

## **Safety Announcement**

Regarding the following products: OPUS 1-08 5, OPUS 1-090, OPUS 1-0110, OPUS 1-120

Document ID: Serial number ID

Type of action: Risk of squeezing foot in the gap of the foot board

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Date: 21.06.2016

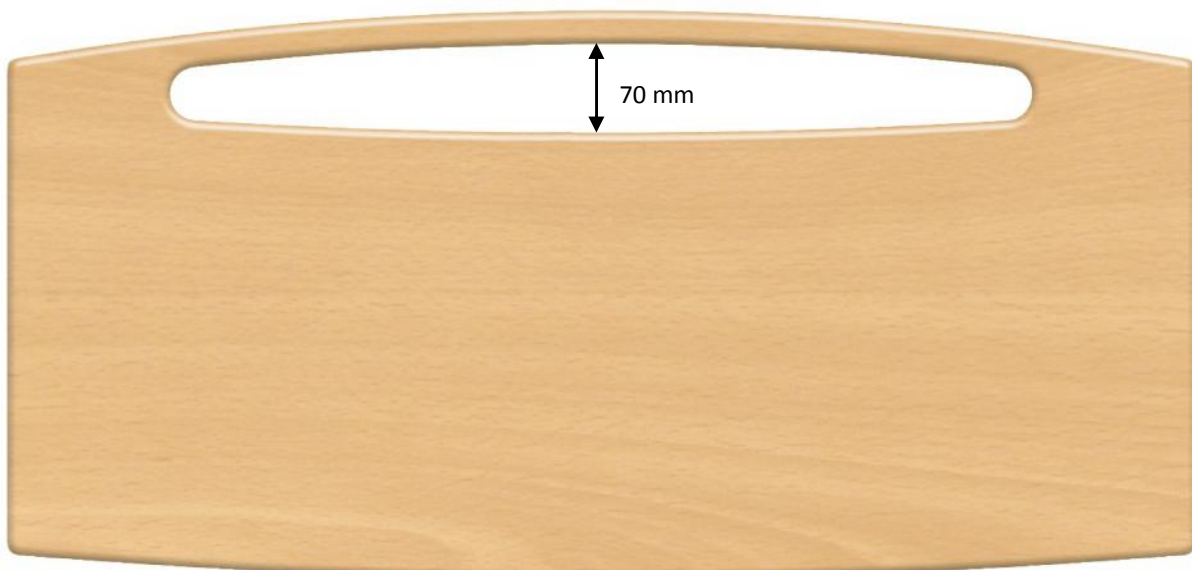
Attention: For whom it may concern – Care givers and technical staff

### **Description of the problem:**

KR Hospitalsudstyr have been made aware, that it is possible for users of care beds in the OPUS 1-series with foot boards with the item number: 15046, to put their feet through the gap in the foot board and get stuck.

### **Description of the affected product:**

The following product is affected: Foot boards with the item number: 15046, sold between the years of 2011 and 2016 with the following design:





**Advise on measures:**

The following safety announcement will be added to the user manual:

**“When using the bed, it is important to be aware of whether the user is restless or has involuntary movements.**

**If this is the case, it is possible to mount a soft cover on the foot board, that covers the gap.**

**The soft cover can be bought from KR Hospitalsudstyr and has item number 158850.**

**The bed is not to be used by people with involuntary movements or restless people, without first ensuring, that the gap in the foot board is properly shielded”**

**Disclosure of information pertaining to this safety announcement:**

KR Hospitalsudstyr has sent this information to customers, that have purchased OPUS 1-beds with the affected foot boards and enclose an appendix for the user manual, “Appendix for User Manual”, that must follow the bed.

The information in the Safety announcement must be passed on to all relevant staff in your organization, and to other organizations/companies, where the affected equipment has been distributed to/used.

Also the information in this Safety announcement must be passed on to other organizations, to whom said information is deemed of influence.

We ask You to maintain awareness of this Safety announcement and resulting action for an appropriate amount of time, to ensure the efficiency of the corrective measures.

This information has been sent to the Danish Medicines Agency.

**Contact:**

If you have any questions regarding this Safety announcement, please contact:

KR Hospitalsudstyr A/S  
v/ Tom Ingemar Rasmussen (Project Manager)  
Tlf: +45 86982499  
Mail: [tir@krbed.dk](mailto:tir@krbed.dk)  
Mågevej 16  
DK-8370 Hadsten  
Danmark