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Urgent Field Safety Notice
Recall – replacement of the Auto-Lock hand control
concerning
paediatric care beds KayserBett IDA, EMMA, OLAF

20.09.2026

Sender:

KayserBetten GmbH & Co. KG, Rieper Str. 12, 29683 Bad Fallingbostel, Germany

SRN: DE-MF-000006910

Manufacturer reference: FSN-KB-2026-001 · continuation of the earlier Auto-Lock field safety corrective action

Addressee:

Specialist dealers and operators

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
Paediatric care bed	KayserBett OLAF 98	426038961OLAF98AE
Paediatric care bed	KayserBett OLAF 135	426038961OLAF135D5

The paediatric care beds listed above are affected. The product designation and UDI identify the model, not the individual affected unit; which specific unit is affected can be determined solely from the bed serial number. There is no public serial-number list. The identification of the affected units and the exchange are coordinated with the specialist dealer/distributor that supplied the beds, who holds the relevant field list.

Description of the problem including the identified cause:

The hand control of the beds named above locks automatically after use (Auto-Lock). This automatic locking is the safety function that prevents an unsupervised child from operating the hand control.

Due to a component defect (a defective transistor in the hand control), this automatic locking can fail on a proportion of the hand controls: the hand control remains operable but no longer locks by itself after use.

If the automatic locking fails and the hand control is not locked with the blue key while a child is unattended, there is a risk during further use that the child or third parties (children) operate the hand control and become trapped beneath the lying surface or between the adjustable elements of the lying surface. This can lead to serious injury or even death of the child or third parties (children).

The risk is assessed as not acceptable, because a failed lock is not necessarily recognised or reported as safety-relevant in everyday use. As a continuation of the ongoing Auto-Lock field action, KayserBetten is therefore carrying out a proactive exchange of the affected hand controls.

What measures are to be taken by the addressee?**For users / operators – safe use until the exchange:**

While a child is unattended, first move the lying surface horizontally to its lowest position, then lock the hand control with the blue key, and then close the doors or side rails. Details are given in the enclosed safety notice for bed users (Appendix I).

Measures to be taken by the specialist dealer:

Passing on to users: please give the enclosed safety notice for bed users (Appendix I) to the affected users. It contains the safeguards to be observed by users until the exchange.

The specialist dealer/distributor that supplied the beds organises and carries out the free-of-charge exchange of the affected hand controls for the tested, corrected version. The dealer/distributor will contact you and explain the specific procedure.

Please wait until they contact you; no further steps are required for now.

Timetable:

The exchange of the hand controls takes place once the tested, corrected hand controls are available – expected from the turn of the year 2026/2027 and spread over several months. The exact start may shift depending on the availability and delivery of the components.

Passing on the information described here:

Please ensure within your organisation that all users of the products named above, and any other persons to be informed, are made aware of this Field Safety Notice. If you have passed the products on to third parties, please forward a copy of this information or inform the contact named below.

Please keep this information at least until the action has been completed.

The relevant competent authority has received a copy of this Field Safety Notice.

Contact:

Specialist dealer/distributor — the supplier of your beds (for the exchange and any questions). Manufacturer — KayserBetten GmbH & Co. KG · medizintechnik@kayserbetten.de

Appendix I: Safety notice for bed users (separate A4 page, to be passed on to the users).

Important safety information

for users of the KayserBett paediatric care beds IDA, EMMA and OLAF

With the hand control of your care bed you can adjust the bed. The hand control normally locks by itself shortly after use (Auto-Lock). This protects children: an unsupervised child cannot then adjust the bed.

The hand control of your bed contains a defective component. Because of this, the automatic locking can fail: the hand control still works, but no longer locks by itself after use. You must therefore lock the hand control with the blue key when the bed is unattended. Please follow the instructions below.

Danger:

If the hand control is not locked, an unsupervised child can operate it. The child can adjust the bed and become trapped: beneath the lying surface or between the moving parts. This can lead to serious injury. In the worst case, a child can die.

Please observe the following until the hand control is exchanged:

- Never leave a child unattended when the hand control is within reach.
- First move the lying surface horizontally to its lowest position.
- **Then lock the hand control with the blue key. See the instructions in the user manual or the quick guide on the bed.**
- Close the doors or side rails of the bed.
- If the hand control no longer locks by itself after use, please contact the specialist dealer that supplied your bed without delay. Until then, please continue to secure it with the blue key.

The hand control of your bed will be exchanged free of charge. You do not need to arrange anything yourself: the specialist dealer that supplied your bed will contact you, arrange the exchange and carry it out free of charge. The exchange is expected from the turn of the year 2026/2027. Until then you can continue to use the bed; please observe the notes above. Please wait until the dealer contacts you; there is nothing else you need to do for now.

Important until the exchange: lock the hand control with the blue key when the bed is unattended.

If you have any questions, please contact the specialist dealer that supplied your bed.

Appendix I to the Field Safety Notice (FSN) · Reference: FSN-KB-2026-001 · Date: 20.09.2026