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ÖSSUR ACADEMY




Pro-Flex®

Less load, More dynamics

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Össur Australia

Introduction

The indication, general clinical facts:

- Traditional prosthetic feet show limited range of ankle motion, low ankle power generation resulting in increased sound side impact. ESAR feet show improvements. Soares et. al. 2009

The prevalence of the indication, current treatments with references:

- ESAR feet are standard for K3 and K4 amputees to which increased range of motion, increased ankle power, and sound side protection are relevant and potentially may help reduce comorbidities like OA. Morgenroth et al 2011

Current outcomes from the literature:

- ESAR feet have shown numerous benefits (LIT2015092365) but they still show quite a gap to the physiological performance. Range of motion, ankle power and the effect on the sound limb are typical performance measures for ESAR feet.

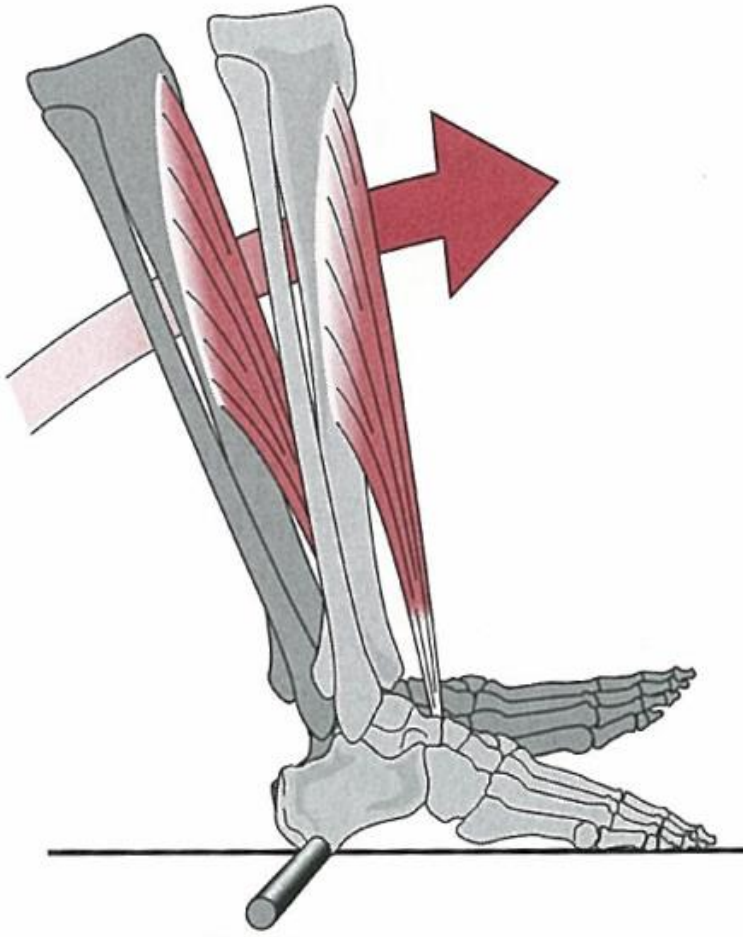
Opportunities to improve:

- **By introducing increased range of motion, shortcomings on ramp descent can be addressed. Increased push-off may assist to improve the energy cost of walking and reduce the impact on the sound side.** Darter et al, Delussu et al.,Houdjik 2009 and Au 2007

Ankle/Foot Biomechanics

Heel Rocker:

- Initial Contact & Loading Response:
  - 0-12% of the gaitcycle
- Mechanical Axis:
  - Contact point of calcaneus with the floor
- Range of Motion: 10° Plantarflexion
- Muscular Action: Pre-tibial muscles
- Functional Importance:
  - Shock absorption
  - Initiation of tibial progression

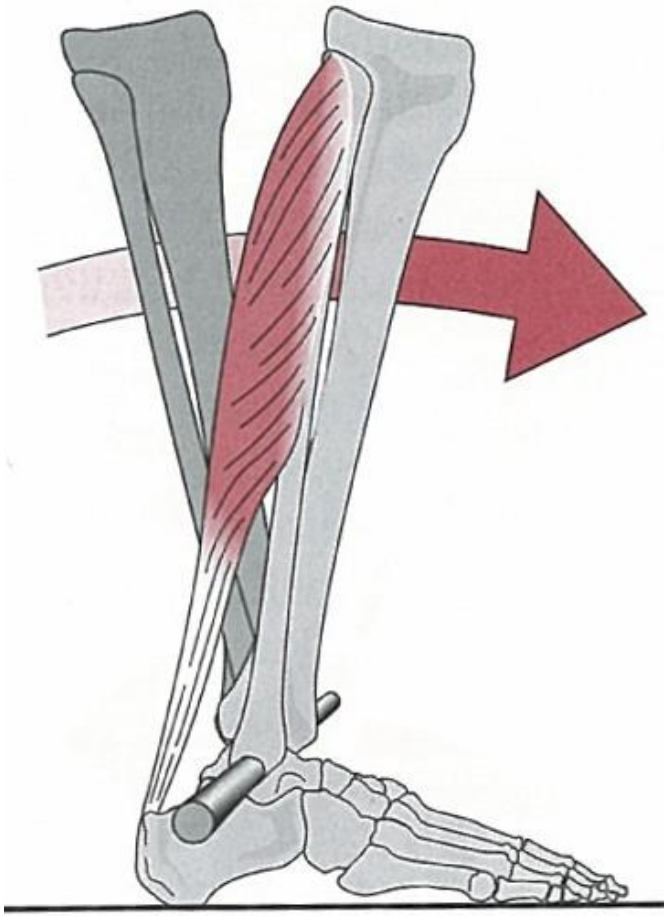


Ankle/Foot Biomechanics

ÖSSUR ACADEMY

Ankle Rocker:

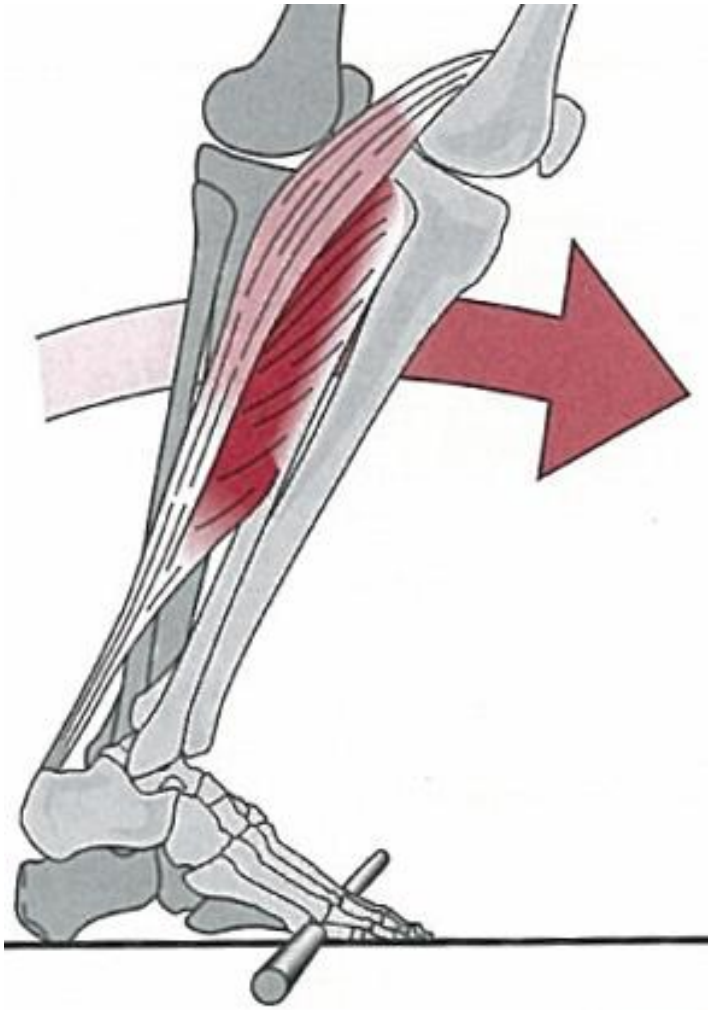
- Midstance:
  - 12-31% of the gaitcycle
- Mechanical Axis: Through talocrural joint
- Range of Motion: 5°PF to +5°DF
- Muscular Action: Soleus & Gastrocnemius restrain excessive tibial progression
- Functional Importance:
  - **Tibial progression AND restraint**
  - **Controlled dorsiflexion**
  - Stability



Ankle/Foot Biomechanics

Fore Foot Rocker:

- Terminal Stance
  - 31-50% of the gaitcycle
- Mechanical Axis:
  - Through metatarsal articulation
- Range of Motion: 5-10°DF to 5°PF
- Forces: Maximum DF torque
- Muscular Action: Soleus & Gastrocnemius
  - **Activity of the muscles during terminal stance phase is 3X that of midstance**
- Functional Importance: **Propulsion**



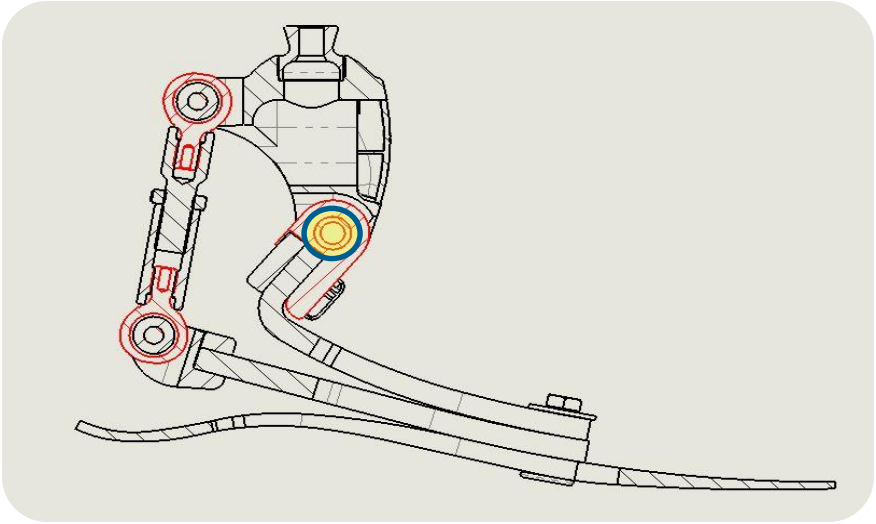
Advancing medical and mobility benefits

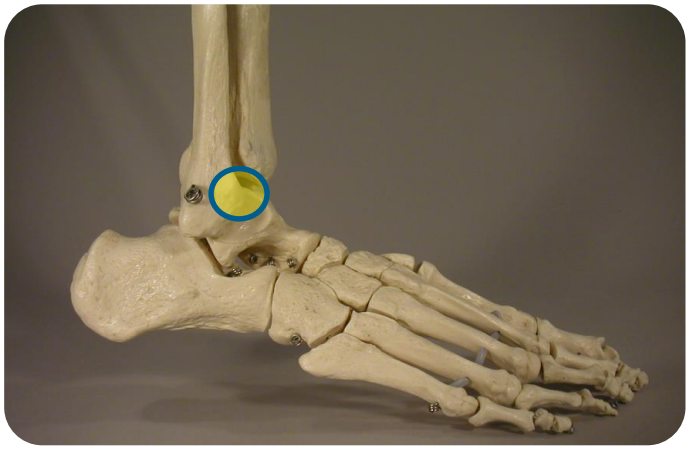
Pro-Flex® delivers the following functional improvements and benefits (Data reflects direct comparison to Vari-Flex – on file at Össur):

- Increased ankle range of motion of 82.2%
  (82.2% on level ground; 104.8% and 84.3% for ramp descent and ascent)
- Increased ankle power of 93.3%, resulting in increased push-off at terminal stance (93.3% on level ground; 150.0% and 100.0% for ramp descent and ascent)
- More physiological center of pressure movement during roll-over extends stance phase period of support (on the affected side)
- This combination of functional features delivers overall medical benefit:
  Reduced impact of 11% on the sound side
  Reduced varus moment of 15% on the sound side

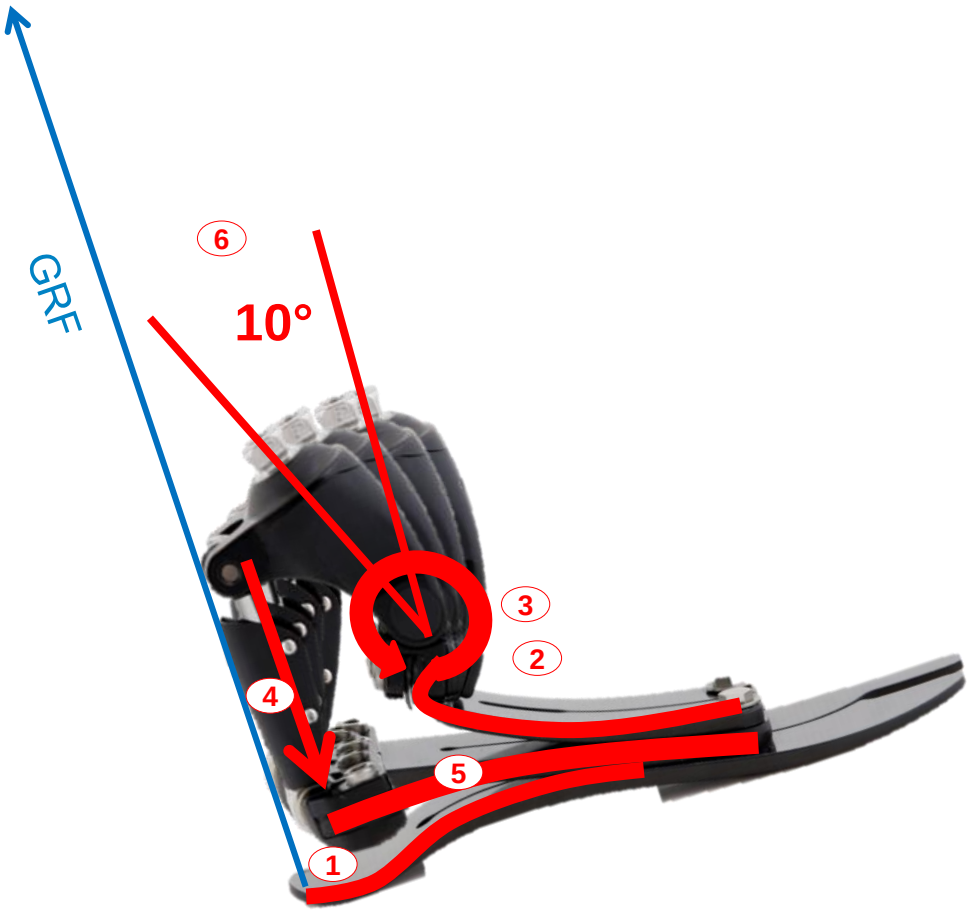
Pro-Flex® Mechanics

- Interaction of 3 carbon fibre blades through new Pivot Technology:
  - Polycentric ankle geometry
  - Optimizes range of motion
  - Optimizes power production
- Defined physiological center of rotation (mimics ankle rocker – talocrural joint): fixed central pivot axis anchored by middle spring
- Blades interact to control stiffness and rate of plantar flexion and dorsiflexion:
  - Low stiffness (high flexibility) in mid-stance range:
    - Delivers greater range of motion (27°)
  - Higher stiffness (terminal stance to pre-swing) assists propulsion:
    - Delivers higher ankle power (nearly 2X Vari-Flex)





Loading Response



1. Active Heel compresses under load
2. Upper Blade compresses under load

So far, just like a normal ESAR Foot

In addition, Pro-Flex provides:

3. Backward rotation around main pivot
4. Back-link transfers load onto mid-lever
5. Mid-lever loads and deflects downward
6. 10° real plantarflexion

Mid-stance

Rotation through physiological center of rotation
Maintain full toe lever for maximum mechanical advantage

Terminal Stance

1. Sole blade compresses storing energy
2. Upper blade compresses storing energy

So far, just like a normal ESAR Foot

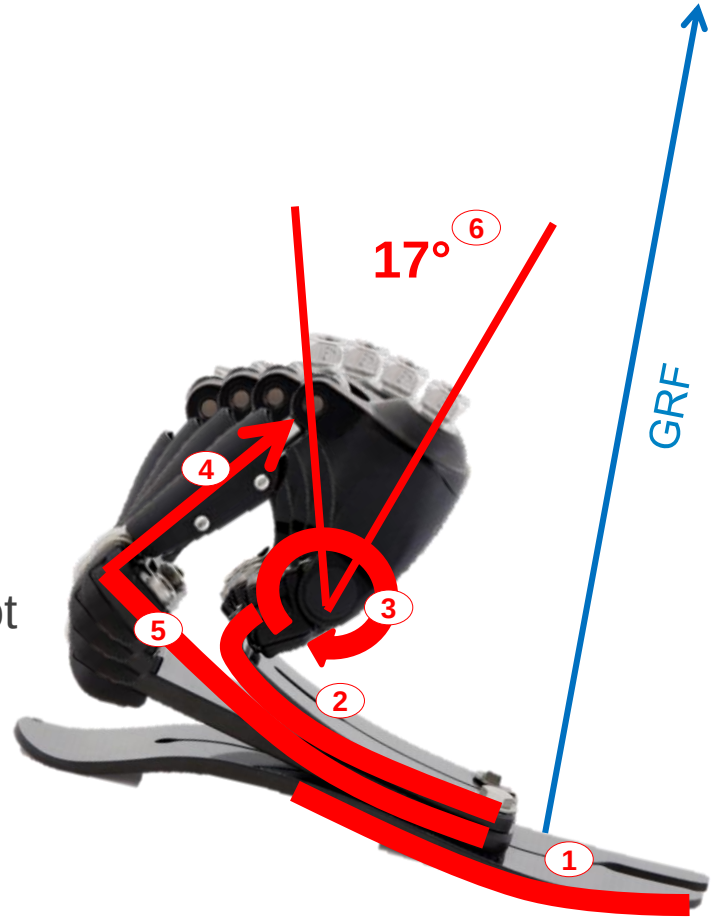
Terminal Stance

1. Sole blade compresses storing energy
2. Upper blade compresses storing energy

So far, just like a normal ESAR Foot

In addition Pro-Flex provides:

3. Forward rotation around main pivot
4. Back-link “pulls” mid-lever up
5. Mid-lever deflects upward
6. 17° real dorsiflexion



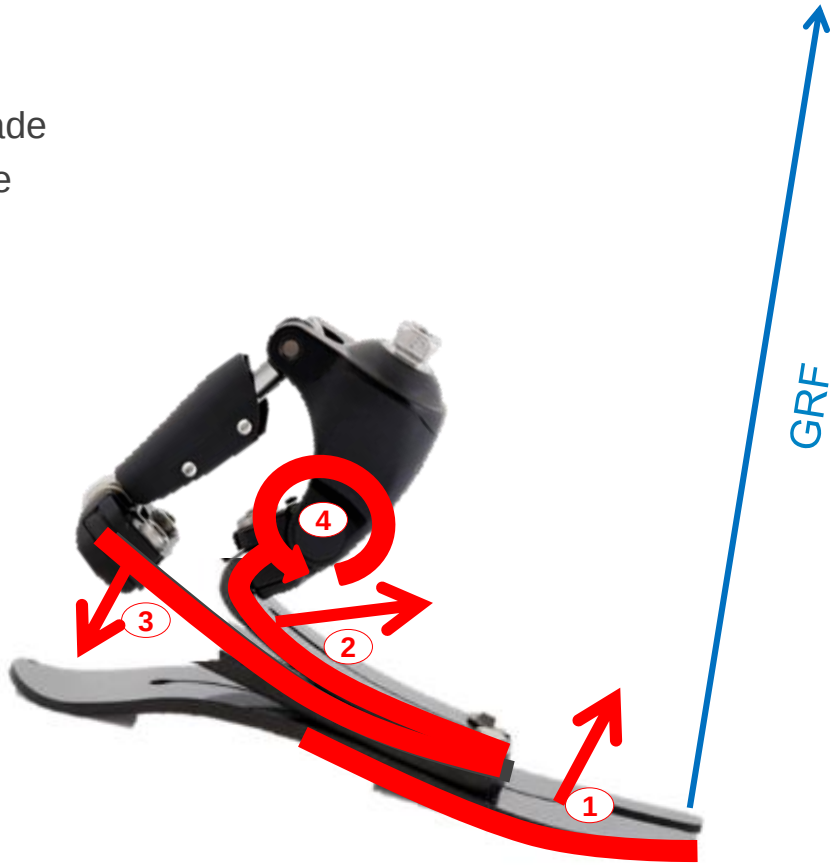
Push-Off

1. Energy return from the compressed sole blade
2. Energy return from compressed upper blade

So far, just like a normal ESAR Foot

In addition Pro-Flex provides:

3. Mid-lever creates active plantarflexion moment
4. Main pivot undergoes backward PF-torque



Push-Off

1. Energy return from the compressed sole blade
2. Energy return from compressed upper blade

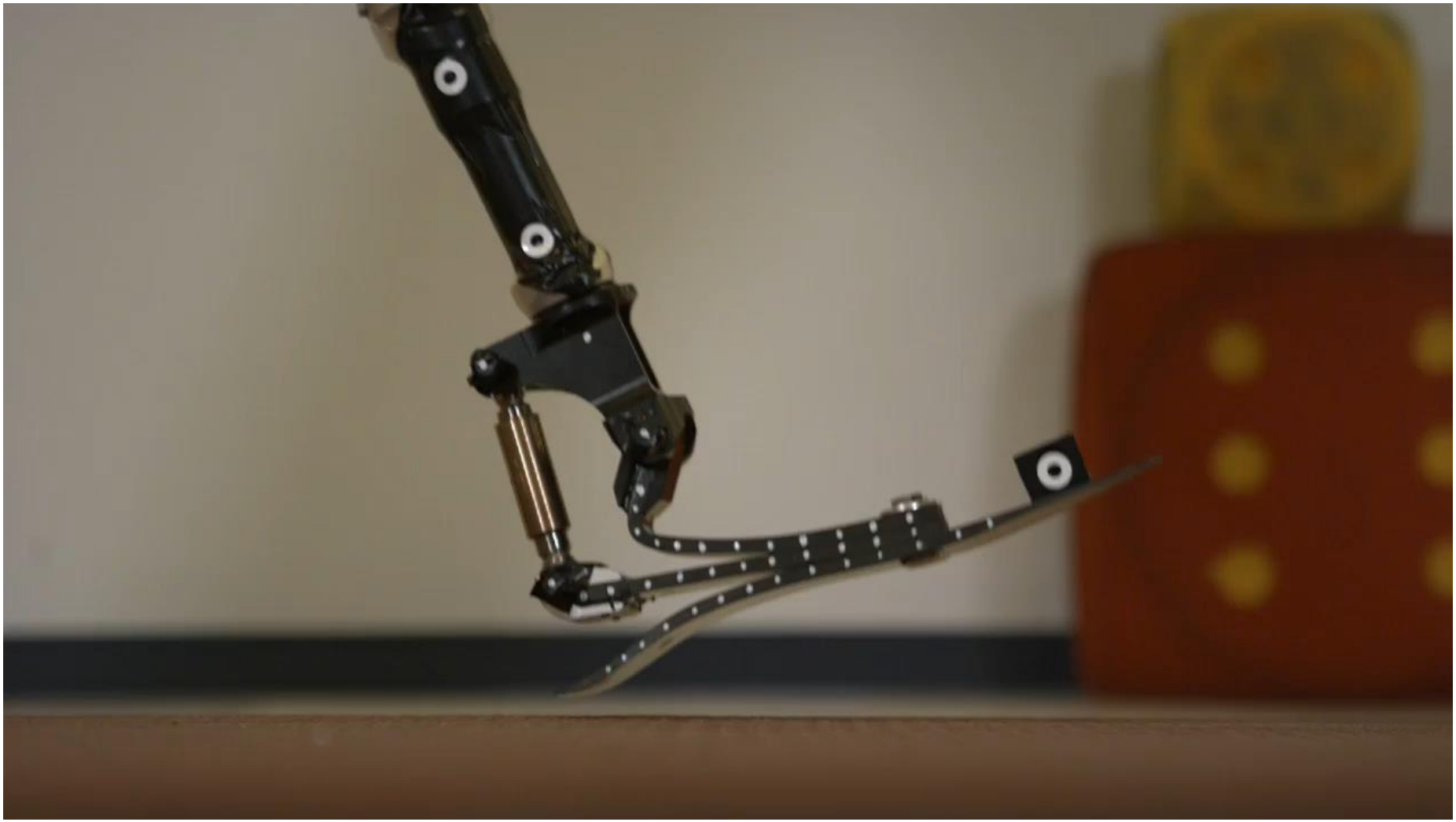
So far, just like a normal ESAR Foot

In addition Pro-Flex provides:

3. Mid-lever creates active plantarflexion moment
4. Main pivot undergoes backward PF-torque
5. At toe-off the mechanically powered ankle generates 2.9W/kg*

***93% more than ESAR feet (1.5W/kg)**
***only 12% less than BIOM (3.27W/Kg)**

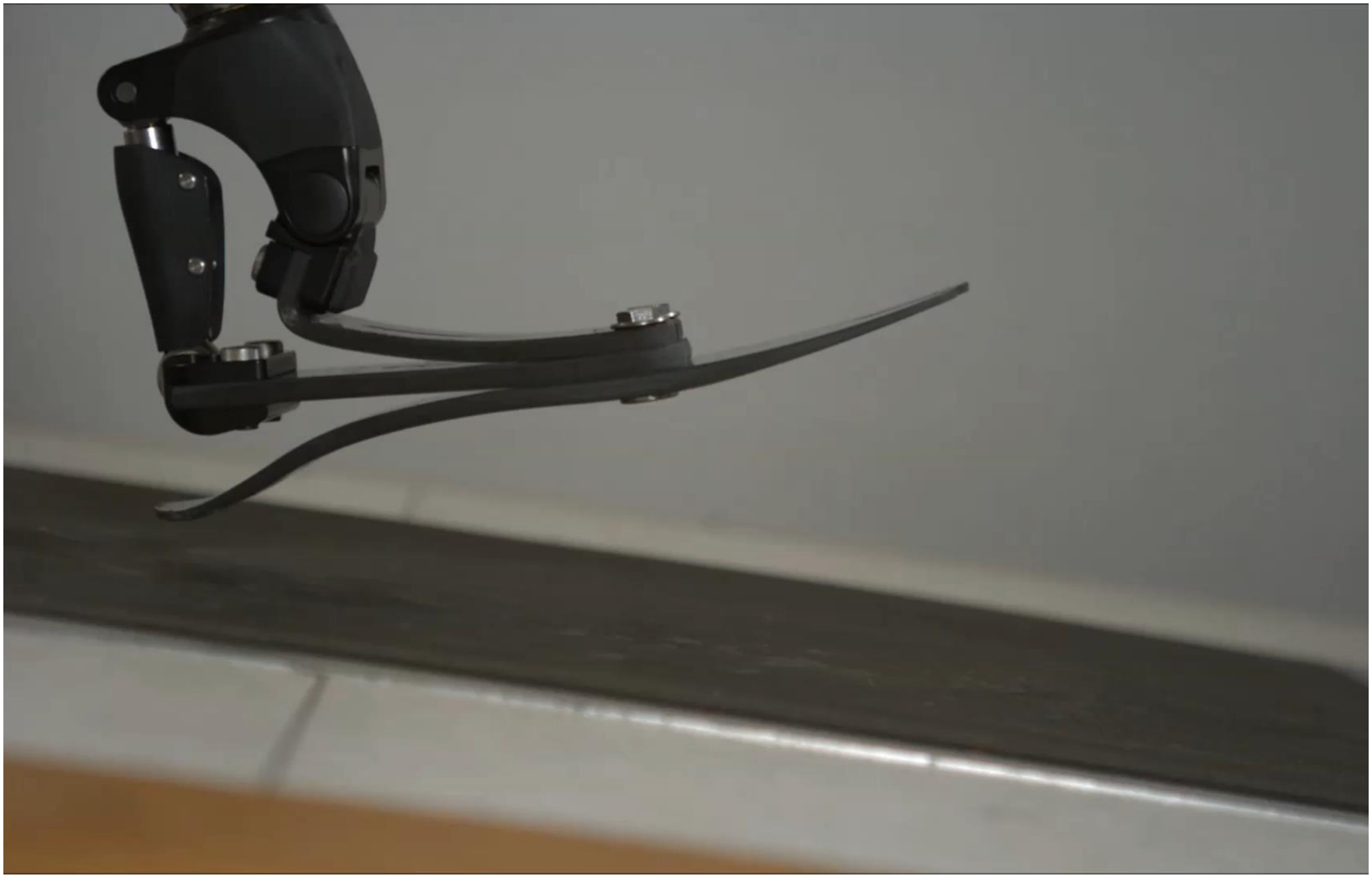
Pro-Flex® Mechanics



Pro-Flex® Stair ascent

Pro-Flex® Ramp ascent

Pro-Flex® Ramp descent



Ramp ascent and descent

More physiological ankle motion (increased ROM with progressive moment)

Significant increase in ankle range of motion with 11 users: **Pro-Flex vs. Vari-Flex**

Condition	involved side ankle ROM in stance [deg] PF	CF	involved side peak ankle moment in stance [Nm/kg] PF	CF	peak ankle power in stance [W/kg] PF	CF	sound side peak vertical GRF 0-30% of GC [N/kg] PF	CF
Level ground	27.7* (5.2)	15.2 (1.9)	1.2* (0.2)	1.1 (0.2)	2.9* (0.9)	1.5 (0.3)	11.0# (1.6)	12.4 (1.3)
Ramp decent	25.4* (5.2)	12.4 (1.7)	1.1* (0.2)	0.9 (0.2)	2.5* (0.8)	1.0 (0.3)	13.1# (1.5)	14.2 (1.6)
Ramp ascent	25.8* (5.3)	14.0 (1.8)	1.3* (0.2)	1.1 (0.2)	2.6* (0.8)	1.3 (0.4)	11.3# (1.4)	12.2 (1.3)

Table 1: Involved sides prosthetic ankle kinematics and kinetics in stance and sound sides peak vertical ground reaction force (GRF) for 0-30% of the gait-cycle (GC)
*mean values (SD); ROM = range of motion; GC = gait-cycle; PF = prototype foot; CF = conventional foot; * = significant increase for PF (all p values <0.005) ; # = significant reduction for PF (all p values <0.005)*

Evaluation of a novel prosthetic foot while walking on level ground, ascending and descending a ramp
Heitzmann, D.W.W. et al. Gait & Posture, Volume 42, S94-S95
Department of Orthopedics and Trauma Surgery, Heidelberg University Hospital, Heidelberg, Germany

More physiological ankle power

Mechanical testing aim: separate stiffness measurement for ankle motion depending on location in stance phase

- Low stiffness around mid-stance: reduce moment and pressure on the residual limb
- Higher stiffness in late stance: create higher ankle power

The high energy return along with progressive stiffening, similar to what seen in anatomical ankle, is an indication of a powerful push-off during late stance.

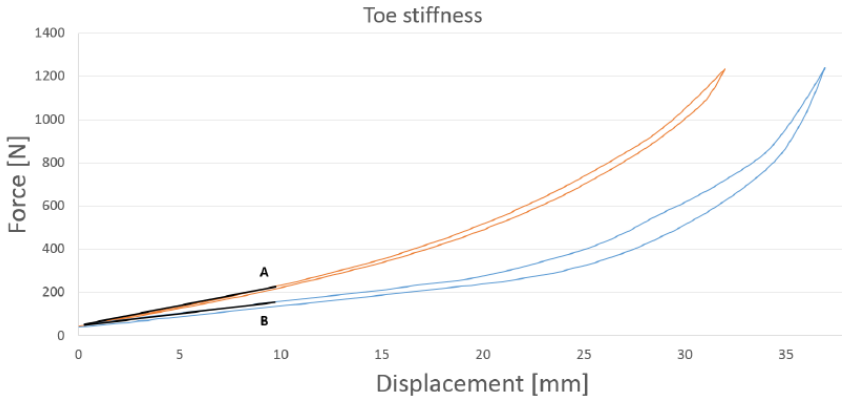


Figure 1: Stiffness curves for Pro-Flex™ (B) and Vari-Flex® (A). The black lines show the linear part of each curve.

More physiological ankle power

Significant increase in peak ankle moment and peak ankle power with 11 users

	ankle ROM in stance [deg]		involved side peak ankle moment in stance [Nm/kg]		involved side peak ankle power in stance [W/kg]		sound side peak vertical GRF 0-30% of GC [N/kg]	
Condition	PF	CF	PF	CF	PF	CF	PF	CF
Level ground	27.7* (5.2)	15.2 (1.9)	1.2* (0.2)	1.1 (0.2)	2.9* (0.9)	1.5 (0.3)	11.0# (1.6)	12.4 (1.3)
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Reduced load and impact on sound side (effectively protects sound side)

Significant reduction in peak impact on the sound side with 11 users

	involved side						sound side	
	ankle ROM in stance [deg]		peak ankle moment in stance [Nm/kg]		peak ankle power in stance [W/kg]		peak vertical GRF 0-30% of GC [N/kg]	
Condition	PF	CF	PF	CF	PF	CF	PF	CF
Level ground	27.7* (5.2)	15.2 (1.9)	1.2* (0.2)	1.1 (0.2)	2.9* (0.9)	1.5 (0.3)	11.0# (1.6)	12.4 (1.3)
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Reduced load and impact on sound side (effectively protects sound side)

- Osteoarthritis in the sound side knee joint of amputees is 17x higher than in age-matched non-amputees and knee pain is 2x as common[1]

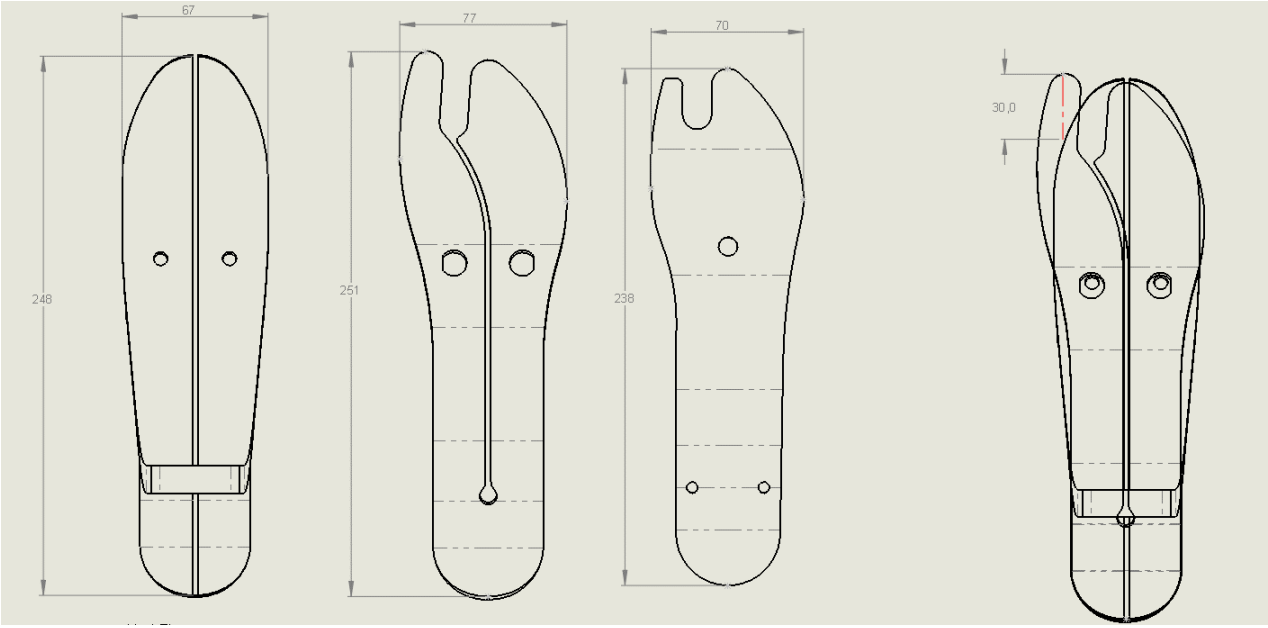
- Reduction of sound side loading and sound side knee external coronal varus moment

- Pro-Flex® is tackling the two principal mechanical causes of knee OA for people with limb loss, helping to enhance gait symmetry and **reducing peak impact by 11% and reducing the knee varus moment by 15%.**

[1]Struyf, Pieter A., et al. "The prevalence of osteoarthritis of the intact hip and knee among traumatic leg amputees." Archives of physical medicine and rehabilitation 90.3 (2009): 440-446.

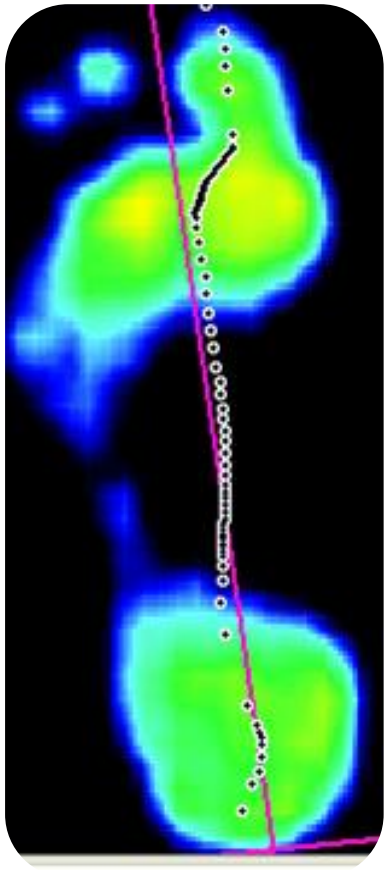
Pro-Flex® Sole Blade

- Sole blade offers **longer effective foot length** for push off and control
  - 12mm longer than Talux sole blade
  - 30mm longer than Vari-Flex, active big toe support
- **Split from the mid-foot section to the forefoot**
- **Wider sole blade offers increased stability**

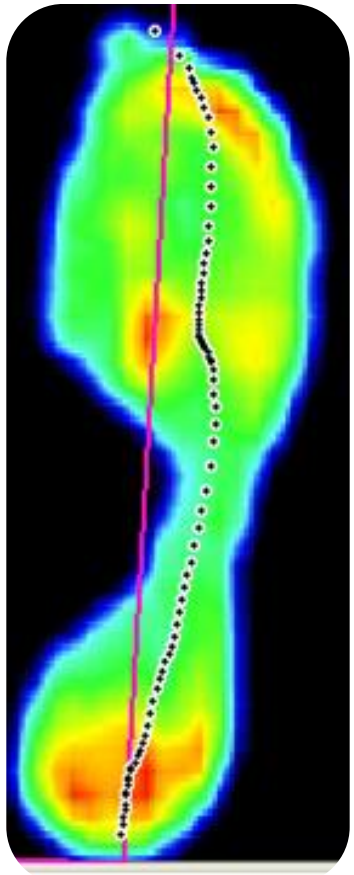


Clinical Benefits / Functional Outcome

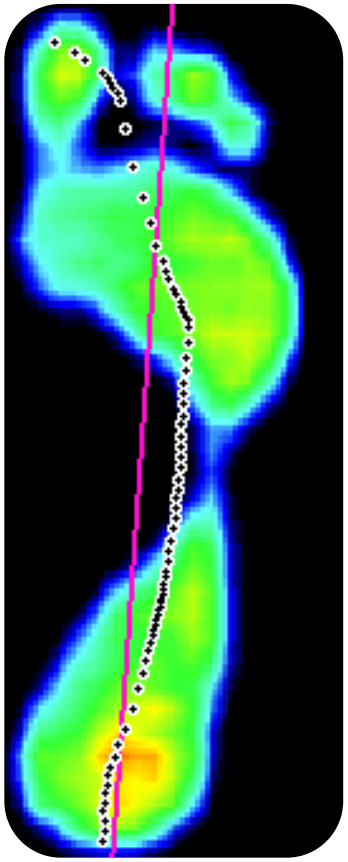
Co-morbidity



Sound side



Vari-Flex



Pro-Flex

User Profile

- Transtibial, Knee disarticulation, Transfemoral, and Hip disarticulation amputees
- K-level: K2 and K3
- Impact level: Low to Moderate
- ADL's and recreational activities like hiking (uneven ground, ramp surfaces, stairs)
- Weight limit: 125 kg
- **Pro-Flex is NOT intended for high impact use**

Pro-Flex® – NEW EVA foot cover design

	Waterproof
	Shoe fit
	Anatomical features
	Lightweight
	Curved opening
	Full length toe
	Sandal clamping
	Friction
	Washable
	Toe nails
	Black spectra sock

EVA (Ethylene Vinyl Acetate): Extremely elastic copolymer with excellent toughness properties

FOOT COVER KIT, BEIGE AND BROWN*

PART#

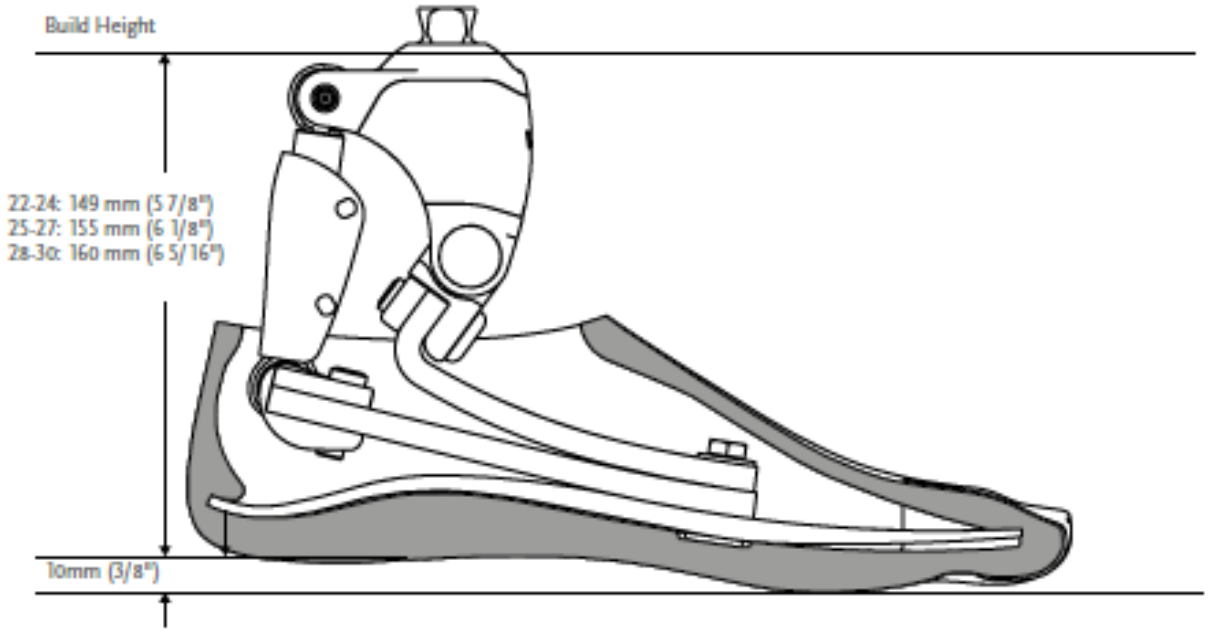
FST0 — FOOT SIZE (22-30) — L/R (LEFT/RIGHT)

Includes:
- Foot Cover*
- Foot Cover Attachment
- Black Spectra Sock

*Note: Please specify when ordering brown covers, add "BR" to the part#.

Technical Details

- **CAT 1-7 – Selection is important – use chart specific to Pro-Flex**
- Male pyramid
- Weight of foot with foot cover: 920 g
- Weight of foot cover: 165 g
- Build height: 155 mm
- Foot size: 22–30
- 125kg weight limit
- Low-mod impacts

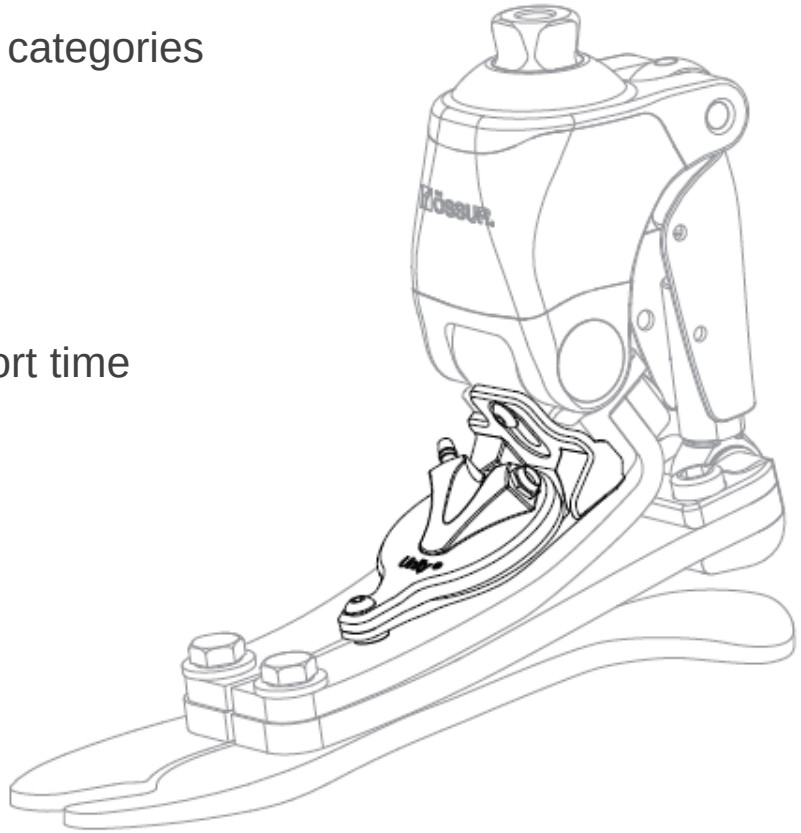


- Vari-Flex: 700g, 170 mm

Unity® for Pro-Flex®

- Mechanical, sleeveless Elevated Vacuum Suspension
- Lightweight
- No extra build height
- ONE retrofitable pump for all foot sizes and categories

- Contraindications:
  - Wide sockets
  - Reliefs in sockets
  - Great volume reduction expected in short time



Pro-Flex® & the Unity® system

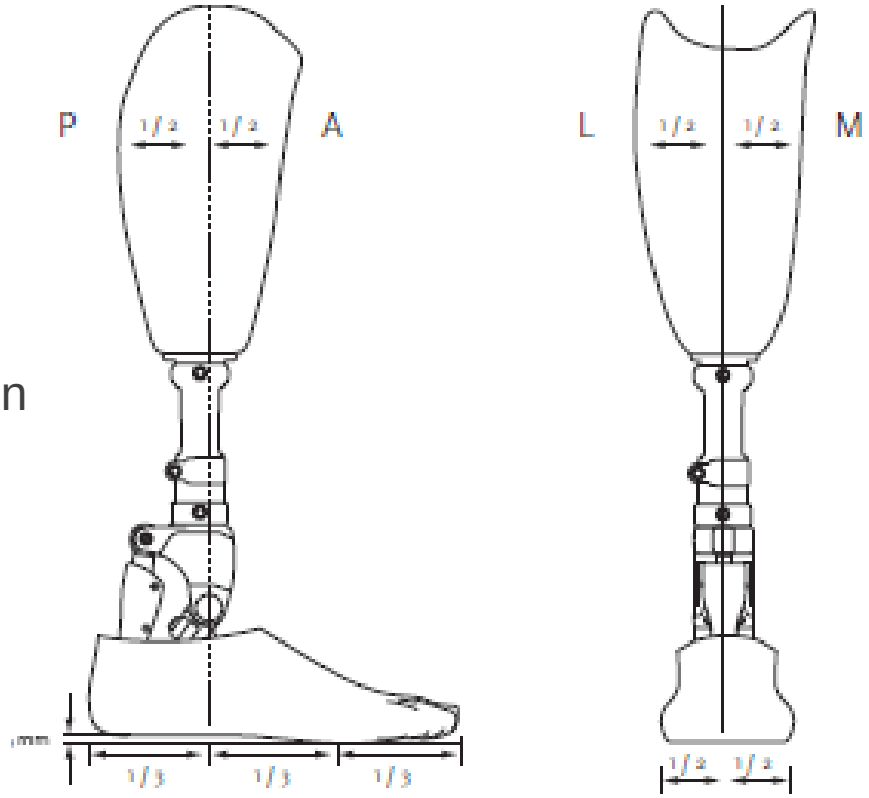
Unity™

- **SLEEVELESS:** Increased knee flexion range with greater comfort and user acceptance
- **LIGHT WEIGHT AND DISCREET:** 130g added weight and housed within foot shell
- **SIMPLE AND EFFICIENT:** Quick and easy to elevate and release vacuum levels
- **INDEPENDENT PUMP:** Not dependent on shock mechanisms and can be added to a wide range of performance Flex-Foot systems to meet every mobility need.
- **VOLUME STABILISATION:** Optimizes socket stability, proprioception and comfort throughout the day while limiting the need to add socks
- **INCREASED RELIABILITY:** Minimizes risk of leaks and puncture issues associated with sleeve dependent vacuum methods
- Integrates **PERFORMANCE FLEX-FOOT** technology to meet all activity requirements

Fitting Procedure

Bench alignment

- Adjust to appropriate heel height, including the shoe
- Introduce appropriate socket angles: flexion/extension and abduction/adduction
- The load line should fall on the posterior 1/3 line



Fitting Procedure

Static alignment:

- User stands with equal weight on both feet
- Pelvis level
- Check Length

Dynamic alignment:

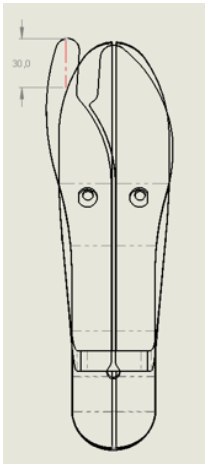
- Foot provides progressive energy storing during whole stance phase and a powerful push-off at the end of stance
- The heel to toe action can be influenced by:
  - Shoe performance
  - A-P positioning of foot
  - Dorsi-Plantarflexion
- **DO NOT USE ANY HEEL WEDGE WITH PRO-FLEX®**

Note: For transfemoral users, please follow alignment recommendation of corresponding knee joint.

Pro-Flex® LP

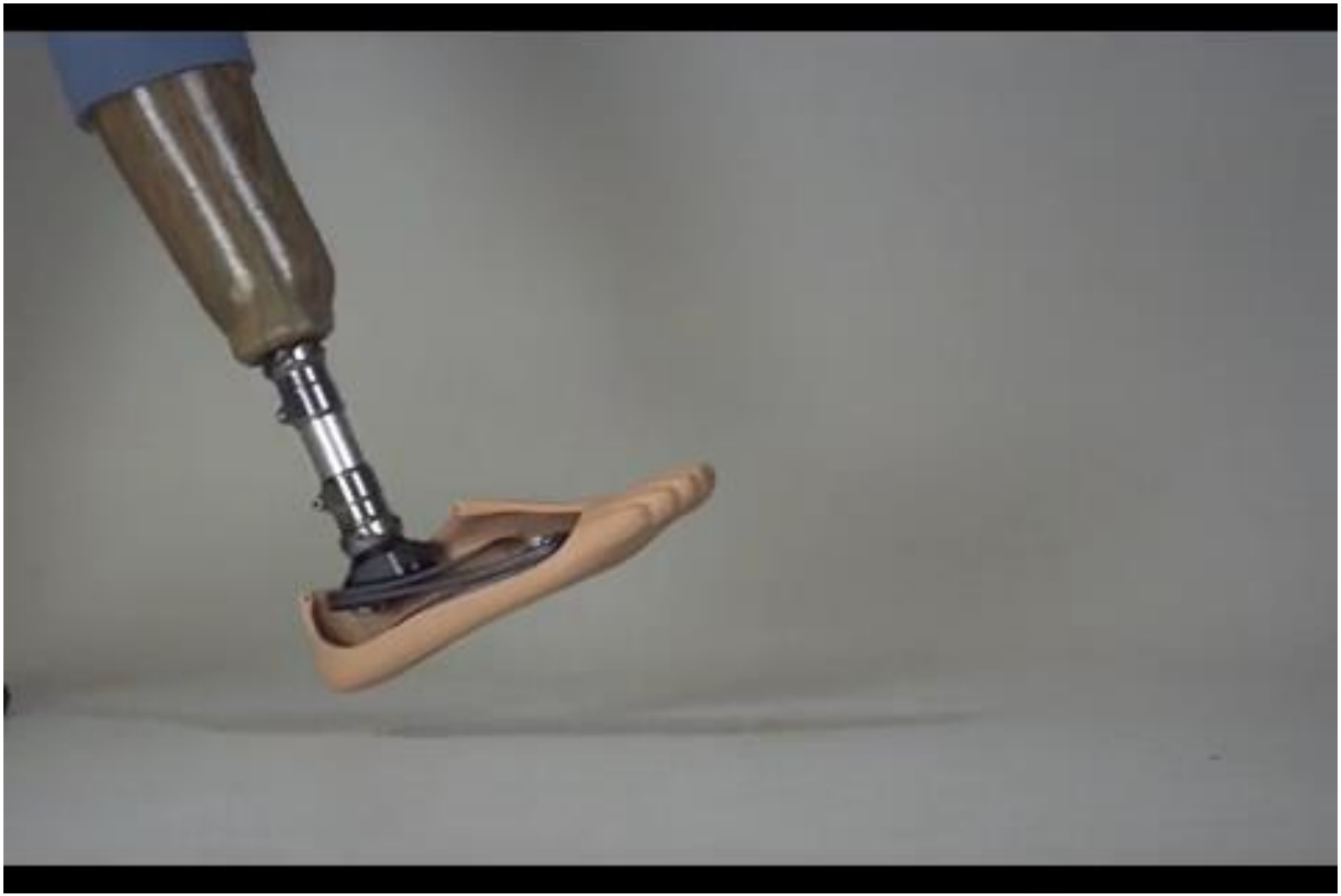
Unity Compatible

- Pro-Flex® LP offers greater ankle range of motion than other feet with low build height (LP Vari-Flex)
- Improved physiological gait
- Increased function and satisfaction



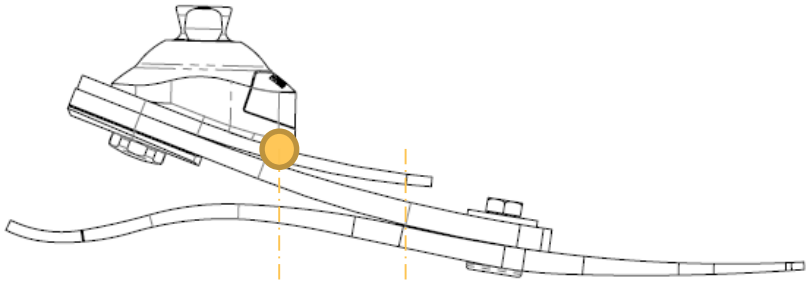
Pro-Flex® LP is recommended for clients up to 166kg with longer residual limbs (where clearance is an issue) and moderate to high impact levels.

Level ground walking

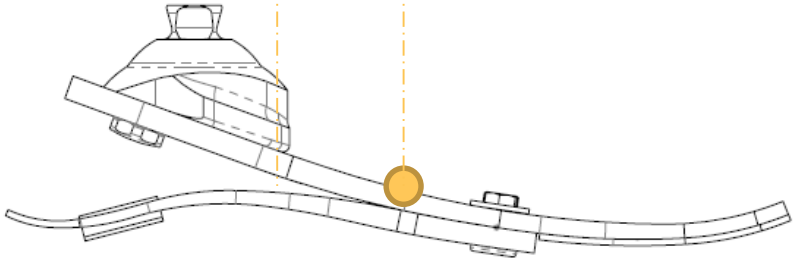


Pro-Flex® LP

Pro-Flex® LP



LP Vari-Flex



Pro-Flex® LP introduces a patent pending blade lay-up technology.
Mid-blade is reversed tapered allowing more flex anteriorly.

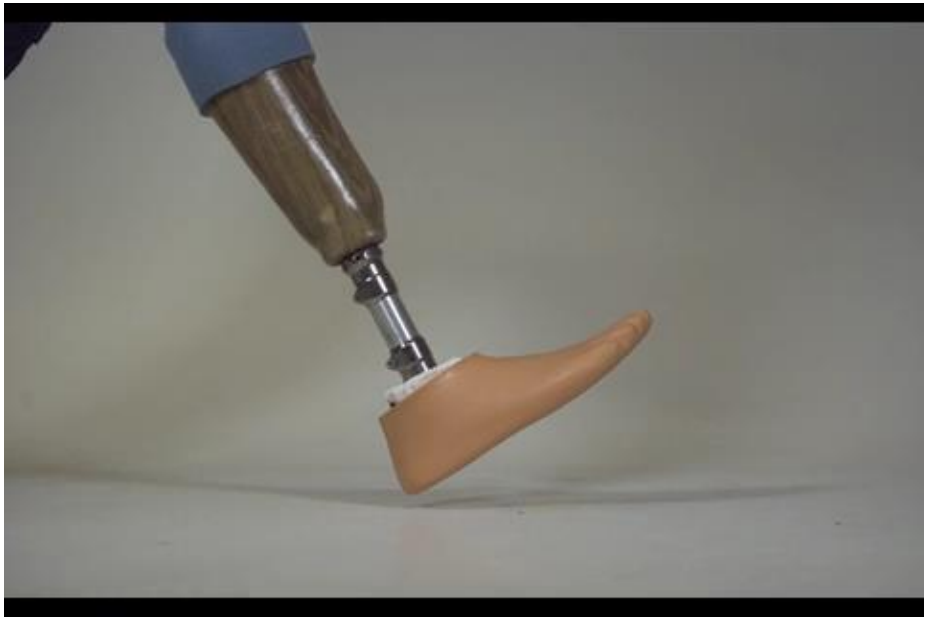
Posterior part of the mid-blade is thinner and gets gradually thicker anteriorly towards the sole blade attachment bolts.

Sketch shows approximate location of the functional ankle joint center of Pro-Flex® LP and LP Vari-Flex.

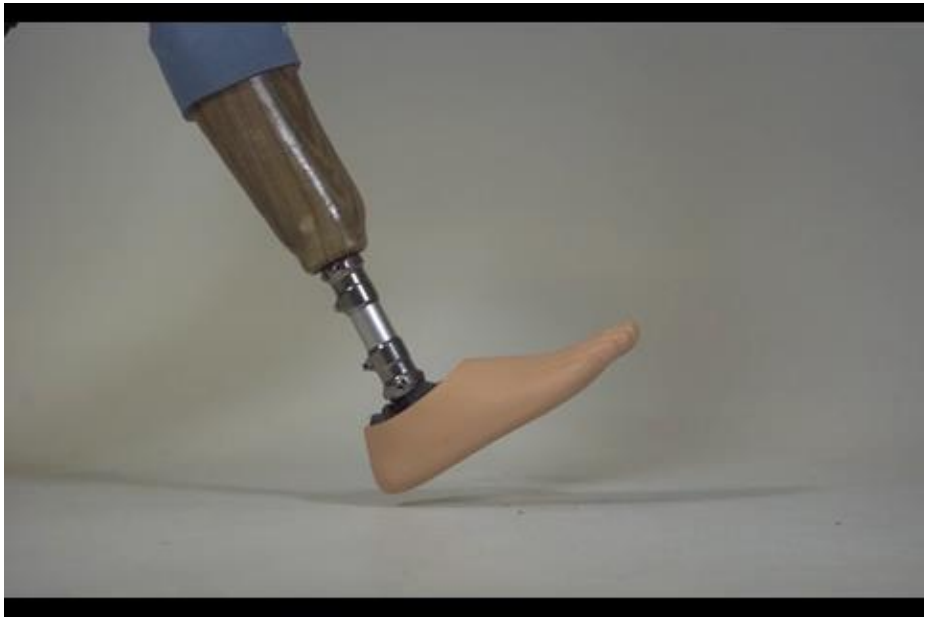
Level ground walking

- Foot flat
- Range of motion

LP Vari-Flex

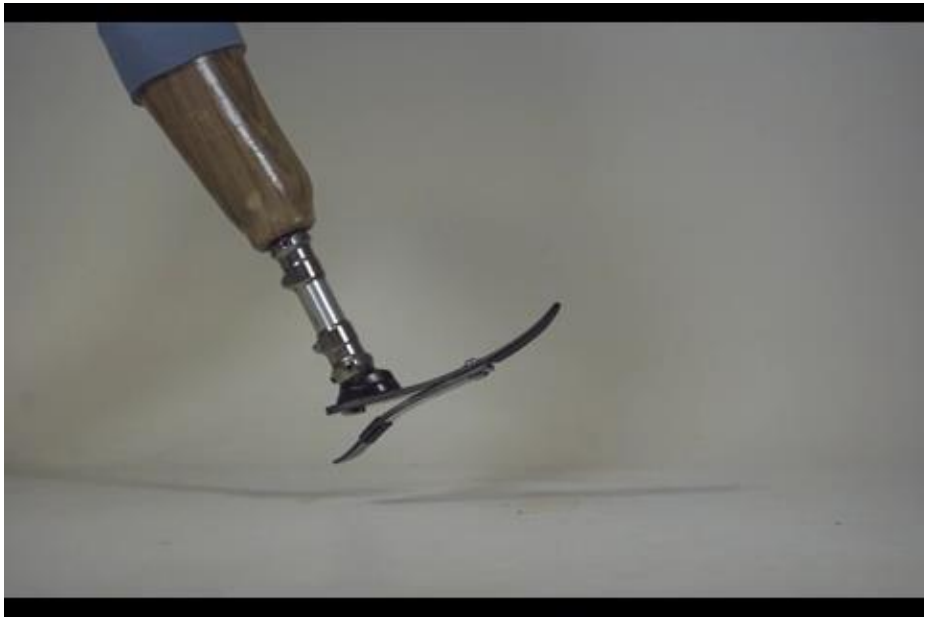


Pro-Flex® LP

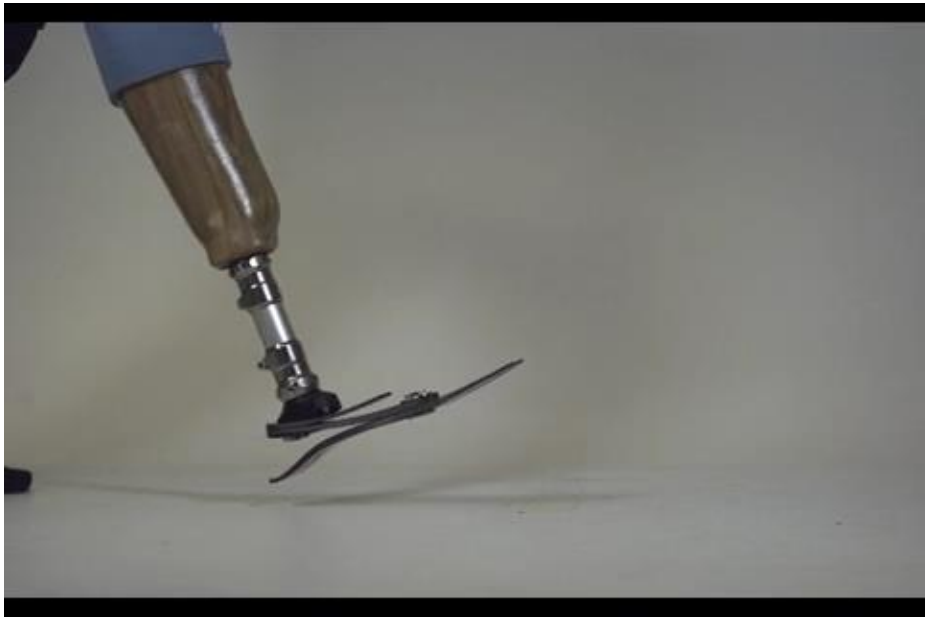


Level ground walking

LP Vari-Flex

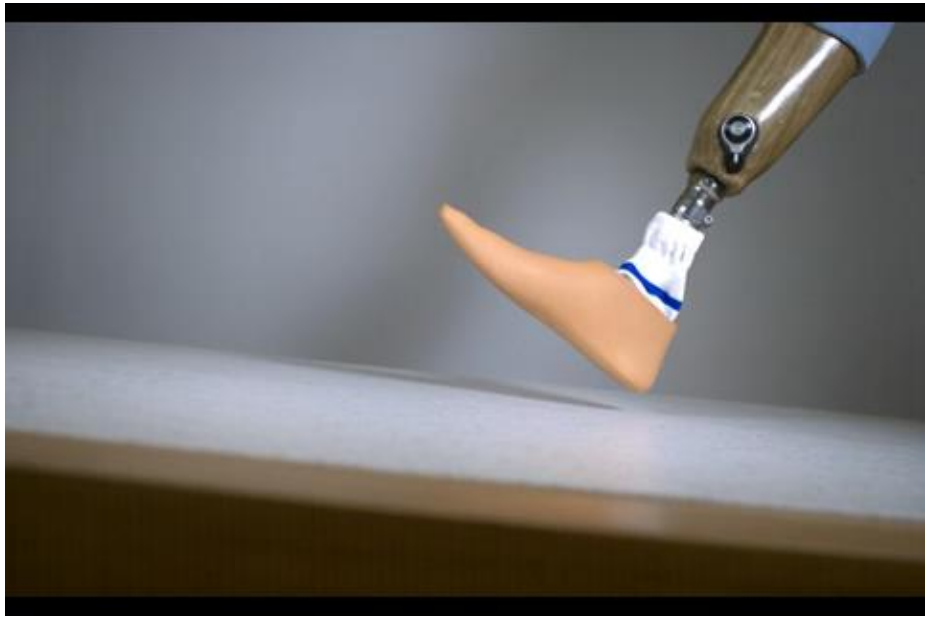


Pro-Flex LP

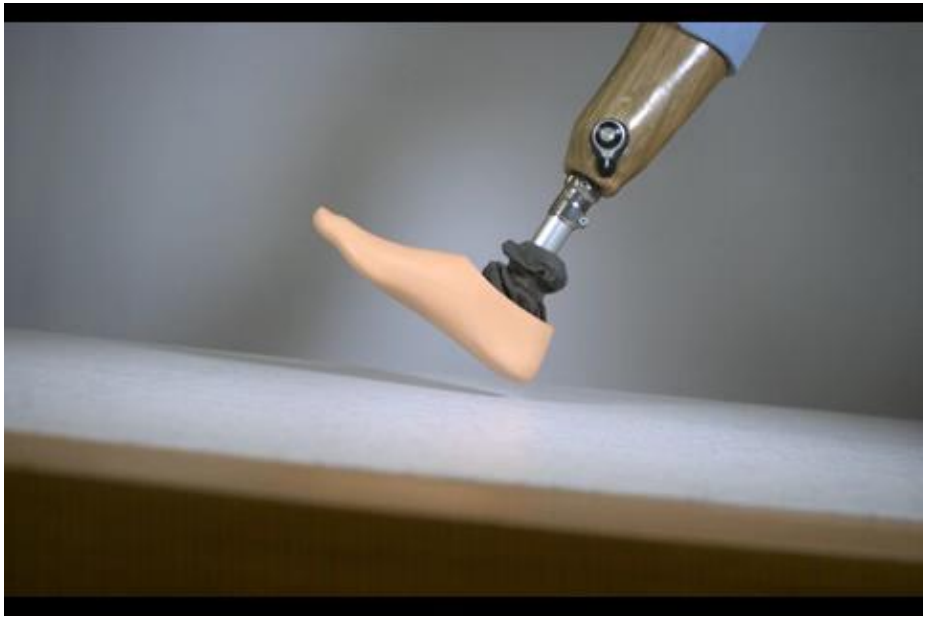


Ramp ascent

LP Vari-Flex



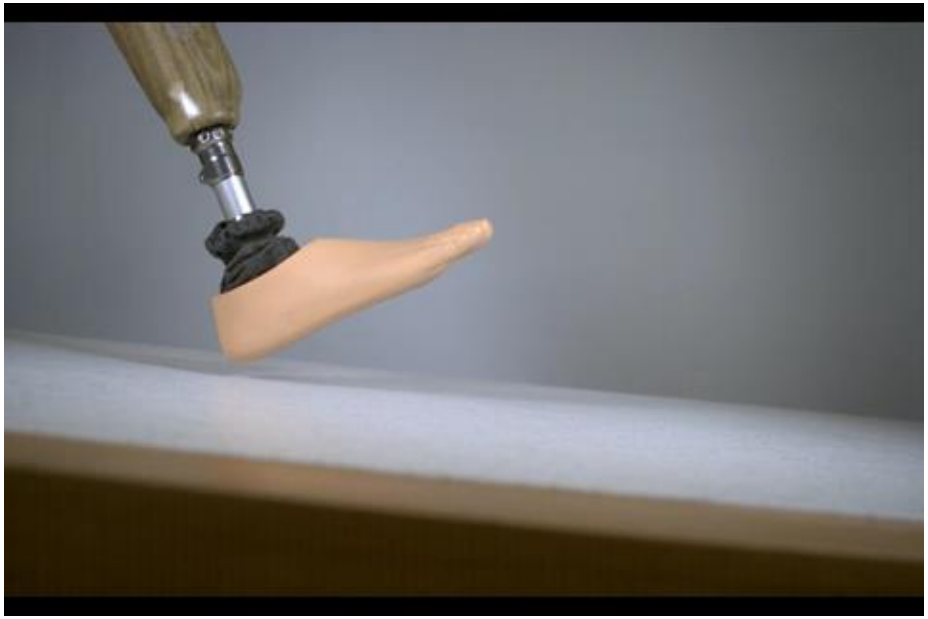
Pro-Flex® LP



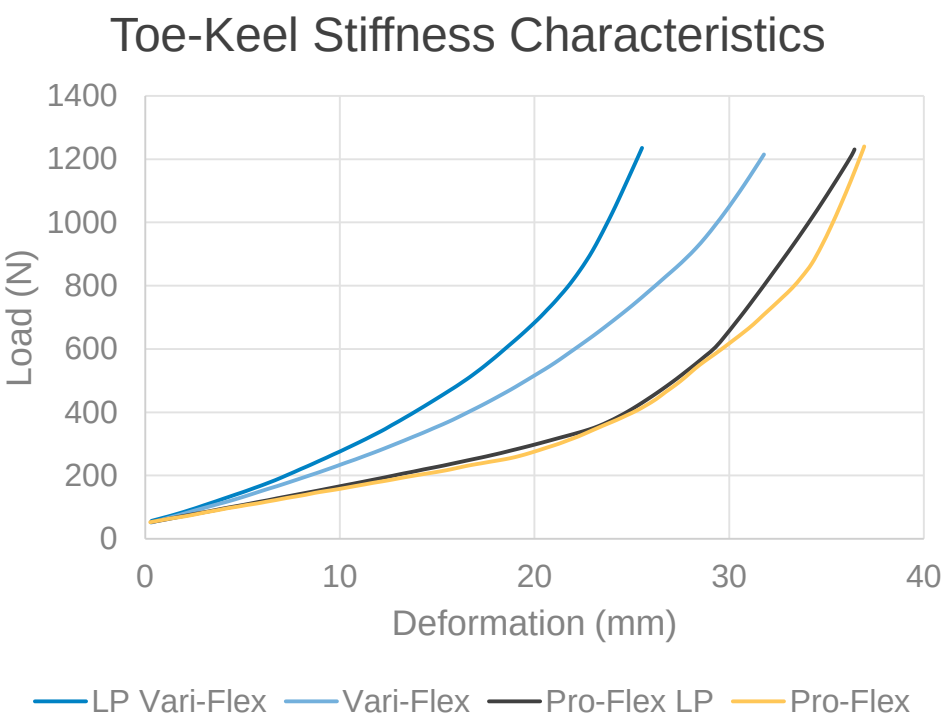
Ramp descent

LP Vari-Flex

Pro-Flex® LP



Test Results



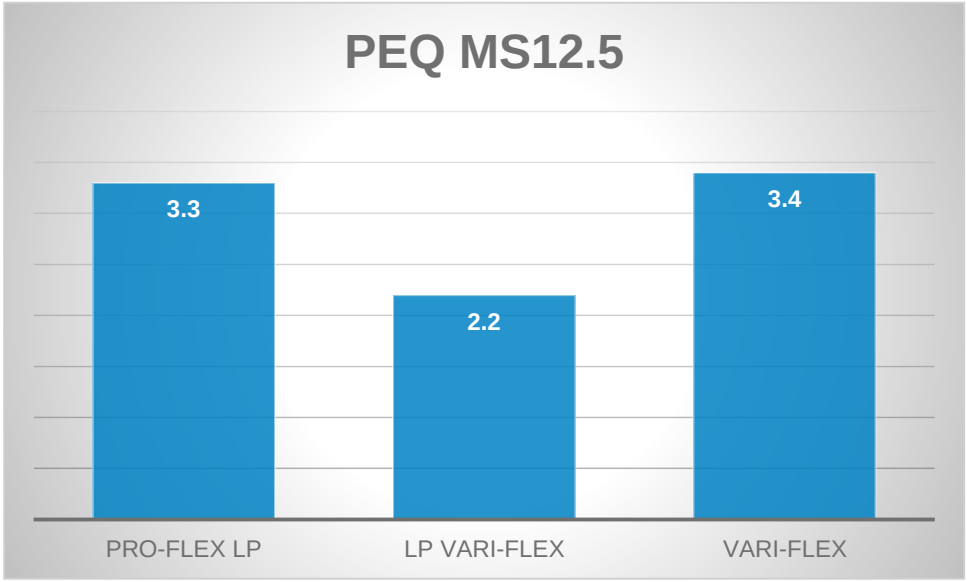
All samples cat 5 size 27 tested with foot cover.

- **Progressive stiffness** of Pro-Flex® LP
- **Much lower stiffness during the first part** of the loading curve for Pro-Flex® LP compared to LP Vari-Flex
- Clinically, this indicates:
  - lower resistance to initial dorsiflexion for Pro-Flex® LP, meaning **less moment needed** from the residiual limb to load the foot
  - higher displacement for the Pro-Flex® LP indicates **more ankle range of motion** with the same load.

Test Results

- Greater user satisfaction when compared to LP Vari-Flex (almost equal to Vari-Flex)*

- User comments:
  - feels like foot has more give to it
  - lot of energy in toe
  - very smooth
  - roll-over feels more natural



*testing performed on 4 users indicates differences between feet.

Pro-Flex® XC

Unity Compatible

- Increased ankle motion and reduced sound side loading when compared to Vari-Flex
- **Similar ankle motion & sound side loading when compared to Vari-Flex XC**
- **Improved roll-over when compared to Vari-Flex XC**
- **Easier to cosmetically finish than Vari-Flex XC**
- Increased Functioning and Satisfaction when compared to Vari-Flex and Vari-Flex XC

Pro-Flex® XC is recommended for clients up to 166kg that engage in moderate to high impact levels activities on a regular basis.

RHEO KNEE® 3 and RHEO KNEE ® XC

Stability and Dynamics, Whatever the Weather

Weatherproof Design






A weatherproof device allows the use in a wet and/or humid environment but does not allow submersion. Fresh water splashing against the enclosure from any direction has no harmful effect.

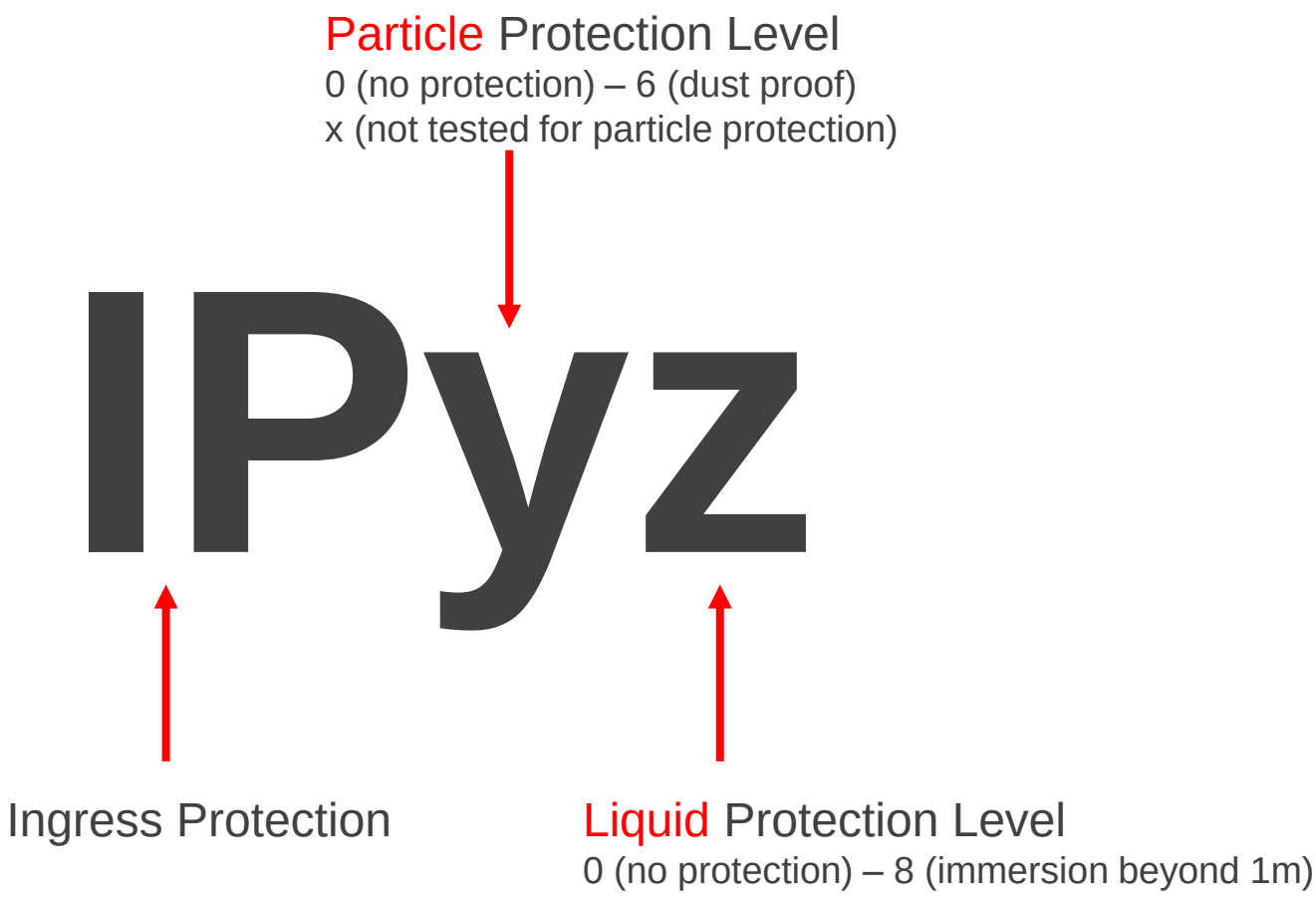
Weatherproof Design

RHEO KNEE 3 and XC are rated: IP34

- **3:** Protected from solid objects greater than 2.5mm
- **4:** Water splashing against the enclosure from any direction shall have no harmful effect

- Possible scenarios:
  Condensing environments, ambient humidity and fog, spilling water, splashing water and heavy rain

Weatherproof Design



PLEASE NOTE: The IP standard only describes the ingress protection level of electronic devices. It does not cover the mechanical parts of a product.

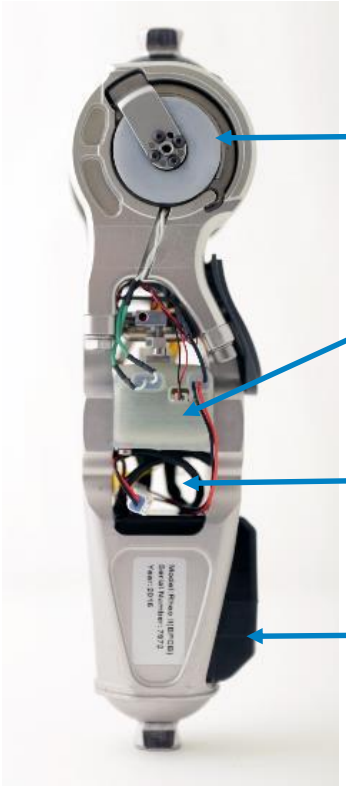
Weatherproof Design

Coated angle sensor

Water proof vibrator

Silicone plugs around wires

Water proof battery connector



Coated spring

Redesigned electronics in closed box

Water protection of load cell wire

Enclosed battery pack

Water resistance testing

Setting up Bluetooth connection is easy

Standard

Bluetooth

RHEOLOGIC

Low Energy

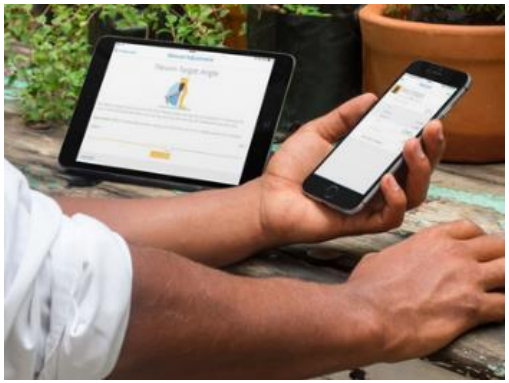
Bluetooth

Össur Logic

Össur Logic / RHEOLOGIC Software

RHEO KNEE 3 is accompanied by the RHEO KNEE CPO software and includes two Bluetooth communication channels:

- Standard Bluetooth
- Bluetooth Low Energy, which allows wireless connection with iOS devices



RHEO KNEE CPO software is available for Windows and iOS:

- **Össur Logic***: Available in the AppStore (requires iOS8 or higher)
  Customer number required to get access to full CPO version
- **RHEOLOGIC***: Online distribution center (via email) for downloading to Windows PCs

***Both versions include exactly the same functions. However, Össur Logic is formatted with instructions for each adjustment – hints on how to adjust the parameter.**

***To connect through Össur Logic, the pairing code is the full six-digit serial number of the product. For Rheologic, use ONLY the last 4 digits of serial number.**

Össur Logic

The Össur Logic app requires iOS 8.0 or later and is compatible with:

iPhone

iPhone 4s
iPhone 5
iPhone 5c
iPhone 5s
iPhone 6
iPhone 6 Plus

iPad

iPad 2
iPad 3rd generation
iPad 4th generation
iPad Air
iPad mini
iPad mini with Retina display

iPod

iPod touch 5th generation

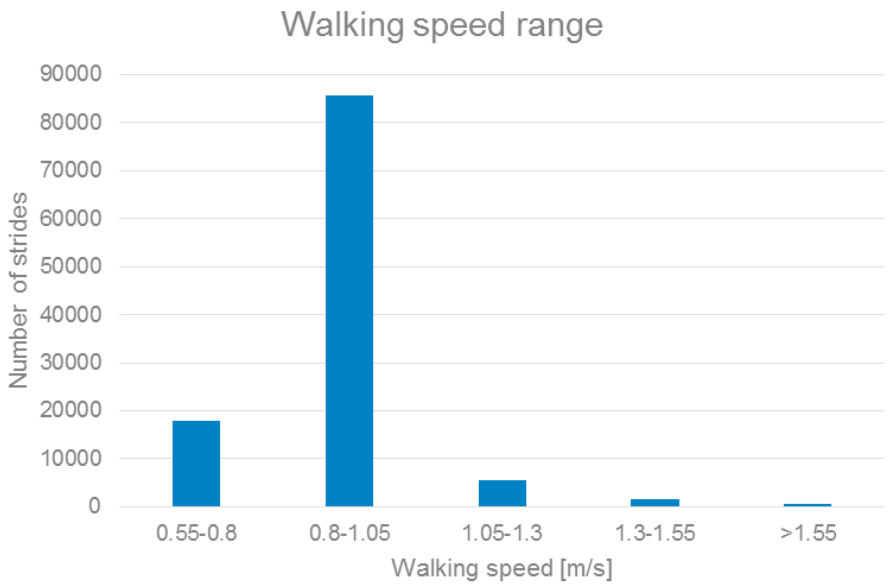
Össur Logic – Expert App

CPO Functions

- Calibration
- Loading
- Auto adjustment
- Manual adjustment
- Activity report
- Battery status
- Step count
- Knee angle
- User information
- Instructions for use
- Firmware version

Activity reports include:

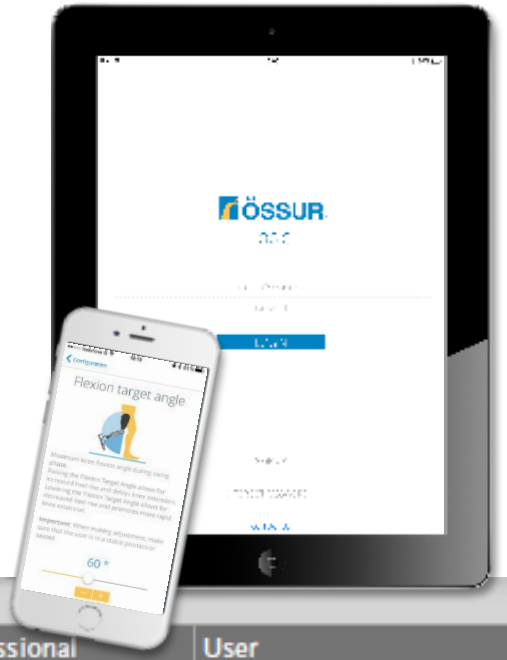
Total step count since last reset	✓
Walking speed distribution	✓
Average walking speed	✓
Activity report PDF	✓



Össur Logic – User App

RHEO KNEE 3 users can access:

- Battery status
- Charging status
- Step count
- User information
- Instructions for Use (link)
- Firmware version
- Alarms and alerts (link)



- **ÖSSUR LOGIC** - RHEO KNEE 3 comes with software that enables professionals and users to access valuable reports and adjust system settings to suit their needs*. Software is available for both PC and iOS devices (iOS8 or later), and communicates wirelessly with iOS devices via Bluetooth.

Professional	User
Step Count	Battery Status
Walking Speed Distrib	Battery Charging Status
Avg Walking Speed	Step Count
Activity Report PDF	Links to alarms, alerts and IFUs

* License code required for professional access

RHEO KNEE® XC

RHEO KNEE XC offers increased functionality for the more demanding prosthetic user without compromising RHEO KNEE's unique combination of stability and dynamics.

Featuring a weatherproof design, improved gait dynamics, **stair ascent**, **running** and **automatic cycling recognition**. RHEO KNEE XC is the affordable microprocessor-controlled prosthetic knee for the more demanding prosthetic user.

Stair Ascent Mode: step-over-step

Requires:

- >25° knee flexion and loading to engage mode
- Activates swing extension stop at 25° flexion
- Prevents hitting next step and pre-positions foot for loading

Stair Ascent strategies:

- Prosthetic side first
- Sound side first

Training is needed to achieve proficiency:

- Rhythm / timing
- Posture
- Loading the prosthesis
- Hip extension & flexion control
- Confidence

Stair Ascent Mode: step-over-step
Sound side first

Results: Stair Assessment Index

- The Stair Assessment Index (SAI) is a 14 level scale that assesses the functional ability of transfemoral amputees for stair ascent and/or descent. The assessment is performed by a clinical professional.
- The SAI was carried out for each participant using their own microprocessor knee (baseline). The assessment was repeated using RHEO KNEE XC once the users had had three weeks of experience using the new knee (3 weeks).
- The results related to this test can be attributed to the automatic stair ascent mode.
- These results only apply to RHEO KNEE XC.

Results: Stair Quality Index

The Stair Quality Index improved when using the RHEO KNEE XC ascending stairs. The improvements measured when ascending stairs are statistically significant (*).

Baseline	Own prosthesis	5,69
3 weeks	RHEO KNEE XC	8,75*

RHEO KNEE XC allows for step over step stair climbing with easy, smooth transitioning into and out from the stair cases.

Advanced actuator and resistance control ensure best possible resistance in all activities, including stairs.

Genium users that did not use the stair ascent feature on a daily basis where able to use the stair ascent with the RHEO KNEE XC. **It was easier to trigger the stair mode.** Being quicker and easier to learn increases the potential to actually use the feature.

Automatic Cycling Recognition

- Enter the cycling mode:
  - 2 rotations with minimum load on the knee.
  - One long beep confrmation: your are in cycling mode

  → The knee moves freely with no resistance during cycling mode supporting a wide range of cadence and activity levels and efficient power transfer to the pedals.

- Exit the cycling mode:
  - Extending the knee to 15 degrees of flexion or less
  - One short beep confirmation: you are out of the cycling mode

- Correct saddle/pedal height: The knee should not fully extend during pedaling

Running Mode

The RHEO KNEE XC has been designed and tested for intermittent running, typical in the everyday active life.

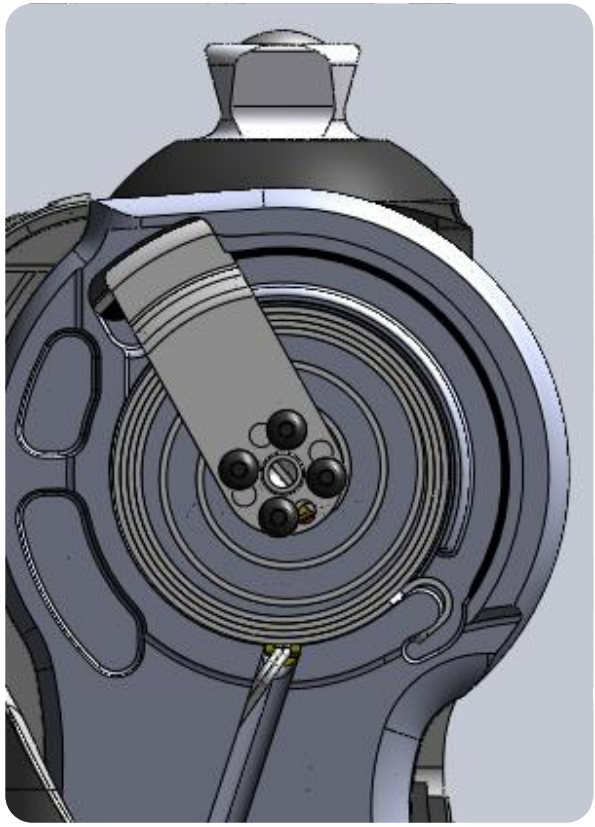
- User weight <110 kg
- Activates when stance time is < 0.3s
- Automatic – no mode switching required
- During running: the stair ascent step-over-step is blocked.
- Tested at speeds up to 12.6 km/h
- Recommended feet:
  - Re-Flex Shock
  - Re-Flex Rotate
  - Pro-Flex XC

Extension assist enhancements

- Faster extension rate
- Promotes heel rise and toe clearance
- Enhances perceived safety
- Lowers energy consumption / exertion
- Assists in running for RHEO KNEE XC

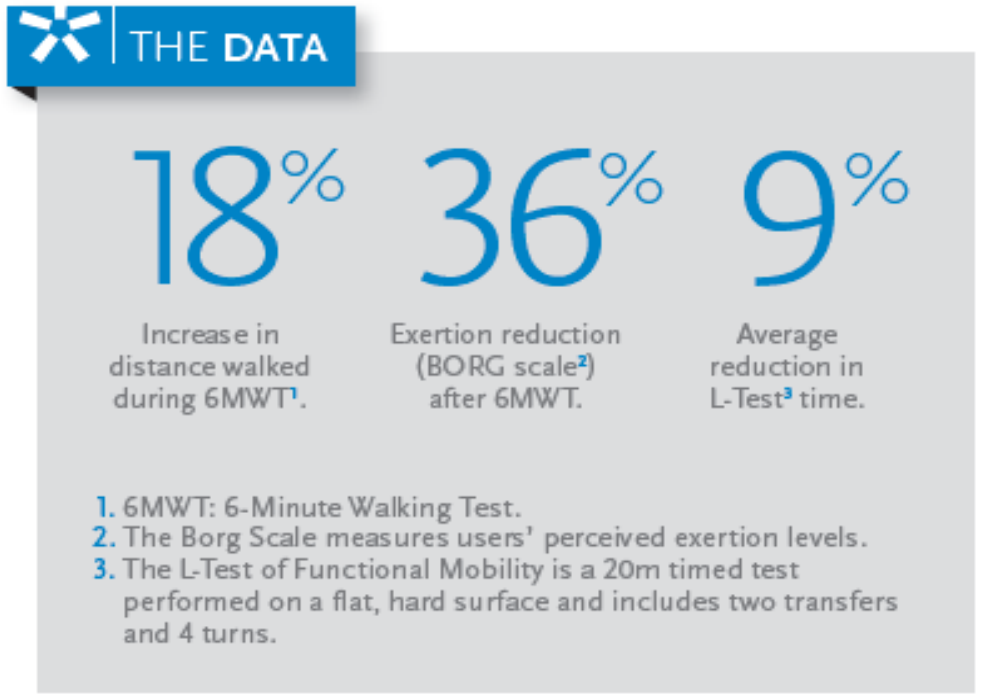
The fine-tuned dynamic spring release mechanism results in faster swing extension during level ground walking and stair and ramp descent activities.

In house, clinical tests show that users walk farther, faster and feel less exhausted after performing tasks.



Improved Clinical Outcomes

- Internal Össur Medical Office study
- 13 unilateral transfemoral users:
  - 3 RHEO KNEE 2 users
  - 6 original RHEO KNEE 3 users
  - 4 hydraulic MPK users (1 Cleg 4, 2 Genium, 1 X3)
- K3 – K4 population:
  - Age: Average 42 Years (29-68)
  - Weight: Average 82kg (57-104)
- Comparisons of existing knee to Rheo Knee XC (after 3 weeks of use)



Results: 6 MWT

- A 6 minute walk test (6MWT) aims to measure the distance covered on a flat, hard surface in 6 minutes [1].
- The 6 minute walk test was performed by each participant using their own microprocessor knee (baseline). The test was repeated using the new RHEO KNEE design once the users had had three weeks of experience using the new knee (3 weeks).
- The results related to this test can be attributed to the nature of the RHEO actuator technology and a faster swing extension than in previous models.
- These results apply to RHEO KNEE XC and RHEO KNEE 3 Upgrade.

Results: 6 MWT

The walking distance during 6MWT increased on average for all users when using the new RHEO KNEE design. The improvements measured are statistically significant (*).

Baseline	Own prosthesis	428,23m
3 weeks	New RHEO KNEE	506,00m*

When using the new RHEO KNEE design, users increased their mobility compared to when using other existing MP knees in the market.

According to literature, the following performance levels during 6MWT have been described:

- The 6MWT performance of K4 Level amputees is 419.76 m [1]
- The 6MWT performance of active duty soldiers with transfemoral amputation is 542m +/- 67 [2]

With RHEO KNEE XC, K4 users in the trial stepped up to another performance level which is within the range of active duty service members of the US army.

Results: Borg Scale

- The Borg Scale CR 10 [1] of Perceived Exertion aims to gauge how a user perceives his exertion levels. Using a scale from 0 to 10, users grade their feeling of exertion during an exercise.
- The Borg Scale test was taken by each user before the 6MWT and after it to measure the difference in exhaustion before and after exericise. The same sequence was repeated on the new RHEO KNEE design once users had had 3 weeks experience using the new knee.
- The results related to this test can be attributed to the nature of the RHEO actuator technology and a faster swing extension than in previsous models.
- These results apply to RHEO KNEE XC and RHEO KNEE 3 Upgrade.

Results: Borg Scale

When using the new RHEO KNEE design, the Borg Scale difference decreased from pre-6MWT to post-6MWT.

Baseline	Own prosthesis	3,04
3 weeks	New RHEO KNEE	1,93

When using the new RHEO KNEE design, users reported less exhaustion than they did when using their own prosthesis. At the same time they walked longer distances on the new RHEO KNEE design.

The new RHEO KNEE design reduces the perceived exertion and thereby allows for walking longer distances.

Results: L-Test

- The L-Test of Functional Mobility is a 20m timed test performed on a flat, hard surface and includes two transfers and 4 turns [1].
- The L-Test was performed by each participant using their own microprocessor knee (baseline). The test was repeated using the new RHEO KNEE design once the users had had three weeks of experience using the new knee (3 weeks).
- The results related to this test can be attributed to the nature of the RHEO actuator technology and a faster swing extension than in previsous models.
- These results apply to RHEO KNEE XC and RHEO KNEE 3 Upgrade.

Results: L-Test

The time required to complete the 20m L-test decreased when using the new RHEO KNEE design. The improvements measured are statistically significant (*).

Baseline	Own prosthesis	21,46 sec
3 weeks	New RHEO KNEE	19,46 sec*

When using the new RHEO KNEE design, users walk faster.

Results: PEQ MS 12/5

- The Prosthesis Evaluation Questionnaire [1] (PEQ) is a self administered questionnaire, aimed to evaluate prosthetic function and prosthetic related changes to quality of life. The evaluation gives results on the scale of 0-4.
- Each participant filled out the PEQ for their own microprocessor knee (baseline). The assessment was repeated using RHEO KNEE XC once the users had had three weeks of experience using the new knee (3 weeks).
- These results only apply to RHEO KNEE XC.

Results: PEQ MS 12/5

The PEQ average increased when using the RHEO KNEE XC.
PEQ scale is 0-4. The improvements measured are statistically significant (*).

Baseline	Own prosthesis	3,07
3 weeks	RHEO KNEE XC	3,59*

Users grade their prosthetic device and their quality of life higher when using the RHEO KNEE XC than other MPK devices in the market.

RHEO KNEE 3 & XC Warranty and Reliability

- 5 year warranty included
- No scheduled service required in first three years
- Mandatory service at 40 months
- **High Reliability Record:** Only 2% return rate for repairs to units sold globally since January 2014 (RHEO KNEE 3 introduction)

RHEO KNEE® 3

2014 - Design Transformation

New Extension Assist

Kinematic Sensor (Gyroscope)

Increased Battery Power

Stronger Actuator

Enhanced processor, angle sensor and software

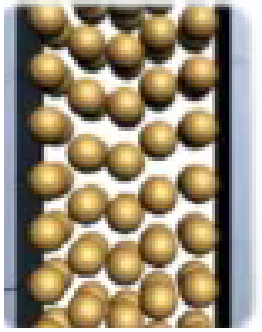
Structural Reinforcements

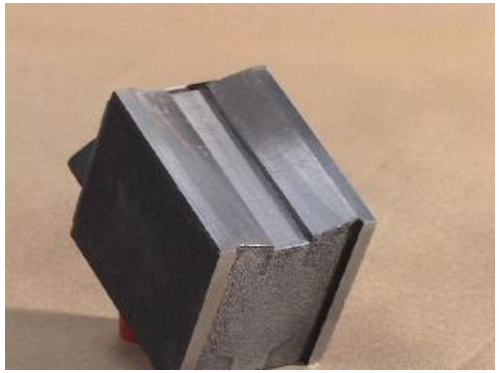
Actuator Technology

Actuator design

- Immediate and proportional response to gait and loading changes
- Increased maximum torque for additional support and stability
- Easy swing initiation and natural swing motion (zero pressure, low-drag) actuator

Magnetorheologic technology





RHEO KNEE® 3

MR + AI = Sustainable Comfort & Efficiency

- Initial automatic programming (Set-Up Mode) – **ONLY 30 steps to set up**
- Long-term continuous monitoring & adaptation to changes in gait (Software design: set targets → match targets)
- ***Result:*** Enhance and maintain walking comfort and efficiency

RHEO KNEE® 3

Design Transformation

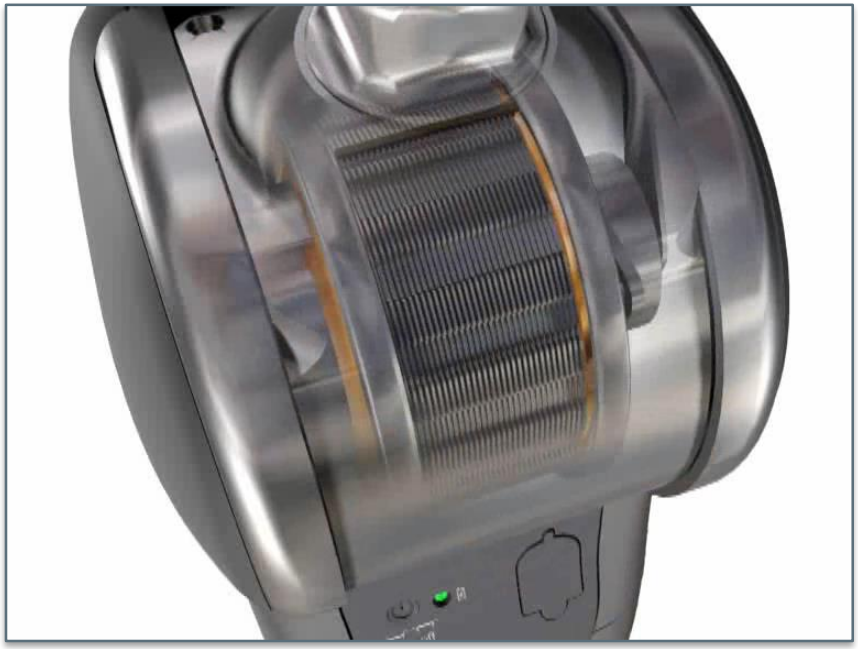
- 25% more torque than the previous versions
- More resistance over wider range of knee motion
- Greater confidence and stability when descending stairs and ramps and traversing uneven terrain

Stronger Actuator

RHEO KNEE® 3

Stronger Actuator

- Larger blade surface area
- Increased number of blades
- Increased voltage = greater magnetic field production
- **Result = Increased peak torque**



RHEO KNEE® 3

Design Transformation

- Enhances stability and security for stance to swing transitions
- Increases quiet standing stability

RHEO KNEE® 3

Kinematic Sensor (Gyroscope)

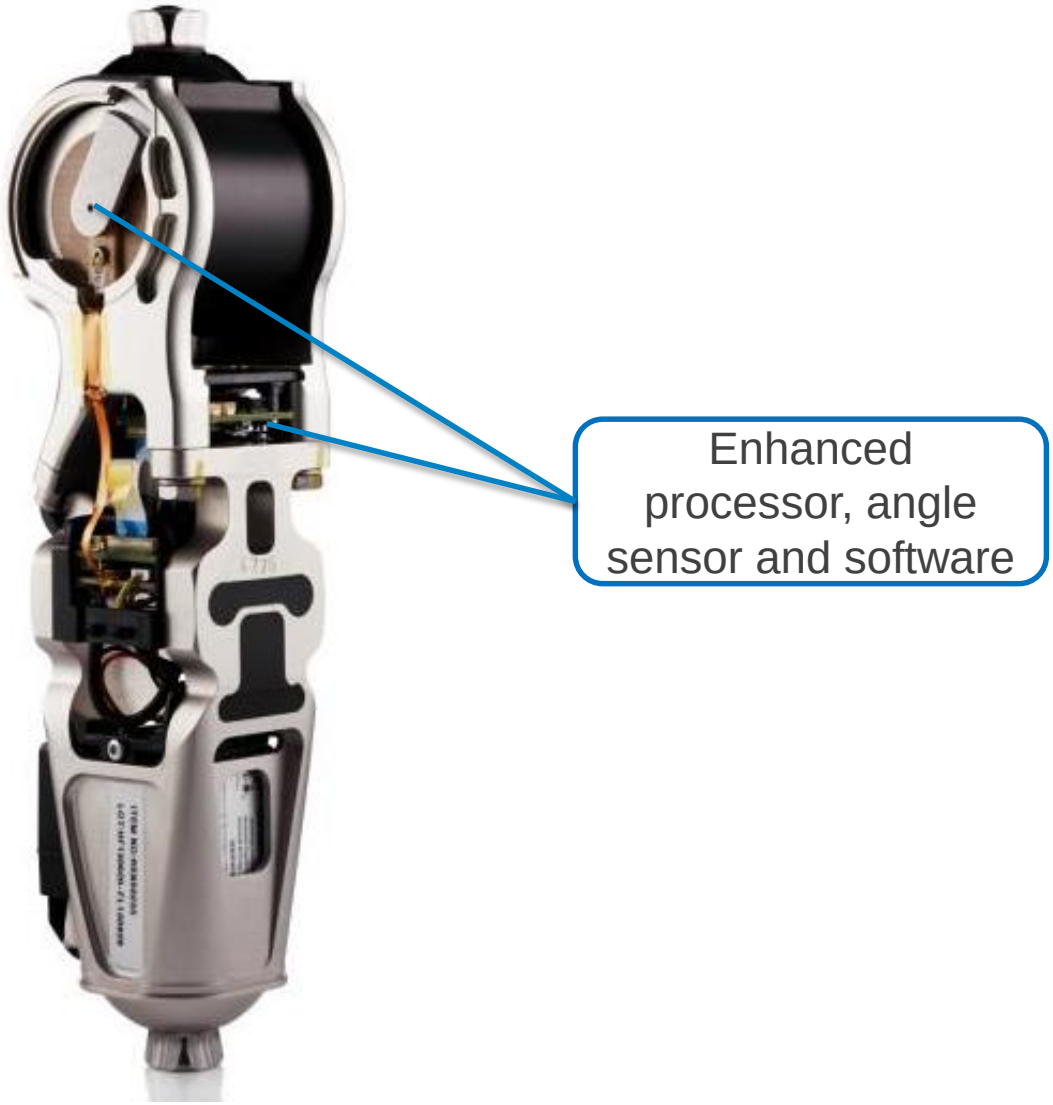
- Detects angular velocity changes:
  - Identifies angular orientation changes (vs. time) from mid-stance to terminal stance
- Uses this information to create safer and more predictable transitions from stance to swing
- Identifies quiet standing and increases stance resistance for better stability and reduced stress to sound limb
- Significantly increases user confidence
- **Useful performance examples:**
  - Increases stance resistance while standing still with knee extended or flexed
  - Prevents inadvertant release from stance while walking backward

RHEO KNEE® 3

Design Transformation

Enhanced angle sensor, processor and software:

- Digital angle sensor for greater accuracy and reliability
- More powerful CPU and circuit board
- Continuously monitors and adapts resistance levels



RHEO KNEE® 3

Design Transformation

- Up to **72 hours** of continuous use on one charge
- Allows for more extended trips and activities with less charging frequency
- 3-4 hours to fully charge unit

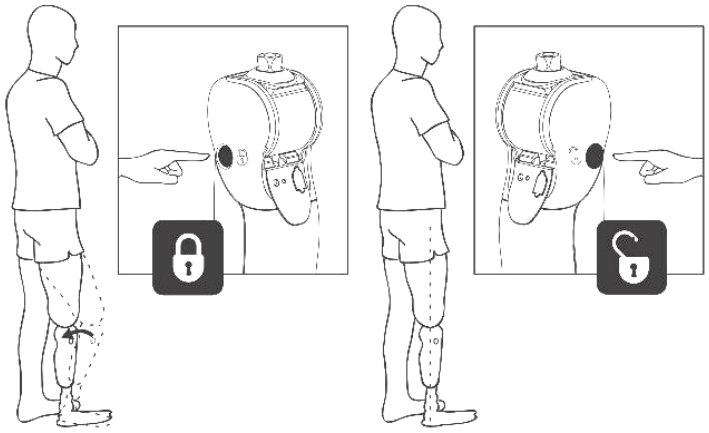
- Weight limit increased to 136 kg for low to moderate impact levels

Increased Battery Power

Structural Reinforcements

Manual Extension Lock

- Extreme circumstances, such as:
  - Extended standing
  - Traversing extreme terrain (steep/slippery slopes, deep snow or grass, icy surfaces)
  - Power-off: Choose to walk in free swing or lock



Accessories

RHEO KNEE protector: BIC00110

- Cut shin fairing to desired height and apply over RHEO KNEE 3 and tube
- Posterior velcro closure

Threaded Top Adapter: A-145310

- For knee-disarticulation and long residual limbs
- Titanium = 166kg

Angular/Linear Shift Adapter: A-554700

- Flexion + AP anterior offset
- S.S. = 100kg

RHEO KNEE® 3

Technical specifications

- Aluminum Frame
- Build height: 236mm
- Unit weight: 1.61kg
- Maximum flexion: 120°
- Battery charges in 3 h
- Up to 72 hours of continuous use

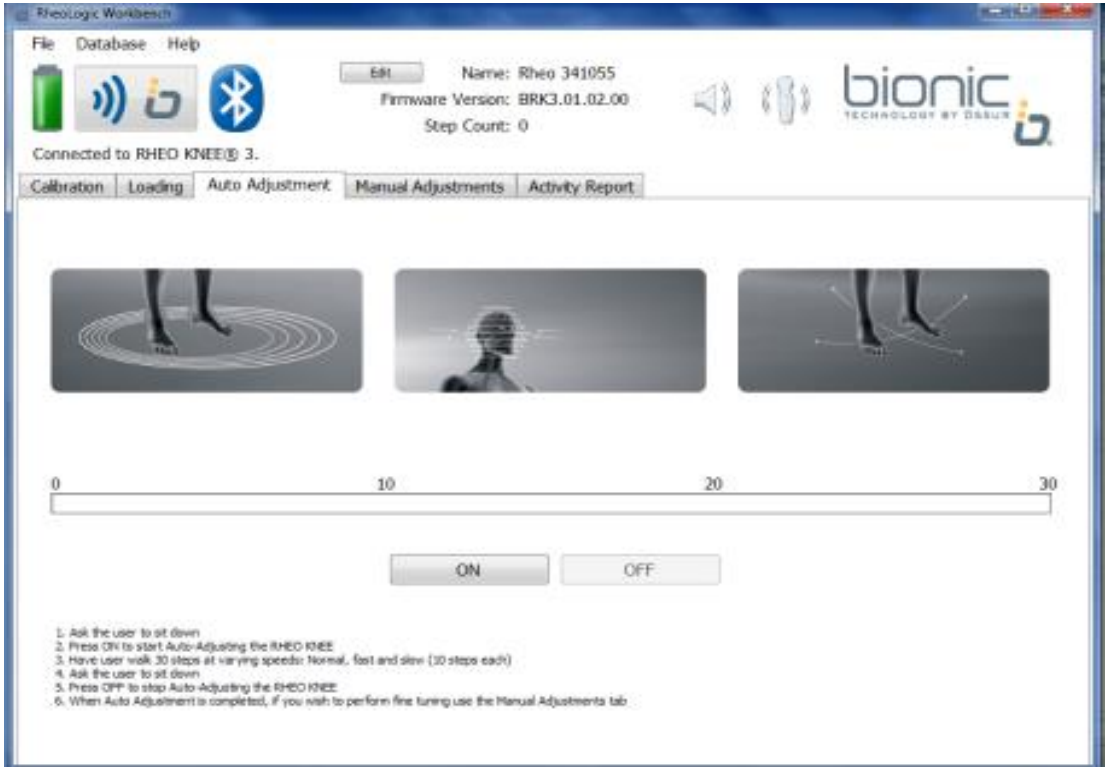
Alignment Support Tool

The alignment tab in the RHEOLOGIC software can be used…

- As an alignment check for the CPO (Alignment support tool)
- As a tool to train the heel-load and forefoot-load with the user
- To check 50/50 weight distribution between both legs while standing

Set Up (Auto Adjustment)

- Press “ON” to start auto-adjustment
- Have the user walk 30 steps at varying speeds (slow, SS, fastest)
- Press “OFF” to stop Auto Adjustment



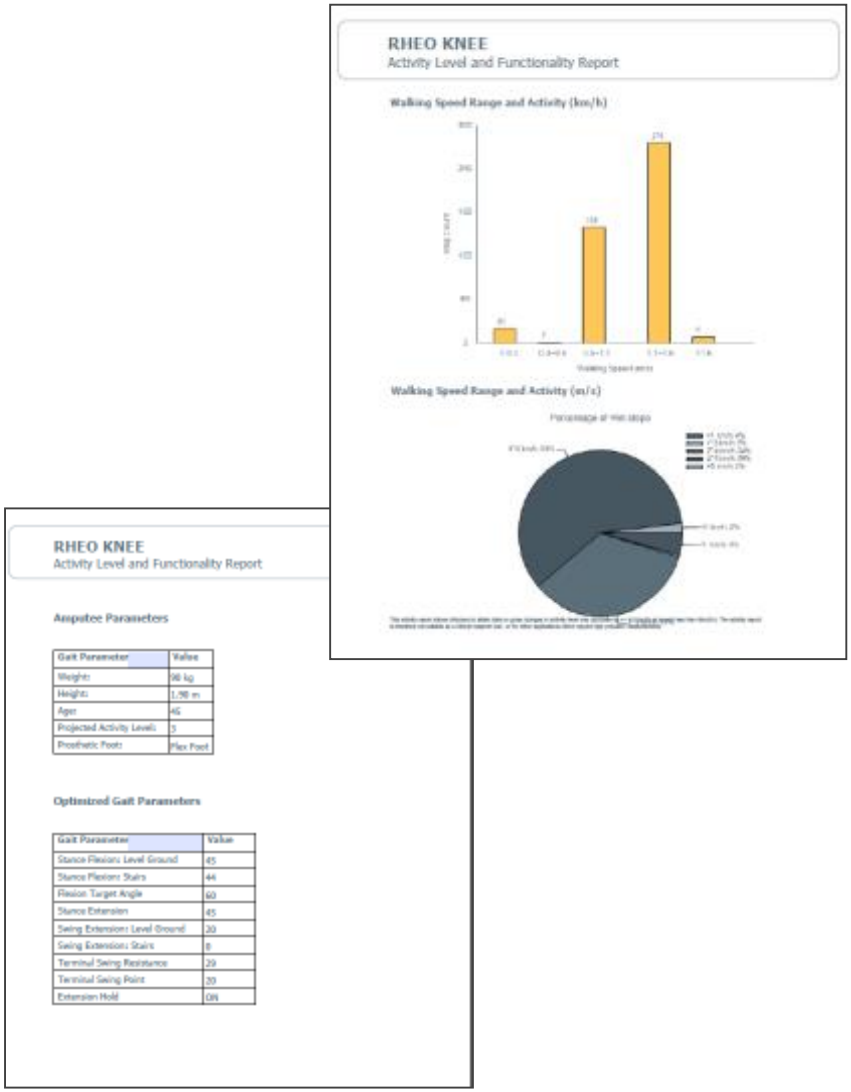
Manual Adjustments

- Personalize setting adjustments as required per individual client
- “Flexion Target Angle” is not fixed but adjusted automatically during set up.
- **Swing Initiation Setting - NEW**

Activity Report

Activity Report contains:

- Step count
- An objective overview of the different walking speeds
- Values of the program settings



ÖSSUR®
LIFE WITHOUT LIMITATIONS

WE IMPROVE PEOPLE'S MOBILITY