Urgent Medical Device Field Action

AUG-29-2024 | FSCA 2023-006 Customer letter | Rev 01

Subject: MEERA Error Code 50037

Products affected:

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

Item number	Getinge Order Reference	Serial number	Manufacturing date
700001B0	n/a	491 - 603	28.03.2023 - 31.08.2023
700001F0	n/a	9	29.09.2023
710001B0	n/a	680 - 707	17.04.2023 - 31.08.2023
710001B2	n/a	252 - 254	08.12.2022 - 07.09.2023
720001B0	n/a	11399 - 11746	24.02.2023 - 22.12.2023
720001B2	n/a	10894 - 11128	03.03.2023 - 28.08.2023
720001F0	n/a	1059 - 1091	30.05.2023 - 19.10.2023
720001F2	n/a	579 - 639	14.03.2023 - 29.09.2023

Description of the issue

Under certain conditions, we have identified that an issue might prevent the device from performing as intended. As a consequence, it is possible that the error code "50037" occurs on the IR-Hand Control when a MEERA-table is controlled, and the table stops the movement. This error may occur sporadically when the MEERA-table is controlled via an IR-Hand Control. With a cable-hand Control the error does not occur. If the error "50037" occurs the movement is not permanently blocked. The MEERA-table turns off after the key is released and restarts when the key is pressed again, the table restarts. The MEERA-table works normally again until the error occurs again. 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 no movement of the MEERA-table as there is no function via IR remote control due to the error code “50037”. This can lead to the following hazardous situations:

- Procedural delay
- User inconvenience.

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

Precautions

If the event occurs, the error code ”50037” will be shown on the remote control. The user has the possibility to use a) a corded control device or b) the override control panel of the operating table.

The device can be used in accordance with the instructions for use, with extra attention to the following: (*IFU700001XYEN05_01 / IFU710001XYEN07_01 / IFU720001XYEN14_01*):

- Error messages and instructions for handling errors are described in chapter § 7.3.
- The function of the override is described in chapter § 4.3.

  The override control panel is available for the user at any time to move the patient in the required position. It is pointed out in the instruction for use, that the mobile 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 mobile operating table can be controlled using the override control panel.

Corrective action

A solution 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 MEERA table 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 outmost to carry through this action as swiftly as possible.

Attachments:

- FSCA 2023-006 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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720001F2	n/a	579 - 639	14.03.2023 - 29.09.2023

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. *

Form: SOP-0921-A8 rev2

* 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)