INTERNATIONAL STANDARD

ISO 16840-6

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Wheelchair seating —

Part 6:

Simulated use and determination of the changes in properties of seat cushions

Sièges de fauteuils roulants —

Partie 6: Simulation d'utilisation et détermination des changements de propriétés des coussins de sièges

(https://standards.iteh.ai)

ISO 16840-6:2015

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 173, Assistive products for persons with disability, Subcommittee SC 1, Wheelchairs.

ISO 16840 consists of the following parts, under the general title Wheelchair seating:

- Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces
- Part 2: Determination of physical and mechanical characteristics of devices intended to manage tissue integrity — Seat cushions
- Part 3: Determination of static, impact and repetitive load strengths for postural support devices
- Part 4: Seating systems for use in motor vehicles
- Part 6: Simulated use and determination of the changes in properties of seat cushions
- Part 9: Clinical interface pressure mapping guidelines for seating [Technical Report]
- Part 10: Resistance to ignition of non-integrated seat and back support cushions Part 10: Requirements and test methods
- Part 11: Determination of perspiration dissipation characteristics of seat cushions intended to manage tissue integrity [Technical Specification]
- Part 12: Apparatus and method for cushion envelopment testina [Technical Specification]

Future parts dealing with methods for determining heat and water vapour characteristics and clinical guidelines for the measurement of postural support surfaces and body segments are planned.

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 their ability to perform under a range of circumstances, from intermittent use to robust sports use, and 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 part of ISO 16840 describes test methods that characterize the changes in physical and mechanical properties of seat cushions based on their age and use. The standard 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 aging processes, then re-testing the cushion proprieties. 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 may be modified or eliminated based on suitability for materials, architecture, or use conditions, i.e. 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 may be selected to accelerate the aging of the cushion over a longer period of time to simulate a failure more typical of aging. Any deviations are to be documented.

These tests are not appropriate for ranking or scoring cushions or for directly matching these characteristics 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 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 part of ISO 16840 will evolve when clinical relevance is confirmed. Further parts of the ISO 16840 series will describe test methods for characterizing other surface characteristics that can further aid the clinician in the care and treatment of patients.

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Wheelchair seating —

Part 6:

Simulated use and determination of the changes in properties of seat cushions

1 Scope

This part of ISO 16840 specifies apparatus, test methods, and disclosure requirements for generating aging effects in a seat cushion that reproduce those seen in use. It also provides methods of determining changes in the physical and mechanical properties of seat cushions based on their age and use. This part of ISO 16840 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 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 16840-2, Wheelchair seating — Part 2: Determination of physical and mechanical characteristics of devices intended to manage tissue integrity — Seat cushions

ASTM D5672-09, Standard Test Method for Testing Flexible Cellular Materials Measurement of Indentation Force Deflection Using a 25-mm (1-in.) Deflection Technique

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 F1980-2, Standard Guide for Accelerated Aging of Sterile Medical Device Packages

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

RESNA SS-1:2011 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.

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3.1

accelerated aging

procedure to simulate normal usage by subjecting a product to stresses that are more severe or more frequent than normal environmental or operational stresses

3.2

ballooning

pillow effect created when air is trapped within a shrinking bag

3.3

bacterial enzymatic action failure

failure due to bacterial enzymatic action

Note 1 to entry: See failure (3.17).

3.4

broken seams

separation of a welded or sewn seam or the material immediately adjacent to seam

Note 1 to entry: May be a cosmetic change or a failure.

3.5

buckling

collapsing of the material due to pressure or stress

3.6

bottoming

while applying a compressive load to a cushion, the point where additional load causes the slope of the force deflection curve to approach vertical (force plotted on the *y* axis, deflection on the *x*)

3.7

creep

tendency of a solid material to slowly move or permanently deform under the influence of mechanical stress and/or elevated temperature $\frac{|SO||16840-62015}{|SO||16840-62015}$

3.8 https://standards.iteh.ai/catalog/standards/iso/b564a297-8aec-4c59-ac21-ce2a347403a0/iso-16840-6-2015

colour change

change of colour (lightness, hue, chroma, or any combination), visibly discernible by comparing the test specimen with a corresponding untested specimen from the same batch

3.9

column buckling

elastic yield or permanent yield of components with a stiff construction

3.10

compression set

amount of deformation (expressed as a percentage of original dimensions) which a material retains after compressive stress is released (per ASTM D395 B)

3.11

cosmetic change

change that affects appearance without affecting performance

3.12

cyclic loading

repeated application of degradation agents and stress over a period of time at a set frequency

3.13

disinfection

treatment to remove or to significantly reduce potentially harmful organisms

3.14

exposures

subjection of the subject material to the elements of the test

3.15

permanent set

changes from the original dimensions that remain after the removal of stress

3.16

extreme temperature exposure

highest and lowest temperature values attained during a given time interval

3.17

failure

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

3.18

fatigue

change in stiffness, loss of mechanical strength, and/or ruptures based on repeated cyclic deformation

3.19

foam disintegration

process by which foam is reduced to fragments or particles

3.20

fractures

tractures
propagation of pre-existing cracks based on stress

3.21

gross leaks

leaks that compromise the function of a material

3.22

hvsteresis

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

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

3.23

impact damping

characterization of a material's ability to absorb vibration and impact according to ISO 16840-2

3.24

laundering

washing or other process to cleanse materials of soil

3.25

leak

hole, tear, or break in a surface that allows the release of inner contents over time

3.26

load deflection

degree to which a structural element deviates under a load

3.27

load deflection and hysteresis

degree to which a structural element deviates under a load and the degree to which the deviation is delayed, according to ISO 16840-2

3.28

mechanical degradation

deterioration of materials (particularly polymeric materials) by swelling, dissolution, and chain scission