

Lower limb orthoses —

Part 1: Guide to the design and manufacture of lower limb orthoses, excluding foot orthoses

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Committees responsible for this British Standard

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- British Institute of Surgical Technologists
- British Investment Casting Trade Association
- British Limbless Ex-service Men’s Association
- British Medical Association
- British Narrow Fabrics Association
- British Orthopaedic Association
- British Retailers Association
- British Surgical Trades Association
- Chartered Society of Physiotherapy
- College of Occupational Therapists
- Consumer Policy Committee of BSI
- Department of Health
- Disablement Services Authority
- International Society for Prosthetics and Orthotics (United Kingdom National Society)
- Knitting Industries Federation Ltd.
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- National Centre for Training and Education in Prosthetics and Orthotics
- Opportunities for the Disabled
- Orthotic and Prosthetic Training and Education Council (OPTEC)
- Royal College of Nursing and National Council for Nurses of the United Kingdom
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- SATRA Footwear Technology Centre
- Scottish Home and Health Department
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- Society of Chiropodists
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Foreword

This Part of BS 2574 has been prepared under the direction of the Health Care Standards Policy Committee.

BS 2574-1:1977 “*Specification for orthopaedic calipers*” Part 1 “*Basic design*”, was withdrawn in March 1984 because the details contained were too design specific, thus inhibiting the use of modern materials and technologies. Moreover it was limited to only one type of orthosis. In this third edition of this Part of BS 2574, the scope has been expanded to include all lower limb orthoses except foot orthoses.

This third edition of BS 2574-1, which is intended for those conversant with the orthotics industry and the manufacture of lower limb orthoses, gives guidance on design considerations as well as recommendations for the materials, manufacture, marking and packaging of various types of lower limb orthoses. Although there are a number of common features within the different types of orthoses, in many instances the precise details will depend markedly upon the function that the orthosis is intended to perform in service. Consequently this Part of BS 2574 deals separately with individual types of orthosis categorized by the joint(s) of the body that the orthosis encompasses, namely ankle-foot orthoses (AFO), hip-knee-ankle-foot orthoses (HKAFO), hip-knee orthoses (HKO), hip orthoses (HpO), knee-ankle-foot orthoses (KAFO) and knee orthoses (KO).

Foot orthoses (FOs) are not covered by this Part of BS 2574 because they differ fundamentally from the other types of orthosis.

Within each category, the orthoses have been further categorized according to their primary function, and recommendations have been presented for each functional category.

This Part of BS 2574 is not intended to define or recommend particular designs of orthosis and therefore it only gives recommendations for particular designs if specific guidance is believed to be necessary to ensure the satisfactory functioning and quality of that design. For information, sources of examples of widely known designs are listed in a bibliography (see Appendix C).

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 16, an inside back cover and a back cover

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 2574 provides guidance on the design, manufacture, marking and packaging of lower limb orthoses, except foot orthoses (FOs). Guidance on the materials used and on the manufacture of lower limb orthoses is given in Appendix A and Appendix B, respectively.

This Part of BS 2574 does not apply to orthotic devices for use in the immediate treatment of acute trauma cases, nor to resting splints.

NOTE 1 BS 2574-2 and BS 2931 specify requirements for metal knee joints and steel ankle joints, respectively.

NOTE 2 The titles of the publications referred to are listed on the inside back cover. See also the bibliography listed in Appendix C.

2 Definitions

For the purposes of this Part of BS 2574, the definitions given in BS 2574-2 and BS 7313-1.1 and BS 7313-1.3 apply, together with the following¹⁾.

2.1 Orthoses

2.1.1

ankle-foot orthosis (AFO)

an orthosis that encompasses the ankle joint and the whole or part of the foot

2.1.2

foot orthosis (FO)

an orthosis that encompasses the whole or part of the foot

2.1.3

hip-knee-ankle-foot orthosis (HKAFO)

an orthosis that encompasses hip, knee and ankle joints and the foot

2.1.4

hip-knee orthosis (HKO)

an orthosis that encompasses the hip and knee joints

2.1.5

hip orthosis (HpO)

an orthosis that encompasses the hip joint

2.1.6

knee-ankle-foot orthosis (KAFO)

an orthosis that encompasses the knee and ankle joints and the foot

2.1.7

knee orthosis (KO)

an orthosis that encompasses the knee joint

2.2 Functions

2.2.1

assist

a system of external forces designed to increase the range, velocity or force of a desired movement of an anatomical joint

2.2.2

resist

a system of external forces designed to decrease the range, velocity or force of a desired movement of an anatomical joint

2.2.3

stop

a system in an orthosis designed to prevent an undesired movement of an anatomical joint

2.2.4

hold

a system in an orthosis designed to eliminate all movement in a plane of an anatomical joint

2.2.5

free

a system in an orthosis designed to allow unrestrained movement in a plane of an anatomical joint

2.2.6

free with stop

a system in an orthosis designed to allow, within a restricted range, unrestrained movement in a plane of an anatomical joint

2.3 Components

2.3.1

socket

tubular section, fixed within the structure of the shoe, designed to accept the spur of an orthotic side member

2.3.2

stirrup

a base plate, fixed within the structure of the shoe, with integral bilateral side members which may incorporate an orthotic ankle joint

2.3.3

spur

a round, rectangular or square section peg, set at a right angle to the lower extremity of a side member, to provide a fixed or pivoted connection with the footwear

¹⁾ The definitions given in 2.1.1 to 2.1.7 are identical to those given in BS 7313-1.3, but are included here because of their direct relevance. The definitions given in 2.2.1 to 2.2.5 are based on those put forward in "A new orthotics terminology — a guide to its use for prescription and fee schedules" by Dr E. E. Harris in the journal "Orthotics and Prosthetics" Vol. 27, No.2, June 1973.

2.3.4 side member

a medial or lateral component of either one-piece or composite construction and including side pieces, end pieces, joints or adjustment devices

2.3.5 T-strap

a broad strap in the shape of the letter “T”, which is secured to a shoe and which, when used in conjunction with a side member, exerts a force to the region of the malleolus producing an inverting or everting moment

2.3.6 Y-strap

a broad strap in the shape of the letter “Y”, which is secured to a shoe and which, when used in conjunction with a side member fitted with a strap-retaining loop, exerts a force to the mid-tarsal region producing an inverting or everting moment

2.3.7 calf band

band connecting the side members, padded and covered as necessary, complete with a suitable fastening at the calf level

2.3.8 ankle/foot section

structural interface section encompassing, in whole or in part, the ankle and foot

2.3.9 calf section

structural interface section located between or replacing the side members below the knee; it may be integral with the ankle/foot section

2.3.10 thigh section

structural interface section located between or replacing the side members above the knee; it may or may not be ischial-bearing

2.3.11 thigh band

band at the thigh connecting the side members, padded and covered as necessary, complete with a suitable fastening

2.3.12 ring top

an anatomically-shaped padded ring, which is intended to encircle the thigh completely, usually composed of round-section metal

2.3.13 bucket top

mouldable support with ischial bearing, reinforced when necessary by means of a posterior structural element, to which the side members are attached

3 Categories

A lower limb orthosis is categorized according to the joint(s) it encompasses as follows:

- a) AFO: ankle-foot orthosis (see clause 4);
- b) KO: knee orthosis (see clause 5);
- c) KAFO: knee-ankle-foot orthosis (see clause 6);
- d) HpO: hip orthosis (see clause 7);
- e) HKO: hip-knee orthosis (see clause 7);
- f) HKAFO: hip-knee-ankle-foot orthosis (see clause 7).

4 Ankle-foot orthoses (AFOs)

4.1 Design principles based on functional requirements

In general, an AFO applies selective forces at the foot, ankle and calf.

When designing AFOs, consideration should be given to the individual patient's degree of functional loss, physical activity level and body mass, and to the underlying pathology. The shape and skin of the lower limb at the patient/orthosis interface should also be taken into account. The interface (i.e. at the calf section and ankle/foot section) should be designed to transmit the generated loads taking account of areas of sensitivity or high tolerance and, also, of the characteristics of the underlying tissue.

Controls applied at the ankle can influence other anatomical joints. This effect may generate additional requirements (e.g. control of knee hyper-extension) and on other occasions may produce undesirable results. The design and construction of AFOs should take account of these considerations.

Because of the cyclic nature of applied loads to these AFO devices, it is important that the materials used should have good fatigue resistance. The surface finish of the materials should also be of good quality and sharp corners at changes of section should be avoided in order to minimize stress concentrations.

Intricate mouldings may be necessary for plastics materials used in some devices and, in these cases, mouldability will be an additional consideration to those of strength and fatigue resistance.

If side members are combined with a T-strap or Y-strap attached to the shoe, the distal migration of the strap should be prevented if the orthosis is to be effective.

A pair of orthotic joints, if fitted at a single anatomical joint, should have a common axis aligned with that of the joint.

4.2 Specific types of AFO

NOTE References to particular designs of some of the types of orthosis described in this subclause can be found in Appendix C.

4.2.1 AFOs to control plantarflexion and/or dorsiflexion of the ankle

These orthoses should modify the plantarflexion or dorsiflexion moments about the ankle resulting from muscular activity or ground reaction forces due to any form of lower limb activity.

The form of control exerted by the orthosis will normally be dictated by the design of the ankle joints incorporated in the orthosis. The function provided may be one of the following:

- a) hold;
- b) free with stop;
- c) assist;
- d) resist.

4.2.2 AFOs to control supination and/or pronation of the subtalar joint

These orthoses should modify the supination or pronation moments about the subtalar joint resulting from muscular activity or ground reaction forces due to any form of lower limb activity.

These orthoses may also control plantarflexion and/or dorsiflexion of the ankle (see 4.2.1).

The forms of control exerted by the orthosis will normally be dictated by the design of the joints incorporated in the orthosis. The function provided may be one of the following:

- a) hold;
- b) free with stop;
- c) assist;
- d) resist.

4.2.3 AFOs to relieve the limb loading below the knee

These orthoses should reduce or eliminate the forces and moments on the limb below the knee. It may be necessary for these devices to withstand forces considerably in excess of the body weight because of the dynamic effects of lower limb activity. These forces will usually be combined with torsional forces and bending moments.

These orthoses may also control plantarflexion and/or dorsiflexion of the ankle (see 4.2.1) as well as supination and/or pronation of the subtalar joint (see 4.2.2).

5 Knee orthoses (KOs)

5.1 Design principles based on functional requirements

A KO generally applies forces to the lower limb in areas immediately adjacent to the knee joint. For this reason, a KO usually has short lever arms which means that the ability of these arms to produce controlling and bending moments is limited because the forces required soon exceed those that are acceptable to patients or are clinically permissible. Consequently, the prescription of KOs is usually restricted to cases with small degrees of deformity or where they are needed for symptomatic relief.

When designing a KO, consideration should be given to the pathological problem, the anatomy and stature of the patient and the activity to be undertaken when the device is being worn. In many cases cyclical loadings may be applied and fatigue failure will then be a factor which requires consideration. In order to minimize fatigue problems, it is always good practice to avoid sharp changes of section in the components of the device and to ensure that the surface of KOs is free from blemishes.

When designing a KO, attention should be given to the condition of the patient's skin in the area on which forces are to be applied. The interface of the KO should be designed to transmit the generated loads taking account of areas of high pressure and high sensitivity and of the characteristics of the underlying tissues. There should be a close fit between the orthosis and the femoral and tibial condyles.

A pair of orthotic joints, if fitted at a single anatomical joint, should have a common axis aligned with that of the joint.

5.2 Specific types of KO

NOTE References to particular designs of some of the types of orthosis described in this subclause can be found in Appendix C.

5.2.1 KOs to control flexion and/or extension of the knee

These orthoses should modify the flexion or extension moments about the knee due to muscular activity or ground reaction forces during any form of lower limb activity.

The form of control exerted by the orthosis will normally be dictated by the design of the orthotic knee joints incorporated in the orthosis. The function provided may be one of the following:

- a) hold;
- b) free with stop;
- c) assist;
- d) resist.