

Protecting Patient Safety:

Bed Entrapment Compliance Overview

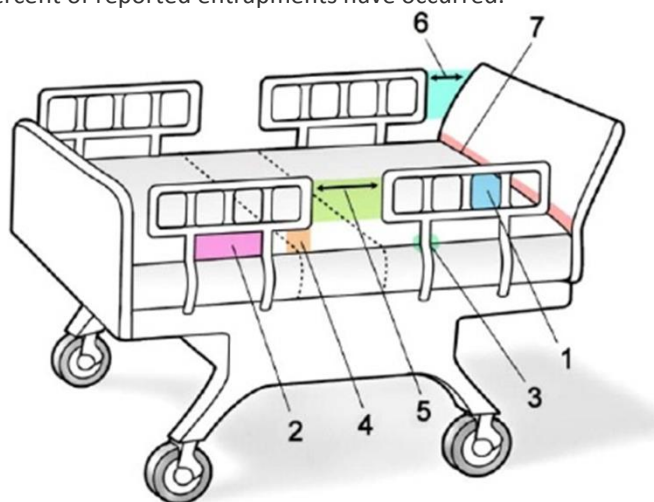


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Background: FDA/HBSW Guidance on Entrapment Risk

"Entrapment" describes an event in which a patient/resident is caught, trapped, or entangled in the space in or about the bed rail, mattress, or hospital bed frame and may result in deaths or serious injury. In partnership with the US Dept. of Veterans Affairs, Health Canada's Medical Devices Bureau, and other stakeholders, in 1999 the US Food and Drug Administration (FDA) formed the Hospital Bed Safety Workgroup (HBSW). 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.

The HBSW identified seven potential entrapment zones in healthcare beds, and established dimensional guidelines for Zones 1-4 where 80 percent of reported entrapments have occurred.



- **Zone 1: Within the rail**
FDA dimensional guidance: <120 mm (< 4 3/4 ")
- **Zone 2: Under the rail, between rail supports or next to a single rail support**
FDA dimensional guidance: < 120 mm (< 4 3/4 ")
- **Zone 3: Between rail and mattress**
FDA dimensional guidance: <120 mm (< 4 3/4 ")
- **Zone 4: Under the Rail, at the Ends of the Rail**
FDA dimensional guidance: less than 60 mm (< 2 3/8 inches).
- **Zone 5: Between 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**

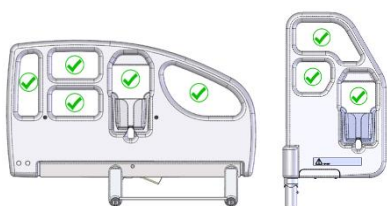
The HBSW also developed educational materials, clinical practice guidelines, evidence-based dimensional guidelines, test tools and methods to assess gaps in hospital bed systems, as well as information to assist in mitigating entrapment risks in currently used healthcare beds.

The HBSW's expertise assisted FDA in producing ***Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff***, which was originally published in 2006. Span-America urges all healthcare facilities to read and become familiar with this guidance document. The FDA also provides many resources designed to help facilities maintain compliance by routinely evaluating the safety of its beds, support surfaces and related accessories [see "additional resources", page 4.] These resources include ordering instructions for the approved Testing Kit that facilities can use to maintain compliance with the FDA dimensional guidelines.

Bed entrapment compliance when combining beds, surfaces and bed accessories from Span.

At time of shipping, all Geo-Mattress® therapeutic mattress firm perimeter models [see partial list below] are documented to meet Hospital Bed Safety Workgroup (HBSW) dimensional guidelines as published in the FDA's ***Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*** and Health Canada's guidance document ***Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards*** when used in conjunction with appropriately-sized MC REXX, Advantage and Encore® beds, assist devices, rails, head and footboards [Standard, Essex, Lincoln, Lethbridge, Pembroke, Trenton and Princeton models] and related components from Span Medical Products Canada/Span-America Medical Systems.

Examples of common Span bed /surface/rail combinations that ensure compliance with FDA dimensional guidelines:



Zone 1: Within the rail:

Pictured— molded 3-position pivot assist; molded half-rail.

All openings are within dimensional guidance.



Zone 2: Under the rail, between rail supports or next to a single rail support

Pictured—Surface: Geo-Mattress® Plus FP; Bed: REXX



Zone 3: Between rail and mattress

Pictured—Surface: Geo-Mattress® UltraMax®; Bed: Encore



Zone 4: Under the Rail, at the Ends of the Rail

Pictured—Surface: Geo-Mattress® Max; Bed: Advantage

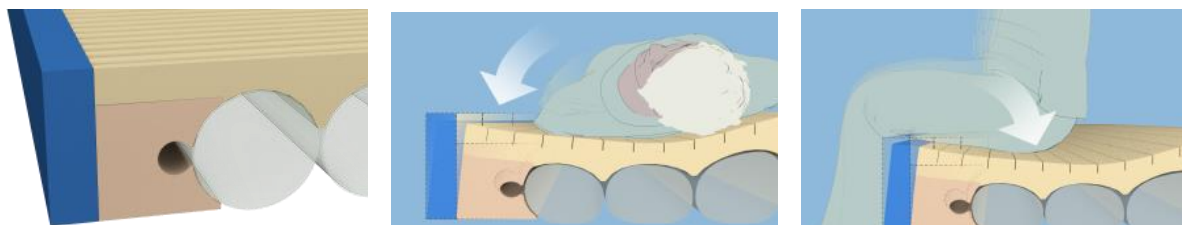
Entrapment compliant Geo-Mattress® series models include the following:

<u>Pro Models</u>	<u>Plus models</u>	<u>Max Models</u>	<u>UltraMax Models</u>
PR7635FP-29	PL7635FP-29	MX7535-29	UMX7536-29
PR8035FP-29	PL8035FP-29	MX8035-29	UMX8035-29
PR8435FP-29	PL8435FP-29	MX8435-29	UMX8436-29
PR7639FP-29	PL7639FP-29	MX7639-29	UMX7639-29
PR7642FP-29	PL7642FP-29	MX7642-29	UMX7642-29
PR8039FP-29	PL8039FP-29	MX8039-29	UMX8039-29
PR8042FP-29	PL8042FP-29	MX8042-29	UMX8042-29
PR8439FP-29	PL8439FP-29	MX8439-29	UMX8439-29
PR8442FP-29	PL8442FP-29	MX8442-29	UMX8442-29

Note: This list is not exhaustive. For example “RP” (Raised Perimeter) models such as PL8035RP-29, PR8035RP, etc. also meet dimensional requirements, as do many other models not specifically listed here. Your Span sales representative can assist you with questions about a particular model number.

Air therapy surfaces and bed entrapment risk

The FDA guidance excludes air therapy surfaces from the dimensional guidance “due to the highly compressible nature of these mattresses, which poses technical difficulties with measuring certain dimensional gaps in these types of products.” The document does however recognize the potential entrapment dangers of typical roll-up style air mattresses, warning that **“if a powered air mattress is replacing a mattress on a bed system that meets the recommendations in the guidance with the original mattress, the resulting bed system with the new air mattress may still pose a risk of entrapment.”** To help caregivers address entrapment concerns in this situation, as well as the danger of falls, Span-America has designed its PressureGuard® series of air therapy surfaces with a proprietary, two-part Safety Edge™ bolster system. This design allows PressureGuard models to provide best-in-class alternating pressure, lateral rotation, powered flotation and microclimate management outcomes without the edge-of-bed safety compromise typical of traditional, roll-up style surfaces.



PressureGuard® Safety Edge™ bolster design helps eliminate entrapment and patient fall concerns by providing firm, stable edge-of-bed support that will not collapse under user's weight.

Additional resources:

FDA provides a variety of helpful online documents on the topic, which can be found at [Hospital Beds](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/).
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Available documents include:

- [HBSW/FDA Frequently Asked Questions \(FAQ\) on Entrapment Issues](#)
- [A Guide for Modifying Bed Systems and Using Accessories to Reduce the Risk of Entrapment](#)
- [Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment](#)
- [Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings](#)

BED ENTRAPMENT COMPLIANCE
CO#1273