International Standard

ISO 16840-6

Wheelchair seating —

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

Sièges de fauteuils roulants —

Partie 6: Détermination des changements de propriétés des coussins de sièges après simulation d'utilisation

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Foreword

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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).

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

The main changes are as follows:

— testing has been made less onerous and therefore more practicable; this involves the selection of tests being made by the manufacturer so as to be 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. Therefore, the manufacturer is guided 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 proprieties. Changes that occur are reported.

Prior to following the protocol, the manufacturer is guided 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 test, 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.

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

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

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 medical devices intended for processing by health care facilities: A guide for 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*

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.

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

— ISO Online browsing platform: available at https://www.iso.org/obp