

Urgent Field Safety Notice

Progressa bed surfaces

Field Action Reference: FA-2025-006

Manufacturer: Hill-Rom, Inc. (Single Registration Number: US-MF-000007306)

Type of Action: Correction

February 25, 2025 (to be adapted locally)

Dear Sir/Madam, (to be adapted locally)

Baxter Healthcare Corporation is issuing an Urgent Field Safety Notice for the **Progressa** bed surfaces (mattresses) listed below to inform customers of a potential issue where the air bladders inside the mattress may move out of position when the head of the bed is elevated, causing a dip in the mattress. This issue may only be noticeable when a patient or weight is on the bed and the head of the bed is elevated. The affected product was distributed in the United States between 12/14/2023 and 1/24/2024. (to be adapted locally)

Affected Product (to be adapted locally)

Product Description	Serial Numbers	Product Code	UDI Number
Progressa bed surfaces	All Progressa bed surfaces manufactured between 10/25/2023 and 12/1/2024. Manufacturing date can be found on the product label attached to the bed surface. See Figure 1 below.	P7520A23	00887761999855
		P7520A45	00887761999671
		P7520A21	00887761999879
		P7520A39	00887761999701
		P7520A31	00887761999756
		P7520A19	00887761999893
		P7520A15	00887761999923
		P7520A24S	00887761999848

Hazard Involved

The **Progressa** bed surface air bladders may move out of position as the head of the bed is elevated, potentially resulting in uneven pressure distribution and/or the patient's body contacting plastic and foam components below the support layer of air bladders inside the surface. If this issue is not recognized, the patient may experience discomfort and/or the development or worsening of pressure injuries. Patients at higher risk include those who have a history of immobility, malnourishment, sensory loss, pressure injuries, incontinence, or reduced tissue perfusion. To date, Baxter has received five reports of serious injury potentially related to this issue.

Actions to be Taken by Customers

1. Please locate all affected units within your facility by reviewing the product label at the head end of the **Progressa** bed surface with the affected product details provided above. See Figure 1 below.

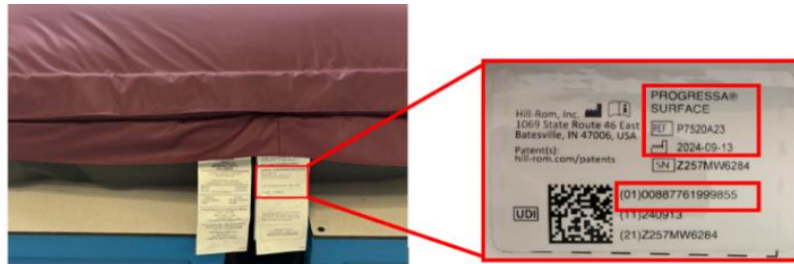


Figure 1 - Progressa Bed Surface Label



2. Baxter recommends identifying patients at a higher risk for pressure injuries and placing these patients on alternate beds, if available.
3. A Baxter representative will contact your facility to schedule the correction of your impacted surfaces, or you may contact the Baxter Technical Support Team at [\(insert local contact information\)](#). Please work with your Baxter representative to ensure that the affected beds are available for correction (not in use). [\(to be adapted locally\)](#)
4. Complete the enclosed customer reply form and return it to Baxter by either 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.
5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. 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.
7. 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 [\(to be adapted locally\)](#)

Attachment 1: Customer Reply Form [\(to be adapted locally\)](#)