

FIOR & GENTZ – Dorette-von-Stern-Str. 5 – D-21337 Lüneburg

«Name1»

«Name2»

Geschäftsleitung, Qualitätsbeauftragter

«LieferStrasse»

«LieferLand»-«LieferPLZ» «LieferOrt»

Lüneburg, December 2014

Important Software Update NEURO TRONIC

Dear Ladies and Gentlemen,

With this letter we send you an "Urgent Safety Information" and would like to ask you to pass it on to the personnel qualified in the orthotic field in your company.

The automatic knee joint system NEURO TRONIC which is used in custom-made orthoses is electromechanically locked and unlocked. In the course of launching a new software version, we noticed a possible problem. In order to be sure to avoid this problem, the software must be updated.

You will find all recommended measures in the "Urgent Safety Information" enclosed to this letter. Furthermore, you can find information and help on our website at www.fior-gentz.com/download or www.fior-gentz.com/updates.

Enclosed we also send you a reply fax. We would appreciate it if you filled out the fax and sent it back to us. You also have the possibility to give us the data by calling us. You would help us a lot.

The safety of your patients as well as your satisfaction are very important to us. We would like to expressly apologise for any inconveniences.

With best regards from Lüneburg,
Your FIOR & GENTZ Team

Urgent Safety Information

Software update

regarding

**controllers of the NEURO TRONIC knee joint system using e-Motion
software version V2.24 to V2.52**

Lüneburg, December 2014

Sender:

FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH
Dorette-von-Stern-Strasse 5
D-21337 Lüneburg

Addressee:

Certified supplier, distributor of the orthotic product

Identification of the medical devices concerned:

Concerned are controllers of the NEURO TRONIC knee joint system using e-Motion with the software version V2.24 to V2.52

Identification of the software version:

- Connect the multi-purpose device with the controller
- After a successful connection, the version is displayed on the multi-purpose device

Manual:

PB3800-SK NEURO TRONIC multi-purpose device, chapter 11.2 Pairing (Putting into Operation Controller), page 43 f.

Description of problem including detected cause:

After inserting the batteries or rechargeable batteries, an error can occur in rare cases while initialising. This leads to the controller doing a self-test. During this self-test, 18 signals sound in a frequency getting lower, similar to a scale. After this test, the controller is set to using a pressure sensor, the so-called p-Motion. If the foot piece of the orthosis does not have a pressure sensor (e-Motion), then the controller cannot recognise the moment when the foot touches the floor and therefore does not lock the system knee joint.

Which measures have to be taken by the addressee?

In order to avoid this happening to your patients, we recommend the following measures for patients using the NEURO TRONIC system knee joint with e-Motion:

Software version controller	Distributed since	Recommended measures	Way of proceeding
V.1.0-V2.24		No measures necessary	-
V2.24-V2.40	02.2012	Exchange controller	Send the controller(s) to FIOR & GENTZ; if desired, replacement is possible in advance
V2.41-V2.52	03.2014	Software update by using the multi-purpose device*	<ul style="list-style-type: none">- Download the latest software on our website www.fior-gentz.com/updates- Update the controller via the multi-purpose device to version V2.60 or higher (status October 2014)
From V2.60 on	12.2014	No measures necessary	-

- * To carry out the software update, you need a multi-purpose device with a USB port. If your multi-purpose device does not have a USB port, please contact us.

Passing on the information described here

Please make sure that all users of the above mentioned products and other persons that have to be informed in your company receive knowledge of this "Urgent Safety Information". In case you have passed on these products to third parties, please send them a copy of this information or inform the contact person indicated below.

Please keep this information at least until the measures have been carried out.

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

Contact person (Mo-Fr 8 a.m. until 5 p.m.):

Mr Henrik Düffert

Phone: 0049 4131 24445-66

Email: henrik.dueffert@fior-gentz.de

You also have the possibility to contact your field representative from the company FIOR & GENTZ, Mr «ADM» by calling the mobile phone number «mobil_ADM» so that, if necessary and with prior appointment, he can help you finding out the version, exchanging the controller or updating the software.

Ralf Gentz



REPLY FAX FIOR & GENTZ
FAX +49 4131 24445-57

Customer no.: «Empfaenger»

Contact person: _____

From the total [«MENGE»] of received controllers, __ can be updated in our company.

We will send __ controllers to the company FIOR & GENTZ for controlling, updating or, if necessary, exchanging.

e-Motion is used for __ patients.

Please fill out this section and fax it back to us to the number +49 4131 24445-57. Of course, you can also send it to us via email or by post or give us a call.

Thank you for your help!