

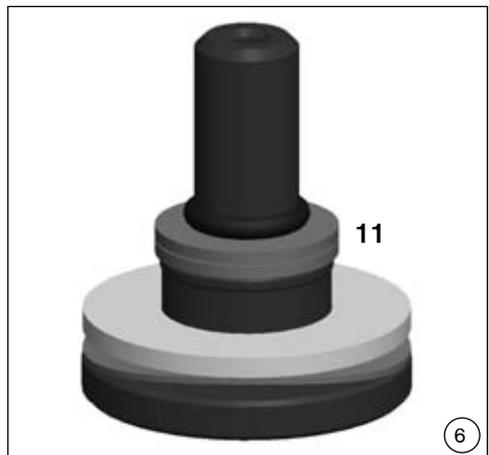
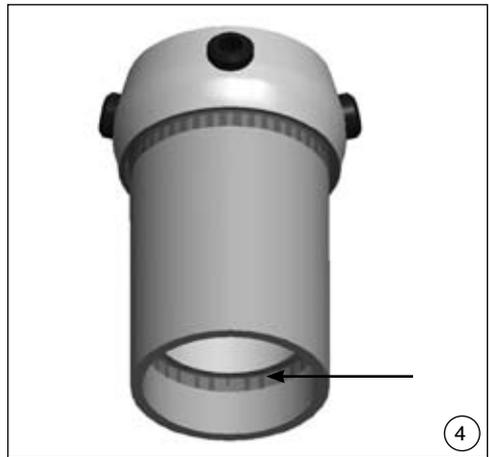
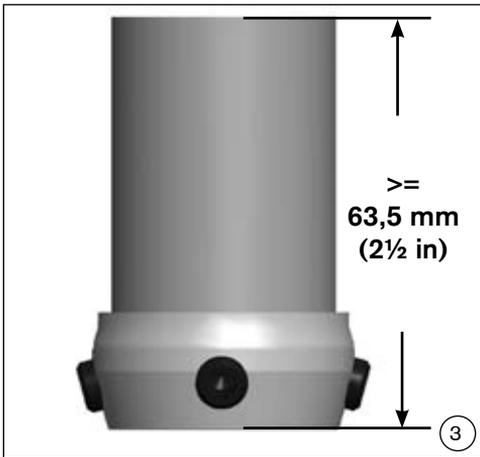
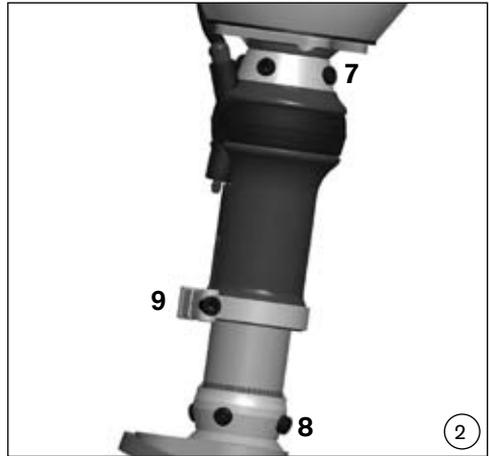
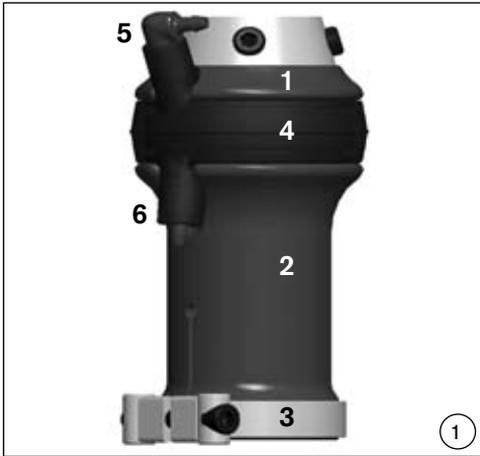
Otto Bock®

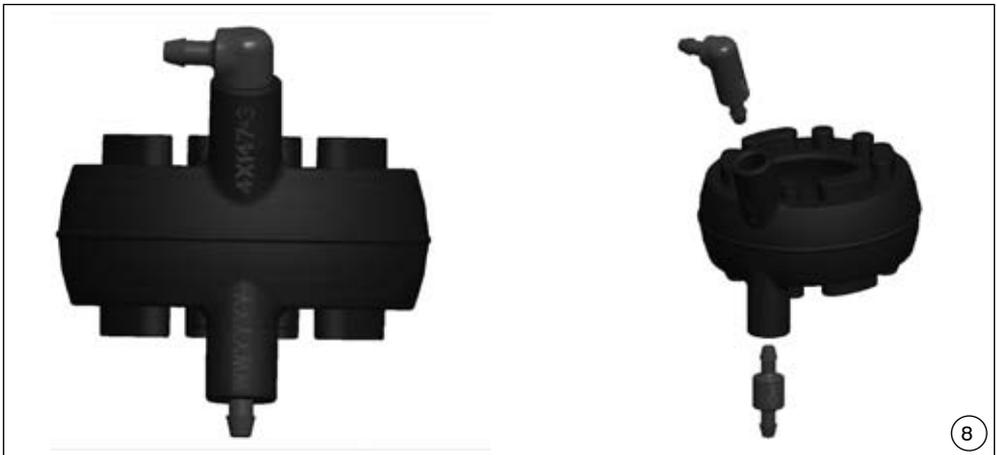
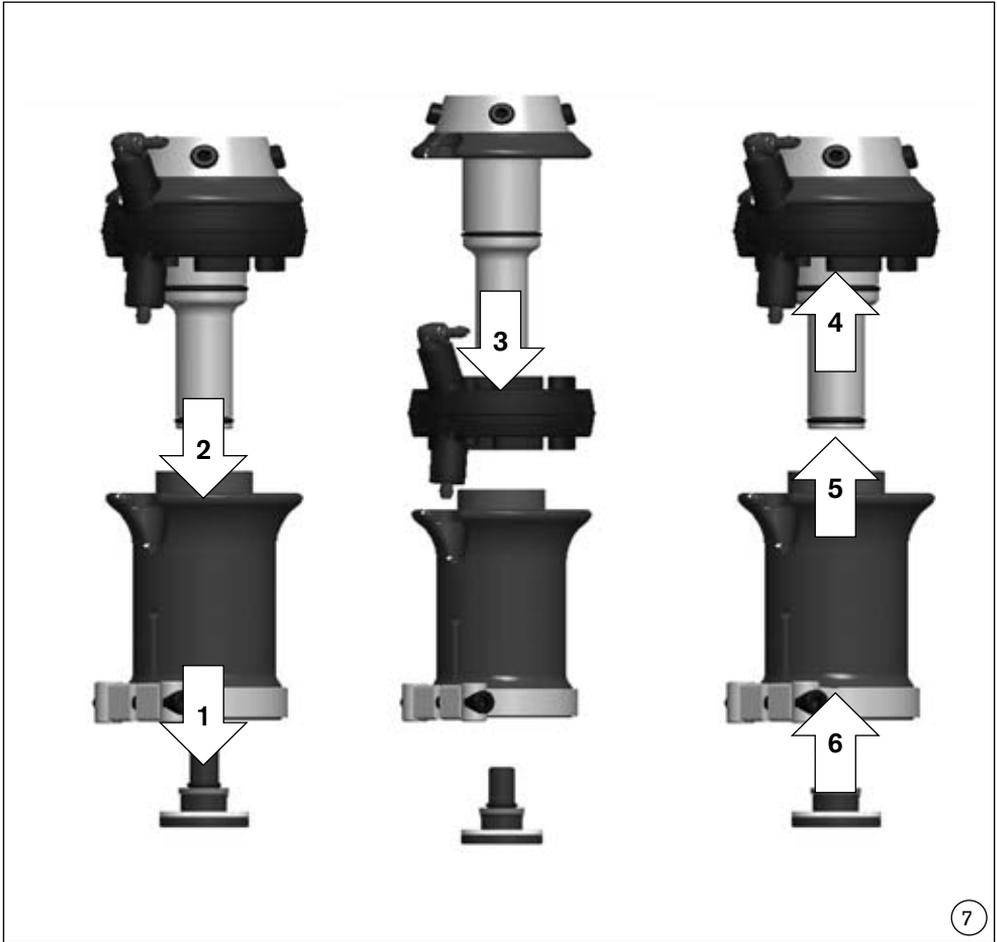
QUALITY FOR LIFE

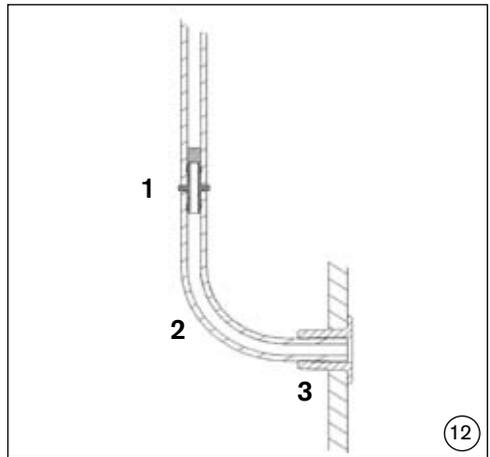
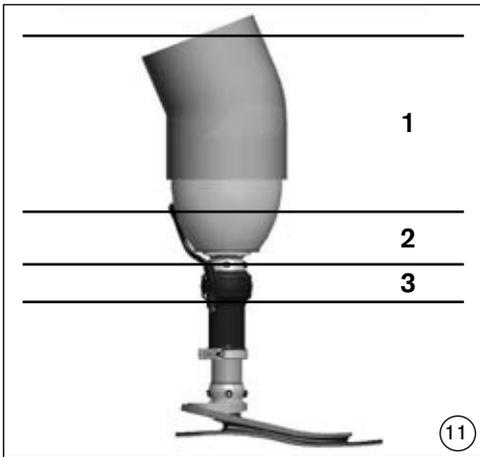
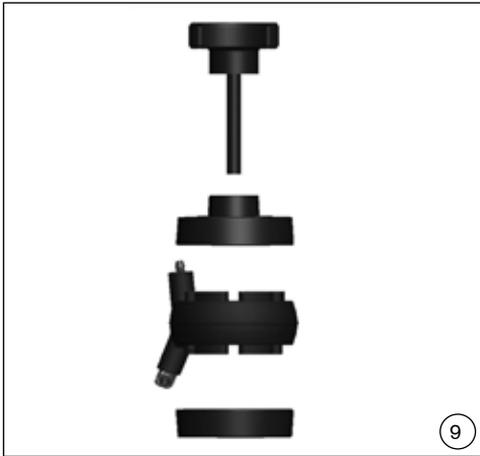


4R147

Ⓧ	Harmony®P3	5
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 CAUTION	Warnings regarding possible risks of accident or injury.
 NOTICE	Warnings regarding possible technical damage.
 INFORMATION	Additional information on the fitting/ use.

INFORMATION

Please read these instructions for use carefully and pay special attention to the safety instructions!

1 Scope of Delivery

The Harmony® P3 is delivered with the following components:

1. 4R147 Harmony® P3 Pump (incl. 4X147 Functional Ring*)
2. 2R117 Socket Connector (2x)
3. 4Y360 Muffler
4. 4Y383 Exhaust Flange Kit
5. 647H14 Instructions for Use

* Additional versions of the 4X147 Functional Ring can be ordered separately (for selections refer to Section 4.5.1).

2 Description

2.1 Intended Use

The Harmony® P3 Pump is a component of the Harmony® Elevated Vacuum System, which also includes a Total Surface Weight Bearing Socket, Polyurethane Liner, Air Wick, and Sealing Sleeve. The Harmony® System is to be used **solely** for the prosthetic fitting of the lower limbs.

2.2 Field of Application



Field of application according to the Otto Bock MOBIS® Mobility System:

Recommended for amputees with Mobility Grade 2 to 4 (restricted outdoor walker, unrestricted outdoor walker, unrestricted outdoor walker with particularly high demands).

Approved for a patient weight of max. 100 kg/220 lbs. A minimum weight of 45 kg/100 lbs is required to activate the pump.

2.3 Safety Instructions

2.3.1 General Safety Instructions

CAUTION

Health risk as a result of using wrong prosthetic socket. The application of wrong socket techniques can cause health risks for the patient (increased accumulation of fluid in the residual limb, e.g. oedemas). The prosthetic socket has to be fabricated following **exclusively** the Harmony® socket fabrication technique.

NOTICE

Function loss due to mechanical damage. If the Functional Ring shows any signs of damage, proper operation of the device cannot be ensured (impossible to create an elevated vacuum). The Functional Ring is to be protected against mechanical damage. The Functional Ring must be replaced by qualified personnel if it shows any signs of damage (see Sections 4.5 and 5).

NOTICE

Function loss as a result of improper use. The patient should be properly instructed in the use of the Harmony® Pump and Harmony® System (see Section 2.3.2).

2.3.2 Patient Information

Please pass this information on to your patients.

NOTICE

Function loss as a result of dirty valves. Proper maintenance and care require periodic flushing 30-60 ml (1-2 fl-oz) of distilled water with about 5 to 10 pumps/steps through the Harmony® System in order to clean the valves. If flushing does not solve the issue the plastic valves (4Z106 straight & 4Z108 elbow) can be easily replaced (see figure 8).

INFORMATION

- Handle the Harmony® Pump carefully and examine regularly for any signs of damage and wear.
- Work with your prosthetist to make sure you understand how the Harmony® System feels when functioning properly, when loss of vacuum occurs and what the overall effects of applying an elevated vacuum to the limb are.

2.4 Qualification of the Prosthetist

The fitting of a patient with a Harmony® System may only be carried out by prosthetists who have been authorized by Otto Bock after completion of a corresponding training course.

2.5 Function

2.5.1 Description of the Components (Fig. 1)

- (1) Shaft
- (2) Base
- (3) Clamp Ring
- (4) Functional Ring
- (5) Intake Valve
- (6) Expulsion Valve

2.5.2 Vacuum Pump

The Harmony® P3 is a mechanical pump that can create an elevated vacuum in a prosthetic socket, thereby improving the connection between the amputee and the prosthesis. The system consists of a polyurethane liner, an airwick, a rigid socket (which is connected to the pump), a sealing sleeve and the Harmony® P3 Pump.

Once the environment is sealed, the Functional Ring – which is compressed and released during normal walking – draws air from the socket through one-way valves and evacuates it through the

pump. After multiple cycles of compression an elevated vacuum of 508-847 mbar (15-25 inHg) is created in the sealed socket environment.

2.5.3 Shock Absorption and Rotational Function

The Functional Ring in the Harmony® P3 Pump has a shock absorption and rotational function that help to reduce vertical and torsional forces in the extremities during walking. The result is an improvement for both the function and loading situation of the prosthesis wearer.

3 Technical Data

4R147 Harmony® P3 Pump	
Pump Weight	425 grams
Pump Height	117 mm (4.6in)
Pump System Height	175 mm (6.9 in)
Weight range	45-100 kg (100-220 lbs)
Torques	Receiver Set Screws (Fig. 2, items 7 & 8): 15 Nm (133 in-lbs) Clamp Ring Screw (Fig. 2, item 9): 10 Nm (88 in-lbs) Retaining Screw (Fig. 5, item 10): 7 Nm (60.0 in-lbs)
Material	Aluminium/Titanium/Nylon

4 Handling

CAUTION

Health risk as a result of using of wrong prosthetic socket. The application of wrong socket techniques can cause health risks for the patient (increased accumulation of fluid in the residual limb, e.g. oedemas). The prosthetic socket has to be fabricated following **exclusively** the Harmony® socket fabrication technique.

4.1 Installing the Socket Connector

On a new socket, drill a 6mm (¼") hole into the socket at a distal, posterior position. For sockets with a 4R136 or 4R138=5 Otto Bock One-Way Valve, remove valve from socket and drill into existing hole. Remove burrs from the inside of the socket. Lightly sand the exterior of the socket with medium grit sandpaper to roughen the bonding surface. Wipe with isopropyl alcohol to clean the bonding surface. Also clean the 2R117 Socket Connector with isopropyl alcohol.

Next, apply a thin coating of adhesive (Otto Bock recommends 2 Component Urethane Adhesive SL=P091) to the flat surface of the flange as well as the collar. Be careful not to get adhesive in the tapered end.

Insert tapered end of flange into the 6mm (¼") hole with the tube directed towards the Harmony® Pump. Use needle nose pliers to pull the tapered end of flange into the socket until the flat surface of the flange is tight against the outer surface of the socket. Tape the flange in place with vinyl tape. Allow to cure for at least 45 minutes.

Note: For particularly deep or narrow sockets, the tapered flange can be marked with a pen first, then removed and cut. This may require a slightly larger hole (6,5mm or ¼"). Glue as with normal socket.

Use a round-edge knife to trim the tapered end of the flange inside of the socket. It should be flush with the inside surface of the socket.

4.2 Attaching the Socket and Adapter to the Harmony® P3 Pump

Tighten the set screws on the proximal receiver of the Shaft (Fig. 2, item 7) onto the socket pyramid adapter and torque to **15 Nm** (133 in-lbs). Use 636K13 Loctite® 241 on screws for final adjustment.

4.3 Attaching the Tube Adapter to the Harmony® P3 Pump

INFORMATION

- The 4R147 pump must be used with a 34 mm tube adapter.
- The minimum cut height of the tube adapter is 63.5 mm (2 ½ in) (Fig. 3).
- The tube extends into the pump 42 mm (1.65 in).
- If the tube adapter is cut shorter than 100mm (4 in), ensure the adhesive on the inside diameter of the tube adapter (Fig. 4) does not interfere with the blue screw and washer in the distal end of the pump. Scrape excess adhesive away with a knife.

Cut the tube adapter to the required length; insert the tube adapter into the distal end of the pump completely. Torque the Clamp Ring Screw (Fig. 2, item 9) to **10 Nm** (88 in-lbs). Use 636K13 Loctite® 241 on screws for final adjustment.

4.4 Connecting the Socket Connector

Cut the Socket Connector tube to length, slip the black tube collar 4Y310 onto the Socket Connector. Attach to the proximal intake valve (Fig. 1, item 5) on the Harmony® P3 pump and press tube collar down to secure the Socket Connector.

4.5 Selecting and Adjusting the Functional Ring

NOTICE

Function loss as a result of improper use. The Functional Ring may only be selected/adjusted by prosthetists that have been authorized by Otto Bock.

4.5.1 Selecting the right Functional Ring

Use the following selection table to select the right Functional Ring. The Functional Ring version is marked on the intake valve receiver (Fig. 8).

	Body Weight				
kg	45-50	50-60	60-73	73-86	86-100
lbs	100-110	110-130	130-160	160-190	190-220
	↓	↓	↓	↓	↓
Recommended Functional Ring	0	1	2	3	4

Please note that the recommendations do not necessarily represent the optimal selection for the patient. When deviating from the selection data, the Functional Ring with the highest possible stiffness should be selected that nevertheless still creates a sufficient vacuum. Otto Bock recommends that a vacuum of approx. 500 mbar (15 inHg) or more should be reached within 50 steps with the prosthesis.

If the patient feels like they are “bottoming out”, a stiffer Functional Ring should be used. If the pump does not reach a sufficient vacuum level, a softer Functional Ring should be used.

4.5.2 Changing the Functional Ring

1. Loosen the retaining screw on the distal end of the Base (Fig. 5, item 10) and remove it (Fig. 7, Step 1). If the pump is mounted completely, remove the tube adapter with foot beforehand.
2. Pull the Base away from the Shaft (Fig. 7, Step 2).
3. Pull off the installed Functional Ring (Fig. 7, Step 3).
4. Select the desired Functional Ring (Section 4.5.1)
5. Preparing the Functional Ring for initial use

Prior to its first use, Otto Bock recommends that separately ordered Functional Rings should be pre-compressed with the separately available Pre-compression Tool 4X247 to ensure proper function. Without pre-compression, new Functional Rings can be overly stiff. If using the pre-installed Functional Ring or an already pre-compressed unit please continue with step 6.

- a. Open the Pre-compression Tool
 - b. Place the Functional Ring in the Pre-compression Tool (Fig. 9)
 - c. Completely compress the Functional Ring by tightening the screw completely (Fig. 10)
 - d. Compression time: Minimum 3 minutes to a maximum of 15 minutes
 - e. Open the Pre-compression Tool remove the Functional Ring and install it in the pump
6. Slide the Functional Ring over the Shaft (Fig. 7, Step 4).
 7. Reassemble the pump (Fig. 7, Step 5&6).
 8. Secure the Retaining Screw with 636K13 Loctite® 241 and tighten it clockwise with **7 Nm** (60 in-lbs).
 9. Reassemble the tube adapter and foot

4.5.4 Fine Tuning of Pump Stiffness

Rough setting of the pump's compression stiffness is provided by Functional Ring selection. Fine adjustment of the compression stiffness can be achieved by adding or removing washers (Fig. 6, Item 11).

1. Loosen the Retaining Screw on the distal end of the pump (Fig. 5, item 10).
2. The pump is shipped with 2 washers on the Retaining Screw. Do not use more than two washers. One or both washers may be removed. A small o-ring is used to keep the washers on the screw. The o-ring has no other function.
 - a) Removing a washers increases the preload on the Functional Ring, thereby reducing the vertical displacement (and the extension of the pump during the swing phase). Additional effect: slight decrease in maximum vacuum achieved.
 - b) Adding washers reduces the preload on the Functional Ring, thereby increasing the vertical displacement (and the extension of the pump during swing phase). Additional effect: slight increase in maximum vacuum achieved.
3. Test the achieved vacuum once the desired shock absorption has been reached.

4.6 Monitoring the Elevated Vacuum Environment

To verify that the Harmony® System maintains an elevated vacuum environment, it is necessary to temporarily install the Vacuum Gauge 755Z37 (available separately from Otto Bock).

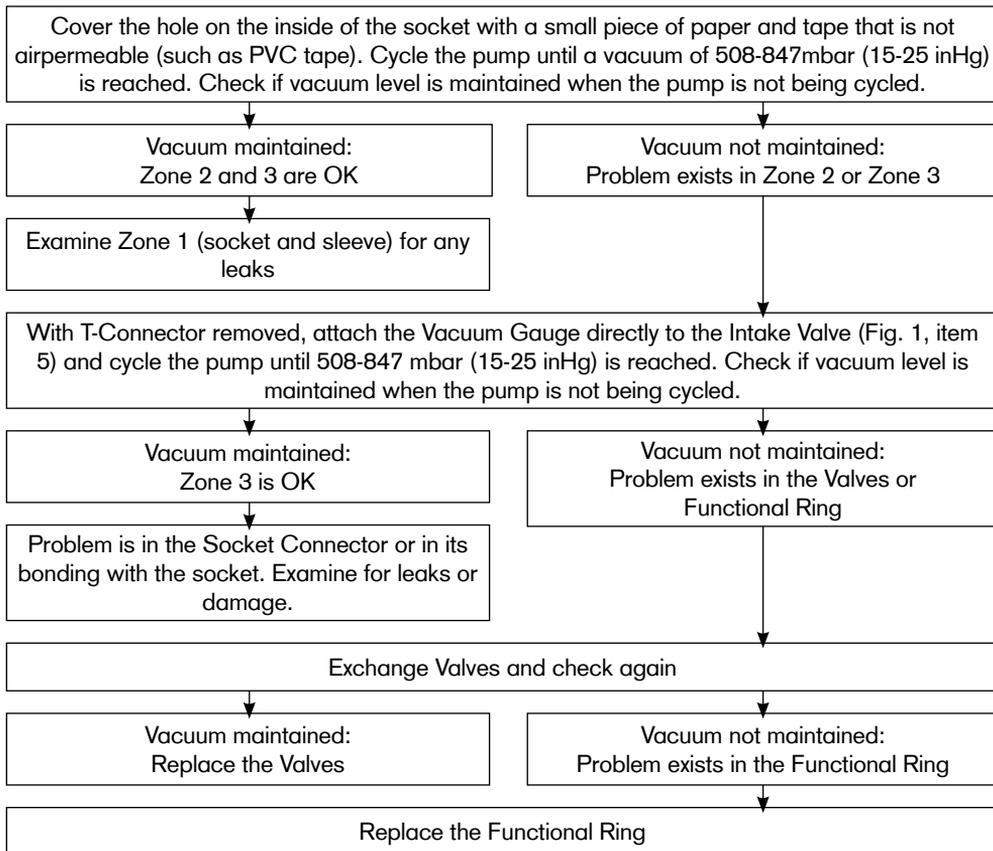
1. To do this, remove the vacuum line from the Harmony® P3 Pump's intake valve.
2. Next, attach the vacuum line of the Vacuum Gauge (short side) to the pump's Intake Valve and connect the loosely hanging Socket Connector to the open barb on the Vacuum Gauge.
3. While the patient is standing and wearing the properly fitting Harmony® System, cycle the Harmony® P3 Pump to generate a vacuum between 508-847 mbar (15-25 inHg).

4. Stop cycling the pump. If the vacuum is maintained, the system is functioning correctly. If vacuum loss does occur, it will be necessary to check the system (see Section 4.6.1).

4.6.1 Troubleshooting the System if Vacuum Loss Occurs

To determine if the vacuum loss exists in Zone 1, 2 or 3 (Fig. 11) install the gauge as described in section 4.6. Then proceed as follows:

Flow chart:



4.7 Cosmetic finish of the Prosthesis

The Harmony® P3 is delivered with two different exhaust valve attachments:

- a short piece of tubing with installed muffler and Double Barb Connector pre-installed at the exhaust valve
- a long piece of tubing with an exhaust flange

If a cosmetic cover of the prosthesis is desired use a cover with a 34 mm centre hole.

NOTICE

Function loss as a result of improper installed cosmetic cover. If using a 6R8 Foam Cover, it is important that the cover is not compressed along the length of the foam, as this can affect the function of the Harmony® pump.

Once the Foam Cover is in place, determine location of exhaust flange and drill or cut a 6 mm hole. Otto Bock recommends placing the exhaust flange medially at the ankle, just above the top of a patient's shoe. Next, insert tubing (Fig. 12, Pos. 2) and flange (Fig. 12, Pos.3) into the hole of cosmetic cover and connect tubing to Double Barb Connector (Fig. 12, Pos. 1). Make sure that the tubing is not crimped or compressed in any way. The flange can be glued in place if necessary: apply thin layer of glue to flange surface and press into place. Once flange is secure, any extra tubing can be cut to length or simply pressed into the cosmesis until end of tubing is flush with flange.

Note: To achieve the best cosmetic appearance, we recommend that the foam cover is finished with a Soft Touch stockinette.

Note: If salt appears on the outside of the stockinette, it can be washed away with warm water.

5 Maintenance

Otto Bock recommends replacing the 4X147 Functional Ring after approximately 1 year of use because the stiffness and restoring force can decrease over time. Depending on activity and environmental conditions, this may become necessary at an earlier (or later) point in time. Reduced shock absorption and slower generation of vacuum are typical indicators the patient may notice.

Note: New Functional Rings may feel stiffer for the patient on the initial days of use.

If vacuum performance decreases without a corresponding decrease in shock absorption performance, one or both of the valves may have become clogged with debris. The best remedy is to replace the valves. Blow any accumulated debris out of the Functional Ring using compressed air while the valves are removed.

When replacing the Functional Ring at the recommended service interval, wipe all old grease from the shaft and bearings, apply new grease, and replace the two o-rings on the shaft. These o-rings do not affect vacuum performance. They are used to cushion undesirable but necessary movement in the bearing system.

6 Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the Instructions for Use. The device must only be operated with tested modular components in accordance with the Otto Bock Mobility System. The manufacturer is not liable for damage caused by component combinations that were not authorised by the manufacturer.

7 Warranty

Otto Bock warrants this device/these devices from the date of purchase. The warranty covers defects that can be proven to be a direct result of flaws in the material, production or construction. Because warranty conditions may differ by country, please contact your local Otto Bock distribution company for more information.

8 CE Conformity

This device meets the requirements of the 93/42/EEC guidelines for medical devices. This device has been classified as a class I device according to the classification criteria outlined in appendix IX of the guidelines. The declaration of conformity was therefore created by Otto Bock with sole responsibility according to appendix VII of the guidelines.

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The Harmony P3 is covered by the following patents:

Australia: AU 2002 232424 B2
USA: Patent US 5,735,906; US 6,508,842; US 6,726,726
European Patent: EP 1 771 659 in CZ, GB, FR, DE, IS, IT, NL, PL, SE, TR
Patents pending international and in the USA.