

CARROLL HEALTHCARE - CARROLL HOSPITAL GROUP
INVACARE CONTINUING CARE GROUP

HBSW COMMENTS

NOTE:

Due to the related business nature of the Invacare Corporation and Carroll Healthcare, some collaboration between the two companies was made regarding the submission of comments. There will be some duplication and similarities between the comments below and those provided by Invacare Corporation. However, because of the differences in the markets that are served by both companies (home care, long term care, acute care), we will provide two different sets of comments.

OVERVIEW

Carroll Healthcare, a division of Invacare Continuing Care Group, and all its divisions, including Carroll Hospital Group, have been active members of the Hospital Bed Safety Workgroup since inception in 1999. As always, we will continue to support the FDA. We will also endorse the newly proposed guidelines and will provide any further assistance that is requested from us. It is our belief that these guidelines will prevent injuries and deaths, and should be published without further delay.

As its stated goal, the Hospital Bed Safety Workgroup was formed in order to “improve the safety of hospital beds for patients who are most vulnerable to the risk of side rail entrapment”. Over the last six years, the group has made great strides in discussing, debating, defining, and making recommendations involving all of the issues surrounding bed rail entrapment, in order to achieve this end.

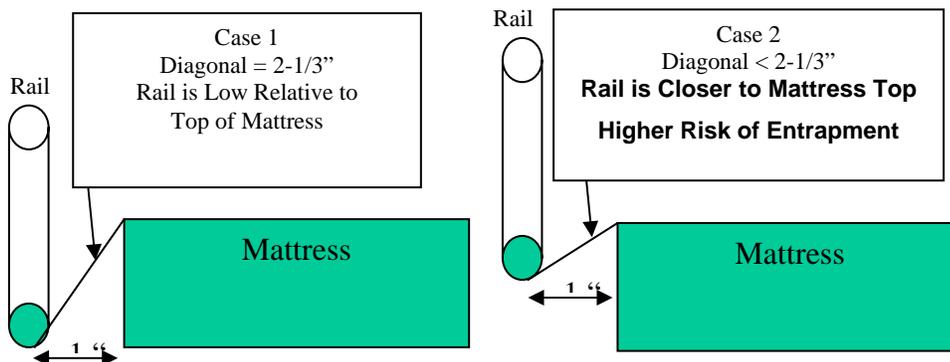
At this point, it has been well circulated that the FDA is preparing to publish guidelines that will change how the industry deals with this issue. However, the recent delays in releasing these official guidelines have paralyzed the industry. The delays have inadvertently resulted in the following detrimental activities:

- the continued fatality rate as a result of bed rail entrapment;
- the majority of decision-makers in the health care setting are aware of the ‘entrapment guidelines’ in some respect, yet, because of a lack of official details, are unsure of what action to take;
- facilities are avoiding much needed replacement or repair of bed systems until a defined standard is published, for fear of wasting capital expenditures on products that may be considered ‘non-compliant’ in a matter of months;
- in order to avoid duplicate tooling costs, certain manufacturers are withholding both ‘retrofit’ designs for older beds and newer bed rail designs for current beds until a defined standard is published;
- various states are implementing their own official rail standards, which will have at least some inconsistencies with the final FDA Guidelines;

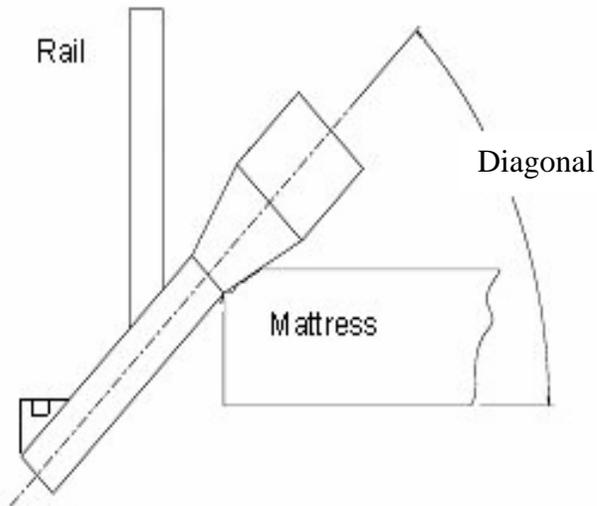
- individual surveyors and inspectors are citing facilities for rails that are non-compliant, yet they are being measured against a standard that does not yet exist;
- to avoid being cited, many health care facilities are removing rails from beds altogether or placing patients and residents on mattresses on the floor.

GENERAL COMMENTS ON DRAFT GUIDANCE

1. Carroll Healthcare, Invacare Continuing Care Group, and Carroll Hospital Group (CHC) believe that the assessment methods defined in the Guidance must be more completely defined. By not specifying the details of the referenced HBSW and IEC assessment methods, some of the assessment methods specified in the Draft Guidance are ambiguous and misleading.
 - a. The Guidance instructs the assessor to take mattress compressibility into account without defining the method. Without defining the method to simulate or account for mattress compression, assessments will be performed in many different ways resulting in large variation. To rectify that situation, CHC recommends that the Guidance present the details of the HBSW assessment methods, including the weighted assessment tool and the details of the IEC assessment methods in Zone 2 and Zone 4.
 - b. Zone 2 and Zone 4 directs: ...FDA is recommending a diagonal dimensional limit less than 2-1/3" inches in Zone 4 (4-3/4" in Zone 2) ... from the inside bottom edge of the rail... to the top of a compressed mattress... These directions are correct only if the HBSW Assessment Tool is used for the measurement; following the directions as described (without the assessment tool) can actually lead to higher risks of entrapment (see illustration below).



** Case 2 where the Diagonal is less than 2-1/3" has a higher risk of entrapment than Case 1 where the Diagonal = 2-1/3". The desired results would be achieved if the HBSW assessment tool and method were used as illustrated below.*



CHC recommends using the HBSW assessment tool and method for diagonal measurements. CHC also recommends that where the HBSW Assessment Methods are specified that the entire HBSW Assessment Method be defined in the Guidance either directly or by reference.

2. CHC recommends that both the HBSW and the IEC Assessment Methods continue to be used in the guidance. CHC specifically recommends that the IEC method be added to Zone 4 in addition to the HBSW method currently specified in this zone.

Note: CHC encourages the use of the IEC assessment methods wherever possible because they are easier to follow/implement and are therefore more likely to be correctly implemented and used. CHC proposes that the IEC assessment method be added to Zone 4 with the addition of the 60-degree assessment point.

SPECIFIC COMMENTS ON DRAFT GUIDANCE

Exclusions

The risks associated with the use of framed flotation therapy products are real and accurate. There are, also, definite clinical benefits that can be achieved through their use. While there may be other additional factors that need to be recognized with respect to these products, at this point, the Guidelines are the most complete method of measuring any bed system's risk of entrapment. We recommend removing these products from the list of exclusions, while proceeding with a more in-depth review and discussion into the clinical guidelines for their use.

Zone 1

The written description of the recommended space is not sufficient. Without specifically stating that the dimension is a circle with diameter of 4-³/₄" , testers will 'fail' bed rail systems that quite obviously should 'pass'. For example, by the current definition, a space within a rail that measured 1" width x 5" length would technically fail (because the "space" is not "less than 4-³/₄"), even though there is obviously no risk of head entrapment in a space that is only 1" wide.

Zone 2

CHC recommends that both the HBSW Assessment Method and the IEC Assessment Methods be specified. A 4-³/₄" dimensional limit as measured in each assessment method should be specified.

Supporting Comments:

1. CHC believes that entrapment can only occur in this zone if the head slips under that rail and therefore this zone's acceptance criteria should be based on head size.
2. Considerable substantiative study and consideration by the HBSW and the IEC have come to the same conclusion. They both specify 4-³/₄" as the standard dimension to simulate a small female head; CHC believes the Guidance should follow the results of that work and specify a gap less than 4-³/₄" in this zone.
3. Compressibility -- Both the IEC and HBSW assessment methods take compressibility into account.
 - a. HBSW uses a weighted probe to simulate the weight of a head, which accordingly compresses the mattress in simulated manner.
 - b. IEC specifies that the gap between the mattress platform and the bottom of the rail to be less than the 4-³/₄" (small female head size). In real life situations, any additional mattress thickness, even if the mattress is highly compressed, will further decrease the risk of entrapment. Note: The same reasoning applies to the 2-1/₃" limit in Zone 4.

Zone 3

CHC recommends that Zone 3 follow the HBSW assessment method and use 4-¾” as the dimensional limits.

Supporting Comments:

1. Zone 2 comments #2 and #3a support these recommendations.

Zone 4

CHC recommends that both the HBSW assessment method and the IEC assessment methods be specified. A 2-1/3” dimensional limit as measured in each assessment system should be specified. Both methods should take into account the 60-degree triangular entrapment zone at the end of the rail.

Supporting Comments:

1. CHC believes that entrapment can only occur in this zone if the neck slips under the rail and therefore this zone’s acceptance criteria should be based on neck size.
2. After studies similar to those noted above for head size, the HBSW and IEC both specify 2-1/3” as the standard dimension to simulate a small female neck; CHC believes the Guidance should follow the results of that work and continue to specify a gap less than 2-1/3” in this zone.
3. Zone 2 comments #3a and #3b support the above recommendation relative to compressibility.

Zones 5-7

Consistent with the previous zones, we feel that these zones should be measured in a flat deck position.

Health Care Settings

The risks of bed rail entrapment are apparent across the entire continuum of health care – acute, long term, and home care. We do not believe that any of these environments should be excluded from the guidance document.