Urgent Field Safety Notice
follow up communication

TruSystem 7000
FA-2024-056
Manufacturer: Baxter Medical Systems GmbH + Co. KG (Single Registration Number:
Correction

November 29, 2024

Dear Healthcare Provider and CC Surgical Director:

On September 24, 2024, - Baxter Healthcare Corporation issued an Urgent Medical Device Correction for the **TruSystem** 7000 Surgical Table listed below due to customer reports stating that the batteries and their connectors experienced electrical short-circuits, emitted smoke, or caught fire. Investigation of the reports identified that the power supply cable which runs along the battery was incorrectly positioned under the battery after replacement. This issue only occurs after servicing if the battery has been incorrectly positioned during servicing activity or battery replacement.

The purpose of this letter is to reinforce the hazard(s), provide specific guidance on leveraging trained technicians to service the surgical tables, and ensure that this communication is shared with all relevant facilities and departments within your institution.

Incorrect battery placement may cause batteries and their connectors to short-circuit, emit smoke, and/or catch fire. To ensure proper battery placement in accordance with the Instructions for Use, service manuals, and other relevant service standards, only Baxter technicians or personnel authorized, trained, and certified by Baxter should perform service activities, especially battery replacement and/or service activities requiring battery adjustment.

Baxter has implemented a design improvement to decrease the likelihood of incorrectly positioning the battery and power supply cable during servicing activity or battery replacement. Customers who recently had their batteries replaced will be contacted to inspect and confirm accurate placement of the battery and power supply cable. **Baxter will contact your facility to implement the design improvement in the impacted surgical tables.**

Affected Product

Product Code	Product Name	Serial Number	UDI Number
1841046	**TruSystem** 7000	All	00887761968714
1841048	**TruSystem** 7000 (MBW)		00887761968707
1841049	**TruSystem** 7000 (dV)		00887761968691
1841050	**TruSystem** 7000 V		00887761974241
1841082	**TruSystem** 7000 (MBW) V		00887761974234
1841083	**TruSystem** 7000 (dV) V		00887761974227
2065385	**TruSystem** 7000 U14 (MBW)		00887761968653
2065386	**TruSystem** 7000 U14 (MBW) V		00887761973794

Hazard Involved

Incorrect battery replacement may result in short-circuit of the battery, leading to patient and healthcare provider exposure to fire and/or smoke. This may result in critical outcomes including burns, dehydration, reduced oxygenation, and/or interruption of an ongoing major surgical procedure. To date, Baxter has received 13 complaints, including one serious injury, related to this issue.

Actions to be Taken by Customers

1. **If battery replacements or any servicing have been performed in-house or by third parties, contact Baxter Technical Support** at 800-445-3720 (select Option 2, then Option 7) between 8:00 am and 6:00 pm Eastern Time, Monday through Friday, or emailing Baxter at HRC_Trumpf_Tech_Support@baxter.com to schedule an inspection of your TruSystem 7000 Surgical Table.

2. **Until the design improvement is implemented, Baxter recommends customers to reach out directly to Baxter for any servicing or battery replacement to ensure correct installation.** Contact Baxter Technical Support at 800-445-3720 (select Option 2, then Option 7) between 8:00 am and 6:00 pm Eastern Time, Monday through Friday, or emailing Baxter at HRC_Trumpf_Tech_Support@baxter.com.

3. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to (shs_fca_dublin@baxter.com), 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.

4. Please provide this information to all users of the **TruSystem** 7000 Surgical Table. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

5. 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.

6. 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 at shs_fca_dublin@baxter.com.If you have any issues related to these products please contact HRC_UKCustomerCare@baxter.com
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,

Petra Bascones
Business Unit Head
Healthcare Systems and Technologies UKI & Nordics
Baxter Healthcare Limited

Enclosure: Baxter Customer Reply Form

CUSTOMER REPLY FORM related to Product Correction letter FA-2024-056-FU dated 29.11.2024

Product Name: **TruSystem** 7000

Product code: **1841046, 1841048, 1841049, 1841050, 1841050, 1841082, 1841083, 2065385, 2065386**

Serial/Batch Number: All

Please complete and return one copy of this form per facility either by fax e-mail (____ uk_shs_fca@baxter.com _____) 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/Lot 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, other services or facilities, and customers as applicable..

Signature/Date: REQUIRED FIELD	_____