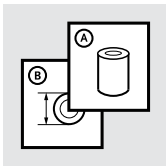




EN | Instructions for Use

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RHEO KNEE<sup>®</sup> 3



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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

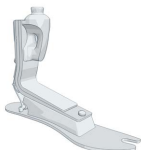


This marking on the product, packaging, accessories or literature indicates that the product contains electronic components and/or batteries that should not be disposed of in regular waste at the end of its usable life. To prevent possible harm to the environment or human health from uncontrolled waste 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.

## RECOMMENDED FOOT SELECTION



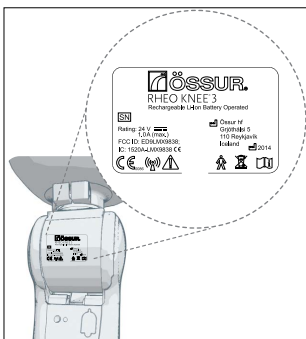
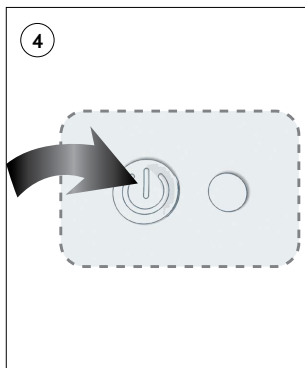
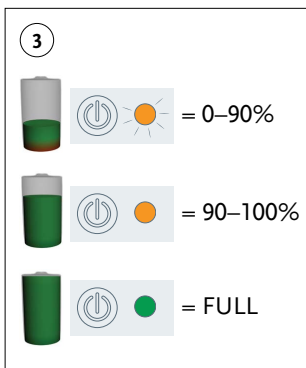
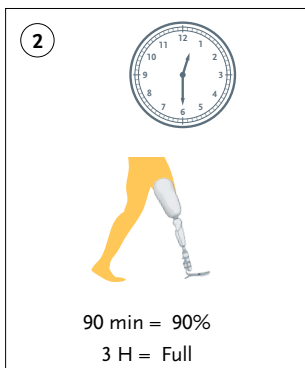
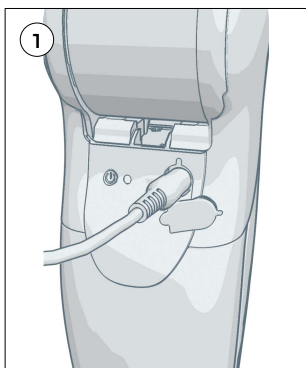
Re-Flex Rotate™ with EVO™



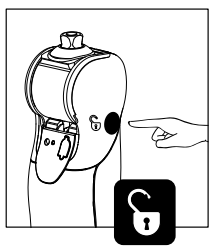
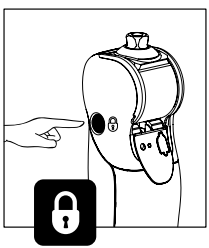
Talux®



Vari-Flex® with EVO



5



## SAFETY PRECAUTIONS

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Please follow the safety precautions as failure to do so can lead to malfunction of the RHEO KNEE® 3 and risk injury to the user.

1. The RHEO KNEE 3 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 3 to break down or malfunction, and will void the warranty.
2. If the RHEO KNEE 3 loses power, the knee loses its ability to provide stance support. In such cases it is recommended to manually engage the integrated extension lock to lock the knee in full extension. The knee allows full weight bearing when locked.
3. For maximum safety use a handrail when descending stairs and ramps.
4. 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. Engage the extension lock and proceed to walk with caution.
5. Avoid any impact to the socket, frame, adapter contact, or the interface panel on the back of the RHEO KNEE 3. Damage to this panel or any of its components may cause the product to malfunction.
6. Do not use in highly electrical and/or magnetic environments (electrical transformers, high-power radio/TV transmitters). Avoid exposure to extreme heat and/or cold (see chapter Technical Specifications). Avoid exposure to intense dust, smoke, or mechanical vibrations.
7. The RHEO KNEE 3 may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones or other equipment, even if that other equipment complies with CISPR EMISSION requirements.
8. Because the RHEO KNEE 3 is battery operated, caution should be taken about exposure to water and excessive mechanical shocks or vibrations.
9. Do not attempt any repairs (no matter how minor) on the RHEO KNEE 3. This may damage the knee, cause malfunction or failure, and will void the warranty.
10. 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.
11. 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.
12. 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.

## INDICATIONS FOR USE

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- Activity level: Low, moderate and high
- Activity examples: Shopping, longer walks, golfing
- Weight limit: 136 kg (300 lbs)
- Distance from knee center to floor:  $\geq 45$  cm (17½")

## CONTRAINDICATIONS FOR USE

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### DO NOT:

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

## CHARGING THE RHEO KNEE 3

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### *How to charge the RHEO KNEE 3*

- Insert the charger cable into the charging port on the user interface panel (**Figure 1**).
- It will take approximately 1.5 hours to charge the RHEO KNEE 3 battery to 90%, and 3 hours to fully charge it (100%) (**Figure 2**).
- RHEO KNEE 3 should be charged daily for optimal performance.
- It is not possible to overcharge the RHEO KNEE 3.
- The RHEO KNEE 3 can be charged regardless of whether it is turned ON or OFF

### *Battery warnings (Figure 3)*

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 3 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).

### *Battery capacity*

Rechargeable Lithium Ion Battery (1880mAh): Fully charged battery is sufficient for 48–72 hours of continuous use, depending on activity.

## TURNING THE RHEO KNEE 3 ON AND OFF

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### *How to turn the RHEO KNEE 3 on*

To turn the RHEO KNEE 3 on press the ON/OFF button (**Figure 4**). You will hear a 2 beep confirmation.

When the RHEO KNEE 3 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 3 off*

To turn the RHEO KNEE 3 off press the ON/OFF button and hold it down until you hear 4 short beeps and 1 long beep.

When the RHEO KNEE 3 is off, the light indicator on the user interface panel will also turn off.

## EXTENSION LOCK

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See Figure 5

## MAINTENANCE

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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 3 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.

## **TECHNICAL SPECIFICATIONS**

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### ***Safety standards and classification***

The RHEO KNEE 3 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 40 °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: 5% - 90% relative humidity (non-condensing)

### ***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: 10% to 90% relative humidity (non-condensing)
- Manufacturer: UE Electronic
- Model No.: UE24WCP-240100SPA



**EN – Caution:** Össur products and components are designed and tested to ISO. 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. å slutte å bruke enheten og rådføre seg med klinisk spesialist. Dette produktet er utformet og testet basert på at det brukes av én enkelt pasient. Det er et engangsprodukt, og det skal ikke brukes av flere pasienter. Ta kontakt med legen din umiddelbart dersom det oppstår problemer relatert til bruk av produktet.

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