

**Hillrom™**

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

Avis de sécurité

Baxter**FA-2022-016**

Date :

Nom du client :

Identifiant FSCA : FA-2022-016

Type d'action : Avis de sécurité

Objet : Risque de désengagement de la ridelle AD271B

Nom commercial du produit concerné :

Hill-Rom 900, Ampera et Centuris Pro

Appareils concernés :

Voir l'annexe A pour les numéros de série concernés.

Nom	Modèle
Hill-Rom 900	LI900B2
Ampera	LI901A0
Centuris Pro	LI900B1

Tous les produits fabriqués entre le 20 avril 2020 et le 10 mars 2022 peuvent être concernés.

Destinataires : gestionnaire des risques de l'établissement/administrateur d'établissement, administrateur en chef de l'établissement, ingénieur de l'établissement, responsable surveillance, ingénieur biomédical, agent de liaison pour les dispositifs médicaux

Description du problème :

Hillrom, une société de Baxter, a été informée d'un problème potentiel où la ridelle des lits LI900B1, LI900B2 et LI901A0 peut ne pas s'engager correctement. Si la ridelle n'est pas correctement engagée, elle risque de tomber et donc de ne plus protéger le patient, ce qui pourrait entraîner sa chute.

Contexte :

Hillrom produit des lits (modèles de produits LI900B1, LI900B2 et LI901A0) qui sont équipés de ridelles AD271B ¾ (barrières de sécurité pour les patients). En février 2022, Hillrom a détecté une ridelle qui n'était pas correctement engagée dans le cadre du lit en raison d'une bavure dans le connecteur en plastique. Voir l'image 1 ci-dessous.



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Image 1 : Connecteur ridelle avec bavure

Risque potentiel :

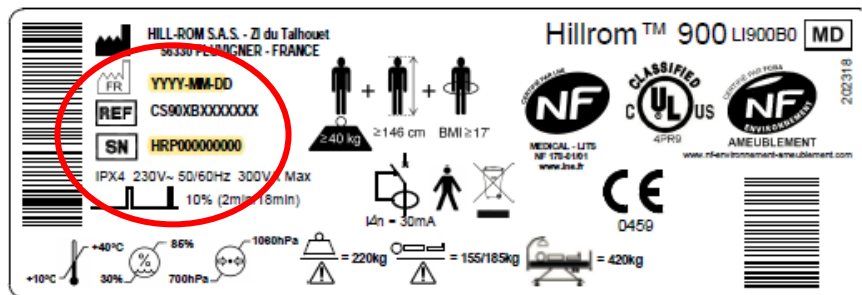
Si la ridelle n'est pas correctement engagée, elle risque de tomber et donc de ne plus protéger le patient, ce qui pourrait entraîner sa chute.

Il n'y a eu aucune plainte concernant ce problème sur le terrain.

Mesures devant être prises par le client :

- Veuillez indiquer si votre établissement possède un ou plusieurs produits concernés (voir annexe A).

Le numéro de série et la date de fabrication se trouvent sur la plaque d'identification du cadre (voir l'exemple ci-dessous).



- Veuillez suivre les instructions du mode d'emploi sur la manière de désengager et de réengager votre ridelle. Veuillez vous assurer qu'il y a eu un « clic » audible pour confirmer qu'elle est correctement engagée. Voir les images ci-dessous

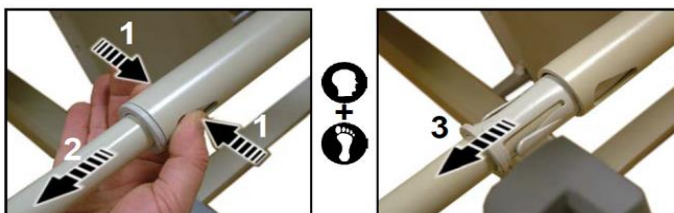
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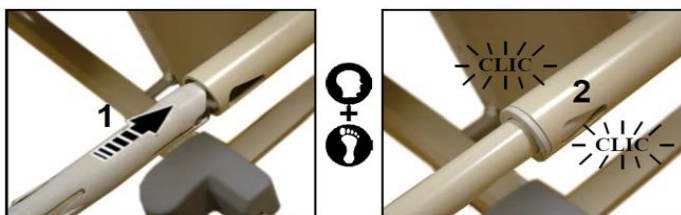
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Retirer les longues ridelles



Installer les longues ridelles



- Renvoyez le formulaire de réponse ci-joint dans les deux semaines, en confirmant que l'inspection est terminée.

Mesures devant être prises par le revendeur :

Veuillez partager cet avis de sécurité sur le terrain avec vos utilisateurs finaux et remplir le formulaire de réponse ci-joint et le renvoyer à hillromPLU016@Sedgwick.com sous deux semaines.

Veuillez aider vos utilisateurs finaux si une inspection par un technicien est demandée.

Mesures devant être prises par Hillrom :

Hillrom s'est attaqué à ce problème pour éviter que des bavures ne se produisent dans les futures productions.

Personne à contacter :

Si vous avez des questions concernant cet avis de sécurité, veuillez contacter le support technique de Hillrom en utilisant l'adresse e-mail ou le numéro ci-dessous.

Marché/Région/Pays	Numéro de téléphone	Adresse e-mail de l'assistance technique
Autriche	(+ 43) 2 243 285 50	service-administration.dach@hillrom.com
Allemagne	(+ 49) 2 0149869500	service.dach@hillrom.com
Suisse	(+ 41) 8 48 81 1530	service-administration.dach@hillrom.com
Pays-Bas	(+ 31) 347 323 532	service.nl@hillrom.com
Espagne	(+ 34) 9 36856000	asistencia@hillrom.com
Italie	(+ 39) 02 950541	assistenza.tecnica@hillrom.com
France	(+ 33) 0 820 012345	sav@hillrom.com
Suède	(+ 46) 20-781030	ordernordic@hillrom.com
Royaume-Uni/Irlande	(+ 44) 1530 562176	UKCustomerCare@hillrom.com

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Pays d'Europe de l'Est

Contactez votre
revendeur local Hillrom

Transmission de cet avis de sécurité :

Assurez-vous que cet avis est distribué à l'ensemble du personnel concerné. Ce personnel peut inclure, sans toutefois s'y limiter, les employés et les agents des services suivants :

Les services des urgences	Le personnel de maintenance interne
Les unités de soins intensifs pour adultes	Le personnel infirmier spécialisé en soins
L'ensemble des services et des cliniques	Les directeurs d'établissements de santé
Le personnel d'ingénierie biomédicale	Les responsables des soins infirmiers
Les responsables de la gouvernance clinique	Les unités d'oncologie
Les blocs opératoires en ambulatoire	Les unités de soins intensifs pédiatriques
Les services d'ingénierie électrique et	Les gestionnaires de risques
Les magasins d'équipement et les	Les responsables des approvisionnements
Les responsables de la santé et de la sécurité	Les blocs opératoires

Le soussigné confirme que le présent avis a été communiqué à l'organisme de réglementation approprié.

Cordialement,

Maurice Herve
Directeur, Assurance qualité

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Formulaire de réponse/récépissé

Objet : Risque de désengagement de la ridelle AD271B (FA-2022-016)

Il est important que vous renvoyiez ce formulaire/récépissé afin d'en accuser réception et que vous nous fournissiez les informations nécessaires.

Veuillez compléter le formulaire suivant avec les informations correctes et **renvoyer ce formulaire de réponse sous deux semaines.**

Merci.

Numéro de compte Hillrom (le cas échéant) : _____

Nom de l'établissement : _____

Adresse de l'établissement : _____

Ville : _____ Code postal : _____ Pays : _____

Nom de la personne à contacter au sein de l'établissement (en caractères d'imprimerie) : _____

Signature : _____ Date : ____/____/____

Titre: _____ Téléphone: _____

E-mail : _____

Vérification des mesures prises :

☐ Nous avons examiné et compris l'avis de sécurité ci-joint

Les résultats de l'inspection de notre inventaire de produits montrent que :

☐ Nous ne possédons pas de produits potentiellement concernés, comme repris dans l'annexe A.

☐ Nous confirmons avoir inspecté et réengagé la ridelle avec un « clic » audible selon les instructions du mode d'emploi. Veuillez énumérer les numéros de série ci-dessous.

☐ Nous confirmons avoir inspecté et réengagé la ridelle, mais nous avons besoin d'un technicien de Hillrom pour confirmer que tout est conforme aux instructions du mode d'emploi. Veuillez énumérer les numéros de série ci-dessous.

Veuillez identifier vos numéros de série concernés dans le tableau ci-dessous.

Numéro de série	Numéro de série	Numéro de série

La réponse doit être renvoyée à hillromPLU016@Sedgwick.com sous deux semaines

**Hillrom™**Hill-Rom S.A.S, ZI du Talhouet
56330 Pluvigner, France**Avis de sécurité****Baxter****FA-2022-016****Annexe A - Numéros de série concernés**

Numéro de série	Numéro de série	Numéro de série	Numéro de série	Numéro de série	Numéro de série
HRP004109793	HRP004182264	HRP004209574	HRP004237611	HRP004270607	HRP004282433
HRP004109794	HRP004182265	HRP004209577	HRP004237612	HRP004270608	HRP004282434
HRP004109796	HRP004182266	HRP004209578	HRP004237613	HRP004270609	HRP004282435
HRP004109797	HRP004182267	HRP004209585	HRP004240436	HRP004270610	HRP004282436
HRP004109798	HRP004187084	HRP004209587	HRP004240437	HRP004270611	HRP004282437
HRP004109799	HRP004187432	HRP004211298	HRP004239905	HRP004270612	HRP004282438
HRP004109800	HRP004187434	HRP004211299	HRP004239907	HRP004270613	HRP004282439
HRP004109801	HRP004187435	HRP004209169	HRP004240579	HRP004270614	HRP004282450
HRP004109802	HRP004187436	HRP004210782	HRP004240580	HRP004270615	HRP004282451
HRP004109789	HRP004187437	HRP004210787	HRP004240581	HRP004270616	HRP004282456
HRP004109792	HRP004187603	HRP004210788	HRP004240582	HRP004270617	HRP004282457
HRP004109795	HRP004187604	HRP004213472	HRP004240583	HRP004270082	HRP004282458
HRP004109516	HRP004187605	HRP004213473	HRP004240584	HRP004270083	HRP004282459
HRP004109517	HRP004187606	HRP004213711	HRP004240585	HRP004270084	HRP004282460
HRP004109519	HRP004187808	HRP004213712	HRP004240586	HRP004270085	HRP004282461
HRP004109520	HRP004187809	HRP004213713	HRP004239921	HRP004270086	HRP004282462
HRP004109529	HRP004187810	HRP004213714	HRP004241804	HRP004270087	HRP004282497
HRP004109530	HRP004187811	HRP004213715	HRP004241805	HRP004270088	HRP004282498
HRP004109531	HRP004187812	HRP004213716	HRP004242639	HRP004270089	HRP004281987
HRP004109532	HRP004187985	HRP004213766	HRP004242659	HRP004270090	HRP004281988
HRP004109540	HRP004187986	HRP004213767	HRP004240988	HRP004270091	HRP004281989
HRP004109541	HRP004187987	HRP004213768	HRP004240989	HRP004270092	HRP004281990
HRP004109790	HRP004187988	HRP004213769	HRP004240601	HRP004270093	HRP004282387
HRP004109791	HRP004188210	HRP004213770	HRP004240602	HRP004270094	HRP004282388
HRP004111238	HRP004188211	HRP004213771	HRP004240603	HRP004270281	HRP004282389
HRP004111239	HRP004188212	HRP004213772	HRP004240604	HRP004270307	HRP004282390
HRP004111240	HRP004188213	HRP004213773	HRP004240605	HRP004270628	HRP004282392
HRP004111241	HRP004188378	HRP004213096	HRP004240606	HRP004270631	HRP004282397
HRP004111242	HRP004188379	HRP004213104	HRP004240607	HRP004270636	HRP004282398
HRP004111243	HRP004188380	HRP004213105	HRP004240608	HRP004270637	HRP004282399
HRP004111244	HRP004188381	HRP004213106	HRP004240609	HRP004270638	HRP004282400
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HRP004116986	HRP004187424	HRP004213112	HRP004243058	HRP004271741	HRP004278583
HRP004116987	HRP004187425	HRP004213440	HRP004243892	HRP004271772	HRP004278584
HRP004116988	HRP004187426	HRP004213445	HRP004243893	HRP004271773	HRP004278585
HRP004116989	HRP004187431	HRP004213446	HRP004241414	HRP004271774	HRP004278586

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HRP004116990	HRP004190003	HRP004213447	HRP004240587	HRP004271775	HRP004278587
HRP004111511	HRP004190009	HRP004213468	HRP004240588	HRP004271790	HRP004278588
HRP004111512	HRP004190020	HRP004213469	HRP004240589	HRP004271791	HRP004278589
HRP004111513	HRP004190021	HRP004213470	HRP004240590	HRP004271792	HRP004278590
HRP004111514	HRP004190022	HRP004213471	HRP004240591	HRP004271793	HRP004278591
HRP004111515	HRP004186967	HRP004213774	HRP004240592	HRP004271794	HRP004278592
HRP004111237	HRP004186968	HRP004209534	HRP004240593	HRP004271946	HRP004278593
HRP004125976	HRP004186969	HRP004209540	HRP004240594	HRP004271947	HRP004278594
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HRP004095491	HRP004187088	HRP004210416	HRP004244715	HRP004271952	HRP004278606
HRP004095492	HRP004187433	HRP004210417	HRP004244716	HRP004271953	HRP004278607
HRP004095493	HRP004188579	HRP004210418	HRP004244717	HRP004272346	HRP004278608
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HRP004145994	HRP004190481	HRP004214222	HRP004248377	HRP004271939	HRP004281991

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HRP004146546	HRP004190482	HRP004214223	HRP004248378	HRP004272544	HRP004281992
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HRP004158093	HRP004190987	HRP004209512	HRP004249632	HRP004270630	HRP004282264

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