

## URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

<b>Subject:</b>	Under specific circumstances, patient records from unrelated individuals are automatically merged into one patient record.
<b>Product Reference:</b>	Origin Data Management software versions 3.1.0, 3.1.1, 3.1.2, 3.2.0, 3.2.1 UDI-DI: 04056481145118 (ODM v. 3.1) & 04056481146078 (ODM v. 3.2). European Single Registration Number: DE-MF-000006183
<b>Date of Notification:</b>	January 22, 2025
<b>Individual Notifying:</b>	Kasyoka Kilonzo, Vigilance Manager
<b>Brainlab Identifier:</b>	CAPA-20250117-002791
<b>Type of action:</b>	Advice regarding use of device; Device modification

We are writing to inform you of a potential safety issue when using **Brainlab Origin Data Management (ODM) software versions 3.1 or 3.2**, the intermediate actions users shall apply to avoid the issue, and the corrective actions that Brainlab is taking to correct this issue.

### **Effect:**

Under certain circumstances, it can occur that patient records from unrelated individuals are automatically merged into one patient record without user notification.

### **Circumstances in which the issue occurs:**

The problem occurs if specific workflows are applied either in the Brainlab **Patient Selection** application, **OR** in a **Hospital Information System (HIS) that is connected to the above-listed versions of Brainlab ODM software:**

1. If the **Patient ID** is changed via **Merge** or **Edit** function **AND** subsequently only the **Gender** of that patient record is changed, **OR**,
2. If the **Patient ID** of one patient record is changed from its original value to a new value **AND** subsequently, **this original value** is applied (via **Merge** or **Edit** function) as the target **Patient ID** of another patient record.

For a more detailed description of the individual steps that lead to this error, please refer to [Appendix 1](#).

### **Potential Risk:**

Due to this issue, for example, data from Patient\_A may be automatically and incorrectly merged into an unrelated Patient\_B by the **ODM** software, which leads to:

- the unintended display of data from Patient\_A in Patient\_B. (Brainlab **Data Selection**, Figure 1)
- the unintended removal of Patient\_A from the patient list. (Brainlab **Patient Selection**, Figure 2)

*NOTE: Initially, only the way the data is displayed for the user in the Brainlab system is affected. However, if the data is exported, the changes are applied to the exported DICOM instances.*

If the automatic erroneous merging of data from two unrelated patient records is not detected by the user in the subsequent steps of treatment preparation, and data from Patient\_A is used to make clinical decisions for Patient\_B, this could, in a worst-case scenario result in **treatment error or serious injury**.

At the time of writing, there has been **no reported negative clinical effect on patient treatment due to this issue**.

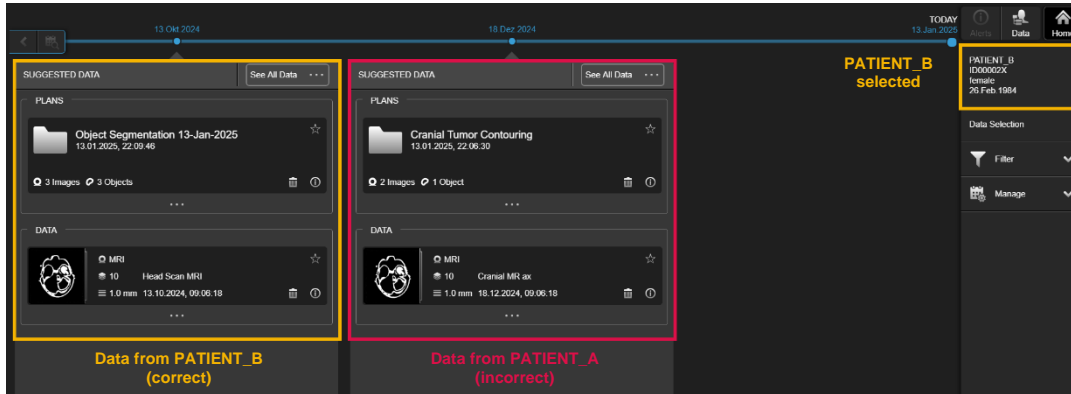


Figure 1: A treatment plan belonging to Patient\_A (pink) is merged into Patient\_B (yellow).

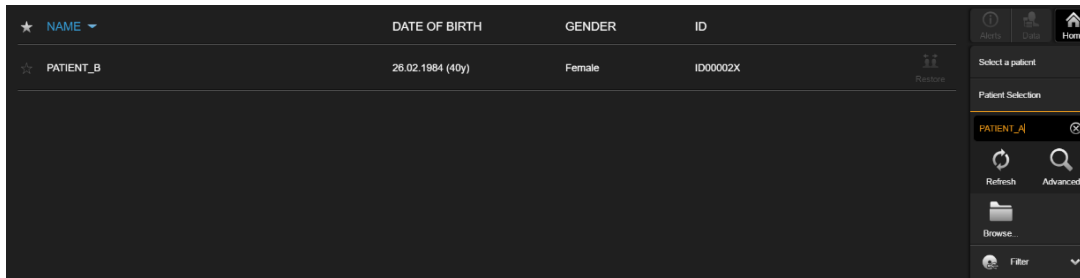


Figure 2: When searching for Patient\_A, Patient\_B appears in the search results. Patient\_A is not deleted but contained in Patient\_B.

**User Corrective Action:**

According to our records, at least one of the affected software versions is installed at your site. Therefore, when handling patient data intended to be used with Brainlab Software, adhere to the following instructions:

Sequence 1 (Gender)

- **Do not edit** only the **Gender** field of any already merged/edited patient record. (In the **Patient Selection** application, such a patient record is displayed with a **Restore** button next to it.)
- For patient records that have not already been merged/edited, adapt all necessary fields including **Gender in one single operation using Edit**. Only then can you merge additional patient records to the edited patient record, if applicable. (In the **Patient Selection** application, such a patient record does **not** have a **Restore** button next to it.)

Sequence 2 (ID)

- **Do not edit** a **Patient ID** to a value that was the original ID of a previously merged/edited unrelated patient record.  
To **verify whether a Patient ID has been previously used**, perform the following steps before making any edits that affect **Patient ID**:
  1. Search for the **Patient ID** that you want to use as the target ID in the search field in **Patient Selection** (do not use the **Advanced Search**).
  2. If entries with the **Restore** button are shown in the patient list,
    - **AND** the searched **Patient ID** is not displayed
    - **AND** the **Patient Name** does **NOT** correspond to the individual intended to be treated, do not proceed with editing or merging and contact Brainlab support.

For merges/edits originating externally from a Hospital Information System (HIS) that is connected to the above-listed versions of Brainlab ODM software:

- **Contact your HIS administrator (for the ADT interface) and clarify whether ADT A40 (merge patient) messages are used to edit Patient IDs in the system.** If Patient IDs are changed via ADT A40 messages, contact Brainlab support so that we can verify whether our system is reacting to the ADT A40 messages. If not, you are not affected by the software anomaly via this route.

In general:

- Ensure that treatment plans have meaningful names to enable clear identification. See Figure 3 for an example.

Before patient treatment, always:

- Verify that the name of the data set and/or treatment plan and its date are correct.
- Verify that the images and/or plan are correct for the intended treatment.

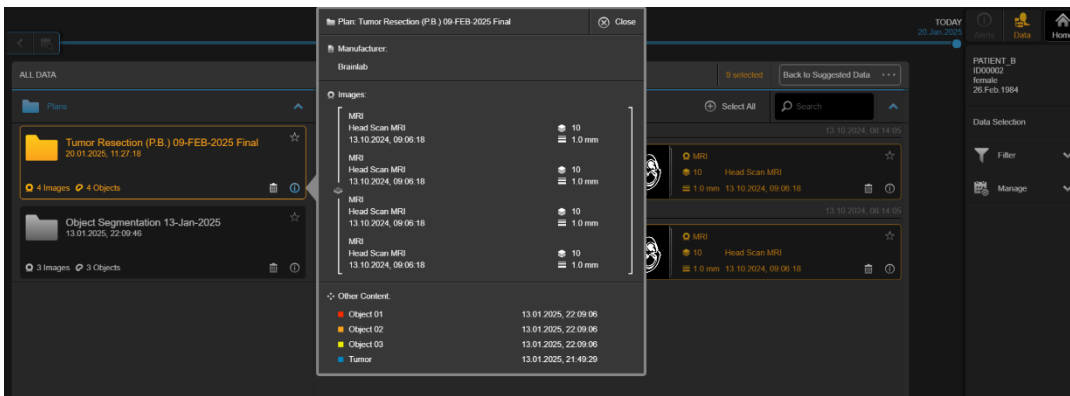


Figure 3: Example of a meaningful **Plan Name** that will enable better detection if the issue occurs. Abbreviation “**P.B.**” indicates the initials of the patient name, in this case Patient\_B.

**Brainlab Corrective Action:**

1. Potentially affected customers receive this product notification information.
2. Brainlab will provide a software solution, in which the described issue is corrected, to all affected customers. Depending on the regulatory clearance in your market, Brainlab will actively contact you as early as May 2025 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 cooperation.

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

**Customer Hotline:** +49 89 99 15 68 1044 or +1 800 597 5911 (for US customers)

**E-mail:** [support@brainlab.com](mailto:support@brainlab.com) (for US customers: [us.support@brainlab.com](mailto:us.support@brainlab.com))

**Fax:** Brainlab AG: + 49 89 99 15 68 5033

**Address:** Brainlab AG (headquarters): Olof-Palme-Strasse 9, 81829 München, Germany

January 22, 2025

Kind Regards,



Kasyoka Kilonzo, Vigilance Manager

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

**Appendix 1 - Detailed description of the individual steps that lead to this error**

**Important! Do not recreate the below operations as they will trigger the issue in your software.**

Sequence 1 (Gender)

- a. **Change the ID of a patient record** using the **Merge/Edit** functions, i.e.:

Via <b>Merge</b> :	Via <b>Edit</b> :
<ul style="list-style-type: none"> <li>- Under <b>Manage</b>, select <b>Merge</b>.</li> <li>- Select the patient records you wish to merge from the patient list and select <b>Merge</b>.</li> <li>- In the dialog that opens, select the target patient.</li> </ul> <p><i>NOTE: After the merge, all data is stored under the selected (target patient record's) <b>Name</b> and <b>ID</b>.</i></p> <ul style="list-style-type: none"> <li>- Select <b>OK</b> to confirm.</li> </ul>	<ul style="list-style-type: none"> <li>- Under <b>Manage</b>, select <b>Edit</b>.</li> <li>- Select the <b>ID</b> field and change the existing value.</li> <li>- Select <b>Done</b> to save.</li> </ul>

- b. Select **this patient record** (now shown with a **Restore** button next to it)

- c. Under **Manage**, select **Edit**.

- d. Select the desired **Gender**.

- e. Select **Done** to save.

(The next **Merge/Edit** of an unrelated patient record will cause the automatic incorrect merge of unrelated patient records. The described issues will become apparent only after the system is restarted.)

Sequence 2 (ID)

- a. Select a patient record.

- b. Under **Manage**, select **Edit**.

- c. Select the **ID** field and type in a **value that was the original ID of a previously merged/edited** unrelated patient record.

(The issue will occur regardless of any changes to other fields at the same time).

- d. Select **Done** to save.

(The described issues will become apparent only after the system is restarted.)

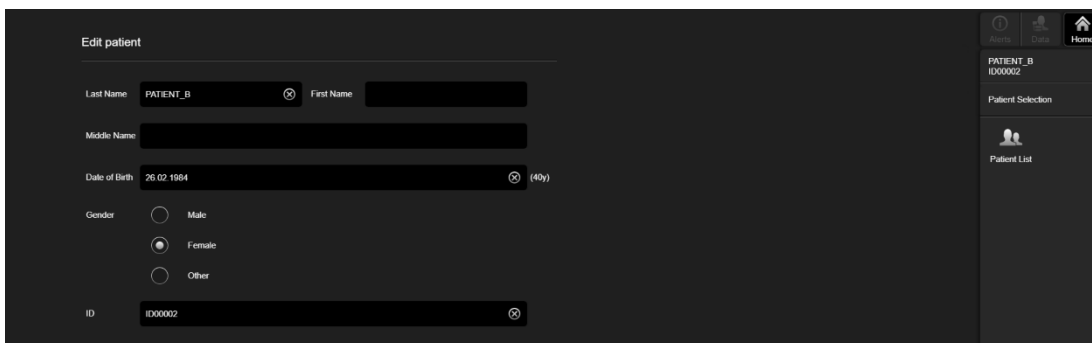


Figure 4: Edit dialog to change patient information