

August 6, 2020

Urgent Field Safety Notice

PA-003, c4D Software application v 6.1.0 and 6.1.1, Catalyst family systems with treatment field patient synchronization.

Subject: c4D not changing Site upon synchronization during the Setup workflow step

This field safety notice is intended to provide clarification of the use of the c4D Software application version 6.1.0 and 6.1.1 in conjunction with Catalyst family systems with treatment field patient synchronization.

For Attention of: Physicians and other medical professional users of the Catalyst family systems configured for treatment field patient synchronization.

Details

If a field is selected at the linac, c4D will automatically load the corresponding field when configured for treatment field patient synchronization (e.g. Elekta iCOM or Varian ADI interfaces).

When a field of a new Site is selected, c4D will automatically enter the Pre-setup workflow step. *



Figure 1: c4D Pre-setup

When at the Setup workflow step and selecting a field of another Site for the current patient, an issue has been identified where c4D enter Pre-setup with the current Site remaining incorrectly loaded, not changing to the Site of the selected field.

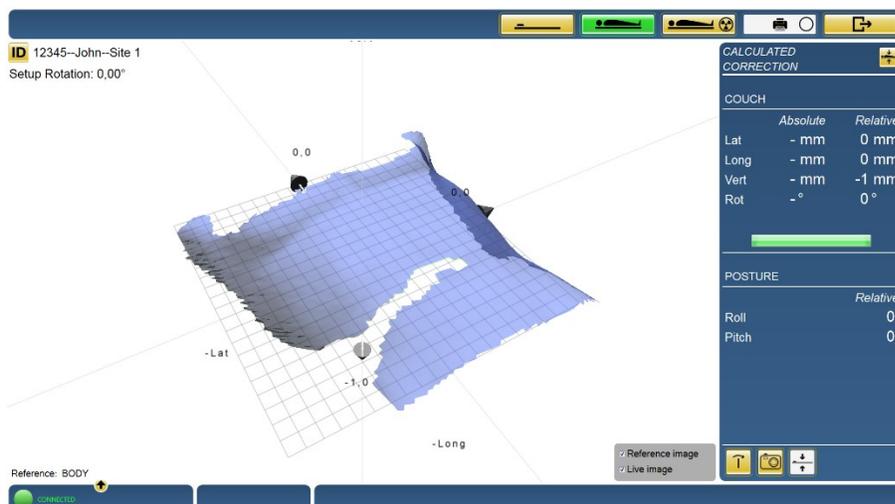


Figure 2: c4D Setup

If the user then continues to Setup, the patient can be positioned according to the position reference of the incorrectly loaded Site, which may result in a patient misalignment relative to the current field loaded in the linac.

NOTE: * For multi-plan workflows fulfilling certain conditions, c4D will remain in the current workflow step and the issue will not occur.

Affected systems

The issue is affecting all Catalyst family systems with the c4D software application v. 6.1.0 and 6.1.1, configured for treatment field patient synchronization using the Elekta iCOM or Varian ADI interfaces.

Potential issue

An issue has been identified when a Catalyst family system is configured for treatment field patient synchronization. The issue can only occur if selecting a field of a new Site for the same patient while in the Setup workflow step.

The occurrence rate of the issue resulting in a patient misalignment has been assessed to be improbable, however since the severity has been assessed to be critical the risk has been defined as ALARP.

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

Type of action to mitigate the risk

Recommended User actions

Ensure that all the staff operating the Catalyst family systems and the c4D software application are aware of this information.

As an immediate action the affected users are recommended to:

- Avoid selecting fields while in the Setup workflow step, all other workflow steps are ok.

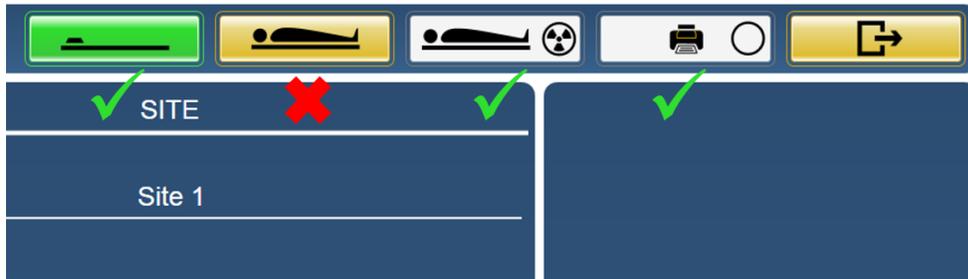


Figure 3: c4D Workflow steps

- Verify the loaded Site at the Pre-setup workflow step. If not correct, reload the selected field in the linac.

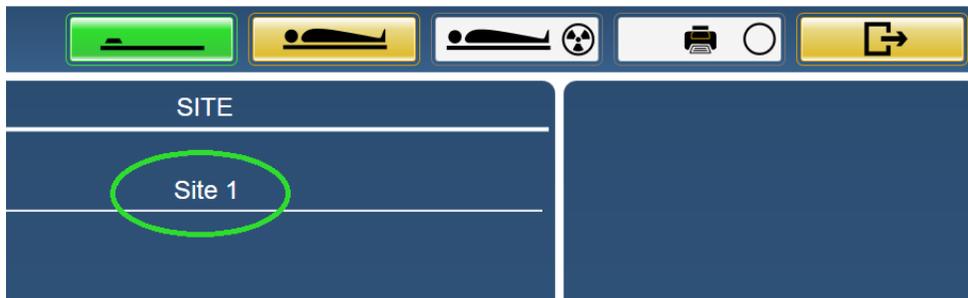


Figure 4: Loaded Site

- Verify the active position reference at the Setup workflow step. If being the position reference of an incorrectly loaded Site, enter Pre-setup and reload the selected field in the linac.



Figure 5: Active position reference

- Verify the current loaded field at the Setup workflow step. If the field information is missing, enter Pre-setup and reload the selected field in the linac.



Figure 6: Loaded field

C-RAD Actions

C-RAD will notify all affected users regarding this issue and provide the recommended users actions.

C-RAD will release a new version of the software application c4D, resolving the issue.

Field Safety notice type: New

Further advice or information: Not yet known

Regulatory Authority informed: Yes

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