

Focus

# Correct use of bed rails

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Agence française  
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## 2. Authors

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### 3. Goals

The purpose of this document is to disseminate the data collected by the French Health Products Safety Agency (AFSSAPS) concerning the correct use of bed rails.

It aims both to provide answers to buyers' and users' questions, to inform them of the risks induced by the use of bed rails and to reinforce the idea that the bed and its rails are medical devices, as per the definition of directive 93/42/EC, thus requiring compliance with correct usage rules in order to guarantee patient safety and good healthcare conditions.

*The bed and  
its rails are  
medical  
devices as per  
directive  
93/42/EC*

This focus concerns medical beds for adults, used in healthcare facilities, retirement homes/EHPAD<sup>1</sup> and at home, with the exception of transfer devices (stretcher-beds and transfer trolleys).

This document is aimed at:

- healthcare workers and other medical beds users
- individuals responsible for purchasing medical beds
- individuals in charge of medical bed maintenance
- medical beds manufacturers and retailers (indirectly)

### 4. Sources

This document is based upon data gathered from:

- medical devices vigilance : Since 2001, accidents involving bed rails reported to the Agency in the context of materiovigilance have given rise to an investigation aimed at collecting as much information as possible concerning the circumstances in which these accidents occurred.
- international cooperation: Summary of data disseminated and gathered by other competent authorities
- standardisation: Recommendations made by prevailing standards, data taken from the current update process of these standards
- documents previously published in France: Study of physic restraint-related risks for elderly person performed by the ANAES, circular letter concerning the use of bed rails for medical purposes

*Further reading:*

- . Bibliography at the end of this document

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<sup>1</sup> EHPAD: Etablissement d'Hébergement pour Personnes Agées Dépendantes - Home for dependent elderly persons

## 5. Context : the French installed field

According to INSEE statistics, the number of complete hospitalisation beds in France in 2003 was of 465,495 beds.

*An installed  
base of  
728,000  
medical beds  
in France*

To determine the number of medical beds in France, to this number must be added the number of day hospitalisation beds, medical beds in retirement homes/EHPAD and medical beds used at home.

At the end of 1998, the number of hospitalisation beds was estimated at 492,104 and home beds at 103,097, i.e. a total of 595,201 beds in France. (1)

The latest available statistics are:

- Number of home and EHPAD medical beds, covered by the LPP: 200,000 (SNITEM and CNAMTS estimate for 2004)
- Number of medical beds in healthcare establishments: 457,000 in full-time hospitalisation and 48,000 in part-time hospitalisation (2)
- Number of beds in medico-social establishments other than retirement homes at the end of 2001: 23,081, considering that each hosted individual has one medical bed. (3)
- The installed base in France can thus be estimated at 728,000 beds.

A survey with medical bed manufacturers selling in France was initiated on April 26th 2005 in view of appraising the current state of the market on the one hand and the state of the installed base on the other hand.

### *Further reading:*

Summary of the manufacturer survey [\[Download\]](#)

Manufacturer survey form [\[Download\]](#)

(1) "L'hospitalisation en France – Informations Hospitalières" Review, March 2000, Special issue No.53

(2) "L'hôpital public en France : bilan et perspectives", Conseil économique et social, June 28th 2005

(3) "Le handicap en chiffres", document published by the Ministry of Health, February 2004

## 6. Identified types of risk

The accidents that occur with bed rails are as follows:

- **Injuries** (from scratches to severe cuts to limbs) caused by sharp elements, or by entrapment or pinching limbs in the rail lift mechanism.
- **Falls** either over the rail, or in the spaces left free by the rail  
Falls may occur with agitated patients, but also when patients attempt to leave their bed despite the presence of the rails. Falls may have a significant clinical impact, possibly leading to patient death by trauma.
- **Entrapment:** of limbs, but also of the thorax, head and neck. Entrapment in the bed rails may lead to death by asphyxiation, breathing being prevented by compression of the thorax and/or blocking of the nose/mouth. Cases of strangulation (crushing of the neck) have also been

reported, along with cases of patients found trapped at the thorax level, with their body on the bed and their head hanging down.

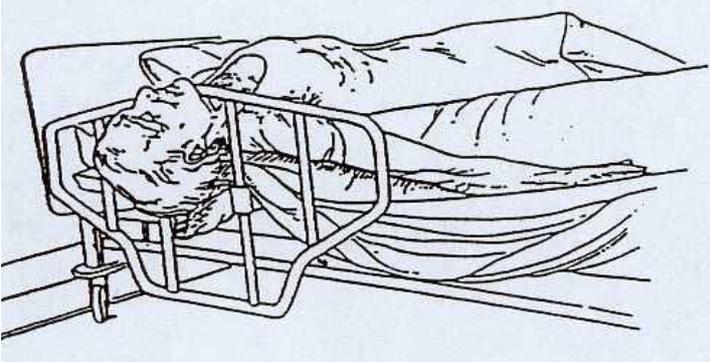
These accidents have given rise to work conducted by several European or international competent authorities. They are therefore not specific to France.

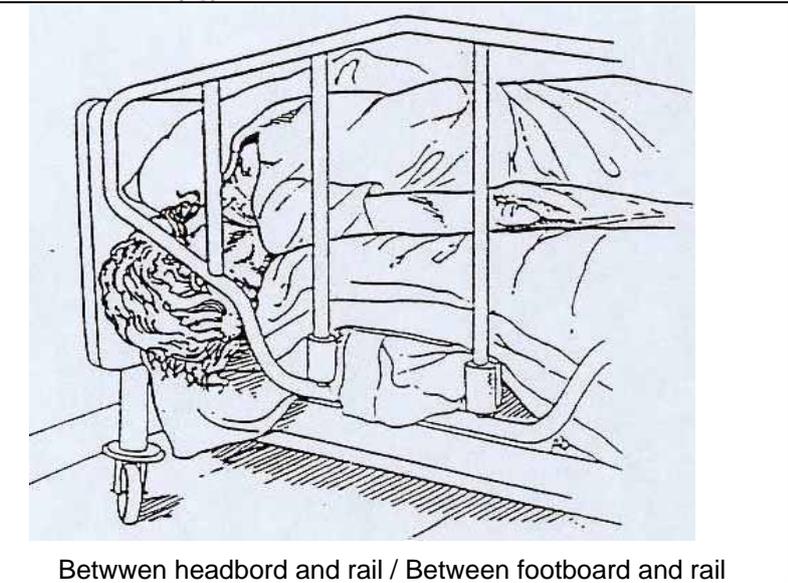
*Falls and entrapment occasionally have fatal outcomes.*

The types of accident that represent the most serious hazard are falls and entrapments, which occasionally lead to patient death.

Forty deaths in France related to falls or entrapments have been reported in medical devices vigilance since 1996, a figure that must be considered in light of the number of medical beds in use (approximately 700,000) and the occupancy rate of these beds.

Areas presenting a high risk of falling and/or entrapment:

Risk area	Accident exemple
 <p style="text-align: center;">Between the half-rails</p>	<p>Agitated patient found dead during the night, body trapped between the two half-rails.</p>
 <p style="text-align: center;">Between the bars of the rail</p>	<p>Patient found with head between two bars of the bed rails. Strangulation to the neck. Patient highly cyanotic.</p>

	<p>Under the rail/Between the mattress and rail</p>	<p>Patient found with head trapped between rails and mattress. Facial injuries and breathing difficulties.</p>
	<ul style="list-style-type: none"> <li>• The patient swung the top half of his/her body into the space between the rails and the headboard.</li> <li>• Patient found with thorax trapped between bed rails and footboard. The patient's head was lower than his/her thorax. All resuscitation attempts failed.</li> </ul>	
<p>Between an accessory (pendant control, perfusion arm, etc.) and rail</p>	<p>Patient found in her bed, unconscious, with head between the pendant control and the bed rail.</p>	
<p>Over the rail</p>	<p>An elderly patient suffering from dementia, while attempting to leave her bed, caught her feet in the rail and fell, banging her head against the bedside table. She died.</p>	

*Further reading:*

• Circular letter 011180 of December 16th 1997

• Publications by other competent authorities: 6, 7, 8, 9, 11,

## 7. Accident occurrence factors

The causes are very diverse and frequently multiple for a given accident. Three general factors, however, may be distinguished: patient's environment, bed rail design and bed rail use.

### ➤ Patient's environment

Some accidents may be related to some characteristics of a patient. The data collected are used to define specific categories of patients for whom the risk of falling and/or entrapment is particularly high.

- **The patient attempts to leave his/her bed** while the rails are raised
  - If he passes through the spaces left open (between the 1/2 rails, between a bed board and the rail), he may remain trapped by the thorax and may suffocate.
  - If he attempts to climb over the rail, he may trap a foot or arm in the bars and/or fall. The consequences may also be dramatic.
- **The patient is agitated, demented.** He may slip of his bed and become trapped, sometimes with the head pointing downwards. He may exert significant pressure to the rails, causing them to loosen, or even force his head between the bars.
- The patient is **disabled, atonic**. If he becomes trapped, he won't be able to free himself.
- The patient is **a child, placed in an adult bed**. The rails are designed to avoid risks of entrapment for adults. They do not take a child's body size into account.

The most "at risk" type of patient is not able-bodied (slight invalidity, low tonus), agitated and non-lucid (confused, disorientated, behavioural disorders following a disease or recent surgery).

#### *Further reading:*

- Medical devices vigilance data - patient characteristics and circumstances surrounding accidents [\[Download\]](#)
- Publications by other competent authorities: 6, 7, 9

*The most "at risk" patients are disabled, agitated and non-lucid*

➤ Bed rail design - dimensions

Currently, two standards define the safety recommendations for bed rail dimensions (cf. entrapment areas):

- Standard **NF EN 60601-2-38** and its amendment 1 pertaining to particular requirements for the safety of electrically operated hospital beds
- Standard **NF EN 1970** pertaining to adjustable beds for disabled persons

*2 Standards:  
- NF EN 60601-  
2-38 +  
amendment no. 1  
- NF EN 1970*

As these standards were published in December 1999 and August 2000 respectively, many devices purchased before these dates do not conform to their safety recommendations.

Main dimensions recommended by the prevailing standards (with bed in flat position):

- The space between bars must be less than or equal to 120mm (to avoid entrapment of the head)
- The space between the headboard and the bed rail must be less than or equal to 60mm (to avoid entrapment of the neck) or
  - o greater than or equal to 235mm, as per standard 60601-2-38 (to avoid entrapment of the head)
  - o greater than or equal to 250mm, as per standard 1970
- The space between the half-rails must be less than or equal to 60mm (to avoid entrapment of the neck) or
  - o greater than or equal to 235mm, as per standard 60601-2-38 (to avoid entrapment of the head)
  - o between 250 and 400mm, as per standard 1970

These dimensions were defined based on statistical studies of adult body sizes.

Standardization process

An international standardization group is currently working on the revision of these 2 standards, the aim being to obtain a single standard covering all types of medical beds. This work may result in stricter dimensional requirements. The current project for this new standard is more stringent than the current standards, meaning that a bed rail that conforms to the requirements of this project shall conform to those of the prevailing standards. The AFSSAPS is part of this group in order to improve the standard as a safety reference for beds and their rails.

*Bed rails that fail to conform to the requirements of the current standards should be replaced first.*

In the context of materiovigilance, incidents have also been reported involving beds compliant with prevailing standards, though these are less common than those involving non-compliant beds. Recent data collected tend to suggest that the space between headboard and rail should be reduced and that a distance of 235 mm between half-rails can lead to entrapment (of the thorax). These data have been forwarded to the international standardization group.

Older rails that do not conform to current standards present the highest risk and should therefore be replaced first.

When you buy new bed rails, make sure that they are compatible with existing beds!

Some manufacturers propose accessories (protective netting, etc.) used to modify the dimensions of their rails, thus reducing the risks. These accessories are particularly useful in the following situations:

- old bed rails that do not conform to current standards, while awaiting their replacement with more secure rails
- "at risk" patients (see above)

*Some manufacturers propose accessories aimed at increasing the safety of certain bed rails.*

*Further reading:*

- Standards NF EN 60601-2-38 amendment 1 and NF EN 1970

- Publications by other competent authorities: 4, 7, 8, 10, 11

➤ Use of beds / bed rails

- **Benefits and risks of bed rails:**

The rails are designed to prevent patients from falling during their sleep and transport

BUT

they are not designed to prevent patients from deliberately leaving their bed. Many accidents occur when patients attempt to leave their bed, despite the presence of bed rails.

*The bed rails are not designed to prevent patients from deliberately leaving their bed*

Restraint devices can be adapted to keep patients in bed. Specific restraint systems exist for beds,

BUT

These devices should be used with reservations and by prescription. The inappropriate use of retraining devices may have very serious clinical consequences. Actual restraint management for each patient is therefore necessary.

In certain cases, the rail can prevent falls,

BUT

it may represent a hazard: injuries, falls after entrapment of a limb in the rail, asphyxiation after entrapment of the head, neck or thorax.

A risk/benefit analysis should be conducted on the rail to decide whether it should be used or not.

This assessment must take into consideration:

- the department's surveillance capacity: a department-specific bed rail usage protocol can be drafted
- the patient's physical and mental condition: his/her needs, abilities, lucidity, size and agitation. This assessment should be reiterated regularly.

- **Need for surveillance:**

No technical means can replace patient surveillance. Special surveillance is required for agitated, disabled, non-lucid persons and children.

Regular surveillance allows rapid intervention if the patient is trapped and can avoid serious clinical consequences.

Regular surveillance allows healthcare workers to respond to patients' needs, thus reducing the reasons for them to leave their beds.

In light of the data collected by the medical devices vigilance system, most accidents occur at night, when surveillance is not as sustained. [Cf. "patient profile and consequences", p7]

*Most accidents occur at night, when surveillance is less frequent*

- **Training:**

A poorly fitted or inappropriate rail may represent a risk. It is important to ensure that all individuals handling bed rails are suitably trained. A large number of different rails are available. To ensure safe use, the manufacturer's instructions must be followed. Whenever a device is purchased, the concerned users must be suitably trained. Training should then be continued, to accompany the turnover of healthcare workers.

Healthcare staff training should cover, in particular, the following points:

- fitting and locking medical bed rails
- appropriate surveillance of at risk populations when rails are used
- compatibility of the different bed elements, normal conditions of use, along with maintenance, cleaning and disinfection of these devices.

*It is important to ensure that all individuals handling bed rails are suitably trained*

- **Compatibility issues:**

*Attention must be paid to rail / bed and mattress / bed + rail compatibility*

Considering the large number of beds and their specific characteristics, not all bed rails are compatible with all bed models. Some user manuals list these compatibilities. If not, the bed manufacturers can inform you concerning the compatibility of their beds with the various accessories.

Accidents may occur with bed/rail assemblies that have neither been designed for this purpose, nor validated: creation of entrapment areas, poor attachment.

Similarly, not all mattresses are compatible with all bed/rail systems. Two elements may represent a hazard:

- the dimensions of the mattress must match the bed to avoid the creation of entrapment and fall areas. In particular, the use of a very thick mattress (or mattress topper) may reduce the relative height of the bed rails, thus increasing the risk of falling). The current standards define this safety dimension: the height difference between the upper edge of the side rail and the top of the uncompressed mattress must be greater than 220mm (over at least 50% of the length of the lying surface. Similarly, a very thin mattress may increase the risk of sliding under the rail.
- the shape of the mattress must match the bed with its accessories (pendant control, perfusion arm, etc.)

If a mattress overlay is used to prevent bedsores, then a thinner mattress should be used in order to compensate for the additional thickness conferred by the topper. The use of a therapeutic mattress that reduces relative rail height, must give rise to an assessment of the benefit to risk of falling ratio. Increased surveillance is important.

- **Steps to be taken to reduce the seriousness of potential accidents:**

- Study, as a team, the alternatives to the use of bed rails.
- Placing the bed in the lowest position when treatment is not being administered reduces the risks in the event of a fall.
- Systematically checking, on each use, that the bed rails are locked in their raised position and that they are correctly fitted to the bed frame (for removable bed rails), prevents risks due to falling or partial removal of the bed rails.
- Inform the maintenance services of any malfunction or suspicious part.
- Foam cushions can be placed on the floor to reduce risks in the event of a fall.

- Restraining devices may be used to hold agitated patients in their beds, if prescribed and subject to compliance with instructions for use.
- If the bed is fitted with half-rails, the foot-side half-rail may be left in the low position to allow the patient to leave his/her bed without the risk of becoming trapped.
- Use of beds in very low position, without rails.
- If the bed is fitted with a selective electric function locking unit, some functions may be locked, depending on the type of patient.
- If the patient is a child, use a cot if his/her body size allows it (according to cot instructions for use). If not, the child must be placed, whenever possible, in a bed adapted to his/her morphology.

- **Maintenance**

Like any mechanical device, bed rails wear with time and use. This wear mainly involves broken, damaged or corroded parts on the one hand, or loosened nuts on the other. Bed and bed rail traceability allow for preventive maintenance, in accordance with the manufacturer's recommendations, thus preventing accidents due to bed rail collapse. The bed is not a piece of furniture: it is a sophisticated medical device requiring organised maintenance.

A quality control assistance document for medical beds, including inspection of bed rails, is currently being finalized by the concerned professional associations, in the context of the SNITEM.

*Preventive maintenance prevents risks of bed rail detachment.*

*Further reading*



- [sensitisation document](#) to the correct use of bed rails, intended to be broadly distributed amongst healthcare workers (in particular nurses and auxiliaries) [\[Download\]](#)
- [Poster](#) summarising this document's key points, intended for display in healthcare units [\[Download\]](#)
- ANAES document "Assessment of professional practices in healthcare establishments - Limiting the risks of physically restraining elderly patients", October 2000. Circular letter 011180 of December 16th 1997 (Training and maintenance)
- Publications by other competent authorities: 1, 2, 3, 5, 6, 7, 8, 9, 10

 **8. Additional actions**

The AFSSAPS is currently conducting a survey of commercially available bed rail compliance with prevailing standards and encourages industry to take into account data collected in via the medical devices vigilance system and made available to them.

The SNITEM has proposed to draft the template of a simplified manual for medical beds, in collaboration with the other concerned unions. This document will be submitted to the AFSSAPS for validation.

The AFSSAPS is working alongside the concerned industries towards defining solutions for securing existing medical beds currently in use.

Work concerning the adaptation of beds to big children is ongoing.

The AFSSAPS is part of an international standardization work group aimed at defining the future medical beds standard, contributing the medical devices vigilance data.

## 9. Medical devices vigilance reporting

Furthermore, in the context of medical devices vigilance, we would ask you to report, via your facility medical devices vigilance correspondent, by filling in the "bed rails" questionnaire, available from the Website ([www.afssaps.fr](http://www.afssaps.fr)), any incidents or risks of incident involving medical bed rails, to:

l'Agence française de sécurité sanitaire des produits de santé – Département des vigilances  
Fax: +33 (0)1.55.87.37.02.

Your reports enable us to better inventory, study and process existing problems and risky situations.

### Declaration form:

- CERFA medical devices vigilance reportform [\[Download\]](#)
- Specific questionnaire for falling and/or entrapment incidents related to bed rails [\[Download\]](#)

## 10. Bibliography

### French or international documents

- Circular letter 011180 of December 16th 1997 « Utilisation des barrières de lit à usage médical » [\[Download\]](#)
- Règlement particulier de la marque NF médical – lits médicaux NF178, juillet 2000 2000 [available from the Laboratoire National d'Essais (National Test Laboratory)]
- Standard EN 60601-2-38 amendment 1 "Special safety rules for electric hospital beds", December 1999 [Available from AFNOR]
- Standard NF EN 1970 "Adjustable beds for disabled persons - Requirements and test methods", August 2000 [Available from AFNOR]
- ANAES document « Evaluation des pratiques professionnelles dans les établissements de santé – Limiter les risques de la contention physique de la personnes âgée », October 2000 [\[Download\]](#)
- Draft standard NF EN 60601-2-52 "Particular requirements for the safety and essential performance of medical beds", January 2005 draft
- "L'hospitalisation en France – Informations Hospitalières" Review, March 2000, Special issue no. 53 « L'hôpital public en France : bilan et perspectives », Economic and Social Council, June 28th 2005
- « Le handicap en chiffres », document published by the Ministry of Health, February 2004

Publications by the British competent authority (MHRA)

- [1] SN 2001(11) - Bed Grab Handles: Risk of Head Entrapment, February 2002 [\[Download\]](#) [2]
- HN 2000(10) - Bed Side Rails (Cotsides) - Risk of Entrapment and Asphyxiation, July 2000 [\[Download\]](#)
- [3] SN 2001(35) - Bed Rails (Cotsides) - Risk of Entrapment and Asphyxiation Supplement to HN2000(10), March 2002 [\[Download\]](#)
- [4] MDA/2004/007 - Bed rails: twin-bar designs, February 2004 [\[Download\]](#)
- [5] MDA/2004/014 - Replacement mattresses for hospital beds used in hospitals and the community, March 2004 [\[Download\]](#)
- [6] DB 2001(04) Advice on the Safe Use of Bed Rails, July 2001 [\[Download\]](#) (report + poster)

Publications by the US competent authority (FDA)

- [7] FDA Safety Alert: Entrapment Hazards with Hospital Bed Side Rails, August 1995 [\[Download\]](#)
- [8] Draft Guidance for Industry and FDA Staff - Hospital Bed System Dimensional Guidance to Reduce Entrapment, August 2004 [\[Download\]](#) (document distributed for comments)

Publications by the Canadian competent authority (Santé Canada):

- [9] L'utilisation des côtés de lit à l'hôpital dans les foyers de soins et dans le cadre des soins à domicile, May 2001 [\[Download\]](#)
- [10] Risques que posent les côtés de lit d'hôpital demi-longueur, alerte n°107, August 1995 [\[Download\]](#)

Publications by the German competent authority (BFARM)

- [11] Einklemmungen bei Kranken- und Pflegebetten, June 2004 [\[Download\]](#)

## 11. Conclusion

The main purpose of this document is to make medical and paramedical staff in healthcare facilities and EHPAD aware of the risks associated with the use of bed rails; this awareness being the basis of a better choice and better use of bed rails. A summary [\[Download\]](#) lists the key points of this document.

In parallel to the distribution of this information, the AFSSAPS is working in collaboration with the concerned industries, in particular to search for possible solutions for securing existing beds in use.

Your information shall be updated as the actions are implemented.