

14th December 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
USA

Dear Sir/Madam

Please find enclosed comments from Huntleigh Healthcare Ltd on:

**Draft Guidance for Industry and FDA Staff; Hospital Bed System Dimensional Guidance
to Reduce Entrapment**

Yours faithfully



Dave Bentley
Group Regulatory Director

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2004D-0343

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**Comments On:
Draft Guidance for Industry and FDA Staff
Hospital Bed System Dimensional Guidance to Reduce Entrapment**

Introduction

The following comments relate to document number 1537, issued by CDRH on 30th August 2004. The comments below are a summary of all comments from Huntleigh Healthcare Ltd. Contact Details: Mr Dave Bentley, Group Regulatory Director, Huntleigh Healthcare Ltd, 310-312 Dallow Road, Luton, Beds, LU1 1TD.

Comments

Page 5 – Exclusions

It is noted that air fluidised therapy beds are excluded from the scope of this guidance on the understanding that the benefit to the patient is expected to outweigh the risk of entrapment. This exclusion should apply to all therapy or specialised systems where the benefit to the patient will outweigh the risk.

Page 6 – Pressure Reduction Therapeutic Products

A definition is required for pressure reduction therapeutic products. It is not clear which foam mattresses this would apply to. It is also not clear how pressure relieving mattresses (e.g. alternating pressure systems) fit into this definition.

Page 7 – Request for Comments 1 – Exclusions

There is an assumption in this document that it is reasonably practicable to make products which comply with the requirements. This obviously becomes more difficult when a product is being designed to provide optimum tissue pressure reduction. Such products, by their nature, tend to be more forgiving and less solid. These products benefit a huge number of patients and entrapment incidents are very rare.

Consequently, we do not believe that there should be any specific requirements within this document covering powered air mattresses and the acceptable decision should be based on risk management philosophy.

Page 8 – Head

This paragraph does not make sense unless “openings” are defined. Obviously, there needs to be a gap large enough to get a person into and out of the bed, but the current wording states that all gaps should be small enough to prevent passage of the widest part of the head.

Page 9 – Neck Entrapment

Unfortunately, there is not enough detail in this section to cover complex angles and curves. The requirement should state that the angle is measured at the point where contact is made with the 60mm cylinder and that the angle of the side, or (if the side is curved) the angle of the tangent to the curve is greater than 60 **degrees**

Page 11 – Potential Zones of Entrapment

The opening paragraph states that entrapment may occur in flat or articulated bed positions. However, the tests in the subsequent paragraphs all seem to be based on the flat position. Attention should be paid particularly to zone 5, in articulated positions of the bed.

The tests specified for the various zones are often complex. The test for zones 2 and 4 need not be so complex if the bed complies with IEC 60601-2-38 (soon to be IEC 60601-2-52). Assessment of the complex interaction with the mattress is not required since the bed design will have already reduced the risk to an acceptable level.

Therefore, the best option is compliance with the IEC standards. However, it is understood that a test may be required for establishments which have a stock of beds which do not comply with the IEC documents, and hence mattresses are being used to control the risk. The new test of 2 and 4 should be restricted to this situation only. There is no requirement for such complex tests for IEC compliant beds.

Page 13 – Zone 1

We agree with these dimensional limits. They are consistent with HPSW, IEC and current practice.

Page 14 – Zone 2

There is no test given for this particular requirement. The mattress is compressed by the “weight of a patients head”, however no such test sample is provided and consequently consistency is unlikely. As mentioned previously, if the bed and side rail comply with the IEC dimensional limits there is no need to do this test, since an acceptable level of safety is already provided.

This should be explicitly stated in the guidance and a test provided for situations where the bed does not comply with the IEC dimensional limits. In this situation a test sample will need to be specified to provide the appropriate compression.

Page 15 – Request for Comments 2

In response to the FDA request for comments and data, on whether it should modify its recommendation to recommend a dimensional limit of less than 60mm in Zone 2, we have the following comments:

The IEC 60601-2-38 standard was amended in 2000 to include a requirement for a 120mm (or less) gap between the bottom of the safety side and the mattress support platform. There is no history of Zone 2 entrapments on beds complying with this standard.

In order for a patient to be trapped at the neck between the side rail supports, the head would need to pass through the gap. Taking measurements from “The Measure of Man and Woman – Human Factors in Design” by Henry Dreyfuss, we can see that a less than 60mm requirement is an over stringent requirement. The smallest head dimension is the breadth (temple to temple). This dimension on the 1st percentile female is 132mm. The average 12-15 month old child has a head breadth of 127mm.

We can see from the above measurements and data that the 120mm requirements of IEC 60601-2-38 is sensible and acceptable.

In the FDA draft document there are various factors stated, however, there is some doubt about several of the statements.

In the first bullet point, it is stated that retrospective measurements in the flat deck position range between 76 and 191mm. It is not possible that an adult head would pass through a gap of 76mm. If this dimension is correct and the entrapment mechanism was zone 2, then it can only be assumed that the dimension changed when the deck was not flat. This situation would be better dealt with by measuring the zone 2 in contoured positions.

The second bullet point states that if the reported entrapment occurred at zone 2, the 120mm would have prevented only about half of them. Taking into consideration the dimensions stated above, it is highly likely that the reason for this perceived problem is that the events reported were not actually zone 2 events but were zone 3 or 4.

The third bullet point states that the IEC dimension of less than 120mm is not comparable to this new dimension. This is true. However, the IEC dimensional limit will prevent zone 2 entrapment and is far easier to measure. Use of a bed complying with the IEC dimension will reduce the need for individual assessments of zone 2 entrapment with each bed/mattress combination in a healthcare establishment.

The fourth bullet point states that older mattresses are more compressible. This is true for foam mattresses. For this reason, and also for the restless patient reason given in the next bullet point, it would seem appropriate to work towards the IEC 60601-2-38 compliant

side rail as a gold standard and as a less favourable option create a compressible mattress test.

The sixth bullet point is correct to state that patient care does not occur in a flat deck position only. Appropriate tests should be conducted in various positions of the bed.

Page 16 – Request for Comments 3

In response to the request for comments on the possibility of reducing the dimension from 120mm to 60mm, we have the following comments.

The requirement is based on the fact that there have been a number of incidents which **possibly** occurred in this gap but it is not clear that this is actually the case.

A review of the practicalities of entrapment in this particular position has shown that with a good design of side rail (i.e. one which complies with IEC 60601-2-38) there is very little risk of entrapment when using a gap of 120mm. For side rails where the gap between the rails is greater than the 120mm it is possible for the body to pass further through the side rails and hence make its positioning between the mattress and side rail more likely. Once again, use of an IEC compliant bed will certainly make this type of entrapment less likely.

It should also be noted that the rest of the body has a major part to play in this particular type of entrapment since it is virtually impossible to get the head trapped down the side of the mattress without involving the rest of the body.

In relation to the proposed 60mm gap, we feel that this could create more problems than it solves. In the event that somebody became entrapped down the side of the mattress there would be a much larger clamping force holding the person in place. Such a small gap is also likely to create a greater potential for entrapment of other devices and, for example, squeezing of drainage tubing. There will also be issues of interference between the mattress and side rail.

We do not feel that a move to 60mm is either necessary or sensible.

Page 17 – Zone 4

As with Zone 2 the test described in these paragraphs are not required for a product which complies with IEC 60601-2-38. We would therefore suggest that this complicated test is only performed where the bed does not comply with the IEC standard.

Page 19/20 – Zone 5 (+ Request for Comments 4)

The data from the retrospective study does not mention how many of the incidents occurred where the gap was between 235 and 318mm. In principle, if there are many incidents in this range it would make sense to change the dimension to 318mm from

235mm, however if there are very few incidents it would not. If a dimension is to be increased to 318mm, consideration should be given to the additional risks created. In this case, the risk of falling would be increased due to the reduction in length of side rails. Side rails are intended to provide protection against falling.

Page 21 – Request for Comments 5

The suggestion is agreed as a good way forward.

Page 22 – Request for Comments 6

In response to the request for comment:

- There have been no reported incidents in fifteen years with regards to head entrapment of the head/foot end as per the illustration.
- It is physically difficult to position the body and head so that a suffocation risk exists at the head/foot board end of the bed.

Page 23 – Additional Request for Comments 7

- We do not have records of events in articulated bed positions. However, our beds are designed to generally comply with the dimensional requirements in all positions of use, so this is unlikely to occur on our particular designs. Where beds are not designed to be compliant in all positions of use, it is quite likely that these structures moved under power could create an entrapment hazard or crushing hazard.
- There is a risk of entrapment in articulated bed positions with split side rails (which do not meet the dimensional requirements in all positions). It should be noted that patients are often left for long periods of time with the bed in an articulated position.

Page 23 – Additional Request for Comments 8 – Care Settings

The guidance document should apply to beds in all care settings. Patients in long term care and at home are often at greater risk since they are left for longer periods of time without attendance.

Additional Comments

We believe that the document is lacking information in terms of the height of side rails. The purpose of a side rail is to prevent falls and this document does not address the issue at all. Many of the design issues involving side rails relate to the inter-relationship between side rail height and side rail gaps. Concentrating only on entrapment may introduce additional risks.

It should also be noted that side rails are not defined in this document. The requirement should also relate to any aid or accessory which is attached to the side of the bed, since

the risks are the same and items such as grab handles should be treated in the same way as side rails.