

Safe use of bed rails

December 2013

Medicines and Healthcare Products Regulatory Agency

Contents

| 1 Executive summary4 |
|--|
| 1.1 Who this document is for4 |
| 1.2 Scope |
| 2 Introduction |
| 2.1 Bed rails5 |
| 2.2 Bed grab handles6 |
| 3 Risk management and assessment7 |
| 3.1 Risk management7 |
| 3.2 Risk assessment7 |
| 3.3 Risk assessment checklist example |
| 4 Purchase, selection, safe fitting and use of bed rails 10 |
| 4.1 Purchase10 |
| 4.2 Selection10 |
| 4.3 Safe fitting and use11 |
| 4.4 What to avoid11 |
| 4.5 Alternatives12 |
| 5 Special considerations12 |
| 5.1 Adjustable or profiling beds12 |
| 5.2 Using bed rails with children13 |
| 5.3 Mattress overlays for pressure ulcer prevention or reduction13 |
| 5.4 Inflatable bed sides13 |
| 5.5 Bed rail bumpers14 |
| 5.6 Mattress dimensions14 |
| 6 Maintenance 14 |
| 7 Illustrated examples |
| 7.1 Incorrect or omitted risk assessment and consideration of the |
| physical size of the bed occupant17 |
| 7.2 Incompatibility or unsuitability of a bed rail for the bed18 |
| 7.3 Entrapment in inappropriate gaps19 |
| 7.4 Bed occupants falling over the top of the bed rails21 |
| 7.5 Bed rails in poor condition from lack of maintenance22 |

| 7.6 Use of a mattress that was too light to keep the bed rail | |
|---|-----|
| assembly in position | .23 |
| 8 Legislation | 23 |
| 8.1 Health and Safety at Work Act | .24 |
| 8.2 The Management of Health and Safety at Work Regulations | .24 |
| 9 Adverse incidents | 24 |
| 10 References and bibliography | 25 |
| 10.1 References | .25 |
| 10.2 Bibliography | .26 |
| Appendix Comparison of dimensions in product standards | 27 |

Revision history

| This version | Date published | Changes |
|--------------|----------------|---------------|
| V2.1 | December 2013 | New MHRA logo |

© Crown copyright. Published by the Medicines and Healthcare Products Regulatory Agency



For full details on accreditation visit: http://www.evidence.nhs.uk/Accreditation

1 Executive summary

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

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

1.1 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:

- MHRA liaison officers (for onward distribution)
- nurses in hospitals and the community
- occupational therapists
- physiotherapists
- care home managers and staff
- hospice managers and staff
- · carers in the community and care-at-home staff
- community equipment stores (CES) and loan store managers
- those responsible for purchasing beds and bed rails
- maintenance staff
- health and safety managers
- risk managers.

1.2 Scope

This bulletin 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
- 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 bulletin is not intended to inform clinical decision making. Please refer to the National Patient Safety Agency (NPSA) guidance 'Safer practice notice 17' [1].

2 Introduction

Bed rails are used extensively in care environments to prevent bed occupants falling out of bed and injuring themselves.

However, there have been serious incidents reported to MHRA. The majority of these involved third party bed rails (see section 2.1 below) used on domestic, divan and metal framed beds that have led to injury and death by asphyxiation after entrapment of the head or neck.

Most incidents occurred in community care environments, 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 16 [2] covers entrapment in bed rails.

2.1 Bed rails

For the purpose of this document the term **bed rail** will be adopted, although other names are often used, such as: bed side rails, side rails, cotsides, 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 also be CE marked as medical devices to the Medical Devices Regulations [3], in combination with, or as an accessory to the bed.

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

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.

2.2 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 are **not** designed to prevent patients falling from their bed. Bed grab handles come in a variety of sizes and designs (Figures 1, 2 and 3). They should not be used as, or instead of, bed rails.



Figure 1



Figure 2



Figure 3

3 Risk management and assessment

3.1 Risk management

When bed rails and bed safety equipment 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 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 passed on to all users of the equipment 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.

3.2 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, together with the uniqueness of each bed occupant, means that a careful and thorough risk assessment is necessary if serious incidents are to be avoided.

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.

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 section 4.5)?

- if not an appropriate solution, can an alternative method of bed management be used?
- could the use of a bed rail increase risks to the occupant's physical or clinical condition for example, if an active but disorientated bed occupant tries to climb over it?

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.

3.3 Risk assessment checklist example

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.

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.

Risk assessment checklist example

| Is the bed rail to be used with a typically sized adult bed occupant? (for a child or a small adult, see section 5.2) | □ 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 | 🗆 Yes 🗆 No |
| through any gap between the bed rail and side of the mattress? 120 mm max | □ Yes □ No |
| 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 |
| 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.

4 Purchase, selection, safe fitting and use of bed rails

4.1 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 (see section 3.2).

Advice given by the NPSA Safer practice notice [1], the MHRA's Managing Medical Devices [4] and evaluation reports originally published by the Centre for Evidence-based Purchasing, now archived by the Department of Health (http://nhscep.useconnect.co.uk/Default.aspx), should be taken into account.

Third party bed rails require careful selection, see 4.2 below.

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, such as BS EN 60601-2-38 [5], BS EN 1970 [6] or BS EN 60601-2-52 [7] (see appendix for guidance)
- whether they are suitable for children or small adults (see section 5.2)
- the instructions for use should contain information on the selections of the mattress, including dimensions and characteristics, to reduce the risk of entrapment

4.2 Selection

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. In all cases it is essential that the selection process still follows a risk assessment considering the needs of the bed occupant (see section 3.2).

4.3 Safe fitting and use

It is essential that all bed rails can be fitted correctly allowing safe use to an appropriate bed base. This 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?

4.4 What to avoid

From our investigations (see section 7), the MHRA has identified a number of issues largely associated with third party bed rails that, if avoided during the selection process, may reduce the likelihood of adverse incidents. 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.

4.5 Alternatives

Alternatives to bed rails may be considered, such as:

- 'netting' or mesh bed sides
- ultra 'low height' beds
- positional wedges
- alarm systems to alert carers that a person has moved from their normal position or wants to get out of bed.
- fall mats

5 Special considerations

5.1 Adjustable or profiling 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.

They will be CE marked to the Medical Devices Regulations [3] 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.

5.2 Using bed rails with children

Most bed rails 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.

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

5.3 Mattress overlays for pressure ulcer prevention or reduction

Before and during use of mattress overlays 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 (see Figure 20 in section 7.4)
- the hazard of entrapment in the vertical gap between the side of the mattress and the bed rail may be exacerbated due to the soft, easily compressible nature of the overlay and/or mattress edge (see Figures 15 and 16 in section 7.3)
- 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.

5.4 Inflatable bed sides

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.

5.5 Bed rail bumpers

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.

5.6 Mattress dimensions

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.

6 Maintenance

MHRA adverse incident investigations have revealed that some incidents with bed rails have been caused by poor or no maintenance. Bed rails should be included in planned preventative maintenance (PPM) schemes.

Bed rails should be maintained in accordance with the manufacturer's recommendations in the instructions for use. For more information on this topic, refer to our publication 'Managing Medical Devices' [4].

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. Poor transport and storage can also cause such damage. Telescopic components can also become loose or jammed, discouraging correct adjustment. Duvets, blankets, sheets and valances may need to be removed for good access to check these areas properly. Material fatigue can also occur. Bed occupants who rattle the bed rails can exacerbate this tendency. Plastic components also need particular attention as they can degrade due to age, exposure to light and some cleaning chemicals.

Bed rail assemblies should be traceable, for example by labelling with an in-house number. This will assist in ensuring they are regularly inspected and maintained in a satisfactory condition. 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. Traceability also allows them to be recalled should a safety issue arise, such as a manufacturing fault.

Bed rails found to be unsuitable or in poor condition should be withdrawn from use and appropriately destroyed. If they are kept or stored (Figure 4), they often find their way back into use. Bed rails should be stored in matched pairs in a suitable area where they will not get damaged.



Figure 4

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 (Figures 5 and 6)
- loose fixings these affect the rigidity of the assembly. Nuts should be of the self-locking type (Figure 7)
- free play in joints this can point towards loose, worn or incompatible components (Figure 8)
- stripped threads on bed frame clamps does not allow them to be tightened securely
- bent or distorted components (Figure 9)
- damaged plastic components (Figure 10)
- intact manufacturers labelling.



Figure 5



Figure 6



Figure 7



Figure 8



Figure 9

Figure 10

7 Illustrated examples

In this section we provide pictures of common problems that arise with bed rails and give some examples of the adverse incidents that have been reported to us.

7.1 Incorrect or omitted risk assessment and consideration of the physical size of the bed occupant

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. The gap between the horizontal bedrail bars was too large. The child slipped through the gap and was asphyxiated as a result of head entrapment between the bed rail bars. See Figure 11 below.

In another case, a bed rail with a bar spacing of 170 mm was being used for an older person being cared for in a nursing home. No risk assessment was carried out to determine if the device was suitable for use, or that it considered the space between the bars and the bed occupant's size. The person asphyxiated as a result of head and neck entrapment when their body slipped between the bars.



Figure 9

Figure 11

7.2 Incompatibility or unsuitability of a bed rail for the bed

A bed rail intended for use on a divan bed (i.e. having a flat base, the common domestic type of bed) was used on a hospital type bed. This produced a large gap between the bottom of the bed rail and the bed. 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 (i.e. compression of the chest). Figure 12 below shows a compressed mattress revealing the gap.



Figure 10

Figure 12

7.3 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, as shown in Figures 13 and 14 below.



Figure 13

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. See Figure 15.

Figure 16 shows how the compressible nature of the edge of most mattresses can contribute towards the entrapment potential of existing gaps. This is further illustrated by the bed occupant's weight compressing the mattress in both Figures 17 and 18.





Figure 15

Figure 16



Figure 17



Figure 18

7.4 Bed occupants falling over the top of the bed rails

This could occur if the bed rails are not high enough or are compromised by too high a mattress or mattress combination. Standards for adjustable and hospital beds require that the top surface of the bed rails is at least 220 mm from the top of the uncompressed mattress.

For example, a pressure ulcer reduction overlay system was added to a bed that already had a bed rail fitted to it. The additional height of the overlay mattress was not taken into consideration and this compromised the effectiveness of the bed rail (Figure 19). The bed occupant fell over the rail, sustaining a head injury (Figure 20). This illustrates that a combination of a large user and thick mattress or mattress combination may mean some beds rails are unsuitable and present a risk of injury.



Figure 19



Figure 20

7.5 Bed rails in poor condition from lack of maintenance

A care home had fitted 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. The incident could have been prevented if regular maintenance checks had been in place. Figure 21 shows the overall bed rail assembly and its poor fit on the divan bed base. Figure 22 shows a close-up of the foot end cross bar; the set screw, essential to lock the cross bar to the correct width for the divan base, is missing. Figure 23 shows the large entrapment gap that can result.



Figure 21



Figure 22



Figure 23

7.6 Use of a mattress that was too light to keep the bed rail assembly in 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. See Figure 24 below.



Figure 24

8 Legislation

8.1 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 [8] 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.

8.2 The Management of Health and Safety at Work Regulations

The Management of Health and Safety at Work Regulations [9] 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. Advice on the issues that need to be taken into account, when assessing the risks from bed rails, is contained in section 3.

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

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 the device 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.

Please refer to our latest advice on how to report adverse incidents, which is available from our website (www.mhra.gov.uk).

10 References and bibliography

10.1 References

1 National Patient Safety Agency. Safer practice notice 17. Using bedrails safely and effectively. NPSA/2007/17. 26 February 2007 http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59815

2 Department of Health. NHS Never Events. January 2012. http://www.dh.gov.uk/health/2012/01/never-events-update/

3 The Medical Devices Regulations 2008. Statutory Instrument 2008 No. 2936.

http://www.legislation.gov.uk/uksi/2008/2936/contents/made

4 Medicines and Healthcare products Regulatory Agency. Managing Medical Devices, DB 2006(05), MHRA 2006. http://www.mhra.gov.uk

5 BS EN 60601-2-38: 1997, Revision 1, 'Medical Electrical Equipment – Part 2. Particular requirements for the safety of electrically operated hospital beds'. http://www.bsigroup.com/ *This will be superseded by BS EN 60601-2-52:2010 from April 2013.*

Note: Contains a similar clause on the requirements and dimensions for bed rails as published in BS EN 1970:2000.

6 BS EN 1970:2000 'Adjustable Beds for Disabled Persons'. Contains a clause that specifies requirements and dimensions for bed rails. http://www.bsigroup.com/ *This will be superseded by BS EN 60601-2-52:2010 from April 2013.*

Note: this standard covers beds that are intended for use by adults and adolescents (i.e. people over 12 years old or 1.5 m (4' 1") in height).

7 BS EN 60601-2-52:2010 Particular requirements for basic safety and essential performance of medical beds. http://www.bsigroup.com/

8 Health and Safety at Work etc. Act 1974. London: HMSO, 1974. ISBN 0105437743. *See sections 2 and 3*.

9 Management of Health and Safety at Work Regulations 1999. Statutory Instrument 1999 No. 3242. ISBN 0 11 085625 2. http://www.opsi.gov.uk/SI/si1999/19993242.htm

10.2 Bibliography

Medicines and Healthcare products Regulatory Agency. Medical Device Alert MDA/2007/009, Bed rails and bed grab handles. 2007 http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2025839

Medicines and Healthcare products Regulatory Agency. One Liner, issue 61, September 2008, 'Falling out' http://www.mhra.gov.uk/Publications/Safetyguidance/OneLiners/CON025962

Medicines and Healthcare products Regulatory Agency. One Liner issue 58, May 2008, 'Cracking Up!!' http://www.mhra.gov.uk/Publications/Safetyguidance/OneLiners/CON018088

Medicines and Healthcare products Regulatory Agency. One Liner issue 75, March 2010: Beds http://www.mhra.gov.uk/Publications/Safetyguidance/OneLiners/CON076295

Medicines and Healthcare products Regulatory Agency. Safe use of bed rails – poster http://www.mhra.gov.uk/Publications/Postersandleaflets/CON2025709

National Patient Safety Agency. Bed Rails – Reviewing the Evidence. March 2007. http://www.nrls.npsa.nhs.uk/

Provision and Use of Work Equipment Regulations 1998. Statutory Instrument 1998 No. 2306. ISBN 0 11 079599 7. http://www.opsi.gov.uk/SI/si1998/19982306.htm

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. SI 1995 No. 3163. London: HMSO, 1995. ISBN 0110537513. http://www.opsi.gov.uk/SI/si1995/Uksi 19953163 en 1.htm

Website links correct at time of publication.

© Crown copyright 2013

Appendix Comparison of dimensions in product standards

| Description | Ref on diagrams (see below) | Current standards (to be withdrawn in 2013) | | New combined standard | Notes |
|---|--|---|--|------------------------------|---|
| Description | | BS EN 1970:2000 | BS EN 60601-2-38:1997 | BS EN 60601-2-52:2010 | Notes |
| Height of the top edge of the side rail above the mattress without compression | 1 | ≥ 220mm | ≥ 220mm | ≥ 220mm ª | ^a 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 | ≤ 120mm | < 120mm | |
| Gap between head board and end of side rail | 3 | ≤ 60 or ≥ 250mm ^b | ≤ 60 or ≥ 235mm ^b | < 60mm ^c | ^o Side elevation between head board and side rail |
| | | | | | [°] Most disadvantageous angle between head board and side rail |
| Gap between foot board and end of side rail | 4 | ≤ 60 or ≥ 250mm ^d | ≤ 60 or ≥ 235mm ^d | < 60 or > 318mm ^e | ^d Side elevation between foot board and side rail |
| | | | | | ^e Most disadvantageous angle between foot board and side rail |
| Distance betweenk open end of side rail(s) and mattress platform ^f | e betweenk open ide rail(s) and 5 s platform ^f | If ID4 is ≥ 250mm then gap is ≤60mm | If ID4 is ≥ 235mm then gap is ≤60mm | < 60mm | ^f The gap between the open end of |
| | | If ID4 is ≤60mm then gap is ≤120mm | lf ID4 is ≤60mm then gap is ≤120mm | | relevant to this ID |
| Gap between split side rails | n split side 6 | ≤60mm or ≥250mm to ≤ 400mm ^g | ≤ 60 or ≥ 235mm ^g | < 60 or > 318mm ^h | ^g when in flat position |
| | | | | | ^h When in most disadvantageous position |
| Gap between side rail and mattress in 'plan' elevation | 7 | Not specified | Not specified | Perform test ⁱ | ⁱ 120mm aluminium cone is positioned between mattress and side rail to determine if gap is acceptable or not |

Figure 25 Diagram of side view of bed with split side rails



Figure 26 Diagram of side view of bed with cantilever side rails



Figure 27 Diagram of bed in plan view

