BRITISH STANDARD

BS EN
980:1997
Incorporating Amendments Nos. 1 and 2

Graphical symbols for use in the labelling of medical devices

The European Standard EN 980:1996, including its amendments A1:1999 and A2:2001, has the status of a British Standard

ICS 01.080.20; 11.040.01

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/68, General terminology, symbols and information provided with medical devices, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland

Association of British Dispensing Opticians

Association of British Health-care Industries

Association of Contact Lens Manufacturers

British Anaesthetic and Respiratory Equipment Manufacturers' Association

British Dental Trade Association

British Institute of Radiology

College of Radiographers

Department of Health

Health and Safety Executive

Institution of Physics and Engineering in Medicine and Biology

Medical Sterile Products Association

Ministry of Defence

National Blood Authority

Royal College of Surgeons of England

Surgical Dressings Manufacturers' Association

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Contents

National foreword

This British Standard has been prepared by Technical Committee CH/68 and is the English language version of EN 980:1996, *Graphical symbols for use in the labelling of medical devices,* including amendments A1:1999 and A2:2001, published by the European Committee for Standardization (CEN).

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 10, an inside back cover and a back cover.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 980
May 1996
+A1
August 1999
+A2
August 2001

ICS 01.040.11; 01.080.20; 11.020

Descriptors: Medical equipment, labelling, information, graphic symbols, specifications

English version

Graphical symbols for use in the labelling of medical devices

(includes amendments A1:1999 and A2:2001)

Symboles graphiques utilisés pour l'étiquetage des dispositifs médicaux
(inclut les amendements A1:1999 et A2:2001)

Graphische Symbole zur Kennzeichnung von Medizinprodukten
(enthält Änderungen A1:1999 und A2:2001)

This European Standard was approved by CEN on 1996-05-01; amendment A1 was approved by CEN on 1999-08-01; amendment A2 was approved by CEN on 2001-06-16. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comite Europeen de Normalisation
Europaisches Komitee fur Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 980:1996 + A1:1999 + A2:2001 E

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 257, Terminology, symbols and information provided with medical devices, the secretariat of which is held by SFS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1996, and conflicting national standards shall be withdrawn at the latest by November 1996.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s)

For relationship with EU Directives, see informative Annex ZA and Annex ZB, which are an integral part of this standard.

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Foreword to amendment A1

This amendment EN 980:1996/A1:1999 to EN 980:1996 has been prepared by Technical Committee CEN/TC 257, Symbols and information provided with medical devices and nomenclature for regulatory data exchange, the Secretariat of which is held by SFS.

This amendment to the European Standard EN 980:1996 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2000, and conflicting national standards shall be withdrawn at the latest by February 2000.

This amendment to the European Standard EN 980:1996 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Foreword to amendment A2

This amendment EN 980:1998/A2:2001 to the EN 980:1996 has been prepared by Technical Committee CEN/TC 257, Symbols and information provided with medical devices and nomenclature for regulatory data exchange, the Secretariat of which is held by SFS.

This amendment to the European Standard EN 980:1996 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2002, and conflicting national standards shall be withdrawn at the latest by February 2002.

This amendment to the European Standard EN 890:1996 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

0 Introduction

This European Standard has been prepared to reduce the need for multiple translation of words into national languages, to simplify labelling wherever possible and to prevent separate development of different symbols to convey the same information. It has been prepared to harmonize the presentation of information required by all EEC Directives on medical devices including active implantable and in vitro diagnostic medical devices (in the course of preparation).

The meaning of some of these symbols is self-evident. Some are already in widespread use and familiar to health-care professionals. The meaning of others will become clear with use or when viewed in the context of the device itself. If appropriate, the meaning of symbols should be explained in accompanying literature when provided. Symbols used with medical devices for use by other than health-care professionals can require additional explanations.

It is not always possible to develop symbols for all information presented with the device. Not all symbols are appropriate for all types of medical devices. The validity of information conveyed by a symbol can be adversely affected by subsequent events, e.g. damage to a package can affect the sterility of a device.

Annex A provides examples of how each of the symbols can be used. These are illustrative only and do not represent the only ways in which the requirements of this standard can be met. An additional informative bibliography is given in Annex B.

1 Scope

This European Standard specifies graphical symbols for use in the information supplied by the manufacturer with medical devices.

NOTE This standard does not specify the circumstances under which particular symbols are used. Guidance on this is given in prEN 1041.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile"*.

EN 28601:1992, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

(ISO 8601, 1st edition 1988 and technical corrigendum 1:1991).

3 General requirements

Graphical symbols used to convey the information given in 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8 and 4.9 are given in this standard.

NOTE 1 Other symbols may be used to convey other information. Where graphical symbols are not taken from a Harmonized Standard, their meaning should be described in the documentation supplied with the device.

Enclosures shown in 4.1, 4.3, 4.6, 4.7.1, 4.7.2, 4.7.3 and 4.9 shall be included as part of these symbols.

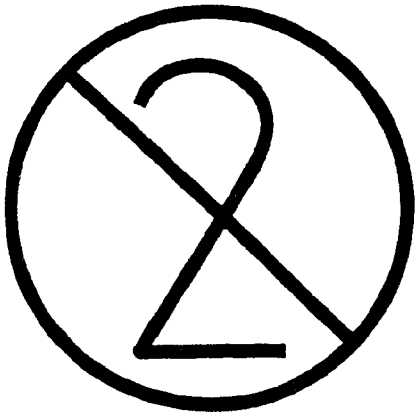
NOTE 2 The use of similar enclosures around other symbols is not precluded.

All symbols and accompanying information shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary, at a distance which takes into account the specifics and size of the individual medical device.

NOTE 3 Colours and minimum dimensions are not specified in this standard.

4 Symbols

4.1 Symbol for "DO NOT REUSE"

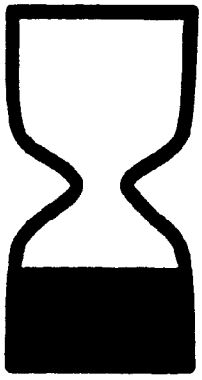


NOTE 1 This symbol is as given in ISO 7000/1051.

NOTE 2 Synonyms for "do not reuse" are "single use", "use only once".

NOTE 3 See Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 f).

4.2 Symbol for "USE BY"



This symbol shall be accompanied by the date expressed as given in EN 28601 as four digits for the year and two digits for the month and where appropriate, two digits for the day. The date shall be adjacent to the symbol.

NOTE 1 For example, June 1998 becomes 1998-06.

NOTE 2 The relative size and location of the symbol and the date are not specified.

NOTE 3 The symbol is intended to indicate that the device should not be used after the end of the month shown or the day, if applicable.

NOTE 4 Synonym for "use by" is "the time limit for implanting a device safely" for active implantable medical devices only.

NOTE 5 See Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 e).

4.3 Symbol for "BATCH CODE"

This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.

NOTE 1 Synonyms for "batch code" are "lot number", "batch number".

NOTE 2 The relative size and location of the symbol and the batch code are not specified.

NOTE 3 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 11 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 d).

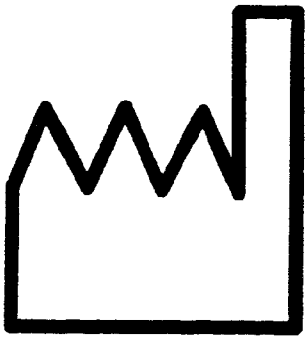
4.4 Symbol for "SERIAL NUMBER"

This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol.

NOTE 1 The relative size and location of the symbol and the serial number are not specified.

NOTE 2 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 11 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 d).

4.5 Symbol for "DATE OF MANUFACTURE"



For active implantable medical devices, the symbol shall be adjacent to the date expressed as four digits for the year and two digits for the month. For active devices the symbol shall be accompanied by the year. The year shall be expressed as four digits in accordance with 5.2.1.2 a) of EN 28601:1992.

NOTE 1 The relative size and location of the symbol and the date are not specified.

NOTE 2 See Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 l).

4.6 Symbol for "STERILE"

This symbol is for terminally-sterilized medical devices only. EN 556:1994, 4.1 applies.

NOTE See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 c).

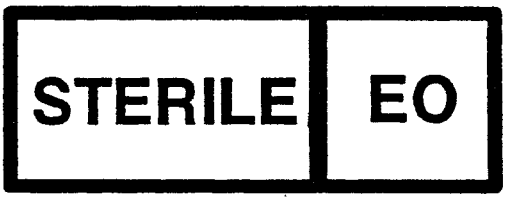
4.7 Symbols for "STERILE" including the "METHOD OF STERILIZATION"

These symbols are for terminally-sterilized medical devices only. EN 556:1996, 4.1 applies.

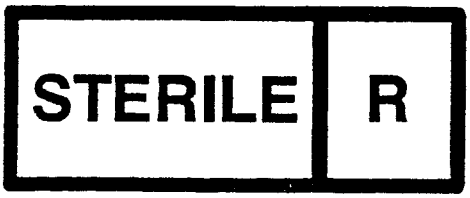
NOTE 1 If any of the symbols given at 4.7.1, 4.7.2 and 4.7.3 are used, it is not necessary in addition to use the symbol for sterile as shown in 4.6.

NOTE 2 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 c), m).

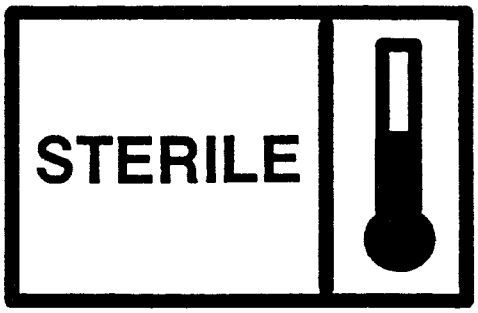
4.7.1 *Symbol for method of sterilization using ethylene oxide*



4.7.2 *Symbol for method of sterilization using irradiation*



4.7.3 *Symbol for method of sterilization using steam or dry heat*



4.8 Symbol for "CATALOGUE NUMBER"

REF

The manufacturer's catalogue number shall be adjacent to the symbol.

NOTE 1 The relative size and location of the symbol and the catalogue number are not specified.

NOTE 2 Synonyms for "catalogue number" are "reference number", "reorder number".

NOTE 3 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.2 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 b).

4.9 Symbol for "ATTENTION, SEE INSTRUCTIONS FOR USE"

NOTE 1 This symbol appears with similar meaning in other documents. (See EN 60601 and Symbol No. 14 of EN 61010-1 "Attention, consult accompanying documents").

NOTE 2 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.2 and 15 and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 j), k).

4.10 This symbol is for sterile medical devices processed using aseptic technique

NOTE 1 Aseptic technique may include filtration.

NOTE 2 A European Standard on aseptic processing is in the course of preparation.

Annex A (informative)

Examples of uses of symbols given in this standard

NOTE These examples are illustrative only and do not represent the only ways in which the requirements of this standard can be met.

A.1 Examples of use of symbol for "USE BY"

1998-06-30

1996-06

A.2 Example of use of symbol for "BATCH CODE"

ABC123

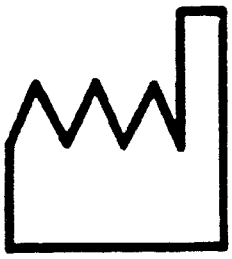
A.3 Examples of use of symbol for "SERIAL NUMBER"

SN ABC123

SN/ABC123

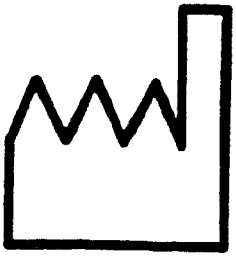
SN-ABC123

A.4 Examples of use of symbol for "DATE OF MANUFACTURE"



1996-06

1995



A.5 Example of use of symbol for "CATALOGUE NUMBER"

REF ABC123

Annex B (informative)

Bibliography

EN 60601-1, *Medical electrical equipment. Part 1: General requirements for safety.*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements.*

prEN 1041, *Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer with medical devices.*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis.*

IEC 416, *General principles for the creation of graphical symbols for use on equipment.*

IEC 417, *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.*

IEC 878, *Graphical symbols for electrical equipment in medical practice.*

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of Council Directive 93/42/EEC concerning medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

WARNING. Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.
Table ZA.1 lays out which clauses of this standard are likely to support the relevant requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Relationship between this standard and Directive 93/42/EEC

Essential requirements from Annex I of Council Directive concerning medical devices (93/42/EEC)	Relevant clause of this standard
13.2	This standard
13.3 b)	4.8
13.3 c)	4.6, 4.7.1, 4.7.2, 4.7.3
13.3 d)	4.3, 4.4
13.3 e)	4.2
13.3 f)	4.1
13.3 j), k)	4.9
13.3 l)	4.5
13.3 m)	4.7.1, 4.7.2, 4.7.3

Annex ZB (informative)

Clauses of this European Standard addressing essential requirements or other provisions of Council Directive 90/385/EEC relating to active implantable medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 90/385/EEC.

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Table ZB.1 lays out which clauses of this standard are likely to support the relevant requirements of Directive 90/385/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1 — Relationship between this standard and Directive 90/385/EEC

Essential requirements from Annex I of Council Directive concerning active implantable medical devices (90/385/EEC)	Relevant clause of this standard
11	4.3, 4.4
14	This standard
14.1	4.2, 4.5, 4.6, 4.7.1, 4.7.2, 4.7.3
14.2	4.2, 4.5, 4.6, 4.8, 4.9
15	4.3, 4.4, 4.6, 4.7.1, 4.7.2, 4.7.3, 4.9

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