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surface_SN2000-4506_230531_en.docx

31.05.2023

Safety notice

Restricted use for Treatment chairs 500 XLE with serial numbers 2000-4506

Affected are:

Art.no. / REF no.: 15000004 Serial number range: 2000- 2999

Art.no. / REF no.: 15000006 Serial number range: 3000-4506

Recipient:

This safety notice is addressed to all affected healthcare institutions, UFSK-OSYS distributors and their customers.

Description of the problem:

Within the scope of our continuous worldwide market surveillance and the evaluation of information from the field, we have determined that in the case of 500 XLE treatment chairs with the serial number ranges 2000-2999 and 3000-4506 (date of manufacture between 2012-10 to 2020-07), increased, externally undetectable wear of the seat drive can occur under certain circumstances in the event of exceptionally heavy use. In very rare individual cases, this can lead to a possibly sudden lowering of the lying surface on the head side when positioning a patient with the seat section in an inclined position (see attachment).

Description of the identified causes:

We have information that after several years of use, the intended service life of the seat section drive may be shortened. This results in a wear-related reduction of the self-locking of the seat section drives that are factory-fitted in the above-mentioned treatment chairs (manufacturing dates between 2012-10 to 2020-07). An unusually high stress due to various deterioration parameters (collision travel, incorrect lifting during transport, improper use) is to be assumed. Potentially increased wear or pre-damage of the seat drive may remain undetected under certain circumstances, especially if the recommended maintenance of the dental chairs has not been carried out or has been carried out inadequately.

In the very few individual cases that came to our attention, there was **no patient injury** or other personal damage.

Identification of the affected treatment chairs:

You will find the serial number of your treatment chair on the nameplate (see attachment). The affected treatment chairs are also marked on the nameplate with manufacturing dates between 2012-10 and 2020-07. Treatment chairs with other serial numbers are not affected by this problem.

What safety measure should be taken immediately?

The above-mentioned 500 XLE treatment chairs can still be used safely if you observe the following safety measure:

The seat part drive must be retracted so far with the patient in position that the seat part is in a horizontal position; the seat part must no longer be adjusted with the patient in position (see Annex: Illustration of safe and critical positioning positions).

All other adjustment functions of the treatment chair can be fully used.

Attach this safety information to the instructions for use of the respective treatment chair. Label the treatment chair appropriately using the information in the attachment to ensure safe use by changing users. **Please complete the enclosed reply form and send it to the address indicated there.**

Follow-up measure

It is strongly recommended to replace the seat drive at the latest when carrying out the next safety check (interval 12 months) and to observe the service schedule for safety-relevant components.

The successor model of the drive has a technically advanced self-locking of the motor and a mechanical end stop. The risk of the seat drive overrunning its end position due to wear when the seat part is tilted is then absolutely minimized.

Update the instructions for use with the enclosed supplement. Included: Service plan for safety-relevant components, amended spare parts list and installation instructions for the spare parts drive.

For spare parts procurement, please contact UFSK-OSYS or your authorized dealer.

UFSK-OSYS contact:

Tel: 0049 941 78862-47

E-mail: Fabian.Lang@ufsk-osys.com

Passing on this safety notice:

Please ensure that this safety notice is passed on to the medical device safety officer, if applicable, as well as to all users of the treatment chairs within the healthcare institutions where the concerned treatment chairs are operated.

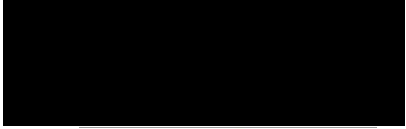
Please keep this notice, at least until the safety measure is completed.

For distributors:

As a distributor, please immediately forward this safety notice to all healthcare institutions to which you have supplied one of the affected treatment chairs and confirm to us that you have forwarded the letter using the reply form attached below. Note: Check your stocks for potentially affected demo- and pre-owned devices.

We apologize in advance for any inconvenience caused and thank you for your support.

With kind regards
UFSK-International OSYS GmbH



Diane Compala
Regulatory Affairs & Quality Management

Reply Form

I have received the **safety notice for Treatment chairs 500 XLE with serial numbers: 2000-4506** and have forwarded this information to the affected users and all other affected persons or healthcare institutions.

Organization/Company:

Name and address

(Stamp)

Please tick the relevant box

Healthcare institution

Distributor

Signatory person

Name, First name (in block letters):

Function:

City, Date:

Signature:

Please return this page promptly as confirmation to:

UFSK-International OSYS GmbH

Department Regulatory Affairs

Attn: Diane Compala

Kirchhoffstraße 1, 93055 Regensburg, Germany

E-Mail: md-vigilance@ufsk-osys.com

fax: 0049 941 78862-35

Attachment to: Safety notice-Treatment chair 500 XLE-SN 2000-4506-31.05.2023

Safe patient positions of 500 XLE (SN 2000 - 4506)



ATTENTION! The seat part must be in a horizontal position to the floor (see green cushion), the seat part drive remains in the retracted position (green marked component). Adjustment movements, e.g. into the reset position, are still possible (see adjustment positions of back and leg part shown in grey).

PROHIBITED - Critical patient positions!



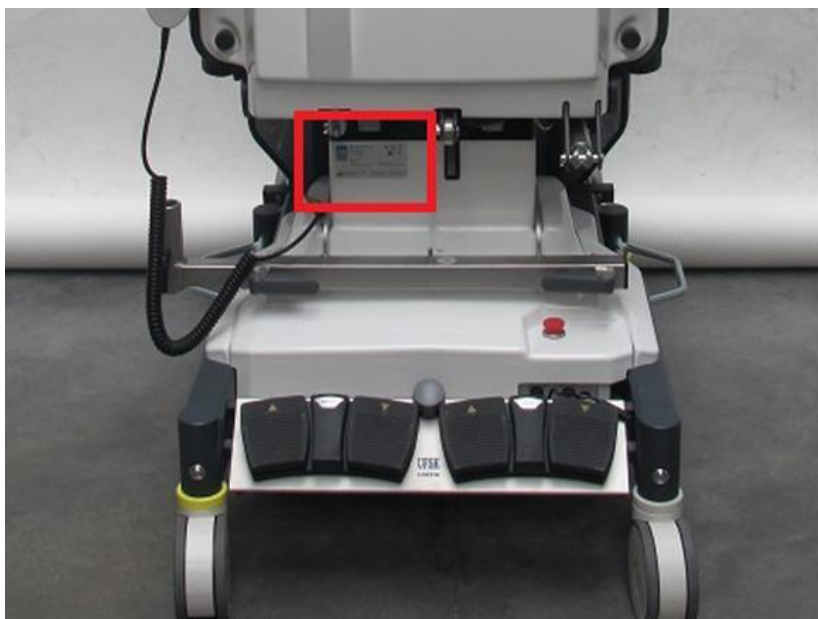
PROHIBITED! Tilting of the seat part by extending the seat part drive is prohibited. Memory positions that have been saved must be adjusted

ATTENTION - WORST CASE!



If the safe patient positions are not observed - in "worst case scenario" - this will cause the separation of the seat drive.

Where is the nameplate with the serial number (SN)?



Here you can find the nameplate of Treatment chair 500 XLE.
Identify the SN number! **Only SN-range of SN 2000 - 4506 is affected!**

Treatment chair



500 XLE SN 2000 - 4506

Supplementary application notes to the sections
Maintenance, Spare parts list and Replacement of a component

Occasion: Seat drive
Item No.: 4000 2535



Supplement for



500 XLE

Item No.: 1500 0006
Item No.: 1500 0004



500 XLE comfort

Item No.: 1500 0006 + 3037 0080
Item No.: 1500 0004 + 3037 0080

Note:

The illustrations show the treatment chair Item.No.: 1500 0006 from SN 3000 (white chassis covers). The predecessor version Item.No.: 1500 0004 (SN 2000-2999) has grey chassis covers. The treatment chairs with SN 2000-2602 require a slightly modified mounting of the seat drive (see Fig. gb).

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Conceptual Design and Completion/Layout and Design:

UFSK-International OSYS GmbH, Kirchhoffstrasse 1, D- 93055 Regensburg

English translation of the original German version, produced and printed in Germany.

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1. Service plan for safety-relevant wear parts

The seat drive is a safety-relevant component that is subject to expected wear due to regular use and must be replaced as a precaution after a usage interval of 5 years at the latest. If faults occur before then, observe the overview of malfunctions and act as instructed. Pay attention to noticeable noises during each function check.



Caution

Wear-promoting deterioration parameters due to incorrect handling must be avoided:

- Collision travel
- Improper use such as driving with patient against the set direction of the wheels,
- Incorrect transport when changing location: lifting by the handles instead of by the chassis



Important Information

Note the replacement of the seat drive with date in your device documents.

2. Change in the spare parts list



Important Information

- Be sure to use only components and spare parts approved by the manufacturer. The use of original components and original spare parts ensures safe and failure-free operation of the equipment.
- The Art. No. refers to the number in the technical drawing.
- All previously designated Item No. for replacement seat drives are discontinued and must be replaced by Item No. 4000 2535. This seat drive is downward compatible for all **500 XLE** SN 2000-4506 treatment chairs.
- Further information is available at info@ufsk-osys.com

| Art. No. | Description | Item No. |
|-----------|-----------------|-----------|
| 0000 5940 | Seat part drive | 4000 2535 |

3. Required tools

Screwdriver and Phillips screwdriver

4. Replacement seat drive

To replace the seat drive, please move the chair all the way up into its highest position, then move the chair's backrest into the horizontal position to allow removal of the seat cushion.



1. Move the treatment chair all the way up and the backrest element down.



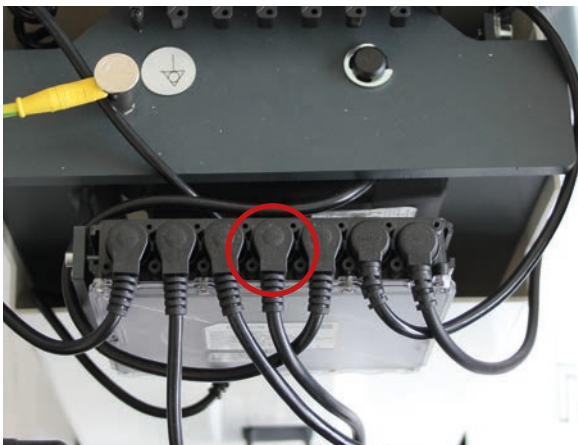
2. Disengage the seat cushion upwards at side marked with 1, then slide it out in the direction (2) of the back section.



3. Switch the treatment chair off and push the emergency stop button.



4. Unfasten the screws (marked red) and remove the plug cover.



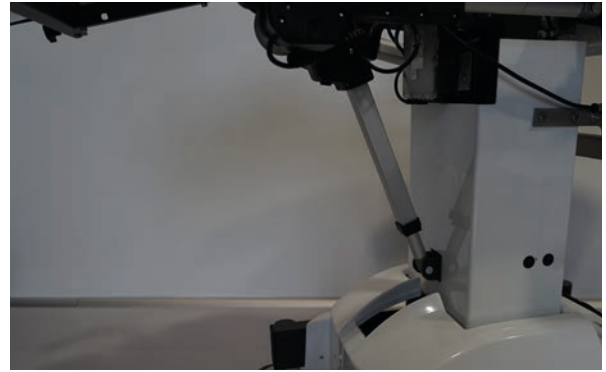
5. Remove the plug of the seat drive.



6. Remove both clips...below and...



7. ...on top.



8. **Attention:** Danger of tipping over!
Caution: Risk of injury! Hold the upper frame with your hand and remove both bolts. Do not lose the black washers.



9.a. Remove seat drive, install the new seat drive centrally with both bolts including the two (2) black washers i.e. place one (1) washer on each side of the clevis.

Note:

Observe the two different lengths of the bolts.

SN 2603-4506



9.b. Remove seat drive, install the new seat drive centrally with both bolts including the two (2) black washers **outside centre** (!) i.e. both washers are to be fitted on the left in front view of the chair (on the right in the direction of the patient's view). Then retract the seatrest completely and slowly move the lifting column downwards.

Attention: Check the adjustment path with regard to collision travel (yellow arrow), if necessary align the left and right chassis cover! Make sure that the lower clip is correctly seated.

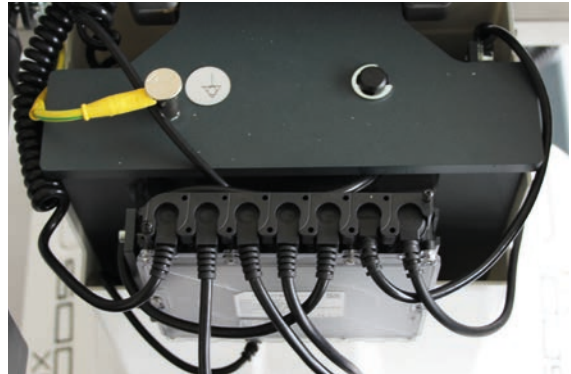
SN 2000-2602



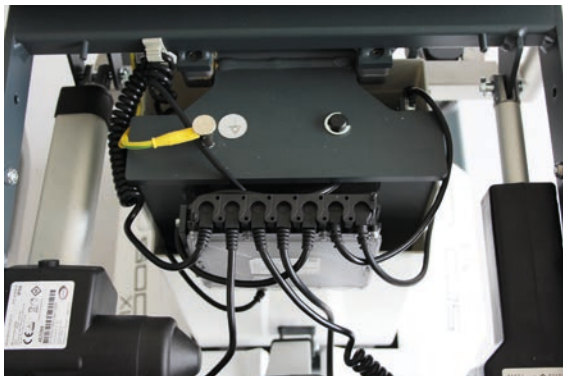
10. Secure both bolts with the clips.

Attention:

Lower and upper clip are different



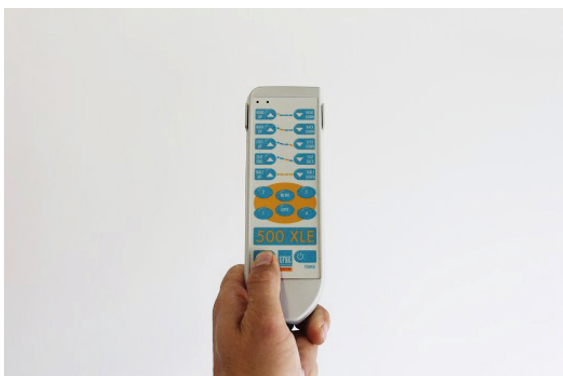
11. Plug in seat drive to control box...



12. ...and reattach the plug cover.



13. Refasten the cushions. Rotate the emergency stop switch in clockwise direction to release it.



14. Instructions on how to power up and initialize the treatment chair. Please keep the Auto button pushed for 2 seconds, then push the Reset button. Please perform a function test to make sure that all functions of the treatment chair are in perfect working condition.

5. Electrical measurement according to IEC 62353

The replacement of an electrical component requires an electrical test to be carried out in accordance with IEC 62353. For more information, please refer to the main manual, section 8.2.

6. Protection of the environment and waste disposal

The packaging materials used are recyclable. Please do not dispose of packaging materials with normal household waste, but recycle them properly - in accordance with the local legal regulations that apply to you. UFSK-International OSYS GmbH and UFSK-authorized EU distributors and third country representatives make their specified contributions to collection systems. Properly disposing of old equipment is to be done in accordance with the legal regulations currently in force.

**If you need any further help, please do not hesitate to contact us:
Phone 0049 941 78862-15**