Urgent Medical Device Field Action

AUG-25-2023 | 2023-002 | Rev 05

Subject: Unintended movement from travel unit at MEERA operating tables

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	Serial number
720001B2	6 – 11046
720001F2	3 – 599
710001B2	1 - 252

Record the total number of affected products currently located at your facility here please □ ___.

Description of the issue

Under certain conditions, we have identified that an issue might prevent the device from performing as intended. A specific sequence of commands on the control unit activates the traction drive and triggers an unintended driving (autodrive) of max. 7 sec.

Potential hazards

This issue of unintended driving (autodrive) may result in the following reasonably foreseeable injury or damage to the health of patients and/or users:

1) Musculoskeletal/Blunt injury, self-limiting of a patient and/or user.
2) Minor musculoskeletal/Blunt injury, Minor soft tissue contusion (Hematoma, Bruise) of a patient and/or user.
3) Major musculoskeletal/Blunt injury (Hematoma, Contusion) of a patient and/or user.
4) Procedural delay.
5) User inconvenience.

Precautions

The device can be used in accordance to the instructions for use, with extra attention to the following:

- **Do NOT press the following sequence of commands** on the operator panel;
  1st version:
  MEERA is locked
  1. Press the unlock button on the operator panel
  2. Press the lock button again during the unlock operation
  3. Press the motor drive button during the lock operation
  4. When Meera is in the locked state, press the unlock button again.
- **Do NOT press the following sequence of commands** on the operator panel;
  2nd version:
  MEERA is locked
  1. Press the unlock button on the operator panel
  2. Press the motor drive button and release it
  3. Press the lock button within 5 seconds after release of the motor drive button (2.)

Corrective action

A software solution that will correct this issue has been developed.
Getinge will initiate a 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.

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. The competent authority has been informed about this communication and issue.

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

Attachment:
Reply Form Customer - FA 2023-002

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

Sincerely,

Quality Management

Simon Burkart, Quality Compliance Engineer

D. Gutekunst, Director Quality Regulatory Affairs

Reply Form

Aug-25-2023 | REF- FA 2023-002 | Rev 01

Subject: FA 2023-002 Unintended movement from travel unit at MEERA operating tables

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

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)