
**Prosthetics and orthotics —
Classification and description of
prosthetic components —**

**Part 2:
Description of lower limb prosthetic
components**

*Prothèses et orthèses — Classification et description des composants
de prothèses —*

*Partie 2: Description des composants de prothèses des membres
inférieurs*



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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 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](#)

The committee responsible for this document is ISO/TC 168, *Prostheses and orthotics*.

This second edition cancels and replaces the first edition (ISO 13405-2:1996), which has been technically revised.

The major technical changes are the following:

- a) classification tree for lower limb prosthetic components added in [Clause 5](#);
- b) levels of amputation extended to include all partial foot levels;
- c) methods of socket suspension extended;
- d) classification tree for functional components added in [Clause 6](#);
- e) range of types of ankle foot units, knee units, hip units, and external (side) joints extended;
- f) load attenuators and turntables added to [Clause 6](#).

ISO 13405 consists of the following parts, under the general title *Prosthetics and orthotics — Classification and description of prosthetic components*:

- *Part 1: Classification of prosthetic components*
- *Part 2: Description of lower limb prosthetic components*
- *Part 3: Description of upper limb prosthetic components*

Introduction

This part of ISO 13405 was the first internationally accepted standard method to describe the components of lower limb prostheses. It is designed to permit users to describe systematically each component which is incorporated in a finished prosthesis in a manner which clearly explains its principal characteristics. It is envisaged as being suitable for use by both manufacturers producing literature describing their products and practitioners who are reporting on the components used in the treatment of persons requiring prosthesis.

Prosthetic technology has made considerable advances since the publication of this part of ISO 13405. This first revision is designed to include the new types of components which have come into use during this period.

Manufacturers' trade names and details of the materials and manufacturing methods employed have been avoided.

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Prosthetics and orthotics — Classification and description of prosthetic components —

Part 2: Description of lower limb prosthetic components

1 Scope

This part of ISO 13405 specifies a method for describing lower limb prosthetic components.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 8549-2, *Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses and wearers of these prostheses*

ISO 8549-4:2014, *Prosthetics and orthotics — Vocabulary — Part 4: Terms relating to limb amputation*

ISO 13405-1:2014, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 1: Classification of prosthetic components*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-2, and the following apply.

3.1

jointed ankle-foot unit

ankle-foot unit where motion(s) is (are) obtained by rotation at a joint(s) within the unit

3.2

unjointed ankle-foot unit

ankle-foot unit where motion(s) is (are) obtained by deformation of a part(s) of the unit

4 Classification and description

The components of lower limb prostheses include five classes identified in ISO 13405-1:2014, 3.1 shown in [Figures 1](#) and [2](#) and described in [Clauses 5](#) to [9](#).

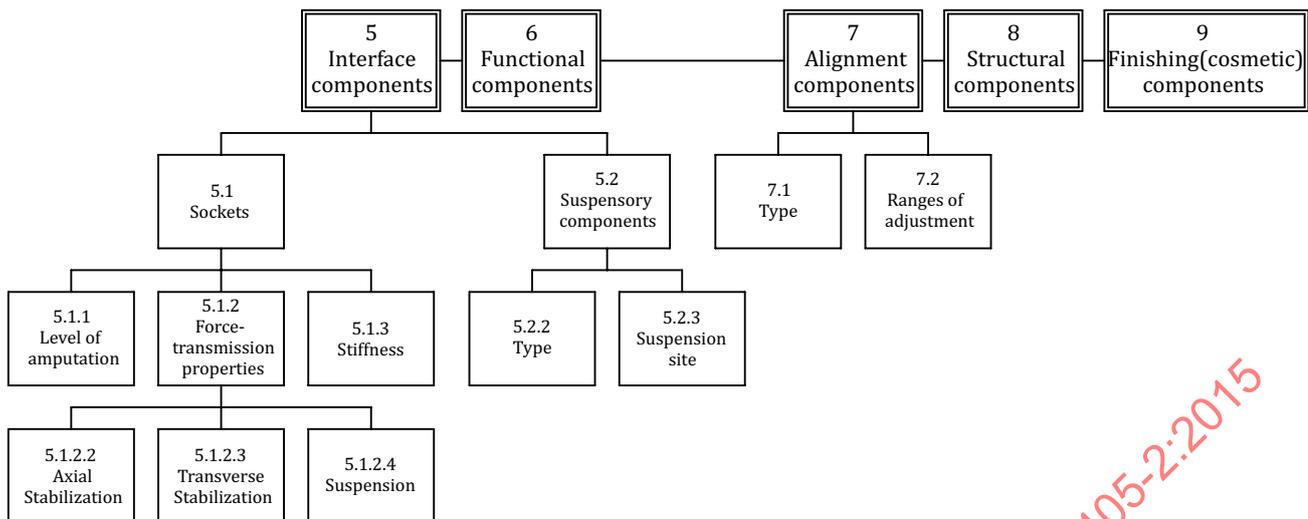


Figure 1 — Lower limb prosthetic components — Classification tree

5 Interface components

5.1 Sockets

5.1.1 Level of amputation

State the level of amputation for which the prosthesis, and hence the socket, is intended by reference to the list of levels defined in ISO 8549-4:2014, 3.1.4, that is, as one of the following:

- a) partial foot amputations; these include;
 - 1) phalangeal,
 - 2) metatarso-phalangeal disarticulation,
 - 3) metatarsal,
 - 4) tarso-metatarsal disarticulation, and
 - 5) tarsal;
- b) ankle disarticulation;
- c) trans-tibial amputation;
- d) knee disarticulation;
- e) trans-femoral amputation;
- f) hip disarticulation;
- g) trans-pelvic amputation.

5.1.2 Force-transmission properties

5.1.2.1 General

The force-transmission properties of a socket relate to the features of the socket which are concerned with the transfer of the forces necessary for axial stabilization, transverse stabilization, and suspension. In some instances the socket is designed to be used with a liner.

Various terms (e.g. total contact and total surface bearing) have been proposed to describe the way these forces are transferred between the stump and the socket. The biomechanical principles, upon which these terms are based, are ill-defined. Thus, the use of these terms is discouraged.

5.1.2.2 Axial stabilization

Axial stabilization is necessary to minimize axial movement between the stump and the socket during weight bearing (e.g. during stance phase).

State the principal intended method(s) of axial stabilization as one or more of the following:

- a) proximal stabilization, in which the principal stabilizing forces are generated by the shaping of the proximal region of the socket;
- b) distal stabilization, in which the principal stabilizing forces are generated by the shaping of the end of the socket; or
- c) total socket stabilization, in which the stabilizing forces are generated by the shaping of the whole surface of the socket.

State whether the axial stabilization forces of the socket are modified by the use of a liner.

5.1.2.3 Transverse stabilization

Transverse stabilization is necessary to minimize angular movement between the stump and the socket during prosthetic use. Three forms of stabilization are required: anteroposterior, mediolateral, and rotational.

State when appropriate, any particular features of the socket shape associated with transverse stabilization.

State whether the transverse stabilization forces of the socket are modified by the use of a liner.

5.1.2.4 Suspension

Suspension is necessary to minimize axial movement between the stump and the socket when the prosthesis is unloaded (e.g. during swing phase).

The socket can be suspended either by:

- a) anatomical suspension, in which the suspensory properties are obtained by shaping the socket to the underlying bony anatomy. This might require the socket to be opened using removable sections, splits, or other means to allow donning and doffing; or
- b) pressure-differential (suction) suspension, in which the suspensory properties are obtained using a socket with an air-tight fit which resists removal by virtue of the pressure differential resulting from such action. It might be necessary to use an external sleeve to achieve the air tight fit; or
- c) using a liner.

Suspension between the stump and the liner is obtained by pressure differential while suspension between the liner and the socket may be obtained either by

- 1) mechanical coupling to the socket,

- 2) pressure differential, or
- 3) both.

The pressure differential effect in methods b) and c) may be enhanced using a vacuum pump.

In any of these methods, adhesion between stump and liner and/or socket can contribute to the suspensory properties.

State when appropriate, the type of suspension provided by the socket and any means of opening the socket.

5.1.3 Stiffness

The stiffness of the socket refers to its elastic deformability in normal usage.

State whether the socket is

- a) rigid (when the socket is designed not to deform),
- b) flexible (when the socket is designed to deform), or
- c) partly flexible (when specific areas of the socket are designed to deform).

Flexible and partly flexible sockets might be supported and/or constrained by a rigid frame/container.

5.2 Suspensory components (other than sockets and liners)

5.2.1 General

Suspensory components provide a mechanical link between the socket and a suitable proximal anatomical site.

External (side) joints which might be part of the suspension system are classified as functional components because their principle function is to constrain unwanted joint motion (see [6.4](#)).

5.2.2 Type

Types of suspensory components include straps, sleeves, cuffs, thigh corsets or shells, and belts.

State the type of suspensory component(s).

5.2.3 Suspension site

Anatomical suspension sites include:

- a) shoulder;
- b) pelvis;
- c) thigh;
- d) femoral condyles;
- e) malleoli.

State the anatomical site(s) used for suspension.

6 Functional components

6.1 General

The motions of the functional components of prostheses are described with respect to the standard reference planes of the body, which are

- a) the sagittal plane,
- b) the frontal plane, and
- c) the transverse plane,

with the component in its intended position of use and the body in the anatomical position (see 6.2 to 6.8).

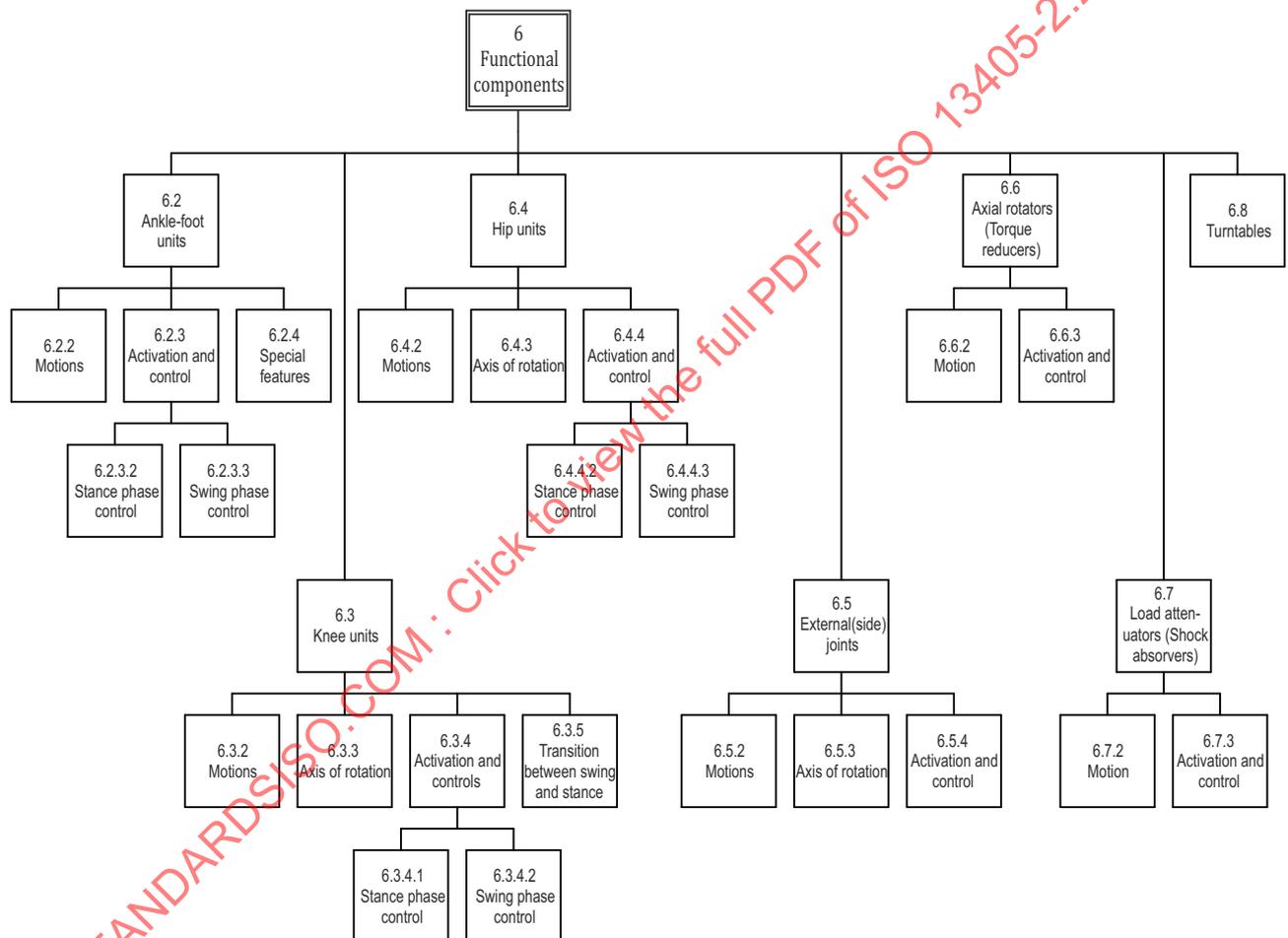


Figure 2 — Functional components — Classification tree

6.2 Ankle-foot units

6.2.1 General

Prosthetic ankle-foot units are designed to substitute for some of the functions of the normal ankle and foot by means of controlled motions. Units can be jointed or unjointed or combined.

Describe the ankle-foot unit by including the following information.

6.2.2 Motions

The motions of an ankle-foot unit can be

- a) plantar flexion/dorsiflexion (motion in a sagittal plane),
- b) inversion/eversion (motion in a frontal plane),
- c) internal/external rotation (motion in a transverse plane),
- d) dorsiflexion of the toe part of the unit (motion in a sagittal plane),
- e) axial translation (motion perpendicular to transverse plane).

State the motions and their ranges.

State if any of these motions are combined.

6.2.3 Activation and control

6.2.3.1 General

Prosthetic ankle-foot units may incorporate features which are designed to activate and control their motions during the stance and swing phases of gait. This can be achieved by the mechanical properties of the unit and/or by the application of external power.

6.2.3.2 Stance phase control

In jointed units, motion can be

- a) activated by
 - 1) the ground reaction force, or
 - 2) the ground reaction force modified by the application of energy from an external power source, and
- b) controlled by
 - 1) the mechanical properties of the unit, or
 - 2) a control signal from an external site.

In unjointed units, motion is activated by the ground reaction force and controlled by the mechanical properties of the unit.

State for each motion how it is activated and controlled, and relevant features of the design.

State if the control characteristics are adjustable, adaptable, or auto-adaptive (e.g. an adjustable stiffness keel).

The precise specification of the control characteristics may require the inclusion of performance measurement data.

6.2.3.3 Swing phase control

In jointed units, dorsal flexion can be activated by the application of an external power source and controlled by a signal from an external control site.

State how motion is activated and controlled.

The precise specification of the control features might require the inclusion of performance measurement data.

6.2.4 Special features

State if it is possible to alter the range of motion(s) (e.g. an ankle joint which permits extreme fixed plantar flexion for swimming, or a foot rotator which facilitates kneeling).

6.3 Knee units

6.3.1 General

Prosthetic knee units are designed to substitute for some of the functions of the normal knee joint by means of controlled motions.

Describe the unit by including the following information.

6.3.2 Motions

The motions of a knee unit can be

- a) flexion/extension (motion in a sagittal plane), and/or
- b) axial translation (motion perpendicular to the transverse plane).

State the motions and their ranges and whether they are adjustable.

6.3.3 Axis of rotation

Rotation is either

- a) monocentric, in which the axis of rotation is constant for all angles of flexion, or
- b) polycentric, in which the axis of rotation changes with the angle of flexion.

State the type of rotation and, if polycentric, the design of the knee unit.

6.3.4 Activation and controls

Prosthetic knee units may incorporate features which are designed to activate and control flexion/extension during the stance and swing phases of gait. This reduces the risk of falling in the event of an accidental loss of stability. Control can be achieved by mechanical (including pneumatic and hydraulic) and/or electronic means.

6.3.4.1 Stance phase control

Stability is affected by the position of the knee unit relative to the load line.

Stability provided in this manner is described as alignment stability.

Stability may also be provided by the knee unit and its control mechanisms.

These include:

- a) units which hold the knee joint in full extension (locks);
 - 1) The method of activation of the lock can be either
 - i) manual lock and unlock,
 - ii) automatic lock and manual unlock, or
 - iii) automatic lock and automatic unlock.

An automatic lock can be activated either by applying a load to the prosthesis or by using a remote control.

- b) units which resist flexion and/or extension (brakes);
 - 1) These can provide
 - i) constant resistance, or
 - ii) variable resistance.

The magnitude of the resistance can be dependent on

- I) the ground reaction force,
 - II) the knee joint angle,
 - III) the knee joint angular velocity,
 - IV) the acceleration of the prosthesis, or
 - V) the position in space of the prosthesis.
- c) monocentric posterior offset units, which are free to flex and extend but which facilitate knee-joint stabilization by virtue of the position of their axis of rotation;
 - d) polycentric units, which are free to flex and extend but which facilitate knee-joint stabilization by causing their instantaneous axis of rotation to move posteriorly as the joint moves into extension;
 - e) units which permit a limited range of controlled flexion at initial foot contact and which may also control the rate of return to extension;
 - f) combinations of these types.

State the type of unit.

- For locks, describe the method of activation.
- For brakes, state whether the resistance to motion is constant or variable and whether the resistance is adjustable, adaptable, or auto-adaptive. If auto-adaptive state, what physical parameter determines the magnitude of resistance.
- For posterior offset units, polycentric units, and controlled flexion units, state whether their properties are adjustable or adaptable.

Specify the ranges of adjustment, and/or adaptation, and/or auto-adaptation.

The precise specification of the stance-phase control characteristics might require the inclusion of performance data.

6.3.4.2 Swing phase control

Swing-phase control may be provided by the unit and/or its control mechanism.

These include:

- a) units which resist flexion and/or extension either by
 - 1) constant resistance, or
 - 2) variable resistance.

The magnitude of the resistance to motion can be dependent on

- i) the direction of motion,
 - ii) the knee joint angle,
 - iii) the knee joint angular velocity,
 - iv) the acceleration of the prosthesis, and/or
 - v) the position in space of the prosthesis.
- b) units which resist knee flexion and assist knee extension;
 - c) combinations of these types.

State the type of unit and, when appropriate, the type of resistance.

State whether the unit is adjustable and/or adaptable and/or whether it is auto-adaptive.

Specify the ranges of adjustment, and/or adaptation, and/or auto-adaptation.

The precise specification of the swing-phase control characteristics might require the inclusion of performance data.

6.3.5 Transition between swing and stance

Some units require an input in order to alter their mode of control between swing and stance.

State the input.

State whether it is adaptable or auto-adapted and whether it is voluntarily or automatically generated.

6.4 Hip units

6.4.1 General

Prosthetic hip units are designed to substitute for some of the functions of the normal hip joint by means of controlled motions.

Describe the hip unit by including the following information.

6.4.2 Motions

The motion(s) of a hip unit can be

- a) flexion/extension (motion in a sagittal plane), and/or
- b) internal/external rotation (motion in a transverse plane).

State the motion(s) and their range(s) and whether they are adjustable.

State if the motions are combined.

6.4.3 Axis of rotation

Rotation is either

- a) monocentric, in which the axis of rotation is constant for all angles of flexion,
- b) polycentric, in which the axis of rotation in the sagittal plane changes with the angle of flexion, or
- c) polycentric, in which the axis of rotation changes with the angle of flexion in both the sagittal and transverse planes simultaneously.

State the type of rotation and, if appropriate, the design of the hip unit.

6.4.4 Activation and control

6.4.4.1 General

Prosthetic hip units may incorporate features which are designed to activate and control flexion/extension during the stance and swing phases of gait.

6.4.4.2 Stance phase control

Stability is affected by the position of the hip unit relative to the load line. Stability provided in this manner is described as alignment stability.

Stability may also be provided by the hip unit and its controlling mechanisms:

These include:

- a) units which hold the hip joint in a neutral position (locks);

The method of activation of the lock can be either

- 1) manual lock and unlock, or
- 2) automatic lock and manual unlock.

- b) units which resist extension immediately following initial foot contact.

State the type of unit and, when appropriate, the method of activation of the lock.

State when appropriate, whether the resistance is adjustable and specify the range of adjustment.

The precise specification of the stance-phase control characteristics can require the inclusion of performance data.

6.4.4.3 Swing phase control

Swing-phase control can be provided by the hip unit and/or its control mechanism.

These include:

- a) units which assist hip flexion at the beginning of the swing phase;
- b) units which resist and/or limit hip flexion at the end of the swing phase;
- c) units which provide combinations of these features.

State the type of unit.

State whether the assistance/resistance is adjustable and specify the range of adjustment.

The precise specification of the swing-phase control characteristics might require the inclusion of performance data.

6.5 External (side) joints

6.5.1 General

External (side) joints are designed to constrain unwanted motion of the related anatomical joint(s). They include hip joints and knee joints.