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Hoists for the transfer of disabled persons - Requirements and test methods (ISO/DIS 10535:2020)

Lifter zum Transfer von Menschen mit Behinderungen - Anforderungen und Prüfverfahren (ISO/DIS 10535:2020)

Lève-personnes pour transférer des personnes handicapées - Exigences et méthodes d'essai (ISO/DIS 10535:2020)

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Hoists for the transfer of disabled persons — Requirements and test methods

Lève-personnes pour transférer des personnes handicapées — Exigences et méthodes d'essai

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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*, Working Group 13 Hoists for transfer of persons, in conformance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10535:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Aspects on hoists with robotic features has been included

— Guidelines regarding compatibility of hoists/body-support units have been included

— The informative annex on Inspection has been further developed

— Lowering of minimum capacity of a mobile hoist from 120 kg to 100 kg

— Requirement of emergency lowering device for mobile hoist and standing/raising hoists has been included

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

It appears from studies that the nursing and caring profession involves many physically burdening factors in the caring for and nursing of disabled persons. A hoist offers a safe means of supportive lifting and moving, either assisted or independently.

This document specifies requirements and test methods that are relevant to hoists for the transfer of disabled persons. In the process of revising this document ISO 10535, the working group experts have addressed further needs in terms of providing safety for both the disabled person and the caregiver. At the same time taking into account the potential new development within robot technology on the hoist area.

This document covers different types of mobile and stationary hoists. Some of the requirements and test methods are general and others are only valid for specific product types.

In addition to the requirements in this document it includes annexes with general recommendations:

— Annex A Rational for specific safety requirements

— Annex B Periodic inspection and maintenance

— Annex C Compatibility of hoist/spreader bar/body-support units

Hoists for the transfer of disabled persons — Requirements and test methods

1 Scope

This document specifies requirements and test methods only for hoists and body-support units intended for the transfer of disabled persons as classified in ISO 9999:2016:

- 12 36 03, Mobile hoists for transferring a person in sitting position with sling seats
- 12 36 04, Mobile hoists for transferring a person in standing position
- 12 36 06, Mobile hoists for transferring a person in sitting position with solid seats
- 12 36 09, Mobile hoists for transferring a person in lying position
- 12 36 12, Stationary hoists fixed to walls, floor or ceiling
- 12 36 15, Stationary hoists fixed to, or mounted in or on, another product
- 12 36 18, Stationary free-standing hoists
- 12 36 21, Body-support units for hoists

This document does not apply to devices that transport persons between two levels (floors) of a building.

It does not include methods for the determination of ageing or corrosion of such hoists and units.

It does not include methods to qualify individual units prior to use.

The requirements of this document are formulated with regard to the needs of both the disabled persons being hoisted and the attendant using the hoist.

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 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 3758, *Textiles — Care labelling code using symbols*

ISO 8191-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

ISO 8191-2, *Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent*

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

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

ISO 14253-1, *Geometrical product specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for verifying conformity or nonconformity with specifications*

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

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

ISO/FDIS 20417, *Medical devices — Information to be supplied by the manufacturer*

EN 614-1, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 853, *Rubber hoses and hose assemblies — Wire braid reinforced hydraulic type — Specification*

EN 854, *Rubber hoses and hose assemblies — Textile reinforced hydraulic type — Specification*

EN 1021-1:2014, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

EN 1021-2:2014, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

EN 12182:2012, *Assistive products for persons with disability — General requirements and test methods*

EN 13480-3:2017, *Metallic industrial piping — Part 3: Design and calculation*

IEC 60068-21:2006, *Environmental testing — Part 2-21: Tests — Test U: Robustness of terminations and integral mounting devices*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

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

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

IEC 60601-1-2:2005, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

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

IEC 61000-3-3, *Am1, Electromagnetic compatibility (EMC) — Part 3: Limits — Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current u 16 A*

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

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

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
adverse condition
condition in which failure is most likely to occur

3.2
attendant
person who operates the hoist if not the lifted person

3.3
backrest
part of the body-support unit that supports the back of the person being lifted, transferred or moved along with the associated attachment structure

EXAMPLE A body-support unit can be a sling, seat or stretcher

3.4
backwards
180° to the forwards direction of travel

3.5
bathtub hoist
piece of equipment that is specifically designed to be used in or adjacent to a bathtub and with which a disabled person is lifted, transferred or moved

3.6
body-support unit
part of the hoist that supports the person being lifted, transferred or moved along with its associated attachment structure

EXAMPLE A body-support unit can be a sling, seat or stretcher.

3.7
ceiling hoist
overhead mounted hoist system fixed to the ceiling or wall(s), including the tracking system

3.8
central suspension point
CSP
reference point on the hoist to be used for measurements

Note 1 to entry: This point may be a connecting point.

3.9
connecting point(s)
part(s) to which the body-support unit attaches

3.10
control devices
part or parts of the hoist which operate the lifting and lowering mechanisms of the CSP as well as other functions

EXAMPLE A function can be the leg opening of the mobile base.

3.11
end limiting device
device that stops any movement at a predetermined end position

3.12
field of application
* application 1intensive/critical care provided in a hospital where 24 h medical supervision and constant monitoring is required, and provision of life support system/equipment used in medical procedures is essential to maintain or improve the vital functions of the disabled person.* application 2acute care provided in a hospital or other medical facility where medical supervision and monitoring is required, and hoists used in medical procedures is often provided to help maintain or improve the condition of the disabled person.* application 3long-term care in a medical area where medical supervision is required, and monitoring is provided if necessary and hoists used in medical procedures may be provided to help maintain or improve the condition of the disabled person.

Note 1 to entry: This includes use in nursing homes and in rehabilitation and geriatric facilities.

* application 4care provided in a domestic area where hoists are used to alleviate or compensate for an injury, disability or disease

Note 2 to entry: This excludes use in all other application environments (e.g. nursing homes, rehabilitation and geriatric facilities) when a hoist is purely designed for application environment 4.

* application 5outpatient (ambulatory) care, which is provided in a hospital or other medical facility, under medical supervision where hoists are provided for the need of persons with illness, injury or disability for treatment, diagnosis or monitoring

3.13
flexible device
component along with any associated joining components that functions as a lifting device

EXAMPLE A flexible device can be a chain, tape or rope.

3.14
footrest
part of the body-support unit that supports the feet

3.15
forwards
intended direction of travel, as indicated by the manufacturer in the instructions for use

3.16
free-standing stationary hoist
equipment for transferring by lifting and moving a disabled in an area limited by the system with the hoist free-standing on the floor

3.17
hoisting range
vertical difference between the maximum and minimum heights of the CSP

Note 1 to entry: See Figure 1

3.18
hoisting reach
unimpeded horizontal distance between the structure and a vertical line through the CSP at a given height within the hoisting range

Note 1 to entry: See Figure 1 (b, c).

3.19
hold to run control device
control device(s) which initiate and maintain operation of the hoist elements only as long as the manual control is actuated and where the manual control automatically returns to the 'Stop' or 'Off' position when released

3.20
lifted person
person who is transferred by the hoist

3.21
lifting cycle
raising and lowering of the lifting machinery for the same distance in both directions

3.22
lifting device
means of lifting and lowering the body-support unit

3.23
lifting machinery
device that performs the lifting function

EXAMPLE The lifting machinery can be a hydraulic, mechanical or electrical apparatus.

3.24
locking gate
device that ensures a hoist cannot move from one track to another unless both tracks are in the correct position

3.25
locking system
means by which the rigid body-support unit is secured to the hoist

3.26
maximum load
greatest permissible load, excluding the body-support unit, that can be applied to the hoist

Note 1 to entry: Also called safe working load (SWL)

3.27
mobile hoist
piece of equipment, fitted with a device or devices (e.g. wheels) that are freely movable and propellable along the floor, and with which a disabled person is lifted, transferred or moved independent of a fixed installation or other allied device

3.28
multi-purpose hoist
piece of equipment that can be assembled, possibly with the use of different parts, to provide a variety of operations

3.29
non-rigid body-support unit
device that is manufactured from flexible materials and which adapts to the body shape, with the associated connecting means for attaching to the lifting device of the hoist. Examples of connecting means include loops or clips

3.30
pendant control
handheld device, which has a functional connection to the hoist, controlling at least hoist articulations and/or movements

Note 1 to entry: pendant controls may be wired, or wireless, and may integrate other functions, (e.g. communications, radio/tv, etc.).

3.31
portable
equipment intended to be moved from one location to another while being carried by one or more person