

Urgent Field Safety Notice

Hugo™ Robotic-Assisted Surgery (RAS) System

Arm Cart Assembly Model # MRASC0002, Tower Model # MRASC0005
Service

August 2023

Medtronic Reference: FA1228

< For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000028763 >

Dear Risk Manager, Healthcare Professional, and OR Materials Manager,

This correspondence serves as a follow-up to the communication from April 2023, providing a correction regarding "Hugo™ RAS System Updates Overview" (Attachment 3) aspect of the new software functionality. Additionally, it includes additional serial numbers IN the scope of the FCA. This letter is to notify you that Medtronic has released a software update to address system errors during preoperative calibration of the Hugo™ RAS system robotic arm cart assembly. A Medtronic representative will be performing this software update on your impacted Hugo™ Robotic-Assisted Surgery (RAS) system(s). Should your system already have been updated to software version 2.0, no additional steps are necessary from your end. As an acknowledgment to the modification made to the "Hugo™ RAS System Updates Overview", please complete the Customer Confirmation Form.

The failure mode identified in the initial phase of FA1228 was the arm cart assembly (MRASC0002); however, further investigation identified the root cause as a software issue in the tower (MRASC0005). System updates will be implemented throughout all components of the Hugo™ RAS system resolving this issue with the implementation of software version 2.0 (from version 1.2).

This software update affects the part number: Tower Model # MRASC0005, which includes the Arm Cart Assembly Model # MRASC0002.

The procedures, as outlined in the Arm Cart Calibration Guide (Attachment 2) that you received previously, should continue to be followed until the software has been updated.

Issue Description:

As background, the urgent field safety notice was initiated in March 2022 following our investigation of four (4) reports of a system error during preoperative calibration self-tests of the Hugo™ robotic arm cart assembly. At

that time, Medtronic provided an outline in **Attachment 2**: Arm Cart Calibration Guide, which should continue to be followed until the software has been updated.

A copy of the original consignee notification (**Attachment 1**), provided in March 2022, has been attached for your convenience that further outlines the issue description, risk to health, and mitigation strategy and actions.

Actions to be taken by the Customer:

- Notify personnel in all care environments in which the Hugo™ RAS system is used and provide them with the applicable version of **Attachment 2**: Arm Cart Calibration Guide.
- Ensure all users adhere to the procedures, as outlined in the Arm Cart Calibration Guide until the software has been updated.
- Review the **Attachment 3**: Hugo™ RAS System Updates Overview V2
- Complete the enclosed Customer Confirmation Form, please return the form to rs.ranordic@medtronic.com
- Please maintain a copy of all records associated with this action.

Actions being taken by Medtronic:

- Medtronic representatives will contact you to schedule services of the system.

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 Medtronic representative.

Sincerely,

[Local / OU Manager](#)

Enclosed:

- Attachment 1: March 2022 Consignee Notification
- Attachment 2: Arm Cart Calibration Guide
- Attachment 3: Hugo™ RAS System Updates Overview V2
- [Appendix 1: Phase 2 Affected Products](#)

Appendix 1 - Phase 2 Affected Products*

Product Name	Model #	UDI-DI/ GTIN	Serial Number
TOWER 240V MRASC0005	MRASC0005	10884521756359	C21CAG0052, C21CAG0048, C21CAF0044, C21CAF0043, C21CAD0036, C21CAD0035, C21CAB0029, C21CAB0027, C21CAB0025, C20CAK0022, C21CAB0028, C21CAB0031, C21CAA0023
TOWER 240V MRASC0005	MRASC0005	10884521826663	C22CAF0116, C22CAF0114, C22CAF0113, C22CAF0112, C22CAF0110, C22CAF0109, C22CAE0107, C22CAE0106, C22CAE0104, C22CAE0103, C22CAE0102, C22CAD0101, C22CAD0100, C22CAD0099, C22CAD0098, C22CAD0097, C22CAD0096, C22CAC0095, C22CAC0093, C22CAC0092, C22CAC0091, C22CAC0090, C22CAB0089, C22CAB0088, C22CAB0087, C22CAB0086, C22CAA0085, C22CAA0084, C22CAA0083, C21CAM0082, C21CAM0080, C21CAK0078, C21CAK0077, C21CAK0076, C21CAK0075, C21CAK0074, C21CAK0073, C21CAH0059, C21CAH0057, C21CAH0056, C21CAG0054, C21CAG0053, C21CAG0047, C21CAD0039, C21CAE0042, C21CAG0049, C21CAG0051, C21CAH0055, C21CAH0058, C21CAK0071, C22CAF0108, C22CAF0117, C22CAF0118

*The bolded information in this appendix are additional serial numbers that have been added as compared to the April 2023 consignee notification letter.