URGENT FIELD SAFETY NOTICE

REAL 9000 PLUS series

Call for inspection to prevent risk of material failure in base frame

Information on affected devices

The information in this FSN concerns every individual chair in the REAL 9000 PLUS series with size 48 base frame. They are easily identified by their name on the product label found on the base frame. Affected devices are those with commercial names according to the list below, regardless of manufacturing date and serial number:

- REAL 9000 PLUS EL COXIT,
- REAL 9000 PLUS EL,
- REAL 9000 PLUS MANUAL ADULT,
- REAL 9000 PLUS,
- REAL 9100 PLUS EL ADULT,
- REAL 9100 PLUS,
- REAL 9500 PLUS,
- REAL 9600 PLUS EL,
- REAL 9700 PLUS COXIT,
- REAL 9700 PLUS MANUAL COXIT,
- REAL 9800 PLUS EL COXIT.

The REAL 9000 PLUS chairs are assistive ergonomic chairs and Class I medical devices for users with disablement relating to neck, back, legs and/or arms. A generic model of the REAL 9000 PLUS series is shown in Figure 1 below.

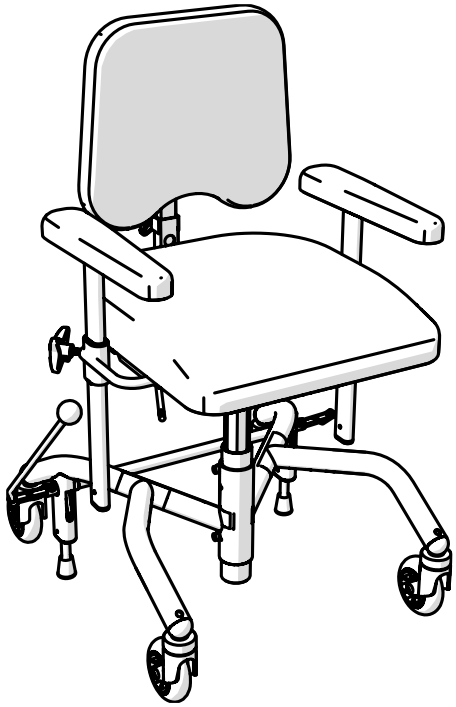

Figure 1. A generic model of the REAL 9000 PLUS series.

Reason for Field Safety Corrective Action (FSCA)

Mercado Medic have knowledge of 4 incidents where one of the front support legs of the base frame has been bent out of position. The frames have split in the weld between the front and rear support legs. This affected area is show in Figure 2 below. We want to stress that we don't see any reason to make a bigger effort than the proposed actions below in this document. The probability of material failure is low (less than 0,005% of sold products), and should it occur the risk of harm is also low. In case of material failure, there is a risk of the user falling out of the chair. There are no reports of serious injuries in relation to this failure. The FSN and FSCA are initiated upon request from the Swedish Medical Products Agency.

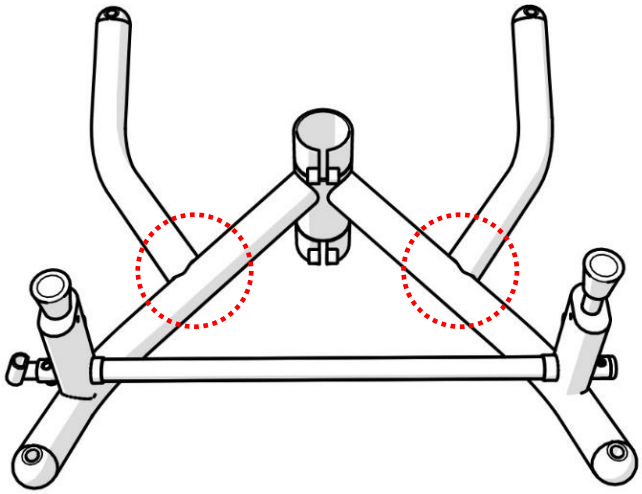

Figure 2. REAL 9000 PLUS base frame from underneath, with affected area marked with dotted red circles.

Type of action to mitigate the risk

The actions below shall be performed during normal service, maintenance, repair and refurbishing routines. Add these 3 inspection items to the routines:

a) **Inspection of welds.** The welds in the areas marked in Figure 2 above, and the areas around those, shall be inspected by a technician during normal service procedures. Any cracks in the material or surface treatment is to be considered a reason to replace the base frame.
b) **Inspection of balance performance.** If a chair has lessened brake performance, the base frame should be checked for imbalance in addition to the standard condition check of the rubber brake feet. If the chair doesn't stand on all four wheels when the brake is disengaged, this is to be considered a reason to replace the base frame. The check for imbalance should be performed at different places and in different directions to exclude that the imbalance is due to the floor.
c) **Inspection of manufacturing date.** 10 years is the expected service life for the product unless otherwise stated in accompanying specific documentation. After the expected service life, Mercado Medic cannot guarantee the suitability and safety of the device, as Mercado Medic has no control over how the device has been used and its wear and tear. After the expected service life, Mercado Medic AB cannot guarantee the provision of spare parts.

After the expected service life, it is important to make an overall assessment of the device before continuing to use it. The overall assessment of the device shall be carried out by authorised personnel of the healthcare organisation if the device has been prescribed and should at least take into account:

- how the device has been used,
- what condition the device and its components are in,
- whether the device has been reconditioned and serviced,
- when reconditioning and servicing have been carried out,
- what has been remedied on the above occasions,
- and the reason for the above remedial measures.

Manufacturing date can be found on a label on the frame, on the format year/week. If the product is used by individuals with spasticity or users exhibiting repetitive rocking movements, more frequent inspections should be carried out.

Customer reply

Customers shall reply using document *FSN S02461 Customer reply form.doc* and send this back to Mercado Medic AB in accordance with the instructions in that document before 2020-10-01.

General information

This is an update to the FSN with the same reference number S02461, dated 2020-03-16. We do not expect to send out further advice or information with any follow-up FSN.

The national Competent Authorities of the following countries are informed about this communication to customers: Belgium, Germany, Finland, France, Great Britain, Ireland, Iceland, Italy, Netherlands, Norway, Sweden.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (as appropriate).

Please transfer this notice to other organisations on which this action has an impact (as appropriate).

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.