INTERNATIONAL STANDARD

ISO 10535

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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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Contents

Page

Forewo	ord	v
Introdu	ıction	. v i
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements and test methods	7
4.1	General requirements	7
4.2	General test methods	
4.3	Safety requirements	
4.4	Requirements for body-support units	
4.5	Central suspension point	
4.6	Spreader bar	
4.7	Performance	
4.8	Rate (velocity) of lifting and lowering	
4.9 4.10	Operating forces/torques	10
4.10 4.11	Durability T. Charles T. A. V.D. A. R.D. P.R.E.V.E. V. Hydraulic components	18
4.11	Proumatic components (at a salar at a la sal	21
4.13	Pneumatic components (stranglands iteh ai) Information supplied by the manufacturer	22
5	Mobile hoists — Specific requirements and test methods	28
5.1	General requirements	28
5.2	Static strength	28
5.3	Static stability	
5.4	Immobilizing device (brakes)	
5.5 5.6	Moving forces Instructions for use	
5.6		
6	Standing and/or raising hoists — Specific requirements and test methods	
6.1	General requirements	
6.2	Static strength	
6.3	Static stability	
6.4	Immobilizing device (brakes)	
6.5	Moving forces	
6.6 6.7	Durability	
0 . <i>1</i>		
7		35
7.1	General requirements	
7.2	Specific safety requirements	35
7.3	Static strength (free-standing stationary hoists only)	36
7.4	Static stability (free-standing stationary hoists only)	
7.5	Static strength for all other stationary hoists	
7.6	Instructions for use	აგ
8	Non-rigid body-support units — Specific requirements and test methods	
8.1	General requirements	
8.2	Requirements for material and seams of the non-rigid body-support unit	
8.3	Test methods for non-rigid body-support unit	
8.4	Information supplied by the manufacturer	38
9	Rigid body-support units — Specific requirements and test methods	39

ISO 10535:2006(E)

9.1	General requirements	39
9.2	Requirements for backrest	39
9.3	Requirements and test methods for durability	39
9.4	Information supplied by the manufacturer	
10	Bathtub hoists — Specific requirements and test methods	41
10.1	General requirements	
10.2	General test methods	41
10.3	Safety requirements	42
10.4	Body-support units	42
10.5	Spreader bar	42
10.6	Performance	42
10.7	Rate (velocity) of lifting and lowering	42
10.8	Operating forces	43
10.9	Durability	43
10.10	Static strength and stability	43
10.11	Hydraulic components	
10.12	Pneumatic components	44
10.13	Specific safety requirements	44
10.14	Non-rigid body-support units	44
10.15	Rigid body-support units — Requirements	44
10.16	Information supplied by the manufacturer	45
Annex	A (informative) Structure of ISO 10535	46
Annex	B (informative) Periodic inspection	47

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10535 was prepared by Technical Committee CEN/TC 293, Assistive products for persons with disability, of the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 173, Assistive products for persons with disability, Subcommittee SC 6, Hoists for transfer of persons, in conformance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10535:1998), which has been technically revised.

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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.

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

1 Scope

This International Standard specifies requirements and test methods only for hoists and body-support units intended for the transfer of disabled persons as classified in ISO 9999:2002:

- 12 36 03 Mobile hoists with sling seats
 12 36 04 Standing mobile hoists
 12 36 06 Mobile hoists with solid seats
 12 36 09 Hoist trolleys
 12 36 12 Stationary hoists fixed to the wall/walls, floor and/or ceiling
 12 36 15 Stationary hoists fixed to, mounted in or on another product
- 12 36 18 Stationary free-standing hoists

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— 12 36 21 Body-support units for heists g/standards/sist/a415a910-6f3a-4f7b-b5e6-

08c5a685a455/iso-10535-2006 This International Standard 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.

The requirements of this International Standard 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 referenced documents are indispensable for the application 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 9999:2002, Technical aids for persons with disabilities — Classification and terminology

ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing

ISO 14253-1, Geometrical Product Specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for proving conformance or non-conformance with specifications

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

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 980, Graphical symbols for use in the labelling of medical devices

EN 1021-1, Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: Smouldering cigarette

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

EN 12182:1999, Technical aids for disabled persons — General requirements and test methods

EN 13480-3:2002, Metallic industrial piping — Part 3: Design and calculation

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 (Standards.iteh.ai)

IEC 61000-3-2, Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current \leq 16 A per phase) 105352006

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IEC 61000-3-3 am1, Electromagnetic compatibility (EMC) Son Part 32 Limits — Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤ 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.

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 This point may be a connecting point. DARD PREVIEW

3.9

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

tacnes

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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

3.10

end limiting device

device that stops any movement at a predetermined end position

3.12

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.

3.13

footrest

part of the body-support unit that supports the feet

3.14

forwards

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

3.15

free-standing stationary hoist

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

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3.16

hoisting range

vertical difference between the maximum and minimum heights of the CSP

See Figure 1.

3.17

hoisting reach

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

See Figure 1 (b, c).

3.18

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

3.19

legrest

part of the body-support unit that supports the legs

3.20

lifted person

person who is transferred by the hoist

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3.21

lifting cycle

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

ISO 10535:2006 3.22

lifting device

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means of lifting and lowering the body-support unit $^{0.08c5a685a455/iso-10535-2006}$

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

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

3.30

rigid body-support unit

preformed seat or recumbent device, manufactured from rigid materials (if necessary padded), or flexible materials encased by a frame, with connecting means for attaching to the lifting device of the hoist

3.31

single fault condition

condition in which a single means for reducing the risk resulting from a hazard is defective or a single abnormal condition is present

3.32

sitting part

part of the body-support unit that is intended for sitting on

3.33

spreader bar iTeh STANDARD PREVIEW

rigid construction with more than one connection point, on to which the body-support unit is attached (standards.iteh.ai)

3.34

standing and/or raising hoist

device to assist the lifting, transferring and moving of a disabled person where some of the mass of the disabled person is supported by some means of the disabled person is supported by some means of the disabled person is supported by some means of the disabled person where some of the mass of the disabled person is supported by some means of the disabled person where some of the mass of the disabled person where some of the mass of the disabled person is supported by some means of the disabled person where some of the mass of the disabled person is supported by some means of the disabled person is supported by some means of the disabled person where some of the mass of the disabled person is supported by some means of the disabled pe

3.35

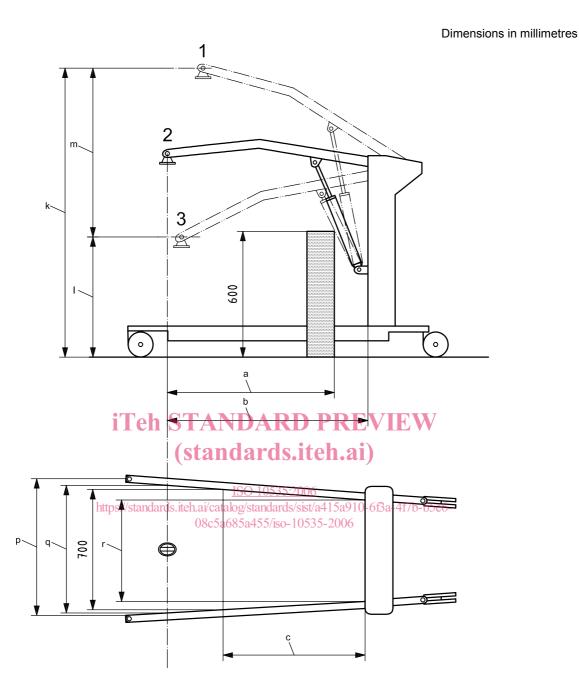
stationary hoist

piece of equipment, with which a person is lifted, transferred or moved within a pre-defined area and which is fixed to a wall, ceiling or floor or is mounted or placed in or on other allied devices, or is free-standing

3.36

turning diameter

diameter of the narrowest circle encompassing the extreme points of the hoist, when it is turned 360° without being reversed



Key

- 1 highest position
- 2 maximum reach position
- 3 lowest position
- ^a Maximum reach at 600 mm (reference height).
- b Maximum reach from base.
- c Reach from base with legs spread to 700 mm.
- k Maximum height of CSP.
- Minimum height of CSP.
- ^m Hoisting range.
- p Maximum internal width.
- q Internal width at maximum reach.
- Minimum internal width.

NOTE Example, schematic presentation only.

Figure 1 — Key dimensions of mobile hoist

4 General requirements and test methods

4.1 General requirements

4.1.1 Risk analysis

The relevant clauses of ISO 14971 regarding risk analysis apply.

4.1.2 Ergonomic factors

Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use and meet with the following requirements:

- a) the distance between any handle (part intended to be grabbed) requiring an operating force of more than 10 N and any construction part of the hoist shall not be less than 35 mm;
- b) the distance between any upper surface of a pedal (in its operating position) and any other part of the hoist shall have a vertical toe clearance of not less than 75 mm;
- c) the diameter of any operating handles and/or knobs requiring an operating force of more than 10 N shall be between 19 mm and 43 mm;
- d) for hoists operated from a standing position, pedals shall be placed not more than 300 mm above the surface of the floor;
- e) for hoists operated from a standing position, hand operated controls shall be placed at a height of 800 mm to 1 200 mm above the floor; (Standards.iteh.ai)
- f) handles for pushing and/or pulling shall be placed at a minimum height of 900 mm.

NOTE Operating controls used by the lifted person may require other positions.

For further information on this subject see EN 6144-10-10535-2006

4.1.3 Noise

The maximum A-weighted sound power level of the hoist shall be measured in accordance with ISO 3746 during a transfer using the maximum load. This measurement shall also be undertaken with the hoist in an unloaded situation.

The results of these measurements shall be stated in the instructions for use.

4.2 General test methods

4.2.1 Test conditions

The hoist shall be tested in the as-delivered state (to the customer). However, if the hoist is of a multi-purpose design that can be assembled in different formats, it shall be assembled according to the instructions supplied by the manufacturer. If the hoist is intended to be used in different combinations, then all combinations shall be tested in the most adverse condition.

The tests shall be carried out under normal indoor conditions. All tests shall be carried out in the order stated and on one and the same sample hoist.

If the hoist is of a multi-purpose design that incorporates a standing and/or raising function, then the durability tests of Clause 5 only shall apply, however the requirements of Clause 5 and Clause 6 shall apply with regard to stability, static strength and push/pulling forces.

The test report referred to in 4.2.4 shall be placed in the manufacturer's technical file.

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4.2.2 Test equipment

- **4.2.2.1** Test surface, rigid, flat, inclinable and with stops preventing the hoist from sliding but not tilting.
- **4.2.2.2** Stops no smaller than half of the wheel diameter and no greater than the wheel diameter.
- **4.2.2.3** Loads suitable for the loading of hoists and body-support units, e.g. cylindrical load(s), made of steel with rounded edges, (not less than R25) and with diameter 350 mm. For the testing of non-rigid body-support units the load can be made to represent the proposed body to be lifted.
- **4.2.2.4** Equipment capable of simulating use in practice (e.g., test fingers).
- **4.2.2.5** Equipment for applying loads, with negligible dynamic factor.
- **4.2.2.6** Sound level meter in accordance with IEC 61672-1.
- **4.2.2.7** Equipment for measuring pressure of water, oil and air.
- **4.2.2.8** Device for applying loads to standing and/or raising hoists (see Figure 2). The centre of gravity of the load shall be positioned as indicated and the centre of gravity shall be able to move as demonstrated by the joints.
- **4.2.2.9** Device for applying loads to rigid body support units [see Figures 3, 4 a) and 4 b].

4.2.3 Permissible errors of test equipment ANDARD PREVIEW

The following maximum permissible error(s) of test equipment apply:

— pressures \pm 5 %

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— forces/loads https://standards/sist/a415a910-6f3a-4f7b-b5e6-

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-- velocities \pm 5 %

— angles $\pm 0,25^{\circ}$

— dimensions $\leq 100 \text{ mm}$ $\pm 0.5 \text{ mm}$

— dimensions > 100 mm $\pm 0.5 \%$

— time \pm 0,1 s

For proving conformance or non-conformance with this specification, the procedures in accordance with ISO 14253-1 shall apply.

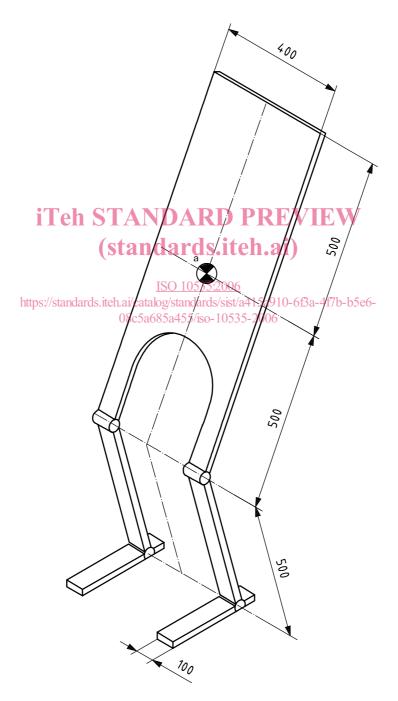
4.2.4 Test report

The test report shall include at least the following information:

- a) a reference to this International Standard, i.e. ISO 10535:2006;
- b) a description of the product, including type, designation and serial number;
- c) name and address of the manufacturer;
- d) a photograph of the hoist equipment as presented during test;
- e) the name and address of the testing laboratory;

- f) the stability values to the nearest 0,5° rounded down;
- g) result of tests including record of maintenance, if any;
- h) any deviations from the standardized test procedure;
- i) date of test;
- j) test conditions regarding humidity and temperature.

Dimensions in millimetres



a Centre of gravity.

Figure 2 — Test dummy for standing and/or raising hoists