URGENT FIELD SAFETY NOTICE

Regarding **ProteusPLUS and ProteusONE**

MID-59393 REV. A

General information	
Subject	Pencil Beam Scanning system cannot detect dark current from cyclotron
IBA reference	Problem Report PR-83365
Device Details	
Product	Proteus 235
Brand name	ProteusPLUS and ProteusONE
Component	Beam Management System
Versions	all
Mode	Pencil Beam Scanning
Serial Number	PAT.000, PAT.003, PAT.006, PAT.107, PAT.108, PAT.109, PAT.111, PAT.112, PAT.113, PAT.114, PAT.115, SAT.116, SAT.117, SAT.119, SAT.120, SAT.122, SAT.123, SAT.126
Problem description	
Description	It has been observed during testing that there could be clinically non-negligible amount of dark current in Pencil Beam Scanning (PBS) treatment mode when system is not irradiating between layers. Dark current is a well-known physics effect observed in cyclotron. This issue has only been observed when the cyclotron parameters[1] are not optimized. In that case, the dark current value could go up to

[1] When beam is requested, the dee voltage of the cyclotron is set at a high value to produce beam while it is set at a lower voltage when no beam is requested to prevent dark current. To determine the setpoint of the low dee voltage beam intensity will be measured in a treatment room for different dee voltage setpoint.

	5cGy/s at maximum energy. Beyond that value, the safety checks present in the system will stop the irradiation. IBA is currently not aware of any patient injury specific to this issue at any of IBA Proton Therapy sites. IBA is proactively addressing this issue.
Risk for the patient	Mistreatment
Risk for the user	N/A
Actions	
User action	A specific QA map that would detect dark current is provided with this field safety notice. Instruction for use are provided in Annex 1. It is recommended to perform a check to detect potential dark current on a regular basis (IBA recommends monthly) and after each intervention on the cyclotron listed (see Annex 1**)**.
IBA action	Until a solution is implemented on site, IBA operation team will perform dark beam measurement after each intervention on the cyclotron and optimize cyclotron parameters if deemed necessary (see Annex 1). IBA is developing a long term solution consisting of a new IC-cyclo (ionization chamber located at the cyclotron exit) and a Beam Absence Electronic Unit (BAEU). This solution will detect presence of dark current between irradiations. It will prevent starting a new irradiation if dark current is present. This solution will be deployed to all sites using PBS treatment mode. This solution will be validated on the most recent platform in the coming months and deployment after that validation could take up to 2 years depending on the platform.
Contact	
Customer Services PT Operations Director	Sophie DESSART Sophie.Dessart@iba-group.com +32 10 475 997
Customer Complaints and Vigilance Director	Sylviane BERGER Vigilance@iba-group.com +32 10 203 787
Helpdesk	+32 2 507 20 81 (available 24/7)

By signing below, the customer representative confirms that this notice has been read and 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 sign and return only the version in your national language.

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.

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

IBA		Customer
Name	Sylviane BERGER	**Name**
Title	Customer Complaints and Vigilance Director	**Title**
Date	February 9, 2017	**Date**
Signature		**Signature**

ANNEX 1

The dark current test needs to be run after the following cyclotron interventions and, additionally, on regular basis (IBA recommends monthly):

- Cyclotron opening,
- Modification of parameters influencing beam or Radio-Frequency regulation,
- Replacement of the IC-cyclo,
- Replacement of the Radio-Frequency pick-up,
- Replacement of the Low-Level Radio-Frequency rack,
- Replacement of the Beam Current Regulation Electronic Unit,
- Replacement of central region.

IBA engineers actions based on the frequency above:

- Perform the dark current measurement (IBA int. ref. MID-18829 §7.1.1),
- If it fails, calibrate the Low-Level Radio-Frequency settings (IBA int. ref. MID-19373) and perform the dark current measurement again,
- Inform the customer about the cyclotron intervention as described in IBA handover process (IBA int. ref. MID-48059).

Customer actions based on the frequency above:

- Run the “Dark Beam” QA Map[2] with the LYNX dosimetry tool at maximum energy,
- If there is a peak in the center of the beam profile as shown on Figure 1:
  - Confirm it is due to dark current by running the same QA Map at the lowest energy (if there is no peak, it is most probably due to dark current),
  - Contact IBA to analyze and fix the issue.

In case a peak is observed on the beam profile, it is suggested to open a downtime event until the dark current issue is fixed.

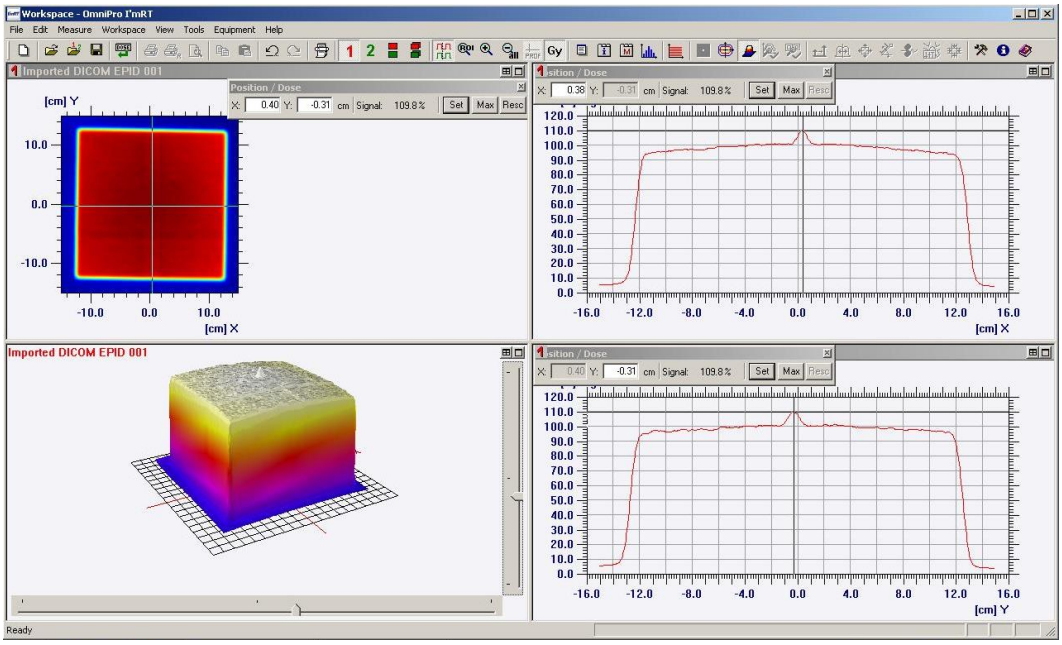

Figure 1 *- Peak in the center of a beam profile due to dark current. Here the pick value is 110% of the dose but it could be a higher or lower value depending on the intensity of the dark current.*

[2] If the « Dark Beam » QA map has not been provided with this field safety notice, please contact IBA.