



ERGO-FIT GmbH & Co. KG - Blocksbergstraße 165 - 66955 Pirmasens

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YOUR CONTACT:

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Pirmasens, den 02.02.2017

Urgent Field Safety Notice

Type of action: Field Safety Corrective Action (FSCA, MEDDEV 2.12-1)

relating to multifunctional bed

XRCISE STRESS ECHO MED

Sender:

Manufacturer company **cardiowise** GmbH, Blocksbergstraße 165, 66955 Pirmasens

Consignee:

To the specialized trade and users of our devices

XRCISE STRESS ECHO MED

Identification of the affected medical devices:

Multifunctional beds XRCISE STRESS ECHO MED, affected serial numbers in annex.

ERGO-FIT GmbH & Co. KG

Blocksbergstraße 165
66955 Pirmasens

USt-ID: DE 149 554 400
Steuer-Nr. 35/200/3370/0

Kontakt:

Tel.: +49 (6331) 2461-0
Fax: +49 (6331) 2461-55
Mail: info@ergo-fit.de
Web: www.ergo-fit.de

Handelsregistereintrag

Amtsgericht Zweibrücken, HR A 22344
PhG: Ergo-Fit Geschäftsführungsgesellschaft mbH
Amtsgericht Zweibrücken, HR B 22421
Geschäftsführer: Michael Resch



Dear Ladies and Gentlemen,

herewith, we would like to inform you about the occurrences regarding our a. m. devices.

Description of the problem and the determined cause:

The XRCISE STRESS ECHO MED is the combination of an adjustable examination table and a tiltable ergometer. It allows for non-invasive cardiological diagnostics and all conventional ultrasonic examinations.

The table top can be adjusted via electric motors and two axes in both the longitudinal and transverse directions (respectively by 45°), allowing it to be used for all conventional ultrasonic examinations .

The suspension respectively connection of the servomotor with the table top is fixed with a bolt. The bolts themselves are secured against axial shifting with a spring cotter pin.

On one multifunctional bed the spring cotter pin became loose. As a consequence, the bolt was disconnected from the mount as well, thereby the table top suddenly tilted back into the rest position.

During an in-house control we found out that some spring cotter pins may not have sufficient insertion force. Also, the rotating bolt may partly press the spring cotter pin out of the mount – another reason for insufficient insertion force.

For safety reasons, the bolts including the adapted pin must be replaced.

Our service division will contact you/your customer in advance to make an appointment.

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Which action has to be taken by the consignee?

It is utmost necessary to control the support of the table tops.

The correct position of the spring cotter pins must be controlled before use (shown in illustration 1). If one spring cotter pin is missing or cannot be brought into the correct position, the XRCISE STRESS may not be used.

Important:

The spring cotter pins must be fixed and „locked“ in the shown positions.

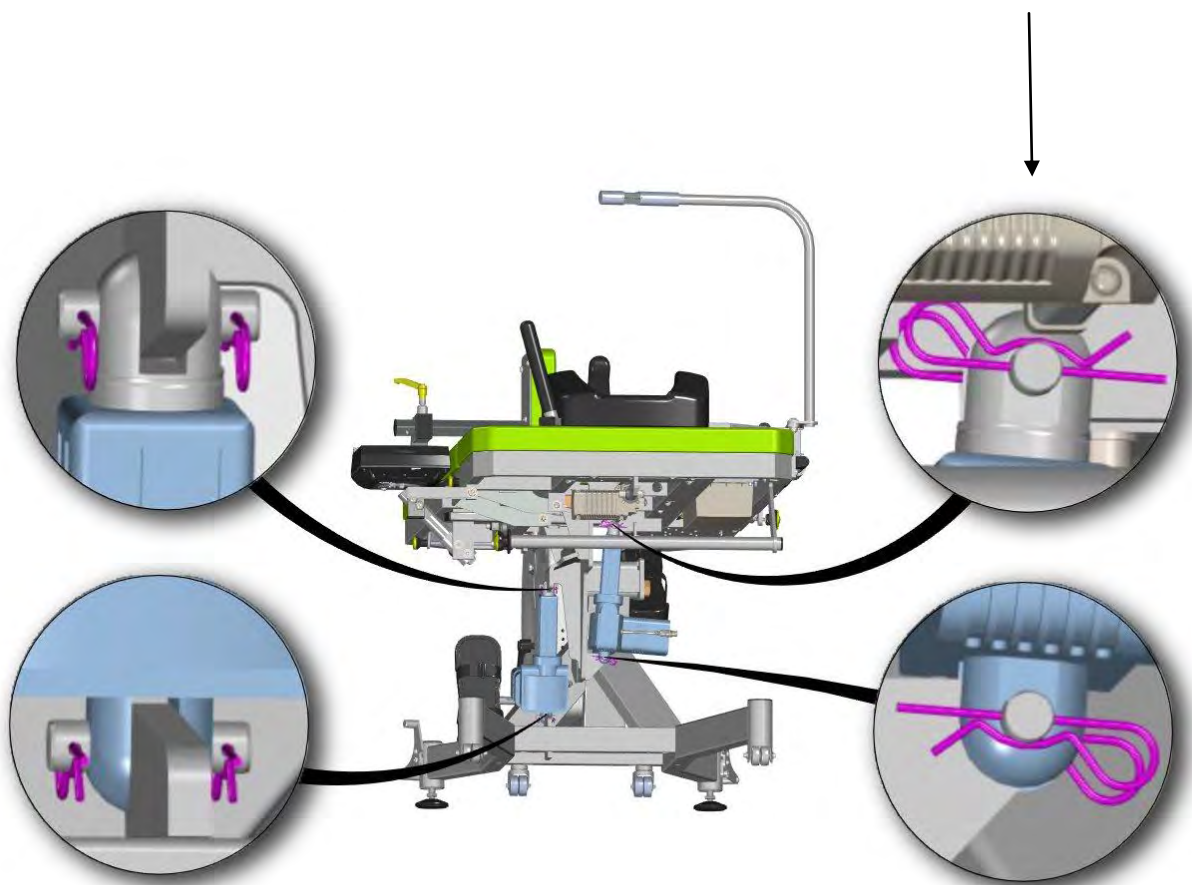


Illustration 1: Linear actuators secured with new spring cotter pins



Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred or to the below mentioned reference person.

Please keep this notice filed until this action has been closed.

The „Bundesinstitut für Arzneimittel und Medizinprodukte“ (Federal Institute for Drugs and Medical Devices) received a copy of this „Urgent Field Safety Notice“.

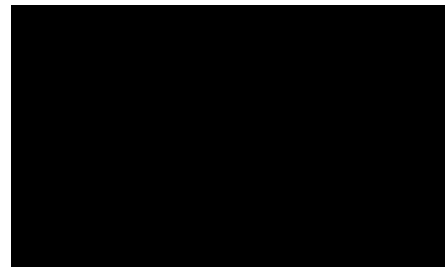
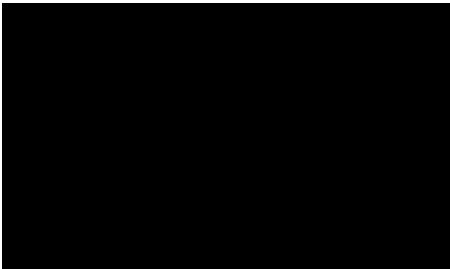
Our service staff will contact you in advance to make an appointment with you/your customer.

Enclosed please find the serial numbers concerned.

Please contact our service division under the following telephone numbers:
+49 6331-2461-28, 2461-23, 2461-29, 2461-45 oder 2461-20.

Or send an email to: service@ergo-fit.de

Mit freundlichen Grüßen





Anhang: Identifikation der betroffenen Medizinprodukte:

1000062346, 1000063398, 1000063399, 1000063817, 1000063819, 1000063820,
1000064007, 1000064426, 1000064506, 1000064507, 1000064508, 1000065001,
1000065002, 1000065061, 1000065336, 1000065382, 1000065925, 1000065927,
1000066162, 1000066950, 1000067301, 1000067425, 1000067851, 1000068179,
1000068180, 1000069295, 1000070760, 1000071253, 1000071255, 1000072169,
1000073561, 1000073921, 1000074704, 1000075249, 1000065926, 1000066925,
1000068188, 1000068577, 1000068669, 1000070915, 1000071747, 1000071748,
1000071862, 1000072028, 1000074476, 1000074478, 1000074662, 1000074757,
1000075328, 1000073562, 1000068858, 1000071129, 1000071536, 1000071810,
1000075757

1000072283, 1000073421

1000074014

1000072419, 1000072907

1000069048

1000070847

1000070661

10063398

1000063645, 1000063818, 1000063981, 1000064429, 1000064430, 1000065062
1000065337, 1000070160, 1000071254, 1000071780, 1000072027, 1000074661
1000074705, 1000075593

1000070662

1000074018

1000070577

1000068767

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