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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

Reference number
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Foreword

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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).

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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 4.2.5.2, 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.

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.

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

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
connecting point
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

EXAMPLE The leg opening of the mobile base.

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
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

3.31
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
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

3.41
sitting part
part of the *body-support unit* (3.6) that is intended for sitting on

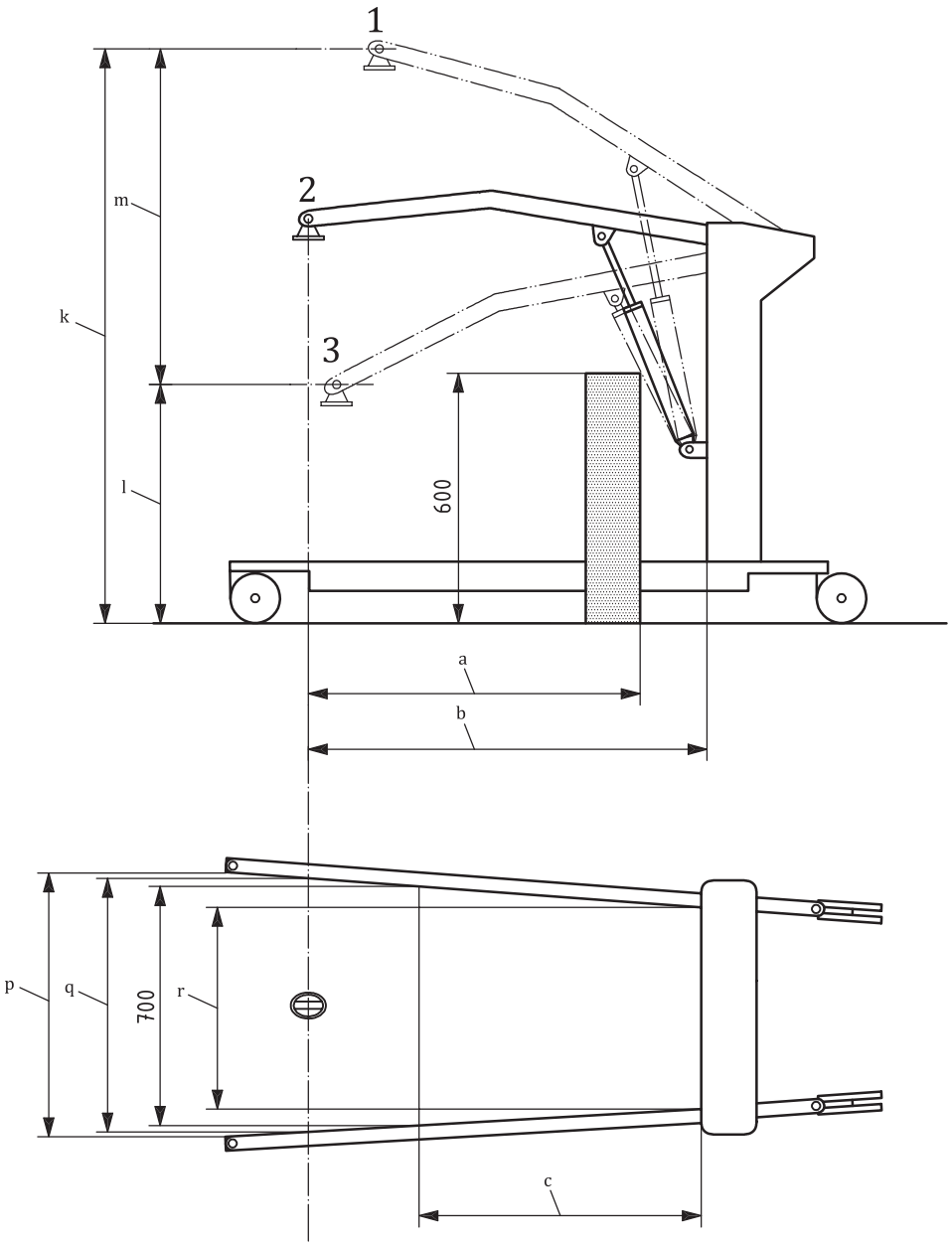
3.42
spreader bar
rigid construction with more than one connection point on to which the *body-support unit* (3.6) is attached

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



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.
l Minimum height of CSP.
m Hoisting range.
p Maximum internal width.
q Internal width at maximum hoisting reach.
r 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 management

ISO 14971 shall apply. Further information on risks in relation to combination of hoist/spreader bar/body-support unit can be found in Clause C.1.

4.1.2 Ergonomic factors

If the hoist or a part of the hoist has a mass of more than 10 kg and is intended by the manufacturer to be portable, then the hoist shall either be provided with suitable handling devices (e.g. handles, lifting eyes) placed to enable the hoist to be carried by two or more persons, or the manufacturer's information shall indicate the points where the hoist can be lifted safely and describe how it shall be handled during lifting, assembly and/or carrying. If practical, the component parts shall be labelled to indicate where the hoist can be lifted safely and/or how it shall be handled during lifting, assembly and/or carrying.

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, fixed hand operated controls shall be placed at a height of 800 mm to 1 200 mm above the floor;

f) handles for pushing and/or pulling shall be placed at a minimum height of 900 mm.

NOTE Operating controls used by the person with disability might require other positions.

For further information on this subject, see EN 614-1.

4.1.3 Noise and vibration

4.1.3.1 General

Hazards and nuisance from noise and vibration shall be assessed in the risk analysis and management (see 4.1). Noise should be reduced as much as possible at its source.

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.

NOTE Some hoists include two or more lifting devices and are considered as one hoist.

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.

The emission sound pressure level on the operation position and position of the person with disability shall be ≤65 dB(A). The sound power level of the hoist shall be ≤65 dB(A). The values of the emission sound pressure level and the sound power level shall be displayed in the instruction for use.

4.1.3.2 Sound levels and frequencies of audible warning devices

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

NOTE Requirements for alarm systems can be found in IEC 60601-1-8.

4.1.4 Safety of moving and folding parts

4.1.4.1 Squeezing

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

a) any moving parts that constitute a safety hazard shall be provided with guards that can only be removed by the use of a tool;

b) the gap between exposed parts of a hoist 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 1.

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

Table 1 — 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
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm

[a] Also including adults with a height less than 146 cm, or a mass less than 40 kg, or a Body Mass Index (BMI) less than 17.

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 by the use of a tool;

d) the movement is in the operator's field of view and the hoist shall incorporate a continuous activation system that 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).

   If the continuous activation system is defeated in a single fault condition, then a second risk control measure shall be provided, such as one or more emergency stopping device(s) (see 4.2.5.16), or the hoist shall otherwise be single fault safe;

e) the hoist 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).

In case the programmable control system is used as the risk control measure, the system shall conform to the requirements given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14.

The risk of a spreader bar or lifting arm squeezing the person with disability when it is lowered is covered in 4.2.5.11.

f) the hoist shall be provided with an electronic control system consisting of one or more sensors, logic units, and actuators that interrupts the operation in an orderly manner as stipulated in IEC 60204-1.

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

A hoist intended for a child will be operated by an adult, therefore both safe distances for adults and children according to Table 1 shall be applied.

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

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

or

— if the intended purpose of a hoist cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the hoist 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.

4.1.5 Prevention of traps for parts of the human body

4.1.5.1 Holes and clearances

Holes in and clearances between stationary parts of the hoist that are accessible to the user and/or attendant during the intended use of a hoist shall be as specified in Table 2.

Clearances between stationary parts of the hoists and the surroundings, e.g. the floor, shall be considered in the risk analysis.

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

Table 2 — Safe distances 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
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm

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

If the intended purpose of a hoist 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 hoist 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.

A hoist intended for a child will be operated by an adult, therefore both safe distances for adults and children according to Table 2 shall be applied.

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

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

The lower limit shall not apply on holes with the shape of a keyhole or V-shaped openings. When inspecting the hoist for traps for body parts, any flexibility/elasticity of adjacent parts shall be taken into account.

4.1.6 V-shaped openings

The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. A V-shaped opening should be at least 75°. This will reduce the risk of a user being trapped by the head at any position.

NOTE See Annex A.

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 the most adverse combination 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 unless otherwise specified and on one and the same sample hoist. A new product can be chosen if the original test object breaks down and cannot be repaired. Some tests relevant to the safe functioning of the product might have to be repeated on the new product. This is up to the manufacturer of the product to consider in each separate case.

If the product is tested by a test house, the decision shall be taken in cooperation between the third party and the manufacturer.

If the hoist is of a multi-purpose design that incorporates a function for transferring a person in standing position, then only the durability tests of Clause 5 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 in 4.2.4 shall be included in the manufacturer's technical file.

4.2.2 Apparatus

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, of a sufficient size to stop/fixate the hoist.

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 any of the following:

— air;

— water;

— oil.

4.2.2.8 Device, for applying loads to mobile hoists for transferring a person in standing position (see Figure 4). 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 Figure 3, footnote a and Figure 4 footnote a).

4.2.3 Permissible errors of test equipment

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

— pressures ±5 %

— forces/loads ±5 %

— velocities ±5 %

— angles ±0,25°

— dimensions <100 mm ±0,5 mm

— dimensions >100 mm ±0,5 %

— time ±0,1 s

4.2.4 Test report

The test report shall include at least the following information:

a) a reference to this document, i.e. ISO 10535:2021;

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

c) name and address of the manufacturer;

d) a photograph of all the hoist equipment being tested;

e) the name and address of the testing laboratory;

f) the stability values to the nearest 0,5° rounded down;

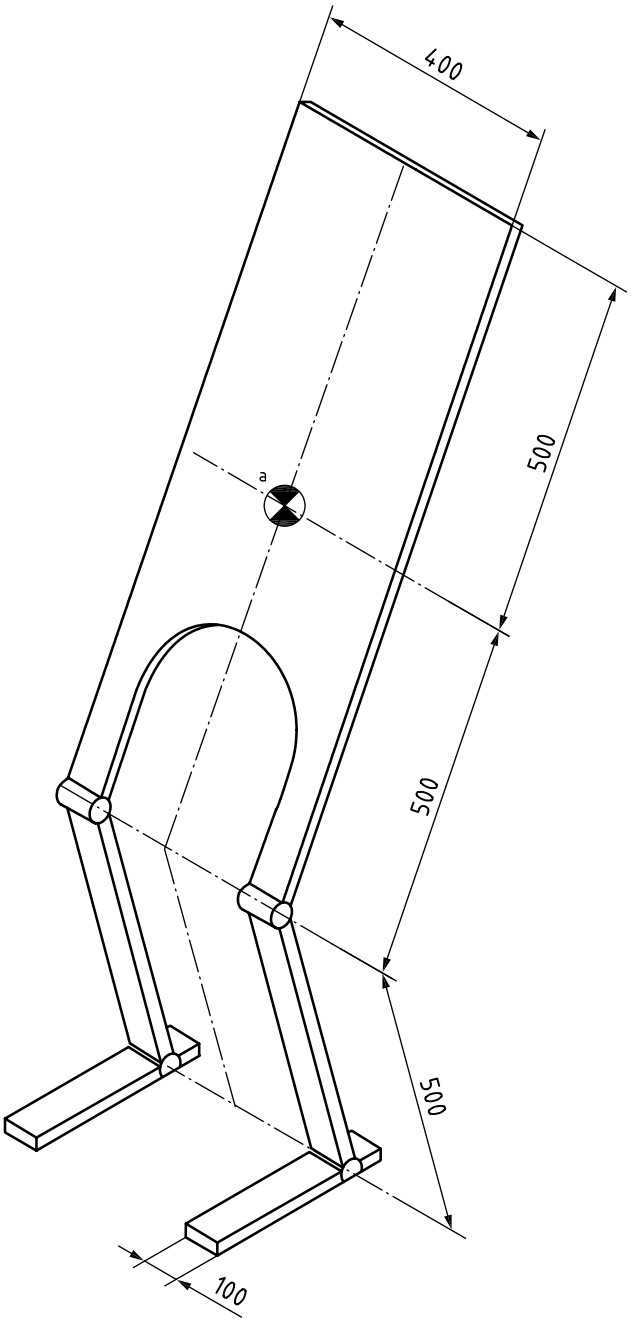
g) result of tests including record of maintenance, if any;

h) any deviations from the standardized test procedure;

i) date of test;

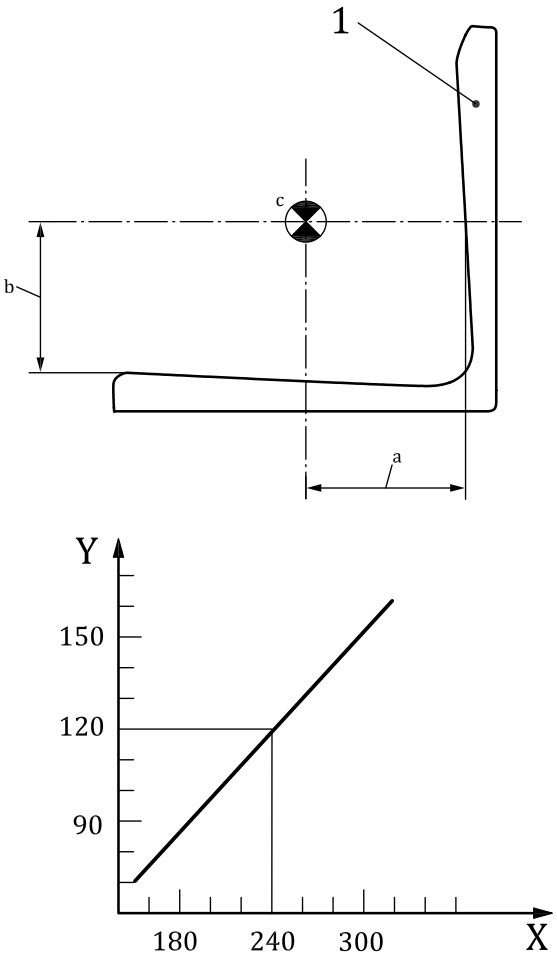
j) test conditions regarding humidity and temperature.

Dimensions in millimetres



[a] Centre of gravity.

Figure 2 — Test dummy for mobile hoists for transferring a person in standing position



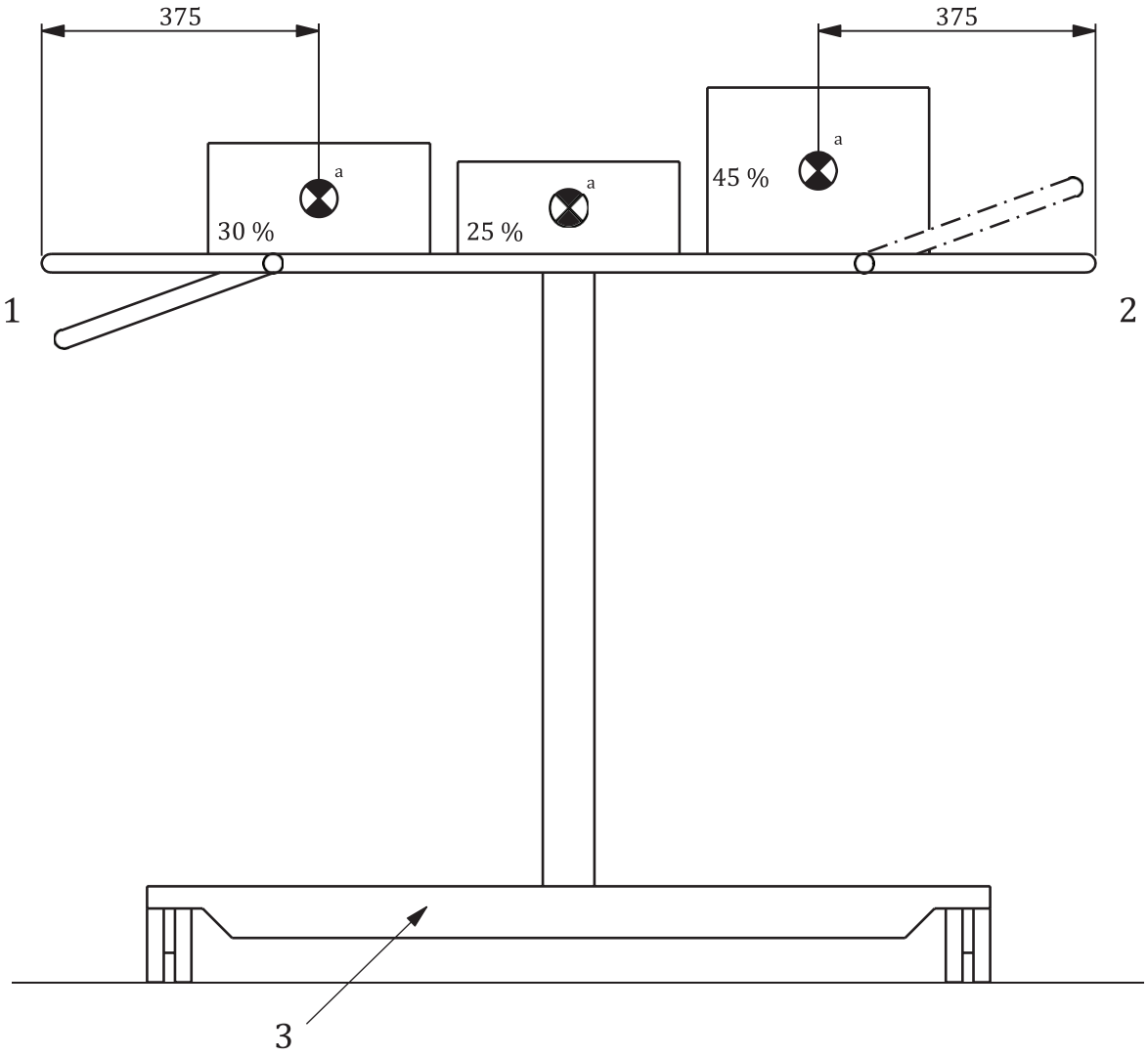
Key

X width in millimetres
Y load in kilograms
1 backrest
a Width, in millimetres = 2 × maximum load in kilograms.
b Height = 200 mm.
c Centre of gravity.

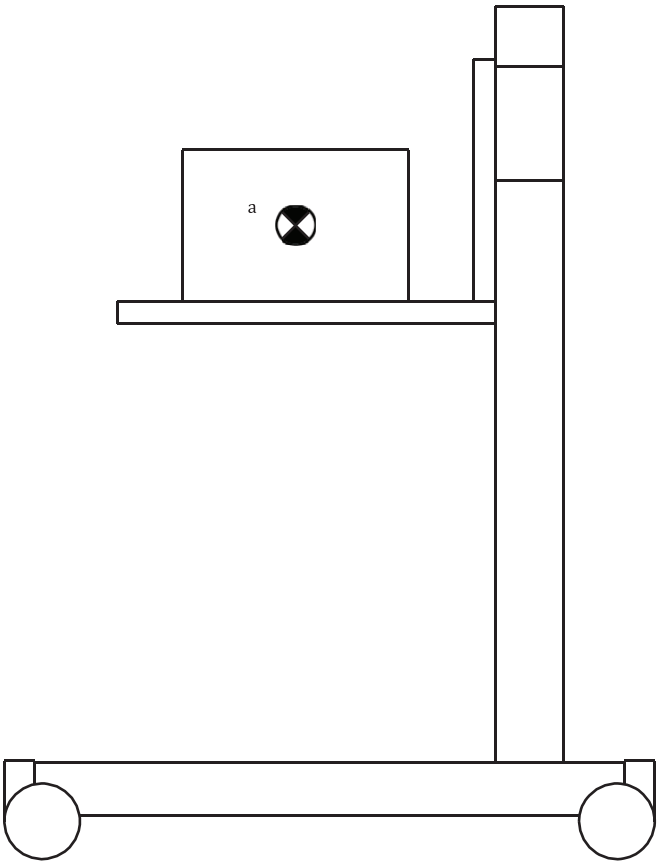
NOTE Dimension “a” starts where dimension “b” contacts the backrest.

Figure 3 — Placing of loads on rigid body-supports

Dimensions in millimetres



a) Front view



b) Side view

Key

1 feet
2 head
3 base
a Centre of gravity.

Figure 4 — Placing of loads on fixed stretcher

4.2.5 Safety and performance requirements

4.2.5.1 Every hoist shall be capable of lifting a person of the mass given below excluding the mass of any body-support unit.

— For mobile hoists, at least 100 kg.

— For all other hoists, at least 120 kg.

NOTE See Annex A.

4.2.5.2 Electrically operated hoists shall conform to IEC 60601-1:2005+AMD1:2012, Clause 14 regarding electrical safety unless requirements are covered by this document. For electrical safety covered by both this document and IEC 60601, the requirements of this document shall prevail over the ones given in IEC 60601-1.

Where software is used to control the motion of the hoist, the requirements in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 shall apply.

For electrically operated hoists intended to be used in a home care environment, IEC 60601-1-11 shall apply.

Flammability requirements stipulated in IEC 60601-1 shall apply.

4.2.5.3 If there is a risk of a pendant control falling to the floor, it shall not result in an unacceptable risk as a result of one thousand (1 000) free falls.

4.2.5.4 The manufacturer shall ensure that the choice of materials used in the construction of the hoist shall be well suited to the intended area of use.

4.2.5.5 Materials that come into contact with the human body shall be assessed for biocompatibility using ISO 10993-1. The assessment shall take into account the intended use and contact by the users.

4.2.5.6 All load-bearing fasteners shall be so designed as to prevent inadvertent detachment.

4.2.5.7 Single-use components (e.g. wood screws or self-tapping screws) shall not be used for the assembly of any component that is intended to be removed for the purpose of dismantling for transport or storage.

4.2.5.8 Handgrips shall be fixed in such a manner as to prevent inadvertent detachment.

4.2.5.9 Unless required for a specific function of the hoist, all accessible edges, corners and surfaces shall be smooth and have no burrs or sharp edges. All projections shall be avoided or fitted with adequate protection to prevent damage or injury.

4.2.5.10 It shall not be possible to assemble the hoist in a manner that affects the overall safety of the unit. If the lifting device incorporates a mast, it shall be so located in relation to its base that it can only be assembled or adjusted in the correct safe working position.

If the design of the hoist is such that the load is allowed to move in a horizontal manner, then the hoist shall not move or operate unless the hoist has been properly secured to prevent inadvertent tipping.

EXAMPLE If a mobile hoist has the function to transfer the person with disability sideways by swivelling the lifting arm (e.g. to lift the person with disability into a bathtub), this function might only be activated if the mobile hoist is secured against tipping over (e.g. by locking the undercarriage to the floor).

4.2.5.11 The hoist shall include in its design some means (e.g. limiting switches, the principal of free-wheeling, etc.) that will ensure that, when lowering, should the spreader bar, the lifting arm or the rigid body-support unit comes into contact with the person with disability, the total load imposed on the person with disability shall not be greater than the total mass of those parts and shall not increase by more than 50 N due to the lifting machinery of the hoist.

4.2.5.12 When a hoist is used in accordance with the manufacturer's instructions, the spreader bar, lifting arm or rigid body-support unit which comes into contact with the person with disability, during a horizontal transfer, then the total force imposed on that person shall not increase by more than 100 N due to the machinery of the hoist.

4.2.5.13 When operated, the means provided in 4.2.5.11 shall not allow the hoist to become unsafe.

4.2.5.14 All operating controls shall be marked for their intended function.

4.2.5.15 All controls, for lowering or raising the person with disability shall be easily accessible and operable by the person operating the hoist.

4.2.5.16 If the hoist is provided with motorized horizontal movement, it shall be fitted with means that will allow pushing/pulling by an attendant, in case of failure of the motorized function.

4.2.5.17 Electrically operated hoists shall be provided with an emergency stopping device for fulfilling the requirements in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.2.4.

The manufacturer shall consider in the risk management process that resetting the emergency stop device will not restart the hoist but only permit restarting.

4.2.5.18 All hoists shall incorporate an emergency lowering device (except for bathtub hoists) that is easily accessible and operable by the person operating the hoist.

When a hoist is intended to be used by a person with disability on their own, it is necessary to ensure that in the event of a failure of the hoist, the person with disability is not left in a potentially dangerous situation.

NOTE This can, for example, take the form of a warning in the instructions for use, the fitting of an alarm system or the supply of a conveniently placed telephone, etc.

4.2.5.19 On all battery-powered hoists, a warning device(s) shall be provided that will indicate when the battery(ies) require charging.

When this device operates, there shall be sufficient power available to complete one full lifting cycle with maximum load.

4.2.5.20 Electrically operable movements that can create a hazardous condition shall only be possible by the activation of control device(s) 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.

The mass and rate of non-electrically operable movements (e.g. by hand or foot) shall allow adequate control of, e.g. positioning, without causing an unacceptable risk.

Hoists with robotic features can have automated means to stop movements that are at least equally safe as compared to 'hold to run' type.

4.2.5.21 The hoist shall be designed in such a way so that it shall not allow lifting more than 1,5 × the maximum load.

4.2.5.22 The hoist shall be designed with a safety factor of minimum 2 × the maximum load.

4.2.5.23 Hoists shall be provided with a safety device that shall ensure that the person with disability do not fall in the event of a single-fault condition of the lifting machinery and other critical parts as identified in the risk analysis. See IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.7 and 9.8.2.

4.2.5.24 After the static test, in accordance with 4.2.6.24, any flexible device shall show no sign of damage that will affect the function of the hoist as stated by the manufacturer.

4.2.5.25 A connection point shall be so designed that the body-support unit shall not become inadvertently detached during intended use. A locking device in use shall not create an immediate risk to the safety of the person with disability. The connection point and any locking device should not cause a pinch or entrapment point for the attendant.

4.2.5.26 If any load-bearing accessories are used in combination with the hoist, e.g. scales and lengthening equipment for the body-support unit, then the combination shall be safe and fulfil the safety requirements in this document.

4.2.5.27 Where necessary, all precautions shall be taken, e.g. by the fitting of a safety devices(s) to protect the person with disability from inadvertently falling off/from the body-support unit.

4.2.5.28 Electrically operated hoists shall fulfil the requirements specified in IEC 60601-1-2:2014+AMD1: 2020 regarding electromagnetic compatibility.

4.2.5.29 Any electrical component that can be splashed, during 'normal' operation shall have an IP rating of at least IPX4. Any electrical component that can be submerged during normal operation shall have an IP rating of at least IPX7.

4.2.5.30 The connection point(s) shall be smooth, thus avoiding excessive wear of any connectors.

4.2.5.31 Where a stretcher system is suspended from the CSP of the hoist, the stretcher shall be marked to ensure that the person with disability is correctly positioned according to the intended use as stated by the manufacturer (e.g. head end/foot end). For an example of marking of stretcher, see Figure 5.

Figure 5 — Example of marking of stretcher, head end and foot end (ISO 7000-3851)

4.2.6 Test methods for general safety requirements

4.2.6.1 The requirements described in 4.2.5.1 shall be confirmed through practical test and inspection.

4.2.6.2 The requirements described in 4.2.5.2 shall be determined by verification in accordance with IEC 60601-1.

4.2.6.3 The requirements described in 4.2.5.3 shall be tested as follows.

The pendant control shall fall 1 000 times from a height of 1 m on to a 50 mm ± 5 mm thick hardwood board (>600 kg/m^3) lying flat on a concrete or similar rigid base. After the test, the pendant control is checked by inspection, functional test, and relevant electrical safety tests.

4.2.6.4 The requirements described in 4.2.5.4 shall be determined through inspection.

4.2.6.5 The result of the assessment for biocompatibility will provide verification methods.

4.2.6.6 The requirements described in 4.2.5.6 shall be determined through inspection.

4.2.6.7 The requirements described in 4.2.5.7 shall be determined through inspection.

4.2.6.8 The requirement described in 4.2.5.8 shall be determined by testing as follows, according to the following procedure:

a) with the hoist standing on a horizontal and smooth test plane, set up the 'loading method' in accordance with Figure 6, method A or method B;

b) prevent the hoist from tipping and/or moving;

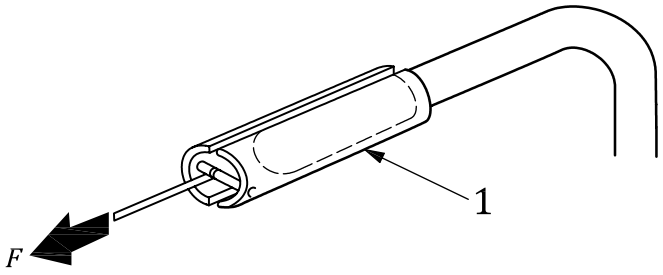
c) if necessary, fit some means of restraint that will support the handle and prevent it flexing under the test load; this restraint shall not touch the handgrip being tested;

d) slowly apply a force to each handgrip in the direction that simulates the pushing of the hoist until a maximum of 750 N is reached;

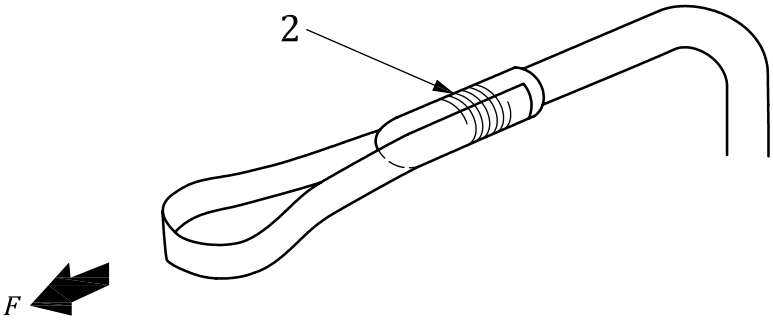
   1) maintain the load for a period of between 5 s and 10 s;

   2) remove the load;

e) repeat the above test with the load applied in the direction that simulates the pulling of the hoist



a) Method A



b) Method B

Key

1 split tube secured with adhesive

2 webbing strap secured with adhesive (bound in place with string until adhesive secure)

F = 750N ± 3 %

Figure 6 — Handgrip loading methods

4.2.6.9 The requirements described in 4.2.5.9 shall be determined through inspection.

4.2.6.10 The requirements described in 4.2.5.10 shall be determined through inspection and functional test.

4.2.6.11 The requirements described in 4.2.5.11 shall be tested by driving the spreader bar (or other part of the hoist that is used to support the body-support unit) with no load, down and on to a solid

surface that incorporates a load-sensing device. The hoist shall not impart a load that is in excess of the combined mass of the body-support unit, the spreader bar and the lifting arm, etc. plus 50 N.

4.2.6.12 The requirements described in 4.2.5.12 shall be tested in the following manner.

An assessment shall be made which will determine the potential trapping points.

Once determined, a load cell shall be placed between the potential trapping point and a solid vertical surface. The force indicated by the load cell shall not exceed 100 N when the hoist is powered in a horizontal manner. The test shall be performed both with no load and with maximum load.

4.2.6.13 The requirements described in 4.2.5.13 shall be determined through functional test.

4.2.6.14 The requirements described in 4.2.5.14 shall be determined through inspection.

4.2.6.15 The requirements described in 4.2.5.15 shall be determined through functional test.

4.2.6.16 The requirements described in 4.2.5.16 shall be determined through functional test.

4.2.6.17 The requirements described in 4.2.5.17 shall be determined through functional test and inspection.

4.2.6.18 The requirements described in 4.2.5.18 shall be determined through functional test and inspection of the instructions for use.

4.2.6.19 The requirements described in 4.2.5.19 shall be determined through functional test.

4.2.6.20 The requirements described in 4.2.5.20 shall be determined through functional test.

4.2.6.21 When loaded with a mass as described in 4.2.5.21, the hoist shall be prevented from lifting.

4.2.6.22 The requirement described in 4.2.5.22 shall be determined by functional test.

A mobile hoist shall be placed on a horizontal surface.

The hoist shall be loaded with 2 × maximum load. The load shall be applied gradually to the hoist in the most adverse position intended for use by the manufacturer. The hoist shall be in equilibrium after 1 min of loading or otherwise not result in an unacceptable risk.

This test shall be performed at the end, after all the verifications or inspections, durability, static strength and static stability of the hoist.

4.2.6.23 The requirements described in 4.2.5.23 shall be determined by verification and, where possible, inspection.

4.2.6.24 The requirement described in 4.2.5.24 shall be determined as follows.

Flexible devices used for lifting shall be tested separately. They shall be loaded statically with 6 × maximum load for 20 min. Locking systems used in the lifting process shall be tested separately. They shall be loaded statically with 4 × the maximum load for 20 min and the results determined by inspection.

4.2.6.25 The requirements described in 4.2.5.25 shall be determined through inspection and functional test.

4.2.6.26 The requirements described in 4.2.5.26 shall be determined by the relevant load tests.

4.2.6.27 The requirements described in 4.2.5.27 shall be determined through inspection and judgement.

4.2.6.28 The requirements described in 4.2.5.28 shall be determined through verification in accordance with IEC 60601-1-2.

4.2.6.29 The requirements described in 4.2.5.29 shall be determined through verification in accordance with IEC 60529.

4.2.6.30 The requirements described in 4.2.5.30 shall be determined through inspection.

4.2.6.31 The requirements described in 4.2.5.31 shall be determined through inspection.

4.3 Requirements for body-support units

The manufacturer of the body-support unit shall indicate which hoist(s) (as specified in Clause 1) and spreader bar(s) (e.g. spreader bar with 2, 3, 4 or more attachment points) it is compatible with, and which type of connection means, e.g. loop, clip or other, in order to ensure a safe combination.

The method by which the body-support unit can be adjusted or removed shall be clearly stated in the accompanying operating instructions.

Any organization that purchases hoists and body-support units shall make sure that the combination(s) is/are safe either by requiring compatibility documentation for the combination(s) from the manufacturer(s) or by performing compatibility testing themselves, hereby transferring the responsibility for a safe combination to the organization.

NOTE Further information can be found in Annex C.

4.4 Central suspension point

4.4.1 Requirements for central suspension point

The central suspension point, if any or other alternative suspension point(s), shall be constructed in such a way as to prevent inadvertent detachment of the spreader bar during normal usage.

4.4.2 Test method for the central suspension point

The requirements of 4.4.1 shall be verified by functional test.

4.5 Spreader bar

4.5.1 Requirements for spreader bar

4.5.1.1 If the width of the spreader bar is designed to be adjustable in use, the range shall be marked, e.g. by linear measurement indicator fixed to the adjustable parts.

4.5.1.2 The spreader bar shall be designed for supporting at least 1,5 × the maximum load of the hoist on which it is mounted.

4.5.1.3 In the instructions for use, information shall be given about the type(s) and design(s) of body-support units, e.g. number of connection points, dimensions and material of connection means, which can be used in combination with the spreader bar.

NOTE 1 This information can also be given on the spreader bar.

NOTE 2 Further information can be found in Annex C.

4.5.1.4 Detachable spreader bars shall be marked with the maximum load.

4.5.1.5 The spreader bar shall be marked with the year and month of manufacture.

4.5.2 Test methods for the spreader bar

4.5.2.1 The requirements of 4.5.1.1 shall be determined through inspection and functional test.

4.5.2.2 The requirements of 4.5.1.2 shall be confirmed after the static strength test.

4.5.2.3 The requirements of 4.5.1.3 shall be determined through inspection.

4.5.2.4 The requirements of 4.5.1.4 shall be determined through inspection.

4.5.2.5 The requirements of 4.5.1.5 shall be determined through inspection.

4.6 Performance

4.6.1 Requirements for performance

4.6.1.1 The hoist shall be designed for the purpose of transferring a person with disability according to the field or fields of application (1, 2, 3, 4 or 5), as stated by the manufacturer, and it shall be able to be operated by one person. If not, this shall be stated in the instructions for use.

When being used in the designated manner, the hoist should enable the person with disability to be positioned in such a way as to minimize the need for attendant repositioning.

4.6.1.2 Unless specifically designed to do so, the hoist shall not contain any cavities in which liquid could accumulate.

4.6.1.3 When loaded with the maximum load, the CSP or the point of the hoist/body-support unit that moves over the largest distance shall have a vertical stopping distance of not more than 50 mm.

4.6.1.4 When loaded with the maximum load, the motor unit with a powered horizontal movement shall have a horizontal stopping distance of not more than 400 mm.

4.6.2 Test methods for performance

4.6.2.1 The requirements described in 4.6.1.1 shall be determined through inspection and judgement.

4.6.2.2 The requirements described in 4.6.1.2 shall be determined through inspection and functional test.

4.6.2.3 The requirements described in 4.6.1.3 shall be determined in the following manner:

a) load the hoist with maximum load;

b) set the CSP to top position;

c) lower the CSP at full rate;

d) at a position approximately equal to the middle of the lifting range, remove the energy source from the hoist by either releasing the relevant control button, closing the relevant valve(s), ceasing to wind manually, or by automated or manual switching;

e) measure the vertical distance from this point to the point where the lowering stops.

4.6.2.4 The requirements described in 4.6.1.4 shall be determined in the following manner.

a) load the hoist with maximum load;

b) start the horizontal movement;

c) stop the horizontal movement when the hoist has reached its maximum rate;

d) measure the horizontal distance from the motor unit.

4.7 Rate of movements of the hoist

4.7.1 Requirements for rate of lifting and lowering

4.7.1.1 The rate of lifting or lowering the CSP (reference point on bathtub hoists) shall not exceed 0,15 m/s when loaded.

4.7.1.2 The rate of lifting or lowering the CSP (reference point on bathtub hoists) shall not exceed 0,25 m/s when unloaded.

4.7.2 Test methods for rate of lifting and lowering

4.7.2.1 When measured with the maximum load, the rate of lifting and lowering shall not exceed the rate stated in 4.7.1.1.

4.7.2.1 When measured unloaded, the rate of lifting and lowering shall not exceed the rate stated in 4.7.1.2.

4.7.3 Requirements for rate of powered horizontal movement

The rate of powered horizontal movement of CSP shall not exceed 0,4 m/s, when loaded.

The rate of powered horizontal movement of CSP shall not exceed 0,8 m/s, when unloaded.

If the requirement cannot be met and the safety is addressed in another way, this shall be justified by the manufacturer in the risk management file.

NOTE See Annex A.

4.7.4 Test methods for rate of powered horizontal movement

When measured the rate of horizontal movement shall not exceed the rate stated in 4.7.3.

Measure the horizontal maximum rate both with the maximum load and unloaded.

4.8 Operating forces/torques

4.8.1 Requirements for operating forces/torques

The operating forces or torques required for those parts of the hoist that are designed to be operated by fingers, hands/arms or feet shall not exceed the following values:

a) operation by using a finger: 5 N

b) operation by using a hand/arm: 105 N

c) operation by using a foot: 300 N

d) operation by a turning: 1,9 N.m

NOTE For hoists operated by persons with disabilities or other non-professionals, ISO 21856:—[2], A.24 can be used as a guideline.

4.8.2 Test methods for operating forces/torques

With the hoist loaded with the maximum load, the operating forces/torques of all the controls stated in 4.9.1 shall be measured. These measurements shall be taken at the mid-point of intended use as stated by the manufacturer.

4.9 Durability

4.9.1 Requirements for durability

After testing in accordance with the requirements of 4.9.2, the hoist shall function as intended with the maximum load as well as when unloaded and shall show no signs of permanent deformation or wear that could affect its function.

4.9.2 Test methods for durability

4.9.2.1 In the case of mobile hoists, they shall be placed on a horizontal surface with the base locked in the most adverse position. The hoist shall be secured against moving on the surface.

4.9.2.2 In the case of stationary hoists, they shall be fixed/mounted/placed in the most adverse condition in accordance with the manufacturer's installation instructions.

4.9.2.3 For manually operated hydraulic hoists, the stroke of the pump lever shall be as long as possible, but the end stops of the pump shall not be activated at any time.

4.9.2.4 The working: pause ratio (duty cycle) during testing shall be 15:85 if not otherwise stated by the manufacturer. If the hoist is intended to be operated at varying rates, then the durability test will be performed using the rate that represents the most adverse condition as stated by the manufacturer.

4.9.2.5 If necessary, it is permissible to use an alternative power supply instead of the battery for the purpose of durability test only, as agreed with the manufacturer of the hoist.

4.9.2.6 Maintenance during testing shall only be carried out if specifically required by the manufacturer in the service manual.

4.9.2.7 The hoist shall be loaded to reflect the loading that would be applied to the hoist in normal use. For hoists with rigid body-support and fixed stretchers, the load shall be positioned as shown in Figures 3 and 4. For hoists with suspended stretchers the load shall be positioned as shown in Figure 7. Raise and lower the hoist 250 mm or 25 % of the vertical movement, whichever is the greater in the lifting range, as stated in 4.9.2.8. Ensure that the pause in the lifting cycle and the loading and unloading always occur when the hoist is at the lowest position of the lifting cycle.

2) Under preparation. Stage at the time of publication ISO/FDIS 21856:2021.

4.9.2.8 Repeat the lifting cycle of the hoist for a total of 11 000 lifting cycles according to the following schedule, and conduct the tests in the order shown.

a) Raise and lower the CSP of the hoist at its maximum rate with no load for 1 000 cycles ensuring that the top limiting device(s) is/are activated.

b) 1 000 lifting cycles with the maximum load at the lower end of the lifting range of the hoist: for electrical hoists, activate the lower end-limiting device for approximately 1 s in every lifting cycle. For hoists with only one horizontal axis of rotation of the spreader bar, the test shall be performed with 1/3 of the load on one side and 2/3 of the load on the other side of the spreader bar.

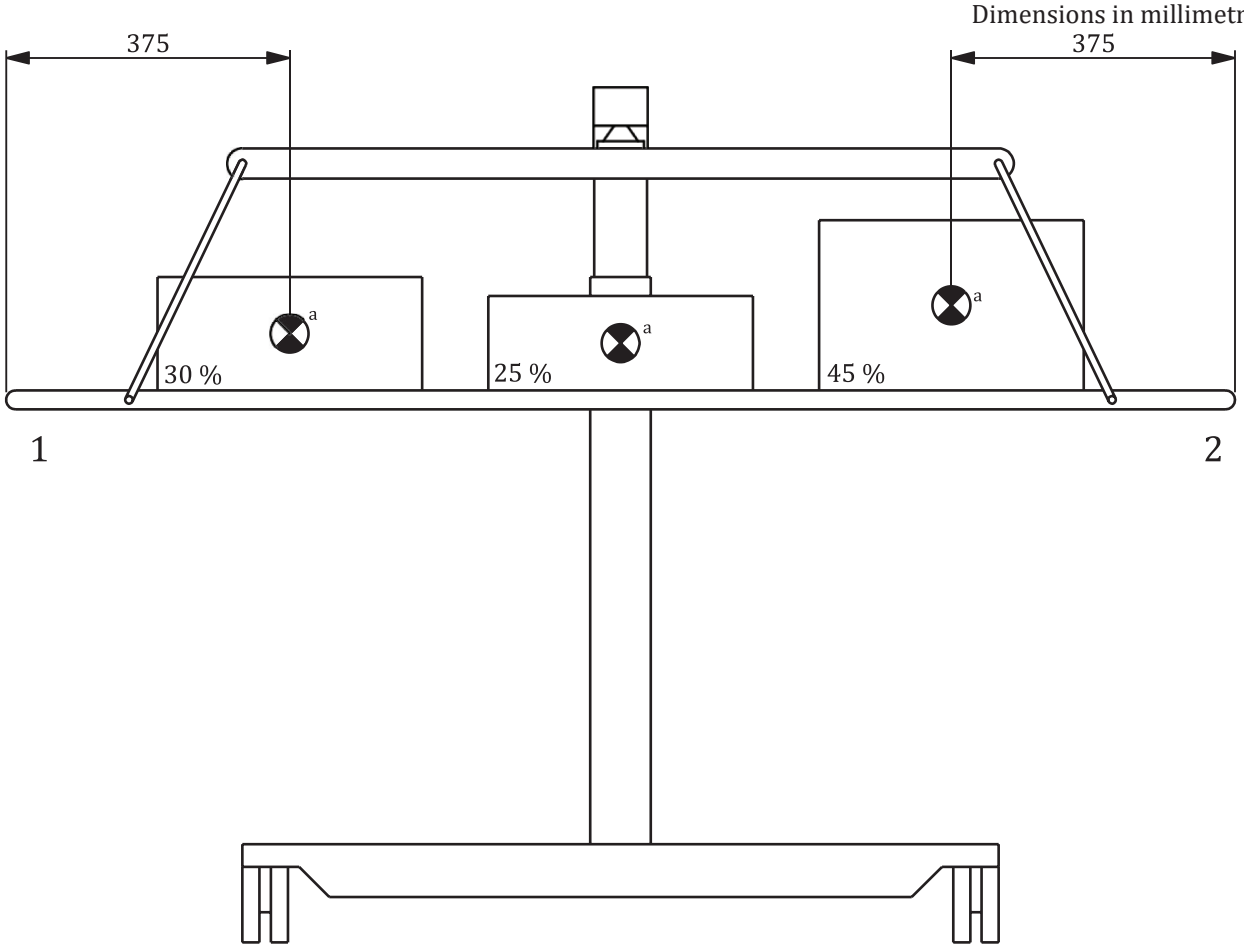
c) 1 000 lifting cycles with the maximum load at the top of the lifting range of the hoist: for electrical hoists activate, the top-end limiting device for approximately 1 s in every lifting cycle.

d) 8 000 lifting cycles with the maximum load, in the middle of the lifting range of the hoist.

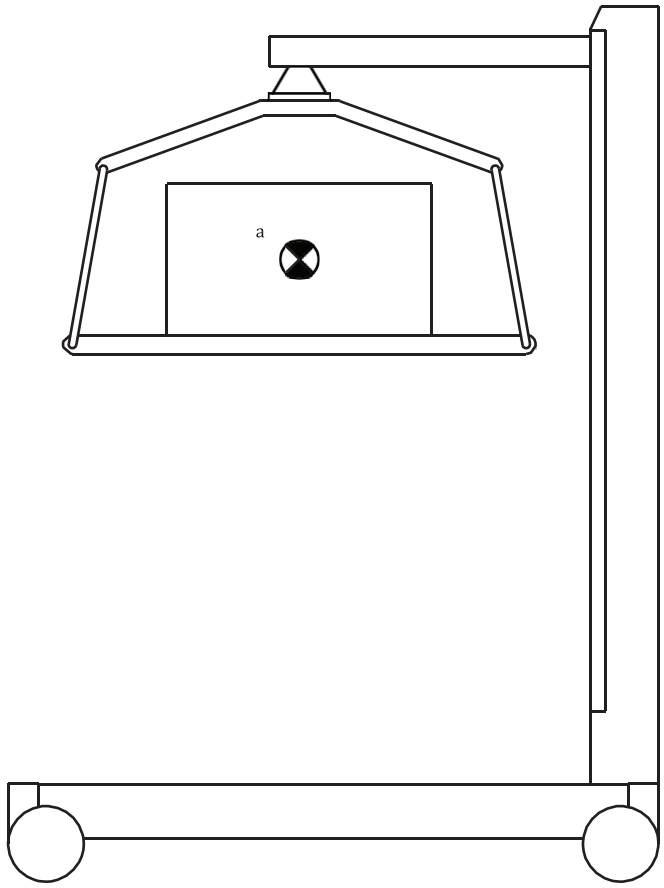
NOTE The above tests are designed to simulate the normal use of the hoist.

4.9.2.9 During the lifting cycle, the load shall be allowed to adjust to the vertical in such a way that the swing induces only a negligible dynamic element.

Dimensions in millimetres



a) Front view



b) Side view

Key

1 feet
2 head
[a] Centre of gravity.

Figure 7 — Placing of loads on a suspended stretcher

4.10 Hydraulic components

4.10.1 Requirements for hydraulic components

4.10.1.1 Hydraulic actuators, including all hoses, pipes, connectors and other components on the pressure side shall be rated to account for all loads occurring through pressure force. In addition, they shall be compatible with the hydraulic fluid being used and be designed to take account of direct stresses induced by torsion, vibration and physical damage.

4.10.1.2 The requirements for hydraulics shall be as follows:

a) for outer cylinders, the dimensions shall be calculated in accordance with EN 13480-3:2017. If the calculations are made using only the static pressure, then it shall be assumed that the calculated pressure will be 1,8 × the actual static pressure;

b) for rigid pipes and fittings, the dimensions of the pipes and associated fittings shall be calculated in accordance with EN 13480-3:2017. If the calculations are made using only the static pressure, then it will be assumed that the calculated pressure will be 2 × the actual static pressure;

c) for flexible hoses, the hoses shall be manufactured in accordance with the requirements of EN 853 or EN 854.

4.10.1.3 A non-return valve shall be fitted, which shall be capable of holding the rated load of the hoist at any point when the supply pressure drops below the minimum operating pressure.

A non-return valve shall be either

a) integral with the lifting cylinder,

b) directly and rigidly flange-mounted, or

c) placed close to the cylinder and connected to it by means of rigid pipes (as short as possible), having welded or flanged connections and being calculated in the same way as the cylinder.

Other types of fittings such as compression fittings or flared pipe fittings are not permitted between the cylinder and the lock valve.

NOTE Hose burst valves or parachute valves alone do not fulfil this requirement.

4.10.1.4 Closing of the non-return valve shall be effected by the hydraulic pressure from the jack and by at least one guided spring and/or by gravity.

4.10.1.5 A pressure-relief valve shall be fitted, which shall be adjusted to limit the pressure to 1,5 × the full load pressure. The relieved hydraulic fluid shall be returned to the reservoir.

4.10.1.6 The hydraulic system shall be capable of being bled of air.

4.10.1.7 For powered hydraulic systems, means shall be provided to easily check the level of the hydraulic fluid in the reservoir.

4.10.2 Test methods for hydraulic components

4.10.2.1 The requirements 4.10.1.1 and 4.10.1.2 are tested through verification of calculations and dimensions.

4.10.2.2 The requirements 4.10.1.3 to 4.10.1.7 are tested through inspection and functional test.

4.11 Pneumatic components

4.11.1 Requirements for pneumatic components

4.11.1.1 Where applicable, the requirements in 4.10 shall apply.

4.11.1.2 Pneumatic actuators, including all hoses, pipes, connectors and other components on the pressure side, shall be rated to account for all loads occurring through pressure force.

4.11.1.3 Means shall be provided that prevent pressure in working cylinders and air bellows exceeding 1,5 × the static pressure caused by the application of the maximum load. The means provided shall be protected against adjustment by unauthorized personnel.

4.11.2 Test methods for pneumatic components

4.11.2.1 The requirements of 4.11.1.1 are tested through verification of calculations and dimensions.

4.11.2.2 The requirements of 4.11.1.2 are tested through inspection and functional test.

4.11.2.3 The requirements of 4.11.1.3 are tested through inspection and functional test.

4.12 Machine washable hoists

4.12.1 Requirements for machine washable hoists

Hoists specified by the manufacturer to be machine washable by an automatic washing system shall function normally after the test. Variations to the test procedure regarding test-cycle, temperature, time and cleaning fluids shall be covered in the risk management file of the manufacturer. The present test method represents a basic procedure for disinfection of a hoist in a washing machine.

4.12.2 Test methods for machine washable hoists

The requirements of 4.12.1 are verified through the following test:

a) Parts and access cover that can be detached/opened without the use of a tool should be detached/opened:

   — temperature preconditioning treatment of 10 days at 65 °C ± 2 °C or at maximum value of the rated storage temperature, if higher, is carried out;

   — the hoist should then be kept at room temperature for not less than 16 h.

b) 50 test cycles according to the procedure below:

   — 2 min wash with 70 °C water at a ph-value 5 to 8, 0,5 % cleaning and disinfectant solution as specified by the manufacturer;

   — 20 s rinse with 85 °C water at a ph-value 5 to 8, and 0,2 % clear rinsing solution according to the data of the manufacturer;

   — 10 min cooling at 20 °C ambient temperature.

Acceptance criteria:

1) Immediately after the test cycles, the hoist is connected to mains; no unintentional movements should arise;

2) The hoist should function as specified by the intended use at the following intervals:

   — immediately after the test cycles;

   — 5 min (± 1 min) after the test cycles;

   — 60 min (± 5 min) after the test cycles;

   — 24 h (± 30 min) after the test cycles.

3) Perform dielectric strength and leakage current tests according to IEC 60601-1 at the following intervals:

   — immediately after the test cycles;

   — 24 h (± 30 min) after the test cycles.

4) Perform a visual inspection for ingress of water that can result in an unacceptable risk (i.e. shorting of isolation barriers and violation of creepage distances).

NOTE For some hoists, not all acceptance criteria apply (i.e. for manually operated hoists, electrical acceptance criteria would not apply).

4.13 Requirement for information supplied by the manufacturer

4.13.1 General

The information supplied by the manufacturer comprises the data in the instructions for use (see 4.13.2) and on the label (see 4.13.3).

The information applied to, and supplied with, hoists shall conform to ISO 20417.

Where hoists by reference in this document are covered by other International Standards, e.g. IEC 60601-1, they shall in addition to this document, conform to the requirements according to the relevant clause dealing with information supplied by the manufacturer in that International Standard.

Where a remote control is used, it shall be possible to identify the combination of the hoist and the remote control both in the instructions for use and on the label.

Any means of provision of information with hoists shall take into account the intended users, the conditions of use and any issues specific to individual hoist type that are necessary for the safe and effective use of the product.

Special attention shall be paid to accessibility of the user information, particularly the operation instructions, the design of labels and the design and presentation of warnings. Information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities shall be considered.

NOTE 1 Further guidance can be found in ISO 21856:—, Annex A and C.

NOTE 2 Further guidance in relation to cognitive accessibility can be found in ISO 21801-1.

4.13.2 Instructions for use

The manufacturer should provide the information in the instructions for use in three separate sections: pre-sale, user and service information as specified in 4.13.2.1, 4.13.2.2 and 4.13.2.3 respectively. They may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their attendants.

4.13.2.1 Pre-sale information

In addition to the requirements of 4.13.1, pre-sale information shall include the following, where applicable:

a) a description of the intended use, the intended user group and the intended environment; including specific contraindications;

b) expected lifetime of the hoist and body-support unit;

c) maximum user mass, minimum user mass and maximum load;

d) the overall dimensions (width, length and height) of the hoist and body-support unit, expressed in millimetres, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled;

e) the mass expressed in kilograms if the hoist is intended to be dismantled without the use of tools or has any removable parts that have a mass which is heavier than 10 kg;

f) operating forces of controls;

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

h) the A-weighted sound power level (see 4.1.3);

i) name and address of the manufacturer, supplier or agent;

4.13.2.2 User information

User information shall be provided by the manufacturer with each hoist/body-support unit. Information shall contain all pre-sale warnings and information and the following information, where applicable:

a) check list before use;

b) operating instructions;

c) operator control adjustments;

d) 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;

e) maintenance instructions;

f) cleaning instructions and suitable cleaning materials, including precautions needed to avoid corrosion;

g) disinfection instructions and suitable disinfection materials, including any precautions needed to avoid corrosion;

h) if the hoist is intended to be used in combination with other products, the manufacturer shall state to which products, and how this can be done in a safe way;

i) warning about dangerous combinations of devices;

j) information on the designs and types of body-support units to be used in combination with the spreader bar;

k) information on the designs and types of body-support units to be used in combination with the attachment point;

l) whether and how the hoist can be folded or dismantled to assist in storage or transport;

m) instructions regarding transport of the hoist (e.g. in a car or airplane);

n) safety precautions (to include, if necessary, that if the maximum load differs between hoist, spreader bar and body-support unit, then the lowest maximum load shall always be used);

o) sufficient drawings/illustrations in order to show the key dimensions (to include those shown in Figures 1, 9, 10, 11, 12 and 13);

NOTE 1 Further information can be found in Annex C.

p) electrical information in accordance with IEC 60601-1;

q) limits of accuracy of any measuring device;

NOTE 2 See also 2014/31/EC[20] Non-automatic weighing instruments.

r) a warning if a hoist is intended to be used without any attendant, followed by a description of a sufficient emergency procedure;

s) any warning according to the risk assessment (e.g. for mobile hoists, be aware of stability problems due to side forces imposed on the person with disability);

t) any warning/attention marks used on the product shall be explained in more detail;

u) an indication of the forwards direction of travel;

v) details for trouble shooting/assistance;

w) a list of replaceable spare parts shall be available on request;

x) name, address and telephone number to contact for service.

4.13.2.3 Service information

The service information shall contain all the pre-sale information, user information and instructions necessary for the maintenance, adjustment and repair of the hoist and for replacement of parts.

The service information shall provide information for the safe performance of such routine maintenance and/or calibration necessary to ensure safe use of the hoist.

The service information shall provide all the information needed to verify whether the hoist is properly installed and can operate correctly and safely (inspection), plus details of the nature and frequency of the maintenance and calibration needed to ensure that the hoist operate properly and safely at all times.

NOTE See also 2014/31/EC[20] Non-automatic weighing instruments.

Starting point for the work is the information given by the manufacturer's instruction.

If maintenance and/or calibration is required, the manufacturer shall specify that it shall be carried out by demonstrably competent and specifically trained people, familiar with the design, use and care of the hoist (see guidance in Annex B).

4.13.3 Labelling

All warnings used as risk control shall be clearly labelled.

Symbols for use in the labelling of medical products shall be in accordance with ISO 15223-1:2021.

All operating controls shall be marked for their intended function.

Every hoist (and any main part of a multi-purpose hoist) and body-support unit shall be permanently marked with at least the following information, if applicable:

a) name and address of the manufacturer and, in addition, name and address of the supplier if different from the manufacturer;

b) model definition;

c) lot or batch and/or serial number;

NOTE Serial number is preferred for traceability and inspection records.

d) year and month of manufacture;

e) Unique Device Identification (UDI) ;

f) electrical details in accordance with IEC 60601-1;

g) product IP rating (see 4.2.5.29);

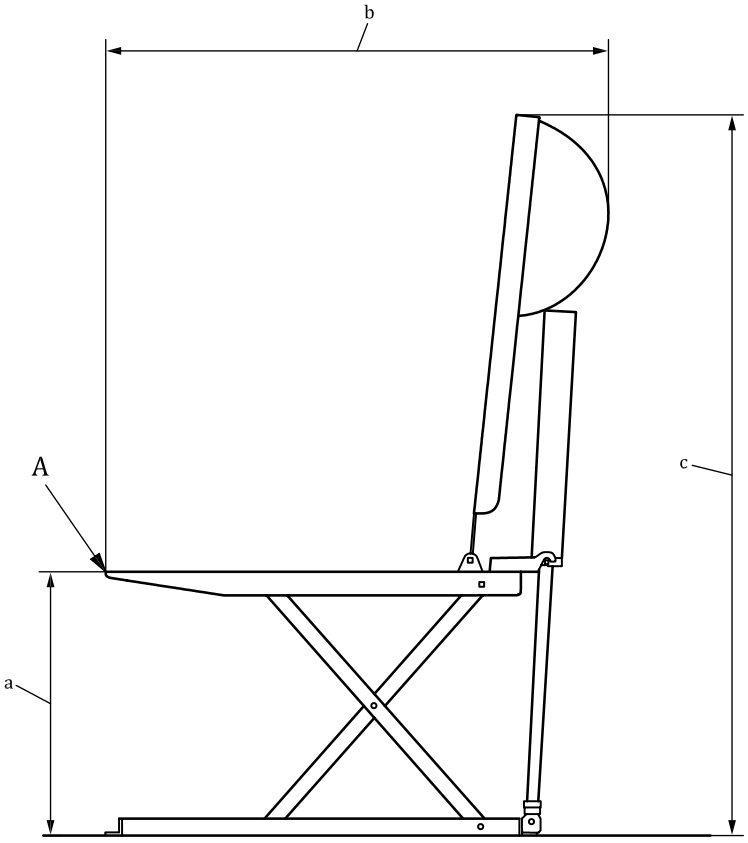
h) details of any other energy source used (e.g. water/air operated, operating pressure range);

i) linear measurements on width adjustable spreader bar;

j) maximum load;

k) hoists and detachable parts (intended to be detached without the use of tools) of a hoist with a mass of more than 10 kg shall be marked with an appropriate symbol, see 4.13.2.1 list item e) (see example in Figure 8);

Figure 8 — Example of graphical symbol for parts weighing more than 10 kg (application of ISO 7000-1321B)



Key

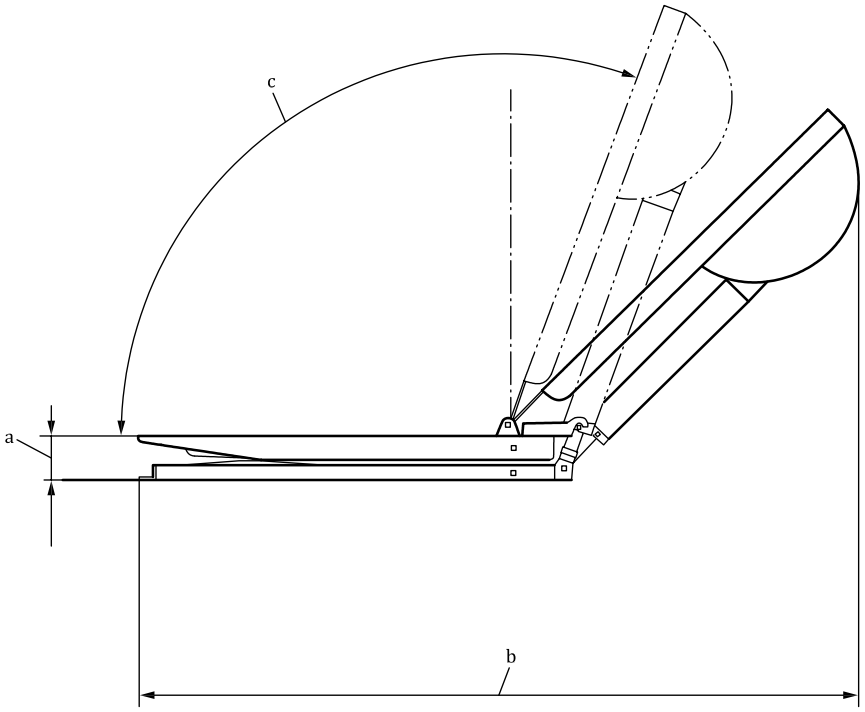
a Height of seat in its highest position.

b Overall length in highest position.

c Overall height in highest position.

A reference point measured halfway across the width of the body-support unit

Figure 9 — Key dimensions in highest position of bathtub hoist



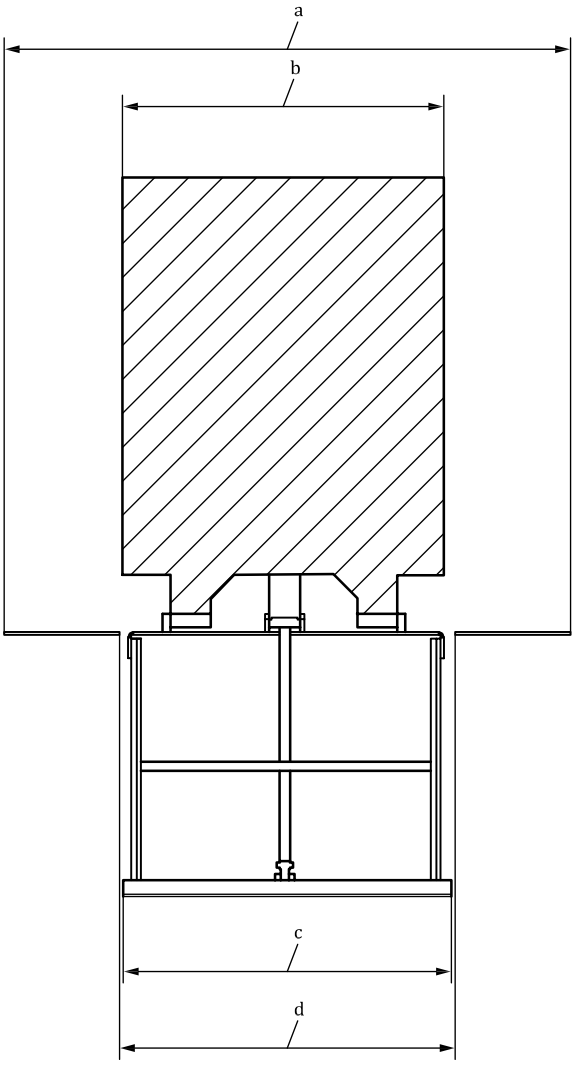
a Height of seat in its lowest position.

b Overall length in lowest position.

c Minimum angle of backrest.

NOTE Schematic presentation only.

Figure 10 — Key dimensions in lowest position of bathtub hoist



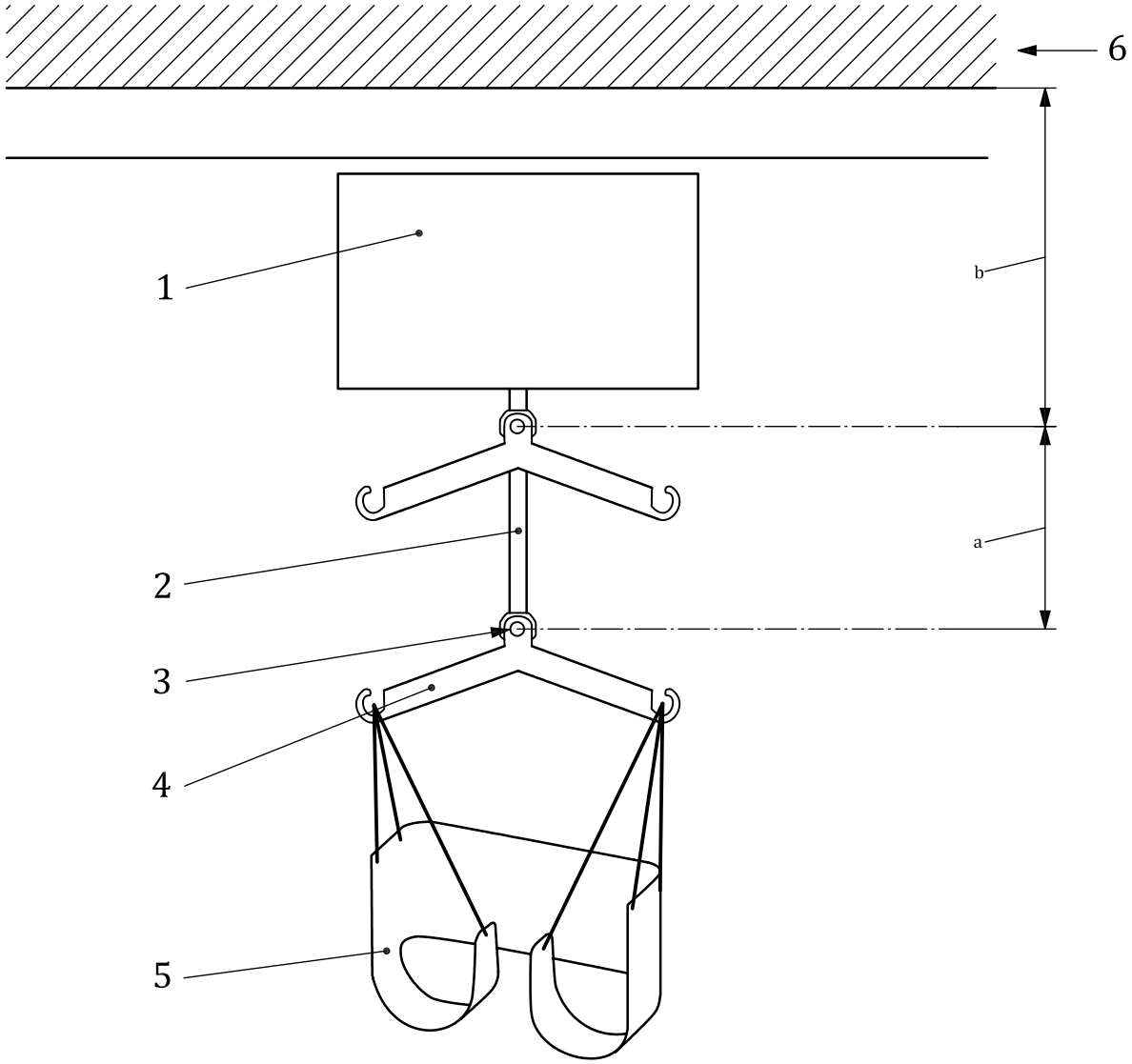
a Width of seat with extended seat flaps.

b Width of backrest.

c Width of basis plate.

d Width of seat excluding side flaps.

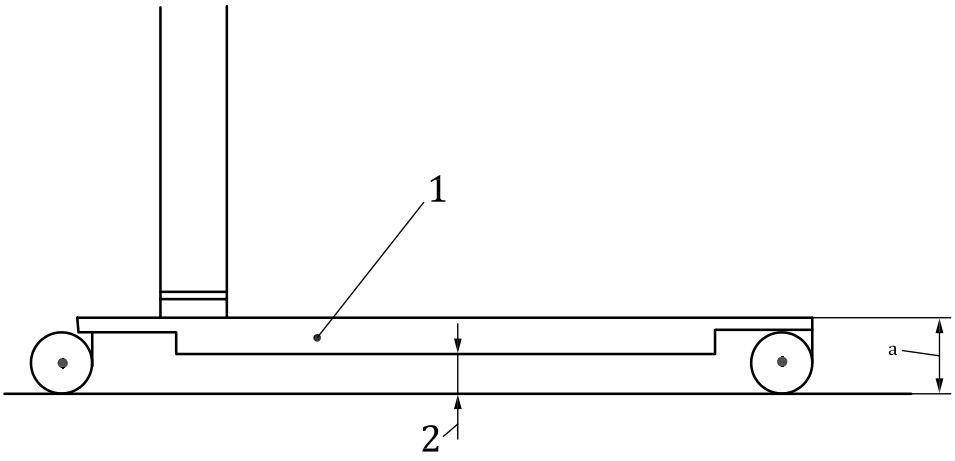
Figure 11 — Key dimensions with extended seat side flaps of bathtub hoist



Key

1 lifting machine
2 flexible device
3 CSP
4 spreader bar
5 non-rigid body-support
6 ceiling
a Hoisting range.
b Minimum distance from ceiling to CSP.

Figure 12 — Key terminology and dimensions for ceiling hoist



Key

1 base

2 clearance

[a] Base height.

Figure 13 — Base height/clearance

5 Mobile hoists — Specific requirements and test methods

5.1 General requirements

This clause specifies requirements and test methods for mobile hoists in addition to those specified in Clause 4.

5.2 Static strength

5.2.1 Requirements for static strength

After the static test as defined in 5.2.2, the hoist shall function as defined by the manufacturer. There shall be no deformation or wear that could affect its function.

5.2.2 Test methods for static strength

The hoist and lifting devices shall be loaded statically according to the procedures and order described below (see Figures 4 and 7). The hoist shall be loaded so as to reflect the loading that would be applied to the hoist in normal use.

The hoist shall be placed on an inclined surface and secured against tipping but not against deformation. The lifting boom/actuator shall be set in the most adverse position. The hoist shall then be loaded with 1,25 × maximum load for 5 min in the following directions:

a) 10° forwards;

b) 10° backwards;

c) 5° sideways in the most adverse direction (both left and right sides where applicable).

The test is then performed with the surface horizontal and with 1,5 × maximum load for 20 min.

5.3 Static stability

5.3.1 Requirements for static stability

During the static stability test according to 5.3.2, both unloaded and under maximum load, the hoist shall not lose its equilibrium (balance) at the following angles:

a) forwards and backwards directions 10° with the base in the intended travelling position;

b) forwards and backwards directions 7° with the base in the most adverse condition;

c) any other direction, 5°.

5.3.2 Test methods for static stability

5.3.2.1 Test procedures for 5.3.1 a), b) and c)

a) The tests shall be carried out in the forwards and backwards travelling directions and with the base in the travelling position as indicated by the manufacturer and with the load placed in the most adverse position.

b) The tests shall be carried out in the forwards and backwards directions and in the most adverse direction. If there is more than one intended direction of travel (forwards), they shall all be regarded as forwards.

c) The tests shall be carried out with the hoist in its most adverse position regarding the position of the wheels, CSP, base and brakes.

5.3.2.2 Unloaded

Position the unloaded hoist on the test surface with the wheels towards the stop(s) (see Figure 14).

Incline the test plane gradually until the required angle is reached or the hoist loses its equilibrium (balance). If the hoist loses its equilibrium (balance), record the angle of inclination.

Repeat the test in the backwards and sideways directions.

5.3.2.3 Loaded

Attach the maximum load to the hoist's CSP in such a way that the load is able to move freely. Repeat the procedure as for the unloaded hoist. For hoists with rigid body-supports, the centre of gravity of the load shall be placed in relation to the backrest according to Figure 3, but not more than 350 mm from the front edge of the seat.

For stretchers that are suspended from a hoist, apply the loads as shown in Figure 7.

For stretchers that are not suspended from a hoist, apply the loads as shown in Figures 4.

5.4 Immobilizing device (brakes)

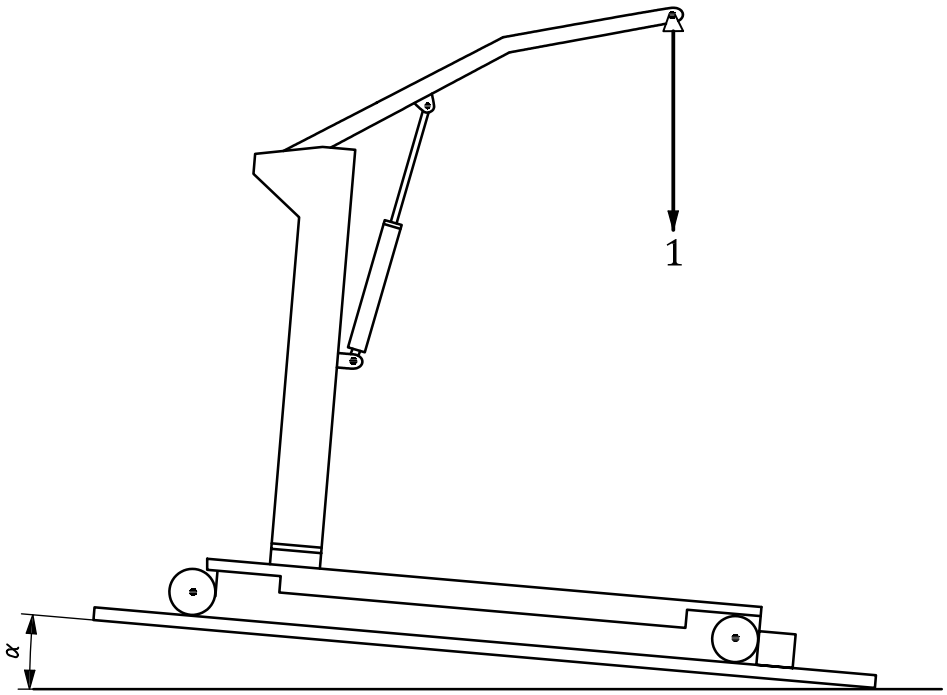
5.4.1 Requirements for immobilizing device (brakes)

An immobilizing device shall be provided for mobile hoists. When tested in accordance with 5.4.2, a maximum movement of 10 mm in any direction is allowed.

5.4.2 Test methods for immobilizing device (brakes)

To ensure that the requirement described in 5.4.1 is fulfilled, a hoist shall be positioned on a 1°angle with the immobilizing device(s) activated. The maximum load shall be applied to the hoist in the most

adverse position. Hold that position for a minimum time period of 1 min and measure the distance the device has moved.



Key

1 test load

α stability angle

Figure 14 — Example of forward stability test

5.5 Moving forces

5.5.1 Requirements for moving forces

The maximum forces required for moving the hoist shall be as follows when tested with the maximum load on the hoist

a) starting: 160 N

b) driving (pushing/pulling): 85 N

5.5.2 Test methods for moving forces

The test shall be carried out on a flat, smooth and horizontal steel plate.

The hoist shall be loaded with the maximum load with the lifting arm set to obtain the maximum reach.

For the test in the forwards and backwards directions, the castors shall be set at 180° to the direction of pushing/pulling.

Using a dynamometer, a starting force is gradually applied to the push handle until the hoist begins to move. Repeat 5 times. The highest force noted during these tests shall be recorded as the starting force.

The starting force shall be applied and recorded as follows:

a) in the forwards direction;

b) in the backwards direction.

5.6 Requirement for information supplied by the manufacturer

5.6.1 Pre-sale information

This subclause specifies requirements for mobile hoists in addition to those specified in 4.13.2.1.

The manufacturer shall provide at least the following information:

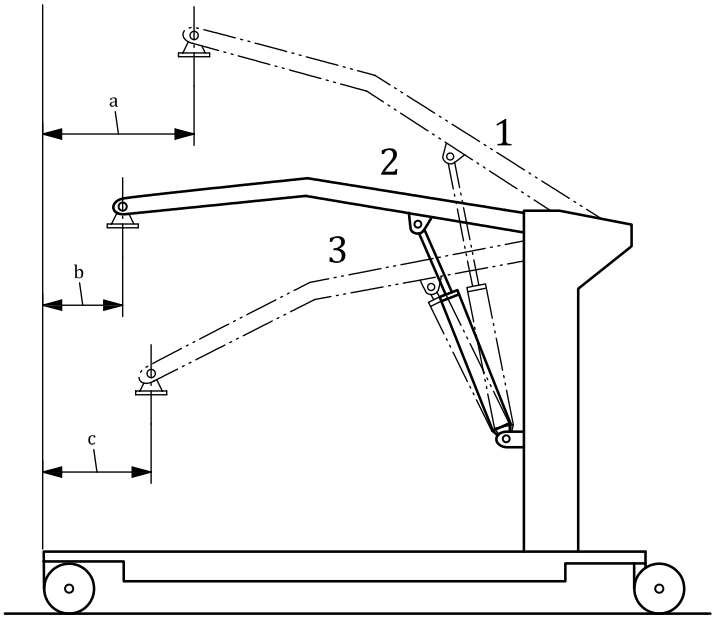
a) functional dimensions as given in Figures 1, 13 and 15;

b) the turning diameter;

c) the total mass of the hoist excluding body-support unit;

d) the number of parts and the identification of those parts into which the hoist can be disassembled without the use of tools;

e) the mass of the heaviest detachable part of the hoist.



Key

1	highest position	a	Minimum distance from wall to CSP at maximum height (legs spread).
2	mid position	b	Minimum distance from wall to CSP at maximum hoisting reach (legs spread).
3	lowest position	c	Minimum distance from wall to CSP at minimum height (legs spread).

NOTE Schematic presentation only.

Figure 15 — Key dimensions of mobile hoists

6 Mobile hoists for transferring a person in standing position— Specific requirements and test methods

6.1 General requirements

This clause specifies requirements and test methods for mobile hoists for transferring a person in standing position that are additional to or modifications to those specified in Clause 4.

Mobile hoists for transferring a person in standing position shall not fulfil the requirements in Clause 5, as the applicable requirements have been included in this clause.

The requirements and test methods for durability given in 6.6 replace those given in 4.9.

6.2 Static strength

6.2.1 Requirements for static strength

After the static test as defined in 6.2.2, the hoist shall function as defined by the manufacturer. There shall be no deformation or wear that could affect its function.

6.2.2 Test method for static strength

The hoist and lifting devices shall be loaded statically according to the procedures and order described below.

The hoist shall be placed on an inclined surface and secured against tipping but not against deformation. The lifting arms and/or hooks shall be set in the most adverse position. With no load being supported by the footrest, the hoist shall be loaded to a maximum for 20 min in the following directions:

a) 10° forwards;

b) 10° backwards;

c) 5° sideways in the most adverse direction (both left and right sides where applicable).

The test is then performed with the surface horizontal and with 1,5 × maximum load for 20 min.

The test is then performed using a load equal to 1,25 × the maximum load (using a dummy as shown in Figure 2) with the centre of the load placed in the most adverse position on the footrest in which failure is most likely to occur, for 5 min.

6.3 Static stability

6.3.1 Requirements for static stability

During the static stability test according to 6.3.2, both unloaded and under maximum load applied using the dummy as shown in Figure 2, the hoist shall not lose its equilibrium (balance) at the following angles:

a) forwards and backwards directions 10° with the base in the intended travelling position;

b) forwards and backwards directions 7° with the base in the most adverse condition;

c) any other direction, 5°.

6.3.2 Test methods for static stability

6.3.2.1 Test procedures for 6.3.1 a), b) and c)

The following tests will be carried out using the test dummy as described in Figure 2.

a) The tests shall be carried out in the forwards and backwards travelling directions and with the base in the travelling position as indicated by the manufacturer and with the load placed in the most adverse position.

b) The tests shall be carried out in the forwards and backwards directions and in the most adverse direction. If there is more than one intended direction of travel (forwards) they shall all be regarded as forwards.

c) The tests shall be carried out with the hoist in its most adverse position regarding the position of the wheels, CSP, base and brakes.

6.3.2.2 Unloaded

Position the unloaded hoist on the test surface with the wheels towards the stop(s) (see Figure 14).

Incline the test plane gradually until the required angle is reached or the hoist loses its equilibrium (balance). If the hoist loses its equilibrium (balance), record the angle of inclination.

Repeat the test in the backwards and sideways directions.

6.3.2.3 Loaded (backwards stability)

Position the hoist on the test surface with the wheels towards the stop(s) (see Figure 14).

Using the dummy shown in Figure 2, apply the maximum load to the hoist. The dummy shall be in the most upright position the hoist is able to achieve.

Incline the test plane gradually until the required angle is reached or the hoist loses its equilibrium (balance). If the hoist loses its equilibrium (balance), record the angle of inclination.

6.3.2.4 Loaded (forwards stability)

Position the hoist on the test surface with the wheels towards the stop(s) (see Figure 14).

Using the dummy shown in Figure 2, apply the maximum load to the hoist. The dummy shall be in the most adverse position the hoist is able to achieve.

Incline the test plane gradually until the required angle is reached or the hoist loses its equilibrium (balance). If the hoist loses its equilibrium (balance), record the angle of inclination.

6.3.2.5 Loaded (sideways stability)

Position the hoist on the test surface with the wheels towards the stop(s) (see Figure 14).

Using the dummy shown in Figure 2 and having the body-support unit (if fitted) at its maximum length, apply the maximum load to the hoist. The dummy shall be in the most adverse position the hoist is able to achieve.

Incline the test plane gradually until the required angle is reached or the hoist loses its equilibrium (balance). If the hoist loses its equilibrium (balance), record the angle of inclination.

6.4 Immobilizing device (brakes)

6.4.1 Requirements for immobilizing device (brakes)

An immobilizing device shall be provided for mobile hoists. When tested in accordance with 6.4.2 a maximum movement of 10 mm in any direction is allowed.

6.4.2 Test methods for immobilizing device (brakes)

To ensure that the requirement described in 6.4.1 is fulfilled, a hoist shall be positioned on a 1° slope with the immobilizing device(s) activated. The maximum load shall be applied to the hoist in the most adverse position using the dummy shown in Figure 2. Hold that position for a minimum time period of 1 min and measure the distance the device has moved.

6.5 Moving forces

6.5.1 Requirements for moving forces

The maximum forces required for moving the hoist when tested with the maximum load on the hoist shall be:

a) starting: 160 N;

b) driving (pushing/pulling): 85 N.

6.5.2 Test methods for moving forces

The test shall be carried out on a flat, smooth and horizontal steel plate.

The hoist shall be loaded with the maximum load using the dummy shown in Figure 2 with the lifting arms/hooks set to obtain the maximum hoisting reach.

The castors shall be set at 180° to the direction of pushing/pulling.

Using a dynamometer, a starting force is gradually applied to the push handle until the hoist begins to move. Repeat five (5) times. The highest force noted during these tests shall be recorded as the starting force.

The starting force shall be applied and recorded as follows:

a) in the forwards direction;

b) in the backwards direction.

6.6 Durability

6.6.1 Requirements for durability

After testing in accordance with the requirements of 6.6.2 the hoist shall function as intended with the maximum load and when unloaded and shall show no signs of permanent deformation or wear that could affect its function.

6.6.2 Test methods for durability

6.6.2.1 The hoist shall be placed on a horizontal surface with the base locked in the most adverse position. The hoist shall be secured against moving on the surface.

6.6.2.2 For manually operated hydraulic hoists, the stroke of the pump lever shall be as long as possible, but the end stops of the pump shall not be activated at any time.

6.6.2.3 The working:pause ratio (duty cycle) during test shall be 15:85, if not otherwise stated by the manufacturer. If the hoist is intended to be operated at varying rates, then the durability test will be performed using the rate that represents the most adverse condition, as stated by the manufacturer.

6.6.2.4 If necessary, it is permissible to use an alternative power supply instead of the battery for the purpose of durability test only, as agreed with the manufacturer of the hoist.

6.6.2.5 Maintenance during testing shall only be carried out if specifically required by the manufacturer in his service manual.

6.6.2.6 Suspend a load equal to 75 % of the maximum load on the hoist lifting arms and/or hooks. Raise and lower the arms and/or hooks of the hoist through the full stroke/range. Ensure that the pause in the lifting cycle and the loading and unloading always occurs when the hoist is at the lowest position of the lifting cycle.

6.6.2.7 Repeat the lifting cycle of the hoist for 11 000 lifting cycles ensuring that the bottom and top end-limiting devices are activated.

6.6.2.8 During the lifting cycle the load shall be allowed to adjust to the vertical in such a way that the swing induces only a negligible dynamic element.

6.7 Requirement for information supplied by the manufacturer

6.7.1 Pre-sale information

This subclause specifies requirements for mobile hoists for transferring a person in standing position in addition to those specified in 4.13.2.1.

The manufacturer shall provide at least the following information:

a) functional dimensions as given in Figures 1, 13 and 15;

b) the turning diameter;

c) the total mass of the hoist excluding body-support unit;

d) the number of parts and the identification of those parts into which the hoist can be disassembled without the use of tools;

e) the mass of the heaviest detachable part of the hoist.

7 Stationary hoists — Specific requirements and test methods

7.1 General requirements

This clause specifies requirements and test methods for stationary hoists in addition to those specified in Clause 4.

7.2 Specific safety requirements

7.2.1 Requirements for specific safety requirements

7.2.1.1 Ceiling hoists that are able to move from one system to another via a "points or switch" system shall incorporate a locking gate. The locking gate shall be fitted with an interlock device that only allows the hoist to move between one system and the other when the locking gate is in its correct position.

7.2.1.2 If a hoist is able to produce motorized horizontal movement, then its linear rate shall be limited to 0,3 m/s.

7.2.1.3 After the test specified in 7.2.2.3, the hoist and end stop shall not be adversely affected.

7.2.1.4 If the vertical movement of the CSP is limited by using electrical switches, then an additional device shall be fitted to ensure that any failure of the limiting switches does not create a dangerous situation.

7.2.1.5 Maximum deflection of any horizontal track used in the construction of a hoist system shall not be more than 1 mm in every 200 mm of track length.

7.2.2 Test methods for specific safety requirements

7.2.2.1 The requirements of 7.2.1.1 shall be determined through functional test and verification of the manufacturer's installation instructions and by inspection.

7.2.2.2 The requirements of 7.2.1.2 shall be determined by measurement.

7.2.2.3 For hoists that are moved manually in a horizontal direction, the hoist under load shall be driven into the end stop of the track 100 times at 1,5 m/s. For hoists that are moved with the use of motors the hoist will be driven into the end stop at the maximum linear rate of the hoist.

7.2.2.4 The requirements of 7.2.1.4 shall be determined by rendering the normal limit switch inoperative and checking that the second device operates.

7.2.2.5 When a track, installed in accordance with the manufacturer's instructions is loaded with the maximum load, the deflection between each set of fixings of the track shall be recorded in the test report.

7.3 Static strength (free-standing stationary hoists only)

7.3.1 Requirements for static strength (free-standing stationary hoists only)

After the static test as defined in 7.3.2, the hoist shall function as defined by the manufacturer. There shall be no deformation or wear that could affect its function.

7.3.2 Test methods for static strength (free-standing stationary hoists only)

The hoist and lifting devices shall be loaded statically according to the procedures and order described below.

The hoist shall be set in the most adverse position and placed on a 10° inclined surface and secured against tipping but not against deformation. The hoist shall then be loaded with 1,25 × maximum load for a period of 5 min in the most adverse condition.

The test is then performed with the surface horizontal and with 1,5 × maximum load for 20 min.

7.4 Static stability (free-standing stationary hoists only)

7.4.1 Requirements for static stability (free-standing stationary hoists only)

During the static stability test according to 7.4.2, both unloaded and under maximum load, the hoist shall not lose its equilibrium (balance) at the following angle:

— any direction 10°.

7.4.2 Test methods for static stability (free-standing stationary hoists only)

7.4.2.1 General

The tests shall be carried out in the most adverse direction with the hoist in its most unstable position regarding the position of the CSP and supporting structure.

7.4.2.2 Unloaded

Position the unloaded hoist on the test surface (see Figure 16).

Incline the test plane gradually until the required angle is reached or the hoist loses its equilibrium (balance). If the hoist loses its equilibrium (balance), record the angle of inclination

Repeat the test in the other three directions.

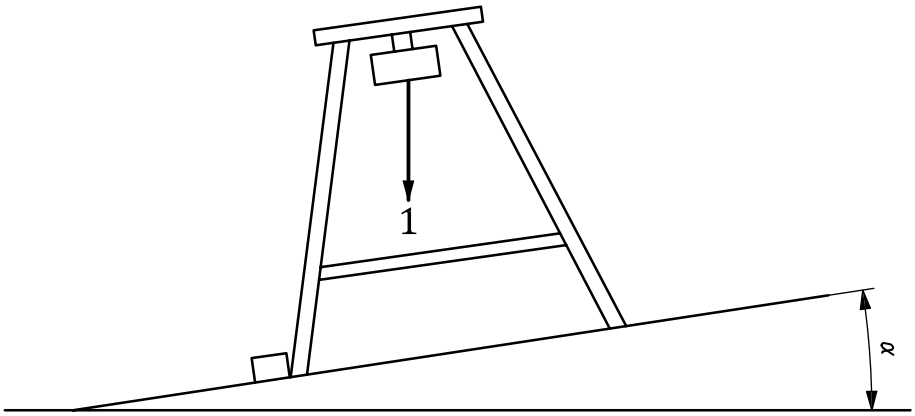
7.4.2.3 Loaded

Attach the maximum load to the CSP in such a way that the load is able to move freely. Repeat the procedure as for the unloaded hoist.

For hoists with rigid body-support units, the centre of gravity of the load shall be placed in relation to the back rest according to Figure 3 but not more than:

— 350 mm from the front edge of the seat.

For stretchers, apply the loads as shown in Figures 4 and 7.



Key

1 test load

α stability angle = 10°

Figure 16 — Stability test for free-standing stationary hoists

7.5 Static strength for all other stationary hoists

7.5.1 Requirements for static strength for all other stationary hoists

After the static test according to 7.5.2, the hoist shall function as defined by the manufacturer.

There shall be no deformation or wear that could affect its function.

7.5.2 Test methods for static strength for all other stationary hoists

The hoist shall be fixed to a building structure in accordance with the manufacturer's instructions.

The hoist shall then be loaded with 1,5 × maximum load for a period of 20 min.

7.6 Requirement for information supplied by the manufacturer

7.6.1 User information

This subclause specifies requirements for stationary hoists in addition to those specified in 4.13.2.2

The manufacturer shall provide the installer of the hoist with details of the loads being applied to the attachment points.

8 Non-rigid body-support units — Specific requirements and test methods

8.1 General requirements

This clause specifies requirements and test methods for non-rigid body-support units in addition to those specified in Clause 4.

After being tested according to 8.3, the body-support unit shall show no signs of damage that can affect the safety and function.

After the tests in 8.3, the body-support unit shall be subjected to an extensive inspection during which attention shall be given to all parts, i.e. fabric, seams, stitching, loops, loop fixations, and fabric at the positions in which rigid parts are received in the fabric.

The connecting means on the non-rigid body-support unit shall still function normally after the test.

The unit shall be provided with an indication showing the types and design of spreader bar with which it can be used. This information may be given in the instructions for use. Further information can be found in Annex C.

8.2 Requirements for material and seams of the non-rigid body-support unit

8.2.1 If the material used in the construction of the body-support unit is claimed by the manufacturer to be flame-retardant, then the material shall not exhibit progressive ignition or flaming ignition when subjected to the test methods in EN 1021-1 and EN 1021-2.

NOTE There is guidance on other test methods in EN 1021-1:2014, Annex A and EN 1021-2:2014.

8.2.2 When cleaned and/or disinfected according to the manufacturer's instructions, the body-support unit shall not shrink more than 5 % of its length and width.

8.2.3 When cleaned and/or disinfected according to the manufacturer's instructions the label shall be readable by persons with normal eyesight or corrected-to-normal eyesight

8.3 Test methods for non-rigid body-support unit

8.3.1 Test methods for non-rigid body-support unit designed to be laundered

If the body-support unit is designed to be laundered, it shall be cleaned and dried 10 times in accordance with the manufacturer's instructions.

Any dimensional change shall be determined by measurement.

8.3.2 Test method for durability for non-rigid body-support unit

The non-rigid body-support unit shall be attached to the spreader bar of the hoist or to the attachment points at hoists not designed with a spreader bar.

The non-rigid body-support unit is loaded with the maximum load. The load can be shaped as to reflect the loading that would be applied to the non-rigid body-support unit in normal use, e.g. a dummy or other load without sharp edges can be used. The most adverse position/part in relation to the non-rigid body-support unit connecting means shall be used.

Non-rigid body-support units shall be loaded for 25 s per cycle. The non-rigid body-support unit is loaded and unloaded as many times as calculated by the manufacturer based on the expected lifetime, making sure that the connection point is not weight-bearing between the test cycles.

The number of cycles for washable and wipeable non-rigid body-support unit shall be at least 500 lifting cycles.

NOTE Unless otherwise specified by the manufacturer, the number of cycles representing one year of normal use is 500 lifting cycles. See Annex A.

The number of cycles for disposable or single person use non-rigid body-support unit shall be at least 100 lifting cycles.

After the durability test, the body-support units shall be tested with a static load of 1,5 × the maximum load for 20 min.

8.4 Requirement for information supplied by the manufacturer

8.4.1 Pre-sale information

This subclause specifies requirements for non-rigid body-support units in addition to those specified in 4.13.2.1.

The following shall be included as a note:

Any organization that purchases hoists and body-support units shall make sure, that the combination(s) are safe either by requiring compatibility documentation for the combination(s) from the manufacturer(s) or by performing compatibility testing themselves hereby transferring the responsibility for a safe combination to the organization.

8.4.2 User information

This subclause specifies requirements for non-rigid body-support units in addition to those specified in 4.13.2.2.

The manufacturer shall provide the following information:

a) details about the materials used in the manufacture of the body-support unit, flammability included;

b) details about the method by which the body-support unit can be adjusted or removed;

c) a warning to the user that a risk assessment shall be carried out to ensure that the correct size, type and shape of body-support unit is being used for the person with disability.

8.4.3 Labelling

This subclause specifies requirements for non-rigid body-support units in addition to those specified in 4.13.3.

The manufacturer shall provide the following information on a label that is permanently fixed to the body-support unit:

a) the size of the body-support unit;

NOTE Further information regarding colour coding can be found in Annex D.

b) a warning/attention mark that which refers the carer to the instructions for use of the hoist and/or body-support unit;

c) marking to indicate if the body-support unit is designed only to be used on one dedicated type of spreader bar;

d) an indication of the method by which the body-support unit shall be cleaned and/or disinfected. Any symbol used shall conform with ISO 3758;

NOTE It might not be possible to include all the following information on the body-support unit. It is suggested that any other information be given in the instructions for use.

e) field of application, directions for use for each design of the body-support unit;

f) the method of lifting, particularly the attitude, namely sitting, sitting/recumbent or recumbent, and any other important information regarding choice of type, design and application method;

NOTE Further information can be found in Annex C.

g) if a body-support unit is unsuitable for a specific target group(s);

h) a warning not to use a damaged or badly worn body-support unit;

i) a warning/attention mark that indicates that if a non-washable body-support unit has been laundered, it shall not be used;

j) a warning/attention mark that indicates if the body-support unit is not intended to be laundered. The following symbol from ISO 3758 shall be used, see Figure 17;

Figure 17 — Symbol for 'not washable' (ISO 7000-3123)

9 Rigid body-support units — Specific requirements and test methods

9.1 General requirements

This clause specifies requirements and test methods for rigid body-support units in addition to those specified in Clause 4.

Should the body-support unit not be permanently attached to the hoist, the design shall prevent inadvertent detachment. If the material used in the construction of the body-support unit is claimed to be flame-retardant by the manufacturer, the material shall not exhibit progressive ignition or flaming ignition when subjected to the test methods in EN 1021-1 and EN 1021-2.

NOTE There is guidance on other test methods in the EN 1021-1:2014, Annex A and EN 1021-2:2014.

9.2 Requirements for backrest

The angle between the sitting part and the backrest shall be not less than 90°.

9.3 Requirements and test methods for durability

The rigid body-support unit, in combination with the hoist, shall be subjected to the same tests as for the complete lifting-device.

The locking system of detachable body-support units shall be function tested for at least 1 000 cycles.

After the durability tests, the rigid body-support unit and the locking system shall still function as specified by the manufacturer.

9.4 Requirement for information supplied by the manufacturer

9.4.1 User information

This subclause specifies requirements for rigid body-support units in addition to those specified in 4.13.2.2.

The manufacturer shall provide the following information:

a) details about the materials used in the manufacture of the body-support unit;

b) details about the method by which the body-support unit can be adjusted or removed;

c) the size of the body-support unit, if applicable;

NOTE Further information regarding colour coding can be found in Annex D.

d) a warning to the user that a risk assessment shall be carried out to ensure that the correct size, type and shape of body-support unit is being used for the person with disability.

9.4.2 Labelling

This subclause specifies requirements for rigid body-support units in addition to those specified in 4.13.3.

The manufacturer shall provide the following information on a label that is permanently fixed to the body-support unit:

a) a warning/attention mark that refers the carer to the instructions for use of the hoist and/or body-support unit;

b) an indication if the body-support unit is designed only to be used on one dedicated type of hoist;

c) an indication of the method by which the body-support unit shall be cleaned and/or disinfected. Any symbol used shall conform to ISO 3758;

NOTE It might not be possible to include all of the following information on the body-support unit. It is suggested that any other information be given in the instructions for use.

d) field of application, directions for use for each design of the body-support unit;

e) the method of lifting, particularly the attitude, namely sitting, sitting/recumbent or recumbent, but also other important information regarding choice of type, design and application method;

f) if a body-support unit is unsuitable for a specific target group(s);

g) a warning not to use a damaged or badly worn body-support unit;

h) the size of the body-support unit, if applicable.

NOTE Further information regarding colour coding can be found in Annex D.

10 Bathtub hoists — Specific requirements and test methods

10.1 General requirements

10.1.1 General

This clause specifies requirements and test methods for bathtub hoists. Therefore, unless specifically stated, bathtub hoists shall not fulfil the requirements in Clause 4 and Clause 7 as the applicable requirements have been included in the present clause.

For the purposes of this clause, it is necessary to create a reference point. This shall be the point on the front edge of the body-support unit measured halfway across the width of the said body-support unit (see Figure 9).

10.1.2 Risk analysis

The requirement of 4.1.1 shall apply.

10.1.3 Ergonomic factors

10.1.3.1 The requirements of 4.1.2 shall apply.

10.1.3.2 The maximum weight of a complete bathtub hoist shall be indicated on a label that shall be placed in a prominent position.

If the bathtub hoist is able to be split into a number of parts, and any one of those parts weighs more than 10 kg, the maximum weight of each part over 10 kg shall be indicated on those parts.

10.1.4 Noise

The requirements of 4.1.3 shall apply.

10.1.5 Safety of moving and folding parts

The requirements of 4.1.4 shall apply.

10.1.6 Prevention of traps for parts of the human body

The requirements of 4.1.5 shall apply.

10.1.7 V-shaped openings

The requirements of 4.1.6 shall apply.

10.2 General test methods

10.2.1 Test conditions

The requirements of 4.2.1 shall apply.

10.2.2 Test equipment

10.2.2.1 The requirements of 4.2.2.1 and 4.2.2.2 shall apply.

10.2.2.2 Test load: for the purposes of this subclause, this shall take the form of a load that is able to simulate the loads as applied by the human body.

NOTE See Figures 3 and 4 for positioning the loads.

10.2.2.3 The requirements of 4.2.2.4 to 4.2.2.7 shall apply.

10.2.2.4 The requirements of 4.2.2.8 shall not apply.

10.2.2.5 The requirements of 4.2.2.9 shall apply.

10.2.3 Permissible errors of test equipment

The requirements of 4.2.3 shall apply.

10.2.4 Test report

The requirements of 4.2.4 shall apply.

10.3 Safety requirements

10.3.1 General safety requirements

10.3.1.1 Unless specifically designed to do otherwise, every bathtub hoist shall be capable of lifting a person of 120 kg mass, excluding the mass of any body-support unit.

10.3.1.2 The requirements of 4.2.5.2 to 4.2.5.17 shall apply.

10.3.1.3 When a hoist is intended to be used by a person with disability on their own, it is necessary to ensure that, in the event of a failure of the hoist, the person with disability is not left in a potentially dangerous situation.

EXAMPLE This could be an incorporated emergency raising device, or it could take the form of a warning in the instructions for use, the fitting of an alarm system or the supply of a conveniently placed telephone etc.

10.3.1.4 The requirements of 4.2.5.19 to 4.2.5.30 shall apply.

10.3.2 Test methods for general safety requirements

10.3.2.1 The requirements described in 10.3.1.1 shall be confirmed through practical test and inspection.

10.3.2.2 The test methods of 4.2.6.2 to 4.2.6.17 shall apply.

10.3.2.3 The requirements described in 10.3.1.3. shall be confirmed through inspection.

10.3.2.4 The test methods of 4.2.6.19 to 4.2.6.30 shall apply.

10.4 Body-support units

The requirements and test methods of 4.3 shall apply.

10.5 Spreader bar

The requirements and test methods of 4.5 shall apply.

10.6 Performance

The requirements and test methods of 4.6 shall apply.

10.7 Rate of movements of the hoist

The requirements and test methods of 4.7 shall apply.

10.8 Operating forces/torques

The requirements and test methods of 4.8 shall apply.

10.9 Durability

10.9.1 Requirements for durability

After testing in accordance with the requirements of 10.9.2, the hoist shall function as intended with the maximum load and shall show no signs of permanent deformation or wear that could affect its function.

10.9.2 Test methods for durability

10.9.2.1 The hoist shall be fixed/mounted as specified by the manufacturer and/or placed in the most adverse condition on the test surface as specified in 4.2.2.1 or in accordance with the manufacturer's installation instructions. The hoist shall be tested in the most adverse position regarding the body-support unit.

10.9.2.2 The working: pause ratio (duty cycle) during test shall be 15:85 if not otherwise stated by the manufacturer. If the hoist is intended to be operated at varying rates, then the durability test will be performed using the rate that represents the most adverse condition as stated by the manufacturer.

10.9.2.3 If necessary, it is permissible to use an alternative power supply instead of the battery for the purpose of durability test only, as agreed with the manufacturer of the hoist.

10.9.2.4 Maintenance during testing shall only be carried out if specifically required by the manufacturer in the service manual.

10.9.2.5 Position the load on the hoist as shown in Figures 3, and 4. Raise and lower the hoist through one complete lifting cycle.

10.9.2.6 Repeat the lifting cycle of the hoist for a total of 11 000 lifting cycles, according to the following schedule, and conduct the tests in the order shown:

a) raise and lower the CSP of the hoist at its maximum rate with no load for 1 000 cycles, ensuring that the top and bottom limiting devices are activated;

b) 10 000 lifting cycles with the maximum load; for electrical hoists, activate the lower end-limiting device for approximately of 1 s in every lifting cycle.

10.10 Static strength and stability

10.10.1 Requirements for static strength and stability

10.10.1.1 After the static test as defined in 10.10.2.1, the hoist shall function as defined by the manufacturer. There shall be no deformation or wear that could affect its function.

10.10.1.2 Maximum deflection of any horizontal track used in the construction of a hoist system shall not be more than 1 mm in every 200 mm of track length.

The requirements do not apply to bathtub hoists that are placed in or mounted on a bathtub.

10.10.1.3 After the static test as described in 10.10.2.3, the hoist shall function as defined by the manufacturer. There shall be no deformation or wear that could affect its function.

10.10.2 Test methods for static strength and stability

10.10.2.1 The hoist and lifting devices shall be loaded statically according to the procedures and order described below.

The hoist shall be mounted as specified by the manufacturer and/or placed in the most adverse condition on the test surface as specified in 4.2.2.1 or in accordance with the manufacturer's installation instructions.

The hoist shall be tested in the most adverse position regarding the body-support unit.

The hoist shall then be loaded with 1,25 × maximum load and the hoist on the plate or test bath tilted for 5 min in the following directions:

— 5° forwards, backwards and sideways.

The test is then performed with the plate or test bath horizontal and with 1,5 × maximum load for 20 min.

10.10.2.2 If applicable for the hoist, a test sample of a track installed in accordance with the manufacturer's instructions (but with a minimum of two fixings) is put under maximum load. Deflection between each set of fixings of the track shall be recorded in the test report.

10.10.2.3 If applicable, the hoist shall be fixed to a typical building structure in accordance with the manufacturer's instructions. The hoist shall then be loaded with 1,5 × maximum load for a period of 20 min.

10.11 Hydraulic components

The requirements and test methods of 4.10 shall apply.

10.12 Pneumatic components

The requirements and test methods of 4.11 shall apply.

10.13 Specific safety requirements

10.13.1 Requirements for specific safety requirements

If a hoist is able to produce powered horizontal movement, then its linear rate shall be limited to 0,3 m/s.

10.13.2 Test methods for specific safety requirements

The requirements of 10.13.1 shall be determined by measurement.

10.14 Non-rigid body-support units

The requirements and test methods of Clause 8 shall apply.

10.15 Rigid body-support units — Requirements

The requirements and test methods of Clause 9 shall apply.

10.16 Requirement for information supplied by the manufacturer

10.16.1 General

The requirements of 4.13.1 shall apply.

10.16.2 Instructions for use

The requirements of 4.13.2 shall apply.

10.16.3 Labelling

The requirements of 4.13.3 shall apply.

In addition, the manufacturer shall provide relevant labelling indicating to the user the correct position(s) for lifting and handling the bathtub hoist (see 10.1.3). The manufacturer shall also provide relevant labelling to indicate the mass of each of the components in the event that any of those components has a mass in excess of 10 kg.

Annex A
(informative)

Rationale for specific safety requirements

A.1 Rationale for noise

ISO 17966:2016, 6.2 states that audible warning device shall generate alarm signal of at least 65 dBA. Noise emitted by the hoist should not exceed 65 dBA in order not to interrupt alarm signals.

A.2 Rationale for minimum maximum load

Rationale for 4.2.5.1:

Only for mobile hoists: 120 kg maximum load requirements are excessive because of the following reasons.

— In some countries, there is a demand from some people for smaller mobile hoists that can easily be transported in the boot of a car, e.g. in relation to holiday trips.

— Starting force requirements in 5.5.1 can be very difficult to fulfil for some mobile hoists with maximum load of 120 kg.

— Large mobile hoists are not compatible with building code in some Asian countries and, as a result, do not fit in some houses and care facilities in Asia.

A.3 Rationale for rate of powered horizontal movement

Rationale for 4.7.3:

In Europe and USA, a low gait rate is defined as a walking rate below 0,8 m/s in the 4-m walking test. This is used as one of the criteria for diagnosing sarcopenia (a type of muscle loss). And transferring a person with disability with 0,8 m/s is considered inherently safe. For powered horizontal movement, a safety factor of 2 is applied to compensate additional risks associated with automation.

The safe velocity of horizontal movement of 6 km/h is adopted from the ISO 7176 series.

A.4 Rationale for durability test of non-rigid body-support unit

Rationale for 8.3.2:

The 10 000 lifting cycles of a hoist at maximum load has typically been translated into 10 years of intended use. Factored into 1 year, the number of cycles at maximum load per year is 1 000. Considering the sling is washable and needs to be taken out of use for washing. A person with disability re-using the sling should have more than one sling, so at least 2, which results in the 500 lifting cycles per year.

It is intended to be disposed of after a short duration (e.g. a few weeks) or when they are soiled or damaged. It typically has a shorter expected life than non-rigid body-support unit which are intended to be washed or cleaned. It is therefore considered acceptable that the number of loading cycles for testing be lowered from 500 cycles per year for non-rigid body-support unit to 100 cycles in total for disposable non-rigid body-support unit, considering their shorter expected operational lifetime.

A.5 Rationale for V-shaped openings

Rationale for 4.1.6:

To reduce neck entrapment with regards to wedging of the neck, angles for V-shaped entry into the openings should be greater than 75°. The 75° angle reflects an understanding that at some point, a narrow angle creates a V-shaped space or geometry that could be conducive to entrapment. The 75°angle was chosen by reviewing the tools to assess entrapment risk for swimming pool equipment (see EN 13451-1) and making changes suitable to application on assistive products by increasing the wedging minimum angle of 60° to 75°. The 75° angle reduces the risk of entrapment of the person with disability, through hooking of the neck and head in the V-shaped opening the wider angle allows the person to pull his head free from a vertical opening with less effort. This is essential when considering a weak or confused person with disability.

Annex B
(informative)

Periodic inspection and maintenance

B.1 General

When defining the recommendations for periodic inspection and maintenance, a distinction was made between inspection and maintenance. Periodic inspection and any needed maintenance of the hoist and body-support unit shall be performed according to the manufacturer's instructions. In general, an annual inspection is advised on the critical parts.

NOTE Inspection and maintenance can be carried out simultaneously.

B.2 Requirements and responsibilities

B.2.1 Logbook and labelling

All maintenance records shall be recorded in the logbook stored on paper or digitally. The logbook shall be kept by the owner, who is responsible for the inspection and the logbook and maintenance of the hoist.

Each hoist shall have its own logbook, which is identifiable of the serial number of the hoist. This means that it shall be immediately available for carrying out the inspection and maintenance of the hoist.

Every inspection or maintenance of the hoist shall be recorded in the logbook and reported to the owner, together with the signature of the inspector or the technician. The due date of the next inspection or other indication displayed shall also be reported.

Labelling on hoists and any rail system shall indicate next inspection/maintenance as with a minimum year and month and be marked with the name of the company, facility, organization who has performed the inspection and maintenance.

B.2.2 Inspection of the hoist

The hoist should be inspected visually and/or physically where applicable:

— inspection for irregularities and defects that are immediately visible;

— inspection for the presence and the legibility of any label of the product information;

— inspection of welds;

— inspection for corrosion;

— inspection for the presence of the instructions for use and/or the user's operating instructions;

— physical inspection and locking of fasteners. The fastening to the wall, floor or ceiling of stationary hoists fixed to a wall, floor or ceiling should be inspected; see B.2.3;

— inspection of the operation of turntables, transition gates and dynamic coupling;

— inspection of pivot and hinge points;

— inspection of the wheels of the mobile hoist;

— inspection of the electrical installation;

— inspection of the hydraulic system;

— inspection of the runners;

— inspection of mobile hoists shall include a full lifting cycle with maximum load of the hoist. For stationary hoists the inspection shall include a lifting cycle of minimum of 500 mm. This shall be performed in the top of the lifting range, using extensions if needed in order to prevent dangerous situations. Inspection shall include a test through the entire rail system with maximum load of the hoist.

B.2.3 Inspection of fastening systems of stationary hoists

Conduct inspection of all fastening of the rail system, which shall include:

— Check that all connection points, brackets to structure are tightened with recommended torque;

— Check that all connection points, brackets to rail system are tightened with recommended torque;

If the above is not possible:

— Perform a load test according to maximum load of the rail system on crucial places/points and register in logbook:

— Deflection before load test;

— Deflection with maximum load;

— Deflection after load test.

Alternative:

— Perform a static load test with 1,5 × maximum load (not full lifting cycle) of the rail system on crucial places/points, e. g. rail connections, rail ends for a period of minimum 20 min.

B.2.4 Inspection of body-support units

Periodic inspection of the non-rigid body-support unit should be undertaken at the time intervals stated by the manufacturer, but at least every 6 months. More frequent inspections can be required where a non-rigid body-support unit is used or cleaned more frequently than normal.

Inspections should be performed by a person who is suitably and properly qualified and well acquainted with the design, use and care of the body-support unit. The inspection should focus on finding signs of damage, wear or potential failure and readability of labels.

— The inspection record should be retained safely for examination in the event of an incident;

— The inspection record should include the following information:

  — date of inspection;

  — identification details and serial number of the body-support unit;

  — information about the condition of the body-support unit;

  — date next inspection is due;

  — identification and signature of the inspector.

B.2.5 Specification of approval and of rejection

After maintenance or inspection of the hoist, rail system, or body-support unit, a clear indication of the outcome (approved/not approved) shall be applied to the device.

If the outcome is 'not approved', the hoist, rail system or the body-support unit it shall be taken out of service.

Annex C
(informative)

Compatibility of hoist/spreader bar/body-support units

C.1 Introduction

This annex is a guideline to assist manufacturers in informing the users/prescribers of the intended safe combination of hoist/spreader bars/body-support units in order to reduce foreseeable misuse. It is related to requirements of this document.

Hoists can be used to complete a wide variety of tasks that require attendants to lift and mobilize persons. There are a broad range of hoists and body-support units that are available to complete these tasks. These devices are used with a population that varies in body weight and shape, and that has a diverse range of medical, physical, and psychological conditions, and rehabilitation needs. In addition, hoists and body-support units are used by attendants with diverse healthcare qualifications and skills in different application environments.

The proper use and combination of hoists and body-support units significantly reduces the risk of injury to the person with disability and attendants during moving and handling tasks.

However, there have been numerous reported adverse events as a result of inappropriate selection and combination of hoist spreader bars (or other connecting means) and body-support units that have resulted in injury and in some cases death of the persons with disabilities.

The following are examples of issues noted in reports of adverse events from several countries related to the use of hoist spreader bars and non-rigid body-support units resulting in injury to or death of the person being lifted primarily due to a fall from a hoist.

— Failure to attach, or to attach securely to a spreader bar one or more non-rigid body-support unit clips and loops.

— Wrong size or type of non-rigid body-support unit used e.g. a non-rigid body-support unit that was too large for the person with disability or provided inadequate support.

— Wrong configuration of non-rigid body-support unit attachments connected to a spreader bar that resulted in the wrong position of the person with disability.

— Non-rigid body-support unit loop or clip connection means broken, damaged, or worn.

— Non-rigid body-support unit material and seams damaged or worn.

— Non-rigid body-support unit was incompatible with hoist spreader bar, e.g. clip connections attached to spreader bar designed for loop connections and vice versa.

C.2 For manufacturers of body-support units

C.2.1 General recommendations

C.2.1.1 Specify which type of hoist the body-support is intended for (according to the scope of this document and ISO 9999:—)

— 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 the 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.

If only intended for dedicated(s) hoists, specify the model(s) of hoists for which the body-support unit is intended, e.g. by brand name and model number.

C.2.1.2 Specify the dimensions and type of spreader bar(s) the body-support unit is intended for, for example:

— Spreader bar with 2 connecting points;

— Spreader bar with 3 connecting points;

— Spreader bar with 4 connecting points and configuration;

— If more connecting points specify the actual number and configuration (e.g. six, eight-point bar and use of two or dual spreader bars);

— Specify the corresponding width of the spreader bar.

If only intended for use with a dedicated spreader bar(s), specify the model of hoist/spreader bar for which the body-support unit is intended, e.g. by brand name and model number.

C.2.1.3 Specify the type and material of connecting means, for example:

— Loops. Examples of materials include textile, plastic, metal or synthetic (Figure C.1);

Figure C.1 — Example of a loop connection

— Clips. Examples of materials include plastic, metal or synthetic (Figure C.2);

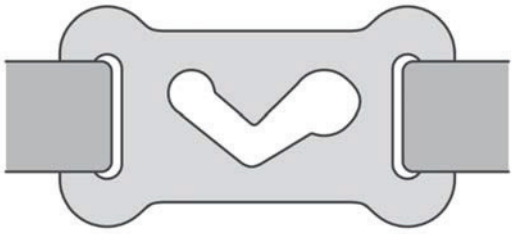


Figure C.2 — Example of a clip connection

— Others.

C.2.1.4 Specify the type of body-support unit(s), size(s), dimensions, material (s), and the maximum load

All essential dimensions of the body-support unit shall be specified in the instructions for use. The dimensions shall be measured on a flat surface, if possible, e.g. height and length, overall measurements and dimensions of any cut-outs. Key dimensions of seats on bathtub hoists are specified in Figures 9, 10 and 11.

The essential body dimensions of the intended person with disability shall be specified, if applicable. See Table C.1.

The maximum load of the body-support unit shall be specified in the instructions for use and in the marking.

The material of the body-support unit shall be specified in the instructions for use.

The intended use and possible contraindications shall be specified in the instructions for use.

Information regarding design and type of the body-support unit shall be specified in the instructions for use.

Table C.1 is provided as a guideline for the manufacturer when specifying some of the above information:

Table C.1 — Body dimensions

Dimension	Figure	Definition
a) Hip breadth, sitting		Measured horizontally across the widest part of the hips. The person sits erect, with the legs and feet together.
b) Sitting height		Measured vertically from the seat surface to the top of the head, compressing the hair. The person sits erect, looking straight ahead, hands in lap. The feet are either unsupported or supported at a level that ensures the thighs are horizontal.
c) Shoulder breadth (deltoid)		Measured horizontally between points of maximum protrusion of the deltoid muscles on the upper, outer border of the arm and shoulder. The person stands erect with the arms at the sides.

Table C.1 *(continued)*

Dimension	Figure	Definition
d) Body length		Measured vertically from the floor to the top of the head. The person stands erect, looking ahead, the arms hanging loosely at the sides.
e) Chest circumference		Measured horizontally around the chest at the widest part. The person sits erect, looking forwards, with shoulders relaxed and breathing quietly.
f) Waist circumference		Measured horizontally at the level of the waist (where the smallest abdominal circumference occurs). The person stands erect with the arms held slightly away from the sides of the body.
g) Thigh circumference		Measured horizontally around the thigh immediately below the fold of buttock (gluteal fold). The person stands erect, legs slightly apart, weight evenly balanced.
h) Hip breadth, lying		Measured horizontally at the level of the widest part of the hips. The person is lying in a supine position.

C.2.2 Non-rigid body-support units

C.2.2.1 Seated slings

Used to transfer the person with disability in a seated and/or semi-reclined position.

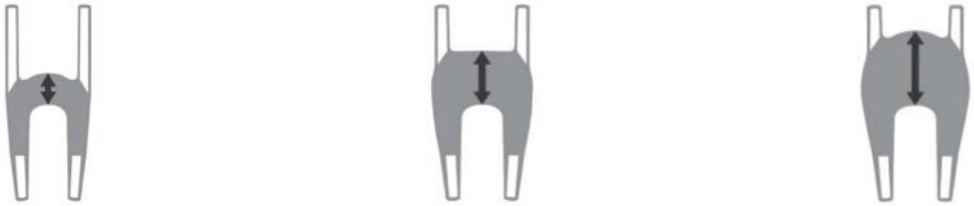
— Weight range of the sling;

— Level of trunk and head support (Figure C.3), e.g.

  — High back (with head support);

  — Medium back (without head support but supporting the complete torso) and shoulders;

  — Low back supporting the pelvic and waist.



a) LB Low Back **b) MB Medium Back** **c) HB High Back**

Figure C.3 — Example of seated slings with level of trunk and head support

— Slings with split leg support opening, the type of opening support (Figure C.4), e.g.

  — Narrow split-leg support opening;

  — Standard split-leg support opening;

  — Wide split-leg support opening;

a) Narrow split-leg support opening **b) Standard split-leg support opening** **c) Wide split-leg support opening**

Figure C.4 — Example of seated slings with the type of split leg support opening

— Slings with no leg support opening, the type of opening support (Figure C.5), e.g.

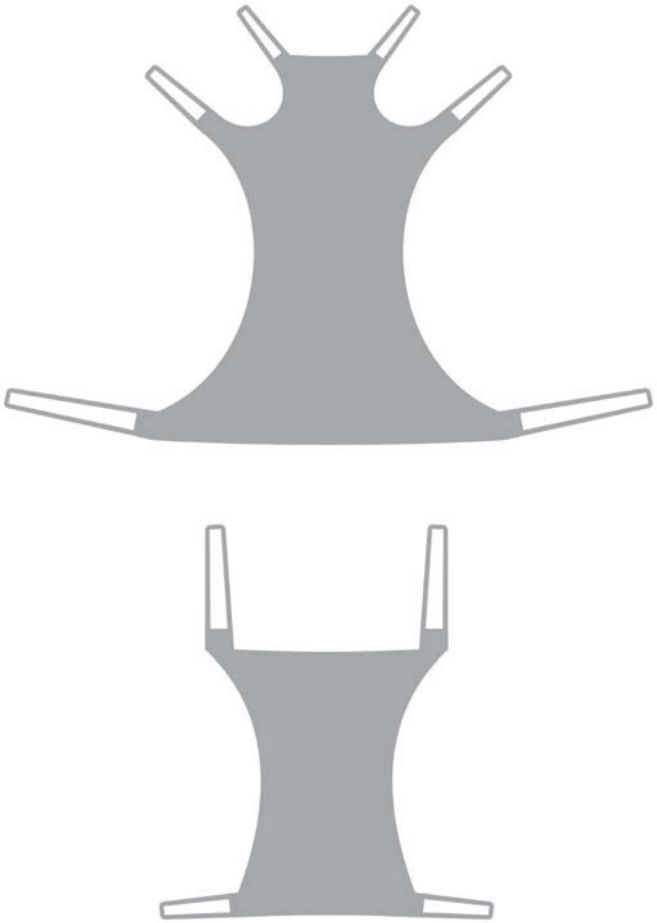


Figure C.5 — Example of seated slings with no leg support opening

— Describe the following essential body dimensions, if applicable, of the intended person with disability according to Table C.1, e.g.

a) Hip breadth;

b) Sitting height;

c) Shoulder breadth;

d) Body length;

e) Chest circumference;

g) Thigh circumference.

C.2.2.2 Supine slings

Sling(s) for lifting persons in a horizontal position (Figure C.6), some slings may also be used for positioning and turning

— Describe the following essential body dimensions, if applicable, of the intended person with disability according to Table C.1, e.g.:

c) Shoulder breadth (deltoid) and if other part of body is broader, e.g.

f) Hip breadth in supine position;

d) Body length.

Measured horizontally at the level of the widest part of the hips. The person lying supine.

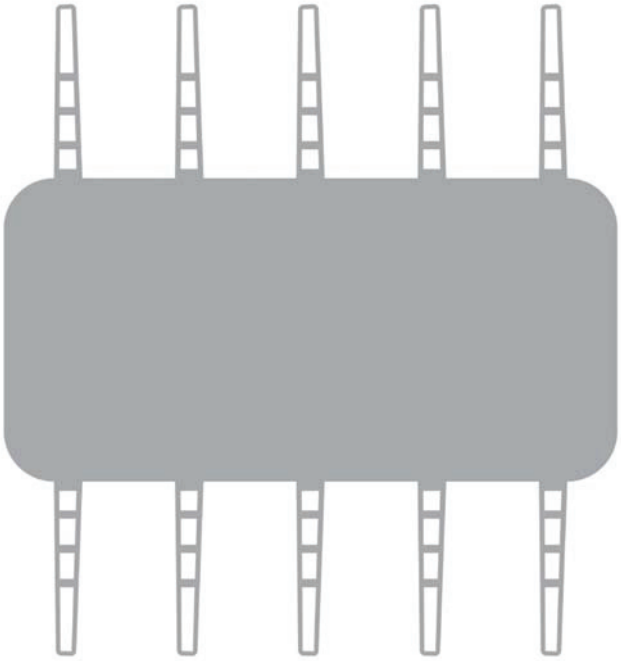


Figure C.6 — Example of supine sling for lifting persons in a horizontal position

C.2.2.3 Slings for supporting, repositioning and/or lifting a part of a body (Figure C.7)

Slings can consist of one or multiple straps or bands designed to lift and support a body part(s).

— Essential body dimensions will depend on the intended use of the sling and can include:

  — Maximum weight of the sling in relation to the lifted body part.

Figure C.7 — Example of sling for supporting, repositioning and/or lifting a part of a body

C.2.2.4 Slings for standing/walking training (Figure C.8)

Lifting vests fastened around the trunk with or without crotch straps or lifting panties with slings or straps fastened around the crotch. These slings assist movement of a person in a standing position.

— Describe the essential body dimensions, if applicable, of the intended person with disability according to Table C.1, e.g.:

  b) Sitting height;

  e) Chest circumference;

  f) Waist circumference;

  g) Thigh circumference for legs straps if present.

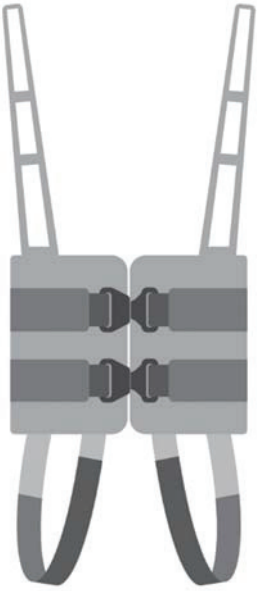


Figure C.8 — Example of sling for standing/walking training

C.2.2.5 Slings for mobile hoists for transferring a person in standing position (Figure C.9)

Slings that consist of one or more straps used with mobile hoists for transferring a person in standing position.

— Describe the essential body dimensions, if applicable of the intended person with disability according to Table C.1, e.g.:

  b) Sitting height;

  d) Body length;

  e) Chest circumference;

  f) Waist circumference.

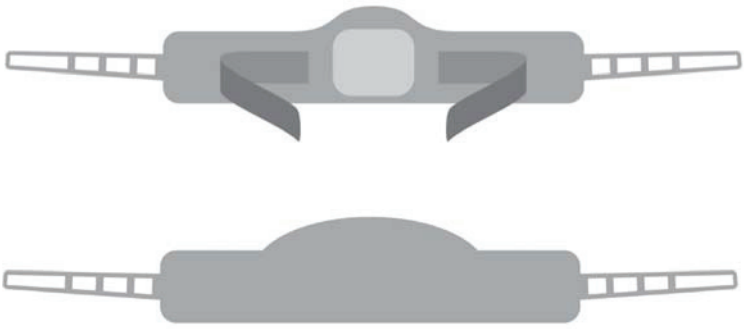


Figure C.9 — Example of slings for mobile hoists for transferring a person in standing position

C.2.2.6 Accessories for non-rigid body-support units, such as extension loops, belts, separate padding, separate head support, etc.

C.2.2.7 Other solutions

None of the above-mentioned types of non-rigid body-support units.

C.2.3 Rigid body-support units

C.2.3.1 Seated rigid body-supports

Body-support units consisting of a solid seat, a spade seat or equivalent.

A rigid body-support for seated transfers can also have non-rigid body-support components such as bands or straps that support the person with disability's legs.

— Level of trunk and head support (Figure C.3), e.g.
  — High back (with head support);
  — Medium back (without head support but supporting the complete torso);
  — Low back supporting the pelvic and waist.
— Describe the essential body dimensions, if applicable, of the intended person with disability according to Table C.1, e.g.:
  a) Hip breadth;
  b) Sitting height;
  e) Chest circumference;
  f) Waist circumference.

C.2.3.2 Rigid body-support for supine transfers. (Figure C.10)

Solid stretcher or frame with straps for lifting a person in a supine position

— Describe the following essential body dimensions, if applicable, according to Table C.1:
  c) Shoulder breadth (deltoid) and if other part of body is broader;
  d) Body length;
  h) Hip breadth, lying.

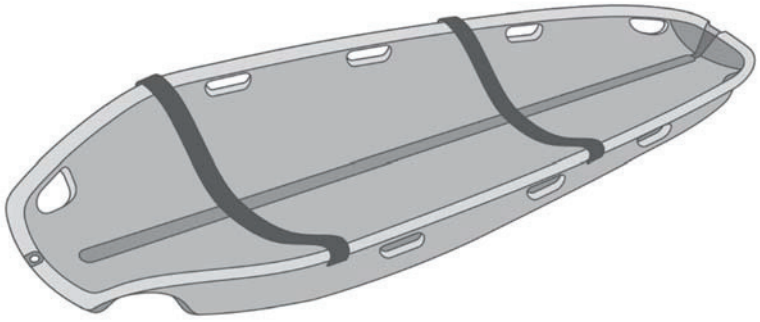


Figure C.10 — Example of rigid body-support for supine transfers

C.2.3.3 Accessories for rigid body-support units, such as extension loops, belts, separate padding, separate head support, etc.

C.2.3.4 Other solutions

None of the above-mentioned rigid body-support units.

C.3 For Manufacturers of Hoists

Spreader Bars

— If the spreader bar is not permanently mounted on the hoist specify the dimensions and type of spreader bar (if any) the hoist is intended for, e.g.

  — width adjustable;

  — position adjustable;

  — other.

If only intended for dedicated(s) hoists, specify the model(s) of hoists for which the spreader bar is intended for, e.g. by brand name and model number.

— Specify the type and allowed material in the connecting means. See C.2.1.3.

— Specify the types of body-support units that are compatible with the hoist and spreader bar (if any). See C.2.1.2.

— Specify the sizes, dimensions and the maximum load of body-support units that are compatible with the hoist and spreader bar (if any). See, C.2.1.4.

C.4 Checklists for safe use, inspection and attachment of a body-support unit to a hoist

The following checklists provide guidance for prescribers and operators of hoists when evaluating the intended safe combination of hoist/spreader bars/body-support units in order to reduce foreseeable misuse.

For Prescribers of Hoists and Body-support Units i.e. the person who evaluates and recommends the use of a specific hoist and body-support unit for a person with disability			
A. When prescribing a hoist and body-support unit		**Yes**	**If No – note action required**
1. Ensure that the Body-support Unit to be used:			
a)	Is compatible with the spreader bar connection points e.g. loops or clips and style of 2, 3, 4, 5, 6 and/or 8-point spreader bar according to the manufacturer's instructions.		
b)	Is suitable for the person with disability, in terms of: i. Clinical needs and precautions, and medical equipment attached		
	ii. Size - e.g. weight, height, torso and hip width		
	iii. Style - suitable for the hoisting task to be performed		
	iv. Material for comfort on skin (e.g. wounds; irritation, sensory deficits)		
c)	Does not create any pinch points or other hazards in all positions of intended use (use a full lifting cycle), e.g. squeezing risk between the person with disability and constructional parts of the hoist e.g. lifting arm, lifting mast, spreader bar.		
d)	That the design of the body-support unit when attached to a spreader bar does not change the centre of gravity or affect the hoist's stability in a hazardous way		
e)	Has a maximum load that exceeds the weight of the person with disability. The maximum load capacity of a body-support unit, lift or spreader bar can differ; the weight of the person with disability shall not exceed the lowest maximum load capacity of any of these individual component parts.		
f)	Is documented in the care plan of the person with disability, e.g. the type and size of body-support unit and any special instruction for use.		

For Operators of Hoists and Body-support Units		
A. Before using a hoist and body-support unit conduct a visual inspection and safety check of the hoist, spreader bar and body-support unit	**Yes**	**If No Do not use or substitute. Take out of service**
1. Ensure the Body-support Unit to be used:		
a) Is the correct style and size for the hoisting task to be performed as documented in the care plan of the person with disability		
b) Has a body-support unit manufacturer's label		
c) Has a body-support unit label that is easy to read (e.g. is not faded or damaged)		
d) Has not been laundered, if the body-support unit is designed for single use		
e) That the material of the body-support unit has: i. Stitching that is intact – there are no signs of fraying or loose stitching especially where the straps/loops are attached to the body of the body-support unit		
ii. No rips, tears, holes, or fraying		
iii. Has not been damaged by chemicals or heat, e.g. stiff, rough, brittle, puckered		
f) Ensure the following for fastenings, straps, and coupling or connecting attachment point(s): i. Textile connectors (if present), e.g. loops, have no rips, tears, or holes, fraying, shrinkage or stretching		
ii. Plastic or metal connectors (if present), e.g. clips, key or clip connectors, are not cracked or worn		
iii. Plastic or metal connectors (if present) are securely attached to straps		
iv. Straps are securely fixed to the body-support unit		
v. Fastenings such as hook-and-loop-fasteners or security buckles are securely fixed		
vi. Have not been altered, e.g. knots in the attachment straps		
2. Ensure the Spreader Bar to be used:		
a) Is compatible with the hoist to be used (if using a removable spreader bar) according to the manufacturer's instructions		
b) Has not detached from the hoist		
c) Is compatible with the body-support unit to be used e.g. loop body-support unit / loop hangar bar, clip body-support unit clip spreader bar; and the number of loop/ clip attachments		
d) Has no sign of damage (e.g. dents, chips, bent out of shape, etc.) including all connections e.g. fasteners between the spreader bar and lifting strap or arm		
e) Has no damaged or missing connection points capping/safety locks (if applicable)		
f) Has no sharp edges or burrs that could damage the body-support unit connection point		
g) Has not been altered		

B. Checking the body-support unit and spreader bar during hoisting		Yes	If No Do not use or substitute
a)	Attach the body-support unit connection points to the spreader bar per manufacturer's instructions and in accordance with the documented care plan for the person with disability		
b)	The body-support unit /spreader bar combination should provide the best angle and position:		
	i. To meet the physical and clinical needs of the person with disability		
	ii. For the hoisting task to be performed		
c)	Body-support units with loop style attachment points: All loops are seated and secured in the spreader bar connection point:		
	i. Without risk of shearing, crushing, or trapping or damaging the body-support unit and		
	ii. So that the locking device if one is present, can be closed correctly		
d)	Body-support units with key or clip attachment points: The key or clip attachment point should be properly attached to the spreader bar and should not become loose		
e)	Ensure straps and/or loops are not twisted and buckles on belts or any other fasteners are secured		
f)	Before raising the person for lifting off the surface - raise the spreader bar until there is tension on the body-support unit straps and:		
	i. Ensure all attachment points are securely fastened to the spreader bar		
	ii. All load bearing loops, or straps are secured to the body of a body-support unit		
	iii. Check that spreader bar is positioned to allow sufficient clearance for taller persons when being moved in a body-support unit		
	iv. That the person with disability is comfortable and that the body-support unit has not shifted into potentially unsafe position on their body		
g)	Ensure that there are no pinch points or other hazards in all positions of intended use (use a full lifting cycle), e.g. squeezing risk between the person with disability and constructional parts of the hoist, e.g. lifting arm, lifting mast, spreader bar		
h)	Ensure that medical attachments to the person with disability (e.g. intravenous line, catheters, feeding tube, chest tube, tracheotomy, monitors, orthopaedic supports such as Halo brace, Thoraco-Lumbo-Sacral-Orthosis (TLSO) brace, traction of extremities do not interfere during the hoisting process		

Annex D
(informative)

Guidelines for colour coding for size of non-rigid body-support units

D.1 Introduction

The proper choice and combination of hoists and body-support unit significantly reduces the risk of injury to attendants and persons with disability. However, there have been reported incidents of unintentional harm to a person with disability as a result of using a body-support unit that is too large or that provides inadequate support. Refer to Annex C for more information.

According to 8.4, the manufacturer shall specify the size of the body-support unit. Additionally, the manufacturer may also use colour coding to indicate the size of the body-support unit. This annex is provided to assist manufacturers who use colour coding, to adopt a standardized colour coded system.

However, there might be a foreseeable risk of choosing the wrong body-support unit if the attendant only uses colour coding as a parameter for choosing the right body-support unit. It is important to remember that manufacturers use different parameters, e.g. in relation to body dimensions and weight range to determine the size of the body-support unit. As a result, a medium size from one manufacturer could be a small size or even a large size from other manufacturers. Colour coding can be indicated by a variety of methods such as coloured border around the edge of the body-support unit; and/or colour indicated on the body-support unit label.

D.2 Recommendations for colour coding

The colour coding in Table D.1 should be used to indicate the size of a body-support unit.

Table D.1 — Size ranges with colour coding applied

Size	Recommendation		
	Colour	CMYK	RGB
XX Small	Violet	30,95,0,0	153,0,153
Extra Small	White	0,0,0,0	255,255,255
Extra Small	Light grey	15,10,10,0	200,200,203
Small	Red	0,75,90,0	255,75,0
Medium	Yellow	0,0,100,0	255,241,0
Large	Green	75,0,65,0	3,175,122
Extra Large	Sky blue	55,0,0,0	77,196,255
XX Large	Orange	0,45,100,0	246,170,0
NOTE 1 Extra small can be white or grey, depending on visibility NOTE 2 Values given in CMYK is a graphical and digital colour identification made of the colour C: Cyan M: Magenta Y: Yellow K: Keyblack. NOTE 3 Values given in RGB us composed by the colour R: Red, G: Green, B; Blue.			

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