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FREI AG

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Urgent Safety Notice

Precautionary replacement of motors on older treatment tables

Re: THERA treatment tables from FREI AG

From: FREI AG Aktive Reha-Systeme, Am Fischerrain 8, 79199 Kirchzarten, Germany

Target Group: Owners, operators and distributors of the THERA treatment table from FREI AG

Identification of the affected medical devices:

THERA treatment tables with article numbers:

Standard: 8.5200.03 ; 8.5200.04 ; 8.5200.10
Universal: 8.5205.00 ; 8.5205.03 ; 8.5205.04 ; 8.5205.10
Manual: 8.5210.00 ; 8.5210.03 ; 8.5210.04 ; 8.5210.10
pro: 8.5207.04 ; 8.5207.05 ; 8.5212.04 ; 8.5212.05
Edition: 8.5206.03 ; 8.5206.04 ; 8.5206.05 ; 8.5211.03
Vojta: 8.5215.00 ; 8.5215.03 ; 8.5215.04



Description of the problem including the determined cause:

In rare cases, the adjustment motor may fail on treatment tables with power adjustment that are older than 10 years, leading to a possible collapse of the treatment table. This is associated with a considerable risk for the patient and therapist. The causes for this possible failure are:

- Continuous load on the motor
- Natural wear due to the adjustment movement (number of cycles)
- Ageing of internal plastic parts

The damage may be indicated in advance by unusual motor noises, reduced operating comfort and possibly a slower adjustment speed.

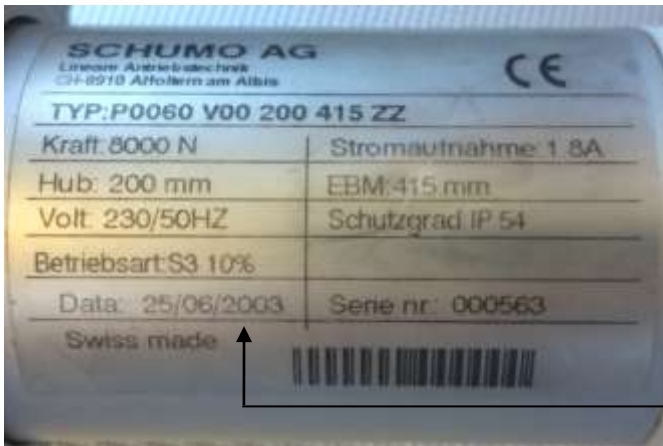
In these cases, please stop using the treatment table immediately until it is professionally repaired.

What steps have to be taken by the addressee?

Check the year of manufacture of all adjustment motors on your treatment tables. Motors older than 10 years should be replaced as a precaution. The age of the motor is indicated on the type plate of the motor or on the treatment table.

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Example of a motor type plate:



Year of manufacture

If this inspection fails or cannot be carried out, please stop using these treatment tables and contact FREI AG. We are happy to assist you with any questions regarding this measure. The age of the motors and thereby the replacement interval must be checked in the course of the recurring safety inspection.

Dissemination of the information provided here:

Please ensure that all users of the power adjustment tables who need to be informed in your organisation are advised of this urgent safety notice.

If you have transferred products to third parties, please pass on a copy of this information or inform the contact person below regarding the whereabouts of the treatment tables in question.

Please retain this information at least until the measure has been implemented.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Notice".

Contact person for further enquiries:

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 FREI AG Aktive Reha-Systeme

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 FREI AG Aktive Reha-Systeme

FREI AG, Aktive Reha-Systeme
 Kirchzarten, Germany,
 June 2018

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Customer Address

D-No.

Name 1:

Name 2:

Street:

Postal Code, City

Country:

FREI AG FAX – number: 0049 7661 933 67 33

Confirmation of receipt form

**for the Urgent Safety Notice "THERA treatment table
manufactured in before 2009" dated June 2018**

- We hereby confirm that we **have received and taken note** of the
aforementioned Urgent Safety Notice.
- We have tables with the critical motors (older than 10 years)
in use.
- We have **no** tables with the motors -older than 10 years in use.
- Tables** with the critical motors (older than 10 years) were **passed on to:**

Date

Signature