

## Urgent Medical Device Field Action

OCT-21-2024 | FSCA 2024-001 Customer letter | Rev 01

### Subject: Issues with 100925A0 Universal Remote Control

#### Products affected:

Our records indicate that the below listed product were delivered to your location. Please verify if you have the listed product and complete the information below.

Item number	Item name
100925A0	Universal Remote Control

#### Description of the issue

---

Under certain conditions, we have identified that an issue might prevent the device from performing as intended. It has been determined that with Getinge IR remote control 100925A0 in some cases no function occurs and therefore no movement of the operating table is possible. We are not aware of instances where a patient was injured due to one of the described issues.

#### Potential hazards

---

This issue may stop the intended functioning of the device resulting in Patients undergoing surgery with pre-existing medical conditions that may diminish major body structures/systems, complicate management, prolong recovery, Children (neonatology), 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 one of the described issues.

## Precautions

---

In the event no function of Getinge IR Remote Control 100925A0 occurs the user has the possibility to use the override control panel of the operating table:

- The override control panel is available for the user at any time to move the patient in the required position (IFU700001XYEN05\_01 / IFU710001XYEN07\_01 / IFU720001XYEN14\_01 / IFU116001XYEN16\_01 § 4.3 Override control panel). It is pointed out in the instruction for use, that the operating table is fitted with an override control panel for emergency operation. If there are any malfunctions or if the control device is defective, then the operating table can be controlled using the override control panel.

The user has also the possibility to use a corded control device.

As stated above, it is assumed that the operating table is only operated by trained professionals and that they are familiar with the operating instructions and materials provided, including warnings and precautions. It should be noted that we are not aware of instances where a patient was injured due to one of the described issues.

Nevertheless, the potential of a procedural delay in an emergency case, which represents a stressful situation for the user, is given and could extend procedural/operative time of the patient; lead to a prolong anesthesia time and user inconvenience as described above.

## Corrective action

---

A Software update that will correct this 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.

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

## Distribution

---

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 utmost to carry through this action as swiftly as possible.

### Attachments:

- FSCA 2024-001 Reply Form

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

Sincerely,

QcRM, Maquet GmbH

*Thomas Kanzler*  
Electronically signed by: Thomas Kanzler  
Reason: I created this document.  
Date: Oct 24, 2024 10:09 GMT+2

---

Thomas Kanzler  
Local Capa Coordinator,  
Quality Compliance Engineer  
[thomas.kanzler@getinge.com](mailto:thomas.kanzler@getinge.com)  
Maquet GmbH  
Kehler Str. 31, 76437 Rastatt  
Germany

*Diana Gutekunst*  
Electronically signed by: Diana Gutekunst  
Reason: I approve this document.  
Date: Oct 24, 2024 10:16 GMT+2

---

Diana Gutekunst  
Local Quality Manager, PRRC,  
Director Quality Regulatory Compliance  
[diana.gutekunst@getinge.com](mailto:diana.gutekunst@getinge.com)  
Maquet GmbH  
Kehler Str. 31, 76437 Rastatt  
Germany

Contact details of local representative for your market

**Contact Name**

**Contact e-mail**

**Contact phone**

**Contact office address**