visionrt

Dove House, Arcadia Avenue
N3 2JU London, UK

URGENT MEDICAL DEVICE CORRECTION NOTIFICATION
URGENT FIELD SAFETY NOTICE

October 15th, 2014

Subject	Potential failure of AlignRT to assert interlock.
Commercial name of product:	AlignRT.
Affected hardware configuration:	Vision RT Integrated Gate Controller (IGC-CS) with Varian Motion Management Interface (MMI) for C-Series. Please note that only Vision RT's recently introduced IGC-CS is affected. Previous versions of the interface (Gate Controller/Gate Commander) are not affected.
Affected software version:	Software versions 5.0.1738 and 5.0.1742 only.
Affected serial numbers:	248-052, 248-066, 248-088, 249-0059, 249-0133, 249-0134, 249-0139. Only two of these systems were used for patient treatment. Six devices are installed in facilities in the USA and one in the Republic of Ireland.
Reference/FSCA identifier:	3010769039-15/10/14-001-C (Vision RT reference).
Type of action:	Notification and device modification (correction).

Dear Customer,

Vision RT is writing to you because it has identified an issue with your AlignRT device.

Reported harm

There have been no injuries reported due to this issue.

Patient harm is not possible as a result of this issue as Vision RT has already disabled the MMI interface on all affected devices, and therefore at this time automated beam-hold is not possible with the affected devices. The affected AlignRT devices may continue to be used for all functions other than automated beam-hold.

The issue was identified during non-clinical testing which was performed two days after the affected configuration was first used for patient treatment. There are no reports of the issue having occurred when treating patients.

Description of the problem and potential risk

When patient motion that exceeds a pre-set tolerance is detected by AlignRT, in rare circumstances and only for the affected configurations referenced above, AlignRT may display a Warning Message on the main screen (see Figure 1) that states a beam hold interlock has been asserted, when in fact no interlock has actually been asserted on the C-Series Linac. Instead, in such circumstances, the beam will be enabled.

Dove House, Arcadia Avenue
N3 2JU London, UK

URGENT MEDICAL DEVICE CORRECTION NOTIFICATION
URGENT FIELD SAFETY NOTICE

As illustrated below in Figure 1, the issue is readily detectable by the user from the AlignRT User Interface because, in addition to the Warning message, the system correctly shows that the Gate Beam functionality is OFF (blue circle), that the beam is currently ENABLED (green circle), and that the real time deltas are out of tolerance (yellow circle in the example). Additionally, the C-Series console should provide visible and audible indication of the actual status of the beam.

When AlignRT displays this message, the software may no longer be controlling beam delivery on the C-Series Linac, which will continue to deliver dose until manually stopped. If the user does not detect the anomaly and does not take appropriate action in a timely fashion, **the issue may lead to the delivery of an unintended dose of radiation.**

Please note that this issue can occur only when the MMI connection is enabled. The MMI connection has been disabled on all affected systems.

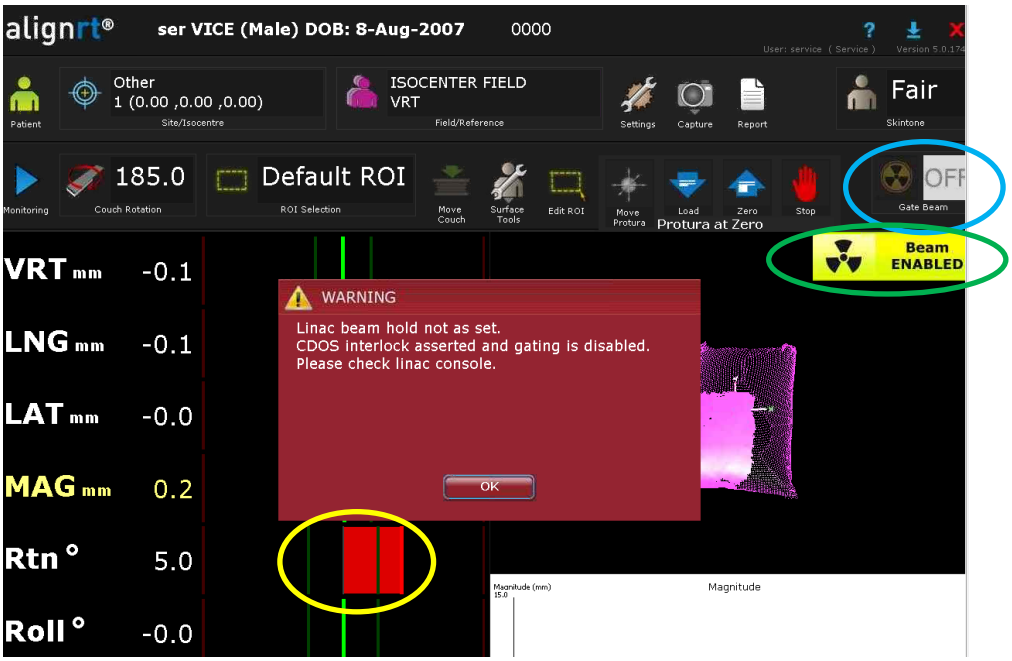

Figure 1: Warning message.

Actions required to be taken by Vision RT

Vision RT has already disabled the MMI interface on all affected devices and did so within 48 hours of identifying the issue.

Vision RT is designing an upgrade that will resolve the issue, and will subsequently contact you in order to install the upgrade on your device. Until the upgrade is available the automated beam-hold function will remain disabled.

In the meantime, your device is safe for any intended use that does not involve the automated beam-hold function, which is disabled.

Dove House, Arcadia Avenue
N3 2JU London, UK

URGENT MEDICAL DEVICE CORRECTION NOTIFICATION
URGENT FIELD SAFETY NOTICE

Actions required to be taken by users and transmission of this communication

Vision RT does not require customers to return their devices.

Customers shall pass this letter to all those who need to be aware of it within their organisation. Awareness of this issue shall be maintained until all actions indicated in this letter have been successfully completed.

Customers shall promptly inform Vision RT if they believe that patient harm occurred due to this issue.

Customers shall complete the acknowledgement in Appendix 1 and return it via email to service@visionrt.com.

Contact Vision RT

Should you have any queries on this letter, please do not hesitate to contact Vision RT by telephone on +44 20 83464300 (866 778-2379 from the US) or as per http://www.visionrt.com/contact/details.

Thank you for your cooperation

Vision RT is committed to the highest standards of excellence, product safety and customer satisfaction and would therefore like to thank you for your support on this matter.

The undersigned confirms that the US Food and Drug Administration (FDA) has been notified by Vision RT of this communication.

Sincerely,

DocuSigned by:

1A1F695F0E324C2...

Francesco Sapia
Quality Assurance and Regulatory Affairs Manager

15 October 2014

visionrt

Dove House, Arcadia Avenue
N3 2JU London, UK

URGENT MEDICAL DEVICE CORRECTION NOTIFICATION
URGENT FIELD SAFETY NOTICE

Appendix 1 - Customer Acknowledgment Response

Recall / FSN ID	3010769039-15/10/14-001-C	
Facility Name		
Contact details (name, job title, telephone and email address) of person completing this Customer response card	Name	
	Job title	
	Telephone	
	Email	
Serial/PCR Number of the device(s)		
I confirm that this notification has been read, understood and distributed within the hospital	☐ **YES** ☐ **NO** **If No, detail rationale:**	