

Urgent Field Safety Notice

Charging unit mounted W/T AC TS7500

FSCA Ref: FA-2025-029

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

Field Action Type: Correction

September XX, 2025 (to be adapted locally)

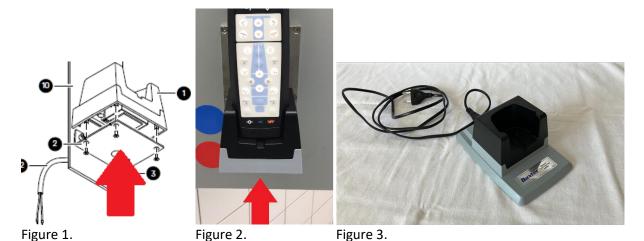
Dear Healthcare Provider:

Baxter Healthcare Corporation is issuing an Urgent Field Safety Notice for the wall-mounted charging unit listed below due to the wall mount not providing the correct level of protection against hazardous voltage required by the International Electrotechnical Commission (IEC) Standard. The wall-mounted charging unit houses a wireless remote control that is compatible with multiple surgical tables.

Baxter currently has two items in the wall-mounted charging unit to protect against hazardous voltage, insulated wires and a tie to bind the wires into place. It is also important to note that the following actions need to occur for a user to be at risk of hazardous voltage: The wire needs detach, then the wire needs to be touching the metal plate to make the plate under voltage, and a user needs to touch the metal plate while under voltage.

If unit fails to power on or malfunctions, avoid touching metal baseplate (below, figures 1 and 2, product code 1451204). Power should be discontinued to device immediately in the case of a failure to power on or device malfunction and Baxter should be contacted.

Please use mobile charging unit (below, figure 3, product code 1557243) if one is available at your facility.



Affected Product (to be adapted locally)

Product Code	Product Description	Serial Number	UDI Number
	TS7500	All product manufactured between May 12, 2009, and December 17, 2024	00887761974586



Hazard Involved

In the unlikely scenario of a user touching the metal base plate of the charging unit that is under voltage from wires touching the metal base in the casing, it could lead to electrocution, severe burns, seizures, cardiac arrhythmias, cardiac and respiratory arrest, among others. No complaints, serious injuries or deaths have been reported due to this issue.

Actions to be Taken by Customers

- 1. If wall-mounted charging units should malfunction or fail to start user should immediately stop using device and disconnect power source.
- 2. A device inspection will be scheduled, and replacement options will be discussed.
- 3. Complete the enclosed customer reply form and return it to Baxter by either faxing it to (insert local contact information) or scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), 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 surgical tables. 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 (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Sincerely,

Name (to be adapted locally)

Title (to be adapted locally)

Baxter Healthcare Corporation (to be adapted locally)

Enclosure: Baxter Customer Reply Form