

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 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.

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).

MOBILITY BENEFITS

	Product feature	Microprocessor-controlled swing
-	Mobility benefit	Increases user mobility while red
	Reference	 The effect of a design change and performance based meas S., Sverrisson R. OT-World, 13
		2. A clinical comparison of varia knee devices. Johansson et. a

Product feature	Mi	croprocessor-controlled swing
Mobility benefit	Au	tomatic cadence adaptation fo
	3.	User-adaptive control of a ma Wilkenfeld, A. Industrial Robo
Reference	4.	Spatial parameters of gait in t mechanically –Temporal pass David Zahradnik, Roman Fara Prosthetics and Orthotics Int

Product feature	RHEO KNEE actuator provides re
Mobility benefit	Increases stability and confidence
Reference	 The effect of a design change and performance based mease S., Sverrisson R., OT-World, 12

Product feature	Kinematic Sensor (Gyroscope)
Mobility benefit	Enables prolonged standing as th resistance when the user is stand contralateral limb. Enables users

Product feature	Microprocessor-controlled swing
Mobility benefit	Provides a light feel and easy initi
Reference	2. A clinical comparison of varia knee devices. Johansson et. a





g and stance

ucing metabolic costs and perceived exhaustion.

e of a microprocessor-controlled knee on quality of life sures of mobility. Lechler K., Ikelaar L., Sigurthorsson 13.-16.05.2014, Leipzig, poster 4997, abstract 1418.

iable-damping and mechanically passive prosthetic al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.

g and stance

or maintaining comfort and walking efficiency.

agnetorheological prosthetic knee. Herr, H. & pot: An International Journal 30, 42-55 (2003).

transfemoral amputees: Comparison of bionic and sive knee joints. Jaroslav Uchytil, Daniel Jandacka, rana and Miroslav Janura; published online 3 July 2013 iternational.

esistance over a wide range of knee motion

e walking downstairs.

e of a microprocessor-controlled knee on quality of life sures of mobility. Lechler K., Ikelaar L., Sigurthorsson 13.-16.05.2014, Leipzig, poster 4997, abstract 1418.

he knee identifies quiet standing, increasing stance ding for better stability and reduced stress on the s to walk and step backwards safely.

and stance (Magnetorheologic technology)

tiation of swing.

able-damping and mechanically passive prosthetic 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 stanceReduces conscious effort and stress to maintain knee stability.	
Mobility benefit		
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
	Health benefit	Increases user comfort by allowir
	Reference	3. User-adaptive control of a ma Wilkenfeld, A. Industrial Robo
		 Comparative Biomechanical A Prosthetic Knee Joints. Bellma Physical Medicine and Rehab

	Product feature	Microprocessor- controlled swing
	Health benefit	Provides natural gait dynamics.
	Reference	3. User-adaptive control of a ma Wilkenfeld, A. Industrial Robo
		2. A clinical comparison of varia knee devices. Johansson et. a

LIFESTYLE BENEFITS

Product feature	Weatherproof, IP34 rated. Fresh w
Lifestyle benefit	Patient works/lives in a wet enviro withstand splashing of fresh wate wider range of conditions/weathe
Reference	5. RHEO KNEE Clinical Test Rep

	Product feature	Microprocessor-controlled swing	
	Lifestyle benefit	Provides increased security and co	
	Reference	 Verbesserung der Teilhabe dur Erfahrungen einer Kohortenst Medizinisch Orthopädische Te 	
		 The effect of a design change and performance based mease Sverrisson R. OT-World, 131 	





g and stance

ing shock absorption and dampening extension forces.

nagnetorheological prosthetic knee. Herr, H. & pot: An International Journal 30, 42 -55 (2003).

Analysis of Current Microprocessor-Controlled nann, M., Schmalz, T. & Blumentritt, S. Archives of bilitation 91, 644-652 (2010).

g and stance

agnetorheological prosthetic knee. Herr, H. & ot: An International Journal 30, 42 -55 (2003).

able-damping and mechanically passive prosthetic al., Am J Phys Med Rehabil. 2005, Aug; 84(8):563-75.

water splashing from all angles

ronment: RHEO KNEE & RHEO KNEE XC can er from all angles, permitting the user to utilise it in a er/humidity.

port/IFU.

g and stance

confidence for users.

urch mikroprozessorgesteuertes Kniegelenk – erste studie. Greitemann, B, Lechler, K. & Ludviksdottir, A. Technik 1, 90-101 (2011)

e of a microprocessor-controlled knee on quality of life sures of mobility. Lechler K, Ikelaar L, Sigurthorsson S, 16.05.2014, 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.
ABC	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	Referen
Timed Up and Go	Fall Risk	Podsiad basic fu the Ame
L-Test	Fall Risk	Deathe measur timed u amputa
LCI	Prosthetic Use	Grise M with low question
Oswestry Disability Index	Lower Back Pain	Fairban 2000; S
WOMAC	OA in Hip or Knee	Westerr
SFCS	Socket Fit	Hanspa Comfor
PLUS-M	Mobility	Morgan develop Researc





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adlo S. Richardson S. The timed "Up & Go": a test of functional mobility for frail elderly persons. Journal of nerican Geriatrics Society. 1991; 39(2):142-148.

e AB, Miller WC. The L test of functional mobility: irement properties of a modified version of the up and go test designed for people with lower-limb cations.

MC. Gauthier-Gagnon C. Prosthetic profile of people ower extremity amputation: concept of a follow up onnaire. Arch Phys Med Rehabil 1993: 74(8):862-70.

nk JCT, Pynsent PB. The Oswestry Disability Index. Spine, 25(22); 2940-2953.

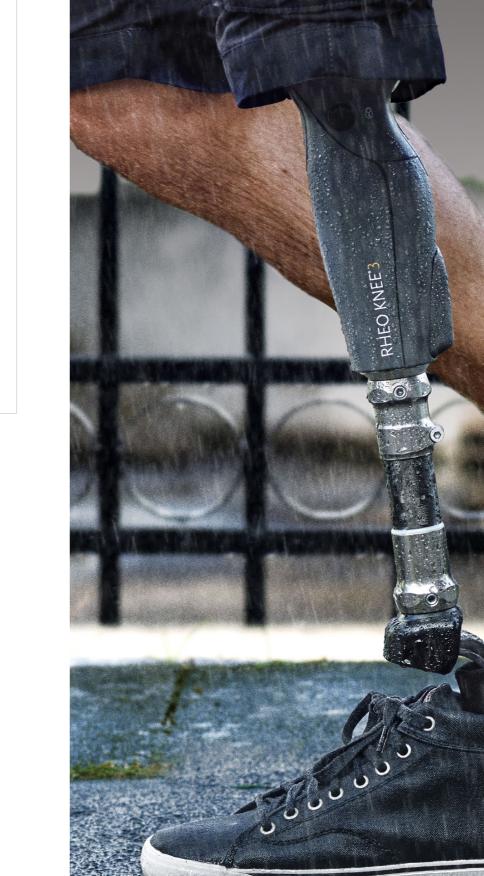
rn Ontario and McMaster Osteoarthritis Index.

oal RS, Fischer K, Nieveen R. Prosthetic Socket Fit ort Score Disability Rehabilitation 2003: 25(22):1278-80.

n, Sara J et al. "Use of cognitive interviews in the pment of the PLUS-M item bank." Quality of Life rch 23.6 (2014): 1767-1775.

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- 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).
- 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://media.ossur.com/image/upload/f_pdf/v1620070524/</u> documents/CA/reimbursement-resources/Canada-Rheo_Knee_Clinical_Test_Report.pdf</u>
- 6. Verbesserung der Teilhabe durch mikroprozessorgesteuertes Kniegelenk erste Erfahrungen einer Kohortenstudie. Greitemann, B, Lechler, K. & Ludviksdottir, A. Medizinisch Orthopädische Technik 1, 90-101 (2011)
- 7. 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

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