BRITISH STANDARD

BS EN
592:2002

Instructions for use for in vitro diagnostic instruments for self-testing

The European Standard EN 592:2002 has the status of a British Standard

ICS 11.100

National foreword

This British Standard is the official English language version of EN 592:2002. It supersedes BS EN 592:1995 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/69, In vitro diagnostic systems, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the 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 or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 3 May 2002

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 592

February 2002

ICS 11.100

Supersedes EN 592:1994

English version

Instructions for use for in vitro diagnostic instruments for self-testing

Instructions d'utilisation d'instruments pour le diagnostic in vitro pour usage comme auto-test

Gebrauchsanweisungen für Geräte für in-vitro-diagnostische Untersuchungen zur Eigenanwendung

This European Standard was approved by CEN on 20 December 2001.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

The European Diagnostic Manufacturers Association (EDMA) has contributed to its preparation.

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 August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.

This European Standard supersedes EN 592:1994.

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 Directive(s), see informative annex ZA, which is an integral part of this standard.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This European Standard specifies the requirements for the contents of instructions for use for in vitro diagnostic instruments including apparatus and equipment for self-testing which hereafter are called IVD instruments.

NOTE 1 Instructions for use are essential to enable the safe and proper operation of IVD instruments by lay persons.

NOTE 2 This standard can also be applied to accessories.

This standard is not applicable to field repair instructions.

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 editions of the publication referred to applies (including amendments).

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units.*

3 Terms and definitions

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

3.1
in vitro diagnostic instrument
IVD instrument
in vitro diagnostic medical device which is an instrument, apparatus or equipment

NOTE 1 For the definition of an in vitro diagnostic medical device, see [1].

NOTE 2 In some cases a particular IVD instrument, as defined for use in human medicine, may serve also in veterinary medicine.

[EN 591:2001]

3.2
instructions for use
information supplied by the manufacturer with an IVD instrument concerning the proper use and the safe and correct operation, maintenance and basic trouble-shooting of the IVD instrument [EN 591:2001]

3.3
lay person
individual who does not have specific medical education [EN 376:2002]

3.4
self-testing
use in the home or similar environments by a lay person who will relate the result of the test to him- or herself [EN 376:2002]

3.5
specimen
biological material which is obtained in order to detect or to measure one or more quantities [EN 375:2001]

4 Form and presentation of the instructions for use

The wording shall be readily understood. Consideration shall be given to the following aspects of presentation, where appropriate:

a) overview of operating elements;

b) flow and block diagrams;

c) integration and arrangement of text/illustrations;

d) graphic emphasis of warnings;

e) examples;

f) diagrams of procedural steps.

5 Requirements for the content of the instructions for use

5.1 General

Instructions for use for IVD instruments shall contain the information given in 5.2 to 5.19. The information provided shall be easy to read and well-organized. The print shall be easily legible and terms simple and not unnecessarily technical or scientific. Symbols and illustrations shall be used wherever possible. A statement that the instructions for use are to be read carefully shall be made.

Where appropriate, instructions for use shall include a table of contents and an index.

The language(s) used shall be (an) official Community language(s), legally acceptable in the country in which

the IVD instrument is distributed; additional languages are optional, bearing in mind the needs of the anticipated users.

5.2 Graphical symbols

Any graphical symbols used on the IVD instrument shall be explained in the instructions for use. There are, however, certain well-understood symbols already in use which are recognised to be suitable without need for further explanation, i. e. those symbols as so identified in EN 980.

5.3 Manufacturer

The name and address of the manufacturer shall be given.

NOTE The manufacturer is the entity which has taken the legal responsibility for the IVD instrument.

The name and address of the authorized representative shall also be given when this is a legal requirement.

5.4 Identification

The name of the IVD instrument and/or separate instrument components shall be provided.

5.5 Storage and handling

Instructions relevant to any particular storage and/or handling conditions shall be given.

5.6 Warnings and precautions

Any warnings and precautions relevant to any special, unusual risks related to installation, operation, maintenance, transportation, storage or disposal of the IVD instrument shall be given.

5.7 Intended purpose

The intended purpose of the IVD instrument and the fact that it is intended for self-testing shall be clearly stated.

5.8 Installation

5.8.1 General

Where appropriate, instructions for setting up the IVD instrument shall be given.

5.8.2 Action upon delivery

Where appropriate, information shall be provided on the following:

a) unpacking;

b) checking delivery for completeness;

c) checking for damage during transport.

5.8.3 Preparation prior to installation

Where appropriate, information shall be provided on the following:

a) installation site requirements;

b) technical prerequisites.

5.8.4 Bringing into operation

Where appropriate, information shall be provided on the following:

a) setting up;

b) introduction, brief description;

c) checks for proper installation.

5.9 Principles of measurement

A short summary of the basic principles of measurement to enable a lay person to understand the used method shall be given.

5.10 Performance and limitations of use

Information on the performance and limitations of use of the instrument and/or system shall be given.

5.11 Preparation prior to operation

Where appropriate, information shall be provided on the following:

a) any special materials and/or equipment required in order to use the IVD instrument properly;

b) reagent(s);

c) type of specimen to be used, any special conditions of collection and, if necessary, storage conditions;

d) instrument checks and adjustment for safe and correct operation.

5.12 Operating procedure

5.12.1 General

A detailed description of the procedure to be followed ("how to carry out the test") which can be clearly understood by a lay person shall be provided. If applicable, procedures for carrying out a control shall be given. Where appropriate, the operating procedure should be illustrated by a flow diagram.

5.12.2 Operation

Information shall be provided describing the operation of the IVD instrument, e. g. switching on, placing on stand-by, switching off, taking out of operation.

5.12.3 Performance checks

Where appropriate, information shall be provided on the following:

a) automatic checks on the system;

b) user controls, i. e. a procedure by which the user can reasonably verify that, at the time of use, the IVD instrument will perform as intended;

c) some form of simple performance checks of the entire system.

5.13 Analytical result

Information shall be provided on how the analytical result can be interpreted by the user of the IVD instrument. Results shall be expressed and presented in a way that is readily understood by a lay person.

Information shall be provided on the possibility of false results.

When possible, results shall be expressed in units according to ISO 1000.

5.14 Disposal information

Where appropriate, information shall be provided on the safe disposal of waste materials, e. g. consumables, used reagents or reagent products including those mixed with specimens, instruments or components thereof.

5.15 Maintenance

Where appropriate, information shall be provided on the following:

a) preventive maintenance (nature and frequency);

b) cleaning instructions;

c) sterilization, decontamination or disinfection;

d) components list, including relevant working materials, tools;

e) consumables.

5.16 Trouble-shooting

Where appropriate, information shall be provided on the following:

a) messages, error signals;

b) establishing causes of errors;

c) correction and elimination of error by the user;

d) errors necessitating service calls;

e) measures to be taken in the event of a change of the analytical performance of the IVD instrument.

5.17 Technical specifications

Where appropriate, information shall be provided on the following:

a) physical environment (e. g. humidity, temperature);

b) dimensions, mass;

c) basic settings made by the manufacturer;

d) physical data (e. g. voltage);

e) consumption values in units according to ISO 1000 (e. g. electrical power, water).

5.18 Follow-up action

Advice shall be given on actions to be taken in light of the obtained results taking into account the possibility of false results. Where appropriate, the information shall include a statement clearly directing the user not to make any decision of medical relevance without first consulting his or her physician and having received appropriate training.

5.19 Date of issue or revision

The date of issue or latest revision of the instructions for use shall be given.

6 Requirements for supplementary information

6.1 General

If appropriate, instructions for use for IVD instruments shall provide the supplementary information given in 6.2 to 6.6.

6.2 List of uses and applications

Information on uses and applications shall be provided.

6.3 Warranty limitations

A statement of specific warranty limitations shall be provided.

NOTE An example is any action by users which may invalidate the manufacturer's warranty.

6.4 Ordering information

Information shall be provided on the following:

a) list of spare parts and consumables;

b) relevant addresses.

6.5 Possibilities of extension

Information shall be provided on the following:

a) interface description;

b) modules.

6.6 Assistance

Information shall be provided on the following:

a) training;

b) list of offices and sources of service (mailing addresses, telephone numbers, telephone trouble-shooting, etc.).

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

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 the Directive 98/79/EC.

> **WARNING:** Other requirements and other EU Directives **may** be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard, as detailed in Table ZA.1, are likely to support requirements of the Directive 98/79/EC.

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 - Correspondence between this European Standard and Directive 98/79/EC

Clauses/subclauses of this European Standard	Essential requirements of Directive 98/79/EC	Qualifying remarks/Notes
5.1	B.7, B.8.7	
5.2	B.8.2	
5.3	B.8.4 (a), B.8.7 (a)	
5.4	B.8.4 (b), B.8.7 (a)	
5.5	B.8.4 (h), B.8.7 (a)	
5.6	B.8.4 (j), B.8.7 (a), B.8.7 (s)	
5.7	B.8.4 (k), B.8.5, B.8.7 (a)	
5.8	B.8.7 (n)	
5.9	B.8.7 (h), B.8.7 (t)	
5.10	B.8.7 (d)	
5.11	B.7.1, B.8.7 (e), B.8.7 (f), B.8.7 (m), B.8.7 (n), B.8.7 (o)	
5.12	B.7.2, B.8.4 (i), B.8.7 (g), B.8.7 (h)	
5.13	B.8.7 (t)	
5.14	B.8.7 (n)	
5.15	B.8.7 (n), B.8.7 (p), B.8.7 (q)	
5.17	B.4.2, B.8.7 (r)	
5.18	B.8.7 (t)	
5.19	B.8.7 (u)	
6.6	B.8.7 (t)	

Bibliography

EN 375:2001, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.*

EN 376:2002, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

EN 591:2001, *Instructions for use for in vitro diagnostic instruments for professional use.*

EN 980*, Graphical symbols for use in the labelling of medical devices.*

EN 28601, *Data elements and interchange formats – Information interchange; representation of dates and times (ISO 8601:1988 and technical corrigendum 1:1991).*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements (IEC 61010-1:1990 + A1:1992, modified).*

ISO/IEC Guide 2, *Standardization and related activities – General vocabulary.*

[1] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJEC, 1998, No L 331.

[2] International Vocabulary of Basic and General Terms in Metrology (VIM), 2nd edition, Geneva: ISO, 1993.

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