

Urgent Field Safety Notice

Accella therapy air mattresses

FSCA Ref: FA-2025-040

Manufacturer: Hill-Rom S.A.S. (Single Registration Number: FR-MF-000003176)

Field Action Type: Correction

October XX, 2025 (to be adapted locally)

Dear Healthcare Provider:

Baxter Healthcare Corporation is issuing an Urgent Field Safety Correction Notice for **Accella** therapy air mattresses (and spare parts associated with **Progressa** frames) listed below due to reports of technical box cracks that can cause air leaks. If this issue occurs, the mattress pressure can stay in a higher-pressure phase or a non-functioning Alternating Low-Pressure (ALP) mode. The mattress will provide visible and audible alerts (Error codes: 1006 or 1014). If the patient cannot be moved to another mattress, the patient will be exposed to the risk of pressure injury. The impacted product was manufactured between March 21, 2024, and June 2, 2025.

In addition, this issue can also potentially impact **Accella** therapy air mattress's spare part kits shipped between March 21, 2024 and June 2, 2025. **Progressa** Frames may be used with **Accella** therapy air mattresses, and spare part kits associated with a **Progressa** frame are noted in attachment A. See attachment A for details on spare parts associated with **Accella** therapy air mattresses.

Baxter will send a representative to replace the technical boxes of all impacted **Accella** therapy air mattresses and spare parts (including spare parts associated with **Progressa** Frames).

Affected Product (to be adapted locally)

Product Code	Product Description	Serial Number	UDI-DI Number
P006789A	Accella therapy mattress	All serial numbers HRPM10022464 to HRPM10029270	00887761978331
P006792A			00887761978409
P006793A			00887761978362
P006788A			00887761978355
Accella therapy air mattress Spare Parts (and Spare Parts associated with Progressa Frames)		See attachment A. Serial numbers distributed between March 21, 2024 and June 2, 2025	

Hazard Involved

The hazardous situation that may result is excessive pressure being placed against the patient and their skin while lying or sitting in bed. In most cases, no harm or mild discomfort is expected; however, in higher-risk patients, skin deterioration and pressure injuries are possible. Baxter has received 11 reports of serious injury potentially related to this issue.

Actions to be Taken by Customers

1. If the care provider experiences the error codes listed above on an affected **Accella** mattress (or a mattress used with Spare Parts associated with a **Progressa** frame), please discontinue use of the product until a technical service representative can replace it. If the error code alarms while a patient is on the mattress, please move the patient to an alternative surface. If the error codes do not occur, the mattress is safe to continue use.
2. If the care provider experiences a service indicator light on a stand-alone affected mattress, the light could be one of the error codes. Out of caution, please discontinue use of the product until a technical service representative can troubleshoot the service indicator error. If the service indicator light alarms while a patient is on the mattress, please move the patient to an alternative surface. If the service indicator light does not occur, the mattress is safe to continue use.
3. To correct the issue, Baxter will be sending personnel onsite to replace the technical box of all impacted **Accella** therapy air mattresses (and Spare Parts associated with **Progressa** Frames). A Baxter representative will contact your facility to schedule a time to complete the correction.
4. 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.
5. 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.
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 [\(to be adapted locally\)](#)

Enclosure: Baxter Customer Reply Form
Attachment A