INTERNATIONAL STANDARD

ISO 8551

First edition
2003-08-15

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

Reference number
ISO 8551:2003(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 8551 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Introduction

The orthotic treatment of a person depends not only on the causes and underlying conditions for which the orthosis is being prescribed, but also on other clinical conditions and attributes of the person. The various members of the clinical teams in different countries often develop their own nomenclature to record this information. Hence there is a need for an international system to allow comparisons of clinical practice.

The system described in this International Standard is designed to meet the needs of the members of the clinic team to assess the person and to present and evaluate treatment. Such a system will also allow this information to be recorded in a way which can easily be incorporated into reports and used for analysis. It will also be of value to epidemiologists and government health officials.

ISO 8551 defines the minimum information to be described.

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 International Standard 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 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*

ICD-10:1992, *International Statistical Classification of Diseases and Related Health Problems,* World Health Organization, Geneva

3 Terms and definitions

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

3.1
alignment of a skeletal segment
spatial relationship between the ends of the segment

NOTE 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 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
alignment of the trunk (or any part thereof)
spatial relationship between the relevant two end vertebrae

NOTE The alignment of the trunk is determined by the alignment of the intervening skeletal segments and joints.

3.4
instability
tendency of a skeletal segment or joint, whose integrity is impaired, to change to an abnormal alignment when subjected to muscle forces and/or external loading

NOTE A skeletal segment or joint exhibiting such instability is said to be unstable.

3.5
deformity
abnormal alignment of a skeletal segment or joint

3.6
preventable deformity
deformity for which the application of an external force system will prevent an unstable skeletal segment or joint moving into an abnormal alignment

3.7
reducible deformity
deformity for which the application of an external force system will improve the alignment of a skeletal segment or joint

3.8
irreducible deformity
fixed deformity
deformity for which the application of an external force system has no effect on the abnormal alignment of a skeletal segment or joint

4 Description of the person to be treated with an orthosis

4.1 General

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

4.2 Personal factors

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

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

Describe any significant and relevant medical history.

4.3 Clinical condition to be treated with an orthosis

State the diagnosis and the ICD-10 codes (International Statistical Classification), whether the condition is constant or changing, the involved body segment(s) or joint(s) and the presence of pain or tenderness.

Describe any abnormalities of

— the alignment, shape and dimensions (e.g. length and circumference) of the involved body segment(s),

— the alignment, stability, range(s) of motion and neuromuscular control of the involved joint(s),

— superficial and deep sensations.

4.4 Other clinical conditions

Disorders of the following may influence orthotic treatment:

a) the cardiovascular system;

b) the respiratory system;

c) the musculoskeletal system;

d) the neurological system;

e) endocrine system;

f) the special senses;

g) the nutritional status;

h) the cognitive state;

i) the mental and psychological status;

j) other systems.

State if there is a disorder of any of these which influences the orthotic treatment, and note any other 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 marked effect upon their rehabilitation. They are interdependent and are influenced by the person's clinical condition, personality and physical, social and cultural environment.s Motivation is difficult to describe but both poorly motivated and highly motivated individuals can be recognized by clinicians.

4.6 Functional abilities

The clinical condition and resulting impairments will affect the person's functional abilities and participation in aspects of daily life.

Any functional limitations should be identified as follows:

a) bed mobility:

   If the person is unable to transfer from bed independently, state whether they are:

   1) immobile; or

   2) able to change their lying position independently.

b) transferring:

   State if the person is unable to transfer from sitting to standing independently.

   State if the person is unable to transfer from standing to sitting independently.

c) sitting:

   State if the person requires support in order to sit.

d) standing/walking:

Describe the person's standing/walking ability as

1) unable to stand, or

2) able to stand, or

3) able to walk with an assistant, or

4) able to walk independently on smooth level surfaces, or

5) able to walk independently on smooth level surfaces and can manage stairs or a step with a hand rail, or

6) able to walk independently on uneven surfaces and can manage stairs or a step without a hand rail.

e) upper limb function:

If the person's upper limb function is abnormal, state whether

1) the person is able to position the hand in space to allow its use,

2) the person is able to grasp objects,

3) the person is able to achieve prehension.

f) use of technical aids:

Specify any technical aids used to assist any of these activities.

5 Clinical objectives of treatment

The clinical objectives of treatment may be

a) to relieve pain,

b) to manage deformities

— which are preventable (e.g. ruptured collateral ligament of knee),

— which are reducible (e.g. developmental dysplasia of the hip),

— which are irreducible (e.g. a malunited fracture),

c) to prevent an excessive range of joint motion (e.g. knee hyperextension),

d) to increase joint range of motion (e.g. joint stiffness),

e) to compensate for abnormalities of segment length or shape, (e.g. limb length or soft tissue discrepancy),

f) to manage abnormal neuromuscular function, which includes

— compensating for weak muscle action (e.g. poliomyelitis),

— controlling the effects of muscle hyperactivity (e.g. spasticity);

g) to protect tissues (e.g. diabetic neuropathy and Charcot neuroarthropathy),

h) to promote healing (e.g. following knee-joint surgery),

i) to provide other effects (e.g. placebo, warmth, postural feedback).

State the clinical objective(s) of treatment, specifying the joint(s) and/or segment(s) involved.

State, where appropriate,

— what induces the pain; and/or

— the type of deformity to be managed; and/or

— the joint motion to be prevented or increased; and/or

— the alteration of segment length or shape required; and/or

— the muscle action to be compensated for or controlled; and/or

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

6 Functional requirements of the orthosis

To achieve the clinical objectives, the orthosis may be required to provide the following functions:

a) deformities

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

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

   3) to stabilize a deformity (i.e. to prevent an irreducible deformity from increasing);

b) joint motion

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

   2) to increase the range of motion of a joint;

c) segment dimensions

   1) to add to the length of a segment;

   2) to improve the shape of a segment;

d) muscle activity

   1) to compensate for weak muscle activity;

   2) to control the effect of muscle hyperactivity;

e) to reduce or redistribute the load on tissue (e.g. to redistribute the pressure on the plantar surface of the foot or to reduce the load on a tibial fracture).

State the functional requirement(s) of the orthosis, and specify the joint(s) and/or segment(s) which it is to affect.

State, where appropriate,

— the nature of the deformity, and/or

— the range of motion of a joint which is required, and/or

— the magnitude of segment length addition required, and/or

— the muscle action to be compensated for or controlled, and/or

— the tissues to be relieved of loading.

Annex A
(informative)

Biomechanical effects of orthoses

The majority of orthoses achieve the function for which they have been prescribed by the application of a system of forces (hereafter referred to as the orthosis/body force system) to the body segments which the orthosis encompasses.

The precise nature of the orthosis/body force system and the location of the individual forces which constitute it will depend on the clinical objective(s) of treatment, the joints and/or segments involved, the functional requirement(s) of the orthosis, and the biomechanical effect(s) required to achieve the functional requirement(s).

The biomechanical effect of the orthosis may be to generate:

a) a force at a joint or upon a body segment and hence:

   — reduce or redistribute the external load on skin and/or subcutaneous tissues and/or the internal load on tissues. (It may additionally prevent abnormal translatory motion occurring at a joint or within a segment.)

b) a moment at a joint or upon a body segment and hence:

   — prevent, reduce or stabilize a deformity; and/or

   — limit or increase the range of motion of a joint; and/or

   — compensate for weak muscle activity; and/or

   — control the effect of muscular hyperactivity; and/or

   — reduce or redistribute the load on tissues.

It should be noted that the orthosis/body force system and hence its biomechanical effect will only be generated when the orthosis is loaded with a force by the user, e.g.:

— the force system which generates a posteriorly directed force at the knee joint to prevent anterior displacement will only exist when the knee is subjected to an anteriorly directed force;

— the axially directed force applied under an ischial tuberosity to reduce the internal loading on the knee joint will only exist when the leg is weight-bearing;

— the force system which generates a moment at a joint to resist muscle hyperactivity will only exist when the involved muscles contract.

An appreciation of the specific orthosis/body force system and the specific biomechanical effect which the orthosis is required to create is necessary to permit the evaluation of the adequacy of the fit and function of the orthosis.

ICS 11.040.40

Price based on 7 pages