Urgent Field Safety Notice

MMM-DD-YYYY | FSCA 2026-001 – OT 1518899 | Rev 01

Subject: ALPHAMAQUET Operating table column

Products affected

Our records indicate that at least one (1) affected ALPHAMAQUET operating table column or affected spare part may be present at your location. Please verify the affected product(s) based on the information provided by your local Getinge representative and follow the information in this notification.

Item number	UDI	Item name
115002A0	04046768003248	ALPHAMAQUET Operating table column
115002B0	04046768003255	ALPHAMAQUET Operating table column
115002C0	04046768003262	1150 OR-table column, mobile
115002D0	04046768030978	1150 OR-table column, independently manoeuvrable

The affected spare part is column control unit 9711022, version 01–10, which may be installed in the listed ALPHAMAQUET operating table columns or may be present as a spare part not yet installed.

Description of the issue

Under certain conditions, a malfunction in the column control unit (9711022, version 01-10) may prevent adjustment of the operating table using the cable remote control and the override panel.

If this issue is present, operation of the table may only remain possible via the IR remote control.

The issue may not always be detected during installation of the spare part and may occur intermittently.

Potential hazards

If the issue occurs, adjustment of the ALPHAMAQUET operating table column via the cable remote control and the override panel may no longer be available. In a critical step before, during, or after a surgical procedure, the inability to adjust the table as intended could result in a procedural delay.

The risk may be greater in time-critical procedures where delayed table adjustment could introduce additional clinical risk, for example emergency procedures or neurosurgery.

To date, no patient injury, serious deterioration of health, or death has been reported in association with this issue.

Precautions

Continue to perform the pre-use checks described in the Instructions for Use before each use. Please note that these checks may not reliably detect the issue described above.

If adjustment via the cable remote control or the override panel is not possible, do not use the affected device and contact your local Getinge service representative immediately.

If the table is operated via the IR remote control, ensure that the IR remote control is available and functional before use.

Customer Actions

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices or spare parts have been transferred.
2. Please complete and send the Customer Reply Form to your local Getinge representative via email at <insert local Getinge representative email>.
3. Your Customer Service Contact will contact you to schedule the correction as soon as possible.
4. Getinge will perform the Field Action by replacing the affected spare part in installed devices or by coordinating the appropriate disposition of affected spare parts that are not installed in a table.
5. If you have an affected spare part that is not installed in a table, do not use or install it. Please follow the disposition instructions provided by your local Getinge representative.

Attachments

- FSCA 2026-001 – OT 1518899 Reply form

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

Getinge is communicating this information to the appropriate regulatory agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Diana Gutekunst
Local Quality Manager, PRRC
Maquet GmbH
Kehler Str. 31, 76437 Rastatt
Germany

Signature: Electronically signed by: Diana Gutekunst
Reason: I approve this document.
Date: Jul 13, 2026 20:40:01 CEST

Email: diana.gutekunst@getinge.com

Contact details of your local Getinge representative

Contact Name
Contact e-mail
Contact phone
Contact office address

GETINGE

Reply Form

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Subject: ALPHAMAQUET Operating table column

Products affected:

Our records indicate that the below listed product(s) may be present at your location. Please verify the information below and complete this form.

Getinge order no.	Item / spare part number	Serial number
X	X	XXXX
Y	Y	YYYY
Z	Z	ZZZZ

Record the total number of affected product(s) currently located at your facility here please → ___.

Confirmation:

Please check the boxes below as appropriate. Make sure to tick the first box. If you do not understand this communication, please contact your local Getinge representative for guidance. Your organization's reply is the evidence we need to monitor the progress of this Field Safety Notice.

- ☐ We have read the Field Safety Notice and understand the communication and required actions.
- ☐ The listed product(s) are in our use and located at the address to which this communication was sent.
- ☐ The listed product(s) are in our use but located at a different location. Please complete the "New location" section below.
- ☐ We have sold, moved, transferred, or otherwise provided the listed product(s) to another facility. Please complete the "New location" section below.
- ☐ The listed product(s) are no longer in use or available at our facility.
- ☐ The listed spare part(s) are not installed in a table and will not be used or installed. We will follow the disposition instructions provided by Getinge.

New location (if applicable)

Serial number(s) 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 distributors only:

- ☐ We have checked our stock and quarantined inventory and reviewed the list of product(s) to identify any affected downstream customers.
- ☐ We will share the list of product(s), updated with customer details, with Getinge to support Field Safety Notice tracking and authority reporting, where required.
- ☐ We will share the final status of each affected product with Getinge after completion of the field action.

Please return your completed form to:

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