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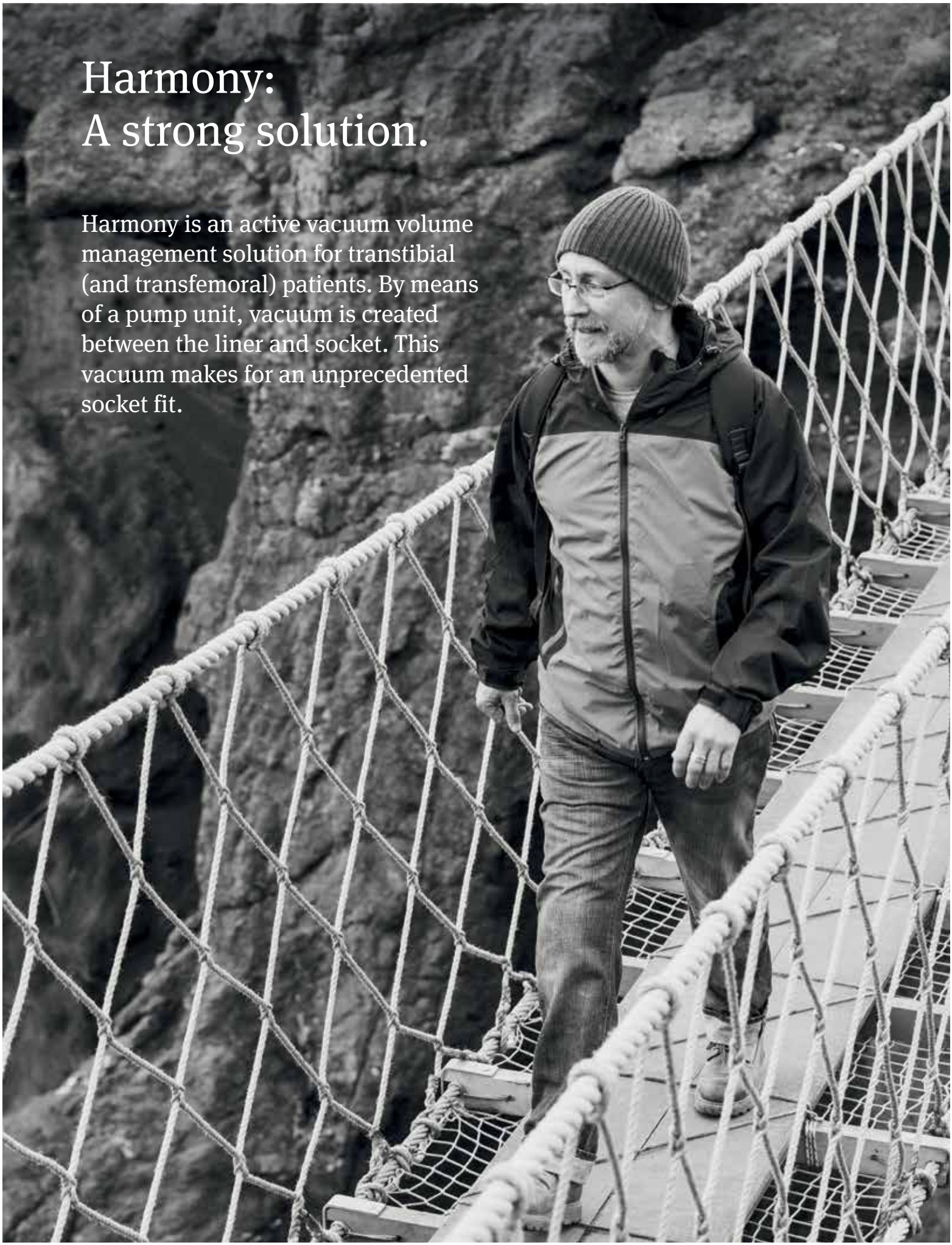
Harmony®

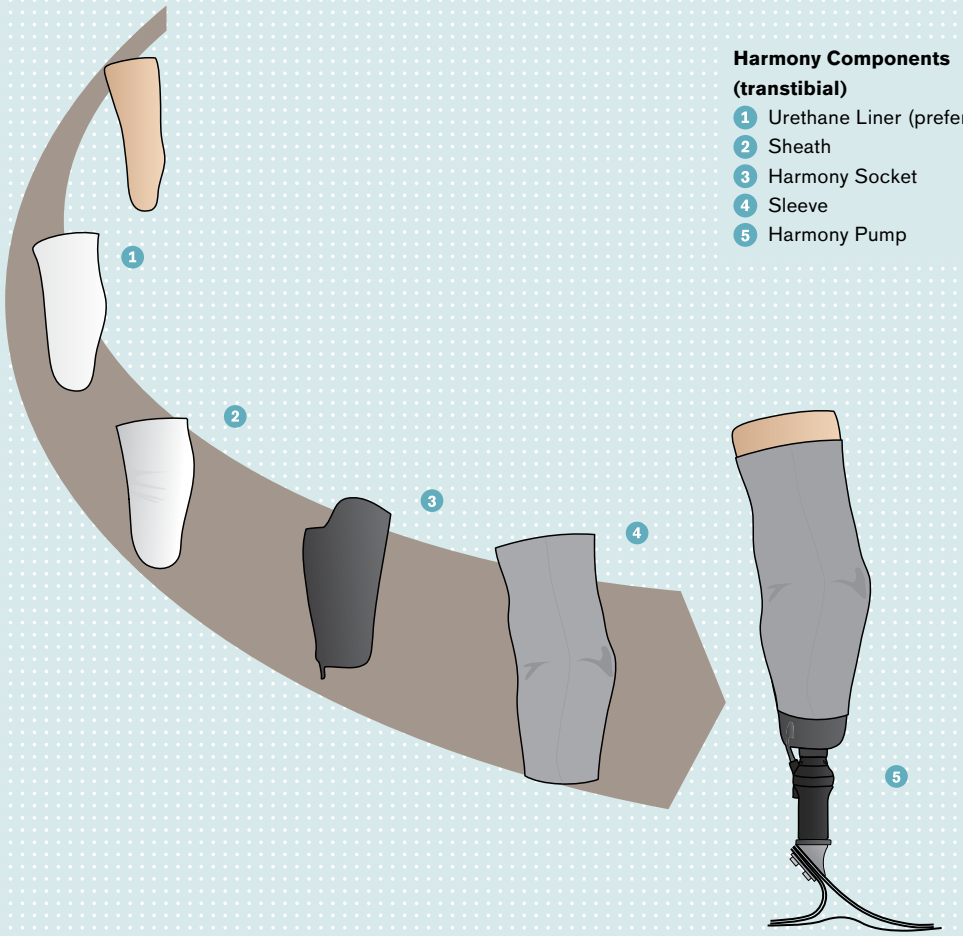
Active vacuum volume management

Information for Practitioners



Harmony:
A strong solution.

Harmony is an active vacuum volume management solution for transtibial (and transfemoral) patients. By means of a pump unit, vacuum is created between the 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 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 management[1], which can reduce the need to add socks
- Reduces pistoning between the limb and socket[2]
- Improves residual limb health[3]
- Helps improve balance, reduce risk of falls and improve walking[4]

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:

- Interim fittings
- Dialysis patients
- Neuroma, preventing patient from being able to bear pressure on the residual limb
- Missing cognitive abilities of the patient to "manage" the system

Harmony
Volume Management

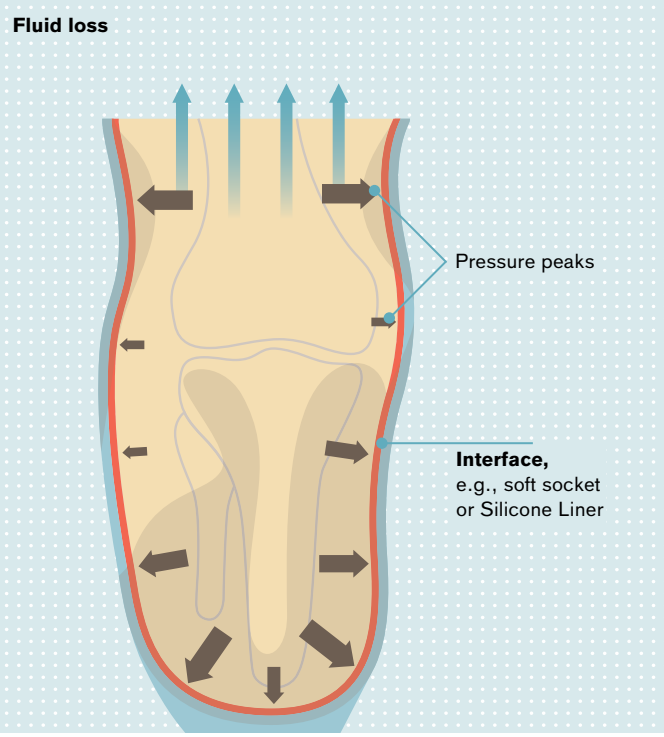
Residual limb fluctuations

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.

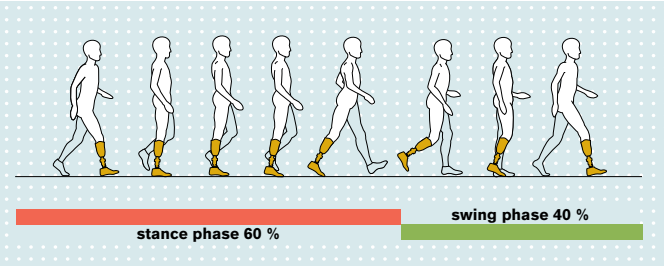
Each residual limb is subject to volume fluctuations. The extent of the fluctuations depends on different factors such as the condition of the connective tissue, age of the patient, vascular diseases and, of course, the kind and fit of the socket.

To compensate 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.

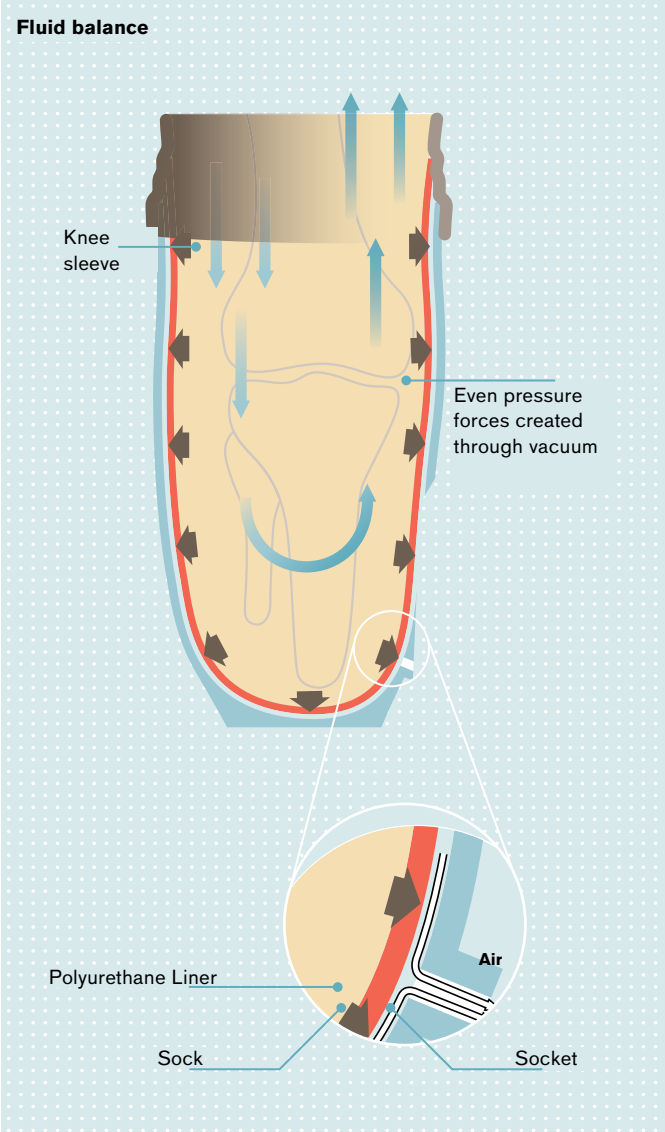
Simple one-way valves release only the amount of air that the residual limb volume can press out. Although the suction created in this way provides for sufficient connection, it cannot prevent volume fluctuations in the residual limb. Even shuttle lock systems cannot prevent volume fluctuations. The 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 weigh-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 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 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 course required for fitting the Harmony vacuum pumps.

Harmony P4 and P4HD
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.

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

Harmony E2
Features & Benefits

Harmony E2 is an 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 waterproof to 10ft submersed.

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. (3 m) 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 end-users up to 275 lbs. body weight.

The 1C62 Triton Harmony combines the excellent functionality of the 1C60 Triton carbon fiber foot with the proven Harmony P3 technology. The Triton Harmony with its compact design is suitable for highly active end-users up to 330 lbs. body weight.

Harmony P3

Triton Harmony

1 **Carbon Forefoot Spring**
The split forefoot spring allows the foot to adapt to unevensurfaces. 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 fiber 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.

Technical Data and Order Information
Harmony Pumps

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 into the patient's clothing or prosthesis.

Article number	Harmony P4 4R180	Harmony P4 HD 4R181
Mobility grade	K3–K4	K3–K4
Material	Aluminum	Aluminum/Titanium
Weight limit	110 - 220 lbs (50 - 100 kg)	110 - 330 lbs (50 - 150 kg)
Clearance height	4 1/2 in (114 mm)	4 1/2 in (114 mm)
Part weight	16.4 oz (465 g)	20.8 oz (590 g)

4R147 Harmony P3
The slim pump weighs only 425 g (0.94 lbs) which is 20% lighter than Harmony P2, 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	K3–K4							
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 (lbs.)	88–105	106–122	123–144	145–166	167–192	193–220	221–248	249–275
Clearance height	4 5/8″ (117 mm)							
Weight	425 g							
Max. body weight	275 lbs. (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
88–103 lbs (40–47 kg)		1-0 special order – please contact Customer Service					–	–	–	–
104–121 lbs (48–55 kg)	1-1	1-1	1-1	1-1	1-1	1-1	–	–	–	–
122–143 lbs (56–65 kg)	2-2	2-2	2-2	2-2	2-2	2-2	2-2	2-2	2-2	2-2
144–165 lbs (66–75 kg)	2-3	2-3	2-3	2-3	2-3	2-3	2-3	2-3	2-3	2-3
166–192 lbs (76–87 kg)	3-4	3-4	3-4	3-4	3-4	3-4	3-4	3-4	3-4	3-4
193–220 lbs (88–100 kg)	3-5	3-5	3-5	3-5	3-5	3-5	3-5	3-5	3-5	3-5
221–247 lbs (101–112 kg)	–	–	–	–	4-6	4-6	4-6	4-6	4-6	4-6
248–275 lbs (113–125 kg)	–	–	–	–	4-7	4-7	4-7	4-7	4-7	4-7
276–302 lbs (126–137 kg)	–	–	–	–	5-8	5-8	5-8	5-8	5-8	5-8
303–330 lbs (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 10 ft. 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	6.5 oz (185 g)	4.4 oz. (125 g)	5.6 oz (160 g)
Clearance height	3 ¾″ (95 mm)	⅞″ (22 mm)	⅞″ (22 mm)
Material	–	Aluminum	Aluminum
Max. body weight	–	330 lbs. (150 kg)	330 lbs (150 kg)
Temperature range for use	-10°C–60°C (14°F–140°F)	–	–
Battery charger 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 ProFlex Plus Sleeves

Complementary components for TF prosthesis

6Y81 ProSeal SIL Liner

452A1 ProSeal Ring

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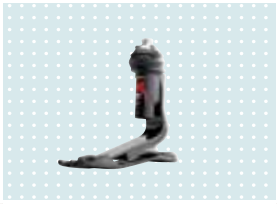
Harmony Vacuum Pump Selection Chart

						
	4R180 Harmony P4	**4R181 Harmony P4 HD**	**4R147 Harmony P3**	**1C62 Triton Harmony**	**3R60=VC 3R60 Harmony**	**4R152 Harmony E2**
Type (electronic/mechanical)	Mechanical	Mechanical	Mechanical	Mechanical	Mechanical	Electronic
Pump Mechanism	Piston	Piston	Functional ring	Functional ring	Piston	Peristaltic
TT	●	●	●	●		●
TF				●	●	●
Mobis/K-Level	K3 - K4	K3 - K4	K3 - K4	K3 - K4	K3	K2 - K4
Max. body weight	220 lbs	330 lbs	275 lbs	330 lbs	275 lbs	330 lbs
Vertical shock	●	●	●	●		
Torsion	●	●	●	●		
Adjustable vacuum						●
Removeable by user						●
Vacuum (max.)	24 inH 800 mbar	24 inH 800 mbar	20 inH 650 mbar	20 inH 650 mbar	21 inH 700 mbar	21 inH 700 mbar
Weight	16.4 oz (465 g)	20.8 oz (590 g)	14.1 oz (400 g)	26.5 oz (750 g) incl foot	31.7 oz (900 g)	6.6 oz (188 g) pump 4.4 oz (125 g) plate
Clearance	4 1/2“ (114 mm)	4 1/2“ (114 mm)	5 in (127 mm)	8.125 in (203 mm) size 26	8 5/8 in (222 mm)	pump w/ plate 3.75 in (95 mm) Plate .875 in (22 mm)
Waterproof	●	●	●	●		submersible to 10 ft.
Suggested L-Codes	L5781, L5984, L5988	L5782, L5984, L5988	L5781, L5984, L5988	L5781, L5986, L5987	L5781, 3R60 knee codes	L5781

The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME Supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

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, Traballesi 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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