



FSN – Urgent Field Safety Notice

FSN / FSCA Ref: FSN-S03338

Date: 04/12/2020

Issued by: Martin Bonnevier Kronlid

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URGENT FIELD SAFETY NOTICE

Clarified guidelines in user manuals on the expected service life of chairs in the REAL 9000, 6100 and 2000 series

Intended recipients

Head of Operations

Technical Manager

Purchasers of current products

Product manager for current products

Responsible for patient safety issues

Relevant product consultants, prescribers and operators in the supply chain

Other relevant personnel in any healthcare organisation

Contact information for representative at Mercado Medic AB

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Urgent Field Safety Notice (FSN)

Clarified guidelines in user manuals on the expected service life of chairs in the REAL 9000, 6100 and 2000 series

1. Information on affected products

1.	1. <i>Product type(s)</i>
	<p>Affected products are chairs from Mercado Medic AB in the series REAL 9000, REAL 6100 and REAL 2000. Examples of what these chairs look like are illustrated below. There may be variations in equipment on the chairs that make the appearance different.</p>  <p>The image displays four different chair models arranged in a 2x2 grid. The top row shows two blue chairs with armrests and casters. The bottom row shows two black chairs with casters. The chairs vary in design, including different backrest shapes and base configurations.</p>
1.	2. <i>Main clinical purpose</i>
	<p>The products are used as indoor mobility aids for people with different types and degrees of disabilities depending on the chair model. The disabilities can include, for example, walking difficulties or inability to walk, great difficulty in standing up or inability to stand up.</p>
1.	3. <i>Affected product models</i>
	<p>All model designations beginning with REAL 9XXX, REAL 6XXX and REAL 2XXX. The model designation can be found on the model label on the product, as well as in its user manual.</p>


2. Reason for field safety corrective action (FSCA)

2.	1. Problem description
	Information on expected service life and actions required during and after expected service life is missing or unclear depending on the chair model.
2.	2. Hazards that gave rise to this FSCA
	There is a risk of components breaking and a risk of patient injury (fall from chair) if expected service life is not taken into account and if actions currently recommended are clearly not taken. If the actions are taken according to the recommendations, the product can be considered safe for continued use.

3. Type of action to reduce the risk

3.	1. Action to be taken by the user
	Organisations handling Mercado Medic AB's products described in section 1 above must note the change in the user manuals and implement actions in their own procedures. The organisations must ensure that products are followed up during and after their expected service life in accordance with the recommendations in the user manuals.
3.	2. No customer response is required for this FSCA.
3.	3. Action taken by Mercado Medic AB
	Mercado Medic AB has added and clarified information in the user manuals relating to the expected service life of the affected products, as well as information about periodic service actions and actions to be taken when expected service life is reached and before the product's continued use. See the <i>Expected service life</i> section of the user manuals.
3.	4. Mercado Medic AB does not believe that this FSN needs to be communicated to end users, as the recommended actions are to be taken by the organisations that handle Mercado Medic AB's products.

4. General information:

4.	1. Type of FSN	New
4.	2. In updated FSN: reference number and date of previous FSN	-
4.	3. In updated FSN: crucial new information as below	-
4.	4. Are further recommendations or information expected to be communicated with a future follow-up FSN?	No
4.	5. The national competent authority (NCA) has been informed of this safety notice to the market and Mercado Medic AB's customers.	
4.	6. Annexes to this FSN	All amended user manuals are listed in Annex 20-08391.xlsx. This file shows the product to which each user manual relates, as well as the document number applicable to each language. All these user manuals are sent together with the original FSN and are also available on Mercado Medic AB's website on www.mercado.se .
4.	7. Name / Signature	Martin Bonnevier Kronlid Head of R&D, RA 

5. Forwarding of this field safety notice (FSN)

This field safety notice must be forwarded to anyone who needs to know the information within your organisation and to any organisations that may have received the relevant products from you, where this is appropriate.

Please ensure that your organisation remains aware of this safety notice and its recommended actions for an appropriate period of time to ensure that the actions are adopted and implemented effectively and correctly.

Please report accidents and incidents involving Mercado Medic AB's products to the national competent authority and Mercado Medic AB or distributor. This provides valuable feedback for the continued provision of safe products.