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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Patient Data Manager:
	Object shifts applied in iPlan not reflected when exported into DICOM
Product Reference:	iPlan CMF/Cranial/ENT/Spine 3.0.5, 3.0.6 used in combination with
	Patient Data Manager 2.1.1, 2.2.0, 2.2.1, 2.3.0, 2.3.1, 2.4.0, 2.5.0, 2.5.1
Date of Notification:	October 08, 2019
Individual Notifying:	Andrea Miller, Vigilance Manager
Brainlab Identifier:	CAPA-20190904-002337
Type of action:	Advice regarding use of device; Device modification

We are writing to advise you of a safety issue when using the Brainlab iPlan CMF/Cranial/ENT/Spine software in combination with the Brainlab Patient Data Manager (PDM) software (applicable versions see above) that may lead to shifts applied to segmentation objects in iPlan being not reflected when exported into DICOM under specific circumstances.

There has been no reported negative impact on patient treatment by any user site due to this issue until the time of writing. The purpose of this Product Notification letter is to provide you with the relevant user information on how this issue occurs and to inform you of the corrective actions Brainlab is taking to address this.

Effect:

When saving a treatment plan in the iPlan software, the application stores the plan data in the Brainlab Advanced File Format (xBrain). Additionally the data is converted to DICOM in the background, if e.g. iPlan is integrated in a Brainlab Elements workflow, and thus used in combination with PDM. Under specific circumstances, after an object was moved using the feature "Object Movement" in iPlan, the new object position is available only in the xBrain data, but not reflected in the converted DICOM data.
When loading the DICOM data in another Brainlab application (not iPlan), e.g. navigation software, the object is displayed in an obsolete position.
When subsequently, the DICOM data (including the specific segmentation object) is converted back to xBrain, the incorrect object position is transferred to the xBrain data as well. Thus when loading the object again in iPlan, the object is displayed in the obsolete position also in iPlan.

This effect might occur if <u>all</u> of the following preconditions are met:
- iPlan and PDM / Elements are used in combination, i.e. both applications access the same treatment plan data, and data conversion (xBrain to DICOM) is triggered.
- The feature "Object Movement" of iPlan was used to change the position of an object ("Fine" or "Coarse" button).
- No other property of this specific object was changed in iPlan like object name, color, volume, and/or organ type.
- This specific object was already saved to DICOM once before (either resulting from automatically converted xBrain data, as outlined before, or created directly as DICOM object by PDM / Elements).

The incorrect information displayed can have an effect on clinical decisions. If the object shift is not detected by the user, this could, in a worst case scenario, **mislead the user in regards to assessing the surgical region of interest, e.g. for tumor resection, biopsy location, or implant placement**.

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Details:

Due to the different file formats used by Brainlab applications (xBrain and DICOM), a conversion is necessary when using treatment plan data by both iPlan and PDM / Elements.

When the conversion from xBrain to DICOM is initiated, all segmentation objects within an xBrain plan are analyzed whether they have a DICOM predecessor instance, which is the case if the specific xBrain object originates from a DICOM object. If there is a DICOM predecessor instance, it is determined whether the DICOM predecessor can be re-used or a new conversion is required. Due to a software anomaly, the position of the object is not taken into account in this verification step. This leads to the effect that if only the position of the object is modified, and all other object parameters remain exactly the same, a new conversion of this object to DICOM is not triggered, and its new position is not reflected in DICOM.

Any further planning in DICOM or xBrain, involving this specific DICOM object, may therefore show the obsolete position.

For the avoidance of doubt:

If iPlan is used in combination with PDM / Elements, and the segmentation object was created by iPlan initially: This issue does not come into effect, if data is converted to DICOM for the first time (the specific segmentation object does not yet have a DICOM predecessor instance).

User Corrective Action:

Users shall adhere to the following:

➢ When using the "Object Movement" functionality in iPlan to assign a new position to an object, additionally change the name or color of this specific object. This will trigger a correct data conversion.

Please continue to follow the instructions and warnings as described in the user guides. Especially relevant is the following warning in the Software User Guide of corresponding iPlan applications:

> ⚠ **The appearance and visualization could differ between Brainlab applications (e.g. planning and navigation software) due to different user interfaces and workflows. Exported data should always be verified on the target platform prior to a surgery.**

Further, note the following extracts from the Software User Guide of the affected PDM versions:

> Plans marked with "*" ① were automatically converted from Brainlab Advanced File format to DICOM.
> Planning content must be reviewed carefully prior to use.

> *NOTE: Content created using Brainlab Elements is automatically converted to Brainlab Advanced File format when starting **iPlan** in order to allow for further planning with **iPlan** software. Plans created by **iPlan** are automatically converted back to DICOM. Converted plans must be inspected carefully prior to further use.*

Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification information.

2. Brainlab will provide a software revision with the described issue corrected to all affected customers. Brainlab will actively contact you, starting in May 2020 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 1044 or +1 800 597 5911 (for US customers)

E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)
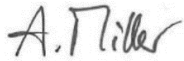
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October 08, 2019

Kind Regards,

A. Miller

Andrea Miller, Vigilance Manager

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

TOGETHER WE ARE MAKING MEDICAL TECHNOLOGY AND KNOWLEDGE MORE IMPACTFUL AND ACCESSIBLE TO PHYSICIANS AND THEIR PATIENTS.