

IMPORTANT SAFETY AND REGULATORY INFORMATION

FEDERAL REGULATIONS REQUIRE INDEPENDENT TESTING/LISTING TO THE IEC60601-2-38 FOR ELECTRIC HOSPITAL BEDS

Dear Directors of Nursing and Safety Administrators,

Many hospital administrators are unaware that all beds in their facility, including bariatric beds should meet the IEC 60601-2-38(2-38) U.S. electric hospital bed standard. The 2-38 is the first and only standard ever developed to specifically test the safety and effectiveness of electric hospital beds. The Occupational Safety and Health Administration (OSHA) requires that any new hospital bed used in a hospital, nursing home or any public facility be tested to meet the 2-38 standard by a nationally recognized testing laboratory (NRTL), such as UL, ETL or CSA. The NRTL 2-38 standard certification mark must be placed on the bed. For many years, the Food and Drug Administration has used the 2-38 as the recognized consensus standard for testing all electric hospital beds, defining the minimum allowable construction and performance requirements.

A bed's failure to meet the 2-38 standard raises questions of patient and staff safety as well as creating additional issues of product liability for the facility. Some bed manufacturers are currently claiming listings to invalid standards that are unacceptable to use in place of the 2-38. One current practice is placing a confusing UL label on the bed without listing the standard to which it was tested.

Any incident involving a non 2-38 NRTL tested bed puts your facility at greater liability risk. The following numbers demonstrate some of the incidents facilities are currently encountering. The FDA's website reports 116 deaths by side rail entrapment, 12 bed fire incidents and 8 possible deaths by fire since 2002. In addition, there have been multiple bed recalls including one recall of over 200,000 beds for potential fires. The vast majority of these incidents involve beds that were not tested to the 2-38 standard. Protect your facility by requesting a certification letter issued by the NRTL, for any new bariatric bed rented or purchased for your facility. The letter

should specifically state that the bed was tested and meets the IEC 60601-2-38 U.S. electric hospital bed standard.

For more information, visit our website, BurkeBariatric.com, for a listing of:

- Bariatric hospital beds that have been NRTL tested to the 2-38 standard
- Information about the IEC 60601-2-38 standard
- An explanation of the evolution of hospital bed standards including inappropriate standards usages
- An example of an appropriate NRTL 2-38 safety mark.

We believe the Burke Tri-flex II™ and Tri-lift™ beds are two of the relatively few bariatric beds that meet the OSHA requirement of being independently tested to the 2-38 by a NRTL (ETL: Intertec testing lab).

Protect your patients, staff and facility by requiring a 2-38 certification letter from a Nationally Recognized Testing Laboratory (NRTL) for any bariatric bed you rent or buy.