

Name 1
Name 2
Additional Address Info
Street
Postal Code City

Kirchzarten, 03.03.2015

**Urgent recall notice regarding the FREI treatment tables
AXXIS, GYM and THERAGYM manufactured during the period 1997 –
2000.**

This letter is intended for users, operating companies, dealers and distribution partners.

Dear Ladies and Gentlemen,

Please be advised that we have received notice from the company SKF GmbH, who supplied the motors used to adjust our treatment tables (SKF took over the company Magnetic Elektromotoren in 2009). The information pertains to the magnetic motor type Max 64 manufactured during the period 1997-2000, which was installed in the FREI treatment tables AXXIS, GYM and THERAGYM at the time. In some instances, this motor type may malfunction due to wear. If such a malfunction occurs, then this may result in a serious risk of injury to the user and the patient.

According to our records, you purchased one or more FREI treatment tables of the AXXIS, GYM or THERAGYM series between 1997 and 2000.

Please check your inventory of treatment tables!

For your safety, we urgently recommend no longer using the specified treatment tables and taking them out of operation immediately, insofar as they are still equipped with the motor described above.

You can identify the affected motor types in your medical devices as follows:

On the motor rating plate, you will see the motor type ("MAX64" in this example), and to the right of that the serial number which may be appended with "LO", in this example "No. 2517907".

The affected motors have serial numbers below 3163116.



Description of the problem by the motor manufacturer:

Due to the long service life of the drive, the rubber bumper at the upper mechanical stop can wear out. This can result in the recirculating ball screw nut running past the end of the thread, thus losing balls. If operation of the drive is nevertheless continued after this occurs, then this may result in uncontrolled movement of the drive.

Additional information from FREI AG

The motor used to adjust the height of the table top carries the weight of the table top by bracing the table top against the base frame.

Potential risk

Sudden lowering of the table top can lead to significant injury of patients or third parties.

Recommended action

For your safety, we urgently recommend no longer using the specified tables and taking them out of operation immediately.

Please take the necessary steps within your facility / your company to ensure that all users and/or purchasers of the aforementioned tables receive a copy of this recall notice and take note of it. If you have provided the table(s) to third party(s), then please pass a copy of this recall notice on to them as well or inform our safety officer (see below for contact information).

Please retain this recall notice until the required measure(s) have been implemented. The BfArM – German Federal Institute for Pharmaceuticals and Medical Products - has been informed by FREI AG about this recall notice.

Safety Officer / Service Department

FREI AG Safety Officer

Bernhard Schweizer
Electronics Department Manager
Phone 07661 – 9336 0
bernhard.schweizer@frei-ag.de

FREI AG Service Department

Our service department will be happy to assist you with any questions about this recall notice. You can reach our service department via the hotline at 07661 / 9336 699 or via info@frei-ag.de.

Confirmation

Please use the attached confirmation of receipt form to confirm at your earliest convenience to confirm that you have received and taken note of this recall notice. As a specialist dealer, please provide this recall notice to all of your affected customers and pass their responses on to FREI AG. We also require complete documentation of the feedback from your customers for our proof of action for BfArM.

Thank you for your understanding and support.

Sincerely

[Signature]



Director

[Signature]



Director

Customer Address

D No.
Name 1
Name 2
Street
Postal Code, City

FREI AG FAX – number: 07661 / 9336 50

Confirmation of receipt form

for the urgent recall notice "FREI treatment tables AXXIS,
GYM and THERAGYM manufactured in 1997 – 2000" dated 05.03.2015

- We hereby confirm that we **have received and taken note** of the
aforementioned recall notice.
- We have _____ tables with the specified critical motor serial numbers
(below 3163116) in use.
- We have **no** tables with the specified critical motor serial numbers
(below 3163116) in use.
- Tables** with the specified critical motor serial numbers (below 3163116) were
passed on to:

Date

Signature