

**URGENT – FIELD SAFETY NOTICE**  
**FSCA IDENTIFIER FSN/03/2011/MBD**  
**28 OCTOBER 2011**

**Subject:** Failure of CPR release on Huntleigh Healthcare bed frames

**Type of action:** Performance check as an addition to a previous FSN

**Products affected:** Contoura® 880 series manufactured between January 1999 & April 2001

**Model numbers:** C880, C881, C885, C886, C888 suffixed /N (no side rails) or /L (¾ length side rails). Model numbers suffixed /S (split side rails) are not affected.

**Serial numbers:** 184234 to 364832 inclusive

Dear Customer,

This letter is to inform you that our records show your facility has purchased one or more of the Contoura® 880 series hospital bed frames listed above.

A previous Field Safety Notice (SAN/02/10/MBD) highlighted an issue with these products whereby the CPR release arm on the backrest actuator could break during use and render the emergency CPR function inoperable. This SAN required the fitting of a kit of new parts (806.399) to the CPR release mechanism to prevent this happening.

One customer has since reported an incident in which the CPR release on a bed with new parts fitted failed to work in an emergency. Investigation indicated that this happened because the replacement CPR release arm was not installed in accordance with the instructions provided by ArjoHuntleigh.

The purpose of this FSN is to reiterate and reinforce the procedures outlined in the fitting instructions (part no. 779-89) supplied with the CPR release upgrade kit.

The Irish Medicines Board (IMB) recommends:

- Any outstanding upgrades should be carried out by an ArjoHuntleigh technician.
- All upgrades previously carried out by the facility's own personnel should be inspected by an ArjoHuntleigh technician to ensure correct fitting and operation.

### **Indications**

This notice applies to the Contoura 880 series bed frames listed above, previously fitted with the CPR release upgrade kit 806.399 as described in SAN/02/10/MBD.

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

Complete and return Appendix 1 as soon as possible. A free of charge visit will then be scheduled to your facility for an ArjoHuntleigh technician to inspect the bed frames as detailed below. No further action is required on your part.

1. Pull off the thigh section deck sheet to allow access to the CPR release mechanism from above.

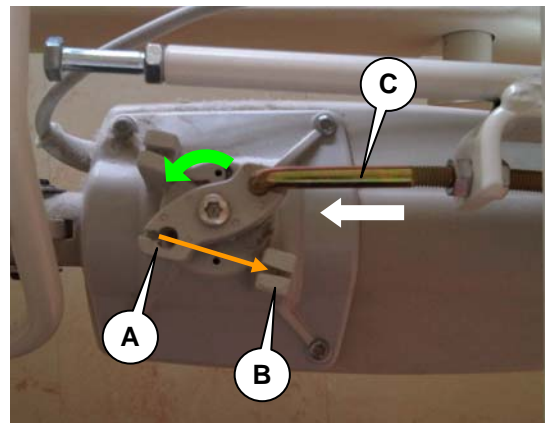
Check that the release arm is correctly installed as shown below. Note that the photos show the mechanism when the CPR handle is **not** pulled.



2. This photo shows the top view of the release arm **CORRECTLY INSTALLED.**

The groove in the release arm (A) is in a straight line with the groove in the square post (B), as shown by the orange arrow.

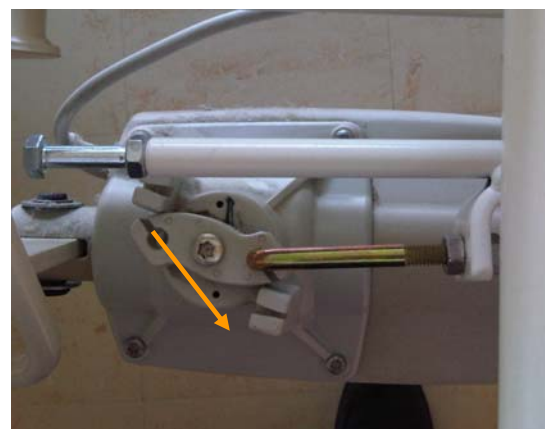
When the CPR lever is operated, the pin (C) pushes the release arm in the direction indicated by the white arrow. The arm rotates in the direction shown by the green arrow; this releases the actuator and lowers the backrest.



3. This photo shows the top view of the release arm **INCORRECTLY INSTALLED.**

The groove in the release arm is not in a straight line with the groove in the square post.

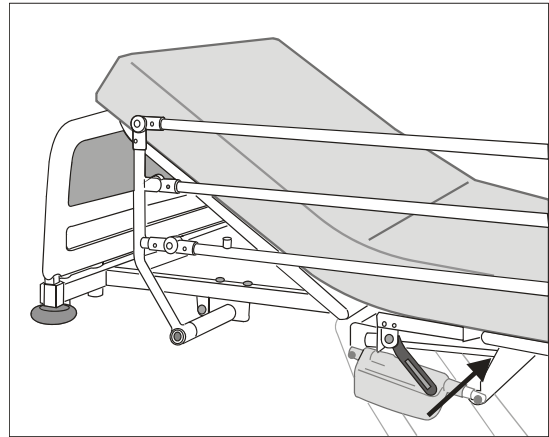
When the CPR lever is operated, the pin attempts to push the release arm, however because the pin is acting in line with the rotational axis of the arm, it cannot rotate and the actuator does not release.



4. When you are satisfied that the modification has been correctly carried out, test the installation as follows:

- Use the handset to raise the backrest to about 45°.
- Pull the CPR handle and check that the backrest lowers quickly (you might need to apply some initial downward force to the backrest; this would normally be provided by the patient's own weight).
- Replace the thigh section deck sheet.

**DO NOT RETURN THE BED TO SERVICE UNTIL YOU ARE SURE THAT THE CPR RELEASE FUNCTIONS PROPERLY!**



### **Transmission of this Field Safety Notice**

Please pass this notice to all those who need to be aware within your organisation 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 Rachel Dempster at ArjoHuntleigh (Ireland) Ltd.:

Tel. 01 809 8960

Fax 01 809 8971

E-mail [ComplianceALIE@ArjoHuntleigh.com](mailto:ComplianceALIE@ArjoHuntleigh.com)

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

Yours sincerely,

Colin Walters  
Quality Assurance Manager

### **ARJOHUNTLEIGH Medical Beds Division**

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**Appendix 1 - Completion Notification FSN/03/2011/MBD**

Our records indicate that CPR release mechanism update kits for Huntleigh Healthcare Contoura 880 series bed frames (ref. SAN/02/10/MBD) were previously shipped to your location.

Please tick as appropriate:

- We have read the Field Safety Notice and understand the communication.
- We understand that ArjoHuntleigh require access to these bed frames to inspect the CPR release mechanism and that this will be scheduled as soon as possible.

To signify compliance with this notification, please sign and date below and e-mail or fax the signed copy of this notification to ArjoHuntleigh (Ireland) Ltd. – contact details are on the previous page.

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

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

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

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