

FSN - Field Safety Notice

R82, High-low:xo & Wombat Living

Dear customer,

We, R82 A/S, are issuing a *Field Safety Notice* to inform customers (users, caregivers, healthcare facilities and distributors) of a recommended safety procedure to be performed on the devices below, for continuous safe use of them.

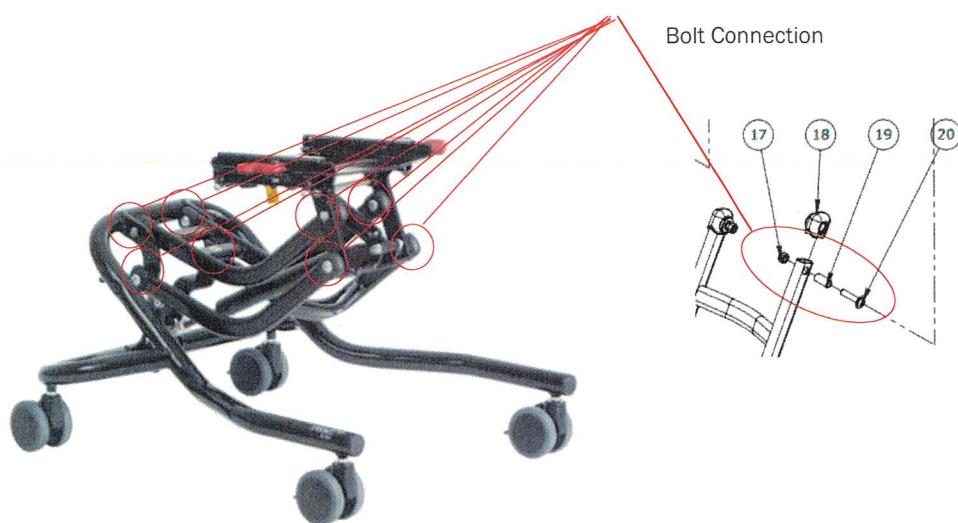
Devices included in this Field Safety Notice.

Device	High-low:xo (all configurations and all sizes)	Wombat Living (all configurations and all sizes) with production date newer than 2023-02-08
Basic UDI-DI	570729212221828	57072921809034J
EMDN	Y180999	Y180999
GMDN	58827	58827
Manufacturer	R82 A/S	R82 A/S
SRN	DK-MF-000000772	DK-MF-000000772

Background

A low number of reports received from the market less than 0,12% of units sold indicates that a bolt or bolts in the bolt connections in the carry arms may not be sufficiently tightened and this can lead to a wobbly frame or broken bolt connection if bolts are not securely tightened. This can pose a risk for the device and the user.

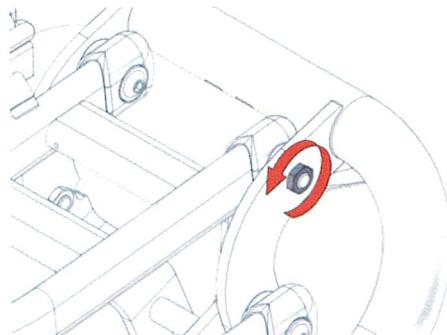
An instruction to perform a retightening procedure of bolts and nuts in the bolt connections on the device. See below in red circles (8 places).



Mitigation - retightening procedure

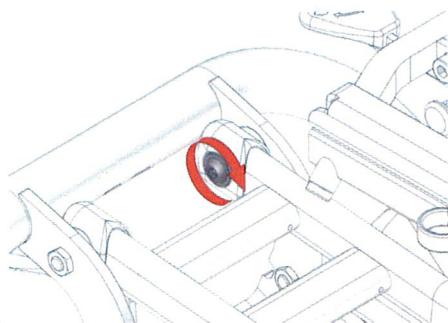
To mitigate this risk, we hereby recommend you perform a retightening of the bolts in the carry arms of the device. Please complete the following retightening procedure for all 8 bolt connections on the device (without the user in the device). Perform the retightening procedure before continuing to use the device or delivering it to your customers.

1: Loosen Nut (position 17) with 13 mm spanner (1 round)



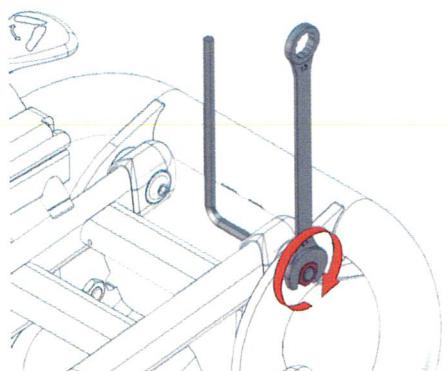
Picture 1:

2: Tighten Bolt (Position 20) with 5 mm Allen key



Picture 2:

3: Insert the Allen key in the bolt (Position 20) to make sure that it is not loosening) and then tighten the nut (position 17) again using a 13 mm spanner. (tightening the nut) in the opposite direction to lock the bolt in place)



Picture 3:

Mitigation (Confirmation)

We kindly ask you to help us ensure that this notice will be shared with all relevant personnel and any organizations where these devices have been delivered to. Please forward this information to whom you have delivered the devices to.

For Distributors:

Please inform back to where you have purchased the devices that you will pass the safety information on to your customers and secure similar confirmation from your customers as it is your obligation and responsibility according to **Article 14 General obligations of distributors of MDR REGULATION (EU) 2017/745**. Also please perform the mitigation on the devices in your possession

For end customers (users of the device):

Please perform the mitigation

We expect that this Field Safety Notice will be **shared and finalized before the end of January 2026**.

This notice has been submitted to the appropriate regulatory authorities.

Gedved, 2025-12-18

Sincerely,



Claus Riis, QA/RA Manager, PRRC

R82 A/S

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