FSN Ref: IBA PR-122324

FSCA Ref: IBA PR-122324

March 7, 2023

Amended Urgent Field Safety Notice

Regarding **Proteus235**

For the attention of all the users of Proteus235.

CONTACT DETAILS OF IBA REPRESENTATIVE	
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FSN Ref: IBA PR-122324 **FSCA Ref:** IBA PR-122324

March 7, 2023

Amended Urgent Field Safety Notice

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

Layers of Uniform Scanning treatment fields may be delivered with incorrect Scanning Magnet setpoints

Please note that this revision of this document supersedes any previous revision

INFORMATION ON AFFECTED DEVICE	
DEVICE TYPE	Proton Therapy System
PRODUCT	IBA Proton Therapy System - Proteus 235
UNIQUE DEVICE IDENTIFIER (UDI-DI)	Not applicable
BRAND NAME	ProteusPLUS
PRIMARY CLINICAL PURPOSE OF THE DEVICE	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	All
MODE	Uniform Scanning
CONFIGURATION	Copley Scanning Magnet Power Supply
SERIAL NUMBERS	PAT107, PAT108, PAT112, SAT116.
REASON FOR THIS NOTICE	
DESCRIPTION OF THE PRODUCT PROBLEM	Layers of Uniform Scanning treatment fields are sometimes irradiated with incorrect Scanning Magnet setpoints. Normally, during operations, the system sends two different setpoints to the Scanning Magnets for X and Y axes. Those setpoints determine the extension of the treatment field. For a Uniform Scanning field, the tuning is carried out only before the first layer irradiated for that field. And if a partially delivered field is resumed, the tuning is carried out before the first layer of the resumed field.

	The analysis shows that the first layer of Uniform Scanning fields is sometimes irradiated with the Scanning Magnets still set at the tuning setpoints instead of being set to the setpoints required for this layer. Other layers are also sometimes irradiated with the setpoints of the previous layer. The impact of the latter case on the treatment is lower because the difference in the Scanning Magnets setpoints between two successive layers is smaller than between the first layer and the tuning. The cause of these events has been identified as a software race condition between the different tasks that handle the Scanning Magnet Electronic Unit (SMEU).
HAZARD FOR THE PATIENT	Mistreatment When a layer is irradiated while the Scanning Magnet setpoints are smaller than expected: - the field size may be smaller than prescribed and the boundaries of the treatment field may not receive the prescribed dose, - and as the dose may be more focused towards the central axis, the scanned area may receive more dose than prescribed. Quantitative information about the impact on the dose distribution is provided in the section Background on issue. When a layer is irradiated while the Scanning Magnet setpoints are bigger than expected: - the field is larger than expected but as it is cut by the aperture, the field size at isocenter remains correct. - and the dose rate is lower than expected but the total dose delivered at isocenter is not impacted. Nevertheless, the dose might not be delivered uniformly.
HAZARD FOR THE USER	None
BACKGROUND ON ISSUE	The malfunction has been identified after an event on a Proton Therapy site that happened during the QA for a specific patient with a Uniform Scanning treatment field. Irradiation logs of Uniform Scanning treatment fields delivered between January 16, 2016 and January 12, 2022 in the Proton Therapy site where the issue has been detected have been analyzed. This analysis identified other occurrences of this issue in the past. On this Proton Therapy site, 494 fields of the 9352 analyzed fields (around 5%) had their first layer entirely delivered with the tuning setpoints and a significant difference between the prescribed setpoints and the tuning setpoints (the tolerance is set to 0.3V).

IBA has computed the maximum and average dose errors (see Figure 1) based on IBA uniformity model :

- the maximum dose error is the maximum difference between the nominal Spread-Out Bragg Peak (SOBP) and the SOBP affected by the issue. For the 494 fields identified, the maximum error varies between 0 and 22,5%.

- the average dose error is the dose error computed over the SOBP uniformity region, defined as the region between the proximal 98% and two distal fall-off widths from the distal 50%. For the 494 fields identified, the average error varies between 0 and 12%.

Similar analyses are being carried out for the other Proton Therapy sites impacted.

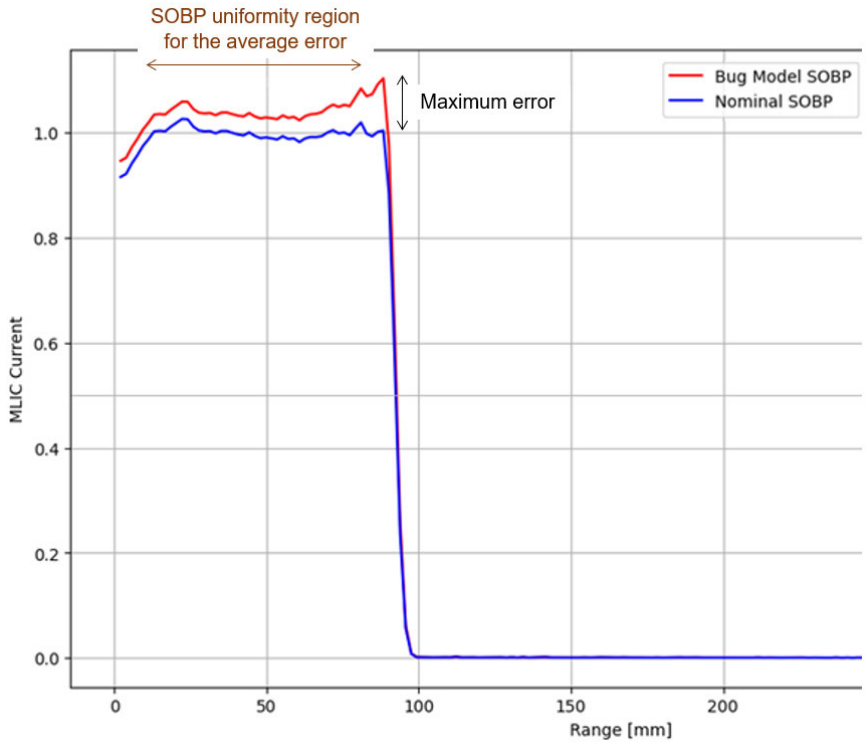


Figure 1: Maximum dose error and uniformity region for the computation of the average dose error

The model was also used to estimate the lateral impact of the issue on these 494 fields. For a normal Uniform Scanning irradiation, the scanned field size is larger than the variable collimators and the apertures. For these fields, the 50-50% field sizes at the tuning setpoints were always larger that the requested field sizes. However, lateral underdoses could not be ruled out, due to the non-flat field in the case of tuning setpoints (see Figure 2).

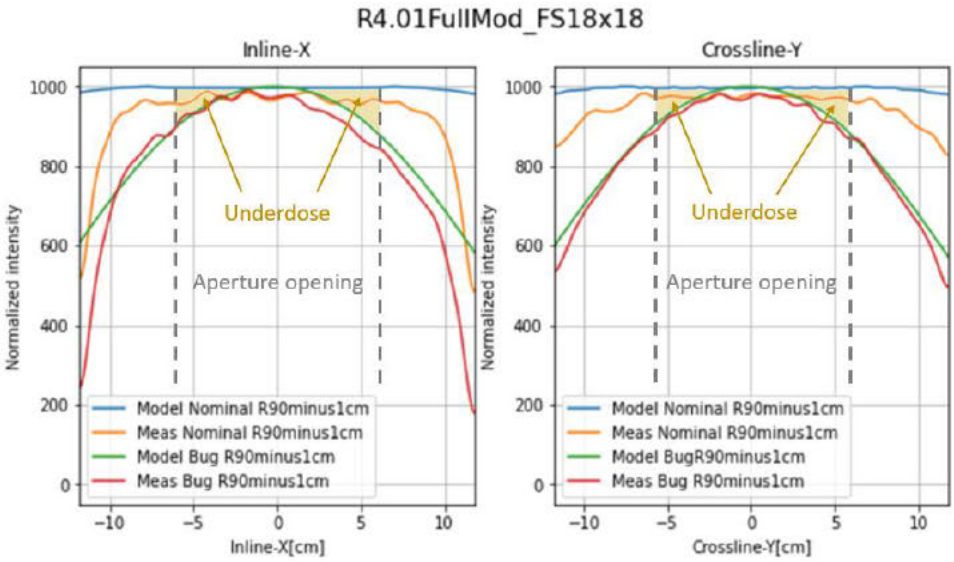
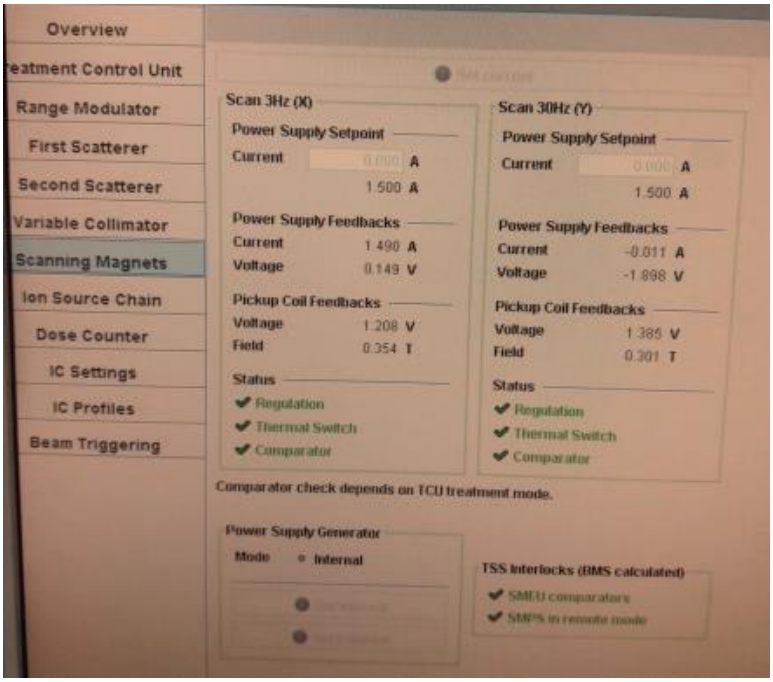


Figure 2: Lateral underdoses with tuning setpoints

On the Proton Therapy site where the issue was detected, the customer identified cases where the 80-80% field sizes at the tuning setpoints did not cover the aperture opening, leading to underdoses superior to 20%. IBA is carrying out further investigation to better quantify the lateral impact.

FURTHER INFORMATION	When the request for setting the Scanning Magnet setpoints fails, the Scanning Magnets setpoints cyclic checks do not identify any discrepancy between the setpoint and the feedback because the system does not update its internal reference. Therefore, these checks do not trigger and do not stop the irradiation. Other cyclic checks, on the field size or/and dose rate, may detect the incorrect proton beam properties and pause the irradiation. However, they are indirect checks and may not prevent from delivering the entire first layer with the tuning setpoints.
TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE USER	Waiting for the solution to be provided, wait at least 10 seconds between the manual reset of the Dosimetry Counter Electronic Unit (DCEU) and the request from the therapist to start the irradiation. This delay will prevent from delivering the first layer with the Scanning Magnets still set at the tuning setpoints. In addition, if a beam pause is generated during the first layer despite the delay between the reset of the DCEU and the start of the irradiation, call IBA operator to check the Scanning Magnets in the nozzle service screen (see Figure 3). If the “Pickup Coil Feedbacks” are still set to 1.5V (+/-0.2V) from the tuning, abort the field and re-load it for another attempt (since the

	problem happens infrequently, the chances are high that the partial irradiation will be able to proceed as expected).  **Figure 3: Nozzle service screens – Scanning Magnets**
ACTION BEING TAKEN BY IBA	The Uniform Scanning field size and dose rate cyclic checks are indirect checks but may pause the irradiation when the aforementioned issue happens. Therefore, IBA is verifying that the field size and dose rate cyclic check thresholds are tight enough and adapting them if necessary. On the site where these actions are not finalized yet, they will be completed by March 31, 2023. IBA will provide each impacted customer with a report including: - The list of the Uniform Scanning fields with the first layer entirely delivered with the tuning setpoints and a significant difference (above 0.3V) between the prescribed setpoints and the tuning setpoints, - The modelled maximum and average dose errors for these fields. The report will be provided by April 30, 2023. IBA is deploying a new PTS version to ensure that: - the irradiation of a layer cannot be started if the Scanning Magnet setpoints for the layer are not properly sent to the Scanning Magnet Power Supply, and - no setpoints request can be lost (even if previous requests are not yet executed or completed).

	On the sites where the new PTS version is not deployed yet, it will be released by March 31, 2023.
GENERAL INFORMATION	
FSN TYPE	Update
REFERENCE NUMBER AND DATE OF PREVIOUS FSN	MID 106777 revC (December 21, 2022) is superseded by the present Amended Field Safety Notice.
KEY NEW INFORMATION	Lateral impact of the issue on the affected fields (in section "background on issue") Actions being taken by IBA and associated dates
FURTHER ADVICE OR INFORMATION ALREADY EXPECTED IN FOLLOW-UP FSN ?	Yes IBA will provide further information about the lateral impact of the issue on the dose distribution.

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 of this notice and the resulting action for an appropriate period to ensure the 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 can 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	[redacted]	**NAME**
TITLE	Head of Post Market Vigilance	**TITLE**
DATE	March 7, 2023	**DATE**
SIGNATURE	[redacted]	**SIGNATURE**