INTERNATIONAL STANDARD

ISO 10535

Third edition 2021-10

Corrected version 2023-08

Assistive products — Hoists for the transfer of persons — Requirements and test methods

Produits d'assistance — Lève-personnes pour transférer des personnes — Exigences et méthodes d'essais

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10535:2021 https://standards.iteh.ai/catalog/standards/sist/33316009-c1ad-4c1b-84c9



iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10535:2021 https://standards.iteh.ai/catalog/standards/sist/33316009-c1ad-4c1b-84c9e5e8fbch107b/iso-10535-2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Co	ntent	S	Page		
For	eword		vii		
Intr	oductio	on	viii		
1		oe			
2	-	native references			
3	Terms and definitions				
4		eral requirements and test methods			
	4.1	General requirements			
		4.1.1 Risk management			
		4.1.2 Ergonomic factors 4.1.3 Noise and vibration			
		4.1.4 Safety of moving and folding parts			
		4.1.5 Prevention of traps for parts of the human body			
		4.1.6 V-shaped openings			
	4.2	General test methods			
		4.2.1 Test conditions			
		4.2.2 Apparatus			
		4.2.3 Permissible errors of test equipment			
		4.2.4 Test report			
		4.2.5 Safety and performance requirements			
	4.2	4.2.6 Test methods for general safety requirements			
	4.3 4.4	Requirements for body-support units	22		
	4.4	4.4.1 Requirements for central suspension point	22		
		4.4.2 Test method for the central suspension point	22 22		
	4.5	Spreader bar	22		
	h	4.5.1 an Requirements for spreader bar			
		4.5.2 Test methods for the spreader bar			
	4.6	Performance Performance	23		
		4.6.1 Requirements for performance			
		4.6.2 Test methods for performance			
	4.7	Rate of movements of the hoist			
		4.7.1 Requirements for rate of lifting and lowering			
		4.7.2 Test methods for rate of lifting and lowering.			
		4.7.3 Requirements for rate of powered horizontal movement4.7.4 Test methods for rate of powered horizontal movement			
	4.8	Operating forces/torques			
	1.0	4.8.1 Requirements for operating forces/torques	2.4		
		4.8.2 Test methods for operating forces/torques	25		
	4.9	Durability			
		4.9.1 Requirements for durability	25		
		4.9.2 Test methods for durability			
	4.10	Hydraulic components			
		4.10.1 Requirements for hydraulic components			
	4 4 4	4.10.2 Test methods for hydraulic components			
	4.11	Pneumatic components			
		4.11.2 Test methods for pneumatic components			
	4.12	Machine washable hoists			
	1.12	4.12.1 Requirements for machine washable hoists			
		4.12.2 Test methods for machine washable hoists			
	4.13	Requirement for information supplied by the manufacturer			
		4.13.1 General	30		
		4.13.2 Instructions for use	30		

ISO 10535:2021(E)

		4.13.3 Labelling	32
5	Mob	ile hoists — Specific requirements and test methods	37
	5.1	General requirements	37
	5.2	Static strength	
		5.2.1 Requirements for static strength	
		5.2.2 Test methods for static strength	
	5.3	Static stability	
		5.3.1 Requirements for static stability	
		5.3.2 Test methods for static stability	
	5.4	Immobilizing device (brakes)	
		5.4.1 Requirements for immobilizing device (brakes)	
		5.4.2 Test methods for immobilizing device (brakes)	
	5.5	Moving forces	
		5.5.1 Requirements for moving forces	
		5.5.2 Test methods for moving forces	
	5.6	Requirement for information supplied by the manufacturer	
		5.6.1 Pre-sale information	40
6		ile hoists for transferring a person in standing position— Specific requirements	
		test methods	
	6.1	General requirements	
	6.2	Static strength	
		6.2.1 Requirements for static strength	
	6.0	6.2.2 Test method for static strength	
	6.3	Static stability	
		6.3.1 Requirements for static stability	41
	<i>C</i> 1	6.3.2 Test methods for static stabilityImmobilizing device (brakes)	42
	6.4	immobilizing device (brakes)	43
		6.4.1 Requirements for immobilizing device (brakes)	43
	<i>(</i>	6.4.2 Test methods for immobilizing device (brakes)	
	6.5	Moving forces	
		6.5.1 Requirements for moving forces 6.5.2 Test methods for moving forces	
	6.6	6.5.2 Test methods for moving forces	
	0.0	6.6.1 Requirements for durability	
		6.6.2 Test methods for durability	
	6.7	Requirement for information supplied by the manufacturer	
	0.7	6.7.1 Pre-sale information	
_			
7		ionary hoists — Specific requirements and test methods	
	7.1	General requirements	
	7.2	Specific safety requirements	
		7.2.1 Requirements for specific safety requirements	
	7.2	7.2.2 Test methods for specific safety requirements	
	7.3	Static strength (free-standing stationary hoists only)	
		7.3.1 Requirements for static strength (free-standing stationary hoists only)	
	7.4	7.3.2 Test methods for static strength (free-standing stationary hoists only)	
	7.4	Static stability (free-standing stationary hoists only)	
		7.4.1 Requirements for static stability (free-standing stationary hoists only)	
	7 5		
	7.5	Static strength for all other stationary hoists	4/ 47
		7.5.1 Requirements for static strength for all other stationary hoists	4/ 17
	7.6	Requirement for information supplied by the manufacturer	4/ 17
	7.0	7.6.1 User information	
8		-rigid body-support units — Specific requirements and test methods	47
	8.1	General requirements	
	8.2	Requirements for material and seams of the non-rigid body-support unit	47

	8.3	Test methods for non-rigid body-support unit	
		8.3.2 Test method for durability for non-rigid body-support unit	
	8.4	Requirement for information supplied by the manufacturer	
	0.1	8.4.1 Pre-sale information	48
		8.4.2 User information	
		8.4.3 Labelling	
9	Rigid	body-support units — Specific requirements and test methods	49
	9.1	General requirements	
	9.2	Requirements for backrest	
	9.3	Requirements and test methods for durability	
	9.4	Requirement for information supplied by the manufacturer	
		9.4.1 User information	
40	ъ.1.		
10	Batht 10.1	rub hoists — Specific requirements and test methods General requirements	51
	10.1	10.1.1 General	
		10.1.2 Risk analysis	
		10.1.2 Risk analysis	
		10.1.4 Noise	
		10.1.5 Safety of moving and folding parts	
		10.1.6 Prevention of traps for parts of the human body	
		10.1.7 V-shaped openings	
	10.2	General test methods	
		10.2.1 Test conditions	
		10.2.2 Test equipment	52
		10.2.2 Test equipment	52
		10.2.4 Test report	52
	10.3	Safety requirements ISA 10525-2021	
		10.3.1 General safety requirements	52
		10.3.2 Test methods for general safety requirements	52
	10.4	Body-support units	
	10.5	Spreader bar	
	10.6	Performance	
	10.7	Rate of movements of the hoist	
	10.8	Operating forces/torques	53
	10.9	Durability	53
		10.9.1 Requirements for durability	
	10.10	10.9.2 Test methods for durability	
	10.10	Static strength and stability	
		10.10.1 Requirements for static strength and stability	
	10 11	10.10.2 Test methods for static strength and stability	
		Hydraulic components	
		Pneumatic components	
	10.13	10.13.1 Requirements for specific safety requirements	
		10.13.2 Test methods for specific safety requirements	
	10 14	Non-rigid body-support units	
		Rigid body-support units — Requirements	
		Requirement for information supplied by the manufacturer	
	_0.10	10.16.1 General	
		10.16.2 Instructions for use	
		10.16.3 Labelling	
Anna	x A linf	ormative) Rationale for specific safety requirements	
	-	ormative) Periodic inspection and maintenance	
		ormative) Compatibility of hoist/spreader har/hody-support units	
Anne	ayı IInt	ormativel Lomnatinility of noist/snreader har/hody-siinnort linits	61

ISO 10535:2021(E)

Annex D (informative)	Guidelines for colour coding for size of non-rigid body-support units	74
Bibliography		75

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10535:2021 https://standards.iteh.ai/catalog/standards/sist/33316009-c1ad-4c1b-84c9 e5e8fbcb107b/iso-10535-2021

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

The main changes 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.

This corrected version of ISO 10535:2021 incorporates the following correction:

— in <u>4.2.5.2</u>, the sentence "Electrically operated hoists shall conform to IEC 60601-1:2005+AMD1:2012, Clause 14 regarding electrical safety unless requirements are covered by this document." has been added at the beginning of the first paragraph.

Introduction

It appears from studies that the nursing and caring profession involves many physically burdening factors in the caring for and nursing of persons with disabilities. 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 persons with disabilities. This document addresses further needs in terms of providing safety for both the person with a disability and the attendant, while taking into account the potential new development within robotic technology on hoist solutions.

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10535:2021
https://standards.iteh.ai/catalog/standards/sist/33316009-c1ad-4c1b-84c9-e5e8fbcb107b/iso-10535-2021

Assistive products — Hoists for the transfer of persons — Requirements and test methods

1 Scope

This document specifies requirements and test methods for hoists and body-support units intended for the transfer of persons with disabilities. The document applies to the following products classified in ISO 9999:—1).

- 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 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.

Annexes A, B and C provide general recommendations. st/33316009-clad-4clb-84c9-

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

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

1

¹⁾ Under preparation. Stage at the time of publication: ISO/FDIS 9999:2021.

ISO 10535:2021(E)

ISO 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

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

IEC 60204-1, Safety of machinery - Electrical equipment of machines - Part 1: General requirements

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014, Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

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

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

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

adverse condition

condition in which failure is most likely to occur

3.2

attendant

person who operates the hoist if not the *person with disability* (3.36)

3.3

backrest

part of the *body-support unit* (3.6) that provides support to the back of the person being lifted in a hoist

3.4

backwards

180° to the *forwards* (3.20) direction of travel

3.5

bathtub hoist

equipment specifically designed to be used in or adjacent to a bathtub for transferring by lifting and moving a person in an area limited by the system

3.6

body-support unit

device for providing support to a person being lifted, transferred or moved in a hoist, with its associated attachment structure

EXAMPLE A sling, seat or stretcher.

3.7

ceiling hoist

equipment for transferring by lifting and moving a person in a specific location by an overhead mounted 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

part to which the *body-support unit* (3.6) attaches

3.10

control device

part or parts of the hoist that operate the lifting and lowering mechanisms of the central suspension point (3.8) as well as other functions

The leg opening of the mobile base. EXAMPLE

3.11

disposable non-rigid body-support unit

non-rigid body-support unit (3.34) that is not intended to be washable or cleanable and that is designed to be used by only one person

3.12

end-limiting device

device that stops any movement at a predetermined end position

3.13

field of application 1

intensive/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 person with disability (3.36)

Note 1 to entry: Hoists used in medical procedures are often provided to help maintain or improve these functions.

3.14

field of application 2

acute care provided in a hospital or other medical facility where medical supervision and monitoring is required

Note 1 to entry: Hoists used in medical procedures are often provided to help maintain or improve the condition of the person with disability.

3.15

field of application 3

long-term care in a medical area where medical supervision is required, and monitoring is provided if necessary

Note 1 to entry: Hoists used in medical procedures may be provided to help maintain or improve the condition of the person with disability.

Note 2 to entry: This includes use in nursing homes and in rehabilitation and geriatric facilities.

3.16

field of application 4

care provided in a domestic area where hoists are 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 a hoist is purely designed for application environment 4.

3.17

field of application 5

outpatient (ambulatory) care that 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

3.18

flexible device

component along with any associated joining components that functions as a *lifting device* (3.26)

EXAMPLE A chain, tape or rope.

3.19

footrest

part of the *body-support unit* (3.6) that provides support to the feet of the person being lifted in a hoist

3.20

forwards

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

3.21

free-standing stationary hoist

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

3.22

hoisting range

vertical difference between the maximum and minimum heights of the central suspension point (3.8)

Note 1 to entry: See Figure 1, footnote m.

3.23

hoisting reach

unimpeded horizontal distance between the structure and a vertical line through the *central suspension* point (3.8) at a given height within the *hoisting range* (3.22)

Note 1 to entry: See Figure 1, footnotes a, b, c.

3.24

hoist with robotic features

hoist combining all the following techniques to simulate, replace or assist human function or interaction in performing intended task:

information and communication technology;

- combining sensing and controlled actuation technology;
- autonomy.

Note 1 to entry: Detailed information about degree of autonomy can be found in IEC/TR 60601-4-1.

3.25

lifting cycle

raising and lowering of the *lifting machinery* (3.27) for the same distance in both directions

3.26

lifting device

means of lifting and lowering the body-support unit (3.6)

3.27

lifting machinery

device that performs the lifting function

Note 1 to entry: The lifting machinery can be a hydraulic, mechanical or electrical apparatus.

3.28

locking gate

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

3.29

locking system Teh STANDARD PRE

means by which the *rigid body-support unit* (3.39) is secured to the hoist

3.30

maximum load

greatest permissible load, excluding the *body-support unit* (3.6), that can be applied to the hoist

a 21 https://standards.iteh.ai/catalog/standards/sist/33316009-c1ad-4c1b-84c9

mobile hoist

equipment for transferring by lifting and freely moving a person independent of a fixed installation or other allied device

Note 1 to entry: See Figure 1.

3.32

mobile hoist for transferring a person in standing position

equipment for transferring and repositioning a person from a sitting position into an upright standing position; the equipment can be moved around freely; the body support consists of slings, a foot support and leg or knee support

3.33

multi-purpose hoist

piece of equipment that can be assembled, possibly with the use of different parts, to provide a variety of operations

3.34

non-rigid body-support unit

device, with its associated attachment structure, that is manufactured from flexible materials and which adapts to the body shape, providing support to a person being lifted in a hoist

Note 1 to entry: Examples of connecting means include loops or clips.

3.35

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 can be wired, or wireless, and can integrate other functions, e.g. communications, radio/tv, etc.

3.36

person with disability

person with one or more impairments, one or more activity limitations, one or more participant restrictions, or a combination thereof

[SOURCE: ICF 2001, WHO]

3.37

portable

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

3.38

powered horizontal movement

movement that includes fully automated functions activated from a pendant, but excludes manual movement assisted by a motor.

3.39

rigid body-support unit

preformed seat or recumbent device, manufactured from rigid materials (if necessary padded), or flexible materials encased by a frame, for providing support to a person being lifted in a hoist, with its associated attachment structure

3.40 <u>ISO 10535:2021</u>

single-fault condition //standards.iteh.ai/catalog/standards/sist/33316009-c1ad-4c1b-84c9-

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

3.41

sitting part

part of the *body-support unit* (3.6) that is intended for sitting on

3.42

spreader bar

rigid construction with more than one connection point on to which the *body-support unit* (3.6) is attached

3.43

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

3.44

turning diameter

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

Note 1 to entry: See Figure 1.

Dimensions in millimetres

m. 0 700

Key

- 1 highest position
- 2 maximum hoisting reach position
- 3 lowest position
- ^a Maximum hoisting reach at 600 mm (reference height).
- b Maximum hoisting reach from base.
- ^c Hoisting 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.
- $^{\rm q}$ Internal width at maximum hoisting reach.
- Minimum internal width.

NOTE Example, schematic presentation only.

Figure 1 — Key dimensions of mobile hoist