Name
Addition
Street
LOCATION

<u>Urgent safety information</u>
Call for compliance with the safety instructions in the operating instructions
on the necessity of locking the manual switch,
concerning
KayserBett OLAF paediatric care bed

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08 Oct. 2024

Sender:
KayserBetten GmbH & Co KG, Rieper Str. 12, 29683 Bad Fallingbostel
SRN: DE-MF-000006910

Addressee:
Specialist dealers, operators and users

Identification of the medical devices concerned:

Product category	Product designation	Basis UDI-DI
Paediatric care bed	KayserBett OLAF 98	426038961OLAF98AE
Paediatric care bed	KayserBett OLAF 135	426038961OLAF135D5

See table in Appendix II for affected serial numbers

Description of the problem including the identified cause:
Due to a serious incident with a KayserBett, as part of our risk management, we have classified misuse due to negligent non-observance of the safety instruction for locking the hand control after use as foreseeable misuse with an unacceptable risk for the above-mentioned KayserBett.

If the adjustment functions of the handcontrol <u>are not</u> locked with a key when the patient (child) is unattended, there is an increased risk that the patient (child) or third parties (children) will operate the handcontrol and trap themselves or others under the mattress base or between the adjustable elements of the mattress base. This can lead to serious injuries or even death of the patient (child) or third parties (children).

This statement does not imply that the listed medical device failed in any way and/or led to the serious incident. The occurrence of the risk is solely due to human error.

What measures are to be taken by the addressee?
Please inform all users/operators of a KayserBett OLAF that by implementing the following safety measures, the above-mentioned risk to patients or third parties can be eliminated during further use of the product.

If the patient is unattended,

- the mattress base must be levelled and moved to its lowest position.
- the adjustment functions on the handcontrol must be locked using a key.
- the doors must be closed.

Use the user safety instructions (Appendix I) to implement the measure.

With this safety information you will receive a feedback form and a table with the affected serial numbers (Appendix II), which you should complete in full and return to us once the measure has been successfully implemented.

From the end of the 1st quarter of 2025, a final measure will be taken to convert all affected beds in the field to a self-locking manual switch as part of a 2nd safety correction measure, about which you will be informed in good time.

Passing on the information described here:
Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are aware of this Urgent Safety Information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.
Please keep this information at least until the measure has been completed.
The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact person:
KayserBetten GmbH & Co KG
Jens Lübben
Head of Medical Technology and Quality Management, PRRC
Phone: +49 5163 29004 14
E-mail: luebben@kayserbetten.de

ANNEX I:User safety instructions
ANNEX II: Table of serial numbers

ANNEX I

User safety instructions

IMPORTANT SAFETY NOTE!

If the adjustment functions of the handcontrol are not locked with the key when the patient (child) is unattended, there is an increased risk that the patient (child) or third parties (children) will operate the handcontrol and trap themselves or others under the mattress base or between the adjustable elements of the mattress base. This can lead to serious injuries or even death of the patient (child) or third parties (children).

If the patient is unattended,

- the mattress base must be levelled and moved to its lowest position.
- **the adjustment functions on the handcontrol must be locked using a key.**
- the doors must be closed.

Safety instruction video

KayserBetten GmbH & Co KG
Rieper Street 12
29683 Bad Fallingbostel

Phone 0 51 63 - 65 95
Fax 0 51 63 - 20 76

info@kayserbetten.de
www.kayserbetten.de

Feedback form

By signing this document, you confirm that you have read and understood this safety information and that the required measures have been implemented.

Company:
Address:
Contact person:
Phone: (contact person)
e-mail: (contact person)
Date:
Signature:

Please confirm in the following table (see APPENDIX II) for which KayserBetts you have successfully carried out the measure and which are no longer in the field. KayserBetts that are not included in the list but are still in use, please enter at least the serial number in the table.

In order to finalise the measure, it is essential that the feedback form and the table (ANNEX II) are completed in full.

table (ANNEX II) is mandatory.

This will make it easier for you and us to retrofit all affected beds in the field and avoid unnecessary queries on our part.

Please complete and return the feedback form and the table (ANNEX II) to us.

E-mail: medizintechnik@kayserbetten.de

Fax: 05163 2076

Pattern:

ANNEX II - ID 00000

OK	a.B.	Serial no.	Order No.	Commission
☐	☐	SN000001	18/00000	Sample man 1
☐	☐	SN000002	21/00000	12345
...				
...				

OK Action successfully completed.

a.B. Out of service, bed is no longer in the field.

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