



Urgent Safety Information re.

Treatment chair PODOLOG MOON PROFESSIONAL

Quality management for improved safety,

Dear customers,

The reliability and safety of our products are RUCK's top priority. For many years now, RUCK is certified to the quality standards EN ISO 13485 and EN ISO 9001. This involves annual audits with strict conditions regarding safety and structured procedures. The normative and regulatory conformity of products is an integrative part of our quality management. These processes guarantee high security standards for all applications and consequently for our customers.

To maintain this high standard of quality, we are obliged to inform you should changes or product-specific risks occur.

This is now the case for the following serial numbers of our treatment chair PODOLOG MOON PROFESSIONAL: 16PMP001 – 18PMP045, as well 18PMP047 und 18PMP048

To date, RUCK has received four customer complaints specifying that the fixing screws between the hoisting system and the seat became loose.

Both parts are joined by 10 visible screws.

If these were loose, the following risk scenarios are possible:

For the unlikely case - which has not happened yet - that all screws of the fixing joints become loose, it would no longer be safe to use the treatment chair. As a result, the seat would fall off because it would no longer be fixed to the hoisting system.

What steps do you need to take?

After reading this letter, immediately check whether or not the screws on your treatment chair are loose, following the steps described in the enclosed „Service Instructions“. A simple visual inspection will suffice.



01 start position



02 move the to the highest position and pull plug from socket



03 move foot-rests to the upward position



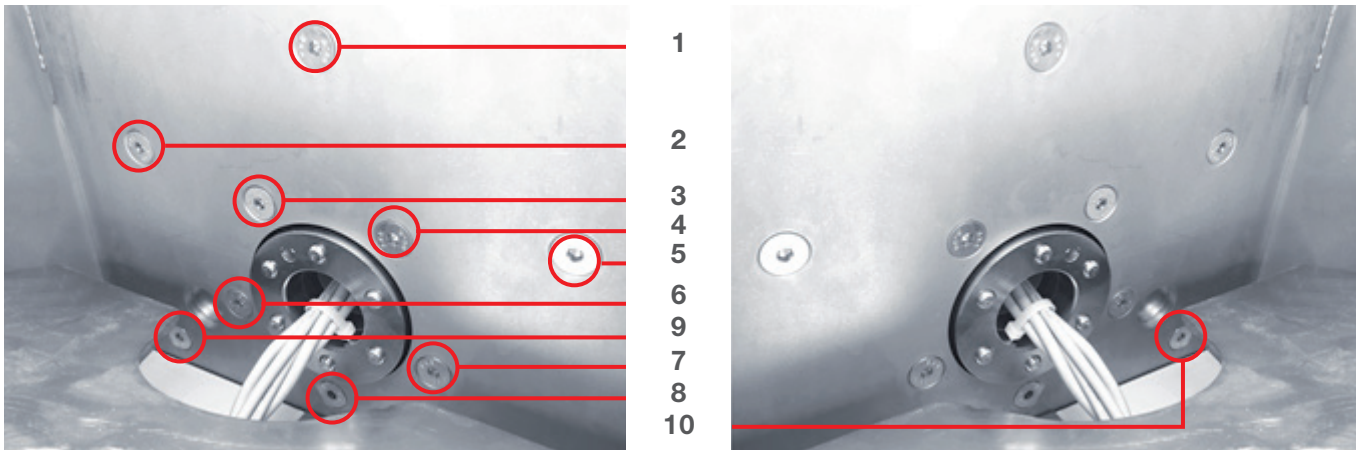
04 lift the housing (middle segment)



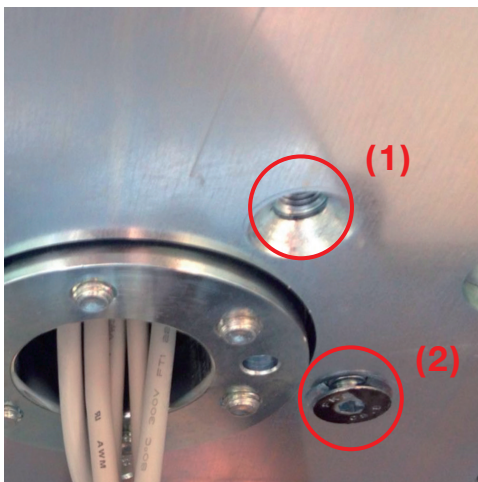
05 view to the insight



06 view onto the screws



07 view onto all 10 screws from two angles (in order to see screw 9 AND 10).
In this case all screws are in order.



08 screw lost (#1) or not correctly placed (#2)

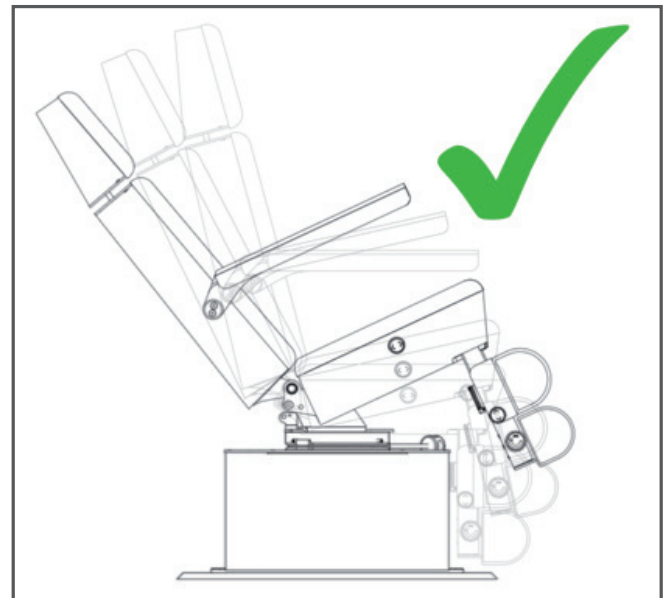
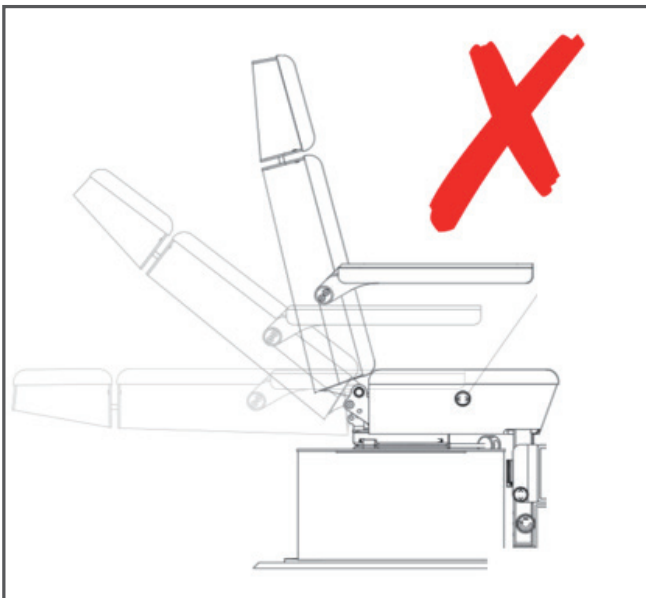
Option 1:

- If all screws are tight in their sockets (compare enclosed pictures), the treatment chair can be used without restrictions.
- Please make this visual inspection a monthly routine until we were able to service the chair on-site (the screws will be replaced and locked with adhesive). You are welcome to fix your service-date using the below mentioned contact number. As part of this free-of-cost service these screws will be replaced and locked with adhesive. This measure will prevent future loosening of the screws.
- Should one of the future monthly visual inspections reveal loose screws, please refer to **Option 2** as described below.



Option 2:

- Should the visual inspection reveal one or more loose screws (compare enclosed picture 8), the treatment chair can only be used in a restricted manner.
- In this case, you must refrain from tilting the back section of your chair. It is imperative that the back section remains fully upright during treatment.



- All other functions can be used without limitations.
- **Please contact RUCK immediately.** We will set a date for on-site service appointment free of charge to replace the screws and secure them with adhesives. This measure will prevent future loosening of the screws.

Information disclosure:

Please make sure that all your employees and colleagues receive information on this important and urgent safety matter. Should you have passed on the product in question, please send a copy of this information to the party involved or contact us (see details below).

Please keep this information until the chair has been serviced by a qualified RUCK employee or representative, respectively.



WHAT DOES RUCK DO TO SOLVE THE PROBLEM?

RUCK will service your chair on-site free of charge, replace all loose screws, and lock them with adhesives.

We ask you for your understanding of this measure. There is always the chance of technical problems when a product such as this is heavily used. For RUCK it is mission and duty to inform you immediately and take prompt corrective actions.

The German Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this urgent "Safety Information".

Please contact us if you have any questions:

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| Service department of Hellmut Ruck GmbH service@hellmut-ruck.de +49/7082 9442-259 | |
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26.04.2018

Bernd Stadter, Security Officer (medical devices) of HELLMUT RUCK GmbH, Germany



RESPONSE FORM

Urgent Safety Information

Treatment chair **PODOLOG MOON PROFESSIONAL**

Name, Surname: _____

Address: _____

City, Country, postal code : _____

Customer no. _____

Serial no. of treatment chair: _____

1. I have received and read this security information.
2. I have ensured that all my employees and colleagues have received full knowledge of this security information.
3. I will contact Hellmut Ruck GmbH in case of questions.

Signature: _____

Date: _____

PLEASE FAX OR E-MAIL THIS RESPONSE FORM TO

service@hellmut-ruck.de

Re. Urgent Safety Information Response Form

or fax to

+49/7082 9442 44 -222