

## URGENT DEVICE CORRECTION

7 November 2011

Attention: CyberKnife® System Users

Subject: Lung Optimized Treatment

Affected Product: CyberKnife Systems with the Lung Optimized Treatment Option

Accuray has identified a deficiency in the labeling provided with the Lung Optimized Treatment option. Please review the following information with all applicable members of your staff.

### Description of the Potential Problem

The deficiency identified in the documentation applies to the following points:

1. A discussion of the 0-View Internal Target Volume (ITV), 1-View ITV, and the Internal Target Tracking Volume (ITTV).
2. The importance of the correct CT acquisition process and CT reproducibility.
3. Use of the untracked image as a qualitative alignment check in 1-View tracking treatments.
4. The absence of an ITTV outline displayed during treatment when a Lung Optimized Treatment plan is not based on a Simulation plan.
5. A discussion of the Planning Target Volume (PTV) for 0-View tracking and 1-View tracking.

Failure to comprehend these concepts could result in misplaced dose and potential serious injury to the patient.

### Required Actions

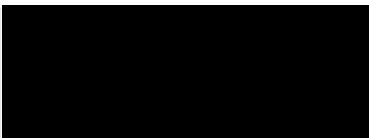
- Read carefully and share the attached information with all applicable staff members.
- Insert the attached information in your user manual.

### Resolution

The information provided in this letter will be incorporated in user manuals shipped with the CyberKnife system.

If you have any questions or concerns regarding this issue, please do not hesitate to contact Accuray Customer Support at +1.877.668.8667 (USA) or +1.408.716.4700 (non-USA).

Sincerely,



Vice President, Regulatory Affairs & Quality Assurance

Accuray Reference: 1475 Rev A

User Manual Addendum:

### 0-View ITV

In the situation that no intra-fraction motion tracking is performed (0-View tracking), then the Internal Target Volume (ITV) corresponds with the standard definition of ITV made in ICRU Report 62 [Ref. 1]. That is, the ITV encompasses the Clinical Target Volume (CTV) and an internal margin (IM) that accounts for all changes in its position during delivery of the fraction.

### 1-View ITV

In the situation that intra-fraction motion tracking is performed using one imaging projection but not both (1-View tracking), the relevant ITV definition is not the same the ICRU 62 definition. In this case, the CTV motion along two orthogonal axes is tracked within the Motion Tracking Plane (see Figures 1 and 2), and therefore the ITV should only be large enough to encompass the motion of the CTV along the remaining non-tracked axis.

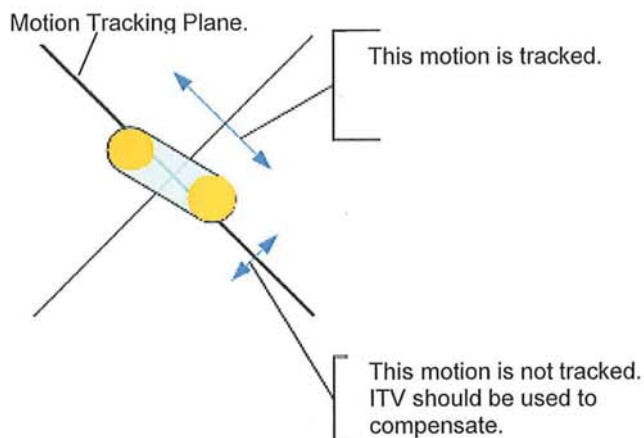


Figure 1: Tracked and untracked motion for 1-View tracking

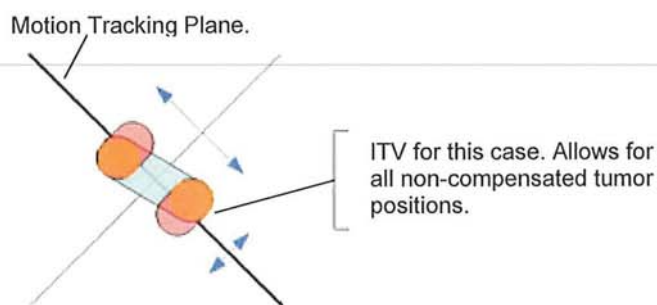


Figure 2: The ITV for 1-View tracking

Figures 1 and 2 illustrate the concept of tracked and untracked motion for a case where 1-View tracking is selected. The orange circle is the CTV at the two extremes of respiratory motion. The ITV for 1-View tracking is different from that for 0-View tracking. As shown in Figure 1, the 0-View ITV (shown in blue) encompasses the full range of CTV motion. In the 1-View scenario, the untracked motion is perpendicular to the plane of the image being used for tracking, represented in Figures 1 and 2 as the Motion Tracking Plane. For 1-View tracking, the pink shapes shown in Figure 2, which include only the untracked component of motion, represent the ITV at each extreme of the respiratory cycle.

### **ITTV**

While the ITV described above is based on the Clinical Target Volume (CTV) and is delineated by the Physician, the Internal Target Tracking Volume (ITTV) is based on the Target Tracking Volume (TTV) and is generally delineated by the Physicist or Dosimetrist during creation of a Simulation plan.

The ITTV represents the expected respiratory excursion of the TTV. The ITTV is defined from the delineation of the TTV on the two respiratory phases represented by the CT scans used to create a Simulation plan. The shape and position of the ITTV is independent of the tracking mode subsequently selected when creating a treatment plan.

During treatment of a case where 1-View tracking is selected **and** the treatment plan was based on a Simulation plan, the projected overlay of the ITTV is displayed in the untracked Live X-ray image.

### **CT acquisition process and CT reproducibility**

Both 1-View and 0-View treatments are based on the assumption that the position and motion range of the target during treatment with respect to the spine alignment center are well represented by the CT scans used for treatment planning. For this reason, it is very important that the CT scans be taken during natural (not forced) inhalation and exhalation, and that the same immobilization applied to the patient is used for both CT scanning and treatment delivery. If any compression device is placed on the patient, it is essential that it be present for both CT scanning and treatment delivery.

### **Use of the untracked image as a qualitative alignment check in 1-View tracking treatments**

When 1-View tracking is selected **and** the treatment plan is based on a Simulation plan the projected overlay of the ITTV is displayed in the untracked Live X-ray image. This overlay displays the excursion of the target in this view, as represented by the CT scans used in treatment planning. When X-ray images are taken and the treatment target is visible in the untracked image, it is possible to perform a qualitative check that the position and motion range of the target still correspond with the position and range from the treatment plan. If the target appears in a position distal from the ITTV overlay, it is an indication that the position and/or motion range of the target has changed. We recommend that a qualified person evaluates the degree of change and determines how to proceed based on the clinical implications for that particular case.

### **ITTV outline not displayed when Lung Optimized Treatment plan not based on a Simulation plan**

When a Lung Optimized Treatment plan is created that is not based on a Simulation plan, the projected overlay of the ITTV will not be displayed in the untracked Live X-ray image for 1-View tracking treatments. In this situation, the qualitative alignment check described above cannot be performed.

### **PTV**

It is important to recognize that there are additional geometrical uncertainties involved in treatment delivery which should be combined into a setup margin that is applied to the ITV to form a Planning Target Volume (PTV) [Ref. 1]. These should include an estimate of the Synchrony modeling uncertainty in the Motion Tracking Plane with 1-View tracking, together with an estimate of the uncertainty in the position of the ITV relative to the spine region covered by the Xsight Spine Region of Interest (ROI) in the untracked out-of-plane direction for 1-View tracking or in all directions for 0-View tracking.

### **References**

1. ICRU Report 62 (1999) Prescribing, Recording and Reporting Photon Beam Therapy. International Commission on Radiation Units and Measurements, Bethesda, MD. (Supplement to ICRU Report 50.)