

---

---

**Assistive products for tissue integrity  
when lying down —**

**Part 7:  
Foam properties, characteristics and  
performance**

**iTeh STANDARD PREVIEW  
(standards.iteh.ai)**

[ISO/TR 20342-7:2021](https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021)

<https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021>



## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/TR 20342-7:2021](https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021)

<https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>2</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Test samples and foam properties</b> .....	<b>4</b>
4.1 General.....	4
4.2 Test samples.....	4
4.3 Presale literature.....	5
4.4 Composite APTIs.....	5
4.5 Foam density and hardness.....	5
4.6 Aging effects.....	5
<b>5 Test methods</b> .....	<b>6</b>
5.1 General.....	6
5.2 Determination of foam type.....	6
5.2.1 Resilience (ball rebound).....	6
5.2.2 Hysteresis.....	6
5.2.3 Support/SAG factor.....	6
5.3 Characterization of foam durability.....	6
5.3.1 Density (core or apparent).....	6
5.3.2 Tensile strength and elongation.....	7
5.3.3 Tear strength.....	7
5.3.4 Compression set (wet and/or dry).....	7
5.4 Characterization of foam hardness.....	7
5.4.1 General.....	7
5.4.2 Indentation hardness.....	8
5.4.3 Compression hardness.....	8
5.5 Characterization of other properties.....	8
5.5.1 Dynamic Fatigue Test (Pounding).....	8
5.5.2 Dynamic Fatigue Test (Roller).....	8
5.5.3 Air flow/permeability.....	8
5.5.4 Flammability.....	8
5.5.5 Microbial resistance.....	9
5.5.6 Restricted substances.....	9
<b>Annex A (informative) Cross-reference guide between related ISO, ASTM, CEN and JIS standards</b>	<b>10</b>
<b>Bibliography</b> .....	<b>11</b>

## 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](http://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](http://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](http://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](http://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.

## ISO/TR 20342-7:2021(E)

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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/TR 20342-7:2021](https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021)

<https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021>

# 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]

ITeh STANDARD PREVIEW  
(standards.iteh.ai)

### 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 diisocyanate (MDI) rather than toluene diisocyanate.

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

[ISO/TR 20342-7:2021](https://standards.iteh.ai/catalog/standards/sist/603e5fe6-fc33-4483-8638-d4b2774c2cac/iso-tr-20342-7-2021)

**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 diisocyanate (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 diisocyanate (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

ITeH STANDARD PREVIEW  
(standards.iteh.ai)

### 4.1 General

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

ISO/TR 20342-7:2021

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<sup>[5]</sup> can be followed for assessing sample dimensions, and ISO 291<sup>[1]</sup> 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<sup>[Z]</sup> 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<sup>[10]</sup>.