ARJOHUNTLEIGH

GETINGE GROUP

URGENT – Field Safety Notice (FSN)

Product:	**Contoura 1000, Contoura 1080**
Serial Numbers:	**All beds manufactured since it was placed on the market on 2001**
Issue Date:	**2013-10-04**
Type of action:	**Safety Notice / Update to Instructions for Use and modification of labelling**
Ref:	**FSN-002-2013-MBD**

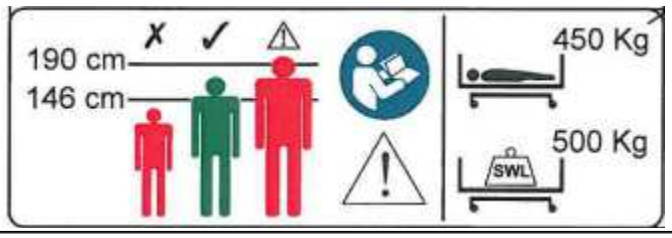
Dear Customer,

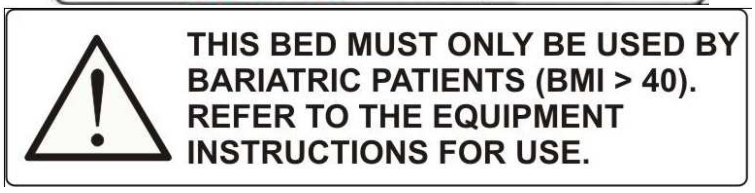
We would like to remind you that the Contoura 1000 and Contoura 1080 range beds are intended to be used as a bariatric medical device which is designed for patients with BMI >40.

There is a low but existing entrapment risk for a patient being treated on this bed while being under this BMI level - as not all patients are at equal risk for entrapment. In particular, small, lightweight patients are generally at the greatest risk for entrapment because their small physical dimensions may enhance their ability to fit into a gap, in whole or in part.

Our records indicate that your facility has purchased one or more of the ArjoHuntleigh Contoura 1000/1080 indicated above. To help the users of these devices to always be aware of the intended use, we would like to offer additional labelling: indicating that the bed is designed for patients with BMI >40 : the instruction for use will contain more details on the issue and labelling indicating that the recommended patient height is between 146 cm and 190 cm. As the discretion of the carer, patients taller than 190 cm may be accommodated by extending the bed, the carer should refer to product instruction for use which described functionality of the extension system. Two additional labels (shown below) will be placed on the bed frame. These measures will also be present on new products.

Please note that to date; we do not appear to have received any adverse event report caused by the use of the Contoura 1000 or 1080 bed by a non-bariatric person. We perform this field action as part of our vigilance efforts and our strategy of continuous product improvement.





Sample in English Text will differ per market

Advice on actions to be taken by the user.

1. Please make sure all caregivers and clinical staff are aware that the Contoura 1000 or 1080 range bed is intended to be used as the bariatric medical bed as is designed for the patients with BMI>40.

2. Please make sure that a copy of this field safety corrective action notice is placed with the instructions for use documents for the products listed in this notice.

3. Please make sure the users of the bed, your staff, are trained in following the new Instructions for Use, and that they understand the new labels.

4. It is very important that Appendix A of this FSN is completed and returned to the ArjoHuntleigh Sales and Service office (SSU) or representative as soon as is reasonably possible.

5. The ArjoHuntleigh Sales and Service office shall arrange for an ArjoHuntleigh service technician to visit your facility to carry out these updates - retrieve and destroy the copies of the old instruction for use and replace it with the new one as well as adhere the label to the bed.

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 equipment may have been transferred to.

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

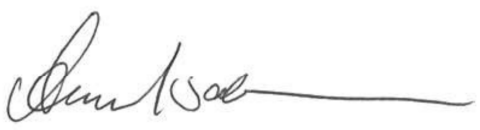
In cases where customers opt not to proceed with completion of these actions, regrettably ArjoHuntleigh cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond.

We regret any and all inconveniences that this Field Safety Notice may cause; however we ask that you please see this preventive action as extended resident safety vigilance.

Contact reference person

Should you have questions or require additional information, please contact your local ArjoHuntleigh Sales and Service office or representative.

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



Anna Isaksson – Product Quality Director

Appendix 1 - Completion Notification FSN-002-2013-MBD

Our records indicate that your facility has purchased one or more of the ArjoHuntleigh Contoura 1000 or 1080 beds involved. An ArjoHuntleigh representative will visit you in the near future or during the next planned preventive maintenance to conduct the labelling correction in the nearest future.

Please record the serial numbers of all Contoura at your location in the table below (continue on a separate sheet if necessary).

Serial number	Serial number	Serial number	Serial number	Serial number	Serial number

The number of Contoura bed affected by this FSN at this location is _____.

Please tick the box below:
□ We have read the attached FSN and understand the communication.

To show compliance with this notification, please fill in the details below and e-mail or fax the signed copy of this notification to your local ArjoHuntleigh Sales/Service Unit (SSU) or representative.

Customer signature _____ Print name _____

Name of facility _____

Address of facility _____

_____

_____

Postcode _____ Date _____