

James Wells Associates / SleepSafe™ Beds
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

November 17, 2004

Reference: DOCKET NUMBER 2004-0343: The Draft Guidance for Industry and Food and Drug Administration Staff, from the document: Hospital Bed System Dimensional Guidance to Reduce Entrapment issued August 30, 2004.

Thank you for this opportunity to express my concerns regarding the proposed dimensional guidance program for hospital beds. Your consideration of the following comments is appreciated and I look forward to possibly discussing them with your committee(s).

COMMENT: WHY JUST TRY TO REDUCE ENTRAPMENT OCCURRENCES WHEN THEY CAN BE VIRTUALLY ELIMINATED BY PROVEN PROGRAMS AND EXISTING APPARATUS?

Brief background:

James Wells Associates (JWA) was providing ordinary bedroom furniture to New York State's Office of Mental Retardation and Developmental Disabilities (OMRDD) for several years. In the course of changing marketplaces, I became aware of the bed safety problems experienced within their system.

Twin and hospital beds being utilized within their facilities were found to cause injuries or even deaths due primarily to gaps between the sleeping surface and the bed system. These gaps are now being referred to as "Zones of Entrapment" within the sleeping environment.

My thinking was, and still is: If the current design(s) create "Zones of Entrapment", then a new design must be take into consideration these "Zones" and provide a safe sleeping environment for the users.

™ Patent Number 6,453,491 B1

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Action taken:

With research, cooperation, and field studies, a bed system that addresses these "Zones of Entrapment" was developed. The objective of the design was to virtually eliminate those "Zones of Entrapment" as identified by the Hospital Bed Safety Workgroup (HBSW).

*Utilizing New York State's strict guidelines as a foundation for the design, the first prototype **SleepSafe™** Bed was presented for field study to New York State in March 2001. More research and field studies were exercised from the "front line" providers / caregivers and modifications were made accordingly.*

Result:

*A **safe sleeping environment** and a **user friendly** apparatus were perfected. A Patent on the design was received in September 2002 as well as a three-year contract with New York State's OMRDD.*

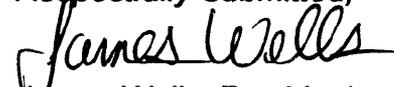
Conclusion:

*The **SleepSafe™** Bed system meets or exceeds any established guidelines presented by either the FDA or New York State thus far. (Please refer to Exhibit One, enclosed.) Zones of Entrapment occurrences have been virtually eliminated.*

Over the last three years, approximately 500 beds have been indoctrinated into various facilities and homes, and not one entrapment incident has been reported.

*Again, thank you for this opportunity to voice my concerns as well as present the **SleepSafe™** Bed system to you. Please feel free to contact me with questions or comments. For more information, please visit JWA's web site: www.jwasleepsafe.com.*

Respectfully Submitted,



James Wells, President
Enclosures



Jim Wells

™ Patent Number 6,453,491 B1

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Summary of Zones of Entrapment Dimensions as Recognized by the F.D.A. versus SleepSafe Beds' Dimensioning

EXHIBIT ONE:

EXHIBIT ONE:		FDA Standards	New York State Standards	SleepSafe™ Actuals
Zone 1	Within the Rail	4 3/4"	2 1/3"	Zero"
Zone 2	Between the Top of the Compressed Mattress and the Bottom of the Rail Between Rail Supports: see below *	4 3/4"	Zero"	Zero " See Zone 3 and "Zone B" NO Lateral Play in Guard Rail.
Zone 3	Between the Rail and the Mattress	4 3/4"	Open hand Approx. 3/4"	Width of Open Hand, Approx 3/4" NO Lateral Play in Guard Rail!
Zone 4	Between the Top of the Compressed Mattress and the Bottom of the Rail at the End of the Rail: see below *	2 1/3"	Does not recognize this Zone	Zero " See Zone 3 and "Zone B" NO Lateral Play in Guard Rail.
Zone 5	Between the Split Bed Rails	2 1/3" – 12 1/2"	2 13" – 10"	Zero" / Not Applicable
Zone 6	Between the End of the Rail and the Side Edge of the Head or Foot Board	Head: 2 1/3" Foot: 12."	Head: 2 1/3" Foot: 10"	Head: 3/4" Foot: 3/4"
Zone 7	Between the Head or Foot Board and the End of the Mattress	4 3/4"	Open Hand Approx. 3/4"	Zero" or Tight Fit

DRAFT GUIDANCE for INDUSTRY and FDA STAFF:

"Zone A"	Between Sleeping Surface and Bottom of Head or Foot Board	Not Specified	NS	> 8" Overlap
"Zone B"	* Between FLAT Sleeping Surface and Bottom of Guard Rail	NS	NS	4" Overlap

ALL THE ABOVE ARE IDENTIFIED WITH DOCKET NUMBER 2004-0343.

SleepSafe®

Virtually eliminate the Zones of Entrapment as identified by Hospital Bed Safety Workgroup: Why just try to reduce the risk of entrapment?

These beds have been designed with input from professionals in the health / daycare field and from actual use of prototype beds, utilizing New York State's stringent bed safety standards as a guideline in development.

JWA CONTRACT FURNITURE

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A solution to safety bed rail and gap citations

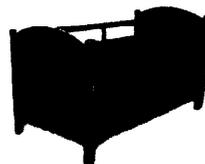
The SleepSafe®

Revolutionary Adaptive Bed Meets or Exceeds Safety Standards with Classic Style!



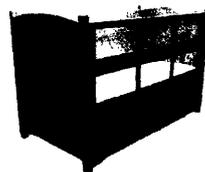
The SleepSafe II® & SleepSafe II Plus®

Our SleepSafe II® Bed combines the mattress adjustability of our SleepSafeR® Bed with the design of our SleepSafe® Bed. The SleepSafe II® is an attractive alternative to a hospital bed. (See back page)



The SleepSafeR®

The SleepSafeR® was designed for very active customers or those with the ability to pull themselves over conventional 8" high tubular rails. Tailgate-type guardrails make for easy access/egress. Adjustable sleeping surface to top-of-guardrail distance makes for a customized, safe sleeping environment.



The SleepSafe Plus®

The SleepSafe Plus® Bed Offers Full Articulation, Easy Patient Access and Side Rail Safety Features! The SleepSafe Plus® is perfect for adult home or home care environments. Offering twin or full size bed frames, the SleepSafePlus® offers an attractive alternative to a traditional hospital bed. Non-articulating version available. (See back page)

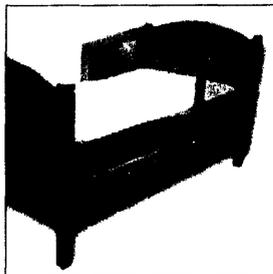
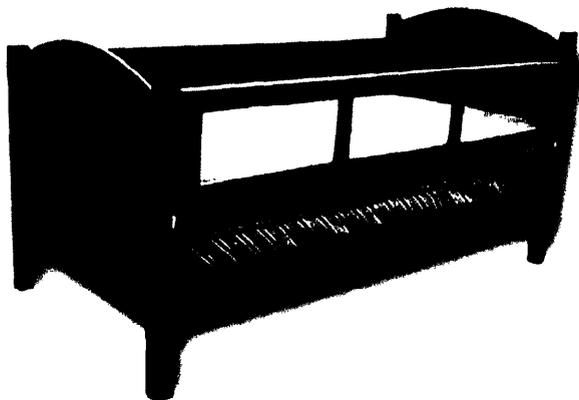


Non-restraining partial guardrails available for nursing home applications on most beds.

Visit us on the web at www.jwasleepsafe.com

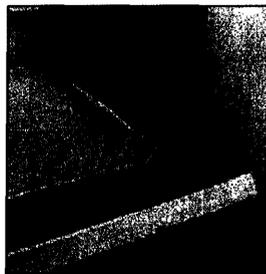
NYS - OMRDD PA# 03073 • PATENT: 6,453,491 B1

SleepSafe®



Partial Safety Rail Option

**NON-RESTRAINING
PARTIAL RAILS FOR
NURSING HOME
APPLICATIONS**



**Adaptive Side Safety Rails
SleepSafe®'s design is
unique to the industry!**

*Put rails up when you need
to protect the patient. The
clear window reduces
claustrophobia. Take them
down or off as you please.*



* 8" Twin or Full Size Mattresses and 8" Box Springs need to be purchased separately.

**The SleepSafePlus® Bed
Safety Rail Options:**

- A. 2 Full Length Safety Rails
- B. 2 Partial Length Safety Rails
for Nursing Home use

Locking Rails Positive locking safety rails insure the patient's well-being. All hardware is adjustable for easy maintenance.

- Standard 75" Twin
- Extra Long 80" Twin
- Full Size Available
- Sleeping surface to top of rail is 11 inches.

**ON NYS
OMRDD CONTRACT
PA 03073**

*** VIRTUALLY ELIMINATES THE**
A solution to safety be

The Benefits of all :

*** NO LARGE GAPS!**



Only a 1/4" gap between the mattress and the SleepSafe® Beds' interior sides to virtually eliminate the chance of having an appendage caught or entrapped between the sleeping surface and the bed itself.

• LOCKING RAILS

Positive locking safety rails insure the consumer's well being. All hardware is adjustable for easy maintenance.

• USER FRIENDLY!

All of the SleepSafe® Beds are very easy to use by all providers and caregivers. They are easy to maintain, too!

• NYS SAFETY STANDARDS

Compare these beds with the New York State Safety standards at www.jwasleepsafe.com and click "COMPARE" on the home page for those standards.

• OPTIONS for MOST Models

- Twin or Full-Size widths available.
- 80-inch lengths are available.
- Pads for Guardrails.
- Pressure reducing mattresses are available.

• Full or Partial Length Safety Rail

Features! Choose either full length safety rails or partial length safety rails! The full-length rails swing down. The partial side rails swing open for easy bed access for caregivers and users. Either rail option is removable.

E ZONES OF ENTRAPMENT * d rail and gap citations

SleepSafe® Models

• CAREGIVERS

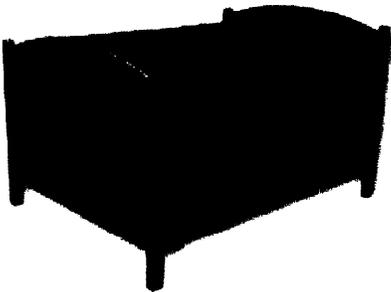
Caregivers have full view for easy monitoring. The bed's user can see their environment, reducing the chance of claustrophobia, and encouraging a comfortable rest.

* REDUCES RISK

Reduces the risk of a user's appendage becoming entrapped. The headboard and footboard extend below the mattress, reducing the chance of entrapment.

• ADAPTIVE GUARDRAILS

Adaptive full-length guardrails or partial length guardrails combine the strength solid wood with clear, acrylic panels that exceed bed safety standards.

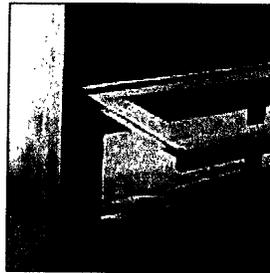
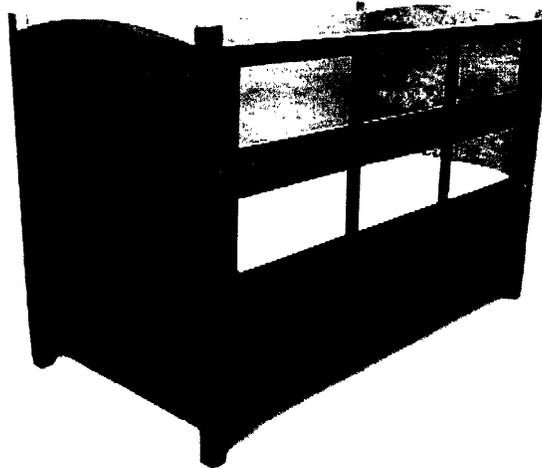


SleepSafe II shown with pads

www.jwasleepsafe.com

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SleepSafe®



Adaptive Side Safety Rails

Like the SleepSafe®, the SleepSafeR®'s design is unique to the industry and offers even more safety! Put one or two rails up when you need to protect the patient. The clear acrylic panels allow you to see in and the user to see out!

• Adjustable Mattress Height!

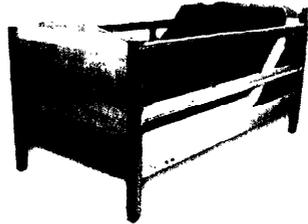
The distance from the top of the mattress to the top of the rail can be adjusted incrementally to 24," 27," or 30." 36" can be achieved if a plywood bedboard is used instead of box springs.

• **Adaptive, full-length, double tier, safety rails** combine the strength of solid wood with clear, acrylic panels.



Also available as a *Plus Model*
with adjustable mattress height of 24" or 28".

SleepSafe Plus®



New SleepSafe Plus® Bed Offers Full Articulation, Easy Patient Access and Side Rail Safety Features!

Non-Restraining Partial Rails for Nursing Home Applications

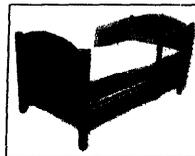
- The SleepSafe® Bed plus full articulation! The SleepSafePlus® does it all. It keeps the user safe during rest and electrically adjusts smoothly for user comfort and caregiver ease of use.

- Adaptive full-length side safety rails, or partial length side safety rails, combine the strength of solid wood with clear, acrylic panels and exceed bed safety standards.

- Sleeping surface to top of rail is 11 inches.

The SleepSafePlus® Bed Safety Rail Options:

- A. 2 Full Length Safety Rails
- B. 2 Partial Length Safety Rails for Nursing Home use



Full or Partial Length Safety Rail Features!

Choose either full length safety rails or partial length safety rails! The full-length rails swing down. The partial side rails swing open for easy bed access for caregivers and users. Either rail option is removable.



Full Articulation Remote Control

Simply adjust SleepSafePlus® Bed's articulation with handy remote control unit. Great for the caregiver, as well as the user!

Shipping & Handling: All SleepSafe Plus® Beds cannot be shipped FedEx and will incur additional shipping and handling fees.

SleepSafe II® & SleepSafe II Plus®

Adjustable Mattress Height!

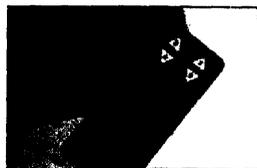
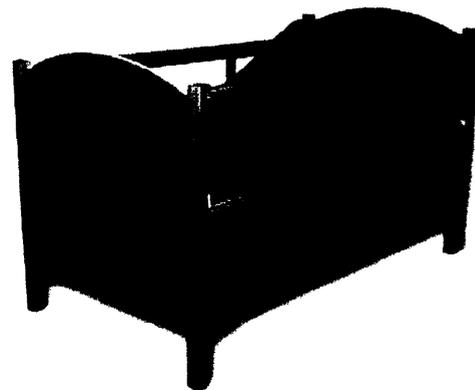
The distance from the top of the mattress to the top of the rail can be adjusted incrementally to 10," 13," or 16" on the SleepSafe® II bed and 10" or 14" on the SleepSafe® II Plus.

- The SleepSafe® II has full articulation! The SleepSafe® II Plus does it all. It keeps the user safe during rest and electrically adjusts smoothly for user comfort and caregiver ease of use.

- The user can see their environment, reducing the chance of claustrophobia as well as providing a more comfortable and safe rest.

The SleepSafe® II Beds Safety Rail Options:

- A. 2 Full Length Safety Rails
- B. 2 Partial Length Safety Rails for nursing home use
- C. 1 Partial Length and 1 Full Length Safety Rail



Full Articulation Remote Control *Simply adjust the SleepSafe® II Plus articulation with handy remote control unit. Great for the caregiver, as well as the user!*