
**Prosthetics and orthotics — Soft
orthoses — Uses, functions,
classification and description**

*Prothèses et orthèses — Orthèses souples — Utilisations, fonctions,
classification et description*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

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

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Introduction

No internationally accepted method is available to describe externally applied devices constructed from flexible materials which apply pressure to the body segments which they encompass. In some countries these devices are referred to as “bandages”.

This situation has created problems for practitioners prescribing these devices, for manufacturers when describing their products and for those reporting on the devices used in the treatment of their patients and their effects.

This document proposes the adoption of the term “soft orthoses” for this group of devices. It specifies their uses and functions, and classifies and describes the devices and their components.

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

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Prosthetics and orthotics — Soft orthoses — Uses, functions, classification and description

1 Scope

This document specifies the uses and functions of soft orthoses. It also classifies and describes the devices and their components. It does not describe the materials or manufacturing methods used for their fabrication.

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 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*

ISO 13404, *Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3, ISO 8551 and ISO 13404 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 soft orthoses

orthoses whose soft interface materials apply pressure circumferentially and, if required, locally (using pads and/or inserts) to the surface of the body segments which they encompass

Note 1 to entry: They can incorporate orthotic joints and/or other components intended to control the motion and/or alignment of joints. Taping, stockings and garments used to treat burns are excluded.

4 Uses

Soft orthoses may be used to achieve the following clinical objectives:

- a) to stimulate motor-sensory feedback;
- b) to prevent or reduce swelling;
- c) to control the motion(s) of a joint(s);

- d) to control the alignment of a joint(s);
- e) to relieve pain;
- f) to promote healing;
- g) to protect tissues.

5 Functions

Soft orthoses can have the following functions:

- a) to provide continuous circumferential pressure on the underlying tissues;
- b) to control the motion(s) of a joint(s);
- c) to control the alignment of a joint(s);
- d) to apply pressure on tissue locally.

6 Classification of devices

Classify the soft orthosis by reference to the body segment(s) and joint(s) 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
Hip orthosis	HpO
Finger orthosis	FiO
Hand orthosis	HdO
Wrist-hand orthosis	WHO
Elbow orthosis	EO
Shoulder orthosis	SO
Sacro-iliac orthosis	SIO
Lumbo-sacral orthosis	LSO
Thoraco-lumbo-sacral orthosis	TLSO

NOTE Some soft orthoses encompass only the digits while others encompass multiple body segments (e.g. full body suits).

7 Description

7.1 Type of fabrication

Soft orthoses can be either

- a) custom fabricated, or
- b) prefabricated.

Prefabricated orthoses may require adjustment for the individual user. State whether the orthosis is custom fabricated or prefabricated.

7.2 Types of orthotic component

Soft orthoses comprise the following types of component:

- a) interface components;
- b) orthotic joints.

7.3 Description of orthotic components

7.3.1 Interface components

Interface components of soft orthoses are those in direct contact with the user. They are manufactured from soft material which can be:

- a) non-elastic;
- b) elastic;
- c) part elastic/part non-elastic.

The direction of action of the elastic part can be:

- circumferential;
- longitudinal;
- both.

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State if the interface material is elastic or non-elastic; if elastic, describe the position of the elastic part and its direction of action.

The interface component pressure distribution can be modified by the inclusion of pads, inserts and straps.

State, if appropriate, how the interface component is modified.

7.3.2 Orthotic joints

Orthotic joints are described by reference to the anatomical joints whose motions they are intended to control. They include:

- a) ankle joint;
- b) knee joint;
- c) hip joint;
- d) wrist joint;
- e) elbow joint;
- f) shoulder joint.

State the type of orthotic joint.