

Oct 14, 2022 | FA2020-011 | Rev 02

Subject: FA2020-011 – 1140.20AN Extension Table Top

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	Manufacturing date
1140.20AN	all	1990 - 2008
1140.20F0	all	1999 - 2001

Please check the appropriate boxes below:

Description of the issue

Under certain conditions, we have identified that an issue might prevent the device from performing as intended.

As a consequence by swinging one extension bar outwards from its parking position below the table top or rather underneath the back plate, the extension bar may collide with eccentric lever of the back plate and releases it unintentionally.

The suspect operating table tops 1140.20AN and 1140.20F0 are equipped with extension bars, which can be swung into a parking position under the operating table bar, if not needed. In this position, the extension bar stretches along and underneath the back plate.

The back plate is hold and locked into position by eccentric levers, one on the left and one on the right side of the table top. These two levers shall always be positioned in a way that they do not hinder swinging the extension bars in and out [cf. GA114020EN08 p.11 §V.2 Back plate].

However, it is possible that a swung out extension bar collides with an unfavorable positioned eccentric lever of the back plate causing the eccentric lever to being opened when it is not properly locked and/or worn.

Potential hazards

Independently of the sequence, if one eccentric lever is open intentionally and second is being opened unintentionally by accident or collision with a swung out extension bar, the back plate is now fully released and in consequence will suddenly fold down.

Precautions

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

- Always position the safety eccentric levers in a way that does not hinder swinging the extension bars in and out. We recommend always leaving the levers in a position where they are turned at an angle of about 45° towards the head end. [cf. GA114020EN p.11]
- Be aware of potential collision between extension bar and eccentric lever
- Verify proper functionality of the eccentric levers (shall not open without pressed push button) and its safety / lock mechanism

Corrective action

Advise ...

- To perform pre-use checks of all table top functionalities (including and specifically the safety eccentric levers).
- To perform / request regular preventive maintenance by a Getinge authorized field service technician.
 - Furthermore, if the last service is more than 12 month ago, an appointment to service the device is indispensable

Please complete & return the attached acknowledgement form and maintain awareness on this notice and related actions until your operating table top 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. 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.

[List of attachments]

- Reply Form
- Confirmation of distribution

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

Sincerely,

Quality Management

Oct 14.

Alexander Maurer
Electronically signed by: Alexander Maurer
Reason: I created this document.
Date: Oct 14, 2022 14:16 GMT+2

Alexander Maurer

created, date Signature

Quality Engineer

Oct 14, 202:

Diana Gutekunst
Electronically signed by: Diana Gutekunst
Reason: I approve this document.
Date: Oct 14, 2022 14:22 GMT+2

Diana Gutekunst

approved, date Signature

Person Responsible for Regulatory Compliance Maquet GmbH