



Hillrom™

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

Obvestilo o varnostnem popravnem ukrepu

Baxter

FA-2022-016

Datum:

Ime stranke:

Številka ukrepa FSCA: FA-2022-016

Vrsta ukrepa: Obvestilo o varnostnem popravljalnem ukrepu

Zadeva: AD271B Tveganje za odpoved varovalne stranske ograje

Trgovsko ime prizadetega izdelka:

Hill-Rom 900, Ampera in Centuris Pro

Prizadete naprave:

Za prizadete serijske številke glejte Prilogo A

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

Prizadeti so lahko vsi izdelki, proizvedeni med 20. aprilom 2020 in 10. marcem 2022.

Prejme naj: odgovorna oseba za upravljanje tveganj ustanove/upravitelj ustanove, izvršni direktor za upravljanje ustanove, inženir ustanove, vodja vigilance, oddelek za biomedicinski inženiring in predstavnik za stike za medicinske pripomočke

Opis težave:

Hillrom, eno izmed podjetij v skupini Baxter, je ugotovil obstoj morebitne težave, zaradi katere se varovalna ograja na posteljah LI900B1, LI900B2 in LI901A0 Bed Assembly ne zaskoči pravilno. V primeru, da se stranska varovalna ograja pravilno ne zaskoči, se lahko zgodi, da se podre, kar pomeni, da pacient ni več zaščiten in lahko pade.

Ozadje:

Hillrom proizvaja montažne postelje (modeli LI900B1, LI900B2 in LI901A0), ki so opremljene s stranskimi ograjami AD271B ¾ (varovalne pregrade za paciente). Hillrom je februarja 2022 opazil stransko ograjo, ki zaradi udrtine v plastičnem priključku ni bila pravilno zaskočena v posteljni okvir. Glejte sliko 1 spodaj.



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Slika 1: Prikluček za stransko ograjo z udrtno

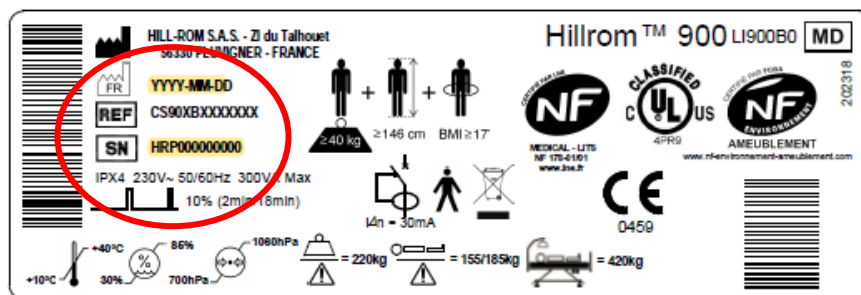
Potencialno tveganje:

V primeru, da se stranska varovalna ograja pravilno ne zaskoči, se lahko zgodi, da se podre, kar pomeni, da pacient ni več zaščiten in lahko pade.

Na terenu nismo prejeli pritožb o tej napaki.

Ukrepi, ki jih mora izvesti stranka:

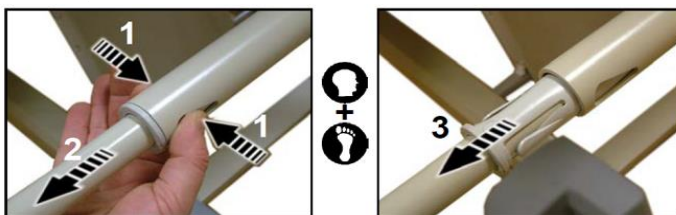
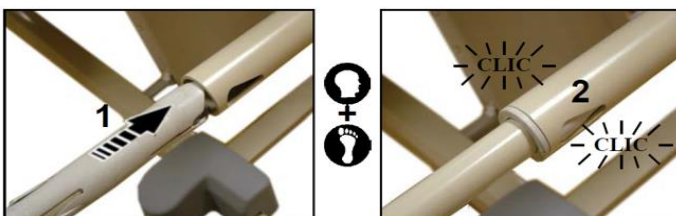
- Preverite, če v vaši ustanovi uporabljate prizadeti izdelek, omenjen v Prilogi A. Serijsko številko in datum proizvodnje lahko najdete na identifikacijski ploščici na posteljnem okvirju – glejte spodnji primer.



- Sledite navodilom za uporabo za napotke, kako zaskočiti in spustiti stransko ograjo. Prepričajte se, da zaslišite »klik«, ki vam sporoči, da je ograja pravilno zaskočena. Glejte slike spodaj.

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Odstranjevanje dolge stranske**Nameščanje dolge stranske ograje**

- V dveh tednih pošljite nazaj priloženi obrazec, ki potrjuje, da je bil pregled opravljen.

Ukrep, ki ga mora izvesti distributer:

To obvestilo o varnostnem popravnem ukrepu izročite svojim končnim uporabnikom in izpolnite priložen obrazec za odgovor ter ga v dveh tednih vrnite na naslov hillromPLU016@Sedgwick.com.

Nudite potrebno podporo svojim končnim uporabnikom, če zaprosijo pregled s strani tehnika.

Ukrep, ki ga mora izvesti družba Hillrom:

Hillrom je poskrbel, da se takšne udrtine med prihodnjo proizvodnjo ne bodo več pojavljale.

Pristojna kontaktna oseba:

Če imate kakršna koli vprašanja glede tega obvestila o varnostnem popravnem ukrepu, se obrnite na tehnično podporo družbe Hillrom, elektronski naslov in telefonska številka sta navedeni v nadaljevanju.

Trg/regija /država	Telefonska številka	Elektronski naslov za tehnično podporo
Avstrija	(+ 43) 2 243 285 50	service-administration.dach@hillrom.com
Nemčija	(+ 49) 2 0149869500	service.dach@hillrom.com
Švica	(+ 41) 8 48 811 530	service-administration.dach@hillrom.com
Nizozemska	(+ 31) 347 323 532	service.nl@hillrom.com
Španija	(+ 34) 9 36856000	asistencia@hillrom.com
Italija	(+ 39) 02 950541	assistenza.technica@hillrom.com

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Francija	(+ 33) 0 820 012345	sav@hillrom.com
Švedska	(+ 46) 20-781030	ordernordic@hillrom.com
VB/Irska	(+ 44) 1530 562176	UKCustomerCare@hillrom.com
Države vzhodne Evrope	Stopite v stik s svojim lokalnim distributerjem za Hillrom	

Posredovanje tega obvestila o varnostnem popravljalnem ukrepu:

Poskrbite, da bo to obvestilo posredovano vsemu osebju, ki ga zadeva. To lahko med drugim vključuje naslednje osebe:

Urgentni oddelki	Interno vzdrževalno osebje
Oddelki za intenzivno nego za odrasle	Bolničarji specialisti za intravenozno
Vsi bolnišnični oddelki in klinike	Direktorji zavodov/ambulant
Osebje oddelka za biomedicinski inženiring	Izvršni direktorji zdravstvene nege
Vodje kliničnega nadzora	Onkološki oddelki
Ambulantni oddelki	Oddelki za pediatrično intenzivno nego
Oddelki biomehanskega in biomedicinskega	Upravitelji tveganj
Prodajalne in izposojevalnice medicinskih	Vodje nabave
Vodje oddelka za zdravje in varnost pri delu	Operacijske dvorane

Podpisnik potrjuje, da je bilo to obvestilo poslano ustrezni regulativni agenciji.

S spoštovanjem,

Maurice Herve
Direktor zagotavljanja kakovosti

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Odzivni obrazec / potrdilo**Zadeva: AD271B Tveganje za odpoved varovalne stranske ograje (FA-2022-016)****Pomembno je, da nam ta obrazec/potrdilo vrnete in s tem potrdite prejem obvestila ter nam posredujete vse potrebne podatke.**Izpolnite naslednja polja s pravilnimi podatki in nam pošljite ta **obrazec za odgovor**
v roku dveh tednov.

Hvala!

Številka računa družbe Hillrom (če jo poznate): _____

Ime ustanove: _____

Naslov ustanove: _____

Mesto: _____ Poštna številka: _____ Država: _____

Ime kontaktne osebe ustanove: (s tiskanimi črkami) _____

Podpis: _____ Datum: ____/____/____

Naslov: _____ Telefonska številka: _____

Elektronski naslov: _____

Preverite izvedene ukrepe: Priloženo Obvestilo o varnostnem popravilnem ukrepu smo prebrali in ga razumemo.**Rezultati pregleda naših zalog izdelka kažejo:** Nimamo morebitnih zadevnih izdelkov, opisanih v Prilogi A. Potrjujemo, da smo pregledali in ponovno zaskočili stransko ograjo, pri čemer smo zaslišali »klik«, kot je navedeno v navodilih za uporabo. Spodaj navedite serijske številke. Potrjujemo, da smo pregledali in ponovno zaskočili stransko ograjo, vendar rabimo Hillrom tehnika, da potrdi skladnost z navodili za uporabo. Spodaj navedite serijske številke.

V spodnji tabeli navedite prizadete serijske številke.

Serijska številka	Serijska številka	Serijska številka

Obrazec za odgovor nam v dveh tednih vrnete na naslov hillromPLU016@Sedgwick.com

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Serijska številka	Serijska številka	Serijska številka	Serijska številka	Serijska številka	Serijska številka
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HRP004109798	HRP004187084	HRP004209587	HRP004240437	HRP004270611	HRP004282437
HRP004109799	HRP004187432	HRP004211298	HRP004239905	HRP004270612	HRP004282438
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HRP004109801	HRP004187435	HRP004209169	HRP004240579	HRP004270614	HRP004282450
HRP004109802	HRP004187436	HRP004210782	HRP004240580	HRP004270615	HRP004282451
HRP004109789	HRP004187437	HRP004210787	HRP004240581	HRP004270616	HRP004282456
HRP004109792	HRP004187603	HRP004210788	HRP004240582	HRP004270617	HRP004282457
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HRP004158092	HRP004190986	HRP004209448	HRP004249631	HRP004270629	HRP004282263

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HRP004158093	HRP004190987	HRP004209512	HRP004249632	HRP004270630	HRP004282264
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HRP004177421	HRP004209153	HRP004231478	HRP004264310	HRP004280489	HRP004285073
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HRP004179116	HRP004209164	HRP004231701	HRP004266003	HRP004272737	HRP004283986

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