INTERNATIONAL STANDARD

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Wheelchair seating —

Part 12: **Envelopment and immersion** characterization of seat cushions a ng a New Market Marke using a dual semispherical indenter



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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 first edition of ISO 16840-12 cancels and replaces ISO/TS 16840-12:2015, which has been technically revised.

The main changes are as follows:

- clarification of technical ambiguities;
- the removal of a gel cap to protect the pressure sensors;
- removal of former Annex A (which addressed method adaptations for cushions that utilize offloading);
- addition of a new <u>Annex A</u> giving guidance on the estimation of uncertainty.

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 <u>www.iso.org/members.html</u>.

Introduction

This document provides details of test equipment (an 'indenter'), and a method, for the measurement of 'performance' of a wheelchair cushion intended to use immersion and envelopment to reduce local areas of pressure (by effectively supporting more tissue). Envelopment is maximized when the contact area between the support surface and the body part increases which thereby reduces the pressure across the weight bearing surface. The method as presented in this document is intended to quantify envelopment and immersion of the body by the cushion. Alternatively, the test method and resulting data can provide an indication of other cushion construction and seating and positioning strategies, such as strategic pressure offloading.

Issues related to the use of devices that measure interface pressure between the body and a support surface (e.g. a pressure mapping system) have led to the use of an instrumented indenter, which has fewer sensors, but sensors that are high quality and exhibit repeatability and accuracy and thus reliability.

In this test, the distribution of pressure across the surface of the indenter is evaluated with multiple indenter sizes and loads. The pressure sensors within the indenter are positioned at multiple elevations along the buttock form, to simulate and record the pressures experienced at the ischial tuberosities of the pelvis, the greater trochanters, and at positions along the curve of the buttocks between those anatomical markers. The review of the values at these various positions, and the variation, or lack of variation, in the readings, is an indication of the mechanics of the cushion's interaction with the body and ability to envelop and protect the tissues.

EXAMPLE A fluid filled cushion with the ability to transfer material between cells can have the potential to distribute the load to maintain consistent interface pressure regardless of the depth at which the measurement is taken, as opposed to a foam or other homogeneous surface that behaves more like a spring, in that the greater the depth of immersion, the greater the interface pressure.

The accommodation of the cushion to the changes in indenter size and load are representative of the changes in size and mass of the occupant that can occur in the life of a user or between different users. The indenters are sized to represent changes in size and shape as a user of an approximately 410 mm width cushion gains weight, and the size of the buttocks increases. The overall width of the indenters stays the same, but the size of the semi spheres changes. The loads used in this document are approximate to the 50th percentile user and are not intended to characterize envelopment or immersion under higher loading conditions, nor to assess the weight capacity of a cushion.

This document describes test methods that might not be appropriate for all cushions, and therefore the tester is responsible for determining which, if any, are appropriate for their cushion construction and use.

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Wheelchair seating —

Part 12: Envelopment and immersion characterization of seat cushions using a dual semispherical indenter

1 Scope

This document specifies apparatus, test methods, and disclosure requirements for characterization of wheelchair seat cushion immersion and envelopment properties using indenters instrumented with pressure sensors.

This document expands the characterization of products intended to manage tissue integrity (ISO 16840-2) and provides a standardized indenter for other wheelchair seating tests.

It does not provide information specific to cushion performance for a particular individual user, nor is it intended to characterize envelopment or immersion under higher loading conditions, nor to assess the weight capacity of a cushion.

This document includes a method that is specific to 220 mm and 255 mm indenters. Dimensions are provided for a 380 mm indenter to allow for extension of the method to larger patient simulation.

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 1302, Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

- ISO Online browsing platform: available at <u>https://www.iso.org/obp</u>
- IEC Electropedia: available at <u>https://www.electropedia.org/</u>

3.1

clinical offloading

reduction, removal, or transfer of pressure from one area of the body to another

EXAMPLE Reduction of pressure under the ischial tuberosities, but increased pressure on the thighs or other parts of the seated body.

3.2

cushion envelopment

ability to conform around a shape