Second Notification
March 19, 2024

URGENT MEDICAL DEVICE CORRECTION

March 5, 2024

Dear Healthcare Provider,

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Medical Device Correction for the pro+ mattress**.** Inconsistencies were identified with service records associated with corrections performed for a previous Medical Device Correction issued by Baxter (ref number: FA-2022-026). Your devices have been identified as potentially impacted by these service inconsistencies and therefore, Baxter will need to reassess the impacted mattresses to confirm they have been corrected as identified by the service order, and to confirm the correct serial numbers have been identified.

Details regarding the previous Baxter Medical Device Correction can be found in the attached customer letter originally sent on June 24, 2022. Baxter has completed corrections for the mattresses impacted by this field action.

Baxter will contact you to arrange for the reassessment of your pro+ mattress and will perform a correction of the product, if required.

The affected product was distributed to customers in the United States between 1/7/2022 to 3/21/2022.

Affected Product

Product Code	Product Description	Serial Numbers	UDI Number
P7924A03	pro+ mattress for **Centrella** Smart+ (non-integrated), **CareAssist**, and **Advanta 2** beds (36” (91 cm) wide)	Refer to Attachment A	00887761977884

Hazard Involved

The identified failure mode from the previous Medical Device Correction (ref number: FA-2022-026) can cause a reduction in the performance of the Microclimate Management (MCM) feature of the pro+ mattress. MCM is used to pull heat and moisture away from the patient. Less than optimal performance of this feature may increase the patient’s risk of pressure ulcer development. No patient injuries have been reported due to this failure mode.

Actions to be taken by Customers

1. Healthcare providers may continue to use the pro+ mattress if no error is detected. If an error is detected, it is recommended to move the patient to another mattress with no errors and/or continuously monitor the patient for any indication of a pressure injury.

2. Please inspect your product and check for any indication of error present. If an error is present, the status indicator will turn yellow. See Figure 1 below.

Yellow: Error | Off: No power or Device Unplugged | Green: Operating correctly

Figure 1. Status Indicator

3. If you detect an error, contact Baxter Technical Support by phone at 800-445-3720, available Monday through Thursday, between 8:00 am and 6:30 pm Eastern Time, and Friday, between 8:00 am and 6:00 pm Eastern Time, or by email at HRC_Technical_Support@baxter.com to have the pro+ mattress corrected.

4. A Baxter representative will contact your facility to arrange for an inspection of your device and correction, if required.

5. **Please acknowledge receipt by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com**. Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

6. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further information and support If you have additional questions, please contact your Baxter sales representative, or contact Baxter Technical Support at 800-445-3720 Monday through Thursday, between 8:00 am and 6:30 pm Eastern Time, and Friday, between 8:00 am and 6:00 pm Eastern Time.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Technical Support at 800-445-3720, Monday through Thursday, between 8:00 am and 6:30 pm Eastern Time and Friday, between 8:00 am and 6:00 pm Eastern Time or emailing Baxter at: HRC_Technical_Support@baxter.com
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

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

Sincerely,

Beth Dihel

Beth Dihel
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Form Instruction Sheet
Attachment A: Affected Serial Numbers
Medical Device Correction letter dated June 24, 2022 (ref number: FA-2022-026)

Baxter

Attachment A: Affected Serial Numbers

Product Code: P7924A03 - pro+ mattress for Centrella Smart+ (non-integrated), CareAssist, and Advanta 2 beds (36” (91 cm) wide)

Serial Numbers							
W330BP6363	W333BP6439	W334BP6477	W334BP6535	W337BP6631	W341BP6675	X047BP7353	X049BP7431
W330BP6365	W333BP6440	W334BP6478	W334BP6536	W337BP6632	W341BP6676	X047BP7354	X049BP7432
W330BP6366	W333BP6442	W334BP6480	W334BP6537	W337BP6633	W341BP6678	X047BP7355	X049BP7433
W330BP6367	W333BP6445	W334BP6481	W337BP6565	W337BP6634	W341BP6679	X047BP7356	X063BP7505
W330BP6368	W333BP6446	W334BP6485	W337BP6566	W337BP6635	W341BP6681	X047BP7357	X063BP7506
W330BP6382	W333BP6447	W334BP6486	W337BP6567	W337BP6636	W341BP6683	X047BP7358	X063BP7507
W330BP6383	W333BP6448	W334BP6487	W337BP6568	W337BP6637	W341BP6684	X047BP7359	X063BP7508
W330BP6385	W333BP6450	W334BP6489	W337BP6569	W337BP6638	W341BP6687	X047BP7360	X063BP7509
W330BP6387	W333BP6451	W334BP6492	W337BP6570	W337BP6641	X046BP7330	X047BP7361	X063BP7510
W330BP6397	W333BP6452	W334BP6493	W337BP6571	W337BP6642	X046BP7331	X047BP7362	X063BP7511
W333BP6399	W333BP6453	W334BP6496	W337BP6572	W337BP6643	X046BP7332	X047BP7363	X063BP7512
W333BP6400	W333BP6455	W334BP6500	W337BP6573	W337BP6644	X046BP7333	X047BP7364	X063BP7513
W333BP6401	W333BP6456	W334BP6501	W337BP6574	W337BP6645	X046BP7334	X047BP7365	X063BP7514
W333BP6404	W333BP6457	W334BP6502	W337BP6575	W341BP6646	X046BP7335	X047BP7366	X066BP7516
W333BP6405	W333BP6458	W334BP6504	W337BP6577	W341BP6647	X046BP7336	X047BP7367	X066BP7517
W333BP6406	W333BP6459	W334BP6505	W337BP6578	W341BP6648	X046BP7337	X047BP7368	X066BP7518
W333BP6415	W333BP6460	W334BP6511	W337BP6579	W341BP6655	X046BP7338	X047BP7369	X066BP7519
W333BP6418	W333BP6461	W334BP6513	W337BP6583	W341BP6658	X046BP7339	X047BP7370	X066BP7520
W333BP6420	W333BP6463	W334BP6514	W337BP6614	W341BP6659	X046BP7340	X047BP7371	X066BP7521
W333BP6421	W333BP6465	W334BP6525	W337BP6615	W341BP6660	X047BP7342	X047BP7372	X066BP7522
W333BP6422	W333BP6466	W334BP6526	W337BP6621	W341BP6661	X047BP7343	X047BP7373	X066BP7523
W333BP6423	W333BP6467	W334BP6527	W337BP6622	W341BP6663	X047BP7344	X047BP7374	X066BP7524
W333BP6424	W334BP6468	W334BP6528	W337BP6623	W341BP6666	X047BP7345	X047BP7375	X066BP7525
W333BP6425	W334BP6469	W334BP6529	W337BP6624	W341BP6667	X047BP7346	X047BP7376	X066BP7526
W333BP6426	W334BP6470	W334BP6530	W337BP6625	W341BP6668	X047BP7347	X047BP7378	X066BP7527
W333BP6427	W334BP6471	W334BP6531	W337BP6626	W341BP6669	X047BP7348	X047BP7379	X066BP7531
W333BP6431	W334BP6473	W334BP6532	W337BP6628	W341BP6670	X047BP7350	X047BP7381	X066BP7532
W333BP6432	W334BP6475	W334BP6533	W337BP6629	W341BP6671	X047BP7351	X049BP7429	X066BP7533
W333BP6435	W334BP6476	W334BP6534	W337BP6630	W341BP6674	X047BP7352	X049BP7430	X066BP7540

Subject: Pro+ Hospital Bed Surface - Microclimate Management (MCM)

Commercial name of the affected product: PRO+ Surface

Details off the affected product: See appendix 1- Affected Serial Numbers

Manufacturing Dates: Aug 5th, 2021-March 17th, 2022

FCA-identifier: FA-2022-026

Type of action: Medical Device Correction.

Date: June 24, 2022.

To: Chief Executive; Facility Risk Manager; Facility Administrator; Facility Engineer; Vigilance Manager; Biomedical Engineering; Medical Device Liaison Officer; Information Security Director

Description of the problem:
Hillrom, a Baxter owned company has become aware through customer complaints of an issue related to the Pro+ Hospital Bed Surface. Two error codes were identified in the Graphic Caregiver Interface, 0XC006(MCM timeout) and 0XC100(Blower Board Communication).

The root cause of these error codes was related to two lots of faulty Printed Circuit Boards (PCB's) provided by one of our suppliers.

Potential risk
The identified failure mode can cause a reduction in the performance of the Microclimate Management (MCM) feature of the Pro+ Hospital Bed Surface. Microclimate Management is used to pull heat and moisture away from the patient. Less than optimal performance of this feature may increase the patient's risk of pressure ulcer development. No patient injuries have been reported due to this failure mode.

Actions to be taken by the user:
Please inspect your product and check for any indication of error codes present. Depending on the configuration of your product, the presence of error codes can be identified as follows:

Centrella Integrated Surfaces: A yellow wrench will be displayed in the top bar of the Graphic Caregiver Interface. See *Figure 1.*

Figure 1: Yellow Wrench.

Non-Integrated Surfaces: If an error code is present the status indicator will turn yellow. See *Figure 2.*

Yellow: Error codes Off: No power or Device Unplugged Green: Operating correctly

Figure 2. Status Indicator

For patients that are at high risk of developing a pressure injury, it is recommended to move the patient to another product with no error codes and/or continuously monitor patient for any indication of pressure injury.

If you detect an error code, contact Hillrom Technical Support to have the PRO+ Surface corrected. Complete the attached response form and return it to HillromFA2022_026@sedgwick.com within 2 weeks. Hillrom will contact you to arrange the correction of your Pro+ Surface.

Actions to be taken by the distributor:
Please share this notification with your end users, complete the attached response form, return to HillromFA2022_026@sedgwick.com within 2 weeks.

If you require an editable copy of this notification for further distribution, please contact HillromFA2022_026@sedgwick.com and request the editable copy. To avoid your customers contacting Hillrom, please include your contact details on the editable copy to allow your customers contact you directly.

Action to be taken by Hillrom:
Hillrom will contact you to arrange for the component replacement of your Pro+ Surface.

Contact reference person:
If you have any questions regarding this notification, please contact Hillrom Technical Support, using email or number below.

Country	Phone Number	Technical Support Email
United States	1-800-445 3720	technical.support@hillrom.com

The US Food and Drug Association (FDA) has been notified of this action.

Adverse reactions or quality problems associated with this product may be reported to the FDA's MedWatch Adverse Event Reporting program, either online, by FAX, or by regular mail:

- Online: www.fda.gov/medwatch/report.htm
- FAX: 800-FDA-0178
- Regular mail: use the postage-paid FDA form 3500, available at www.fda.gov/medwatch/getforms.htm , and mail to:

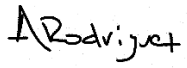
MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

Transmission of this Field Safety Notice:
Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

• A&E departments	• In-house or contracted maintenance
• Adult intensive care units	• IV nurse specialists
• All wards & Clinics	• Medical directors
• Biomedical engineering staff	• Nursing executive directors
• Clinical governance leads	• Oncology units
• Day case theatres	• Pediatric intensive care units
• EBME departments	• Risk managers
• Equipment stores & Libraries	• Supplies managers
• Health and safety managers	• Skilled Nursing Units

Hillrom considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading and disseminating this important product notification.

Yours sincerely,



Alfredo Rodriguez
Director QA/RA