

RHEO KNEE[®] and RHEO KNEE[®] XC Reimbursement Support

RHEO KNEE'XC

PRODUCT FEATURES

The RHEO KNEE is a microprocessor knee suitable for unilateral and bilateral transfemoral and knee disarticulation users. It is operated using Magnetorheologic fluid to effectively create an 'electronic brake' whereby resistance is continually adapted to the user's needs and situation, optimising safety and efficiency. Magnetorheologic fluid is highly responsive technology, utilising electromagnetic forces to rapidly alter the viscosity of the magnetic fluid in the knee. This allows an almost instantaneous shift from the high resistance required for stability in stance phase to the low resistance needed for a dynamic, free swing phase, simulating the natural function of the physiological knee joint.

The RHEO KNEE 3 is aimed at K2-K3 users, and the RHEO KNEE XC is aimed at K3-K4.

Clinical evidence conducted with the RHEO KNEE compared to previous versions and two hydraulic MPKs, showed significant improvements in user's ability to walk further, faster, with less exertion. The 6-minute walk test revealed that users on the RHEO KNEE walked longer distances and faster than on other MPKs. The Borg test revealed they exerted less energy than other users on different MPKs whilst performing a physical exercise. The satisfaction levels of the test subjects revealed that users reported less fatigue, could walk faster and further and their mobility increased in comparison to their usual MPK.

Please refer to the clinical test report for more detailed information. https://assets.ossur.com/library/36572/RHEO%20KNEE%20XC%20Comparison%20Study.pdf

SUMMARY OF FEATURES

- Weatherproof for use in wet/humid environments. Rated: IP34
- Magnetorheologic technology eliminates fluid drag and is highly responsive to cadence variations.
- Effortless swing initiation enables a smoother gait, even in crowds and confined spaces, and can now be adjusted using Össur LOGIC and RHEOLOGIC to provide optimal results for the user.
- Enhanced extension assist allows for a faster swing extension rate, lower energy consumption and an improved perception of safety.
- RHEO KNEE actuator has been improved to allow a greater resistance over a wide range of knee motion, increased stability, safety and support on ramps, stairs and on uneven ground.
- Kinematic Sensor (Gyroscope) identifies quiet standing and increases stance resistance for maximum stability and reduced stress on the contralateral limb. Users can step and walk backwards safely.
- Artificial Intelligence: Advanced control features continually monitor and adapt resistance levels for the user. For example, the knee will automatically adapt resistances if a user changes from a heavy shoe to a light shoe, ensuring optimal heel rise and swing extension is maintained without the requirement to re-program the knee.
- 72 hours battery life with the potential to extend by turning the power off (e.g. overnight when not in use)
- Free (no resistance) in swing when the power is off. Option to use manual extension lock feature for maximum stability and user safety. When activated, the knee remains in full extension until release button is reciprocated. The manual lock can be utilised for safety and security in extreme environments (e.g. steep or loose terrain), as well as recreationally (e.g. yoga, gym work).
- Step-over-step stair ascent (RHEO KNEE XC only).
- Automatic cycling recognition (RHEO KNEE XC only).
- Running capability (RHEO KNEE XC only).
- 5-year warranty, including service check at 40 months.



MOBILITY BENEFITS

Product feature	Microprocessor-controlled swing and stance
Mobility benefit	Increases user mobility while reducing metabolic costs and perceived exhaustion.
Reference	 The effect of a design change of a microprocessor-controlled knee on quality of life and performance based measures of mobility. Lechler K., Ikelaar L., Sigurthorsson S., Sverrisson R. OT-World, 1316.05.2014, Leipzig, poster 4997, abstract 1418. A clinical comparison of variable-damping and mechanically passive prosthetic

Product feature	Microprocessor-controlled swing and stance
Mobility benefit	Automatic cadence adaptation for maintaining comfort and walking efficiency.
	3. User-adaptive control of a magnetorheological prosthetic knee. Herr, H. & Wilkenfeld, A. Industrial Robot: An International Journal 30, 42-55 (2003).
Reference	4. Spatial parameters of gait in transfemoral amputees: Comparison of bionic and mechanically –Temporal passive knee joints. Jaroslav Uchytil, Daniel Jandacka, David Zahradnik, Roman Farana and Miroslav Janura; published online 3 July 2013 Prosthetics and Orthotics International.

Product feature	RHEO KNEE actuator provides resistance over a wide range of knee motion
Mobility benefit	Increases stability and confidence walking downstairs.
Reference	1. The effect of a design change of a microprocessor-controlled knee on quality of life and performance based measures of mobility. Lechler K., Ikelaar L., Sigurthorsson S., Sverrisson R., OT-World, 1316.05.2014, Leipzig, poster 4997, abstract 1418.

Product feature	Kinematic Sensor (Gyroscope)
Mobility benefit	Enables prolonged standing as the knee identifies quiet standing, increasing stance resistance when the user is standing for better stability and reduced stress on the contralateral limb. Enables users to walk and step backwards safely.

Product feature	Microprocessor-controlled swing and stance (Magnetorheologic technology)
Mobility benefit	Provides a light feel and easy initiation of swing.
Reference	2. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Johansson et. al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.



MOBILITY BENEFITS

Product feature	Step-over-step stair ascent (RHEO KNEE XC only)
Mobility benefit	Enables user to ascend stairs. Accelerometer allows knee to detect when user is ascending stairs, permitting leg-over-leg stair ascent, for a normal gait pattern.
Reference	5. RHEO KNEE Clinical Test Report (Stair Assessment Index).

Product feature	Manual Lock
Mobility benefit	Increased stability for extreme terrain, climbing ladders, steep slopes. Can utilise for gym work and exercise such as yoga.

Product feature	Microprocessor swing and stance control
Mobility benefit	Improves gait symmetry and enhances comfort.
	3. User-adaptive control of a magnetorheological prosthetic knee. Herr, H. & Wilkenfeld, A. Industrial Robot: An International Journal 30, 42 -55 (2003).
Reference	4. Spatial parameters of gait in transfemoral amputees: Comparison of bionic and mechanically –Temporal passive knee joints. Jaroslav Uchytil, Daniel Jandacka, David Zahradnik, Roman Farana and Miroslav Janura; published online 3 July 2013 Prosthetics and Orthotics International.

Product feature	Running capability (RHEO KNEE XC only)
Mobility benefit	Enables transition from walk to run allowing the user to go for a jog without having to change the prosthesis. Use in the gym for fitness and run from danger.

Product feature	Automatic cycling recognition (RHEO KNEE XC only)
Mobility benefit	Enables cycling with ease and confidence. Enables stable transition when exiting bike.

Product feature	Microprocessor- controlled swing and stance
Mobility benefit	Reduces conscious effort and stress to maintain knee stability.
Reference	 Verbesserung der Teilhabe durch mikroprozessorgesteuertes Kniegelenk – erste Erfahrungen einer Kohortenstudie. Greitemann, B, Lechler, K. & Ludviksdottir, A. Medizinisch Orthopädische Technik 1, 90-101 (2011).



HEALTH BENEFITS

Product feature	Microprocessor-controlled swing and stance
Health benefit	Increases user comfort by allowing shock absorption and dampening extension forces.
Reference	3. User-adaptive control of a magnetorheological prosthetic knee. Herr, H. & Wilkenfeld, A. Industrial Robot: An International Journal 30, 42 -55 (2003).
	 Comparative Biomechanical Analysis of Current Microprocessor-Controlled Prosthetic Knee Joints. Bellmann, M., Schmalz, T. & Blumentritt, S. Archives of Physical Medicine and Rehabilitation 91, 644-652 (2010).

Product feature	Microprocessor- controlled swing and stance	
Health benefit	Provides natural gait dynamics.	
Reference	3. User-adaptive control of a magnetorheological prosthetic knee. Herr, H. & Wilkenfeld, A. Industrial Robot: An International Journal 30, 42 -55 (2003).	
	2. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Johansson et. al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.	

LIFESTYLE BENEFITS

Product feature	Weatherproof, IP34 rated. Fresh water splashing from all angles	
Lifestyle benefit	Patient works/lives in a wet environment: RHEO KNEE 3 & RHEO KNEE XC can withstand splashing of fresh water from all angles, permitting the user to utilise it in a wider range of conditions/weather/humidity.	
Reference	5. RHEO KNEE Clinical Test Report/IFU.	

Product feature	Microprocessor-controlled swing and stance	
Lifestyle benefit	Provides increased security and confidence for users.	
Reference	 Verbesserung der Teilhabe durch mikroprozessorgesteuertes Kniegelenk – erste Erfahrungen einer Kohortenstudie. Greitemann, B, Lechler, K. & Ludviksdottir, A. Medizinisch Orthopädische Technik 1, 90-101 (2011) 	
	1. The effect of a design change of a microprocessor-controlled knee on quality of life and performance based measures of mobility. Lechler K, Ikelaar L, Sigurthorsson S, Sverrisson R. OT-World, 1316.05.2014, Leipzig, poster 4997, abstract 1418.	



LIFESTYLE BENEFITS

Product feature	Microprocessor-controlled swing and stance	
Lifestyle benefit	Increased quality of life: Users participated in the PEQ MS 12/5 (self-administered questionnaire aimed at evaluating prosthetic function and prosthetic related changes to quality of life). The improvements with the RHEO KNEE over their previous MPK were statistically significant with users grading their prosthetic device and their quality of life higher when using the RHEO KNEE than other MPK devices.	
Reference	5. RHEO KNEE Clinical Test Report.	

OUTCOME MEASURES

Outcome measures are used by health care professionals to help determine the patient's baseline function and progression throughout rehabilitation and beyond. They are an important tool to utilise to provide credible and reliable justification for treatment and reimbursement.

This table outlines examples of validated outcome measures used in practice to objectively determine function, progress and treatment efficacy.

Outcome Measures	Use	Reference
6 Minute Walk Test	General Mobility	Kenneth H. Cooper, MC. A Means of Assessing Maximal Oxygen Intake Correlation Between Field and Treadmill Testing. JAMA. 1968;203(3):201-204.
Amputee Mobility Predictor	Amputee Function	Gailey RS, et al. The Amputee Mobility Predictor: an instrument to assess determinants of the lower-limb amputee ability to ambulate. Arch Phys Med Rehabil 2002;83:613-27.
АВС	Balance/Confidence	Powell LE, Myers AM. The Activities-Spwecific Balance Confidence (ABC) Scale. The Journals of gerontology. Series A, Biological sciences and medical sciences. 1995; 50A (1):M28-34.
PEQ-MS	Prosthetic Function and Satisfaction	Franchignoni, et al. Measuring mobility in people with lower limb amputation: Rasch analysis of the mobility section of the prosthesis evaluation questionnaire. J Rehabil Med 2007: 39(2):138-144.
TAPES-R	Prosthetic Function and Satisfaction	Gallagher et al. Trinity amputation and prosthesis experience scales: a psychometric assessment using classical test theory and rasch analysis. American Journal of Physical Medicine and Rehabilitation. 2010; 89(6): 487-96



OUTCOME MEASURES

Outcome Measures	Use	Reference
Timed Up and Go	Fall Risk	Podsiadlo S. Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. Journal of the American Geriatrics Society. 1991; 39(2):142-148.
L-Test	Fall Risk	Deathe AB, Miller WC. The L test of functional mobility: measurement properties of a modified version of the timed up and go test designed for people with lower-limb amputations.
LCI	Prosthetic Use	Grise MC. Gauthier-Gagnon C. Prosthetic profile of people with lower extremity amputation: concept of a follow up questionnaire. Arch Phys Med Rehabil 1993: 74(8):862-70.
Oswestry Disability Index	Lower Back Pain	Fairbank JCT, Pynsent PB. The Oswestry Disability Index. 2000; Spine, 25(22); 2940-2953.
WOMAC	OA in Hip or Knee	Western Ontario and McMaster Osteoarthritis Index.
SFCS	Socket Fit	Hanspal RS, Fischer K, Nieveen R. Prosthetic Socket Fit Comfort Score Disability Rehabilitation 2003: 25(22):1278-80.
PLUS-M	Mobility	Morgan, Sara J et al. "Use of cognitive interviews in the development of the PLUS-M item bank." Quality of Life Research 23.6 (2014): 1767-1775.

PRODUCT INFORMATION

- RHEO KNEE XC Information:
 <u>http://www.ossur.com.au/prosthetic-solutions/products/impact-solutions/rheo-knee-xc</u>
- RHEO KNEE Clinical Test Report: <u>https://assets.ossur.com/library/36572/RHEO%20KNEE%20XC%20Comparison%20Study.pdf</u>
- RHEO KNEE XC Brochure: <u>https://assets.ossur.com/library/36729/RHEO%20KNEE%20XC%20Brochure%20-%20.pdf</u>
- RHEO KNEE XC Flyer: <u>https://assets.ossur.com/library/36573/RHEO%20KNEE%20XC%20Brochure%20-%20Sell%20Sheet.pdf</u>
- Instructions for Use:
 <u>https://assets.ossur.com/library/36562/RHEO%20KNEE%20XC%20Instructions%20for%20use.pdf</u>
- Össur RHEO KNEE XC from Early Rehabilitation to Full Recovery Video: <u>https://www.youtube.com/watch?v=7e6-5uRkwfl</u>



TESTIMONIALS

- Mitch Farrar (Prosthetist) on his experience with the RHEO KNEE XC: <u>https://www.ossur.com.au/about-ossur/amputee-events-community-groups/client-experiences/brad-smyth-s-story</u>
- Brad Smyth on his RHEO KNEE XC experience: <u>https://www.ossur.com.au/about-ossur/amputee-events-</u> <u>community-groups/client-experiences/brad-smyth-s-story</u>
- Graham Hamilton on his RHEO KNEE 3 experience: <u>https://www.ossur.com.au/about-ossur/amputee-</u> events-community-groups/client-experiences/graham-hamilton-s-story
- Toby Bird on his RHEO KNEE 3 experience: <u>https://www.ossur.com.au/about-ossur/amputee-events-</u> community-groups/client-experiences/toby-bird-rheo-knee-3-experience

RECOMMENDED TREATMENT PATHWAY AND ESSENTIAL STEPS

Trial units may be requested by the clinical facility and utilised with clients for up to 3 weeks.

Clinicians are instructed to contact Customer Service for availability and details.

Please see also the AOPA accredited course for the RHEO KNEE 3 and RHEO KNEE XC: https://www.aopa.org.au/events/event/ossur-rheo-knee-3-and-rheo-knee-xc-course

COMPLEMENTARY CARE/SUPPORT CONSIDERATIONS

PHYSIOTHERAPY RECOMMENDATIONS:

- We recommend that a physiotherapist be in attendance for the client's first RHEO KNEE fitting appointment. This enables gait training to begin immediately, encouraging the user to load the prosthesis for maximum confidence and improved weight bearing, which can assure more optimal alignment.
- A minimum of 6 physiotherapy sessions is recommended for experienced walkers who are changing from a mechanical knee joint to a RHEO KNEE.
- This can be broken down into 2 sessions in the first week, followed by 1 session per week, allowing the user time to practice the skills covered in the sessions.
- A minimum of 12 physiotherapy sessions is recommended for Primary amputees receiving a RHEO KNEE. More may be required depending on the skill/strength/work ethic of the user.



COMPLEMENTARY CARE/SUPPORT CONSIDERATIONS

RECOMMENDED TRAINING ORDER:

- 1. Basic gait training walking well using the foot successfully disengaging the knee at toe off.
 - The client is encouraged to use the entire foot (i.e. fully extend the hip) to achieve easy breaking of the knee at toe off with a high hip position. This means that optimum length of the prosthesis is likely to be accepted by the patient without requests for lowering of the height of the prosthesis.
- 2. Minimisation of Lateral trunk bending.
- 3. Initial training of stance phase resistance for confidence.
- 4. Descent of stairs.
- 5. Descent of slopes.
- 6. More advanced gait training and activities using the stance phase resistance to flexion (e.g. return to gym strengthening activities, advanced hip and pelvic stability activities).
- 7. Clearing objects.
- 8. Changing direction.
- 9. Hop-skip running, leg over leg running if appropriate, any other recreational activity requirements.
- **10**. To achieve leg over leg running (for the RHEO KNEE XC) the program may need to be extended beyond 12 sessions as considerable core and hip strength and control is needed to avoid injury.

FOLLOW UP CONSIDERATIONS/MAINTENANCE REQUIREMENTS

A 5-year warranty is included with the RHEO KNEE 3 and RHEO KNEE XC, with the requirement for 1 mandatory service at 40 months. A loaner unit will be supplied for this time. Össur provides support to the customer with loaner units if any repairs or maintenance are required. The RHEO KNEE is not field serviceable.



REFERENCES

- The effect of a design change of a microprocessor-controlled knee on quality of life and performance based measures of mobility. Lechler K., Ikelaar L., Sigurthorsson S., Sverrisson R. OT-World, 13.-16.05.2014, Leipzig, poster 4997, abstract 1418.
- 2. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Johansson et. al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.
- 3. User-adaptive control of a magnetorheological prosthetic knee. Herr, H. & Wilkenfeld, A. Industrial Robot: An International Journal 30, 42 -55 (2003).
- 4. Spatial parameters of gait in transfemoral amputees: Comparison of bionic and mechanically Temporal passive knee joints. Jaroslav Uchytil, Daniel Jandacka, David Zahradnik, Roman Farana and Miroslav Janura; published online 3 July 2013 Prosthetics and Orthotics International; <u>http://poi.sagepub.com/content/early/2013/07/01/0309364613492789</u>
- 5. **RHEO KNEE Clinical Test Report.** <u>https://assets.ossur.com/library/36572/RHEO%20KNEE%20</u> XC%20Comparison%20Study.pdf
- 6. Verbesserung der Teilhabe durch mikroprozessorgesteuertes Kniegelenk erste Erfahrungen einer Kohortenstudie. Greitemann, B, Lechler, K. & Ludviksdottir, A. Medizinisch Orthopädische Technik 1, 90-101 (2011)
- Comparative Biomechanical Analysis of Current Microprocessor-Controlled Prosthetic Knee Joints. Bellmann, M., Schmalz, T. & Blumentritt, S. Archives of Physical Medicine and Rehabilitation 91, 644-652 (2010)



RHEO KNEE 3

RHEO KNEE'3



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