

# Exoskeletal walk training Medical Clearance Form

Please answer the following questions carefully, so that we can better assess the suitability of ReWalk for you. Please check off, underline or add as applicable. If necessary, we will be happy to help you fill out the form (n = no / y = yes)

Patient data (first name, last name, address):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Gender:**     Male         Female  
                  Non-binary

Contact details Physiotherapeutic facility (if available):

\_\_\_\_\_  
\_\_\_\_\_

Phone number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

**Date of birth:** \_\_\_\_\_

**Health insurance number:** \_\_\_\_\_

Payers: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

## ReWalk Personal 6.0 Exoskeleton

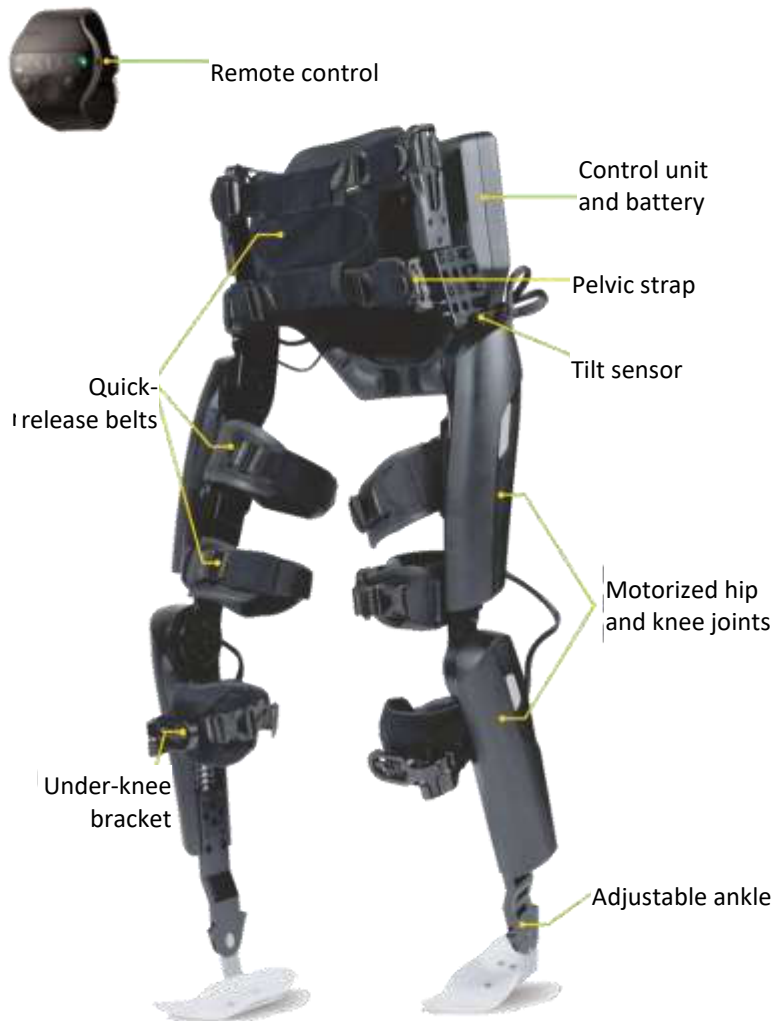
The ReWalk Personal 6.0 system is a wearable robotic exoskeleton for personal use, developed for all-day use, both at home and in the community.

People with a spinal cord injury that leads to complete or partial paralysis of the legs can use the ReWalk Personal 6.0 Exoskeleton to sit, stand, walk, turn and climb stairs. The device is designed for use with crutches.

Independent and controlled walking in the ReWalk mimics the natural gait.

The ReWalk Personal 6.0 exoskeleton is entered in the list of medical aids under the number 23.29.01.2001.

More information on ReWalk:  
[www.rewalk.com/de](http://www.rewalk.com/de) or by email:  
[contact@rewalk.com](mailto:contact@rewalk.com)



**ReWalk 6.0 Personal System**

# Exoskeleton Gait Training - Medical Clearance Form

(This section is only to be completed by the physician)

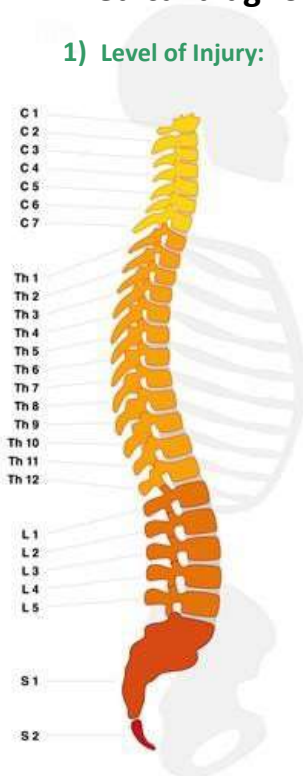
Height: \_\_\_\_\_ cm  
Right lower leg length: \_\_\_\_\_ cm  
Right upper leg length: \_\_\_\_\_ cm  
Left lower leg length: \_\_\_\_\_ cm  
Left upper leg length: \_\_\_\_\_ cm

Weight: \_\_\_\_\_ kg

Shoe size: \_\_\_\_\_

## Medical diagnoses

### 1) Level of Injury:



- |                               |                             |
|-------------------------------|-----------------------------|
| <input type="checkbox"/> C1   | <input type="checkbox"/> L1 |
| <input type="checkbox"/> C2   | <input type="checkbox"/> L2 |
| <input type="checkbox"/> C3   | <input type="checkbox"/> L3 |
| <input type="checkbox"/> C4   | <input type="checkbox"/> L4 |
| <input type="checkbox"/> C5   | <input type="checkbox"/> L5 |
| <input type="checkbox"/> C6   |                             |
| <input type="checkbox"/> C7   | <input type="checkbox"/> S1 |
|                               | <input type="checkbox"/> S2 |
| <input type="checkbox"/> TH1  |                             |
| <input type="checkbox"/> TH2  |                             |
| <input type="checkbox"/> TH3  |                             |
| <input type="checkbox"/> TH4  |                             |
| <input type="checkbox"/> TH5  |                             |
| <input type="checkbox"/> TH6  |                             |
| <input type="checkbox"/> TH7  |                             |
| <input type="checkbox"/> TH8  |                             |
| <input type="checkbox"/> TH9  |                             |
| <input type="checkbox"/> TH10 |                             |
| <input type="checkbox"/> TH11 |                             |
| <input type="checkbox"/> TH12 |                             |

### 2) Degree of injury:

- ASIA Scale:  A  B  C  D
- (please check)  
Alternative to ASIA Scale  
 Complete  
 Incomplete

### 3) Date of injury:

\_\_\_\_\_

### 4) Cause of injury:

- Traffic accident  Leisure time accident  Work accident  
 Other: \_

### 5) Has there been a diagnosis of any of the following illnesses in the past?

- Multiple sclerosis (MS)  
 Stroke  
 Cerebral sclerosis  
 Parkinson's disease  
 Traumatic brain injury  
 Amyotrophic lateral sclerosis (ALS)  
 Cerebral palsy

### 6) Current physical condition:

- a. Are there **currently severe illnesses**?  n  y  
i.e. circulatory disorders, heart or lung disease, infections such as with MRSA? If yes, which?  
\_\_\_\_\_
- b. Does the patient suffer from severe **spasticity**, Ashworth 4 or greater despite medication/therapy?  n  y
- c. Are there **currently ulcers**?  n  y  
If so, please provide more detailed information:  
\_\_\_\_\_
- d. Is there sufficient mobility in the knee joint?  n  y  
(**Extension deficit less than 10 °**)
- e. Can the **neutral 0** position in the **ankle joint** be achieved?  n  y
- f. Can the **neutral 0** position in the **hip joint** be achieved?  n  y
- g. Is there a **heterotopic ossification** that affects the mobility of the joints?  n  y
- h. Are there **restrictions on mobility** in the shoulders, elbows, wrists?  n  y
- i. Are there not healed **fractures**?  n  y
- j. Can the patient support himself with hands and shoulders on forearm crutches or a walker?  n  y
- k. Are there **psychiatric disorders** that could interfere with the proper operation of the system?  n  y
- l. Are there **cognitive limitations** that could affect the proper operation of the system?  n  y
- m. **If female**, is the patient currently **pregnant**?  n  y

**7) Mobility and activity in everyday life**

- a. Can the patient **stand up** and **actively stand**, if necessary with help, e.g. with crutches or standing devices?  n  y
- b. **Does the patient stand regularly?**  n  y  
 e.g. with a standing aid  
 If so:  less than 1x / week  
            1 – 3 x /week  
            More than 3 times a week
- c. Is the patient able to **independently carry out transfers** from and into the wheelchair?  n  y

**8) Assistance in using the ReWalk Personal 6.0 Systems**

- a. **Who** can be **helped** by the ReWalk Personal 6.0 Exoskeletons in everyday life?  
 Spouse  
 Significant other  
 Children  
 Others: \_
- b. Is the **availability** of the helper **assured**?  n  y

**Recommendation**

**I recommend the inpatient or outpatient training measures for ReWalk training. If this is successful, I recommend continuing to use the ReWalk Personal 6.0 exoskeleton in everyday life.**

- Yes
- No

Do you have any further comments or recommendations regarding the diagnosis/therapy of the patient? Please comment briefly:

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**INCLUSION CRITERIA**

- Hands and shoulders can support crutches or a walker
- Healthy bone density, meaning sufficient bone density according to the judgment of the prescribing physician after clinical examination of the patient – including radiological proof if needed. (For clarification if radiological evaluation is performed a whole hip t-score of > -3.5 meets the healthy bone density criteria).
- Skeleton does not suffer from any fractures
- Able to stand using a device such as EasyStand
- In general good health
- Height is between 160 cm and 190 cm (5' 3" - 6' 2")
- Weight does not exceed 100 kg (220 lbs)

**EXCLUSION CRITERIA**

- History of severe neurological injuries other than SCI (MS, CP, ALS, TBI etc.)
- Severe concurrent medical diseases: infections, circulatory, heart or lung
- Pressure ulcers
- Severe spasticity (Modified Ashworth 4)
- Unstable spine or unhealed fractures of the limb or pelvis
- Heterotopic ossification that impairs joint mobility.
- Significant contractures (plantar flexion > 0°, knee > 10°, hip flexion > 0°)
- Psychiatric or cognitive situations that may interfere with proper operation of the device
- Pregnancy

My physician informed me about the **benefit-risk profile** (see appendix) of the ReWalk exoskeleton.

**Date/signature of the patient**

In accordance with the inclusion and exclusion criteria specified above, **there are no objections to gait training with the ReWalk Personal 6.0 exoskeleton** for this patient.

Physician's signature:

**Date/signature/stamp of the physician**

Please send the completed form to: **ReWalk Robotics GmbH**  
 Leipziger Platz 15 Fax: +49 (0) 30 2589 4100  
 10117 Berlin E-Mail:  
 kontakt@rewalk.com www.rewalk.com

# Exoskeleton Gait Training - Medical Clearance Form

## Appendix 1: Benefits and Risks of Using the ReWalk Personal 6.0 Exoskeleton

### Benefits

The ReWalk Personal 6.0 serves as an exoskeleton to compensate for disabilities and is used for clearly defined user groups. The objective of the supply is to compensate for the lost body functions “walking” and “standing”. After training in the use of the ReWalk Personal 6.0, the paralyzed user will be able to:

- stand up from sitting,
- stand,
- walk,
- climb stairs
- sit down.

### Risks

Using the ReWalk Personal 6.0 without training in its use can result in injury. The following injuries are possible when using the ReWalk:

- Falls
- Skeletal fractures
- Skin injuries including abrasions, bruises
- Soft tissue injuries such as bruising from soft tissue, ecchymosis, edema, and hematoma

Date/signature of the patient

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