

IMPORTANT HOSPITAL BED SAFETY STANDARDS INFORMATION

Today there is great confusion in the medical community concerning hospital bed safety standards.

Much of the unnecessary confusion is caused by misleading claims from manufacturers trying to hide their bed's inability to meet the U.S. standards requirement. These manufacturers are claiming compliance to inappropriate standards that do not apply, claiming compliance of the entire bed when only a subcomponent has been tested or using an out of date general standard when they were required to test to the OSHA and FDA consensus standard.

The following information is provided so decision makers can recognize the difference between false misbranding standards claims and the gold standard in safety, quality and effectiveness for patient and staff provided by beds certified to the U.S. national electric hospital bed standard.

The IEC 60601-2-38, (2-38) the particular requirement for safety of electrically operated hospital beds, is the first and only specific electric hospital bed standard. The 2-38 is the key testing standard for both OSHA and the FDA which have jurisdiction for electric hospital (medical) beds used in public facilities.

2-38 & OSHA

OSHA has jurisdiction in public facilities. Metlabs.com states "OSHA covers all workplaces which include all hospitals, clinics, therapy centers and other similar facilities." Medical Equipment Compliance Associates @ ULmedical.com explains "In the U.S. OSHA requires a safety mark from a nationally recognized testing lab (NRTL) for equipment used in a public facility." In addition, the article "Regulatory Requirements for Medical Equipment" explains that the Electric Hospital Bed standard 2-38 takes testing priority over the umbrella UL 60601-1 General Requirement of Safety of Medical Electrical Equipment. Electric hospital beds must be tested to both standards. OSHA has the authority to impose a \$70,000 fine and a 6 month jail sentence per piece of non-certified equipment.

2-38 & FDA

The 2-38 is the FDA recognized consensus standard for electric hospital beds. A consensus standard defines the products minimum construction and performance requirements. Published in 1996 the 2-38 is a comprehensive 87 page standard used as the key electric hospital bed testing standard to support a manufacturer's declaration of conformity. This conformity declaration is required before placing an electric medical bed on the market in the United States.

The IEC-60601-2.38 is the World standard for testing electric hospital beds.

Why is the 2-38 important for medical staff and patients?

The 2-38 has the most advanced safety requirements. For instance, with 116 deaths reported since 2002 involving side rails, the 2-38 provides the most comprehensive testing for side rails with 7 test zone requirements, three more than the entrapment guidelines published by the FDA. As an example, the 2-38 standard amendments published in 1999, require that there be ≥ 220 mm or 8.6" for the height of the top edge of the side rail above the mattress without compression. OSHA nationally recognized testing labs (NRTLs), like ETL and UL will not certify a bed with side rail height ≤ 8.6 ". If air mattresses or mattress overlays are used that reduce side rail height to less than 8.6", the bed loses certification.

In death and injury reports involving air mattresses or mattress overlays, the side rail height is often reduced to less than 4". Incidents where the patient goes over the shortened side rail of these uncertified beds will result in additional serious safety and legal issues for the facility.

The 2-38 requires the total length of the side rails must be \geq half the length of the mattress support platform. Thus, if a platform is 90" long the side rails combined must be 45" or longer. If the platform expands in length the side rail must also expand in length or the bed loses its certification.

The 2-38 provides the best assurance available of the bed's reliability and quality. Unique structural tests such as impact resistance, rated weight threshold climbing with rated weight and multi direction stability testing are required to meet the standard.

The 2-38 static weight performance test requires the capacity of the bed be tested at 2 times the working load. So a 1,000 lb. patient capacity bed is tested with a 2,000 lb load. Other standards do not require any weight capacity testing.

How Can You Tell if A Bed Is Tested To The 2-38 US Electric Hospital Bed Standard?

A bed that complies with the OSHA requirements has a NRTL label that shows testing to the IEC STD 60601-2-38 on the bed. The example given, of an ETL label, clearly shows the testing standards conformed to by the bed; the IEC 60601-2.38 bed standard, the UL60601-1 general medical standard and the certification to the CAN/CSA STD C22.2 NO 601.1. If there is not a 2-38 mark or certification ask the manufacturer for the authorization to mark letter from the NRTL lab.



Examples of Inappropriate Standards Usages

Claiming compliance to the UL 60601-1.

Manufacturers can not claim compliance to the UL 60601-1 by itself. The FDA, OSHA, and NRTL require testing to the 2-38 and the UL 60601-1 with the 2-38 particular standard taking precedence. A misbranding example, one manufacturer has a label on the end of the bed claiming testing by a NRTL to the UL 60601-1. In research at a NRTL, the mark was for an evaluation to a very old UL 2601 for a bariatric bed control box. The manufacturer is misbranding because the mark can only be placed on the tested component, the control box. By placing the label on the bed end frame they are saying the entire bed was tested when in reality, only the control box was tested.

The UL2601

The UL 2601 is an obsolete General Medical Standard not a particular specifically designed Electric Bed standard. The UL 60601-1 Medical Electrical Equipment General Requirement for safety replaced the UL 2601 in 2003. There were no substantial differences.

UL73

Some bed manufacturers claim testing marks to the UL 73 on beds used in nursing home and hospitals. The UL 73 is a Motor-Operated Appliances Standard. The UL 73 covers small utilization appliances such as vibrators. These requirements do not cover other motor operations that are covered by individual requirements. While the standard may cover small electric appliances it is not a comprehensive Electric Hospital Bed Standard like the 2-38 or even a General Medical Standard. “Medical equipment is highly regulated and held to a higher level of safety than nearly all other types of equipment on the market.” from article in MECA.

The UL 962

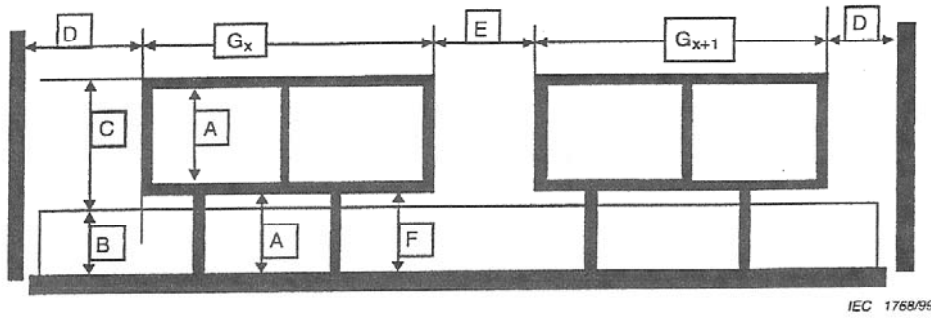
Some new fully electric homecare beds promote their UL 962 approval. These beds have a medicare code and are therefore medical devices. The UL 962 is a standard for household and commercial furnishings. While it is correct that UL 962 covers motor operated beds, chairs and lava lamps, the UL 962 specifically states that these requirements do not cover product intended for “patient care”.

The UL 544

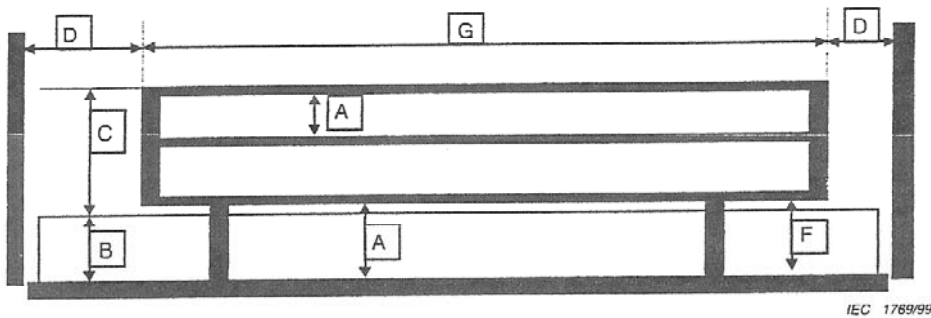
The 544 is the UL standard for Safety for Medical and Dental Equipment, published in 1972. The UL 544 is a general medical standard and therefore, is not product specific. The UL 544 is an obsolete testing standard that was state of the art in the 1980’s. The UL 544 is the ancestor of the UL 2601 General Standard. It is not a specific hospital bed test standard like the 2-38. The UL 544 cannot be transferred to other beds. Manufacturers cannot claim compliance to one subcomponent while changing other components and claim compliance for the bed. If bed component changes are made the manufacturer must retest the complete bed to the 2-38 as the 544 certificate is no longer valid. For products that do not change, the 544 certification is being withdrawn as of January 1, 2010.

The General UL Label

The general UL label that does not list the standard the bed is tested to is meaningless. A general NRTL label could refer to a component or an inappropriate standard. The label must list the IEC 60601-2-38 to meet the gold standard in testing.



Example (only) of a BED with segmented SIDE RAILS



Example (only) of a BED with single-piece SIDE RAILS

DESIGNATOR	DESCRIPTION	DIMENSION	
*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	
B	Thickness of NORMAL USE mattress	Specified by the manufacturer	
*C	Height of the top edge of the SIDE RAIL above the mattress (see B) without compression	≥220 mm	
*D	Distance between HEAD PANEL or FOOT PANEL and SIDE RAIL	≤60 mm or ≥235 mm	
*E	Distance between segmented SIDE RAIL with the MATTRESS SUPPORT PLATFORM in the flat position	≤60 mm or ≥235 mm	
*F	Smallest dimension of any accessible opening between the SIDE RAIL and the MATTRESS SUPPORT PLATFORM	If D or E ≥ 235 mm then F ≤ 60 mm	If D or E ≤ 60 mm then F ≤ 120 mm
*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	

Figure 114 – Examples (only) of BEDS with segmented SIDE RAILS and single-piece SIDE RAILS