URGENT FIELD SAFETY NOTICE MID-52553 REV.A

General information	
Subject	General safety risk for use of non-IBA accessories and/or third party equipment or modifications to the IBA medical devices
IBA reference	Problem Report PR-68914
Type	Warning
Product	All
Component	N/A
Versions	N/A
Mode	N/A
Problem description	
Description	It has come to IBA attention that some IBA proton therapy users are using the IBA System in conjunction with non-IBA accessories which have not been validated as being compatible with the IBA System. This Field Safety Notice is to remind you to comply with good practices when using IBA medical devices. These specific warnings will be also added in IBA user manuals. IBA waives, denies and disclaims any and all liability or responsibility for the regulatory compliance, safety, reliability, availability or performance of the IBA System when used in combination with non-IBA accessories or third-party equipment (unless approved in writing and in advance by IBA) or when the IBA System has been modified by the user in an unauthorized way.
Risk for the patient	Various risks that might lead to serious injury or death
Risk for the user	Various risks that might lead to serious injury or death
	Might expose the User to civil, medical and/or product liability.

Actions	
User action	Users are requested not to make any unauthorized modification to the IBA System or IBA accessories. Unless approved in writing and in advance by IBA, any modification to the IBA System or to IBA accessories by the user may cause the loss of the regulatory approval and will void the warranty, and/or be classified as an abnormal failure under the uptime commitment. Users are further advised to integrate / use in conjunction with IBA medical devices only authorized third-party equipment or non-IBA accessories which are qualified by IBA as compatible with the IBA System (like proprietary software installation such as the Oncology Information System).
IBA action	Considering the potential safety risk generated by the use of the IBA System after an unauthorized modification or in combination with unauthorized non-IBA accessories or third party equipment, IBA advises any user to stop using the equipment in this manner. For users that continue using the unauthorized equipment clinically, IBA waives, denies and disclaims any liability or responsibility for the regulatory compliance, safety, reliability, availability or performance of the IBA System and waives, denies and disclaims any liability or responsibility for any and all associated damages, claims, costs, losses or requests. IBA will update the user manuals to include these warnings.
Contact	
Customer Services PT Operations Director	Sophie.Dessart@iba-group.com +32 10 475 997
Regulatory Affairs Director	Anne-Sophie.Grell@iba-group.com +32 10 475 816
Helpdesk	+32 2 507 20 81 (available 24/7)

By signing below, the customer representative confirms that this notice has been received and understood and communicated to the appropriate employees.

The IBA Site Staff or the Customer Services PT Operations Director is able to provide you with additional information and/or guidelines if necessary.

Please return the signed customer copy within 10 working days.

IBA		Customer
Name	Anne-Sophie GRELL	**Name**
Title	Regulatory Affairs Director	**Title**
Date	September 9, 2016	**Date**
Signature	[redacted]	**Signature**

Failure to sign a [redacted] pact the contents herein.