

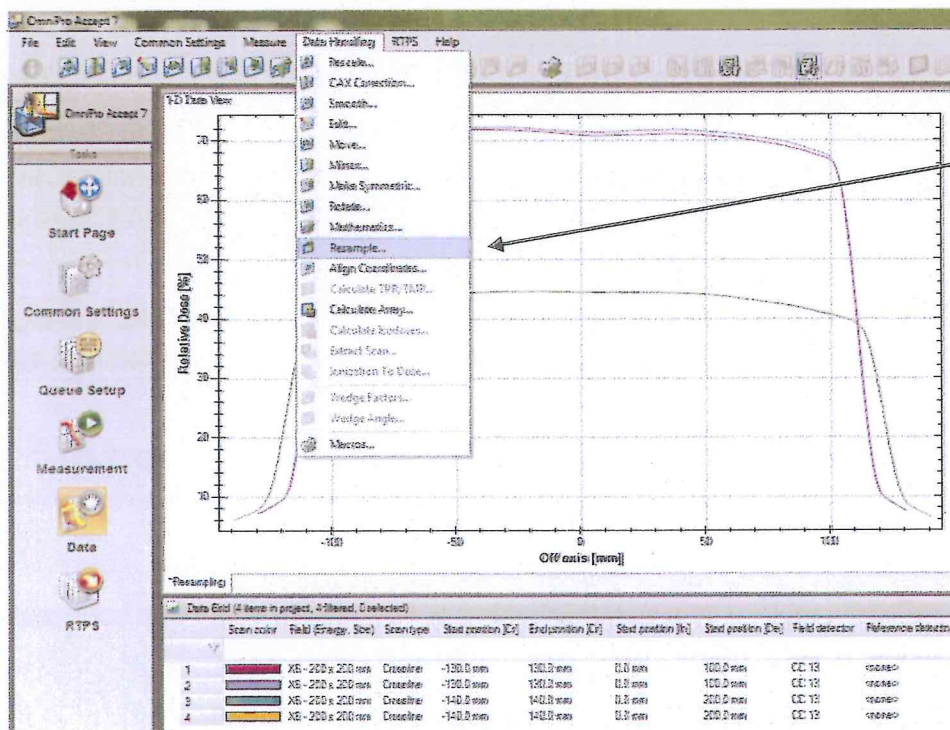
Field Safety Notice

Subject: Software error in *Resampling* Function
Product affected: OmniPro-Accept, Version 7.4a
SW function affected: *Resampling* of measured curve(s)
Type of action: Do not use the *Resampling* function
FSCA-identifier: CAPA-2013-002

Dear Customer,

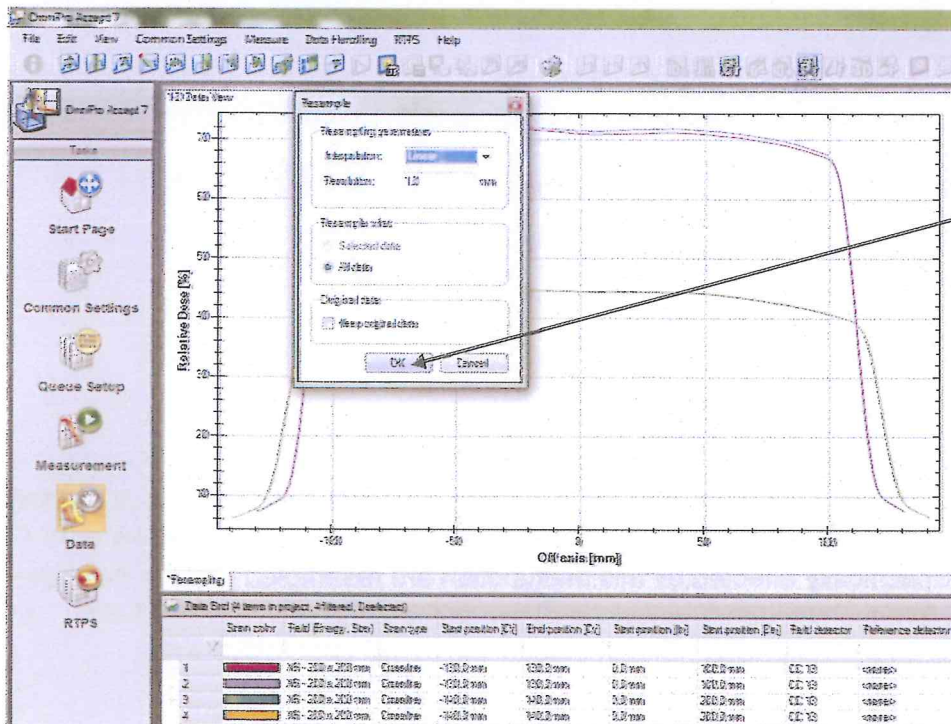
As a result of our continuous product monitoring, we have identified a malfunction in our software OmniPro-Accept Version 7.4a which may potentially lead to inappropriate data transfer to Treatment Planning Systems. Specifically affected by this malfunction are resampled profiles that have been measured without reference chamber (typically e.g. dynamic wedge profile, small fields,...). This constitutes a risk that incorrect profiles may be transferred to the TPS.

The following screenshots illustrate the error's reproduction:



Error occurs if:

Menu item
Resample...
is selected



Problem description:

Using the *Resampling* function for profiles measured without reference chamber results in a mirrored profile curve. X and Y coordinates are flipped, Z coordinates are not affected.

While standard profiles measured without reference chamber are considered less critical, this is not the case for dynamic wedges. We do see a possible risk that the error may go unobserved and therefore may affect the quality of your patient treatment.

We would like to emphasize that validation measurements for a commissioned system are good clinical practice, and are necessary before starting treatments on any new commissioned system. By doing so, critical errors should be detected.

The measured original profiles as stored, regardless of parameter settings used for the measurements, are not affected.

Actions to be taken to prevent the error from re-occurring:

If you have used OmniPro-Accept 7.4a for commissioning or QA, please verify that your profiles are correctly transferred to the TPS.

If you are planning to use OmniPro-Accept 7.4a, please follow below instructions:

- a. To prevent this specific error from occurring, and for best measurement results, always use a reference detector.
- b. Avoid the use of the *Resampling* function for profiles measured without reference detector. Perform the measurement with the requested step-width from your TPS system.



- c. The *Resampling* function can be performed a second time (as illustrated above). This reverses the X and Y coordinates again to the original correct orientation. Attention: The reversal will occur with every resampling. Careful observation is required.

Distribution of this Field Safety Notice:

Please distribute this notice to all those who need to be aware within your area of responsibility where the affected software have been installed (e.g. colleagues, satellites).

Please maintain awareness of this notice and resulting action until we have provided you with a new software version.

We would kindly ask you to acknowledge the receipt of this *Field Safety Notice*. Please sign and send back the attached *Confirmation of Receipt* within four weeks after the receipt of this *Field Safety Notice*.

We deeply apologize for the inconvenience. We are working on a new software version with corrected functionality. This should become available during next fall and we will ship it to you as soon as it is released, together with the installation and verification instructions.

Should you have questions or require additional information, please contact the Customer Service Team at:

Service Department
IBA Dosimetry GmbH
Bahnhofstrasse 5
DE-90592 Schwarzenbruck, Germany
Tel.: +49 9128 607 38
Fax: + 49 9128 607 26
Email: service@iba-group.com

Yours sincerely,

Dr. Lutz Müller
Safety Officer

Andreas Strempl
Product Manager

Andreas Suchi
Director QA / RA



Confirmation of Receipt

Products	OmniPro-Accept v7.4a
Subject	Software Error in Resampling Function in OmniPro-Accept v7.4a
Reference	997-103_FSN001_130722 01

Please sign and date this form and return it in one of the three ways indicated below

<input type="checkbox"/> I have read and understood this notice and confirm my system is <u>not</u> affected by the reported problem.
<input type="checkbox"/> I have read and understood this notice and confirm my system was affected by the reported problem. The recommended corrective action has been applied to my system.
<input type="checkbox"/> I need further support, please contact me.
Site Name _____
Site Address _____ _____ _____
Recipient's Title and Name _____
Phone number _____
Signature _____
Date _____

Fax to: +49 9128 607 26
Service Department, IBA Dosimetry GmbH

Scan and email to: service@iba-group.com
Service Department, IBA Dosimetry GmbH

Mail to (requires postage): Service Department
IBA Dosimetry GmbH
Bahnhofstrasse 5
DE-90592 Schwarzenbruck, Germany

Confirmation of Receipt of 997-103_FSN001_130722 01