

Urgent safety information

Correction of the product labeling
concerning

care beds of the model series domiflex and combiflex

Sender

Hermann Bock GmbH

Nickelstr. 12
33415 Verl

Addressees

Users, operators, distributors, patients

Identification of the affected medical devices

Nursing beds with the article and serial numbers ("REF") listed below may be affected.

REF	Designation	Serial numbers
261	Nursing bed domiflex Serial numbers: 2304000151 - 2304000160 2304000165 - 2304000184 2304000203 - 2304000210 2304000227 - 2304000246 2304000255 - 2304000306 2304000377 - 2304000416 2304000661, 2304000685 2304000744 - 2304000757 2304000760 - 2304000761 2304000788 - 2304000793 2304000870 - 2304000889	2304000912 - 2304000913 2304000922 - 2304000929 2305000972 - 2305000979 2305000982 - 2305000983 2305000990 - 2305000993 2305000998 - 2305000999 2305001002 - 2305001007 2305001010 - 2305001011 2305001047 - 2305001066 2305001071 - 2305001072 2305001087 - 2305001098 2305001101 - 2305001102 2305001228 - 2305001229 2305001232 - 2305001239
272	Nursing bed domiflex 2 wash (P&R)	2303000109 - 2303000144
293	Care bed combiflex	2304000505, 2304000682

Description of the problem including the identified cause

Medical devices must be labeled with the name or trade name of the product and the expiration or manufacturing date in accordance with the Medical Device Regulation 2017/745 (MDR). Care beds must also be labeled with an indication of the safe working load and the maximum patient weight.

Due to a software error, this information is missing on some products of the production period March to May 2023.


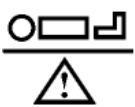
The information on the safe working load and the maximum patient weight is contained in the "Technical data" chapter of the operating instructions. The date of manufacture is included in the serial number in four-digit format "YMMM", e.g. "2305".

Nursing beds which, contrary to the specification of the maximum working load or the maximum patient weight, are subjected to permanent loads in excess of this can exhibit premature material fatigue, with the result that individual components can bend or break. In the event of a sudden movement triggered by this, the patient or resident or a third party may be injured or traumatized.



What measures are to be taken by the addressee?

1. Please check the list above to see if you have received and put into service any of the affected care beds.
2. If you have already put the care bed into operation:
 Please check whether the safe working load or the maximum patient weight exceeds the specifications in the instructions for use. For the care beds concerned, these values are:


Model series domiflex:


	Safe workload	170 kg
	Maximum patient weight	135 kg

Model series domiflex 2 wash:

	Safe workload	190 kg
	Maximum patient weight	155 kg

combiflex model series:

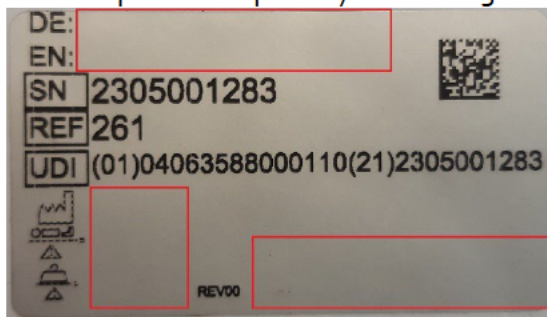
	Safe workload	220 kg
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	Maximum patient weight	185 kg
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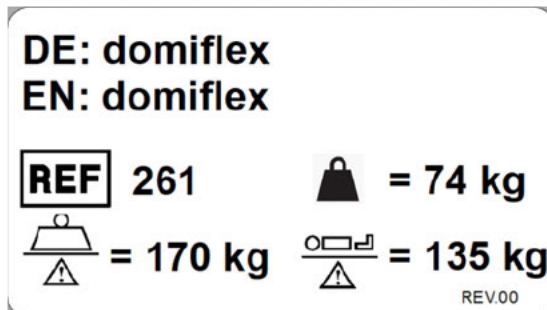
- In the event that the safe working load or the maximum patient weight is exceeded:
Please take the care bed out of service and transfer the person to a care bed with a higher load capacity. Your customer advisor or the contact person indicated below will be pleased to advise you on a suitable alternative.

Then carry out an inspection in accordance with the instructions for use. If any damage is found, please contact the person listed below.

- Check the labeling of the care bed
The following illustrations represent an incomplete individual nameplate. You can recognize an incomplete nameplate by the missing information in the areas marked in red:



- If you notice an incomplete nameplate:
Identify the bed using the part number indicated on the nameplate. (REF). Enclosed with this Urgent Safety Information you will receive a matching additional label with the same article number and the missing information:



Attach the enclosed additional label with the information on safe working load and maximum patient weight next to the type plate on the frame of the care bed. Make sure that the article numbers (REF) match.



Do not paste over the original, incomplete label! It contains important information for the traceability of the product!

- In order for us to verify that you have received and understood this information, please return the completed response letter in any case by **June 30, 2023** to the fax number or e-mail address indicated on the form.

Disclosure of the information described herein

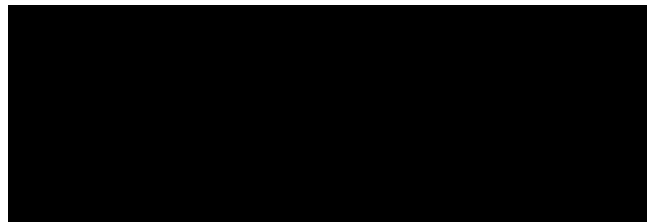
Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

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

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact

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Person responsible for regulatory compliance

Reply letter

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CAPA No. K-2023-0030

to Fax: +49 (0) 5246 9205-25 or Mail: qm@bock.net

Customer: }, "name"
 "str"
 "plz" "city"

We hereby acknowledge receipt of this safety information and the distribution of the safety information and supplementary labels to all persons to be informed in our departments and to all third parties to be informed.

- We no longer have any affected products in our inventory.**
- We have provided the following number of affected products with the supplementary label.**

Article number REF / designation		Quantity
261	Nursing bed domiflex	
272	Nursing bed domiflex 2 wash (P&R)	
293	Care bed combiflex	

Name contact person: _____

Date: _____

Signature: _____