

# Harmony System

Active volume management

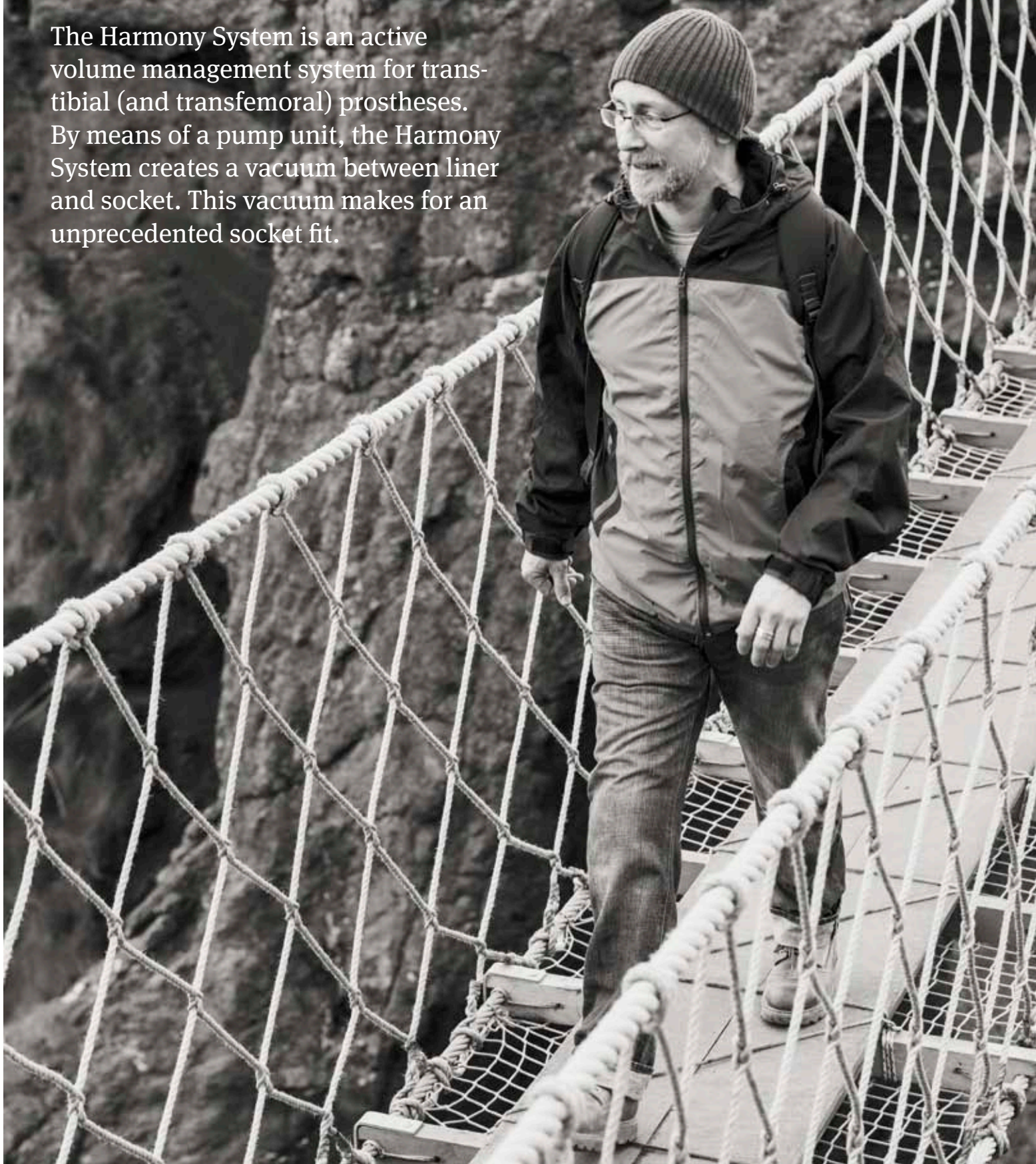


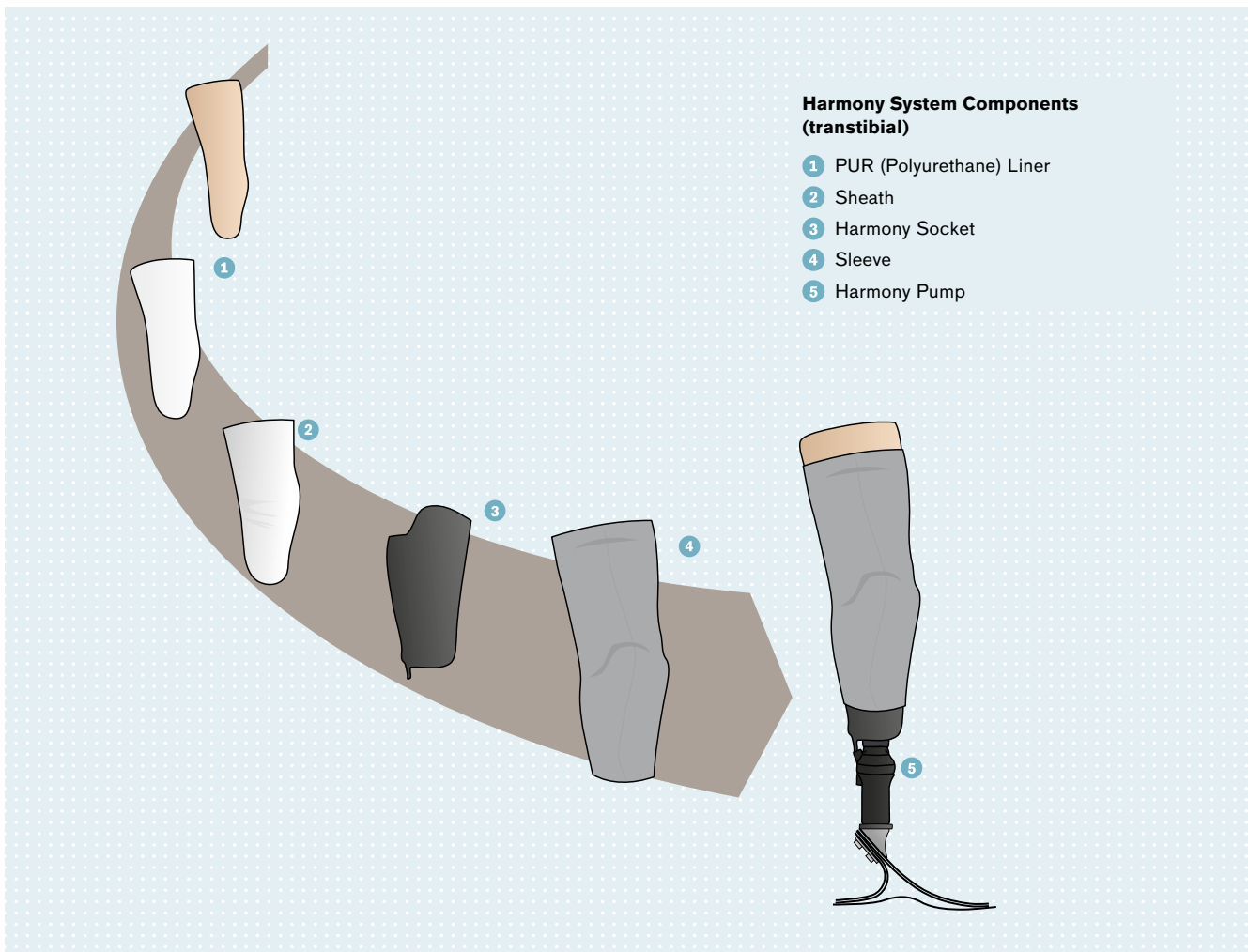
Quality for life

# The Harmony System

## A strong connection. For sure.

The Harmony System is an active volume management system for trans-tibial (and transfemoral) prostheses. By means of a pump unit, the Harmony System creates a vacuum between liner and socket. This vacuum makes for an unprecedented socket fit.





Studies carried out at St. Cloud State University in Minnesota (USA) have shown that the Harmony System prevents volume loss and minimizes volume fluctuations in the residual limb throughout the day.

The excellent adhesion between prosthesis and residual limb reduces tissue elongation and displacement and thereby prevent limb/socket pseudoarthrosis and improve proprioception. Furthermore, a study has pointed out that a prosthetic fitting with this system promotes residual limb blood circulation.

**What are the effects of the Harmony System?**

- Reduced volume fluctuations
- Improved adhesion
- Reduced forces within the socket
- Improved proprioception

**Indication:**

- Volume fluctuations of the limb up to 2cm in circumference
- Diabetes and occlusive arterial diseases
- Prominent bone structures and difficult scar conditions
- Need for increased suspension due to higher activity level
- Need for continuous, adjustable suspension (only Harmony E2)

**Contra indication:**

- Interims fittings
- Dialysis patients
- Residual limbs that are not able to bear weight distally
- Neuroma, preventing patient from being able to bear pressure on the residual limb
- Missing cognitive abilities of the patient to “manage” the system

# Harmony System

## Volume Management

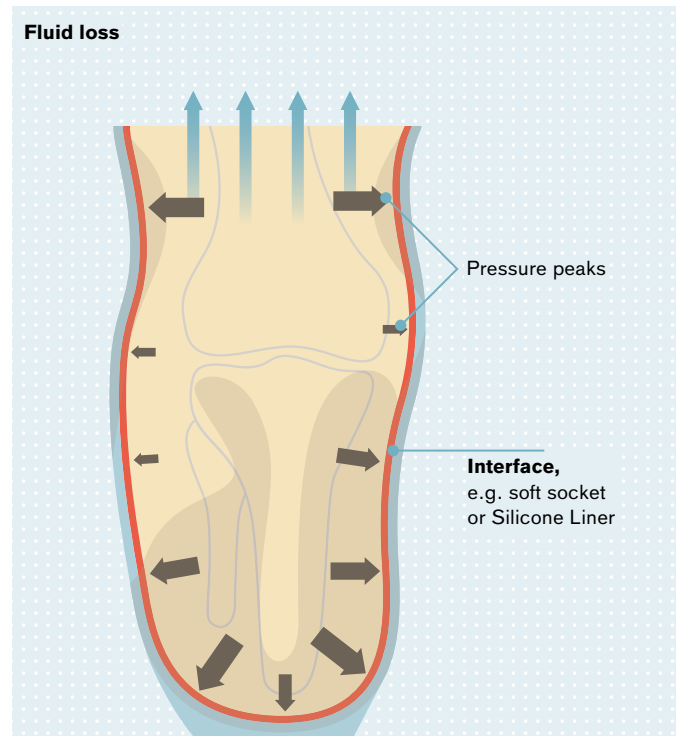
### Residual limb fluctuations

Why is it that our feet are thicker in the evening than in the morning? The reason lies in the pressure of our blood circulation. Arterial pressure is higher than venous pressure. In the course of the day, the arteries transport more fluid into our tissue than the veins are able to transport back. So why do prosthesis wearers often complain about their residual limb volume diminishing in the course of the day? Conventional sockets are specific weight bearing sockets that influence the fluid balance in the tissue of the residual limb. During the stance phase, these sockets carry or “press” tissue fluid out of the residual limb. The volume of the residual limb is furthermore decreased by the basic biomechanical function of the gait cycle.

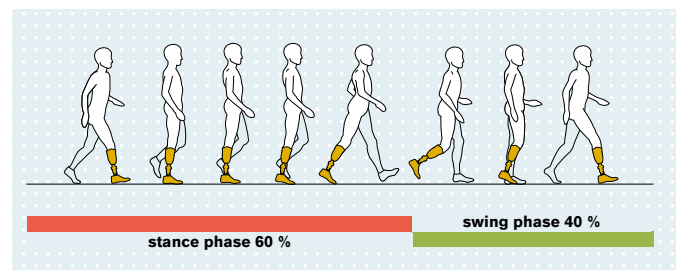
Each residual limb is subject to volume fluctuations. The extent of the fluctuations depends on different factors such as the condition of the connective tissue, age of the patient, vascular diseases and, of course, the kind and fit of the socket.

To compensate volume loss, amputees often wear an additional sock over their residual limb or liner in the afternoon. However, this measure only provides short-term relief from the symptoms and does not eliminate the cause. In the long term, the measure even causes partial pressure build-up, because the fluid in the residual limb tissue is not drawn out evenly.

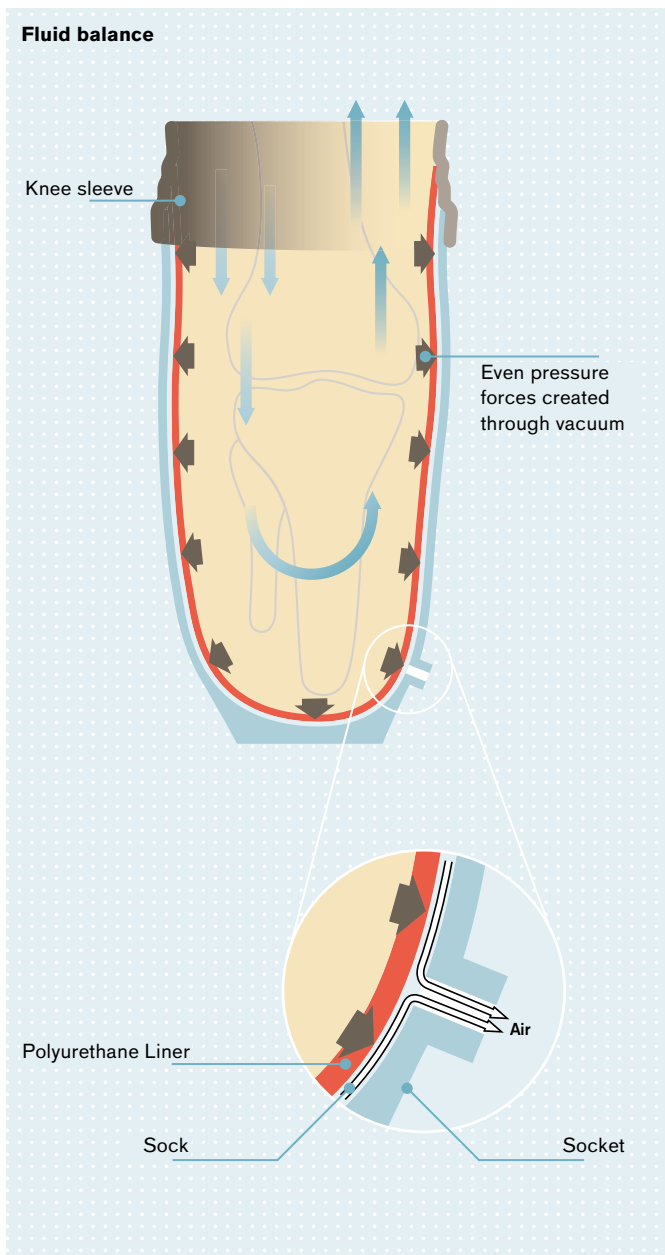
Simple one-way valves release only the amount of air that the residual limb volume can press out. Although the vacuum created in this way provides for sufficient adhesion, it cannot prevent volume fluctuations in the residual limb. Even shuttle lock systems cannot prevent volume fluctuations. The adhesion is ensured as the prosthesis is secured by the pin. Nevertheless, both mechanisms entail volume loss that reduces the residual limb circumference. This leads to residual limb/socket pseudarthrosis and can thus result in painful skin irritations. Volume management through fluid balance is the right way to counteract these consequences.



- With conventional specific weight bearing sockets, fluid loss throughout the day results in reduced residual limb volume and reduction of surface area to distribute pressures.



- A prosthetic gait cycle consists of 60% stance phase and 40% swing phase. This means that while walking, tissue fluid flows out longer and faster than it can flow back, given that the back flow is shorter and slower. Consequently, more fluid flows out than flows back.



• A total surface weight bearing socket with the Harmony System balances the flow and backflow of tissue fluid, thus preventing volume fluctuations and improving blood circulation in the residual limb.

### Volume Management

The Harmony System prevents volume fluctuations in the residual limb. Unlike conventional, specific weight bearing sockets, Harmony sockets are total surface weight bearing sockets. Pressure peaks in the load areas are prevented and replaced by full contact.

The pump unit of the Harmony System creates vacuum in the socket. It draws the entire surface of the liner onto the socket, thereby relieving pressure from the residual limb. During the stance phase, the pressure increases evenly over the entire surface rather than partially. De facto, this effectively reduces the total pressure affecting the tissue. The residual limb tissue is thereby relieved, while the amount of fluid, i.e. the residual limb volume, is kept stable – in each phase of the gait.

### Fitting

Only an optimal socket fit can allow amputees to make full use of their prostheses. Up to now, the natural contour of the residual limb had to adapt to a specific weight bearing socket. The more the contour differed from the socket shape, the greater the compromise between comfort and technical feasibility. A new plaster cast and modeling technique now makes it possible to represent individual residual limb structures in a plaster negative and to transfer them into the socket shape. The new technique not only optimizes the socket fit, but also simplifies the modeling process. Moreover, it is also applicable for ordering custom liners.

This plaster cast and modeling technique is taught in the certification seminar required for fitting the Harmony System. In the seminar, orthopedic technicians will fabricate a socket and take part in static and dynamic trial fittings up to the completion of the prosthesis.

# Harmony E2

## Features & Benefits

Harmony E2 is the new electronic pump option for the Harmony System. It has been designed for intuitive and easy use by the amputee. For example the Rotary Switch to select and indicate the pump setting at the same time, to just mention one feature.

It is also the first removable solution. Due to its connection to the prosthesis by a special 4-hole adapter plate it can easily be removed e.g. to charge it without removing the leg. The adapter plate with its integrated valve keeps the vacuum in the socket.

### ► Easy Installation



**4-hole Adapter Plate**  
for convenient use with e.g. 5R2 plate and the desired distal adapter

**Free orientation**  
around the pylon: medial, lateral or even anterior, posterior



**Two Air Channels**  
in adapter plate for direct tubeless distal connection or use of a socket connector (e.g. for retro-fittings)

► **No computer or programming required!**

### ► Flexibility



**Easy Removability**  
of the pump unit e.g. for charging, weight reduction or switching between different legs. The adapter plate with its integrated valve keeps the vacuum in the socket.



**Rechargeable AA Batteries**  
(also replaceable in case no power supply is available)

**USB Charging Cable**



**NEW**

- 1 Automatic Mode**  
adjusts elevated vacuum according to activity level. No manual switching necessary.
- 2 4 Manual Levels**  
to adjust vacuum to personal preferences from comfort (small dots) to high suspension (large dots).
- 3 Reverse Mode**  
allows to flush the pump and to reverse air flow for a quick pressure relief.
- 4 Top Air channel**  
for direct tubeless socket connection.
- 5 Side Air channel**  
for use with a socket connector.



**Rotary Switch**  
to select and indicate setting at the same time. No sight necessary, touch is sufficient to “read” setting

**Waterproof**  
up to 3m water depth. Splash water, rain or even swimming in fresh water is no problem

# Harmony P3 and Triton Harmony Features & Benefits

Harmony P3 and Triton Harmony are the mechanical pump options for the Harmony System in BK fittings. With every step the end-user makes these pumps create (or maintain) the vacuum in the socket. In addition the 3-in1 functional ring, that creates the vacuum, provides vertical shock absorption and a natural rotation function.

The 4R147 Harmony P3 is a slim and lightweight modular pump. It can be combined with a huge variety of feet and is suitable for active end-users up to 125kg body weight.

The 1C62 Triton Harmony combines the excellent functionality of the 1C60 Triton carbon fibre foot with the proven Harmony P3 technology: Smooth roll-over characteristics, split forefoot for more safety and control on uneven surfaces and excellent energy storage and energy return combined with active vacuum for volume management of the residual limb and unmatched suspension. The Triton Harmony with its compact design is suitable for high active end-users up to 150kg body weight.

## **1 Carbon Forefoot Spring**

The split forefoot spring allows the foot to adapt to uneven surfaces. It offers energy return, stability and control at rollover and toe-off

## **2 Base Spring**

The split base spring made of high-performance polyester has a separate big toe and connects the forefoot and the heel spring to form a complete system

## **3 Carbon Attachment Spring**

The attachment spring made of carbon fibre material gives the foot the required stability

## **4 Carbon Heel Spring**

The heel spring dampens the impact at heel strike and stores the energy for a smooth rollover

## **5 Replaceable Heel Wedge**

The optional heel wedges provide a simple method for adapting the Triton to the individual needs of the patient





## Harmony P3

### Adapter

Pyramid receiver  
made of Titanium



**Pylon Receiver**  
for 34 mm pylons

### 3-in-1 Functional Ring

Exchangeable elastomeric ring  
with intake and exhaust valve  
for vacuum generation, vertical  
shock absorption and torsion

### Housing

Harmony P3 and Triton  
Harmony housing made of  
lightweight Aluminum

## Triton Harmony

### Adapter

Pyramid adapter  
made of Titanium



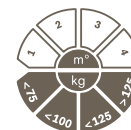
# Technical Data and Order Information

## Harmony Pumps



### 4R152 Harmony E2

Harmony E2 is the new electronic pump option for the Harmony System. It provides volume management for the residual limb, enhanced suspension and reduced forces in the socket.



Article number	Harmony E2 4R152	4-hole adapter plate 4X267
Weight	185 g	125 g
System height	95 mm	22 mm
Material	–	Aluminium
Max. body weight	–	150 kg
Temperature range for use	-10°C to +60°C (14°F to 140°F)	–
Battery charger operating voltage	100–240 V	–
Battery charger operating frequency	50–60 Hz	–
Battery charging temperature	0–40 °C (32°F to 104°F)	–



### 4R147 Harmony P3

The slim pump weighs only 399 g (0.88 lbs) which is a 20% reduction in weight, and it has a reduced system height. The core function of the Harmony P3 is provided by a functional ring. It assumes the pumping function, offers vertical shock absorption and permits natural rotation. The functional rings can be easily adjusted and exchanged to meet the user's needs. The 3-in-1 functional rings additionally make the Harmony P3 field-serviceable.

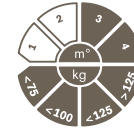


Article number	4R147=0	4R147=1	4R147=2	4R147=3	4R147=4	4R147=5	4R147=6	4R147=7
Mobility grade	2–4							
Material	Steel, Titanium							
Connection	Distal tube clamp 34 mm							
Connection	Proximal pyramid receiver							
Size	0	1	2	3	4	5	6	7
Recommended for body weight	40–47	48–55	56–65	66–75	76–87	88–100	101–112	113–125
System height	95 mm							
Weight	399 g							
Max. body weight	125 kg							
Scope of delivery	Harmony P3 Pump, 4X147 Functional Ring, 2R117 Socket Connector, sound absorber and cosmetic connection							



### 1C62 Triton Harmony

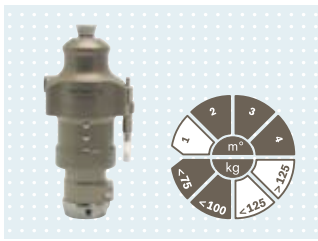
The high-performance prosthetic foot with integrated Harmony pump.



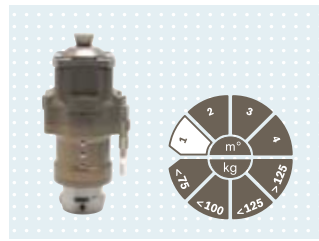
Body weight	Sizes									
	21 cm	22 cm	23 cm	24 cm	25 cm	26 cm	27 cm	28 cm	29 cm	30 cm
40–47 kg	1-0 special order – please contact Customer Service									
48–55 kg	1-1	1-1	1-1	1-1	1-1	1-1	-	-	-	-
56–65 kg	2-2	2-2	2-2	2-2	2-2	2-2	2-2	2-2	2-2	2-2
66–75 kg	2-3	2-3	2-3	2-3	2-3	2-3	2-3	2-3	2-3	2-3
76–87 kg	3-4	3-4	3-4	3-4	3-4	3-4	3-4	3-4	3-4	3-4
88–100 kg	3-5	3-5	3-5	3-5	3-5	3-5	3-5	3-5	3-5	3-5
101–112 kg	-	-	-	-	4-6	4-6	4-6	4-6	4-6	4-6
113–125 kg	-	-	-	-	4-7	4-7	4-7	4-7	4-7	4-7
126–137 kg	-	-	-	-	5-8	5-8	5-8	5-8	5-8	5-8
138–150 kg	-	-	-	-	5-9	5-9	5-9	5-9	5-9	5-9

- Slim footshell available
- Both footshells available
- Normal footshell available

#### Also still available



4R144 Harmony P2



4R150 Harmony HD

## Complimentary system components for TT prosthesis



6Y512 Anatomic 3D PUR Liner



453A3 Derma ProFlex

## Complimentary system components for TF prosthesis



6Y81 ProSeal SIL Liner



452A1 ProSeal Ring

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