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URGENT: MEDICAL DEVICE SOFTWARE CORRECTION
Mazor X™ robotic guidance system
Model TPL0059, Software Version 5.0.1 or 5.1.2 or 5.1.3
System Software update to version 5.2

11 December 2025 | 09:21 SGT

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Risk Manager,

The purpose of this letter is to advise you that Medtronic is issuing an update to the software for the Mazor X™ robotic guidance system model TPL0059 ("Mazor X™ systems"). The updated version 5.2 is applicable to systems running versions 5.0.1, 5.1.2 or 5.1.3 of the system software. The availability of this software is dependent upon regulatory approval timing and may vary by country. Medtronic field service engineers will reach out to accounts to schedule the update of all Mazor X™ systems from version 5.0.1, 5.1.2 or 5.1.3 to version 5.2 once the software becomes available.

Issue Description:

Software version 5.2 contains incremental software improvements and corrections. The update includes refinements identified during internal testing and post-market surveillance. The majority of updates are associated with negligible patient severity impact. Seven (7) issues were corrected to further enhance system reliability and patient safety. Pending availability and installation of software version 5.2, you may continue to use the Mazor X™ system as detailed in the user manual and as described in Appendix A.

Potential Patient Harm:

Regarding the seven issues being corrected in software version 5.2, in rare circumstances and/or atypical workflows the issues have the potential to result in temporary workflow interruptions, extended procedure duration, the inability to

proceed with robotic guidance or inaccuracy of the system with the potential for neurological injury. No patient injuries or adverse clinical outcomes have been associated with the issues corrected with software version 5.2.

Product Scope:

Product Information			
Product Name	**Model Number**	**GTIN**	**Software Versions**
Mazor X System	TPL0059	07290109180465 07290109184524 07290109181158 00763000635169 07290109183213 07290109184517 00763000419134 00763000431761 07290109184098 07290109184838 07290115751376 07290115751895	5.0.1, 5.1.2, 5.1.3

Customer Actions:

- Please review this information with all physician users and/or post a copy of this notification with your Mazor X system until the software update is completed.
- Please confirm via the enclosed confirmation form that this notification has been communicated within your facility with all physician users. Return the completed Customer Confirmation Form to your local Medtronic representative.
- Provide this notification to those who need to be aware within your organization or to any organization where the affected systems have been transferred.
- Maintain a copy of this notice in your records.
- Continue to use the Mazor X™ system as instructed in the user manual and with the mitigations provided below in Appendix A.

Medtronic Actions:

Medtronic field service engineers will reach out to accounts to schedule the software update of all Mazor X™ systems once your country's regulatory body has provided the necessary approvals.

If you have questions regarding this update, you may contact your local Medtronic Representative.

Additional Information:

Medtronic will notify all applicable regulatory agencies and competent authorities about this matter.

Adverse events or quality problems experienced with this product should be reported to your local Medtronic representative.

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,

Signed by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 11 December 2025 | 09:20 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Senior Director

Asia Region-Led Market

Enclosures:
Appendix A
Customer Confirmation Form

Appendix A

Pending availability and installation of software version 5.2, you may continue to use the Mazor X™ system as detailed in the user manual and with the mitigations as described below.

Issues present in software versions 5.0.1, 5.1.2, and 5.1.3:

Note: Medtronic has not received any customer complaints associated with these issues.

1. *Potential accuracy impact when adjusting the Planning Bone Reference System in the Axis Validation process post-registration*

   Changing the Planning Bone Reference System (PBRS) in the Axis Validation screen during operation, without re-registering the patient, may cause misalignment between planned screw positions and the patient's actual anatomy. This change occurs without any warning of potential inaccuracy.

   Mitigation: Verify that the PBRS is adjusted in the Axis Validation before entering operation. If there is need to modify the PBRS in the Axis Validation screen during the operation, re-register the patient to maintain accurate positioning. Furthermore, frequently confirm navigation accuracy during live navigation as directed in the instructions for use.

2. *Screw is auto-mounted, compatible to the selected driver, but is not the planned screw*

   Under a specific, non-standard workflow, the navigation screen may display an incompatible screw model relative to the planned screw. This only occurs when the user selects the same NavLock for the screws and the Anteralign implant tools, while also selects an incompatible driver for the planned screw. These actions deviate from the standard workflow.

   Mitigation: Follow the clinical workflow presented in the user manual in order to select and navigate the correct tools and their matching drivers. Verify that the tools used are correctly presented on the navigation screen.

3. *The robotic arm moves through the Screw Extender after the work volume vanished in Edit Work Volume screen.*

   During a specific workflow, if a new 3Define scan is started while screw extenders are already present in the work volume, and the scan fails, the system may no longer display the work volume or the screw extenders. This could result in the surgical arm moving unexpectedly into the work area.

   Mitigation: Review the 3Define scan movement of the surgical arm while capturing new images. For any unintended surgical arm movement, the user can stop the surgical arm via the emergency stop button.

Issues present only in software version 5.0.1:

Note: Medtronic has not received any customer complaints associated with this issue.

1. *The lateral default work volume is incorrectly changed to prone after entering the Edit Work volume.*

When entering the *Edit Work Volume* screen in the lateral orientation procedure, the system might default to prone orientation. If this happens, the system does not present lateral positioning as an option for selection. This does not occur in SW 5.1 or later.

Mitigation: Following Work Volume edit, review the new work volume presented on the screen to make sure the system shows correct alignment with the procedure orientation.

Issues present in software versions 5.1.2 or 5.1.3:

Note: Medtronic has not received any customer complaints associated with issue #1 and #2 below. Regarding issue #3, Five (5) field complaints have been reported with patient impact of surgical delay, non-robotic procedure, or additional surgery.

1. Spine Shifting Tool used outside the registered area.

   When a spine shifting tool is navigated outside the facet levels but still in the registered area, the system incorrectly indicates that the tool is outside the registered area (even though it is inside) and therefore does not display relevant warning messages about potential loss of robotic accuracy.

   Mitigation: The use of Spine-Shifter Tools for the Interbodies workflow is recommended only after executing all pedicles drilling. The use of spine shifting tools may cause spinal movement, therefore make sure to verify accuracy, or re-register the system when using these tools.

2. *Incorrect Work Volume is displayed when using same patient ID for Scan & Plan workflow to existing CT-FL patient.*

   When using the same patient ID to a revision Scan & Plan procedure or while changing between CT-FL to Scan & Plan procedure, an incorrect work volume may appear. The location of the screw extender display may be incorrect, or the user may not be able to proceed to operation screen.

   Mitigation: Before sending the surgical arm, verify that the work volume and screw extenders are correctly displayed on the screen. If needed, you can initiate a new 3Define scan or select the default work volume option. For any unintended surgical arm movement, stop the surgical arm via the emergency stop button.

3. *Unresponsive screen when importing O-Arm scan to an existing patient record when the existing patient is not selected on Patient Folder.*

   When importing an O-Arm scan into an existing patient record, using a scan with a different patient ID than the patient folder may cause the import screen to freeze, preventing the scan from being transferred.

   Mitigation: When importing an O-Arm scan, use the "Create a New Patient" option to avoid this issue. If you use the "Select Existing Patient" option, make sure the correct patient folder is selected before starting the Scan and Plan procedure.

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For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately.

<table>
<tr><th colspan="2">Customer Contact Details</th><th>Medtronic Contact Details</th></tr>
<tr><td colspan="2" rowspan="2">Distributor / Hospital / Clinic / Physician / Patient name:</td><td>Name:</td></tr>
<tr><td>Mobile no:</td></tr>
<tr><td colspan="2">Address:</td><td rowspan="2">Email:</td></tr>
<tr><td>Phone no:</td><td>Email:</td></tr>
</table>

By signing this form, I confirm that I have read the Urgent Medical Device Correction Notification Letter, dated 11 December 2025 | 09:21 SGT **, from Medtronic regarding the Mazor X System and taken appropriate action.**

Please complete all fields and sign the form as indicated below and return the completed form to your local Medtronic representative.

Name (print): _____ Signature: _____ Date: dd Mmm yyyy

For questions, contact your local Medtronic Representative.
Note: The addressee may continue to receive reminders of this notice until a response is received.