



URGENT: MEDICAL DEVICE CORRECTION

Subject: TotalCare® Bed System with 3-Level Patient Position Monitoring (PPM) – Bed Exit Alarm Failures

FSCA-identifier: MOD1260

Type of action: Medical Device Correction

Date:

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

The purpose of this letter is to advise you that Hill-Rom is conducting a voluntary correction of some TotalCare® beds with 3-Level Patient Position Monitoring.

Description of the Issue:

Hill-Rom has become aware of a potential issue with the bed exit alarm functionality on TotalCare® beds equipped with the 3-Level Patient Position Monitoring. The bed exit alarm may not function properly if the alarm has been armed for a period longer than seventy-two (72) hours without the alarm being triggered by patient movement or removal of the patient weight within that time period. The bed exit alarm functions as intended if the alarm is triggered by patient movement or removal of patient weight within 72 hours of being armed. If the bed exit alarm is not functioning properly, there is a risk of a delay in response and/or a fall related injury to the patient. The root cause of the issue has been identified as a software error.

Hill-Rom has been informed of two events related to this issue; there have been no serious injuries related to this issue.

Affected devices:

TotalCare® bed models P1900/PR1900/U1900 with 3-Level Patient Position Monitoring manufactured between November 11, 2009 and December 8, 2016 with serial numbers in the ranges listed below are potentially affected. **Standard scale or non-scale TotalCare® beds are not affected by this issue.**

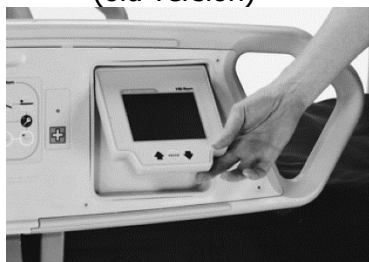
Item Number	Begin Serial Number	End Serial Number
P1900	K328AM6065	Q245AM0691
PR1900	L082AL7316	R343AL4516
U1900	L257AM0541	O311AM7169

In addition, TotalCare® beds that were upgraded with PPM upgrade kit P1957A may also be impacted.

Follow the steps below to confirm if your TotalCare® beds are affected.

- 1) Review all of your TotalCare® beds to confirm if the bed has the latest version of the Graphical Caregiver Interface (GCI)®. See the photos below to help identify the bed's GCI type:

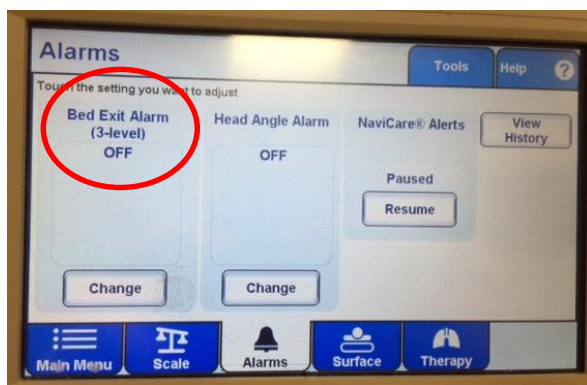
NOT AFFECTED
(old version)



POTENTIALLY AFFECTED
(latest version)



- 2) For beds with the latest version of the GCI, confirm if the "Bed-Exit Alarm (3-Level)" option is available in the Alarms tab on the GUI from the home screen of the bed. See example below. If the TotalCare® bed's GUI does not have the text as indicated in the red circle below, then it is not affected.



Action to be taken by the user:

A software update for the TotalCare® bed's GCI has been released to resolve this issue. Enclosed with this letter are a USB stick with the updated software, instructions on how to update the GCI software, and a response form to be returned within 30 days.

- 1) Identify any affected TotalCare® beds with 3-Level Patient Position Monitoring in your facility by using the criteria above.
- 2) Please use the enclosed instructions and update the software on each potentially affected TotalCare® bed immediately.
- 3) Record the serial numbers of the beds being updated on the response form and return to Hill-Rom within 30 days of receipt of this letter.

Additional USB sticks with the updated software may be obtained by contacting Technical Support at 1-800-445-3720 (select Option 2, then Option 2 again).

Until each of the affected TotalCare® beds are updated with the new software, we recommend you do one or more of the below to avoid any potential occurrences of bed exit not functioning.

1. Power cycle (unplug and plug in the bed mains power cord) once every 48 hours.
2. Remove the Patient and re-zero the scale once every 48 hours.
3. Turn off and do not use the Bed Exit Alarm functionality.

Continued use of the bed exit alarm without the mitigations listed above may cause risk to patient.

If you have an upgrade kit (P1957A) that has not been installed, please contact Hill-Rom for return and replacement.

Transmission of this Medical Device Correction: (if appropriate)

Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Contact reference person:

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

If you have any questions concerning this request or the procedure as outlined, please contact Hill-Rom Technical Support at 1-800-445-3720 Option 2, then Option 2 again.

Yours sincerely

Hill-Rom Technical Support

Customer Response Form

Subject: TotalCare® Beds - Bed Exit Alarm - Three Level PPM Error MOD1260

It is important that you return this form as acknowledgement of your Completion of the Software Upgrade.

Please complete the following with the correct information, and **return this Response Form within 30 days to Hill-Rom**. See specific instructions at bottom of page. Thank you!

Hill-Rom account number: _____

Name of the facility: _____

Address of the facility: _____

City: _____ State: _____ Zip: _____

Facility Authorized Name: (print) _____

Signature: _____

Date: ____/____/____

Title: _____

Phone: _____

Email: _____

Fax: _____

Check action(s) taken:

We do not have any affected or potentially affected products.

We have loaned/sold/donated affected units to: _____

The products have been upgraded with the New Software version 2.0.0.2 in accordance with the installation instructions and are listed by serial number on the attached ____ page(s).

Please within the next 30 days; fax or email this form and all associated forms to:

Fax: [\(812\)-931-2410](tel:812-931-2410)

Email: us.service@hill-rom.com

If you have any questions or needs assistance, please contact Technical Support at 1-800-445-3720 Option 2 then Option 2 again to directly speak with a Technical Support Representative.

Page ____ of ____

Customer Response Form

Subject: TotalCare® Beds - Bed Exit

Alarm - Three Level PPM Error

MOD1260

Hill-Rom account number: _____

Name of the facility: _____

List in the following table all units inspected and updated with the software

No.	Hill-Rom Serial number (located at patient left head of frame)	Completion Date	Initial
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
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Make additional copies as necessary