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## Walking trolleys — Requirements and test methods

*Trolleys de marche — Exigences et méthodes d'essai*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://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](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee 173, *Assistive products for persons with disability*.

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](http://www.iso.org/members.html).

## Introduction

Some elderly or disabled persons need assistive products for walking. A rollator as defined in ISO 11199-2 can be used effectively to assist such population, but rollators are unnecessary large for many such people because rollators are designed to host the user inside the frame and to possibly carry the full weight of the user. Walking trolleys are designed to improve stability and balance while the user is located outside the frame. The walking trolley does not carry the full body weight of the user while walking. A walking trolley is substantially lighter and more compact than a rollator while providing necessary support to maintain the stability and balance of the user. Walking trolleys can be equipped with accessories such as seats and shopping bags. Walking trolleys are not intended to be moved with the user on the seat like wheelchairs, rather the seat is provided as a resting seat with brakes engaged. In addition to the requirements in this document, [Annex B](#) gives general recommendations.

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# Walking trolleys — Requirements and test methods

## 1 Scope

This document specifies the requirements and test methods for the testing strength, torque, and durability of parts, and stability and running durability as a whole for walking trolleys.

This document also provides requirements relating to general safety, folding and adjusting mechanisms, lifting and carrying means, ergonomics and information supplied by the manufacturer including marking and labelling.

The requirements and tests are based upon every-day usage of walking trolleys as assistive products for walking, for a maximum user mass as specified by the manufacturer. This document includes walking trolleys specified for a user mass of no less than 35kg.

Excluded are rollators specified in ISO 11199-2.

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

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

ISO 9227, *Corrosion tests in artificial atmospheres — Salt spray tests*

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

ISO 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60695-1-10, *Fire hazard testing — Part 1-10: Guidance for assessing the fire hazard of electrotechnical products — General guidelines*

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

### 3 Terms and definitions

For the purposes of this document, the terms and definitions provided with the following sites apply in addition to the ones described in this clause.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1

##### **walking trolley**

frames which can be moved by pushing and/or lifting that enable a person to improve stability and balance while walking and standing, with hand grips, without forearm supports and with four or more wheels

Note 1 to entry: All parts are placed in front of the user to guide his/her gait effectively (see [Figure 1](#)).

EXAMPLE Walking trolleys with a seat for resting, and/or a bag for carrying goods.

Note 2 to entry: The difference between a walking trolley and a rollator is described in [Figure 1](#).

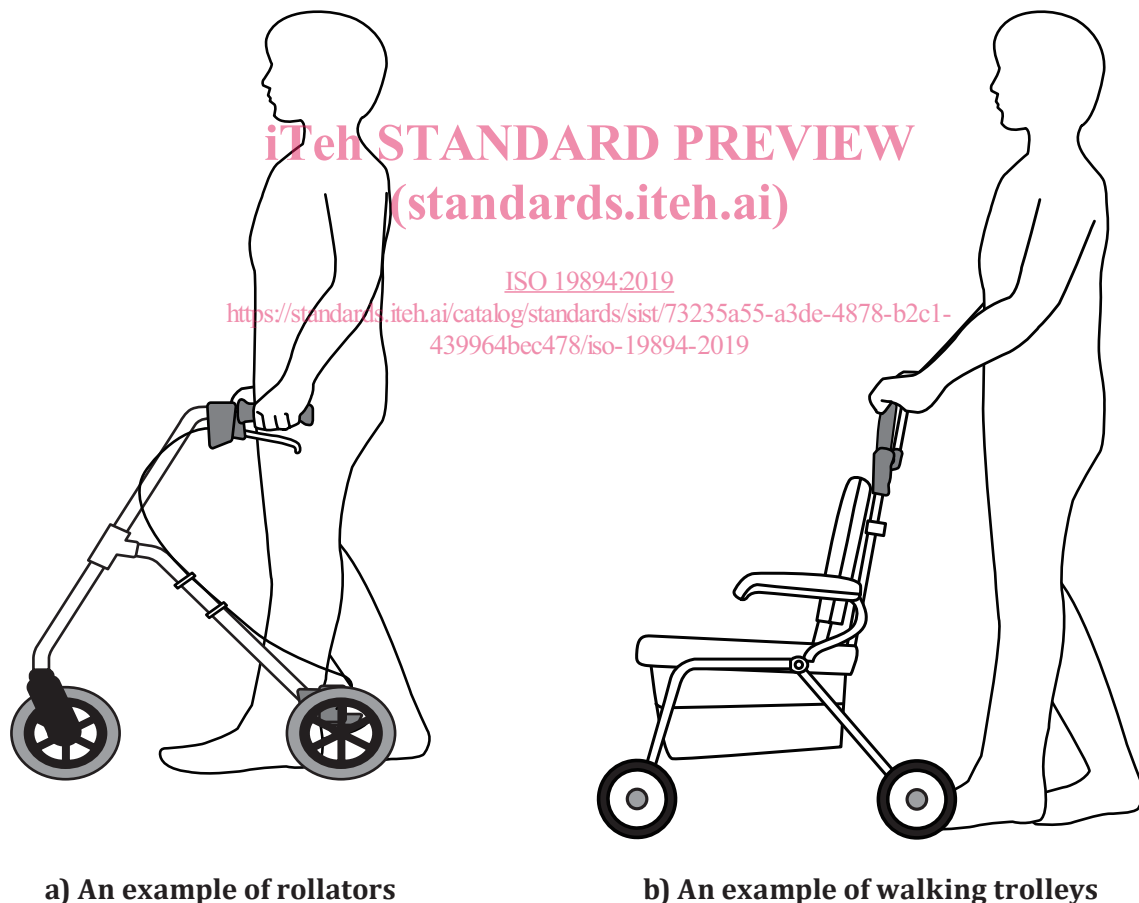
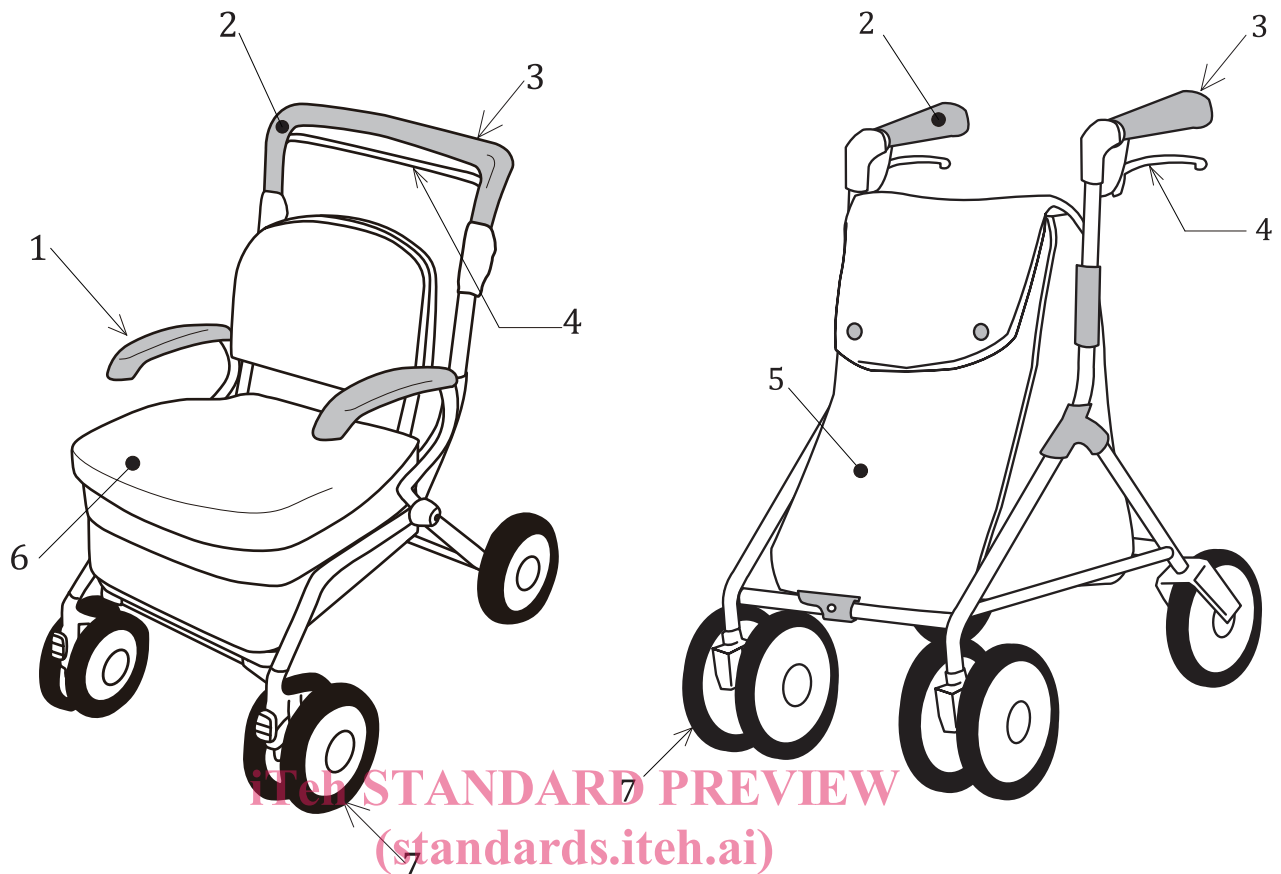


Figure 1 — Rollators and walking trolleys





a) Example of unified-handle type

b) Example of separated-handle type

**Key**

- 1 arm support
- 2 handle
- 3 hand grip
- 4 brake lever

- 5 bag
- 6 resting seat
- 7 caster

**Figure 2 — Types and names of each part****3.2****user mass**

body mass of the person using walking trolleys

**3.3****maximum width**

maximum outside dimension of a walking trolley when the width is adjusted at its maximum, measured horizontally at right angles to the direction of movement when the walking trolley is in normal use

**3.4****handle height**

vertical distance from the highest point of the handle to the ground surface

**3.5****handgrip**

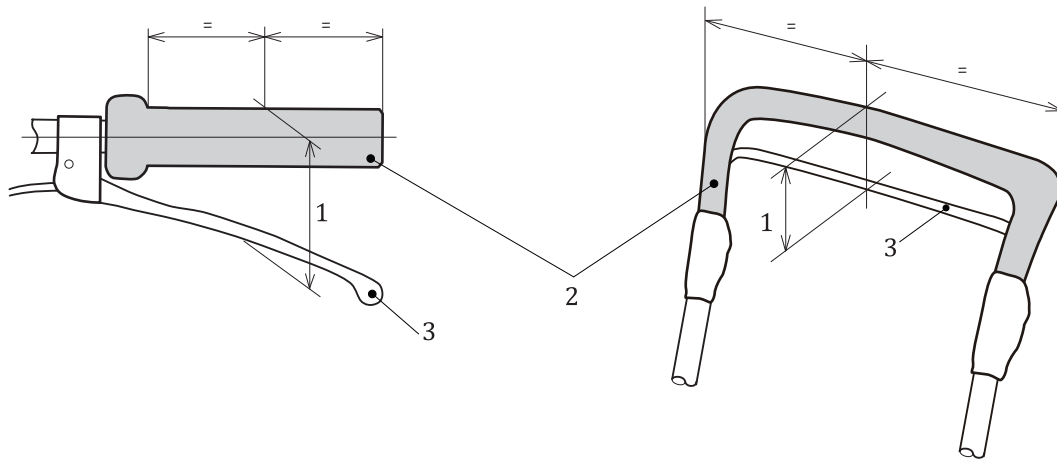
part of the walking trolley which is specified by the manufacturer as normally held by the hand when the walking trolley is in use

Note 1 to entry: See [Figure 2](#) and [3](#).

### 3.6 grip distance

distance between the upper surface of the handgrip and the lower surface of the brake lever measured vertically at the centre of the hand grip

Note 1 to entry: See [Figure 3](#).



a) Example of separated-handle type

b) Example of unified-handle type

#### Key

- 1 grip distance
- 2 handgrip
- 3 brake lever

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Figure 3 — Details of handle and handgrip

### 3.7 parking brake

brake to hold the halt condition

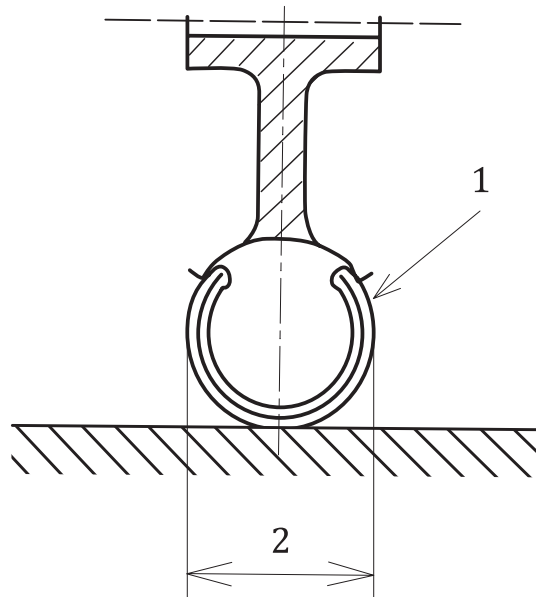
### 3.8 running brake

brake to control the speed while walking

### 3.9 wheel width

maximum dimension of the tyre of the wheel when the walking trolley is unloaded

Note 1 to entry: See [Figure 4](#).

**Key**

- 1 tyre
- 2 wheel width

**Figure 4 — Wheel width**  
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**3.10****resting seat**

seat for the user to take a rest when necessary while walking

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**3.11****shopping bag**

bag attached on the walking trolley to carry goods bought

**3.12****test plane**

flat and stiff floor to place the test product on it

## 4 General requirements and test methods

### 4.1 Risk analysis

The safety of a walking trolley shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in ISO 14971 and, if relevant, ISO 12100.

When a walking trolley is intended by the manufacturer to be used in combination with a device that is not a medical device the device shall behave in a safe way, as a system.

NOTE 1 In the case of certain disabilities, there is a possible need for higher levels of safety for equipment used to offset the effects of that disability.

NOTE 2 For precise information on the hazard causes a risk, refer to [Annex A](#).

### 4.2 Intended performance

A walking trolley shall have sufficient strength and durability to sustain all loads expected during intended use. This shall be confirmed by using, as appropriate, references to relevant clinical and

scientific literature in addition to the requirements in this document, strength and/or durability calculations, appropriate test standards and their test results.

The intended performance including, if appropriate, strength, durability and tipping stability of a walking trolley shall be described in the information supplied by the manufacturer which sets out its functional characteristics, its application(s) and conditions of use.

The information supplied by the manufacturer shall include, if appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, conformity with appropriate test standards and their test results.

#### 4.3 Clinical evaluation and investigation

If the risk management demonstrates a need for a clinical evaluation, a clinical evaluation shall be done for all walking trolleys. If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of ISO 14155. A clinical evaluation shall always be done before performing a clinical investigation.

#### 4.4 Walking trolleys that can be dismantled

If it is intended that a walking trolley can be dismantled for storage or transportation, it shall not be possible to reassemble it in a manner that presents a hazard.

#### 4.5 Fasteners

The fasteners which are loosened or removed to allow this dismantling shall not be single use fasteners.

NOTE For further information, see EN 12182.

EXAMPLE Single use fasteners include wood screws and self-tapping screws. Bolts are examples of fasteners that can be used more than once.

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

#### 4.6 User mass/load limits

The maximum user mass shall be declared. If the maximum load is different, both shall be declared by the manufacturer.

All products with the intended purpose of supporting an occupant/user in a seated or lying position shall be capable of supporting a person with at least 100 kg body mass.

The maximum user mass and the maximum load as specified by the manufacturer shall be used in the relevant test methods of this document.

When the loading pad is used for testing, the mass thereof shall be taken into account for the test value of loading.

#### 4.7 Apparatus

**4.7.1 Means to apply a force** with an accuracy of  $\pm 5\%$  and with a rate of application less than 1 N/s.

**4.7.2 Means to measure force** with an accuracy of  $\pm 5\%$  in increments of 1 N.

**4.7.3 Means to measure distance** in the range of 0 m to 3 m with an accuracy of  $\pm 5$  mm or  $\pm 2\%$  whichever is the greater.

**4.7.4 Means to measure angles** to an accuracy of  $\pm 0,5^\circ$ .

**4.7.5 Means to measure torque** with an accuracy of  $\pm 5\%$  in increments of 1 Nm in the range of 0,5 Nm to 10 Nm.

**4.7.6 Means to measure sound levels and frequencies** calibrated in accordance with the manufacturer's instructions, using an acoustic calibrator class 1 as described in ISO 3746 with an accuracy of  $\pm 3$  dB(A).

**4.7.7 A hard horizontal and inclinable test plane** of sufficient size to support the walking trolley during testing, such that the whole surface is contained between two imaginary parallel planes 5 mm apart. A non-adjustable test plane can be used, if it is set to the correct angle.

NOTE A hardwood board (e.g.  $>600$  kg/m<sup>3</sup>) is an example of material used.

**4.7.8 Stoppers** for walking trolley not smaller than half of the wheel diameter and not greater than the wheel diameter.

**4.7.9 Equipment capable of simulating human body parts** as used in practice (e.g. test fingers).

**4.7.10 Equipment for applying loads** with negligible dynamic factor.

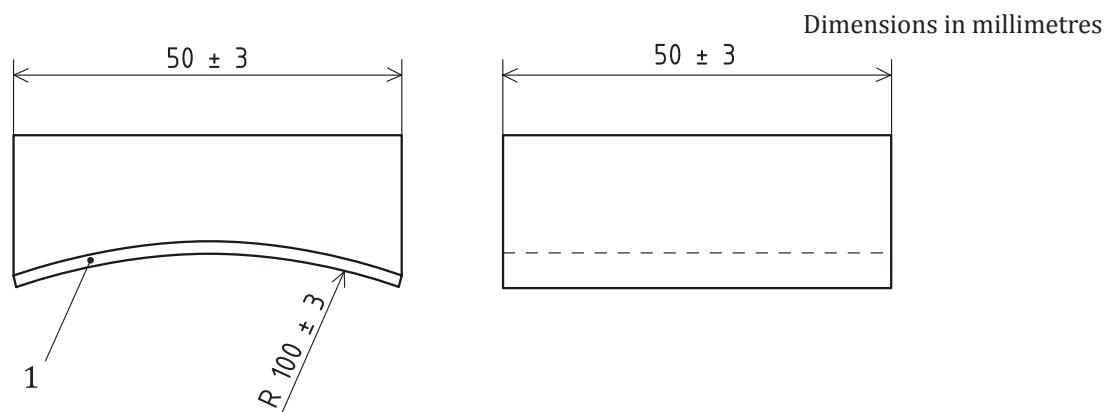
NOTE Negligible dynamic force is a small force that does not have a big impact.

**4.7.11 Equipment for measuring pressure of water, oil and air** with an accuracy of  $\pm 5\%$ .

**4.7.12 Loading pads** as follows.

**4.7.12.1 Seat loading pad**, the loading pad shall be made of metal or hard wood with no sharp edges. The pad shall be round with a diameter of  $355 \text{ mm} \pm 5 \text{ mm}$ , or rectangular with the dimensions:  $340 \times 200 \text{ mm} \pm 5 \text{ mm}$  and the height to be sufficient for loading pad to be stiff enough to take the test load without deforming significantly.

**4.7.12.2 Arm support loading pad**, the loading board shall be made of metal or hard wood with no sharp edges. The shape and dimensions are shown in [Figure 5](#).



**Key**

1 loading surface

**Figure 5 — Arm support loading pad**

NOTE The loading surface can be covered with non-slip material up to 3 mm thick, e.g. plastic foam.

**4.7.12.3 Seat loading pad for stability test in a horizontal position**, the loading pad shall be made of metal or hard wood with no sharp edges. The pad shall be round with a diameter of 200 mm  $\pm$  5 mm and the height to be sufficient for loading pad to be stiff enough to take the test load without deforming significantly.

## 4.8 Test conditions

- a) The tests shall be conducted under a room temperature of 21 °C  $\pm$  5 °C.
- b) The height of every adjustable part of the product shall be adjusted to the most adverse position as far as a condition is not specified in the test procedure.
- c) The wheels shall be adjusted to the most adverse condition as far as a condition is not specified in the test procedure.
- d) The handle shall be positioned most adversely as far as a condition is not specified in the test procedure.
- e) The running brake and parking brake shall not be operated as far as the test procedure does not specify it.
- f) All abnormalities such as breakage on each test shall be recorded and be distinguished from the abnormalities on the subsequent tests.

## 5 Materials

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### 5.1 General

Manufacturers should, wherever possible, use materials that can be recycled for further use. It should be stated in the instructions for use which parts can be recycled.

### 5.2 Flammability

#### 5.2.1 General

Manufacturers shall consider the environments and methods of use to which a walking trolley, or any materials that are usually used in combination with this walking trolley, will be exposed and take appropriate steps to minimise any fire hazard.

The manufacturer shall include a warning in the instructions for use about safe combinations of flame resistant and non-flame resistant materials.

NOTE For guidance, see [B.5.2](#).

#### 5.2.2 Upholstered parts and moulded parts

If the manufacturer claims that the upholstered parts are resistant to ignition by cigarette, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with ISO 8191-1 and ISO 8191-2.

If the manufacturer claims that moulded parts are resistant to ignition by small flames, such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with IEC 60695-1-10.

### 5.3 Biocompatibility and toxicity

Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in ISO 10993-1.

The assessment shall also take into account the intended use and contact by those involved in user care. The result of the assessment shall be incorporated in the risk analysis (see [4.1](#)).

The assistive products shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs).

The assessment should follow the guidance given in [Annex C](#).

## 5.4 Infection and microbiological contamination

### 5.4.1 Cleaning and disinfection

If a walking trolley is intended to be cleaned and/or disinfected, the method and suitable cleaning or disinfection materials shall be described in the information supplied by the manufacturer.

NOTE For guidance, see [B.5.4.1](#).

If a walking trolley is intended to be cleaned by automatic washing systems or hand-held jet stream/steam washing the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution shall be described in the instructions for use. Where practicable, the walking trolley shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling and an example of testing of machine washable walking trolley in [B.5.4.1](#).

### 5.4.2 Resistance against temperature alternations

If a walking trolley is intended to be heated up during the disinfection or washing process, it shall pass the following test.

The test sample is exposed to the maximum temperature  $\pm 2$  °C during the washing and disinfection process as described by the manufacturer and afterwards cooled down to a temperature of 30 °C. This cycle of alternating temperatures is repeated ten times.

For products intended to be disinfected by heat one of the following three temperatures and duration of exposition can be used:

- a) a temperature of 90 °C for 1 min;
- b) a temperature of 85 °C for 3 min;
- c) a temperature of 80 °C for 10 min.

The test shall be performed before any strength and/or durability tests of the product.

After the test, the product shall fulfil the following requirements: coating or any relevant labelling on the product shall not come loose from the basic sheet metal, show blisters or any other quality-reducing changes.

### 5.4.3 Animal tissue

Where a device has been manufactured utilising tissues of animal origin or their derivatives, risk assessment shall be performed and documented according to ISO 22442-1.

NOTE For guidance, see [B.5.4.3](#).

## 5.5 Resistance to corrosion

The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis. Assistive products that are identified to be at risk of corrosion shall be sufficiently protected