INTERNATIONAL STANDARD

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Second edition
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Prosthetics and orthotics — Classification and description of prosthetic components —

Part 3: Description of upper limb prosthetic components

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

Partie 3: Description des composants de prothèses des membres supérieurs

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, *Prosthetics and orthotics.*

This second edition cancels and replaces the first edition (ISO 13405-3:1996), which has been technically revised with the following changes:

a) classification tree of upper limb prosthetic components added to Clause 4;

b) levels of amputation extended to include all partial hand levels;

c) methods of socket suspension extended;

d) classification tree for functional components added in Clause 5;

e) range of the types of terminal devices, wrist units, elbow units, and shoulder units extended;

f) range of adjustment of alignment components deleted.

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 upper limb prostheses. It is designed to permit the users to describe systematically each component which is incorporated in a finished prosthesis in a manner which clearly explains its principal characteristics. This part of ISO 13405 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 the first edition 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 3:
Description of upper limb prosthetic components

1 Scope

This part of ISO 13405 specifies a method for describing upper 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 8549-4, *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 following terms and definitions apply.

3.1
grip configuration
position of function of a prosthetic hand

4 Classification

The components of upper limb prostheses include the five classes identified in ISO 13405-1:2014, 3.1, as shown in Figure 1 and Figure 2, and as described in Clauses 5 to 9.

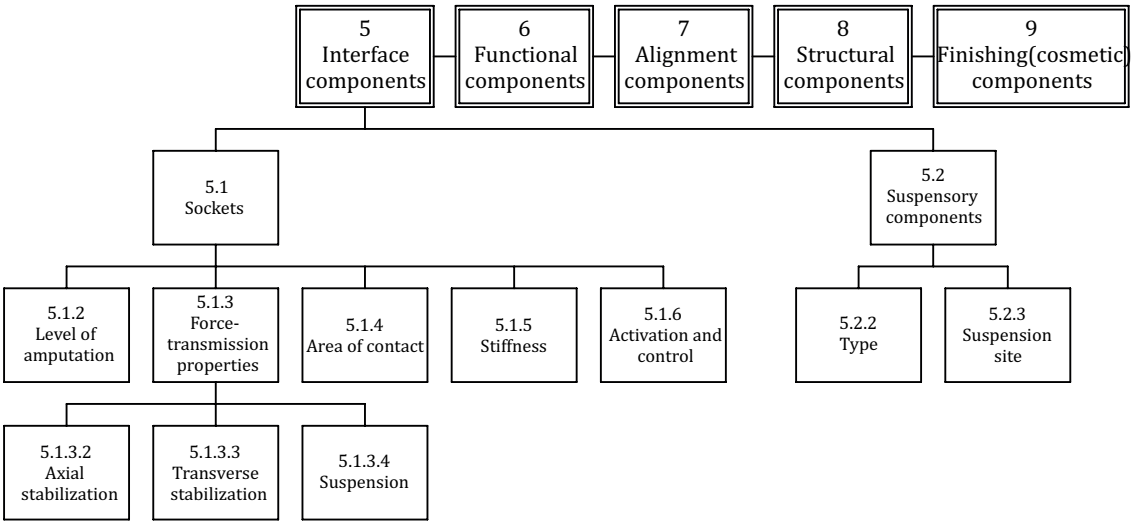

Figure 1 — Upper limb prosthetic components — Classification tree

5 Interface components

5.1 Sockets

5.1.1 General

Describe the socket by including the following information.

5.1.2 Level of amputation

State the level of amputation for which the socket, and hence, the prosthesis, is intended by referring to the list of levels defined in ISO 8549-4:2014, 3.1.3, that is, as one of the following:

a) partial hand amputations; these include:
   - thumb;
   - phalangeal;
   - metacarpo-phalangeal disarticulation;
   - metacarpal;
   - carpo-metacarpal disarticulation;
   - carpal;

b) wrist disarticulation;

c) trans-radial amputation;

d) elbow disarticulation;

e) trans-humeral amputation;

f) shoulder disarticulation;

g) scapulo-thoracic disarticulation amputation (forequarter).

5.1.3 Force-transmission properties

5.1.3.1 General

The force-transmission properties of a socket relate to that aspect of the shaping of the socket which is concerned with axial stabilization, transverse stabilization, and suspension.

5.1.3.2 Axial stabilization

State the principal intended method of axial stabilization as one of the following:

a) proximal stabilization, in which the principal stabilization forces are generated by the shaping of the proximal region of the socket;

b) distal stabilization, in which the principal stabilization forces are generated by the shaping of the end of the socket;

c) total socket stabilization, in which the stabilization forces are generated by the shaping of the whole surface of the socket.

5.1.3.3 Transverse stabilization

Transverse stabilization is necessary to minimize the 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 shaping associated with transverse stabilization.

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

5.1.3.4 Suspension

Suspension is necessary to minimize axial movement between the stump and the socket when the external longitudinal forces are distally directed.

The socket may be suspended either by

a) anatomical suspension, in which the suspensory properties are obtained by shaping the socket to the underlying anatomy (this might require the socket to be opened using removable sections, splits, or other means to allow donning and doffing),

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, or

c) using a liner, which creates a pressure differential by virtue of its intimate contact with the stump and which is mechanically coupled to the socket distally.

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

State the types of suspension provided and any means of opening the socket.

5.1.4 Area of contact

State the area of contact of the socket with the stump as either

a) total, or

b) partial.

5.1.5 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 or container.

5.1.6 Activation and control

Part(s) of the socket can contribute to the activation and/or control of functional components. This can include movement of any part of the socket or the generation of forces between the stump and the socket.

State which part(s) of the socket contribute(s) and their mode of action, when appropriate.

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 can be part of the suspension system, are classified as functional components because their principle function is to constrain unwanted joint motion (see 6.7).

5.2.2 Type

Types of suspensory components include straps, sleeves, and cuffs.

State the type of suspensory components.

5.2.3 Suspension sites

State the anatomical location of the principal suspension site(s) as the

a) trunk,

b) shoulder(s),

c) upper arm,

d) humeral epicondyles,

e) radial/ulnar styloids,

f) carpals/metacarpals, or

g) phalanges.

6 Functional components

6.1 General

Functional components of a prosthesis substitute for some of the dynamic and sensory attributes of the normal limb. They can be passive or active. Active components can be body powered or externally powered. This part of ISO 13405 does not include a description of the power source (e.g. battery/batteries) required by externally powered components.

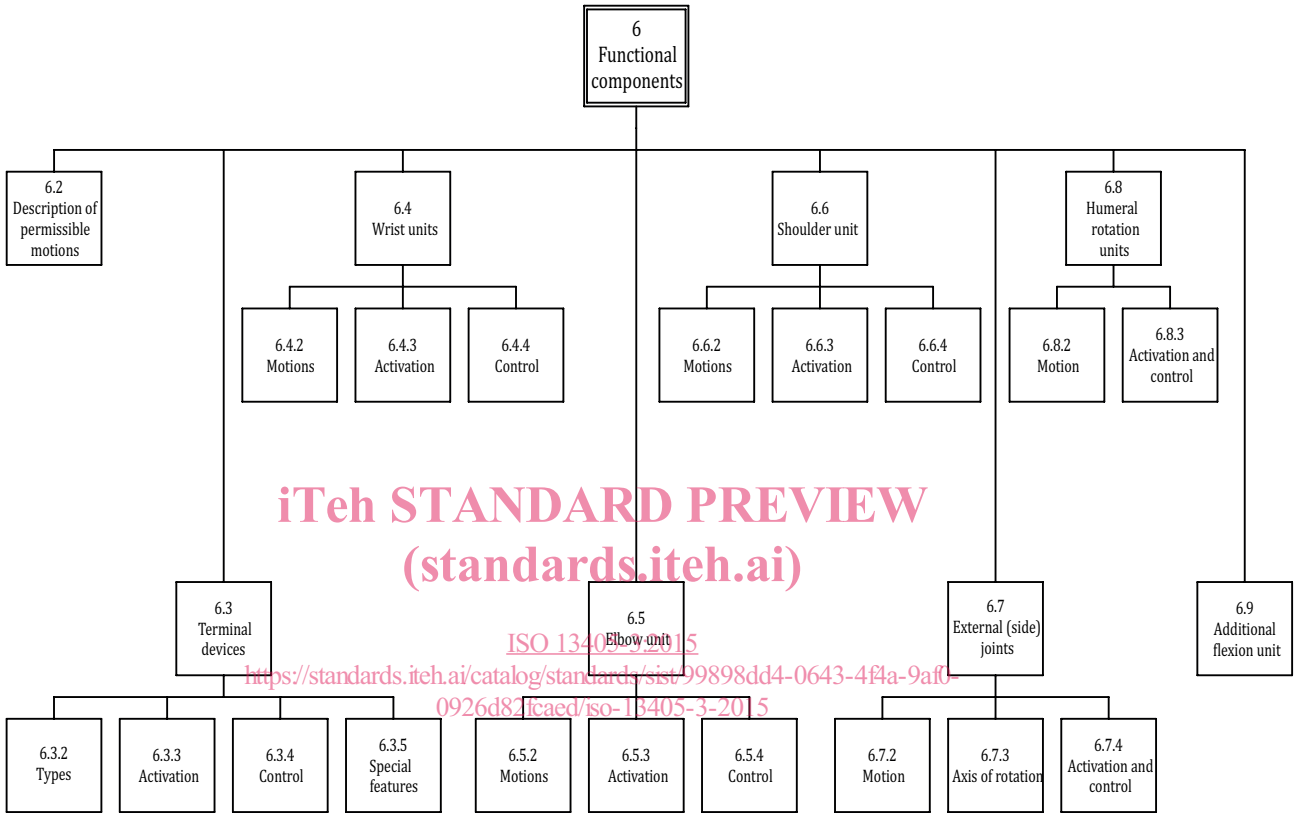

Figure 2 — Functional components — Classification tree

6.2 Description of permissible motions

The permissible motions of the functional components of prostheses are described with respect to the standard reference planes of the body that 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 6.3 to 6.9).

6.3 Terminal devices

6.3.1 General

Terminal devices are designed to substitute for some of the functions of the normal hand.