INTERNATIONAL STANDARD

ISO 13405-3

Second edition
2015-01-15

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
ISO 13405-3:2015(E)

Contents

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.

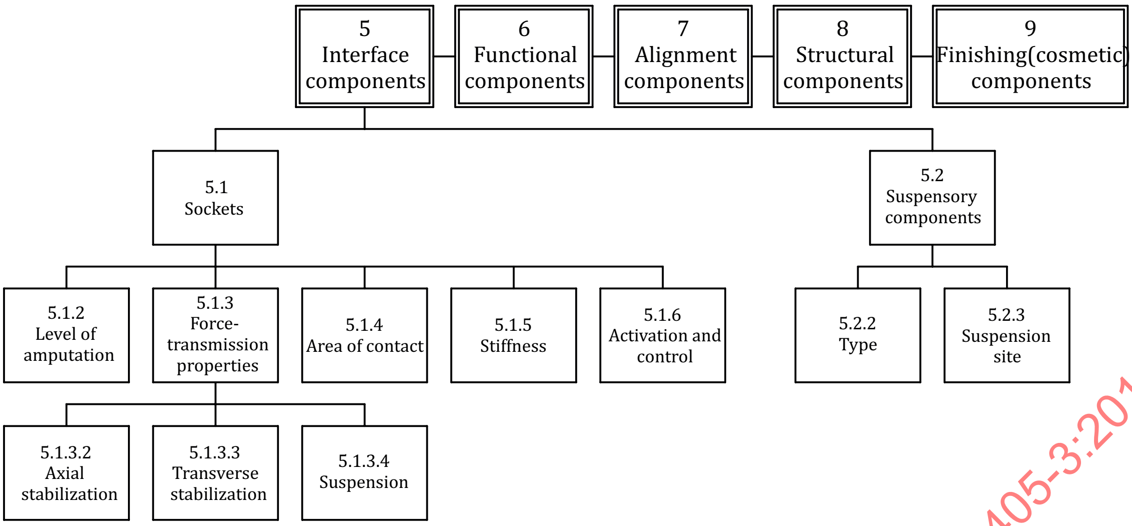

Figure 1 — Upper limb prosthetic components — Classification tree

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.

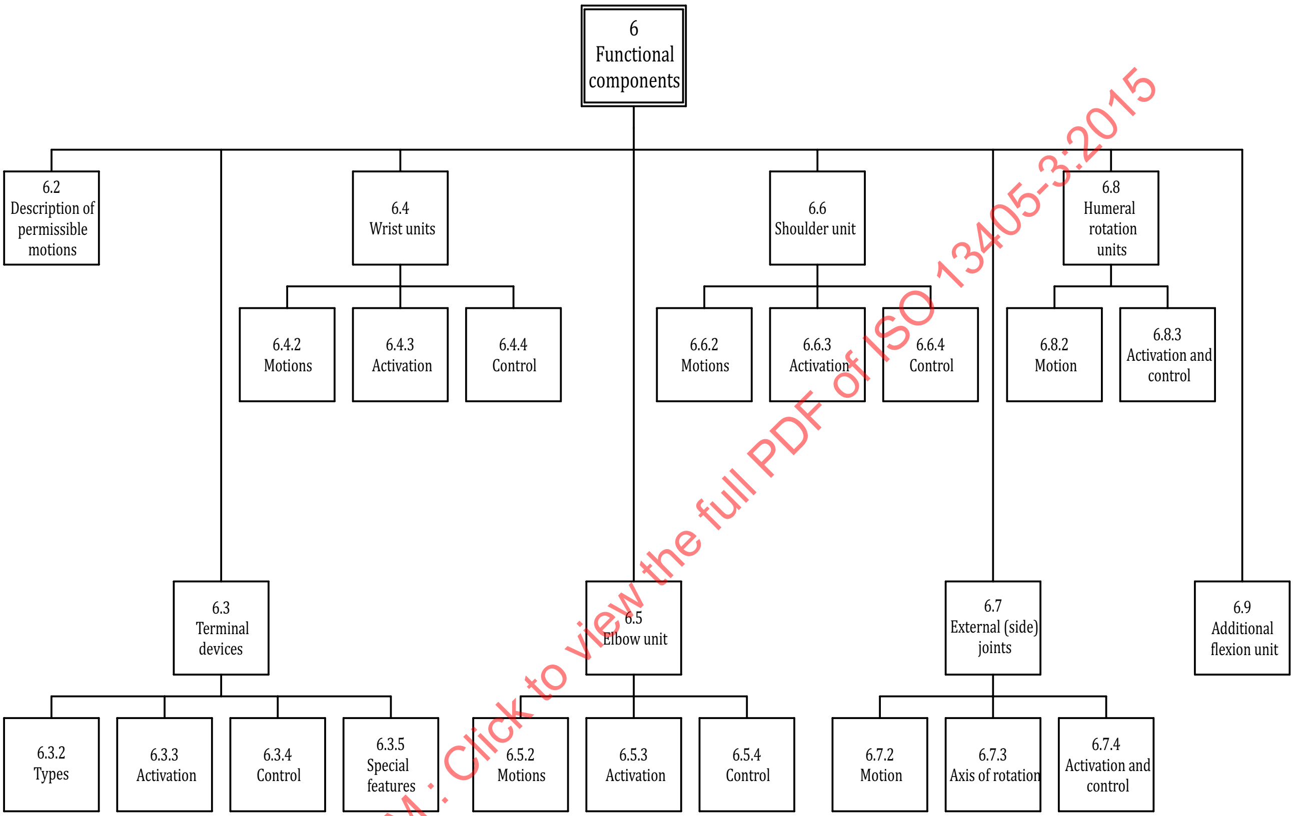

Figure 2 — Functional components — Classification tree

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.

6.3.2 Types

Types of terminal device include:

a) prosthetic hands and digits, which may be either

   1) passive, in which any alteration of position of all, or part of the device, is achieved by the direct application of external forces,

   2) active, in which motion between adjacent parts of the device is produced by its activating mechanism, or

   3) combined passive/active, in which the grip configuration is achieved by the application of an external force, followed by motion between adjacent parts produced by the hand's activating mechanism;

b) split hooks and other terminal devices that employ a pincer action which, by their nature, are active devices;

c) specialized appliances or tools designed to perform a wide range of specific functions.

Terminal devices can be detachable, and therefore, interchangeable.

State the type of terminal device, and when appropriate, whether it is passive, active, or combined passive/active.

State for the prosthetic hand its grip configuration (and how it is obtained).

State for the specialized appliance its function.

State whether the terminal device is detachable.

6.3.3 Activation

Active terminal devices include the following.

a) body-powered devices which are activated by the movement of body segments

   1) The type of activation can be either

      i) opening,

      ii) closing, or

      iii) opening and closing.

   2) The position can be maintained either by

      i) body power,

      ii) elastic resistance,

      iii) a manual lock, or

      iv) an automatic lock.

b) externally powered devices

   1) The actuators can be either

      i) intrinsic or

ii) extrinsic (e.g. proximally located with a mechanical linkage).

2) The type of activation can be

i) opening,

ii) closing, or

iii) opening and closing.

State if the terminal device is body-powered or externally-powered, and its type of activation.

State for body-powered devices the method of maintaining the terminal device position.

State for externally powered devices the location of the actuator.

6.3.4 Control

Control of the body-powered terminal device is inherent in the method of activation. The coupling between the body segment(s) and the terminal device provides some feedback to the user.

In externally powered devices, the control of movement is achieved either by

a) signal(s) from an electro-mechanical device(s), or

b) myopotentials.

The type of control can be either

a) on/off, or

b) proportional.

These methods of control may be associated with a programme selection option.

Feedback resulting from the vibration arising in an electrically driven device is assumed, but additional information concerning integrity of grip position or force applied can be provided by open- or closed-loop methods.

State the method and type of control and, when appropriate, the design of signal processing and feedback.

6.3.5 Special features

State if there are any special features related to the grip of externally powered devices, and whether these are automatic; for example,

a) means of increasing the grip strength beyond that which is normally obtainable,

b) means by which the grip can be released in an emergency,

c) means of adjusting the grip to prevent slippage.

6.4 Wrist units

6.4.1 General

Prosthetic wrist units are designed to substitute for some of the functions of the normal wrist joint by means of controlled motions. Describe the wrist unit by including the following information.

6.4.2 Motions

Wrist units may incorporate mechanisms which permit:

a) pronation/supination (motion in a transverse plane);

   Motion can be either

   1) continuous,

   2) stepped, with a detent (ratchet).

b) flexion/extension (motion in the sagittal plane);

c) adduction /abduction (motion in the frontal plane).

These motions are monocentric, with the axis of rotation constant for all angles.

State what motions are possible, their ranges, and when appropriate, whether the motion is continuous or stepped.

6.4.3 Activation

6.4.3.1 Pronation/supination may be either

a) passive, that is, achieved by the application of external force, or

b) active, which can be body-powered or externally powered.

   1) Body-powered units can be activated either by

      i) movement of a body segment, or

      ii) linkage from another functional component.

   2) Externally powered units can be activated either

      i) intrinsically, or

      ii) extrinsically (through a linkage), from another functional component.

State whether pronation/ supination is passive or active.

State for body-powered units the method of activation.

State for externally powered units the location of the actuator.

6.4.3.2 Flexion/extension may be either

a) passive, that is, achieved by the application of external force and maintained by an automatic lock, or

b) active, which is externally powered either by

   1) an intrinsic actuator, or

   2) extrinsically (through a linkage) from another externally powered joint.

State whether flexion/extension is passive or active, and when appropriate, the type of activation.

6.4.3.3 Adduction/abduction may be either

a) passive, that is, achieved by the application of external force, or

b) active, which is externally powered.

State whether adduction/abduction is passive or active.

6.4.4 Control

6.4.4.1 General

Prosthetic wrist units incorporate features to control their motions.

6.4.4.2 Passive units and active body-powered units

In passive units and active body-powered units, the control of movement is inherent.

Position may be maintained either by

a) friction,

b) a detent, or

c) a lock operated either

    1) manually, or

    2) by movement of a body segment.

State the method of maintaining the position for each of the possible motions.

6.4.4.3 Externally powered units

In externally powered units, the control of the movement is achieved either by

a) signal(s) from an electro- mechanical control site, or

b) myopotentials.

In both cases, this can be associated with a sequential-, priority-, or microprocessor-based programme.

Feedback resulting from the vibration arising in an electrically driven device is assumed, but additional positional information may be provided, by open- or closed-loop methods.

Position is maintained either by

a) resistance offered by the mechanism transmission, or

b) an electric lock.

State the method of controlling the movements, and when appropriate, the design of signal processing, and feedback for each of the possible motions.

State the method of maintaining the position for each of the possible motions.

6.5 Elbow unit

6.5.1 General

Prosthetic elbow units are designed to substitute for some of the functions of the normal elbow joint by controlled motions. Describe the elbow unit by including the following information.

6.5.2 Motions

Prosthetic elbow units incorporate mechanisms which permit flexion/extension (motion in the sagittal plane).

Motion is monocentric with the axis of rotation constant for all angles.

State the range of motion.

Prosthetic elbow units can include a humeral rotation unit to compensate for a restriction of shoulder-joint rotation in prosthesis for a trans-humeral amputation. This is considered as a separate functional component (see 6.8.).

6.5.3 Activation

Flexion/extension may be either

a) passive, that is, achieved by the application of an external force, or

b) active, which may be body-powered or externally powered.

    1) Body-powered units can be activated either by

        i) movement of a body segment, or

        ii) linkage from another functional component.

    2) Externally powered units can be activated either

        i) intrinsically, or

        ii) through a linkage from another functional component.

State whether the unit is passive or active, and when appropriate, the method of activation.

6.5.4 Control

Prosthetic elbow units incorporate features designed to control flexion/extension.

6.5.4.1 Passive units and active body-powered units

In passive units and active body-powered units, the control of movement is inherent. Position can be maintained either by friction or a lock.

Locks may be either

a) body-powered, which can be activated either

    1) manually, or

    2) by movement of a body segment;

or

b) externally powered, which can be activated either by

    1) signal(s) from an electro-mechanical control, or

    2) myopotentials.

State if the position is maintained by friction or a lock.

State whether the lock is body-powered or externally powered, and the method of activation, when appropriate.

6.5.4.2 Externally powered units

In externally powered units, the control of movement is achieved either by

a) signal(s) from an electro-mechanical control, or

b) myopotentials.

In both cases, this can be associated with a sequential-, priority-, or microprocessor-based programme.

Feedback resulting from the vibration, arising in an electrically driven device is assumed, but additional positional information may be provided by open- or closed-loop methods.

The position of externally powered elbow units is normally maintained by the resistance offered by the mechanism transmission, but an optional free-swing mode can be incorporated.

State the method of controlling the movement, and when appropriate, the design of signal processing and feedback.

State whether a free-swing mode is incorporated, and how it is activated and deactivated.

6.6 Shoulder unit

6.6.1 General

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

6.6.2 Motions

Shoulder units incorporate mechanisms which permit

a) flexion/extension (motion in a sagittal plane),

b) abduction/adduction (motion in a frontal plane), and

c) internal/external rotation (motion in a transverse plane).

Motions are monocentric, in which, the axes of rotation are constant for all angles of motion.

State the range(s) of motion in each plane.

6.6.3 Activation

Shoulder units can be either

a) passive, that is, positioned by the application of external force, or

b) externally powered.

State whether the unit is passive or externally powered for each of the permissible motions.

6.6.4 Control

6.6.4.1 General

Prosthetic shoulder units incorporate features designed to control its motions.