⚠ IMPORTANT SAFETY NOTICE

IMPAC Product Safety Issue Affecting Jaw Symmetry in CFS Fields

IMPAC Medical Systems has identified a safety issue that results from incorrect assignment of jaw modes in Consolidated Field Sequencing (CFS) delivered on Elekta Desktop linear accelerators (linacs). The cause of the safety issue is a defect in SEQUENCER for MOSAIQ.

Affected MOSAIQ Product Versions

The following versions of MOSAIQ contain the defect: 1.40, 1.41, 1.50, 1.60 (up to and including 1.60 T2 SP4) and 2.0.

Affected Radiotherapy Configurations

This issue is limited to sites using Elekta Desktop linacs 6.0 and higher with the affected MOSAIQ versions identified above. Additionally, the linac must be characterized with the [AFS] Consolidated Field setting = YES.

Treatment Field (Beam) Specific Causation

The virtual field constructed from the Consolidated Field Sequencing feature may contain incorrect jaw positions, which can result in the delivery of some fields within the CFS with the jaws in the wrong position. The following treatment field conditions apply:

The first treatment field in the consolidated sequence must be defined as symmetric in the same dimension (X or Y) that a subsequent treatment field in the non-initial position in the consolidated sequence has asymmetric jaws defined.

If the first treatment field in the consolidated sequence has asymmetric jaws defined, the CFS virtual field will be unaffected by the defect and constructed correctly.

CFS Resumption Scenario

If you are delivering the remaining fields in a CFS that has been partially treated, the first treatment field in the virtual consolidated field is the first treatment field for the remaining sequence (the first fully undelivered field remaining in the sequence). This scenario is subject to the same treatment field criteria indicated above for delivering the CFS with jaws in the wrong position.

Effect

For each affected consolidated field, the initial treatment field in the sequence will be delivered correctly; however, all subsequent fields defined with asymmetric jaws in that dimension will be delivered with the jaws at a symmetric position, based on the field size in that dimension.

Clinical Impact

This could result in unintended exposure to some tissue from jaws extruding from the defined treatment aperture and/or unintended blockage of some tissue from jaws intruding into the defined treatment aperture. The clinical impact on the patient is potentially significant, but IMPAC's risk assessment indicates a low probability of actual harm. There have been no reported mistreatments related to this issue to date.

Interim Mitigations

IMPAC advises users to review the IMRT segments of the consolidated field in the Historic View and compare them with the IMRT segments in Treatment Field Definition.

The user is also advised to create a Quality Assurance (QA) check specific to CFS on each consolidated field.

Final Resolution

Sites are strongly encouraged to contact Impac Software Support for an immediate patch or upgrade. Impac Software Support shall follow-up with your site to confirm receipt of this notice and schedule an upgrade or patch.

Current Version	Upgrade/Patch
1.40	None: Upgrade required
1.41	None: Upgrade required
1.50	1.50N4SP3 (available) 1.50N6+ (next major release) (Recommend upgrade to 1.60 or later)
1.60	1.60T2SP5, 1.60V1SP1 (available) 1.60V4+ (next major release)
2.00	2.00R9 (available)

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Please distribute this notice to any and all users of IMPAC software at your organization who are potentially affected by this issue. The applicable regulatory agencies have been notified of this corrective field action.

For questions, concerns, and requests for upgrade, email support@impac.com or call:
European customers: 44 1293 654320. American & rest of world customers: 800.488.4672.