FSN Ref: IBA PR-118514 **FSCA Ref:** IBA PR-118514

June 10, 2021

Urgent Field Safety Notice

Regarding **Proteus235**

For attention of all the users of Proteus235.

CONTACT DETAILS OF IBA REPRESENTATIVE	
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Proteus235 users may be misled by the popup message displayed by the Proton Therapy System when the Oncology Information System appears disconnected

INFORMATION ON AFFECTED DEVICE	
DEVICE TYPE	Proton Therapy System
PRODUCT	Proteus 235
UNIQUE DEVICE IDENTIFIER (UDI-DI)	Non applicable
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	Treatment Center
SOFTWARE VERSION	All
MODE	Electronic Medical Record Centric mode (EMRC)
SERIAL NUMBERS	PAT.006, PAT.107, PAT.108, PAT.110, PAT.112, PAT.113, PAT.114, PAT.115, SAT.116, SAT.118, SAT.119, SAT.120, SAT.122, SAT.123, SAT.125, SAT.126, SAT.132, SBF.101, SBF.103, SBF.104, SBF.105, SBF.107, SBF.109, SBF.110, SBF.113, SBF.115, SBF.117.
REASON FOR THIS NOTICE	
DESCRIPTION OF THE PRODUCT PROBLEM	A usability issue related to the verification of the connection between the Proton Therapy System (PTS) and the Oncology Information System (OIS polling monitoring) has been reported to IBA. The PTS monitors regularly that the OIS is polling in order to guarantee that EMRC OIS recording and irradiation authorization are accurate and based on the latest equipment positions. When there has been no OIS polling for 5 seconds, a popup message is displayed in AdaPTdeliver. This popup message is an indication that

	there may be communication issues between the PTS and the OIS. The popup message warns the user that the OIS appears disconnected and asks whether the user would like to close the current treatment session: *"The OIS polling has stopped. It seems that the OIS is not connected anymore. Do you agree to close the current treatment session ?"* The user can click on [Yes] or [No]. If the user clicks [Yes], the session is canceled by disconnecting from the OIS. If the user clicks [No], the session remains open and the OIS polling monitoring restarts. As soon as the popup message is displayed, the PTS does not accept further incoming communication from the OIS until the user responds to the popup message. As long as the popup message is displayed, data on the OIS side do not get refreshed and updated. Therefore, there is a risk of mistreatment if the user does not verify with X-ray images or other means, after the display of the popup message, that the patient positions (represented by the couch position, mainly the 3 translations and 3 rotations parameters) recorded in the OIS are correct.
HAZARD FOR THE PATIENT	Mistreatment
HAZARD FOR THE USER	N/A
BACKGROUND ON ISSUE	IBA identified the usability issue while investigating the cause of a complaint.
FURTHER INFORMATION	There has been no known serious injury at any of IBA Proton Therapy sites related to this usability issue.
TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE USER	IBA would like to remind Proteus235 users to verify with X-ray images or other means, after the display of the popup message, that the patient positions (represented by the couch position, mainly the 3 translations and 3 rotations parameters) recorded in the OIS are correct.
ACTION BEING TAKEN BY IBA	Labelling change IBA will update the user manuals to: - Describe under which conditions the popup message appears and the subsequent risks, especially that the equipment positions may not be up to date in the OIS,

	- Remind the user to verify with X-ray images or other means, after the display of the popup message, that the patient positions (represented by the couch position, mainly the 3 translations and 3 rotations parameters) recorded in the OIS are correct, - Recommend the user to verify the OIS user manuals for measures preventing saving outdated patient positions in case of disconnection and to apply these measures before saving the positions in the OIS. The action will be completed for your site by May 31, 2022.
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.

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

IBA		CUSTOMER
NAME	Sylviane BERGER	**NAME**
TITLE	Quality Assurance Director	**TITLE**
DATE	June 10, 2021	**DATE**
SIGNATURE	Sylviane Berger Digitally signed by Sylviane Berger Date: 2021.06.10 20:15:56 +02'00'	**SIGNATURE**