

Name
Addition
Street
LOCATION

Urgent safety information
Call for compliance with the safety instructions in the operating instructions
on the necessity of locking the manual switch,
concerning
Paediatric care bed KayserBett EMMA, KayserBett IDA

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 EMMA 1	426038961EMMA17V
Paediatric care bed	KayserBett EMMA 2	426038961EMMA27X
Paediatric care bed	KayserBett IDA	426038961IDAGU

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 categorised misuse due to negligent non-observance of the safety instructions for locking the handcontrol after use as foreseeable misuse with an unacceptable risk for the above-mentioned KayserBetts.

If the adjustment functions of the handcontrol are not 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 EMMA/ IDA 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 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).

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

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.

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
<input type="checkbox"/>	<input type="checkbox"/>	SN000001	18/00000	Sample man 1
<input type="checkbox"/>	<input type="checkbox"/>	SN000002	21/00000	12345
...				
...				
OK	Action successfully completed.			
a.B.	Out of service, bed is no longer in the field.			

Seriennummer	Produkt
SN 000015	KB Emma 1 natur 200/90
SN 002429	KB Emma 1 mit 8 Türen Va
SN 003395	KB Emma 1 natur 200/90
SN 004309	KB Emma 1 natur 200/90
SN 004394	KB Emma 1 natur 200/90
SN 005403	KB Emma 1 natur 200/90
SN 005428	KB Ida 8 Türen Variante
SN 006508	KB Ida 4 Türen Variante
SN 009444	KB Ida 8 Türen Variante
SN 012161	KB Emma 1 natur 200/90
SN 013148	KB Emma 2 natur 200/90
SN 016675	KB Emma 1 mit 4 Türen Va
SN 001721	KB Emma 1 natur 170/90
SN 007334	KB Emma 1 natur 200/90
SN 012503	KB Emma 1 natur 200/90
SN 014255	KB Emma 1 natur 200/90
SN 002860	KB Emma 2 1AG Variante
SN 006532	KB Ida 4 Türen Variante
SN 010003	KB Ida natur 170/90
SN 012279	KB Ida natur 170/90
SN 000796	KB Ida natur 200/90
SN 008387	KB Emma 1 mit 4 Türen Va
SN 017198	KB Emma 1 natur 170/90
SN 017573	KB Emma 1 natur 200/90
SN 017598	KB Ida natur 200/90
SN 019059	KB Ida natur 170/90
SN 019136	KB Emma 2 2AG Variante
SN 019386	KB Emma 1 transparent 20
SN 019387	KB EMMA 2 light 200/90