



Complaint: CN-000284

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November 28, 2019

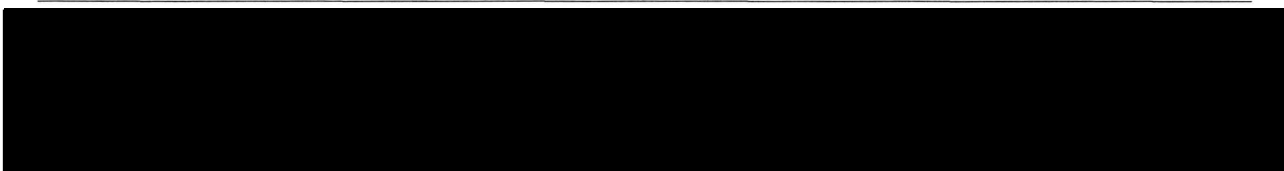
Urgent Field Safety Notice

PA-003, c4D Software application v 5.4.2 and earlier, Catalyst and Catalyst HD client with C-RAD Gating Box HZ-009, used for gating on Varian C-Series accelerators

Subject: No beam control if Gating box HZ-009 loses power during treatment

This notice is intended to provide clarification of the use of the C-RAD Gating Box HZ-009.

For Attention of: Physicians and other medical professional users of Catalyst and Catalyst HD client with C-RAD Gating Box HZ-009, used for Varian C-Series EXGI interface



Details

Gating Box HZ-009 is a C-RAD product, compliant to the Varian EXGI interface specification at current revision. Gating Box HZ-009 can send beam hold and interlocks to the Varian C-series Linac and facilitates gated treatment with Catalyst. The Catalyst and the Gating Box HZ-009 have been fully verified and validated together with Varian and the combined system is proven to be compatible and patient safe.

In order to not interfere with non-gated treatment, the system is designed according to interface specification with an override/bypass functionality. The system is also designed to be able to override an ongoing gated treatment. The override/bypass mode is entered when the switch box key is switched off or when box is powered off (in line with interface specification).

The potential issue is that if the gating box loses power the override mode is entered even if the power loss was unintended and the gated treatment may be unintentionally overridden/bypassed.

If the gating box is disconnected from power c4D will display a status indicating that gating is bypassed, see Figure 1. (the status "GATING BOX BYPASSED" is shown both when the switch box key is switched off, or regardless of key switch status if the gating box is disconnected from power)

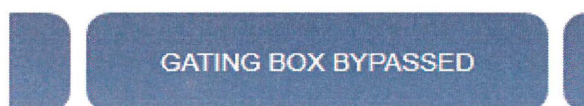
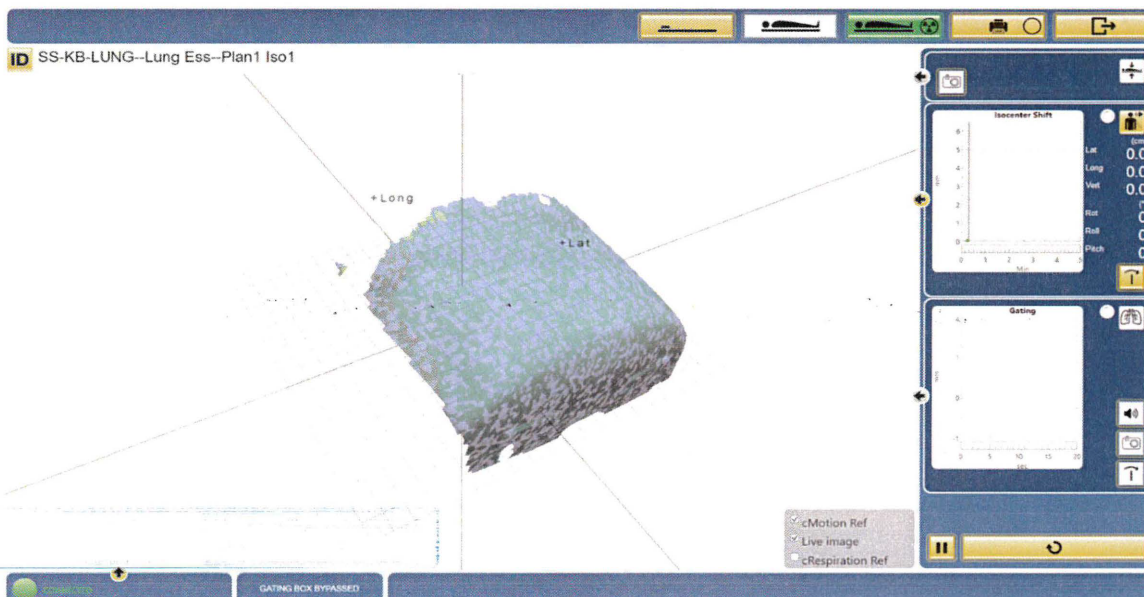


Figure 1, Gating Box bypassed GUI indication.

If the user continues the treatment after this message is displayed, the treatment can proceed without the beam being gated. The situation is equivalent to the switch box key being switched to off. Treating the plan without gating may lead to mistreatment and patient harm.

The potentially missed beam control affects only the ongoing treatment fraction, for subsequent treatment fractions the C-RAD c4D host computer software will raise a warning dialogue if trying to

enter the Treatment state if the gating box is bypassed (which is equal to gating box without power). The user needs to act on this warning dialogue in order to activate the gating box.

Affected systems

The issue is potentially affecting all Catalyst customers doing gated treatments using the Gating Box HZ-009.

Potential issue

The issue can only occur if the power to Gating Box HZ-009 is lost during gated treatment and the potential risk is that the power failure of the gating box can result in a treatment session without intended gating (the gating is unintentionally overridden/bypassed).

C-RAD has not received any reports or complaints of injury due to this issue.

Type of action to mitigate the risk

User actions

Ensure all staff working with the Gating Box HZ-009 and c4D software are aware of this information.

As an immediate action affected customers should ensure to use a common power source for the Catalyst Client computer and the Gating Box HZ-009. A power failure to this power line will then also stop the C-RAD side of the communication link, causing the Varian Linac side to pull an interlock.

After receiving this notice, you can contact your C-RAD representative for consultation and further action (see below).

C-RAD Actions

C-RAD notifies affected customers with this clarification of use.

This issue will be resolved:

- in a service pack that will be available for all affected customers.
- in the next software version.

