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Dear Ms. Harkless:

Thank you for the opportunity to comment on the proposed data collection tool for the acute care health care setting: The CARE Tool. As a registered nurse and a wound care specialist, I find that the assessment tool is comprehensive and covers all the important areas needed for this purpose.

I would like to share some concerns about section III: Under III. Current Medical Items, D-24 Specialty Bed. After serving on a NPUAP Support Surface Initiative Task Force for more than 6 years, I find that the descriptive definitions and terms used in this section will not be useful because after much education, there has been overwhelming acceptance of the new support surface terms and definitions. These terms and definitions were developed with the consensus of many wound care organizations. I have placed a copy of these terms and definition as an attachment. Also, **"Alternating Air Pressure Support Surfaces"** a very important support surface design and technology has been completely omitted. Clinical efficacy and cost savings reports related to alternating air pressure mattresses are available for review in many wound care journals.

I urge you to refer to the NPUAP Support Surface Terms and Definitions in the CARE tool.

Thank you for your consideration in this matter.

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National Pressure Ulcer Advisory Panel
Support Surface Standards Initiative

Terms and Definitions Related to Support Surfaces

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Historically, support surfaces were characterized in many different ways: by Medicare B category; by design; by materials in the finished product; by pressure decreased to below 32 mmHg; and as static or dynamic. (The preceding list is not exhaustive.)

Terms such as "static" and "dynamic" refer to clearly different conditions or states of activity. In the world of support surfaces, however, the initial descriptive intent of these words changed and came to mean "non-powered" and "powered," respectively.

Other phrases applied to support surfaces have included "pressure reduction" and "pressure relief." The word "pressure" describes a force over an area. We know that a person cannot be weightless and so cannot be completely free of pressure. Attempts to reduce pressure on a bony prominence, for instance, must look to the other component of the description: area. Either the area in contact with the support surface can be increased, or contact can be temporarily removed or shifted to other areas. In the first case, immersion and envelopment are the phenomena that produce reduction in pressures at bony prominences. In the second, the change in areas of contact over time is the therapeutic consideration.

We therefore propose the term "pressure redistribution" to supersede these two terms.

It was clear that other terms were also misused, confused, and confusing. These terms and definitions are proposed to supplant terms that have been commonly used and confused. They have been developed to provide a common understanding of terms that refer to basic physical concepts and design considerations; and product characteristics.

Let us begin with the **definition of support surface**: "A specialized device for pressure redistribution designed for management of tissue loads, micro-climate, and/or other therapeutic functions (i.e. any mattresses, integrated bed system, mattress replacement, overlay, or seat cushion, or seat cushion overlay)."

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PHYSICAL CONCEPTS RELATED TO SUPPORT SURFACES

Term	Definition
FRICTION (FRICTIONAL FORCE)	The resistance to motion in a parallel direction relative to the common boundary of two surfaces
COEFFICIENT OF FRICTION	A measurement of the amount of friction existing between two surfaces
ENVELOPMENT	The ability of a support surface to conform, so to fit or mold around irregularities in the body.
FATIGUE	The reduced capacity of a surface or its components to perform as specified. This change may be the result of intended or unintended use and/or prolonged exposure to chemical, thermal, or physical forces.
FORCE	A push –pull vector with magnitude(quantity) and direction(pressure, shear) that is capable of maintaining or altering the position of a body
IMMERSION	Depth of penetration (sinking) into a support surface.
LIFE EXPECTANCY	The defined period of time during which a product is able to effectively fulfill its designated purpose.
MECHANICAL LOAD	Force distribution acting on a surface
PRESSURE	The force per unit area exerted perpendicular to the plane of interest
PRESSURE REDISTRIBUTION	The ability of a support surface to distribute load over the contact areas of the human body. This term replaces prior terminology of pressure reduction and pressure relief surfaces.
PRESSURE REDUCTION	This term is no longer used to describe classes of support surfaces. The term is pressure redistribution; see above.
PRESSURE RELIEF	This term is no longer used to describe classes of support surfaces. The term is pressure redistribution; see above.
SHEAR (SHEAR STRESS)	The force per unit area exerted parallel to the plane of interest
SHEAR STRAIN	Distortion or deformation of tissue as a result of shear stress

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COMPONENTS OF SUPPORT SURFACES

Note: Components of any support surface may be used alone or in combination.

Term	Definition
AIR	A low density fluid with minimal resistance to flow
CELL/BLADDER	A means of encapsulating a support medium.
VISCOELASTIC FOAM	A type of porous polymer material that conforms in proportion to the applied weight. The air exists and enters the foam cells slowly which allows the material to respond slower than a standard elastic foam(memory foam)
ELASTIC FOAM	A type of porous polymer material that conforms in proportion to the applied weight. Air enters and exists the foam cells more rapidly, due to greater density.(non-memory)/
CLOSED CELL FOAM	A non-permeable structure in which there is a barrier between cells, preventing gases or liquids from passing through the foam.
OPEN CELL FOAM	A permeable structure in which there is no barrier between cells and gases or liquids can pass through the foam.
GEL	A semisolid system consisting of a network of solid aggregates, colloidal dispersions or polymers which may exhibit elastic properties. (Can range from a hard gel to a soft gel)
PAD	A cushion-like mass of soft material used for comfort, protection or positioning.
VISCOUS FLUID	A fluid with a relatively high resistance to flow of the fluid.
ELASTOMER	Any material that can be repeatedly stretched to at least twice its original length; upon release the stretch will return to approximately its original length.
SOLID	A substance that does not flow perceptibly under stress. Under ordinary conditions retains its size and shape
WATER	A moderate density fluid with moderate resistance to flow

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FEATURES OF SUPPORT SURFACES

A feature is a functional component of a support surface that can be used alone or in combination with other features.

TERMS	DEFINITION
AIR FLUIDIZED	A feature of a support surface that provides pressure redistribution via a fluid-like medium created by forcing air through beads as characterized by immersion and envelopment.
ALTERNATING PRESSURE	A feature of a support surface that provides pressure redistribution via cyclic changes in loading *and unloading* as characterized by frequency, duration, amplitude, and rate of change parameters.
LATERAL ROTATION	A feature of a support surface that provides rotation about a longitudinal axis as characterized by degree of patient turn, duration, and frequency.
Low Air Loss	A feature of a support surface that provides a flow of air to assist in managing the heat and humidity (microclimate) of the skin.
Zone	A segment with a single pressure redistribution capability.
Multi-Zoned Surface	A surface in which different segments can have different pressure redistribution capabilities.

CATEGORIES OF SUPPORT SURFACES

Term	Definition
REACTIVE SUPPORT SURFACE	A powered or non-powered support surface with the capability to change its load distribution properties only in response to applied load.
ACTIVE SUPPORT SURFACE	A powered support surface, with the capability to change its load distribution properties, with or without applied load.
INTEGRATED BED SYSTEM	A bed frame and support surface that are combined into a single unit whereby the surface is unable to function separately.
NON-POWERED	Any support surface not requiring or using external sources of energy for operation. (Energy = D/C or A/C)
POWERED	Any support surface requiring or using external sources of energy to operate. (Energy = D/C or A/C)
OVERLAY	An additional support surface designed to be placed directly on top of an existing surface.
MATTRESS	A support surface designed to be placed directly on the existing bed frame.

References:

Agostin JV, Baker DI, Bogardus ST (). "Making Health Care Safer; A Critical Analysis of Patient Safety Practices." AHRQ Evidence Report/Technology Assessment. 43 (27); 302.

Allman RA, Walker JM, Hart MK, LaPrade CA, Noel LB, Smith CR (1987). "Air-Fluidized Beds or Conventional Therapy for Pressure Sores." Annals of Internal Medicine 107; 641- 648.

Barrard K (1997). "Know How: Pulsating Air Suspension Therapy." Nursing Times.

Beiser, A. Schaum's (1998) Outline of Theory and Problems of Applied Physics, 2nd ed. New York, NY; Mc Graw Hill pg.. 47, 172, 238

Beiser, Arthur (1991) Physics 5th Edition, Addison Wesley pg 271

Besancon, Robert (1990) The Encyclopedia of Physics 3rd Edition, Van Nostrand Reinold. Pg. 227, 727

Beuche, Frederick (1998) College of Physics 8th Edition, Mc Graw Hill pg. 43,119,

Bergstrom N., Allman, R.M., Carlson, C.E. et al., (1992). Pressure Ulcers in Adults: Prediction and Prevention. Clinical Practice Guideline. No.3. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service Agency, Agency for Health Care Policy and Research. AHCPR Publication No. 92-0050.

Bergstrom N., Bennett M.A., Carlson C.E., et al., (1994). Treatment of Pressure Ulcers. Clinical Practice Guideline, No. 15. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service Agency, Agency for Health Care Policy and Research. AHCPR Publication No. 95-0652.

Biggie J (1998) " Support Surfaces and Their Effect on Moisture, Heat, Shear and Friction."

Blue Cross and Blue Shield Association, (1998). Special Report: Pressure-Reducing Support Surfaces in the Prevention and Treatment of Pressure Ulcers: Group 1 Technologies. (TEC Assessor: M. Sharp-Pucci) Chicago, Illinois.

Blue Cross and Blue Shield Association (1998). Special Report: Pressure-Reducing Support Surfaces in the Prevention and Treatment of Pressure Ulcers: Group 2 Technologies. (TEC Assessor: M. Sharp-Pucci) Chicago, Illinois.

Blue Cross and Blue Shield Association (1998). Special Report: Pressure-Reducing Support Surfaces in the Prevention and Treatment of Pressure Ulcers: Group 3 Technologies. (TEC Assessor: M. Sharp-Pucci) Chicago, Illinois.

NATIONAL PRESSURE ULCER ADVISORY PANEL

Braden, B. (2001). Risk Assessment in Pressure Ulcer Prevention, in Krasner, D., Rodeheaver, G. & Sibbald, G. (2001). Co-Editors. Chronic Wound Care: A Clinical Source Book for Healthcare Professionals, 3rd edition, p. 646. Wayne PA: HMP Communications.

Brienza, D (2005). "Pressure Mapping." Advance for Provider of Post Acute Care. 8(3); 81.

Brienza DM and Geyer MJ (2000). "Understanding Support Surface Technologies." Advances in Skin and Wound Care, Clinical Management. 13(5); 237-244.

Clark M, Rowland LB (1989). Preventing Pressure Sores: Matching Patient and Mattress Using Interface Pressure Measurements. Decubitus 2 (1); 34- 39.

Collier ME (1996). Pressure-reducing Mattresses. Journal of Wound Care 5 (5); 207- 211.

Colin, D., Loyant, R., Abraham, P., Saumet, J., (1996). "Changes in Sacral Transcutaneous Oxygen Tension in the Evaluation of Different Mattresses in the Prevention of Pressure Ulcers." Advances in Wound Care 9(1), 25- 28.

Cullum N, Deeks J Sheldon TA, Song F, Fletcher AW (2001). Beds, Mattresses and Cushions for Pressure Sore Prevention and Treatment. The Cochrane Library 3; 1-20.

Daechsel, D and Conine, T.A., (1985). "Special Mattresses: Effectiveness in Preventing Decubitus Ulcer in Chronic Neurologic Patients." Archives of Physical Medicine Rehabilitation 66; 246- 248.

Dealey C (1994). A Prevention and Management Aid: Evaluation of the Nimbus II Mattress. Professional Nurse 9 (12); 798- 803.

Devine, B., (1995). "Alternating Pressure Air Mattresses in the Management of established Pressure Sores". Journal of Tissue Viability, 5 (3); 94-98.

ECRI (2004). "Beds, Air-Fluidized; Low-Air-Loss; Mattress Systems, Alternating-Pressure; Low-Air-Loss." Healthcare Products Comparison System.

ECRI (2001). "Beds, Air-fluidized; Low-air Loss." Healthcare Products Comparison System.173258; 424-1008.

Ferrell, B.A., Osterweil, D., Christenson, P., (1993). "A Randomized Trial of Low-Air-Loss Beds for Treatment of Pressure Ulcers." Journal of the American Medical Association, 269; 494- 497.

NATIONAL PRESSURE ULCER ADVISORY PANEL

Flam E and Raab L (1991). "Dynamics of Pressure Ulcer Management: Interaction of Load and Duration." Journal of Enterosotmal Therapy. 18 (6); 184- 189.

Fleck, C. (2001). Support Surfaces: Criteria and Selection, in Krasner, D., Rodeheaver, G. & Sibbald, G. (2001). Co-Editors. Chronic Wound Care: A Clinical Source Book for Healthcare Professionals, 3rd edition, p. 664. Wayne, PA: HMP Communications.

Fontaine R (2000). "Investigating the Efficacy of a Nonpowered Pressure-reducing Therapeutic Mattress: A Retrospective Multi-site Study." Ostomy Wound Management. 46 (9); 3- 11.

Gebhart K, Bliss MR, Winwrigth PL, Thomas J (1996). Pressure-relieving Supports in an ICU. Journal of Wound Care 5 (3); 116-121.

Hand book of Chemistry and Physics, 39th Edition

Hecht, Eugene , (1980) Physics in Perspective, Addison Wesley. Pg. 293, 298

Hedrick-Thompson J, Halloran T, Strader MK, McSweeney M (1993). Pressure-reduction Products: Making Appropriate Choices. Journal of Enterostomal Therapy Nursing 20; 239- 244.

Hoover AE and Korsakov T (1992). "Pressure Relief Characteristics of New Foam Overlay: A Preliminary Performance Evaluation." Journal of Enterostomal Therapy Nursing. 19; 42-47.

International Standards Organization (ISO) 1382:1996

Jay, E. (1995). "How Different Constant Low Pressure Support Surfaces Address Pressure and Shear Forces". Durable Medical Equipment Review. 2 (2); 60-67.

Kenedi RM, Cowden JM, Scales JM (eds.) (1976). Bedsore Biomechanics. University Park Press.

Korsakov T and Rijswik, LV (1995). "Standardizing Performance-based Criteria for Support Surfaces." Ostomy/Wound Management. 41;134-144.

Maklebust, J. (1999). "An Update on Horizontal Patient Support Surfaces". Ostomy Wound Management, 45 (1A Suppl), 70S- 77S.

Maklebust J and Sieggreen M (eds.) (1998). "Pressure Ulcers: Guidelines for Prevention and Nursing Management." 2nd Edition.

NATIONAL PRESSURE ULCER ADVISORY PANEL

Maklebust J, Mondoux L, Sieggreen M (1986). Pressure Relief Characteristics of Various Support Surfaces Used in Prevention and Treatment of Pressure Ulcers. Journal of Enterostomal Therapy 13; 85-89.

McLeod A (1997). "Principles of Alternating Pressure Surfaces." Advances in Wound Care. 10 (7); 30-36.

Mayrovitz, H.N. and Sims, N. (2002). "Effects of Different Cyclic Pressurization and Relief Patterns on Heel Skin Blood Perfusion". Advances in Skin and Wound Care. 15 (4); 158-164.

NHS Centre for Reviews and Dissemination and Nuffield Institute for Health (1995). The Prevention and Treatment of Pressure Sores. Effective Health Care. 2 (1); 1- 16.

Parker, Sybil, (1992) Encyclopedia of Physics 2nd Edition, McGraw Hill. Pg. 1341

Patel UH and Jones JT (1993). "The Evaluation of Five Specialized Support Surfaces by Use of a Pressure Sensitive Mat." Decubitus. ;2.

Pieper B (1996). "Mechanical Forces: Pressure, Shear and Friction", Chapter. 11 In. Bryant, R. (Ed).Acute and Chronic Wounds Nursing Management, 2nd Edition. Mosby, St. Louis.
Polyurethane Foam Association.

Rithalia, S., Heath, G.H., Gonsalkorale, M. (2000). "Assessment of Alternating-pressure Air Mattresses Using a Time-based Pressure Threshold Technique and Continuous Measurements of Transcutaneous Gases." Journal of Tissue Viability. 10(1); 13-20.

Rithalia, S. (2005) "Assessment of patient support surfaces: principal, practice and limitations." Journal of Medical Engineering and Technology 29 (4); 163- 169.

Ryan W, Allen V, Murray A (1997). "An Investigation of Interface Pressures in Low Air Loss Beds." International Journal of Clinical Practice. 51 (5); 296.

Sentech Medical Systems (1999). "Understanding Support Surfaces."

Sentech Medical Systems (2000). "Frequently Asked Questions".

Sentech Medical Systems (2001). "Thera Turn Brochure".

NATIONAL PRESSURE ULCER ADVISORY PANEL

Sprigle S, Press L, Davis K (2001). "Development of Uniform Terminology and Procedures to Describe Wheelchair Cushion Characteristics." Journal of Rehabilitation and Development. 38 (4); 449-461.

Stedman's Medical Dictionary 26th Edition

Taler G, Bauman T, Breeding C, et al. (1996). "Pressure Ulcer Clinical Practice Guideline." Columbia, MD: American Medical Directors Association.

Webster's New World Dictionary of the American Language, 2nd Edition

Whittemore R, Bautista C, Smith C and Bruttomesso K (1993). "Interface Pressure Measurements of Support Surfaces with Subjects in the Supine and 45-degree Fowler Positions." Journal of Enterostomal Therapy Nursing, May/June 1993, (p. 112)

Winn S, Happ E, Morris BS, Kerstein D (1997). "Pressure Ulcers; Collaboration in Wound Care. Is There A Reasonable Approach." Wounds, A Compendium of Clinical Research and Practice. 9 (2); 34- 42.

WOCN (1998). "Medicare Part B Coverage for Support Surfaces in the Home Health Setting." Professional Practice Sheet.

Wound Care Association of New South Wales (2000). "Pressure Ulcer Prevention Guidelines- An Expert Consensus.

www.kci1.com/ glossary/ index.2002

www.gaymar.com/eduresearch/2002

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