INTERNATIONAL STANDARD

ISO 13405-3

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Prosthetics and orthostics — 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 prothèse des membres supérieurs

Reference number
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Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet: CENTRAL@ISOCS.ISO.CH
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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13405-3 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

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

At present no internationally accepted method exists to classify or describe the components of prostheses. This situation causes considerable difficulty for manufacturers who are producing literature describing their products and for practitioners who are reporting on the prescriptions they employ in the treatment of particular patients.

The system proposed is designed to permit users to classify and describe systematically each component which is incorporated in a finished prosthesis, in a manner which clearly explains their principal characteristics.

Manufacturers' tradenames and details of the materials and manufacturing processes employed have been avoided.

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Prosthetics and orthotics — Classification and description of prosthetic components —

Part 3: Description of upper-limb prosthetic components

1 Scope

This part of ISO 13405 establishes a method for describing upper-limb prosthetic components.

2 Normative references

The following standards contain provisions, which, through reference in this text, constitute provisions of this part of ISO 13405. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 13405 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8549-1: 1989 *Prosthetics and orthotics — Vocabulary — Part 1: General terms.*

ISO 8549-2: 1989 *Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses and wearers of these prostheses.*

3 Definitions

For the purposes of this part of ISO 13405, the definitions given in ISO 8549-1 and ISO 8549-2 apply.

4 Classification

The components of upper-limb prostheses include the five classifications identified in 4.1 of ISO 13405-1:1996.

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 reference to the list of levels defined in ISO 8549-2, that is, as one of the following:

a) partial hand amputation;

b) wrist disarticulation;

c) transradial (below-elbow) amputation;

d) elbow disarticulation;

e) transhumeral (above-elbow) amputation;

f) shoulder disarticulation; or

g) forequarter amputation.

5.1.3 Force-transmission properties

NOTE — The force-transmission properties of a socket relate to that aspect of the shaping of the socket which is concerned with the transfer of the forces necessary for support, stabilization and suspension.

5.1.3.1 Support

State the principal intended method of support as one of the following:

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

b) distal support, in which the principal support forces are developed by the shaping of the distal region of the socket; or

c) total support, in which the support forces are developed along the entire length of the socket rather than by any specific proximal or distal shaping.

5.1.3.2 Stabilization

Three forms of stabilization are required: anteroposterior, mediolateral and rotational. State when appropriate any particular features of the socket shaping associated with each of these forms of stabilization.

5.1.3.3 Suspension

The socket may provide either

a) anatomical suspension, in which the suspensory properties are obtained by anchoring the socket to the underlying anatomy which may require the socket shape to be adjustable by means of removable sections, splits or other means;

b) pressure differential (suction) suspension, in which the suspensory properties are obtained by creating a socket with a closed end which will resist removal by virtue of the pressure differential which would result from such action; or

c) a combination of these.

Any of these methods may be used in conjunction with an inner sleeve, designed to enhance the suspensory properties which may be coupled to the socket.

In any of these methods, adhesion between the stump and the socket may contribute to the suspensory properties.

State, when appropriate, the type of suspension provided by the socket.

State also, when appropriate, the type of inner sleeve used and the means, if any, of adjusting the shape of 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

NOTE — 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);

c) partly flexible (when specific areas of the socket are designed to deform or when a flexible socket is constrained by a rigid frame or container).

5.1.6 Liner

State if the socket is designed to be used with a liner.

NOTE — This does not include inner sleeves designed to enhance the suspensory properties of the socket nor stump socks.

5.1.7 Activation and control

Parts of the socket may contribute to the activation and/or control of functional components. This may include movement of any part of the socket or the generation of forces between the stump and the socket. State the position and mode of action of any such part, when appropriate.

5.2 Suspensory components (other than the socket)

5.2.1 General

Describe the suspensory components by including the following information.

5.2.2 Suspension sites

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

a) trunk;

b) shoulder(s);

c) upper arm;

d) humeral condyles; and/or

e) radial/ulnar styloids.

5.2.3 Design of the suspension system

State the design of the principal suspension system and its position of attachment to the socket.

NOTE — External (side) joints which are part of the suspension system are also classified as functional components because of their effect on the permissible motions between the suspension system and the socket. See also 6.6.

6 Functional components

6.1 Description of permissible motions

The permissible motions of the functional components [terminal devices (6.2), wrist units (6.3), elbow units (6.4), shoulder units (6.5), external joints (6.6), humeral rotation units (6.7), humeral additional flexion unit (6.8)] of prostheses are described with respect to the standard reference planes of the body, that is:

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.

6.2 Terminal devices

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

6.2.1 Types

Types of terminal device include:

a) prosthetic hands, which may be either

   1) passive, in which any alteration of shape is achieved by the direct application of external forces; or

   2) active, in which motion between adjacent parts is achieved by the hand's own activating mechanism;

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

c) specialized appliances or tools designed to perform a wide range of individual functions, which may be

   1) passive;

   2) adjustable; or

   3) active.

NOTE — Terminal devices may be detachable and therefore interchangeable.

State the type of terminal device, whether it is passive, active or adjustable, its grip configuration or function, when appropriate, and whether the device is detachable.

6.2.2 Activation

Active terminal devices include the following.

a) Body-powered devices which are activated by movement of (a) body segment(s)

The mode of operation may be

1) voluntary opening;

2) voluntary closing; or

3) voluntary opening and closing.

The position may be maintained by

1) a manual lock; or

2) an automatic lock.

b) Externally-powered devices in which the motor(s) may be either

1) integral; or

2) proximally mounted with a mechanical linkage

The mode of operation may be

1) powered movement in both directions;

2) powered opening; or

3) powered closing.

State if the terminal device is body-powered or externally-powered, its mode of operation and, if appropriate, the power source, mounting position of the motor and the type of lock.

6.2.3 Controls

Control of movement of the body-powered terminal device is inherent in the manner 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 by either

a) a signal(s) from a mechanical control site; or

b) myopotentials.

In each case one or two transducer(s) may be used to provide either

a) digital (on/off) control;

b) proportional control.

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

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

State the method of controlling movement, the number of transducers and, if appropriate, the design of signal processing and feedback. The precise specification of the control features may require the inclusion of performance measurement data.