

Urgent FIELD SAFETY NOTICE

date	28.01.2020
ref. FSCA	25c/5488.2-10
Type of action	device modification

Product	Model	Serial No.
Rollator B	4003	D4003R000000135 - D4003R000055000

In the course of market surveillance, Rollator B passed the test according to DIN EN ISO 11199-2: 2005-07, the following contents were not passed:

stability

- Safety against tipping in the reverse direction
- · Safety against tipping in lateral direction

static and mechanical fatigue strength

- static load
- fatigue test

Adjustment of the handles

 no clear marking of the maximum permissible setting for the height adjustment of the handles

Marking on the rollator and / or accessories

• the maximum load capacity is only stated on the product, not on the accessories

Risk for the user

There is a risk that the user can tip over and fall during use.

With a user weight> 100kg there is a possibility that the product will deform permanently or that fatigue fractures can occur within the service life of 5 years.

If the basket is loaded with more than 5 kg, the fastening rakes could break and would therefore no longer be usable.

So far, there have been no confirmed incidents. So the risk is present but in relation, the risk is low.

FSN (Field Safety Notice) / Rollator B - 4003



Corrective measures

The following points are required as a technical measure to reduce risks as far as possible, in line with the state of the art:

1. Change the permissible loads

User weight: max. 100kg

The warning (Fig. 1) is provided by Bischoff and Bischoff or their specialist retailers. Please clean the surface beforehand and stick the warning label on the frame next to the manufacturer's label.

The corrected information on the warning notice is binding information on the safe use of the Rollator B.



Fig.1

We offer a rollator for users who can no longer use the product due to the change in the permissible load. Please contact your specialist dealer.

A revised instruction manual is available on the homepage of Bischoff & Bischoff available. If you wish, we will send you a copy of the operating instructions. If you have any questions, please feel free to contact our customer service or your specialist dealer.



2. Tilt stability - use and adjustment of the push handles

2.1. Height of the push handles

Push handle height: max. 940mm

To prevent the maximum push handle height from being exceeded, make sure that the corrugation of the push handle tubes is always visible in the marked area (Fig. 2).

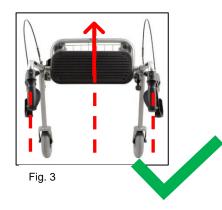


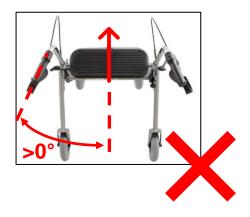


2.2. Alignment of the push handles

Push handle angle: max. 0°

So that the lateral tipping stability is fulfilled, both push handles must be aligned parallel to the direction of travel (Figure 3).







3. Labeling of the basket

Max. Load capacity: 5 kg

Marking the maximum load of the basket with 5kg with a self-adhesive tape (Fig. 4) The tear-resistant and self-adhesive tape is folded over the upper frame of the basket.



Fig. 4

contact:

Kundenservice

Telefon: $+49(0)700 - 6000\ 7070$ Telefax: $+49(0)700 - 6000\ 8080$ Email: info@bischoff-bischoff.de

Homepage

www.bischoff-bischoff.com



Verification Form - FSCA 25c/5488.2-10

Dear Sirs and Madames,

please confirm receipt of the safety notice for corrective action in the field. The forestry step of the measure is documented by us and forwarded to the authorities. If you have any questions about the process, we are available and will be glad to support you with our options.

Affected Products:

product name - type: Rollator B - 4003 prouction date: Mai 2016 – Dez 2018

serial No.: D4003R000000135 – D4003R000055000

name		
TelNo.		
E-Mail		
adresse		
date	signature	

Bischoff & Bischoff Medizin- & Rehabilitationstechnik GmbH Becker-Göring-Str. 13 D-76307 Karlsbad

Tel.: (07248) 9209-2 Fax: (07248) 9209-3 www.bischoff-bischoff.com info@bischoff-bischoff.de