

IEC 60601-2-52: Do your beds measure up?

medstrom⁺
Improved Patient Outcomes



The IEC is an independent, not-for-profit organisation that includes 170 countries representing over 99% of the world population. It brings together experts from the private and public sectors.

What does IEC 60601-2-52 apply to?

- IEC 60601-2-52 is one part of a range of standards defining the requirements for the basic safety and essential performance of **all Medical electrical equipment**.
- IEC 60601-2-52 particularly focuses on the design safety for **Adult medical beds**.
- It is important to note that there are many other standards that can be applied to Medical Devices.
- Those standards include requirements for risk management, labelling, electromagnetic safety (electrical interference) and many other aspects of safety.

Did you know?

For medical devices to be certified with a CE mark and a declaration of conformance, they must meet the Medical Device Regulation (MDR).

This is a legal requirement and within this regulation it calls for medical devices to meet the generally acknowledged 'State of the Art' standards. These are defined as the most highly recognised industry standards for its product type.

Post 'Brexit', beds sold in the UK will need to transition to a UKCA mark.



What Do I Need to Know?

IEC60601-2-52 is a standard that is generally considered to be 'State of the Art' for adult hospital beds.

It provides criteria on numerous safety elements and features dimensions for:

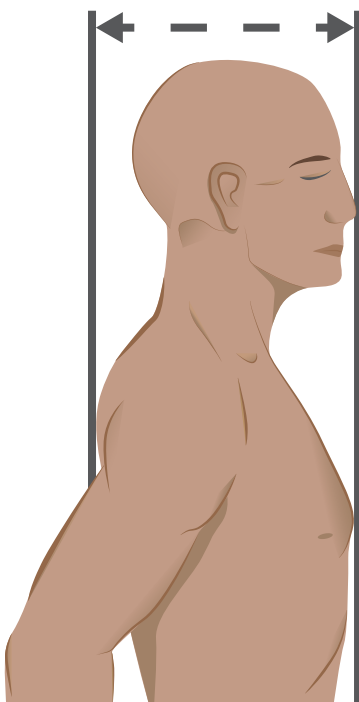
- Reducing the risk of entrapment
- Ensuring lateral stability
- Promoting a safe side rail height

These dimensions, noted by the standard, take into consideration adult patient sizes across the world. The following body parts are associated with each highlighted dimension:

Did you know?

The >31.8cm gap required between the footboard and the end of the side rail, as well as between segmented or split side rails, is based on the 95th percentile male chest depth.

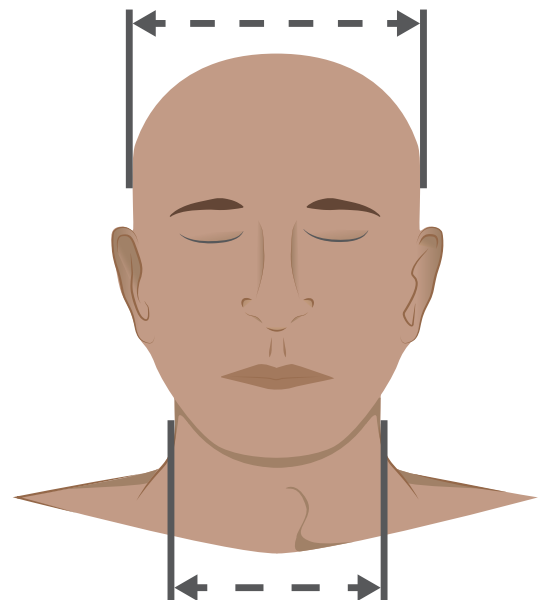
Chest Depth:
31.8cm



Did you know?

The 12cm gap noted between the side rail and mattress platform, plus between side rail bars, is based on the 5th percentile of Sri Lankan female head breadth. This also accommodates for most 1st percentile international references.

Head:
12cm



Neck:
6cm

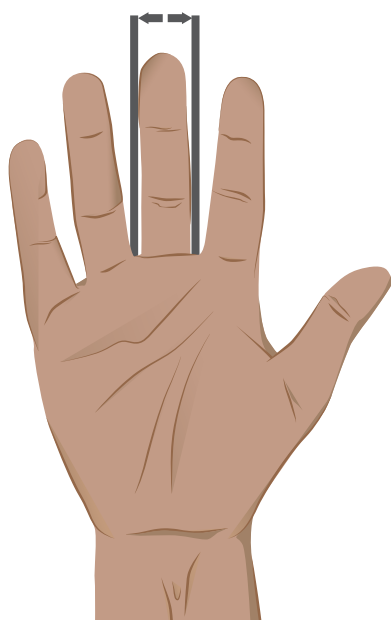
Did you know?

To avoid neck entrapment between bed frame components, a conservative measurement of less than 6cm is used; significantly less than the 1st percentile female neck measurement (7.9cm).

This accommodates for factors such as neck compression, loss of muscle mass in the neck of an ageing patient and the asymmetrical shape of the neck.

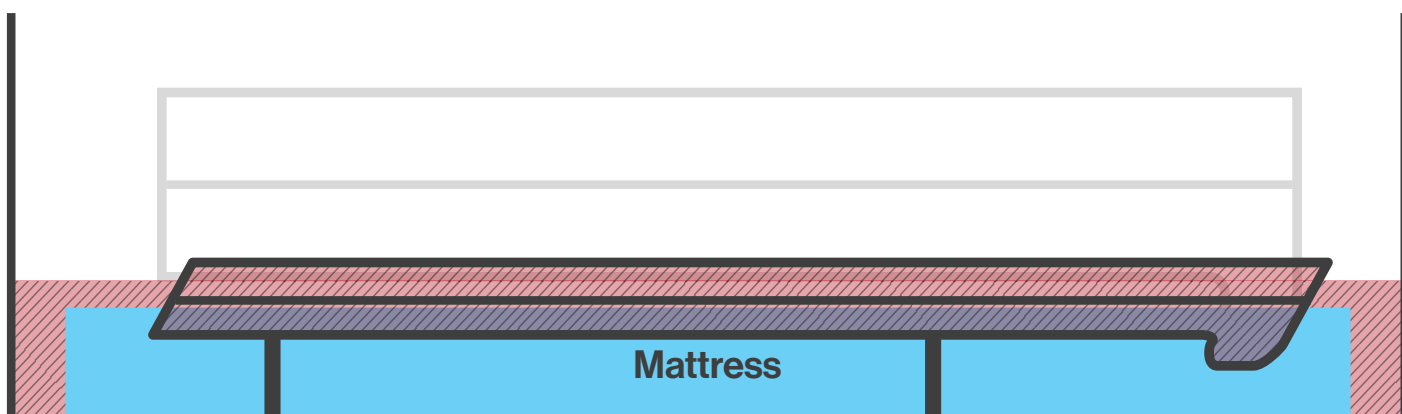


Finger Width:
2.5cm



Distances between moving parts shall always be $>2.5\text{cm}$.

The checked area indicates where these measurements should be considered in order to avoid finger entrapment e.g. in between side rails when folded down.



Side Rail Compliance

According to IEC 60601-2-52, the side rail height must measure 22cm above the mattress support platform along at least 50% of the mattress support platform.

This ensures that the side rails reduce the risk of the patient accidentally slipping or rolling off the mattress.

Did you know?

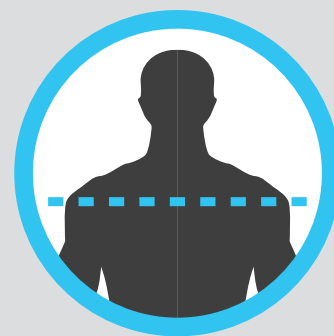
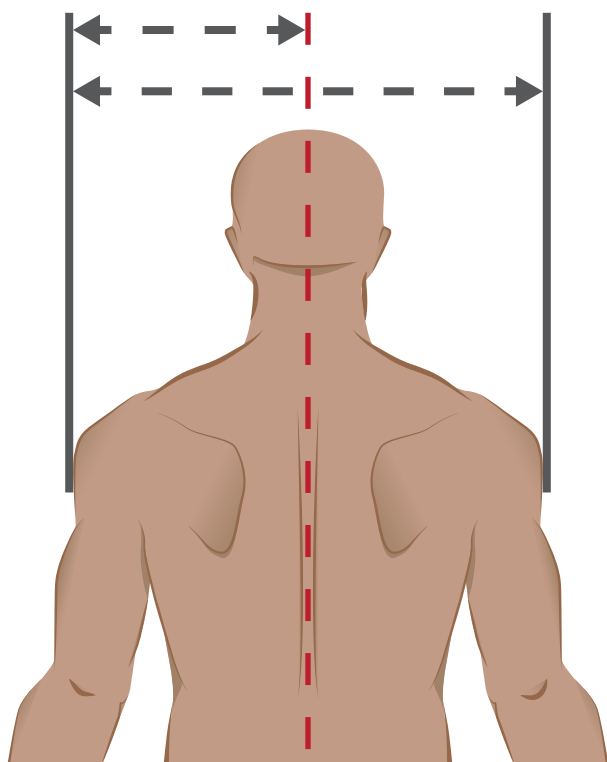
This measurement is half the width of the 95th percentile male chest.

Safe Side Rail Height:

22cm

Chest Width:

44cm



Split side rails are designed with higher and lower points according to their position on the bed. For instance, the highest parts of the side rail will be next to the highest parts of the body e.g. shoulder.



This does not cover all potential risks, so a risk assessment should be completed for each individual prior to using side rails.



If a special mattress or overlay is used and the side rail does not provide 22cm depth, a risk assessment should be completed.

Applying the Measurements

It is important to put these measurements into context, by applying them to the bed frame. Have you checked the measurements on your fleet of beds?

1

Gaps between foot board and end of side rail must be $<6\text{cm}$ or $>31.8\text{cm}$.

2

Gaps between the side rail and mattress platform, plus between side rail bars, must be $<12\text{cm}$.

3

Gap between top of mattress and top of side rail should be $\geq 22\text{cm}$.

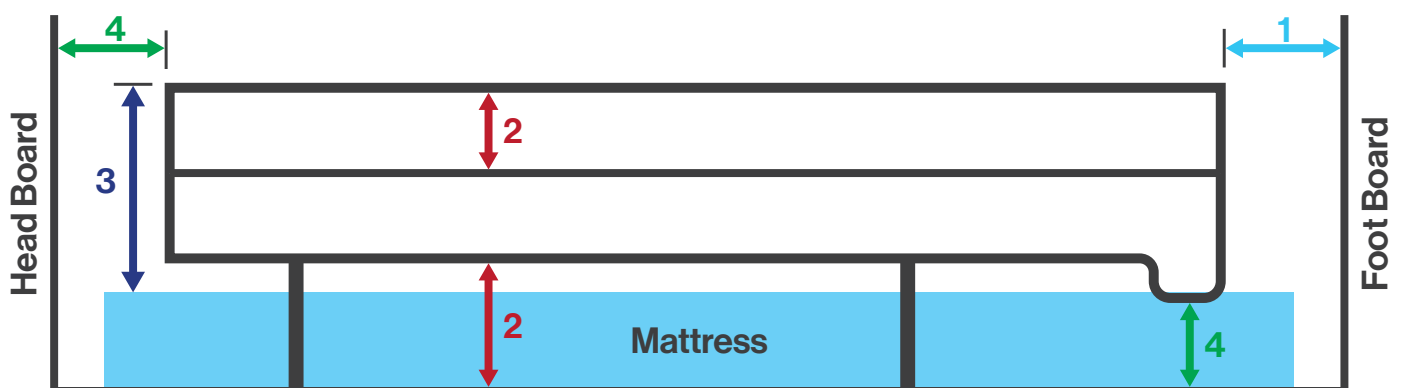
4

Gap between head board and end of side rail, plus smallest gap from side rail to mattress platform, must be $<6\text{cm}$.

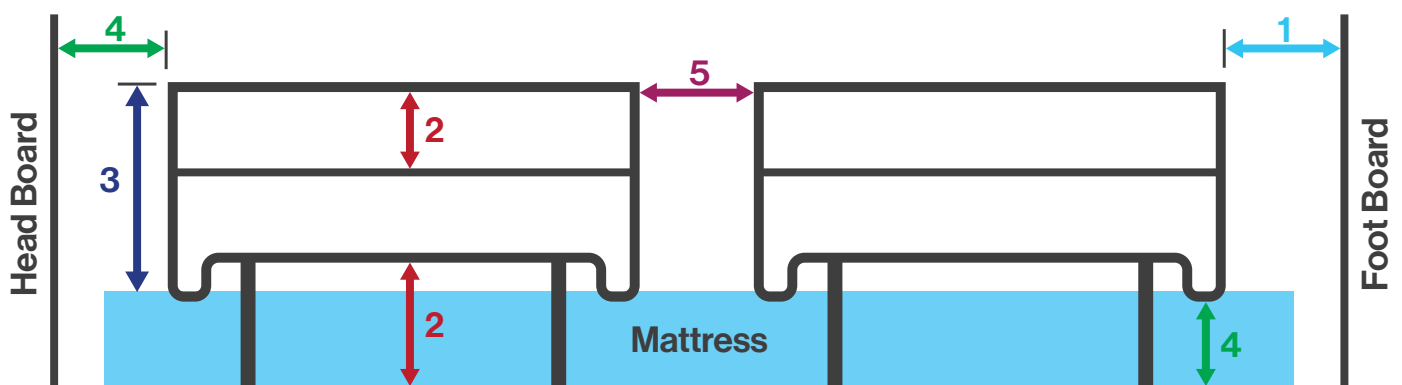
5

Gap between segmented or split side rails, with both rails raised is required to be $<6\text{cm}$ or $>31.8\text{cm}$.

Full Length Side Rails:



Split Side Rails:



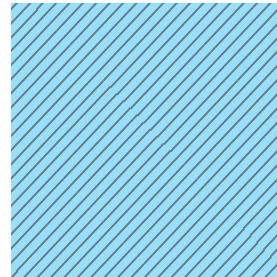
Lateral Stability

220kg (or maximum patient weight if the manufacturer claims it is higher) is to be placed evenly in each corner of the bed without imbalance.

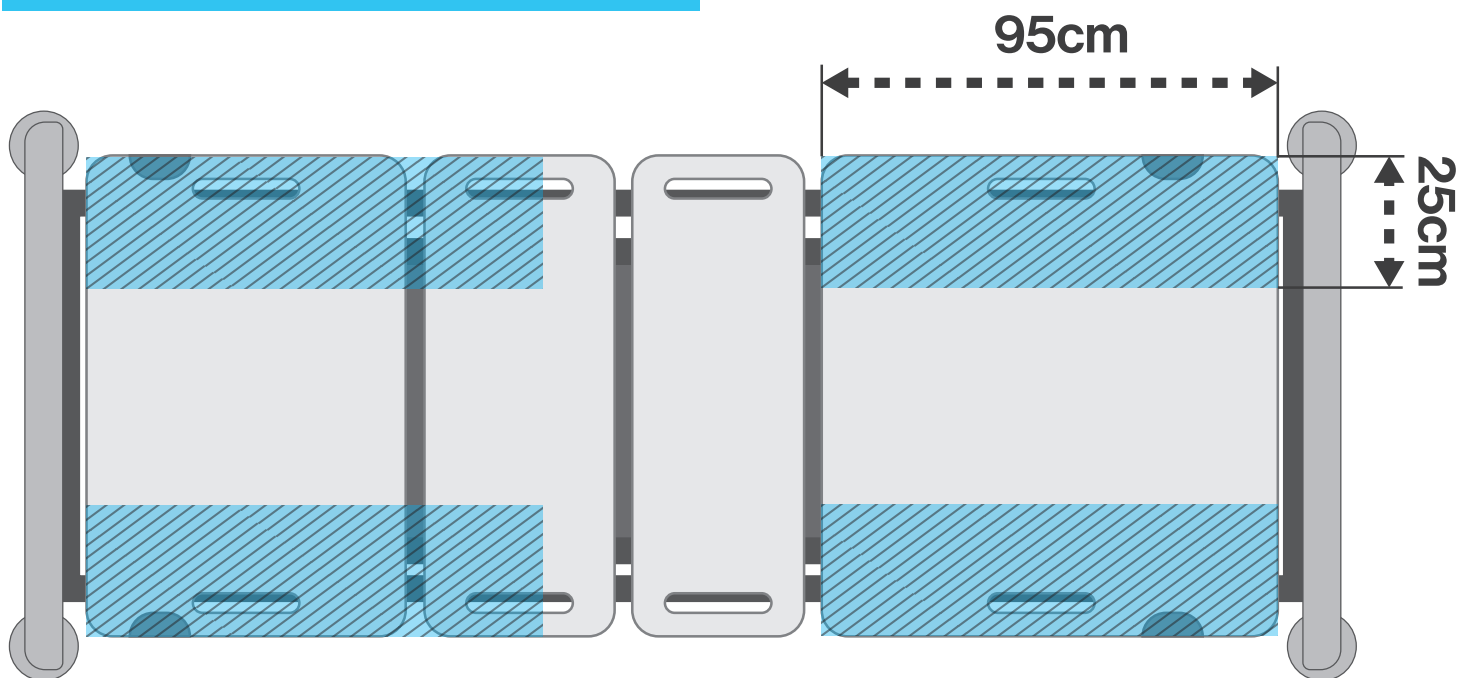
If the maximum **patient** weight according to the **manufacturer** exceeds 220kg, the maximum patient weight is to be used and is evenly distributed over an area 95cm long and 25cm wide. This test mimics having two people sitting on the side edge of the bed, as this is considered to be a reasonable risk.

Did you know?

Safe Working Load (SWL) is the overall load that the bed can accept, taking into account the Maximum Patient Weight (MPW), as well as any additional equipment e.g. mattress & bedding.



Areas highlighted are designed to accept the maximum patient weight.

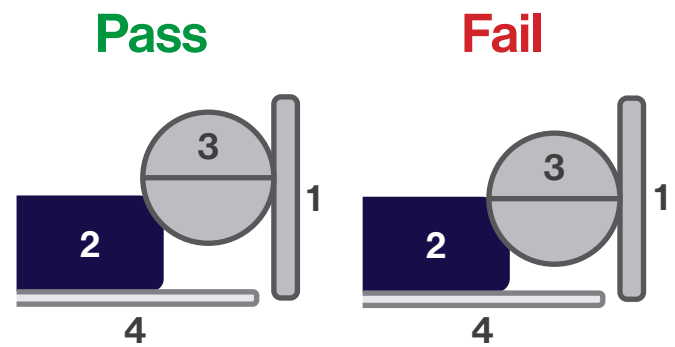


Mitigating Entrapment Risk

The space between the inside surface of the side rail and the mattress (compressed by the weight of a patient's head) should be small enough to prevent head entrapment.

This accounts for:

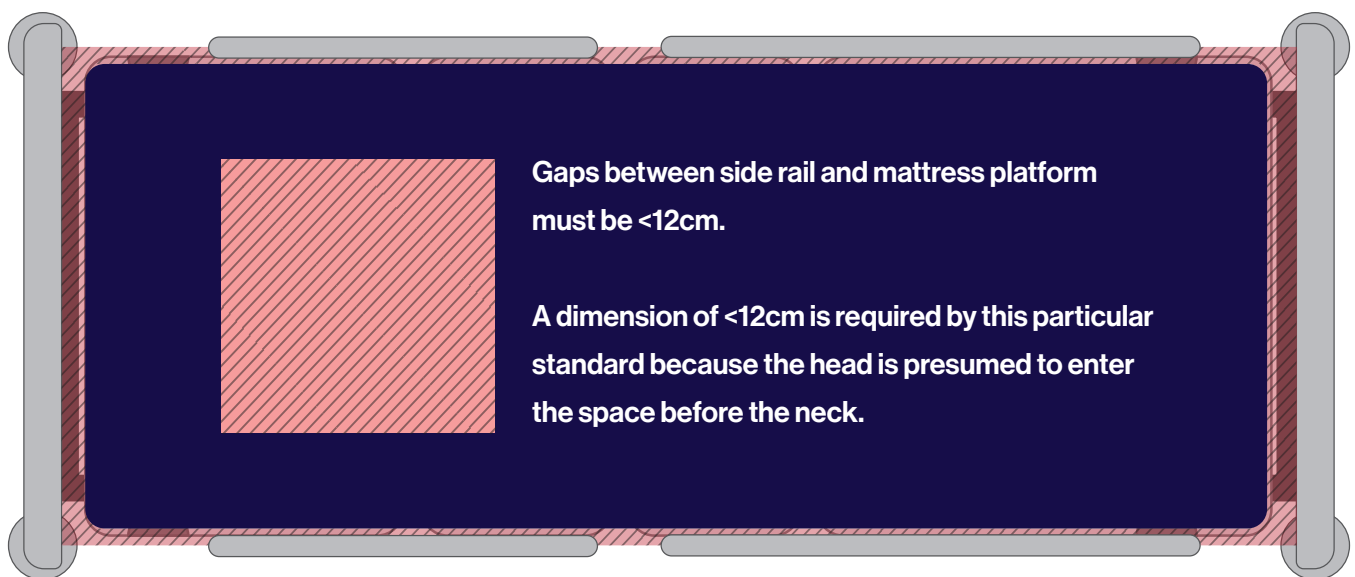
- Mattress compression
- Any lateral shift of the mattress or side rail
- The degree of play from loosened side rails.



Key:

1. Side Rail
2. Mattress
3. Test Cone
4. Mattress Platform

IEC 60601-2-52 calls for a standardised testing cone, that uses the aforementioned measurements, to complete this risk assessment. The diagram below shows where the gaps pass or fail. All manufacturers must provide guidance on the measurements of mattresses that comply with the bed.



medstrom solo[®]

Safety Without Compromise

The Medstrom Solo is a unique bed frame that delivers the functionality of an ultra low bed and a general medical bed all in one, so patients and caregivers are safely supported.

The Medstrom Solo is **fully compliant with IEC 60601-2-52** requirements. This includes a range of side rail options that have been optimised for patient safety.

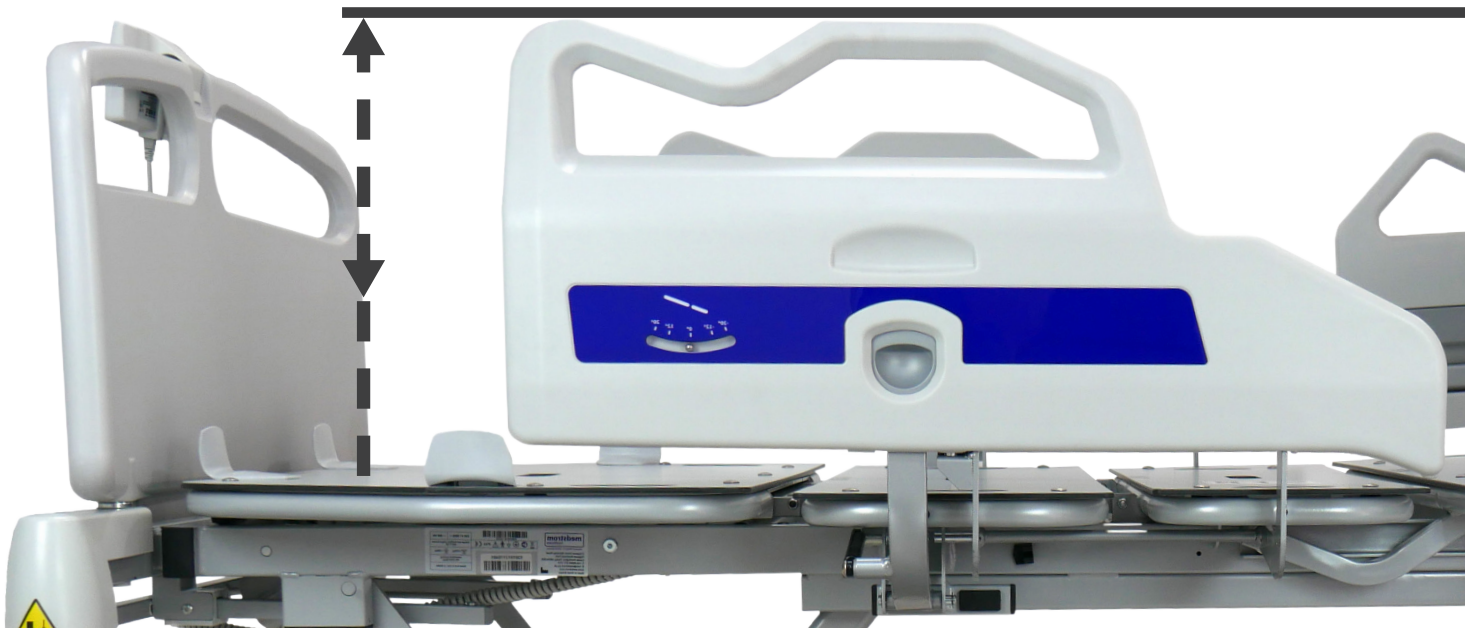
The distance between the mattress platform and top of the side rail is:

- **4 bar Full Length Side Rails – 50cm**
(maximum mattress depth 28cm)
- **Solo Split Side Rails – 42cm**
(maximum mattress depth 20cm)

Did you know?

The Medstrom Solo is the only split side rail, general medical bed on the market that can achieve the same ultra-low height as its full length side rail counterpart (21cm).

Side rail height is optimised for IEC 60601-2-52 compliance for mattresses with a greater depth.



For further guidance, or for clinical & technical support, contact Medstrom:

Tel: +41 26 323 20 30
Email: info@medstrom.ch