



Hillrom™

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

**Powiadomienie
dotyczące
bezpieczeństwa**

Baxter

FA-2022-016

Data:

Nazwa klienta:

FSCA-identifiier: FA-2022-016

Rodzaj działania: powiadomienie dotyczące bezpieczeństwa

Temat: AD271B Ryzyko odłączenia się barierek bocznych

Nazwa handlowa produktu, którego dotyczy problem:

Hill-Rom 900, Ampera oraz Centuris Pro

Urządzenia, których dotyczy problem:

Numery seryjne można znaleźć w Załączniku A

| Nazwa | Model |
|--------------|---------|
| Hill-Rom 900 | LI900B2 |
| Ampera | LI901A0 |
| Centuris Pro | LI900B1 |

Może dotyczyć wszystkich produktów wyprodukowanych w okresie od 20 kwietnia 2020 r. do 10 marca 2022 r.

Odbiorca: kierownik ds. ryzyka / administrator placówki, dyrektor wykonawczy odpowiedzialny za administrację placówki, inżynier placówki, kierownik nadzoru, dział techniki biomedycznej, przedstawiciel ds. urzędzeń medycznych

Opis problemu:

Hillrom, firma Baxter, została poinformowana o potencjalnym problemie polegającym na tym, że barierka boczna łóżka LI900B1, LI900B2 i LI901A0 może nie być prawidłowo zamocowana. W takim przypadku barierka może odłączyć się i nie chronić pacjenta, który w związku z tym może spaść z łóżka.

Informacje ogólne:

Hillrom jest producentem łóżek (modeli LI900B1, LI900B2 i LI901A0) wyposażonych w barierki boczne AD271B ¾ (barierki zabezpieczające pacjenta). W lutym 2022 roku firma wykryła, że barierka nie była prawidłowo osadzona w ramie łóżka, ponieważ plastikowe łącze miało zadziory. Patrz: rysunek 1 poniżej.



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Zadziór



Ilustracja 1: Łącze barierki bocznej z zadziorem

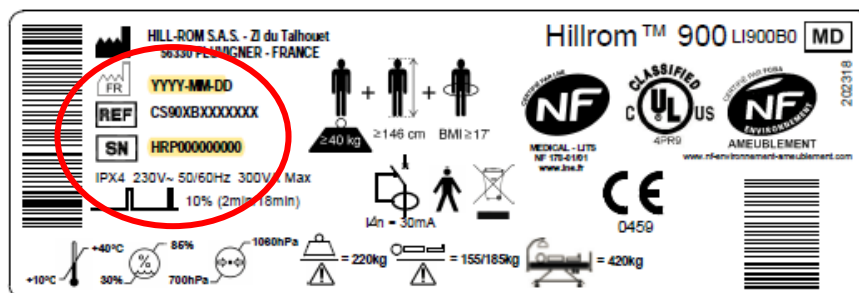
Potencjalne ryzyko:

W takim przypadku barierka może odłączyć się i nie chronić pacjenta, który w związku z tym może spaść z łóżka.

Nie było żadnych skarg dotyczących tego problemu.

Działania, które powinien podjąć Klient:

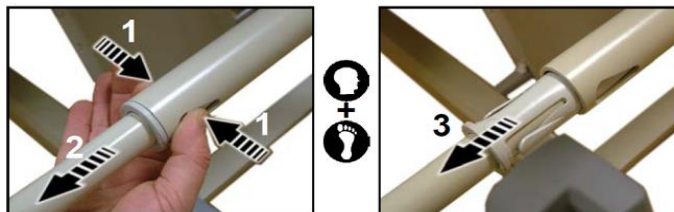
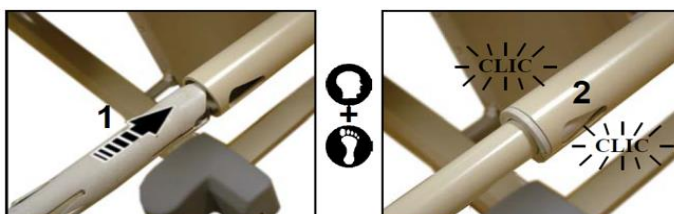
- Prosimy sprawdzić, czy posiadają Państwo w swoim obiekcie produkt, którego dotyczy problem, zgodnie z Załącznikiem A. Numer seryjny i data produkcji znajduje się na tabliczce identyfikacyjnej umieszczonej na ramie – poniżej pokazujemy przykład.



- Należy postępować zgodnie z instrukcjami IFU dotyczącymi odłączania i ponownego zamocowywania barierki bocznej. Poprawność montażu potwierdzi dźwięk kliknięcia. Prosimy zapoznać się z poniższymi ilustracjami.

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Zdemontowanie długich barierek**Montaż długich barierek bocznych**

- Prosimy o przesłanie załączonego formularza odpowiedzi, potwierdzając dokonanie inspekcji.

Działania, które powinien podjąć dystrybutor:

Prosimy o przekazanie niniejszego powiadomienia dotyczącego bezpieczeństwa użytkownikom końcowym oraz o wypełnienie dołączonego formularza odpowiedzi i odesłanie go na adres: hillromPLU016@Sedgwick.com w ciągu dwóch tygodni.

Na prośbę użytkowników końcowych prosimy zapewnić im pomoc technika.

Działania, które powinna podjąć firma Hillrom:

Firma Hillrom podjęła działania, aby w przyszłej produkcji uniknąć problemu występowania zadziorów.

Osoba do kontaktu:

W razie jakichkolwiek pytań dotyczących niniejszego powiadomienia dotyczącego bezpieczeństwa prosimy kontaktować się z Działem Wsparcia Technicznego firmy Hillrom e-mailowo lub dzwoniąc pod podany poniżej numer.

| Rynek/region/kraj | Numer telefonu | Adres e-mail Działu Wsparcia Technicznego |
|-------------------|---------------------|---|
| Austria | (+ 43) 2 243 285 50 | service-administration.dach@hillrom.com |
| Niemcy | (+ 49) 2 0149869500 | service.dach@hillrom.com |
| Szwajcaria | (+ 41) 8 48 811530 | service-administration.dach@hillrom.com |
| Holandia | (+ 31) 347 323 532 | service.nl@hillrom.com |
| Hiszpania | (+ 34) 9 36856000 | asistencia@hillrom.com |
| Włochy | (+ 39) 02 950541 | assistenza.tecnica@hillrom.com |
| Francja | (+ 33) 0 820 012345 | sav@hillrom.com |

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| | | |
|----------------------------|--|----------------------------|
| Szwecja | (+ 46) 20-781030 | ordernordic@hillrom.com |
| Wielka Brytania / Irlandia | (+ 44) 1530 562176 | UKCustomerCare@hillrom.com |
| Kraje Europy Wschodniej | Prosimy o kontakt z lokalnym dystrybutorem firmy Hillrom | |

Przekazanie niniejszego powiadomienia dotyczącego bezpieczeństwa:

Prosimy upewnić się, że niniejsze powiadomienie zostanie przekazane wszystkim właściwym stronom. Mogą to być na przykład:

| | |
|--|---|
| Izby przyjęć | Pracownicy wewnętrznej obsługi |
| Oddziały intensywnej terapii dla dorosłych | Pielęgniarki infuzyjne |
| Wszystkie oddziały szpitalne i przychodnie | Szefowie ds. medycznych |
| Biomedyczni pracownicy techniczni | Szefowie wykonawczy działów |
| Osoby zarządzające działalnością kliniczną | Oddziały onkologii |
| Ambulatoria | Pediatryczne oddziały intensywnej terapii |
| Działy opieki technicznej nad sprzętem | Menedżerowie ds. ryzyka |
| Magazyny urządzeń i biblioteki | Menedżerowie ds. dostaw |
| Menedżerowie ds. BHP | Sale operacyjne |

Osoba podpisana poniżej potwierdza, że niniejsze powiadomienie zostało przekazane Państwa odpowiedniemu organowi regulacyjnemu.

Z poważaniem,

Maurice Herve
Dyrektor Działu Zapewnienia Jakości



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Formularz odpowiedzi / potwierdzenie otrzymania

Temat: AD271B Ryzyko odłączenia się bariereki bocznej

Należy zwrócić niniejszy formularz/pokwitowanie w celu potwierdzenia otrzymania i przekazać nam konieczne informacje.

Prosimy podać właściwe informacje i **zwrócić niniejszy formularz odpowiedzi** w ciągu **dwóch tygodni**. Dziękujemy!

Numer konta Hillrom (jeśli jest znany): _____

Nazwa placówki: _____

Adres placówki: _____

Miejscowość: _____ Kod pocztowy: _____ Kraj: _____

Imię i nazwisko osoby do kontaktu w placówce (dużymi literami):

Podpis: _____ Data: ____/____/____

Stanowisko/funkcja: _____ Nr telefonu: _____

Adres e-mail: _____

Kontrola podjętych działań:

Zapoznaliśmy się z treścią załączonego powiadomienia dotyczącego bezpieczeństwa i potwierdzamy, że je rozumiemy

Kontrola posiadanych przez nas produktów wykazała, co następuje:

Nie posiadamy żadnych produktów, których potencjalnie może dotyczyć problem, zgodnie z Załącznikiem A.

Potwierdzamy, że przeprowadziliśmy inspekcję i zgodnie z instrukcjami IFU założyliśmy ponownie barierekę boczną tak, iż było słyszalne kliknięcie. Prosimy wymienić numery seryjne poniżej.

Potwierdzamy, że sprawdziliśmy i założyliśmy ponownie barierekę boczną, jednak wymagamy od technika firmy Hillrom potwierdzenia, że mocowanie jest teraz zgodne z instrukcjami IFU. Prosimy wymienić numery seryjne poniżej.

Prosimy poniżej zaznaczyć numery seryjne produktów, których dotyczy problem.

| Numer seryjny | Numer seryjny | Numer seryjny |
|---------------|---------------|---------------|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Formularz odpowiedzi należy przesłać na adres hillromPLU016@Sedgwick.com w ciągu dwóch tygodni

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| Numer seryjny | Numer seryjny | Numer seryjny | Numer seryjny | Numer seryjny | Numer seryjny |
|---------------|---------------|---------------|---------------|---------------|---------------|
| 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 |
| HRP004116699 | HRP004188382 | HRP004213107 | HRP004240610 | HRP004270639 | HRP004282401 |
| HRP004116705 | HRP004188383 | HRP004213108 | HRP004240611 | HRP004270640 | HRP004278559 |
| HRP004116706 | HRP004188384 | HRP004213109 | HRP004241415 | HRP004270641 | HRP004278580 |
| HRP004116712 | HRP004188577 | HRP004213110 | HRP004241416 | HRP004270642 | HRP004278581 |
| HRP004116713 | HRP004188578 | HRP004213111 | HRP004241417 | HRP004270643 | HRP004278582 |
| 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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|--------------|--------------|--------------|--------------|--------------|--------------|
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| HRP004111512 | HRP004190020 | HRP004213469 | HRP004240589 | HRP004271791 | HRP004278589 |
| HRP004111513 | HRP004190021 | HRP004213470 | HRP004240590 | HRP004271792 | HRP004278590 |
| HRP004111514 | HRP004190022 | HRP004213471 | HRP004240591 | HRP004271793 | HRP004278591 |
| HRP004111515 | HRP004186967 | HRP004213774 | HRP004240592 | HRP004271794 | HRP004278592 |
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| HRP004125976 | HRP004186969 | HRP004209540 | HRP004240594 | HRP004271947 | HRP004278594 |
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| HRP004125978 | HRP004187085 | HRP004209575 | HRP004240596 | HRP004271949 | HRP004278596 |
| HRP004125979 | HRP004187086 | HRP004209576 | HRP004244713 | HRP004271950 | HRP004278604 |
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| HRP004095492 | HRP004187433 | HRP004210417 | HRP004244716 | HRP004271953 | HRP004278607 |
| HRP004095493 | HRP004188579 | HRP004210418 | HRP004244717 | HRP004272346 | HRP004278608 |
| HRP004095494 | HRP004188580 | HRP004211243 | HRP004244905 | HRP004272347 | HRP004278609 |
| HRP004095519 | HRP004188581 | HRP004211244 | HRP004244906 | HRP004272348 | HRP004278610 |
| HRP004140146 | HRP004188592 | HRP004211245 | HRP004244907 | HRP004272349 | HRP004281942 |
| HRP004140147 | HRP004188593 | HRP004211247 | HRP004244908 | HRP004272350 | HRP004281943 |
| HRP004140148 | HRP004189734 | HRP004211261 | HRP004244909 | HRP004272351 | HRP004281964 |
| HRP004140149 | HRP004189735 | HRP004211262 | HRP004247049 | HRP004272352 | HRP004281973 |
| HRP004140150 | HRP004189736 | HRP004214065 | HRP004247050 | HRP004272449 | HRP004281974 |
| HRP004140151 | HRP004189737 | HRP004214116 | HRP004247051 | HRP004272450 | HRP004281975 |
| HRP004140406 | HRP004190339 | HRP004214520 | HRP004247052 | HRP004272451 | HRP004281976 |
| HRP004140407 | HRP004190340 | HRP004214528 | HRP004247053 | HRP004272452 | HRP004281977 |
| HRP004140408 | HRP004190341 | HRP004214531 | HRP004247054 | HRP004272453 | HRP004281978 |
| HRP004140417 | HRP004190342 | HRP004214532 | HRP004247055 | HRP004272454 | HRP004281979 |
| HRP004140418 | HRP004190343 | HRP004214994 | HRP004247056 | HRP004272455 | HRP004278225 |
| HRP004140419 | HRP004190344 | HRP004214995 | HRP004247685 | HRP004271429 | HRP004278226 |
| HRP004142624 | HRP004190412 | HRP004214996 | HRP004247686 | HRP004271430 | HRP004279657 |
| HRP004142625 | HRP004190413 | HRP004214997 | HRP004243057 | HRP004271431 | HRP004279658 |
| HRP004142626 | HRP004190414 | HRP004214652 | HRP004243059 | HRP004271432 | HRP004279659 |
| HRP004142627 | HRP004190415 | HRP004214653 | HRP004243060 | HRP004271433 | HRP004279660 |
| HRP004142628 | HRP004190416 | HRP004214654 | HRP004244695 | HRP004271728 | HRP004279661 |
| HRP004144775 | HRP004190417 | HRP004214655 | HRP004238900 | HRP004271729 | HRP004279663 |
| HRP004144776 | HRP004189556 | HRP004214656 | HRP004247687 | HRP004271730 | HRP004279664 |
| HRP004144777 | HRP004189557 | HRP004214209 | HRP004247688 | HRP004271739 | HRP004280792 |
| HRP004145990 | HRP004189702 | HRP004214218 | HRP004247689 | HRP004271740 | HRP004281245 |
| HRP004145991 | HRP004190478 | HRP004214219 | HRP004247690 | HRP004272545 | HRP004281246 |
| HRP004145992 | HRP004190479 | HRP004214220 | HRP004248375 | HRP004272546 | HRP004281247 |
| HRP004145993 | HRP004190480 | HRP004214221 | HRP004248376 | HRP004271938 | HRP004281248 |
| HRP004145994 | HRP004190481 | HRP004214222 | HRP004248377 | HRP004271939 | HRP004281991 |

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|--------------|--------------|--------------|--------------|--------------|--------------|
| HRP004146546 | HRP004190482 | HRP004214223 | HRP004248378 | HRP004272544 | HRP004281992 |
| HRP004146547 | HRP004190488 | HRP004214224 | HRP004248379 | HRP004269061 | HRP004282356 |
| HRP004146548 | HRP004190489 | HRP004214225 | HRP004248380 | HRP004269062 | HRP004280240 |
| HRP004146549 | HRP004190490 | HRP004214226 | HRP004248381 | HRP004269063 | HRP004280241 |
| HRP004146550 | HRP004190491 | HRP004214227 | HRP004248382 | HRP004269064 | HRP004280242 |
| HRP004145394 | HRP004190492 | HRP004214228 | HRP004190375 | HRP004269066 | HRP004281629 |
| HRP004145395 | HRP004190493 | HRP004214233 | HRP004190377 | HRP004269633 | HRP004281630 |
| HRP004145396 | HRP004190494 | HRP004214234 | HRP004190381 | HRP004269634 | HRP004281631 |
| HRP004145501 | HRP004190495 | HRP004214235 | HRP004190391 | HRP004269635 | HRP004283375 |
| HRP004145502 | HRP004190496 | HRP004214236 | HRP004190577 | HRP004269636 | HRP004283391 |
| HRP004145503 | HRP004190640 | HRP004214237 | HRP004190578 | HRP004269637 | HRP004283392 |
| HRP004155245 | HRP004190662 | HRP004214238 | HRP004190579 | HRP004269638 | HRP004283393 |
| HRP004155246 | HRP004190663 | HRP004214239 | HRP004190580 | HRP004269639 | HRP004283394 |
| HRP004155264 | HRP004190664 | HRP004214240 | HRP004190581 | HRP004269640 | HRP004283395 |
| HRP004155265 | HRP004190665 | HRP004214241 | HRP004190582 | HRP004269829 | HRP004283396 |
| HRP004155266 | HRP004190666 | HRP004214242 | HRP004190587 | HRP004269830 | HRP004283397 |
| HRP004155273 | HRP004190667 | HRP004214064 | HRP004190588 | HRP004269831 | HRP004283398 |
| HRP004155274 | HRP004190668 | HRP004214519 | HRP004190744 | HRP004269832 | HRP004283399 |
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| HRP004173416 | HRP004207500 | HRP004227129 | HRP004264358 | HRP004280791 | HRP004283796 |
| HRP004173417 | HRP004207501 | HRP004227130 | HRP004264359 | HRP004280793 | HRP004283797 |

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| HRP004173421 | HRP004207531 | HRP004227138 | HRP004264294 | HRP004280205 | HRP004283801 |
| HRP004173422 | HRP004207897 | HRP004227139 | HRP004264295 | HRP004280216 | HRP004283802 |
| HRP004173423 | HRP004207898 | HRP004227140 | HRP004264296 | HRP004280217 | HRP004283803 |
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| HRP004179117 | HRP004209165 | HRP004231702 | HRP004266004 | HRP004272738 | HRP004283987 |

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| HRP004176754 | HRP004209152 | HRP004231705 | HRP004266007 | HRP004272846 | HRP004283990 |
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