

# ALTERNATING PRESSURE MATTRESSES AND BED ENTRAPMENT – AN UNFORESEEN HAZARD

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## INTRODUCTION

The hazards of patient entrapment in hospital beds have been widely publicized. Many patients have died as a result of these hazards. The hazards relate to the gaps between the mattress and the bed rails or headboard. In 2006 The US Food and Drug Administration (FDA) published guidelines for healthcare facilities to assist them to minimize these risks. These guidelines had been developed by an international Bed Safety Working Group (Reference [1]) In 2008, Health Canada published similar guidelines [2]. The guidelines specify the maximum gap that can occur between a mattress and a side rail, or a mattress and a headboard. The guidelines contain illustrations showing the types of entrapment that have occurred. These are reproduced here in Figures 1-4 (From Reference [1])



Figure 1: Zone 1 - Within The Rail

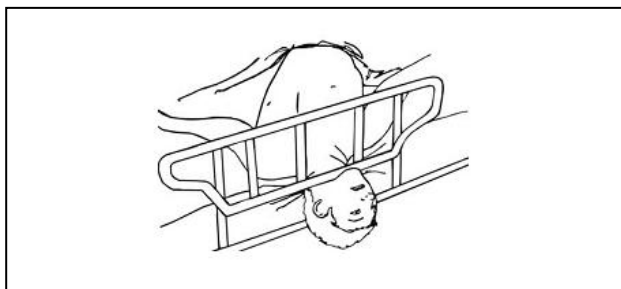


Figure 2. Zone 2 – Under the Rail, Between the Rail Supports or Next to a Single Rail Support.

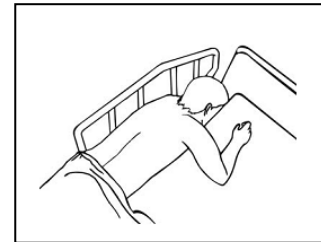


Figure 3: Zone 3 – Between the Rail and the Mattress.



Figure 4: Zone 4 – Under the Rail at the Ends of the Rail.

These gaps can be measured with a test tool that is described in the guidelines. The test tool simulates the size and weight of a small human head and neck. This test tool is shown in Figure 5.

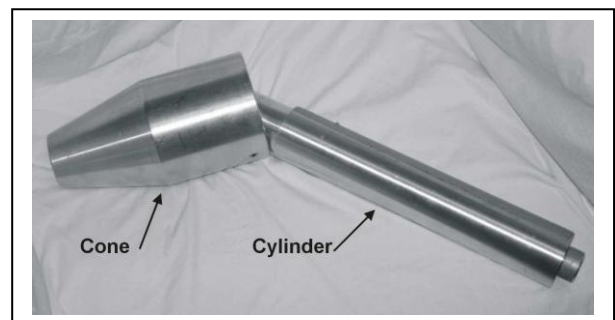


Figure 5: Bed Entrapment Test Tool

The diameter of the large end of the cone represents the width of a small adult head (120 mm, or approximately 4 ¾ inches). The diameter of the cylinder represents the size of a small adult neck (60 mm, or approximately 2 3/8 inches). The cone and cylinder together weigh 15 lbs. This represents the

combined weight of an adult head (12 lb or 5.5 Kg) and neck (3 lb or 1.4 Kg).

### AN UNFORSEEN HAZARD

This paper will document a situation that was not foreseen by the above guidelines and test methodology. That situation is the dynamically changing profile of an alternating pressure mattress. Such mattresses are widely used to treat bed sores, both in acute care and chronic care facilities.

An example of such a mattress is shown in Figure 6.



Figure 6. Alternating Pressure Mattress system with control unit.

The author has been involved in several incident investigation in which a patient became entrapped by an alternating pressure mattress. The patients died as a result of these entrapments. The tests conducted on one of these mattresses will be illustrated here.

Tests were conducted on the bed and mattress as recommended by the above guidelines [1]. The bed and mattress passed all tests. Figure 7 illustrates the criteria for a zone 3 test using the test tool (From [1])

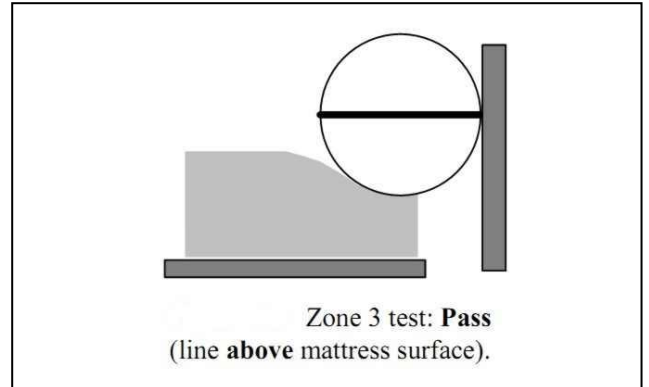


Figure 7: Test criterion to pass Zone 3 test

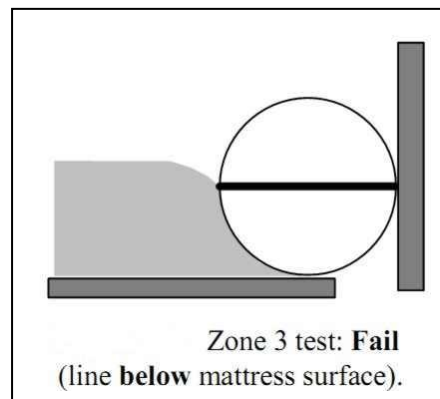


Figure 8: Test criterion to fail Zone 3 test

Figure 9 shows the test tool placed on the alternating pressure mattress in static mode, and resting against the side rail. The test passes.



Figure 9: Zone 3 Test Passes with mattress in static mode.

However, when the test tool was left in place at the edge of the mattress, resting against the side rail, and the mattress was allowed to cycle in alternating pressure mode, it was observed that the test tool gradually sank into a gap that it created by its weight. This occurred over a period of about 25 minutes. The peristaltic action of the alternating inflation and deflation of adjacent cells in the mattress also pushed the test tool forward until the "neck" of the tool was pressed against the edge of the partial side rail. This was exactly the position in which the deceased patient was found. This is illustrated in Figures 10 - 15



Figure 12: 11:55 AM. One cycle later, head has begun to sink and move forward.

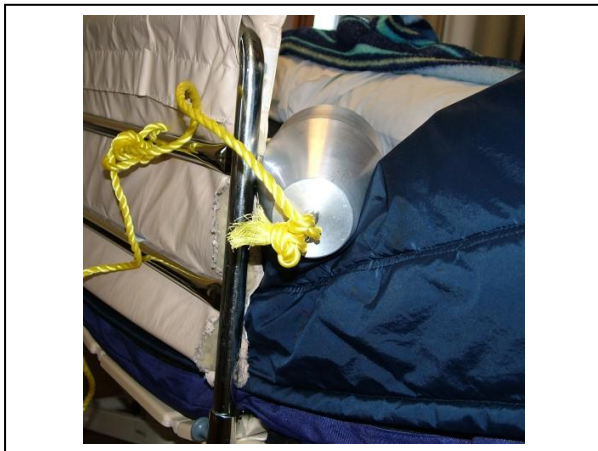


Figure 10. 11:50 AM Front view



Figure 13: 12:03 PM. After another 1/2 cycles, the head has moved farther forward.



Figure 11: 11:50 AM. Same time, top view. Mattress passes zone 3 test.



Figure 14: 12:10 PM. The head is now almost completely past the end of the side rail.



Figure 15.: 12:15 PM. The head drops. Zone 3 test fails.

### CONCLUSIONS

It is recommended that the bed safety guidelines be amended to take into account the use of alternating pressure mattresses. It is also recommended that manufacturers make changes in the design of alternating pressure mattresses to reduce the risks of entrapment.

### REFERENCES

- [1] US Food and Drug Administration, "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment," (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf>), March 2006.
  
- [2] Health Canada Guidance Document, "Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards", [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/md-im/md\\_qd\\_beds\\_im\\_ld\\_lits-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/md_qd_beds_im_ld_lits-eng.pdf), March, 2008