

The International Organisation for Standardisation (ISO)

Technical Committee (TC) 168

Prosthetics and orthotics

Classification and Terminology Standards

ISO

ISO is an international federation of 160 national standards bodies, known as member bodies, that has its Central Secretariat in Geneva, Switzerland.

The purposes of the standards produced by ISO are:

- to create uniform terminology and hence ease communication
- to discourage incorrect and inaccurate language
- to ensure that products and services are safe, reliable and good quality
- to inform industry and help marketing

The task of developing ISO standards is performed by Technical Committees (TCs) and their Working Groups (WGs). Every national member body that expresses an interest in the work of a TC is entitled to be represented on that TC and its WGs.

The process of developing a new standard is a complex and lengthy process designed to ensure that the resulting standard genuinely reflects the consensual view of the relevant professional groups.

The principal stages of this process are;

- New Work Item Proposal (**NWIP**)
- Committee Draft (**CD**)
- Draft International Standard (**DIS**)
- Final Draft International Standard (**FDIS**)
- International Standard (**IS**)

Technical Committee 168 – Prosthetics and orthotics

TC 168 was formed in 1979 The Secretariat for the TC is provided by the German national standards body DIN. The TC currently has 16 participating national bodies.

The TC operates through three Working Groups:

- WG1 Nomenclature and terminology
- WG2 Medical aspects
- WG3 Physical Testing

This brief article describes solely the work of WG1&2 which has resulted in the publication to date of 19 standards with three further new standards recently published as DIS.

Why do we need terminology Standards in Prosthetics and Orthotics?

Before describing the standards it is perhaps appropriate to attempt to answer this question.

The intended use for each standard is stated in each part of the following text however it is possible to make here a general statement which applies to all the available standards.

Historically there were no internationally accepted methods of describing either the persons being treated prosthetically or orthotically, the devices they were being provided with or the outcomes of treatment. As a consequence the members of the clinic teams in different countries developed and used their own terminology for these purposes.

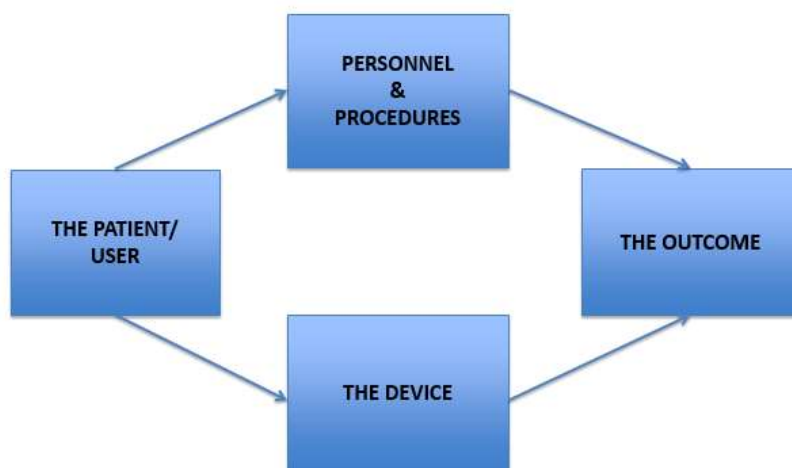
This situation created considerable difficulty for practitioners prescribing devices and for manufacturers describing their products and made the reporting of the treatment and the outcomes of treatment of particular patient groups almost impossible.

The programme of standard development instituted in 1979 and which continues today is designed to address these difficulties and by doing so to facilitate communication between all parties involved in both the manufacturing and clinical aspects of both fields.

The Standards – the Scope Model

One of the first tasks undertaken by WG1 and WG2 at their inaugural meeting in 1980 was to attempt to define the scope of their future work. This resulted in the model illustrated in Figure 1.

The progress to date in developing standards to satisfy the needs of each of the fields of this model in both the fields of prosthetics and orthotics is described below



Figur 1: The Scope Model

Prosthetic Standards

The Patient/User

ISO 8548- Limb deficiencies - 1,2,3,4 & 5

The ISO 8548 series of standards (published between 1989 and 2003) has been developed to allow the comprehensive description of the users of prostheses using standardised terminology.

The purpose for the development of these standards was the perceived need for a standard terminology which would permit clinicians in different countries to compare their patients and their clinical experiences. The design of the standards is intended to make the information recorded suitable for inclusion in patient records.

The titles of the individual standards in the series are:

Part 1 – Method of describing limb deficiencies present at birth

Part 2 – Method of describing lower limb amputation stumps

Part 3 – Method of describing upper limb stumps

Part 4 – Description of causal conditions leading to amputation

Part 5 – Description of the clinical condition of the person who has had an amputation

Parts 2 & 3 are currently undergoing revision

ISO 8549 – 4 Vocabulary - Terms relating to limb amputation

Published more recently this standard complements the ISO- 8548 series by providing standard terminology to describe:

- levels of amputation,
e.g. trans-radial and trans-femoral etc,
- amputation procedures,
e.g. initial amputation and revision amputation etc, and
- persons who have had an amputation
e.g. upper limb amputee and bilateral lower limb amputee etc.

Personnel and procedures

ISO 8549-1 Vocabulary - General terms for external limb prostheses and external orthoses

This standard was published in 1989 when there was virtually no internationally accepted terminology for any aspect of the fields of prosthetics and orthotics. Its purpose was to provide a set of basic definitions and standard terminology for:

- the fields of prosthetics and orthotics

- prostheses and orthoses and
- the personnel and procedures involved in their supply

ISO 29782 Prostheses and orthoses – Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation

This standard published in 2008 highlights the many considerations which can contribute to the formulation of a prosthetic prescription including:

- the stump characteristics
- the physical characteristics, medical condition , functional capabilities and motivation of the user
- the anticipated activity of the user including, vocational, sporting , recreational, social and cultural activities.
- the environment it will be exposed to
- the available supply and maintenance arrangements
- the social and financial circumstances of the intended user

The purpose of this standard is to inform the prosthetic team when making a choice of components for the construction of a prosthesis

ISO/DIS 21065 – Terms relating to the treatment and rehabilitation of persons having a lower limb amputation

This new Draft Standard (DIS), which was recently issued, defines the phases of the treatment and rehabilitation of the person having had a lower limb amputation and lists the interventions which are normally provided during each phase, the complications which may occur and the additional interventions which may be provided in response to them.

In common with many other previous standards it is designed in a manner which makes the information suitable for inclusion in patient records. It is also hoped that the standardised terminology it uses will facilitate the comparison of clinical experience in different countries and treatment centres.

The Devices

ISO 8549-2 Glossary of terms relating to external limb prostheses and wearers of external prostheses

This pioneering standard, published in 1989, introduced the terms and definitions to be used to describe the level of an amputation and the different forms of limb discrepancy present at birth which are still in use today.

ISO 13405 1, 2, & 3 Prosthetics and orthotics – Classification and description of prosthetic components.

This three part standard, which was revised in 2015, in Part 1 proposes a system of classification of prosthetic components as either:

- interface components,
- functional components,
- alignment components,
- structural component, or
- finishing (cosmetic) components

Parts 2 & 3 provide terminology to systematically describe each component which is incorporated in a finished lower limb or upper limb prostheses.

This standard is envisaged as being of particular use to manufacturers producing products describing their products and to prosthetic practitioners reporting on the components they use with their patients.

Outcomes

ISO 29781 Prosthetics and orthotics – Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or who has a deficiency of a lower limb segment present at birth.

This first attempt to describe the activity of a person with an absent or deficient lower limb segment(s) was published in 2008.

The factors suggested include:

- transfer and mobility (both with and without a prosthesis),
- ability to negotiate surfaces and obstacles (indoors and outdoors),
- activities of daily living and
- prosthetic wearing and usage times

This standard was designed to meet the needs of a clinic team when assessing a person referred for prosthetic treatment and evaluating the result of their treatment

ISO 29783 – 1 Vocabulary – Normal gait

ISO 29783 – 2 Vocabulary – Prosthetic gait

Published in 2008, ISO29783 Part 1, establishes a vocabulary for the description of normal gait.

This standard defines the phases and sub-phases of the normal gait cycle and describes the motions of the pelvis and limb segments in all three planes during each sub-phase

Published in 2015, ISO 29783 Part 2, proposes a method and provides terminology to describe the gait of a person having a unilateral lower limb amputation using a prosthesis.

The method requires the user to identify the departures from a normal pattern of gait (described in Part 1) which the person exhibits.

The standard defines the different types of gait abnormality as:

- an abnormal range of joint motion
- abnormal timing of joint motion
- abnormal speed of joint motion

The gait abnormalities commonly exhibited during each sub-phase of the gait cycle by a person with:

- a trans-tibial amputation and
- a trans-femoral amputation

are defined and described.

This standard is designed to enable practitioners to systematically describe the gait of persons they are treating and facilitate comparisons with the experience of other practitioners

Orthotic Standards

The Patient/User & Personnel and Procedures

ISO 8551 Prosthetics and orthotics – Functional deficiencies – Description of the person to be treated with an orthosis, clinical objectives of treatment and functional requirements of the orthosis..

This ambitious standard published in 2003 has three defined objectives, as stated in the title.

The first, the description of the person being treated with an orthosis is achieved by providing terminology to record:

- personal details (e.g. age, height, significant medical history)
- clinical condition to be treated (including diagnosis and ICD 10 codes)
- other clinical conditions
- motivation and personal needs
- functional abilities

The second objective, describing the clinical objectives of treatment is achieved by defining nine objectives

- to relieve pain
- to manage deformities

- to prevent an excessive range of joint motion
- to increase the range of joint motion
- to compensate for abnormalities of segment length or shape
- to manage abnormal neuromuscular function (i.e weakness or hyperactivity)
- to protect tissues
- to promote healing
- to provide other effects (e.g. warmth, postural feedback)

In each case the standard specifies what information should be recorded to fully specify the objective

The final objective is to describe the functional requirements of an orthosis which will achieve the desired clinical objectives. This is achieved by defining the five ways in which orthoses function.

- to prevent, reduce or stabilize a deformity
- to modify the range of motion of a joint
- to add to the length or alter the shape of a segment
- to compensate for weak muscle or control muscle hyperactivity
- to reduce or redistribute the load on tissues.

Once again the standard specifies what information should be recorded for each of these functions to fully define the orthotic requirement.

This standard is currently undergoing revision with the principal objective of making the terminology consistent with the ICL terminology.

The Device

ISO 8549 - 3 Prosthetics and orthotics – Vocabulary – Terms relating to external orthoses

This important standard published in 1989 introduced the system of categorizing orthoses by reference to the body segments and joints which they encompass.

Egs.

An *ankle- foot orthosis (AFO)* is defined as an orthosis which encompasses the ankle joint and the whole or part of the foot.

A *wrist-hand – finger orthosis (WHFO)* is defined as an orthosis which encompasses the wrist joint, the hand and one or more fingers

A *lumbo-sacral orthosis (LSO)* is defined as an orthosis which encompasses the whole or part of the lumbar and sacro-iliac regions of the trunk..

All three parts of ISO 8549 are scheduled for immediate revision.

ISO 13404 Prosthetics and orthotics – Classification and description of orthoses and orthotic components

This standard published in 2007 was designed to complement both ISO 8551 and ISO 8549 - 3 by providing a method of classifying and describing the orthotic components used in the construction of an orthosis capable of achieving the requisite functional requirements.

Four categories of component are identified:

- interface components (such as shells, pads, straps, foot orthoses and shoes)
- articulating components the orthotic joints)
- structural components (which connect the interface and articulating component)
- cosmetic components (which provide shape colour and texture)

The standard also specifies the information required to fully describe the function of each component in each class used in the construction of the orthosis.

Like ISO 13405 in the field of prosthetics, this standard is envisaged as meeting the needs of manufacturers of orthotic components describing their products and practitioners describing the prescriptions they use when treating particular patient groups. .

ISO/DIS 21063 Soft orthoses and

ISO/DIS 21064 Foot orthotics

These two new Draft Standards (DIS) which have recently been issued propose additional terminology specific to these specialist areas of orthotic provision.

Outcomes

ISO 29783-3 Prosthetics and orthotics – Vocabulary – Pathological gait (excluding prosthetic gait)

This final part of ISO 29783 was published in 2016.

The purpose of the standard is to provide clinicians with a method of systematically describing the gait of the persons they are treating (orthotically or otherwise)

As with Part 2, the method described requires the user to identify the departures from the normal gait pattern (described in Part 1)

Two types of abnormality are identified, abnormal foot contact and abnormalities of joint motion.

Abnormalities of joint motion are further classified as either abnormal angular motion, or abnormal timing of joint motion, or abnormal speed of joint motion

The standard specifies terminology to be used to describe any abnormality (of each type) occurring during each sub-phase of the gait cycle

Availability of Standards

ISO derives a significant part of its funding from the sales of standards. Because of this consideration all ISO documents are protected by copyright. This consideration has limited the detail of the content of the standards which could be described in this article.

Standards may be purchased on –line at the ISO web-site

WWW.ISO.ORG

A brief description of each standard may be obtained by consulting their Online Browsing Platform (OBL) at <https://www.org/obp/ui/>