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

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

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See Eesti standard EVS-EN ISO 20342-1:2019 sisaldab Euroopa standardi EN ISO 20342-1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 20342-1:2019 consists of the English text of the European standard EN ISO 20342-1:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 17.07.2019.	Date of Availability of the European standard is 17.07.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.180.01

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20342-1

July 2019

ICS 11.180.01

English Version

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 20342-1:2019)

This European Standard was approved by CEN on 27 May 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 20342-1:2019 E

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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

The text of ISO 20342-1:2019 has been approved by CEN as EN ISO 20342-1:2019 without any modification.

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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).

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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*.

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.

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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

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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:

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.

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18 12 15 Bedding such as but not limited to:

— draw sheets.

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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 9614-1, *Acoustics — Determination of sound power levels of noise sources using sound intensity — Part 1: Measurement at discrete points*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

IEC 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-11, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60695-11-10, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods*

IEC 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤16 A per phase)*

IEC 61000-3-3, *Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

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IEC 61000-4-8, *Electromagnetic compatibility (EMC) — Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 61672-2, *Electroacoustics — Sound level meters — Part 2: Pattern evaluation tests*

IEC 80601-2-35, *Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use*

EN 716-2:2017, *Furniture — Children's cots and folding cots for domestic use — Part 2: Test methods*

EN 1041, *Information supplied by the manufacturer of medical devices*

CISPR 11, *Industrial, scientific and medical (ISM) radio-frequency equipment — Electromagnetic disturbance characteristics — Limits and methods of measurement*

European Commission, MEDDEV 2.7/1 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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
application environment 4
care provided in a domestic area where the APTI is used to alleviate or compensate for an injury, disability or disease

Note 1 to entry: This excludes use in all other application environments (e.g. nursing homes, rehabilitation and geriatric facilities) when an APTI is purely designed for application environment 4.

[SOURCE: IEC 60601-2-52, 201.3.204, modified — "APTI" replaced "ME equipment"]

3.2
applied part
part of the *APTI* (3.5) that in normal use comes into physical contact with the user of the *APTI* (3.5) or a medical system to perform its function

[SOURCE: IEC 60601-1:2006, 3.8, modified — "APTI" replaced ME Equipment", "of the" replaced "for", "user" replaced "patient" and "necessary" and notes not included]

3.3
assistant
person who is helping a *user* (3.30) of the *APTI* (3.5)

EXAMPLE The ways assistants help persons with a *disability* (3.11) can be reposition in bed, bed ingress and egress, operating hoists and assisting with transferring in/out of seats.

Note 1 to entry: An assistant can be a health care professional or a non-professional e.g. a relative.

3.4
assistive product
instrument, equipment or technical system intended by the manufacturer to be used for the prevention, treatment or alleviation of or compensation for *impairment* (3.13)

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