Medtronic

Urgent Field Safety Notice

Hugo™ Robotic-Assisted Surgery (RAS) System

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

Service

July 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.

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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

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Attachment 1- March 2022 Consignee Notification

Urgent Field Safety Notice

Hugo™ Robotic-Assisted Surgery (RAS) System

ARM CART ASSEMBLY MRASC0002

Notification

March 2022

Medtronic Reference: FA1228

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

The purpose of this letter is to advise you that Medtronic is conducting a voluntary Urgent Field Safety Notice for the Hugo™ robotic-assisted surgery (RAS) system. This field action affects the part number listed below:

ARM CART ASSEMBLY MRASC0002

Issue Description:

This Urgent Field Safety Notice is being taken following our investigation of three reports of a system error during preoperative calibration self-tests of the Hugo robotic arm cart assembly. Below we will explain this system error and the steps that should be taken to address it.

Calibration self-tests are performed by internal software during preoperative setup. These self-tests verify proper functioning of the robotic arm cart assembly and signal a non-recoverable error[1] if at least one of the self-tests fail.

The system will display a system notification of the failure giving the user the option to either recalibrate the arm cart assembly or ignore the arm and continue. If the user chooses the recalibrate option the robotic arm cart assembly will be prevented from entering teleoperation even if the calibration is successful. This may cause procedural delays when the user subsequently attempts to enter teleoperation.

[1] A non-recoverable error means an error that can only be resolved by power cycling (i.e. turning off power to a component and then turning it back on).

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Risk to Health:

There have been no patient injuries reported as a result of this system error. There is a potential for procedural delay and/or harm for unspecified tissue injury in a worst-case scenario, if this system error occurs and is not resolved during set up. Because this system error can be resolved preoperatively, the Hugo system may be safely used.

How to Address this System Error:

This system error can be addressed by following the Arm Cart Calibration Guide listed in Attachment #1 CE Arm Cart Calibration Guide.

Actions to be taken by the Customer:

- Notify all personnel in all care environments in which the Hugo RAS system is used about this urgent field safety notice.
- Provide all users with the applicable version of attached Arm Cart Calibration Guide.

Actions being taken by Medtronic:

- Medtronic is providing customers with an Arm Cart Calibration Guide.
- Medtronic is developing a software update that is expected to resolve this system error.
- Our Medtronic Technical Support/Field Service Department will assist customers with installing the software update after it is released.

Additional Information:

We regret any inconvenience that this issue may have caused. 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

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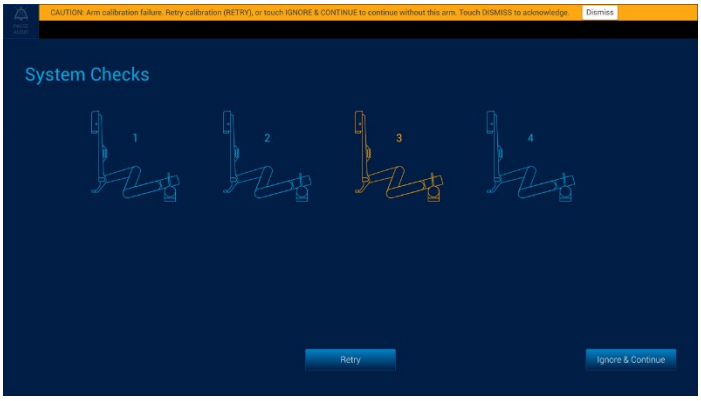
Attachment 2 - Arm Cart Calibration Guide

Arm Cart Calibration Guide

This guide includes updated instructions to (1) determine if there is an arm cart calibration error and (2) recover from an arm calibration error. After completing arm calibration, the **Messages** log should always be viewed from the Surgery screen to confirm there are no arm calibration errors present. In the event of an arm calibration error, restart the arm cart by unplugging and reconnecting the arm cart data cable.

1. If any arms encounter a problem calibrating, the System Checks screen will show the particular arm with the error and provide options to either re-calibrate the arm or ignore the arm and continue.

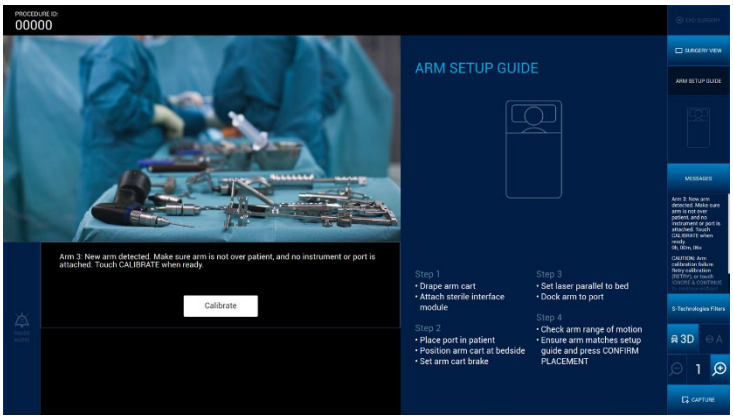


   If an arm has failed calibration, do not select the **Retry** or **Ignore & Continue** button. Instead, restart the arm by performing the following steps:

   a. Unplug the arm cart data cable from the arm with the error. The arm will shut down and the system will display a message that the arm is no longer connected.

   b. Reconnect the arm cart data cable. When the arm completes its startup, the arm cart LEDs will be green and the system will detect the connected arm and display the following message:

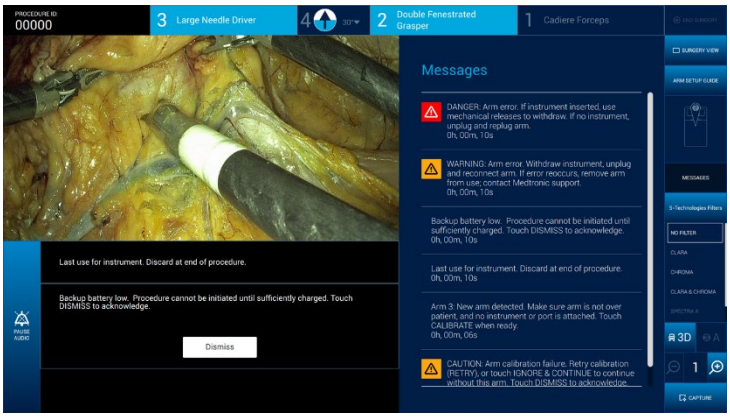
      “Arm [ARM #]: New arm detected. Make sure arm is not over patient, and no instrument or port is attached. Touch CALIBRATE when ready.”



Press **Calibrate**.

c. If the arm fails calibration again, shut down the arm by unplugging the arm cart data cable and remove the arm from service.

2. Press the "**Messages**" button located on the menu located at the right of the OR team interactive display. The messages for this procedure are displayed in reverse chronological order (the most recent will be displayed first).



3. If either of the following errors appear in the list of messages, restart the arm according to the instructions in Step 1. If the error appears again, shut down the arm by unplugging the arm cart data cable and remove the arm from service.

   "Arm[ARM#]: WARNING: Arm error. Withdraw instrument, unplug and reconnect arm. If error reoccurs, remove arm from use; contact Medtronic support."
   "Arm [ARM#]: WARNING: Arm error. If instrument inserted, use mechanical releases to withdraw. If no instrument, unplug and replug arm."

4. Continue to Arm Setup.

Attachment 3 - Hugo™ RAS System Updates Overview

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Hugo™ Robotic-Assisted Surgery (RAS) System Updates Overview

Medtronic will be implementing hardware and software updates to support future capabilities of the Hugo™ Robotic-Assisted Surgery (RAS) system. The updated hardware is intended to enhance computing performance, increase memory, and optimize processing power, while new software (version 2.0) will support enhanced system performance, improved memory management, and advanced cyber security features. Additionally, software version 2.0 resolves the system error during preoperative calibration self-tests of the Hugo™ RAS arm cart assembly.

What to expect

- Medtronic will be conducting hardware and software updates to your Hugo™ RAS system(s) at no cost to you.
- Hugo™ RAS system updates will take an estimated 3-4 days to complete. During this time, the system will not be available for use.
- A Medtronic representative will contact you to coordinate scheduling of this service with the goal to minimize disruption to your robotics program.
- The hardware and software updates will not change the Hugo™ RAS System user experience.
- Hugo™ RAS system updates include:

Current	**Replacement**
mITX motherboards	D3633 motherboards
4th Generation Intel CPUs	8th and 9th Generation Intel CPUs
1.2 Tower Monitor	2.0 Tower Monitor
Software version **1.2**	Software version **2.0**

If you have any questions regarding this communication, please contact a Medtronic representative at rs.globalroboticservicesupport@medtronic.com.

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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, C22CAF0115, 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, C21CAK0071, C21CAH0059, C21CAH0057, C21CAH0056, C21CAG0054, C21CAG0053, C21CAG0047, C21CAD0039