

**James L. Cunniff**  
Vice President, General Manager

6300 South Sprinkle Road  
Kalamazoo, MI 49001  
t: 269 324 6601  
f: 269 329 2313  
www.stryker.com

**stryker**<sup>®</sup>

---

**Medical**

December 21, 2004

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

*Re: Draft Guidance for Industry and Food and Drug Administration Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment (“the Guidance”) [Docket No. 2004D-0343]*

Ladies and Gentlemen,

Our Quality Policy at Stryker Medical read as follows: “We are committed to earning customer loyalty by providing best-in-class products, services and quality, which reduce our customer’s cost and improve patient care and outcomes.” We applaud the efforts of the FDA and HBSW in your work to reduce the frequency of patient entrapments. We also think it is imperative to attempt to make the Guidance reasonable to caregivers and to bed manufacturers (“Industry”) in light of the various types of care delivered, the cost of delivering the care versus the risk of entrapment in the various zones contained in the Guidance, and FDAMA’s vital goal of global standardization for safety requirements.

To achieve that end, we strongly feel that for caregivers to properly dispense care, certain hospital environments should be excluded from the Guidance. Specifically, acute care, maternity, pressure reduction products, bed systems with bed exit alarms, and bariatric / pediatric products should all be excluded. Each of these very unique care settings require hospital staff to be focused on the specific needs of each patient, which requires greater one-on-one care. Some patients (critical care, maternity) are either too ill or too closely monitored to reasonably be exposed to an entrapment scenario. Bed exit systems monitor a patient’s location on the bed, thereby eliminating the risk that the caregiver will not be alerted if the patient does become entrapped. As mentioned in page three of the Guidance, the population most vulnerable to entrapment are elderly, especially those who are frail or confused. It is imperative to focus the Guidelines on areas where entrapments are most likely to occur so that the goals of the Guidance are achieved (reducing entrapments) without unnecessarily overburdening caregivers with patients that are not at risk.

Second, legacy products should be exempt. There is no doubt that our customers will experience a great deal of confusion as to how to measure their existing beds to determine whether they are compliant with the Guidance, not to mention a great deal of time, energy and expense. What they will discover is that virtually none of their current beds meet the Guidance. It will cost millions of dollars to purchase and install some sort of retrofit kit to upgrade their beds. The money to cover this expense is just not available in the extremely tight health care budgets hospitals face today. This will leave caregivers with the choice of not complying with the Guidance or facing additional financial burdens. Allowing hospitals to make the decision to purchase Guidance compliant bed systems will accomplish the goals at hand; requiring hospitals to convert legacy products will be unduly burdensome.

There is also cause for concern regarding the future management of this Guidance and the expectations it sets forth. There is no current plan for the FDA or HBSW to maintain the final Guidance or to have a group that will answer questions from hospitals as they arise. As conditions in the healthcare community change in the future and as new technologies become available, there needs to be processes to reassess and/or update the Guidance as needed. Even more dire is the fact that the tools needed to measure a bed systems compliance may not even exist, based on ECRI's recent "business decisions," as mentioned by the FDA Hospital Bed Team in its e-mail dated November 23<sup>rd</sup>. Releasing the Guidance document with measurements only but no validated testing tool and no entity committed to its existence is doing an injustice to the caregivers who will be forced to find some way to assess their compliance.

I understand that Congress asked the FDA to attempt to harmonize its standards with worldwide requirements so that Industry would not be held to varying standards depending on where a product is sold. Obviously, if standards vary from country to country, it makes the manufacturing of medical products much more expensive to the consumer (because it is more expensive to manufacture different versions of the same product). The IEC standards currently contain side rail entrapment standards, with upcoming revisions to those standards even more closely aligned to the Guidance. The management of two separate entrapment standards will be extremely difficult for both caregivers and Industry to manage. It is also important to note that the most significant difference between the two standards is that the Guidance requires that measurements be taken with the mattress on the bed, while the IEC standards do not. The incorporation of the mattress into the measurements is very problematic for caregivers – they routinely change mattresses on hospital beds and mattresses' shape changes with wear. While a bed system may be compliant with the Guidance one day, it may become noncompliant a week later if the mattresses are changed or a year later when a mattress becomes worn. It would be very difficult for already short-staffed hospitals to keep up with measuring constantly changing bed systems in addition to all of their other job duties. Moreover, because the Guidance would be the preeminent design requirement for side rail safety, it would become a de facto legal standard in court. It is also inevitable that some states would adopt the Guidance as law; this was openly discussed at the HBSW validation meeting earlier this month. The end result would be a Guidance document that becomes a

legal standard for both new bed systems and legacy product – this would be an unmanageable situation for caregivers.

Finally, we feel it is also overly emotional to include pictorials of the entrapment zones. The drawing on page 11 clearly defines the zones described in the Guidance. Moreover, the illustration used to describe Zone 5 is clearly modeled after a Stryker product. None of the other illustrations depict manufacturer specific bed products. This illustration should be changed to a non-identifiable bed like the other illustrations, particularly in light of the fact that our beds have *zero reported entrapments* in the United States! We are willing to provide an alternate illustration if you wish.

Finally, attached please find a detailed review of the Guidance text with an eye toward the very important aspect of having the text itself as pristine as possible. I hope that you find this detail helpful.

I would like to personally thank you for taking the time to consider these comments that I make on behalf of Stryker Medical. Patient safety is of the utmost concern to us; yet, so is creating a Guidance that accomplishes that goal while being easily administered by Industry and caregivers.

Thank you,



James Cunniff  
Vice President and General Manager  
Stryker Medical

cc: Michael Cartier  
Paul Freestone  
Anne Mullally

## TEXT COMMENTS -- DETAILED

Page 1 -- The Guidance provides recommendations intended to reduce “life-threatening entrapments.” The definition of entrapment needs to be set forth. If it is not life threatening, is it still an entrapment that is meant to be covered by the Guidance? The dimensions suggest that entrapments only involve the head, neck and chest. Is this a correct assumption? This differs from the original definition found in the May 3, 2002 Draft Guidance Preamble.

Page 6 – The Guidance should include a definition of “extended stay stretcher”. It should be defined as a product designed for patient stays exceeding 24 hours. Patients are commonly kept overnight for observation in emergency departments, but not usually more than 24 hours.

In addition, all “Pressure reducing therapeutic products” (including framed floatation therapy products and bed systems using powered air mattress replacements) should be excluded from the scope of the Guidance. The huge benefit gained by the use of these products greatly outweighs the entrapment risks. A standard definition of “pressure reduction” products within the Industry is commonly defined as one that provides less than 70mmHg interface pressure, which should clarify which products would and would not be excluded.

Page 15 – The Request for Comment #2 (regarding a more stringent requirement of 2  $\frac{1}{3}$  inches (instead of 4  $\frac{3}{4}$  inches) for Zone 2) should remain 4  $\frac{3}{4}$  inches. This measurement is appropriate because to become an entrapment, the head must pass through the zone in question. With the inclusion of the mattress as part of the measurement, this can only help to restrict the area between the rail supports. At 4  $\frac{3}{4}$  inches, the 5<sup>th</sup> percentile head diameter applied with the 95<sup>th</sup> percentile head weight would be a conservative measure to mitigate against entrapment.

Page 16 – The Request for Comment #3 (regarding a more stringent requirement of 2  $\frac{1}{3}$  inches (instead of 4  $\frac{3}{4}$  inches) for Zone 3) should remain 4  $\frac{3}{4}$  inches. HBSW chose 4  $\frac{3}{4}$  inches because entrapment cannot occur when the head cannot become wedged between the mattress and the side rail. Further, a linear measurement is not appropriate – a uniquely shaped and weighted measurement tool (simulating the size and weight of a human head) would be needed to accurately judge compliance with this zone.

Moreover, by reducing the gaps for the various zones, serious pinch points may result. EN-389 (1993) as well as ISO 13852 (referenced by the third edition of 60601-1), considers dimensions to limit pinch and shearing points. Although limiting gaps to those specified in the Guidance may reduce the risk of entrapment for the patient, the reduced gaps would also increase the risk of pinching and shearing for the patient and the user. An example of this is the choice of allowing less than 2  $\frac{1}{3}$ ” between side rails, or between the head end side rail and the head board. While mitigating the risk of

entrapment, the 2 1/3” dimension increases the risk of a pinch/shearing point of the hand (the requirement is approximately 4”).<sup>1</sup>

Page 17 – The measurement for Zone 4 at the end of the rails states, “<2 1/3 inches (60mm) and >60 degree angle.” This dimensional specification is unclear as to where within 60 degrees the 2 1/3 inches should be measured. Zone 4 is a complicated area that requires a testing tool with a validated method to properly measure it.

Page 20 – Request for Comment #4 (the inclusion of “an angle greater than 60 degrees in the V-shaped spaces between the rails.”) An independent retrospective study by the IEC (see attached) on entrapment in these zones (including rail design) show that the majority of the incidents occurred in beds without such an angled opening. Therefore, there is no empirical data to support the requirement of an angle of greater than 60 degrees.

Moreover, the 60 degree requirement at the top of the rails runs contrary to the patient population at risk for entrapment. Entrapment at the top of the rail would mean that the patient would have to have the strength to pick themselves up, put themselves into the entrapment zone, then not have enough strength to pull themselves out. The requirements for Zone 4 would therefore be appropriate to mitigate the risk of the patient sliding out of bed between the rails and becoming entrapped.

Finally, the angle measurement requirement for Zone 5 should be eliminated in its entirety. The requirements for IEC 60601-2-38, Dimension E, that is currently in force covers safety for this zone completely. Many good, safe siderail design options will have to be abandoned because of the dimensional requirements of this zone, including 60 degrees.

Page 21 – Request for Comment #5 (“an angle greater than 60 degrees in the V-shaped spaces between the rails.”) In addition to the comments set forth in the previous section, data needs to be provided establishing that “FDA has reports of entrapment in Zone 6.” Also, in the IEC study (see attached), the entrapment in this zone between the side rail and the head board was substantially equivalent to the occurrences of patients expiring with their neck compressed *on the top* of the side rail. IEC took this data into account with the development of the test methods described in IEC 60601-2-52 and hence has not included the angle requirement.

Page 23 – Request for Comment #7 (“Articulated Bed Positions”). Data for entrapments resulting from articulation should be provided to show the need for such an onerous requirement. It is important that a validated test methodology be developed to avoid confusion during the evaluation of this zone. Data supporting entrapments in articulated positions should be collected and presented for comment before this requirement should be included in the Guidance.

---

<sup>1</sup> This is also a problem in Zone 5 where the patient may have a hand in the zone during articulation, and the view of the patient may be obscured from the user. It is additionally a problem in Zone 6 where a nurse may be managing the cables to a patient (as in the Intensive Care environment) during articulation.

Page 23 – Additional Request for Comment #8 (“Application of this Guidance to all health care settings”). Statistics need to be provided as to where entrapments occurred. Although entrapments can happen in all care environments, supervision is substantially increased in acute care, critical care and emergency or ambulatory care environments. Because of the increased supervision, risk of entrapment may be reduced by other means. In an increased supervision environment, for example, a patient bed exit system based upon monitoring of the patient’s center of gravity, and integrated into the nurse communications system can provide substantial risk mitigation against entrapment. This would not be the case in a long-term care environment with substantially less supervision provided to patients.

Page 24 – The proposed Zone 6 dimensions are inconsistent. The requested comment on Zone 6 between end of boards and rail having a dimension of  $< 2 \frac{1}{3}$ ” or  $> 12 \frac{1}{2}$ ” is much different than the dimensions on Page 21 that states  $< 2 \frac{1}{3}$ ” near the head board and  $< 2 \frac{1}{3}$ ” or  $> 12 \frac{1}{2}$ ” near the footboard. It is unclear which dimensions are being proposed.

Moreover, the  $< 2 \frac{1}{3}$  creates problems in the intensive care environment involving tube management. Larger cables or tubes (e.g., ventilation) fit too tightly in the opening and movement of the bed could cause pulling on the tubing.

## SUSPECTED "TOP OF RAIL" INCIDENTS, MAUDE & MDR DATABASES, TO DEC 31, 2002

MDR REPORT	DATE RECEIVED	INCIDENT DESCRIPTION	MANUFACTURER NARRATIVE	MFR NAME	MODEL NUMBER	BRAND NAME
M350788	11/19/1992	RESIDENT OF NURSING FACILITY WAS FOUND IN HER BED WITH HER HEAD IN THE SPACE BETWEEN THE HEAD BOARD AND SIDE RAIL OF THE BED. THE SIDE RAIL WAS IN A RAISED POSITION. RESIDENT WAS REPOSITIONED AND LACK OF RESPIRATION WAS NOTED. THERE WAS A LACK OF VITAL SIGNS AND PUPILS WERE NONREACTIVE. THERE WAS A MARK ON THE LEFT SIDE OF NECK WHERE IT WAS LAYING AGAINST SIDE RAIL. BED WAS REMOVED FROM SERVICE AND EVALUATED. IT WAS DETERMINED THAT THE BED OPERATED PROPERLY AND WAS USED BY FACILITY IN PROPER MANNER. THIS TYPE OF BED HAS BEEN IN USE AT FACILITY FOR OVER 10 YEARS WITHOUT INCIDENT. THE SIDERAILS INSTALLED ON THIS BED ARE FULL LENGTH WHICH WILL RESTRICT PT EGRESS FROM THE BED. IN DISCUSSING THE INCIDENT WITH THE FACILITY ADMINISTRATOR, THE ONLY RATIONALE OFFERED LEADING TO THE PT ENTRAPMENT WAS THAT SHE HAD PREVIOUSLY EXHIBITED SIGNS OF AGITATION AND POSSIBLY ATTEMPTED TO CLIMB OVER THE SIDERAIL.		HILL-ROM CO., INC.	723	A.C. POWERED HOSPITAL BED CENTURY SERIES
M383656	05/05/1993	NURSE FOUND PT LYING ACCROSS THE BED WITH HER NECK WEDGED BETWEEN THE SIDERAIL AND HEADBOARD. THE RESIDENT WAS WITHOUT PULSE OR RESPIRATION. THE MD WAS NOTIFIED AND THE RESIDENT WAS PRONOUNCED DEAD. DUE TO THE NATURE OF THE INCIDENT AND PT STATISTICS THE FACILITY WAS UNABLE TO DETERMINE WITH CERTAINTY ANY CAUSAL RELATIONSHIP BETWEEN THE DEVICE AND THE INCIDENT.		HILL-ROM CO., INC.	425	MANUAL HILO BED
5098	05/17/1993	AT 0200 HRS ON 4/18/93 WHEN THE PMA WENT TO THE RESIDENT'S ROOM TO CHECK ON THE RESIDENT, THE PMA FOUND THE RESIDENT LYING HORIZONTALLY ACROSS THE BED WITH HER NECK WEDGED BETWEEN THE SIDE-RAIL AND THE HEADBOARD. THE RESIDENT WAS WITHOUT PULSE OR RESPIRATION. THE PHYSICIAN WAS NOTIFIED IMMEDIATELY AND THE RESIDENT WAS PRONOUNCED DEAD. THE CORONER WAS NOTIFIED. AN AUTOPSY REPORT IS PENDING DEVICE NOT LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: SATISFACTORY CONDITION. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT. INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY. NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED. DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: ACTUAL DEVICE INVOLVED IN INCIDENT WAS EVALUATED, MECHANICAL TESTS PERFORMED, PERFORMANCE TESTS PERFORMED, VISUAL EXAMINATION. RESULTS OF EVALUATION: DESIGN - HUMAN FACTORS. CONCLUSION: NONE OR UNKNOWN. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: OTHER. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.		HILL ROM COMPANY, INC.	425	HILL-ROM
5147	04/27/1993	THE ALLEGED INCIDENT HAPPENED ON 3/13/93 AND INVOLVED A FLEXICAIR BED. PATIENT WAS FOUND BETWEEN UPPER END OF SIDE RAILS AND HEAD OF BED. PATIENT EXPIRED ON 3/15/93. WE BELIEVE A PROBABILITY MAY EXIST THAT THE MEDICAL DEVICE MAY HAVE CONTRIBUTED TO THE DEATH. INVALID DATA - REGARDING SINGLE USE LABELING OF DEVICE. PATIENT MEDICAL STATUS PRIOR TO EVENT: INVALID DATA. INVALID DATA - REGARDING MULTIPLE PATIENT INVOLVEMENT. INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY. NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED. DEVICE WAS NOT EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: NO DATA. RESULTS OF EVALUATION: NO DATA. CONCLUSION: NO DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: MAYBE. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.		SUPPORTS SYSTEM INTERNATIONAL	FLEXICAIR BED	FLEXICAIR BED

MDR REPORT	DATE RECEIVED	INCIDENT DESCRIPTION	MANUFACTURER NARRATIVE	MFR NAME	MODEL NUMBER	BRAND NAME
12111	03/18/1994	PT FOUND <b>WEDGED BETWEEN THE UPPER AND LOWER BEDRAIL</b> . NO INJURY OCCURRED TO THIS PT. HOWEVER, THIS INCIDENT IS BEING REPORTED BECAUSE IT IS ANOTHER IN A SERIES OF INCIDENTS INVOLVING THE SAME TYPE OF BED AND SIDERAILS. THE EXACT BED CANNOT BE IDENTIFIED.		HILL-ROM CO., INC.	850C55	CENTRA RETRACTABLE BED
17959	07/29/1994	PATIENT FOUND <b>WEDGED BETWEEN THE UPPER AND LOWER BEDRAIL</b>		HILL-ROM	850C55	HILL-ROM CENTRA RETRACTABLE BED
23162	06/28/1995	RESIDENT WAS <b>FOUND WITH NECK BETWEEN SPLIT BEDRAILS</b> . RESIDENT WAS ASSESSED FOR VITALS AFTER REMOVING NECK FROM BEDRAILS & FOUND TO HAVE NO VITALS. RESIDENT HAD METASTATIC STOMACH CANCER & WAS A HOSPICE PT. DEATH CERTIFICATE STATES "ASPHYXIATION BY MECHANICAL COMPRESSION HEAD CAUGHT BETWEEN BEDRAILS".		HILL ROM COMPANY, INC.	70	RETRACTABLE BED SPLIT SIDE RAILS
27366	10/23/1995	INVOLUNTARY STATE FACILITY PSYCHIATRIC PT ADMITTED TO AN ACUTE GENERAL MED UNIT FOR FEEDING DISORDER. PT WAS PSYCHOTIC WITH AGITATED BEHAVIOR. PT CONSTANTLY YELLING & SCREAMING. PT RESTLESS IN BED, MOVING ABOUT IN BED WITH YELLING (SIDERAILS UP). HAD 1:1 MENTAL HEALTH TECH IN ROOM WITH PT AT ALL TIMES. <b>PT SUDDENLY THRUST HER HEAD DOWN &amp; BETWEEN END OF SIDERAIL &amp; EDGE OF FOOTBOARD OF BED. GAP WIDTH WAS LATER MEASURED AT 2 1/2" TO 3". STAFF IMMEDIATELY SUMMONED WHO COULD NOT EXTRICATE PT'S HEAD WITHOUT INJURING PT.</b> HEAD WAS STABILIZED BY STAFF & SECURITY OFFICERS SUMMONED. SECURITY OFFICERS RESPONDED PROMPTLY & PULLED THE FOOTBOARD AWAY FROM PT WHICH RELEASED PT FROM PREDICAMENT. PT SUSTAINED <b>SCRATCHES TO BOTH SIDES OF NECK</b> . PT GIVEN IM MEDICATION FOR AGITATION & PLACED IN SOFT WRIST RESTRAINTS FOR A SHORT PERIOD UNTIL CALMED DOWN.		UNKNOWN	P7013AS2	MANUAL HOSPITAL BED
31713	03/05/1996	PT <b>FOUND DEAD WEDGED BETWEEN UPPER AND LOWER BED SIDE RAILS</b> . INCIDENT IS UNDER INVESTIGATION. NO FURTHER DETAILS ARE AVAILABLE AT THIS TIME.		HILL ROM CO., INC.		ADVANCE 2000 ALL ELECTRIC BED

MDR REPORT	DATE RECEIVED	INCIDENT DESCRIPTION	MANUFACTURER NARRATIVE	MFR NAME	MODEL NUMBER	BRAND NAME
33235	05/29/1996	RESIDENT FOUND WITH LIFELESS BODY PARTIALLY OFF THE BED BETWEEN THE SIDERAIL AND HEADBOARD. BED WITH 3/4 LENGTH SIDERAILS IN RAISED POSITION.		JOERNS HEALTH CARE, INC.	B 4030	FREE STYLE, HIGH-LOW, HEAVY DUTY SPRING HOSPITAL BED
64282	01/16/1997	PT FOUND WITH HEAD STUCK BETWEEN TOP AND BOTTOM SIDERAIL ON THE RIGHT SIDE OF THE BED. BOTH RAILS WERE IN THE RAISED POSITION.	THE DEVICE WAS EXAMINED AND FOUND TO BE IN WORKING CONDITION AND THE STAFF WAS FAMILIAR WITH ITS OPERATION.	HILL-ROM, INC.	M4000	FLEXICAIR
113544	08/15/1997	RESIDENT FOUND BY CNA IN BED WITH HER NECK AGAINST THE TOP END OF THE SIDE RAIL. LPN WAS SUMMONED TO ROOM. RESIDENT WAS ASSESSED. NO PULSE OR RESPIRATIONS NOTED. CPR STARTED. TRANSPORT TO HOSP. RESIDENT FAMILY MEMBER CONTACTED. DOCTOR NOTIFIED. NOTIFIED OF RESIDENT'S DEATH. SHERIFF & CORONER INVESTIGATING. NO MALFUNCTION OF EQUIPMENT.		UNK	*	UNK
122788	09/23/1997	PT FOUND LYING ON LEFT SIDE WITH LEFT ARM UNDERNEATH HIM AND NECK CAUGHT BETWEEN TWO SIDE RAILS OF THE BED.		HILL-ROM	840	HILL-ROM
139984	12/22/1997	MFR REC'D A REPORT OF A PT FOUND DEAD WITH HER NECK BETWEEN THE BED RAIL AND THE HEAD BOARD. NO ONE WITNESSED THE INCIDENT AND NO MALFUNCTION HAS BEEN IDENTIFIED.		INVACARE CORPORATION	BED, FULL/SEMI ELECTRIC	INVACARE FULL/SEMI ELECTRIC HOME CARE BED
157723	03/19/1998	RESIDENT WAS FOUND TO BE ON HER RIGHT SIDE WITH HER LEFT ARM OVER THE SIDE RAIL AND HER HEAD OVER THE SIDE OF THE BED WITH HER NECK LEANING AGAINST THE SIDE GAIT. RESIDENT WAS PULSELESS AND CYANOTIC.		INVACARE	6630	INVACARE
198932	11/25/1998	RPTR WISHES TO REPORT ON AN INCIDENT THAT WAS INVESTIGATED BY HEALTH SERVICES. RESIDENT IN A LONG TERM CARE FACILITY WAS CHANGED AND REPOSITIONED IN BED AT APPROX 2 PM. REPORTEDLY, THE SIDE RAIL ON THE BED WAS BENT, LOOSE AND SHAKEY. AT APPROX 2:30 PM, STAFF FOUND RESIDENT WEDGED BETWEEN THE END OF THE SIDE RAIL AND THE HEAD OF THE BED. HER LEGS WERE ENTANGLED IN THE SIDE RAIL AND BETWEEN THE MATTRESS. RESIDENT WAS PRONOUNCED DEAD AT THE SCENE. THE SIDE RAIL WAS REPLACED PRIOR TO THE INVESTIGATION, SO NO PRODUCT INFO IS AVAILABLE. ALL INFO PERTAINING TO THE ACTUAL EVENT WAS COMPILED THROUGH INTERVIEWS WITH STAFF MEMBERS TO PROVIDE THIS REPORT.		UNK	UNK	UNK

MDR REPORT	DATE RECEIVED	INCIDENT DESCRIPTION	MANUFACTURER NARRATIVE	MFR NAME	MODEL NUMBER	BRAND NAME
214815	03/12/1999	RESIDENT FOUND LAYING ACROSS TOP OF BED WEDGED BETWEEN SIDERAIL AND HEADBOARD OF BED. 10" INDENTATION LEFT MID THIGH AND SKIN SCRAPER NOTED.		HILL-ROM, INC.	870 AFO	LTC RESIDENT BED
238291	08/03/1999	A PT WAS KILLED WHEN HE APPARENTLY SLID INTO SPACE BETWEEN BEDRAILS AND HEADBOARD OF BED IN NURSING HOME. NURSING HOME DID NOT REPORT DEATH AS OTHER THAN NATURAL CAUSES, AND MORTUARY, DURING EMBALMING NOTICED THE BLACK MARKS ON THE BODY AND CALLED THE MEDICAL EXAMINER. THE MEDICAL EXAMINER THEN CONDUCTED AN EXAMINATION AND LEARNED ABOUT THE ACCIDENTAL DEATH. BED WAS ORDERED ON 5/24/94.		INVACARE CORP.	NI	SMITH AND DAVIS
244460	10/11/1999	MFR RECEIVED A MEDWATCH REPORT FROM FDA ALLEGING THAT A PT DIED DUE TO ENTRAPMENT BETWEEN BEDRAILS & HEADBOARD OF BED. THE MFR OF THE BED RAIL & BED IS NOT KNOWN. THERE IS INSUFFICIENT INFO TO CONDUCT FOLLOW-UP INVESTIGATION.	DEVICE IS UNAVAILABLE FOR EVAL.	INVACARE CORP.	BED ACCESSORY	5143 BED EXTENDER KIT
268094	03/06/2000	NURSING STAFF ENTERED PT ROOM AND FOUND PT'S FEET ON THE FLOOR; HEAD AND SHOULDERS ON BED. PT'S BODY WAS WEDGED BETWEEN THE BEDRAILS. ALL FOUR BEDRAILS WERE UP. NO RESPIRATIONS NOTED; PT WARM TO TOUCH. PT WAS LOWERED TO THE FLOOR; RESPIRATIONS RESUMED WITH THIS INTERVENTION. PT PLACED BACK IN THE BED. BRUISE NOTED TO RIGHT UPPER QUADRANT APPROX 2" BELOW RIB CAGE. LEFT HIP ALSO REDDENED. NO BROKEN SKIN NOTED.	INFO RECEIVED FROM THE FIELD INVESTIGATION CONDUCTED BY A HILL-ROM TECH, INDICATED THAT THE UNIT INVOLVED WITH THE ADVERSE EVENT COULD NOT BE LOCATED BY THE FACILITY'S PERSONEL. ADDITIONAL INFO RECEIVED FROM THE FACILITY DURING THE INVESTIGATION SUGGESTS THAT THE UNIT EXHIBITED NO MALFUNCTION. THE FACILITY HAD STATED THAT THERE WAS NOT A PRODUCT PROBLEM, AND HAD PUT THE BED INTO SERVICE ELSEWHERE. THE INFO RECEIVED REASONABLY SUGGESTS A POSSIBLE PT MONITORING ISSUE.	HILL ROM, INC.	ADVANCE 2000	THE ADVANCE 2000 BED
						
282095	06/12/2000	RESIDENT WEDGED THEMSELV BETWEEN TOP AND BOTTOM SIDE RAILS. RESIDENT WAS FOUND IN RESIDENT ROOM BETWEEN TOP AND BOTTOM SIDE RAILS WITH ARMS HOLDING PT ON BED AND FEET AND BOTTOM HALF OF BODY OFF BED. RESIDENT WAS UNRESPONSIVE AND CYANOTIC WHEN FOUND. FOUR HALF RAILS WERE UP AND RESIDENT TRIED TO GET OUT OF BED BETWEEN TOP HALF RAIL AND BOTTOM HALF RAIL.		SUNRISE MEDICAL, JOERNS-HAYER-PARKER	1401 SERIES	JOERNS
323188	03/28/2001	PT WAS FOUND WEDGED BETWEEN SIDE RAIL. CHEST WAS COMPROMISED AND PT WAS BLUE IN COLOR. PT PLACED BACK IN BED, SUCTIONED AND PT REGAINED COLOR. NO OTHER INFO COULD BE OBTAINED.	INFO RECEIVED FROM THE FIELD INVESTIGATION AND FUNCTIONAL INSPECTION OF THE UNIT CONDUCTED BY THE HILL-ROM TECHNICIAN, INDICATED THE UNIT WAS FUNCTIONING PROPERLY. THE FACILITY DID NOT REPORT A PRODUCT PROBLEM. CORRECTIVE ACTION: FACILITY PLACED SIDE RAIL PADS ON BED TO REDUCE THE OPENING IN THE SIDE RAILS.	HILL-ROM, INC.	837	HILL-ROM
						