

**FIELD SAFETY NOTICE / PRODUCT NOTIFICATION**

**Subject:** Potential incorrect display of objects created with Brainlab iPlan, when exporting to the Navigation System

**Product Reference:** iPlan CMF 3.0, iPlan Cranial 3.0, iPlan ENT 3.0, iPlan Flow 3.0, iPlan Spine 3.0, iPlan Stereotaxy 3.0 (including all subversions)

**Date of Notification:** Jun 7, 2013

**Individual Notifying:** Julia Mehlretter, MDR & Vigilance Manager

**Brainlab Identifier:** CAPA-20130527-000355

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

[www.brainlab.com](http://www.brainlab.com)

We are writing to advise you of the following effect that has been identified for iPlan CMF/Cranial/ENT/Flow/Spine/Stereotaxy (“iPlan”) versions 3.0.0, 3.0.1, 3.0.2 and 3.0.3, when exporting a treatment plan for usage with Brainlab Navigation Software. 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 exporting a treatment plan created with Brainlab iPlan 3.0 for usage with Brainlab Navigation Software, planned objects may not be correctly displayed in the Navigation Software **if all of the following conditions are met:**

1. Standard Brainlab Format is used. That means the plan is exported to one of the following Navigation Software versions:
  - VectorVision Cranial/ENT, version 7.x
  - Kolibri Cranial/ENT, version 2.x
  - Cranial/ENT Essential/Unlimited, version 1.x
  - VectorVision Spine, version 5.5.1
  - VectorVision Spine, version 5.6
2. One or more slices of the image set – or of any image set that is fused to it – exceeds in any direction (x/y/z) a coordinate of +511 mm or -511 mm, and the contours of the planned object extend into those slices.
3. The standard export settings have been changed:  
The feature “Enable interpolation for non-512x512 images” is disabled (see Figure 1)  
By default this feature is enabled for every user login/account.



Figure 1 – Changed export settings: “Enable interpolation for non-512x512 images” is unchecked

In case all of the above mentioned conditions are met, the planned objects may be shown cropped, the boundaries may be shaped differently or the objects may appear larger or smaller in the Navigation System than originally planned.

If the potentially incorrect object shape is not detected by the user during review of the imported plan, and the object is used within surgery performed with the aid of a Brainlab Navigation System, the information displayed could potentially mislead the surgeon, ultimately **leading to ineffective treatment, serious injury or even death of the patient.**

**User Corrective Action:**

Users of iPlan CMF 3.0, iPlan Cranial 3.0, iPlan ENT 3.0, iPlan Flow 3.0, iPlan Spine 3.0, iPlan Stereotaxy 3.0 (including all subversions) shall adhere to the following:

- **When exporting from iPlan to Standard Brainlab Format ensure that in the Settings the checkbox “Enable interpolation for non-512x512 images” is checked.**
- **This has to be ensured separately for each of your iPlan versions. (e.g. for iPlan Cranial and iPlan ENT)**
- **When using the software with iPlan Net, the corrective action has to be performed for every user login/account.**



Please refer to the Appendix for detailed instructions on User Corrective Actions.

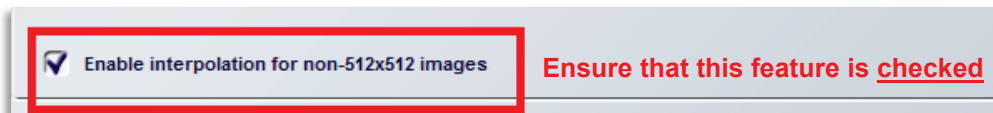
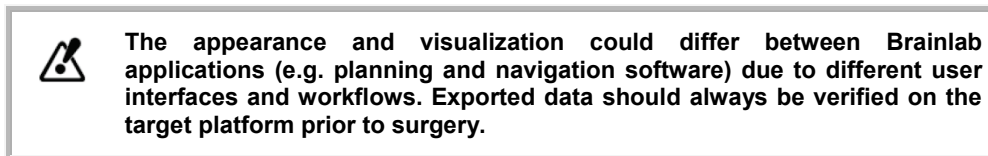


Figure 2 – Brainlab Standard dialog with the **enabled** checkbox “Enable interpolation for non-512x512 images”

In general, please continue to always follow the instructions and warnings as described in the according iPlan User Guides, in particular:

**Brainlab Corrective Action:**

- Existing potentially affected iPlan 3.0 customers receive this product notification information.
- Brainlab will provide a software update with this issue solved to affected customers. Tentative planned timeline for availability: December 2013.

**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)

**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 33

**Address:** Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

Jun 7, 2013

Kind Regards,



Julia Mehlretter  
MDR & Vigilance Manager

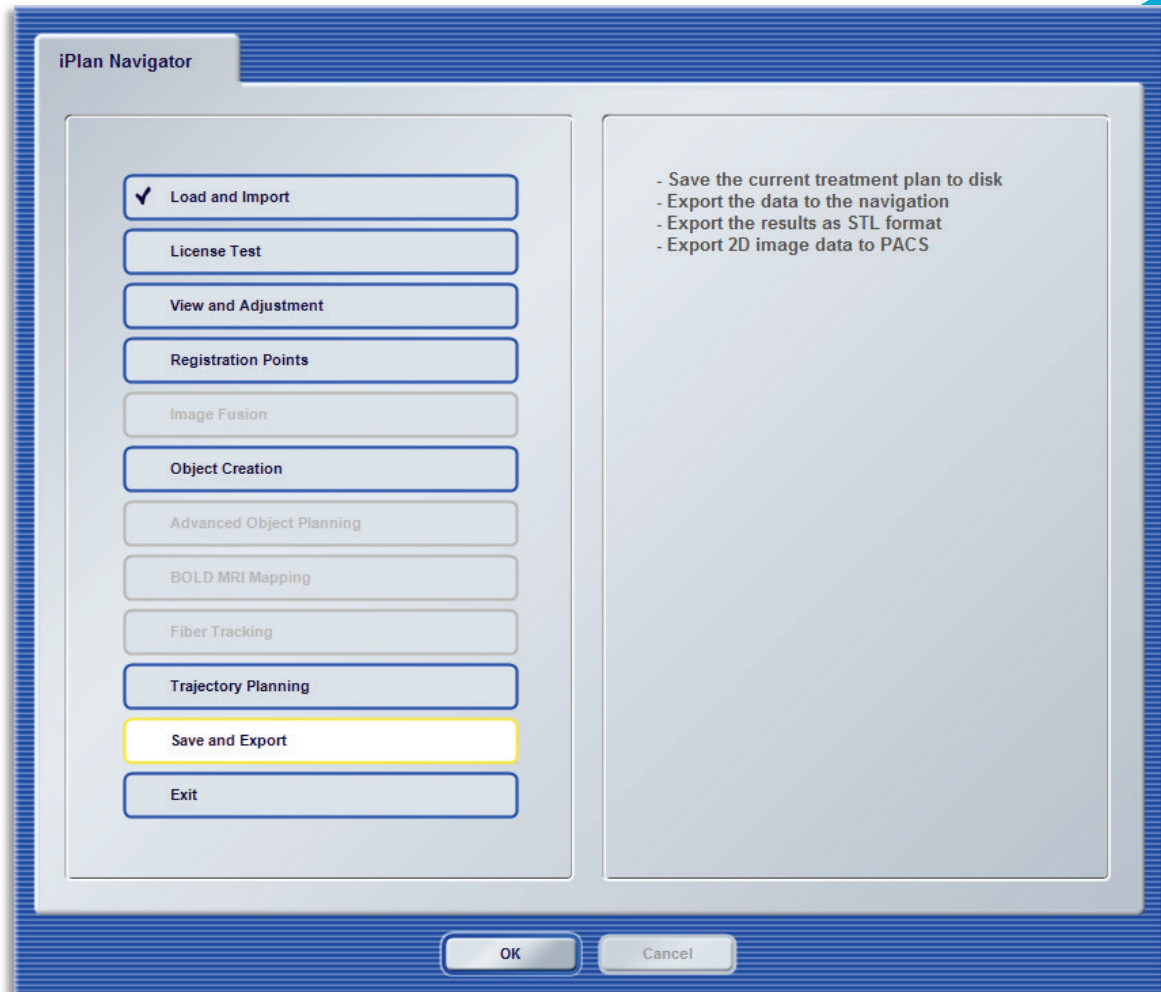
[brainlab.vigilance@brainlab.com](mailto:brainlab.vigilance@brainlab.com)

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

## Appendix: User Corrective Actions – Detailed Instructions

### 1. Load any patient data into iPlan.

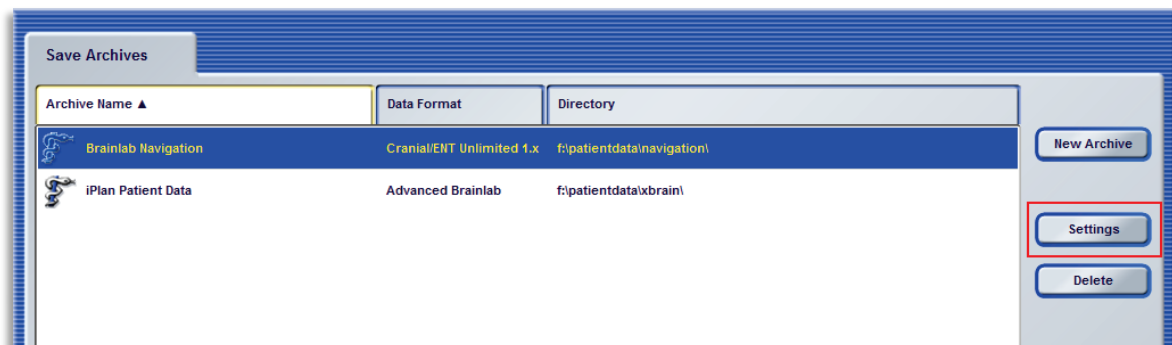
After loading, select the "Save and Export" task in the iPlan Navigator.



### 2. You will be forwarded to the "Save Archives" page.

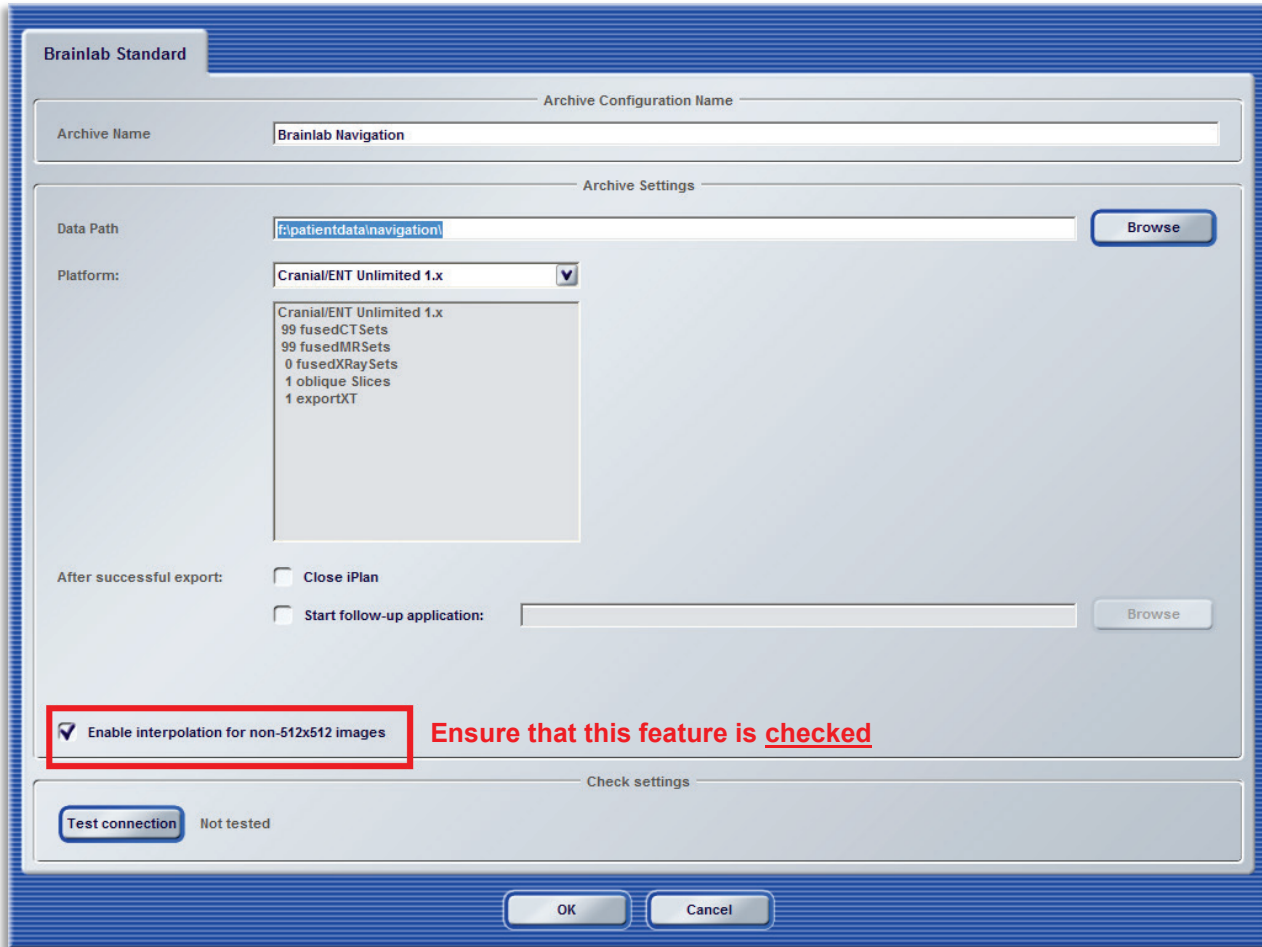
Select the Brainlab Navigation export archive marked with a blue Brainlab snake, and press the "Settings" button on the right of the page.

- Please note that there can be several Brainlab Navigation export archives.
- Please note that the archive name can differ from "Brainlab Navigation"



**3. You will be forwarded to the "Brainlab Standard" page.**

Make sure that the checkbox "Enable interpolation for non-512x512 images" **is checked**.



**Brainlab Standard**

Archive Configuration Name

Archive Name: Brainlab Navigation

Archive Settings

Data Path: f:\patientdata\navigation Browse

Platform: Cranial/ENT Unlimited 1.x

Cranial/ENT Unlimited 1.x  
 99 fusedCT Sets  
 99 fusedMRSets  
 0 fusedXRaySets  
 1 oblique Slices  
 1 exportXT

After successful export:

Close iPlan

Start follow-up application: Browse

Enable interpolation for non-512x512 images **Ensure that this feature is checked**

Check settings

Test connection Not tested

OK Cancel

- Perform step 2-3 for all Brainlab Navigation export archives marked with the blue Brainlab snake.
- Perform step 1-3 for all your potentially affected iPlan versions:
  - iPlan CMF 3.0.0 / 3.0.1 / 3.0.2 / 3.0.3
  - iPlan Cranial 3.0.0 / 3.0.1 / 3.0.2 / 3.0.3
  - iPlan ENT 3.0.0 / 3.0.1 / 3.0.2 / 3.0.3
  - iPlan Flow 3.0.0 / 3.0.1 / 3.0.2 / 3.0.3
  - iPlan Spine 3.0.0 / 3.0.1 / 3.0.2 / 3.0.3
  - iPlan Stereotaxy 3.0.0 / 3.0.1 / 3.0.2 / 3.0.3
- When using the software with iPlan Net: Perform step 1-3 for every user login/account.