

## URGENT SAFETY ADVISORY NOTIFICATION

Date: January 22, 2016

Attention: Users of the CyberKnife® System

Affected Product: CyberKnife® Robotic Radiosurgery Systems limited to certain G4, VSI, and G3 systems with the Cosmetic Appearance Package installed.

Accuray has become aware of a potential safety issue involving the mechanical gun box mounting bracket (see Figure 1). This issue is limited to certain CyberKnife® Robotic Radiosurgery Systems of type G4, VSI, and G3 systems with the Cosmetic Appearance Package installed.

### **Description of the Issue:**

In rare instances, the gun box mounting bracket may fail to support the weight of the gun box when in a vertical (inverted) position (see Figure 2). If this failure occurs, the gun box may become loose and could come into contact with a patient. The mounting bracket failure is unlikely to occur and there are no reported incidents of any patient contact due to this issue, to date.



Figure 1: Image of the gun box

### **Inspection of the Gun Box Mounting Bracket:**

Until your gun box mounting bracket is replaced, Accuray recommends a monthly inspection of the mounting bracket. This inspection is expected to take between 20-40 minutes. Your local service team is available to support and/or perform the inspection. Please contact your local field service team for support in performing these inspections.

The procedures in Appendix A provide step-by-step instructions to perform the inspection of the mounting bracket, including the treatment robot position for inspection. To perform this check, the gun box needs to be placed in a vertical position (see Figure 2).

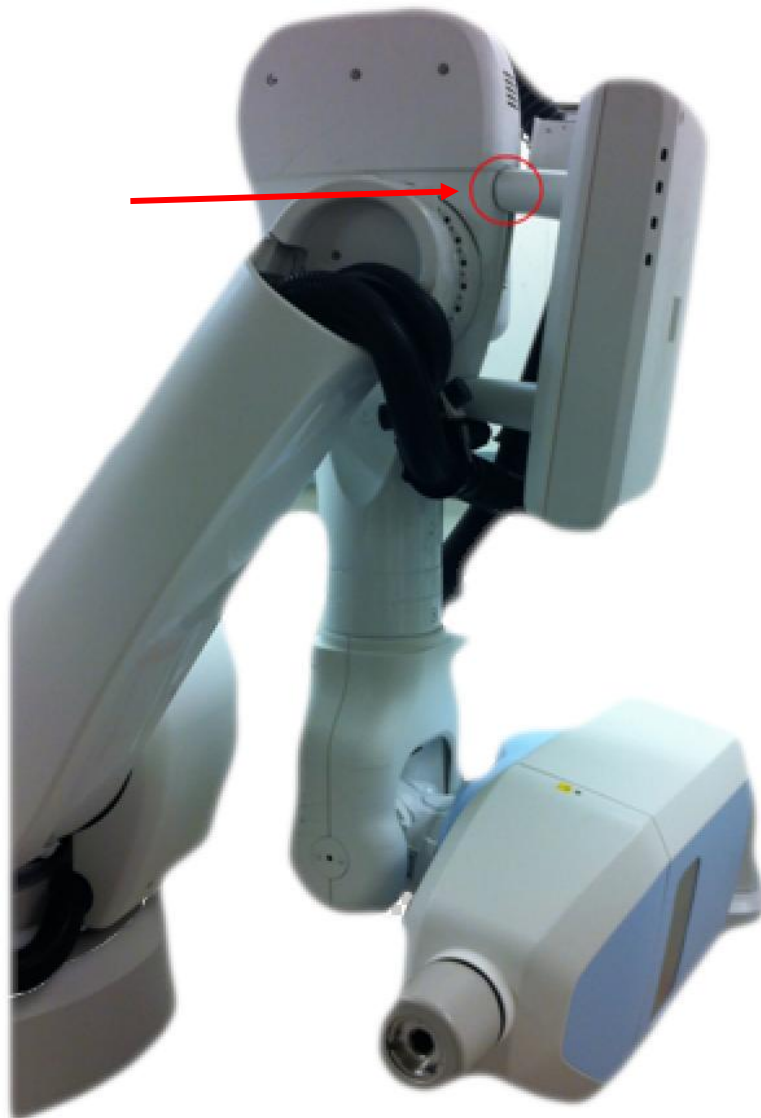


Figure 2: Gun box mounting bracket in the vertical position

**Resolution:**

Final resolution will result in the replacement of the gun box mounting bracket. You will be contacted by Accuray to schedule replacement of the mounting bracket once the redesigned mounting assemblies are available.

**Additional Information:**

For more information or any questions about this notification or assistance with the procedures outlined in Appendix A, please contact Accuray Customer Support at 1-877-668-8667 or visit the Accuray Technical Solution Center at <http://www accuray.com/services-support> or call: **North America:** +1.877.668.8667, **Europe:** +800.4141.9595, **Hong Kong:** +852.2247.8688, **Japan:** +81 3 6265 1530.

Please complete the attached acknowledgment for this notification and return to Accuray.

Sincerely,

Cécile Vedrenne  
Regulatory Affairs EIMEA

# ACKNOWLEDGMENT FORM

## URGENT SAFETY ADVISORY NOTIFICATION

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I acknowledge that I have received the following document from Accuray:

Urgent Safety Advisory Notification concerning the gun box mounting bracket on the CyberKnife® Robotic Radiosurgery Systems limited to certain G4, VSI, and G3 systems with the Cosmetic Appearance Package installed.

I confirm that I understand the content of this Field Safety Advisory Notification dated January 22 and have distributed the information to all applicable members of my staff.

Hospital Name: \_\_\_\_\_

System Serial Number(s): \_\_\_\_\_

Signature: \_\_\_\_\_

Name (print): \_\_\_\_\_

Date: \_\_\_\_\_

Please keep this Field Safety Notification regarding the Gun Box Mounting Assembly with your User Manual.

Send to:  
Accuray International  
REGULATORY AFFAIRS & QUALITY ASSURANCE EIMEA :  
E-mail : [EIMEA-RAQA@accuray.com](mailto:EIMEA-RAQA@accuray.com)

## Appendix A: Gun Box Mounting Bracket Inspection Procedure

### **Method 1 (Preferred)**

1. Create a phantom/demonstration plan using Head template paths that include nodes applicable to the configuration of your CyberKnife System from the following table.
2. Load and start the plan on the CyberKnife System. Stop the treatment when the treatment robot reaches the node listed in the table.
3. **Perform Gun Box Bracket Inspection (see page 9).**

| Imaging Configuration                        | Robot Location    | Node # | Node Position (X,Y,Z)     |
|--|-------------------|--------|---------------------------|
| 45° Imaging Stands                           | HFS Patient Left  | 89     | -412.78, -680.30, -82.48  |
|  |                   | 90     | -279.32, -731.28, -164.96 |
| Horizontal imagers<br>(below or above floor) | HFS Patient Left  | 103    | -412.78, -680.30, -82.48  |
|  |                   | 104    | -279.32, -731.28, -164.96 |
| 45° Imaging Stands                           | HFS Patient Right | 59     | -412.78, 680.30, -82.48   |
|  |                   | 62     | -279.32, 731.28, -164.96  |
| Horizontal imagers<br>(below or above floor) | HFS Patient Right | 61     | -412.78, 680.30, -82.48   |
|  |                   | 64     | -279.32, 731.28, -164.96  |

## **Method 2**

A site Physicist familiar with the operation of the Teach Pendant is required to perform the following QA check. Please read these instructions prior to performing the procedure. The required QA check will take between 20-40 minutes.

### **Set Up (All system configurations)**

1. Move the couch to the **Inferior** position.
2. Move the treatment robot:
  - For software **version 9.x** and earlier, move to **prch**.
  - For software **version 10.x**, move to **PathStart**.

#### **Moving to the Perch (9.x) or PathStart (10.x) Position**


When the Teach Pendant is used to move the treatment robot to the perch position using the **prch** and **PathStart** program, the treatment robot takes the most efficient route based on joint motion.








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**WARNING:** Keep your eyes on the treatment robot at all times, not the Teach Pendant, when using the **prch** or **PathStart** program to avoid collision.

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- **To move the treatment robot to the perch (9.x) or PathStart (10.x) position using the Teach Pendant:**
- Move the mode selector switch from External mode to manual teach mode T2.
    - 
  - Press the button for the **Ackn.** or **Ackn. All** soft key located at the bottom right corner of the Teach Pendant screen.
  - Press the blue Toggle button to highlight the top of the Teach Pendant screen.
  - Use the arrow buttons at the bottom right of the Teach Pendant to select the **CKMAIN** program folder in the left panel of the Teach Pendant screen. The selected folder will be highlighted in blue.
  - Press the Enter button (yellow button) to open the folder.
  - Use the arrow buttons at the bottom right of the Teach Pendant to highlight the **prch** or **PathStart** program in the right panel of the Teach Pendant screen.
  - Launch the **prch** or **PathStart** program by pressing the button for the **Select** soft key displayed at the bottom of the Teach Pendant screen.
  - **NOTE:** If the **Deselect** soft key is displayed instead, another program is active. Press the button for the **Deselect** soft key to toggle the display to the **Select** soft key. Then press the button for the **Select** soft key to launch the **prch** or **PathStart** program.

- Depress and hold one of the enable switches halfway to enable the treatment robot drives. On the status indicator located at the bottom left of the Teach Pendant screen, the middle indicator changes from red
-  to green.
- 
- Press the green Program Start button once and then release the button when the message "programmed path reached (BCO)" is displayed in the message window in the bottom panel of the Teach Pendant screen.
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- Press and hold the green Program Start button a second time. The **prch** or **PathStart** program checks the current position of the treatment robot to see if it can safely be moved to the perch or PathStart position.
- If the treatment robot can safely be moved to the perch or PathStart position, it begins moving. All three status indicators will be green.
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- Keep the green Program Start button depressed until the treatment robot returns to the perch or PathStart position, as indicated by the black indicator.
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3. From the treatment robot teach pendant, access the specific robot position. Go to **Monitor > 1 Rob. Position > 1 Axis specific.**
4. Move each joint of the robot to within 0.5 degrees of the stated target:

**Normal System (Robot to the right of a Head-First-Supine patient):**

1. Current position should be: **-36.64 -109.60 107.02 16.64 3.70 -15.17**
2. Put the treatment robot into T1 mode and set the jog speed to 30%. Keep your eyes on the treatment robot to avoid collision.
3. Move A2 joint to -75 → -36.64 -75.00 107.02 16.64 3.70 -15.17
4. Move A4 joint to +90 → -36.64 -75.00 107.02 90.00 3.70 -15.17
5. Move A6 joint to -90 → -36.64 -75.00 107.02 90.00 3.70 -90.00
6. Move A4 joint to +170 → -36.64 -75.00 107.02 170.00 3.70 -90.00
7. Move A5 joint to +80 → -36.64 -75.00 107.02 170.00 80.00 -90.00
8. Move A3 joint to +140 → -36.64 -75.00 140.00 170.00 80.00 -90.00
9. Move A2 joint to -50 → -36.64 -50.00 140.00 170.00 80.00 -90.00
10. **Perform Gun Box Bracket Inspection (see below, page 9).**
11. Move A2 joint to -75 → -36.64 -75.00 140.00 170.00 80.00 -90.00
12. Move A3 joint to +107 → -36.64 -75.00 107 170.00 80.00 -90.00
13. Move A5 joint to +3.7 → -36.64 -75.00 107 170.00 3.70 -90.00
14. Move A4 joint to +90 → -36.64 -75.00 107 90.00 3.70 -90.00
15. Move A6 joint to -15 → -36.64 -75.00 107 90.00 3.70 -15
16. Move A4 joint to +17 → -36.64 -75.00 107.02 17 3.70 -15
17. Move A2 joint to -110 → -36.64 -110.00 107.02 17 3.70 -15
18. Run **prch** to return the robot to the perch position to resume normal system operations.
19. Return Teach Pendant to **External** mode.

**Mirror System (Robot to the left of a Head-First-Supine patient):**

1. Current position should be: **36.64 -109.60 107.02 -16.64 3.70 15.17**
2. Put the treatment robot into T1 mode and set the jog speed to 30%. Keep your eyes on the treatment robot to avoid collision.
3. Move A2 joint to -75 → 36.64 -75.00 107.02 -16.64 3.70 15.17
4. Move A4 joint to -90 → 36.64 -75.00 107.02 -90.00 3.70 15.17
5. Move A6 joint to +90 → 36.64 -75.00 107.02 -90.00 3.70 90.00
6. Move A4 joint to -170 → 36.64 -75.00 107.02 -170.00 3.70 90.00
7. Move A5 joint to +80 → 36.64 -75.00 107.02 -170.00 80.00 90.00
8. Move A3 joint to +140 → 36.64 -75.00 140.00 -170.00 80.00 90.00
9. Move A2 joint to -50 → 36.64 -50.00 140.00 -170.00 80.00 90.00
10. **Perform Gun Box Bracket Inspection (see below, page 9).**
11. Move A2 joint to -75 → 36.64 -75.00 140.00 -170.00 80.00 90.00
12. Move A3 joint to +107 → 36.64 -75.00 107 -170.00 80.00 90.00
13. Move A5 joint to +3.7 → 36.64 -75.00 107 -170.00 3.70 90.00
14. Move A4 joint to -90 → 36.64 -75.00 107 -90.00 3.70 90.00
15. Move A6 joint to +15 → 36.64 -75.00 107 -90.00 3.70 15.00
16. Move A4 joint to -17 → 36.64 -75.00 107 -17.00 3.70 15.00
17. Move A2 joint to -110 → 36.64 -110.00 107 -17.00 3.70 15.00
18. Run **prch** to return the robot to the perch position to resume normal system operations.
19. Return Teach Pendant to **External** mode.



## **Gun Box Bracket Inspection**

Check the joint where the gun box bracket connects to the robot (see Figure 2). There should be a small gap (Figure 3). If, at the check position, the gap at its narrowest point is less than 10 mm, a failure is not likely. If the gap is large (Figure 4) or changes in size during robot motion, you may have imminent failure.



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**CAUTION:** Do not push or pull on the gun box. If the bracket has failed, pulling or pushing on the gun box may dislodge it from its mounting and create a hazardous situation.

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Figure 3 Typical gap



Figure 4 Oversized gap

If the gap is small, less than 10 mm at its narrowest point, and does not change during robot motion, proceed to step 11, if using method 2 above. **If a large gap is observed, stop using your system and contact Accuray Customer Support.**