

Urgent Safety Communication

Urgent FSN's of THERA-Trainer balo incl. Model BALANCE-Trainer / THERA-Trainer verto Manufactured by Medica Medizintechnik GmbH

Device/ Product Name:	Movement therapy device: THERA-Trainer balo include Model BALANCE-Trainer, THERA-Trainer verto
Lot numbers/Serials:	Manufacturing date: between CW21/2013 and CW04/2018 and can clearly be identified by serial number. Serial numbers consist of A002-308-XX-YYCWXXXX, A003-215-XX-YYCWXXXX or A002-678-XX-YYCWXXXX YY = the last two figures of the manufacturing year (e.g. 2015) CW = Calendar week of production (e.g. 07) Check the affected serial numbers below.
Manufacturer:	Medica Medizintechnik GmbH
Problem:	Saudi FDA would like to bring your attention that Medica Medizintechnik GmbH is issuing an Urgent FSN's to inform you that you have to STOP exercising with THERA-Trainer balo/THERA-Trainer verto until a modification was done. That because the hexagon socket set screw of the mounting mechanism of the knee support is broken. Please read the manufacturer' FSN below.
Recommendation/Actions:	- Please stop exercising with THERA-Trainer balo/THERA-Trainer verto until a modification was done. - Medica Medizintechnik GmbH, will send t their customers within the next 2-3 weeks spare parts incl. service manual in order to exchange the relevant components. - If ho have these products Make sure to contact your distributor to complete the corrective action.

Devices/Products photo:		
	Picture: THERA-Trainer verto Picture: THERA-Trainer balo, BALANCE-Trainer	
Authorized Representative Details	Company name:	Care Techniques Est.
	Contact Person:	Faisal Al-Haitty
	Phone:	+966 567047034
	Email:	plan.med@gmail.com

For further information, please **see the FSN below or [Click Here.](#)**

Healthcare Professionals should report any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit ([NCMDR Website](#))

Sincerely,
NCMDR Team

Serial no. Medical device
A002-678-01-16341309
A002-308-02-17445117
A002-308-02-16384727
A002-308-02-16384724
A002-308-02-16074114
A002-308-02-16074112
A002-308-00-13204153
A002-308-02-15374321
A002-308-02-15374314
A002-308-01-14464457
A002-308-01-14464456
A002-308-01-14463002
A002-308-00-13282057
A002-308-00-13282058
A002-308-00-13282059
A002-308-00-13282060

medica Medizintechnik GmbH
Blumenweg 8 | 88454 Hochdorf

To:
Importers and distributors

Ihr Ansprechpartner
Dirk Neurohr
07355-93 14-67

Datum
24. Juli 2018

**Ref: Urgent Safety Information THERA-Trainer balo incl. model BALANCE-Trainer /
THERA-Trainer verto**

Dear Sir or Madam,

We need to implement a corrective action for our products THERA-Trainer balo incl. model BALANCE-Trainer /
THERA-Trainer verto in the field. Please note following references.

Identification of the concerned medical products:

Movement therapy device – THERA-Trainer balo incl. model BALANCE-Trainer, THERA-Trainer verto

Manufacturing date of all relevant medical devices is between CW21/2013 and CW04/2018 and can clearly be
identified by serial number.

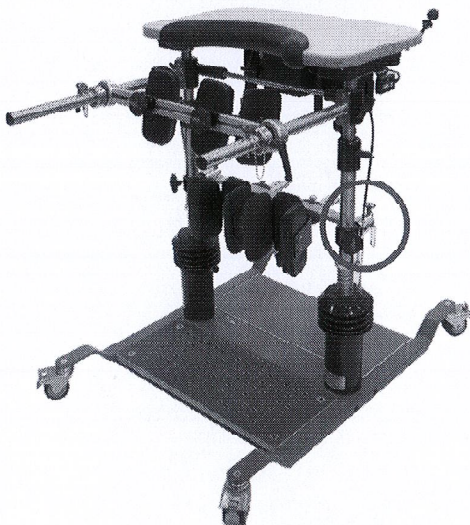
Serial numbers: A002-308-XX-YYCWXXXX, A003-215-XX-YYCWXXXX or A002-678-XX-YYCWXXXX

YY = the last two figures of the manufacturing year (e.g. 2015)

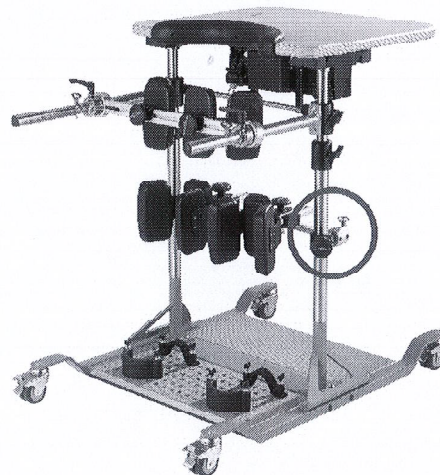
CW = Calendar week of production (e.g. 07)

Description of the problem including the determined cause:

The hexagon socket set screw of the mounting mechanism of the knee support is broken.



Picture: THERA-Trainer balo, BALANCE-Trainer



Picture: THERA-Trainer verto

medica Medizintechnik GmbH

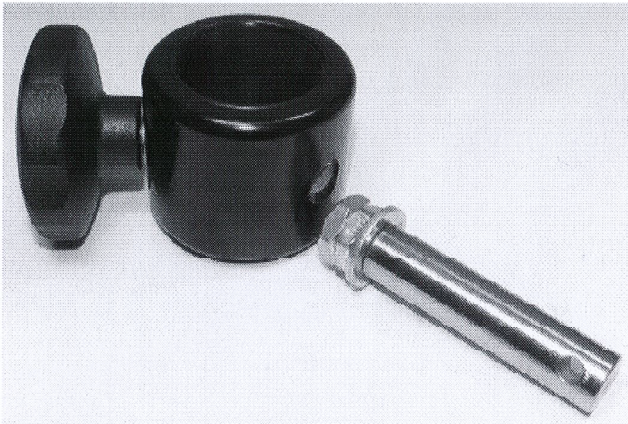
Blumenweg 8
88454 Hochdorf
Tel +49 7355-93 14-0 | Fax -15
www.thera-trainer.de
info@thera-trainer.de

Kreissparkasse Biberach
BLZ 654 500 70
KTO 23 14
IBAN DE88654500700000002314
SWIFT SBCRDE66

Commerzbank Biberach
BLZ 654 400 87
KTO 130 45 67
IBAN DE20654400870130456700
SWIFT COBADEFF654

Geschäftsführer
Peter Kopf/Otto Hübel
Rgr. Ulm
HRB 640839
USt.-IdNr. DE144890393

medica Medizintechnik GmbH
Blumenweg 8 | 88454 Hochdorf



Picture: Broken hexagon socket set screw

As a cause, we detected a hydrogen embrittlement of the galvanized hexagon socket set screw with the strength ≥ 10.9 . This hydrogen embrittlement can occur irregularly. The damage can happen during low load already. If the hexagon socket set screw breaks, the knee support can fall off on one side and the patient will become instable during lifting process or during therapy.

Health risk:

We carried out an evaluation of the health risk, in order to identify potentially harmful situations that might occur if the hexagon socket set screw breaks suddenly. The highest possible level of harmful situation for the patient is injury to the skin (e.g. laceration) which needs medical attendance.

Until now, we faced no injuries in connection to this problem.

There are no risks for patients that were already treated with the device, as well as for users and third persons.

Which measurements need to be taken in action by the receiver?

During this corrective action, we kindly ask you to do the following:

- Please stop exercising with THERA-Trainer balo incl. model BALANCE-Trainer /THERA-Trainer verto until a modification was done.
- We, medica Medizintechnik GmbH, will send you within the next 4-5 weeks spare parts incl. service manual in order to exchange the relevant components. Please exchange the components and return the completed answer form to us.

medica Medizintechnik GmbH

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Transferring the information described above:

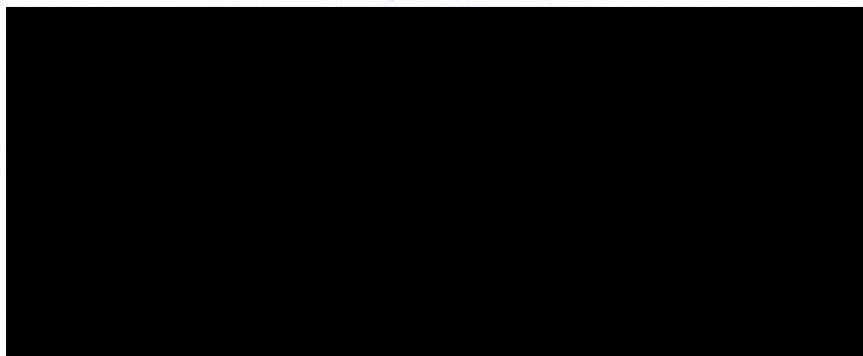
Please take care that the safety information provided reaches all persons necessary within your organization or other organizations that were in touch with the relevant products.

Please distribute this safety information to other organizations, which might be concerned by the action, and ensure that the corrective action stays public until it is closed.

The Federal Institute for Drugs and Medical Devices received a copy of this „urgent safety information“.

Contact Person:

Dirk Neurohr, Head of Service & Quality
medica Medizintechnik GmbH
E-Mail: dirk.neurohr@thera-trainer.de
Phone: 07355/9314-67
Homepage: www.thera-trainer.de



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Customer Answer Form

Ref: Urgent safety information THERA-Trainer balo incl. model BALANCE-Trainer / THERA-Trainer verto

Product description: THERA-Trainer balo incl. model BALANCE-Trainer / THERA-Trainer verto
Manufactured between CW21/2013 and CW04/2018
Serial number: Beginning with A002-308-..., A003-215-... or A002-678-...
Our reference no.: PKOHDN20180515

CONFIRMATION OF RECEIPT OF THE SAFETY INSTRUCTIONS AND COMPLETION OF THE ANSWER FORM

Please tick the applying boxes below and return the completed form to us:

☐ We read the medica-safety instructions and understand the information given as well as the required actions. We confirm the receipt of the spare parts and the implementation of the exchange.

If you ticked this box: Please inform us which device, when and who did the exchange.

Serial number:	
Company/Facility:	
Date of the exchange:	
Name / Title of the person in charge:	

☐ We sold/moved the THERA-Trainer balo incl. model BALANCE-Trainer / THERA-Trainer verto to a different facility.

If you ticked this box: Please give us the contact date of the new facility.

Serial number:	
Name of the new facility:	
Name / Title of contact person:	
Address:	
City, Zip Code, Country:	
Phone:	
E-Mail:	

☐ The THERA-Trainer balo incl. model BALANCE-Trainer / THERA-Trainer verto is no longer in the field!

Serial number:	
Company/Facility:	
Name / Title of the contact person:	

We offer following ways of contact:

Mail: medica Medizintechnik GmbH, Blumenweg 8, D-88454 Hochdorf
Fax: +49 7355-93 14-15
E-Mail: service@thera-trainer.de

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