

# REL-K™

## Microprocessor Knee System

### **User Manual**

(United States and Canada Only)

For Use with Medical Prescription Only

Version 2.0 - September 2011





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# 1 Introduction

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## 1.1 - General warnings

The following manual provides information about the use REL-K microprocessor knee system. The purpose of this instruction manual is to assist the user to become familiar with the product and use it in a manner that is safe and problem free.



**ATTENTION:**

**The following user manual must be kept on hand at all times.**

The manufacturer does not assume any liability for damage caused by an incorrect use of the product or the non-compliance with the instructions and the warnings contained in the manual. The manufacturer also reserves the right to make technical modifications that improve the product.

Specifically, one must:

- Use the device only according to the doctor's prescription and indications.
- Keep the product clean and debris free to ensure safe use.
- Insure that all scheduled periodic maintenance is performed.
- Make periodic visits, as recommended by your personal physician every 6 months.



**Any improper use of the prosthesis, or load that is different from normal ambulation, may compromise performance or functionality.**



**If the device has been subject to severe load, or malfunctions, an authorized service center should be contacted immediately.**



**24 hour continual use is not recommended.**






**Information in this manual is subject to change without notice.**

**Read this entire manual before using the REL-K microprocessor knee system.**

## 1.2 Symbols used in this manual

The symbols listed here below are used within the manual to identify safety warnings and precautions relating to product use. It is very important to read these warnings carefully and completely understand their meaning before using the prosthesis for the first time.

	<b>User safety</b> Refers to a potential danger. Ignoring this warning may cause physical damage.
	<b>Note</b> This refers to any information regarding product usage and manipulation.
	<b>Precautions about the product</b> This refers to potential dangers for the product. Ignoring this warning may damage the product and/or functionality.

## 1.3 Information about the manufacturer

Data about the manufacturer is included here below:



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## 1.4 Product Identification

The REL-K prosthesis is a microprocessor controlled prosthetic knee, and a critical element of a lower limb transfemoral, hip disarticulation, or knee disarticulation prosthesis. It is intended for use as a medical device that functionally replaces a missing or deformed limb knee in both static and dynamic ambulation functions. REL-K prosthesis uses an electronic control with power supplied by a rechargeable battery.



**A LOWER LIMB PROSTHETIC PROSTHESIS IS A MEDICAL DEVICE THAT MAY ONLY BE SOLD WITH A MEDICAL PRESCRIPTION.**

### **Classification according to the directive 93/42 CE**

The device belongs to the “CLASS I” risk class according to what is included in the directive 93/42/EEC and subsequent modifications, received with Legislative decree 46/97, attachment IX, and has been appropriately cleared to use in the U.S. by the U.S. Food and Drug Administration for use as a lower limb prosthetic device.

Class 1 was determined by applying rule number 1:

*“All non invasive devices are part of class I, unless one of the following rules applies.”*

and rule number 12:

*“All other active devices fall within class I.”*

### **Usage class**

The device conforms to ISO 10328:2006 - class P5 legislation.

FDA - Intended Use Statement:

The Rel-k is prosthetic knee, important element of a lower limb prosthesis, a medical device that is used to replace a missing or deformed limb in both static and dynamic deambulation functions.

Canadian Licence: Medical Device Establishment Licence Number 3263, 2011 OROTOPED Inc. Company ID. 106086

### **Functioning principle**

Physiological human locomotion is made of two fundamental phases: the stance phase and the swing phase. During the stance phase, the prosthesis provides stability that makes it possible for it to support body weight. During the swing phase, the prosthesis is allowed to swing freely in knee flexion and

extension.

In order to optimize the function of the device, the adjustment of a hydraulic damper is necessary to control rigidity and movement.

The hydraulic damper is adjusted based on the use of a series of load and position sensors, which are processed analyzed by a microprocessor-controlled system that recognizes the different phases of gait.

A knee rotation/ position sensor and a load sensor that are employed to measure the mechanical state of the prosthesis and make continual hydraulically-controlled adjustments.

**This prosthesis enables a natural step and increases stability during stance on different types of surfaces, including slopes and uneven terrain. The device also makes it possible to regulate and adjust to different walking speeds, ride a bicycle, and descend stairs.**

## 1.5 Intended use

The REL-K prosthesis should not be used by patients greater than 220lbs (100kg).

The REL-K prosthesis makes it possible for the patient to achieve an erect posture and walk easily. At the time of installation, the Prosthetist will adjust the prosthesis for optimized walking during normal use.

Beside the normal use mode, the REL-K prosthesis software can set and recall other modes useful for different activities.

These additional modes should be set with the Prosthetist who is responsible to set the adjustment parameters.

The additional modes can be chosen between:

- **“bicycle”** mode,
- **“maximum rigidity”** for maximum safety,
- **“maximum mobility”** mode for maximum freedom,
- **“(2) two Custom”** mode.

The prosthesis comes equipped with a remote control that allows the user to select any of the normal walking and 3 additional modes set by the Prosthetist.

## 1.6 Precautions



All moving parts must be free of all obstruction. Therefore, attention should be given to avoid interference with body parts, prosthesis socket, and/or clothes.

○	Because there are metal and carbon fiber parts, during clinical testing, such as Computerized Axial Tomography (CAT) and Magnetic Resonance Imaging (MRI). It is necessary let medical personnel know when one has prosthesis.
○	Any improper use of the prosthesis, and abnormal use other than normal ambulation, may compromise performance or functionality of the REL-K prosthesis.
○	Do not expose the REL-K prosthesis to high heat or excessive humidity.
⚠	<p>Contact personal physician if:</p> <ul style="list-style-type: none"> <li>• Any redness or signs of skin allergies to the interface materials</li> <li>• Hip or knee motion results in pain or gait changes during walking</li> </ul> <p>Any other side effect to prosthetic use identified should be immediately relayed to the user's personal physician, not a specialist.</p>

## 1.7 Usage restrictions

The effective and safe use of the device is paramount when using the REL-K prosthesis. **Any type of improper use of the device may compromise its safety and functionality, terminating the warranty immediately.**



- Before using the prosthesis it is recommended to go through a training period assisted by a qualified Prosthetist.
- Avoid overloading the device above weight limit. Loads carried may exceed the maximum allowable prosthesis load (220lbs.).
- User must not use the prosthesis for activities other than normal walking, ascending/descending stairs, or designed programmed activities that can be selected from the remote control. Activities such as running, jumping, extreme sports (climbing, paragliding, etc.) and similar are strictly prohibited.
- When the device is subject to an unusual event, such as a fall, immediately contact the Prosthetist for inspection.

- The user must not immerse the device in water or other liquids. The REL-K prosthesis IS NOT INDICATED FOR USE IN SWIMMING POOLS OR IN THE OPEN WATER.
- If the device comes in contact with salt water, immediately clean it with a cloth that has been moistened in fresh water, then allow it to dry. Immediately contact the Prosthetist for inspection. Do not use the prosthesis until it has been inspected by the Prosthetist.
- To prevent exposure to mud, significant dust, salt water, and humidity, a cosmetic covering (not included) can be used.
- If the prosthesis should come into contact with liquids, remove the cosmetic covering and allow the device to dry completely. Immediately contact the Prosthetist for inspection.
- User must not go near high powered electrical transformers, TV or radio transformers, or similar sources of electrical and magnetic fields that exceed the intensity of normal household appliances. They may cause intermittent functions.
- The device must not be exposed to temperatures less than 14°F and greater than 140°F (-10°– 60°C).
- The device must not be used with humidity above 90%.
- The device must not be exposed to sources of high-energy radiation such as X-rays. If the user must undergo diagnostic testing such as X-rays, CAT or MRI, the prosthesis must be removed and kept away from the exposed area. Notify a medical professional if you require these tests.
- Keep fingers away from the posterior (rear) of the prosthetic knee in order to prevent the risk of injury in case of accidental flexion and pinch point.
- Keep tools and any kind of object away from the posterior (rear) of the prosthesis in order to avoid risk of breaking them in case of accidental flexion.
- When the device is not used for a prolonged period of time, the battery may have lost its charge. Recharging, as is outlined in Section 2.2 *Recharge the Battery*, is recommended before its use.
- If the battery is not recharged within 3 months, it may not be rechargeable.
- Give special attention to all audio and vibration alarms regarding battery usage and functionality. They are provided for your safety and optimal performance.
- For your safety, before using the “bicycle” mode, make sure the battery is fully charged (see Section 2.2 *Recharge the Battery*). If the battery runs out of power, the device goes into safety mode and the prosthesis becomes rigid making it impossible to pedal. This may cause a fall from the bicycle.
- When changing mode using the remote control, it is important to note the procedure and subsequent response signals from the REL-K prosthesis. This confirms that the status has been changed correctly. If the mode change procedure was not complete, the device may not be inherently safe, and there is a risk of falling.

- If an unwanted mode has accidentally been selected from the remote, immediately unweight the prosthesis and select a new mode, or remove and reinsert the battery to get back to normal use or walking mode.
- The use of the handrail while on stairs is highly recommended.
- Follow the periodic maintenance program established by the manufacturer. Ignoring maintenance for a prolonged period of time may cause the prosthesis to malfunction and result in a fall.
- Ignoring the maintenance program, as described in Section 3 *Periodic Maintenance*, will terminate the manufacturer's warranty.
- **Device maintenance and repair must only be carried out by personnel authorized by Rizzoli Ortopedia S.p.A and Fillauer, LLC.**

## 1.8 Technical specifications

### Mechanical specifications

- For patients up to 220 lbs.(100 kg) – medium to active mobility.
- Maximum knee flexion: 120°
- Frame: Carbon Fiber
- Net weight: 3.5 lbs.(1600 g)

### Electrical specifications - Prosthesis

- Power supply voltage: 3,6 V rated 18 mAH
- Ques: 100 mA average

### Electrical specifications - Battery charger

- Power supply voltage: 100-240 Vac
- Frequency: 50-60 Hz
- Current absorbed: 25 mA Max
- Output voltage: 5 Vdc
- Output current: 1 A Max

### Battery

- Lithium-ion rechargeable (1800 mAh): 24-48 hours of use depending on the activity

### Environmental specifications

- Temperature range that the knee is operational in: 14 °F to 140 °F (-10°/60° C)
- Humidity range that the knee is operational in: 0% - 90% relative humidity
- Shipping and storing temperature: From 14 °F to 140 °F (-10°/60 °C)
- Shipping and storing humidity: 0% - 90% relative humidity

## 1.9 System components

### REL-K knee RK01 model

Includes:

- **the microprocessor knee** (fig. 1);



Fig. 1

- **1 - 120V wall power supply** (fig. 2);



Fig. 2

- **A1- battery charger** (fig. 3);
- **2 - rechargeable batteries** (fig. 3);
- **1 - mini USB connection cable**, 90° male connector - female straight, 0.5 ft. (fig. 3);
- **2- cables with mini USB connection-** standard male USB, 5.0 ft. (fig. 3)



Fig. 3

- A1 - 4 channel remote control (fig. 4).

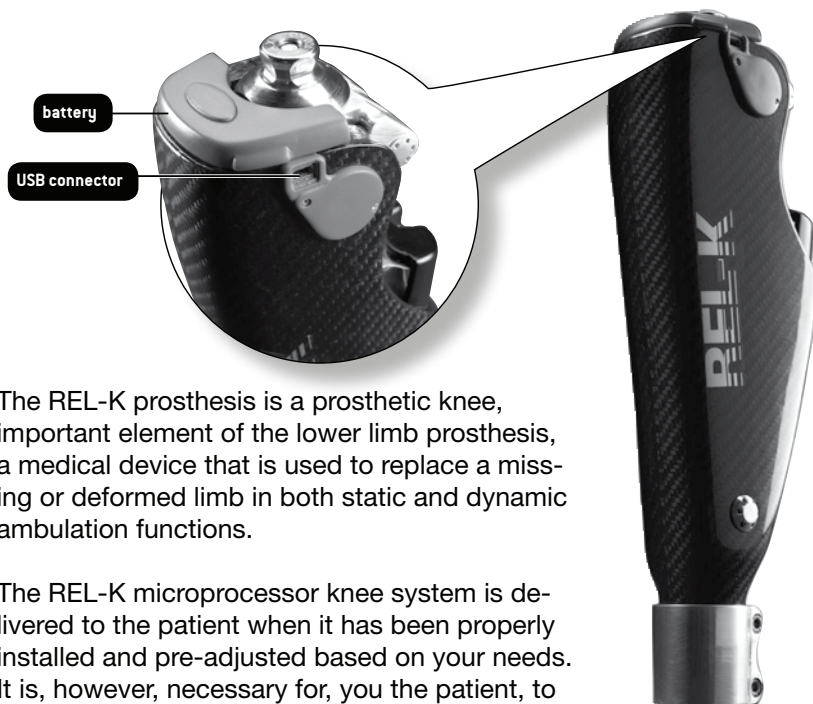


### **Options**

- a **12 VDC power supply** for car (fig. 5).



## 2 Instructions for use



The REL-K prosthesis is a prosthetic knee, important element of the lower limb prosthesis, a medical device that is used to replace a missing or deformed limb in both static and dynamic ambulation functions.

The REL-K microprocessor knee system is delivered to the patient when it has been properly installed and pre-adjusted based on your needs. It is, however, necessary for, you the patient, to learn how to handle the device in its daily use.

Therefore you are required to learn how to:

- activate and deactivate the device;
- charge the battery;
- correctly interpret the signals and alarms coming from the device;
- correctly use the prosthesis for its intended use;
- use the additional modes.



For the device to be used correctly it is necessary to verify that the device is worn properly. The residual limb (stump) must sit inside of the socket and be covered by it or the liner/suspension sock.



The effectiveness of the device is strictly related to the rehabilitation program used to train on walking and using the device. This program must be agreed upon with the personal prescribing physician.

## 2.1 Activate and deactivate the device

The device is activated by simply inserting the battery into the battery compartment. Once the battery is inserted the device emits a notification signal with one short beep and a short vibration, this announces the beginning of operation (see section 2.3 *Interpreting Signals from the Device*).



During start-up, the device configures itself for normal use or walking mode.

To insert the battery into the compartment complete the following procedure:

- Hold the battery cover over the battery compartment and firmly push into place (fig. 6);



Fig. 6

- insert the battery until the magnets of the cover lock the battery inside of the compartment (fig. 7);



Fig. 7

- wait for the acoustic and vibration notification signal from the prosthesis.

Deactivate the device by removing the battery from the compartment, following the procedure described below:

- grab the top lid of the battery cover. Grasping the battery cover makes easier to remove the battery (fig. 8);



Fig. 8

- pull on the battery until it unlocks and then slip it off until it is removed completely (fig. 9).



Fig. 9





When the prosthesis is not used for a long period of time it is advised to remove the battery in order to preserve the residual charge.



If the cover is already detached from the battery, pull on the upper tab of the battery.

## 2.2 Recharge the battery

The battery can be recharged internally or externally.

	The capacity of a charged battery is sufficient for more than one day of use (36 hours); recharging the battery during the night, or having a charged spare battery, is recommended if the prosthesis is used daily.
	When recharging, only use the power supply that the device came equipped with.

### External Charging

External charging requires removing the battery from the prosthesis and using the recharging system that was supplied. The recharging system is the battery charger and wall power supply. To use this method, complete the following procedure:

- insert the plug from the USB cable into the power supply (fig. 10);



- connect the other end of the USB cable to the battery charger (fig. 11);



- connect the power supply to the electrical socket (fig. 12);



Fig. 12

- make sure that the green LED on the battery charger is turned on [**lighted LED = battery charger turned on**] (fig. 13);



Fig. 13

- remove the battery and pull it off the lid making it slide sideways off of its guides (fig. 14);



Fig. 14

- insert the battery into the specific compartment in the battery charger (fig. 15);



Fig. 15

- make sure the **yellow LED** on the battery charger is on [**lighted LED =battery charging, LED off = battery charged or absent**] (fig. 16);



- wait for the yellow LED to turn off;

- remove the battery and re-attach to the lid (fig. 17).



If the yellow LED does not turn on once the battery is inserted, it means that it is already fully charged.

- insert the battery into the prosthetic knee (fig. 18).



## Internal Charging



**ATTENTION:** Do not wear the prosthesis during the internal re-charging process.

The battery may be recharged inside of the prosthesis by two methods

The simplest method is to insert the power supply directly on the mini USB connector of the device (fig. 19). This way there are no indications about the battery charge status and it must be left charging for a minimum of 4 hours



Fig. 19

The second method is to connect the power supply to the battery charger and then connecting the charger to the device using the cable supplied (fig. 20). The yellow LED of the battery charger correctly shows the charge status of the battery inside of the device.

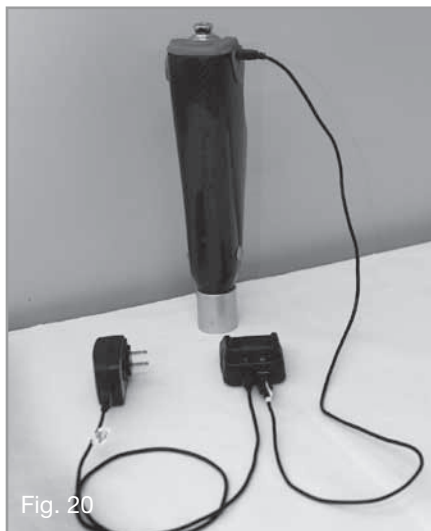


Fig. 20



In this mode, if another battery is inserted into the compartment of the battery charger, it will not be charged



When the battery charge lasts less than 6 hours, contact an authorized service center.

## Recharging using car charger (not supplied with the REL-K prosthesis)



**ATTENTION:** do not wear the prosthesis while using the car charger to avoid tripping, interference with driving or electric connection issues.

The battery can be recharged using a car charger and cable designed specifically for the electrical supply of the car. This charger must have a plug that is made to be inserted into the car's accessory power socket. A standard USB cable can be used to recharge the battery while within the REL-K prosthesis.

Complete the following procedure to recharge from inside of a car:

- first, connect the car charger with mini-USB adaptor (not provided) to the mini-USB port on the knee. Insert the recharging plug into the accessory power socket (fig. 21); NOTE: Automotive USB ports cannot function as recharging port;



Fig. 21

- Second, connect the other end of the supplied USB cable to the accessory power socket (fig. 22);
- wait at least 4 hours for the charge to be complete.



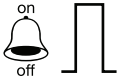
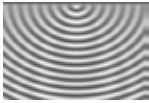
Fig. 22



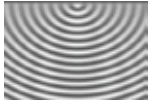
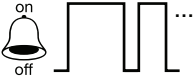
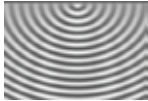
### 2.3 Interpreting signals from the device

The device has two kinds of signals for the prosthetic user: acoustic (beep) and vibration (buzz). The signals are intended to function as a notification or provide an alarm. Changing device mode during normal operation triggers an alert. A condition that potentially reduces normal device performance will cause an alarm warning.

Informational signals are described in the following table.



#### Table of informational signals

Device status	Acoustic signal	Vibration signal	Actions that must be carried out in absence of this message
<b>Start-up: when the battery is inserted</b>	<p>1 short beep (0.2 seconds)</p> 	<p>1 short vibration</p> 	<p>Check the status of the battery or the power outlet otherwise contact an authorized service center</p>

<p><b>Connection to an external power supply</b></p>	<p>2 very short beeps (0.1 seconds)</p> 	<p>No Vibration</p>	<p>Check the status of the battery or the power outlet otherwise contact an authorized service center</p>
<p><b>Activating the remote control</b></p>	<p>1 long beep (0.4 seconds)</p> 	<p>1 long vibration</p> 	<p>Check the status of the remote battery, otherwise contact an authorized service center</p>
<p><b>Mode change</b></p>	<p>1 long beep (0.4 seconds) followed by a number of short beeps (0.2 seconds) that corresponds to the number of the selected mode</p> 	<p>1 long vibration followed by a number of short vibrations that correspond to the number of the selected mode</p> 	<p>Check the status of the remote battery, otherwise contact an authorized service center</p>

The prosthesis is equipped with safety controls that are in place to ensure that a performance reduction does not cause discomfort or danger for the user.

Once these situations present themselves the prosthesis immediately goes into maximum safety mode that is characterized by the REL-K prosthesis becoming more rigid.

	<p>The safety condition lasts until the cause of the alarm has been removed and the electronics are reset by removing and reinserting the battery.</p>
	<p>If the battery is run down, it is sufficient to recharge the battery, or replace it with a charged one, to remove the safety condition.</p>



The beginning of the safety mode is announced by the prosthesis through acoustic and vibration signals, according to what is described in the following table.

The conditions that cause an unforeseeable performance reduction are of two kinds:



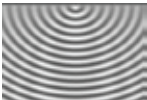
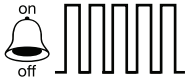
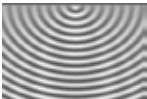
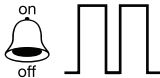
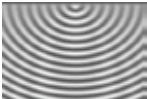
- low residual charge in the battery causing an insufficient electrical power level.
- failure of the internal circuitry of the prosthesis.

The control system of the prosthesis continually monitors the charge in the battery and the operation of the main electronic and sensor components to quickly determine situations that may potentially be dangerous.

Warning regarding the charge status of the battery is given at 3 charge levels: 20% of the nominal charge, 5% and 1%. When the battery charge falls below one of these levels, the device emits a signal, as described in the following table. Once the battery has been completely discharged, the device immediately goes into maximum safety mode.

	<p>In case of internal malfunctioning, the knee designed to be able to determine a dangerous condition and is expected to put itself into the safety mode. There are, however, some failures that may make it impossible for the system to place itself into safety mode. Although extremely rare, it is recommended that the user, if the knee signals a malfunction, always verify that the prosthesis has entered safety mode before continuing to use it.</p>
	<p>In case of sudden events such as stumble or impacts that may cause potential walking problems, an additional safety measure intervenes automatically, without emitting any type of signal, stiffening the prosthesis for a short amount of time and then restoring normal functioning shortly after. This feature significantly increases walking safety. This intervention may be, in certain cases, so brief that the prosthetic user is unable to sense it.</p>

## Table of alarm signals

Alarm situation	Acoustic signal	Vibration signal	Actions that need to be taken
<b>Battery charge at caution level</b>	No Sound	1 short vibration (0.2 seconds) 	Prepare for battery replacement: remaining battery power at about 20%
<b>Battery charge at safety level</b>	3 short beeps (0.2 seconds) 	3 short vibrations 	Prepare for battery replacement: remaining battery power at about 2%
<b>Empty battery</b>	5 short beeps (0.2 seconds) 	5 short vibrations 	Replace the battery: the device puts itself into safety mode
<b>Internal malfunctioning</b>	2 short beeps (0.2 seconds) 	2 short vibrations 	The device attempts to put itself into safety mode. Pay attention to device use and, cease using it and as soon as possible, contact an authorized service center

## 2.4 Using the prosthesis correctly

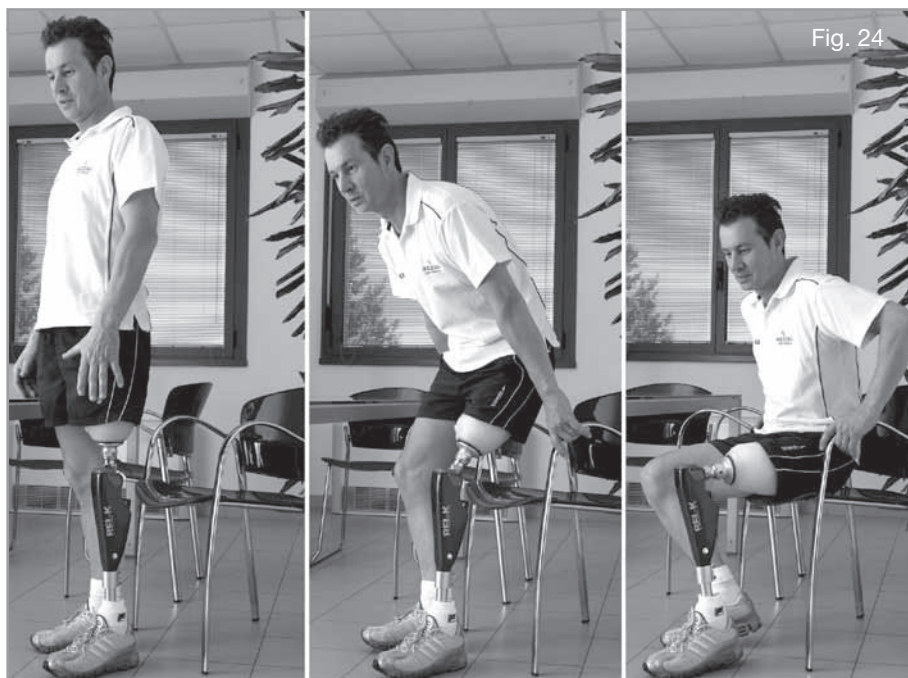
### How to walk correctly

Always roll from the heel first and then to the midfoot, and finally to the toes. At this point the knee flexes and makes it possible to swing the leg through to the next step (fig. 23).



## How to sit down

Make sure that the weight is concentrated towards the heel while moving to a sitting position (fig. 24).



## How to walk up and go down stairs



Always use the handrail when walking up or down stairs.

In order to obtain the maximum level of safety while descending stairs, the foot must be placed on the step in a way that avoids contact between the front of the foot and the actual step (fig. 25). Placing the foot with the heel on the tread of the step, makes bending the prosthesis easier.

**This guarantees a more natural descent of stairs and ramps, while maintaining a controlled rate of descent.**

Fig. 25



## 2.5 Using the additional modes

In addition to the standard walk mode, the prosthesis has 5 additional modes available: “bicycle” mode, “maximum rigidity” mode, “maximum freedom” mode, “two custom programmable” modes. From these modes the Prosthetist, and user, will be able to choose three that will then be available for selection from the remote control supplied (fig. 26) in addition to the standard walk mode.



Fig. 26

Mode change is communicated through acoustic and vibration signals, according to the table included here below:





Device status	Acoustic signal	Vibration signal	Actions that must be carried out in absence of this message
<b>Mode change</b>	<p>1 long beep (0.4 seconds) followed by a number of short beeps (0.2 seconds) that correspond to the number of the selected mode</p>	<p>1 long vibration followed by a number of short vibrations that correspond to the number of the selected mode</p>	<p>Check the status of the remote battery, otherwise contact an authorized service center</p>

The “**bicycle**” mode makes it possible to use a bicycle by programming the prosthesis for pedaling. The microprocessor control maintains the safety mode (prosthesis more rigid) until a short interval of time has passed after the prosthesis is unweighted. This allows the knee to move freely enabling pedaling. It also makes it possible for the user to safely climb on to the bicycle. When the user loads the prosthesis with an extended knee, the microprocessor control detects the load condition and stiffens, making it possible to get off the bicycle safely.

The “**maximum rigidity**” mode stiffens the prosthesis walking on uneven or rough terrain, such as mountain trails.

The “**maximum freedom**” mode sets a minimum rigidity level that makes it possible to easily bend the prosthesis for special needs such as getting into the car, or working in tight spaces.

The “**custom**” modes make it possible to program special characteristics for specific patient activities. These situations must be evaluated and agreed upon with the Prosthetist who will set the custom parameters of the different modes. These modes can then be activated with the remote control with three buttons programmed by the Prosthetist.

	The user has 4 possible modes that can be selected by way of the remote control consisting of the normal use mode and the 3 modes selected among the additional ones.
	Setting and adjusting these modes must be agreed upon and carried out by the Prosthetist completing the installation of the prosthesis in order to ensure maximum safety in its use.
	Every time the system is reset by inserting the battery, the system goes back to the normal use mode.
	In order to reduce the risk of falling, remember to go back to the normal use mode after using the other modes.

## Activating the remote control

1. press the # 1 button to unlock the knee and enable communication to the knee. Wait for the confirmation signal from the knee (see paragraph 2.3 *Interpreting signals from the device*)



If the remote control is not first unlocked the system does not recognize commands from the other buttons. After unlocking the remote control with the #1 button it is then possible to set the other modes on the other buttons. If no mode is selected the remote control deactivates within 10 seconds.

### Setting mode #1:

1. Unweight the prosthesis by transferring all user weight to the unaffected physiological leg;
2. Unlock the remote control with the #1 key and press the #1 key again to select normal walking until the system responds with acoustic and vibration signals (see paragraph 2.3 *Interpreting signals from the device*).

### Setting mode #2:







1. Unweight the prosthesis by transferring all user weight to the unaffected physiological leg;
2. Unlock the remote control with the #1 key and press the #2 key until the system responds with acoustic and vibration signals (see paragraph 2.3 *Interpreting signals from the device*).

### Setting mode #3:

1. Unweight the prosthesis by transferring all user weight to the unaffected physiological leg;
2. Unlock the remote control with the #1 key and press the #3 key until the system responds with acoustic and vibration signals (see paragraph 2.3 *Interpreting signals from the device*).

### Setting mode #4:

1. Unweight the prosthesis by transferring all user weight to the unaffected physiological leg;
2. Unlock the remote control with the #1 key and press the #4 key until the system responds with acoustic and vibration signals (see paragraph 2.3 *Interpreting signals from the device*).

	<p>The type of mode selected, depends on the choice made at the time of remote control programming with the Prosthetist. The user and Prosthetist must record the mode positions for easy reference.</p>
	<p>Use the following safety instructions:</p> <ul style="list-style-type: none"> <li>• find a stable position and unweight the prosthesis;</li> <li>• press the appropriate button on the remote control for at least one second;</li> <li>• wait for a confirmation signal from the device;</li> <li>• carefully and gradually make sure that the mode change took place.</li> </ul>
	<p>Insure the "maximum mobility" and "bicycle" modes are adjusted to the correct levels with enough safety while walking around. Failure to make the correct adjustments may cause an unsafe condition for the user.</p>
	<p>The remote control is not waterproof. If it comes in contact with water, let it dry at room temperature for at least 1 day. If the remote control is defective contact the Prosthetist.</p>
	<p>For safety reasons the remote must be used at a distance within 20 in (50 cm) from the knee. This insures deliberate mode change by user only. If a mode is not recognized by the prosthesis, move the remote control closer to the knee.</p>
	<p>If there is no response signal after the mode change, first check the red indicator light. If no light is present, replace the remote control battery. Always verify that the prosthesis is in a safe condition before using it.</p>

## Replacing the remote control battery

Proceed as follows to replace the remote control battery:

- open the back panel of the battery compartment pressing on the unlocking clip (fig. 27);



Fig. 27

- remove the empty battery (fig. 28);



Fig. 28

- insert the new battery, noting the polarity (fig. 29);



Fig. 29







Replacement battery is a 12V, Classification "23AE".

### 3 Periodic maintenance

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It is necessary to periodically clean the REL-K prosthesis. Parts made of plastic can be cleaned using a cloth with a product with a neutral or possibly alcohol-based cleaning product. Other parts must be cleaned using a cloth moistened with clean water and then allowed to dry.

The prosthesis is configured based on the needs of the individual user. For this reason the user must not adjust the prosthesis him or herself. If any adjustment is necessary, the prosthetist should be contacted immediately.

	The device requires maintenance at 6 and 12 months after purchase according to the manufacturer's warranty. Maintenance must then be carried out every 12 months. <u>Do not tamper, repair or adjust the device.</u>
	Following programmed maintenance ensures the efficient operation of the prosthesis and reduces any malfunctioning that may be dangerous to the safety of the user.
	Non-compliance with the maintenance program established by the manufacturer automatically terminates the warranty.
	If maintenance or repairs are needed, only contact a Prosthetist authorized by Rizzoli Ortopedia S.p.A. and/or Fillauer, LLC.

## 4 Disposal

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The device must be disposed of properly, according to current regulations regarding the disposal of dangerous waste.

For this reason, if retiring the device, it must be brought to the closest authorized service center for disposal.

## 5 Information about certification

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The REL-K microprocessor knee system was tested by an independent and accredited laboratory, its conformity with the EN 60601-1:1990+A1:1993+A2:1995 standard has been confirmed (electro medical devices, part I) and with its collateral EN 60601-1-2:2003 (electromagnetic compatibility, requirements and testing), like for the European directive 93/42/EEC and successive modifications occurred (and the related Italian application of Legislative decree 46/97, and subsequent modifications occurred), and the ISO 10328:2006 standard.

Device engineering and Risk Analysis were carried out in conformity with the UNI CEI EN ISO 14971:2009 standard (medical devices – application of risk management for medical devices).

The following User Manual was drawn up considering what is instructed by the UNI EN 1041:2000 standard (Information supplied by the manufacturer with medical devices). The REL-K microprocessor knee system has been cleared for sale in the US under the FDA 510(k) pre-marketing notification process.

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REL-K™ is a trademark in registration in the USA and in Canada of Rizzoli Ortopedia S.p.A.  
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See Manufacturer Warranty. All conditions and exclusions apply.

Patent numbers and patents pending.





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