

August,8th 2013

**Important Security Information
regarding
Stress Test-ECG (PADSY-Ergo)
with Treadmills
using Ramp Protocols**

according to our files you are using the PADS Y Flashlight ERGO software together with a treadmill. Quite recently Medset has been advised that during a recovery phase of a ramp protocol an unexpected starting of the treadmill has been occurred

The non ramp protocols like Bruce, Bruce modified and Balke are not affected.

Products involved	PADSY from version 6.1a up to version 7.2a with FLASHLIGHT ERGO 2.2a up to 2.11a together with treadmills using ramp protocols .
Description of the problem	The problem exists when using ramp protocols only . If 2 equal stages with 0 km/h or 0 mp/h following on each other it could happen very seldomly that the treadmill is starting in the second stage with a speed of 1,9 mp/h or 3,1 km/h.
Security problem	Due to the results of our risk assessment the risk of falling for the patient by the unexpected start of the treadmill during the recovery stage is not acceptable.

Necessary actions of the user Get the patient off the treadmill after the first recovery stage or use non ramp protocols like Bruce, Bruce modified und Balke instead of a ramp protocol.

Scheduled actions by Medset Medset is currently working on a solution for this problem and will inform you as soon as there is a solution available.

Disclosure of the described information:

Please make sure that all users in your organisation will be informed about this important security information, especially those who are performing stress tests with patients on a treadmill.

Please forward a copy of this security information, if you have handed the products over to third parties. Contact the author mentioned below, if you cannot forward this information.

Please keep this information at least until this problem is solved.

The German institution „Federal Institute for Drugs and Medical Devices“ (BfArM) has received a copy of this security information.

If you have further questions regarding this letter or the actions to be taken, please contact our technical service department:

phone: +49 -(0)40 / 725 822-40

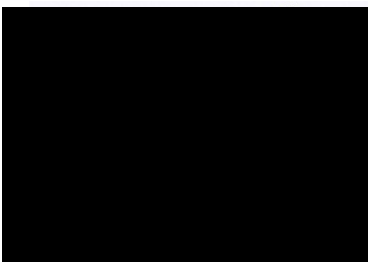
fax: +49 -(0)40 / 725 822-11

email: service@medset.com

I would like to apologise for any inconveniences caused and thank you in advance for your understanding.

Best regards

Medset Medizintechnik GmbH



Safety Officer for Medical Devices



August, 2013

To
Medset Medizintechnik GmbH
Quality assurance
Curslacke Neuer Deich 66
21029 Hamburg

Fax: +49 - 40 / 725 822-11

Letter of acknowledgement

**of the
Security Information
regarding
Stress Test-ECG (PADSY-Ergo)
with Treadmills
using Ramp Protocols**

from

Please confirm the receipt of the security information with date and signature by fax (+49-40-72582211).

date

name

signature