

Assistive products for tissue integrity when lying down - Part 4: Test methods for durability (ISO 20342-4:2026)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 20342-4:2026 sisaldab Euroopa standardi EN ISO 20342-4:2026 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.02.2026.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 20342-4:2026 consists of the English text of the European standard EN ISO 20342-4:2026.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 18.02.2026.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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English Version

## Assistive products for tissue integrity when lying down - Part 4: Test methods for durability (ISO 20342-4:2026)

Produits d'assistance pour l'intégrité des tissus en  
position allongée - Partie 4: Méthodes d'essai de  
durabilité (ISO 20342-4:2026)

Hilfsmittel zur Gewebeintegrität im Liegen - Teil 4:  
Testmethoden für Haltbarkeit (ISO 20342-4:2026)

This European Standard was approved by CEN on 6 February 2026.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

## European foreword

This document (EN ISO 20342-4:2026) has been prepared by Technical Committee ISO/TC 173 "Assistive products" in collaboration with Technical Committee CEN/TC 293 "Assistive products and accessibility" the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2026, and conflicting national standards shall be withdrawn at the latest by August 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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## Endorsement notice

The text of ISO 20342-4:2026 has been approved by CEN as EN ISO 20342-4:2026 without any modification.



**International  
Standard**

**ISO 20342-4**

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

**Part 4:  
Test methods for durability**

*Produits d'assistance pour l'intégrité des tissus en position  
allongée —*

*Partie 4: Méthodes d'essai de durabilité*

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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](http://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](http://www.iso.org/members.html).

## Introduction

Assistive products for tissue integrity (APTIs) play an integral role in any care plan for the prevention and treatment of pressure injuries. They can make a difference in quality of life for any user with limited mobility. Since no one APTI is best for all users, a wide variety of APTIs, including mattresses, mattress overlays and integrated bed systems, are available in a broad array of materials. Choosing from this growing list of alternatives has become a daunting task for clinicians, care givers and users. Selecting from the available alternatives is further complicated by the lack of consistent information regarding APTI characteristics.

Clinicians, manufacturers, distributors and users all stand to benefit from the development of standardized procedures to evaluate the characteristics of APTI. Detailed information provided by standardized testing will help clinicians objectively match the characteristics of an APTI to the needs of individual users. Testing standards will also aid manufacturers by guiding new product development and in the redesign of existing products. Testing standards will promote quality assurance within the manufacturing process. Distributors too, will benefit by being able to clearly describe and compare products from multiple manufacturers. Lastly, users will benefit by having APTIs that truly support their needs.

This document includes the test methods for the evaluation of the durability of APTIs in the lying position in different application environments, such as hospitals, home care and institutions. Some of the devices can be used or reused in more than one application environment. This means that different test methods can be applied to the same APTI depending on the application environment. This document offers several test methods, not all of which are appropriate for all APTIs, and, therefore, the manufacturer should determine which are appropriate for their APTIs' construction and use.

APTIs play a very important role in the prevention and treatment of pressure injuries. Healthcare workers implement prevention and treatment strategies, which include risk assessment, skin monitoring and repositioning. Guidance on the role of APTIs can be found in Reference [6].

# Assistive products for tissue integrity when lying down —

## Part 4: Test methods for durability

### 1 Scope

This document specifies conditions and test methods for the durability of assistive products for tissue integrity (APTIs) when lying down. These methods are additional to the ones in ISO 20342-1.

This document is applicable to both reactive and active APTIs, such as mattresses and overlays, and includes single-patient multiple-use products.

This document does not apply to single-use products.

NOTE This document is intended to help differentiate the durability characteristics between APTIs. It is not intended for determining overall performance or for ranking or scoring of such APTIs.

### 2 Normative references

There are no normative references in this document.

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

#### 3.1 durability

ability of a product to perform its required function over an expected period under normal conditions of use and maintenance

Note 1 to entry: Several units of measure can be used to express the expected lifetime of a product according to its field of application, such as years of life, hours of use or operational cycles.

#### 3.2 expected lifetime

manufacturer's design life of the assistive product for tissue integrity (APTIs) which is the period of time during which the APTI performs as intended by the manufacturer under normal conditions

Note 1 to entry: Different components of an APTI can have different expected lifetimes.