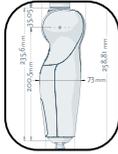




RHEO KNEE® 





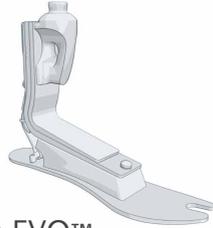
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EN – Caution: Össur products and components are designed and tested to ISO 10328. Compatibility and compliance with this standard is achieved only when Össur products and components are used with other recommended Össur or authorized components. If un-usual movement or product wear is detected in a structural part of a prosthesis at any time, the patient should be instructed to immediately discontinue use of the device and consult his/her clinical specialist. This product has been designed and tested based on single patient usage. This device should NOT be used by multiple patients. If any problems occur with the use of this product, immediately contact your medical professional.

A



Flex-Foot Talux®



Re-Flex Rotate™ with EVO™

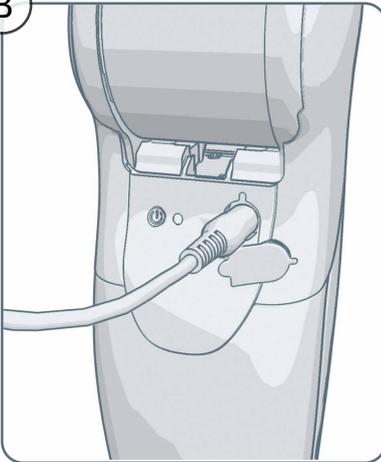


Elation®



Vari-Flex® with EVO™

B

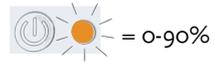


C



90 min = 90%

3 H = Full



= 0-90%



= 90-100%



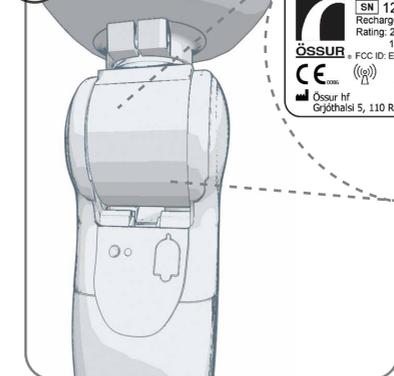
= FULL

D



ON OFF

E



RHEO KNEE®
 SNJ 123456
 Rechargeable Li-Ion Battery Operated
 Rating: 24 V

ÖSSUR 1.0 A (max.)
 FCC ID: EDR8-LMX0838; IC: 1520A-LMX0838 C E

Össur hf
 Grjóthalsi 5, 110 Reykjavík, Iceland 2011

SAFETY PRECAUTIONS

Please follow the safety precautions as failure to do so can lead to malfunction of the RHEO KNEE® and risk injury to the user.

Prosthetists should make sure their clients are aware of, and understand, the safety precautions.

- The RHEO KNEE® is designed and tested for everyday activities, but not for sports and other high impact activities (e.g., running and climbing). Doing activities causing high impact on the leg can injure the user, can cause the RHEO KNEE to break down or malfunction, and will void the warranty.
- If the RHEO KNEE loses power, the knee will NOT provide stance support. The knee becomes a swing only, single axis joint. In this case the user has to actively secure the knee and he or she should be provided with the training to do so.
- It is highly recommended that the user walks with the power off prior to setting swing and stance controls, but always use caution when walking with the power off.
- The RHEO KNEE stance control settings can be customized to maximize security or terrain recognition. However, for maximum safety use a handrail when descending stairs and ramps.
- Improper handling or adjustment of the RHEO KNEE may cause the stance control to malfunction, which can increase the risk of falls.
- Make sure that the user is able to recognize the auditory and/or vibratory signal for power loss.
- When malfunctions occur or the power reaches critical levels, auditory and/or vibratory warnings alert the user. If warning signals are detected, check if the knee can provide stance control. Proceed to walk with caution.
- Avoid any impact to the socket, frame, adapter contact, or the interface panel on the back of the RHEO KNEE. Damage to this panel or any of its components may cause the product to malfunction.
- Do not use in highly electrical and/or magnetic environments (for example electrical transformers, high power radio/TV transmitters).
- Because the RHEO KNEE is battery operated, caution should be taken about exposure to water and excessive mechanical shocks or vibrations.
- Do not attempt any repairs (no matter how minor) on the RHEO KNEE. This may damage the knee, cause malfunction or failure, and will void the warranty. The battery should only be replaced by an authorized service technician.
- Never operate this product if it is not working properly, if it has been dropped or damaged, or immersed in water. In such cases return the product to your healthcare provider for examination and repair.
- The power supply provided with the unit is certified to comply with medical electrical equipment standards and it is therefore not safe to use any other power supply equipment.
- Follow local ordinances or regulations for proper disposal of device, accessories and packaging. The battery should be disposed of in accordance with local laws and regulations. It should not be incinerated.

CAUTION: Federal law requires this device to be sold by a prosthetist and by the order of a physician. The healthcare practitioner must provide each client with training for appropriate use and proper application of the RHEO KNEE.

SUMMARY OF SYMBOLS ON THE RHEO KNEE®

 Attention - See instructions for use

 On / Off

 Type B Applied Part (IEC60601-1)

 CE label with Notified Body identification number

 Non-ionizing radiation

 Manufacturer

 Year of manufacture

 Direct current

 Consult instructions for use

 This marking on the product, packaging, accessories or literature indicates that the product contains electronic components and/or batteries that should not be disposed of in regular waste at the end of its usable life. To prevent possible harm to the environment or human health from uncontrolled waste disposal users are requested to separate these items from other types of waste and recycle them responsibly to support sustainable reuse of material resources. Users should contact their local government office for information on how these items can be recycled or disposed of in an environmentally sound manner.
To protect natural resources and to promote material reuse, please separate batteries and electrical components from other types of waste and recycle them through your local, free electronic parts return system.

INDICATIONS FOR USE

LOW TO MODERATE IMPACT USE ONLY

- Description: Community and workplace ambulators with ability or potential for cadence variation and ramp/ stair descent.
- Activity examples: Shopping, gardening, longer walks, golfing.
- Weight limit: 125kg (275lbs).
- Distance from knee center to floor should be greater than or equal to 45cm (17 1/2").

CONTRAINDICATIONS FOR USE

Do not:

- Immerse in water or any other fluids.
- Use in dirty environments.
- Expose to extreme heat and /or cold.

RHEO KNEE® OVERVIEW

The RHEO KNEE® is the world's first microprocessor knee system to use the power of artificial intelligence and is the most adaptable solution of its kind; it adapts automatically to individual walking styles and different environments, continuously learning and improving its responses over time.

The RHEO KNEE can be fitted to a much wider range of prosthetic feet than any other microprocessor knee on the market because of its low build height (length).

RECOMMENDED FOOT SELECTION (FIGURE A)

Re-Flex Rotate with EVO
Flex-Foot Talux
Vari-Flex with EVO
Elation

AUTOMATIC ADJUSTMENT TO DIFFERENT SURFACES AND WALKING SPEED

Microprocessor controlled stance phase resistance assists the user in maintaining knee stability on a variety of surfaces.

Microprocessor controlled swing phase resistance samples and adjusts to the users walking speed during swing at a rate of 1000 times per second (1000Hz). This allows the user to achieve comfortable and symmetric transitions among wide ranges of walking speeds.

EXCELLENT ADJUSTABILITY

Adjustable stance flexion provides adjustable stance resistance for varying degrees of knee flexion during loading response.

Adjustable stance extension provides adjustable stance resistance to knee extension between loading response and midstance. Leads to dampened extension force and shock absorption.

MAGNETORHEOLOGIC FLUID ACTUATOR MEANS LIGHT WEIGHT FEEL AND FRICTIONAL RESISTANCE

Magnetized fluid provides frictional resistance to flexion and extension movement.

The actuator weight is located proximal in the knee providing a light-weight feel during swing phase.

SYSTEM FLEXIBILITY AND SIMPLICITY

Integrated sensor pylon allows for simple connections to foot and shock systems without use of specialized pylons.

Provides the ability to change height or foot rotation without recalibration or system reset.

Contributes to low build of prosthesis and allows for increased number of foot options.

SUPERIOR FUNCTION WITH OSSUR FOOT PRODUCTS

The RHEO KNEE has proven compatibility with Össur feet and shock systems for optimal knee function.

For best results use the RHEO KNEE with Reflex Rotate with Evo or Variflex with Evo.

TECHNICAL SPECIFICATIONS

SAFETY STANDARDS AND CLASSIFICATION

The RHEO KNEE® is tested and certified to comply with the IEC/EN60601-1, standard of electrical safety of medical devices and IEC/EN60601-1-2, electromagnetic compatibility for medical electrical devices and ISO 10328. The company fulfills the requirements of ISO13485, MDD 93/42/EEC, and carries the CE mark accordingly.

“This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.”

ENVIRONMENTAL CONDITIONS

- Operating temperature: -10°C to 45°C (14°F to 113°F)
- Operating humidity: 0% - 90% relative humidity (non-condensing)
- Shipping and storage temperature: -10°C to 45°C (14°F to 113°F)
- Shipping and storage humidity: 0% - 90% relative humidity (non-condensing)

MAINTENANCE

The unit should be sent to Össur for repairs or service. No other company or individual is allowed to service or repair the unit in any way.

Before sending the RHEO KNEE for repairs or service, make sure that the operating instructions have been followed accurately.

WARNING: DO NOT disassemble the knee joint or attempt repairs as this might create a hazard for the user and will automatically void warranty.

CLEANING

- Clean the knee with a damp cloth and mild soap or isopropyl alcohol.
- DO NOT use solvents stronger than isopropyl alcohol.
- DO NOT use compressed air to clean the knee, as it can cause the knee to malfunction and deteriorate prematurely.

CHARGING THE RHEO KNEE®

Before fitting the RHEO KNEE, charge the unit for 3 hours to ensure full charge.

CAUTION: Take the prosthesis off prior to charging.
RHEO KNEE should be charged daily for optimal performance.

It is not possible to overcharge the RHEO KNEE.

The RHEO KNEE can be charged regardless of whether it is turned ON or OFF

BATTERY CAPACITY

Rechargeable Lithium Ion Battery (1880mAh): Fully charged battery is sufficient for 24-48 hours of continuous use, depending on activity.

BATTERY WARNINGS (FIGURE C)

When battery is low a repeating warning pulse will appear: A short sound repeats every 15 seconds and orange light flashes on the interface panel. At this point the RHEO KNEE should be recharged. How much time is left on the battery depends on activity (approximately 30 minutes of walking on level ground or 5 min of stair descent). When battery is critically low, a buzzing, vibrating and a flashing red light will signal an imminent shut down (after 5 seconds).

HOW TO CHARGE THE RHEO KNEE

Insert the charger cable into the charging port on the user interface panel.

It will take approximately 1.5 hours to charge the RHEO KNEE battery to 90%, and 3 hours to fully charge it (100%).

POWER SUPPLY INFORMATION

- Power input: An external power supply for medical use.
- Input: 100-240 VAC
- Input frequency: 50-60 HZ
- Input current: 0.6A
- Output voltage: 24 VDC
- Output current: 1.0 A
- Operating temperature: 0°C to 40°C
- Operating humidity: 5% to 95% relative humidity (non-condensing)
- Manufacturer: UE Electronic
- Model No.: UE24WCP-240100SPA

TURNING THE RHEO KNEE® ON AND OFF

HOW TO TURN THE RHEO KNEE ON

To turn the RHEO KNEE on press the ON/OFF button (**Figure D**). You will hear a 2 beep confirmation. When the RHEO KNEE is on, you will see a pulsing green light on the light indicator beside the ON/OFF button on the user interface panel.

HOW TO TURN THE RHEO KNEE OFF

To turn the RHEO KNEE off press the ON/OFF button and hold it down until you hear 4 short beeps and 1 long beep.

When the RHEO KNEE is off, the light indicator on the user interface panel will also turn off.

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