



Hillrom™

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

Avis de sécurité – Mise à jour

Baxter

FA-2022-016

Date :
Nom du client :

Identifiant FSCA : FA-2022-016

Type d'action : Avis de sécurité – Mise à jour des appareils concernés.

Objet : Risque de désengagement de la barrière AD271B

Nom commercial du produit concerné :
Hill-Rom 900, Ampera et Centuris Pro

Appareils concernés : Vous avez déjà reçu une notification concernant le risque de désengagement de la barrière AD271B. Une mise à jour des appareils concernés a depuis été effectuée. Veuillez consulter l'Annexe A pour identifier les nouveaux numéros de série ajoutés (voir les numéros de série mis en évidence dans l'Annexe A mise à jour ci-dessous)

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

Tous les produits pourvus de barrière en métal 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 barrière des lits LI900B1, LI900B2 et LI901A0 peut ne pas s'engager correctement. Si la barrière 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 barrières en métal AD271B ¾ (barrières de sécurité pour les patients). En février 2022, Hillrom a détecté une barrière 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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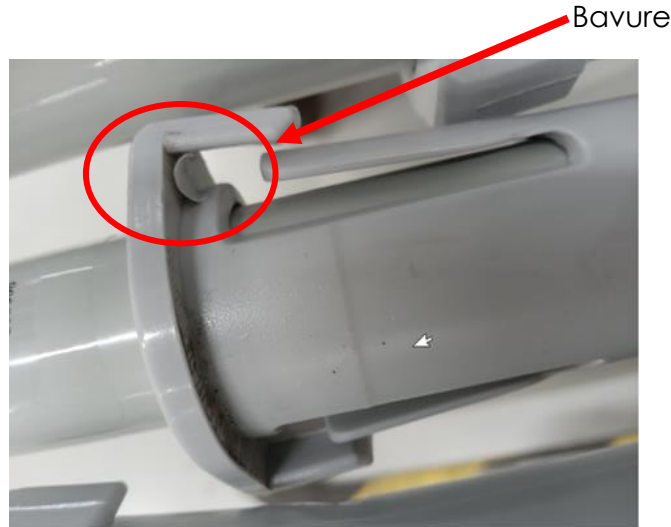


Image 1 : Connecteur ridelle avec bavure

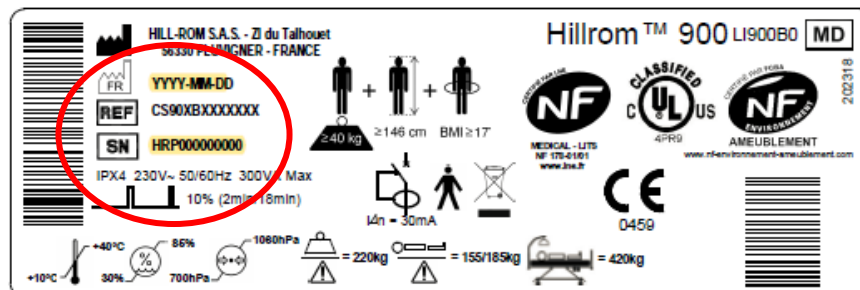
Risque potentiel :

Si la barrière 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 barrière. 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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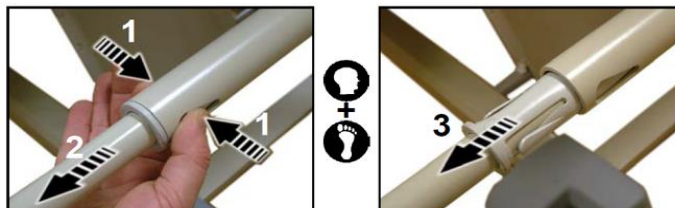
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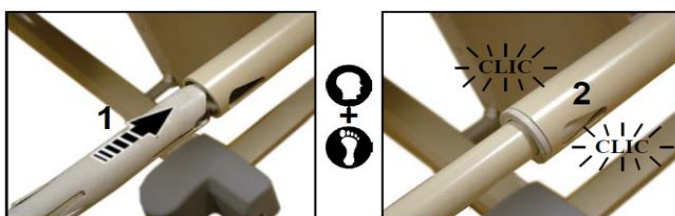
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Retirer les longues barrières



Installer les longues barrières



- 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 :

Veillez transmettre cet avis de sécurité sur le terrain à vos utilisateurs finaux, puis remplir le formulaire de réponse ci-joint et le renvoyer à hillromPLU016@Sedgwick.com sous deux semaines.

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

Mesures devant être prises par Hillrom :

Hillrom a pris les mesures nécessaires 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 811530	service-administration.dach@hillrom.com
Pays-Bas	(+ 31) 347 323 532	service.nl@hillrom.com



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Espagne	(+ 34) 9 36856000	asistencia@hillrom.com
Italie	(+ 39) 02 950541	assistenza.technica@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
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	Les infirmiers spécialisés 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 bibliothèques	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 Hervé
Directeur, Assurance qualité



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Formulaire de réponse

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

Il est important que vous renvoyez ce formulaire/récépissé afin d'accuser réception de cet avis et que vous nous fournissiez les informations nécessaires.

Veillez 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 de suivi ci-joint

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

Nous ne possédons pas de produits potentiellement concernés, conformément aux numéros de série mis à jour 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 barrière, 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.

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

Numéro de série	Numéro de série	Numéro de série

Le formulaire de réponse doit être renvoyé à hillromPLU016@Sedgwick.com sous deux semaines



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Annexe A - Numéros de série concernés

**Les numéros de série mis en évidence ont été ajoutés*

HRP002469397.	HRP004145375	HRP004169308	HRP004185561	HRP004209229	HRP004238423	HRP004270835
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HRP002717123	HRP004145377	HRP004169310	HRP004185563	HRP004209247	HRP004238425	HRP004270837
HRP004007979.	HRP004145378	HRP004169311	HRP004185564	HRP004209248	HRP004238426	HRP004270993
HRP004007980.	HRP004145379	HRP004169491	HRP004185565	HRP004209249	HRP004238427	HRP004270994
HRP004037054.	HRP004145380	HRP004169492	HRP004185566	HRP004209250	HRP004238428	HRP004270995
HRP004046377	HRP004145381	HRP004169493	HRP004185567	HRP004209251	HRP004238429	HRP004270996
HRP004095490	HRP004145382	HRP004169494	HRP004185568	HRP004209424	HRP004238430	HRP004270997
HRP004095491	HRP004145383	HRP004169495	HRP004185569	HRP004209425	HRP004238431	HRP004270998
HRP004095492	HRP004145389	HRP004169520	HRP004185570	HRP004209426	HRP004238432	HRP004270999
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HRP004104684	HRP004145394	HRP004169571	HRP004185575	HRP004209435	HRP004238572	HRP004271004
HRP004104685	HRP004145395	HRP004169572	HRP004186146	HRP004209440	HRP004238573	HRP004271005
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