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Prosthetics and orthotics — Limb deficiencies —

Part 2: Method of describing lower limb amputation stumps

iTeh STProthèses et orthèses – Malformations des membres –

Partie 2: Méthode de description des moignons d'amputation des membres inférieurs

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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.

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 168, Prosthetics and orthotics.

This second edition cancels and replaces the first edition (ISO 8548-2:1993) which has been technically revised. The main changes to the previous edition are as follows:020

- the stump descriptors (<u>Tables 1</u> to <u>7</u>) have been revised;
- the lists of measurements to be taken by all members of the team and the additional measurements to be taken only by the prosthetist have been revised (<u>Table 8</u>).

A list of all parts in the ISO 8548 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <u>www.iso.org/members.html</u>.

Introduction

This document provides a standard method for describing and measuring amputation stumps. Such a method is essential to allow comparisons of the outcomes of amputation surgery and rehabilitation provided by different teams.

The healthcare professionals who will use the method include surgeons of different disciplines, other doctors (especially those concerned with rehabilitation), nurses, physical and occupational therapists and prosthetists.

Such a method is also of value to epidemiologists and government health officials.

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Prosthetics and orthotics — Limb deficiencies —

Part 2: Method of describing lower limb amputation stumps

1 Scope

This document establishes a method of describing and measuring lower limb amputation stumps. It also lists the measurements required for the provision of a prosthesis.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 8549-4, Prosthetics and orthotics Vocabulary Part 4. Terms relating to limb amputation (standards.iteh.ai)

3 Terms and definitions

<u>ISO 8548-2:2020</u>

For the purposes of this/document, the terms and definitions given in ISO 8549-2 and ISO 8549-4 apply. b3b9aed57fd7/iso-8548-2-2020 ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

4 Stump description

4.1 General

Specify the amputation side and describe the stump using the relevant descriptors listed in the appropriate tables (<u>Tables 1</u> to <u>7</u>) and the guidance given in <u>4.2</u> to <u>4.6</u>.

4.2 Stump characteristics

The shape of the stump should be described as either conical, bulbous or cylindrical. In this context, the meanings of these terms are self-evident.

The soft tissues of the stump should be described by reference to their amount and consistency. The amount should be described as sufficient, insufficient or excessive and the consistency described as normal, flabby or indurated. If the heel pad is retained, its position should be recorded as correctly positioned, displaced or mobile.

It is important to record whether the stump musculature is attached, detached or displaced.

Relevant bony features such as prominences, remnants, length or position should be described. The presence of any prominent foreign bodies, for example grafts, implants or shrapnel, should be noted.

Where appropriate, the end-bearing status of the stump should be recorded.

For partial foot amputations, record the level of amputation specified in ISO 8549-4. The complete description requires the identification of the amputated bones and their levels of amputation.

4.3 Skin

Record whether the skin barrier is intact or not, and whether the skin has normal sensation.

The position/orientation of the incisional scar and whether it is healed or not and mobile or adherent should be recorded. Additionally, the presence and condition of other scarring or skin grafting should be noted.

Any history of skin pathology, for example contact dermatitis, skin allergy and/or hyperhidrosis, should be noted.

4.4 Circulation

The factors which should be described concerning the circulation are colour, temperature and oedema.

The skin should be described as either normal in colour, cyanotic or otherwise discoloured, and as warm to examination or not.

The presence of excessive oedema should be noted. Excessive oedema is considered as that which would adversely affect stump healing or prosthetic fitting and use.

4.5 Pain

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Significant pain is regarded as that which is greater than expected at the stage of treatment.

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The presence of significant pain or tenderness from whatever source (e.g. painful neuroma, pain after exercise or from prosthetic use) should be recorded using an appropriate pain scale.

4.6 Phantom sensation and phantom pain

Phantom sensation and phantom pain are sensation and pain felt as if in the amputated part of the limb. Phantom sensation is common after amputation and does not normally require treatment. Phantom pain varies in intensity and should be recorded using an appropriate pain scale.

4.7 Joint function

4.7.1 Measurement of abnormal range of joint movement

Abnormalities of the range of joint movement in the proximal joint(s) of the amputated limb should be recorded using the neutral zero method in which zero is the anatomical position.

4.7.2 Assessment of stump muscle strength

Reduced strength of the muscle groups responsible for producing movements at the proximal joint(s) of the amputated limb should be recorded using the manual muscle testing 0–5 scale.

4.7.3 Assessment of joint stability

Instability of the proximal joint(s) of the amputated limb, which is a consequence of bony or ligamentous impairments, should be recorded.

4.7.4 Joint pain

Pain in the proximal joint(s) should be recorded.

5 Measurement of lower limb amputation stumps

5.1 Reference levels and reference planes

5.1.1 General

Identify the reference levels and planes relevant to the particular level of amputation as described in 5.1.2 and 5.1.3.

5.1.2 Reference levels

5.1.2.1 Waist

The level midway between the costal margin and the iliac crest.

5.1.2.2 Iliac crest

5.1.2.3

The level defined by a line joining the highest point on the crest of each ilium.

Proximal iTeh STANDARD PREVIEW

The most proximal level at which a circumferential measurement, perpendicular to the mid-line of the thigh, can be obtained.

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In knee and ankle disarticulation stumps only, the level of the minimum circumference.

5.1.2.5 Femoral condylar

In knee disarticulation and transcondylar amputation stumps only, the level of the maximum condylar circumference.

5.1.2.6 Inflection

In transfemoral and transtibial stumps only, the level on the stump at which the slope of the stump shape changes as it curves in towards the end.

5.1.2.7 Stump end

The level of the stump end.

5.1.2.8 Medial joint line

The level of the medial tibial plateau, unless there is a fixed deformity of the knee, in which case this level is the highest at which a circumferential measurement perpendicular to the mid-line of the stump can be obtained.

5.1.2.9 Mid-patellar tendon

The level mid-way between the origin and insertion of the patellar tendon.

5.1.2.10 Malleolar

In ankle disarticulation stumps only, the level of the maximum distal circumference.

5.1.2.11 Ground

The level on which the patient is standing barefoot.

5.1.3 Reference planes used for partial foot amputations

5.1.3.1 Heel

The plane at the posterior aspect of the heel parallel with the mid-line of the leg.

5.1.3.2 Anterior tibial

The plane at the anterior aspect of the tibia at the ankle joint line parallel with the mid-line of the leg.

5.1.3.3 Stump end

The plane at the stump end parallel with the mid-line of the leg.

5.1.3.4 Toe

The plane at the tips of the toes of the contralateral leg parallel with the mid-line of the leg.

5.2 Measurements

This document does not specify the method to be used to obtain the measurements. It specifies both the measurements which should be taken by the team responsible for the rehabilitation of the person and those to be taken only by the prosthetist responsible for the provision of a prosthesis.

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In order that the description of the stump can be related to the person as a whole, the contralateral limb needs some minimal measurement.

Measure and record the length, circumferential, width and antero-posterior measurements as specified in <u>Table 8</u> and illustrated in <u>Figures 1</u> to <u>6</u> for the level of amputation.

The posture of the person in which the measurements are taken should be recorded.

Descriptor	Statement to be recorded		
Stump characteristics			
Pelvic remnant	Present/absent		
Soft tissues of the stump			
Amount	Sufficient/insufficient/excessive		
Consistency	Normal/flabby/indurated		
Skin			
General	Skin barrier intact/skin barrier not intact		
	Sensation normal/sensation impaired		
Incisional scar	Healed/unhealed		
	Mobile/adherent		
Additional scarring or grafting	Healed/unhealed		
	Mobile/adherent		

Table 1 — Descriptors for transpelvic amputations

Descriptor	Statement to be recorded		
Pathology	Inflammatory conditions (specify)		
Circulation			
Oedema	None/present/excessive		
Pain			
Pain	Present/absent		
	Site, intensity (pain scale score), frequency and duration		
Tenderness	Present/absent		
	Site		
Phantom pain	Present/absent		
	Intensity (pain scale score), frequency and duration		

 Table 1 (continued)

These descriptors should also be used for patients with femoral remnant proximal to the intertrochanteric line.

Descriptor	Statement to be recorded		
Stump characteristics			
Femoral remnant iTeh ST	Present but not prominent/present and prominent/absent		
Soft tissues of the stump			
Amount (St	Sufficient/insufficient/excessive		
Consistency	Normal/flabby/indurated		
Skin	<u>ISO 8548-2:2020</u>		
General https://standards.iten.ar	catalog/standards/sist/c730c1b6-d5de-4b3a-98cd- Skin barrier intact/skin barrier not intact b9aed5/id//iso-8548-2-2020		
	Sensation normal/sensation impaired		
Incisional scar	Healed/unhealed		
	Mobile/adherent		
Additional scarring or grafting	Healed/unhealed		
	Mobile/adherent		
Pathology	Inflammatory conditions (specify)		
Circulation			
Oedema	None/present/excessive		
Pain			
Pain	Present/absent		
	Site, intensity (pain scale score), frequency and duration		
Tenderness	Present/absent		
	Site		
Phantom pain	Present/absent		
	Intensity (pain scale score), frequency and duration		

Table 2 —	Descriptors	for hip	disarticulations
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