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Wheelchair seating —

Part 12: Envelopment and immersion characterization of seat cushions 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 Annex A 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 www.iso.org/members.html.

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.

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 https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

3.3
cushion immersion
depth from an uppermost plane to which a body penetrates

3.4
cushion performance
ability to immerse and envelop

3.5
indenter
shaped item designed to simulate the shape of the buttocks area of the human body

3.6
indenter base point
lowest point on the curved surface of each of the two halves of the *indenter* (3.5)

Note 1 to entry: The base points correspond with the ischial tuberosities on the human pelvis.

3.7
indenter sensor elevation
location of sensors relative to the *indenter base points* (3.6)

4 Indenter construction

4.1 Materials

The indenter shall be constructed from hardwood or similar material that is sufficiently rigid so as not to deform when subjected to the forces required for simulating the application of a human body mass to surfaces. The indenter material shall be treated (if necessary) to minimize the effects of moisture, and shall not be adversely affected by normal laboratory testing conditions (0 °C to 35 °C; 25 % to 75 % relative humidity). Surface finish shall be at least N7, in accordance with ISO 1302, approximate average surface roughness.

4.2 Tolerances and finishes

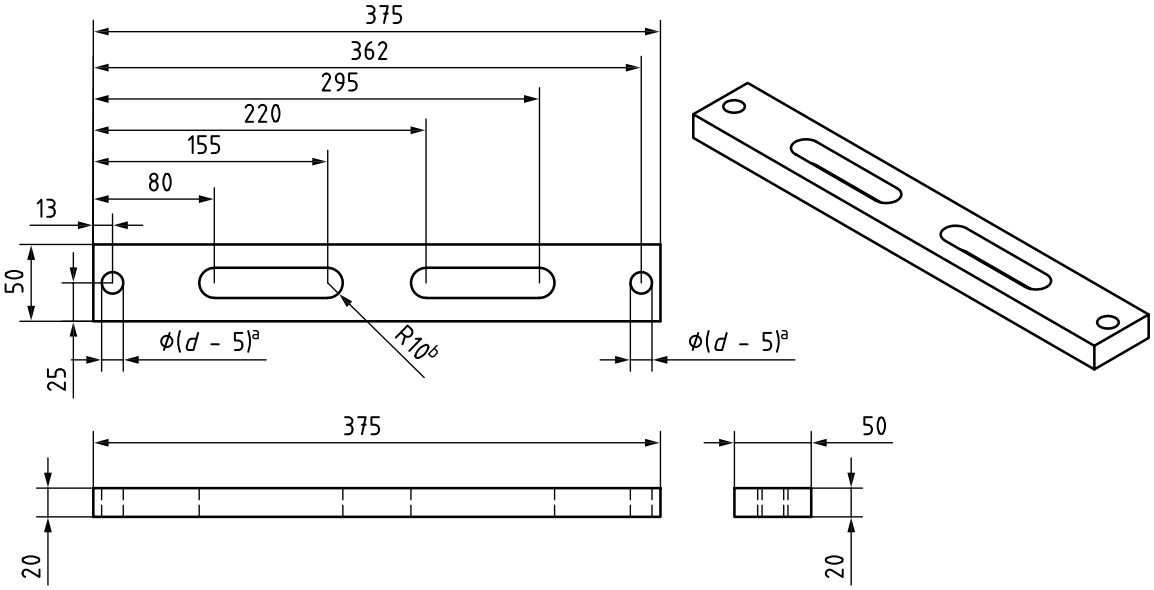
Unless otherwise stated, all dimensions in Clause 4 shall be ±0,5 mm and all edges and corners shall be finished with a minimum 5 mm radius.

4.3 Indenter elements

4.3.1 Trochanter bar

A 375 mm x 50 mm x 20 mm bar with a series of openings as shown in Figure 1. These openings are for mounting the indenter halves and trochanter blocks as well as for routing of wires.

Dimensions in millimetres



a THRU ALL.

b Typ. THRU ALL.

d is the diameter of the pressure sensor selected to meet requirements of 5.1. See 4.1 and 4.2 for materials, tolerances, and finishes.

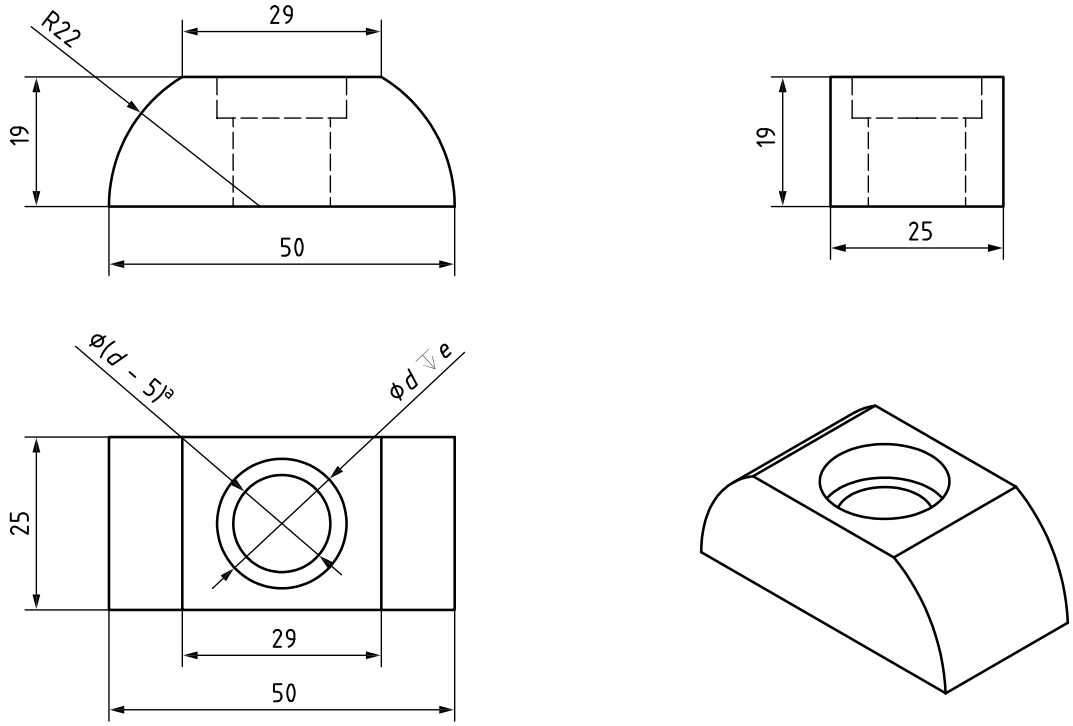
Figure 1 — Trochanter bar construction

4.3.2 Trochanter blocks

50 mm × 25 mm × 19 mm blocks as shown in Figure 2, which emulate the trochanters. Each trochanter bar shall have two trochanter blocks that house the sensors.

NOTE Trochanter bar and blocks are not required on the 380 mm indenter.

Dimensions in millimetres



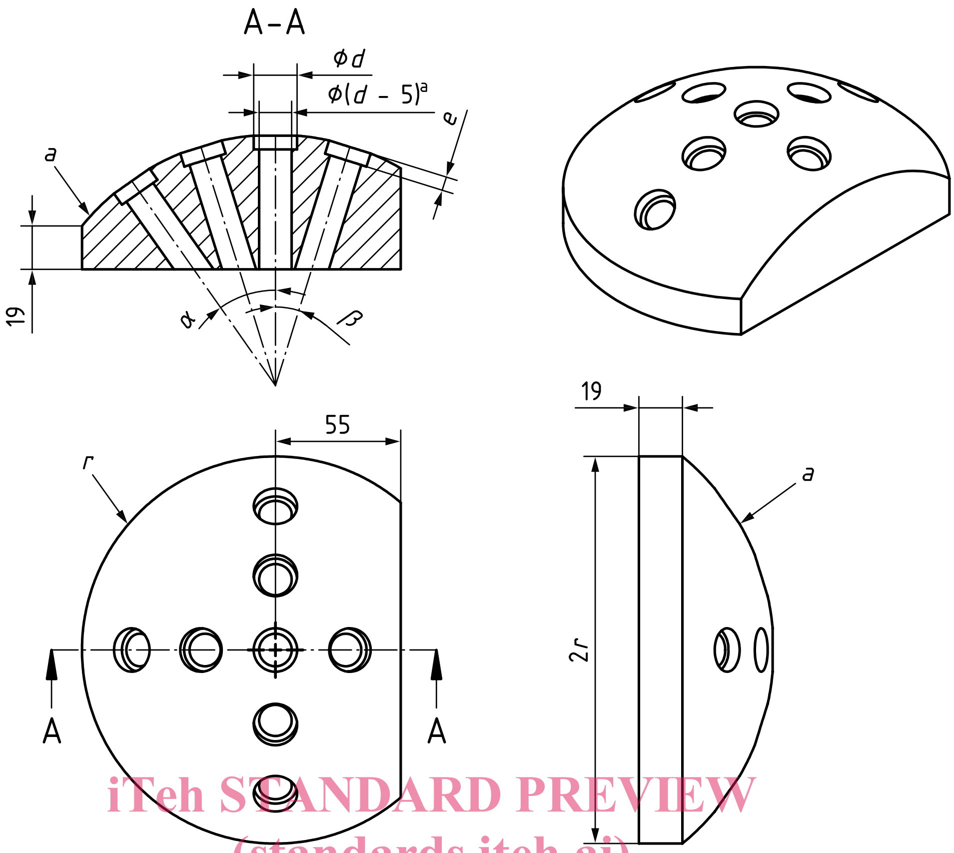
a THRU ALL.

d is the diameter of the pressure sensor selected to meet the requirements of 5.1. Sensor location depth *e* shall be such that the sensing surface is flush with the indenter surface. See 4.1 and 4.2 for materials, tolerances and finishes.

Figure 2 — Trochanter block construction

4.3.3 Semispherical indenter half

The semispherical indenter half is a portion of a sphere (see Figure 3). The sphere diameter defines the size of the indenter (e.g. a 220 mm indenter has two semispherical halves sectioned from a 220 mm diameter sphere) (see Table 1). Each half has eight sensor locations, as described in 4.5.



a	surface of a sphere with radius value of a (Table 1)
α	angle from centre sensor to farthest sensor (in all directions except cut direction)
β	angle from centre sensor to sensor adjacent to cut
d	diameter of hole for pressure sensor specified in 5.1
e	depth of hole for pressure sensor specified in 5.1
r	radius of disc
[a]	THRU ALL.

See Table 1 for dimensions. Sensor location depth e shall be such that the sensing surface is flush with the indenter surface. See 4.1 and 4.2 for materials, tolerances, and finishes.

Figure 3 — Semispherical indenter half

Table 1 — Semispherical indenter dimensions

INDENTER	*a*	*α*	*β*	*r*
220 mm	110 mm	35,0°	17,5°	85,0 mm
255 mm	127,5 mm	32,5°	16,0°	92,5 mm
380 mm	190 mm	26,5°	13,0°	128,5 mm

4.4 Indenter assembly

Assemble the indenter using appropriate fasteners that will maintain the structural integrity of the indenter in all aspects of testing. See Figure 4 for assembly drawings for the 220 mm and 255 mm indenter and Figure 5 for the 380 mm indenter.