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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 16840-6

Wheelchair seating — Part 6: Determination of changes in properties of seat cushions following simulated use

ICS: 11.180.10

ISO/TC 173/SC 1

Secretariat: **SABS**

Voting begins on:
2025-01-13

Voting terminates on:
2025-04-07

This document is circulated as received from the committee secretariat.

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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 01, *Wheelchairs*.

This second edition cancels and replaces the second edition (ISO 16840-6:2015), which has been technically revised.

The main changes have been to make testing less onerous and therefore more practicable. The selection of tests is to be made by the manufacturer as are relevant to the construction of the cushion and its intended use.

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.

Introduction

Wheelchair seat cushions provide improved support and injury prevention for the user. They are used by those with a variety of needs and by those with varying degrees of disability. Wheelchair seat cushions are prescribed based on the cushions' ability to perform under a range of circumstances, from intermittent use to robust sports use, or use by those with regular incontinence. Each application presents different conditions that can change the performance of the cushion and can expose the user to hidden risks. Standards for the evaluation of wheelchair cushions under a wide range of conditions are paramount.

This document describes test methods that characterize the changes in physical and mechanical properties of seat cushions based on their use and age. This document offers a suite of test methods, not all of which will be appropriate for all cushions, and therefore, the manufacturer is to determine which are appropriate for their cushion construction and use. It is designed to provide a close approximation of the changes that have been observed to occur over time. The protocol consists of performing tests to characterize the properties of a new cushion, subjecting the cushion to multiple simulated ageing processes, then re-testing the cushion properties. Changes that occur are reported.

Prior to following the protocol, the manufacturer is to recommend the environment of use of the cushion, the anticipated failure modes of the cushion, and the cushion characterization tests appropriate for their product. Just as not all tests are appropriate for all cushions, the exposures within the tests might not be appropriate for all cushions. Tests can be modified or eliminated based on suitability for materials, architecture, or use conditions, e.g. a rotational component could be added to the cyclic loading, generating additional wear. For some materials, 70 °C can change the failure mode from typical to temperature-based, depending on the material properties of this cushion. In such a case, 50 °C can be selected to accelerate the ageing of the cushion over a longer period of time to simulate a failure more typical of ageing. Any deviations are to be documented.

These tests are not appropriate for ranking or scoring cushions or for matching these characteristics directly with the requirements of individual users. While the results of these tests can aid the clinician in providing care to the patient through selection of support surface characteristics that will, in their professional judgment, aid the care, treatment, or recovery of the patient, these tests are not to be interpreted as prescriptive in and of themselves. The link to clinical efficacy, although implied, has not been validated. It is intended that this document will evolve when clinical relevance is confirmed. Further parts of the ISO 16840 series describe test methods for characterizing other support surface characteristics that can aid the clinician further in the care and treatment of patients.

Wheelchair seating —

Part 6:

Determination of changes in properties of seat cushions following simulated use

1 Scope

This document specifies apparatus, test methods, and disclosure requirements for generating ageing effects in a seat cushion that reproduce those seen in use. It provides methods of determining changes in the physical and mechanical properties of seat cushions based on their age and use. This document provides a set of tests that simulate wear and tear, which can be useful to validate warranty claims and to provide information about product, life, and performance limitations associated with product use.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 1856:2018, *Flexible cellular polymeric materials — Determination of compression set*

ISO 4892-3, *Plastics — Methods of exposure to laboratory light sources — Part 3: Fluorescent UV lamps*

ISO 9073-8, *Textiles — Test methods for nonwovens — Part 8: Determination of liquid strike-through time (simulated urine)*

ISO 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

ISO 16840-2, *Wheelchair seating — Part 2: Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity*

ISO 16840-12, *Wheelchair seating — Part 12: Envelopment and immersion characterization of seat cushions using a dual semispherical indenter*

AAMI TIR 12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*

ASTM D395-03, *Standard Test Methods for Rubber Property — Compression Set*

ASTM D4265-98, *Standard Guide for Evaluating Stain Removal Performance in Home Laundering*

ASTM F1980-07, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

RESNA SS-1:2019 Section 3, *Standard Protocol for Measuring Heat and Water Vapor Dissipation Characteristics of Full Body Support Surfaces — Body Analog Method*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16840-2 and the following apply.

3.1

column buckling

collapse of a structure resulting from a compression load

3.2

compression set

difference between the initial thickness and the final thickness of a test piece of a material after compression for a given time at a given temperature and after a given recovery time

Note 1 to entry: The difference is referred to the initial thickness.

3.3

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

SOURCE: ISO 11139:2018 3.84

3.4

permanent set

irreversible change from the original dimensions that remain after the removal of stress

3.5

failure

change in properties or a loss of integrity that inhibits the ability of a cushion to perform as intended

Note 1 to entry: Changes in properties can include fractures, leaks, delamination, seam failure, etc.

3.5.1

seam failure

change in integrity as demonstrated by one or more of

- fabric tear at a seam;
- breakage of two or more sewing threads within a 25 mm seam length;
- partial or complete slippage (“comb out”) of fabric yarns at a seam creating a gap of 5 mm or more between adjacent fabric surfaces;
- visible separation of the mating surfaces

Note 1 to entry: Separation can include partial separation, such as peeling of the edges, or a full gap between the layers extended transverse to the direction of a seam.

3.6

hysteresis

measure of the loading energy lost during a cycle of loading and unloading

Note 1 to entry: A lag in response exhibited by a material reacting to changes in force.

3.7

impact damping

characterization of a material’s ability to absorb vibration and impact

3.8

load deflection

degree to which a structural element deviates under a load