July 17, 2017

Urgent Field Safety Notice

Regarding **ProteusPLUS**

GENERAL INFORMATION	
SUBJECT	Potential range effect due to non-conformity of degrader graphite block 8.
IBA REFERENCE	Problem Report PR-58816
INFORMATION ON AFFECTED DEVICE(S)	
PRODUCT	Proteus 235
BRAND NAME	ProteusPLUS
COMPONENT	Beam Management System
SOFTWARE VERSIONS	N/A
MODE	All
SERIAL NUMBER	SAT.115, SAT.116
REASON FOR FIELD SAFETY NOTICE	
DESCRIPTION OF THE PRODUCT PROBLEM	IBA discovered that the holes for the screw inserts to attach the graphite block 8 to the degrader wheel are too deep. See Annex 1 for a schematic description and x-ray image of the non-conformity. As a result of the non-conformity, the beam could go through an air pocket due to the excess depth of the screw hole instead of graphite leading to range errors and the potential mistreatment of a patient. The graphite block 8 is only used for high ranges (see Annex 2 for detailed values).
RISK FOR THE PATIENT	Mistreatment
RISK FOR THE USER	N/A
FURTHER INFORMATION	IBA is not aware of any patient injury specific to this issue at any of the IBA Proton Therapy sites. IBA is proactively addressing this issue.
ACTIONS	
USER ACTION	In case a patient treatment plan requires the use of the block 8 (see Annex 2 for corresponding ranges), it is recommended to perform a full range verification during the patient treatment plan QA check. After the replacement of the graphite block 8, it is recommended to verify there is no effect on the Bragg peak (see Annex 5 for details).

IBA ACTION	IBA tested the conformity of the graphite block 8 as described in Annex 3. IBA is testing the impact of the graphite block 8 non-conformity with respect to the range accuracy (see Annex 4). IBA will replace on site any non-conforming graphite block (see Annex 5). The date of replacement will be agreed between customer and IBA site team.
CONTACT	
CUSTOMER COMPLAINTS & VIGILANCE DIRECTOR	Sylviane BERGER Vigilance@iba-group.com +32 10 203 787
Helpdesk	+32 2 507 20 81 (available 24/7)

By signing below, the customer representative confirms that this notice has been read and understood and communicated to the appropriate employees within the organization. The customer representative confirms also that this notice has been received in both English and national language (if different than English).

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Your National Competent Authority has been informed of this Field Safety Notice.

We apologize for any inconvenience that this may cause, and we would like to thank you for your cooperation.

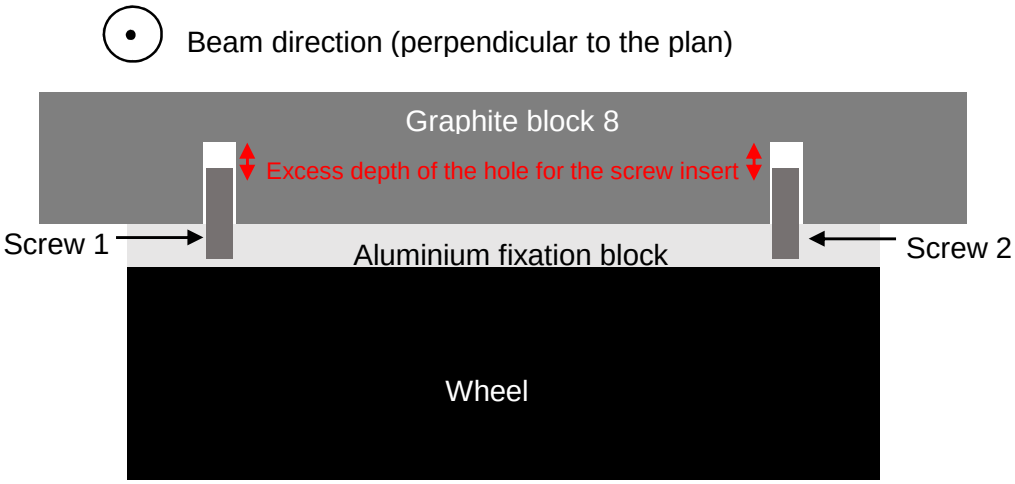
Your IBA representative is able to provide you with additional information and/or guidelines if necessary.

Please return the copy of the notice signed to IBA within 10 working days.

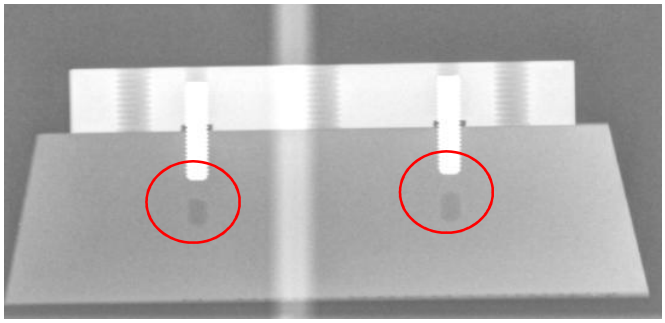
IBA		CUSTOMER
NAME	Sylviane BERGER	**NAME**
TITLE	Customer Complaints and Vigilance Director	**TITLE**
DATE	July 17, 2017	**DATE**
SIGNATURE	[redacted]	**SIGNATURE**

Annex 1 Graphite block 8 screw holes depth non-conformity

Schematic description of the graphite block 8 screw holes depth non-conformity:



X-ray image of non-conforming degrader graphite block 8:



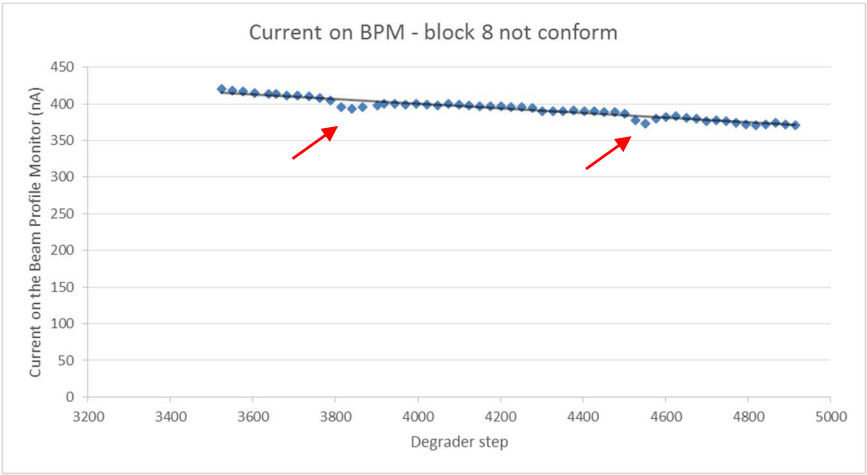
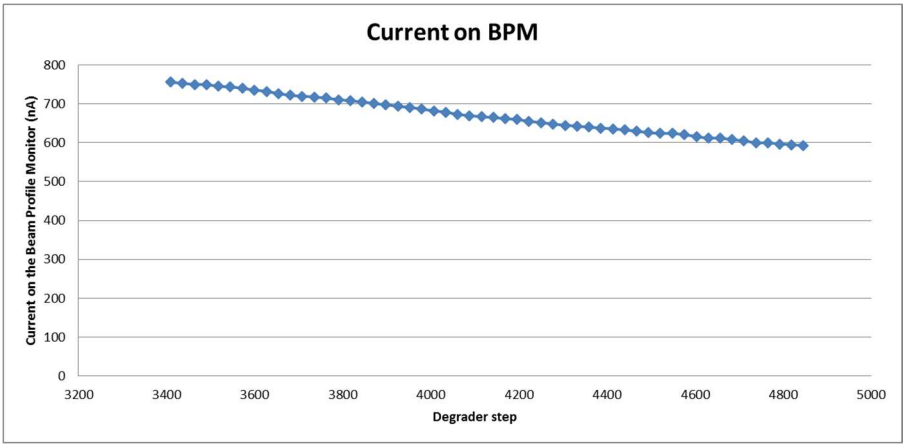
Annex 2 Range at nozzle entrance corresponding to block 8

Sites code	Min range (cm)[1]	Max range (cm)[1]
PAT.115	29.35 (degrader step 4914)	31.00 (degrader step 3524)
SAT.116	29.11 (degrader step 4988)	31.07 (degrader step 3497)

[1] In water equivalent material

Annex 3 Test to detect the non-conformity

This test shall be performed by a trained IBA engineer.

Conformity test	
Tools & Method:	Measure the current after the Energy Selection System on the Beam Profile Monitor using a 25nA Look Up Table and internal pulse generator. Do the measurement between ranges defined in Annex 2 in steps of 0.03cm. Each range corresponds to a degrader step. Create a chart of the Current on the Beam Profile Monitor in function of the degrader step.
Results analysis:	Non-conform block:  Conform block: 

Annex 4 Test to evaluate the impact of the non-conformity

This test shall be performed by a trained IBA engineer.

Range measurement	
Tools & Method:	Measure the range with the calibrated water phantom and ionization chamber. Measure 3 ranges in the good region to confirm the measurement accuracy. Measure 3 ranges in each bad region to estimate the highest range error due to the non-conformity. For Pencil Beam Scanning treatment mode, use procedure IBA int. ref. MID-18825 (latest validated version) as reference. For other treatment modes, use procedure IBA int. ref. MID-7742 (latest validated version) as reference.
Results analysis:	If the error on the range in the bad region is within tolerances for all treatment modes (±1mm), the block 8 does not have to be replaced. However, IBA recommends to replace it. If the error on the range in the bad region is out of tolerances for any treatment mode (±1mm), the block 8 has to be replaced and the error communicated to the customer.

Annex 5 Test after block 8 replacement

Test after block 8 replacement	
IBA side :	*This test shall be performed by a trained IBA engineer.* Run "CCI intervention procedure" IBA int. ref. MID-48513 (latest validated revision). Mock treatment for all treatment modes (create a plan with 3 layers, all on block 8).
Customer side :	It is recommended to verify that the ranges covered by the graphite block 8 (see Annex 2) are within tolerances.