Urgent Field Safety Notice

TruSystem 7500 surgical table systems

Field Action Reference: FA-2025-004

Manufacturer: Baxter Medical Systems GmbH + Co. KG (Single Registration Number: DE-MF-000005071)

Type of Action: Correction

March 2025

Dear Sir/Madam,

Baxter Healthcare Corporation is issuing an Urgent Field Safety Notice for the **TruSystem** 7500 surgical table systems listed below due to a software issue which causes the upper back section of Model 26-series tabletops, listed below, to become inoperable (non-adjustable) when the emergency mode function is enabled. The emergency mode of the operating table is used to ensure that the tabletop functions as needed in case of a functional failure and can only be manually activated by the user on the column keypad. This issue *only* occurs when emergency mode is enabled. The tabletop and upper back section function normally when used outside "emergency mode". To correct the issue, Baxter will install a software upgrade in the impacted **TruSystem** 7500 surgical table systems.

Affected Product

Product Code	Product Description	Serial Number	UDI Number
1704695	OP-Tischsäule **TruSystem** 7500 MOBIUS	All serial numbers manufactured until 14-Nov-2024.	00887761974425
1717020	OP-Tischsäule **TruSystem** 7500 SF		00887761974418
1717021	OP-Tischsäule **TruSystem** 7500 SB		00887761974401
1717022	OP-Tischsäule **TruSystem** 7500 SF NET		N/A
1717023	OP-Tischsäule **TruSystem** 7500 SM		00887761974395
1730732	OP-Tischsäule **TruSystem** 7500 SB U		00887761974364
1773204	**TruSystem** 7500 Hybrid (MC)		00887761974326
1854085	**TruSystem** 7500 Hybrid (FC)		00887761974081
1854086	**TruSystem** 7500 Hybrid (SC)		00887761974074
1854087	**TruSystem** 7500 Hybrid Plus (FC)		00887761974067
1854088	**TruSystem** 7500 Hybrid Plus (SC)		00887761974050
4091000	**TruSystem** 7500		00887761968639
The software issue is in the table columns listed above; however, the issue only occurs with the below tabletops:			
1846382	OR tabletop U26 S		
1846384	OR tabletop U26 V		
1846390	OR tabletop ST26 S		
1846391	OR tabletop ST26 V		
1909793	OR tabletop U26 H V		
1909794	OR tabletop U26 H V U		
1909795	OR tabletop U26 H V W		
1947991	OR tabletop U26 H V J		
2029417	OR tabletop ST26 H V		
2029418	OR tabletop ST26 H V U		

Hazard Involved

The issue could increase the risk of ineffective CPR and cause temporary interruption or delay of therapy. A suboptimal angle in patient position for conducting CPR might compromise its effectiveness and may lead to critical adverse health consequences in certain patients even though medical personnel are present. To date, there have been no reports of injuries related to this issue.

Actions to be Taken by Customers

1. Baxter will contact you to install a software upgrade in the impacted surgical table systems.
2. Complete the enclosed customer reply form and return it to Baxter by either scanning and e-mailing it or sending it by post, even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
4. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Correction in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter.

The local Ministry of Health (MOH) has been notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Baxter Healthcare Corporation

Baxter

(Customer communication)

CUSTOMER REPLY FORM related to Product Correction letter dated March 2025

Please complete and return one copy of this form per facility to Baxter as confirmation that you have received this notification.

Facility Name and Address:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and/or Telephone Number (including Area Code):	

Please list the specific products and serial/lot numbers in your facility below*:

Product Code	Serial Number

*You may attach an additional sheet if required.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____