International Standard

ISO 13404-1

First edition
2024-11

Prosthetics and orthotics — External orthoses and orthotic components —

Part 1: Uses, functions, classification and description of lower limb orthoses

Prothèses et orthèses — Orthèses externes et composants d'orthèses —

Partie 1: Utilisations, fonctions, classification et description des orthèses pour les membres inférieurs

Reference number
ISO 13404-1:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: 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.

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 first edition of ISO 13404-1 cancels and replaces ISO 13404:2007, which has been technically revised.

The main changes are as follows:

— introduction of a new Clause 4 on uses;

— update of Clause 5;

— 8.4.5 has been renamed “Control and activation” and its content has been updated to reflect the development of modern orthotic components;

— addition of functional electrical stimulators to Clause 8.

— a focus on lower limb orthoses.

A list of all parts in the ISO 13404 series can be found on the ISO website.

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

This document is intended for practitioners prescribing and/or providing external lower limb orthoses, for manufacturers describing their products, and for those researching and reporting on orthotic use.

External lower limb orthoses are used to treat a wide range of impairments of body functions and structures that impact the lower limb and to assist in overcoming limitations during everyday activities.

Definitions of prefabricated, adaptable, user-matched and custom-made orthoses were changed due to international regulations. Users can refer to the applicable national regulatory documents for details in definitions and local differences in terminology and responsibilities.

Uses, functions, classification, method of fabrication, types, and components of the orthotic device should be described within general healthcare procedures.

For further specifics on foot orthoses, refer to ISO 21064 and for further specifics on soft orthoses for the lower limb, refer to ISO 21063.

Prosthetics and orthotics — External orthoses and orthotic components —

Part 1:
Uses, functions, classification and description of lower limb orthoses

1 Scope

This document specifies the uses and functions of external lower limb orthoses. It classifies and describes the devices and their components. It 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.

This document does not specify the materials or manufacturing methods used for the fabrication of lower limb orthoses.

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 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 21063, *Prosthetics and orthotics — Soft orthoses — Uses, functions, classification and description*

ISO 21064, *Prosthetics and orthotics — Foot orthotics — Uses, functions, classification and description*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3, ISO 8551, ISO 21063, ISO 21064 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
prefabricated orthosis
mass-produced orthosis
orthosis that is produced by a manufacturer and based on standardized dimensions/designs, normally available in a range of sizes, and that is not designed for a particular individual

Note 1 to entry: 'Mass-produced' is used in regulatory language, 'prefabricated' is common in clinical practice.

Note 2 to entry: see also References [6] and [7].

3.2
adaptable orthosis
prefabricated orthosis that is adapted, adjusted, assembled or shaped at the point of care by a healthcare professional in accordance with the manufacturer's validated instructions to suit a particular individual prior to use

Note 1 to entry: According to EU MDR art. 16(1),[4] a person (e.g. clinical practitioner) who adapts, adjusts, assembles or shapes an adaptable medical device for a particular user is not regarded as a manufacturer, as long as the adaptation, adjustment, assembly and shaping does not change the intended purpose or modify the device in such a way that compliance with the applicable requirements may be affected.

Note 2 to entry: see also References [6] and [7].

3.3
user-matched orthosis
patient-matched orthosis
orthosis matched to an individual's anatomy within a specified design envelope (intended range of design variation) using techniques such as scaling based on anatomic references, or by using the full anatomic features from patient imaging, and designed and produced by a manufacturer typically in a batch through a process that is capable of being validated and reproduced

Note 1 to entry: The fit of a user-matched orthosis should be controlled by a healthcare professional and can be adapted at the point of care.

Note 2 to entry: 'User-matched' is a synonym for 'patient-matched' in References [6] and [7].

3.4
custom-made orthosis
orthosis specifically made by a clinical practitioner in accordance with a prescription provided by an authorised healthcare professional and intended for the sole use of a particular individual to meet their specific anatomical, pathological and/or functional requirements

Note 1 to entry: An orthosis that is patient-matched, adaptable or prefabricated shall not be considered custom-made. However, a custom-made orthosis can contain prefabricated, adaptable or user-matched components.

Note 2 to entry: see also References [6] and [7].

Note 3 to entry: Personalized orthosis can be adaptable, user-matched or custom-made orthosis.

3.5
static orthosis
orthosis that does not permit movement of the joints which it encompasses

Note 1 to entry: It can be adjustable and can be used to position, hold and/or apply pressure to the joints and body segments that it encompasses.

3.6
dynamic orthosis
orthosis that includes moving parts and/or components or allows intended deformation of non-articulating parts

Note 1 to entry: It can be adjustable and/or automatically controlled and can be used to perform the same functions as *static orthoses* (3.5).

Note 2 to entry: It can allow, lock, limit, assist or resist the motion of the joints and segments that it encompasses.

3.7
adjustable orthosis
orthosis whose physical properties can be varied manually to support a desired clinical outcome

Note 1 to entry: The adjustments can include the alignment of their components, the movements that they control, or the forces that they are capable of exerting.

3.8
automatically controlled orthosis
orthosis whose physical properties are automatically varied by a system that receives and processes signals in a predefined manner to support a desired clinical outcome

Note 1 to entry: The signals are measured or detected from the user's body or its environment and represent a physical or physiological status.

4 Uses

Lower limb orthoses can achieve the following intended uses and purposes:

a) to relieve pain;

b) to promote healing;

c) to protect tissues;

d) to prevent or reduce oedema;

e) to manage scarring;

f) to control alignment;

g) to prevent the progression of a deformity;

h) to manage deformities that are

   1) totally or partially reducible (flexible), or

   2) irreducible (fixed);

i) to assist weakened muscles;

j) to control the effects of abnormal muscle function (e.g. spasticity, muscle hypotonia, muscle hypertonia);

k) to promote sensory-motor input and feedback from leg and body positions;

l) to promote mobility:

   1) rising to stand;

   2) sitting down;

   3) standing;

   4) ambulation;

   5) transfers;

m) to improve appearance of the leg.

The intended uses and purposes of the orthosis should be thoroughly detailed, including its roles in relieving pain, promoting healing, protecting tissues, preventing or reducing oedema, managing scarring, controlling

alignment, preventing deformity progression, assisting weakened muscles, managing abnormal muscle function, enhancing sensory-motor feedback, promoting mobility, and improving the appearance of the leg.

5 Functions

The functions provided by the lower limb orthosis to achieve the intended uses can include:

a) to hold a deformed or unstable joint or limb segment in a preferred alignment;

b) to alter the range of motion of (an) anatomical joint(s) by

   1) holding the joint(s) at a specific angle,

   2) limiting the range of motion of the joint(s),

   3) increasing the range of motion of the joint(s);

c) to manage the effects of weak or excessive muscle function on activity by

   1) controlling the movement of the ankle joint during stance phase of gait,

   2) actively dorsiflexing the ankle joint during swing phase of gait,

   3) actively plantar flexing the ankle joint during late stance phase of gait,

   4) resisting knee and/or hip flexion during stance phase of gait,

   5) controlling knee and/or hip flexion /extension during swing phase of gait,

   6) controlling knee and/or hip flexion during stance and/or sitting down,

   7) locking the ankle, knee and/or hip during prolonged standing,

   8) switching between stance and swing mode of an ankle, knee and/or hip during gait,

   9) actively assisting rising to standing from sitting,

   10) mechanically coupling the contralateral leg or actively moving legs reciprocally to produce a gait pattern,

   11) stimulating muscles or nerves to produce motions of anatomical joints;

d) to change the dimensions of (a) body segment(s) by

   1) adding to the length,

   2) improving the shape,

   3) or both;

e) to manage the load on a tissue by

   1) redistributing the load,

   2) reducing the load,

   3) or both.

The functions of the orthosis in achieving its intended uses should be clearly detailed, including how it aligns joints, adjusts range of motion, supports muscle function, changes body segment dimensions, and manages tissue load.

6 Classification

Orthoses are classified by reference to the body segments and joints which they encompass. The terminology shown in Table 1 is in accordance with ISO 8549-3.

Table 1 — Terminology defined in ISO 8549-3

Lower limb orthosis	Abbreviation
Toe orthosis	TO
Foot orthosis	FO
Ankle-foot orthosis	AFO
Knee orthosis	KO
Knee-ankle-foot orthosis	KAFO
Hip orthosis	HO
Hip-knee orthosis	HKO
Hip-knee-ankle-foot orthosis	HKAFO

NOTE While the name of the device and abbreviation used remains consistent with those listed in Table 1, descriptive information can be added to clarify variations in any one orthosis.

7 Description

7.1 Method of fabrication

The orthosis can be

a) prefabricated,

b) user-matched orthosis, or

c) custom-made.

A prefabricated orthosis can be an adaptable orthosis.

Whether the orthosis is prefabricated, user-matched, or custom-made should be indicated.

7.2 Type

The orthoses can be

a) static, or

b) dynamic.

The type of the orthosis (i.e. whether the orthosis is static or dynamic) should be specified.

8 Components of orthoses

8.1 General

External lower limb orthoses are made from different components comprising:

— structural components;

— interface components;

— orthotic joints;

— functional electrical stimulators (FES);

— finishing components.

NOTE Some components can belong to more than one class.

8.2 Structural components

Structural components of orthoses provide the function of the orthosis and connect the interface components.

They include:

a) shells (including bands or cuffs) which partially or totally encompass body segments;

NOTE Narrow shells are sometimes called bands or cuffs.

b) bars;

NOTE bands can be required to maintain alignment of the bars.

c) straps (closures) which transmit forces and hold the orthosis in place.

Details on the structural components and their functions should be provided.

When referring to structural components, the placement of any shells, bands, or cuffs in relation to the anatomical segments they cover should be specified.

Additionally, the location (medial, lateral, dorsal, volar) of any bars and whether they are adjustable in length should be indicated.

8.3 Interface components

Interface components are those in contact with the body.

Interface components include the following:

a) shells, which partially or wholly encompass body segments;

b) pads, which apply a localized force perpendicular to the surface of a body segment or at a joint;

c) shoes, insoles, inserts, pads, arch supports, heel cushions and heel cups, which modify the distribution of the forces on the surface of the foot and/or increase the length of a body segment (refer to ISO 21064);

d) straps (closures), which hold the orthosis in place and transmit forces;

e) liners.

The interface components utilized in the construction of the orthosis should be described according to the criteria mentioned in 8.3.

8.4 Orthotic joints

8.4.1 General description

Orthotic joints control the motion of anatomical joints.

The orthotic joint(s) by reference to the anatomical joint(s) whose motions it is intended to control should be described. They include:

a) hip joint;

b) knee joint;

c) ankle joint;

d) foot joints;

e) toe joints.

8.4.2 Motions

The motion(s) which the orthotic joint controls can be:

a) flexion/extension;

b) abduction/adduction;

c) internal rotation/ external rotation;

d) inversion and eversion.

For each orthotic joint, the motion(s) which it controls should be described. Additionally, if the orthotic joint simultaneously controls more than one motion, this should be indicated.

8.4.3 Mode of motion

The motion in an orthotic joint can be achieved by:

a) movement between parts of the orthotic joint;

b) intended deformation of a part of the orthosis;

c) or both.

For each motion of the orthotic joint(s), the mode of motion should be described.

8.4.4 Axis of rotation

Rotation in the orthotic joint can be 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.

For each rotation, whether it is monocentric or polycentric, the axis of the rotation should be described.

8.4.5 Control and activation

8.4.5.1 General

The control and activation of an orthotic joint is described by:

— the control mechanisms used;

— the type of activation;

— the type of variability of is physical properties;

— the function(s) achieved.

8.4.5.2 Control mechanism

Orthotic joint control mechanisms include:

a) locks;

b) limiters;

c) brakes;

d) elastic elements;

e) fluid control elements (pneumatic or hydraulic/visco-elastic);

f) systems using sensors (e.g. microprocessor-controlled systems);

g) actuators (e.g. motors);

h) or combinations thereof.

Based on the list above, an overview of the control mechanism used in the orthotic joint should be provided, including locks, brakes, elastic elements, fluid control elements, sensor-based systems, actuators, or combinations of these components.

8.4.5.3 Activation

Orthotic joints can be activated by:

a) manual activation (e.g. manual unlock);

b) mechanical switches (e.g. automatic lock, automatic unlock);

c) systems including sensors that measure forces (e.g. torque sensor or switch measuring the ground reaction force);

d) systems including sensors that measure the state of the orthotic joint (e.g. joint angle, joint angle velocities, inertial angle);

e) systems including sensors that measure voluntary user input (e.g. switches, nerve- or myopotentials);

f) or combinations thereof.

The activation methods of the orthotic joint should be specified, including manual activation, mechanical switches, systems with force-measuring sensors, systems with joint-state sensors, systems with sensors for voluntary user input, or combinations of these methods.

8.4.5.4 Variability of physical properties

The mechanical properties of the orthotic joint can be:

a) adjusted manually (adjustable orthosis);

b) altered automatically (automatically controlled orthosis);

c) or both.

Information should be provided on whether the orthotic joint is adjustable and/or automatically controlled.

8.4.5.5 Function

The functions achieved through the control and activation mechanisms, as specified in Clause 5, should be described.

8.5 Functional electrical stimulators

Functional electrical stimulators can be integrated in an orthosis to achieve functions as in Clause 5. They comprise a stimulator unit producing the electrical stimulus, and electrodes that apply the stimulus to the body. They can be activated according to 8.4.5.3.