

**URGENT – FIELD SAFETY NOTICE**  
**FSCA IDENTIFIER SAN 02/10/MBD**  
**28<sup>TH</sup> JUNE 2010**

**Subject:** Manual CPR mechanism on some Huntleigh Contoura 880 hospital beds may fail to operate

**Type of action:** Retrofit by purchaser of the MANUFACTURER'S modification

**Products affected:** Huntleigh Healthcare Ltd Contoura 800 series beds produced between January 1999 and April 2001 inclusive, sold as:-

**Model numbers:** 200800, C880, C881, C882, C885, C886, C888 all followed by /L or /N

**Serial numbers:** 184234 to 364832

Dear Customer,

The purpose of this letter is to inform you that our records show your facility purchased one or more of the Contoura 800 series hospital beds listed above.

We have received a report of an incident in which the manual CPR release handle of a C880 failed to lower the backrest of the bed when it was pulled in an emergency. A review of the performance of these early models has shown that there is the potential for parts of the CPR mechanism to be damaged, leading to a failure to operate.

Please note that in addition to the manual CPR release, all of these models are also fitted with a CPR button on the attendant handset. **Electric CPR operation using the CPR button is not affected and will operate as expected.**

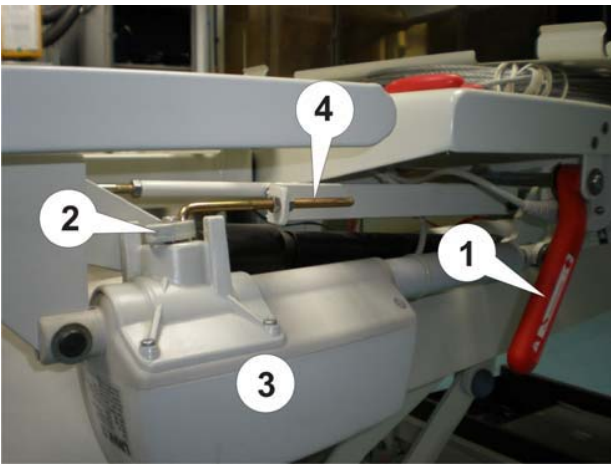


**Please also note that this notice only affects Contoura 800 series bed models fitted with folding three-quarter length side rails [A above]. Beds with split side rails [B] are not affected**

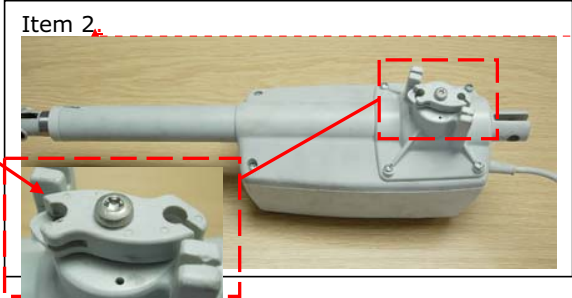
**Indications**

The Huntleigh Contoura 800 series beds were launched in January 1999 and were made obsolete in August 2007, although many may remain in service.

Beds made between January 1999 and April 2001 inclusive may suffer damage to their manual CPR mechanism if the CPR lever [1] has been pulled with excessive force. Damage may occur to the plastic release arm [2] fitted to the backrest actuator [3] or to the CPR adjustment pin [4].

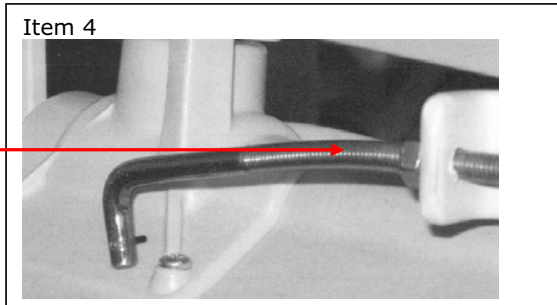


**Item 2**  
In this photo the corner of the release arm has been broken off



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**Item 4**  
CPR adjustment pin bent



A modification to the CPR design was introduced for beds manufactured after April 2001 and a retrofit kit, part number 806.399, has been developed which allows pre-April 2001 beds to be modified in line with the later specification. The later design prevents over travel of the CPR lever and thus prevents the mechanism from being damaged.

**Advice on action to be taken by the user**

- 1) Examine all Contoura 800 series beds in use or in stock which were manufactured between January 1999 and May 2001. 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 *184234 to 364832*
- 2) If you have beds in this serial number range, locate the backrest actuator and examine the CPR adjustment pin and the release arm to determine whether there has been any damage to these parts
- 3) If these parts are damaged the bed should be removed from use until the retrofit kit can be fitted. Beds from this period which have not been damaged may continue to be used safely but should have the retrofit parts fitted at the earliest opportunity
- 4) Complete and return Appendix 1 to your nearest ArjoHuntleigh Sales office who will arrange for the appropriate number of kits to be supplied to you.

If you have redistributed these beds to another location or if the beds have been sold or removed from Service, please mark Appendix 1 appropriately and advise us immediately

**Corrective action**

ArjoHuntleigh will provide a free of charge retrofit kit for all beds manufactured during the affected period.

The kits can be fitted by a competent person or by arrangement with your local ArjoHuntleigh Service representative. Please note that this activity will be chargeable.

We apologize for any inconvenience these actions may cause you and we will do our utmost to carry through this action as swiftly as possible.

**Transmission of this Field Safety Notice**

Please pass this notice to all those who need to be aware within your organization and/or to any organisation where the devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action

In cases where customers opt not to proceed with completion of these actions, ArjoHuntleigh cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond.

**Contact reference Person**

Should you have questions or require additional information, please contact your local ArjoHuntleigh representative at this address

**ArjoHuntleigh Sales Address details:**

Local SSU insert details here

Address line

Address line

Address line

Telephone

Fax number

**ARJOHUNTLEIGH**  
GETINGE GROUP

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

Sincerely,



Quality & Regulatory Manager

**ARJOHUNTLEIGH Medical Beds Division**  
Trident Drive Unit 3, Britannia Park  
Wednesbury, West Midlands WS10 7XB  
United Kingdom  
[www.ArjoHuntleigh.com](http://www.ArjoHuntleigh.com)

**Appendix 1 - Completion Notification SAN 02 2010**

Our records indicate that Huntleigh Contoura 800 series beds were shipped to your location. Please examine your bed stocks as per the attached Field Safety Notice to determine whether the affected parts have been damaged.

Please remove any beds from service if their CPR components have been damaged and note the quantity of retrofit kits required below.

<i>Part Description</i>	<i>Quantity of beds checked</i>	<i>Quantity of retrofit kits required</i>	<i>Serial numbers of affected beds*</i>
Manual CPR mechanism			

\* list any further serial numbers on a separate sheet

Please tick two boxes in the section below:

- We have read the Field Safety Notice and understand the communication
- We checked our inventory and confirmed that we do have Huntleigh Contoura 800 series beds in use. We have listed the quantity checked and the number of retrofit kits required in the table above.
- We do not have any Huntleigh Contoura 800 series beds in use

Please tick one box in this section

- We will fit the retrofit kit(s) ourselves
- We would like ArjoHuntleigh service representatives to fit the retrofit kits on our behalf. We understand that this work will be chargeable
- We do not require any retrofit kits

To signify compliance with this notification, please sign and date below and fax the signed copy of this notification to your local ArjoHuntleigh sales office:

Customer signature \_\_\_\_\_

Print name: \_\_\_\_\_

Institution: \_\_\_\_\_

Date: \_\_\_\_\_

**Local SSU insert details here**  
**Fax number**  
**Email address**