

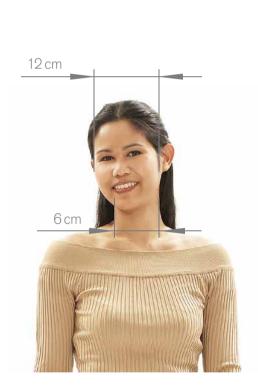
Safer beds

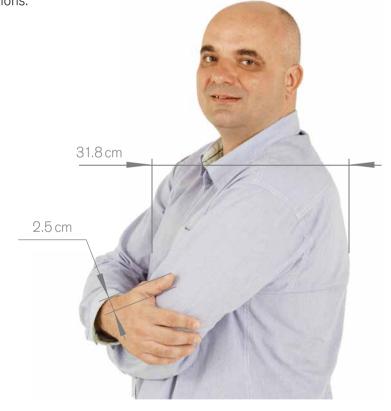
with the EN 60601-2-52 standard

Everyday hazards

...also endanger your patients

Trying to minimise any health risks to the patient/healthcare staff whilst in hospital is one of the top priorities in today's healthcare environment. Adverse events relating to the bed (patient falls, entrapment or pinching) do not only cause financial loss but also endanger reputation. Knowledge of the potential risks and awareness of options available to avoid these constitute the first step towards eliminating such unwanted situations.

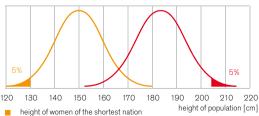




SAFE DIMENSIONS I.

The dimensions are very stringent and extreme. However, they are set so as to protect patients all over the world. To avoid entrapment of a patient's head or neck, the gaps and clearances must be calculated to include all patients internationally, including women from Sri Lanka who are amongst the smallest in the world.

STATISTICAL DISTRIBUTION OF PATIENT **HEIGHT**

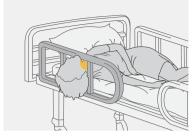


internationally

height of men of the tallest nation internationally

SAFE DIMENSIONS II.

All gap dimensions are defined so that the chest cannot be entrapped or fingers pinched. This takes into consideration even the tallest nation for men, i.e. the Dutch.



HEAD ENTRAPMENT [1]



CHEST ENTRAPMENT [2]



NECK ENTRAPMENT [3]



NECK STUCK [4]



FINGER PINCHING [5]



FALLS OVER THE SIDE RAIL [6]



HEAD ENTRAPMENT [7]



BED INSTABILITY [8]



FOOT/TOE ENTRAPMENT UNDER THE BED [9]



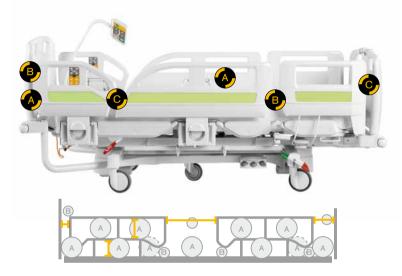
COMPRESSION
IN THE ABDOMINAL AREA [10]

- [1] The head is most at risk if it passes through and is subsequently entrapped in a gap wider than 12 cm. This hazard exists in the side rail gaps or clearances between the side rails and the head board.
- [2] Insufficient clearance (narrower than 31.8 cm) between the side rails or between a side rail and the foot board can lead to a patient's chest entrapment, potentially with fatal consequences.
- [3] + [4] Too large a gap (larger than 6 cm) in the side rail area can cause the soft tissues of the neck to be entrapped and, in the most unfortunate cases, a patient can be asphyxiated. The most hazardous areas are:
 - [3] between a side rail and the head board
 - [4] between a side rail and the mattress
- [5] If the gap between the movable parts of the bed is less than 2.5 cm, a patient's or nurse's fingers may be pinched. Particular attention should be paid to the position of the side rails, head board and mattress (adjustable mattress platform).
- [6] Appropriate protection from falls may be required for disoriented and confused patients. Some causes of patient falls and subsequent injury may include unreliable, too low or insufficiently long side rails.
- [7] A patient's head can be trapped between the mattress and a side rail if this gap is too large. In the most unfortunate situation, this again can lead to patient asphyxiation.
- [8] If a bed is unstable it could tip under the load of a patient or visitor sitting on the side of the bed and injury may occur.
- [9] There is a risk of foot/toe entrapment to both patients/nursing staff when the side rail is in its lowest position and when the TR/ATR position is being adjusted.
- [10] Adjusting the back rest and knee break inappropriately to an acute angle may bring about unwanted complications, especially after abdominal surgery.

EN 60601-2-52 Standard

definition of a safe bed

A number of standards and guidelines exist aimed at enhancing medical bed safety. Currently, the combination of the basic EN 1970 and EN 60601-2-38 standards is being replaced by the latest standard EN 60601-2-52. Beds manufactured to the initial EN 60601-2-38 standard may only be marketed within the EU until 1 December 2012.

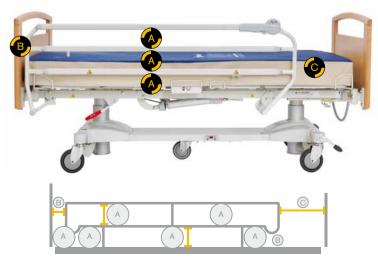


DIVIDED SIDE RAIL

The new EN 60601-2-52 standard is based on thorough analyses of all documented recent adverse events associated with medical beds. This is the most comprehensive and most stringent standard in this area on a global scale.

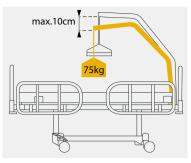


New norm aims especially for the side rails as a basic safety feature of a bed. Side rails primarilly protect the patient against the fall and the design of gaps in or between side rails must not endanger patient's health.

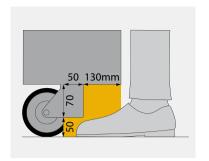


SINGLE SIDE RAIL

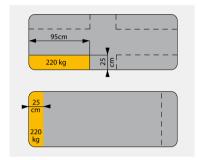
| CLEARANCE | | SAFE VALUE |
|-----------|---|------------------------------|
| A | In the side rails | |
| | Between the side rails, head board and mattress | 12 cm |
| | Between a side rail and the mattress | |
| B | Between a side rail and the head board | 2.5 – 6.0 cm |
| | Between the side rail edge and the mattress | |
| © | Between the side rails | 2.5 – 6.0 cm or > 31.8 cm |
| | Between a side rail and the foot board | |



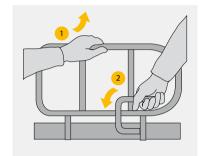
LIFTING POLE DEFLECTION [1]



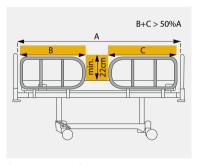
CLEARANCE FOR THE FOOT [2]



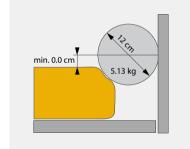
BED STABILITY [3]



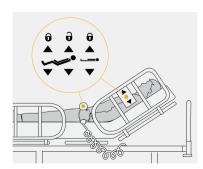
A MINIMUM OF 2 ACTIONS ARE NEEDED TO UNLOCK THE SIDE RAILS [4]



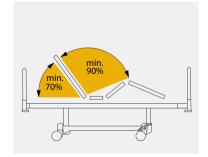
SIDE RAIL HEIGHT [5]



HEAD ENTRAPMENT BETWEEN A SIDE RAIL AND THE MATTRESS [6]



LOCKING OF THE FUNCTIONS [7]



ANGLE FORMED BY THE BACK AND THIGH SEGMENTS [8]

- [1] The trapeze bar must provide a safe and secure support to a patient when they are sitting up. Therefore, the standard stipulates that the Lifting pole deflection under a normal load of 75 kg must not exceed 10 cm.
- [2] A minimum height of 12 cm for safe clearance of the foot must exist under the outer edge of the bed. Further underbed clearance (13 cm) must be a minimum of 5 cm to accommodate shoe toe caps.
- [3] The bed must be stable in any position. Therefore, the standard defines maximum admissible loads in precisely defined zones at the bed edges, including any extension.
- [4] Inadvertent lowering of the side rails can endanger a patient's health. Therefore, any side rail must be provided with a locking mechanism requiring two independent (pressing) actions for unlocking. Adverse events are thereby avoided.
- [5] The standard defines a side rail as safe if its height above the surface of the highest recommended mattress (uncompressed) is 22 cm. It must not be less than 50% of the mattress support platform length (including the maximum bed length extension).
- [6] The head entrapment test between the mattress and a side rail uses a cone 12 cm in diameter and 5.13 kg weight, which must not drop to lower than one-half of its height.
- [7] All beds must be provided with a device that locks all functions on the hand-held controls, therefore preventing any functions of the bed inadvertently being activated.
- [8] The standard stipulates that the back segment angle should be 70° or more for a patient to sit comfortably. The angle between the back segment adjusted to the maximum extent and the thigh segment must exceed 90°

LINET beds

...guarantee of safety

Continuous innovation and safety enhancement are among LINET's main priorities. LINET is one of the first manufacturers to present a complete range of beds complying with all requirements of EN 60601-2-52.

DESIGN

Design is a key stage in respect to the final safety of the bed. This is the main reason why LINET focuses on the innovation and careful design of every detail of the bed.

TECHNOLOGY

Fully automated state-of-the-art technology along with certification of the whole manufacturing process guarantee that the final product always complies with the most stringent safety and quality requirements.

CONTROL, INSPECTION AND TESTING

All products are subject to continual control and testing by LINET's own plant laboratory. The compliance of all beds with EN 60601-2-52 is documented by successfully performed tests and certificates issued by independent testing laboratories.





Dec 2011

Jan 2011

Feb 2012

Clearance between a side rail and the foot board

In series production in compliance with EN 60 601-2-52

Oct 2010

Apr 2012







