
**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**

*Prothèses et orthèses — Malformations des membres — Description
de la condition de l'utilisateur d'orthèse, objectifs cliniques, et
exigences fonctionnelles et biomécaniques de l'orthèse*



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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 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 168, *Prosthetics and orthotics*.

This second edition cancels and replaces the first edition (ISO 8551:2003), which has been technically revised. The main changes compared to the previous edition are as follows:

- the terminology used in this document has been revised to make it fully consistent with the terminology used in Reference [5].

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.

Introduction

The quality of life of a person will depend on the health conditions which affect them, the consequential impairments to the body functions and structures, and the resulting activity limitations

The aim of orthotic treatment is to manage the impairments, reduce the activity limitations and thus improve participation in all aspects of daily life.

This document provides clinicians with a method of recording the relevant information regarding the condition of their patients, the clinical objectives of treatment and the functional requirements of the orthoses provided to achieve these objectives.

A standard method is essential for comparing the clinical practices and the outcomes of treatment provided in different centres. Such a method is also of value to epidemiologists and government health officials.

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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

1 Scope

This document establishes a method of describing the person to be treated with an orthosis, the clinical objectives of treatment and the functional requirements of the orthosis.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3 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 <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

alignment of a skeletal segment

spatial relationship between the ends of the segment

Note 1 to entry: The alignment of a skeletal segment is determined by its integrity and/or shape.

3.2

alignment of a joint

spatial relationship between the skeletal segments which comprise the joint

Note 1 to entry: The alignment of a joint is determined by the integrity and shape of the skeletal segments of which it is comprised, and the action of associated muscular and ligamentous/capsular tissues. These factors also govern the type and range of motion at the joint.

3.3

stability

ability of a segment or joint to maintain its alignment when subjected to muscle forces and or external loading

Note 1 to entry: A skeletal segment or joint whose stability is impaired is said to be unstable (or exhibit instability)

3.4

deformity

abnormal *alignment of a skeletal segment* (3.1) or joint

3.5

reducible deformity

deformity (3.4) of a skeletal segment or joint for which the application of an external force system will change the alignment

3.6

irreducible deformity

deformity (3.4) of a skeletal segment or joint for which the application of an external force system has no effect on the abnormal alignment

4 Description of the person to be treated with an orthosis

4.1 General

Describe the person to be treated with an orthosis as specified in 4.2 to 4.6.

4.2 Personal factors

State the person's age, gender, height, weight and side dominance.

Describe, where relevant, the person's social and physical environments and their vocational and recreational activities.

4.3 Health conditions to be treated with an orthosis

4.3.1 Disorders or diseases

State the diagnoses and the relevant ICD codes.

4.3.2 Impairments of body structures and functions

Describe any impairments of

- shape, alignment and dimensions of the structures (i.e. the bones, joints, muscles and tendons, ligaments, other soft tissues and segments of the trunk),
- stability and range(s) of motion of the joint(s),
- muscle strength and neuromuscular control, and
- sensation, or the presence of pain.

4.4 Other health conditions

Impairments of the following body systems and functions might influence orthotic treatment:

- a) cardiovascular;

- b) respiratory;
- c) musculoskeletal;
- d) skin;
- e) neurological;
- f) endocrine;
- g) the senses;
- h) nutrition;
- i) cognition;
- j) mental health;
- k) other systems.

State if there is an impairment of any of these which could influence the orthotic treatment, and note any other related current treatment.

4.5 Motivation and perceived needs

State the clinical impression of the person's motivation and their perceived needs.

NOTE The motivation and perceived needs of the person have a major effect upon the rehabilitation objectives. They are interdependent and are influenced by the person's clinical condition, and personality, and environmental factors.

4.6 Activity limitations

4.6.1 General

The health condition and resulting impairments might limit the person's activities and restrict their participation.

Any activity limitations should be identified as detailed in [4.6.2](#) to [4.6.4](#).

4.6.2 Changing and maintaining body position

a) Bed mobility:

State if the person is immobile.

b) Transferring:

Describe the person's ability to transfer from

- 1) bed to chair,
- 2) sitting to standing, and
- 3) standing to sitting

as

- 1) unable to transfer, or
- 2) able to transfer with assistance from a person, and/or

3) able to transfer using an assistive device.

c) Sitting:

State if the person requires support in order to maintain a seated position.

d) Standing:

Describe the person's standing as

- 1) unable to stand, or
- 2) able to stand only with assistance from a person, and/or
- 3) able to stand using an assistive device.

4.6.3 Walking

Describe the person's walking as

- a) unable to walk,
- b) able to walk with assistance from a person,
- c) able to walk with a mobility device,
- d) able to walk independently only on smooth level surfaces,
- e) able to walk independently on smooth level surfaces and can manage stairs or a step with a hand rail, or
- f) able to walk independently on uneven surfaces and can manage stairs or a step without a hand rail.

4.6.4 Hand and arm use

State if the person is

- a) unable to use the hand and arm,
- b) unable to use the arm but able to use the hand, or
- c) able to use the arm but unable to use the hand.

4.7 Use of assistive devices

Specify any assistive device used to compensate for activity limitations.

5 Clinical objectives of treatment

The clinical objectives of treatment are to manage the impairments of the body functions and structures. They include the following.

Specify the objective(s) which apply to the person being treated and state the relevant details in each case.

a) To relieve pain:

State the joint(s) and/or segment(s) involved and what induces the pain.

b) To promote activity:

State what activity is to be promoted.

c) To manage deformities:

- 1) which are reducible/flexible (e.g. developmental dysplasia of the hip);
- 2) which are irreducible/fixed (e.g. a rheumatoid arthritic knee in valgus).

State the joint(s) and/or segment(s) involved and the type of deformity.

d) To prevent an excessive range of joint motion (e.g. knee hyperextension).

e) To increase a reduced joint range of motion (e.g. elbow joint stiffness):

State the joint motion(s) to be prevented or increased.

f) To compensate for abnormalities of segment length or shape (e.g. limb length or soft tissue discrepancy):

State the segment(s) involved and the shape or length alteration required.

g) To manage abnormal neuromuscular function which includes:

- 1) compensating for weak muscle activity (e.g. poliomyelitis);
- 2) controlling the effects of excessive muscle activity (e.g. spasticity).

h) To protect tissues.

i) To promote healing:

State the tissues to be protected or whose healing is to be promoted.

j) To promote other effects (warmth, enabling sensory input, stimulation of motor-sensory feedback, reduction of swelling, psychological support):

State any other effects to be promoted.

6 Functional requirements of the orthosis

To achieve each of the clinical objectives, the orthosis is required to provide some of the following functions.

Specify the functions the orthosis is required to provide for the person being treated and state the relevant details in each case.

a) Manage deformities:

- 1) prevent a deformity (i.e. to stop a joint or segment moving into an abnormal alignment);
- 2) reduce a deformity (i.e. to move a joint or segment to an improved alignment and maintain the correction obtained);
- 3) stabilize and hold a deformity (i.e. to prevent an irreducible deformity from increasing).

Specify the joint(s) and /or segment(s) which the orthosis will affect and the types of management required.

b) Alter joint range of motion:

- 1) prevent the motion of a joint(s);
- 2) limit the motion of a joint(s);
- 3) increase the range of motion of a joint.