SLOVENSKI STANDARD
SIST-TP CEN ISO/TR 20342-7:2022

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Tehnični pripomočki za celovitost tkiv v ležečem položaju - 7. del: Lastnosti, značilnosti in delovanje pene (ISO/TR 20342-7:2021)

Assistive products for tissue integrity when lying down - Part 7: Foam properties, characteristics and performance (ISO/TR 20342-7:2021)

Unterstützende Produkte zur Gewebeintegrität im Liegen - Teil 7: (ISO/TR 20342-7:2021)

Produits d'assistance pour l'intégrité des tissus en position allongée - Partie 7: Propriétés, caractéristiques et performances des mousses (ISO/TR 20342-7:2021)

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11.180.01	Pripomočki za onesposobljene in hendikepirane osebe na splošno	Aids for disabled and handicapped persons in general

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Produits d'assistance pour l'intégrité des tissus en position allongée - Partie 7: Propriétés, caractéristiques et performances des mousses (ISO/TR 20342-7:2021)

Unterstützende Produkte zur Gewebeintegrität im Liegen - Teil 7: (ISO/TR 20342-7:2021)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

The text of ISO/TR 20342-7:2021 has been prepared by Technical Committee ISO/TC 173 "Assistive products" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TR 20342-7:2022 by Technical Committee CEN/TC 293 "Assistive products and accessibility" the secretariat of which is held by SIS.

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Endorsement notice

The text of ISO/TR 20342-7:2021 has been approved by CEN as CEN ISO/TR 20342-7:2022 without any modification.

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 173 *Assistive products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 20342 series can be found on the ISO website.

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Introduction

Although the phrase 'high specification foam mattress' has been common in the industry for several decades, its continued use today is now a cause for concern.

The first 'high specification foam mattresses' were introduced around the 1990s. These incorporated multiple construct layers of different foams, some of which might be castellated and/or shaped, and then enveloped in stretch covers to provide improved pressure reducing properties when compared with the then, 'standard hospital mattress', which was essentially a single rectangular block of foam protected by a non-stretch cover. Over time these more advanced, complicated multi-layer constructs have themselves now become the norm, completely replacing the old product in most modern hospitals.

Continued use of the 'high specification' terminology creates the risk of confusion and allows manufacturers to lay claim to providing a 'high specification foam mattress' without an agreed benchmark against which to justify this claim. The continued use of this phrase also takes the focus away from the principles of holistic care and the correct risk assessment leading hopefully to the selection of the mattress that will most likely deliver the desired outcome depending on the needs of the patient.

Looking at the different clinical requirements and physical properties for foam mattresses, different properties and their values come into play depending on the identified needs. A single property that might be considered 'high' specification or highly desirable in relation to one patient or healthcare environment could well be deemed 'low' or somewhat unimportant when considered against the needs of the next patient in a different environment. Ultimately, it is the performance of the mattress as a whole, within its environment, rather than any individual component part of it, that is important.

Understanding the characteristics of foam can help inform and potentially aid in the choice when several products are available. However, it is the performance of the complete product, based on the individual's assessed needs, which is critical to ensure optimal patient care.

Without knowing the current (and often evolving) clinical needs of every particular user, it is not possible to define clearly a nominal or minimal/maximal performance specification that needs to be met or surpassed by the final product.

Additional safety standards, such as fire resistance at a component and/or final product level, exist in relation to the foam product addressed in this document. The minimum level of resistance legally required potentially differs depending on the application environment, for example domestic versus hospital use. The flammability requirements and test methods used currently differ depending on the country or state of use.

The manufacturer is required to explain and corroborate any claims made concerning the important features of their product and how these features assure the clinical efficiency of their product over its expected lifetime.

Based on this information and/or local, national or international requirements, it remains, however, the responsibility of the user to determine if the foam proposed provides merely adequate behaviour or exceeds by a significant amount the performance required.

Not all of the proposed tests need to be carried out to give an indication of a foam's performance and some of the proposed tests will not be considered relevant for some types of foam.

These test methods can be used to identify differing performance characteristics between products thus indicating the potential superior performance of one foam over another.

It is emphasized that the test methods specified in this document do not necessarily simulate conditions of use in practice. The use of resulting data is therefore restricted to a broad comparative assessment between different foam products.