

URGENT FIELD SAFETY NOTICE

Hugo™ Robotic-Assisted Surgery (RAS) System - Surgeon Console Unintended Motion

UDI-DI: 0763000B00006347V

Service

March 2024

Medtronic Reference: FA1364

EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is initiating an Urgent Field Safety Notice for the Hugo™ robotic-assisted surgery (RAS) system surgeon console (MRASC0001). Only a sub-population of the surgeon consoles are impacted by this issue; impacted serial numbers listed below.

Issue Description:

This Field Safety Notice is being issued following our investigation of three (3) reported complaints of unintended motion of the lever on the Surgeon Console hand controller that occurred while Medtronic personnel were performing routine servicing of and/or training on the Hugo™ RAS system. The investigation identified a faulty soldering process of a circuit board within the identified sub population of Surgeon Consoles. In the unlikely event that this failure occurs during teleoperation while the surgeon is engaged with the Surgeon Console hand controllers, the surgeon would feel pressure that was attempting to close the hand controller lever. To mitigate any unintended motion, the user can restrain the lever from actuating. If this failure were to occur while the system is not in teleoperation, unintended movement of the hand controller lever would not be translated to the robotic arms or instruments.

Risk to health:

None of the reported complaints occurred during a procedure and no patient harm has been reported in relation to this Field Safety Notice. However, the potential for harm does exist and includes, but is not limited to, unspecified tissue injury and hemorrhage/bleeding/blood loss. This Field Safety Notice has no impact on patients who have previously undergone a procedure using the Hugo™ RAS system. These patients should continue to be monitored per your practice's normal follow-up procedures.

Product Scope:

Model Number	Product Description	GTIN	Serial #
MRASC0001	SURGEON CONSOLE MRASC0001	10884521826625	C21AJK0136

Actions to be taken by customer:

- Immediately notify all personnel in all care environments in which the Hugo™ RAS system is used about this Urgent Field Safety notice.
- The continued use of Hugo™ RAS System is considered appropriate based on an internal review taking into account the benefit provided to patients compared to any potential risk that may be posed. This assessment may be augmented in individual surgeries by determining any circumstances that materially change the benefit or risk.
- To mitigate any unintended motion, the user would restrain the hand controller lever from actuating and then immediately disengage teleoperation.
- Please post this notification in a prominent location and maintain awareness of this matter until the issue is resolved.

Actions being taken by Medtronic:

- Your Medtronic representatives will schedule a service call to inspect the impacted product and will service the device within the coming months.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic representative.

Sincerely,

[Local / OU Manager](#)