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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 —

Partie 1: Exigences générales

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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.

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:

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.

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*

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)

3.5
assistive product for tissue integrity
APTI
surface intended to protect body tissue, designed to interface with the body when *lying down* (3.15) or in adjusted position

3.6
bedding
items normally placed on a *mattress* (3.16)

EXAMPLE Mattress covers, underlays, sheets, blankets, quilts (duvets) and their covers, cushions, pillows, bolsters and pillow cases.

3.7
body mass index
BMI
value derived from the mass (weight in kilograms) and height (in metres) of an individual, defined as the body mass divided by the square of the body length, expressed in units of kg/m^2, calculated by the following formula:

$$BMI = m/l^2$$

where

m is the mass in kg;

l is the length in metres.

3.8
clinical evaluation
assessment and analysis of clinical data pertaining to a *medical device* (3.21) to verify the clinical safety and performance of the device when used as intended by the manufacturer

Note 1 to entry: Can include a compilation of clinical data, any scientific literature and the results of any *clinical investigations* (3.9), taking into account any relevant harmonized standards.

Note 2 to entry: Guidance for clinical data evaluation is given in MEDDEV 2.7/1.

[SOURCE: ISO 13485:2016, 3.3, modified — notes added]

3.9
clinical investigation
systematic study into human subjects, undertaken to verify the safety and performance of a specific *medical device* (3.21), under the manufacturer's intended conditions of use

[SOURCE: ISO 22523:2006, 3.7]

3.10
detachable part
part designed to be unfastened or disconnected without damage to the part or the whole

3.11
disability
impairments (3.13), 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]

3.12
expected service life
time specified by the manufacturer during which the APTI is expected to remain safe for use (i.e. maintain basic safety and claimed performance)

Note 1 to entry: Maintenance may be necessary during expected service life

[SOURCE: IEC 60601-1:2006, 3.28, modified — "APTI" replaced "ME equipment or ME system", "may" replaced "can" and "claimed" replaced "essential"]

3.13
impairment
problem in body function or structure, such as a significant deviation or loss

[SOURCE: ICF 2001, WHO]

3.14
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer

Note 1 to entry: This information includes pre-sale information.

[SOURCE: ISO 14971: 2007, 2,5, modified — "of" replaced "of which"]

3.15
lying down
position when the *user* (3.30) is in prone, supine, semi-recumbent or lateral on a full body support surface

3.16
mattress
full body support surface designed to be placed directly on the existing bed frame

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

3.17
mattress overlay
additional support surface designed to be placed directly on top of an existing support surface

[SOURCE: RESNA SS-1:2014, modified — "Mattress" changed to "support surface"]

3.18
maximum load
Safe Working Load
SWL
greatest permissible load specified by the manufacturer

Note 1 to entry: This load is related to safety of the product; e.g., strength and durability, and covers the mass of the *user* (3.30), accessories, and other loads placed on the *APTI* (3.5).

3.19
maximum user weight
greatest allowable user weight for the intended use of the APTI

3.20
medical bed
device for which the *intended use* (3.14) 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

[SOURCE: IEC 60601-2-52: 2009, 201.3.212, modified — notes are not included]

3.21
medical device
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 can 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 "medical device" includes dental devices.

3.22
minimum user weight
lowest allowable user weight for the intended use of the APTI

3.23
normal use
use of a product, process, or service in accordance with the specifications, instructions, and information provided by the manufacturer, not only intended for medical use, but also, for example, maintenance, service and transport

Note 1 to entry: Normal use is not to be confused with *intended use* (3.14). While both include the concept of use as intended by the manufacturer, *intended use* (3.14) focuses on the medical purpose while normal use incorporates not only the medical purposes, but also maintenance, service, transport, etc.

[SOURCE: ISO 17966: 2016, 3.19, modified — "etc" deleted and "and" and note added]

3.24
operator
person managing the *APTI* (3.5)

Note 1 to entry: The operator can be a number of roles depending on the application environment; for example, the *user* (3.29), the *assistant* (3.2), or the service personnel.

3.25
pressure injury
pressure ulcer
localized damage to the skin and/or underlying soft tissue, often over a bony prominence

Note 1 to entry: The injury can present as intact skin or as an open ulcer and can 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 can also be affected by microclimate, nutrition, perfusion, co-morbidities and the condition of the soft tissue.

3.26
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

3.27
single fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2006, 3.116]

3.28
technical documentation
manufacturer's data that shows that an *assistive product* (3.4) conforms to the specified requirements

Note 1 to entry: For the purposes of this document, such requirements include requirements specified in this document and/or any regulatory requirements.

3.29
usability
characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction

[SOURCE: ISO 14708-1:2014, 3.37]

3.30
user
person for whom the *APTI* (3.6) is intended

Note 1 to entry: The user can also be the *operator* (3.24)

4 General requirements and safety

4.1 General requirements

This document describes the minimum requirements and necessary APTI development activities to be met by manufacturer(s) or distributor(s) of an APTI to ensure safety and conformity with applicable standards. Further guidance around medical device development, manufacturing and management can be found in ISO 13485.

An APTI is a medical device and like any other medical devices it shall be designed, manufactured and promoted for the appropriate use. Many application environments, types of caregivers and people sizes, shapes and capabilities exist. These need to be considered during the development, manufacturing and promotion of an APTI.

NOTE An example of the methodology for development, manufacturing and promotion of an APTI is given in A.1.

4.2 Intended use

4.2.1 General requirements

As part of this document, manufacturers shall develop an intended use statement for their APTI. This should include the application environment, the appropriate patient population (based on patient risk), and general medical claims (such as claims to reduce the risk of pressure injuries).

The intended use should be given proper consideration throughout the development of an APTI and considered during risk evaluation.

4.2.2 Consideration regarding intended use

Defining the intended use of an APTI will help with identifying boundaries, thereby guiding users through the selection and usage of an APTI, and developers through the development cycle. The