
**Tehnični pripomočki za celovitost tkiv v ležečem položaju - 1. del: Splošne zahteve
(ISO 20342-1:2019)**

Assistive products for tissue integrity when lying down - Part 1: General Requirements
(ISO 20342-1:2019)

Unterstützende Produkte zur Gewebeintegrität im Liegen - Teil 1: Allgemeine
Festlegungen (ISO 20342-1:2019)

Produits d'assistance pour l'intégrité des tissus en position allongée - Partie 1: Exigences
générales (ISO 20342-1:2019)

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**Assistive products for tissue integrity when lying down -
Part 1: General Requirements (ISO 20342-1:2019)**

Produits d'assistance pour l'intégrité des tissus en
position allongée - Partie 1: Exigences générales (ISO
20342-1:2019)

Unterstützende Produkte zur Gewebeintegrität im
Liegen - Teil 1: Allgemeine Festlegungen (ISO 20342-
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This European Standard was approved by CEN on 27 May 2019.

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European foreword

This document (EN ISO 20342-1:2019) 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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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

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Assistive products for tissue integrity when lying down —

Part 1: General requirements

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

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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).

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*.

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

This document specifies general requirements that are relevant to assistive products for tissue integrity (APTI) in the lying position in different application environments such as hospitals, home care, and institutions. Some of the devices can be used/reused in more than one application environment. This means that different requirements and test methods can apply to the same Assistive Products for Tissue Integrity (APTI), depending on the application environment. For an APTI to conform with this document, all relevant clauses need to be fulfilled, depending on the type of APTI. For example, some APTI do not include electrical components; therefore, the clauses related to electrical components might not be relevant.

APTI play a very important role in the prevention and treatment of pressure injuries. Another important role in the prevention and treatment of pressure injury is the clinical practice and the clinical evaluation. Guidance can be found in the NPUAP/EPUAP/PPPIA Guidelines, "Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline," from 2014.

Surfaces applied on operating theatre tables can also impact in the process of patient management and may need to be taken into consideration. It should be recognized however, patient stability and specialist equipment used during an operation often create conflicting priorities to those of an APTI.

Using this document, clinicians and manufacturers should consider the impact of other items (including additional APTI) used in conjunction with an APTI on tissue integrity and safety.

This document only covers general requirements to ensure safety of *users*. However, the intention is to develop a series of standards to cover the broad range of issues related to the APTI.

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Assistive products for tissue integrity when lying down —

Part 1: General requirements

1 Scope

This document specifies general requirements and related test methods that are relevant to assistive products for tissue integrity (APTI) in the lying position in different application environments such as hospitals, home care and institutions. This document applies to the safety of APTI, which are intended to remain in situ during periods of lying, and to prevent and/or treat pressure injuries.

This document covers a range of different lying support surfaces intended to be used in combination with the appropriate support platform or as a whole integrated system.

This document also covers assistive products primarily intended for tissue integrity for changing a lying position and assistive products for maintaining a lying position.

This document does not apply to lying support surfaces used in combination with incubators.

This document addresses the combination of a full body support surface and an adjustable mattress support platform. It also covers safety and performance test methods to ensure protection against injuries to the user.

This document specifies requirements and test methods for APTI within the following classifications of ISO 9999:2016: <https://standards.iteh.ai/catalog/standards/sist/a207cc98-033f-4230-b365-01b3aa485690/sist-en-iso-20342-1-2019>

04 33 06 Assistive products for tissue integrity when lying down such as but not limited to:

- Mattresses and mattress overlays for pressure injury prevention;
- Mattress coverings for pressure injury prevention mattresses.

12 31 03 Assistive products for sliding and turning such as but not limited to:

Devices for changing position or direction of a person using sliding or turning techniques. The only products included are those intended to be used in a lying position and remain in situ as part of the lying support surface. They are the following:

- sliding products that glide one way and lock the other way;
- sheets and underlays in flexible materials with low friction;
- fabric sold by the metre, cut as required for repositioning use;
- powered turning product;

This excludes sliding boards unless the product is intended to be left in situ.

09 07 06 Positioning pillows, positioning cushions and positioning systems such as but not limited to:

- leg positioners,
- arm positioners, and
- multipurpose body positioners.