

Functional elegance in nursing care

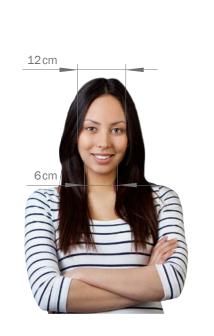


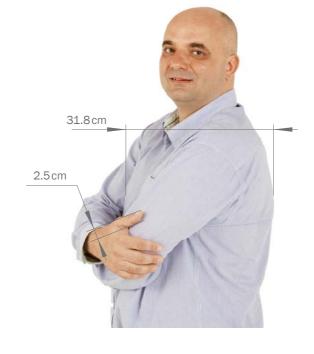
# Safe beds

in accordance with EN 60601-2-52

# Everyday risks related to medical beds

One of the top priorities in today's health care involves minimizing all risks related to resident or patient care in nursing homes and hospitals. Accidents in the bed or bedside (e.g. when a resident/patient\* falls, gets caught or becomes entangled) may result not only in financial damages but may also harm the facility's reputation over the long term. Being aware of such potential risks and knowing how to avoid them are essential when it comes to preventing undesirable situations.

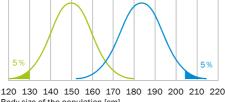




#### Safe dimensions 1.

Requirements for exact dimensions are very high. They are defined in such a strict manner so as to appropriately protect all residents throughout the world. To prevent the head or neck of a resident from getting stuck, gaps and clearances have to be calculated in such a way that they offer protection for all residents on an international scale (e.g. for women from Sri Lanka who are among the smallest worldwide).

### Statistical distribution of residents' body sizes

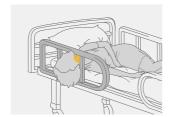


Body size of the population [cm]

- Women of the country with the smallest body sizes Men of the country with the tallest body sizes
- internationally

#### Safe dimensions 2.

All information regarding dimensions of gaps are specified in such a way so that neither the patient's upper body may become trapped nor the fingers may become jammed. As part of that, the smallest and largest body sizes among an international population were also taken into account.



01 Getting the head stuck



03 Getting the neck stuck



05 Getting the fingers stuck



07 Getting the head stuck



09 Getting the foot / toes stuck under the bed



02 Getting the upper body stuck



04 Getting the neck stuck



06 Falling over the side guard



08 Instability of the bed



10 Compression in the abdominal

**01** The resident's head is particularly at risk if it passes through a gap of more than 12 cm and then gets caught. Such a risk exists with respect to gaps in the side guards or clearances between the side guards and the head end of the bed.

02 Insufficient clearances (less than 31.8 cm) between the side guards or between one side guard and the bed's head or foot end may lead to the resident's upper body becoming caught. That can then lead to respiratory distress and serious injuries.

03 + 04 In the case of a gap that is too large (greater than 6 cm) in the area of the side guards, the soft tissue of the resident's neck may become caught, and in the worst case the patient may suffocate. The most dangerous areas are: 03 between the side guard and the head end

**04** between the side guard and the mattress

**05** If the gap between several movable parts of the bed is narrower than 2.5 cm, the resident or the nursing staff may jam a finger. Particular attention should be paid to the position of the side guards, the head end and the mattress (adjustable patient surface).

06 Appropriate protection against falls may be necessary in the case of disoriented and confused residents. A possible cause of falls and resulting injuries include side guards that are unsecured, too low or too short.

07 If the gap between the mattress and the side guard is too large, the resident's head may become lodged in between. That could also lead to suffocation in the worst-case scenario.

08 If a bed is unstable, it could tip over under the weight of the resident, or a visitor who is sitting on the edge of the bed.

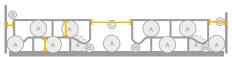
**09** If the side guards are in the lowest position and the TR/ATR position\*\* is set, there is a risk that the resident and nursing staff may get a foot or toes caught.

10 If the back rest and knee bend are set at an angle that is too acute, that may lead to undesirable complications, particularly following surgery in the abdominal area.

### New standard EN 60601-2-52

To enhance the level of safety for beds used for medical purposes in hospitals and nursing homes, the EN 60601-2-52 standard was introduced in 2012 as a mandatory international standard for manufacturers of beds.





Divided side guards



The new EN 60601-2-52 standard is based on a thorough analysis of all adverse events that were documented recently in connection with beds used for medical purposes. It is the most comprehensive and demanding international standard in this sector.



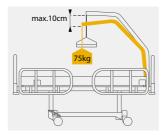
The new standard targets in particular the side guards as a fundamental safety feature for the bed. Side guards especially serve to protect the resident while sleeping or during mobilization.



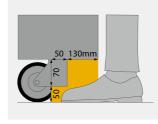
Continuous side guards

### Clearance Safe value Within the side guards Between side guards, head end and ≤ 12 cm Between side guards and mattress Between side guards and head end 2.5 - 6.0 cm Between the edge of the side guards and head end Between the side guards 2.5 - 6.0 cm Between side guards or > 31.8 cm and foot end

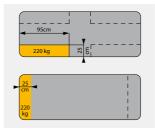
### Definition of a safe bed



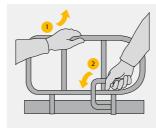
**01** Elasticity of the lifting pole



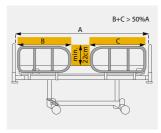
02 Freedom of movement for the feet



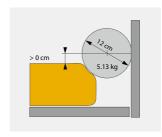
**03** Stability of the bed in terms of not tipping over



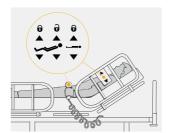
**04** At least two separate actions are required to unlock the side guards



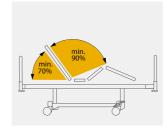
05 Height of the side guards



**06** Head getting trapped between side guard and mattress



07 Blocking of functions



**08** Angle between the back rest and thigh rest

01 The trapeze handle must provide the resident with safe support should the resident wish to sit up in bed. Therefore, the standard stipulates that with a normal load of 75 kg the lifting pole may not sag more than 10 cm.

**02** A safe gap of at least 12 cm in height must be present under the outer edge of the bed in order to provide freedom of movement for the feet. Further beneath the bed (13 cm) an area of at least 5 cm in height has to remain clear for the tips of shoes. Exceptions are possible in the case of low nursing beds.

**03** The bed must be stable in every position. For this reason, the standard defines the respective maximum permitted load for clearly defined areas on the edges of the bed (including all extensions).

**04** An unintentional lowering of the side guards can endanger the health of the resident. For that reason, each side guard must be equipped with a locking device that can only be unlocked with two independent hand movements (pushing movements) in order to prevent adverse events.

05 The standard describes a side guard as being safe when its height above the surface of the highest recommended mattress (without any weight on it) is 22 cm. The side guard must extend across at least 50% of the length of the bed's patient surface (including the maximum patient surface extension).

**06** To examine the risk of getting a head caught between the mattress and side guard, a standardized cone with a diameter of 12 cm and a weight of 5.13 kg is used, and no more than half its height is allowed to slip through.

**07** To avoid an inadvertent activation of bed adjustments, a central locking of all functions must be possible.

08 The standard stipulates that the angle of the back rest must be  $70^{\circ}$  or more so that the patient can sit up comfortably. The angle between the maximum raised back rest and the thigh rest must be greater than  $90^{\circ}$ .

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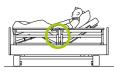
# Safety and customer benefits

### Greater safety without a central gap\* > 60 mm

- Safety in the working position, i.e. even with raised backrest or leg rest.
- Safety without using an additional central gap protector as an accessory
- Safety when using abdominal belts in line with the BfArM\*\* recommendation



Certificate for the central gap issued by BerlinCERT



Compliance with IEC 60601-2-52 with central gap < 60 mm in the working position without a central gap protector as an accessory



Special expertise: Suitable to reduce freedomdepriving measures.

### Patented SafeFree side guard concept

- · With individual adjustment of the height of the side guard
- With the right support angle according to the resident's height





Mobilization with the right support angle based on the resident's size

## Proven safety

Voluntarily, wissner-bosserhoff has its production processes and management audited by TÜV (Technical Inspection Authority) on a regular basis. The company is certified according to the provisions of EN ISO 9001:2008 for quality management systems and EN ISO 13485:2012/AC:2012 for the production of medical products.

Each nursing home bed is produced according to the demanding requirements of the Medical Products Act (abbreviated MPG in German) and each bed bears the CE mark in accordance with EU directive 93/42 EWG and 2007/47/EG. Nursing home beds are certified and produced in accordance with the standard IEC 60601-2-52:2010-12. Recommendations from BfArM (German Federal Institute of Drugs and Medical Devices, Berlin) that go beyond that are taken into account when developing the product.











Certificate for side guards





Inspection label for product certification and auditing

6 'Central gap = distance between the divided side guards "Information for specialists from the German Federal Institute for Drugs and Medical Devices dated 07/08/2004 (Reference No. 913/0704) Wissner-bosserhoff | Safe beds Wissner-bosserhoff | Safe beds





Members of LINET Group

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