TECHNICAL REPORT

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Assistive products for tissue integrity when lying down —

Part 7: Foam properties, characteristics and performance

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Foreword

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20342-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
assistive product for tissue integrity
APTI
surface intended to protect body tissue, designed to interface with the body when lying down or in adjusted position

[SOURCE: ISO 20342-1:2019, 3.5]

3.2
bottoming out
insufficient support provided by an *assistive product for tissue integrity* (3.1) for the mass of patient concerned, at the place where the assistive product for tissue integrity is no longer capable of redistributing the pressure applied

Note 1 to entry: Localized pressure risks are now placed onto the patient by the bed frame or support surface onto which the assistive product for tissue integrity has been placed.

3.3
destructive test
test method resulting in damage or destruction of the sample being tested

Note 1 to entry: The preparation of this test part renders an *assistive product for tissue integrity* (3.1) unsuitable for use afterwards.

3.4
Dunlop process
action where foamed liquid latex is poured into a mould before *vulcanization* (3.10)

Note 1 to entry: Continuous production [see *slabstock foam* (3.11.6)] using the Dunlop process is also possible.

3.5
elongation
length of elongation at the rupture point as a percentage of the original length

3.6
tensile strength
force necessary to rupture the *foam* (3.11) when pulled by opposite forces

3.7
hydrolysis
chemical reaction in which the interaction of a compound with water results in the gradual decomposition of that compound

3.8
non-destructive test
test method that can be carried out without damaging the sample being tested

Note 1 to entry: An *assistive product for tissue integrity* (3.1) is not significantly altered by the test and is deemed suitable for use afterwards.

3.9
Talalay process
action where foamed liquid latex is poured into a mould then placed under vacuum before *vulcanization* (3.10)

3.10
vulcanization
chemical cross linking of rubber-based polymers to increase product rigidity and durability

3.11
foam
flexible cellular material in which the cells are all or partly intercommunicating

3.11.1
high resilience foam
HR foam
foam (3.11) characterized by higher elasticity, measured by ball rebound or comfort factor (SAG factor), as compared with standard polyether polyurethane foams

Note 1 to entry: Special high resilience polyols are used frequently in combination with methylene diphenyl di-isocyanate (MDI) rather than toluene di-isocyanate.

Note 2 to entry: The higher elasticity is attributed to a more irregular cell structure than that present in standard ether based foams.

3.11.2
latex foam
flexible cellular material made from natural or *synthetic latex* (3.11.2.2), in which the cells are all or partly intercommunicating

3.11.2.1
natural latex
latex produced from the sap of the Hevea Brasiliensis rubber tree

3.11.2.2
synthetic latex
petroleum based alternative to *natural latex* (3.11.2.1)

3.11.3
moulded foam
cellular *foam* (3.11) product, having the form of the mould cavity in which it was produced

3.11.4
polyester polyurethane foam
foam (3.11) manufactured using polyester polyols in combination with toluene di-isocyanate (TDI)

Note 1 to entry: Polyester foams have a higher natural stability against solvents than polyether foams, but a lower stability towards *hydrolysis* (3.7).

3.11.5
polyether polyurethane foam
foam (3.11) manufactured using high levels of polyether polyols in combination with toluene di-isocyanate (TDI)

Note 1 to entry: Sometimes also referred to as a conventional foam, conventional polyurethane foam, or standard polyurethane foam.

3.11.6
slabstock foam
cellular *foam* (3.11) product, produced from an often continuous manufacturing process, where the slab of foam produced is then cut to shape to produce the final part

3.11.7
viscoelastic foam
modified polyurethane *foam* (3.11) obtained by the use of special polyols or a modified cellular structure

Note 1 to entry: Viscoelastic foam is characterized by a low final hardness, a delayed recovery after compression, and low elasticity.

Note 2 to entry: Often also known as a memory foam. Its capacity of enveloping/adapting to the shape of the patient can help reduce and redistribute pressure.

4 Test samples and foam properties

4.1 General

The supplier of a foam will indicate whether their foam product is polyurethane or latex based.

The characterization of the physical properties of a foam product is determined by subjecting the foam to a number of standardized laboratory tests that are referenced in Clause 5. The results of these tests allow the comparative performance of different products, under laboratory conditions, to be evaluated.

4.2 Test samples

For the test methods listed in this document, ISO 1923[5] can be followed for assessing sample dimensions, and ISO 291[1] for conditioning the test samples.

Some tests are carried out on normalized (i.e. predetermined and constant shape and size) sample parts. The reported value for these tests is therefore not influenced by the original shape or size of the product.

Examples such as core density, compression hardness, and compression set require destructive (parts cut to the correct shape and size) tests. Results from these tests will then generally allow direct comparison between differing foam products. Other test methods, such as indentation hardness, are carried out directly on the final product using non-destructive methods. However, the results obtained from different products will not be directly comparable unless the parts tested have identical shapes/dimensions.

NOTE It is important, when comparing resulting values between different foams, to ensure that the same test method has been used. Whilst many test methods are common across the industry some minor differences still exist - for example the percentage of compression used when measuring foam hardness or the units used to express the result.

For both types of test typical values given are on the basis of the following:

a) The foam has been correctly manufactured to ensure normal properties and performance.