FSN Ref: IBA NCIPT-22638

FSCA Ref: IBA NCIPT-22638

March 18, 2024

Urgent Field Safety Notice

Regarding **IBA Proton Therapy System - Proteus 235**

For attention of all the users of IBA Proton Therapy System - Proteus 235 with a PTS-10, PTS-11 or PTS-12 version.

CONTACT DETAILS OF IBA REPRESENTATIVE	
HEAD OF POST MARKET VIGILANCE	Sonia PINEL Vigilance@iba-group.com +32 10 497 516
HELPDESK	+32 2 507 20 81 (available 24/7)

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Irradiation is not prevented when safety parameters checked by the Beam Access Point Process are out of tolerance.

INFORMATION ON AFFECTED DEVICE	
DEVICE TYPE	Proton Therapy System
PRODUCT	IBA Proton Therapy System - Proteus 235
UNIQUE DEVICE IDENTIFIER (UDI-DI)	(01)05404013801138
BRAND NAME	ProteusPLUS and ProteusONE
PRIMARY CLINICAL PURPOSE OF DEVICE	Proteus 235: "The Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE) is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. The PTS may include a fixed small beam treatment room dedicated to the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation localized to the head and neck."
COMPONENT	Beam Management System
SOFTWARE VERSION	PTS-10 versions, PTS-11 versions, and PTS-12 versions.
TREATMENT DELIVERY TECHNIQUE	All
CONFIGURATION	All
SERIAL NUMBERS	SAT.122 (SE), SAT.123 (US), SAT.125 (IN), SAT.126 (US), SAT.127 (TW), SAT.132 (NL), SAT.133 (US), SAT.136 (IN), SAT.140 (US), SBF.101 (FR), SBF.103 (JP), SBF.104 (JP), SBF.105 (US), SBF.107 (FR), SBF.112 (BE), SBF.113 (US), SBF.117 (ES), SBF.124 (IT), SBF.125 (SG), SBF.128 (US), SBF.135 (US).
REASON FOR THIS NOTICE	
DESCRIPTION OF THE PRODUCT PROBLEM	The Proton Therapy System (PTS) does not prevent irradiation when a safety parameter checked by the Beam Access Point Process (BAPP) is out of tolerance in the clinical site configuration.

	The analysis of the issue showed that there is a malfunction in the Safety Parameters verification mechanism within the BAPP. The expected behavior of the system is that the SafetyParameterCheckerComponent checks for safety parameters violations in the BAPP, i.e. if a safety parameter has its values out of tolerance, and sends notifications to the SafetyParameterCheckerProxy that stops the Treatment Process if one violation is detected in the BAPP. However, due to a communication routing issue between the SafetyParemeterCheckerComponent and the SafetyParameterCheckerProxy, the Treatment Process is not stopped when a violation is detected.
HAZARD FOR THE PATIENT	Mistreatment If a safety parameter has its values outside of the defined thresholds, and there is a failure in the system during the treatment that has an impact on the patient's treatment, the treatment field may be delivered with incorrect beam properties.
HAZARD FOR THE USER	None
BACKGROUND ON ISSUE	The issue was identified during the validation of a new software version of the Proton Therapy System.
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.
TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE USER	None
ACTION BEING TAKEN BY IBA	Immediate action: IBA carried out an analysis to determine if the impacted sites have some safety parameters checked by the BAPP in their clinical site configuration with values leading to violations.

	The result of this analysis showed that there are no sites with safety parameters checked by the BAPP out of tolerance. <u>Intermediate action:</u> Waiting for the solution to be deployed on your site, a regular automatic check that the safety parameters are within tolerances will be implemented. IBA will distribute an Internal User Notice to IBA operators of impacted sites to inform them that operators shall monitor alarms triggered by this check and directly inform you if a violation is detected. The intermediate action will be implemented for your site by April 30th, 2024, at the latest. <u>Final solution:</u> IBA will ensure that the system cannot be used in clinical with safety parameters checked by the BAPP out of tolerances. The final solution will be implemented for your site by December 2025.
GENERAL INFORMATION	
FSN TYPE	New
FURTHER ADVICE OR INFORMATION ALREADY EXPECTED IN FOLLOW-UP FSN ?	No

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 transfer this notice to other organizations on which this action has an impact.

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.

March 18, 2024

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

IBA		CUSTOMER
NAME	Sonia PINEL	**NAME**
TITLE	Head of Post Market Vigilance	**TITLE**
		SERIAL NUMBER
DATE	March 18, 2024	**DATE**
SIGNATURE	Sonia Pinel Digitally signed by Sonia Pinel Date: 2024.03.18 12:35:14 +01'00'	**SIGNATURE**