

URGENT FIELD SAFETY NOTICE

Subject: **Field Shape Changes after Converting from 120 to 80-leaf MLC in Eclipse™ and RT Chart**

Commercial Name of Affected Product: Eclipse and RT Chart (ARIA™ Radiation Oncology)
Client versions 8.1 and 8.5 (builds 8.1.x through 8.2.x)

FSCA Identifier: CP-02234
Date of Notification: **2010-09-09**
Type of Action: Notification and Correction
Details on Affected Devices: See attached list.

Description of Problem:

We are writing to inform you of an anomaly in the Eclipse and RT Chart software when a plan is converted from the 120 leaf Multi-Leaf Collimator (MLC) to an 80 leaf MLC.

Details:

A static multi-leaf collimator (MLC) field aperture created for a Millennium 120-leaf MLC is affected after converting it to a Millennium 80-leaf MLC. An error occurs during the conversion process with the result that the MLC aperture defined by the 80-leaf MLC may differ significantly from that of the original 120-leaf MLC field. This issue occurs both in Eclipse and RT Chart (ARIA Radiation Oncology) software. The problem is caused by a defect in the software routine that calculates the new positions of the MLC leaves. The problem only occurs when converting static MLC field apertures from 120-leaf to 80-leaf MLCs. The problem does not affect dynamic MLC fields.

As an example, consider the MLC field apertures shown below in Figure 1. The left-hand image shows the original 120-leaf MLC aperture. The right-hand image shows the aperture after converting it to an 80-leaf MLC. Note the incorrect leaf positions in the superior portion of the converted field.

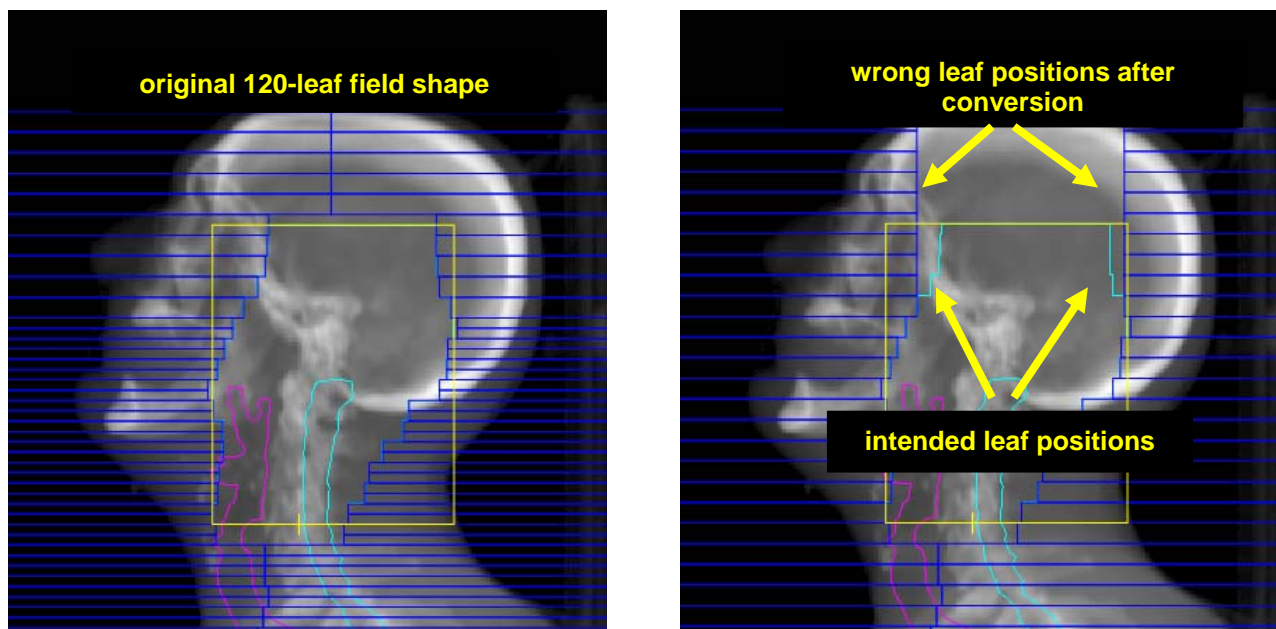


Figure 1. The original 120-leaf MLC aperture (left) and the incorrectly converted 80-leaf aperture (right).

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Treating a plan with incorrectly converted MLC field apertures could result in mistreatment if the field shapes are not verified prior to treatment and the user does not heed the on-screen cautions regarding MLC device changes from 120 to 80-leaf MLCs.

Since the conversion is correct going from 80-leaf back to 120-leaf MLC, reversing the conversion simply converts the incorrect shape to a 120-leaf aperture. The “twice converted” 120-leaf MLC aperture will thus be incorrect.

Recommended User Action

- If the MLC conversion is done in Eclipse, a recalculation of the doses for the converted fields will be required. Verify the shape of MLC aperture before proceeding with dose calculation and treatment plan approval. Also verify that reference images (for example, DRRs) display the updated field aperture.
- If the conversion is done in RT Chart, a recalculation of monitor units (MU) will NOT be forced. Therefore, it is extremely important to verify the MLC aperture and reference images prior to treatment plan approval and treatment.
- Observe and act on all caution messages displayed before, during, and after the MLC conversion process.
- If necessary, reposition the MLC leaves in Eclipse (or other treatment planning system), recalculate the dose, and review the results before proceeding with treatment plan approval and treatment.

Varian Actions:

- Varian is notifying all possibly affected customers with this document.
- Varian is developing a correction for this issue. You will be contacted by a Customer Service rep when this correction is available to schedule its installation on your system.

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 cooperation. If you require further clarification, please feel free to contact your local Varian Customer Support District or Regional Manager.

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



_____ on behalf of _____
 Manager Reporting and Corrections

_____ 2010-09-09 _____
Date

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APPENDIX

LIST OF SERIAL NUMBERS

H480006	H480255	H480634	H480901	H481215	H481645	H482191	H482447	H482840	H483237
H480007	H480265	H480635	H480902	H481216	H481646	H482192	H482464	H482841	H483238
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H483724	H484159	H484496	H484880	H485479	H485853	H486158	H486457	H486599	H486810
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H486903	H487067	H487258	H487408	H487510	H487767	H487891	H487998	H488117	H488261
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H488379	H488475	H488701	H489015	H489844	H48A950	HIT0341M	HIT0647	HIT0958
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H488433	H488534	H488820	H489149	H48A066	HIT0109	HIT0485	HIT0773M	HIT1062
H488434	H488541	H488823	H489150	H48A108	HIT0112	HIT0486	HIT0773R1	HIT1066
H488435	H488542	H488826	H489151	H48A177	HIT0143M	HIT0487	HIT0777M	HIT1070
H488436	H488543	H488827	H489161	H48A185	HIT0147	HIT0503M	HIT0790	HIT1074
H488437	H488544	H488834	H489168	H48A186	HIT0148	HIT0505	HIT0793	HIT1080
H488441	H488545	H488835	H489203	H48A187	HIT0154	HIT0509	HIT0795	HIT1087
H488442	H488546	H488836	H489346	H48A270	HIT0187	HIT0510	HIT0799	HIT1089
H488446	H488565	H488837	H489347	H48A287	HIT0195M	HIT0520M	HIT0814M	HIT1090
H488447	H488566	H488838	H489348	H48A317	HIT0195R1	HIT0522	HIT0835	HIT1092
H488448	H488567	H488839	H489384	H48A335	HIT0199	HIT0532	HIT0837	HIT1095
H488449	H488570	H488840	H489411	H48A336	HIT0204	HIT0540	HIT0839M	HIT1098
H488450	H488574	H488852	H489412	H48A390	HIT0205	HIT0541	HIT0839R1	HIT1110M
H488453	H488578	H488863	H489472	H48A563	HIT0211	HIT0551	HIT0840	HIT1115
H488454	H488579	H488864	H489473	H48A590	HIT0215	HIT0565	HIT0857	HIT1116
H488457	H488585	H488865	H489474	H48A591	HIT0242	HIT0593	HIT0864	HIT1121
H488459	H488592	H488866	H489475	H48A592	HIT0249	HIT0598	HIT0885	HIT1128
H488465	H488602	H488867	H489476	H48A593	HIT0254	HIT0604	HIT0886	HIT1137
H488466	H488603	H488868	H489563	H48A648	HIT0262	HIT0617	HIT0892	HIT1144
H488467	H488623	H488892	H489568	H48A649	HIT0264M	HIT0622	HIT0905M	HIT1149M
H488468	H488632	H488893	H489661	H48A650	HIT0265	HIT0625	HIT0905R1	HIT1149R1
H488469	H488634	H488919	H489662	H48A651	HIT0266	HIT0629M	HIT0907	HIT1151
H488470	H488635	H488944	H489666	H48A666	HIT0284	HIT0629R1	HIT0919	HIT1157
H488471	H488648	H488945	H489760	H48A812	HIT0293	HIT0629R2	HIT0925	HIT1168
H488472	H488649	H488979	H489792	H48A813	HIT0312	HIT0633	HIT0933	HIT1172
H488473	H488698	H488984	H489818	H48A836	HIT0315	HIT0643	HIT0951M	HIT1211
H488474	H488699	H488991	H489826	H48A949	HIT0323	HIT0643	HIT0951R1	HIT1212

URGENT FIELD SAFETY NOTICE

Field Shape Changes after Converting from 120 to 80-leaf MLC in Eclipse™ and RT Chart

HIT1213	HIT1392	HIT1546	HIT1693	HIT1885	HIT2016	HIT2199	HIT2431
HIT1216	HIT1394	HIT1551	HIT1704	HIT1888	HIT2018	HIT2202	HIT2441
HIT1225	HIT1397	HIT1554	HIT1711	HIT1890	HIT2022	HIT2212	HIT2491
HIT1231	HIT1400	HIT1558	HIT1716	HIT1893	HIT2027	HIT2215	HIT2531
HIT1235M	HIT1401	HIT1563	HIT1718	HIT1894	HIT2029	HIT2215	HIT2541
HIT1236	HIT1404	HIT1565M	HIT1719R2	HIT1895	HIT2034	HIT2219	HIT2546
HIT1241	HIT1408	HIT1565R1	HIT1738	HIT1898	HIT2036	HIT2225	HIT2568
HIT1245	HIT1410	HIT1565R2	HIT1760	HIT1903	HIT2041	HIT2229	HIT2572
HIT1260	HIT1418	HIT1565R3	HIT1763	HIT1904M	HIT2044	HIT2231	HIT2605
HIT1267	HIT1420	HIT1567	HIT1764M	HIT1905	HIT2045M	HIT2236	HIT2621
HIT1278	HIT1428	HIT1579M	HIT1764R1	HIT1907	HIT2047M	HIT2241	HIT2647
HIT1284	HIT1430M	HIT1579R1	HIT1765	HIT1911	HIT2047R1	HIT2267M	HIT2655
HIT1298	HIT1430R1	HIT1580	HIT1770	HIT1913	HIT2049	HIT2267R1	HIT2662
HIT1301	HIT1430R2	HIT1581	HIT1773	HIT1921	HIT2051	HIT2275M	HIT2670
HIT1303	HIT1430R3	HIT1584	HIT1778	HIT1922	HIT2063	HIT2275R1	HIT2686
HIT1306	HIT1436	HIT1585	HIT1788	HIT1926	HIT2068	HIT2275R2	HIT2688
HIT1308	HIT1440	HIT1592	HIT1803	HIT1928	HIT2074	HIT2275R3	HIT2704
HIT1313	HIT1444	HIT1594	HIT1804M	HIT1932	HIT2080	HIT2275R4	HIT2716
HIT1315	HIT1446	HIT1597	HIT1804R1	HIT1934M	HIT2098	HIT2277	HIT2752
HIT1318	HIT1451	HIT1600R1	HIT1805	HIT1934R1	HIT2101M	HIT2279	HIT2754
HIT1325	HIT1452	HIT1600R2	HIT1806	HIT1945	HIT2101R1	HIT2282	HIT2761
HIT1327	HIT1454	HIT1600R3	HIT1822	HIT1947	HIT2105	HIT2289	HIT2823
HIT1329	HIT1460	HIT1602M	HIT1829	HIT1948	HIT2105	HIT2303	HIT2868
HIT1332	HIT1462	HIT1602R1	HIT1830	HIT1952	HIT2112	HIT2320	HIT2937
HIT1332	HIT1466	HIT1609M	HIT1838	HIT1953	HIT2115	HIT2321	HIT2943
HIT1344M	HIT1469	HIT1609R1	HIT1839	HIT1955M	HIT2119	HIT2327	HIT2995
HIT1344R1	HIT1473	HIT1610M	HIT1840	HIT1955R1	HIT2123	HIT2329	HIT3262
HIT1344R2	HIT1475	HIT1610R1	HIT1843M	HIT1961	HIT2124	HIT2333	HIT3329
HIT1346M	HIT1478	HIT1610R2	HIT1843R1	HIT1964	HIT2131	HIT2357	HIT3338
HIT1348	HIT1486	HIT1614	HIT1845	HIT1965	HIT2132	HIT2364	HIT3449R2
HIT1350	HIT1488	HIT1617	HIT1852	HIT1980M	HIT2136	HIT2367	HIT3454
HIT1353R1	HIT1489	HIT1623	HIT1857	HIT1981	HIT2138	HIT2376	HIT3481
HIT1354	HIT1492	HIT1624	HIT1861	HIT1982	HIT2140	HIT2388	
HIT1359	HIT1494	HIT1628	HIT1864	HIT1986	HIT2149	HIT2390	
HIT1360	HIT1506	HIT1642	HIT1866	HIT1987	HIT2151	HIT2394	
HIT1361	HIT1510	HIT1651	HIT1871M	HIT1988	HIT2156	HIT2397	
HIT1361	HIT1517M	HIT1653	HIT1871R1	HIT1989	HIT2164	HIT2399	
HIT1369	HIT1518M	HIT1655	HIT1871R2	HIT1994	HIT2171	HIT2400	
HIT1371	HIT1518R1	HIT1674	HIT1874	HIT1996	HIT2173	HIT2402	
HIT1373	HIT1521	HIT1677	HIT1875	HIT2004	HIT2183	HIT2409R1	
HIT1381	HIT1522	HIT1678	HIT1876	HIT2007	HIT2188	HIT2411	
HIT1383	HIT1536	HIT1679	HIT1879	HIT2010M	HIT2190M	HIT2417	
HIT1385M	HIT1539	HIT1680	HIT1880	HIT2010R1	HIT2190R1	HIT2429	
HIT1386	HIT1541	HIT1691	HIT1882	HIT2012	HIT2196	HIT2430	