



Urgent Field Safety Notice

Nursing bed Invacare Scanbed 400

Amended Instructions for Use – Precautions & New Safety Information

Invacare Ref: FSN037

Date: 16th May 2011

Ref: Case Reference Number 6302

Urgent Safety Information:

This information is applicable to all Invacare Scanbed 400 nursing beds.

In the interests of our customer's safety, we would like to bring your attention to new safety information in the Instructions for Use for Scanbed 400. The Instructions for Use (IFU) are amended with information regarding precautions that have to be taken when the patients are of small body size, restless or confused; these stated warnings are presented on page 6 in the IFU.

The Instruction for Use also include details of the new accessory; the safety cover. If in certain circumstances the bed is to be used by restless, unattended patients; the safety cover should be fitted to avoid any potential entrapment between the side rail and the mattress support. Failure to follow the recommended advice could lead to injury of the patient.

These amendments are presented on Instruction for Use for Invacare Scanbed 400, version 9, 2011-02. An extract from the Instruction for Use is attached on page three of this Field Safety Notice.

- The amended IFU can be downloaded from Invacare website at www.invacare.co.uk
- Or a copy can be ordered from the Invacare sales organisation by contacting Technical Services on 01656 776333.

ACTION REQUIRED

Action to be taken by the receiver of this Field Safety Notice is to investigate if there is a need to reassess the risk analysis for the users of this bed model.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and / or any organisation where the potentially affected products have been transferred. Also please ensure that awareness is maintained for an appropriate period of time.



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Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

Technical Services Department

Tel. 01656 776333

Fax. 01656 776330

Invacare confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.



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Extract from Instruction for Use – Invacare Scanbed 400

1.1 Safety and Warnings



The bed fulfils all requirements regarding maximum distances. However, if the bed is used for the care of patients with a small body dimensions, it must be especially noted that there is a risk of such a patient slipping through the openings between the side rails or through the opening between the side rail and the mattress support.



The bed must not be used by patients under 12 years of age, or by patients with body size equivalent to an average 12-year-old or smaller.



The bed, in combination with side rails, must not be used for persons under 45 kg or under 150 cm's height, or for persons that are restless (spasms) or confused, unless a professional risk assessment has taken place and been accepted, or a correctly installed safety cover on the side rails are used.

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Covers

Upholstered cover for Britt II and III wooden side rail.....	1449412
Upholstered cover for Scala Basic side rail.....	1449423
Net cover for Britt II and III wooden side rail.....	1449413
Safety cover for Britt III, IV wooden side rail.....	1511890
Safety cover for Britt III wooden side rail, short.....	1513592
Safety cover for Britt II wooden side rail, extended.....	1511892



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