BRAINLAB

Appendix to URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Brainlab Identifier:	CAPA-20250117-002791
Date of Original Notification:	January 22, 2025
Subject:	Under specific circumstances, patient records from unrelated individuals are automatically merged into one patient record.
Product Reference:	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

Appendix 2 - Treatment verification and (retrospective) review for existing patient records

To retrospectively identify if incorrectly merged patient records exist in your Brainlab system, you can exercise either/both of the options described below:

1. Inspect the suspected patient record:
    a) In **Patient Selection**, open the patient record that has a **Restore** button next to it, and verify whether:
        - The name and date of the data set and/or treatment plan are correct.
        - The images and/or plan are correct for the intended treatment.
    b) If an incorrectly merged patient record is identified please inform your local Brainlab Customer Support Representative.

2. Contact your local Brainlab Customer Support Representative to arrange a service visit (in person or remotely, if remote access is available).
    a) During the service visit, the service engineer will temporarily install a service tool on the system and run it locally to extract an overview of all merged patient records, including merges created by users. The extracted overview displays a list of source and target patient records side by side and can be reviewed in a spreadsheet (you can easily compare the names, IDs, genders, and dates of birth).
    b) The service engineer will then provide you with the overview to review it for the correctness of the merges.

    Note:
    An incorrect merge of patient records does not directly mean that it is caused by the software issue described in this Field Safety Notice, as incorrect merges can also be inadvertently created by the user.

    c) If an incorrectly merged patient record is identified, please inform your local Brainlab Customer Support Representative.