

HEALTH CANADA'S NEW GUIDANCE ON HOSPITAL BED SAFETY: PATIENT ENTRAPMENT, SIDE RAIL LATCHING RELIABILITY, AND OTHER HAZARDS

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INTRODUCTION

Between 1980 and 2006, Health Canada received 51 reports of life-threatening bed entrapment incidents, 26 of which led to deaths. Entrapment events account for almost one fifth (18.3%) of all the bed-related events that are reported to Health Canada. These same entrapment incidents account for 63% of all deaths that have been reported with the use of beds. There have been at least 17 coroners' inquests or investigations into deaths related to beds and side rails; many of these deaths are included in the above statistics.

In response to continued reports of patient entrapment, the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau, health care organizations, equipment manufacturers and other stakeholders, formed a working group in 1999 known as the Hospital Bed Safety Workgroup (HBSW) to improve patient safety associated with the use of hospital beds.

Health Canada has published a new guidance entitled *Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards*, based on the HBSW recommendations to assist health care institutions in assessing and reducing the risk of entrapment posed by hospital beds. The guidance is available on the Health Canada medical devices website at

http://hc-sc.gc.ca/dhp-mps/md-im/index_e.html

The HBSW developed a safety guide which has been published by the US FDA, and is available at the following address:

<http://www.fda.gov/cdrh/beds/guidance/1537.html>

SCOPE OF THE NEW GUIDANCE

New Beds

Under the Canadian Medical Devices Regulations, most beds are classified as Class I devices, which do not require a medical device licence and therefore are not subject to pre-market review by Health Canada. Some specialty beds (e.g., powered patient rotation

beds and powered flotation therapy beds) are Class II and a few (e.g., breathing assist rocking beds) are Class III. There are no criteria to adequately review the design of hospital beds. At present, there are no national standards or regulations specific to beds or side rails in either Canada or the United States.

The new guidance provides recommendations for the devices listed in Table 1.

Table 1: Bed classifications covered by the guidance

Preferred Name Code	Classification Name	Class
80FNJ	Manual adjustable hospital bed	I
80FNK	Hydraulic adjustable hospital bed	I
80FNL	AC-powered adjustable hospital bed	I
89IKZ	Powered patient rotation bed	II
89INY	Manual patient rotation bed	I
89IOQ	Powered flotation therapy bed	II
73CCO	Breathing assist rocking bed	III

Legacy beds

Legacy beds are ones that are no longer sold and for which the manufacturer no longer provides parts or service. Many of these older beds are still in use and may no longer have the original mattress or bed rails, and may present an entrapment hazard because the use of replacement components has created or enlarged gaps or spaces between various parts of the bed system. Because beds often have very long service lives, one of the most important purposes of the guidance is to assist health care professionals in assessing the entrapment risk posed by the legacy beds still present in their facilities.

OVERVIEW OF THE GUIDANCE

Key body parts at risk

Three key body parts at risk for life-threatening entrapment are the head, neck, and chest. International anthropometric data references have been used to determine the relative sizes of these body parts for the population at greatest risk for

entrapment and to provide a guide for the dimensional limits on bed components that would reduce their risk of entrapment.

Table 2 presents the anthropometric data used by the HBSW in determining the dimensional limits for the different entrapment zones.

Table 2: Key body part dimensions

Body part at risk	Dimension used for recommendation
Head	120 mm (4 3/4 inches)
Neck	60 mm (2 3/8 inches)
Chest	318 mm (12 1/2 inches)

Potential zones of entrapment

The guidance describes seven zones in the hospital bed system where there is a potential for patient entrapment. Entrapment may occur in flat or articulated bed positions, with the rails fully raised or in intermediate positions. The seven entrapment zones are identified in Figure 1 and briefly described in Table 3.

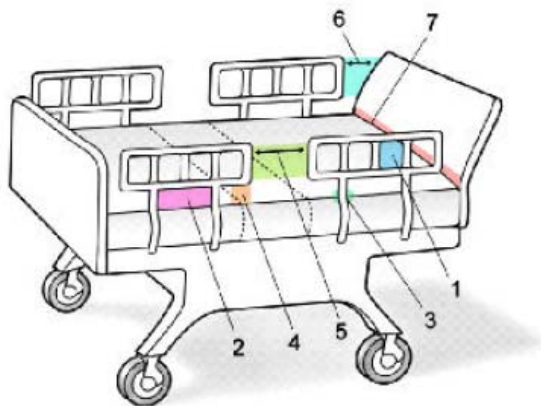


Figure 1: Seven zones presenting entrapment risks

Table 3: Identification of entrapment zones

Regions with dimensional recommendations	
Zone 1	Within the rail
Zone 2	Under the rail, between the rail supports or next to a single rail support
Zone 3	Between the rail and the mattress
Zone 4	Under the rail, at the ends of the rail
Regions without dimensional recommendations	

Zone 5	Between split bed rails
Zone 6	Between the end of the rail and the side edge of the head or foot board
Zone 7	Between the head or foot board and the mattress end

Dimensional Limits for Identified Entrapment Zones

Health Canada is recommending dimensional limits only for zones 1 through 4 at this time because it is believed the majority of the entrapments reported to FDA and Health Canada have occurred in these zones. Health Canada’s dimensional limits are based on the body parts which became trapped in the identified zones, as identified from adverse event reports. Table 4 presents a summary of recommended dimensional limits for hospital beds.

Table 4: Summary of dimensional limits

Zone	Recommended dimensional limits
Zone 1	< 120 mm (< 4 3/4 inches)
Zone 2	< 120 mm (< 4 3/4 inches)
Zone 3	< 120 mm (< 4 3/4 inches)
Zone 4	< 60 mm (< 2 3/8 inches) and > 60 degree angle

Mattress compatibility

If the mattress used in a hospital bed is incompatible with the bed system, certain entrapment zones may be become enlarged and pose a greater risk to the patient.

The guidance recommends that bed manufacturers provide specifications for mattresses that are compatible with their beds. These specifications should be permanently marked directly on the bed, in case the original bed documentation is ever misplaced.

TEST METHODS

The HBSW has developed a test method and tools for properly measuring the dimensions of the 4 entrapment zones for which Health Canada has published dimensional recommendations.

The tools were designed to be easy to use and to minimize ambiguous results, and the test methods

were designed so that measurements taken with the tool are reliable and easily interpreted.

The guidance gives detailed instructions for taking the measurements and interpreting the results obtained.



Figure 2: Cone and cylinder test tool

The test tool (Figure 2) is simply a cylinder with a cone on the end. The diameter of the cylinder is that of a small adult neck and the diameter of the large end of the cone is that of a small adult head.

The test tool is available through *National Safety Technologies* (<http://www.nst-usa.com/>). The NST website features videos demonstrating proper use of the test tool for entrapment zones 1, 2, 3, and 4.

RELIABILITY OF SIDE RAIL LATCHING

Another hazard of hospital beds is the possibility that the latching mechanism on side rails may not remain raised when subjected to normal forces, allowing the rails to drop, or that side rails may only appear to be secured in the raised position, again allowing the rails to drop.

A test method for assuring the reliability of side rail latching is given in the guidance. The test is designed to ensure that side rails can withstand the forces applied during reasonably foreseeable misuse over the product life cycle without creating an unacceptable risk.

REPORTING ENTRAPMENT INCIDENTS

The guidance was based on user reports of entrapment incidents. Unfortunately, many of these reports lacked sufficient detail to identify the region of the bed system or the body part involved in the incident.

In order to more thoroughly and precisely document bed-related entrapment events, Health

Canada has also published a specialized incident report form.

CONCLUSIONS

It is hoped that the new Health Canada guidance for the safe design of hospital beds will help to reduce the number of patient deaths and injuries from entrapment. Health professionals are encouraged to download the guidance and use it to assess the safety of the hospital beds in their institutions.