Dove House, Arcadia Avenue
N3 2JU London, UK

MEDICAL DEVICE CORRECTION NOTIFICATION
FIELD SAFETY NOTICE

FAO The Chief Physicist
Address
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Country

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09 August 2018

Subject	IGC PCB (for TrueBeam installations only) does not provide an RTInterface error in the event of an I/O error between the IGC PCB and the Framegrabber PCB
Commercial name of product:	AlignRT
Affected hardware configuration:	Any configuration with the IGC TB PCB fitted (part V000172, firmware 1171 only).
Affected software version:	Not applicable – this recall relates to the IGC TB PCB's firmware only. All affected customers will have either V5.0.1747, V5.0.1748 or V5.0.1749 but this is irrelevant to the scope of the problem or its resolution.
Facility name:	……
Affected serial numbers:	Refer to attached Meddev 2.12/1 FSCA Form
Reference/FSCA identifier:	3004832819-07/25/18-001-C
Type of action:	Notification and device modification (correction) through the remote fix of PCB firmware.

Dear Customer,

Vision RT is writing to you because it has identified a *potential* issue with your AlignRT device – specifically your AlignRT device that is integrated with a Varian TrueBeam linac. If you have multiple AlignRT systems, used without integration with a TrueBeam linac or used with any other type of linac, proton or CT machine then there is no issue or risk with those devices.

Vision RT have identified a fault during the internal testing of new software that is under development, this highlights a *potential* fault in fielded product. This *potential* issue only affects AlignRT systems that are integrated with a Varian TrueBeam linac (including STx and Edge), no other types of linacs, CT or proton devices are affected.

While Vision RT has been unable to reproduce the fault in normal conditions or in high-use (stress) conditions, and while we believe the possibility of the fault occurring is so remote that it is not likely to cause a hazard, our firm believes the potential risk must be addressed.

The risk relates to a Vision RT interface hardware failure during delivery, the likes of which have never been reported. This can only occur if a hardware fault occurs after beam-on has been asserted and during therapy. In this case the AlignRT system would display if a patient moved out of tolerance as normal but the system would not gate the beam. However, due to the nature of the system's design, the system would not be able to reassert beam-on subsequently, so any unintended delivery of radiation could only ever happen to one patient in one field or arc.

Vision RT can confirm that the firm has had no complaints of this issue ever occurring. Additionally, the firm has no evidence of any type of hardware fault occurring with fielded product on any of the PCBs or components which could cause the hazardous situation. Consequently, the firm considers

the chance of such a hardware fault occurring at all to be extremely improbable with a probability of close to zero.

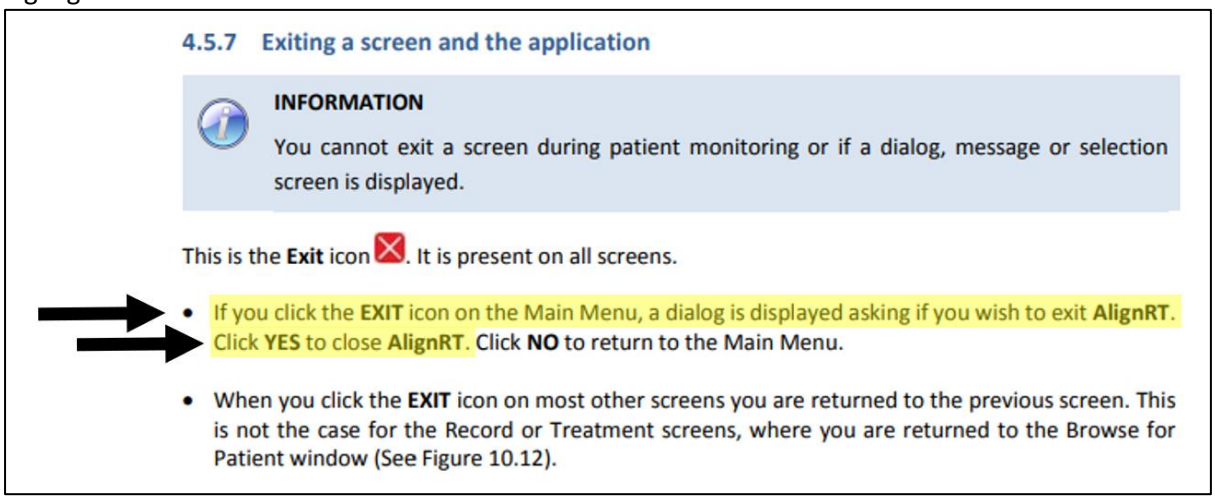
Vision RT reiterates that this is a theoretical condition which we have not been able to reproduce in the current fielded product configuration.

Vision RT does not require customer to return their devices or any part of their devices.

We expect to provide a firmware fix through a remotely-delivered automatic update to your AlignRT workstation. The firmware fix will be provided by our field service staff. This will **be delivered, between the hours of 12pm and 5am (your local time) in the nights of the 21st August through to 31st August**. The process of updating the firmware should take less than 15 minutes.

In order to allow the firmware fix to be uploaded, it is **VITAL that your AlignRT workstation is switched on (the Microsoft desktop is showing) and the AlignRT application is switched off**.

The instructions to close the AlignRT application are provided in the product's User Guide but are highlighted below:



4.5.7 Exiting a screen and the application

INFORMATION

You cannot exit a screen during patient monitoring or if a dialog, message or selection screen is displayed.

This is the **Exit** icon. It is present on all screens.

- If you click the **EXIT** icon on the Main Menu, a dialog is displayed asking if you wish to exit **AlignRT**. Click **YES** to close **AlignRT**. Click **NO** to return to the Main Menu.
- When you click the **EXIT** icon on most other screens you are returned to the previous screen. This is not the case for the Record or Treatment screens, where you are returned to the Browse for Patient window (See Figure 10.12).

Figure 1 - Instructions for Closing the AlignRT Application

Once the application has been closed, the Windows® desktop will be shown, an example for AlignRT is shown below:

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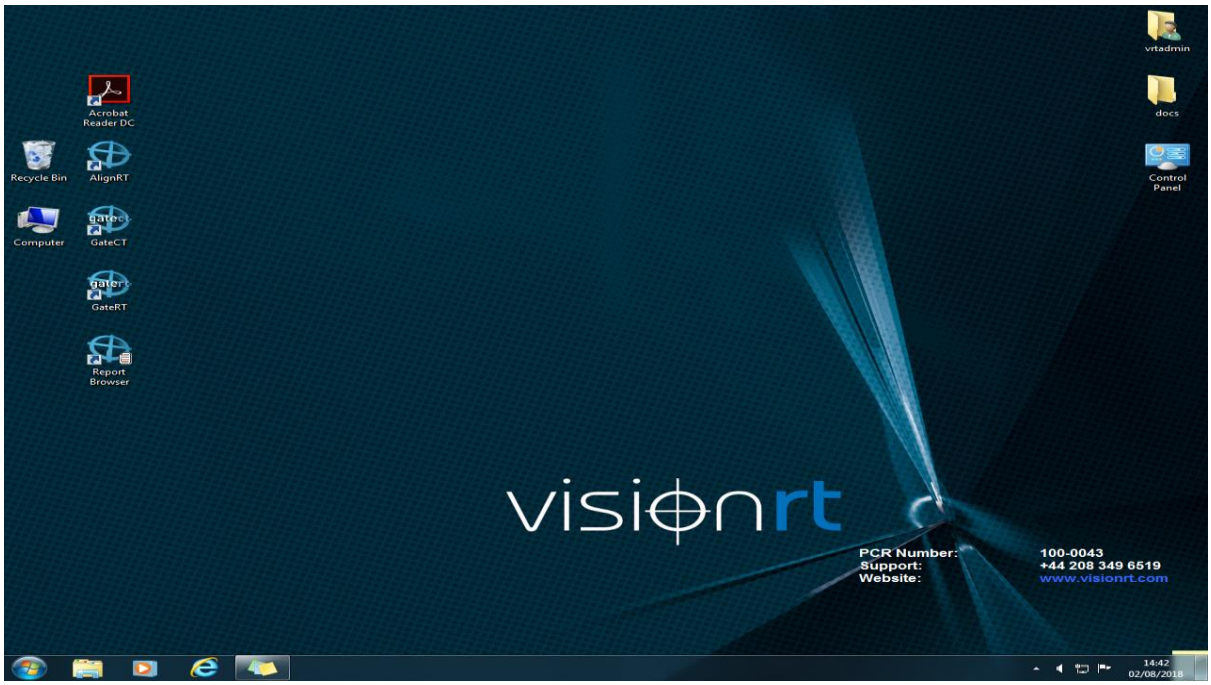

Figure 2 - Typical Desktop Showing AlignRT Has Been Closed

IMPORTANT – ensure that the application has been closed and not simply minimised. Check this by ensuring that the application is NOT shown in the task bar at the bottom of the desktop.

Please ensure that your workstation is left in this state between 12pm and 5am (your local time) in the nights of the 21st August through to 31st August. If you do not do this, or do not have a network connection to your workstation, this will be identified by our service team who will make contact with you to arrange the update of your system directly. In some cases, you may be contacted by our local distributor instead.

Once the fix has been implemented, you will not be required to do anything other than restart your machine.

Please note, this will not require any hardware or software changes, replacements or modifications – only a firmware fix to a single PCB is required. The firmware will be loaded onto a single PCB within your system, it will not affect any software within the workstation or the camera. This fix does not require a service contract.

The fix will not affect any existing system settings or files. The firmware change will not require any recalibration or retest of the system. Until your firmware is fixed, Vision RT recommends that users check and ensure that beam hold is asserted on your linac when AlignRT signals that beam hold should be asserted.

We request that customers 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.

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Vision RT requests that customers promptly inform us at ComplaintsHandling@visionrt.com, if they believe the issue may have occurred and particularly if there was any patient harm involved.

Customers are requested to complete the acknowledgement in Appendix 1 and return it via email to RecallSupport072518@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.

Sincerely,

Chris Hannan
Vice President - Quality Assurance and Regulatory Affairs

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Appendix 1 - Customer Acknowledgment Response

Recall / FSN ID	3004832819-07/25/18-001-C	
Facility Name (please ensure the information is legible)		
Contact details (name, job title, telephone and email address) of person completing this Customer response card	Name	
	Job title	
	Telephone	
	Email	
	Signature	
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:**	