

Urgent Field Safety Notice

Regarding **Proteus235**

GENERAL INFORMATION	
SUBJECT	Gantry rotation or proton irradiation can be allowed even if apertures or accessories are not correctly positioned in snout 300x400 or snout XL
IBA REFERENCE	Problem Report PR-97145
INFORMATION ON AFFECTED DEVICE	
PRODUCT	Proteus 235
BRAND NAME	ProteusPLUS
COMPONENT	Positioning Management System and Beam Management System
SOFTWARE VERSIONS	Not applicable
MODE	Uniform and Pencil Beam Scanning
CONFIGURATION	Universal Nozzle with snout 300x400 PBS Dedicated Nozzle with snout XL
SERIAL NUMBERS	PAT.003, PAT.006, PAT.107, PAT.108, PAT.109, PAT.110, PAT.111, PAT.113, PAT.114, PAT.115, SAT.116, SAT.120, SAT.126, SAT.132.
REASON FOR THIS NOTICE	
DESCRIPTION OF THE PRODUCT PROBLEM	<p><u>Snout 300x400 (Universal Nozzle):</u></p> <p>The Proton Therapy System prevents gantry rotation if an aperture's or accessory's (range shifter, ridge filter, range compensator) locking pin is not activated, regardless of the status of the insertion pins. It is however possible for the user to insert an aperture or accessory incorrectly and have the locking pin activated (see annex 1). If the gantry is rotated in this configuration, the accessory may fall.</p> <p>The Proton Therapy system prevents proton irradiation if at least one insertion pin or one locking pin is not activated.</p> <p><u>Snout XL (PBS Dedicated Nozzle):</u></p> <p>The Proton Therapy System prevents gantry rotation or proton irradiation if an aperture's or accessory's (range shifter, ridge filter, range compensator) locking pin is not activated, regardless of the status of the apertures' insertion pins.</p> <p>It is however possible to insert an aperture only partially with both sides in the guides and have the locking pin considered activated</p>

	<p>(see annex 2). It is also possible to insert apertures with one side outside the guide and have the locking pin activated (see annex 3). Therefore, there are two cases:</p> <ol style="list-style-type: none"> 1) If snout XL is used with apertures and accessory on top, it is not possible to have apertures with one side in the guide and the other side outside the guide and there is no risk of aperture fall. But if the treatment is performed with one aperture only partially inserted (see annex 2), it may lead to a mistreatment. 2) If snout XL is used with apertures but without accessory on top, it is possible to insert apertures with one side outside the guide and have the locking pins activated (see annex 3). If the gantry is rotated in this configuration, apertures may fall. The second risk linked to mistreatment if one aperture is only partially inserted is also present in this case (see annex 2).
RISK FOR THE PATIENT	Crushing Mistreatment
RISK FOR THE USER	Crushing
ACTIONS	
USER ACTION	Verify that apertures and accessories are fully inserted with both sides in the guide.
IBA ACTION	<p>All IBA Proton Therapy sites using snout 300x400 or snout XL will receive a solution to prevent occurrences of possible consequences described.</p> <p>This solution will be deployed on or before May 31, 2019.</p>
CONTACT	
CUSTOMER COMPLAINTS & VIGILANCE DIRECTOR	<p>Sylviane BERGER</p> <p>Vigilance@iba-group.com</p> <p>+32 10 203 787</p>
Helpdesk	+32 2 507 20 81 (available 24/7)

By signing below, the customer representative confirms that this notice has been read, 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.

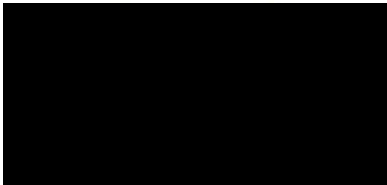


June 24, 2018

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	June 24, 2018	DATE	
SIGNATURE		SIGNATURE	

Annex 1: Snout 300x400 - range shifter support with the left side out of the guide, insertion pins not activated but locking pin activated



Locking pin
activated

Insertion pins
not activated

Range shifter support with
left side outside the guide

Annex 2: Snout XL – aperture partially inserted with both sides in the guides and locking pin considered activated



Annex 3: Snout XL – aperture inserted with one side outside the guide and locking pin activated



Locking pin
activated

Aperture with right
side out of the guide