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URGENT
MEDICAL DEVICE CORRECTION

Subject: Dose not calculated in certain body regions
Reference: Eclipse DCS 7.2.34 and earlier (PBC and GGPB algorithms only)
Date of Notification: 12/22/2004
Contact Information: Treatment Planning Systems Helpdesk
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We are writing to advise you that an anomaly regarding “*Dose not calculated in certain body regions*” has been identified in Eclipse DCS 7.2.34 and earlier (PBC and GGPB algorithms only). This advisory notice is to provide you with a description of the anomaly, to explain corrective actions, and to advise you of the steps Varian is taking to address the issue.

Anomaly:

If the planes defined by the collimator jaws intersect the external body surface in such a way that two or more non-contiguous body regions are formed within the field, then Eclipse will calculate dose only within the region having the smallest coordinate value along the superior-inferior patient axis. The anomaly depends on the positions of the collimator jaws and not on the field edges defined by blocks or MLCs.

Details:

The conditions for the anomaly are most easily detected in the beam's eye view (BEV). If the intersection of the collimator jaw edges forms two disconnected regions of the body, the anomaly will occur. This situation is illustrated for two cases in Figure 1 below.

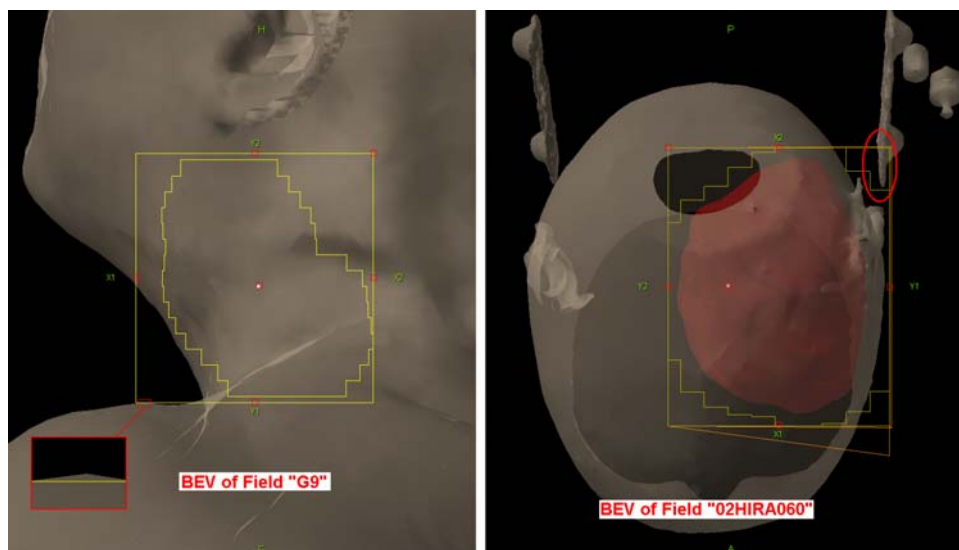


Figure 1. The BEV on the left shows a head and neck field where the positions of the collimator jaws form a body region at the top of the shoulder that is disconnected from the region being treated (see magnified inset). The BEV on the right shows a vertex field where the collimator jaws edges intersect a part of the head frame that was contoured as the part of the body. This results in an extraneous, non-contiguous body region (see oval). In both cases, the body regions may or may not be attached in 3D, but from the BEV perspective they are separate.

If there are multiple separate body regions within the space formed by the collimator jaw opening (not the block/MLC aperture), dose will be calculated only in the region where the patient coordinate value along the superior-inferior direction is smallest. For the most common patient coordinate system geometries, the Z-coordinate is increasing from the patient's feet to head. Therefore, the dose is calculated within the inferior region (closest to the patient's feet). In the examples in Figure 1, dose will be calculated only in the shoulder (left example) and in the head frame (right example).

Another indication of the anomaly is a warning message that appears in the calculation notes displayed after dose calculation. The message reads, “The equivalent field size of the field or one of its sub-fields is below measured range. The resulting dose distribution may be incorrect.” and the calculation log will show that the equivalent field size (EQFS) is zero for the affected field. However, monitor units (MU) will be calculated for those fields although no contributions from those fields will be visible in the dose distributions. For single fields or a single pair of opposing fields the effect will be quite obvious, but for more complicated multi-field arrangements the effect on the dose distribution may go unnoticed. In any case, manual verification of MU values will clearly reveal the anomaly.

This anomaly affects all Eclipse dose calculation server (DCS) versions 7.2.34 or earlier for both Pencil Beam Convolution (photon) and Generalized Gaussian Pencil Beam (electron) algorithms. The Anisotropic Analytical Algorithm (AAA), Electron Monte Carlo algorithm, and the Dose Volume Optimizer (Helios/IMRT optimization) are not affected by the anomaly.

Affected Serial Numbers:

H480001 – H483080.

User Corrective Action:

It is recommended that the BEV be examined and used when designing treatment fields to detect and avoid the conditions causing the anomaly. The calculation notes should always be reviewed for warnings or errors. Finally, independent monitor unit checks should be performed as part of a routine quality assurance program.

Varian Corrective Action:

Varian is notifying Eclipse users of this anomaly via this letter.

Please advise the appropriate personnel working in your radiotherapy department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Varian Customer Support Representative.