for Siemens SOMATOM Definition AS CT Scanner

Product Reference: Navigation Software Spine & Trauma 3D 2.0 and 2.1

Date of Notification: May 21, 2014

Individual Notifying: [REDACTED], MDR & Vigilance Manager

Brainlab Identifier: CAPA-20140520-000702

Type of action: Advice regarding use of device; Device modification



We are writing to advise you of the following effect, which has been identified for Brainlab Navigation Software Spine & Trauma 3D version 2.0 and 2.1, when performing Automatic Registration of iCT Data with Siemens SOMATOM Definition AS CT scanner. The purpose of this Product Notification letter is to provide you with corrective action information and to advise you of the action Brainlab is taking to address the issue.

Effect:

Brainlab Navigation Software Spine & Trauma 3D 2.0/2.1 offers automatic registration of intraoperatively acquired CT image data sets. To enable automatic registration, the software requires the gantry position of the scanner.

The gantry position can either be entered manually or submitted automatically from the CT scanner. If automatic gantry communication is available, the so-called "table-zero-position" is sent from the CT scanner to the Brainlab navigation software in a special format.

Due to a change in the corresponding Siemens data output, the information from the CT scanner cannot be correctly processed in the navigation software, when using:

- **Automatic Registration of iCT Data**, in combination with
- **Siemens SOMATOM Definition AS** CT scanner with Software Somaris SOM 7 (or higher), and
- **Automatic Gantry Communication** (available for Spine & Trauma 3D 2.0 and 2.1 only).

As a result, in the navigation software the CT image data set appears shifted in the scanner movement direction (patient head-feet direction). The scale of the shift can differ in each scan, varying from sub-millimeters to meters.

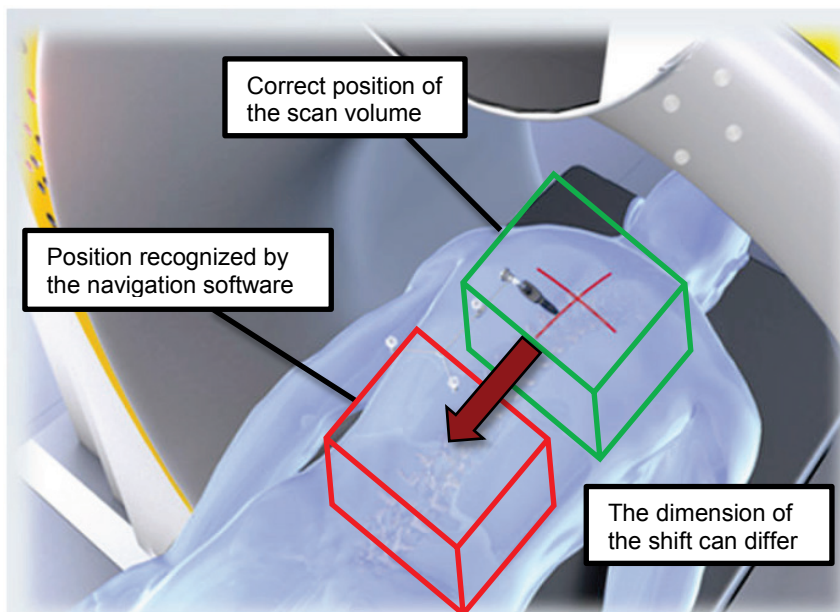


Figure 1: Schematic diagram of a potential virtual shift of CT image data set

The result of the registration (the match between CT data displayed in the navigation software and the actual patient anatomy) must always be verified by the user. This is performed by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software, as prompted by the software and as described in the Software User Guide.

In most cases the error described above will lead to a large and obvious shift between the information shown in the navigation and the actual patient position. This will be clearly visible during the verification, as the display of instruments by the navigation system would be significantly shifted compared to the actual patient anatomy.

However, if a non-obvious shift would occur and not be detected during user verification, the deviation in the navigation software could mislead the user regarding clinical decisions. This could ultimately lead to **ineffective treatment, serious injury or even death of the patient.**

User Corrective Action:

Brainlab will schedule a service visit for affected customers, to change the gantry communication from automatic to manual.

In the meantime, until Brainlab service has changed the gantry communication, **do not use Automatic Registration of iCT Data, in combination with Siemens SOMATOM Definition AS CT scanner** (with Software Somaris SOM 7 or higher), **and Automatic Gantry Communication** (available for Spine & Trauma 3D 2.0 and 2.1 only)

Please use other methods for patient registration, e.g.:

- Paired Point Matching
- Region Matching
- Fluoro Match

Please note that the change from automatic to manual gantry communication requires a recalibration that can only be performed by Brainlab service personnel.

When using manual gantry communication, the software prompts you to enter additional information. Please follow the instructions on the screen accordingly (see figure 2) and refer to the descriptions in the Software User Guide, section Automatic Registration of iCT Data.

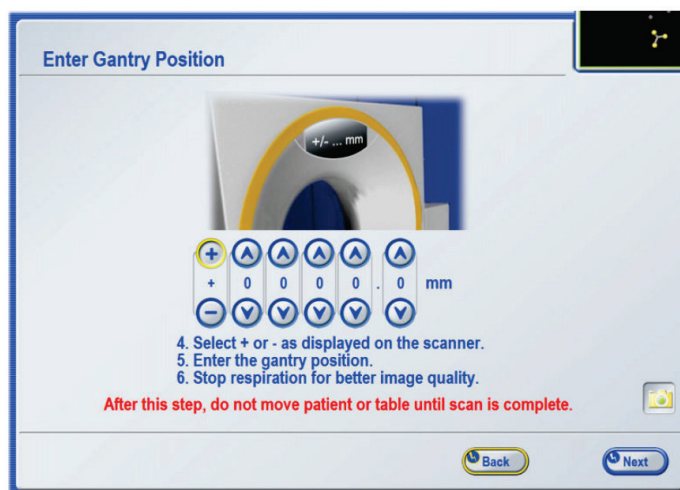


Figure 2: Brainlab Spine & Trauma 3D: Enter Gantry Position dialog

For clarification: Automatic Gantry Communication is only available for Brainlab Navigation Software Spine & Trauma 3D versions 2.0 and 2.1. Other Brainlab Software, e.g., Cranial/ENT version 2.1, does not use Automatic Gantry Communication and therefore is not affected.

Please note that, even if your Spine & Trauma Navigation System is currently not affected by this issue, it may become affected in the future in case the Somaris SOM 7 (or higher) software is installed on your Siemens SOMATOM Definition AS CT scanner.

In general:

The accuracy of the scanner calibration must be checked by Brainlab support, if:

- the cover of an intraoperative scanner is opened or mechanically altered
- routine maintenance by the scanner manufacturer has been performed
- any other changes have been performed on the scanner, e.g. software update.

Always make sure to perform **careful accuracy verification** according to the instructions in the Software User Guide:

- Always verify registration accuracy by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software.
- Verify that the registration is at the correct level on the patient and data set. Accuracy must be checked on the bone structure you will treat.

If accuracy is insufficient, it is recommended to perform a manual registration. It is not recommended to proceed to navigation with low accuracy.

Brainlab Corrective Action:

- Existing potentially affected Spine & Trauma 3D 2.0/2.1 customers (with Automatic Registration of iCT Data (AIR) function enabled) receive this product notification letter.
- Brainlab will perform corresponding service visits to change the gantry communication from automatic to manual, to enable a safe and effective usage of this device combination.

Please advise the appropriate personnel working in your department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation.

If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

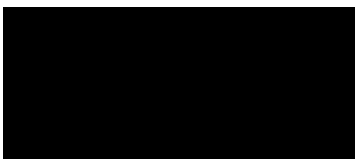
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Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.

