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Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components

Prothèses et orthèses — Classification et description des orthèses externes et des composants d'orthèses

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13404 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Introduction

No internationally accepted method has been available to classify or describe external orthoses and the components from which they are assembled. This situation has created difficulty for practitioners prescribing orthoses, for manufacturers producing literature describing their products, and for those reporting on prescriptions employed in the treatment of particular patient groups.

This International Standard permits the systematic classification and description of both the finished orthosis and the components from which it is assembled in a manner that clearly explains their principal characteristics.

Manufacturers' trade names and details of materials and manufacturing processes have been avoided.

Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components

1 Scope

ISO 13404 establishes a means of classifying and describing external orthoses and the components from which they are assembled.

2 Normative references

The following referenced documents are indispensable for the application 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 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 8549-3, *Prosthetics and orthotics — Vocabulary — Part 3: Terms relating to external orthoses*

ISO 8551, *Prosthetics and orthotics — Functional deficiencies — Description of the person to be treated with an orthosis, clinical objectives of treatment, and functional requirements of the orthosis*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3 and ISO 8551 and the following apply.

3.1
custom fabricated orthosis
device that is designed and manufactured to meet the functional requirements of the individual user based on information such as moulds, models, measurements and images

3.2
prefabricated orthosis
device that has been designed to meet particular functional requirements and is normally available in a range

NOTE The selected orthosis might require adjustment for the individual user.

4 Classification of orthoses

4.1 General description

Describe the orthosis by reference to the body segments and joints which it encompasses using the terminology defined in ISO 8549-3 and shown in Table 1.

Table 1 — Terminology defined in ISO 8549-3

Device	Abbreviation
Foot orthosis	FO
Ankle-foot orthosis	AFO
Knee orthosis	KO
Knee-ankle-foot orthosis	KAFO
Hip orthosis	HpO
Hip-knee orthosis	HKO
Hip-knee-ankle-foot orthosis	HKAFO
Finger orthosis	FO
Hand orthosis	HdO
Wrist-hand orthosis	WHO
Wrist-hand-finger orthosis	WHFO
Elbow orthosis	EO
Elbow-wrist-hand orthosis	EWHO
Shoulder orthosis	SO
Shoulder-elbow orthosis	SEO
Shoulder-elbow-wrist-hand orthosis	SEWHO
Sacro-iliac orthosis	SIO
Lumbo-sacral orthosis	LSO
Thoraco-lumbo-sacral orthosis	TLSO
Cervical orthosis	CO
Cervico-thoracic orthosis	CTO
Cervico-thoraco-lumbo-sacral orthosis	CTLSO

4.2 Function

4.2.1 The function of the orthosis may be to manage a deformity:

a) to prevent a deformity (i.e. to stop a joint or segment moving into an abnormal alignment);

b) to reduce a deformity (i.e. to move a joint or segment to an improved alignment and hold the correction obtained);

c) to hold a deformity (i.e. to prevent an irreducible deformity from increasing).

Specify the joint(s) and/or segment(s) and the alignment which the orthosis is designed to achieve.

4.2.2 The function of the orthosis may be to change the range of motion of a joint(s):

a) to limit the range of motion of a joint;

b) to increase the range of motion of a joint.

Specify the joint(s) and the range(s) of motion which the orthosis is designed to achieve.

4.2.3 The function of the orthosis may be to change the dimensions of a limb segment(s):

a) to add to the length of a segment;

b) to improve the shape of a segment.

Specify the segment and the magnitude of the length addition and/or the change of shape that the orthosis provides.

4.2.4 The function of the orthosis may be to manage abnormal neuromuscular function:

a) to compensate for weak muscle activity;

b) to control the effect of muscle hyperactivity.

Specify the joint moment(s) which the orthosis is designed to produce.

4.2.5 The function of the orthosis may be to reduce or redistribute the load on tissue (e.g. to redistribute pressure on the plantar surface of the foot or to reduce the load on a tibial fracture).

Specify the tissue loading that the orthosis is designed to reduce or redistribute.

4.3 Type of fabrication

The orthosis may be:

a) **custom fabricated**

or

b) **prefabricated**.

State the type of fabrication.

5 Classification of orthotic components

5.1 General

External orthoses are constructions comprising the following classes of components:

a) interface components;

b) articulating components;

c) structural components;

d) cosmetic components.

NOTE Some components might belong to more than one class, e.g. moulded plastic shells may serve as interface, articulating and structural components.

5.2 Interface components

Interface components of orthoses are those in direct contact with the user. They transmit the forces between the orthosis and the user which result from its function and may retain the orthosis in place.

Interface components include the following.

a) **Shells**, which encompass body segments (or parts thereof). They are wholly or partially circumferential and may be stiff or flexible and may be opened for entry. Open shells may be closed by straps. Shells apply forces perpendicular to the surface of the body.

   A shell may be shaped to be weight bearing:

   1) the proximal part of a shell is sometimes referred to as the **brim**;

   2) stiff narrow shells are sometimes referred to as **bands**;

   3) flexible narrow shells are sometimes referred to as **cuffs**.

b) **Pads**, which apply a localized force perpendicular to the surface of a body segment or at a joint and may require straps to achieve this effect.

c) **Straps**, which apply a localized force mainly perpendicular to the surface of a body segment or at a joint.

d) **Foot orthoses**, comprising insoles, inserts, pads, arch supports, heel cushions and heel cups which modify the distribution of the forces on the surface of the foot.

e) **Shoes**, which even when not an integral part of orthoses may be essential for their function.

State the interface components utilized in the construction of the orthosis.

5.3 Articulating components

NOTE Articulating components of orthoses allow or control the motions of anatomical joints.

5.3.1 General

Describe the articulating components by including the information given in 5.3.2 to 5.3.6.

5.3.2 Types of articulating component

The types of articulating component are identified by reference to the anatomical joints whose motions they are intended to allow or control. They include:

a) joints for spinal orthoses;

b) hip joints;

c) knee joints;

d) ankle joints;

e) foot/toe joints;

f) shoulder joints;

g) elbow joints;

h) wrist joints;

i) hand/finger joints.

State the types of articulating component, i.e. the joints, in the orthosis.

5.3.3 Permissible motions

The permissible motions of the joints when assembled in the specific orthosis may be:

a) flexion/extension;

b) dorsiflexion/plantarflexion;

c) dorsal/palmar flexion;

d) abduction/adduction;

e) internal/external rotation;

f) supination/pronation;

g) lateral flexion;

h) lateral rotation.

State for each joint the permissible motions.

State if the action of the joint results in simultaneous motion in more than one of these planes.

5.3.4 Form of articulation

State for each permissible motion whether it is achieved by:

a) movement between parts of the joint

and/or

b) deformation of a part of the joint.

5.3.5 Axis of rotation

Motion is either

a) **monocentric**, in which the axis of rotation is constant for all angles of the joint

or

b) **polycentric**, in which the axis of rotation changes with the angle of the joint.

State for each permissible motion whether it is monocentric or polycentric.

5.3.6 Controls

Joints may incorporate features which control their motion during use.

These include mechanisms which:

a) **lock** the joint at a specified angle

— activation of locking/unlocking may be **manual** or **automatic,** in the following combinations:

— manual lock/manual unlock;