

BSI Standards Publication

Prosthetics and orthotics — Terms relating to the treatment and rehabilitation of persons having a lower limb amputation



BS ISO 21065:2017 BRITISH STANDARD

National foreword

This British Standard is the UK implementation of ISO 21065:2017.

The UK participation in its preparation was entrusted to Technical Committee CH/168, Prosthetics and orthotics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2017 Published by BSI Standards Limited 2017

ISBN 978 0 580 93051 5

ICS 11.040.40

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2017.

Amendments/corrigenda issued since publication

Date Text affected

BS ISO 21065:2017

INTERNATIONAL STANDARD

ISO 21065

First edition 2017-07-15

Prosthetics and orthotics — Terms relating to the treatment and rehabilitation of persons having a lower limb amputation

Prothèses et orthèses — Termes associés au traitement et à la réadaptation de personnes amputées du membre inférieur



BS ISO 21065:2017 **ISO 21065:2017(E)**



COPYRIGHT PROTECTED DOCUMENT

 $\, @\,$ ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Ch. de Blandonnet 8 • CP 401 CH-1214 Vernier, Geneva, Switzerland Tel. +41 22 749 01 11 Fax +41 22 749 09 47 copyright@iso.org www.iso.org

ForewordIntroduction			Page
			iv
			v
1		De	
	-		
2	Norn	mative references	1
3	Tern	ns and definitions	1
4	Phas	ses of treatment and rehabilitation	2
5	Modes of treatment		
	5.1	General	
	5.2	Pre-operative care	3
		5.2.1 Treatments	
	5.3	Surgery	
		5.3.1 Treatments	
	5.4	Immediate post-operative care	
		5.4.1 Treatments	
		5.4.2 Complications	
		5.4.3 Treatment of complications	
	5.5	Early rehabilitation	
		5.5.1 Treatments	
		5.5.2 Complications	
	5.6	5.5.3 Treatment of complications	
	5.0	5.6.1 Treatments	
		5.6.2 Complications and their treatments	
	5.7	Rehabilitation with a prosthesis	
	5.7	5.7.1 Treatments	
		5.7.2 Complications and their treatments	
	5.8	Continuing care	
		5.8.1 Treatments	
		5.8.2 Complications	
		5.8.3 Treatment of complications	6

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 on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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

Introduction

Currently there is no internationally accepted terminology to describe the phases of treatment and rehabilitation of persons having a lower limb amputation and the treatments which are used during these phases.

As a consequence the members of the clinic teams in different parts of the world have adopted their own terminology to meet their own needs. This situation makes it difficult to compare the clinical practices adopted in different treatment centres.

This document proposes a terminology which is designed to overcome this problem. It is suitable for use in clinical records and will facilitate the analysis of treatment outcomes.

Prosthetics and orthotics — Terms relating to the treatment and rehabilitation of persons having a lower limb amputation

1 Scope

This document specifies a vocabulary for the description of the phases of treatment and rehabilitation of persons having a lower limb amputation and the treatments which are used during these phases.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

3.1

pre-operative care

treatment provided from the time the decision to amputate is made until surgery is performed

3.2

surgery

treatment provided when the person is in the operating room

3.3

stump

residuum

that part of the limb remaining after amputation surgery

3.4

immediate post-operative care

treatment provided after surgery where the focus is recovery from the procedure, achieving medical stability, preventing complications and initiating mobility

Note 1 to entry: This is normally up to three days.

3.5

complication

adverse event affecting the expected progress of treatment

3.6

debridement

surgical removal of non-viable and necrotic tissues

3.7

phantom pain

pain felt as if in the amputated part of the limb

ISO 21065:2017(E)

3.8

early rehabilitation

treatment, provided once the person is medically stable, to achieve optimum conditions for rehabilitation with or without a prosthesis

3.9

early walking aids

EWA

prefabricated assistive devices applied to the stump

Note 1 to entry: They can be used to assess suitability for prosthetic fitting, to promote early mobilization and gait re-education and to control oedema and promote healing. They are intended for use during the early rehabilitation phase.

3.10

temporary prostheses

preparatory prostheses

individually manufactured prostheses, to permit early mobilization and gait re-education prior to provision of a definitive prosthesis

3.11

definitive prostheses

individually manufactured prostheses intended for continuing use

3.12

rehabilitation with a prosthesis

treatment provided to the person who is being supplied with a prosthesis

3.13

rehabilitation without a prosthesis

treatment provided to the person who is not being supplied with a prosthesis

3.14

continuing care

education and treatment intended to maintain optimal medical, physical and functional status and quality of life

4 Phases of treatment and rehabilitation

The treatment and rehabilitation of a person having a lower limb amputation, from the time the decision is made to amputate, and for the remainder of their lives, may be considered as comprising the following phases:

- preoperative care;
- surgery;
- immediate postoperative care;
- early rehabilitation;
- rehabilitation with or without a prosthesis;
- continuing care.

5 Modes of treatment

5.1 General

During each phase a range of modes of treatment (including education and provision of information) are routinely delivered and a number of complications may occur which will require further treatment, as specified below.

5.2 Pre-operative care

5.2.1 Treatments

- Assessment (medical, functional, psychological and social) of suitability for amputation and to determine level of amputation.
- Counselling of patient, family and/or carer.
- Obtaining informed consent and marking the site(s) of operation(s).
- Medical, physical therapy and psychological treatment as appropriate.

5.3 Surgery

5.3.1 Treatments

- Anaesthesia and pain management.
- Positioning.
- Amputation.
- Infection prophylaxis.
- Thromboembolic prophylaxis.
- Surgical site dressing (including rigid dressings).

5.4 Immediate post-operative care

5.4.1 Treatments

- Routine postoperative medical, physical therapy and nursing care.
- Pain management.
- Surgical site management.
- Stump (residuum) management (including oedema control, muscle strengthening and contracture prophylaxis).
- Psychological support.
- Physical therapy (including positioning, mobility in bed, general strengthening, standing and balance training, falls awareness, and transfers).
- Care of the contralateral limb (including prevention of pressure ulcers and contractures, and thromboembolic prophylaxis).

5.4.2 Complications

BS ISO 21065:2017

ISO 21065:2017(E)

- Surgical site infection.
- Bleeding and haematoma.
- Wound dehiscence.
- Excessive oedema.
- Other infections (e.g. pneumonia, urinary).
- Excessive wound or unexplained pain.
- Phantom pain.
- Pressure ulcers (contralateral limb).
- Venous thrombosis.
- Psychological issues.

5.4.3 Treatment of complications

- Antimicrobial therapy.
- Debridement.
- Revision amputation.
- Re-amputation.
- Intensified compression therapy.
- Additional pain management (e.g. medication, nerve block).
- Pressure relieving measures.
- Anti-coagulation therapy.
- Wound dressings (e.g. negative pressure).

5.5 Early rehabilitation

5.5.1 Treatments

All the treatments used in the previous phase as appropriate, plus:

- occupational therapy (e.g. ADL, wheelchair mobility, assessment of living environment);
- physical therapy (e.g. intensified strength and mobility training, residuum conditioning, hopping and single leg walking training, falls strategy);
- education and training in stump care and hygiene;
- training using early walking aids and temporary/preparatory prostheses;
- assessment of suitability for prosthetic fitting;
- provision of information regarding prosthetic options and supply procedures.

5.5.2 Complications

All the complications of the immediate postoperative phase, plus:

- joint stiffness and/or contracture;
- phantom pain;
- cognitive impairment;
- depression.

5.5.3 Treatment of complications

All the treatments of complications used in the immediate postoperative phase, plus:

- psychological therapy (e.g. cognitive behavioural therapy) and medication;
- provision of pressure relieving orthoses and/or footwear;
- mirror therapy, transcutaneous electrical nerve stimulation (TENS) and alternative therapies;
- manual and mechanical joint stretching, serial casting and orthoses.

5.6 Rehabilitation without a prosthesis

5.6.1 Treatments

All the treatments of the early rehabilitation phase as appropriate, plus:

- discharge planning (including placement, home adaptation and assistive product provision);
- wheelchair provision and training;
- cosmetic-only prosthesis provision if appropriate;
- appropriate ADL training;
- specialized rehabilitation (e.g. recreational, sporting and vocational activities).

5.6.2 Complications and their treatments

All the complications and their treatments of the early rehabilitation phase.

5.7 Rehabilitation with a prosthesis

5.7.1 Treatments

All the treatments of the early rehabilitation phase as appropriate, plus:

- discharge planning (including placement, home adaptation and assistive product provision);
- prosthetic provision;
- education and training in the use, care and acceptance of the prosthesis (including handling, putting on and taking off, hygiene and cleaning);
- gait training and provision of walking aids;
- wheelchair provision and training (when appropriate);
- appropriate ADL training;

ISO 21065:2017(E)

specialized rehabilitation (e.g. recreational, sporting and vocational activities).

5.7.2 Complications and their treatments

All the complications and their treatments of the early rehabilitation phase.

5.8 Continuing care

5.8.1 Treatments

All the treatments of the non-prosthetic and prosthetic phases, as appropriate, plus:

- social support (including funding sources, information to relatives and carers);
- medical, surgical and nursing care and therapy as required;
- prosthetic, wheelchair and assistive products review and maintenance as required;
- education in the maintenance of physical fitness and a healthy lifestyle;
- information on disease management and prevention of secondary complications.

5.8.2 Complications

All the complications of the earlier rehabilitation phases, plus:

- neuromata;
- redundant/excessive soft tissue;
- heterotopic bone formation;
- excessive bone growth;
- adherent scar tissue;
- stump problems related to poor surgical technique.

5.8.3 Treatment of complications

All the treatments of complications in the earlier rehabilitation phases, plus:

- management of neuromata by injection or surgery;
- medication and radiotherapy;
- revision surgery.



British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Copyright in BSI publications

All the content in BSI publications, including British Standards, is the property of and copyrighted by BSI or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use.

Save for the provisions below, you may not transfer, share or disseminate any portion of the standard to any other person. You may not adapt, distribute, commercially exploit, or publicly display the standard or any portion thereof in any manner whatsoever without BSI's prior written consent.

Storing and using standards

Standards purchased in soft copy format:

- A British Standard purchased in soft copy format is licensed to a sole named user for personal or internal company use only.
- The standard may be stored on more than 1 device provided that it is accessible
 by the sole named user only and that only 1 copy is accessed at any one time.
- A single paper copy may be printed for personal or internal company use only.

Standards purchased in hard copy format:

- A British Standard purchased in hard copy format is for personal or internal company use only.
- It may not be further reproduced in any format to create an additional copy.
 This includes scanning of the document.

If you need more than 1 copy of the document, or if you wish to share the document on an internal network, you can save money by choosing a subscription product (see 'Subscriptions').

Reproducing extracts

For permission to reproduce content from BSI publications contact the BSI Copyright & Licensing team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email subscriptions@bsigroup.com.

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Useful Contacts

Customer Services

Tel: +44 345 086 9001

Email (orders): orders@bsigroup.com **Email (enquiries):** cservices@bsigroup.com

Subscriptions

Tel: +44 345 086 9001

Email: subscriptions@bsigroup.com

Knowledge Centre

Tel: +44 20 8996 7004

Email: knowledgecentre@bsigroup.com

Copyright & Licensing

Tel: +44 20 8996 7070

Email: copyright@bsigroup.com

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

