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

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.

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.

International Standard ISO 10535 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 173, *Technical systems and aids for disabled or handicapped persons*, Subcommittee SC 6, *Hoists for transfer of persons*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Annexes C and ZZ form a normative part of this International Standard.

Annexes A and B are for information only.

Annex ZZ provides a list of corresponding International and European Standards for which equivalents are not given in the text.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

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Foreword

The text of EN ISO 10535:1998 has been prepared by Technical Committee CEN/TC 293 "Technical aids for disabled persons", the secretariat of which is held by SIS, in collaboration with Technical Committee ISO/TC 173 "Technical systems and aids for disabled or handicapped persons".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

There are three levels of European Standards dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

Level 1: General requirements for technical aids

Level 2: Particular requirements for families of technical aids

Level 3: Specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower level standards take precedence over higher level standards. Therefore, to address all requirements for a particular aid, it is necessary to start with standards of the lowest available standard.

This is a combined level 2- and 3-standard (lowest possible) for hoists for the transfer of disabled persons, as specified in the scope.

Clause 4 of this standard contains requirements and test methods applicable to all relevant types of hoists.

Clause 5 contains additional requirements and test methods for mobile hoists.

Clause 6 contains additional requirements and test methods for stationary hoists.

Clause 7 contains additional requirements and test methods for non rigid body supports units.

Clause 8 contains additional requirements and test methods for rigid body supports units

Clause 9 contains additional and modified requirements and test methods for hoists that are intended to be free standing within the bathtub.

NOTE 1: Clause 9 is under consideration.

Annex A is included to offer information regarding the periodic examination and inspection of hoist equipment.

Annex B is included to assist the manufacturer and purchaser with regard to the category into which certain hoists can fall.

Annex C is included to give specific requirements and testing for hydraulics and pneumatics.

NOTE 2: This standard is valid as a combined level 2/3-standard within the 3-level system used in the European standardization for medical devices concerning technical aids for disabled persons. This standard is an International Standard as well (ISO 10535). The use or the status as an International Standard is not affected by the European 3-level system.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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 may constitute a useful means for preventing overloading of the attendant and the disabled person.

1 Scope

This European standard specifies requirements and test methods only for hoists and body support units intended for the transfer of disabled persons as classified in EN ISO 9999:1998:

12 36 03	Wheeled hoists with sling seats
12 36 06	Wheeled 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
12 36 21	Body-support units for hoists

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

This standard does not include methods for determination of ageing or corrosion of such hoists and units.

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

2 Normative references

other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 292	Safety of machinery. Basic concepts, general principles for design Part 1: Basic terminology, methodology Part 2: Technical principles and specification
EN 614-1	Safety of machinery. Ergonomic 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

This European standard incorporates by dated or undated reference, provisions from

EN 980	Graphical symbols for the use in the labelling of medical devices
EN 1021-1:1993	Assessment of the ignitability of upholstered furniture - Part 1: Ignition source: Smouldering cigarette
EN 1041	Information supplied by the manufacturer with medical devices
EN 1441	Medical devices - Risk analysis
EN ISO 9999:1998	Technical aids for disabled persons - Classification
EN 60601-1	Medical electrical equipment Part 1: General requirements for safety
EN 60601-1-2	Electromagnetic compatibility - Requirements and tests
prEN 12182:1997	Technical aids for disabled persons - General requirements and test methods
ISO 3741:1988	Acoustics - Determination of sound power levels of noise sources - Precision methods for broad band sources in reverberation rooms
ISO 3744:1988	Acoustics - Determination of sound power levels of noisesources - Methods for free field conditions over a reflecting plane
ISO 3758	Textiles - Care labelling code using symbols
DIN 2413	Steel pipes Part 1: Design of steel pressure pipes Part 2: Design of elbows and bends for steel pressure pipes

3 Definitions

For the purposes of this standard the following definitions apply:

3.1 Adverse condition : The condition in which failure is most likely to occur and which is based on continual trial and error.

3.2 **Attendant**: The person who operates the hoist if not the lifted person.

3.3 **Backrest**: The part of the body support unit that supports the back of the person being lifted, moved or transferred (e.g. sling, seat, stretcher etc.) along with the associated attachment structure.

3.4 **Backwards**: 180° to the forwards direction of travel.

3.5 **Body support unit:** The part of the hoist that supports the person being lifted, moved or transferred (e.g. sling, seat, stretcher etc.) along with its associated attachment structure.

3.6 **Ceiling hoist**: An overhead mounted hoist system fixed to the ceiling or wall(s), including the tracking system.

3.7 **Central Suspension Point (CSP)**: A reference point on the hoist to be used for measurements (this point may be a connecting point).

3.8 **Connecting point(s)**: The part(s) to which the body support unit attaches.

3.9 **Control devices**: That part or parts of the hoist which operates the lifting and lowering mechanisms of the CSP as well as other functions, e.g. leg opening of the mobile base.

3.10 **End limiting device**: A device that stops any movement at a predetermined end position.

3.11 **Flexible device:** A component along with any associated joining components that functions as a lifting device (e.g. chain, tape, rope).

3.12 **Footrest**: The part of the body support unit that supports the feet.

3.13 **Forwards**: The intended direction of travel, as stated by the manufacturer, in relation to the person who is moving the hoist.

3.14 **Hoisting range**: The vertical difference between the maximum and minimum heights of the CSP (see figures 7 and 8)

3.15 **Hoisting reach:** The unimpeded horizontal distance between the structure and a vertical line through the CSP at a given height within the hoisting range (see figure 7).

3.16 **Hold to run control device**: Control device(s) which initiates and maintains operation of the hoist elements only as long as the manual control is actuated. The manual control automatically returns to the 'Stop' or 'Off' position when released.

3.17 **Legrest**: The part of the body support unit that supports the legs.

3.18 **Lifted person**: The person who is transferred by the hoist.

3.19 **Lifting cycle:** The raising and lowering of the lifting machinery for the same distance in both directions.

3.20 **Lifting device**: Means of lifting and lowering the body support unit.

3.21 **Lifting machinery**: Device that performs the lifting function, e.g. the hydraulic, mechanical or electrical apparatus.

3.22 **Locking gate**: A device that ensures a hoist cannot move from one track to another unless both tracks are in the correct position.

3.23 **Locking system**: The means by which the rigid body support unit is secured to the hoist.

3.24 **Maximum load**: The greatest permissible load, excluding the body support unit, that can be applied to the hoist.

3.25 **Mobile hoist**: A hoist fitted with a devices or devices (e.g. wheels) that is freely movable and propellable along the floor, and with which a disabled person is lifted, transferred or moved independently of a fixed installation or other allied device.

3.26 **Multi-purpose hoist**: A hoist that can be assembled, possibly with the use of different parts, to provide a variety of operations.

3.27 **Non-rigid body support unit**: A device that is manufactured from flexible materials which adapts to the body shape, with the associated connecting means for attaching to the lifting device of the hoist.

3.28 **Rigid body support unit**: A preformed seat or recumbent device, manufactured from rigid materials (if necessary padded), or flexible materials encased by a frame, with associated connecting means for attaching to the lifting device of the hoist.

3.29 **Single fault condition :** Condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present.

3.30 **Sitting part**: Part of the body support unit that is available for sitting on.

3.31 **Spreader bar**: A rigid construction with more than one connection point, onto which the body support unit is attached (for example see figures 8 and 9).

3.32 **Stationary hoist**: A hoist 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 in or on other allied devices, or is free standing.

3.33 **Turning radius**: The radius of the narrowest circle encompassing the extreme points of the hoist, when it is turned 360° without being reversed.

4 General requirements and test methods

4.1 General requirements

4.1.1 Risk analysis

The requirements of EN 1441 apply.

4.1.2 Ergonomics factors etc

The ergonomics of the hoist shall be based on the requirements of EN 614-1.

Grips and handles shall suit the functional anatomy of the hands and meet with the following requirements:

- 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;

- 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;

- the diameter of any operating handles and or knobs requiring an operating force of more than 10 N shall be between 19 mm and 43mm.

- pedals shall be placed not more than 300 mm above the surface of the floor;

- hand operated controls shall be placed at a height of 800 mm to 1200 mm above the floor;

- 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.

4.1.3 Sound level

The maximum sound level of any hoist shall not exceed 65 dB(A) as measured in accordance with ISO 3741:1998 and/or ISO 3744:1998 during one raising or lowering lifting cycle with the hoist loaded with the maximum load.

4.2 General test conditions

4.2.1 Test conditions

The hoist shall be tested as it is delivered to the customer. However, if of a multi-functional design and 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 indoors conditions.

All tests shall be carried out in the order stated.

The test report referred to in 4.2.4 shall be placed in the manufacturers technical file.

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 not smaller than half of the wheel diameter and not greater than the wheel diameter.

4.2.2.3 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 unit 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 ISO 3741:1998 or ISO 3744:1998.

4.2.3 Tolerances

The following tolerances on measurements apply.

Forces/Loads	± 5%	
Velocities	± 5%	
Angles	± $0{,}25^{0}$	
Dimensions	≤ 150 mm	± 0,5 mm
	> 150 mm	± 5,0 mm
Time	± 0,1 s/m	

4.2.4 Test report

The test report shall include at least the following information:

a) a reference to this standard;

b) a description of the product, including type and designation;

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 downwards;

g) result of tests including record of maintenance, if any;

h) any deviations from the standardizsed test procedure;.

i) date of test.

4.3 General safety requirements

The following requirements apply.

4.3.1 Every hoist shall be capable of lifting a lifted person of 120 kg mass excluding the mass of any body support unit.

4.3.2 Electrically operated hoists shall conform to EN 60601-1 regarding electrical safety.

4.3.3 All load-bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment.