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Standardizing Support Surface Testing and Reporting

A National Pressure Ulcer Advisory Panel Executive Summary

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■ ABSTRACT

In 2001, the National Pressure Ulcer Advisory Panel's Research Committee identified the need to create uniform terminology, test methods, and reporting technical standards for support surfaces. As a result, the S3I Committee was formed and initial meetings of interested stakeholders who included clinicians, researchers, academics, manufacturers, providers, and regulators were held. The group's initial goal was to (1) establish common language to facilitate understanding by developing standardized terminology for describing and discussing support surfaces, (2) establish a suite of standardized tests of performance capable of repeatedly, reliably, and accurately reporting upon characteristics common to all support surfaces that are believed to be related to the extrinsic risk factors associated with skin breakdown, as indicated by the literature to date, and (3) identify and standardize methods to evaluate the effective life of a support surface. The purpose of this article was to summarize the current status of the effort of the Support Surface Standards Initiative (S3I) Committee to identify and standardize methods to evaluate the many characteristic factors that determine the effective life of a support surface.

KEY WORDS: Pressure ulcer, Prevention, Support surface, Technical standards

■ Introduction

Technical standards are documents that provide requirements, specifications, guidelines, or characteristics that can be used to consistently ensure that materials, products, processes, and services are fit for their purpose.[1] From a historical perspective, performance factors identified as candidates for support surface standardization were: terms and definitions; pressure distribution; immersion; envelopment; friction; shear forces; microclimate (temperature and humidity); lifespan; and safety. The Committee chose terms and definitions, temperature and humidity, and immersion as the first factors to address in the standards. This effort will result in the publication of *RESNA SS-1: 2013 Volume 1: Requirements and Test Methods for Full Body Support Surfaces*. RESNA SS-1 includes the following specifications and tests: a standardized vocabulary (Terms and Definitions); a method to measure and report on immersion; a method to measure heat and moisture dissipation using a body analog (Environment/Microclimate); and a method to measure heat and moisture dissipation using a sweating guarded hot plate (Environment/Microclimate) (Table 1) (Appendices 1 and 2).

Additional tests currently in the validation stage of development include a method to measure and report on horizontal sliding stability (Horizontal Stiffness) as a predictor of shear dissipation. We are also validating a method to measure and report on the efficiency of envelopment as a predictor of spatial pressure distribution and a method to predict and identify the end of a support surface's useful life.

Clinicians, patients, and other users will benefit from having product descriptions, information, and performance data presented in a consistent manner. Technical standards terms and methods will empower consumers. In addition, they will assist researchers, manufacturers, and

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TABLE 1.

Comparison of Tests of Microclimate Management Performance

	Section 3	Section 4
Standard	Heat and Water Vapor (HWV)	Sweating Guarded Hot Plate (SGHP)
Measures	Skin humidity and temperature at specific times	Resistances of surface to flows of heat and humidity from skin, evaporative capacity
Time	Measurement at 1, 2, 3 h	Measurement taken at steady state regardless of how long it may take to achieve equilibrium
Time consideration	Surface may not have reached equilibrium and 3-h measurement may not reflect long-term performance	The time to reach steady state conditions varies. Therefore, the length of the test is unknown prior to conducting the test.
Other considerations	Results obtained reflect only the specific bed and surface considerations employed during the actual test. Head-of-bed angle, surface firmness setting, any airflow or temperature settings, for example, should be documented for each test and results should not be generalized beyond these conditions.	Results obtained reflect only the specific bed and surface considerations employed during the actual test. Head-of-bed angle, surface firmness setting, any airflow or temperature settings, for example, should be documented for each test and results should not be generalized beyond these conditions.

BOX 1.

Note to Manufacturers

These standardized test methods were developed to be compatible with all known and reasonably predictable future designs and materials. They are intended to measure properties believed universally important using technology-neutral processes with the expectation of producing nominal data without bias or prejudice. Nothing in these technical standards is intended to create a threshold of acceptance and there are no "pass-fail" values. Do not use them as such. Rather, we invite you to accept these standardized methods of testing and reporting as an important initial step in creating a body of understanding.

These technical standards represent an opportunity for the entire industry to begin speaking a common language. The simple act of reporting standardized performance metrics will enable researchers to more fully establish which of the numerous properties associated with support surfaces are most significant. We anticipate the road map produced from these activities will give you greater freedom to innovate and focus your investment in Research and Development on performance rather than design around a product descriptor.

BOX 2.

Note to Researchers

Clinicians encounter a variety of patients having unique clinical needs predicated by a variety of underlying comorbidities. In meeting these needs, caregivers are faced with having to make a clinically relevant choice from a vast array of support surface options incorporating different designs and technologies without solid comparable information upon which a decision can be made.

Standardized reports of measured metrics data are anticipated to enable researchers to effectively compare the clinical outcomes associated with the use of various support surfaces. We encourage the development of tools wherein test results are associated with clinical needs, such as pressure ulcer prevention and treatment, tissue preservation, moisture management, mobility, quality of sleep, and cost-effectiveness. This will enable patient needs to be matched with relevant support surface performance metrics.

We propose the performance data obtained from these standardized test methods be used both retrospectively and in the design of prospective studies. As the relationships between performance data and outcomes are established, so will the ability to predict the appropriateness of a support surface in meeting specific patient needs. Quantifying the relationship between performance data and clinical outcomes is an important factor in mitigating risk and improving patient care.

BOX 3.

Note to Clinicians

The various workgroups involved in the development of these technical standards are acutely aware of the clinician's desire for bedside tools to assess the appropriateness of a given support surface in meeting a specific patient's needs. Although the initial publication of these technical standards is not the entire answer to the request for selection tools, they are an important first step in this process. The technical standards provide a means to obtain comparable performance data for support surfaces using common language and metrics to aid in the selection process.

We caution against efforts to apply the data obtained from these test methods in isolation. The data will be a metric of the performance of a single property of a support surface, but it is not an endorsement of a specific brand and model. In establishing the performance metrics, we invite you to remain active and participate in research efforts to confirm the relevance of each of these tested performance metrics.

BOX 4.

Note to Regulators/Payers

The workgroups tasked with developing and publishing these technical standards have been acutely aware of the need regulators and payers have for quantitative information on support surface performance upon which medical coverage policy and payment can be based. The technical standards were developed to differentiate a wide range of Support Surface performance characteristics using common language and metrics to aid in the grouping of support surfaces based on performance.

These technical standards will not indicate the relative importance of the various performance metrics and clinical outcomes. Clinical validation will occur over time as additional technical standards are completed and data are produced from research using standardized methods.

As stakeholders in this process, we invite you to work with, and potentially sponsor, the research necessary to quantify the relationship between performance data and clinical outcomes. This research will empower you to effectively create medical policy determinations. Reimbursement can then be based on performance value rather than device description. This would allow manufacturers to focus on designing support surfaces that meet and exceed performance expectations rather than being obliged to work within the limitations of established product descriptors.

providers by establishing a level playing field for discussing, evaluating, and comparing support surfaces (both existing and in development) based on clinically relevant criteria.

Qualifiers

The process of technical standards development initially requires identification of factors that are generally agreed as important for (1) defining the performance of an item relative to an application and (2) developing methods to establish a common measurement for comparison. Technical standards are not intended to be tools for defining "good" or "bad" performance.

As living documents, these technical standards follow review procedures established by members of the RESNA SS (Support Surface) Committee as supported by the NPUAP. The order of test method release was predicated on the workgroup's ability to develop and agree upon a specific method rather than the relative importance in predicting support surface performance. Finally, each test method is intended to evaluate only the specific performance metric it is designed to consider. For example, a test method looking at immersion is only intended to determine how deeply a subject can be immersed into a support surface and provide data for support surfaces on this subject. It does not consider other factors known to impact pressure redistribution and should not be taken out of context. No individual test can fully evaluate a support surface's performance against the variety of risk factors, nor should any of these standardized test methods be considered a panacea because doing so would undermine the complex interactions of the functional characteristics in all support surfaces and their clinical application.

With the release of these technical standards, it should be understood that no evidence is yet available to associate a specific test value with any level of clinical outcomes, safety expectations, or indications of acceptability for any given purpose. As manufacturers and evaluators of support surfaces begin to adopt these technical standards and report the data generated, a critical database of device specific performance metrics will be developed. We have included 4 boxes that provide notes to manufacturers, researchers, clinicians, and regulators/payers concerning these technical standards (Boxes 1–4).

Conclusions

The National Pressure Ulcer Advisory Panel's S3I Committee is in the process of developing standardized terminology for describing and discussing support surfaces. The committee has also established a suite of standardized tests of performance capable of repeatedly, reliably, and accurately reporting upon characteristics common to all support surfaces that are believed to be related to the extrinsic risk factors associated with skin breakdown, as indicated by the literature to date. The committee is working to identify and standardize methods to evaluate the effective life of a support surface.

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Appendix 1
Pressure Redistribution: Envelopment and Immersion

Support surfaces are available in various configurations. While numerous factors are involved in the development of pressure ulcer(s), among them are the mechanical forces creating pressure at the interface of the skin and support surface, especially over bony prominences. These pressures can contribute to tissue deformation that can lead to tissue injury. Pressure redistribution is the ability of a support surface to distribute load over a greater contact area of the person who is supported by the surface.[1]

Among Newton's laws is a principle described as "action-reaction." This means when a load is applied to "something" this same "something" pushes back equally on the load.[2] When applied to support surfaces, as a person's weight applies a load onto a support surface, the support surface will push back on the person to achieve equilibrium. The pressure at the interface between the support surface and the body is influenced by many variables, the most significant of which are the person's weight, anatomical structure, and the area of contact on the support surface. These variables are not affected by the characteristics of the support surface, rather the contact area of the support surface is impacted by the variables. Generally, for a given load, a larger area of contact will produce a lower interface pressure. Sinking into a support surface has the potential to increase contact area.

The bony prominences where pressure ulcers tend to develop most frequently are areas of the body that protrude when a person is lying supine (on their back) or on their side.[3] These areas include the sacrum, heels, and trochanters of the femur. In the immediate vicinity surrounding these bony prominences, high pressure areas can develop if the support surface does not conform to the shape of the bony prominence. These high pressures can exist independent of the average pressure across the whole contact area. Support surfaces designed for pressure ulcer prevention aim to redistribute pressure by both lowering average pressure through *immersion* and conforming to the irregular shapes of bony prominences by *envelopment*.

The technical standards define methods to quantify a device's potential for pressure redistribution by measuring immersion and envelopment. Immersion and envelopment are defined as follows:

Envelopment: The ability of a support surface to conform, so to fit or mold around irregularities in the body.[4]

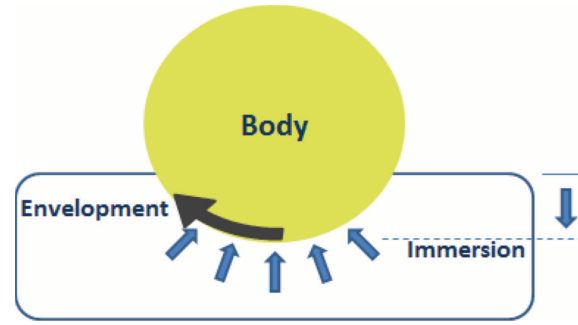

FIGURE A1. Measurement of *Immersion* determines the depth of penetration into a support surface for a defined indenter.

Immersion: The depth of penetration (sinking) into a support surface.[4]

In order to evaluate pressure redistribution of a support surface, S3I is developing test methods to evaluate Immersion and Envelopment. Many factors contribute to how a support surface will perform under immersion or envelopment testing; the rationale for this document is to understand the physics behind each property so that clinicians can select the appropriate support surface.

Measurement of *Immersion* determines the depth of penetration into a support surface for a defined indenter, *RESNA SS-1:2013: Volume 1: Section 2*. The result will provide the caregiver with information on how deeply the indenter penetrates into the support surface (Figure A1).

Measurement of *Envelopment* will determine the ability of the support surface to conform to the irregularities of the human body. The result will provide the caregiver with information on how a support surface conforms to the irregularities of the human body.

Note: Envelopment cannot occur without immersion, but immersion does not guarantee envelopment. Both results need to be looked at before selecting a support surface for a given patient.

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Appendix 2
Tests for Microclimate Management Performance

Microclimate Defined

The temperature and relative humidity observed in a specified location. For the purposes of this standard, microclimate refers to the temperature and humidity at the full body support surface/body interface.[1]

What

Microclimate tests assess the ability of a support surface to manage skin microclimate, that is, the heat and humidity at the skin surface. The Heat and Water Vapor test (HWV test) measures the temperature and humidity on the skin at specific intervals. The Sweating Guarded Hot Plate (SGHP test) measures the surface's resistance to the flows of both moisture and heat from the skin to the environment.

Why

The effects of the microclimate on the skin can be summarized as follows:

1. When the skin becomes moist, the friction between the skin and common bedding materials is approximately doubled, increasing the forces transmitted to the skin.[2]
2. Skin that is wetted gradually loses much of its mechanical strength and is therefore susceptible to deformation tearing at lower force levels.[3]
3. Because increased local skin temperature is one of the drivers of local perspiration, when the skin warms beyond a "perspiration threshold," moisture production from the skin itself increases markedly.[4-9]
4. The metabolic demand of the skin is increased by approximately 10% per degree of warming.[10]
5. When blood flow within the integument is limited, ischemia becomes more severe in warm skin than in cooler skin under the same loading conditions. Warm skin, when loaded, is therefore more susceptible to ischemic injury.[11,12]

In summary, when the microclimate is not managed appropriately, the risk of an individual developing pressure ulcers increases.

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