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Munich, 02.09.19

Urgent Field Safety Notice

Type of Corrective Action: Firmware-Update

affected: munevo DRIVE, Serial numbers: MD18V10001-MD18V10030

To whom it may concern,

we would like to inform you that the adapter supplied by us, part of the munevo DRIVE product, in conjunction with some wheelchair models, causes a joystick error when the wheelchairs are switched on.

Description of the problem

Due to the delayed boot-up of an electronic component of the munevo adapter, some electric wheelchair models from different manufacturers switch on showing a joystick error. Due to these errors, the wheelchair cannot be used properly. The errors do not represent any risk for users or third parties. There is a way to switch on the wheelchair and avoid the error, but this cannot be done completely independently by the wheelchair user.
A measure can prevent the occurrence of the error and reduce the inconvenience for the users.

Therefore, munevo GmbH has decided to initiate a product recall (Field Safety Corrective Action). This also applies to units for which no errors have occurred so far.

Measures to be taken (for end-users):

- The firmware of the adapter will be updated by munevo. For this we need your unit back.
- munevo GmbH will send you a replacement unit. After receiving it, please send us your current unit in the same box so that we can process it. A shipping label will be enclosed.
- Until you receive the replacement unit, you can use the product as usual, there is no risk for you.
- After the corrective action you will receive your unit back within 5 working days. Please return the borrowed replacement unit to us. A shipping label will also be enclosed for the return.

Measures to be taken (for manufacturers, medical suppliers and other partners):

- The firmware of the adapter will be updated by munevo from 28.08.2019. For this we need your unit back.
- Please send us your unit by 10.09.2019 so that we can process it. We will send you a shipping label by e-mail.
- Until you send the unit to us, you can use the product as usual, there is no risk for you.
- After the corrective action you will receive your unit back within 5 working days.

Transmission if this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this Urgent Field Safety Notice.

Contact person

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