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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).

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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.

b) The foam has been recently manufactured and not subject to any ageing (real or artificial) or other post-manufacturing treatment, other than any demanded by the test method, that could alter its claimed properties and performance.

The following variations are relevant:

a) Foam material test piece

If an APTI has been created with multiple stacks, profiles and holes, the test result of a foam alone does not necessarily indicate the full characteristics of the complete APTI.

b) Laminated test piece of a structure used in an APTI

The cited International Standards are test evaluations of a single material, but it is desirable to evaluate an APTI in a complete form to compare the characteristics of different APTIs.

Some APTIs have different structures in different places on the APTI. Therefore, it is likely that the site from which a test sample is extracted is obtained from multiple sites for a complex APTI.

4.3 Presale literature

Technical marketing information, normally provided pre-sale, will often outline several key characteristics (claims) for the product.

As a minimum, these might typically include

— the size and weight of the finished product,

— density and type of foam(s) used, and

— fire resistance.

NOTE Due to the flexible nature of foam, the exact dimensions of the APTI are sometimes difficult to measure. In these instances, dimensions given will be indicative only. In case of doubt the dimensional compatibility of the APTI with the support or bed frame should be checked according to the relevant safety standard.

4.4 Composite APTIs

In many cases, more complicated mattress APTIs are a composite of several types of foam:

a) Multi-layer – Some mattress APTIs have layers of different foams to improve product durability, patient comfort, and/or pressure distribution;

b) Multi-hardness – Some mattress APTIs have zones of different hardness to improve patient comfort and/or aid pressure distribution.

4.5 Foam density and hardness

Generally, higher density foams will be more durable than a similar product at lower density. For latex foams a higher density will normally also equate to a higher hardness. However, for polyurethane foams due to the wide variety and complexity of starting raw materials, a higher density will not automatically equate to a higher hardness. Variations in the alignment of polymer chains and modifications to the microcellular structure of the final product allows, for example, the production of viscoelastic foams where a very low hardness can be achieved despite the foam having a high density, thus creating the possibility of a very soft, yet durable product.

4.6 Aging effects

Accelerated aging is covered in ISO 2440[7] and is being handled in other parts of ISO 20342, and therefore is not covered in this document. On a related subject, colour fastness/foam discolouration are covered in ISO 4582[10].

5 Test methods

5.1 General

In this document the ISO standards are cited. The equivalent ASTM and Japanese standards are listed in Annex A.

5.2 Determination of foam type

5.2.1 Resilience (ball rebound)

Foam can be tested using ISO 8307[14].

This test is often used to differentiate between conventional polyurethane and HR foam.

Viscoelastic foam typically gives values of below 20 %.

Conventional foam gives values between 30 % - 50 %.

High Resilience and latex foams give values typically higher than 50 %.

NOTE A value of 55 % is often considered as the minimum value required for polyurethane foam to be considered as high resilience.

5.2.2 Hysteresis

Foam can be tested using ISO 2439[6] for indentation hardness (5.4.2), or using ISO 3386-1[9] for compression hardness (5.4.3).

These tests are often used to compare relative performance between different viscoelastic foams.

Conventional HR and latex foams give low values, typically between 10 % and 30 %.

Viscoelastic foam typically gives values between 30 % and 70 %.

NOTE A value of >30 % is often considered as the minimum value required for a foam to be considered as having a “memory” effect.

5.2.3 Support/SAG factor

Foam can be tested using ISO 2439[6].

This test is often used to differentiate between conventional and HR foams. A value of 2,4 is often considered as the absolute minimum value required for a foam to be considered as high resilience.

A high SAG factor is often considered desirable in a mattress to prevent bottoming out.

This test is not normally used to characterize viscoelastic foam.

HR and latex foams typically give values between 2,4 and 3,4.

Conventional polyurethane foams typically give values between 1,5 and 2,0.

5.3 Characterization of foam durability

5.3.1 Density (core or apparent)

Foam can be tested using ISO 845[2].

Generally, the higher the foam density, the longer the foam will be able to maintain its properties (i.e. it is more durable). Core density is measured on a cut sample whilst apparent density is simply the total part weight divided by the part volume. Results are expressed in kg/m^3.

NOTE 1 If tested to ASTM D3574-A[18] the results will be quoted in lb/ft^3. Conversion between the two measures is

$$1\ kg/m^3 = 0{,}062\ lb/ft^3 \text{ or } 1 lb/ft^3 = 16{,}02\ kg/m^3$$

HR foams are generally considered to require a core density of at least 34 kg/m^3.

Viscoelastic foams typically show the highest values and are often between 60 kg/m^3 and 90 kg/m^3.

Latex foams also show values of between 65 kg/m^3 and 85 kg/m^3.

NOTE 2 Talalay produced latex foams are generally of a lower density than Dunlop produced foams.

5.3.2 Tensile strength and elongation

Foam can be tested using ISO 1798[3].

Flexible foams are not normally subject to high levels of tensile stress. However, these properties are considered a useful guide on the ability of a foam to be manipulated without tearing during its lifetime.

5.3.3 Tear strength

Foam can be tested using ISO 8067[13].

Tear strength is the force necessary to propagate a slit, pre-cut into a sample part, when pulling both sides apart.

5.3.4 Compression set (wet and/or dry)

Foam can be tested using ISO 1856[4] and, for wet, ISO 13362[15].

Compression set is an accelerated creep test that measures the height loss of a small foam sample after it has been compressed to a given percentage of its original height, for a predetermined time, at a stated temperature and humidity. A small percentage loss can be interpreted as indicating that the foam is durable and will not suffer significant height loss during its lifetime.

Using the dry test method, a value of <5 % is generally considered as excellent performance and between 5 % and 10 % as good performance.

5.4 Characterization of foam hardness

5.4.1 General

The load bearing property of a flexible foam is often considered to be its primary function.

Hardness can be measured by indentation (foam part larger than the indenter used) or compression (foam part smaller than the indenter used). A higher density (see 5.3.1) does not necessarily result in a higher hardness foam.

During these tests, the sample is normally compressed to around 70 % of its initial height and then released to create a complete stress/strain curve. Measurements are taken at 25 %, 40 %, and 65 % height compression levels.

NOTE The % compression relative to the hardness quoted and the units used will vary: manufacturers using the imperial system quote psi (pounds per sq. inch) at 25 %, whereas manufacturers using the metric system quote N (Newtons) or kPa (Kilopascals) at 40 %.

The resulting stress/strain curve is also used to calculate foam hysteresis (see 5.2.2) and SAG factor (see 5.2.3).

5.4.2 Indentation hardness

Indentation hardness is derived from indentation force/load deflection (IFD/ILD)

Foam can be tested using ISO 2439[6].

A non-destructive test is often carried out on the final product. The form of the final product can influence the result, therefore making comparison between different products difficult.

5.4.3 Compression hardness

Compression hardness is derived from compression force/load deflection (CFD/CLD)

Foam can be tested using ISO 3386-1[9].

A destructive test can be carried out on a standardized sample cut from the final product. Direct comparison between different foams is possible because the result of the test is not influenced by the shape of the original product.

5.5 Characterization of other properties

5.5.1 Dynamic Fatigue Test (Pounding)

Foam can be tested using ISO 3385[8].

This is similar to the Compression Test (see 5.3.4) but performed at normal laboratory temperature with continued loading and unloading of the foam using a weighted Indenter. Losses in foam height and indentation hardness (see 5.4.2) are measured and used as an indication of the durability of the foam during normal use.

5.5.2 Dynamic Fatigue Test (Roller)

Foam can be tested using EN 1957[16].

This is similar to the Compression Test (see 5.3.4) but performed at normal laboratory temperature with continued loading and unloading of the foam using a weighted roller. Additional shear effect can also be applied. Losses in foam height and indentation hardness (see 5.4.2) are measured and used as an indication of the durability of the foam during normal use.

5.5.3 Air flow/permeability

Foam can be tested using ISO 7231[12].

NOTE Airflow can be linked to comfort as air movement through the foam can transport heat and humidity away from the surface. However, it is important to note that the value for the foam can be significantly reduced by the performance of the material used as a cover.

5.5.4 Flammability

No overall international consensus exists around which of the many test methods available, or which parameters, should be monitored when checking the flammability of a foam. Local or nationally imposed regulations will often specify the relevant standard to use along with the level of testing required, taking into account not only the materials involved, but also the level of risk associated with the application environment.

Some countries will only accept test reports issued from their list of government approved laboratories: this will also determine the official language used for the report.

Reference standards help assess flammability of foam materials. However, an APTI is composed of a composite of materials such as adhesives, films, and covers, in addition to the foam materials. The flame retardancy of an APTI cannot be evaluated by evaluation of the individual foam components alone. Therefore, normally, it is the final product that is tested, in accordance with locally recognized test methods, and relevant to the application environment concerned.

In some situations, testing of individual components is required. However, it is also useful that the finished product be tested, to ensure no problems related to the product's form or adverse interaction between component parts exists.

The use of some flame-retardant additives can negatively affect other foam properties. Some historically used additives, despite excellent flame-retardant properties, are no longer acceptable due to environmental or other issues (see 5.5.6).

5.5.5 Microbial resistance

In certain cases, additives are incorporated into polyurethane foam to improve its resistance to microbial attack. However, this is not usually considered necessary for a foam APTI, which will normally be protected by a fabric cover.

NOTE Natural latex foams offer some intrinsic resistance to microbial growth.

5.5.6 Restricted substances

In the production of foam, in various jurisdictions there are restrictions on the use of some chemicals that are not restricted in other jurisdictions. There are also local regulations on the registration of chemicals.

For example, in the European Union, the foam of an APTI cannot contain any restricted substance as defined by REACH, Annex XVII. Fairly good consistency exists between REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and the TSCA (Toxic Substances Control Act) in the USA.

Annex A
(informative)

Cross-reference guide between related ISO, ASTM, CEN and JIS standards

	Standards body:	ISO	CEN	ASTM	JIS
Clause	**Title**				
4.2	Sample dimensions	ISO 1923		ASTM D1622	JIS K 7248
	Sample conditioning	ISO 291			JIS K 6400-1
5.3.1	Density (core or apparent)	ISO 845		ASTM D3574-A	JIS K 7222
5.4.3	Compression hardness	ISO 3386		ASTM D3574-C	JIS K 6400-2
5.4.2	Indentation hardness; Support/SAG factor	ISO 2439		ASTM D3574-B	JIS K 6400-2
5.3.4	Compression set	ISO 1856		ASTM D3574-D	JIS K 6400-4
5.3.4	Wet compression set	ISO 13362			JIS K 6400-4
5.2.1	Resilience	ISO 8307		ASTM D3574-H	JIS K 6400-3
5.3.2	Tensile strength & elongation	ISO 1798		ASTM D3574-E	JIS K 6400-5
5.3.3	Tear strength	ISO 8067		ASTM D3574-F	JIS K 6400-5
	Accelerated ageing	ISO 2440		ASTM D3574-J/K	JIS K 6400-8
	Flex fatigue	ISO 5999		ASTM D3453	JIS K 6401
5.5.1	Dynamic flex fatigue	ISO 3385		ASTM D3574-I1/ I3	JIS K 6400-4
5.5.2	Flex fatigue (mattress)		EN 1957		
5.5.3	Air flow	ISO 7231		ASTM D3574-G	JIS K 6400-7
	Colour fastness	ISO 4582		ASTM E313	JIS K 7363
5.5.4	Flammability				