



Hillrom™

Hill-Rom S.A.S, ZI du Talhouet
56330 Pluvigner, France

Field Safety Notice

Baxter

FA-2022-016

Date

Customer Name

FSCA-identifier: FA-2022-016

Type of action: Field Safety Notice

Subject: AD271B Siderails disengagement risk

Commercial name of the impacted product:
Hill-Rom 900, Ampera and Centuris Pro

Impacted devices:

See Appendix A for impacted Serial Numbers

Name	Model
Hill-Rom 900	LI900B2
Ampera	LI901A0
Centuris Pro	LI900B1

All products manufactured between 20 April 2020 to 10 March 2022 may be impacted.

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

Description of the problem:

Hillrom, a Baxter company, has become aware of a potential issue where the siderail of the LI900B1, LI900B2 and LI901A0 Bed Assembly may not properly engage. If the siderail is not properly engaged, it could result in the siderail falling and would therefore no longer protect the patient, possibly leading to patient fall.

Background:

Hillrom produces bed assemblies (product models LI900B1, LI900B2 and LI901A0) that are equipped with AD271B ¾ siderails (patient safety barriers). In February 2022, Hillrom detected a siderail that was not properly engaged into the bed frame due to a burr in the plastic connector. See Figure 1 below.



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Figure 1: Siderail connector with burr

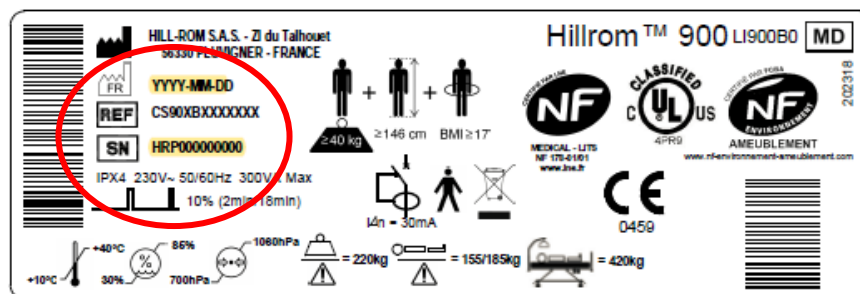
Potential Risk:

If the siderail is not properly engaged, it could result in the siderail falling and would therefore no longer protect the patient, possibly leading to patient fall.

There have been no complaints of this issue occurring in the field.

Actions to be taken by Customer:

- Please identify if you have the impacted product, per Appendix A, in your facility.
Serial number and manufacturing date can be found on frame identification plate – see example below.



- Please follow IFU instructions on how to disengage and re-engage your siderail. Please ensure there is an audible “click” to confirm it is properly engaged. See images below



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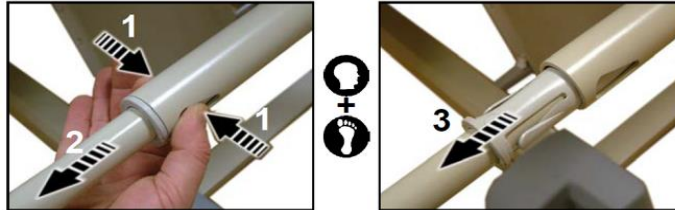
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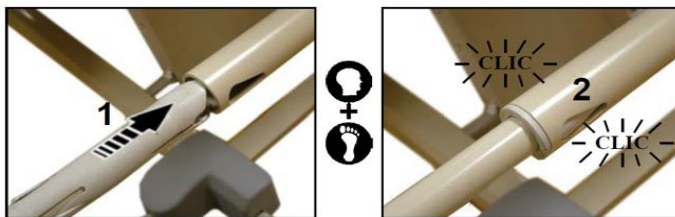
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Removing the long siderails



Installing the long siderails



- Return the enclosed response form within two weeks, confirming inspection complete.

Action to be taken by the Distributor:

Please share this Field Safety Notice with your end users and complete the attached response form and return to hillromPLU016@Sedgwick.com within two weeks.

Please support your end users if inspection by technician is requested.

Action to be taken by Hillrom:

Hillrom have addressed this issue to prevent burrs from occurring in future productions.

Contact Reference Person:

Should you have any questions regarding this Field Safety Notice, please contact Hillrom Technical Support using email or number below.

Market /Region/ Country	Phone Number	Technical Support Email
Austria	(+ 43) 2 243 285 50	service-administration.dach@hillrom.com
Germany	(+ 49) 2 0149869500	service.dach@hillrom.com
Switzerland	(+ 41) 8 48 811530	service-administration.dach@hillrom.com
Netherlands	(+ 31) 347 323 532	service.nl@hillrom.com
Spain	(+ 34) 9 36856000	asistencia@hillrom.com
Italy	(+ 39) 02 950541	assistenza.tecnica@hillrom.com
France	(+ 33) 0 820 012345	sav@hillrom.com

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Sweden	(+ 46) 20-781030	ordernordic@hillrom.com
UK/Ireland	(+ 44) 1530 562176	UKCustomerCare@hillrom.com
Eastern Europe Countries	Contact your Local Hillrom Distributor	

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 maintenance staff
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	Theatres

The undersigned confirms that this notice has been communicated with the appropriate Regulatory Agency.

Sincerely



Maurice Herve
Director, Quality Assurance



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Response Form / Receipt

Subject: AD271B Siderail disengagement risk (FA-2022-016)

It is important that you return this form/receipt as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and **return this Response Form** within two weeks.

Thank you!

Hillrom account number (if known): _____

Name of the facility: _____

Address of the facility: _____

City: _____ Zip: _____ Country: _____

Facility Contact Person Name: (print)

Signature: _____ Date: ____/____/____

Title: _____ Phone: _____

Email: _____

Check actions taken:

- We have reviewed and understand the attached Field Safety Notice

Results from the inspection of our product inventory show:

- We do not have any potentially affected products per Appendix A.
- We confirm we have inspected and re-engaged the siderail with an audible "click" as per IFU instructions. Please list serial numbers below.
- We confirm we have inspected and re-engaged the siderail however, we require a Hillrom technician to confirm it is conforming per IFU instructions. Please list serial numbers below.

Please identify your impacted serial numbers in the table below.

Serial Number	Serial Number	Serial Number

Response form shall be returned to hillromPLU016@Sedgwick.com within two weeks



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Appendix A – Impacted Serial Numbers

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
HRP004138921	HRP004252551	HRP004177852	HRP004173428	HRP004182265	HRP004181045	HRP004128753
HRP004144524	HRP004252552	HRP004177853	HRP004173429	HRP004182266	HRP004181046	HRP004128754
HRP004144525	HRP004252553	HRP004177854	HRP004173430	HRP004182267	HRP004181049	HRP004153452
HRP004210429	HRP004252559	HRP004177855	HRP004208832	HRP004153313	HRP004181050	HRP004153453
HRP004210430	HRP004252560	HRP004177856	HRP004208833	HRP004153314	HRP004181051	HRP004153454
HRP004210445	HRP004252723	HRP004177857	HRP004208834	HRP004183572	HRP004181052	HRP004153455
HRP004210446	HRP004252967	HRP004177858	HRP004208835	HRP004277612	HRP004181053	HRP004153456
HRP004164745	HRP004252968	HRP004177859	HRP004208836	HRP004277613	HRP004160677	HRP004153481
HRP004186146	HRP004252969	HRP004177860	HRP004208837	HRP004277614	HRP004160678	HRP004153482
HRP004255189	HRP004252970	HRP004177861	HRP004208842	HRP004277615	HRP004160679	HRP004153483
HRP004255190	HRP004254473	HRP004177611	HRP004208843	HRP004277616	HRP004160680	HRP004153592
HRP004255194	HRP004254474	HRP004177453	HRP004208844	HRP004277617	HRP004160681	HRP004153593
HRP004255215	HRP004254475	HRP004177847	HRP004208845	HRP004277618	HRP004160682	HRP004176861
HRP004255216	HRP004254476	HRP004177848	HRP004208846	HRP004277619	HRP004160683	HRP004176862
HRP004255356	HRP004254477	HRP004177849	HRP004209162	HRP004277620	HRP004160684	HRP004176863
HRP004255357	HRP004199037	HRP004177851	HRP004209163	HRP004277621	HRP004176499	HRP004176864
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