Risk Assessment and Health Hazard Evaluation	
Risk Assessment ID and Revision	RA2016-000029
Description	Robot can automatically move to perform Laser Alignment Check as soon as accessory contact sensors are cleared.
Product Line or Process	CyberKnife
Affected Sub-System(s) & Version(s)	CyberKnife Treatment Robot
Risk Assessments and Version(s)	CK-PRMR-1061, Revision 1 31 MAR 2015
Associated Documents	
Complaint Case Number	C036023
Anomaly Number	42724 Also associated with Anomalies 31339, 33363, and 42868
Service Order Number	N/A
Other	N/A

Summary of the Potential Safety Risk issue

A report was received from Field Service Engineering that Laser Alignment Check motion started unexpectedly on a CyberKnife treatment system, while a user was in the treatment room removing an accessory attachment from the robot.
The user was asked to perform an end-to-end test with Iris on the CK system. However, when loading the plan and setting up the phantom for treatment, the user did not notice that the birdcage accessory mount was still attached to the robot. The user was surprised that the LAC button on treatment couch phase was blinking instead of being disabled. They clicked the LAC blinking button to see if the robot would move, and it did not because the accessory mount was still installed. The user entered the room and started to remove the birdcage accessory mount. As soon as the accessory mount was released, they heard the robot activation noise (robot releasing its brakes) and the robot started moving to perform the laser alignment check.
It was reported that no injury occurred, as the user stepped away from the robot when the robot activation sound was heard (this sound is emitted when the robot releases its brakes before it begins motion, with the time between the emission of this sound and robot motion being about 1 second).

Detailed Investigation and Analysis of Potential Risk

A user left the birdcage accessory mount (not the birdcage itself) on the robot. The user then loaded a treatment plan that required the accessory mount to be attached to the robot, but also required the system to first require a Laser Alignment Check. The user went to the Couch phase in treatment and noticed the message "Manual action required: Accessory mount attached to robot, please remove." The user also noticed that the LAC button was blinking and clicked it to make sure no robot motion was going to occur. The user then proceeded into the room to remove the accessory mount from the robot. As soon as the connection sensor for the accessory mount was released, the robot initiated the latent user request to perform a laser alignment check and started its motion.

Issue 1 (Anomaly 31339 and 33363) is that the LAC button is blinking. This user interface bug is only in the 10.6.x platform and affects only M6 sites.

The LAC button is on two treatment screens:

1) Couch phase – where this workflow is optional. LAC button in this phase is incorrectly blinking and allows the user to click it when it is supposed to be disabled.
2) Readiness phase – where this workflow is mandatory. LAC button in this phase functions properly and is disabled (not enabled or blinking).

Issue 2 (Anomaly 42724) here is that the "perform Laser Alignment Check" was held on the server side as the next action while in "not allowed to move" state. As soon as the accessary mount was removed (contact sensor released) the "not allowed to move" state was replaced by "allowed to move". The undesirable behavior is that the command to "perform Laser Alignment Check" was still held as a pending action, and subsequently acted on.

The reported situation was due to the above two issues:

1) cosmetic display issue (blinking LAC button) which allowed the end user to inject a message/request of the system at an inappropriate time (while an accessory was installed in the robot) and the button should have been disabled.
2) The system knowing that the laser alignment check request was not allowed at that time, did not reset its internal state and instead held onto the request.

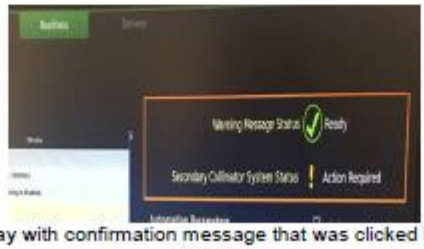
The situation was also impacted by contributing use and events:

1) An accessory was left attached on the robot.
2) The same collimator housing was on the robot as the collimator housing that was required for use with the treatment plan. This is where the Laser Alignment Check workflow detailed in this analysis occurs.
3) The Laser Alignment Check button was noticed to be blinking in the Alignment - Couch phase of the treatment workflow.
4) The user clicked on the blinking screen display button.
5) The user went into the room to remove the attached accessory.

The cause of the event was due to software defects. The products that are involved are the CK Treatment Delivery Software module. All systems with software versions 10.6.0.0 through 10.6.0.4 are potentially affected by the anomaly.

Robot Treatment Head with accessory attached

Treatment Console Display with message at bottom of screen to remove accessory

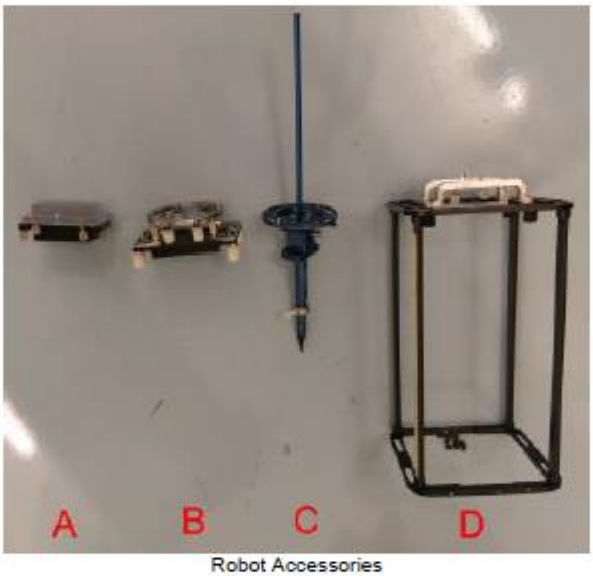


Treatment Console Display with confirmation message that was clicked by user prior to accessory removal

In addition, from review of the CyberKnife Treatment Delivery Guide P/N 1048119, the section detailing "Checking Equipment Readiness" pages 7-71 and 7-72 does not advise that the condition reported in the Warning Message should be addressed prior to clicking the "Confirm" screen button. This issue has been logged as anomaly 42868.

Additional analysis was conducted on the differences in size/connection of the various accessories, the relationship between the robot perch position and the exchange table, the instructions for use and the likely position of the user when accessories are attached/detached, the motion/clearances of the various accessories, and robot torque sensors, and the effectiveness of the contact sensor.

The accessories that can be mounted to the robot include the Small Film Holder (A in diagram below), Pin Hole (B in diagram below), Pointer (C in diagram below), and Birdcage (D in diagram below).



Robot Accessories

Accessories (size and connection):
The Pin Hole (B) and Birdcage (D) accessories require connection to accessory mounts (attached in the picture above) that then are secured to mounting holes on the robot. The Small Film Holder (A) and Pointer (C) mount directly to the mounting holes on the robot. Based on the experience of service support, it is typical for users to detach the Pinhole and Birdcage accessories by detaching the accessory mount directly from the robot mounting holes, instead of first removing the birdcage from the accessory mount and then subsequently detaching the accessory mount from the robot.

Perch Position and attaching/detaching accessories:
The location of the perch position immediately next to the exchange table with minimal clearance has been designed specifically to prohibit a user from positioning their body or occupying a space between the robot and the exchange table. If the robot was not at the perch position, software will prevent robot motion and require the user to move the robot to the perch position before continuing. User documentation includes instructions on how to stand clear of the robot, and a user would need to attach/detach robot accessories from an area that is not between the robot and the exchange table.

Accessories (motion and clearance):
The Small Film Holder and Pinhole accessories and the Birdcage accessory mount have low enough profiles that they will not contact or pinch against the exchange table in a manner that should risk injury to personnel. The Pointer and Birdcage accessories have longer profiles and could be driven against the side of the exchange table.

Robot Torque Sensors:
The Robot axis motors include torque sensors that may interrupt motion if a collision results in unacceptable resistance, but these sensors are mainly designed for and effective in limiting damage to equipment, and these sensors would not likely be effective in reducing injury to personnel.

Robot Contact Sensor:
The Contact Sensor on the tip of the robot remains functional with any of the Robot Accessories attached, regardless of whether the accessory requires a separate accessory mount or not. However, the location of the contact sensor above the accessory will not likely be tripped by personnel or equipment being pinched between accessories and the exchange table. In the unlikely event that this situation occurs, a user may be able to stop motion by independently tripping the contact sensor, but this is not the intended or instructed use of the contact sensor, and this would only be coincidental.

Review existing Risk Management File

From a review of the PRMR file, it has been identified that comparable risk condition and consequent possible contact with an Operator/Bystander/Patient are considered and documented in:

Hazard 99 – Physical contact with Treatment Robot in operation mode
Harm – Tissue Damage
Cause 1 – Patient, Operator, or Bystander in the path of a Laser Alignment Check motion executed automatically (i.e. executed without user invocation)
Mitigation 1 – User manual instructing users to stand clear of Treatment robot's workspace
After application of risk controls for this issue, the likelihood and severity levels noted in the PRMR are:

Probability of 1 - Death:	6 - Incredible	(1: 1,000,000+)
Probability of 2 - Serious Injury:	6 - Incredible	(1: 1,000,000+)
Probability of 3 - Minor Injury:	6 - Incredible	(1: 1,000,000+)
Probability of 4 - Negligible Injury:	6 - Incredible	(1: 1,000,000+)

Root Cause Determination
The root cause of this issue is a software anomaly.

Severity Assessment

Death
This is based on the possibility that unexpected laser alignment check motion of the robot arm while the operator is potentially in contact with the robot will result in Death.

Serious Harm
This is based on the possibility that unexpected laser alignment check motion of the robot arm while the operator is potentially in contact with the robot will result in Serious Harm.

Minor Harm
This is based on the possibility that unexpected laser alignment check motion of the robot arm while the operator is potentially in contact with the robot will result in Minor Harm.

Negligible Harm
This is based on the possibility that unexpected laser alignment check motion of the robot arm while the operator is potentially in contact with the robot will result in Negligible Harm.

Probability Assessment

Item	Likelihood Item Description	Probability of Occurrence				Justification for the Probability
		4 Negligible	3 Minor	2 Serious	1 Death	
P1 = Exposure or Probability of a Hazardous Situation Occurring						
1	The housing attached to the robot is the same housing that is called out for the plan. (LAC workflow)	1: 3				Three potential housings (Fixed, Iris, and MLC)
2	Manual action required during LAC workflow. (Fixed collimator changes, Accessory left on robot, etc.)	1: 10				Attachments are clearly distinguishable, and instructions identify required accessory for the specific work task
3	User clicks on a blinking Laser Alignment Check button in Couch phase (following IFU workflow)	1: 5				The Treatment Delivery Guide does not have specific guidance to prevent this possible workflow. Difficult to click the button and being aware of the button blinking.
4	User enters bunker and removes incorrectly mounted accessory	1: 1				Desired work activity (i.e. LAC) cannot be continued without manual user action
5	User fails to use E-Stop or move out of the way (per general IFU guidance)	1: 5				System makes noise as locks release momentarily before the start of robot arm movement, alerting user of impending motion, and user will typically not be positioned or have body parts positioned between accessory and exchange table
	P1 Total	1: 750				
P2 = Probability of the Hazardous Situation leading to Harm						
	P2 Total	1: 1	1: 10	1: 100	1: 1,000	Conservative estimates based on open space around CK system, and ability of user to move away from system
	Total P (P1 x P2)	1: 750 Acceptable RBA	1: 7,500 Acceptable RBA	1: 75,000 Unacceptable	1: 750,000 Unacceptable	

Risk Acceptability Criteria

Does this issue represent a new Hazard?	Yes
Does this issue represent a Hazard, Harm, Failure Mode-Cause etc. that is identified in the relevant Risk Management File?	Yes
If the issue represents an existing risk what is the Hazard, Harm, Failure Mode-Cause:	
Associated Hazard(s) and Cause(s) identifiers	99-1
Associated Mitigation identifiers	99-1-1
Does this issue represent a significant change to the risk (occurrence over limit) classification per Accuray Risk Criteria?	Yes
Justification:	N/A. The risk score indicates that a S/W patch is required.

Risk acceptability scoring for this issue is based on the event based Likelihood Assessment above.

The risk for Death is scored as **Unacceptable**

The risk for Serious Harm is scored as **Unacceptable**

The risk for Minor Harm is scored as **Acceptable RBA**

Based on existing RBA for the product.

The risk for Negligible Harm is scored as **Acceptable RBA**

Based on existing RBA for the product.

Risk Assessment Team Approvals

Department	Representative	Signature and Date
Author	[redacted]	[redacted]
Engineering	[redacted]	[redacted]
Engineering Technical/ Functional Lead or Engineering Manager	[redacted]	[redacted]
Clinical	[redacted]	[redacted]
Development QA	[redacted]	[redacted]
Risk Management or RA Manager	[redacted]	[redacted]