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TNI	**Pomocné výrobky na zachovanie integrity tkanív imobilných pacientov Časť 7: Vlastnosti, charakteristiky a výkonnosť (ISO/TR 20342-7: 2021)**	**TNI CEN ISO/TR 20342-7** 84 7078

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

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

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

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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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Assistive products for tissue integrity when lying down —

Part 7: Foam properties, characteristics and performance

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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.

It is recommended that no single result be taken in isolation. The clinical efficiency of the final product will also be the result of many different contributory factors, a large number of which will not be related to the foam's physical properties.

The type of cover (fabric or other) used on the APTI can have a significant effect on overall clinical performance of the final product. An incorrectly fitted cover, or changing the cover to a product other than that specified by the manufacturer, will possibly affect product safety, performance and durability.

Continued use of a damaged cover can result in penetration of liquids into the foam, not only potentially affecting its performance, but also increasing the risk of cross contamination.

The type of bedframe, or support, onto which the APTI is placed potentially affects the performance of the final product. Overall product dimensions need to be taken into account not only to ensure that the APTI can function correctly, but also to ensure that no entrapment hazards are created between the frame and the APTI.

TECHNICAL REPORT **ISO/TR 20342-7:2021(E)**

Assistive products for tissue integrity when lying down —

Part 7: Foam properties, characteristics and performance

1 Scope

This document lists the terminology and common test methods used by manufacturers and laboratories to quantify the performance of a foam material. It also and gives information to users or buyers of these products to make an educated assessment of the relevance of the physical characteristics between various products offered to them.

This document summarizes/gives information about the tests for

— polyurethane foams – typically polyether (polyether polyurethane foam) or polyester based (polyester polyurethane foam) – produced by either slabstock (slabstock foam) or moulded foam process, and

— latex foams produced by either the Dunlop process or Talalay process.

The physical properties addressed in this document are

a) resilience,

b) hysteresis,

c) support/SAG factor,

d) density,

e) hardness,

f) compression set,

g) tensile strength,

h) tear strength,

i) air flow/permeability,

j) resistance to fatigue, and

k) microbial resistance.

NOTE The test methods presented 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.

This document addresses only the characterization and performance of foam materials used in APTIs. It does not address the design, construction method or other factors relating to the final clinical efficiency of the product.

Test methods for characterizing the physical properties of any coverings, or the effects of any coverings on the physical properties of the foams, are not addressed in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20342-1, *Assistive products for tissue integrity when lying down — Part 1: General requirements*

