URGENT SAFETY NOTICE, CAPTUS 4000E THYROID UPTAKE SYTEM

ACTION REQUIRED

Captus 4000e Serial Numbers 940001 through 940547

Date Range: August 2015 through April 2019

Revised April 1, 2024- adding risk of retention plate failure

Dear Radiology or Nuclear Medicine Department Manager,

Capintec received several complaints of unexpected movement of the Captus 4000e arm and collimator.

After evaluation of the failed components, it was determined two potential failures exist. Initially, a safety notice issued in December 2023 reported a potential failure of the tension rod in the arm, causing the arm to unexpectedly fall to its lowest position, which is approximately 25 inches (63.5 cm) from the ground. In the reported cases, the failure occurred during vertical movement of the spring arm. Additionally, it was determined that the retention plate holding the collimator in place is insufficiently robust for long term use when repeatedly rotated in a circular motion or when rotated with excessive force. Failure of the retention plate will cause the collimator to unexpectedly detach from the spring arm. Then, spring arm can rapidly move upward to its highest position if the collimator detaches.

The collimator and arm assembly weigh approximately 45 pounds (20.4 kg), and there is the potential for injury if the collimator were to detach or arm were to unexpectedly fall or spring upwards and come into contact with a patient or operator.

Hardware replacement components will be available soon which will correct any problems. To receive the replacement component, you must complete and return the acknowledgement form on page 2. This will assure accurate contact and shipping information is available.

In the interim, as a precautionary measure, preventative actions are listed on page 3. In addition, a detailed and easy to follow inspection procedure of the retention plate is included. The inspection can be performed in a few minutes, and any retention plate defect would be easily identified. Should a defect be identified, please contact Mirion Technologies (Capintec), Inc. for immediate assistance.

Sincerely,

Capintec Technical Support Team
capintecsupport@mirion.com
1-210-631-3826
1-800-631-3826

Please confirm receipt and review of this CAPTUS 4000e SAFETY ALERT by completing the online form found here. The confirmation form can be accessed using the previous link, or accessed using the following QR code.

Alternatively, you may complete, print and return this page.

Captus 4000 Serial Number: _____

Facility Name: _____

Facility Address: _____

_____

_____ _____
Contact Name Date

_____ _____
Contact email Contact Phone Number

I acknowledge receipt of the attached Captus 4000e Safety Notice and agree to perform preventative actions.

If you have any questions about this Safety Alert, the Preventive Action steps outlined below, or your Captus 4000e Thyroid Uptake System, please contact Capintec Customer Support at the phone number or email listed below. If you notice any unusual change in the performance or functional response of the arm in your system (e.g. arm is making an unusual noise or arm does not move smoothly at any articulation joint), please contact Capintec Customer Support immediately.
Please report all device-related incidents to the Capintec, or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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Immediate Preventative Actions:

1. Review this Alert and ensure that all affected personnel, including all operators of Captus 4000e Thyroid Uptake Systems, are aware of the contents.

2. Instruct affected personnel and operators to comply with the following steps in the interest of patient and operator safety:

    a. Prior to moving the arm, ensure that the positioning locks are released.

    b. Use caution when moving the spring arm vertically. Ensure that when the spring arm is moved vertically, the operator and patient are not below the spring arm or in its travel path to extent possible. Move the spring arm using an outstretched arm, ensuring no body parts are in the spring arms travel path to extent possible.

    c. Use caution when rotating the collimator in a circular motion. Move is slowly and gently and avoid excessive force.

Figure 1: Spring Arm Locking Handle

    d. Once in position, secure the arm by tightening the locking handle prior to performing Thyroid Uptake and Bioassay Procedures, as shown in figure 1.

    e. Perform Thyroid Uptake and Bioassay Procedures with patient (or employee, for Bioassay Procedures) in a **seated position**, rather than a supine position on a table.

    f. Store the arm in an upright position. This places the least amount of stress on the internal components. Engage the locking handle when the spring arm is not being raised or lowered. Avoid putting the spring arm in its lowest position as much as possible. This position puts the most stress on the internal components.

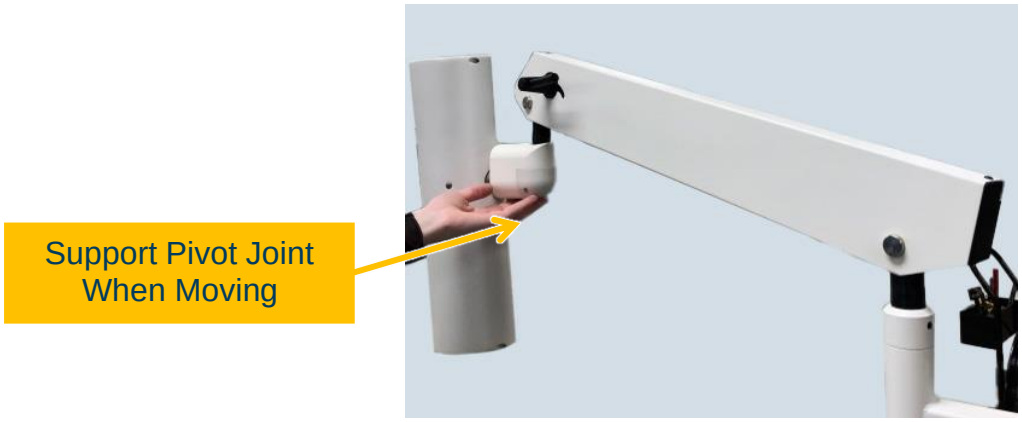
RETENTION PLATE INSPECTION

1. Review this Alert and ensure that all affected personnel are aware of the contents.

2. Instruct affected personnel and operators to comply with the following steps in the interest of patient and operator safety:

    a. Prior to moving the arm, ensure that the positioning locks are released and the Captus 4000e is turned off and unplugged.

    b. Use caution when moving the arm. **Support** the arm at the collimator pivot point as shown in the photograph below when moving the arm. Note: In the event that the collimator falls out, whether during this inspection or during general use, the spring arm has the potential to swing up to its fully upright position because it is no longer counterbalanced by the weight of the collimator.



    c. Once in position, secure the arm by tightening the locking handle prior to performing Thyroid Uptake and Bioassay Procedures.

    d. Until an inspection has been completed and confirmed with a satisfactory status, Perform Thyroid Uptakes and Bioassay Procedures with the patient (or employee, for Bioassay Procedures) in a **seated position**, rather than a supine position on a table.

    e. Always store the arm in an upright position. This places the least amount of stress on the internal components.

Pin Retention Plate Inspection Procedure

Materials Required:

a) 3/32 Allen Wrench (2-inch length)
b) Camera (a phone camera is acceptable)

Please read through instructions fully before starting the inspection. If you have any questions about how to perform the inspection procedure, contact Capintec Technical Support for assistance on how to proceed.

1. Turn the Collimator to the horizontal position as indicated in figure 1.

Figure 2: Collimator Positioning

2. Using a 3/32 Allen Wrench (Allen Key, Hex Key) remove the two screws holding the Cable Cover, shown in figure 2, in place. Counterclockwise motion of the Allen Wrench will loosen the screws, while clockwise motion will tighten the screws. Care should be taken to hold the housing in place until both screws are removed. Please note that the Allen wrench needs to be at least 2 inches in length to reach the screw head. Remove the Cable Cover to access the Collimator Block Assembly.

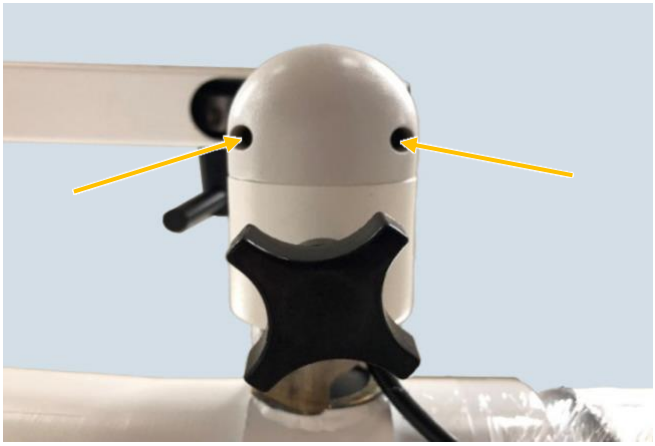


Figure 3: Cable Cover

3. First, perform a visual inspection of the Pin Retention Plate to determine if the tab is properly secured. *NOTE: Do NOT remove or attempt to remove the screws holding the retention plate (shown in Figure 5). Removal of screws may cause injury or damage to equipment.*

3.1. Take digital pictures (cell phone works well) of the Pin Retention Plate, shown in figure 3, in the views shown in figures 6-8 and send to Capintec along with any comments.

Figure 4: Pin Retention Plate

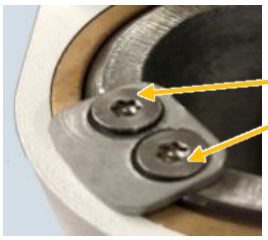


Figure 5: Torx Screws

Figure 6: Bottom View

Figure 7: Front View

Figure 8: Left View

3.2. Visually inspect the two screws, identified in figure 4. The internal steel insert, brass liner and outer protective plastic cover should all be even, retention plate should be level, straight, and flush against the collimator, and the screws should level and flush with the retention plate. Figures 6, 7 and 8 show a properly assembled collimator.

3.3. Carefully inspect the area where the Pin Retention Plate is attached. Look for any signs that the screws are backing off or not flush, that the steel insert is raised and not even with the brass liner and outer protective cover, or that the retention plate is misaligned. Figures 9 and 10 show examples of a collimator which is not properly attached. Also note the screws may be either spanner screws from older models, or torx screws.
NOTE: If the screws show any sign of backing off (not flush) or the steel insert is raised, immediately take the unit out of service and contact Capintec Technical Support.

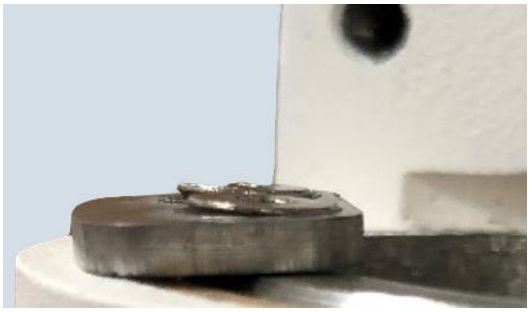


Figure 9: Example 1

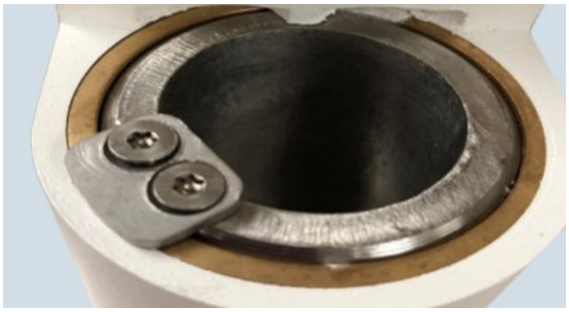


Figure 10: Example 2

4. Next, check whether or not the retention plate is loose and can move. With one hand grab the Collimator as indicated in figure 11 and with the other hand gently attempt to move the Pin Retention Plate in the modes indicated in figures 12 and 13 below.

Figure 11: Hand Support Positioning

Figure 12: Movement 1

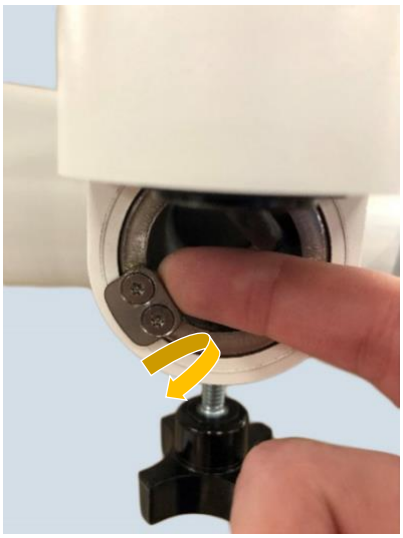


Figure 13: Movement 2

4.1. If you do not believe that you can fully support the collimator with one hand, get someone to help you. The retention plate on a properly attached collimator should feel snug and should not move when pushed gently with one finger. Do not try to forcibly move the plate or use a tool to try and move it. **Note: If the plate is loose and moves with gentle pressure immediately take the unit out of service and contact Capintec Technical Support.**

5. Document the status of your inspection with digital pictures and any comments noted below. If you are unsure about the status of your system, please send the pictures of the assembly to Capintec. Our technical support staff will review and advise you how to proceed. Please complete page 2 of this form and return together with any pictures and inspection comments to Capintec.

Inspection Notes:

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6. Once the inspection has been completed, the back housing can be reattached to the collimator block assembly. Insert the first screw into the back housing as shown in figure 14, then move the housing to the collimator block assembly. Initially turn the screw counterclockwise until it is properly seated, then turn the Allen Wrench clockwise to tighten the screw. Insert the second screw into the housing assembly and fully tighten.

Figure 14: Housing Re-Assembly

If this inspection shows that the collimator is properly attached as shown in figures 6, 7, and 8 then your Captus 4000e System can continue to be operated. However, please be cautious when moving the collimator. Please refrain from quickly spinning the collimator or using strong pulling forces on it. The plate is still at risk from failing if the collimator is used too aggressively.

If your inspection shows that the collimator is not properly attached, please contact Capintec Technical Support at the phone number or email listed below. If you have any questions about this Inspection procedure of your Captus 4000 System, please contact Capintec Technical Support. If you notice any unusual change in the performance or functional response of the arm in your system (e.g. arm is making an unusual noise or arm does not move smoothly at any articulation joint), please contact Capintec Technical Support immediately.

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