



Urgent Field Safety Notice

Regarding **ProteusPLUS** and **ProteusONE**

GENERAL INFORMATION	
SUBJECT	Risk of misalignment for plans with multiple isocenters
IBA REFERENCE	Problem Report PR-90463
INFORMATION ON AFFECTED DEVICE	
PRODUCT	Proteus 235
BRAND NAME	ProteusPLUS and ProteusONE
COMPONENT	Treatment Center
SOFTWARE VERSIONS	All
MODE	All
CONFIGURATION	All
SERIAL NUMBER	
REASON FOR FIELD SAFETY NOTICE	
DESCRIPTION OF THE PRODUCT PROBLEM	<p>When creating/importing a treatment plan with multiple isocenters, the user has to enter Patient Positioning System positions manually.</p> <p>The Patient Positioning System positions should have a delta between them that is equal to the delta between the positions of the different isocenters¹.</p> <p><i>E.g.: case of two treatment beams with different isocenters positions</i></p> <ul style="list-style-type: none">- treatment beam 1 with isocenter position (1,1,1)- treatment beam 2 with isocenter position (3,3,3) <p><i>If the Patient Positioning System position for beam 1 is (0,0,0) then Patient Positioning System position for beam 2 should be (2,2,2).</i></p> <p>The Proton Therapy System does not check the delta of the Patient Positioning System positions and delta of actual isocenters. If a Patient Positioning System position is wrongly prescribed, the user is not notified.</p>

¹ Some sites use a sliding table, in this instance, the delta could differ and the example is not valid.



	<p>The Proton Therapy System accepts a plan with multiple isocenters when the Patient Positioning System positions are present, but there is no check on the consistency of those positions and the positions of the different isocenters.</p> <p>If a Patient Positioning System position is wrongly prescribed and if the user does not verify patient positioning with X-ray image for each treatment beam as recommended in the IBA clinical user guide, any offset is possible (no limit).</p> <p>Note that the versions of Oncology Information System MOSAIQ before 2.60 do not support plans with multiple isocenters.</p>
RISK FOR THE PATIENT	Misalignment
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	When using the multiple isocenters workflow, IBA recommends the user to ensure that the delta between the different Patient Positioning System positions corresponds to the delta between the positions of the different isocenters.
IBA ACTION	<p>IBA will implement a check of consistency of the delta between Patient Positioning System positions and the delta between the positions of the different isocenters. In case of mismatch, the proton therapy system will warn the user.</p> <p>This solution will be deployed by December 31, 2018 on all impacted sites.</p>
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, including the Chairman Medical Board and relevant Head of Departments. 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.




August 27, 2018

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	August 27, 2018	DATE	
SIGNATURE		SIGNATURE	