

«Company»

«Road»

«City»

Volketswil, 18.05.2020

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Important Field Safety Notice Use of the medical device Lokomat and the Body Weight Support Rope

Dear customer

The safety of your patients and staff is very important to us, just as it is to you. For this reason, we are contacting you to ask for your support in the implementation of this field safety notice, which concerns the motor-controller which is used to control the Body Weight Support Rope of your Lokomat device.

Under very rare circumstances, a risk of failure of the motor-controller in your Lokomat cannot be excluded. Our records show that the motor-controller in your Lokomat could possibly be affected. A failure of the motor-controller in the Lokomat can potentially lead to an unintended error in functionality of the Body Weights Support Rope which means that the rope can go up or down in an uncontrolled way.

To minimize a risk in relation to a potential failure of the motor-controller, we advise you to do the following:

- **As indicated in the Instruction for Use, permanently monitor patients, which perform a training with the Lokomat.** The scenario is especially critical for **pediatric patients**.
- In any case of unusual behavior of the Body Weight Support Rope (e.g. the rope goes up unintendedly) immediately press the **Emergency button on the handrail or on the Tele Stop in order to stop the treadmill and the orthosis**. Immediately afterwards **switch off the power supply in order to stop the rope going up**. Afterwards release the patient with the emergency release knob. See Details attached.
- **Make sure that all possible users of the Lokomat in your institution are informed of this temporary precautionary approach.**

We will continue to work on a technical solution to further minimize the risk of the potential motor-control failure.

In your country, this field safety notice is being coordinated with the national competent authority. We are therefore required to demonstrate the receipt of this information, without exception and need to ask you to confirm by your signature that you have received this notice and acted in accordance with this notice. Please send us this signature via scanned version to **«Hub EMail»**

We apologize for the inconvenience and thank you in advance for your support. For further questions, please do not hesitate to contact us. Please contact our service hotline at **«Hub Phone»** or **«Hub EMail»**

Sincerely,
Hocoma AG

Annex: Field safety notice attachment

Please attach this notice on the Lokomat in a visible place

Field safety notice attachment: How to prevent possible danger in case of a motor-controller failure of the Body Weight Support Rope.

Possible incident:



The Body Weight Support Rope goes suddenly up without pressing the “up” button on the handheld control.

As stated in the User Manual, **always monitor** the training of your patient.

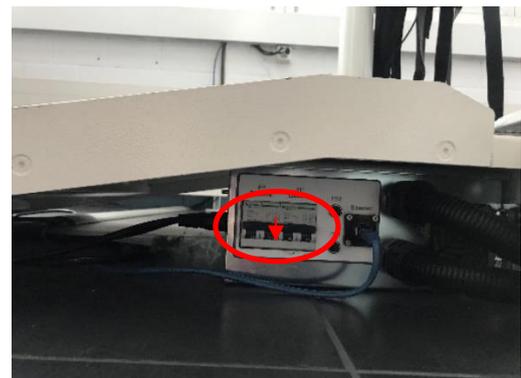
This scenario is especially critical for **pediatric patients**.

1. Press Emergency Stop or the Emergency Button on the Telestop in order to stop the Treadmill and the Orthosis



2. Switch the Power off to stop the rope going up.

The power supply is situated under the ramp. The safety mechanism (fuse) to cut the power is accessible on the side, please flip all the switches down.



3. Emergency Release

Pull out the knob slowly.

When the patient has been lowered to the desired level, release the knob.

- If possible, a second person should support the patient, while the first person pulls the emergency release knob.
- The knob has to be pulled out very carefully and straight out from the base column in order to control the speed at which the patient is being lowered (the speed when lowering heavy patients tends to be greater than that when lowering lighter patients). For very light patients, you may also have to pull down on the spreader bar to help bring the patient down.



Please send this document to:

E-mail: «Hub EMail»

**Important Field Safety Notice
Use of the medical device Lokomat and the Body Weight Support Rope**

We hereby confirm the receipt of the Field Safety Notice from Hocoma AG in regards to the motor-controller. We further confirm that:

- We have informed all possible users of the Lokomat in our institution about how to react according to the attached notice.

Hospital: «Company»

The serial number can be found as follows: Serial number: «serial number»

(Please double check on your device)



Place / date

.....

Name:
(in block letters)

.....

Function / position:

.....

Signature

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