



## Training Guide



*SleepSafer® - Tall Bed with one safety rail fastened above and one safety rail rotated down.  
(Shown with optional flip open safety rails.)*

*SleepSafe II® - Medium Bed with Padding, IV Pole and Medical Tubing Access Cut-out.*

U.S. Pat. No. 7,681,260



## How to Use this Guide

### Introduction

This User's Guide is intended for professionals providing care to patients in the SleepSafe® Bed who have successfully completed the SleepSafe® Bed In-Service Training Program.

In addition to this manual, you should also review:

- The Assembly Instructions for prescribed SleepSafe® Bed product.
- Any relative information available at SleepSafeBed.com

### Definitions

The following words have special meaning when used in this Guide:

**Entrapment** – an event in which a patient is caught, trapped, or entangled in a confined space. This can result in serious injury or death from suffocation, compressions, or lack of proper blood flow.

**Transfer Height** is an important measurement when specifying a SleepSafe® Bed for a client. Refers to the distance from the top edge of the folded down safety rail to the floor.

**Safety Rail Height** is another key measurement. It refers to the distance from the top of the mattress to the top of the safety rail. Typically, the more active the user, the more safety rail height is needed.

### Need help?

If you need help or have any additional questions, please call SleepSafe® Beds' Customer Support toll-free at 1.866.852.2337. between 8:00 am EST, and 5:00 pm EST. You may also contact an authorized DME provider.



## Welcome to SleepSafe® Beds

### Introduction

The SleepSafe® Bed is a safety bed, with removable side safety rails, and a mattress system designed to help provide a safe, controlled environment for users at extreme risk of injury from a fall or unassisted bed exit.

SleepSafe® Beds are considered *Durable Medical Equipment* and are a proven, safe solution to address the problems with entrapment and falls. The beds meet or exceed FDA guidelines on the *7 Zones of Entrapment*.

### Prescriptions Only and Recommended Training

The use of a SleepSafe® Bed should be prescribed by a licensed physician. Anyone interacting with the bed are recommended to complete the SleepSafe® Bed In-Service Training Program which includes proficiency in the use of this guide.

### Benefits

The SleepSafe® Bed was designed to help provide these benefits:

- A controlled user environment
- Reduce the risk of user falls from bed.
- Reduce the risk of user being entrapped between the mattress and the side rails or between the mattress, headboard and footboard.
- Provides user with features deemed necessary for *medical necessity* for those with physical and cognitive disabilities.
- Each bed is customized and manufactured to address the user's specific medical necessities.

### Risks

Improper use of the SleepSafe® Bed may lead to injury. Monitoring of the user should be established by the user's care plan.

As with any bed safety system, it is important to be familiar with the indications for use, the contraindications for use and in particular, risks associated with entrapment, suffocation, choking, and falls.

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## About the SleepSafe® Bed

### Indications for Use

The SleepSafe® Bed is a safety bed designed to provide a safe, controlled, medically suitable environment for users at high risk of injury from falls and entrapment.

The SleepSafe® Bed is a less restrictive alternative to physical restraints such as belts, vests, or jackets.

### Bed Use

The bed must be used in accordance with:

- All state regulations
- Federal Center for Medicare & Medicaid Services (CMS) Regulations
- The user's care medical and therapy plan
- The policies of the user's facility, if applicable.

### Users Who May Benefit

Users who may benefit from the use of the SleepSafe® Bed include those who are at extreme risk for a fall and/or entrapment including those with:

- Physical and cognitive disabilities,
- Risk of fractures due to congenital medical conditions,
- Insufficient muscle, fat, and tissue to absorb the impact of a fall,
- A history of trauma in a prior fall,
- Conditions that cause uncontrollable movement and seizures such as Rett Syndrome, Cerebral Palsy, Muscular Dystrophy , Angelman Syndrome and Autism Spectrum Disorders.
- Conditions where bed articulation relieves medical disorders such as Cystic Fibrosis and Congenital Diaphragmatic Hernias (CDH), as well as those conditions associated with respiratory, digestive or circulatory challenges.

### Clinical Conditions

Certain users at-risk for a serious injury from a fall may also benefit from the use of the SleepSafe® Bed.

- Musculoskeletal problems that cause an unsteady gait or impaired strength or biomechanics,
- Altered awareness due to medication or neural illnesses or conditions that impair alertness and balance, and/or dementing illnesses,
- Visual or peripheral neuropathies that impair positional sense.

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## Contraindications

### When Not to Use this Bed

Given the nature of some users' diagnoses, activity level, or uncontrolled movements, the SleepSafe® Bed is not suitable for every patient.

The SleepSafe® Bed is not intended for use with:

- Users who weigh 350 pounds or more.
  - This is the working load capacity of the bed's mattress.
- Users diagnosed with any condition that may cause violent or self-destructive behaviors.
  - These could result in self-injury.
- Users with an excessive Pica eating disorder.
  - This refers to a person who may attempt to eat the padding or mattress of the SleepSafe® Bed.
  - Patients who suffer from this disorder include children who are developmentally disabled.
- Benefits associated with the caregiver.
- Non-medical conditions such as behavior disorders.
- Users who are claustrophobic while in the SleepSafe® Bed.

### Possible Adverse Reactions

Although it is a safe sleeping environment, use of the SleepSafe® Bed could cause emotional, psychological, or physical problems in certain patients.

These include:

- A change in mental status, such as claustrophobia or depression,
- Sudden mood changes which lead to a change in medical conditions,
- An increase in aggression or self-destructive behaviors.

Get help from the physician or therapist if these symptoms appear and do not improve as the patient becomes used to the SleepSafe® Bed . You may need to find a different method of treatment.

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## A Special Note

### Background

All hospital beds pose safety and entrapment risks. The U.S. Food and Drug Administration (FDA) received approximately 803 entrapment reports in the U.S. for standard hospital beds over a period of 24 years from January 1, 1985 to January 1, 2009.

The FDA formed the Hospital Bed Safety Workgroup (HBSW) to develop solutions to reduce the risk of patient entrapment in hospital beds. The HBSW issued guidelines in 2006 describing seven potential zones of entrapment and recommendations to reduce life-threatening entrapments associated with hospital bed systems.

The SleepSafe® Bed meets or exceeds FDA guidelines for the *7 Zones of Entrapment*, when the head of the bed is down and the mattress is flat.

### At-Risk Users

- Users who, because of mental or physical disability, cannot reposition or remove himself or herself from a confined area in the bed.
- Any other user identified by the physician, therapist, the care plan, or Interdisciplinary Healthcare Team

### Reducing the Risk of Entrapment

To help reduce the risk of entrapment, do the following:

- Keep the mattress flat while user is sleeping.
  - If you need to elevate the head or torso of an at-risk user, keep the mattress flat and use a cushion to position the user.
  - If you must leave the head of the bed up while an at-risk user is unattended, we recommend using positioning cushions.
- Provide extra monitoring.
  - Monitor user to ensure that the cushions cannot be removed by an at-risk user and that an at-risk user cannot crawl under or around the cushions.

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