Harmony Vacuum System

Reimbursement Reference Guide

Effective January 1, 2015

Harmony Vacuum System

Elevated vacuum suspension has been commercially available in the U.S. since 1999 when Total Environmental Control (TEC) introduced the Vacuum Assisted Socket System (VASS). Today, the VASS is manufactured by Ottobock and marketed as the Harmony® Vacuum System.

Harmony Coding¹

The Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Primary codes for vacuum pumps were issued in 2003. Since then, additional features have been added to our pumps. Depending on which model is ordered, functions, such as shock absorption, torsion, or rotation may be provided in addition to vacuum, which are described by add-on codes.

The following HCPCS¹ codes are applicable to Harmony Products:

- **4R144 Harmony P2**: L5781 (vacuum pump), L5984* (axial rotation), L5988 (vertical shock pylon)
- **4R147 Harmony P3**: L5781 (vacuum pump), L5984* (axial rotation), L5988 (vertical shock pylon)
- **4R150 Harmony HD**: L5782 (vacuum pump heavy duty), L5984* (axial rotation), L5988 (vertical shock pylon)
- **4R152 Harmony E2**: L5781 (vacuum pump)
- **1C62 Triton Harmony**: L5781 (vacuum pump), L5986* (multi-axial rotation), L5987** (shank foot system)
- **3R60=VC**: L5781 (vacuum pump), L5814** (polycentric knee), L5845 (stance flexion), L5848** (stance extension damping), L5930*** (high activity knee frame)

* Medicare covers for K2 and higher; ** Medicare covers for K3 and higher; ***Medicare covers for K4 only

Other items that may be coded on a claim related to Harmony® (not all inclusive):

- Total Surface Weight Bearing (TSWB) Socket and additional materials/features added to the socket (various codes)
- Flexible Inner Socket – L5645, L5651
- Cushion Socket – L5646
- Supracondylar Suspension - L5670
- Test Sockets, L5618 - L5628
- Custom Socket Inserts (liners), L5681 or L5683 (initial insert), L5679 (additional insert)
- Prefabricated Socket Inserts (liners) L5679
- Sheaths L8400, L8410
- Sealing Sleeves L5685
- Socks L8420, L8430, L8470, L8480

Harmony® Certification Training

Ottobock lists Harmony® Trained Practitioners on its website. These practitioners have taken a 3.0 CEU on-line course and passed the exam.

FDA Status

Under FDA’s regulations, the Harmony® Vacuum System is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device’s safety and effectiveness; therefore, safety and effectiveness research is not required for this device.

Harmony has met all the General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing(21 CFR part 807), Quality System Regulation (21CFR part 820), Labeling (21CFR part 801), and Medical Device Reporting(21 CFR Part 803). The Harmony Vacuum System is listed under External Limb Prosthetic Component; Listing Number E253231.

Harmony® Warranty

Otto Bock HealthCare (Ottobock) warrants all of its products, to the original purchaser, to be free from defects in materials and workmanship. The Limited Warranty for the Harmony® is 24 months. For additional information on the Harmony® System Warranty, see Harmony® Instructions for Use (IFU).

¹ 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 alphanumeric system changes.
The Harmony® Vacuum System

Features and Benefits

Volume Control
Compared to a standard transtibial prosthetic socket, the Harmony® System’s elevated vacuum pulls more oxygenated fluids into the residual limb during swing phase and pushes less fluids out during weight bearing. The result is less than 1% volume loss during the course of the day.¹,² As a result, the socket fit is more consistent and may eliminate the need for the user to remove the prosthesis multiple times/day while attempting to manage volume changes with socks and/or spots.

Reduced Forces
In standard sockets daily volume fluctuations inherently cause an inconsistent fit for many amputees not under vacuum and can lead to pressure points on the limb.²,³ Controlling volume under vacuum may reduce these forces and promote better limb health.²

Proprioception
The Harmony® System’s elevated vacuum leads to heightened proprioception which increases the awareness a user has of her or his leg during walking. As a result, users may experience increased balance, stability and control over the prosthesis.²

Reduced Moisture Build-up
The Harmony® System pulls air from the sealed socket creating an even pressure total contact environment reducing the likelihood of sweating. The Harmony system can also be configured for direct evacuation of moisture from the socket system thus greatly reducing moisture buildup.

Shock Absorber and Torsion Adapter
The Harmony® System mechanical pump has an integrated, adjustable shock absorber and torsion adapter, which work together to increase walking comfort and relieve strain on joints and spine. These features may also contribute to a more natural gait pattern.⁴

Harmony® System Elements

1. **Liner** ........ Protects your limb

2. **Sheath** ..... Makes it easy to slide into socket and creates an airspace for the vacuum

3. **Socket** ...... Your connection to the prosthesis

4. **Gaiter** ...... Protects the sleeve from the socket edges

5. **Sleeve** ...... Seals the vacuum air space

6. **Tubing** ...... Connects the pump to the socket's air space

7. **Pump** ....... Creates an elevated vacuum in the socket so your limb stays connected

Ottobock
800.328.4058
http://professionals.ottobockus.com
Clinical Research Summary

The Benefits of Vacuum Compared to Other Suspension Methods

Elevated vacuum suspension systems manage limb volume fluctuation, a problem that people with limb loss are challenged with. Over time and on a daily basis, these volume changes can affect how the socket fits. When the limb volume increases, the socket becomes tighter, exerting pressure, restricting blood flow, and allowing for accumulated cell waste. When limb volume decreases, the socket is loose-fitting often causing pressure to bony prominences, which may result in pain and/or injury to the limb.¹

Vacuum Compared to Pin Suspension

Ferraro (2011) conducted an outcomes study (n=13) comparing pin suspension to electronic vacuum suspension. All subjects used each suspension system for at least 30 days.² A validated measurement tool called the Activity-specific Balance Confidence (ABC) scale was used to evaluate the subject’s confidence when performing certain activities (n=16) with regard to balance. Subjects taking the survey rated their confidence in performing each activity on a scale from 0 (no confidence) to 100 (completely confident).³ A score below 67 indicates a risk for falling.⁴

Results: Four surveys were excluded from the final analysis; (survey not complete, subject did not use both suspension systems, vacuum system was not electronic, and incorrect amputation level). The ABC scores for the remaining 9 surveys were Vacuum Suspension (80±10) and Pin Suspension (65±20), resulting in a confidence level of 95% (p=0.0359) in favor of vacuum. Subjects (n=13) were also surveyed on a variety of related problems experienced with suspension systems. Results for pistoning, blisters, volume change, difficulty knee bending, redness, falls, and walking time, all favored vacuum suspension over pin suspension; however the results were not significant, possibly due to small sample size.¹

An earlier study by Beil⁵ (2004) compared pin suspension to suction suspension (n=9) by measuring impulse and peak pressures in the socket during ambulation. Results: During stance phase there was no difference between the two suspension methods (p=0.076); however, during swing phase, differences were significant (positive pressure impulses p=0.008, average positive pressure p=0.004, distal negative impulse p=0.053 and peak pressure p=0.026) demonstrating that pin suspension exerts an occlusive pressure on the proximal tissues of the residual limb, while at the same time generating considerable suction at the distal end of the socket, and that these pressures are likely causing both the persistent and the day-to-day skin issues witnessed with pin suspension users.
The Benefits of Vacuum Compared to Other Suspension Methods (cont.)

Vacuum compared to Suction Suspension

Board⁶ (2001) conducted a randomized trial comparing suction suspension to vacuum-assisted suspension; evaluating changes in volume, tibia and liner pistoning, and stance phase and step length symmetry. **Volume:** Residual limb volume (n=10) was measured prior to and after a 30 minute treadmill walk, and a significant increase of 3.7% or 30 ml (p=0.007) was found when using vacuum as compared to a significant decrease of 6.5% or 52 ml when using suction. **Pistoning:** Pistoning of the tibia and liner (n=11) were measured using X-ray and extraction force and a significant decrease (p=0.000) in both tibia and liner pistoning was found in favor of the vacuum system. **Symmetry:** Gait symmetry (n=10) was assessed with video and found significant improvements in both stance phase symmetry (p=0.037) and step length symmetry (p=0.000). **Conclusion:** The authors concluded that while suction suspension fits well, it also causes volume loss due to the pressure that it exerts, which in turn worsens the fit, subjecting the skin to higher stresses and “shear forces” with potential for ulcers. Vacuum suspension, such as the Harmony®, retains correct fit, averts volume loss, and lessons pistoning in the socket; maintaining skin integrity, symmetry, and comfort.

Beil⁷ (2002) also compared vacuum suspension to suction suspension (using total surface weight-bearing sockets) by measuring impulse and peak pressures during ambulation (n=9). **Results:** Findings were favorable for vacuum, both during stance phase (impulse p=0.00, peak p=0.003) and during swing phase (impulse p=0.000, average p=0.000, and peak 0.001). It is believed that lower pressures seen during stance when using the vacuum-assisted socket force less fluid out and greater negative pressures seen during swing increases the amount of fluid drawn into the limb, thereby preventing volume loss.

---

1 Sanders JE, Harrison DS, Myers TR, Allyn KJ. Effects of elevated vacuum on in-socket residual limb fluid volume: Case study results using bioimpedance analysis. JRRD. 2011;48(10):1231-1248
2 Ferraro C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. Journal of Prosthetics and Orthotics. 2011;23(2):78-81
5 Beil TL, Street GM. Comparison of interface pressures with pin and suction suspension systems. JRRD. 2004;41(6A): 821-828
Clinical Research Summary

The Harmony®: Early Fitting of Transtibial Amputees with Unhealed Residual Limb Wounds

According to the most recent update by the Amputee Coalition (2012), close to two-million persons with limb loss reside in the United States, and of those, 54% of their amputations were a result of vascular disease.1,2 Furthermore, in 2009, hospitals reported costs related to limb loss as being greater than 8.3 billion dollars.1,3

When there is Presence of Unhealed Wounds

Until recently, standard practice was to delay the prosthetic fitting until the residual limb was in good condition and could withstand the forces generated by the prosthesis. In his research, VanVelzen (2005) found that ideally, the surgical wound from the amputation must be healed, the stump matured and conically shaped, and there should be no remaining edema when the prosthesis is fit.4,5,6

Persons with transtibial limb loss have (4X) greater likelihood of successful prosthetic use than persons with higher-level amputations.6 However, they are also more likely to experience skin complications on the residual limb.7, 8 Presence of ulcers or unhealed surgical wounds may delay prosthetic rehabilitation and increase the need for medical treatment.6,9

A randomized controlled trial recently published by Traballesi, et al.7 evaluated fitting of the Harmony® System on subjects with open ulcers/wounds (n=10) compared to fitting a standard suction socket (n=10) after wounds were healed to 1cm² (control group). Subjects were limited community ambulators (MFCL-2) or full community ambulators (MFCL-3), average age 61.3±13.2, with recent admission to the rehabilitation hospital after transtibial amputation due to dysvascular cause.

A twelve-week rehabilitation program was initiated for all subjects and additional follow-up conducted at weeks 28 and 36. First Steps: Harmony® users took their first step at 16±8.6 days, while the control group took their first step at 58.6±24.7 days (p=0.012). Independent Walking: At week 12 all Harmony® users were independent walkers, while only 5 in the control group were independent (p=0.001). Prosthetic Use: At 2-months the Harmony® group used their prostheses 62 hours/wk. (mean), while the control group used theirs 12 hours/wk. (p=0.003). At 6 months, prosthetic use was 80 hours/wk. for the Harmony® group compared to 59 hours/wk. for the control group; however, results were no longer significant (p=0.191).

Locomotor Capability Index (LCI): At week 12 the median LCI score for the Harmony® group was 42 (maximum score possible) versus 21 for the control Group (p=0.002). Drop-outs: Three subjects dropped out of the control group (one each at 4 weeks, 6 weeks, and 16 weeks) and one dropped out of the Harmony® group at 20 weeks. Wound Healing and Pain: Considering the difference in prosthetic use between the two groups, one would expect the Harmony® users to experience increased...
The Harmony*: Early Fitting of Transtibial Amputees with Unhealed Residual Limb Wounds (cont.)

pain and possibly less healing. However, wound-healing and pain perception scores were not statistically significant between the groups. **Conclusion:** The authors concluded that that early use of the Harmony* in the presence of open ulcers/wounds did not impede healing, nor did it increase pain.

**When Compared to Amputees without Ulcer/Wound Healing Failure**

An earlier study by Brunelli,12 conducted at the same rehabilitation facility, reported on 24 transtibial amputees; 7 subjects with ulcer/wound healing failure fit with the Harmony* and 17 subjects with no ulcer/wound healing failure fitted with a standard PTB socket (PTB Group). **Locomotor Capability Index (LCI):** Subjects were measured using LCI to determine prosthetic use. At nine months, the Harmony* group scored 36±6.7 on the LCI compared to the PTB group which scored 28±4.2. **Pain Perception:** Subjects were measured using the Visual Analog Scale (VAS) for pain perception. VAS scores were favorable for the Harmony* group both at 1 month (6.3±2.2 compared to 7.5±2.5) and at 9 months (4.6±1.3 compared to7±1.8). **Conclusion:** The authors concluded that patients fit with the Harmony* were compliant in its use, and their ulcers/wounds improved during the study.

**Large Wound Case Study**

Traballesi4 also reported on a 60 year-old, dysvascular, transtibial amputee with a 43.5cm² category IV wound on his residual limb. Measurements included the LCI for prosthetic use, the Barthel Index (BI) for functional independence, and digital photos of the wound for healing. The subject wore the Harmony* 8 hours per day for 4 months and participated in outpatient gait therapy.

**Results:** Despite having such a large open wound, when tested using the Harmony*, the subject’s LCI score was 41 and BI was 85. Additionally, after 3-4 hours of continuous ambulation and standing activities, VAS (pain) score was 0. At the end of 4 months, the wound area was reduced to 28cm², which equated to a 34% reduction in wound area.

---


http://journals.lww.com/jpojournal/Fulltext/2010/07000/A_Vacuum_Suspension_Measurement_Tool_for_Use_in.8.aspx?WT.mc_id=HPxADx20100319xMP


