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Bed Rail Standards and
Side Rail Provision –
it's still a hot topic!

Jayne Brewer -Occupational Therapist
Curtis Farrington – Account Manager

Learning outcomes

- To understand the indications and contraindications for the use of bed rails
- To be aware of why people fall out of bed and measures we can put in place
- Update on the recent MHRA alert and guidance
- An overview of Children's Standard – BS EN 50637 and adult standard – BS EN 60601-2-52
- To gain an idea of what needs to be included in a risk assessment
- To demonstrate the features, functions and accessories of the Accora Junior Bed

Why do we prescribe bed rails?

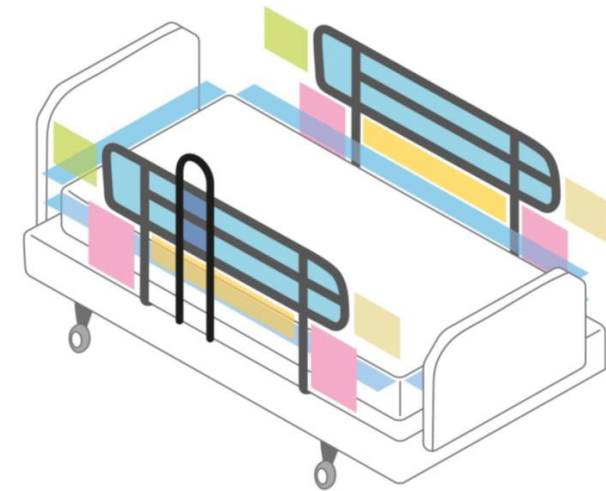
To prevent or reduce the likelihood of occupants falling and sustaining injury

RISKS

- Risk of injury, entrapment , suffocation
- <https://www.youtube.com/watch?v=4gaRR4DNfGg>
- NOT to limit the freedom of people by preventing them leaving their beds
- NOT to restrain them in any way
- NOT to help the person to move around in bed
- NOT for Confidence issue's

Risks of bed rails

- Risk of injury (climbing over bed rails)
- Risk of entrapment
- High or low body mass (change entrapment risk)
- Risk of suffocation
- Reduce independence
- Risk of bed rails outweighing the possible benefits
- Different configuration of bed, mattress and rail system is being used



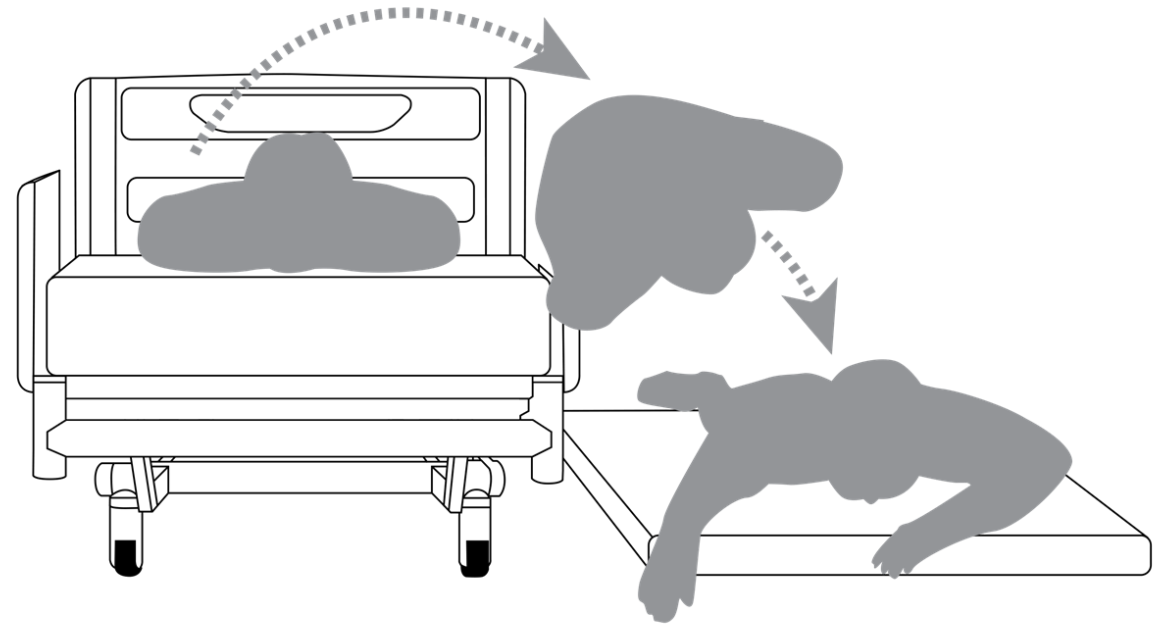
- ◆ Within rails
- ◆ Between headboard and rail
- ◆ Between footboard and rail
- ◆ Between bottom of rail and mattress
- ◆ Between rail and bed base
- ◆ Between bed frame and mattress
- ◆ Between rail and other equipment

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/868786/Figure_5_-_Bed_rail_entrapment_areas.jpg

<https://www.gov.uk/guidance/bed-rails-management-and-safe-use>

Why do people fall out of bed?

- While turning
- While transferring
- Impaired or restricted mobility
- Repetitive or involuntary movements
- Confusion / disorientation
- Agitation / delirium
- Medications / variable levels of consciousness
- Toileting habits



Other measures to reduce falls

- Floor beds and ultra-low beds
- Fall mats
- Wider mattress
- Firm edge mattress
- Positional wedges
- Inflatable bed sides and bumpers
- Alarm systems



MHRA Guidance



Medicines & Healthcare products
Regulatory Agency

Guidance

Bed rails: management and safe use

Guidance on managing and using bed rails safely.

Published 30 August 2023

<https://www.gov.uk/guidance/bed-rails-management-and-safe-use>

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MHRA Safety Alert



Medicines & Healthcare products
Regulatory Agency

Medical beds, trolleys, bed rails, bed grab handles and lateral turning devices: risk of death from entrapment or falls

Date of Issue:	30-Aug-23	Reference No:	NatPSA/2023/010/MHRA
This alert is for action by: All those responsible for the use, purchase, prescription and maintenance of medical beds, trolleys, bed rails, bed grab handles and lateral turning devices including all Acute and Community healthcare organisations, care homes, equipment providers, Occupational Therapists and early intervention teams			
This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards), supported by persons with responsibilities for discharge planning, training, equipment provision, maintenance and ongoing patient care.			
Explanation of identified safety issue:		Actions required	
<p>The MHRA continues to receive reports of deaths and serious injuries from entrapment or falls relating to medical beds, bed rails (also known as bed safety rails), trolleys, bariatric beds, lateral turning devices and bed grab handles (also known as bed levers or bed sticks). Chest or neck entrapment in bed rails is currently listed (number 11; 2018) as a 'Never Event' according to the NHS.</p> <p>According to investigations, deaths were found to involve factors including inadequate risk assessment, maintenance issues and children and adults of small stature using beds which are designed for use by adults with typical body dimensions.</p> <p>Other risk factors (such as inappropriate use or incompatibility) are included in the MHRA's updated guidance on the management and safe use of bed rails and should be considered as part of an appropriate risk assessment. An example risk assessment is provided in Appendix 1 of the guidance. Assessment of appropriate bed rails should be routinely incorporated in the clinical assessment of all patients.</p> <p>There are two international standards for medical beds which include requirements for acceptable gaps in order to reduce entrapment risks. BS EN 60601-2-52:2010+A1:2015 is the standard for adult beds, and there is a separate standard, BS EN 50637:2017, for medical beds and cots for children and adults with atypical anatomy (in other words physical size less than 146 cm, mass less than 40kg or a body mass index of less than 17), as physically smaller patients can get trapped in smaller gaps.</p> <p>Children and adults with atypical anatomy should be using beds or cots compliant with BS EN 50637:2017 unless there is a clinical reason for using a non-compliant bed, which should be documented, including any steps which need to be taken to reduce risk. Older beds, which might previously have been intended for children, may not comply with the requirements set out in this standard, as it was introduced in 2017, and therefore there may be a higher risk of entrapment with these beds.</p>		<p>When: Begin as soon as possible and complete by 1 March 2024</p> <ol style="list-style-type: none">1. Update your organisation's policies and procedures on procurement, provision, prescribing, servicing and maintenance of these devices in line with the MHRA's updated guidance on the management and safe use of bed rails.2. Develop a plan for all applicable staff to have training relevant to their role within the next 12 months with regular updates. All training should be recorded.3. Review the medical device management system (inventory/database) for your organisation or third-party provider for devices within your organisation, including those which have been provided to a community setting (for example, the patient's own home). Keep this system up to date.4. Implement maintenance and servicing schedules for the devices in the inventory/database, in line with the manufacturer's instructions for use and/or service manual. Prioritise devices which have not had regular maintenance and servicing. If this is outsourced, compliance with the schedule should be monitored.5. Review patients who are children or adults with atypical anatomy as a priority. Ensure the equipment they have been provided with is compliant with BS EN 50637:2017 unless there is a reason for using a non-compliant bed. Record this on the risk assessment and put in place measures to reduce entrapment risks as far as possible.6. Review all patients who are currently provided with bed rails or bed grab handles to ensure there is a documented up-to-date risk assessment. Complete risk assessments for patients where this has not already been done and for each patient who is provided with bed rails or bed grab handles.7. Implement systems to update risk assessments where the equipment or the patient's clinical condition has changed (for example, reduction/improvement in weight or mobility), and also at regular intervals.	

At the MHRA we **continue to receive reports of adverse incidents** involving these devices. The most serious of these have led to **injury due to falls** and **death by asphyxiation** as a result of entrapment of the head, neck or chest.

From 1 January 2018 to 31 December 2022, we received **18 reports of deaths** related to bed rails and associated equipment, and **54 reports of serious injuries**.

Most incidents occurred in community care settings, particularly in nursing homes or the patient's own home. Adequate and appropriate **risk management** should be carried out **to prevent the occurrence** of such incidents. Healthcare professionals or competent persons should **carefully consider the benefits and risks** of bed rails before they are used for a patient.

<https://www.gov.uk/guidance/bed-rails-management-and-safe-use#introduction>

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Safety issues identified



Appendix 1 – Example adult entrapment risk assessment checklist

This is an example of a basic risk assessment of a bed rail installation for an adult. It should not be adopted or used without adequate consideration of a specific bed occupant's needs and local policies and may need to be preceded by an assessment of whether rails are necessary at all. A separate checklist would be necessary for a child or very small adult user.

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 an adult-sized user (i.e. a patient taller than 1.46m/4'11")?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the bed rail been inspected and maintained regularly, if previously used?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the manufacturer/supplier provide any information on special considerations or contra-indications?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Do you have enough information from the supplier to be able to select and fit the bed rail appropriately?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the bed rail suitable for the intended bed, according to the supplier's instructions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Do the fittings or mattress allow the bed rail to be fitted to the bed securely, so that there is no excessive movement?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the bed rail height take into account any increased mattress thickness or additional overlay?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you made sure that there are no gaps present that could present an entrapment risk to any part of patient's body? <ul style="list-style-type: none">• between the bars of the bed rails? 120 mm max• through any gap between the bed rail and side of the mattress?• through the gap between the lower bed rail bar and the mattress platform, allowing for compression of the mattress at its edge?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
Is the headboard to bed rail end gap appropriate?	<input type="checkbox"/> Yes <input type="checkbox"/> 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.

Deaths were found to involve factors including:

- Inadequate or no risk assessment
- Maintenance issues
- Children and adults of small stature (atypical anatomy)

Other incident risk factors included:

- Inappropriate use of bed rails
- Incompatibility between bed / bed rail system / mattress
- Risk assessment not being updated following a change of equipment or a change in a patient's condition.

<https://www.gov.uk/guidance/bed-rails-management-and-safe-use#appendix>

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Actions required – by 1 March 2024

1. Update policies and procedures (procurement, provision, prescribing, servicing and maintenance)
2. Staff training within the next 12 months
3. Review medical device management system (database)
4. Implement maintenance and servicing schedules (those within database)
 - <https://www.gov.uk/government/publications/managing-medical-devices>
5. Review residents who are (children or) adults with atypical anatomy as a priority
 - Ensure compliance with BS EN 50637
6. Review all residents currently provided with bed rails or bed grab handles
7. Update risk assessments where equipment or resident's clinical condition has changed

Adult standard – BS EN 60601-2-52

What is it?

BS EN 60601-2-52 is a part of the IEC 60601 series of standards related to the safety and performance of medical electrical equipment.

Why has it been introduced?

Adult beds have an intended service user group.

- over 40 kg/6.4 stone
- over 1.46 m/4.8ft in height
- with a BMI of more than 17

Anyone outside of these dimensions, particularly children, therefore, fall out of this user group.



Children's Standard – BS EN 50637

What is it?

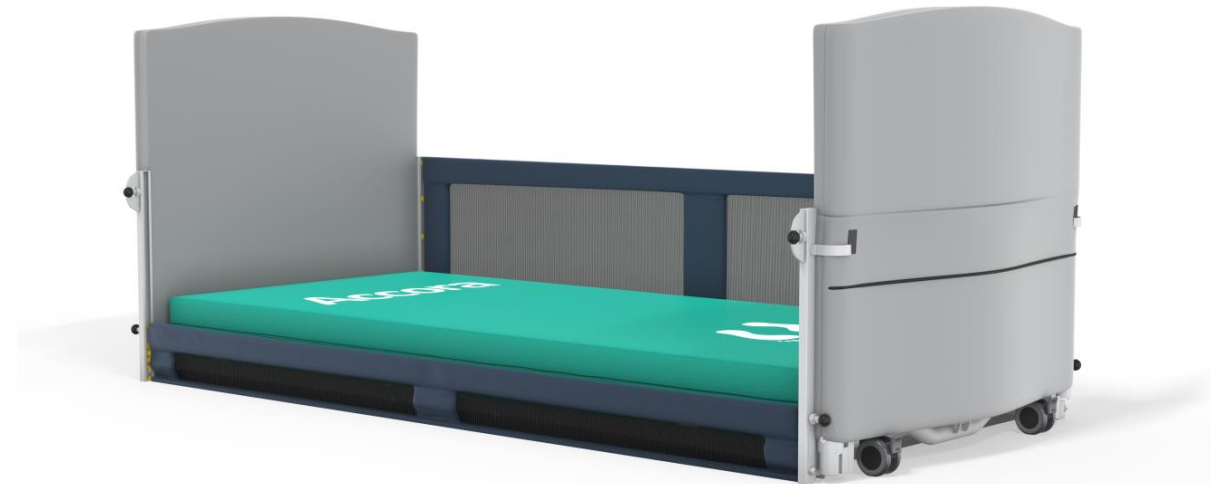
BS EN 50637:2017 – is a new children's standard for medical beds suitable for children and adults with atypical anatomy.

Why has it been introduced?

Physically smaller residents, with atypical anatomy are more at risk to get trapped within the gaps on the bed rails and a bed frame.

This includes residents that are;

- Less than 40 kg/6.4 stone
- Less than 146 cm/4.8ft in height
- BMI less than 17



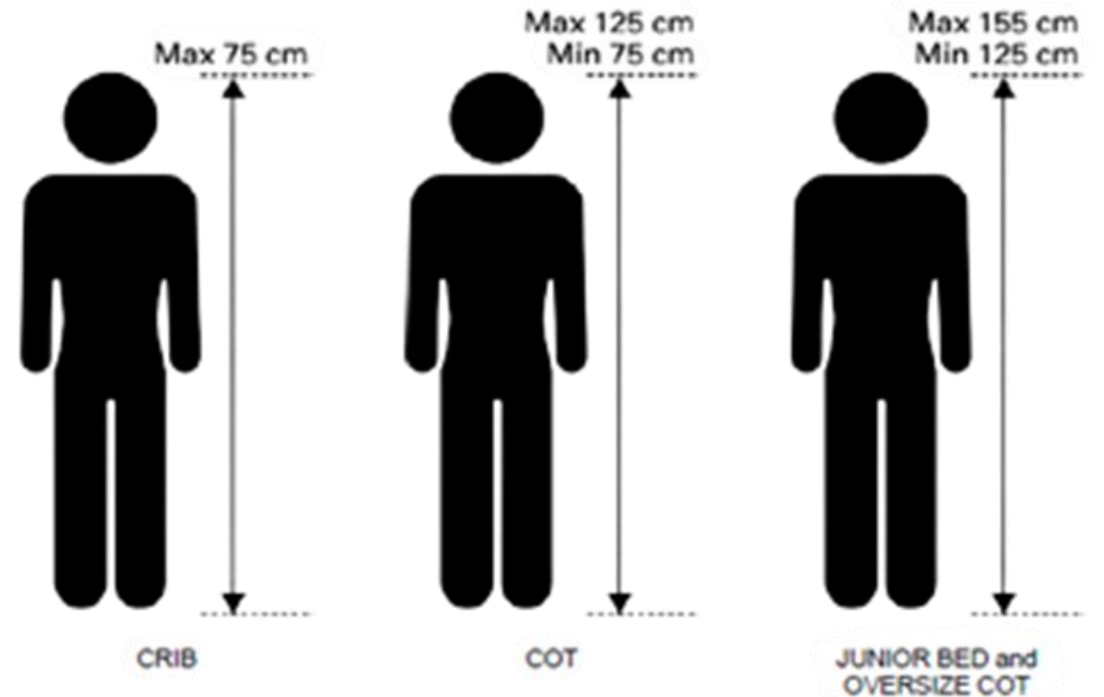
Children's Standard – BS EN 50637

What is different in the new standard?

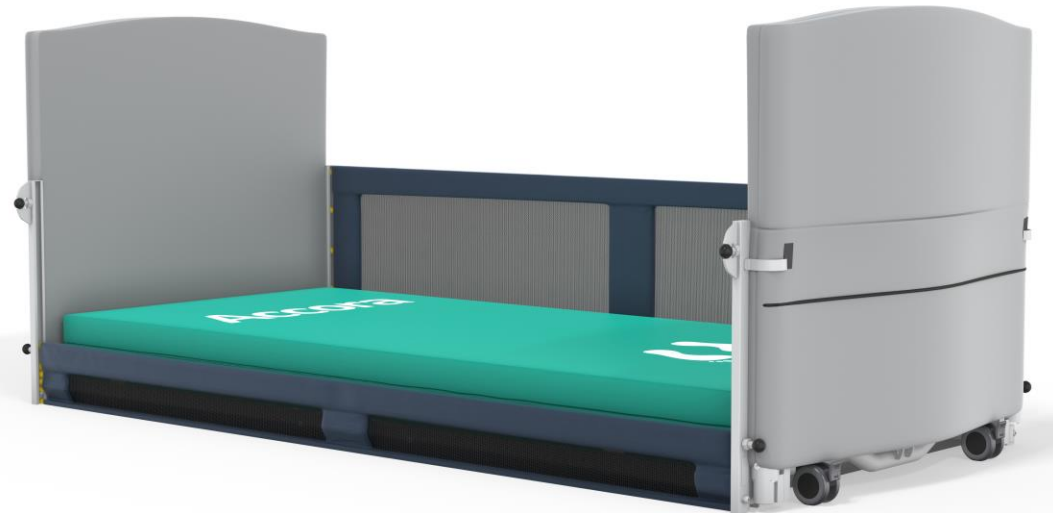
The main difference in the standard is the size of the gaps between siderails, mattress platform and closing gaps. These are much smaller than with adult beds.

Who does this refer to?

There is no reference to ages of the residents, but sizes instead.



<https://www.gov.uk/guidance/bed-rails-management-and-safe-use>



Thank you

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