

URGENT FIELD SAFETY NOTICE

Subject: CIAO incorrectly calculated in RT Chart

Commercial Name of Affected Product: RT Chart, a function of ARIA™

FSCA Identifier: CP-03103

Date of Notification: 2011-02-18

Type of Action: Notification and field correction

Details on Affected Devices: RT Chart, a function of ARIA™ versions 8.0 and 8.1

We are writing to advise you of an issue that has been identified with calculating the Completely Irradiated Aperture Opening (CIAO) in RT Chart. This issue may pose a hazard in cases where a second field is matched to the CIAO field edge at treatment.

This notice provides a description of the issue, the actions you can take to avoid the issue, and steps Varian is taking to address the issue.

Description of Problem:

When an image sequence template is added to a field in RT Chart and a CIAO is calculated, the resulting CIAO display at 4DITC may be incorrect. This CIAO calculation interprets the following data incorrectly:

- a) Closed leaf motions ($\leq 0.5\text{mm}$) are incorrectly considered as part of the field
- b) Leaves travelling over isocenter are truncated to the central axis

The result is a CIAO which is in many cases larger than the actual largest extent of irradiated area – possibly leading to an unintentional gap if that outline is used for edge matching of a second field.

Details:

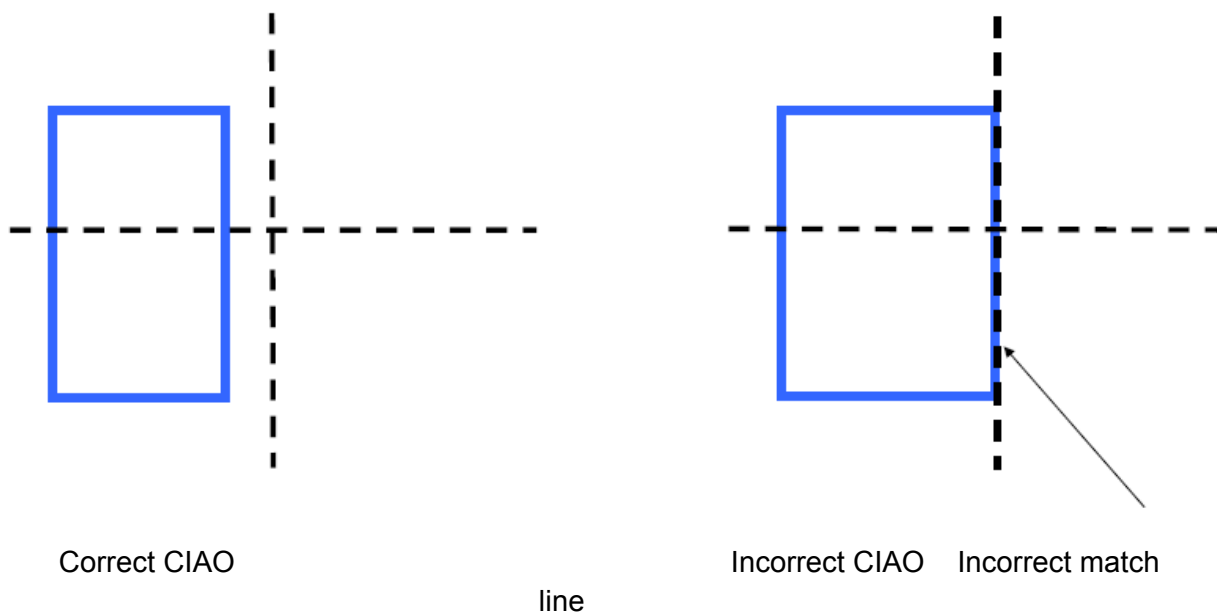
When a portal image sequence image is scheduled for a session in RT Chart, the daemon will create an image beam for the 4DITC during the plan load. This image beam contains the associated field aperture and the MLC leaf positions.

Due to the misinterpretation of the closed leaf motions and leaves travelling over isocenter, the display of the CIAO may differ when visualized in RT Chart, Eclipse, 4DITC, and offline review.

Note that 4DITC will display the outline from the image source; since offline review is unaffected by the issue, for example, the CIAO displayed at 4DITC after being viewed in offline review, will be correct.

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Recommended User Action:

1. Varian recommends a QA practice that includes routine patient setup and planned isocenter/treatment volume verification prior to treatment delivery regardless of documented patient plan setup instructions. This verification can be done through the use of MV imaging or use of film prior to patient treatment.
2. In the case where an erroneous CIAO exists and a correct image is required for use for edge matching, view the CIAO in offline review prior to treatment

Varian Corrective Action:

1. Varian is notifying potentially affected users by way of this Urgent Field Safety Notice.
2. Varian has made design changes to address this issue in ARIA Radiation versions 8.2 and later. A corrective action will be undertaken to upgrade all affected systems to an unaffected later version of the software. If this has not already been done on your system, you will be contacted to schedule the update on your system.

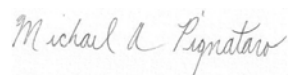
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Please advise the appropriate personnel working in your Radiotherapy Department of the content of this letter.

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 District or Regional Manager.

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.



Michael Pignataro, Manager, Reporting and Corrections

2011-02-18

Date

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APPENDIX

LIST OF AFFECTED DEVICE SERIAL NUMBERS

Listed are the affected system Serial Numbers. The last four digits represent the serial number of the device.

HIT0001	HIT0206	HIT0426	HIT0606R1	HIT0805	HIT0963	HIT1188	HIT1385R1	HIT1522	HIT1703
HIT0013	HIT0210	HIT0427	HIT0613	HIT0808M	HIT0968	HIT1189	HIT1386	HIT1541	HIT1704
HIT0025	HIT0219	HIT0429M	HIT0615M	HIT0808R1	HIT0970	HIT1203	HIT1389	HIT1546	HIT1714
HIT0028	HIT0225	HIT0429R1	HIT0615R1	HIT0809	HIT0972	HIT1207	HIT1392	HIT1548	HIT1719M
HIT0032	HIT0234	HIT0444	HIT0615R2	HIT0813	HIT0982M	HIT1211	HIT1394	HIT1551	HIT1719R1
HIT0040	HIT0236	HIT0448	HIT0620	HIT0814M	HIT0982R1	HIT1212	HIT1396	HIT1554	HIT1719R2
HIT0055	HIT0238	HIT0450	HIT0625	HIT0814R1	HIT0988	HIT1225	HIT1397	HIT1558	HIT1723
HIT0059	HIT0244	HIT0459	HIT0627	HIT0820	HIT0996	HIT1227	HIT1402	HIT1563	HIT1729
HIT0061	HIT0247	HIT0467	HIT0630	HIT0823	HIT0998	HIT1231	HIT1404	HIT1567	HIT1731
HIT0066	HIT0262	HIT0474	HIT0631	HIT0827	HIT1010	HIT1234	HIT1408	HIT1577	HIT1736
HIT0072	HIT0265	HIT0475	HIT0633	HIT0829	HIT1022	HIT1241	HIT1410	HIT1580	HIT1738
HIT0076	HIT0268	HIT0483	HIT0637	HIT0830	HIT1027	HIT1245	HIT1415	HIT1581	HIT1745
HIT0077	HIT0286	HIT0485	HIT0647	HIT0833	HIT1029	HIT1260	HIT1418	HIT1584	HIT1760
HIT0082	HIT0292	HIT0487	HIT0649	HIT0837	HIT1039	HIT1267	HIT1420	HIT1592	HIT1765
HIT0084	HIT0293	HIT0494	HIT0651	HIT0838	HIT1043	HIT1278	HIT1426	HIT1594	HIT1768
HIT0088	HIT0297	HIT0498	HIT0655	HIT0843	HIT1050	HIT1284	HIT1428	HIT1597	HIT1771
HIT0090	HIT0303	HIT0503M	HIT0658	HIT0849	HIT1052	HIT1294	HIT1436	HIT1600M	HIT1773
HIT0095	HIT0305	HIT0510	HIT0665	HIT0851	HIT1060	HIT1296	HIT1440	HIT1600R1	HIT1778
HIT0100	HIT0310	HIT0513	HIT0668	HIT0857	HIT1062	HIT1298	HIT1444	HIT1600R2	HIT1788
HIT0105R1	HIT0312	HIT0516	HIT0683	HIT0864	HIT1066	HIT1301	HIT1446	HIT1600R3	HIT1799
HIT0112	HIT0315	HIT0519	HIT0697	HIT0866	HIT1070	HIT1306	HIT1450	HIT1602M	HIT1803
HIT0114	HIT0320M	HIT0520R1	HIT0699	HIT0868	HIT1072	HIT1318	HIT1451	HIT1602R1	HIT1811
HIT0117	HIT0320R1	HIT0522	HIT0701	HIT0876	HIT1074	HIT1321	HIT1452	HIT1606	HIT1820
HIT0124	HIT0326	HIT0523	HIT0703M	HIT0879	HIT1079M	HIT1325	HIT1454	HIT1612M	HIT1824
HIT0127	HIT0329	HIT0532	HIT0703R1	HIT0886	HIT1079R1	HIT1327	HIT1460	HIT1612R1	HIT1829
HIT0130	HIT0331	HIT0533	HIT0712	HIT0887	HIT1084	HIT1329	HIT1462	HIT1617	HIT1830
HIT0132	HIT0333	HIT0537	HIT0716	HIT0892	HIT1095	HIT1331M	HIT1466	HIT1620M	HIT1838
HIT0139R1	HIT0335	HIT0539	HIT0721	HIT0896	HIT1110R1	HIT1331R1	HIT1469	HIT1620R3	HIT1845
HIT0140	HIT0342	HIT0541	HIT0726	HIT0898	HIT1113	HIT1332	HIT1470M	HIT1620R5	HIT1852
HIT0143M	HIT0348	HIT0542	HIT0729	HIT0925	HIT1115	HIT1338	HIT1470R1	HIT1620R6	HIT1854
HIT0143R1	HIT0365	HIT0547	HIT0737	HIT0928	HIT1121	HIT1346M	HIT1470R2	HIT1625	HIT1860
HIT0150	HIT0366M	HIT0549	HIT0747	HIT0930	HIT1128	HIT1346R1	HIT1473	HIT1628	HIT1861
HIT0152	HIT0366R1	HIT0555	HIT0749	HIT0932M	HIT1129	HIT1347	HIT1488	HIT1633	HIT1865
HIT0157	HIT0370	HIT0563	HIT0754	HIT0932R1	HIT1131	HIT1348	HIT1489	HIT1642	HIT1866
HIT0162	HIT0372	HIT0565	HIT0757	HIT0933	HIT1132R1	HIT1350	HIT1492	HIT1651	HIT1867
HIT0165M	HIT0376	HIT0566	HIT0762	HIT0940	HIT1134	HIT1353M	HIT1493	HIT1655	HIT1880
HIT0165R1	HIT0397	HIT0570	HIT0767	HIT0942	HIT1135	HIT1353R1	HIT1494	HIT1668	HIT1882
HIT0167	HIT0401	HIT0585M	HIT0769	HIT0944	HIT1137	HIT1356	HIT1496	HIT1674	HIT1889
HIT0174	HIT0402	HIT0589M	HIT0776	HIT0948M	HIT1144	HIT1359	HIT1498M	HIT1679	HIT1894
HIT0178	HIT0404	HIT0589R1	HIT0777R1	HIT0948R1	HIT1151	HIT1361	HIT1498R1	HIT1680	HIT1895
HIT0183	HIT0405	HIT0592	HIT0782	HIT0950	HIT1152	HIT1369	HIT1506	HIT1688	HIT1901
HIT0185	HIT0406	HIT0593	HIT0789	HIT0951M	HIT1159	HIT1376	HIT1507	HIT1691	HIT1903
HIT0195M	HIT0413	HIT0594	HIT0792	HIT0951R1	HIT1163	HIT1380	HIT1518M	HIT1693	HIT1904M
HIT0199	HIT0419	HIT0604	HIT0795	HIT0952	HIT1166	HIT1381	HIT1518R1	HIT1697M	HIT1904R1
HIT0205	HIT0424	HIT0606M	HIT0803	HIT0954	HIT1170	HIT1385M	HIT1521	HIT1697R2	HIT1905

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HIT1913	HIT2317	HIT3130	HIT3505	HIT3679
HIT1914	HIT2319	HIT3131M	HIT3509	HIT3691
HIT1922	HIT2350	HIT3131R1	HIT3513	HIT3692
HIT1924M	HIT2409M	HIT3179	HIT3515	HIT3700
HIT1924R1	HIT2409R1	HIT3195	HIT3516	HIT3702
HIT1925	HIT2434	HIT3198	HIT3519	HIT3705
HIT1926	HIT2475	HIT3209	HIT3521M	HIT3706
HIT1932	HIT2510	HIT3227	HIT3521R1	HIT3708
HIT1945	HIT2531	HIT3242	HIT3521R2	HIT3710
HIT1947	HIT2546	HIT3261	HIT3524	HIT3713
HIT1951	HIT2547	HIT3267	HIT3525	HIT3720
HIT1956	HIT2557	HIT3270	HIT3527	HIT3722
HIT1963	HIT2574A2	HIT3274	HIT3529	HIT3725
HIT1967	HIT2574R3	HIT3279	HIT3537	HIT3726
HIT1968	HIT2574R4	HIT3290	HIT3541	HIT3732
HIT1969	HIT2577	HIT3298M	HIT3549	
HIT1980R1	HIT2595	HIT3298R1	HIT3555	
HIT1987	HIT2615	HIT3298R2	HIT3564	
HIT2003	HIT2623M	HIT3298R3	HIT3573	
HIT2009	HIT2623R1	HIT3302	HIT3585	
HIT2016	HIT2623R2	HIT3304	HIT3587	
HIT2018	HIT2688	HIT3314	HIT3588	
HIT2027	HIT2693	HIT3315	HIT3591	
HIT2029	HIT2777	HIT3322	HIT3592	
HIT2056	HIT2779	HIT3329	HIT3598M	
HIT2068	HIT2831	HIT3338	HIT3598R1	
HIT2076	HIT2840	HIT3342	HIT3601	
HIT2078	HIT2856M	HIT3354	HIT3607	
HIT2087	HIT2900	HIT3360	HIT3614	
HIT2095	HIT2909	HIT3365	HIT3615	
HIT2098	HIT2939	HIT3370	HIT3624	
HIT2119	HIT2968	HIT3394	HIT3627	
HIT2126	HIT2980	HIT3397	HIT3630	
HIT2129M	HIT2999	HIT3404M	HIT3631	
HIT2129R1	HIT3010	HIT3404R1	HIT3633	
HIT2129R2	HIT3018	HIT3413	HIT3635	
HIT2129R3	HIT3052	HIT3425	HIT3642	
HIT2129R4	HIT3054	HIT3435	HIT3652	
HIT2129R5	HIT3100	HIT3439	HIT3658	
HIT2164	HIT3109	HIT3441	HIT3659	
HIT2171	HIT3112	HIT3454	HIT3660	
HIT2198	HIT3116M	HIT3469	HIT3661	
HIT2222	HIT3116R1	HIT3473	HIT3664	
HIT2223	HIT3117	HIT3483	HIT3671	
HIT2236	HIT3126	HIT3499	HIT3677	