INTERNATIONAL STANDARD

ISO 20342-1

Second edition
2022-07

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
ISO 20342-1:2022(E)

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

Published in Switzerland

Contents

Page

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,* 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).

This second edition cancels and replaces the first edition (ISO 20342-1:2019), which has been technically revised.

The main changes are as follows:

— the Scope was clarified;

— Clause 2 was updated;

— Clause 3 was updated;

— subclause 7.3 about V-shaped openings was amended;

— subclause 7.7 and Table 4 were amended (regarding surface temperature);

— the bibliography was updated.

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.

Introduction

This document addresses Assistive Products for Tissue Integrity (APTI). As some devices can be used/reused in more than one application environment, different requirements and test methods can apply to the same APTI, depending on the application environment.

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[24].

Surfaces applied on operating theatre tables can also impact in the process of patient management and might 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.

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 that 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 (adjustable included) or as a whole integrated system.

This document does not apply to medical beds.

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 or operating/surgical tables.

It also covers safety and performance test methods to ensure protection against injuries to the user.

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 9999:2022:

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, and

— mattress coverings for pressure injury prevention mattresses.

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

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 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 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 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *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 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 60601-2-35, *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 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
application environment 4
care provided in a domestic area where the *assistive product for tissue integrity* (3.5) 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 *assistive product for tissue integrity* (3.5) is purely designed for application environment 4.

[SOURCE: IEC 60601-2-52:2009+AMD1:2015:201.3.204, modified — "assistive product for tissue integrity" replaced "ME equipment".]

3.2
applied part
part of the *assistive product for tissue integrity* (3.5) that, in normal use, comes into physical contact with the user of the assistive product for tissue integrity or a medical system to perform its function

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020:3.8, modified — "assistive product for tissue integrity" 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 *assistive product for tissue integrity* (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 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:

$$BMI = m/l^2$$

where

m is the mass in kg;

l is the length in m.

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 to entry added.]

3.9
clinical investigation
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness, or safety of a medical device

[SOURCE: ISO 14155:2020:3.8, modified — Note 1 to entry was removed.]

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 *assistive product for tissue integrity* (3.5) is expected to remain safe for use (i.e. maintain basic safety and claimed performance)

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

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020:3.28, modified — "assistive product for tissue integrity" 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: 2019:3,6, modified — "of" replaced "for which", note to entry modified.]

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 *assistive product for tissue integrity* (3.5).

3.19
maximum user weight
greatest allowable user weight for the intended use of the *assistive product for tissue integrity* (3.5)

3.20
medical bed
device for which the *intended use* (3.14) is sleeping/resting, which 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+AMD1:2015:201.3.212, 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, and

— 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 *assistive product for tissue integrity* (3.5)

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 to entry added.]

3.24
operator
person managing the *assistive product for tissue integrity* (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 60601-1:2005+AMD1:2012+AMD2:2020 3.116]

3.28
technical documentation
manufacturer's data that shows that an *assistive product* (3.4) conforms to 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 *assistive product for tissue integrity* (3.5) is intended

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

4 General requirements and safety

4.1 General requirements

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 Clause A.1.

4.2 Intended use

4.2.1 General requirements

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 objective is not to limit the use of an APTI, but to make sure the context in which the APTI is supposed to be used is well defined and understood.

4.2.3 Intended use statement

4.2.3.1 Claims

To define better the intended use, it is key to identify what the APTI will do from a clinical standpoint. These are called claims. These help to position the clinical value of the APTI.

Ultimately, claims related to intended use statements shall be substantiated and supported by evidence; either a specific test or a clinical evaluation showing the claimed outcome is provided by the APTI.

4.2.3.2 APTI description

Once claims are defined, the next step is to provide a description of the support surface. This description will enhance the understanding of the physical characteristics of the APTI.

EXAMPLE The manufacturer could define the overall dimension of the APTI, which would help in the selection process as it relates to the pairing of an APTI to a bed and/or medical bed.

4.2.3.3 Users and application environments

In addition to the manufacturers claims and the APTI description, the manufacturer shall also define the APTI users and the application environment(s) in which the APTI can be used.

User definition will at a minimum define both the type of caregivers and persons who can use the APTI. Comprehensive APTI and targeted user descriptions will assist with the selection of an appropriate APTI.

Maximum load shall be declared by the manufacturer. It shall be included in the instructions for use and in the marking of the APTI.

Maximum and minimum user weight shall be declared by the manufacturer and then be included in the instructions for use and be labelled on the APTI.

Clearly defining the environment(s) will help provide guidance on where to use the APTI. Multiple application environments exist, such as acute care, long-term care, home care, etc. This becomes relevant to ensure the appropriate risk mitigation strategy is applied.

If an APTI has limits to suitable application environments, these shall be clearly stated in the instruction for use. The application environments can modify the application of requirements.

Consideration should also be given to contraindications for an APTI, thereby providing caregivers and users with clear indications of potentially hazardous situations.

4.3 APTI risk management

Manufacturers shall address potential APTI risks (e.g. using ISO 14971). ISO 14971 provides a methodology and a process for manufacturers to identify potential hazards and hazardous situations associated with medical devices, to estimate and evaluate the associated risks and to control for these risks.

4.4 APTI usability

4.4.1 General

The manufacturer shall address usability using IEC 62366-1 or IEC 60601-1-6, where applicable.

4.4.2 Design requirements in relation to persons with cognitive impairment

Cognitive impairment aspects shall be considered in the design, performance and use of an APTI.

Considerations of cognitive impairment shall be addressed in the APTI's technical documentation.

NOTE 1 Cognition is the understanding, integrating and processing of information. Cognition involves fundamental mental characteristics such as the capacity to learn, remember, understand, solve problems, plan, keep focused, etc.

NOTE 2 For further guidance, see ISO 21801 and ISO 21802.

4.5 Design controls

Two types of input will help define a medical device and more particularly an APTI:

a) functional requirements characterize the APTI and are inherent to the design;

b) performance requirements characterize and quantify operational criterion of an APTI.

NOTE For guidance on developing design control, see Figure A.2.

4.6 Clinical evaluation

A clinical evaluation in accordance with MEDDEV 2.7/1 shall be done for all APTIs. If a clinical evaluation requires a formal clinical investigation, the clinical investigation shall conform to the requirements of ISO 14155. A clinical evaluation shall always be done before performing a clinical investigation.

4.7 Foreseeable misuse

The manufacturer shall assess risk the (e.g. using ISO 14971) to assess the compatibility of the APTI with commonly used devices, and specify contraindications and cautions in the instructions for use. If the care provider chooses to combine an APTI with another APTI or medical device in another way than indicated in the instructions for use, it is the responsibility of the care provider to perform a risk assessment.

4.8 Test conditions

When conducting performance testing, the APTI shall be tested in the intended configuration (for the user). However, if the APTI is of a multipurpose design that can be assembled in different formats, it shall be assembled according to instructions given by the manufacturer. If the APTI is intended to be used in different combinations/configurations, then the most adverse combination/configuration shall be tested. If the APTI is delivered disassembled, it shall be assembled according to manufacturer´s instructions before testing.

The tests are performed within the range of the environmental condition indicated in the technical description.

Unless prescribed by the test document, the testing shall be performed in an environment in the normal use environment and the designated environment shall be declared. If the conditions deviate from ISO 554 or if prescribed in the test document, the condition shall be reported.

Test are performed on a representative sample. Different samples may be used for each test if the validity of the results is not significantly affected. Unless otherwise stated in a specific clause of this document, the order of tests is not important. A new APTI can be chosen if the original test object breaks down, and cannot be repaired, this is assuming that the part or section of the APTI that breaks is not related to the part or section of the APTI under testing: If it is directly related, the test would be deemed to have failed. Some tests relevant to the safe functioning of the APTI might have to be repeated on the new APTI. It is the responsibility of the manufacturer of the APTI to consider in each separate case.

If the APTI is tested by an independent test house, the decision shall be taken through cooperation of the test house and the manufacturer.

4.9 Lifting and carrying means

If an APTI or a part of an APTI has a mass of 20 kg or more and the intended use is for it to be portable or to be handled according to manufactures instructions, it shall either

a) have one or more carrying-handles suitably placed which enable portability of the APTI, or part, to be carried by two or more persons, or be provided with suitable handling equipment, or

b) the instructions for use shall indicate the points where the APTI, or its part, can be lifted safely and describe how they should be handled during lifting, assembly and/or carrying. If practical, the APTI or component parts shall be labelled to indicate where it can be lifted safely and/or how it can be handled during assembly and/or carrying.

Manufacturers should note that other requirements can demand loads of less than 20 kg.

5 Safety requirements

5.1 Requirements for information supplied by the manufacturer

5.1.1 General

The information supplied by the manufacturer comprises the data in the instructions for use and the details on the label. Information should be available in a recognized official language of the country the APTI is to be sold and used in.

The information applied to, and supplied with the APTI shall conform to EN 1041.

All information provided for an APTI shall take into account the intended users, the conditions of use and any issues specific to an APTI types that are necessary for the safe and effective use of the APTI.

Special attention shall be paid to the operator information, particularly the instructions on operation, the design of labels as well as the design and presentation of warnings.

NOTE 1 Further guidance on requirements for persons with different types of impairments can be found in ISO/IEC Guide 71:2014, Tables 1, 2, 4 and 6, ISO 21801 and ISO 21802.

In addition, the manufacturer should provide the information in the instructions for use in three separate sections: pre-sale, user and service information, as specified in 5.1.5, 5.1.6 and 5.1.7. These can be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants.

NOTE 2 Further guidance on the preparation of instructions can be found in ISO 20417 and IEC/IEEE 82079-1.

5.1.2 APTI traceability

The manufacturer shall establish a means of ensuring the traceability of the APTI including any detachable part where there is a risk associated with the combination and usability. It is appropriate that the marking of an APTI is indicated on a visible part of the APTI and clearly mention the supplier/manufacturer, its model or batch number, and its date of manufacture.

5.1.3 Education and training

Where manufacturers and suppliers provide pre/post market education and training to ensure the safe and appropriate use of the APTI, the program implications, intentions and outcomes shall be clearly described. These will define intention, outcomes, qualifications, duration, and cost implications. All relevant test, examinations and certifications will also be provided. Follow-up programs and updating should be described.

5.1.4 Pre-sale information

Pre-sale information shall include the following:

a) information on how to obtain the user information in alternate formats appropriate for use by people with visual, reading or cognitive disabilities, if needed for user to safely operate the APTI;

b) a description of the intended use and the intended environment;

c) maintenance instructions, if applicable;

d) if the APTI is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion or other damage, if applicable;

e) if the APTI is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion or other damage, if applicable;

f) the overall dimensions (width, length and height) of the APTI, expressed in millimetres, when it is ready for use and, if applicable, when it is folded or dismantled;

g) the weight expressed in kilograms and, if the APTI can be dismantled or has any removable parts, those parts that have a mass that is heavier than 20 kg shall be separately identified. Manufacturers should note that other requirements can demand loads of less than 20 kg;

h) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the assistive product;

i) if a programmable controller is fitted, information on the method of programming, the competence required to carry out the programming and the effects on performance;

j) operator control adjustments;

k) information on whether and how the APTI can be folded or dismantled to assist in storage or transport;

l) instructions regarding transport of the APTI;

m) all information shall, where practicable and possible, be available in pictogram;

n) measure sound pressure;

o) minimum and maximum weight of equipment.

5.1.5 User information

User information shall be provided by the manufacturer with each APTI. Information shall contain all instructions, pre-sale information and any warnings plus the following, as applicable, for each APTI:

a) the location and the type of the unique identification code and lot number of the APTI;

b) the intended user;

c) any adjustments or setting requirements before the APTI can be used plus information on how adjustments or setting affect the APTI;

d) information on the adjustment possibilities and the competence required to carry out these adjustments;

e) instructions on the operation of all controls;

f) the battery type and nominal voltage;

g) instructions for battery maintenance, replacement and verification as well as emergency backup options if available;

h) instructions for operating the battery charger, including warnings regarding any potential safety hazards (e.g. a possibility of gas accumulating in the charging area);

i) instructions on dismantling and re-assembly of the APTI or any removable parts;

j) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handling during dismantling, assembly or carrying;

k) an appropriate warning that external sources of heat or cold (e.g. sunlight, or environmental conditions) can impact the surface temperature of the APTI;

l) a clear warning stating that deviations from the manufacturer's cleaning and disinfection instructions can cause serious hazards, and adversely affect the life and efficacy of the APTI;

m) if the APTI is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion/other damage;

n) if the APTI is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion/other damage;

o) if the intended purpose of the APTI cannot be met without a hazard (e.g. holes, V-shaped opening), a warning and instructions on how to operate the APTI safely;

p) if the intended purpose of the APTI cannot be met without a hazard due to moving parts (e.g. squeezing), a warning and instructions on how to operate the APTI safely;

q) the level of resistance to ignition of materials stating the other standards with an equivalent safety level or any other relevant flammability standards with which the APTI conforms. If no relevant flammability standards exist, then all flammability standards with which the APTI conforms;

r) information on the recycling of used batteries and other parts of the APTI;

s) if the APTI is designed for use with multiple support platforms and combinations, it shall have the following caution in the instructions for use: "Incompatible support platforms (e.g. a bed frame or mattress) can create safety hazards". The user information shall contain criteria, such as the necessary dimensions and characteristics as a guide for the selection of compatible support platforms;

It is recommended to include instructions on how to solve simple problems for the ease of use (frequently asked questions).

t) measure sound pressure;

u) minimum and maximum weight.

5.1.6 Service information and inspection

The service information shall contain all the pre-sale information, user information and instructions necessary for the maintenance, adjustment and repair of the APTI and for the replacement of parts. The service information shall be sufficiently detailed concerning inspection, preventative maintenance and calibration, including the frequency of each. The service information shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the APTI. Additionally, the service information shall identify the parts on which inspection and preventative maintenance shall be performed by service personnel, including the periods to be applied and details about the actual performance of such maintenance.

Where applicable, manufacturers shall ensure that the procedures for periodic inspections and preventative maintenance are clearly defined in the user documentation.

NOTE See Annex C for further guidance.

Information on the expected service life of the APTI shall be provided.

5.1.7 Labelling

The information applied to and supplied with the APTI shall conform to EN 1041.

Detachable parts of the APTI with a mass of more than 20 kg shall be marked with the actual mass on the part.

Symbols for use in the labelling of medical devices shall be in accordance with ISO 15223-1.

5.1.8 Marking of user weight and maximum load

The APTI shall be marked with the maximum user weight, the minimum user weight, if appropriate, and the maximum load, (for symbol see Figure 1).

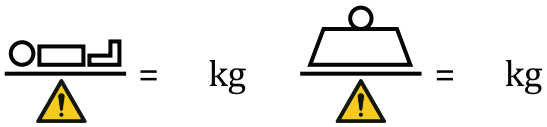

Figure 1 — Maximum/minimum user weight and maximum load

[SOURCE: IEC 60601-2-52:2009+AMD1:2015, 201.7.2.2.101[1)] Copyright © 2015 IEC Geneva, Switzerland. www.iec.ch]

NOTE A weight interval can be added before the "kg", e.g. 45 to 120.

5.1.9 Packaging

The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis (see 4.3).

5.2 APTI that can be dismantled

5.2.1 General requirements

If it is intended that the APTI can be dismantled for storage, transportation, or cleaning, the reassembly shall not create an unacceptable risk.

Manufacturer's design and instruction shall not allow reassembly in a way that presents a hazard.

5.2.2 Small parts

Any part that can be detached without the use of a tool shall not fit wholly within the cylinder as specified in EN 716-2:2017, 5.5 nor be of a size where it can create a choking hazard to small children (under the age of 36 months).

5.2.3 Fasteners and connections

If it is intended that the APTI can be dismantled for storage, transportation and/or cleaning and the manufacturer uses single use fasteners, then the risk of attempted reuse of the single use fasteners shall be considered and if necessary, mitigated, through risk analysis.

5.3 Resistance to corrosion

The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis. The APTI or part of the APTI that is identified to be at risk of corrosion shall be sufficiently protected against corrosion. This can be confirmed, for example, by using the salt spray test according to ISO 9227 or other appropriate test methods.

5.4 Noise and vibration

If noise and vibration are not part of the intended performance of the APTI, hazards and nuisance from noise and vibration shall be assessed by risk management (see 4.3).

The audible noise produced by the APTI during its normal operation shall be measured using ISO 3746 and ISO 9614-1 with sound measuring equipment that are in accordance with IEC 61672-1. This sound pressure level shall be detailed in the accompanying documents. The noise and vibration of the installed device shall take into account the manufacturer's recommendation and be considered in the person's environment by the operator.

1) Reproduced with permission from IEC 60601-2-52:2009+AMD1:2015, 201.7.2.2.101. IEC has no responsibility for the placement and context (including other content or accuracy) in which the extracts are reproduced, nor is IEC in any way responsible for the other content or accuracy therein.

5.5 Sound audible acoustic energy

In normal use, the person, operator and other persons shall not be exposed to acoustic noise from the APTI, with the exception of sound from auditory alarm signals, exceeding the levels specified below:

— 80 dBA for a cumulative exposure of 24 h over a 24 h period. An offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 83 dBA for 12 h over a 24 h period);

— 140 dB un-weighted dBA (peak) sound pressure level for impulsive or impact acoustic energy (noise).

Interpolation or extrapolation is allowed for exposure times of 80 - 10* log10(h/24), in dB, where h is cumulative exposure time over a 24 h period.

Since persons can have a higher sensitivity to acoustic energy (noise), a lower level could be more appropriate. Consideration should also be given to perception of auditory alarm signal.

NOTE The World Health Organization has recommended a maximum impulse or impact acoustic energy (noise) level for children of 120 dB.

If the A-weighted sound pressure level exceeds 80 dB, noise protection measures should be considered.

Conformity is checked by measuring the maximum A-weighted sound pressure level in accordance with ISO 11202 at the minimum distances of person, operator and other persons from the noise source in normal use, and if necessary, calculating the sound pressure level produced by the APTI in accordance with ISO 3746 or ISO 9614-1 with sound measuring equipment that are in accordance with IEC 61672-1.

The following conditions shall apply:

a) the APTI is operated under worst-case normal condition;

b) any protective means provided or called for in accompanying documents are to be in place during sound measurement;

c) sound level meters used in the measurement shall conform to IEC 61672-1 and IEC 61672-2;

d) the test room is semi-reverberant with a hard-reflecting floor. The distance between any wall or other object and the surface of the APTI is not less than 3 m;

e) when sound measurements in a test room are not feasible (e.g. for a large permanently installed APTI), measurements can be done in situ.

5.6 Default indicators

For critical functions, there shall be an audible and/or visible indicator signalling the failure mode of critical functions.

The alarm or feedback signal shall be distinguished from the noise of the APTI itself either by frequency or sound pressure level.

Where alarms are applicable, IEC 60601-1-8 shall apply, see Table 1.

Alarm conditions shall be assigned to one or more of the following priorities: high priority, medium priority or low priority. The priority of each alarm condition shall be disclosed in the instruction for use.

Priorities can be identified in groups.

Conformity is checked by inspection of the instructions for use and in the risk management file.

Table 1 — Alarm condition priorities

Potential result of failure to respond to the cause of alarm condition	Onset of potential harm[a]		
	Immediate[b]	Prompt[c]	Delayed[d]
Death or irreversible injury	High priority	High priority	Medium priority
Reversible injury	High priority	Medium priority	Low priority
Minor injury or discomfort	Medium priority	Low priority	Low priority or no alarm signal

NOTE Where practicable, an APTI with a therapeutic function incorporate an automatic safety mechanism to prevent immediate death or irreversible injury caused by the APTI. See also appropriate particular standards.

[a] Onset of potential harm refers to when an injury occurs and not to when it is manifested

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under "prompt".

[e] Where practicable, APTI with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the APTI. See also appropriate particular standards.

[SOURCE: IEC 60601-1-8: 2006, Table 1, "APTI" replaced "ME EQUIPMENT"[2]. Copyright © 2006 IEC Geneva, Switzerland. www.iec.ch]

5.7 Feedback

All user commands impacting safety shall have some kind of feedback, e.g. audible, visible or tactile, that clearly indicates that a command has been given and/or executed. The feedback shall be accessible for all relevant operators where appropriate.

6 Flammability

6.1 General

Manufacturers shall consider the environments and methods of use to which an APTI or any materials that are usually used in combination with this APTI, will be exposed and take appropriate steps to minimize any fire hazard.

The manufacturer shall include a warning in the instruction for use that the use of other materials in combination with the APTI can degrade the fire performance.

NOTE For guidance, see A.5.

Every effort should be made to use products that meet the flammability requirements as it is of particular importance to persons with a disability who are unable to escape from a fire. The use of non-flame retardant materials should be reviewed regularly, as there is continuous development in this field.

When an APTI is tested for flammability requirements, the test shall be performed according to the flammability standard's guidelines.

Where possible, the efficacy of any flame-retarding agents should last for the service life of the product. The manufacturer should advise the user should there be any special cleaning or care requirements to ensure the continued efficacy of a flame retardant. Should the flame retardant effect not last the service life of the product, the manufacturer shall warn and advise the user (for example number of washes that will remove the flame retardant effect).

2) Reproduced with permission from IEC 60601-1-8:2006, Table 1. IEC has no responsibility for the placement and context (including other content or accuracy) in which the extracts are reproduced, nor is IEC in any way responsible for the other content or accuracy therein.

Manufacturers should identify the relevant standards for their intended uses and specify which test methods the product passes in relevant documentation, product tags and labelling as appropriate and required by statute.

6.2 Flammability

The APTI shall conform with either of the following:

a) if the manufacturer claims that an APTI is resistant to ignition, it shall conform with the appropriate requirements. Consideration shall be made for other flammability requirements and fire source such as by a cigarette, a small flame, crib, or others. Flammability standards applied shall be included in the instructions for use;

b) if the clinical benefit outweighs the risk of flammability, the reasons shall be included in the technical documentation and the APTI shall be supplied with a warning that it is not flame resistant. If possible, the warning should be placed on the product and included in the instructions for use and a description of the precautions required to offset the increased risk.

See the bibliography for examples of standards manufacturers can conform with.

6.3 Moulded parts used as enclosures for electrical equipment

If a risk can be caused by an electronic component, the housing of the moulded part shall be tested in accordance with IEC 60695-11-10 FV-2 or better. If the product is of a type that the user cannot escape from or detect as a dangerous situation it shall be IEC 60695-11-10 FV-1.

7 Mechanical safety

7.1 Prevention of traps for the human body

Holes in, and clearances between stationary parts that are accessible to the user and/or assistant during the intended use of an APTI shall be as specified in Table 2. If the APTI is intended for both adults and children, then the most demanding of the distances below shall be used.

Table 2 — Safe distance between stationary parts

To avoid	Safe distances for adults	Safe distances for children[a]
Finger traps	Less than 8 mm or more than 25 mm	Less than 5 mm or more than 12 mm
Foot traps	Less than 35 mm or more than 100 mm	Less than 25 mm or more than 45 mm
Head traps	Less than 120 mm or more than 250 mm	Less than 60 mm or more than 250 mm
[a] Also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or a BMI of less than 17.		

[SOURCE: ISO 17966:2016, Table 4]

If the intended purpose of an APTI cannot be met without a hazard caused by the size of holes and the clearance between stationary parts, a warning and instructions on how to operate the APTI safely shall be provided in the instructions for use. For stationary parts that can cause a trap, manufacturers shall take into consideration those parts of the body that are at risk. The user/user group shall be specified, so that correct safety distances can be applied.

NOTE 1 An APTI intended to be used by a child can also be operated by an adult.

The design of parts that contain a hole or clearance shall take into consideration the forces that can be applied in normal use.

NOTE 2 A force can cause a hole/clearance to widen. This could then cause a failure, as shown in Table 2.

On holes with the shape of a keyhole or V-shaped openings (see 7.3) the lower limit shall not apply. When inspecting the APTI for traps for body parts, any flexibility/elasticity of adjacent parts shall be taken into account.

The dimensions in IEC 60601-2-52 regarding combination of mattress and constructional part of the bed and/or medical bed should not be compromised.

7.2 Safety of moving and folding parts

Unless the intended purpose of an APTI, or part of an APTI, is to grip, cut, squeeze, etc., or if the intended use cannot be achieved without a hazard such as risk of squeezing:

a) any moving parts that constitute a safety hazard shall be provided with guards that can only be removed using a tool;

or

b) the gap between exposed parts of an APTI that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in Table 3.

Table 3 — Safe distances between moving parts

To avoid	Safe distances for adults	Safe distances for children[a]
Finger traps	Less than 8 mm or more than 25 mm	Less than 4 mm or more than 25 mm
Foot traps	Less than 35 mm or more than 120 mm	Less than 25 mm or more than 120 mm
Head traps	Less than 120 mm or more than 300 mm	Less than 60 mm or more than 300 mm

[a] Also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or a BMI of less than 17.

[SOURCE: ISO 17966:2016, Table 3]

These measurements shall be done before and after any relevant strength, durability and impact testing;

or

c) if cords (ropes), chains and drive belts are used, they shall either be confined so that they cannot run off or jump out of their guiding devices, or a safety hazard shall be prevented by other means (mechanical means applied for this purpose shall be removable only using a tool);

or

d) the APTI shall incorporate a control device which initiates the movement when it is operated and stops the movement when it is released (e.g. a spring loaded control device that returns to the stop position when released).

NOTE 1 Also known as hold to run control operations.

Replacement of a hold to run function by an automatic function shall only be permissible when validated under appropriated risk management, design, and manufacturing controls;

or

e) the APTI shall incorporate a means for detecting that a person is in danger of being trapped and automatically activate a means of preventing injury (e.g. by stopping the movement).

For moving parts that can cause squeezing, manufacturers shall take into consideration those part/parts of the body that are at risk. The user/user group shall be specified, so that correct safety distances can be applied.

The barrier for preventing access to the fingers should be a safe distance from 200 mm representing the reach of a hand.

NOTE 2 An APTI intended for a child can also be operated by an adult.

To avoid a hazard where parts of the body can be trapped when the APTI is folded, the following shall be assessed:

— the APTI shall incorporate means to protect the user from trapping and/or squeezing hazards;

or

— the gap between exposed parts of an APTI that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in Table 3;

or

— if the intended purpose of an APTI cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the APTI safely shall be provided in the instructions for use.

If guards are applied, the design of a guard shall take into consideration the forces that can be applied in normal use.

7.3 V-shaped openings

The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. This will reduce the risk of a user being trapped by the head at any position.

A V-shaped opening shall be greater than 60°. This will reduce the risk for a user to be trapped by the head or other parts of the body at any position.

For the assessment of V-shaped openings less than 75°, the manufacturer shall perform the risk analysis in accordance with ISO 14971.

The manufacturer should give information in the instructions for use about safe combinations.

7.4 Surfaces, corners, edges and protruding parts

If not required for the intended function of an APTI, all accessible edges, corners and surfaces shall be smooth and be free from burrs and sharp edges.

If not required for the intended function, an APTI shall not have any protruding parts. Where possible, necessary protruding parts shall have protection to prevent injury and/or damage.

The requirements set in EN 1888-1:2018, 8.7, should apply.

NOTE For guidance on test methods for protruding parts, see EN 716-2:2017, 5.10 and IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.3.

7.5 Folding and adjusting mechanisms

Any dimensions shall fulfil the dimensions in 7.1 or 7.2.

Folding and adjusting mechanisms can cause a hazard if parts of the body can enter a gap between parts and be trapped when the gap is closed.

The mechanisms shall be capable of being safely locked when the APTI is in any fixed working configuration. The locking mechanism shall not increase any risk. It shall also be capable of being safely locked when folded if it constitutes a risk for the user or assistant. The APTI shall fold in a manner that does not create a hazard.

NOTE "Safely locked" is intended to mean that a locking device will not create entrapment, or inadvertent slippage or movement.

7.6 Instability hazard

For safety of stability (i.e. unintentional movement or overbalance) of any APTI, the relevant parts of IEC 60601-1:2005+AMD1:2012+AMD2:2020, including IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.4, shall be used.

NOTE Relevant parts are dependent on the intended use of the product.

An APTI designed for use with multiple support platforms and combinations shall have the following warning in the instructions for use: "Incompatible support platforms (e.g. a bed frame or mattress) can create stability hazards." The user information shall contain information on the selection of compatible support platforms and necessary dimensions and characteristics.

7.7 Temperature of parts that come into contact with human skin

The risk analysis shall identify hazards and evaluate the risks associated with the surface temperature of parts that can come into contact with human skin during the intended conditions of use.

If the APTI is intended to increase the user temperature, the APTI shall be provided with a specific safety mechanism that will warn the operator when 41° is exceeded as required in IEC 60601-2-35.

The risk analysis shall take account of the following:

a) the range of ambient temperatures to be expected during the intended use and foreseeable misuse;

NOTE These temperatures could include direct exposure to sunshine, extreme cold, etc.

b) temperatures that can result from single fault conditions;

c) the ergonomic data on acceptable temperatures of touchable surfaces in ISO 13732-1;

d) the use of an APTI by people with insensate skin (i.e. cannot feel heat or cold) and/or damaged skin.

For an APTI provided with a heating function, the manufacturer shall conform with IEC 60601-2-35 and consider IEC 60601-1 in the risk analysis. It can be justified to add an additional margin of safety for a person with immature and sensitive skin where heating devices are used for more than 6 hours.

For an APTI without a heating function the ergonomic data on acceptable temperatures of touchable surfaces in IEC 60601-1, shall be used. The surface temperature shall not exceed 41 °C (see Table 4) when measured by the methods of test in IEC 60601-1.

Table 4 — Allowable maximum temperatures for skin contact with an APTI applied part

Applied part of an APTI		Maximum temperature[a b] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
Application of part having contact with a person for a time t	$t < 1$ min	51	56	60
	1 min ≤ t < 10 min	48	48	48
	10 min ≤ t	41	41	41

[a] These temperature limit values are applicable for the healthy skin of adults, but in the limitation for temperature for duration more than 10 min also disabled persons with sensible skin or no sensation have been considered. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the risk management file.

[b] Where it is necessary for applied parts to exceed the temperature limits of Table 4 in order to provide clinical benefit, the risk management file shall contain documentation showing that the resulting benefit exceeds any associated increase in risk.

[SOURCE: IEC 60601-2-52:2009+AMD1:2015, Table 24[3)] Copyright © 2015 IEC Geneva, Switzerland. www.iec.ch]

NOTE The 41 °C will only occur in the test environment due to waste heat during testing. This temperature will not come into contact with the human skin.

If a manufacturer cannot meet this requirement without impairing the intended performance of the APTI, each APTI should be supplied with a warning identifying which surfaces can reach a higher temperature than that specified and a description of the precautions necessary to offset the increased risk.

7.8 Ergonomic principles

An APTI can be used not only by whom it is primarily intended for, but also by an assisting person. The ergonomic principles set out in EN 614-1 should apply to all involved persons. See also 4.4.

7.9 Additional consideration

The manufacturer shall identify and mitigate the specific hazards that can occur with the blockage of air flow into and out of enclosures intended for location within a support surface.

8 Safety of electrical equipment

8.1 General electrical requirements

The following standards for general electrical requirements shall apply:

— IEC 60601-1:2005+AMD1:2012+AMD2:2020 (All applicable clauses, if not otherwise specified in this document);

— IEC 60601-1-2;

— IEC 60601-1-11 for application environment 4.

3) Reproduced with permission from IEC 60601-2-52:2009+AMD1:2015, Table 24. IEC has no responsibility for the placement and context (including other content or accuracy) in which the extracts are reproduced, nor is IEC in any way responsible for the other content or accuracy therein.

8.2 Electromagnetic compatibility

8.2.1 General

An APTI containing electrical or electronic devices/components shall conform to IEC 60601-1-2 and shall, in addition, conform to 8.4, 8.5 and 8.6.

8.2.2 Emissions

The equipment shall meet the radiated emissions limits specified in CISPR 11.

The requirements in IEC 61000-3-2 shall apply, if applicable.

The requirements in IEC 61000-3-3 shall apply, if applicable.

8.2.3 Immunity

An APTI shall, in addition to the requirements in IEC 60601-1-2, also be tested with a field strength of 10 V/m (RMS value of the unmodulated carrier) in the frequency range of 800 MHz to 2,7 GHz. The test shall be performed in accordance with IEC 61000-4-3.

If, as a result of the application of this test, the APTI presents a hazard, or there is any unintentional operation of the APTI, the APTI fails the test.

NOTE 1 It can be necessary to assess the risk associated with the APTI when used in close proximity to mobile telephone(s) or other forms of transmitter. In this case, higher field strength values over a broader range of frequency can apply.

NOTE 2 An APTI is used in a wide range of environments and can be used in the presence of other electronic equipment. The electromagnetic compatibility (EMC) needs to be carefully matched to the intended use of the APTI.

8.2.4 Power frequency magnetic field immunity

When the equipment is tested in accordance with IEC 61000-4-8 using test level 4, at 50 Hz and 60 Hz,

a) the equipment shall operate safely in the presence of the applied field, and

b) electrically powered devices or electrically moved functions shall not make any unintentional operation in the presence of the applied field.

Perform the continuous field immunity test specified in IEC 61000-4-8 on the equipment as table-top equipment. Test the equipment for not less than one minute for each orientation of the applied field.

NOTE For guidance, see A.7.

8.3 Liquid ingress

Enclosures shall be classified according to the degree of protection against harmful ingress of water as detailed in IEC 60529.

For APTIs to be used in the Application environment 4, see IEC 60601-1-11.

Conformity is checked by tests in IEC 60529 with the APTI placed in the least favourable position for normal use.

An APTI that is not in contact with water during normal use or reasonably foreseeable misuse (e.g. during the cleaning process) shall at least be protected to IPX2.

An APTI that is normally in contact with water or body fluids shall at least be protected to IPX4.

An APTI that is temporarily submerged into water during normal use shall at least be protected to IPX7.

An APTI that is normally submerged into water during normal use shall at least be protected to IPX8.

If water unintentionally can come into an enclosure, there shall be a way for the liquid to get out of the enclosure, or the liquid shall not cause any kind of hazard.

8.4 Interruption of power supply/supply mains to an APTI

In an emergency situation when mains voltage has been interrupted, essential performance functions (performance necessary to achieve freedom from unacceptable risk), defined by the manufacturer (for example the lowering of the back section) shall be able to be operated by other means.

The emergency position specified by the manufacturer (for example the lowering of the back section) shall be achievable within 30 s.

Conformity is checked by functional test in the most adverse conditions.

8.5 Hold to run activation

Electrically operable movements that can create a hazardous condition shall only be possible by the activation of control devices that initiate and maintain operation of the device only as long as the manual control is actuated and where the manual control automatically returns to the 'Stop' or 'Off' position when released. Replacement of a hold to run function by an automatic function shall only be permissible when reviewed and validated under appropriate risk management, design, and manufacturing controls.

NOTE Non-electrically operable movements (e.g. by hand or foot) are considered to conform with this clause, as long as mass and velocity allow adequate control of e.g. positioning without causing an unacceptable risk.

8.6 Emergency stop functions

If the risk analysis demonstrates that there is a risk for the user or any other person around the APTI to be pinched or a single fault appearing that can create a safety hazard as a potential way to mitigate, there could be an emergency stop as specified in ISO 13850 together with the following requirements:

a) the APTI shall be designed to prevent accidental injury. If this is not feasible, the APTI shall stop moving;

b) the emergency stop device shall be readily accessible to the operator, and stop the dangerous situation within one action;

c) the stop device shall maintain the equipment in a safe position, but not interfere with any essential performance functions, as defined by the manufacturer;

d) the emergency stop device shall maintain the APTI in a stopped position until it is released by a designated procedure;

e) a safe stopping distance shall be considered in the risk analysis;

f) the designated procedure for the release of the emergency stop shall be different from the movement needed to activate the emergency stop.

9 Biocompatibility

9.1 Biocompatibility and toxicity

Materials that come into contact with the human body shall be assessed for biocompatibility using ISO 10993-1 and shall fulfil the following requirements:

NOTE 1 Additional issues related to nanotechnology can also be considered, e.g. anti-microbial functions, environmental impact (e.g. micro plastic) and performance over life.

a) the assessment shall take into account the intended use and contact by those involved in user care or transportation and storage of the APTI;

b) the APTI shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the APTI. Special attention shall be given to substances that are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern;

c) the result of the assessment shall be incorporated in the risk analysis.

NOTE 2 For additional guidance and test methods, see Annex B.

9.2 Animal tissue

Where a device has been manufactured utilizing tissues of animal origin or their derivatives, a risk assessment shall be performed and documented in accordance with ISO 22442-1.

10 Contamination

10.1 Liquid ingress

An APTI should be designed to minimize fluid ingress to help prevent cross infection.

Throughout its working life, the outside of an APTI will be regularly subject to contamination with blood, urine, faeces, other bodily secretions and bacteria. It is important that these contaminants can be easily removed from the surface and that they are not able to reach the internal components of the APTI. Manufacturers shall incorporate liquid and moisture management into the design, manufacture and risk management process to prevent the ingress of fluids that support microbial growth.

Most APTI will incorporate a fluid impermeable cover. Where a cover is removable, consideration shall be given to ensure that the openings do not create an opportunity for liquid ingress in normal use, for example, by the use of fluid impermeable zips, or protective flaps over the closure.

Seams can be a source of liquid ingress therefore consideration should be given to the manufacturing process used, to ensure that the end product is as specified for the intended use.

Unless the manufacturer has defined a replacement schedule for the fluid impermeable cover, the APTI shall be designed using materials to ensure that it remains fluid impermeable throughout its expected service life.

Any openings or vents in the fluid impermeable cover shall be constructed so that in normal use, they will not create an opportunity for liquid ingress.

10.2 Cleaning and disinfection

An APTI, other than an APTI for single use, which can come into contact with body fluids shall be able to be disinfected repeatedly according to the manufacturer's instructions without compromising the expected service life of the APTI.

If an APTI is intended to be cleaned, deodorized and/or disinfected, the method and suitable cleaning or disinfection materials shall be described in the information supplied by the manufacturer. The effect of these cleaning and disinfection processes should be verified and validated.

In addition, the methods for inspection in relation to continued safe use shall be described in the information supplied by the manufacturer.

It shall be included in the instruction for use that deviations from the manufacturer's cleaning and disinfection instructions can cause serious hazards and adversely affect an APTI's life and efficacy.

If an APTI is intended to be cleaned by automatic washing systems or hand-held jet stream or steam washing, the details of the procedure, such as temperature, pressure, flow and pH value of cleaning and/or rinsing solution shall be described in the instructions for use. Where practicable, the APTI shall be labelled with appropriate symbols to represent the method of cleaning, e.g. in accordance with ISO 7000 or equivalent.

10.3 Cross infection and microbial contamination

Processes for examination of surfaces to detect the presence of defects and contaminants shall be considered, along with appropriate processes for mitigation and/or elimination. Repair, cleaning and disinfection practices shall be developed to address these to maximize service life while preventing cross contamination between occupants. If there is a difference between the daily/ weekly cleaning and disinfection and the cleaning and disinfection when the product returns from a user and will go to storage in order to be re-used by another person, the manufacture shall inform about the two different methods in the instructions for use.

Manufacturers shall provide cleaning and disinfection procedures that are compatible with the materials of construction and the manufacturing processes. If the user and/or operator deviates from these procedures, the burden of validation of the effectiveness of the deviation falls to that user and/ or operator and it is up to the user and/or operator to prove the proper effect of the cleaning and disinfection method.

When developing cleaning protocols, the materials used should not have a detrimental effect on the performance of the cover materials, including service life, and the protocol should not leave any residues that would be detrimental to the biocompatibility of the surface.

Due to a high risk of cross contamination, special consideration shall be given to exclusion or disinfection of pathogens that can be introduced to the surface by one occupant. These considerations shall be implemented between occupants to ensure a safe environment for the user of the APTI throughout its life.

NOTE 1 Advice on cleaning and disinfection can be found in the British Health Trades Association document "Protect, Rinse & Dry" https://bhta.com/wp-content/uploads/2016/06/BHTA-PRD-A4-16pp.pdf

NOTE 2 Proper application of the manufacturer's instructions for use provides protection against cross infection and microbial contamination where indicated.

Annex A
(informative)

General information

A.1 General requirements (see 4.1)

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

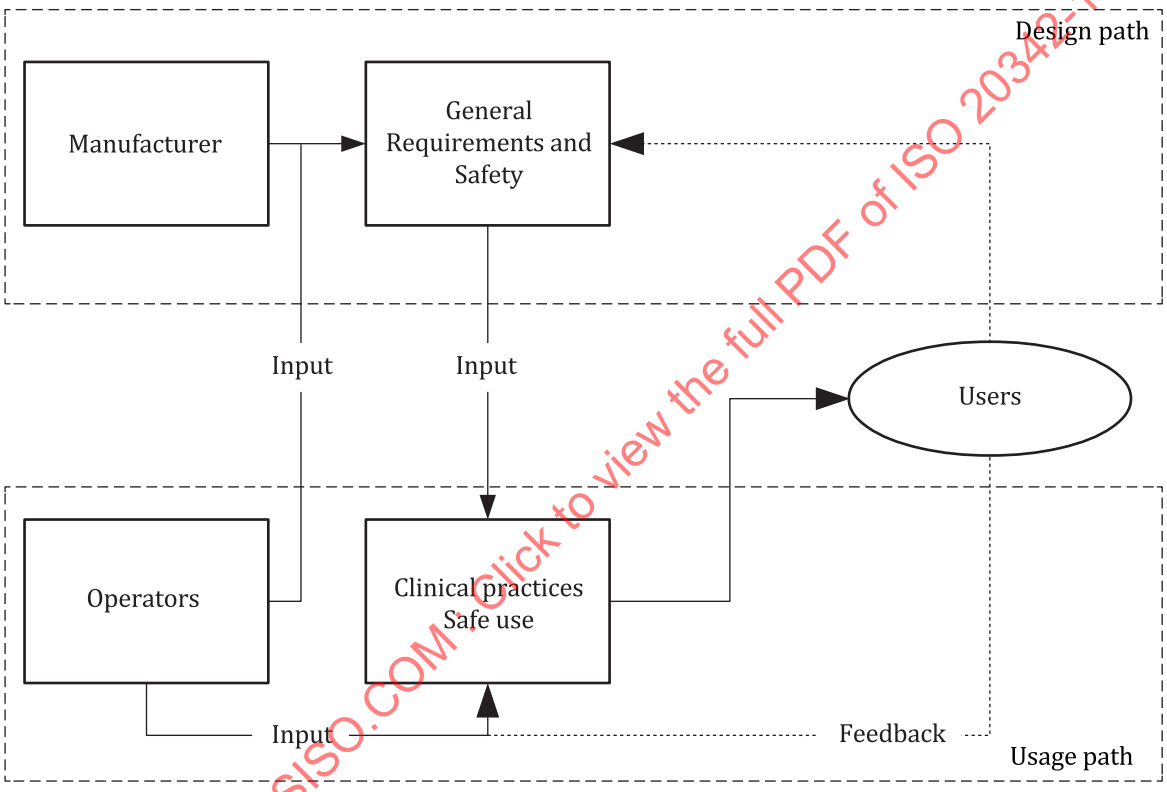

Figure A.1 — Example of a methodology for development, manufacturing and promotion of an APTI

A.2 Design controls (see 4.5)

The intent of the methodology in Figure A.2 is to bridge the gap between the manufacturer and the institution selecting an APTI keeping patient safety in mind. Elements shown provide an overview to help take into consideration key aspects of the development, manufacturing and promotion of an APTI.

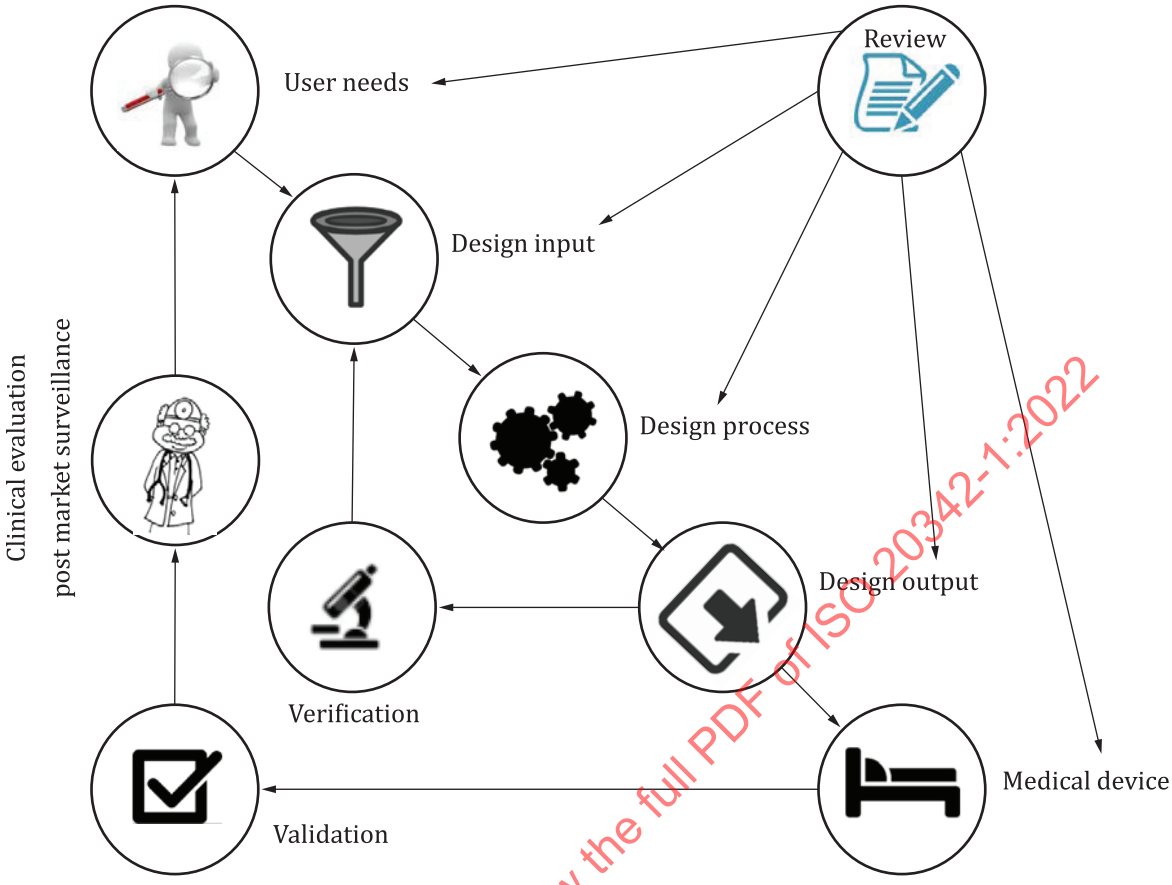

Figure A.2 — Proposed design controls process

A.3 Packaging (see 5.1.9)

The packaging of an assistive product is intended to provide appropriate protection against damage, deterioration or contamination during storage and transportation to the point of use. The various forms of storage and the types of transportation that can be encountered therefore should be considered, and the effectiveness of the packaging checked.

A.4 Noise and vibration (see 5.4)

Manufacturers should evaluate any noise and vibration emitted by APTI in all intended use environments.

Where specific standards are not available, manufacturers should determine what appropriate methods of testing are available in other standards and supplement these with a panel consisting of users with disabilities, care givers and appropriate professionals to assess the acceptability of noise and vibration.

Sound pressure should be related to the circumstances in which an APTI is used.

Noise should be reduced as much as possible at its source.

Manufacturers should consider the following International Standards relating to the effects of vibration:

ISO 2631-1, ISO 5349-1 or ISO 5349-2.

A.5 Flammability (see Clause 6)

When considering the flame resistance of an APTI, manufacturers should note that persons with a disability can be at greater risk than able-bodied persons as they can be unable to escape from fire.

Hazards that should be considered include

a) smoker´s materials,

b) stoves, ovens and other cooking devices,

c) fires and other space heaters, and

d) electrostatic charges.

Particular care is needed if an APTI can be used near or in conjunction with flammable substances.

It is recommended that the system is tested as a whole system and not as individual components.

Every effort should be made to undertake flammability testing on the finished article. Testing component parts that are in conformity with flammability tests relevant to their material make-up does not, by design ensure that the product will pass the flammability requirements of the finished article.

Wherever possible, the manufacturer should state that the support surface has been tested in its complete state and to the full scope of the test and make claim if only tested in part.

For examples of different test methods, see bibliography.

A.6 Ergonomic principles (see 7.8)

Guidance and requirements on the design and location of control actuators for able people in industry is given in EN 894-3. It should be used with caution as persons with a disability can need special features to suit their disability. In most cases control forces should not exceed the following:

a) the operating force for levers used to activate or release a feature by hand should not exceed 60 N;

b) the operating force for levers used to hold or move a feature for a significant time should not exceed 13 N (e.g. a joystick);

c) the operating force for levers used to activate or release a feature by foot should not exceed 60 N in a "pulling direction" and 100 N in a "pushing direction";

d) the operating force for devices used to activate or release a feature by finger action should not exceed 5 N. Persons with a disability can have a weakness and limited control of their limbs. In order to facilitate the operation of a particular feature and also to avoid accidental operations, certain ergonomic criteria should be considered. A minimum threshold for the operating force to be applied by the user is advisable, e.g. size, position and spacing between control mechanisms should be appropriate.

A.7 Immunity (see 8.2.3)

When specifying the EMC performance of an APTI, manufacturers are recommended to consider the already widely established environments:

a) residential, commercial and light industrial;

b) industrial;

c) other (typically meaning harsher environments and some specific places such as surgical theatres or near specific machinery, e.g. transmitters).

A user should be able to use an APTI in all the manufacturer's intended environments of use for the APTI with the minimum of limitation. The manufacturer should make it clear in simple language when limitations exist by describing the circumstances that shall be avoided and should explain the consequences of exposing the APTI to a potentially dangerous environment, e.g. radio transmitters. If possible, any appropriate actions that will offset any hazard should be described.

A.8 Cleaning and disinfection (see 10.2)

An APTI should be easy to clean and should not incorporate features which will retain dust, liquid and/or contaminated material, except where the intended function of the APTI is to retain such material.

An APTI, other than an APTI for single use, that can come into contact with body fluids should be able to be disinfected repeatedly by readily available disinfectants according to manufacturer's instructions without damage to the APTI.

A.9 Moisture vapour permeability/microclimate management

Many APTIs use a fluid impermeable cover that is water vapour permeable. This is desirable as it allows water vapour transpired by the user (transepidermal water loss or sweat) to pass through the cover, helping to keep the user's skin dry. Some APTIs feature specifically engineered microclimate management devices to move moisture away from the body. In some cases, the water vapour that has passed through the cover fabric can condense inside the cover. This is undesirable as the warm moist environment is ideal for the cultivation of mould and evidence of water staining or mould growth can wrongly suggest that the cover has been breached. When using moisture vapour permeable cover fabrics and microclimate management devices, consideration should be given as to how moisture vapour will move both in and out of the cover.