Draft Guidance for Industry and FDA Staff

Hospital Bed System Dimensional Guidance to Reduce Entrapment

DRAFT GUIDANCE

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Preface

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Draft Guidance for Industry and FDA Staff

Hospital Bed System Dimensional Guidance to Reduce Entrapment

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This draft guidance provides recommendations for manufacturers of hospital beds[1] and hospital bed accessories. The guidance provides recommendations intended to reduce life-threatening entrapments associated with hospital bed systems. It characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, and recommends dimensional criteria for these devices. Manufacturers may use this guidance when designing new beds to help ensure compliance with applicable FDA regulations such as the Quality System Regulation[2] to assist in ensuring that their devices are safe when used as labeled and to assess current hospital bed systems[3]. In addition, this guidance may be used by healthcare facilities as part of a bed safety program to help identify entrapment risks that may exist with current hospital bed systems.

[1] The terms "medical bed" and "hospital bed" are used interchangeably. See discussion in Scope, page 4.

[2] Title 21, Code of Federal Regulations, Part 820 – Quality System regulation.

[3] FDA considers the term "hospital bed system" to encompass the bed frame and its components, including the mattress, bed side rails, head and foot board, and any accessories added to the bed.

FDA classifies hospital beds as Class I and Class II devices[4]. Regardless of the device class, FDA believes that manufacturers of hospital beds and bed accessories should consider the safety recommendations in this guidance.

Questions appear in certain sections in the draft guidance identifying areas where FDA is seeking comments on specific questions. FDA intends to consider public comments in addition to adverse event reports, information from the medical literature, discussions within the IEC 62D, Joint Working Group 4 on Medical Beds, and comments from health care practitioners as a means of making final recommendations. Comments in response to the specific questions will assist FDA in ensuring that its recommendations provide the most benefit to the public health.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

This draft guidance document reflects our careful review of what we believe are the relevant issues related to reducing hospital bed entrapment and what we believe would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

Background

For more than 19 years, there have been events reported[5,6] in which vulnerable patients[7,8] have become entrapped in hospital beds while undergoing care and treatment in health care

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[4] 21 CFR 880.5100, 880.5110, 880.5120. See also Table 1 for other devices considered "hospital beds" for the purpose of this guidance.

[5] Ferlo Todd J, Ruhl C, Gross T P, "Injury and Death Associated with Hospital Bed Side Rails: Reports to the U.S. Food and Drug Administration from 1985 to 1995." American Journal of Public Health 1997; 87:1675-1677.

[6] U.S. Food and Drug Administration. "A Guide to Bed Safety", <http://www.fda.gov/cdrh/beds/>

[7] U. S. Food and Drug Administration. FDA Safety Alert: Entrapment Hazards with Hospital Bed Side Rails (August 23, 1995), U.S. Department of Health and Human Services.

[8] "Vulnerable patients" is defined in "A Guide to Bed Safety," published by the Hospital Bed

facilities. The term entrapment describes an event in which a patient/resident is caught, trapped, or entangled in the space in or about the bed rail[9], mattress, or hospital bed frame. Entrapments have resulted in death or serious injury.

Approximately 575 entrapment reports have been received over a period of 19 years from January 1, 1985, to January 1, 2004[10]. In these reports, 358 people died, 111 were injured, and 106 were near-miss events with no injury, as a result of intervention. These entrapment events have occurred in openings between the bed rails, between the bed rail and mattress, under bed rails, between split rails, and between the bed rail and the head or foot boards. The population most vulnerable to entrapment are elderly patients and residents, especially those who are frail, confused, restless, or who have uncontrolled body movement. Entrapments have occurred in all patient care settings, including hospitals, nursing homes, and private homes.

In response to continued reports of patient entrapment, the FDA, in partnership with the U.S. Department of Veterans Affairs, Medical Devices Bureau/Health Canada and representatives from national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers, formed a working group in 1999 known as the Hospital Bed Safety Workgroup (HBSW). A list of HBSW participating organizations is found in Appendix A. The HBSW also worked in cooperation with the Joint Commission on Accreditation of Healthcare Organizations, the U.S. Centers for Medicare and Medicaid Services, and the U.S. Consumer Product Safety Commission to improve patient safety associated with the use of hospital beds.

Safety Workgroup as: Patients who have problems with memory, sleeping, incontinence, pain, uncontrolled body movement or who get out of bed and walk unsafely without assistance. These patients most often have been frail, elderly or confused.

[9] The term "bed rails" is used frequently throughout this document. Commonly used synonymous terms are side rails, bed side rails, and safety rails. Bed rails are rigid bars that are attached to the bed and are available in a variety of sizes and configurations from full to half, one-quarter, and one-eighth in lengths. A historical review can be found in "Braun & Capezuti, The Legal and Medial Aspects of Physical Restraints and Bed Side rails and Their Relationship to Falls and Fall-Related Injuries in Nursing Homes," DePaul Journal of Health Care Law, vol. 4, Fall 2000.

[10] Several limitations of the adverse event report data are acknowledged. First, many adverse events may not be reported to the FDA; thus the true number of adverse events may be unknown. Second, the number of reported events does not represent incident rates for a given problem in the absence of a defined denominator—the number of individuals at risk for a given adverse event. Finally, many reports lack a complete and detailed description of the adverse event or are not verified. Despite these limitations, adverse event reports can suggest a profile of the areas or locations on a hospital bed that presents a risk of entrapment, as well as the parts of the body at risk of entrapment.

The HBSW identified 7 potential entrapment zones (See Potential Zones of Entrapment, Page 11) in hospital beds based on the adverse events of entrapment reported to the FDA. The workgroup developed 1) evidence-based dimensional guidelines for hospital beds, 2) clinical practice guidelines to reduce the occurrence of patient entrapment, and 3) educational materials regarding entrapment associated with hospital beds. Consistent with 21 CFR 10.115(f), the HBSW submitted to FDA recommendations for dimensional criteria for consideration as an FDA guidance document. The FDA has considered these HBSW recommendations in preparing this guidance. Members of the HBSW are also developing procedures for measuring and assessing hospital bed systems and intend to make these available shortly.

Standards and Future Harmonization

The International Electrotechnical Commission (IEC) has promulgated an internationally recognized standard that applies to a certain segment of the products affected by this draft guidance, products labeled as "powered hospital beds." This standard is the IEC 60601-2-38, Amendment 1[11]. This current IEC standard recognizes that the bed frame, deck, and rails are the major elements involved in entrapment, but does not include the mattress as a contributor or mitigator. It also does not address safety issues associated with the use of non-electric hospital beds or the use of hospital beds in the home or in long-term care settings. The IEC standard is currently undergoing revision and will likely undergo significant change prior to its expected publication in 2006/2007.

Scope

The goal of the Hospital Bed System Dimensional Guidance to Reduce Entrapment is to reduce potential life-threatening entrapments associated with hospital bed systems.

The term "hospital bed" is used in this guidance to refer to a variety of medical devices that are classified as "beds." These devices are used for adult patients in acute care, long-term care, or home care settings. Because hospital bed systems primarily intended for one type of care setting can be moved into other care settings during the life of a bed system, beds used in all healthcare settings are included within the scope of this guidance. Additionally, the term "hospital bed system" is used throughout this document and is defined for the purposes of the guidance in footnote 3. Stretchers that are used for extended stay in health care facilities (because they are used like hospital beds) are also considered a hospital bed for purposes of this guidance.

This guidance provides recommendations related to devices in the following table. Class II devices are subject to design controls under the Quality Systems regulation (QS regulation). For those beds in class II, we recommend that manufacturers consider this guidance when

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[11] International Electrotechnical Commission standard IEC 60601-2-38, amendment 1, 1999 on Medical Electrical Equipment – Part 2-38: Particular Requirements for the Safety of Electrically-Operated Hospital Beds.

developing their design controls. Manufacturers of all devices listed in Table 1 below should consider the recommendations in this guidance to assist them in manufacturing hospital beds that will present a lower risk for patient entrapment.

Table 1

Product Code	CFR Section	Classification Name	Class	510(k) Exempt
FMR	880.6785	Manual patient transfer device	I	Yes
FNJ	880.5120	Manual adjustable hospital bed	I	Yes
FNK	880.5110	Hydraulic adjustable hospital bed	I	Yes
FNL	880.5100	AC-powered adjustable hospital bed	II	Yes
FPO	880.6910	Wheeled stretcher*	II	Yes
IKZ	890.5225	Powered patient rotation bed	II	Yes
ILK	890.5150	Powered patient transport*	II	No
INK	890.3690	Powered wheeled stretcher*	II	No
INY	890.5180	Manual patient rotation bed	I	Yes
IOQ	890.5170	Powered flotation therapy bed	II	Yes

*When labeled for extended-stay use

Likewise, this guidance provides recommendations related to the same devices listed in Table 1 that have been manufactured prior to this guidance. FDA does not intend to take enforcement actions that involve "corrections and removals" under 21 CFR Part 806 for actions taken in response to this guidance that correct or improve hospital beds currently in use or held as inventory. However, manufacturers should maintain records in accordance with 21 CFR Part 806 and implement adequate design controls to satisfy the Quality System Regulation (21 CFR section 820.30).

All hospital bed rails are included within the scope of this guidance. Bed rails (see footnote 9) are also called "side rails." Bed rails may be an integral part of the bed frame or they may be removable. Bed rails may consist of one full-length rail per side or one or more shorter rails per side. Bed rails may be a fixed height or adjustable in height and may move as the head or foot sections of the bed are raised or lowered. This movement of the bed is known as articulation. FDA recognizes that articulation of the bed introduces complex geometries that make applying the dimensional criteria to reduce entrapment difficult. Presently, the dimensional recommendations in this draft guidance apply to hospital beds in the flat deck position and rails in the fully raised position, except where noted.

Exclusions

The dimensional criteria described on pages 13 – 24 may not be applicable to a number of products. We are listing those products below; more detailed descriptions of these products can be found in 21 CFR Parts 880 and 890.

Total exclusion from the scope of this guidance:

- Air fluidized therapy beds are excluded because the nature of the therapy does not allow the patient to exit the bed easily. When these products are used, the therapeutic benefit is expected to outweigh the risk of entrapment.

- Bariatric (obesity) beds, pediatric beds and infant cribs are excluded because the population that uses these beds is different from the population that uses the beds included in the guidance and the anthropometric data for these groups were not used in determining the recommended dimensional limits of the entrapment zones.

- Stretchers not used for extended-stay, examination tables, operating room tables, radiology tables, proning tables, exercise and range of motion tables, bathing units, and mechanical lifting devices are excluded from the guidance because they are not used as hospital beds.

Partial Exclusion from the scope of this guidance:

- Kinetic treatment tables and rotation beds are excluded from the dimensional limits except for those within the perimeter of the rail due to the special design requirements of these beds. When these products are used, the therapeutic benefit is expected to outweigh the risk of entrapment.

- Labor, delivery, recovery, and postpartum (LDRP) specialty beds are excluded from the dimensional limits for the area between the top of the compressed mattress and the bottom of the rail at the ends of the rail because of the special design requirements of these beds for obstetric care.

- Pressure Reduction Therapeutic Products

  Framed flotation therapy beds, powered air mattress replacements, mattress overlays and similar pressure reduction products have therapeutic benefits such as reducing pressure on skin. These therapeutic air-filled beds, replacement mattresses, and overlays are easily compressed by the weight of a patient and may pose an additional risk of entrapment when used with conventional hospital bed systems. Entrapments have occurred with the use of framed flotation therapy beds, air mattress replacements, and overlays.[12, 13]

  - Framed flotation therapy beds (specialty air beds built into a hospital bed frame) and bed systems using powered air mattress replacements are excluded from all dimensional limits except for those within the perimeter of the rail. Additional caution should be taken when using these products to ensure a tight fit of the mattress to the bed system. When these mattresses compress, the space between the mattress and the bed rail may increase and pose an additional risk of entrapment. Thus, if a powered air mattress is replacing a mattress on a bed system that meets the recommendations in the guidance, the resulting bed system

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[12] Miles SH. Deaths between Bedrails and Air Pressure Mattresses. Journal of the American Geriatrics Society 2002; 50:1124-5

[13] Joint Commission on Accreditation of Healthcare Organizations, Issue 17 Sentinel Event Alert: *Bed Rail-Related Entrapment Deaths* (Sept. 6, 2002).

may pose a risk of entrapment. When these products are used, the therapeutic benefit is expected to outweigh the risk of entrapment. We encourage manufacturers to make new pressure reduction therapeutic products that meet all of the recommendations in this guidance.

NOTE: Bed systems using mattress overlays should comply with the dimensional guidance. The therapeutic benefit to the patient of a mattress overlay that has been applied to a noncompliant bed system should be assessed and should outweigh the risk of entrapment presented by use of such a system.

Request for Comments: 1. Exclusions.

Given the risks and benefits of using framed flotation therapy products and bed systems using powered air mattress replacements, should FDA reconsider these exclusions and recommend the application of dimensional limits for all entrapment areas to these products.

Background:

- Published information[12, 13] indicates that framed flotation therapy products, powered air mattress replacements, and mattress overlays can pose an entrapment risk for the vulnerable population.
- Some patients have died by suffocation or by becoming entrapped between air-filled mattresses and bed rails.
- However, these products provide high clinical benefit for patients needing pressure reduction surfaces.

Organization of this Guidance

This draft guidance:

- identifies key parts of the body at risk for entrapment.
- describes potential entrapment areas or zones.
- recommends maximum and minimum dimensional limits of gaps or openings in hospital bed systems.
- provides a scientific basis for the dimensional limits derived from a review of international anthropometric data, a review of historical entrapment data, and a retrospective study to verify the proposed dimensional limits.
- provides additional resources about hospital bed entrapment (Appendix E) and
- provides information for health care providers and health care facilities, including suggestions about what information to include when reporting entrapment adverse events (Appendix F).

Key Body Parts at Risk

Three key body parts at risk for life-threatening entrapment in hospital bed systems are the head, neck, and chest. International anthropometric data references were used to determine the relative sizes of these body parts for the vulnerable, at-risk population and to provide a guide for the dimensional limits that would reduce their entrapment. See Appendix B.

Head

To reduce the risk of head entrapment, openings in the bed system should be small enough to prevent passage of the widest part of the head (head breadth measured across the face from ear to ear). From country-specific anthropometric data, it is noted that people of small stature may have a 1st percentile female head breadth as small as 3 ¾ inches (95 mm). A dimension of 4 ¾ inches (120 mm) includes all 5th percentile female head breadth references and most 1st percentile international references. FDA is recommending less than 4 ¾ inches (120 mm) for the head breadth dimension for the population vulnerable to entrapment. This dimension is consistent with the dimensions used by the HBSW and the IEC.

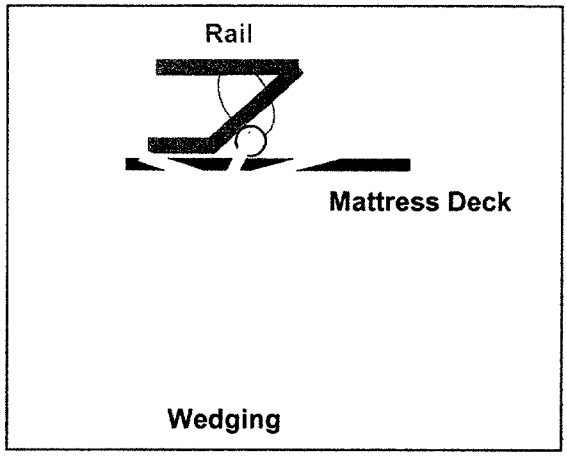
Neck

To reduce the risk of neck entrapment, openings in the bed system should be small enough to prevent passage of a small neck. The IEC recommends that the neck dimension for the purposes of a medical bed standard (IEC 60601-2-38-1) should be 2 1/3 inches (60 mm). Consistent with the IEC, the HBSW is using a dimension of less than 2 1/3 inches (60 mm) for neck diameter.

It is noted that people of small stature may have a 1st percentile female neck diameter of 3 1/8 inches (79 mm) [5th percentile = 3 1/4 inches (83 mm)]. Both IEC and HBSW recognize that several factors, such as neck compressibility[14], loss of muscle mass in the neck when patients age, and the asymmetrical shape of the neck, support a recommendation of less than 2 1/3 inches (60 mm) as an appropriate dimension for neck diameter in the population vulnerable for entrapment.

Based upon a published international standard for head and neck entrapment in swimming pool equipment, which identifies a critical angle of 60 degrees for neck

[14] One published estimate for neck compressibility is 25%. ASTM International. "Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures." Annual Book of ASTM Standards, Vol. 15.07, Appendix X2, Designation F 1004.



entrapment[15], the HBSW has recommended that V-shaped openings be greater than 60 degrees to avoid neck entrapment.

The concept of a wedging effect, which occurs when the neck is trapped in a V-shaped opening, recurs throughout many national and international entrapment-prevention standards (See Appendix C); however, the standards differ with respect to what is considered to be the critical angle for wedging. Some standards specify minimum angles to prevent neck entrapment based on a theoretical analysis of the forces on a cylindrical object (representing the cross-section of a neck) in an angled space. Depending on whether the wedging is considered to be caused by the total resultant forces on the neck or the horizontal components of the forces, the critical angles are identified as either 60 or 53 degrees (rounded up to 55), respectively. Other standards specify a 75 degree minimum angle.[13] The U.S. Consumer Product Safety Commission (CPSC) analyzed reports of entrapments in expandable baby gates and determined that many entrapments occurred in V-shaped openings with angles greater than the identified critical angles of 55 or 60 degrees. Based on reports of fatal and non-fatal entrapments that occurred in openings with angles ranging from 33 to 77 degrees, CPSC determined that expandable baby gates with openings with angles less than approximately 75 degrees present an entrapment risk to children.

Given the adult population at risk for wedging entrapments in hospital beds, and consistent with the HBSW, FDA is recommending a dimension of less than 2 1/3 inches (60 mm) to represent neck diameter, and a limit of greater than 60 degrees for V-shaped openings.

Chest

There have been reports of chest entrapment in hospital beds in the space between split rails. This space (See Potential Zones of Entrapment, page 11) is not included in the HBSW dimensions because entrapments in this space were thought to occur less frequently than at other areas. However, because FDA has reports of entrapment between split rails, a dimension for this space is included. The space should be wide enough to allow a large chest to slip through. A 95th percentile male chest depth is

[15] European Committee for Standardization. "Swimming Pool Equipment – Part 1: General Safety Requirements and Test Methods." Ref. No. EN 13451-1.

used to represent the largest chest measure[16]. The IEC is proposing to adopt a dimension for chest entrapment of greater than 12 ½ inches (318 mm). Consistent with IEC's proposal, FDA recommends a dimension of greater than 12 ½ inches (318 mm) to represent chest depth in the population vulnerable to entrapment.

The recommended dimensions for the three body parts at risk for entrapment are summarized in Table 2 below.

Table 2

Key Body Part Dimensions

Key Body Part	Dimension
Head	<4 ¾ inches (120 mm)
Neck	<2 1/3 inches (60 mm) and > a 60 degree angle
Chest	>12 ½ inches (318 mm)

[16] Although one would assume that the largest chest size belongs to women, breast tissue is compressible and diminishes in size as aging occurs. Male chests, however, have less compressible tissue and do not diminish as significantly in size with aging. A 95th percentile male chest depth of 12 ½ inches (318 mm), measured from the nipple to the back, including the pectoral muscles, is used to represent the largest chest measure. Using a measure of greater than 12 ½ inches (318 mm) adds an increased safety margin to the chest depth dimension.

Potential Zones of Entrapment

The HBSW identified seven zones in the hospital bed system where there is a potential for patient entrapment. Entrapment may occur in flat or articulated bed positions, with the rails fully raised or in intermediate positions. Descriptions of the seven entrapment zones appear on pages 13 – 24 in this guidance. Summary drawings of entrapment for all of the zones appear in Appendix D.

The seven areas in the bed system where there is a potential for entrapment are identified in the drawing below.

Zone 1: Within the Rail

Zone 2: Between the Top of the Compressed Mattress and the Bottom of the Rail, Between the Rail Supports

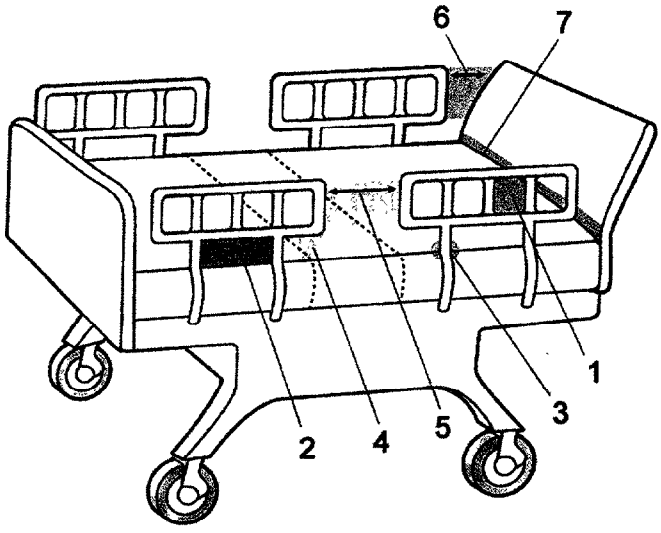
Zone 3: Between the Rail and the Mattress

Zone 4: Between the Top of the Compressed Mattress and the Bottom of the Rail, at the End of the Rail

Zone 5: Between the Split Bed Rails

Zone 6: Between the End of the Rail and the Side Edge of the Head or Foot Board

Zone 7: Between the Head or Foot Board and the Mattress End



Entrapment at the Bed Deck or Frame

Many of the entrapment event reports FDA received involved entrapment between the rail and the bed's "frame." It is unclear from the event descriptions whether this refers to the mattress deck or even the bed frame that supports the deck. While this guidance does not recommend dimensional limits on the space at the deck or frame locations, FDA believes that, if the other recommended dimensional limits are met, the possibility of entrapment at the deck or frame locations would be reduced.

A Retrospective Study of Entrapment Reports to FDA

In 2000, HBSW reviewed the mandatory and voluntary adverse event reports of patient entrapment in hospital beds that were sent to FDA by manufacturers, hospitals, nursing homes, and consumers. FDA's adverse event reporting system helps ensure product safety by monitoring products that are currently on the market. FDA's reporting system collects reports of adverse events[17] that caused or may have caused a death, a serious injury, or a malfunction. From January 1985 to March 2000, FDA received 390 entrapment event reports to its adverse events database. From these adverse event reports, HBSW identified entrapment areas or zones in the bed system and the body parts at risk. Based on its analysis of the reported adverse events, HBSW made recommendations for dimensional limits.

A retrospective study conducted by members of HBSW compared the HBSW recommended dimensions with dimensions of the bed models identified in the adverse events reports. For each of the entrapment adverse events in the study where the model number of the bed was reported, a participating bed manufacturer provided information on the dimensions of the identified area where an entrapment was believed to have occurred[18]. Four manufacturers provided this information. These data represented 215 (55%) of the 390 entrapment events. This information provided a reference range typical of hospital beds currently available for use in acute, long term care, and home settings.

The retrospective study compared the manufacturer-supplied information, in the aggregate, to the dimensions recommended by the HBSW. If the size of the openings in the reported bed models did not meet the HBSW recommended limits, i.e., the openings in the reported beds were outside the limits of the recommended gap sizes, then the HBSW dimensional limits were considered to be an appropriate limit to reduce entrapments at that area.

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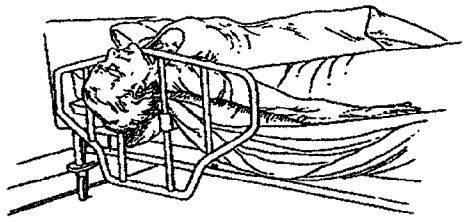
[17] Note: Many reports lack a complete and detailed description of the adverse event. The beds involved in these adverse events may not have had compatible mattresses or bed rails specifically designed for the particular bed model involved in the reported entrapment. Also, information was limited regarding the condition of the beds, bed rails, and mattress at the time of the entrapment. Specific details about the exact location of the entrapment within the beds were sometimes lacking. Despite these limitations, adverse event reports can suggest a profile of the areas or locations on a hospital bed where entrapment can occur, as well as the parts of the body at risk for entrapment.

[18] When manufacturers measured the gaps for the retrospective study, they used mattresses of the size, type and thickness typically recommended for use with their bed models. Mattresses involved in reporting entrapment events may have been different from the manufacturers recommended mattresses, which means actual gap sizes in entrapments involving the mattresses may have been different from those identified by the manufacturers in the retrospective study. The manufacturers' measurements may have been representative of "best case measurements." It is also noted that spaces in a hospital bed system may vary in size when the hospital bed system is articulated through the various ranges of motion. For the retrospective study, manufacturers measured gap sizes with the beds in the flat position. This means that if the bed was articulated in reported entrapments, the size of the gap may have been different from that provided by the manufacturers in the retrospective study.

Recommended Dimensional Limits for the Identified Entrapment Zones

Zone 1 - Within the Rail



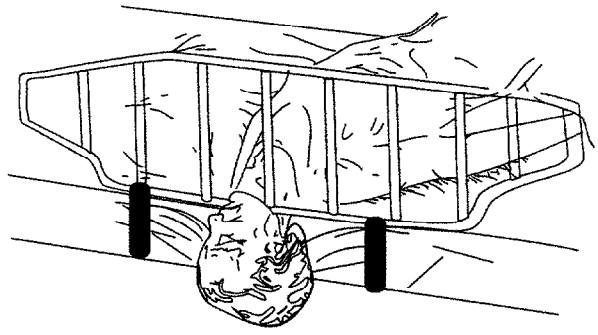
Zone 1 is any open space within the perimeter of the rail. Openings in the rail should be small enough to prevent the head from going through. This takes into account any degree of play from loosened bars or rails which could increase the size of the space. The HBSW and IEC recommend that the space be less than 4 ¾ inches (120 mm), representing head breadth.

Data from the Retrospective Study

Adverse events identified as occurring within the rail occurred in bed models with spacing greater than the recommendation of less than 4 ¾ inches (120 mm). Manufacturers' measurements of representative bed models identified in these incidents had spacing within the rail of between 6.97 inches (177 mm) and 7.48 inches (190 mm). Nearly all of these entrapment events may have been prevented if the spaces within the rails had been less than 4 ¾ inches (120 mm).

Consistent with HBSW's and the IEC's recommendations, FDA is recommending less than 4 ¾ inches (120 mm) as the dimensional limit for any open space within the perimeter of a rail.

Zone 2 – Between the Top of the Compressed Mattress and the Bottom of the Rail, Between Rail Supports



This space is the maximum gap that forms between a mattress compressed by the weight of a patient's head and the bottom edge of the rail, between the rail supports. This is a diagonal distance from the top of the compressed mattress to the bottom of the rail between rail supports. Factors to consider are the mattress compressibility, lateral shift of the mattress or rail, and any degree of play from loosened rails. This space may change as the head or foot sections of the bed are raised and lowered. The space may increase, decrease, become less accessible, or disappear entirely. Thus, in some positions, the potential for entrapment in this zone may still exist when the deck is articulated. (See question 7.) If there is only one rail support, entrapment in Zone 2 can occur anywhere along the bottom length of the rail beyond the support, up to the end of the rail. (Entrapment at the end of the rail is explained in Zone 4.)

It is thought that preventing the head from entering under the rail might prevent neck entrapment in this space. Therefore, HBSW recommends that this space should be small enough to prevent head entrapment, less than 4 ¾ inches (120 mm). Likewise, IEC recommends 4 ¾ inches (120 mm) however, the IEC dimensional limit applies to the area between the mattress support platform and the bottom edge of the rail, without the compressible mattress.

Data from the Retrospective Study

The diagonal measure between the lowest inside edge of the rail and the top edge of the compressed mattress between the rail supports ranged between 3 inches (76 mm) and 7.5 inches (191 mm). If the reported entrapments occurred at Zone 2, the data suggest that the HBSW recommended dimensional limit of less than 4 ¾ inches (120 mm) would have prevented only about half of the reported events between the top of the compressed mattress and the bottom edge of the lowest bar of the rail. However, given the scenarios in the reports, some of these events may have occurred at the rail end, beyond the support (Zone 4). Incidents reported as neck entrapment between the rail supports might have occurred when the head entered under the rail first.[18]

The adverse event report information for identification of Zones 2, 3, and 4 was at times not

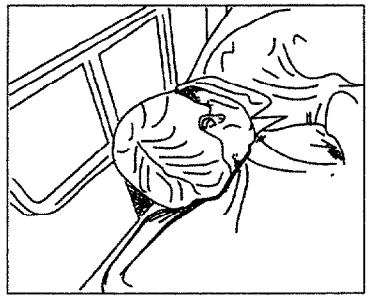
clear. It was difficult to determine the precise location of the entrapment, and to determine whether it occurred in Zone 2, 3, or 4. Most reports only stated that an entrapment occurred "between the rail and the mattress."

Request for Comments: 2. More stringent dimensional limit at Zone 2.

FDA considered both the HBSW and the IEC recommended dimension of less than 4 ¾ inches (120 mm) as a dimensional limit and at this time recommends a dimensional limit of less than 4 ¾ inches (120mm). FDA believes, however, that because of mattress compressibility and wear, an additional degree of protection may be needed to reduce entrapment at this zone. Therefore, FDA requests comments and data on whether it should modify its recommendation to recommend a dimensional limit of less than 2 1/3 inches (60 mm) because of the following factors.

- The retrospective study measurements in the flat deck position ranged between 3 inches (76 mm) and 7.5 inches (191 mm) [18].
- The retrospective data suggest that if the reported entrapments occurred at Zone 2, the HBSW recommended dimensional limit of less than 4 ¾ inches (120 mm) would have prevented only about half of the reported events at this zone.
- The IEC dimensional limit of less than 4 ¾ inches (120mm) is measured without a mattress and is not comparable to the same space with a mattress because of mattress compressibility.
- Mattresses that have been in use for a while may be more compressible because of wear than new mattresses.
- A restless patient may enlarge the space by compressing the mattress beyond the specified dimensional limit.
- The size of this zone may change with articulation of the head or foot sections of the bed. Patient care and patient rest does not occur in the flat deck position only.

Zone 3 – Between the Rail and the Mattress



This area is the distance between the inside surface of the rail and the top edge of the compressed mattress. The space should be small enough to prevent entrapment when taking into account the mattress compressibility, any lateral shift of the mattress or rail, and degree of play from loosened rails. This space may change as the head or foot sections of the bed are raised and lowered. The space may increase, decrease, become less accessible, or disappear entirely. Thus, in some positions, the potential for entrapment in this zone may still exist when the deck is articulated. HBSW and IEC recommend a dimension of less than 4 ¾ inches (120 mm) because it is believed the head enters the space before the neck.

Data from the Retrospective study

A review of the manufacturers' supplied measurements indicates that the horizontal gap between the rail and the mattress for bed models involved in entrapments believed to have occurred at Zone 3 was between 1 1/2 inches (38 mm) and 5 inches (127 mm). It could not be determined from the description of entrapment events whether entrapments occurred at Zones 2, 3 or 4. If the incidents identified as possibly occurring in Zones 2, 3 or 4 actually occurred in Zone 3, many of them still might have occurred despite the HBSW recommended dimensional limit for that Zone, greater than 4 ¾ inches (120mm).

Request for Comments: 3. More stringent dimensional limit at Zone 3.

Consistent with HBSW's and IEC's recommendation, FDA is recommending a dimensional limit of less than 4 ¾ inches (120 mm) for the area between the inside surface of the rail and the top edge of the compressed mattress. FDA requests comments and data, however, on whether it should modify its recommendation for this zone to recommend a dimensional limit of less than 2 1/3 inches (60 mm). See the following background.

- In the retrospective study, horizontal gap measurements ranged from 1.5 inches (38 mm) to 5 inches (127 mm).
- The mattresses used by the manufacturers for measuring the gaps in the retrospective study may have been different from those involved in the actual entrapments. This may be especially true for older beds which may have had their mattresses replaced over the years.
- If the incidents identified as possibly occurring in Zones 2, 3, or 4 actually occurred in Zone 3, many of them still might have occurred despite the HBSW recommended dimensional limit of greater than 4 ¾ inches (120mm) for Zone 3.
- This zone may change with articulation of the head or foot-sections of the bed. Patient care and patient rest does not occur in the flat deck position only.
- A restless patient may enlarge the space by compressing the mattress beyond the specified dimensional limit.

Zone 4 – Between the Top of the Compressed Mattress and the Bottom of the Rail, at the End of the Rail

This space is the maximum gap that forms between a mattress compressed by the patient's weight and the lowermost portion of the rail at the end of the rail. Factors that may increase the gap size are: mattress compressibility, lateral shift of the mattress or rail, and degree of play from loosened rails. The space created between the inside bottom edge of the end of the rail and the top of a compressed mattress poses a risk for entrapment of a patient's neck. This space may change as the head or foot sections of the bed are raised and lowered. The space may increase, decrease, become less accessible, or disappear entirely. Thus, in some positions, the potential for entrapment in this zone may still exist when the deck is articulated. (See Additional Request For Comments: 7. Articulated bed positions.)

At the time of this publication, the international standard being developed by the IEC recommends a dimensional limit of less than 2 1/3 inches (60 mm) measured between the mattress support platform and the lowest portion of the rail at the rail end to prevent neck entrapment. The HBSW recommends that the dimensional limit for this space also be less than 2 1/3 inches (60 mm); however, it is measured in the diagonal space between the top of the compressed mattress and the bottom of the rail at the end of the rail. Further, the HBSW recommends that the V-shaped opening under the rail at its end be of an angle wide enough (greater than 60 degrees) to prevent wedging entrapment (See Neck Section on pages 8 and 9 for a description and diagram of wedging entrapments).

Data from the Retrospective Study

The retrospective study measures for Zone 4 ranged between 4 inches (102 mm) and 6 inches (152 mm) for the diagonal measure between the inside bottom edge of the rail at the end of the rail and the top of the compressed mattress.

The diagonal measures in the retrospective study were greater than 2 1/3 inches (60 mm), therefore, the diagonal dimensional recommendation of less than 2 1/3 inches (60 mm), should reduce the number of incidents of neck entrapment at Zone 4.

Consistent with HBSW's recommendations, FDA is recommending a diagonal dimensional limit of less than 2 1/3 inches (60 mm) from the inside bottom edge of the rail at the end of the rail, to the top of a compressed mattress, and greater than a 60 degree angle at the end of the rail for Zone 4.

Zones 5-7

Although seven potential zones of entrapment have been identified, HBSW recommended dimensional limits for only Zones 1-4. Additionally, IEC intends to set dimensional limits for areas comparable to HBSW's zones 1-6 in IEC's proposed international standard for hospital beds. FDA, however, continues to receive entrapment reports for Zones 5 and 6. Because of this and other factors, FDA has considered the dimensional limits for Zones 5-7 that might reduce entrapment and addresses these below. FDA is requesting comments on the dimensional limits for each zone.

Zone 5 - Between the Split Bed Rails

This zone is created when partial length head and foot side rails (split rails) are used on the same side of the bed. The space at its narrowest point between the split rails should be either small enough to prevent neck entrapment, or large enough to prevent chest entrapment between the rails if a patient attempts to, or accidentally, exits the bed at this location. In addition, the V-shaped space between the rails should be large enough to prevent wedging of the neck.

To represent the key body parts at risk for entrapment between split rails, a female 5th percentile neck diameter of 2 1/3 inches (60 mm) and a male 95th percentile chest depth of 12 ½ inches (318 mm) were used. Based on these anthropometric data, the space between the rails should be either less than 2 1/3 inches (60 mm) or more than 12 ½ inches (318 mm) and of an angle greater than 60 degrees to reduce wedging of the neck (see wedging entrapment discussion, pages 8 and 9). These spaces may vary in size and angle when the hospital bed system is articulated through the various ranges of motion.

For the space between split bed rails, an opening of either less than 2 1/3 inches (60 mm) or greater than 12 ½ inches (318 mm) was discussed and acknowledged by HBSW and is being proposed by IEC.

Data from the Retrospective Study

For the bed models with split rails involved in neck or chest entrapment incidents, the manufacturers' measurements provided a range of minimum and maximum dimensions. A review of the manufacturers' supplied data for this zone, indicated that the gap sizes were between 3 inches (76 mm) and 22 inches (559 mm). It was found that, for 20 out of the 24

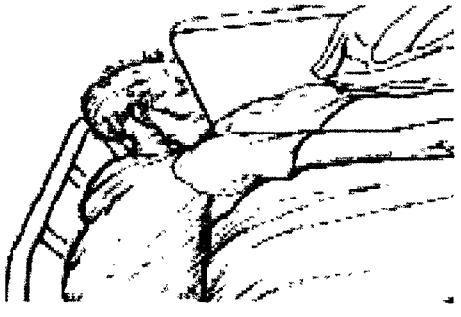
events involving entrapment between split bed rails, the range of the measurements provided by the manufacturers was between 2 1/3 inches (60 mm) and 12 ½ inches (318 mm). Therefore, these events might not have occurred had the bed rail measurements met the dimensional limits of either less than 2 1/3 inches (60 mm) or greater than 12 ½ inches (318 mm) for neck and chest entrapment.

Request for Comments: 4. Recommendation for a dimensional limit for Zone 5.

Even though entrapments in split rail configured beds can be eliminated by lowering the foot rail, the FDA believes that dimensional limits of either less than 2 1/3 inches (60 mm) or greater than 12 ½ inches (318 mm) and an angle of greater than 60 degrees in the V-shaped spaces between the rails, would reduce entrapments in this zone. Adding the recommendation regarding angles greater than 60 degrees to V-shaped spaces is believed to provide an additional margin of safety to reduce entrapment by wedging of the neck. (See wedging entrapment discussion, pages 8 and 9.) Thus, FDA is requesting comments and data on whether its final guidance should include the recommendation for Zone 5 of a dimensional limit of either less than 2 1/3 inches (60 mm) or greater than 12 ½ inches (318 mm) and an angle of greater than 60 degrees in the V-shaped spaces between the rails. Please see the following background.

- Split rails are the predominant rail configuration in many health care facilities.
- FDA continues to receive reports of entrapment in Zone 5.
- The foot rail is not always lowered during patient care.

Zone 6 – Between the End of the Rail and the Side Edge of the Head or Foot Board



Zone 6 is the space between the end of the rail and the side edge of the headboard or footboard. The space at its narrowest point should be small enough to prevent neck entrapment or large enough to prevent chest entrapment. In addition, the angle formed by the V-shaped space between the end of the rail and the head or footboard should be large enough to prevent wedging of the neck.

The IEC is proposing a dimensional limit of less than 2 1/3 inches (60 mm) between the end of the upper (head) side rail and the side edge of the headboard. Additionally, for the foot end, the IEC is proposing a dimensional limit of either less than 2 1/3 inches (60 mm), or greater than 12 ½ inches (318 mm) between the end of the lower (foot) side rail and the side edge of the footboard.

This space may change as the head or foot sections of the bed are raised and lowered. The space may increase, decrease, become less accessible, or disappear entirely. Thus, in some positions, the potential for entrapment in this zone may still exist when the deck is articulated. (See Additional Requests for Comments: 7. Articulated bed positions.)

Data from the Retrospective Study

The retrospective study data for the bed models involved in entrapment incidents at this zone, show the manufacturers' measurements ranged from 0.9 inches (22 mm) to 12 ½ inches (318 mm). Based on this data, nearly all of the incidents might not have occurred had the recommended dimensional limits for neck and chest entrapment been met for this zone.[19] Therefore, FDA believes that a dimensional limit of less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees between the end of the upper (head) side rail and the side edge of the headboard for Zone 6 would reduce entrapment. Additionally, FDA believes a dimensional limit at the foot end of either less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees, or greater than 12 ½ inches (318 mm), between the end of the lower (foot) side rail and the side edge of the footboard would reduce entrapment in this Zone. This dimensional limit is also consistent with IEC's proposal.

Request for Comments: 5. Recommendation for dimensional limits for Zone 6.

FDA requests comments and data on whether the final guidance should include the recommendation for zone 6 of a dimensional limit at the head end of less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees between the end of the upper (head) side rail and the side edge of the headboard. Further, FDA is requesting comments and data on whether it should include a dimensional limit at the foot end of either less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees or greater than 12 ½ inches (318 mm) between the end of the lower (foot) side rail and the side edge of the footboard. Please see the following background. (See pages 8 and 9, description of wedging entrapment.)

- FDA has reports of entrapment in Zone 6.

[19] Many of the reports of entrapment between the rail and the end board did not specify which end (head or foot) was involved. In those cases, manufacturers were asked to report the minimum and maximum gaps over both ends. Thus, the gap data may not relate directly to the entrapment location. For example, if the measured minimum gap distance occurred at the foot end, but the entrapment actually occurred at the head end, then the measured gap has no relation to the gap involved in the entrapment.

Zone 7 – Between the Head or Foot Board and the End of the Mattress

Zone 7 is the space between the inside surface of the head board or foot board and the end of the mattress. The space should be small enough to prevent head entrapment when taking into account the mattress compressibility, any shift of the mattress, and degree of play from loosened head or foot boards. According to anthropometric data sources identified to prevent head entrapment, a head breadth of 4 ¾ inches (120 mm) was identified. The bottom edge of the head or foot board should be below the compressed mattress surface to prevent entrapment under the head or foot board.

It is noted that the space between the head or foot board and the end of the mattress may change with head or foot elevation. A potential for entrapment in this area may exist whether the bed is in the flat position or when the deck is articulated. Thus, in some positions, the potential for entrapment in this zone may still exist when the deck is articulated. (See question 7). Even though there are no reports of entrapment at this zone, it was one of the original seven zones identified by the HBSW as posing a potential risk of head entrapment.

Data from the Retrospective Study

The adverse event report descriptions do not clearly identify entrapments as having occurred in zone 7. However, because of patient movement within the bed and the potential for large gaps in this space, this area may pose a risk of entrapment. There are no retrospective study data for comparison.

Request for Comments: 6. Recommendation for a dimensional limit for Zone 7.

FDA requests comments and data on whether its guidance should include a dimensional limit of less than 2 1/3 inches (60 mm) for this zone. Specifically, FDA is requesting data on entrapment reports or near-miss entrapment events that may have occurred in Zone 7, including any details on these events and their frequency. See the following background.

- The adverse event report descriptions do not clearly identify entrapments in Zone 7, but gaps can be created that may be large enough to entrap at this zone.
- Potential entrapments could also involve a compressible mattress that may further enlarge the size of the gap.

Additional Request for Comments: 7. Articulated bed positions

This guidance generally addresses entrapment in the flat deck position. FDA's adverse event reports of entrapment do not specify that entrapments are occurring only in a flat deck position. FDA believes that patient care occurs in many different deck positions. Some entrapment areas change in size when the bed is articulated and may pose additional entrapment risks. FDA is seeking comment on the need to apply these dimensional limits to articulated positions.

- **Are you aware of entrapment events or near-entrapment events occurring when the bed is articulated? Please provide information on these events and their frequency.**
- **Do you believe entrapments only occur in the flat deck position?**

Background:

- The sizes of the gaps in all zones except Zone 1 will change with articulation.
- Articulation of the bed deck can either increase or decrease the size of many gaps. This variance in gap size along with the variety of articulating positions results in a complex set of parameters that may affect the potential for entrapment.
- Entrapment events may have occurred at either flat or articulated positions.
- Patient care and patient rest do not occur solely in a flat deck position.

Additional Request for Comments: 8. Application of this guidance to all health care settings.

- **Is there a reason why this guidance document should not apply to hospital beds used in all care settings: acute care, long-term care, and at home?**

Background:

- Adverse event reports to FDA indicate entrapment has occurred in all care settings.
- Hospital bed systems primarily intended for use in one care setting may be moved into other care settings during the life of a bed system.

Table 3 below presents a summary of the retrospective study measurement ranges, the dimensional limits recommended by FDA based upon the recommendations of HBSW and the IEC, and alternative dimensional limits on which FDA is seeking public comment.

Table 3

	Retrospective Study Measurement Ranges		**Recommended Dimensional Limits**		**Alternative Dimensional Limits FDA is Seeking Comment On**	
Zone	Horizontal	Diagonal	Horizontal	Diagonal	Horizontal	Diagonal
1 Within the rail	111 mm - 191 mm		< 4 3/4 " (120 mm)			
2 Between rail supports	38 mm - 127 mm	76 - 191 mm		< 4 3/4 " (120 mm)		< 2 1/3" (60 mm)
3 Between rail and mattress	38 mm - 127 mm	76 mm – 191 mm	< 4 3/4 " (120 mm)		< 2 1/3 " (60 mm)	
4 At ends of the rail	76 mm - 102 mm	102 mm - 152 mm		< 2 1/3 " (60 mm) AND >60° angle*		
5 Between split rails	76 mm - 559 mm		Not Specified**		< 2 1/3 " (60 mm) and > 60° angle* **OR** >12 ½ " (318 mm)	
6 Between end of boards and rail	22 mm - 318 mm		Not Specified**		< 2 1/3 " (60 mm) and > 60° angle* **OR** >12 ½ " (318 mm)	
7 Between end of boards and mattress	Not Measured		Not Specified**		< 2 1/3 " (60 mm)	

*See footnote 15; **Discussed by HBSW but not specified (See Request for Comments for Zones 5, 6 and 7).

APPENDIX A
List of Hospital Bed Safety Workgroup (HBSW) Participating Organizations

- AARP
- American Association of Homes and Services for the Aging
- American Health Care Association
- American Medical Directors Association
- American Nurses Association
- American Society for Healthcare Risk Management/American Hospital Association
- Basic American Metal Products
- Beverly Enterprises, Inc.
- Care Providers of Minnesota
- Carroll Healthcare, Inc.
- ECRI
- Exceptional Parent Foundation For Education
- Evangelical Lutheran Good Samaritan Society
- Hard Manufacturing Co., Inc.
- HealthSafe Inc.
- Hill Rom, Inc.
- Huntleigh Healthcare
- Iona Senior Services
- Kinetic Concepts, Inc.
- Law Offices of Julie A. Braun
- Medical Devices Bureau, Health Canada
- M.C. Healthcare Products
- National Association for Home Care
- National Citizens Coalition for Nursing Home Reform
- National Patient Safety Foundation/American Medical Association
- Posey Company
- RN+ Systems / Tactilitics, Inc.
- Span-America Medical Systems, Inc.
- Stryker Medical
- Sunrise Medical, Inc.
- The ROHO Group, Inc.
- Untie the Elderly, The Kendal Corporation
- U.S. Department of Veterans Affairs
- U.S. Food and Drug Administration
- Vail Products Inc.

Consulting Organizations to the Hospital Bed Safety Workgroup

- Joint Commission on Accreditation of Healthcare Organizations
- U.S. Centers for Medicare & Medicaid Services
- U.S. Consumer Product Safety Commission

APPENDIX B
References

Anthropometric References used:

Hall, Judith. Handbook of normal physical measurements. New York : Oxford University Press, 1990.
[Note: Head width and neck circumference data for both sexes,-2SD (2.5th percentile), from birth to age 16. Data visually extrapolated from graphs.]

Jurgens, H., Pieper, U. International data on anthropometry. Geneva, Switzerland : International Labour Office, 1990. (Occupational safety and health series; no. 65).
[Note: Data was reviewed for following regions: North America, Latin America (Indian population), Latin America (European and Negroid population, Northern Europe, Central Europe, Eastern Europe, South-Eastern Europe, France, Iberian Peninsula, North Africa, West Africa, South-Eastern Africa, Near East, North India, South India, North Asia, South China, South-East Asia, Australia (European Population), Japan.]

Peebles, Laura, Norris, Beverly J. Adultdata - The handbook of adult anthropometric and strength measurements: data for design safety. London : Department of Trade and Industry, 1998.
[Note: Data is a collection of data from various sources for the following countries: UK, Brazil, France, Germany, Italy, Japan, Poland, Sri Lanka, Sweden, Netherlands, and USA; note that data was not available from ALL these countries for EACH measurement.]

Smith, Stuart, Norris, Beverly, Peebles, Laura. Older adultdata – The handbook of measurements and capabilities of the older adult: data for design safety. London : Department of Trade and Industry, 2000.
[Note: Data is a collection of data from various sources, for the following countries: UK, Brazil, France, Germany, Italy, Japan, Poland, Sri Lanka, Sweden, Netherlands, and USA; note that data was not available from ALL these countries for EACH measurement.]

Snyder, JRG. Anthropometry of infants, children and youths to age 18 for product safety design: final report. Bethesda, MD : Consumer Product Safety Commission, 1977.

Others references consulted:

Association for the Advancement of Medical Instrumentation. Human factors engineering guidelines and preferred practices for the design of medical devices. 2nd ed. Arlington, VA : Association for the Advancement of Medical Instrumentation, 1993 ; AAMI HE-48 1993.

British Standards Institution. 1987 Ergonomics – standards and guidelines for designers. United Kingdom : British Standards Institution, 1987 ; document no. PP 7317.

Damon, Albert, Stoudt, Howard W., McFarland, Ross A. The human body in equipment design. Cambridge, MA : Harvard University Press, 1966.

Diffrient, Niels. Humanscale one-two-three. Cambridge, MA : MIT Press, 1974.

Human engineering design data digest. Washington, DC : U.S. Government Printing Office, 1975.

National Center for Health Statistics. Weight, height, and selected body dimensions of adults, United States, 1960-62. Hyattsville, MD: National Center for Health Statistics, 1980; DHHS publication no. (PHS) 80-1301. Vital and health statistics; series 11, no. 8.

Salvendy, Gavriel, ed. Handbook of human factors. New York : John Wiley & Sons, 1987.

Woodson, Wesley E. Human factors design handbook : information and guidelines for the design of systems, facilities, equipment and products for human use. New York : McGraw-Hill Book Company, 1981.

Woodson, Wesley E., Conover, Donald W. Human engineering guide for equipment designers. 2nd ed. Berkeley, CA : University of California Press, 1970.

Woodson, Wesley E., Tillman, Peggy, Tillman, Barry. Human factors design handbook. 2nd ed. New York : McGraw-Hill Professional, 1992.

APPENDIX C
References for National and International Entrapment Standards

ASTM International. "Standard Consumer Safety Performance Specification for Playground Equipment for Public Use." Annual Book of ASTM Standards, Vol. 15.07, Designation F 1487.

ASTM International. "Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures." Annual Book of ASTM Standards, Vol. 15.07, Designation F 1004.

ASTM International. "Standard Consumer Safety Specification for Bunk Beds." Annual Book of ASTM Standards, Vol. 15.07, Designation F1427.

U.S. Department of the Army. "Child Development Center Play Area Inspection and Maintenance Program." Publication No. TM 5-663.
Public domain document available at www.army.mil

European Committee for Standardization. "Playground Equipment – Part 1: General Safety Requirements and Test Methods." Ref. No. EN 1176-1.
Adopted and published under various national designations by 28 member countries of CEN, including France, Great Britain, Germany, and Sweden.

European Committee for Standardization. "Swimming Pool Equipment – Part 1: General Safety Requirements and Test Methods." Ref. No. EN 13451-1.
Adopted and published under various national designations by 25 member countries of CEN, including France, Great Britain, Germany, and Sweden.

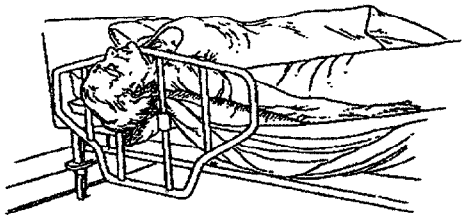
16 CFR Part 1213, "Safety Standard for Entrapment Hazards in Bunk Beds."

16 CFR Part 1513, "Requirements for Bunk Beds."

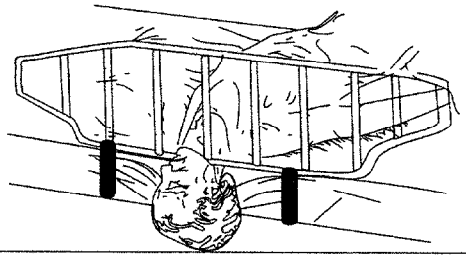
U.S. Consumer Product Safety Commission. "Handbook for Public Playground Safety." Publication No. 325.
Public domain document, available at www.cpsc.gov

APPENDIX D
Drawings of Potential Entrapment in Hospital Beds

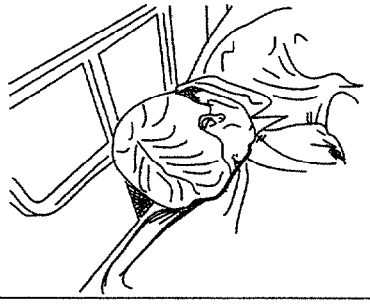
Zone 1 – Entrapment within the rail



Zone 2 – Entrapment between top of compressed mattress and the bottom of rail, between rail and supports

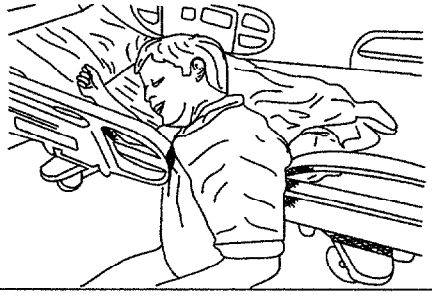


Zone 3 – Entrapment in the space between the bedrail and mattress



Zone 4 – Entrapment between top of compressed mattress and bottom of rail at end of rail

Zone 5 – Entrapment between split rails



Zone 6 – Entrapment between the rail end and edge of head/foot board

Zone 7 – Entrapment between head or foot board and mattress

APPENDIX E
Additional Information

Websites:

Food and Drug Administration:
http://www.fda.gov/cdrh/beds

Bureau of Medical Devices, Health Canada:
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_professionals_e.html

ECRI:
http://www.ecri.org/Patient_Information/Patient_Safety/BedSafetyClinicalGuidance.pdf

Untie the Elderly, Kendal Corporation:
http://www.ute.kendal.org

American Association of Homes and Services for the Aging:
http://www.aahsa.org

American Health Care Association:
http://www.ahca.org

Documents:

- *A Guide to Bed Safety* (a brochure) from the Hospital Bed Safety Workgroup
- *Clinical Guidance and Decision Tree For The Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities and Home Care Settings* from the Hospital Bed Safety Workgroup
- *A Guide for Modifying Bed Systems and the Use of Accessories to Reduce the Risk of Entrapment from the Hospital Bed Safety Workgroup*

Educational videotapes:

- An educational videotape, *Do No Harm – Hospital Bed Safety,* explaining hospital bed and bed rail safety issues produced by AARP.

APPENDIX F
Healthcare Facilities

This draft guidance provides recommendations for the hospital bed equipment industry to aid in the design of new bed systems. Industry, health care facilities and care givers may also use it as a guide to evaluate the potential entrapment risks associated with a healthcare facility's current and future hospital bed systems as part of a bed safety program. Members of the HBSW are developing procedures for the measurement and assessment of hospital bed systems.

The issue of hospital bed patient entrapment is complex. Reducing the risk of entrapment involves a multi-faceted approach that includes bed design, clinical assessment and monitoring, as well as meeting patient, resident, and family needs for vulnerable patients in all health care settings - hospitals, long term care facilities, and at home. Many beds now in use may no longer have the original mattress or bed rails, and thus, may present an entrapment hazard by increasing or creating gaps or spaces between components of the bed.

The HBSW developed three documents entitled:

- "A Guide to Bed Safety"
- "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings"
- "A Guide for Modifying Bed Systems and the Use of Accessories to Reduce the Risk of Entrapment" (to be finalized upon publication of this Guidance in final).

These publications are intended to help caregivers and health care providers assess the individual patient's needs, consider and address entrapment risks, and recommend mitigation strategies. Facilities are encouraged to consult the three HBSW documents identified to optimize bed safety in their facilities.

Every effort should be made to reduce the risk of patient entrapment in hospital bed systems. Like HBSW, the FDA believes the risk of entrapment can be reduced through the development of new hospital bed or rail design configurations and the assessment and modification of existing (legacy) hospital bed systems.

Healthcare facilities should check with their bed system manufacturers to ensure that their hospital beds, mattresses, rails, and accessories are compatible. Healthcare facilities are encouraged to contact their equipment suppliers for entrapment mitigating solutions that may already be available. When evaluating the safe use of a hospital bed, component or accessory, manufacturers and caregivers should recognize that the risk for entrapment may increase if a hospital bed system is used for purposes, or used in a care setting, not intended by the manufacturer.

Healthcare facilities should assess current hospital bed system combinations that are used in their facilities. Reassessment should be done 1) when there is reason to believe that some components are worn (e.g., rails wobble, rails have been damaged, mattresses are softer) and could cause increased spaces within the bed system, 2) when accessories such as mattress

overlays or positioning poles are added or removed, or 3) when components of the bed system are changed or replaced (e.g., new bed rails or mattresses).

The HBSW considered various aspects of the care environment in which hospital beds are used. The term "hospital bed" is used in this guidance to refer to a variety of medical devices which are classified as "beds" and used for adult patients primarily in acute care, long term care or home care settings. Because hospital bed systems primarily intended for one type of care setting can be moved into other care settings during the life of a bed system, beds used in all healthcare settings are included within the scope of this guidance.

FDA recognizes that this draft guidance document, when finalized, may be used by healthcare facilities, home health agencies and oversight entities for evaluating legacy equipment. Legacy equipment is defined as hospital bed systems currently in use and purchased prior to the effective date of this guidance. A risk-benefit analysis should also be conducted by healthcare providers to ensure that appropriate steps are taken to mitigate the risk of entrapment without creating different, unintended risks or reducing clinical benefits available to patients using legacy equipment. Refer to the additional three companion documents mentioned above.

Additional suggestions to reduce entrapment include:

- Entrapment between split rails can be eliminated by leaving the foot-end side rail in the down position or removing the foot-end rail.
- Add stuffers in gaps between the rail and mattress or between the head and foot board and mattress.
- Place the patient in a lower bed without rails and place mats on the floor.
- Use a mattress with raised sides.
- Use alarms for patients exiting the bed.
- The top of the compressed mattress should be above the bottom edge of the lowest rail and above the bottom of the head or foot board in all articulated bed positions and rail height settings.

In addition, when reporting past entrapment events, manufacturers and users often failed to report the events to regulatory agencies such as the FDA and Health Canada, as well as taking notes of details of the events. This results in events that are either not reported, or reports of events that are too vague. To improve the quality of entrapment adverse event reports, the following details are examples of important and helpful information that should be reported:

1. The exact location or zone of entrapment,
2. the body part that was entrapped, and if possible, the size of the entrapped body part (i.e., head breadth, neck diameter, chest depth),
3. the position of the rails (fully raised, intermediate, or lowered,
4. type of rails in use (full length, ¾ length, ½ length, split rails or ¼ length and the number of side rails raised a the time of the event,
5. the articulation of the bed deck (which sections of the deck were raised, and the approximate degree of elevation for each deck section),
6. mattress height and height of the rail from the top of the mattress and
7. information on the size of the gap which contributed to the entrapment.