

Urgent Field Safety Notice

**Eckert & Ziegler
BEBIG GmbH**

Robert-Rössle-Str. 10
13125 Berlin
Germany
www.bebig.com
SRN: DE-MF-000005760

Contact: Sales Department
Tel: +49 30 94 10 84 119
E-Mail: sales@bebigmedical.com

Subject: DICOM image sequence plane separation precision error in HDRPlus 3.x and SagiPlan

Commercial Name of Affected Product: HDRPlus 3.x, SagiPlan 1.0, SagiPlan 2.0 and SagiPlan 2.2

UDI-DI: N/A, N/A , 04049223118211, 04049223132088

Reference: 2023-10 SagiPlan

Date of Notification: 16th of October 2023

Type of Action: Field Safety Notice

Summary

Recently, an internal rounding error was detected during internal tests with CT images where the slice thickness was specified with two decimal numbers. It was found that the software rounds the input data derived from the DICOM headers to a single decimal number instead of retaining the original two decimal numbers, depending on the specific settings described below. This error may lead to dose deviation in the range of approx. 5-10%. With this field safety notice we inform users how to avoid the error.

Description of technical problem

CT simulations for brachytherapy can vary in slice thickness depending on the specific case, purpose, or application. Manufacturers typically provide a reference protocol for CT scans, which can have a slice thickness range of 0.5 to 6 mm based on the machine's specifications. However, a slice thickness of 3 mm is commonly used for GYN applications without interstitial needles, while a thickness of 1 mm is preferred when interstitial needles are used to achieve more precise reconstruction of applicators and needles. Consequently, users may have the option to select slice thickness with one or two decimal numbers instead of only integers.

In such cases, when users import CT images into HDRPlus 3.x and SagiPlan, an automatic *Image Sequence Check* is performed after loading new images. The results are displayed in the *Image Sequence Check* window (refer to Figure 1).

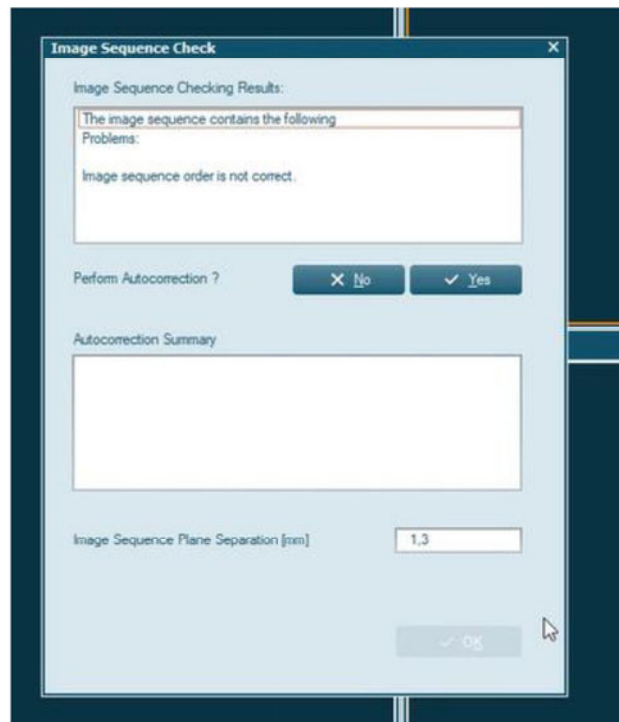


Figure 1 Image sequence check window

The *Image Sequence Check* evaluates image sequences for potential errors and allows for automatic correction when possible or necessary. This primarily applies to DICOM images, as they contain essential information about their position, resolution, and size. For DICOM image sequences, it verifies identical pixel size and consecutive distances. Often, the images are not initially in the correct order, but the *Autocorrection function* automatically sorts them based on their position information.

The *Image Sequence Plane Separation* indicates the slice distance of the loaded image sequence. When DICOM images are loaded, the value is automatically assigned from the DICOM data as the default setting. The *Length Unit* can be in millimeters (mm) or centimeters (cm) and can be selected from the *Plan Setup* section. If the length unit is set to mm, the image sequence plane separation is assigned with only one decimal number, whereas it is assigned with three decimal numbers if cm is the chosen length unit. Consequently, if the CT images have a slice thickness with two decimal numbers (e.g., 1.25 mm), it will be rounded to one decimal number (e.g., 1.3 mm in this example) and presented to the user as the image sequence plane separation. If the user does not manually adjust the number to the correct value with two decimals, the images will be imported into the software with the incorrect slice thickness. This issue can be avoided if cm is used as the length unit for *Image Sequence Plane Separation* (e.g., 0.125 cm in this example).

Risk to patient

In case *Length Unit* in *Plan Setup* section is **cm**, there is no risk as long the setting is not changed.

In case *Length Unit* in *Plan Setup* section is **mm** but the image sequence is with **one** decimal number in mm, there is no risk as long the setting is not changed to two decimal numbers in mm.

In case *Length Unit* in *Plan Setup* section is **mm** and the image sequence is with **two** decimal numbers in mm, carefully read the following to evaluate the risk for your case:

If the user does not modify the setting during import to correct two decimal numbers in mm for *Image Sequence Plane Separation*, the imported images will have an incorrect slice thickness, resulting in inaccuracies in the Z-direction (longitudinal). In brachytherapy, the region of interest is typically confined within a 10 cm range in each direction relative to the applicators. For instance, in the case of a 1.25 mm slice thickness, this would mean that 80 slices are positioned within a 10 cm length. Consequently, there would be a 4 mm deviation in the region of interest, calculated as 80 slices multiplied by 0.05 mm.

It's important to emphasize that this deviation occurs only in the Z-direction, while the image dimensions in the X and Y directions remain accurate, as the slice thickness only affects the Z-direction. Consequently, the dose distribution presented to the user during treatment planning will be especially incorrect in the Z-direction (refer to Figure 2). This discrepancy impacts the parameters used for evaluating treatment plans for both tumors and organs at risk, leading to a slight overdose/underdose of tumors and organs at risk in this example. As the image will be stretched in Z direction, dose deviation has more effects on Z direction and depends on organ and tumor locations, dose deviation might result overdose/underdose in different cases. We currently estimate maximum 5-10% dose error on target and nearby OARs in different cases.

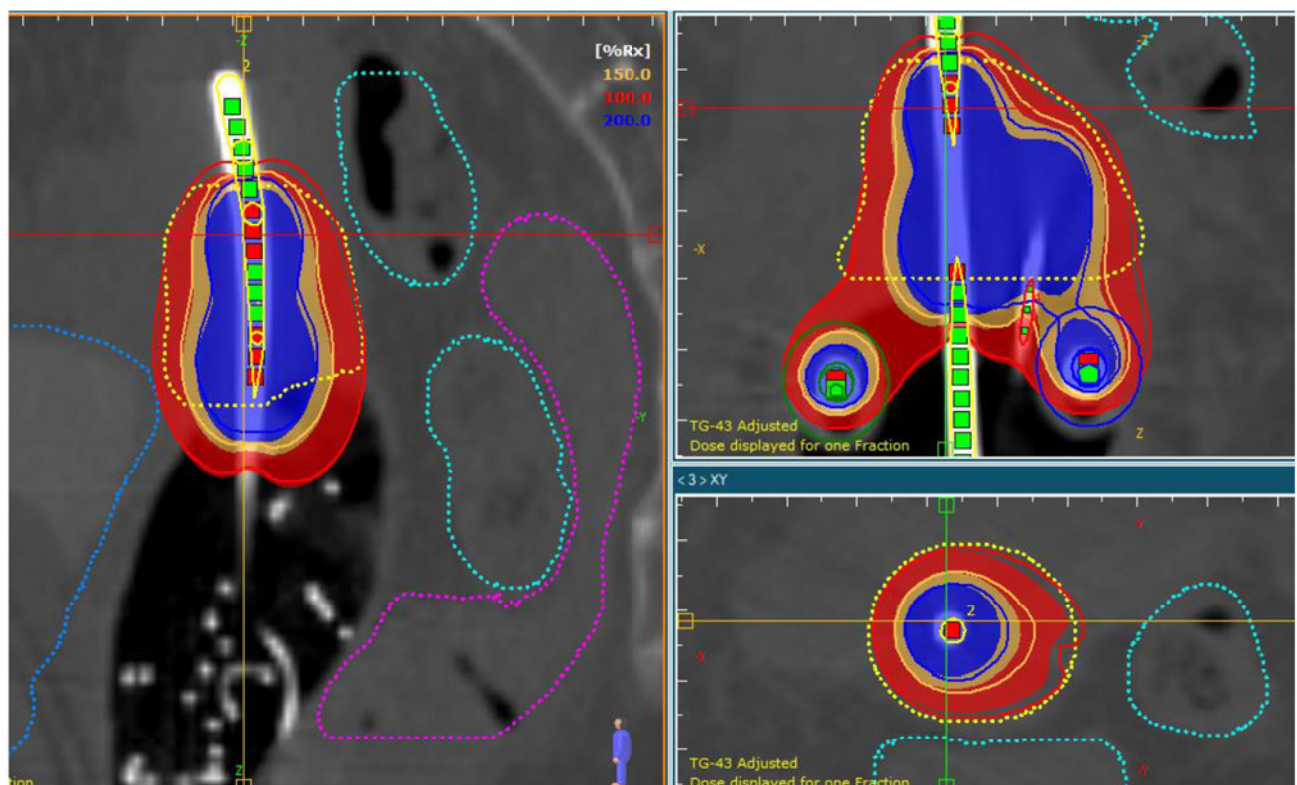


Figure 2 Example of treatment planning with imported wrong (1.3mm in this example) and correct (1.25mm in this example) slice thickness. Colorwash is dose distribution with correct slice thickness while isodose line is dose distribution with incorrect slice thickness. In this example, upper part of tumor is overdosed and lower part is underdose. In total, D90 and V100 of tumor increased 4.7% and 3.3%, respectively. D2cc for bladder, rectum and sigmoid increased 2.6%, 2% and 4.1%, respectively.

Advise on action

To ensure accurate treatment planning and avoid potential errors, all users must follow the steps indicated below:

1. If the user selects a standard slice thickness with integer numbers like 1-3 mm or one decimal number in mm, no problems will occur (Steps 2 and 3 not required).
2. Otherwise, in the *Plan Setup* section, under *Miscellaneous*, ensure that the *Length Unit* is set to centimeters (refer to Figure 3). Once this setting is in place, there will be no issues when importing CT images (Step 3 not required).
3. If the *Length Unit* is set to millimeters, user must carefully review and, if necessary, adjust the Image Sequence Plane Separation value during import when working with slice thicknesses that have two decimals, as shown in Figure 1. Users must consider that this approach is not intrinsically safe, therefore solution 1 or 2 is highly recommended.
4. If you have used mm as length unit and may have used two decimal numbers in mm for slice thickness, carefully review the patient cases and act accordingly.

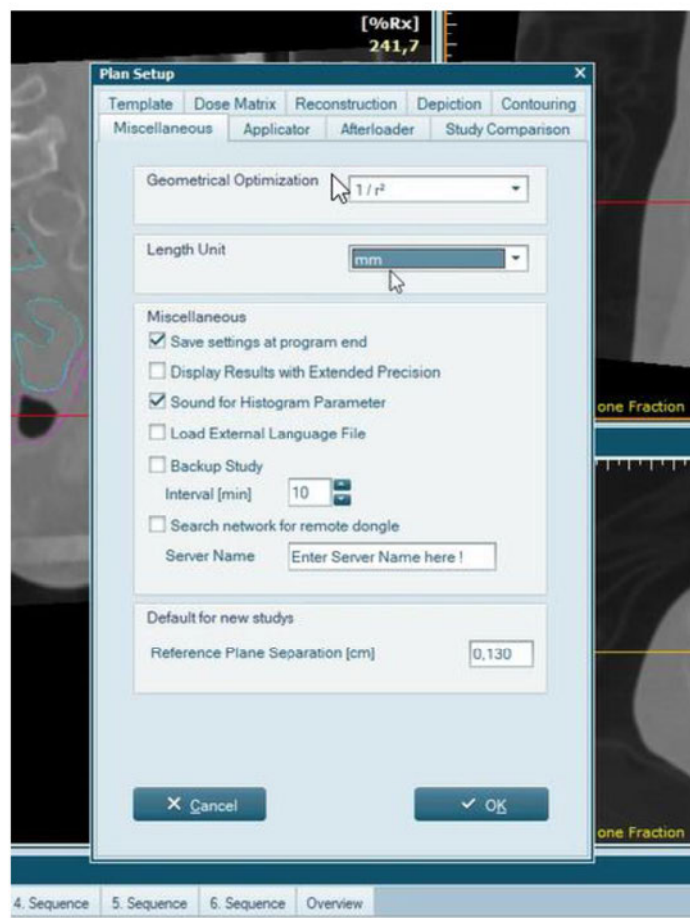


Figure 3 Plan Setup section, under Miscellaneous, the Length Unit

Note

Please note that after the initial installation of HDRplus and SagiPlan (all versions), the default *Length Unit* settings are **centimeters** and **millimeters**, respectively. So, HDRplus users need not worry if they haven't altered the default settings. However, SagiPlan users should review and act according above mentioned instructions.

According to the recommendations provided by ICRU89 and GEC-ESTRO, the prescribed dose for cervical cancers should fall within the range of 80-90 Gy EQD2. Furthermore, publications like RetroEMBRACE and EMBRACE have specified dose constraints for the target in image-guided adaptive brachytherapy (IGABT). The planning objective should aim for a dose greater than 90 Gy EQD2, with limits for the prescribed dose exceeding 85 Gy EQD2. It's essential for users to assess the dose uncertainty on an individual case basis, and as long as it remains within the range indicated by these guidelines, there should be no significant concern regarding treatment failure.

On the other hand, a publication titled "Review of clinical brachytherapy uncertainties: Analysis guidelines of GEC-ESTRO and the AAPM" has estimated total uncertainties ranging from 8-13% for various gynecological (GYN) cases. The margin of error in treatment planning is approximately 3-4%. Therefore, even accounting for the potential maximum dose error, it is unlikely to have a severe impact on treatment outcomes. However, it is highly recommended for users to estimate dose deviations, as these can vary based on different factors and are not a fixed value for all cases.

Solution

This problem will be fixed in the upcoming release of SagiPlan (Subject to market clearance in some markets). If clients want to continue using versions of SagiPlan / HDRPlus that are affected by this notice, all users must be aware of it. Customers can also update to the latest version once it is released for clinical use.

Medical Systems User Actions

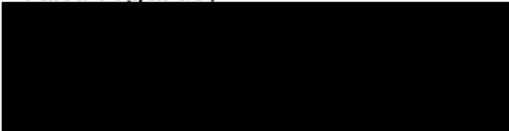
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the devices have been transferred to.

Please reply to this email by 20th of October 2023 confirming that you have received and understood this information and that you have forwarded it to the people which already have received the named products or will receive them.

The undersign representative from Eckert & Ziegler BEBIG GmbH confirms that this notice has been notified to the appropriate Regulatory Agency.

We sincerely apologise for any inconvenience and thank you in advance for your cooperation. For further information please feel free to contact us.

Kind regards,


Regulatory Affairs Manager

CONFIRMATION

**Urgent Field Safety Notice from Eckert & Ziegler BEBIG GmbH,
Reference # 2023-10 SagiPlan**

This is to confirm that we have received and understood the Field Safety Notice. It was forwarded inside our clinic to the respective personnel.

Name of clinic:

Country, City:

Treatment planning system type: HDRplus SagiPlan

Afterloader type: SagiNova MultiSource GyneSource

Afterloader Serial Number:

Name:

Signature, date: