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Active Vacuum Solutions

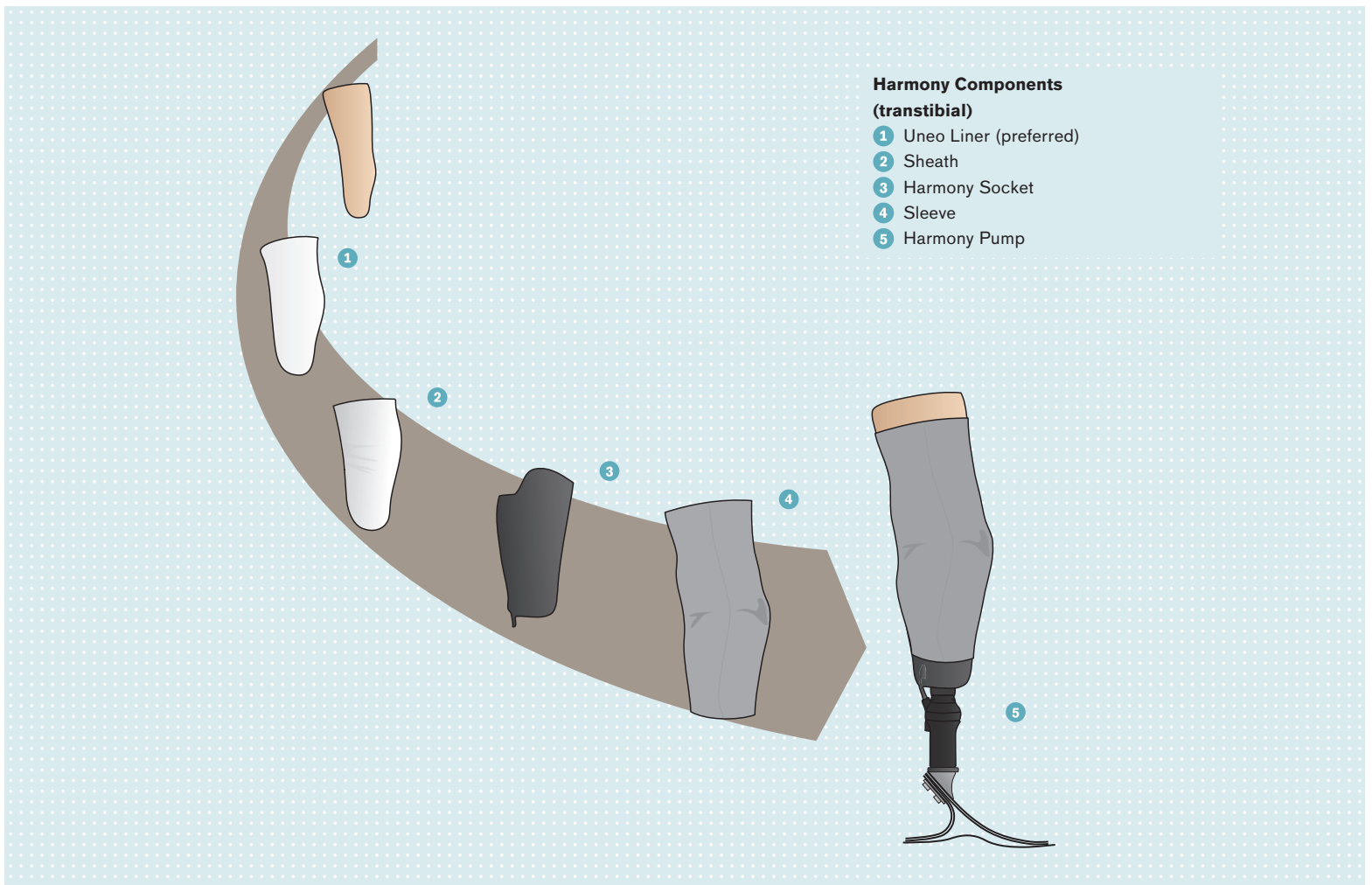


Quality for life

Information for Clinicians

Active vacuum volume management solutions for transtibial (and transfemoral) patients provides the ultimate socket comfort. By means of a pump unit, vacuum is created between the liner and the suspension sleeve. This vacuum makes for an unprecedented socket fit.





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

The excellent connection between prosthesis and residual limb reduces tissue elongation and displacement and thereby prevents limb/socket movements and improves proprioception.

Furthermore, a study has pointed out that a prosthetic fitting with this vacuum volume management promotes residual limb blood circulation.

Harmony’s proven clinical benefits:

- Limb volume management¹, which can reduce the need to add socks
- Reduces pistoning between the limb and socket²
- Improves residual limb health³
- Helps improve balance, reduce risk of falls and improve walking⁴

Indications:

- 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)

Contraindications:

- Primary fittings (Harmony only)
- Dialysis patients
- Neuroma, preventing patient from being able to bear pressure on the residual limb
- Reduced cognitive ability of the patient to “manage” the system

Active Vacuum

Volume Management

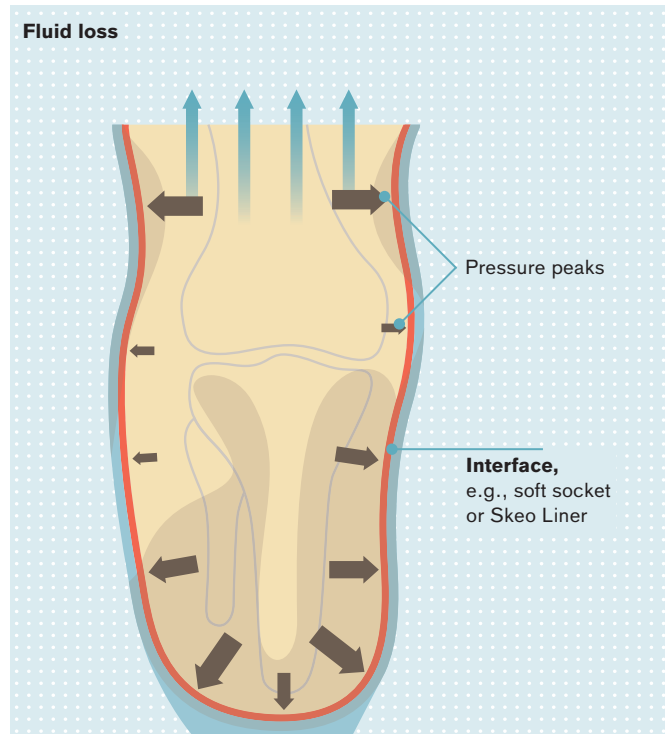
Residual Limb Fluctuations

Why is it that our feet are more swollen in the evening than in the morning? The reason lies in the pressure of our blood circulation. Arterial pressure is higher than venous pressure. Throughout 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 throughout 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.

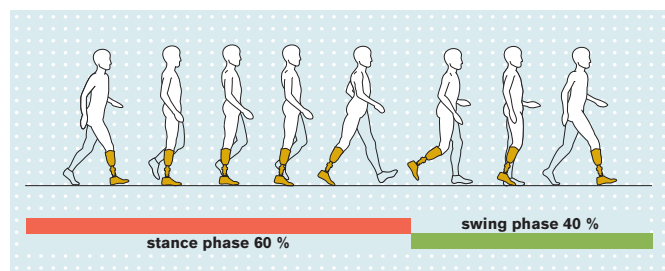
Each residual limb is subject to volume fluctuations. The extent of the fluctuations depends on different factors such as the condition of the connective tissue, age of the patient, vascular diseases and, of course, the kind and fit of the socket.

To compensate for volume loss, amputees often add 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.

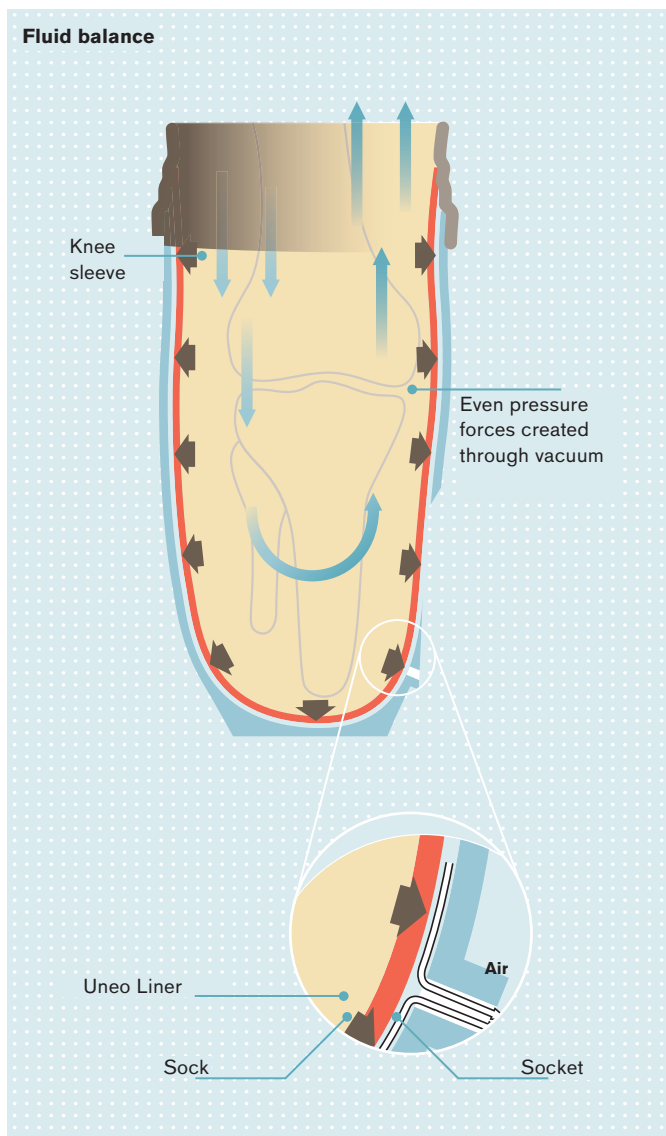
Simple one-way valves release only the amount of air that the residual limb volume can press out. Although the suction created in this way provides for sufficient connection, it cannot prevent volume fluctuations in the residual limb. Even shuttle lock systems cannot prevent volume fluctuations. The connection 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 movement 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 reduces daily 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 a 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. 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 special plaster cast and modelling technique now makes it possible to represent individual residual limb structures in a plaster negative and to transfer them into the socket shape. The technique not only optimises the socket fit but also simplifies the modelling process. Moreover, it is also applicable for ordering custom liners.

This plaster cast and modelling technique is taught in the certification course required for fitting the Harmony vacuum pumps.

Dynamic Vacuum System (DVS) Features & Benefits

DVS is bridging the gap between valve and Harmony socket technology. Integrating innovative design with simplicity, DVS reduces the movement between the limb and socket associated with limb volume fluctuations.

The DVS is designed to suit a variety of lifestyles and daily activities. Providing comfort and stability, DVS offers confidence with each step so that your patient can focus on what they are doing and not their prosthesis. With the winning combination of key components the DVS can go almost anywhere!



DVS Structural 4R220

DVS Non-structural 4R220=1

Magnetic connection
The piston of the DVS connects to the liner with a magnet, making the prosthesis easy to put on.

Protection against dirt
Thanks to an insert ring and valves, the DVS is completely sealed. This prevents any dirt from getting in.

Two connection versions available:

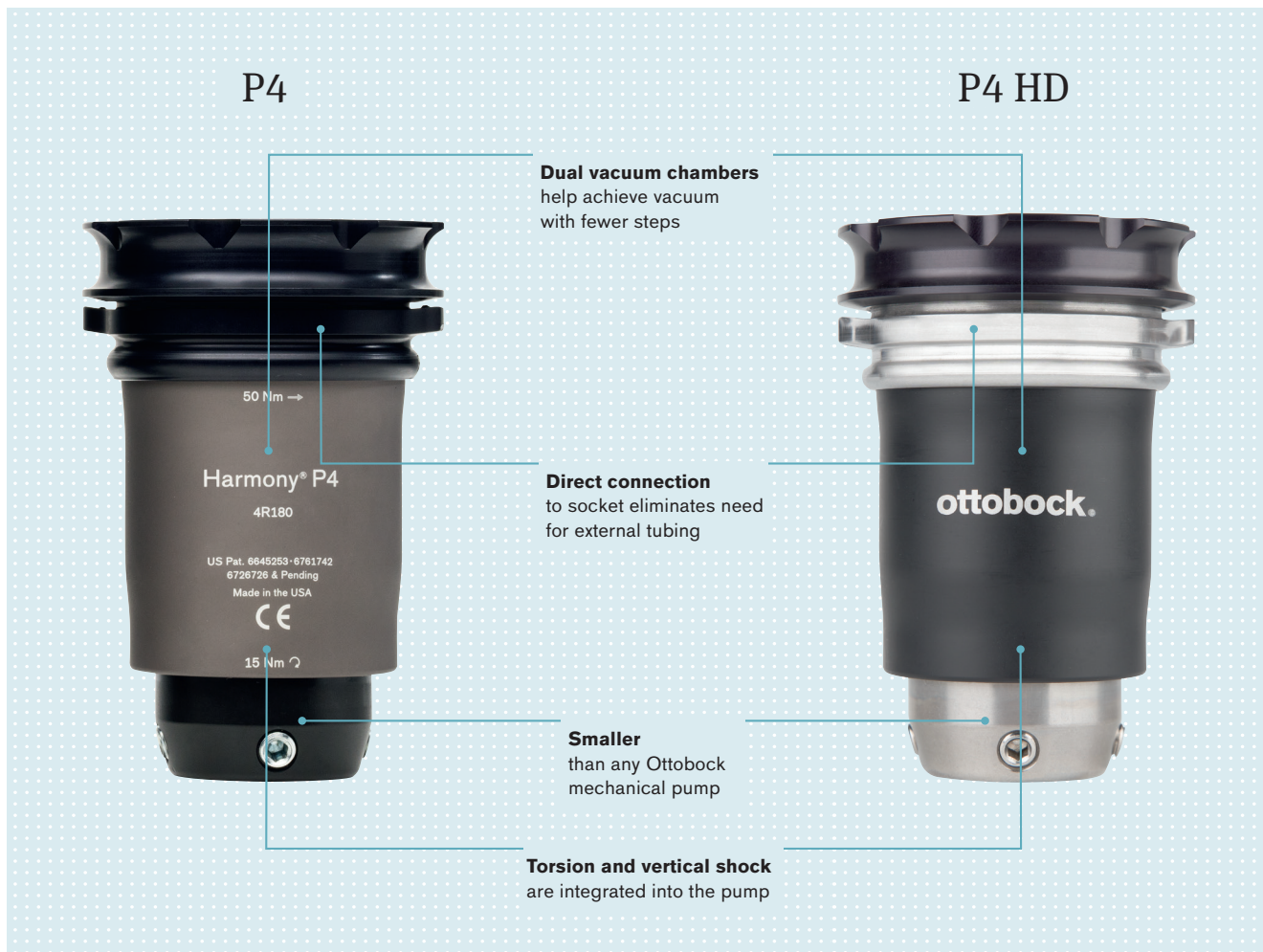
- 1.) 4R220 with 4-hole connector facilitates prosthetic alignment. Distal adapters can be directly attached.
- 2.) 4R220=1, non-structural bearing version, for greater freedom in the prosthetic alignment.

Harmony P4 and P4 HD

Features & Benefits

Harmony P4 combines superb vacuum suspension with torsion and vertical shock into a compact package. That gives patients with longer residual limbs access to the outstanding suspension of Harmony vacuum while enjoying the benefits of rotation and shock absorption, along with the ability to have access to a greater range of prosthetic feet.

No external tubing is required for the Harmony P4 so there is no risk of tubing getting tangled in the patient's clothing or prosthesis. The amount of vertical compression can be dialed in for specific patient weight and gait pattern.



Harmony E2

Features & Benefits

Harmony E2 is a chargable, electronic pump option for the Harmony System. It has been designed for intuitive and easy use by the amputee. It is very quiet, removable, and submersible to a depth of 3 metres in fresh water.

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.



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 patient to flush the pump and reverse air flow for quick pressure relief.

4 Top Air Channel
for direct tubeless socket connection.

5 Side Air Channel
for use with a socket connector.

6 Rechargeable AA Batteries
(also replaceable with standard AA in case no power supply available)

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

Waterproof
up to 10 ft. (3m) water depth. Splash water, rain, or even swimming in fresh water is no problem.

Harmony P3 and Triton® Harmony Features & Benefits

With every step, the weight activated pumps create (or maintain) the vacuum in the socket. In addition, the 3-in-1 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 patients up to 125 kg. body weight.

The 1C62 Triton Harmony combines the excellent functionality of the 1C60 Triton carbon fibre foot with the proven Harmony P3 technology. The Triton Harmony with its compact integrated design is suitable for highly active patients up to 150 kg body weight.



Harmony P3



Triton Harmony

- 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 solution.
- 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 heel wedge provides a simple method for adapting the Triton to the individual needs of the patient.

3R60 Vacuum

Features & Benefits

The 3R60 Vacuum Knee Joint is based on the proven mechanical principle of the 3R60 EBS. Vacuum generation in the socket ensures there is active volume management and improves the connection between the prosthesis and residual limb with reduced fluctuations in volume, improved adhesion, reduced forces in the socket and improved proprioception.

Featuring an integrated pump the 3R60 vacuum uses the knee flexion movement during swing phase to create negative pressure in the socket. Air and perspiration fluids are expelled through the discharge valve by means of an additional tube.



Article number	3R60=VC
Mobility grade	2-3
Max. body weight	125 kg
Weight	900 g
Field of application	TT
Proximal connection	Pyramid adapter
Distal connection	Pyramid adapter
Max. knee flexion angle	173°
System height	174 mm
Vacuum (max)	21 inHg

Technical Data and Order Information

Active Vacuum Solutions



DVS Structural and DVS Non-structural

DVS for transtibial amputees combines two important features integrating innovative technology with ease of use. DVS is an active vacuum system which adjusts itself to the needs of the patient in a dynamic manner.

Article number	4R220 Structural	4R220=1 Non-structural
Max. body weight	150 kg	-
System height	37 mm	27 mm
Weight	210 g	110 g
Spare parts	4X320 piston, 4X339 fixation ring, 4X322 valve bushing for lamination adapter, 4X326 dummy set, 4X338 wrench, 4X314 spacer plate	4X320 piston, 4X339 fixation ring, 4X322 valve bushing for lamination adapter, 4X326=1 dummy set, 4X338 wrench



Harmony P4 and Harmony P4 HD

Harmony P4 and Harmony P4 HD combine superb vacuum suspension with torsion and vertical shock into a compact package. That gives patients with longer residual limbs access to the outstanding suspension of Harmony vacuum while enjoying the benefits of rotation and shock absorption. No external tubing is required so there is no risk of tubing getting tangled in the patient's clothing or prosthesis.



Article number	Harmony P4 4R180	Harmony P4 HD 4R181
Mobility grade	2-4	2-4
Material	Aluminium	Titanium, steel, aluminium
Max. body weight	100 kg	150 kg
System height	132 mm	132 mm
Component weight	465 g	590 g



4R147 Harmony P3

The slim pump weighs only 425g and has a reduced build 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 servicable at your centre.

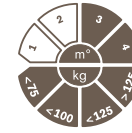


Article number	4R147=0	4R147=1	4R147=2	4R147=3	4R147=4	4R147=5	4R147=6	4R147=7
Mobility grade	2-4							
Material	Aluminium, titanium							
Distal connection	34 mm tube clamp							
Proximal connection	Proximal female pyramid							
Size	0	1	2	3	4	5	6	7
Recommended for body weight (kg)	40–47 kg	48–55 kg	56–65 kg	66–75 kg	76–87 kg	88–100 kg	101–112 kg	113–125 kg
System height	175 mm							
Weight	400 g							
Max. body weight	125 kg							
Scope of delivery	Harmony P3 Pump, 4X147 Functional Ring, 2R117 Socket Connector, sound absorber							



1C62 Triton Harmony

The high-performance prosthetic foot with integrated Harmony pump.
Clearance - 8" (size 26)



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



4R152 Harmony E2

Harmony E2 is an electronic pump option for the Harmony System. It provides volume management for the residual limb, enhanced suspension, and reduced forces in the socket. Quiet, removable, and waterproof up to 3m. submersed. Harmony E2 with offset adapter (=1) allows for fitting above wider components such as microprocessor knees and certain feet.



Article number	Harmony E2 4R152 (=1)	4-hole adapter plate 4R153	4R153=1 Offset 4-Hole Adapter Plate
Weight	185 g	125 g	160 g
System height	95 mm	22 mm	22 mm
Material	-	Aluminium	Aluminium
Max. body weight	-	150 kg	150 kg
Operating temperature	-10°C–60°C (14°F–140°F)	-	-
Operating voltage	100–240 V	-	-
Battery charger operating frequency	50–60 Hz	-	-
Battery charging temperature	0–45 °C (32°F–113°F)	-	-

Complementary components for TT prosthesis



6Y512 Uneo 3D Liner



453A3/453A30/453A4/453A40
ProFlex Sleeve Family

Active Vacuum Pump Selection Chart

							
	4R220/4R220=1 DVS	4R180 Harmony P4	4R181 Harmony P4 HD	4R147 Harmony P3	1C62 Triton Harmony	3R60=VC 3R60 Vac	4R152 Harmony E2
Type (electronic/mechanical)	Mechanical	Mechanical	Mechanical	Mechanical	Mechanical	Mechanical	Electronic
Pump mechanism	Pump	Piston	Piston	Functional ring	Functional ring	Piston	Peristaltic
TT	●	●	●	●	●		●
TF					●	●	●
Mobility grade	1-4	2-4	2-4	2-4	3-4	3	2-4
Max. body weight	150 kg	100 kg	150 kg	125 kg	150 kg	125 kg	150 kg
Vertical shock		●	●	●	●		
Torsion		●	●	●	●		
Adjustable vacuum							●
Vacuum (max.)	8 inHg 250mbar	24 inHg 800 mbar	24 inHg 800 mbar	20 inHg 650 mbar	20 inHg 650 mbar	21 inHg 700 mbar	21 inHg 700 mbar
Weight	210 g / 110g	465 g	590 g	400 g	750 g (incl foot)	900 g	188 g pump 125 g plate
System height	37 mm / 27 mm	114 mm	114 mm	127 mm	203 mm	222 mm	95 mm
Waterproof		●	●	●	●		submersible to 3m

- 1 Kahle et al. 2014, Sanders et al. 2011, Street et al. 2006, Goswami et al. 2003, Board et al. 2001.
- 2 Darter et al. 2016, Kahle et al. 2014, Kahle et al. 2013, Beil et al. 2002.
- 3 Kahle et al. 2014, Hoskins et al. 2014, Trallesi et al. 2012, Brunelli et al. 2009.
- 4 Samitier et al. 2014, Kahle et al. 2014, Kahle et al. 2013, Ferraro et al. 2011.

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