Safer Seating

ISO 16840-10 Flammability

December 14, 2022 ISWP



AGENDA

- 1. ISO 16840 History
- 2. Benefits / Risks of Seating and Flame Retardants
- 3. Comparison to Open Flame Standards
- 4. Publication
- 5. Evolution Hot Wire Method
- 6. Hot Wire interlaboratory validation
- 7. Addendum to ISO 16840-10 to add Hot Wire
- 8. Timing



Commitment to Test Standards





ICS > 11 > 11.180 > 11.180.10

ISO 16840-10:2021

Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method





Flammability Requirements Drive Design. Previous Restrictions:



Wheelchair Seating has Clinical Benefits, Unlike Furniture



What is safer / best for the wheelchair user?

A risk management approach was taken, considering

- Intended use as a medical device (pressure injury prevention and positioning)
- Potential compromise of function (immersion and envelopment) when FR materials are employed
- Potential health hazards from flame retardants
- Incidence rate of fire/flame events and wheelchairs
- Global shift to remove flame retardants and open flame testing for furniture
- Pressure injury risk
- Overall benefits vs risk
- NOTE: from a lab perspective, an electronic ignition source is more controllable and repeatable than an open flame or cigarette

Risk document available on ISO website

https://committee.iso.org/sites/tc173/home/library.html

Flammability Risk Report Feb 2019

2/6/19 The ISO TC 173 committee for Assistive Products for Persons with Disabilities, specifically, subcommittee SC1 Wheelchairs, and Working Group WG 11 Wheelchair Seating, wish to inform you of the challenges to adoption of the flammability testing standard ISO 16840-10 in Europe. Thank you for your consideration as we collaborate with CEN on a path to European adoption of this clinically focused safety standard.

Kara Kopplin

ISO TC 173 / SC1 / WG 11 committee member, SC1 liaison to CEN Chair, RESNA Wheelchair and Related Seating Standards Committee (ANSI, USA)

I. Introduction to ISO 16840-10

Wheelchairs -- Resistance to ignition of non-integrated seat and back support cushions

The committee TC 173 / SC / WG11 developed ISO 16840-10 after careful assessment of the potential risks and benefits that wheelchair seat and back cushions can provide an individual, as described in their "open letter on the use of cushion flammability standards". [1] The standard expresses this intention:

"The tissue integrity devices [see list item c]] are the subject of this part of ISO 16840, and permit a less stringent resistance to ignition than in ISO 7176-16, based upon the priority of these components for their clinical function, which might override the need for a high resistance to ignitability"

"c) devices to manage tissue integrity, such as seat and back support cushions which are intended to have primarily a clinical function to minimize the risks of skin damage (these may also be intended to control posture)"

II. The Problem

Although ISO 16840-10 was published in 2014, specifically for clinical wheelchair seat and back cushion technologies, tender and registration bodies continue to request furniture flammability standards such as EN 1021-1 and EN 1021-2 in 2018, particularly through the more general requirements of EN 12182, EN 12183, and EN 12184.

The work of the WG11 committee, in writing this standard, has not yet benefited the users of wheelchairs as desired.

III. Risk Considerations

In considering the intended clinical benefits of wheelchair seating, the associated risk from ignition sources, as well as unintended risks, the following are considered:

A. Intended Use / Intended Function

 Wheelchair seat and back cushion design is critical to providing skin/soft tissue protection. ISO 16840-10 states "The intent of this part of ISO 16840 is primarily to cover removable cushions whose described purpose is that of protecting skin tissue against pressure, shear, and maceration related damage.", which have been identified as key contributors to pressure injuries [2]

- Immersion and envelopment are key design strategies to provide tissue protection. Per the National Pressure Ulcer Advisory <u>Panel</u>, "Cushion construction achieves pressure redistribution in one of two basic methods: immersion/envelopment or redirection/off-loading" [2]
- Cover design is critical, as the NPUAP notes "select a pressure redistribution cushion that...has a
 stretchable cover that fits loosely on the top of cushion surface and is capable of conforming to the
 body contours" [2]
- Biocompatibility is important for the end user, with ISO 16840-10 stating "Materials chosen are to comply also with biocompatibility requirements (ISO 10993–1 and ISO 10993–10)."

B. Unintended Risks from Flame Retardants

- Stiffer Materials are typically employed to achieve the flammability resistance of open flame, furniture standards, which can limit the necessary immersion and envelopment of the body in the cushion, thereby reducing the intended benefit and limiting efficacy.
- Stiffer Cover Materials, in particular, do not allow for the recommended stretching and yielding to
 facilitate compliance of the cover and cushion combination with the body.
- Toxic chemicals, as recognized in the European Union and/or other regions of the world, are often
 employed to provide the flame resistance.
 - In 2018 The State of California issued a regulatory amendment to eliminate the use of open flame standards for furniture in public buildings, because compliance to current open flame test TB 133 presents "unnecessary health risks", further stating "by reducing the need for flame retardant chemicals, this action is anticipated to improve public health by reducing exposure to carcinogenic organohalogen flame retardants" [3]
 - Jan 22, 2019 California's Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation (Bearhfti) repealed Technical Bulletin (TB) 133 – The Flammability Test Procedure for Seating Furniture for Use in Public Occupancies. Bearhfti said TB 133 has become "obsolete" in most areas, as it overlaps with the recently updated <u>TB 117-2013</u>. Furthermore, it said, the use of organohalogen flame retardants typically used to meet TB 133 "present significant health risks to consumers, as established by overwhelming scientific research. [4]
 - In 2015 Minnesota legislators passed into law the "Firefighter and Children Health Protection Act" which prohibits the sale and distribution of children's products and upholstered residential furniture that contain more than a certain amount of one or more flame retardant chemicals named within the bill. [5]
 - The Minnesota research [4] examined numerous <u>flame retardant</u> chemicals, all of which are banned in the Cal Prop 65 list, and many are banned in the REACH Substances of Very High Concern (SVHC) list. The report cites evidence that flame retardants may present exposure and health concerns, including:
 - Crossing the placenta and passing through breast milk
 - · Altering the endocrine system, causing fluctuations in thyroid production.
 - Altering sex hormones
 - Affecting the nervous system
 - Causing uterine tumors
 - Affecting reproductive health
 - Affecting early development
 - Causing cancer

Flammability Risk Report Feb 2019

 Harmful chemicals can be released by ignition itself. ISO 16840-10 states "Good practice is also to use materials which minimize the risk of release of toxic substances as a result of ignition."

Probability of Occurrence

- Ignition of wheelchair components is extremely low as evidenced by the FDA MAUDE database of reportable events [5]. There are an estimated 3.6 million US citizens who use wheelchairs [6], and events tagged as flammability occurrences accounted for less than one one-hundredth of a percent, with at least a third being unrelated/incorrectly tagged.
- Commercially available cigarettes now have a reduced ignition propensity (RIP). The WHO reports
 "adoption of the RIP standard by US appears to be the 'principal reason for a 30% decline in smoking
 material deaths from 2003 to 2011...All 50 US States, Australia, Canada, Iceland, South Africa, and all 28
 European Union Member States have adopted policies enforcing RIP cigarettes" [7]
- Smoking as an ignition source has decreased. Per the Centers for Disease Control "cigarette smoking among U.S. adults (aged ≥18 years) declined from 20.9 percent in 2005 to 15.5 percent in 2016 [8]
- Unlike a mattress or couch, in a wheelchair seating system, the amount of material that could be
 exposed to an ignition source is extremely low, and many of those areas are vertical surfaces on which
 a flame or match could not rest.

Overall Risk Management:

- Underwriters Laboratories commented upon the California regulations, which are used throughout the
 US: "environmental advocates, health professionals and academics, expressed concern about the use of
 FR chemicals in upholstered furniture. These concerns ultimately led to an executive order from the
 California Governor instructing the BHFTI to revise California TB 117 to eliminate the need for FR
 chemicals in furniture sold in California, while at the same time not reducing the level of safety to the
 public. [9]
- ISO 16840-10 "The day to day usage of a wheelchair may affect its materials' resistance to
 ignition...Different environments commonly encountered by some wheelchair occupants may also affect
 the flammability of materials... Wheelchair manufacturers and occupants should be aware of these
 risks, and design and use wheelchairs accordingly as covered by ISO 14971"
- ISO 16840-10 "Requirements for the control of risks from sources of fire created by electrical and
 electronic components are included in ISO 7176–14" Per the MAUDE database search, electrical sources
 accounted for the vast majority of the (extremely limited) flammability incidents, [5] so this risk is
 managed through the ISO 7176-14 standard.
- MDR_Regulation (EU) 2017/745 All known and foreseeable risks, and any undesirable side-effects, shall be gioinised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. [10]

5/19 Update- Given the minimal risks of flammability as a hazard in wheelchair seating, and the significant tential health effects of flame retardants, strong consideration should be given to utilizing ISO 16840-10 as a ignition resistance standard for all wheelchair seating textiles / soft components (not just tissue integrity mponents). Eliminating the extreme flame resistance required for ISO 7176-16 compliance would allow more nically appropriate textiles to be used, for the health and comfort of the wheelchair user.

<u>Standards</u>

EN 1021-1 Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source smouldering cigarette

EN 1021-2 Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source match flame equivalent

EN 12182 Assistive products for persons with disability - general requirements and test methods

EN 12183 Manual Wheelchairs - Requirements and test methods

EN 12184 Electrically powered wheelchairs, scooters, and their chargers. Requirements and test methods

ISO 14971 Medical Devices - Application of risk management to medical devices

ISO 16840-10 Wheelchairs - Resistance to ignition of non-integrated seat and back support cushions --Part 10: Req. and test methods

ISO 7176-14 Wheelchairs-Part 14: Power and control systems for electrically powered wheelchairs and scooters - Req. and test methods

ISO 7176-16 Wheelchairs - Part 16: Resistance to ignition of postural support devices

Citations

[1] Open letter from ISO TC 173 / SC1 / WG11

https://isotc.iso.org/livelink/livelink?func=ll&objld=16468463&objAction=browse&viewType=1

[2] National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) "Prevention and treatment of pressure ulcers: clinical practice guideline." (2014). <u>http://www.npuap.org/nationalpressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-thestages-of-pressure-injury/</u>

[4] TB 133 has been repealed by California's Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation, effective January 22, 2019

https://www.sgs.com/en/news/2019/02/safeguards-02019-california-technical-bulletin-133-flammability-test-for-seating-furniture

[5] 2015 Minnesota - "Firefighter and Children Health Protection Act" (Minn. Stat. 2015 325F.071) http://www.health.state.mn.us/divs/eh/risk/studies/retardantreport.pdf

[6] U.S. FDA MAUDE database frequency of occurrence – medical device reports submitted to the FDA by mandatory reporters – (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[7] U.S. Disability Statistics and Information, 2013-05-29 (Rev. 2013-07-10)US Census Bureau https://www.disabled-world.com/disability/statistics/info.php

[8] World Health Organization report on RIP cigarettes https://www.who.int/tobacco/industry/product regulation/factsheetreducedignitionpropensitycigarettes/en/

[9] Centers for Disease Control and Prevention https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm

[10] 2014 UL Report Understanding the Changes to California TB 117 – 2013 https://industries.ul.com/wp-content/uploads/sites/2/2014/10/TB-117 Article.pdf

[11] Annex 1 General Safety and Performance Requirements MDR Regulation (EU) 2017/745 https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX:32017R0745

Q: What is the Fire Fatality rate? A: <4 per million



Calder, J., and Kirby, L. (1990). "Fatal Wheelchair-related Accidents in the United States." American Journal of Physical Medicine & Rehabilitation. 69(4): 184-190.

11 Confidential

Q: What is the Pressure Injury Fatality Rate? A: 60,000/yr in US alone



Dr. Padula's report to US Congress: Value of hospital resources for effective pressure injury prevention: a cost-effectiveness analysis:

"pressure injuries affect **2.5 million patients**, resulting in **60,000 deaths** and over \$26 billion in U.S. healthcare expenditures" *per year*

2014 Document Revised in 2021

- Wiring details clarified/corrected
- Scope expanded to be applicable to all wheelchair support surfaces
- ISO 7176-16 (open flame test for wheelchairs) replaced by ISO 16840-10:2021
- Opportunity to use other ignition sources (that achieve the temperature profile) were noted
- Standard allows NO flaming, as opposed to 2 min of flaming in other standards

Committee recommendation of ISO 16840-10 available on ISO website:

https://committee.iso.org/sites/tc173/home/library.html



Furniture vs Wheelchair Seating Flammability Standards

EN 1021-2 Open Flame

Furniture – Assessment of the ignitability of upholstered furniture. Part 2: Ignition source match flame equivalent

Test construction is unlike wheelchair. Small PSDs and pediatric devices may be excluded



15 sec flame applied (no temp given, butane, difficult to control)

F<u>laming ALLOWED for 120 sec</u>after source removed . Progressive **smouldering** allowed for **1 hr (3600 sec)**.

3.2 Flaming ignition

For 3.2 Flaming ignition

- ign ,
- ¹⁹¹¹ For the purposes of this European Standard, all the following types of behaviour are considered to be flaming a) ignitions:
- a) any test assembly that displays escalating combustion behaviour so that it is unsafe to continue the test and active extinction is necessary;
- c) b) any test assembly that burns until it is essentially consumed within the test duration;
- any test assembly on which any flame front reaches the lower margin, either side or passes through its full thickness within the duration of the test;
 - d) any flaming which continues for more than 120 s after removal of the burner tube.

ISO 16840-10 Electronic Ignition Source Wheelchair Seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method

Test applied to wheelchair PSDs, horizontal or vert. surfaces, including small PSDs and pediatric devices



60 sec 575 C controllable, repeatable ignition source applied

NO flaming is allowed.

Progressive smouldering allowed for 120 sec. (12/21 correction)

8 Requirements

In horizontal and vertical orientations, when subjected to the heat source specified in <u>6.4</u>, PSDs used in a wheelchair shall

- a) show no evidence of flaming in the interior and/or surface during or after the test, and
- b) show no evidence of progressive smouldering $20 \text{ s} \pm 1 \text{ s}$ after the end of the maximum temperature plateau of the temperature heating curve.



Tests <u>resistance</u> to ignition / flame

ISO 7176 vs ISO 16840 Wheelchair Seating Flammability Standards

ISO	71	76	-16
Оре	n	Fla	ime

Wheelchairs – Part 16: Resistance to ignition of postural support devices (replaced by ISO 16840-10)

Test applied to wheelchair PSDs, horizontal or vert. surfaces. Does not cover small PSDs and pediatric devices





ISO 16840-10 Electronic Ignition Source Wheelchair Seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method

Test applied to wheelchair PSDs, horizontal or vert. surfaces, including small PSDs and pediatric devices



20 sec flame applied (no temp given, butane, difficult to control)

Flaming is ALLOWED for **120 sec**after source removed as well as afterglow, smoking, smouldering.

Burn area <600 mm² (horizontal) or <4500 mm² (vertic...)

- 8.1 Following the test procedure specified in Clause 7, all postural support devices of the wheelchair shall:
- a) show no evidence of progressive smouldering or flaming in the interior and/or surface after 120 s after removal of the ignition source;
- b) $exhibit no burn damage area greater than 600\,\mathrm{mm^2}\,of any layer when tested in a horizontal orientation;$
- c) exhibit no burn damage area of any layer greater than $4\,500\,\mathrm{mm^2}$ when tested in a vertical orientation.

8.2 Burn damage shall include discolouration but shall exclude discolouration caused by deposition of smoke particles.

60 sec 575 C controllable, repeatable ignition source applied

NO flaming is allowed.

Progressive smouldering allowed for 120 sec. (12/21 correction)

8 Requirements

In horizontal and vertical orientations, when subjected to the heat source specified in <u>6.4</u>, PSDs used in a wheelchair shall

- a) show no evidence of flaming in the interior and/or surface during or after the test, and
- b) show no evidence of progressive smouldering $20 \text{ s} \pm 1 \text{ s}$ after the end of the maximum temperature plateau of the temperature heating curve.

Tests<u>time</u> for flame to <u>self extinguish</u>

Tests resistance to ignition / flame



This standard has been revised by ISO 16840-10:2021



European Standards and MDR

		EUR	OPEAN INN	ovat	TION PA	RTNER	SHIP	
	Commission on Active and Healthy Ageing							
European Commission > EIP on AHA > Standards > Healthcare > Personal autonomy > EN 12183:2014								
÷	About the partnership	Action Groups	Reference Sites	I2M	Blueprint	MAFEIP	Library	Nev

EN 12183:2014

Subject: Healthcare

Sub-subject: Personal autonomy

Reference: EN 12183:2014

Title: Manual wheelchairs - Requirements and test methods

Kind of resource: Standard

Year of publication: 2014

URL: http://standards.cen.eu/dyn/www/f? p=204%3A110%3A0%3A%3A%3A%3AFSP_PROJECT%2CFSP_O...

Description:

This European Standard specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not greater than 250 kg. It also specifies requirements and test methods for manual wheelchairs with electrically powered ancillary equipment. This European Standard does not apply in total to: - wheelchairs intended for special purposes, such as sports, showering or toileting, - manual wheelchairs with handrim-activated power-assisted propulsion, - custom-made wheelchairs, - stand-up wheelchairs, and - manual wheelchairs with add-on power kits used for propulsion. NOTE Requirements for electrically powered wheelchairs are specified in EN 12184.



EUROPEAN INNOVATION PARTNERSHIP

Commission on Active and Healthy Ageing									
European Commission > EIP on AHA > Standards > Healthcare > Personal autonomy > EN 12184:2014									
ŧ	About the partnership	Action Groups	Reference Sites	I2M	Blueprint	MAFEIP	Library	News	Events

EN 12184:2014

Subject: Healthcare

Sub-subject: Personal autonomy

Reference: EN 12184:2014

Title:

Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

Kind of resource: Standard

Year of publication:

2014

URL:

http://standards.cen.eu/dyn/www/f?p=204%3A110%3A0%3A%3A%3A%3A%3AFSP_PROJECT% 2CFSP_O...

Description:

This European Standard specifies requirements and test methods for electrically powered wheelchairs, including electrically powered scooters with three or more wheels, with a maximum speed not exceeding 15 km/h intended to carry one person of mass not greater than 300 kg. It also specifies requirements and test methods for battery chargers for wheelchairs and scooters. This European Standard does not apply in total to: - electrically powered wheelchairs intended for special purposes, such as sports, showering or toileting, - manual wheelchairs with handrimactivated power-assisted propulsion, - custom-made electrically powered wheelchairs, - electrically powered stand-up wheelchairs, - manual wheelchairs with add-on power kits used for propulsion and - electrically powered office chairs. NOTE Requirements for manually propelled wheelchairs are specified in EN 12183.



Publication – CEN EN 12183, EN 12184 including ISO 16840-10

ATSC Wheelchair & Related Seating

Post New Message

European Wheelchair Standards to Include ISO 16840-3 and ISO 16840-10

Reply to Group

Reply to Sender



Jul 19, 2022 3:37 PM Kara Kopplin

Dear WRS Committee Members:

On July 12, 2022, we received word that the updated European test standards for manual and power wheelchairs, EN 12183 and EN 12184, completed EU voting and were accepted for publication. ISO 16840-3 is noted in the static, impact, and fatigue testing section, and ISO 16840-10 is the preferred and referee flammability test method. It is exciting to have our international seating standards included within these EU wheelchair standards, for the very first time!

Thank you to all of you for your ongoing support developing and promoting seating standards which are critical to the health, safety, and independence of wheelchair users. Your work matters and is appreciated.

perm_obil

Aug 2022 – Updated to recommend 16840-10

EN 12184:2022 (E)

cen

EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPAISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Gentre: Rue de la Science 23, B-1040 Brussels

9.5 Resistance to ignition

9.5.1 General

The surfaces of components which support the occupant, or which stay in contact with the occupant or the occupant's clothing, shall be tested as specified in 9.5.2. Progressive smouldering ignition or flaming ignition as defined in the standard applied shall not occur.

This requirement does not apply to components of the power and control system, which are covered by 9.5.3.

It is not necessary to test components that are inherently resistant to ignition, e.g. steel frame tube.

NOTE ISO 7176-19 provides related requirements for belt-type restraints. See 8.3.

9.5.2 Test methods

9.5.2.1 Selection of test method

The test method specified in 9.5.2.2 is the preferred test method. It is the referee test method, which is used to resolve doubts or dispute.

The test methods specified in 9.5.2.3 may be used as alternatives.

9.5.2.2 Referee test method

Select and test a sample of the component as specified in ISO 16840-10:2021.

NOTE The introduction to ISO 16840-10:2021 provides a rationale for use of the test method.

9.5.2.3 Alternative test methods

Test the material of each component in accordance with EN 1021-2:2014 or ISO 8191-2:1988.





ICS > 11 > 11.180 > 11.180.10

ISO 16840-10:2021

Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method







2021 Document Allows:

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.

- Committee members had developed a coil hot wire alternative
 - Low cost
 - Readily available components
 - Ease of setup and use
- Verification of temperature output and validation to a cigarette burn confirmed within development lab at Bodypoint
- Inter-laboratory testing needed
- Testing conducted across 5 labs, with identical apparatus and methods, throughout 2022

Correlation of Temperatures to Amperage to Cigarette



Cigarette, Paper Ignition, and Wire Amperage Correlation



Interlaboratory Test Results – Paper Strip Calibration



Interlaboratory Test Results



Recommendation to WG11: Hot Wire apparatus preferred. Calibration with paper burn of 10-14 seconds

Annex to Detail Hot Wire build and Method

- Working Group secretary and convenor recommended updates be drafted based on inter-lab results. Work began at ESS in Dublin June '22
- Draft including detailed components lists, precise build instructions, and refined method presented at WG11 standards meeting in Berlin Oct '22. Group approved proceeding with Annex
- Document submitted to ISO secretariat 12/10/22 for balloting

Annex includes full details for Hot Wire Build



perm_obil







Rehabilitation Engineering and Assistive Technology Society of North America



European Committee for Standardization





Kara Kopplin

Chair, US ANSI/RESNA Standards Committee on Wheelchair and Related Seating

ISO/TC 173/ SC1 Elected Liaison to CEN ISO / TC 173 / SC1 / WG11 US Expert ISO/TC 173 / WG11 US Expert

Director of Regulatory Science, Permobil

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