MEDIZINTECHNIK
Dipl.-Ing. P. Hettmer GmbH

Hanse-Medizintechnik · Zeiss-Straße 42 · D-23626 Ratekau

Customer Information

concerning the

Mobilisation and Rehabilitation Wheelchairs

Thekla II and Thekla II 85° (Handset)

01 October 2018

Dear customers and users,

Based on our monitoring of product behaviour in the field, we consider it our duty to inform you about the risks to patients and users that may arise in connection with the following products:

Mobilisation and rehabilitation wheelchairs concerned:

Thekla II, item number 4-02-00, all serial numbers

Thekla II 85°, item number 4-03-00, all serial numbers

Handsets concerned:

HB54E09-23021 (item number), (all serial numbers)

Description of the potential problem and of the identified cause:

Hanse-Medizintechnik Dipl.-Ing. P. Hettmer GmbH has become aware of a small number of cases where an automatic movement of the mobilisation/rehabilitation wheelchair was caused by a faulty key (i.e. nobody had actively pressed it). There were no injuries to patients or users.

In all cases, investigations identified a key with a defect. This may have been caused by excessive operating pressure or by high impact on the key or handset. As a result of a key defect, one of the key components might create a conductive connection and cause an unexpected movement of the wheelchair. The handsets concerned showed damage which was clearly visible in some cases.

The following action has to be taken by the users:

Before using the mobilisation and rehabilitation wheelchair, perform an inspection for damage. This will significantly reduce the risk of the above-mentioned fault.

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- Before using your mobilisation and rehabilitation wheelchair Thekla II / Thekla II 85°, check the handset for external damage.
- Check the handset keys. A faulty key can be identified by the fact that it **does not make a clicking sound** when pressed.
- An additional way of identifying a faulty key is by checking its function. If you check the function of a particular key and the actuator does not react, you should bear in mind that this might be due to the automatic safety software which disables some of the keys when the wheelchair is in certain positions.

If you notice the above-mentioned defects, stop using the handset and contact Hanse-Medizintechnik.

As an additional measure against unintended chair movement, please press the "OFF switch" whenever the wheelchair is not in use or when no movements should be made. Enclosed please find stickers for easier identification of the OFF switch on your mobilisation and rehabilitation wheelchairs concerned.

This Customer Information is also accompanied by an amended version of the Instructions for Use which describe the fault and how to prevent it.

In addition to the Instructions for Use, we recommend that the handset should be exchanged at regular intervals every 4 years, as a precaution. This allows you to further reduce the risk of an undiscovered fault.

To prevent the aforementioned problems, the manufacturer of the handset has developed an improved handset for us. If you wish to order the improved handset model, please contact our Technical Service Hotline (+49 4504 8182 32) to place your order.

Distribution of this information

Please ensure within your organisation that this information is passed on to all the users of the above products and to anyone else who may need to be made aware of it.

A copy of this Customer Information should be kept together with the attached Instructions for Use. Please replace the Quick Guide on the wheelchair with the amended one attached; please attach the stickers in the appropriate places to identify the OFF switch.

If you have passed the products to any third parties, please forward a copy of this information on to them or inform the contact person listed below.

The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) has received a copy of this Customer Information.

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Contact person:

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Dipl.-Ing. Volker Urbschat
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Enclosures:
Enclosure 1: Instructions for Use
Enclosure 2: Quick Guide
Enclosure 3: Indicating sticker "OFF switch" including attachment instructions