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URGENT - FIELD SAFETY NOTICE

Subject:	**Potential for incorrect arc delivery after third party plan transfer using LINK procedures**
Commercial Name of Affected Product:	**LINK**
FSCA Identifier:	**CP-01451**
Date of Notification:	***TBD***
Type of Action:	**Notification**
Details on Affected Devices:	***LINK when used in conjunction with VARiS Vision version 6.2, 6.1 and 6.0***

Description of Issue :

We are writing to advise you of the following anomalies with LINK procedures if used in conjunction with VARiS Vision version 6.2, 6.1 and 6.0:

1. If an Arc therapy treatment field with either a start angle or a stop angle in the extended range is transferred to VARiS Vision via LINK, the Arc rotation direction will be reversed in VARiS Vision.
2. If an Arc therapy treatment field, containing an arc that exceeds the physical limitations of the treatment delivery device, is transferred to VARiS Vision via LINK, the Arc rotation direction will be reversed by the treatment delivery device.

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.

Following are the known 3rd party products exchanging data with VARiS 6.2, 6.1 and 6.0 via LINK:

- BrainSCAN™ (BrainLAB)
- iPlan® (BrainLAB)
- RTP Exchange
- CadPlan

Please be aware that there might be other products exchanging data with VARiS 6.2, 6.1 and 6.0 via LINK. Please check with your respective vendor in case you are not sure whether a specific product is making use of LINK to exchange data with VARiS 6.2, 6.1 and 6.0.

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Details:

Accelerators that do not have the capability to rotate the gantry continuously throughout 360 degrees may allow a few degrees of rotation past the nominal rotation limit when approached from one side of the limit or the other. This region of the gantry rotation is referred to herein as the *extended range*, see Figure 1. For example, a Varian linear accelerator using, the IEC 621217 scale convention, has a nominal rotation range of 0 +/- 180 degrees but cannot complete a 360-degree rotation starting from 0 degrees. However, when rotating towards 180 degrees from start angles between 0 and 180 degrees, gantry rotation can extend a few degrees more than 180. Similarly, gantry rotations starting at angles between 180 and 360 degrees and rotating towards 180 degrees can extend a few degrees less than 180.

Extended Gantry Angle Region

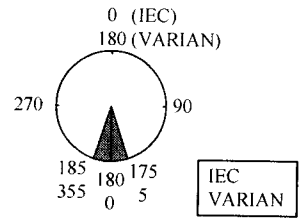

Figure 1: Definition of the extended region in red. The upper angle is in IEC scale and the lower angle is in VARIAN scale.

1. **Arc therapy treatment field with either a start angle or a stop angle in the extended range:**

   It may sometimes be desirable to plan arc treatments where one or more arcs start or stop in the extended range. When such a treatment plan is sent to VARiS Vision via LINK, the VARiS LINK procedures do not transfer explicit information regarding the direction of rotation. In addition, VARiS Vision does not interpret the extended range angles correctly and assigns a direction of rotation that is opposite to what was intended.

2. **Arc therapy treatment field, containing an arc that exceeds the physical limitations of the treatment delivery device:**

   Treatment planning systems (TPS) might allow a user to plan for an Arc treatment using parameters that exceed the physical capabilities of the treatment delivery device. For example, using, the IEC 621217 scale convention, an Arc treatment with a clockwise direction, a start angle of 150 degrees and a stop angle of 200 degrees would require for the gantry to travel through 180 degrees see Figure 1. The treatment delivery device will perform the only arc that is physically possible to match these two parameters, which is a counterclockwise direction.

   LINK procedures only support values for start angle and stop angle but do not support values for gantry direction when a arc treatment is transferred. VARiS Vision will store start and stop angles as received by LINK and will pass it on to the treatment delivery device. There is only one direction that the treatment delivery device is able to deliver the treatment starting from the start angle and ending at the stop angle which might be in the opposite direction than it was planned for originally. In the example above this would result in a counterclockwise direction.

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User Corrective Action:

After transferring arc fields to VARiS Vision 6.2, 6.1 or 6.0, via LINK procedures, a user must manually examine and verify the treatment field information in VARiS Vision to ensure the proper gantry rotation direction (clockwise or counter-clockwise).

Varian Corrective Action:

The anomaly will remain in LINK for VARiS Vision versions 6.2, 6.1 and 6.0, since Varian Medical System has ceased the active support of these versions on December 31, 2006. In this case, the user is advised to split the extended arc field into two non-extended arc fields.

Newer versions of VARiS Vision and ARIA prevent treatment of plans containing Arc fields transferred via LINK to VARiS with start angles in the extended range, since the gantry direction (clockwise or counter-clockwise) is a mandatory field for Arc treatments and the user needs to use RT Chart to provide the gantry direction before the plan can be approved for treatment. A treatment plan must be "Treatment Approved" in order for ARIA to allow it to be exported to 4DITC for treatment delivery.

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 Manager.

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

[redacted], Manager, Reporting and Corrections _____ 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.

H850004	H850610	H850920	H851138	H851524
H850008	H850616	H850930	H851145	H851557
H850012	H850686	H850962	H851205	H851576
H850033	H850696	H850963	H851207	H851586
H850078	H850699	H850964	H851220	H851641
H850098	H850703	H850965	H851252	H851642
H850110	H850720	H850967	H851290	H851658
H850129	H850734	H850968	H851294	H851670
H850130	H850739	H850969	H851327	H851671
H850211	H850759	H851020	H851333	H851674
H850217	H850788	H851025	H851353	H851838
H850221	H850809	H851032	H851354	H851839
H850258	H850830	H851033	H851388	H851865
H850322	H850831	H851037	H851389	H851895
H850345	H850861	H851059	H851392	H851951
H850350	H850862	H851080	H851410	H851993
H850449	H850877	H851087	H851482	H852003
H850451	H850904	H851091	H851483	H852049
H850474	H850907	H851102	H851484	H852623
H850555	H850912	H851132	H851515	