Urgent Field Safety Notice

TruSystem 7000
FA-2024-056
Manufacturer: Baxter Medical Systems GmbH + Co. KG (Single Registration Number: DE-MF-000005071)
Correction

01 October, 2024

Dear Customer:

Baxter Healthcare Corporation is issuing 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 and/or emitted smoke. 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 replacement.

Baxter will implement a design improvement to decrease the likelihood of incorrectly positioning the battery and power supply cable during replacement. Baxter will contact customers who recently had their batteries replaced to inspect and confirm accurate placement of the battery and power supply cable.

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 12 complaints related to this issue. One complaint resulted in a serious injury.

Actions to be Taken by Customers

1. Once available, Baxter will contact you to implement the design improvement in the impacted surgical tables. Battery replacements must only be performed by personnel authorized, trained, and certified by Baxter.

2. Complete the enclosed customer reply form and return it to Drugsales Ltd by e-mailing it to device.safety@drugsalesltd.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.

3. 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.

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 Drugsales Ltd on 21419070/1/2 or email: device.safety@drugsalesltd.com

The Malta Medicines Authority has been notified of this action.

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

Sincerely,

Adrian Busuttil
RP/Regulatory Affairs Manager
Drugsales Ltd
Baxter Healthcare representative and distributor in Malta

Enclosure: Baxter Customer Reply Form