Official Product Name:

ROHO® AirLITE® Cushion

Short Name:

AirLITE

Product-Specific Logo:

Product Image

Intended Use:

The ROHO® AirLITE® Cushion (AirLITE) is a wheelchair support surface with a non-adjustable, air-filled, segmented-design ROHO AIR FLOATATION™ insert encased in contoured foam. The AirLITE is intended to conform to an individual's seated shape to provide positioning. There is a weight limit of 300 lbs. (136 kg), and the cushion must be properly sized to the individual. The AirLITE must be used with the supplied cover.

ROHO, Inc. recommends evaluation by a clinician who is experienced in seating, positioning and mobility: 1) to determine whether the cushion is appropriate for the individual; and 2) to determine whether a solid seat platform is recommended if using the cushion on a sling-seat wheelchair.

Applications:

Based on clinical, scientific or engineering evidence, this product may be suitable for individuals who:

- are at risk for skin/soft tissue breakdown
- have normal sensation
- require increased stability
- require lower extremity alignment
- need a lightweight, non-adjustable seating system
- require a more stable environment for transfers
- experience discomfort from prolonged sitting

Features & Benefits:

- Reactive distribution of load
- Adds little weight to entire mobility system
- Cover is breathable, fluid-resistant, machine washable, and can be disinfected
- Lower anterior height for improved transfers
- Non-adjustable ROHO AIR FLOATATION™ air insert built into the cushion for improved immersion capability

Specifications*:

Product Includes:

AirLITE cushion, cover, operating instructions, product registration card

Accessories:

Contour Base: For more information, refer to the *ROHO Contour Base Product Detail Sheet.*
Planar Solid Seat Insert: For more information, refer to the *ROHO Planar Solid Seat Insert Product Detail Sheet.*
Privacy Shield: For more information, refer to the *ROHO Privacy Shield Product Detail Sheet.*
Cushion Retainer: Lightweight, made of sturdy nylon webbing and used to help prevent cushion from moving backward in a wheelchair.

Construction:

Cushion: Contoured polyurethane foam; polyethylene base
Sealed air insert: Non-adjustable, segmented, ROHO AIR FLOATATION insert made of polyurethane
Cover: Fluid-resistant, two-way stretch, polyurethane-coated polyester top, sides and non-skid bottom

Sizes:

ITEM #	Width (in.)	Depth (in.)	Width (cm)	Depth (cm)	Fits Chair Size (in.)	Fits Chair Size (cm)
AL1313HD AL1313HDCS	13	13	33	33	13 x 13	33 x 33
AL1315HD AL1315HDCS	13	15	33	38	13 x 15	33 x 38
AL1414HD AL1414HDCS	14	14	35.5	35.5	14 x 14	36 x 36
AL1416HD AL1416HDCS	14	16	35.5	40.5	14 x 16	36 x 41
AL1515HD AL1515HDCS	15	15	38	38	15 x 15	38 x 38
AL1517HD AL1517HDCS	15	17	38	43	15 x 17	38 x 43
AL1616HD AL1616HDCS	16	16	40.5	40.5	16 x 16	41 x 41
AL1618HD AL1618HDCS	16	18	40.5	45.5	16 x 18	41 x 46
AL1717HD AL1717HDCS	17	17	43	43	17 x 17	43 x 43
AL1718HD AL1718HDCS	17	18	43	45.5	17 x 18	43 x 46
AL1720HD AL1720HDCS	17	20	43	51	17 x 20	43 x 51
AL1816HD AL1816HDCS	18	16	45.5	40.5	18 x 16	46 x 41
AL1818HD AL1818HDCS	18	18	45.5	45.5	18 x 18	46 x 46
AL1820HD AL1820HDCS	18	20	45.5	51	18 x 20	46 x 51
AL1917HD AL1917HDCS	19	17	48.5	43	19 x 17	48 x 43
AL1919HD AL1919HDCS	19	19	48.5	48.5	19 x 19	48 x 48
AL2017HD AL2017HDCS	20	17	51	43	20 x 17	51 x 43
AL2018HD AL2018HDCS	20	18	51	45.5	20 x 18	51 x 46

Custom Cushion Guidelines:
Unable to customize.

Height:
Approximately 2 in. to 3¾ in. / 5cm to 9.5cm without load. Height range is due to the contour of the cushion.

Average Weight:
2¼ lbs. / 1.0 kg – based on AL1816HD (Weight varies by size.)

Weight Limit:
Refer to the intended use statement for weight limit information.

*All measurements are approximate.

Limited Warranty Term:

24 months

The warranty does not apply to punctures, tears, or burns; nor does it apply to the removable cover.

Certifications:

Complies with EN 1021-1 and EN 1021-2 flammability requirements.

ROHO, Inc. products meet the provisions of Council Directive 93/42/EEC (MDD) and of ISO 14971 which apply to them. All devices are in Risk Class I and Category Code 11.

ROHO, Inc. Therapeutic Seat Cushions meet the applicable U.S. FDA provisions of 21 CFR Parts 801, 803, 806, 807, and 820 and are classified as Risk Class I devices under 21 CFR 890.3175 (flotation cushion). Flotation cushions are classified in 21 CFR Part 890-Physical Medicine Devices, Subpart D-Physical Medicine Prosthetic Devices, Product Code KIC.

The Quality Management System of ROHO, Inc. is certified to ISO 9001:2008 and ISO 13485:2003.

U.S. Medicare Code**:

HCPCS Code E2605

***Since U.S. Medicare coding is subject to change, the provider should always confirm the HCPCS code and coverage criteria as part of the client assessment process. For coverage criteria in other countries, consult your local ROHO distributor.*

Trademarks, Copyright and Patents:

This product may be covered by one or more U.S. or worldwide patents. For further details, please refer to ROHO.com.

Clinical and Case Study Evidence:

Product Studies

1. Fleck, C. R. N., B.S.N., E.T., C.W.S. (1997). "Addressing a Geriatric Client's Needs for Seating Support and Comfort - Clinical Case Study." The ROHO Group, Belleville, IL.

   -"With decreased peak pressures afforded by the built-in air support pad in the ischial area of the cushion, the risk of ischemic (pressure) ulcers is dramatically decreased."

   -"Long term care and geriatric clients at low risk for ischemic (pressure) ulcers need a lightweight, low-maintenance, durable cushion to promote increased stability, optimal leg and pelvic positioning as well as comfort and the ability to perform activities of daily living as independently as possible. The Roho Airlite cushion achieves these objectives."

Predicate Device Studies

1. Levy, A., Kopplin, K., and Gefen, A. (2014). "Computer Simulations of Efficacy of Air-Cell-Based Cushions in Protecting Against Recurrence of Pressure Ulcers." Journal of Rehabilitation Research & Development. **51**(8): 1297-1310.

   NOTE: This published paper was the culmination of a research partnership between ROHO, Inc. and Tel Aviv University. The "Air Cell Based" cushion used in the study was a ROHO® QUADTRO SELECT® HIGH PROFILE® Cushion and can be promoted as such.

   -"When seated on the ACB cushion, soft tissue scarring interestingly induced, in general, lower peak stress values in the soft tissues of the buttocks with respect to the stress levels in the (non-scarred) R configuration. Specifically, gluteus muscle peak effective and shear stresses decreased by 10 to 45 percent in 9 of the 10 scars simulated herein."

   -"Likewise, peak effective and shear stresses in fat tissue of a scarred buttocks generally decreased on the ACB cushion with respect to the R case by 40 to 65 percent in all the simulated scar types apart from the hourglass-shaped scars (HG I, HG II cases). The two aforementioned scar severities were associated with a milder (10%–15%) decrease in peak effective and shear stresses which could again be attributed to the alignment of these scars with the loading vector." HG I= hourglass mild shaped scar, HG II= hourglass severe shaped scar.
   -"For example, we found that on a flat foam cushion, the HG II scar type caused an average increase of 155 and 70 percent in peak fat and muscle stresses, respectively, when compared against the R case on the same flat foam cushion."

   -"Contrarily to that, here we found decreased peak muscle stresses adjacent to the scar region in all the simulated scar cases excluding the HG I case. This means that, based on the present computational simulations, the ACB cushion is likely to better protect patients with deep scars against DTIs than flat foams, presumably through the improved immersion and envelopment facilitated by the ACB cushion, unless the scar is so large that it occupies most of the volume of the muscle tissue under the IT."

   -"The most important result from the present study was that an ACB cushion generally tends to lower peak stresses in muscle, fat, and skin tissues when scars of different shapes and dimensions exist."

2. Shoham, N., Levy, A., Kopplin, K., and Gefen, A. (2014). "Contoured Foam Cushions cannot Provide Long-Term Protection Against Pressure Ulcers for Individuals with a Spinal Cord Injury: Modeling Studies." Advances in Skin &Wound Care.

NOTE: This published paper was the culmination of a research partnership between ROHO, Inc. and Tel Aviv University. The intention was to evaluate a cushion that immerses and envelops in a custom way, but is not adjustable or adaptable, as ROHO is, to body changes in weight and shape over time. Resulting hazards are demonstrated.

-"In model variants #2-6, where the fat mass was decreased by 25% and was then increased gradually by up to 40% in order to simulate the bodyweight changes which are typical to the first months and years post the injury, the levels of effective and shear strains and stresses increased considerably with the chronological time-course of development of these bodyweight changes (Figs. 2, 4-5). For example, the peaks of effective and shear strains and the respective ranges of strain values which developed in fat tissues increased by ~220% and 110%, respectively, in the model variant where the fat mass was increased by 40% (variant #6), again with respect to the 'ideal fit' model"

-"For example, while the maximum effective and shear strain values in muscle tissue in the 'ideal fit' model were ~9 and 5.5%, they increased to ~16 and 9%, respectively, in the model where the fat mass was increased by 40%. Likewise, the maximum effective and shear stress values in the 'ideal fit' model were ~1.4 and 0.8kPa, respectively, but increased to ~2.2 and 1.3kPa in the model where the fat mass was increased by 40%"

-"…but the most prominent increase in internal tissue loading appeared where the fat mass was increased by 40%."

-"The maximal increase in fat strain and stress values occurred when severe MA [muscle atrophy] was simulated to accompany the 40%-fat-mass increase. In this particular case, peak effective and shear strains in fat increased from the ~100% and 60% values calculated for the 'ideal fit' model up to ~350% and 180%, respectively, that is, about a 3-fold increase."

-"Simulating severe FI [fat infiltration] considerably increased the strain and stress values in muscle tissues in all the model variants which included this type of pathoanatomy. For example, the maximal effective and shear strain values which developed in muscle tissues in the model variant where 40% additional fat mass and severe FI were simulated increased by more than a factor of 2, i.e. to 24% and 15%, respectively, compared to corresponding strain values of 11% and 6% in the 'ideal fit' model." FI= fat infiltration

-"The results from the present FE analyses indicate that a CFC which has been fitted at a time close to the SCI but has not been replaced for several years thereafter substantially loses its efficacy in protecting patients from developing PUs, particularly DTIs, since shear loads and deformations are increasing internally in the soft tissues as the body responds to the disuse. Specifically, simulating the pathoanatomical changes that are associated with the disuse-related adaptation of the soft tissues in the buttocks during the months and years following the occurrence of injury, i.e., the increase in body and fat mass, FI and the development of MA or combinations of these conditions, all resulted in greater strain and stress magnitudes and more inhomogeneity in the loading state."

-"A desirable cushion design is such that can accommodate to the body changes which take place continuously, not only in the SCI population but also in the elderly and frail. Healthcare authorities and medical insurance planning should take these body changes into account when developing or revising reimbursement policies for wheelchair cushions."

3. Shabshin, N., G. Zoizner, et al. (2010). "Use of weight-bearing MRI for evaluating wheelchair cushions based on internal soft-tissue deformations under ischial tuberosities." The Journal of Rehabilitation Research and Development 47(1): 31.

   -"If however, cushion D is used, muscle tissue deformations reduce to 64 percent, and at this deformation level, a subject can, theoretically, sit continuously for 115 minutes without risking a DTI. Hence, though reducing muscle tissue deformations by only 8 percent with respect to the rigid support, cushion D may provide a considerable additional time- 40 minutes (53% more)- of safe sitting." - Cushion D is a foam cushion with 10.1 cm of thickness.

   -"Interestingly, foam cushion D, which was the stiffest of all, was found to be the most effective in reducing internal soft-tissue deformations: muscle, fat, and both together (effective soft tissue).

4. Samuelsson K, B. M., Erdugan AM, Hansson AK, Rustner B (2009). "The Effect of Shaped Wheelchair Cushion and Lumbar Supports on Under-Seat Pressure, Comfort, and Pelvic Rotation." Disability and Rehabilitation: Assistive Technology 4(5): 329-336.

   -"To support a neutral pelvic position and spinal curvature, a combination of a shaped cushion and a marked lumbar support is most effective."

5. Berry, L. (2015). “Seating and Cushions for Preventing Pressure Damage among Patients in the Community.” Wounds UK. **11**(1):32-44.

   -“The 1 cm gel cushion that the author looked at was ideal for not affecting the seating height of the chair. However, the author felt it would not provide such good pressure-reducing properties over bony prominences as some of the static air or foam cushions. The reason for this is that, as NPUAP (2014) suggested, the body immerses into cushions, which are designed to increase the body surface area in contact with it (reducing interface pressures); however, this is can’t be the case with the gel cushion due to the minimal depth for immersion.”

   -“Medline Industries (2008) suggested gel and air cushions have been shown to be the most effective for pressure relief.”

   -“Through interface pressure mapping, Levy et al (2014) compared air cell cushions to flat-foam cushions for spinal cord injury patients in wheelchairs. They reported that the mechanical stresses in muscle, fat and skin tissue under the ischial tuberosities during sitting were better when the participants used air cell rather than foam cushions.”

6. Keller, B. P. J. A., Van Overbeeke, J., and Van Der Werken, C. (2006). "Interface Pressure Measurement During Surgery: A comparison of Four Operating Table Surfaces." Journal of Wound Care 15(1): 5-9.

   -Roho synopsis: The viscoelastic polyurethane foam mattress had the second lowest peak pressures at the scapular area, sacral area, and the heels, only to the KCI RIK Fluid operating Table Pad. Total surface contact was also the second highest only to the RIK. The four mattresses studied were the standard hospital mattress, the Roho Dry Floatation OR Pad, the viscoelastic polyurethane mattress, and the KCI RIK Fluid Operating Table Pad.

7. Robert Ragan, T. W. K., Mani Bidar, J.W. Matheson (2002). "Seat-interface pressures on various thicknesses of foam wheelchair cushions: A finite modeling approach." Archives of Physical Medicine and Rehabilitation June 2002 (Vol. 83)(Issue 6): Pages 872-875.

   -"One of the main findings of this study is that the seat-interface pressures and the subcutaneous compressive stresses decrease with cushion thickness."- Cushions were urethane foams of 0-16 cm

-"For a 70 kg, able bodied man, the optimal cushion thickness seemed to be about 8 cm for the urethane cushions being investigated."

-"Cushion use reduced the maximum subcutaneous stress inferior to the ischial tuberosity."

8. Colin, D. M. P. (1998). "Evaluation of Four Supports for the Prevention of Bedsore by Measurement of Transcutaneous Oxygen Pressure." Functional Rehabilitation Unit of the Angers University Hospital.

   -"This preliminary study shows that trancutaneous oxygen pressure in the sacral area drops by approximately 30 % when patients are placed on the three pheumatic supports, while it drops by more than 50% when they are placed on the foam mattress."

9. Shaw, G., PhD (1998). "Retention of Supportive Properties by Eggcrate and Foam Wheelchair Cushions." Journal of Rehabilitation Research & Development 35(4): 396-404.

10. Takechi, H. and A. Tokuhiro (1998). "Evaluation of Wheelchair Cushions by Pressure Distribution Mapping." Okayama University Medical School (Okayama, Japan) (October).

    -"Peak pressures measured for each cushion were as follows (in descending order): the Cubicushion, the polyurethane foam cushion, the contour cushion, the silicone gel cushion, and the air cushion. The areas of total contact measured for each cushion were as follows (in descending order): the air cushion, the silicone gel cushion, the polyurethane foam cushion, the contour cushion, and the Cubicushion."

    -"The polyurethane foam cushion and the contour cushion have quite similar characteristics of pressure distribution, however, the contour cushion decreases buttock pressure exerted at the skin covering the ischial tuberosities."

11. Shaw, C. G. (1993). "Seat cushion comparison for nursing home wheelchair users." Assist Technol 5(2): 92-105.

    -"Nevertheless, the study did identfy three cushions, the eggcrate, the gel/foam, and the foam which provided significantly lower peak sitting pressures than those recorded for the mix of cushions and pads surveyed by the 1990 study."

12. Palmiere, V., Haelen, G., and Cochrane, G., MD (1980). "A Comparison of Sitting Pressures on Wheelchair Cushions as Measured by Air Cell Transducers and Miniature Electronic Transducers." Bulletin of Prosthetics Research 17(1): 5-8.

    -" Concerning type categories of cushions, it may be noted that foam, viscoelastic foam, and fluid filled cushions gave mean readings in the range of 70-77 mmHg with both types of transducers in the selected configuration with this subject. On the other hand, the mean reading from gel cushions was approximately 15 mmHg higher (over 90 mmHg).