

# Urgent Medical Device Field Action

JUL-10-2025 | FSCA 2025-013 Customer letter | Rev 01

## Subject: Corin Operating Tables

### Products affected:

Our records indicate that some of the below listed products were delivered to your location. Please verify if you have any of the listed products and follow the information below.

Item number	Item name	Serial number
770001A0	CORIN w/o autodrive, IPC, EU	1-28 (27 devices)
770001A2	CORIN w autodrive, IPC, EU	5-59 (46 devices)
770001B0	CORIN w/o autodrive, SFC, EU	5-97 (87 devices)
770001B2	CORIN w autodrive, SFC, EU	3-194 (146 devices)
770001F0	CORIN w/o autodrive, SFC, US, bodyel.	1-7 (7 devices)
770001F2	CORIN w autodrive, SFC, US, bodyel.	4-15 (5 devices)

### Description of the issue

Under certain conditions – such as the simultaneous use of the operating table with other medical devices that may cause interference, including high-frequency (HF) surgical equipment – we have identified a potential issue that could prevent the device from performing as intended. If the issue occurs, the Corin operating table (7700.01XY) does not respond to any command. It is impossible to actuate any movement of the Corin operating table, neither with the universal remote control nor the override panel. We are not aware of instances where a patient was injured due to the described issue.

### Potential hazards

The described issue may stop the intended functioning of the Corin operating table potentially resulting in a procedural delay in a critical step of the procedure, e.g. emergency caesarean section, neurosurgery procedure or polytrauma.

This poses a risk primarily to patients undergoing surgery with pre-existing medical conditions that may diminish major body structures/systems, complicate management, prolong recovery, children (neonatology), obese patients, pregnant women or for whom procedural delay may introduce additional risk, e.g., emergency cases.

To date we have no information that a patient was injured due to the described issues.

## Precautions

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The device can be used in accordance with the instructions for use. If the issue occurs, the user should, if possible, deactivate or disable any devices that may interfere with the proper functioning of the Corin operating table.

Furthermore, if the device fails to function with the remote control connected wirelessly and/or via cable, the user should attempt to operate the Corin operating table using the override control panel of the operating table (see IFU 7700.01 EN 02 2024-06-05; § 4.3 Override control panel).

## Corrective action

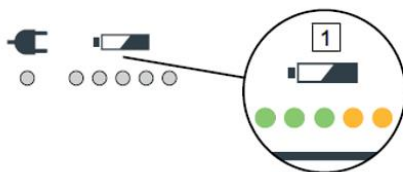
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A software update that will mitigate the described issue has been developed.

Getinge will initiate an immediate field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

In the improbable case that, after the software update, the Corin operating table can no longer be operated by the control device or the override control panel, you may proceed as follows:

1. Disconnect the network connection [See IFU Page 63], if present.
2. Connect the network connection [See IFU Page 63] and disconnect it again within 15 seconds.
  - LED pattern green, green, green, orange, orange is displayed on the battery charge status indicator ① on the override control panel.



3. Plug in and disconnect the mains plug 3 times within the 15 seconds after the initial plug-in.
  - Each time it is disconnected, one green LED in the battery charge status indicator ① will go out.
  - The third time it is disconnected, all green LEDs in the battery charge status indicator will be switched off.
4. Wait 30 seconds.
  - The orange LEDs will switch off.
  - Internal residual charges will discharge.
5. Plug in the mains plug.
  - The software will be restarted.
  - The status display for mains operation on the override control panel is illuminated green.
  - The OR table batteries will be charged (the battery charge status indicator on the override control panel will indicate the charge level).
6. Notify Getinge authorized service.

Please complete & return the attached acknowledgement form and maintain awareness on this notice and related actions until your Corin table has been updated to ensure effectiveness of the corrective action.

## Distribution

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This Getinge Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action. In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

### Attachments:

- FSCA 2025-013 Reply form

Should you have questions or require additional information, please let us know.

Sincerely,

QcRM, Maquet GmbH

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Contact details of local representative for your market

**Contact Name**

**Contact e-mail**

**Contact phone**

**Contact office address**

# Reply Form

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### Products affected:

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Record the total number of affected products currently located at your facility here please → \_\_\_\_.

### Confirmation:

Please check the boxes below as appropriate. Make sure to tick the first box. Should you not understand the communication please reach us for guidance. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

- ☐ We have read the Field Safety Notice and we understand the communication and the required actions.
- ☐ The devices are in our use and located at the address this communication was sent to.
- ☐ The devices are in our use but in a location different from where this communication was sent to, namely: \*
- ☐ We have sold / moved our devices to another facility. \*

\* New device location (if applicable)

Serial numbers at this new location: _____		
_____		
New Facility Name	Contact name / title	e-Mail address
New Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)

For device distributors only:

- ☐ We have checked our stock and quarantined inventory. We have reviewed the list of devices to identify any affected customers.
- ☐ We will share the list of devices, updated with customer details with Getinge in order to be able to report this information to the applicable authorities that request this information.
- or -
- ☐ We will share the list of devices with Getinge after finalizing the field action, and identify the state of each device in the list.

Please return your completed form to:

Getinge market organisation	Contact name / title	e-Mail address
Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)