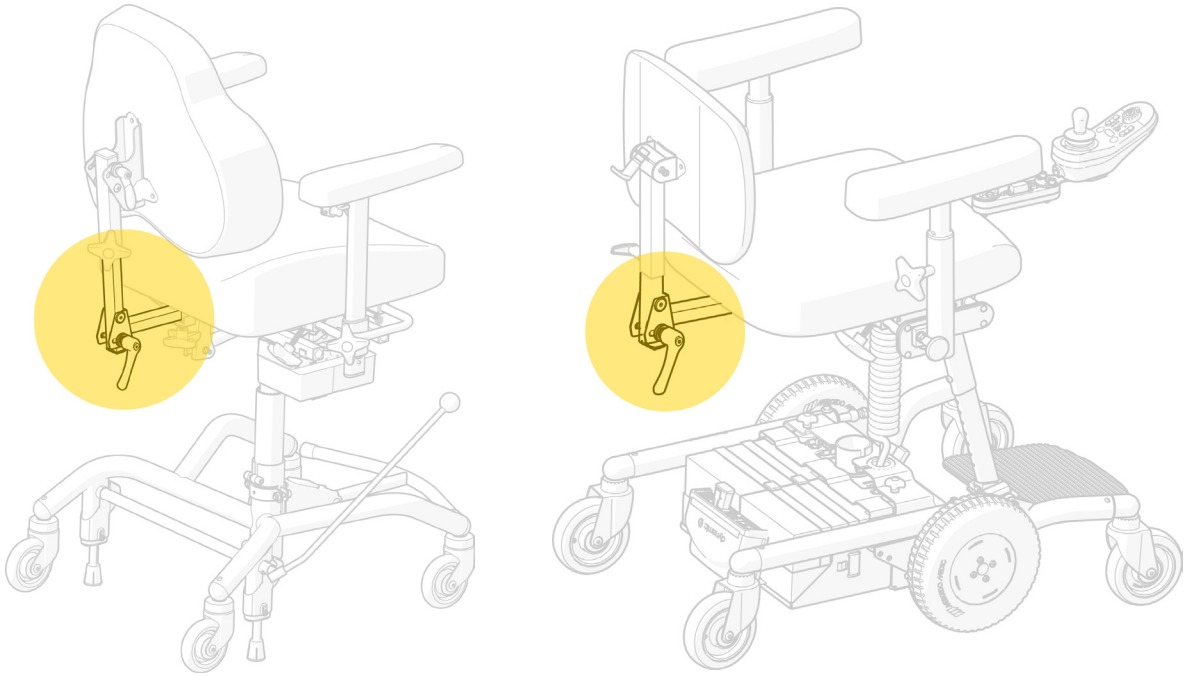
URGENT FIELD SAFETY NOTICE

Regarding Medic Back Recliner for REAL 9000 PLUS, REAL 9200 TWIN and REAL 6100 PLUS



Example of chairmodels

Background
The Medic back recliner has, on several occasions, failed at the weld, which may lead to personal injury. Therefore, actions need to be taken to ensure patient safety and prevent future injuries.

Action to be Taken
Back recliners with the design shown in Image 1 and Image 2 must be replaced at the first service or reconditioning opportunity. These units were manufactured between 2019-02-27 and 2023-05-09.

Design of Units to be Replaced

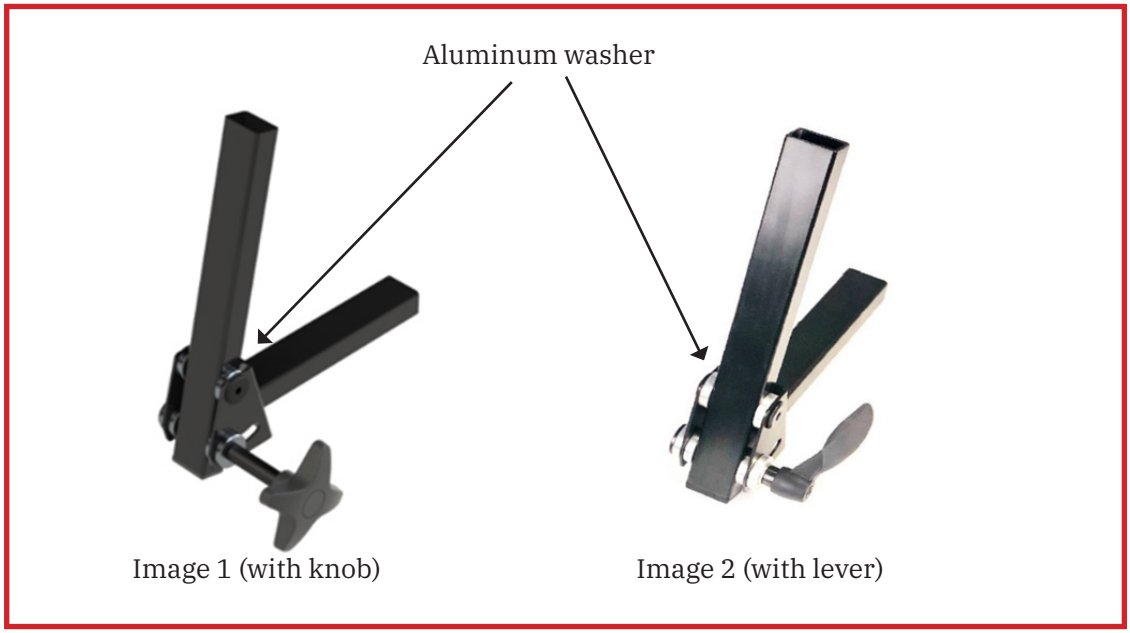


Image 1 (with knob) Image 2 (with lever)

Identification of Affected Back Recliners
The back recliners to be replaced have six aluminum washers, as seen in *Image 1* and *Image 2*. They can be identified by checking for four aluminum washers between the wide bent bracket and the tube of the back recliner, as indicated by the arrows below. These four aluminum brackets are not present in the new back recliners.

For information regarding affected serial numbers, please contact Mercado Medic AB:
https://mercado.se/kontakta-oss/
vigilance@mercado.se

Actions Taken by Mercado Medic
The construction and welding method of the Medic back recliner has been modified, according to ECN-S06873 Medic Back Recliner, as shown in *Image 3*. These updated back recliners have been supplied since 2023-05-10.

New Design

Image 3

Affected Article Numbers
801082 Back Recliner Medic 155mm L Cla/ErgoM (Upper Tube 240mm)
801083 Back Recliner Medic 112mm L Cla/ErgoM (Upper Tube 240mm)
801084 Back Recliner Medic 155mm XL Cla/ErgoM (Upper Tube 340mm)
801085 Back Recliner Medic 112mm XL Cla/ErgoM (Upper Tube 340mm)
801922 Back Recliner Medic 155mm S Cla/ErgoM (Upper Tube 200mm)
801923 Back Recliner Medic 112mm S Cla/ErgoM (Upper Tube 200mm)
805262 Back Recliner Medic L 200mm Cla/ErgoM (Upper Tube 240mm)
805508 Back Recliner Medic 200mm XL Cla/ErgoM (Upper Tube 340mm)

These articles are included in BRM1400, BRM1500, BRM1600, BRM1700, BRM1800, BRM1900, BRM2000, BRM4300, BRM4400, BRM4500, BRM4600, BRM4700, BRM4800, BRM4900, BRM5000, BRM5300, BRM5400, BRM5600, BRM5700, BRM5800, and BRM5900.

Replacement of Identified Medic Back Recliner
If a defective back recliner is identified, the following conditions apply for replacement:
- A case must be registered at https://mercado.se/en/support including the chair's serial number.
- Identified back recliners must be handled so that they are not used on another product.

If these criteria are met, Mercado Medic AB will provide a replacement product under warranty.

Timeline
To ensure patient safety, Mercado Medic AB considers this a permanent addition to your procedures rather than a one-time action. The measures shall be implemented progressively until all relevant reclining backrests have been replaced within the organisation.

Our Recommendations

Although the construction has been improved, there are still recommendations for when a Double Medic Back Recliner should be prescribed to ensure patient safety:

- When there is a risk of prolonged high load on the backrest due to involuntary movements.
- When the user is over 200 cm tall, and the seating unit can tilt more than 8° backward, combined with a posteriorly tilted pelvis and headrest.
- When the seating unit can tilt more than 15° backward, and the user weighs over 100 kg.
- When a reinforced adjustable seat frame (+15°/-23°) is chosen due to high loads.
- When the chair is used by spastic users or those with repetitive rocking movements.
- When a backplate wider than 46 cm is mounted on the chair and tilted 15° backward.

After the expected product lifespan, it is important to perform a comprehensive assessment before continued use. This assessment should be conducted by authorized personnel from the healthcare provider if the product is prescribed, and should at least consider:

- How the product has been used
- The condition of the product and its components
- Whether the product has been reconditioned and serviced
- When reconditioning and service occurred
- What was addressed during those occasions
- The reason for the performed actions

The manufacturing date is stated on a label on the frame (year/week). If the product is used by spastic users or users with repetitive rocking movements, more frequent inspections should be carried out.