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Technical Specification

ISO/DTS 16840-15

Wheelchair seating —

Part 15:

Selection, placement and fixation of flexible postural support devices in seating

ISO/TC 173/SC 1

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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 document 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*.

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.

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Introduction

Postural support devices, such as positioning supports, are typically used to provide increased postural stability and/or to maintain or correct the occupant's posture, in order to help maintain and increase day-to-day functionality for the individual. Postural support devices can also help to reduce the development of skeletal deformities, or to correct them. These devices, having postural support purposes, are not to be confused with belts and similar devices designed to act as vehicular occupant restraints. Postural support devices may improve the occupant's safety in other ways, especially when used to prevent falls in or out of the seating system.

In the US, Axelson reported that deaths from strangulation had occurred due to wheelchair occupants slipping down in their chairs as a result of inappropriate placement of pelvic positioning belts^[1]. In the UK, the records of the MHRA (Medicines and Healthcare Products Regulatory Agency) show that, over a 15-year period, there had been four reported deaths and 17 serious injuries involving, or attributed to, pelvic postural support devices or anterior trunk postural support devices. These deaths are thought to have occurred as a result of inappropriate placement or adjustment of the supports, or their failure.

There appears to be confusion as to best practice in the selection and fixation of flexible postural support devices (e.g. the updated MHRA recommendations in the UK^[2]), and the reasons why postural supports need to be placed and adjusted according to the occupant's needs. This document has been produced to specify these criteria to be applied to positioning supports when used in seating systems and chairs, including wheelchairs and bathroom equipment (such as shower chairs), and, where applicable, hoists. This document has been created to support clinicians, engineers, carers, manufacturers, retailers and repairers.

NOTE 1 In this document, nomenclature has been based on ISO 7176-26 and ISO 16840-1. Thus, a support described as a positioning support can have the name adapted to include a description of its function based on the part of the body to which it is applied: e.g. a pelvic positioning support helps to position the pelvis, but might not be applied directly to the pelvis (e.g. the thighs) to achieve this. On the other hand, an anterior pelvic support would be applied anterior to the pelvis.

NOTE 2 Positioning support placement can differ based on clinical and risk assessment.

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Wheelchair seating —

Part 15:

Selection, placement and fixation of flexible postural support devices in seating

1 Scope

This document specifies requirements for the selection, placement and fixation of flexible postural support devices within seating devices and systems and to chairs, including wheelchairs and bathroom equipment. Seating devices can be involved in one or more situations, including hoists, static seating, wheelchair seating, shower chairs, etc. The devices enable the seated person (the occupant) to be positioned to maximize their functional activities in a safe environment. These requirements are formulated to achieve a balance of posture maintenance and safety.

This document covers flexible positioning supports (padded or otherwise) used for postural positioning and/or safety. It does not cover belts and harnesses used in transportation for restraint, postural support devices made from rigid materials such as metal, wood, or hard plastics, or postural support devices designed solely for use in sports-related seating.

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 7000:2019, *Graphical symbols for use on equipment — Registered symbols*

ISO 7176-26:2007, *Wheelchairs — Part 26: Vocabulary*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 16840-1, *Wheelchair seating — Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces*

ISO 16840-3, *Wheelchair seating — Part 3: Determination of static, impact, and repetitive load strengths for postural support devices*

ISO 16840-10, *Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method*

3 Terms, definitions, and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007, ISO 16840-1, 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>

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

3.1.1 support

3.1.1.1 anterior support

postural support device (3.1.5.2) intended to contact the anterior surface of a body segment

EXAMPLE Anterior head support, anterior lower leg support, anterior pelvic support, anterior shoulder support, anterior trunk support, and anterior upper arm support.

Note 1 to entry: The anterior surface is based on the anterior surface when the person is seated in a typical upright sitting position.

Note 2 to entry: The term can include the part of the anatomy receiving the support.

Note 3 to entry: The following are deprecated terms: anterior head strap, forehead strap, forehead support, headband, knee block, knee strap, lap belt, pelvic stabilizer, pelvic strap, safety belt, seat belt, sub-ASIS bar, backpack strap, shoulder bar, shoulder hook, shoulder retractor, shoulder strap, anterior thoracic support, butterfly strap, butterfly harness, chest harness, chest strap, H-strap, harness, spiderman strap, Y-strap, humeral strap.

[SOURCE: ISO 7176-26:2007, 4.7.23, modified — Examples and Notes to entry have been updated.]

3.1.1.2 circumferential support

postural support device (3.1.5.2) which supports a body segment on at least three sides from at least three directions

EXAMPLE Circumferential ankle support, circumferential chest support, circumferential neck support, and circumferential wrist support.

Note 1 to entry: The term can include the part of the anatomy receiving the support.

Note 2 to entry: The following are deprecated terms: ankle strap, cervical collar, circumferential cervical support, collar, Houdini strap.

[SOURCE: ISO 7176-26:2007, 4.7.29, modified — Examples and Notes to entry have been updated.]

3.1.1.3 inferior support

postural support device (3.1.5.2) intended to contact the inferior surface of a body segment

EXAMPLE Inferior lower leg support, inferior pelvic support, and inferior thigh support.

Note 1 to entry: The inferior surface is based on the inferior surface when the person is seated in a typical upright sitting position

Note 2 to entry: The term can include the part of the anatomy receiving the support.

Note 3 to entry: The following are deprecated terms: stump support, obliquity pad, thigh wedge.

Note 4 to entry: An inferior support usually applies to the buttocks and thighs, and is used with, or as part of, a seat cushion.

[SOURCE: ISO 7176-26:2007, 4.7.28, modified — Examples and Notes to entry have been updated.]

3.1.1.4 lateral support

postural support device (3.1.5.2) intended to contact the lateral surface of a body segment

EXAMPLE Lateral head support, lateral knee support, lateral lower leg support, lateral pelvic support, lateral trunk support, lateral upper arm support, and lateral thigh support.

Note 1 to entry: The term can include the part of the anatomy receiving the support.

Note 2 to entry: The following are deprecated terms: head side support, lateral headrest, adductor pad, adductor strap, calf strap, calf support, leg block, leg guide, leg pad, leg strap, leg rest pad, hip block, hip guide, hip pad, lateral hip support, body side support, lateral, lateral support on its own, lateral pad, lateral thoracic pad, lateral thoracic support, scoliosis pad, side cushion, trunk pad, humeral block, protractor, adductor pad, adductor wedge, leg block, leg pad, leg strap, thigh block, thigh strap.

[SOURCE: ISO 7176-26:2007, 4.7.26, modified — Examples and Notes to entry have been updated.]

3.1.1.5 medial support

postural support device (3.1.5.2) intended to contact the medial surface of a body segment

EXAMPLE Medial knee support, medial lower leg support, and medial thigh support.

Note 1 to entry: The term can include the part of the anatomy receiving the support.

Note 2 to entry: The following are deprecated terms: pommel, adduction strap, adductor pad, adductor wedge, leg adductor support, leg dividing support, wedge, wedge pad.

[SOURCE: ISO 7176-26:2007, 4.7.25, modified — Examples and Notes to entry have been updated.]

3.1.1.6 posterior support

postural support device (3.1.5.2) intended to contact the posterior surface of a body segment

EXAMPLE Posterior foot support, posterior head support, posterior lower leg support, posterior lumbar support, posterior sacral support, and posterior upper arm support.

Note 1 to entry: The posterior surface is based on the posterior surface when the person is seated in a typical upright sitting position.

Note 2 to entry: The term can include the part of the anatomy receiving the support.

Note 3 to entry: The following are deprecated terms: heel cup, heel loop, heel strap, calf pad, calf panel, calf strap, calf support, leg strap, leg support, leg rest pad, lower leg support, posterior leg support, lower leg support, lumbar pad, lumbar roll, posterior pelvic support, elbow block, humeral block, protractor.

[SOURCE: ISO 7176-26:2007, 4.7.24, modified — Examples and Notes to entry have been updated.]

3.1.1.7 superior support

postural support device (3.1.5.2) intended to contact the superior surface of a body segment

EXAMPLE Superior foot support, superior forearm support, and superior thigh support.

Note 1 to entry: The superior surface is based on the superior surface when the person is seated in a typical upright sitting position.

Note 2 to entry: The term can include the part of the anatomy receiving the support.

Note 3 to entry: The following are deprecated terms: toe cup, toe loop, forearm hook, forearm strap, leg strap, thigh strap.

[SOURCE: ISO 7176-26:2007, 4.7.27, modified — Examples and Notes to entry have been updated.]

3.1.2 linear support surface measures

Note 1 to entry: Where the support's local axis is referred to, the axis system is that used in *A clinical application guide to standardized wheelchair seating measures of the body and seating support surfaces*^[3].

Note 2 to entry: When describing the *width* (3.1.2.4) and *depth* (3.1.2.1) of an item used in the horizontal plane, the width dimension is expressed before the depth dimension.

Note 3 to entry: When describing the width and *length* (3.1.2.2) of an item used in the vertical plane and viewed from the front, the width dimension is expressed before the length dimension.

3.1.2.1

depth

linear dimension of a seating support surface measured along or parallel to the support's local horizontal X axis

Note 1 to entry: This is the measure from the back to the front of the item.

3.1.2.2

length

linear dimension of a seating support surface measured along or parallel to the support's local vertical (Y) axis

3.1.2.3

thickness

dimension measured perpendicular to a seating support surface

3.1.2.4

width

linear dimension of a seating support surface measured along or parallel to the support's local horizontal (Z) axis

Note 1 to entry: This is the measure from one lateral side to the other when viewed from the front.

Note 2 to entry: When describing a *postural support device* (3.1.5.2) (PSD), width is stated prior to a second dimension such as *depth* (3.1.2.1).

3.1.2.5

height

distance from a top point on a seating support surface to a specified reference horizontal surface, measured along the vertical (Y) axis of the seating support surface, and at right angles to its horizontal (Z) axis

3.1.2.6

vertical height

gravitational vertical distance from the highest point on a seating support surface to a specified reference horizontal surface

Note 1 to entry: The vertical *height* (3.1.2.5) often does not equate to the height when a seating support surface is not in an upright sitting position.

3.1.3

posture

3.1.3.1

fixed posture

non-reducible posture

position at a one or more joints where there is no passive range of motion in any direction

Note 1 to entry: This is a clinically related term and application.

3.1.3.2

flexible posture

reducible posture

position at one or more joints where there is passive range of motion in one or more directions

Note 1 to entry: Clinically this is usually applied to movement towards a more neutral reference posture.

3.1.4

occupant

DEPRECATED: user

person supported by the wheelchair seating system

[SOURCE: ISO 7176-26:2007, 4.2.2]

3.1.5

support device

3.1.5.1

flexible postural support device

flexible PSD

postural support device (3.1.5.2) that is capable of conforming to the shape of the anatomy when applied to the *occupant* (3.1.4)

Note 1 to entry: This includes any component of a flexible postural support device which can in itself be non-flexible, such as a frame mount or adjustment buckle.

3.1.5.2

postural support device

PSD

structure, attached to a seat or chair, which has a surface that contacts the *occupant's* (3.1.4) body and is used either to support, correct or stabilize the occupant's sitting posture

Note 1 to entry: The structure of the terms is such that they describe the application rather than the construction of each device. Therefore, many of the terms describe both flexible and non-flexible solutions amongst the deprecated terms.

Note 2 to entry: Postural support device is also referred to in this document as positioning support or postural support.

[SOURCE: ISO 7176-26:2007, 4.7.3, modified — The deprecated term “postural support” has been removed. In the definition, “wheelchair” has been changed to “a seat or a chair” and “modify or accommodate” has been changed to “support, correct or stabilize”. Example has been removed. Notes to entry have been added.]

3.1.6

restraints

3.1.6.1

restraint

measure or condition that keeps someone or something under control

3.1.6.2

occupant restraint

vehicular occupant restraint

system or device intended to restrain a motor-vehicle *occupant* (3.1.4) during an impact in order to prevent ejection, and prevent or minimize contact with the vehicle interior components and other occupants

Note 1 to entry: Securement points may be located on hardware components that are permanently or temporarily fastened to a wheelchair.

[SOURCE: ISO 7176-26:2007, 4.11.16, modified — The preferred term “vehicular occupant restraint” has been added.]

3.1.6.3

protective restraint

device, including, but not limited to, a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap that is intended for medical purposes and that limits the *occupant's* (3.1.4) movements to the extent necessary for treatment, examination, or protection of the occupant or others

[SOURCE: FDA Code of Federal Regulations Title 21,^[4] modified — “Patient” has been replaced by “occupant”.]

3.2 Abbreviations

For the purpose of this document, the following abbreviations apply.

ASIS	anterior superior iliac spine
PEG	percutaneous endoscopic gastrostomy
PSIS	posterior superior iliac spine

4 Aims and principles of application of flexible PSDs

4.1 General

Flexible PSDs are designed to control body movements, either blocking, minimising or guiding movements of specific body segments to achieve desired outcomes, including safety. Typical outcomes include increased sitting stability, maintained or corrected posture, increased reach, enhanced propulsion of a mobility device, and maintenance of a desired seated position for safety purposes. In many cases, the purpose of a flexible PSD can be a combination of one or all of these factors.

NOTE 1 This can also apply to abdominal compression devices to improve exhalation which are attached to the seating system (see 6.2.5). In this case, there can be safety considerations as to the effect on the device that a change in seated position can incur.

NOTE 2 Often impairments and activity limitations can be addressed by optimizing the seating system's angular and linear dimensions specific to the occupant. Only thereafter should flexible PSDs be added to compliment the system.

A flexible PSD shall be prescribed for stability when the primary purpose is to stabilize part of the body, in static or dynamic situations, to enhance function in other parts (e.g. to stabilize the lower body segments in order to increase the ability to reach outside the base of support or prevent forwards sliding, or to stabilize one arm for an occupant with dystonia to enable functioning of the other arm). This shall be achieved by restricting movement of the related body segment (e.g. using a pelvic postural support in conjunction with an anterior flexible trunk support to enable a powered wheelchair occupant to navigate uneven terrain safely).

NOTE 3 Where the occupant's posture is assessed to be flexible, a flexible PSD can be used in conjunction with other PSDs to improve postural alignment by applying a combination of corrective forces. In turn, this can reduce strain on joints and internal organs and help prevent further secondary complications (such as contractures, pressure injuries or respiratory complications) as well as increase comfort and function.

NOTE 4 Where the occupant's posture is assessed as being fixed, a flexible postural support device can be used in conjunction with other PSDs to support and maintain the optimal achievable and tolerable posture by applying a combination of maintaining forces. This can help prevent further postural decline.

The occupant should be assessed as to the correct style of PSD to be prescribed, and measured in accordance with Annex A so that the correct size of PSD is prescribed in accordance with Annex B.

A flexible PSD shall be prescribed for safety when the primary purpose is to protect the occupant from injury (e.g. to prevent falling from the seat).

NOTE 5 This can be achieved by limiting movement of one or more body segments.

Where the occupant is unable to remove the device independently, by consequence or design, prior to prescription a risk assessment shall be carried out to ascertain whether the device can be considered a restraint (see 4.2 and Annex C).

Seating systems and chairs shall be prescribed which have space available to mount PSDs in the positions required by this document.

4.2 Restraint versus positioning

'Restraint' is a term that has contextually different meanings and connotations. For this reason, RESNA (Rehabilitation Engineering and Assistive Technology Society of North America) has produced a position paper on restraints. This includes clarification on the differences between supports and restraints and the respective purposes of vehicular occupant restraints and protective restraints (see RESNA, 2013^[5]).

If a pelvic positioning support can be perceived as a restraint, the decision to use the support should be made by an interdisciplinary team, including carers, with the justification documented. The justification shall show that appropriate thought was given to alternative interventions, including, but not limited to, contracture management, tone management, and therapeutic intervention to address behavioural issues. Decisions shall, where practicable, be taken with the consent of the occupant, in the best interests of the occupant to ensure safety and function.

Any desired outcome resulting from the limitation of movement shall also be documented (e.g. to minimize the risk of falls). It shall also be documented where there is an aim to restrict movement in one part of the body, in order to facilitate greater function in another (e.g. stabilization of the trunk to improve functional reach).

Where positioning supports are determined as being the best method of postural management, a comprehensive clinical assessment shall be carried out demonstrating that the support is essential to achieve an appropriate postural position. See also RESNA's position paper on restraints, which includes clarification on the differences between supports and restraints and the respective purposes of vehicular occupant restraints and protective restraints (RESNA, 2013^[5]).

4.3 Safety

4.3.1 General

The health risks and benefits of the use of a PSD shall be assessed.

4.3.2 PSD-body interface

The risk to the occupant's skin integrity from where the PSD interfaces with the body shall be assessed and minimized.

4.3.3 Forces on bony prominences

The risk of increasing pressure and shear forces from bony prominences such as the ischial tuberosities, ASISs, PSISs, iliac crests and sternum on the tissues covering these parts of the body shall be assessed and minimized.

4.3.4 Physiological function

The impact on breathing, swallowing, vision, digestive function, cardiovascular function, bladder function, etc. shall be assessed and optimized.

4.3.5 Ancillary medical devices

The positioning of PSDs shall not impede the positioning and function of catheters, pumps, or other ancillary medical devices.

4.3.6 Skeletal structure

The forces applied through the positioning of PSDs shall not create or lead to worsening of skeletal deformities.

4.4 Paediatric needs

4.4.1 General

The needs of a child with a developing skeleton and function means that the positioning of supports to accommodate growth and development requires particular attention and therefore should be reviewed regularly.

NOTE 1 The frequency of review depends on the age of the child, the child's rate of growth and the rate of change of the causes of their need for supports.

4.4.2 Hip joint development

The hip joint, or acetabulofemoral joint, is the joint between the head of the femur and the acetabulum. Its primary function is to support the body's weight and aid balance in standing. The development of both the head of the femur and the acetabulum depends on weight-bearing activities and walking during childhood. In a non-ambulatory child, the hip joint is under-developed, and is extremely vulnerable to dislocation. In individuals with cerebral palsy in particular, hip subluxation or dislocation can be common during the teenage years. In some cases, corrective surgery is required.

When applying a PSD, the impact of the applied force on the hip joint shall be taken into account.

EXAMPLE A medial (to lateral) strap (to encourage abduction) places an abducting/external rotation force on the hip. This can be painful when the hip is subluxed or dislocated.

NOTE 1 Even when a person has been previously ambulant, a long-term disability causing weakness and muscle tone changes around the hip joint can increase the chance of hip dislocation. Changes in range of motion are also common.

A full physical assessment should be carried out prior to prescription of a flexible PSD to fully understand the abilities and limitations in range of motion.

NOTE 2 Differentiating between the hip range of motion and the posterior pelvic tilt in particular is critical for optimal positioning.

NOTE 3 Where the seat to back support angle of the seat is too acute for the individual to tolerate due to limitations in hip flexion range of motion, applying a postural support to hold the individual in that position can be painful.

The natural abduction angle of the femur is 5° from the midline; the cushion, and any medial and lateral thigh supports, shall facilitate this position unless the clinical seating assessment indicates an alternative position is required (e.g. to support a fixed deformity or joint contracture).

4.5 Materials

4.5.1 Testing

4.5.1.1 Static, impact and repetitive load strengths

PSDs shall be tested in accordance with the tests in ISO 16840-3, and shall pass the tests where there are pass or fail criteria.

4.5.1.2 Flammability

PSDs shall be tested in accordance with the flammability test in ISO 16840-10.