INTERNATIONAL STANDARD

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Second edition
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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

Reference number
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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.

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.

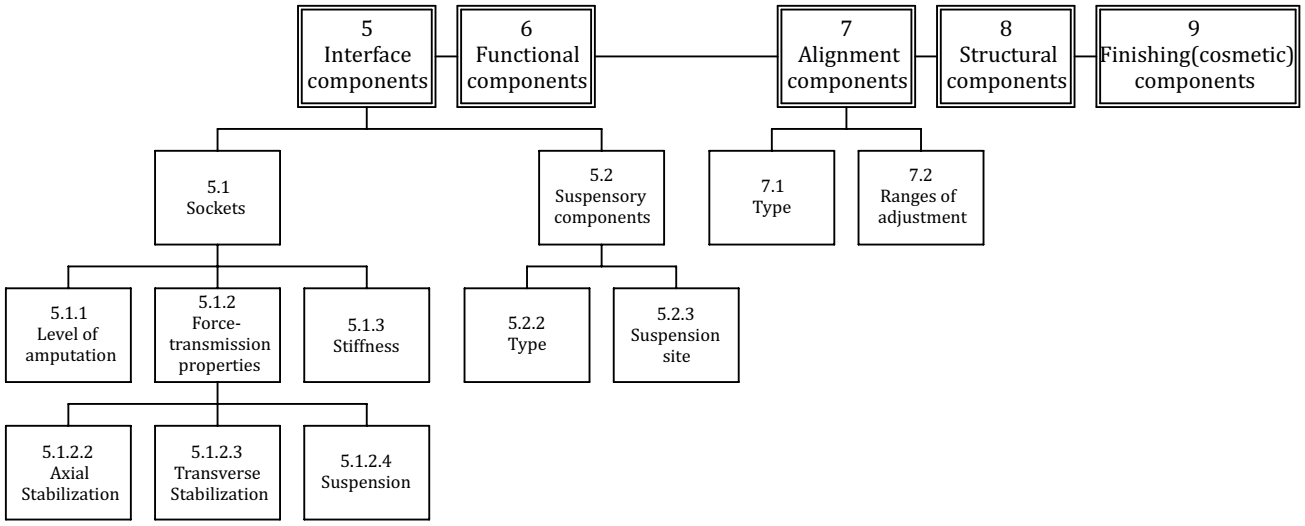

Figure 1 — Lower limb prosthetic components — Classification tree

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, 3.14, 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).

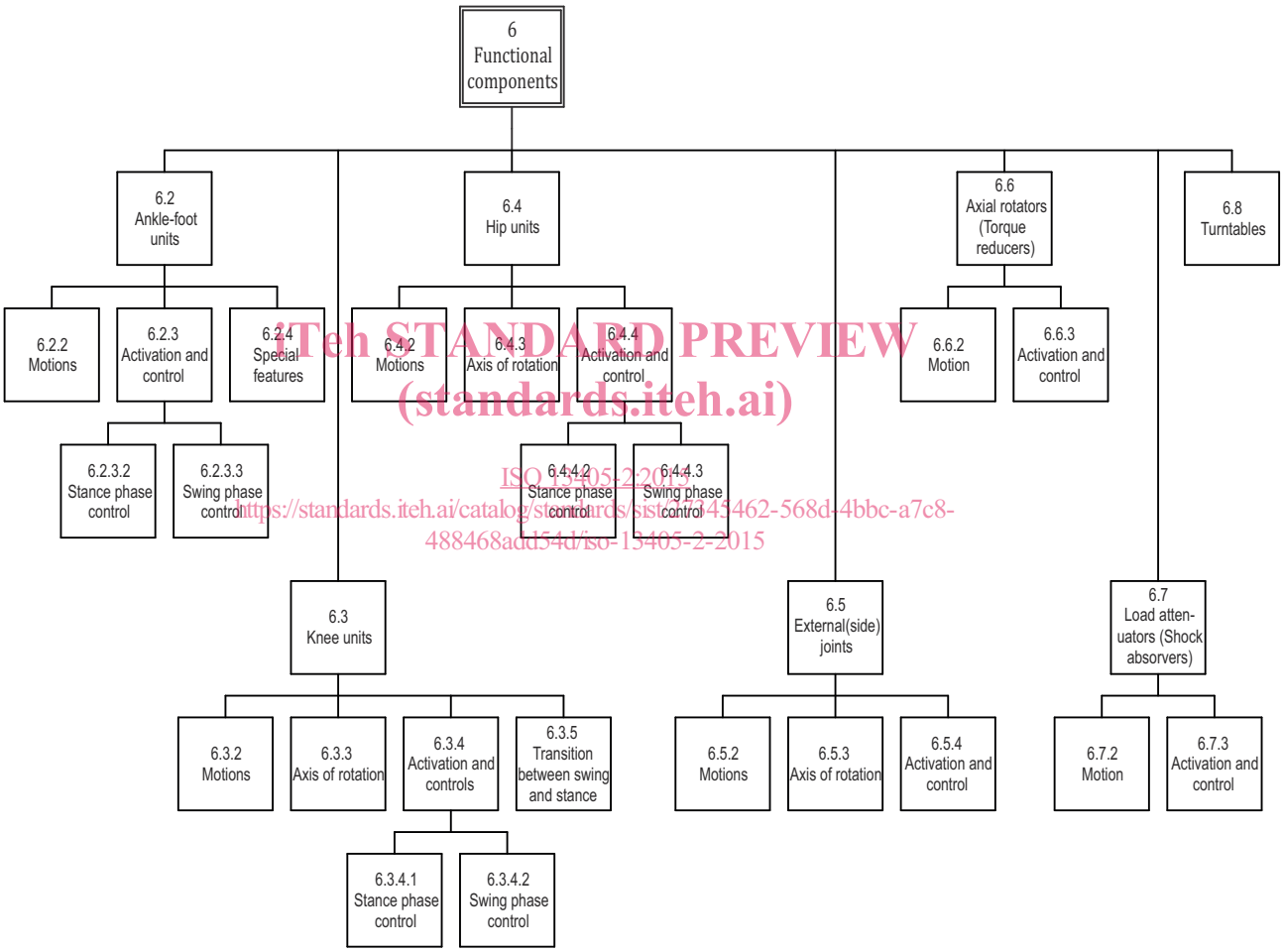

Figure 2 — Functional components — Classification tree

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.

