BS 8625:201X

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

BS 8625 draft, 14 August 2018

This draft contains all the standard material and a few suggestions/notes for the panel.

This is a skeleton draft for a specification. The standard wording in the Foreword, and the way in which the provisions of the standard are written, will be different for a code of practice, test method or guide.

BS 8625:201X

BRITISH STANDARD

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Foreword

This British Standard is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on XX Month 201X. It was prepared by Technical Committee CH/173/01, *Wheelchairs*. A list of organizations represented on this committee can be obtained on request to its secretary.

Information about this document

This element gives, as appropriate:

- information relating to the structure of the standard;
- any problems in preparation (e.g. matters omitted).

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Requirements in this standard are drafted in accordance with *Rules for the structure and drafting of UK standards*, subclause **J.1.1**, which states, "Requirements should be expressed using wording such as: 'When tested as described in Annex A, the product shall ...'". This means that only those products that are capable of passing the specified test will be deemed to conform to this standard.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Introduction

[An introduction is not a mandatory part of the standard, but if it is included, this is where it is placed. Give technical background information here, if it is needed and if it is too long to go in the Foreword. Do not give recommendations in the Introduction.]

Posture support devices, such as positioning belts, have a specific purpose, i.e. to support an individual, to help maintain and increase day to day functionality for the individual, and to protect against the development of skeletal deformities, or to correct them. These devices, with their postural support purposes, are not to be confused with belts and similar devices designed to act as vehicular occupant restraints.

Over the last x decades there have been y reported deaths (in the UK, globally?) involving or attributed to posture belts or anterior postural support devices. These deaths have been occurring as a result of inappropriate placement of belts and harnesses. Users are currently confused as to best practice, and the reasons. The MHRA in the UK originally provided guidance on the placement of pelvic positioning belts, but the advice was appropriate for restraints, and not for positioning belts. This advice was updated in 2015 in MDA/2015/018. However, this new guidance placed the onus on the manufacturer or prescriber to decide what might be best for an individual.

For this reason, this document has been produced to advise on the selection and placement of positioning belts when used in seating systems and wheelchairs. The guidance in this document has been created for use by therapists, engineers, carers, manufacturers, retailers, and repairers.

Wheelchair positioning belt: Strap based device that supports a person's posture, or position in their wheelchair, e.g. to prevent forward sliding in the seat. These belts do not have the inherent strength necessary, and thus are not suitable for, use as occupant restraints in transportation

1 Scope

This document provides guidance as to the correct placement and fixation of postural support devices within seating devices and systems, and wheelchairs. Seating devices may be involved in one or more situations including static seating, wheelchairs and wheelchair seating, shower chairs, etc. The devices enable the seated person to be positioned to maximise their functional activities in a safe environment. These requirements have a balance of maintenance of posture, and of safety.

This edition of the standard covers belts and harnesses (padded or otherwise) used for postural positioning and/or safety. Not included are belts and harnesses used in transportation for restraint, nor are postural support devices not made from strapping/webbing (padded or otherwise).

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.

FDA (2013) CFR Code of Federal Regulations Title 21 Section 880.6760. Revised 4/2013. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=880.6760.

ISO 16840-1 (2006) Wheelchair seating - Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces

ISO 16840-3 (2014) Wheelchair seating -- Part 3: Determination of static, impact, and repetitive load strengths for postural support devices

ISO 7176-16 (2012) Wheelchairs – Part 16: Resistance to ignition of upholstered parts – Requirements and test methods

ISO 7176-26 (2007) Wheelchairs -- Part 26: Vocabulary

RESNA (2013) RESNA Position on the Application of Wheelchairs, Seating Systems, and Secondary Supports for Positioning vs Restraint

Waugh, K. and Crane, B. et al. (2013). A Clinical Application Guide to Standardized Wheelchair Seating Measures of the Body and Seating Support Surfaces: Rev Ed. AT Partners, School of Medicine, University of Colorado.

3 Terms and definitions

Terms and definitions as published in ISO 7176-26 and ISO 16840-1 with the following modifications:

3.1 occupant restraint

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

NOTE Securement points may be located on hardware components that are permanently or temporarily fastened to the wheelchair.

ISO 7176-26: 4.11.6

3.2 postural support device

positioning belt

PSD

structure, attached to a seat or wheelchair, which has a surface that contacts the occupant's body and is used either to modify or accommodate the occupant's sitting posture

ISO 7176-26: 4.7.3 - Modified to add 'seat or'

3.2.1 anterior support

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

ISO 7176-26: 4.7.23

3.2.1.1 anterior head support

anterior head strap (deprecated) forehead strap (deprecated) forehead support (deprecated) headband (deprecated)

ISO 7176-26: 4.7.23 Example 1

3.2.1.2 anterior lower leg support

knee block (deprecated) knee strap (deprecated)

ISO 7176-26: 4.7.23 Example 6

3.2.1.3 anterior pelvic support

lap belt (deprecated)
pelvic stabilizer (deprecated)
pelvic strap (deprecated)
safety belt (deprecated)
seat belt (deprecated)
subasis bar (deprecated)

ISO 7176-26: 4.7.23 Example 5 - Modified with 'safety belt' added

3.2.1.4 anterior shoulder support

backpack straps (deprecated) shoulder bar (deprecated) shoulder hook (deprecated) shoulder retractor (deprecated) shoulder strap (deprecated)

ISO 7176-26: 4.7.23 Example 2

3.2.1.5 anterior trunk support

anterior thoracic support (deprecated) butterfly strap (deprecated) butterfly harness (deprecated) chest harness (deprecated) chest strap (deprecated) H-strap (deprecated) harness (deprecated) spiderman strap (deprecated)

ISO 7176-26: 4.7.23 Example 4

3.2.1.6 anterior upper arm support

humeral strap (deprecated)

ISO 7176-26: 4.7.23 Example 3

3.2.2 circumferential support

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

ISO 7176-26: 4.7.29

3.2.2.1 circumferential ankle support

ankle strap (deprecated)

ISO 7176-26: 4.7.29 Example 2

3.2.2.2 circumferential neck support

cervical collar (deprecated) circumferential cervical support (deprecated) collar (deprecated) ISO 7176-26: 4.7.29 Example 1

3.2.3 inferior support

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

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

ISO7176-26: 4.7.28

3.2.3.1 inferior lower leg support

stump support (deprecated)

ISO 7176-26: 4.7.28 Example 3

3.2.3.2 inferior pelvic support

obliquity pad (deprecated)

ISO 7176-26: 4.7.28 Example 1

3.2.3.3 inferior upper leg support

thigh wedge (deprecated)

ISO 7176-26: 4.7.28 Example 2

3.2.4 lateral support

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

ISO 7176-26: 4.7.26

3.2.4.1 lateral head support

head side support (deprecated) lateral headrest (deprecated)

ISO 7176-26: 4.7.26 Example 1

3.2.4.2 lateral knee support

adductor pad (deprecated) adductor strap (deprecated)

ISO 7176-26: 4.7.26 Example 6

3.2.4.3 lateral lower leg support

calf strap (deprecated)

calf support (deprecated)

leg block (deprecated)

leg guide (deprecated)

leg pad (deprecated)

leg strap (deprecated)

legrest pad (deprecated)

ISO 7176-26: 4.7.26 Example 7

3.2.4.4 lateral pelvic support

hip block (deprecated)

hip guide (deprecated)

hip pad (deprecated) lateral hip support (deprecated)

ISO 7176-26: 4.7.26 Example 4

3.2.4.5 lateral trunk support

body side support (deprecated)
lateral (deprecated)
lateral support (deprecated)
lateral pad (deprecated)
lateral thoracic pad (deprecated)
lateral thoracic support (deprecated)
scoliosis pad (deprecated)
side cushion (deprecated)

NOTE 1 In this case, the term "lateral support" is deprecated as a synonym for "lateral trunk support."

ISO 7176-26: 4.7.26 Example 3

3.2.4.6 lateral upper arm support

humeral block (deprecated) protractor (deprecated)

trunk pad (deprecated)

ISO 7176-26: 4.7.26 Example 2

3.2.4.7 lateral upper leg support

adductor pad (deprecated)
adductor wedge (deprecated)
lateral thigh support (deprecated)
leg block (deprecated)
leg pad (deprecated)
leg strap (deprecated)
thigh block (deprecated)
thigh strap (deprecated)

ISO 7176-26: 4.7.26 Example 5

3.2.5 medial support

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

ISO 7176-26: 4.7.25

3.2.5.1 medial knee support

pommel (deprecated)

ISO 7176-26: 4.7.25 Example 2

3.2.5.2 medial lower leg support

ISO 7176-26: 4.7.25 Example 3

3.2.5.3 medial upper leg support

adduction strap (deprecated) adductor pad (deprecated)

adductor wedge (deprecated)
leg adductor support (deprecated)
leg dividing support (deprecated)
wedge (deprecated)
wedge pad (deprecated)

ISO 7176-26: 4.7.25 Example 1

3.2.6 posterior support

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

ISO 7176-26: 4.7.24

3.2.6.1 posterior foot support

heel cup (deprecated) heel loop (deprecated) heel strap (deprecated)

ISO 7176-26: 4.7.24 Example 6

3.2.6.2 posterior head support

ISO 7176-26: 4.7.24 Example 1

3.2.6.3 posterior lower leg support

calf pad (deprecated)
calf panel (deprecated)
calf strap (deprecated)
calf support (deprecated)
leg strap (deprecated)
leg support (deprecated)
legrest pad (deprecated)
lower leg support (deprecated)
posterior leg support (deprecated)

NOTE 1 In this case, the term "lower leg support" is deprecated as a synonym for "posterior lower leg support."

ISO 7176-26: 4.7.24 Example 5

3.2.6.4 posterior lumbar support

lumbar pad (deprecated) lumbar roll (deprecated)

ISO 7176-26: 4.7.24 Example 3

3.2.6.5 posterior sacral support

posterior pelvic support (deprecated)

ISO 7176-26: 4.7.24 Example 4

3.2.6.6 posterior upper arm support

elbow block (deprecated) humeral block (deprecated) protractor (deprecated) ISO 7176-26: 4.7.24 Example 2

3.2.7 superior support

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

ISO 7176-26: 4.7.27

3.2.7.1 superior foot support

toe cup (deprecated) toe loop (deprecated)

ISO 7176-26: 4.7.27 Example 3

3.2.7.2 superior lower arm support

forearm hook (deprecated) forearm strap (deprecated)

ISO 7176-26: 4.7.27 Example 1

3.2.7.3 superior upper leg support

leg strap (deprecated) thigh strap (deprecated)

ISO 7176-26: 4.7.27 Example 2

3.3 restraint

device that is used to limit harmful motion during vehicular transportation, or a device that is carefully controlled in many settings

RESNA 2013

3.3.1 protective restraint

a 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 patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

FDA CFR21

[Clause heading]

[Write your requirements using the word "shall". Text that is entirely informative should be placed in notes. Make sure that every clause and subclause has at least one requirement in it. If you need to refer to other documents, make sure it is clear whether the reference is "normative" (i.e. the user of the standard has to comply with it in order to claim compliance with the standard) or "informative" (i.e. it contains useful information that the user may refer to if he/she wishes to, but it is not essential for the use of the standard).]

[An example of a normative reference:]

Xxxxx shall be designed/carried out/installed/etc. in accordance with [ref].

[An example of an informative reference:]

NOTE Guidance on xxxxx is given in [ref].

4 Aims and Principles

Safety vs restraint vs positioning – physiology/anatomical/health benefits – correction vs maintenance KC

Flexible PSDs are designed to increase sitting stability, maintain or correct posture, or to maintain a seated position for safety purposes. In many cases, the purpose of a flexible PSD may be a combination of all of these factors.

A flexible PSD is considered to be for safety when the primary purpose is to protect the user from injury, e.g. to prevent falling from the seat. This is achieved by limiting movement of one or more body segments.

A flexible PSD is considered to be for stability when the primary purpose is to reduce instability of the trunk in static or dynamic situations, or to stabilise the lower body segments in order to increase the ability to reach outside of the base of support or prevent forwards sliding. This is achieved by restricting movement of the related body segment, e.g. using an anterior flexible PSD and posture belt to enable a powered wheelchair user to navigate uneven terrain safely.

Where the user's posture is assessed to be flexible, a flexible PSD can be used in conjunction with other PSDs to improve postural alignment, reducing abnormal postures by applying a combination of corrective forces. In turn this can reduce strain on joints and internal organs, and increase comfort and function.

Where the user's posture is assessed to be 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 damaging posture from deteriorating further.

Where the user is unable to remove the device independently, by consequence or design, consideration shall be given as to whether the device could be considered to be a restraint, prior to prescription.

4.1 Restraint vs Positioning

Restraint is a term that has different meanings and connotations, depending on the context of use. For this reason, RESNA has produced a Position paper to clarify the issue, in which the differences between supports and restraints are covered, as well as vehicular occupant restraints, and protective restraints (RESNA 2013). Positioning belts shall not be used with the primary purpose of restraint, within these definitions.

If a postural support belt could be perceived as a restraint, the decision shall be made by an interdisciplinary team, including carers, with the justification documented. The justification shall show that appropriate consideration has been made for alternative interventions, including, but not limited to, contracture management, tone management, and intervention to address behavioural issues.

Any desired outcome to limit movement shall also be documented, e.g. minimise 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 more function in another, e.g. fixation of the pelvis to improve postural stability.

Where positioning belts are considered the best method of postural support, a comprehensive clinical assessment shall be carried out which shall demonstrate that the support is essential to achieve an appropriate postural position [1].

4.2 Safety

Assessment shall be made as to the health risks and benefits of the use of a PSD.

4.2.1 PSD-body interface

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

4.2.2 Forces on bony prominences

The risk of increasing pressure from bony prominences such as the ischial tuberosities, anterior and posterior iliac spines, iliac crests, sternum, etc on the tissues covering these parts of the body shall be assessed and minimised.

4.2.3 Physiological function

The impact on breathing, digestive function, cardiovascular function, bladder function, etc shall be assessed and optimised.

4.2.4 Ancillary medical devices

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

4.2.5 Skeletal structure

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

4.3 Paediatric needs

The needs of a child with a developing skeleton and function mean that the positioning of belts to accommodate for growth and development shall have particular attention.

4.3.1 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 head of the femur and the acetabulum both rely on weight bearing activities and walking in childhood in order to develop. In a non-ambulatory child, the hip joint will be underdeveloped, and is extremely vulnerable to dislocation. In individuals with cerebral palsy in particular, hip dislocation in teenagers can be common. In some cases corrective surgery is required.

When applying a posture belt, consideration should therefore be given of the impact of the applied force on the hip joint. For example, a dual medial to lateral strap (abductor), will place an abducing/external rotation force on the hip. This may be painful when the hip is dislocated or subluxed.

Even when a person has been previously ambulant, 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 shall be carried out prior to prescription to understand fully the abilities and limitations in range of motion: differentiating in particular between the hip range of motion and posterior pelvic tilt is critical for optimal positioning. Where the seat to back angle of the seat is too acute for the individual to tolerate, applying a posture belt to hold the individual in that position will be painful.

The natural angle of the femur is positioned at 5 degrees of abduction from the midline. The cushion, and any medial and lateral supports, shall facilitate this position.

4.4 Materials

4.4.1 Testing

4.4.1.1 Static, impact, and repetitive load strengths

PSDs that have been tested to, and that have passed, the tests in ISO 16840-3 shall be used

4.4.1.2 Flammability

PSDs that have passed the ISO 7176-16 flammability tests shall be used

4.4.2 Padding

To protect the wheelchair occupant from harm from the PSD webbing materials, padding shall be provided where the PSD interacts the occupant's body.

Note. Webbing under tension has a tendency to curl, meaning that the webbing can dig into the tissues of the occupant, causing potential tissue damage

Padding shall be designed to follow the contours of the occupant's body, and to dissipate evenly the forces of the belt on the occupant's body. Care shall be taken that the pad design does not lead to curling of the padded belt so that the forces no longer follow the contours of the occupant's body. Where edging is applied to the pad to stop fraying of the pad, the edging material shall not provide a risk to the tissue integrity of the occupant, from wrinkling or other deformations or localised pressure points.

The dimensions of the webbing and padding shall be selected to meet the positioning needs of the occupant, taking into account the body mass of the part of the body that the PSD is interacting with, and the forces needed to manage the occupant's posture with that PSD.

4.5 Transportation

It is important to be clear on the difference between wheelchair *postural support* belts and *occupant restraint* belts. The difference is evident in the descriptors: support vs restraint:

- Wheelchair postural support belts are designed to support a person's posture, or position in their wheelchair. These belts do not have the inherent strength necessary, and thus are not suitable for use as occupant restraints.
- Wheelchair occupant restraint belts are generic devices designed to restrain a wheelchair occupant in the event of a vehicular collision.

Where a postural support belt, or other secondary support has been clinically prescribed, this is done to assist in the corrective positioning of a wheelchair user who cannot independently maintain an optimal position in their wheelchair. Removal of a postural support belt may therefore compromise the wheelchair user's posture and impinge on the correct routing and functioning of the occupant restraint. Where a positioning support belt has been clinically prescribed, and is fitted to a wheelchair, it must be left in position during transport unless risk assessment dictates otherwise. However, postural support belts ARE NOT intended to substitute for occupant restraint belts, and an occupant restraint belt SHALL be used IN ADDITION to a clinically prescribed postural support belt when a wheelchair user is being transported in a vehicle - Occupant restraints shall always be used in transport.

Some wheelchairs are designed so that the occupant restraint belt can be fitted directly to the wheelchair rather than by the more conventional method of attaching it to the vehicle. They do not possess the design characteristics of postural support belts, e.g. option to select anchor point on the wheelchair frame, padding to distribute force, anatomical sub-ASIS pads

etc. The occupant restraint belt serves the purpose of wheelchair occupant restraint in vehicle *only*, and is not intended to act as a postural support belt. Where corrective positioning is required, a clinically prescribed postural support belt shall be fitted and used.

Postural support belts shall not be removed for transportation, unless indicated by a documented risk assessment. Without such support, the user may not independently maintain position in the wheelchair, potentially causing them to slide down in the wheelchair during motion.

Postural support belts shall not be used as a substitute for an occupant restraint belts, unless indicated by a documented risk assessment, e.g. when the postural support belt impinges on the correct routing of the occupant restraint.

In transportation where the use of an occupant restraint belt is indicated, an occupant restraint shall be used in addition to any clinically prescribed postural support belts.

Prior to every journey, posture belts and anterior support devices shall be checked for position and fit, to minimise the risk to the user of sliding or submarining during the journey.

5 Where on the body, What and Why (+ (fixed vs flexible) KC

5.1 Pelvis

The pelvis is formed by two hip bones, the sacrum and coccyx. Each adult hip bone is itself formed of three bones (ilium, ischium, and pubis) which are fused together. This usually occurs during the late teens.

The sacrum is a wedge shaped bone inferior to the spine, which forms a solid base on which the spinal column sits. This supports the weight of the upper body which is then spread across the pelvis to the legs. Position and control of the pelvis is critical to postural alignment and control. This is because the lowest vertebra in the spinal column, L5, is attached to the top of the pelvis. Postural reflexes drive us to strive to maintain the centre of gravity within the base of support. Therefore, any change in position of the pelvis in turn affects the shape of the spinal column. For example, when the pelvis tilts posteriorly, kyphosis occurs in the spine, whereas when the pelvis is oblique, scoliosis occurs.

The position of the pelvis will also greatly change the distribution of interface pressure between the user and support surface. This is an important consideration for the prevention of pressure ulcers.

The positioning of the pelvis is therefore critical for the alignment of the spine.

5.1.1 Anterior pelvic supports

Pelvic positioning belts are described by the number of points on which they need to be placed on a chair. Secondary to this, and where there is a built in adjustability, they are described by the arrangement for making the width adjustment when tightening the belt into position.

5.1.1.1 2-point pelvic positioning belts

2-point positioning belts are usually chosen to manage the positioning of a person with a tendency towards a posterior pelvic tilt. The belt therefore needs to be placed where it will help to stop the pelvis from sliding forward. To achieve this it should be attached on the seat frame to ensure that the belt falls anterior to the greater trochanters (Fig. X). In doing so, this will permit the pelvis to rotate forward, thereby allowing unweighting of the ischial tuberosities and allowing increased forward reach, while preventing the pelvis from submarining under the belt, and at the same time removing any risk of the belt rising into the soft tissues of the belly.

Note: Commonly wheelchairs are delivered with a belt in place at the junction of the back support and the seat frame. These belts should be moved to an attachment point on the seat frame to enable the belt to be positioned anterior to the greater trochanters.

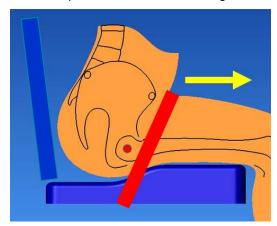


Fig. X. Positioning of posture belt anterior to the greater trochanter

5.1.1.1.1 Centre Pull

The belt shall have adjustability around the area of the buckle, with the means to tighten the belt, preferably with a D-ring on the end of the tightening strap (Fig. X).

Note The carer or user can make use of the two pads coming together, as a visual indication that the belt is adjusted tightly enough.



Fig. X. Centre Pull belt

5.1.1.1.2 Dual Pull

The belt shall have adjustability around the area of the buckle, with the means to tighten the belt, preferably with a D-ring, on the end of each of two tightening straps (Fig. X).



Fig. X. Dual Pull belt

5.1.1.1.3 Rear Pull

The belt shall have adjustability around the lateral ends of the padding, with the means to tighten the belt, preferably with a D-ring on the end of two tightening straps (Fig. X).



Fig. X. Rear Pull belt

5.1.1.2 4-point pelvic positioning belts

Where there is a tendency towards anterior pelvic tilt, or anterior rotation of the pelvis, control is achieved by pulling back on the anterior superior iliac spines. A 4 point belt consists of a pair of wider straps, and a pair of narrower straps (Fig. X). The wider straps shall pull back to attach to the canes of the back support at the level of posterior superior iliac spines. The narrower straps shall be attached to the seat frame, preferably anterior to the greater trochanters.



Fig. X. 4-point Centre Pull Belt

5.1.1.2.1 Centre Pull

The wider (padded) straps of a padded 4-point pelvic positioning belt shall have a means to tighten the belt. If by Centre Pull, the belt shall have adjustability around the area of the buckle, with the means to tighten the belt, preferably with a D-ring on the end of the tightening strap.

5.1.2 Lateral pelvic supports

5.1.3 Posterior pelvic supports

5.2 Trunk

The trunk plays a critical physiological and anatomical role. The trunk contains and supports the body cavity in which most key physiological activities take place: cardiovascular, respiratory, digestive, urological, and reproductive.

Poor alignment of the spine results in unequal pressure through the spinal discs, placing them at greater risk of damage.

The positioning of the vertebrae and the ribs are therefore of critical importance to permit optimal physiological function, and the positioning of any supports intended to accommodate or correct any mis-positioning of the anatomical features.

The trunk is pivotal in providing support of the head, the correct position of which affects communication, socialisation, breathing, eating, hearing, balance, seeing, and other day-to-day functional activities. Thus, helping an individual's control of their trunk assists the control of their head.

5.2.1 Anterior trunk supports

An anterior trunk support shall never be used without an appropriately positioned and adjusted pelvic positioning belt in use. There is a risk of asphyxiation if the anterior trunk support can ride up, or the occupant slip down in the seat. See Annex B.

5.2.1.1 Chest harness

A chest harness features a single pad that fits anterior to the sternum, affixed by two upper and two lower straps. Chest harnesses are available in a variety of shapes such as vest or X (butterfly). Vest harnesses may or may not feature a front zipper. In some cases a modified chest harness may be provided, based on an individual risk assessment to accommodate an individual clinical requirement, e.g. to avoid pressure to a PEG tube or Baclofen pump.

A chest harness is designed with one central pad which fits anteriorly to the sternum, fixed by 4 adjustable straps, two of which go over the shoulder. It enables the user to extend the trunk in order to reduce a flexible kyphosis.

5.2.1.2 Shoulder Harness

Features two padded shoulder straps, fastened by two upper and two lower straps and connected by a central strap to prevent the shoulder straps from coming off the shoulders. The central strap shall be affixed to the padded shoulder straps to prevent the centre strap from rising up.

Rear Pull

Front Pull

5.2.2 Lateral trunk supports

5.2.3 Posterior trunk supports

5.3 Legs

5.4 Feet

There are times where there is an advantage to the individual to restrict the movement of one or both feet, or to have them positioned in a fixed position. This may be for safety (for example, to stop the feet falling from the foot support and getting trapped) or for positioning control, to help to achieve a more functional position.

Foot position can also be critical to postural positioning. This is because the hamstrings originate at the ischial tuberosity and insert at the head of fibular and lateral condyle of the tibia, consequently acting over both the hip and the knee joint. When the feet are positioned out in front of the body, the hamstrings pull anteriorly on the ischial tuberosity, encouraging the pelvis to tilt backwards.

5.4.1 Circumferential ankle supports

Circumferential ankle supports comprise of a padded strap that wraps around the ankle.

5.4.2 Superior foot supports

Superior foot supports comprise of one or two straps, which may be padded.

5.5 Head

Head alignment and stability is critical for breathing, communication, swallowing, hearing, balance, and vision.

5.5.1 Anterior head supports

Anterior head support straps are sometimes used across the forehead in combination with a posterior head support, in order to prevent the head falling forwards. Dynamic head supports are designed to support the head whilst allowing neck rotation.

Where this solution is considered, a risk/benefit analysis shall be documented to demonstrate that the benefits of the support outweigh the risks, e.g. neck injury resulting from hitting an obstacle while the wheelchair is in motion. Particular consideration shall be given to alternative solutions such as a soft collar, as well as carer training to ensure correct usage.

5.6 Wrist

5.6.1 Circumferential wrist straps

Circumferential wrist straps comprise of a padded strap applied to the wrists.

6 Placement on Equipment of Flexible Postural Support Devices

6.1 Pelvis

The positioning belt that is being used to position the pelvis will need to be attached to the seating or wheelchair frame so that it will keep the belt firmly in position to achieve the functions described in Clause 5.1. It is generally not recommended by manufacturers to drill holes in the framework, since this could weaken the structure of the framework, and does not allow for moving the belt to a different position. Further challenges are that different manufacturers use different constructions for the framework, from circular tubing to rectangular extrusions. In addition there are often pieces of wheelchair architecture precisely where you wish to position the belt.

Thus, a means shall be found to attach the belt in the required position, and which can be adjusted as the occupant's needs change. Various solutions are described in Annex A.

6.2 Anterior trunk – chest/shoulder (+ lower belt)

Diagram here

- The upper harness straps shall be fitted to the back support or harness mounting bar, with the straps running over the top of the back support, or through harness guides
- The upper straps shall be positioned apart such that each strap will sit over the shoulder, medial to the acromioclavicular joint, at least 20 mm lateral to the neck.
- The back support height shall be set level with, or be adjustable to, the users sitting shoulder height +/-10mm.
- The lower straps shall be fitted to the bottom ¼ of the back support such that the straps pull downwards towards the seat

Fitting and adjusting anterior postural supports to the user

- The user shall be positioned in the optimal posture prior to the fitting and adjustment of a harness
- An appropriate posture belt, as described in part x, shall be applied prior to the fitting and adjustment of a harness
- Suitable posterior pelvic support and anterior ischial support shall be provided to prevent posterior pelvic tilt, and consequential collapse into kyphosis
- The fixation point of the upper straps shall be adjusted to ensure that the angle of pull is level with the user's shoulders +/- 5 degrees. If they are two low they will push the user down in the seat. If they are too high they will not provide appropriate force to hold the shoulders against the seat, and the straps may cause irritation to the ears.
- The fixation points of the upper straps shall be adjusted to sit mid clavicle such that they do not impinge on the neck
- The main body of the harness shall sit over the sternum
- The lower straps shall be fitted such they do not impede chest expansion during inhalation
- Once the upper straps and harness body have been positioned correctly, the final fitting shall be achieved using the adjustment on the lower straps
- The centre point of a chest harness shall not sit above the suprasternal/jugular notch.
- The centre strap of a shoulder harnesses shall sit below the sternum level with the lower ribs, and fasten at the front

- Only shoulder harnesses explicitly recommended by the manufacturer for use in a cross over configuration, should be crossed over
- The cross over point on any shoulder harness designed to be used in a cross over configuration shall not sit higher than mid sternum

Check position of in situ medical devices such as PEG tubes or Baclofen pumps. Where required harnesses and straps can be adjusted, in line with the above

6.4 Leg

6.5 Foot

6.5.1 Superior foot supports

Superior foot supports are one means of achieving control of the foot. Consideration must be taken of the effect of pulling down on the top of the foot since this can stimulate a reflex to pull the foot upwards against the strap. Where this type of support is used, consideration shall be given to the likelihood of the foot being removed, leaving the shoe alone being strapped to the inferior foot support.

6.5.2 Circumferential ankle support

A circumferential ankle support is a strap that encircles the foot above the ankle, with webbing straps which pull the foot down on the foot support. This added pressure under the sole of the foot stimulates a plantar reflex, which has a positive effect on the person's posture. Note: The webbing straps can pull down vertically for close control of the foot's position, or be placed at an angle away from the heel, to allow for some degree of voluntary movement.

Note. When using superior foot supports and circumferential ankle supports, consideration should be given to the security of the fixation of the inferior foot support they are fitted to. E.g. where fitted to flip up foot supports, foot movement may not be sufficiently restricted.

6.6 Head

Anterior head supports shall be fixed to a solid head support with the strap fitted over the forehead, ensuring sufficient counter support posterior to the head/occiput. Any additional, anterior head support shall only be employed as part of an overall postural support system that stabilise the lower legs and the trunk.

7 Disclosure information

7.1 Product labelling

- All postural belts shall be labelled as "not suitable for use as an occupant restraint in transportation" or carry the symbol in fig 1
- All anterior postural supports shall be labelled as "only use in conjunction with properly adjusted posture belt" or carry the symbol in fig 2.

Note: symbols may be preferable where the belt is to be used multiple countries or to countries when more than one language is spoken.

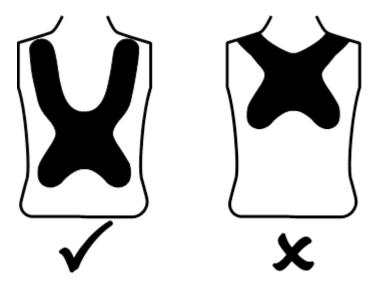


Fig 1

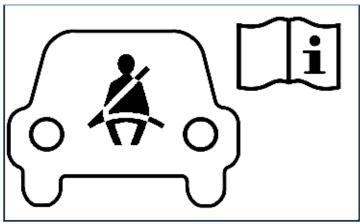


Fig 2

Size?

NB: Copyright Chas A Blatchford Ltd. Can get permission to use.

7.2 Fitting Instructions

- Manufacturers shall provide fitting instruction for all non-factory fitted belts and harnesses
- Manufacturers shall provide fitting instructions for all factory fitted belts and harnesses, where their removable is reasonably expected during the lifespan of the seat, e.g. to enable seat covers to be washed
- Fitting instructions shall include directions on how, where, and where not to fit the belt/harness in accordance with X

7.3 Instructions for use

- Manufacturers shall provide user instructions for all belts and harnesses
- Instructions for use shall include...

- Who can prescribe and fit a posture belt or anterior postural support
- How to close and open
- o How to adjust to fit the use
- How to check for correct positioning, and how often
- How to check for correct tightness
- Safety warnings
 - How to spot signs of distress
 - How to check skin for associated pressure areas
- o Emergency release
- Use, and limitation of use in transportation
- How to use in combinations with other critical items, e.g. posture belt and harness used together
- Cleaning instructions
- Emergency release

All instructions for use shall contain:

- Safety Information
- Information on how to fit the posture belt or anterior postural support (where not factory fitted, or is removable e.g. to allow washing of covers)
- Information on how to use, adjust and release
- Transportation
- Cleaning

Safety Information shall include, but is not limited to...

Always ensure that posture belts and posture harnesses are fitted snugly. Failure to do so could result in the user sliding down in the seat which poses a risk of choking.

Always use a posture harness with a fully functional and correctly adjusted posture belt. Failure to do so could result in the user sliding down the seat which poses a risk of choking.

Posture belts and posture harnesses provide postural support only and should not be used as a passenger restraint in a vehicle. Always use a separate passenger restraint system that is fastened to the vehicle.

Keep all posture belts and posture harnesses clean and free from debris. Failure to do so could result in food and other particles getting caught in the mechanisms, which could result in the failure of buckles, adjustments and other closure systems.

Check daily that the posture harness is free from the neck area. If the posture harness is too close to the neck area, adjust the bottom straps to lower the posture harness over the breast bone or the chest. If this procedure is not possible, stop using the seat and immediately contact the prescribing clinician or service. Check daily the skin areas where the posture belt and harnesses are fitted for any signs of pressure marks. Immediately report any signs of pressure marks to the prescribing clinician or service.

If the user shows any continued signs of distress or discomfort, stop using the seat and report immediately to the prescribing clinician or service.

To avoid delays in releasing the buckles in an emergency, ensure that all carers know how to release the posture belt and posture harness.

Bibliography

Standards publications

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

[List informative references]

Non-standards publications

[List informative references]

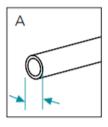
- 1. RESNA (2013). RESNA Position on the Application of Wheelchairs, Seating Systems, and Secondary Supports for Positioning vs Restraint. Rehabilitation Engineering & Assistive Technology
- 2.

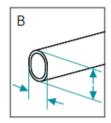
Annex A (Informative)

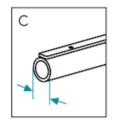
Mounting Devices

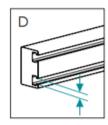
A.1 Framework

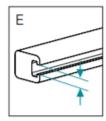
Tubing on seating systems and on wheelchairs varies across different manufacturers. Common examples are shown in Fig. A1.











Key:

A Round tube (19, 22, 25, 29, 30, 32mm diameter)

B Oval tube

C Tube with threaded holes

D Track taking 6mm T nuts

E Track taking 10mm Y nuts

Fig. A1 Common examples of seating and wheelchair tubing

A.2 Framework attachment devices

Devices available to attach to these different types of framework, avoiding the need to make holes in the framework include:

A.2.1 Plastic clamps and shims

Plastic clamps with shims to match different diameter tubing have a threaded bolt to tighten them in place (Fig A2). Suitable for round tubing (Type A).



Fig A2 Plastic clamp and shim

A.2.2 Frame clamp

Open-jaw design that fits underneath seat upholstery and arm support pads. The clamp splits into two parts, and is adjusted by a bolt with a hollow centre to join the two parts. The hollow centre is threaded to take a bolt to fasten the belt to the clamp. (Fig A3.) Suitable for round tubing (Types A and C).



Fig A3 Frame clamp

A.2.3 Band clamp

Flexible stainless spring steel that fits into tight gaps under seats on a wide variety of frames. The clamp splits into two parts, and is adjusted by a bolt with a hollow centre to join the two parts. The hollow centre is threaded to take a bolt to fasten the belt to the clamp. (Fig A4.) Suitable for round tubing (Types A, B, and C).



Fig A4 Band clamp

A.2.4 Seat tube mounting bracket

The Seat tube mounting bracket is a mounting solution for chairs with sling seat upholstery or a solid seat base. Elongated holes allow for fine adjustment of the position for attaching the belt (Fig A5). Suitable for round tubing (Type C) or for solid bases.



Fig A5 Seat tube mounting bracket

A.2.5 Belt mounting extension arms

Thermoplastic extension arms that can be placed around existing items of chair furniture to enable a belt to be positioned exactly where required (Fig A6). Suitable for use with all types of framework, and can be moulded to fit around solid bases.



Fig A6 Belt mounting extension arms

A.2.6 T slot fastener kit

A means to mount belts directly to power wheelchair slotted seat rails (Fig A7). Suitable for use with Type D and E frameworks.



Fig A7 T slot fastener kit

A.3 Belt fixation and adjustment devices

Belt webbing needs to have a means to be attached to the framework attachment devices, but needs to have a means of adjustment so that the webbing fits snugly over the occupant.

A.3.1 Belt flat mount end fitting

A flat mounting system provides a means to loop the belt webbing through an attachment. Such a device usually has a hole through which a bolt can be placed to attach to a framework attachment device (Fig A8).

Note. A grommet placed into the webbing is unlikely to pass the ISO 16840-3 tests.



Fig A8 Flat mount end fitting

A.3.2 Slide

If using a flat mount end fitting, a slide will be needed to fix the belt webbing in place once adjusted to the selected width. The slide is in a figure of 8 conformation (Fig A9): the webbing needs to be threaded through the two slots in a downward direction, passed through the end fitting, passed back through the slots in an upward direction, and then (to avoid the risk of slippage) back through the slots in a downward direction.



Fig A9 Slide

A.3.3 Camlock clamp

As an alternative to a flat mount and slide, a camlock style clamp can be used to hold and adjust the belt webbing (Fig A10). The clamp needs to have a hole in it through which to bolt the clamp to the framework attachment device. It is essential that the clamp is tested with the webbing to be used to the ISO 16840-3 standard to confirm that there is no slippage when the clamp is closed, under the test condition.

Note. The profile of the clamp will need to be a low profile when being placed between the seat frame and the wheels of a wheelchair when using a framework attachment device.



Fig A10 Camlock clamp

Annex B (Informative)

Prevention of risk of asphyxiation

Asphyxiation can arise from the use of posture belts and harnesses for one of following reasons

- B.1 The harness is too high such that it occludes the airway (strangulation). This may be because
 - a. The harness has been fitted too high
 - b. The harness has been adjusted since fitting, to sit too high
- B.2 The user collapses down in the seat such that the airway is occluded by the harness. This may be because
 - a. There is insufficient lateral trunk support such that the user collapses to one side
 - b. There is insufficient posterior pelvic or lumbar-thoracic support to maintain an upright posture, such that the user collapses down into kyphosis
- B.3 The user slides down in the seat such that the airway is occluded by the harness. This may be because the posture belt is
 - a. absent or not in use
 - b. fitted too loosely
 - c. poorly positioned
 - d. or malfunctioning
- B.4 Mechanical compression is otherwise applied to the neck, ribcage and/or diaphragm, due to
 - a. harness or chest strap/pad is fitted too tightly
 - b. the user slides underneath the posture belt until stopped by their arms and ribcage placing pressure on the ribcage
 - c. the user submarining totally underneath a posture belt until they are stopped by the belt being caught around their neck

The risk of injury or death due to strangulation is greater when a chest type harness is used, as compared with a shoulder harness, due to the neck shape integral to the design of the harness. The risk of injury or death is increased when the user is unable to recognise that something is incorrect about their seating, and cannot verbally express their distress.

Annex C (Normative)

How to measure a person

Annex D (Normative)

How to measure a device

30