INTERNATIONAL STANDARD

ISO 16840-6

First edition
2015-09-15

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

Reference number
ISO 16840-6:2015(E)

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Contents

Page

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 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 testing* [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.

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.

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

3.8
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
propagation of pre-existing cracks based on stress

3.21
gross leaks
leaks that compromise the function of a material

3.22
hysteresis
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

3.29
observed failure
mode by which a failure is observed to occur

EXAMPLE Ruptured bladders, broken or separated seams, gross leaks, fractures, cracking, disintegration, and extreme permanent set.

3.30
odour
detectable smell, whether fragrant or offensive

Note 1 to entry: Odour can be divided into the following categories according to intensity: "0" = no odour; "1" = very weak (odour threshold); "2" = weak; "3" = distinct; "4" = strong; "5" = very strong; "6" = intolerable.

3.31
overload deflection
additional deflection imparted by a 33 % overload

3.32
ozone exposure
exposure of materials to ozone by black lights

3.33
pressure mapping
characterization and comparison of the magnitude and distribution of forces when a surface is loaded according to ISO 16840-2 and ISO TIR WG 11

3.34
ruptured bladders
hole, tear, or break in a surface that allows the release of inner contents immediately

3.35
separated seams
see *broken seams* (3.4)

3.36
shelf life
length of time a product can be stored without deterioration

3.37
sliding resistance
characterization of the interaction between the skin and the support surface while force is applied laterally according to ISO 16840-2

3.38
stress crack
ISO 472
external or internal crack in a material caused by stresses less than its short-time mechanical strength

3.39
surface abrasion
loss of material from a surface due to frictional forces

Note 1 to entry: The result of two surfaces being rubbed together.

3.40
UV exposure
exposure of a material to ultraviolet light using black lights

4 Symbols and abbreviated terms

IFD indentation force deflection

IPSA interface pressure sensor array

RCLI rigid cushion loading indenter

5 Apparatus for characterizing and ageing cushions

To avoid duplication, the apparatus for tests normalized by reference here are described only in the referenced standard.

5.1 Apparatus for characterizing cushions

The following apparatus are associated with the related test in this part of ISO 16840.

5.1.1 Column buckling:

a) Apparatus constructed to apply a load and displacement to a 13 mm diameter glass rod indenter.

b) A 13 mm diameter glass rod, ground to a sphere on one end and mounted in a collet or other device to allow the application of force and displacement to the rod as an indenter.

c) Mechanism to record both displacement and force applied to the glass rod.

5.1.2 Heat and humidity:

A system equivalent to RESNA SS-1:2011, Section 3 (or ISO 16840-7 when published).

5.1.3 Heated indenter compression set:

Heated RCLI or chamber heated to 70 °C ± 2 °C that can maintain a cushion under compression testing at the nominal 70 °C. An indenter RCLI shall be as described in ISO 16840-2, Annex A and able to apply a constant load to the cushion over the period of the test.

5.1.4 Accelerated aging apparatus or cyclic loader apparatus:

A mechanism by which a repetitive load can be applied to a cushion by an RCLI (ISO 16840-2, Annex A).

The cyclic loader shall include a means to heat the cushion and indenter to either 50 °C or 70 °C, as required by the cushion material of construction.

5.1.5 Impact damping rigid cushion loading indenter (IDRCLI):

A means of loading a cushion using an RCLI with a uniformly distributed mass of 500 N ± 10 N with an accelerometer attached to the reference plane to measure the deceleration of the indenter as it suddenly loads the cushion, as specified in ISO 16840-2, 5.3.

5.1.6 Interface pressure measurement:

A means of applying a 500 N load to a cushion using a RCLI as defined in ISO 16840-2 and an interface pressure sensing array (pressure map). Ensure robust methods are used to reduce the variability inherent in pressure mapping.

5.1.7 Lateral and forward stiffness rig:

A means to support an RCLI at the end of a rigid shaft, allowing the RCLI to move in the lateral and forward direction on the seat cushion in one plane as described in ISO 16840-2, C.1.1 and Annex C.

5.1.8 Leak detection apparatus:

Apparatus capable of detecting the escape of a cushion fill material; this might include a water immersion tank to detect escaping bubbles, a magnifying glass, stereo microscope, or other instrument capable of inspecting seals under magnification for escaping cushion fill material.

While a microscope is not required, it can be useful in some situations.

5.1.9 Loaded contour jig (LCJ) (for loaded contour depth and overload deflection):

A means of supporting an RCLI at the end of a rigid shaft allowing the RCLI to move in the lateral and forward directions on the seat cushion in one plane as described in ISO 16840-2.

5.1.10 Rigid cushion loading indenter (RCLI) (for load deflection and hysteresis):

An RCLI as described in ISO 16840-2, Annex A.

5.1.11 Force deflection measurement:

Based on 10 mm force deflection (see ASTM D5672-09).

5.2 Apparatus for aging cushions

5.2.1 Accelerated aging chamber:

Enclosed chamber with minimal air flow to eliminate thermal gradients and means for controlling and maintaining a specific temperature within ±2 °C, as referenced in ASTM F1980-02.

5.2.2 Bacterial soiling:

Cyclic loader (described below) and incubation chamber. Polyimide bags capable of containing the cushion.

5.2.3 Cyclic loading at elevated temperature — Cyclic loading jig:

Pneumatic cyclic loading fixture with compressive loading that contains a loading indenter as specified in ISO 16840-2, with high accuracy air regulator and high resolution test gauge, capable of repeatedly applying a load of (500 ± 10) N to the material, with a cyclic rate of 20 to 40 cycles per minute.

5.2.4 Cold exposure apparatus:

Commercial chest freezer capable of maintaining a temperature of –23 °C.

Cold constriction of polymers is shown to drive out plasticizers and reduce flexibility of the polymer after it is rewarmed.

5.2.5 Means for disinfection:

Apparatus to employ in performing the disinfection process as described by the cushion manufacturer. In the absence of such instructions, a basin large enough to receive the cushion and provide for full immersion with a mechanism to maintain submersion of the cushion (weights, wire rack, bars, etc.) during the disinfection period.

5.2.6 Faecal soiling with cyclic loading:

Polyimide bag capable of containing the cushion soiled with artificial faecal soil while being aged in the cyclic loader or accelerated aging chamber.

5.2.7 Heat and humidity: 5.1.2

5.2.8 Laundering:

Washing machine capable of performing domestic level agitation or tumble style wash as described in ASTM D4265-98. Consideration shall be given to the laundry composition (i.e. washing separate or with other laundry) on the outcome of this test.

5.2.9 Urinary soiling with cyclic loading:

Cyclic loading apparatus (described above) and a polyimide bag capable of containing the cushion.

5.2.10 UV light and ozone exposure apparatus:

The design of the exposure chamber might vary but it shall meet the following criteria:

a) construction from inert material;

b) closed chamber;

c) temperature control;

d) fluorescent UV lamp with emission in the ultraviolet region of the spectrum (below 400 nanometers) that provides at least 80 % of the total light output with uniform irradiance.

6 Test environment

An environment with ambient temperature of 23 °C ± 2 °C and relative humidity of 50 % ± 5 % as specified in ISO 554. This part of ISO 16840 does not attempt to address all safety concerns. Always utilize appropriate safety equipment and conditions.

7 Preparation and setup of cushion

Obtain an unused sample seat cushion for testing. If a cover is provided, ensure that it is fitted to the cushion in the orientation specified by the manufacturer.

Precondition the seat cushion prior to each test as specified in ISO 16840-2.

8 Selection and order of testing

8.1 Testing consists of three stages

— **Stage 1** Pre-aged cushion testing includes all tests in Clauses 9 to 20. These tests may be conducted in any order. Refer to Table 1 for a list of tests.

— **Stage 2** Simulated age testing is based on the tests in Clauses 22 to 31. Refer to Clause 21 and Table 2 for the specific tests and order to be applied.

— **Stage 3** Post-aged cushion testing (repeat Stage 1 tests, Clauses 9 to 20).

Table 1 — Stage 1 List of tests

Test Name	Clause
Envelopment	9
Column buckling	10
Heat and humidity	11
Heated indenter compression set	12
Impact damping under normal conditions	13
Interface pressure measurement (pressure mapping)	14
Lateral stiffness	15
Leak	16
Loaded contour depth and overload deflection	17
Hysteresis Test	18
Sliding resistance	19
10 % force deflection	20

NOTE The tests listed in Table 1 have varying levels of validation. Some come from published standards (heat and humidity, heated indenter compression set, interface pressure measurement, loaded contour depth, and 10 % force deflection), others from widely utilized industry protocols (leak), some from peer reviewed research (envelopment, impact damping), with the remainder under multilab validation.

9 Envelopment

9.1 Rationale

This test characterizes and compares wheelchair cushions. The test applies two loads (433 N and 520 N) to each of two bulbous indenters (22 cm and 25,5 cm bulbous indenter) to the cushion and the pressure relief magnitude, immersion, and pressure distribution are examined through the use of pressure sensors mounted in a bulbous indenter loaded onto the cushion surface.

9.2 Test method and reporting

Follow the method and reporting outlined in ISO/TS 16840-12.

10 Column buckling

10.1 Rationale

This clause does not apply to cushions that comprise small free elements within a larger containment cover.

The use of columnar structures in a cushioning device, usually air or fluid filled, creates a naturally stiff element that typically cushions due to buckling or elastic deformation of the column. When buckling occurs, the column's ability to support load is drastically reduced. This process can be impacted by the structure or shape, the material of construction, or the material filling the column (air or fluid) and can be dramatically affected by the aging of the material. Before and after aging, this test is designed to characterize the buckling force, independent of the fill material.

Cushions that use membranes of material to contain air or fluids tend to harden with age; this test is sensitive in detection of that hardening. Pressure mapping and instrumented indenter testing are not as sensitive in the detection of this property. This test is applicable to any cushion technology that contains air or fluids, whether the structure consists of single or multiple cells or bladders.

10.2 Test method

a) Cut column structure from test cushion and place the individual cushion column so that the bottom of the cushion column is completely open and free standing.

b) Measure and record the height of the cushion column from the highest point to the lowest point.

c) Place the cushion column on the test table in the same orientation as when in use.

d) Apply a vertical load adequate to compress the cushion column 10 mm (±0,5 mm) at the apex of the sample. Record, at 10 Hz or faster, the force applied throughout the 10 mm deformation at 30 mm/min.

e) Release the load.

f) Record a "No Buckling" status if the column returned to full height within 5 min or record a "Buckling" status if it did not return to the full height.

g) Measure and record the height of the cushion column.

h) Repeat steps a) to g) two more times to generate three total data sets.

10.3 Method of calculation

Calculate the percentage change in height of the column.

10.4 Test report

a) Report individual buckling percentage.

b) Report median force.

c) Report all "No Buckling" and "Buckling".

d) Report any deviations from the method.

11 Heat and humidity

11.1 Rationale

The purpose of this test is to describe the heat and water vapour retention/dispersion characteristics of the test cushion. A heated indenter provides the weight, moisture, and heat for this test. This test characterizes the cushion performance in interface temperature and interface relative humidity.

11.2 Test method

When ISO 16840-7 is published, follow the test method described in that standard.

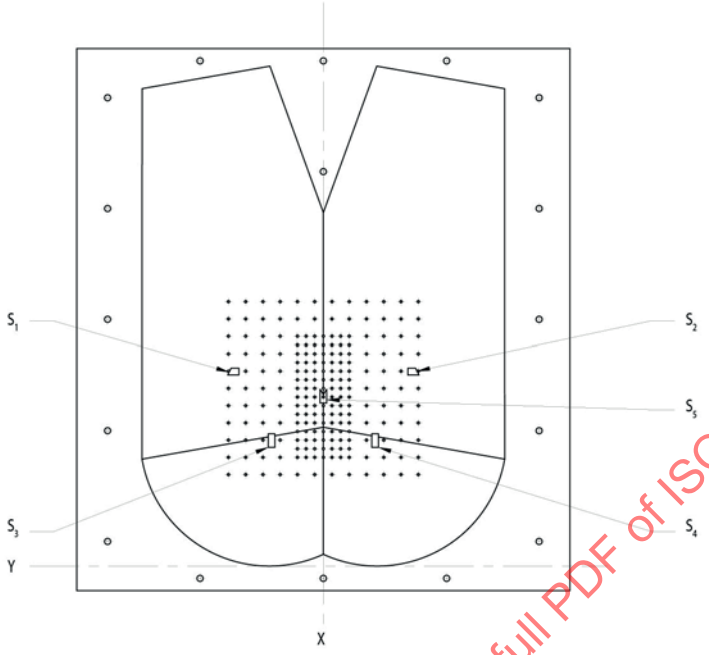
Until ISO 16840-7 is published, follow the method outlined in RESNA SS-1:2011, Section 3 with the following modifications to allow the test to be applicable to cushions:

a) Place the test cushion on a flat, horizontal surface;

b) Place five temperature/humidity sensors on/in the indenter as shown in Figure 1. One sensor is placed inside the indenter between the heated tank and the clear plexiglass indenter. Other sensors are placed on the outside of the indenter in the machined slots as indicated. Sensors are set to gather data (temperature and relative humidity) once every 30 s.

c) Place the indenter on the cushion with base points located 13 cm (±2 cm) from the rear edge of the cushion, unless the contours of the cushion require different positioning.

d) For this method, substitute 500 N (±10 N) for the vertical force.



Sensor Number	X_{loc} (mm)	Y_{loc} (mm)	Sensor location by rows and columns of holes (from top left corner)
S_1	-70	200	Row 5, Column 1,5
S_2	70	200	Row 5, Column 11,5
S_3	-55	130	Row 9, Column 3,5
S_4	55	130	Row 9, Column 9,5
S_5	0	175	Row 6,5, Column 6,5

NOTE All distances to have a tolerance of ±2,5 mm.

Figure 1 — Placement of sensors on the heated indenter

11.3 Method of calculation

Report the average temperature and humidity of three independent trials.

11.4 Test report

a) Report the values for temperature and humidity for each sensor at 0,5 h, 1,0 h, 2,0 h, and 3,0 h.

b) Plot a graph of temperature and humidity values vs. time for each sensor.

c) Report any deviations from the method.

12 Heated indenter compression set

12.1 Rationale

Elastomeric material held under a compressive load might take a compression set and when the load is released, it will not return to the original uncompressed dimension. This process is accelerated by the presence of heat.

Temperature shall be selected based on suitability for the product being tested, as advised by the product manufacturer. In some cases, 70 °C is too hot and 50 °C would be more suitable. In other cases, 70 °C is preferred due to the accelerated exposure advantage.

NOTE In collapsing foam, the loss of cellular structure and trapped air will cause the foam to conduct more heat than new foam without compression set, making this test desirable in demonstrating the change that occurs in a cushion as it ages in thermal performance.

12.2 Test method

Follow the test method described in ASTM D395, with the following modifications appropriate to wheelchair cushions:

a) Measure the cushion height at the location loaded by the base points of the heated indenter [lowest two points which represent the ischial tuberosities of a pelvis (see ISO 16840-2)];

b) Indenter is heated to 50 °C to 70 °C and allowed to equilibrate at this temperature for 60 min prior to use;

NOTE The test method also allows for use of ambient 50 °C test environment in lieu of the indenter (i.e. a test oven or chamber).

c) Position the indenter on the test cushion with the base points of the indenter 125 mm ± 10 mm forward of the rear edge of the cushion;

d) Adjust according to manufacturer's instructions, if adjustable;

e) Load the indenter to 500 N;

f) Allow the cushion and the heated indenter to remain loaded and undisturbed for 48 h;

g) Unload the cushion and allow it to recover, undisturbed, for 5 min;

h) Measure the cushion height at the base points.

12.3 Method of calculation

Subtract the end of test height from the beginning height and divide the result by the beginning height giving the percent compression set.

12.4 Test report

a) Report the percent compression set as calculated above.

b) Report any deviations from the method.

13 Impact damping under normal conditions

13.1 Rationale

This test identifies the characteristics of a wheelchair cushion that reduce impact loading of tissues and help to maintain postural stability. The cushion's ability to absorb vibration and impact decreases peak pressures associated with impact loading, such as rolling off a curb or other obstacle. Impact damping is related to hysteresis (see Clause 18).

13.2 Test method

a) Perform testing and calculations according to ISO 16840-2.

b) Report any deviations from the method.

14 Interface pressure measurement test (pressure mapping)

14.1 Rationale

Interface pressure measurements (pressure mapping) characterize the magnitude and distribution of forces when a cushion is loaded. Pressure mapping is being presented here as an option due to its ubiquitous availability.

14.2 Test method

a) Calibrate the IPSA device as per manufacturer's instructions.

b) Insert the cushion underneath the RCLI.

c) Position the cushion so that the sides are centred within the test fixture. The base points of the RCLI shall be 125 mm ± 10 mm from the rear edge of the cushion.

d) Place the calibrated IPSA device on top of the cushion, symmetrically of the midline of the RCLI, so that the rear sensor row is located against the rear of the cushion.

e) Select IPSA instrumentation options so that

   1) no averaging of sensor outputs is performed, and

   2) hysteresis and creep correction algorithms are activated.

f) Activate the IPSA instrumentation to sample at least one pressure sensor array data set per second.

g) Apply 500 N ± 10 N vertical load to the cushion for 60 s ± 2 s.

h) Record the pressure values produced by the pressure sensor array for the frame corresponding to the 60 s of loading.

i) Release the load.

j) Reset the cushion after each test by flattening or kneading.

k) Repeat c) to j) a total of five times.

14.3 Method of calculation

14.3.1 The base point zones are squares around each base point, 110 mm wide by 110 mm deep (12 100 cm^2 each), each centred 130 mm forward of the rear of the cushion, and 55 mm lateral to the centre-line. Identify the highest pressure area produced by the IPSA device in these zones.

14.3.2 The central rear zone is the area posterior to the base point zones.

14.3.3 Calculate the peak pressure index for the right and left base point zones by averaging the highest pressure value with the four sensor readings at the corners surrounding the peak (average of five values).

14.3.4 Calculate the following:

a) Total force: The sum of the pressure readings multiplied by the sensing area of the pressure mapping system. The five trial mean is calculated for this value and is expressed in Newtons;

NOTE Check that the total force is within ±10 % of the force applied to the seat cushion by the indenter. If it is not within ±10 %, the test results are not valid.

b) Percent total force: The total force in each zone divided by the total force for the whole seat cushion. This is calculated for three zones: the left base point zone, the right base point zone, and the central rear zone. The five trial mean is calculated for each of these three values;

c) Dispersion index: The sum of the pressure readings in the base point zones and divided by the sum of all pressure readings expressed as a percentage. The five trial mean is calculated for this value;

d) Contact area: The area of a pressure map of a cushion where the IPSA sensors display values of 5 mmHg or greater. The mean of this value from five trials is calculated;

$$C = A \times N_{\geq 5mmHg} \quad (1)$$

where

C is the contact area, in mm^2;

A is the area per sensor, in mm^2;

$N_{\geq 5mmHg}$ is the number of sensors displaying pressure readings 5 mmHg or greater.

14.4 Test report

a) Report the results of the calculations in 14.3.4.

b) Report any deviations from the method.

15 Lateral stiffness

15.1 Rationale

Measurements of lateral or forward stiffness characterize the interaction between the cushion and the skin following slight perturbations in the horizontal forces at the interface between the seat cushion and the buttocks. The cushion's ability to deform in response to these horizontal forces from slight body movements is based upon the theory that skin integrity is adversely affected by high shear strain. Lateral and forward stiffness can affect tissue integrity even if the pelvis does not move. A cushion that allows the soft tissue to move and relax without shear stress promotes integrity. However, stability could be reduced if the horizontal stiffness is decreased. Therefore, a cushion with high horizontal stiffness will be more stable but will impart more deformation and shearing to tissue with slight perturbations. A low horizontal stiffness cushion will not impart as much deformation and shearing but might be less stable for the user.

15.2 Test method

Perform testing as outlined in ISO 16840-2, Annex C.

15.3 Method of calculation

Determine the average force (F_{60}) at 60 s using the following:

$$\bar{X}\ F_{60} = \left(\frac{\sum \left(F_{60\ \#1}, F_{60\ \#2}, F_{60\ \#3} \right)}{\text{number of tests}} \right) \quad (2)$$

15.4 Test report

a) Report the average force calculated in 15.3.

b) Report any deviations from the method.

16 Leak

16.1 Rationale

Leaks that occur due to aging shall be functionally repairable according to manufacturer's instructions.

16.2 Test method

Air-containing cushions perform the following:

a) Over-inflate the cushion to locate pinholes or fractures that could leak;

b) If necessary, immerse the cushion in water to locate the leak(s);

c) Mark the leak(s);

d) Deflate the cushion and allow to dry thoroughly;

e) Clean and dry the area around the leak(s);

f) Apply self-adhesive patch(es), making sure there is a good seal.

Cushions containing fill materials other than air shall perform testing according to manufacturer's instructions.

16.3 Test report

a) Report location of leak.

b) Report total number of leaks found, number repaired, and number unrepairable.

c) Report any deviations from the method.

17 Loaded contour depth and overload deflection

17.1 Rationale

The ability of a cushion to maintain tissue integrity relates to its ability to envelop the pelvis. It is also important for the user to maintain a margin of safety in cushioning effect before an overload condition is experienced. Certain functional movements such as leaning and reaching effectively overload an aspect of the cushion. These events might exceed the margin of safety. The overload test measures the amount of deflection resulting from an increase in load of 33 % over the loaded test. A cushion that has been loaded beyond the margin of safety is identified when an increase in load does not produce a commensurate increase in deflection that is more than 5 mm.

This test characterizes the following cushion capabilities:

a) the ability to contour, taking into account the initial contour and contouring produced by loading;

b) the ability of the cushion to withstand overloading conditions.

17.2 Test method

Perform testing according to ISO 16840-2.

17.3 Method of calculation

a) Perform calculation and reporting according to ISO 16840-2.

b) Report any deviations from the method.

18 Hysteresis test

18.1 Rationale

The hysteresis test provides information about the hysteresis characteristics of a seat cushion. Hysteresis is a measure of the energy lost to the cushion during a cycle of loading and unloading. Hysteresis is often related to impact damping (Clause 13). Cushions with larger hysteresis values will tend to absorb energy when used on rough surfaces or when dropping down steps, rather than transfer the impact energy to the user's tissues.

18.2 Test method

a) Perform testing, calculations, and reporting as specified in ISO 16840-2.

b) Report any deviations from the method.

19 Sliding resistance

19.1 Rationale

The sliding resistance test reflects the surface and bulk characteristics of the wheelchair cushion. Sliding resistance assists a user's ability to maintain an upright posture. A low sliding resistance enhances the user's ability to slide out of the cushion for transfer. The forces of gravity and the backrest might combine to nudge a person forward and out of the chair. This sliding tendency can have detrimental effects on both function and pressure distribution. Quantifying the sliding resistance of a cushion helps to define how the cushion performs in these respects. Sliding resistance is related to the frictional characteristics of the cushion.

19.2 Test method

Perform testing as outlined in ISO 16840-2, C.3.

19.3 Method of calculation

Determine the average peak force (Fm) using Formula (3):

$$\bar{X}\ F\mathrm{m} = \left(\frac{\sum \left(F\mathrm{m}\#1, F\mathrm{m}\#2, F\mathrm{m}\ \#3 \right)}{\text{number of tests}} \right) \tag{3}$$

19.4 Test report

a) Report the average peak force calculated in 19.3.

b) Report any deviations from the method.

20 10 % force deflection

20.1 Rationale

The elastic deformation of a cushion under the load of a body is the characteristic that represents "cushioning". This is represented by force applied to an area and the measurement of the resulting deflection. The plotting of this curve or its measurement at specific deflections allows a relative comparison of a material's ability to "cushion" the body that is compressing it. This test measures the surface effect of ageing, which is the earliest indication of how the cushion might age.

20.2 Test method

Apply the method specified in ISO ASTM D5672-03, with the exception of applying a 10 % force deflection, which would be 10 mm, on a 100 mm cushion, using the cushion height in the specific test area.

20.3 Method of calculation

a) Apply calculation specified in ISO ASTM D5672-03.

b) Report any deviations from the method.

21 Stage 2: Simulated age testing

Identify which category from Table 2 most closely fits the intended use of the cushion. Conduct specified tests in Clauses 22 to 31 in the sequence shown in Table 2 according to recommended use environments.

Certain tests might be inappropriate for some materials or architectures. For example, cushions containing hydrogels might outgas (volatilize components) at 70 °C or they might be irreversibly damaged. Materials that soften or degrade with elevated temperature shall be tested at 50 °C, with longer exposure times as outlined in each test. Testing shall reflect the characteristics of the materials of construction.

NOTE While data are not available correlating these aging exposures to actual time periods, they are intended to represent 12 months of exposure, with the exception of the robust utility and incontinence environments, which represent two years.

Table 2 — Aging exposures

Simulated exposure environment (see Note)	Aging exposures by Clause (to be performed in sequence)
Typical minimum testing	**26, 25, 22, 29, 23, 27, 26, 30, 29, 28**
Intermittent use without incontinence	26, 25, 22, 29, 23, 26, 31, 28
Wet environment (shower/toileting)	26, 25, 22, 23, 27, 26, 30, 28, 25, 22, 28
Perspiration (sport or hot environment)	26, 25, 22, 29, 23, 27, 26, 30, 31, 28
Incontinence (faecal and/or urinary)	26, 25, 22, 29, 23, 27, 29, 26, 29, 30, 29, 23, 26, 29, 30, 29, 28
Heavy use (including outdoor)	29[a], 26, 25, 22, 23, 27, 29, 26, 30, 31, 28, 24, 29
Extremes of climate: hot	26, 25, 22, 29, 23, 26, 29, 28, 25, 22, 28
Extremes of climate: cold	26, 25, 22, 29, 23, 27, 26, 30, 29, 24
Utility (multiple environments during normal daily use)	26, 25, 22, 29, 23, 27, 26, 30, 29, 31, 28, 24
Robust utility (incontinence with heavy use, washing and disinfection)	26, 25, 22, 29, 23, 27, 26, 30, 29, 23, 27, 26, 30, 29, 31, 28, 24
Hybrid (minimum plus special case)	Minimum plus manufacturer's special case

[a] Laundering is utilized to remove any manufacturing surface treatments prior to testing, thus exposing the cushion system to a more arduous test during heavy use.

NOTE 1 The protocols listed are examples of tests based on manufacturer's recommended use.

NOTE 2 Table 2 was developed by WG 11 experts during the early development phase of this part of ISO 16840 (2007) based on existing protocols and experience, and then formed the basis for subsequent test processes. Work to validate this through multiple interlab or research protocols is encouraged.

22 Accelerated aging

22.1 Rationale

The accelerated aging chamber provides a means of simulating and accelerating the aging process such that age-related degradation can be observed in a shortened time frame.

NOTE This part of ISO 16840 follows the guidance of established regulatory bodies, which recommend simulated age testing as described above. In the absence of other broadly material aging methods, recommendations are to limit test temperature options as described.

22.2 Test method

22.2.1 70 °C accelerated aging procedure

a) Place the cushion in the accelerated aging chamber maintained at (70 ± 2) °C with ample room for air to circulate around the cushion.

b) Set temperature sensors to record temperatures once every 30 s.

c) Leave cushion in the accelerated aging chamber for 11 d [approximately one year simulated use (see ASTM F1980-2)].

d) Remove and inspect for signs of degradation.

22.2.2 50 °C modified accelerated aging procedure (for cushions made with hydrogels or other materials not intended for high temperature exposure)

a) Place the cushion in the accelerated aging chamber maintained at (50 ± 2) °C with ample room for air to circulate around the cushion.

b) Set temperature sensors to record temperatures once every 30 s.

c) Leave cushion in the accelerated aging chamber or analogous chamber capable of maintaining (50 ± 2) °C for 33 d [approximately one year simulated use (see ASTM F1980-2)].

d) Remove and inspect for signs of degradation.

22.3 Method of calculation

Examine the cushion for observed failures, cosmetic failures, functional failures, and bacterial enzymatic action failures, including but not limited to ruptured bladders, broken or separated seams, gross leaks, fractures, cracking, disintegration, extreme permanent set, abrasions, adhesions, degradation, odours, or colour change.

Gather data from temperature probe.

22.4 Test report

a) Plot the data (temperature and time).

b) Report temperature used during the exposure process.

c) Report any failure mode(s).

d) Report any deviations from the method.

23 Bacterial soiling

23.1 Rationale

This procedure provides a method of preparing and applying bacterial cultures to wheelchair cushions with intent to approximate bacterial and enzymatic degradation during the aging process.

NOTE Follow universal precautions, wear safety glasses, gloves, and other protective devices as prescribed.

23.2 Test method

23.2.1 Preparation of bacterial soiling broth

a) Prepare bacterial soil by thawing the following eight frozen bacterial stock cultures with their accompanying American Type Culture Collection (ATCC) numbers:

— *Escherichia coli:* 25922;

— *Pseudomonas aeruginosa:* 27853;

— *Staphylococcus aureus*: 25923;

— *Shigella boydii:* 9207;

— *Proteus mirabilis*: 25933;

— *Enterococcus faecalis*: 19433;

— *Bacillus subtilis:* 6051;

— *Staphylococcus epidermidus:* 14990.

b) Transfer the entire volume of each separate bacterial culture shipping vial to individual sterile culture vials and dilute each one 10:1 with Trypticase Soy Broth (TSB).

c) Mix thoroughly.

d) Incubate at 35 °C (±2 °C) for 24 h with regular agitation.

e) Transfer 5 (±0,1) ml of each bacterial culture to separate sterile flasks with 45 (±5) ml TSB and incubate for another 24 h. At the end of the second 24 h period, individual cultures shall be turbid containing 10^5 bacteria/ml to 10^7 bacteria/ml.

f) Combine all eight cultures in a sterile glass flask and mix thoroughly.

NOTE When refrigerated, bacterial soiling broth can be used for up to one week.

23.2.2 Bacterial exposure

a) Cyclically load cushion with 500 N (±10 N) for 1 000 cycles at 50 °C (±5 °C).

b) Remove cushion from cyclic loader.

c) Place the seat cushion into an open containment bag.

d) Pour 80 ml (±2 ml) of bacterial soiling broth onto the seat cushion at the midline of the cushion 13 cm to 15 cm from the back of the cushion.

e) Seal bag and incubate bagged cushion at 35 °C (±2 °C) for 24 h.

f) Remove from incubator and place in cyclic loader at 50 °C (±5 °C).

g) Begin a 24 h period of incubation at 50 °C (±5 °C) while loading with 500 N (±10 N) for 1 000 cycles at 50 °C.

h) Following cyclic loading, incubate the bagged cushion for the remainder of the 24 h incubation period.

NOTE Total time (during loading and in incubator) at 50 °C (±5 °C) is 24 h.

i) Inspect the cushion for wear or damage and record observations.

j) Remove the cover from the cushion and inspect the cushion's internal components.

k) Repeat a) to i) eight times (approximately one year of soiled aging).

23.3 Method of calculation

Examine the cushion for observed failures, cosmetic failures, functional failures, and bacterial enzymatic action failures, including but not limited to ruptured bladders, broken or separated seams, gross leaks, fractures, cracking, disintegration, extreme permanent set, abrasions, adhesions, degradation, odours, or colour change.

23.4 Test report

a) Report any failure modes after each test.

b) Report any deviations from the method.

24 Cold exposure

24.1 Rationale

This procedure simulates the alternating hot and cold temperatures experienced in many climates during the life of a wheelchair cushion.

24.2 Test method

a) Cyclically load cushion with 500 N ± 10 N for 20 000 cycles at 70 °C ± 5 °C.

NOTE Use 50 °C ± 5 °C and 30 000 cycles for cushions not intended for high temperature exposure.

b) Place the cushion in the cold exposure apparatus at –23 °C ± 2 °C for 24 h.

c) Monitor the cushion's temperature throughout the cold exposure with a temperature probe set to take samples once every 30 s.

d) Inspect the cushion for signs of degradation. If a repair kit is included and degradation can be repaired such that function is restored, repair and proceed with test. Note that cushion was repaired.

e) Repeat as required by cushion performance requirements.

24.3 Method of calculation

Examine the cushion and cover for observed failures, cosmetic failures, and functional failures, including but not limited to ruptured bladders, broken or separated seams, gross leaks, fractures, cracking, disintegration, extreme permanent set, abrasions, adhesions, degradation, odours, or colour change.

Gather data from temperature probe.

24.4 Test report

a) Plot the data (temperature and time).

b) Report temperature used during exposure process.

c) Report temperature used during cyclic loading process.

d) Report total number of cycles completed.

e) Report any failure modes after each test, including those that were repairable.

f) Report any deviations from the method.

25 Cyclic loading at elevated temperature

25.1 Rationale

This procedure simulates repeated loading and unloading at elevated temperatures.

25.2 Test method

a) Heat the cyclic loading rig to 70 °C ± 5 °C.

b) Place the cushion in the cyclic loader.

c) Apply a vertical load of 500 N ± 10 N to the cushion.

d) Remove the load entirely from the cushion.

e) Repeat c) and d) for a total of 17,500 cycles (approximately one year loading use).

NOTE Use 50 °C ± 5 °C and 30 000 cycles for cushions not intended for high temperature exposure.

25.3 Method of calculation

Examine the cushion for observed failures, cosmetic failures, functional failures, and bacterial enzymatic action failures, including but not limited to ruptured bladders, broken or separated seams, gross leaks, fractures, cracking, disintegration, extreme permanent set, abrasions, adhesions, degradation, odours, or colour change.

25.4 Test report

a) Report temperature used during cyclic loading process.

b) Report number of cycles completed.

c) Report any failure modes.

d) Report any deviations from the method.

26 Disinfection

26.1 Rationale

This procedure simulates normal disinfection that is necessary during the lifetime of wheelchair cushions.

26.2 Test method

Remove the cushion cover and disinfect both cover and cushion per manufacturer's instructions. If no instructions are provided, disinfect as follows.

26.2.1 Cover of cushion disinfection

For home use, launder according to ASTM D4265-98 using 60 ml (1/4 cup) sodium hypochlorite bleach as a bacterial disinfectant.

Repeat as required by the test exposure list (see Table 2).

For institutional use, launder according to Center for Disease Control (CDC) Guidelines for Environmental Infection Control.

Centers for Disease Control Morbidity and Mortality Weekly Report: Recommendations and Reports June 6, 2003/52 (rr10);1-42 "Guidelines for Environmental Infection Control in Healthcare Facilities — Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)" Available online: www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

26.2.2 Interior cushion disinfection

a) Mix 60 ml sodium hypochlorite bleach with approximately 20 l room temperature potable water.

b) Submerge cushion completely so that all bubbles are released.

c) Soak for 10 min ± 1 min and rinse with room temperature potable water.

d) Hang to drip dry.

e) Repeat as required by the test exposure list (see Table 2).

f) Report any deviations from the method.

27 Faecal soiling with cyclic loading

27.1 Rationale

This procedure provides a method of preparing and applying simulated faecal soil to wheelchair cushions to approximate degradation during normal use.

27.2 Test method

a) Prepare Hucker artificial soil as per AAMI TIR 12.

b) Warm soil (using oven or microwave) to 37 °C ± 2 °C.

c) Spread 25 ml ± 2 ml of Hucker artificial soil on the top of the cushion at the midline, 11 cm to 15 cm from the back of cushion.

d) Place the cushion inside a contamination control bag.

e) Cyclically load for a total of 1 000 cycles at 70 °C ± 5 °C using 500 N ± 10 N.

NOTE Use 50 °C (±5 °C) and 30 000 cycles for cushions not intended for high temperature exposure.

f) Remove cushion from cyclic loader and contamination control bag.

g) Inspect for signs of degradation.

h) Repeat as required by the test exposure list (see Table 2).

27.3 Method of calculation

Examine the cushion for observed failures, cosmetic failures, functional failures, and bacterial enzymatic action failures, including but not limited to ruptured bladders, broken or separated seams, gross leaks, fractures, cracking, disintegration, extreme permanent set, abrasions, adhesions, degradation, odours, or colour change.

27.4 Test report

a) Report total amount of faecal soil used.

b) Report temperature used during cyclic loading process.

c) Report number of cycles completed.

d) Report any failure modes that were noted after test.

e) Report any deviations from the method.

28 Heat and humidity

28.1 Rationale

The heat and humidity method is the same method from Stage 1 (Clause 11). It is used in Stage 2 as an aging exposure, rather than to determine the retention and dispersion characteristics of the cushion. Here, the procedure simulates exposure to heat and moisture during the life of the cushion.

