Optics and photonics — Medical endoscopes and endotherapy devices —

Part 6: Vocabulary

 $ICS\ 01.040.37;\ 11.040.55;\ 37.020$



National foreword

This British Standard reproduces verbatim ISO 8600-6:2005 and implements it as the UK national standard.

The UK participation in its preparation was entrusted to Technical Committee LBI/33, Microscopes, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement international publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

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

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the ISO title page, pages ii and iii, a blank page, pages 1 to 7 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Amendments issued since publication

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 24 August 2005

© BSI 24 August 2005

Comments

Comments

INTERNATIONAL STANDARD

ISO 8600-6

First edition 2005-03-15

Optics and photonics — Medical endoscopes and endotherapy devices —

Part 6: Vocabulary

Optique et photonique — Endoscopes médicaux et dispositifs d'endothérapie —

Partie 6: Vocabulaire



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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 8600-6 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 5, *Microscopes and endoscopes*.

ISO 8600 consists of the following parts, under the general title *Optics and photonics* — *Medical endoscopes* and endotherapy devices:

- Part 1: General requirements
- Part 2: Particular requirements for rigid bronchoscopes
- Part 3: Determination of field of view and direction of view of endoscopes with optics
- Part 4: Determination of maximum width of insertion portion
- Part 5: Determination of optical resolution of rigid endoscopes with optics
- Part 6: Vocabulary

Optics and photonics — Medical endoscopes and endotherapy devices —

Part 6:

Vocabulary

Scope

This part of ISO 8600 defines terms for endoscopes and endotherapy devices commonly used in the endoscopic area.

1 Types of endoscopes

1.1

endoscope

medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically-created body opening for examination, diagnosis or therapy

NOTE 1 Endoscopes may be of rigid or flexible type; all types may have different image pick-up systems (e.g. via lenses or ultrasonic sensors) and different image-transmitting systems (e.g. optical, via lenses or fibre bundles, or electrical).

NOTE 2 IEC 60601-2-18 deals with electrical safety aspects of endoscopic systems and therefore the endoscope is regarded as an applied part of medical electrical equipment introduced into a patient. In IEC 60601-2-18:1996, the endoscope is defined as the "applied part of medical electrical equipment introduced into a patient to provide an internal view or image for examination, diagnosis and/or therapy".

1.2

fiberscope

endoscope (1.1) in which the image is transmitted via a fibre bundle

1.3

rigid endoscope [endotherapy device]

endoscope (1.1) [**endotherapy device** (4.1)] whose insertion portion is intended to be unyielding to natural or surgically-created body cavities or instrument channels

1.4

flexible endoscope [endotherapy device]

endoscope (1.1) [**endotherapy device** (4.1)] whose insertion portion is intended to conform to natural or surgically-created body cavities or instrument channels

1.5

video endoscope

endoscope (1.1) in which the image is transmitted by a solid state imaging device

1.6

ultrasonic endoscope

ultrasound endoscope

endoscope (1.1) with an electro-acoustical image pick-up system

1.7

telescope

rigid optical device for endoscopic imaging

1.8

rigid bronchoscope

open straight tube-type **rigid endoscope** (1.3) fitted with a means of illumination through the distal end and intended to be introduced into the tracheobronchial airway, having an internal lumen sufficiently large to permit free respiration of the patient

[ISO 8600-2:2002]

1.9

rigid ventilation bronchoscope

rigid bronchoscope (1.8) fitted with a removable end-cap at the proximal end of the open straight tube and having an internal lumen sufficiently large to permit ventilation of the patient through an integral ventilation connector

[ISO 8600-2:2002]

1.10

rigid jet-ventilation bronchoscope

rigid bronchoscope (1.8) provided with a jet-injector

[ISO 8600-2:2002]

2 Optical specifications

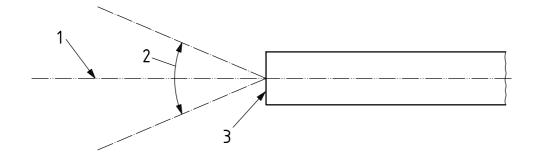
2.1

field of view

size of the object field viewed through an optical **endoscope** (1.1), expressed as the vertex angle (in degrees) of the cone whose vertex is at the distal window surface of the endoscope

See Figure 1.

NOTE The field of view is not appropriate when the endoscope is intended to be in contact with the object.



Key

- 1 central axis of field of view
- 2 field of view
- 3 distal window surface of endoscope

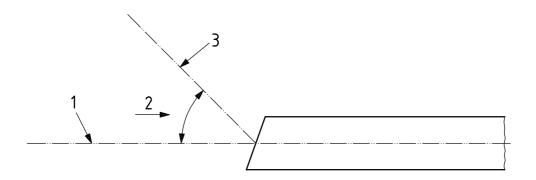
Figure 1 — Field of view

2.2

direction of view

location of the centre of the object field relative to the normal axis of the **endoscope** (1.1), expressed as the angle (in degrees) between the normal axis of the endoscope (0°) and the central axis of the **field of view** (2.1)

See Figure 2.



Key

- 1 endoscope normal axis
- 2 direction of view
- 3 central axis of field of view

Figure 2 — Direction of view

2.3

forward-viewing

type of **endoscope** (1.1) having a 0° **direction of view** (2.2)

NOTE The term "end viewing" is used in IEC 60601-2-18.

2.4

forward oblique viewing

fore-oblique

side-viewing with θ ° forward view

type of endoscope (1.1) having a direction of view (2.2) larger than 0° and less than 90°

2.5

side-viewing

type of an **endoscope** (1.1) having a 90° **direction of view** (2.2)

2.6

retro-viewing

backward side-viewing

side-viewing with θ ° retro-view

type of endoscope (1.1) having a direction of view (2.2) larger than 90°

Portions of endoscopes 3

3.1

French

 $F_{\rm r}$ Charrière

measure of the size of certain circular or non-circular cross-section endoscopes (1.1) defined as:

$$F_r = 3u/\pi$$

where u is the perimeter of the cross-section, expressed in millimetres

3.2

distal. adi

any location of that portion of an endoscope (1.1) or endotherapy device (4.1) which is farther from the user than some referenced point

3.3

proximal, adj

any location of that portion of an endoscope (1.1) or endotherapy device (4.1) which is closer to user than some referenced point

3.4

instrument channel

portion of an endoscope (1.1) or endotherapy device (4.1) through which an endoscope or an endotherapy device is intended to pass

3.5

insertion portion

insertion tube

that portion of an endoscope (1.1) or endotherapy device (4.1) which is intended to be inserted into a natural or surgically-created body opening or which is intended to be inserted into the instrument channel (3.4) of an endoscope or endotherapy device

NOTE ISO 8600-1:— only defines "insertion portion".

3.6

maximum insertion portion width

maximum external width of an endoscope (1.1) or endotherapy device (4.1) throughout the length of the insertion portion (3.5)

3.7

minimum instrument channel width

minimum internal width of an instrument channel (3.4)

3.8

working length

maximum length of the insertion portion (3.5)

3.9

controllable portion

that part of the insertion portion (3.5) of an endoscope (1.1) or endotherapy device (4.1) whose motion is intended to be remotely controlled by the user

3.10

air/water nozzle

air/water feed nozzle

that part of the distal (3.2) end for feeding air or water

3.11

angulation range

bending capability

tip deflection

bending range

angle (in degrees) between the normal axis of the **endoscope** (1.1) (0°) and the central axis of the deflected **distal** (3.2) end

3.12

flexible portion

flexible section

that part of the **insertion portion** (3.5) of a **flexible endoscope** (1.4) excluding the **distal** (3.2) end and bending section

3.13

light guide cord

light guide (or umbilical) cable

light guide flexible section

that part of an endoscope (1.1) which connects to a light source for transmitting illumination

3.14

eyepiece

that part of an **endoscope** (1.1) located at its **proximal** (3.3) end through which an image can be observed or to which a photographic or video camera can be attached

3.15

end-cap

removable fitting at the proximal (3.3) end of a rigid ventilation bronchoscope (1.9) to seal its lumen

[ISO 8600-2:2002]

3.16

working element

handle

element which secures an **endotherapy device** (4.1) and connects it to a **sheath** (4.2) which, when operated, moves the device backwards and forwards

3.17

bridge

element which connects a telescope (1.7) to a sheath (4.2)

3.18

ventilation connector

breathing system connector

integral part of a **rigid ventilation bronchoscope** (1.9) that permits connection to a breathing system of an anaesthetic or breathing machine

[ISO 8600-2:2002]

3.19

jet-injector

narrow-lumen tubular device utilizing compressed gases (often using the Venturi principle) to provide intermittent positive gas pressure to the lungs of a patient

[ISO 8600-2:2002]

3.20

jet ventilation

providing inflation of the lungs by intermittent release of compressed gases by means of a jet-injector within or towards the trachea and/or bronchi of a patient

[ISO 8600-2:2002]

4 Endotherapy devices

4.1

endotherapy device

medical device intended to be inserted into a natural or surgically-created body opening during endoscopic procedures, whether through the same or a different orifice from the **endoscope** (1.1) for examination, diagnosis or therapy

NOTE 1 Endotherapy devices include the instrument through which an endoscope or endotherapy device is inserted, such as a guide tube, trocar tube or sliding tube, etc. Endotherapy devices include the devices to be inserted through the openings other than the opening for an endoscope, to ensure the safety of the devices for the intended use under the endoscopic view.

NOTE 2 The term "endoscopically-used accessory" is used in 2.1.102 of IEC 60601-2-18:1996.

4.2

sheath

outer insertion tube for guiding a **telescope** (1.7) or an **endotherapy device** (4.1)

4.3

obturator

mandrin

element inserted into a **sheath** (4.2) having a **distal** (3.2) profile such that it minimizes any risk of trauma during insertion into a body cavity

Bibliography

- [1] ISO 8600-1:—¹⁾, Optics and photonics Medical endoscopes and endotherapy devices Part 1: General requirements
- [2] ISO 8600-2:2002, Optics and optical instruments Medical endoscopes and endoscopic accessories Part 2: Particular requirements for rigid bronchoscopes
- [3] IEC 60601-2-18:1996, Medical electrical equipment Part 2: Particular requirements for the safety of endoscopic equipment

¹⁾ To be published. (Revision of ISO 8600-1:1997)

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001. Email: orders@bsi-global.com. Standards are also available from the BSI website at http://www.bsi-global.com.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: +44 (0)20 8996 7111. Fax: +44 (0)20 8996 7048. Email: info@bsi-global.com.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration.

Tel: +44 (0)20 8996 7002. Fax: +44 (0)20 8996 7001.

Email: membership@bsi-global.com.

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsi-global.com/bsonline.

Further information about BSI is available on the BSI website at http://www.bsi-global.com.

Copyright

Copyright subsists in all BSI publications. BSI also holds the copyright, in the UK, of the publications of the international standardization bodies. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means — electronic, photocopying, recording or otherwise — without prior written permission from BSI.

This does not preclude the free use, in the course of implementing the standard, of necessary details such as symbols, and size, type or grade designations. If these details are to be used for any other purpose than implementation then the prior written permission of BSI must be obtained.

Details and advice can be obtained from the Copyright & Licensing Manager. Tel: +44 (0)20 8996 7070. Fax: +44 (0)20 8996 7553. Email: copyright@bsi-global.com.

BSI 389 Chiswick High Road London W4 4AL