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Wheelchair seating —

Part 10:

Resistance to ignition of postural support devices — Requirements and test method

Sièges de fauteuils roulants —

Partie 10: Résistance à l'inflammation des dispositifs de soutien postural — Exigences et méthode d'essai

<u>ISO 16840-10:2021</u> https://standards.iteh.ai/catalog/standards/sist/6fdc9301-86f3-478e-910c-076bc4549aa4/iso-16840-10-2021



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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, Subcommittee SC 1, *Wheelchairs*.

This second edition of ISO 16840-10 cancels and replaces ISO 16840-10:2014 and ISO 7176-16:2012, which have been technically revised.

The main changes compared to the previous edition are as follows:

- inclusion of the other postural support devices originally covered by ISO 7176-16:2012 rather than just seat and back support cushions;
- inclusion of integrated as well as non-integrated postural support devices;
- provision for postural support devices that are smaller than the specified test sample size.

A list of all parts in the ISO 16840 series can be found on the ISO website.

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 16840-10:2021 incorporates the following corrections:

"20 s" was corrected to "120 s" in 7.2, 7.3 and Clause 8.

Introduction

The ignition and subsequent burning of wheelchairs is very rare, but this can occur as a result of

- being close to a burning object such as a fire beside the wheelchair,
- overheating of any electrical or electronic device on the wheelchair, and
- contact from sparks or flames (such as welding sparks, cigarettes, or matches).

Wheelchair occupants are at particular risk of injury or death from these fires and resulting fumes because it is very possible that they do not have the ability to move away from the wheelchair.

NOTE In the United States, data collected in the 1990s showed that only a small number of individuals per million wheelchair users had died due to fire [$^{\text{Z}}$]. Public FDA records indicate that most 21^{st} century flammability incidents involving wheelchairs are from electrical faults [$^{\text{B}}$].

Wheelchairs can be considered to comprise the following components:

- a) structural components such as the frame, wheels, etc., that are essential to the mechanical integrity of the wheelchair;
- b) power-related components, such as motors, energy sources, controllers, etc., that are required for the functioning of powered devices on wheelchairs.
- c) integrated or non-integrated devices to manage tissue integrity, such as seat and back support cushions, that are intended to have primarily a clinical function to minimize the risks of skin damage (these can also be intended to control or accommodate posture);
- d) postural support devices, including, but not limited to, sling seats, sling back supports, arm supports, foot supports, pelvic positioning supports (hip belts), anterior trunk supports (harnesses and chest belts), lateral pelvic/trunk supports (lateral pads), etc., that are attached to the wheelchair and are primarily intended to give positioning and postural support to the wheelchair occupant (these can also be intended to aid in pressure redistribution).

Each of the above components has a different severity of risk associated with its likelihood of igniting and its resulting harm to the wheelchair occupant. This document specifies requirements and test methods to help manufacturers and purchasers of wheelchairs to design and procure wheelchairs and their components that are appropriate for the risk of ignition balanced against the functional needs of the wheelchair occupant. The aim of this document is to provide appropriate alternatives to using furniture-based flammability standards, to reflect the uses and purposes of wheelchairs and their accessories.

At the time of publication of this document, there is yet no International Standard on the resistance to ignition of structural components [see list item a) above].

The power related components [see list item b) above] are the subject of ISO 7176–14, which specifies requirements to prevent overheating in electrical components that could lead to a fire.

The tissue integrity devices [see list item c) above] and postural support devices [see list item d) above] are the subject of this document. For this purpose, using a smouldering cigarette as a standardized heat source is not necessarily a reproducible heat source, since the heat output between cigarettes from within one pack is variable, and between different packs even more so. Since the early furnishing flammability standards were introduced, filter tipped and fire safe cigarettes have evolved, and thus today, testing is not being carried out with the equivalent heat source as when the furnishing flammability standards were first drafted. The aim of this document is to describe a reproducible standardized heat source output comparable with that employed in the original flammability standards, and that can be scaled to equate with other heat sources.

The pass criteria within this document have been set at a basic minimum level and are less severe than current requirements in some countries. However, given the minimal risks of flammability as a

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hazard in wheelchair seating and the significant potentially adverse health effects of flame retardants, strong consideration should be given to utilizing this document as the ignition resistance standard for all wheelchair seating textiles/soft components that interface with the human body. Eliminating the more severe flame resistance required by furniture standards and in ISO 7176-16:2012 allows the use of more clinically appropriate textiles for the health and comfort of the wheelchair user.

Good practice is also to use materials that minimize the risk of release of toxic substances as a result of ignition and that do not pose a biocompatibility risk to the wheelchair user. The change of emphasis around the materials to use minimizes the use of toxic and hazardous flame-retardant chemicals, which is preferable due to the minimal contribution of seating system materials to fire severity. Materials chosen are required to conform to biocompatibility requirements and risk management guidance of ISO 10993–1, which includes consideration of cytotoxicity, sensitization, and irritation evaluation for surface devices in contact with the skin as covered by ISO 10993-5 and ISO 10993-10.

The day to day usage of a wheelchair can affect its materials' resistance to ignition through cyclic loading, movement of materials, washing, cleaning, etc. Manufacturers will often take this effect into account as part of their risk assessment when selecting materials for their products to minimize the effects of this normal use. However, although this document can be used on parts that have been used, etc., the test samples specify new or unused parts.

Different environments commonly encountered by some wheelchair occupants can also affect the flammability of materials. For example, home oxygen systems, delivery systems for drugs carried in an inflammable medium, etc., can turn a non-combustible material into a flammable one. Dust and other materials accumulated within the chair have also been found to be a source of readily ignitable material. Wheelchair manufacturers and occupants should be aware of these risks and should design and use wheelchairs accordingly, as covered by ISO 14971.

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Wheelchair seating —

Part 10:

Resistance to ignition of postural support devices — Requirements and test method

1 Scope

This document specifies requirements and test methods to assess the resistance to ignition by smouldering cigarette equivalent of integrated or non-integrated components of a wheelchair intended to protect tissue integrity and/or provide postural support. The electronic ignition source is also a simulation of other potential sources of environmental ignition hazards.

The tests measure only the resistance to ignition of the items tested, and not the ignitability of the complete wheelchair. It gives an indication, but cannot guarantee, the ignition behaviour of the assembled devices of a complete wheelchair.

This document does not apply to resistance to ignition of structural parts of a wheelchair. This document does not cover changes in resistance to ignition as a result of regular washing or use of the postural support devices.

This document does not apply to the control of risks created by electrical and electronic components.

This document allows for the separate testing of components of a wheelchair that are normally used in the horizontal plane (e.g. a seat cushion) from those normally used in the vertical plane (e.g. a back support). standards itch ai/catalog/standards/sist/6fdc930|-86 β -478e-910c-076bc4549aa4/so-

This document describes testing an assembly of the composite of materials as used in the component. The results of the tests in this document do not give any indication of the resistance to ignition of any of the separate individual materials of the test sample.

NOTE The intent of this document is primarily to address components that interface with the human body, such as cushions for positioning, or whose described purpose is that of protecting skin tissue against pressure, shear, and maceration related damage, as well as textile, foam, and plastic-based postural support devices.

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 554, Standard atmospheres for conditioning and/or testing — Specifications

ISO 7176-15, Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling

ISO 7176-26:2007, Wheelchairs — Part 26: Vocabulary

ISO 8191-1:1987, Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176–26 and ISO 8191–1:1987 and the following apply.

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

flaming

undergoing combustion in the gaseous phase with the emission of light

[SOURCE: ISO 8191-1:1987, 3.2]

3.2

non-integrated

detachable without the use of tools

Note 1 to entry: Seat or back support cushions held in place by hook and loop fastenings are also considered non-integrated.

3.3

postural support device

structure, attached to a wheelchair, that has a surface that contacts the occupant's body and is used either to modify or to accommodate the occupant's sitting posture

EXAMPLE seat, back support, lateral support, head support, pelvic positioning belt, anterior trunk support

[SOURCE: ISO 7176-26:2007, 4.7.3]

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3.4

progressive smouldering

exothermic oxidation, not accompanied by flaming (3.1), that is self-propagating, i.e. independent of the ignition source

Note 1 to entry: It might or might not be accompanied by incandescence.

[SOURCE: ISO 8191-1:1987, 3.1]

4 Principle

Test materials used in integrated and non-integrated seat and back support, and other postural support devices as used in wheelchairs are assembled in either horizontal or vertical samples and subjected to a heat source that is equivalent to a smouldering cigarette. The resulting effects on the test materials are observed and measured.

NOTE The tests are repeated one time to ensure that they are repeatable, but without incurring the costs of more tests than needed as a minimum

The pass criteria within this document have been set at a basic minimal level and are less severe than current requirements in some countries. Where practical, manufacturers shall use materials with superior resistance to ignition, when the overall risk analysis indicates the benefits outweigh any unintended harm, in accordance with ISO 14971.

5 Health and safety of test personnel

5.1 General

WARNING — The following test requirements call for the use of procedures that can be hazardous to health if adequate precautions are not taken.

The precautions listed in 5.2 and 5.3 are drawn from ISO 8191–1:1987, Clause 6.

Ensure that there is no hidden smouldering of the sample before disposal.

5.2 Enclosure

For safety, the tests should be conducted in a non-combustible fume cupboard. If such a cupboard is not available, a test enclosure shall be constructed (see 6.2) so that the operator is protected from the fumes.

5.3 Extinguishers

Adequate means of extinguishing the assembly shall be provided, bearing in mind that some product combinations can produce severe flaming during the test.

NOTE A hand and/or a fixed water spray that can be directed over the burning area is useful. Other means such as fire extinguishers (water and halogenated hydrocarbons), fire blankets, and a bucket of water will assist in extinguishing. In some cases, smouldering can be difficult to extinguish completely and complete immersion in water can be necessary.

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6 Apparatus

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6.1 Test righttps://standards.jteh.ai/catalog/standards/sist/6fdc9301-86f3-478e-910c-076bc4549aa4/iso-

An example of a suitable test rig is found in ISO 8191-1:1987.

NOTE The frame of the test rig described as the back frame with a width of 450 mm \pm 2 mm, but with a height of 450 mm \pm 2 mm can be used for both the horizontal and vertical tests.

6.2 Test enclosure

The test enclosure shall consist of either a room with a volume greater than $20~\text{m}^3$ (that contains adequate oxygen for testing) or a smaller enclosure with a through flow of air. Inlet and extraction systems providing air flows of 0.02~m/s to 0.2~m/s in the locality of the rig provide adequate oxygen without disturbing the burning behaviour.

NOTE This enclosure is the equivalent to that specified in ISO 8191–1:1987, 7.2.

6.3 Timer

A means of measuring time for a period of 5 s to 1 000 s with an accuracy of ± 0.1 s.

6.4 Heat source

A temperature-controlled heat source consisting of two separate parts.

- a) A heat source conforming to the following:
 - 8 mm \pm 0,5 mm diameter;
 - 75 mm ± 5 mm heated length;

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- 200 W ± 20 W heat output;
- K-type thermocouple integrated in the centre of the heat source;
- minimum wire length of 3 m;
- heat resistant wire insulation;
- a fixture to hold the heat source in place throughout the test, designed to avoid burns while handling the heat source.
- b) A temperature controller conforming to the following:
 - temperature controller with automatic identification of the control area or model based tuning of the controller parameters;
 - the temperature values follow the temperature heating curve in <u>Figure 1</u> and <u>Table 1</u> automatically during the test cycle.
- NOTE 1 Annex A provides details of an apparatus that meets these specifications.
- NOTE 2 This source has been designed to give a calorific output approximating to that of a stabilized smouldering cigarette (ISO 8191–1:1987).
- NOTE 3 By adjusting the parameters of the set point curve, this apparatus can be utilised to simulate a 'match' or other heat source.
- NOTE 4 Other means, such as a NiCr coil, that achieve the same heat transfer to the test sample, can be used as an alternative heat source.

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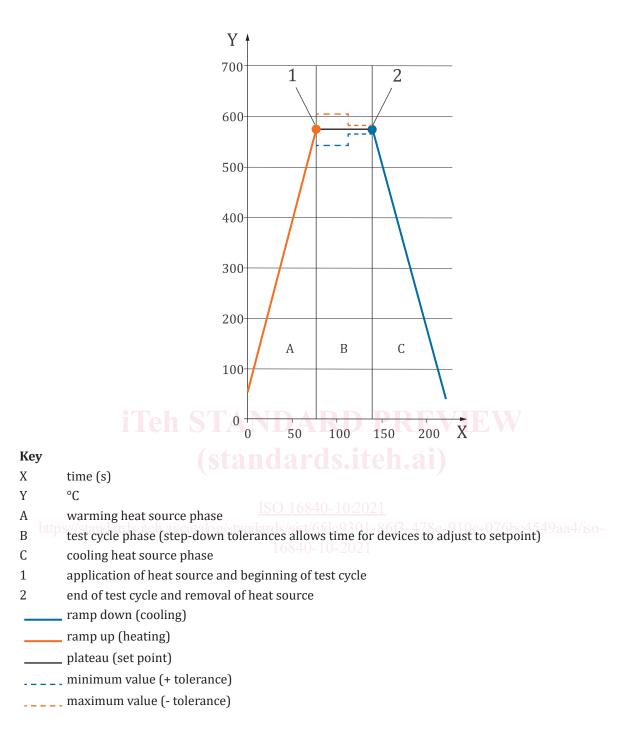


Figure 1 — Temperature-time-diagram of the test cycle with set point curve and allowed tolerances

Table 1 — Set point table for the test

	Duration	Initial set point	Final set point
Ramp	Variable	<150 °C	575 ± 30 °C
Plateau	30 s ± 1 s	575 °C ± 30 °C	575 °C ± 10 °C
Plateau	30 s ± 1 s	575 °C ± 10 °C	575 °C ± 10 °C