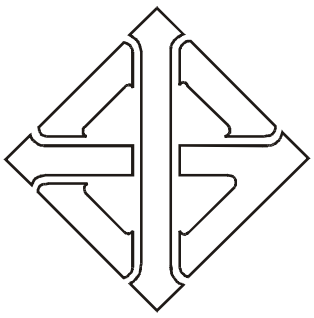

มาตรฐานผลิตภัณฑ์อุตสาหกรรม

THAI INDUSTRIAL STANDARD

มอก. 2401 เล่ม 3–2551

ISO 13405-3 : 1996

กายอุปกรณ์เทียมและกายอุปกรณ์เสริม-การแบ่งประเภทและการเรียกส่วนประกอบของกายอุปกรณ์เทียม

เล่ม 3 : การเรียกชิ้นส่วนของแขนเทียม

PROSTHETICS AND ORTHOTICS - CLASSIFICATION AND DESCRIPTION OF PROSTHETIC COMPONENTS-

PART 3 : DESCRIPTION OF UPPER-LIMB PROSTHETIC COMPONENTS

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กระทรวงอุตสาหกรรม

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มาตรฐานผลิตภัณฑ์อุตสาหกรรม

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มอก. 2401 เล่ม 3– 2551

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม
กระทรวงอุตสาหกรรม ถนนพระรามที่ 6 กรุงเทพฯ 10400
โทรศัพท์ 0 2202 3300

ประกาศในราชกิจจานุเบกษา ฉบับประกาศและงานทั่วไป เล่ม 126 ตอนพิเศษ 59ง
วันที่ 22 เมษายน พุทธศักราช 2552

กายอุปกรณ์เป็นอุปกรณ์ที่จำเป็นสำหรับผู้พิการ เพื่อช่วยให้ผู้พิการมีคุณภาพชีวิตที่ดี สามารถดำรงชีวิตและประกอบอาชีพได้เหมือนบุคคลปกติทั่วไป จึงกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม กายอุปกรณ์เทียมและกายอุปกรณ์เสริม-การแบ่งประเภทและการเรียกส่วนประกอบของกายอุปกรณ์เทียม เล่ม 3 : การเรียกชิ้นส่วนของแขนเทียม ขึ้น

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นโดยรับ ISO 13405-3 : 1996 Prosthetics and orthotics-Classification and description of prosthetic components-Part 3 : Description of upper-limb prosthetic components มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO ฉบับภาษาอังกฤษเป็นหลัก

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นเพื่อให้ทันกับความต้องการของผู้ใช้ และจักได้แปลเป็นภาษาไทยในโอกาสอันสมควร หากมีข้อสงสัยโปรดติดต่อสอบถามที่สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

คณะกรรมการมาตรฐานผลิตภัณฑ์อุตสาหกรรมได้พิจารณามาตรฐานนี้แล้ว เห็นสมควรเสนอรัฐมนตรีประกาศตามมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511

ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ 3959 (พ.ศ. 2551)

ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม

พ.ศ. 2511

เรื่อง กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กายอุปกรณ์เทียมและกายอุปกรณ์เสริม-การแบ่งประเภท

และการเรียกส่วนประกอบของกายอุปกรณ์เทียม

เล่ม 3 : การเรียกชิ้นส่วนของแขนเทียม

อาศัยอำนาจตามความในมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ.2511 รัฐมนตรีว่าการกระทรวงอุตสาหกรรมออกประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม กายอุปกรณ์เทียมและกายอุปกรณ์เสริม-การแบ่งประเภทและการเรียกส่วนประกอบของกายอุปกรณ์เทียม เล่ม 3 : การเรียกชิ้นส่วนของแขนเทียม มาตรฐานเลขที่ มอก. 2401 เล่ม 3-2551 ไว้ ดังมีรายการละเอียดต่อท้ายประกาศนี้

ประกาศ ณ วันที่ 24 พฤศจิกายน พ.ศ. 2551

พลตำรวจเอก ประชา พรหมนอก

รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

มาตรฐานผลิตภัณฑ์อุตสาหกรรม
กายอุปกรณ์เทียมและกายอุปกรณ์เสริม – การแบ่งประเภทและการเรียกส่วนประกอบของกายอุปกรณ์เทียม
เล่ม 3 : การเรียกชิ้นส่วนของแขนเทียม

บทนำ

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นโดยรับ ISO 13405-3 : 1996 Prosthetics and orthotics-Classification and description of prosthetic components-Part 3 : Description of upper-limb prosthetic components มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO ฉบับภาษาอังกฤษเป็นหลัก

ขอบข่าย

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดวิธีการเรียกชิ้นส่วนต่าง ๆ ของแขนเทียม

เอกสารอ้างอิง

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 2

บทนิยาม

ความหมายของคำที่ใช้ในมาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ ให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 3

การแบ่งประเภท

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 4

ส่วนที่มีพื้นที่สัมผัสระหว่างผิวของตอแขนกับผิวของผนังเบ้า

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 5

ชิ้นส่วนวัสดุที่ช่วยการทำงานของกายอุปกรณ์

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 6

การจัดส่วนต่างๆของแขนเทียมให้ถูกต้องสัมพันธ์กัน

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 7

ชิ้นส่วนโครงสร้างของแขนเทียม

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 8

ชิ้นส่วนตกแต่งแขนเทียม

รายละเอียดให้เป็นไปตาม ISO 13405-3 : 1996 ข้อ 9

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.

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.

6.2.4 Special features

State if there are any special features related to the grip of externally powered devices, for example:

a) means of increasing the grip strength beyond that normally obtainable; or

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

6.3 Wrist units

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.

6.3.1 Permissible motions

The range of permissible pronation/supination (which is considered to be a rotation about the longitudinal axis of the forearm) is usually unlimited. Rotation may be either

a) continuous; or

b) stepped, with a detent.

State whether rotation is continuous or stepped.

A passive flexion unit, positioned by the application of external force and maintained by an automatic lock, may be incorporated between the wrist unit and the terminal device.

Active flexion/extension of the wrist, transmitted by a linkage from another externally-powered joint, may be incorporated.

State if flexion/extension is possible, whether it is active or passive, the method of control and, where appropriate, the design.

6.3.2 Axis of rotation

Pronatory/supinatory rotation is monocentric, with the axis of rotation constant for all angles.

6.3.3 Types and activation

Prosthetic wrist units may be either

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

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

Body-powered units may be activated by either

1) movement of a body segment; or

2) a linkage from another functional component.

Externally powered units may be activated by power transmitted either

1) directly; or

2) via a linkage from another functional component.

State whether the unit is passive or active and, if appropriate, the type of power source and mode of activation.

6.3.4 Controls

Prosthetic wrist units incorporate features designed to control pronation/supination.

6.3.4.1 Passive units and active body-powered units

In passive units and in active body-powered units, the control of movement is inherent. Position may be maintained either by friction or by a detent and/or a lock operated manually or by movement of a body segment.

State the method of maintaining position.

6.3.4.2 Externally powered units

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

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

b) myopotentials.

Either may 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 wrist units is normally maintained by the effect of the transmission.

State the method of controlling movement 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.

6.4 Elbow unit

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.

6.4.1 Permissible motions

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

NOTE — Prosthetic elbow units may include a humeral rotation unit to compensate for restriction of shoulder-joint rotation in a prosthesis for a transhumeral amputation. This is considered as a separate functional component. See also 6.7.

6.4.2 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 elbow unit.

6.4.3 Types and activation

Prosthetic elbow units may be either

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

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

Body-powered units may be activated by either

1) movement of a body segment, which may also activate a terminal device; or

2) a linkage from another functional component.

Externally powered units may be activated by power transmitted either

1) directly; or

2) via a linkage from another functional component.

State whether the unit is passive or active and, if appropriate, the type of power source and mode of activation.

6.4.4 Controls

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

6.4.4.1 Passive units and active body-powered units

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

Locks may be either

a) body-powered, which may be operated manually or by movement of a body segment; or

b) externally powered, which may be operated by a signal(s) from a mechanical control site or by myopotentials.

State the type of lock and the method of operation.

6.4.4.2 Externally powered units

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

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

b) myopotentials.

Either may 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 effect of the transmission, but an optional free-swing mode may be incorporated.

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

State if a free-swing mode is incorporated.

The precise specification of the control features may require the inclusion of performance measurement data.

6.5 Shoulder unit

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

6.5.1 Permissible motions

State the range(s) of permissible motions(s) of the shoulder unit as:

a) flexion/extension (i.e. rotation in a sagittal plane);

b) abduction/adduction (i.e. rotation in a frontal plane);

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

6.5.2 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.

6.5.3 Types and activation

Prosthetic shoulder units may be either

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

b) active, which are externally-powered.

State whether the unit is passive or active and, if appropriate, the type of power source.

6.5.4 Controls

Prosthetic shoulder units incorporate features designed to control movement.

6.5.4.1 Passive units

In passive units, the control of movement is inherent. Position may be maintained either by friction or by a lock operated either

a) manually; or

b) by movement of a body segment.

State the type of lock and the method of operation.

6.5.4.2 Externally-powered units

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

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

b) myopotentials.

Either may 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 shoulder units is normally maintained by the effect of the transmission, but an optional free-swing mode may be incorporated.

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

State if a free-swing mode is incorporated.

The precise specification of the control features may require the inclusion of performance measurement data.

6.6 External (side) joints

External (side) joints may encompass wrist and/or elbow joints. Describe the external (side) joints by including the following information.

6.6.1 Permissible motion

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

6.6.2 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 which human joints are encompassed, the type of rotation and, if appropriate, the design for each joint used.

6.6.3 Types, activation and controls

Prosthetic external (side) joints are designed to either

a) constrain motion of the joint encompassed, by means of locks which may either

   1) lock against extension, usually operated automatically; or

   2) lock against flexion and extension, usually operated manually or by movement of a body segment;

b) assist motion of the joint encompassed by providing either

   1) assistance to flexion; or

   2 assistance to extension;

c) transfer movement and/or power of the joint encompassed, by either

   1) converting a small angular movement of the human joint into a large angular movement of the prosthetic joint; or

   2 transferring angular movement and power by linkage to control or by activating other functional components of the prosthesis.

State the purpose and design of the external (side) joints used and, if appropriate, the type of lock.

6.7 Humeral rotation units

The socket provided for a transhumeral amputation stump may extend so far proximally that it restricts the range of internal/external rotation of the shoulder. In such cases a humeral rotation unit may be included above the elbow unit.

6.7.1 Permissible motion

State the range of permissible motion of the humeral rotation unit as internal/external rotation (i.e. rotation in a transverse plane).

6.7.2 Types, activation and controls

The humeral rotation unit is passive, that is, positioned by application of external force. The control of movement is inherent.

Position may be maintained either by

a) Friction, with or without an optional manual lock; or

b) a spring detent, with or without an optional manual lock.

State the method of maintaining position.

6.8 Humeral additional flexion unit

The inclusion of a humeral additional flexion unit between the shoulder and elbow in a prosthesis for shoulder disarticulation improves the effective flexion range of the elbow and allows the prosthetic hand to reach the face of the wearer. Such joints are positioned by the application of an external force and maintained in position by friction.

State if the prosthesis includes such a unit.

7 Alignment components

7.1 General

Alignment components (devices) may be

a) integrated, which remain in the prosthesis as part of its structure; or

b) transferred, which are removed from the prosthesis and replaced by a structural component which maintains the same configuration.

State the type of alignment component(s) used.

7.2 Ranges of adjustment

State the ranges of adjustment which the alignment component provides in each of the standard reference planes of the body (see 6.1), as follows:

a) lengthening/shortening (i.e. translation perpendicular to the transverse plane);

b) mediolateral shift (i.e. translation perpendicular to the sagittal plane);

c) anteroposterior shift (i.e. translation perpendicular to the frontal plane);

d) abduction/adduction, mediolateral tilt (i.e. rotation in the frontal plane);

e) flexion/extension, anteroposterior tilt (i.e. rotation in the sagittal plane);

f) internal/external rotation (i.e. rotation in the transverse plane).

8 Structural components (prosthetic construction)

State whether the prosthetic construction is

a) endoskeletal, or

b) exoskeletal.

9 Cosmetic (finishing) components

Cosmetic components of prostheses include:

a) shells;

b) fillers;

c) skins, stockings and gloves;

d) combinations of these.

State the cosmetic components used.