



## **FIELD SAFETY NOTICE**

**Subject:** Stealth Chamber as a reference detector in relative dosimetry  
**Product affected:** Stealth Chamber  
**Function affected:** PDD and profile measurements  
**Type of action:** Follow the instruction in this Notice  
**FSCA-identifier:** CA-2017-004  
**Date:** 2017-04-21

Dear Customer,

We have identified a potential safety issue related to the Stealth Chamber as a reference detector for water phantom measurements. This Field Safety Notice is intended to provide you details about the issue and actions to **be taken by you** to avoid the occurrence of the identified issue.

Please read the following paragraphs attentively.

### **Affected device:**

Stealth Chamber, Part No.: DS50-001-XL-T, DS50-002-XL-T, DS50-003-XL-T, DS50-102-XL-T, DS50-103-XL-T

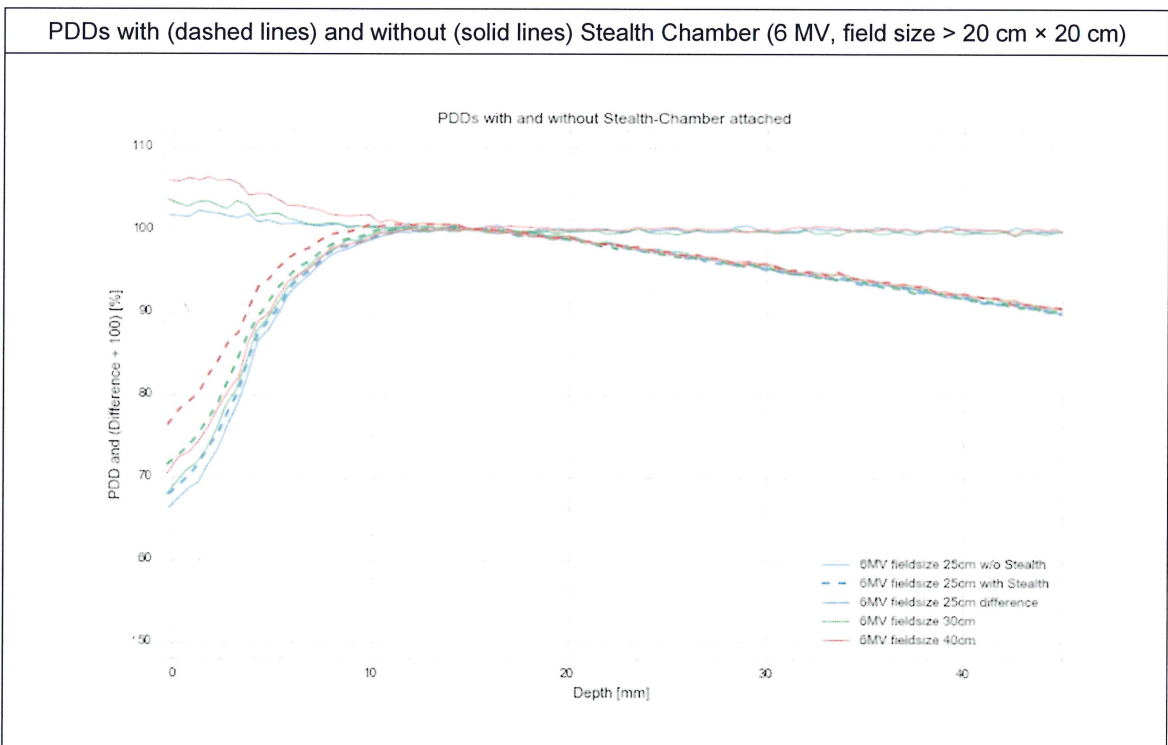
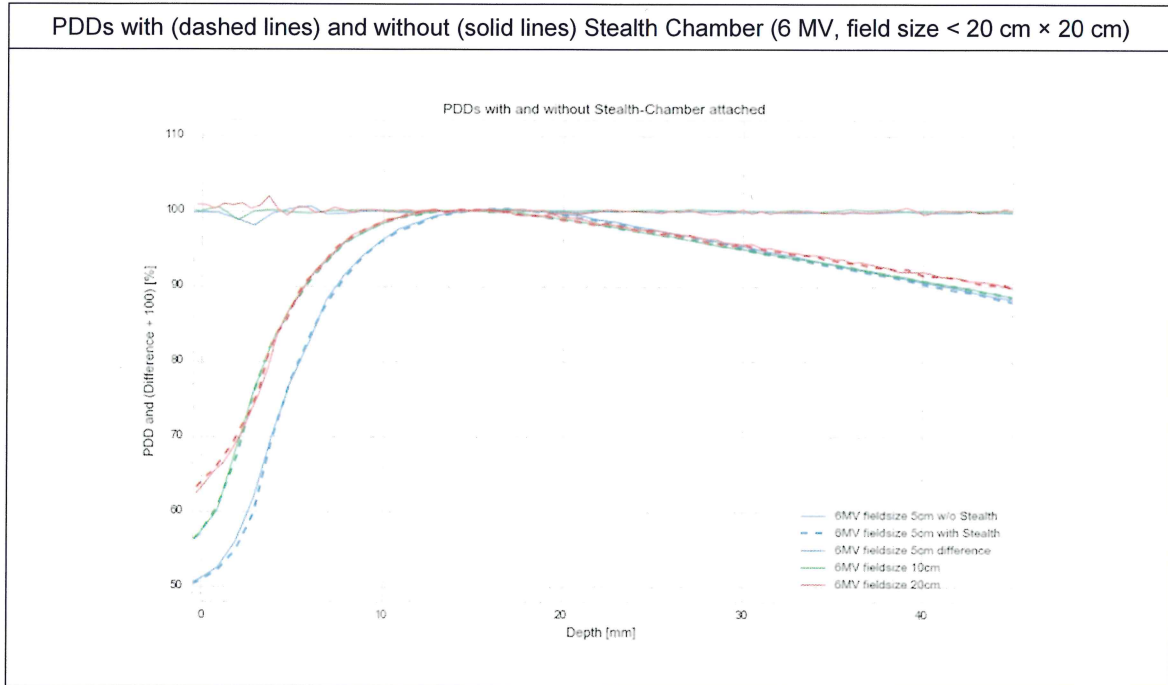
### **Problem Description:**

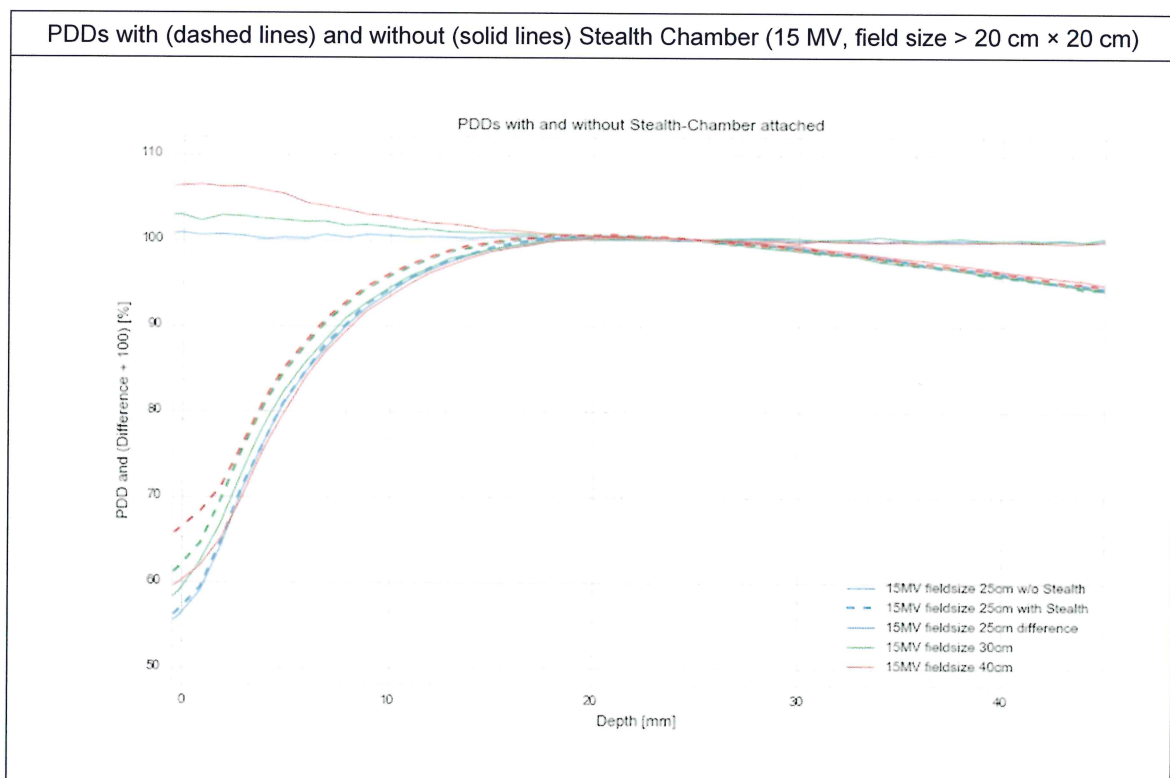
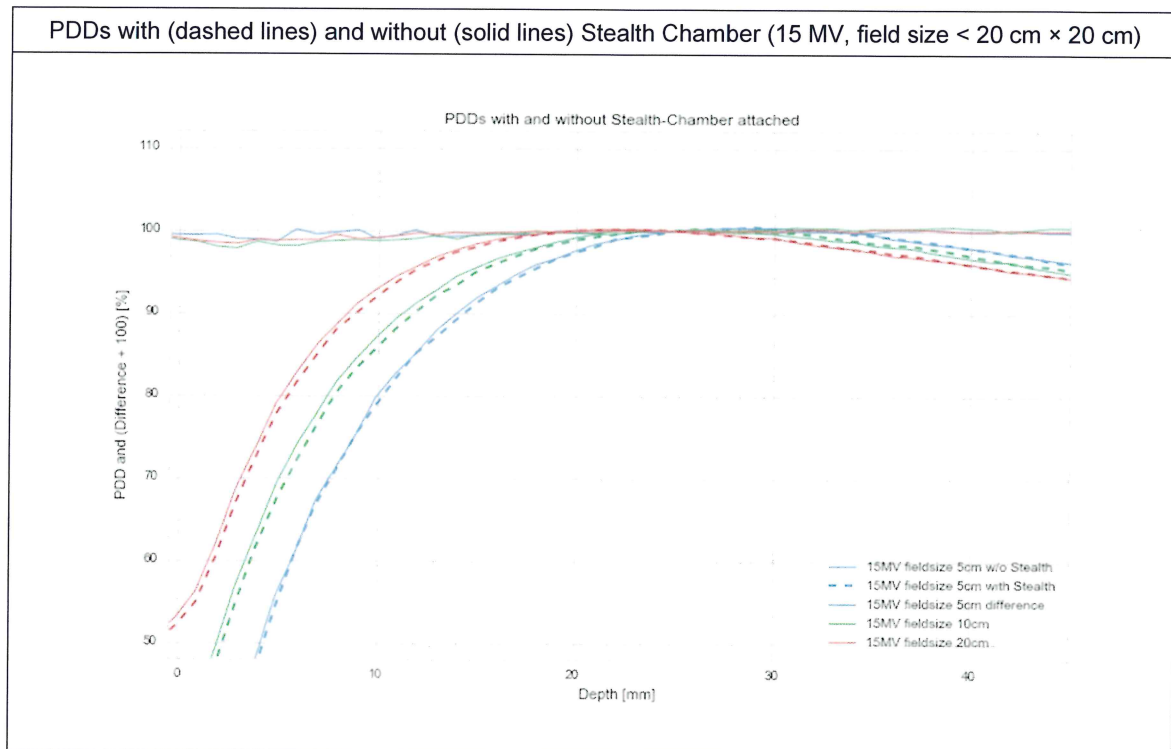
When Stealth Chamber is used as a reference detector in relative dosimetry, deviation in the measured PDDs at shallow depths and geometric shadowing of measured profiles may appear.



## PDDs

Deviation in the measured PDDs at shallow depths is presented on the plots below, where X-axis is presenting depth and Y-axis PDD and (Difference+100)%

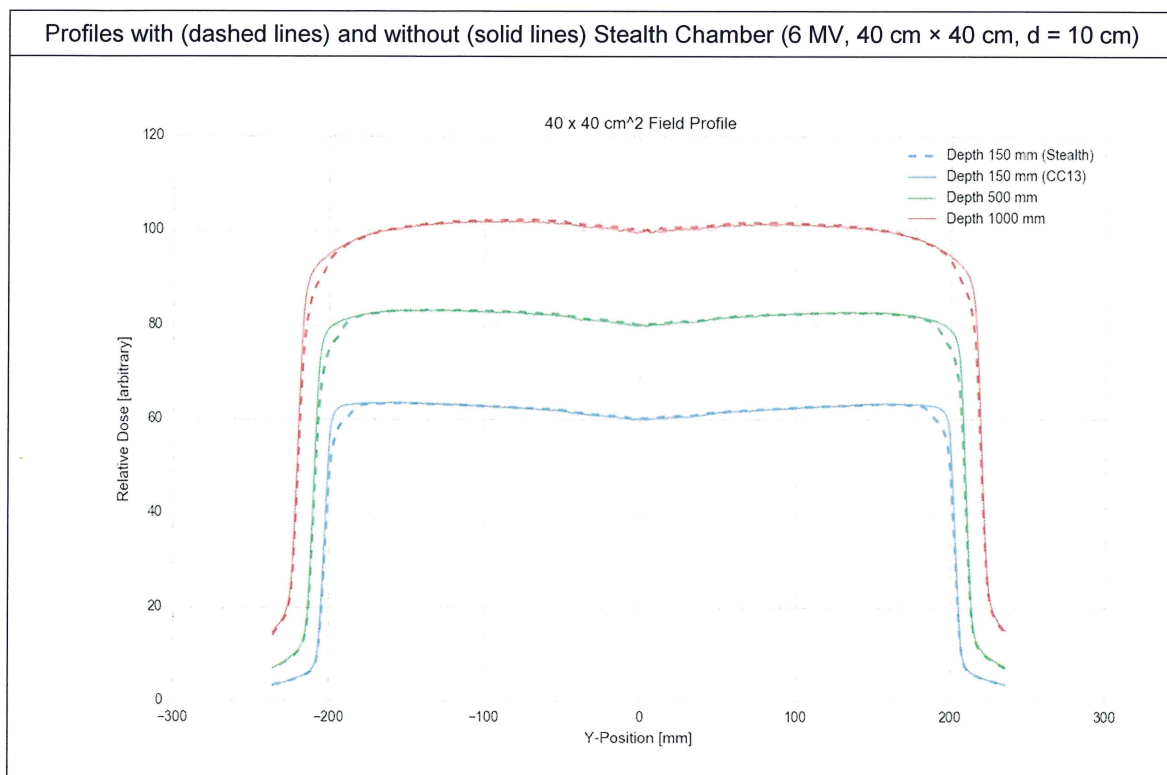






## Profiles

For certain field sizes, profile differences can be observed; see an example showing 40 cm × 40 cm field below. The deviation may occur in the shoulder region, due to the insufficient inner clearance of the Stealth Chamber.



## Summary

For PDDs, the higher energy and larger field size, the greater the deviation. The deviation occurs in lower depth region.

For profiles, the deviation only occurs in the shoulder region for the large field size (40 cm × 40 cm).

## Actions to be taken:

If a Stealth Chamber has been used during commissioning of Linear Accelerator and Treatment Planning System, we kindly ask you to consider those deviations for larger field sizes (> 20 cm × 20 cm) and higher energies (> 6 MV). Please recheck the influence of the PDD deviations and insufficient clearance for 40x40 profile on your beam model and its clinical relevancy. Also, check how they affect the treatment methods used in your clinic. Please return attached confirmation form to us within two weeks after receipt of this notice.



## **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 product is in use.

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 **two weeks after the receipt of this Field Safety Notice**.

We sincerely apologize for any inconvenience caused.

## **Contact information**

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

### **South and Middle America, USA, and Canada:**

IBA Dosimetry America

Bartlett, TN, USA

[USService@iba-group.com](mailto:USService@iba-group.com)

Phone: +1 901 386-2242

Fax: +1 901 382-9453

### **Asia Pacific, Australia and New Zealand:**

IBA China, Dosimetry Dept.

Beijing, China

[ServiceAPAC@iba-group.com](mailto:ServiceAPAC@iba-group.com)

Phone: +86 10 8080 9107

Fax: + 86 10 80809298

### **All other countries:**

IBA Dosimetry GmbH, Service Dept.

Schwarzenbruck, Germany

[service@iba-group.com](mailto:service@iba-group.com)

Phone: +49 9128 607-38

Fax: +49 9128 607-26

Yours sincerely,

Salih Arican

Safety Officer and Product Manager

Andreas Suchi

Director QA / RA



## Confirmation of Receipt

<b>Product</b>	Stealth Chamber
<b>Subject</b>	Stealth Chamber as a reference detector in relative dosimetry
<b>Reference</b>	DS50_FSN001_20170421_StealthChamber_CA-2017-004 01

- I have read and understood this *Field Safety Notice* and confirm that treatment methods used in my clinic are **not** affected by the reported problem.
- I have read and understood this *Field Safety Notice* and confirm that treatment methods used in my clinic were affected by the reported problem.
- I need further support, please contact me.

Site Name \_\_\_\_\_

Site Address \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Recipient's Title and Name \_\_\_\_\_

Phone number \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

**Please print, sign and scan this form and return it to following E-mail address:**

[fsn@iba-group.com](mailto:fsn@iba-group.com)

Service Department, IBA Dosimetry GmbH