

To the Chief Executive:

Address Line 1

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Advisory Notice – date of issue:

Huntleigh Healthcare Contoura 880 beds – examination of safety side mounting fabrications. Type of action required: Potential fitting of replacement parts.

Please bring this notice to the attention of all those who need to know or be aware of it, both within your organisation or any organisation where the potentially affected devices have been transferred.

Description of the issue

Huntleigh Healthcare previously manufactured the Contoura 800 range of hospital beds. In June 2001 we received reports of problems with the welding process applied to some mounting fabrications of beds fitted with ¾ length folding safety sides. These were fitted to beds manufactured between December 1999 and June 2001. No injuries or deaths resulted from these problems, which only affected 17 beds. In that period we manufactured 13000 safety sides of this design. Beds manufactured after June 2001 are not affected, nor are beds fitted with the "split" safety side design, where the safety side has a head and foot section which swing down individually.

Our records show that we supplied you with XX of the potentially affected beds in this period.

The production process was changed at the time and modified parts were retrofitted to the beds where problems had been experienced. However in 2006 an incident was reported in which a safety side fell off a Contoura 880 bed. Investigation showed that the safety side fabrication was of the original, unmodified design produced in the period December 1999 and June 2001.

Advice on action to be taken

- Identify whether these beds are in use. The model and serial numbers are printed on a label located on the base of the bed, where the power lead connects to the control box. Beds which potentially could be affected have a serial number in the range 167368 to 382938.
- If you have Contoura 880 beds in this serial number range, locate the mounting fabrications that connect the safety sides to the bed frame beneath the mattress platform. There are two mounting fabrications on each side of the bed.
- Examine these fabrications for any signs of weld failure or cracking in the areas shown on Fig 1.



• If any evidence is found of these failures contact Huntleigh will provide replacement parts free of charge.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Authority.

Brian Acheson



Possible weld cracking in this area.

Note: Crack on the left is much exaggerated in this photo. The circled area should be examined for cracking.