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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.

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 13405-2 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 its 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 2: Description of lower-limb prosthetic components

1 Scope

This part of ISO 13405 establishes a method for describing lower-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 indicated 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 lower-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 foot amputation;

b) ankle disarticulation;

c) transtibial (below-knee) amputation;

d) knee disarticulation;

e) transfemoral (above-knee) amputation;

f) hip disarticulation;

g) transpelvic 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 end 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 stump and 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(s) of the principal suspension site(s) as the

a) shoulder;

b) pelvis;

c) thigh;

d) femoral condyles; and/or

e) malleoli.

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 classified as functional components because they constrain the permissible motions between the suspension system and the socket. See also 6.5.

6 Functional components

6.1 Description of permissible motions

The permissible motions of the functional components [ankle-foot devices (6.2), knee units (6.3), hip units (6.4), external (side) joints (6.5) and torque reducers (6.6)] of prostheses are described with respect to the standard reference planes of the body, that is:

a) the saggital 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 Ankle-foot devices

Prosthetic ankle-foot devices are designed to substitute for some of the functions of the normal ankle and foot by means of controlled motions. Describe the ankle-foot device by including the following information.

6.2.1 Permissible motions

State the ranges of permissible motions of an ankle-foot device as

a) plantarflexion/dorsiflexion (which is considered to be rotation in a saggital plane);

b) inversion/eversion (which is considered to be rotation in a frontal plane);

c) internal/external rotation (which is considered to be rotation in a transverse plane);

d) dorsiflexion of the toe part of the device (which is considered to be rotation in a saggital plane and substitutes for some of the normal motion of the metatarsophalangeal joints).

State if any of these motions are combined.

6.2.2 Types of motion

State for each permissible motion whether the motion is

a) movement between adjacent parts of the device;

b) deformation of parts of the device;

c) a combination of these.

6.2.3 Controls

In all currently available devices, motion is initiated by the effect of the ground reaction force.

a) In those devices in which movement occurs between adjacent parts of the device, the nature of the control mechanism may be

   1) elastic; or

   2) energy-absorbing (e.g. viscous).

b) In those devices in which motion occurs by deformation of parts of the device, control is exercised by the nature of the materials employed and the manner in which they are assembled.

State the nature of the control mechanism and/or the materials and manner of assembly for each permissible motion.

State if it is possible to adjust the normal control characteristics (e.g. an adjustable stiffness keel), and specify the adjustability. The precise specification of the control features may require the inclusion of performance measurement data.

6.2.4 Special features

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

State if the heel height for which the device is designed is adjustable and specify the range of adjustment.

6.3 Knee units

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

6.3.1 Permissible motions

State the range of permissible motion of a knee unit as flexion/extension (i.e. rotation in a sagittal plane).

6.3.2 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 appropriate, the design of the knee unit.

6.3.3 Controls

NOTE — Prosthetic knee units may incorporate features which are designed to control flexion/extension during the stance and swing phases of gait. Control characteristics may be varied by mechanical and/or electronic means.

6.3.3.1 Stance-phase control

Stability is affected by position of the knee unit relative to the socket and the ankle-foot device. Stability provided in this manner is described as alignment stability.

Additional stability may be provided by control mechanisms, including

a) locks, which fix the unit in full extension;

Activation of the lock may be either manual, or automatic lock/manual unlock.

b) brakes, which resist flexion and/or extension.

c) monocentric types, which are free to flex and extend but which, by the posterior offset position of their axis of motion, facilitate knee-joint stabilization;

d) polycentric types, which are free to flex and extend but which, by their changing instantaneous axis of motion, facilitate knee-joint control;

e) types which permit a limited range of controlled flexion; or

f) a combination of these types.

State the type of stance-phase control and, when appropriate, the mode of activation.

State whether it is possible to adjust the control characteristics and specify the adjustability. The precise specification of the stance-phase control characteristics may require the inclusion of performance measurement data.

6.3.3.2 Swing-phase control

Types of swing-phase control include the following:

a) types which resist flexion/extension either by

1) constant resistance

2) variable resistance, e.g. where the resistance to motion is dependent on the knee angle and/or knee angular velocity.

b) types which resist knee flexion and assist knee extension; or .

c) a combination of these types.

State the type and, when appropriate, the design of swing-phase control.

State whether it is possible to adjust the control characteristics and specify the adjustability.

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

6.3.4 Special features

State if it is possible to alter the normal permissible motions or their ranges, e.g. rotation in a transverse plane to permit cross-legged sitting.

6.4 Hip units

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.