

Bariatric Hospital Bed Safety and Selection

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Abstract

Bariatric care providers should be aware that preventable injuries and deaths occur due to the malfunction of electric bariatric hospital beds; these malfunctions include beds catching fire, side rail failure, high mattresses that allow the patient to fall to the floor, and patient entrapment involving bed, side rails, and/or mattresses. Facilities and care providers need to be aware of the tested level of safety of their electric hospital beds and ensure that their beds meet or exceed minimum standards for patient and caregiver safety. This article will discuss current electric hospital bed standards and current regulatory processes in the United States and provide a guide for selecting bariatric hospital beds and implications for future research.

Bariatric Hospital Bed Safety and Selection

BARIATRIC CARE providers should be aware that preventable injuries and deaths occur due to the use of bariatric electric hospital beds for patients. Hospitalized patient deaths and injuries occur every year from electric hospital bed malfunctions such as beds catching fire, side rail failure, high mattresses that allow the patient to fall to the floor, and patient entrapment involving bed, side rails, and/or mattresses.¹⁻⁴ In 2008 there were at least 14 deaths, 30 injuries, and multiple manufacturer recalls for well over 100,000 electric hospital beds and mattresses reported to the Food and Drug Administration (FDA).⁴⁻⁹ These numbers come from the manufacturers who are acting professionally and are diligent in reporting incidences, but how many manufacturers fail to report such incidents is unknown. Facilities and care providers need to be aware of the tested level of safety of their electric hospital beds and ensure their beds meet or exceed minimum standards for patient and caregiver safety. This article will discuss current electric

hospital bed standards and current regulatory processes in the United States. We also provide a guide for selecting bariatric hospital beds and implications for future research.

U.S. Electric Hospital Bed Safety Standards

According to Biersach and Marcus, "medical equipment is held to a higher level of safety than nearly all other types of equipment on the market."¹⁰ One reason for this is that medical equipment is used with patients who may be unable to respond to hazardous conditions or pain.¹⁰ Safety manufacturing standards for U.S. electric hospital bed manufacturers have become more product specific as new standards have been issued increasing requirements for safety and effectiveness (see Table 1). The Underwriters Laboratory (UL) 544 *General Standard for Dental and Medical Equipment* was not specific to hospital beds and ceased to be a testing standard for new or modified hospital beds on January 1, 2005.^{10,11} The UL 60601-1 is the *Medical Electrical Equipment General Requirement Safety Standard for the United States*¹¹⁻¹³ and tests main circuits,

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TABLE 1. TIMELINE OF U.S. HOSPITAL BED STANDARDS

Standard number	Standard title	What standard does	Date first published	Date no longer in effect
UL 544	<i>Safety for Medical and Dental Standard</i>	General medical equipment standard. Not product specific.	1972	2005 for modified products; 2010 for original products.
UL 60601-1	<i>Medical Electrical Equipment General Requirement for Safety</i>	Electrical standard that is not product specific. No substantial differences from the international standard IEC 60601-1. It replaces the UL 544.	2003	Still in effect.
IEC 60601-2-38	<i>Particular Requirements for the Safety of Electrically Operated Hospital Beds</i>	Specific to electric hospital beds. FDA-recognized standard. Encompasses the IEC 60601-1 electrical safety standard.	1996	Still in effect.
IEC 60601-2-52	<i>Particular Requirements for the Safety and Essential Performance of Medical Beds</i>	Specific to electric hospital beds. Encompasses the third edition of the IEC 60601-1, the IEC 60601-2-38 amendment, and the EN 1970.	Due 2010 or 2011	n/a

FDA, Food and Drug Administration; IEC, International Electrotechnical Commission; n/a, not applicable; UL, Underwriters Laboratory.

component requirements, lower leakage current limits, enclosure flame ratings, and production line testing.¹⁰ The International Electrotechnical Commission (IEC) 60601-1 standard, originally published in 1970 and used globally, has no substantial differences from the UL 60601-1.^{11,12}

The IEC 60601-2-38 *Particular Requirements for the Safety of Electrically Operated Hospital Beds* was originally published in 1996 and is the first standard developed that details minimum construction and performance requirements specifically for electric hospital beds.¹⁴ It builds on the UL 60601-1 electrical standard testing requirements to further ensure hospital bed safety and performance through numerous required tests, including mechanical strength (i.e., safe working load), protection against patient entrapment, lateral and horizontal stability (i.e., bed stability), bed function, suspended mass (i.e., side rail locking and holding, or trapeze function), electromechanical compatibility (i.e., electrical testing in complete product), human factors (i.e., requirements for cardiopulmonary resuscitation [CPR] and Trendelenburg's position).¹⁴

The IEC is currently working on the next standard, the IEC 60601-2-52 *Particular Requirements for the Basic Safety and Essential Performance of Medical Beds*. This standard is projected to expand the scope of the current

IEC 60601-2-38 standard to include all medical beds.¹⁵ It will combine the IEC 60601-2-38 amendment with the EN 1970 *Standard for Adjustable Beds for Disabled Persons* and the third edition of the IEC 60601-1 *Medical Electrical Equipment General Requirement for Safety Standard*.¹⁵ Once approved and published, it could take several years for the IEC 60601-2-52 standard to be adopted in the United States and several more years for this standard to replace the current IEC 60601-2-38 standard.

U.S. Regulatory Process

Food and Drug Administration testing requirements

In the United States, the Food and Drug Administration (FDA) is the medical device regulatory agency, and its Center for Devices and Radiological Health (CDRH) oversees the regulation of electrical medical devices.¹² The CDRH requires a 510K premarket notification report from manufacturers for some medical devices coming onto the market. This report provides documentation to a specialized FDA reviewer of the product's substantial equivalency to a product currently on the market or to a recognized consensus standard. The FDA recognized the IEC 60601-2-38 for electric hospital beds as a recognized consensus standard in 1998.^{16,17} The FDA does not require that the

beds be tested to the IEC 60601-2-38, but a manufacturer must then provide equivalent safety documentation or justify that noncompliance does not create a hazard.¹⁸ However, declaring conformity to a consensus standard eliminates the need to submit the bulk of test data for all aspects of the device already addressed by the consensus standard.¹² Additionally, the FDA believes that “a declaration of conformity to the recognized consensus standard should suffice both to document conformance to the standards and to provide evidence of device safety and/or effectiveness with respect to those aspects covered by these standards.”¹⁹

In 1998, the FDA also exempted some class II products such as electric hospital beds from the premarket notification process (510K report).²⁰ Although these reports are no longer required for hospital bed manufacturers, other class II products such as electric wheelchairs are required to go through the 510K premarket notification process.²⁰ This means class II hospital bed manufacturers no longer file a premarket notification report, provide safety standard testing to the FDA, or have their report for the bed stringently reviewed by the FDA before the bed goes on the market.

The FDA requires U.S. and international manufacturers of hospital beds sold in the United States to register their facility, list the product with the FDA, and conduct their own internal substantially equivalent determination, which is not submitted to the FDA.²¹ This decreased supervision becomes a problem when a manufacturer is unaware of, or willfully does not comply with, hospital bed testing standards. For example, any Chinese manufacturer/distributor can bring a product into the United States by simply registering the facility and listing the product with the FDA. Currently, there is no submission of bed-testing results or routine inspection of the manufacturer’s facility;²² therefore there is no assurance that the manufacturer is meeting the requirements of the FDA or any other standard.

Occupational Safety and Health Association labeling requirements

There are authorities, such as the Occupational Safety and Health Association (OSHA) in

the United States, that require a safety certification mark, or label, on the hospital bed listing the standard to which the bed was tested.^{10,11} The Medical Equipment Compliance Associates goes on to say that the safety mark must be from a nationally recognized testing lab (NRTL)¹¹ and states that “while this requirement is not often enforced, it is specified in OSHA Standards Part 1910, Subpart S-Electrical, Sec. 1910.399.”¹¹ Figure 1 shows an NRTL IEC 60601-2-38 bed label.

NRTLs will test a bed to the standard requested by a manufacturer. Some manufacturers, unaware of the hospital bed-specific standards, request NRTLs to test their beds to inappropriate standards, as evidenced by some manufacturer websites and product literature. A few examples of inappropriate testing standards include the UL 73 requirements (small appliances such as vibrators) and the UL 962 requirements (lava lamps, home furnishings, and motor-operated beds *not* intended for patient care where oxygen is in use).²³

To meet the IEC 60601-2-38 requirement, which is the FDA-recognized consensus standard for electric hospital beds, the manufacturer or third-party nationally recognized testing laboratory must test the completed bed to both the IEC 60601-1 and IEC 60601-2-38 standards. In regard to medical electrical equipment, where a particular requirement exists (e.g., IEC 60601-2-38), the general standard (e.g., IEC 60601-1) cannot be used alone.²⁴ Manufacturers may not test components of the bed (e.g., only the motor) by themselves and then label the completed bed tested to a standard.²⁵ Manufacturers and distributors are prohibited from misbranding the bed—for example, by removing a component label from the motor and placing it on the bed itself.²⁵



FIG. 1. Example of Nationally Recognized Testing Lab (NRTL) 2-38 Safety Mark.

It is important to know that if a facility or personnel in the facility alters a bed component by changing or removing side rails or using a specialty mattress or overlay that takes the bed out of standard compliance, the facility's liability is greatly increased. The burden of assuring that the bed meets the safety standard previously tested by the manufacturer is placed on the facility. The facility should do a risk assessment before performing any product modifications or selecting patient surfaces such as foam or air mattresses.

Bariatric Hospital Bed Selection Guide

Many facilities purchase or rent bariatric beds based on selective features or price and not on bed safety standards and quality, increasing the risk of patient or staff injury and litigation. The following bariatric bed selection guide is a worksheet that lists important safety items that can assist with the selection process conducted by facility staff, care providers, and safety teams (Table 2). Many safety items are from the recommended IEC 60601-2-38 standard for electric hospital beds. This worksheet should be completed for each bariatric hospital bed being considered by marking "yes," "no," or "not applicable" for each criterion. The results can then be compared and a determination made of the hospital bed that best meets the facility's needs.

Item 1. A label with IEC 60601-2-38 from a National Recognized Testing Laboratory (NRTL) is on the bed. This assures that the hospital bed was tested to the recognized consensus standard for electric hospital beds by an independent testing facility other than the manufacturer. If there is no label it is not possible to know what testing criteria were used to determine safety and effectiveness. For example, the 60601-2-38 standard requires that a bed be tested with two times the rated weight in static testing (e.g., when a patient sits on it). If the IEC 60601-2-38 was not used, the safety weight factor used by the manufacturer is not known. If there is no 60601-2-38 label on the bed, then request the following responses in writing from the manufacturer: (1) Is the bed in compliance with the 60601-2-38 standard? (2) What standard was used to evaluate safety and effectiveness if the

60601-2-38 standard was not used? (3) What is the written rationale for why this standard is more appropriate for safety and effectiveness than the 60601-2-38 standard?

Item 2. Maximum weight capacity of bed clearly labeled. While the 60601-2-38 standard requires the safe working load to be printed on a clearly visible label, many manufacturers are now listing the maximum patient weight to simplify decisions about what patient weights are appropriate for the bed. This avoids staff calculating the maximum patient weight, maximum accessory weight (e.g., infusion pumps, vital sign monitoring machines, and trapeze), and maximum mattress weight that is appropriate for the safe working load of the bed. Patients have died from being inappropriately placed in a bed in which they exceed the maximum weight capacity, allowing them to roll against the side rails and causing the bed to tip over.²⁶ Additionally, there can be a difference between the maximum patient weight for the bed and the patient weight rated safe for transport. Often the patient weight rated safe for transport is less than the safe working load or maximum patient weight. Some manufacturers state that their bed is not to be used to transport a patient or to be repositioned in a room while occupied. Transport of a bariatric patient is an important issue to consider. If the safe weight rated for transport is not labeled on the bed, it must be located in the bed operations manual.

Item 3. Width of bed. The width of the bariatric bed should allow patients to roll side to side for care and position changes. The bed should be able to expand or decrease in width while the mattress and patient are on the bed to allow the bed to move through doorways and onto elevators in case of emergencies. Patients have died because the bed could not fit through a room door or elevator door during an emergency.²⁷ Facility doorways should be measured before making a purchase. The risk for tipping is greatest when the bed is in its widest position and the patient weight is on the edge of the bed, such as when the patient rolls toward the side rails or tries to transfer from the bed. Beds with an IEC 60601-2-38 label have been tested for and meet this lateral stability requirement.

TABLE 2. BARIATRIC BED SELECTION GUIDE

Item	<i>Bed model and manufacturer</i> _____	<i>Criteria met?</i>
		Y, N, N/A
1.	IEC 60601-2-38 NRTL certification label on hospital bed	
2.	Maximum weight capacity of bed (safe working load or maximum patient weight) a. Maximum patient weight label clearly visible on bed.* b. Bed is rated for patient's weight during transport (500 lbs or 1000 lbs). c. What standard was the bed's weight capacity tested to? How was it tested?	
3.	Width of bed a. Bed width should be wide enough to allow patient to roll side to side for care and position change. Bariatric bed width range: 48" to 54". b. Bed can be decreased in width, with mattress and patient on bed, to transport bed through doorways and onto elevators in case of emergencies. Bariatric bed transport width range: 39" to 41".	
4.	Height of bed a. Bed can lowered to a height of 10" to 14" from platform to floor. b. Use caution with beds lower than 9".	
5.	Side rails and entrapment a. Side rail testing: what is the side rail capacity to raise, latch, and lock?*" b. Does the bed have the original manufactured side rails or replacement side rails from the manufacturer?*" c. Are the side rails on the bed? (Do not remove them.)*" d. Side rail entrapment: Zone A: IEC 2-38* and HBSG recommend ≤ 120 mm (4.72") Zone B: specified by manufacturer Zone C: IEC 2-38* recommends ≥ 220 mm (8.66") Zone D: IEC 2-38* and HBSG recommend ≥ 235 mm (9.25"); may change to 318 mm (12.52") Zone E: IEC 2-38* and HBSG recommend ≥ 235 mm (9.25"); may change to 318 mm (12.52") Zone F: IEC 2-38* recommends if D or E ≥ 235 mm (9.25"); may change to 318 mm, then $F \leq 60$ mm (2.36"). Zone G: IEC 2-38* recommends \geq half the length of the mattress support platform	
6.	Mattresses and entrapment a. Zone C ≥ 220 mm (8.66") of space from mattress top to top of side rails?*" b. Is the mattress manufacturer same as the bed?*" c. Is the mattress antimicrobial, easy to clean, fire retardant and have a low-coefficient of friction? d. Consider mattress entrapment and overlay entrapment issues. e. Has the specialty mattress been tested for use with a bariatric bed system?	
7.	Bed system testing a. Has the bed system been tested as a whole (mattress, bed, side rails, attached lifts)? b.1 Have the electrical system and motor been tested while in bed?*" b.2 Electric compatibility: does the bed conform to standards for electrical safety IEC-60601-2-1/IS-13450?*" b.3 Electric current protection: Class-1.* b.4 Electric shock protection level: Class-B.* b.5 Electromagnetic compatibility: meets IEC-60601-1-2.* c. Have you performed impact threshold testing?*" d. Perform mechanical strength tests (moving parts): friction and entrapment; withstanding a SWL greater than 2X the SWL.* e. Have you performed stability testing; latitude and longitudinal testing done?*" f. Is the bed certified to be compliant with IEC 60601-2-38, <i>Medical Electrical Equipment Part 2-38 Particular Requirements for Safety of Electrically Operated Hospital Beds</i> ?*"	
8.	Required features a. Emergency CPR release: manual quick release mechanism for back section adjustment during emergency situation.* b. Trendelenburg's minimum 12° achievable in normal use and in emergencies.* c. Electric adjustable height of bed, head, and leg sections of bed: Height: 400 to 800 mm (15.75" to 31.50")* Head section: 0° to 70°* Foot section: 0° to 20°* d. Castors and breaks tested in transit to standard.* e. Capable of being stored at ambient temperature of 0° to 50° C and relative humidity of 15% to 90%.*	

(Continued)

TABLE 2. (CONTINUED)

<i>Bed model and manufacturer</i>	<i>Criteria met?</i>
f. Rental label on bed of who to call in case of bed malfunction.	
g. Owner's manual attached to bed in language appropriate to users.	
9. Optional or recommended features	
a. Transport power drive reduces patient transfers and caregiver injuries.	
b. Scale system should be user intuitive.	
c. Trapeze to assist with boost.	
d. Cardio chair function for patient care.	

*Item required to meet the 60601-2-38 standard.

CPR, cardiopulmonary resuscitation; FDA, Food and Drug Administration; HBSG, Hospital Bed Safety Workgroup; IEC, International Electrotechnical Commission; IS, International Standard; N, no; N/A, not applicable; NRTL, nationally recognized testing lab; SWL, static weight load; Y, yes.

This worksheet for selecting bariatric hospital beds uses the FDA 60601-2-38 electric hospital bed standard as its guide. (*Particular Requirements for the Safety of Electrically-Operated Hospital Beds*. IEC 60601-2-38, Amendment 1, 1999 Medical Electrical Equipment—Part 2-38.)

Item 4. Height of bed. Beds should be able to be raised to full working height to reduce caregiver injury during care procedures and when boosting patients. Bariatric beds should also function in a low position. A common low platform range is 10" to 14" in the lowest position. Low platform heights reduce the distance patients might fall to the floor and make it easier for shorter bariatric patients to transfer off the bed (16" to 20" height with mattress) to a wheelchair (16" to 18" height). Problems are being reported with ultra low beds (<9" platform) that are creating new risks such as caregiver feet entrapment; there has been at least one recall for low bed actuator failures.²⁸ The actuator is a mechanical part commonly used to raise and lower beds. Additionally, bariatric patients face increased discrimination when placed in an ultra low bed, which is similar to lying on the floor and could be considered dehumanizing.²⁹

Item 5. Side rails and entrapment. Side rails should be evaluated for their function of raising, lowering, and locking in an upright position. One of the most recent hospital bed recalls involved a bed with side rails that did not lock.³⁰ Malfunctioning side rails increase the risk for patient falls, injury, and death.^{31,32} Side rails should always be safety tested while attached to the bed as part of the bed system. They should not be removed from the bed unless being replaced. Replacement side rails should only be obtained from the bed's manufacturer and only from models originally tested for the bed.

Hospital bed side rail and mattress entrapment is currently considered the number one

cause of death associated with hospital beds. The FDA received approximately 722 reports of incidents of patients caught, trapped, entangled, or strangled in hospital beds from 1985 to 2008, and 460 of those 722 reports were deaths.³³ The Hospital Bed Safety Workgroup (HBSW) created recommendations for side rail dimensions in the publication "Guidance for Industry and FDA Staff for Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment."¹ However, this guidance excludes bariatric beds and pressure-reduction products such as air mattresses.¹ The HBSW found that not all patients are at equal risk for entrapment. In particular, small, lightweight patients are generally at the greatest risk for entrapment because their small physical dimensions may enhance their ability to fit into a gap, in whole or in part.²⁹ Frail and/or confused patients are also at greater risk.²⁹ In regard to bariatric patients, the HBSW recommends that facilities should identify and address areas of potential entrapment for each patient through a comprehensive bed safety program.¹ Side rail entrapment test kits are also available to assist facilities in maintaining their bariatric hospital beds. The IEC 60601-2-38 standard does apply and requires testing seven zones (A through G) for specific dimensions (Table 3). Be aware that the IEC 60601-2-38 entrapment zones and their dimensions are subject to change again with the adoption of the 60601-2-52 (see Table 3).

Item 6. Mattresses and entrapment. Mattresses should be obtained from the same manufacturer as the bed so the bed and mattress are

TABLE 3. SIDE RAIL ENTRAPMENT ZONES

2-38 Zone	2-38 zone description	2-38 Dimension		HBSW Zone	HBSW zone description
A	Smallest dimension between elements inside the perimeter of the side rail in its raised/locked positions or perimeters created between the side rail and fixed parts of the bed	≤120 mm (4.72")		Zone 1 and Zone 2	Zone 1. Within the rail Zone 2. Under the rail, between the rail supports, or next to a single rail support
B	Thickness of normal use mattress	Specified by manufacturer			
C	Height of the top edge of the side rail above the mattress (see B) without compression	≥220 mm (8.66")			
D	Distance between head panel or foot panel and side rail	≤60 mm (2.36") or ≥235 mm (9.25")*		Zone 6	Zone 6. Between the end of the rail and the side edge of the headboard or footboard
E	Distance between segmented side rail with the mattress support platform in the flat position	≤60 mm (2.36") or ≥235 mm (9.25")†		Zone 5	Zone 5. Between split bed rails
F	Smallest dimension of any accessible opening between the side rail and the mattress support platform	If D or E ≥ 235 mm (9.25") then F ≤ 60 mm (2.36")	If D or E ≤ 60 mm (2.36") then F ≤ 120 mm (4.72")	Zone 4	Zone 4. Under the rail, at the ends of the rail
G	Total length of the side rail or sum of the length of segmented side rails on one side of the bed	ΣG _x ≥ half the length of the mattress support platform		Zone 3 Zone 7	Zone 3. Between the rail and the mattress Zone 7. Between the headboard or footboard and the mattress end

*Potential changes with the IEC 60601-2-52: ≥235 mm may change to 318 mm (12.52").

†Potential changes with the IEC 60601-2-52: ≥235 mm may change to 318 mm (12.52").

HBSW, Hospital Bed Safety Workgroup; IEC, International Electrotechnical Commission.

This table shows the similarities and differences between the hospital bed safety workgroup hospital side rail zones and the IEC 60601-2-38 hospital side rail zones. The diagram of the hospital bed safety workgroup zones is available on the website, and the IEC 60601-2-38 is also available for purchase on the website.

Data from Hospital Bed Safety Workgroup, Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment—Guidance for Industry and FDA Staff, 2006, available at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072622.htm (accessed June 1, 2009); and International Electrotechnical Commission, IEC 60601-2-38 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Electrically Operated Hospital Beds, 1996, CE/IEC 601-2-38.

safety tested together. Not all mattresses and rails are designed to work safely with every bed frame.³⁴ A bariatric air mattress designed for use with a bariatric bed system should be tested with the bed for certification. The top of the mattress to the top of the raised side rails should be at least 220 mm, or 8.66".¹⁴ This will help to prevent patients from rolling over side rails, collapsing side rails, and falling to the floor, resulting in injury or death.^{35,36} This may be a more serious problem for bariatric patients than normal weight patients. Bariatric patients have a higher center of gravity and greater

force when rolling side to side in the bed. Specialty mattresses or overlays create an added problem of decreasing this height measurement from the top of the mattress to the top of the side rail and possibly increasing patient falls, injuries, and deaths.^{29,14,37}

Of the FDA's 381 entrapment reports received from 1995 through 2001, 9% of the deaths involved air pressure mattresses (either overlay air mattresses placed on top of a regular bed mattress or beds with built-in air mattresses).^{2,38,39} Overlays can contribute to entrapment risks by sliding if they cannot be tied down and secured.

Specialty mattresses must be obtained from the same manufacturer as the bed and tested as a whole bed system. Alternatively the facility should specifically test the parts of the bed system intended to be used together.³⁴ If a facility believes there is a benefit to using a specialty mattress or overlay for a patient (that decreases the space between the mattress and top of the side rails to less than 220 mm, or 8.66") and this benefit outweighs the risk of patient injury from falling, the facility should conduct a risk assessment and document the results before using the specialty mattress. Additionally, mattresses need to be antimicrobial, easy to clean, have a low-coefficient of friction, and be fire retardant.

Item 7. Bed system testing. From 1993 to 2003 the FDA reported 95 fires involving electric hospital beds.³ The FDA reported that "most of the fires were associated with such factors as overheated bed motors, electrical arcing from ill-fitting plugs, damaged plugs, missing ground pins, fluid leaks that damaged the circuit boards, missing components in the wiring, poor maintenance, or failure to heed manufacturers' warnings."³ The electrical system (including the motor) should be tested to the IEC 60601-2-38 standard with all parts assembled as a whole bed system (not tested individually). Injuries have occurred in which there was an electrical connection between the hospital bed and patient or hospital bed and nurse, shocking the individual.⁴⁰ Some examples of additional testing under the IEC 60601-2-38 include: impact threshold testing to check castor wheel breakage when transporting the bed through thresholds or onto elevators; stability testing for bed tipping when the patient rolls in bed; and mechanical strengths testing to see if the bed can withstanding a static load of twice the safe working load.¹⁴

Item 8. Required bariatric bed features. Beds should have features of CPR release for patient emergencies, Trendelenburg's position to help with boosting, and adjustable head and leg/feet sections of the bed. Rental beds should be labeled with contact information for service and repairs. The owner's manual should be attached to the head or foot of the bed (head preferable) and written in a language appropriate for care providers and staff.

Item 9. Suggested bariatric bed features. Additional features should be considered when selecting a bariatric hospital bed for their benefits to patients, ease of patient care, and staff safety.⁴¹ One feature to consider is a transport power drive, a propulsion system that allows one staff member to move the bed and patient throughout the facility, reducing the number of patient transfers and staff injury. A second feature to consider is the cardio chair, which benefits patient function and assists with positioning patient into a sitting position. Third, a patient bed scale system should be worker intuitive and accurate to up to 2% of the patient's weight, $\pm 1\%$ of error (important for medical treatment). Fourth, a trapeze can help patients with their own care or movement and enable them to assist staff with boosting and repositioning.

Patient-fall prevention teams and reducing bariatric falls through bed selection

The Joint Commission is asking facilities to implement and evaluate a patient fall-prevention program.^{42,43} Bariatric bed selection should be a concern for patient fall-prevention teams because of the increased risk of falls from some bariatric beds. Increased risk of fall situations include: (1) mattresses being too tall compared to side rails so patients are allowed to fall from bed; (2) side rail collapse enabling patients to fall from bed; (3) electrical fires that force the patient from the bed unexpectedly, increasing the chance of a fall; and (4) falls during transfers from beds with or without the use of lifts. Bariatric patients are a specific patient population whose characteristics influence how and when they fall and the injury resulting from the fall. Bariatric patient environments and equipment, including hospital beds, should also be evaluated during patient fall-prevention programs. If possible, patient fall-prevention teams should assist clinicians and researchers in gathering data on bariatric patient falls and bed-related falls in future research.

Implications for Future Research

Researchers and clinicians should consider conducting research in the following areas:

1. What bariatric hospital bed features benefit patient care?
2. What bed features reduce or increase bariatric fall risk in the clinical setting (e.g., low beds, side rail height and dimensions, side rail use, specialty mattress use)?
3. What combination of low bed use, lack of side rails, and specialty mattresses increases bariatric patient-fall risk? Is there a correlation between specialty mattress use and an increased bariatric patient-fall risk?
4. What bed features increase side rail and mattress entrapment conditions for bariatric patients? How serious is this problem for the bariatric population?
5. How can manufacturers improve bed safety features for bariatric patient care needs (e.g., preventing electrical system fires, side rail entrapment, and falls)? How can manufacturers improve bed safety features for bariatric care provider needs (e.g., drive systems, patient lifts, boosting assistance)?
6. What are the most common extrinsic falls in the bariatric population? How can clinicians use this data to start developing a bariatric patient-fall risk assessment tool?
7. How can a patient fall-prevention team contribute to development of the best practices and procedures for bariatric patients?

Conclusion

Bariatric care providers should be aware that preventable injuries and deaths related to electric hospital beds are occurring. To ensure product reliability and patient and caregiver safety beds should be at or above minimum safety standards. Facilities and care providers need to know what safety standard was used in testing their electric hospital beds. The most consistent way to establish bed safety and effectiveness is by meeting the FDA's IEC 60601-2-38 recognized consensus standard for electric hospital bed safety. Some manufacturers are unaware of U.S. electric hospital bed testing standards, and U.S. regulators are currently not using the 510K premarket notification process to ensure safety and effectiveness compliance. Many facilities are unaware of current electric hospital bed standards for safety and effectiveness that should be used when selecting a bariatric hospital bed to rent or buy. They may also not know that if they modify the bed system, it may no longer meet the current safety standard to which it was tested, resulting in increased liability risk for the facility. By using the bariatric bed selection guide and the IEC 60601-2-38 standard as tools during the

bed selection process, facilities can make better choices that increase the reliability and safety of the selected hospital bed and reduce preventable patient and staff injuries related to electric hospital beds.

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Disclosure Statement

Dr. Kramer-Jackman is an assistant clinical professor at the University of Kansas, School of Nursing. DuWayne Kramer, Jr., is president of Burke Manufacturing, a company that has manufactured bariatric hospital beds for more than 25 years. Burke Manufacturing has previously purchased advertisements in *Bariatric Nursing and Surgical Patient Care*. The authors are related.

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