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Assistive products for tissue integrity when lying down – Part 1: General Requirements (ISO/DIS 20342-1:2018)

Unterstützende Produkte zur Gewebeintegrität im Liegen -Teil 1: Allgemeine Festlegungen (ISO/DIS 20342-1:2018)

Produits dassistance à lintégrité des tissus en position allongée - Partie 1: Exigences générales (ISO/DIS 20342-1:2018)

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Assistive products for tissue integrity when lying down —

Part 1:
General requirements

Produits d'assistance à l'intégrité des tissus en position couchée

ICS: 11.180.01

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 173, *Assistive products for persons with disability*.

Introduction

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. Some of the devices can be used/reused in more than one application environment. This means that different requirements and test methods can be applied to the same APTI depending on the application environment. In order for an APTI to claim compliance 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 may 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. Good guidance can be found in the NPUAP/EPUAP/PPPIA Guidelines, "Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline," from 2014.

The intention is to develop a series of standards to cover the broad range of issues related to the APTI. However, Part 1 only covers general requirements in order to ensure safety of participating persons.

Assistive products for tissue integrity when lying down —

Part 1:
General requirements

1 Scope

This document applies to the safety of APTI, which make claims to redistribute the load of the full body, 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 will address the combination of a full body support surface and an adjustable mattress support platform. Safety and performance test methods to ensure protection against injuries to the user are the aspects that this document will cover.

This document specifies requirements and test methods for assistive products within the following divisions of ISO 9999:2016:

04 33 06 Assistive products for tissue integrity (APTI) when lying down:

— Mattresses and mattress overlays for pressure injury prevention;

— Mattress coverings for pressure injury prevention mattresses.

12 31 03 Assistive products for sliding and turning:

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

— 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.

09 07 06 Positioning pillows, positioning cushions and positioning systems e.g:

— Leg positioners;

— Arm positioners;

— Multipurpose body positioners.

18 12 15 Bedding:

— Draw sheets

NOTE Through the use of 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.

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 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

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

ISO 9999:2016, *Assistive products for persons with disability — Classification and terminology*

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

ISO 12952-1, *Textiles — Assessment of the ignitability of bedding items — Part 1: Ignition source: smouldering cigarette*

ISO 12952-2, *Textiles — Assessment of the ignitability of bedding items — Part 2: Ignition source: match-flame equivalent*

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 17966:2016, *Assistive products for personal hygiene that support users — Requirements and test methods*

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

IEC 60601-1:2005, *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 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*

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 597-1, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source smouldering cigarette*

EN 597-2, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 2: Ignition source: match flame equivalent*

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 Commision. MEDDEV 2.7/1 Guidelines on medical devices

RESNA. 2014: SS-1 American National Standard for Support Surfaces – **Volume 1**: Requirements and Test Methods for Full Body Support Surfaces

WHO. 2001: International Classification of Functioning, Disability and Health (ICF)

3 Terms and definitions

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
assistive product for tissue integrity (APTI)
surface designed to interface with the whole body when lying down or adjusted position which is intended to protect body tissue

3.2
assistive product(s)
instrument, equipment, or technical system intended by the manufacturer to be used for the prevention, treatment, or alleviation of or compensation for *impairment* (3.9)

Note 1 to entry: The definition is not identical to the definition in EN ISO 9999 because ISO/EN 20342-1 is restricted to *medical devices* (3.15).

3.3
pressure injury
pressure ulcer
localized damage to the skin and/or underlying soft tissue usually over a bony prominence

Note 1 to entry: The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities, and condition of the soft tissue.

3.4
lying down
position when the *user* (3.5) is in prone, supine, semi-recumbent, or lateral on a full body support surface

3.5
user
person for where the *APTI* (3.1) is intended

Note 1 to entry: The user can also be the *operator* (3.7)

3.6
assistant
person who is helping a person with a *disability* (3.8)

Note 1 to entry: Examples of the ways assistants help persons with a *disability* (3.8) are reposition in bed and bed ingress and egress, operating hosts, assisting with transferring in/out of seats and beds.

Note 2 to entry: An assistant can be a health care professional or a non-professional; for example, a relative.

Note 3 to entry: A person with disability is a person with one or more *impairments* (3.13), one or more activity limitations, one or more participation restrictions or a combination thereof.

3.7
operator
person handling the *APTI* (3.1)

Note 1 to entry: The operator can be a number of roles depending on the application environment; for example, the *user* (3.5), the *assistant* (3.6), or the service personnel.

3.8
disability
impairments (3.9), activity limitations, and participation restrictions denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)

[SOURCE: ICF 2001, WHO]

3.9
impairments
problems in body function or structure, such as a significant deviation or loss

[SOURCE: ICF 2001, WHO]

3.10
medical bed
device for which the *intended use* (3.21) is sleeping/resting that contains a mattress support platform and intended to assist in diagnosis, monitoring, prevention, treatment, alleviation of disease, or compensation for an injury or handicap

3.11
mattress
full body support surface designed to be placed directly on the existing bed frame

[SOURCE: RESNA SS-1: 2014, Section 1]

3.12
bedding
items normally placed on a *mattress* (3.11)

Note 1 to entry: Examples are mattress covers, underlays, sheets, blankets, quilts (duvets) and their covers, cushions, pillows, bolsters, and pillow cases.

3.13
mattress overlay
additional support surface designed to be placed directly on top of an existing support surface

[SOURCE: RESNA SS-1:2014]

3.14
reclining chair
adjustable chair which can be adjusted to a horizontal lying position

3.15
medical device
any instrument, apparatus, appliance, material, or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of:

— diagnosis, prevention, monitoring, treatment, or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;

— investigation, replacement, or modification of the anatomy or of a physiological process;

— control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: Devices are different from drugs and their biological evaluation requires a different approach.

Note 2 to entry: Use of the term “medical device” includes dental devices.

[SOURCE: Adapted from ISO 13485]

3.16
detachable part
part designed to be unfastened or disconnected without damage to the part or the whole

3.17
risk management
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk

