Safe use of bed rails

[month] 2019 Version 3.0

Produced by Devices Safety and Surveillance

Contents

Revision History

Version	Date Published	Changes
V3.0	TBD	Layout and format updated. New images added for risk areas. Content altered to reference BS EN 50627. Content updated to reflect changes in reported incidents and common queries.
V2.1	December 2013	New MHRA logo
V2.0	November 2012	Referenced updated standards
V1.0	December 2006	Original document

1. Executive Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) continues to receive reports of incidents relating to bed rails and associated equipment. These incidents are of concern as several have resulted in patient harm or death, primarily from entrapment.

This publication has been updated to reflect changes in devices and practices, as well as information gained from the investigation of adverse incidents.

Who this document is for:

This document is aimed at all users, carers and staff with responsibility for the provision, prescription, use, maintenance and fitting of bed rails. This includes:

- Medical Device Safety Officers (MDSOs) for onward distribution
- care home managers and staff
- carers in the community and care-at-home staff
- community equipment stores (CES) and loan store managers
- health and safety or risk managers
- hospice managers and staff
- maintenance staff
- nurses in hospitals and the community
- occupational therapists
- physiotherapists
- those responsible for purchasing beds and bed rails

Scope

This document identifies areas for safe practices, so that policies and procedures can be reviewed and put in place. This includes:

- risk management
- management responsibilities
- meeting legal requirements
- training
- planned preventative maintenance.

It also identifies areas of good practice, such as:

- checking and ensuring that a bed rail is necessary
- the need for good communication between bed occupant and carers or staff
- compatibility of the bed rail and bed, mattress and occupant combination
- taking into account the use environment and possible interaction with any other equipment or devices present in that environment
- correct fitting and positioning of the bed rails initially and after each period of use
- re-assessing for changing needs of the bed occupant.
- the need for risk assessment before the provision and use of bed grab handles.

This document is not intended to replace clinical decision making.

2. Introduction

Bed rails are used extensively in acute and community care environments to reduce the risk of bed occupants falling out of bed and injuring themselves.

However, MHRA continues to receive reports of adverse incidents involving these devices. The most serious of these have led to injury and death by asphyxiation after entrapment of the head or neck.

Most incidents occurred in community care settings, particularly in residential and nursing homes. These could have been prevented if adequate risk assessments and appropriate risk management had been carried out.

NHS ‘Never events’ are defined as ‘serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. NHS ‘Never events’ number 11 (1) covers chest or neck entrapment in bed rails.

Bed Rails

For the purpose of this document the term **bed rail** will be adopted, although other names are often used, e.g. bed side rails, side rails, cot sides, and safety sides.

In general, manufacturers intend their bed rails to be used to prevent bed occupants from falling and sustaining injury. They are **not** designed or intended to limit the freedom of people by preventing them from intentionally leaving their beds; nor are they intended to restrain people whose condition disposes them to erratic, repetitive or violent movement.

They may be CE marked as medical devices to the Medical Devices Regulations (2), in combination with, or as an accessory to the bed if their intended use meets the definition of a medical device.

Rigid bed rails can be classified into **two basic types:**

- **integral** types that are incorporated into the bed design and supplied with it or are offered as an optional accessory by the bed manufacturer, to be fitted later.

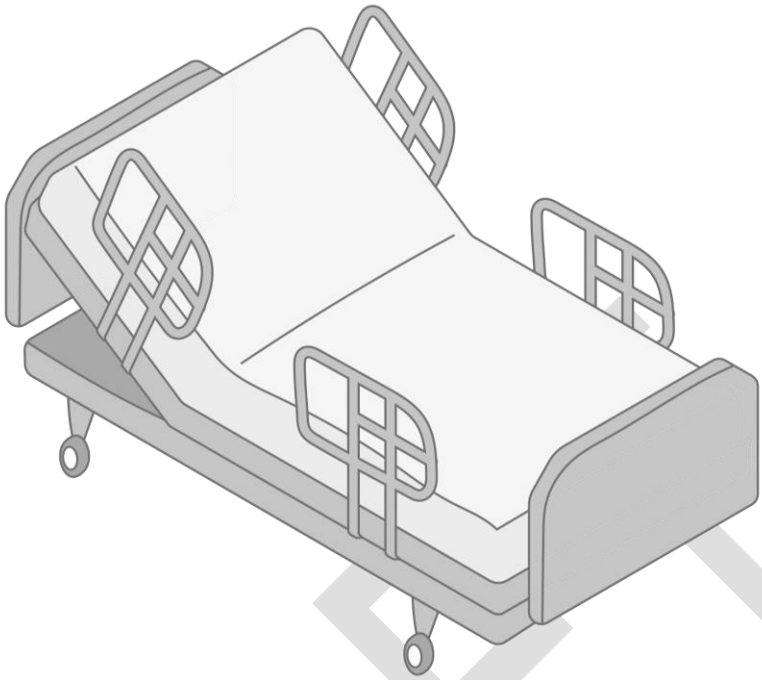


Figure 1 - Example of an integral bed rail

- **third party** types that are not specific to any particular model of bed. They may be intended to fit a wide range of domestic, divan or metal framed beds from different suppliers.

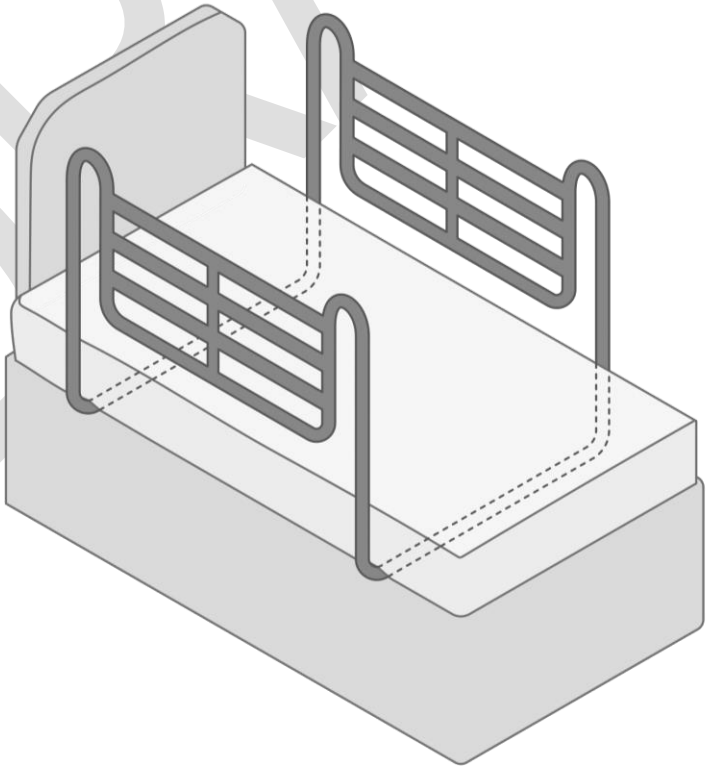


Figure 2 - Example of a 3rd-party bed rail

The integral type is involved in far fewer adverse incidents than the third-party type. Bed rails should meet recognised product standards that include acceptable gaps and dimensions when fitted to the bed (See Legislation and Standards).

Bed Grab Handles

Bed rails, which fit under the mattress or clamp to the bed frame should not be confused with **bed grab handles** (also known as bed sticks) which are designed to aid mobility in bed and whilst transferring to and from bed.

Bed grab handles can pose the same hazards to users as bed rails, and their use should be considered carefully and risk assessed.

Bed grab handles are **not** designed to prevent patients falling from their bed. Bed grab handles come in a variety of sizes and designs (Figure 33). They should not be used as, or instead of, bed rails.

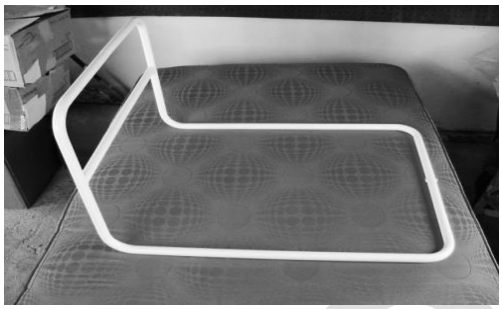


Figure 3 - Example of a bed grab handle

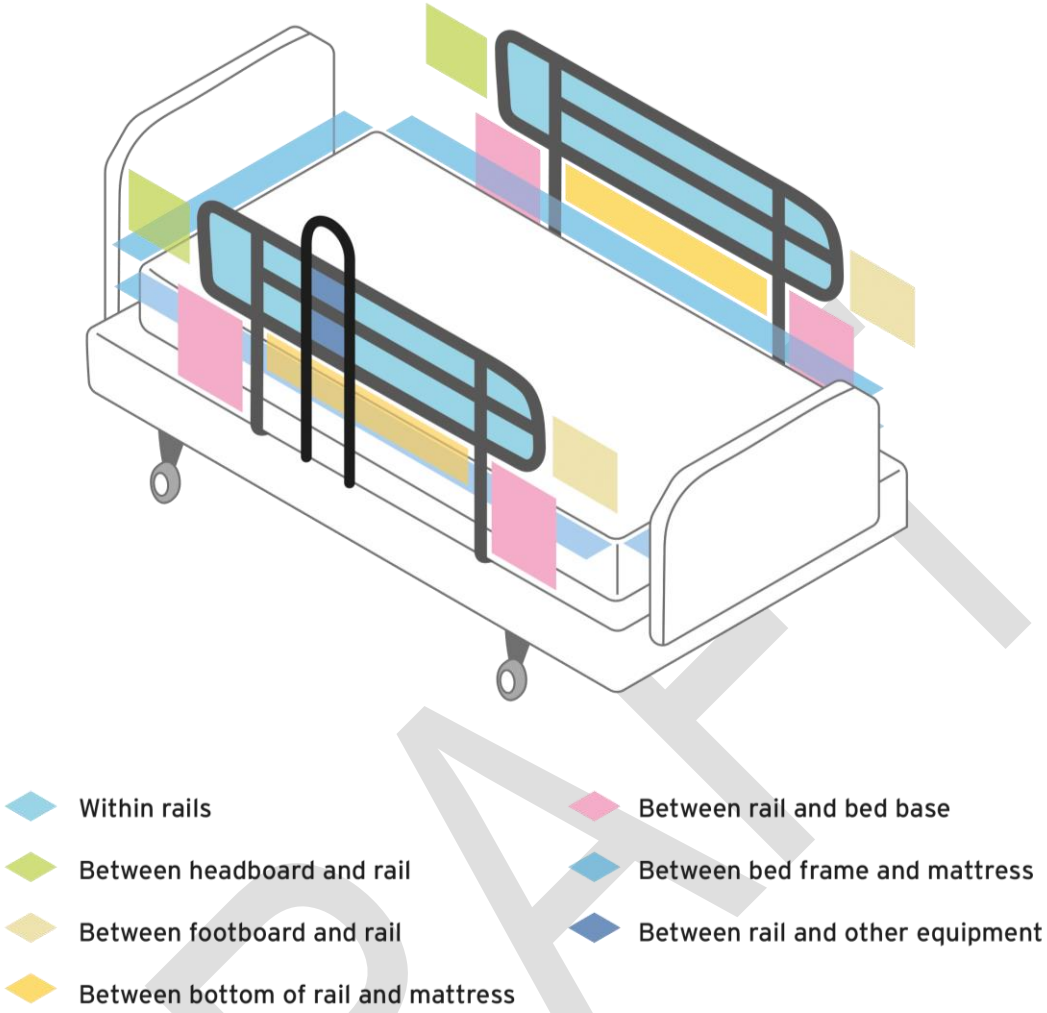
Other Devices

Bed rails are often used at the same time as medical devices or equipment. This would naturally include a bed frame and a mattress. Other bed equipment could include pressure-relieving surfaces either passive or active, or other systems such as monitoring equipment depending on the patient's needs.

The decision to use bed rails should always consider the patient environment and what other equipment is or may be present.

Hazard and areas of risk

The use of bed rails is associated with a number of **direct and indirect risks** to patients. Direct hazards include entrapment and entanglement either within gaps in the rails themselves, between the rails and the mattress or between the rails and the bed frame. In the most serious cases, this has led to asphyxiation and death of bed users if they have trapped their head between rails or been unable to free themselves from a position and suffered postural asphyxiation. Severe limb damage has also been reported in cases where someone has become entangled in bed rails. Figure 4 shows the main areas of the bed-bed rail system where entrapment may occur.



164

165 **Figure 4 - Bed rail entrapment areas**
166

167 Indirect hazards are also present: cases have been reported where bed users have been confused
168 or disoriented and have tried to exit the bed by climbing over the bed rails. Users have then fallen
169 from a greater height than would otherwise be the case, increasing the severity of injury.

3. Risk management and use assessment

Risk management

When medical devices are prescribed, issued or used, it is essential that any risks are balanced against the anticipated benefits to the user.

Where manufacturers cannot remove risks during the design process, subsequent warnings of any remaining acceptable risk should be clearly displayed in the user instructions and product markings. Any such warnings or limitations to use, including the necessary maintenance schedules throughout its intended life, should be considered by prescribers, passed on to all users and carers of the equipment and steps taken to ensure that they are understood and complied with.

Users, carers and prescribers need to follow the manufacturer's instructions for use and any warnings about associated risks. The equipment should only be used and maintained in line with the manufacturer's instructions for use.

Risk assessment

There are many bed rails on the market, having a variety of fitting and operation methods.

The possible combinations of bed rails, beds and mattresses (and other equipment in the environment), together with the differences between bed occupants, means that **a careful, thorough and individual risk assessment is necessary if serious incidents are to be avoided.**

Risk assessments should be carried out before the initial prescription of bed rails and then reviewed and recorded after each significant change in the bed occupant's condition, replacement of any part of the equipment combination and regularly during its period of use, according to local policy.

It is unlikely that one type of bed and bed rail will be suitable for a wide range of users with different physical sizes and needs.

The points to consider during a risk assessment include:

- is the person likely to fall from their bed?
- if so, are bed rails an appropriate solution or could the risk of falling from bed be reduced by means other than bed rails (see Alternatives to bed rails)?
- could the use of a bed rail increase risks to the occupant's physical or clinical condition? (See Case Study 1)

Our adverse incident investigations have shown that the physical or clinical condition of bed occupants means that some are at greater risk of entrapment in bed rails. Those at greater risk could include older people, adults or children with:

- communication problems or confusion
- dementia
- repetitive or involuntary movements
- impaired or restricted mobility.

Risk assessments should account for any patient characteristics which might put them at greater risk from use of bed rails.

CASE STUDY 1 – Inappropriate prescription leading to fall
A bed occupant died after climbing over the bed rails and falling. The user accessed the bed position control and raised the bed to its maximum height. They then tried to exit the bed by climbing over the rail, only to fall and suffer a broken neck. The additional height likely increased the severity of the injury.
Advice – If patients are known to be in a confused state, then bed rails may serve to increase the overall risk of injury. A complete risk assessment should have identified the hazard of leaving bed controls accessible and the potential for an increased fall height.

We provide an example of a risk assessment checklist, as a result of feedback from users of bed rails and the findings of adverse incident investigations in Appendix 1 – Example adult risk assessment checklist.

Please note that it should not be adopted or used without adequate consideration of a specific bed occupant's needs and local policies.

The checklist should be used in conjunction with the guidance in this document, together with the judgement of the nurse, therapist, user and carer involved.

4. Purchase and selection

Purchase

Adjustable or profiling beds usually have compatible integral type bed rails available from the manufacturer; these are preferable to other systems that may not fit as well. In all cases it is essential that the selection process follows a risk assessment considering the needs of the bed occupant and the use environment.

Third party bed rails require particularly careful selection.

If bed rails are being purchased for stock, general factors can be considered at the purchase stage:

- the types of bed they are likely to be used on; specific models or range
- whether they meet any recognised product standards regarding dimensions, (see

Is the bed rail to be used with a typically sized adult bed occupant?	☐ Yes ☐ No
Has the bed rail been inspected and maintained regularly, if previously used?	☐ Yes ☐ No
Does the manufacturer/supplier provide any information on special considerations or contra-indications?	☐ Yes ☐ No
Do you have enough information from the supplier to be able to select and fit the bed rail appropriately?	☐ Yes ☐ No
Is the bed rail suitable for the intended bed, according to the supplier's instructions?	☐ Yes ☐ No
Do the fittings or mattress allow the bed rail to be fitted to the bed securely, so that there is no excessive movement?	☐ Yes ☐ No
Does the benefit of any special or extra mattress outweigh any increased entrapment risk by the bed rails created by extra compression at the mattress edge?	☐ Yes ☐ No
Are the bed rails high enough to take into account any increased mattress thickness or additional overlay?	☐ Yes ☐ No
Have you made sure that there no gaps present that could present an entrapment risk to any part of patient's body? • between the bars of the bed rails? 120 mm max • through any gap between the bed rail and side of the mattress? 120 mm max • through the gap between the lower bed rail bar and the mattress, allowing for compression of the mattress at its edge? 120 mm max	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
Is the headboard to bed rail end gap less than 60 mm?	☐ Yes ☐ No

‘Yes’ boxes indicate the desired outcome. If any ‘No’ box has been ticked, there may be a serious risk of entrapment with the proposed combination. Review immediately.

Risk assessments should be carried out before use and then reviewed and recorded after each significant change in the bed occupant’s condition, replacement of any part of the equipment combination and regularly during its period of use, according to local policy.

- Appendix 2 – Bed rail dimensions in BS EN 60601-2-52 for additional information
- whether they are suitable for children or small adults
- the instructions for use should contain information on the selections of the mattress, including dimensions and characteristics, to reduce the risk of entrapment. They should also contain information on compatibility with other equipment.

Selection

In all cases it is essential that the selection process still follows a risk assessment considering the needs of the bed occupant.

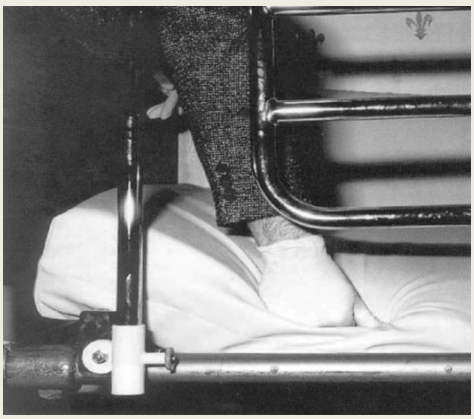
In community care environments it is common for beds and bed rails to have been acquired from different sources. Often bed rails from unknown sources are found to be in use and in many cases they have been found to be unsuitable or unfit for purpose.

Bed rails for divan beds (domestic) are nearly always a third-party type, not tailored for one specific bed or mattress length and width, or a specific mattress density.

CASE STUDY 2 – Unsuitable combination of a bed and a bed rail

A bed rail intended for use on a domestic divan bed was used on a hospital type bed. This produced a large gap between the bottom of the bed rail and the bed when the mattress was compressed.

A child slipped feet first between the bed rail and the bed. The gap was not large enough for the child to pass completely through and the child was trapped at chest level and died from postural asphyxiation.



Advice – When supplied, the suitability of the installation should be checked including following the instructions for use regarding compatibility with other devices.

Alternatives to bed rails

Alternatives to bed rails may be considered, such as:

- ‘netting’ or mesh bed sides
- ultra ‘low height’ beds that minimise the risk of fall injuries
- positional wedges to reduce movement across the bed
- alarm systems to alert carers that a person has moved from their normal position or wants to

get out of bed.

- fall mats that can be placed beside the bed to reduce the severity of the impact if the bed occupant does fall

Each of these options may act to introduce different hazards even as they reduce the risk of bed fall injury or the risk from bed rails, and so should be managed appropriately.

5. Correct fitting

Fitting and use

It is essential that all bed rails can be fitted correctly allowing safe use to an appropriate bed base. Aspects to consider at the start of the fitting process will include points such as:

- can the bed rails be fitted to the bed correctly?
- do staff understand how to fit it properly?
- are mounting clamps, if present, used in the correct orientation and in good condition?
- is there a gap between the lower bar of the bed rail and the top of the mattress or does the mattress compress easily at its edge which could cause entrapment?
- is there a gap between the bed rail and the side of the mattress, headboard or footboard that could trap the bed occupant's head or body?
- is the bed rail secure and robust – could it move away from the side of bed and mattress in use, creating an entrapment or fall hazard?
- do the dimensions and overall height of the mattress(es) compromise the effectiveness of the bed rail for the particular occupant – are extra height bed rails needed?

CASE STUDY 3 – User entrapment in inappropriate gaps

Entrapment can happen between the end of the bed rail and the headboard if the gap is inappropriate. Avoid gaps over 60 mm which could be sufficient to cause neck entrapment.

Entrapment can also occur in the space between a poorly fitting mattress and side of the bed rail or bed rail that does not fit the bed base snugly enough.

The compressible nature of the edge of most mattresses can contribute towards the entrapment risk.

Advice – Assess the possible gaps between rails and other equipment, particularly in the high-risk areas shown in Figure 4 during the rail fitting process.

What to avoid

From our investigations, the MHRA has identified a number of issues that, if they had been avoided during the selection process, may have reduced the likelihood of adverse incidents occurring. For example, **avoid:**

- gaps of over 60 mm between the end of the bed rail and the headboard which could be sufficient to cause neck entrapment.
- gaps over 120 mm from any accessible opening between the bed rail and the mattress platform

- using bed rails designed for a divan bed on a wooden or metal bedstead; this can create gaps which may entrap the occupant
- using insecure fittings or designs which permit the bed rail to move away from the side of the bed or mattress, creating an entrapment hazard
- using only one side of a pair of third-party bed rails when the other side is against a wall – the single rail may be insecure and move
- mattress combinations whose additional height lessens the effectiveness of the bed rail and may permit the occupant to roll over the top. Extra height bed rails are available if mattress overlays are to be used
- mattress and bed rail combinations where the mattress edge easily compresses, introducing a vertical gap between the mattress and the bed rail.

The length, width and height of the mattress should be checked to ensure that these dimensions are within the limits specified by the bed manufacturer and do not introduce gaps that could increase the risk of entrapment. If the mattress is not the right size, the bed rails may not fit properly and create entrapment gaps.

Training

Suitable evaluation of a patient before providing a bed rail is a skill. Organisations responsible for the provision, installation and maintenance of rails should ensure that those carrying out these tasks are appropriately trained in the competent use of these devices, in the skills needed to properly conduct a risk assessment in accordance with local policy and that they understand the risks posed by this equipment.

Organisations should develop processes to ensure that staff are appropriately trained and that risk assessments are carried out and recorded to a suitable standard.

6. Special Considerations

Use in the community

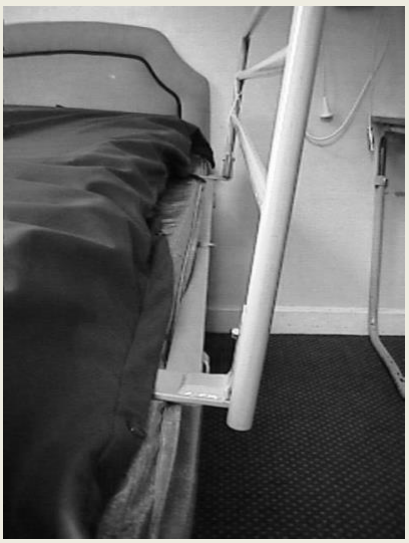
The majority of reported injuries relating to bed rails are now from incidents that take place in community settings.

Use of bed rails in the community comes with additional challenges. There may be greater variability in available equipment, and the quality of maintenance is often poorer than in hospitals. Those responsible for day to day care may be less aware of the serious risk that can be present with improper use of bed rails. Any risk assessment is likely to be less thorough and less frequent than in more intensive care settings, and any subsequent changes in the patient situation and the associated risks may mean greater chance of inappropriate bed rail use.

Wherever bed rails are used to reduce fall risk, a complete risk assessment should be made, and the rails should be regularly assessed for suitability and for correct function. Carers should be aware of the risks, should have access to the instructions for use supplied devices and should know when to carry out or request reassessment.

CASE STUDY 4 – Mattress too light to keep bed rail in correct position

Some designs rely on the weight of the divan or standard mattress to keep the bed rails in position. A lighter mattress can allow the rails to move away from the side of the bed, creating an entrapment gap, or can allow the rails to fall off the bed completely.



Advice – Check the compatibility of any installed equipment, the suitability of this for the patient and that all these devices are fitted correctly.

Use with children

The majority of bed rails on the market are designed to be used only with adults over 1.5 m in height (4’ 11”), which is also the height of an average 12-year-old child. A risk assessment should always be carried out on the suitability of the bed rail for the individual child or small adult, as bar spacing and other gaps will need to be reduced.

When purchasing or making assessments of bed rails for children, seek guidance on suitable rails from the manufacturers and assess their compatibility with the size of the individual and the specific circumstances of use.

A new standard for medical beds for use with children has been published: it is not yet clear how many products are available that comply with the standard (See section Standards).

It is recommended that all gaps between the rail bars should be a maximum of 60 mm.

CASE STUDY 5 – Insufficient risk assessment which failed to account for the user's body size

A bed rail was supplied to the parents of a child being cared for in the community. No assessment of the child's physical size was carried out to determine if an entrapment hazard existed: in this case the gap between the horizontal bars of the bed rail was too large. The child slipped between the bars and asphyxiated as a result of head entrapment.

Advice – Risk assessments should include an evaluation of the suitability of the equipment for the physical characteristics of the intended user.

Adjusting or profile beds

Most adjustable and profiling beds feature integral bed rails that are incorporated into the bed design or are offered as an optional accessory by the bed manufacturer. We have found they are involved in far fewer adverse incidents than the third-party type.

The bed rails will be CE marked to the Medical Devices Regulations (2) in combination with, or as an accessory to, the bed.

Some beds have a single-piece bed rail along each side of the bed; these require care in use because when the bed profile is adjusted entrapment hazards can be created, which are not present when the bed is in the horizontal position.

Split bed rails (one pair at the head end and one pair at the foot end) also require care in use because the space between the head and foot end rails may vary according to the bed profile adjustment. Therefore, on some designs, entrapment hazards may be created when the bed is adjusted to profiles other than flat.

Care should be taken to use the rails as instructed by the bed manufacturer.

Active mattresses, hybrid mattresses and mattress overlays

Active, dynamic or hybrid mattresses or mattress overlays may be prescribed in order to reduce the risk of pressure injury. As these will raise the resting level of the user relative to the top of the

bed rail, the effective height of the rail will be reduced. In turn this may increase the risk of the patient falling from bed. Highly compressible surfaces may also create additional entrapment hazards.

The bed, mattress and rail system should be assessed in all configurations as these risks may not be obvious in a single arrangement. The risk assessment should consider the 'worst case' condition in particular: for example, the effective height of the top of the bed rail with the bed plus a fully inflated active mattress.

Before and during use of specialist mattresses with bed rails, consider:

- the reduction in the effective height of the bed rail relative to the top of the mattress may allow the occupant to roll over the top of it; extra height bed rails may be required
- the risk of entrapment in the vertical gap between the side of the mattress and the bed rail may be increased with an easily compressible overlay and/or mattress edge
- if the standard mattress is replaced with an air mattress or lightweight foam mattress, third party bed rail assemblies (including the mattress and bed occupant) can tip off the bed when the bed occupant rolls against the bed rail. This is because many third-party bed rails rely on the weight of a standard mattress to hold the assembly in place.

CASE STUDY 6 – Bed occupant fell over the top of the bed rails after additional equipment installed

A pressure ulcer reduction overlay was added to a bed that already had a bed rail fitted. The additional height of the combined mattress/overlay reduced the effectiveness of the bed rail. The bed occupant fell over the rail, sustaining a serious head injury.

Advice – Risk assessments should be revised when substantial changes to the bed system are made. Particular attention should be given when the effective height of the bed rail may be compromised.

The risk assessment should consider the whole patient environment and possible interactions between any equipment that is in that environment.

Inflatable bed sides and bumpers

Inflatable or padded bed sides are not generally adjustable and may need to be used with a mattress and bed rails of particular dimensions. It is therefore important not to change the mattress or bed rails from the size or specification recommended by the manufacturer, to avoid creating entrapment gaps and instability. Inflatable rails may change shape when the bed occupant leans against them and this should be taken into account when carrying out the assessment of the risk of entrapment.

Some inflatable or padded bed sides house the mattress in its own ‘pocket’ or compartment, a feature which greatly reduces entrapment risks between the mattress and the side walls.

Inflatable bed sides need to be fully inflated to be effective. They may deflate over time so regular checks should be made to ensure this has not happened.

Care should be taken to use inflatable and padded bed sides correctly, as specified in the manufacturer’s instructions for use.

Bed rail bumpers, padded accessories or enveloping covers are primarily used to prevent impact injuries, but they can also reduce the potential for limb entrapment when securely affixed to the bed or rail, according to the instructions for use. However, bumpers that can move or compress may themselves introduce entrapment risks.

7. Maintenance

Ongoing use

Bed and bed rail devices may have a useful lifetime measured in years and might be used in various locations with many different patients. Manufacturers should specify how devices should be maintained so that they remain in good working order and continue to be safe to use.

Maintenance

MHRA adverse incident investigations have revealed that some incidents with bed rails have been caused by inadequate maintenance. Bed rails should be included in planned preventative maintenance schemes.

Bed rails should be maintained in accordance with the manufacturer's recommendations in the instructions for use. Examples of common types of damage include:

- Adjusters, clamps and fixings can wear, work loose, crack, deform or be missing completely, giving rise to unwanted free play which can increase important gaps.
- Material fatigue can also occur. Bed occupants who rattle the bed rails can exacerbate this tendency.
- Telescopic components can become loose or jammed, discouraging correct adjustment.
- Plastic components can degrade due to age, exposure to light and some cleaning chemicals.
- Poor transport and storage can also cause damage to components.
- Duvets, blankets, sheets and valances may need to be removed to check these areas properly.

Bed rail assemblies should be traceable, for example by using the manufacturers serial number, the Unique Device Identification number (when available), a system like Scan4Safety or labelling with an in-house number. This will assist in ensuring that every device is regularly inspected and maintained in a satisfactory condition. Traceability also allows devices to be suitably identified should a safety issue arise, such as a manufacturer recall due to a fault. Records should be kept of inspections, repairs and maintenance completed on bed rails. Suppliers of the bed rails should be contacted for advice and replacement parts.

Bed rails found to be unsuitable or in poor condition should be withdrawn from use and appropriately destroyed. If they are kept or stored, MHRA has received incident reports of them finding their way back into use.

When not in use, bed rails should be stored in matched pairs in a suitable area where they will not get damaged.

CASE STUDY 7 – Bed rails in poor condition from lack of maintenance

A care home had fitted third-party bed rails to a resident's divan bed. One of the bed rails moved away from the side of the bed, creating a gap in which the resident became trapped and died as a result.

On inspection, the locking mechanism to secure the bed rails against the sides of the bed (under the mattress) was missing.

Advice – This incident could have been prevented if appropriate installation and maintenance checks had been in place, and if users were more aware of the correct configuration of the device.

Follow the instructions for use supplied by the manufacturer. Typical aspects to check during planned maintenance include:

- presence of rust – this can affect the ease of adjustability of telescopic tubes
- welded joints are sound, not showing signs of cracking or failure
- cracking of paint or coating – can point to deeper structural failure
- flaking or peeling chrome plating – can cause lacerations
- missing locking handles and fixing clamps, clamp pads and other components
- loose fixings – these affect the rigidity of the assembly. Nuts should be of the self-locking type
- free play in joints – this can point towards loose, worn or incompatible components
- stripped threads on bed frame clamps – does not allow them to be tightened securely
- bent or distorted components
- damaged plastic components
- intact labelling

For more information on this topic, refer to our publication 'Managing Medical Devices' (3).

8. Legislation and Standards

Health and Safety at Work Act

People responsible for making decisions on the provision of bed rails and the care of people for whom they have been provided need to be aware of their duties under relevant health and safety legislation.

The Health and Safety at Work Act (4) places duties on:

Employers and self-employed persons – to avoid exposing those not in their employment (e.g. members of the public and patients) to health and safety risks.

Employees – to take reasonable care for the health and safety of themselves and others affected by their acts, and to co-operate with their employer on health and safety obligations.

The Management of Health and Safety at Work Regulations

The Management of Health and Safety at Work Regulations (5) require that employers and the self-employed should make a suitable and sufficient assessment of the risks to the health and safety of persons not in their employment which arise out of or in connection with their undertaking.

Employers also need to ensure that all employees who are responsible for selecting, fitting, maintaining and checking bed rails have received appropriate training.

Medical Device Regulations

All products classed as medical devices are subject to the medical device directive (6). This will include many beds and bed rail systems intended for use with patients. This directive instructs manufacturers as to the requirements for placing the CE mark on their device and placing it on the market. To do this, they must comply with the essential requirements listed in Annex I of the directive. This includes requirements such as making sure that the design of equipment is suitable for the products intended purpose, that the device is labelled appropriately and is supplied with instructions for use.

In 2017 the Medical Device Regulations (MDR) was published and will replace the Medical Device Directive once the transition period is over in May 2020 (2). In a similar process to the MDD, manufacturers will have to comply with the General Safety and Performance Requirements listed in Annex I of the MDR.

Not all beds or fall protection equipment will be classed as medical devices. This will depend on the intended use described by the manufacturer and without a clear medical purpose the definition of a medical device may not be met. In these cases, the product should still meet the requirements imposed by general consumer protection legislation.

Standards

Manufacturers may opt to demonstrate compliance with aspects of the medical device directive by making sure their products meet agreed standards. When purchasing or specifying equipment, it

may be desirable to confirm what technical standards are met by the device. This should be available either in the device instructions for use or from the manufacturer themselves.

The current harmonised medical bed standard is:

BS EN 60601-2-52: 2010+A1:2015 “Particular requirements for the basic safety and essential performance of medical beds”.

This standard contains requirements for the dimensions and function of beds and includes information on the permissible gaps between rails and the rails and the bed frame.

A separate standard has now been published that beds intended for use with children:

BS EN 50637:2017 “Medical electrical equipment. Particular requirements for the basic safety and essential performance of medical beds for children”.

As this is recent document, it may be some time before manufacturers market beds which meet this standard.

Standards such as these are primarily intended for manufacturers to evidence that the products they supply are suitable to be CE marked and placed on the market. The dimensions and measurements that they specify may not be appropriate to conduct in a clinical environment and may not assure safety if they uncritically applied to all bed users.

Previous medical bed standards were largely replaced by BS EN 60601-2-52, but older beds may have been assessed against these earlier standards. Previous standards include:

BS EN 1970:2000 “Adjustable beds for disabled persons”.

BS EN 60601-2-38:1997 Revision 1 “Medical Electrical Equipment – Part 2. Particular requirements for the safety of electrically operated hospital beds”.

9. Adverse Incidents

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.

Adverse incidents can be caused by:

- shortcomings in the device itself
- inadequate instructions for use
- insufficient servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practices, including inadequate training
- inappropriate management procedures
- the environment in which devices are used or stored
- incorrect provision.

We strongly encourage device users to report all adverse incidents to us. By reporting to us we can:

- collate information to identify trends in device safety and performance
- disseminate advice to the healthcare professions to prevent adverse incidents and promote good practice for use and maintenance of devices.

Healthcare professionals and members of the public in England can report adverse incidents or near misses via the Yellow Card system:

https://yellowcard.mhra.gov.uk/

Professional users in Wales, Scotland and Northern Ireland can report locally: for more information please visit:

https://www.gov.uk/report-problem-medicine-medical-device

10. References and Bibliography

References

1. *Never Events list 2018* January 2018 [Online]. [Accessed 30 April 2019]. Available from https://improvement.nhs.uk NHS Improvement. London, UK.

2. *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC* [Online]. [Accessed 30 April 2019]. Available from: http://eur-lex.europa.eu/.

3. *Managing Medical Devices Guidance for healthcare and social services organisations* April 2005 [Online]. [Accessed 30 April 2019]. Available from: http://www.gov.uk/ Medicines and Healthcare Products Regulatory Agency, London UK.

4. *Health and Safety at Work etc. Act. 1974* Chapter 37 [Online]. [Accessed 30 April 2019]. Available from http://legislation.gov.uk

5. *The Management of Health and Safety at Work Regulations 1999. 1999 p. No. 3242* [Online]. [Accessed 30 April 2019]. Available from: http://legislation.gov.uk

6. *Council Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market* [Online]. [Accessed 30 April 2019]. Available from: http://eur-lex.europa.eu/.

Bibliography

Haugh J, O Flatharta T, Griffin TP, O'Keeffe ST. High frequency of potential entrapment gaps in beds in an acute hospital. Age Ageing. 2014;43(6):862–5.

Anderson O, Boshier PR, Hanna GB. Interventions designed to prevent healthcare bed-related injuries in patients. Cochrane Database Syst Rev. 2012;(1).

Healey FM, Cronberg A, Oliver D. Bedrail use in English and Welsh hospitals. J Am Geriatr Soc. 2009;57(10):1887–91.

Healey FM, Oliver D, Milne A, Connelly JB. The effect of bedrails on falls and injury: A systematic review of clinical studies. Age Ageing. 2008;37(4):368–78.

NPSA. Bedrails; reviewing the evidence; a systematic literature review. 2007;

Appendix

Appendix 1 – Example adult risk assessment checklist

This is an example of a risk assessment for use of bed rails with an adult. It should not be adopted or used without adequate consideration of a specific bed occupant's needs and local policies. The checklist should be used in conjunction with the guidance in this document, together with the judgement of the nurse, therapist, user and carer involved.

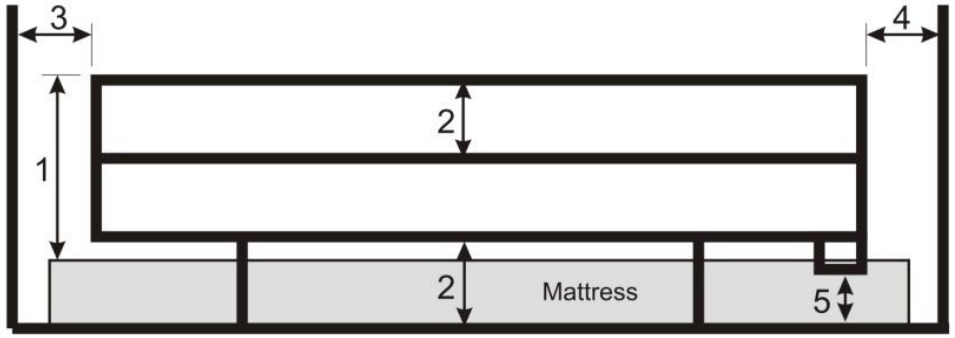
Is the bed rail to be used with a typically sized adult bed occupant?	☐ Yes ☐ No
Has the bed rail been inspected and maintained regularly, if previously used?	☐ Yes ☐ No
Does the manufacturer/supplier provide any information on special considerations or contra-indications?	☐ Yes ☐ No
Do you have enough information from the supplier to be able to select and fit the bed rail appropriately?	☐ Yes ☐ No
Is the bed rail suitable for the intended bed, according to the supplier's instructions?	☐ Yes ☐ No
Do the fittings or mattress allow the bed rail to be fitted to the bed securely, so that there is no excessive movement?	☐ Yes ☐ No
Does the benefit of any special or extra mattress outweigh any increased entrapment risk by the bed rails created by extra compression at the mattress edge?	☐ Yes ☐ No
Are the bed rails high enough to take into account any increased mattress thickness or additional overlay?	☐ Yes ☐ No
Have you made sure that there no gaps present that could present an entrapment risk to any part of patient's body? • between the bars of the bed rails? 120 mm max • through any gap between the bed rail and side of the mattress? 120 mm max • through the gap between the lower bed rail bar and the mattress, allowing for compression of the mattress at its edge? 120 mm max	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
Is the headboard to bed rail end gap less than 60 mm?	☐ Yes ☐ No

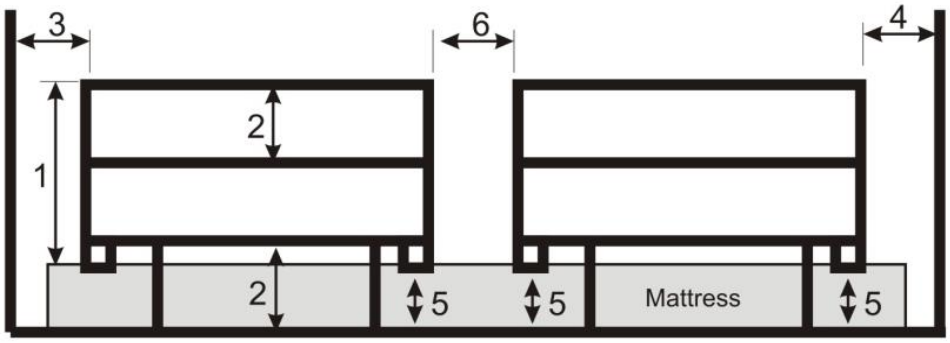
'Yes' boxes indicate the desired outcome. If any 'No' box has been ticked, there may be a serious risk of entrapment with the proposed combination. Review immediately.

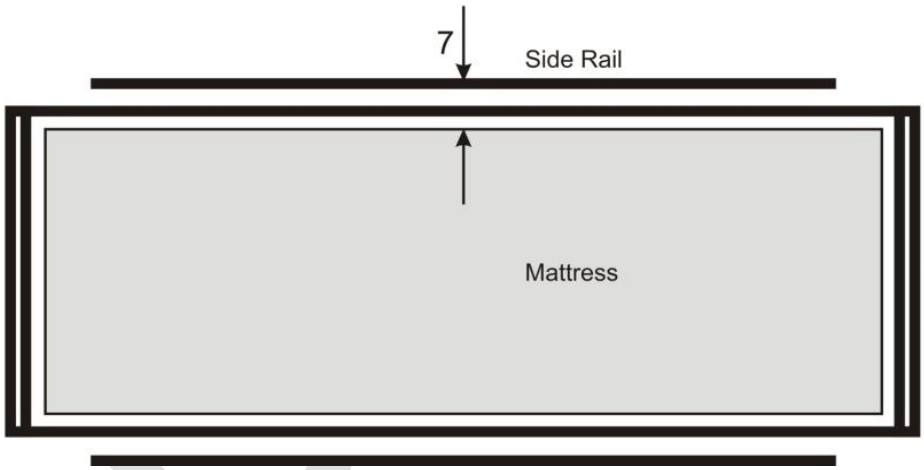
Risk assessments should be carried out before use and then reviewed and recorded after each significant change in the bed occupant's condition, replacement of any part of the equipment combination and regularly during its period of use, according to local policy.

Appendix 2 – Bed rail dimensions in BS EN 60601-2-52:2010+A1:2015 Medical Electrical Equipment. Particular requirements for basic safety and essential performance of medical beds.

Description	Diagram Reference	BS EN 60601-2-52:2010	Notes
Height of the top edge of the side rail above the mattress without compression	1	≥ 220mm	Where a speciality mattress or mattress overlay is used and the side rail does not meet ≥ 220mm a risk assessment shall be performed to assure equivalent safety
Gaps between elements within the perimeter of the side rail and between the side rail and mattress platform	2	< 120mm	
Gap between head board and end of side rail	3	< 60mm	Most disadvantageous angle between head board and side rail
Gap between foot board and end of side rail	4	< 60mm OR > 318mm	Most disadvantageous angle between foot board and side rail
Distance between open end of side rail(s) and mattress platform	5	< 60mm	The gap between the open end of the side rail and head board is not relevant to this ID
Gap between split side rails	6	< 60mm OR > 318mm	When in most disadvantageous position
Gap between side rail and mattress in 'plan' elevation	7	Perform test	120mm aluminium cone is positioned between mattress and side rail to determine if gap is acceptable or not







Head board **Foot board**

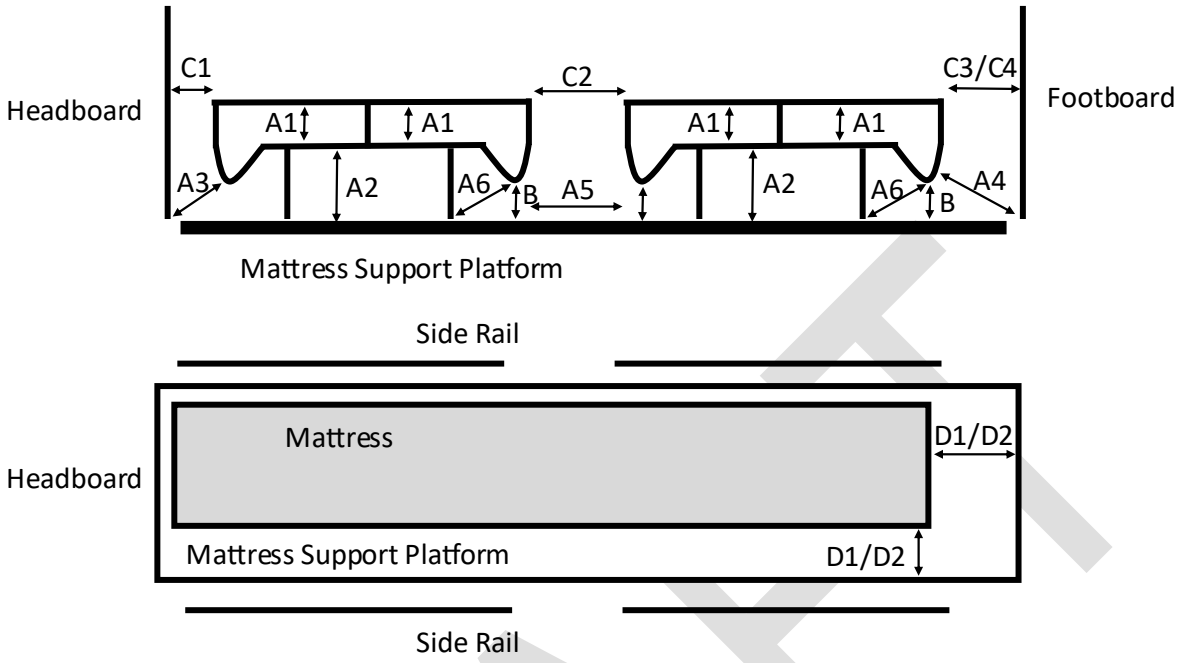
Appendix III – Bed Rail Dimensions in BS EN 50637:2017 Medical electrical equipment. Particular requirements for the basic safety and essential performance of medical beds for children.

Description	Diagram Reference	BS EN 50637:2017	Notes
Fully enclosed openings within a side rail, head/foot board, mattress support platform	A1	<60mm	
Fully enclosed opening defined by the side rail, its supports and the mattress support platform	A2	<60mm	
Partially enclosed opening defined by the head board, mattress support platform and side rail	A3	<60mm	
Partially enclosed opening defined by the foot board, mattress support platform and side rail	A4	<60mm	Except when gap between side rail and foot board is >300mm
Partially enclosed opening between segmented or split side rail and the mattress support	A5	<60mm	Except when gap between side rails is >300mm
Partially enclosed opening defined by lowest point of a side rail, the adjacent side rail support and mattress support platform, to the outside of the side rail supports	A6	<60mm	
Other openings defined by accessories (e.g. IV poles, fracture frames) and side rails, head or foot boards and or mattress support platform. Not shown in figures.	A	<60mm	
Distance between mattress support platform and the lowest point of the side rail outside the side rail support. AND The angle between the side rail and mattress support platform at the range of the mattress height defined by the manufacturer ± 2 cm.	B	<40mm AND Angle between mattress support platform and side rail interface >75° over the entire range of mattress heights from minimum recommended height minus 2 cm to the maximum recommended mattress height plus 2 cm.	
Gap between head board and adjacent side rail	C1	<40mm	

Description	Diagram Reference	BS EN 50637:2017	Notes
Gap between segmented or split side rails with both side rails raised	C2	<40mm OR >300mm	For a gap >300mm: the gap shall be >300mm or <400mm for the entire vertical distance
For all medical beds except junior beds: gap between side rail and foot board. Other openings defined by accessories (e.g. IV poles, fracture frames etc.) and side rails, head board, foot board, and or mattress platform	C3	<40mm	
For junior beds: gap between side rail and foot board. Other openings defined by accessories (e.g. IV poles, fracture frames etc.) and side rails, head board, foot board, and or mattress platform	C4	<40mm OR >300mm	For a gap >300mm: the gap shall be >300mm or <400mm for the entire vertical distance
Region defined by side rail/head board/foot board and the mattress for cribs and cots	D1	Perform test	Cone tool does not sink below the mattress surface by 50% or more of its 60mm diameter.
Region defined by the side rail/head/foot board and the mattress for junior beds and oversize cots	D2	Perform test OR Gap between side rail/head/foot board and mattress <30mm	Cone tool does not sink below the mattress surface by 50% or more of its 60mm diameter.

Note that 50637:2017 defines different sized beds: cots, oversized cots, cribs and junior beds. Please see the text of the standard for full definitions or contact the manufacturer of a particular bed in your control that complies with this standard.

Split Rail Beds



Single Rail Beds