

## Product Notification

**Subject:** Movement limits and calibration of Varian EXACT couch in combination with BrainLAB ExacTrac Robotics  
**Reference:** 49700 ExacTrac Robotics  
**Date of Notification:** June 2, 2006  
**Individual Notifying:** [REDACTED] BrainLAB Product Support Manager Radiotherapy

We are writing to advise you of the following effect that has been identified when using the ExacTrac Robotics in combination with the Varian EXACT couch. This Notification letter is to provide you with corrective action information, and to advise you of the actions BrainLAB is taking to address the issue.

### Effect:

With the ExacTrac Robotics installed and moving the Varian EXACT couch down the following effects may occur

- the couch will not gradually reduce its speed when approaching its lowest position but will be stopped mechanically
- it occurred once that after the couch reached its lowest position it faced difficulties moving upwards again with loaded weight

### Details:

The ExacTrac Robotics adds a height of 10cm to the Varian EXACT couch. The EXACT couch position indication has been re-calibrated by BrainLAB during the Robotics installation to read out the correct positions.

This re-calibration is the root cause for the EXACT couch to not reduce its speed and stop before reaching its lowest possible mechanical position, which may cause damage to the couch.

### User Corrective Action:

To avoid the effect described above please be advised not to move the treatment couch to its lowest possible position.

Instead please use the 50cm position (IEC scale) as the lowest position of the couch (with the ExacTrac Robotics installed).

This position can be read out from the Position Indicators of the In-Room and Console Monitor.

The 50cm (IEC Scale) position is equivalent to the table top being at 50cm below isocenter or at about 78cm above turntable surface.

50cm IEC scale equals to 150cm Varian scale or 150cm Linac internal scale.

BrainLAB recommends to remove the couch height calibration applied during the installation with a BrainLAB service visit free of charge. A BrainLAB Support Representative will contact you to discuss and schedule this action.

### BrainLAB Corrective Action:

1. Existing ExacTrac Robotics customers receive this product notification information
2. BrainLAB restores original couch calibration and proper couch operation is verified.
3. BrainLAB and Varian are cooperating closely to provide a permanent solution.
4. BrainLAB will inform all affected customers once a permanent solution is available including corresponding implementation.



Please advise the appropriate personnel working in your 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 BrainLAB Customer Support Representative or Product Support Manager [REDACTED]

**Customer Hotline:** +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by  
**E-mail:** [support@brainlab.com](mailto:support@brainlab.com). Fax BrainLAB AG: + 49 89 99 15 68 33  
**Address:** BrainLAB AG (headquarters), Ammerthalstrasse 8, 85551 Heimstetten, Germany.

Thank you for paying attention to this information.

June 2, 2006

Kind Regards,



Product Support Manager Radiotherapy Solutions  
E-Mail: [REDACTED]@brainlab.com

entering possibilities

## URGENT MEDICAL DEVICE NOTIFICATION

**Subject:** Potential Patient Safety Hazard when combining the Varian EXACT couch with the BrainLAB Robotics  
**Reference:** 49700 Robotics and Product Notification dated June 2, 2006  
**Date of Notification:** June 7, 2006  
**Individual Notifying:** [REDACTED] BrainLAB Product Support Manager Radiotherapy

This letter is to advise you of potential patient safety hazard that may occur when operating the couch, corrective actions you must implement to eliminate the effects, and steps BrainLAB is taking to address the issue.

### Background information

BrainLAB Robotics adds a height of 10cm to the Varian EXACT couch. The EXACT couch position indication has been re-calibrated by BrainLAB during the Robotics installation to read out the correct positions. The lower limit of travel of the couch is limited by software (normal limit), an electrical switch and a hardware stop. This re-calibration has effectively eliminated the software limit, as this point is not reached before the mechanical lower limit of travel. This results in a condition where a single point failure of the electrical switch may result in the couch being driven into the hardware stop.

### Potentially hazardous scenarios

With the ExacTrac Robotics installed and moving the Varian EXACT couch downward the following effects may occur:

A) When approaching its lowest position the couch will not be stopped by the software limit but will be stopped by the electrical limit switch. As the electrical switch is slightly lower than the software limit, the couch start point may be too low for the weight of the patient, possibly resulting in fatigue in the scissors lift and/or worm drive mechanism.

B) In the event that the electrical limit switch fails and this is not noticed by the user, the couch may be driven (repeatedly) into the hardware stop. This may result in a sudden stop of motion and may also result in damage to and eventual failure of the couch lift mechanisms.

Under worst case conditions the above-described scenarios may eventually cause failure of the vertical lift mechanism of the couch which might result in patient injury or death.

### User Corrective Action

Never lower the treatment couch below the 50cm IEC scale position or 150cm Varian/Internal scale position. This will avoid the scenarios and corresponding hazards described above.

This position can be read out from the Position Indicators of the In-Room and Console Monitor.

The 50cm (IEC Scale) position is equivalent to the table top being at 50cm below Isocenter and about 78cm above turntable surface. 50cm IEC scale equals to 150cm Varian scale or 150cm Linac internal scale.



**BrainLAB Corrective Action**

Notification of existing Robotics customers by way of this Product Notification Letter

A BrainLAB Support Representative will schedule a visit to calibrate the couch position indication restoring the couch software limit, and verify proper operation of the couch.

The above calibration and restoration of the couch software limit will result in a 10cm difference between the actual Robotic device table height and the height position indication. Thus BrainLAB will temporarily remove the Robotic device during the visit until a modification is tested and available.

BrainLAB and Varian are cooperating closely to provide a permanent solution.

BrainLAB will inform all affected customers once a permanent solution is available including corresponding implementation.

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

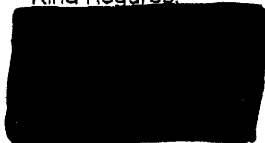
We sincerely apologize for any inconvenience and thank you in advance for your co-operation.

If you require further clarification, please feel free to contact your local BrainLAB Customer Support Representative or Product Support Manager [REDACTED]

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June 7, 2006

Kind Regards,



Product Support Manager Radiotherapy Solutions  
E-Mail: [REDACTED]@brainlab.com

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