November, 2025

URGENT MEDICAL DEVICE *CORRECTION*
OTESUS OR table column
FSCA 2025-020 – OT-1394552

Model Number	UDI	Model Name	Serial/Lot Numbers
116001A0	04046768100657	OTESUS OR table column, stationary	SN 3754 – 3782 (26 devices)
116001B0	04046768100664	OTESUS OR table column, stationary	SN 459 (1 device)
116001C0	04046768100671	OTESUS OR table column, mobile	SN 4137 - 4189 (18 devices)
116001D0	04046768122161	OR table column, manoeuvrable	SN 1323 – 1337 (11 devices)
Manufacturing Dates:		Starting 06/2025	
Distribution Dates:		Starting 06/2025	
Expiration Dates:		*n/a*	

Dear Customer,

our records indicate that some of the above listed products were delivered to your location. Please verify if you have any of the listed products and follow the information below.

Issue Description

The new LEDs of the Optic and contact carrier module can cause interfering signals (Wider beam angle) between the OR-Table Columns and the OR-Table Tops.
These interfering signal can cause the following issues with the Otesus OR-Table System:

1.1

Issue: If the head-down/ feet-down trend function is moved to the end position and the button on the control device is kept pressed, it may happen that the OR-Table Top moves in the opposite trend direction until the button is released.

1.2

Issue: OR-Table Top cannot be moved to the zero-position (With 0-Button and Leg-/ Back function buttons).

Then there is no leg-/ back movement possible.

Still available functions:

- Trend/ Reverse-Trend
- Tilt
- Height

If one of the errors occurs and no key on an input device is pressed for at least 15 seconds, the system goes into standby. If the desired command is pressed again on an input device afterwards, there is a possibility that it will be executed before one of the described errors occurs again.

Risks to Health

The described issue may stop the intended functioning of the Otesus OR-Table System potentially resulting in a procedural delay in a critical step of the procedure, e.g. emergency caesarean section, neurosurgery procedure or polytrauma.
This poses a risk primarily to patients undergoing surgery with pre-existing medical conditions that may diminish major body structures/systems, complicate management, prolong recovery, children (neonatology), obese patients, 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 the described issues.

Customer Actions

The device can be used in accordance with the instructions for use.
If one of the errors occurs and no key on an input device is pressed for at least 15 seconds, the system goes into standby. If the desired command is pressed again on an input device afterwards, there is a possibility that it will be executed before one of the described errors occurs again.

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.
2. Please complete and send the Customer Response Form 2025-020 – OT-1394552 to your Customer Service Contact via email at <insert SSU Service Contact email>.
3. Your Customer Service Contact will contact you to schedule the correction as swiftly as possible
4. Getinge will perform a corrective action to solve the issue.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative.

Attachements

- Customer Response Form 2025-020 – OT-1394552

Sincerely,

QcRM, Maquet GmbH

Contact details of local representative for your market

Contact Name

Contact e-mail

Contact phone

Contact office address