

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Potentially incorrectly displayed objects when actively deselecting a fused reference dataset

Product Reference: Content Manager (versions 2.0.0, 2.0.1, 2.0.2, 2.0.3, 2.1.0)
 Patient Browser (versions 4.0.0, 4.0.1, 4.0.2, 4.0.3, 4.1.0)
 DICOM Viewer (versions 2.0.0, 2.0.1, 2.0.2, 2.0.3, 2.1.0)

Trade Names: Patient Data Manager, Origin Data Management

Date of Notification: August 27, 2015

Individual Notifying: Julia Mehlretter, Manager MDR & Vigilance

Brainlab Identifier: CAPA-20150804-001474

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

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We are writing to advise you of the following effect that Brainlab has internally identified for the unusual workflow of actively deselecting a fused reference dataset in combination with the software versions listed above. 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:

When actively deselecting a fused reference dataset in Content Manager (the default setting is "selected"), a contained Point, Object or Trajectory may appear shifted and/or distorted in the subsequently used Brainlab navigation or planning software.

The potential problem arises if the following sequence of events occurs (refer to *Figure 1*):

- 1) A treatment or surgery plan is created with any Brainlab software containing:
 - Multiple fused image datasets (*Dataset A and Dataset B*), and
 - A Point, Object or Trajectory created in one of these datasets (*Object in Dataset A*).
- 2) The individual reference dataset that contains the Point, Object or Trajectory **is actively deselected** by clicking X on the **Data Selection page** available in certain types of Brainlab software.
- 3) The plan is used in Brainlab Navigation Software or Brainlab Surgery / Radiation Treatment Planning Software (iPlan).

In this case, the Point, Object or Trajectory will not be correctly transferred to the remaining selected dataset. Depending on the differences between the datasets (e.g., different slice distance or field of view), the **Point, Object or Trajectory may appear shifted and/or distorted in the treatment or surgery plan**.

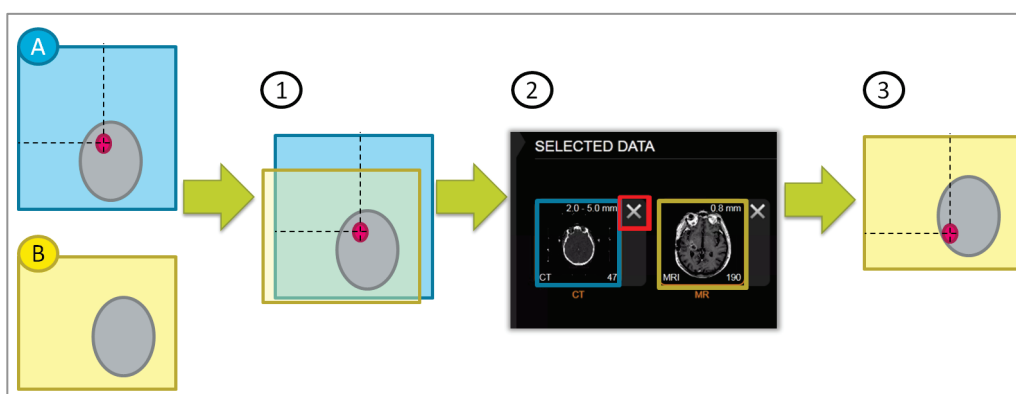


Figure 1: Schematic diagram of the potential problem

For the avoidance of doubt:

- All datasets appear **selected per default**
- If **none of the datasets of a fusion group are deselected** before transferring the plan to other Brainlab software, the **error will not occur** and the data is displayed correctly.
- **The error will not occur if only Brainlab Elements are used** (i.e., if a treatment or surgery plan was created using a Brainlab Element and will subsequently only be used by a Brainlab Element).

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If a reference dataset is deselected and the error occurs, the magnitude of shift or distortion varies, depending on the differences between the two datasets. Therefore, for some cases, the shift or distortion will be clearly visible when the plan is used in a Brainlab planning or navigation system. However, a shift could also be non-obvious. If a shift or distortion occurred and was not detected during review of the data, the deviation of the information displayed in the Brainlab planning or navigation software could mislead the user regarding clinical decisions. This could ultimately lead to **ineffective treatment, serious injury or even death of the patient**.

Details:

The Brainlab software **Content Manager, Patient Browser and interactive DICOM Viewer** form a system intended for the display of medical images or treatment / surgery plans from picture archiving and communication systems (PACS), file servers, or removable storage media. The software is installed per default on various Brainlab systems and opens after logging on to your system.

This error can only occur if the software installed is one of the following versions:

- Content Manager (versions 2.0.0, 2.0.1, 2.0.2, 2.0.3, 2.1.0)
- Patient Browser (versions 4.0.0, 4.0.1, 4.0.2, 4.0.3, 4.1.0)
- DICOM Viewer (versions 2.0.0, 2.0.1, 2.0.2, 2.0.3, 2.1.0)

A second pre-condition for the occurrence is the deselection of individual image datasets from the "SELECTED DATA" section (see *Figure 2*) before using the plan, to prevent the dataset opening automatically. Datasets can be deselected in the Data Selection pages of different applications, but the error can present itself in follow-up applications e.g., Navigation Software, Surgery Planning Software, Brainlab Elements and Radiation Treatment Planning Software. If all pre-conditions are fulfilled, the objects, which were created in a deselected image dataset, are potentially incorrectly displayed during further usage of the plan.

Treatment verification and (retrospective) review for existing plans

To retrospectively identify if incorrectly transferred objects have been used for treatment planning:

- 1) Export the potentially affected plan again from Brainlab software that was first used (e.g., Brainlab Elements) to the treatment planning software without deselecting any dataset – this ensures that the described issue does not occur and a correct plan is exported. This plan serves as a reference for comparison with the potentially affected plan.
- 2) By opening both plans – the potentially affected plan and the reference plan – in the planning software, the size and position of objects can be compared and an affected plan can be identified.

For radiation treatment planning, please note: The error only occurs if a plan has been created in one Brainlab software (e.g., Brainlab Elements) and a dataset is deselected on the Data Selection page before the plan is opened in another Brainlab radiation treatment planning software (iPlan RT / iPlan RT Dose).

There has been no negative effect on a patient due to this issue reported to Brainlab by any user site.

User Corrective Action:

According to our records, one of the affected software versions is installed at your site. Therefore, when using Brainlab Navigation Software or Brainlab Surgery / Radiation Treatment Planning Software, please adhere to the following instructions:

Do not deselect individual datasets where a Point, Object or Trajectory was planned in.

If you are unsure in which dataset a Point, Object or Trajectory was planned, **do not deselect any content from the plan**. Open the entire plan instead.

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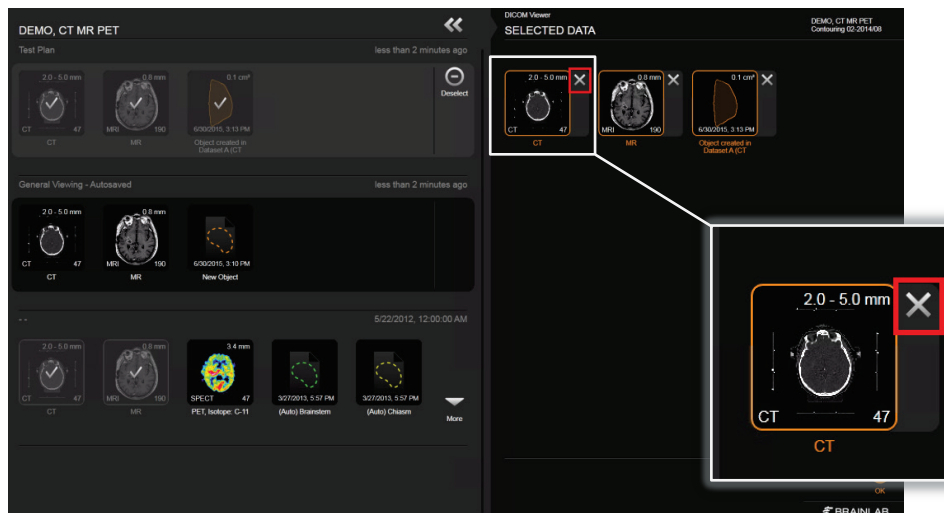


Figure 2: Data Selection: **Do not deselect individual datasets** by pressing the X next to the image.

Before patient treatment, always review the plausibility of all information input to and output from the device.

Brainlab Corrective Action:

- Existing potentially affected customers receive this product notification information.
- Brainlab will provide a software solution to prevent the described scenario from occurring. Brainlab will actively contact affected customers tentatively starting February 2016 to schedule the update.

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.

Customer Hotline: +49 89 99 15 68 44 or +1 800 597 5911 (for US customers)

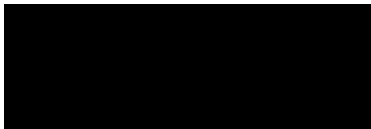
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August 27, 2015

Kind Regards,



Julia Mehlretter

Manager MDR & Vigilance

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

A blue circular graphic containing the website address.

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