

Rehasense Sp. z o. o.
Sulejowska 45 g
93-700 Piotrków Trybunalski
Poland
SRN: PL-MF-000004772



Date: 21.02.2023

Urgent Field Safety Notice

With this letter we would like to inform you that the screw connection of the front wheel to the frame is faulty (screw loosening) and that corrective measures must be taken on the Rehasense rollators Router, Navigator and branded rollators EVA and Navigon.

FSN (Field Safety Notice): 01/2023
Ref. FSCA: 01/2023

To all Users and Dealers of Rehasense Router, Navigator, EVA and Navigon rollators

Implementation of the corrective measures: Send the device back to Rehasense or have it repaired by the specialist dealer

Affected Devices: Please note Appendix 01/2023 with the listed serial numbers

Dear Users and Dealers of Router, Navigator, EVA, Navigon rollators,

PLEASE READ THIS DOCUMENT CAREFULLY.

Rehasense was made aware of a screwing loosening. In reported cases, the front fork has come loose during use. The cases are related to Router and Navigator rollators.

Due to the identified risk of screw loosening, an additional risk for the user has been defined. As a supplier of high-quality medical products, we have decided to take corrective action on the listed products.

Risk to the user:

There is a risk of the user falling during use. It could happen that the user falls forward and injures himself. The corrective measures are necessary as a measure for the greatest possible risk reduction according to the state of the art.

Corrective measures:

1. Information for users

Your authorized specialist dealer will contact you with this letter and coordinate/carry out the repair/correction of your product.

The rollators listed above must be taken out of service until they are replaced/reworked.

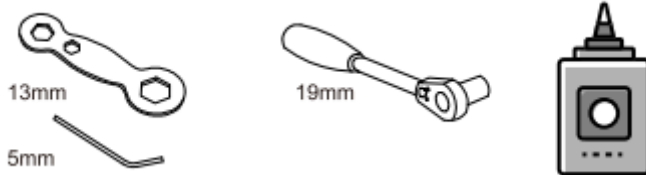
2. Information for dealers

2.1. Please return the completed and signed FSCA 01/2023 confirmation form to info@rehasense.com by April 28, 2023.

The affected rollators (see list of serial numbers in the appendix) must be taken out of service until they are replaced/reworked.

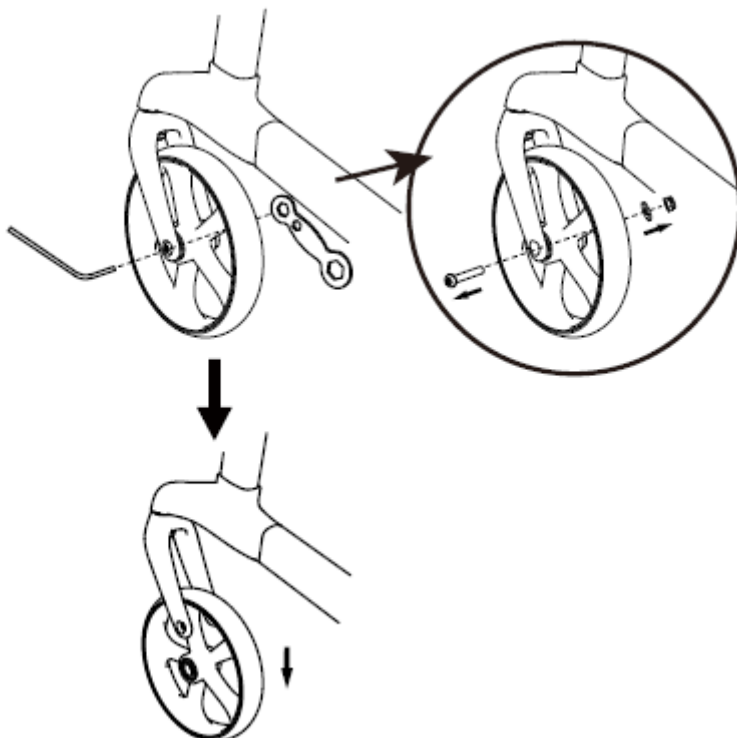
2.2. The screw connection is repaired by adding LOCTITE 243 screw locking glue or a comparable product.

2.2.1. Required tools:

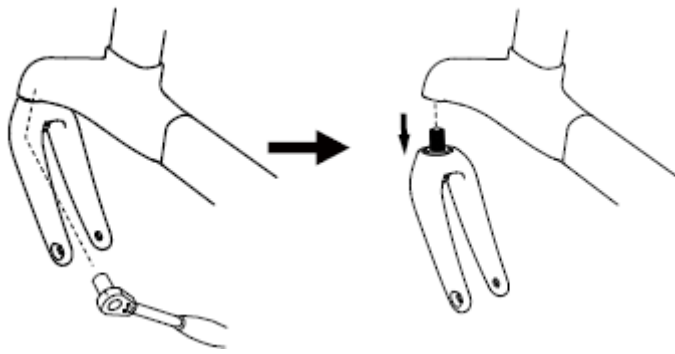


Glue: Loctite 243

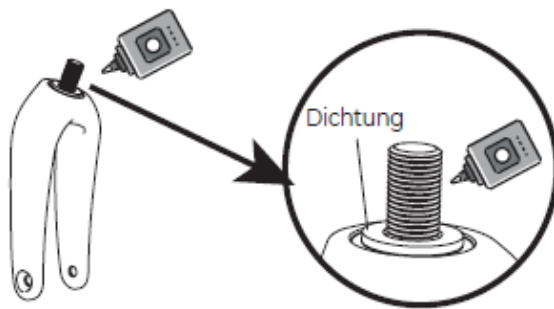
2.2.2. Unscrew the front wheel. Tools:



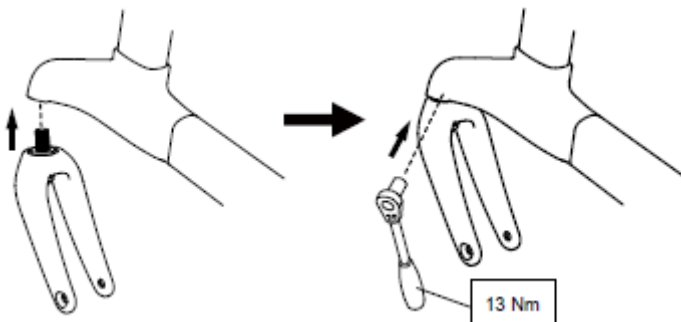
2.2.3. Loosen the M12 bolt and remove the front fork. Tool:



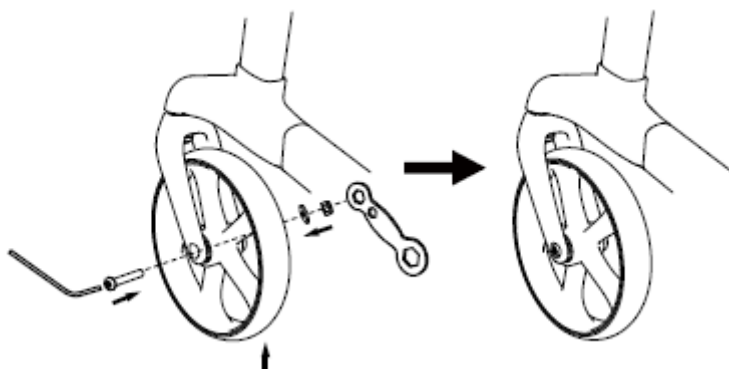
2.2.4. Apply glue to the thread only. Please ensure that the gasket remains on the screw for reassembly.



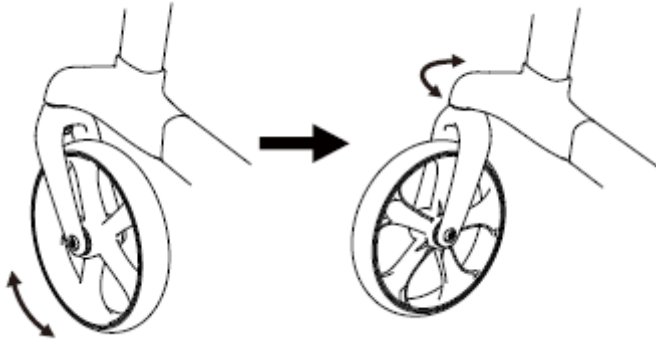
2.2.5 Reattach the front fork to the frame with the M12 bolt. Tighten the bolt with a torque of 13 Nm. Tool:



2.2.6. Screw the front wheel back on. Tools:



2.2.7. Check the wheel for functionality. To do this, make several turns around the axle to see if it turns smoothly.



2.3. You can also send the affected devices (see list of serial numbers in the appendix) back to Rehasense for repair.

Please contact our customer service to arrange return details.

Contact:

E-Mail: info@rehasense.com

Phone: +48 502 728 074

2.4. Action plan

No.	Description	Target date	Status
1	Direct communication to dealers - our goal to communicate all customers/ dealers (FSN with affected serial numbers and required corrective measures)	03.03.2023	In-process
2	Direct communication to final users - our goal to communicate all final users (FSN with affected serial numbers and required corrective measures)	10.03.2023	Open
3	Rework kits available to conduct corrective measures - our goal to deliver rework kit (glue and torque key).	31.03.2023	Done
4	Conduct rework - our goal to conduct steps from point 2.2	31.03.2023	Open

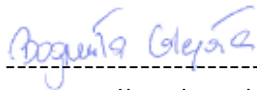
Please ensure that all users of the above products and all dealers and their personnel who have or are selling the products are made familiar with this important safety information. If you have given the products to a third party, please forward a copy of this information or inform the contact person given below. Please keep the letter at least until the action is completed.

If you have any further questions, please contact: info@rehasense.com or +48 502 728 074.

The Swiss Agency for Therapeutic Products (SwissMedic) has been informed of this notification.

We would like to take this opportunity to apologize for any inconvenience.

With best regards



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Confirmation form -FSCA 01/2023

Dear Sir or Madam,

please acknowledge both receipt of the corrective action safety notice and the implementation of the actions by returning the completed form to Rehasense.

If you have any questions about the process, we are of course at your disposal and will be happy to support you. You can reach us at info@rehasense.com or 48 502 728 074.

Affected devices:
Please note Appendix 01/2023 with the listed serial numbers.

Name:.....

Phone:.....

E-mail:

Address:

Date:.....

Signature:

Rehasense Sp. z o. o.
Sulejowska 45 g
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Poland
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REHASENSE

Datum: 17.02.2023

Anlage: 01/2023.

FSN (Sicherheitsanweisung im Feld): 01/2023

Item code	Serial number	Invoice no.
RRSGL600BB	010764017251052011220201218008	INEU/2132/22
RRSGL600BB	010764017251052011220201218011	INEU/2132/22
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RRSGL600BB	010764017251052011220201218002	INEU/2132/22
RRSGL600BB	010764017251052011220201218003	INEU/2132/22
RRSGL600BB	010764017251052011220201218004	INEU/2132/22
RRSGL600BB	010764017251052011220201218005	INEU/2132/22
RRSGL600BB	010764017251052011220201218006	INEU/2132/22
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Bożena Głęka

Item code	Serial number	Invoice no.
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RRWRL600BB	010764017251055111220217218002	INEU/3229/22
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RRSGL600BB	010764017251052011220602218007	INEU/10773/22
RRSGL600BB	010764017251052011220602218008	INEU/10773/22

Boğumla Çelebi

Item code	Serial number	Invoice no.
RRSGL600BB	010764017251052011220602218009	INEU/10773/22
RRSGL600BB	010764017251052011220602218005	INEU/10773/22
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Boğumla Çelebi