

Urgent Field Safety Notice

Hugo™ Robotic-Assisted Surgery (RAS) System

Arm Cart Assembly Model # MRASC0002, Tower Model # MRASC0003, MRASC0005
Service

March 2023

Medtronic Reference: FA1228

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

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

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). 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 (MRASC0003 and 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 # MRASC0003 and 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 three (3) reports of a system error during preoperative calibration self-tests of the Hugo™ robotic arm cart assembly. At that time, Medtronic provided an outlined 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
- 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,

Medtronic GmbH

Enclosed:

- Attachment 1: March 2022 Consignee Notification
- Attachment 2: Arm Cart Calibration Guide
- Attachment 3: Hugo™ RAS System Updates Overview
- Attachment 4: Affected Products

Attachment 4 -Affected Products

Product Name	Model #/CFN	UDI-DI/ GTIN	Serial Number
TOWER 120V MRASC0003	MRASC0003	10884521739925	C22AKE0080, C22AKE0079, C21AKJ0061, C21AKJ0060, C21AKF0055, C21AKB0046
TOWER 240V MRASC0005	MRASC0005	10884521756359	C21CAG0052, C21CAG0048, C21CAF0044, C21CAF0043, C21CAD0036, C21CAD0035, C21CAB0029, C21CAB0027, C21CAB0025, C20CAK0022
TOWER 240V MRASC0005	MRASC0005	10884521826663	C22CAF0116, C22CAF0114, C22CAF0113, C22CAF0112, C22CAF0110, C22CAF0109, C22CAE0107, C22CAE0106, C22CAE0104, C22CAE0103, C22CAE0102, C22CAD0101, C22CAD0100, C22CAD0099, C22CAD0098, C22CAD0097, C22CAD0096, C22CAC0095, C22CAC0094, C22CAC0093, C22CAC0092, C22CAC0091, C22CAC0090, C22CAB0089, C22CAB0088, C22CAB0087, C22CAB0086, C22CAA0085, C22CAA0084, C22CAA0083, C21CAM0082, C21CAM0080, C21CAK0079, C21CAK0078, C21CAK0077, C21CAK0076, C21CAK0075, C21CAK0074, C21CAK0073, C21CAH0059, C21CAH0057, C21CAH0056, C21CAG0054, C21CAG0053, C21CAG0047, C21CAD0039